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Forensic Analysis of the 38 Subject Deaths in the 6-Month Interim Report of the Pfizer/BioNTech BNT162b2 mRNA Vaccine Clinical Trial

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Abstract

The analysis reported here is unique: it is the first study of the original data from the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial (C4591001) to be carried out by a group unaffiliated with the trial sponsor. Our study is a forensic analysis of the 38 trial subjects who died between July 27, 2020, the start of Phase 2/3 of the clinical trial, and March 13, 2021, the end date of the official 6-Month Interim Report. Phase 2/3 of the trial involved 44,060 subjects who were equally distributed into two groups and received dose 1 of either the BNT162b2 mRNA vaccine or a placebo consisting of a 0.9% normal saline solution. At week 20, when the BNT162b2 mRNA vaccine received Emergency Use Authorization from the US FDA, subjects in the placebo arm were given the option to receive the BNT162b2 vaccine and switch to the vaccinated group. Of the reported 20,794 unblinded placebo subjects, 19,685 received at least one dose of BNT162b2 vaccine. Surprisingly, a comparison of the number of subject deaths per week during the 33 weeks of this study found no significant difference between the number of deaths in the vaccinated versus placebo arms for the first 20 weeks of the trial — the placebo-controlled portion of the trial. After week 20, as subjects in the placebo group were unblinded, and after the majority of them received a BNT162b2 injection, deaths among those sticking with the placebo slowed and eventually plateaued. Deaths in the BNT162b2 vaccinated subjects continued at the same rate. Our analysis reveals inconsistencies between the subject data listed in the 6-Month Interim Report and in publications authored by Pfizer/BioNTech trial site administrators. Most importantly, we found evidence of an over 3.7-fold increase in number of deaths due to cardiac events in the BNT162b2 vaccinated individuals compared to those who received only the placebo. Delayed reporting of the subject deaths into the Case Report Form obscured the cardiac adverse event signal and allowed the Pfizer/BioNTech Emergency Use Authorization to proceed unchallenged.

Keywords: *BNT162b2 vaccine, cardiac events, placebo-controlled clinical trial, COVID-19, Pfizer/BioNTech*

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INTRODUCTION

Human cases of a "novel" Coronavirus respiratory disease called COVID-19 were reported in Wuhan, People's Republic of China in December 2019. However, there is now significant evidence suggesting that the virus was circulating in the United States as early as the fall of 2019 (Basavaraju *et al.*, 2021; Huang *et al.*, 2020; Wu *et al.*, 2020). On January 30, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a Public Health Emergency of International Concern and on March 11, 2020, declared it a world-wide "pandemic". In the United States, then Secretary of Health and Human Services, Alexander Azar, on March 10, 2020, issued a Public Health Emergency Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) for medical countermeasures against COVID-19. That legislation was passed by the United States Congress and signed into law 15 years earlier by President George W. Bush in December 2005. It provided a virtually impenetrable shield for vaccine manufacturers from liability for whatever "medical countermeasures" they might produce in response to any "public health emergency" declared by the Secretary of Health and Human Services (Office of the Secretary of Preparedness and Response, April 13, 2021; Martinez, 2021). Thus, the race already underway to develop a vaccine against COVID-19 (Fleming, 2021; Altman *et al.*, 2022) became part of the public narrative, and the usually tedious and time-consuming processes required in developing any ordinary vaccine — foundational animal laboratory studies, the establishment of a manufacturing and distribution plan reviewed by regulatory agencies — could be by-passed.

Multiple pharmaceutical corporations jumped onboard to accept the challenge to develop, manufacture, animal test, and conduct massive human trials, in what was referred to as Operation Warp Speed (Trump, November 13, 2020; US Government Accounting Office, February 11, 2021). On December 10, 2020, a mere 9 months after HHS Secretary Azar's Declaration and less than 6 months from the start of human trials, the US Food and Drug Administration (FDA) made the highly controversial decision to grant Pfizer/BioNTech Emergency Use Authorization for their experimental BNT162b2 mRNA vaccine. Unfortunately, the evidence that this experimental product was "safe and effective" and "prevented transmission and serious illness" was not available for public review until June 2022.

BioNTech is a German biotechnology company that develops and manufactures active immunotherapies for patient-specific treatment of cancer and rare or so-called "orphan" diseases (ones not singled out for treatment by other manufacturers) as well as techniques for targeted protein replacement. In early 2020, BioNTech partnered with Pfizer, Inc. to carry out a clinical trial to determine the efficacy and safety of BioNTech's novel BNT162b2 mRNA SARS2-CoV vaccine. Pfizer/BioNTech applied to the US FDA for a collaborative multi-national clinical trial entitled: "A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals" (*Https://Cdn.Pfizer.Com/Pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.Pdf*). The application was approved and subject enrollment for Phase 1 of a 3-Phase trial began in April 2020. The purpose of Phase 1 was to determine the optimal dosing level of the vaccine. Phase 2/3 trial, the "safety and efficacy" phase involving over 43,548 subjects, began on July 27, 2020.

On November 20, 2020 Pfizer/BioNTech submitted to the U.S. FDA an *Application for Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum*

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(*Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*). The Application described the clinical trial results to the data cut-off of November 14, 2020. The FDA made a copy of the EUA Application available on their website on December 11, 2020. This was the first opportunity for the public and medical professionals to evaluate the clinical trial data reportedly supporting the safety and efficacy of their BNT162b2 mRNA vaccine. Polack *et al.* (2020) published a journal article on December 10, 2020, entitled, "Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine." The authors of Polack *et al.* (2020) consisted of the site administrators of the 153 clinical trial sites in over 6 different countries. Fernando P. Polack, MD, was Principal Investigator and site administrator of the trial site in Argentina and Stephen J. Thomas, MD, the lead co-author, was the chief Principal Investigator of Clinical Trial C4591001. Thus, the authors of these publications were obliged to be and should have been intimately familiar with the trial findings. On September 15, 2021, the same group of site administrators published another journal article entitled: "Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine through 6 months" (Thomas *et al.*, 2021). With the knowledge and approval of the US FDA, *none* of the original clinical trial data was to be made available for study by the world's medical research community for 75 years.

Public Health and Medical Professionals for Transparency (PHMPT), a non-profit alliance of over 80 public health officers and medical researchers, filled a FOIA lawsuit in the US District Court, Fort Worth, Texas in September 2021 to obtain and disseminate the original clinical trial data upon which the FDA relied when it licensed Pfizer's (Comirnaty) COVID-19 mRNA vaccine. To quote Aaron Kheriaty, MD, one of the US physicians leading this court filing: "A group of us were concerned about the trial design, the shortened duration of the clinical trial, and the patchwork system that was in place for the post-marketing surveillance of adverse events." The PHMPT case was approved. Over the objections of the FDA, a Federal Court Judge ordered the expedited release of Pfizer's clinical trial data and documents at the rate of 55,000 per month. Data release began early in June 2022 to the Public Health and Medical Professionals for Transparency Documents site and was projected to take 8 months to complete. Unfortunately, it is taking much longer than estimated and documents continue to be downloaded to this site. The overwhelming size and complexity of these documents stimulated the formation of the DailyClout Pfizer/BioNTech Document analysis volunteers, a group of medical professionals, scientists, data analysts, statisticians, lawyers, and more, who have offered up their time and skills to analyze the Pfizer/BioNTech clinical trial documents. Team 3 is a subset of these volunteers dedicated to data investigation.

This report focuses on the 38 trial subjects listed in the Pfizer/BioNTech 6-month Interim Report (*6-Month Interim Report of Adverse Events C4591001*) who died between the start of the trial on July 27, 2020, and March 13, 2021, the data end date of the 6-Month Interim Report. Our analysis revealed important inconsistencies between the subject data listed in the 6-Month Interim Report and the materials on this data submitted by Pfizer/BioNTech to the FDA: Pfizer/BioNTech's FDA Application for Emergency Use Authorization (*Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*), Polack *et al.* (Polack 2020), and Thomas *et al.* (2021). Most alarming, we found evidence of an over 3.7-fold increase in number of deaths due to cardiac events in BNT162b2 vaccinated subjects that Pfizer/BioNTech did not report. Had this information been known at critical time points, it might have been sufficient to question the safety of the BNT162b2 mRNA vaccine, delay EUA approval of the vaccine, and alter recommendations made to the public during the worldwide roll-out.

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Methods

The original Pfizer/BioNTech documents are available at Public Health and Medical Professionals for Transparency (PHMPT) website (https://phmpt.org/pfizers-documents/). The following documents were downloaded from this site and were the main sources of data for our analysis.

- 6-Month Interim Report (16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age) (*6-Month Interim Report of Adverse Events C4591001*)

- Randomization Scheme and Actual Vaccine Received (16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age) (*Listing of Randomization Scheme and Actual Vaccine Received*)

- Listing of Discontinued Subjects (16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age) (*Listing of Discontinued Subjects*)

- 6-Month Summary of Clinical Safety (2.7.4 Summary of Clinical Safety (*Summary Clinical Safety 6-Month Report*)

- Narrative Reports on Subject Deaths from 6-Month Interim Report (125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive) (https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf)

Documents 16.2.7.4.1 Listing of Adverse Events (*6-Month Interim Report of Adverse Events C4591001*) and 16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received (*Listing of Randomization Scheme and Actual Vaccine Received*) were converted from PDF to Excel files and merged into a single Excel Pivot Table file. This allowed duplicate entries for a particular Subject ID to be removed and enabled searching for specific Preferred Terms for an Adverse Event. Thus, in a single searchable file listing all Subjects exhibiting an Adverse Event, we could determine the type of dose received (BNT162b2 mRNA vaccine or placebo), the date that each dose was administered, the date of onset of the Adverse Event, the Preferred Term for the Adverse Event, the Study Site physician's diagnosis of the Adverse Event, and the decision of Pfizer's safety physician whether the event was related to the trial.

Additional information came from the following.

- Pfizer/BioNTech Clinical Trial C4591001 – A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-blind, Dose-finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals (https://classic.clinicaltrials.gov/ct2/show/NCT04368728)

- Emergency Use Authorization (EUA) for an Unapproved Product (Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum)

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- Analysis Data Reviewer Guide – BLA Analysis for Participants ≥16 Years of Age, BioNTech SE and PFIZER INC, Study C4591001 (Analysis Data Reviewer Guide BLA Analysis for Participants ≥16 Years of Age BioNTech SE and PFIZER INC. Study C4591001 Https://Phmpt.Org/Wp-Content/Uploads/2022/03/125742_S1_M5_c4591001-A-Adrg.Pdf#page=85)

We also used the Abstractor search tool available on the DailyClout website (https://vaccines.shinyapps.io/abstractor/) to search for Case Report Forms, Narratives, and other documents specific to a particular Subject ID's, Preferred Terms, or clinical investigational data.

Expected number of deaths were estimated as follows. Pfizer/BioNTech 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*, n.d.) and the Randomization scheme (*Listing of Randomization Scheme and Actual Vaccine Received*, n.d.) were used to determine the number of subjects in each age group enrolled at each of the 153 trial sites: 15-24 years, 25-34 years, 35-44 years, 45-54 years, 55-64 years, 65-74 years, 75-84 years, and 85+ years. Age-adjusted mortality rates per 100,000 persons for 2020 were obtained from National Center for Health Statistics Data Brief 427 (Murphy *et al.*, 2021). The number of subjects in each category was multiplied by the mortality rate to estimate the number of deaths expected at each trial site within each age-group. These estimates were summed and multiplied by 33/52.2 to adjust for the 33-week trial period.

Results

On July 1, 2022, Pfizer/BioNTech released their report on the adverse events that occurred during the first 33-week period of the clinical trial, July 27 to March 13, 2021 entitled, 16.2.7.4.1 Listing of Adverse Events — All Subjects ≥16 Years of Age (*6-Month Interim Report of Adverse Events C4591001*). Section 16.2.7.7 of this document, found on pages 3640 – 3642, is a "Listing of Deaths — All Subjects ≥16 Years of Age". Thirty-eight (38) subjects are reported as having died during this initial period. This document provides their Subject ID, Sex and Age at Death, and the Date of Death as well as the Primary Cause of Death for all 38 deceased subjects and a Secondary Cause of Death for 8 individuals.

We determined the vaccination status (BNT1626b2 mRNA vaccine or placebo) of each deceased subject and the date that they received the first injection (dose 1) using document 16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received — All Subjects ≥16 Years of Age (*Listing of Randomization Scheme and Actual Vaccine Received*). To facilitate working with these two PDF files, they were converted to Excel files and merged into searchable pivot table format.

