**Leveraging CORE for Real-Time Validation –
No More Endless Iterations!**

Eyal Wultz, President & Co-founder, Bioforum

# Meet the Speaker

Eyal Wultz

Title: President & Co-founder
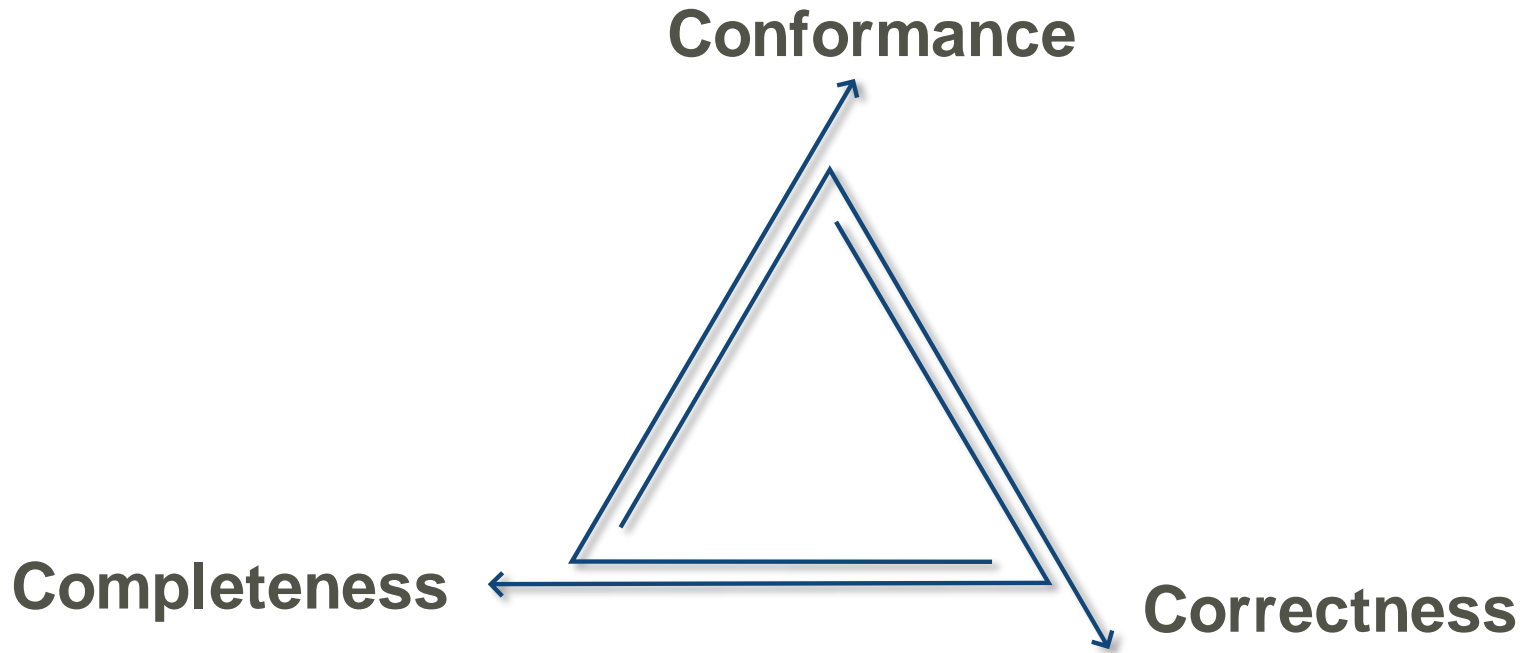
Organization: Bioforum

20+ being passionate about clinical data and technology innovation!

# Disclaimer and Disclosures

*The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

# DATA QUALITY



**Conformance**

**Completeness**

**Correctness**

# RAFFLE

**Answer the following two questions…**

**Get into the raffle!**

Microsoft Surface Pro 9

cdisc

# How can I know **for sure** that **all my clinical data** end up in SDTM?

# Double Programming?

## 💡 Double programming is not the answer…

➢ **Changing data** (re-runs)…
  • If changes in data values, variables, etc. are not updated in both programs – results will be the same, leaving out the data changes
➢ **Same specs – same errors**
➢ Two programmers working in the same organization are **never really independent**
  • Same SOPs
  • Same programing practices
  • Same macros/snippets

# How can you show an **audit trail** of your SDTM data transformations?

**Code of Federal Regulations (CFR) Title 21**
**Part 11 - ELECTRONIC RECORDS; ELECTRONIC SIGNATURES**

(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and **actions that create, modify, or delete electronic records**. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

If you have answers or want to hear ours and see how **CDISC** can helps drive this forward…

# CDISC CORE and real-time validation

# JetConvert.

## SDTM SUBMISSION READY PACKAGE

in **3 weeks** with **superior quality**
and at least **25% less cost**
compared to the industry average

No SAS & no programming

ML-guided mapping recommendations

Real-time validation

Automatic aCRF & Define.xml generation

▦ **Data Table** ⓘ  💡 Insights 3

| VISIT | VSTAT | SUBJECT | TEMP | HGT_U | HGT | HGT_STAT |
|---|---|---|---|---|---|---|
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | cm | 184 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | cm | 184 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | cm | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | meter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | | | 38.4 | | | ND |
| Visit 2 | | 707-01 | 38.4 | cm | 184 | |
| Visit 2 | | 707-01 | 38.4 | meter | 1.84 | |
| Visit 2 | Y | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | Y | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | Y | 707-01 | 38.4 | | | |
| Visit 2 | Y | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | | 707-01 | 38.4 | | | ND |
| Visit 2 | | 707-01 | 38.4 | | | ND |
| Visit 2 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | Y | 707-01 | 38.4 | cm | 184 | ND |
| Visit 2 | Y | 707-01 | 38.4 | centimeter | 184 | |

📄 **CRF** ⓘ

Version 1.0 - Example (07-Nov-19)
Form: Vital Signs

Date of Assessment: ☐ Same as Visit Date ☐ Different than Visit Date ☐ Not Done, please specify:

Date of Assessment: _____

Time of Assessment: _____

Systolic Blood Pressure _____ Fixed Unit: mmHg

Test not performed? (Y/N) _____

Diastolic Blood Pressure _____ Fixed Unit: mmHg

Test not performed? (Y/N) _____

Heart Rate _____ Fixed Unit: beats/min

Test not performed? (Y/N) _____

Body Temperature _____

Test not performed? (Y/N) _____

Version 1.0 Example (07-Nov-19) (17)    24 of 117

Version 1.0 - Example (07-Nov-19)
Form: Vital Signs

Date of Assessment: ☐ Same as Visit Date ☐ Different than Visit Date

< 1/12 >    65% − +

⧉ **Mapping** ⓘ

**Variables (9)**    Domains    Add Domain

All
No Domain

With Domain

SYSBP VS ⚡
DIABP VS ⚡
SUBJE... DM ⚡
HGT VS ⚡
VISIT DM ⚡
TEMP VS ⚡
Event AE

No Domain

IDLABEL
STATPRC

0 Domains, Please add

Approve Or Dismiss The Following Domains:

DM ⚡ Demographics ✓ ✗
VS ⚡ Vital Signs ✓ ✗
AE ⚡ Adverce Events ✓ ✗

# Consolidated user interface linking all artefacts

**Raw data**    **CRF**    **Mapping Rules**

≡ **Results Tables** Vital Signs *SDTM Preview* **ALL MAPPINGS / VS / MAPPING 1**

| STUDYID | DOMAIN | USUBJID | VSTESTCD | VSTEST | VSPOS | VSSTRESN | VSSTRESU | VSSTAT | VISIT | VST |
|---|---|---|---|---|---|---|---|---|---|---|
| XMR-FMQ-02 | VS | XYZ-707-01 | TEMP | Temperture | Recommended | 38.4 | C | Recommended | Screen 1 | 10I |
| XMR-FMQ-02 | VS | XYZ-707-01 | TEMP | Temperture | Recommended | 38.4 | C | Recommended | Screen 1 | 10I |
| XMR-FMQ-02 | VS | XYZ-707-01 | TEMP | Temperture | Recommended | 38.4 | C | Recommended | Screen 1 | 10N |
| XMR-FMQ-02 | VS | XYZ-707-01 | TEMP | Temperture | Recommended | 38.4 | C | Recommended | Screen 1 | |

**SDTM data**

## ▦ Data Table ⓘ | 💡 Insights 3

📊 🔽 🔍 ⬈ ⤢

| VISIT | VSTAT | SUBJECT | TEMP | HGT_U | HGT | HGT_STAT |
|-------|-------|---------|------|-------|-----|----------|
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | cm | 184 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | cm | 184 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | cm | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
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| Visit 1 | Y | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | Y | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | Y | 707-01 | 38.4 | centimeter | 184 | |
| Visit 1 | | 707-01 | 38.4 | meter | 1.84 | |
| Visit 1 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | | 707-01 | 38.4 | meter | 1.84 | |
| Visit 2 | | 707-01 | 38.4 | | | ND |
| Visit 2 | | 707-01 | 38.4 | cm | 184 | |
| Visit 2 | | 707-01 | 38.4 | meter | 1.84 | |
| Visit 2 | Y | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | Y | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | Y | 707-01 | 38.4 | | | |
| Visit 2 | Y | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | | 707-01 | 38.4 | | | ND |
| Visit 2 | | 707-01 | 38.4 | | | ND |
| Visit 2 | | 707-01 | 38.4 | centimeter | 184 | |
| Visit 2 | | 707-01 | 38.4 | cm | 184 | |
| Visit 2 | Y | 707-01 | 38.4 | | | ND |
| Visit 2 | Y | 707-01 | 38.4 | centimeter | 184 | |

## 📄 CRF ⓘ

⬈ ⤢

Version 1.0 - Example (07-Nov-19)
Form: Vital Signs

Date of Assessment:　　　　　　　　Same as Visit Date ☐
　　　　　　　　　　　　　　　Different than Visit Date ☐
　　　　　　　　　　　　　　　Not Done, please specify: ☐

Date of Assessment: _____

Time of Assessment: _____

Systolic Blood Pressure　　　　　Fixed Unit: mmHg

Test not performed? (Y/N) _____

Diastolic Blood Pressure　　　　　Fixed Unit: mmHg

Test not performed? (Y/N) _____

Heart Rate　　　　　　　　　Fixed Unit: beats/min

Test not performed? (Y/N) _____

Body Temperature _____

Test not performed? (Y/N) _____

Version 1.0 Example　　　　　　24 of 117
(07-Nov-19) (17)

Version 1.0 - Example (07-Nov-19)
Form: Vital Signs

Date of Assessment:　　　　　　　Same as Visit Date ☐
　　　　　　　　　　　　　Different than Visit Date ☐

