Did Pfizer Fail to Perform industry Standard Animal Testing Prior to Initiation of mRNA Clinical Trials?

TrialSite Staff
May 28, 2021

TrialSite has learned of material information regarding mRNA vaccine safety revealed by a freedom of information act (FOIA) request filed by a group of Canadian physicians. These doctors have become concerned about COVID-19 mRNA vaccine safety. This new safety information involves the Pfizer mRNA-based vaccine known as BNT162b2 or "Comirnaty." The FOIA documents reveal animal study results demonstrating that the Pfizer mRNA-based vaccine does

produced data sets are incomplete, so the full meaning of these data cannot be determined at this time. TrialSite has also learned via regulatory documents that apparently (at least in their European Medicines Agency submission), Pfizer did not follow industry-standard quality management practices during preclinical toxicology studies during vaccines, as key studies did not meet good laboratory practice (GLP). The full panel of industry-standard reproductive toxicity and genotoxicity studies were apparently also not performed. But does this matter in light of the risk-benefit analysis associated with regulatory emergency use authorization (EUA)?

Recently, there has been speculation regarding potential safety signals associated with COVID-19 mRNA vaccines. Many different unusual, prolonged, or delayed reactions have been reported, and often these are more pronounced after the second shot. Women have reported changes in menstruation after taking mRNA vaccines. Problems with blood clotting (coagulation) – which are also common during COVID-19 disease – are also reported.

Among the most critical tests, which must be performed prior to testing any drug or vaccines in a human being, is whether it can cause mutations in the DNA (genotoxicity), or whether it could cause problems with cells or tissues of the reproductive tract – including ovaries (reproductive toxicity). In the case of the Pfizer COVID mRNA vaccine, these newly revealed documents raise additional questions about both the genotoxicity and reproductive toxicity risks of this product. Standard studies designed to assess these risks were not performed in compliance with accepted empirical research standards. Furthermore, in key studies designed to test whether the vaccine remains near the injection site or travels throughout the body, Pfizer did not even use the commercial vaccine (BNT162b2) but instead relied on a "surrogate" mRNA producing the luciferase protein.

These new disclosures seem to indicate that the U.S. and other governments are conducting a massive vaccination program with an incompletely characterized experimental vaccine. It is certainly understandable why the vaccine was

delivering the mRNA and producing spike protein in unintended organs and tissues (which may include ovaries). Unfortunately, there is no way to know if this is related to vaccine safety signals or reports of menstrual irregularities; the required studies were either not done or not done properly.

How mRNA Vaccines are Believed to Work

The current mRNA vaccines are theorized to act locally in draining lymphoid tissue. Formulated lipid nanoparticles that contain mRNA able to produce the spike protein are syringe injected into a muscle such as the deltoid (shoulder muscle). Once the injection occurs, the muscle cells near the injection site are impacted by the mRNA-based vaccine (e.g. the lipid nanoparticles), while much of the dose moves into the intracellular fluid surrounding the muscle cells and consequently drains to lymph nodes (see for example here).

According to this theory, a properly functioning mRNA-based vaccine is delivered into and drives production of the SARS-CoV-2 Spike protein in muscle and lymph node cells. The cells then produce the Spike protein, which is then moved to the surface of these cells where it becomes attached. The foreign virus Spike protein then triggers the immune system to recognize and attack any cell in the body that is either infected by SARS-CoV-2 or has Spike protein on its surface. The vaccine was designed so that the Spike protein is affixed via a transmembrane anchor region, so that it cannot circulate around the body via the bloodstream (see here). The same general scenario applies to all mRNA-based vaccines as well as recombinant adenoviral vectored vaccines (such as the J&J vaccine) designed to use gene-therapy technology to express Spike protein in cells and tissues. This general strategy is designed to reduce the risk that any residual vaccine dose that does somehow end up in the bloodstream (or organs and tissues) ends up not being a safety risk due to unintended biologic effects. Spike protein will remain affixed to cell surfaces, and therefore is not released into the blood where circulating Spike might cause problems by binding to its natural target, ACE-2

words, if very active mRNA delivery particles or recombinant adenoviral-vectored vaccines spread throughout the body, the resulting production of the vaccine antigen (Spike, in this case) will both stimulate immunity and also cause those same cells to be attacked by the immune system. If this actually happens, the resulting "vaccine reactogenicity" could resemble clinical symptoms seen with autoimmune syndromes.