Overview of the initial 33 weeks of the trial

Phase 2/3 of the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial began on July 27, 2020. Starting on this date, subjects who were deemed eligible by the screening process were randomized equally into the vaccinated or control arms of the clinical trial and received dose 1 of either BNT162b2 mRNA vaccine or 0.9% normal saline placebo, respectively. Almost all randomized subjects had received dose 2 by November 14, 2020 (week 16). During this vaccination period to week 16 and the initial weeks of the follow-up period to week 20, subjects were followed for the occurrence of any adverse events (AE) and returned to the trial site for scheduled check-ups. This period of the trial is referred to by Pfizer/BioNTech as the "Blinded Placebo-Controlled Period" and includes events from July 27 to December 10, 2020. The term "blinded" refers to the fact that

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the subjects did not know whether the dose received was the BNT162b2 vaccine or the saline placebo. Because the subjects were randomly distributed to the trial arms, the only difference between the arms of the trial is whether the subject received the treatment or the placebo. Thus, the placebo represents the "control" situation. Placebo-controlled clinical trials allow one to compare the results in the arms of the trial and any differences in outcome can be directly attributed to the treatment, in this case the BNT162b2 vaccine.

In addition to July 27, 2020, four other important landmark dates are noteworthy.

- November 14, 2020 (end of week 16) was the data cutoff date for Pfizer/BioNTech's application to the US Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) for their BNT162b2 mRNA vaccine (Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum).

- The application was submitted to the FDA on November 20, 2020 and included all data submitted to Pfizer/BioNTech from the 153 clinical trial sites through November 14, 2020. Data was collected several times each week from the trial sites. Since November 14, 2020 was a Saturday, we can assume that the data reported in the November 20th application, one week later, was completely up to date.

- December 10, 2020 (end of week 20) Pfizer/BioNTech reported their results to the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). The briefing documents (Pfizer-BioNTech COVID-19 Vaccine FDA Briefing Document VRBPAC December 10, 2020 Meeting Https://Archive.Org/Details/Vrbpac-12.17.20-Meeting-Briefing-Document-Fda-0) and a video of this meeting can be found (https://www.youtube.com/watch?v=owveMJBTc2I).

- December 11, 2020 began what Pfizer/BioNTech refers to as the "Open-label" or "Unblinded" Period. Their EUA application was approved by the FDA on December 11, 2020. The FDA also approved their request to unblind all subjects in the clinical trial. Unblinding means that all subjects could be informed whether they had received the BNT162b2 mRNA vaccine or the placebo in doses 1 and 2. Unblinded placebo subjects were offered the BNT162b2 mRNA vaccine, doses 3 and 4. The term "open-label" was used to indicate that the label on the vial could be shown to the subject to assure them that they were now getting the vaccine.

The period from December 11, 2020 to January 24, 2021 is referred to as the "Open-Label Follow Up Period". All subjects of all vaccine status continued to be followed for 24 months regarding their general health and COVID-19 infection status, thus the term "follow up". Required follow-up appointments were scheduled and, if needed, subjects were seen for emergency medical care. Trial site investigators were notified of hospitalizations and deaths. Deaths were immediately reported to Pfizer/BioNTech via an electronic reporting system. No explanation is given for the choice of January 24, 2021 but this date became evident from our analysis of the data reported in Thomas *et al.* (2021).

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- January 25, 2021 begins what Pfizer refers to as the "Open-Label Observational Period", which ended at the March 13, 2021 data cutoff date of the 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*). Observation regarding the general health of all subjects was to be continued until 24 months after receiving dose 1.

Flow charts showing the numbers of subjects at different stages of the trial are shown in Polack *et al.* (2020) and Thomas *et al.* (2021). We found that the numbers reported were often not internally consistent within the published article and with numbers we determined based on the Listing of Discontinued Subjects (*Listing of Discontinued Subjects*). Nevertheless, it is important to keep in mind that the number of Phase 2/3 subjects that were randomized and received dose 1 were 22,030 BNT162b2 vaccinated and 22,030 placebo for a total of 44,060 subjects. This number of doses could not be administered to all participants on the same day nor could return visits, whether scheduled or not, happen on the same day. Instead, all visits occurred over the course of weeks during the periods outlined above. Moreover, of the 20,794 subjects who originally received the placebo and were still trial subjects on December 11, 2020, only 19,685 were vaccinated after unblinding. Administration of the BNT162b2 vaccine to these individuals stretched over weeks 20 to 33.

DEATHS DURING 6-MONTH SAFETY PERIOD

Figure 1 plots the number of subject deaths per week over the period covered in Pfizer/BioNTech's 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*) as reported in Section 16.2.7.7. This document was generated on April 1, 2021 and thus should have accurate listings for the Date of Death. Important trial dates discussed above are referred to in Figure 1.

Week 1 started on Monday July 27, 2020, the date that subjects began to receive dose 1. November 14, 2020, the EUA application data cutoff, was at the end of week 16. December 11, 2020, the date the Pfizer/BioNTech EUA was approved, was the Saturday of week 20. March 13, 2021, the data cutoff for the 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*), fell on the Saturday of week 33. This 33-week period was divided into 3 blocks, as described above and shown on Figure 1: the Blinded placebo-controlled Period (July 27 to December 10, 2020); the Open-label Follow-up Period (December 11, 2020 to January 24, 2021); and the Open-label Observation Period (January 25 to March 13, 2021). The importance of these time periods will become clear later in this report.

The number of subject deaths in the BNT162b2 vaccinated and placebo arms of the trial are plotted separately in Figure 1. It also presents a plot of the cumulative number of deaths in each arm of the trial, as determined at the end of each week. The first placebo subject death occurred in week 5 and the first BNT162b2 vaccinated subject death occurred in week 7. Only 3 deaths were recorded in the first 12 weeks of the trial contrasted with 35 in the remaining 21 weeks. Presumably the contrast is owed in part to the increasing number of people who got vaccinated as the study progressed, including eventually all but about 5% of the participants who initially received only a saline placebo but later opted to join those who got the BNT162b2 injection. Two things stand out from the results in Figure 1.

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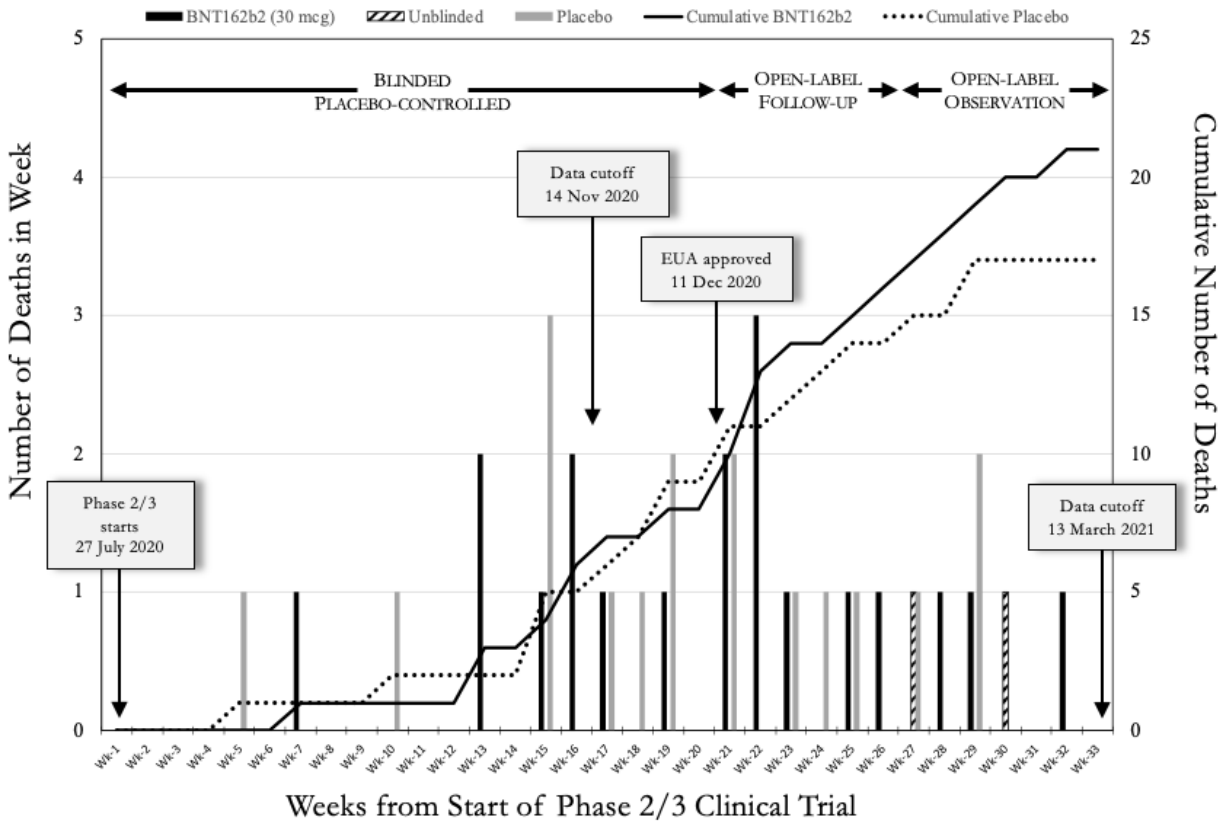

Figure 1: Weekly subject deaths during the initial 33 weeks of Pfizer/BioNTech Clinical Trial C4591001. The 38 subjects who died are accounted for in the order of their date of death during the 33 weeks starting Monday, July 27, 2020, and ending Saturday, March 13, 2021. Each bar between the horizontal lines on the graph represents a single death (no more than 3 ever occurred on the same day). Solid black bars represent BNT162b2 vaccinated subjects who died; solid grey bars represent placebo subjects; hatched bars are unblinded placebo subjects who accepted a BNT162b2 injection after December 11, 2020. The cumulative number of deaths for BNT162b2 recipients is shown in the solid line rising from left to right whereas the dotted line shows cumulative deaths of the placebo only recipients. The placebo recipients who opted to accept a BNT162b2 injection and died are counted as BNT162b2 recipients. The three trial periods from left to right are: Blinded placebo-controlled period, July 27 – December 10, 2020; Open-label Follow-up period, December 11, 2020 – January 24, 2021; Open-label Observation period, January 25 – March 13, 2021.

38 DEATHS IS A SURPRISINGLY LOW NUMBER

Given the large number of participants in the clinical trial, 44,060 subjects receiving dose 1, the 38 deaths reported in the 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*) seemed unexpectedly low, particularly in the midst of the COVID-19 pandemic. To test this, we estimated the number of deaths based on the age-adjusted US rates of death in 2020 (Murphy *et al.*, 2021) as described in the Methods section. Our estimate assumes that age-adjusted mortality is similar to US mortality rates at sites in the other countries participating in clinical trial C4591001. Of the 153 trial sites, 132 were in the US with about 80% of the trial subjects. With this caveat in mind, we estimated that 222 subjects deaths should have occurred during the trial period from July 27, 2020 to March 13, 2021. The actual number of trial deaths (38) is about 18% of the expected number. With the exception of the smaller sites, every site had fewer deaths than expected.

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One possible explanation for the low number of subject deaths lies in the large number of "Discontinued Subjects" in C4591001, 4.2% of the randomized subjects. Several reasons for discontinuing a subject are listed. The most disturbing of these was "Lost to Follow-up". Subjects who did not show up for scheduled visits or other required protocol tasks were considered Lost to Follow-up. According to protocol procedures, trial site staff made attempts to contact these individuals via phone and certified mail or via an emergency contact but eventually after multiple attempts the effort was abandoned. We found 395 unique subjects listed as "Lost to Follow-up" during the period of 6-Month Interim Report: 178 in the BNT162b2 vaccine and 217 in the placebo arms. Of these, 203 (99 in the BNT162b2 vaccine and 104 in the placebo arms) were lost prior to November 14, 2020, the data cutoff date for the Pfizer/BioNTech EUA application and 192 (79 in the BNT162b2 vaccine and 113 in the placebo arms) after that date up to March 13, 2021.

