

Specifications for SDTM Validation Criteria (v3.1, 3.1.1)

Revision History

Date	Description	Version
1/9/2008	Draft of validation criteria used for Janus operational pilot	0.1

DRAFT

Specifications for Study Data Tabulation Model Validation Criteria for the Janus Operational Pilot

This specification details the validation criteria applied when FDA processes study data received in the Study Data Tabulation Model (SDTM) format during iterative phases of the Janus operational pilot. This specification provides a description of the business rules used for the validation process (based on the SDTM Implementation Guide, v1.1), explains the errors and severity levels assigned for each rule, and describes the impact of each error.

Severity Levels

The severity levels that define the impact of errors on the official receipt of SDTM submissions are as follows:

Severity	Description
High	The error is serious and will prevent the study data from being loaded successfully into the Janus repository. The SDTM study <u>will not</u> be loaded into the Janus repository.
Medium	The error may impact the reviewability of the submission, but will not have an impact on loading the study data into the Janus repository. The SDTM study <u>will</u> be loaded into the Janus repository.
Low	The error may or may not impact the reviewability or the integrity of the submission but will not have an impact on loading the study data into the Janus repository. The SDTM study <u>will</u> be loaded into the Janus repository.

An error report describing errors by severity and domain will be produced for all submissions processed.

Validation Process Overview

Errors in an SDTM submission may have an impact at different steps in the end-to-end process of extracting, validating, and loading study data into the Janus repository.

Each study submitted in SDTM format must include a define.xml file—submissions that do not include a define.xml file will not be sent to the Janus staging area during the process of locating and extracting SDTM datasets from CDER’s Electronic Document Room (EDR).

Validation errors in the staging area that will cause submissions to fail the validation process are as follows:

- Define.xml that fails the structural validation check or check for controlled vocabularies¹
- Missing mandatory domains—mandatory domains for Janus include DM (demographics), EX (exposures), and DS (disposition)
- Missing mandatory fields in either the mandatory domains or optional domains provided in the submission
- Date fields in the submission (all domains) are not compliant with the SDTM specification
- Domain-specific errors as described in the detailed specifications described below.

Errors occurring during the process of loading the Janus Oracle database that will cause submissions to fail the validation process are as follows:

- SITEID (site study identifier) is null for all rows in the required DM (demographics) domain in the submission
- TA (trial arm) domain is not provided and ARMCD (planned arm code) is null for all rows in the required DM (demographics) domain in the submission

Detailed SDTM Validation Criteria

Detailed validation criteria, including business rule ID, domain affected, a description of the rule, error severity, effective date, error message, and impact, are described below.

¹ Per Release Notes for WebSDM v1.5, used to perform the validation checks in the staging area for the Janus repository, "WebSDM checks data structure definitions in the SAS transport files against the define.xml, and checks data in the SAS transport files against the SDTM guidelines. If a MedDRA version is included in the define.xml, that MedDRA version is associated with the study. If the define.xml includes a codelist for a variable that is not subject to controlled terminology, WebSDM automatically creates a rule to check data values against that codelist."

