

Complaint ...

The undersigned, Geanina - Elena HAGIMĂ, residing in ..., Pitești, Argeș County, postal code ..., CNP ..., tel. ..., email: ..., identified by ... series ..., no. ... issued by ... Pitești,

[...] wish to submit a report to you regarding the results of my own research (via optical microscopy) into the experimental anti-Covid serums termed „vaccines”, as well as more advanced and restricted laboratory analyses of these products, conducted at my request within an institution by a researcher whose identity I prefer not to disclose at this time. The results obtained from my personal investigations converge toward the same findings and conclusions as those of several independent researchers worldwide, including the group of researchers from Argentina (who determined the presence of 55 undeclared elements in the covid vaccines, results of which were published in an article on 11-10-2024 and are presented below in this complaint), the working group from Germany which held a conference on this subject in Reutlingen on 20-09-2021 and published a brochure on 6-07-2022 containing their investigation results (the conclusions of which I have also presented within this report), as well as other researchers whom I shall mention in the report. These investigations reveal that the so-called anti-Covid vaccines contain foreign substances, some toxic, which are undeclared in the patient information leaflets; consequently, the Romanian state has been defrauded through the Government and the relevant Ministry of Health of Romania, and the informed consent of the entire population of Romania injected with such experimental serums has been vitiated, as regulated by the Civil Code, Law no. 287/2009, specifically: art. 1204 ¹, art. 1206 ² para. 1, and art. 1214 ³. Accordingly, through this report, I hereby notify you of the aspects regarding the undeclared content of the covid vac- as well as the context of pressure, censorship, disinformation, and medical fraud surrounding the administration of these products, and I urgently implore you to take the necessary measures to notify the concerned entities, such as: the Ministry of Health, the Prime Minister's Control Body, and the Government of Romania, the National Authority for Consumer Protection (ANPC), and the National Agency for Medicines and Medical Devices of Romania, the National Institute of Public Health, and the College of Physicians of Romania, the National Committee for Special Emergency Situations (chaired at the material time by Valeriu Gheorghiuță), the World Health Organization (WHO), the European Medicines Agency (EMA), the Food and Drug Administration (FDA), RENAR, and pursuant to the provisions of DIRECTIVE (EU) 2020/1828 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC published in the Official Journal of the European Union No. 409/1 of 04.12.2020, I hereby request, through the ANPC of Romania, that you conduct investigations and initiate representative actions on behalf of the Romanian state against the manufacturers of these experimental serums, specifically:

*Moderna, Pfizer-BioNTech, Johnson & Johnson, Astra Zeneca, specifically Art. 7⁴ paras. 1, 2, 3, 4, 5, 6, 7; **whereby you shall seek measures to cease the marketing of these experimental products termed anti-Covid vaccines within the territory of Romania, pursuant to point (a) of paragraph 4, Article 7 of EU Directive 2020/1828, and order remedial measures for the prejudice caused to the Romanian state by these manufacturers, as well as for the damages to public health and the physical and psychological integrity of the population of Romania vaccinated with these experimental serums containing toxic elements, which were left undeclared in the patient information leaflets of these so-called vaccines by the aforementioned manufacturers, pursuant to point (b) of paragraph 4, Article 7 of EU Directive 2020/1828.***

I hereby request that you authorize investigative measures pursuant to Article 29⁽⁵⁾ of REGULATION (EU) 2017/2394 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws published in the Official Journal of the EU, No. 345/1 of 27.12.2017.

I wish to state that I am a senior consultant physician specializing in obstetrics and gynecology, having acquired multiple clinical competencies over time, as evidenced by my CV, reflecting my commitment to practicing medicine at the highest professional standard.

A. Personal investigations concerning COVID-19 vaccines

Even prior to the distribution of COVID-19 vaccines in Romania, I harbored suspicions regarding these products. The suspicions were initially medical in nature, pertaining to the rationale for the administration of these vaccines as well as their safety and efficacy; subsequently, they concerned the identification of a context involving non-medical political objectives, which entail the introduction of these products into the human body with intentions other than the resolution of the COVID-19 pandemic.

Furthermore, I observed the rejection of COVID-19 treatment options proposed by certain physicians—despite their efficacy being substantiated by studies—while authorities simultaneously asserted that a vaccine represented the sole solution for exiting the pandemic. I was extremely surprised by the speed with which the COVID vaccines were developed, studied, and conditionally approved, and by the pharmaceutical companies' choice to utilize new technologies and compounds previously untested on humans for their production. I observed with indignation how clinical trials for certain vaccines continued even after the reporting of severe adverse reactions and even deaths among participants, as was the case with the death of a 28-year-old physician who received the AstraZeneca vaccine <https://www.portalmed.ro/stiri-de-ultima-ora/brazilia-confirma-decesul-unui-voluntar-inrolat-in-studiul-clinic-al-vaccinului-dezvoltat-de-oxford-si-astrazeneca/>.

When I managed to come into possession of certain vials of COVID-19 vaccines, I conducted my own investigations regarding the optical microscopy aspects of the COVID-19 vaccine droplets, as well as investigations

concerning the composition of the COVID-19 vaccines through collaboration with a researcher who performed electron microscopy and X-ray spectroscopy (EDX) analyses. Upon optical microscopy analysis, I observed particles of various shapes and sizes—some moving within the microscopic field in the first minutes to hours following application, some luminescent, and others larger with the appearance of flakes or fibers; I noted unusual characteristics and behaviors of the vaccine droplets, which exhibited a tendency to organize into a perfectly ordered structure over time. Upon analysis by electron microscopy with X-ray spectroscopy, I established the presence of undeclared elements (silicon, titanium, tin, aluminum, magnesium, and Yttrium) and the absence of nitrogen and phosphorus. These observations and investigations were consistent with other international investigations also conducted by independent researchers.

Subsequently, conducting my own research, I became aware of a broader context; I learned of the plans of organizations such as the World Economic Forum, UN, NATO, ITU, IEEE, and IEC regarding bio-digital convergence or the Fourth Industrial Revolution—plans involving a profound transformation of the world we live in, about which the public has not been informed. This plan, which provides for the implementation of the Internet of Bodies and the Internet of Things through communications at both a macro and, more specifically, a nano scale—under the pretext of combating poverty and resolving major global issues—is currently being implemented through largely invisible, heavily funded, and long-studied technologies. These remain little known to the general public and even to specialists in various fields, specifically: nanotechnology, electromagnetic radiation within the 5G/6G spectrum originating from both terrestrial and aerial infrastructure, Artificial intelligence, materials with special properties such as graphene, synthetic biology, and gene editing. The Internet of Bodies envisages the introduction of nano-devices into human bodies which, by forming intracorporeal networks, communicate bidirectionally with the internet using 5G/6G technologies and Artificial intelligence. I shall detail this information throughout the report; however, I deemed it useful to mention the general context from the outset so that those reading this report may understand both the gravity of the situation and **the reason for my involvement despite the risks and significant personal resources committed to this research and information process**, my constant effort of information and research exceeding medical boundaries, as bio-digital convergence is a multidisciplinary issue. The reason for my involvement was the discovery of a global fraud with profound implications, which began to unfold under a medical pretext, whereby people are being led through the current cognitive warfare—characterized by disinformation, pressure, manipulation, and the use of advanced, invisible technologies—toward a dystopian future and total control, which no ordinary person would desire for

Suspensions regarding the safety and efficacy of these products have intensified, **noting the discrepancy between the information read in English (as it was not available in Romanian at that time) within official medical documents (for instance, the “SUMMARY OF PRODUCT CHARACTERISTICS” of the Comirnaty vaccine produced by Pfizer, initially published in December 2020 and subsequently republished on February 19, 2021, on the EMA website**

https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf **and the information disseminated to citizens, and even to the physicians, by the authorities and professional organizations such as the CMR.** It should be noted that **the Romanian translation of the documents regarding the product summary for the COVID-19 vaccines was located by me only recently**, on the website of the National Agency for Medicinal Products of Romania, where it was not clearly visible—a condemnable fact for both this agency and professional organizations like the CMR, which ought to have informed the physicians of the existence of these documents to ensure they were informed directly from the source— <https://www.anm.ro/medicament-de-uz-uman/ftarmacovigilenta/informatii-vaccinuri-covid-19/>, last updated on 10-11-2021!!!).

Suspicions regarding the composition of the COVID-19 vaccines arose when I learned about the magnetism appearing at the injection site for almost all vaccinated persons “ [STUDY ON THE ELECTROMAGNETISM OF VACCINATED PERSONS IN LUXEMBOURG](https://efvv.eu/images/content/2021/0617/study-on-electromagnetism-of-vaccinated-persons-in-luxembourg_6edfa.pdf) ” June 6, 2021 https://efvv.eu/images/content/2021/0617/study-on-electromagnetism-of-vaccinated-persons-in-luxembourg_6edfa.pdf , <https://efvv.eu/actions-lawsuits/study-on-the-electromagnetism-of-vaccinated-persons-in-luxembourg> . This fact was tested and confirmed by me as well on several recently vaccinated persons. Additionally, information appeared in the official media regarding lots of vaccines withdrawn from the market because metallic particles were identified within them: “ The vaccine doses withdrawn from Japan contained metallic particles ”, September 1, 2021. https://www.dcmmedical.ro/doza-de-sanattatte/vaccinuri/dozele-de-vaccin-rettrase-din-japonia-contineau-particule-mettalice_633229.html . Other data corroborating suspicions regarding the composition of the COVID-19 vaccines included **the immunity of pharmaceutical companies from liability for adverse reactions** <https://www.ncbi.nlm.nih.gov/books/NBK216813/> , <https://globalnews.ca/news/7521148/coronavirus-vaccine-safty-liability-government-anand-pfizer/> , **independent reports from other researchers** who conducted both optical microscopy investigations and, more importantly, advanced investigations (X-ray electron microscopy, spectrometry) through which elements undeclared by the manufacturer were detected, including graphene, as well as **information/studies regarding magnetism at the injection site and the detection of MAC addresses identified in the proximity of individuals vaccinated for COVID-19** <https://natural-health-community.org/news/dr-luis-de-benitto-shares-an-advance-of-his-report-on-the-mac-address-phenomenon-in-inoculated-individuals> , and even in unvaccinated individuals who underwent COVID-19 PCR testing, identified within the Bluetooth network and investigated by certain independent researchers—“Projet Bluetooth Expérience X” <http://www.nakim.org/israel-forums/download.php?id=92>

Furthermore, the discovery following my research of numerous documents referring to the Internet of Bodies and of things and bio-digital convergence published in international scientific journals such as IEEE and ITU (some of which are presented hereafter), as well as patents such as <https://patenttis.google.com/patentti/US11406266B2/en> pertaining to nanoscale communications for the healthcare system and other documents found on official websites regarding these topics, have strengthened my suspicion that COVID-19 vaccination may be part of a large-scale, long-planned global operation.

The COVID vaccines—composition declared by the manufacturers

Prior to presenting the results of my investigations and those of other independent researchers , I shall enumerate the composition and the list of excipients of the COVID-19 vaccines, as they appear in the Summary of Product Characteristics published on the ANMDMR website: <https://www.anm.ro/medicamente-de-uz-uman/farmacovigilenta/informatii-vaccinuri-covid-19>

/ Comirnaty vaccine (BioNTech and Pfizer)

2. COMPOZIȚIA CALITATIVĂ ȘI CANTITATIVĂ

Acesta este un flacon multidoză cu capac fără filet, de culoare violet și trebuie diluat înainte de utilizare.

După diluare, un flacon (0,45 ml) conține 6 doze a câte 0,3 ml, vezi pct. 4.2 și 6.6.

O doză (0,3 ml) conține 30 micrograme de tozinameran, un vaccin de tip ARNm COVID-19 (înglobat în nanoparticule lipidice).

Tozinameranul este un ARN mesager (ARNm) monocatenar cu capăt 5', produs prin utilizarea unei transcripții *in vitro* aceluare, de la modele de ADN corespunzătoare, cu codificarea proteinei S (spike) virale a SARS-CoV-2.

Pentru lista tuturor excipienților, vezi pct. 6.1.

6. PROPRIETĂȚI FARMACEUTICE

6.1 Lista excipienților

((4-hidroxi-butil)azanediil)bis(hexan-6,1-diil)bis(2-hexildecanoat) (ALC-0315)
2-[[[polietilenglicol]-2000]-N,N-ditetradecilacetamidă (ALC-0159)
1,2-Distearoil-sn-glicerol-3-fosfocolină (DSPC)
Colesterol
Clorură de potasiu
Dihidrogenofosfat de potasiu
Clorură de sodiu
Fosfat disodic dihidrat
Sucroză
Apă pentru preparate injectabile
Hidroxid de sodiu (pentru ajustarea pH-ului)
Acid clorhidric (pentru ajustarea pH-ului)

Spikevax vaccine (formerly Moderna vaccine)

Concentrație	Recipient	Doză (doze)	Compoziție per doză
Spikevax 0,2 mg/ml dispersie injectabilă	Flacon multidoză (capac: fără filet detășabil roșu)	Maximum 10 doze a câte 0,5 ml fiecare	O doză (0,5 ml) conține elasonem 100 micrograme, un vaccin ARNm COVID-19 (cu nucleotide modificate) (integrat în nanoparticule lipidice).
		Maximum 20 doze a câte 0,25 ml fiecare	O doză (0,25 ml) conține elasonem 50 micrograme, un vaccin ARNm COVID-19 (cu nucleotide modificate) (integrat în nanoparticule lipidice).
Spikevax 0,1 mg/ml dispersie injectabilă	Flacon multidoză (capac: fără filet detășabil albastru)	5 doze a câte 0,5 ml fiecare	O doză (0,5 ml) conține elasonem 50 micrograme, un vaccin ARNm COVID-19 (cu nucleotide modificate) (integrat în nanoparticule lipidice).
		Maximum 10 doze a câte 0,25 ml fiecare	O doză (0,25 ml) conține elasonem 25 micrograme, un vaccin ARNm COVID-19 (cu nucleotide modificate) (integrat în nanoparticule lipidice).
Spikevax 50 micrograme dispersie injectabilă în seringă presuplută	Seringă presuplută	1 doză de 0,5 ml Exclusiv de unică folosință. Nu utilizați seringă presuplută pentru a administra un volum parțial de 0,25 ml.	O doză (0,5 ml) conține elasonem 50 micrograme, un vaccin ARNm COVID-19 (cu nucleotide modificate) (integrat în nanoparticule lipidice).

6. PROPRIETĂȚI FARMACEUTICE

6.1 Lista excipienților

SM-102 (heptadecan-9-il 8-{{(2-hidroxietyl)[6-oxo-6-(undeciloxi)hexil]amino}octanoat})
Coolesterol
1,2-distearoil-sn-glicerol-3-fosfocolină (DSPC)
1,2-dimiristoil-rac-glicerol-3-metoxipolietilen-2000 (PEG2000-DMG)
Trometamol
Clorhidrat de trometamol
Acid acetic
Acetat de sodiu trihidrat
Sucroză
Apă pentru preparate injectabile

ICOVDEN vaccine (formerly Janssen vaccine)

2. COMPOZIȚIA CALITATIVĂ ȘI CANTITATIVĂ

Acesta este un flacon multidoză care conține 5 doze a câte 0,5 ml.

O doză (0,5 ml) conține:

Adenovirus tip 26 care codifică glicoproteina spike* a SARS-CoV-2 (Ad26.COV2-S), nu mai puțin de 8,92 log₁₀ unități infectioase (U Inf.).

* Produs în Linie de Celule PER.C6 TetR prin tehnologia ADN recombinant.

Vaccinul conține organisme modificate genetic (OMG).

Excipienți cu efect cunoscut

Fiecare doză (0,5 ml) conține etanol aproximativ 2 mg.

Pentru lista tuturor excipienților, vezi pct. 6.1.

6. PROPRIETĂȚI FARMACEUTICE

6.1 Lista excipienților

Cutie cu 10 flacoane

2-hidroxiopropil-β-ciclodextrină (HBCD)
Acid citric monohidrat
Etanol
Acid clorhidric
Polisorbat 80
Clorură de sodiu
Hidroxid de sodiu
Citrat trisodic dihidrat
Apă pentru preparate injectabile

Cutie cu 20 de flacoane

2-hidroxiopropil-β-ciclodextrină (HBCD)
Acid citric monohidrat
Etanol
Acid clorhidric
Polisorbat 80
Clorură de sodiu
Hidroxid de sodiu
Apă pentru preparate injectabile

Vaxzevria vaccine (formerly AstraZeneca vaccine)

2. COMPOZIȚIA CALITATIVĂ ȘI CANTITATIVĂ

Acesta este un flacon multidoză care conține 10 doze a câte 0,5 ml (vezi pct. 6.5).

O doză (0,5 ml) conține:

Adenovirus preluat de la chimpanzeu care codifică glicoproteina S (spike) a SARS-CoV-2 (ChAdOx1-S)*, nu mai puțin de 2,5 × 10⁷ unități infectioase (U Inf.).

*Produs în celule renale de embrion uman modificate genetic (HEK), linia celulară 293 și prin tehnologia ADN recombinant.

Acest vaccin conține organisme modificate genetic (OMG).

Excipient cu efect cunoscut

Fiecare doză (0,5 ml) conține aproximativ 2 mg de etanol.

Pentru lista tuturor excipienților, vezi pct. 6.1.

6. PROPRIETĂȚI FARMACEUTICE

6.1 Lista excipienților

L-histidină
Clorhidrat de L-histidină monohidrat
Clorură de magneziu hexahidrat
Polisorbat 80 (E 433)
Etanol
Sucroză
Clorură de sodiu
Edetat disodic (dihidrat)
Apă pentru preparate injectabile

Personal investigations—optical microscopy

Observing the significant pressure for vaccination, while also possessing information from independent researchers regarding the composition of the vaccines, I deemed it necessary to verify such information by conducting my own research. Thus, it was not until August **2023** that I managed to obtain several vials of COVID-19 vaccines **Pfizer-Comirnaty-Omicron XBB.1.5** (PAA194703, lot GJ1987, expiry July 2023) and **Moderna** (Lot 3005835, expiry 24/02/2022) and, subsequently, in December, Johnson & Johnson-JANSEN (LOT ACA5775, EXP 06-2023), **Pfizer Comirnaty** (lot FL5324, EXP

02/2022) as it was considerably difficult to take possession of such products. As you are likely aware, the distribution, administration, and collection of expired vaccine products were conducted under strict militarized supervision and rigorous control, making it extremely difficult to procure these products for the purpose of independent investigations.

I acquired an optical microscope capable of capturing photographs and short video clips, and I proceeded to examine these products both between the slide and coverslip and as a droplet applied directly to the slide without a coverslip. I observed, at various time intervals, the appearance of the slides under the optical microscope at magnifications of up to 400x.

I determined that these products contain particles of diverse shapes and dimensions. Certain small particles, visible at magnifications exceeding 200x during examination between the slide and coverslip, are luminescent in dark field and exhibit movement/displacement within the microscopic field for a duration of several minutes in the Johnson & Johnson vaccine, several hours in the Pfizer Omicron vaccine, and 24 hours in the case of the Moderna vaccine. Upon optical microscopic examination, I also identified larger particles: some resembling folded or crumpled foil (Moderna, Comirnaty-Omicron), others amorphous and black (present in all), and others appearing as blue fibers (in the case of the Moderna vaccine).

In the case of drops applied to the slide without a coverslip, I observed the formation over time—within a gelatinous liquid from the drop's composition—of luminescent geometric crystalline structures; some resembling flowers, rectangles, lines, or tubes, and others exhibiting branched forms with right angles, as shown in the images below.

These varied structures, the mobility of small particles, the diversity of larger particles, and the organizational patterns of the drops—both those applied to the slide without a coverslip and those applied between a slide and coverslip—are not accounted for by the declared composition of the COVID-19 vaccines. The observed aspects are rather suggestive of active structures with the capacity for self-assembly, a process that in all likelihood also occurs within the human body following the injection of these particles. Biodistribution studies of the mRNA COVID-19 vaccines indicate that the lipid nanoparticles do not remain localized at the injection site; a portion enters the systemic circulation and reaches the vast majority of organs, even crossing physiological barriers such as the blood-brain barrier. The nanoparticles within the COVID-19 vaccines, whether self-assembled or otherwise, are accepted by the organism with varying degrees of ease or difficulty depending upon their biocompatibility. In cases of reduced biocompatibility, immune phenomena arise which may be interpreted by those in the medical field as reactogenicity—that is, evidence that the “organism is working,” that the immune system is activating in response to the injected antigens for the purpose of producing antibodies. Thus, many of the mild and moderate adverse reactions can be ignored and left unreported. However, following the administration of COVID-19 vaccines, there were also severe adverse reactions and even deaths which, unfortunately, were not properly investigated; in my opinion, this omission was premeditated. The occurrence of severe adverse reactions, including the deaths, should have been investigated with great care by the INSP and ANMDMR; according to the INSP’s “Guide for the investigation of severe and serious cases of AEFI” (<https://cnscbt.ro/index.php/metodologii/rapi/661-ghid-investigare-cazuri-rapi/file>), these investigations should have involved performing analyses regarding the composition of these products—a requirement that was systematically avoided, as I have described below in this report. All these investigative and monitoring deficiencies occurred within the context in which the COVID-19 vaccines held a conditional authorization, a status requiring even more rigorous monitoring and reporting for the periodic assessment of the risk-benefit ratio; the continuation of the conditional marketing authorization for these products was contingent upon this ratio until the completion of safety and efficacy clinical trials, at which point definitive authorization could be granted.

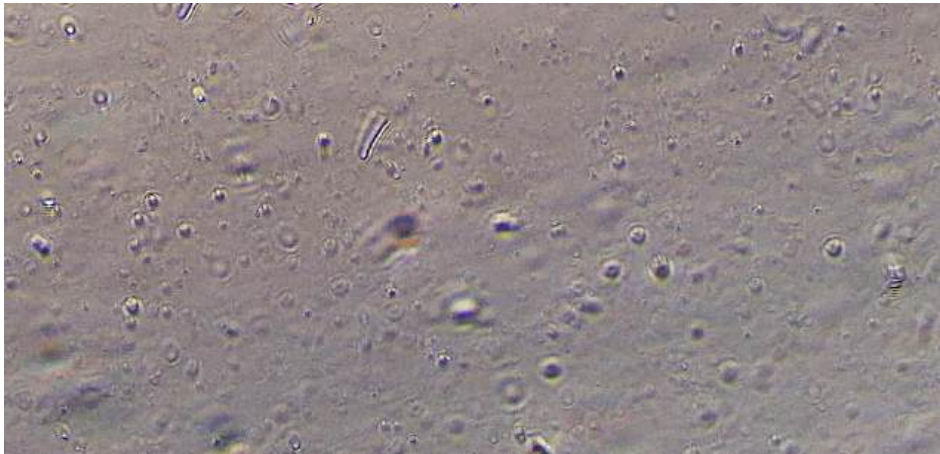


Image of the drop of Comirnaty-Pfizer vaccine applied between slide and coverslip, at 15 minutes, 400x magnification, in transmitted light. Particles of various sizes are observable, many of the smaller ones exhibiting translational movements.

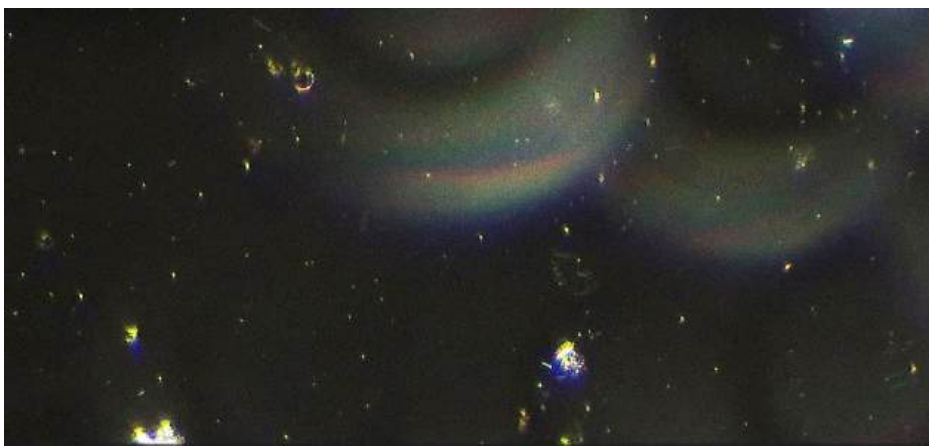


Image of Comirnaty-Pfizer vaccine between slide and coverslip, 35 minutes post-application, 400x magnification in dark field – luminescent particles of various sizes; some of which, specifically those of smaller dimensions, exhibit displacement movements.

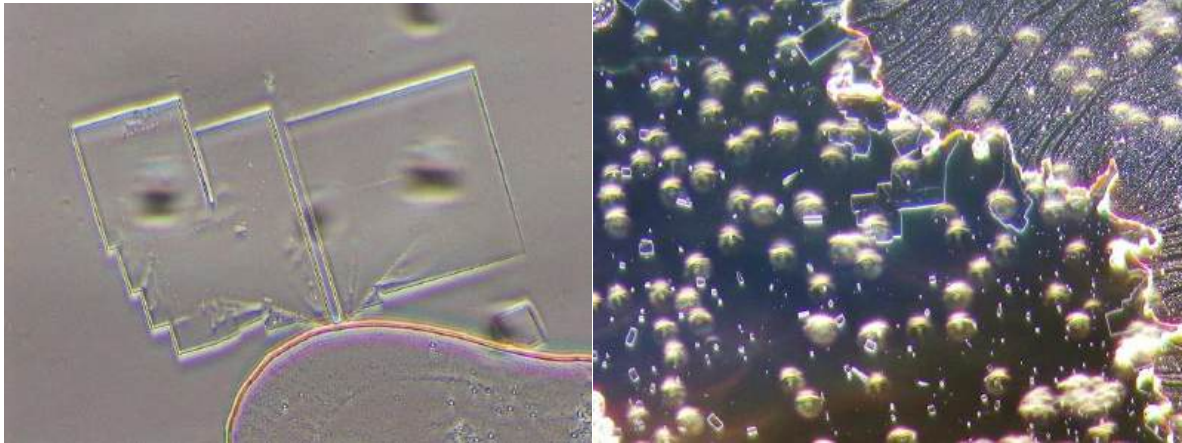
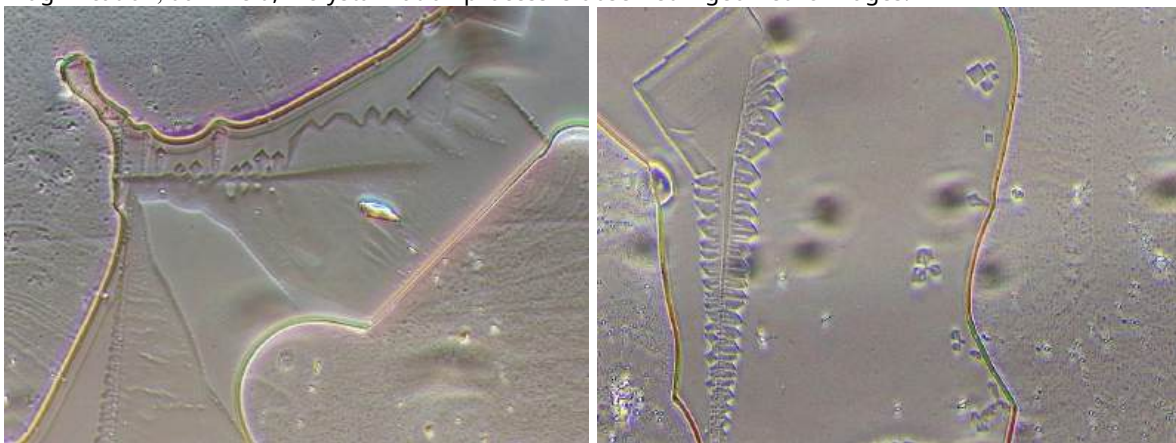
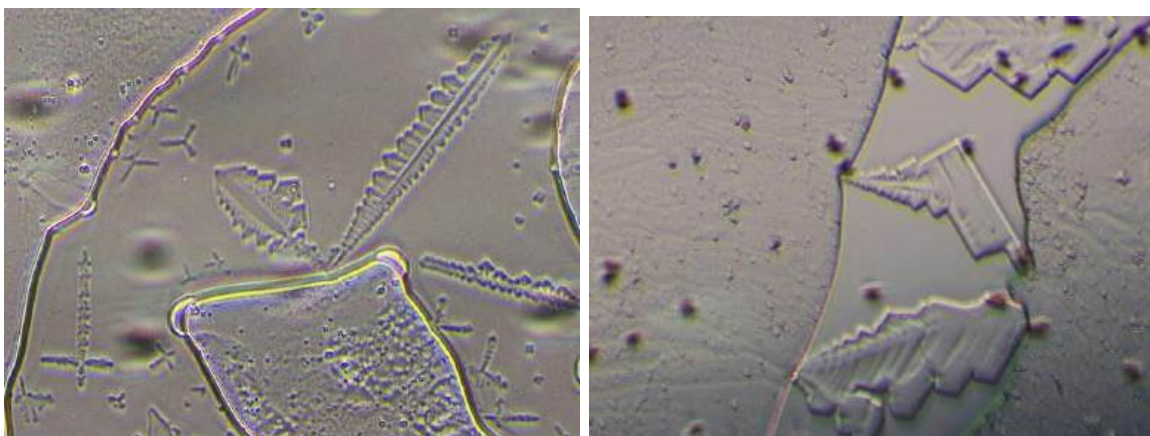


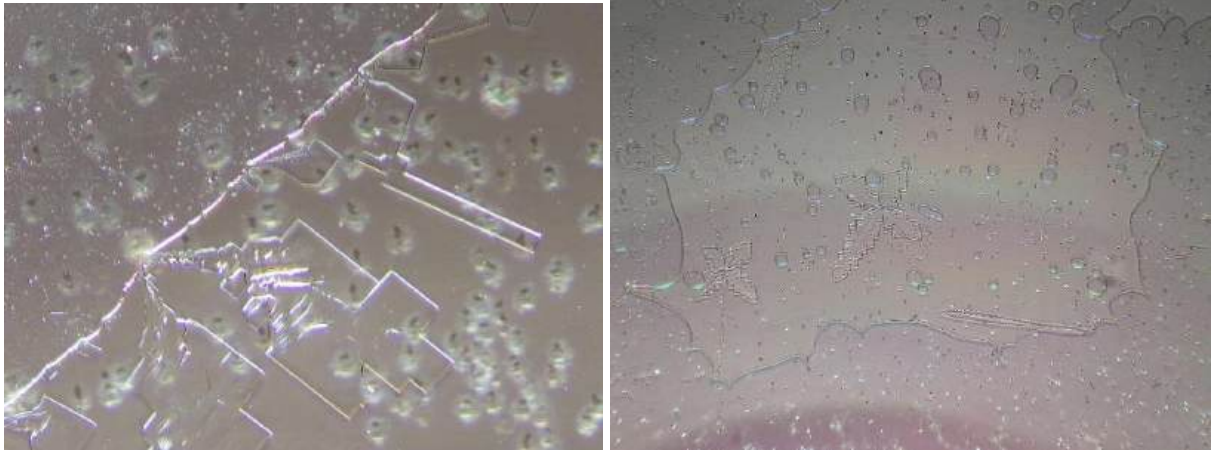
Image of crystallization/self-assembly in the drop of Comirnaty-Pfizer vaccine applied between slide and coverslip, 20 hours post-application; on the left 400x magnification, phase contrast; and on the right, 100x magnification, dark field; A crystallization process is observed – geometric images.



Images of crystallization/self-assembly in the drop of Comirnaty-Pfizer vaccine applied between slide and coverslip, at 20 hours, 400x magnification in transmitted light – appearance of various geometric structures.



Images of crystallization/self-assembly in the drop of the Comirnaty-Pfizer vaccine applied between the slide and coverslip, at 20 hours, at 400x magnification in transmitted light—the appearance of various geometric structures.



Images of crystallization/self-assembly in the drop of the Comirnaty-Pfizer vaccine applied between the slide and coverslip, at 20 hours, 100x magnification, phase contrast; the appearance of various geometric structures.

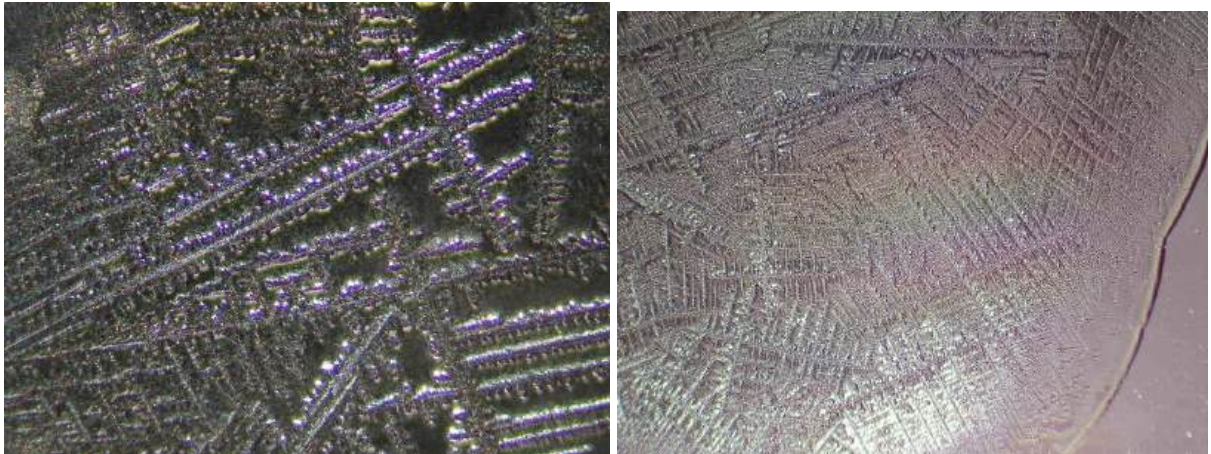


Image of crystallization/self-assembly in the drop of the Comirnaty-Pfizer vaccine applied on the slide, at 2 hours, 40x magnification, in dark field and transmitted light, respectively; the appearance of linear, branched structures, resembling antennas, luminescent in a dark field.

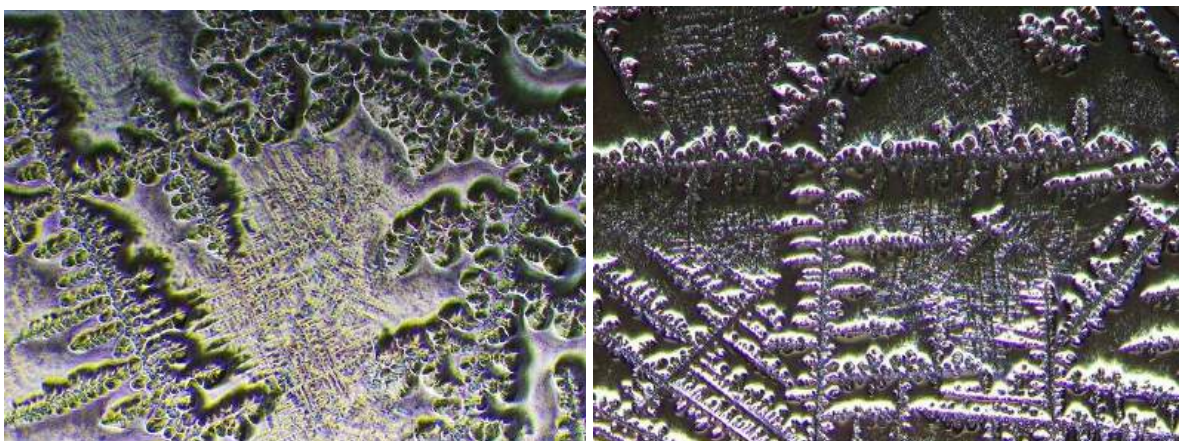
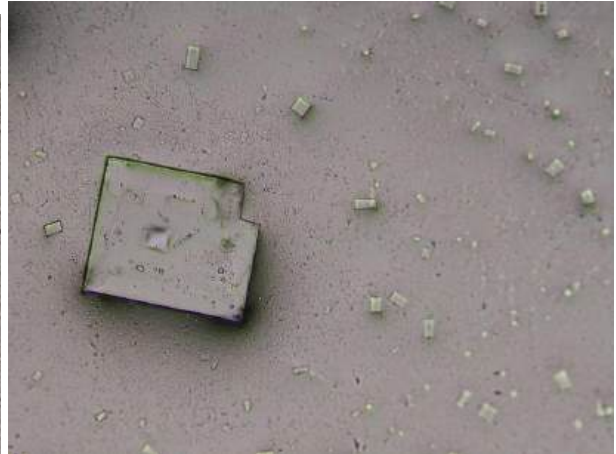
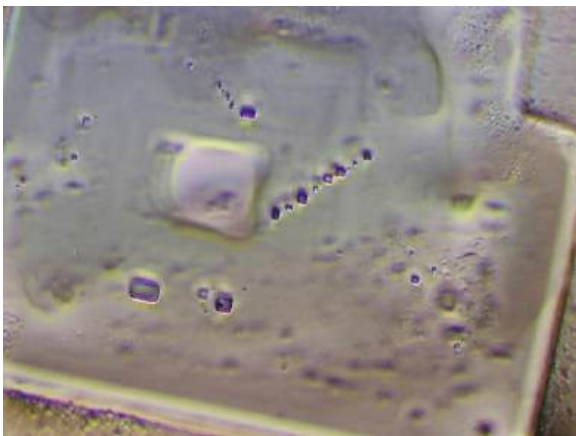
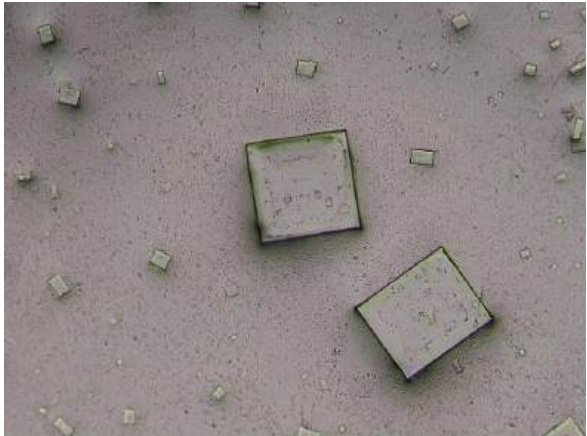


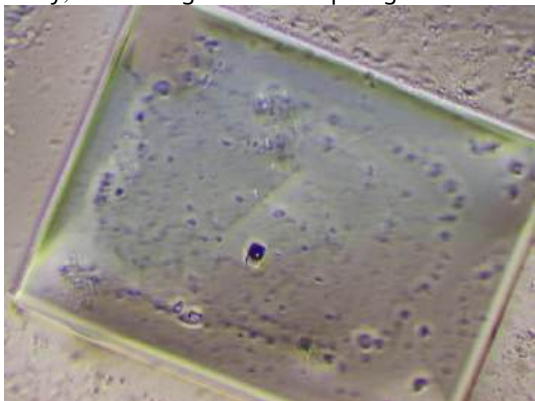
Image of crystallization/self-assembly in the drop of Comirnaty-Pfizer vaccine applied to the slide, 20 0x magnification; On the left: 40 minutes post-application, phase contrast examination; on the right: 2 hours post-application, dark field examination.



Comirnaty Pfizer vaccine administered on the slide 1.5 years after application as a drop on the slide, without coverslip (applied in December 2023, re-examined in April 2025), 200x magnification; The emergence of complex geometric structures of various dimensions is observed.



Comirnaty Pfizer vaccine administered on the slide 1.5 years after application as a drop on the slide, without coverslip (applied in December 2023, re-examined in April 2025), 200x and 400x magnification respectively; The emergence of complex geometric structures of various dimensions is observed.



Comirnaty Pfizer vaccine administered on the slide 1.5 years after the application of the drop on the slide, without a coverslip (applied in December 2023, re-examined in April 2025), 400x magnification; – geometric image.

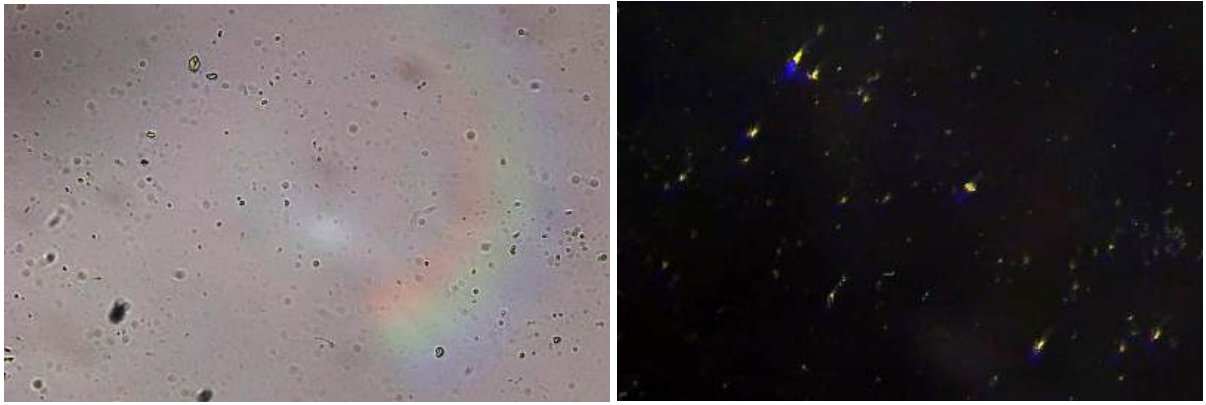


Image of the Moderna vaccine drop applied between the slide and coverslip, 400x magnification, a few minutes after application, examination in transmitted light on the left and in dark field on the right; particles of various sizes and shapes, in motion, luminescent.

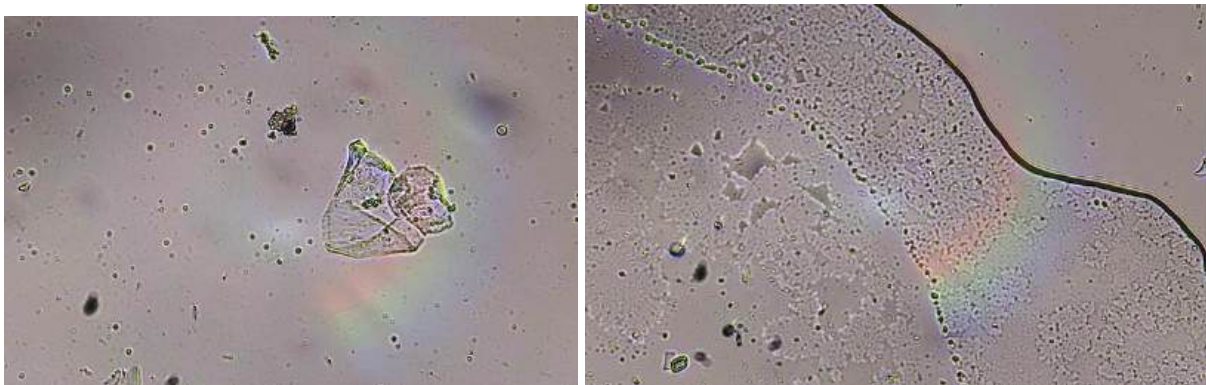


Image of the Moderna vaccine drop applied between the slide and coverslip, 400x magnification, examination in transmitted light; Many smaller particles of various shapes are observed moving, alongside some larger, immobile particles with a flat, folded structure. The images were captured a few minutes after application between the slide and coverslip (left image) and at 1 hour post-application (right image); The image on the right reveals the appearance of demarcation lines between the lower-left zone, where a crystallization process is initiating, and the upper-right zone, which remains more homogeneous and still contains mobile particles.

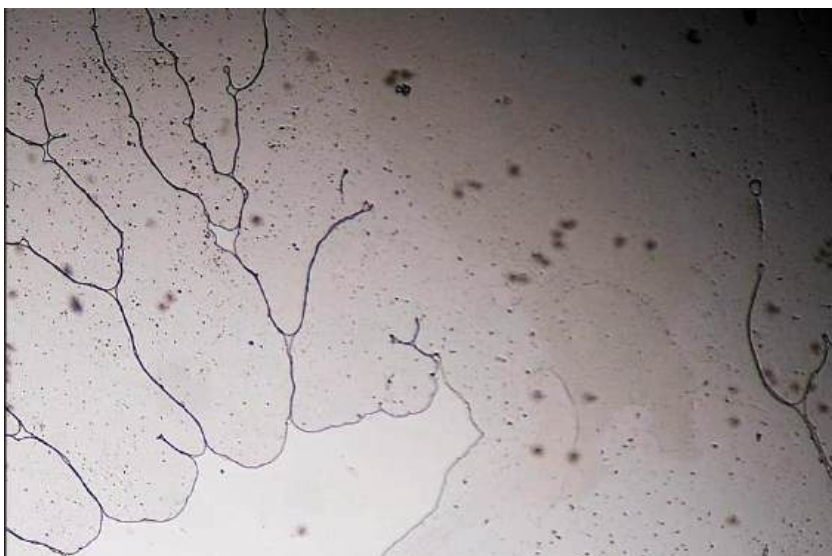


Image of the Moderna vaccine drop applied between slide and coverslip, 40x magnification, under transmitted light, 40 hours after application

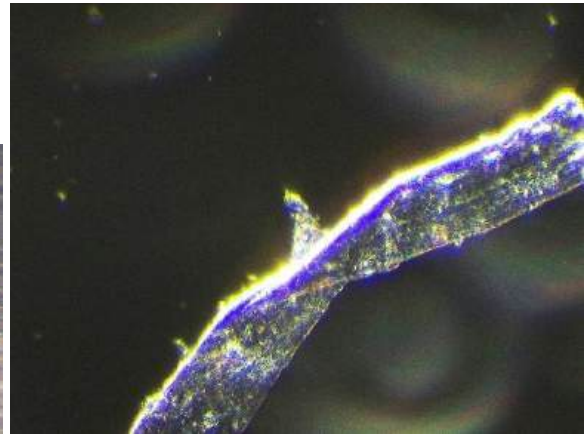


Image of the Moderna vaccine drop applied between slide and coverslip; 200x magnification in transmitted light (left) and 400x magnification in dark field (right); Particles in the form of fibers present in the image

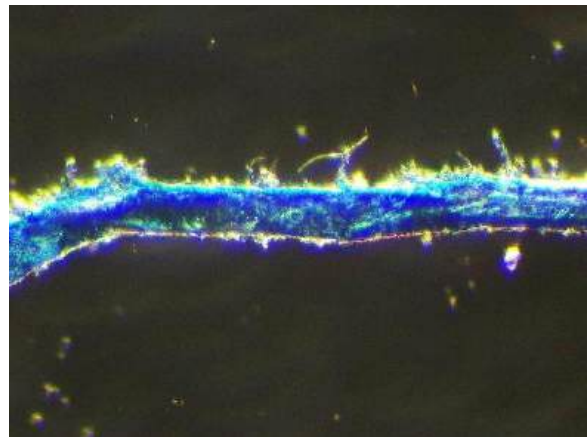
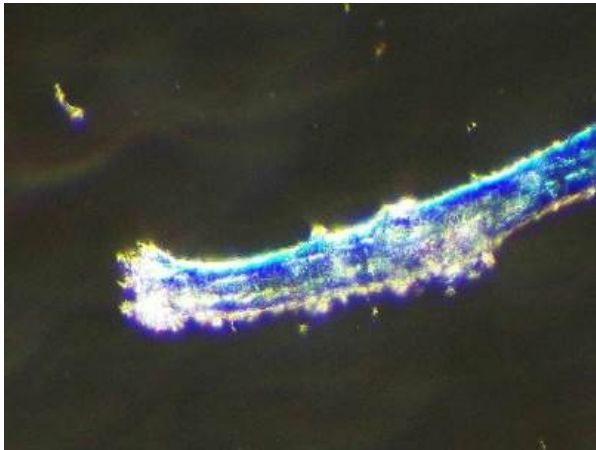
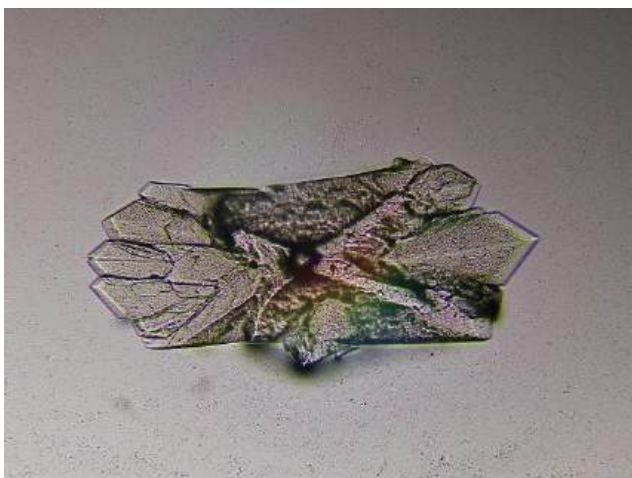


Image of the Moderna vaccine drop applied between slide and coverslip; 400x magnification in dark field; Particles in the form of blue fibers



Crystallization/self-assembly process in the Moderna vaccine drop; 40x magnification, 20 hours after application on the slide, without coverslip; examination in transmitted light (left) and in dark field (right)

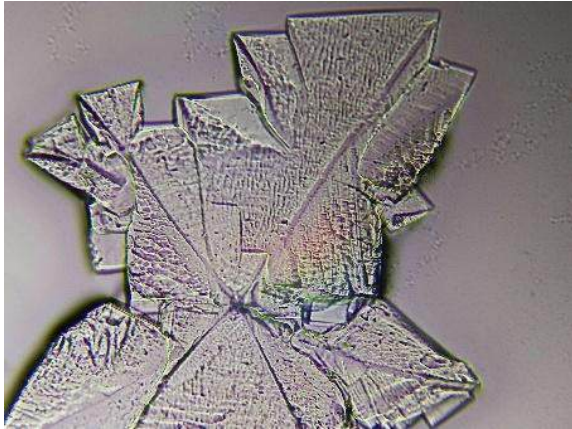


Image of crystallization/self-assembly in the Moderna vaccine drop applied on the slide; 20 hours after application, 100x magnification, examination in transmitted light

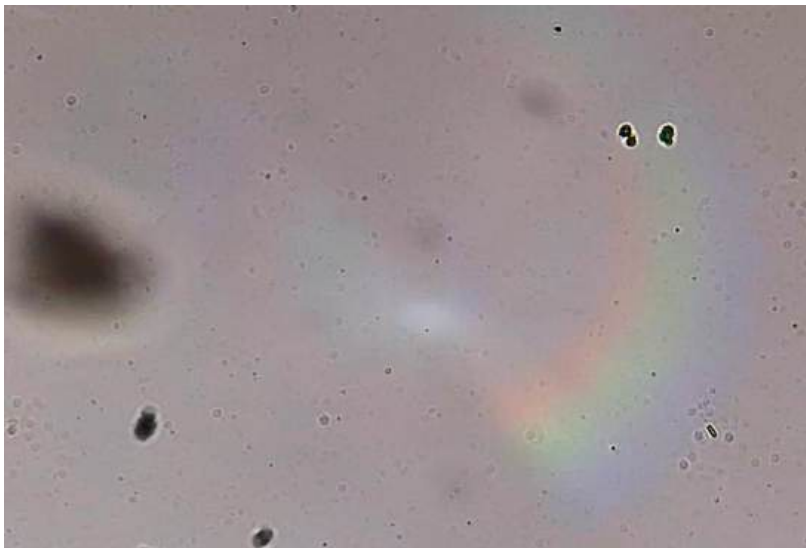


Image of a Comirnaty Omicron XBB.1.5 vaccine drop applied between slide and coverslip, several minutes after application, 400x magnification, examination in transmitted light; particles of different sizes, the small ones in motion.

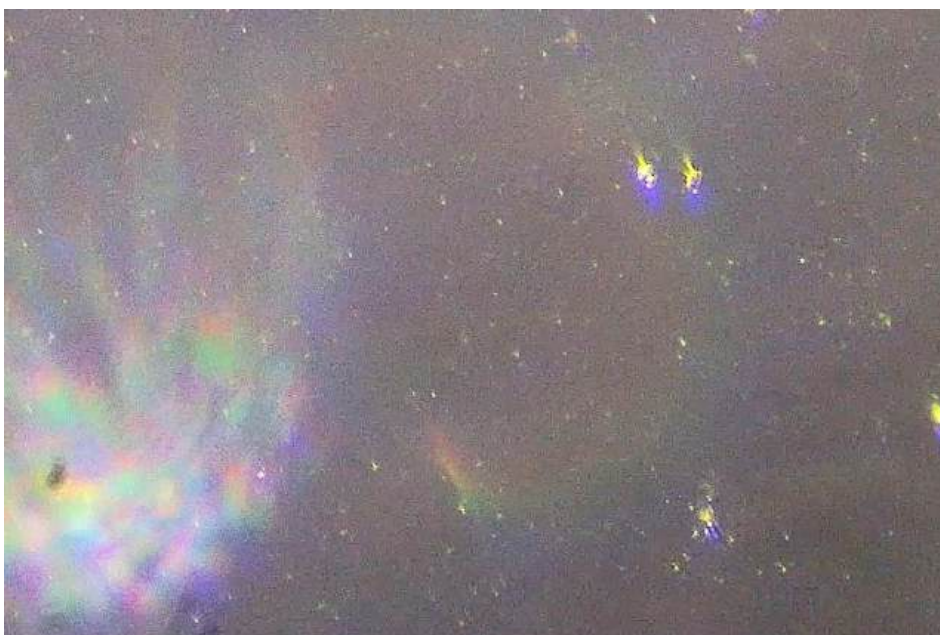


Image of a Comirnaty Omicron XBB.1.5 vaccine drop applied between slide and coverslip, several minutes after application, 400x magnification, dark-field microscopy; Particles of various sizes; The small ones, in motion, luminescent in dark field;

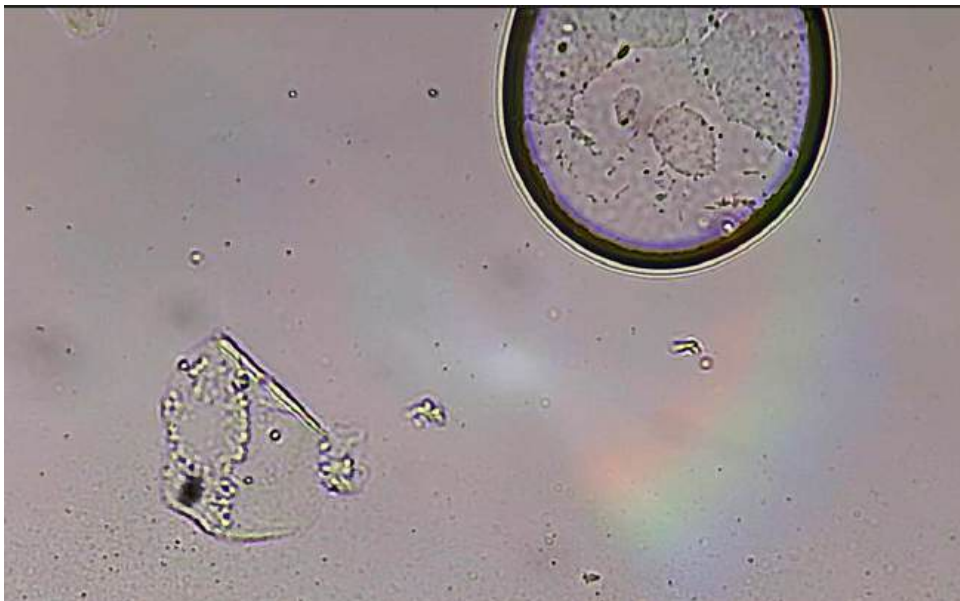


Image of a Comirnaty Omicron XBB.1.5 vaccine drop applied between slide and coverslip, several minutes after application, 400x magnification, in Transmitted light; Smaller particles of various sizes and shapes in motion; Certain particles possess an apparently flat, folded structure and are immobile; Demarcation lines and bubbles also appear, within which a crystallization/organization process begins.



Image of Comirnaty Omicron XBB.1.5 Vaccine drop applied between slide and coverslip, several minutes after application, 400x magnification, under transmitted light; Smaller particles of various sizes and shapes in motion; A larger, folded, immobile particle.



Image of Comirnaty Omicron XBB.1.5 Vaccine drop applied between slide and coverslip, 40x magnification, examined under transmitted light 23 hours after application.

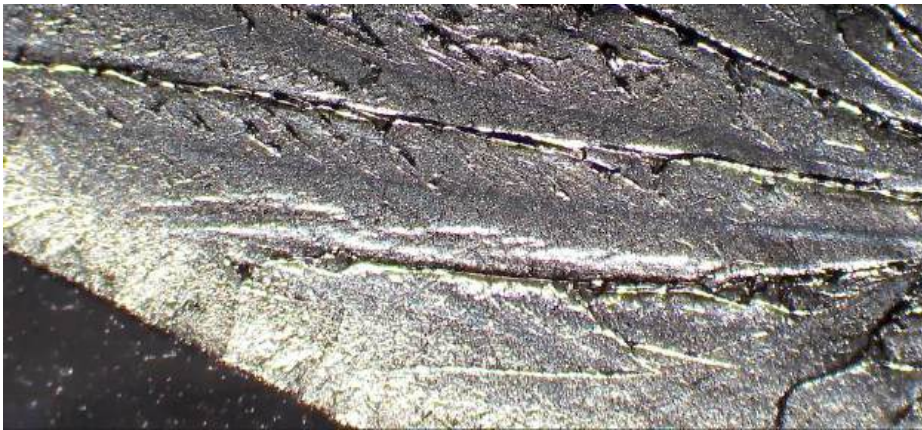


Image of crystallization/self-assembly in the drop of Moderna vaccine applied on the slide, without coverslip, examined after a period of approximately 1.5 years, 40x magnification, in dark field.

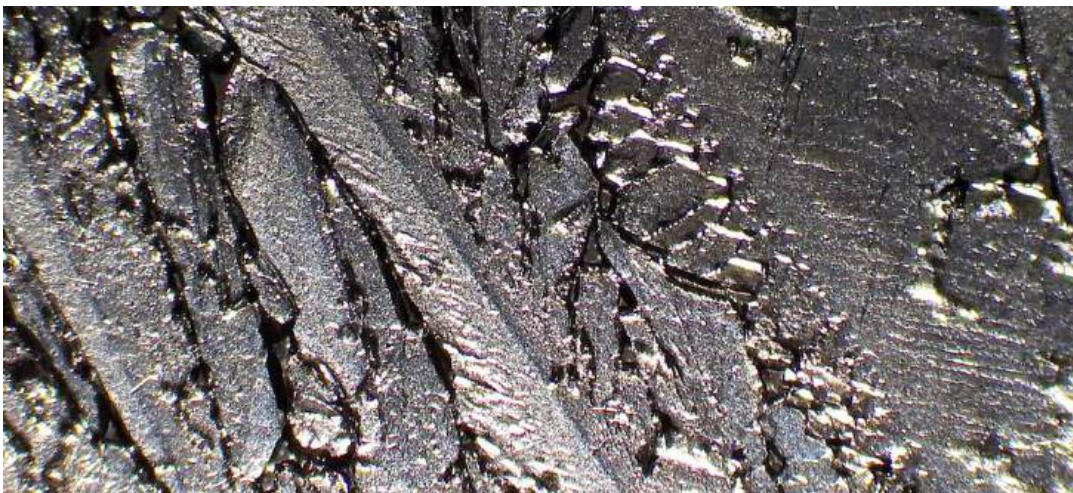


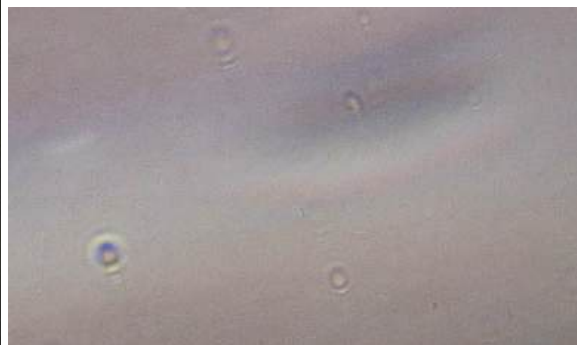
Image of crystallization/self-assembly in the drop of Moderna vaccine applied on the slide, without coverslip, examined after a period of 1.5 years, 40x magnification, in dark field.



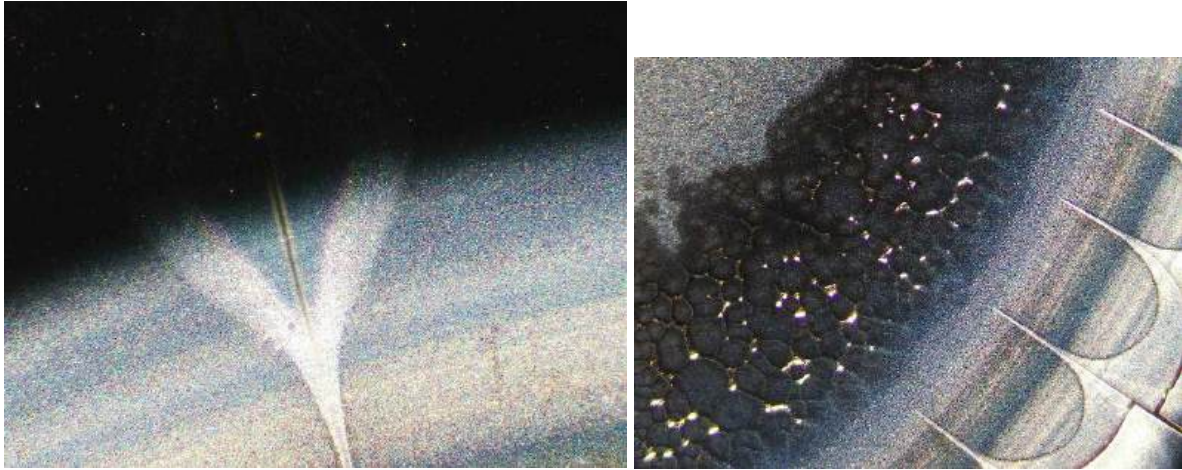
Image of crystallization/self-assembly at 23 hours after application on the slide, measuring approximately 3 mm (left) in the drop of Comirnaty-Omicron BA 4-5 vaccine, applied on the slide, without coverslip, 40x magnification, examined in transmitted light on the left and in dark field on the right.



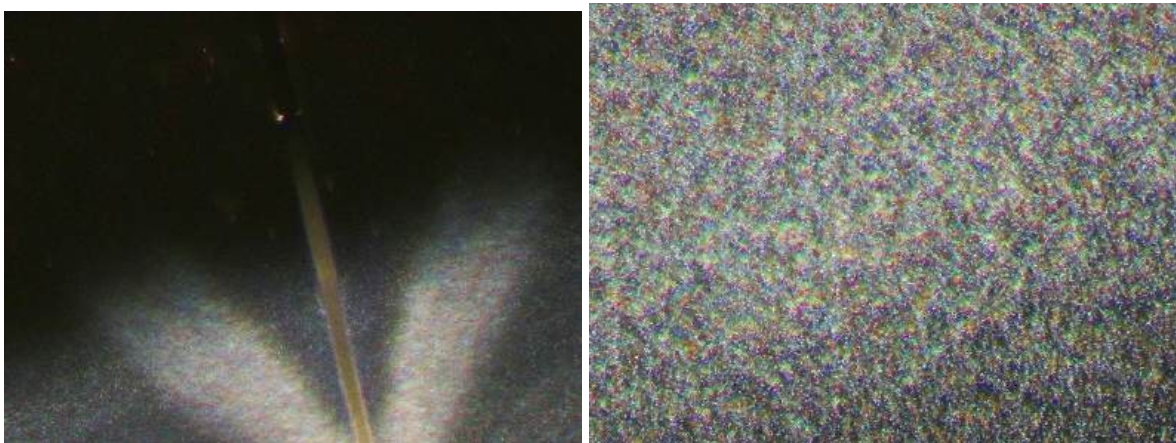
Image of crystallization/self-assembly in the drop of Comirnaty Omicron BA 4-5 vaccine applied on the slide, without coverslip, after 1.5 years, 40x magnification, examination in transmitted light.



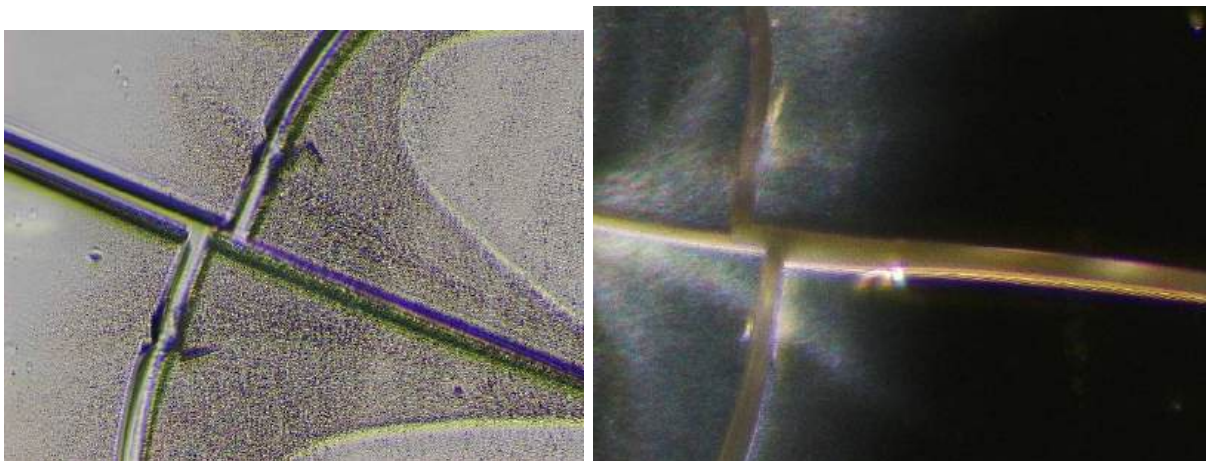
The Janssen vaccine (Johnson & Johnson), 400x magnification, the drop applied on the slide without coverslip, 10 minutes post-application; On the left, examination in dark field; on the right, examination with phase contrast. Mobile, luminescent particles are observed in dark field.



The Janssen vaccine (Johnson & Johnson), dark field, 100x magnification, the drop applied on the slide, without coverslip, 15 minutes post-application. Luminescent particles of various colors, following a perfectly regular organizational pattern.



The Janssen vaccine (Johnson & Johnson), dark-field microscopy, 400x magnification, the drop applied to the slide, without coverslip, at 30 minutes post-application.



The Janssen vaccine (Johnson & Johnson), dark-field microscopy, 400x magnification, the drop applied to the slide, without coverslip, at 1h 20min post-application; examination in transmitted light on the left and in dark field on the right.

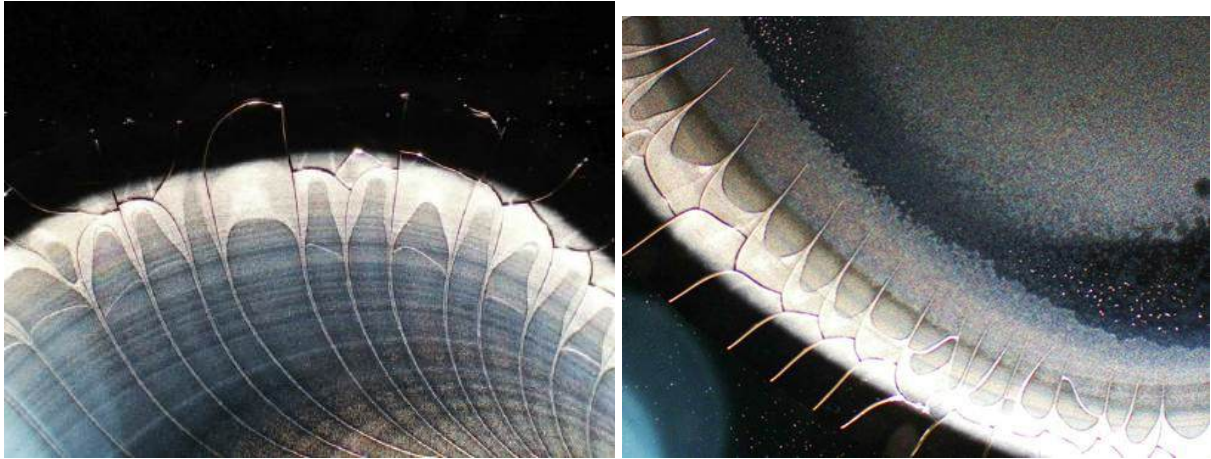


Image of crystallization/self-assembly—the Janssen vaccine (Johnson & Johnson), 40x magnification, the drop applied to the slide, without coverslip, dark-field microscopy, at one hour post-application.

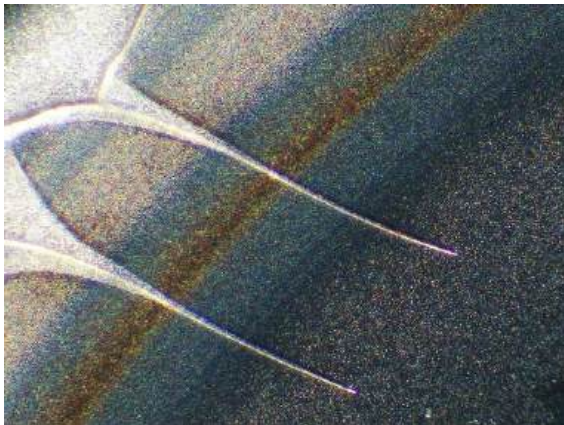
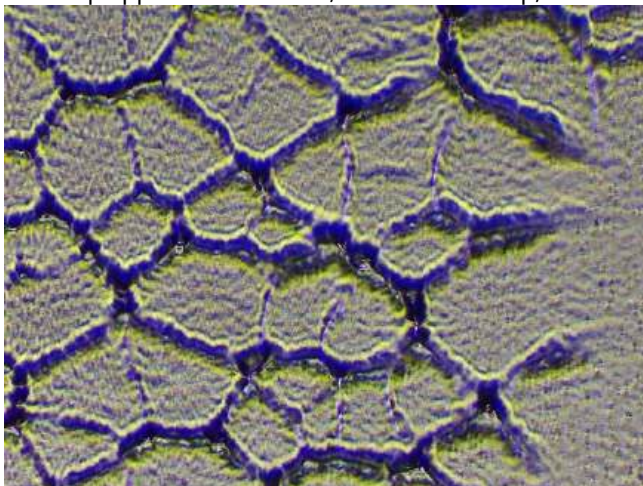


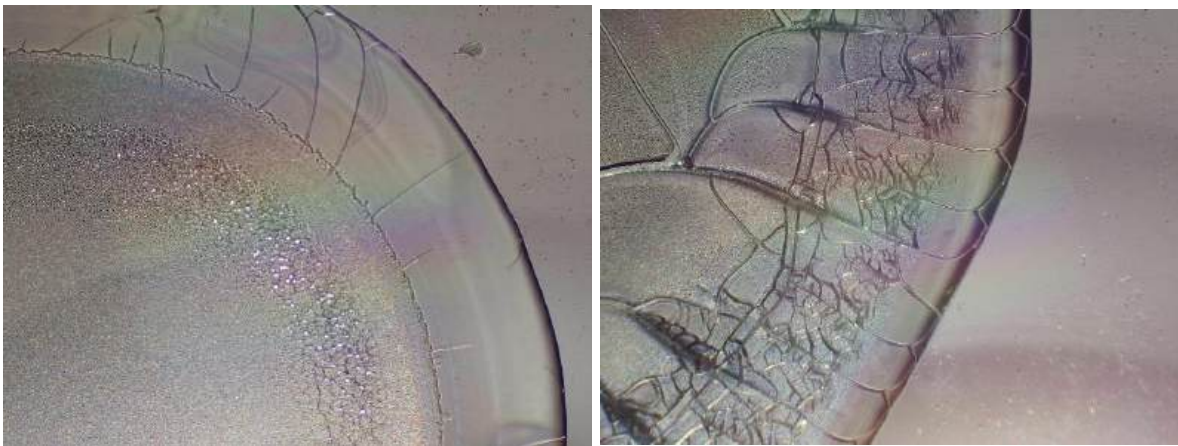
Image of crystallization/self-assembly - the Janssen vaccine (Johnson & Johnson), 200x magnification, the drop applied on the slide, without coverslip, dark-field microscopy, one hour after application.



The Janssen vaccine (Johnson & Johnson), 400x magnification, the drop applied on the slide without coverslip, examination of the central portion of the drop, 1h 30 min after application, dark-field microscopy.



Image of crystallization/self-assembly - the Janssen vaccine (Johnson & Johnson), the drop applied on the slide, without coverslip, 20 hours after application on the slide; On the left 40x magnification, dark-field microscopy, and on the right 100x magnification, examination in transmitted light.



The Janssen vaccine (Johnson & Johnson), the drop applied on the slide, without coverslip, examination in transmitted light; On the left 40x magnification, one hour after application, and on the right 100x magnification, 15 days after application on the slide

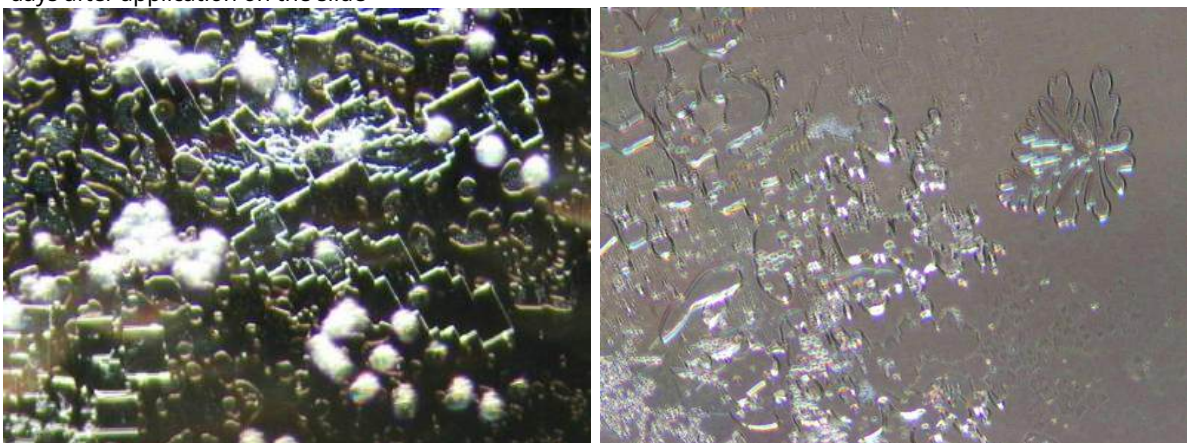


Image of crystallization/self-assembly - the Janssen vaccine (Johnson & Johnson), the drop applied between slide and coverslip, 200x magnification, on the left dark-field microscopy and on the right examination in transmitted light 15 days after application

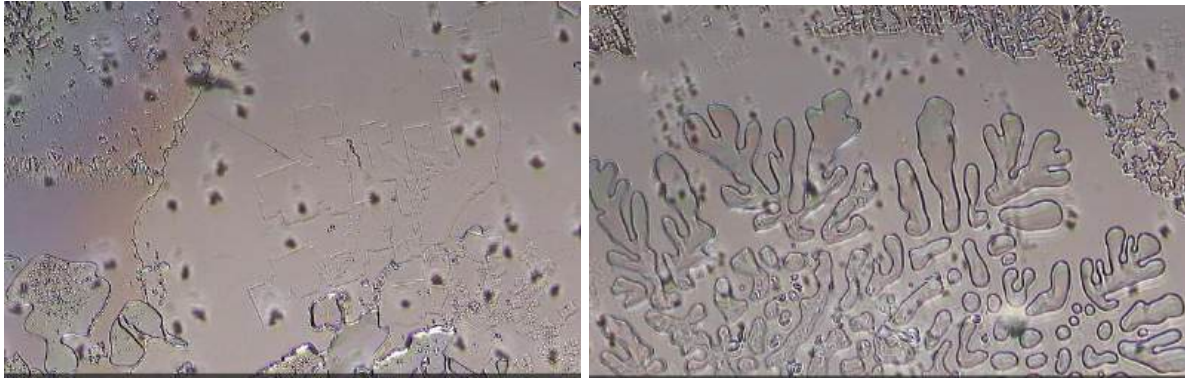


Image of crystallization/self-assembly - the Janssen vaccine (Johnson & Johnson), 100x magnification, the drop applied between slide and coverslip, examination in transmitted light, 15 days after application

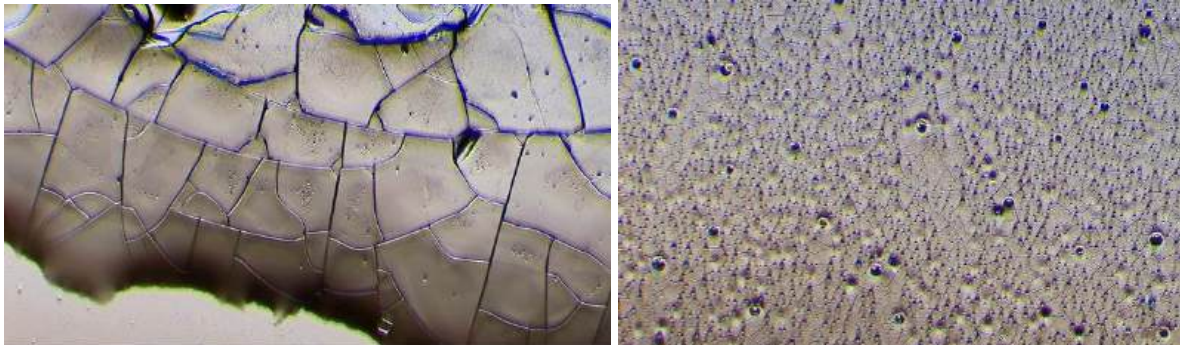


Image of crystallization/self-assembly within the drop of Janssen (Johnson & Johnson) vaccine applied to a slide, without coverslip, at 1.5 years; 200x magnification, examination in transmitted light.

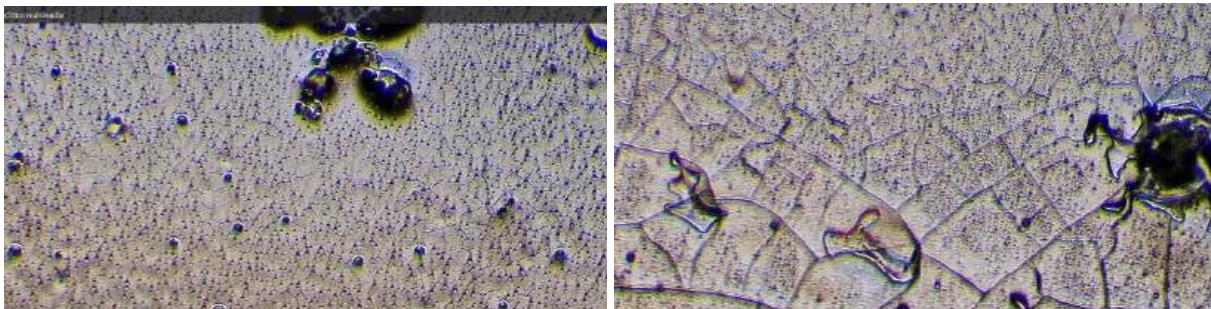


Image of crystallization/self-assembly within the drop of Janssen (Johnson & Johnson) vaccine applied to a slide, without coverslip, examined 1.5 years after application to the slide; 200x magnification, in transmitted light.

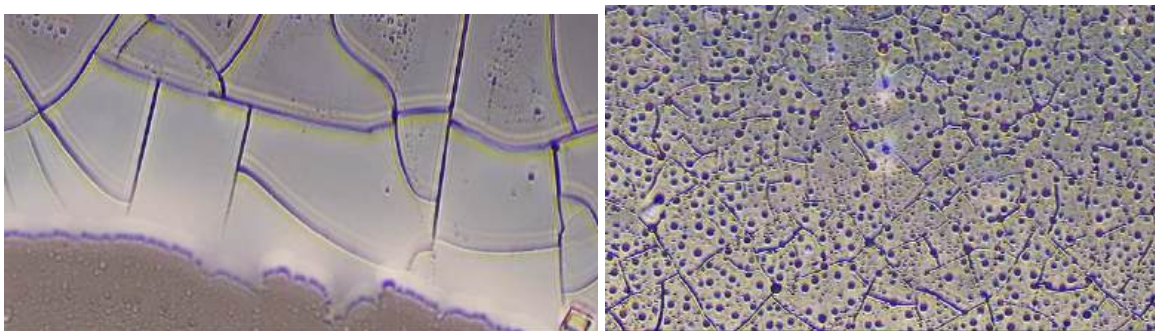


Image of crystallization/self-assembly within the drop of Janssen (Johnson & Johnson) vaccine applied to a slide, without coverslip, examined 1.5 years after application to the slide; 400x magnification, in transmitted light.

Personal investigations – Scanning Electron Microscopy (SEM) and X-ray spectroscopy (EDX)

With great difficulty, after extensive searches for an electron microscopy specialist willing to investigate the COVID-19 vaccines, I succeeded in performing a scanning electron microscopy (SEM) and X-ray spectroscopy (EDX) analysis in October 2023 for two vials: one from Moderna and one of Comirnaty-Omicron B4-5. This investigation represents a determination of the elements and atoms within a specific compound.

From the very brief and difficult discussion held via email with the electron microscopy specialist, who wished to remain anonymous, I understood that EDX analyzes very small samples on the order of microliters; that analyzing an entire vaccine vial would take months and be very costly; that certain elements with a concentration of less than 1% might not be detectable; and that, because the examination grid/support is composed of nickel, any nickel within the sample cannot be quantified.

It has been established that both products, the Moderna and Comirnaty Omicron XBB.1.5 vaccines, primarily contain carbon, oxygen, and silicon atoms, with no nitrogen or Phosphorus atoms identified, as would be expected if these products contained mRNA or DNA. Furthermore, in the Comirnaty Omicron product, magnesium, titanium, and a rare element, Yttrium, were also identified. In the Moderna product, titanium, tin, aluminum, and magnesium atoms were also found. I note that the identification of elements such as silicon, magnesium, titanium, tin, aluminum, and Yttrium was unexpected, as they were not declared by the manufacturer.

I initially released the scanning electron microscopy (SEM) and energy-dispersive X-ray spectroscopy (EDX) results on December 13, 2023 in the ActiveNews journal – “**Dr. Geanina Hagimă: “The mRNA COVID-19 vaccines” - updates regarding their composition. Nanotechnology – the elephant in the room. Solutions?**”

<https://www.activenews.ro/opinii/Dr.-Geanina-Hagima-Vaccinurile-covid-ARNm-noutati-in-ce-priveste-compozitia.-Nanotehnologia-%E2%80%93-elefantul-din-camera.-Solutii-186261>.

These results were subsequently reviewed by Dr. Ana Mihalcea from the USA, with whom I recorded a broadcast later shared by ActiveNews - “**VIDEO: Dr. Ana-Maria Mihalcea conducted an interview with Dr. Geanina Hagima - New analysis of C19 biological weapons: silicon and Toxic substances used in nanotechnology, found even in dental anesthetics and in the Pneumovax vaccine**” <https://www.activenews.ro/stiri-sanatate/VIDEO-Dr.-Ana-Maria-Mihalcea-a-realizat-un-interviu-cu-Dr.-Geanina-Hagima-Noua-analiza-a-armelor-biologice-C19-siliciu-si-metale-toxice-folosite-in-nanotehnologie-gasite-inclusiv-in-anestezice-dentare-si-in-vaccinul-Pneumovax-185909>.

In order for the findings of my investigations to reach other researchers on an international level, I decided in **September 2024** to publish the results in English on the Academia.edu platform; I was aware, following extensive efforts to expose the falsehoods regarding the COVID-19 vaccines, that no scientific journal would publish my article due to the censorship of any independent studies that did not align with official narratives.

https://www.academia.edu/124251340/The_Moderna_and_Comirnaty_B4_5_vaccines_do_not_contain_nitrogen_and_phosphorus_energy_dispersive_X_ray_spectroscopy_so_they_do_not_contain_mRNA_Nanotechnology_in_covid_vaccines. I hereby attach the content of my article entitled “**The Moderna and Comirnaty B4-5 vaccines do not contain nitrogen and phosphorus**”

(energy-dispersive X-ray spectroscopy), therefore they do not contain mRNA. Nanotechnology in the anti-COVID vaccines ”. I present hereafter the content of this article.

Introduction

The fact that the anti-COVID vaccines contain nanoparticles obtained through nanotechnology is officially declared. According to studies, nanotechnology can cause various adverse effects, including damage to the DNA. However, the product leaflet of these experimental products clearly states that carcinogenicity and genotoxicity studies were not performed, as it was assumed that these products have no genotoxic potential.

It is little known, even among physicians and pharmacists, that nanotechnology is not clearly regulated and that nano-elements possess properties distinct from those of larger dimensions. The nano-industry is extremely well-funded, and nanotechnology is being utilized in numerous fields, including the pharmaceutical sector. Toxicity of nanotechnological products is poorly studied, which raises serious suspicions regarding the safety of their use. Professionals across various fields are unfamiliar with the special properties of the nanoproducts and the toxicity issues they pose; this is difficult to comprehend, given that these technologies have been employed for many years across numerous sectors

Although the manufacturers were aware of these regulatory issues regarding nanotechnology and its possible toxic effects, the anti-COVID vaccines were approved, distributed, and promoted as being 'safe and effective'. This observation could be useful in legal actions against both the manufacturers and those who presented them to the public as being safe.

Given the numerous uncertainties regarding the anti-COVID vaccines, including their composition , I decided to conduct an analysis of the Moderna vaccine, as well as the Comirnaty-Omicron B4-5 vaccine, in October 2023, with the assistance of a professional in electron microscopy.

Methodology

The analysis consisted of scanning electron microscopy and energy-dispersive X-ray spectroscopy (EDX). It should be noted that EDX may not detect elements with a concentration of less than 1%. Furthermore, since the examination grid/support is composed of nickel, the nickel within the sample is not quantified.

Results

It was found that both products, the vaccines Moderna and Comirnaty Omicron XBB.1.5, primarily contain carbon atoms, oxygen, and silicon, without any identification of nitrogen atoms or Phosphorus, as would be expected if these products contained mRNA or DNA. Additionally, in the Comirnaty product, magnesium, titanium, and a rare element, Yttrium, were also identified. In the Moderna product, we also found atoms of titanium, tin, aluminum, and magnesium

The following are images obtained through scanning electron microscopy and energy-dispersive X-ray spectroscopy (EDX) of the Moderna vaccine.

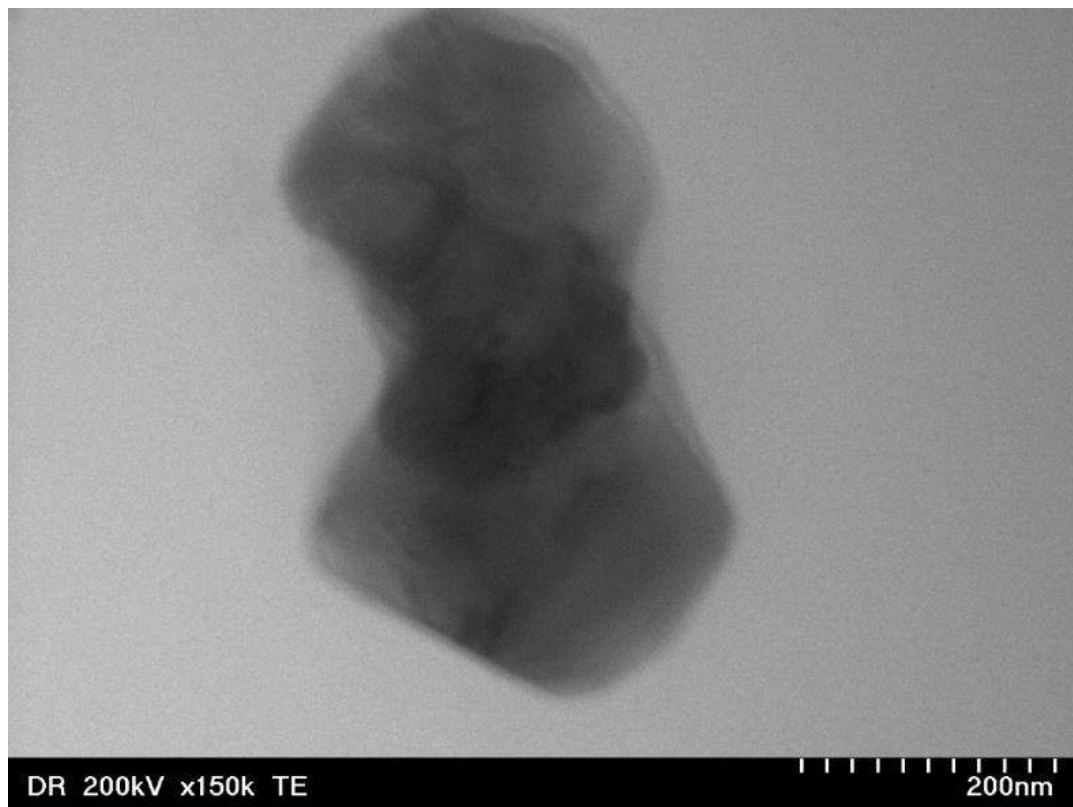


Fig. 1. Scanning electron microscopy – the Moderna vaccine.

Electron Image 1

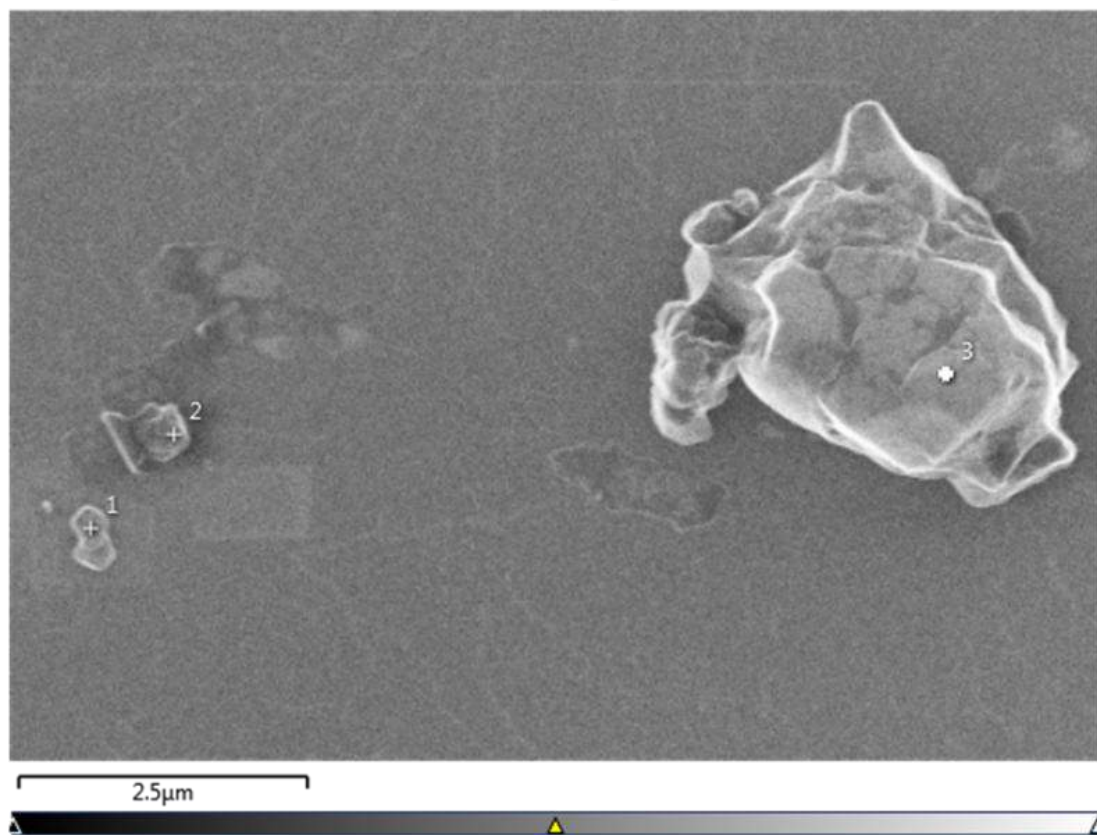


Fig. 2. Scanning electron microscopy – the Moderna vaccine.

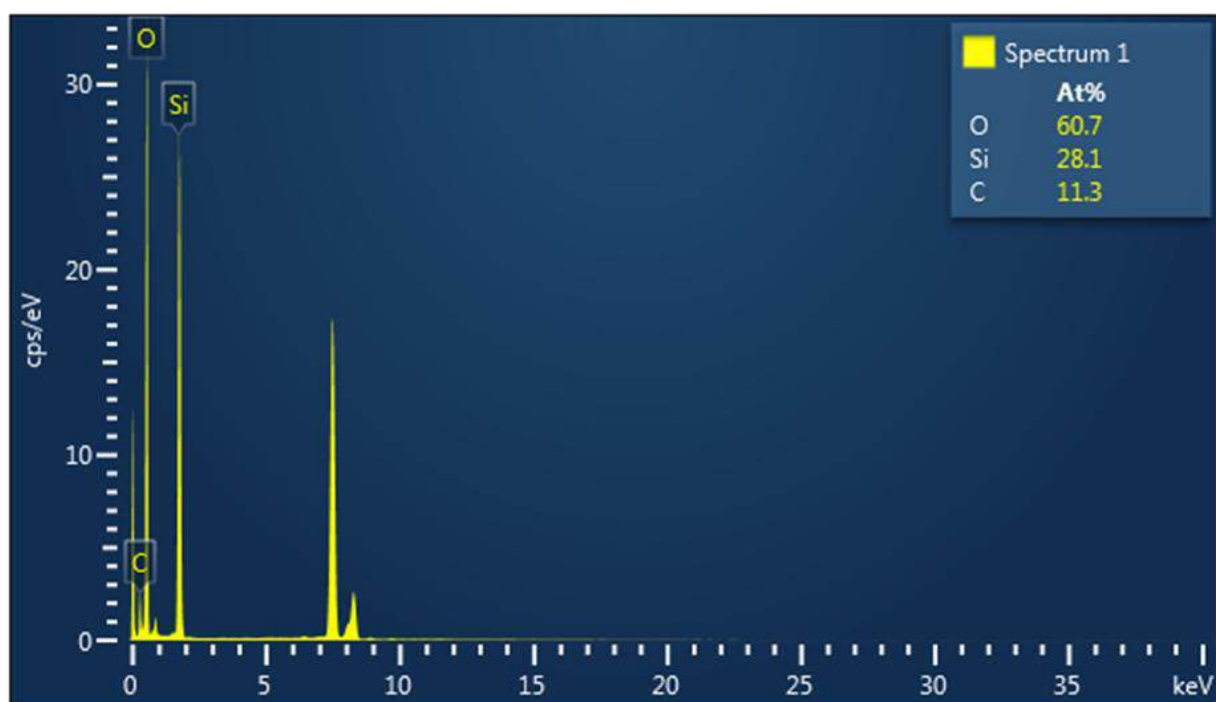


Fig. 3 Energy-dispersive X-ray spectroscopy – the Moderna vaccine

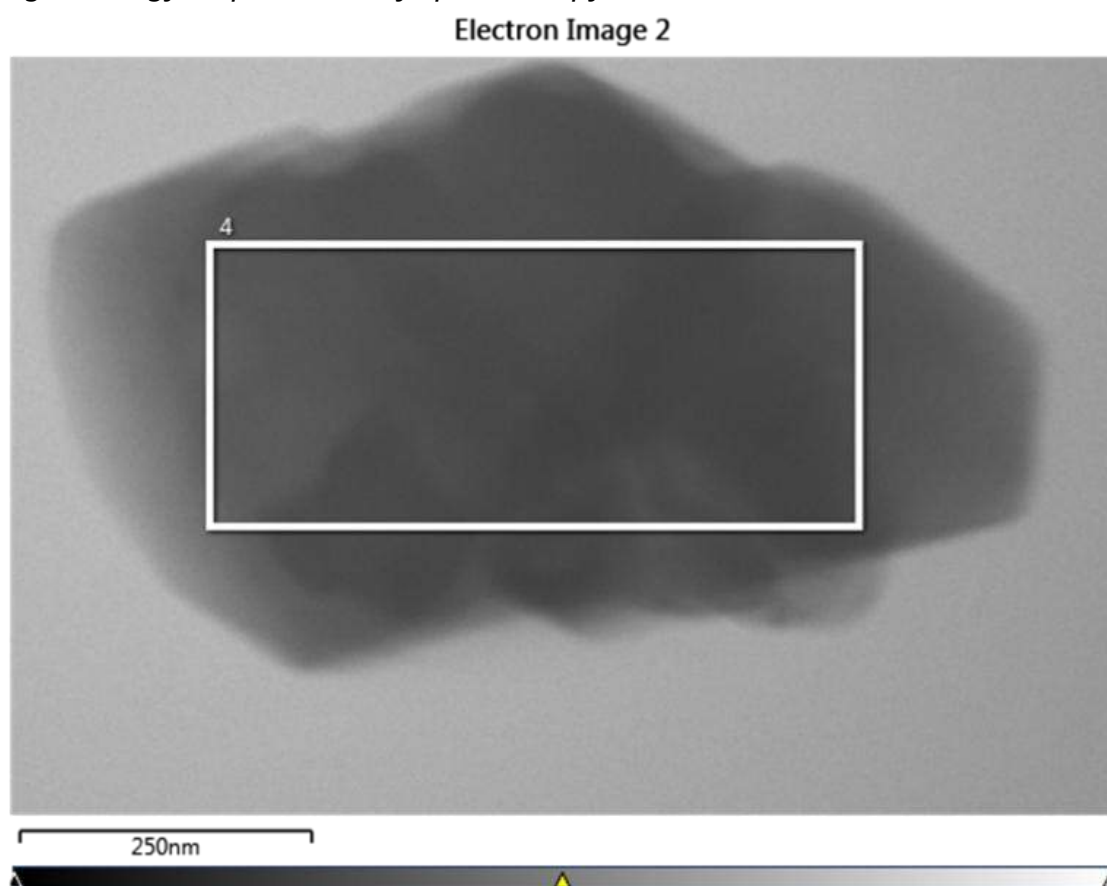


Fig. 4 Scanning electron microscopy – the Moderna vaccine.

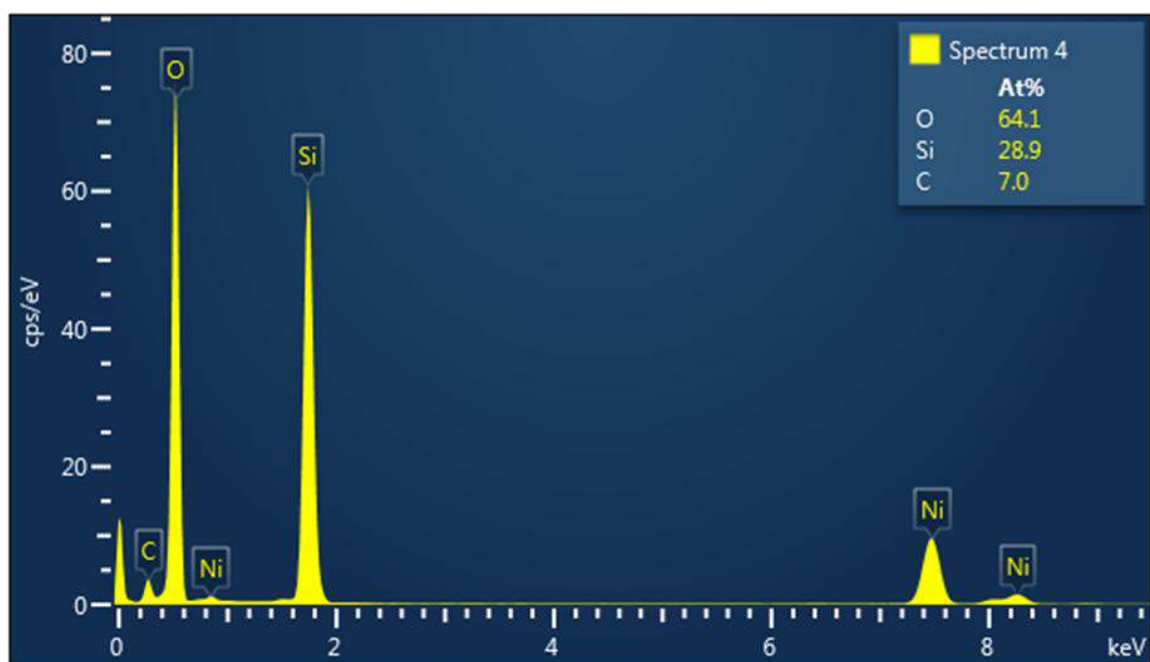


Fig. 5. Energy-dispersive X-ray spectroscopy – the Moderna vaccine

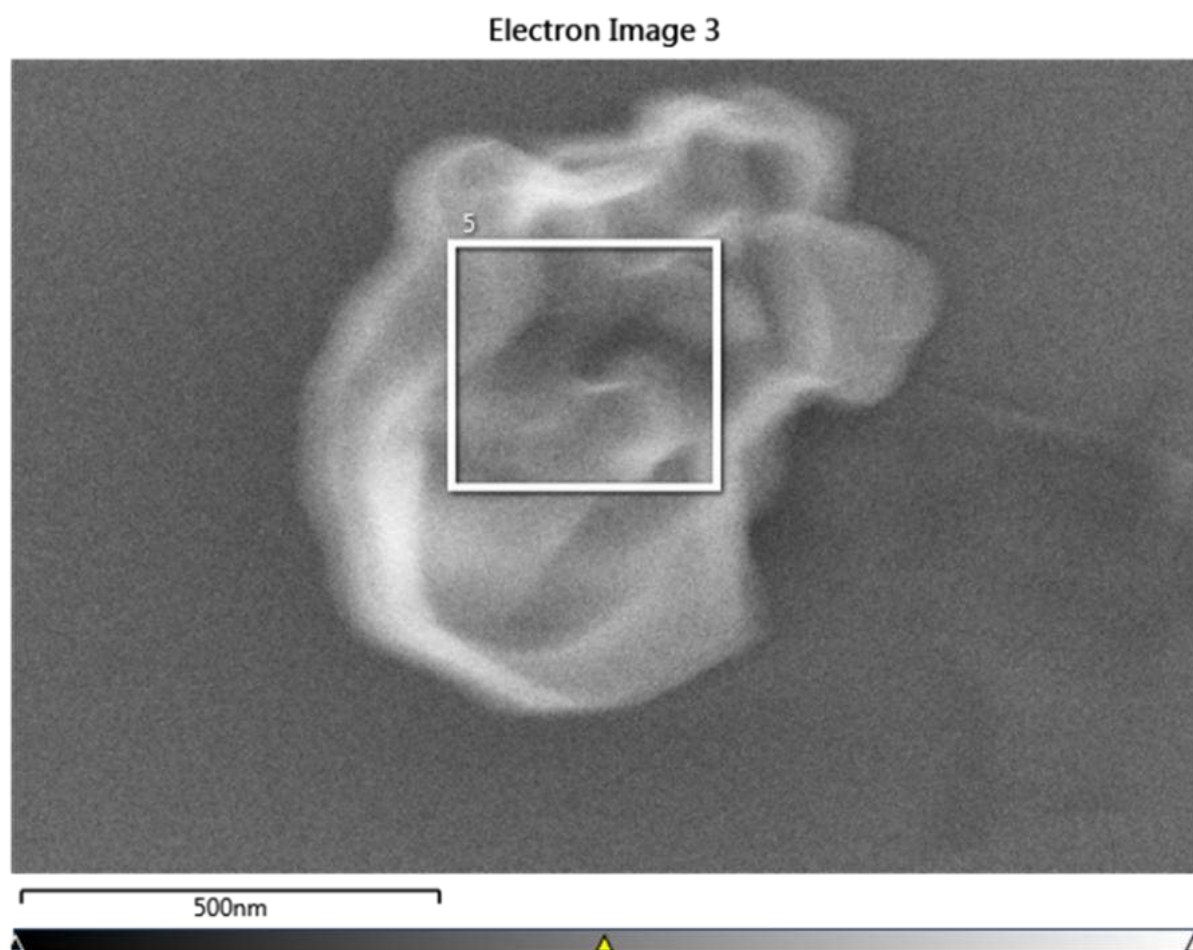


Fig. 6 Scanning electron microscopy – the Moderna vaccine.

