Medical Doctor Package Q&A

The Pfizer Adverse Event Reports Document Explained

This Q&A document was created to accompany the Medical Doctor Package (MDP) to help explain and better understand the complex world of clinical trials and processes as well as pharmaceutical data in relation to Pfizer and vaccines.

This includes defining terms, concepts, general practices and much more. The Pfizer data on adverse events, as well as all other Pfizer related information that has been released became available only because of a court order filed by a group of Doctors, Scientists, and Journalists who created a group called The Public Health and Medical Professionals for Transparency (**PHMPT)**, a non-profit for public health and medical professionals' group.

Disclaimer - This information is not legal or medical advice but rather answers to common questions regarding the Pfizer document.

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I: Clinical Trials, Emergency Authorization Use and the Health Act

1. **Question:** What is the normal and typical clinical trial and EAU process, in simplest terms?

Answer: Let's break down the details of Clinical Trials and EAU specifically

a.) Clinical Trials

A typical **clinical trial** tests new ways of diagnosing, treating or preventing health conditions in a four-phase process. Such clinical trials are strictly monitored and must follow the *Code of Federal Regulations* (CRFs) and strict Guidelines where all side effects are monitored and documented. If a serious adverse event (SAE) is identified, a report must be filed by the physician within a 24-hr period to the pharmaceutical company, who is then obliged to provide such reports to health authorities (Health Canada and/or Food & Drug Administration (FDA)). Each patient participating in a typical clinical trial must go through a consenting process that involves presentation of the written consent form (which meets specific requirements as per regulations for the content, e.g., clearly outlines the risks and benefits). Typical clinical trials also go through the central or local Institutional Ethics (IE) review and approval process prior to the start at each location where patients will be recruited.

In general, **clinical trials consist of 4 Phases**.

- **Phase 1**: physicians (investigators) spend several months looking at the effects of the medication on approx. 20 to 80 people who have no underlying health conditions. During this phase, physicians are checking if the product is safe.
- **Phase 2**: physicians continue to look at safety while collecting preliminary information on the effectiveness of the product and appropriate dosing. This phase can take 1-2 years.
- **Phase 3**: should ensure the drug is effective; monitoring of side effects in a larger population for a longer period takes place. Usually, this phase includes 800 to 1000s or more of patients and lasts 2-3 years.
- **Phase 4**: completed after the product has been approved and it may take years in length

b.) Emergency Authorization Use

The **Emergency Authorization Process** does not follow any strict monitoring requirements, dissimilar to clinical trials, despite an unapproved product is being used in the population. Under Section 564 of the Federal *Food, Drug, and Cosmetic Act*, when the government declares that an emergency use authorization is appropriate, the FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN (chemical, biological, radiological, and nuclear) threat agents when certain criteria are met, including that there are no adequate, approved, and available alternatives or treatments.

2. **Question:** Why was the Pfizer Adverse Event document (and 100,000+ more pages) only recently released on 01-March-2022, when the product had been given to and even mandated to the public, including children and pregnant women, for more than one year previously since 01-Dec-2020?

Answer: Four days after the Pfizer vaccine was **approved for Emergency Use** for ages 16+, the Public Health and Medical Professionals for Transparency (PHMPT), in the US, submitted a Freedom of Information Act (FOIA) request to the FDA to obtain data within Pfizer's COVID-19 vaccine biological product file and sued the FDA for not releasing the data sooner. As per the court decision, the release of Pfizer documents was ordered. At the beginning of each month, Pfizer is court-ordered to release a minimum of 50,000 pages of data that is available on the PHMPT website: https://phmpt.org.

3. **Question:** When were clinical trials done and where are the results?
Answer: Clinical trials for Covid-19 vaccines are still ongoing. Pfizer Phase 3 clinical trial is planned to end **in January 2023** (see source below) whereas Moderna clinical trials are planned to end in **December 2022**. All clinical trials initiated, ongoing or completed can be viewed on here: https://clinicaltrials.gov/. All companies conducting clinical trials are required to register each clinical trial on that site. Pfizer source: (https://www.clinicaltrials.gov/ct2/show/NCT04368728?term=NCT04368728&draw=2&rank=1)

4. **Question:** Who conducted these trials?
Answer: Clinical trials of Covid-19 vaccine are being conducted by pharmaceutical companies with the help of Contract Research Organizations which are usually contracted by pharmaceutical company to conduct clinical trials on their behalf with pharmaceutical company oversight during the trial.