‹ 1/12 › 　65% ─ +

## 🔗 Mapping ⓘ

⬈ ⤢

### Variables (9)

All
No Domain

With Domain

SYSBP ⚡
DIABP ⚡
SUBJE... ⚡
HGT ⚡
VISIT ⚡
TEMP ⚡
Event ⚡

No Domain

IDLABEL
STATPRC

### Domains

Add Domain

⊕ 0 Domains, Please add

Approve Or Dismiss The Following Domains:

DM ⚡ Demographics ✓ ✗

VS ⚡ Vital Signs ✓ ✗

AE ⚡ Adverce Events ✓ ✗

## ≡ Results Tables — Vital Signs — *SDTM Preview* **ALL MAPPINGS / VS / MAPPING 1**

🔽 ⬈ ⤢

| STUDYID | DOMAIN | USUBJID | VSTESTCD | VSTEST | VSPOS | VSSTRESN | VSSTRESU | VSSTAT | VISIT | VST |
|---------|--------|---------|----------|--------|-------|----------|----------|--------|-------|-----|
| XMR-FMQ-02 | VS | XYZ-707-01 | TEMP | Temperture | Recommended | 38.4 | C | Recommended | Screen 1 | 10 |
| XMR-FMQ-02 | VS | XYZ-707-01 | TEMP | Temperture | Recommended | 38.4 | C | Recommended | Screen 1 | 10 |
| XMR-FMQ-02 | VS | XYZ-707-01 | TEMP | Temperture | Recommended | 38.4 | C | Recommended | Screen 1 | 10 |
| XMR-FMQ-02 | VS | XYZ-707-01 | TEMP | Temperture | Recommended | 38.4 | C | Recommended | Screen 1 | 10 |

## Raw Data Table
237 records — 82.99%

| ...S | DIABP_VSORRE... | DIABP_VSORRE... | BP_VSCLSIG | BP_ |
|---|---|---|---|---|
| 84 | mmHg | | | |
| 74 | mmHg | | | |
| 80 | mmHg | | | |
| 74 | mmHg | | | |
| 67 | mmHg | | | |
| 85 | mmHg | | | |
| 73 | mmHg | | | |
| 56 | mmHg | Not Clinically signifi... | N | |
| 82 | mmHg | Not Clinically signifi... | N | |
| 60 | mmHg | | | |
| 51 | mmHg | | | |
| 59 | mmHg | Not Clinically signifi... | N | |
| 49 | mmHg | Not Clinically signifi... | N | |
| 61 | mmHg | | | |
| 80 | mmHg | | | |
| 75 | mmHg | | | |
| 72 | mmHg | | | |
| 60 | mmHg | | | |

## CRF

Draft 5 active EC: Unique
Form: Vital Signs
Generated On: 29 Jun 2020 07:24:36

Systolic Blood Pressure Unit — mmHg

Diastolic Blood Pressure — Fixed Unit: mmHg

Diastolic Blood Pressure Unit — mmHg

Blood Pressure Clinical Significance — Not Clinically significant / Clinically significant

Heart Rate — Fixed Unit: beats/min

Heart Rate Unit — beats/min

Heart Rate Clinical Significance — Not Clinically significant / Clinically significant

34 / 107    70%

## Mapping

/ Mappings — Add Mapping
Variable 0   Mapping 8   Additional Sources 0

Variables (46)

All
VS only
Not on CRF
Not Submitted

Search Variable..

PULSE_VSOR...
PULSE_VSCL...

Not mapped to VS

NOTE

Not Submitted

StudyEnvSiteNu...

| DIABP_VSORRES | SDTM Variables 11 |
|---|---|

229 / 237 records — Add Variable +

| VSTEST | "Diastolic Blood Pressure" |
| VSORRES ⚠ | DIABP_VSORRES |
| | DIABP_VSORRE... |
| VSSTRESC | Select Source |
| VSSTRESN | Select Source |
| VSSTRESU | Select Source |
| VSSTAT | STAT ⚡ |
| VSBLFL | Select Source |

## Results Table
100 / 229 records    Vital Signs / DIABP_VSORRES

| STUDYID | DOMAIN | USUBJID | VSTEST | VSORRES | VISIT | VSDTC |
|---|---|---|---|---|---|---|
| ACME_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 84 | Screening | 2020-06-23 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 74 | Day 01 | 2020-06-25 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 80 | Day 14 | 2020-07-07 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 74 | Day 30 | 2020-07-27 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 67 | Day 05 | 2020-06-29 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 85 | Day 60/Termination | 2020-08-25 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 73 | Day 0 - Surgery | 2020-06-24T05:18 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-002 | Diastolic Blood Pressure | 56 | Screening | 2020-07-05 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-002 | Diastolic Blood Pressure | 82 | Day 0 - Surgery | 2020-07-06T04:00 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-003 | Diastolic Blood Pressure | 60 | Screening | 2020-07-15 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-003 | Diastolic Blood Pressure | 51 | Day 01 | 2020-07-23 |

## Raw Data Table
237 records  82.99%

| DIABP_VSORRE... | DIABP_VSORRE... | BP_VSCLSIG | BP_ |
|---|---|---|---|
| 84 | mmHg | | |
| 74 | mmHg | | |
| 80 | mmHg | | |
| 74 | mmHg | | |
| 67 | mmHg | | |
| 85 | mmHg | | |
| 73 | mmHg | | |
| 56 | mmHg | Not Clinically signifi... | N |
| 82 | mmHg | Not Clinically signifi... | N |
| 60 | mmHg | | |
| 51 | mmHg | | |
| 59 | mmHg | Not Clinically signifi... | N |
| 49 | mmHg | Not Clinically signifi... | N |
| 61 | mmHg | | |
| 80 | mmHg | | |
| 75 | mmHg | | |
| 72 | mmHg | | |
| 60 | mmHg | | |

## CRF

Draft 5 active EC: Unique
Form: Vital Signs
Generated On: 29 Jun 2020 07:24:36

Systolic Blood Pressure Unit — mmHg

Diastolic Blood Pressure — Fixed Unit: mmHg

Diastolic Blood Pressure Unit — mmHg

Blood Pressure Clinical Significance — Not Clinically significant / Clinically significant

Heart Rate — Fixed Unit: beats/min

Heart Rate Unit — beats/min

Heart Rate Clinical Significance — Not Clinically significant / Clinically significant

34 /107   65%

## Mapping

VS / Mappings   Add Mapping

Variable 1  Mapping 8  Additional Sources 0

### Variables (46)
- All
- VS only
- Not on CRF
- Not Submitted

Search Variable..

Mapped to VS

- *VISIT
- STAT
- STAT_STD
- DTC
- VSTIM

| DIABP_VSORRES | SDTM Variables 11 |
|---|---|
| 229 / 237 records | Add Variable + |
| VSTEST | "Diastolic Blood Pressure" |
| VSORRES ⚠ | DIABP_VSORRES ▾ |
| VSORRESU | DIABP_VSORRESU ▾ |
| VSSTRESC | Select Source ▾ |
| VSSTRESN | Select Source ▾ |
| VSSTRESU | Select Source ▾ |
| VSSTAT | STAT ⚡ |
| VSBLFL | Select Source ▾ |

## Results Table
100 / 229 records   Vital Signs / DIABP_VSORRES

| STUDYID | DOMAIN | USUBJID | VSTEST | VSORRES | VSORRESU | VISIT | VSDTC |
|---|---|---|---|---|---|---|---|
| ACME_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 84 | mmHg | Screening | 2020-06-23 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 74 | mmHg | Day 01 | 2020-06-25 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 80 | mmHg | Day 14 | 2020-07-07 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 74 | mmHg | Day 30 | 2020-07-27 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 67 | mmHg | Day 05 | 2020-06-29 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 85 | mmHg | Day 60/Termination | 2020-08-25 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-001 | Diastolic Blood Pressure | 73 | mmHg | Day 0 - Surgery | 2020-06-24T05:18 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-002 | Diastolic Blood Pressure | 56 | mmHg | Screening | 2020-07-05 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-002 | Diastolic Blood Pressure | 82 | mmHg | Day 0 - Surgery | 2020-07-06T04:00 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-003 | Diastolic Blood Pressure | 60 | mmHg | Screening | 2020-07-15 |
| AMCE_301_102 | VS | D-PLEX 311-5-1200-003 | Diastolic Blood Pressure | 51 | mmHg | Day 01 | 2020-07-23 |

# Real-time validation in JetConvert

Study Package (Data, CRFs…)

FDA-converted SDTM CORE Rules (510)

User-defined CORE rules
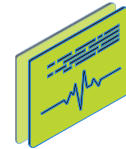
JetConvert.

Map
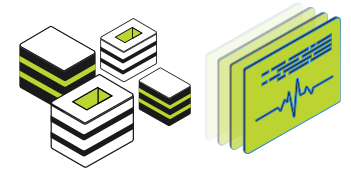
Validate

Submission Package (SDTM, aCRF, Define.xml, SDRG)

Validation Report

## Raw Data Table
4,337 records | **42.66%** Completed

| *VISIT | *USUBJID | StudyEnvSiteNu... | STAT |
|---|---|---|---|
| Day 0 - Surgery | DEMO-ALS-5-0003... | 200 | Same as visit date |
| Screening | DEMO-ALS-5-0003... | 200 | Same as visit date |
| Day 1 | DEMO-ALS-5-0003... | 200 | Same as visit date |
| Day 14 | DEMO-ALS-5-0003... | 200 | Same as visit date |
| Day 30 | DEMO-ALS-5-0003... | 200 | Same as visit date |
| Day 5 | DEMO-ALS-5-0003... | 200 | Same as visit date |
| Day 60/Termination | DEMO-ALS-5-0003... | 200 | Same as visit date |
| Day 0 - Surgery | DEMO-ALS-5-0003... | 200 | Same as visit date |
| Screening | DEMO-ALS-8-0004... | 206 | Same as visit date |
| Day 1 | DEMO-ALS-8-0004... | 206 | Same as visit date |
| Day 14 | DEMO-ALS-8-0004... | 206 | Same as visit date |
| Day 30 | DEMO-ALS-8-0004... | 206 | Same as visit date |
| Day 5 | DEMO-ALS-8-0004... | 206 | Same as visit date |
| Day 60/Termination | DEMO-ALS-8-0004... | 206 | Same as visit date |
| Day 0 - Surgery | DEMO-ALS-8-0004... | 206 | Same as visit date |
| Screening | DEMO-ALS-8-0004... | 206 | Same as visit date |
| Day 1 | DEMO-ALS-8-0004... | 206 | Same as visit date |
| Day 14 | DEMO-ALS-8-0004 | 206 | Same as visit date |

## CRF

DEMO_ALS - Production v3 - Unique
Project Name: DEMO_ALS
Form: Vital Signs (VS)
Generated On: 05 Dec 2022 11:25:38

Date of assessment: (STAT)
Same as visit date ☐
Different than visit date ☐
Not Done (specify) ☐

Date of Assessment, if different than Visit Date (DTC)
Please note that Vital Signs should be measured prior to surgery. (NOTE)
Time of Measurements (VSTIM)
Height (HEIGHT_VSORRES)
Weight (WEIGHT_VSORRES)
BMI (BMI_VSORRES)
The variable BMI_VSORRES is derived based on WEIGHT_VSORRES,HEIGHT_VSORRES,HEIGHT_VSORRES
Body Temperature (TEMP_VSORRES)
Temperature Clinical Significance (TEMP_VSCLSIG)
Not Clinically significant ☐
Clinically significant ☐

17 /42 | 75 − +

## Mapping

**Variables (45)**

All
VS only
Not on CRF
Not Submitted

🔍 Search Variable..

