

Data Fitness Findings Report

IND27034

BioNTech SE and Pfizer, April 2021

| Findings | | | Notes |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|------------|-------|
| C4591001 EUA Amendment (12-15 Years of Age) | | | |
| Title: <i>A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals.</i> | | | |
| Document / Standard | Version | Notes | |
| annotated CRF | | Seems fine | |
| SDTM Implementation Guide | SDTM-IG v3.2 | | |
| SDTM Controlled Terminology | 2020-03-27 | | |
| SDTM define.xml | V2.0 | Seems fine | |
| Medications Dictionary | WHODD GLOBALV3Mar20, WHO DDE v202003 | | |
| Medical Events Dictionary (MedDRA) | V23.1 | | |
| SDTM Reviewer's Guide | PhUSE template | Seems fine | |

Data Issues

Adverse event marked as AEREL = RELATED, but subject didn't receive dose yet

- USUBJID = C4591001 1226 12261520, AETERM = Pain at injection site, AESTDTC = 2020-09-02T21:00
 - 2 EX records: EXSTDTC = 2020-09-03T15:06:00 and 2020-09-22T10:22:00

Subjects have AE records with AEACN = DRUG WITHDRAWN but no ADVERSE EVENT record in DS

- 26 subjects – see report "[IND27034 - 12-15years - AEACN of DRUG WITHDRAWN but no DS ADVERSE EVENT record.xlsx](#)"

Duplicate value for CESEQ variable

- 1 record (0%)
- cSDRG explanation: "This is a false positive by P21 and is part of a known issue for SD0005 -- rule logic is flagging falsely (per P21 support). The team confirmed that there is only one record with USUBJID='C4591001 1231 12315324' and CESEQ=460000000004 in CE domain."

VIEWTABLE: Study1.Ce (Clinical Events)

| | STUDYID | DOMAIN | USUBJID | CESEQ | CEGRPID | CELNKGPR | CETERM | CEOCCUR | CESTDTC |
|--------|----------|--------|------------------------|--------------|---------|----------|--------------------------------------|---------|------------|
| 348978 | C4591001 | CE | C4591001 1231 12315324 | 460000000001 | | | COVID-19 | | |
| 348979 | C4591001 | CE | C4591001 1231 12315324 | 460000000002 | | | COVID-19 confirmed | Y | 2020-12-25 |
| 348980 | C4591001 | CE | C4591001 1231 12315324 | 460000000003 | | | COVID-19 like illness | Y | 2020-12-25 |
| 348981 | C4591001 | CE | C4591001 1231 12315324 | 460000000004 | | | CHILLS | Y | |
| 348982 | C4591001 | CE | C4591001 1231 12315324 | 460000000004 | | | Acute Kidney Failure | | 2021-01-14 |
| 348983 | C4591001 | CE | C4591001 1231 12315324 | 460000000005 | | | DIARRHEA | N | |
| 348984 | C4591001 | CE | C4591001 1231 12315324 | 460000000006 | | | FEVER | Y | |
| 348985 | C4591001 | CE | C4591001 1231 12315324 | 460000000007 | | | NEW LOSS OF TASTE OR SMELL | N | |
| 348986 | C4591001 | CE | C4591001 1231 12315324 | 460000000008 | | | NEW OR INCREASED COUGH | Y | |
| 348987 | C4591001 | CE | C4591001 1231 12315324 | 460000000009 | | | NEW OR INCREASED MUSCLE PAIN | N | |
| 348988 | C4591001 | CE | C4591001 1231 12315324 | 460000000010 | | | NEW OR INCREASED SHORTNESS OF BREATH | N | |
| 348989 | C4591001 | CE | C4591001 1231 12315324 | 460000000011 | | | NEW OR INCREASED SORE THROAT | N | |
| 348990 | C4591001 | CE | C4591001 1231 12315324 | 460000000012 | | | VOMITING | N | |

| <p>Value for CEHLGT not found in MedDRA dictionary</p> <ul style="list-style-type: none"> • 1 record (0%) • cSDRG explanation: "Manually coded as "Virus infectious disorders"." • The correct value per the MedDRA dictionary is: Viral infectious disorders | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------|-----------------------------------------------------|---------------------------------------------------------------------|----------|--------------|--------------|---------|-------------|-------------|----------------------------------------------------------|------------------------------------------|---------------------------------------------------------------------|----------|----|------|-------------|------------------------|-----------------------|-----------------------------------------------------|---------------------------------|----------|---|------|--|
| <p>NULL value in DDTEST variable marked as Required</p> <ul style="list-style-type: none"> • 2 records (4.17%) <p>NULL value in DDTESTCD variable marked as Required</p> <ul style="list-style-type: none"> • 2 records (4.17%) <p>Missing value for DDSTRESC, when DDSTAT is null</p> <ul style="list-style-type: none"> • 2 records (4.17%) <p>cSDRG explanation: "Subject C4591001 1135 11351033 - official death certificate and autopsy results are awaited so that cause of death can be updated. Query is present to track the issue. subject C4591001 1088 10881126 - Primary cause of death is already reported as Cardiac Arrest, there is a blank extra log line on the form that has already been queried to be deleted."</p> | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Inconsistent coding of MHTERM</p> <table border="1" data-bbox="149 808 1759 1105"> <thead> <tr> <th>mhterm</th> <th>mhdecod</th> <th>mhhlt</th> <th>mhhlgt</th> <th>mhbodsys</th> <th>STUDYID</th> <th>count_of_mhs</th> <th>meddrav</th> </tr> </thead> <tbody> <tr> <td>SKIN CANCER</td> <td>SKIN CANCER</td> <td>SKIN NEOPLASMS MALIGNANT AND UNSPECIFIED (EXCL MELANOMA)</td> <td>SKIN NEOPLASMS MALIGNANT AND UNSPECIFIED</td> <td>NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)</td> <td>C4591001</td> <td>20</td> <td>23.1</td> </tr> <tr> <td>SKIN CANCER</td> <td>SKIN NEOPLASM EXCISION</td> <td>SKIN LESION EXCISIONS</td> <td>SKIN AND SUBCUTANEOUS TISSUE THERAPEUTIC PROCEDURES</td> <td>SURGICAL AND MEDICAL PROCEDURES</td> <td>C4591001</td> <td>1</td> <td>23.1</td> </tr> </tbody> </table> | mhterm | mhdecod | mhhlt | mhhlgt | mhbodsys | STUDYID | count_of_mhs | meddrav | SKIN CANCER | SKIN CANCER | SKIN NEOPLASMS MALIGNANT AND UNSPECIFIED (EXCL MELANOMA) | SKIN NEOPLASMS MALIGNANT AND UNSPECIFIED | NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) | C4591001 | 20 | 23.1 | SKIN CANCER | SKIN NEOPLASM EXCISION | SKIN LESION EXCISIONS | SKIN AND SUBCUTANEOUS TISSUE THERAPEUTIC PROCEDURES | SURGICAL AND MEDICAL PROCEDURES | C4591001 | 1 | 23.1 | |
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