CDISCPILOT02 – Updated for SDTMIG v3.2

Test Data Factory Project Team

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# Introduction

The PhUSE organization initiated the Test Data Factory (TDF) project to make test data for CDISC-based processes and programs publicly available. The CDISCPILOT02 datasets from 2013 were updated to conform to newer standards. The TDF project team used the following approach:

* The team ran the datasets through Pinnacle 21 Community v2.2 using SDTM 3.2 as the Configuration and 2016-06-24 as the CDISC CT.
* Based on the reported findings each dataset was updated so that no more unexplained findings (see section 3) are reported.
* Pinnacle 21 Community v2.2 was again used on all updated datasets to find additional issues resulting from inconsistencies between the datasets. The datasets were updated again.
* For updating the datasets, the team used SAS and R programs.

The team used Pinnacle 21 as a conformance checking tool because it is a commonly used tool to evaluate conformance and is openly available to everyone. The team is very well aware of shortcomings and knows that is it not perfect and comprehensive but decided that for lack of better alternatives, this would be the right choice. In order to resolve some of the findings, the team needed to make some decisions on how the datasets should be updated. These changes should not be construed as definitive approaches for resolving conformance issues in general. Users of the updated CDISCPILOT datasets should be aware that depending on the situation, several options can and need to be considered.

Note that the rather large LB and QS domain datasets were split (see section 2.1) to accommodate limitations of the repository that was used during the work. This also demonstrates splitting of domains. This was not done because of any guidance or other requirement to split these domains.

Section 3 of this document provides explanations for the Pinnacle 21 findings that are still seen in the report. Some of these findings cannot be fully addressed because information on how the data was originally collected was not included in the pilot materials.

Note that this document is not intended to represent a full-fledged Study Data Reviewer’s Guide (SDRG). Instead, its purpose is to serve as documentation for the updated test data, and to explain some of the decisions that were made during the update process. In turn, the test data is intended to be used for the development and testing of standard reporting and analysis scripts, and is not meant to represent a complete regulatory submission package. The original CDISCPILOT02 data may be downloaded from <https://www.cdisc.org/sdtmadam-pilot-project>, if desired.

# Specific Comments

## Split datasets

The LB, SUPPLB, and QS domain datasets were split based on the values of the indicated variable as recommended in the SDTMIG. Note that this splitting was done to reduce the size of the resulting datasets and to demonstrate split datasets and not because of any guidance or other requirement to split these domains.

|  |  |  |  |
| --- | --- | --- | --- |
| Domain | Split Domain | Value of split Variable | Comment about Split Variable |
| QS | qsco.xpt | QSCAT: ADAS-COG | Alzheimer's Disease Assessment Scale-Cognitive CDISC Version Questionnaire |
| QS | qsda.xpt | QSCAT: DAD | Disability Assessment for Dementia Questionnaire |
| QS | qsgi.xpt | QSCAT: ADCS-CGIC | Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change Questionnaire |
| QS | qshi.xpt | QSCAT: MHIS-NACC | Modified Hachinski Ischemic Scale-NACC Version Questionnaire |
| QS | qsmm.xpt | QSCAT: MMSE | Mini-Mental Status Exam |
| QS | qsni.xpt | QSCAT: NPI | Neuropsychiatric Inventory Questionnaire |
| LB | lbch.xpt | LBCAT: CHEMISTRY | Chemistry |
| LB | lbhe.xpt | LBCAT: HEMATOLOGY | Hematology |
| LB | lbur.xpt | LBCAT: URINALYSIS | Urinalysis |
| SUPPLB | supplbch.xpt | IDVARVAL | Split based on IDVARVAL matching LBSEQ in lbch.xpt |
| SUPPLB | supplbhe.xpt | IDVARVAL | Split based on IDVARVAL matching LBSEQ in lbhe.xpt |
| SUPPLB | supplbur.xpt | IDVARVAL | Split based on IDVARVAL matching LBSEQ in lbur.xpt |

## AE Domain Modification

AE information was collected by visit, with a new record entered each time. In the CDISCPILOT02 dataset, these duplicate records caused 230 validation warnings “Duplicate records in AE domain” for the AE variables “AEDECOD, AETERM, AESEV, AESTDTC, USUBJID”. These records have been collapsed.

# Data Conformance Summary – Explanation on Remaining Pinnacle 21 Findings

The following table explains the remaining warnings from a Pinnacle 21 Community Edition validation.