WEIGHT_VSOR...
BMI_VSORRES_...
TEMP_VSORRES
TEMP_VSORRE...
TEMP_VSOR... VS
TEMP_VSORRE...

VS / Mappings | Select | Add Mapping
Variable 2  Mapping 8  Additional Sources 0

🛒 4175 / 4337 records | Add Variable +

| | |
|---|---|
| VSTEST | "Temperature" ⌄ |
| VSORRES | (17) ⚡ ⌄ |
| VSORRESU | ▦ Condition ⌄ |
| VSSTRESU | Select Source ⌄ |
| VSSTAT | STAT_STD ⌄ |
| VSBLFL | Select Source ⌄ |
| VISITNUM | Select Source ⌄ |
| VISIT | *VISIT ⌄ |
| VSCLSIG | TEMP_VSCLSIG_STD |

## Results Table
4,175 records | Vital Signs / TEMP_VSORRES | ⚠ 1 Issue ◉ | View Log

⚠ **Domain Level Validation Error** — Missing Required Variable – VSORRES | View In Log | Dismiss

| STUDYID | DOMAIN | USUBJID | VSTEST | VSORRESU | VSSTAT | VISIT | VSCLISIG |
|---|---|---|---|---|---|---|---|
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | | NOT DONE ⓘ | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | | | Day 14 | |

### Raw Data Table  4,337 records  **42.66%** Completed

| RES | BMI_VSORRES_... | TEMP_VSORRES | TEMP_VSORRES... | TEMP_V |
|---|---|---|---|---|
| 25.28 | 36.7 | 36.7 | C |
| | 36.8 | 36.8 | C |
| | 36.4 | 36.4 | C |
| | 36.3 | 36.3 | C |
| | 36.3 | 36.3 | C |
| | 36.3 | 36.3 | C |
| | 36.8 | 36.8 | C |
| 30.80 | 36.8 | 36.8 | C |
| | 36.4 | 36.4 | C |
| | 37 | 37.0 | C |
| | 36.6 | 36.6 | C |
| | 36.8 | 36.8 | C |
| | 36.9 | 36.9 | C |
| | 36.6 | 36.6 | C |
| 22.99 | 36.9 | 36.9 | C |
| | 36.9 | 36.9 | C |
| | 36.6 | 36.6 | C |

### CRF

DEMO_ALS - Production v3 - Unique
Project Name: DEMO_ALS
Form: Vital Signs (VS)
Generated On: 05 Dec 2022 11:25:38

Date of assessment: (STAT)                    Same as visit date ☐
                                        Different than visit date ☐
                                        Not Done (specify) ☐

Date of Assessment, if different than Visit Date (DTC) _____
Please note that Vital Signs should be measured prior to surgery. (NOTE) _____
Time of Measurements (VSTIM) _____
Height (HEIGHT_VSORRES) _____
Weight (WEIGHT_VSORRES) _____
BMI (BMI_VSORRES) The variable BMI_VSORRES is derived based on WEIGHT_VSORRES,HEIGHT_VSORRES,HEIGHT_VSORRES

Body Temperature (TEMP_VSORRES) _____
Temperature Clinical Significance (TEMP_VSCLSIG)  Not Clinically significant ☐
                                        Clinically significant ☐

◄► ⤢ ✛ 🔍  ‹  17 /42  ›   75  − +

### Mapping

Variables (45)

All
VS only
Not on CRF
Not Submitted

🔍 Search Variable..

WEIGHT_VSOR...

BMI_VSORRES_...

TEMP_VSORRES
Type: Number Name: TEMP_VSORRES
Variable Label: Temperature

TEMP_VSOR... vs

TEMP_VSORRE...

**/ Mappings**  Select  Add Mapping
Variable 2  Mapping 8  Additional Sources 0

TEMP_VSORRES
🛒 4175 / 4337 records  Add Variable +

| VSTEST | "Temperature" ⌄ |
| VSORRES | (17) ⚡ ⌄ |
| VSORRESU | 🔲 Condition ⌄ |
| VSSTRESU | Select Source ⌄ |
| VSSTAT | STAT_STD ⌄ |
| VSBLFL | Select Source ⌄ |
| VISITNUM | Select Source ⌄ |
| VISIT | *VISIT ⌄ |
| VSCLSIG | TEMP_VSCLSIG_STD |

### Results Table  4,175 records  Vital Signs / TEMP_VSORRES      ⚠ 1 Issue ⬤  View Log

⚠ Domain Level Validation Error    Missing Required Variable – VSORRES                    View In Log  Dismiss

| STUDYID | DOMAIN | USUBJID | VSTEST | VSORRESU | VSSTAT | VISIT | VSCLSIG |
|---|---|---|---|---|---|---|---|
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | | NOT DONE | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | C | | Day 1 | |

## Raw Data Table
4,337 records **42.66%** Completed

| ...RES | BMI_VSORRES_... | TEMP_VSORRES | TEMP_VSORRES... | TEMP_V... |
|---|---|---|---|---|
| 25.28 | | 36.7 | 36.7 | C |
| | | 36.8 | 36.8 | C |
| | | 36.4 | 36.4 | C |
| | | 36.3 | 36.3 | C |
| | | 36.3 | 36.3 | C |
| | | 36.3 | 36.3 | C |
| | | 36.8 | 36.8 | C |
| 30.80 | | 36.8 | 36.8 | C |
| | | 36.4 | 36.4 | C |
| | | 37 | 37.0 | C |
| | | 36.6 | 36.6 | C |
| | | 36.8 | 36.8 | C |
| | | 36.9 | 36.9 | C |
| | | 36.6 | 36.6 | C |
| 22.99 | | 36.9 | 36.9 | C |
| | | 36.9 | 36.9 | C |
| | | 36.6 | 36.6 | C |

## CRF

DEMO_ALS - Production v3 - Unique
Project Name: DEMO_ALS
Form: Vital Signs (VS)
Generated On: 05 Dec 2022 11:25:38

Date of assessment: (STAT)
Same as visit date ☐
Different than visit date ☐
Not Done (specify) ☐

Date of Assessment, if different than Visit Date (DTC)
Please note that Vital Signs should be measured prior to surgery. (NOTE)
Time of Measurements (VSTIM)
Height (HEIGHT_VSORRES)
Weight (WEIGHT_VSORRES)
BMI (BMI_VSORRES)

The variable BMI_VSORRES is derived based on WEIGHT_VSORRES, HEIGHT_VSORRES, HEIGHT_VSORRES

Body Temperature (TEMP_VSORRES)
Temperature Clinical Significance (TEMP_VSCLSIG)
Not Clinically significant ☐
Clinically significant ☐

17 /42    75

## Mapping

**Variables (45)**

All
VS only
Not on CRF
Not Submitted

Search Variable..

WEIGHT_VSOR...

BMI_VSORRES_...

TEMP_VSORRE...

TEMP_VSOR...

TEMP_VSORRE...

/ Mappings    Select    Add Mapping
Variable 2  Mapping 8  Additional Sources 0

TEMP_VSORRES

🛒 4175 / 4337 records    Add Variable +

| Variable | Mapping |
|---|---|
| VSTEST | "Temperature" ⌄ |
| VSORRES | (17) ⚡ ⌄ |
| VSORRESU | ▣ Condition ⌄ |
| | TEMP_VSORRES / Select Source ⌄ |
| VSSTAT | STAT_STD ⌄ |
| VSBLFL | Select Source ⌄ |
| VISITNUM | Select Source ⌄ |
| VISIT | *VISIT ⌄ |
| VSCLSIG | TEMP_VSCLSIG_STD |

## Results Table
4,175 records    Vital Signs / TEMP_VSORRES

⚠ 1 Issue    View Log

⚠ Domain Level Validation Error    Missing Required Variable – VSORRES    View In Log    Dismiss

| STUDYID | DOMAIN | USUBJID | VSTEST | VSORRESU | VSSTAT | VISIT | VSCLSIG |
|---|---|---|---|---|---|---|---|
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | | NOT DONE | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | C | | Day 1 | |

Waiting for cc-api-data.adobe.io...

## Raw Data Table
4,337 records  **42.66%** Completed

| ...RES | BMI_VSORRES_... | TEMP_VSORRES | TEMP_VSORRES... | TEMP_V... |
|---|---|---|---|---|
| 25.28 | | 36.7 | 36.7 | C |
| | | 36.8 | 36.8 | C |
| | | 36.4 | 36.4 | C |
| | | 36.3 | 36.3 | C |
| | | 36.3 | 36.3 | C |
| | | 36.3 | 36.3 | C |
| | | 36.8 | 36.8 | C |
| 30.80 | | 36.8 | 36.8 | C |
| | | 36.4 | 36.4 | C |
| | | 37 | 37.0 | C |
| | | 36.6 | 36.6 | C |
| | | 36.8 | 36.8 | C |
| | | 36.9 | 36.9 | C |
| | | 36.6 | 36.6 | C |
| 22.99 | | 36.9 | 36.9 | C |
| | | 36.9 | 36.9 | C |
| | | 36.6 | 36.6 | C |

## CRF

DEMO_ALS - Production v3 - Unique
Project Name: DEMO_ALS
Form: Vital Signs (VS)
Generated On: 05 Dec 2022 11:25:38

Date of assessment: (STAT)
Same as visit date ☐
Different than visit date ☐
Not Done (specify) ☐

Date of Assessment, if different than Visit Date (DTC)
Please note that Vital Signs should be measured prior to surgery. (NOTE)
Time of Measurements (VSTIM)
Height (HEIGHT_VSORRES)
Weight (WEIGHT_VSORRES)
BMI (BMI_VSORRES)
The variable BMI_VSORRES is derived based on WEIGHT_VSORRES,HEIGHT_VSORRES,HEIGHT_VSORRES
Body Temperature (TEMP_VSORRES)
Temperature Clinical Significance (TEMP_VSCLSIG)
Not Clinically significant ☐
Clinically significant ☐

17 /42    75

## Mapping

Variables (45)

All
VS only
Not on CRF
Not Submitted

🔍 Search Variable..