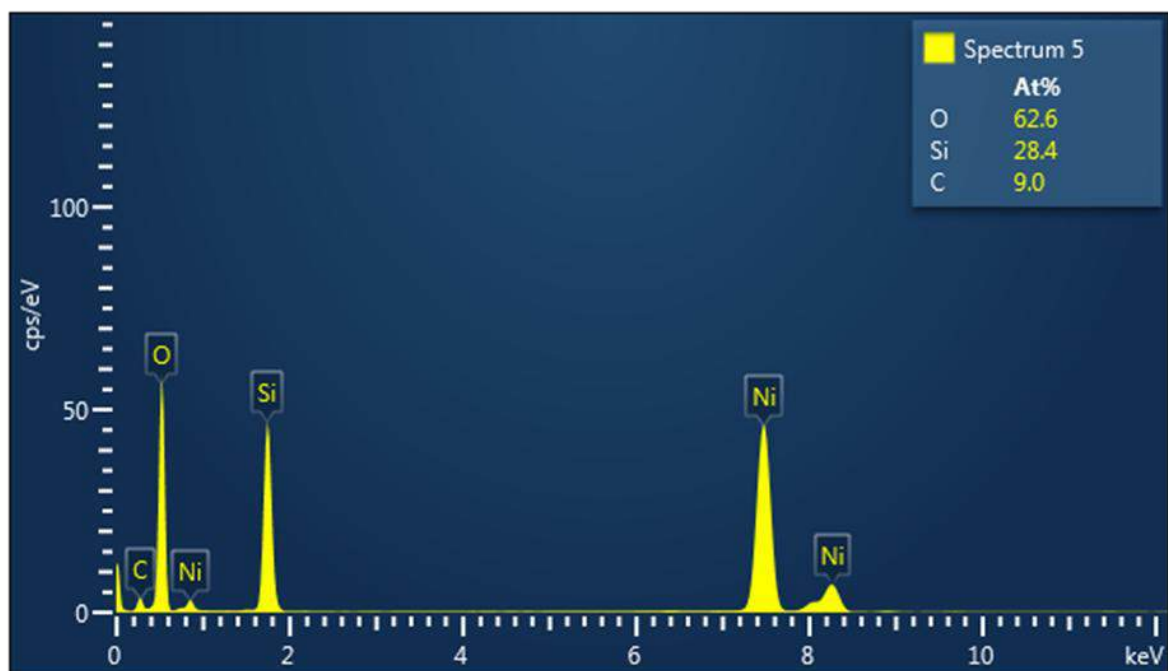


Fig. 7 Energy-dispersive X-ray spectroscopy – the Moderna vaccine

Electron Image 4

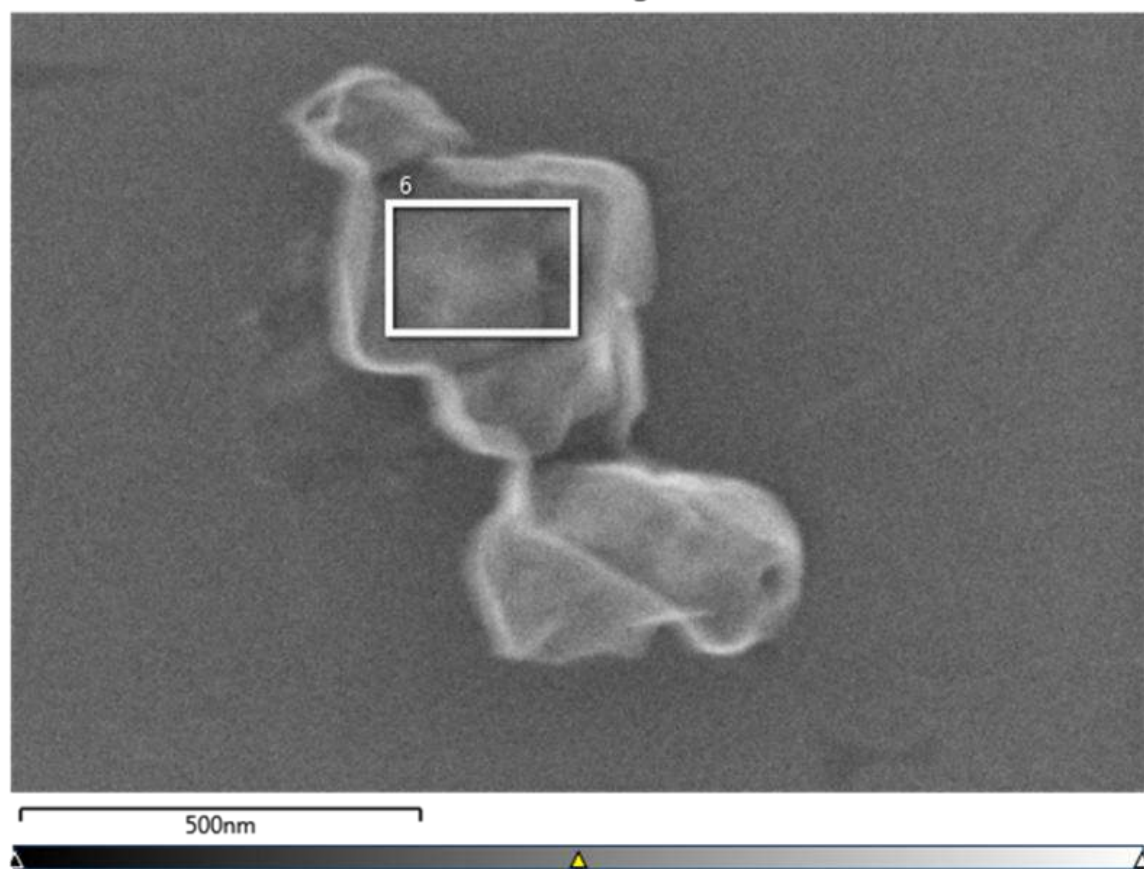


Fig. 8 Scanning electron microscopy – the Moderna vaccine.

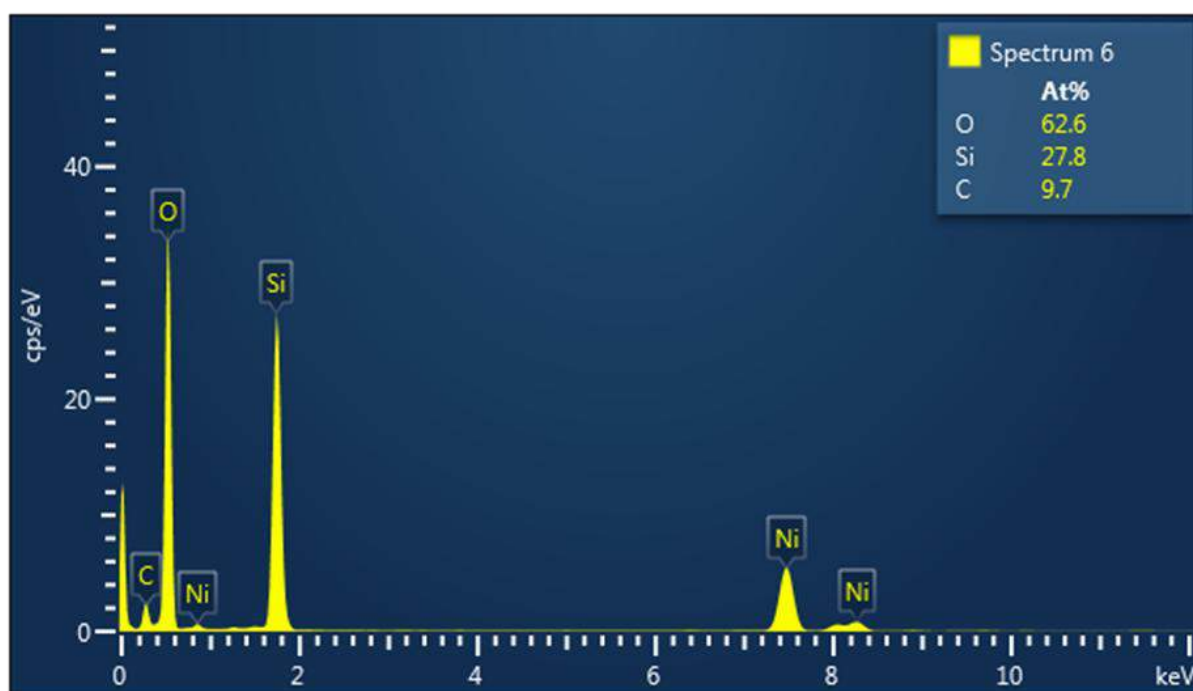


Fig. 9 Energy-dispersive X-ray spectroscopy – the Moderna vaccine

Electron Image 5

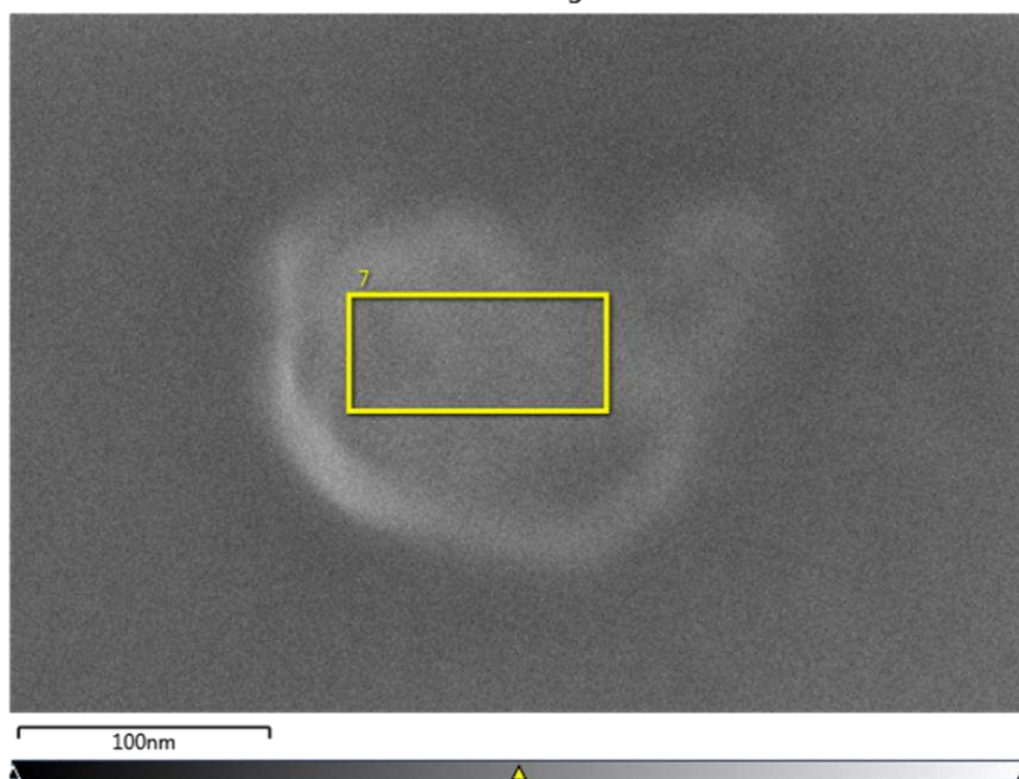


Fig. 10 Scanning electron microscopy – the Moderna vaccine.

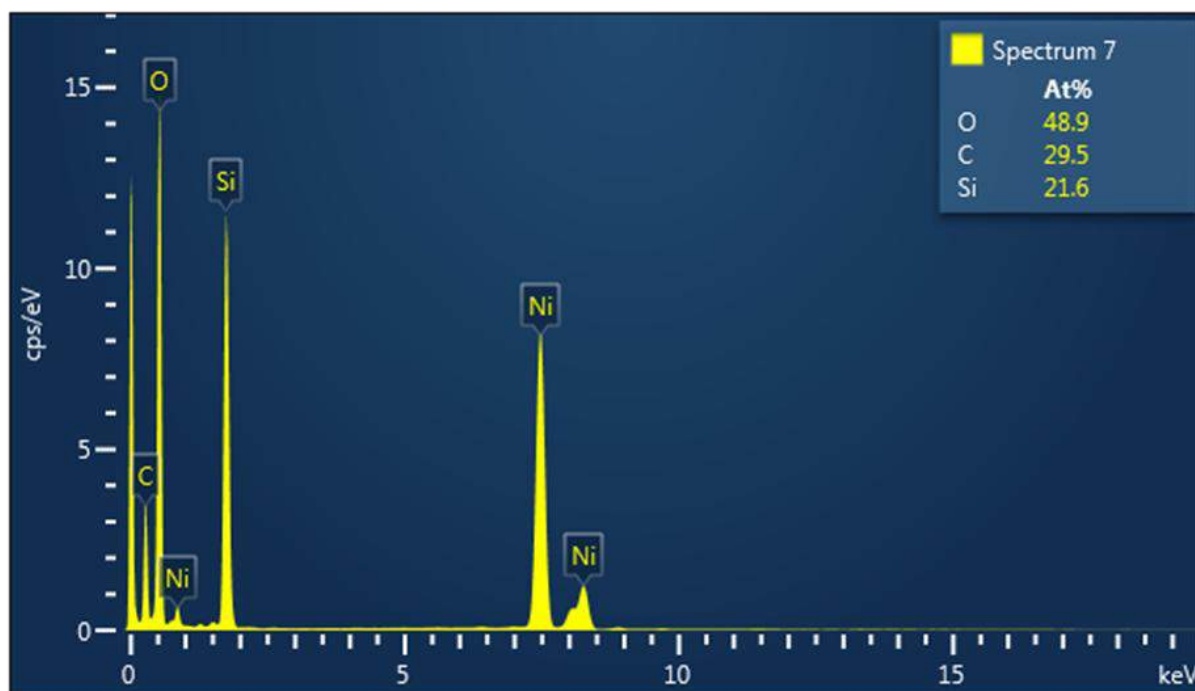


Fig. 11. Energy-dispersive X-ray spectroscopy – The Moderna vaccine

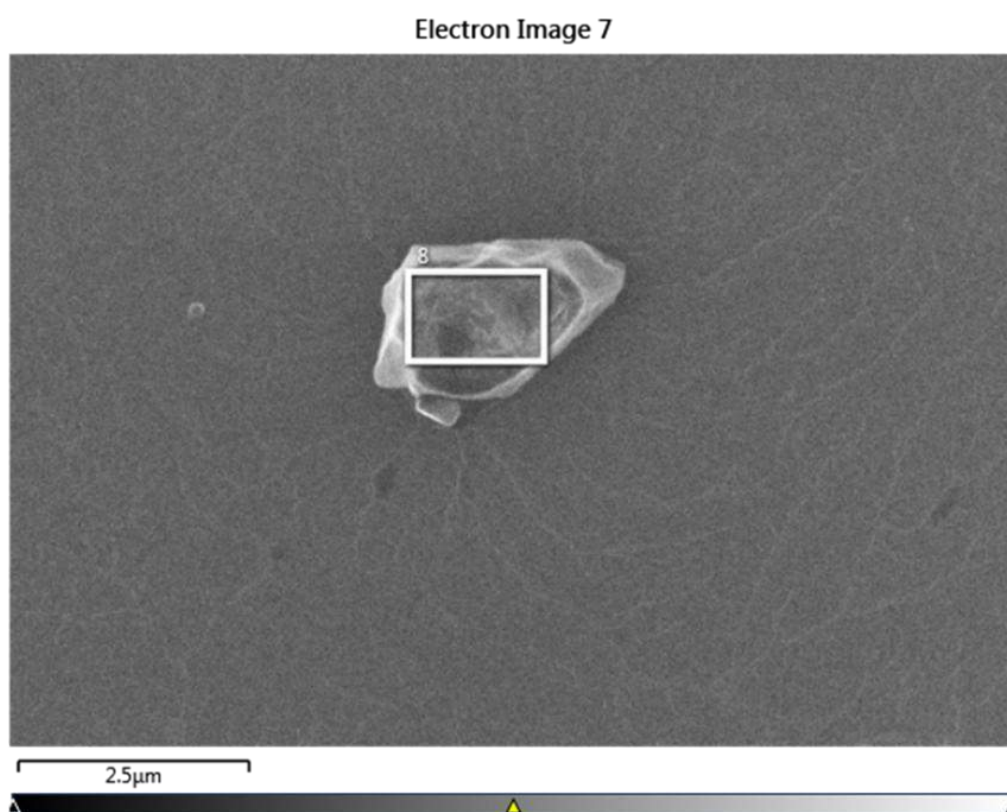


Fig. 12 Scanning electron microscopy – the Moderna vaccine

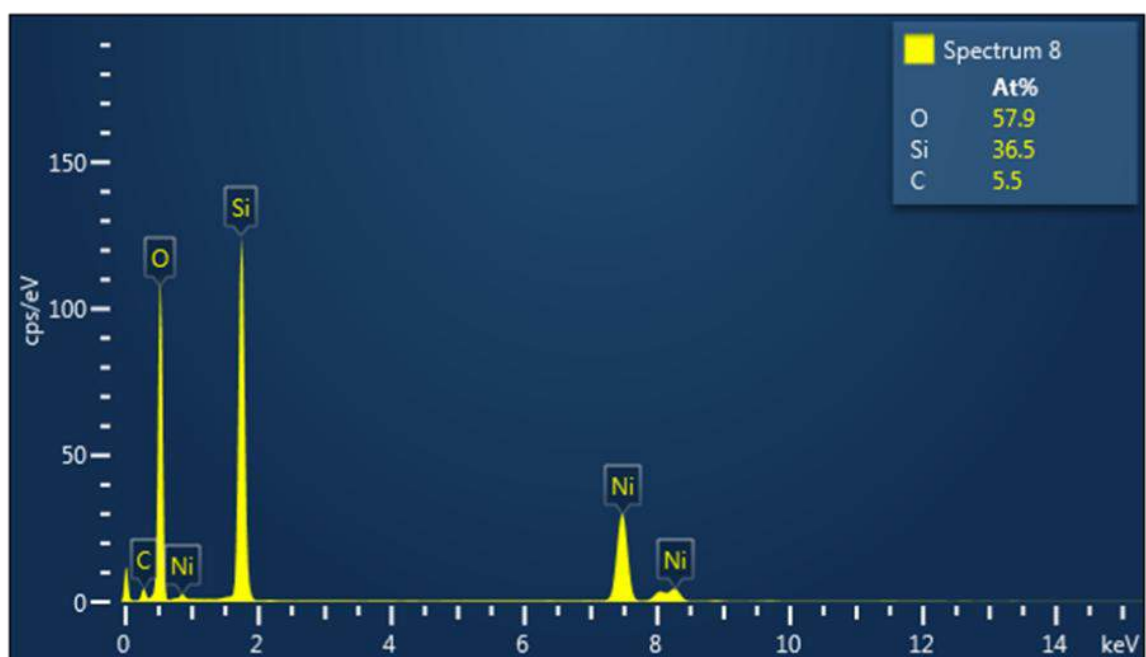


Fig. 13 Energy-dispersive X-ray spectroscopy – The Moderna vaccine

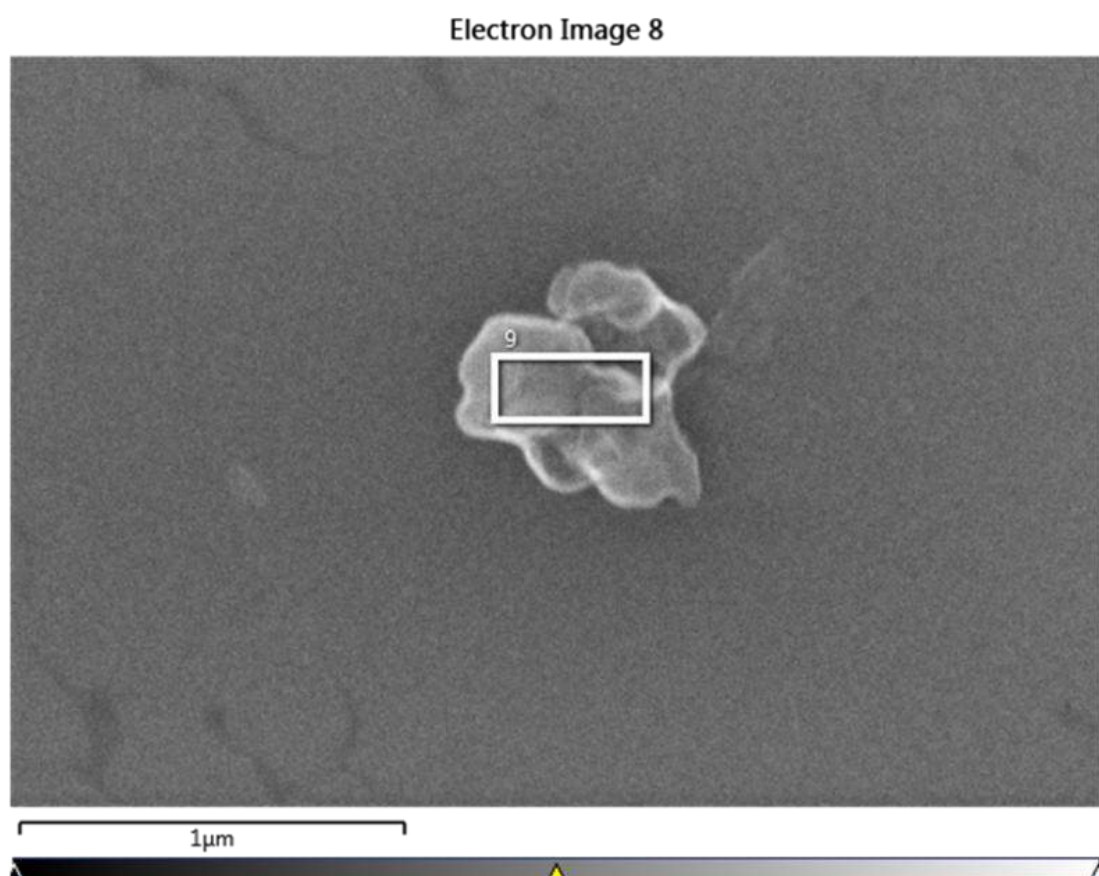


Fig. 14. Scanning electron microscopy – the Moderna vaccine.

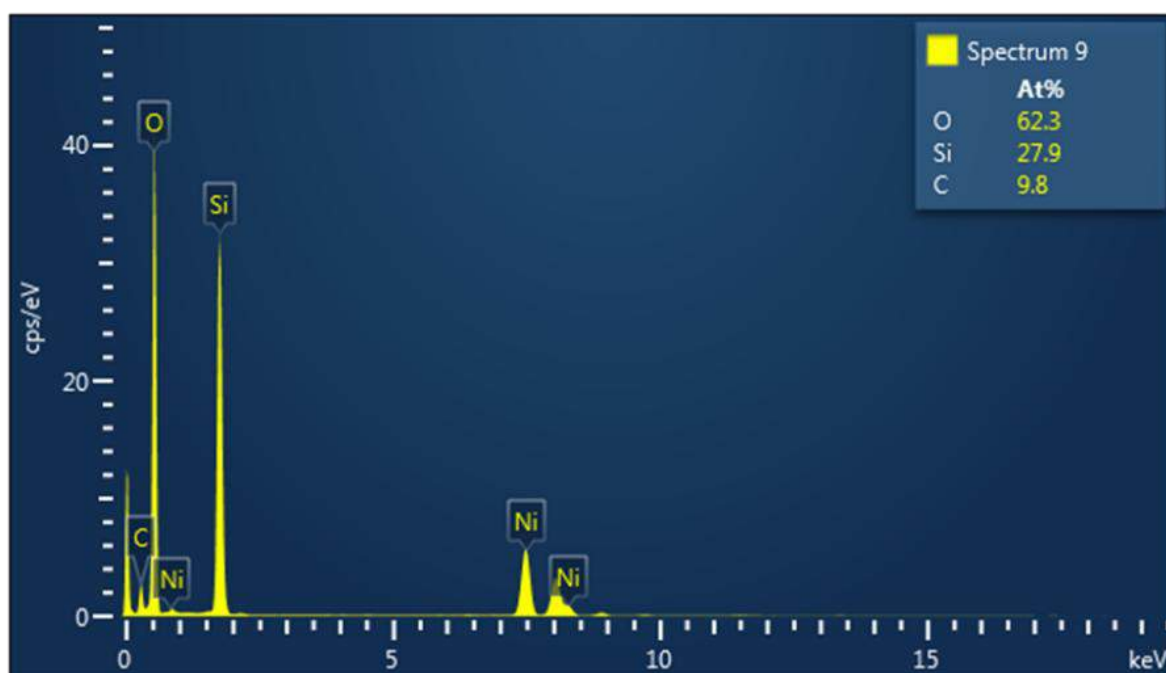


Fig. 15 Energy-dispersive X-ray spectroscopy – The Moderna vaccine

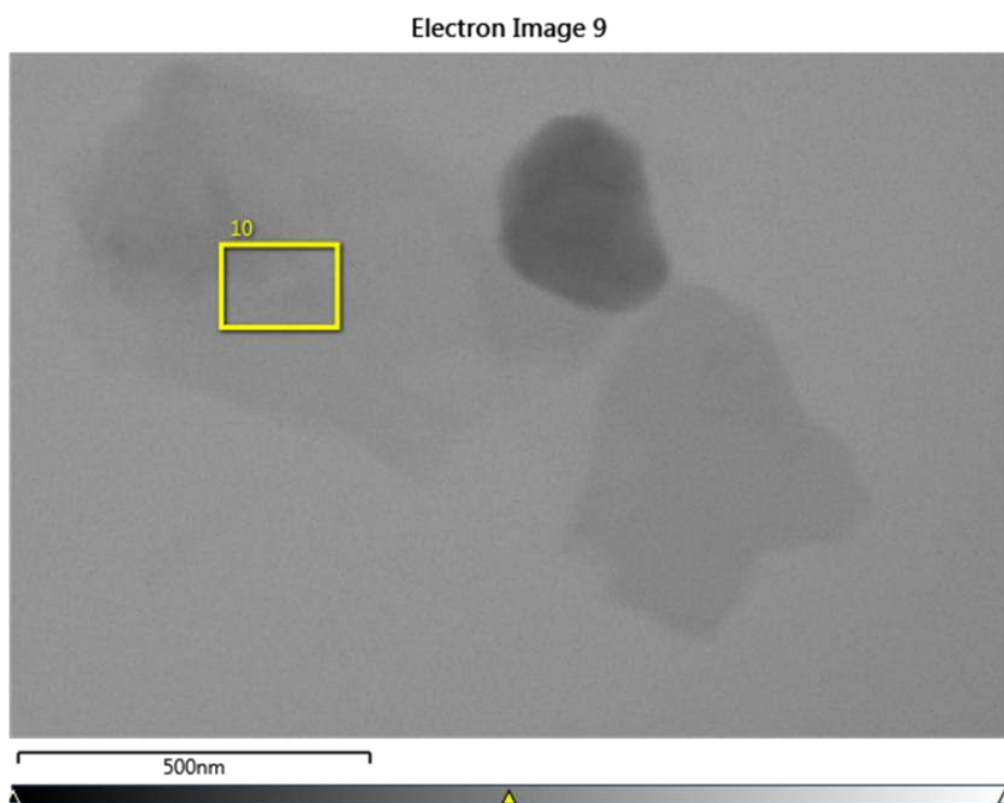


Fig. 16. Scanning electron microscopy – the Moderna vaccine.

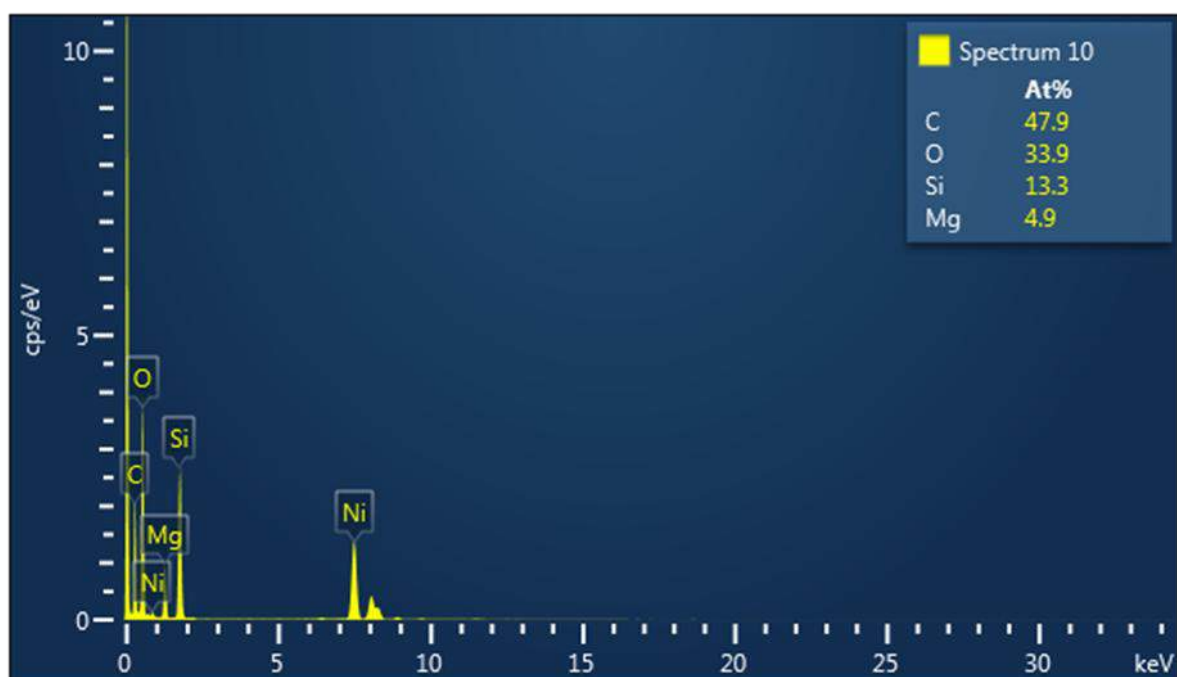


Fig. 17. Energy-dispersive X-ray spectroscopy – The Moderna vaccine

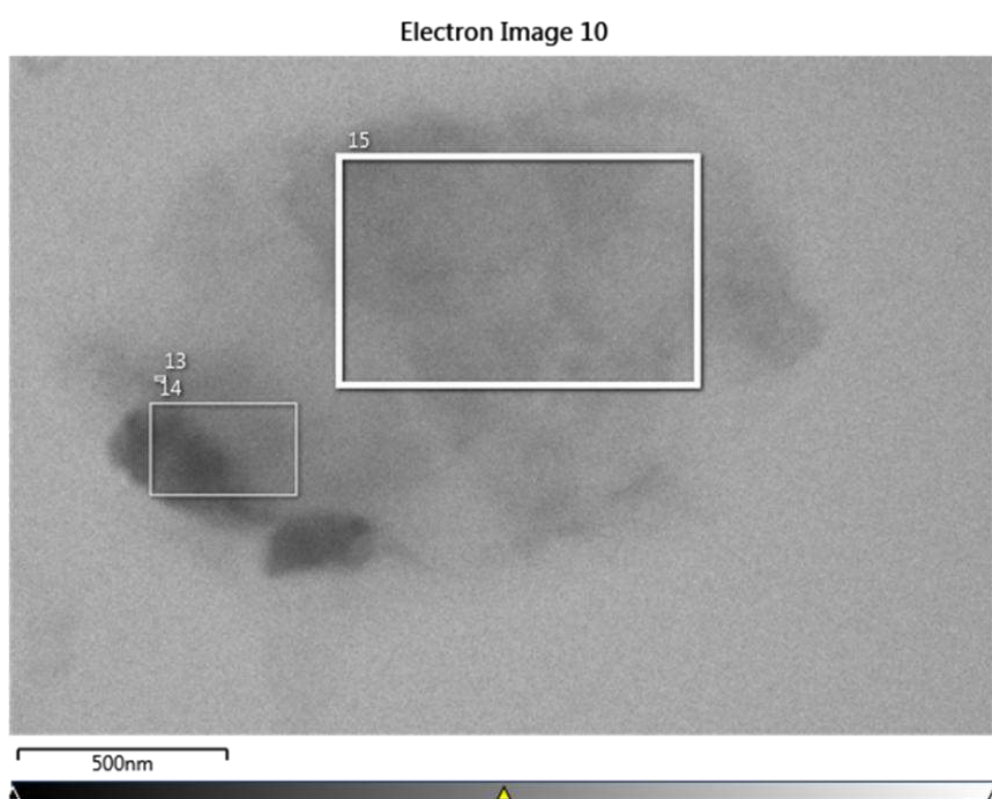


Fig. 18. Scanning electron microscopy – the Moderna vaccine.

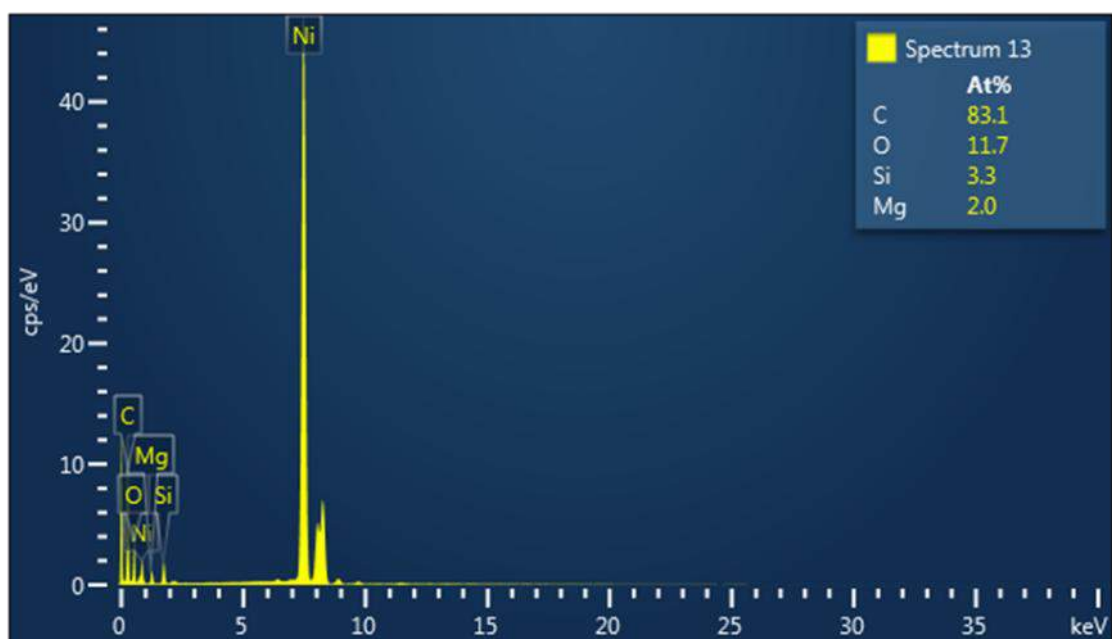


Fig. 19. Energy-dispersive X-ray spectroscopy – The Moderna vaccine

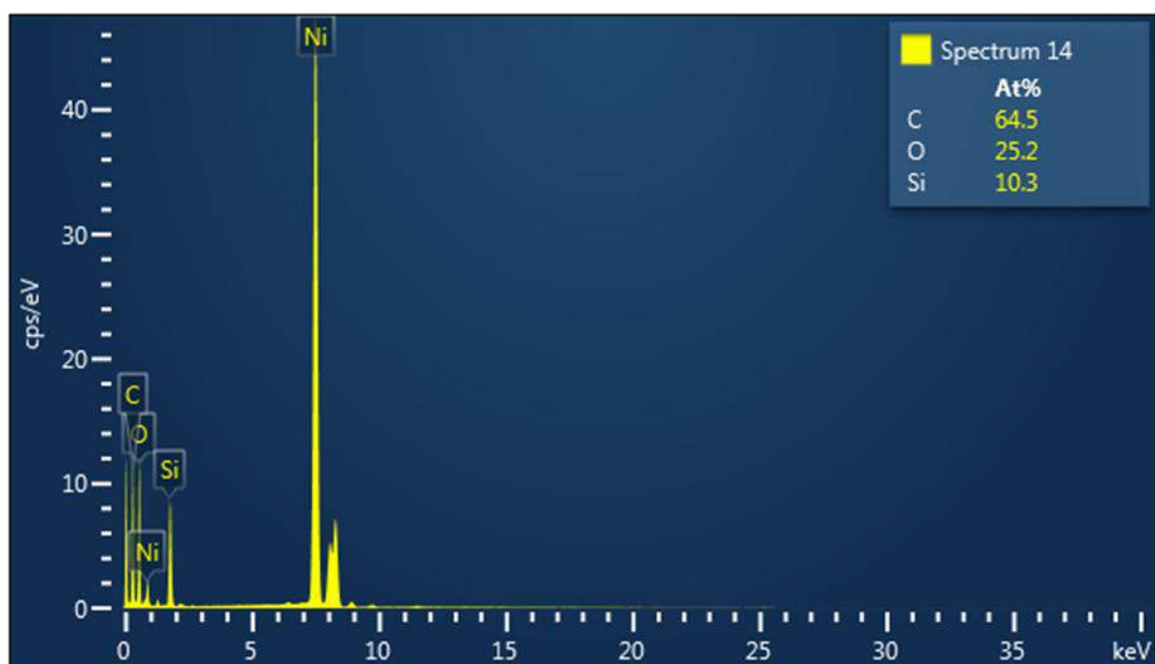


Fig. 20. Energy-dispersive X-ray spectroscopy – The Moderna vaccine

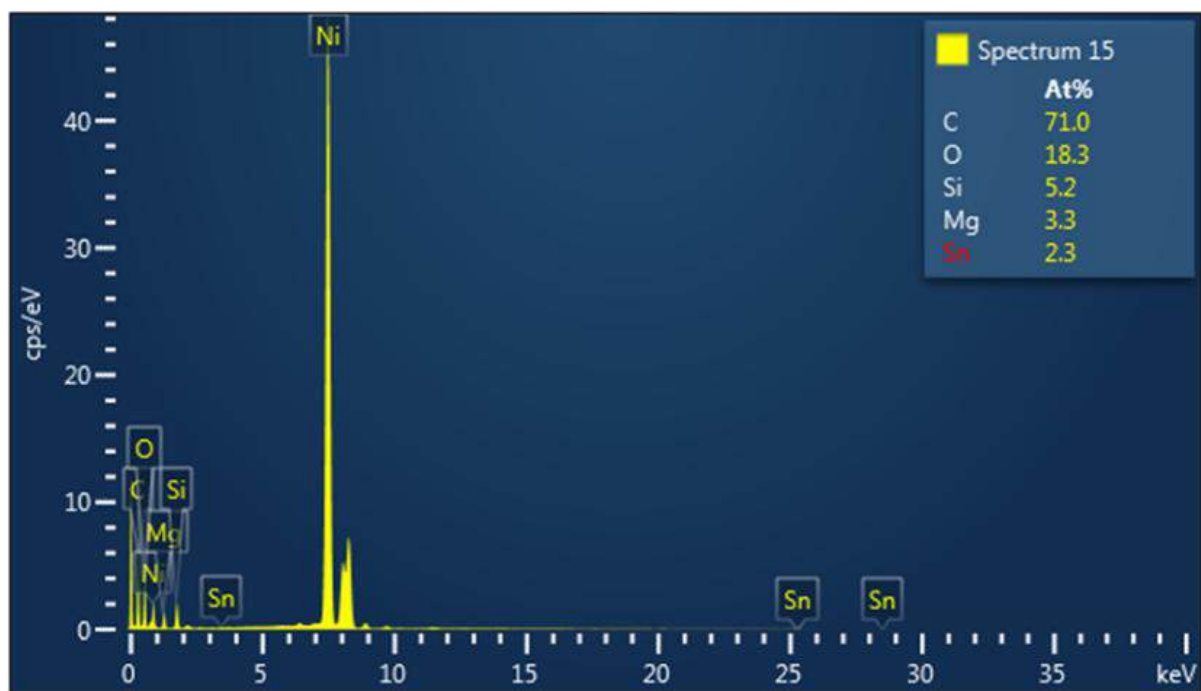


Fig. 21. Energy-dispersive X-ray spectroscopy – The Moderna vaccine

Electron Image 11

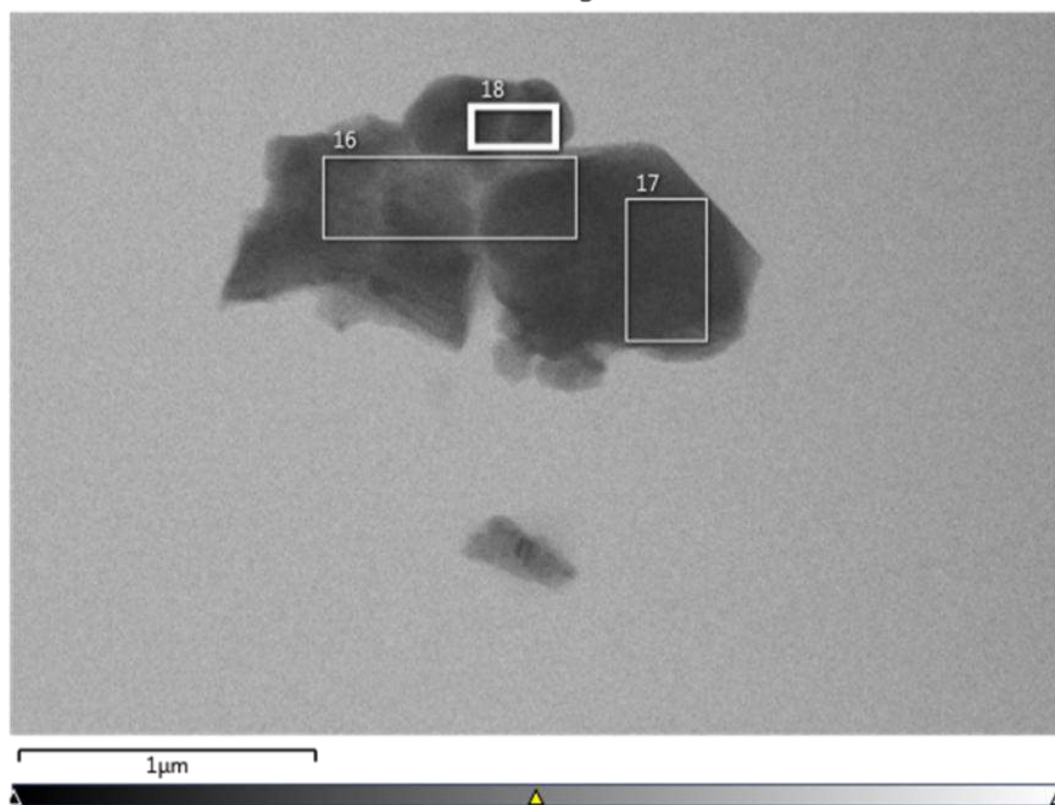


Fig. 22. Scanning electron microscopy – the Moderna vaccine.

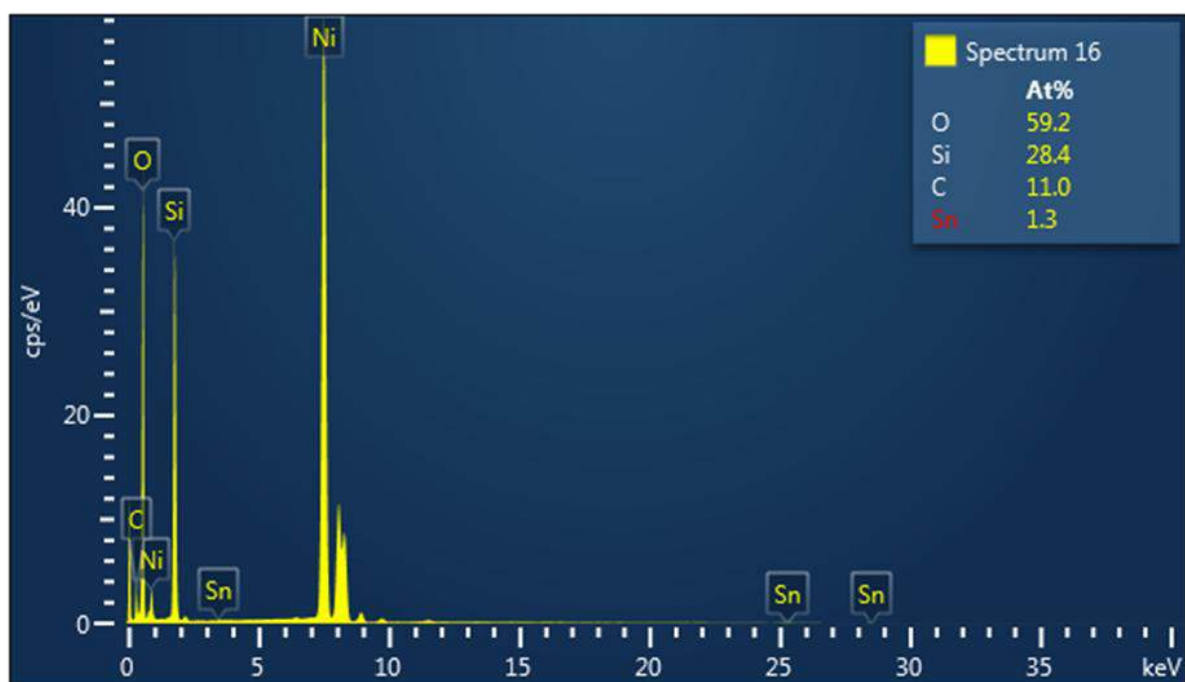


Fig. 23. Energy-dispersive X-ray spectroscopy – The Moderna vaccine

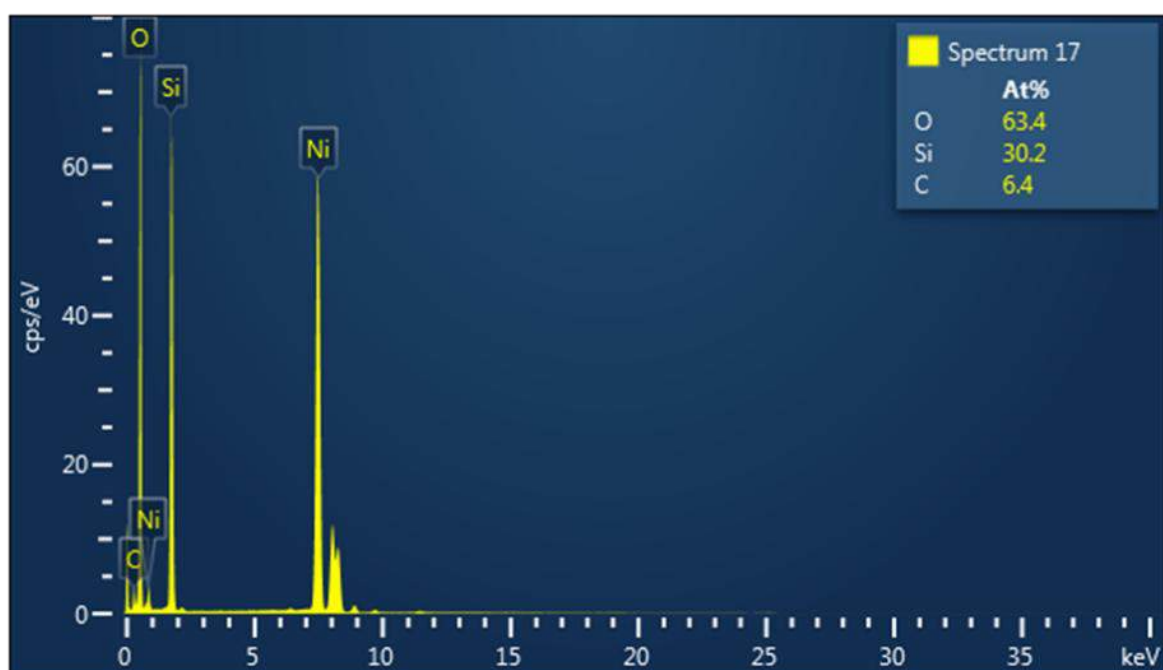


Fig. 24. Energy-dispersive X-ray spectroscopy – The Moderna vaccine

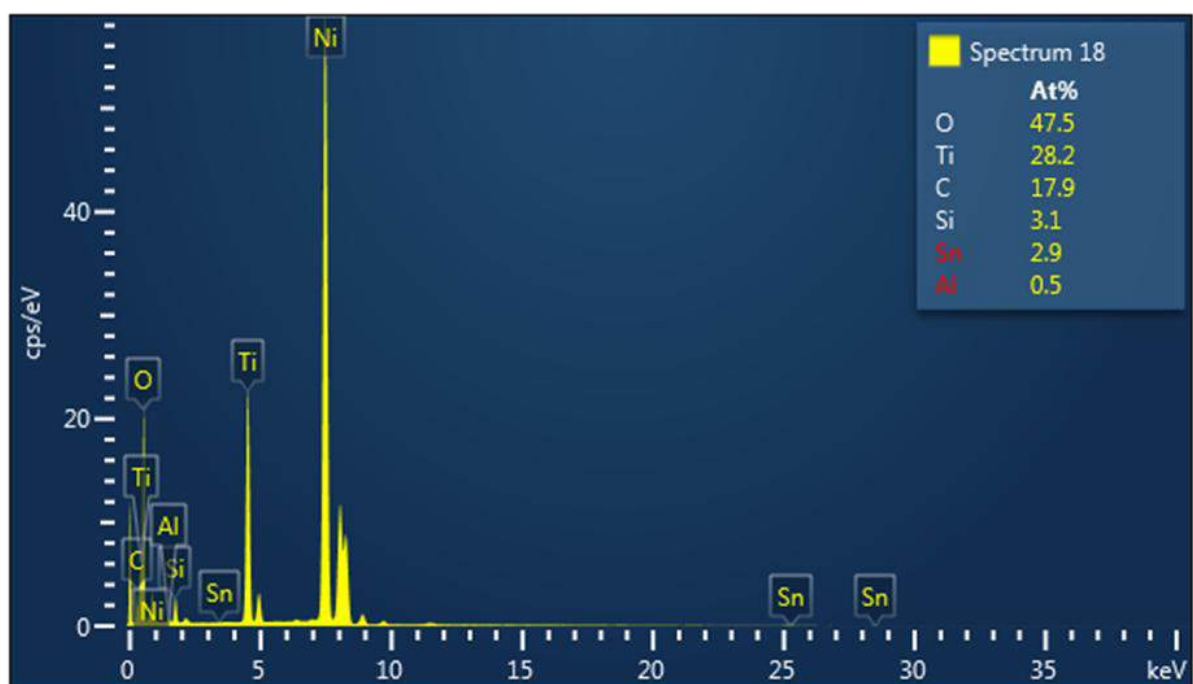


Fig. 25. Energy-dispersive X-ray spectroscopy – The Moderna vaccine

The following are images obtained through scanning electron microscopy and energy-dispersive X-ray spectroscopy (EDX) of the Comirnaty Omicron XBB.1.5 vaccine.

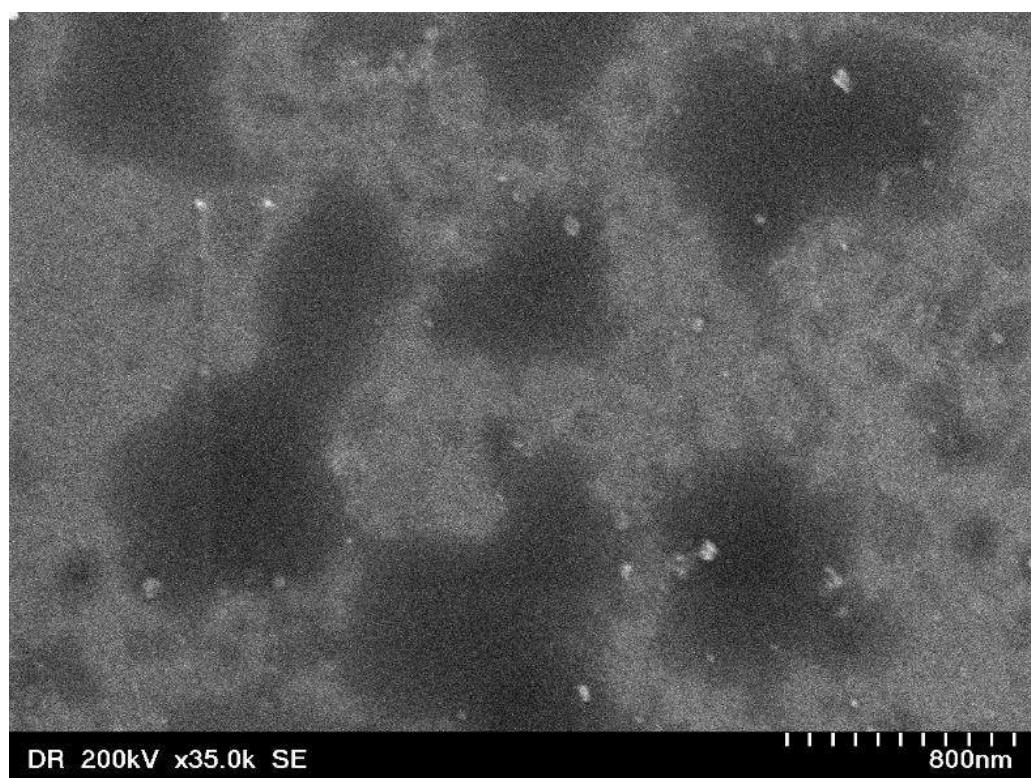


Fig. 26 Scanning electron microscopy - Comirnaty Omicron XBB.1.5 Vaccine.

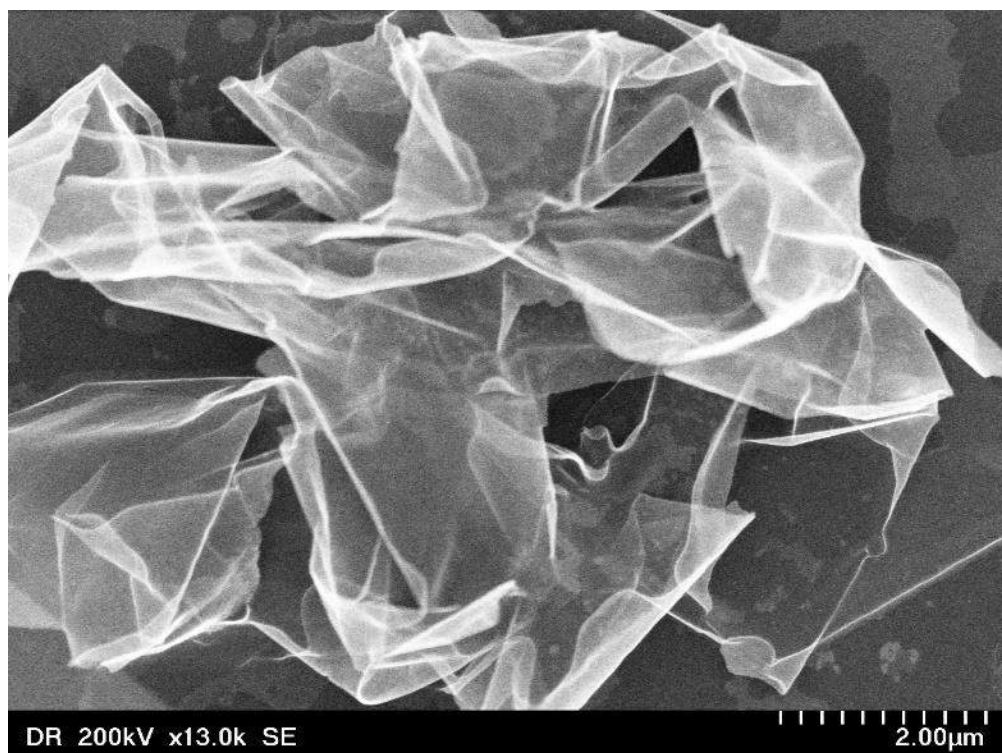


Fig. 27 Scanning electron microscopy - Comirnaty Omicron XBB.1.5 vaccine.

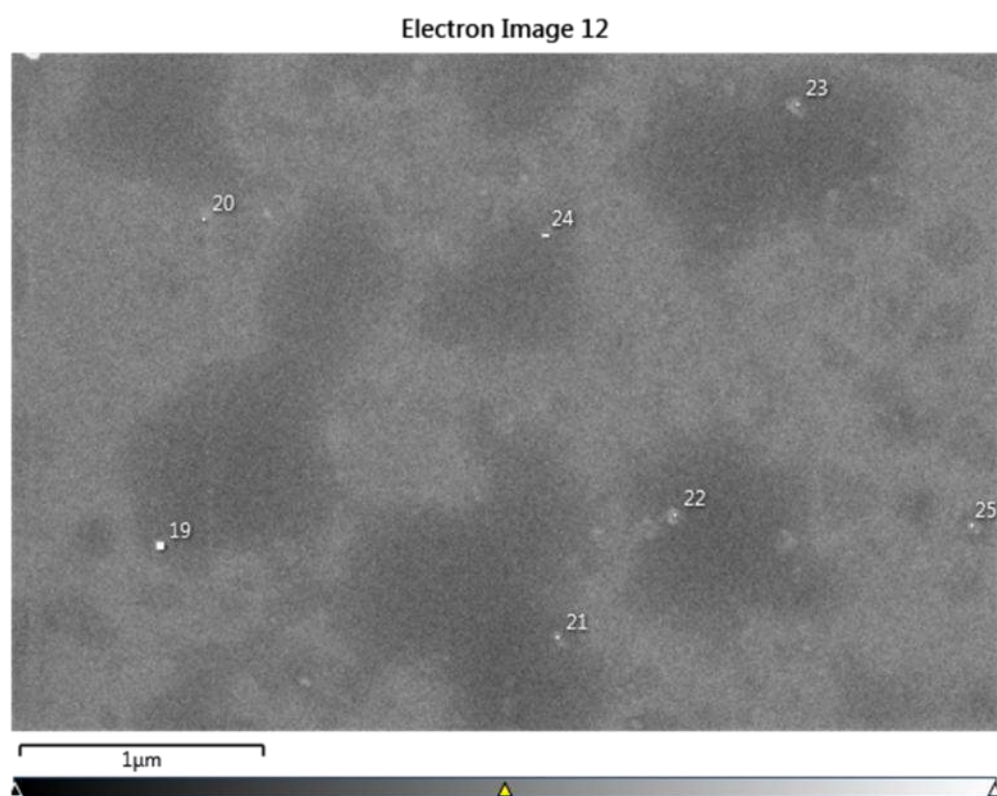


Fig. 28. Scanning electron microscopy - Comirnaty Omicron XBB.1.5 vaccine.

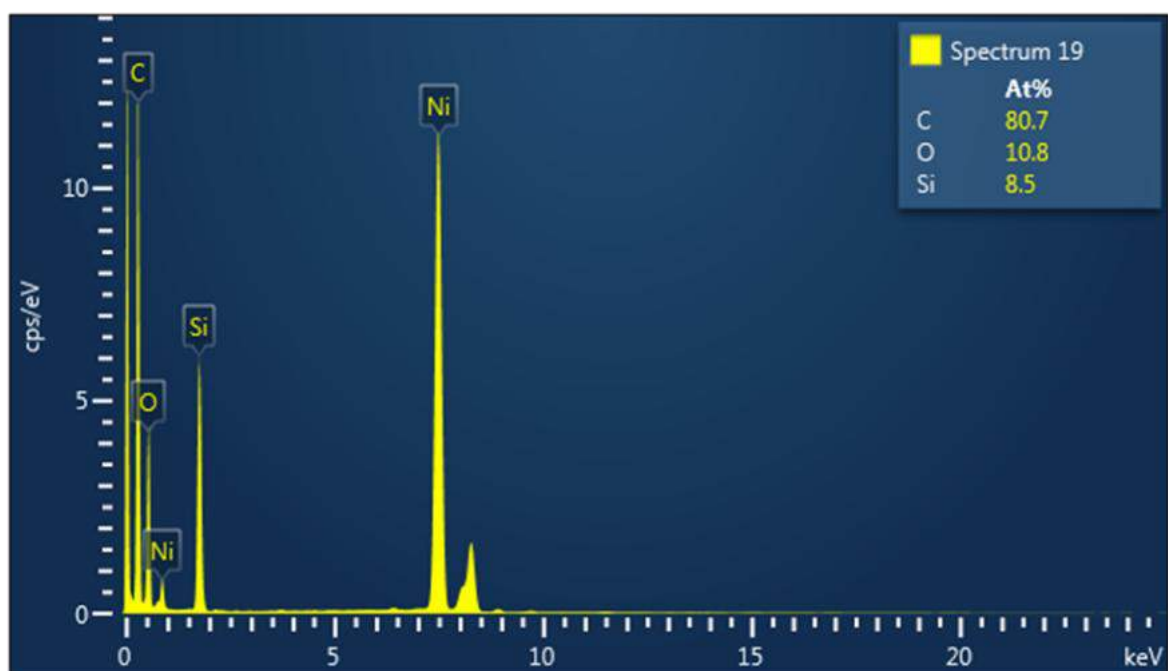


Fig. 29 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

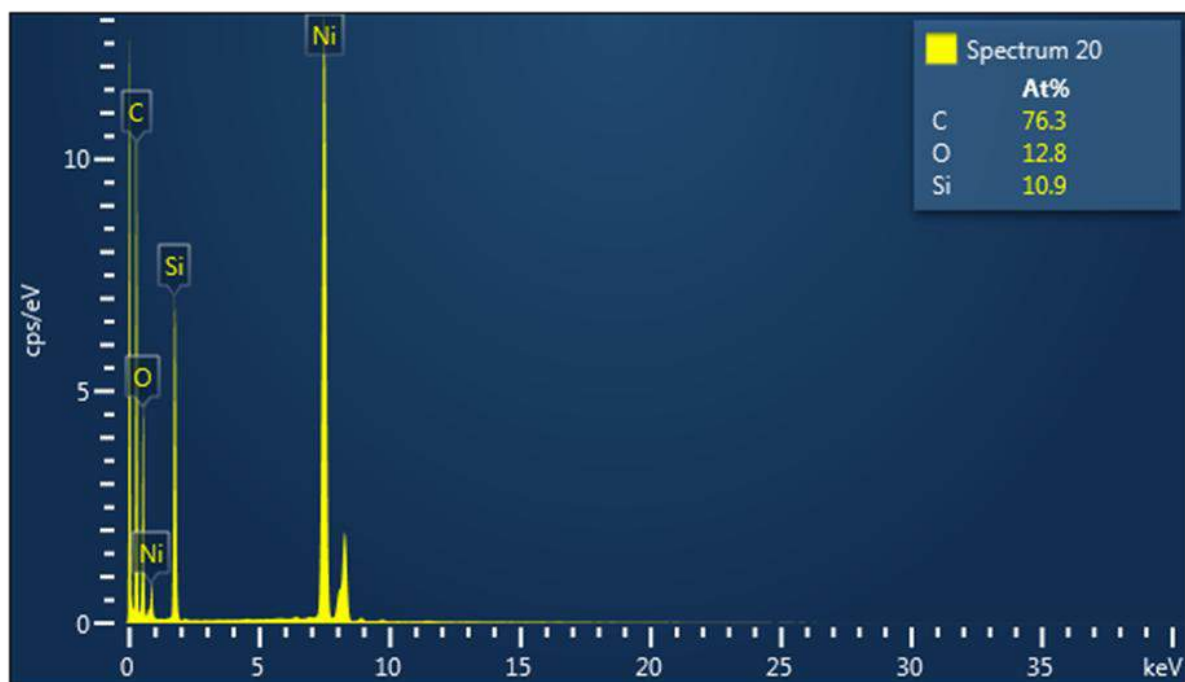


Fig. 30 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

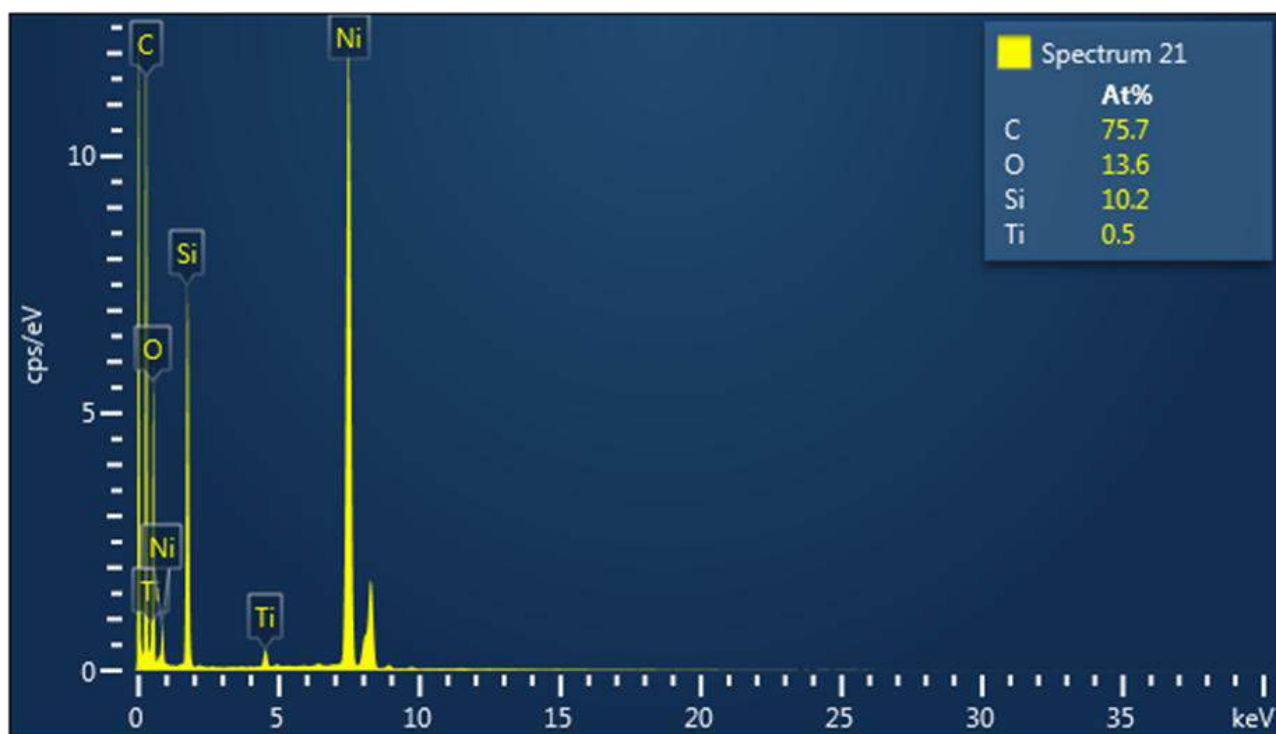


Fig. 31. Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

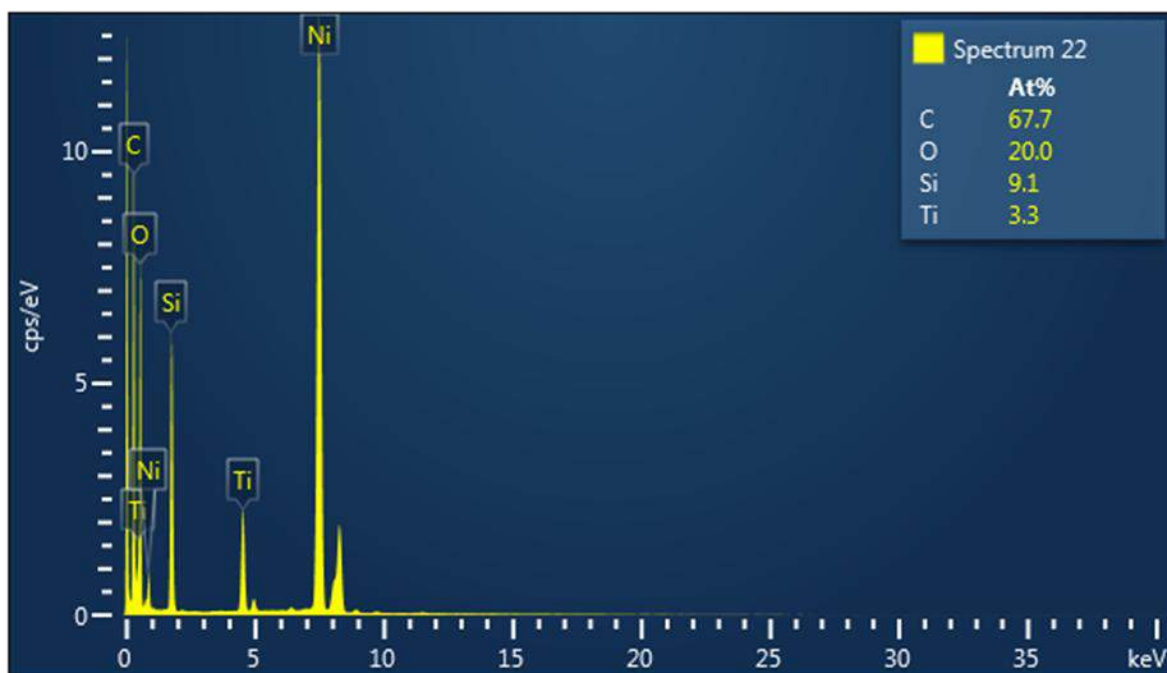


Fig. 32 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

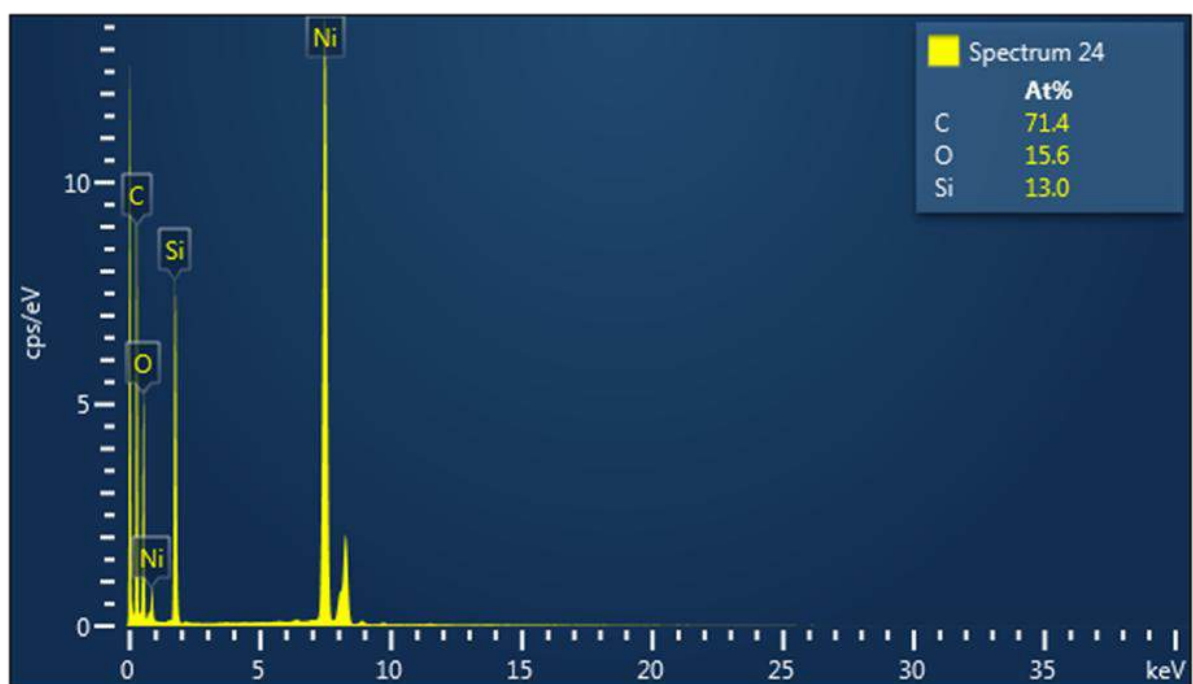


Fig. 33 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

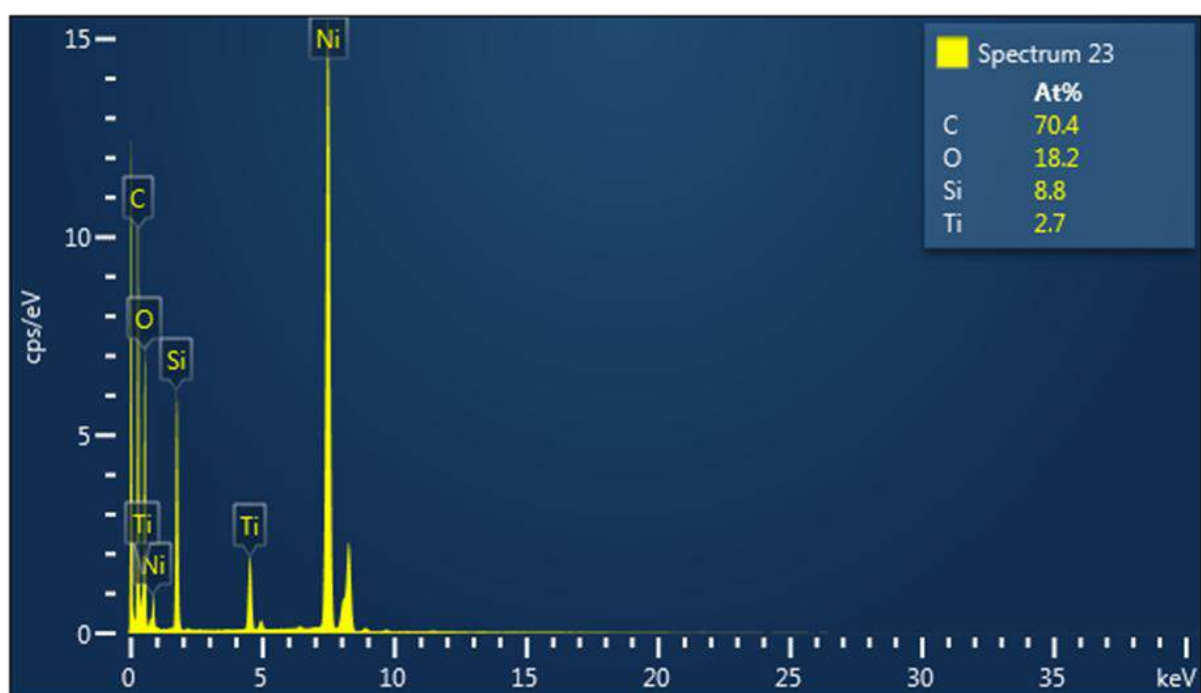


Fig. 34 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

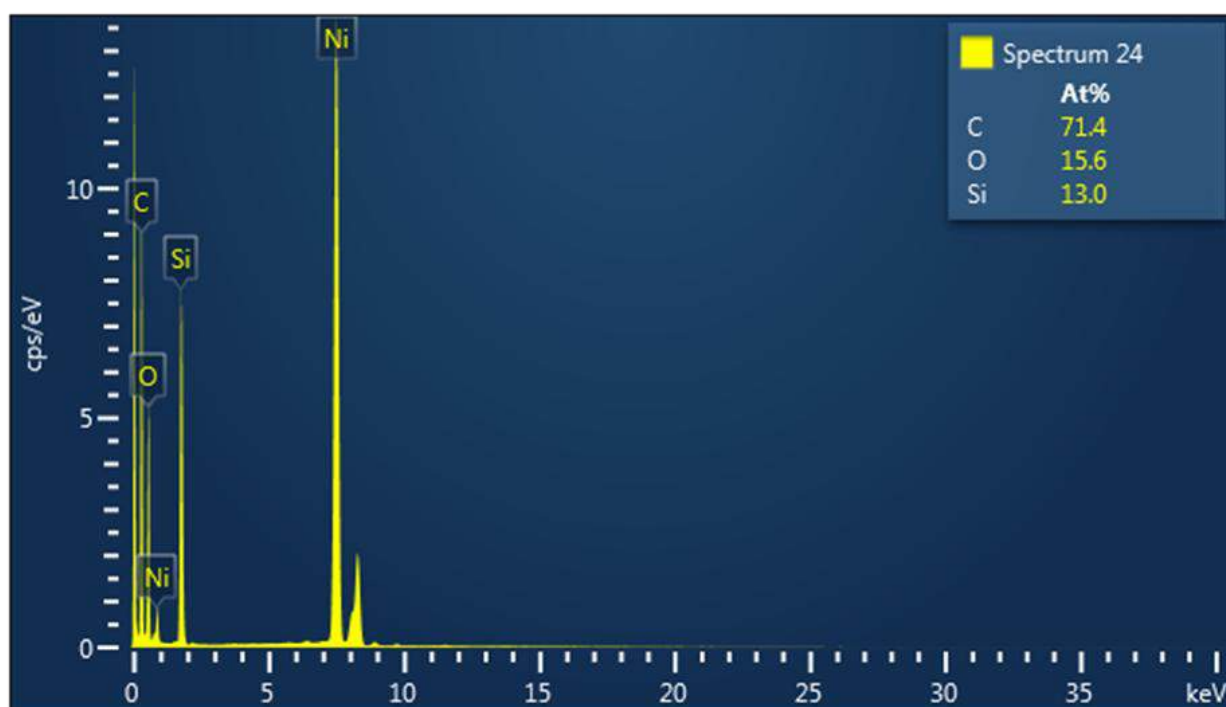


Fig. 35 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

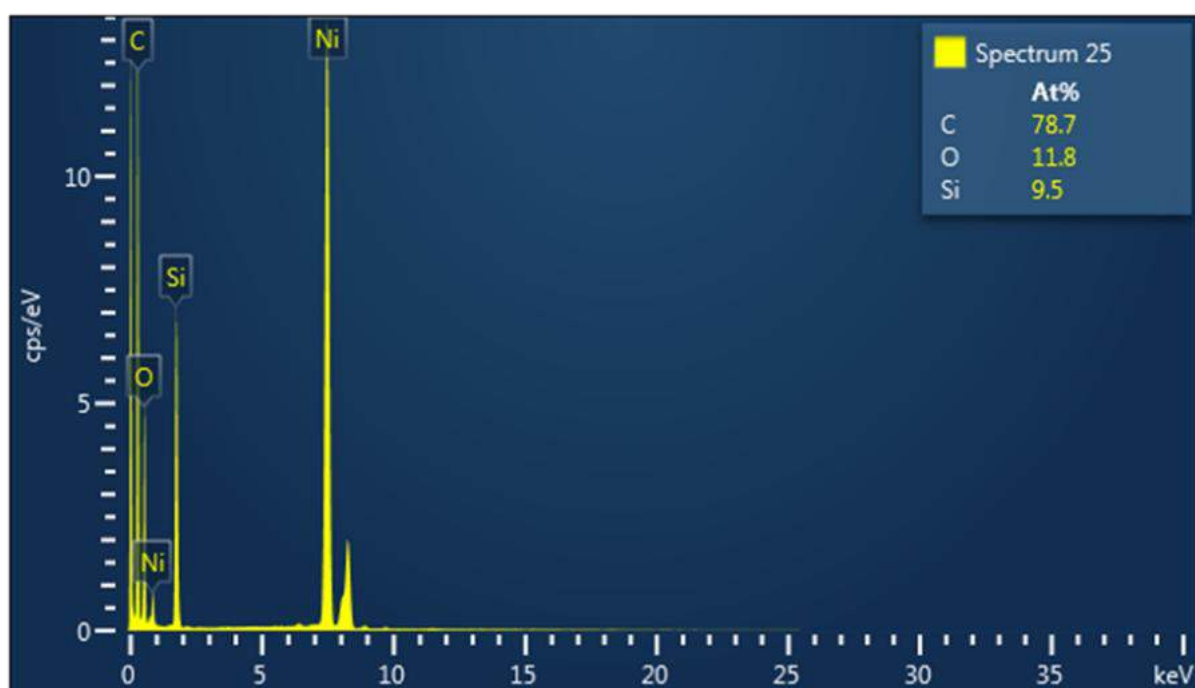


Fig. 36 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

Electron Image 13

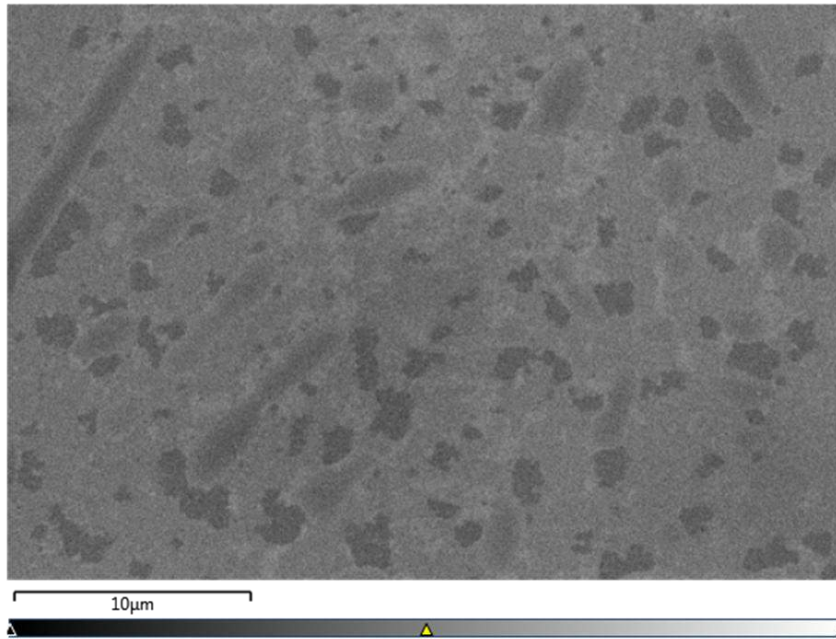


Fig. 37 Scanning electron microscopy - Comirnaty Omicron XBB.1.5 Vaccine.

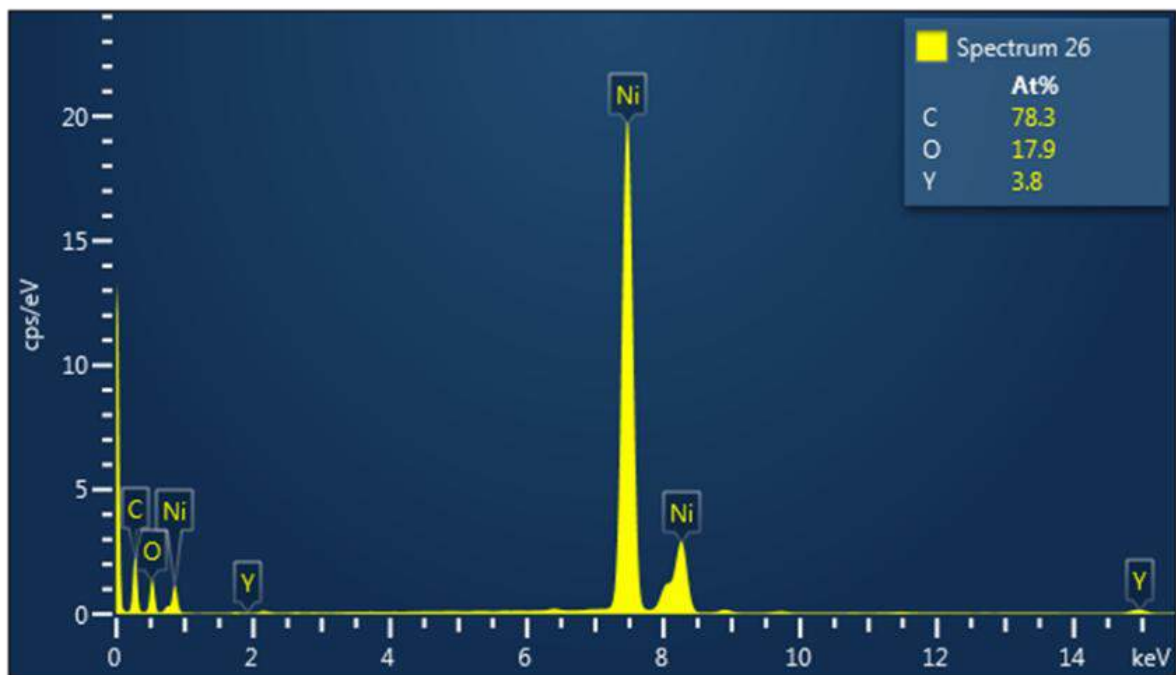


Fig. 38 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

Electron Image 14

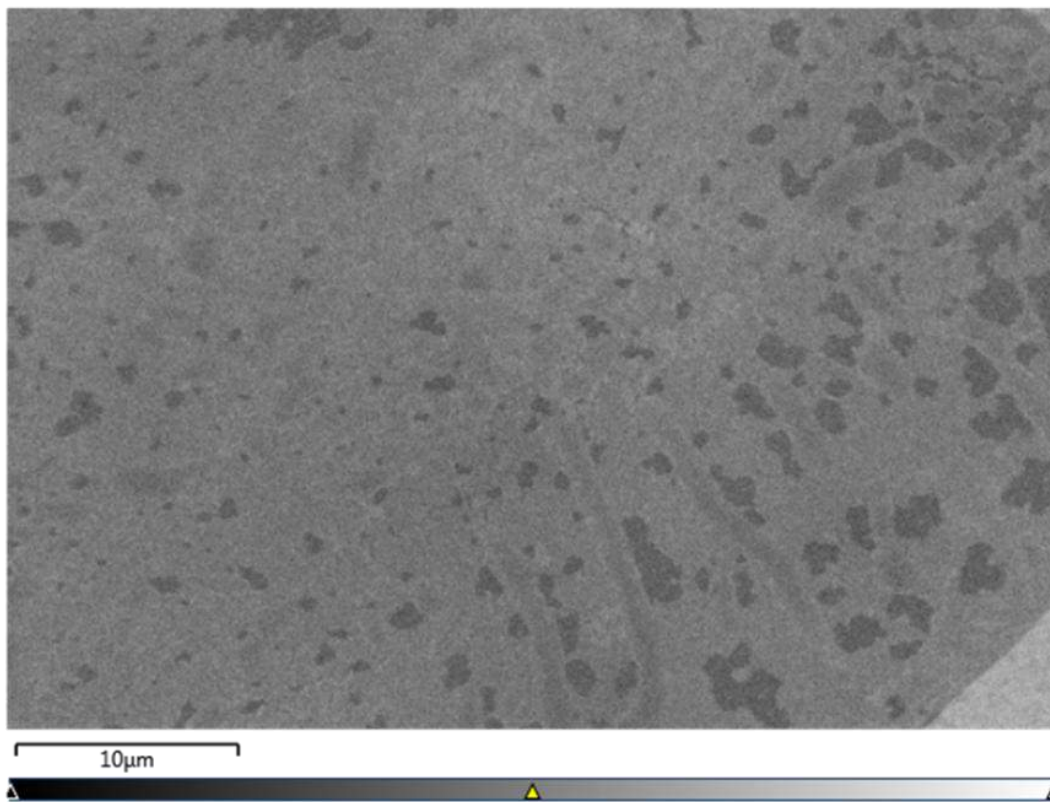


Fig. 39 Scanning electron microscopy—Comirnaty Omicron XBB.1.5 Vaccine.

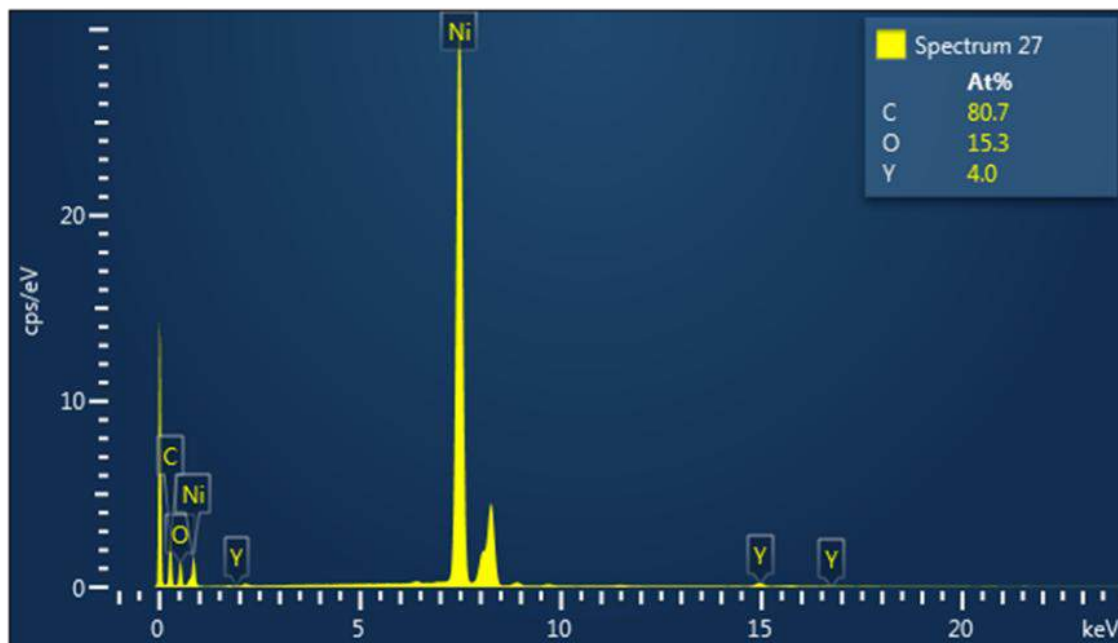


Fig. 40 Energy-dispersive X-ray spectroscopy—Comirnaty Omicron XBB.1.5 Vaccine

Electron Image 15

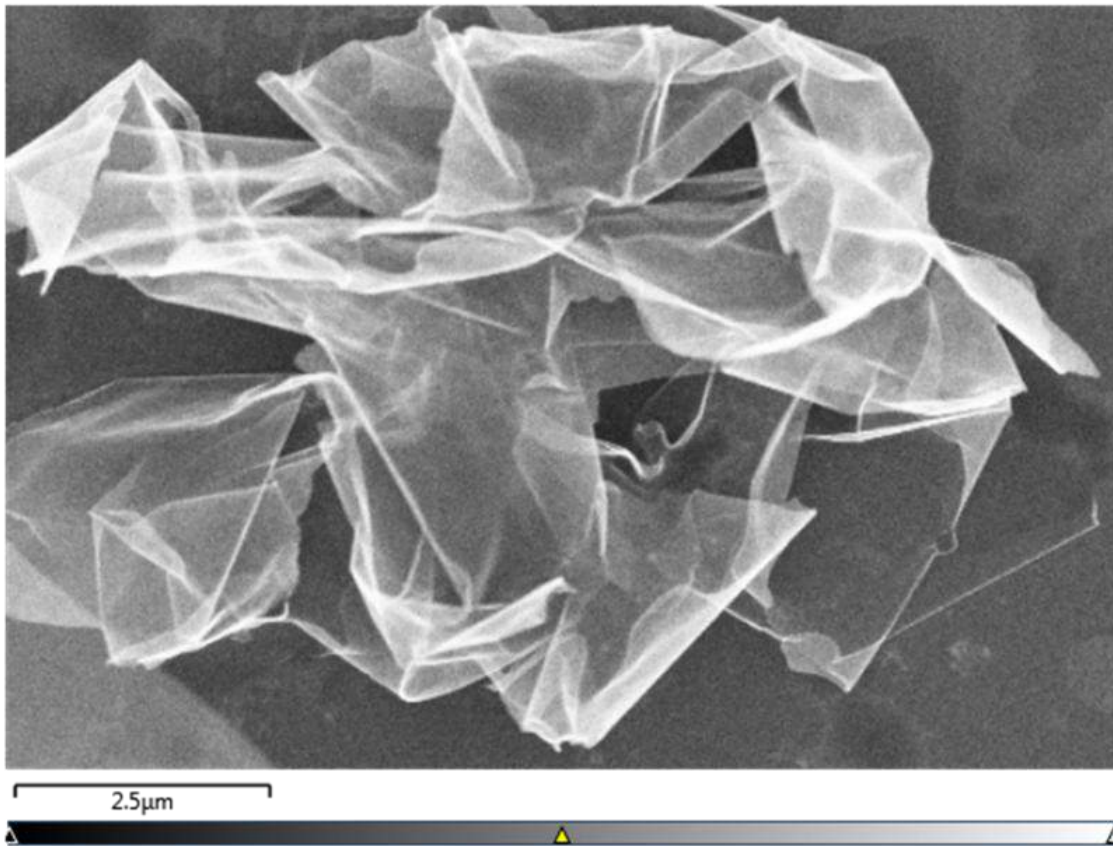


Fig. 41 Scanning electron microscopy—Comirnaty Omicron XBB.1.5 Vaccine—note the surprising sheet/ribbon appearance in this image, the composition of which is reflected in Figure 42—C, O, Si

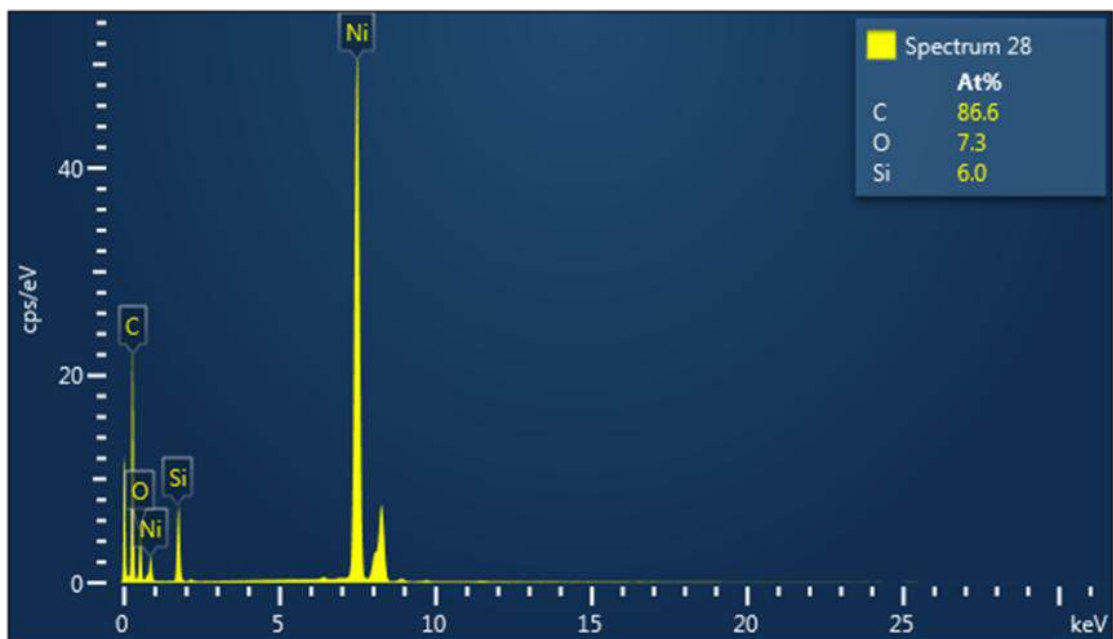


Fig. 42 Energy-dispersive X-ray spectroscopy—Comirnaty Omicron XBB.1.5 Vaccine

Electron Image 17

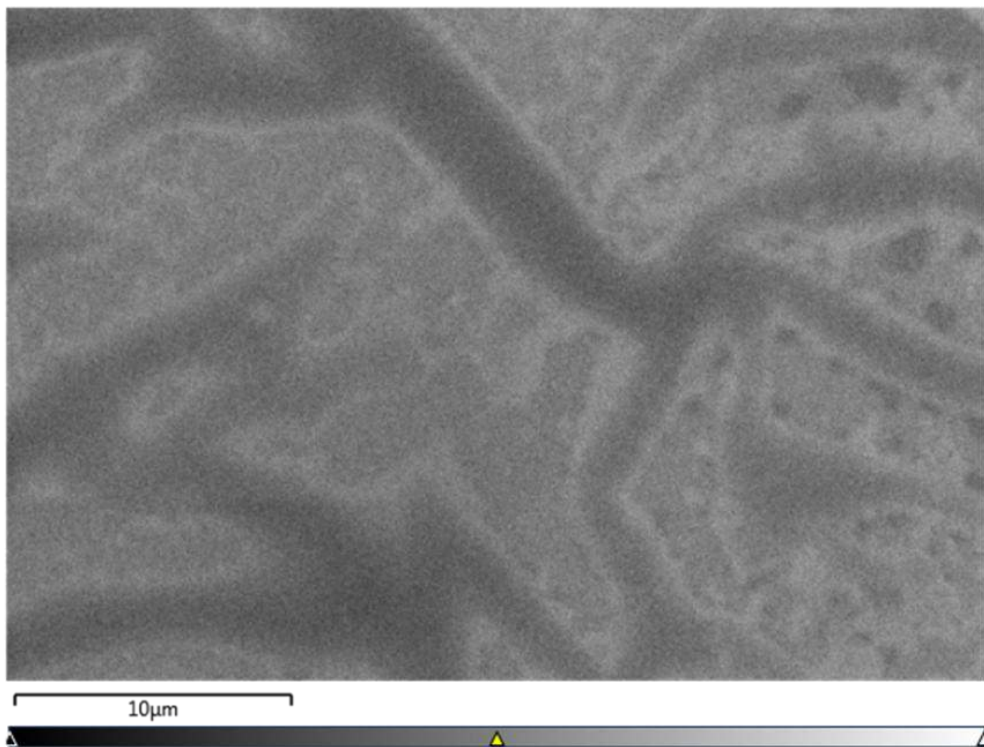


Fig. 43 Scanning electron microscopy—Comirnaty Omicron XBB.1.5 Vaccine.