Rule ID (v3.1.1)	IR4000
Same Rule in v3.1	Yes (same as IR3000 for v3.1)
Domain	All
Description of Rule	Identifies domain table that has zero rows and therefore contains no data
Severity	Low
Effective Date	08/01/2007
Error Message	No rows in domain table
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4001
Same Rule in v3.1	Yes (same as IR3001 for v3.1)
Domain	All
Description of Rule	Identifies a null (empty) value found in a column where (Standard) Core attribute is 'Req'
Severity	Medium
Effective Date	08/01/2007
Error Message	Null value in column
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4002
Same Rule in v3.1	Yes (same as IR3002 for v3.1)
Domain	All
Description of Rule	Identifies records where the value for a date does not conform to the ISO 8601 standard
Severity	High
Effective Date	08/01/2007
Error Message	Invalid ISO 8601 value
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4003
Same Rule in v3.1	Yes (same as IR3003 for v3.1)
Domain	All
Description of Rule	Identifies records where the value in the DOMAIN column does not match the name of the Domain
Severity	Low
Effective Date	08/01/2007
Error Message	Inconsistent value for DOMAIN
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4004
Same Rule in v3.1	Yes (same as IR3004 for v3.1)
Domain	All
Description of Rule	Identifies records where the non-unique values for Sequence Number variable exist within a subject
Severity	High
Effective Date	08/01/2007
Error Message	Non-unique values for SEQ
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4005
Same Rule in v3.1	Yes (same as IR3005 for v3.1)
Domain	Findings
Description of Rule	Identifies subjects where there are no records with a value of "Y" in the baseline flag variable (Baseline Flag)
Severity	Low
Effective Date	08/01/2007
Error Message	No baseline result
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4006
Same Rule in v3.1	Yes (same as IR3006 for v3.1)
Domain	Findings, LB
Description of Rule	Identifies Short Name of Measurement, Test or Examination values where standard units value (Standard Units) is not consistent across all records
Severity	High
Effective Date	08/01/2007
Error Message	Inconsistent value for Standard Unit
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4007
Same Rule in v3.1	Yes (same as IR3007 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where the value for the Preferred Term could not be found in the MedDRA dictionary
Severity	High
Effective Date	08/01/2007
Error Message	Invalid value for Preferred Term
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4008
Same Rule in v3.1	Yes (same as IR3008 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where Serious Event='Y' but none of Involves Cancer, Congenital Anomaly or Birth Defect, Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other medically Important Serious Event, or Occurred with Overdose equals 'Y'
Severity	Low
Effective Date	08/01/2007
Error Message	AE is Serious but no qualifiers set to 'Y'
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4009
Same Rule in v3.1	Yes (same as IR3009 for v3.1)
Domain	All
Description of Rule	Identifies records where Result or Finding in Original Units and Status both have a value, or where both are null
Severity	Medium
Effective Date	08/01/2007
Error Message	Either Original Result or Status should be specified, but not both
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4010
Same Rule in v3.1	Yes (same as IR3010 for v3.1)
Domain	All
Description of Rule	Identifies records where the value for Visit Number is formatted to more than two decimal places
Severity	Low
Effective Date	08/01/2007
Error Message	VISITNUM should not be formatted to more than 3 decimal places
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4011
Same Rule in v3.1	Yes (same as IR3011 for v3.1)
Domain	Special Purpose, DM
Description of Rule	Identifies records that violate the condition [If Arm Code='SCRNFAIL' then Description of Arm must equal 'Screen Failure', and vice versa]
Severity	Medium
Effective Date	08/01/2007
Error Message	If ARMCD equals 'SCRNFAIL' then ARM must equal 'Screen Failure'
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4012
Same Rule in v3.1	Yes (same as IR3012 for v3.1)
Domain	Trial Design, TA
Description of Rule	Identifies records that violate the condition [If Arm Code='SCRNFAIL' then Description of Arm must equal 'Screen Failure', and vice versa]
Severity	High
Effective Date	08/01/2007
Error Message	If ARMCD equals 'SCRNFAIL' then ARM must equal 'Screen Failure'
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4100
Same Rule in v3.1	Yes (covers IR3040 (for CM), IR3064 (for EX), IR3084 (for AE) for 3.1)
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [(Study Day of Start of Observation less than or equal to Study Day of End of Observation)], limited to records where [Study Day of Start of Observation is not null and Study Day of End of Observation is not null)]
Severity	High
Effective Date	08/01/2007
Error Message	Begin day must be less than or equal to end day
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4101
Same Rule in v3.1	Yes (covers IR3059 (for EX), IR3079 (for AE) for 3.1)