WEIGHT_VSOR...
BMI_VSORRES_...
TEMP_VSORRE...
TEMP_VSOR... VS
TEMP_VSORRE...

/ Mappings    Select    Add Mapping
Variable 2  Mapping 8  Additional Sources 0

TEMP_VSORRES
🛒 4175 / 4337 records    Add Variable +

| VSTEST | "Temperature" ⌄ |
| VSOR | TEMP_VSORRES ⌄ |
| VSORRESU | Condition ⌄ |
| VSSTRESU | Select Source ⌄ |
| VSSTAT | STAT_STD ⌄ |
| VSBLFL | Select Source ⌄ |
| VISITNUM | Select Source ⌄ |
| VISIT | *VISIT ⌄ |
| VSCLSIG | TEMP_VSCLSIG_STD |

## Results Table
4,175 records  Vital Signs / TEMP_VSORRES  **Updating Table...**

⚠ 1 Issue 🔘  View Log

⚠ **Domain Level Validation Error**  Missing Required Variable – VSORRES    View In Log   Dismiss

| STUDYID | DOMAIN | USUBJID | VSTEST | VSORRESU | VSSTAT | VISIT | VSCLSIG |
|---|---|---|---|---|---|---|---|
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | | NOT DONE | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | C | | Day 1 | |

## Raw Data Table
4,337 records   **42.66%** Completed

| ...RES | BMI_VSORRES_... | TEMP_VSORRES | TEMP_VSORRES... | TEMP_V... |
|---|---|---|---|---|
| 25.28 | | 36.7 | 36.7 | C |
| | | 36.8 | 36.8 | C |
| | | 36.4 | 36.4 | C |
| | | 36.3 | 36.3 | C |
| | | 36.3 | 36.3 | C |
| | | 36.3 | 36.3 | C |
| | | 36.8 | 36.8 | C |
| 30.80 | | 36.8 | 36.8 | C |
| | | 36.4 | 36.4 | C |
| | | 37 | 37.0 | C |
| | | 36.6 | 36.6 | C |
| | | 36.8 | 36.8 | C |
| | | 36.9 | 36.9 | C |
| | | 36.6 | 36.6 | C |
| 22.99 | | 36.9 | 36.9 | C |
| | | 36.9 | 36.9 | C |
| | | 36.6 | 36.6 | C |

## CRF

DEMO_ALS - Production v3 - Unique
Project Name: DEMO_ALS
Form: Vital Signs (VS)
Generated On: 05 Dec 2022 11:25:38

Date of assessment: (STAT)          Same as visit date ☐
                                    Different than visit date ☐
                                    Not Done (specify) ☐

Date of Assessment, if different than Visit Date (DTC)
Please note that Vital Signs should be measured prior to surgery. (NOTE)
Time of Measurements (VSTIM)
Height (HEIGHT_VSORRES)
Weight (WEIGHT_VSORRES)
BMI (BMI_VSORRES)          The variable BMI_VSORRES is derived based on WEIGHT_VSORRES,HEIGHT_VSORRES,HEIGHT_VSORRES
Body Temperature (TEMP_VSORRES)
Temperature Clinical Significance (TEMP_VSCLSIG)          Not Clinically significant ☐
                                    Clinically significant ☐

17 /42    75

## Mapping

**Variables (45)**

All
VS only
Not on CRF
Not Submitted

🔍 Search Variable..

⚓ Mapped to VS

*VISIT
STAT ⚡
STAT_STD 🆅🆂
DTC ⚡
VSTIM ⚡

**/ Mappings**    Select   **Add Mapping**
Variable 3   Mapping 8   Additional Sources 0

TEMP_VSORRES

🏆 4175 / 4337 records          Add Variable +

VSTEST          "Temperature" ⌄
VSORRES ⚠         TEMP_VSORRES ⌄
VSORRESU         ▣ Condition ⌄
VSSTRESU         Select Source ⌄
VSSTAT          STAT_STD ⌄
VSBLFL          Select Source ⌄
VISITNUM         Select Source ⌄
VISIT          *VISIT ⌄
VSCLSIG         TEMP_VSCLSIG_STD

## Results Table
4,175 records   Vital Signs / TEMP_VSORRES

⚠ 2 Issues ‹ 1/2 ›   View Log

| STUDYID | DOMAIN | USUBJID | VSTEST | ⚠ VSORRES | VSORRESU | VSSTAT | VISIT |
|---|---|---|---|---|---|---|---|
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | 36.9 | C | | Day 0 - Surgery |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 37.5 | C | | Screening |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.5 | C | | Day 1 |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.8 | C | | Day 5 |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.9 | C | | Day 0 - Surgery |
| ⚠ Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.9 | | NOT DONE | Screening |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.6 | C | | Day 1 |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 37.1 | C | | Day 30 |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.8 | C | | Day 5 |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.7 | C | | Day 60/Termination |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.3 | C | | Day 0 - Surgery |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.6 | C | | Screening |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 37.3 | C | | Day 1 |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.6 | C | | Day 14 |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.8 | C | | Day 5 |

## ▦ Raw Data Table  4,337 records  **42.66%** Completed  📊 ↗ ⤢

| RES | BMI_VSORRES_… | TEMP_VSORRES | TEMP_VSORRES… | TEMP_V… |
|---|---|---|---|---|
| 25.28 | | 36.7 | 36.7 | C |
| | | 36.8 | 36.8 | C |
| | | 36.4 | 36.4 | C |
| | | 36.3 | 36.3 | C |
| | | 36.3 | 36.3 | C |
| | | 36.3 | 36.3 | C |
| | | 36.8 | 36.8 | C |
| 30.80 | | 36.8 | 36.8 | C |
| | | 36.4 | 36.4 | C |
| | | 37 | 37.0 | C |
| | | 36.6 | 36.6 | C |
| | | 36.8 | 36.8 | C |
| | | 36.9 | 36.9 | C |
| | | 36.6 | 36.6 | C |
| 22.99 | | 36.9 | 36.9 | C |
| | | 36.9 | 36.9 | C |
| | | 36.6 | 36.6 | |

## 🗋 CRF  ↗ ⤢

DEMO_ALS - Production v3 - Unique
Project Name: DEMO_ALS
Form: Vital Signs (VS)
Generated On: 05 Dec 2022 11:25:38

Date of assessment: (STAT)
Same as visit date ☐
Different than visit date ☐
Not Done (specify) ☐

Date of Assessment, if different than Visit Date (DTC)
Please note that Vital Signs should be measured prior to surgery. (NOTE)
Time of Measurements (VSTIM)
Height (HEIGHT_VSORRES)
Weight (WEIGHT_VSORRES)
BMI (BMI_VSORRES)   The variable BMI_VSORRES is derived based on WEIGHT_VSORRES,HEIGHT_VSORRES,HEIGHT_VSORRES
Body Temperature (TEMP_VSORRES)
Temperature Clinical Significance (TEMP_VSCLSIG)   Not Clinically significant ☐
Clinically significant ☐

↔ ⤢ ✥ 🔍 ‹ 17 /42 › 75 − +

## ⚛ Mapping  ↗ ⤢

**Variables (45)**

All
VS only
Not on CRF
Not Submitted

🔍 Search Variable..

⚛ Mapped to VS

*VISIT
STAT ⚡
STAT_STD vs
DTC ⚡
VSTIM ⚡

‹ VS / Mappings  ⟳ Select  **Add Mapping**
Variable 3  Mapping 8  Additional Sources 0

TEMP_VSORRES
🏷 **4175** / 4337 records  Add Variable +

| | | |
|---|---|---|
| ⊸ VSTEST | "Temperature" ⌄ | ⎘ ⋮ |
| ⊸ VSORRES ⚠ | TEMP_VSORRES ⌄ | ⎘ ⋮ |
| ⊸ VSORRESU | ▣ Condition ⌄ | ⋮ |
| ⊸ VSSTRESU | Select Source ⌄ | ⋮ |
| ⊸ VSSTAT | STAT_STD ⌄ | ⎘ ⋮ |
| ⊸ VSBLFL | Select Source ⌄ | ⋮ |
| ⊸ VISITNUM | Select Source ⌄ | ⋮ |
| ⊸ VISIT | *VISIT ⌄ | ⎘ ⋮ |
| ⊸ VSCLSIG | TEMP_VSCLSIG_STD | |

## ☰ Results Table  4,175 records  Vital Signs / TEMP_VSORRES

⚠ 2 Issues ‹ 2/2 › 🔘  View Log  📊 ↗ ⤢

| STUDYID | DOMAIN | USUBJID | VSTEST | ⚠ VSORRES | VSORRESU | VSSTAT | VISIT |
|---|---|---|---|---|---|---|---|
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | 36.9 | C | | Day 0 - Surgery |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 37.5 | C | | Screening |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.5 | C | | Day 1 |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.8 | C | | Day 5 |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.9 | C | | Day 0 - Surgery |
| ⚠ Demo-ALS | | DEMO_ALS-3-000438 | Temperature | 36.9 | | NOT DONE | Screening |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.6 | C | | Day 1 |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 37.1 | C | | Day 30 |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.8 | C | | Day 5 |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.7 | C | | Day 60/Termination |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.3 | C | | Day 0 - Surgery |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.6 | C | | Screening |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 37.3 | C | | Day 1 |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.6 | C | | Day 14 |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.8 | C | | Day 5 |

**VSSTAT Not Null When VSORRES Not Null**
Source FDA  ID SD1123  Instances 27  ‹ 1/27 ›
View In Log

## Issue Log ⓘ

| | | | |
|---|---|---|---|
| ALL | Issues: FDA (30) ⚙ (2) | Instances: 3,310 ⟳ | ⌄ |
| AE | Issues: FDA (2) | Instances: 4 ✓ | ⌄ |
| CM | Issues: FDA (1) | Instances: 19 ⚠11 ⟳3 | ⌄ |
| DM | Issues: FDA (1) | Instances: 1 ⚠ | ⌄ |
| DS | Issues: FDA (3) | Instances: 24 ⟳ | ⌄ |
| LB | Issues: FDA (6) ⟳ (1) | Instances: 2301 ⟳ | ⌄ |
| MH | Issues: FDA (1) | Instances: 9 ✓ | ⌄ |
| QS | Issues: FDA (8) | Instances: 797 ✓ | ⌄ |
| SE | Issues: FDA (6) | Instances: 38 ✓15 ⟳23 | ⌄ |
| VS | Issues: FDA (3) | Instances: 117 ⟳ | ⌃ |

💬 👁 **VSTEST value not found in extensible codelist** ⌄
Source FDA   ID CT2002   Instances 89 ⚠

💬 👁 **VSORRES value is populated, when VSSTAT is 'NOT DONE'** ⌃
Source FDA   ID SD1123   Instances 27 ⚠

