CDISC ADaM Validation Checks

Version 1.3

Prepared by

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Notes to Readers

- The validation checks within this document can be implemented with software to test rules defined within the ADaM Implementation Guide 1.0, Data Structure for Adverse Events, and The ADaM Basic Data Structure for Time-to-Event Analyses.
- Future updates, including ADaM IG 1.1 and Occurrence Data Structure, will be covered in a subsequent release of this document.

Revision History

Date	Version	Summary of Changes
2010-09-20	1.0	Final Production version based on team review
2011-01-11	1.1	Maintenance release to correct errors and remove duplicate checks
2012-07-05	1.2	Maintenance release to correct text, remove checks, and add new checks
2015-03-17	1.3	Maintenance release to correct text, remove checks, and add new checks for TTE and ADAE

See Appendix B for Representations and Warranties, Limitations of Liability, and Disclaimers

CONTENTS

1 Introduction

CDISC's Analysis Data Model (ADaM) specifies the fundamental principles and standards to follow in the creation of analysis datasets and associated metadata and supports efficient generation, replication and review of analysis results.

The definitions within the ADaM Implementation Guide 1.0 include specific guidelines and rules for defining and creating ADaM data sets. This document contains a list of requirements which may be used to validate datasets against a subset of these rules which are objective and unambiguously evaluable. The validation checks within this document are defined to be machine readable (i.e. programmable within computer software) and capable of being implemented by ADaM users.

2 Scope

The validation checks within this document can be implemented with software to test rules defined within the ADaM Implementation Guide 1.0, Data Structure for Adverse Events (ADAE), and The ADaM Basic Data Structure for Time-to-Event Analyses. Future updates, including ADaM IG 1.1 and Occurrence Data Structure (OCCDS), will be covered in a subsequent release of this document. The checks are meant to test the structure and certain standardized content of the ADaM data sets. These checks are not meant to define the whole spectrum of ADaM compliance including content and well defined metadata.

The following are examples of aspects of ADaM compliance that cannot be tested by a software program:

- Within section 4.3.1 of the Implementation Guide the text says "Include all observed and derived rows for a given analysis parameter."
- Within section 4.6.1 of the Implementation Guide the text says, "To identify population-specific analyzed rows, use population-specific indicator variables."
- Many ADaM variables are conditionally required (required if a condition is true), but some conditions are not testable by a software algorithm.
- One of the key components of ADaM is the inclusion of thorough and well defined metadata. The thoroughness and clarity of metadata cannot be tested by a machine-readable algorithm but is necessary to enable the traceability that ADaM requires.

While the examples above are rules that must be followed while implementing ADaM, they cannot be tested by a machine-readable algorithm. Instead, a complete assessment of compliance must be based on an understanding of the scope of the study data and the analyses which the datasets should support coupled with the published validation checks within this document and the general rules and principles published in the ADaM Implementation Guide.

3 Description of ADaM Validation Checks Table

The ADaM Validation Checks table contains seven columns:

- **Check Number**: an identifying number with no inherent meaning
- **ADaM IG Section Number**: the section number within the IG (or ADAE or TTE documents) which references the requirement. Note that requirements may be mentioned many times in the IG document; this field is just one citable source.

- **Text from ADaM IG**: the requirement paraphrased from the ADaM IG (or ADAE or TTE documents)
- **ADaM Structure Group**: groups checks based on the ADaM structure that the requirement relates to. In general a colon indicates a relationship between data structures; whereas, a comma is equivalent to the text "and/or" and indicates that a check applies to more than one data structure. The groupings are:
    - ALL (applies to all structural categories)
    - ADSL (applies to the standard Subject Level analysis dataset)
    - BDS (applies to Basic Data Structure datasets)
    - ADAE (applies to ADAE datasets)
    - ADAE, BDS (applies to both ADAE data and BDS data)
    - ALL:SDTM (relationships between any ADaM data and SDTM data)
    - ADSL:SDTM (relationships between ADSL data and SDTM data)
    - ADSL:ALL (relationships between ADSL data and any ADaM data)
    - ADSL:BDS (relationships between ADSL data and BDS data)
    - ADSL:ADAE:SDTM (relationships between ADSL data, ADAE data, and SDTM data)
    - BDS:SDTM (relationships between BDS data and SDTM data)
    - ADAE:SDTM (relationships between ADAE data and SDTM data)

- **Functional Group**: groups checks based on the nature of the requirement. The groupings are:
    - Value Consistency (the value of one variable is logically consistent with the value of another variable, e.g. end date is greater than start date)
    - Metadata (attributes of variables, e.g. labels, lengths)
    - Present/ Populated (the existence of variables [Present] and whether they have non-missing values [Populated])
    - Controlled Terminology (whether values comply with controlled terminology)
    - Valid Value (whether values conform to a variable's standard definition, e.g. PARAMN must be an integer)

- **ADaM Variable Group**: groups checks based on the type of variable covered by the requirement. In general, the groupings are taken from the section headings of ADaM IG 1.0:
    - Study Identifiers
    - Subject Identifier Variables
    - Time to Event Variables
    - Subject Demographics
    - Population Indicator(s)
    - Treatment Variables
    - Trial Dates
    - Timing Variables
    - Analysis Parameter Variables
    - Analysis Visit Windowing Variables
    - Toxicity and Range Variables
    - Flag Variables
    - Data Point Traceability Variables
    - General (requirements which span several types of variables)

  - ADAE Variables
  - Coding Variables
  - MedDRA Query Variables

- **Machine-Testable Failure Criteria**: a programmable test, written such that an affirmative response represents a failure of the requirement. This text is intended for use as a requirement specification which could be implemented in a variety of programming languages.