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [(Start Date/Time of Observation less than or equal to End Date/Time of Observation)], limited to records where [Start Date/Time of Observation is not null and End Date/Time of Observation is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Begin day must be less than or equal to end day
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4102
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Baseline Flag either 'Y' or null]
Severity	Medium
Effective Date	08/01/2007
Error Message	Invalid YES code
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4103
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Derived Flag either 'Y' or null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YES code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4104
Same Rule in v3.1	No
Domain	Events, Interventions
Description of Rule	Identifies records that violate the condition [End Relative to Reference Period in ('BEFORE', 'DURING', 'DURING/AFTER', 'U')], limited to records where [End Relative to Reference Period is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid BEFOREAFTER code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4105
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Fasting Status in ('Y', 'N', 'U')], limited to records where [Fasting Status is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNOUNK code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4106
Same Rule in v3.1	Yes (covers R3498 (for AE), R3505 (for CM), R3506 (for SU) for 3.1
Domain	Events, Inverventions
Description of Rule	Identifies records that violate the condition [Occurrence in ('Y', 'N')], limited to records where [Occurrence is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4107
Same Rule in v3.1	Yes (covers R3508 (for CM), R3509 (for SU), R3510 (for MH), R3511 (for LB), R3512 (for EG), R3513 (for QS), R3514 (for PE), R3515 (for VS), R3516 (for SC) for 3.1
Domain	All
Description of Rule	Identifies records that violate the condition [Status='NOT DONE'], limited to records where [Status is not null]
Severity	Medium
Effective Date	08/01/2007
Error Message	Invalid NOTDONE code
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4108
Same Rule in v3.1	Yes (covers R3495 (for CM) for 3.1
Domain	Events, Interventions
Description of Rule	Identifies records that violate the condition [Start Relative to Reference Period in ('BEFORE', 'DURING', 'AFTER'), limited to records where [Start Relative to Reference Period is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid BEFOREAFTER code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4109
Same Rule in v3.1	Yes (covers R3048 (for EX) for 3.1
Domain	Interventions
Description of Rule	Identifies records that violate the condition [Dose greater than or equal to 0], limited to records where [Dose is not null]
Severity	High
Effective Date	08/01/2007
Error Message	DOSE must be non-negative
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4110
Same Rule in v3.1	No
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [Duration greater than or equal to 0], limited to records where [Duration is not null]
Severity	Medium
Effective Date	08/01/2007
Error Message	Duration must be non-negative
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4111
Same Rule in v3.1	Yes (covers R3519 (for EG), R3520 (for LB), R3521 (for QS), R3522 (for VS) for 3.1
Domain	Findings
Description of Rule	Identifies records that violate the condition [Result or Finding in Original Units is null], limited to records where [Derived Flag='Y']
Severity	Low
Effective Date	08/01/2007
Error Message	Derived Flag = 'Y' but Original Result is not null
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4112
Same Rule in v3.1	Yes (covers R3523 (for EG), R3524 (for LB), R3525 (for QS), R3526 (for VS) for 3.1
Domain	Findings
Description of Rule	Identifies records that violate the condition [Result or Finding in Standard Format is not null], limited to records where [Derived Flag='Y']
Severity	Low
Effective Date	08/01/2007
Error Message	Derived Flag = 'Y' but (Character) Standard Result is null
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4113
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [LENGTH(Name of Measurement, Test, or Examination) less than or equal to 40 characters]
Severity	Low
Effective Date	08/01/2007
Error Message	Invalid value for __TEST variable
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4114
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [LENGTH(Short Name of Measurement, Test, or Examination) less than or equal to 8 characters, cannot start with a number or contain special characters]
Severity	Low
Effective Date	08/01/2007
Error Message	Invalid value for __TESTCD variable
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4115
Same Rule in v3.1	No
Domain	Trial Design, TS
Description of Rule	Identifies records that violate the condition [LENGTH(Trial Summary Parameter) less than or equal to 40 characters]
Severity	Low
Effective Date	08/01/2007
Error Message	Invalid value for __PARM variable
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4116
Same Rule in v3.1	No
Domain	Trial Design, TS
