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# Pfizer BioNtech Study: Vaccine has adverse event risks

By **DEEPCENTER05**

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Pfizer-BioNTech COVID-19 Vaccine
VRBPAC Briefing Document

**Table 3. Disposition of All Randomized Participants, Phase 2/3 Safety Population**

| Treatment Group | BNT162b2 N=18904 n (%) | Placebo N=18892) n (%) | Total N=37796 n (%) |
|---|---|---|---|
| Randomized | 18904 (100.0) | 18892 (100.0) | 37796 (100.0) |
| Vaccinated | | | |
| Completed 1 dose | 18858 (99.8) | 18849 (99.8) | 37707 (99.8) |
| Completed 2 doses | 18555 (98.2) | 18533 (98.1) | 37088 (98.1) |
| Withdrawn from Study | 180 (1.0) | 259 (1.4) | 439 (1.2) |
| Reason for Withdrawal | | | |
| Adverse Event | 8 (0.0) | 5 (0.0) | 13 (0.0) |
| Death | 2 (0.0) | 4 (0.0) | 6 (0.0) |
| Withdrawal by Subject | 84 (0.4) | 157 (0.8) | 241 (0.6) |
| Lost to Follow-up | 80 (0.4) | 86 (0.5) | 166 (0.4) |
| No longer meets eligibility criteria | 1 (0.0) | 2 (0.0) | 3 (0.0) |
| Refused further study procedures | 0 | 1 (0.0) | 1 (0.0) |

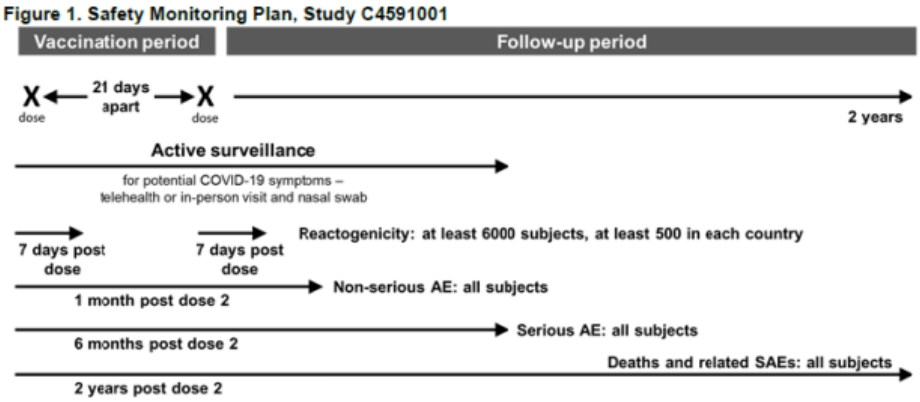
Source: EUA 27036, amendment 3, Table 2; c4591001-safety-tables-cos-reacto.pdf, page 43.
Note: One participant was randomized but did not sign informed consent and therefore not included in any analysis population.
Note: 120 HIV-positive participants included in this table. HIV population analyses were summarized separately from analyses based on the phase 2/3 safety population, but included in the all-enrolled poplation analyses presented in this briefing document.
%:n/N. n = number of subjects with the specified characteristic. N = number of participants ≥16 years of age enrolled by October 9, 2020, including 120 HIV-positive participants, and received at least 1 dose of study vaccine or placebo. N is the denominator used for the percentage calculations.
Data analysis cutoff date: November 14, 2020

One cannot stress how untested this vaccine is. How the FDA would approve this against the known risks of COVID-19, which are very low (under 0.2%), but for a specific population *with comorbidity issues* that impact them for every flu season (approximately 5%). These people are, in totality, over 55, that have been most impacted (90%+ of U.S. Deaths).

Meanwhile, this study, noted:

> ***The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%); severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after Dose 2 than after Dose 1, and were generally less frequent in participants ≥55 years of age (≤2.8%) as compared to younger participants (≤4.6%). The frequency of serious adverse events was low (<0.5%), without meaningful imbalances between study arms. Among non-serious unsolicited adverse events, there was a numerical imbalance of four cases of Bell's palsy in the vaccine group compared with no cases in the***

> ***placebo group, though the four cases in the vaccine group do not represent a frequency above that expected in the general population.***
>
> *https://www.fda.gov/media/144245/download*




Even Pfizer notes a need for a 2-year follow up period. So what we are witnessing is an unethical push of immediate vaccine approval, **without the approximate study run time to deduce "actual fallout rates"** from this vaccine. The rates at present for adverse events, should give one pause.

The prophylactic route is FAR FAR MORE ethical and reasonable and cost effective. The reasoning I gather is to push vaccine to get compliance on a host of other issues BIG centralized government feel is necessary. To follow a one-world desire that CHINA caused and is profiting from. That the UK, Russia, China have begun vaccination on the general population should give one great concern.

All within a year of Jan 14 WHO statement of "no human to human transmission." And 11 months later, we have vaccines for the super-virus that isn't at all. (1968-69 was 4X as lethal, with much less population. The world did not panic.)

