

SAS Clinical Standards Toolkit 1.3 CDISC-ADAM 2.1 VALIDATION

Report Summary

| Report Parameter | Value |
|---------------------------------------|---------------------------------------------------------------------------------------------------------------|
| SASReferences data set | work._cstsasrefs |
| Results data set | results.validation_results |
| Metrics data set | results.validation_metrics |
| CST Process datetime | 2011-02-15T16:58:38 |
| Report only errors, warnings & notes? | Yes |
| # records to report | 50 |
| Report results by table | No |
| Report output file | !sasroot/.../SASClinicalStandardsToolkitADAM21/1.3/sample/cdisc-adam-2.1/sascstdemodata/results/cstreport.pdf |

SAS Clinical Standards Toolkit 1.3 CDISC-ADAM 2.1 VALIDATION

Process Inputs/Outputs

| Type | Path |
|------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Autocall Libraries | (adamauto sasautos) |
| | adamauto: c:/cstGlobalLibrary/standards/cdisc-adam-2.1-1.3/macros |
| Format Search Path Libraries | (srcfmt) |
| | srcfmt: !sasroot/.../SASClinicalStandardsToolkitADAM21/1.3/sample/cdisc-adam-2.1/sascstdemodata/terminology/formats |
| Source Data | !sasroot/.../SASClinicalStandardsToolkitADAM21/1.3/sample/cdisc-adam-2.1/sascstdemodata/data |
| Source Metadata | !sasroot/.../SASClinicalStandardsToolkitADAM21/1.3/sample/cdisc-adam-2.1/sascstdemodata/metadata |

SAS Clinical Standards Toolkit 1.3 CDISC-ADAM 2.1 VALIDATION

Process Metrics

| Summary Metrics | | Check Metrics | | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------|---|---------------|---------------------|-----------------------|----------|-----------------------------|
| Metric | # | Check ID | # Check Invocations | # Recs (if available) | # Errors | # Check Invocations Not Run |
| # of distinct check invocations | 1 | ADAM0001 | 1 | 1 | 1 | 0 |
| # check invocations not run | 0 | | | | | |
| Errors (severity=High) reported | 1 | | | | | |
| Warnings (severity=Medium) reported | 0 | | | | | |
| Notes (severity=Low) reported | 0 | | | | | |
| Structural errors, warnings and notes | 0 | | | | | |
| Content errors, warnings and notes | 1 | | | | | |
| <small>Note: "# Check Invocations Not Run" includes both checks that did not run and checks that failed to complete successfully.</small> | | | | | | |

SAS Clinical Standards Toolkit 1.3 CDISC-ADAM 2.1 VALIDATION

General Process Reporting

| Seq # | Source Data | Result Identifier | Severity | Problem Detected? | Message |
|-------|---------------------|-------------------|----------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | CST_SETPROPERTIES | CST0108 | Info | No | The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst-framework-1.3/programs/initialize.properties |
| 1 | CST_CREATEDS | CST0102 | Info | No | work.sasreferences was created as requested |
| 1 | CSTUTIL_PROCESSETUP | CST0200 | Info | No | Process setup is using this SASReferences: C:\Users\sasses\AppData\Local\Temp\SAS Temporary Files_TD6216\sasreferences |
| 1 | CST_SETPROPERTIES | CST0108 | Info | No | The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-adam-2.1-1.3/programs/initialize.properties |
| 1 | CST_SETPROPERTIES | CST0108 | Info | No | The properties were processed from the PATH !sasroot/../../SASClinicalStandardsToolkitADAM21/1.3/sample/cdisc-adam-2.1/ sascstdemodata/programs/validation.properties |
| 1 | ADAM_VALIDATE | CST0200 | Info | No | PROCESS STANDARD: CDISC-ADAM |
| 2 | ADAM_VALIDATE | CST0200 | Info | No | PROCESS STANDARDVERSION: 2.1 |
| 3 | ADAM_VALIDATE | CST0200 | Info | No | PROCESS DRIVER: ADAM_VALIDATE |
| 4 | ADAM_VALIDATE | CST0200 | Info | No | PROCESS DATE: 2011-02-15T16:58:38 |
| 5 | ADAM_VALIDATE | CST0200 | Info | No | PROCESS TYPE: VALIDATION |
| 6 | ADAM_VALIDATE | CST0200 | Info | No | PROCESS SASREFERENCES: C:\Users\sasses\AppData\Local\Temp\SAS Temporary Files_TD6216\sasreferences.sas7bdat |
| 7 | ADAM_VALIDATE | CST0200 | Info | No | PROCESS STUDYROOTPATH: !sasroot/../../SASClinicalStandardsToolkitADAM21/1.3/sample/cdisc-adam-2.1/ sascstdemodata |
| 8 | ADAM_VALIDATE | CST0200 | Info | No | PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary |
| 9 | ADAM_VALIDATE | CST0200 | Info | No | PROCESS CSTVERSION: 1.3 |

**SAS Clinical Standards Toolkit 1.3
CDISC-ADAM 2.1 VALIDATION**

Process Results, CheckID: ADAM0001

Description: There is only one ADSL per study

Check scope: (Tables) ADSL, (Columns)

Source: CDISC (1)

Validation check macro: cstcheck_zeroobs, using source metadata

| Check Invocation | Seq # | Source Data | Result Identifier | Message | Severity | Problem Detected? | Actual Value | Keys |
|------------------|-------|--------------|-------------------|-----------------------------|----------|-------------------|--------------|------|
| 1 | 1 | SRCDATA.ADSL | ADAM0001 | ADSL dataset does not exist | Error | Yes | | |