We compared number of subjects Lost to Follow-up at each trial site in relation to the number of total enrolled subjects. The average number of subjects per site was about 300 with 4 sites between 1,200 – 4,500 enrolled subjects. Ninety-six (96) of the 153 trial sites reported none to 1 subject lost to follow-up. Another 34 reported 2-5 subjects lost to follow-up. Four sites reported over 20 subjects lost to follow-up, 4-5% of the trial site subjects: 27 of 611 subjects, 32 of 611 subjects, 24 of 572 subjects, and 22 of 412 subjects. These are not insignificant numbers and could easily account for the low number of deaths reported in this safety period of the trial. Given the importance of knowing the status of each trial subject, there should have been greater effort to locate these individuals. Additionally, Pfizer/BioNTech was responsible for oversight of the trial sites. Sites with excessive numbers of lost to follow-up should have been evaluated for performance.

RATE OF ALL-CAUSE DEATHS IS NOT DECREASED BY BNT162B2 VACCINATION

Figure 1 clearly shows that the plots of the cumulative numbers of death in both the BNT162b2 vaccinated and placebo arms of the trial overlie each other for about the first 20 weeks (July 27, 2020 to December 11, 2020). This is an entirely unexpected finding. During the fall of 2020 the spread of COVID-19 was at its peak. To state that the BNT162b2 vaccine saved lives, Pfizer/BioNTech should have shown a reduction in all-cause mortality due to a decrease in COVID-19 mortality in the vaccinated arm of the trial. Figure 1 does not support any such claim for weeks 1 – 20 and, in fact, speaks against this conclusion in the weeks following week 20 in which the placebo cumulative plot is distinctly below that of the BNT162b2 vaccinated. Week 20 is the point at which unblinding began, that is, subjects were informed whether they had received the vaccine or the placebo. Starting about December 11, 2020 and continuing into February, 2021, 19,685 of the 20,794 placebo participants who entered this phase of the trial opted to be BNT162b2 vaccinated (Thomas *et al.* 2021). It is likely that the slowed rate of increase in the number of placebo deaths and the plateau at week 30 resulted from the gradual reduction in the size of the placebo group. If the BNT162b2 vaccine were 95% effective, as claimed, the plots would have been reversed.

CAUSES OF SUBJECT DEATHS

Table 1 details the information on the 38 deceased subjects shown in Figure 1. The data sources for Table 1 were the same as for Figure 1, the *6-Month Interim Report of Adverse Events C4591001* and the *Listing of Randomization Scheme and Actual Vaccine Received*. BNT162b2 vaccinated and placebo subjects are listed separately. Within each grouping, subjects are listed according to their date of death. The

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two unblinded placebo subjects who died after receiving at least one dose of BNT162b2 vaccine are listed with the BNT162b2 vaccinated group and are highlighted in light gray. Table 1 includes the Subject ID assigned at the time of randomization for each deceased trial participant as well as their sex, age at death, and date of death. The data in Table 1 can be confirmed and original copies of the Case Report Form and the Narrative on Subject Deaths can be obtained using the DailyClout Abstractor and searching with the Subject ID.

Table 1 also lists the primary cause of death, and secondary cause of death for some, as given in the *6-Month Interim Report of Adverse Events C4591001*. Investigators at each trial site were responsible for reporting all subject medical information to Pfizer/BioNTech for inclusion in the subject's Case Report Form. The Narrative Reports on Subject Deaths summarizes the timeline leading up to the Subject's death and the circumstances surrounding the death. Taken together, the Case Report Form and the Narrative provide additional insights into the causes of death not available from the listings in the *6-Month Interim Report of Adverse Events C4591001* alone.

Deaths were to be reported immediately. Pfizer/BioNTech used a list of Preferred Terms that is based on the MedDRA coding dictionary, a standardized resource listing medical terminology for safety monitoring studies. The list includes 1,519 different Preferred Terms but, surprisingly, Death is not one of them. Often the Preferred Terms used were vague and duplicative, which contributed to confusion regarding diagnoses. As we will show below, the lack of specificity in the terminology allowed the investigators to avoid requiring an autopsy to clarify the true cause of death, particularly in cases where a cardiac event was a possibility. We defined cardiac events as those limited to the heart muscle and vasculature. These included Preferred Terms such as myocardial infarction, congestive heart failure, cardiac arrest, sudden cardiac death. Myocardial infarction is a specific hypoxic irreversible injury to cardiac muscle tissue. This diagnosis is best made by autopsy but other indicators of heart damage are available, such as presence of troponin in blood. Troponin levels were occasionally reported.

In many of these 38 cases, the documentation provided in the Case Report Form and the Narrative Reports did not adequately support the cause of death diagnosis or did not allow one to rule out the possibility of a cardiac event with an autopsy. Frequent communications between Pfizer/BioNTech physicians and trial site medical staff are obvious in the Case Report Form, which were often quite lengthy some well over 400 to 900 pages. The Narrative Reports were shorter but offered details that enabled us to report in Table 1 which subjects died suddenly (SAD) or were found dead (FD) at home or medical facility, and whether an autopsy was done to confirm the cause of death. With the possible exception of accidental deaths, it is our experience that unexpected deaths are most often the results of cardiac events or stroke. Unfortunately, in most cases an autopsy was either not done or the results were unavailable for review.

Table 1. Diagnosed Cause of death of Pfizer/BioNTech Clinical Trial Subjects*

	Subject ID	Sex	Age at Death	Date of Death	Days Post Dose 1	Primary Cause of Death (Secondary Cause of Death)	SAD/FD (Autopsy)
BNT162b2 mRNA vaccinated subjects (21 Subjects)							
1#	11621327	M	60	13Sept2020	4	*Arteriosclerosis[1]	FD (UNK)

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2	11141050	F	64	19Oct2020	63	*Sudden cardiac death[1]	FD (Yes)
3#	10071101	F	56	21Oct2020	84	*Cardiac arrest	FD (UNK)
4	11201050	F	58	07Nov2020	96	*Cardiac arrest[1]	FD (Yes-NA)
5	11521497	M	72	11Nov2020	36	Shigella sepsis	
6	10891073	F	63	12Nov2020	99	Chronic obstructive pulmonary disease	
7	10391010	M	85	18Nov2020	90	*Arteriosclerosis (Hypertensive heart disease)	SAD (None)
8	11271112	M	53	04Dec2020	107	*Cardio-respiratory arrest[3]	SAD (Yes-NA)
9	11361102	M	76	19Dec2020	52	*Cardiac arrest[2]	SAD (UNK)
10	10211127	M	54	19Dec2020	111	*Cardiac failure - congestive	
11	10971023	F	87	21Dec2020	120	Septic shock[4]	
12	11561160	F	62	24Dec2020	95	Road traffic accident[1]	
13	12521010	M	81	26Dec2020	132	COVID-19 pneumonia	
14	11401117	M	59	29Dec2020	137	*Cardiac arrest[2]	SAD (None)
15	10841266	M	77	12Jan2021	144	*Sepsis[3] (Emphysematous cholecystitis)	
16	11201266	M	51	19Jan2021	132	Lung cancer metastatic	
17	11351033	M	67	29Jan2021	178 (5)	Suicide[2]	
18	11291166	F	79	03Feb2021	149	*Myocardial infarction[1,2]	FD (None)
19	10361140	M	64	10Feb2021	112	Road traffic accident[1]	
20	11311204	M	84	15Feb2021	147 (26)	Cardio-pulmonary arrest (Cerebrovascular accident)	FD (None)
21	10881139	M	83	06Mar2021	186	Metastases to lung (Pancreatic carcinoma metastatic)	
	Subject ID	Sex	Age at Death	Date of Death	Days Post Dose 1	Primary Cause of Death (Secondary Cause of Death)	SAD/FD (Autopsy)
Placebo subjects (17 Subjects)							
1#	11521085	F	42	26Aug2020	8	Death (Undetermined causes)[1]	SAD (Yes-NA)
2#	12313972	F	61	28Sept2020	35	Haemorrhagic stroke	
3	11561124	M	53	02Nov2020	54	Overdose	
4#	10661350	M	58	03Nov2020	16	*Myocardial infarction	FD (None)
5#	10811194	F	51	04Nov2020	56	*Myocardial infarction[1,2]	FD (None)

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6	11681083	M	65	18Nov2020	86	Aortic rupture	SAD (Yes)
7	11281009	M	66	28Nov2020	121	Pneumonia[1]	
8	10881126	M	66	01Dec2020	93	*Cardiac arrest[2]	FD (None)
9	12314987	M	47	06Dec2020	101	Cardio-respiratory arrest[1,2]	
10	10191146	M	67	17Dec2020	108	Metastases to liver (Biliary cancer metastatic)	
11	10941112	F	57	18Dec2020	102	Acute respiratory failure (COVID-19 pneumonia)	
12	10891088	F	82	30Dec2020	146	Dementia	
13	12291083	F	56	05Jan2021	97	Diabetes mellitus[4] (COVID-19 pneumonia)	
14	10841470	M	65	11Jan2021	104	Multi-organ dysfunction[4] syndrome (COVID-19)	
15	12315324	F	59	31Jan2021	156	Multi-organ dysfunction syndrome (COVID-19)	
16	12071055	M	65	09Feb2021	97	Bacterial pneumonia	
17	10271191	F	68	13Feb2021	156	Respiratory failure (COVID-19)	

*The 38 subjects who died during the period July 27, 2020 to March 13, 2021 are listed separately according to their Clinical Trial arm, BNT162b2 vaccinated or placebo, and numbered in order of their date of death after receiving their first trial dose (dose 1). Rows for Subjects 11351033 and 11311204 are shaded in grey to indicate that these subjects were Unblinded placebo subjects, from the original placebo arm but BNT162b2 vaccinated after the unblinding. In parentheses, are the number of days until these subjects died after they received dose 3, the BNT162b2 vaccine dose. SAD is Sudden Adult Death. FD indicates Found Dead. Autopsy was not done (None), not known if an autopsy was done (UNK), was done but the results were not made available (Yes-NA), or was done and results reported (Yes).

#Indicates those subjects included in the EUA application and Polack *et al.* (2020).

*Indicates that the cause of death diagnosis was considered a cardiac event.

[1]Case Report Form does not provide sufficient clinical data to support diagnosis.

[2]Case Report Form is incomplete; needs autopsy results to confirm diagnosis.

[3]Case Report Form supports "cardiac event" as the underlying cause of death.

[4]Subject did not meet criteria for randomization or had a protocol deviation.

All 38 Case Report Forms and Narrative Reports for those subjects who died were made available by Pfizer/BioNTech. In general, our review of these reports found them to be lacking in detail and extremely difficult to interpret and confirm the reported cause of death. Often, a subject's pre-trial clinical history was absent. Absent also were results of the extensive array of medical testing carried out at the pre-trial screening and at other regularly scheduled visits. These test results include complete blood counts, metabolic tests, pregnancy tests, COVID-19 tests, a comprehensive list of active medications, and more, and would have clarified the subject overall medical status. More detailed clinical data on the trial subjects exists but is still being withheld. Given the limitations of what has been provided, we determined that the information in the Case Report Form and

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Narrative Reports was frequently insufficient to support the investigator's conclusions regarding the cause of death. In the more glaring cases, we indicated such in Table 1 with a superscript of 1 and 2. Interestingly, many of these concerns were also voiced by the Pfizer/BioNTech physician responsible for the dialog with the site medical managers suggesting that this critical interchange was often less than ideal even for internal review.

Working with what was available and through DailyClout's Abstractor, we evaluated each Case Report Form and Narrative Report. Our overall comments and concerns regarding the diagnosis of the causes of death are indicated in Table 1. The findings from this evaluation were particularly revealing and brief reports on several subjects are presented below. Two subjects, #11271112 and #10841266, are especially important because their Case Report Form and Narrative Report indicated that cardiac events likely contributed to their death, something that was not mentioned in Pfizer/BioNTech's listing of their cause of death. Subjects #12291083 and #10971023 should also have been excluded from this list of 38 deceased subjects because they did not meet eligibility requirements at the time of randomization. Subject #10841470 had serious protocol deviations after randomization (see below). Because these 3 subjects are included in Pfizer/BioNTech's list of 38 deaths, we did not remove them in our analysis. Subjects #11311204 and #12314987 were listed as having died of cardio-pulmonary arrest and cardio-respiratory arrest, respectively. Analysis of their Case Report Form and Narrative Reports support a cardiac event as the possible cause of death based on their personal medical history and circumstances of their death. Nonetheless, in the absence of an autopsy, we chose to take the conservative approach and not include them as a "cardiac event signal".