Description   ⬤ Group Instances
Value Of Original Result (VSORRES) Variable Is Expected To Be Missing, When Observation Was Not Performed (Status (VSSTAT) Is 'NOT DONE')

| | USUBJID | VISIT | VSTESTCD | VSORRES | VSSTAT | R |
|---|---|---|---|---|---|---|
| 👁💬⚠ | **DEMO_ALS-3-000438** | Screening | **TEMP** | **36.9** | **NOT DONE** | |
| 👁💬⚠ | DEMO_ALS-7-000540 | Day 0 - Surgery | TEMP | 36.2 | NOT DONE | 1 |
| 👁💬⚠ | DEMO_ALS-5-000656 | Screening | TEMP | 36.6 | NOT DONE | 1 |

## Results Tables   Vital Signs

| STUDYID | DOMAIN | USUBJID | VSTEST | ⚠ VSORRES | VSORRESU | VSSTAT | VISIT | VS |
|---|---|---|---|---|---|---|---|---|
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | 36.3 | C | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | 36.7 | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.6 | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.8 | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.8 | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.7 | C | | Day 0 - Surgery | |
| ⚠ Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.9 | | NOT DONE | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 37.1 | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.9 | C | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.8 | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.8 | C | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.9 | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.6 | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36 | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.4 | C | | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.3 | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.7 | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 37 | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.9 | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.5 | C | | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.4 | C | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.8 | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.5 | C | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.5 | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.7 | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.6 | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.8 | C | | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.4 | C | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.7 | C | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.4 | C | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.7 | C | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.7 | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.8 | C | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 37 | C | | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.2 | C | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.6 | C | | Day 5 | |
| ⚠ Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.2 | | NOT DONE | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-7-000541 | Temperature | 36.9 | C | | Screening | |
| Demo-ALS | VS | DEMO_ALS-7-000541 | Temperature | 36.9 | C | | Day 1 | |

# VSORRES value is populated, when VSSTAT is 'NOT DONE'

**ID** SD1123    **Instances** 27

**Description**
Value Of Original Result (VSORRES) Variable Is Expected To Be Missing, When Observation Was Not Performed (Status (VSSTAT) Is 'NOT DONE')

## Status (Click status to change)

⚠ **New** ✓

⟳ **Pending** ○

✓ **Approved** ○

## Comments

Comment Here...

**Add Comment**

**Cancel**    **Save changes**

---

**Issue Log** ⓘ

| | | | |
|---|---|---|---|
| Issues: FDA (1) | Instances: 1 | ⚠ |
| Issues: FDA (3) | Instances: 24 | |
| Issues: FDA (6) ⟳ (1) | Instances: 2301 | |
| Issues: FDA (1) | Instances: 9 | ✓ |
| Issues: FDA (8) | Instances: 797 | ✓ |
| Issues: FDA (6) | Instances: 38 | |
| Issues: FDA (3) | Instances: 117 | |

**VSTEST value not found in extensible codelist**
Source FDA   ID CT2002   Instances 89 ⚠

**VSORRES value is populated, when VSSTAT is 'NOT DONE'**
Source FDA   ID SD1123   Instances 27 ⚠

Description
Value Of Original Result (VSORRES) Variable Is Expected To Be Missing, When Observation Was Not Performed (Status (VSSTAT) Is 'NOT DONE')

| USUBJID | VISIT | VSTESTCD | VSORRES | |
|---|---|---|---|---|
| DEMO_ALS-3-000438 | Screening | TEMP | 36.9 | |
| DEMO_ALS-7-000540 | Day 0 - Surgery | TEMP | 36.2 | NOT DONE | 1 |
| DEMO_ALS-5-000656 | Screening | TEMP | 36.6 | NOT DONE | 1 |
| DEMO_ALS-3-001667 | Screening | TEMP | 37 | NOT DONE | 6 |
| DEMO_ALS-8-001850 | Screening | TEMP | 37.2 | NOT DONE | 9 |

**VSORRES Type Mismatch VSORRES Numeric Instead Of String**
Source FDA   ID SD1073   Instances 1 ⚠

---

## Results Tables   Vital Signs

| | VSORRESU | VSSTAT | VISIT |
|---|---|---|---|
| | | C | Day 60/Termination |
| | | C | Day 0 - Surgery |
| | | C | Screening |
| | | C | Day 1 |
| | | C | Day 5 |
| | | C | Day 0 - Surgery |
| | | C | NOT DONE | Screening |
| | | C | Day 1 |
| | | C | Day 30 |
| | | C | Day 5 |
| | | C | Day 60/Termination |
| | | C | Day 0 - Surgery |
| | | C | Screening |
| | | C | Day 1 |
| | | C | Day 14 |
| | | C | Day 5 |
| | | C | Day 30 |
| | | C | Day 5 |
| | | C | Day 60/Termination |
| | | C | Day 0 - Surgery |
| | | C | Screening |
| | | C | Day 1 |
| | | C | Day 14 |
| | | C | Day 30 |
| | | C | Day 5 |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.4 | | Day 60/Termination |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 30.7 | | Day 0 - Surgery |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.7 | | Screening |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.8 | | Day 1 |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 37 | | Day 14 |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.2 | | Day 30 |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.8 | | Day 5 |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.2 | NOT DONE | Day 60/Termination |
| Demo-ALS | VS | DEMO_ALS-7-000541 | Temperature | 36.9 | | Screening |
| Demo-ALS | VS | DEMO_ALS-7-000541 | Temperature | 36.9 | | Day 1 |

⚠ **Issue Log** ⓘ

| | | | | | |
|---|---|---|---|---|---|
| DM | Issues: FDA (1) | Instances: 1 | ⚠ |
| DS | Issues: FDA (3) | Instances: 24 | |
| LB | Issues: FDA (6) ⟳ (1) | Instances: 2301 | |
| MH | Issues: FDA (1) | Instances: 9 | ✓ |
| QS | Issues: FDA (8) | Instances: 797 | ✓ |
| SE | Issues: FDA (6) | Instances: 38 | |
| VS | Issues: FDA (3) | Instances: 117 | |

**Results Tables** Vital Signs

| VSORRESU | VSSTAT | VISIT |
|---|---|---|
| | | Day 60/Termination |
| | | Day 0 - Surgery |
| | | Screening |
| | | Day 1 |
| | | Day 5 |
| | | Day 0 - Surgery |
| | NOT DONE | Screening |
| | | Day 1 |

## VSORRES value is populated, when VSSTAT is 'NOT DONE'

**ID** SD1123   **Instances** 27

**Description**
Value Of Original Result (VSORRES) Variable Is Expected To Be Missing, When Observation Was Not Performed (Status (VSSTAT) Is 'NOT DONE')

### Status (Click status to change)

| ⚠ New ✓ | ⟳ Pending ○ | ✓ Approved ○ |
|---|---|---|

### Comments

Dear **@Jack A.**, please send a note to the vendor to check this issue.

**Add Comment**

**Cancel**   **Save changes**

**Issue Log**

Results Tables  Vital Signs

VSORRESU  VSSTAT  VISIT

| Issues: | FDA (1) | Instances: | 1 |
| Issues: | FDA (3) | Instances: | 24 |
| Issues: | FDA (6) | (1) | Instances: | 2301 |
| Issues: | FDA (1) | Instances: | 9 |
| Issues: | FDA (8) | Instances: | 797 |
| Issues: | FDA (6) | Instances: | 38 |
| Issues: | FDA (3) | Instances: | 117 |

**VSTEST value not found in extensible codelist**
Source FDA   ID CT2002   Instances 89

**VSORRES value is populated, when VSSTAT is 'NOT DONE'**
Source FDA   ID SD1123   Instances 27

Description
Value Of Original Result (VSORRES) Variable Is Expected To Be Missing, When O...
Was Not Performed (Status (VSSTAT) Is 'NOT DONE')

| | USUBJID | VISIT | VSTESTCD | VSORRES | | |
| DEMO_ALS-3-000438 | Screening | TEMP | 36.9 | | |
| DEMO_ALS-7-000540 | Day 0 - Surgery | TEMP | 36.2 | NOT DONE | 1 |
| DEMO_ALS-5-000656 | Screening | TEMP | 36.6 | NOT DONE | 1 |
| DEMO_ALS-3-001667 | Screening | TEMP | 37 | NOT DONE | 6 |
| DEMO_ALS-8-001850 | Screening | TEMP | 37.2 | NOT DONE | 9 |

**VSORRES Type Mismatch VSORRES Numeric Instead Of String**
Source FDA   ID SD1073   Instances 1

---

## VSORRES value is populated, when VSSTAT is 'NOT DONE'

ID SD1123   Instances 27

**Description**
Value Of Original Result (VSORRES) Variable Is Expected To Be Missing, When Observation Was Not Performed (Status (VSSTAT) Is 'NOT DONE')

### Status (Click status to change)

| New | Pending ✓ | Approved |

### Comments

Comment Here...

Add Comment

Dear **@Jack A.**, please send a note to the vendor to check this issue.

John D.   Oct 2 2022, 11:00

Cancel   Save changes

# Jet Convert ✈ Demo-ALS-1

## Issue Log ⓘ

| DM | Issues: FDA (1) | Instances: 1 | ⚠ | ∨ |
| DS | Issues: FDA (3) | Instances: 24 | ◌ | ∨ |
| LB | Issues: FDA (6) ◌ (1) | Instances: 2301 | ◌ | ∨ |
| MH | Issues: FDA (1) | Instances: 9 | ✓ | ∨ |
| QS | Issues: FDA (8) | Instances: 797 | ✓ | ∨ |
| SE | Issues: FDA (6) | Instances: 38 | ✓15 ◌23 | ∨ |
| VS | Issues: FDA (3) | Instances: 117 | ◌ | ∧ |

**VSTEST value not found in extensible codelist**
Source FDA    ID CT2002    Instances 89 ⚠    ∨

**1  VSORRES value is populated, when VSSTAT is 'NOT DONE'**
Source FDA    ID SD1123    Instances 27 ◌27    ∧

Description                                    ⬤ Group Instances
Value Of Original Result (VSORRES) Variable Is Expected To Be Missing, When Observation Was Not Performed (Status (VSSTAT) Is 'NOT DONE')

| USUBJID | VISIT | VSTESTCD | VSORRES | VSSTAT | R |
|---|---|---|---|---|---|
| DEMO_ALS-3-000438 | Screening | TEMP | 36.9 | NOT DONE | |
| DEMO_ALS-7-000540 | Day 0 - Surgery | TEMP | 36.2 | NOT DONE | 1 |
| DEMO_ALS-5-000656 | Screening | TEMP | 36.6 | NOT DONE | 1 |
| DEMO_ALS-3-001667 | Screening | TEMP | 37 | NOT DONE | 6 |
| DEMO_ALS-8-001850 | Screening | TEMP | 37.2 | NOT DONE | 9 |