Description of Rule	Identifies records that violate the condition [LENGTH(Trial Summary Parameter Short Name) less than or equal to 8 characters, cannot start with a number or contain special characters]
Severity	Low
Effective Date	08/01/2007
Error Message	Invalid value for __PARMCD variable
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4117
Same Rule in v3.1	No
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [End Relative to Reference Period is not null], limited to records where [End Date/Time of Observation is not null]
Severity	Low
Effective Date	08/01/2007
Error Message	__ENRF expected when __ENDTC is null
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4118
Same Rule in v3.1	No
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [Start Relative to Reference Period is not null], limited to records where [Start Date/Time of Observation is not null]
Severity	Low
Effective Date	08/01/2007
Error Message	__STRF expected when __STDTC is null
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4119
Same Rule in v3.1	Yes (same as R3092 for 3.1)
Domain	Interventions, EX
Description of Rule	Identifies records that violate the condition [Planned Elapsed Time from Reference Pt greater than or equal to 0], limited to records where [Planned Elapsed Time from Reference Pt is not null]
Severity	Medium
Effective Date	08/01/2007
Error Message	__ELTM must be non-negative
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4120
Same Rule in v3.1	No
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [Evaluation Interval greater than or equal to 0], limited to records where [Evaluation Interval is not null]
Severity	High
Effective Date	08/01/2007
Error Message	__EVLINT must be non-negative
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4121
Same Rule in v3.1	No
Domain	Events
Description of Rule	Identifies records that violate the condition [Toxicity Grade is a valid number], limited to records where [Toxicity Grade is not null]
Severity	Low
Effective Date	08/01/2007
Error Message	Invalide value for **TOXGR variable
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4122
Same Rule in v3.1	No
Domain	All
Description of Rule	Identifies records that violate the condition [Reason Not Done is null], limited to records where [Status is null]
Severity	Low
Effective Date	08/01/2007
Error Message	STAT is NOT DONE but no reason given
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4123
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Date/Time of Collection is not null], limited to records where [End Date/Time of Observation is not null]
Severity	Low
Effective Date	08/01/2007
Error Message	Start date expected when end date provided
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4124
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Date/Time of Collection less than or equal to End Date/Time of Observation], limited to records where [Date/Time of Collection is not null and End Date/Time of Observation exists)
Severity	High
Effective Date	08/01/2007
Error Message	Start date must be before end date
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4125
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Result or Finding in Original UnitsU is not null], limited to records where [Result or Finding in Original Units is not null]
Severity	Medium
Effective Date	08/01/2007
Error Message	Missing units on value
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4126
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Result or Finding in Original UnitsU is null], limited to records where [Result or Finding in Original Units is null]
Severity	Low
Effective Date	08/01/2007
Error Message	Missing value although units provided
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4127
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Normal Range Upper Limit-Standard Units greater than or equal to Normal Range Lower Limit-Standard Units], limited to records where [Normal Range Upper Limit-Standard Units is not null and STNRHI is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Upper limit must be greater than or equal to lower limit
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4128
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Standard Units is not null], limited to records where [Result or Finding in Standard Format is not null]
Severity	Medium
Effective Date	08/01/2007
Error Message	Missing units on value
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4129
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Standard Units is null], limited to records where [Result or Finding in Standard Format is null]
Severity	Low
Effective Date	08/01/2007
Error Message	Missing value although units provided
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4130
Same Rule in v3.1	No
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [Start Date/Time of Observation is not null], limited to records where [End Date/Time of Observation is not null]
Severity	Low
Effective Date	08/01/2007
Error Message	Start date expected when end date provided
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4131
Same Rule in v3.1	No
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [Planned Time Point Name is not null], limited to records where [Planned Time Point Name is not null]