Based the Narrative Reports, Table 1 also includes information on the circumstances of a subject's death. Six subjects, 2 placebo and 4 vaccinated, died suddenly (SAD for Sudden Adult Death). We defined SAD as a death that occurred unexpectedly and quickly in the presence of witnesses. Nine subjects, 3 placebo and 6 vaccinated, were found dead (FD). These were subjects who died in their sleep or at home alone without witnesses. It is interesting to note that 12 of the 15 subjects who died suddenly (SAD) or were found dead (FD) died of a cardiac adverse event.

Subject # 10841266 was a 77-year-old male with a history of severe vascular disease, gangrene, and multiple toe amputations likely related to diabetes and other comorbidities. He received a single dose of BNT162b2 vaccine after which he developed cholecystitis, had surgery, became septic, and died of multi-organ failure. No autopsy report is mentioned in the Case Report Form, which is unfortunate because the Case Report Form describes some confusion as to the primary cause of death. Emphysematous cholecystitis is a deadly bacterial form of gall bladder infection, which further increased the subject's risks related to his severe diabetes. This infection started the cascade of events leading to death. The NSTEMI, a non-ST elevation myocardial infarction, first reported on November 23 was likely part of the cascade of organ failure. On November 23, the subject was hospitalized with elevated troponin levels and a suspected NSTEMI. Elevated troponin levels were confirmed on December 1 but on December 2 the entry into the Case Report Form indicated that the NSTEMI was not considered a SAE, serious adverse event. This case had significant back and forth between the trial site and Pfizer/BioNTech regarding the primary cause of death and whether or not the subject had an NSTEMI in the hospital in addition to other reported issues. It appears that "sepsis" was his immediate cause of death but the NSTEMI should be listed as a contributing factor, at least as a secondary cause of death.

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Subject # 10841470 is an obese 65-year-old Hispanic male with a medical history including pulmonary fibrosis and hypertension. He was in the placebo arm of the trial and received doses 1 and 2 on September 30 and October 21, 2020, respectively. On December 23, 2020, the subject received dose 1 of the Moderna mRNA vaccine. This protocol deviation was reported in his Case Report Form after the subject reported symptoms of COVID-19 on December 28, 2020 and was admitted to the hospital on December 31, 2020. While hospitalized, he became hypoxic and was intubated on January 2, 2021. He received monoclonal antibodies as part of his treatment in the hospital. Despite these efforts, the subject continued to deteriorate, lapsed into multisystem organ failure, and ultimately died on January 11, 2021. Subject #10841470 was in the List of Discontinued Subjects (*Listing of Discontinued Subjects*) as a "Death" and in the 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*) as a placebo death with COVID-19 as the secondary cause of death. This is a misrepresentation of the subject's clinical information. The subject should have been discontinued from the Pfizer/BioNTech clinical trial because the "subject received non-study COVID-19 vaccine".

Subject #11271112 was a 53-year-old Native American male with COPD and history of "stress related myocardial infarction". According to the Narrative Report, on December 4, 2020, the patient was at home going up and down the stairs at which time he was found dead by his mother sitting "cross-legged, leaning forward, and blue in his face". This Sudden Death occurred less than two months after dose 2 of the BNT162b2 vaccine. An autopsy was performed but the results were not available for review. On December 18, after the subject's death, the trial site medical monitor listed the cause of death as "cardiopulmonary arrest related to myocardial infarction". On December 19, Pfizer/BioNTech informed the trial site that multiple causes of death cannot be entered into the Case Report Form and requested that "related to myocardial infarction" be deleted. The medical monitor refused to change the wording of the entry. On January 5, 2021, Pfizer/BioNTech overrode the trial site and changed the cause of death to "cardiopulmonary arrest" and chose not to list "myocardial infarction" as a secondary cause of death, which was an option that could have been used to deal with such conflicting conclusions. It is not clear why a specific diagnosis of an AESI was later changed to something undefined. Without the critical autopsy report to either confirm or deny the on-site medical monitor's diagnosis, we felt it most appropriate to include this subject in the cardiac signal event group.

Subject #11621327 was found dead shortly after receiving dose 1 of the BNT162b2 vaccine on September 10th. His body was found at home (with lividity) on the 13th of September when the police performed a welfare check. "According to the medical examiner, the probable cause of death was progression of atherosclerotic disease." The cause of death listed in the *6-Month Interim Report of Adverse Events C4591001* is "Arteriosclerosis". However, there were multiple queries in the Case Report Form about the cause of death being ascribed to atherosclerosis. Atherosclerosis was not documented in the Case Report Form as a comorbidity of the patient. The subject's Case Report Form is only 127 pages in length and does not include the pre-screening portion of comorbidities, the section of the Case Report Form that would have provided evidence on whether the subject had a history of atherosclerosis. Moreover, if an autopsy had been done, progression of atherosclerosis would have been documented but autopsy results were not provided or available. Based only on the medical documentation in the Case Report Form, there is no basis for ascribing the subject's death to advanced atherosclerosis or concluding that the death was unrelated to the vaccine. The following statement taken from the interim narrative document for the corresponding subject, in our opinion, is unfounded. "In the opinion of the investigator, there was no reasonable possibility that the

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arteriosclerosis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to suspected underlying disease." Pfizer/BioNTech concurred with the investigator's causality assessment. It is likely that the subject died within a day or two of vaccination. This was a clear indication that his death could have been related to the BNT162b2 vaccine and this should not have been ruled out without a more rigorous investigation. In our opinion, this diagnosis was premature and an egregious misjudgment of the evidence at hand.

Subject #12291083 received the placebo and died 76 days after dose 1. The primary cause of death was first diagnosed as Diabetes mellites based on the subject's medical history. This diagnosis was revised several times, despite the presence of very high blood-glucose levels, until finally settling on COVID-19 pneumonia as a secondary cause of death. The subject was HIV positive with a HIV RNA load of 50 copies per ml, which is just over the acceptable limit for inclusion in the trial. The subject should not have been randomized and approved as a trial participant.

Subject ID #12314987 was a 47-year-old male with a history of hypertension, obesity, and a smoker for 27 years. He received the placebo and died 82 days after dose 1. At an unscheduled visit he presented with abdominal pain, vomiting, and back pain at 9 PM on December 5, 2020 and died in the hospital at 7 AM the next morning, December 6, 2020. No record of an autopsy is available and the family was not responsive to inquiry. The cause of death was deemed "non traumatic cardiorespiratory arrest" but given the subject's medical history, a firmer diagnosis should have been aggressively pursued.

Subject ID #12315324 received the placebo and died 136 days after dose 1. The primary cause of death was listed as "Multiple organ dysfunction syndrome" but the symptoms support a diagnosis of COVID-19. It appears that the otherwise healthy subject was hospitalized with COVID-19 symptoms. The patient required mechanical ventilation due to lobar pneumonia in the ICU and was documented as having acute kidney failure requiring dialysis. Other than vasopressors, there is no record of any other medication that the patient received as part of their hospital care.

In conclusion, we had no choice but to accept the cause of death diagnoses listed in the 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*) as accurate, with the exception of subjects #11271112 and #10841266. Based on our medical expertise and in the interest of simplifying the search for potential safety signals among these 38 deceased subjects, we grouped the terms myocardial infarction, cardiac arrest, sudden cardiac death, cardiac failure congestive, and arteriosclerosis under the umbrella term "cardiac events". Subjects diagnosed to have died as a result of a cardiac event are indicated with an asterisk* in Table 1. In the two exceptional cases, subjects #11271112 and #10841266, Table 1 still lists the cause of death as determined by Pfizer/BioNTech but in our opinion myocardial infarction could not be excluded as a cause of death. Therefore, subjects #11271112 and #10841266 were included in our "cardiac events" group, as indicated by the asterisk* next to the diagnosis of the cause of death.

DISCREPANCIES IN REPORTS ON SUBJECT DEATHS

Comparison of the data plotted in Figure 1 to the results reported in the Pfizer/BioNTech EUA application (*Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*), Polack *et al.* (2020), and Thomas *et al.* (2021) revealed several discrepancies. Discrepancies among these various data sources are particularly disconcerting. The data with which

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we are working comes directly from Pfizer/BioNTech's 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*) on Clinical Trial C4591001 in the section entitled "Listing of Deaths – All Subjects ≥16 Years of Age". As such, it should be entirely consistent with data presented in the other Pfizer/BioNTech documents and published reports. These discrepancies are illustrated in Table 2.

Table 2 compares the results reported by Pfizer/BioNTech, Polack *et al.* (2020), and Thomas *et al.* (2021) (left column) to the data from our analysis of the 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*) (right column). The data is reported by time periods as shown in Figure 1: Blinded Placebo-Controlled Period to EUA application Data Collection Cutoff (July 27 to November 14, 2020), the Blinded Placebo-Controlled and Open-label Follow-up Period (July 27 to January 24, 2021), and the Open-label Observational Period to Data Collection Cutoff of the 6-Month Interim Report (January 25 to March 13, 2021). The basis for selecting January 24, 2021 as

Table 2: Comparison of subject deaths reported during periods of the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial C4591001*

PFIZER/BIONTECH PUBLICATIONS DATA	**PFIZER/BIONTECH 6-MONTH INTERIM REPORT DATA**
BLINDED PLACEBO-CONTROLLED PERIOD TO EUA APPLICATION DATA COLLECTION CUT-OFF: July 27 to November 14, 2020	
6 Deaths • 4 from Placebo arm • 2 from BNT162b2 vaccinated arm Cardiac events: 2 BNT162b2 *vs* 2 Placebo Conclusion by Pfizer/BioNTech: None considered vaccine-related	11 Deaths • 5 from Placebo arm • 6 from BNT162b2 vaccinated arm Cardiac events: 4 BNT162b2 *vs* 2 Placebo
BLINDED PLACEBO-CONTROLLED PERIOD AND OPEN-LABEL FOLLOW-UP PERIOD: July 27, 2020 to January 24, 2021	
29 Deaths • 14 from Placebo arm • 15 from BNT162b2 vaccinated arm Cardiac events: 8 BNT162b2 *vs* 3 Placebo Conclusion: "No new safety signals relative to the previous report."	30 Deaths • 14 from Placebo arm • 16 from BNT162b2 vaccinated arm Cardiac events: 10 BNT162b2 *vs* 3 Placebo
OPEN-LABEL OBSERVATIONAL PERIOD TO DATA COLLECTION CUTOFF OF 6-MONTH INTERIM REPORT: January 25, 2021 to March 13, 2021	
5 Deaths • 3 from originally BNT162b2 vaccinated arm • 2 from original Placebo arm who were unblinded and BNT162b2 vaccinated Cardiac events: 1 BNT162b2 *vs* 0 Placebo Conclusion: "Causes of death were balanced between BNT162b2 and Placebo groups."	8 Deaths • 3 from originally BNT162b2 vaccinated arm • 2 from original Placebo arm who were unblinded and BNT162b2 vaccinated • 3 deaths from the original Placebo arm who were unblinded but NOT vaccinated Cardiac events: 1 BNT162b2 *vs* 0 Placebo
SUMMARY OF DEATHS IN 6-MONTH REPORTING PERIOD: July 27, 2020 to March 13, 2021	

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34 Deaths: 18 BNT162b2 vs 16 Placebo • 14 from original Placebo arm who were never BNT162b2 vaccinated • 15 from original BNT162b2 vaccinated arm • 3 from BNT162b2 vaccinated arm who died during the OPEN-LABEL PERIOD to March 13, 2021 • 2 Unblinded Placebo subjects who were BNT162b2 vaccinated and died during the OPEN-LABEL PERIOD to March 13, 2021 Cardiac events: 9 BNT162b2 *vs* 3 Placebo Conclusion: No summary of causes of death for all deceased subjects presented.	38 Deaths: 21 BNT162b2 vs 17 Placebo • 14 from original Placebo arm who were never BNT162b2 vaccinated • 16 from original BNT162b2 vaccinated arm • 3 from BNT162b2 vaccinated arm who died during the OPEN-LABEL PERIOD to March 13, 2021 • 2 Unblinded Placebo subjects were BNT162b2 vaccinated and died during the OPEN-LABEL PERIOD to March 13, 2021 • 3 deaths from the original Placebo arm who were unblinded but NOT vaccinated Cardiac events: 11 BNT162b2 *vs* 3 Placebo

*****Comparison of subject deaths reported during periods of the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial C4591001. The lefthand column presents data taken from the following publications: Pfizer/BioNTech EUA application (*Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*), Polack *et al.* (2020), and Thomas *et al.* (2021). The righthand column presents data from the Pfizer/BioNTech 6-Month Interim Report on Adverse Events (*6-Month Interim Report of Adverse Events C4591001*). Cardiac event numbers are based on our analysis of subject Case Report Form as presented in Table 1. Conclusion statements are taken from the texts of Pfizer/BioNTech EUA application (*Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*), Polack *et al.* (2020), and Thomas *et al.* (2021). The table is divided into 4 different time periods of the 6-Month Interim Report: Blinded Placebo-Controlled Period to EUA application Data Collection Cut-off (July 27 to November 14, 2020); Blinded Placebo-Controlled and Open-label Follow-up Period (July 27 to January 24, 2021); Open-label Observational Period to Data Collection Cut-off of the 6-Month Interim Report (January 25 to March 13, 2021); and a summary of the 6-Month Interim Report (July 27, 2020 to March 13, 2021).

the end of the Open-label Follow-up Period is unclear and not explained in Thomas *et al.* (2021). The last section of Table 2 is a summary of the full 6-Month Period (July 27, 2020 to March 13, 2021). It should be noted that both Polack *et al.* (2020) and Thomas *et al.* (2021) have internal inconsistencies between the number of deaths reported in their flow charts and the number reported the text of the manuscript. These inconsistencies do not appear to have been identified by reviewers of either manuscript.