The three grouping columns can be used individually or in combination, allowing users to focus on specific types of checks.

For ease of interpretation and implementation, complex evaluations have been split into unique checks for each separable part of the algorithm. For example, the requirement that TRTAN must be a one-to-one match to TRTA is expressed as two conditions: 1) there cannot be more than one value of TRTAN for each value of TRTA, and 2) there cannot be more than one value of TRTA for each value of TRTAN. Similarly, a requirement that a value "C" must be between "A" and "B" is expressed as: 1) "C" must be greater than "A" and 2) "C" must be less than "B"

4 ADaM Validation Checks

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
1	S2.3.1	There is only one ADSL per study	ADSL	Present/ Populated	General	ADSL dataset does not exist
2	S3	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label and values must not be modified	ALL:SDTM	Metadata	Data Point Traceability Variables	A variable is present in ADaM with the same name as a variable present in SDTM but the variables do not have identical labels
3	S3	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label and values must not be modified	ALL:SDTM	Metadata	Data Point Traceability Variables	A variable is present in ADaM with the same name as a variable present in SDTM but the variables do not have identical formats
4	S3	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label and values must not be modified	ALL:SDTM	Metadata	Data Point Traceability Variables	A variable is present in ADaM with the same name as a variable present in SDTM but the variables do not have identical lengths
5	S3	The names of all other character flag (or indicator) variables end in FL	ALL	Controlled Terminology	Flag Variables	A variable with a suffix of FL has a value that is not Y, N or null
6	S3	The names of the corresponding numeric flag (or indicator) variables end in FN	ALL	Controlled Terminology	Flag Variables	A variable with a suffix of FN has a value that is not 0, 1 or null

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
7	S3	If the numeric flag is used, the character version (*FL) is required	ALL	Present/ Populated	Flag Variables	A variable with a suffix of FN is present but a variable with the same root and a suffix of FL is not present
10	S3	*FN and *FL must be a one-to-one mapping	ALL	Value Consistency	Flag Variables	A variable with a suffix of FL is equal to Y and a variable with the same root and a suffix of FN is not equal to 1
11	S3	*FN and *FL must be a one-to-one mapping	ALL	Value Consistency	Flag Variables	A variable with a suffix of FL is equal to N and a variable with the same root and a suffix of FN is not equal to 0
12	S3	*FN and *FL must be a one-to-one mapping	ALL	Value Consistency	Flag Variables	A variable with a suffix of FL is equal to null and a variable with the same root and a suffix of FN is not equal to null
13	S3	ADaM variable names must be no more than 8 characters in length	ALL	Metadata	General	The length of a variable name exceeds 8 characters
14	S3	ADaM variable names must start with a letter (not underscore), and be comprised only of letters (A-Z), underscore (_), and numerals (0-9)	ALL	Metadata	General	A variable name does not start with an English letter (A-Z, a-z)
15	S3	ADaM variable names must start with a letter (not underscore), and be comprised only of letters (A-Z), underscore (_), and numerals (0-9)	ALL	Metadata	General	A variable name contains a character other than English letters (A-Z, a-z), underscores (_), or numerals (0-9)

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
16	S3	All ADaM variable labels must be no more than 40 characters in length	ALL	Metadata	General	The length of a variable label is greater than 40 characters
17	S3	All ADaM character variables must be no more than 200 characters in length	ALL	Metadata	General	The length of a character value is greater than 200 characters
18	S3	In general, the variable labels specified in the tables in Section 3 are required. There are only two exceptions to this rule (1) descriptive text is allowed at the end of the labels of variables whose names contain indexes “y”, "xx", or “zz”; and (2) asterisks (*) and ellipses (...) in specified variable labels should be replaced by the sponsor with appropriate text	ALL	Metadata	General	Labels for ADaM variables do not match the standard labels for ADaM variables listed in the implementation guide that cannot be modified (with the exception of 1) variables whose names contain indexes “y”, "xx", or “zz”; and (2) variable labels with asterisks (*) and ellipses (...) indicated for sponsor appropriate text)
19	S3	For subject-level character population flag variables: N = no (not included in the population), Y = yes (included). Null values are not allowed	ADSL	Controlled Terminology	Population Indicator(s)	COMPLFL is present and has a value that is not Y or N
20	S3	For subject-level character population flag variables: N = no (not included in the population), Y = yes (included). Null values are not allowed	ADSL	Controlled Terminology	Population Indicator(s)	FASFL is present and has a value that is not Y or N

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
21	S3	For subject-level character population flag variables: N = no (not included in the population), Y = yes (included). Null values are not allowed	ADSL	Controlled Terminology	Population Indicator(s)	ITTFL is present and has a value that is not Y or N
22	S3	For subject-level character population flag variables: N = no (not included in the population), Y = yes (included). Null values are not allowed	ADSL	Controlled Terminology	Population Indicator(s)	PPROTFL is present and has a value that is not Y or N
23	S3	For subject-level character population flag variables: N = no (not included in the population), Y = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	SAFFL is present and has a value that is not Y or N
24	S3	For subject-level character population flag variables: N = no (not included in the population), Y = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	RANDFL is present and has a value that is not Y or N
25	S3	For subject-level character population flag variables: N = no (not included in the population), Y = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	ENRLFL is present and has a value that is not Y or N