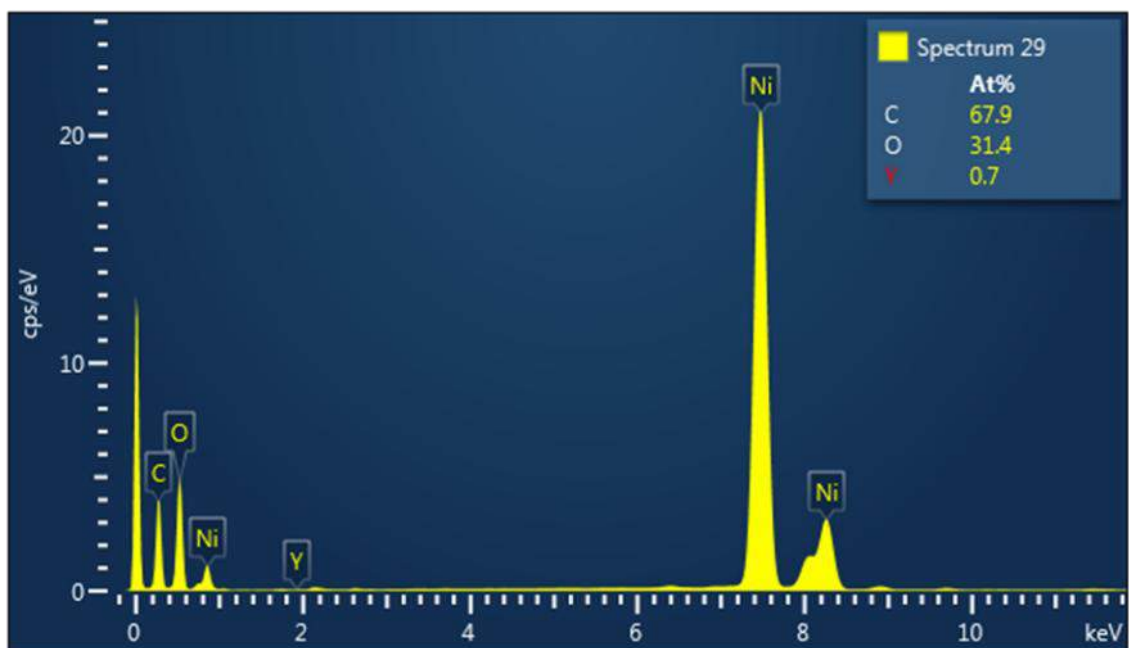


Fig. 44 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

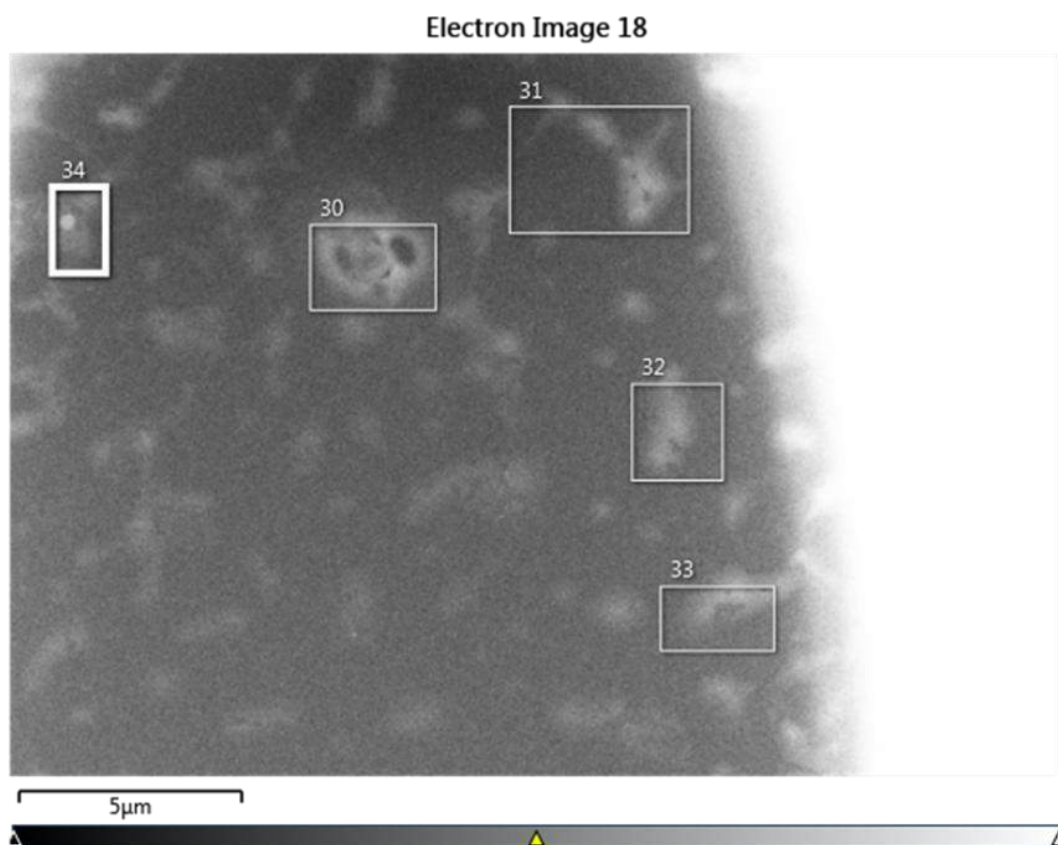


Fig. 45 Scanning electron microscopy - Comirnaty Omicron XBB.1.5 Vaccine

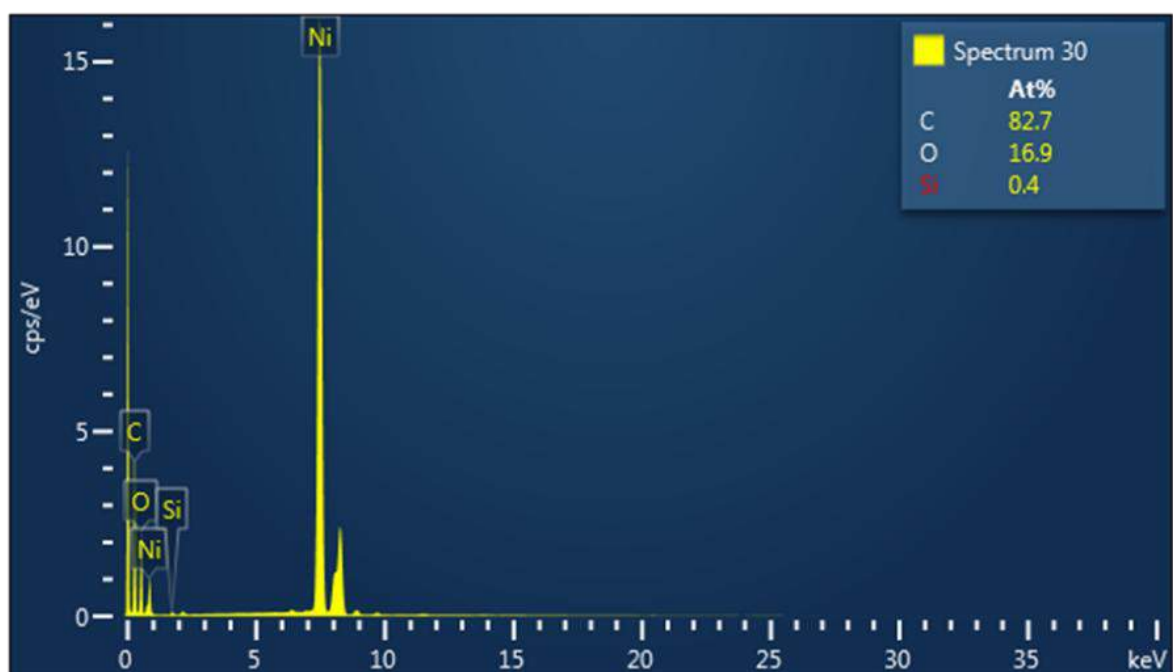


Fig. 46 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

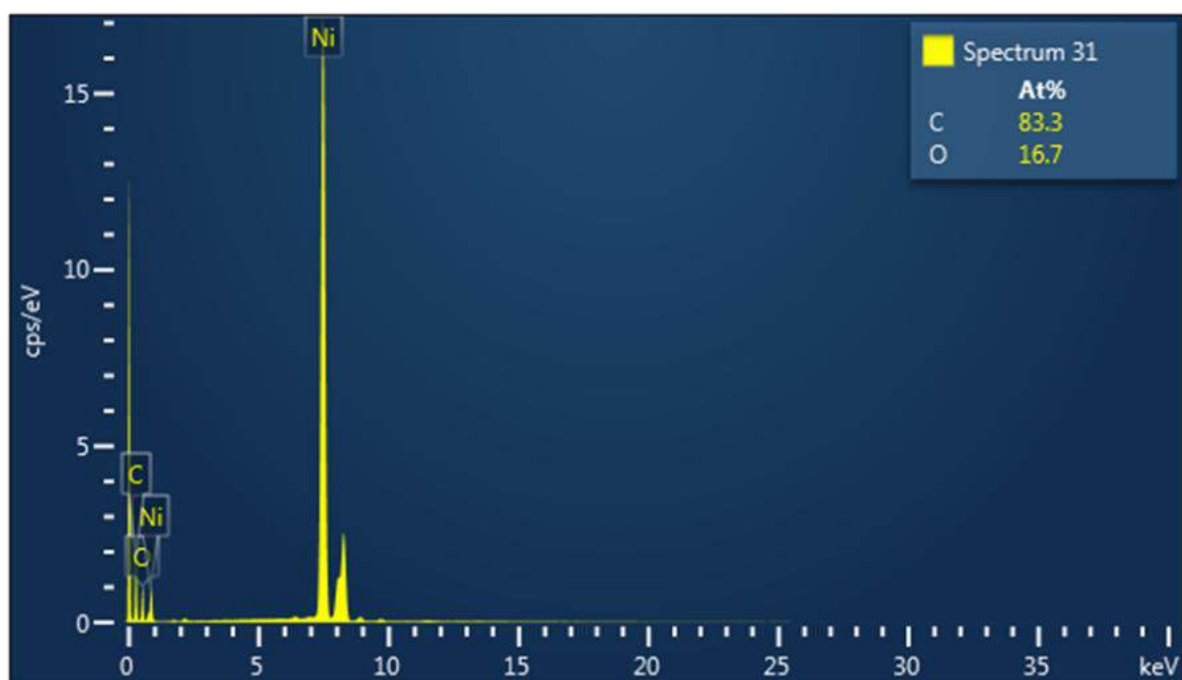


Fig. 47 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

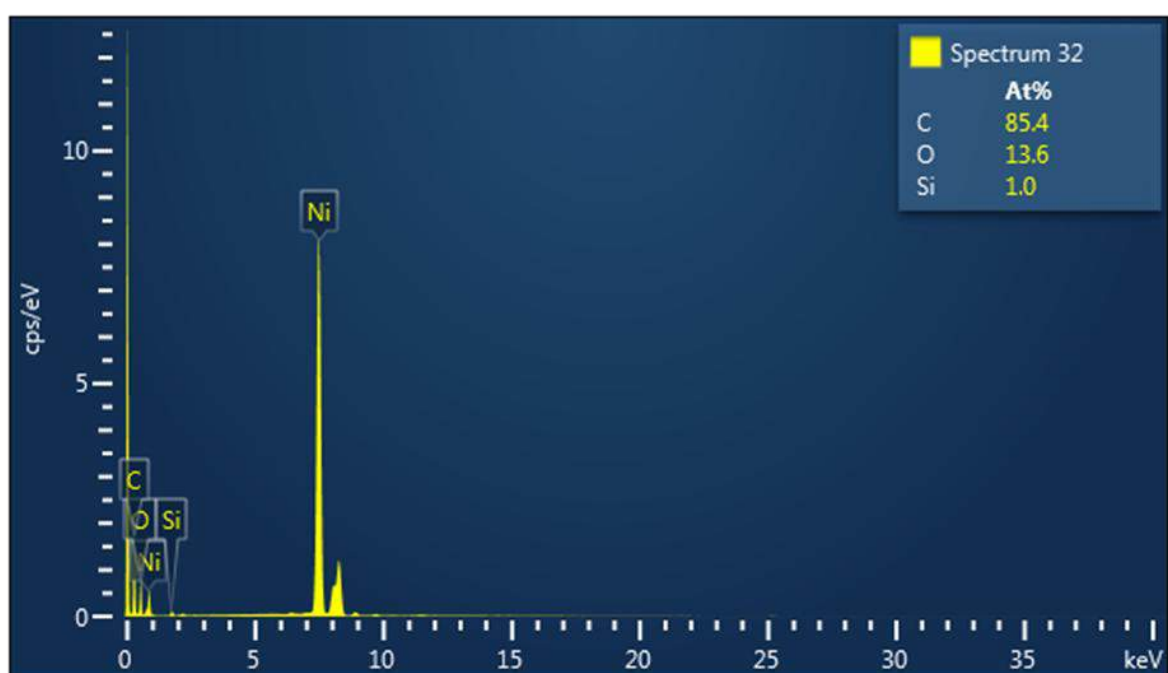


Fig. 48 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

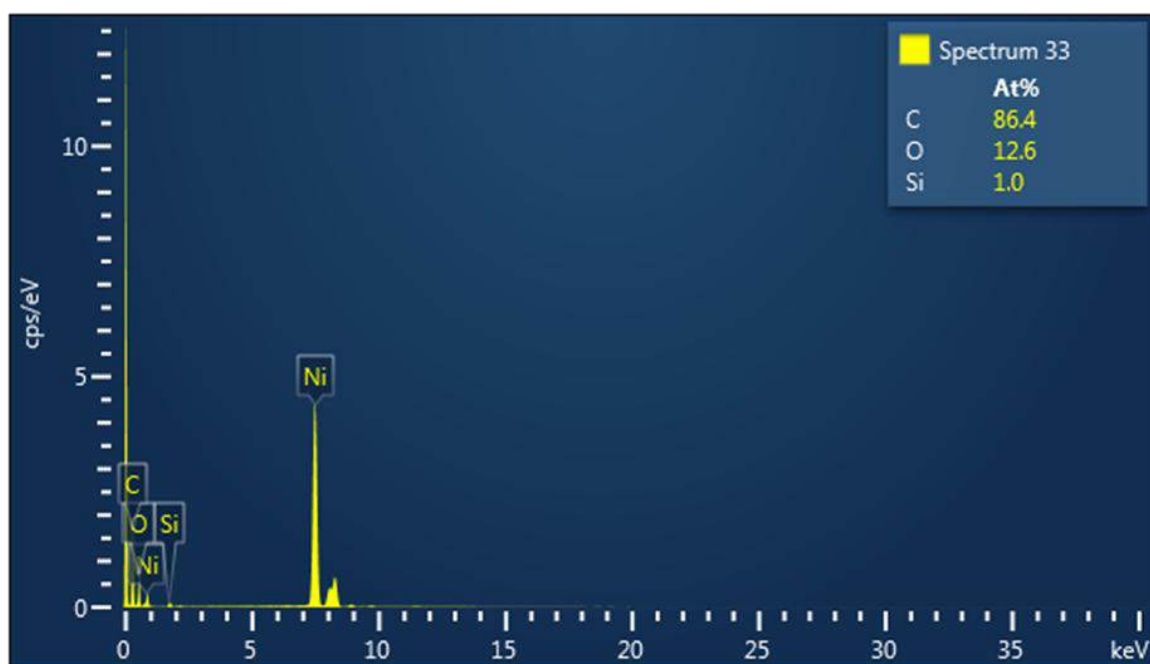


Fig. 49 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

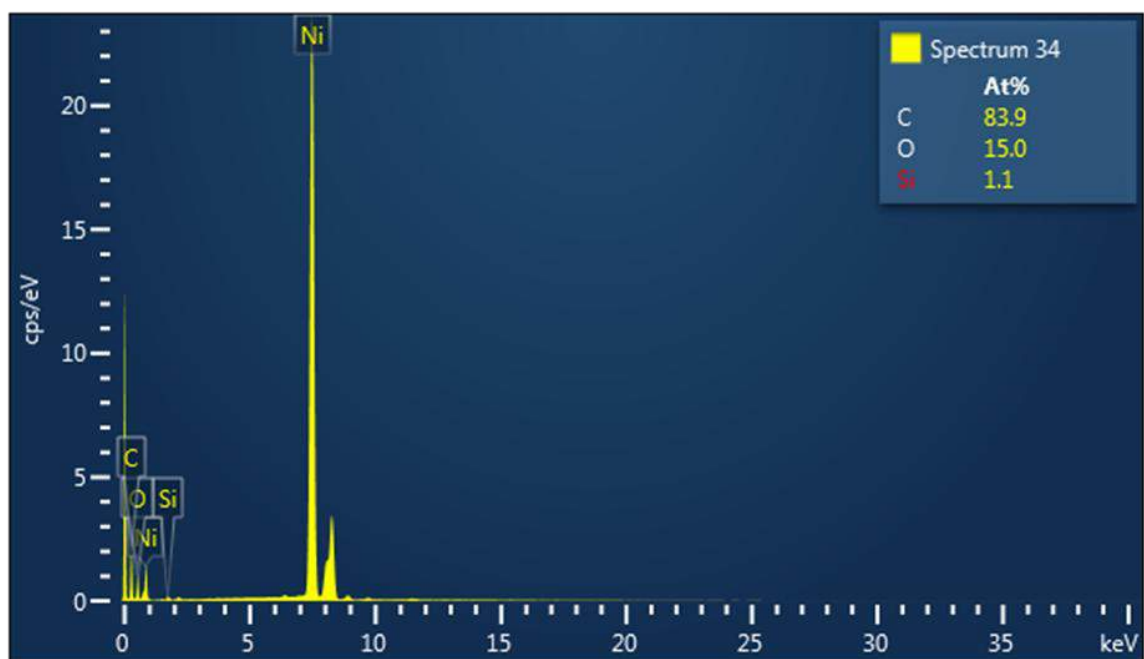


Fig. 50 Energy-dispersive X-ray spectroscopy - Comirnaty Omicron XBB.1.5 Vaccine

Electron Image 20

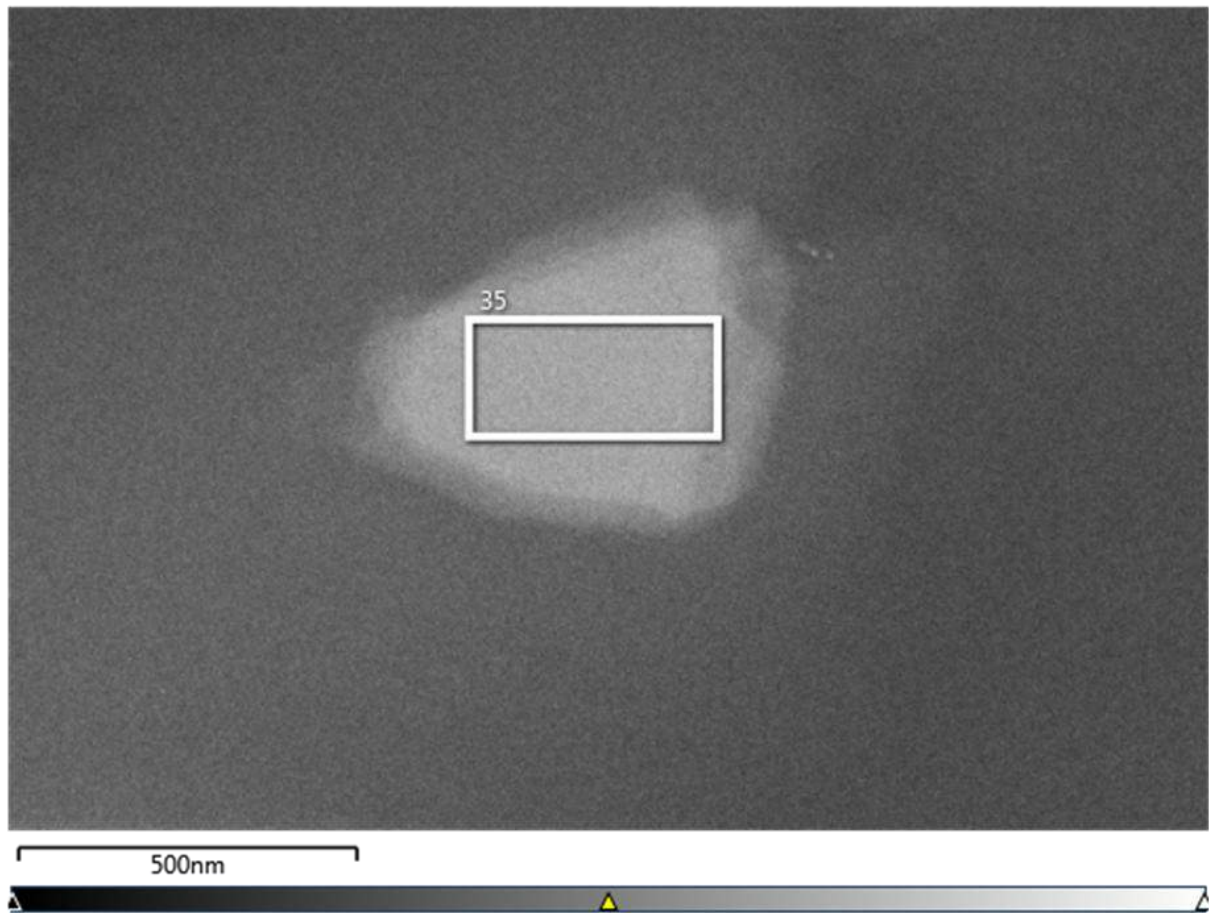


Fig. 51 Scanning electron microscopy - Comirnaty Omicron XBB.1.5 Vaccine

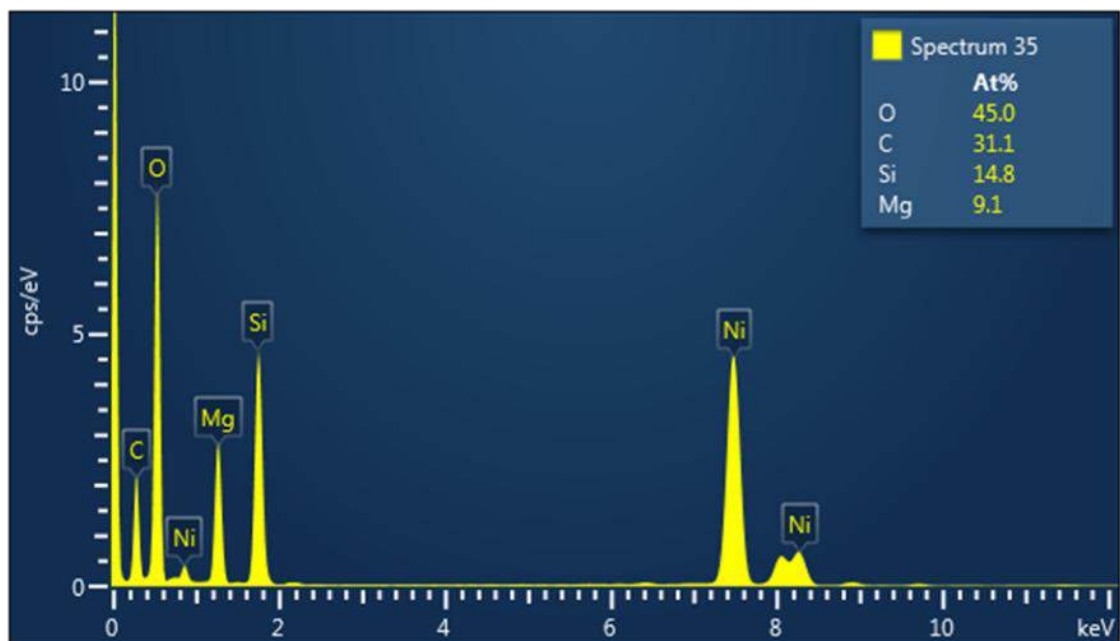


Fig. 52 Energy-dispersive X-ray spectroscopy - Comirnaty Vaccine Omicron B4-5

Discussion

Elements such as silicon, yttrium, titanium, aluminum, tin, and magnesium were not reported in the product leaflet of these products. Therefore, as these products do not contain nitrogen and phosphorus (elements found in the structure of mRNA) but do contain elements other than those declared, it is highly probable that their composition consists solely of nanotechnology.

Yttrium is utilized in nanoelectronics and optoelectronics. Yttrium silicate is used in the production of anti-COVID-19 disinfectants that are activated by natural light or LED light. I believe it is no coincidence that the FP9 program (2021-2027) invests heavily in photonics. It is established that silicon is used for the production of nanosensors and biocompatible quantum dots.

Regarding the absence of nitrogen and phosphorus (i.e., mRNA or DNA), it may be argued that variations exist within the lot. However, what would the probability be of encountering two vials produced by different companies, neither of which contained mRNA? The data obtained through my investigations are corroborated by the findings of other researchers.

What solutions are available to obtain an official analysis regarding the composition of the COVID vaccines? How did the entire system of regulation, approval, and distribution allow more than two-thirds of the world's population to be injected with products that lack the declared composition?

Conclusion

In view of the discrepancies identified between the composition observed via electron microscopy and the declared composition of the COVID vaccines, urgent pressure for an official analysis of these products is necessitated. Only by determining their precise composition will we be able to identify effective solutions for combating and treating adverse reactions.

Furthermore, it is of the utmost importance to ascertain the purpose for which these products were administered to the global population and to ensure that those who premeditated these acts, exploiting the good faith and naivety of the people and, unfortunately, of physicians, are held accountable and punished.

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12. Real-Time Self-Assembly of Stereomicroscopically Visible Artificial Constructions in Incubated Specimens of mRNA Products Mainly from Pfizer and Moderna: A Comprehensive Longitudinal Study <https://mail.ijvtp.com/index.php/IJVTPr/article/view/102>

B. Investigations of the COVID-19 vaccines conducted by other independent researchers who detected undeclared elements in these products

1. Professor Pablo Campra of the University of Almeria

At the time I commenced the investigations, I was cognizant of the findings of other research which I sought to verify to the extent possible, such as those conducted as early as November 2021 in Spain by Professor Pablo Campra of the University of Almeria, holder of a Doctorate in Chemical Sciences and a degree in Biological Sciences.

In the article *“DETECTION OF GRAPHENE IN COVID19 VACCINES”* https://www.researchgate.net/publication/355979001_DETECTION_OF_GRAPHENE_IN_COVID19_VACCINES he presented the personal results of the analysis of the COVID vaccines conducted via micro-Raman spectroscopy. In the COVID vaccines, he detected certain structures which he could state with certainty are graphene, as well as other structures compatible with graphene; these materials were not declared by the manufacturer in the product leaflet. In the abstract of the article, the researcher urged other independent researchers to conduct investigations: *“ This research remains open and is made available to the scientific community for discussion. **We call upon independent researchers, free from conflicts of interest or institutional coercion, to conduct a more extensive counter-analysis of these products , to obtain more detailed knowledge regarding the composition and potential health risks of these experimental medicinal products, while recalling that graphene-based materials possess potential toxicity toward human beings and their presence was not declared in any emergency use authorization .**”*

2. Steve Kirsh, American entrepreneur

Further research calling into question the content of the vaccines is that conducted at the request of Steve Kirsh, American entrepreneur and inventor of the optical mouse. The conclusions of this research were posted on August 2, 2022, on his Substack page.

In this post <https://kirschsubstack.com/p/want-to-know-whats-inside-the-vaccine> , Steve Kirsch stated that one of his colleagues performed a mass spectrometry analysis of **4 vaccine vials : two from Moderna and two from Pfizer** and stated that *“ He found PEG, but no Phosphorus, which means he found the lipid nanoparticles, but not the active substance or the preservative. A bunch of empty evidence . **No mRNA** . Some speculate that this is due to the decomposition of the mRNA, as it was not maintained at the required temperature. A fine theory, but one that would violate the laws of physics: stable elements do not decompose. If mRNA were present in the vials, we would find Phosphorus, regardless of whether the segments are fractured or degraded. Stable elements do not degrade. Do I believe that all the vials are empty? No! If they were all empty, we would not be seeing so many adverse effects of the vaccines . **I am astonished that no state actor seeks to ascertain the contents of the vials. Everyone places 100% trust in the government** . Is the mRNA intact in all the vials? They do NOT want to know. The CDC does not conduct research nor does any other state, including Texas and Florida. **No one wants to disrupt the narrative** . ”*

3. Dr. Daniel Nagase-Canadian physician

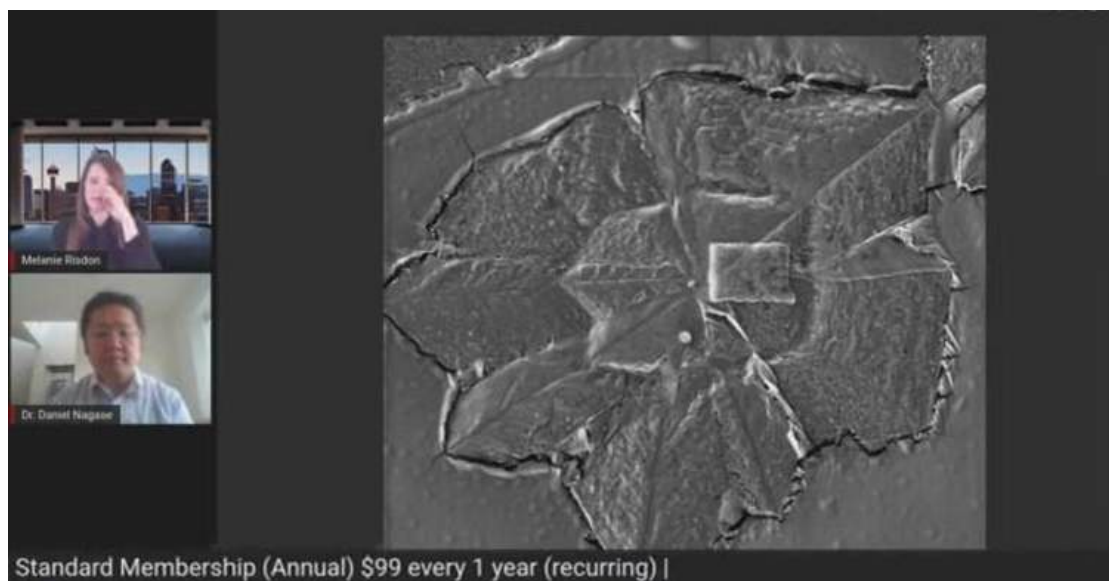
On May 27, 2022, an interview was published in 'The Exposee' magazine with a Canadian physician, Daniel Nagase, who also conducted electron microscopy and X-ray spectroscopy (EDX) analyses of certain Pfizer and Moderna COVID-19 vaccine vials <https://ro.expose-news.com/2022/05/27/carbon-nanotech-and-thulium-in-covid-injections/> . In these vials, carbon, oxygen, silicon , traces of aluminum and Thulium were identified; however, elements such as nitrogen and Phosphorus (elements which constitute the mRNA composition) were not detected. In the published interview, he stated “that , in an

Strange, the content of the Pfizer and Moderna “vaccines” shows no signs of biological material, including mRNA or DNA ”; “X-ray spectroscopy did not detect nitrogen or Phosphorus .” “A surprising and new discovery that Dr. Nagase and the researchers made was an unusual element from... the series of lanthanides—Thulium—in a fiber-like structure found in a Pfizer sample.”

“Carbon and oxygen can certainly be a sign that there is graphene in it, but how they make graphene take all these different forms: from spheres to fibers and crystals, this is *a technology that exceeds my scientific knowledge* .” “I do not even know if this carbon technology, this carbon nanotechnology is found in every lot or if it is only in the lots sent to Canada ?”

Is Canada one half of an experiment, and are certain states in the USA receiving a slightly different batch, without the carbon nanotechnology?

An image similar to that observed by me under the optical microscope (presented above) was also identified by Dr. Nagase in the drop of Moderna vaccine left to crystallize on the slide, without a coverslip.



4. Results of the German and Austrian researchers

On 20-09-2021, a conference titled “ Cause of death after vaccination against COVID-19. Undeclared components of the vaccines against COVID-19 ” was held in Reutlingen, Germany , in which the autopsy results of individuals who died after COVID-19 vaccination were presented, alongside optical microscopy findings regarding the COVID vaccines https://odysee.com/@en:a5/PK_Tott-durch-Impfung_english:a?r=D7isXqLftPaRywXjxkFWsKr3nYd6cRPRU .

This conference was attended by physicians, engineers, and lawyers, including university professors Prof. Burkhardt (anatomical pathologist), Prof. Dr. Walter Lang (anatomical pathologist), Prof. Dr. Werner Bergholz (electrical engineering), Dr. Uta Langer (general surgery), and Dr. Maria Hubmer-Mogg and Viviane Fischer (lawyer).

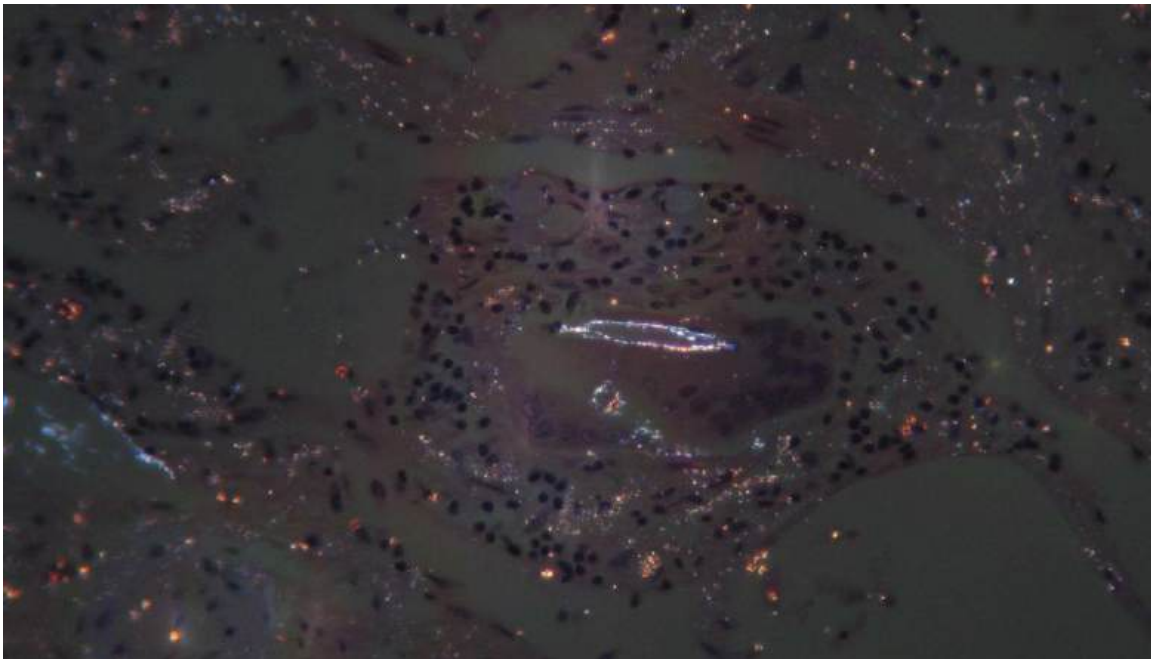
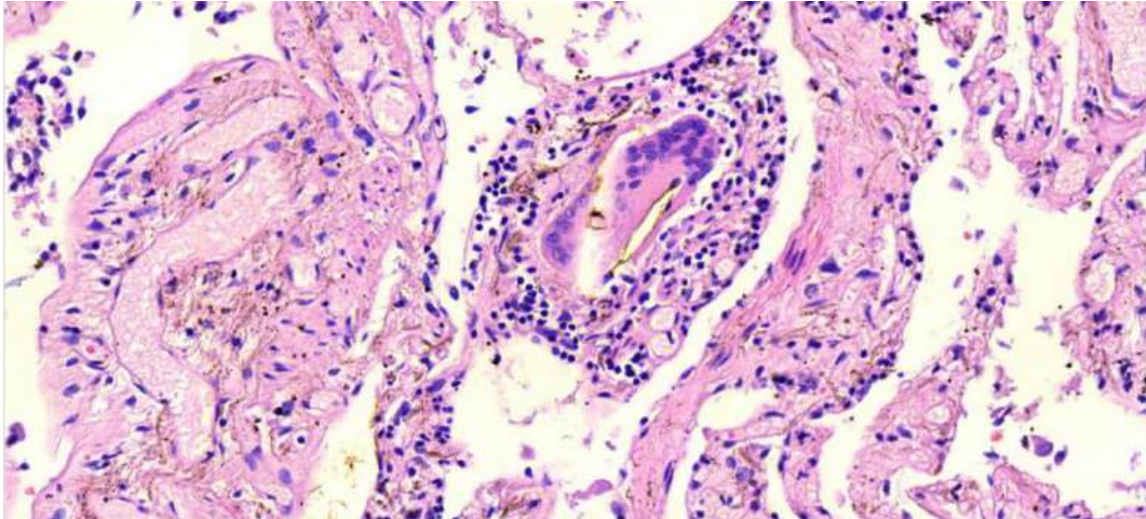
On the conference page <https://pathologie-konferenz.de/en/> it is stated that **Prof. Burkhardt's research confirms the findings of Prof. Dr. Peter Schirmacher—chief pathologist at Heidelberg University, himself vaccinated against COVID-19—stating that, out of more than 40 autopsies performed on persons who died within two weeks of COVID-19 vaccination, approximately one-third of these deaths were caused by vaccination.**

<https://freewestmedia.com/2021/08/03/german-chief-pathologist-sounds-alarm-on-fatal-vaccine-injuries/>.

It must be emphasized that Prof. Schirmacher, mentioned in this conference, had previously stated publicly that **the frequency of fatal consequences of the vaccination was underestimated**. At that time, this statement was considered politically explosive, as it was made at a moment when the vaccination campaign was losing momentum, the Delta variant was spreading rapidly, and restrictions for unvaccinated persons were being discussed <https://www.augsburger-allgemeine.de/panorama/obduktionen-von-geimpften-choft-pathologe-der-uni-heidelberg-draengt-darauf-id60235361.html>. **However, his study, officially conducted, was taken into consideration, with his work being posted in PDF format on the website of the European Medicines Agency https://www.ema.europa.eu/en/documents/presentation/presentation-sars-cov-2-vaccination-autopsies-peter-schirmacher_en.pdf**. The conclusions of this study state: **“mRNA vaccine-induced myo-/pericarditis with a lethal outcome or severe evolution is a proven fact. Only an autopsy can clarify unclear lethal cases. But: an extremely low autopsy rate; insufficient workflows; poor autopsy skills, insufficient reporting/recognition. Structural causes of under-recognition: Lack of support, obstruction, administrative deficiencies, precarious state of post-mortem examination; mistrust (physicians/politicians). Significant number of cases; substantial underreporting and non-recognition.”**

Furthermore, the Reutlingen conference proceedings state that the analysis results of the COVID-19 vaccine evidence conducted by **the Austrian research group** align with the findings of scientists from Japan and the USA, who also identified **undeclared metallic components**. It is asserted that the investigation results have prompted legal and political demands for the immediate collection of data by authorities to evaluate the risk posed to the health of the population by the COVID-19 vaccines. For instance, early indicators of fertility impairment in vaccinated persons may be examined by consulting IVF registries. Additionally, through the cancer registry, information can be obtained regarding **the development of cancer resulting from genetic modifications induced by the RNA within the vaccines**. It is maintained that, based on these results, **the suspension of COVID-19 vaccination should be considered <https://pathologie-konferenz.de/en/>**.

In the first lecture of this conference, **Professor Arne Burckhardt**, anatomical pathologist, presented **images of tissues sampled from eight individuals who died following COVID-19 vaccination <https://www.pathologie-konferenz.de/en/>**. The anatomopathological aspects were interpreted by **Prof. Dr. Arne Burckhardt and Prof. Dr. Walther Lang**. In the sampled tissues, they identified endotheliitis, vasculitis, lymphocytic infiltrates, and numerous foreign body giant phagocytic cells containing brownish material. Professor Burckhardt, **possessing extensive experience, considered these observations to be surprising**. Furthermore, particles with distinct edges were identified inside the small vessels, about which Prof. Burckhardt stated: *„this particle has very clear edges and I do not believe it is stainless steel; let me leave it at that. How does that get in there? Have you examined the manner in which the vaccines are produced for these mass vaccinations?”* Professor Burckhardt emphasized the fact that **many of those administering the vaccines did not aspirate prior to injecting the liquid**, in order to verify that they had not punctured a blood vessel—a maneuver that would have mitigated the risk of embolization by the dubious particles identified in the COVID-19 vaccines by other colleagues participating in the conference. On the [presentation slides, one can read the question](#) of whether these fragments are graphene or not https://odysee.com/@en:a5/PK_Tott-durch-Impfung_english:a?r=D7isXqLftPaRywXjxkFWsKr



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Fremdkörper / Verunreinigung / Adjuvantien im Impfstoff

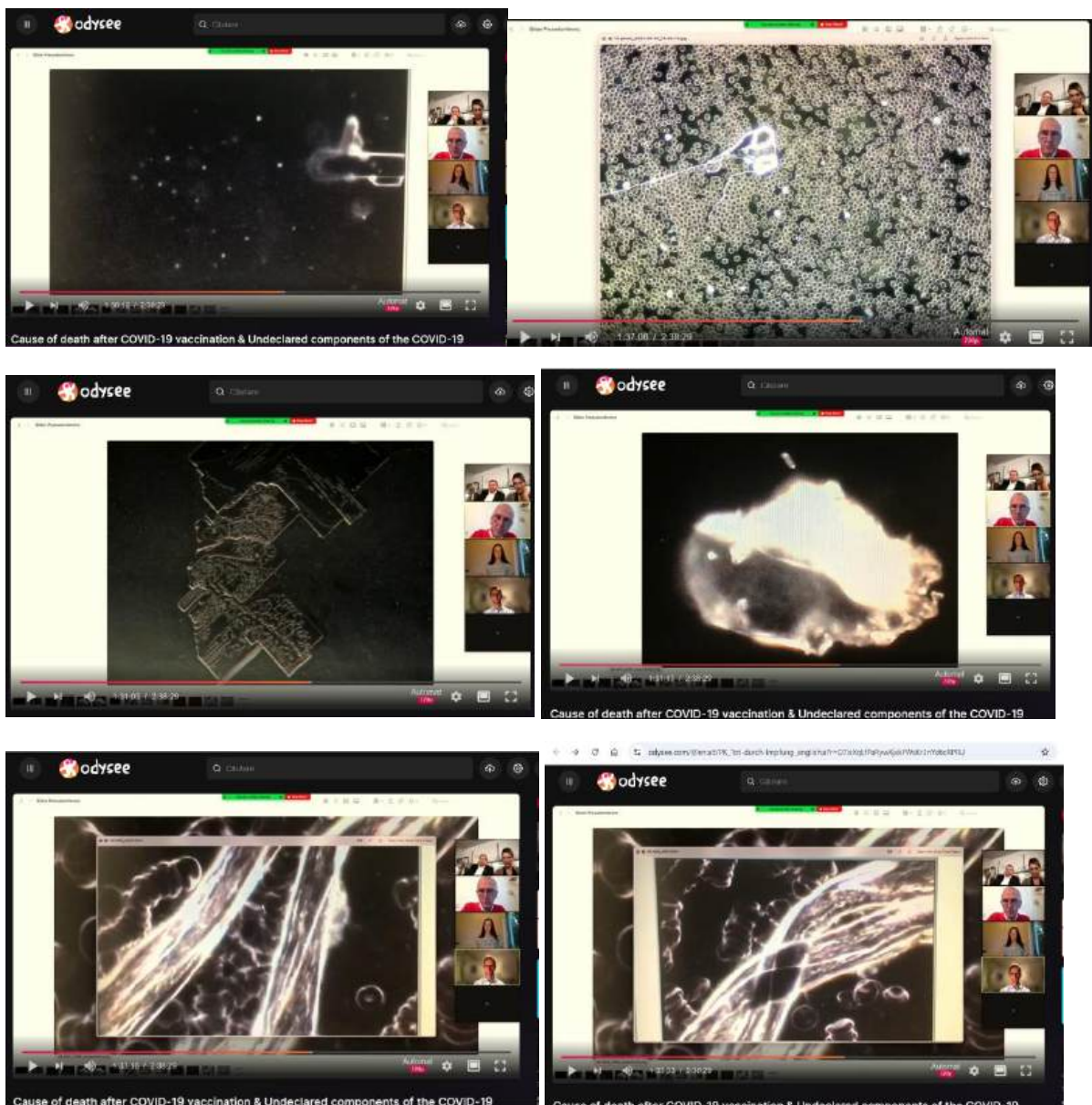
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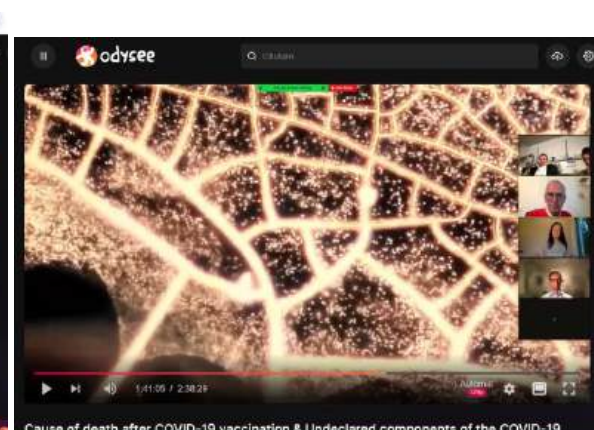
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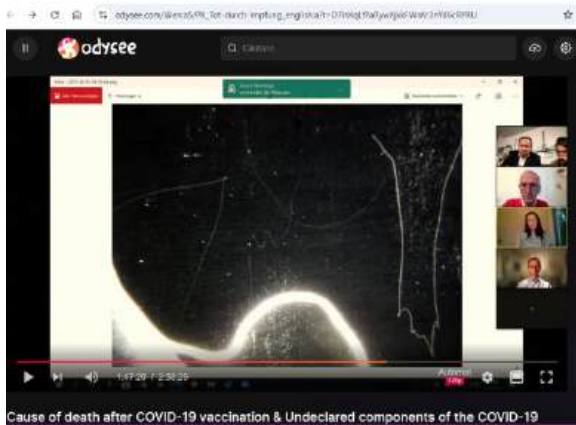
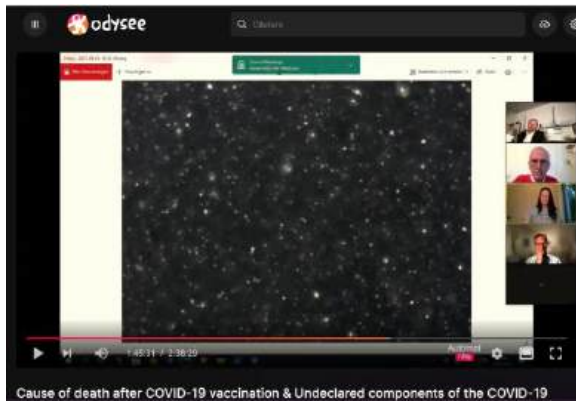
In the subsequent presentation of this conference, another German physician, Dr. Uta Langer, specializing in general surgery, presented dark field optical microscopy images and clips of the COVID-19 vaccines—Pfizer, Johnson, and AstraZeneca—as well as blood smears from vaccinated individuals. The optical microscopy images recorded by these physicians resemble the images I observed during the examination of these products, as detailed above. Upon examining the Pfizer-BioNTech and Johnson COVID-19 vaccines, Dr. Uta Langer observed luminescent particles, some of which were moving within the drop applied to the slide. Upon examination of the blood of vaccinated individuals disturbing images were observed—fibers and other particles among the erythrocytes, as well as the aggregation and deformation of the erythrocytes. In response to the question addressed to Professor Burckhardt regarding the unusual images in the blood of vaccinated individuals, he stated that the structures in question are not organic and should not be present within the body. It was hypothesized that these structures might be graphene. Upon optical microscopy examination of drops of the Janssen - **Johnson & Johnson** vaccine, it was observed that after a certain interval of time, a network appeared on the slide, within the meshes of which luminescent points could be identified. The researchers stated that they seek to ascertain the composition of these structures from the competent authorities. It was noted that these structures could be observed by any individual using a microscope, and that they are perfectly reproducible

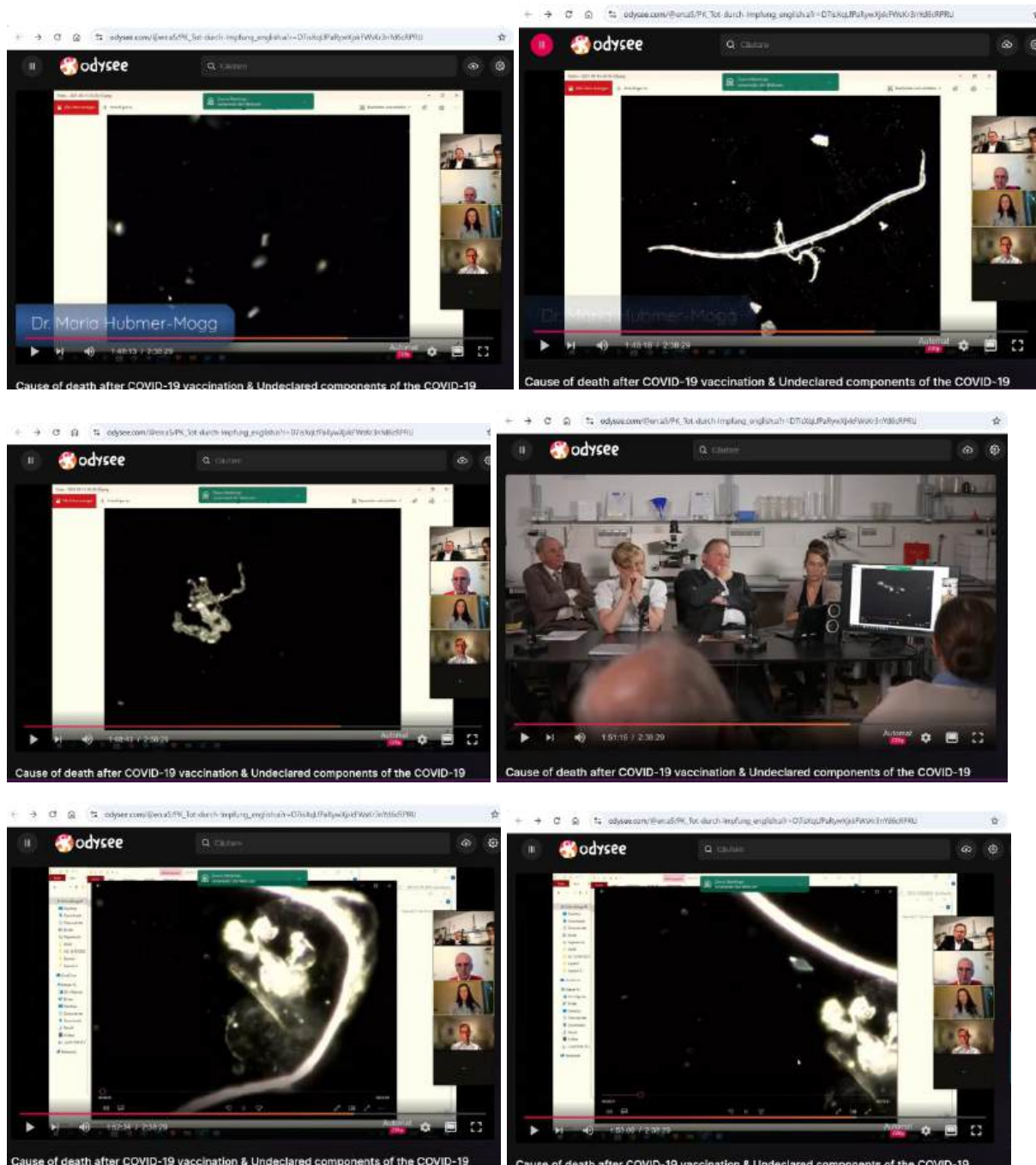




In the subsequent presentation at the Reutlingen conference, delivered by Dr. Maria Hubmer-Mogg, the results of the optical microscopy analysis of the COVID-19 vaccines (Pfizer ,

AstraZeneca) by an Austrian research group were presented. In the Pfizer vaccines, objects, potentially metallic, of various shapes and sizes—some with sharp edges—were observed in motion . Certain of these striking objects have been compared to microchips. Upon the examination of AstraZeneca vaccine slides, it was established that **they crystallized into chain-like structures**.





The conference was attended by Ms. Viviane Fischer in her capacity as an observer and representative of the Corona Investigative Committee —“Corona Investigative Committee” <https://corona-investigative-committee.com/sessions/> . This committee has conducted numerous international hearings regarding the abuses occurring during the COVID-19 period <https://odysee.com/@Corona-Ausschuss:3> .

During this conference, as well as at a hearing of the Corona Investigative Committee held on September 24, 2021, one of the participants of the Reutlingen conference, Prof. Dr. Werner Bergholz, presented a comprehensive analysis utilizing electron microscopy with X-ray spectroscopy (EDX) of the COVID-19 vaccines https://www.pathologie-konferenz.de/SEM_AZ_BP_JJ_shortt_online.pdf , https://odysee.com/SCA-Sitzung-71_-Wann-wenn-nicht-jetzt:d , <https://www.pathologie-konferenz.de/> .

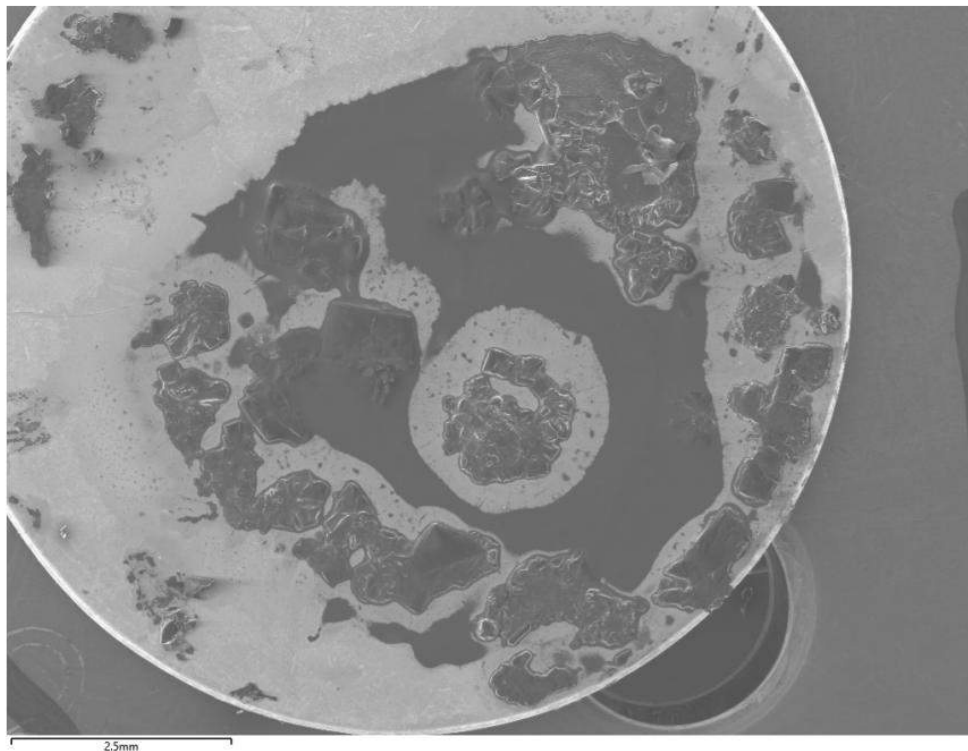
Prof. Dr. Werner Bergholz was a professor of electrical engineering, with an emphasis on quality and risk management at Jacobs University in Bremen . Prior to his appointment, Prof. Bergholz

worked for 17 years in chip production management at Siemens . Upon analysis by electron microscopy-energy dispersive X-ray spectroscopy (EDX)—an investigation determining the elements within a specific product— **Professor Bergholz detected in the PfizerBioNTech, AstraZeneca, and Johnson & Johnson vaccines, in addition to carbon and oxygen , undeclared elements such as iron and chromium**

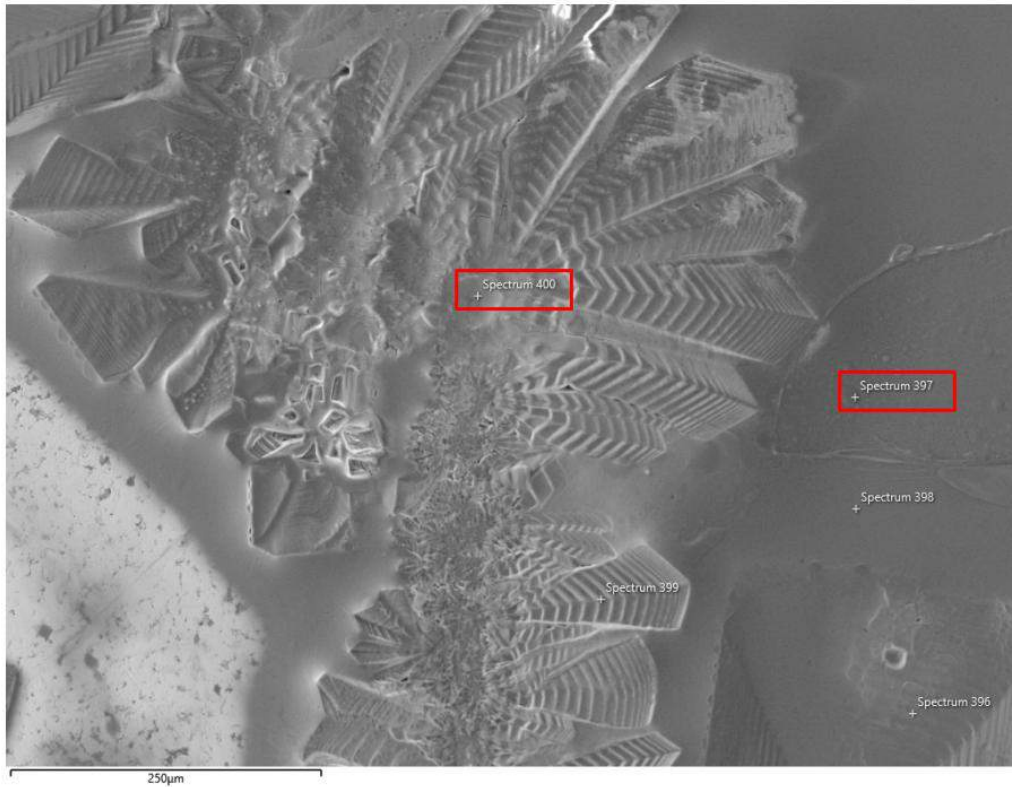
Astra-Zeneca, Biontech-Pfizer and Johnson&Johnson COVID-19 „vaccines“ investigated by means of Scanning Electron Microscopy (SEM)



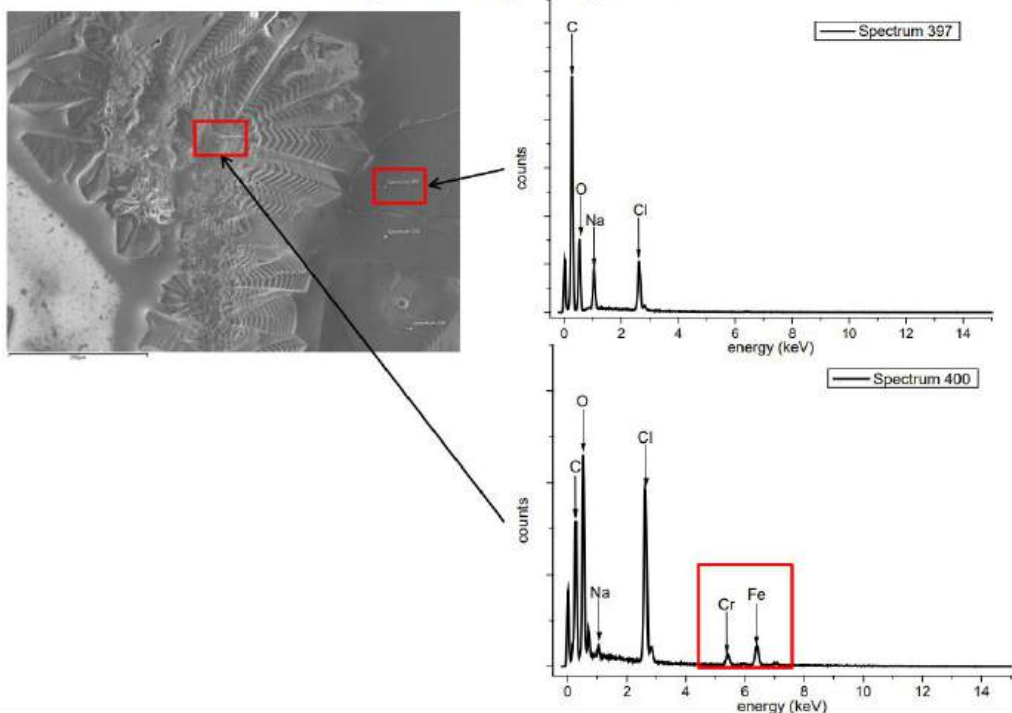
SEM/EDX Analysis of Astra-Zeneca Overview



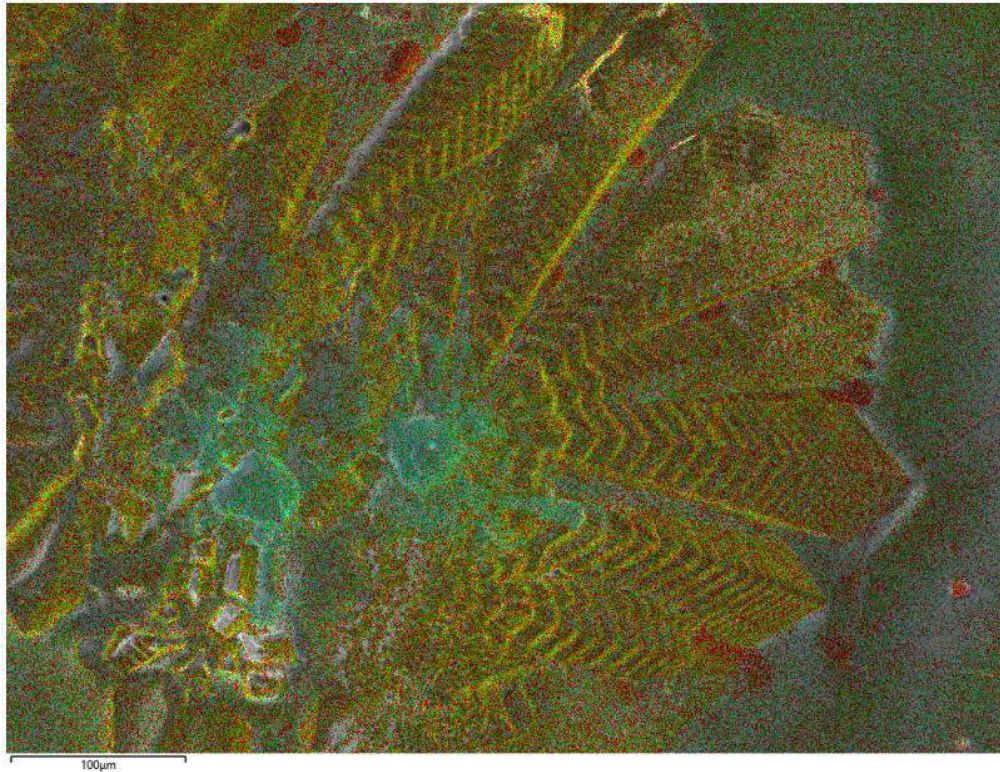
SEM/EDX Analysis of Astra-Zeneca Region comprising Fe and Cr



SEM/EDX analysis of Astra-Zeneca Region comprising Fe and Cr

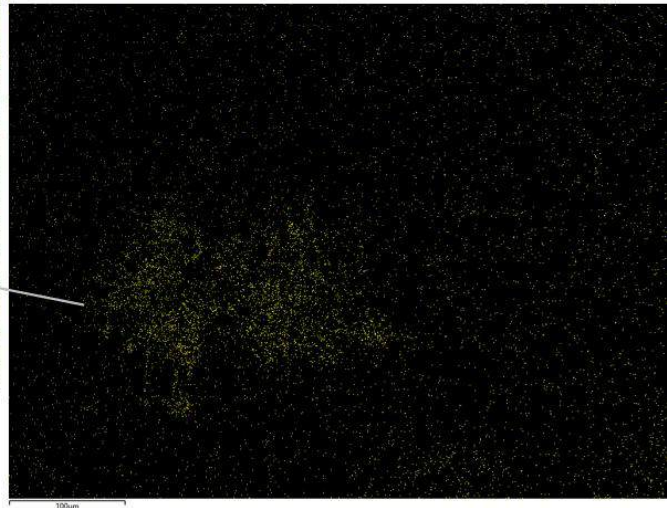
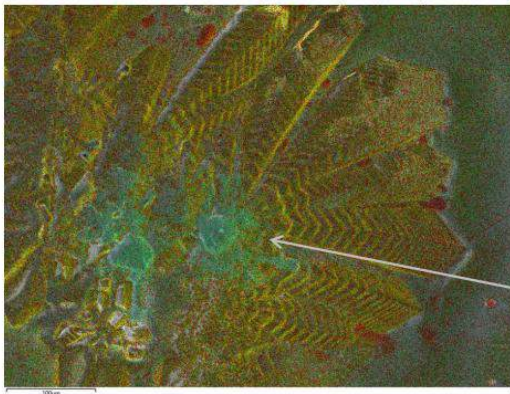


SEM/EDX analysis of Astra-Zeneca
EDX-mapping of spatial distribution of chemical elements



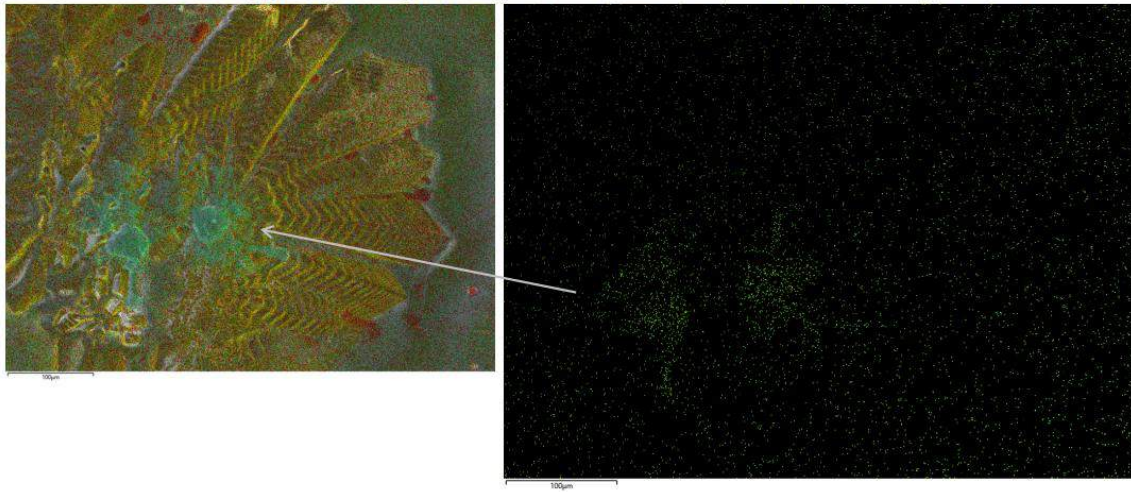
Layered image: Each color represents a different chemical element

SEM/EDX analysis of Astra-Zeneca
EDX-mapping of spatial distribution of chemical elements



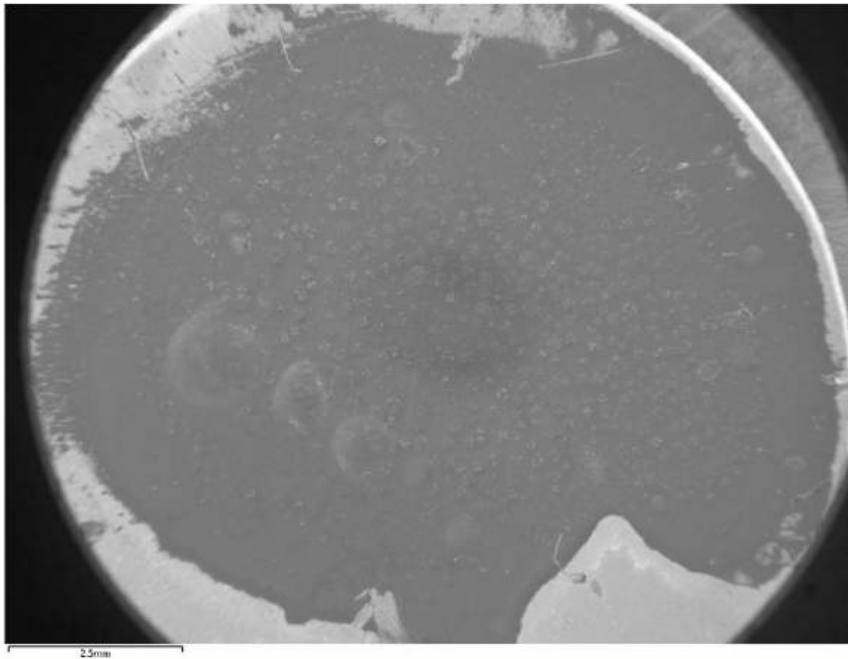
EDX mapping: spatial distribution of Fe

SEM/EDX analysis of Astra-Zeneca
EDX-mapping of spatial distribution of chemical elements

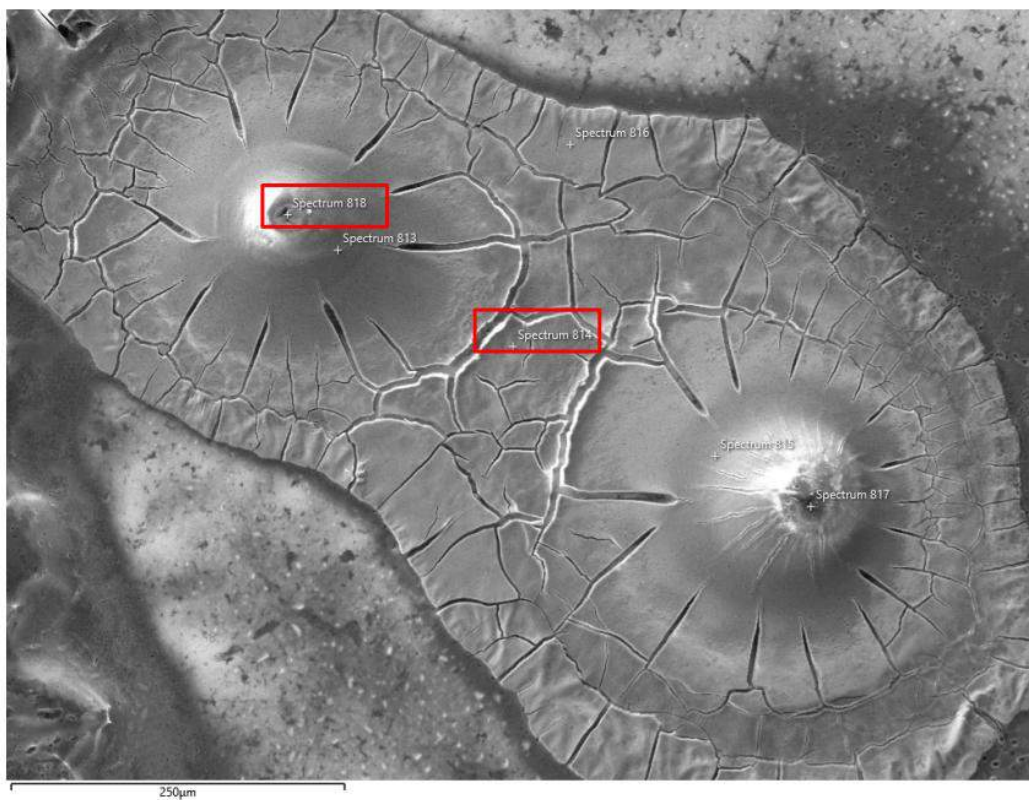


EDX mapping: spatial distribution of Cr

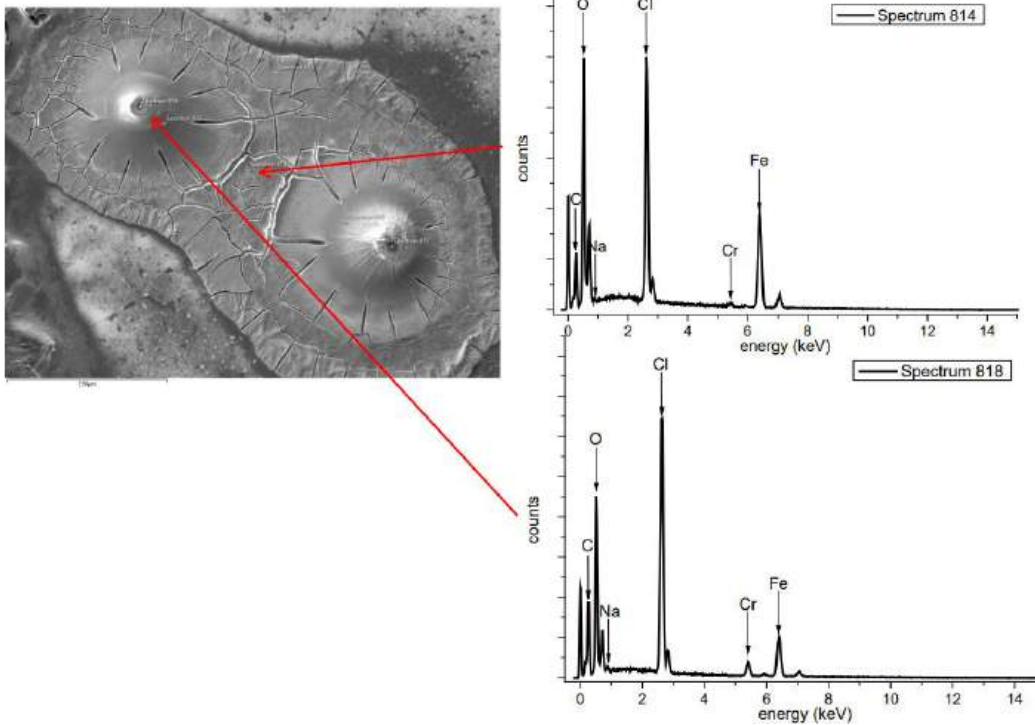
SEM/EDX Analysis of Biontech - Pfizer Overview



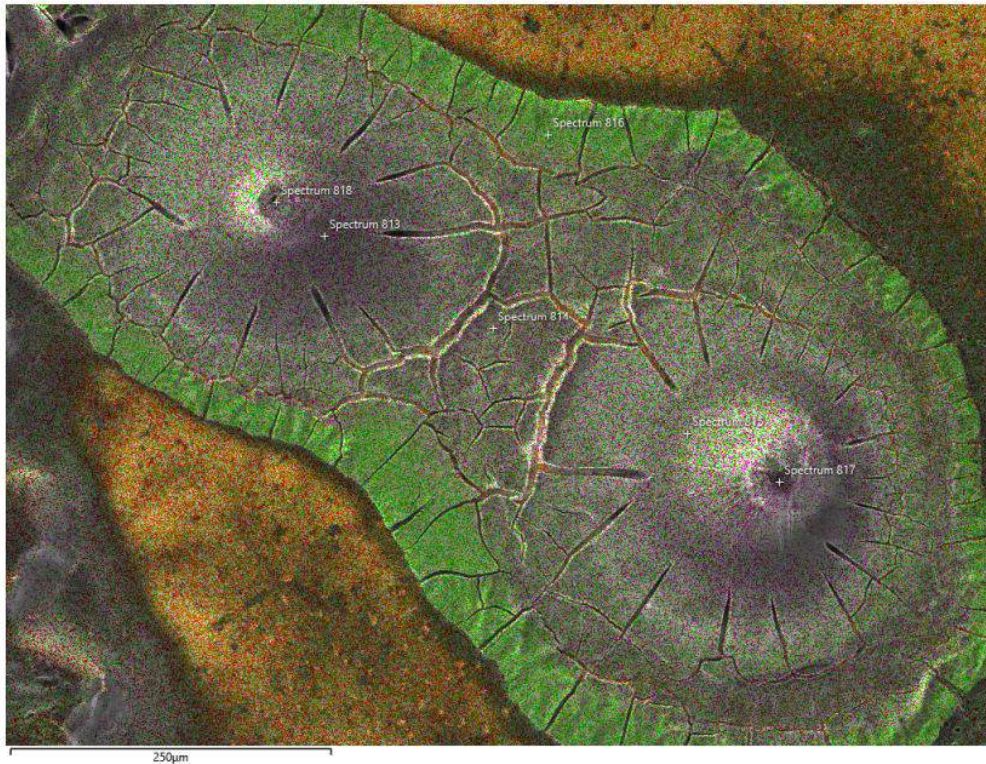
SEM/EDX Analysis of Biontech - Pfizer Regions comprising Fe and Cr



SEM/EDX Analysis of Biontech - Pfizer Regions comprising Fe and Cr

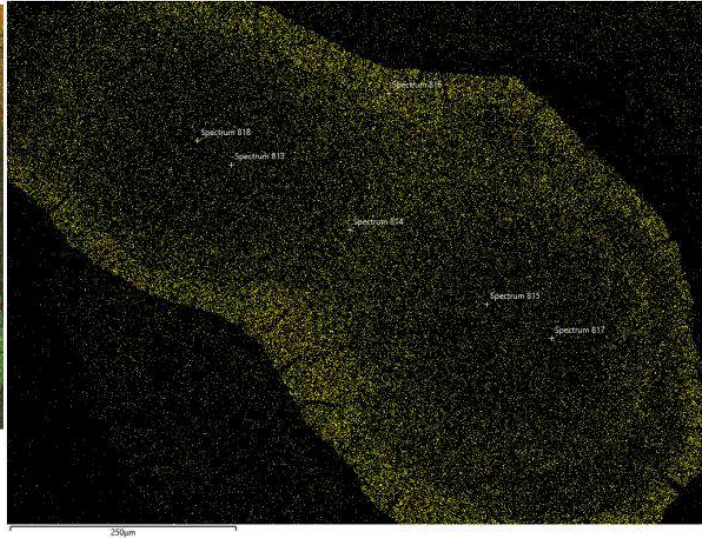
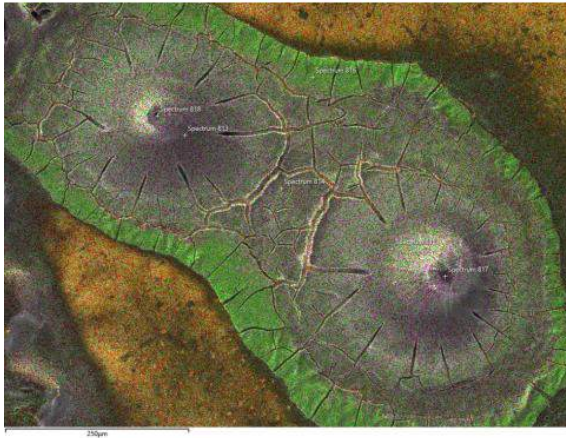


SEM/EDX Analysis of Biontech - Pfizer Regions comprising Fe and Cr



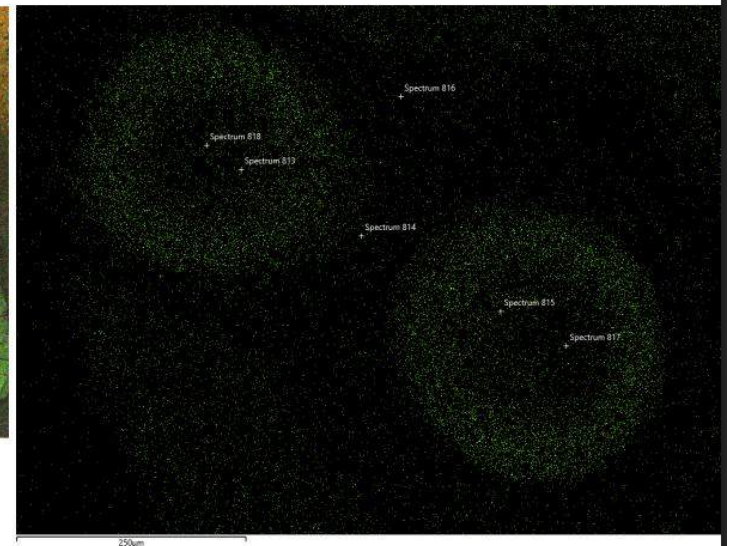
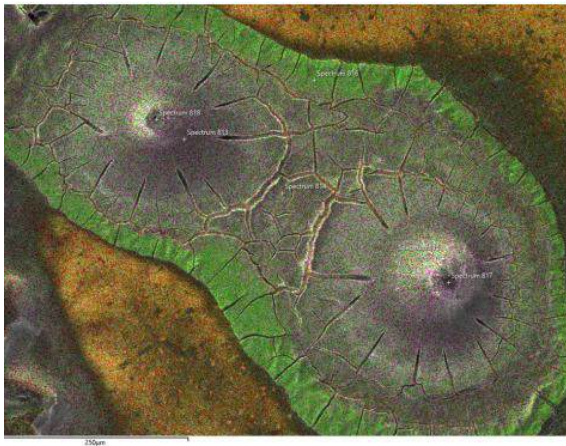
Layered image: Each color represents a different chemical element

SEM/EDX Analysis of Biontech - Pfizer Regions comprising Fe and Cr



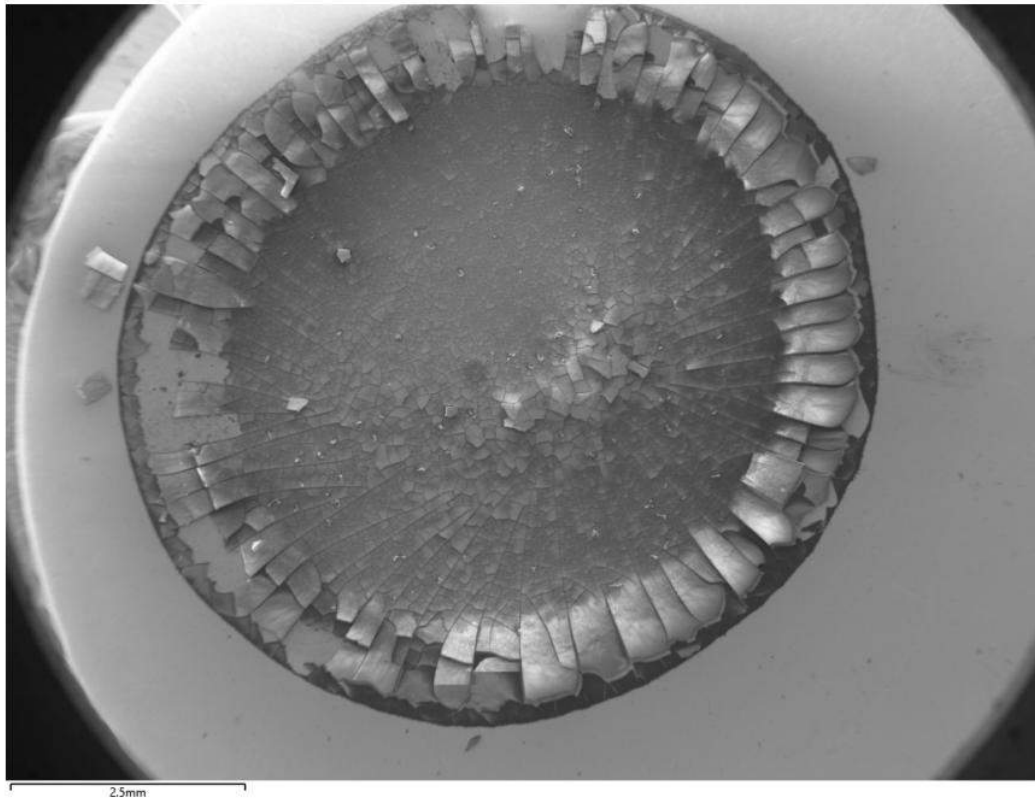
EDX mapping: spatial distribution of Fe

SEM/EDX Analysis of Biontech - Pfizer Regions comprising Fe and Cr

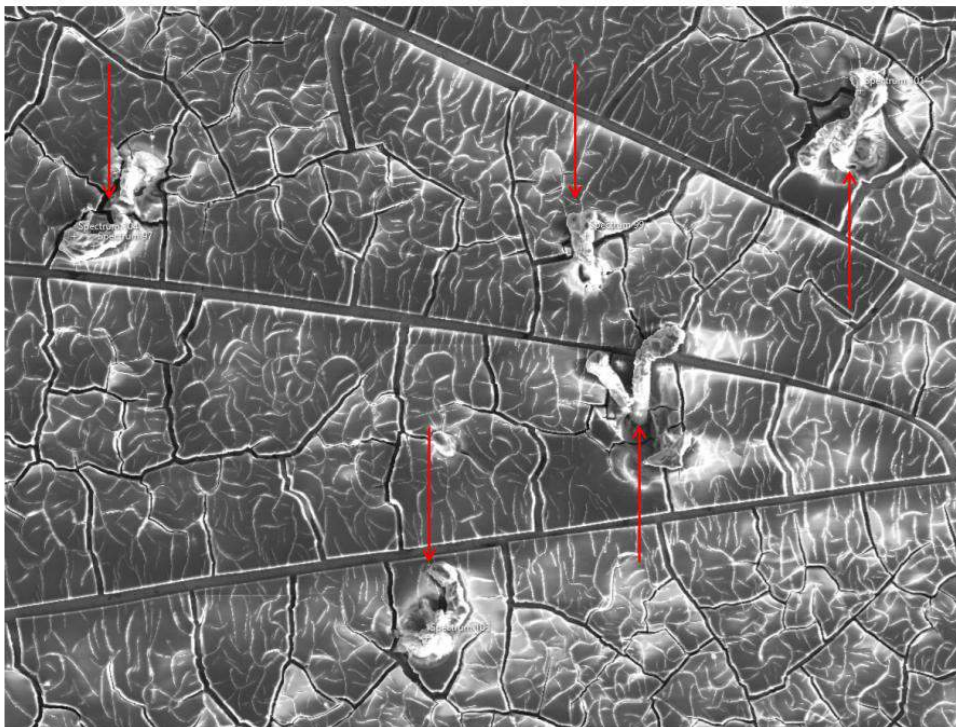


EDX mapping: spatial distribution of Cr

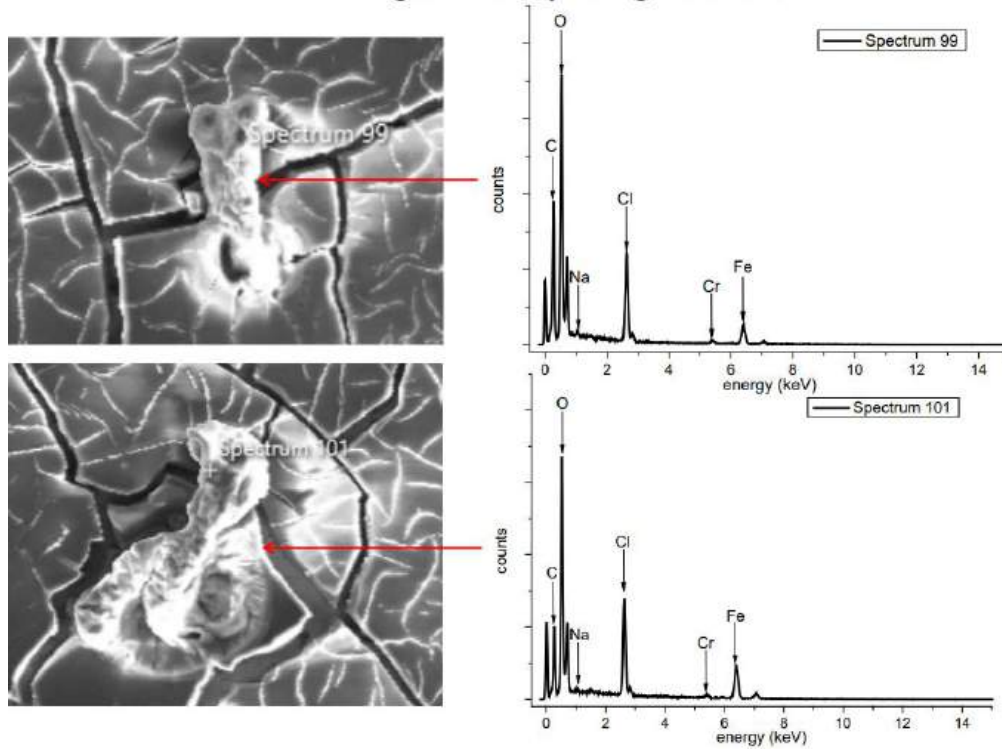
SEM/EDX Analysis of Johnson & Johnson Overview



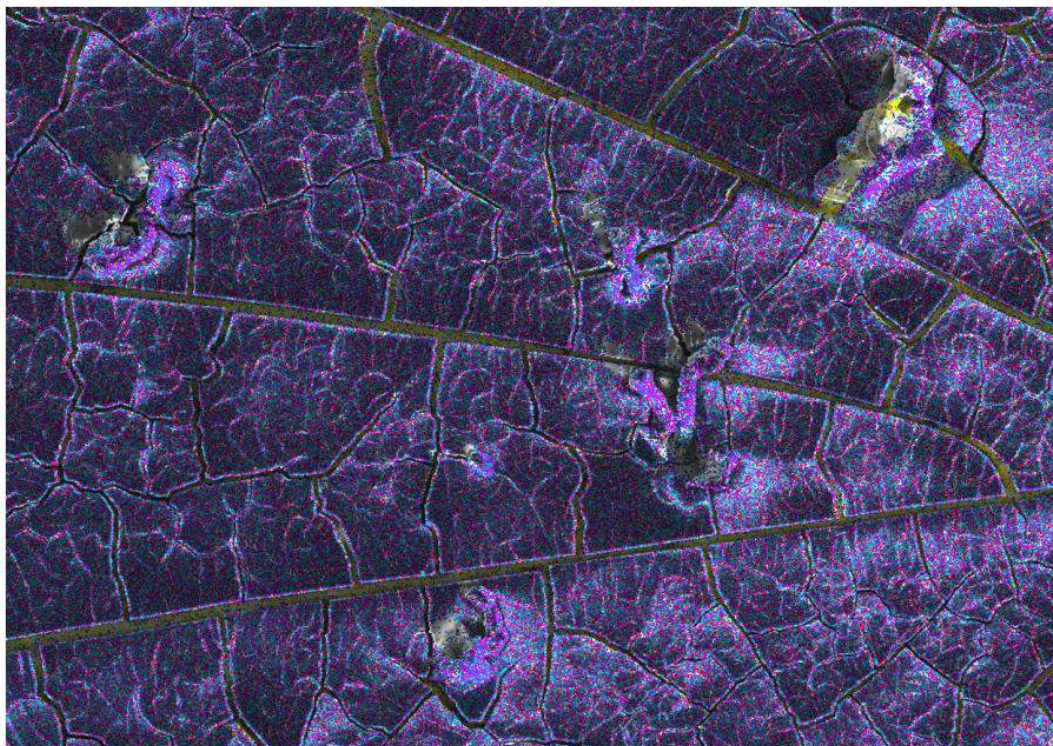
SEM/EDX Analysis of Johnson & Johnson Regions comprising Fe and Cr



SEM/EDX Analysis of Johnson & Johnson Regions comprising Fe and Cr

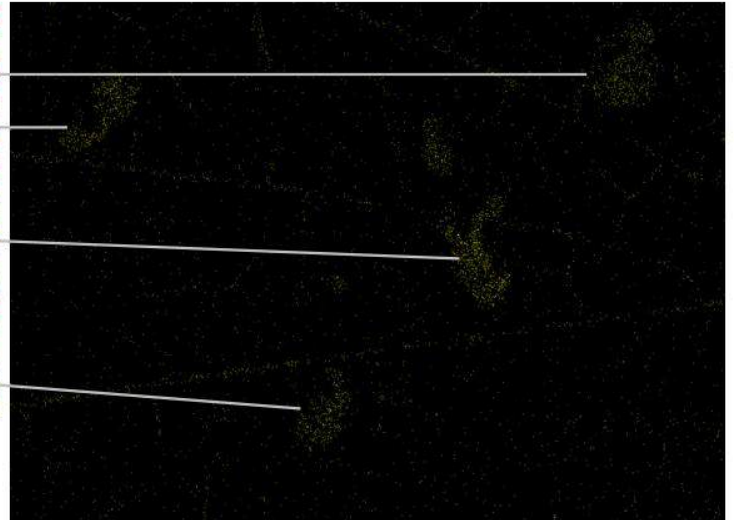
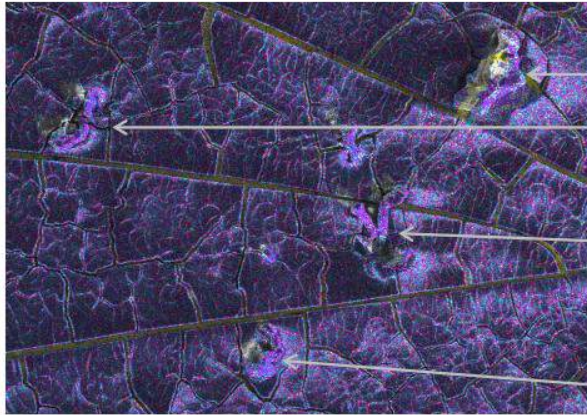


SEM/EDX Analysis of Johnson & Johnson EDX-mapping of spatial distribution of chemical elements



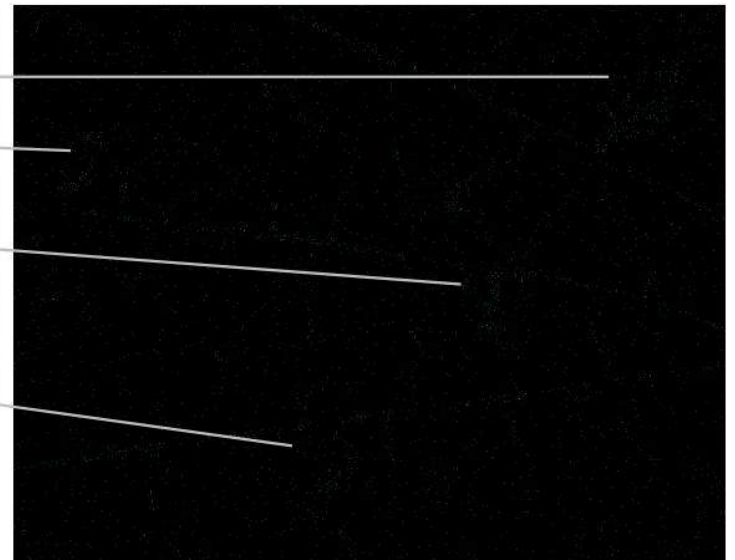
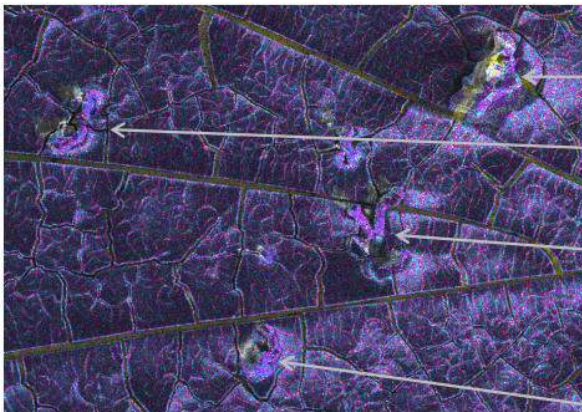
Layered image: Each color represents a different chemical element

SEM/EDX Analysis of Johnson & Johnson
EDX-mapping of spatial distribution of chemical elements



EDX mapping: spatial distribution of Fe

SEM/EDX Analysis of Johnson & Johnson
EDX-mapping of spatial distribution of chemical elements



EDX mapping: spatial distribution of Cr

SAMMLUNG ERSTER ERGEBNISSE



06.07.2022

Arbeitsgruppe Impfstoffe Aufklärung

Unsere Sammlung ist eine vorläufige, sich fortlaufend weiterentwickelnde Darstellung unserer Untersuchungen und Erkenntnisse über die so genannten COVID-19-Impfstoffe, sowie der von uns gefundenen Wirkungen auf den Organismus und das Blut, für die Öffentlichkeit und zur kritischen Diskussion.

An interdisciplinary team of researchers called “ **Arbeitsgruppe Impfstoffe Aufklärung** („ **Vaccination Awareness Working Group**”) <https://www.aerzte-ftuer-aufklaerung.de/>, composed of **over 60 independent scientists—physicians, physicists, chemists, microbiologists, pharmacists, and alternative practitioners, supported by lawyers, psychologists, analysts, and journalists**, drafted on 6-07-2022 a report of the analysis of the COVID vaccines, as well as of the blood of vaccinated individuals compared to that of unvaccinated individuals https://www.aerzte-ftuer-aufklaerung.de/wp-content/uploads/2022/07/Sammlung_erster_Ergebnisse_der_AG_Impfstoffe_Aufklaerung_20220706.pdf. This report, although anonymous, is produced with a high degree of professionalism; as it contains many of the images presented by the participants of the Reutlingen conference (Prof. Dr. Arne Burkhardt, Professor Werner Bergholz, Dr. Uta Langer, Dr. Maria Hubmer-Mogg), it follows that the 60 scientists who compiled this report include the participants of said conference.

The report presents the results of investigations conducted via modern medical and physical measurement methods, which confirmed and complemented one another : **scanning electron microscopy (SEM), energy dispersive X-ray spectroscopy (EDX), mass spectroscopy (MS), inductively coupled plasma analysis (ICP), bright-field microscopy (HFM), dark field microscopy (DFM) of blood smears, and image analysis using Artificial intelligence**. It is noted that this group collaborates closely with several international working groups conducting similar studies with consistent results. Therefore, the results may be regarded as having undergone multiple validations.

I deem it useful to cite an excerpt from the **introductory remarks of this report**: “ **We have combined our expertise and technical capabilities to contribute to the clarification of what we consider to be the greatest pharmacological experiment on humanity. Never before in the history of science and of medicine has anyone dared to make an entire population, almost an entire species, the subject of medical or genetic experiments. The justification for rejecting such a research**

*proposal would likely have been the conservation of species. **The fact that this has now been applied to humanity and will continue, that there has never been such an outrageous number of side effects and injuries caused by vaccines, that the statistics regarding the deaths show a correspondingly significant excess mortality, that no prosecutor intervenes despite the consequences being already evident, and that, instead, critics are publicly defamed, marginalized, and economically ruined, makes us tremble. Therefore, contrary to good scientific practices, we have decided, for self-protection, to remain anonymous as authors.*** "

The report states from the outset that the vaccination programs against COVID-19 must be terminated immediately. "In order to avert a concrete and imminent threat to life and physical integrity, as well as to public safety, the vaccination programs against COVID-19 must be stopped immediately ." Readers are encouraged to critically evaluate these studies, to reproduce them, and to expand upon them.

The group of independent German researchers discovered Toxic substances—predominantly metallic—in all COVID-19 vaccine samples analyzed, **"without exception."** **Certain toxic elements found in the AstraZeneca, Pfizer, and Moderna vials are not included in the manufacturers' ingredient lists.** Thus, the following were identified: cesium (Cs), potassium (K), calcium (Ca), barium (Ba), cobalt (Co), iron (Fe), chromium (Cr), titanium (Ti), cerium (Ce), gadolinium (Gd), aluminum (Al), silicon (Si), sulfur (S).

Furthermore, upon examination of the vaccines, researchers identified structures that „are visible under a dark field microscope as distinct and complex structures of various dimensions, which can only be partially explained as a result of crystallization or decomposition processes [and] cannot be explained as contamination originating from the manufacturing process ". They declared the findings to be preliminary.

Dr. Janci Lindsay, toxicology physician, discussing this study for The Epoch Times; the article was also republished by The Defender, the journal of the Children's Health Defense association. <https://childrenshealthdefense.org/defender/ttoxic-mettallic-compounds-covid-vaccines-german-scienttists/> asserts that the observations in this report **"are similar to the work of other researchers within the international community who have described similar findings, such as Dr. Young, Dr. Nagase, Dr. Botha, Dr. Flemming, Dr. Robert Wakeling, and Dr. Noak "**. **"The number and consistency of the allegations of contamination, corroborated by the eerie silence of global safety and regulation organisms, are distressing and baffling with respect to the «transparency» and continuous assertions by these bodies that genetic vaccines are «safe»"**, stated Lindsay. Helena Krenn, the founder of the group, submitted the findings to the German governmental authorities for examination.

Two other significant findings were that blood evidence from vaccinated persons exhibited " significant changes " and that a higher frequency of side effects was observed in proportion to the " stability of the lipid nanoparticles envelope ." Utilizing a small sample of live blood analyses from both vaccinated and unvaccinated individuals, it was established that **Artificial intelligence (AI) can distinguish, with a probability exceeding 98%, between the blood of vaccinated persons and that of the unvaccinated .**

In the article from The Defender <https://childrenshealthdefense.org/defender/ttoxic-mettallic-compounds-covid-vaccines-german-scienttists/> it is stated: " It must be acknowledged, of course, that the work [of the German Working Group] is described as «Preliminary findings», has not yet been published in a peer-reviewed journal, and the identity of many of these scientists remains unknown ." **„Nevertheless, in this heavily charged and censored climate regarding any challenges to the «safety and efficacy» of genetic vaccines, I myself can attest to the difficulties encountered in**

conducting fundamental research, as well as in publishing said research in a peer-reviewed journal to address these questions and disseminate the results ,” said Lindsay.

However, given that many of the images presented in this study are similar to those from the Reutlingen conference, at least some of the 60 group members can be identified—Prof.

Dr. Arne Burkhard, Professor Werner Bergholz, Dr. Uta Langer, Dr. Maria Hubmer-Mogg.

Upon reviewing this study, I have observed that many of the optical microscopy images of the COVID-19 vaccines which I personally obtained are similar to those presented herein. Furthermore, several of the elements identified by these researchers were also identified in the results of the scanning electron microscopy and X-ray spectroscopy (EDX) obtained through my own investigations (C, O, Si, Ti, Al), which are elements not declared by the vaccine manufacturers. Although not specified in the conclusions of the German researchers' study, I did not observe any image among the electron microscopy images with EDX in this study in which the elements nitrogen and phosphorus were identified, a finding consistent with my own results, as well as those of other researchers

The cautious attitude of the German researchers who chose to remain anonymous, stems from incidents such as the police raid conducted during a live broadcast by German researcher Andreas Noack, an expert in the field of nanotechnology (specifically graphene structures), in which he discussed the presence of graphene hydroxide in the COVID-19 vaccines <https://forbiddenknowledge.tv/murder-justt-hours-afttter-publishing-tthe-secrett-oft-tthe-vaxx-dr-noack-is-dead/> , as well as **his premature death under unclear circumstances on November 26, 2021, three days after the video in which he spoke about the presence of graphene in the COVID-19 vaccines** <https://gattesoftvienna.net/2021/12/tthe-mysterious-death-oft-dr-andreas-noack/> (the original video was recorded on November 23 <https://www.bittchutte.com/video/X9oMvft6dbhCi/> , according to the statements of his widow <https://www.youtube.com/watch?v=TbmyGPPZlqY>). **The wife of Andreas Noack states that Andreas fell ill inexplicably and rapidly, just a few hours after posting the video warning regarding vaccines, and deceased three days later, on November 26, 2021 .** Although the onset of illness and subsequent death could suggest poisoning, his (pregnant) wife did not believe poison was involved, as she had consumed the same food as he had; she instead attributed it to a directed energy

Dr. Andreas Noack asserted in said video that the injections contain Graphene hydroxide, rather than graphene oxide, as had been claimed by other independent researchers. He stated that **graphene hydroxide is akin to a razor blade at the nanoscale . This material is non-degradable; it remains in the body, lacerating tissues and causing damage.** He maintained that this explains why athletes expire on the field after being vaccinated individuals, as their blood circulates at higher velocities, potentially causing sudden internal injuries. The presence of graphene hydroxide would account for the instances of syncope or death observed shortly after the administration of the vaccine. He further asserted that the administration of the vaccine is akin to Russian roulette, with the vaccine becoming lethal upon entering a blood vessel. He moreover stated that there is no justification for graphene hydroxide to be present in the vaccine, qualifying the situation as biological warfare. The graphene hydroxide structures are 50 nm long and 0.1 nm thick. In the video, he expressed concern that in Austria, Minister Schallenberg was also recommending the vaccination of children, despite the vaccine not being approved. **He was convinced that pediatric physicians had never heard of graphene.** Furthermore, he expressed his opinion that **the theory of the mRNA content of the vaccines is a diversion(!!!)** . He considered that there is a need for debate and an explanation regarding the presence of graphene hydroxide in the COVID-19 vaccines. Additionally, **he stated that anyone who continues to inject these products is guilty of murder** . He urged people to distribute his video—“ **Go out, write it down, give it to your physician, give it to your politicians** . *And if you continue, I promise you that no court in the world will save you. What you are doing is a mass crime. Austria bears the responsibility. They have initiated a vaccination mandate. And you, Mr. Schallenberg, require the most qualified consultants. If you are unable to select the best consultants, you are incompetent and must resign. The same applies to the Minister of Health. How competent are you?*

prepared to inject the entire population of Austria with non-biodegradable razor blades? To lend weight to his observations, Andreas Noak insisted on mentioning that **the leading German carbon specialist, Dr. Dr. Harmut von Kienle, was his mentor and that no one else possesses his level of expertise. He stated that he wrote his doctoral thesis in this field and established his company in this field.**

Furthermore, it is pertinent to note herein that Prof. Dr. Arne Burkhard and Prof. Dr. Walter Lang, participants in the Reutlingen conference, submitted 10 critical inquiries to BioNTech — headquartered at Goldgrube in Mainz — which markets Comirnaty, the most prominent and widely administered mRNA „vaccination” in Germany . The company provided a response on February 16, 2022, <https://pathologie-konferenz.de/BIONTECH%20Antwort%20an%20Pathologie-Konferenz.pdf> , upon which the professors comment <https://www.patthologie-konferenz.de/> :

“Comirnaty vaccination involves the injection into the body of modified mRNA encapsulated in lipid nanoparticles to induce the production of the spike protein, a surface structure of coronaviruses. Subsequently, an immune response is triggered against this spike protein, which is intended to protect against coronavirus infections.

*However, **an immune response against the spike proteins emerging from the surfaces of the body's cells may also lead to unwanted side effects** . Therefore, the distribution of Comirnaty within the body and its subsequent processing represent a significant aspect of the safety of medicinal products. Studies regarding the distribution of medicinal products are typically a prerequisite for the approval of the medicinal product.*

*Unfortunately, **BioNTech did not respond to the inquiry regarding which cells and tissues produce spike proteins** . However , in response to a subsequent inquiry, **reference was made to studies regarding the distribution of vaccine particles in mice and rats, which demonstrated that these were detectable throughout the body following injection . Consequently, the vaccine particles do not remain localized at the injection site.***

*The inquiry regarding the **duration of the spike protein formation remained unanswered**. Interested scientists identified information from the founder of BioNTech, Ugur Sahin, in a 2014 publication, stating that **half of an injected dose of modified RNA, such as that utilized in Comirnaty, degrades after approximately 10 days** .*

*By utilizing a vessel of water and several drops of oil, one may observe the process by which small lipid droplets coalesce into larger ones. **Scientists sought to determine whether similar phenomena could be expected in the case of lipid nanoparticles**. BioNTech found no report regarding this matter in the specialized literature, yet it failed to conduct any independent experiments. **To prevent the aggregation (= fusion?) of the lipid nanoparticles within the organism, polyethylene glycol (PEG) was added, a substance known to induce severe allergic reactions.***

*It appears that substantial information exists concerning the ingredients of the lipid nanoparticles ALC-0159 and ALC-0315, **which are not approved for human use** , a point upon which **BioNTech provided commentary despite scientists not having raised inquiries in this regard.***

*However, **BioNTech declined to respond to inquiries regarding the number of lipid nanoparticles per dose of Comirnaty. 'We cannot provide information regarding the number of lipid nanoparticles in a Comirnaty dose or the variance between individual doses, as this constitutes commercially sensitive information.'***

*Based on the responses concerning the modified RNA utilized, scientists have concluded that a modRNA format is employed, which the founder of BioNTech, Ugur Sahin, has described as a „ **deimmunizing variant** ”.*

Reutlingen, February 20, 2022, Prof. Dr. Arne Burkhardt, Prof. Dr. Walter Lang"



BioNTech SE - An der Goldgrube 12 - 55131 Mainz

Herr Prof. Dr. Arne Burkhardt
Pathologisches Institut
Obere Wässere 3-7
Reutlingen
Deutschland

16. Februar 2022

Sehr geehrte(r) Herr Prof. Dr. Burkhardt,
Sehr geehrte(r) Herr Prof. Dr. Lang,

Vielen Dank für Ihre kürzliche Anfrage an BioNTech Medical Information. Sie haben um die folgenden Informationen gebeten:

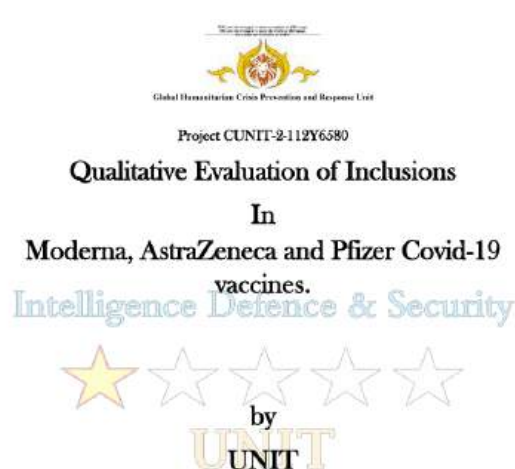
- Anfrage der Pathologen Prof. Dr. Arne Burkhardt und Prof. Dr. Walter Lang hinsichtlich des Impfstoffes Cormirnaty

Dr. Tess Lawrie—Researchers from the United Kingdom

On **February 12, 2022**, a **study by researchers from the United Kingdom was published, which aimed to verify the findings of the researcher Campa** published in 2021, asserting that the COVID-19 vaccines contain graphene compounds—graphene oxide and graphene hydroxide—as well as to identify other biological inclusions that may be characterized as Toxic substances for the human body: "Project CUNIT-2-112Y6580 Qualitative Evaluation of Inclusions In Moderna, AstraZeneca and Pfizer Covid-19 vaccines." <https://www.nottonthebeeb.co.uk/postt/uk-lab-reportt> .

The independent laboratory UNIT, at the request of EbMCsquared within project UNITC-112980, analyzed the content of four vaccine vials <https://ebmcsquared.org/statementt-lab-ttesting-on-vaccine-contentt> . The four vaccines that were the subject of this initial investigation conducted by UNIT belonged to the following companies: **Moderna (2 vials), Pfizer (1 vial), and AstraZeneca (1 vial)**. EbMCsquared is a non-profit, community interest company (CIC) dedicated to promoting health and well-being for the benefit of humanity <https://ebmcsquared.org/tthe-tteam> . The directors of this company are Dr. **Tess Lawrie** , who since 2013 has headed Evidence-based Medicine Consultancy Ltd, a company specializing in providing evidence to support clinical practice guidelines; retired engineer Mike Austin; Christof Plothe, naturopath; Dr. Mark Trozzi, a physician who has practiced emergency medicine for twenty-five years and serves as a professor of Advanced Trauma Life Support at the American College of Surgeons; and journalist Shabnam Palesa Mohamed , who chairs the steering committee of Children's Health Defense Africa. **The results were presented during a conference of the World Council for Health** and the **Alliance for Natural Health International** (ANH-Intl) by **Rob Verkerk** , PhD, founder, executive, and scientific director of ANH- <https://odysee.com/@ANHInternational:5/JabFindings:7?src=embed&tt=142.069971> . In the article <https://anheurope.org/news/is-there-graphene-in-the-jabs/> , **Verkerk claims that it is difficult to obtain vials of COVID-19 vaccines for analysis, as they are all closely monitored, including the physicians or other vaccinators who administer them** . Despite these difficulties, Dr. Tess Lawrie's company, EbMCsquared, located in the East of England, acquired four vials. The laboratory that performed the Raman spectroscopy is a top-tier, ISO-accredited laboratory in Cambridge, **the name and coordinates of which are confidential** . The name or coordinates of the source of the vials are also confidential, but are known by those who commissioned the study.

I hereby present the results of this project, which I have translated into Romanian.
<https://www.nottonthebeeb.co.uk/postt/uk-lab-reportt> .



Project CUNIT-2-112Y6580 was titled "Qualitative evaluation of particles in the Moderna, AstraZeneca, and Pfizer COVID-19 vaccines."

*The vaccine vials were evaluated at four laboratory locations. The vials for analysis remained sealed. The report confirms the presence of graphene compounds in every analyzed vial. **Although a quantitative examination was not conducted, the presence of graphene was observed with very high frequency.** The following were identified:*

1. Graphene nano-ribbons coated with polyethylene glycol,
2. Graphene Composite Form 1-GC1
3. Graphene Composite Form 2-GC2
4. Microcrystalline calcite with carbonaceous inclusions
5. Graphene nanoforms with and without fluorescence
 - a. Graphene nano-objects
 - b. Graphene nano-scrolls

At high magnifications of 40x, the lamellar structures can be identified as sheets. The Raman spectrum of these sheets indicates a carbon-oxygen bond with added polyethylene glycol fingerprints.

Graphene composite form 1-GC1 appears in a translucent folded form with a diameter of approximately 10-15 microns. The form is transparent to translucent in Transmitted light and exhibits a luminous structure within. Raman spectroscopic results for this form show dominant double peaks of calcite at 1100 cm^{-1} and a specific form of iron oxide at approximately 500 cm^{-1} . The spectrum beyond 1300 cm^{-1} is notably noisy due to the presence of certain fluorescence.

Composite form of graphene2-GC2 These forms are visibly more complex and yield a highly intricate Raman signature. The identified components were graphene with iron oxide and calcite. The forms are highly distinctive owing to their lamellar structure. The carbon-carbon bond signature is clearly distinct at 1600 cm^{-1} ; for calcite, a peak at 1100 cm^{-1} is observed.

Microcrystalline calcite constitutes another inclusion present in the evidence. The form can be described as coarse, containing inclusions of graphene nanoforms. The morphology provides a very clear Raman signal for calcite. Calcite is also present in GC1 and GC2, as identified via Raman spectra.

Graphene nanoforms were identified in all evaluated evidence. During Raman imaging, while focusing on some of these nano-objects (in various vaccines), it was observed that the obtained signals are significantly masked by fluorescence. Consequently, the identification of graphene nanoforms was performed based on the microscopic morphological correlation with structures where the signal was clear and indisputable. Graphene nanoforms dominated the count in all evidence. These were found in both rounded and long spiculate forms. The rounded forms were found almost entirely in association with nanoparti-

All four vaccines are sugar-based, and on the edges of the slide, as the material dried, it crystallized into sugar crystals of various shapes. shows several varied forms of these crystals under polarized light.



Figure 3.6. Four different forms of sugar base crystals identified in a dried Moderna slide. The crystals display third order interference colours under polarised light with an angular extinction in most cases. The crystals stem from distinctive nucleii.

The Moderna vaccine sample exhibited several filamentous forms. Small flakes appeared to be peeling away from these.

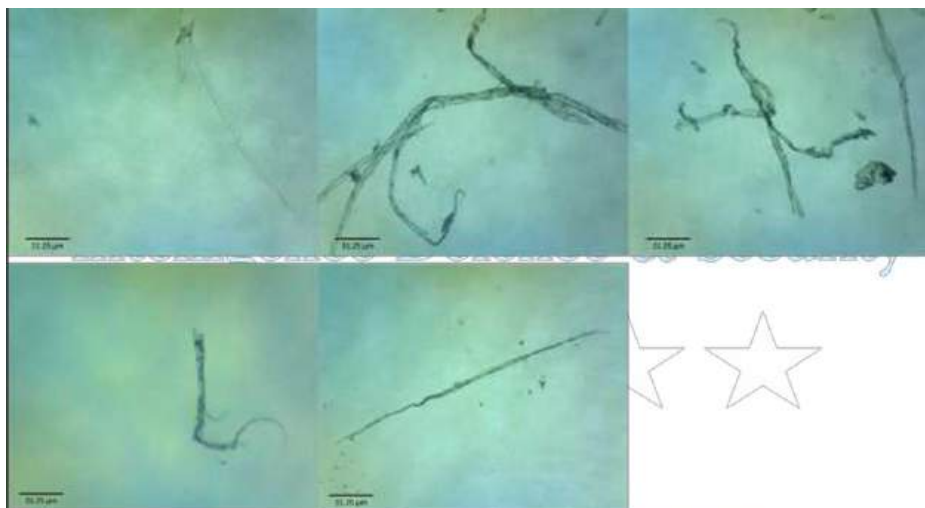


Figure 3.7. Filament forms as observed under wet microscopy.

Transparent ribbon-like structures were observed.

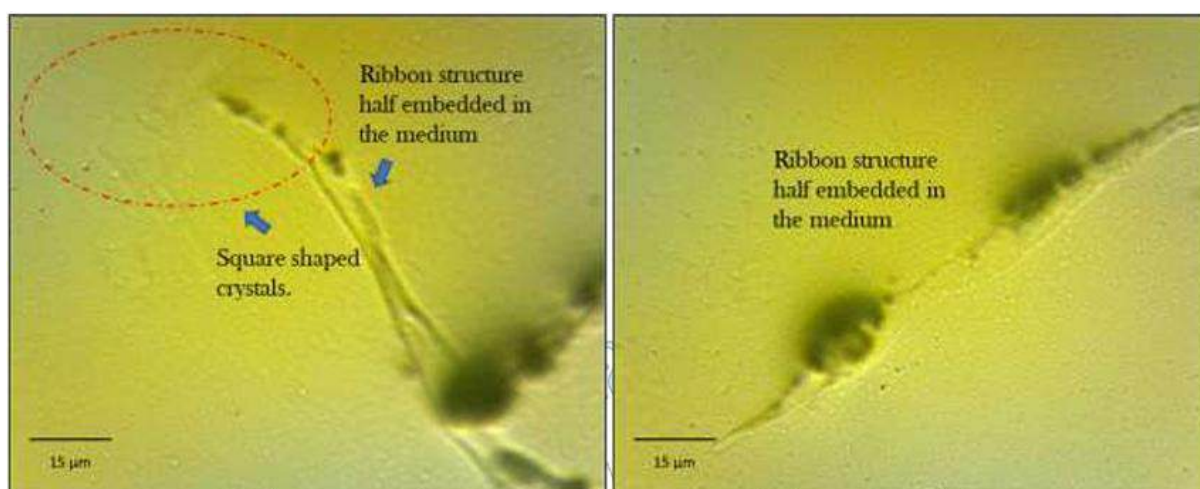


Figure 3.8. Ribbon shaped forms half embedded in the medium. Square and quadrilateral crystals in the background.