Data reported in the EUA application (July 27 to November 14, 2020)

The first section of Table 2 compares Pfizer/BioNTech's published data to the data reported here in Figure 1 and Table 1. The first 16 weeks are the most important period of the clinical trial because the decision as to whether to approve the BNT162b2 vaccine rested entirely on these results. Pfizer/BioNTech's EUA application (*Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*) and Polack *et al.* (2020), which was published on December 10, 2020 and updated on December 16th, reported that only 6 trial participants died prior to November 14, 2020: 2 in the vaccinated arm of the trial and 4 in the placebo arm. Based on comments on the cause of death in Polack *et al.* (2020), we determined the Subject IDs of these 6 subjects. These are marked

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with a superscript # in Table 1. In contrast, our findings in Figure 1 and Table 1 show 11 deaths in total prior to November 14 (week 16), 6 subjects in the vaccinated arm and 5 in the placebo arm. A careful review of the date of death of the 6 deceased subjects reported by Polack *et al.* (2020) shows that they include only 2 of the 6 vaccinated and 4 of the 5 placebo subjects whose date of death we found to be before November 14. This is the first discrepancy noted in our analysis.

Of the 6 deceased subjects reported by Pfizer/BioNTech, Table 1 indicates that 2 of the BNT162b2 vaccinated subjects and 2 of the placebo subjects died of a cardiac event. In Polack *et al.* (2020) and the Pfizer/BioNTech EUA application (*Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*), it is stated that the trial investigators did not consider any of these deaths to be related to the vaccine. By comparison, our analysis of the 11 deaths observed in the Blinded placebo-controlled period shows that about half were due to cardiac events: 4 in the BNT162b2 vaccinated and 2 in the placebo arms. While the numbers are small, they represent a 2-fold increase in cardiac events in BNT162b2 vaccinated subjects. This should have alerted Pfizer/BioNTech to the possibility that cardiac events could be a vaccine-related signal event. It did not because information on 5 subjects who died prior to November 14 had not been reported to the FDA in the EUA application. Long gaps exist between the actual date of death and the date that this was officially recorded in the subject's Case Report Form (Table 3). The origin of these gaps is discussed below.

December 10, 2020 presentation to the FDA

On December 10th, Pfizer/BioNTech presented their evidence supporting their request for Emergency Use Authorization of their BNT162b2 mRNA vaccine (*Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*) to the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). This presentation took place 25 days after the November 14th data cutoff date for the EUA application. It was an opportunity for Pfizer/BioNTech to update their results to December 10th. Instead, Pfizer/BioNTech representatives reported the exact same results as those that appeared in the EUA application 25 days prior. C4591001 was an ongoing clinical trial. It would not have been unusual to find additional deaths during this time period. In fact, our analysis of the 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*) indicates that 6 more subjects died between November 14 and December 10, 2020 bringing the actual total number of deaths to 17 between July 27th and December 10th. Sixteen (16) of these 17 subjects, 8 BNT162b2 vaccinated and 8 placebo, were known to Pfizer/BioNTech by December 10th. This is the second discrepancy noted in our analysis.

A careful review of the Case Report Form for each of the 38 deceased subjects revealed that the date of death recorded in the 6-Month Interim Report was not officially recorded in the subject's Case Report Form for several days, sometimes weeks. We decided to explore a possible pattern in the delay. Table 3 groups the 38 deceased subjects based on whether they received the only the placebo or the BNT162b2 vaccine, either originally or after unblinding. The 6 subjects reported in the Pfizer/BioNTech EUA application (*Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*) and in Polack *et al.* (2020) are indicated by superscript #. Subjects whose listing is highlighted in gray are those whose death was not discussed at the FDA's VRBPAC meeting but whose death was in fact known to Pfizer/BioNTech on December 10th, the date of their

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presentation. Based on the information in Table 3, Pfizer/BioNTech knew of 10 more subjects who died between November 14 and December 10th bringing their total number of officially recorded deaths to 16 (see Table 3 rows shaded in gray or marked with #). (Subject #10881126's death on December 1 was not officially recorded in the Case Report Form until 72 days later on February 11, 2021 and is not included.) These 16 deaths known to Pfizer/BioNTech were equally distributed to both arms of the trial, 8 in the BNT162b2 vaccinated arm and 8 in the placebo arm. The causes of death are not. Based on our determination of the number of the cardiac events as reported in Table 1, the number of deaths related to a cardiac event is 6 in the BNT162b2 vaccinated arm and 3 placebo arm, a 2-fold increase in the cardiac signal in BNT162b2 vaccinated subjects. If instead we use "cardiac arrest" and "myocardial infarction", the only cardiac events reported by Pfizer/BioNTech by this date, the numbers are 2 in the BNT162b2 vaccinated arm and 2 placebo arm, that is, balanced between the trial arms.

Pfizer/BioNTech should have voluntarily made known any new information that could contribute to the FDA's decision. It was factually misleading for them not to do so. On the other hand, everyone at the VRBPAC meeting should have realized that the data from November 14th was outdated. Surprisingly, no members of VRBPAC requested an update on adverse events that occurred between the EUA data cutoff date (November 14) and the date of this meeting (December 10) (https://www.youtube.com/watch?v=owveMJBTc2I). Nor did they request more information on the causes of death and independently evaluate the deceased subjects' Case Report Form. Sixteen deceased subjects is a manageable number and this was a critical point in the approval process. It appears that the FDA decision to approve the Pfizer/BioNTech EUA was based solely on 16 weeks of data, data that was a misrepresentation of the full story that was not evaluated with a critical eye.

Blinded Placebo-Controlled and Open-label Follow-up periods

This section of Table 2 reports on the first 26 weeks of the trial. Here, the numbers and causes of subject deaths reported in the Pfizer/BioNTech 6-Month Summary Clinical Safety (*Summary Clinical Safety 6-Month Report*) and Thomas *et al.* (2021) are compared to those reported in the Pfizer/BioNTech 6-Month Interim Report. The Summary Clinical Safety (*Summary Clinical Safety 6-Month Report*) was submitted to the FDA on May 5, 2021 and includes data up to March 13, 2021. Table 7 of this report lists the number of subjects who died in each arm of the trial from receipt of dose 1 to the Unblinding Date (not defined) and Table 16 gives the cause of death. The information in Table 16 is reproduced in Table S4 of Thomas *et al.* (2021) with no updating despite the fact that Thomas *et al.* (2021) was published on September 15, 2021. Conclusions reported in both documents are identical: 15 deaths in the BNT162b2 group and 14 deaths in the placebo group during the blinded placebo-controlled period for a total of 29 deaths.

Section 2.7.4.2.4.2.2.1.1 of the Summary Clinical Safety (*Summary Clinical Safety 6-Month Report*) reports that two deaths occurred among the subset of 200 HIV-positive Phase 2/3 participants, one from each trial arm, and both were withdrawn from the study. Subject IDs for these participants were #11561160 and #12291083. Thomas *et al.* (2021) appears to have included these 2 subjects in the flow chart figure that shows the disposition of subjects during the trial. It appears that only one of these subjects was excluded to arrive at the final number of 29 deaths reported in the text of the article. Our analysis of the Case Report Form for subject #12291083 indicates that this individual was ineligible for randomization (discussed above) but, because subject #12291083 was retained in the list of 38 deceased subjects, we did not exclude this individual from our accounting in Table 2.

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No information is available on why subject #11561160 might also have been excluded or if these were the excluded subjects. The disposition of the HIV positive subjects in Thomas *et al.* (2021) and how Thomas *et al.* (2021) arrives at the total of 29 subject deaths is not presented clearly. This confusion represents an internal inconsistency in their data and could explain one of the difference between our data showing total number of 30 subject deaths and that of Thomas *et al.* (2021).

Of the 30 deaths during this first 26-week period of the trial, we found a total of 13 deaths due to a cardiac event, 10 in the BNT162b2 vaccinated group and 3 in the placebo. Cardiac events clearly constitute an adverse event safety signal for the BNT162b2 vaccine. Surprisingly, this signal was not mentioned by Pfizer/BioNTech. Thomas *et al.* (2021) states, "No new serious adverse events were considered by the investigators to be related to BNT162b2 after the data cutoff date of the previous report" and "No new safety signals were observed during the longer follow-up period." Since 3 of the 6 subjects that Pfizer/BioNTech reported to have died prior to November 14 died of cardiac events (myocardial infarction and arteriosclerosis), Thomas *et al.* (2021) presumably did not consider deaths after that date to be due to a "new" adverse event. The number of total subject deaths and the imbalance in the causes of death is the third discrepancy noted in our analysis.

Open-label Observational Period to March 13, 2021. Thomas *et al.* (2021) and Pfizer/BioNTech in the Summary Clinical Safety (*Summary Clinical Safety 6-Month Report*) report 3 deaths in the BNT162b2 group and 2 in the unblinded BNT162b2 vaccinated originally placebo group in the trial period we entitled "Open-label Observational Period", as shown in the third section of Table 2. We show a total of 8 subjects who died in this period: 3 in the BNT162b2 group, 2 in the unblinded BNT162b2 vaccinated original placebo group, and 3 in the original placebo group that were never vaccinated. It is not clear why Pfizer/BioNTech excludes this last group of subjects. Of the 8 deaths we report during weeks 27-33, we found 1 cardiac event in the BNT162b2 vaccinated group and none in the placebo arm. Thomas *et al.* (2021) says that the "Causes of death were balanced between the BNT162b2 and placebo groups". Again, the number of total subject deaths during this final period of the 6-Month Interim Report and the small imbalance in the cardiac deaths is the fourth discrepancy noted in our analysis.

Summary of subject deaths

The last section of Table 2 provides a full accounting of the deaths that occurred over the first 33 weeks of the Pfizer/BioNTech C4591001 clinical trial. Pfizer/BioNTech account for a total of 34 subjects who died during the 6-month follow-up period, 20 subjects who received BNT162b2 vaccine and 14 who were in the placebo control group. As discussed above, four of the 38 deaths listed in the 6-Month Interim Report are not included in their calculations: possibly the 2 HIV positive subjects, #12291083 and 11561160, and 2 placebo subjects who died after January 24, 2021. Our results account for all 38 subject deaths: 21 deaths in the BNT162b2 vaccinated subjects and 17 in the placebo. Three of the 38 should not have been listed in the 6-Month Interim Report, which would have brought that number to 35 subject deaths. Subjects #12291083 (placebo) and #10971023 (BNT162b2) did not meet eligibility requirements and should have been excluded before randomization. Subject #10841470 (placebo) received a received non-study COVID-19 vaccine. Interestingly, COVID-19 is given as the cause of death of both of these placebo subjects.

Of the 38 deaths reported in the 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*), the foundational document of our forensic analysis, we revealed that 14 subjects died from a cardiac event, over one-third of all deaths (36.8%). Of these 14, 11 were from the

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BNT162b2 vaccinated trial arm and 3 from the placebo-only trial arm. This represents a 3.7-fold increase in cardiac events in subjects who received the BNT162b2 vaccine. Thomas *et al.* (2021) and Pfizer/BioNTech's Summary Clinical Safety (*Summary Clinical Safety 6-Month Report*) do not identify or remark on this clear serious adverse event signal.