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
26	S3	For subject-level numeric population flag variables: 0 = no (not included), 1 = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	COMPLFN is present and has a value that is not 1 or 0
27	S3	For subject-level numeric population flag variables: 0 = no (not included), 1 = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	FASFN is present and has a value that is not 1 or 0
28	S3	For subject-level numeric population flag variables: 0 = no (not included), 1 = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	ITTFN is present and has a value that is not 1 or 0
29	S3	For subject-level numeric population flag variables: 0 = no (not included), 1 = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	PPROTFN is present and has a value that is not 1 or 0
30	S3	For subject-level numeric population flag variables: 0 = no (not included), 1 = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	SAFFN is present and has a value that is not 1 or 0
31	S3	For subject-level numeric population flag variables: 0 = no (not included), 1 = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	RANDFN is present and has a value that is not 1 or 0

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
32	S3	For subject-level numeric population flag variables: 0 = no (not included), 1 = yes (included). Null values are not allowed.	ADSL	Controlled Terminology	Population Indicator(s)	ENRLFN is present and has a value that is not 1 or 0
33	S3	For record-level character population flag variables: Y = yes (included). Null values are allowed	BDS	Controlled Terminology	Population Indicator(s)	A variable with a suffix of RFL has a value that is not Y or null
34	S3	For parameter-level character population flag variables: Y = yes (included). Null values are allowed	BDS	Controlled Terminology	Population Indicator(s)	A variable with a suffix of PFL has a value that is not Y or null
35	S3	For record-level numeric population flag variables: 1 = yes (included). Null values are allowed	BDS	Controlled Terminology	Population Indicator(s)	A variable with a suffix of RFN has a value that is not 1 or null
36	S3	For parameter-level numeric population flag variables: 1 = yes (included). Null values are allowed	BDS	Controlled Terminology	Population Indicator(s)	A variable with a suffix of PFN has a value that is not 1 or null
37	S3	The *GRy and associated *GRyN variable must have a one-to-one relationship	ADSL	Value Consistency	Subject Demographics	There is more than one value of a variable which has a suffix of GRyN for a given value of a variable with the same root name and suffix of GRy.
38	S3	The *GRy and associated *GRyN variable must have a one-to-one relationship	ADSL	Value Consistency	Subject Demographics	There is more than one value of a variable which has a suffix of GRy for a given value of a variable with the same root name and suffix of GRyN.

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
39	S3	The names of date imputation flag variables end in DTF	ALL	Controlled Terminology	Timing Variables	A variable with a suffix of DTF has a value that is not within Controlled Terminology for DATEFL
40	S3	The names of time imputation flag variables end in TMF	ALL	Controlled Terminology	Timing Variables	A variable with a suffix of TMF has a value that is not within Controlled Terminology for TIMEFL
41	S3	Numeric dates, times and datetimes should be formatted so as to be human readable with no loss of precision	ALL	Metadata	Timing Variables	A variable with a suffix of DT does not have a SAS Date format
42	S3	Numeric dates, times and datetimes should be formatted so as to be human readable with no loss of precision	ALL	Metadata	Timing Variables	A variable with a suffix of TM does not have a SAS time format
43	S3	Numeric dates, times and datetimes should be formatted so as to be human readable with no loss of precision	ALL	Metadata	Timing Variables	A variable with a suffix of DTM does not have a SAS datetime format
44	S3	If a *DTM and associated *TM variable exist, then the *TM variable must match the time part of the *DTM variable	ALL	Value Consistency	Timing Variables	A variable with a suffix of TM and a variable with a suffix of DTM with the same root name have different time values
45	S3	If a *DTM and associated *DT variable exist, then the *DT variable must match the date part of the *DTM variable	ALL	Value Consistency	Timing Variables	A variable with a suffix of DT and a variable with a suffix of DTM with the same root name have different date values
46	S3	*DY cannot = 0	BDS	Valid Value	Timing Variables	A variable with a suffix of DY has a value of zero

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
47	S3.1	ADSL must have the variables SUBJID, SITEID, AGE, AGEU, SEX, RACE, ARM	ADSL	Present/ Populated	General	SITEID is not present within ADSL
48	S3.1	ADSL must have at least one variable that ends in FL because you need at least one population flag	ADSL	Present/ Populated	Population Indicator(s)	A variable with a suffix of FL is not present in ADSL
49	S3.1	ADSL must have the variables SUBJID, SITEID, AGE, AGEU, SEX, RACE, ARM	ADSL	Present/ Populated	Subject Demographics	AGE is not present within ADSL
50	S3.1	ADSL must have the variables SUBJID, SITEID, AGE, AGEU, SEX, RACE, ARM	ADSL	Present/ Populated	Subject Demographics	AGEU is not present within ADSL
51	S3.1	ADSL must have the variables SUBJID, SITEID, AGE, AGEU, SEX, RACE, ARM	ADSL	Present/ Populated	Subject Demographics	SEX is not present within ADSL
52	S3.1	ADSL must have the variables SUBJID, SITEID, AGE, AGEU, SEX, RACE, ARM	ADSL	Present/ Populated	Subject Demographics	RACE is not present within ADSL
53	S3.1	Invalid-USUBJID not found in the SDTM Demographics domain	ALL:SDTM	Value Consistency	Subject Demographics	The values of USUBJID are not present in SDTM.DM
54	S3.1	ADSL is one record per USUBJID	ADSL	Value Consistency	Subject Identifier Variables	Within ADSL there is more than one record for a unique value of USUBJID
55	S3.1	ADSL must have the variables SUBJID, SITEID, AGE, AGEU, SEX, RACE, ARM	ADSL	Present/ Populated	Subject Identifier Variables	SUBJID is not present within ADSL
58	S3.1	All *DT variables must be numeric	ALL	Metadata	Timing Variables	A variable with a suffix of DT is not a numeric variable
59	S3.1	All *TM variables must be numeric	ALL	Metadata	Timing Variables	A variable with a suffix of TM is not a numeric variable