These forms varied from transparent or translucent sheet-like shapes to almost opaque, carbon-like amorphous materials of various sizes.

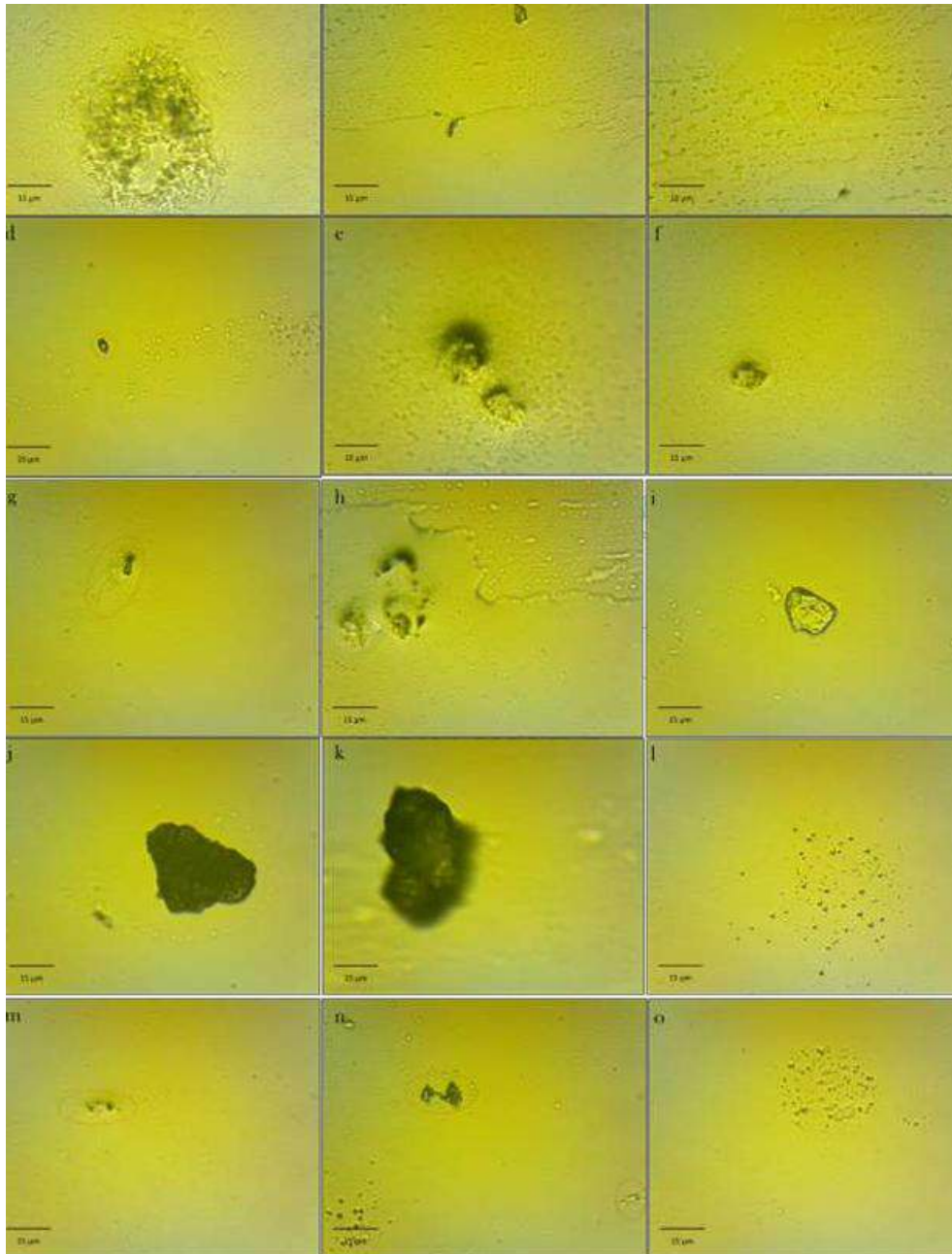
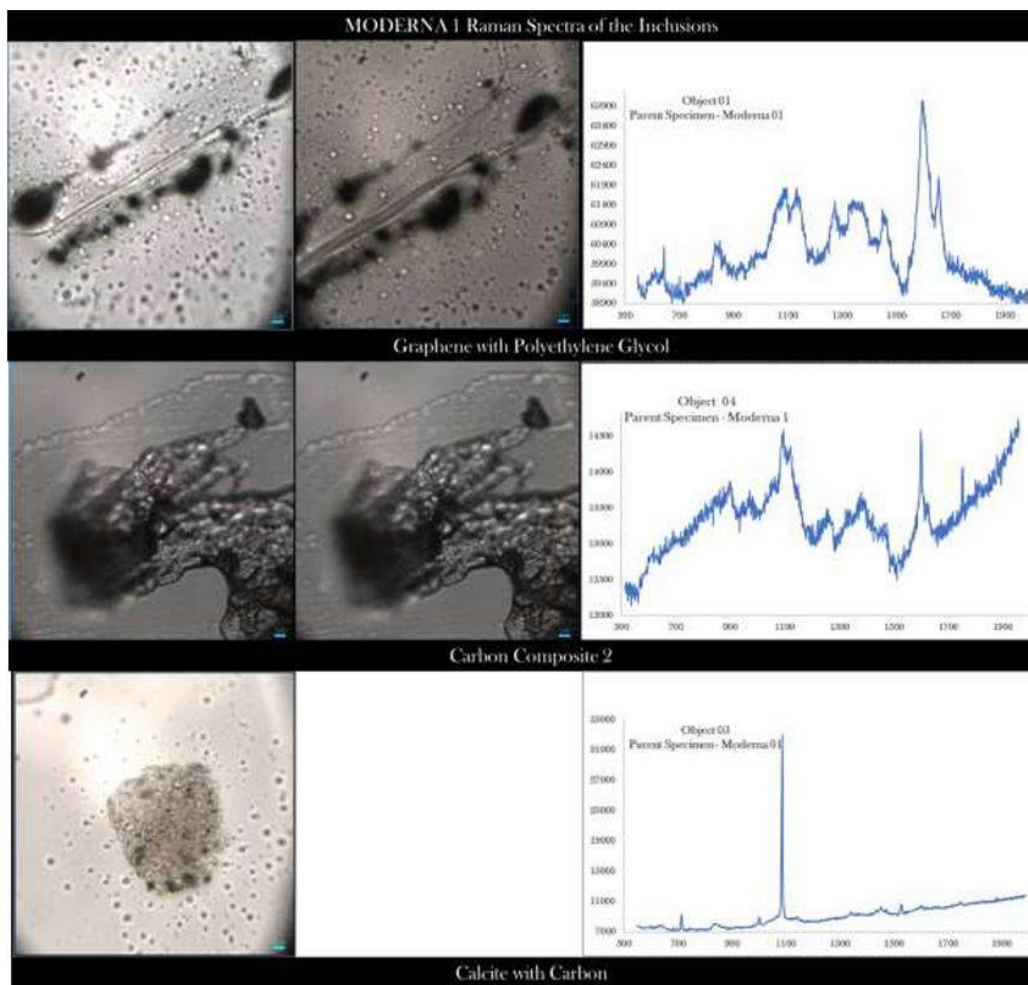


Figure 3.10. Various inclusions found within Moderna 01.

Representative inclusions from Moderna were examined via Raman spectroscopy. The investigation clearly demonstrated that all inclusions exhibit a strong carbon signal, confirming the presence of graphene in several instances.



The two Raman signals clearly suggestive of graphene were obtained from two distinct objects. The flat, ribbon-like inclusions exhibited clear graphene spectra integrated with the spectrum of polyethylene glycol and other minor compounds. The other clear signal was obtained from a microcrystalline form of calcite, with a distinct strong peak at 1100 cm^{-1} . The carbon composites exhibited an extremely complex signal, with a clear graphene peak at 1600 cm^{-1} , as well as other peaks at 1100 cm^{-1} , rendering the signal quite difficult to isolate. Further analyses are underway to isolate these signals and to identify the other components of this form of carbon. Certain forms of nano-amorphous carbon exhibited a clear graphene signal; however, these forms also exhibited fluorescence, which masked the graphene peak.

At low resolution, a predominance of GC1-type particles is observed. The distribution of counts is dominated by these particles. At higher resolution, the distribution is reversed, with GC2 particles becoming dominant. At higher resolution, graphene nano-objects become dominant.

It must be noted that graphene nano-scrolls were omitted from the enumeration. This stage was necessary because, although these nano-scrolls constitute a significant percentage of the total counts, confirmation of their composition could not be obtained within the constraints of this project. The thorough investigation of these forms now constitutes the subject of a second, enhanced investigation project, which follows this report.

The material of the second Moderna vial was translucent, containing granular material in the form of suspended particles. Upon microscopic observation of the material applied as a droplet on the slide, several floating pieces of transparent, sheet-like objects were observed. The material more

It settled heavily onto the slide as the medium evaporated under the heat of the microscope lamp.

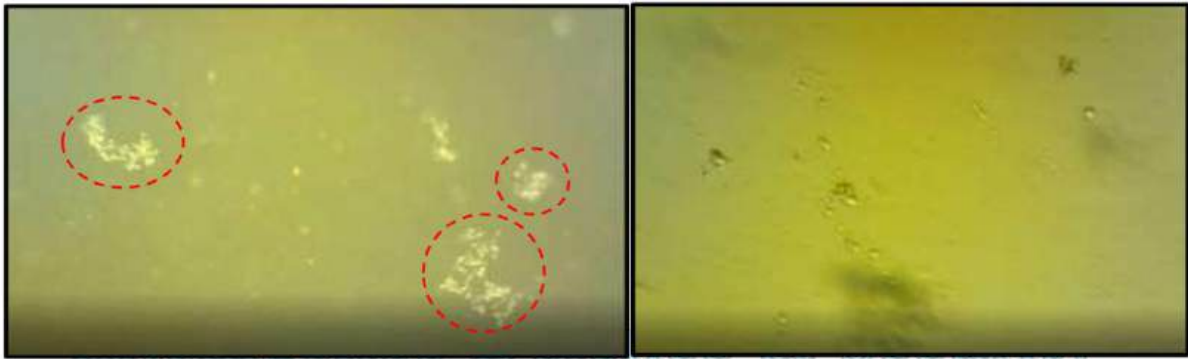


Figure 3.13. Floating sheets of translucent material in a wet sample as observed under an optical microscope. (b) The settled detrital material at the bottom of the slide. The shadows of the lighter floating material can be seen as dark hazy figures.

In regions where the drop maintained significant thickness, bubbles were observed migrating with the convection current toward the periphery of the drop. The trajectories obtained by tracking the movement of these particles were characteristic of self-assembly systems composed of particles that aggregate under the influence of various intermolecular forces. These particles appear to assemble through hydrophobic interactions.

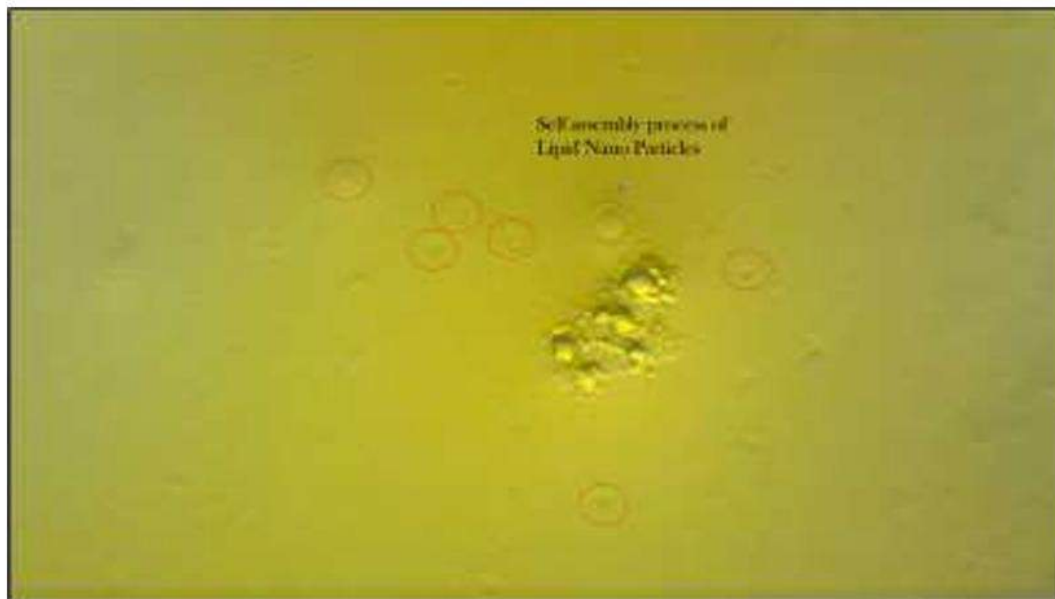


Figure 3.15. Self-Assembled Nano Particles with Payload of mRNA.

The appearance of the dried slide at low resolution consisted of a translucent medium containing fiber-like structures and transparent sheets on the upper surface. At higher magnification, the material on the slide appears to be abundant in carbon forms. Figure 3.17 presents various forms observed across different fields of the slide.

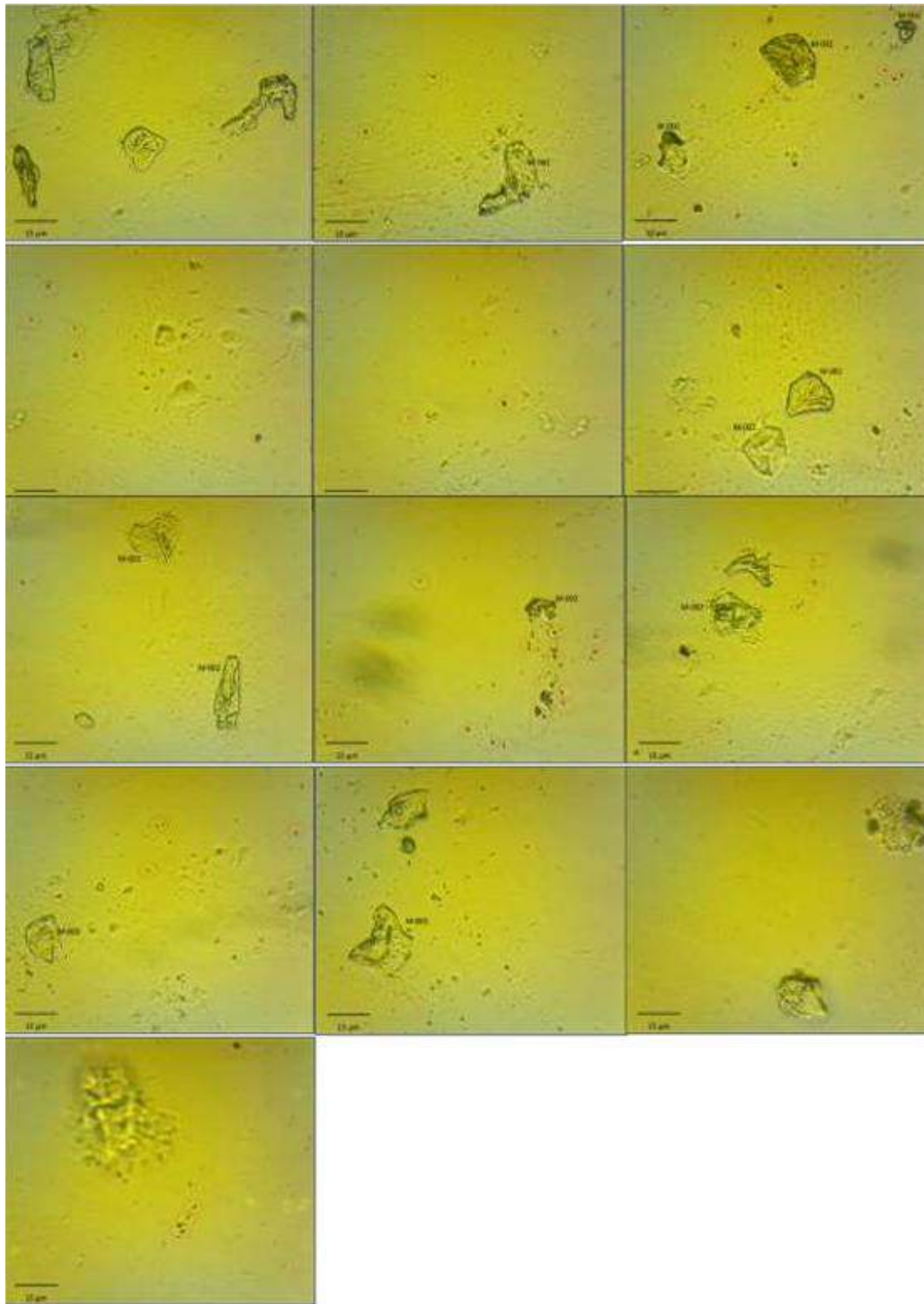
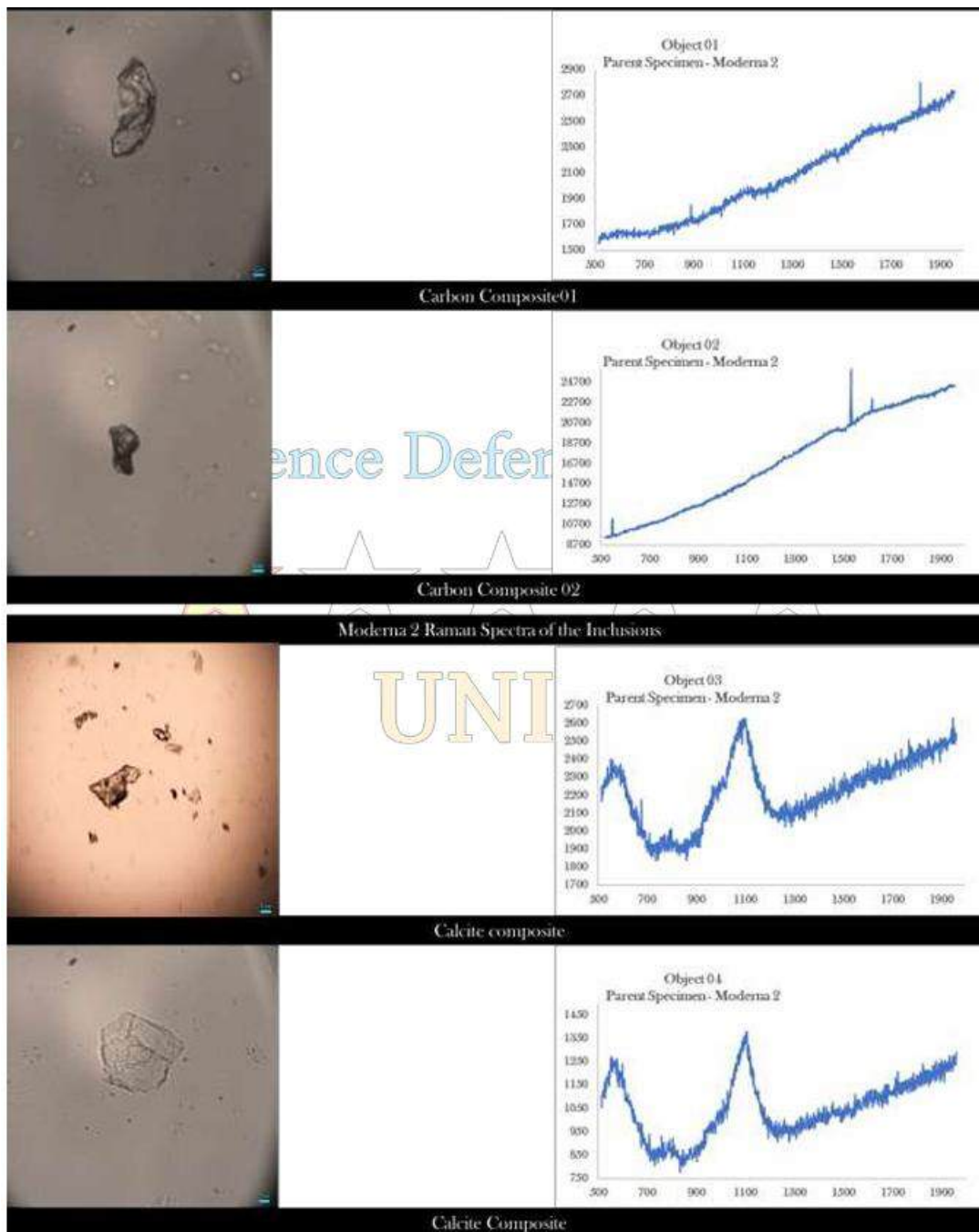


Figure 3.17. Representative inclusions across Moderna 02 at high magnification.

Raman spectroscopy was utilized on the structures from the second Moderna vial. With the exception of the composite calcite evidence, the remainder exhibited a strongly interfered spectrum. Carbon peaks at approximately 1600 cm^{-1} and 1350 cm^{-1} were only faintly distinguished in the graphene nano-objects. Due to the fluorescent background, it was extremely difficult to interpret the spectrum for any component other than carbon. Re-imaging and subsequent data processing are highly recommended so that these particles in Moderna may be reasonably identified with a degree of confidence



The counting of particles at low and high magnifications yielded results consistent with those of the first Moderna vial. Graphene composite 1–GC1 was predominant. The count clearly demonstrates that the number of nano-scale structures far exceeds the density of microscopic structures.

It must be noted that graphene nano-scrolls were omitted from the enumeration. This stage was necessary because, although these structures represent a significant percentage of the total particles, confirmation of their composition could not be obtained within the scope of this project.

As with the analysis of the first Moderna vial, the detailed investigation of these forms currently constitutes the subject of a second, enhanced investigation project following this report.

AstraZeneca was the third vaccine evaluated for its particles. Multiple droplets were observed under the microscope. The AstraZeneca vaccine is nearly transparent when viewed through

the microscope, which facilitates the identification of any particles. Upon microscopy of fresh droplets, a movement of nanometer-sized particulate material was observed, which was initially driven by convection currents and subsequently became random.

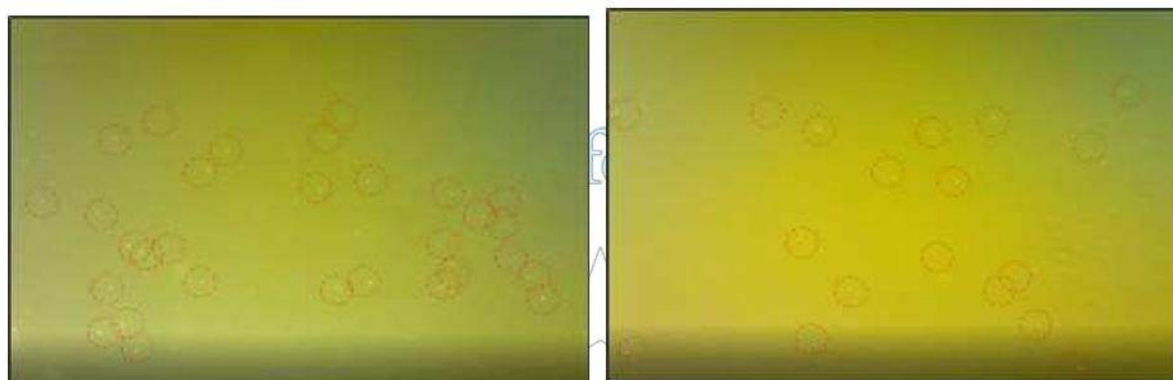


Figure 3.20. Nano Particles in motion when depth of the solution is greater than the height of the particle. The particles coalesce to form bigger particles and the dominating influence on the direction of the movement is through the currents within the solution.

These nanometer particles were initially quite visible as white spots, moving like a swarm in the same general direction. Over time, these evolved into larger droplets with more random vectors, following the principles of self-assembly. As the solution dried under the heat of the microscope lamp, the sedimentation process commenced; sheet-like structures were deposited upon the surface of the medium, which began early crystallization while the underlying liquid retained partial fluidity. Various forms of particles were observed. These are described in detail below. The movement of the nanoparticles and the process of their self-assembly were observed in the AstraZeneca product, consistent with observations regarding the Moderna vaccines. In this instance as well, the nanoparticles self-assembled via characteristic movements dictated by inter-particle forces. As the solution dried, the heavier carbon material settled at the bottom of the slide. A subsequent high-resolution examination of the lower layers reveals a multitude of graphene nano-objects, including graphene

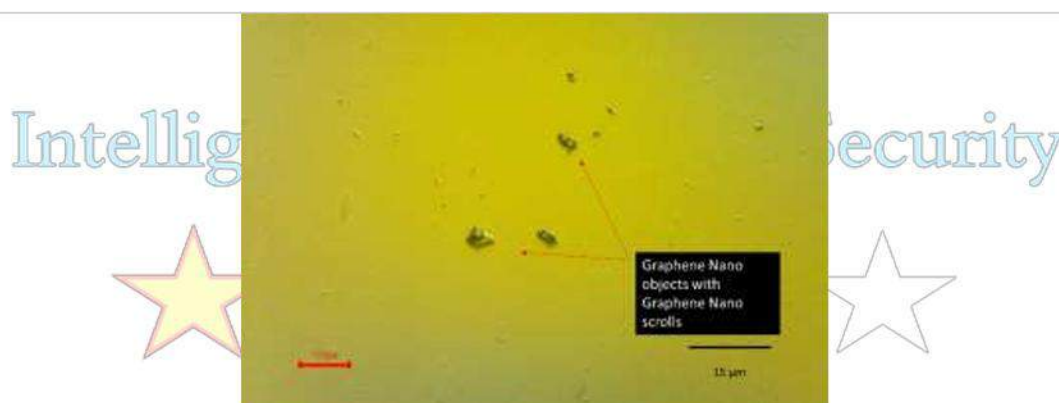


Figure 3.23. Graphene based structures settled down on drying. These structures demonstrated self-movement against the growing viscosity of the drying solution. When the solution dried, they were found to have settled at the bottom of the slide.



Figure 3.24. Graphene scrolls or spicules dumped at the bottom of the slide.

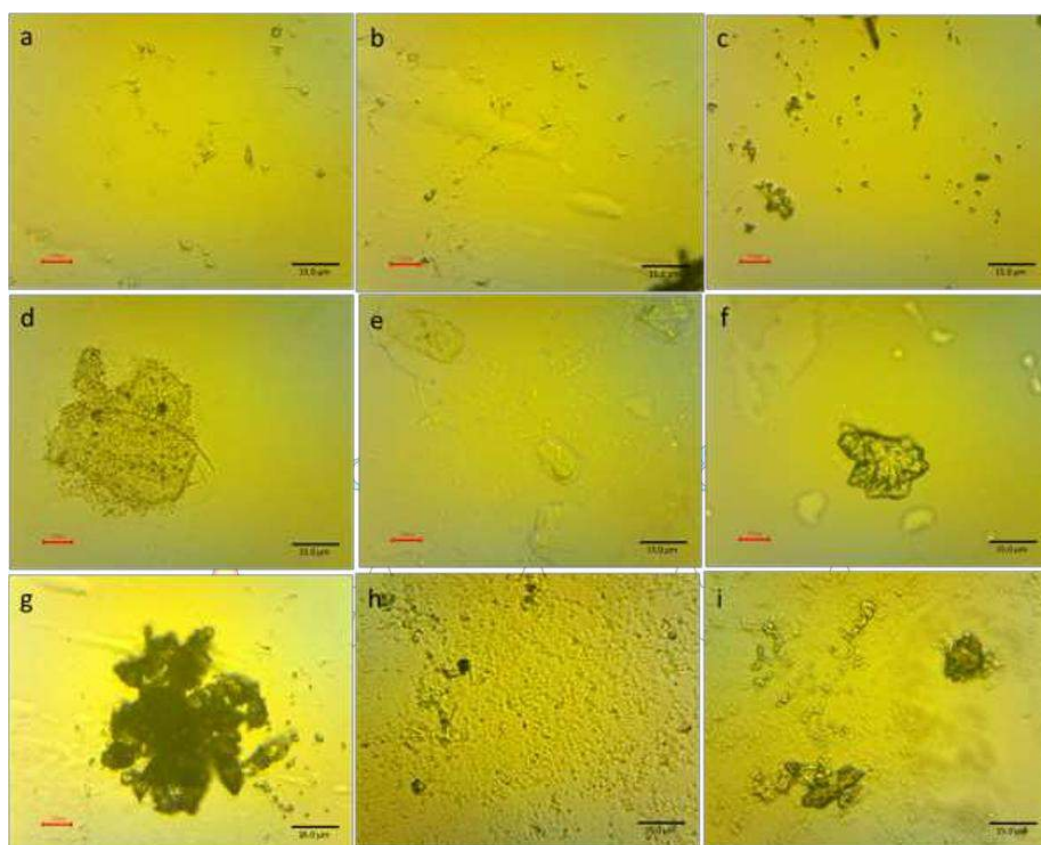
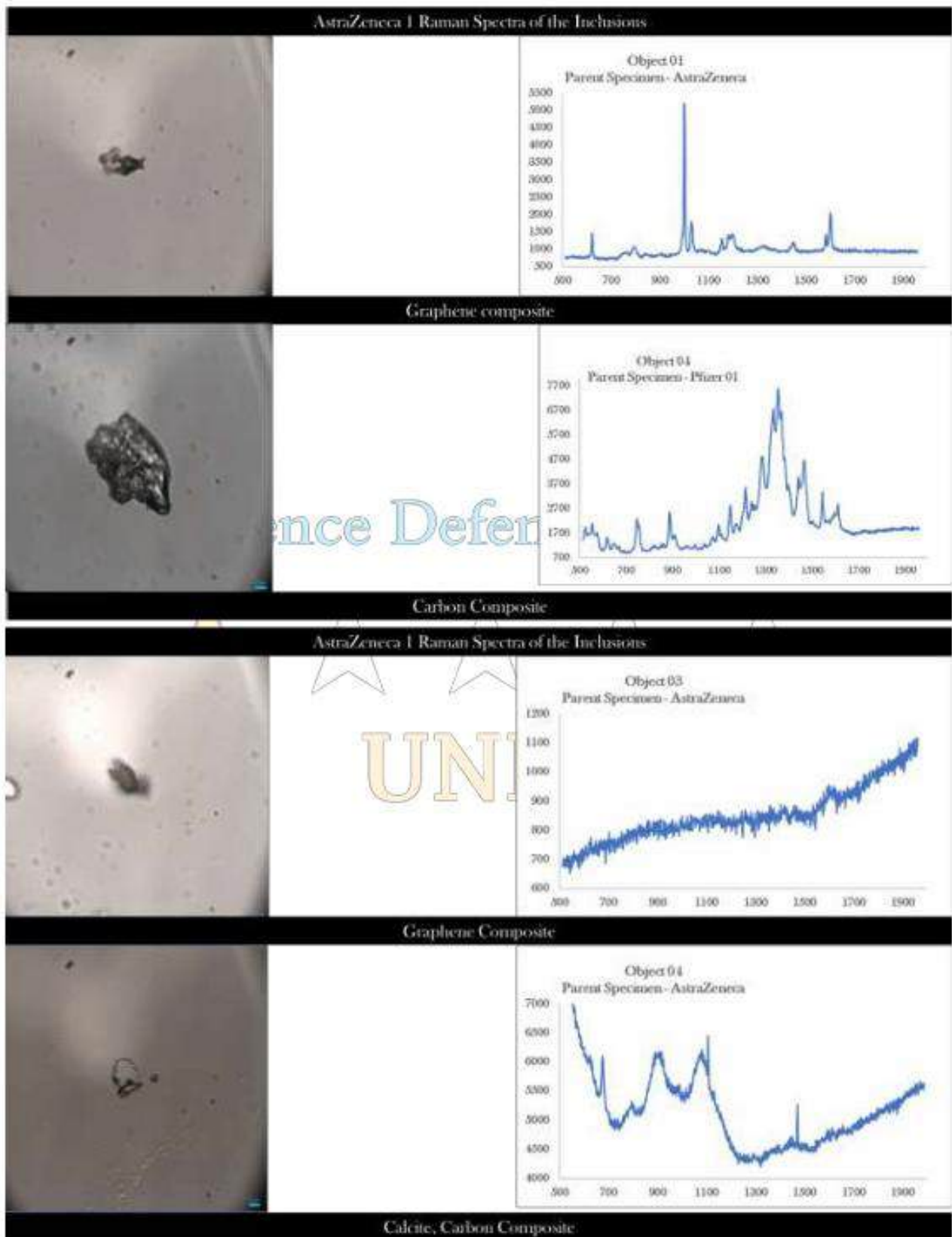


Figure 3.25. Representative inclusions found within AstraZeneca vaccine.

The particles identified within the AstraZeneca product were varied. These included graphene composites GC1 and GC2, graphene ribbons impregnated with polyethylene glycol, and graphene nano-objects, including a vast number of nano-spirals and amorphous carbon. Calcite was also distinctly present in the vaccine in microcrystalline form. The particles were examined using the Raman technique.

3.4.2. Raman Spectroscopic Investigation



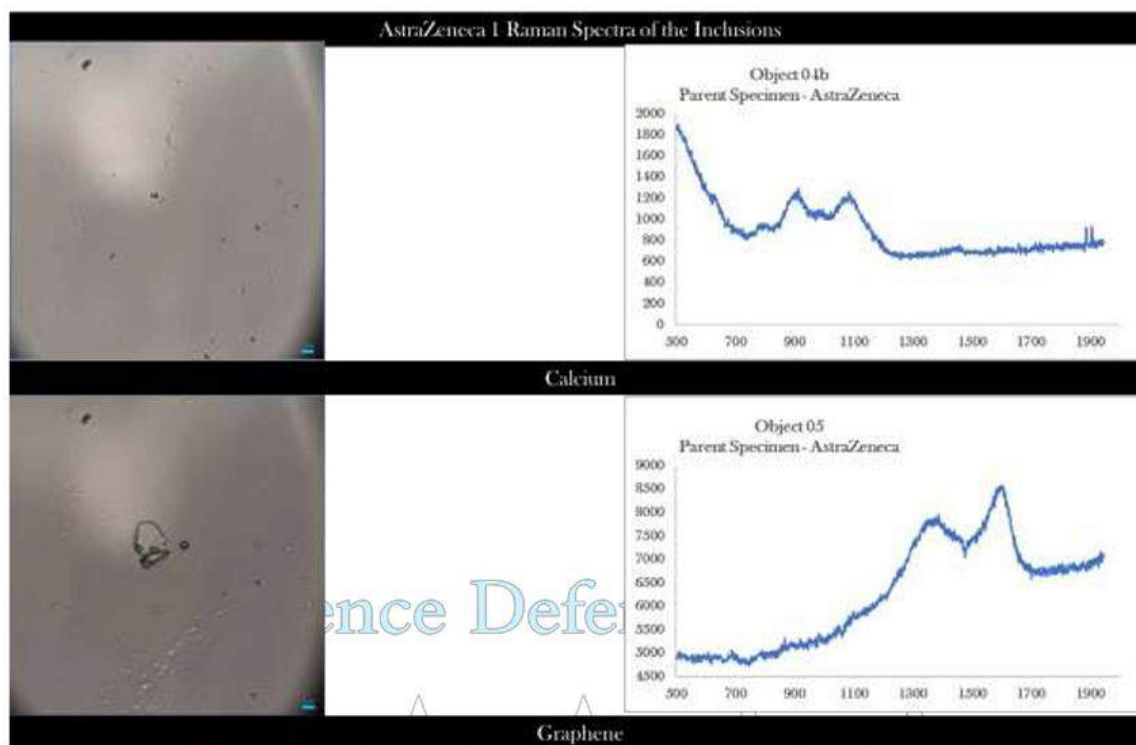


Figure 3.26. Raman spectra of various inclusions in AstraZeneca.

The results of the Raman spectroscopy performed on the inclusions within the AstraZeneca product have directly confirmed the presence of graphene in all identified representative forms. Carbon composites GC1 and GC2 are present, as they are in the Moderna vaccines. These two forms exhibited distinct graphene signatures via the characteristic graphene peaks at 1600 cm^{-1} and 1350 cm^{-1} . In addition to graphene, the spectrum is dominated by iron oxide and other forms of carbon associations. Further research is required to isolate the signals and to facilitate the identification of individual compounds. With the exception of one graphene composite particle, the fluorescence effect was minimal in the selected AstraZeneca particles. Calcium-carbon composites also exhibited the same signature as those present in the two Moderna vaccines. Inclusions within the calcite composites contain pure graphene nanoparticles. These particles were evaluated and demonstrated a clear signal for graphene. Although graphene nano-objects were present in clear association with graphene nano-scrolls, Raman investigations were not performed on the scrolls due to the limitations of the laser size and microscope magnification. In a future study on AstraZeneca, Raman imaging of the scrolls will be one of the primary objectives in the quantification of graphene concen-

The particle count in AstraZeneca identifies the graphene 2 composite at higher magnifications. At higher resolutions, graphene nano-objects represent a dominant percentage of the particles. Graphene nano-scrolls were omitted from the count. Although nano-scrolls constitute a significant percentage of the total counts, confirmation of their composition could not be obtained within the constraints of this project.

Pfizer was the fourth vaccine vial evaluated for particles. The vaccine was observed to possess the same yellowish-white color as Moderna. A 0.006 μL volume of the sample was transferred onto the slide for wet evaluation, while an equal amount was retained in a slightly tilted pipette to permit examination within a closed 3D environment. The pipette sample exhibited several highly significant inclusions that were not detected upon the drying of the slide. As the material was aspirated into the pipette, distinct sheets, varying from translucent to transparent, were observed floating. These were identified from previous observations in AstraZeneca and Moderna as Graphene Composite 1-GC1. The active sedimentation of

The denser material in the lower region of the cylinder was observed immediately thereafter (Figure 3.29).

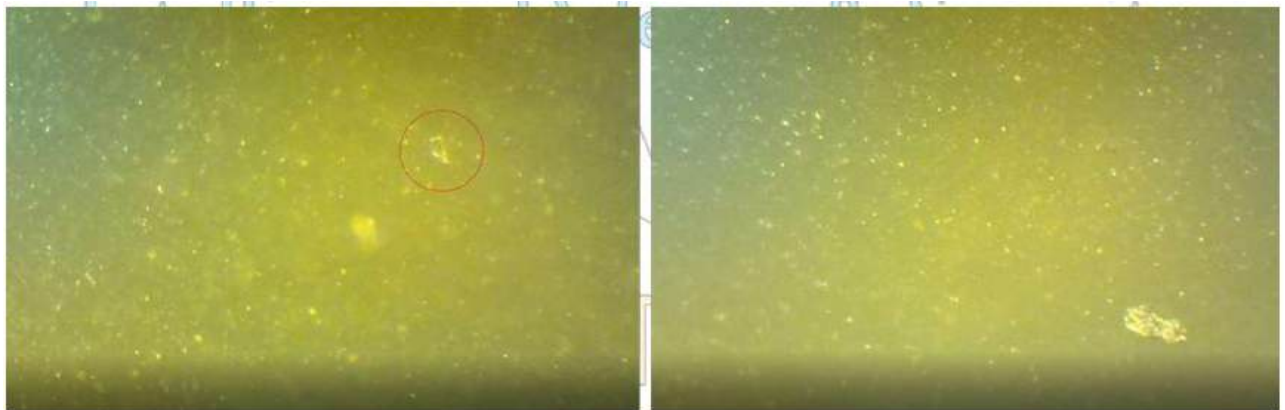


Figure 3.28. Floating lighter material. In the background, the golden sparkly particles are the future self-assembly nano particles that will encapsulate the mRNA.

The two objects of interest that were clearly observed floating, but which could not be located after the slide had dried, were: (1) an extremely sharp, transparent object resembling a spike (Figure 3.30), and (2) a thin, translucent perforated sheet (Figure 3.31).

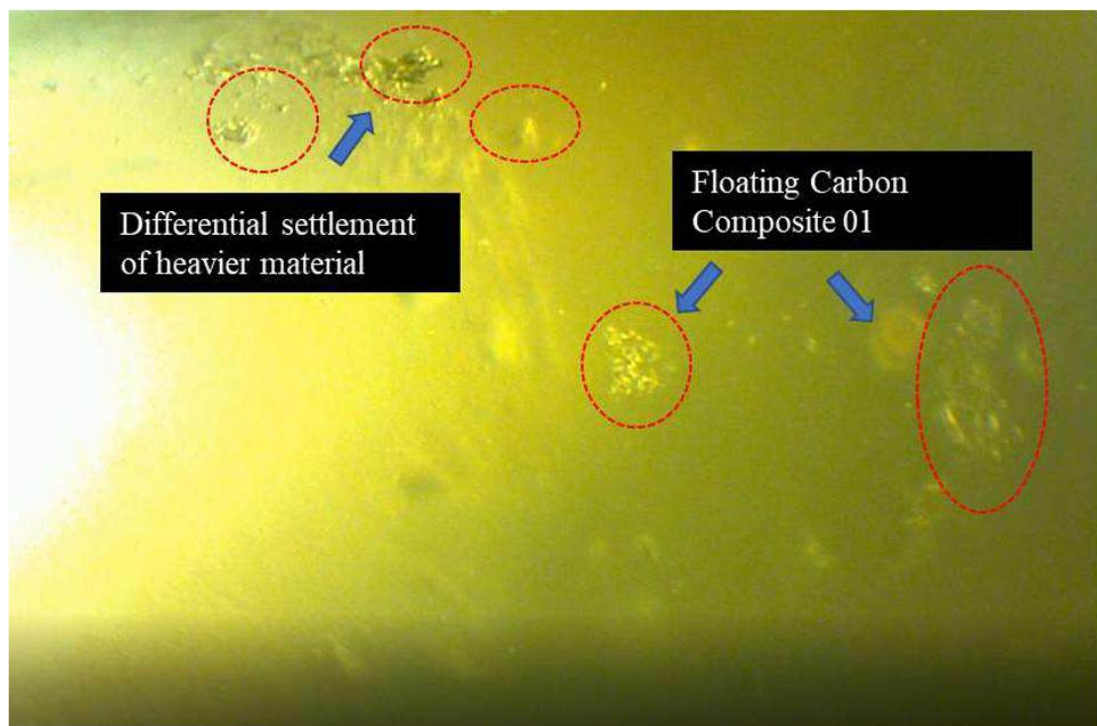


Figure 3.29. Sedimentation of the heavier load on the curved bottom of the pipette and the floating transparent composite 01.

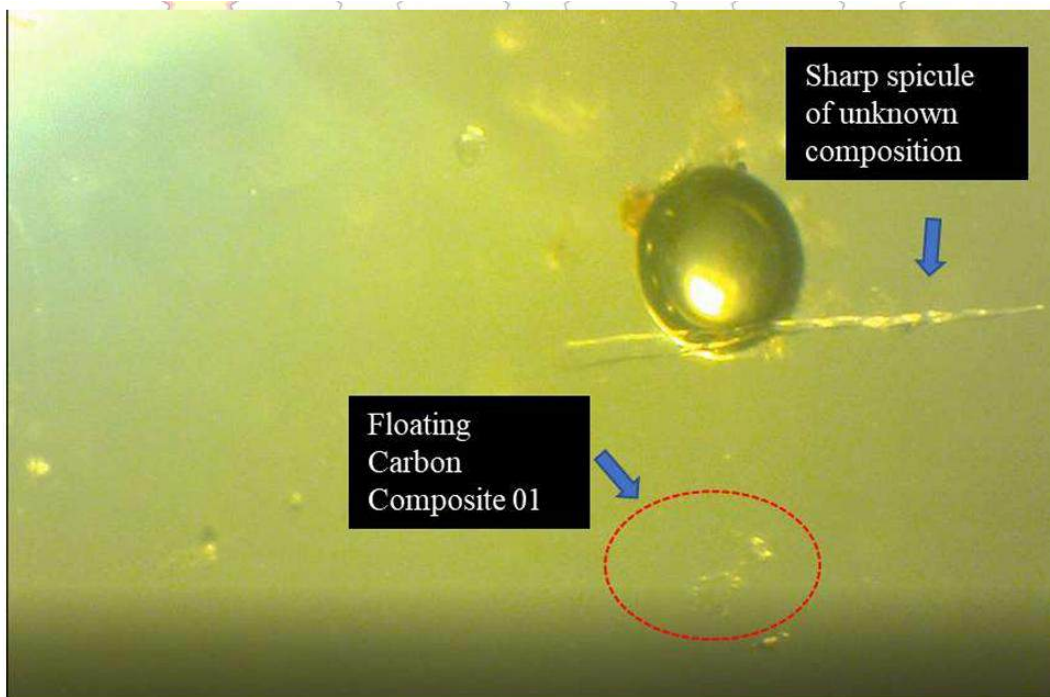


Figure 3.30. Sharp transparent spicule floating in the liquid.

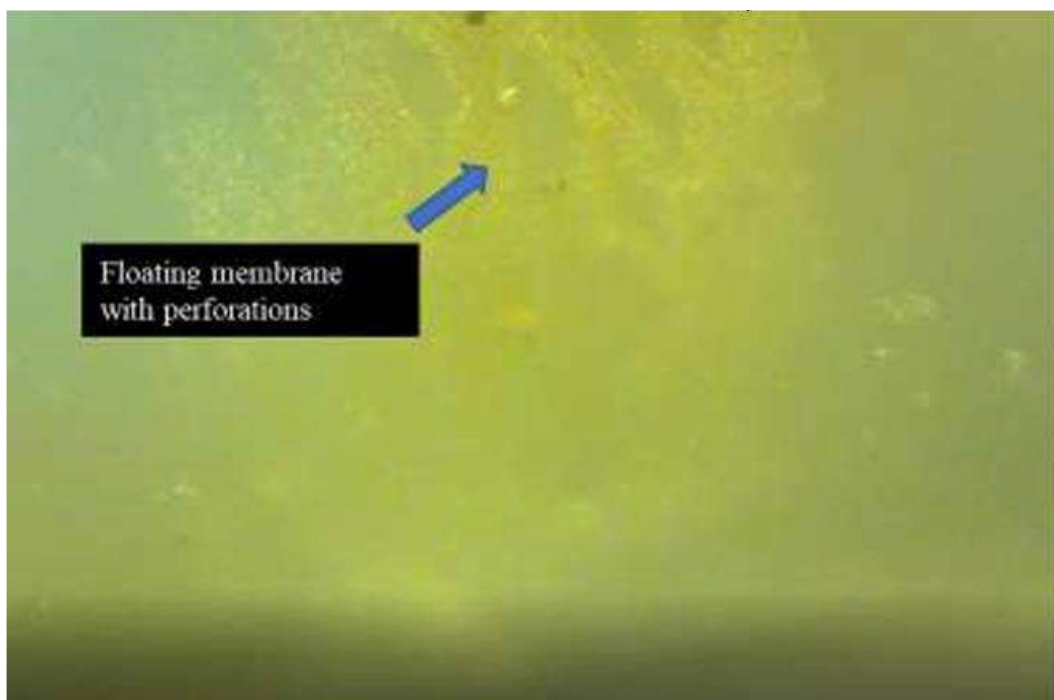


Figure 3.31. Floating perforated membrane.

Although both particles are of interest to this study, the nature of the spike will be identified in future works. Upon being placed on the slide, it was observed that the mixture exhibited the same mechanism of self-assembly of the nanoparticles as seen in the Moderna and AstraZeneca vaccines. As the material dried, the inclusions settled at different depths according to their relative densities.

Figure 3.32 presents an assembly of particles of different shapes identified in the Pfizer vaccine.

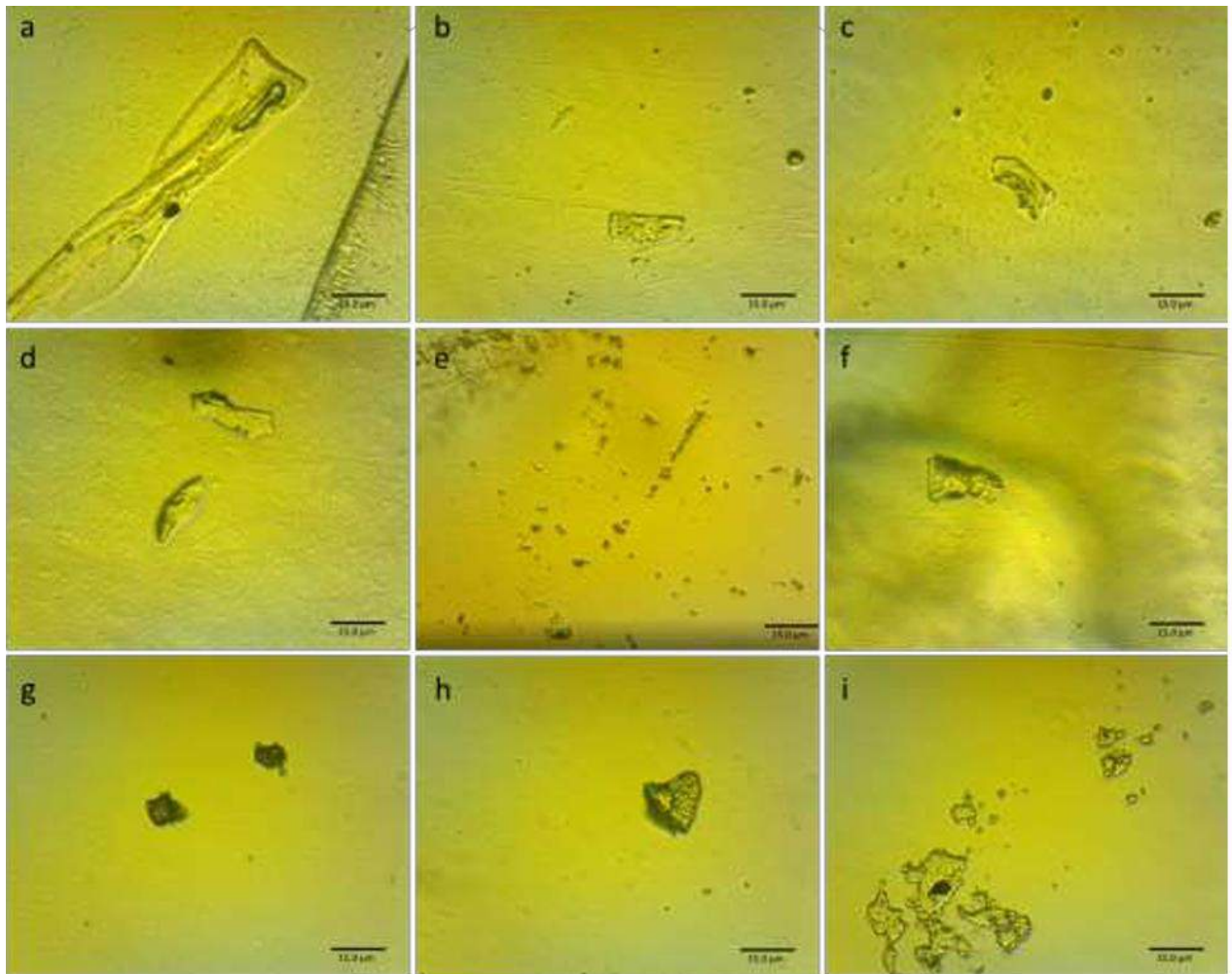
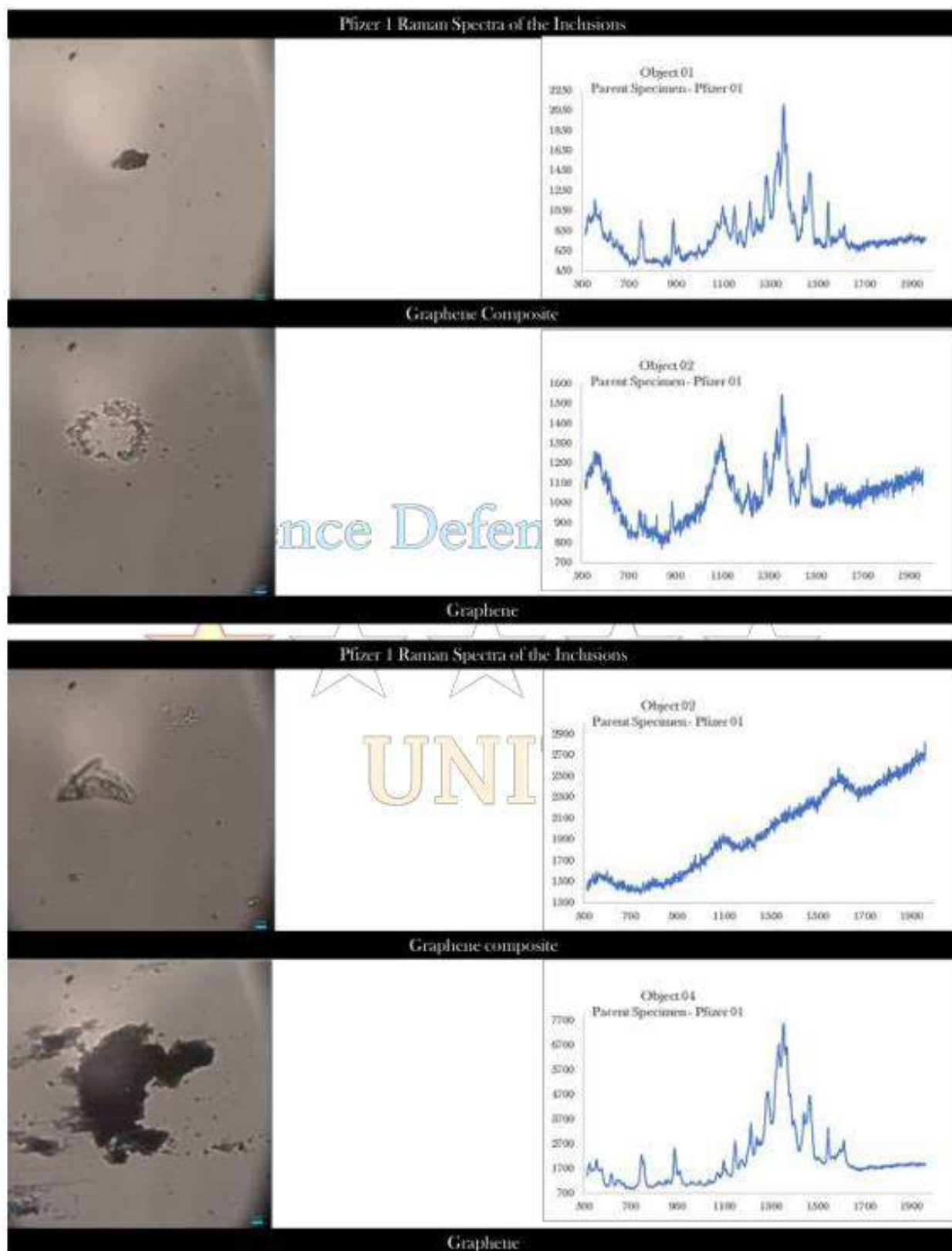


Figure 3.32. Representative inclusions found within Pfizer vaccine.



Raman spectroscopy was performed on four representative evidence samples selected for Pfizer (see figure above). Three of these evidence samples presented carbon composite signatures indicating the possible presence of graphene. The signals from amorphous carbon-like materials were extremely complex, containing iron oxide and several other compounds. Graphene complex 1 consists of graphene with a polyethylene glycol signal and constitutes the largest part of the spectrum. Although this is an initial evaluation,

the study can confirm the presence of graphene in the Pfizer vaccine; however, the complex with which it is associated must be established through additional research. One of the evidence samples photographed was considerably influenced by fluorescence. Recapturing this evidence at a longer exposure is important for separating the signal of the article of interest from the background signal.

In conclusion, Raman spectroscopy assisted in the identification of particles within the Pfizer product. At lower magnification, the relative number of GC2 was notably high in one of the analyzed areas, whereas it was entirely absent in the other. At higher magnifications, the dominant percentage of particles is represented by graphene nano-objects.

As with the other vaccine vials, graphene nano-spirals were omitted from the count.

This step was necessary because, although these nano-spirals constitute a significant percentage of the total counts, confirmation of their composition could not be obtained within the constraints of this project.

4. Interpretation, Discussions, and Conclusions

The objective of this study was to examine four vaccine samples (2 from Moderna, 1 from AstraZeneca, and 1 from Pfizer) and to document any undeclared ingredients in the composition of the vaccines, with a special emphasis on graphene and related products, as well as any biological forms.

It must be noted that the three vaccines contain vastly different chemical ingredients as observed in the product documentation. Despite the differing genetic compositions, upon examination, **common particles, undeclared by the manufacturers, were identified.**

These particles consist primarily of graphene and carbon-linked nanostructures in the form of carbon composites or graphene, graphene in association with polyethylene glycol, graphene oxide, iron oxide compounds, and calcite. The variety of particle forms indicates diverse purposes for their utilization within the broader field of administration of medication and biosensors.

The forms identified during this project can be classified into five distinct categories:

1. Ribbon forms (G-PEG)
2. Sheet forms (GC-1)
3. Tubular forms (GC-2)
4. Nanodots
5. Nano-scrolls

While the roles of the ribbons and sheets remain unclear due to their microscopic dimensions, the tubular forms, together with the nanodots and nano-scrolls, appear to be intended to enhance the cellular uptake of the medicinal product. All three vaccines commonly employ self-assembled lipid nanoparticles as mechanisms for the administration of medication. Although the central finding of this project was the confirmation of the presence of graphene in all four samples, it is imperative to evaluate this discovery within the context of the situation.

As mentioned above, self-assembly processes constitute the fundamental mechanisms of the three types of vaccines. Self-assembly depends primarily on weak intermolecular interactions (Mendes et al. 2013), which, in the case of lipid nanoparticles, are determined by kinetics and the thermodynamic environment. However, based on the observations within this study, graphene nanoparticles appear to play an important role in triggering the nucleation of these particles. This

interpretation is derived from the observation that each of the nanoparticles appears to possess a graphene core.

As is already well established, the structure of the lipid nanoparticle plays a crucial role in determining its efficiency in transporting the nucleic acid payload. However, it is the payload structure that defines the geometry of the lipid nanoparticles (Hajj et al. 2019, Kulkarni et al. 2018).

Although these structures may vary depending on the payload itself, the primary responsibilities of the lipid nanoparticles remain the same: namely (1) protection of nucleic acids from nucleases, (2) controlled release of the nucleic acid, (3) cellular and tissue selectivity, (4) high delivery efficiency, (5) minimal toxicity, and (6) stability, particularly during long-term storage. **These essential characteristics for a vector can be significantly enhanced through the use of carbon nanotubes, graphene, and graphene oxide. This was observed during the course of this study.**

Nanotubes, both single-walled and multi-walled, along with forms of graphene, are targeted for the targeted administration of medication (Sattari et al. 2021, Wu et al. 2018, Wierzbicki 2017, Eatemadi et al. 2014). **The evidence evaluated during this project identified graphene and other carbon composites as constituting a significant percentage of the ingredients in these vaccines. Given the context of the increasing use of graphene in the administration of medication, the findings of this project appear to align with efforts to improve and adapt the administration of medication.**

The investigation conducted in this study was essentially a qualitative assessment of the content. There are several particles within these vaccines that require evaluation and quantitative determination.

A major obstacle in obtaining a quantitative result was the failure to isolate the solid fraction. The method utilized in this project was the traditional method of slide preparation. It is hoped that, if similar work were performed on additional evidence, vacuum filtration would be adopted as a mechanism for obtaining cleaner evidence for both Raman and

SEM imaging. Additionally, it is critical to note that the source of fluorescence within the evidence was unknown while the Raman investigations were in progress. Due to extremely tight deadlines, it was not possible to complete the Raman testing reruns, which would have eliminated fluorescence effects through targeted emittance and data processing. Notwithstanding this, signals were interpreted using comparable data from various catalogs. It is anticipated that Raman spectroscopic investigations will proceed to obtain clearer spectra and to isolate the individual spectra of the current specimens.

In conclusion, it can be affirmed that all four vaccine samples (Moderna 1, Modern 2, AstraZeneca, Pfizer) contain a significant quantity of carbon composites, graphene compounds, and Iron oxide. These ingredients were not declared by the manufacturers and are absent from the list of ingredients for the vaccines.

As previously mentioned, the thorough investigation of these forms now constitutes the object of a second improved investigation project, which follows this report.

In view of the frequent adverse reactions of the COVID-19 vaccines and the detection of undeclared particles in these vaccines according to the aforementioned study, a petition was initiated at <https://www.notonthebeeb.co.uk/v-injunction-experts> addressed to the British Police which, as of February 12, 2025, has been signed by 16,329 citizens and by 1,359 doctors and other healthcare workers. Within this petition drafted by counsel, there is a dedicated section for healthcare professionals. The petition was formulated as follows:

"Petition signed by healthcare professionals and experts calling for an urgent investigation and analysis of the C19 vaccines. This petition is intended for physicians, nurses, healthcare professionals, and scientists.

If you are not a healthcare professional, please sign the public petition here.

To the Police, the Judiciary, the Crown Prosecution Service, and members of the British Parliament. In our capacity as health professionals from the United Kingdom and across the globe, we hereby petition the British Police to seize multiple vials of evidence from various vaccines and to perform exhaustive, public, and independent analyses of their content.

1 - Why are such a significant number of individuals experiencing adverse events and deaths following COVID-19 vaccination?

2 - Why are so many of our elite athletes collapsing and suffering from myocarditis, cardiac arrest, and death post-vaccination?

3-Why have the vaccine manufacturers withheld the disclosure of these ingredients? The inclusion of undisclosed ingredients is unlawful and constitutes a deception of the public.

4. Why have independent scientific reports concerning graphene oxide and other contaminants not been subject to public investigation?

5. Why are the vaccine lots evidently inconsistent? According to VAERS data, the majority of adverse reactions originate from a limited number of lots. This clearly indicates suspicious manufacturing practices.

6. (January 2022) Given these prevailing doubts regarding safety, why does the implementation of the vaccines continue in British schools?

7. As of December 6, 2022, why was a product with such a track record authorized for our youngest children, aged 6 months to 4 years?

8-(2023 Update)-Why are excess deaths not being investigated?

The undersigned hereby requests the British Police to seize vaccine samples and initiate an urgent public scientific analysis regarding the safety, legitimacy, and ethical implications of the ingredients and biotechnology causing widespread serious adverse reactions and deaths following COVID-19 vaccination.

5. Research from Argentina: Lorena Diblasi-biotechnologist, Marcela Sangorin—physician.

On **October 11, 2024**, the article "**At least 55 Undeclared Chemical Elements Found in COVID-19 Vaccines from AstraZeneca, CanSino, Moderna, Pfizer, Sinopharm and Sputnik V, with Precise ICP-MS**"

was published in the medical journal International Journal of Vaccine Theory, Practice, and Research <https://ijvtpr.com/index.php/IJVTPr/article/view/111/361> by a team of researchers from Argentina, with the primary author being Lorena Sangorin, biotechnologist at the Faculty of Biochemistry, Chemistry and Pharmacy, National University of Tucumán, Argentina. I shall proceed to present the data from this article.

The authors of the study conclude that by the end of 2023, **24** undeclared chemical elements were detected in the COVID-19 vaccines of various manufacturers by diverse research groups worldwide using Scanning Electron Microscopy coupled with Energy-Dispersive X-ray Spectroscopy (SEM-EDX). This work employed an additional identification method, namely high-precision Inductively Coupled Plasma Mass Spectrometry (ICP-MS). The content of vials from various lots of the AstraZeneca/Oxford, CanSino Biologics, Pfizer/BioNTech, Sinopharm, Moderna, and Sputnik V brands was analyzed. Among the undeclared chemical elements, 12 of the 15 cytotoxic lanthanides utilized in electronic devices and optogenetics were detected. Furthermore, the undeclared elements included

all 11 heavy metals: chromium was identified in 100% of the evidence; arsenic in 82%; nickel in 59%; cobalt and copper in 47%; tin in 41%; thallium (24%), cadmium, lead, and manganese in 18%; and mercury in 6%. **A total of 55 undeclared chemical elements were identified and quantified using ICP-MS. Combining these findings with the results obtained via SEM-EDX, a total of 62 undeclared chemical elements were identified across various products.** In all brands of COVID-19 vaccines, boron, calcium, titanium, arsenic, nickel, chromium, copper, gallium, strontium, niobium, molybdenum, barium, and hafnium were identified. **Through ICP-MS, a heterogeneous content was found in samples taken from the same vial, with the elemental composition varying across this evidence.**

The authors note that technologies such as those contained in messenger RNA and recombinant DNA products had never been used in humans, yet were applied to the entire global population. When the aggressive inoculation campaigns commenced, the extent of their toxicity and efficacy remained unknown due to the experimental nature of the products. **The speed of their approval evidently implies a lack of adequate clinical trials and quality controls.**

Argentinian researchers have investigated the underlying cause of the extensive list of highly diverse clinical symptoms and morbidities following the global distribution of COVID-19 injectable products. This **list includes fulminant cancers, autoimmune disorders, bilateral pneumonias, arrhythmias, hepatitis, renal failures, aggressive forms of arthritis, thrombosis, thrombocytopenia, heart disease, cerebrovascular accidents, various types of paralysis, spontaneous abortions, perinatal deaths, infertility, neurodegenerative diseases, and numerous other debilitating and life-threatening conditions**. *Nevertheless, despite the extreme gravity of the situation at a global level, only hesitant and fragmentary measures have been implemented to address it. Among these, one is renowned and highly significant—on January 6, 2022, the Pfizer company was compelled to declassify documents and publish 55,000 pages monthly following a lawsuit presided over by Judge Mark T. Pittman in the United States, the pharmaceutical company Pfizer <https://phmptt.org/pftizers-documents/>. Among these documents, one cites at least 1,290 adverse events that had not been previously disclosed <https://phmptt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>. Similarly, in Uruguay, the judiciary requested the national government to conduct studies 'explaining the notable increase in deaths caused by [or attributed to] COVID-19 since March 2021', in comparison with the preceding year, despite the increase in the number of individuals vaccinated against COVID-19, which, theoretically, should have reduced the mortality rate. The lack of information, maintained by the powerful pharmaceutical lobby that imposes its products upon the market, prevents the sound judgment of healthcare professionals, who are discouraged from establishing a link between numerous post-vaccination symptoms and vaccines, as well as other medicinal products and harmful medical procedures directly or indirectly involved in their causation.*

Promoters of the mass administration of vaccines have been compelled to acknowledge the absence of post-authorization studies necessary to fully characterize the safety profile of a new vaccine. They assert that pre-authorization clinical trials possess limited sample sizes, restricted follow-up durations, and excessive population heterogeneity. For all these reasons, it is imperative to investigate and determine the components of the COVID-19 vaccines. **Owing to their 'experimental' status, even the most fundamental safety protocols were bypassed in a hazardous manner.** This issue alerted independent scientists worldwide, as the declared ingredients were known to be Toxic substances and evidence has increasingly accumulated indicating that manufacturers failed to disclose all ingredients in their products. One of the alarming phenomena observed is magnetization <https://dn720001.ca.archive.org/0/items/eventtos-alarmanntes-en-inoculados/EVENTOS%20ALARMANTES%20EN%20INOCULADOS.pdf> - a phenomenon not accounted for by the declared ingredients.

In early studies regarding the content of COVID-19 vaccines, certain researchers (Campra, 2021; Clayton, 2022) determined the presence of graphene oxide in Pfizer Comirnaty products using micro-Raman techniques and transmission electron microscopy (TEM). Graphene oxide is an undeclared component that is toxic to human cells (Ou et al., 2016). The group known as 'Club 12' reported, utilizing scanning electron microscopy and energy-dispersive X-ray spectroscopy (SEM-EDX), the presence of carbon, oxygen, fluorine, sodium, magnesium, potassium, calcium, phosphorus, chromium, sulfur, chlorine, bismuth, nitrogen, manganese, cobalt, nickel, selenium, cadmium, antimony, lead, titanium, vanadium, iron, copper, and silicon in products from Pfizer-BioNtech, Moderna-Lonza, and AstraZeneca's Vaxzevria, and

Janssen from Johnson & Johnson (Aristeo et al., 2021, p. n40). In an initial study conducted in Argentina, 'Tango Club', utilizing SEM-EDX applied to samples from vials of AstraZeneca, Moderna, Sinopharm, and Sputnik V, the following chemical elements were found therein: carbon, oxygen, sodium, aluminum, silicon, calcium, magnesium, chlorine, bismuth, and technetium (Aristeo et al., 2021, p. n66). In 2022, Dr. Martín Monteverde and his collaborators (Anabela Femia, biotechnologist; and Lisandro Lafferriere, also a biotechnologist) detected particles with morphology identical to graphene oxide in a total of 49 vials, using optical microscopy. The brands analyzed were CanSino, Pfizer, Sinopharm, AstraZeneca, and SputnikV. In Japan, metallic contaminants were discovered within the vials of the Moderna vaccine (Swift & O'Donnell, 2021), resulting in the withdrawal of three lots, equivalent to 1.63 million doses. Furthermore, regarding the same Pfizer lot FF5357, healthcare workers at several vaccination centers in Japan—specifically in the cities of Sagami-hara, Kamakura, and Sakai—detected anomalous flakes of white material within the vials and notified the authorities to ensure the compromised material was not administered to the population (Kyodo News, 2021), findings which are essentially similar to those documented by Lee and Broudy (2024a, 2024b). In 2022, a group of 60 German scientists—including Helena Krenn, Klaus Retzlaff, Holger Reißner, and the late pathologist Arne Burkhardt—analyzing vials from AstraZeneca, BioNTech/Pfizer, Moderna, Janssen by Johnson & Johnson, Lubecavax, and Influxplit Tetra, detected the following chemical elements: cerium, potassium, calcium, barium, cobalt, iron, chromium, titanium, gadolinium, aluminum, silicon, sulfur, sodium, magnesium, antimony, copper, silver, Phosphorus, carbon, oxygen, chlorine, and cesium. These studies were submitted to the government authorities in Germany for review (Retzlaff, 2022). In England, the UNIT group commissioned by EbMCsquared CIC, under project UNITC-112980, conducted an analysis of AstraZeneca, Moderna, and Pfizer vials using the Micro-Raman technique, identifying graphene oxide, calcium carbonate with graphene inclusions, and iron oxide, in addition to the known toxicant polyethylene glycol (PEG), which is associated with anaphylaxis (Cabanillas et al., 2021). PEG is declared as a component of the cationic lipids in Pfizer BNT162b and Moderna-1273 (Segalla, 2023), but not in AstraZeneca. Furthermore, they reported particles with various morphologies: ribbons, sheets, nanotubes, nano-dots, and nano-scrolls (EBMCsquared CIC, 2022). In 2022, Dr. Daniel Nagase of Canada conducted SEM-EDX studies on Moderna and Pfizer vials, detecting carbon, oxygen, sodium, magnesium, aluminum, silicon, sulfur, chlorine, potassium, calcium, palladium, and Thulium (Nagase, 2022; Wilson, 2022). In the same year, in Argentina, fluorescent particles of varying sizes with a fluorescence pattern identical to the graphene oxide standard were detected in vials from Pfizer, CanSino, Sinopharm, and AstraZeneca via optical microscopy coupled with fluorescence; this study was conducted in the presence of a public notary (Sangorrín & Diblasi, 2022a). Subsequently, foreign particles of varying morphology, dimensions, and quantity, exceeding the limits specified for particulate matter in various pharmacopoeias, were detected in the same evidence via SEM-EDX. The following chemical elements were detected: carbon, nitrogen, oxygen, fluorine, sodium, magnesium, copper, bromine, titanium, silicon, aluminum, phosphorus, sulfur, chlorine, potassium, calcium, iron, chromium, manganese, and cesium (Sangorrín & Diblasi, 2022b). Geanina Hagimă, a specialist physician in obstetrics and gynecology from Romania, examined Moderna and Pfizer vials using SEM-EDX and identified carbon, oxygen, magnesium, aluminum, silicon, titanium, Yttrium, and tin (Hagimă, 2023a, 2023b). Pursuant to previous studies, by the end of 2023, independent researchers from various regions globally had detected 24 undeclared chemical elements within the COVID-19 vaccines formulations. These consisted of micro and nanoparticles primarily composed of carbon and oxygen. Furthermore, many of these findings were consistent with prior studies conducted in Italy, wherein micro- and nanoparticles containing the following elements were detected via SEM-EDX in 44 of the vaccines within the vaccination schedule: aluminum, silicon, magnesium, titanium, tungsten, chromium, manganese, nickel, iron, calcium, copper, zirconium, gold, silver, cerium, bromine, potassium, zinc, and lead (Gatti & Montanari, 2017). Also in 2021, Martínez, MD, and his collaborators from Argentina conducted studies via SEM-EDX on 5 scheduled or programmed vaccines—specifically, Prevenar pneumococcal from Pfizer, Infanrix Hexa from GlaxoSmithKline Biologicals, and Viraflu from Sinergium Biotech—finding: carbon, oxygen, sodium, magnesium, aluminum, silicon, chlorine, potassium, calcium, silver, and bromine (Aristeo et al., 2021; p. n74). Based on the 24 undeclared chemical elements detected through SEM-EDX that were omitted from the formula components by the pharmaceutical companies, the objective of this study was the corroboration and detection of possible additional chemical el-

To this end, thirteen vials of COVID-19 vaccines were analyzed. The vials examined in this study were sourced from the following pharmaceutical companies or research institutes: AstraZeneca/Oxford, CanSino

Biologics, Pfizer/BioNTech, Sinopharm, Moderna, and the Gamaleya National Research Center for Epidemiology and Microbiology of Russia.

For the analysis and identification of the constituent elements within the content of the vials, inductively coupled plasma mass spectrometry (ICP-MS) was utilized. This technique enables the detection, identification, and quantification of metals and metalloids with high sensitivity and precision. Through this methodology, nearly 95% of the periodic table can be analyzed, ranging from trace levels to significantly higher concentrations (ng/L–mg/L). Its primary advantage over other methodologies is high sensitivity (low detection limits) and simultaneity (possessing the capacity to detect multiple elements concurrently in a single analysis). Most chemical elements in the periodic table can be determined, with the exception of: hydrogen, helium, carbon, nitrogen, oxygen, sulfur, fluorine, neon, argon, iodine, bromine, chlorine, astatine, and those with an atomic mass greater than uranium.

Thirteen vials from different lots of the so-called COVID-19 vaccines were analyzed. The brands, lot numbers, and expiration dates are presented in Table 1.

Samples Analyzed by ICP-MS			
Manufacturing Laboratory	Brand	Lot	Expiration date
Astrazeneca/Oxford	Covishield	ABZ3413	Nov-21
Astrazeneca/Oxford	Covishield	210581	Mar-22
CanSino Biologics	Convidecia	NCOV202106034V	Jun-21
Centro Gamaleya y RDIF*	Sputnik V	II-840621	Dec-21
Centro Gamaleya y RDIF*	Sputnik V	II-640821	Feb-22
Centro Gamaleya y RDIF*	Sputnik V	LYM8	Dec-22
Moderna	Spikevax	045C22A	Jan-23
Moderna	Spikevax	940915	Jun-22
Pfizer/BioNTech	Comirnaty	SELY6	Nov-22
Pfizer/BioNTech	Comirnaty	FJ1966	Jan-22
Pfizer/BioNTech	Comirnaty	FK8892	Mar-22
Sinopharm	COVIL0	202108B2715	Aug-23
Sinopharm	COVIL0	202108B2087	Jul-23

*(RDIF) Russian Direct Investment Fund (2024) paid for just the three marked items.

Table 2 presents the components declared by the manufacturing companies, extracted from the product leaflets requested from INAME-ANMAT (National Institute of Medicinal Products-National Administration of Medicinal Products, Food Products and Medical Technology) of Argentina, via a public information request.

Table 2 Components Declared by the Different Manufacturing Companies						
Components Declared by Manufacturers	Products with Modified mRNA to Produce Spike Protein		Products Using Adenovirus Vector to Produce Spike Protein			Inactivated Viruses
	Pfizer/Comirnaty	Moderna	AstraZeneca	Sputnik V I/II	CanSino Biologics	
Sodium acetate trihydrate		✓				
Acetic acid		✓				
Recombinant adenovirus			✓	✓	✓	
Water for injections	✓	✓	✓	✓	✓	
ALC-0159	✓					
ALC-0315	✓					
Virus antigens						✓
Inactivated SARS-CoV-2						
ARNm with modified nucleotides (Elasomeran)		✓				
ARNm with modified nucleotides (Tozinameran)	✓					
L-histidine hydrochloride monohydrate			✓			
Trometamol Hydrochloride		✓				
Magnesium chloride				✓	✓	
Potassium chloride	✓					
Sodium chloride	✓		✓	✓	✓	✓
Cholesterol	✓	✓				
Potassium dihydrogen phosphate	✓					
Sodium dihydrogen phosphate						✓
DSPC	✓	✓				
EDTA			✓	✓		
Ethanol			✓	✓		
Disodium hydrogen phosphate	✓					✓
Glycerin					✓	
HEPES					✓	
Aluminum hydroxide						✓
L-Histidine			✓			
Mannitol					✓	
PEG 2000-DMG		✓				
Polysorbate 80			✓	✓	✓	
Sucrose	✓	✓	✓	✓	✓	
SM-102		✓				
Tris (hydroxymethyl) aminomethane				✓		

It must be noted that **the only brands declaring the quantities of excipients are Sputnik V and Sinopharm (COVILCO), unlike Pfizer (Comirnaty), AstraZeneca (Covishield), Moderna, and CanSino, which do not declare the quantities of excipients : this constitutes a very serious omission at the regulatory level**.

Global regulations for the pharmaceutical industry are based on **GMP (Good Manufacturing Practices), which stipulate that the declaration of all formula components and their corresponding quantities is mandatory**.

Sampling of evidence and digestion. The studies were conducted at ICYTAC (Institute of Food Science and Technology Córdoba—National University of Córdoba—CONICET) by the technical personnel responsible for the equipment. The evidence was stored under refrigeration between 8°C and 11°C from the moment of receipt until the day of digestion (decomposition into its constituent chemical elements). Each ampoule was agitated using circular motions to ensure homogeneity prior to sampling from any ampoule. Samples were collected using a 5 ml Hamilton syringe ("Gas tight"); a puncture was made in each rubber septum, extracting a sample volume into a polypropylene tube and recording the mass of the extracted sample on an analytical balance (between 0.22 and 0.33g). This procedure was performed in duplicate for each sample of evidence. Empty test tubes were likewise prepared in duplicate, utilizing the same elements and handled in a manner identical to the evidence, with the exception of the addition of the evidence itself, which was replaced with ultrapure water (between 0.22 and 0.24 g in each case). For the digestion of the evidence, 1 mL of bidistilled nitric acid was added to each test tube, and the blank evidence samples were treated in the same manner. These were homogenized using circular vortex motions and left for 6 days at room temperature (26-29°C). Digested samples were stored at 10°C in sealed polypropylene tubes until dilution. Prior to measurement, 9 mL of nitric acid solution (MERCK brand, lot K54405956 223) in ultrapure water 1:50 (v/v) was added to each tube to achieve an approximate dilution of 1:10. Ultrapure water was utilized (conductivity 0.055µS/cm, Sartorius equipment, model Arium 311, equipped with a 0.22µm final filter). It must be noted that the presence of chemical elements and their subsequent identification are independent of temperature fluctuations, such as a breach in the

Digested samples were stored at 10°C in sealed polypropylene tubes until dilution. Prior to measurement, 9 mL of nitric acid solution (MERCK brand, lot K54405956223) in ultrapure water at a 1:50 (v/v) ratio was added to each tube to achieve an approximate dilution of 1 to 10. Ultrapure water was utilized (conductivity 0.055µS/cm, Sartorius brand equipment, model Arium 311, equipped with a 0.22µm final filter). It should be noted that the presence of chemical elements and their subsequent identification are independent of temperature fluctuations, such as a breach in the cold chain.

2.3 Equipment and measurement via ICP-MS The analysis utilized Agilent brand ICP-MS equipment, model 7500cx, featuring an ASX-500 series automatic sampler. The plasma, make-up gas, and other gases employed were 5.0 grade argon (>99.999% Air Liquide, type Argon N50: Alphagaz). For specific elements, helium collision (grade 5.0, Linde) was employed. The software used was Agilent G1834B, ChemStation B.04.00.001. Four types of external calibration curves were prepared from commercial mixtures, encompassing all elements to be quantified.

2.4 Data analysis Following acquisition, the calibration curve was adjusted based on the counts per second (CPS) range exhibited by the samples. To achieve greater precision, points on the curve with CPS values exceeding the maximum value of the evidence for each element were excluded. Replicates were measured at two temperatures (the standard 2°C and 30°C) to determine a correction factor for the measured calibration curves. Each reported evidence is the result of subtracting the mean value of the procedural blank tubes for each element, corrected by the digestion dilution factor and the weighed mass. Furthermore, the replicate incorporates a correction factor for the measured temperature differential. The reported detection limit was calculated as 3.3 times the standard deviation of the evidence for the measured values of the blank samples. The limit of quantification

highlighted by the bolded values in the concentration tables and was calculated as being 10 times the standard deviation of the evidence for the same control samples. The hypothetical mass of the digestion procedure in the control samples was the mass of water used to simulate each sample. 3. Results 3.1 AstraZeneca (Covishield) Vials Two lots of the AstraZeneca product were studied. In the lot ABZ3413, 15 chemical elements were detected, of which 13 are undeclared, and in the lot 210581, 21 elements were detected, of which 19 are undeclared.

Table 3
Chemical Elements Found by ICP-MS in AstraZeneca (Covishield)
Lots: †Declared

	Chemical Elements	Isotopes	AstraZeneca ABZ3413 (µg/L)	AstraZeneca 210581 (µg/L)
B	Boron	11	20	360
Na†	Sodium	23	1100000	9100000
Mg	Magnesium	24	30000	350000
Al	Aluminum	27	810	
K†	Potassium	39	5100	
Ca	Calcium	40		1800
V	Vanadium	51	2.23	
Cr	Chromium	52	21	44
Fe	Iron	56	82	
Ni	Nickel	58		50
Co	Cobalt	59	0.4	
Cu	Copper	63		34
Ga	Gallium	71	0.1	
As	Arsenic	75	4.4	15
Se	Selenium	79		5.1
Rb	Rubidium	85	1	1.8
Sr	Strontium	88		1.4
Nb	Niobium	93		0.22
Mo	Molybdenum	96		13
Pd	Palladium	105		2
Ba	Barium	137		2.8
Ce	Cerium	140	0.22	
Tb	Terbium	159	0.0037	
Hf	Hafnium	178		37
Pt	Platinum	195		2.2
Au	Gold	197		3.9
Tl	Thallium	204		0.7
Bi	Bismuth	209		12
Th	Thorium	232		9.9
U	Uranium	238	0.022	
Total Elements Detected			15	21
Sample Analysis Date			3-Nov-23	27-Dec-23

3.2 CanSino Biologics vials (Convidecia) One lot of the CanSino brand was analyzed, and **22 elements** were detected. Of those detected, **20 were not declared by the manufacturer** (Table 4).

Table 4
Chemical Elements Found by ICP-MS in a Batch of CanSino
Biologics (Convidecia): †Declared

Chemical Elements		Isotopes	CanSino Biologics NCOV202106034V (µg/L)
Li	Lithium	7	20
B	Boron	11	800
Na†	Sodium	23	13000000
Mg†	Magnesium	24	870000
Ca	Calcium	40	1900
Ti	Titanium	48	150
Cr	Chromium	52	38
Ni	Nickel	58	21
Cu	Copper	63	37
Ga	Gallium	71	0.1
As	Arsenic	75	28
Se	Selenium	79	68
Rb	Rubidium	85	0.54
Sr	Strontium	88	9.2
Nb	Niobium	93	0.6
Mo	Molybdenum	96	5
Pd	Palladium	105	1.3
Ba	Barium	137	14
Hf	Hafnium	178	11
Au	Gold	197	1.2
Tl	Thallium	204	0.2
Th	Thorium	232	2.5
Total Elements Detected			22
Sample Analysis Date			27-Dec-23

3.3 Pfizer vials (Comirnaty). Vials from three lots of the Pfizer brand were analyzed. The lot SELY6 was analyzed on two dates: in November 2023, **23 chemical elements were detected, of which 21 elements are undeclared**; in January 2024, **25 chemical elements were detected, of which 22 elements are undeclared**. In the lot FJ1966, **22 elements were detected, of which 19 are undeclared** (Table 5); in the lot FK8892, **19 elements were detected, of which 16 are undeclared**.

Table 5
Chemical Elements Found by ICP-MS in Pfizer (Comirnaty) Lots: †Declared

Chemical Elements	Isotopes	Pfizer SELY6* µg/L	Pfizer FJ1966 µg/L	Pfizer FK8892 µg/L	Pfizer SELY6* µg/L
Li	Lithium	7	62		17
B	Boron	11	2200	1400	860
Na†	Sodium	23	4900000	27000000	58000000
Mg	Magnesium	24		54000	
Al	Aluminum	27	61	230000	34000
P†	Phosphorus	31		940000	6700000
K†	Potassium	39	110000	7000000	64000000
Ca	Calcium				66000
Ti	Titanium	48		1000	2400
V	Vanadium	51	9.2		21
Cr	Chromium	52	30	56	57
Mn	Manganese	55			19
Ni	Nickel	58		27	18
Co	Cobalt	59	0.87		4.8
Cu	Copper	63		90	1.7
Zn	Zinc	65		540	71
Ga	Gallium	71	0.35	0.55	2.2
As	Arsenic	75	27	18	22
Se	Selenium	78			7.5
Rb	Rubidium	85	1.5	1.1	1.9
Sr	Strontium	88		2.3	1.4
Nb	Niobium	93		0.6	0.8
Mo	Molybdenum	96		12	
Ru	Ruthenium	101	0.00084		
Rh	Rhodium	103			0.044
Pd	Palladium	105	0.1	0.51	0.8
Sn	Tin	118	0.29		0.25
Sb	Antimony	121			0.43
Ba	Barium	137	69	64	3.3
La	Lanthanum	139	0.56		
Ce	Cerium	140	5.1	1.4	
Pr	Praseodymium	141		0.14	
Sm	Samarium	150			0.025
Eu	Europium	152	0.022		0.025
Gd	Gadolinium	157			0.02
Tb	Terbium	159	0.00024		
Er	Erbium	167	0.062		0.0056
Hf	Hafnium	178		3.1	2
W	Wolfram	183		4.8	
Pt	Platinum	195	0.42		
Pb	Lead	208	45		
U	Uranium	238	0.25		
Total Elements Detected		23	22	19	25
Sample Analysis Date		3-Nov-23	27-Dec-23	27-Dec-23	3-Jan-24

*This lot was tested twice: once on each of the respective dates.

3.4 Moderna Vials (Spikevax) Two lots of the Moderna brand were analyzed. In lot 940915, **23** elements were detected, of which **21** elements are undeclared ; in lot 045C22A, **17** elements were detected, of which **16** were undeclared (Table 6). This last lot was quantified again in January 2024, at which time **31** elements were detected, of which **29** were undeclared .

Table 6
Chemical Elements Found by ICP-MS in Moderna Vials: †Declared

Chemical Elements	Isotopes	Moderna 045C22A* (µg/L)	Moderna 940915 (µg/L)	Moderna 045C22A* (µg/L)
B	Boron	11	320	
Na†	Sodium	23	1300000	180000
Mg	Magnesium	24	170	13000
Al	Aluminium	27		17000
P†	Phosphorus	31	4300000	400000
K	Potassium	39	39000000	36000
Ca	Calcium	40		4500
Ti	Titanium	48	9500	
V	Vanadium	51	1.7	5.2
Cr	Chromium	52	23	46
Mn	Manganese	55	3.6	15
Fe	Iron	56	270	2400
Ni	Nickel	58	15	20
Co	Cobalt	59	0.18	2.6
Cu	Copper	63	44	
Zn	Zinc	65		4600
Ga	Gallium	71	0.11	0.47
As	Arsenic	75	1.31	
Se	Selenium	79	3.3	
Rb	Rubidium	85	1	2.9
Sr	Strontium	88	5.1	17
Y	Yttrium	89		0.22
Zr	Zirconium	91	550	
Nb	Niobium	93	2.2	
Mo	Molybdenum	96	3.9	
Ru	Ruthenium	101		0.007
Pd	Palladium	105	2.8	
Ag	Silver	107	5.1	
Cd	Cadmium	112		3.2
Sn	Tin	118	17	
Sb	Antimony	121		1.1
Ba	Barium	137	11	
La	Lanthanum	139	0.38	0.18
Ce	Cerium	140	0.17	0.27
Pr	Praseodymium	141		0.025
Nd	Neodymium	144		0.14
Tb	Terbium	159	0.011	
Dy	Dysprosium	162	0.019	0.0051
Ho	Holmium	165	0.0045	
Yb	Ytterbium	173	0.0082	
Hf	Hafnium	178	15	3.3
W	Tungsten	183		11
Au	Gold	197		1.8
Hg	Mercury	200		13
Tl	Thallium	204		0.28
Pb	Lead	208		130
Th	Thorium	232	0.82	
U	Uranium	238	0.023	
Total Elements Detected		17	23	31
Sample Analysis Date		3-Nov-2023	27-Dec-2023	3-Jan-2024

*This lot was tested twice: once on each of the respective dates.

3.6 Sinopharm Vials (COVILO) In the two analyzed lots from Sinopharm, 202108B2087 and 202108B2715 COVILO, various elements were detected; specifically, **25** elements were identified, of which **22** and **23** respectively were undeclared elements. The determination of the lot 202108B2715 was repeated in January 2024, at which date **17** undeclared elements were found out of the **20** detected (Table 7).

Table 7
Chemical Elements Found by ICP-MS in Sinopharm (COVILO) Lots: †Declared

Chemical Elements		Isotopes	Sinopharm 202108B2715 (µg/L)*	Sinopharm 202108B2087 (µg/L)	Sinopharm 202108B2715 (µg/L)*
Li	Lithium	7	13	42	
B	Boron	11	2000	2500	690
Na†	Sodium	23	5000000	39000000	4200000
Mg	Magnesium	24			38000
Al†	Aluminum	27	205000	3100000	2700000
P†	Phosphorus	31		3000000	2000000
Ca	Calcium	40		1700	2800
Ti	Titanium	48		3200	
V	Vanadium	51	8.15	17	17
Cr	Chromium	52	28.5	76	61
Fe	Iron	56	31		
Ni	Nickel	58		20	
Co	Cobalt	59	0.43		0.16
Cu	Copper	63		100	
Ga	Gallium	71	6.25	5.5	7.7
As	Arsenic	75	6.65	9.6	
Se	Selenium	79			4.8
Sr	Strontium	88		3.6	2.8
Y	Yttrium	89	0.15		0.21
Nb	Niobium	93		0.5	
Mo	Molybdenum	96		2.8	
Ru	Ruthenium	101	0.00084		
Pd	Palladium	105	0.027	0.4	
Sn	Tin	118	1.2		
Sb	Antimony	121		3.2	
Te	Tellurium	127	0.4		
Ba	Barium	137	16.5	360	
La	Lanthanum	139		3.5	0.055
Ce	Cerium	140	1.2	21	0.68
Pr	Praseodymium	141			0.018
Nd	Neodymium	144			0.16
Sm	Samarium	150			0.044
Eu	Europium	152	0.019		
Gd	Gadolinium	157			0.023
Tb	Terbium	159	0.0061		
Dy	Dysprosium	162	0.026		
Ho	Holmium	165	0.0056		
Er	Erbium	167	0.039	0.47	0.0028
Yb	Ytterbium	173	0.015		
Hf	Hafnium	178		2.4	
W	Tungsten	183		1.9	
Pt	Platinum	195	0.29		
Au	Gold	197		0.7	
U	Uranium	238	0.11		
Total Elements			25	25	20
Sample Analysis Date			3-Nov-23	27-Dec-23	3-Jan-24

*Measurements on this lot were taken on both of these dates.

3.7 Vials from the Gamaleya Center and RDIF, Russia (SputnikV) Of the three SputnikV lots analyzed, lot II-840621 was analyzed on two separate dates and contained **a total of 22 and 27 elements, respectively, of which 19 and 24, respectively, are undeclared**. Lot LYM8 contained **21 elements, of which 19 are undeclared** (Table 8). Finally, lot II-640821 contained **14 elements, of which 11 are undeclared** (Table 8).

Table 8
Chemical Elements Found by ICP-MS in Sputnik Lots: †Declared

Chemical Elements	Isotopes	Sputnik V II-840621 (µg/L)*	Sputnik V I-LYM8 (µg/L)	Sputnik V II-640821 (µg/L)	Sputnik V II-840621 (µg/L)*
Li	Lithium	7	12		
B	Boron	11	2500	1000	700
Na†	Sodium	23	4300000	58000000	3000000
Mg†	Magnesium	24	27000	280000	50000
Al	Aluminum	27	200		2600
P†	Phosphorus	31		33000	
K†	Potassium	39	9500		7200
Ca	Calcium	40	2000	5000	
Ti	Titanium	48		56	
V	Vanadium	51	9.6	16	17
Cr	Chromium	52	38	95	63
Ni	Nickel	58	33	51	
Co	Cobalt	59			0.37
Cu	Copper	63	160	170	
Zn	Zinc	65	150	140	
Ga	Gallium	71	0.36	0.33	
As	Arsenic	75	9.6	9.2	
Se	Selenium	79		4.1	
Rb	Rubidium	85	2.5	3.2	
Sr	Strontium	88	4.1	4.5	
Nb	Niobium	93		0.2	
Mo	Molybdenum	96		2.8	
Ru	Ruthenium	101			0.017
Pd	Palladium	105	0.065	0.7	
Cd	Cadmium	112	10		2.3
Sn	Tin	118	88	8.8	
Ba	Barium	137	18	21	
Ce	Cerium	140	62	30	22
Nd	Neodymium	144			0.051
Gd	Gadolinium	157	0.27	0.3	0.23
Tb	Terbium	159	0.006		
Ho	Holmium	165	0.0054		
Yb	Ytterbium	173	0.0057		
Hf	Hafnium	178		5	
Au	Gold	197	1.1	2	0.43
Tl	Thallium	204		0.3	
Pb	Lead	208	24		
Th	Thorium	232	0.6	1.1	
Total Detected		22	21	27	14
Analysis Date		3-Nov-23	27-Dec-23	27-Dec-23	3-Jan-24

*This lot was tested twice: once on each of the respective dates.

4. Discussion

4.1 Elemental composition of the COVID-19 vaccines

Our analysis, summarized in Tables 9 and 10, demonstrates the presence of 55 undeclared chemical elements across the 17 samples of evidence analyzed from the 6 brands of COVID-19 vaccines . Among the undeclared elements, all groups from the Periodic Table were represented, with the exception of noble gases. Numerous heavy metals were detected in the evidence analyzed, all of which are associated with toxic effects on human health . The European Union recognizes 11 Toxic substances as heavy metals: arsenic, cadmium, cobalt, chromium, copper, mercury, manganese, nickel, lead, tin, and thallium (Witkowska et al., 2021; Hogan, 2010). All these elements were identified across various lots with differing frequencies of occurrence within the sampling : chromium (100%), arsenic (82%), and nickel (59%), followed by 47% cobalt and copper; with 41% tin, 24% thallium, and 18% cadmium, lead, and manganese; and, finally, 6% of the evidence contains mercury (Table 9). The evidence contains 12 of the 15 lanthanides listed in the periodic table of chemical elements. The percentage frequency of their occurrence is presented in Table 9: lanthanum (35%), cerium (76%), praseodymium (18%), neodymium (18%), samarium (12%), europium (18%), gadolinium (35%), terbium (29%), and dysprosium (18%),

holmium (18%), erbium (29%), and ytterbium (18%) . These elements possess **luminescent and magnetic properties** (Echeverry & Parra, 2019); to date, **their safety for use in the human body has not been demonstrated** . In fact, the **ICH Q3D guideline (ICH, 2022)** does not mention the lanthanides among the elemental impurities . It must be noted that this guideline does not cover biological products, such as vaccines .

Table 9
Frequency of Elements in the Analyzed Samples and Maximum Concentration

#	Chemical Elements	Isotopes	Samples with	% Samples with	Max Concentration (ug/L)	
1	Sodium	Na	23	17	100	55000000
2	Chromium	Cr	52	17	100	110
3	Boron	B	11	13	88	2500
4	Gallium	Ga	71	13	88	7.7
5	Arsenic	As	75	14	82	28
6	Strontium	Sr	88	13	76	17
7	Cerium	Ce	140	13	76	62
8	Vanadium	V	51	12	71	26
9	Palladium	Pd	105	12	71	7.6
10	Barium	Ba	137	12	71	920
11	Magnesium	Mg	24	11	65	870000
12	Rubidium	Rb	85	11	65	3.2
13	Aluminum	Al	27	10	59	3100000
14	Nickel	Ni	58	10	59	51
15	Potassium	K	39	9	53	64000000
16	Hafnium	Hf	178	9	53	37
17	Phosphorus	P	31	8	47	6700000
19	Cobalt	Co	59	8	47	2.6
20	Copper	Cu	63	8	47	170
21	Niobium	Nb	93	8	47	2.2
18	Calcium	Ca	40	7	41	5000
27	Tin	Sn	118	7	41	88
22	Gold	Au	197	7	41	3.9
23	Lithium	Li	3	6	35	62
24	Titanium	Ti	48	6	35	9500
25	Selenium	Se	79	6	35	68
26	Molybdenum	Mo	96	6	35	13
28	Lanthanum	La	139	6	35	3.5
29	Gadolinium	Gd	157	6	35	0.3
30	Zinc	Zn	65	5	29	4600
31	Terbium	Tb	159	5	29	0.011
32	Erbium	Er	167	5	29	0.47
33	Thorium	Th	232	5	29	9.9
34	Iron	Fe	56	4	24	2400
37	Thallium	Tl	204	4	24	0.7
38	Uranium	U	238	4	24	0.25
39	Manganese	Mn	55	3	18	19
40	Yttrium	Y	89	3	18	0.22
35	Ruthenium	Ru	101	3	18	0.017
41	Cadmium	Cd	112	3	18	10
43	Praseodymium	Pr	141	3	18	0.14
44	Neodymium	Nd	144	3	18	0.16
46	Europium	Eu	152	3	18	0.025
36	Dysprosium	Dy	162	3	18	0.026
47	Holmium	Ho	165	3	18	0.0056
48	Ytterbium	Yb	173	3	18	0.015
49	Tungsten	W	183	3	18	11
50	Platinum	Pt	195	3	18	2.2
51	Lead	Pb	208	3	18	130
42	Antimony	Sb	121	2	12	3.2
45	Samarium	Sm	150	2	12	0.044
52	Zirconium	Zr	91	1	6	550
53	Rhodium	Rh	103	1	6	0.044
54	Silver	Ag	107	1	6	5.1
55	Tellurium	Te	127	1	6	0.4
56	Mercury	Hg	200	1	6	13
57	Bismuth	Bi	209	1	6	12

The lanthanides are frequently used in the electronics industry and in no case as part of biosensors due to their cytotoxic effects (Voncken, 2016; Balaram, 2019). To date, **if the results obtained both through SEM-EDX** (Aristeo et al., 2021, pp. n40, n66; Rettzlaf, 2022; Nagase, 2022;

Sangorrín and Diblasi, 2022b; Hagimă, 2023a, 2023b) **as well as through ICP-MS are taken into account for the brands studied here, a total of 62 undeclared chemical elements have been detected (Table 10). The two techniques are complementary and also have their limitations and differences. In SEM-EDX, the sample volume varies between 10-20µL, whereby only particles found in that small volume can be observed, while through ICP-MS a sample volume of 200µL is taken , which is more representative. In turn, SEM-EDX can detect carbon, nitrogen, oxygen, silicon, fluorine, chlorine, bromine, and sulfur (which could not be determined through ICP-MS). Although all these elements were present in the evidence, only carbon, nitrogen, and oxygen were declared in the manufacturers' formulas (Table 2). Hydrogen cannot be detected by any of these techniques. In the ICP-MS technique, the sample is digested with HNO₃, leaving the chemical elements free in solution, whereas through SEM-EDX, chemical elements are detected within the micro- and nanoparticles found in the sample. One of the advantages of the ICP-MS technique is that chemical elements can be quantified .**

Upon examining lines three and six of Table 10, it is observed that the brands most frequently analyzed by both SEM-EDX and ICP-MS were Pfizer, Moderna, and AstraZeneca. The highest number of undeclared chemical elements was detected in these specific brands. By contrast, the fewest undeclared elements were found in the Sputnik V and CanSino brands; however, it must be taken into account that for these two brands only one sample was taken from each of the vials, thus the absolute minimum number of analyses was performed. Obviously, **the presence of more or fewer elements depends partially on the number of analyses that could be performed. It does not depend entirely on the brand sampled. In addition, it is obvious that, despite the different declared chemical contents, there are common undeclared chemical elements, such as boron, calcium, titanium, aluminum, arsenic, nickel, chromium, copper, gallium, strontium, niobium, molybdenum, barium, and hafnium across all brands**

Table 10
Chemical Elements Detected by SEM-EDX and ICP-MS

Manufacturers	CanSino Biologics	AstraZeneca	Pfizer	Moderna	Sinopharm	Sputnik V I	Sputnik V II
Elements Declared by Manufacturer	C, H, O, N, Cl, Na, Mg, P	C, H, O, N, P, Cl, Na	C, H, O, N, P, Cl, Na, K	C, H, O, N, P, Cl, Na	C, H, O, N, P, Cl, Na, Al	C, H, O, N, P, Cl, Na, Mg	C, H, O, N, P, Cl, Na, Mg
Number of Samples Analyzed by ICP-MS	1	2	4	3	3	1	3
Chemical Elements Detected by ICP-MS	Li, B, Na, Mg, Al, Ca, Ti, Cr, Ni, Cu, Ga, As, Se, Rb, Sr, Nb, Mo, Pd, Ba, Hf, Au, Tl, Th	B, Na, Mg, Al, K, Ca, V, Cr, Fe, Co, Ni, Cu, Ga, As, Se, Rb, Sr, Nb, Mo, Pd, Ba, Ce, Tb, Hf, Pt, Au, Tl, Bi, Th, U	Li, B, Na, Mg, Al, P, K, Ca, Ti, V, Cr, Mn, Co, Cu, Ni, Zn, Ga, As, Se, Rb, Sr, Nb, Mo, Ru, Rh, Pd, Sn, Sb, Ba, La, Ce, Pr, Sm, Eu, Gd, Tb, Dy, Er, Hf, W, Pt, Pb, U	B, Na, Mg, Al, P, K, Ca, Ti, V, Cr, Mn, Fe, Co, Ni, Cu, Zn, Ga, As, Se, Rb, Sr, Y, Zr, Nb, Mo, Ru, Pd, Ag, Cd, Sn, Sb, Ba, La, Ce, Pr, Nd, Tb, Dy, Ho, Yb, Hf, W, Au, Hg, Tl, Pb, Th, U	Li, B, Na, Mg, Al, P, Ca, Ti, V, Cr, Fe, Co, Ni, Cu, Ga, As, Se, Sr, Y, Nb, Mo, Ru, Pd, Sn, Sb, Te, Ba, La, Ce, Pr, Nd, Sm, Eu, Gd, Tb, Dy, Ho, Er, Yb, Hf, W, Pt, Au, U	B, Na, Mg, Al, Ca, V, Cr, Ni, Cu, Zn, Ga, As, Rb, Sr, Nb, Pd, Ba, Ce, Gd, Hf, Au, Th	Li, B, Na, Mg, Al, P, K, Ca, Ti, V, Cr, Co, Ni, Cu, Zn, Ga, As, Se, Rb, Sr, Nb, Mo, Ru, Pd, Cd, Sn, Ba, Ce, Nd, Gd, Tb, Ho, Yb, Hf, Pt, Au, Tl, Pb, Th
Total Elements Not Declared but Detected by ICP-MS	21	29	40	46	41	19	36
Number of Samples Analyzed by SEM-EDX	1	4	5	5	2	1	0
Chemical Elements Detected by SEM-EDX	C, O, F, Na, Mg, Al, Si, P, S, Cl, K, Ca, Ti, Fe, Cu, Br	C, N, O, F, Na, Al, Si, S, Cl, Ca, Ti, Cr, Fe, Co, Ni, Cu, Tc, Ag, Sn, Ce, Gd	C, N, O, F, Na, Mg, Al, Si, P, S, Cl, K, Ca, Ti, V, Cr, Mn, Fe, Cu, Y, Tm, Bi	C, N, O, Na, Mg, Al, Si, P, S, Cl, K, Ca, Ti, Cr, Fe, Cu, Se, Pd, Cd, Sn, Sb, Cs, Ba, Ce, Pb, Bi	C, O, F, Na, Mg, Al, Si, P, S, Cl, K, Ca, Cu	C, O, Na, Cl	Not available
Total Not Declared but Detected by SEM-EDX	10	17	15	20	7	0	Not available
Total Not Declared but Found by Both ICP-MS and SEM- EDX	27	37	47	51	45	19	36

4.2 Structural content of the COVID-19 vaccines

Sodium and chromium were detected in all samples (100%, Table 9). **Sixteen of the undeclared elements were detected in the majority of our analyses, including boron and gallium in 88% of them , vanadium, cerium, platinum, and barium in 71% to 76%,** while the remainder are listed in Table 9, numbered 11 through 57. Given the diversity and specific characteristics of the elements identified, along with their notable presence across all brands, **it is extremely unlikely, in our opinion, that the results reported in this report are due to fortuitous events such as contamination. We do not believe that accidental occurrences due to chance could manifest so consistently and ubiquitously across the various brands of vaccines studied.** While the emergence of a daunting diversity of undeclared chemical elements remains anomalous, **the indications appear to point toward a form of global technological experimentation. Given that the lanthanides, as previously noted, are known to be highly cytotoxic** (Woncken, 2016; Balaram, 2019), their detection in significant quantities across the full range of products examined herein **suggests a form of nanotechnological experimentation** , consistent with the findings discussed by Kyrie and Broudy (2022), Lee and Broudy (2024a), Hughes (2024), and others. All evidence exhibited a specific viscosity and density. None of the content was aqueous, **but rather viscous and dense** ; we believe this is likely a consequence of a certain amount of water associated with the evidence, as observed during several weeks of incubation by Lee and Broudy. This humidification was likely produced by **gelling agents** , as these possess a high affinity for water. Given all the observed characteristics of the fluids in the vials analyzed, their content appears to change over time. **The content of all vials was heterogeneous in unexpected ways. Despite their apparently common viscous matrix, even with repeated sampling from the same ampoule, we never found a homogeneous content across different evidence, even when samples were taken from the same ampoule.** This occurred despite the fact that, prior to the collection of any sample from any of the ampoules, each ampoule was invariably subjected to vortex mixing to ensure the highest possible degree of homogeneity. Furthermore, I assumed that if the initial content of any ampoule were uniform and homogeneous, the distribution of the components would remain unaffected by

It is well established that well-mixed homogeneous solutions consistently exhibit a specific distribution of their constituent solutes, even when such solutes are present in very low concentrations. If this were the case for the vials examined, **all constitutive elements should be consistently present in every solution sample from a specific ampoule. In fact, these should appear in the same proportion and in the same relative quantities.** But that is not what was established. Due to the complex, dynamic, and changing content within all brands studied in this work, consistent with the findings of Lee and Broudy (2024a), **the observed heterogeneity makes the precise quantification of elements or extrapolation from a specific sample to the content of the residual fluid in any given ampoule impossible. It appears that the presence and relative quantities of elements found in the evidence collected at different times vary according to the phases of the self-assembly cycles** , as observed, for example, in the diligent research of Lee and Broudy. Notably, it was praised for its consistency and reliability even by its highly competent critic (Ulrich, 2024). However, to the best of our knowledge, **there is no way to determine the number or duration of the growth phases beginning at the nanometers level within the content of the vaccines studied , as the construction phases progress toward the visible microstructures observed in the incubated evidence and in the blood of the recipients of the injectables** (Lee et al., 2022; Benzi-Cipel-It appears that the elements within the evidence, characterized by diverse distributions, are associated in discrete units of self-assembled microstructures visible under optical microscopes. **Beyond generally known chemical properties, such as luminescence, electromagnetism, and Toxicity, our findings cannot provide extensive information regarding the roles played by these widely observed self-assembled microstructures. The determination of their identities,**

functions, and implications remains a high priority. What is certain is that these are empirically associated with numerous and extreme adverse reactions, including millions of deaths, evidently caused by the administration of the products studied herein. The temperature variable is of particular interest, as any crucial genetic material intentionally placed in vials would be well preserved at temperatures near 20°C below zero. Thus, we question why Pfizer initially recommended a cold chain of custody at a temperature not exceeding 80°C below zero. Naturally, subjecting genetic material encapsulated in lipid nanoparticles to freeze-thaw cycles causes its denaturation and drastically reduces the capacity of the genetic material to penetrate cells as intended (Segalla, 2024). Consequently, a certain cold chain of custody appears justified; however, unless the purpose was to prevent the formation of complex self-assembled microstructures inside the vials before their content could be injected into human recipients, the initial setting at 80°C below zero is anomalous.