SOURCES OF THE DATA DISCREPANCIES

The data discrepancies described above are critical to understanding why the cardiac adverse event signal was not reported to the FDA, especially prior to EUA approval. Our analysis of the data in Table 3 discussed above, showed that Pfizer/BioNTech used the date that the death was officially recorded in the Case Report Form to determine in which time period to report the death NOT the actual date of death, although both dates were available to them. The C4591001 Protocol required that Pfizer/BioNTech be notified of a subject death immediately. The Narrative Reports confirm that the trial sites were diligent reporting the circumstances of a subject's death. Only a few of the Narrative Reports provide the exact date of death. It appears that other steps in the death notification process exist. A few are alluded to in the Case Report Form, such as a Death Details Form. Nonetheless, it is clear that Pfizer/BioNTech knew the actual date of death for each subject within the requisite 24 hours but recordkeeping and review procedures that are unknown to us contributed to delays in entering the date of a subject's death into their Case Report Form.

Why did Pfizer/BioNTech use the date a subject's death was entered into the Case Report Form and not the actual date of death, since both were available to them when they prepared the EUA application and their VRBPAC presentation. To answer this, we explored possible patterns in this recordkeeping delay. The gap between the actual date of death and the date that the death was officially recorded in the Case Report Form is shown in Table 3 for all 38 deceased subjects. We divided this into two time periods comparing the recording delays prior to December 11, 2020, the date the EUA was approved by the FDA, to those after EUA approval. Deaths prior to EUA approval are shaded in grey. The 6 subjects included in the EUA application and Polack *et al.* (2020) are indicated with a superscript hatch mark($^{\#}$).

Of the 8 BNT162b2 vaccinated subjects that should have been reported to the VRBPAC on December 10th, the median reporting delay was 18 days (average of 17.5 days). Among the 8 placebo subjects, the median delay was 5 days (average of 5.9 days). When the recording delay after December 11 is analyzed, we found a dramatic decrease in both arms of the trial. The median delay in the BNT162b2 arm of the trial was 7 days (average 9.8 days) and in the placebo arm the delay was 3 days (average of 15.9 days). The median is a better measure of the delay because a small number of outliers such as 50 and 72 skew the average. These results indicate that the delay between the date that Pfizer/BioNTech was notified of a subject's death and the date that it was entered into the Case Report Form depended on whether the trial arm of the subject and whether the subject died before or after EUA approval.

Figure 2 plots the reporting delay for the 19 subjects in the original BNT162b2 vaccinated trial arm *versus* the actual date of death. In Figure 2A, the date that the subject's death was entered into the Case Report Form is plotted. The 6 subjects whose actual date of death was before November 14, the EUA data cut-off, are indicated with their subject ID#. Subjects #10071101 and #11621327 were the two vaccinated subjects whose death was reported in the EUA application (square marker). Subjects #11141050, #11201050, #10891073, and #11521497 should have been reported in the EUA application but were not because of the reporting delay (triangle marker). The remaining

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vaccinated subjects died after November 14 and are indicated with filled circles. The dotted line is the best fit to the data.

Table 3: Delay in Recording Subject Death*[1]

Period	Subject ID	Date of Death	Officially Recorded Date (from Case Report Form)	Delay Recording Death (Days)
BNT162b2 mRNA vaccinated subjects				
#P-C	11621327	13Sept2020	24Sept2020	11
P-C	11141050	19Oct2020	25Nov2020	37
#P-C	10071101	21Oct2020	5Nov2020	15
P-C	11201050	07Nov2020	3Dec2020	26
P-C	11521497	11Nov2020	18Nov2020	7
P-C	10891073	12Nov2020	4Dec2020	22
P-C	10391010	18Nov2020	9Dec2020	21
P-C	11271112	04Dec2020	05Dec2020	1
O-L, F	11361102	19Dec2020	22Jan2021	34
O-L, F	10211127	19Dec2020	30Dec2020	11
O-L, F	10971023	21Dec2020	28Dec2020	7
O-L, F	11561160	24Dec2020	14Jan2021	21
O-L, F	12521010	26Dec2020	29Dec2020	3
O-L, F	11401117	29Dec2020	05Jan2021	7
O-L, F	10841266	12Jan2021	15Jan2021	3
O-L, F	11201266	19Jan2021	25Jan2021	6
O-L, O	11351033	29Jan2021	24Feb2021	26
O-L, O	11291166	03Feb2021	5Feb2021	2
O-L, O	10361140	10Feb2021	22Feb2021	12
O-L, O	11311204	15Feb2021	18Feb2021	3
O-L, O	10881139	06Mar2021	08Mar2021	2
Placebo subjects				
#P-C	11521085	26Aug2020	27Aug2020	1
#P-C	12313972	28Sept2020	1Oct2020	3
P-C	11561124	02Nov2020	19Nov2020	17
#P-C	10661350	03Nov2020	10Nov2020	7
#P-C	10811194	04Nov2020	11Nov2020	7

1

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O-L, F	11681083	18Nov2020	19Nov2020	1
O-L, F	11281009	28Nov2020	8Dec2020	10
O-L, F	10881126	01Dec2020	11Feb2021	72
O-L, F	12314987	06Dec2020	7Dec2020	1
O-L, F	10191146	17Dec2020	5Feb2021	50
O-L, F	10941112	18Dec2020	21Dec2020	3
O-L, F	10891088	30Dec2020	04Jan2021	5
O-L, F	12291083	05Jan2021	5Jan2021	0
O-L, F	10841470	11Jan2021	19Jan2021	8
O-L, O	12315324	31Jan2021	3Feb2021	3
O-L, O	12071055	09Feb2021	11Feb2021	2
O-L, O	10271191	13Feb2021	16Feb2021	3

*Delay in recording subject death. Subjects who died during the period July 27, 2020 to March 13, 2021 are listed. Subjects receiving BNT162b2 vaccine are listed separately from those who received the placebo and in order of the true date of death. #Indicates those subjects included whose death was reported in the Pfizer/BioNTech EUA application (*Emergency Use Authorization for an Unapproved Product Review Memorandum Https://Archive.Org/Details/Emergency-Use-Authorization-Eua-for-an-Unapproved-Product-Review-Memorandum*) and Polack *et al.* (2020). The rows shaded in grey highlight those individuals whose death was officially recorded in their Case Report Form between July 27 and December 10, 2020 indicating that Pfizer/BioNTech knew the subject died during this period. Periods of the trial: P-C is Placebo-Controlled, Blinded period; O-L, F is the Open-label Follow-up period (December 11, 2020 to January 24, 2021); O-L, O is the Open-label Observational period (January 25 to March 13, 2021).

Consistent with the values reported above, Figure 2A shows that the length of the reporting delay decreases significantly after the EUA application is submitted. There is no reasonable explanation for this difference given that a similar trend is not observed in the placebo subjects (Table 3). Narrative Reports on key subjects who died prior to November 14th clearly state when Pfizer/BioNTech was notified of the subject's date of death. Protocol C4591001 required that Serious Adverse Events such as death or hospitalization be immediately reported to Pfizer/BioNTech or at the most within the 24 hours. This requirement was likely adhered to by the trial site staff but not all of the Narrative Reports mention the exact date. We used the dates of death reported in the key Narrative Report to replace the date of death taken from the Case Report File in Figure 2B. A dramatic shift in the position of markers for 2 subjects is noted, #11141050 (37 day drop) and #11201050 (26 day drop), a smaller drop is seen for subject #11621327 (11 days), and a modest drop was seen for #10891073 (3 days). For Given these changes, the recording delays throughout the trial are similar, as indicated by the best fit trend line in Figure 2B.

If Pfizer/BioNTech had reported the actual date of death instead of the date the deaths were recorded in the Case Report Forms, Subjects #11141050 and #11201050 would have been included in the EUA application. Given this scenario, there would have been 4 vaccinated and 4 placebo subjects who died prior to the November 14th data cut-off date and whose deaths should have been included in the EUA application. Of these, there were 4 deaths due to a cardiac event in vaccinated subjects *versus* 2 in the placebo arm (Table 1). Thus, 100% of the vaccinated subject deaths were due to a cardiac event. By delaying recording of these patients' deaths into their Case Report File and by

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not using the actual date of death, their deaths were not discoverable at the critical juncture of the EUA approval process and the cardiac adverse event signal was obscured.

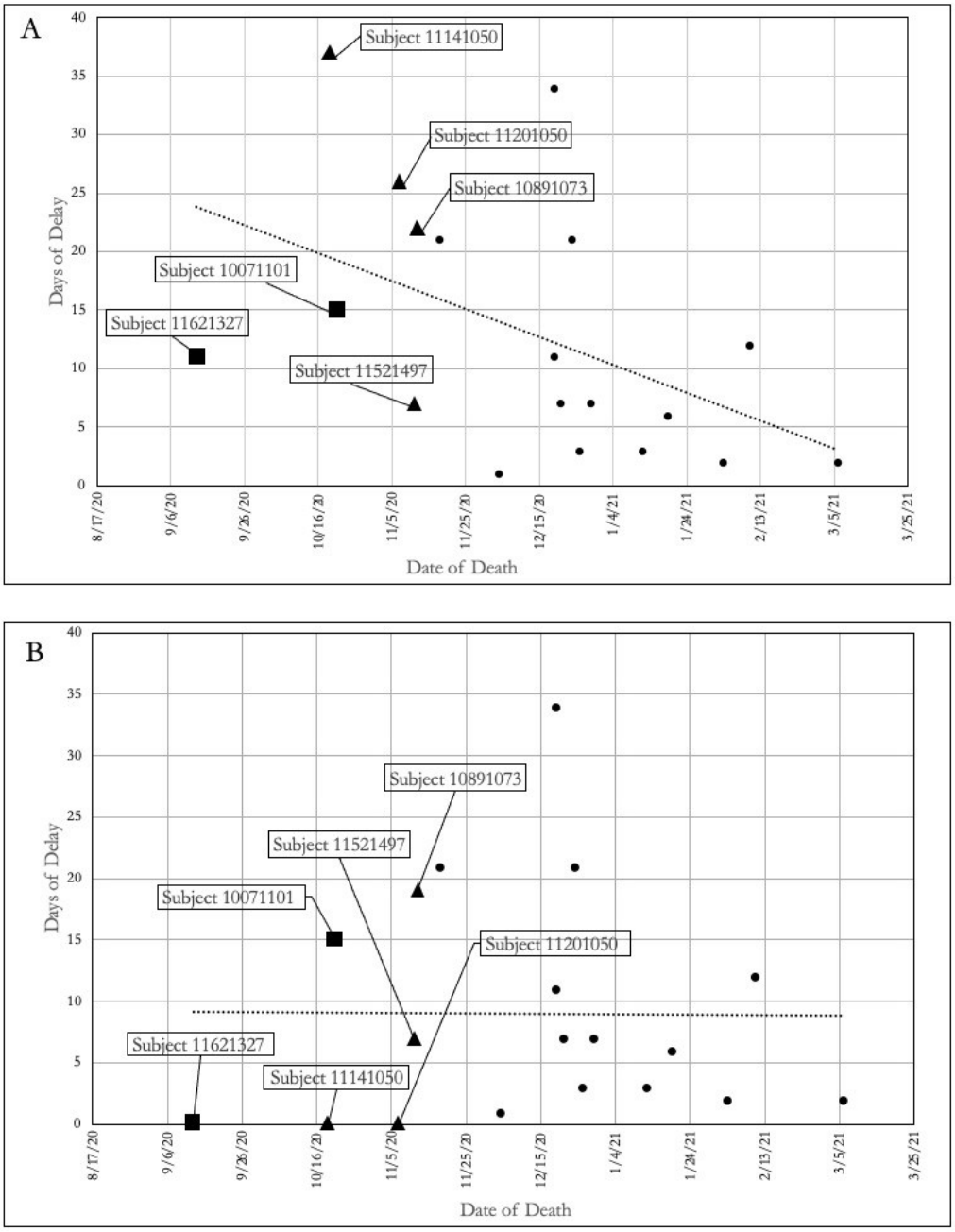

Figure 2: Delay in recording BNT162b2 vaccinated subject deaths. Subject ID#'s are provided for the 6 subjects who died prior to data cut-off date of the EUA application, November 14th. Filled square ( ), subjects whose death was reported in the EUA application. Filled triangles ( ), subjects whose death was not reported in the EUA but who died prior to November 14th. Small filled circles ( ), subjects who died after November 14th. Figure 2A plots the date that the subject's death was recorded in their Case Report File.Figure 2B plots the date of the subject's death reported in their Narrative Report.