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
60	S3.1	All *DTM variables must be numeric	ALL	Metadata	Timing Variables	A variable with a suffix of DTM is not a numeric variable
61	S3.1	TRTSDT or TRTSDTM variables are required if there is an investigational product	ADSL:SDTM	Present/ Populated	Timing Variables	SDTM.EX is present and neither TRTSDT or TRTSDTM are present
62	S3.1	Any ADSL variable beginning with TRT and ending in A or beginning in TRT and ending in AN must include xx where xx is a 2 digit number	ADSL	Metadata	Treatment Variables	A variable with a prefix of TRT and a suffix of A has xx fragment appended after TRT that is not a zero-padded two-digit integer [01-99], excluding TRTSEQA
63	S3.1	Any ADSL variable beginning with TRT and ending in A or beginning in TRT and ending in AN must include xx where xx is a 2 digit number	ADSL	Metadata	Treatment Variables	A variable with a prefix of TRT and a suffix of AN has xx fragment appended after TRT that is not a zero-padded two-digit integer [01-99], excluding TRTSEQAN
64	S3.1	Any variable beginning with TRT and ending in AN must have a corresponding variable beginning with TRT, having the same increment and end in A	ADSL	Present/ Populated	Treatment Variables	TRTxxAN is present and TRTxxA is not present
65	S3.1	Any ADSL variable beginning with TR and containing PG must have a padded numeric of 01 and increment	ADSL	Metadata	Treatment Variables	A variable with a prefix of TR and containing PG has xx fragment appended after TR that is not a zero-padded two-digit integer [01-99]

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
66	S3.1	Any variable beginning with TR, containing PG and ending in N must have a corresponding variable beginning with TR, containing PG, and having the same increment	ADSL	Present/ Populated	Treatment Variables	A variable with a prefix of TR, containing PG and a suffix of N is present and a variable with the same root without a suffix of N is not present
68	S3.1	Any ADSL variable beginning with TR and containing AG must have numeric where xx is a 2 digit number	ADSL	Metadata	Treatment Variables	A variable with a prefix of TR and containing AG has xx fragment appended after TR that is not a zero-padded two-digit integer [01-99]
70	S3.1	Any variable beginning with TR, containing AG and ending in N must have a corresponding variable beginning with TR, containing AG, and having the same increment	ADSL	Present/ Populated	Treatment Variables	A variable with a prefix of TR, containing AG with a suffix of N is present and a variable with the same root without a suffix of N is not present
71	S3.1	ADSL must have the variables SUBJID, SITEID, AGE, AGEU, SEX, RACE, ARM	ADSL	Present/ Populated	Treatment Variables	ARM is not present within ADSL
72	S3.1	ADSL must have at least one TRTxxP variable	ADSL	Present/ Populated	Treatment Variables	ADSL does not contain a variable with a prefix of TRT, a zero-padded two-digit integer [01-99] appended to TRT, and a suffix of P
73	S3.1	Any ADSL variable beginning with TRT and ending in P must have a suffix that is a two-digit integer [01-99]	ADSL	Metadata	Treatment Variables	A variable with a prefix of TRT and a suffix of P has xx fragment appended after TRT that is not a zero-padded two-digit integer [01-99], excluding TRTSEQP

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
74	S3.1	Any ADSL variable beginning with TRT and ending in PN must have a suffix that is a two-digit integer [01-99]	ADSL	Metadata	Treatment Variables	A variable with a prefix of TRT and a suffix of PN has xx fragment appended after TRT that is not a zero-padded two-digit integer [01-99], excluding TRTSEQPN
75	S3.1	Any variable beginning with TRT and ending in PN must have a corresponding variable beginning with TRT, having the same increment and end in P	ADSL	Present/ Populated	Treatment Variables	TRTxxPN is present and TRTxxP is not present
76	S3.1	Any variable beginning with TRT and ending in PN must have a corresponding variable beginning with TRT, having the same increment and end in P	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRTxxPN for a given value of TRTxxP
77	S3.1	Any variable beginning with TRT and ending in PN must have a corresponding variable beginning with TRT, having the same increment and end in P	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRTxxP for a given value of TRTxxPN
78	S3.1	If there is more than one treatment period then TRxxSDT and TRxxEDT should exist in ADSL	ADSL	Present/ Populated	Treatment Variables	At least one TRTxxP is present where xx is greater than 01 and (TRTxxP is present and TRxxSDT is not present)
79	S3.1	If there is more than one treatment period then TRxxSDT and TRxxEDT should exist in ADSL	ADSL	Present/ Populated	Treatment Variables	At least one TRTxxP is present where xx is greater than 01 and (TRTxxP is present and TRxxEDT is not present)