4.3 Undeclared nanotechnology found in the COVID-19 vaccines

In addition to composition analysis, researchers from various parts of the world have conducted studies on samples of COVID-19 vaccines and observed the phenomenon of **self-assembly of nano- and microparticles with orthogonal morphology** (Delgado, 2022; Nixon, 2023; Lee and Broudy, 2024a; Zelada, 2024). **The increasing presence of nanotechnology-based products in almost all spheres of science**, particularly in pharmaceutical products, raises concerns regarding their quality, safety, efficacy, and toxicity (Mahamuni-Badiger & Dhanavade, 2023). **The majority of available nanomedicinal products function through interaction at a biomolecular level with cellular components and the genetic material, influencing genomic functions directly and indirectly** (Ali et al., 2023). Of particular interest in the present study is the emerging concept of “nanoarchitecture,” in which self-assembly processes involve a wide range of materials and applications (Devaraj et al., 2021). These include transmembrane channels, peptide conjugates and vesicles, delivery of medicinal products, cell culture, supramolecular differentiation, molecular recognition, optics, and energy storage (Ariga et al., 2019). To develop these materials, **in many cases, graphene oxide is used, functionalized with chemical elements such as palladium, nickel, tin, gold, cobalt, and copper** (Hejazi et al., 2021), which are present **in over 40% of the vaccine samples analyzed in this work** (Table 9). Furthermore, **other undeclared chemical elements, known to be used for self-assembling materials** (Hejazi et al., 2021), **were found in percentages of evidence ranging between 18% and 35%: selenium (35%), titanium (35%), Zinc (29%), cadmium (18%), manganese (18%), and platinum (18%).**

Given the wide variety of nanomaterials, **colloidal quantum dots offering unique optoelectronic characteristics for neural interfaces** (Hu et al., 2024) **targeting neural control** (Karatum et al., 2022), we find it particularly noteworthy that researchers such as Hu and his colleagues have been occupied **evaluating the toxicity of various types of quantum dots** (CdSe, CdTe, MoS₂, graphene quantum dots, etc.) **at various doses** (10-100 ppm, 1-25 nM, etc.) **in various cell cultures** (BV2, U87, U373, U251, etc.). In recent years, **upconversion nanoparticles have been developed. These are nanocrystals doped with lanthanide ions** (Dy³⁺, Er³⁺, Eu³⁺, Gd³⁺, Ho³⁺, Lu³⁺, Sm³⁺, Tb³⁺, Tm³⁺, Y³⁺, Yb³⁺), **excitable by infrared light and used in optogenetics to activate or deactivate light-sensitive membrane proteins present in neurons, such as opsins and rhodopsins, corresponding to a neuromodulation mechanism** (Chen et al., 2016; Yi et al., 2021). **NaGdF₄, NaYF₄, NaErF₄ upconversion nanoparticles doped with lanthanides** were tested in various populations of neurons **for optogenetic modulation** (Liu et al., 2021). It has been established that NaYF₄ UCNPs doped with Yb³⁺, Er³⁺, Tm³⁺, and Ho³⁺ **can be internalized by neurons through clathrin- and caveolae-mediated endocytosis** (Zajdel et al., 2023).

5. Conclusions

*Based on the identification and the quantitative ranges of the chemical elements discovered, as well as the physical and chemical characteristics of the content of the vaccines studied, **it is of the highest importance to underscore the significant similarity existing between the products of different brands**. The differences observed regarding the chemical elements found in the various brands, we believe, are attributable to **the time interval between the sampling of evidence, resulting from the mutable structure of the self-assembled entities within the fluids contained in the vials. We do not believe that the observed differences are due to manufacturing processes specific to a particular brand or to variations between lots resulting from stochastic fluctuations in the production processes**. Despite the small size and the limited number of evidence analyzed in this exploratory study, we believe that the analysis of a larger number of samples and lots will confirm the trends we have highlighted. We believe that **the diverse and varied pathologies in the inoculated population are not due to fortuitous manufacturing or distribution problems, but rather to the technology** which appears to be common to all these products that appear to be universally harmful to humans.*

C. My research on the literature regarding the COVID-19 vaccines (studies , efficacy, safety) in the context of the politico-medical pressure for vaccination characterized by disinformation and manipulation

I shall briefly recount the medical grounds that led me to harbor suspicions regarding the COVID vaccines and to further my research concerning these products.

During the COVID-19 period, I closely monitored the unfolding of events, particularly as I operate my own private practice and was concerned with the measures implemented during this timeframe. Thus, from the onset of the declared state of emergency, I observed an attempt at manipulation through the Transmission across all media channels of the cumulative number of COVID-19 cases, regardless of severity, and the cumulative number of deaths, rather than the daily case counts categorized by age group and associated pathologies. I searched for information regarding the deceased individuals and found from the website <https://coronavirusromania.ro/decese>, currently non-functional, that COVID-19 deaths mortality, at least until the month of June in Romania, primarily involved individuals whose state of health was severely compromised—terminal cancers, hepatic or renal insufficiencies in advanced stages, severe dementia, or severe cardiac diseases. These were declared as COVID-19 deaths, following the WHO recommendations: “

A-RECORDING COVID-19 ON THE MEDICAL CERTIFICATE OF CAUSE OF DEATH: COVID-19 must be recorded on the medical certificate of cause of death for ALL deceased individuals in cases where the disease caused, **it is presumed to have caused, or contributed to the death** ” <https://insp.gov.ro/wp-content/uploads/2021/10/PRECIZARILE-OMS-PENTRU-COMPLETAREA-CERTIFICATULUI-CONSTATATOR-DE-DECES-PENTRU-COVID-19.pdf> .

Given my proficiency in the English language, I have monitored international developments. I have observed that the course of action was nearly identical across various countries; the media disseminated the same propaganda of fear, and the message “ **the world will never be the same** ” was repeatedly broadcast. In Romania, however, the restrictions were among the most severe. At an international level, there were significant voices from physicians at prestigious academic centers, active in the field of public health, who warned that the lockdown constitutes a catastrophic policy. One of these was **Jay Bhattacharya**, a professor at the Stanford University School of Medicine, who authored, alongside two other professors, the **Great Barrington Declaration** <https://gbdeclaration.org/> stating that **natural herd immunity is superior to lockdown measures and that only elderly, vulnerable individuals should be protected**. This statement was signed by **16,176 public health workers, 47,839 medical practitioners**, and 877,246 citizens. Jay Bhattacharya, currently a director of the National Institute of Health in the USA, calls the lockdown “**the worst**

public health mistake of the last 100 years” <https://www.newsweek.com/sttanford-doctor- calls-lockdowns-biggestt-public-health-mistake-weve-ever-made-1574540> . **Therefore, a scientific consensus did not exist; rather, there were certain physicians who became the voice of the authorities, claiming to represent the opinions of the scientific community.**

Within a relatively short period following the global declaration of the pandemic, the COVID-19 vaccines were granted emergency approval in December 2020, despite the fact that phases 1, 2, and 3 of the clinical trials overlapped and clinical trials had not been completed. In Europe, the COVID-19 vaccines received conditional marketing authorization from the European Medicines Agency (EMA) and were administered to the population, notwithstanding that phase 3 clinical trials for adults were not scheduled for completion until **august 2023–march 2024 at the earliest** – page 118/140 https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf

Vaccination was heavily publicized and promoted by the authorities, as well as by professional organizations such as the College of Physicians of Romania, which convened conferences including the session held on January 8, 2021 <https://www.facebook.com/ColegiulMedicilorDinRomania/videos/178531710689753> , unfortunately recently deleted from the website of this institution. Should you consider this evidence relevant, I note that I have downloaded the conference proceedings into a file. At this online conference, members of the governing bodies of this institution as well as members of the MS took the floor, asserting—without providing bibliographic references—that vaccination is safe and effective, that the inoculated substance remains at the injection site, and that the mRNA rapidly clears from the body. Although I and other colleague physicians submitted questions in the comments, accompanied by scientific references, no response was provided during the conference or subsequently to these inquiries.



The lack of communication from professional organizations such as the College of Physicians continued throughout the period of 2021–2025, during which time I submitted to this institution—and others—numerous petitions regarding the efficacy and safety of the COVID-19 vaccination for adults and children, the wearing of masks, and mortality rates during the COVID-19 period, both prior to and following vaccination. The College of Physicians of Romania was not the only institution that failed to respond to petitions on these matters or failed to provide clarifying, evidence-based answers. Between the years 2020–2024, I also addressed petitions on these topics to the **Ministry of Health, the National Institute of Public Health, and the National Agency for**

the MS, MAPN, MAI, the Parliament of Romania, the President of Romania, the People's Advocate, as well as to other authorities that have not provided a clarifying response to my arguments, which are based on medical evidence. If you consider my petitions relevant, I can attach them subsequently.

Furthermore, both I and other colleagues, as well as the Physicians for Informed Consent Association, **have repeatedly requested public debates regarding the COVID vaccines, without these requests being answered.**

Instead, the CMR requested the initiation of two disciplinary investigations against me in the year 2022 for participating in a protest and a broadcast, respectively, in which I expressed my opinions based on scientific evidence related to the unjustified measures taken by the authorities during the COVID-19 period and the lack of safety and efficacy of the COVID vaccines. Relevant to the censorship of that period is also the conclusion of the response bearing registration number **REG2/50/27-01-2022 issued by the MS** in reply to a petition submitted by me on 2-01-2022 regarding the COVID-19 vaccination, in which I raised, in my capacity as a physician and citizen, questions of medical common sense supported by scientific studies. This response contains, among its assertions, **one that is catastrophic and self-incriminating because it encourages the unnecessary vaccination of persons who have recovered from the COVID disease**, individuals who, according to the studies available at that time, **possessed long-term immunity and protection against severe disease and mortality**. Thus, the Ministry of Health stated that a person who has recovered from the disease may be vaccinated “**irrespective of the time elapsed since the diagnosis of the COVID-19 infection, as long as they are asymptomatic at the time of the vaccination**,” not because the vaccination would be of use to them, but because in the clinical trials regarding the vaccination of persons who had recovered from the disease, “**no higher frequency of adverse reactions was observed in these individuals compared to the rest of the volunteers**.” This statement, one of many erroneous claims made by the authorities, reflects the non-medical reasoning underlying the COVID-19 vaccination and simultaneously **the premeditation to introduce the content of these experimental products, containing undeclared ingredients by the manufacturers, into the bodies of all Romanians for purposes other than medical benefit, without even accounting for the financial fraud of massive proportions**. Furthermore, at the conclusion of the petition, a threat directed at me by the MS is evident, issued because I took the liberty of posing several medically sound questions supported by scientific studies regarding the vaccination of the entire population of Romania, including children, with experimental vaccines using new technology—“**promoting anti-vaccination messages implies a degree of complicity in the deaths of so many victims of COVID-19, and the denial of hundreds of years of science is entirely unprofessional.**” We hereby inform you that we reserve the right to notify the College of Physicians regarding your statements.”

In studiile clinice nu a fost criteriu de excludere un anumit interval de timp după boală, ci chiar a fost încurajată înrolarea persoanelor recent trecute prin boala pentru a putea observa eventualele efecte adverse. Nu s-a observat o frecvență mai mare a reacțiilor adverse în rândul acestora comparativ cu restul voluntarilor. Prin urmare orice persoană care dorește să se vaccineze o poate face, indiferent cât timp s-a scurs de la diagnosticarea infecției cu COVID-19, atâta timp cât este asimptomatică la momentul vaccinării. Se recomandă precauție pentru persoanele care au necesitat tratament cu plasmă convalescentă sau anticorpi monoclonali. Aceste persoane pot fi vaccinate însă la 90 de zile după tratament, pentru a minimiza riscul neutralizării proteinei Spike și a da șansa celulelor B să producă proprii anticorpi. (<https://vaccinare-covid.gov.ro/>)

Recomandarea CDC este ca toți copiii de peste 5 ani să se vaccineze pentru a se proteja împotriva COVID-19. Pe site-ul instituției amintite se precizează că "Vaccinul împotriva COVID-19 pentru copii este sigur și eficient. Acesta fost supus unei revizuri riguroase, a fost autorizat de FDA și recomandat de CDC pentru copii cu vârste cuprinse între 5 și 11 ani, după teste amănunțite de siguranță efectuate la mii de copii. Vaccinurile COVID-19 pentru copii cu vârste cuprinse între 5 și 11 ani au fost dezvoltate și testate în același mod ca vaccinurile pentru adulți împotriva COVID-19. În studiile clinice, reacțiile adverse ale vaccinului au fost ușoare și similare atât cu cele observate la adulți, cât și cu alte vaccinuri recomandate copiilor. Cel mai frecvent efect secundar înregistrat a fost durerea de braț. Aceste reacții adverse pot afecta capacitatea copilului dumneavoastră de a face activități zilnice, dar ele ar trebui să dispară în câteva zile. Unii oameni nu prezintă niciun efect secundar, iar reacțiile alergice severe sunt rare." (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/children-facts.html>)

Promovarea mesajelor antivacciniste presupune un soi de complicitate în raport cu moartea atâtor victime, bolnavi de Covid, și este total neprofesionistă negarea a sute de ani de știință. Vă informăm că ne rezervăm dreptul de a sesiza Colegiul Medicilor cu privire la afirmațiile dvs.

Cu stimă,

Director General de Asistență Medicală,
Medicină de Urgență și Programe de
Sănătate Publică

Director General,
Dr. Amalia Șerban

Enescu, D.M. 802

Director Relații cu Presa,
Afaceri Europene și Relații
Internationale

Director
Oana Cătălina Grigore

I shall attach to this complaint both my petition and the full response of the MS, should you deem them relevant.

Likewise, the Government of Romania unjustifiably recommended, from a medical standpoint, the vaccination of individuals who had already recovered from the disease. At this link https://vaccinare-covid.gov.ro/wp-content/uploads/2021/02/Comunicat_rapel_bolnavi.pdf I no longer have access, but I have saved this recommendation in a Power Point document.

GUVERNUL ROMÂNIEI

COMITETUL NAȚIONAL DE COORDONARE A ACTIVITĂȚILOR PRIVIND VACCINAREA ÎMPOTRIVA COVID-19

București, 05 februarie 2021

PRECIZARE DE PRESĂ

La nivelul Comitetului Național de Coordonare a Activităților privind Vaccinarea împotriva COVID-19 (CNCAV), a fost aprobată instrucțiunea privind vaccinarea în situații speciale, cu vaccin de tip ARNm.

Conform prevederilor regăsite în acest document, vaccinarea persoanelor care au fost infectate cu SARS-CoV-2 nu este contraindicată, iar vaccinarea acestora se poate realiza după vindecare.

Totodată, în cazul în care o persoană dezvoltă infecție cu SARS-CoV-2 după administrarea primei doze de vaccin împotriva COVID-19, aceasta va putea fi vaccinată după vindecare, prin continuarea schemei de vaccinare, fără reluarea primei doze.

Pentru situațiile în care o persoană căreia i s-a administrat prima doză de vaccin Pfizer împotriva COVID-19 are contraindicații temporare pentru cea de-a doua doză, administrarea rapelului va putea fi amânată până la un interval optim de maximum 42 de zile. În situații excepționale, rapelul poate fi administrat și după această perioadă. În cazul vaccinului Moderna, intervalul optim de amânare a dozei de rapel este până la 35 de zile, însă, în situații excepționale, rapelul poate fi administrat și după această perioadă.

De asemenea, dacă o persoană prezintă reacție anafilactică după administrarea primei doze de vaccin tip ARNm nu va mai primi a doua doză, fiind recomandată reluarea vaccinării cu un alt vaccin fabricat după o tehnologie diferită.

In the conclusions of the EMA and FDA evaluation report of the vaccine Pfizer, it is clearly stated that there is no evidence of obtaining additional protection against the disease through the vaccination of individuals who have recovered from the disease; furthermore, it is stated that they possess at least partial protection through prior infection (page 96 https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf): “It is not possible to draw conclusions regarding the efficacy of the vaccine in subjects with a history of COVID-19 or signs of SARS-CoV2 infection, because only a small number of subjects were seropositive individuals at baseline (approximately 550 in each vaccine and placebo group) and only 2 cases of disease were reported in this subset (1 in each group). Additional data may become available as the study progresses, but it is unlikely that the study will be able to provide conclusive evidence for several reasons (for example, it is very likely that the number of seropositive individuals will remain limited and that there will be a lower incidence of the disease in seropositive patients on placebo compared to seronegative patients on placebo, due to existing partial protection). The degree of additional protection in seropositive individuals is currently uncertain. Studies regarding efficacy can provide us with information in this regard

It is not possible to conclude on vaccine efficacy in subjects with prior COVID-19, or signs of infection with SARS-CoV2 because only a small number of subjects were found to be seropositive at baseline (approximately 550 in each vaccine and placebo group), and only 2 cases of disease were reported in this subset (1 in each group). Further data may become available as the trial proceeds, but it is unlikely that the study will be able to deliver conclusive evidence for a number of reasons (e.g. it is very likely that the number of subjects seropositive will remain limited, and that there will be a lower incidence of disease in seropositive placebo recipients compared to seronegative placebo recipients due to existing partial protection). The extent of additional protection in seropositive subjects is presently uncertain. Effectiveness studies may give us some information on this regard.

The fact that **the injection of the entire population of Romania** with these products was premeditated—and not just with two doses, but with approximately 6 doses per Romanian—is further evidenced by the fact that the Prime Minister at the time, Mr. Cițu, ordered 120 million doses even as the College of Physicians of Romania and other professional medical organizations **asserted an efficacy of over 95% for certain COVID-19 vaccines** such as the Pfizer vaccine. Prime Minister Cițu justified ordering these doses as follows: „We did not buy them; these doses are ordered and they are not for one year, **they are for several years. Because from the beginning it was clearly known that the pandemic might not pass in the first year and perhaps doses would be needed for the following years. These doses are also for next year** “ <https://digiPRES.ro/cittu-explica-de-ce-a-cumparatt-120-de-milioane-de-vaccinuri-sunt-pentru-mai-multi-ani/> .

The MS's persistent lack of response throughout the COVID-19 period to the requests made by myself , my colleagues, and the Physicians for Informed Consent Association to organize public debates regarding COVID-19 vaccination, coupled with the military's coordination of the vaccination and the prevailing pressures to undergo vaccination, reflects the fact that **the COVID vaccination operation was a politico-military action** in which the professional opinions of physicians were disregarded <https://www.digi24.ro/stiri/actualitate/armata-se-implica-in-vaccinarea-populatiei-mapn-a-anuntat-unde-va-fi-tinut-vaccinul-anti-covid-dupa-ce-ajunge-in-tara-1406190?grsc=cookiesUndeft0&grts=58656778&grua=33d0ft257a817d1ca4c4381b87ft8ad83ft&grn=1> . On television networks such as CNN, it was reported that during the 2021 G7 summit, the Prime Minister of Great Britain, **Boris Johnson, called for the entire population of the planet to be vaccinated by the end of 2022 with the experimental vaccines** , despite the fact that the clinical trials were not scheduled for completion until August 2023 at the earliest.



In the year 2024, the Minister of Health of the Netherlands publicly stated that the COVID-19 action was a NATO operation.

The COVID vaccines were a premiere in many respects.

- **The use of new technologies, not properly tested, with an impact on safety.**

Although it was claimed that the COVID-19 pandemic was a health emergency, instead of choosing to produce a vaccine variant for which more experience existed—namely, a vaccine developed through classic methods containing an antigen to which the body would react—it was bizarrely preferred to create vaccines using new technology based on the introduction of genetic material and nanoparticles into human bodies. Furthermore **a process of creation, testing, and approval for a classic vaccine, which usually lasted 8-10 years, was compressed to a period of less than one year for the COVID vaccines.** Relevant to the manner in which the COVID-19 vaccines were produced is the November 2022 statement by the recently retired director of the vaccine research and development department at Pfizer, Kathrin Jansen: “ **We flew the plane while we were still building it** ” <https://www.nature.com/articles/d41573-022-00191-2> . This aspect was unknown to the vast majority of physicians and citizens, who were instead informed that “The mRNA vaccines against

COVID-19 have been rigorously evaluated for safety,” and “The mRNA vaccines have recently become available to the public, but they have been studied for decades”

<https://web.archive.org/web/20220721092000/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html> .

nature > nature reviews drug discovery > an audience with > article
AN AUDIENCE WITH | 11 November 2022

COVID vaccines: “We flew the aeroplane while we were still building it”

Recently retired head of vaccine R&D at Pfizer, Kathrin Jansen, discusses the lightning speed development of SARS-CoV-2 vaccines – and the implications for vaccine platforms.



The unique power of vaccines to prevent disease captured Kathrin Jansen's imagination at an early age. “I remember lining up in the school auditorium for my smallpox vaccine. I thought it was amazing: one shot and you're done. Great!”

Vaccines have not provided quite such a simple solution for COVID, but the ultra-rapid development of these products has been a game-changing lifeline for a world in the throes of a global pandemic. Jansen talks

- The use of Artificial intelligence, which was unregulated at that time

Few are aware that, under the pretext of finding rapid solutions, the COVID vaccines were designed using Artificial intelligence, an imperfect technology that was not regulated at that time . On the website of GAVI—the Global Alliance for Vaccines and Immunization—the following information is found: <https://www.gavi.org/vaccineswork/using-ai-lab-jab-how-did-artificial-intelligence-help-us-develop-and-deliver-covid> -“ When COVID-19 first spread across the globe, researchers rushed to develop a vaccine that could save lives and end the pandemic as quickly as possible. Artificial intelligence (AI) has emerged, accelerating the process in a manner never before seen in the development of vaccines . Machine learning algorithms have analyzed vast amounts of viral genomic data, identifying potential vaccine targets in a fraction of the time it would have taken human researchers . The selection from the genome of the virus of the antigen represented by the contested spike protein was also achieved with the help of artificial intelligence: “For the vaccines against COVID-19, such as those from Pfizer-BioNTech and Moderna , artificial intelligence was essential in the rapid analysis of viral genomes to identify how to trigger a strong immune response , which is crucial for an effective vaccine.” This led to the identification of the spike protein as the optimal target for priming our immune system .”“ Computational models based on artificial intelligence were able to simulate various molecular configurations of the spike protein, allowing scientists to quickly evaluate which configurations were most likely to elicit an effective immune response . This ability to model and optimize potential vaccine candidates contributed to reducing the timeframe from concept to the clinical trials from years to months ” <https://www.gavi.org/vaccineswork/using-ai-lab-jab-how-did-artificial-intelligence-help-us-develop-and-deliver-covid> .“ Moderna's mRNA-1273 vaccine was designed and ready for human testing just 42 days after the publication of the SARS-CoV-2 genome . Similarly, Pfizer/BioNTech's BNT162b2 progressed from sequence selection to an authorized vaccine in less than one year, compressing a typical 8–10 year development process into a mere 269 days ” <https://intuitionlabs.ai/articles/generative-ai-mrna-vaccine-covid19-case-study> , <https://www.medrxiv.org/content/10.1101/2024.10.23.24315991v1> . Therefore, artificial

intelligence, which was unregulated at that time, was utilized for the design, production, and conduct of the clinical trials of the COVID vaccines—an unprecedented fact that the authorities and the physicians who promoted vaccination “forgot” to disclose.

- **The use of nanotechnology is not appropriately regulated, possessing toxic potential**

The lipid nanoparticles utilized for the transport of mRNA were obtained through nanotechnological processes. <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-enters-agreement-acuitas-therapeutics-lipid> Despite being studied and utilized for an extended period, nanotechnology is not appropriately regulated; considering that nano-level particles possess properties distinct from those of the same materials at larger scales, and that—for this reason as well as their minute, intracellular dimensions—these particles also exhibit a different toxicological profile.

Nanotechnology is defined as the understanding and control of matter at the nano-scale, within dimensions ranging from approximately 1 to 100 nanometers, where **unique phenomena enable novel applications**.

Nanomaterials are unique because **they possess SPECIAL PROPERTIES** (mechanical, electronic, chemical, biological, optical) determined by a HIGH SURFACE-TO-VOLUME RATIO, as well as the QUANTUM EFFECT (which occurs at dimensions below 100 nm). <https://www.nano.gov/about-nanotechnology/> . **Due to these unique properties, many researchers contend that nanomaterials must be regulated separately** from the same materials in larger dimensions.

Nanotechnology is a field little known to the public, despite being studied and funded for a very long time, exceeding 25 years.

The regulation of nanomaterials, toxicity assessments, and the ethics of their use have lagged significantly behind technological evolution, owing to the fact that the field of nanotechnology is highly diverse and offers numerous development opportunities purportedly aimed at resolving humanity's challenges, whereas regulation would hinder such progress.

Numerous articles draw attention to regulatory issues as well as the toxicity of nanomaterials <https://www.sciencedirect.com/science/article/abs/pii/S1773224722010292> .

The regulation of nanomaterials has been stalled for the last 20 years—an incomprehensible fact, given the large-scale use of nanotechnology in various industries, as well as in medicinal products, vaccines, food products, cosmetics, the electronics industry, and micro and nanosensors.

In July 2021, European Parliamentarian **Pettiar Vittianov**, a member of the European Committee on the Environment, Public Health and Food Safety, remarked that “ **the innovative mRNA vaccines contain nanoparticles** ” <https://www.theparliamentmagazine.eu/partner/article/nanomedicines-and-nanosimilars-building-a-robust-legislative-framework> . He raised **the necessity of regulating nanomedicinal products and nanosimilars**, stating that “ *the EU has the opportunity to be a world leader in developing a centralized regulation procedure for nanomedicinal products and nanosimilars* ”.

His arguments were as follows:

- *“The assembly of various chemical components into complex nanoparticles requires highly standardized and complex manufacturing processes capable of guaranteeing consistent quality, clinical efficacy, and safety.”*
- *“Changes in quality, size distribution, surface properties, loading and release profiles of medicinal products, aggregation state, and stability can alter the way a nanomedicinal product acts within the body, with a significant impact on patient safety and efficacy.”*

- *"This aspect was highlighted in a recent scientific report by the EAASM, which provides essential recommendations to ensure the safety of patients and to enable the EU to fully capitalize on the potential of nanotechnology."*
- *"The report calls for the development of a scientific consensus regarding the definitions of nanomedicinal products in Europe, the improvement of education, and the promotion of awareness regarding the complexity and sophistication of the nanomedicinal product among political decision-makers, prescribers, payers, and patients."*
- *"Furthermore, the report advocates for the adoption of a centralized procedure by the European Medicines Agency (EMA) for all nanomedicinal products and nanosimilars, which would ensure enhanced scrutiny of these complex products."*

New excipients were used - in the Pfizer-Comirnaty vaccines, the functional lipids ALC-0315 and ALC-0159, and in Moderna-Spikevax, SM-102 and PEG2000-DMG. **At the time of the conditional marketing authorization, complete information for these excipients was not available .**

https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf , https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf

The discrepancy between the official documents of the COVID vaccines and the messages conveyed by the authorities to citizens, and also to physicians

I shall further mention several relevant aspects from the "SUMMARY OF PRODUCT CHARACTERISTICS" for Pfizer Comirnaty, which I have examined in greater depth, as published on the EMA websites (published on February 19, 2021, on the EMA website)

https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf and FDA <https://www.fda.gov/media/144416/download> , <https://www.fda.gov/media/148542/download> , information that was "omitted" from the communications of the CMR, professional organizations, or the authorities:

a. The clinical trials of Pfizer have certain issues, including the following:

- it was not established as a study objective to demonstrate that these products stop the Transmission of the virus
 - the average follow-up period until the EMA conditional marketing authorization was obtained was **only 1.5 months!!!**
 - the efficacy for severe COVID was **66.5%, evaluated based on only 4 cases** (3 in the unvaccinated group and 1 in the vaccinated group) within the study group of approximately 40,000 people, rendering the data statistically irrelevant.
 - The decision that, after **only 6 months of study, the placebo group should also be vaccinated**, on the pretext of the disease's severity, led to **the dissolution of the placebo group**, which ought to have been maintained until the conclusion of the phase III study in 2023.
- <https://web.archive.org/web/20210128003544/https://www.pfizer.com/science/coronavirus/vaccine> ; **this decision was reached despite the fact that during the 6-month period, among the 40,000 study participants , there were only 2 deaths from COVID-19 in the unvaccinated group and one in the vaccinated group, with no statistically significant difference existing between the two lots.**
- https://www.nejm.org/doi/suppl/10.1056/NEJMoa2110345/suppl_file/nejmoa2110345_appendix.pdf . **The dissolution of the placebo group severely compromised the ability to monitor the long-term adverse effects of the COVID vaccines .**

b. The Comirnaty vaccine was developed based on **the genomic sequencing** of the SARS-CoV-2 Wuhan-Hu 1p isolate, **provided by the Chinese** <https://pmc.ncbi.nlm.nih.gov/articles/PMC7094943/> , sequencing

also posted in the GenBank database of the National Institute of Health in the USA <https://www.ncbi.nlm.nih.gov/nuccore/mn908947> ,practically without the manufacturing companies verifying whether the genome indeed corresponds to this virus.

About the product

BNT162b is a mRNA vaccine for prevention of COVID-19. The vaccine is made of a mRNA encoding for the full-length SARS-CoV-2 spike glycoprotein (S) encapsulated in lipid nanoparticles (LNPs). The sequence of the S protein was chosen based on the sequence for the "SARS-CoV-2 isolate Wuhan-Hu-1", which was available when the program was initiated: GenBank: MN908947.3 (complete genome) and GenBank: QHD43416.1 (spike surface glycoprotein).

c.From the „Summary of Product Characteristics,“ it is established that different manufacturing processes were used!!! for the vaccines used in the clinical trials and those intended for administration to the population, the latter having a different quality. “ In the comparability studies, a decrease in RNA integrity was observed for the initial lots of Process 2 compared to the lots of Process 1 ”. (page 17) Process 1 was used for the production of mRNA for the clinical trials and Process 2 for the production of commercial mRNA (https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf page 18). For Process 2 of manufacturing of the vaccine Comirnaty intended for commercialization, plasmid DNA (linearized, derived from E. coli bacteria) was used instead of a PCR-derived DNA template used in manufacturing Process 1, intended for the clinical study (page 19).

Manufacturing process development

Process development changes were adequately summarised. Two active substance processes have been used during the development history; Process 1 (clinical trial material) and Process 2 (commercial process). Details about process differences, justification for making changes, and results from a comparability study are provided. The major changes between active substance process versions were described in the dossier.

and Process 2 AS batches. The Applicant explains that the redistribution is probably due to the use of a linearised DNA plasmid template in Process 2 instead of a PCR-derived DNA template in Process 1. For both processes, the poly(A)tail is anticipated to be sufficiently long to guarantee stability of the RNA and function in translation. This explanation is considered reasonable by the CHMP.

d. Truncated RNA was also found in the composition of the vaccine!!! “Truncated RNA is reflected in the AS specification regarding RNA integrity. However, the characterization of BNT162b2 AS is currently incomplete with respect to this specific parameter. This is particularly significant given that the current acceptance criteria for the AS and of the finished product permit a certain proportion of fragmented species. The applicant must provide additional data to better characterize the truncated and modified mRNA species present in the finished product. Relevant data regarding the characterization of proteins/peptides should be provided for the predominant species” (p. 20)

e. Although it is specified that **the active substance, namely mRNA, requires storage at temperatures between -15 and -20 °C (page 16) , nevertheless, the Comirnaty vaccines were transported and stored at much lower temperatures, from -90 to -60 °C (page 27);** this implies that the low temperatures were recommended to maintain the integrity of the other components of the vaccines, likely the nano-lipid particles. Information in specialized literature regarding the storage temperature of nano-lipid particles and the reason why it must be so low is practically non-existent, a fact that is incomprehensible for products regarding which it was claimed that a certain degree of experience exists. https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf pages 16, 27.

The active substance is stored between -15°C and -25°C. Transportation using an insulated shipper is qualified and shipping time to finished product manufacturing sites are defined. Shipping validation of the intermediate has been agreed as recommendation.

The shipping temperature range of -90 to -60 °C is based on available stability data.

f. The lipid nanoparticles used to transport mRNA are obtained **through nanotechnological processes** . <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-enters-agreement-acuitas-therapeutics-lipid> These nanoparticles **contained new excipients, never before used in humans !!!** – in the vaccines **Pfizer functional lipids ALC-0315** (4-hydroxybutyl)azanediy)bis(hexane-6, 1- diyl)bis(2-hexyldecanoate) , **ALC-0159** (2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide), and in Moderna **SM-102** (Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino)Octanoate) **and PEG2000-DMG** (1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000). At the time of the conditional marketing authorization, complete information regarding these excipients did not exist (page 34–Comirnaty), with such data to be provided at a date subsequent to the granting of the conditional marketing authorization. **This further implies that the EMA and FDA approved products whose exact composition was unknown, cited as proprietary production secrets—a grave matter given the pressure exerted to inject the entire global population and the fact that** , subsequently, independent studies revealed the presence of undeclared elements in these products https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf (page 34), https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf .

Two novel excipients are included in the LNP. Complete information is not provided for both the cationic lipid ALC-0315 and the PEGylated lipid ALC-0159. In order to assure comprehensive control throughout the lifecycle of the finished product and to ensure batch to batch consistency, further information needs to be submitted regarding the synthetic process and control strategy in line with specific obligations (S04, S05).

g. The quantity of excipients , the number of nanoparticles, and the quantity of mRNA per unit volume are not indicated in the product summary!!!

h. There are articles demonstrating that **nanolipid particles** with a composition identical to those used in the mRNA vaccines induce **intense inflammation upon intramuscular administration** in mice **and even death upon intranasal administration** Ndeupen S. The mRNA-LNP platform's lipid nanoparticle component used in preclinical vaccine studies is highly inflammatory. iScience. 2021 Dec 17;24(12):103479. doi: 10.1016/j.isci.2021.103479. Epub 2021 Nov 20. PMID: 34841223; PMCID: PMC8604799. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8604799/#bib53>

i. **No genotoxicity studies were conducted** albeit it is acknowledged that truncated RNA was present in the evidence, despite existing literature regarding the toxicity of the nanoparticles and the possibility that they may affect the integrity of the DNA. <https://www.sciencedirect.com/science/article/abs/pii/S1773224722010292> . In the EMA assessment report for the Pfizer Comirnaty vaccine https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf it is stated on page 50: “ **No genotoxicity studies have been provided** . This is acceptable, as the components of the vaccine formulation are lipids and RNA, which **are not expected to have genotoxic potential** . The new excipient ALC-0159 contains a potential acetamide group. The risk assessment conducted by the Applicant indicates that **the risk of genotoxicity related to this excipient is very low** , based on literature data where the genotoxicity of acetamide is associated with high doses and chronic administration (≥ 1000 mg/kg/day). Given that **the amount of excipient ALC-0159 in the finished product is low (50 µg/dose), its clearance is high, and only two administrations of the product are recommended in humans, the risk of genotoxicity is expected to be very low.** ”

Genotoxicity

No genotoxicity studies have been provided. This is acceptable as the components of the vaccine formulation are lipids and RNA that are not expected to have genotoxic potential.

The novel excipient ALC-0159 contains a potential acetamide moiety. Risk assessment performed by the Applicant indicates that the risk of genotoxicity relating to this excipient is very low based on literature data where acetamide genotoxicity is associated with high doses and chronic administration (≥ 1000 mg/kg/day). Since the amount of ALC-0159 excipient in the finished product is low (50 μ g/dose), its clearance is high and only two administrations of the product are recommended for humans, the genotoxicity risk is expected to be very low.

j. **The lipid nanoparticles in the mRNA experimental products do not remain solely at the injection site, but reach various organs, including the brain**, as evidenced in the table below, obtained from a Pfizer document declassified following the January 6, 2022, decision of a US court whereby the Pfizer company was compelled to declassify documents and publish 55,000 pages monthly: https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf.

Table 3 Mean Recovery of Total Radioactivity in Tissues Following Single Intramuscular Administration of [3 H]-08-A01-C01 to Wistar Han Rats

Target Dose Level: 50 μ g mRNA/Animal; 1.29 mg Total Lipid/Animal

Results expressed as % administered dose

Sample	0.25 min		1 h		2 h		4 h		8 h		24 h		48 h	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Adrenal glands	0.001	*0.001	0.002	0.012	0.005	0.015	0.012	0.018	0.026	0.043	0.083	0.049	0.104	0.108
Bladder	0.000	*0.000	0.001	0.001	0.001	0.001	0.001	0.001	0.002	0.000	0.002	0.001	0.002	0.002
Brain	0.011	*0.002	0.010	0.016	0.021	0.019	0.021	0.011	0.014	0.007	0.012	0.007	0.011	0.007
Eyes	0.000	*0.000	0.000	0.001	0.001	0.001	0.002	0.001	0.002	0.001	0.002	0.001	0.003	0.002
Heart	0.028	*0.008	0.032	0.079	0.065	0.102	0.067	0.052	0.061	0.022	0.035	0.018	0.039	0.020
Injection site	32.887	6.815	68.829	36.411	39.053	24.094	47.710	9.056	18.731	24.993	31.957	26.295	32.823	16.426
Kidneys	0.069	0.030	0.077	0.171	0.149	0.272	0.136	0.082	0.109	0.040	0.068	0.039	0.071	0.042
Large intestine	0.011	*0.004	0.018	0.032	0.054	0.075	0.236	0.148	0.463	0.346	1.091	0.293	0.810	0.714
Liver	0.995	0.209	2.834	2.907	7.629	7.030	15.027	8.699	21.519	14.580	19.901	10.977	13.953	18.357
Lung	0.082	0.022	0.085	0.117	0.189	0.167	0.226	0.112	0.180	0.064	0.136	0.065	0.131	0.070
Ovaries (females)	-	*0.001	-	0.009	-	0.008	-	0.016	-	0.025	-	0.037	-	0.095
Pancreas	0.005	0.001	0.006	0.008	0.015	0.012	0.013	0.017	0.014	0.016	0.013	0.009	0.015	0.023
Pituitary gland	0.000	*0.000	0.000	0.001	0.000	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001
Prostate (males)	0.001	-	0.001	-	0.002	-	0.003	-	0.003	-	0.004	-	0.003	-
Salivary glands	0.004	*0.002	0.005	0.008	0.007	0.009	0.009	0.006	0.007	0.003	0.008	0.003	0.010	0.007
Small intestine	0.032	*0.015	0.124	0.135	0.353	0.285	0.623	0.462	0.972	0.580	1.275	0.536	0.971	0.698
Spinal cord	0.001	*0.000	0.001	0.002	0.001	0.002	0.003	0.002	0.001	0.001	0.001	0.001	0.001	0.001
Spleen	0.014	*0.011	0.087	0.098	0.232	0.418	0.351	0.419	1.118	0.845	0.957	0.685	0.914	1.146
Stomach	0.008	*0.003	0.016	0.022	0.033	0.035	0.037	0.022	0.055	0.024	0.054	0.020	0.049	0.029
Testes (males)	0.007	-	0.010	-	0.017	-	0.030	-	0.034	-	0.074	-	0.074	-
Thymus	0.005	*0.002	0.006	0.008	0.008	0.012	0.018	0.006	0.012	0.003	0.009	0.004	0.008	0.007
Thyroid	0.000	*0.000	0.000	0.001	0.001	0.001	0.001	0.001	0.001	0.000	0.001	0.000	0.001	0.001
Uterus (females)	-	*0.002	-	0.011	-	0.015	-	0.008	-	0.016	-	0.018	-	0.022

*=Mean includes results calculated from data less than 30 cpm above background

Certain information regarding the biodistribution of the nanoparticles from the Pfizer vaccine was also provided in the "SUMMARY OF PRODUCT CHARACTERISTICS" (published on February 19, 2021, on the EMA website for the Comirnaty vaccine produced by Pfizer), pages 46 and 47. Despite being summary in nature, these data should have commanded attention and necessitated a cautious approach from both the authorities who granted conditional authorization for the product and those who promoted vaccination in Romania; however, this did not occur, which incriminates all aforementioned parties, as the cells of the organism that integrate the vaccine particles are predisposed to immune attack. Thus, following plasma clearance, the liver appears to be the primary organ in which ALC-0315 and ALC-0159 are distributed. It was estimated that "the percentage of the dose distributed to the liver is ~60% for ALC0315 and ~20% for ALC-0159" (page 46). „ Over a 48-hour period, the distribution was observed primarily in the liver, adrenal glands, spleen and ovaries, with peak concentrations observed 8-48 hours post-administration. Total recovery (% of the injected dose) of radiolabeled LNP+modRNA outside the injection site was highest in the liver (up to 21.5%) and significantly lower in the spleen ($\leq 1.1\%$), adrenal glands ($\leq 0.1\%$) and ovaries ($\leq 0.1\%$) " (page

Following plasma clearance, the liver appears to be the major organ to which ALC-0315 and ALC-0159 distribute. The applicant has estimated the percent of dose distributed to the liver to be ~60% for ALC-0315 and ~20% for ALC-0159. The observed liver distribution is consistent with the observations from the biodistribution study and the repeat-dose toxicology, both using IM administration.

detected in most tissues, with the greatest levels in plasma observed 1-4 hours post-dose. Over 48 hours, distribution was mainly observed to liver, adrenal glands, spleen and ovaries, with maximum concentrations observed at 8-48 hours post-dose. Total recovery (% of injected dose) of radiolabeled LNP+modRNA outside the injection site was greatest in the liver (up to 21.5%) and was much less in spleen ($\leq 1.1\%$), adrenal glands ($\leq 0.1\%$) and ovaries ($\leq 0.1\%$). The mean concentrations and tissue

Information regarding the **biodistribution of the Moderna vaccine** was disclosed in the Moderna vaccine Assessment Report dated March 11, 2021 (I repeat— **this report was not transmitted to physicians; I found it by chance on the ANMDMR website translated into Romanian , the last update being on 10-11-2021 !!!** <https://www.anm.ro/medicament-de-uz-uman/ftarmacovigilenta/informatii-vaccinuri-covid-19/>) (https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf page 47):

*“Concentrations of mRNA-1647 were **quantifiable in most tissues examined** at the first time point (2 hours post-dose), and maximum concentrations were achieved between 2 and 24 hours post-dose in tissues with exposures higher than those in plasma. **In addition to the injection site [muscle] and the lymph nodes [proximal and distal], elevated concentrations of mRNA** (relative to plasma levels) were identified **within the spleen and eyes** . Both tissues were examined within the toxicological studies conducted on the final formulation of the mRNA-1273 vaccine. **Low levels of mRNA were detectable in all examined tissues** , with the exception of the kidneys. These **included the tissues of the heart, lungs, testes, and also the brain** , indicating that **the mRNA/LNP platform crossed the blood-brain barrier** , albeit at very low levels (2-4% of the plasma level) **The hepatic distribution** of mRNA-1647 is also evident in this study, consistent with reports in the specialized literature stating that **the liver is a common target organ of LNPs** .”*

Concentrations of mRNA-1647 were quantifiable in the majority of tissues examined at the first time point collected (2 hours post-dose) and peak concentrations were reached between 2- and 24-hours post-dose in tissues with exposures above that of plasma. Besides injection site [muscle] and lymph nodes [proximal and distal], increased mRNA concentrations (compared to plasma levels) were found in the spleen and eye. Both tissues were examined in the frame of the toxicological studies conducted with mRNA-1273 final vaccine formulation. Low levels of mRNA could be detected in all examined tissues except the kidney. This included heart, lung, testis and also brain tissues, indicating that the mRNA/LNP platform crossed the blood/brain barrier, although to very low levels (2-4% of the plasma level). Liver distribution of mRNA-1647 is also evident in this study, consistent with the literature reports that liver is a common target organ of LNPs.

k. Furthermore, the systemic distribution of the COVID-19 vaccines was premeditated **by the decision to administer the vaccines intramuscularly!!!** . It was known long ago that the intramuscular administration of lipid nanoparticles results in systemic biodistribution, as clearly demonstrated in this article published in 2015 <https://pmc.ncbi.nlm.nih.gov/articles/PMC4624045/#ref-list1> Pardi N. Expression kinetics of

nucleoside-modified mRNA delivered in lipid nanoparticles to mice by various routes. J Control Release. 2015 Nov 10;217:345-51. doi: 10.1016/j.jconrel.2015.08.007. Epub 2015 Aug 8. PMID: 26264835; PMCID: PMC4624045.

*“When mRNA-LNPs were **injected intramuscularly** or intratracheally, similar to intravenous and intraperitoneal administration, a large part of the luciferase activity was detectable in the liver, demonstrating the systemic spread of the nanoparticles.”” **Subcutaneous and intradermal administration of mRNA-LNP resulted in the production of proteins only at the injection site.**”*

I. Furthermore, **the presence of polyethylene glycol (PEG) in the composition of the lipid nanoparticles**, specifically the molecules ALC-0159 (2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide) in the Pfizer-Comirnaty vaccine, and PEG2000-DMG (1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000) in the Moderna vaccine **SM-102**, constitutes **additional evidence of the premeditated intent for the mRNA nanoparticles to reach the systemic circulation**, spreading to all organs, **including the brain**. Furthermore, **PEG particles serve to decrease the immunogenicity of the nanoparticles** (uptake by immune cells) and **to promote biocompatibility**, thereby facilitating the uptake of vaccine nanoparticles by the body's non-immune cells rather than by the cells of the immune system, contrary to the purpose of a vaccine, as demonstrated in this article <https://www.nature.com/articles/s41598-024-80646-1> Tan, YF., Hii, LW., Lim, WM. et al. Polyethylene glycol-phospholipid functionalized single-walled carbon nanotubes for enhanced siRNA systemic delivery. Sci Rep 14, 30098 (2024). <https://doi.org/10.1038/s41598-024-80646-1> :

*“The **polyethylene glycol (PEG)** component, on the other hand, is renowned for its biocompatibility and its capacity to enhance solubility in physiological fluids. Its hydrophilic nature promotes the stable dispersion of small-walled carbon nanotubes (SWNT), preventing unwanted aggregation in biological environments. Furthermore, **PEGylation reduces the potential immunogenicity of the nanoparticles, facilitating longer circulation times and reducing premature clearance from the bloodstream.**”*

and the aqueous biological environment³⁵. The polyethylene glycol (PEG) component, on the other hand, is renowned for its biocompatibility and ability to enhance solubility in physiological fluids. Its hydrophilic nature promotes stable dispersion of SWNTs, preventing undesirable aggregation in biological media. Furthermore, PEGylation reduces the potential immunogenicity of nanoparticles, facilitating longer circulation times and reducing premature clearance from the bloodstream^{35,36}. This ensures that a higher proportion of the siRNA cargo

Another article asserting the same regarding the role of PEG molecules in nanolipid particles is <https://pubs.acs.org/doi/10.1021/acs.bioconjchem.3c00174> Rumiana Tenchov,

PEGylated Lipid Nanoparticle Formulations: Immunological Safety and Efficiency Perspective, Bioconjugate Chemistry 2023 34 (6), 941-960 DOI: 10.1021/acs.bioconjchem.3c00174 “**PEGylation has proven particularly effective in conferring a longer systemic circulation of the LNPs**, thus considerably improving their pharmacokinetics and efficiency.”

Lipid nanoparticles (LNPs) have been recognized as efficient vehicles to transport a large variety of therapeutics. Currently in the spotlight as important constituents of the COVID-19 mRNA vaccines, LNPs play a significant role in protecting and transporting mRNA to cells. As one of their key constituents, polyethylene glycol (PEG)–lipid conjugates are important in defining LNP physicochemical characteristics and biological activity. PEGylation has proven particularly efficient in conferring longer systemic circulation of LNPs, thus greatly improving their pharmacokinetics and efficiency. Along with revealing the

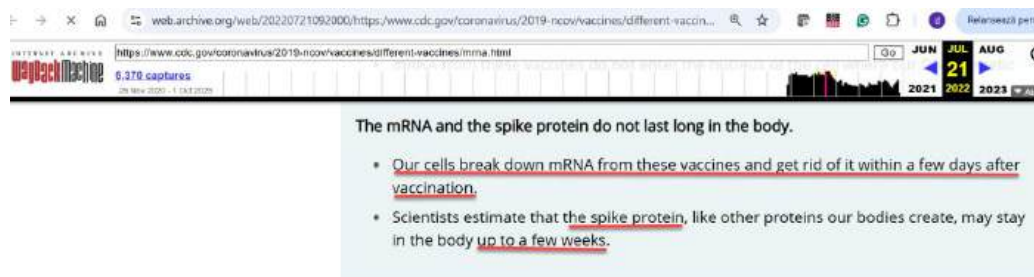
m. Given that the lipid nanoparticles do not remain solely at the injection site but reach various organs, medical logic dictates that **these nanoparticles can fuse with the lipid membranes in the tissues they reach, and the spike protein may be exposed on the membranes of these cells—hepatic, splenic, adrenal, and ovarian—triggering autoimmune responses resulting in destruction of these cells.** This concept is expounded upon in the article

Ndeupen S. The mRNA-LNP platform's lipid nanoparticle component used in preclinical vaccine studies is highly inflammatory. *iScience*. 2021 Dec 17;24(12):103479. doi: 10.1016/j.isci.2021.103479. Epub 2021 Nov 20. PMID: 34841223; PMCID: PMC8604799. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8604799/#bib53> . From this

point of view, I contend that if all lots of the products designated as vaccines had contained mRNA encoding the spike protein, as asserted in the product leaflets, all vaccinated persons should have developed severe autoimmune diseases by now, resulting from the expression of this protein on the surface of all cells in the body—a phenomenon that has not occurred, except to a limited extent. Among the adverse reactions of the COVID-19 vaccines cited in the literature, certain autoimmune diseases are also mentioned, which may have been triggered, to a lesser extent, by the nano particles present in these products:

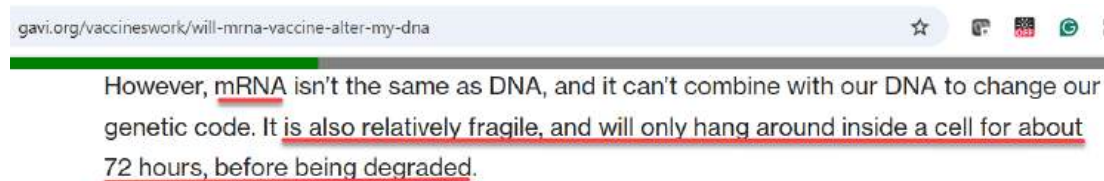
“Although mRNA primarily transfects cells near the injection site, it could hypothetically reach any cell in the body.”, “The resulting translated protein could be presented on MHC-I as peptides or exposed as a whole protein in the cell membrane.” “In both cases, cells expressing the vaccine peptide/protein on their surface could be targeted and destroyed by cells of the adaptive and innate immune system, CD8+T cells and natural killer (NK) cells”, “the so-called delayed-type hypersensitivity reaction, which develops in some patients a few days after vaccination, or the myocarditis/pericarditis recently reported in some of the vaccinated persons, or CNS inflammation observed in a small number of MS patients vaccinated could indeed be evidence of immune responses targeting cells expressing vaccine-derived peptides/proteins.”

n. Another erroneous claim by authorities and professional medical organizations was that **mRNA degrades quickly after injection, a fact refuted by subsequent studies**. Thus, the CDC stated on July 15, 2022 ***“mRNA and the spike protein do not last long in the body. Our cells break down the mRNA from these vaccines and eliminate it within a few days after vaccination. Scientists estimate that the spike protein, like other proteins our body creates, can remain in the body for up to a few weeks.”*** and that ***“the COVID-19 vaccines with mRNA have been rigorously evaluated for safety”*** <https://web.archive.org/web/20220721092000/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>



mRNA COVID-19 Vaccines Have Been Rigorously Evaluated for Safety

Furthermore, on the GAVI website, a post from December 15, 2020, states that mRNA *“is relatively fragile and will remain inside a cell for only approximately 72 hours before being degraded”* <https://www.gavi.org/vaccineswork/will-mrna-vaccine-alter-my-dna>.



Severe disease cases were uncommon in the study: 1 case in the vaccine group and 4 cases in the placebo group (one case in the all evaluable population) after 7 days post second vaccination. None of the severe cases were baseline positive for SARS-CoV-2.

In the evaluable efficacy population, subjects without evidence of prior SARS-CoV-2 infection, the estimated VE against severe COVID-19 occurring at least 7 days after dose 2 was 66.4% (95% CI: -124.8%: 96.3%). The posterior probability for the true VE greater than 30% is 74.29% (7 days) and 74.32% (14 days), which did not meet the pre-specified success criterion for this endpoint, therefore no reliable conclusion can be drawn at this stage. While data on severe COVID-19 are limited, the experience with other vaccines (rotavirus and influenza vaccines with known efficacy against mild disease but better efficacy against severe disease) coupled with the high observed vaccine efficacy observed for BNT162b2 on all COVID-19 cases in populations with any comorbidity gives reassurance that the vaccine is likely to prevent severe disease. However, a precise estimate of its protective effect is presently lacking. The final study report may include additional data to the extent that the study is continued in a randomised fashion with a placebo group.

The assertions regarding the so-called rapid degradation of the injected mRNA have been refuted by several studies, including **a Romanian study from June 2022**, conducted by a team of physicians and researchers from Victor Babeș, the Carol Davila Faculty of Medicine, the Titu Maiorescu Faculty of Medicine, the Bucharest University Emergency Hospital, and the Cantacuzino Institute <https://pmc.ncbi.nlm.nih.gov/articles/PMC9313234/> Ferttig TE, Vaccine mRNA Can Be Detected in Blood at 15 Days Post-Vaccination. Biomedicine. 2022 Jun 28;10(7):1538. doi:

10.3390/biomedicine10071538. PMID: 35884842; PMCID: PMC9313234.

The conclusion of this article is: ***“we have shown that***

the mRNA of the vaccine BNT162b2 remains in the systemic circulation of vaccinated individuals for at least 2 weeks, during which time it likely retains its capacity to induce the expression of the S protein in sensitive cells and tissues. ***We have also shown that leukocytes and platelets are not favorable targets for the expression of the S protein in vitro***. ***More complex human biodistribution and pharmacokinetic studies are necessary to elucidate the tissue tropism of the mRNA vaccine particles***, as well as the efficiency of absorption and transfection for other cell types. ***This would serve to further optimize future mRNA vaccine formulations.*** This study further finds that ***the vaccine particles are taken up by the non-immune cells of the body rather than by the immune cells, a fact which does not satisfy the requirements of a vaccine.***

In conclusion, we showed that BNT162b2 vaccine mRNA remains in the systemic circulation of vaccinated individuals for at least 2 weeks, during which it likely retains its ability to induce S-protein expression in susceptible cells and tissues. We also showed that WBCs and platelets are not favourable targets for S-protein expression in vitro. More complex human biodistribution and pharmacokinetics studies are required to elucidate the tissue tropism of mRNA vaccine particles as well as uptake and transfection efficiencies for other cell types. This would serve to further optimise future mRNA vaccine formulations.

o. The authorities and professional organizations failed to specify, when asserting the 95% efficacy of the vaccine, that this reflected the efficacy for all forms of COVID-19 within the study; these were predominantly mild and moderate forms of the disease which would have produced natural, long-lasting immunity in unvaccinated individuals and, therefore, would not have necessitated the administration of a vaccine to achieve immunization. Thus, during the study period, until the granting of the conditional marketing authorization, there were 170 cases of COVID-19 among the approximately 40,000 persons included in the study, specifically 162 cases in the unvaccinated group and 8 cases in the vaccinated group. **Of the 170 cases, only 4 cases were severe COVID, with 3 in the unvaccinated group and one case in the vaccinated group** . Furthermore, it is important to note that not a single case of critical COVID (**severity grade 4 of the COVID-19 disease**) and no death **were listed in this study** prior to the emergency authorization of the Pfizer-Comirnaty vaccine (the vaccine I have studied most extensively). (pages 95

https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf)

p. Based on the conclusions of the EMA Assessment Reports for the Pfizer-Comirnaty COVID vaccines (which I have studied more closely) https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf , as well as the FDA Emergency Use Authorization reports <https://www.fda.gov/media/144416/download> <https://www.fda.gov/media/148542/download> , the safety and efficacy of the vaccines, and the prevention of the transmission of the virus were not established, contrary to the assertions made by the physicians designated to appear in the media.

“The following are considered MISSING DATA:

- ***Duration of protection***
- ***Efficacy in certain populations at high risk of severe COVID-19***
- ***Efficacy in individuals previously infected with SARS-CoV-2***
- ***Future efficacy of the vaccine, influenced by the characteristics of the pandemic, changes of the virus, and/or potential effects of co-infections***
- ***Efficacy of the vaccine against asymptomatic infection***
- ***Efficacy of the vaccine on long-term effects of the COVID-19 disease***
- ***Efficacy of the vaccine on mortality***
- ***Efficacy of the vaccine against transmission of SARS-CoV-2”*** -(Page 38 <https://www.ftda.gov/media/148542/download>)

5.2 Unknown Benefits/Data Gaps

The unknown benefits and data gaps associated with the Pfizer-BioNTech COVID-19 vaccine when used in adolescents 12-15 years of age are the same as those detailed in the memorandum authorizing the vaccine for emergency use in for the individuals 16 years of age and older.¹ They relate to:

- Duration of protection
- Effectiveness in certain populations at high risk of severe COVID-19
- Effectiveness in individuals previously infected with SARS-CoV-2
- Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections
- Vaccine effectiveness against asymptomatic infection
- Vaccine effectiveness against long-term effects of COVID-19 disease
- Vaccine effectiveness against mortality
- Vaccine effectiveness against transmission of SARS-CoV-2

q. Regarding use during pregnancy, the EMA assessment report for the Pfizer-Comirnaty vaccine dated **February 2021** concluded that insufficient information existed for use during pregnancy, as pregnant women were excluded from the study (pregnancy being an exclusion criterion).

“Since pregnant and breastfeeding women were excluded from the study, no information is available for these populations” https://www.ema.europa.eu/en/documentis/assessmentti-reportti/comirnaty-epar-public-assessmentti-reportti_en.pdf#page=1

Missing information

Since pregnant and breast-feeding women were excluded from the study, no information is available for those populations. It is agreed to include use during **pregnancy** and while breastfeeding as missing information in the RMP.

However, obstetrical and gynecological societies worldwide, including in Romania, rushed to recommend these products to pregnant women, asserting—without evidence—that “**adverse reactions are the same as in the general population, in both frequency and intensity,**” or **assuming (!!!)** that they possess efficacy and safety similar to that of non-pregnant women: “*Given the mechanism of action of these vaccines and the results of phase II and III clinical trials, it is expected that the efficacy and safety of the vaccines in pregnant women will be the same as in non-pregnant women* (ACOG, 2021).”

<https://soqr.ro/wp-content/uploads/2021/01/POZITIA-SOCIETATII-DE-OBSTETRICA-SI-GINECOLOGIE-DIN-ROMANIA-FATA-DE-VACCINAREA-COVID-19-A-FEMEII-GRAVIDE-SI-CARE-ALAPTEAZA.pdf>.



POZIȚIA SOCIETĂȚII DE OBSTETRICĂ ȘI GINECOLOGIE DIN ROMÂNIA (SOGR) FAȚĂ DE VACCINAREA COVID-19 A FEMEII GRAVIDE ȘI CARE ALĂPTEAZĂ

15 Ianuarie 2021

SOGR recomandă tuturor medicilor obstetricieni să discute pe larg cu pacientele lor gravide sau care alăptează aspectele subliniate în continuare în acest material.

Discuția trebuie să ofere informații **echilibrate, balansate, nedirecționate**, să prezinte într-un limbaj accesibil datele științifice și consensurile elaborate de grupurile internaționale de experți prezentate în continuare.

Trebuie subliniat ce se știe sigur dar și ce nu se știe încă, explicând riscurile mamei și fătului în momentul îmbolnăvirii cu Covid-19 și severitatea bolii, eficiența vaccinului, datele limitate încă de siguranță a vaccinului la gravide și motivul acestei limitări. De asemenea, faptul că reacțiile adverse sunt aceleași ca în populația generală, și ca frecvență și ca intensitate.

Decizia de a se vaccina sau nu trebuie să rămână a pacientei, după ce a primit toate informațiile și răspunsurile la întrebările ei din partea obstetricianului. Trebuie să fie

Furthermore, on January 19, 2021, on the national channel TVR1, a video was broadcast featuring several obstetricians urging vaccination, stating that: “ **The Romanian Society of Obstetrics and Gynecology requests the authorities NOT to restrict the access of pregnant women to COVID-19 vaccination** ”.

<https://bitt.ly/3izmHZN> , <https://www.facebook.com/wattech/?v=2553399981625772>

1. Procurement contracts for vaccines entered into by the MS and The European Commission with COVID-19 vaccine manufacturers were unjustifiably classified.
Citizens were requested or coerced to undergo vaccination with products for which the procurement contracts remained classified.
2. In Romania, no funds were established for the compensation of vaccination victims, contrary to the practice in other states.
3. **The deaths post-vaccination did not trigger INSP investigations** involving the analysis of vaccine lots according to the INSP protocol; in effect, **this INSP protocol was not observed** !!!
<https://insp.gov.ro/download/ghid-investigare-cazuri-rapi-pdf/?wpdmdl=96227&reftresh=68cee9078e3aa1758390535> .

The quality control of the COVID-19 vaccines was deficient.

Regarding the vaccines, including the COVID-19 mRNA or viral vector vaccines, these are centrally approved and evaluated through a special EU procedure for the official batch release by the control authority OCABR (Official Control Authority Batch Release).

In response 103247 dated 08.02.2024 to the petition submitted by me on 07.01.2024, ANMDMR states:

*“The EU procedure for the official batch release by the control authority **consists of specific laboratory tests as well as the critical evaluation of the production and batch control protocol (analysis of specific information collected by the manufacturer during manufacturing); The applicant shall provide the OMCL (official medicines control laboratories) with all relevant details regarding in-process testing, testing of the finished product, labeling, testing methods, the specifications approved at the authorization of the vaccine, and any other documents deemed necessary for the evaluation of the batch.** ”*

ANMDMR recognizes the official batch release carried out by the control authority of another EU Member State pursuant to Article 114 of Directive 2001/83/EC of THE EUROPEAN PARLIAMENT and of THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use <https://eur-lex.europa.eu/legal-content/RO/TXT/?uri=CELEX%3A32001L0083>

“(1) Where it considers it necessary in the interests of public health, a Member State may require the marketing authorization holder:

*- vaccines containing live viruses,
- immunological medicinal products used in the primary immunization of infants or other risk groups,
- immunological medicinal products used in public health immunization programs,
- new immunological medicinal products or immunological medicinal products manufactured using new technologies or technologies which are modified or new for a particular manufacturer, during a transitional period normally specified in the marketing authorization, to submit evidence from each lot of the bulk product and/or the medicinal product for examination by a state laboratory or a laboratory designated for that purpose before release onto the market, **unless, in the case of a lot manufactured in another Member State, the competent authority of that Member State has previously examined the lot in question and declared it to be in accordance with the approved specifications.**
Member States shall ensure that any such examination is carried out within 60 days of receipt of the evidence.”*

Referitor la solicitarea nr. 13: "Sunt analize private de microscopie electronică cu raze X care au constatat prezența în vaccinuri dar și în unele anestezice dentare a siliciului, dar și a unor atomi de metale care nu apar în prospectele acestor produse. ANMDMR verifică dacă compoziția trecută în prospectul medicamentelor/vaccinurilor din România corespunde cu cea reală?"

În timpul evaluării unui medicament în vederea autorizării pentru punerea pe piață, ANMDMR verifică dacă compoziția înscrisă în prospectul medicamentelor de uz uman este în conformitate cu documentația referitoare la calitatea medicamentului depusă de către solicitanții autorizațiilor de punere pe piață a medicamentelor (Secțiunea 3.2.P.1 Compoziția medicamentului, Secțiunea 3.2.P.3.2 Formula seriei de fabricație).

Menționăm că, în cazul procedurii europene descentralizate, de recunoaștere mutuală și de utilizare repetată, documentația depusă de solicitanți este aceeași în toate statele membre care participă la procedura de autorizare și este evaluată simultan de către agențiile de reglementare din toate aceste state, nu doar de către ANMDMR.

Vaccinurile intră sub incidența procedurii Uniunii Europene pentru eliberarea oficială a seriei de către autoritatea de control (Office Control Authority Batch Release, OCABR), elaborate de către Directorul European pentru Calitatea Medicamentului și Îngrijirea Sănătății (European Director for the Quality of Medicine and Healthcare, EDQM) și aplicabilă autorităților competente din statele membre ale Uniunii Europene și statelor care au semnat Acordul spațiului Economic European (SEE): Norvegia, Islanda și Liechtenstein.

Procedura OCABR se realizează conform legislației Uniunii Europene, în baza art. 114 din Directiva 2001/83/CE a Parlamentului European și a Consiliului din 6 noiembrie 2001 de instituire a unui cod comunitar cu privire la medicamentele de uz uman, astfel cum a fost transpusă prin prevederile art. 862 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată, cu modificările și completările ulterioare.

Eliberarea oficială a seriilor de vaccin de către autoritatea de control se efectuează înainte de intrarea pe piață, pentru fiecare serie de vaccin și se adaugă aceleia care trebuie efectuată de către fabricant pentru o serie dată.

Procedura Uniunii Europene pentru eliberarea oficială a seriei de către autoritatea de control constă în testări de laborator specifice, precum și evaluarea critică a protocolului de producție și control al seriei (analiza informațiilor specifice colectate de producător în timpul fabricației); aplicantul pune la dispoziția OMCL toate detaliile relevante privind testările în proces, testarea produsului finit, etichetare, metodele de testare și specificațiile aprobate la autorizarea vaccinului și orice alte documente considerate necesare pentru evaluarea seriei.

Conform procedurii Uniunii Europene de eliberare oficială a seriilor, pentru fiecare serie de vaccin testată de un Laborator oficial de control a medicamentului (OMCL) al unei autorități competente din rețeaua europeană, se emite, în cazul conformității tuturor parametrilor testați, certificatul de eliberare oficială a seriei (OCABR), care permite comercializarea ulterioară a seriei respective în Uniunea Europeană. Acest document certifică faptul că seria de produs a fost

examinată și testată de către un OMCL în conformitate cu prevederile ghidurilor OCABR referitoare la medicament și specificațiile aprobate, prevăzute în monografiile relevante ale Farmacopeei Europene și în autorizația de punere pe piață.

În România, OMCL-ul ANMDMR este membru atestat EDQM, cu drepturi depline în rețeaua Laboratoarelor Oficiale de Control al Medicamentului (Official Medicines Control Laboratories = OMCL) din Uniunea Europeană.

În conformitate cu prevederile Legii nr. 95/2006, republicată, cu modificările și completările ulterioare, ANMDMR recunoaște eliberarea oficială a seriilor efectuată de autoritatea de control din alt stat membru al Uniunii Europene. Eliberarea oficială a seriei efectuată de o autoritate de control dintr-un stat membru al Uniunii Europene pentru o serie de vaccin este valabilă în toate celelalte state membre, inclusiv în România.

<https://www.edqm.eu/en/omcl/battich-release-ftor-human-biologicals-vaccines-blood-and-plasma-derivatives> we learn the manner in which the network of OMCL laboratories intended to certify the quality of the COVID vaccines was organized very early on

„Interactions between OMCLs and manufacturers/marketing authorization holders. Manufacturers of medicinal products that may be subject to OCABR in accordance with Article 114 of Directive 2001/83/EC, as amended by Directive 2004/27/EC, **should contact the OMCLs as soon as possible**. As stated in the European Medicines Agency's advice on the pre-authorization procedure for users of the centralized procedure (question 3.3.4), **it is strongly recommended that an applicant initiate early collaboration with one or more OMCLs. Ideally, this should take place at least one year before the submission of the marketing authorization application, to allow for an exchange of information between the OMCL and the applicant, which should be considered during the development of the testing methodology**. It is advisable that this activity also be undertaken with several OMCLs and that **applicants seriously consider designating two OMCLs for the market release of the authorized medicinal product lot, in order to secure the supply chain and minimize the risk of shortages**.“ Given these statements and, simultaneously, the speed with which the COVID-19 vaccines were developed and tested, questions regarding how these tests were performed, the quality of these tests, and the methods used are legitimate. The initial OMCL evaluation guidelines for COVID vaccines dated 2020-11-12 <https://www.edqm.eu/en/-/ftull-ocabr-guideline-ftor-pandemic-covid-19-vaccine-mrna-now-available> can no longer be found online to identify **the laboratory methods utilized for the first approved lots of COVID vaccines** which were distributed rapidly following the granting of the EMA conditional marketing authorization on [https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty#authorisation-details](https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty/comirnaty#authorisation-details). Based on the current OCABR evaluation guidelines for COVID vaccines by the MS laboratories recognized by the EU for the official batch release, it is not clearly established which investigations are performed for the quality analysis of the vaccines. Presented below is the document detailing the OMCL evaluation guidelines for COVID vaccines https://www.edqm.eu/documentts/52006/1913863/13_COVID-19_mRNA150124.doc/8ee60cea-b0e6-8ft57-ftc7a-6a9a98a23706?tt=1705307262485 updated on 17-01-2024

<https://www.edqm.eu/en/omcl/human-ocabr-guidelines#TopHuman>. It does not clearly emerge from this guide whether the analyses to determine the mRNA (identity, content, integrity, impurities, 5'cap, Poly (A) Tail), DNA contamination, proteins, endotoxins, pH, of the lipid nanoparticles, and residual solvents are performed by the OMCL laboratory or are adopted from the documentation submitted by the manufacturer. Furthermore, it is not apparent which methods are approved for the analysis of the COVID vaccines.

The COVID vaccines were developed with unprecedented speed. Stages that previously lasted for years were compressed into months to allow for the conditional authorization of the COVID-19 experimental products.

The tests conducted on the COVID vaccines were certainly not extensive, given the assertions that the OMCL tests only a few critical parameters selected by consensus and approved by the OCABR network. <https://www.iabs.org/~documentts/routte%3A/download/2339/>

PSG: Test Methods for OCABR

OCABR Tests	Methods
<p>Section 2 of the product specific guideline</p> <p><u>OMCLs test only a few critical parameters with added value for independent evaluation</u></p> <p><u>Tests are chosen by consensus and approved by the OCABR network</u></p> <p>The main focus is potency and safety</p> <p>Specifications for pass/fail are outlined in the European Pharmacopoeia monographs and the marketing authorisation (MA). They are not part of product specific guidelines</p>	<ul style="list-style-type: none"> • Use of compendial, MA or fully validated in-house methods • Demonstrate appropriate validation for use of method for the product in the OMCL • Use of official standards Biological Reference Preparations (BRPs) (or validated in-house standard) established in International Units (where possible) • QA systems in place: ISO 17025 is the agreed reference • Obligation to use the fewest animals possible and in the most humane way (application of 3Rs)

On the Paul Ehrlich Institute website, in an article titled “COVID-19 Vaccine Batch Release by EU Medicines Control Laboratories: Challenges and Successes”

<https://www.pei.de/EN/newsroom/press-releases/year/2023/06-covid-19-vaccine-batch-release-challenges-successes.html>

it is stated that **the quality testing of the vaccines by the OMCL laboratories was carried out with great speed**, such that the procedure which should normally have lasted 60 days was at times limited to mere hours. These assertions, coupled with the fact that **these were tests of vaccines involving new technology, and that the analysis of such vaccines required qualified and numerically sufficient personnel, as well as the necessary time to perform complex tests such as those specified in the OCABR guidelines for the quality assessment of mRNA COVID-19 vaccines** by the OMCL

https://www.edqm.eu/documents/52006/1913863/13_COVID-19_mRNA150124.doc/8ee60cea-b0e6-8ft57-ftc7a-6a9a98a23706?tt=1705307262485 such as **the determination of mRNA (identity, content, integrity**

, impurities, 5'cap, Poly (A) Tail), contamination with DNA, proteins, endotoxins, pH, lipid nanoparticles, residual solvents. Therefore, it is difficult to determine whether the OMCL evaluations consisted of the independent execution of these tests, or if the results of these tests were extracted from the manufacturer's documentation and transcribed into the OMCL evaluation reports for the approval of the vaccine lots.

“While it was not possible to foresee which vaccine candidates would receive authorization, preparations were undertaken for a broad spectrum of vaccine candidates. To identify the correct official control laboratory—the OMCL responsible for each vaccine—the OCABR network informed manufacturers of the various testing methods provided by the OMCLs within the network. It must be possible to conduct lot testing for every vaccine product in at least two official control laboratories to account for potential testing failures at any single laboratory.

Quality testing was conducted under extremely constrained timeframes due to the high demand for COVID-19 vaccine doses. Valid results were requested and delivered within a few days, sometimes even within a few hours, instead of the usual 60-day period. At the same time, as before the pandemic, the laboratories continued to test the quality of the lots of other vaccine products and of medicinal products manufactured from human blood and plasma—this activity continued without interruption. The OMCL laboratories worked seven days a week and were thus able to satisfy the requests.”

In the article “Independent control of COVID-19 vaccines by EU Official Control Authorities Batch Release: challenges, strengths and successes”, the manner in which the lots of

vaccine, the issues encountered by the OMCLs. This article indicates that the OCABR's attention was focused on organizing the OMCLs network for the testing of future **COVID-19 vaccines as early as the end of 2019**, at a time when there was no talk of a pandemic; however, individuals within this structure intuited that a global health crisis would follow—a development difficult to foresee **unless it had been premeditated**. Of particular interest is the statement below, asserting that members of the OCABR network were mobilized as early as March 2020, when the COVID pandemic was declared by the WHO. It follows that the decision-makers within these structures prematurely concluded that no effective medicinal product treatment existed, a fact unlikely to have been known at the very onset of the COVID-19 period. **These individuals were determined from the very beginning that vaccination was the sole solution**. Furthermore, the fact that the OMCLs were confronted with **so many challenges—the testing of new vaccines, personnel shortages, COVID-19 infections among staff, infection prevention measures, a lack of reagents and instrumentation, and remote work for a portion of the personnel—raises significant questions regarding the proper testing of the quality of COVID vaccines and explains how it was possible for certain undeclared components to remain unidentified** by those who analyzed these products.

<https://pmc.ncbi.nlm.nih.gov/articles/PMC9950138/> Milne C, Independentt control oft COVID-19 vaccines by EU Offtticial Control Authorittty Battch Release: challenges, sttrengths and successes. NPJ Vaccines. 2023 Feb 23;8(1):22. doi: 10.1038/s41541-023-00617-x. PMID: 36823287; PMCID: PMC9950138.

*“The candidate vaccines against COVID-19 are highly diverse in nature and technology (mRNA, viral vector, recombinant protein, inactivated viral vaccine, certain vaccines using adjuvants, **some being new in terms of vaccine formulations**). For some platforms, for example, the mRNA vaccines and, to a lesser extent, the viral vector vaccines, there is **only limited experience, if any at all, regarding their manufacturing processes and inherent control strategies at the time of the regulation assessment for authorization** . Furthermore, some of the authorized vaccines come from **manufacturers who only have recent expertise in the field of human vaccine production** . **Strict control of intended quality and lot-to-lot consistency for each vaccine against COVID-19 was essential, given that any given lot could be administered to millions of people during mass vaccination campaigns in the EU. Consequently, the rapid development and authorization of this variety of new vaccines against COVID-19 also necessitated rapid preparation for the independent control of the vaccines** .”*

*“Therefore, **in order not to delay access to vaccines following their marketing authorization** , the OMCLs were required to prepare to exercise adequate and comprehensive control over the COVID-19 vaccines, and **all preparatory work and provisions had to be addressed and finalized in parallel with the accelerated authorization procedure. The primary objective was for OMCL testing for the COVID-19 vaccines to be fully established by the time of authorization** .”*

The procedure for lot release by the EU Official Control Authority (OCABR) is established in EU legislation, specifically Article 114 of Directive 2001/83/EC , as amended. If this EU legislation is transposed into national law (as is the case for vaccines in most EU Member States), it mandates that each lot of vaccine, including the vaccines against COVID-19, be inspected by an independent national laboratory (an OMCL) , prior to being released to the public. It is important to note that Article 114 also requires the mutual recognition of results between Member States in order to maximize efficiency and prevent unnecessary redundant testing or delays in the placement of the product on the market .”

*“Therefore, **OCABR represents an additional guarantee of the quality of these sensitive products** . Its use is based on an assessment of underlying risks which **recognizes the fact that the vaccines are biological products and possess the potential for inherent variability due to their production and testing systems** ”*

“The OMCLs that perform OCABR are part of the General European OMCL Network (GEON).

Established in 1994, the network is co-sponsored by the Council of Europe (COE) and the European Commission. The European Directorate for the Quality of Medicines & HealthCare (EDQM) within the COE serves as the secretariat of the network. The members of the OCABR network constitute a subset of the GEON, comprising solely EU/European Economic Area (EEA) Member States, alongside countries that have entered into a formal agreement with the EU, such as Switzerland and Israel.

“OCABR for vaccines against COVID-19

By late 2019 and early 2020, increasingly potent indications suggested the emergence of a global health crisis, and the network monitored the situation accordingly. Concrete emergency planning commenced in earnest upon receiving indications from the European Commission and EU national authorities that an EU-level plan was being formulated to address COVID-19, involving the accelerated authorization of vaccines against COVID-19.

In the context of the pandemic, an accelerated preparation of key elements for OCABR was also required.

This preparation focused on two axes:

- *The preparation of OCABR guidelines in parallel with the evaluation of dossiers by the EMA for the first vaccines (mRNA-based and viral vector-based) for which it was anticipated that a conditional marketing authorization would be obtained.*
- *The early transfer of selected analytical methods to OMCLs to ensure the availability of OMCLs and the EDQM when the first lots became available and the first conditional marketing authorizations were issued.*

Beginning in March 2020, the EDQM mobilized the members of the EU OCABR network and facilitated an early exchange with the manufacturers. *This mobilization was effective due to the commitment of national authorities and OMCLs to prioritize these key lot release activities and to allocate resources, in some cases involving an increase in the workforce. Preparation required the anticipation of all stages to ensure availability, as well as retrospective planning—that is, planning backward from the deadline based on available assumptions. The anticipation of various stages was, however, associated with the risk that certain products might not be accepted by the EMA. Early exchanges with manufacturers were facilitated by close collaboration with the Coalition for Epidemic Preparedness Innovations (CEPI)/COVAX and the willingness of manufacturers to share analytical strategies for their vaccine candidates during the early stages of development.*

Furthermore, continuous communication with the European Commission and EMA was essential to ensuring an alignment of batch release readiness with the timelines for granting conditional marketing authorizations.

The mobilization of the OCABR Network led to the development of a recommendation document for manufacturers regarding the early transfer of methods and a list of OMCL competencies, based on control techniques for the various categories of candidate vaccines against COVID-19, to assist manufacturers in identifying the OMCLs with the relevant skill sets. Both documents were provided to known manufacturers directly and via the manufacturers' association Vaccines Europe in July 2020 and were subsequently provided to COVID-19 manufacturers upon request throughout 2021 and 2022. The list of competencies was updated twice in 2021 to remain current with the evolving situation.

“Of course, the epidemic context represented an additional challenge for the OMCLs, with the potential to affect various aspects of the lot release process. The first anticipated effect was the lack of staff availability, due to illness or other reasons, such as travel restrictions. *The OMCLs mitigated this risk by allocating available human resources to the prioritized lot release process and by suspending other less essential activities. Hiring additional staff was also an option when this was feasible. In addition, telework was implemented for certain staff members, where applicable, and in many instances, personnel worked in team rotations to prevent the spread of the virus within the OMCLs.*

A further obstacle encountered was **the potential shortage of certain “basic” laboratory reagents** (e.g., plates, tips, cell growth media, columns) due to high global demand. In some instances, **the OMCLs were compelled to seek alternative suppliers or reagents, thereby increasing complexity and placing additional pressure on the process**. On the other hand, and fortunately, the transport system for the shipment of reagents or evidence from the manufacturer was not significantly impacted by the epidemic context.”

“From the perspective of public health, **the availability of vaccines against COVID-19 was awaited with great anticipation, which exerted additional pressure**. Consequently, **the OMCLs were mobilized to guarantee the availability of high-quality vaccines within a few days, and sometimes even hours, from the receipt of the manufacturer's completed protocols**; thus, **well within the official 60-day deadline provided in EU Directive 2001/83/EC, as amended [13]**. This necessitated **intensified work schedules, with operations conducted 7 days a week**. Furthermore, it is important to take into account that **all other vaccines and medicinal products derived from blood included in the EU lot release system continued to be subject to OCABR during the same period**, and the timing and number of lots released for these products were not affected by the COVID-19 crisis. To resolve all these challenges, collaboration within the OCABR network was a primary element: allowing for workload sharing among different OMCLs and the easy and rapid exchange of information (regulatory and technical). Once again, the EU OMCL network has demonstrated its resilience even in tense periods. The importance of the lot release process in the EU has been recognized even outside the EU by international organizations (CEPI/COVAX, WHO etc.) and by non-EU countries that have directly contacted the OMCLs in the EU to obtain specific information about the COVID-19 vaccines

In an article published in March 2021 entitled “Addressing the Cold Reality of mRNA Vaccine Stability” <https://www.sciencedirect.com/science/article/pii/S0022354920307851> Addressing the Cold

Reality of mRNA Vaccine Stability, Crommelin, Daan J.A. et al. Journal of Pharmaceutical Sciences, Volume 110, Issue 3, 997-1001

It presents the uncertainties related to the nanolipid component of the mRNA vaccines, the fact that key information regarding the stability profile of the COVID-19 vaccines is not available, **lacking a systematic, mechanism-based approach to analyze chemical and physical degradation pathways**. Literature data regarding the stability and storage of mRNA-nanolipid formulations were scarce until that point. Until that time, specific acceptance criteria for quality and/or stability, developed by the FDA or ICH (The International Council for Harmonisation of Technical Requirements for Medicinal Products for Human Use), were not available to the public

“As the mRNA vaccines became leaders in advanced-stage clinical trials to combat the COVID-19 pandemic, challenges related to their formulation and stability became evident. We conclude that systematic approaches for identifying the key physicochemical degradation mechanism(s) of candidate mRNA vaccines are currently lacking.”

“Particular attention must be paid to the critical issue of mRNA release inside cells and the essential contribution of the formula using various delivery vehicles. 13–15 **For example, lipids (as in the lipid nanoparticles, LNP) and proteins (e.g., protamine, a natural basic/cationic polymer) are used to improve the intracellular release of mRNA. These critical components of an mRNA vaccine modulate the distribution of mRNA in the body, help mRNA molecules enter cells, and affect the expression and immunogenicity of the protein antigen, as well as the safety profile**. 14, 16 Furthermore, it is likely that they have an **impact on the stability of mRNA during storage**. For example, in a theoretical study, Wayment-Steele et al. **predict a hundredfold increase in the rate of mRNA cleavage when it is incorporated into a cationic lipid formulation**. 12 Based on these considerations, the nature, quality, and supplier of these excipients, together with the design of the formulation manufacturing processes, **can affect the pharmaceutical stability of the candidate mRNA vaccines** in terms of the chemical stability of the mRNA/excipients, as well as the colloidal stability of their complexes. Therefore, a reliable supply chain for raw materials is of great importance to ensure a constant quality of the vaccine product, which can be difficult during periods of pandemic, as recently occurred with Pfizer-BioNTech. 17”

"Available information regarding the stability profiles of mRNA-based COVID-19 vaccine candidates currently under development is updated periodically. The current shelf-life and storage temperature conditions published by three vaccine manufacturers (e.g., Moderna, Pfizer-BioNTech, and CureVac) are listed in Table 1 . **As of December 5, 2020, this information has been provided solely by the vaccine manufacturers, without confirmation from the regulatory authorities.** However, it is now clear that the storage conditions required during manufacturing, transport, and at the site of use of the end user are **considered important characteristics of the mRNA-based vaccine medicinal product** , as they could offer a competitive (dis)advantage ."

"Data regarding the stability of the mRNA vaccines in specialized literature: a rare commodity. There is a wealth of information on the stabilization of mRNA molecules themselves, as reviewed by experts.^{8, 9, 18} In contrast, when searching specialized literature for the stability and storage of formulated mRNA medicinal products (e.g., LNP-mRNA and protein-mRNA complexes), little information was found up to the time of writing this article. In a review conducted by Muradliha et al. regarding nucleic acid-based macromolecules (NAM), including, but not limited to, the mRNA vaccines, the authors draw a similar conclusion: ' a comprehensive overview of all challenges and mitigation strategies for the stability and formulation of simple NAMs in non-viral systems is needed ' .¹⁹ This need is even more urgent now, given the emerging importance of the mRNA vaccines in combating the global COVID-19 pandemic.' "

Regulatory guidelines

In June 2020, the FDA published a "Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19" (thus, not only the mRNA vaccines), which contains sections regarding "Chemistry, Manufacturing, and Controls" (CMC).²⁸ The following excerpts are taken from this guidance document: "Qualification/validation data for all assays that indicate quality must be submitted for a BLA" (Biologics License Application) ... and "For authorization of the vaccine, **the stability and expiration date of the vaccine in the final container , when stored at the recommended storage temperature, must be demonstrated using final containers from at least three final lots manufactured from different lots of vaccine."** **Naik and Pesen, of the FDA Office of Vaccines Research, provide more detailed information regarding the FDA's current position on the CMC issues of mRNA vaccines .²⁹ Specific guidelines from the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) or the FDA for mRNA-based vaccines have not yet been established, and no examples of specific quality and/or stability acceptance criteria exist in the public**

The regulatory pathway in the EU for the mRNA vaccines against infectious diseases is described by Hinz et al.³⁰ The EMA considers mRNA vaccines for infectious diseases as a class of medicinal products known as biological medicinal products.

These products fall under the responsibility of the Committee for Medicinal Products for Human Use (CHMP) and follow the centralized procedure for obtaining marketing authorization through the EMA. Schmid summarizes **the quality data required for an EU investigational medicinal product dossier (IMPD)** , which is part of the clinical trial application (CTA).³¹ The latter is similar to the investigational new drug (IND) application in the USA . **The IMPD contains information regarding the mRNA molecule itself, as well as degradation products (i.e., product impurities) and process impurities, such as residual DNA, proteins, and solvents from the manufacturing process. The following section of the IMPD pertains to the control of the medicinal product substance, providing information on analytical procedures and their acceptance criteria (i.e., specifications). Finally, data are requested concerning the critical stability parameters of the mRNA product, wherein the parameters indicating the stability of the mRNA component are: mRNA integrity, content, and potency, alongside pharmaceutical properties, including the pH, appearance, and microbiological status of the medicinal product** . Details regarding the specifications and stability testing for a bulk biological drug substance and for the final medicinal product can be found in the ICH Q6B and ICH Q5C guidelines, respective-

*"In conclusion, mRNA-based candidate products for several therapeutic and prophylactic indications have been tested in the clinic, and numerous publications have reported the nature of the involved mRNA-based medicinal product. However, **key CMC ("Chemistry, Manufacturing, and Controls") information regarding critical quality attributes and the appropriate justification of acceptance criteria, particularly concerning the determination of the stability profile of formulated mRNA-based medicinal products (i.e., shelf life and storage temperature), has not yet entered the public domain.**"*

*"From the above discussion, it is observable that **stability evaluations of mRNA-based candidate vaccines are still in their early stages, as there are currently only isolated reports in the specialized literature.** There is a lack of a systematic, mechanism-based approach to analyze the chemical and physical degradation pathways. Consequently, the adoption of a more rational approach regarding the design of new formulas to ensure the stability of the final mRNA-based medicinal products should be of the highest priority within the pharmaceutical community. Such formula development studies—including the selection of excipients (e.g., stabilizers and/or the inclusion of preservatives), the formulation environment (e.g., pH and tonicity agents), and the manufacturing processes (e.g., liquid or lyophilized dosage forms)—should constitute part of an integrated effort to eliminate the requirement for freezing conditions during long-term storage. To this end, the inherent stability of the active mRNA molecule should be optimized without compromising its potency."*

*"**The composition and structure of the LNP (consisting of mRNA and lipids; cf. Table 2) are essential for in vivo administration, protein antigen generation, and the subsequent immunogenicity and safety of the vaccine.** Therefore, in vivo testing should be part of this development program for **second-generation mRNA vaccine formulations**, as the optimization of shelf life and storage temperatures should not interfere with currently established in vivo performance.*

*Ultimately, since the mRNA vaccines occupy a significant place in global strategies for successfully combating the COVID-19 pandemic, we consider that **it is reckless and unwise to wait for another pandemic before resolving the storage stability issues of this versatile and rapidly deployable vaccine platform technology. Instead, a better understanding of the causes and mechanisms of instability in mRNA vaccines formulas, combined with the rational selection of appropriate stabilization technologies, will undoubtedly lead to improvements in the stability of the mRNA vaccines.** Such second-generation mRNA vaccines formulas with optimized stability—namely, those allowing transport and **storage at refrigerated or ambient temperatures throughout the vaccine supply chain—should be developed now to facilitate a faster global distribution of the mRNA vaccines in the future.**"*

In another article from January 2021 written by Knezevic of the Department of Health Product Policy and Standards, **World Health Organization**, entitled "Development of mRNA Vaccines: Scientific and Regulatory Issues" <https://pubmed.ncbi.nlm.nih.gov/33498787/> Knezevic I, Liu

MA, Peden K, Zhou T, Kang HN. Development of mRNA Vaccines: Scientific and Regulatory Issues. *Vaccines (Basel)*. 2021 Jan 23;9(2):81. doi: 10.3390/vaccines9020081. PMID: 33498787; PMCID: PMC7910833

, it is stated that the lipoprotein nanoparticles are the property of the pharmaceutical companies and their exact composition is not public, which **raises questions regarding the manner in which the independent quality assessment analyses of the vaccines were conducted by OMCL laboratories; it follows that the data concerning the lipid nanoparticles in the OMCL report are adopted from the manufacturer's documentation and are not the result of independent evaluations performed by the OMCL** :

*"LNPs are composed of various lipids, often including phospholipids, cholesterol, ionic lipids, and lipids conjugated with polyethylene glycol, which form an aqueous core containing the charged mRNA molecules. The mRNA is thus protected, and the lipid particle facilitates entry into cells and even exit from lysosomes for mRNA delivery, as described in detail by Reichmuth and colleagues [14]. **The manufacturers possess their own patented LNPs, characterized by distinct properties and manufacturing methods.***

*Since new LNP formulations will be developed (such as the one a manufacturer is currently developing to improve thermostability) and **since the actual composition (such as the percentage***

of each component) and the manufacturing process are their proprietary property, being patented; as such, this information exceeds the scope of this manuscript . “

Given the requirements set forth in the “SUMMARY OF PRODUCT CHARACTERISTICS”, for instance regarding Comirnaty, https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf it appears that the OMCL laboratory reports for the evaluation of vaccine lots were based solely on documentation submitted by the manufacturing companies; no independent analyses were performed for quality assessment—specifically regarding the determination of mRNA (identity, content, integrity, purity, 5'cap, Poly (A) Tail), or contamination with DNA, proteins, endotoxins, pH, lipid nanoparticles, and residual solvents—contrary to what one might be led to believe

- “ **To complete the characterization of the active substance and of the finished product , the marketing authorization holder must provide additional data . Deadline-July 20 21, Interim reports: March 31, 2021**
- **In order to ensure consistent product quality, the marketing authorization holder must provide additional information to improve the control strategy, including the specifications of the active substance and of the finished product .- Deadline: July 2021. Interim reports: March 2021**
- **To confirm the consistency of the manufacturing process of the finished product, the marketing authorization holder must provide additional validation data .- Deadline: March 2021**
- **In order to confirm the purity profile and ensure comprehensive quality control and consistency between lots throughout the entire life cycle of the finished product , the marketing authorization holder must provide additional information regarding the synthesis process and the control strategy for the excipient ALC-0315 . Deadline: July 2021. Interim reports: January 2021, April 2021.**
- **In order to confirm the purity profile and ensure comprehensive quality control and consistency between lots throughout the entire life cycle of the finished product, MAH must provide additional information regarding the synthesis process and the control strategy for the excipient ALC-0159 .-July 2021. Interim reports: January 2021, April 2021 .”**

Specific Obligation to complete post-authorisation measures for the conditional marketing authorisation

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to complete the characterisation of the active substance and finished product, the MAH should provide additional data.	July 2021. Interim reports: 31 March 2021
In order to ensure consistent product quality, the MAH should provide additional information to enhance the control strategy, including the active substance and finished product specifications.	July 2021. Interim reports: March 2021
In order to confirm the consistency of the finished product manufacturing process, the MAH should provide additional validation data.	March 2021
In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0315.	July 2021. Interim reports: January 2021, April 2021.
In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0159.	July 2021. Interim reports: January 2021, April 2021.
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591001.	December 2023

As stated by the EMA, the development of standard vaccines requires years. It is logical that by compressing the duration of development and evaluation for a vaccine produced under emergency conditions, neither the safety nor the efficacy can be at the level of those designed according to standards . Moreover, a portion of

the COVID vaccines were produced using new technologies and new components, representing an increase in the variables upon which safety and efficacy depend. As we know, even for standard vaccines, safety and efficacy are not 100%. **Consequently, presenting the utility of the COVID vaccines in such a subjective manner, without precautions, even by the physicians within professional organizations such as the CMR and others—and furthermore forcing vaccination through censorship and threats directed at the physicians who held differing opinions based on studies—was more than an error of great proportions, if not a premeditated act, suggesting interests other than the well-being of the population.**

Here is what is stated on the very website of the EMA <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-international-concern-2020-23/covid-19-vaccines-development-evaluation-approval-monitoring> :

“Development of standard vaccines

The development of a standard vaccine is a long process, and studies are conducted in sequential stages. Companies first produce small lots and conduct small-scale studies to characterize and optimize the production process. They conduct studies to determine an appropriate formula that can maintain the vaccine components stable until the end of their shelf life.

Subsequently, the company determines whether to proceed with development and scale up production . To ensure that the vaccine fulfills the intended quality profile and adheres to regulation standards, the company shall develop an appropriate and effective quality control strategy .

Pharmaceutical quality studies provide a detailed analysis of the individual components of the vaccine, the final formulation intended for use, and the entirety of the manufacturing process.

The developer of the vaccine performs multiple studies on laboratory models, utilizing in vitro studies (e.g., cells in culture) or animal models (in vivo studies), to demonstrate the mechanism by which the vaccine elicits an immune response and functions to prevent infection.

Ultimately, the developer of the vaccine studies the vaccine in three phases of clinical trials, with an increasing number of volunteers in each phase.

For approval, companies must also demonstrate that large-scale commercial production consistently produces vaccines of the required quality .

Scaling up production and adaptations to commercial manufacturing may continue during the post-authorization phase.”

“The clinical trials concerning medicinal products for human use, including those for vaccines against COVID-19, are authorized and managed at the national level in the EU. National authorities and ethics committees ensure that the studies are scientifically sound and conducted in an ethical manner .

Human pharmacology studies (Phase I studies) generally involve between 20 and 100 healthy volunteers to confirm whether the medicinal product behaves as expected, based on laboratory tests. These studies can establish:

- *whether the vaccine triggers the expected immune response;*
- *whether the vaccine is safe enough to proceed to broader studies;*
- *which doses may be appropriate.*

Therapeutic exploratory studies (Phase II studies) involve several hundred volunteers. The purpose of this phase is to determine the optimal doses to be used, the most frequent side effects, and the number of doses required.

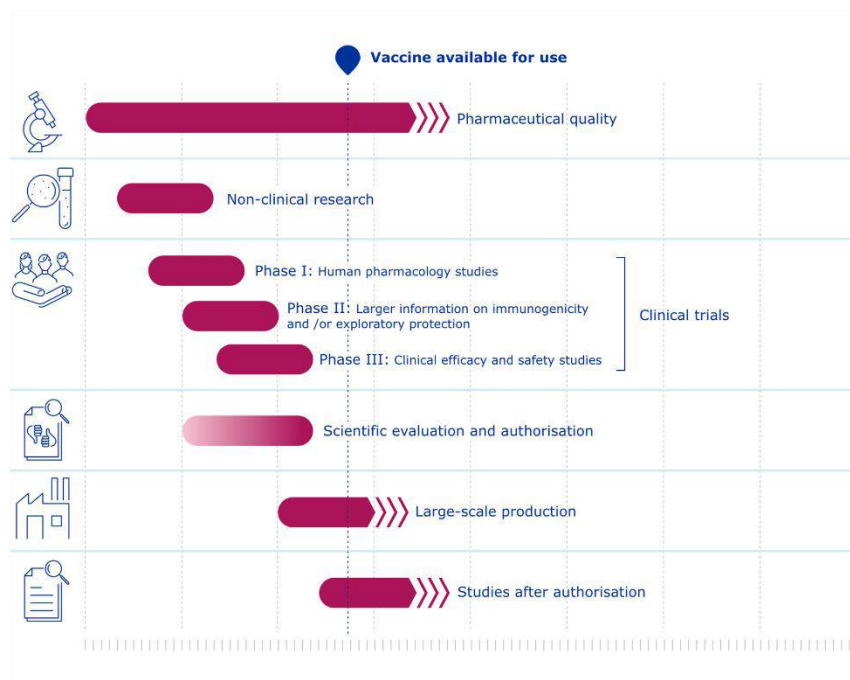
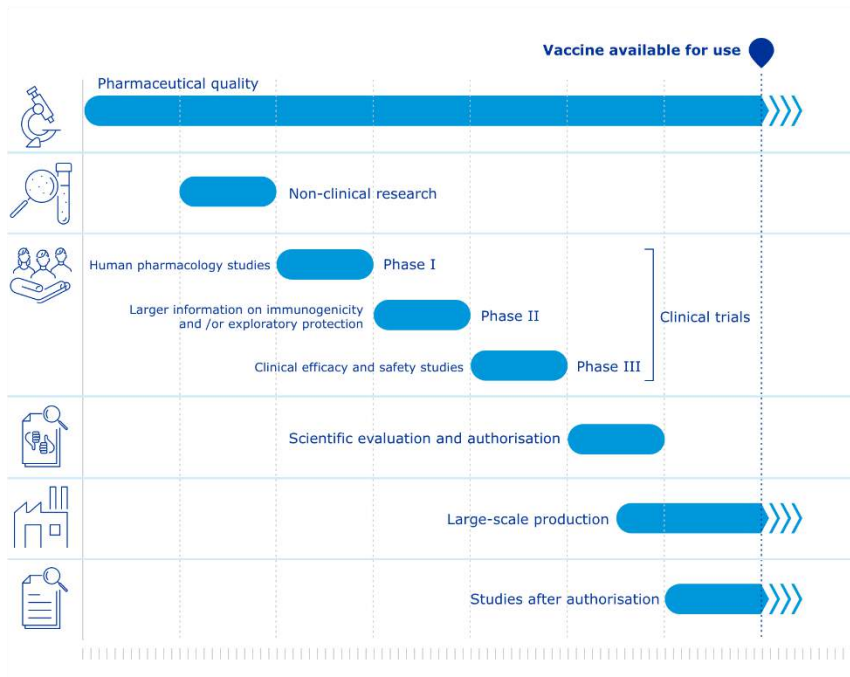
These studies also verify whether the vaccine triggers a robust immune response in a broader population . In certain cases, they could also provide preliminary indications regarding the efficacy of the vaccine.

The clinical trials regarding clinical efficacy and safety (phase III clinical trials) include thousands of volunteers. This phase demonstrates the efficacy of the vaccine in protecting against infection compared to a placebo (inactive preparation) or alternative treatment, and identifies the less frequent side effects in those receiving the experimental vaccine .

Reducing the number of individuals presenting symptoms, severe disease, or a diagnosis of infection may serve to measure the efficacy of the vaccine .”

“The accelerated development of vaccines in the event of a public health emergency

*The development of vaccines against COVID-19 continues to be accelerated globally. **Development is compressed in time, applying vast knowledge regarding the production of vaccines acquired from existing vaccines.***



“Vaccine manufacturers and academic institutions utilize established production systems already employed for safe and effective vaccines. Furthermore, they are continuously researching new approaches for the production and development of vaccines, and some of the progress achieved to date is being applied to the development of vaccines for COVID-19.

Certain COVID-19 vaccines are developed utilizing novel methods , intended to increase production volume and velocity in comparison to other types of vaccines , to enhance product stability, and to elicit potent immune responses.

Other vaccines are developed utilizing established methods employed for vaccines against other diseases, which facilitates the utilization of existing manufacturing facilities for the production of vaccines

against COVID-19 on a large scale. Companies may employ various approaches to accelerate development timelines while ensuring high standards and adherence to legal requirements, such as:

- the simultaneous mobilization of multiple human resources to more rapidly analyze the results of previous studies and to establish the subsequent steps regarding resources, financing, and regulation strategy;
- **combining the phases of clinical trials or conducting parallel studies**, where safe to do so.

Companies also expanded their production capacity and large-scale manufacturing to facilitate the deployment of the vaccines without delay, once they are approved. In the EU, the European Commission provided support to facilitate the development and deployment of the vaccines as rapidly as possible.

Certain vaccine developers commenced production of the vaccine against COVID-19 prior to obtaining an EU marketing authorization. This enabled them to be prepared to distribute the doses with sufficient speed to meet demand once they had been authorized.

The latter statement is incriminating. It follows that certain manufacturers **were certain of obtaining conditional emergency authorization** by producing vaccines prior to the receipt of said authorization.

“In view of the pandemic, the EMA and the regulation agencies in Europe are allocating resources to accelerate processes and reduce the timeframes for the evaluation and authorization of vaccines against COVID-19.”

„A robust regulation framework and scientific expertise in the EU

EU pharmaceutical legislation guarantees that vaccines are approved only after scientific evaluation has demonstrated that their overall benefits outweigh the risks.”

“The benefits of a vaccine in protecting people against COVID-19 must be significantly greater than any side effects or potential risks.”

From this document it can be established that **national authorities** play an important role in the adoption of COVID vaccines, as they **“decide on the introduction of newly approved vaccines and vaccination policies”**.



“The EMA's specialized scientific committees for medicinal products for human use (CHMP and PRAC) conduct the EMA's evaluations. The EMA established the multidisciplinary Task Force for the pandemic of

EMA's COVID-19 (COVID-ETF), which brings together key experts from across the European medicinal products regulation network to ensure a rapid and coordinated response to the pandemic.

Furthermore, **EMA collaborates with international experts during the review of vaccines against COVID-19 through the OPEN initiative, launched in December 2020. OPEN allows regulatory authorities from outside the EU—specifically from Australia, Canada, Japan, Switzerland, as well as the WHO—** to participate as observers in the scientific evaluation of the EMA's ETF and CHMP, while maintaining their scientific and regulatory independence.

"Accelerated assessment

Pursuant to EU pharmaceutical legislation, **the standard timeframe for the evaluation of a medicinal product is a maximum of 210 active days.**

Nevertheless, **the EMA processes marketing authorization applications for COVID-19 products on an accelerated basis. This allows the evaluation timeframe to be reduced to fewer than 150 working days.**

To this end, the EMA may utilize its rolling review procedure for promising medicinal products for COVID-19. This enables the EMA to commence the assessment of data as they become available during the development process, thereby further accelerating the subsequent evaluation of the formal marketing authorization application."

"Upon completion of an evaluation, **the EMA has the option to recommend a conditional marketing authorization**, a type of approval for medicinal products that address unmet medical needs and, specifically, for those intended for use in emergency situations in response to public health threats recognized by the WHO or the EU."

"The conditional marketing authorization is an instrument that allows regulatory authorities to approve a medicinal product rapidly and pragmatically when an urgent need exists.

A conditional marketing authorization differs from an emergency use authorization, which some countries utilize to permit the temporary use of an unauthorized medicinal product in an emergency situation. An emergency use authorization does not constitute a marketing authorization.

EU legislation stipulates that conditional marketing authorization is utilized as a **rapid authorization procedure during public health emergencies to expedite approval and preserve human lives.**

It is the most appropriate instrument for granting simultaneous access to a vaccine for all EU citizens and for supporting mass vaccination campaigns.

"Monitoring the efficacy, safety, and real-world utilization of the vaccine

Scientific evaluation must demonstrate that the benefits of a vaccine in protecting individuals against a specific disease, such as COVID-19, significantly outweigh any potential risks.

As with any medicinal product, vaccines entail both benefits and risks. Even highly effective vaccines are not 100% effective in disease prevention or 100% safe for all vaccinated persons.