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In summary, had Pfizer/BioNTech used the actual date of death for the 38 subjects when preparing their EUA application, as we did in Table 2, it becomes questionable whether the FDA would have approved the BNT162b2 vaccine. Of the 11 deaths prior to November 14th, 4 of the 6 vaccinated subjects died of a cardiac adverse event compared to 2 of the 5 placebo subjects. Had the VRBPAC asked for an update, the cardiac adverse event signal would have been even more obvious given the additional 6 deaths that had occurred by December 10th. By that date, there were a total of 17 deaths, 8 in the vaccinated arm and 9 in the placebo arm. Of the vaccinated subjects, 6 of 8 or 75%, died due to a cardiac event while only 3 of the 9 (33.3%) of the placebo subjects died of a cardiac event. This clear cardiac adverse event signal in the brief 20-weeks of the trial should certainly have given pause to the FDA reviewers, had they been aware of it. The reporting delay and the lack of curiosity by the VRBPAC allowed Pfizer/BioNTech to manipulate the reporting of the results of the only truly placebo-controlled randomized portion of this clinical trial.

Discussion

This study is the first analysis of the original trial data from the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial (C4591001) carried out by a group unaffiliated with the trial sponsor. The small number of deaths reported in Pfizer/BioNTech's initial 6-Month Interim Report (*6-Month Interim Report of Adverse Events C4591001*) allowed us to carry out an in-depth study at a level of detail that would not otherwise have been possible on such a large dataset. As such, it is best described as a forensic analysis of these 38 deaths. We reveal that reports on the BNT162b2 mRNA vaccine clinical trial done in public forums by Pfizer/BioNTech and their representatives were flawed and included serious reporting errors that obscured the actual trial results. As a result, a 3.7-fold increase in cardiac events in subjects who received the BNT162b2 vaccine *versus* the placebo group was not reported to the public at the time of the vaccine rollout.

PLACEBO-CONTROLLED RANDOMIZED CLINICAL TRIAL

The results shown in Figure 1 are a testament to the value of a placebo-controlled clinical trial. Any intervention whether it is a drug or a therapeutic procedure may have unrecognized risks and adverse side effects that could negate any positive effect. But how does one know that the intervention is responsible for the effect? That requires a placebo-controlled randomized clinical trial – what has been referred to as the gold standard of clinical trials. A population of subjects are screened based on particular criteria and randomly placed into either the treatment or placebo arms of a clinical study. Thus, the subject pool should be similar and of known demographics. Any difference in outcomes between the trial arms can then be attributed to the treatment. As in the experimental sciences, the placebo arm serves as the "control" and provides the baseline numbers for the randomized subject population. Without this control, it is impossible to say with confidence that the treatment under study is having a positive, negative, or no effect at all. It is entirely inappropriate and scientifically inaccurate to compare a test subject population to the population at large. Individuals who agreed to be treated could easily differ in any of a variety of ways – health, age, socioeconomic level, *et cetera* – from those who decided not to be treated. Similarly, while very valuable, VAERS, Yellow Card, and other national health surveillance databases do not meet the high standards of a placebo-controlled randomized clinical trial.

The need for properly controlled clinical trials was confirmed in a January 2021 article authored by the WHO Ad Hoc Expert Group on the Next Steps for Covid-19 Vaccine Evaluation (WHO Ad Hoc Expert Group on the Next Steps for Covid-19 Vaccine Evaluation, 2021). The article strongly

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encouraged the continuation of ongoing placebo-controlled randomized clinical trials of vaccines against SARS-CoV-2 even after vaccine rollouts. "There was concern that observational data obtained from nonrandomized studies after vaccine deployment could yield unreliable answers. Observational studies are subject to substantial biases and are much less amenable to unambiguous interpretation." They continue, "even carefully analysed observational studies can yield misleading answers about safety and efficacy." In the Committee's opinion, controlled trials on about 22,000 vaccine recipients and 20,000 placebo recipients may be sufficient for detecting relatively common adverse events but are not sufficient for uncommon ones. Detecting rare adverse events would require much larger numbers of subjects, perhaps in the hundreds of thousands, particularly for short-term trials carried out in emergency situations, like the Pfizer/BioNTech trial being analysed here.

Pfizer/BioNTech halted the placebo-controlled portion of clinical trial C4591001 trial in week 20 with the approval of the FDA. Subjects were unblinded (informed of their vaccination status) and subjects in the placebo arm of this study could request to be BNT162b2 vaccinated. Under usual circumstances, unblinding the placebo is done only when it is considered unethical to continue the trial because the treatment/intervention saved lives. The evidence in Figure 1 does not support this decision as vaccination does not decrease mortality. By unblinding the placebo subjects, the FDA ended all semblance of placebo-controlled clinical trial on December 11, 2020. Amazingly, improved survival was not an endpoint of the C4591001 clinical trial allowing this information to be ignored.

Figure 1 presents the results of just such a placebo-controlled randomized clinical trial of the BNT162b2 mRNA vaccine, at least for the first 20 weeks. The findings were unexpected. First, the number of subject deaths is less than one-fifth of expected. The subject population was pre-screened but the reasons for exclusion were not sufficiently rigorous to explain the low number of deaths. Neither Pfizer/BioNTech, Polack *et al.* (2020), nor Thomas *et al.* (2021) commented on small number of deaths.

Since deaths in both the vaccinated and the placebo subjects were occurring at a similar rate in the first 20 weeks of the trial, it is clear that the vaccine did not decrease all-cause mortality. If BNT162b2 mRNA vaccination were decreasing deaths due to COVID-19, this finding would suggest that any decrease in deaths due to COVID-19 is balanced by an increase in deaths due to other causes. Our results suggest that one of these other causes could be deaths due to cardiac events. Because the numbers are so small, it is difficult to draw any firm conclusion as to what these other causes could be. It should also be noted that, to our knowledge, at no time did any members of any international medical health regulatory agencies or medical literature reviewers, who evaluated the Pfizer/BioNTech trial data comment on this finding or request an explanation.

The finding that vaccination did not decrease the deaths in the trial is consistent with a study of all-cause mortality in the Southern Hemisphere (Rancourt *et al.*, 2023). Seventeen countries on 4 continents and using different COVID-19 vaccines, of which BNT162b2 was one, were included in this analysis that spanned 2020-2022. In all 17 countries, they found no evidence of benefit the COVID-19 vaccines on all-cause mortality. Rather, the data shows "unprecedented" peaks in all-cause mortality that coincide with or immediately precede COVID-19 vaccine booster rollouts.

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CAUSES OF DEATH ARE UNBALANCED BETWEEN THE TWO ARMS OF THE TRIAL

The data in Tables 1 and 2 show that, despite the finding that the all-cause mortality in both arms of the trial are similar, the causes of death are not balanced. We found that 14 of the 38 deaths, well over one-third of the deaths (36.7%), were the result of cardiac events, with a 3.7-fold increase in deaths due to cardiac events in the treatment arm of the clinical trial. Moreover, the increased number of deaths due to cardiac events more than accounts for the difference between the number of deaths in the BNT162b2 arm (21 deaths) compared to the number in the placebo arm (17 deaths).

Finding a cardiac event signal is consistent with studies carried out following the worldwide rollout of the Pfizer/BioNTech mRNA anti-SARS-CoV-2 vaccine. The cardiac event signal identified in this report is confirmed by reports carried out after the worldwide rollout of the Pfizer/BioNTech mRNA anti-SARS-CoV-2 vaccine. It is important to note that the evidence for the cardiac event signal reported here comes directly from a placebo-controlled randomized clinical trial and thus has none of the caveats associated with retrospective observational post-rollout studies, as noted by the WHO Committee (WHO Ad Hoc Expert Group on the Next Steps for Covid-19 Vaccine Evaluation, 2021). Romero *et al.* (2023) reported a clear increase in the number of cases of acute myocardial infarction and deaths due to heart attack based on their review of several US and international vaccine safety databases including VAERS, the US Department of Defense DMED, CDC's V-Safe, Office of National Statistics of England and Wales, EuroStat of the European Union, and others. In addition, using data from the US Centers for Medicare & Medicaid Services (CMS) covering 30,712,101 elderly persons, Wong *et al.* (2023) found a statistically significant increase in acute myocardial infarction (RR = 1.42).

Barda *et al.* (2021) used observational data on a broad range of potential adverse events collected by Israel's largest health system in an effort to emulate a placebo-controlled clinical trial of the BNT162b2 vaccine. Patients were followed for 42 days after dose 1 of the vaccine, which they acknowledge may be insufficient to demonstrate long-term effects. The study revealed a 3-fold increase in Relative Risk (RR) of myocarditis but only a very modest increase (RR= 1.07) in myocardial infarction. In a separate study of the same Israeli patient pool, Witberg *et al.* (2021) found an increase in the number of cases of myocarditis 3-5 days after receiving each dose of vaccine. The overall estimated incidence rate of myocarditis was 2.13 cases per 100,000 persons with the highest incidence among young males between the ages of 16 and 29 years. Myocarditis is an inflammation of cardiac muscle that can over time lead to cellular damage and severe cardiac insufficiency. Taken together, these findings suggest that cardiac muscle damage is increased following mRNA vaccination.

Mechanisms have been proposed to explain the basis of the adverse effects of the BNT162b2 vaccine on the heart. All center around the toxicity of vaccine-encoded Spike protein (reviewed in Santiago & Oller, 2023); Trougakos *et al.*, 2022)). Stimulation of abnormal micro-clots by Spike protein has been proposed as a factor contributing to the observed tissue damage (reviewed in Kell *et al.*, 2022); Nyström & Hammarström, 2022); De Michele *et al.*, 2022). It is suggested that micro-clots could block blood flow to vascularized tissues such as cardiac muscle causing oxygen deprivation and ischemic damage. Spike protein itself has been shown to alter cardiac pericyte function leading to cardiac vasculature damage via binding to CD147 receptor on cardiac pericyte

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(Avolio *et al.*, 2021). They also show that Spike protein induces pericytes to release inflammatory cytokines through a CD147-independent mechanism that can damage neighboring cardiomyocytes and potentially trigger blood clotting and increasing vascular permeability. Krauson *et al.* (2023) autopsied 20 post-vaccinated patients and 5 non-vaccinated control patients for the presence of vaccine mRNA in various tissues. Vaccine was detected in 2 samples of left ventricle and 2 samples of right ventricle from a total of three patients, all of whom had been vaccinated with BNT162b2 within 30 days of death. The presence of vaccine mRNA in tissue areas was associated with healing myocardial injury and macrophage invasion. It also suggests the potential for localized Spike protein expression and attack by Spike immunopathology. Brogna *et al.* (2023) demonstrated the presence of vaccine-derived Spike protein (PP-Spike) in the blood of only vaccinated individuals for 69-187 days post-vaccination. Persistent expression of the PP-Spike is not explained but it opens up possible long-lasting toxic effects of PP-Spike.

FACTORS CONTRIBUTING TO THE LACK OF TRANSPARENT ADVERSE EVENT REPORTING

Given the fact that deaths due to cardiac events had been occurring from at least week 5, why was the imbalance not reported by the sponsors of the trial prior to week 20? Several factors contributed to the lack of transparency in the C4591001 clinical trial the most glaring of these was that Pfizer/BioNTech did not report the actual date of death that can be found in the subject's Narrative Report but instead used the date that the death was entered into the Case Report Form.

The Case Report Form system used by Pfizer/BioNTech for the C4591001 clinical trial did not conform with accepted industry standards and probably contributed to confusions regarding the cause of death of trial subjects (*6-Month Interim Report of Adverse Events C4591001*). The diagnoses listed in Table 1 were often not evidence-based and the Case Report Form lacked transparency, were not user friendly, and did not appear to provide a complete "chain of custody" of the responses between Pfizer/BioNTech and the trial site medical monitors. These issues become particularly relevant with regard to subjects 11271112 and 10841266, whose cause of death should have been attributed, at least in part, to myocardial infarction (MI) or progression of a pre-existing cardiac ischemia. Trial coordinators were dealing with only 38 deaths, the most serious of serious adverse events (SAEs). Their paramount issue should have been to determine the true cause of death.

In a placebo-controlled randomized clinical trial, causality is determined on a statistical basis at the termination of the trial when information on all participants can be taken into consideration. This is a decision that should not be done by the commercial sponsor of the trial who has a conflict of interest regarding the treatment, as was done in this trial by the sponsor Pfizer/BioNTech. Nor should it be done on a case-by-case basis, as was the case in this clinical trial.