EMA Pfizer/BioNTech Vaccine Distribution Studies

As standard practice, the European Medicines Agency (EMA) discloses their assessment of investigational new drug (IND) submissions. In the case of the Pfizer-BioNTech "Comirnaty" vaccine, the EMA assessment can be found on the Web here. This document includes a summary of EMAs evaluation of the non-clinical vaccine distribution studies reported to EMA by Pfizer-BioNTech. These studies were carried out using two methods: 1) use of mRNA producing the luciferase protein and 2) use of radioactive label to mark the mRNA (a more sensitive approach). These studies reveal that the majority of radioactivity initially remains near the injection site. However, within hours, a subset of the stabilized mRNA-containing particles become widely distributed throughout the bodies of test animals.

Upon inspection of the EMA summary document, *TrialSite* found evidence suggesting that the issue of biodistribution and pharmacokinetics of the "Comirnaty" BNT162b2 vaccine was not thoroughly examined in accordance with industry norms prior to the EMA review of the BNT162b2 IND/CTD. The reviewers share an explicit admission that "***No traditional pharmacokinetic or biodistribution studies have been performed with the vaccine candidate BNT162b2***." Rapporteur (Filip Josephson) and Co-Rapporteur (Jean-Michael Race) suggest, however, that Pfizer used "a qualified LC-MS/MS method to support quantitation of the two novel LNP excipients" and suggest that "the bioanalysis methods appear to be adequately characterized and validated for use in the GLP studies." However, the studies that were performed and submitted were non-GLP. Additionally, the EMA document states "Biodistribution: Several literature reports indicate that

TrialSite observed via the FOIA showing concentrations of LNP-formulated RNAs in the spleen, for example.

To obtain independent reviews of these EMA regulatory documents, *TrialSite* contacted both Dr. Robert W. Malone, MD, MS, and another expert that wished to remain anonymous, and provided them copies of the EMA analysis and the FOIA documents. Dr. Malone was the original inventor of the mRNA vaccine technology back in the late 1980s. He currently advises several companies in regulatory affairs and clinical development. One of TrialSite's other sources is a senior regulatory specialist who currently serves as the President of a prestigious European association. When asked to review and comment on the EMA assessment, Dr. Malone noted that normal pharmacokinetic and pharmaco-toxicology studies had not been performed before EUA authorization for the product. "I was particularly surprised that the dossier of regulatory documents indicates allowance for use in humans based on non-GLP PK and Tox studies relying on formulations which are significantly different from the final vaccine." After completing a review, *TrialSite's* other source noted the following:

> *"A quick review the Toxicology Section (2.3.3) of The European Medicines Agency (EMA) Assessment Report on Comirnaty (COVID-19 mRNA vaccine) issued on 19 February 2021, raises concerns about data applicability of preclinical study findings to clinical use:*

non-GLP studies, in mice and rats, and determined the biodistribution of a surrogate luciferase modRNA.

Thus, one might question the validity and applicability of non-GLP studies conducted using a variant of the subject mRNA vaccine.

In addition, no genotoxicity data were provided to EMA."

Based on the FOIA documents, the biodistribution results (which are not disclosed in the public EMA summary document) suggest that the delivery technology results in mRNA delivery and significant concentration of the delivery lipids in ovaries, spleen, and other tissues and organs.

Urgent Emergency?

The discovery and review of the biodistribution and pharmacokinetics data obtained by the FOIA request underscores the reservations disclosed in the public EMA assessment. Although not performed to industry GLP standards, these results seem to indicate that lipid/mRNA nanoparticles, which code for the Spike protein, circulate throughout the body and then collect in a variety of organs and tissues, including the spleen and ovaries. This means that the vaccine is not remaining localized near the injection site and draining lymph nodes, but rather is also circulating in both blood and lymph and is subsequently concentrating in important organs. If this results in Spike protein being produced in

What's the Risk?