Upon approval, the primary evidence concerning the safety and efficacy of the vaccine is derived from randomized, controlled, large-scale clinical trials. Within these trials, selected volunteers are randomly administered either the experimental vaccine or a placebo injection. They are subsequently monitored under controlled conditions according to strict protocols. Following approval, a large number of persons will be vaccinated. **Certain rare or very rare side effects may only manifest once millions of persons are vaccinated. EU legislation mandates the monitoring of the safety of the vaccines during their use in routine clinical practice."**

"Standard monitoring

The EU maintains a comprehensive safety monitoring and risk management system (pharmacovigilance), which ensures the implementation of measures for:

- providing consultancy for risk minimization;
- **reporting suspected adverse reactions;**
- **conducting studies after authorization;**
- **the detection of any potential side effects;**
- **performing rigorous scientific evaluations of all safety data;**

- the timely implementation of any necessary mitigation actions.

The competent authorities may conduct safety and efficacy studies post-authorization and may also require the marketing authorization holder to perform such studies as a condition of the authorization. Public health authorities responsible for the vaccination programs shall also conduct additional studies.

Studies collecting efficacy data provide supplemental information—for instance, regarding long-term protection, the necessity and timing of booster doses, or the efficacy of a vaccine against new variants— in order to supplement the 'efficacy' data obtained in clinical trials prior to the authorization of the vaccine.

“The pharmacovigilance plan for the COVID-19 vaccines establishes how **the EMA and the competent national authorities of the EU Member States** identify and promptly evaluate any new information that arises, including any safety signals relevant to the benefit-risk ratio **of these vaccines:**

The pharmacovigilance plan of the EU regulatory network for COVID-19 vaccines

This plan also guarantees that the regulatory authorities can take any appropriate regulatory measures and communicate them to the public as quickly as possible.

The monitoring activities within the plan apply to all vaccines, but are conducted on a larger scale during this pandemic :

Collection of data regarding exposure to vaccines against COVID-19

Adoption of specific measures for the detection and management of safety signals

Establishment of a European infrastructure for the monitoring of treatments and vaccines against COVID-19

Utilization of real-world data from clinical practice

Application of exceptional transparency measures

The EMA guidelines on the preparation of risk management plans for the COVID-19 vaccines assist marketing authorization applicants in developing risk management plans for the COVID-19 vaccines:”

In the pharmacovigilance plan of the COVID vaccines

https://www.ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf The “Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines” provides for the following objectives:

“The main objectives of this plan include:

- **Active collection of data regarding rare potential risks;**

- **Detection, prioritization, and rapid evaluation of emerging safety information** derived from spontaneous reporting systems, observational studies, and other data sources;

- **Prompt evaluation of the impact of detected safety issues on the benefit-risk report** of the vaccines, taking into account data regarding exposure and efficacy;

- **Active surveillance of vulnerable populations** , such as **pregnant women and elderly vaccinated persons;**

- **Engagement and collaboration with stakeholders, including vaccinated persons and healthcare professionals, marketing authorization holders (MAH), and international partners**

- **Prompt and efficient communication of new information** arising from the aforementioned activities.”

Despite the declared intentions for the careful and accurate monitoring of adverse reactions, these objectives could not be met; consequently, an objective evaluation regarding the accuracy of the benefit-risk report could not be realized. Although in CHAPTER XII, point B of **Decision no. 1031/2020 regarding the approval of the Vaccination Strategy against COVID-19 in Romania**, published in the Official Gazette, Part I, no. 1171 of December 3, 2020 <https://legeaz.nett/monitorul-oficial-1171-2020/htt-1031-2020-ststrategie-vaccinare-covid-19-romania> it is stated that “ *The monitoring and reporting of any adverse reactions recorded after vaccination shall be **conducted on a short-term basis, namely within the first 30 days following the administration of each dose, and on a long-term basis** , according to the recommendations of the EMA and of the*

manufacturer/manufacturers” and that “ **The reporting of adverse reactions is mandatory for any physician who detects such a case.** The monitoring and reporting of suspected adverse reactions after vaccination by physicians shall be performed in compliance with national legislative provisions , **within the first 30 days of becoming aware of the adverse reaction** or in accordance with EMA recommendations established at the time of the authorization of the vaccines.

Provisions shall be made for the development and strengthening of mechanisms for the detection, assessment , and investigation of AEFI cases, in accordance with the safety profile of each vaccine. Furthermore, where possible, mechanisms for the active surveillance of adverse events of special interest shall be developed to estimate frequency, pursuant to EMA recommendations for each specific type of vaccine ”; **in reality, the reporting of adverse reactions for the COVID-19 vaccines was not encouraged, and the physicians were not informed of the mandatory obligation to report short- and long-term post-vaccination**

COVID-19 adverse reactions as stipulated in this decision, with the vast majority of physicians possessing no knowledge of the practical procedures for submitting such reports. Furthermore, the reporting of adverse reactions is a time-consuming, non-remunerated process, and within a physician's heavy workload, it is difficult to find the time required to report the high volume of adverse reactions occurring post-vaccination COVID-19. **Moreover, it is evident from the ANMDMR website that the reporting of post-vaccination adverse reactions is not imperative or mandatory, but merely option-**

<https://www.anm.ro/medicamentie-de-uz-uman/ftarmacovigilentia/raportieaza-o-reactiie-adversa/>



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DISPOZITIVE MEDICALE ▾

INFORMAȚII DE IN

Raportează o reacție adversă

Raportează o reacție adversă

O reacție adversă se definește ca „un răspuns nociv și nedorit, determinat de un medicament”. În acest context, „răspuns” înseamnă că o relație cauzală între medicament și un eveniment advers reprezintă cel puțin o posibilitate rezonabilă.

Sunt considerate reacții adverse și efectele nedorite care apar după supradozarea medicamentului, după utilizare greșită, abuz sau erori de medicație.

Orice pacient/consumator sau profesionist din domeniul sănătății (medic, farmacist, asistent medical, moașă etc.) poate raporta reacțiile adverse suspectate apărute după utilizarea medicamentelor de uz uman, inclusiv cele apărute după utilizarea vaccinurilor.

Agentia Națională a Medicamentului și a Dispozitivelor Medicale (ANMDMR) încurajează raportarea reacțiilor adverse și pune la dispoziția raportorilor următoarele modalități de raportare a acestora la ANMDMR:

Furthermore, the injected persons were not informed that they could personally report adverse reactions directly, without the intervention of a physician, via the ANMDMR website <https://covid19.anm.ro/> . Additionally, many vaccinated persons who reported adverse reactions were never contacted by the INSP or the public health directorates regarding the investigation of said adverse reactions.

Adverse reactions of the vaccines in pregnant women were not actively monitored, nor were they actively monitored for the elderly, despite this being mandated in the EMA document https://www.ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf “Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines”. Even the INSP, in response 23782 dated 5-12-2022 to my petition of November 9, 2022, states that **there was no active pregnancy follow-up** for vaccinated pregnant women. Thus, in regard to my questions 19-21, the INSP provided the following response:

“19. How many cases of severe COVID-19 and how many cases of critical COVID-19 were reported among unvaccinated pregnant women in Romania in the years 2020, 2021, and 2022? Please provide a detailed breakdown based on age and comorbidities.

20. How many COVID-19 deaths were registered in Romania among unvaccinated pregnant women and fetuses, respectively,

and among newborns in the years 2020, 2021, and 2022? How many premature births were determined by COVID-19, and at what gestational age?

21. How many adverse reactions were reported post-vaccination for COVID-19 among pregnant women in the years 2020, 2021, and 2022? How many cases of maternal or fetal deaths were registered post-vaccination for COVID-19 in the years 2021 and 2022? "

20. Institutul National de Sănătate Publică nu detine informatii referitoare la numărul de decese la gravide in funcție de statusul vaccinal.
21. Până în prezent nu a fost raportat niciun caz confirmat RAPI la gravide sau ca decese materne respectiv fetale.
22. In perioada de graviditate, conform legislației in vigoare, gravidele sunt supravegheate de către medicii de familie respectiv de medicii specialiști care le iau în evidență. INSP nu are responsabilitati privind acest tip de supraveghere a acestora.

In the pharmacovigilance plan of the COVID vaccines

https://www.ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf it is further stated that " **Post-authorization safety studies (PASS) are conducted by marketing authorization holders voluntarily or at the request of the regulatory authorities (see GVP modules V and VIII). For the COVID-19 vaccines, the need for observational PASS studies will be carefully analyzed, as routine activities and ongoing or planned clinical trials might not be sufficient to provide adequate data to further characterize the identified and potential risks and to investigate missing information. Additional recommendations are presented in RMP19.**

EMA has entered into contracts with academic and private partners to support the preparation of research networks for conducting observational research, including research regarding COVID-19 treatments and vaccines."

Regarding Romania, I have no knowledge of the organization of such studies. **Furthermore, transparency concerning the reported and recognized adverse reactions has been lacking; the sole report on the INSP website regarding post-vaccination COVID-19 AEFI is limited to the period 27.12.2021–03.10.2021 and fails to address the deaths post-vaccination** <https://www.cnscbt.ro/index.php/analiza-date-supraveghere/rapi-1> .

Severe adverse reactions, including the deaths occurring after COVID-19 vaccination, have not been properly investigated, thereby circumventing the application of the INSP protocol—the "Guide for Investigating Severe and Serious Cases of AEFI"—which mandated the chemical composition analysis of the vaccine lots administered to the deceased individuals: " *Chemical composition analysis: the level of preservatives, adjuvants, or biological tests for the detection of foreign substances or Toxins in the lots responsible for the respective adverse reactions. "*

In the "Guide for Investigating Severe and Serious Cases of AEFI" (AEFI—adverse reactions post-inoculation) issued by the INSP <https://cnscbt.ro/index.php/metodologii/rapi/661-ghid-investigare-cazuri-rapi/ftile> **the primary stages for the investigation of severe AEFI cases are delineated.** Among the AEFI cases requiring investigation, the following are enumerated: - " **serious AEFI cases due to their grave symptomatology," "AEFI cases representing signals within the surveillance system," and "cases generating concern and alarm at the level of the community."**

„If the investigation of an AEFI case or cluster is required, it must be initiated as soon as possible, within the first 24 hours following its detection and reporting by a medical professional. "

„If an investigation is necessary, a **multidisciplinary investigation team shall be formed—consisting of an epidemiologist physician , a clinical physician (the individual who treated or is treating the case in the hospital) , a family physician and a vaccinating physician (if the vaccinating physician is distinct from the family physician)**; the following may be added depending on the severity of the case: **an anatomical pathologist , a laboratory physician , a pharmacovigilance specialist .**”

„4. Measures taken ...**The results of the investigation shall be communicated to the primary level, publicly**”

„**Investigation of deaths following vaccination**

- the investigation must be initiated immediately the investigation team shall include experts from relevant fields, consisting of: an epidemiologist physician , a clinical physician (the individual who treated/is treating the case in the hospital) , a family physician, and a vaccinating physician (if the vaccinating physician is different from the family physician), an anatomical pathologist, a laboratory physician, and a pharmacovigilance specialist .

- **Autopsy is recommended**; however, the decision will depend on religion, culture, and legal norms”

„Laboratory investigations-A. Biological evidence- **in the event of a death involving an AEFI case, the autopsy shall be performed as soon as possible (within 72 hours). Toxicological evidence and organ fragments shall be sent to reference laboratories as soon as possible . It is essential** for the team performing the autopsy to be familiar with the patient's medical history.”

„**Types of evidence collected according to the suspected AEFI case-Death -serology -Venous blood, the suspected vial from the lot**”

„Laboratory evidence based on the AEFI case investigation hypothesis

- Transport and storage of the vaccine-Vials of the vaccine- **Visual test-clarity, presence of foreign bodies, turbidity, color, or flocculation**
- Vaccine issues -Vials of the vaccine-**Sterility tests if an infectious cause is suspected**

Analysis of chemical composition: the level of preservatives, adjuvants or biological tests for the detection of substances foreign or Toxins(if a toxic state is suspected)”

On November 9, 2022, I submitted a petition to the INSP containing several inquiries regarding post-vaccination COVID-19 mortality, the protocol for investigating deaths post-vaccination with the experimental COVID-19 products , post-vaccination COVID-19 adverse reactions, compensation for damages post-vaccination COVID-19, and the appropriateness of recommending COVID-19 vaccination for children and adolescents, given that they did not experience severe forms of the disease or mortality from COVID-19 (I have attached both the petition and the INSP response to this document). From the response received on December 5, 2023, under reference number 23782, I have selected several statements relevant to the superficiality with which severe adverse reactions, the deaths, and the indications for vaccination with the experimental products were handled:

“1. How is a post-vaccination COVID-19 death defined? Does the reporting of a post-vaccination death include among its criteria a specific time interval following vaccination (e.g., was a death occurring within the first week after vaccination reported as a post-vaccination death?)

1. Conform definiției din metodologia de supraveghere: *"Reacția adversă post-vaccinală indezirabilă (RAPI) este orice eveniment medical nedorit/advers (manifestări neașteptate, rezultate de laborator anormale, simptome sau boli) apărut după vaccinare și care nu are în mod necesar o relație de cauzalitate cu administrarea vaccinului. De obicei, aceste reacții apar în primele 30 de zile de la administrarea produsului vaccinal cu posibilitate de extindere: în funcție de tipul reacției adverse manifestate și pentru administrarea unor produse vaccinale recent dezvoltate (exemplu: vaccinul împotriva COVID-19)".* In această definiție se poate include decesul apărut după vaccinare.

"2. How many post-vaccination COVID-19 deaths were reported in Romania in the years 2021 and 2022, and at what ages? What were the figures for Europe? **How many of these were confirmed as having been caused or, respectively, facilitated by vaccination in Romania** ? What were the figures for Europe? What was the mechanism by which the vaccine caused death (e.g., anaphylaxis, Thrombosis, thrombocytopenia, myocarditis, myocardial infarction, hepatic failure)?

2. In România, decesele, indiferent de cauza, nu sunt raportate după statusul vaccinal la nici un tip de vaccin autorizat. Institutul Național de Sănătate Publică nu deține informații referitoare la numărul total de decese indiferent de cauză de decedat la persoanele vaccinate împotriva COVID-19. In ce privește situația la nivel European va rugăm să consultați documentele publicate de Comisia Europeană respectiv ECDC.

"3. What was the total number of deaths reported as post-vaccination, and what was the specific number of deaths confirmed as having been caused or exacerbated by the administration of the vaccine, categorized by vaccine type and the interval of time elapsed since vaccination (within the first 48 hours, within the first month, between one and six months, and exceeding six months)?

3. Investigațiile efectuate în urma raportărilor trimise prin sistemul de supraveghere RAPI, pentru suspiciunile RAPI cu deces (28), releva faptul ca **niciunul nu a fost cauzat de produsul vaccinal.**

"5. How many necropsies have been performed in Romania on individuals whose deaths were reported in connection with vaccination? What is the established protocol for performing these necropsies, and which specific analyses (e.g., immuno-histochemistry) are conducted to establish or exclude a causal relationship with the vaccination?

5. In cadrul sistemului de supraveghere RAPI au fost raportate și investigate 28 de decese aparute după vaccinare. Rezultatul necropsiei acestora a **evidențiat alte cauze de deces decât corelația cu vaccinul.** Pentru a cunoaște protocolul necropsiei va recomandăm să vă adresați Comisiei de Medicina Legală.

"10. How many cases of severe adverse reactions following COVID-19 vaccination were reported in Romania, and how many of these cases were confirmed during the years 2021 and 2022? Please provide a detailed breakdown according to the type of vaccine, the duration of time elapsed since vaccination (within the first 48 hours, within the first month, between one and six months, and after more than six months), and the individual who filed the report (patient or physician)."

10. Reacții adverse post-vaccinale indezirabile (RAPI) din campania națională de vaccinare împotriva COVID-19, au fost raportate zilnic în timpul derulării campaniei, la început pe site-ul CNCAV apoi pe site-ul INSP
<https://vaccinare-covid.gov.ro/comunicate-oficiale/>
<https://insp.gov.ro/centrul-national-de-supraveghere-si-control-al-bolilor-transmisibile-cnsbct/infectia-cu-noul-coronavirus-sars-cov-2/raportare-saptamanala-vaccinare-impotriva-covid-19/>

"11. How many cases of myocarditis, myocardial infarctions, and cerebrovascular accidents have been reported among vaccinated persons? Please further specify based on age and the time interval elapsed since vaccination,

as well as the number of vaccine doses.”

11. In perioada 27.12.2020-02.01.2022 in sistemul de supraveghere al RAPI au fost raportate și confirmate după investigare 10 cazuri de miocardita și un caz de miopericardita, clasificate ca RAPI asociate cu componentele vaccinului.

Cazurile de miocardita au fost înregistrate la persoane cu vârste între 24-47 ani.

Pentru cele 10 cazuri de miocardita: 9 au fost vaccinate cu Comirnaty și o persoană a fost vaccinată cu Johnson&Johnson.

Nu a fost raportat niciun caz RAPI confirmat cu accident vascular, respectiv infarct miocardic post vaccinare.

„12. How many cases of newly diagnosed cancers have been reported among persons vaccinated against COVID-19? At what post-vaccination intervals were these reported, following which types of vaccine, and at what ages?”

12. INSP nu deține informații referitoare la numărul de cazuri de cancer raportate la persoane vaccinate anticovid, întrucât raportarea cazurilor noi de cancer nu se face în funcție de criteriul “status vaccinal”.

„13. What are the safety studies regarding the administration of the fourth vaccination dose (the second booster)? And what about efficacy?”

13. Pentru informații referitoare la studiile de farmacovigilență pentru administrarea dozei a patra de vaccin, vă recomandăm să vă adresați autorității care are această responsabilitate, respectiv, Autoritatea Națională a Medicamentului și Dispozitivelor Medicale (ANMDM).

„16. How do you justify the vaccination of young people up to 35 years of age (0–35 years), given that the percentage of deaths from COVID-19 in this category was below 1% in both 2020 and 2021, and considering that the vaccination does not prevent Transmission?”

16. Strategia de vaccinare împotriva COVID-19 în România a fost implementată prin Hotărârea de Guvern nr. 1.031 din 27 noiembrie 2020 cu modificările și completările ulterioare, prin care au fost stabilite categoriile populaționale și etapele de vaccinare. Decizia de vaccinare a grupelor de populație a fost o decizie de sănătate publică bazată pe informațiile disponibile în momentul respectiv, decizie care a fost schimbată pe măsura existenței de noi informații referitoare la măsurile de prevenție. Grupa de vârstă menționată de dumneavoastră a fost ultima inclusă în etapele de vaccinare (etapa a IIIa). Toate aceste decizii au fost aprobate de Comitetului Național de Coordonare a Activităților privind Vaccinarea împotriva COVID-19 (CNCAV). Vaccinarea este un act voluntar. În privința deceselor pentru perioada menționată o explicație a procentului scăzut o reprezintă atât lipsa afecțiunilor asociate la această grupă de vârstă, cât și faptul că cea mai virulentă dintre tulpinile circulante atunci, tulpina delta, a afectat cu preponderență persoanele imunodeprimăte, cu boli asociate și vârstnicii.

„17. How do you justify the decision for the vaccination of children in the 10–14 age group, given that in 2020 there were no deaths in this age category and the vaccination does not prevent the transmission of the virus?”

17. Strategia de vaccinare împotriva COVID-19 în România s-a desfășurat conform Hotărârii de Guvern nr. 1.031 din 27 noiembrie 2020 cu modificările și completările ulterioare, prin care au fost stabilite categoriile populaționale și etapele de vaccinare. Decizia de vaccinare a grupelor de populație a fost una de sănătate publică bazată pe informațiile disponibile în momentul respectiv, decizie care a fost schimbată pe măsura existenței de noi informații referitoare la măsurile de prevenție. Printre aceste măsuri de prevenție se număra și utilizarea vaccinului la grupa de vârstă 10-14 ani, vaccin aprobat pe baza informațiilor științifice de către EMA (European Medicines Agency). Toate aceste decizii au fost aprobate de Comitetului Național de Coordonare a Activităților privind Vaccinarea împotriva COVID-19 (CNCAV)

„18. How do you justify the higher percentages of positive COVID-19 cases reported among vaccinated persons compared to unvaccinated individuals throughout the entire year of 2022, as evidenced by the weekly INSP reports? What is the percentage of positive cases reported among vaccinated persons relative to the total number of positive cases in 2021 and 2022, respectively, up to the latest INSP report? Does this constitute evidence that the anti-COVID vaccines are ineffective and appear to play a facilitating role in the selection of new strains and the spread of the virus? In providing this response, please also consider the status of positive cases in 2022 within countries where the vaccination rate was significantly higher than in Romania and which, unexpectedly, recorded a higher number of reported positive cases during 2022 compared to the situation in our country.

<https://ourworldindata.org/>”

18. Referitor la întrebările menționate vă precizăm că în această pandemie a existat circulație de tulpini diferite Wuhan, alfa, delta- (recunoscută prin virulența crescută) și omicron. Vaccinurile utilizate asigurau o protecție de 6 luni, iar doza booster a fost recomandată pentru a întări această protecție. Recomandarea în România a fost respectată de un procent scăzut din populație, ceea ce a dus la un număr crescut de cazuri. Un alt factor care a contribuit la creșterea acestor cazuri a fost și eficacitatea scăzută a vaccinurilor disponibile pe noile tulpini circulante.

„24. From which funds are the damages caused by vaccines paid? Who finances these funds? The manufacturing company?”

24. Nu cunoaștem acest aspect, excede atribuțiilor INSP.

„27. What is your position regarding the decision of the European Medicines Agency to approve the COVID-19 vaccination for children aged 6 months to 5 years, considering that the efficacy of the vaccine for the 2–5 age group is only 36.8% and for the 6–23 month group only 50.6%, and furthermore, vaccination does not prevent transmission or illness?”

27. INSP nu are calitatea de a comenta deciziile Agenției Europene a Medicamentului referitor la eficacitate, atribuție de care nu este responsabil.

„29. Are there studies demonstrating the efficacy of mask-wearing by children for the prevention of respiratory viruses and, in particular, of COVID-19?”

29. Decizia de a se purta obligatoriu masca este o masura implementata in functie de mai multe criterii, dar nu si a indicatorului mentionat de dumneavoastra: Greenhalgh si colab. **recomandă purtarea măștilor chirurgicale în public pentru a preveni transmiterea SARS-CoV-2, precizand că uneori ar trebui să acționăm fără dovezi definitive, pentru orice eventualitate, în conformitate cu principiul precauției.** Autorii citează o definiție a principiului de precauție găsit pe Wikipedia, „o strategie pentru abordarea problemelor de potențial prejudiciu atunci când lipsesc cunoștințe științifice extinse în această privință”.
<https://www.bmj.com/content/369/bmj.m1435/rr-40>.

On December 29, 2022, I submitted a petition to several institutions, including the Ministry of Health, regarding the post-vaccination deaths (I will attach the petition and the respective responses to this report, as I deem them relevant) . Among other inquiries, I requested information on whether autopsies were conducted for individuals who died post-vaccination, identifying the personnel and procedures involved, and whether the vaccine lots administered to these individuals were analyzed in accordance with the INSP protocol. As previously stated, the INSP protocol for investigating AEFI stipulates the analysis of the chemical composition of vaccine lots administered to persons experiencing severe adverse reactions, including death—an investigation that was not performed by the INSP !!! The response of the MS is indicative of the superficiality and lack of transparency with which post-vaccination COVID-19 deaths were handled—a fact difficult to explain other than as a premeditated intent not to investigate these cases, which would have required, pursuant to the INSP protocol, the chemical analysis of the COVID-19 vaccine lots. Cases of severe adverse reactions and deaths should have been monitored with heightened scrutiny, given that the COVID vaccines were still in an experimental stage in 2022 (the clinical trials were not finalized until 2023). I have selected several relevant fragments from my inquiries and from the unsigned response No. CRP 1244 / 15.02.2023, transmitted via e-mail by the MS:

„3. What was the temporal relationship of the deaths to the administration of the vaccine (number of deaths between 0–48 hours, 48h–14 days, 15–30 days, >30 days)? ”

“3. Within the first 48 hours of vaccination, 8 deaths were suspected; in the 48h–14 days interval, 14 post-vaccination deaths were suspected; in the 15–30 days interval, 4 post-vaccination deaths were suspected; and after more than 30 days, 3 post-vaccination deaths were suspected . ”

“5. What is the composition of The Commission of Forensic Medicine that performed these necropsies and reported the findings? ”

“5. According to the legislation in force, forensic necropsies (regardless of the specific nature of the case) are performed by a forensic pathologist salaried/employed by the Institute/Service/Office of Forensic Medicine, specifically designated by the director of the institution/head of the laboratory and the head of the SJML, respectively. The deaths following SARS-CoV2 infections were not subjected to autopsy via special procedures. No medico-legal autopsies have been ordered by the judicial authorities to be reported as post-vaccination COVID-19 deaths.”

“8. How many of the post-vaccination COVID-19 deaths have been confirmed by the Commission as being caused or precipitated by the COVID-19 vaccination? ”

“8. After consulting the national network of forensic medicine, the Forensic Medicine Commission found that there were no cases at the national level in which a direct causal relationship between sudden deaths and COVID-19 vaccination could be established via necropsy . As previously mentioned, there was no commission to analyze these necropsies. Furthermore, the necropsy files are part of criminal investigation files; therefore, the information within them cannot be publicly disseminated, and there is no mandatory requirement to report this indicator . ”

“10. Was immunohistochemistry performed on the affected tissues for the detection of the spike protein concurrently with immunohistochemistry for the detection of the viral nucleocapsid, as conducted by German professor Burkhardt, to differentiate between lesions produced by the vaccine and those produced by COVID disease? <https://doctors4covidethics.org/vascular-and-organ-damage-induced-by-mrna-vaccines-ir-refutable-proof-of-causality/> ”

*“10. Immunohistochemistry is not a procedure routinely performed within forensic medical institutions. The decision to expand complementary laboratory investigations rests with the forensic physician responsible for the case. This decision is made in conjunction with the particularities of the case **and the objectives of the ordinance under which the forensic autopsy is performed**, as well as in relation to the laboratory capabilities of the forensic medicine institution. **No requests or objectives were recorded in the ordinances regarding the determination of the cause of death following the vaccination or the causality between vaccination and death, as previously indicated. The necroptic research to which you referred, which is based on a scientific communication by the reputable Professor Burkhardt Madea from Germany, is of a fundamental research nature and does not constitute a methodological norm at either the national or European level.** On the other hand, DECISION no. 1609 of November 8, 2006, regarding the approval of fees for performing forensic expertises, findings, and other medico-legal works, does not provide a fee for the respective immunohistochemical test. ”*

„11. “Were toxicological tests performed on individuals who deceased post-vaccination?”

*“11. Samplings of biological products and complementary toxicological analyses were ordered by each forensic pathologist responsible for the case, in accordance with the particularities of the case and **the objectives of the investigative body as set forth in the ordinance . Toxicological analyses were performed whenever necessary** , according to the methodology and protocols in force, as well as those dictated by the particularities of the case and the objectives of the ordinance **independently of any relation to COVID-19 vaccination.** The fact that no deceased persons were reported post-vaccination renders the question moot. **Autopsy files are part of criminal investigation records; therefore, the information contained therein cannot be publicly disseminated, and there is no mandatory requirement to report this indicator . ”***

“12. Were the deaths occurring as a result of delayed reactions, occurring after the first 30 days following vaccination, also investigated? How many such deaths were investigated and what were the conclusions? ”

*“12. After **30 days post-vaccination, 3 deaths were reported** of which one is under investigation; for the second, the cause of death was: non-resuscitable cardio-respiratory arrest, acute respiratory failure, circulatory failure, sepsis of renal origin; for the third, the cause of death was: cardio-respiratory arrest, heart failure, grade II arterial hypertension, chronic obliterative arteriopathy, and type II diabetes mellitus. All the deaths have been investigated, and one is currently under investigation.*

Regarding 27 deaths, no direct causal link exists between the death and vaccination; one death is currently under investigation, and for another, the investigation has not yet been finalized . ”

“14. Was the composition of the vaccines from the lots involved in the post-vaccination deaths analyzed, as mandated by the INSP AEFI Case Investigation Guide.pdf (<https://insp.gov.ro/centrul-national-de-supraveghere-si-control-al-bolilor-transmisibile-cnscbt/metodologii/>)? ”

“14. In none of the suspected post-vaccination deaths was the composition of the vaccine analyzed, as the hypothesis of a link between the vaccine and the death was not supported by the corroboration of medical data and necropsy results to the extent of necessitating an analysis of the vaccine. Furthermore, the COVID-19 vaccines placed on the market in Romania received authorization from the ANMDM, the institution responsible for pharmacovigilance regarding medicinal products and vaccines

I hereby state that regarding questions 15-17 concerning compensation for persons who suffered damages following the vaccination, the Ministry of Health evaded the answer, asserting that the vaccination was voluntary.

“15. Who is liable and pays for post-vaccination damages (the manufacturing company, the Romanian State, or the European Union?). 16. From what funds are compensations paid for post-vaccination damages (severe adverse reactions, deaths)? 17. What are the steps that must be followed by a person who has suffered post-vaccination damages, or by the family of a person deceased because of the vaccine, in order to obtain these compensations?”

*“15. 16. 17. Strategy for Vaccination against COVID-19 in Romania (<https://vaccinarcovid.gov.ro/strategia-de-vaccinare-impotriva-covid-19-in-romania-este-disponibila/>) establishes the vision, principles, and framework for the administration in Romania of the vaccines authorized by the European Medicines Agency. Currently, a COVID-19 vaccination campaign is underway in our country, coordinated by The Government of Romania, **but no legislation has been adopted to directly mandate COVID-19 vaccination through the imposition of a legal obligation to vaccinate all individuals or specific categories of persons.**”*

Such a response is unacceptable. Does this imply that this was a psychological experiment designed to test human resistance to pressure, whereby weaker or less informed individuals succumbed to manipulation or the pressure to be vaccinated with the experimental products? Was consent obtained from these individuals under conditions where they are deemed to have automatically assumed the adverse reactions of which they were not informed, while the authorities repeatedly asserted that the experimental products are safe and effective? What is the role of the authorities funded by the citizenry? Is it to deceive and induce illness and suffering, rather than providing protection and accurate information? **For this reason, it is all the more imperative to conduct an official analysis of these experimental products which contain, according to independent investigations, undeclared elements and Toxic substances.** In this manner, the consent provided by the individuals who agreed to be injected is nullified, and the authorities, professional organizations, and manufacturing companies must be held accountable for these acts

The two petitions indicate that by the end of 2022, 28 post-COVID-19 deaths were reported and “investigated”; it was subsequently determined—without providing details regarding the investigations conducted or disclosing the age and comorbidities of the deceased—that these deaths were unrelated to vaccination.

However, it appears that post-vaccination deaths were more numerous than those reported by the INSP, the Ministry of Health, and the ANMDMR, as a press release issued by the INSP on June 30, 2022, stated that between December 27, 2020, and March 14, 2021, 89 deaths were recorded among persons confirmed with the SARS-CoV-2 virus who had been vaccinated; 77 of these individuals died, on average, 23 days after the first dose, and 12 died, on average, 14 days after the second dose. It was stated that “the average age of the deceased persons is 72 years, all having comorbidities in their medical history,” and that “data analysis shows that there is no direct link between vaccination and death” <https://insp.gov.ro/2021/06/30/comunicati-de-presa/> .

From these data, it follows that both the INSP and the Ministry of Health lied in the responses provided to my petitions; it is clearly evident from the press release that there were at least 89 post-vaccination deaths, and not merely 28 as asserted by the INSP or 29 as asserted by the Ministry of Health.

Even if they were diagnosed with COVID-19, the 89 deceased individuals had been recently vaccinated within an interval of less than 3 months, a fact which should have mandated their classification as post-vaccination deaths and a corresponding investigation <https://insp.gov.ro/download/ghid-investigare-cazuri-rapi->

[pdf/?wpdmml=96227&refresh=68e81baftd8ft4ft1760041903](https://insp.gov.ro/2021/06/30/comunicat-de-presa/) particularly as numerous individuals reported the onset of COVID-like symptoms following vaccination, which were merely attributed to the reactogenicity of the administration of the vaccine.

insp.gov.ro/2021/06/30/comunicat-de-presa/

luni 30, 2021

PRECIZARE DE PRESĂ

Că urmare a informațiilor vehiculate în spațiul public referitoare la cele 89 de persoane decedate în urma infecției cu virusul SARS CoV-2 și care au fost vaccinate, pentru corecta informare a opiniei publice, Institutul Național de Sănătate Publică face următoarele precizări:

În perioada 27.12.2020-14.03.2021, la INSP au fost raportate RAP și investigate, 5 decese suspecte post vaccinare, fără o legătură de cauzalitate cu vaccinarea.

În intervalul 1.01-14.03.2021, la nivel național au fost înregistrate 89 de decese în rândul persoanelor confirmate cu virusul SARS CoV-2 și care au fost vaccinate. Totodată, în același interval de timp, în 12 dintre situații, persoanele au primit atât prima doză, cât și a doua doză de vaccin.

Pentru prezentarea corectă a contextului în care aceste date au fost preluate în spațiul public, facem precizarea că dintre cele 89 de decese comunicate, 77 de persoane au decedat, în medie la 23 de zile după prima doză. De asemenea, 76 de persoane dintre acestea au fost confirmate cu COVID-19, în medie, la 12 zile după administrarea primei doze, iar o persoană a efectuat prima doză de vaccin la 14 zile după confirmarea infecției.

Menționăm că 12 persoane vaccinate cu a doua doză au decedat, în medie, la 14 zile după administrarea rapelului, iar diagnosticul de COVID a fost stabilit, în medie, la 10 zile după a doua doză.

Media de vârstă a persoanelor decedate este de 72 de ani, toate având în istoricul medical comorbidități.

Analiza datelor arată că nu există nicio legătură directă între vaccinare și deces. Având în vedere timpul scurs de la data vaccinării la data confirmării cu infecție SARS CoV-2, vaccinarea acestor persoane nu a asigurat protecția optimă în fața infecției.

Furthermore, regarding question “ **7. How many COVID-19 deaths occurred among vaccinated persons and unvaccinated persons respectively, by age group, in 2021 and 2022 respectively?** ” contained in my petition to the INSP dated November 9, 2022, the INSP provided the following response (no. 23782, dated 5-12-2023).

7. Până la data prezentei adrese de răspuns datele solicitate de dumneavoastră sunt următoarele:

Grupa de vârstă (ani)	Număr decese	Numar decese la persoane <u>vaccinate</u>
0-4	2	0
5-14	3	0
15-64	9613	645
≥65	31180	2348
Total an 2021	40798	2993

Grupa de vârstă (ani)	Număr decese	Numar decese la persoane <u>vaccinate</u>
0-4	8	0
5-14	2	0
15-64	1310	316
≥65	7023	1410
Total an 2022	8343	1726

Following this response, a legitimate question arises **regarding the involvement of the COVID-19 vaccination in causing or accelerating COVID-19 deaths among persons who died of this disease in both 2021 and 2022, particularly as Vaccine-Associated Enhanced COVID disease (VAED), including Vaccine-Associated Enhanced Respiratory COVID disease (VAERD), was one of the safety concerns in the clinical trials of the COVID vaccines** <https://www.ema.europa.eu/en/documenttis/assessmenttis/>

Important Potential Risks		
Vaccine-associated enhanced disease (VAED) including Vaccine-associated enhanced respiratory disease (VAERD)	<u>Routine risk minimisation measures:</u>	<u>Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:</u>
	None. <u>Additional risk minimisation measures:</u> No risk minimisation measures.	DCA is intended to facilitate the capture of clinical details about the nature and severity of COVID-19 illness in individuals who have received the COVID-19 mRNA vaccine and is anticipated to provide insight into potential cases of vaccine lack of effect or VAED <u>Additional pharmacovigilance activities:</u> Studies (Final CSR Due Date) <ul style="list-style-type: none"> • C4591001 (31-Aug-2023) • C4591011 (31-Dec-2023) • C4591012 (31-Dec-2023) • ACCESS/VAC4EU (31-Jan-2024).

Professional organizations such as the MS and medical associations failed to exercise caution regarding the injection of Romanian citizens with the COVID experimental products; furthermore, they played an active role in the COVID-19 fraud.

The College of Physicians of Romania , which according to its statute <https://www.cmr.ro/stattut> is an apolitical or-
 ganization that defends the honor, freedom, and professional independence of the physician in the exercise of
 the profession, conducted itself during the COVID-19 period as a censorship body, threatening and initiating disci-
 plinary investigations against the physicians who expressed dissenting opinions regarding the measures taken during
 the COVID-19 period, including vaccination, despite the fact that their opinions were not merely personal but were
 scientifically grounded.

*“Art. 1.–(1) The College of Physicians of Romania is organized and operates, pursuant to the law and the
 present statute, as a national professional organization of physicians, being an institution of public law, non-gov-
 ernmental, apolitical, and non-profit.”*

*“(2) The College of Physicians of Romania has legal personality and is autonomous in relation to any public au-
 thority, exercising its powers without the possibility of any interference.”*

*“Art. 2.–(1) As a professional organization, the College of Physicians of Romania defends the dignity and pro-
 motes the rights and interests of its members in all spheres of activity, defends the honor, freedom, and
 professional independence of the physician in the exercise of the profession, and ensures compliance by physi-
 cians with their obligations toward the patient and public health.”*

I have personally been subjected to disciplinary investigations by the CMR on two occasions, following a public
 speech delivered at a protest and based on evidence-based opinions I presented during a television broadcast. In
 both instances—actions in which I participated in my capacity as a physician, a responsible citizen, and,
 above all, a mother—I employed appropriate language and provided evidence regarding the futility and the conse-
 quences of the measures implemented by the authorities during the COVID-19 period, including the COVID vaccines.

I shall present several situations relevant to the role played by the CMR in supporting fraud, censorship,
 and the manipulation of physicians and the trusting population. In addition to the online conferences orga-
 nized at the onset of the COVID-19 vaccination—attended by various members of the CMR leadership
 , academic staff, and representatives of the MS—wherein the vaccination products were presented

as safe and effective, without citing studies or bibliographies and without addressing the inquiries of the physicians who submitted written messages online, I shall further cite several instances.

In November 2021, a WHO commission visited Romania to promote vaccination, noting that the vaccination rate at that time was lower than in other states. During this visit, on November 4, Ms. Dorit Nitzan, the Emergency Director of WHO Europe, issued **an insistent, desperate appeal for vaccination**. The delegation from the World Health Organization (WHO) in Romania met with the President of the Romanian College of Physicians (CMR), Prof. Dr. Daniel Coriu; together, they issued a statement that was recorded and posted by the CMR on Facebook, but has unfortunately been recently deleted.

<https://www.facebook.com/ColegiulMedicilorDinRomania/videos/4590218551035778> . Nevertheless, the transcript was published by Ziare.com https://ziare.com/sttiri/val-patru-covid/director-oms-europa-despre-vaccinare-muttattii-copii-1708515?utm_source=Ziare.com&utm_medium=copy-paste under the title “ **WHO Chief, desperate appeal to Romanians: „Please, I implore you to get vaccination! The next mutations could affect children” VIDEO** ” <https://ziare.com/sttiri/val-patru-covid/director-oms-europa-despre-vaccinare-muttattii-copii-1708515>

*“It is time to work together, to believe in the evidence, to believe in medicine and in health (..) The vaccines administered in Romania are approved, validated, with the clinical trials concluded. We have never had so many vaccinated individuals with the same serum at a global level.” We are at war with a virus that knows no borders or limits. It is not a sophisticated creature, but it knows how to survive, and the following variants, the following mutations could affect children; therefore, let us be careful to act quickly (...) **I beg you, I implore you to get vaccinated** ! (...) Every life matters; we are here to save lives and to save the life of the future generation (...) The vaccine is a shield; if we are united, the virus will not be able to penetrate, said Dorit Nitzan, the director for Emergency Situations, WHO Europe. This text was copied from Ziare.com. WHO Chief, desperate appeal to Romanians : „I beg you, I implore you to get vaccinated! **The following mutations could affect children** ”*



This appeal contains, in addition to manipulation—by asserting that the virus could affect children to stimulate the COVID-19 vaccination of children— **VERY SERIOUS LIES** such as:

- " **the vaccines administered in Romania are approved, validated, with the clinical trials concluded** "—a false statement because, as demonstrated above, the vaccine product summaries clearly stated that **the safety and efficacy studies were to be concluded no earlier than August 2023**(https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-reportt_en.pdf)—page 114

C4591001 <i>Ongoing</i>	The objective of the study is to evaluate the safety, tolerability, immunogenicity and efficacy of COVID-19 mRNA vaccine An unfavorable imbalance between the vaccine and control groups in the frequency of COVID-19, in particular for severe COVID-19, may suggest the occurrence of vaccine associated enhanced disease. Surveillance is planned for 2 years following Dose 2.	Anaphylaxis Vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD) Use in patients with co-morbidities (C4591001 subset) Long term safety data.	CSR submission upon regulatory request:	Any time
			CSR submission 6 months post Dose 2:	31-Dec-2021
			Final CSR submission with supplemental follow-up:	31-Aug-2023

Such blatant lies, insulting to the intelligence of a physician who keeps informed, constitute further evidence of the massive fraud of the COVID-19 vaccination and the fact that through panic, hysteria, and disinformation, the objective was to inject experimental products into the human body for a purpose other than ending the COVID pandemic.

Furthermore, it must be considered that throughout the entire duration of the COVID-19 vaccination, the leadership of the CMR, presided over by Prof. Dr. Daniel Coriu, publicly threatened the physicians who disseminated messages contrary to those of the authorities with the revocation of the right to practice, thereby violating professional freedom, critical thinking, as well as the right to expression and the right to work.

<https://rohealthreview.ro/proft-dr-daniel-coriu-despre-ridicarea-dreptului-de-libera-practiica-penttiru-medicii--care-ttiransmitti-mesaje-anttiivaccin/> - "The President of the Romanian College of Physicians (CMR), Prof. Dr. Daniel Coriu, stated regarding the revocation of the right to practice for the physicians who disseminate anti-vaccine messages that the societal reaction was very positive, qualifying it as "unacceptable" for a physician to appear in public and present messages that gravely impact public health."



The common sense Resolution of THE EUROPEAN PARLIAMENT 2361 (2021) of January 27, 2021, regarding COVID-19 vaccination was not respected; the citizens of Romania were not informed of its existence for their use, amidst the enormous pressures of COVID-19 vaccination <https://pace.coe.intt/en/ftiles/29004/html> . In this document, the following are recommended, among others:

"3. Even quickly implemented, safe, and effective vaccines do not, however, represent an immediate panacea . Following the festive season at the end of 2020 and the beginning of 2021, with its traditional indoor gatherings, infection rates will likely be very high in most Member States.
Furthermore, French physicians have just scientifically established a correlation between outdoor temperatures and the

incidence rate of diseases regarding hospitalizations and the deaths. **It is unlikely that the vaccines will be sufficient to significantly reduce infection rates this winter—especially considering that, at this time, demand far exceeds supply.** Therefore, it will not be possible to resume any semblance of “normal life,” even under the best circumstances, until mid-to-late 2021 at the earliest. ”

„7. 1 regarding the development of vaccines against COVID-19:

7. 1 . 1 to ensure high -quality, robust clinical trials conducted in an ethical manner, in accordance with the relevant provisions of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and of Medicine: Convention on Human Rights and Bio-medicine (ETS No. 164, Oviedo Convention) and its Additional Protocol concerning Biomedical Research (CETS No. 195), and which progressively include children, pregnant women, and breastfeeding mothers;

7. 1 . 2 to ensure that the regulatory bodies responsible for evaluation and authorization of the vaccines against COVID-19 are independent and protected from political pressures;

7. 1 . 3 to ensure that the relevant minimum standards of safety, efficacy, and
quality of the vaccines are respected;

7. 1 . 4 to implement efficient systems for monitoring the vaccines and their safety following their implementation among the general population, including for the purpose of monitoring their long-term effects;

7. 1 . 5 to implement independent vaccination compensation programs in order to ensure compensation for damages and unjustified injuries resulting from the vaccination;

7. 1 . 6 to pay particular attention to potential insider trading practices by the executives of the pharmaceutical industry or pharmaceutical companies that unduly enrich themselves at public expense , through the implementation of the recommendations contained in Resolution 2071 (2015) 'Public health and pharmaceutical industry interests: how to guarantee the primacy of public health interests?'; ”

„7. 3 regarding the assurance of a high vaccination rate:

7. 3 . 1 to ensure that citizens are informed that vaccination is not mandatory and that no one is under political, social, or other pressure to be vaccinated if they do not wish to do so ;

7. 3 . 2 to ensure that no one is discriminated against for non-vaccination, due to possible health risks or the reluctance to be vaccinated;

7. 3 . 3 to take effective and early measures to combat disinformation, misinformation, and hesitation with regard to the vaccines against COVID-19;

7. 3 . 4 the distribution of transparent information regarding the safety and possible side effects of the vaccines , collaborating with social media platforms and regulating these platforms to prevent the spread of disinformation;

7. 3 . 5 to communicate in a transparent manner the content of the contracts with the vaccine manufacturers and to make them available to the public for parliamentary and public scrutiny;”

„7. 5 regarding the assurance of monitoring the long-term effects of the vaccines against COVID- 19 and regarding their safety:

- 7.5.1** to ensure international cooperation for the timely detection and elucidation of any safety signals through the global real-time exchange of data regarding adverse events following immunization (AEFI);
- 7.5.2** to utilize vaccination certificates solely for the designated purpose of monitoring the efficacy of the vaccines, potential side effects, and adverse events;
- 7.5.3** the elimination of any communication gaps between local, regional, and international public health authorities managing AEFI data and the remediation of deficiencies within existing medical data networks;
- 7.5.4** bringing pharmacovigilance closer to healthcare systems;”

Such documents, which protected the freedom of bodily autonomy—even if they served only as recommendations—were not disclosed to the public, despite the fact they would have provided the psychological support necessary to resist the pressure to make an erroneous choice. Thus, Romanian citizens, subjected to pressures regarding vaccination, were misled by the authorities who followed the recommendations of the WHO mandatory vaccination policy guide (**COVID-19 and mandatory vaccination: Ethical considerations** , Policy brief, 30 May 2022 <https://www.who.int/groups/working-group-on-ethics-and-covid-19>) and the guidance provided in articles such as NEJM (Mello MM, Silverman RD, Omer SB. **Ensuring Uptake of Vaccines against SARS-CoV-2** . *N Engl J Med*. 2020 Oct 1 ;383(14):1296-1299. doi: 10.1056/NEJMp2020926. Epub 2020 Jun 26. PMID: 32589371 https://www.nejm.org/doi/10.1056/NEJMp2020926?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20%20pubmed), they came to make decisions against their will, resulting in the violation of their consent, with consequences for their health that were apparent both immediately and continue to manifest more than 4 years after the initiation of the injection of these experimental products . Individuals who have suffered as a result of these products are left to their own devices; the authorities and the manufacturing companies assume no liability, as Romania lacks a compensation program for victims of the vaccination, unlike other states.

In view of their relevance, I present several passages from the guiding article on the vaccination for governments, **published as early as June 26, 2020, prior to the approval of the COVID-19 vaccines !!!** , in the renowned medical journal NEJM: “

Ensuring Uptake of Vaccines against SARS-CoV-2 . *N Engl J Med*. 2020 Oct 1;383(14):1296-1299. doi:

10.1056/NEJMp2020926. Epub 2020 Jun 26. PMID: 32589371

https://www.nejm.org/doi/10.1056/NEJMp2020926?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20%20pubmed).

Through such well-orchestrated plans, health policymakers have ensured that individuals would be compelled to accept, against their will, the experimental COVID-19 vaccines:

*“As COVID-19 continues to exert profound consequences, the development of a vaccine appears to be the most promising means of restoring normalcy to civil life. Perhaps no scientific discovery is more anxiously anticipated . **However, bringing a vaccine to market is only half the challenge** ; it is also essential to ensure a sufficiently high vaccination rate to achieve herd immunity. **Disturbingly, a recent survey found that only 49% of Americans intended to undergo vaccination against SARS-CoV**”.*

„One option for increasing the vaccination rate is the imposition of vaccination . Mandatory vaccination has proven effective in ensuring high rates of child immunization in many high-income countries. However,

With the exception of influenza vaccination for healthcare workers, mandatory vaccination has not been widely utilized for adults.

Although a vaccine may be months or even years away, developing a political strategy to ensure vaccine uptake requires time. We provide a framework that states can implement now to help ensure the adoption of the vaccine when it becomes available—including considering the point at which a mandate could become an option. Our approach is guided by lessons from the experiences of the USA with vaccines for the 1976 'swine flu,' H1N1 influenza, smallpox, and the human papillomavirus (HPV).

"The fifth criterion is that the government must have implemented specific support mechanisms for individuals required to receive the vaccination. Lessons from previous vaccination campaigns suggest that **a generous compensation program for individuals suffering serious side effects of the vaccine should be a central component of these efforts**. A federal compensation fund, such as the Smallpox Vaccine Injury Compensation Program, serves as an attractive model, although **identifying compensable injuries can be difficult in the case of a new vaccine.**"

"The final criterion is that the mandate of the vaccination is imposed only after a time-limited trial period of voluntary vaccination has proven unsuccessful. The principles of public health ethics advocate for the implementation of less burdensome policies prior to transitioning to more restrictive measures, whenever feasible. In this instance, **the costs associated with a failed voluntary scheme are sufficiently high that such an attempt should be limited to a period of a few weeks.** Member States should implement a system to measure the rate of vaccination within each priority group in relation to a defined set of coverage objectives. Ensuring the implementation of the aforementioned economic and logistical support will maximize the probability of success."

"Although state-mandated vaccination requirements are typically associated with admission to schools and nurseries, this approach is inappropriate for SARS-CoV-2, as children will not constitute a priority group. Furthermore, the state vaccination mandate should not be imposed as mandatory vaccination (an absolute requirement); instead, non-compliance therewith should entail a sanction. However, due to the contagiousness and dangerous nature of the virus, relatively substantial sanctions could be justified, including suspension of employment or state stay-at-home orders for individuals in groups designated as high priority who refuse vaccination. Nevertheless, neither fines nor criminal penalties should be utilized; fines disadvantage impoverished persons, and criminal penalties lead to legal challenges on procedural grounds regarding the guarantee of a fair trial. Both represent a poor public health policy for a COVID-19 vaccine, as they can fuel distrust without improving the vaccination rate."

I shall also present several relevant passages from the brochure "**COVID-19 and mandatory vaccination: Ethical considerations**" 30 May 2022, **a definitive guide for governments on how to achieve very high COVID-19 vaccination percentages by avoiding the enactment of mandatory vaccination (which would carry significant ethical implications), but through the application of cunning mandatory vaccination policies which, by means of the constraints, conditions, and pressures they entail, can secure a very high percentage of inoculation with the experimental products** <https://www.who.int/groups/working-group-on-ethics-and-covid-19> , <https://iris.who.int/bitstream/handle/10665/354585/WHO-2019-nCoV-Policy-brief-Mandatory-vaccination-2022.1-eng.pdf?sequence=1> .



“The governments and institutions also have a history of mandating the vaccination as a prerequisite for employment in certain environments/roles or for school attendance . Such policies may be ethically justified, as they can be crucial for protecting the health and well-being of the public.

*This value, however, may conflict with others, such as individual liberty and autonomy (i.e., permitting individuals to make their own decisions regarding their health) (1). While interference with individual liberty or autonomy does not inherently render a policy intervention unjustified, **policies that constrain or eliminate individual choice can be controversial and raise a series of ethical considerations; thus, they must be justified by the promotion of another significant social objective, such as protecting public health .***

Vaccination mandates may be ethically justified; however, their ethical justification depends on a series of conditions and considerations, including the contexts in which they are implemented . This document identifies and articulates important ethical considerations that should be explicitly evaluated and discussed through ethical analysis by governments and/or institutional decision-makers who may consider mandates for COVID-19 vaccination. The purpose of the document is to identify and articulate key ethical considerations to enable decision-makers to engage with them; it does not intend to fully explain or address these ethical considerations and ethical issues.”

“Contemporary forms of “mandatory vaccination” render vaccination a prerequisite, for instance, for employment in specific sectors or contexts, such as healthcare, school attendance, or participation in certain activities. Typically, mandatory vaccination policies permit a limited number of exceptions , such as medical contraindications recognized by the authorities . Despite the terminology, “mandatory vaccination” is rarely compulsory in the sense that individuals are not physically forced to become vaccinated individuals. In other words, a distinction exists between stating “one must be vaccinated” and “one must be vaccinated in order to...”. Nevertheless, mandatory vaccination policies constrain individual choice in non-trivial ways, specifically through consequences that render non-compliance arduous. The mandatory nature of vaccination is not unusual, although it must be noted that the World Health Organization (WHO) does not currently support the implementation of mandates for COVID-19 vaccination , arguing instead that it is preferable to conduct information campaigns and ensure the vaccines are accessible. In addition, the WHO has issued a position statement asserting that national authorities and transport operators should not require COVID-19 vaccination as a condition for international travel . The laws and legal justifications for mandatory vaccination vary by jurisdiction. However , what is ethical or ethically mandatory cannot and should not necessarily be reduced to what the law implies, because not everything that is ethical is legal and

Studies indicating the lack of efficacy of the COVID vaccines, even those conducted by individuals who were actively involved in promoting the COVID-19 vaccination, were not adopted by authorities or professional organizations such as the CMR, despite my efforts to bring them to their attention through petitions that remained unanswered.

The COVID vaccines demonstrated their inefficiency quite rapidly . Consequently, even Anthony Fauci published in January 2023, alongside other authors, the article “ **Rethinking nextt-generation vaccines ffor coronaviruses , infleunzaviruses, and otthier respirattiory viruses** ” <https://pmc.ncbi.nlm.nih.gov/articles/PMC9832587/> (Morens DM, Taubenberger JK, **Fauci AS** . Rethinking nextt-generation vaccines ffor coronaviruses, infleunzaviruses, and other respirattiory viruses. Cell Host Microbe. 2023 Jan 11;31(1):146-157. doi: 10.1016/j.chom.2022.11.016. PMID: 36634620; PMCID: PMC9832587). In this article, the failure of the COVID-19 vaccination is acknowledged, as well as that of other vaccines for various respiratory diseases (influenza, respiratory syncytial virus), urging researchers to develop next-generation vaccines. **Furthermore, this article indicates that multiple unknowns exist regarding the immune system, which limits the development of effective vaccines, and suggests that the failure of COVID vaccines to induce long-term immunity could have been anticipated** . **Therefore, the failure of the global injection campaign using experimental COVID-19 vaccine products could have been anticipated from the outset** . Inasmuch as I considered this article to be of significant importance , given that Anthony Fauci was the coordinator of COVID-19 vaccination in the USA and noting that it remained “unobserved” by professional organizations and authorities , I translated, interpreted, and published it in an online journal <https://www.activenews.ro/opinii/Dr.-Geanina-Hagima-AUTODEMASCAREA-LUI-FAUCI-VACCINAREA-COVID-A-FOST-O-INCERCARE-NEREUSITA-si-UN-ESEC-STIINTIFIC-SI-DE-SANATATE-PUBLICA-CARE-AR-TREBUI-ABORDAT-DE-URGENCY-182789>



I hereby set forth several passages from this article

*“During the COVID-19 pandemic, the rapid development and implementation of SARS-CoV-2 vaccines saved countless lives and **contributed to achieving early partial control of the pandemic** .¹² **However, as SARS-CoV-2 strain variants emerged, deficiencies in these vaccines became evident, reminiscent of influenza vaccines** . **The vaccines for these two very different viruses share common characteristics: they offer incomplete and short-lived protection against evolving viral variants that escape the immunity of the population.** ”*

*“**In view of all these factors, it is unsurprising that none of the predominantly mucosal respiratory viruses have ever been effectively controlled via vaccines** . This observation raises a question of fundamental importance: if natural infections with mucosal respiratory viruses do not elicit complete and long-term protective immunity against reinfection, how can we expect vaccines—specifically systemically administered, non-replicating vaccines—to do so? **This represents a major challenge for future vaccine development, and overcoming it is essential as we work toward the development of “next-generation” vaccines.** ”*

*“**To understand how the vaccines could protect against lower respiratory infections, we must learn** how the “interaction” between the upper respiratory, lower respiratory, and systemic immune systems is coordinated and controlled at the level of cellular receptors, antigen detection, antigen presentation, and numerous effector functions. **Furthermore, we must continue to investigate** the development and maintenance of virus-specific lung-resident memory B and T cells, how to increase their persistence in the lung, and the speed at which they can be mobilized to infected mucosal sites.”*

" Although vaccines against influenza and SARS-CoV-2 reduce the severity of the disease but fail to prevent infection, a significant number of deaths still occur, resulting in tens of thousands of annual influenza-related deaths in the United States. Given the imperfections of these vaccines, it appears to be a public health imperative to aggressively pursue superior vaccines and vaccination strategies."

*"We must think creatively **to develop next-generation vaccines** that provide immune protection against viruses surviving in human populations due to their capacity to remain significantly beyond the reach of the full protection afforded by innate and adaptive human immunity."*

" Past unsuccessful attempts to obtain solid protection against mucosal respiratory viruses and to control the deadly epidemics and pandemics they cause have represented a scientific and public health failure that must be addressed urgently . We are excited and invigorated by the fact that many researchers and collaborative groups are rethinking, from scratch, all our past hypotheses and approaches to prevent important respiratory viral diseases and are working to find new bold paths for progress ."

Despite this evidence of a lack of efficacy of the COVID-19 vaccines, organisms like the WHO continue to recommend inoculation with the COVID-19 vaccines through reports such as the one from December 2024 entitled "COVID-19 vaccination" https://www.who.int/docs/default-source/coronavirus/policy-briefs/policy-brief-covid-19-vaccination.pdf?sfvrsn=8a899cd3_2 „ **Countries are encouraged to explore periodic revaccination** of high-priority groups and certain subpopulations with special considerations, at an interval of 6-12 months, depending on the group"; „ **WHO recommends the integration of COVID-19 vaccination into primary healthcare** and other routine medical services."

The COVID vaccines were never safe and effective, as claimed by the authorities and professional organizations such as the CMR. On the ANMDMR website <https://www.anm.ro/medicament-de-uz-uman/farmacovigilenta/informatii-vaccinuri-covid-19/> the statement "

The COVID-19 vaccines are subject to additional monitoring (▼)."



Agencia Națională a Medicamentului
și a Dispozitivelor Medicale din România



Informatii vaccinuri COVID-19

*** Vaccinurile COVID-19 fac obiectul unor monitorizări suplimentare (▼).**

Prin raportarea reacțiilor adverse post-imunizare este posibilă identificarea rapidă de noi informații referitoare la siguranță.

Pacienții/persoanele vaccinate și profesioniștii din domeniul sănătății sunt rugați să completeze formularele de raportare cu date cât mai complete disponibile la momentul raportării (ex. denumire vaccin, număr lot, data vaccinare – prima doză/a doua doză etc.).

Mai multe informații despre vaccinul administrat sunt disponibile în adeverința de vaccinare.

Post-vaccination adverse reactions, even if under-reported, have multiplied over time in the product leaflets of these vaccine products, which continue to display the warning that these products are subject to ongoing monitoring https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf :



This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

The continuous, significant increase in the number of adverse reactions of the Pfizer vaccine is an example https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf :

Product leaflet December 2020

Table 1: Adverse reactions from Comirnaty clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis ¹	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia ² ; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Product leaflet 3 February 2022

Table 1: Adverse reactions from Comirnaty clinical trials and post-authorisation experience in individuals 5 years of age and older

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Very rare (< 1/10,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy ^a			
Immune system disorders			Hypersensitivity reactions (e.g. rash, pruritus, urticaria ¹ , angioedema ¹)			Anaphylaxis
Metabolism and nutrition disorders			Decreased appetite			
Psychiatric disorders			Insomnia			
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis ²		Paraesthesia ³ ; Hypoaesthesia ³
Cardiac disorders					Myocarditis ⁴ ; Pericarditis ⁴	
Gastrointestinal disorders	Diarrhoea ⁵	Nausea; Vomiting ⁵				
Skin and subcutaneous tissue disorder			Hyperhidrosis; Night sweats			Erythema multiforme ⁶
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia		Pain in extremity ⁷			
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia ⁸ ; Injection site swelling	Injection site redness ⁸	Asthenia ⁹ ; Malaise; Injection site pruritus			Extensive swelling of vaccinated limb ¹⁰ ; Facial swelling ¹⁰

Given the centralized authorization at the level of the EMA for these products, the ANMDMR asserts that it bears no responsibility for investigating these products, disregarding the fact that it has representatives at the level of the EMA both within the CHMP (Committee for Medicinal Products for Human Use) and the PRAC (Pharmacovigilance Risk Assessment Committee)

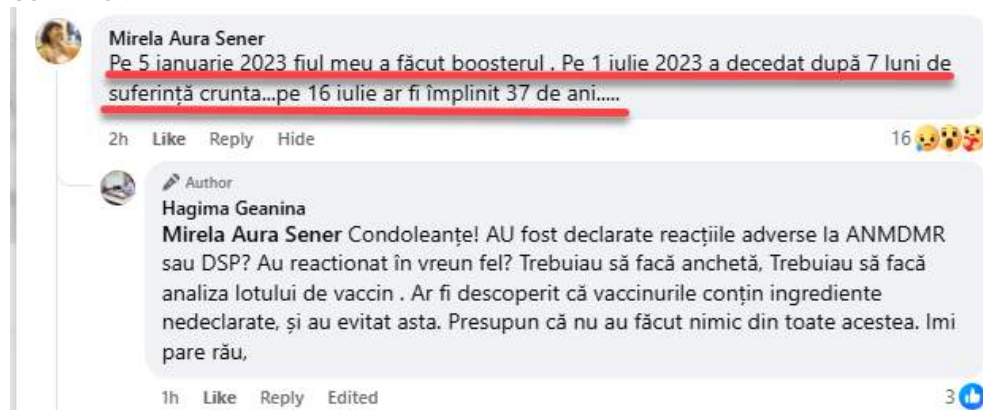
According to the statements of the ANMDMR, the COVID-19 vaccines, as with other vaccine products or medicinal products, are centrally approved by the European Medicines Agency (EMA). In the response dated **31.12.2021** to request no. **66897/31.12.2021** submitted to the ANMDMR (National Agency for Medicines and Medical Devices of Romania), it is stated

- "Pursuant to the provisions of Art. 704, para. (1) of Law No. 95/2006 on healthcare reform, republished, as subsequently amended and supplemented: "No medicinal product may be placed on the market in Romania **without a marketing authorization issued by the ANMDMR, in accordance with the provisions of this title, or without an authorization issued according to the centralized procedure** . ." – it follows, therefore, that **products approved through the centralized procedure at the level of the EMA bypass ANMDMR control**. What role, then, does the ANMDMR still fulfill? **THAT OF AN EXECUTANT?**
- "All the COVID-19 vaccines **received conditional marketing authorization from the European Medicines Agency (EMA) and are strictly monitored both by the EMA and by all Member States of the European Union** ." - From the above investigation into post-vaccination COVID-19 deaths, it is clearly evident that rigor was absent in the monitoring of these experimental products. The fact that they were **CONDITIONALLY AUTHORIZED !!!** is indicative of the fact that they could not be considered **SAFE AND EFFECTIVE**, as the authorities and, unfortunately, representatives of the Romanian College of Physicians (CMR) leadership, medical societies, and university professors from Faculties of Medicine hastily claimed.
- "Therefore, **the authorization of COVID-19 vaccines is carried out through a centralized procedure** ; authorization applications are submitted to the EMA rather than to each competent authority for medicinal products for human use within the European Union states. Thus, **the evaluation of the clinical results forming the basis for the authorization of these vaccines is conducted within the centralized authorization procedure by the Committee for Medicinal Products for Human Use (CHMP) of the**

EMA. Based on the scientific opinion of the CHMP, following the evaluation of quality, efficacy, and safety data submitted by the applicants, **the European Commission issues the marketing authorization decision** pursuant to the Treaty on the Functioning of the European Union and EC Regulation No. 726/2004 of THE EUROPEAN PARLIAMENT and of THE COUNCIL.” – By this assertion, the ANMDMR claims that the decision for the conditional authorization of the COVID vaccines rests with the CHMP-EMA; however, the ANMDMR **neglected to mention that it has two representatives on the CHMP committee:** <https://www.ema.europa.eu/en/committees/committee-medicinal-products-human-use-chmp/chmp-members> .



- ***“The decision of the European Commission represents the authorization of the respective medicinal product in all Member States of the European Union . In the European Union, conditional marketing authorizations allow the authorization of medicinal products that address unmet medical needs based on less complete data than is normally required . This occurs if the benefit to patients of the immediate placement on the market of the medicinal product or of the vaccine outweighs the risk inherent in the fact that not all data are yet available . Conditional marketing authorizations are used in the context of the pandemic to respond promptly to the threat to public health. Nevertheless, the data must demonstrate that the benefits of the vaccine outweigh any risks . Once the conditional marketing authorization has been granted, the companies must provide subsequent data from the ongoing clinical trials at predefined deadlines to confirm that the benefits continue to outweigh the risks . ”– ANMDMR knew that the information regarding the safety of the COVID vaccines was INCOMPLETE, and that the phase III clinical trials determining the safety and efficacy of the COVID vaccines would conclude, at the earliest , in August 2023. Nevertheless, ANMDMR issued no statement when the authorities and the physicians promoting the vaccines asserted that they were safe and effective , which resulted in disastrous consequences for the health of the Romanian people, as evidenced by the specialized literature, as well as by the comments on my posts from grieving families***
(https://www.facebook.com/dragnea.geanina.9/postts/pftbid02C6g6nwjpvMFkqkMRFUHFYj7_UGgKC9cs7ixU5_EVYvU925Frft4bE5BFvqPYELuTKI) and even on the television stations that had previously promoted vaccination—e.g. the documentary broadcast by Antena 3 on April 3, 2024, titled “Vaccinated and Abandoned | Documentary about Romanians with adverse effects from the vaccine against COVID-19”.





In another response from the ANMDMR dated 21-03-2022, following petition no. 52393 of 21-02-2022, it was acknowledged that this institution has representatives in the EMA's CHMP commission—a fact it failed to communicate in its 2021 response, creating the impression that the ANMDMR held no responsibility in the decision-making process for the conditional authorization of the COVID vaccines: ***“We specify that public information regarding the persons designated by the ANMDMR to the scientific working groups of the European Medicines Agency (EMA) can be found on the ANMDMR website at: Grupuri%20de%20lu-cru%2023.02.2022.pdf.”*** This response further states that ***“Within the centralized procedure, The CHMP is responsible for conducting the initial assessment of applications for marketing authorization at the EU level and evaluating changes or extensions (“variations”) to an existing marketing authorization ;The opinion of the Committee for Medicinal Products for Human Use (CHMP) is issued based on the assessment of documentation containing quality data, the results of non-clinical tests, and the results of clinical trials submitted by marketing authorization applicants to the EMA .”***

However, although the ANMDMR has two members on the CHMP committee, this institution insists on informing me that it bears no responsibility for the authorization of COVID vaccines, as if the ANMDMR representatives no longer comply with the rules of the ANMDMR *“In accordance with the provisions of Art. 5 para. (1) of Regulation (EC) No 726/2004 of THE EUROPEAN PARLIAMENT and of THE COUNCIL of 31 March 2004 laying down Union procedures for the authorization and supervision of medicinal products for human use and establishing a European Medicines Agency, the CHMP is part of the EMA, and according to paragraph (2) of the same article, the CHMP formulates the scientific opinion for applications for authorization and marketing placement submitted through the centralized procedure, including for the vaccines and medicinal products for COVID opinions regarding applications for authorization, renewal of the marketing authorization, and variations to the terms of marketing authorizations for the medicinal products submitted to the EMA are not taken at the national level. Consequently, the performance of duties by CHMP members is regulated by the aforementioned European legislation .* I am convinced that the ANMDMR possesses the legislative control levers over its members in the CHMP commission of the EMA in the event that they do not perform their activities in accordance with the interests of the Romanian people (e.g., withdrawal of representative status).

The same response further states: *“ Based on the CHMP opinion of the EMA, following the evaluation of the quality, efficacy, and safety data submitted by the applicants, the European Commission issues the marketing authorization decision, pursuant to the Treaty on the Functioning of the European Union and EC Regulation No. 726/2004 of THE EUROPEAN PARLIAMENT and of THE COUNCIL. The decision of the European Commission constitutes the authorization of the respective medicinal product in all Member States of the European Union .”* The decision of the European Commission represents the authorization for the respective medicinal product to be placed on the market in all Member States of the European Union. The marketing authorization decisions of the European Commission

are directly applicable from a legal standpoint and valid in all states of the European Union; consequently, marketing authorizations are not issued for each individual member state ."

The same response indicates that authorization does not require a verification of the composition of the vaccines, but only the analysis of the documentation presented by the manufacturer and of the clinical trials. *For any centralized authorization procedure, the scientific evaluation of the documentation is carried out by a rapporteur and a co-rapporteur, experts in the evaluation of scientific documentation who lead the teams of evaluators. The responsibilities of the rapporteur and co-rapporteur, which they fulfill alongside the evaluation teams they lead, consist of the scientific evaluation of the authorization documentation and the drafting of evaluation reports regarding quality, non-clinical, and clinical documentation, which include a section for the assessment of the benefit/risk ratio and the submission of these reports to the Committee ; In formulating its scientific opinion, the Committee for Medicinal Products for Human Use relies on the expertise of the Biological Working Party, where assessment reports concerning quality documentation are discussed, as well as on the expertise of the Pharmacovigilance Risk Assessment Committee. In the case of vaccines and medicinal products for the treatment of COVID-19, the assessment reports of the rapporteur and co-rapporteur were also discussed within the COVID-19 EMA Pandemic Task Force (COVID-ETF); In accordance with the EMA Emerging Health Threats Plan, the EMA Pandemic Task Force provided scientific recommendations to the CHMP regarding the vaccines and medicinal products for the treatment of COVID* **For all COVID-19 vaccines and medicinal products authorized through the centralized procedure, the CHMP opinion was reached by consensus among all its members from all EU Member States .**

The evaluation of the data submitted by the marketing authorization holders for the renewal of conditional authorizations is conducted by the same evaluation teams led by the rapporteurs nominated for authorization; thus, the opinion regarding the renewal of the conditional authorization was adopted by the CHMP based on the rapporteur's evaluation reports ." Although the ANMDMR response states, without providing a link, **"The public evaluation reports for the COVID-19 vaccines and the medicinal products for the treatment of COVID-19 are published on the EMA website," I was not provided with a link to find these reports in the Romanian language, which the physicians should be aware of, as would have been standard practice, so that the physicians could inform themselves from the source rather than from the television.** I discovered these reports in Romanian on the ANMDMR website late and by chance; the most recent update of these reports is outdated, dating back to 11-10-2021!!! <https://www.anm.ro/medicament-de-uz-uman/farmacovigilenta/informatii-vaccinuri-covid>

Within the body of the response, the ANMDMR repeatedly emphasized that it bore and continues to bear no responsibility, a claim that is only partially true given that CHMP representatives are employees of the ANMDMR. " Consequently, the decision to utilize centrally authorized COVID-19 vaccines within Romania does not fall under the jurisdiction of the ANMDMR . " Furthermore, if the ANMDMR, having duties in the monitoring of adverse reactions <https://www.anm.ro/medicament-de-uz-uman/farmacovigilenta/raportarea-reactiilor-adverse-suspectate-vaccin-covid-19/> , identified reports of severe adverse reactions and deaths in connection with the COVID-19 vaccination, it should have taken measures to apply the aforementioned INSP protocol <https://insp.gov.ro/download/ghid-investigare-cazuri-rapi-pdf/?wpdmcl=96227&refresh=68e81bafd8f4f1760041903> and to conduct the chemical analysis of the lots of the COVID vaccines.

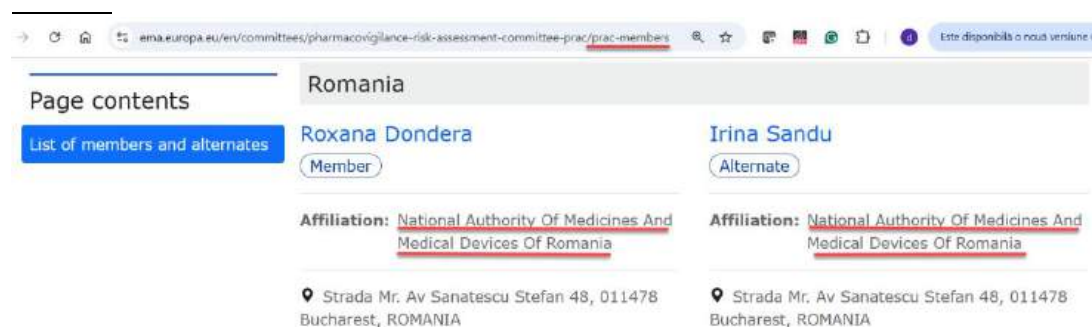
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We also observe how the ANMDMR shifts the responsibility for the COVID-19 vaccination toward other institutions, asserting that it has no jurisdiction regarding the decision of administration or the coordination of vaccination campaigns, although its role, through its representatives in the EMA CHMP, was to oversee the authorization of these products as well as the strict monitoring of adverse reactions „ *In the Summary of Product Characteristics, which is an integral part of the European Commission's marketing authorization decisions, legally applicable in all Member States for the COVID-19 vaccines, it is specified that the use of the vaccines must take official recommendations into account: "The use of this vaccine must take official recommendations into account .", such that the decision to administer a specific COVID-19 vaccine within a Member State falls under the responsibilities of the national authorities coordinating the vaccination campaigns ; this matter is left to the discretion of the competent national authorities coordinating the vaccination campaigns , as they make decisions at the national level*

regarding the administration of COVID-19 vaccines, **depending on the specific epidemiological situation in each Member State . However, the ANMDMR has no jurisdiction regarding the decision to administer a specific COVID-19 vaccine in a Member State and has not coordinated the vaccination campaigns ”.**

In this response, the ANMDMR informs me that the EMA plays a role in monitoring adverse reactions through the PRAC (Pharmacovigilance Risk Assessment Committee), yet neglects to mention that Romania has one designated member and one alternate member on this committee <https://www.ema.europa.eu/en/committees/pharmacovigilance-risk-assessment-committee-prac/prac-members> , both employees of the ANMDMR “Furthermore, at the European level, the assessment of all safety data is conducted by the EMA Committee for Pharmacovigilance Risk Assessment (Pharmacovigilance Risk Assessment Committee-PRAC), the committee responsible for assessing safety issues regarding medicinal products for human use . Once the assessment is finalized, the PRAC issues the necessary recommendations to minimize risks and protect the health of patients.” In addition, the responsibility for monitoring, investigating, and reporting post-vaccination adverse reactions in Romania lies with the specific authorities in Romania (ANMDMR, INSP), and not with the European Medicines Agency (EMA), which likely holds duties for the centralization of adverse reactions (already investigated) submitted by the institutions of each European country and for calculating, based on these reports, the risk-benefit ratio for vaccine products with conditional authorization. This implies that the STRICT monitoring of adverse reactions constituted a significant responsibility, which ought to have been handled with utmost gravity by the ANMDMR and INSP, as the renewal or termination of the conditional marketing authorization for these products was contingent upon such reporting .



In the same response, concerning the reporting of adverse reactions, **ANMDMR acknowledges that, while it was imperative to strictly monitor the adverse reactions of the COVID-19 vaccines and relay them to the EMA to facilitate a final, accurate assessment of the risk-benefit ratio by the EMA, “The reporting of suspected adverse reactions to the ANMDMR is not mandatory”:**

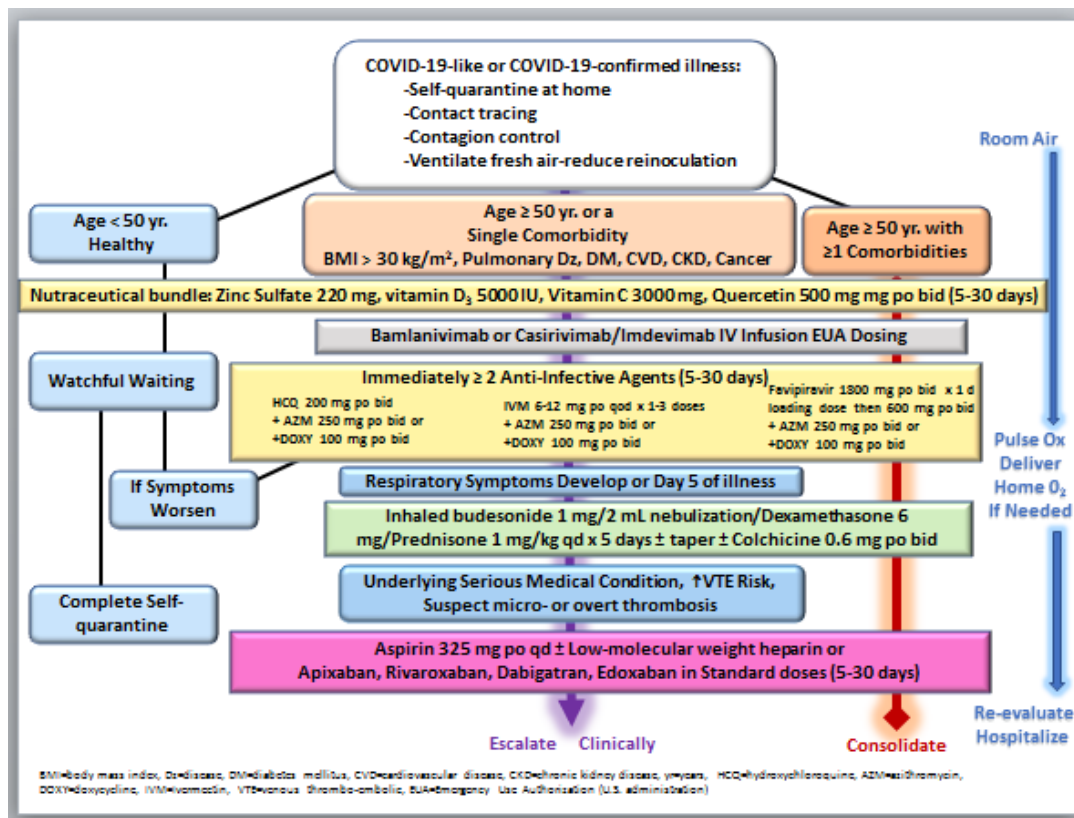
“According to the provisions of Art. 836 para. (1) of Law No. 95/2006, as subsequently amended and supplemented: “NAMMDR shall record all suspected adverse reactions occurring within the territory of Romania **which are brought to its attention by healthcare professionals and by patients** and shall ensure that the reports of these adverse reactions can be submitted via the national web portal regarding the medicinal products or by other means; if applicable”, and pursuant to Art. 836 para. (4) of the same normative act: “ **Within 15 days from the date of receipt of the reports mentioned in para. (1), ANMDMR shall transmit, in electronic format, to the EudraVigilance database the reports of suspected serious adverse reactions . Within 90 days from the date of receipt of the reports mentioned in paragraph. (1), ANMDMR shall transmit, in electronic format, to the EudraVigilance database the reports of suspected non-serious adverse reactions. Marketing authorization holders have access to these reports through the EudraVigilance database . ” The reporting of suspected adverse reactions to ANMDMR is not mandatory . Pursuant to a collaboration protocol in force, of a permanent nature, between ANMDMR through the Pharmacovigilance and Risk Management Directorate within ANMDMR and the National Institute of Public Health (INSP) through the National Center for Surveillance and Control of Communicable Diseases (CNSCBT) regarding the management of adverse reactions following immunization (AEFI), mutual information is exchanged regarding AEFI reported by physicians and patients . All suspected adverse reactions reported to the ANMDMR regarding vaccines are transmitted to the INSP-CNSCBT for investigation , in accordance with the protocol in force. All informa-**

obtained from the investigation of cases is transmitted to the ANMDMR. Suspected adverse reactions to the COVID-19 vaccines reported to the ANMDMR, including those received from the INSP/CNSCBT within the territory of Romania, are managed and subsequently transmitted to the EudraVigilance database pursuant to the provisions of paragraph (4) of Law No. 95/2006, as amended and supplemented. **We observe that the adverse reactions and the deaths should have been investigated by the INSP, which did not occur, as described above, because someone—whose identity remains unknown—decided in an opaque and fraudulent manner that deaths following COVID-19 vaccination are unrelated to the COVID-19 vaccination.** In this manner, the lots responsible for adverse reactions were not analyzed from a chemical standpoint or otherwise, as required by the INSP protocol for investigating post-inoculation adverse reactions. **Thus, the opportunity was missed to identify the undeclared chemical elements in the COVID-19 vaccines—elements identified by several independent researchers as indicated above—and to hold the manufacturing companies accountable by both the states and the individuals whose health was compromised or by the families of those who died.** **This response reveals an absolutely revolting fact: namely, that through the method of investigating post-vaccination COVID-19 deaths, no death can be proven to have been caused or accelerated by the COVID-19 vaccines, even if, as observed hereafter, young persons were also involved.** “ Since the beginning of the vaccination campaign in Romania and up to the present, **26 cases of death among vaccinated persons have been reported to the ANMDMR regarding the COVID-19 vaccines**, including cases received from the INSP-CNSCBT. The statistical breakdown of the number of deaths reported to the ANMDMR for the COVID-19 vaccines, based on the administered vaccine, is as follows: -1 case reported for the Vaxzevria vaccine, marketing authorization holder AstraZeneca AB; -2 cases reported for the COVID-19 Vaccine Janssen, marketing authorization holder Janssen-Cilag International NV; 4 cases reported for the Spikevax vaccine, marketing authorization holder Moderna Biotech Spain, S.L.; -19 cases reported regarding the Comirnaty vaccine, marketing authorization holder BioNTech Manufacturing GmbH. The statistical status of the number of deaths reported to the ANMDMR for the COVID-19 vaccines by age group is as follows: -12-15 years—none reported; -16-19 years—none reported; -20-29 years—none reported; - **30-49 years—5 deaths** ; - **50-59 years—3 deaths** ; - **60-79 years—13 deaths**; - **80-100 years—5 deaths** . The statistical status of the number of deaths reported to the ANMDMR for the COVID-19 vaccines, categorized by the reported time interval between the moment of the vaccination and the date of death: **-0-48 hours—7 cases; -2-7 days—7 cases** ; **-8-14 days—7 cases**; **-more than 14 days—5 cases** . In Romania, **for the cases of death reported to the ANMDMR regarding the vaccines to date (26 reports), no causal relationship has been confirmed between the patient's death and the administered COVID-19 vaccine** . **Reports of suspected adverse reactions to medicinal products are rarely sufficient to prove that a specific adverse effect was indeed caused by a particular vaccine or medicinal product. Such an effect could be a symptom of another underlying condition or potentially associated with another medicinal product administered concurrently to the patient.** Any report of a suspected adverse reaction to medicinal products or the vaccines represents only a small, yet significant, part of the process of accumulating all available data (including global spontaneous adverse reaction reports, clinical trials, epidemiological studies, and toxicological investigations) required to complete the scientific assessment. **There are multiple factors, such as polypharmacy, medical history, existing comorbidities, and others, which may influence the occurrence of an adverse effect for which the vaccination/medicinal product may represent merely a coincidence regarding the time of administration.** Statistics regarding undesirable adverse events following immunization (AEFI) from the national anti-SARS-CoV-2 vaccination campaign for the period 27.12.2020–03.10.2021, compiled by INSP-CNSCBT, are available on the website: <https://www.cnsbtt.ro/index.php/analiza-datte-supraveghere/rapi-1/2777-rapi-din-campania-nationatta-de> . The reports regarding adverse reactions should have been transparently available on the INSP website . Unfortunately, this page contains only one report covering the period 27.12.2021–03.10.2021: <https://www.cnsbtt.ro/index.php/analiza-date-supraveghere/rapi-1> . This report makes no mention of the post-vaccination COVID-19 deaths, specifically those referenced by the ANMDMR in its response. They should have at least been noted and subsequently declared unconfirmed, following the procedure applied to other adverse reactions presented in this report. **Why did the INSP choose not to**

failed to mention at all in its report these post-vaccination deaths, regarding which it is unknown who determined they had no link to the COVID-19 vaccination, despite the fact that monitoring severe reactions and deaths was critical for the risk-benefit assessment by the EMA's CHMP committee to maintain the conditional marketing authorization for these experimental vaccine products, the studies for which were not due to conclude until August 2023 at the earliest? I note that this report lists severe adverse reactions such as myocarditis, thrombosis, and anaphylactic shock, which the INSP states are **confirmed adverse reactions**. **Why did the INSP choose not to comply with the full protocol for investigating adverse reactions, which mandates the chemical analysis of the vaccine lots administered to the individuals in question, particularly as the report includes statements such as:** 'Between 27.12.2020 and 03.10.2021, there were confirmed **6 cases of myocarditis and one case of pericarditis**, classified as **AEFI associated with vaccine components**'; 'Between 27.12.2020 and 03.10.2021, there were confirmed **9 cases of anaphylactic shock**, classified as **AEFI associated with vaccine components**'; 'Between 27.12.2020 and 03.10.2021, there were confirmed **12 cases of thrombosis**, classified as **AEFI associated with vaccine components**.' <https://insp.gov.ro/download/ghid-investigare-cazuri-rapi-pdf/?wpdmdl=96227&refresh=68e81baftd8ft4ft1760041903>. The question arises—and I believe the INSP, the ANMDMR, and the Ministry of Health should have also raised it: **In relation to which components of the vaccine did these adverse reactions occur? With the nanolipid component? With the components used for the first time in humans within the composition of the nanolipid particles? With the mRNA contained in the nanolipid particles? With the particles undeclared by manufacturers, discovered following micro-Raman spectroscopy analysis, electron microscopy with energy-dispersive X-ray spectroscopy (EDX), or high-precision inductively coupled plasma mass spectrometry (ICP-MS) conducted by independent researchers from Spain, Canada, Germany, United Kingdom, Argentina, and Romania?**

VACCINATION WAS DEEMED THE SOLE SOLUTION, WHILE THE USE OF EFFECTIVE MEDICINAL PRODUCTS WAS EITHER PROHIBITED OR DISAPPROVED.

A critical condition for the conditional authorization of new products, such as the COVID-19 vaccines, was the demonstration of the lack of efficacy of existing medicinal products. Although articles by specialists proved that **COVID disease can be treated with medicinal products exhibiting few adverse reactions and a proven longitudinal safety record**, having been utilized for an extended period for other pathologies, **these treatments were deemed unsafe by various international organisms; consequently, certain studies were halted, others prohibited, and others falsified**. Examples of such medicinal products include ivermectin and hydroxychloroquine, which were recommended in protocols such as those described in the medical article published on December 10, 2020, prior to the conditional authorization of the COVID vaccines (!!!) – “Innovative Early Sequenced Multidrug Therapy for Sars-Cov-2 (COVID-19) Infection to Reduce Hospitalization and Death” <https://valleyinternattional.nett/index.php/ijmsci/article/view/2898>.



In another article from March 2021, entitled "Early Ambulatory Multidrug Therapy Reduces Hospitalization and Death in High-Risk Patients with SARS-CoV-2 (COVID-19)"

<https://ijirms.in/index.php/ijirms/article/view/1100> (Procter, MD (2021). Early Ambulatory Multidrug Therapy

Reduces Hospitalization and Death in High-Risk Patients with SARS-CoV-2 (COVID-19). International Journal of Innovative Research in

Medical Science, 6(03), 219–221. <https://doi.org/10.23958/ijirms/vol06-i03/1100>) se afirmă că respectarea protocoalului de

tratatament covid din schema de mai sus, aplicată devreme, **determină o reducere semnificativă a spitalizării și a deceselor "regimul nostru de tratament ambulatoriu timpuriu a fost asociat cu reduceri estimate de 87,6% și, respectiv, 74,9% ale spitalizării și deceselor, p<0,0001."**

Din păcate hidroxichlorochina a fost interzisă la scurt timp pentru tratamentele covidului, desi initial a fost în unele protocoale naționale de tratament. This fact was due to an article containing falsified studies published in The Lancet, which asserted that hydroxychloroquine is a dangerous medicinal product (despite its use in chronic treatment for years for autoimmune diseases such as systemic lupus erythematosus, at the same doses as those recommended for the short-term treatment of COVID-19); **this article was subsequently retracted** "Retraction—Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis" [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31324-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31324-6/fulltext) . **This grave and shameful situation, which demonstrated how science can be manipulated even in renowned journals such as The Lancet, is known as the Lancet-gate scandal** "Lancet gate: a matter of fact or a matter of concern" <https://www.sciencedirect.com/science/article/pii/S2052297520301104> . **Unfortunately, as a result of this fraudulent article, hydroxychloroquine—an efficient, inexpensive medicinal product with few adverse reactions—was not reinstated into the treatment protocols for the COVID-19 dis-**

Ivermectin, despite being deemed a useful treatment for the COVID-19 disease by numerous studies, was denigrated and characterized as a veterinary-use treatment, notwithstanding the fact that ivermectin is approved for human use in the treatment of specific parasitic infections. Thus, through the media campaign to denigrate these treatments for the COVID-19 disease, conducted with the collaboration of certain medical journals—including prestigious ones such as The Lancet—as well as the EMA (<https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-or-treatment-covid-19-outside-randomised-clinical-trials>), the FDA (Food and Drug Administration) (<https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19>), and the World Health Organization ([Ivermectin, despite being deemed a useful treatment for the COVID-19 disease by numerous studies, was denigrated and characterized as a veterinary-use treatment, notwithstanding the fact that ivermectin is approved for human use in the treatment of specific parasitic infections. Thus, through the media campaign to denigrate these treatments for the COVID-19 disease, conducted with the collaboration of certain medical journals—including prestigious ones such as The Lancet—as well as the EMA \(<https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-or-treatment-covid-19-outside-randomised-clinical-trials>\), the**](https://www.who.int/news-room/feature-stories/detail/who-advises-that-</p>
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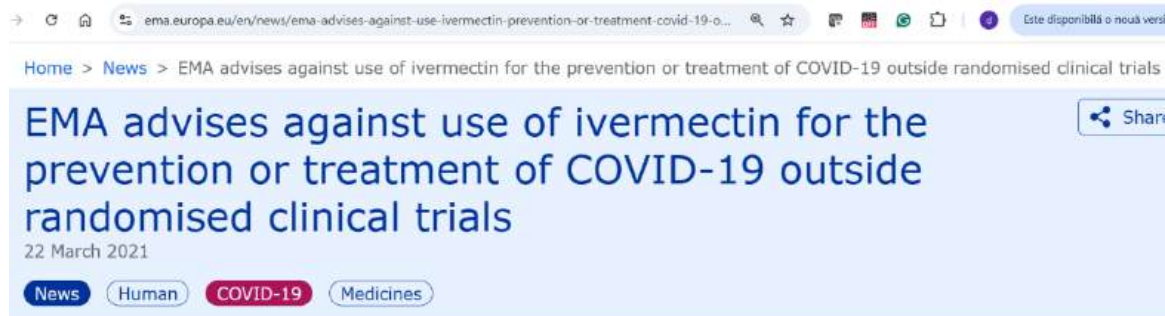
FDA (Food and Drug Administration) (<https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19>),

and the World Health Organization (

[ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials](#), inexpensive medicinal products with few adverse reactions, such as hydroxychloroquine and ivermectin, were excluded from official protocols. However, following legal actions initiated by physicians sanctioned for prescribing ivermectin, the plaintiffs prevailed in their lawsuits in the USA <https://edition.cnn.com/2024/03/27/health/fda-ivermectin-lawsuit>.

On its website, the EMA states that ivermectin should not be administered for the treatment of COVID-19 outside of clinical trials: “EMA has reviewed the latest evidence on the use of ivermectin for the prevention and treatment of COVID-19 and concluded that **the available data do not support its use for COVID-19 outside of well-designed clinical trials.**”

<https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-or-treatment-covid-19-outside-randomised-clinical-trials>



EMA has reviewed the latest evidence on the use of ivermectin for the prevention and treatment of COVID-19 and concluded that the available data do not support its use for COVID-19 outside well-designed clinical trials.

It is important to note that clinical trials for ivermectin or hydroxychloroquine were not conducted in Romania, although such initiatives should have been undertaken prior to the unconditional acceptance of experimental COVID-19 vaccines featuring novel technology, new excipients, and incomplete clinical studies.

Thus, ANMDMR states in its response dated 31.12.2021 to request no. 66897/31.12.2021

“Ivermectin-based medicinal products are not authorized for administration in the treatment of COVID-19 at the level of the European Union, and ANMDMR has received no application to this effect.” Furthermore, the ANMDMR states: *“Laboratory studies have shown that ivermectin could block the replication of the SARS-CoV-2 virus (the virus that causes COVID-19), but at concentrations significantly higher than those achieved by administering ivermectin in the doses currently approved for use.”* Additionally, *there is insufficient evidence to support the use of ivermectin outside of clinical trials for the treatment of COVID-19. Although ivermectin is generally well tolerated when administered in doses approved for other indications, adverse reactions could increase as dosages are raised to the levels required to achieve pulmonary concentrations of ivermectin effective against the virus. Therefore, the toxicity of ivermectin cannot be excluded when used at doses higher than those approved for other indications. Additional, well-designed, randomized clinical trials are required to draw conclusions regarding the efficacy and safety of the medicinal product in the treatment of COVID-19.* On March 22, 2021, the European Medicines Agency (EMA) **published a recommendation against the use of ivermectin for the prevention or treatment of COVID-19 outside of randomized clinical trials** :

“ANMDMR does not hold the capacity of initiator or endorser of the Order of the Minister of Health no. 487/2020 for the approval of the treatment protocol for the SARS-CoV-2 viral infection, as subsequently amended and supplemented, and does not have within its competence the drafting of treatment protocols for medical conditions, including COVID-19. The inclusion of other active substances in the treatment protocol for the SARS-CoV-2 viral infection falls under the responsibility of The Commission for infectious diseases within the MS.” It follows, therefore, that the Ministry of Health should have taken the initiative to conduct such clinical trials, **a measure that was not implemented despite the necessity of the situation and the availability of means**

Furthermore, the ANMDMR response dated 31.12.2021 to request no. 66897/31.12.2021 clearly demonstrates that **the Ministry of Health lacked even the slightest intention of initiating clinical trials**

for the purpose of finding effective medicinal product treatments, waiting to be spoon-fed the results of foreign studies" Pursuant to the provisions of letter B.1.e. 'Other oral antivirals, with insufficiently demonstrated/undemonstrated activity' of the Protocol for the treatment of the SARS-CoV-2 viral infection, approved by Order of the Minister of Health No. 487/2020, as subsequently amended and supplemented, "ivermectin: **although an antiviral effect of ivermectin has been discussed, the data published to date do not support the recommendation for its use, as provided in the NIH guidelines** ". "

The products are authorized based solely on the documentation submitted by the manufacturing companies, without a thorough chemical or nanotechnological analysis of said products being conducted. These products, deemed safe and effective following centralized approval, are imported into Romania, and the ANMDMR asserts that it no longer holds the responsibility to verify them. The quality control of vaccine lots is performed by a laboratory. It is stated

To understand the objectives of the COVID-19 vaccination campaign—in which experimental products were utilized under the designation of vaccines, involving new technology, compounds never before used in humans, and undeclared ingredients according to independent analyses—it is essential to mention several aspects. From my point of view, the COVID pandemic did not occur by chance.

D. The context of the COVID pandemic, the COVID vaccines, and the simulations/preparations for pandemics

The introduction **of undeclared ingredients into the COVID vaccines was not an accidental event**. Nor was the emergence of the COVID pandemic an accidental event.

Although there have been controversies regarding the origin of the so-called SARS-COV2 virus, the initial official version was of natural origin, asserting that this virus of animal origin had undergone mutations and thus came to infect humans. However, there have also been many credible voices asserting that the SARS-COV2 virus is a biological weapon. Among these voices is that of Academician Victor Voicu, Vice President of the Romanian Academy, retired Major General, and former Head of the Department of Clinical Pharmacology, Toxicology, and Psychopharmacology at the Carol Davila University of Medicine and Pharmacy in Bucharest . In May 2020, he stated on the television station Antena 3 <https://www.antena3.ro/coronavirus/victor-voicu-coronavirus-arma-biologica-569079.html> " *The concept of a high-level epidemiological investigation must be pursued , to determine the origin of this pandemic and when the first patient afflicted with COVID-19 emerged. This is absolutely necessary because, out of respect for the world in which we live, we must know in order to prevent. Was it an error? Then let us treat it as such. (...) The SARS-CoV-2 virus is classified as a biological weapon by Johns Hopkins University. I have analyzed the virus from my perspective as a researcher.*

It corresponds to the defining characteristics of a biological weapon at a rate of 95%. We are duty-bound to analyze and remain realistic, rather than wandering aimlessly and losing our sense of direction and conduct ".

As the academician stated, the situation would have necessitated high-level epidemiological investigations; however, **such investigations lacked transparency and instead served the interests of the pharmaceutical industry, which profited immensely. Furthermore, the governments entered enthusiastically and without precaution—as if following a common script—into the framework of measures to limit the spread of the virus and the vaccination with the COVID experimental products, without questioning the origin of the virus or the accuracy of the viral sequencing provided to the world by China** . Based on this sequencing, pharmaceutical companies, through the use of unregulated AI, developed the experimental COVID-19 vaccines with unprecedented speed. Although **even a political novice would harbor suspicions and recommend the verification of information provided by China regarding such a biological weapon, the governments of the world failed to exercise suspicion or caution, suggesting a form of tacit agreement among the governments** .

In April 2025, the White House of the United States officially declared on its website that the SARS-CoV-2 virus, the causative agent of the COVID-19 disease, originated from a laboratory in Wuhan, China.

<https://www.whitehouse.gov/lab-leak-true-origins-of-covid-19/> . This website states that EcoHealth—under the leadership of Dr. Peter Daszak—utilized American taxpayer funds to facilitate dangerous gain-of-function research in Wuhan, China. This disclosure has sparked significant controversy, as it may be regarded as an instance where political considerations influenced, or at least appeared to influence, the interpretation of scientific matters. Unfortunately, despite this information originating from official sources, there is no public debate in Romania regarding these issues which, in turn, would raise further questions leading to the conclusion of the premeditation of the COVID-19 pandemic and the administration of experimental products termed vaccines. Public debate regarding this information would raise questions concerning **the stakeholders and interests** of those involved in this biological warfare on a

On November 19, 2024, **another critical piece of information emerged concerning NATO's involvement in the COVID-19 pandemic.**

The Dutch Minister of Health, Fleur Agema, characterized the coronavirus pandemic as a NATO military operation, stating that it was directed by the North Atlantic Alliance and the Netherlands' National Coordinator for Security and Counterterrorism (NCTV).

<https://easaily.com/en/news/2024/11/19/dutch-minister-of-health-covid-19-is-a-natto-military-operation> . The Minister emphasized that **European governments responded to the pandemic by fulfilling "obligations to NATO"** . At the same time, Fleur Agema stated that the NCTV (Netherlands National Coordinator for Security and Counter-terrorism) policy regarding the pandemic was a **"coup d'état"** . According to Minister Fleur Agema, **both COVID-19 and the current "pandemic preparedness" represent a military operation that has no connection with healthcare in the traditional sense of the word** . Dutch researcher Cies van den Bos reacted to this admission, describing the NCTV as a puppet of NATO. **"This country will only become free if the NCTV is completely abolished and such shadow governments can never impose themselves again,"** he said. The fact that NATO was actively involved in the COVID pandemic is clearly evident from NATO documents posted on its website <https://www.act.nato.int/article/natto-defence-ministters-agree-next-steps-in-fightt-againstt-coronavirus/> , https://shape.natto.int/resources/3/webseite/May%2025%20Factsheet%20COVID-19_en.pdf . It must be noted that NATO is deeply involved in military research involving **bio-digital convergence** ; **this** entails, as I will demonstrate hereafter, the fusion of **the biological with technology (including at the nano-scale)** utilizing technologies such as **nanotechnology** (nano-level communication, nanosensors, Internet of Things, Internet of Bodies, non-invasive brain-computer interface, special materials such as graphene), **5G/6G technology, Artificial intelligence, synthetic biology, genetic editing, big data, quantum computers, and satellites** transmitting in the terahertz band for the Internet of Things as well as for the Internet of Bodies, **3D printing** https://www.nato.int/nato_static_fl2014/assets/pdf/2020/4/pdf/190422-ST_Tech_Trends_Reportt_2020-2040.pdf - "Science & Technology Trends 2020-2040", Exploring the S&T Edge, NATO Science & Technology Organization

The world has been preparing for pandemics for several years . There are organizations whose scope of activity involves such preparatory actions, such as CEPI (the Coalition for Epidemic Preparedness Innovations), which states on its website: "CEPI is a global partnership working to accelerate the development of vaccines and other biological countermeasures against epidemic and pandemic threats".

Thus, in October 2019, in New York **the Johns Hopkins Center for Health Security, in partnership with the World Economic Forum and the Bill & Melinda Gates Foundation** , hosted **Eventti 201** , a **pandemic simulation exercise involving a coronavirus**,

<https://centtierforhealttthsecuritit.org/our-work/ttiablttiop-exercises/eventti-201-pandemic-ttiablttiop-exercise> , <https://www.youtube.com/watch?v=AoLw-Q8X174> . The exercise illustrated areas where public-private partnerships will be necessary during the response to a severe pandemic. At this

<https://centerforhealthsecurity.org/our-work/tabletop-exercises/event-201-pandemic-tabletop-exercise#recommendations> including **Chinese professor George F. Gao, Director General of the Chinese Center for Disease Control and Prevention; professor at the Institute of Microbiology of the Chinese Academy of Sciences; the president of the Chinese Society of Biotechnology and the president of the Asian Federation of Biotechnology (AFOB).** The conclusion of this exercise was that “ ***the next severe pandemic will not only cause serious illness and loss of life but could also trigger major cascading economic and societal consequences , which could contribute greatly to global impact and suffering*** ” and recommendations were made by the Johns Hopkins Center for Health Security, the World Economic Forum, and the Bill & Melinda Gates Foundation, including that “ ***the governments should provide more resources and support for the rapid development and production of vaccines , therapeutics, and diagnostic products that will be needed during a severe pandemic .*** ” Unfortunately, the coincidences between this international event and the occurrences since 2020 were far too significant, Event 201 representing instead the orchestration of the scenario according to which the COVID pandemic unfolded.

In 2018, a brochure was published on the website of the Johns Hopkins Center for Health Security—a center that provides consultancy to the leadership of the USA, the WHO, and the UN regarding biological weapons—presenting a detailed scenario of a pandemic involving the SPARS virus, which also describes late neurological adverse reactions occurring one year after vaccination; this scenario bears significant similarities to the COVID-19 pandemic, including the adverse reactions of the vaccines <https://centerforhealthsecurity.org/sites/default/files/2022-12/spars-pandemic-scenario.pdf>

While the federal government appeared to have appropriately addressed concerns around the acute side effects of Corovax, the long-term, chronic effects of the vaccine were still largely unknown. Nearing the end of 2027, reports of new neurological symptoms began to emerge. After showing no adverse side effects for nearly a year, several vaccine recipients slowly began to experience symptoms such as blurry vision, headaches, and numbness in their extremities. Due to the small number of these cases, the significance of their association with Corovax was never determined. As of this writing in 2030, longitudinal studies initiated by the NIH at the beginning of the vaccination program have not reached the next round of data collection, so formal analysis on these symptoms has not yet been conducted. Furthermore, these cases arose from the initial cohort of vaccine recipients—those in high-risk populations, including those with other underlying health conditions—making it increasingly difficult to determine the extent to which these symptoms are associated with vaccination.

E. THE COVID-19 PANDEMIC—CONSIDERED AN OPPORTUNE MOMENT TO RESET OUR WORLD; LEGACY PLANS FOR BIO-DIGITAL CONVERGENCE (NBIC), AS WELL AS THEIR ACCELERATION IN CONJUNCTION WITH THE COVID-19 PANDEMIC , CONSTITUTE EVIDENCE OF THE PREMEDITATION OF THE PANDEMIC AND THE INJECTION OF INDIVIDUALS WITH NANOTECHNOLOGY FOR THE INTERNET OF BODIES.

The COVID-19 pandemic was considered by **Klaus Schwab**, the founder of the **World Economic Forum**, „***a rare but narrow window of opportunity to reflect, reimagine, and reset our world to create a healthier, more equitable, and more prosperous future .*** ”

<https://www.weforum.org/stories/2020/06/now-is-the-time-for-a-great-reset/>



As early as 2015, in a document of the **World Economic Forum**, https://www3.weforum.org/docs/Media/AM17/AM17_4IR.pdf the Fourth Industrial Revolution was defined and announced—a concept synonymous with bio-digital convergence—and the major implications of this revolution for the future of humanity were presented “

The Fourth Industrial Revolution

*In the summer of 2015, Professor Schwab proposed that the theme of the 2016 Annual Meeting focus on the incredible speed and scale with which technology is disrupting all industries and economies worldwide. Reflecting upon the wealth of work produced by a broad spectrum of experts regarding the impact of digitalization and emerging technologies, including the in-depth contributions of the Forum itself, Schwab realized that **these changes were of such a fundamental nature that they constitute nothing less than a new industrial revolution**. This resulted in **the theme of the 2016 World Economic Forum Annual Meeting becoming 'Mastering the Fourth Industrial Revolution'**, following a series of expert consultations in Abu Dhabi in November 2015 and Professor Schwab's authorship of a bestselling book concerning the dramatic ways in which technology, business, and society are evolving in tandem.*

The Fourth Industrial Revolution describes a global transformation characterized by the convergence of digital, physical, and biological technologies. These technologies influence societies, economies, and individuals in ways that change not only the world around us, but also the very idea of what it means to be human. The resulting transformation is historic in terms of scale, speed, and scope. This transformation is not defined by any specific set of emerging technologies, but rather by a transition toward entirely new systems that are built on the infrastructure of the digital revolution.

As powerful technologies, such as Artificial intelligence, advanced materials, augmented reality, 3D printing, and new computing technologies become increasingly accessible and, ultimately, ubiquitous, they modify the way we produce, consume, communicate, move, generate energy, and interact with each other. And considering the new powers of genetic engineering and neurotechnologies, these can have a direct impact on who we are and the way we think and behave. The fundamental and global nature of this revolution also presents new threats related to the disruptions it may cause—affecting labor markets and the future of work, income inequality and geopolitical security, as well as social value systems and ethical frameworks. Throughout 2016, the Forum deepened and expanded its activity in the field of technology and society, and in October 2016 it announced a new office, to be opened in San Francisco in February 2017: the World Economic Center for the Fourth Industrial Revolution.

The Center will accelerate global cooperation for the efficient and effective governance of the Fourth Industrial Revolution, helping corporations, governments, civil society leaders, researchers, and other stakeholders to achieve the greatest positive societal impact of new technologies and scientific developments. If we do not properly govern the Fourth Industrial Revolution, its entire economic and social potential will not be realized.