Severity	Low
Effective Date	08/01/2007
Error Message	Timepoint (character) missing when timepoint number provided
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4132
Same Rule in v3.1	No
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [Planned Time Point Number is not null], limited to records where [Planned Time Point Number is not null]
Severity	Low
Effective Date	08/01/2007
Error Message	Timepoint number missing when timepoint (character) provided
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4133
Same Rule in v3.1	No
Domain	All (Timing)
Description of Rule	Identifies records that violate the condition [Time Point Reference is not null], limited to records where [Time Point Reference is not null]
Severity	Low
Effective Date	08/01/2007
Error Message	Timepoint reference (character) missing when elapsed time from reference point provided
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4134
Same Rule in v3.1	No
Domain	Interventions
Description of Rule	Identifies records that violate the condition [Dose Units is not null], limited to records where [Dose is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Missing units on value
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4135
Same Rule in v3.1	No
Domain	Findings
Description of Rule	Identifies records that violate the condition [Result or Finding in Standard Format is not null], limited to records where [Result of Finding in Original Units is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Missing character result when original result provided
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4136
Same Rule in v3.1	No
Domain	All
Description of Rule	Identifies records where values are not found in the study-specific code list attached to a variable
Severity	Low
Effective Date	08/01/2007
Error Message	Value for variable not found in code list
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4137
Same Rule in v3.1	?
Domain	All
Description of Rule	Identifies records that violate the condition [Study Day of Visit/Collection/Exam does not equal 0]
Severity	Low
Effective Date	08/01/2007
Error Message	?? (not in original list of rules we approved—this came from LTI's list of validation checks)
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4250
Same Rule in v3.1	No
Domain	All
Description of Rule	Identifies a column that was described in the domain description but not included in the SAS dataset for that domain
Severity	Low
Effective Date	08/01/2007
Error Message	Variable in description file not in dataset
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4251
Same Rule in v3.1	Yes (same as IR3251 for v3.1)
Domain	All
Description of Rule	Identifies a column where the expected data type inferred from the description file does not match the actual data type in the dataset
Severity	Medium
Effective Date	08/01/2007
Error Message	SDTM/dataset variable type mismatch
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4252
Same Rule in v3.1	Yes (same as IR3252 for v3.1)
Domain	All
Description of Rule	Identifies a column listed in the domain description as Required ('Req'), but not included in the SAS dataset for the domain
Severity	High
Effective Date	08/01/2007
Error Message	SDTM required variable not found
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4253
Same Rule in v3.1	Yes (same as IR3253 for v3.1)
Domain	All
Description of Rule	Identifies a column listed in the domain description as Expected ('Exp'), but not included in the SAS dataset for that domain
Severity	Low
Effective Date	08/01/2007
Error Message	SDTM expected variable not found
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4254
Same Rule in v3.1	Yes (same as IR3254 for v3.1)
Domain	All
Description of Rule	Identifies a column that appears in the SAS dataset but is not listed in the domain description
Severity	Medium
Effective Date	08/01/2007
Error Message	Variable appears in dataset but is not in SDTM standard
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4255
Same Rule in v3.1	Yes (same as IR3255 for v3.1)
Domain	Events, AE
Description of Rule	Identifies a Sponsor-provided Flag Variable for 'Treatment emergent AE' where the derivation cannot be executed
Severity	Low
Effective Date	08/01/2007
Error Message	User-specified (non-SDTM) derivation failed to execute
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4256
Same Rule in v3.1	Yes (same as IR3256 for v3.1)
Domain	Findings, LB
Description of Rule	Identifies a Sponsor-provided Flag Variable for 'Clinically Significant Lab' where the derivation cannot be executed
Severity	Low
Effective Date	08/01/2007
Error Message	User-specified (non-SDTM) derivation failed to execute
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4257
Same Rule in v3.1	Yes (same as IR3257 for v3.1)
Domain	Findings, VS
Description of Rule	Identifies a Sponsor-provided Flag Variable for 'Clinically Significant Vital Sign' where the derivation cannot be executed
Severity	Low
Effective Date	08/01/2007
Error Message	User-specified (non-SDTM) derivation failed to execute
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4258
Same Rule in v3.1	Yes (same as IR3258 for v3.1)
Domain	Special Purpose Relationships, Supplemental Qualifiers