The various oversight boards and the FDA's VRBPAC relied on Pfizer/BioNTech to identify and report any adverse event signals. Due diligence was not done to confirm the trial sponsor's data evaluation. The "Related to Vaccination" category should not have been included in the *6-Month Interim Report of Adverse Events C4591001* or any of Pfizer/BioNTech's published reports. Whether an adverse event is related to the treatment under investigation should have been determined by the regulatory agency overseeing the trial. Since C4591001 was an on-going study during a purported medical emergency, the appropriate time to do that would have been on the day Pfizer/BioNTech

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made its presentation to the FDA VRBPAC, December 10, 2020. This was not done nor was Pfizer/BioNTech required to update their trial data to December 10th.

Our analysis (Table 2) shows that discrepancies in the numbers of deaths reported are observed at two critical time points in the study — November 14th, the data cut-off date for the EUA application, and December 10th, the date of Pfizer/BioNTech's presentation to the FDA VRBAC**.** This had the effect of obscuring a 2-fold increase in the number of deaths due to cardiac events, a critically important "safety" signal that the FDA wanted highlighted as an Adverse Event of Special Interest (AESI) in the C4591001 protocol (https://clinicaltrials.gov/ct2/show/NCT04816643). We found that Pfizer/BioNTech used unnecessarily confusing terminology in their reports. Their list of Preferred Terms had more categories than warranted in light of the pervasive lack of specificity in the Case Report Form concerning medical diagnoses. Additionally, rather than simply giving exact start and ending dates for a time period, Pfizer/BioNTech used vague phrases such as "Open-label observational period" or "After the Unblinding". This was particularly relevant during the analysis of the "Open-label follow-up period" and "Open-label observational period" and likely contributed to the loss of 3 placebo subjects by Thomas *et al.* (2021). Titles of tables found in Pfizer/BioNTech's *Summary Clinical Safety 6-Month Report* do more to confuse the reader than to clarify the data reported therein. Two typical examples follow: "Table 13: Number (%) of Subjects Reporting at Least 1 Adverse Event From dose 1 to 6 Months After dose 2, by System Organ Class and Preferred Term — Subjects With at Least 6 Months of Follow-up Time After dose 2 — Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) — Safety Population" and "Table 19: Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term — Open-Label Follow-up Period — Subjects Who Originally Received BNT162b2 — Phase 2/3 Subjects ≥16 Years of Age — Safety Population".

All told, these techniques served to obfuscate the true evidence from being revealed by the C4591001 clinical trial. The Case Report Form format used by Pfizer/BioNTech was not up to normally expected standards and not transparently maintained. A subject's true date of death appears in the subjects Narrative Report but was not recorded in their Case Report Form in a timely fashion for all subjects regardless of their treatment arm, a critically significant lapse in record keeping. Oversight of the clinical trial's commercial sponsor by the regulatory agencies also was lacking. Moreover, the medical literature publications on the clinical trial were not reviewed and edited with a critical eye or, possibly, without appropriate access to the underlying data.

This report shines light on very serious flaws in the processes used by federal agencies such as the FDA, CDC, and NIH in the development and safety/efficacy evaluation of new drugs. In our opinion, the flaws were made possible by a series of Congressional legislations and amendments that date back decades: the Bayh–Dole Act of 1980 on Patent and Trademark Law Amendments Act, the Project Bioshield Act of 2004, the 2005 Public Readiness and Emergency Preparedness (PREP) Act, and the 2016 21st Century Cures Act. These laws allowed Pfizer/BioNTech, the manufacturing and development corporations of the BNT162b2 mRNA vaccine, to retain full control of the trial's original data while side-stepping all liability considerations. With FDA approval, Pfizer/BioNTech was allowed to block access to the original source data by medical and scientific research experts with no conflicts of interest in the trial vaccine. Information on 44,060 subjects was collected, monitored, evaluated, stored, and analyzed by Pfizer/BioNTech personnel. A review of the C4591001 protocol (https://classic.clinicaltrials.gov/ct2/show/NCT04368728) should have made it obvious that the data from this trial would be massive involving a database of potentially millions of

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medical reports, clinical test results, scheduled and unscheduled visit reports, and more, all of which had to be organized, evaluated, and reported in an extremely short time window. Everything was handled by Pfizer/BioNTech personnel who also authored the reports that were submitted to the FDA and other international medical regulatory agencies, who were given only days to complete their evaluation.

Aspects of this particular clinical trial review were unique. Progress of clinical trials is usually monitored by a Data Safety Monitoring Board (DSMB), a small group of independent experts whose role it to review the safety and efficacy data during the course of the trial and provide advice on whether to continue, modify, or terminate the study. But this was not the case for clinical trial C4591001. Because the Pfizer/BioNTech trial was not funded by the US government, Pfizer/BioNTech was allowed to establish its own DSMB. Thus, the Pfizer/BioNTech DSMB members could not be considered independent and without conflicting interests. The FDA had only a matter of days, November 20 – December 11, to review this massive data set of information to make their decisions regarding safety. Most likely the FDA and its VRBPAC relied far too heavily on summarized reports from Pfizer/BioNTech on their massive data bank of information and on the rigor and thoroughness of the oversight provided by Pfizer/BioNTech's DSMB. Had it not been for the successful court case brought by the Public Health and Medical Professionals for Transparency, no one outside of the Pfizer and BioNTech corporations would have had the opportunity to investigate the original data generated by this clinical trial and none of the discrepancies reported here would have been revealed. The decision to approve the BNT162b2 mRNA vaccine by the US FDA and other international regulatory agencies was not an informed decision based on an unbiased, thorough, and transparent evaluation of the evidence intended to demonstrate that this vaccine met the criteria that it was a "safe and effective" means of responding to the COVID-19 "pandemic".

20 Weeks was not sufficient to evaluate the safety of a novel vaccine

The therapeutic uses of RNA show great promise but are still in the developmental stages (Dolgin, 2021; Sahin *et al.*, 2014). Included in these is the use of mRNA for vaccines (Rcheulishvili *et al.*, 2022). Initially, the use of mRNA vaccines was explored in animal models including the mouse and agricultural animals such as pigs and cows (Geall *et al.*, 2012; Lutz *et al.*, 2017; Schnee *et al.*, 2016). Delivery methods varied from naked mRNA to mRNA-LNP particle. The diseases tested were influenza and rabies. Immune responses could be demonstrated but immunological efficacy against disease or disease transmission was not determined.

Early human clinical trials of the mRNA vaccine technology focused on the development of anti-tumor immunotherapy (Sebastian *et al.*, 2019). The composition of the CV9201 mRNA vaccine was proprietary but the mRNAs were a mixture encoding the five tumour antigens. CV9201 induced a very modest immune response but no impact was observed on progression stage IIIB-IV non-small cell lung cancer target. Alberer *et al.* (2017) carried out an open-label, uncontrolled, prospective, phase 1 clinical trial of an mRNA-based rabies vaccine candidate CV7201 in 101 healthy adults aged 18-40 years. CV7201 mRNA encoded the rabies virus glycoprotein (RABV-G) in free form and complexed with the cationic protein protamine. The trial demonstrated stimulation of an immune response. In another non-randomized, open-label, controlled, dose-escalation, phase 1 clinical trial involving 55 human subjects, Aldrich *et al.* (2021) tested the mRNA-LNP delivery system using

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unmodified mRNA encoding rabies virus glycoprotein. They found a significant immune response comparable to that elicited by the existing rabies vaccine *Rabipur* that consists of inactivated rabies viral particles. The efficacy of these mRNA vaccines has not been tested in humans.

As should be clear from the above discussion, prior to the Pfizer/BioNTech C4591001 clinical trial, only a few very clinical trials of mRNA-LNP vaccines have been carried out. None of these progressed beyond Phase 1 testing to determine dosing levels, which involves a very small number of human volunteers who are fully aware of potential risk they are undertaking. Vaccine approval in the past required 5-10 years or more of safety testing before approval was granted. Given the novel and untested nature of the mRNA-LNP delivery platform, it is difficult to understand why 20-weeks was considered sufficient for the FDA to declare the BNT162b2 vaccine safe. Long-term safety of this mRNA-LNP delivery platform is unknown. The longevity of the immune response stimulated by mRNA-LNP platform and whether transmission of the SARS-CoV-2 virus is prevented is also unknown. The lack of information regarding viral transmission is concerning given the well-established theory that leaky and imperfect vaccines promote the evolution of more highly transmissible pathogens (Read *et al*., 2015).

Most concerning about vaccine BNT162b2 is that pre-clinical testing of Spike protein, the encoded antigen, was not explored by Pfizer. Pfizer considered that Spike was an "endogenous protein" and would be degraded by intracellular processes (Nonclinical Evaluation Report to the Australian Department of Health https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf). Sahin *et al.* (2014) describe several potential dangers of mRNA vaccines. One concern relates directly to the use of Spike protein as the encoded antigen. "It is also conceivable that the expression of a foreign protein together with the pro-inflammatory effects mediated by the mRNA backbone may result in immunopathology on the tissue level." They discuss additional concern of what they refer to as 'content'-specific risks that will depend on characteristics and function of the encoded protein. Such risks will have to be evaluated on a case-by-case basis. Unfortunately, this was not considered when Spike protein was selected as the encoded antigen. In summary, the BNT162b2 vaccine was rushed to production and world-wide distribution without adequately pre-clinical testing and in a timeframe that was insufficient to demonstrate the safety of this entirely novel vaccine.

In the past 50 years, the US has undertaken several mass immunization programs to control viral epidemics. In 1976, 362 cases of Guillain–Barré Syndrome occurred in the 6 weeks following the swine influenza vaccination of 45 million persons, an 8.8-fold increase above normal background rates (Nelson, 2012). Guillain–Barré Syndrome is considered a rare disorder and thus is easily recognized as a safety signal. Death and heart attacks are far more common adverse events. As such, they are not easily recognizable as warning signals. Extremely large numbers of trial subjects and longer follow-up periods are required for these to be identified as serious adverse event safety signals. After tens of millions of doses of the swine influenza vaccine were administered it was not until the deaths of 3 elderly patients in 9 states, all of whom died with heart disease soon after receiving the same vaccine lot, did the FDA call a halt to swine flu vaccinations (Schmeck, 1976; Schwartz, 1976).

Had the FDA been aware of the cardiac event signal documented in this report, regulators might have given second thoughts regarding safety problems with the mRNA vaccine, as was seen in the 1976 swine flu vaccine debacle. Despite evidence of the validity of the early warning signals and other adverse events reported in the post-marketing of the mRNA vaccines, this novel type of

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vaccine platform has not been removed from the market and has even been approved for children as young as 6 months. Why?

CONCLUSIONS

1. The C4591001 placebo-controlled randomized clinical trial of 22,030 vaccinated and 22,030 placebo subjects was the world's only opportunity for an unbiased evaluation of the Pfizer/BioNTech BNT162b2 vaccine.
2. Unblinding of placebo subjects starting in Week 20 terminated the placebo-controlled clinical trial, thereby ending all unbiased evaluation of possible adverse event signals.
3. The mRNA-LNP platform is novel, not previously phase 2/3 tested in humans, and the toxicity of PP-Spike protein was unknown. Taken together, a 20-weeks placebo-controlled clinical trial is NOT sufficient to identify any except for the most common safety concerns.
4. The number of all-cause deaths is NOT decreased by BNT162b2 vaccination.
5. Of the 38 deaths reported in the 6-Month Interim Report of Adverse Events, 21 BNT162b2 vaccinated subjects died compared to 17 placebo subjects.
6. Delayed reporting of the subject deaths into the Case Report Form, which was in violation of the trial protocol, allowed the EUA to proceed unchallenged.
7. The number of subject deaths was 17% of the expected number, based on age-adjusted US mortality. One possible explanation could lie in the 395 subjects that were "Lost to Follow-up".
8. There was a 3.7-fold increase in cardiac events in subjects who received the BNT162b2 vaccine *versus* the placebo.
9. Of the 15 subjects who were Sudden Adult Deaths (SAD) or Found Dead (FD), 12 died of a cardiac event, 9 of whom were vaccinated.
10. The cardiac adverse event signal was obscured by delays in reporting the accurate date of subject death that was known to Pfizer/BioNTech in the subject's Narrative Report.

Competing Interests

None.

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16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=4377

16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age https://phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf#page=233

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