5. **Question:** How was the Emergency Authorization Use related to Pfizer's released data documents?
Answer: The data released in documents pertaining to the Covid-19 vaccine titled **"**5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021", is the accumulation of adverse events collected post-authorization of this product but it is part of the documentation supporting or justifying the Emergency Authorization Use. This document provides an analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

6. **Question:** How does the FDA fit into the handling of the Pfizer documents?
Answer: Pfizer's data documents were submitted to the FDA by Pfizer as requested by the regulatory agency in the following request as seen in the 5.3.6 Post Authorization document referenced above:

> *"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA (the Biologics License Application) submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."*

7. **Question:** Is Pfizer's Adverse Events data document and subsequent released data, resulting from clinical trials or from the injections being broadly available to the public?
Answer: As per the Pfizer data contained in the Pfizer Adverse Event (AE) document: "Pfizer's safety database contains cases of AE's reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AE's reported from clinical studies regardless of causality assessment."

8. **Question:** What can you tell me about the *BC Public Health Act* in relation to reporting of Adverse Events. Where do we find information on it?
Answer: The *BC Public Health Act* (BC PHA) can be located at: Public Health Act (gov.bc.ca). The BC PHA outlines reporting requirements by all doctors who have patient(s) presenting possible or confirmed adverse events, including death, after getting a COVID-19 vaccine.

By virtue of section 12 of the BC PHA and section 5 of the Reporting Regulation, health care professionals and facility administrators must report a negative change in a person's health that occurs after an immunization, if it is serious, or if it is unusual or unexpected, or for which medical attention is sought, if it "cannot clearly be attributed to a cause other than the immunization", even if the causal association to the immunization cannot be established at the time of reporting.

Section 108 of the BC PHA confirms that a person who commits an offence under section 12 of the PHA and section 5 of the Reporting Regulation by failing to report a negative change in a person's health after immunization that cannot be clearly attributed to a cause other than the immunization, is liable on conviction to a fine not exceeding $25,000 or to imprisonment of up to 6 months, or both.

Each province in Canada has a unique Public Health Act.

II. Access to Document/Data Questions

9. **Question:** It appears that Pfizer does not want this official document of adverse effects to be exposed and provided to medical doctors. What has Pfizer and the FDA done to provide this information to doctors directly to help them have access to view and understand their data?

Answer: At this time, it appears nothing has been done by regulatory bodies or the pharmaceutical industry to disseminate the Pfizer reports or data. It does not seem to have been shared with health professionals or the public, although the documents are available on the www.PHMPT.org site, from those who went to court to demand access to this data.

10. **Question:** Why would Pfizer and the FDA not share this information with those who are involved like medical doctors and healthcare providers? Wouldn't they be proud of their data and numbers supporting the use of these vaccines unless the data shows to be less than helpful?

Answer: All data, especially safety data whether favorable or not, should be provided in a timely manner to health care providers and institutions who are involved in providing, consulting, or discussing this product. It is a requirement that all parties involved are not only reporting on known adverse events and side effects, but also to share the accumulation of this data to protect the safety of all patients involved.

III. Pfizer Outcomes and 1200+ Adverse Events of Special Interest (AEFI) List

11. **Question:** What is Appendix 1: List of Adverse Events of Special Interest (AESI) referencing?

Answer: As per Pfizer, document Appendix 1 pertains to:

> "*…the list of the company's AESIs for BNT162b2. The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline). The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general. The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.*"

12. **Question:** What exactly is 1p36 deletion syndrome, the first AESI in Appendix 1?

Answer: 1p36 deletion syndrome is caused by a deletion of genetic material from a specific region in the short (p) arm of chromosome 1. The size of the deletion varies among affected individuals. There are several symptoms of 1p36 deletion syndrome, one of them includes intellectual disability and effects on cognitive reasoning in those with this condition.

13. **Question:** Is it true that the Adverse Event outcomes in the Pfizer data were all proven to be undeniably the result of the vaccine, and not due to comorbidity issues?

Answer: Due to a lack of transparency and lack of access to a full set of documentation filed by Pfizer to a regulatory body, such as the FDA, we cannot fully assess this aspect as per available limited data. However, as per the Pfizer report:

> "*Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information."*

Also, as per Pfizer data, there were 9 subjects who died due to anaphylactic reaction out of 9 cases as per Pfizer report:

> "*There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia that likely contributed to their death.*"

One can only conclude that 5 patients who died due to anaphylactic reaction did not have underlying conditions.

14. **Question:** Why are there so many case outcomes shown as Unknown (9400). What does that mean?