Description of Rule	Identifies a domain that appears to contain supplemental qualifier data but does not contain the Unique Subject Identifier
Severity	Medium
Effective Date	08/01/2007
Error Message	Supplemental Qualifiers only allowed for subject-related domains
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4259
Same Rule in v3.1	Yes (same as IR3259 for v3.1)
Domain	All
Description of Rule	Identifies a variable where datatype in (study specific) description is not consistent with datatype implicit in SAS dataset
Severity	High
Effective Date	08/01/2007
Error Message	Description file/dataset variable type mismatch
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4260
Same Rule in v3.1	Yes (same as IR3260 for v3.1)
Domain	All
Description of Rule	Identifies a variable present in SAS dataset, but not present in (study specific) description file
Severity	High
Effective Date	08/01/2007
Error Message	Variable in dataset not in description file
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4500
Same Rule in v3.1	Yes (same as IR3500 for v3.1)
Domain	All
Description of Rule	Identifies non-Sequence Number domain subjects not found in the Demographics domain
Severity	High
Effective Date	08/01/2007
Error Message	Invalid subject
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4501
Same Rule in v3.1	Yes (same as IR3501 for v3.1)
Domain	All
Description of Rule	Identifies Unique Subject Identifier+Visit Name+Visit Number combinations not found in the SV domain
Severity	Low
Effective Date	08/01/2007
Error Message	Invalid Subject Visit/Visit Number
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4502
Same Rule in v3.1	Yes (same as IR3502 for v3.1)
Domain	All
Description of Rule	Identifies records where the value for Arm Code is not found in the TA domain
Severity	Medium
Effective Date	08/01/2007
Error Message	Invalid ARMCD
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4503
Same Rule in v3.1	Yes (same as IR3503 for v3.1)
Domain	All
Description of Rule	Identifies records where the value for Subject element Code is not found in the TE domain
Severity	Medium
Effective Date	08/01/2007
Error Message	Invalid ETCD
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4504
Same Rule in v3.1	Yes (same as IR3504 for v3.1)
Domain	Findings, IE
Description of Rule	Identifies records where the value for Inclusion/Exclusion Criterion Short Name is not found in the TI domain
Severity	High
Effective Date	08/01/2007
Error Message	Invalid IETESTCD
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4505
Same Rule in v3.1	Yes (same as IR3505 for v3.1)
Domain	Special Purpose, DM
Description of Rule	Identifies Sequence Number subjects where no record for the subject is found in the Disposition domain
Severity	Medium
Effective Date	08/01/2007
Error Message	No Disposition record found for subject
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4506
Same Rule in v3.1	Yes (same as IR3506 for v3.1)
Domain	Special Purpose, DM
Description of Rule	Identifies Sequence Number subjects where no record for the subject is found in the Exposure domain
Severity	Low
Effective Date	08/01/2007
Error Message	No Exposure record found for subject
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4507
Same Rule in v3.1	Yes (same as IR3507 for v3.1)
Domain	Special Purpose, DM
Description of Rule	Identifies Sequence Number treatment arms (Description of Arm+Arm Code combination) not found in the TA domain
Severity	High
Effective Date	08/01/2007
Error Message	Invalid ARM/ARMCD
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4508
Same Rule in v3.1	Yes (same as IR3508 for v3.1)
Domain	Special Purpose, CO
Description of Rule	Identifies CO domain reference to an unknown related domain
Severity	High
Effective Date	08/01/2007
Error Message	Referenced Domain not found
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4509
Same Rule in v3.1	Yes (same as IR3509 for v3.1)
Domain	Special Purpose, RELREC
Description of Rule	Identifies Related Records domain reference to an unknown related domain
Severity	Medium
Effective Date	08/01/2007
Error Message	Referenced Domain not found
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4510
Same Rule in v3.1	Yes (same as IR3510 for v3.1)
Domain	Special Purpose, SUPPQUAL
Description of Rule	Identifies Supplemental Qualifiers domain reference to an unknown related domain
Severity	High
Effective Date	08/01/2007
Error Message	Referenced Domain not found
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4511
Same Rule in v3.1	Yes (same as IR3511 for v3.1)
Domain	Special Purpose, RELREC
Description of Rule	Identifies Related Records domain reference to a key variable that is not defined in the target domain
Severity	Medium
Effective Date	08/01/2007
Error Message	Referenced key variable not found
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4512
Same Rule in v3.1	Yes (same as IR3512 for v3.1)
Domain	Special Purpose, SUPPQUAL
Description of Rule	Identifies Supplemental Qualifiers domain reference to a key variable that is not defined in the target domain
Severity	High
Effective Date	08/01/2007
Error Message	Referenced key variable not found
Impact	Study cannot be loaded