| Domain | Variables | Values | Message | Severity | Explanation |
| --- | --- | --- | --- | --- | --- |
| AE | VARIABLE | AEDY | Model permissible variable added into standard domain | Warning | AEDY was included because AEDTC is included. |
| AE | VARIABLE | EPOCH | Model permissible variable added into standard domain | Warning | Per FDA Study Data Technical Conformance Guide, the variable EPOCH should be included for clinical subject-level observations |
| AE | VARIABLE | AEDTC | Model permissible variable added into standard domain | Warning | AEDTC is included because AE information was collected by visit. |
| AE | AEENDTC | null | Missing End Time-Point value | Warning | AEENDTC is missing for some AEs and no value was collected to state that AEs were ongoing or not |
| CM | VARIABLE | EPOCH | Model permissible variable added into standard domain | Warning | Per FDA Study Data Technical Conformance Guide, the variable EPOCH should be included for clinical subject-level observations |
| CM | VARIABLE | CMDTC | Model permissible variable added into standard domain | Warning | ??? |
| CM | VARIABLE | VISITDY | Model permissible variable added into standard domain | Warning | ??? |
| CM | VARIABLE | VISIT | Model permissible variable added into standard domain | Warning | ??? |
| CM | VARIABLE | CMDY | Model permissible variable added into standard domain | Warning | ??? |
| CM | VARIABLE | VISITNUM | Model permissible variable added into standard domain | Warning | ??? |
| DM | ARMCD, ACTARMCD, USUBJID | Xan\_Lo, Xan\_Lo, 01-703-1119 | No baseline result in LB for subject | Warning | According to the study rules for setting the baseline flag, this subject did not have a specific baseline visit. |
| DM | ARMCD, ACTARMCD | Xan\_Hi, Xan\_Lo | ACTARMCD does not equal ARMCD | Warning | Some subjects were not treated according to protocol. This deviation was recorded as required and correctly marked as warning. |
| DS | VARIABLE | VISIT | Model permissible variable added into standard domain | Warning | VISIT was added to DS because protocol specified events were collected at particular visits. |
| DS | VARIABLE | VISITNUM | Model permissible variable added into standard domain | Warning | VISITNUM was added to DS because protocol specified events were collected at particular visits. |
| DS | VARIABLE | DSDY | Model permissible variable added into standard domain | Warning | DSDY was added because DSDTC is captured. |
| EX | VARIABLE | VISIT | Model permissible variable added into standard domain | Warning | VISIT was added to EX was collected by visits. |
| EX | VARIABLE | VISITNUM | Model permissible variable added into standard domain | Warning | VISITNUM was added to EX was collected by visits. |
| EX | VARIABLE | VISITDY | Model permissible variable added into standard domain | Warning | VISITDY was added to EX was collected by visits. |
| LB | VARIABLE | EPOCH | Model permissible variable added into standard domain | Warning | Per FDA Study Data Technical Conformance Guide, the variable EPOCH should be included for clinical subject-level observations |
| LB (LBHE) | LBORRES, LBTEST, LBORRESU, LBTESTCD |  | Missing value for LBORRESU, when LBORRES is provided | Warning | There are lab tests that do not have units. This is acceptable. |
| LB (LBHE) | LBTEST, LBSTRESN, LBTESTCD, LBSTRESC, LBSTRESU |  | Missing value for LBSTRESU, when LBSTRESC is provided | Warning | There are lab tests that do not have units. This is acceptable. |
| LB (LBUR) | LBORRES, LBTEST, LBORRESU, LBTESTCD |  | Missing value for LBORRESU, when LBORRES is provided | Warning | There are lab tests that do not have units. This is acceptable. |
| MH | VARIABLE | VISITDY | Model permissible variable added into standard domain | Warning | ??? |
| MH | VARIABLE | VISITNUM | Model permissible variable added into standard domain | Warning | ??? |
| MH | VARIABLE | VISIT | Model permissible variable added into standard domain | Warning | ??? |
| MH | VARIABLE | MHSEV | Model permissible variable added into standard domain | Warning | ??? |
| MH | VARIABLE | MHHLGT | Model permissible variable added into standard domain | Warning | ??? |
| MH | VARIABLE | MHLLT | Model permissible variable added into standard domain | Warning | ??? |
| MH | VARIABLE | MHHLT | Model permissible variable added into standard domain | Warning | ??? |
| QS | VARIABLE | EPOCH | Model permissible variable added into standard domain | Warning | Per FDA Study Data Technical Conformance Guide, the variable EPOCH should be included for clinical subject-level observations |
| QS (QSCO) | QSSTRESC, QSBLFL | null, Y | Missing QSSTRESC value for Baseline record | Warning | A baseline value was not recorded as it might happen in trials. |
| SE | VARIABLE | SESTDY | Model permissible variable added into standard domain | Warning | Per Pinnacle 21 validation SESTDY variable is required when SESTDTC variable is present. |
| SE | VARIABLE | SEENDY | Model permissible variable added into standard domain | Warning | Per Pinnacle 21 validation SEENDY variable is required when SEENDTC variable is present. |
| SV |  | EPOCH | Model permissible variable added into standard domain | Warning | Per FDA Study Data Technical Conformance Guide, the variable EPOCH should be included for clinical subject-level observations |
| TS | TSPARM | Age Group | TSPARM value not found in 'Trial Summary Parameter Test Name' extensible codelist | Warning | A value was added to the extensible codelist. |
| TS | TSPARMCD | AGESPAN | TSPARMCD value not found in 'Trial Summary Parameter Test Code' extensible codelist | Warning | A value was added to the extensible codelist. |
| VS |  | EPOCH | Model permissible variable added into standard domain | Warning | Per FDA Study Data Technical Conformance Guide, the variable EPOCH should be included for clinical subject-level observations |