

Application: IND27034
Study: c4591001-safety-fa-eff
EDR Sequence: 0001

Generated: 2020-11-21T01:53:41

Version: 2.5.3

[Data Standards Training](#)

[EDR Link: \\cber-fs3\m\CTD_Submissions\IND27034\0001\m5\datasets\c4591001\tabulations\sdm-safety-fa-eff](#)

[EDR Link: \\cber-fs3\m\CTD_Submissions\IND27034\0001\m5\datasets\c4591001\analysis\adam\datasets-safety-fa-eff](#)

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 ADULTS

Summary

Documents

[Study Data Reviewer's Guide](#)
[Analysis Data Reviewer's Guide](#)
[SDTM Define.xml](#)
[ADaM Define.xml](#)

Standards / Dictionaries

SDTM-IG 3.2
SDTM-CT 2020-06-26
MedDRA 23.1

Subjects / Actual Arms

43850 - Subjects
2 (0.0%) -
24 (0.1%) - B1_10
12 (0.0%) - B1_100
24 (0.1%) - B1_20
24 (0.1%) - B1_30
24 (0.1%) - B2_10
24 (0.1%) - B2_20
24 (0.1%) - B2_30
21771 (49.6%) - B2_P23_30
21819 (49.8%) - PLACEBO
102 (0.2%) - Likely Not Treated

Datasets

49 - Total SDTM Datasets
0 - Custom Datasets
19 - Suppqul Datasets
9 - ADaM Datasets (ADAE, ADC19EF, ADCEVD, ADDS, ADFACEVD, ADMH, ADSL, ADSYMP, ADVA)

Potential Data Quality Issues

Demographics

[1,055 of 43,850 \(2.4%\) RACE values not found in CDISC codelist](#)
[2 \(<0.1%\) of values for required variable ACTARM are missing](#)
[2 \(<0.1%\) of values for required variable ACTARMCD are missing](#)
[111 of 43,850 \(0.3%\) subjects have a different actual arm than planned](#)

Disposition

[9 \(<0.1%\) of disposition events are missing Start Date/Time of Disposition Event \(DSSTDTC\) and Study Day of Start of Disposition](#)
[205 \(0.1%\) of disposition statuses or protocol milestones are potential duplicates](#)

Exposure

[7,259 \(8.5%\) of treatments have ended after the last disposition date](#)

Adverse Events

[2,472 of 20,316 \(12.2%\) adverse events have started after the last disposition date](#)
[20,317 \(100.0%\) of adverse events are missing treatment emergent flag in SUPPAE](#)
[1,713 \(8.4%\) of adverse events have neither severity or toxicity grade populated](#)
[Values Not Found in MedDRA Dictionary](#)

Clinical Events

[3 \(<0.1%\) of events are missing start time-point](#)
[72,155 \(24.3%\) of clinical events are potential duplicates](#)

Laboratory

[Laboratory results use inconsistent values for Standard Units \(LBSTRESU\)](#)
[134 of 21,710 \(0.6%\) observations are missing Reference Range Upper Limit in Standard Units \(LBSTNRHI\)](#)
[10,056 \(22.9%\) of subjects are either missing a lab test or a baseline value](#)

Vital Signs

[78 \(<0.1%\) of vital sign results are potential duplicates](#)

General Findings

[1 \(<0.1%\) of CO domain records reference non-existent data in related domain](#)
[Study events are missing end time-points](#)
[Study subjects are missing all baseline flags for all tests present in the dataset](#)
[Standard Results \(-STRESC\) or Standard Units \(-STRESU\) are missing](#)

Traceability

[1,364 \(6.7%\) of Adverse Events in SDTM AE are not present in ADAE](#)

Reports to Help Basic Review Activities

Deaths

[Death Summary](#)

Application: IND27034
Study: c4591001
EDR Sequence: 0135

Generated: 2021-04-11T00:24:53

Version: 2.5.3

[Data Standards Training](#)

[EDR Link: \\cber-fs3\m\CTD_Submissions\IND27034\0135\m5\datasets\c4591001\tabulations\sdm](#)

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Standards / Dictionaries

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MedDRA 23.1

Subjects / Actual Arms

48091 - Subjects
24 (0.0%) - B1_10
12 (0.0%) - B1_100
24 (0.0%) - B1_20
24 (0.0%) - B1_30
24 (0.0%) - B2_10
24 (0.0%) - B2_20
24 (0.0%) - B2_30
23170 (48.2%) - B2_P23_30
23198 (48.2%) - PLACEBO
1295 (2.7%) - Likely Screen Failures
160 (0.3%) - Likely Not Assigned
112 (0.2%) - Likely Not Treated

Datasets

49 - Total SDTM Datasets
0 - Custom Datasets
19 - Suppqual Datasets
11 - ADaM Datasets (ADAE, ADC19EF, ADCEVD, ADCM, ADDS, ADDV, ADFACEVD, ADMH, ADSL, ADSYMPT, ADVA)