Rule ID (v3.1.1)	IR4513
Same Rule in v3.1	Yes (same as IR3513 for v3.1)
Domain	Special Purpose, RELREC
Description of Rule	Identifies Related Records domain reference to a record that does not exist in the target domain
Severity	Medium
Effective Date	08/01/2007
Error Message	Referenced record not found
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	IR4514
Same Rule in v3.1	Yes (same as IR3514 for v3.1)
Domain	Special Purpose, SUPPQUAL
Description of Rule	Identifies Supplemental Qualifiers domain reference to a record that does not exist in the target domain
Severity	High
Effective Date	08/01/2007
Error Message	Referenced record not found
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4005
Same Rule in v3.1	Yes (same as R3005 for v3.1)
Domain	Special Purpose, DM
Description of Rule	Identifies records where values for Unique Subject ID variable(s) are not unique, limited to records where [Unique Subject ID is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Duplicates
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4006
Same Rule in v3.1	Yes (same as R3013 for v3.1)
Domain	Special Purpose, DM
Description of Rule	Identifies records that violate the condition [AGE greater than or equal to 0], limited to records where [AGE is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Negative AGE value
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4007
Same Rule in v3.1	Yes (same as R3016 for v3.1)
Domain	Special Purpose, DM
Description of Rule	Identifies records where value for [SEX] is not found in codelist [SEX]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid SEX code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4008
Same Rule in v3.1	Yes (same as R3022 for v3.1)
Domain	Special Purpose, DM
Description of Rule	Identifies records where value for [COUNTRY] is not found in codelist [COUNTRY]
Severity	Medium
Effective Date	08/01/2007
Error Message	Invalid COUNTRY code
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	R4019
Same Rule in v3.1	Yes (same as R3092 for v3.1)
Domain	Events, AD
Description of Rule	Identifies records where value for [Serious Event] is not found in codelist [YESNO]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4023
Same Rule in v3.1	Yes (same as R3104 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where value for [Congenital Anomaly or Birth Defect] is not found in codelist [YESNO], limited to records where [Congenital Anomaly or Birth Defect is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4024
Same Rule in v3.1	Yes (same as R3106 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where value for [Persist or Signif Disability/Incapacity] is not found in codelist [YESNO], limited to records where [Persist or Signif Disability/Incapacity is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4025
Same Rule in v3.1	Yes (same as R3108 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where value for [Results in Death] is not found in codelist [YESNO], limited to records where [Results in Death is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4026
Same Rule in v3.1	Yes (same as R3110 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where value for [Requires or Prolongs Hospitalization] is not found in codelist [YESNO], limited to records where [Requires or Prolongs Hospitalization is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4027
Same Rule in v3.1	Yes (same as R3112 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where value for [Is Life Threatening] is not found in codelist [YESNO], limited to records where [Is Life Threatening is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4031
Same Rule in v3.1	Yes (same as R3172 for v3.1)
Domain	Findings, IE
Description of Rule	Identifies records where value for [Inclusion/Exclusion Category] is not found in codelist [INCEX], limited to records where [Inclusion/Exclusion Category is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid INCEX code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4043
Same Rule in v3.1	Yes (same as R3499 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where value for [Concomitant or Additional Trtmnt Given] is not found in codelist [YESNO]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4045
Same Rule in v3.1	Yes (same as R3500 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where value for [Involves Cancer] is not found in codelist [YESNO], limited to records where [Involves Cancer is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4046
Same Rule in v3.1	Yes (same as R3501 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where value for [Other Medically Important Serious Event] is not found in codelist [YESNO], limited to records where [Other Medically Important Serious Event is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4047
Same Rule in v3.1	Yes (same as R4047 for v3.1)
Domain	Events, AE
Description of Rule	Identifies records where value for [Occurred with Overdose] is not found in codelist [YESNO], limited to records where [Occurred with Overdose is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4062
Same Rule in v3.1	No
Domain	Special Purpose, DM
Description of Rule	Identifies records where value for [AGEU] is not found in codelist [AGEUNITS2], limited to records where [AGEU is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid AGEUNITS2 code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4071
Same Rule in v3.1	Yes (same as R3531 for v3.1)
Domain	Findings, AE
Description of Rule	Identifies records where value for [I/E Criterion Original Result] is not found in codelist [YESNO], limited to records where [I/E Criterion Original Result is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4072
Same Rule in v3.1	Yes (same as R3532 for v3.1)
Domain	Findings, IE
Description of Rule	Identifies records where value for [I/E Criterion Result in Std Format] is not found in codelist [YESNO], limited to records where [I/E Criterion Result in Std Format is not null]
Severity	High
Effective Date	08/01/2007
Error Message	Invalid YESNO code
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4073
Same Rule in v3.1	Yes (same as R3533 for v3.1)
Domain	Findings, IE
Description of Rule	Identifies records that violate the condition [I/E Criterion Original Result=I/E Criterion Result in Std Format]
Severity	Low
Effective Date	08/01/2007
Error Message	IEORRES and IESTRESC must have the same value
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	R4083
Same Rule in v3.1	Yes (same as R3539 for v3.1)
Domain	Special Purpose, SUPPQUAL
Description of Rule	Identifies records where values for [Study Identifier, Unique Subject Identifier, Identifying Variable, Identifying Variable Value, Qualifier Variable Name] variable(s) are not unique
Severity	High
Effective Date	08/01/2007
Error Message	Duplicates
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4096
Same Rule in v3.1	No
Domain	Special Purpose, DM
Description of Rule	Identifies records that violate the condition [Subject Reference Start Date/Time is not null], limited to records where [Arm Code does not equal 'SCRNFAIL']
Severity	High
Effective Date	08/01/2007
Error Message	RFSTDTC cannot be null when ARMCD<>'SCRNFAIL'
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4097
Same Rule in v3.1	No
Domain	Special Purpose, DM
Description of Rule	Identifies records that violate the condition [Subject Reference End Date/Time is not null], limited to records where [Arm Code does not equal 'SCRNFAIL']
Severity	High
Effective Date	08/01/2007
Error Message	RFENDTC cannot be null when ARMCD<>'SCRNFAIL'
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4101
Same Rule in v3.1	No
Domain	Trial Design, TE
Description of Rule	Identifies records that violate the condition [Rule for End of Element is not null or Planned duration of Element is not null]
Severity	Low
Effective Date	08/01/2007
Error Message	Rule end for element (TEENRL) and planned duration of element (TEDUR) cannot both be null
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	R4102
Same Rule in v3.1	No
Domain	Events, AE
Description of Rule	Identifies records that violate the condition [Results in Death='Y'], limited to records where [Outcome of Adverse Event='Fatal']
Severity	Low
Effective Date	08/01/2007
Error Message	AESDTH='Y' expected when AEOUT='Fatal'
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	R4103
Same Rule in v3.1	No
Domain	Events, AE
Description of Rule	Identifies records that violate the condition [Outcome of Adverse='Fatal'], limited to records where [Results in Death='Y']
Severity	Low
Effective Date	08/01/2007
Error Message	AEOUT='Fatal' expected when AESDTH='Y'
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	R4104
Same Rule in v3.1	No
Domain	Special Purpose, DM
Description of Rule	Identifies records that violate the condition [count (distinct Protocol Deviation Term) = count (distinct Protocol Deviation Coded Term)], limited to records where [Protocol Deviation Term is not null].
Severity	High
Effective Date	08/01/2007
Error Message	Invalid numeric field
Impact	Study cannot be loaded

