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 in that it is the first study of the

original data from the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial (CA4591001) 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 data end date of their 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 vaccinated or the Placebo control (0.9% normal saline). At Week 20, when the BNT162b2 mRNA vaccine received Emergency Use Authorization from the U.S. FDA, subjects in the placebo arm were given the option to be BNT162b2 vaccinated. All but a few accepted. 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 were unblinded and vaccinated, deaths among this still unvaccinated cohort of this group slowed and eventually plateaued. Deaths in the BNT162b2 vaccinated subjects continued at the same rate. Our analysis revealed inconsistencies between the subject data listed in the 6-Month Interim Report and 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 cardiovascular events in BNT162b2 vaccinated subjects compared to Placebo controls. This significant adverse event signal was not reported by Pfizer/BioNTech. Potential sources of these data inconsistencies are identified.

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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

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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