**VSORRES Type Mismatch VSORRES Numeric Instead Of String**
Source FDA    ID SD1073    Instances 1 ⚠    ∨

## Results Tables  Vital Signs

| STUDYID | DOMAIN | USUBJID | VSTEST | ⚠ VSORRES | VSORRESU | VSSTAT | VISIT | VS |
|---|---|---|---|---|---|---|---|---|
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | 36.3 | | C | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-8-000436 | Temperature | 36.7 | | C | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.6 | | C | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.8 | | C | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.8 | | C | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000437 | Temperature | 36.7 | | C | Day 0 - Surgery | |
| ⚠ Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.9 | | NOT DONE | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 37.1 | | C | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.9 | | C | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.8 | | C | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.8 | | C | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-3-000438 | Temperature | 36.9 | | C | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.6 | | C | Screening | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36 | | C | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.4 | | C | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.3 | | C | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-3-000445 | Temperature | 36.7 | | C | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 37 | | C | Screening | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.9 | | C | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.5 | | C | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.4 | | C | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.8 | | C | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.5 | | C | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-7-000538 | Temperature | 36.5 | | C | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.7 | | C | Screening | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.6 | | C | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.8 | | C | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.4 | | C | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.7 | | C | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.4 | | C | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-5-000539 | Temperature | 36.7 | | C | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.7 | | C | Screening | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.8 | | C | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 37 | | C | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.2 | | C | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.6 | | C | Day 5 | |
| ⚠ Demo-ALS | VS | DEMO_ALS-7-000540 | Temperature | 36.2 | | NOT DONE | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-7-000541 | Temperature | 36.9 | | C | Screening | |
| Demo-ALS | VS | DEMO_ALS-7-000541 | Temperature | 36.9 | | C | Day 1 | |

⚠ **Issue Log** ⓘ

**Results Tables** Vital Signs

VSORRES | VSORRESU | VSSTAT | VISIT | VSC

Issues: FDA (2) | Instances: 4
Issues: FDA (1) | Instances: 19
Issues: FDA (1) | Instances: 1
Issues: FDA (3) | Instances: 24
Issues: FDA (6) (1) | Instances: 2301
Issues: FDA (1) | Instances: 9
Issues: FDA (8) | Instances: 797
Issues: FDA (6) | Instances: 38
Issues: FDA (3) | Instances: 117

## VSTEST value not found in extensible codelist

ID CT2002    Instances 89

**Description**
Variable Should Be Populated With Terms From Its CDISC Controlled Terminology. New Terms Can Be Added As Long As They Are Not Duplicates, Synonyms Or Subsets Of Existing Terms.

**Status** (Click status to change)

⚠ New | ⟳ Pending | ✓ Approved

**Comments**

Comment Here...

Add Comment

This is a non-issue because the specified test is not part of the codelist ✎ 🗑

John D.    Oct 2 2022, 11:00

Cancel    Save changes

### VSTEST value not found in extensible codelist
Source FDA   ID CT2002   Instances 89

Description
Variable Should Be Populated With Terms From Its CDISC Controlled Terminology. Terms Can Be Added As Long As They Are Not Duplicates, Synonyms Or Subset Existing Terms.

| USUBJID (Distinct Count) | VISIT (Distinct Count) | VSTESTCD (Distinct Count) | VSTEST (Value) |
|---|---|---|---|
| 45 | 7 | 1 | Toe Brachia |

### VSORRES value is populated, when VSSTAT is 'NOT DONE'
Source FDA   ID SD1123   Instances 27

### VSORRES Type Mismatch VSORRES Numeric Instead Of String
Source FDA   ID SD1073   Instances 1

Screening
Day 1
Day 14
Day 30
Day 5
Day 60/Termination
Day 0 – Surgery
Screening
Day 0 – Surgery
Screening
Day 1
Day 14
Day 30
Day 5
Day 60/Termination
Day 0 – Surgery
Screening
Day 1
Day 14
Day 30
Day 5
Day 60/Termination
Day 0 – Surgery
Screening
Day 1
Day 14
Day 30
Day 5
Day 60/Termination
Day 0 – Surgery
Screening
Day 1

Demo-ALS   VS   DEMO_ALS-8-000416   Toe Brachial Index   1.53
Demo-ALS   VS   DEMO_ALS-8-000416   Toe Brachial Index   1.33
Demo-ALS   VS   DEMO_ALS-8-000416   Toe Brachial Index   1.89
Demo-ALS   VS   DEMO_ALS-8-000416   Toe Brachial Index   0.16
Demo-ALS   VS   DEMO_ALS-8-000417   Toe Brachial Index   1.12
Demo-ALS   VS   DEMO_ALS-8-000417   Toe Brachial Index   0.04
Demo-ALS   VS   DEMO_ALS-8-000417   Toe Brachial Index   0.69
Demo-ALS   VS   DEMO_ALS-8-000417   Toe Brachial Index   1.25

# Issue Log ⓘ

| | | | |
|---|---|---|---|
| AE | Issues: FDA (2) | Instances: 4 | ✓ |
| CM | Issues: FDA (1) | Instances: 19 | ⚠11 ◌5 |
| DM | Issues: FDA (1) | Instances: 1 | ⚠ |
| DS | Issues: FDA (3) | Instances: 24 | ◌ |
| LB | Issues: FDA (6) ◌(1) | Instances: 2301 | ◌ |
| MH | Issues: FDA (1) | Instances: 9 | ✓ |
| QS | Issues: FDA (8) | Instances: 797 | ✓ |
| SE | Issues: FDA (6) | Instances: 38 | ✓15 ◌23 |
| VS | Issues: FDA (3) | Instances: 117 | ◌ |

### 💬 ◉ VSTEST value not found in extensible codelist ⌃

Source FDA   ID CT2002   Instances 89 ✓ 1️⃣

**Description**   ◉ Group Instances

Variable Should Be Populated With Terms From Its CDISC Controlled Terminology. New Terms Can Be Added As Long As They Are Not Duplicates, Synonyms Or Subsets Of Existing Terms.

| | USUBJID (Distinct Count) | VISIT (Distinct Count) | VSTESTCD (Distinct Count) | VSTEST (Value) | Is |
|---|---|---|---|---|---|
| ◉ 1 ✓ | 45 | 7 | 1 | Toe Brachial Index | 4, |

### 1️⃣ ◉ VSORRES value is populated, when VSSTAT is 'NOT DONE'

Source FDA   ID SD1123   Instances 27 ◌27

### 💬 ◉ VSORRES Type Mismatch VSORRES Numeric Instead Of String

Source FDA   ID SD1073   Instances 1 ⚠

---

# Results Tables   Vital Signs

| STUDYID | DOMAIN | USUBJID | VSTEST | VSORRES | VSORRESU | VSSTAT | VISIT | VSC |
|---|---|---|---|---|---|---|---|---|
| Demo-ALS | VS | DEMO_ALS-5-000336 | Toe Brachial Index | 0.89 | | | Screening | |
| Demo-ALS | VS | DEMO_ALS-5-000336 | Toe Brachial Index | 1.19 | | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-5-000336 | Toe Brachial Index | 0.79 | | | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-5-000336 | Toe Brachial Index | 1.77 | | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-5-000336 | Toe Brachial Index | 0.11 | | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-5-000336 | Toe Brachial Index | 1.48 | | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-5-000336 | Toe Brachial Index | 1.95 | | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-5-000362 | Toe Brachial Index | 1.14 | | | Screening | |
| Demo-ALS | VS | DEMO_ALS-5-000362 | Toe Brachial Index | 0.38 | | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-5-000391 | Toe Brachial Index | 1.86 | | | Screening | |
| Demo-ALS | VS | DEMO_ALS-5-000391 | Toe Brachial Index | 0.96 | | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-5-000391 | Toe Brachial Index | 0.29 | | | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-5-000391 | Toe Brachial Index | 0.51 | | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-5-000391 | Toe Brachial Index | 1.42 | | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-5-000391 | Toe Brachial Index | 1.33 | | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-5-000391 | Toe Brachial Index | 0.58 | | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-8-000409 | Toe Brachial Index | 0.56 | | | Screening | |
| Demo-ALS | VS | DEMO_ALS-8-000409 | Toe Brachial Index | 0.56 | | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-8-000409 | Toe Brachial Index | 0.04 | | | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-8-000409 | Toe Brachial Index | 0.71 | | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-8-000409 | Toe Brachial Index | 1.45 | | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-8-000409 | Toe Brachial Index | 1.44 | | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-8-000409 | Toe Brachial Index | 1.81 | | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-8-000415 | Toe Brachial Index | 1.53 | | | Screening | |
| Demo-ALS | VS | DEMO_ALS-8-000415 | Toe Brachial Index | 1.79 | | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-8-000415 | Toe Brachial Index | 0.42 | | | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-8-000415 | Toe Brachial Index | 0.66 | | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-8-000415 | Toe Brachial Index | 1.25 | | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-8-000415 | Toe Brachial Index | 0.35 | | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-8-000415 | Toe Brachial Index | 0.33 | | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-8-000416 | Toe Brachial Index | 0.63 | | | Screening | |
| Demo-ALS | VS | DEMO_ALS-8-000416 | Toe Brachial Index | 1.53 | | | Day 1 | |
| Demo-ALS | VS | DEMO_ALS-8-000416 | Toe Brachial Index | 1.83 | | | Day 14 | |
| Demo-ALS | VS | DEMO_ALS-8-000416 | Toe Brachial Index | 1.99 | | | Day 30 | |
| Demo-ALS | VS | DEMO_ALS-8-000416 | Toe Brachial Index | 0.16 | | | Day 5 | |
| Demo-ALS | VS | DEMO_ALS-8-000416 | Toe Brachial Index | 1.12 | | | Day 60/Termination | |
| Demo-ALS | VS | DEMO_ALS-8-000416 | Toe Brachial Index | 0.04 | | | Day 0 - Surgery | |
| Demo-ALS | VS | DEMO_ALS-8-000417 | Toe Brachial Index | 0.69 | | | Screening | |
| Demo-ALS | VS | DEMO_ALS-8-000417 | Toe Brachial Index | 1.25 | | | Day 1 | |

# Taking the next natural step…

SDTM
ADaM
SEND, Define

FDA/PMDA/
NMPA converted
CORE Rules
(7K+)