Rule ID (v3.1.1)	R4105
Same Rule in v3.1	No
Domain	Trial Design, SE
Description of Rule	Identifies records that violate the condition [Description of Unplanned Element is not null], limited to records where [Subject Element Code='UNPLAN'].
Severity	Low
Effective Date	08/01/2007
Error Message	Missing description of unplanned element when ETCD='UNPLAN'
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	R4106
Same Rule in v3.1	No
Domain	Special Purpose, DM
Description of Rule	Identifies records that violate the condition [AGEU is not null], limited to records where [AGE is not null].
Severity	Medium
Effective Date	08/01/2007
Error Message	Missing units on value
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	n/a
Same Rule in v3.1	n/a
Domain	All
Description of Rule	There must be a numeric value for any field in the SDTM 3.1.1 (or 3.1) specification designed as a “numeric” type.
Severity	High
Effective Date	08/01/2007
Error Message	Invalid numeric field
Impact	Study cannot be loaded

Rule ID (v3.1.1)	n/a
Same Rule in v3.1	n/a
Domain	Trial Design, SV
Description of Rule	If Trial Visits was supplied then: if Description of Unplanned Visits in Subject Visits is blank/null, Visit Number in Subject Visits does not exist in Visit Number in Trial Visits for the same study
Severity	Low
Effective Date	08/01/2007
Error Message	Invalid VISITNUM in SV (when there is not an Unplanned Visit)
Impact	Study loaded and error noted in error report

Rule ID (v3.1.1)	n/a
Same Rule in v3.1	n/a
Domain	Trial Design, TA
Description of Rule	StudyID in Trial Arm does not match StudyID in Demographics domain
Severity	High
Effective Date	08/01/2007
Error Message	Invalid STUDYID in TA
Impact	Study cannot be loaded

Rule ID (v3.1.1)	n/a
Same Rule in v3.1	n/a
Domain	Trial Design, TV
Description of Rule	StudyID in Trial Visits does not match StudyID in Demographics domain
Severity	High
Effective Date	08/01/2007
Error Message	Invalid STUDYID in TA
Impact	Study cannot be loaded