Potential Data Quality Findings

Demographics

[1,166 of 48,091 \(2.4%\) RACE values not found in CDISC codelist](#)
[1 of 1,295 \(<0.1%\) screen failure subjects do not have information in Inclusion/Exclusion Criteria Not Met \(IE\) domain](#)
[120 of 48,091 \(0.2%\) subjects have a different actual arm than planned](#)

Disposition

[1 of 283,689 \(<0.1%\) values for required variable DSTERM are missing](#)
[1 of 283,689 \(<0.1%\) values for required variable DSDECOD are missing](#)
[438 of 283,688 \(0.2%\) disposition statuses or protocol milestones are potential duplicates](#)

Exposure

[8,857 of 128,126 \(6.9%\) treatments have ended after the last disposition date](#)

Adverse Events

[4,558 of 39,500 \(11.5%\) adverse events have started after the last disposition date](#)
[39,501 of 39,501 \(100.0%\) adverse events are missing treatment emergent flag in SUPPAE](#)
[5 of 39,501 \(<0.1%\) adverse events are potential duplicates](#)
[2,627 of 39,501 \(6.7%\) adverse events have neither severity or toxicity grade populated](#)
[Values Not Found in MedDRA Dictionary](#)

Clinical Events

[1 of 57,273 \(<0.1%\) events are missing start time-point](#)
[99,527 of 379,126 \(26.3%\) clinical events are potential duplicates](#)

Laboratory

[Laboratory results use inconsistent values for Standard Units \(LBSTRESU\)](#)
[303 of 30,380 \(1.0%\) observations are missing Reference Range Upper Limit in Standard Units \(LBSTNRHI\)](#)
[10,161 of 48,091 \(21.1%\) subjects are either missing a lab test or a baseline value](#)

Vital Signs

[1 of 419,178 \(<0.1%\) vital sign results are potential duplicates](#)

General Findings

[2 of 12,963 \(<0.1%\) CO domain records reference non-existent data in related domain](#)
[Study events are missing end time-points](#)
[Study subjects are missing all baseline flags for all tests present in the dataset](#)
[Standard Results \(-STRESC\) or Standard Units \(-STRESU\) are missing](#)

Traceability

[2,192 of 39,501 \(5.5%\) Adverse Events in SDTM AE are not present in ADAE](#)

Reports to Help Basic Review Activities

Deaths

Application: IND27034
Study: c4591001
EDR Sequence: 0135

Generated: 2021-04-19T14:50:47

Version: 2.5.3

[Data Standards Training](#)

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Standards / Dictionaries

SDTM-IG 3.2
MedDRA 23.1

Subjects / Actual Arms

29417 - Subjects
12 (0.0%) - B1_10
12 (0.0%) - B1_100
12 (0.0%) - B1_20
12 (0.0%) - B1_30
12 (0.0%) - B2_10
12 (0.0%) - B2_20
12 (0.0%) - B2_30
14206 (48.3%) - B2_P23_30
14253 (48.5%) - PLACEBO
697 (2.4%) - Likely Screen Failures
109 (0.4%) - Likely Not Assigned
68 (0.2%) - Likely Not Treated

Datasets

48 - Total SDTM Datasets
0 - Custom Datasets
19 - Suppqal Datasets
11 - ADaM Datasets (ADAE, ADC19EF, ADCEVD, ADCM, ADDS, ADDV, ADFACEVD, ADMH, ADSL, ADSYMPT, ADVA)

Potential Data Quality Findings

Demographics

[951 of 29,417 \(3.2%\) RACE values not found in CDISC codelist](#)
[71 of 29,417 \(0.2%\) subjects have a different actual arm than planned](#)

Disposition

[328 of 171,496 \(0.2%\) disposition statuses or protocol milestones are potential duplicates](#)

Exposure

[5,231 of 76,685 \(6.8%\) treatments have ended after the last disposition date](#)

Adverse Events

[3,022 of 25,854 \(11.7%\) adverse events have started after the last disposition date](#)
[25,854 of 25,854 \(100.0%\) adverse events are missing treatment emergent flag in SUPPAE](#)
[1,919 of 25,854 \(7.4%\) adverse events have neither severity or toxicity grade populated](#)
[Values Not Found in MedDRA Dictionary](#)

Clinical Events

[1 of 41,729 \(<0.1%\) events are missing start time-point](#)
[64,004 of 247,875 \(25.8%\) clinical events are potential duplicates](#)

Laboratory

[Laboratory results use inconsistent values for Standard Units \(LBSTRESU\)](#)
[129 of 17,718 \(0.7%\) observations are missing Reference Range Upper Limit in Standard Units \(LBSTNRHI\)](#)
[10,162 of 29,417 \(34.5%\) subjects are either missing a lab test or a baseline value](#)

Vital Signs

No significant findings

General Findings

[1 of 9,001 \(<0.1%\) CO domain records reference non-existent data in related domain](#)
[Study events are missing end time-points](#)
[Study subjects are missing all baseline flags for all tests present in the dataset](#)
[Standard Results \(-STRESC\) or Standard Units \(-STRESU\) are missing](#)

Traceability

[1,630 of 25,854 \(6.3%\) Adverse Events in SDTM AE are not present in ADAE](#)

Reports to Help Basic Review Activities

Deaths