In the same context of a profound change in the world we live in, which implies—as stated above by the World Economic Forum—not only changing the world around us but also what defines us as human beings, the UN also published in 2015 the plan “Transforming our world: the 2030 Agenda for

“Sustainable Development” has the motto “no one will be left behind,” a plan that announces from the outset, as does the World Economic Forum, “ **the transformation of our world.** ”

<https://sdgs.un.org/publications/transforming-our-world-2030-agenda-sustainable-development-17981> ,

<https://sdgs.un.org/sites/default/files/publications/21252030%20Agenda%20for%20Sustainable%20Development%20web.pdf>



TRANSFORMING OUR WORLD:



THE 2030 AGENDA FOR
SUSTAINABLE DEVELOPMENT

Although the UN states that this plan pursues humanitarian objectives – “This Agenda is a plan of action for people, planet and prosperity” and “We are determined to free the human race from the tyranny of poverty and want and to heal and secure our planet” – **the means by which these objectives are achieved are bold and transformative, namely through technologies such as nanotechnology, 5G/6G technologies, Artificial intelligence, synthetic biology, gene editing, big data, and technologies not properly regulated, about which the public has not been informed and whose application may have negative effects, some of which are irreversible. Furthermore, the UN is determined to leave no one behind, although the citizenry has not been informed of these plans; essentially, the transformation of the world we inhabit and of our very nature as human beings will be a forced endeavor, implemented under pressure regardless of popular consent— “ We are determined to take the bold and transformative steps which are urgently needed to shift the world onto a sustainable and resilient path ”, “ As we embark on this collective journey, we pledge that no one will be left behind ”, “ The 17 Sustainable Development Goals and 169 targets which we are announcing today demonstrate the scale and ambition of this new universal Agenda ”** <https://sdgs.un.org/2030agen->

The UN resolution to achieve all objectives of this plan is of paramount significance, given that, as stated on the webpage, there shall be a mobilization of **ALL AVAILABLE RESOURCES** :

“39. The scale and ambition of the new Agenda necessitate a revitalized **Global Partnership** to ensure its implementation. We are fully committed to this endeavor. This Partnership shall operate in a spirit of global solidarity, specifically in solidarity with the most impoverished and individuals in vulnerable situations. This shall facilitate intensive global engagement in support of the **implementation of all Goals and targets , bringing together the governments, the private sector, civil society, the United Nations system, and other actors and mobilizing all available resources .**”

If, on a military level, there exists a NATO-China-Russia competition used to justify the funding of military research for the discovery of new technologies useful for bio-digital convergence and human augmentation—research which even NATO asserts has left ethics behind [https://www.nato.int/nato_static_fl2014/assets/pdf/2020/4/pdf/190422-](https://www.nato.int/nato_static_fl2014/assets/pdf/2020/4/pdf/190422-ST_Tech_Trends_Reportt_2020-2040.pdf)

[ST Tech Trends Reportt_2020-2040.pdf](https://www.nato.int/nato_static_fl2014/assets/pdf/2020/4/pdf/190422-ST_Tech_Trends_Reportt_2020-2040.pdf) , regarding the UN, there is no longer any competition here, but rather a GLOBAL PARTNERSHIP; a total collaboration of states (including the governments, the private sector, civil society, and others) to achieve the Agenda 2030 objectives, utilizing for this purpose, as the UN states, „ **ALL RESOURCES** ”.

The right of every individual to reason and to decide to remain a human being, to decide for their own present and future and that of their children, as well as their free will, are not being respected.

Thus, bio-digital convergence is no longer an individual option, but rather a policy applied without the consent of all, constituting a grave violation of human rights.

Nanotechnology—an insufficiently regulated technology with toxic potential that may be utilized as a weapon or for the surveillance of human bodies—is regarded as a powerful instrument in addressing global challenges and promoting sustainable development.

<https://www.sciencedirect.com/science/article/pii/S2405844024074243> Elzein B. Nano Revolution: "Tiny tech, big impact: How nanotechnology is driving SDGs progress". Heliyon. 2024 May;10(10):e31393. DOI: 10.1016/j.heliyon.2024.e31393. PMID: 38818162; PMCID: PMC11137564 .

It is considered that “ ***nanotechnology and nanostructures can contribute to the achievement of the Sustainable Development Goals (SDGs) of the United Nations (UN) by improving energy efficiency and energy conversion, leading to a more sustainable and cleaner energy future; by improving water purification processes, allowing communities access to clean drinking water; by enabling specific systems for the administration of medication, the early detection of diseases, and personalized medicine, thereby revolutionizing healthcare; improving crop yields, enabling efficient nutrient delivery systems and pest control mechanisms, and promising the resolution of food security issues*** ”. Furthermore, it is considered that nanomaterials may be useful for pollution control. Therefore, “ ***by understanding and harnessing the potential of nanotechnology, decision-makers, researchers, and stakeholders can collaborate for a more sustainable future by achieving the 17 UN SDGs*** ”.

UNIDO is, as stated on its website <https://www.unido.org/about-us/who-we-are> “ ***a specialized agency of the United Nations with a unique mandate to promote, energize, and accelerate industrial development***”. This organization has the role of supporting the implementation of the 2030 Agenda and facilitating the achievement of its sustainable development goals. “Our mandate is reflected in Sustainable Development Goal (SDG) 9 : ‘Build resilient infrastructure , promote inclusive and sustainable industrialization, and foster innovation’, ***but UNIDO’s activities contribute to all SDGs*** .

The UNIDO vision is a world without poverty and hunger, where industry drives low-emission economies, improves the level of living and preserves a viable environment for present and future generations, leaving no one behind .

UNIDO ***offers support to its 173 Member States through four mandated functions: technical cooperation; action-oriented research and policy advisory services; activities related to normative standards; and the promotion of partnerships for knowledge and technology transfer.*** ”

On October 14, 2021, UNIDO published a brochure entitled “STANDARDS & DIGITAL TRANSFORMATION. GOOD GOVERNANCE IN A DIGITAL AGE” [https://www.unido.org/sites/default/files/files/2021-](https://www.unido.org/sites/default/files/files/2021-10/Standard_digital_transformation_ONLINE_FINAL.pdf)

[10/Standard_digital_transformation_ONLINE_FINAL.pdf](https://www.unido.org/sites/default/files/files/2021-10/Standard_digital_transformation_ONLINE_FINAL.pdf) . The introduction of this brochure states that we are in the midst of the implementation process of the fourth industrial revolution, a major change,

“***seismic***”, ***about which the public has not been informed***, which aims at ***connecting literally everything that exists on this planet, including humans*** . It is mentioned that this radical change is being achieved through technologies, especially digital technologies, and that ***standards are required to streamline this change*** . These standards were developed, as we will see below, by agencies such as IEC, IEEE. “ ***The world is in the midst of the Fourth Industrial Revolution (4IR), fueled by digital technologies that are transforming society, economies, and the environment. By increasingly connecting objects, machines, people, and the environment, the disruptive nature of these technological innovations makes it difficult to plan for and anticipate the future. What remains clear is that the seismic shift brought about by Digital transformation has major implications for sustainable development. Harmonized and timely standards can play an essential role in shaping the process of digital transformation, complementing regulations and contributing to digital transformation governance . Standards can facilitate the continuous digitalization of industry by increasing productivity and efficiency, while promoting compatibility and***

interoperability between products and processes through a common language, simultaneously guaranteeing minimum levels of quality and safety. Furthermore, standards can serve as accelerators of change, as they promote innovation, the adoption of new digital technologies, and disseminate knowledge through codification.

*This brochure presents a broader publication, developed by the United Nations Industrial Development Organization (UNIDO), which describes the digital transformation, its key drivers, and the **implications for three of the pillars of the Sustainable Development Goals (SDGs)**—people, prosperity, and planet. It also highlights **the role of standards in digital transformation governance**. An analysis of the international standards landscape was conducted for seven of the most popular digital technologies of the 4IR. While standardization reflects the different characteristics and breadth of impact of 4IR technologies, this publication identifies the essential criteria for understanding how to develop appropriate and effective standards for digital transformation worldwide. Based on the analysis, additional attention is given to the principles of good governance necessary to guide the development of standards in the digital technology landscape, to ensure that technologies remain human-centric and aligned with sustainability goals.*

The same document mentions **the significant role played by the COVID-19 pandemic in accelerating the Fourth Industrial Revolution**, a statement that raises grave suspicions, alongside other evidence cited in this report **regarding the premeditation of the COVID-19 action**. It follows from these statements that this UN agency recognizes that this involves an

irreversible, “irrevocable” change, which is why it is stated that **people should understand both the risks and the benefits**. Unfortunately, instead of the public being informed about this process of disruptive, extensive, accelerated, and irreversible change, **they were kept occupied with COVID-19 and subsequently with the disastrous consequences of the measures taken by the governments of the world, consisting of both an increase in sovereign debt and the sickening of the population, both physically and mentally, as a result of COVID vaccines and the measures implemented during the COVID period. Evidence of the bad faith of the governments of the world—acting in collaboration with agencies such as the UN, WHO, and WEF—and of the premeditated implementation of the irreversible, profound, and accelerated transformation of the world we inhabit, including of human beings themselves without their informed consent is the fact that despite the financial and public health disasters caused by the COVID-19 era, the people were not only left uninformed but were actively misinformed within the framework of the cognitive warfare upon which I shall elaborate below, and the plan for forced digitalization, absent the provision of information, it proceeded in an accelerated** “Revolutions and shifts have characterized human development. **What distinguishes the Fourth Industrial Revolution (4RI) from previous industrial revolutions are the parallel technological breakthroughs within and between the digital, biological, and physical spheres. The complexity and rapid pace of change in 4RI also render the revolution unique in comparison to prior industrial revolutions. Furthermore, the COVID-19 pandemic acted as an unforeseen accelerator of the pace of change and the structural transition toward 4RI and the adoption of new technologies. 4RI is still currently taking shape. The digital technologies underlying the 4RI will irrevocably transform systems and, consequently, the way people live, work, and interact; therefore, societies must understand the risks and rewards thereof. It is essential to ensure that new technologies within the digital, biological, and physical spheres remain human-centric and serve society and the planet as a whole.**”



CHANGING WORLD – THE FOURTH INDUSTRIAL REVOLUTION

Revolutions and change have marked human development. What distinguishes the 4IR from previous industrial revolutions is the parallel technological breakthroughs within and across the digital, biological and physical spheres. The complexity and rapid pace of change of the 4IR also make the revolution unique compared to previous industrial revolutions. Moreover, the COVID-19 pandemic has acted as an unanticipated accelerator to the pace of change and structural shift towards the 4IR and the adoption of new technologies.

The 4IR is still being shaped. The digital technologies that sit at the heart of the 4IR will irrevocably transform systems and, consequently, how people live, work and play; therefore, societies need to understand its risks and rewards. It is essential to ensure the new technologies in the digital, biological and physical worlds remain human-centered and serve society and the planet as a whole.

“Digital transformation is sustained by the digital technologies of the Fourth Industrial Revolution (4RI). The rapid adoption of these disruptive technologies is accelerating and has been further impelled by the COVID-19 pandemic . Global expenditures on digital transformation technologies and services increased by 10.4% in 2020 and by more than 10% in 2020. Technological adoption is not a geographically uniform process; A greater volume and higher rate of technology adoption occur within developed countries. Least developed countries are hindered, inter alia, by a lack of information and communications technology (TIC) and access to adequate architecture and core assets, such as computers and smart devices, but most crucially, by the capacity to ensure that the populace possesses the requisite set of fundamental skills. How this inequality is illustrated: in 2019, 92% of Swiss households, compared to 38% of households in Bangladesh, 36% of households in Peru, and 34% of households in Pakistan, had access to ICT. Detailed descriptions are included in the full publication regarding the following seven important digital technologies for Digital transformation: artificial intelligence, big data, blockchain technology/distributed ledger, Internet of Things, robotics, 3D printing, and autonomous vehicles . The scope and impact of these technologies vary, and standardization plays a role in each of them to help ensure trust, privacy, security, interoperability, and sustainability.”

Furthermore, **had the governments and these international organisms acted in good faith, the public should have been informed of these disruptive technologies as early as 2016 or even earlier, when the initial documents concerning the Fourth Industrial Revolution were drafted. Regrettably, information and debates regarding technologies such as nanotechnology, Artificial intelligence, synthetic biology, gene editing, 5G/6G technologies, technologies that communicate with the brain, and big data were absent during the years of stability prior to 2020, as well as following the emergence of COVID-19 after the year 2020. The financial crisis generated by COVID-19 should have decelerated, rather than accelerated, the Fourth Industrial Revolution and the programmed transformation of the world in which we live . In the post-COVID-19 era, states should have addressed the grave issues confronting society, such as the declining birth rate and the rise of various pathologies, rather than focusing on digitalization. This serves as further evidence that the governments have betrayed their citizens.**

The IEC (International Electrotechnical Commission) is a world-leading organization for the preparation and publication of international standards for all electrical, electronic, and related technologies, known collectively as “electrotechnology” <https://iec.ch/who-we-are> . On April 29, 2024, the IEC published a brochure entitled “Bio-digital convergence standardization opportunities” <https://www.iec.ch/basecamp/bio-digital-convergence-standardization-opportunities> . According to the IEC, the definition of bio-digital convergence is as follows: “ The term “ bio-digital convergence ” denotes the convergence of engineering, nanotechnology, biotechnology, information technology, and cognitive sciences . Although the concept has existed for at least 20 years , bio-digital convergence has been accelerated by rapid changes and the evolution of information and digital technologies . ” ” ” ” The IEC considers that biodigital innovations contribute to the achievement of the following nine UN sustainability goals: Zero Hunger (SDG 2), Good Health and Well-being (SDG 3), Clean Water and Sanitation (SDG 6), Industry, Innovation and Infrastructure (SDG 9), Sustainable Cities and Communities (SDG 11), Responsible Consumption and Production (SDG 12), Climate Action (SDG 13), Life Below Water (SDG 14) and Life on Land (SDG 15).

The IEC technological report evaluated the existing standardization within the field of bio-digital convergence and identified pertinent opportunities for further standardization. Standardization Evaluation Group (SEG) 12 of the IEC regarding biodigital convergence (BDC) has systematically evaluated various aspects of BDC: the reverse engineering of living systems (omics, synthetic biology, neurosciences); life systems and bioengineering (biosensors, human virtual twins, synthetic biology, artificial organs and organoids, and CRISPR technology); **human augmentation technologies (including brain-computer interfaces)**; agricultural bioengineering; environmental bioengineering; and the social, risk, and ethical dimensions of the bio-digital domain.

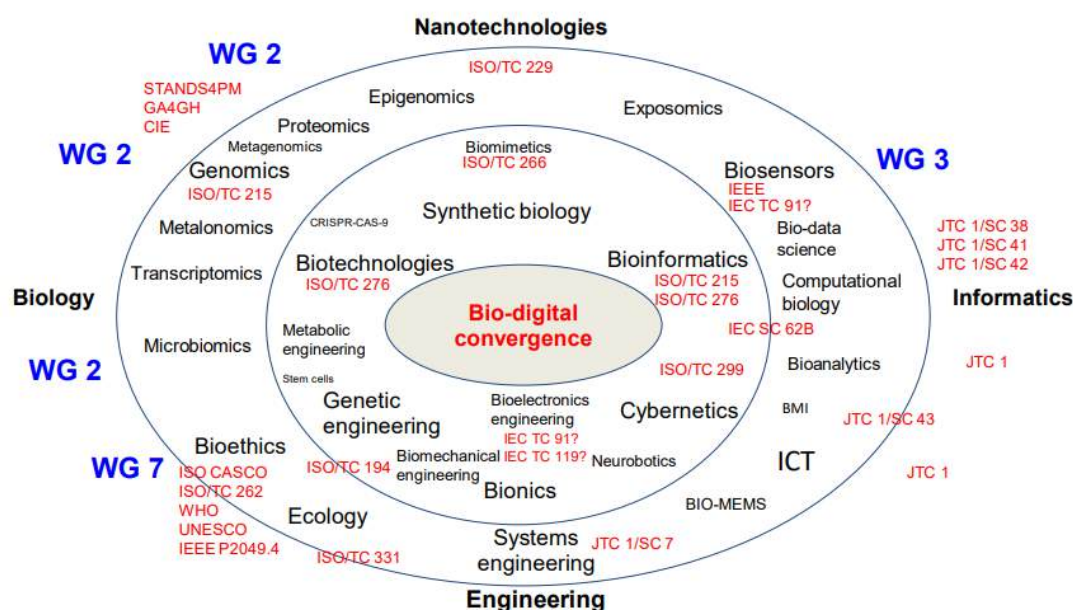


Figure 1 | Bio-digital convergence components

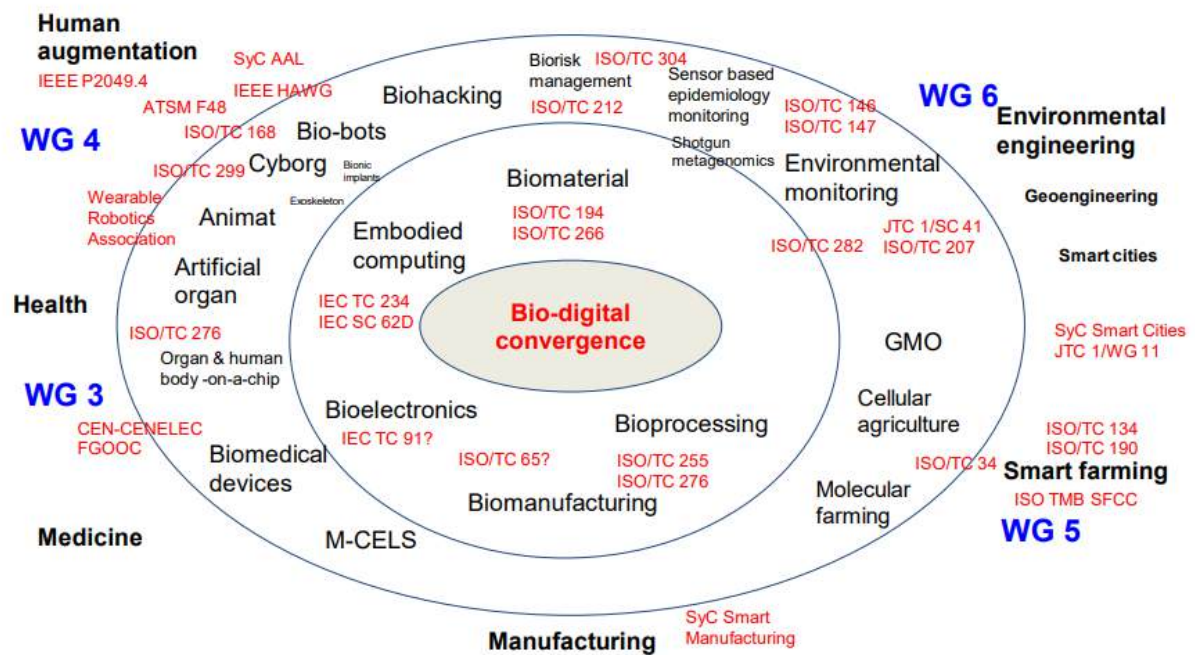


Figure 4 | Bio-digital convergence applications

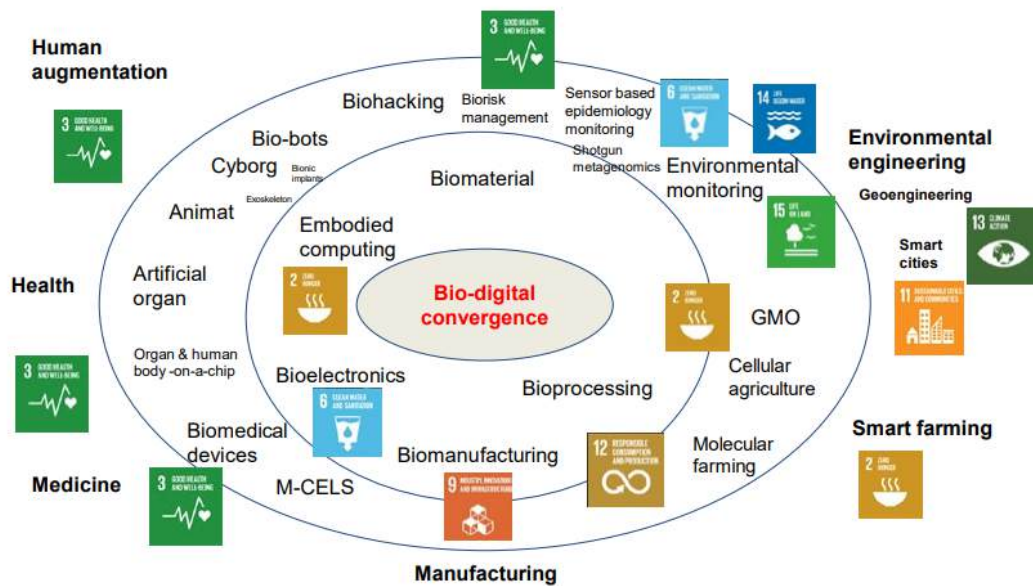
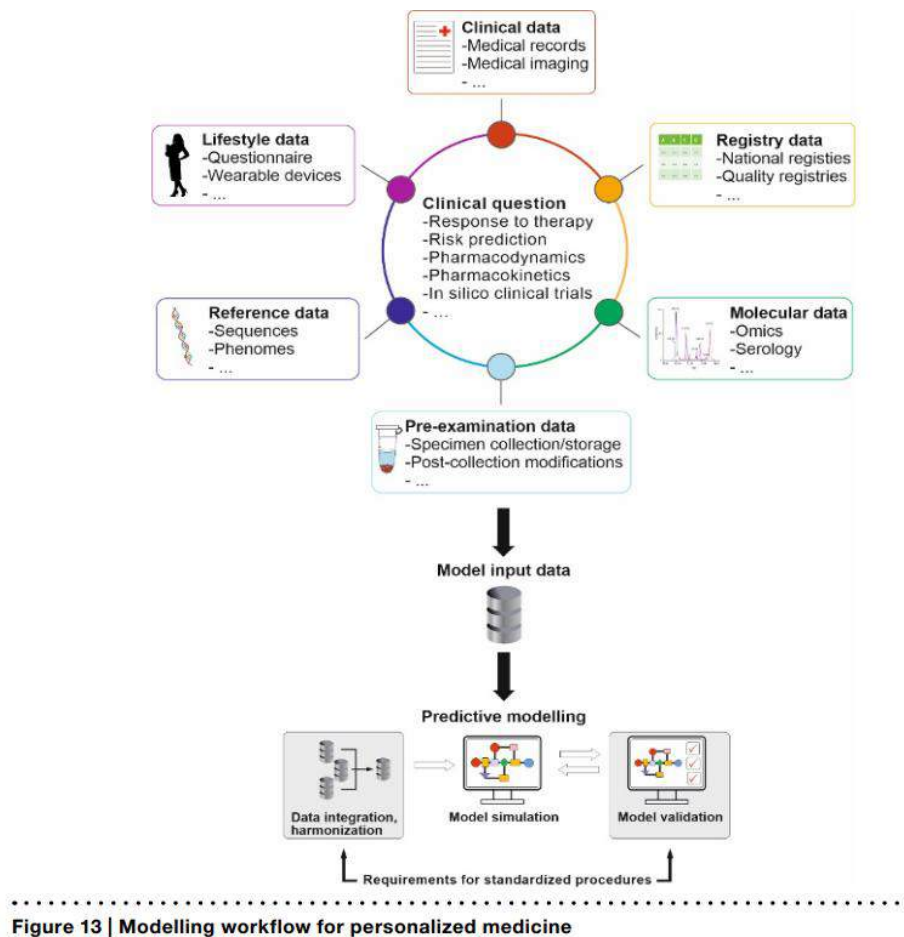


Figure 64 | Bio-digital convergence contributions to sustainability



The IEEE (Institute of Electrical and Electronics Engineers) is an American professional charitable organization for electrical engineering, electronic engineering, and related disciplines. Today, it is a global network of **more than 486,000 professionals in over 190 countries**.

<https://www.ieee.org/aboutt/att-a-glance>. In addition to publishing articles and organizing conferences, this organization is responsible for the **development of certain standards**. Among the IEEE standards is **standard 1901.1 regarding communications at the nano-scale, adopted in 2015 and published in 2016**, a standard intended to facilitate **the fulfillment of the objectives of biodigital convergence / those of the Fourth Industrial Revolution**. This standard paved the way for the introduction of nano-devices into the human body and beyond, which detect biological parameters and communicate with the internet; **essentially, it paved the way for the control of the human body, including the human mind, considering that some nano-devices are designed to reach the human brain**.

<https://ieeexplore.ieee.org/document/8247001> S. Canovas-Carrasco, A.-J. Garcia-Sanchez and J. Garcia-Haro, „Standard IEEE 1906.1: Nanocommunications as a New Data Source“, 2017 ITU Kaleidoscope: Challenges for a Data-Driven Society (ITU K), Nanjing, China, 2017, pp. 1-7, doi: 10.23919/ITU-WT.2017.8247001.

„Nanoscale communications represent a new paradigm encompassing all concerns related to the exchange of information between devices at the nanometric scale. A network infrastructure consisting of an immense number of nano-devices is envisioned to ensure robust, reliable, and coordinated data transmission. This will facilitate a multitude of future applications and services across various research fields, such as personalized medicine, synthetic biology, environmental science, or industry, leading to remarkable and unprecedented progress. The IEEE P1906.1 standard provides a conceptual and general framework to establish the point of departure for future developments in nano-scale communications networks. This paper analyzes the most recent IEEE P1906.1 recommendations, observing their primary characteristics when applied to the field of electromagnetic nano-communications (MS). We contribute by identifying and discussing

of the primary deficiencies of the standard, which necessitate additional research efforts. We also provide significant guidance for focusing the objectives of future investigations.”

The public was not informed regarding communication at the nano level, nor were they notified of this 1901.1 standard, which was published in January 2016 <https://standards.ieee.org/ieee/1906.1/5171/> .

One of the primary areas targeted for the utilization of nano-devices and nano-scale communication has been the medical field, ever since the adoption of the 1901.1 standard <https://ieeexplore.ieee.org/document/8247001> . Those who established these standards envisioned the human body invaded by nano-devices that, to function (for detection and transmission), draw power from its own energy . “These data-driven nano-devices have become a subject of growing interest within the scientific community, as they are purportedly capable of collecting physical parameters at a nanometric scale with remarkable precision. This capability would facilitate the monitoring of previously unexplored scenarios, **permitting a multitude of potential applications in fields as diverse as biomedicine, synthetic biology, environmental science , and industry, among many others. Indeed, one of the most promising applications of these nano-devices aims at the improvement of medicine , as various medical tests, such as blood pressure, the detection of viruses, or oxygen levels in the blood, could be collected in vivo and transmitted directly to medical personnel (for example, information regarding the variation in the number and size of cancer cells will be received by the oncologist). Several papers have addressed the manner in which nano-devices should communicate with each other. This becomes a critical issue, because the extremely limited resources of the nano-devices force them to work in cooperation to achieve a useful application.**

To date, two main variants for nanoscale communication have been considered: electro-magnetic communication (MS) and molecular communication . MS communication is based upon the use of electromagnetic waves to transmit a message between two nano-devices. Advances in carbon electronics, primarily those devices manufactured from graphene and carbon nanotubes (CNTs), have played a key role in the development of a new generation of electronic nanocomponents, such as nano-antennas or nanotransmitter-receivers [1]–[3]. These new radiocommunication nanocomponents possess unrivaled properties, which allow for the radiation of MS waves at THz frequencies using antennas only a few micrometers in length, i.e. , two orders of magnitude smaller than their metallic counterparts. Even so, this radiation frequency exhibits high propagation losses, necessitating the detailed design of a communications network at the nanoscale, also known as a nanonetwork. On the other hand, molecular communication is defined as the Transmission and reception of information encoded in organic molecules [4], [5]. Molecular transmitters are designed to facilitate their integration into nano-devices owing to their extremely small dimensions and limited operational range . These transmitters can react upon receiving certain molecules and release others (in response to stimulation or following the execution of a process). Transmitted molecules propagate in three different ways: moving through a fluid medium via free diffusion (diffusion-based); moving through a fluid medium with a guided flow (flow-based); or through predefined pathways via the use of carrier substances (walkway-based).

Both MS and molecular communications are considered by the IEEE P1906.1 standard; the first approach for the normalization of various aspects related to communications at the nanoscale, launched in December 2015. Under this general premise, this standard first defines the concept of a nanoscale communications network itself, subsequently proposing a conceptual framework for the development of communications.”

First and foremost, it is necessary to emphasize the difficulty of providing a general definition for the concept of a 'nanoscale communications network', as this necessitates the inclusion of requirements from two distinct scientific fields, namely the Molecular and MS domains. These fields are so divergent that concepts such as 'network' and 'communication' may carry different meanings within each respective discipline. Furthermore, to maintain the generality of the definition, a communications system is considered to be at the nanoscale when one or more of its essential components are sized in nanometers in at least one dimension. In fact, following the guidelines of this definition, the majority of works

already published regarding MS nanocommunications [6], [8], [9], [13] (and, therefore, prior to the release of the IEEE P1906.1-draft standard) would be included under the umbrella of the standard, as the antennas utilized in these studies are at the nanoscale. In detail, as can be observed in Table 2 (extracted from [10]), the THz waves radiated by graphene or CNT antennas are both considered “components under 100 nm” and, consequently, “non-standard physics”. Thus, although these studies constructed their designs from electronic devices at the microscopic scale (and, therefore, the resulting design is at the microscopic scale), **the use of THz waves as message carriers is sufficient to consider communication at the nanometric scale**. As can be observed, the concept of a „nanoscale communication network” is sufficiently broad to include micro-devices operating within a nanonetwork.

Regarding the physical level, restrictions on the amount of energy available in each nano-device (referred to as nano-devices, although their dimensions may be at a microscopic scale) have a significant impact on the communication scheme. The most widely accepted solution for powering nano-devices involves **the use of piezoelectric nanogenerators** [6], [8], [13], which are capable of **converting mechanical stresses (e.g., the movement of blood flow) into electrical energy**.

The harvested energy is stored in a nanocapacitor to power the components of the nano-device when the energy level exceeds a certain threshold. However, the primary disadvantage of these nanogenerators is **the low amount of energy harvested per unit of surface area, which strictly limits the communication capabilities of the nano-devices**. Furthermore, the available energy depends on the physical environment in which the nano-devices are deployed (if the nano-devices utilize environmental motion, the harvested energy will be greater than in a static environment) and on the surface area of the nanogenerator. Conversely, parameters related to the transmission and reception of electromagnetic waves, such as transmission power or the signal-to-noise ratio (SNR), are not addressed by the IEEE P1906.1 standard. This recommendation warrants further scrutiny when human bodies are involved, **owing to the fact that the high transmission power intended for nano-devices [9] could adversely affect health**. The SNR at reception is also an important parameter to consider to ensure robust and reliable communications at the nanoscale. Although the standard addresses channel capacity (calculated using the Shannon theorem) and, consequently, the calculation of the upper limit for the physical data rate, in the case of a low SNR value, the receiver would be unable to demodulate the radio signal.

As early as 2015, in numerous IEEE and ITU articles and conferences, it has been asserted that nano-devices—devices undetectable by conventional means, including the optical microscope, when introduced into human bodies—are “NON-INVASIVE.” This is an error; a device cannot be considered non-invasive merely due to its diminutive size if it is employed for the **intimate monitoring of the human organism**. Such assertions clearly demonstrate that

ethics has lagged significantly behind scientific evolution within institutions like the IEEE and ITU. One example is the following abstract from a 2015 article authored by a renowned professor of electrotechnology, Prof. Ian Akyildiz <https://ieeexplore.ieee.org/document/7060516> . F. Akyildiz

Pierobon, S. Balasubramaniam and Y. Koucheryavy, “The intertternett oft Bio-Nano tthings,” in IEEE Communicattions Magazine, vol. 53, no. 3, pp. 32-40, March 2015, doi: 10.1109/MCOM.2015.7060516. keywords: {Cells (biology);Microorganisms;Intternett oft tthings;Embedded computing;Nanoscale devices;Nanobioscience;Research and development;Sttandards;IEEE sttandards;Communicattion sttandards},

„The Internet of Things (IoT) has become a significant research topic over the last decade, the term “things” referring to interconnected machines and objects with integrated computing capabilities used to extend the Internet to numerous application domains. While research and development continue for general IoT devices, **there are numerous fields of application where ultra-small, invisible, and non-invasive 'Things' are required**. **The properties of recently studied nanomaterials, such as graphene**, have inspired the concept of the **Internet of NanoThings (IoNT)**, based on the interconnection of devices at the nanoscale. Despite acting as an enabler for many applications, **the artificial nature of IoNT devices may be hazardous, as the implementation of NanoThings could result in adverse effects on health or lead to environmental pollution**. The new paradigm of the **Internet of Bio-Nano Things (IoBNT)** is introduced in this paper, based on synthetic biology and nanotechnology tools that enable the engineering of devices integrated into

biological systems. Based on biological cells and their functionalities in the biochemical domain, **Bio-Nano Things promise applications such as intra-corporeal sensing and actuation networks** and the environmental control of toxic agents and pollution. **IoBNT represents a revolutionary concept for communications and network engineering**, where it faces new challenges to develop efficient and secure techniques for **the exchange of information, interaction, and the creation of networks in the biochemical domain, while simultaneously allowing an interface with the electrical domain of the Internet**.

Professor Ian F. Akyildiz is a prominent figure in the field of nano-level communications <https://aifor-good.itu.int/speaker/ian-f-akyildiz/>. He is a scientist who lectures worldwide, **the interest in this type of communications being global**. “**He has been the founder and editor-in-chief of the newly established ITU (International Telecommunication Union) journal on future and evolving technologies (ITU -J FET) since August 2020. He has served as the president of Truva Inc., based in Atlanta, since March 1989. He has also been a member of the advisory board of the newly established research center, named the Technology Innovation Institute (TII), in Abu Dhabi, United Arab Emirates, since June 1, 2020. He is the Ken Byers Professor Emeritus in Telecommunications at the Georgia Institute of Technology, former Chair of the Telecom Group at the ECE of GaTech, and Director of the Broadband Wireless Networking Laboratory (1985–2020). Since May 2018, he has served as a Megagrant research coordinator at the Institute for Information Transmission Problems of the Russian Academy of Sciences in Moscow, Russia. Since October 2019, he has been a Distinguished Visiting Professor at the SSN College of Engineering in Chennai, India, and since September 2020, an Adjunct Professor in the Department of Electrical Engineering at the University of Iceland.**

Over the last two decades, he has established numerous research centers worldwide, including at the University of Pretoria, South Africa; Politecnica de Catalunya in Barcelona, Spain; King Abdulaziz University in Jeddah, Saudi Arabia; and the University of Tampere, Finland. He is the Editor-in-Chief Emeritus of the Computer Networks Journal (Elsevier) (1999–2019), founding editor-in-chief emeritus of the Ad Hoc Networks Journal (Elsevier) (2003–2019), founding editor-in-chief emeritus of the Physical Communication (PHYCOM) Journal (Elsevier) (2008–2017), and founding editor-in-chief emeritus of the Nano Communication Networks (NANOCOMNET) Journal (Elsevier) (2010–2017). He has initiated numerous conferences and workshops, serving as General Chair and TPC Chair for many of them. He is a member of the IEEE and ACM and has received numerous awards from both organizations, as well as from other professional bodies. He was granted the Alexander von Humboldt award to conduct research on TeraHertz at the University of Erlangen-Nuremberg from 2014 to 201

His current research interests include 6G/7G wireless communications systems, TeraHertz communication, the Internet of BioNanoThings, molecular communication, reconfigurable intelligent surfaces, nanonetworks, and the Internet of Space Things/CUBESATs; The Internet of Things in challenging environments, such as underwater and underground. According to Google Scholar, as of May 2025, his h-index is 141, and the total number of citations for his works exceeds 153,000. “The ITU (International Telecommunication Union) <https://www.itu.int/en/about/Pages/default.aspx> is “**the United Nations specialized agency for digital technologies (ICT)**. The organization is composed of **194 member states and over 1,000 companies, universities, and international and regional organizations**. With headquarters in Geneva, Switzerland, and regional offices on every continent, ITU is the oldest agency in the UN family—connecting the world since the advent of the telegraph in 1865.” This agency facilitates “**international connectivity in communications networks. We allocate the global radio spectrum and satellite orbits, develop the technical standards that ensure the seamless interconnection of networks and technologies, and work to improve access to digital technologies in underserved communities worldwide. ITU aims to provide digital connectivity to everyone**, providing a trusted multilateral platform for negotiating international agreements and standards, sharing knowledge, developing capacities, and collaborating with members and partners to spread access to technology throughout the world.” Given that the telecommunications agency **ITU is a specialized agency of the UN** (which includes both China and Russia), there is a evident **global interest and global collaboration to interconnect and control**

the world, including human bodies at the nano scale. Therefore, in this area, it is not a matter of competition but of global collaboration.

Prof. Dr. İlhan Akyıldız, **a key figure in the field of biodigital convergence**, has been publishing articles regarding wireless sensor networks since 2002

<https://www.sciencedirect.com/science/article/abs/pii/S1389128601003024?via%3Dihub> (I.F. Akyıldız et al.,

Wireless sensor networks: a survey, Computer Networks, 2002), a concept which "has become viable through the convergence of

micro-electromechanical systems technology, wireless communications, and digital electronics". This article notes the advantages as well as the limitations of wireless networks, **one of the primary applications cited alongside military and security being HEALTH**: "recent advances in micro-electromechanical systems (MEMS) technology, wireless communications, and digital electronics have enabled the development of multifunctional sensory nodes, characterized by low cost, low power consumption, and small size, which communicate wirelessly over short distances." These tiny sensory nodes, which consist of sensing, data processing, and communication components, leverage the concept of sensor networks based on the collaborative effort of a large number of nodes.

„The characteristics described above ensure **a wide range of applications for sensor networks**. Some of the application areas are **health, the military, and security**. For example, **physiological data regarding a patient may be monitored remotely by a physician**. While this **is more convenient for the patient**, it also allows the physician to better understand the patient's current condition.

Sensor networks may also be utilized to detect foreign chemical agents in the air and water. These may assist in identifying the type, concentration, and location of pollutants. In essence, sensor networks will provide the end user with information and a superior understanding of the environment. We envision that, **in the future, wireless sensor networks will be an integral part of our lives, more so than present-day personal computers**.” „Many researchers are currently involved in the development of schemes that fulfill these requirements.”

Unfortunately, the notification of physicians and citizens regarding the intentions and findings of electronics researchers—proposing that wireless networks of micro-devices be utilized for health monitoring—has not occurred, and no public debates have been held on this matter. The information and research results were not published in medical journals, but rather in electrotechnology journals such as IEEE and ITU, or in nanotechnology journals, of which **the vast majority of the medical community was not informed**.

The ethics and regulations governing the use of these advanced technologies have lagged significantly behind the research.

Currently, within the IEEE and ITU journals, there are numerous articles concerning the Internet of Bodies. Since 2021, the website of the ITU journal has stated an increased interest of this organization in the Internet of Bio-Nano-Things, which is intended for implementation in the field of healthcare.

<https://www.itu.int/en/journal/j-ftett/2021/001/Pages/default.aspx>, a subject addressed throughout the entire 2021 Volume 2 of the ITU journal <https://www.itu.int/pub/S-JNL-VOL2.ISSUE3>.

One of the articles on this topic within this volume is “INTERNET OF BIO - NANO THINGS: A REVIEW OF APPLICATIONS, ENABLING TECHNOLOGIES AND KEY CHALLENGES” https://www.itu.int/dms_pub/itu-s/opb/jnl/S-JNL-VOL2.ISSUE3-2021-A08-PDF-E.pdf which is relevant, as are the others, regarding the intimate and irreversible manner in which the human body is controlled by nano-devices. Once introduced into the body, **it is unknown how these devices can be removed should the individual no longer wish to be monitored**. Consequently, assuming that those who designed these devices acted in good faith, their introduction ought to be reversible; specifically, there should also be literature concerning the removal of these devices from the body, a subject that remains unaddressed by researchers. It is noted that in this article, as throughout Volume 2 of the 2021 ITIU journal <https://www.itu.int/pub/S-JNL-VOL2.ISSUE3> there is no discussion regarding the ethical and regulation aspects of the internet of bio-nano things.

„As the Internet of Things (IoT) approaches technological maturity, with a growing number of applications on the market, new integrative ideas are emerging to push the current boundaries of IoT and expand its range of applications. Such an approach follows a holistic vision and **views the universe as an interconnected entity that must be observed, understood, and manipulated using new information and communications technologies (ICT)**. At the core of this approach lies an emerging ICT framework, **the Internet of Bio-NanoThings (IoBNT)**, which provides for **heterogeneous collaborative networks of**

natural and artificial functional nano-biological devices (e.g., modified bacteria, human cells, nanobiosensors), seamlessly integrated into the Internet infrastructure. IoBNT is positioned to extend our connectivity and control over unconventional domains (e.g., the human body) with unprecedented spatiotemporal resolution, enabling paradigm-shifting applications, particularly in healthcare, such as continuous intra-body health monitoring and theranostic systems with unique molecular precision.

The broad application prospects of IoBNT have attracted significant research interest at the intersection of ICT, bio-nanotechnology, and medical sciences, with the vast majority of studies directed toward (i) the design and implementation of Bio-NanoThings (BNT), (ii) understanding natural IoBNT (e.g., the neural nanonetwork), (iii) the development of communication and networking methods for IoBNT (e.g., molecular communications), (iv) the design of bio/cybernetic and nano/macro interfaces, and (v) the development of new IoBNT applications.

In the aforementioned areas, this special edition will present the latest advancements regarding the theoretical foundations and practical implementation of IoBNT in healthcare applications."

One of the articles in this volume of the ITU journal <https://www.itu.int/pub/S-JNL-VOL2.ISSUE3> is titled "*Inttiernetti oft Bio-Nano Things: A review oft applicattiions, enabling ttiotechnologies and key challenges*" <https://www.itu.int/pub/S-JNL-VOL2.ISSUE3-2021-A08>. This article states that "*The Internet of Bio-Nano Things (IoBNT) is conceived as a heterogeneous network of biological and nanoscale devices, the so-called Bio-Nano Things (BNT), which communicate through unconventional means, for example, molecular communications (MC), in unconventional environments, for example, inside the human body. The primary objective of this emerging network framework is to enable direct and seamless interaction with biological systems for the detection and precise control of their dynamics in real time. This close interaction between the biological and cybernetic domains, with an unprecedented spatio-temporal resolution, is expected to open vast opportunities for the design of new applications, particularly in the healthcare field, such as continuous intracorporeal health monitoring. There are, however, substantial challenges to overcome to realize the enormous potential of IoBNT. These range from the development of feasible nanocommunication and energy harvesting techniques for BNT to the management of large volumes of data generated by IoBNT. In this analysis, we aim to provide a comprehensive overview of the IoBNT framework, along with its main components and applications. An investigation into the primary technological challenges is presented, together with a detailed analysis of state-of-the-art approaches and a discussion regarding future research directions.*" While it is claimed that the Internet of Bio-Nano-Things (BNT) will be utilized for detection and actuation within the human body to address health issues, it is evident that through networks of invisible nano-devices introduced into the human body, the individual becomes controlled, including at the level of the brain. Thus, what was stated in the World Economic Forum documents is confirmed: that the Fourth Industrial Revolution does not merely change the world around us, but also changes us as human beings. **Human beings will no longer be human; they will no longer retain ownership of their bodies and minds, but will be at the mercy of those who control these networks. Physical and mental integrity are gravely compromised, without the individuals being** Graphene is also utilized to create nano-antennas for IoBNT. These graphene nano-antennas operate within the terahertz spectrum, specifically that of 6G technology.

"3.1.3 Other nanocommunication modalities for IoBNT a) **Electromagnetic nanocommunication in the THz band** : Conventional electromagnetic communication (MS) is not considered suitable for IoBNT because the size of the BNTs would require extremely high operating frequencies [93]. Fortunately, **graphene-based nano-antennas** utilizing surface plasmon polariton (SPP) waves have been proven to **support frequencies up to 0.1 THz**, significantly lower than their metallic counterparts, showing promise for the development of high-bandwidth EM nanonetworks of the BNTs based on nanomaterials using the unused THz band (0.1-10 THz) [94]. In this regard, **several plasmonic transceiver antenna models using graphene and related nanomaterials have been investigated** (e.g., CNT), the properties of which can be tuned through **material doping and electric fields**, [95, 96]. However, several challenges remain for the practical implementation of

of THz band nanonetworks, such as the severely limited communication range resulting from high propagation losses due to molecular absorption and the low transmission power of resource-constrained nano-devices.

These challenges are addressed through the development of new modulation schemes based on very short pulses to overcome the power limitations of THz transceivers [97, 98] and the design of directional antennas and dynamic antenna networks with beamforming to mitigate propagation losses [99]. The high density of BNTs in envisioned IoBNT applications also presents challenges regarding limited spectrum utilization, which are addressed by new medium access protocols for dense THz nanonetworks [100, 101].

Data transfer from the intracorporeal network to the internet is facilitated through bio-cybernetic interfaces.

“3.2 Biocybernetic and nano-macro interfaces

The majority of envisioned IoBNT applications require a **bidirectional nano-macro interface capable of seamlessly connecting intra-corporeal nanonetworks to external macro-networks and vice-versa** [114, 115]. **Given that MC (molecular communication) is the most promising method for intra-body IoBNT, the interface should be capable of performing conversions between high-level biochemical signals and signal forms** that can be easily processed and communicated through conventional networks, such as electromagnetic, electrical, and optical ones. Several techniques are being considered to facilitate such a nano-macro interface.

In view of emerging reports regarding **MS-based wireless control of cellular functions via specific proteins responsive to electromagnetic fields** [130], **a wireless link is proposed to connect MS and MC modalities in the THz band**, which may be translated into an EM (electromagnetism)-based nano-macro interface [131]. The authors in [132] develop an information-theoretical model for the communication channel via mechanotransduction between an implantable THz nanoantenna acting as a transmitter and a biological protein as a receptor, which undergoes a conformational change upon stimulation by THz waves. **While it has been theoretically demonstrated that THz waves reliably control the conformational states of proteins**, it remains a challenge to investigate the use of the same modality in the detection of protein states to enable a bidirectional wireless interface.

In order for nanosensors and intracorporeal networks of nano-devices to function, they must be supplied with energy. In the case of intracorporeal nanosensors, these can be powered either by the energy of the body into which they are inserted or charged externally and wirelessly.

“3.3.1 Energy harvesting

Setting aside continuous efforts to reduce the complexity of communication methods for IoBNT, such as modulation and detection techniques [13], in the hope of increasing energy efficiency, the most promising solution to enable self-sustainable IoBNT is the integration of EH (energy harvesting) modalities into BNTs. EH has recently garnered extraordinary research interest, partly due to the energy requirements established by emerging IoT and IoE applications. Depending on the application environment and device architectures, **diverse natural energy sources** have been considered for harvesting by IoT devices [135, 136].

For instance, solar energy, vibration sources, and electromagnetic sources—such as ambient MS RF waves—along with metabolic sources, have been deemed feasible for harvesting [137]. With respect to intracorporeal and body-area applications, the human body represents a vast energy source in the form of mechanical vibrations resulting from body movements, respiration, heartbeats, and blood flow within vessels; thermal energy resulting from body heat; and biochemical energy resulting from metabolic reactions and physiological processes [138]. Specialized literature now includes a multitude of successful applications of human body EH for powering miniature biomedical devices and implants, such as thermoelectric EH derived from body heat for wearable devices [139], vibrational EH from heartbeats [140] and respiratory movements [141] for powering cardiac pacemakers, as well as biochemical EH from human sweat [142] **These, together with EH from chemical reactions inside the body, such as glucose absorption,**

lactate release and pH variations [138, 143], can be exploited to power the carbon nanotube bands (BNT) that compose the intracorporeal IoBNT. Among the potential mechanisms of EH for intracorporeal nanoBNT, mechanical EH has attracted the most interest. Research in this field has gained momentum with the use of flexible piezoelectric nanomaterials, such as ZnO nano wires and lead zirconate titanate (PZT) in nanogenerators, allowing energy harvesting from natural and artificial vibrations with frequencies ranging from very low frequencies (< 1 Hz) up to several kHz [144, 145].” “3.3.2 Wireless energy transfer

*Another method of powering BNT and IoBNT applications **may involve wireless power transfer (WPT) from external sources.** WPT has made significant progress in recent years due to the increasing demand for powering battery-free IoT devices, as well as wearable and implantable devices. Various forms of **WPT have been considered for powering medical devices** [146, 147]. For example, **WPT based on near-field resonant inductive coupling (NRIC)**, the oldest WPT technique, has been utilized for widely adopted implants, such as cochlear implants [148, 149]. Other techniques include near-field capacitive coupling, mid-field and far-field electromagnetic-based WPT, and acoustic WPT. Power transfer via capacitive and inductive coupling in the near-field is, however, effective only for distances commensurate with the dimensions of the transmission and reception devices and provided there is correct alignment of said devices; consequently, it may not be suitable for powering BNT at the micro/nano scale [148]. On the other hand, radiative electromagnetic (MS)-based wireless power transfer (WPT) in the mid-field and far-field may be subject to fewer restrictions, depending on the frequency of the MS waves*

The same article addresses the issue of power supply for nano-devices within intracorporeal networks, the solution being provided by graphene—a material also identified in the COVID-19 vaccines by independent researchers in Spain and the United Kingdom who conducted Raman spectroscopy – “3.3.3 Energy storage: Energy storage is also critical when BNTs cannot continuously meet their energy requirements through EH and WPT techniques. There has been considerable interest in miniaturizing energy storage technologies to render them compatible in terms of dimensions with MEMS and NEMS devices. Certain efforts have been dedicated to the development of microbatteries, which are miniaturized versions of conventional thin lithium-ion batteries, utilizing new nanomaterials [162]. There are even several studies focusing on nanoscale versions of lithium batteries [163, 145]. However, these suffer from low energy density, a short lifespan, and potential toxicity in in vivo applications. **A more promising solution is represented by micro-supercapacitors (MSCs), which offer a significantly higher energy storage** capacity, higher charge/discharge rates and, more importantly, scalability and flexibility, which are crucial for their integration into BNTs [164, 165, 166]. Several types of materials have been considered for the design of the MSC electrode to improve energy **Carbon nanomaterials, such as CNTs and graphene, are the most researched materials due to their abundance and stability, which is reflected in an extended lifespan** [164].

Due to its extremely high surface-to-volume ratio, high mobility, and flexibility, graphene has attracted particular attention [167, 168]. In addition, conducting polymers, such as PEDOT/PSS, and graphene/conducting polymer heterostructures are also considered flexible electrodes for MSCs [164]. Research in MSCs is still in its early stages; however, we believe that, with the increase in energy density and further reduction in dimensions, they can be a viable candidate for energy storage units in BNTs. ”

Furthermore, the issue of the biocompatibility of nano-devices is raised “3.4 Biocompatibility and coexistence ***Biological processes are complex and interconnected, often through complicated relationships that have not yet been discovered. The disruption of the homeostasis maintained by these relationships can lead to severe disorders.*** Further complicating the matter is that, concerning the composition of the physiological environment and the interactome, said composition may exhibit significant variation among different members of the same species. For instance, it is established that the gut microbiome is composed of various types of bacteria in different

individuals [169]. Therefore, **the evaluation of in vivo IoBNT applications with respect to biocompatibility is highly challenging; nonetheless, it must be given serious consideration.** Biocompatibility constraints for IoBNT can be examined from two perspectives [170]. Firstly, **an IoBNT application, along with all communication methods and devices it contains, must not disrupt the homeostasis of the organism in which it is implemented**. Such a disruption may occur when the introduced application exerts toxic effects, or is otherwise harmful or adverse to living cells and biochemical processes. Secondly, an implanted IoBNT application must be capable of functioning without its performance being degraded by coexisting biochemical processes. Performance degradation typically occurs when an IoBNT application alters metabolic activities, as **such an alteration invokes an immune response which could, in turn, lead to the rejection of the implemented application. Rejection may manifest as the expulsion of the IoBNT application from the body, the encapsulation of the BNTs by biological cells and tissues, or the inflammation or death of surrounding tissues**. In the case of MC, performance degradation may also occur as a result of interactions caused by natural biochemical signaling. **Biocompatibility concerns both the materials used in the physical architecture of the BNTs and the processes of network, energy harvesting, energy transfer, and interfacing of the IoBNTs**. Regarding the materials, **BNTs based on synthetic biology can be considered highly biocompatible, as they utilize living cells and cellular components as a substrate** [24]. Furthermore, BNTs based on fluorescent proteins and DNA also have biological origins and, therefore, can be expected to offer similar levels of biocompatibility [108]”

However, depending on their exact biological origin and their total quantity in the organism, these can still trigger the immune response. For example, **a synthetic BNT based on a virus may be labeled as a foreign agent and attacked by the immune system, unless it is designed to possess certain hidden proteins that assist in evading immune surveillance** [171]. **For artificial BNTs based on nanomaterials, biocompatibility is more difficult to achieve. There is still no consensus on a universal biocompatibility test for nanomaterials, which leads to contradictory results in the specialized literature regarding almost all materials. The complexity of biological systems and the issue of reproducibility for in vivo and in vitro tests represent the primary causes of continued ambiguity.**

Nevertheless, numerous polymers (e.g., PMMA, Parylene), gold, titanium, and certain ceramics are widely recognized as biocompatible [172, 173, 174]. **Carbon-based materials, such as CNTs and graphene, have been reported as being both biocompatible and Toxic substances in various studies, a fact which precludes a generalization regarding these nanomaterials**. This is attributed to the significant variations in their physicochemical properties—such as size, shape, and surface characteristics—as adopted in various studies [175, 176]. However, **it has been repeatedly reported that their biocompatibility can be modulated through chemical manipulation** [175]. **For example, surface functionalization with dextran has been shown to reduce the toxicity of graphene oxide (GO), suggesting strategies to make carbon-based nanomaterials suitable for safe in vivo applications** [177, 176]. Similarly, the nanoparticles have been shown to be detoxified upon the functionalization of their surfaces with smart/benign ligands [178]. **Regarding the processes, attention must be paid to the processes of communication, biocybernetic interfacing, energy harvesting, transfer, and storage. In communication and power transfer processes based on electromagnetics and acoustics, biocompatibility is crucial for preventing the deterioration of biochemical structures—such as tissue damage through heating—and is strictly correlated with the frequency and power of electromagnetic or acoustic waves. For applications involving the human body, exposure limits are regulated by the Food and Drug Administration (FDA) in the USA, set at 100 W/mm² for RF waves and 7.2 mW/mm² for ultrasonic waves** [125, 179]. These limits must be taken into consideration during the design of IoBNT tech-

Biodistribution studies of nano-lipid particles, which also contain polyethylene glycol, indicate that they reach all organs and may fuse with the membranes of cells from various organs. Given the detection of graphene in the analyses of COVID-19 vaccines performed by independent researchers, it is highly probable that a significant portion of the adverse reactions to these products is attributable to

the controversial biocompatibility of this compound, which, as stated in this article, may be toxic and capable of activating the immune system. To the toxicity of graphene are added the lesions and biochemical disruptions caused by the effects of 5G/6G electromagnetic waves with which these devices interact, as stated in this article

Another article among the many available, relevant to the extent to which research in the field of medical engineering has progressed without even healthcare professionals being informed—aiming for the creation of intracorporeal networks with remote control, at a molecular level, of the processes within the human body—is “ TRANSMISSION AND DETECTION TECHNIQUES FOR INTERNET OF BIO - NANO THINGS APPLICATIONS WITH STATIC AND MOBILE MOLECULAR COMMUNICATION: A SURVEY ”, also from volume 2, 2021, of the ITU journal: <https://www.itu.int/pub/S-JNL-VOL2.ISSUE3-2021-A02>

*“Recent studies have shown that **the design of nanoscale and microscale communications systems for Internet of Bio-NanoThings (IoBNT) applications is possible using Molecular Communication (MC), where two or more nodes communicate with each other through the Transmission of chemical molecules** .*

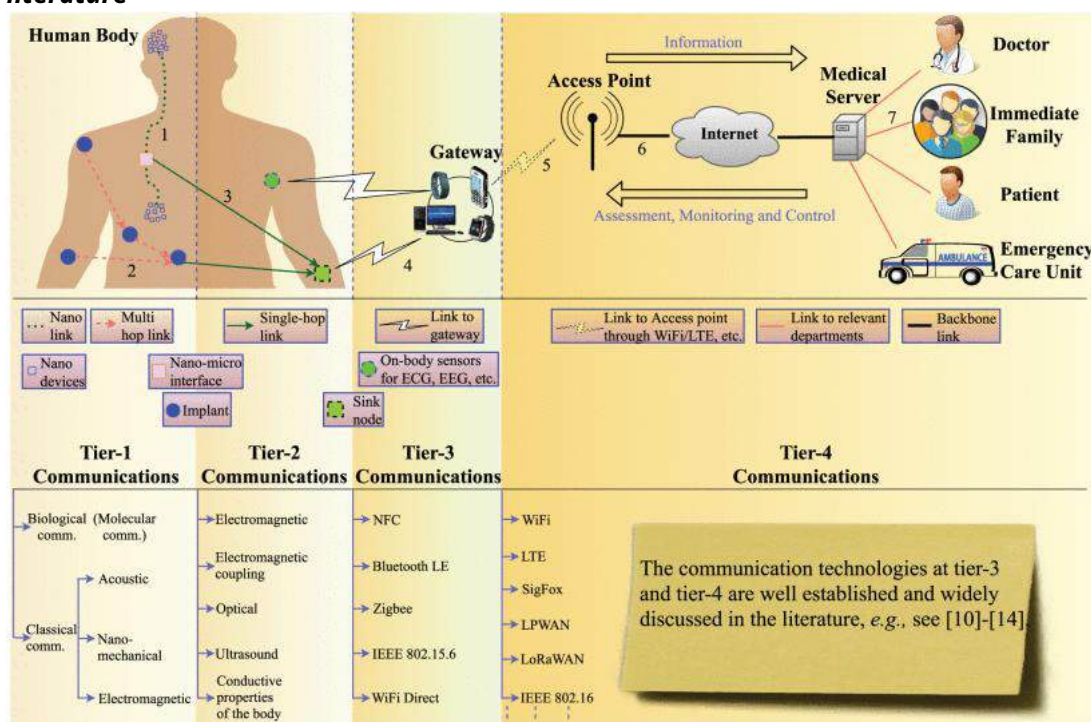
*The basic stages involved in MC are the transmission of molecules, the propagation of molecules in the medium , and the reception of molecules at the receiver. In recent years, various transmission schemes, channel models, and detection techniques for MC have been proposed. Consequently, this paper presents an exhaustive analysis of the existing literature on detection techniques, along with their transmission schemes in various MC configurations. More specifically, for each configuration, this study includes transmission and detection techniques in four different environments to support various IoBNT applications: (i) static transmitter and receiver in a pure diffusive channel, (ii) static transmitter and receiver in a flow-induced diffusive channel, (iii) mobile transmitter and receiver in a pure diffusive channel, and (iv) mobile transmitter and receiver in a flow-induced diffusive channel. Furthermore, the performance and complexities of various detection schemes have been compared. In addition, several detection challenges and their potential solutions were discussed, regarding both static and mobile scenarios. Additionally, several experimental works in the field of MC are presented to demonstrate realistic transmission and detection procedures available in practice. Finally, future research directions and challenges in the **practical design of the transmitter and receiver to achieve MC for IoBNT medical applications are described.** ”*

The presence within human bodies of intracorporeal nanosensor networks capable of emitting and being remotely actuated raises significant security concerns, as highlighted in several articles from non-medical journals such as IEEE and ITU; these publications seek and offer solutions to this issue, one such example being “Security in Wireless Body Area Networks : From In-Body to Off-Body Communications,” published in 2018 in the IEEE journal.

<https://ieeexplore.ieee.org/document/8481660?denied=> “ **Wireless Body Area Networks (WBANs) play a vital role in shaping current healthcare systems.** Given the critical nature of a WBAN for an individual's health, particularly for the automatic monitoring and diagnosis of medical conditions , **the security and privacy of these healthcare systems require special attention** . In this paper, we first propose a new four-tier architecture for remote health monitoring systems , and subsequently identify the security requirements and challenges at each level. We provide a concise review of the specialized literature aimed at enhancing the security and privacy of WBANs, followed by a comprehensive overview of the subject matter. **In particular, we emphasize that the integration of in vivo nanonetworks into a remote health monitoring system is imperative . To this end, we detail the security threats and concerns regarding nanonetworks and medical implants , while outlining a holistic framework for a general WBAN ecosystem, which is essential for ensuring end-to-end security. Finally, we discuss certain limitations of current WBANs.**”

This article also exposes the risk of intra-corporeal networks being subject to cyber-attacks , resulting in the breach of medical data confidentiality “While the feasibility of security threats to wearable devices, medical implants, and nanonetworks is debatable, the consequences of a potentially insecure health monitoring system could be catastrophic. For example, any

software or hardware vulnerability within a remote health monitoring system can violate the confidentiality, integrity, and availability of the system in question.” In the image below, extracted from the article in question, the human being is presented as a device with an intra-corporeal nanonetwork that communicates with the internet through 4 levels of communications “A complete ecosystem of a WBAN system and a remote healthcare system : WBAN communications can be divided into 4 levels. **At the level 1 , both the transmitter and the receiver are located inside the human body** (the communication links are labeled 1 and 2). Level 2 includes **instances where at least one of the communication devices is located inside the human body** (the communication links are labeled 3). Furthermore, we classify the level 3 as being when **at least one of the communication devices is an external device** (the communication links are labeled 4). Finally, **all communications beyond the gateway are classified as level 4** (the communications links are labeled 5 and above). In this work, we focus primarily on the security requirements of level 1 and 2 communications . Security threats and defenses at level 3 and 4 have been thoroughly investigated in numerous works, as evidenced in the specialized literature ”



The components of the medical system based on nanonetworks are also described „With the emergence of nanotechnology, a natural progression of WBANs (wireless body area networks) is represented by **nano-health systems** , which are composed of **nanosensors capable of performing simple tasks such as computation, detection, actuation, communication, and storage** . Therefore, **a complete WBAN ecosystem, including in vivo nano-nodes and remote healthcare monitoring systems** , is presented in the figure.

A. WBAN Architecture

The figure presents a **complete WBAN architecture** , including **in-body, on-body, and off-body communications** . In-body communications involve implants and nano-devices placed inside the human body. On-body communications involve devices placed on the body, such as wearable devices and other sensors for monitoring ECG, EEG, blood glucose, and blood pressure.

The interaction of any device outside the human body is classified as off-body communications. The entities in the Figure may be defined as follows:

Nano-devices : Nano-devices are among the smallest entities within the medical ecosystem, capable of performing fundamental functions at the nanoscale, such as computation, data storage, detection, actuation, and communications [15].

Nano-links: These are communication links between nano-devices and nano-micro-interfaces.

Nano-micro interface : This interface connects nano-devices inside the human body to a receiver node, which ultimately connects them to devices outside the body.

Implantti : This represents a medical device implanted in the human body for the purpose of monitoring specific diseases, vital signs, or even biometric identification.

Sink node : The sink node acts as a **data hub in WBAN networks** that collects data from various devices within the body to transmit it to the medical server and vice versa. In certain sections of this work, I have also used the term **programmer node** (a term occasionally employed in specialized literature to describe the device that controls and communicates with medical implants) interchangeably with the sink node.

Body sensors : These include various sensors placed on the skin or within the clothing of the human body to measure and monitor various vital signs, such as ECG, EEG, blood pressure, blood glucose, and the level of oxygen in the blood.

Gattieway : This represents a gateway device utilized to connect the WBAN with the medical server . It may consist of a **smartphone or any other device** , such as a computer or an Internet-of-Things (IoT) device, connected directly to a base station via, for example, 3G/4G.

Access point : This represents a cellular base station or a WiFi access point intended to route sensor traffic to the medical server.

Medical server : This is a database that stores all sensor information for subsequent actions and data analysis. **It may include real-time monitoring of vital signs and virtual clinics** where patients and the physicians can connect online and transmit critical notifications to physicians or close family members regarding life-threatening conditions. "

The vulnerabilities of the nanonetworks introduced into human bodies and the proposed methods for their resolution transform the human body into a veritable battlefield of nano-devices and Electromagnetic waves; this is unacceptable, particularly as the public has not been informed of this research or the intention to replace traditional medicine with a new paradigm involving nano-devices, „described as “personalized” and involving “real-time tracking”.

“At the level of nano-communications within the human body , it is not a simple matter to enumerate the potential vulnerabilities to which a patient might be exposed by a malicious actor. Nevertheless, the following section lists several possible attacks at the level of the WBANs.

a: Denial of Service (DoS)

In nanocommunications, **the Denial of Service (DoS) attack refers to the blocking of communications between nano-devices or with devices at level 2 of the WBANs , ultimately compromising network availability** . The DoS attack is generally initiated by flooding interferences between nano-devices/molecules inside the human body or by jamming the communication links between level 1 and level 2.

Avoiding DoS attacks in nanonetworks is not an easy task. One strategy to prevent such an attack in nanonetworks may be the establishment of an intrusion detection mechanism for in vivo nanonetworks . A type of AI system can be added to the patient's body , which can not only prevent the system from entering failure mode, but can also manage intrusive nodes. However, the introduction of this type of system into the human body can damage the organism's actual immune system or may react with or attack legitimate nano-machines introduced to treat certain diseases in a patient.”

“b: Data manipulation

The manipulation, modification, or editing of data constitutes an act of altering data through unauthorized means, ultimately compromising the integrity of the network. Unlike wireless sensor networks (WSN), nanonetworks operate within the human body and are not exposed to open environments. Therefore, the manipulation of devices is potentially difficult within in vivo nanonetworks. **However, it is highly possible for an adversary to introduce illegitimate nano-devices into the human body, which can substantially intercept communications between nano-devices, modify data, and/or redirect them .**

To protect nanonetworks from data alteration, **the primary defense may consist of blocking the entry of an unauthorized node into the human body**. This may be achieved **by mandating the exclusive use of prescribed medicinal products**. **The administration of non-prescribed medicinal products from unauthorized sources may potentially increase the likelihood of introducing illegitimate nodes**. To address this matter, the nano-devices must implement a strict authentication procedure prior to establishing a communication link with any node within the human body."

"B. Level 2 communications

1) Security challenges

Prior to analyzing the security challenges of the aforementioned protocols at the level 2, it is logical to establish an understanding of the function of these protocols. Protocols such as WMTS, ISM, and MICS were designed to replace wired telemetry systems, granting patients the freedom of movement via sensors and the ability to be monitored while performing daily activities. In WMTS, the patient wears a small radio transmitter (possibly on the wrist), which acts as an **intermediate node to transmit information to the gateway**. The device referred to as the receiver node represents a WMTS relay node. More precisely, a licensed MICS band is recommended for implant communication in the WBAN [3]. The communication range varies from a few centimeters to 2 meters [3], depending on the type of technology used (see level 2 communications in Figure 1 for possible communication options).

In most of the systems mentioned above, the adversary must be very close to the patient's body. Specifically, in the case of communications utilizing the conductive properties of the body, the adversary requires physical contact with the patient's body. Furthermore, unlike nano-devices, the network topology at this level is a star topology, wherein level 2 nodes connect to the receiver node (or, in certain instances, to a programmer) utilizing one of the aforementioned communications technologies. More precisely, medical implants transmit their data to the receiver node, which is connected to a medical server via a gateway.

Security challenges for a general star-type network (client-server) have been extensively studied in the specialized literature (see, for example, [27], [28]). However, **level 2 communications in WBANs utilize different protocol settings, and the security solutions presented in the specialized literature cannot be applied directly**. More importantly, **the protocols at this level are neither well-established nor well-studied in the specialized literature**. In particular, the security of such protocols is rarely investigated in the specialized literature, and device manufacturers do not take security into account when designing such devices. Consequently, **it becomes very easy for an attacker to gain access to an implanted medical device**. **An important example to note here is the incident in which the wireless interface of Vice President Dick Cheney's pacemaker was disabled** [29]

"C. **The Big Data Challenge** —Recently, Rizwan et al. [16] have drawn the attention of the research community to an emerging field of research, specifically the perspective of nano-communications based on big data and its impact on the medical system as a whole. **Given the scale of nano-communications and their relationship with big data [16], security and privacy issues become even more challenging, not only within the human body but also during the storage and processing of data by medical servers**. **The loss of this data to an adversary can cause serious privacy issues for patients**. This underscores the necessity of an end-to-end security system for WBANs, ensuring that security and privacy challenges are addressed at all lev-

Consequently, it follows that beyond the vulnerabilities of the intracorporeal network and its communication with extracorporeal devices, additional hazards have been identified. The conclusion of any person of common sense is, I believe, that such a solution for the healthcare system causes more harm than good.

The continued implementation of such an idea serves as evidence that the true objective is not the welfare of the people, but rather their absolute and intimate control. From my perspective as a physician, a far more cost-effective prevention program focused on a healthy lifestyle—incorporating genuine and transparent quality control of food products, air, and water—would resolve many of the population's health issues.

Communication within the intracorporeal network and between the intracorporeal-extracorporeal networks is conducted using MAC addresses. Articles in IEEE and ITU journals also address this subject. One such article is "Prioritized Contention Access Based MAC Protocol for In-Vivo Wireless

NanoSensor Networks," published in 2022 <https://ieeexplore.ieee.org/document/9977528> – J. Xu, H. Huang, Y.

Zhao, R. Wang and L. Lin, "Prioritized Contention Access Based MAC Protocol for In-Vivo Wireless NanoSensor Networks," 2022 IEEE 33rd Annual International Symposium on Personal, Indoor and Mobile Radio Communications (PIMRC), Kyoto, Japan, 2022, pp. 469-474, doi: 10.1109/PIMRC54779.2022.9977528.

"In vivo wireless nanosensor networks based on terahertz (iWNSN) represent a new type of nanosensor network that utilizes the terahertz wave as a carrier and operates within the human body. Several nano-devices within the network are connected via wireless communications. The propagation characteristics of terahertz waves in vivo differ from those in free space, characterized by molecular absorption noise and more severe path losses. Furthermore, nano-devices are limited by battery energy; consequently, existing MAC (Medium Access Control) protocols cannot be applied directly to terahertz-based in vivo wireless nanosensor networks. To investigate the MAC protocol suitable for terahertz-based iWNSN networks, this paper proposes a MAC protocol based on prioritized contention access (PCAB-MAC). The nanosensors nodes access the channel through competition, and a bidirectional handshake is established to ensure that nodes can transmit data undisturbed. Given that data have different priorities, PCAB-MAC adopts a priority-based policy and establishes different waiting windows for data with different priorities to ensure priority Transmission. Simulation results show that the PCAB-MAC protocol can ensure conflict-free data transmission and exhibits excellent performance in terms of delay and throughput.

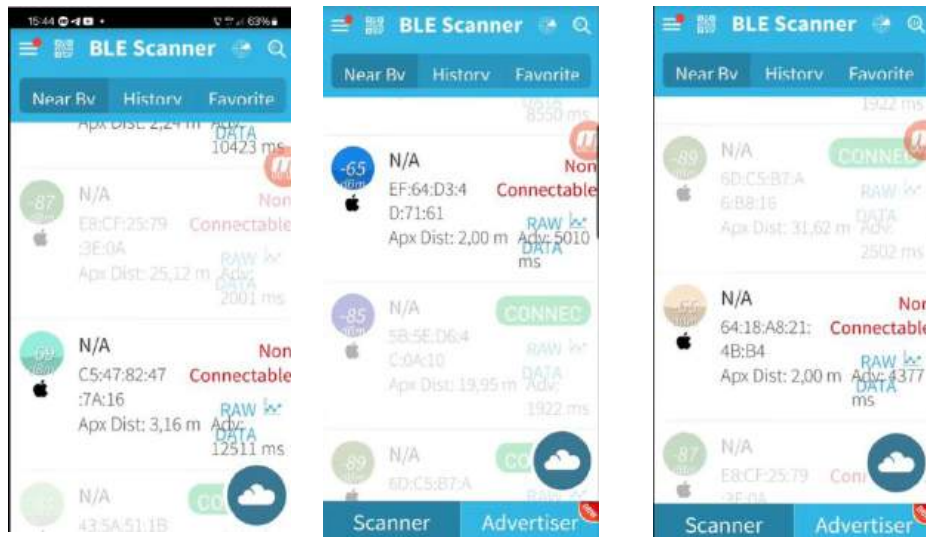
Another such article is "i-MAC: In-Body Sensor MAC in Wireless Body Area Networks for

Healthcare IoT" published in the IEEE journal in 2020— S. Misra, P. K. Bishoyi and S. Sarkar, "i-MAC: In-Body Sensor MAC in Wireless Body Area Networks for Healthcare IoT," in IEEE Systems Journal, vol. 15, no. 3, pp. 4413-4420, Sept. 2021, doi: 10.1109/JSYST.2020.3020306.

"The application of Internet-of-Things (IoT) technology in the modern medical environment has given rise to a new paradigm known as Healthcare IoT. The wireless body area network (WBAN) is one of the fundamental elements of the IoT-based medical system, comprising numerous wearable (on-body) and implanted (in-body) sensors placed in or around the patient's body, connected to a hub for the monitoring of physiological signals. In body sensor-based WBANs, guaranteeing quality of service and extending network lifetime are major impediments due to sensor placement and limited battery capacity. In this article, we propose a new energy-efficient medium access control (MAC) protocol for body sensor-based WBANs according to the IEEE 802.15.6 standard. Typically, body sensor-based WBAN communication is initiated by the hub; however, in the case of an emergency event, the in-body sensor node transmits an emergency frame arbitrarily, without sensing the channel. This accidental transmission initiated by an in-body sensor has a very high probability of collision with the ongoing hub-initiated transmission and/or with another emergency frame transmission initiated by an in-body sensor.

This results in the retransmission of the emergency frame and, consequently, affects the power consumption and the lifespan of the node. To mitigate this issue, we propose a modified super-frame structure in which separate access phases are introduced for the emergency event and the regular event. In the case of an emergency event, a new emergency event management scheme and a classification and priority assignment protocol are proposed to detect and address the critical event of the in-body sensors. In order to minimize collision, a programmed access mechanism is proposed based on the critical importance of the node. The performance analysis of the proposed MAC for the in-body sensor is conducted in terms of latency and total energy consumption, regarding both emergency and routine

Following COVID-19 vaccination, the emergence of MAC addresses that cannot be attributed to any known devices was detected within the Bluetooth network in the proximity of vaccinated individuals.



This fact suggests that the COVID vaccines contain structures that emit such addresses for communication with extracorporeal devices and the Transmission of data . In addition to the fact that independent analyses have determined the presence of undeclared elements, including graphene, in these products termed COVID-19 vaccines, the fact that many COVID-19 vaccinated persons emit MAC addresses is of unprecedented gravity. Through the emission of MAC addresses post-vaccination, it can be asserted that the COVID-19 vaccines represent an interface between human bodies and external internet communication devices; specifically, a bio-cyber interface. This implies that an external party has access to databases containing the physiological parameters of the injected individuals.

Upon investigation, I discovered that MAC address blocks are marketed by the IEEE

<https://standards.ieee.org/products-programs/regauth/mac/> ,

<https://www.youtube.com/watch?v=0nlxVfytXL4&tt=86s> . My conclusion is that, knowing this fact, **it can be easily ascertained from the IEEE, should there be the will to do so, which company acquired the MAC addresses issued by the vaccinated persons** . The fact that vaccinated persons, through the COVID-19 injection, have become devices with identification codes of the MAC address type carries very serious implications **and constitutes a grave matter of national security** , considering that **the majority of individuals in politics, the military, the physicians, and teachers** have been injected with these products. I am not alone in raising these concerns; other researchers have addressed this subject, with the information being reported by certain journals: <https://www.ziuanews.ro/dezvaluiri-investigatii/geanina-hagima-reimpar-irea-lumii-prin-razboiul-nano-prin-presiunea-injectarii-oamenilor-cu-interfa-a-bio-cyber-1586550> . **Who holds control over these devices** ? Who has access to the databases generated by these intracorporeal devices? It is also highly probable that these interfaces could be used to **remote-actuate within the bodies of injected persons** ; it is not excluded that they could even cause their death. Given that the injected particles also penetrate the brain, it is not excluded that through remote actuation **the thoughts and decisions of vaccinated individuals could be influenced. I do not know to what extent employees within the security structures are aware of these matters and have taken measures in this regard.**

The European Commission is by no means unaware of the Internet of Bio-Nano-Things. As early as March 2016, when the UN adopted the 2030 Agenda and the World Economic Forum announced the Fourth Industrial Revolution, a term synonymous with bio-digital convergence, the European Commission published the report "Digital Futures Final Reportt - A journey into 2050 visions and policy challenges "

<https://ec.europa.eu/futurium/en/content/digital-futures-final-reportt-journey-2050-visions-and-policy-challenges.html> . This report is the result of a **large-scale project** conducted between **2011-2013** aimed at evaluating the exponential progress of technologies and their development trends for the near future 2030-2050, in order to expand the **vision of politicians and investors** and to **facilitate the path for the implementation of these technologies** within development policies. It is important to note that those who presented the findings of this project, which discusses

the emergence of a new form of human—the transhuman—meaning the enhanced, augmented human, through fusion with nanotechnology and a “non-invasive” brain-computer interface, assert that this vision is rigorous and scientifically grounded .

In the preface of this document, written by Neelie Kroes, Vice-President of The Commission, it is stated: ***“We live in an era characterized by disruptive technological changes . In recent years, I have considered it both challenging and exciting to contribute to shaping the response of The European Commission to the changes brought about by digital technologies. We witness these benefits daily through digital innovations such as app stores, 3D printing, and new forms of social media. The enthusiastic adoption of ICT (Information and Communication Technology) translates directly into economic growth. According to the World Economic Forum, digitalization has boosted global economic output by 142 billion euros and created 6 million jobs over the last two years . The changes and challenges brought by digital technologies will not cease, but rather persist. Digital technologies will continue to affect every aspect of our lives as both citizens and consumers.***

ICT is not the sole agent of change operating in the world today. There are also other powerful forces at play that will trigger massive innovations and pose immense challenges to current social structures and systems.

We can model some of these changes, such as developments in the life sciences that will extend the human lifespan, making centenarians a common occurrence. Others, such as climate change, are more difficult for us to manage and have potentially much broader repercussions. It is extremely difficult for us to imagine how various changes might interact with one another and what role digital technologies might play in this much broader context during the 2030-2050 period .

The Futurium foresight exercise was launched in the autumn of 2012 with the dual intention of stimulating the imagination of political decision-makers and provoking a broader debate . The goal was precisely to explore potential interactions between various fields of technology, human life, and global resources. Prospectivity does not aim to predict the future as it will occur, but rather to explore various futures that could potentially happen.

Prospectivity is an excellent therapy for busy political decision-makers , whose expectations regarding the future are short-term and linear, based solely on the extension of current events.

Forecasting techniques have been refined over many years, ensuring that the results of any forecasting exercise are not mere conjectures but are scientifically grounded. This report possesses scientific rigor; however, I have also insisted that the Futurium initiative should not be 'just another report by experts from Brussels'.

*It possesses two distinctive features. Firstly, the majority of the underlying visions originate from collective sources, arising from ***a much broader range of interest groups than the usual experts .****

*We have collected contributions from a wider range of interest groups beyond the 'Brussels bubble'—for instance, students from the Erasmus network. They will, after all, build the actual future within the 2030-2050 time horizon. Secondly, the Futurium exercise contains ***a philosophical reflection on how our values could be affected by some of these changes and toward the choices we will face.****

Those who read this report will find that their minds open wider to the range of potential outcomes.

This is a prediction that I am confident will come true . ”

The document summary states “ ***The world is evolving rapidly and will change even more rapidly in the future, driven by long-term advances in digital technologies and other key enabling technologies and sciences . Futurologist Ray Kurzweil predicts that by the end of the 21st century, we will experience the equivalent of 20,000 years of progress at the current rate of change .***

Indeed, we live in times of 'accelerated returns,' where the exponential rate of technological progress impacts our societies at a pace unprecedented in human history.

The future may not be a linear extension of our current activities. The future could generate many new connections between events and trends that remain invisible on our political radars. The governments of Europe must seize the opportunities of digital transformation to provide credible and sustainable responses to systemic issues, such as unemployment or financial stability, and pave the way toward a new era of peace and prosperity. Strategies must be reoriented toward bolder, future-ready policies, drawing inspiration from long-term visions rather than current trend projections, while leveraging Europe's potential for creativity and innovation.

Moreover, the rise of Euroscepticism and the decline of trust in politics clearly demonstrate the necessity of a fundamental change in policymaking: shifting from a centralized approach based on rigid procedures and roles to an open, participatory process that harnesses the potential of digital technologies to engage Europeans in the co-creation of policies that affect them.

Such measures would provide a more solid foundation and legitimacy for public decisions, thereby contributing to the restoration of citizens' trust in EU institutions.

In order to address the aforementioned needs and to experiment with future-oriented, **participatory, and evidence-based policymaking practices**, the Directorate-General for Communications Networks, Content and Technology (DG CONNECT) launched the **Digital Futures foresight project**. The project sponsor was Robert Madelin, Director-General of DG CONNECT, who conceived the initial idea of exploiting advanced technologies and **experimenting with future-oriented policymaking practices**.

The project was launched in the autumn of 2011 and was successfully completed in December 2013 . It involved thousands of stakeholders in the co-creation of long-term visions to inspire future EU strategic choices, particularly in the context of the renewal of the EU policy framework in 2014 ."

From the contents of this report, I have selected several statements relevant to this report:

„Nano-devices and biocomputers offer life-extending treatments."

„Nano-robots will contribute to the diagnosis and treatment of diseases at any age, including the performance of surgical interventions before birth. These will be capable of reading and writing into our biology. Additionally, they can detect and destroy neoplasms, thereby defeating cancer forever ."

„Similar to nano-robots, biocomputers will be inoculated into the human body to perform complex tasks, for example, the detection and monitoring of organ status or the repair of tissues and organs in real time."

„Health and medicine are increasingly becoming digital, virtual sciences, culminating in the creation of an avatar for each person—a "virtual human" involving the storage of all health data.

As more and more people adopt technologies that allow them to quantify and record their daily habits, health software programs could generate specific personal health profiles, combining genetic analysis with the live Transmission of data from personal bio-monitors."

"These profiles could generate "virtual health avatars" for individuals, which could be used as an interactive, highly personalized health coach ."

„3. Societal impact. (...) Nevertheless, it is expected that, beyond the digital society, a new form of humanism (transhumanism) will emerge, in which ICT and other technologies fundamentally improve the human condition, eliminate aging, and enhance human intellectual, physical, and cognitive capacities. This will raise unprecedented ethical issues and will require a revision of our fundamental values and principles ."

"By 2050, a new form of human (a transhuman) will emerge , in which ICT and biomedicine will fundamentally improve the human condition and considerably enhance human intellectual, physical, and psychological capacities. It will be possible to enhance the cognitive and intellectual abilities of human beings through technological implants , such as memory and energy storage.

Humans will benefit from superior biological senses and capacities, which until now have been the prerogative of other species (e.g., speed, endurance, adaptation to extreme conditions, etc.). Conversely, future

cyborgs and softtt robotts could be consttructed ftrm biological componentts.” „**Understanding the ethical and regulation implications of the „enhanced human”, managing change and the impact on individuals (body-mind adaptation), preventing new divisions, and regulating the use of supplements” (e.g., for military use) are the key issues that future policymakers will have to confront.**”

“The pace and distribution of empowerment: **An excessively rapid pace of development of empowerment technologies and their commercialization may lead to fragmented regulation and may generate social or geographical divisions ; new ways of mitigating tensions and conflicts must emerge.** An example of an individual empowerment issue is the set of ethical concerns related to the enhancement and prolongation of human life, which will transform them into cyborgs.”

„**Creating a framework for digital trust** : The main challenge is to create a simple and responsible framework of trust between human beings, which **shall ensure that all data and all digital technologies are collected, developed, and administered ethically . If this challenge is not addressed effectively and rapidly** –1] the development of entire industries, from cloud computing to social media, will be drastically restricted, and 2] **the disintegration of governance systems due to a lack of trust—from political to economic and cultural ones—will worsen .**”



Shape the Future

A trans-humanistic era

By 2050, a new form of human (a trans-human) will emerge, where ICTs and bio-medicine will fundamentally improve the human condition and greatly enhance human intellectual, physical, and psychological capacities.

The augmentation of human beings' cognitive and intellectual abilities through technological implants, such as memory and energy storage, will be possible.

Long Term

Brain-to-Brain communication via implants

- Inter-personal communication will be mediated through technology capable of reading information from the brain (for instance through brain waves interpretation) and exchanging this information with other humans according to "trust" profiles.
- Data and information can be shared with other humans or machines through quantum communication links.
- Data will be received by brain implants and actuated instantaneously, i.e. the rational and emotional states of the originating human will be perceived by the receiving human(s) as if they are actually experienced. This will allow achieving the myth of telepathy.
- With increasingly reliable communication between multiple brains and bodies at the speed of quantum networks, thoughts will be instantaneously captured and shared between humans at a global level.

Genetically Enhanced Humans (GEH) will be the majority in the world

- With improved implant techniques and the creation of direct nerve connectors, body and sense enhancing implants are a common practice in 2050.
- They enhance the capabilities in normal functioning humans and provide normal or enhanced capabilities for impaired people. The visual implants make the blind see and the hearing implants make the deaf hear. Muscle implants make the weak stronger. Neural implants make the lame walk.
- GEH will be characterised by better senses and biological capabilities that are in so far prerogative of other species (e.g. speed, resistance, adaptation to extreme conditions, etc.).
- Following the philosophical path of trans-humanism, the augmentation of human's cognitive and intellectual abilities through technological implants, such as memory and energy storage, will be possible.

Enhancement option available that ensures effective treatment & management of chronic disease

- Nano devices and bio-computers provide life extending treatment.
- Nano-robots will help diagnosis and treatment of diseases at any age, including pre-birth surgery. They will be able to read from and write into our biology. They can also detect and destroy neoplasms, thus defeating cancer forever.
- Similar to nano-robots, bio-computers will be inoculated into the human body to perform complex tasks, for instance sensing and monitoring the status of organs or repairing tissues and organs in real-time, in-situ, at a micro and nano scale.

NBIC-convergence

- NBIC-convergence is the ongoing unification of nanotechnology, biotechnology, information technology and cognitive science.
- NBIC-convergence could allow us to enhance our intelligence, mobility, cognitive qualities or increase industrial productivity.

Health and medicine are increasingly digital, virtual sciences, culminating in a 'virtual human' health avatar for everyone

- As more and more people adopted technologies allowing them to quantify and record their daily habits, health software could generate specific personal health profiles combining genetic analysis with live data streaming from personal bio-monitors.
- These profiles could generate 'virtual health avatars' for individuals, which could be used as an interactive, highly personalised health coach.

3. Societal impacts

Progress in ICT will continue to drive major social transformations. The complexity of society makes those changes the most difficult to anticipate.

However, it is expected that, beyond the digital society, a new form of humanism (trans-humanism) may emerge, where ICTs and other technologies fundamentally improve the human condition, eliminate aging and enhance human intellectual, physical, and cognitive capacities.

This will open up unprecedented ethical issues, and will require a review of our fundamental values and principles.

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This will open up unprecedented ethical issues, and will require a review of our fundamental values and principles.

By 2050, a new form of human (a *trans-human*) will emerge, where ICTs and bio-medicine will fundamentally improve the human condition and greatly enhance human intellectual, physical, and psychological capacities. The augmentation of human beings' cognitive and intellectual abilities through technological implants, such as memory and energy storage, will be possible.

Humans will benefit from better senses and biological capabilities that are so far the prerogative of other species (e.g. speed, resistance, adaptation to extreme conditions, etc.). Conversely, future cyborgs and soft robots could be built out of biological components.

Understanding the ethical and regulatory implications of the "enhanced human", managing change and impacts on individuals (body-mind adaptation), preventing new divides, regulating use of 'add-ons' (e.g. for military use), are the key issues with which future policy makers will have to cope.

- Bioethics and the need for new concepts and regulations: what are the moral implications of using human-enhancement technologies for offensive or competition purposes, like combat, intelligence, or sports? Will humanity be able to agree on strong regulations and enforcement worldwide?
- Clash between regulatory frameworks and demand for human enhancement: too restrictive regulatory policies could lead to a potentially huge shadow economy in the related sectors.
- Divides: emergence of an inequality gap between enhanced and non-enhanced humans.
- Acceptance: what might be the primary ethical debates regarding big data storage about human anatomy, diseases, lifestyles; religious acceptance against human extension?
- Will a shared framework of ethical governance emerge that will help to ensure the integrity of all beings, from human to machine - as interconnectedness between humans, machines, and other life forms accelerates, together with our shared cognition, and perception of cognition?
- The pace and distribution of empowerment: A too rapid pace of development of empowering technologies and their commoditisation may lead to fragmented regulation and generate social or geographical divides; new ways of mitigating tensions and conflicts need to emerge. One instance of an individual empowerment issue is the set of ethical concerns related to the enhancement and life-extension of people that will make them cyborgs.
- Creating a framework for digital trust: The primary challenge is to create a simple, accountable framework of trust among human beings that ensures that all data, and all digital technologies – are ethically collected, developed, and administered. If this challenge is not met effectively, and quickly – 1] the development of entire industries, from cloud computing to social media, will be

severely curtailed, and 2] the disintegration of systems of governance due to lack of trust – from political to economic to cultural – will compound.

Nor is The European Parliament a stranger to terms such as the Internet of Bio-Nano-Things. Thus, in July 2022, a STOA study was posted on the website of The European Parliament with a title suggestive of the large-scale changes in the world we live in and the speed with which they will be implemented: "Ethical and societal challenges of the approaching technological storm" [https://www.europarl.europa.eu/tthinkttank/en/document/EPRS_STU\(2022\)729543](https://www.europarl.europa.eu/tthinkttank/en/document/EPRS_STU(2022)729543) . This page states that the Internet of Bio-Nano-Things will affect **the most intimate aspects of our lives** , a matter of utmost gravity, particularly as the provision of information to the public by the authorities and debates on these topics have been entirely absent. The decision to transform our lives under the pretext of alleged benefits did not originate from the people; rather, it was imposed from the top down. "

Supported by the emergence of 5G and, soon, 6G, digital technologies are evolving toward an Internet of robotic and bio-nano objects based on artificial intelligence. The fusion of artificial intelligence (AI) with other technologies, such as the Internet of Things (IoT), gives rise to acronyms such as "AIoT", "IoRT" (IoT and robotics), and "IoBNT" (IoT and bio-nano technology). Blockchain, augmented reality, and virtual reality add even more technological options. Smart bodies , smart homes, smart industries, smart cities, and governments await us, promising numerous benefits and opportunities . However, unprecedented amounts of personal data will be collected, and digital technologies will affect the most intimate aspects of our lives more than ever before, including the realms of love and friendship. This study provides an overview of the primary societal and ethical challenges to be expected as a result of this convergence, as well as policy options that may be considered to address them effectively."

The screenshot shows the 'Think Tank' section of the European Parliament website. The document title is 'Ethical and societal challenges of the approaching technological storm', dated 25-07-2022. The text is partially highlighted in red, matching the text in the previous blocks. Social media icons for Facebook, Twitter, and LinkedIn are visible on the left.

An interesting passage concerning the STOA vision on the technological storm, extracted from the PDF document attached to the page

[https://www.europarl.europa.eu/RegData/etudes/STUD/2022/729543/EPRS_STU\(2022\)729543\(ANN 1\)_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2022/729543/EPRS_STU(2022)729543(ANN 1)_EN.pdf) is the following, through which an attempt is made to justify the invasiveness of these technologies and the grave violation of our privacy through a presumed social justice; it even raises the issue of **changing our way of thinking regarding privacy (!!!):**

"3.7 From privacy and digital rights to social justice and human capabilities . Confidentiality remains a primary concern regarding the technologies addressed in this report. However, the invasive nature of these new technologies into the private lives of citizens necessitates a departure from traditional frameworks of conceptualizing and addressing matters of privacy . The prevailing ethical and legal paradigm is informational confidentiality, frequently operationalized through the mechanism of informed consent. Nevertheless, certain emerging challenges extend significantly beyond the scope of informational privacy; a pertinent example in this regard is the blurring of social domains. It is necessary to afford due attention to human well-being and capabilities to address the challenge of an increased impact upon the private lives of individuals . Both may require frameworks

legal or regulatory in nature, extending beyond the current emphasis on privacy and (digital) rights, while also placing **weight upon social justice and human capabilities** .”

3.7 From privacy and digital rights to social justice and human capabilities

Privacy is a key concern with the technologies addressed in this report. However, the invasiveness of these new technologies in people's intimate life means that we may need to move beyond traditional ways of thinking about and responding to privacy issues. The dominant ethical and legal paradigm is informational privacy, often operationalised as informed consent. However, some of the new challenges raised extend well beyond informational privacy; an example of this is the blurring of social areas. It is necessary to pay attention to wellbeing and human capabilities, to deal with the challenge

3

STOA | Panel for the Future of Science and Technology

of an increased impact on people's intimate life. Both may require legal or regulatory frameworks that extend beyond the current emphasis on privacy and (digital) right and also emphasise social justice and human capabilities.

Some world governments have nonetheless chosen to inform their citizens regarding the significance of the Fourth Industrial Revolution or bio-digital convergence, even if such information consisted of postings that are often difficult to locate on their official websites. Thus, **the Government of Canada** fulfills its duty to its citizens by informing them, even prior to the COVID pandemic, via a post and a brochure dated 11-02-2020 entitled “Exploring Biodigital Convergence—What happens when biology and digital technology merge?” regarding the meaning and implications of bio-digital convergence <https://horizons.service.canada.ca/en/2020/02/11/exploring-biodigital-convergence/index.shtml> .

Thus, from the preface itself, we learn that the change is so profound that it necessitates a reconsideration of the definition of the human being and the holding of debates on the subject of ethics. Unfortunately, **these debates did not take place due to the occurrence of the “unexpected” COVID-19 event, which did not, however, impede the continuation of the bio-digital convergence plan.**

*„In the coming years, bio-digital technologies could be integrated into our lives just as is currently occurring with digital technologies. Biological systems and digital systems are converging and **could change the way we work, live, and even evolve as a species** . More than a mere technological shift, this bio-digital convergence could transform the way we understand ourselves and **could lead us to redefine what we consider human or natural** . The bio-digital convergence could have a **profound impact on our economy, our ecosystems, and our society** . Preparing to support it, **while managing its risks with care and sensitivity, will shape how we handle social and ethical considerations**, as well as guide conversations regarding policy and governance. Guided by its mandate, Policy Horizons Canada (Policy Horizons) **intends to initiate an informed and meaningful dialogue on the plausible future of biodigital convergence** and the policy questions that may arise.*

The brochure's summary defines the term bio-digital convergence and asserts that the changes driven by it could be disruptive: “ **Digital technologies and biological systems are beginning to combine and merge in ways that could be profoundly disruptive to our vision of society, the economy, and our bodies. We call this bio-digital convergence** .”

new hybrid forms of life and technology, each operating in the tangible world, often with enhanced capabilities .

Robots with biological brains and biological bodies with digital brains already exist, as do human-computer and brain-machine interfaces. The medical use of digital devices in humans, as well as digitally manipulated insects, such as drone dragonflies and surveillance locusts, are examples of digital technology combined with biological entities. By accessing the nervous system and manipulating neurons , technology can be added to an organism to modify its function and purpose. New human bodies and new senses of identity could emerge as convergence continues."

"For example, **gene sequencing combined with artificial intelligence (AI) leads to the understanding of genetic expression, which is then used to modify existing organisms to create organic compounds in new ways or even completely synthetic organisms. The CRISPR/Cas9 approach and other new genetic editing techniques would have been impossible without the evolution of digital technology and bioinformatics** . Advances in digital technologies have contributed to progress in the area of bio-digital convergence."

Suggestive of the deceptive manner in which bio-digital convergence is being implemented upon humanity is the statement describing how synthetic, artificial products are labeled as natural, simply because an authority decided so in an obscure document, invisible to most people.

" There is also a blurring of the lines between what is considered natural or organic and what is digital, artificial, or synthetic. For example, **biosynthetic vanilla** is created using ferulic acid, eugenol, and glucose as substrates, and **bacteria, fungi, and yeasts as microbial production hosts** . **Although it does not originate from a vanilla plant , according to food legislation in both the USA and the EU , its production from " microbial transformations of natural precursors " allows it to be labeled as a "natural flavor "** .

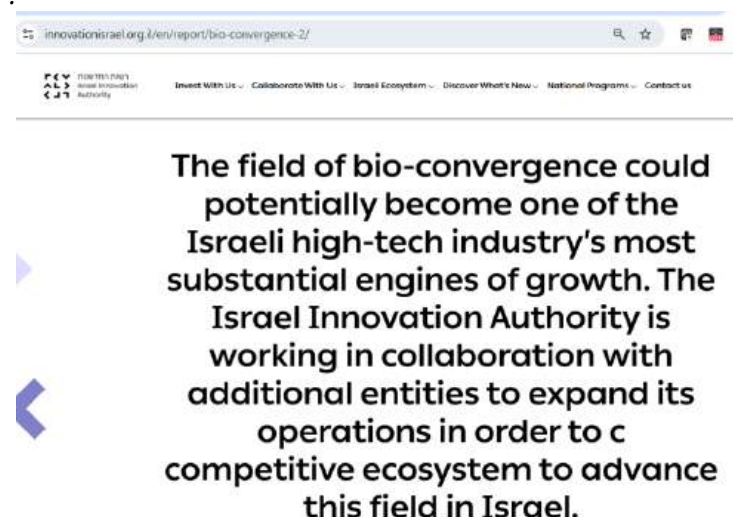
Another state that has officially posted information about bio-digital convergence was Israel.

Thus, on the website of the Israel Innovation Authority, as early as 2019, information and a brochure regarding this subject were posted under the title "Bio-Convergence"

<https://innovationisrael.org.il/en/reportt/bio-convergence-2/> .

It is thus stated:

"The field of bioconvergence could become one of the most important growth engines of the Israeli high-tech industry . The Israel Innovation Authority is working in collaboration with other entities to expand its operations, in order to create a competitive ecosystem that promotes this field in Israel ."



The screenshot shows a web browser displaying the Israel Innovation Authority website. The URL in the address bar is <https://innovationisrael.org.il/en/reportt/bio-convergence-2/>. The website header includes the logo of the Israel Innovation Authority and navigation links: "Invest With Us", "Collaborate With Us", "Israel Ecosystem", "Discover What's New", "National Programs", and "Contact us". The main content area features a quote in English, flanked by two large blue arrows pointing towards it. The quote reads: "The field of bio-convergence could potentially become one of the Israeli high-tech industry's most substantial engines of growth. The Israel Innovation Authority is working in collaboration with additional entities to expand its operations in order to create a competitive ecosystem to advance this field in Israel."

The field of bio-convergence could potentially become one of the Israeli high-tech industry's most substantial engines of growth. The Israel Innovation Authority is working in collaboration with additional entities to expand its operations in order to create a competitive ecosystem to advance this field in Israel.

An important point to note is the fact that this site explains **why the current medical system, including diagnostic means and therapeutic options, must be radically changed** , it being clear from the statements made that **the new technologies in the field of biodigital convergence are considered to be the solution for a new "personalized" and low-cost medicine**. Unfortunately, people are not informed about these technologies which signify both the change of what defines us as

people. Furthermore, the new medicine entails the irreversible introduction into human bodies of certain nano-devices that are wirelessly operated and which, beyond their alleged benefits, raise numerous information security concerns, effectively violating privacy at the molecular level of the human organism and of the human brain.

*"In recent years, global health and medicine have undergone a revolution driven by two main factors : first, **the crisis of global health systems and the biopharmaceutical industry, caused by a sudden increase in healthcare spending and the development costs of new medicinal products** . The second factor refers to recent technological discoveries in the fields of engineering,*

of biology and of medicine. This revolution promotes a new industry multidisciplinary based on the synergy between different technologies in the fields of biology and engineering, known as

"bioconvergence". The Innovation Authority considers that the Israeli innovation ecosystem has a substantial potential to transform the country into a world leader in this developing field . The Authority strives to create the conditions that allow for the growth and success of the bioconvergence industry in Israel.

The crisis of the global health system

Global health expenditures continue to increase dramatically and are expected to reach 10 trillion dollars by 2022 . The primary drivers of this phenomenon are an increase in life expectancy, which results in the aging of the population, coupled with the rising prevalence of chronic conditions such as cancer, cardiovascular disease, and diabetes .1 Currently, approximately 50% of the USA population is classified as chronically ill, and these patients account for approximately 85% of total healthcare service expenditures .2

Timely and effective medical intervention and diagnosis can prevent or delay the onset of most chronic diseases. As a result, the healthcare system has undergone significant transformations in recent years and currently prioritizes early and effective intervention as well as the field of preventive medicine. Technological advancements and a combination of innovative genetic and digital technologies can assist in identifying and managing the complexities inherent in chronic diseases. Furthermore , these facilitate the identification of the "latent" stage of such diseases to prevent the onset of symptoms. Consequently, healthcare systems continue to transition from a model where success is measured by the number of patients treated (Volume-based Model) to a model that measures success by the quality and efficiency of treatment (Value-based Model), which is also expressed through the capacity to avoid medical treatments. This transition , necessary for governments and service providers as well as for the patients themselves, determines the need for technological innovation capable of responding to the new challenges and requirements of the healthcare system.

Western governments invest substantial sums to improve and strengthen the healthcare systems that burden public expenditure. A global comparison of national healthcare expenditures as a percentage of GDP between 1975 and 2018 is presented in Fig. 6.1 below. The comparison between Israel, the USA, the United Kingdom, Canada, Switzerland, and Austria shows that healthcare expenditures as a percentage of GDP in these countries have almost doubled and, in some cases, have increased even further."

The Bio-Convergence Revolution

Technological advancements achieved in recent years allow for the connection and combination of fields in a manner that was previously impossible. The genomic revolution, the dramatic decrease in costs, and the increased speed of DNA sequencing, alongside Artificial intelligence and Big Data, are leading today to the development of advanced diagnostic technologies based on genomic and clinical data at the level of proteins .

Two of the other fields developing alongside biotechnology are gene therapy, which is at the forefront of personalized healthcare, and synthetic biology , which is based on a combination of innovative technologies such as DNA sequencing, the creation and writing of new genes, among others, through the use of CRISPR technology, behavioral modeling of specific genes, and the precise measurement of gene behavior.

In addition to engineering, the Innovation Authority is witnessing other multidisciplinary combinations based on engineering technological discoveries . These technologies include, for example, the miniaturization of electronic components combined with engineered 'living' tissues and materials, smart biosensors, communications, and the 3D printing of tissues. All these constitute the foundation of the technological innovation engine termed bioconvergence.

The 2018-2019 innovation report included a chapter regarding personalized healthcare and its potential. **The bioconvergence revolution is the next stage of this trend and allows for personalized healthcare, not only at the patient level, but also at the molecular level, ensuring that treatments are tailored to the type of disease down to the level of the individual cell.**

For example, **an individual personalized treatment will be based not only on diagnostic tests, but also on a combination of miniature biological sensors that continuously monitor viruses, bacteria and cancer cells etc.** The results of these tests will enable the early detection of diseases and the administration of preventive treatment. Furthermore, **smart nanorobots will enable the precise administration of treatment to damaged cells without affecting healthy cells .7"**

The directions of research and investment in the field of biodigital convergence described on the official website of an Israeli authority appear to belong to the realm of science fiction. Nevertheless , this page also addresses Israel's significant investments in this sector, as Israel is a global leader in research.

„Nanorobotics for the administration of medicinal products : One of the primary challenges in the contemporary pharmaceutical field is the necessity for a more efficient and precise administration of medicinal products to the affected area and to specific cells. Nanorobots designed from biological systems (such as DNA, cells, or bacteria) for the administration of medication to target cells are delivery systems capable of storing other medicinal products and materials, reacting to the external environment to identify the drug discharge signal, and releasing it in a controlled manner at the appropriate time and location ."

„Biological sensors and diagnostics : One of the primary healthcare challenges of the 21st century is reducing the use of antibiotics to limit the evolution of antibiotic-resistant bacteria.

This requires an enhanced capacity to distinguish between a bacterial infection and a viral one.

Biological detection is an emerging new technology that combines biotechnology and nanotechnology. Biological detection utilizes biological molecules such as antibodies, enzymes, and nucleic acids, as well as bacteria, to discover and identify specific materials . Biosensors are genetically modified biological molecules, which constitute a fusion between a sensor and the reporting system . This technology allows for the creation of identification components for almost any material and its advanced development toward faster, more sensitive, more specific, and more efficient sensors .

Optogenetics: An innovative technology that combines genetic engineering and technologies from the field of physics , such as high-speed, precise light pulses and the use of optical fibers.

Optogenetics aims to precisely activate specific neurons in the brain using light."

„Bioelectronics : A multidisciplinary research field that combines elements of chemistry, biology, physics, nanotechnology, and materials science . This field leverages new technological capabilities that allow the combination of biomolecules with electronics to develop a wide range of functional devices."

Two of the other fields developing alongside biotechnology are that of gene therapy, which is at the cutting edge of personalized healthcare, and synthetic biology that is based on the a combination of innovative technologies such as DNA sequencing, creation and writing of new genes, among others by using CRISPR technology,⁵ behavioral modeling of specific genes, and precise measurement of gene behavior.

Apart from engineering, the Innovation Authority is witness to other multidisciplinary combinations that are based on engineering technological breakthroughs. These technologies include for example, miniaturization of electronic components combined with tissues and engineered "living" materials, smart biosensors, communications, and 3D printing of tissues. All these constitute the foundation of the technological innovation engine termed bio-convergence.

The 2018-2019 Innovation Report⁶ included a chapter on personalized healthcare and its potential. The bio-convergence revolution is the next stage of this trend and enables personalized healthcare, not only on the patient level but also on the molecular level so that treatments will be adapted to the disease type down to the level of the individual cell.

For example, an individual personalized treatment will be based not only on diagnostic tests but also on a combination of miniature biological sensors that continuously monitor viruses, bacteria and cancerous cells etc. The results of these tests will allow early detection of disease and administration of preventative treatment. Furthermore, smart nano-robots will allow precise delivery of treatment to damaged cells without harming healthy cells.⁷

No information regarding bio-digital convergence appears on the official websites of the Romanian authorities; however, in 2022, Law No. 293 of November 3, 2022, "for the prevention and combating of cancer," was promulgated and published in the OFFICIAL GAZETTE No. 1077 of November 8, 2022 (<https://legislatie.just.ro/Public/DetaliuDocumentAfis/261246>).