User-defined
rules

## DataGuard

Downloadable
Desktop Application

Cost
free

SAS/R Code
integration

Show errors
on data

Validation
Report

Define.xml

cdisc

DataGuard

**Login**

Don't have an account yet? **Register**

Email

Password

Login

Forgot Password

DataGuard

## Login

Don't have an account yet? **Register**

Email

Johndoe@Caompany.Com

Password

*************** Login

DataGuard

File          Settings          About

# New Validation

Standard

SDTM     ADaM     SEND

Standard Version

3.1.2     3.1.3     3.2     3.3     3.4

Regulatory Agency

FDA     PMDA     NMPA

SDTM CT Version

2022-06-24     ▾     Select Dictionaries

.xpt files

**Drag files**
or
**Browse your computer**

Define.xml

**Drag file** or     **Browse your computer**

⟳ Initiate Validation

DataGuard

# New Validation

Validation Parameters

Standard

**SDTM**    ADaM    SEND

Standard Version

3.1.2    3.1.3    3.2    **3.3**    3.4

Regulatory Agency

**FDA**    PMDA    NMPA

SDTM CT Version

2022-06-24    ▼        Select Dictionaries

Select Files

.xpt files

**Drag files**
or
**Browse your computer**

Define.xml

**Drag file** or    **Browse your computer**

⟳ Initiate Validation

DataGuard

File    Settings    About

# New Validation

## Validation Parameters

**Standard**

SDTM    ADaM    SEND

**Standard Version**

3.1.2    3.1.3    3.2    3.3    3.4

**Regulatory Agency**

FDA    PMDA    NMPA

**SDTM CT Version**

2022-06-24 ▾

Select Dictionaries

## Select Files

.xpt files

ae.xpt

cm.xpt

dm.xpt

ds.xpt

lb.xpt

mh.xpt

qs.xpt

Total **9 files**    Remove all ✕    Add more +

**Define.xml**

**Drag file** or    **Browse your computer**

⟳ Initiate Validation

DataGuard

File          Settings          About

# New Validation

## Validation Parameters

**Standard**

SDTM    ADaM    SEND

**Standard Version**

3.1.2    3.1.3    3.2    3.3    3.4

**Regulatory Agency**

FDA    PMDA    NMPA

**SDTM CT Version**

2022-06-24 ▾          Select Dictionaries

## Select Files

**.xpt files**

ae.xpt

cm.xpt

dm.xpt

ds.xpt

lb.xpt

mh.xpt

qs.xpt

Total **9 files**          Remove all ✕          Add more +

**Define.xml**

define.xml

⟳ Initiate Validation

DataGuard

File    Settings    About

# Validation is in progress

| Standard Type | Standard Version | Regulatory Agency | SDTM CT Version | Files Uploaded |
|---|---|---|---|---|
| **SDTM** | **3.3** | **FDA** | **2022-06-24** | **9** |

Waiting for cdn-sharing.adobecc.com...

DataGuard

# Validation is in progress
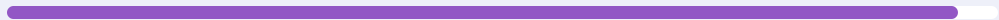
Standard Type
**SDTM**

Standard Version
**3.3**

Regulatory Agency
**FDA**

SDTM CT Version
**2022-06-24**

Files Uploaded
**9**

**DataGuard**

| Standard Type | Standard Version | Regulatory Agency | Files Uploaded |
|---|---|---|---|
| **SDTM** | **3.3** | **FDA** | **9** |

File    Settings    About    Edit Validation

# Validation Successful

| **9** | **206** / 663 | **36** / 206 | **3377** |
|---|---|---|---|
| Domains Checked | Rules Fired | Returned Issues | Instances |

| Standard Type | Standard Version | Regulatory Agency | SDTM CT Version | Files Uploaded |
|---|---|---|---|---|
| **SDTM** | **3.3** | **FDA** | **2022-06-24** | **9** |

Continue to results  1...

Bioforum **Validator**

DataGuard

Standard Type
**SDTM**

Standard Version
**3.3**

Regulatory Agency
**FDA**

Files Uploaded
**9**

File     Settings     About     Edit Validation

⚠️ **Issues Log** ⓘ

| ALL | 👁 | Issues FDA 30 ⟳ 2 | Instances 3,310 | ⌄ |
| xml | 👁 | Issues FDA 4 | Instances 67 | ⌄ |
| AE | 👁 | Issues FDA 2 | Instances 4 | ⌄ |
| CM | 👁 | Issues FDA 1 | Instances 19 | ⌄ |
| DM | 👁 | Issues FDA 1 | Instances 1 | ⌄ |
| DS | 👁 | Issues FDA 3 | Instances 24 | ⌄ |
| LB | 👁 | Issues FDA 6 ⟳ 1 | Instances 2301 | ⌄ |
| MH | 👁 | Issues FDA 1 | Instances 9 | ⌄ |
| QS | 👁 | Issues FDA 8 | Instances 797 | ⌄ |
| SE | 👁 | Issues FDA 6 | Instances 38 | ⌄ |
| VS | 👁 | Issues FDA 3 ⟳ 1 | Instances 117 | ⌄ |

**For more details
click on** 👁 **in the error log**

**DataGuard**

| Standard Type | Standard Version | Regulatory Agency | Files Uploaded |
|---|---|---|---|
| SDTM | 3.3 | FDA | 9 |

File    Settings    About    **Edit Validation**

⚠️ **Issues Log** ⓘ

| ALL | 👁 | Issues FDA 30 ⟳ 2 | Instances 3,310 | ⌃ |

**--ORRES value is populated, when --STAT is 'NOT DONE'**
Source FDA   ID SD1123   Domains 3   Instances 23   ⌄

**Inconsistent value for VISIT within VISITNUM**
Source FDA   ID SD0051   Domains 1   Instances 4   ⌄

**--ORRESU value do not match --TEST**
Source ⟳   ID BD0005   Domains 2   Instances 32   ⌄

**Variable value not found in extensible codelist**
Source FDA   ID CT2002   Domains 1   Instances 23   ⌄

| xml | 👁 | Issues FDA 4 | Instances 67 | ⌄ |
| AE | 👁 | Issues FDA 2 | Instances 4 | ⌄ |
| CM | 👁 | Issues FDA 1 | Instances 19 | ⌄ |
| DM | 👁 | Issues FDA 1 | Instances 1 | ⌄ |
| DS | 👁 | Issues FDA 3 | Instances 24 | ⌄ |
| LB | 👁 | Issues FDA 6 ⟳ 1 | Instances 2301 | ⌄ |
| MH | 👁 | Issues FDA 1 | Instances 9 | ⌄ |
| QS | 👁 | Issues FDA 8 | Instances 797 | ⌄ |
| SE | 👁 | Issues FDA 6 | Instances 38 | ⌄ |

**For more details
click on 👁 in the error log**

DataGuard

## ⚠ Issues Log ⓘ

ALL 👁 | Issues FDA 30 ◐ 2 | Instances 3,310 | ⌃

### --ORRES value is populated, when --STAT is 'NOT DONE'
Source FDA　ID SD1123　Domains 3　Instances 23

**Description**
Value Of Original Result (--ORRES) Variable Is Expected To Be Missing, When Observation Was Not Performed (Status (--STAT) Is 'NOT DONE').

| Domain | --TESTCD | VSORRES | VSSTAT | Rows |
|---|---|---|---|---|
| 👁 LB | WBC | 7.3 | NOT DONE | 14 |
| 👁 LB | WBC | 6.2 | NOT DONE | 147 |
| 👁 LB | WBC | 4.7 | NOT DONE | 227 |
| 👁 LB | BILIRUBIN | 1.1 | NOT DONE | 473 |
| 👁 VS | BMI | 24.5 | NOT DONE | 1 |
| 👁 VS | BMI | 27.9 | NOT DONE | 18 |

### Inconsistent value for VISIT within VISITNUM
Source FDA　ID SD0051　Domains 1　Instances 4

### --ORRESU value do not match --TEST
Source ◐　ID BD0005　Domains 2　Instances 32

### Variable value not found in extensible codelist
Source FDA　ID CT2002　Domains 1　Instances 23

xml 👁 | Issues FDA 4 | Instances 67 | ⌄

AE 👁 | Issues FDA 2 | Instances 4 | ⌄

CM 👁 | Issues FDA 1 | Instances 19 | ⌄

DM 👁 | Issues FDA 1 | Instances 1 | ⌄

**For more details
click on 👁 in the error log**

# DataGuard

| Standard Type | Standard Version | Regulatory Agency | Files Uploaded |
|---|---|---|---|
| SDTM | 3.3 | FDA | 9 |

File   Settings   About   **Edit Validation**

## ⚠️ Issues Log ℹ️

ALL   👁   Issues FDA 30 ⚙️ 2   Instances 3,310   ⌃

### --ORRES value is populated, when --STAT is 'NOT DONE'
Source FDA   ID SD1123   Domains 3   Instances 23   ⌄

#### Description
Value Of Original Result (--ORRES) Variable Is Expected To Be Missing, When Observation Was Not Performed (Status (--STAT) Is 'NOT DONE').

| | Domain | --TESTCD | VSORRES | VSSTAT | Rows |
|---|---|---|---|---|---|
| 👁 | LB | WBC | 7.3 | NOT DONE | 14 |
| 👁 | LB | WBC | 6.2 | NOT DONE | 147 |
| 👁 | LB | WBC | 4.7 | NOT DONE | 227 |
| 👁 | LB | BILIRUBIN | 1.1 | NOT DONE | 473 |
| 👁 | VS | BMI | 24.5 | NOT DONE | 1 |
| 👁 | VS | BMI | 27.9 | NOT DONE | 18 |