Answer: One of the limiting factors of post-authorization collection of data is a voluntary process hence case outcomes are not necessarily followed up by any party. That would be a primary reason for numerous unknown outcomes in this report. As Pfizer document states:

"The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- *Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported, include length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, and awareness by health professionals and consumers of adverse drug event reporting, and litigation.*
- *Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.*
- *In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.*
- *An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.*
- *Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information."*

15. **Question:** What is in the Covid-19 injections? What are the dosages? Are all shots the same?
Answer: We do know some but not all ingredients of Covid-19 products at this time**.** Currently most medical professionals including doctors and pharmacists who are administering these products are not aware of the detailed content of these products. The pharmacy insert that comes with the vaccine is currently blank with a brief statement to refer to the manufacture website for more details.

As per each manufacturer's Monograph for each of the products, there are various doses depending on the producer. We are being told that all products are the same, however, not knowing the full content of ingredients is very difficult to assess whether all products are the same.

IV. Redacted Pfizer Data, Comirnaty and Pregnancy Data

16. **Question:** What was redacted from the first released Pfizer document and why?
Answer: For the unknown reason to the public, the total number of doses of the Pfizer product that were shipped worldwide was redacted in the document released in March 2022. The original document states as follows:

> "*It is estimated that approximately **(redacted)** doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021*."

However, in May 2022 that information became available and read:

> "*It is estimated that approximately **126,212,580** doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021."*

17. **Question:** Why were the Covid shots released if there were 42,000 adverse reactions and 1200 deaths within the first 3 months?

Answer: FDA and/or Health Canada are responsible to ensure that all requirements are met, including safety, prior to the approval. Data contained in the document pertaining to Covid-19 vaccine titled "5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021" is an accumulation of the adverse events collected post-authorization of this product but it is part of the documentation supporting or justifying the Emergency Authorization Use that was put into place.

18. **Question:** Why are there no consent forms filled out by those getting the Covid shots?
Answer: It appears that no standardized process has been followed for consenting patients' prior administration of product under Emergency Authorization Use. Please refer to the BC CDC website for the Informed Consent manual here: Informed Consent for Immunization (bccdc.ca)

19. Comirnaty
    a) **Question:** What does FDA's Comirnaty mean? Why was its approval involved in the other shots?

Answer: Comirnaty and BioNTech products are separate entities, and their Emergency Use approval is not a typical process. It can be best described as per the actual FDA website question and answer section found at: https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna

    b) **Question:** How is Comirnaty (COVID-19 Vaccine, mRNA) related to the Pfizer-BioNTech COVID-19 Vaccine authorized for emergency use?

Answer: The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-emergency use authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to

their respective instructions for use, can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses. The Vaccine Information Fact Sheet for Recipients and Caregivers provides additional information about both the approved and authorized vaccines.

c.) **Question:** Can Comirnaty and the Pfizer-BioNTech COVID-19 Vaccine be used interchangeably? The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older when prepared according to their respective instructions for use, can be used interchangeably.

"The formulation of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age differs from the formulations authorized for older individuals. The Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age should not be used interchangeably with Comirnaty. " Source: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-us-emergency-use-authorization

Additionally, as of this time, Comirnaty has not been manufactured yet.

20. In the May 2022 Pfizer data release, out of 270 pregnant Moms who received the shots how many babies were live births?

Answer: Out of 270 total pregnant women, 238 women outcomes were not recorded, hence their outcome is unknown however, out of the 32 remaining women, there was only 1 (ONE) live birth - the other 31 were various cases of spontaneous abortion and fetal death.

V. Vaccine Injury and Reporting

21. What does it take to get approval to submit a vaccine injury form?

Answer: There is no approval needed however physician after discussing the issue in question with patient will make mutual decision on reporting given side effect. Physicians are required to report vaccine side effect as per BC Health Act and will need to complete Report of AE following Immunisation with Covid –19 vaccine and email or fax it. Currently there is also a possibility for patients to directly report side effect on their own. Here is the link for patient reporting: link needed

22. Who fills out the vaccine injury forms?

Answer: Normally, GPs or family physicians are reporting however any medical professional can complete the AE report.

23. Do the vaccine injured get a copy of the vaccine injury form?

Answer: No, normally patients do not receive copy of the AE report submitted by their physician, however this record can be requested as any other health record.

24. Of the 42,000 people with adverse events, there were 19,000 who are recovered and / or recovering. What does recovered/recovering really mean? Why would we combine 2 very different outcomes as recovering is NOT the same as recovered.

Answer: Recovered means someone who fully recovered from the condition in question. Recovering is someone who did not recovered yet but she/he is in the process of recovery. Pfizer chose to combine these two groups in safety reporting.

25. Who is held liable for the 1223 deaths because of the Covid shots within the initial three (3) months of its release as reported in the Pfizer document?

Answer: As per contractual agreement it appears that all vaccine manufacturers are indemnified and not liable for any injury with some caveats. However, there are specific clauses that outline conditions of the indemnification. Each clause is specified in contracts signed between pharmaceutical company and the applicable country.