This law was inspired by a European Commission brochure (https://health.ec.europa.eu/document/download/26fc415a-1f28-4f5b-9bfa-54ea8bc32a3a_en) which states that every Romanian citizen will be monitored in real time through smart devices and that a human digital twin will be created for every Romanian, under the pretext of personalized medicine, without mentioning the use of these technologies for monitoring and intimate control.

"Personalized medicine will also benefit from High-Performance Computing. Combining an individual's health data with real-time monitoring through smart devices and pharmacokinetics will constitute the basis for creating a digital twin of each person. This will leverage the potential of personalized medical approaches and will enhance screening and prevention strategies, rapid diagnoses, and individualized therapeutic concepts."

Noul Parteneriat pentru medicina personalizată, care urmează să fie înființat în 2023 și finanțat în cadrul programului Orizont Europa, va identifica prioritățile pentru cercetare și educație în medicina personalizată, va sprijini proiectele de cercetare privind prevenirea, diagnosticul și tratamentul cancerului și va face recomandări pentru lansarea abordărilor medicale personalizate în practica medicală zilnică. Ca acțiune pregătitoare pentru parteneriat, Comisia Europeană va stabili o foaie de parcurs către prevenția personalizată, identificând lacunele din cercetare și inovare, și va sprijini o abordare pentru cartografierea tuturor anomalilor biologice cunoscute care duc la susceptibilitatea la cancer, inclusiv a cancerelor ereditare.

Medicina personalizată va beneficia, de asemenea, de High-Performance Computing. Combinarea datelor de sănătate ale unei persoane cu monitorizarea în timp real prin dispozitive inteligente și farmacocinetică va constitui baza pentru crearea unui geamăn digital (digital twin) al fiecărei persoane. Acest lucru va valorifica potențialul abordărilor medicale personalizate și va spori strategiile de screening și prevenire, diagnosticale rapide și conceptele terapeutice individualizate.

Pe de altă parte, acest plan are în vedere o inițiativă prin care să se asigure accesul rapid la servicii de depistare, diagnosticare și tratament în cazul cancerelor pediatrie.

I emphasize the fact that I addressed a petition to several institutions (the Senate of Romania, the Ministry of Health, CMR, the President of Romania, The Government of Romania) on 25-10-2022 regarding this law, which was then in the draft stage **inquiring as to the definition of real-time monitoring and whether the smart devices intended for such monitoring were introduced concurrently with the COVID vaccines, given the MAC codes detected via Bluetooth in the proximity of vaccinated persons** however, although the petition was assigned registration numbers by several institutions, I received only a perfunctory response from the Presidency on November 3, 2022, informing me that **"Mr. Klaus-Werner Iohannis signed on Wednesday, November 2, 2022, the decree regarding the promulgation of the Law for the prevention and combating of cancer (PL-x 530/26.09.2022)"; furthermore, on November 2, I was curtly informed by a senate commission that the law had passed the Senate and had been forwarded for promulgation.**

SESIZARE REFERITOARE LA DEFICIENȚELE Programului National de Combatare a Cancerului SI PROPUNERI DE REMEDIERE

G Geanina Hagima <geaninahagima@gmail.com> 25 oct. 2022, 23:37 ☆ 😊
către bcc: comsan, bcc: Cabu, bcc: relatii.publice, bcc: office, bcc: contact, bcc: conducerea.sogr, bcc: proetatean, bcc: drp, bcc: comap, bcc: steluta.gheorghe, bcc: comisiamediu, bcc: ci

Buna ziua,
atașez acestui e-mail o sesizare referitoare la DEFICIENȚELE Programului National de Combatare a Cancerului SI PROPUNERI DE REMEDIERE.
Va rog să-mi ofeți număr de înregistrare.
Cu stima,
Dr. Geanina Hagima,
medic primar obstetrică -ginecologie
cu competență în oncologie ginecologică,
str Seneslau, Nr. 22, Pitești, Argeș

Un atașament • Scanat de Gmail ⓘ Aadaugă în Drive



O Secretariat CMR <office@cmr.ro> 26 oct. 2022, 15:47
către eu ▼

Buna ziua,

Sesizarea dvs. a fost înregistrată la Colegiul Medicilor din Romania sub nr. 9342/26.10.2022.

Cu stima,
Stefania Branza
Secretariat CMR

Kaspuns petitie Mesaje primite x

? procetatean@presidency.ro 3 nov. 2022, 10:01 ☆ 😊 ↩ ⋮
către eu ▼

ROMÂNIA

**Administrația
Prezidențială**

Telefon: 021.410.05.81 | Fax: 021.410.38.58
E-mail: procetatean@presidency.ro

**Departamentul Administrație,
Politici Publice și Societate Civilă**

Oficiul pentru Relații cu Cetățenii

Petiția nr.19795
Data: 03-11

Doamnă Geanina Hagima,

Referitor la mesajul dumneavoastră transmis pe adresa de corespondență electronică a Administrației Prezidențiale, vă informăm că Președintele României, domnul Klaus-Werner Iohannis, a semnat miercuri, 2 noiembrie 2022, decretul privind promulgarea Legii **pentru prevenirea și combaterea cancerului** (PL-x 530/26.09.2022).

Informația este afișată pe site-ul Administrației Prezidențiale, în secțiunea "Media", la adresa https://www.presidency.ro/ro/media/decrete_si_acte_oficiale/decret-semnat-de-presedintele-romaniei-klaus-iohannis1667401923

Cu stimă, Consilier de Stat Gabriel-Cristian Piscociu

Another piece of evidence indicating that the profound transformation of our world through bio-digital convergence was premeditated is the installation—notwithstanding the opposition of civic activists and associations such as the Stop5G Romania Association <https://sttop5gromania.ro/>—of 5G infrastructure and technology during the COVID-19 period. This technology, which facilitates a high volume of data transfer, is a component of the biodigital convergence. Concurrently, numerous studies indicate the negative effects of 5G radiation on human health and other biological systems. Among the extensive research on this subject, I cite a comprehensive study by the STOA of THE EUROPEAN PARLIAMENT dated July 2021, entitled 'Health impact of 5G'.

[https://www.europarl.europa.eu/RegData/etudes/STUD/2021/690012/EPRS_STU\(2021\)690012_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2021/690012/EPRS_STU(2021)690012_EN.pdf) concluding that **radiation within the 450-6000MHz 5G spectrum likely causes cancers, specifically gliomas and acoustic neuromas, and definitively causes male infertility, while likely causing female infertility and potential complications regarding pregnancy**. Furthermore, it is noted that regarding frequencies between 24-100 GHz, which approach the 6G spectrum, no adequate studies have been conducted to determine the impact on health; this is a grave matter, as this technology was implemented without regard for human health, solely to fulfill the mandatory implementation of the bio-digital convergence agenda.

6.3 Overall evaluation

6.3.1 Cancer

FR1 (450 to 6000 MHz): As a synthesis of what we have managed to analyse in the available scientific literature, in both human and animal studies, we can say that RF-EMF at FR1 frequencies exposure probably cause cancer, and in particular gliomas and acoustic neuromas in humans.

FR2 (24 to 100 GHz): No adequate studies were performed on non thermal effects of the higher frequencies.

150

Health impact of 5G

6.3.2 Reproductive developmental effects

FR1(450 to 6000 MHz): These frequencies clearly affect male fertility. These frequencies *possibly* affect female fertility. They *possibly* have adverse effects on the development of embryos, fetuses and newborns.

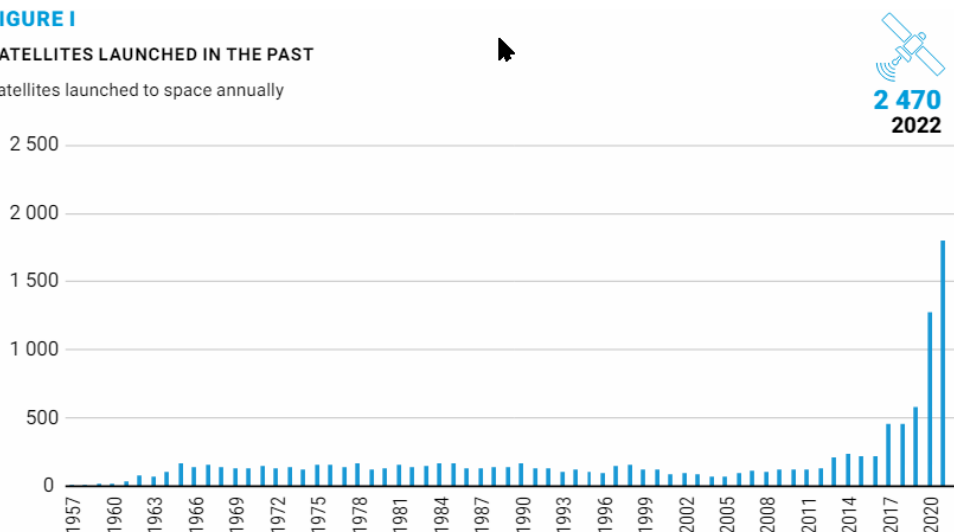
FR2 (24 to 100 GHz): No adequate studies were performed on non-thermal effects of the higher frequencies.

Simultaneously, the deployment of satellites into Earth's orbit is undergoing an accelerated process, as evidenced in the UN document "Our Common Agenda Policy Brief 7 For All Humanity—the Future of Outer Space Governance" dated May 2023 <https://www.un.org/sites/un2.un.org/files/our-common-agenda-policy-brief-outer-space-en.pdf>.

FIGURE I

SATELLITES LAUNCHED IN THE PAST

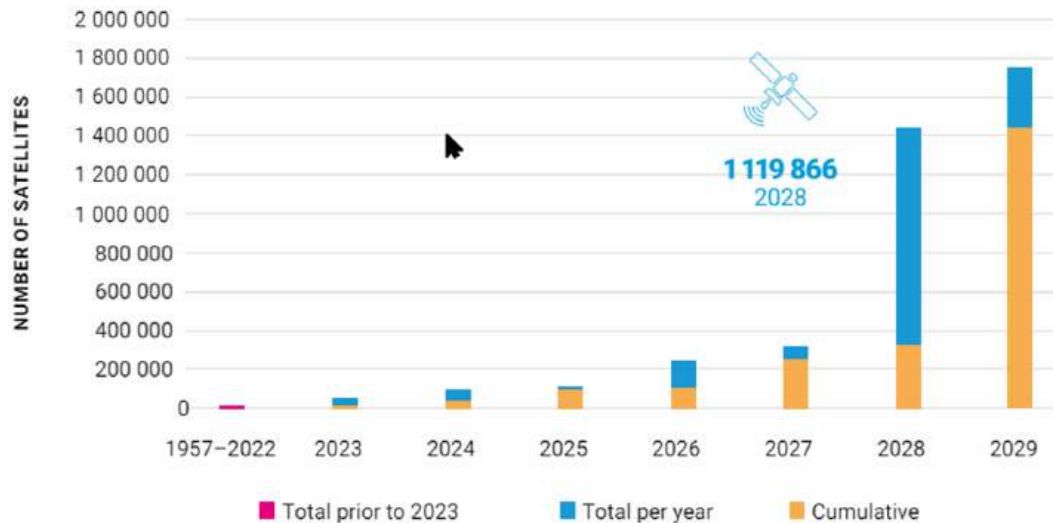
Satellites launched to space annually



SATELLITES REGISTERED TO LAUNCH IN THE FUTURE

Number of non-geostationary satellites for which states have registered radio frequencies with the International Telecommunication Union (by year and cumulative)

For past launches, see figure 1.



From this document, it further emerges that the satellites surrounding the Earth are involved in achieving the objectives of the 2030 Agenda, serving to connect everything on Earth to the internet; that is, **they serve to establish total control** — “Recent innovations have made internet connectivity from low Earth orbits increasingly viable, with the potential to **connect rural schools, hospitals, and communities to the internet**.” This capacity could be a game-changer for **achieving the Sustainable Development Goals**; as studies demonstrate, connecting villages to the internet can contribute to wage growth, skill development, increased business profits, and access to services. Space-based internet also has the potential to help bridge the digital divide by opening access in developing areas and **supporting** students, teachers, farmers, and **healthcare workers, providing essential support in public health emergencies, such as the coronavirus disease (COVID-19).**”

The launching of satellites into low Earth orbit for global connectivity or **for global control** is a rapidly expanding process, agreed upon through the collaboration of UN member states which adopted Resolution 76/3 in October 2021, also known as **The “Space2030” Agenda** <https://docs.un.org/en/A/RES/76/3>. These significant changes in the configuration of the space surrounding the Earth are likewise little known to the public.

In a 2024 ITU article <https://www.itu.int/pub/S-JNL-VOL5-ISSUE2-2024-A20> entitled “Future satellite communications: Satellite constellations and connectivity from space” the role of low Earth orbit satellites communicating with terrestrial 5G/6G infrastructure to achieve global connectivity is underscored. **“Satellite communications are currently undergoing massive growth, with a rapid expansion of low Earth orbit (LEO) networks and a wide range of new satellite technologies. Until recently, satellite communications systems and 5/6G wireless terrestrial networks have been distinct and complementary entities. The opportunity now exists to unify these networks and provide an integrated multi-service network with global coverage.** Achieving this will require addressing key research challenges and leveraging new technologies, including high-frequency phased-array antennas, on-board processing, dynamic beam hopping, physical layer signal processing algorithms, transmission waveforms, and adaptive inter-satellite links and routing. **By seamlessly integrating with 5/6G terrestrial networks and low-altitude access points, future satellite networks promise to provide universal connectivity on a global scale, overcoming geographical limitations.** In this special edition, we focus on the future

of satellite communications, exploring topics ranging from beam hopping and design to spatial routing and THz satellite communications. Our goal is to bring to light **the potential of these emerging technologies and their role in reshaping the landscape of global connectivity** . ”

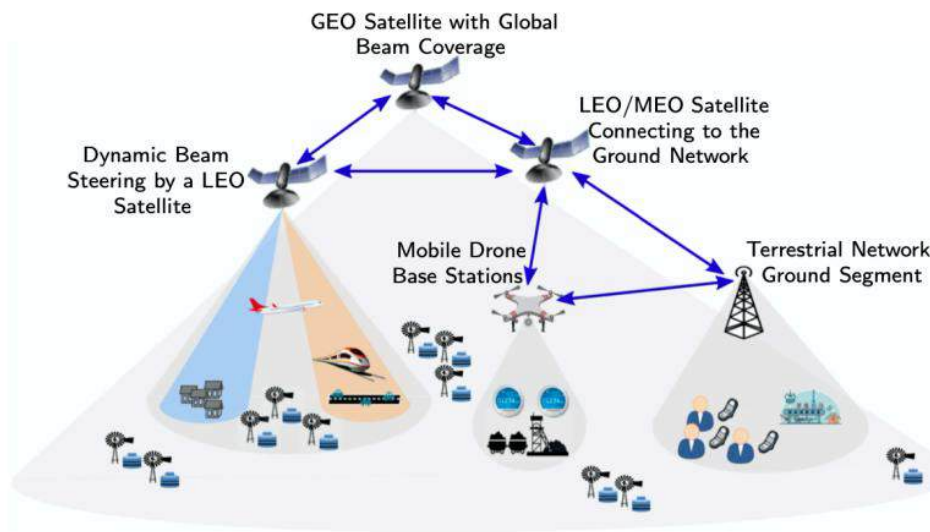


Fig. 1 – A multi-layer space network integrated with terrestrial and low-altitude drone base stations.

This implies that human beings and all living entities on this planet will reside in an **electromagnetically polluted environment, without our consent being sought, with consequences that are highly likely to be deleterious to health** , considering that **the human body functions electrically** (the heart functions electrically—EKG, the brain functions electrically—EEG). Given that the number of these satellites will continually increase to achieve global connectivity, it follows that **the people—unconsulted on this matter and uninformed—** were not offered the choice to live outside of this electromagnetically polluted environment and total control, which transforms the Earth into a prison from which no one escapes intact . Considering that radiation from the 5G/6G spectrum, as well as nanotechnology, are invisible, these actions of the decision-makers have passed almost unnoticed by the majority of the population, leaving the architects of this plan unhindered in continuing their activities.

As previously mentioned, 5G and especially 6G technologies are instrumental for the Internet of Bio-Nano-Things and for the control of living organisms, including humans, down to the molecular level.

F. ACCELERATED BIODIGITAL CONVERGENCE IS FACILITATED BY COGNITIVE WARFARE ABOUT WHICH THE POPULATION WAS NOT INFORMED BY THE MILITARY OR THE AUTHORITIES, DESPITE THE OBLIGATION TO DO SO

The plan for a profound transformation of the world in which we live, aiming for total control, is being executed within the framework of cognitive warfare intended to distract the public by engineering events that induce panic and fear (such as COVID-19); for these events, the authorities offer solutions (COVID-19 vaccination, the use of nanotechnology, and 5G/6G technology for a new healthcare system) which, in fact, facilitate the implementation of the said plan (total control).

In fact, warfare is no longer conducted as it was in the past; it has become far more complex and invasive through the application of subconscious manipulation techniques and advanced, invisible technologies such as nanotechnology and 5G/6G technologies—information that is disclosed in NATO documents. The public remains uninformed about these developments, despite the obligation to be notified, and consequently, individuals lack the knowledge to defend themselves.

From a NATO document 'COGNITIVE WARFARE' authored by Commander Cornelis van der Klaauw, Royal Netherlands Navy, **Subject Matter Expert** , Strategic communications and information operations, NATO Joint Warfare Centre <https://www.jwc.nato.int/wp-content/uploads/2024/12/selectts->

[klaauw.pdf](#) we understand the complexity of cognitive warfare, its targets, the technologies employed, and the necessity for the public to be informed regarding the techniques and technologies utilized in this conflict:

„Cognitive warfare represents a structured and deliberate approach targeting the human cognition of individuals, groups, and societies in a manner that compromises their decision-making processes and, ultimately, their behavior. While cognitive effects are not measurable in the conventional sense, they influence our thoughts, emotions, and actions through the use of brain-centered technologies intended to destabilize structures, foster mistrust, and fracture social cohesion—for instance, by amplifying pre-existing social divisions to undermine democracies and weaken our rules-based systems.“

The NATO Alliance is committed to providing aid to member states in this war according to existing treaties: 'In order more effectively to achieve the objectives of this Treaty, the Parties, separately and jointly, by means of continuous and effective self-help and mutual aid, will maintain and develop their individual and collective capacity to resist armed attack.'

„NATO nations differ in their cultural, social, technological, and governmental structures, and, along with them, in their susceptibility to cognitive attacks. A customized approach is necessary to provide the appropriate support to nations. There is an additional reason why NATO is developing a concept of cognitive warfare: a cognitive attack directly targets the minds of civilians, specifically non-combatants.

As this constitutes a violation of the Law of Armed Conflict.“

„Unlike psychological operations, cognitive activities are not directed at our conscious mind, but rather at the subconscious—the primary drivers of our behavior: emotions.

This occurs through **hyper-personalized targeting that integrates and exploits neuroscience, biotechnology, information, and cognitive techniques (NBIC)**, primarily utilizing **social and digital networks for neuro-profiling and the targeting of individuals**. It must be recognized that **individuals are at the center of all military operations and strategic-political decision-making**.

While they often sound like concepts from a science-fiction film, cognitive attacks are no longer science fiction. They are already occurring, and these attacks **will continue to become increasingly sophisticated**.

Multiple nations are developing NBIC capabilities and harvesting data to be utilized in targeting the cognitive dimension. These activities are supported by processes such as data mining and data analysis, further integrated with Artificial intelligence. **While the majority of cognitive attacks remain below the threshold of armed conflict, the effects can be lethal and multi-domain, impacting all five domains of warfare**. Furthermore, **these attacks are human-centric**, meaning they hold human cognition as their center of gravity; in principle, **this represents a continuous, unending struggle**.”

China is globally **one of the leading nations in the scientific development of NBIC capabilities**. China conducts human research and experimentation deemed unethical by Western standards; nevertheless, these experiments attract scientists from across the globe. Within the framework of the Chinese 'three wars' strategy—an integrated human-centric, psychological, and legal approach—**the Chinese have developed a database containing the profiles of over two million prominent individuals worldwide, intended for use in influencing decision-making processes**.

„The reason cognitive attacks go unnoticed by their targets is that cognitive activities bypass the conscious mind and directly target a person's subconscious. In fact, within the subconscious mind, **the primary target is the amygdala**.”

„Unlike the conscious mind, the subconscious mind is always active; it never sleeps. It regulates our basic organic functions, our emotions, and, surprisingly, the greater part of our decision-making process. The reason the majority of our decisions are made by our subconscious is that our conscious mind consumes a great deal of energy, causing it to quickly reach the limits of its capacity. In fact, only five to ten percent of the decisions we make are rational decisions; otherwise, we rely on our subconscious decision-making process, which is heavily influenced by repetition, automatisms, prejudices, and errors. Then, we tend to use our conscious mind to justify, rationalize, and explain our decision-making process and our emotion-driven behavior.“

„THERE ARE ALSO OTHER RAPID DEVELOPMENTS **in the fields of nanotechnology, biotechnology, and information technology.**

In nanotechnology, we are witnessing the development of nanorobotics, nanosensors, and nanoenergy sources, which make it possible to influence/actuate processes within the body. Inventions in nanorobotics can stimulate perception, cognition, and behavior. In the field of biotechnology, there are encouraging developments in bioengineering, biogenomics, and neuropharmacology.

„In addition, neuronal nanotechnology can be used to bring nanometer-sized robots close to a neuron via the bloodstream and to make it possible to connect the human brain directly (i.e., without being intercepted by our senses) to a computer, utilizing artificial intelligence in this process.

But we must keep in mind that this is a two-way street: such artificial intelligence will be, in turn, connected to a human brain .

„This article aims to raise awareness of a nascent NATO concept that will significantly impact individuals, groups, societies, and the conduct of future warfare: cognitive warfare.”

„IN CONCLUSION, it is imperative to reiterate that **cognitive warfare is no longer science fiction** . Cognitive warfare is a reality of the modern era, and **everyone—whether civilian or military—constitutes a potential target** . Cognitive attacks seek to **exploit emotions rooted in our subconscious, bypassing the conscious rational mind** . This is achieved **through the exploitation of biases, errors, emotions, and automatisms, as well as through nanotechnology, biotechnologist, and information technology.**

In cognitive warfare, the ultimate goal is to **alter our perception of reality and to deceive our brain in order to affect our decision-making process** s. Usually, **we are not aware of such attacks until it is too late and they have already impacted their targets** .

Therefore, we must **protect ourselves by increasing awareness and developing a system of indicators and warnings capable of providing information in real time** .

The human mind is becoming the battlefield of the future; every person is a potential target.

War is no longer a purely military concept; It has become significantly broader and more complex.

In the future, there **will be a single rule in war: There are no rules.**

It follows from this article that NATO is aware of the gravity of the situation; however, this information has not reached the public, **as military representatives have failed to inform the population**. Moreover, the military has been involved in the process of distributing experimental COVID-19 nanotechnological products, further compromising the bodies and minds of individuals through the technologies introduced into these products. **In this manner, the people are rendered certain victims of this warfare.**

In view of these considerations, **it follows that NATO is engaging in a double game** . **Under the pretext of the Chinese or Russian threat, the research and funding of military research in the fields of advanced technologies** such as nanotechnology, 5G/6G technology, artificial intelligence, synthetic biology, gene editing, new materials with special properties such as graphene, and satellites, are justified. In reality, the vast majority of countries, including China and Russia, are members of the UN, deeply committed to achieving biodigital convergence under the pretext of fulfilling the objectives of the **2030 Agenda**, which ostensibly aims to combat poverty and ensure equal opportunities

We hereby establish that the entities funded by our public resources, rather than protecting and informing the citizenry, are acting to their detriment by making major decisions without seeking their consent, **with the people being utilized as subjects in this global experiment.**

Another relevant document proving that the governments and military structures are aware of the ongoing cognitive warfare yet neglect to inform the population—despite their own admission that they ought to do so—is a brochure https://static.ie.edu/CGC/CGC_TheBattleofTheMind_2024.pdf entitled 'THE BATTLE FOR THE MIND-Understanding and addressing cognitive warfare and its enabling technologies'—**„THE BATTLE FOR THE MIND-Understanding and addressing cognitive warfare and its enabling technologies'.**



This document presents the conclusions of a round table held during the MUNICH SECURITY CONFERENCE on February 16, 2024. Eighteen leaders in technology and defense from government, industry, and academia participated in this round table. They discussed how ***“ the human mind is becoming one of the primary battlefields of the 21st century, as revisionist actors seek to manipulate individual and group cognition with the aim of destabilizing liberal democracies from within ”***.

“The participants agreed on the need for a deeper understanding of the mechanisms and implications of cognitive warfare and emphasized the importance of better preparing citizens and legislators to confront imminent threats. They also highlighted how the same knowledge and technologies that enable cognitive warfare have the potential to protect our democracies from it.”

„Operations involving the manipulation and deception of the mind are as old as warfare itself. However, for the first time in the history of human conflict, advances in cognitive science and recent developments in the digital revolution—particularly the rise of generative artificial intelligence (AI)—enable actors to directly influence how 'an enemy community thinks, loves, or believes'.¹ This has prompted discussions within NATO and other security circles regarding the potential emergence of the cognitive domain as the sixth domain of warfare—following land, sea, air, outer space, and cyberspace. ² Furthermore, recent studies on the concept of 'cognitive warfare' are beginning to emerge. Although a universally accepted definition does not yet exist, the concept is used to refer to the set of activities that aim to shape 'attitudes and behaviors by influencing, protecting, or disrupting cognition at an individual, group, or population level to gain an advantage over an adversary'.³

These activities are considered part of broader hybrid warfare tactics, often deployed below the threshold of armed conflict, with diverse objectives ranging from thwarting specific military maneuvers to destabilizing entire societies or alliances. ⁴

The participants in the discussion agreed that actors seeking to challenge the international liberal order now possess both the means and the incentives to manipulate our thoughts and disrupt our shared vision of reality, thereby undermining the trust and social cohesion that underpin our societies.

As the most recent Munich Security report highlights, “key actors in the transatlantic community, powerful autocracies, and the so-called Global South have become dissatisfied with what they perceive to be an unequal distribution of the absolute benefits of the international order.”⁷ Consequently, they will use all means at their disposal to shape the future order to their advantage. This includes AI and other emerging technologies, the development and adoption of which are accelerating. Part of this development is driven by the technological geopolitical race between the United States and China, as both nations recognize the correlation between being leaders in emerging technologies and having influence over the international order.⁸

In fact , in the 2019 National Defense White Paper, the Chinese People's Liberation Army introduced the broader concept of intelligent warfare (智能化 战争) to refer to the way in which AI and other emerging technologies could be used to achieve “mental dominance”.⁹

This includes leveraging AI for enhanced information processing capabilities and rapid decision-making, as well as wearable sensors to refine and maintain the fighting spirit of troops ¹⁰ or the use of platforms such as TikTok ¹¹ to influence public opinion, exploit user data, and shape preferences, biases, and beliefs . According to analysts , the exercise of “direct influence over enemy cognition” is a distinctive feature of China’s intelligent warfare , as the country seeks to control the fate of Taiwan, the United States, and its allies without resorting to conventional warfare .¹²

Other countries may not be as assertive as China regarding their intentions to disrupt groupthink for strategic purposes, but their actions demonstrate otherwise. The use by the Internet Research Agency in Russia of bots and fake social media accounts to fuel polarization and interfere in the 2016 U.S. presidential elections, or the Kremlin’s use of false and misleading narratives to justify military actions against Ukraine prior to the 2022 invasion, are just two examples (Box 2).¹³ Another is the reported use by the Iranian government of ‘cyber-enabled influence operations’ , including the use of images and videos generated by Artificial intelligence, to undermine Israel and ‘create general confusion and mistrust’ in the context of the ongoing Israel-Hamas war. ¹⁴

„HYBRID WARFARE — A method of conflict characterized by the blending of conventional and unconventional instruments of power and tools of subversion. Unlike traditional warfare, which relies primarily on kinetic or lethal force, **hybrid warfare involves a combination of military, economic, political, social, and informational tactics aimed at exploiting an adversary’s vulnerabilities and achieving strategic objectives.** ”

„IDENTIFYING THE SIGNALS: ELEMENTS SHAPING THE FUTURE OF COGNITIVE WARFARE
To understand what cognitive warfare might involve in the coming decades, we must first understand two of the driving forces behind its development .

The first is the expansion of knowledge regarding the functioning of the brain and the fundamental processes underlying our mental circuits and cognitive biases .

Secondly, this manipulation is becoming increasingly feasible due to advancements in nanotechnology , biotechnology, information technology, and cognitive sciences, including neurotechnology (NBIC), as well as the volume of data within our societies.

„During the round table discussion, the participants identified three priority areas of action:

A. CULTIVATING AWARENESS AND UNDERSTANDING OF THREATS

***In recent years, an increasing number of studies have examined the concept of cognitive warfare and its risks, with NATO—through its Science and Technology Organization and the Allied Command Transformation —conducting much of the exploratory work.*³²**

However , the participants in the discussion agreed that, although we are somewhat aware of the threat of cognitive warfare, efforts to conceptualize it remain fragmented, and there is generally a limited understanding of its mechanisms and implications among both citizens and political decision-makers.

To inform policy decision-makers, it is imperative that the academic environment, industry, and the defense sector accelerate their efforts to define cognitive warfare and to better understand how the brain and emerging technologies can be exploited by state and non-state actors . The use of terminology from the physical domains of warfare may hinder the understanding and governance of non-physical domains, such as cyber warfare and cognitive warfare. Therefore, attention should be given to developing a language that accurately describes activity in the cognitive domain , including defining thresholds for terms such as ‘attack’, ‘weapon’, or ‘harm’.³⁴

As has already happened in the case of cyber warfare, **a paradigm shift from a purely physical and coercive understanding of warfare to the inclusion of non-physical and subversive activities is essential for effective policy-making in this field**.³⁵ **When raising awareness about the risks of cognitive warfare among citizens, a careful analysis of the approach is necessary to avoid counterproductivity. As the participants emphasized, asking citizens not to believe in anything they read or hear can lead to skepticism and apathy. Instead, citizens should be encouraged to critically evaluate information sources. Providing resources and tools for fact-checking and critical thinking can enable individuals to navigate the information landscape effectively.** Techniques such as 'prebunking' have proven useful in helping people identify and resist manipulative content (Box 6).³⁶

Moreover, raising awareness regarding the importance of not sharing data too easily and understanding how data is collected is essential for preventing micro-targeting and the risks presented by technologies such as neurotechnology. These awareness initiatives should be promoted across various sectors of society, including schools, workplaces, and public spaces, to ensure a comprehensive understanding of potential threats and to foster responsible data-sharing practices among citizens.

B. THE GOVERNANCE OF COGNITIVE WARFARE AND ITS ENABLING TECHNOLOGIES In this regard, recent initiatives by national governments and international organizations to regulate AI and other drivers of cognitive warfare represent significant steps forward. For example, through its forthcoming AI Act, considered the world's first comprehensive law on AI, the European Union directly prohibits AI uses whose risk is considered unacceptable, including uses aimed at "cognitive-behavioral manipulation" (Box 7).³⁷ Through its Executive Order on AI, the Biden administration, in turn, included provisions for labeling AI-generated content to inform users about its origin.³⁸ Beyond AI, governance efforts focused on the mind are also beginning to emerge, the most significant action within the concept of neurorights being supported by the Neurorights Foundation and UNESCO.³⁹ Although still in the incipient stages, these efforts aim to address the ethical dilemmas related to the use of neurotechnology, such as the means of ensuring mental privacy, autonomy, and integrity, which are essential for preventing cognitive warfare. Decision-makers must develop a comprehensive governance framework addressing both the factors facilitating cognitive warfare and the consequences of its use.

C. HARNESSING THE POWER OF EMERGING TECHNOLOGY TO STRENGTHEN SOCIETAL AND DEMOCRATIC RESILIENCE.

To prevent any risk to individuals, groups, or systems, we must confront both internal vulnerabilities and the threat of any potential actor exploiting these vulnerabilities to cause harm or achieve a specific objective. While previous sections focused on how to understand and govern the threat of cognitive warfare, we must also address the vulnerabilities that cognitive warfare seeks to exploit. During the discussion, there was a broad consensus that, in order to fully prevent the risks of cognitive warfare, we must address the current failures of our liberal democracies, as well as our cognitive biases. **This requires a comprehensive set of actions, ranging from political reform to education in critical thinking.**

While more research is needed regarding the specific set of actions to be taken in this regard, participants agreed that the same knowledge and technologies that enable cognitive warfare can help us address vulnerabilities within our system."

In another military document, a November 2020 study sponsored by the Allied Command Transformation (ACT) entitled "COGNITIVE WARFARE"

https://ia801703.us.archive.org/21/items/20210122-cw-ftinal/20210122_CW%20Final.pdf provides extensive useful information regarding the cognitive warfare in which we find ourselves; information which, unfortunately, has no way of reaching the public except through thorough research such as that which I have initiated :

"Cognitive warfare represents an insidious challenge . It disrupts ordinary understandings and reactions to events in a gradual and subtle manner, but with significant harmful effects over time. Cognitive warfare has a universal reach, from the individual to states and multinational organizations . It feeds on disinformation and propaganda techniques aimed at the psychological exhaustion of information recipients ."

"It provides NATO's adversaries a means of bypassing the traditional battlefield with significant strategic results, which can be used to radically transform Western societies.

The tools of information warfare, along with the addition of "neuro-weapons ," contribute to future technological perspectives, suggesting that the cognitive domain will be one of tomorrow's battlefields. This perspective is further reinforced by the rapid progress of NBICs (Nanotechnology, Biotechnologist, Information Technology, and Cognitive Sciences) and the understanding of the brain."

"Actions taken in the five domains—air, land, maritime, space, and cyber—are all executed to have an effect on the human domain. Therefore, it is time for NATO to recognize the renewed importance of the sixth operational domain, namely the Human Domain. "

"In its broadest sense, cognitive warfare is not limited to the military or institutional spheres . Since the early 1990s, this capacity has tended to be applied in political, economic, cultural, and societal fields.

Any user of modern information technologies is a potential target . This targets the entire human capital of a nation.

The human domain of operations could be provisionally defined as the 'sphere of interest in which strategies and operations can be designed and implemented which, by targeting the cognitive capacities of individuals and/or communities with a set of specific tools and techniques, particularly digital ones, will influence their perception and modify their reasoning capacities, thereby gaining control over decision-making, perception, and behavior to achieve the desired effects.'

"Trust is the target -Cognitive warfare pursues the objective of undermining trust (public trust in electoral processes, trust in institutions, allies, politicians...), therefore, the individual becomes the primary weapon, while the purpose is not to attack what individuals think, but rather how they think . (page 8)

It has the potential to dismantle the entire social contract underpinning societies.(page 8)

Cognitive warfare exploits the innate vulnerabilities of the human mind due to the way it is designed to process information, which have always been exploited in warfare, of course.

However, due to the speed and ubiquity of technology and information, the human mind is no longer capable of processing the flow of information ."

"Following the USA Brain Initiative , initiated in 2014, all major powers (EU/China/Russia) launched their own brain research programs with substantial funding. China views the brain "as the central headquarters of the human body, and precisely attacking the central headquarters is one of the most effective strategies to determine victory or defeat on the battlefield ".

The revolution in NBIC (nanotechnology, biotechnologist, information technology, and cognitive sciences), including advances in genomics, has the potential for the development of dual-use technology. ."

"Although existing treaties and laws (for example, BTWC and CWC40) have addressed certain products of brain sciences (for example, chemical substances, biological agents, and Toxins), other forms of neuroscience/technology (for example, neurotechnologies and neuroinformatics) remain outside the objective, scope, and governance of these conventions.

Technology can influence, if not even shape, the norms and conduct of war, and the future battlefield will depend not only on achieving 'biological dominance,' but also on achieving 'mental/cognitive dominance' and 'intelligence dominance'.

In conclusion, it is not a matter of whether neuroscience/technology will be utilized in military, intelligence, and political operations, but rather when, how, to what extent and, perhaps most importantly, whether NATO nations will be prepared to address, encounter, counter, or prevent these risks and threats. In this light (and based on the information provided), it is and shall remain increasingly

important to address the complex issues generated by the influence of brain sciences on global biosecurity and on the short-term scope and conduct of military and intelligence operations, both non-kinetic and kinetic. 41"

„Ethics —This field of research— human enhancement and cognitive weapons—is likely to be the subject of major ethical and legal challenges, but we cannot afford to be on the defensive when international actors are already developing strategies and capabilities to utilize them ."

„It is equally important to recognize the potential side effects (such as speech disorders, memory disorders, increased aggression, depression, and suicide) of these technologies . For example, if any cognitive enhancement technology were to undermine a subject's ability to comply with the law of armed conflict, this would be a source of very serious concern. The development and use of cognitive technologies present numerous ethical challenges, as well as ethical benefits, such as recovery from post-traumatic stress disorder (PTSD).

Decision-makers should take these challenges seriously as they formulate policies regarding cognitive technologies, exploring the issues in depth and determining whether additional ethical issues may arise as this technology and other related technologies evolve.

„Recommendations for NATO

The need for cooperation—Although the objective of cognitive warfare is to harm societies and not just the military, this type of warfare resembles 'shadow wars' and requires a whole-of-government approach at the national level.

As previously mentioned, the modern concept of war does not refer to weapons, but to influence. In order to shape perceptions and control the narrative during this type of warfare, the battle must be waged in the cognitive domain, employing an all-of-government approach at the national level. This will require enhanced coordination between the use of force and other levers of power within the government.

This could entail changes in the way defense is resourced, equipped, and organized to provide military options below the threshold of armed conflict and to enhance the military contribution to national resilience.

For NATO, the development of actions within the cognitive domain also necessitates sustained cooperation among allies to ensure overall coherence, build credibility, and enable a concerted defense."

„Delays in declaring the Human Domain as a domain of operations could result in fighting the last war."

„Ultimately, ethical issues must be addressed. In the absence of an agreed international legal framework in the field of neuroscience, NATO could play a role in promoting the establishment of an international legal framework that meets the ethical standards of NATO nations

."

Therefore, it can be readily observed that the **technologies developed by the military for the purpose of bio-digital convergence, initiated by the USA, are currently leading toward the destruction of the world in which we live** , altering human cognitive capacities, with cognition becoming the sixth domain of military operations.

Cognitive warfare is extremely convenient for those who planned the bio-digital convergence , facilitating and even accelerating, in a highly intelligent manner, the profound and irreversible transformation of the world in which we live and the acquisition of total control. By utilizing information warfare, manipulation techniques, and NBIC technologies, the desired results were rapidly achieved.

Unfortunately, I note with regret that the Romanian army is complicit in the betrayal of the Romanian people; although this document was **produced five years ago, the army has failed to inform the public even to this day regarding the state of cognitive warfare in which we find ourselves, leaving the population entirely exposed and certain victims in this conflict.**

NATO is deeply involved in conducting military research for human enhancement and the development of more effective weaponry (human augmentation) by utilizing nanotechnology, 5G and 6G technologies, artificial intelligence, new materials (graphene), 3D printing, satellites, and big data, under the pretext of achieving primacy in military competition, as evidenced by the extensive March 2020 document "Science & Technology Trends 2020-2040 Exploring the S&T Edge" https://www.nato.int/nato_static_fl2014/assets/pdf/2020/4/pdf/190422-ST_Tech_Trends_Report_2020-2040.pdf issued by the NATO Science and Technology Organization.

The current importance of new technologies, such as nanotechnology, across various domains—including the medical and military sectors— **was long ago anticipated by military researchers, as evidenced in this 1996 document from the Air University, Maxwell Air Force Base, Alabama, entitled "Alternate Futures for 2025".** This document asserts: **"Nanotechnology will influence society as dramatically as the discovery of fire, writing, and agriculture combined."** ⁴⁸ Nanotechnology appears to have revolutionary applications in all fields of engineering, from computing to medicine and materials science. ⁴⁹ What is nanotechnology, and how will this field influence the technologies of the year 2025? **The pinnacle of nanotechnology is engineering at the molecular level or even the atomic level to create structures at an ultramicroscopic level—structures that can then be assembled like Lego blocks at the designer's discretion. The created structures could even self-organize, aligning themselves in response to external stimuli."**

Nanotechnology

"Nanotechnology will influence society as dramatically as the discovery of fire, writing, and agriculture put together."⁴⁸ Nanotechnology appears to have revolutionary applications across the depth and breadth of engineering, from computers to medicine to materials science.⁴⁹ What is nanotechnology, and how will this field impact the technologies of 2025?

The apex of nanotechnology is engineering at the molecular or even atomic level to create structures at the ultramicroscopic level, structures that can then be plugged together like Lego blocks at the designer's whim. The structures created might even be self-organizing, aligning themselves in response to external stimuli."⁵⁰

These visions have driven the intensive funding of military research which, in the pursuit of supremacy, disregarded both regulations and ethics. Consequently, through ignorance—but more likely by premeditation—the current situation has been reached where these technologies are being deployed against humanity without regulation or established ethical norms, despite their long-known potential for use as weapons.

Recent DARPA military research from 2018 aims to create a brain-computer interface through "non-invasive" methods <https://www.grantts.gov/granttsws/restt/opportunity/attdt/download/271279>. In the document titled "Next-Generation Non-Surgical Neurotechnology (N3)" issued by the Biological Technologies Office on March 23, 2018, a call is made for this research, highlighting the requirements of this project:

“DARPA requests innovative proposals to revolutionize the non-surgical bidirectional neural interface .

Current high-resolution neural interfaces do not represent a feasible solution for able-bodied soldiers, nor are they ideal for therapy and the restoration of function.

*Nevertheless, **given recent advances in biomedical engineering, neuroscience, and nanotechnology, there now exists the opportunity to develop a neural interface that is either entirely external to the body** or includes a non-surgically administered nanotransducer, which shall serve as a signal transduction intermediary between neurons and the external recording and stimulation device.*

*Furthermore, **it is imperative that the candidate technologies be safe and biocompatible.***

It is imperative that combatants be able to interact regularly and intuitively with artificial intelligence (AI), semi-autonomous, and autonomous systems in a manner that is currently not possible with conventional interfaces.

Technologies developed by N3 may surpass traditional voltage recordings associated with action potentials and include various types of signals, such as light, magnetic/electric fields, radio frequency, and neurotransmitter/ion concentrations .

The nanotransducer may include technologies such as, but not limited to, self-assembled/molecular/biomolecular/chemical nanoparticles or viral vectors.

These nanotransducers must be administered in a minimally invasive (non-surgical) manner, which may include ingestion, injection, or nasal administration and involve technology that includes self-assembly inside the body .”

In 2019, DARPA <https://www.darpa.mil/news/2019/nonsurgical-brain-machine-interfaces> awarded funding to six organizations to support the Next-Generation Nonsurgical Neurotechnology (N3) program, announced in March 2018. “ *These wearable interfaces could ultimately enable various national security applications, such as controlling active cyber defense systems and swarms of unmanned aerial vehicles, or collaborating with computer systems to perform multiple tasks simultaneously during complex missions.* ”

Such documents are suggestive of the advancements in research within the field of so-called “non-invasive” brain-computer communication technologies. As is known, **these unclassified documents serve to provide information released by the military for public consumption; however, military research in this field is certainly much more advanced and very likely already applied to humans, consistent with the acknowledged role of nanotechnology in the aforementioned documents regarding cognitive warfare.**

G. NANOTECHNOLOGY, AN UNREGULATED TECHNOLOGY WITH TOXIC POTENTIAL AND THE CAPACITY TO BE TRANSFORMED INTO A WEAPON OR AN INVISIBLE MEANS OF CONTROL, WAS PREMEDITATEDLY UTILIZED IN THE PRODUCTION OF COVID-19 VACCINES.

THE PRESENCE OF UNDECLARED ELEMENTS, MAGNETISM AT THE INJECTION SITE, AND THE DETECTION OF MAC ADDRESSES WITHIN THE BLUETOOTH NETWORK SERVE AS ARGUMENTS FOR THE ROLE OF COVID-19 VACCINATION IN THE SURREPTITIOUS IMPLEMENTATION OF THE INTERNET OF BODIES.

Although I have previously referred to nanotechnology throughout this document, as nanoparticles are included in the composition of COVID-19 vaccines, I deemed it important to address this subject independently.

considering that **nanotechnology is a key technology of biodigital convergence**. Furthermore, it must be taken into account that nanomaterials **are still not properly regulated**, given that nanoparticles possess different properties than the macro-level equivalents of the same materials; that nanomaterials and nanotechnology have been adopted by nearly all industries, including the pharmaceutical industry in the field of medicinal products and vaccines, despite serious warnings regarding the toxicity of nanomaterials and the fact that nanotechnology can be utilized as a weapon or a means of control, in the absence of stringent current regulations in this regard. Nanotechnology represents the understanding and control of matter at the nanoscale, at dimensions ranging approximately between 1 and 100 nanometers, where unique phenomena enable new applications. Nanomaterials possess SPECIAL PROPERTIES (mechanical, electronic, chemical, biological, optical) determined by the LARGE SURFACE AREA TO VOLUME RATIO, as well as by the QUANTUM EFFECT (which occurs at dimensions below 100 nm).

The definition of nanomaterials

In 2009, The European Parliament requested that The European Commission develop a definition of nanomaterials https://www.europarl.europa.eu/doceo/document/TA-6-2009-0328_EN.pdf?redirected=1, **taking into account several reasons, including**

- *the existence of heavily funded development plans for nanoscience by The European Commission, as stated in the communiqué of June 7, 2005, „Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. Second Implementation Report 2007-2009“ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0607:FIN:EN:PDF> which also included healthcare sectors: „In nanomedicine, devices based on ‘nanobiological’ sensors are being developed for the early diagnosis of common diseases, such as cardiovascular diseases and cancers.” Furthermore, it appears possible to selectively target the medicinal products toward diseased cells, thereby minimizing the adverse side effects of these medicinal products in other regions of the body; and to utilize genetically modified tissues for regenerative medicine .”*
- **The 2009 SCENIHR Opinion** (Scientific Committee on Emerging and Newly Identified Health Risks) regarding the definitions and risk assessment of nanomaterials—“Scientific Committee on Emerging and Newly Identified Health Risks—SCENIHR—Risk Assessment of Products of Nanotechnologies” https://ec.europa.eu/health/archive/ph_risk/committees/04_scenihhr/docs/scenihhr_o_023.pdf — ***Certain specific hazards have been identified and discussed within the context of risks to human health. These include the possibility of certain nanoparticles inducing protein fibrillation, the potential pathological effects caused by specific types of carbon nanotubes, the induction of genotoxicity, and dimensional effects pertaining to biodistribution. “For certain nanomaterials, toxic effects on organisms have been demonstrated within the environment, alongside the potential for transfer between environmental species, indicating a potential for bioaccumulation in species at the apex of that segment of the food chain .”***
- “whereas the use of nanomaterials and nanotechnologies (hereinafter referred to as ‘nanomaterials’) promises significant progress with multifaceted benefits across numerous applications for consumers, patients, and the environment, as **nanomaterials may exhibit distinct or novel properties compared to the same substance or material in its conventional form ,”**
- “B. whereas **advances in nanomaterials are expected to have a significant influence on political decisions in the fields of public health, employment, occupational safety and health, the information society, energy, transport, security, and space,**”
- “whereas, despite the introduction of a specific European strategy for nanotechnologies and the subsequent allocation of approximately EUR 3,500,000,000 for research in nanosciences under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (FP7), the European Union lags behind its main current competitors—the USA, Japan, and South Korea—which represent more than half of the investments and two-thirds of the patents filed worldwide,”

- **"whereas nanomaterials, on the other hand, may present significant new risks due to their minute size, such as increased reactivity and mobility, which may lead to increased toxicity in combination with unrestricted access to the human body and may involve quite different mechanisms of interference with the physiology of human and environmental species,"**
- ***„W. whereas the current debate regarding the regulation aspects of nanomaterials is largely limited to expert circles, even though nanomaterials have the potential to produce wide-ranging societal changes, which requires broad public consultation "***
- ***„Y. whereas the probable convergence of nanotechnology with biotechnology, biology, cognitive sciences, and information technology raises serious questions regarding ethics, safety, security, and the respect for fundamental rights, which must be analyzed by a new opinion of the European Group on Ethics in Science and New Technologies ,"***
- ***„Z. whereas the Code of Conduct is an essential instrument for safe , integrated, and responsible research in the field of nanomaterials; whereas the Code of Conduct must be adopted and respected by all manufacturers who intend to manufacture or place goods on the market,"***
- ***„AA. whereas the review of all relevant Community legislation should implement the ' no data, no market ' principle for nanomaterials;***
- ***„3. Disagrees, prior to an adequate evaluation of current Community legislation and in the absence of any specific provisions for nanomaterials therein, with the conclusions of The Commission according to which: a) current legislation covers, in principle , the relevant risks related to nanomaterials and b) that the protection of health, safety, and the environment must be strengthened primarily by improving the implementation of current legislation, when , due to the lack of adequate data and risk assessment methods related to nanomaterials, it is not effectively capable of addressing their risks;***
- ***4. It is considered that the concept of a 'safe, responsible, and integrated approach' to nanotechnologies, as supported by the European Union, is jeopardized by the lack of information regarding the use and safety of nanomaterials already on the market, particularly in sensitive applications involving direct consumer exposure;***
- ***5. Calls upon The Commission to review all relevant legislation within a two-year period to ensure safety for all applications of nanomaterials in products with a potential impact on health, the environment, or safety throughout their life cycle and to ensure that legislative provisions and implementation instruments reflect the specific characteristics of nanomaterials to which workers, consumers, and/or the environment may be exposed;***

The definition of nanomaterials was first established in 2011 at the request of the aforementioned THE EUROPEAN PARLIAMENT. Through the resolution of 24 April 2009 on regulatory aspects of nanomaterials, it requested, inter alia, the introduction into Union legislation of a comprehensive definition of nanomaterials based on scientific evidence.

The 2011 definition (Document 32011H0696) of **The European Commission** <https://eur-lex.europa.eu/eli/reco/2011/696/oj> was formulated as follows:

"Member States, Union agencies, and economic operators are invited to use the following definition of the term 'nanomaterial ' when adopting and implementing legislation, policies, and research programs concerning products of nanotechnologies.

„2. 'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where , for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

In specific cases and where warranted by concerns regarding the environment, health, safety or competitiveness, the 50% number size distribution threshold may be replaced by a threshold between 1 and 50%.

3. By way of derogation from point 2, fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm should be considered nanomaterials.”

The definition was amended in 2022 via Document 32022H0614(01) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOC_2022_229_R_0001

“‘Nanomaterial’ means a natural, incidental, or manufactured material consisting of solid particles present either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50% or more of these particles in the number-based size distribution fulfill at least one of the following conditions:

(a) one or more external dimensions of the particle are in the size range from 1 nm to 100 nm;

(b) the particle has an elongated shape, such as a rod, fiber, or tube, where two external dimensions are less than 1 nm and the other dimension is greater than 100 nm;

(c) the particle has a plate-like shape, where one external dimension is less than 1 nm and the other dimensions are greater than 100 nm.

In determining the size distribution based on the number of particles, it is not necessary to consider particles with at least two orthogonal external dimensions greater than 100 μm .”

It can be observed that in the second definition (the 2022 version), the following formulations from the 2011 definition were removed:

“In specific cases and where justified by concerns related to the environment, health, safety, or competitiveness, the 50% threshold of the number size distribution may be replaced by a threshold between 1% and 50%.

3. By way of derogation from point 2, fullerenes, graphene flakes, and single-wall carbon nanotubes with one or more external dimensions below 1 nm should be considered nanomaterials.

This fact is a grave matter because **products containing less than 50% nanoparticles or those containing particles with multiple dimensions below 1 nm** are no longer considered nanomaterials. Consequently, these products are not investigated as nanomaterials and are not labeled as nanomaterials, regardless of whether they are intended for consumption (medicinal products, vaccines, food products, cosmetics). Thus, **the definition of nanomaterials is misleading, being intended to conceal the presence of nanoparticles in various products**, despite the fact that nanoparticles, even in a concentration of less than 50%, exert toxic effects distinct from those of the same materials at larger dimensions. As demonstrated hereafter, nanoparticles, by virtue of their minute dimensions—well below the size of a cell—can compromise DNA integrity, accumulate in various organs including the brain, and induce a wide spectrum of pathologies (cancers, autoimmune diseases, dementia, infertility, etc.). Furthermore, nanoparticles incorporated into biosensors can be utilized for control and remote operation, as evidenced by numerous IEEE and ITU articles, as well as other publications and documents pertaining to the Internet of Nano-Bio-Things (IoBNT). **Such particles, invisible even to the optical microscope and difficult to identify through standard laboratory methods, can be introduced through various routes into the human body, including into the brain, and can be used as weapons or to influence thoughts and decisions**

Regulation and the Toxicity of nanomaterials

In a 2023 article entitled 'Current regulatory landscape of nanomaterials and nanomedicines : A global perspective' –'The current regulatory landscape of nanomaterials (NM) and nanomedicinal products: a global perspective'

<https://www.sciencedirect.com/science/article/abs/pii/S1773224722010292> the presence of the nanoproducts in almost all aspects of our lives is acknowledged, but concerns from both the public and the scientific community are also raised regarding the parameters of '**quality, safety, efficacy and toxicity**' of these products. Since NMs possess modified properties compared to their macro counterparts, they are deemed to “ **require additional special quality and safety regulations** ”, noting that “**most currently existing rules and regulations**

focus on materials of ordinary dimensions ”. “ *There is evidence of the accumulation of nanoparticles (NPs) in vital organs, such as the liver, when administered intravenously, and of the subsequent translocation of these particles to the cardiovascular, renal, and central nervous systems* ” .

„NPs play a significant role in the development of vaccines, as it has been reported that NPs can be immunogenic, serving as an adjuvant to enhance the immunogenicity of the weaker antigen”

„The majority of NMCs interact at a biomolecular level with cellular components and the genetic material , directly and indirectly influencing genomic function ” .

„Toxic effects can be determined by DNA damage induced by free radicals, lipid peroxidation , and protein denaturation .”

„In order to capitalize on the various benefits that nanotechnology offers to us, humans, in different spheres of our lives, regulatory bodies at a global level are making continuous efforts to develop strategies for the regulation of NMs and NMCs that fall under their jurisdiction. Despite these advancements, it is a known fact that current regulations are not relevant and are not sufficiently effective to address the aspects of nanotechnology-based products, particularly their toxic aspect ” .

Toxicity of nanomaterials

This article acknowledges that nanotechnology, while offering benefits, possesses a toxic potential that is by no means negligible, and highlights the fact that it remains unregulated, particularly regarding its toxicity.

This fact is of critical importance because in recent years, we have observed an increase in pathologies of all kinds, notwithstanding the evolution of science. It is highly probable that a significant portion of these pathologies is attributable to the large-scale and unregulated use of nanotechnology, despite warnings issued by scientists.

In support of these assertions, there are numerous articles and documents which I shall enumerate hereafter.

- Jing-Ai Li. **Polystyrene nanoplastics impair endometrial decidualization via cell cycle arrest and JNK-MAPK pathway-mediated oxidative stress in early pregnant mice**, Food and Chemical Toxicology, 10.1016/j.ftct.2025.115707, 205, (115707), (2025).
<https://analyticalsciencejournals.onlinelibrary.wiley.com/doi/abs/10.1002/jatt.4765>
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<https://www.sciencedirect.com/science/article/pii/S0048969724033242>
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<https://www.sciencedirect.com/science/article/pii/S0890623824002247>
- Josefa Domenech, **Insights into the potential carcinogenicity of micro- and nano-plastics**, Mutation Research - Reviews in Mutation Research, Volume 791, 2023, 108453, ISSN 1383-5742,
<https://doi.org/10.1016/j.mrrev.2023.108453> <https://www.sciencedirect.com/science/article/pii/S1383574223000017>
- Shukla RK. **Genotoxic Potential of Nanoparticles: Structural and Functional Modifications in DNA**. Front Genet. 2021 Sep 29;12:728250. doi: 10.3389/fgene.2021.728250. PMID: 34659351; PMCID: PMC8511513.
<https://pmc.ncbi.nlm.nih.gov/articles/PMC8511513/>
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<https://doi.org/10.1038/s41591-024-03453-1> <https://www.nature.com/articles/s41591-024-03453-1#citeas>
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<https://link.springer.com/article/10.1007/s10311-022-01479-w#citeas>
- F. Anees, D.A. **DNA corona on nanoparticles leads to an enhanced immunostimulatory effect with implications for autoimmune diseases**, Proc. Natl. Acad. Sci. U.S.A. 121 (11) e2319634121,
<https://doi.org/10.1073/pnas.2319634121> (2024). <https://www.pnas.org/doi/10.1073/pnas.2319634121>
- Trieu TM Tran, **Interactions between nanoparticle corona proteins and the immune system**, Current Opinion in Biotechnology, Volume 84, 2023, 103010, ISSN 0958-1669, <https://doi.org/10.1016/j.copbio.2023.103010> .
<https://www.sciencedirect.com/science/article/pii/S0958166923001209>

- Corbo, C., **The Impact of Nanoparticle Protein Corona on Cytotoxicity, Immunotoxicity and Targeted Drug Delivery**. 2015 Nanomedicine, 11(1), 81–100. <https://doi.org/10.2217/nnm.15.188>, <https://www.tandfonline.com/doi/full/10.2217/nnm.15.188>
- Klein, J.-P., **Impact of Nanoparticles on Male Fertility: What Do We Really Know? A Systematic Review**. Int. J. Mol. Sci. 2023, 24, 576. <https://doi.org/10.3390/ijms24010576>, <https://www.mdpi.com/1422-0067/24/1/576>
- Dwivedi PD, Tripathi A, Ansari KM, Shanker R, Das M. **Impact of nanoparticles on the immune system**. J Biomed Nanotechnol. 2011 Feb;7(1):193-4. doi: 10.1166/jbn.2011.1264. PMID: 21485866. <https://pubmed.ncbi.nlm.nih.gov/21485866/>
- Priyanka Ray, **The Impact of Nanoparticles on the Immune System: A Gray Zone of Nanomedicine**, Journal of Immunological Sciences, 10.29245/2578-3009/2021/1.1206, DOI: 10.29245/2578-3009/2021/1.1206, <https://www.ivysci.com/en/articles/1596410-The-Impact-of-Nanoparticles-on-the-Immune-System-A-Gray-Zone-of-Nano-medicine>
- Zheng Y. **The effects of micro- and nanoplastics on the central nervous system: A new threat to human health?** Toxicology. 2024 May;504:153799. doi: 10.1016/j.ttox.2024.153799. Epub 2024 Apr 11. PMID: 38608860. <https://pubmed.ncbi.nlm.nih.gov/38608860/>
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- Hang Sun, **Invisible Invaders: How Nanoplastics Hijack the Brain and Accelerate Alzheimer's Pathology**, Environment & Health, September 25, 2025 <https://pubs.acs.org/doi/10.1021/envhealth.5c00426>
- Ajeet Kaushik, **Nano/micro-plastic, an invisible threat getting into the brain**, Chemosphere, Volume 361, August 2024, 142380, <https://doi.org/10.1016/j.chemosphere.2024.142380>, <https://www.sciencedirect.com/science/article/pii/S0045653524012736>
- **Nanoplastics are everywhere: what is the health impact of these tiny particles?** Blog UK Health Security Agency, 12 March 2025, <https://ukhsa.blog.gov.uk/2025/03/12/nanoplastics-are-everywhere-what-is-the-health-impact-of-these-tiny-particles/>
- Human brain samples contain an entire spoon's worth of nanoplastics, study says, <https://edition.cnn.com/2025/02/03/health/plastics-inside-human-brain-wellness>

Warnings regarding the toxic potential of nanomaterials have existed permanently ; however, the pressure to continue their use and innovation in this field in order to fulfill the objectives of certain visionaries has been immense, and the investments have been enormous.

One of the first, most extensive, and comprehensive documents objectively and professionally analyzing the advantages and disadvantages of nanotechnology and nanomaterials is **the Report of the Royal Society and the Royal Academy of Engineering dated July 29, 2004 – “**

Nanoscience and nanotechnologies: opportunities and uncertainties-Nanoștiința și nanotehnologiile: oportunități și incertitudini- ” <https://royalsociety.org/news-resources/publications/2004/nanoscience-nanotechnologies/> .

The report illustrates that while nanotechnologies offer numerous benefits, public debate regarding their development is necessary. It emphasizes the immediate need to address uncertainties concerning the effects of nanoparticles on health and the environment—a specific subfield of nanotechnologies. It provides recommendations regarding the regulation of exposure control to nanoparticles. The report should have been of international interest, including for decision-makers within and outside of government, researchers working in the academic environment and industry, as well as civil society groups. In this report, it is mentioned

“As new forms of surveillance and detection develop, additional research and specialized legal analysis may be necessary to determine whether current regulatory frameworks and institutions provide adequate safeguards for individuals and societal groups.

In the military context as well, nanotechnologies possess potential for both defense and offense and, consequently, will raise a series of social and ethical issues.

There is speculation that a possible future convergence of nanotechnologies with biotechnology, information, and cognitive sciences could be utilized for the radical enhancement of humanity. Should these possibilities ever be realized, they would raise profound ethical questions.

A series of social and ethical issues potentially generated by developments in nanoscience and nanotechnologies should be further investigated; we recommend that the research councils and The Council for Research in Arts and Humanities fund a multidisciplinary research program to this end.

We also recommend that the ethical and social implications of advanced technologies be integrated into the formal training of all students and research personnel active in these fields."

"Military developments raise several evident social and ethical concerns, the majority of which are not limited to nanotechnologies.

The manipulation of biological and chemical agents through the use of nanotechnologies could result in entirely new threats that may be difficult to detect and counteract.

Certain observers have suggested that the refinement of existing and new weapon systems via the application of nanotechnologies could lead to a new form of arms race.

Furthermore, it remains questionable whether the arms control frameworks developed for existing categories of nuclear, chemical, and biological weapons will suffice to regulate future developments involving nanotechnologies."

"Pursuant to the current regulation in the United Kingdom concerning chemical substances (Notification of New Substances) and the proposal for its replacement currently under negotiation at the European level (REACH – Registration, Evaluation, and Authorization of Chemical Substances), the production of an existing substance in the form of nanoparticles does not trigger additional testing.

We recommend that chemical substances produced in the form of nanoparticles and nanotubes be treated as new chemical substances under these regulatory frameworks.

The annual production thresholds that trigger testing, as well as the testing methodologies pertaining to substances of these dimensions, should be reviewed as further toxicological evidence becomes available."

"Pursuant to European Union regulations on cosmetic products, ingredients (including those in the form of nanoparticles) may be utilized for most purposes without prior approval, provided they are not included on the list of prohibited or restricted chemical substances and that the manufacturers declare the final product to be safe.

In view of our concerns regarding the toxicity of any nanoparticles that penetrate the skin, we recommend that their use in products be contingent upon a favorable opinion from the European Commission's scientific advisory committee for safety.

A favorable opinion was issued for the nanoparticulate form of titanium dioxide (as chemical substances used as UV filters must undergo an evaluation by the advisory committee prior to use), yet the information provided remains insufficient to permit an evaluation of Zinc oxide.

In the interim, we recommend that manufacturers publish details regarding the methodologies employed in the safety assessment of their products containing nanoparticles, demonstrating how they accounted for the fact that the properties of the nanoparticles may differ from those of their bulk counterparts.

Based on our recommendation that chemical substances produced in nanoparticle form be treated as new chemical substances, we maintain that the ingredient lists for consumer products must identify the inclusion of manufactured nanoparticles.

Nanoparticles may be incorporated into a wider range of consumer products in the future; therefore, we recommend that the European Commission, with the support of the United Kingdom, review the current regulatory framework governing the introduction of nanoparticles into any consumer product."

"Future applications of nanotechnologies may impact other regulatory domains; for instance, developments in sensor technology may have implications for privacy legislation.

Therefore, it is imperative that regulatory bodies include future applications of nanotechnologies in their perspective analysis programs to ensure that any regulatory lacunae are identified at an appropriate stage.

Overall, provided there is adequate regulation and research in accordance with the aforementioned guidelines, we find no grounds for the moratorium that some have advocated regarding the laboratory or commercial production of manufactured nanomaterials.

“Ensuring the responsible development of new and emerging technologies

Nanoscience and nanotechnologies are evolving rapidly, and international competitive pressures will ensure the continuation of this process.

The Chief Scientific Adviser to the British Government should convene an independent panel in two years, and again in five years, to analyze the measures taken following our recommendations, to evaluate how nanoscience and nanotechnologies have developed in the interim, and to consider the ethical, social, health, environmental, safety, and regulation implications of these developments.

This study has once again emphasized the value of identifying, as early as possible, new fields of science and technology that have the potential to exert a significant impact on society.

Consequently, the Chief Scientific Advisor should establish a group comprising representatives from a wide range of stakeholders, to meet twice annually to examine new and emerging technologies, to identify as early as possible the areas where issues requiring Government attention may arise, and to provide consultancy on how these might be addressed.

The activities of this group must be made public, and all stakeholders should be encouraged to engage with emerging issues. We await the response to this report from the Government of the United Kingdom and from the other parties to whom these recommendations are addressed.

This study has generated significant interest among a wide range of stakeholders, both in the United Kingdom and internationally. To our knowledge, it is the first study of its kind, and we expect its results to contribute to the responsible development of nanoscience and nanotechnology at a global level.

“The development of appropriate and practical methods for measuring manufactured nanoparticles and nanotubes in the air and other media, including those properties most likely to reflect their toxicity, such as surface area and the potential to release free radicals.

Investigating methods for measuring worker exposure to manufactured nanoparticles and nanotubes within current laboratories and manufacturing processes.

The development of an international agreement regarding measurement standards.

The establishment of protocols for investigating the long-term impact of nanoparticles as products containing them reach the market, to determine whether, how, and to what extent they may come into contact with the natural environment.

Regarding research on environmental remediation and the development of an understanding of the transport and behavior of nanoparticles and nanotubes in air, water, and soil, including their interactions with other chemical substances

Epidemiological investigation of the interrelationships between exposure and health outcomes in industrial processes—such as welding and the manufacturing of carbon black and titanium dioxide—where exposure to nanoparticles has been documented for some time

“Development of internationally agreed-upon protocols and models for investigating exposure pathways and the toxicology of nanoparticles and nanotubes in humans and non-human organisms within indoor and outdoor environments, including the investigation of bioaccumulation.

In collaboration with pharmaceutical nanoresearchers and toxicologists specialized in air pollution, fundamental studies shall be conducted on the interaction mechanisms of the nanoparticles with cells and their components, specifically regarding effects on blood vessels, skin, heart, and the nervous system.

Development of protocols for in vitro and in vivo toxicological studies concerning any new nanoparticles and nanotubes slated for large-scale production which may impact human health or the natural environment.

Further investigations into the dermal absorption of various commercial nanoparticles utilized in topical preparations, with particular emphasis on modifications arising from pre-existing skin damage prior to application.

Determination of the explosion risk associated with a representative range of nanopowders (assuming that HSL has not already received funding for this research).

"From the discussions in the previous chapters, it is clear that nanoparticles often possess different or enhanced properties compared to those of the same chemical substances in a larger form.

It is not yet known to what extent the new or enhanced properties of nanomaterials will be associated with differences in their toxicity; however, evidence exists that some substances are more Toxic substances when in the form of nanoparticles, likely due in part to their larger surface.

Pursuant to current regulations (as of 2004), none of the criteria determining the necessity and scope of testing for chemical substances takes into account the particle size. Existing substances produced in the form of nanoparticles are not defined as new chemical substances, and quantity-based regulations fail to recognize that substances in the form of nanoparticles may exert a different impact on health and the environment per unit of mass.

These distinct properties of the nanoparticles are likewise not taken into account in the latest version of REACH, which is currently under negotiation (2004). Thus, current chemical regulation, and that negotiated within REACH, implicitly assumes that toxicity will not be affected by particle size.

Since the commencement of our study, the European Commission has recognized the need to review the mass thresholds that trigger testing (European Commission 2004b, and we understand that the USA Environmental Protection Agency is evaluating whether nanomaterials should best be regulated as new chemical substances. International cooperation in the development of regulation in this field would be beneficial."

Even NATO identifies risks of nanotechnology. In the article "**NATO's Chemical, Biological, Radiological and Nuclear (CBRN) Defence Policy-Politica de apărare chimică, biologică, radiologică și nucleară (CBRN) a NATO**" dated June 14, 2022

https://www.nato.int/cps/en/natohq/official_texts_197768.htm it is stated :

"21. Emerging and disruptive technologies (EDTs) and dual-use challenges are shaping NATO's security environment in increasingly diverse ways.

For currently known chemical, biological, and radiological materials, EDTs can potentially help proliferators identify new manufacturing processes and bypass internationally controlled materials and equipment. Dual-use concerns may arise regarding advanced biological research and related activities.

New technologies, including nanotechnology, synthetic biology, and additive manufacturing, also threaten to enable the development of even more effective or lethal CBRN (Chemical, biological, radiological, and nuclear materials, such as those that can overcome protective measures and resist detection, decontamination, or medical countermeasures. Furthermore, these may increase the availability of low-cost dispersal systems, as well as dual-use devices for biomanufacturing, which could further enable the use of biological or chemical weapons.

"19. The risk of natural or accidental biological threats may also contribute to the complexity of the security environment.

The COVID-19 pandemic has demonstrated the extraordinary capacity of biological threats, regardless of origin, to disrupt our societies and to overstretch our response capacity across various sectors.

Biological agents, including existing and modified pathogens, also present unique and enduring challenges for NATO operations, with deployed forces facing the prospect of the deliberate use of biological agents by hostile actors, accidental release, and contact with endemic and imported diseases. It is also expected that climate change and associated trends will accelerate the emergence of zoonotic diseases, including potential pandemic threats. **These risks intersect with the proliferation of weapons of mass destruction, as new, natural pathogens and toxins can be used, amplified, or weaponized by malicious actors.**"

In the report of **January 17, 2007, "Opinion on the ethical aspects of nanomedicine"**
<https://op.europa.eu/en/publication-detail/-/publication/4d7d9c99-2129-42e1-993e-c815b91ft256b>

of the European Group on Ethics in Science and New Technologies of the European Commission, under the chapter “Toxicological Aspects”, it is stated: „ Toxic substances effects of certain nanoparticles have already been demonstrated in cells, tissues, and experiments on small animals . Certain materials used at the nanoscale may increase the likelihood that the nanoparticles will penetrate the body and circulate within or be absorbed by specific organs. The nanoparticles may act differently in tissues such as the respiratory organs and may be catabolized differently by the body and recycled differently by the environment, in comparison to larger particles. The nanoparticles may deposit in the respiratory tract after inhalation . Currently, there is limited evidence from studies regarding skin penetration; however, only a few specific nanoparticles have been investigated in a limited number of test systems, and the extrapolation of these data to other materials is not possible. It is imperative to monitor potential adverse effects on health arising from the use of novel free nanoparticles for diagnostic, therapeutic, or cosmetic purposes. Such adverse effects may result from accumulation within tissues or organs; consequences for the cellular metabolism of the organism involved, including potential conformational changes of the proteins, such as prions ; as well as the potential facilitation of tumor formation . Evidence exists indicating that established and widely accepted toxicological methods are insufficient for the detection of possible harmful effects of nanoparticles. ”

In a report compiled under the auspices of the European Union Observatory for Nanomaterials (EUON), entitled „ Survey on State of the Art of CarbonBased Nanomaterial Detection and Quantification in Environmental and Biological Matrices-Study on the state of the art of technology for the detection and quantification of carbon-based nanomaterials in biological and environmental matrices” https://euon.echa.europa.eu/document/2435000/3268573/cbnms+final+reportti-v4_1_final.pdf/8beb3d5c-ft2b5-2ca7-ddc2-eac5ec4fc990?ti=1751266533849 a detailed assessment is conducted regarding the analytical methods utilized for the detection, characterization, and quantification of carbon-based nanomaterials (CBNM) in biological and environmental matrices.

Carbon-based nanomaterials (CBNM) constitute a diverse family of materials possessing unique electrical , thermal, and mechanical properties , rendering them highly valuable for industries such as medicine , electronics, energy storage, and environmental science. Their minute dimensions and structural and chemical variability—exemplified by carbon nanotubes, graphene, graphene oxide, and fullerenes, including doped or functionalized derivatives —alongside transformations and the significant chemical overlap between CBNM and carbon-rich backgrounds, pose substantial challenges for their detection, characterization, and quantification within complex biological and environmental contexts . Despite their increasing presence in consumer products and industrial applications, the behavior, fate, and potential risks of CBNMs when released into the environment or when interacting with biological systems remain poorly understood .” The conclusions of this study were that there is no optimal method for the precise measurement of the dimensions and concentration of nanomaterials:

„Key findings

1. Diversity and limitations of analytical methods:

Spectroscopic and microscopic techniques offer valuable information regarding structure and composition, but there are difficulties in differentiating CBNMs from natural carbon materials in complex environments. Chromatographic and mass spectrometric methods offer high sensitivity and quantification capabilities but require extensive sample preparation and costly instruments—the use of specialized sensors or hybrid approaches, for example, LC-ESI-MS, compared to relatively cheaper techniques, for example, DLS.

No single method provides a complete solution , and a multi-technical approach is often necessary to achieve reliable results.

2. Challenges in detection and characterization—carbon-based nanomaterials exhibit high tendencies toward agglomeration, which complicates the precise measurement of the size and concentration of constituent NMs .”

Despite these risks, nanotechnology has advanced extensively without the public being informed of the dangers, and without regulation or ethics keeping pace. Through the lack of information, the absence of proper regulation, and through fraud—as evidenced by the definition of nanomaterials adopted by the European Commission, which excludes products containing between 1-50% nanoparticles from being classified as nanomaterials—the world and living beings have become infested with nanotechnology, resulting in a significant increase in various pathologies. Furthermore, through techniques of disinformation, manipulation, and bad faith, nanotechnologies were successfully introduced into human bodies, being utilized for control down to the molecular level. Thus, as stated in the documents of the World Economic Forum, this technology changes not only the world around us but also ourselves—however, unfortunately, WITHOUT OUR CON-

Nanomedicine is not regulated

In a 2019 EU brochure, “*Anttiicipattion oft regulattitory needs ffor nanottiechnology-enabled healtth producttis The REFINE whittie paper*”, it is stated: “*Medical products based on nanotechnology are regulated in accordance with the existing regulatory frameworks regarding medicinal products and medical devices, but may require additional quality and safety assessments, triggered by the unique characteristics of the nanomaterial.*” Therefore, the identification of and a general agreement on the regulatory requirements relevant to the evaluation of a product constitute a prerequisite for a seamless approval process of a medicinal product or a medical device containing nanomaterials.

Currently, only limited guidance is available, as robust datasets permitting a definitive conclusion regarding the information requirements necessary for regulatory decisions are lacking.

Furthermore, the increasing complexity and immense variety of the next generation of nanomedicinal products and nanomedical devices may necessitate even more specific guidance .”

„Another aspect concerns the interaction of medical products with biological fluids , wherein the presence of proteins and biomolecules may exert a strong impact on the stability of dispersions and may provoke immunological reactions.

Furthermore, several challenges persist regarding the toxicological evaluation of nanomaterials.

Additionally, the contamination of particles with bacterial endotoxin is highly difficult to measure and can have a significant impact on the results of toxicological studies .

Therefore, existing methods should be reviewed to ensure their adequacy for the testing of nanomaterials and, where necessary, appropriate methods specifically adapted for nanomaterials must be developed . Currently, only a few standardized in vitro methods are specifically developed for medical products based on nanotechnology .”

This situation leads to high uncertainty for product developers, and the lack of such guidance to demonstrate compliance with regulatory requirements can hinder the development and commercialization of nanotechnology-based products.

At the same time , high-quality data regarding the safety, efficacy, and quality of innovative products, necessary for a better definition of regulatory requirements, will not be generated . This vicious circle can only be broken through an iterative process that leads to the identification of physicochemical properties with clinical relevance.”

It is clear from this document that nanomedicinal products are not regulated, as there are insufficient standardized in vitro methods for their evaluation; this raises safety concerns regarding these medicinal products, as well as issues concerning their quality assessment and efficacy. Consequently, the experimental products termed mRNA COVID-19 vaccines—in addition to containing new particles never before used in humans—contained nanolipid particles, despite the fact that nanomedicinal products are not regulated. Nevertheless, the authorities and professional organizations asserted that the COVID-19 vaccines are safe and effective, an act which incriminates them and for which they bear responsibility.

for the adverse reactions observed post-injection. Although these matters are known, no oversight authority has been notified to investigate these facts.

REFINE proposes a scientific regulation framework for the risk-benefit assessment of medicinal products and medical devices based on nanomedicinal products and biomaterials <http://refine-nanomed.eu/external-inter-laboratory-comparison/> .

The screenshot shows the REFINE website with a dark blue header. The header includes the REFINE logo and navigation links: ABOUT, PROJECT, ROUND ROBIN, PARTNERS, NEWS, CONTACT, and a Twitter icon. Below the header, there are two main content areas. The left area is titled 'Detecting DNA damage with the comet assay' and contains text about DNA damage and the comet assay. The right area is titled 'NLRP3 inflammasome activation by nanomedicinal products' and contains text about inflammasomes and their activation.

REFINE
REFINE NANOMED

ABOUT PROJECT ROUND ROBIN PARTNERS NEWS CONTACT

Detecting DNA damage with the comet assay

DNA damage can be manifold ranging from DNA strand breaks to chromosomal aberrations or whole chromosome loss. Resulting mutations or genetic instability may subsequently cause different diseases including cancer or may even lead to death. Assessing DNA breakage is thus of significant interest. One of the most common methods to detect DNA strand breaks is the alkaline single cell gel electrophoresis or comet assay. The comet assay has achieved the status of a standard test. In the cascade of assays used to assess the safety of novel pharmaceuticals, nanomaterials (NM) and other chemicals.

NLRP3 inflammasome activation by nanomedicinal products

Inflammasomes are large intracellular multiprotein complexes that can respond to exogenous and endogenous danger signals and control the activation of caspase-1. Several types of Inflammasomes are identified, each one having its unique activators and proteins that constitute the inflammasome. The NLRP3 inflammasome is the best characterized inflammasome. Sustained NLRP3 inflammasome activation may result in chronic inflammation and subsequent tissue damage. This sustained activation is implicated in a range of chronic diseases such as obesity and type 2 diabetes and Alzheimer's disease. The assay for inflammasome activation described in the *in-vitro* assay is based on concomitant measurement of cell viability and IL- β and IL-18 production.

From these recommendations, it follows that the following may be used as **safety assessment tests for nanoparticles: the comet assay** which evaluates the destructive effects of nanomaterials on the DNA and **the inflammasome activation test** which evaluates chronic inflammation and tissue damage caused by nanomaterials, followed by chronic conditions such as obesity, type 2 diabetes, and Alzheimer's disease.

These tests were not mentioned in the safety assessment of the lipid nanoparticles within the COVID-19 vaccines. Absent a safety assessment of these nanoparticles, it was unethical to assert that these products are safe and effective. .

Despite this evidence regarding the toxicity and carcinogenicity of the nanoparticles, ANMDMR maintains the contrary without proof. In ANMDMR response no. 103247 dated 08.02.2024 concerning nanomedicinal products and the nanoparticles in the COVID-19 vaccines, it is asserted that nanomedicinal products are approved via a centralized procedure, based on documentation pertaining to their quality, non-clinical safety, and efficacy. Regarding non-clinical carcinogenicity and mutagenicity studies, it is asserted that these have demonstrated no risks to humans , providing a link to <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/non-clinical-guidelines/non-clinical-toxicology> where I failed to find the aforementioned studies concerning nanoparticles .

Referitor la solicitările nr. 4 și 5: "Cunoașteți faptul că metodele toxicologice cunoscute și acceptate pe scară largă nu sunt suficiente pentru a detecta posibilele efecte nocive ale nanoparticulelor, acestea având proprietăți diferite față de particulele la scară mai mare https://ec.europa.eu/archives/bepa/european-group-ethics/docs/publications/opinion_21_nano_en.pdf Nanoparticulele pot determina alterarea ADN-ului uman?"

Autorizarea „nanomedicamentelor” prin procedură centralizată și prin proceduri europene descentralizate, de recunoaștere mutuală și de utilizare repetată se face în urma evaluării documentației de calitate, siguranță non-clinică și eficacitate depuse de către solicitanții APP cu stabilirea unui raport beneficiu-risc pozitiv.

Pentru nanomedicamente, studiile non-clinice de mutagenitate și carcinogenitate, efectuate după caz, conform ghidurilor non-clinice EMA, disponibile la adresa web: <https://www.ema.europa.eu/en/scientific-guidelines/non-clinical-guidelines/non-clinical-toxicology>, nu au evidențiat riscuri pentru om legate de componentele acestora obținute prin nanotehnologie.

The vision for nanotechnology and its applications

Plans for the application of nanotechnology in various sectors, particularly within military and medical fields, have long been envisioned. Funding in this sector has been substantial

A relevant document is an official USA publication from 1999 “Nanotechnology Research Directions: IWGN Workshop Report, Vision for Nanotechnology R&D in the Next Decade. SEPTEMBER 1999 ” https://www.nano.gov/sites/default/files/IWGN_rd.pdf issued by the „National Science and Technology Council, Committee on Technology, Interagency Working Group on Nanoscience, Engineering and Technology (IWGN)”. The role of the NSTC was **to establish clear national objectives for federal investments**. The coordinator was the engineer of Romanian origin, M.C. Roco, based in the USA, with significant involvement in the fields of nanotechnology and digital convergence. The participants were from various branches of research, defense, and government: White House, DOD, OSTP, OMB, DOC, DOE, DOT, DoTREAS, NASA, NIH, NSF. In this document it is stated:

“There are numerous other potential applications of nanoscience in biology:

- *Rapid and efficient genome sequencing, revolutionizing diagnosis and therapy*
- **Efficient and less expensive healthcare with the help of remote and in-vivo devices**
- **new formulas and routes of administration of medication , which enormously extend their therapeutic potential by targeting previously inaccessible sites within the body**
- *more durable artificial organs and tissues, without risk of rejection*
- **sensor systems that detect the onset of diseases in the body, which will shift the focus from treating diseases to their early detection and prevention ”**

In another official USA document—National Science Foundation (NSF)—from June 2002, “ **Converging Technologies for Improving Human Performance: NANOTECHNOLOGY, BIOTECHNOLOGY, INFORMATION TECHNOLOGY AND COGNITIVE SCIENCE,**” *sponsored by the* NSF (National Science Foundation) and edited by the same Mr. Mihail C. Roco as well as by William Sims Bainbridge (<https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/bioecon-%28%23%20023SUPP%29%20NSF-NBIC.pdf>), a vision is presented for augmenting and improving human capabilities through bio-digital convergence, achieved through the contributions of nanotechnology, biotechnology, information technology, and cognitive sciences. The themes addressed in this document are indicative of the objectives pursued by research in the USA

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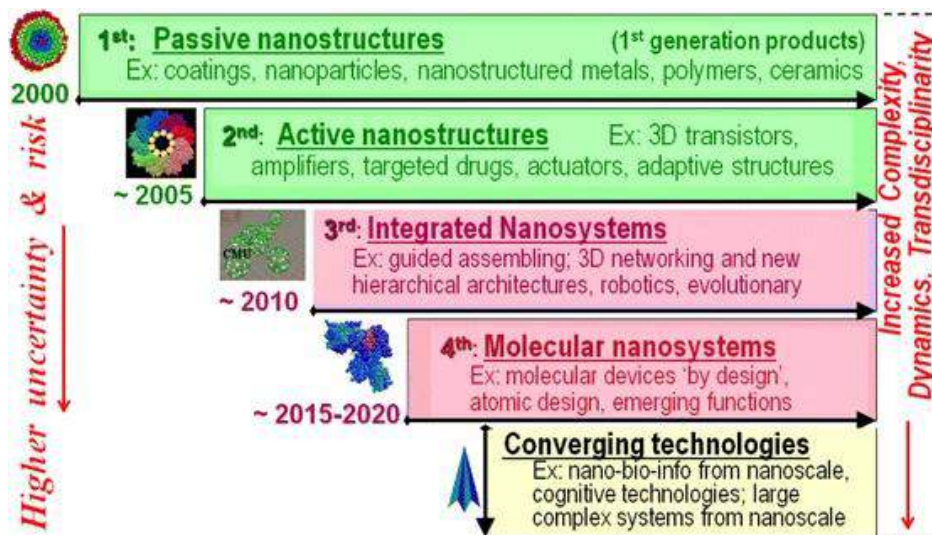
I have also selected several relevant passages from this vast and complex document (exceeding 450 pages), of which, I am convinced, the vast majority of Americans are entirely unaware. Unfortunately, the ethical aspects of so-called human enhancement are not debated in this document, merely mentioned.

“By giving due attention to ethical considerations and societal needs, converging technologies could yield an extraordinary improvement in human capabilities, societal outcomes, national productivity, and the quality of life. This is a broad, transversal, emerging, and timely opportunity, of interest to individuals, society, and humanity in the long term .”

“The term “convergent technologies” refers to the synergistic combination of the four major “NBIC” areas (nano-bio-info-cogno) of science and technology, each of which is currently progressing at a rapid pace: (a) nanoscience and nanotechnology; (b) biotechnology and biomedicine, including genetic engineering; (c) information technology, including advanced informatics and communications; (d) cognitive science, including cognitive neurosciences .”

In the year 2011, Mr. Mihail Roco published an article titled “ The long view oft nanotechnology developmentti: ttihe Nattional Nanottiechnology Inittiattiive atti 10 years ” <https://link.springer.com/article/10.1007/s11051-010-0192-z> in which he states: “A global scientific and social initiative was launched based on the vision of nanotechnology formulated in 1999, which inspired the National Nanotechnology Initiative (NNI) and other national and international research and development programs.” Establishing fundamental knowledge at the nanoscale was the primary objective of the nanotechnology research community during the first decade.

In 2009 , this new knowledge formed the basis **of a global market of approximately a quarter of a trillion dollars, of which approximately 91 billion dollars originated from American products incorporating nanoscale components. Nanotechnology is already evolving to become a general-purpose technology by 2020, encompassing four generations of products with increasing structural and dynamic complexity: (1) passive nanostructures, (2) active nanostructures, (3) nanosystems, and (4) molecular nanosystems. By 2020, the increasing integration of scientific and engineering knowledge at the nanoscale and of nanosystems promises mass applications of nanotechnology in industry, medicine, and informatics, as well as a better understanding and preservation of nature.** The rapid development of nanotechnology worldwide is a testament to the transformative power of identifying a concept or trend and establishing a vision at the synergetic confluence of various fields of scientific research



One must not overlook heavily funded American research initiatives such as the **Brain Initiative**

<https://braininitiative.nih.gov/about/overview>

"The '**Brain Research Through Advancing Innovative Neurotechnologies**' Initiative, or the **BRAIN Initiative**®, is a partnership between federal and non-federal partners, with the common objective of accelerating the development of innovative neurotechnologies. Through the application and dissemination of these scientific advancements, researchers will be able to produce a revolutionary new dynamic mapping of the brain which, for the first time, demonstrates how individual cells and complex neural circuits interact in both time and space.

With the National Institutes of Health (NIH) playing a central and leading role in achieving this ambitious objective, the NIH BRAIN Initiative is comprised of and managed by 10 institutes and centers whose current missions and research portfolios complement the objectives of the BRAIN Initiative."

The launch of the BRAIN (Brain Research through Advancing Innovative Neurotechnologies) Initiative® occurred in April 2013, at the initiative of President Obama.

<https://obamawhitehouse.archives.gov/node/300741>. The initiative, focused on revolutionizing the understanding of the human brain, accelerated "the development and application of new technologies that will allow researchers to produce dynamic images of the brain showing how individual brain cells and complex neural circuits interact at the speed of thought".

From the Brain 2025 report <https://braininitiative.nih.gov/vision/nih-brain-initiative-reports/brain-2025-scientific-vision> we can obtain updates regarding the developments recorded in the field of technologies that communicate with the brain. From my point of view, this evolution is neither reassuring nor encouraging, particularly as parallels can be drawn with the events of the COVID-19 pandemic, wherein infection with the alleged SARS-CoV-2 virus resulted in numerous neurological effects, and the COVID vaccines, for which such immense pressure for injection was exerted, contained mRNA and nanotechnology. I shall hereafter cite several relevant passages:

"1a-ii. Tools for experimental access to defined cell types

Furthermore, **non-genetic methods could be utilized to administer active agents to neurons of specific types, thereby expanding the scope of potential experiments. Viruses or liposomes containing pharmacological agents, proteins, or nanoparticles could be coated with antibodies that target them toward specific types of cells**. Ensuring reliable access to specific cell types within certain neuronal circuits or regions of the brain will accelerate all fields of modern neuroscience.

The next frontier would be gaining access to the human brain, which is more likely to involve the transient delivery of RNA or a chemical substance rather than permanent genetic modification, although viral vectors for human gene therapy are currently being explored within the brain. Several pharmaceutical companies are developing labeled antibodies **that cross the blood-brain barrier** (for example, **via transferrin receptors**), and these could be chemically or genetically modified to include effectors or sensors of neuronal activity.

*In conclusion, **it is possible to characterize all types of cells in the nervous system and to develop tools for the recording, labeling, and manipulation of these precisely defined neurons in vivo.** We envision an integrated and systematic census of neuronal and glial cell types, as well as new genetic and non-genetic tools to deliver genes, proteins, and chemical substances to the cells of interest. Priority should be given to methods that can be applied to many animal species and **even to humans** .” „*

2c-iv. Nanotechnology and unexpected innovations

*As devices transition from the micro to the nano scale, properties emerge that may offer new opportunities to interrogate neurons. **Silicon-based nano-devices** are one such example. Microwires, with a diameter of three microns, protruding from the surface of a conventional electrode, can achieve intracellular access to the cells plated over these wires; nanoposts, with a diameter of less than one micron, can create gigahm seals with intracellular access for sustained periods of time. These devices are highly promising; An important priority is transitioning their development from cell cultures to integrated neural systems, whether in sections or in vivo.*

In the medium or long term, new revolutionary technologies may emerge; the BRAIN Initiative for brain research, by promoting innovative neurotechnologies, aims to accelerate the development and application of groundbreaking technologies to produce a new and dynamic mapping of the brain.

*The Initiative® should encourage their exploration and development. **Nanodiamonds, for example, are particles whose photochemical properties—the emission of fluorescent light—could be adapted to exhibit sufficient sensitivity to applied electric fields, thereby serving as optical reporters of electrical activity.** ”*

Despite the toxicity of nanomaterials and the deficient ethics and regulations in this field, the initial plans for achieving the Internet of Things through nanotechnologies have proceeded unhindered . Thus, from the “ **Sttirattiegic Research and Innovatttion Agenda 2 021-27 European Technology Plattiftorm NettiWorld2020-Smartti Nettiworks in ttihe conttiextti oft NGI((Nextti Generatttiion Inttiernetti)** ” plan oft **2018** <https://www.nettworldurope.eu/wp-content/uploads/2018/11/nettworld2020-5gia-sria-version-2.0.pdf?x22825> we learn that we are far behind in our knowledge of communications; a totally controlled world is being built around and even within us—a world about which we were not informed, which we did not request, and which is toxic due to the use of invisible technologies such as nanotechnologies and electromagnetic radiation. Everything is executed under the pretext of the public good, aimed at resolving issues engineered by the very entities providing the solutions “2.6 Medium Access Control-MAC

*Wireless technology possesses immense potential to transform the manner in which we live, work, and recreate over the coming decades. **Future wireless networks will support communication speeds of 100 Gb/s among individuals, devices, and the 'Internet of Things,' ensuring high reliability and uniform coverage both indoors and outdoors.***

*The scarcity of the frequency spectrum required to sustain such systems shall be mitigated by **advancements in massive MIMO technologies, mmWave (and potentially nmWave), and small cells** . Caching and edge computing (e.g., in base stations and access points) will reduce latency and increase energy efficiency, enabling real-time data analysis, control, and automation.*

***Wireless technology will also enable** the construction of smart, energy-efficient homes and buildings, automated highways and airways, and internal networks for the monitoring, analysis, and treatment of medical conditions.*

Revolutionary architectures, algorithms, and hardware in terms of energy efficiency will allow wireless networks to be powered by tiny batteries , energy harvesting, or wireless energy transfer.

*Ultimately , **new communications systems based on biology and chemistry for bit encoding will enable a wide range of new applications at both micro and macro scales.** In short, key areas for the future include: the use of a wider spectrum (mmWave) and (Massive) MIMO;*

rethinking cellular system design, with enhanced hierarchies and IP support; software-defined wireless networks; and 'smarter' and more agile (cognitive) radios for low-power networks, including energy harvesting designs. In addition, AI/ML will become an essential technique for the improved exploitation of the frequency spectrum utilized."

(page 14) "3.3 Optical wireless communications

Despite significant improvements due to the concept of small cells and the allocation of a new radio frequency (RF) spectrum, the continuous exponential growth of mobile traffic [15] means that the RF portion of the electromagnetic spectrum will inevitably be insufficient to drive the Fourth Industrial Revolution, which is centered around data-driven economies and data-driven societies [16].

Therefore, **it is natural to consider the infrared and visible light spectrum**, both of which are part of the electromagnetic spectrum for future wireless terrestrial systems. In fact, wireless systems utilizing these portions of the electromagnetic spectrum could be classified as nmWave wireless communications systems in report with section 3.2. **Light-based wireless communications systems will not compete with RF communications**; on the contrary, these systems follow a trend observed in cellular communications, analyzing all generations developed over the last 30 years.

Light-based wireless communications simply add a new capability – the available spectrum is 2,600 times larger than the entire RF spectrum. A significant advantage is that commercially available devices can be utilized to exploit these unregulated and free transmission resources. Through the use of advanced devices, laboratory demonstrations have shown **8 Gbps from simple light-emitting diodes (LEDs) and 17.6 Gbps using laser diodes** [17]. Recently, a record data transfer speed of 500 Mbps was demonstrated using a single solar cell. The use of these types of 'data' detectors offers the compelling advantage of **simultaneously achieving energy harvesting and high-speed data communication** —a feature that will become increasingly important in machine-type mobile communications (MTC) [18].

Wireless networks and cellular networks based on visible light communications (VLC) are referred to as LiFi (Light Fidelity) [19]. **LiFi enables bidirectional network communications**, including multi-user access and handover. The blue arrow in Figure 2 indicates that major research efforts over the last 15 years have focused on improving the data transfer rates of intensity modulation (IM) / direct detection (DD) optical wireless communications systems. With the emergence of LiFi, research focus has begun to shift toward challenges related to network issues utilizing light." **Pg. 18**

"More recently, the utilization of graphene has been proposed for the development of new plasmonic devices for THz communications. graphene is a two-dimensional (2D) carbon-based material possessing excellent electrical conductivity, making it highly suitable for the propagation of extremely high-frequency electrical signals [29]. Furthermore, graphene supports the propagation of THz Surface Plasmon Polariton (SPP) waves at room temperature. SPP waves are surface-confined electromagnetic waves generated by the global oscillation of electrons. Utilizing the properties of graphene, nano-transceivers [30] and [31] and nano-antennas [32] and [33] have been proposed and are currently under development.

These devices are intrinsically small, operate efficiently at THz frequencies, and can support very high modulation bandwidths. Furthermore, graphene is 'only the first' of a new generation of 2D materials (such as MoS₂ or Hb-N), which can be stacked to create new types of devices and to leverage new physical properties." **Page 21**

"Satellite networks are an essential complementary component of the 5G ecosystem. In cases where user density or geography limits the economic viability of terrestrial infrastructure, the integration of a satellite network will provide the necessary continuity to ensure there are no gaps in 5G coverage. Furthermore, when users are in transit—whether by car, train, aircraft, bus, or vessel—the addition of satellite communications guarantees they will never be outside of network coverage. **Integrating satellite services into terrestrial deployments creates a comprehensive, redundant, and resilient network capable of delivering on the promise of 5G.**

Satellites are particularly suited for providing backhaul and other vertical applications. **Many of the**

commercial operators in geostationary orbit (“GSO”) and medium Earth orbit (“MEO”) offer mobile backhaul and broadcast distribution as core services . The demand for these services will continue to increase as terrestrial networks adopt 5G protocols, including industrial automation , smart infrastructure, safety and **public surveillance**, and **autonomous vehicles**. In addition, certain satellite networks will play a vital role in the development of machine-to-machine communications (“M2M”) and the **Internet of Things (“IoT”)**. MSL, for example, is currently developing applications to utilize its S-band satellite capacity and terrestrial infrastructure **for IoT connectivity across Europe** .” Page 60

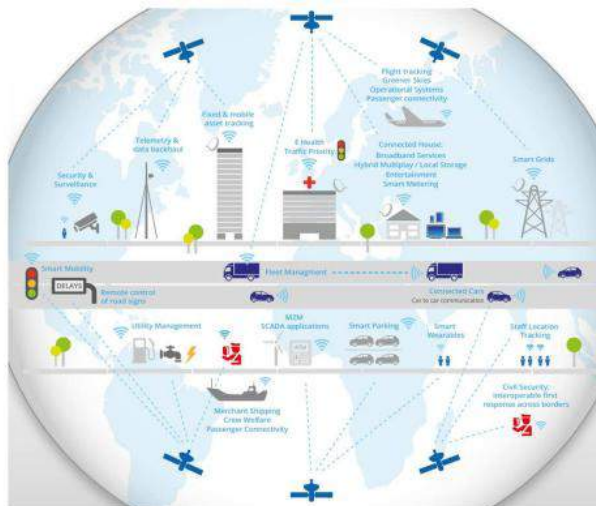


Figure 8 Overall positioning of satellite in current and future society

“9.1 Physical layer: communications and computing resources

9.1.1 **The nano-objects network**

The numerous “objects” that we are progressively interconnecting within the Internet are gradually expanding to micro-objects, i.e., those computing and service elements that operate on small/tiny and non-intrusive objects. **Nano-communications** emerge to extend the scope of smart control at the level of molecules and cells, with an **unprecedented impact on medicine and the manufacturing of materials** [164]. **Combating diseases through autonomous nano-machines** , the ultra-rapid degradation of Toxic substances, and self-healing and self-monitoring materials constitute some of the most visionary applications.”

“Recent research on nanomaterials and the architecture components of nanonetworks (nodes, controllers, gateways) opens new perspectives for the use of nano-scale objects. At the PHY level, graphene antennas allow nano-communication in the 0.1 – 10 THz spectral window, which promises unprecedented communication speeds, despite the nano-scale dimensions . **At the MAC level, essential protocols have been studied, primarily targeting Body Area Network (BAN)** [166] applications and the self-monitoring and adaptation of industrial materials [167].” Page 8 5 “9.1.2 The Bio-Nano-Things network

The Internet of Things (IoT) has evolved toward the Internet of nano-objects (IoNT), inspired by recently discovered nanomaterials, such as graphene and metamaterials , which enable the development of embedded computing device networks at the nanoscale, referred to as nano-objects.

IoNT will revolutionize various fields of application , such as the **military, medical, and industrial sectors** , owing to **miniscule, concealed, implantable, and non-invasive nano-objects that detect, actuate, process, and network cooperatively** . IoNT can serve as the foundation for numerous applications, such as smart grids, intelligent transport, environmental monitoring, **healthcare systems** and home automation. However, **the artificial nature of IoNT devices may be detrimental to certain environments, such as the interior of the human body or natural ecosystems, where the implementation of nano-objects and electro-magnetic communication could result in adverse health effects or environmental pollution**

The new paradigm of the Internet of Bio-Nano Things (IoBNT) is hereby introduced, predicated upon synthetic biology and nanotechnological tools that facilitate the engineering of embedded biological computing devices.

Drawing an analogy between a biological cell and a typical embedded IoT computing device, a cell can be effectively utilized as a substrate for the creation of a so-called Bio-Nano-Thing, by means of controlling, repurposing, and re-engineering biological cells' functionalities, including detection, actuation, processing, and communication. Since cells and their communication are based on biological molecules and biochemical reactions, rather than on electromagnetic waves, IoBNT is expected to shift the paradigm in the field of communications and networks. The execution of DNA-based instructions, biochemical data processing, chemical energy transformation, and the exchange of information through the transmission and reception of molecules, termed molecular communication (MC), underpin a multitude of applications made possible by IoBNT, such as

- i) intra-body detection and actuation, wherein BNT collects health status data and releases medicinal products within the body**
- ii) control of intra-corporeal connectivity, in which the BNTs diagnose and/or repair communication failures between internal organs**
- iii) environmental control and cleaning, in which the BNTs collaboratively check for the presence of toxic agents and transform them through bioremediation, for example, bacteria used for cleaning oil spills."**

"Finally, the realization of interfaces between the electrical domain of the internet and the biochemical domain of IoBNT networks will be the final frontier for creating a seamless interconnection between the current cyber world and the biological environment. A primary challenge is accurately reading the molecular characteristics in which information is encoded and translating them into the modulation of electromagnetic waves. This can be

achieved through new chemical and biological sensors, at the nanoscale, composed of materials characterized by electrical or electromagnetic properties that can be modified by the presence of specific molecules. Electronic tattoos or artificial cells encapsulating electromagnetic antennas may also be considered potential bio-cybernetic interfaces.

IoBNT can revolutionize biomedical technologies and improve human health and the quality of life. A possible application scenario is the use of IoBNT for continuous monitoring and the early detection of infections, earlier than conventional methods relying on laboratory cultures. To implement this system, a small implantable BNT may be designed, composed of electronic circuits and biosensors based on genetically modified cells, which monitor the quorum sensing (QS) communication of bacteria within the body. A gateway BNT shall transfer the infection-related information collected from the other BNTs and transmit it to a portable hub for utilization by medical personnel.

In order to establish minimally invasive, heterogeneous, and externally accessible electrical/molecular communication channels between implantable or wearable IoBNT devices, both electrical and biological, the microbiome-gut-brain axis (MGBA) may be exploited. Molecular information exchanged between bacteria in the gut is translated into electrical signals by the enteric nervous system and transported to the brain and other IoBNT devices inside the body connected to the nervous system. Therefore, MGBA may be considered an IoBNT communication network infrastructure." Page 87

At the congresses he attends, the renowned professor Ian Akyldiz, founder of the ITU (International Communication Union) journal, does not hesitate to assert

- **"First of all, we designed these REMORE; we designed and produced suitable bio-nanosensors, which we will inject into the body as shown here, and then we require a type of interface for the sensors."**- conference **"Inside the Body's Future: How Bio-NanoThings Will Change Disease Detection- Inside the body of the future: How bio-nanotechnology will change disease detection"** - NYUAD Institute, November 2024
<https://www.youtube.com/watch?v=tfpxG9VD9EY>

- *“Furthermore, regarding **bio-nano-objects** , these are intended **for healthcare applications** . I have also conducted extensive research over the past 15 years on bio-nano machines. These are designed **for injection into the body and the constant monitoring of health issues, and this integration proceeds very effectively with these anti-Covid vaccines** .*

*It is advancing in that direction: **these mRNA are nothing more than small-scale machines, at the nano scale. They are programmed and injected** . And as for internal components at the nano scale, these will be part of 7G and beyond; therefore, let us discuss the **terahertz band** .”-ARRC Seminar Series, March 16, 2023*

<https://www.youtube.com/watch?v=YAttQFkEg5-w>

Conclusions

- The COVID vaccines contain elements undeclared by the manufacturer.
- National and international authorities are ignoring reports from independent researchers regarding undeclared elements within the COVID vaccines and remain closed to conducting transparent investigations aimed at determining the actual and complete composition of the COVID vaccines.
- Despite severe adverse reactions and post-vaccination deaths, exhaustive investigations to confirm or refute a causal link to the vaccination were not conducted; furthermore, the protocols and investigations mandated by the INSP Guide for the Investigation of Severe and Grave AEFI Cases—which required the chemical analysis of the lots associated with the occurrence of these adverse reactions—were not followed
- The COVID vaccines have caused magnetic phenomena at the injection site; a large portion of those injected emit MAC addresses within the Bluetooth network. These findings, along with independent studies concerning undeclared elements in the COVID vaccines, indicate the premeditated use of these products for the implementation of the Internet of Bodies and biodigital convergence.
- The recommendations and pressures to inject the entire population with the COVID experimental products without precaution, disregarding the low risks for certain categories such as youth and children of developing severe forms of COVID-19, represented an inexplicable violation of ethics, a lack of professionalism of massive proportions and, in my opinion, a premeditated act of surreptitiously introducing nanotechnology for the Internet of Bodies into the organisms of our children and youth

- **The medical fraud and pressure, the censorship imposed by the authorities, but also by professional organizations such as the CMR, proven throughout this report require the investigation, trial, and conviction of the persons responsible for betraying the interests of the Romanian people-**
- **The post-vaccination adverse reactions that have been recorded so far and continue to appear impose the necessity of urgently discovering the true composition, the true purpose of these products but also finding solutions for remedying their negative effects.**
- **Cognitive warfare recognized by military structures must be brought to the people's knowledge so that they know how to defend themselves**
- **It is necessary to ascertain the reasons why the Romanian people were not informed by the authorities regarding the global bio-digital convergence plan and the technologies that the implementation of this plan entails. Truthful briefings and extensive debates with citizens are required, including ethical and regulation issues regarding bio-digital convergence and the technologies through which it is achieved—nanotechnology, 5G/6G technologies, artificial intelligence, and the use of new materials such as graphene.**

To this report, I attach the following documents:

- My CV
- The ANMDMR petitions and the responses to these petitions
- The petitions to the Ministry of Health and the responses provided by it
- Petitions addressed to the INSP and the responses provided therein
- The INSP Guide "Guide for Investigating Severe and Serious Cases of AEFI" <https://cnsrbt.ro/index.php/metodologii/rapi/661-ghid-investigare-cazuri-rapi/file>
- Report of the German researchers Arbeitsgruppe Impfstoffe Aufklärung ("Vaccination Awareness Working Group") <https://www.aerzte-foer-aufklaerung.de> https://www.aerzte-foer-aufklaerung.de/wp-content/uploads/2022/07/Sammlung_erster_Ergebnisse_der_AG_Impfstoffte_Auftkla%CC%88rung_20220706.pdf .

- The report of Prof. Dr. Werner Bergholz regarding electron microscopy with X-ray spectroscopy (EDX) of the COVID vaccines https://www.patthologie-konferenz.de/SEM_AZ_BP_JJ_shortt_online.pdf
- The British researchers' report, "Project CUNIT-2-112Y6580 Qualitative Evaluation of Inclusions In Moderna, AstraZeneca and Pfizer COVID-19 vaccines."
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- The article by the Argentine researchers, published on October 11, 2024, in the IJVTPr journal : "At Least 55 Undeclared Chemical Elements Found in COVID-19 Vaccines from AstraZeneca, CanSino, Moderna, Pfizer, Sinopharm and Sputnik V, with Precise ICP-MS"
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Respectfully,

Dr. Hagima Geanina Elena

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