VRBPAC-12.10.20-Meeting-Briefing-Document-FDA

***Investigating Adverse Events — I don't need p-value to know these are significantly different from the placebo. This vaccine***

***is worse than the COVID-19! And you are "allegedly" gonna have to take it again and again.***

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| Adverse Event | BNT162b2 Dose 1 N=2238 n (%) | Placebo Dose 1 N=2248 n (%) | BNT162b2 Dose 2 N=2045 n (%) | Placebo Dose 2 N=2053 n (%) |
|---|---|---|---|---|
| Fatigue[a] | | | | |
| Any | 1085 (47.4) | 767 (33.4) | 1247 (59.4) | 479 (22.8) |
| Mild | 597 (26.1) | 46 (20.3) | 442 (21.1) | 248 (11.8) |
| Moderate | 455 (19.9) | 289 (12.6) | 708 (33.7) | 217 (10.3) |
| Severe | 33 (1.4) | 11 (0.5) | 97 (4.6) | 14 (0.7) |
| Headache[a] | | | | |
| Any | 959 (41.9) | 775 (33.7) | 1085 (51.7) | 506 (24.1) |
| Mild | 628 (27.4) | 505 (22.0) | 538 (25.6) | 321 (15.3) |
| Moderate | 308 (13.4) | 251 (10.9) | 480 (22.9) | 170 (8.1) |
| Severe | 23 (1.0) | 19 (0.8) | 67 (3.2) | 15 (0.7) |
| Chills[a] | | | | |
| Any | 321 (14.0) | 146 (6.4) | 737 (35.1) | 79 (3.8) |
| Mild | 230 (10.0) | 111 (4.8) | 359 (17.1) | 65 (3.1) |
| Moderate | 82 (3.6) | 33 (1.4) | 333 (15.9) | 14 (0.7) |
| Severe | 9 (0.4) | 2 (0.1) | 45 (2.1) | 0 (0.0) |
| Vomiting[b] | | | | |
| Any | 28 (1.2) | 28 (1.2) | 40 (1.9) | 25 (1.2) |
| Mild | 24 (1.0) | 22 (1.0) | 28 (1.3) | 16 (0.8) |
| Moderate | 4 (0.2) | 5 (0.2) | 8 (0.4) | 9 (0.4) |
| Severe | 0 (0.0) | 1 (0.0) | 4 (0.2) | 0 (0.0) |
| Diarrhea[c] | | | | |
| Any | 255 (11.1) | 270 (11.7) | 219 (10.4) | 177 (8.4) |
| Mild | 206 (9.0) | 217 (9.4) | 179 (8.5) | 144 (6.8) |
| Moderate | 46 (2.0) | 52 (2.3) | 36 (1.7) | 32 (1.5) |
| Severe | 3 (0.1) | 1 (0.0) | 4 (0.2) | 1 (0.0) |
| New or worsened muscle pain[a] | | | | |
| Any | 487 (21.3) | 249 (10.8) | 783 (37.3) | 173 (8.2) |
| Mild | 256 (11.2) | 175 (7.6) | 326 (15.5) | 111 (5.3) |
| Moderate | 218 (9.5) | 72 (3.1) | 410 (19.5) | 59 (2.8) |
| Severe | 13 (0.6) | 2 (0.1) | 47 (2.2) | 3 (0.1) |
| New or worsened joint pain[a] | | | | |
| Any | 251 (11.0) | 138 (6.0) | 459 (21.9) | 109 (5.2) |
| Mild | 147 (6.4) | 95 (4.1) | 205 (9.8) | 54 (2.6) |
| Moderate | 99 (4.3) | 43 (1.9) | 234 (11.2) | 51 (2.4) |
| Severe | 5 (0.2) | 0 (0.0) | 20 (1.0) | 4 (0.2) |
| Use of antipyretic or pain medication | 638 (27.8) | 332 (14.4) | 945 (45.0) | 266 (12.6) |

Source: adapted from EUA 27036, amendment 3, Table 19.
n = number of participants with the specified reaction.
N = number of participants in the reactogenicity subset reporting at least 1 yes or no response for the specified reaction after the specified dose.
[a] Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity.
[b] Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration.
[c] Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours.
* Participants in the reactogenicity subset of the safety population ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.
Data analysis cutoff date: November 14, 2020.

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**Table 19. Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants in any Treatment Group from Dose 1 to 1-month After Dose 2, Phase 2/3 Safety Population*, 16 Years of Age and Older**

| System Organ Class<br>Preferred Term | BNT162b2<br>N=18801<br>n (%) | Placebo<br>N=18785<br>n (%) | Total<br>N=37586<br>n (%) |
|---|---|---|---|
| General disorders and administration site conditions | 3521 (18.7) | 737 (3.9) | 4258 (11.3) |
| Injection site pain | 2125 (11.3) | 286 (1.5) | 2411 (6.4) |
| Fatigue | 1029 (5.5) | 260 (1.4) | 1289 (3.4) |
| Pyrexia | 1146 (6.1) | 61 (0.3) | 1207 (3.2) |
| Chills | 999 (5.3) | 87 (0.5) | 1086 (2.9) |
| Pain | 455 (2.4) | 36 (0.2) | 491 (1.3) |
| Musculoskeletal and connective tissue disorders | 1387 (7.4) | 401 (2.1) | 1788 (4.8) |
| Myalgia | 909 (4.8) | 126 (0.7) | 1035 (2.8) |
| Arthralgia | 212 (1.1) | 82 (0.4) | 294 (0.8) |
| Nervous system disorders | 1158 (6.2) | 460 (2.4) | 1618 (4.3) |
| Headache | 973 (5.2) | 304 (1.6) | 1277 (3.4) |
| Gastrointestinal disorders | 565 (3.0) | 368 (2.0) | 933 (2.5) |
| Diarrhoea | 194 (1.0) | 149 (0.8) | 343 (0.9) |
| Nausea | 216 (1.1) | 63 (0.3) | 279 (0.7) |

Source: FDA analysis.

***Pfizer Vax. 4.8x more likely than the placebo to get a host of responses. Majority are moderate or severe.***

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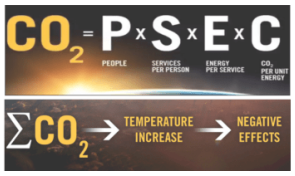


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