According to official government accounts, minimal risk is associated with this vaccine when compared to the risks of COVID-19 infection. That's why the U.S. FDA approved the Emergency Use Authorization (EUA) based on a risk-benefit analysis. *TrialSite*, a vaccine proponent, only raises the issue to ensure full disclosure of any material safety implications to our readership, including clinicians, clinical research safety committees, and public health professionals.

While, according to the CDC's VAERS database, over 4,000 deaths have been entered in association with all the vaccines, the US government argues that none of these deaths are formally linked to the jabs. About 291 million people have been vaccinated to date, hence overall reported adverse event risk is low. While it is true that many people are completely unscathed, the discovery of these documents and associated information may alter the risk-benefit assessment underlying the EUA decision.

TrialSite is aware that one must be particularly cautious about publishing or communicating speculations that might raise skepticism about vaccine use. Should researchers handle findings differently when there is a chance they might frighten the public? Perhaps small, inconclusive, worrying studies should not be published because they could do more harm than good. Dr. Paul Offit, Director of the Vaccine Education Center at the Children's Hospital of Philadelphia, states: *"Knowing that you're going to scare people, I think you have to have far more data."*

One could argue that even an inconclusive paper can be important, as it can spur the larger, more definitive studies that are needed. It should be "*put out there for the scientific community, to look at it, see it, know about it, refine study design and go and look again*," says Gregory Poland, a renowned Mayo Clinic vaccinologist and the Editor-in-Chief of

Other Relevant New Data

A recent study led by researchers at Brigham and Women's Hospital and the Harvard Medical School measured longitudinal plasma samples collected from 13 recipients of the Moderna vaccine. The manuscript has been accepted for publication by "Clinical Infectious Diseases" and the pre-print is available here. Out of these individuals, 11 revealed detectable levels of SARS-CoV-2 protein as early as day one right after first vaccine injection. The authors considered that to be normal clearance.

Clearance of detectable SARS-CoV-2 protein correlated with production of IgG and IgA. Measured mean S1 peak levels were 68 pg/mL ±21 pg/mL, and mean spike peak level was 62 pg/mL ± 13 pg/mL. Assuming an average adult blood volume of approximately 5 liters, this corresponds to peak levels of approximately 0.3 micrograms of circulating free antigen for a vaccine designed to only express membrane-anchored antigen. For comparison purposes, most influenza vaccines administer a total of about 15 micrograms of HA antigen per influenza strain. Total levels of antigen expressed by the experimental SARS-CoV-2 mRNA vaccines currently administered to patients are not known.

Root Cause Analysis Suggested

A root cause assessment is suggested to better understand if any of this information adjusts or modifies the EUA risk-benefit analysis. *TrialSite* suggests that regulators and pharma manufacturers at least review and assess the risk that foreign mRNA-based spike protein delivery and expression in tissues and organs distal to the actual injection site may be contributing to the unusual reactogenicity and adverse event profile associated with these products. The uptake in

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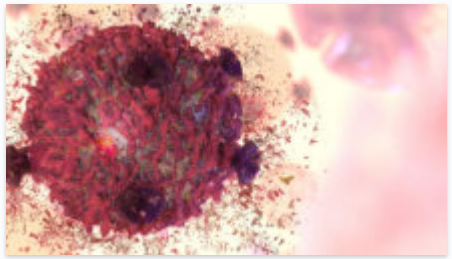

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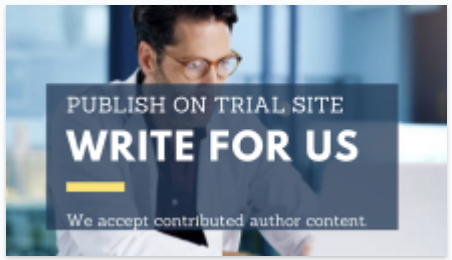

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Tagged: Adverse Reactions, COVID-19, Deaths, Lipid Nano proteins, mRNA, Vaccine

TrialSite Staff

Responses

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Laura
June 11, 2021

In the EMA document page 139 it said " Progress reports have to be submitted on 31 March 2021 and included in the annual renewal application." Do you know if any report has been submitted yet?