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
80	S3.1	If TRTxxA exists then TRTxxP should exist	ADSL	Present/ Populated	Treatment Variables	TRTxxA is present and TRTxxP is not present
81	S3.1	If TRT(xx+1)P exists then TRTxxP should exist for xx+1 > 01	ADSL	Present/ Populated	Treatment Variables	TRTxxP is present and xx is greater than 01 and TRT{xx-1} is not present
83	S3.1	If TR01SDT exists then TRTSDT=TR01SDT	ADSL	Value Consistency	Trial Dates	TR01SDT does not equal TRTSDT
84	S3.1	TRTEDT = maximum(TRxxEDT)	ADSL	Value Consistency	Trial Dates	TRTEDT is not equal to the maximum value of all TRxxEDT variables
85	S3.2.1	Variables STUDYID, USUBJID, SUBJID, SITEID, etc. must match ADSL variable in metadata	ADSL:ALL	Metadata	General	A variable is present with the same name as a variable present in ADSL but the variables do not have identical labels
86	S3.2.1	Variables STUDYID, USUBJID, SUBJID, SITEID, etc. must match ADSL variable in metadata	ADSL:ALL	Metadata	General	A variable is present with the same name as a variable present in ADSL but the variables do not have identical formats
87	S3.2.1	Variables STUDYID, USUBJID, SUBJID, SITEID, etc. must match ADSL variable in metadata	ADSL:ALL	Metadata	General	A variable is present with the same name as a variable present in ADSL but the variables do not have identical lengths
88	S3.2.1	All data sets must have the variables STUDYID and USUBJID	ALL	Present/ Populated	Study Identifiers	STUDYID is not present
89	S3.2.1	All data sets must have the variables STUDYID and USUBJID	ALL	Present/ Populated	Subject Identifier Variables	USUBJID is not present
90	S3.2.2	BDS must have TRTP variable	BDS	Present/ Populated	Treatment Variables	TRTP is not present

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
91	S3.2.2	TRTP must match at least one value in TRT01P-TRTxxP	ADSL:BDS	Value Consistency	Treatment Variables	TRTP is not equal to at least one variable with a prefix of TRT, a suffix of P and containing a two digit number
92	S3.2.2	TRTPN must be a one-to-one match to TRTP	BDS	Value Consistency	Treatment Variables	There is more than one value of TRTPN for a given value of TRTP
93	S3.2.2	TRTPN must be a one-to-one match to TRTP	BDS	Value Consistency	Treatment Variables	There is more than one value of TRTP for a given value of TRTPN
94	S3.0	The lower case letter “y” in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Treatment Variables	A variable with a prefix of TRTPG has y fragment appended after TRTPG that is not a single-digit integer [1-9]
95	S3.2.2	TRTAN must be a one-to-one match to TRTA	BDS	Value Consistency	Treatment Variables	There is more than one value of TRTAN for a given value of TRTA
96	S3.2.2	TRTAN must be a one-to-one match to TRTA	BDS	Value Consistency	Treatment Variables	There is more than one value of TRTA for a given value of TRTAN
97	S3.2.2	Any variable beginning with TRTPG and ending in N must have a corresponding variable beginning with TRTPG, and having the same increment	BDS	Present/ Populated	Treatment Variables	TRTPGyN is present and TRTPGy is not present

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
98	S3.2.3	*SDY is less than or equal to *EDY if both are non-missing	BDS	Value Consistency	Timing Variables	A variable with a suffix of SDY has a value greater than a value of a variable with the same root and a suffix of EDY, and both variables are populated
99	S3.2.3	*STDY is less than or equal to *ENDY if both are non-missing	BDS	Value Consistency	Timing Variables	A variable with a suffix of STDY has a value greater than a value of a variable with the same root and a suffix of ENDY, and both variables are populated
100	S3.2.3	APEREDT must have corresponding APxxEDT value	ADSL:BDS	Value Consistency	Timing Variables	The value of APEREDT when APERIOD is equal to xx is not equal to the value of APxxEDT
101	S3.2.3	APEREDTM must have corresponding APxxEDTM value	ADSL:BDS	Value Consistency	Timing Variables	The value of APEREDTM when APERIOD is equal to xx is not equal to the value of APxxEDTM
102	S3.2.3	APERIOD value must have corresponding TRTxxP/TRxxSDT/TRxxEDT variables	ADSL:BDS	Present/ Populated	Timing Variables	For every unique xx value of APERIOD in BDS datasets, there is not a ADSL variable TRTxxP
103	S3.2.3	APERIOD value must have corresponding TRTxxP/TRxxSDT/TRxxEDT variables	ADSL:BDS	Present/ Populated	Timing Variables	For every unique xx value of APERIOD in BDS datasets, there is not a ADSL variable TRxxSDT
104	S3.2.3	APERIOD value must have corresponding TRTxxP/TRxxSDT/TRxxEDT variables	ADSL:BDS	Present/ Populated	Timing Variables	For every unique xx value of APERIOD in BDS datasets, there is not a ADSL variable TRxxEDT
105	S3.2.3	APERIODC must have one-to-one mapping with APERIOD	BDS, ADAE	Value Consistency	Timing Variables	There is more than one value of APERIODC for a given value of APERIOD