### Inconsistent value for VISIT within VISITNUM
Source FDA   ID SD0051   Domains 1   Instances 4   ⌄

### --ORRESU value do not match --TEST
Source ⏳   ID BD0005   Domains 2   Instances 32   ⌄

### Variable value not found in extensible codelist
Source FDA   ID CT2002   Domains 1   Instances 23   ⌄

xml   👁   Issues FDA 4   Instances 67   ⌄

AE   👁   Issues FDA 2   Instances 4   ⌄

CM   👁   Issues FDA 1   Instances 19   ⌄

DM   👁   Issues FDA 1   Instances 1   ⌄

## SDTM Data   Vital Signs (--ORRES value is populated, when --STAT is 'NOT DONE')

| VSTEST | VSPOS | VSORRES | VSORRESU | VSSTRESC | VSSTRESN | VSSTRESU | VSSTAT |
|---|---|---|---|---|---|---|---|
| Body Mass Index | | 24.5 | Kg/M2 | 24.5 | 24.5 | Kg/M2 | NOT DONE |
| stolic Blood Pressure | SUPINE | 75 | Mmhg | 75 | 75 | Mmhg | |
| stolic Blood Pressure | SUPINE | 109 | Mmhg | 109 | 109 | Mmhg | |
| Temperature | SUPINE | 35.9 | % | 35.9 | 35.9 | % | |
| Heart Rate | SUPINE | 67 | Beats/Min | 67 | 67 | Beats/Min | |
| stolic Blood Pressure | SUPINE | 116 | Mmhg | 116 | 116 | Mmhg | |
| Temperature | SUPINE | 36.5 | C | 36.5 | 36.5 | C | |
| stolic Blood Pressure | SUPINE | 75 | Mmhg | 75 | 75 | Mmhg | |
| Heart Rate | SUPINE | 65 | Beats/Min | 65 | 65 | Beats/Min | |
| stolic Blood Pressure | SUPINE | 115 | Mmhg | 115 | 115 | Mmhg | |
| Temperature | SUPINE | 36.5 | C | 36.5 | 36.5 | C | |
| stolic Blood Pressure | SUPINE | 76 | Mmhg | 76 | 76 | Mmhg | |
| Heart Rate | SUPINE | 56 | Beats/Min | 56 | 56 | Beats/Min | |
| stolic Blood Pressure | SUPINE | 76 | Mmhg | 76 | 76 | Mmhg | |
| stolic Blood Pressure | SUPINE | 120 | Mmhg | 120 | 120 | Mmhg | |
| Temperature | SUPINE | 36.3 | C | 36.3 | 36.3 | C | |
| Heart Rate | SUPINE | 64 | Beats/Min | 64 | 64 | Beats/Min | |
| Body Mass Index | | 27.9 | Kg/M2 | 27.9 | 27.9 | Kg/M2 | NOT DONE |
| stolic Blood Pressure | SUPINE | 125 | Mmhg | 125 | 125 | Mmhg | |
| stolic Blood Pressure | SUPINE | 77 | Mmhg | 77 | 77 | Mmhg | |
| Heart Rate | SUPINE | 55 | Beats/Min | 55 | 55 | Beats/Min | |
| Temperature | SUPINE | 36 | % | 36 | 36 | % | |
| stolic Blood Pressure | SUPINE | 126 | Mmhg | 126 | 126 | Mmhg | |
| stolic Blood Pressure | SUPINE | 75 | Mmhg | 75 | 75 | Mmhg | |
| Heart Rate | SUPINE | 61 | Beats/Min | 61 | 61 | Beats/Min | |
| Temperature | SUPINE | 36.8 | C | 36.8 | 36.8 | C | |
| stolic Blood Pressure | SUPINE | 122 | Mmhg | 122 | 122 | Mmhg | |
| stolic Blood Pressure | SUPINE | 70 | Mmhg | 70 | 70 | Mmhg | |
| Heart Rate | SUPINE | 57 | Beats/Min | 57 | 57 | Beats/Min | |
| Temperature | SUPINE | 36.7 | C | 36.7 | 36.7 | C | |
| Heart Rate | SUPINE | 56 | Beats/Min | 56 | 56 | Beats/Min | |
| Temperature | SUPINE | 36.4 | C | 36.4 | 36.4 | C | |
| stolic Blood Pressure | SUPINE | 119 | Mmhg | 119 | 119 | Mmhg | |
| Body Mass Index | | 26.6 | Kg/M2 | 26.6 | 26.6 | Kg/M2 | |
| Heart Rate | SUPINE | 58 | Beats/Min | 58 | 58 | Beats/Min | |
| stolic Blood Pressure | SUPINE | 61 | Mmhg | 61 | 61 | Mmhg | |
| Temperature | SUPINE | 36.4 | C | 36.4 | 36.4 | C | |

## DataGuard

### ⚠️ Issues Log ℹ️

| | | Issues FDA 6 ⚙️ 1 | Instances 2301 | ∨ |
|---|---|---|---|---|
| LB | 👁 | | | |
| MH | 👁 | Issues FDA 1 | Instances 9 | ∨ |
| QS | 👁 | Issues FDA 8 | Instances 797 | ∨ |
| SE | 👁 | Issues FDA 6 | Instances 38 | ∨ |
| VS | 👁 | Issues FDA 3 ⚙️ 1 | Instances 117 | ∧ |

👁 **Variable label mismatch** ∨
Source FDA    ID SD0063    Instances 1

👁 **VSORRES value is populated, when VSSTAT is 'NOT DONE'** ∨
Source FDA    ID SD1123    Instances 2

👁 **VSORRESU value do not match VSTESTCD** ∨
Source ⚙️    ID BD0005    Instances 16

**Description**
The Unit Value In VSORRESU Variable Do Not Match The Known Units For The Test Value In VSTESTCD Variable

| | USUBJID | VISIT | VSTPT | VSORRESU | VSTESTCD | Rows |
|---|---|---|---|---|---|---|
| 👁 | XFZ-201012-01 | Visit1 | Pre-Dose | % | TEMP | 4 |
| 👁 | XFZ-201012-02 | Visit1 | Pre-Dose | % | TEMP | 22 |
| 👁 | XFZ-201012-18 | Visit1 | Pre-Dose | % | TEMP | 115 |
| 👁 | XFZ-201012-18 | Visit1 | 1Hr Post-Dose | % | TEMP | 240 |
| 👁 | XFZ-201012-25 | Visit1 | Pre-Dose | % | TEMP | 503 |

👁 **Variable value not found in extensible codelist** ∨
Source FDA    ID CT2002    Instances 422

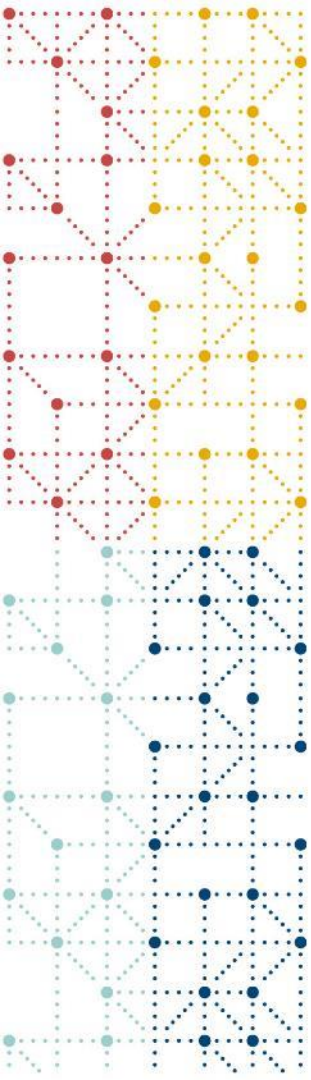### SDTM Data   Vital Signs (VSORRESU value do not match VSTESTCD)

| BJID | VSSEQ | VSTESTCD | VSTEST | VSPOS | VSORRES | VSORRESU | VSSTRESC | VSS |
|---|---|---|---|---|---|---|---|---|
| 01012-01 | 1 | BMI | Body Mass Index | | 24.5 | Kg/M2 | 24.5 | |
| 01012-01 | 2 | DIABP | Diastolic Blood Pressure | SUPINE | 75 | Mmhg | 75 | |
| 01012-01 | 3 | SISBP | Systolic Blood Pressure | SUPINE | 109 | Mmhg | 109 | |
| 01012-01 | 4 | TEMP | Temperature | SUPINE | 35.9 | % | 35.9 | |
| 01012-01 | 5 | HR | Heart Rate | SUPINE | 67 | Beats/Min | 67 | |
| 01012-01 | 6 | SISBP | Systolic Blood Pressure | SUPINE | 116 | Mmhg | 116 | |
| 01012-01 | 7 | TEMP | Temperature | SUPINE | 36.5 | C | 36.5 | |
| 01012-01 | 8 | DIABP | Diastolic Blood Pressure | SUPINE | 75 | Mmhg | 75 | |
| 01012-01 | 9 | HR | Heart Rate | SUPINE | 65 | Beats/Min | 65 | |
| 01012-01 | 10 | SISBP | Systolic Blood Pressure | SUPINE | 115 | Mmhg | 115 | |
| 01012-01 | 11 | TEMP | Temperature | SUPINE | 36.5 | C | 36.5 | |
| 01012-01 | 12 | DIABP | Diastolic Blood Pressure | SUPINE | 76 | Mmhg | 76 | |
| 01012-01 | 13 | HR | Heart Rate | SUPINE | 56 | Beats/Min | 56 | |
| 01012-01 | 14 | DIABP | Diastolic Blood Pressure | SUPINE | 76 | Mmhg | 76 | |
| 01012-01 | 15 | SISBP | Systolic Blood Pressure | SUPINE | 120 | Mmhg | 120 | |
| 01012-01 | 16 | TEMP | Temperature | SUPINE | 36.3 | C | 36.3 | |
| 01012-01 | 17 | HR | Heart Rate | SUPINE | 64 | Beats/Min | 64 | |
| 01012-02 | 1 | BMI | Body Mass Index | | 27.9 | Kg/M2 | 27.9 | |
| 01012-02 | 2 | SISBP | Systolic Blood Pressure | SUPINE | 125 | Mmhg | 125 | |
| 01012-02 | 3 | DIABP | Diastolic Blood Pressure | SUPINE | 77 | Mmhg | 77 | |
| 01012-02 | 4 | HR | Heart Rate | SUPINE | 55 | Beats/Min | 55 | |
| 01012-02 | 5 | TEMP | Temperature | SUPINE | 36 | % | 36 | |
| 01012-02 | 6 | SISBP | Systolic Blood Pressure | SUPINE | 126 | Mmhg | 126 | |
| 01012-02 | 7 | DIABP | Diastolic Blood Pressure | SUPINE | 75 | Mmhg | 75 | |
| 01012-02 | 8 | HR | Heart Rate | SUPINE | 61 | Beats/Min | 61 | |
| 01012-02 | 9 | TEMP | Temperature | SUPINE | 36.8 | C | 36.8 | |
| 01012-02 | 10 | SISBP | Systolic Blood Pressure | SUPINE | 122 | Mmhg | 122 | |
| 01012-02 | 11 | DIABP | Diastolic Blood Pressure | SUPINE | 70 | Mmhg | 70 | |
| 01012-02 | 12 | HR | Heart Rate | SUPINE | 57 | Beats/Min | 57 | |
| 01012-02 | 13 | TEMP | Temperature | SUPINE | 36.7 | C | 36.7 | |
| 01012-02 | 14 | HR | Heart Rate | SUPINE | 56 | Beats/Min | 56 | |
| 01012-02 | 15 | TEMP | Temperature | SUPINE | 36.4 | C | 36.4 | |
| 01012-02 | 16 | SISBP | Systolic Blood Pressure | SUPINE | 119 | Mmhg | 119 | |
| 01012-03 | 1 | BMI | Body Mass Index | | 26.6 | Kg/M2 | 26.6 | |
| 01012-03 | 2 | HR | Heart Rate | SUPINE | 58 | Beats/Min | 58 | |
| 01012-03 | 3 | DIABP | Diastolic Blood Pressure | SUPINE | 61 | Mmhg | 61 | |
| 01012-03 | 4 | TEMP | Temperature | SUPINE | 36.4 | C | 36.4 | |

# When?

**Q1 2024**

**Pending FDA-CDISC agreement on a 'Single Source of Truth'**

# Thank You!

cdisc