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I note that there is no indication that previously skipped testing was undertaken once authorization was received.

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bodzik
May 30, 2021

As a professional who used to evaluate such data for years at a prominent regulatory agency, and as one who has seen the other side of the fence – I am at all not surprised!!!
Data fakery and simple disregard for international guidelines has been a feature of big pharma for years and every regulatory agency knows that very well but they choose to 🙈
Why? cos they are owned SIMPLE 😎

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EAlfiero
May 30, 2021

I believe I am one of the people who's experienced the adverse affects of the vaccine causing my immune system to react in other areas of my body. I have had issues since the second dose in March which have included rash initially, diarrhea for several weeks, digestive issues, burning sensation in throat and head, mucus, and some breathing issues though minor. I initially reported mostly the stomach and breathing to my doctor. She indicated it was most likely an immune reaction to the vaccine and we have my stomach under control and I am having heart tests but had I known of these vaccine trial issues

Ms.Pitre
June 4, 2021

Hopefully your doctor reported your AEs to VAERs. That seems to be a problem in the U.S. and here in Canada. I read of doctors not being able to get the vaccine monitoring site to accept their results. One doctor went on record (putting his medical licence at risk, as docs are effectively muzzled in Ontario for going against the "narrative" of lockdowns, masks, distancing, and vaccines as the saviour) to state five significant reports of AEs he'd treated in the ER, were not accepted as he was missing batch number and time of vaccine given. He is an ER doc, not the doc who administered the vaccine. That is obstructiveness. Why? I think we are getting the big picture, but for those of us who still believe in truth and justice, it is an awfully bitter pill to swallow.

Log in to Reply

Frances_Lilian_Wellington
May 28, 2021

Thank you TSN staff for this important information. The public have the right to know the full story. This raises the questions as to why Pfizer did not get the job done right, and why these shortcomings were overlooked. Knowing Pfizer's financial position one has to ask, "What was Pfizer's credit rating at that time? Was Pfizer behind in their payments to get these tests performed?"... and who (precisely) let Pfizer *off the hook?*
Who turned a *blind eye* to this list of bullshittery?
I gotta say, I've had it with Pfizer. These company directors do not deserve a bailout from taxpayers.

Log in to Reply

Deleted User
May 29, 2021

I am concerned as well. Be aware that Pfizer's financial position was not enhanced by government funding for the development of the vaccine (Moderna's was). No doubt Pfizer's position was bettered by EUAs in multiple countries and subsequent purchase by the US government and others, but that did not amount to a bailout in the usual sense.
If testing of pharmacokinetics was not performed or results ignored then there should be an independent investigation to uncover the reasons and motives. Researchers should also consider whether any adverse effects that undesirable effects described (since we have been told that the immune response might diminish naturally over time. I would suppose this to be better news and perhaps a booster might correct any problems uncovered). Right now we have to hope that the mRNA vaccines do not trigger a long term auto immune response.

Log in to Reply

bodzik
May 30, 2021

hope? we don't know what those fuckccines contain, what happens to the material in storage, how uniform it is after mixing, before injections, what happens to all of its content at the injection site, how much disintegrates with what effect, what happens to much of transported mRNA which is delivered into a target location, what products are generated via transcription of

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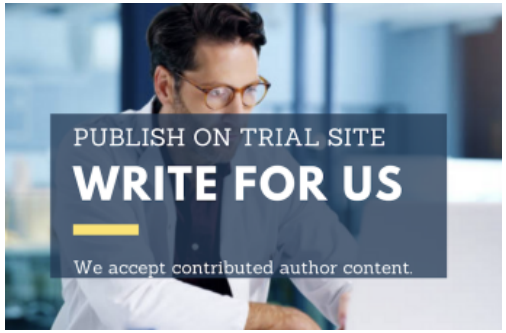

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