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
106	S3.2.3	APERIODC must have one-to-one mapping with APERIOD	BDS, ADAE	Value Consistency	Timing Variables	There is more than one value of APERIOD for a given value of APERIODC
107	S3.2.3	APERSDT must have corresponding APxxSDT value	ADSL:BDS	Value Consistency	Timing Variables	The value of APERSDT when APERIOD is equal to xx is not equal to the value of APxxSDT
108	S3.2.3	APERSDTM must have corresponding APxxSDTM value	ADSL:BDS	Value Consistency	Timing Variables	The value of APERSDTM when APERIOD is equal to xx is not equal to the value of APxxSDTM
109	S3.2.3	AVISITN is a one-to-one mapping with AVISIT	BDS	Value Consistency	Timing Variables	Within a given value of PARAMCD, there is more than one value of AVISITN for a given value of AVISIT
110	S3.2.3	AVISITN is a one-to-one mapping with AVISIT	BDS	Value Consistency	Timing Variables	Within a given value of PARAMCD, there is more than one value of AVISIT for a given value of AVISITN
111	S3.2.3	When ARELTM is present, the anchor time variable and ARELTMU must also be included in the dataset, and the anchor time variable must be identified in the metadata for ARELTM	BDS	Present/ Populated	Timing Variables	ARELTM is present and ARELTMU is not present
112	S3.2.3	When ARELTM is present, the anchor time variable and ARELTMU must also be included in the dataset, and the anchor time variable must be identified in the metadata for ARELTM	BDS	Present/ Populated	Timing Variables	ARELTM is populated and ARELTMU is not populated

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
113	S3.2.3	When ARELTM is present, the anchor time variable and ARELTMU must also be included in the dataset, and the anchor time variable must be identified in the metadata for ARELTM	BDS	Present/ Populated	Timing Variables	ARELTMU is present and ARELTM is not present
114	S3.2.3	When ARELTM is present, the anchor time variable and ARELTMU must also be included in the dataset, and the anchor time variable must be identified in the metadata for ARELTM	BDS	Present/ Populated	Timing Variables	ARELTMU is populated and ARELTM is not populated
115	S3.2.3	If ATPTREF is populated then ATPT must be populated	BDS	Present/ Populated	Timing Variables	ATPTREF is populated and ATPT is not populated
116	S3.2.3	If ATPTREF is populated then ATPT must be populated	BDS	Present/ Populated	Timing Variables	ATPT is populated and ATPTREF is not populated
117	S3.2.3	Within the same parameter there must be a one-to-one mapping between ATPT and ATPTN if both variables are present	BDS	Value Consistency	Timing Variables	Within a given value of PARAMCD there is more than one value of ATPT for a given value of ATPTN
118	S3.2.3	Within the same parameter there must be a one-to-one mapping between ATPT and ATPTN if both variables are present	BDS	Value Consistency	Timing Variables	Within a given value of PARAMCD there is more than one value of ATPTN for a given value of ATPT
121	S3.2.3	If *SDT and *EDT are nonmissing then *SDT <= *EDT	ALL	Value Consistency	Timing Variables	The value of a variable with a suffix of SDT is greater than the value of a variable with the same root and a suffix of EDT

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
122	S3.2.3	If *SDTM and *EDTM are nonmissing then *SDTM <= *EDTM	ALL	Value Consistency	Timing Variables	The value of a variable with a suffix of SDTM is greater than the value of a variable with the same root and a suffix of EDTM
123	S3.2.4	PARAMTYP has the same value for all records within a parameter	BDS	Value Consistency	Analysis Parameter Variables	There is more than one value of PARAMTYP for a given value of PARAMCD
124	S3.2.4	PARCATy has the same value for all records within a parameter	BDS	Value Consistency	Analysis Parameter Variables	There is more than one value of PARCATy for a given value of PARAMCD
125	S3.2.4	PARCATy and PARCATyN have a one-to-one mapping	BDS	Value Consistency	Analysis Parameter Variables	There is more than one value of a variable which has a suffix of PARCATy for a given value of a variable with the same root name and suffix of PARCATyN
126	S3.2.4	PARCATy and PARCATyN have a one-to-one mapping	BDS	Value Consistency	Analysis Parameter Variables	There is more than one value of a variable which has a suffix of PARCATyN for a given value of a variable with the same root name and suffix of PARCATy
127	S3.2.4	If BASE is populated then there must be a corresponding AVAL value with ABLFL=Y	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD for a subject, BASE is populated and there is not at least one record with ABLFL equal to Y
128	S3.2.4	If BASEC is populated then there must be a corresponding AVALC value with ABLFL=Y	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD for a subject, BASEC is populated and there is not at least one record with ABLFL equal to Y

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
129	S3.2.4	If both BASE and BASEC are populated then there must be a one-to-one mapping	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD for a subject, there is more than one value of BASE for a given value of BASEC
130	S3.2.4	If both BASE and BASEC are populated then there must be a one-to-one mapping	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD for a subject, there is more than one value of BASEC for a given value of BASE
131	S3.2.4	If BASETYPE is populated for at least one record within a parameter then it must be populated for all records within that parameter	BDS	Present/ Populated	Analysis Parameter Variables	Within a given value of PARAMCD, BASETYPE is populated for at least one record and is not populated for at least one record
132	S3.2.4	R2BASE must equal AVAL/BASE	BDS	Value Consistency	Analysis Parameter Variables	R2BASE is not equal to AVAL divided by BASE
133	S3.2.4	R2AyLO must equal AVAL/AyLO	BDS	Value Consistency	Analysis Parameter Variables	R2AyLO is not equal to AVAL divided by AyLO
134	S3.2.4	R2AyHI must equal AVAL/AyHI	BDS	Value Consistency	Analysis Parameter Variables	R2AyHI is not equal to AVAL divided by AyHI
135	S3.2.4	SHIFTyN must be a one-to-one mapping with SHIFTy	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD, there is more than one value of SHIFTy for a given value of SHIFTyN
136	S3.2.4	SHIFTyN must be a one-to-one mapping with SHIFTy	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD, there is more than one value of SHIFTyN for a given value of SHIFTy

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
137	S3.2.4	If CRITyFL is populated then CRITy must be populated	BDS	Present/ Populated	Analysis Parameter Variables	CRITyFL is populated and CRITy is not populated
141	S3.2.4	PARAM and PARAMCD are present and have a one-to-one mapping	BDS	Value Consistency	Analysis Parameter Variables	There is more than one value of PARAM for a given value of PARAMCD
142	S3.2.4	PARAM and PARAMCD are present and have a one-to-one mapping	BDS	Value Consistency	Analysis Parameter Variables	There is more than one value of PARAMCD for a given value of PARAM
143	S3.2.4	PARAMCD values should follow SAS V5 variable naming conventions	BDS	Metadata	Analysis Parameter Variables	PARAMCD has more than 8 characters in length
144	S3.2.4	PARAMCD values should follow SAS V5 variable naming conventions	BDS	Metadata	Analysis Parameter Variables	PARAMCD starts with a character other than a letter or underscore
145	S3.2.4	PARAMCD values should follow SAS V5 variable naming conventions	BDS	Metadata	Analysis Parameter Variables	PARAMCD has characters that are not letters, digits, and underscores
146	S3.2.4	PARAMN is a one-to-one mapping with PARAM if present	BDS	Value Consistency	Analysis Parameter Variables	There is more than one value of PARAM for a given value of PARAMN
147	S3.2.4	PARAMN is a one-to-one mapping with PARAM if present	BDS	Value Consistency	Analysis Parameter Variables	There is more than one value of PARAMN for a given value of PARAM
148	S3.2.4	PARAMN must be an integer	BDS	Valid Value	Analysis Parameter Variables	PARAMN is not an integer
149	S3.2.4	If both AVAL and AVALC are populated then there must be a one-to-one mapping	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD, there is more than one value of AVALC for a given value of AVAL

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
150	S3.2.4	If both AVAL and AVALC are populated then there must be a one-to-one mapping	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD, there is more than one value of AVAL for a given value of AVALC
151	S3.2.4	The values of CRITy within a parameter must be constant on all rows on which it is populated	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD, there is more than one value of CRITy
152	S3.2.4	If BASE is populated for a parameter, and BASE is non-null for a subject for that parameter, then there must be a record flagged by ABLFL for that subject and parameter.	BDS	Value Consistency	Flag Variables	BASETYPE is present, BASE is populated, and BASE is not equal to AVAL where ABLFL is equal to "Y" for a given value of PARAMCD and BASETYPE for a subject
153	S3.2.4	If there are multiple baseline records flagged for a given parameter within a subject then BASETYPE should be populated and contain different values for the baseline records within a subject	BDS	Value Consistency	Flag Variables	Within a given PARAMCD for a subject, more than one record has ABLFL="Y" and BASETYPE is null
154	S3.2.4	If there are multiple baseline records flagged for a given parameter within a subject then BASETYPE should be populated and contain different values for the baseline records within a subject	BDS	Value Consistency	Flag Variables	Within a given PARAMCD and BASETYPE for a subject, more than one record has ABLFL="Y"

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
155	S3.2.4	Whenever there is more than one definition of baseline, the BASETYPE column is required. BASETYPE identifies the definition of baseline that corresponds to the value of BASE in each row. There is only one BASE column, and only one column for each qualifying function of AVAL and BASE	BDS	Present/ Populated	Flag Variables	Within a given PARAMCD for a subject, more than one record has ABLFL="Y" and BASETYPE is not present
156	S3.2.4	Variable CRITyFL must be present on the dataset if variable CRITy is present, and vice-versa.	BDS	Present/ Populated	Flag Variables	A variable with a prefix of CRIT, a suffix of FL and containing a one-digit number is present and a variable with the same root without a suffix of FL is not present
157	S3.2.4	Variable CRITyFL must be present on the dataset if variable CRITy is present, and vice-versa	BDS	Present/ Populated	Flag Variables	A variable with a prefix of CRIT and a suffix of a one-digit number is present and a variable with the same root with a suffix of FL is not present
158	S3.2.5	If AWTDIFF is present then AWTARGET must be present	BDS	Present/ Populated	Analysis Visit Windowing Variables	AWTDIFF is present and AWTARGET is not present
159	S3.2.5	If AWTDIFF is populated then AWTARGET must be populated	BDS	Present/ Populated	Analysis Visit Windowing Variables	AWTDIFF is populated and AWTARGET is not populated
160	S3.2.5	If AWU is present then AWLO and AWHI must be present	BDS	Present/ Populated	Analysis Visit Windowing Variables	AWU is present and both AWLO and AWHI are not present

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
161	S3.2.5	If AWU is populated then AWLO and AWHI must be populated	BDS	Present/ Populated	Analysis Visit Windowing Variables	AWU is populated and both AWLO and AWHI are not populated
162	S3.2.5	*LO must be less than or equal to *HI	BDS	Value Consistency	Analysis Visit Windowing Variables	A variable with a suffix of LO has a value greater than the value of a variable with the same root name and a suffix of HI, and both variables are populated
163	S3.2.5	If BTOXGR is present then ATOXGR and ABLFL must be present	BDS	Present/ Populated	Toxicity and Range Variables	BTOXGR is present and ATOXGR is not present
164	S3.2.5	If BTOXGR is present then ATOXGR and ABLFL must be present	BDS	Present/ Populated	Toxicity and Range Variables	BTOXGR is present and ABLFL is not present
165	S3.2.5	If BTOXGR is populated then there must be a corresponding ATOXGR value with ABLFL=Y	BDS	Value Consistency	Toxicity and Range Variables	BASETYPE is present, BTOXGR is populated, and BTOXGR is not equal to ATOXGR where ABLFL is equal to "Y" for a given value of PARAMCD and BASETYPE
166	S3.2.5	If BNRIND is present then ANRIND and ABLFL must be present	BDS	Present/ Populated	Toxicity and Range Variables	BNRIND is present and ANRIND is not present
167	S3.2.5	If BNRIND is present then ANRIND and ABLFL must be present	BDS	Present/ Populated	Toxicity and Range Variables	BNRIND is present and ABLFL is not present
168	S3.2.5	If BNRIND is populated then there must be a corresponding ANRIND value with ABLFL=Y	BDS	Value Consistency	Toxicity and Range Variables	BASETYPE is present, BNRIND is populated, and BNRIND is not equal to ANRIND where ABLFL is equal to "Y" for a given value of PARAMCD and BASETYPE

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
169	S3.2.5	CNSR should be an integer	BDS	Valid Value	Time to Event Variables	The value of CNSR is not an integer
170	S3.2.5	If STARTDT is present then CNSR must be present	BDS	Present/ Populated	Time to Event Variables	STARTDT is present and CNSR is not present
171	S3.2.6	If ONTRTFL ^=Y then TRTSDT <= ADT <= TRTEDT should not be true	ADSL:BDS	Value Consistency	Flag Variables	ONTRTFL is equal to Y and TRTSDT is greater than ADT
172	S3.2.6	If ONTRTFL ^=Y then TRTSDT <= ADT <= TRTEDT should not be true	ADSL:BDS	Value Consistency	Flag Variables	ONTRTFL is equal to Y and TRTEDT is less than ADT
173	S3.2.6	If ONTRTFL ^=Y then TRTSDT <= ADT <= TRTEDT should not be true	ADSL:BDS	Value Consistency	Flag Variables	ONTRTFL is not equal to Y and TRTSDT is less than or equal to ADT and TRTEDT is greater than or equal to ADT
174	S3.2.6	If LVOTFL=Y then TRTSDT <= ADT <= TRTEDT should be true	ADSL:BDS	Value Consistency	Flag Variables	LVOTFL is equal to Y and ADT is less than TRTSDT
175	S3.2.6	A maximum of one record within a parameter can have LVOTFL=Y	BDS	Value Consistency	Flag Variables	There is more than one record with LVOTFL equal to Y for a given value of PARAMCD
176	S3.2.6	ABLFL must have a value of Y or null	BDS	Controlled Terminology	Flag Variables	ABLFL is not equal to Y or null
178	S3.2.6	ANLzzFL must have a value of Y or null	BDS, ADAE	Controlled Terminology	Flag Variables	ANLzzFL is not equal to Y or null
179	S3.2.6	If LVOTFL=Y then TRTSDT <= ADT <= TRTEDT should be true	ADSL:BDS	Value Consistency	Timing Variables	LVOTFL is equal to Y and ADT is greater than TRTEDT
180	S3.2.8	The value of SRCDOM should reference a valid SDTM domain.	BDS:SDTM	Valid Value	Data Point Traceability Variables	SRCDOM has a value that is not a SDTM dataset name or null

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
181	S3.2.4	If BASE is populated then it must be with a value flagged for some record via ABLFL for that parameter	BDS	Value Consistency	Flag Variables	BASETYPE is not present, BASE is populated, and BASE is not equal to AVAL where ABLFL is equal to "Y" for a given value of PARAMCD for a subject
182	S3.2.5	If BTOXGR is populated then there must be a corresponding ATOXGR value with ABLFL=Y	BDS	Value Consistency	Toxicity and Range Variables	BASETYPE is not present, BTOXGR is populated, and BTOXGR is not equal to ATOXGR where ABLFL is equal to "Y" for a given value of PARAMCD for a subject
183	S3.2.5	If BNRIND is populated then there must be a corresponding ANRIND value with ABLFL=Y	BDS	Value Consistency	Toxicity and Range Variables	BASETYPE is not present, BNRIND is populated, and BNRIND is not equal to ANRIND where ABLFL is equal to "Y" for a given value of PARAMCD for a subject
184	S3.0	The lower case letter “y” in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Treatment Variables	A variable with a prefix of TRTAG has y fragment appended after TRTAG that is not a single-digit integer [1-9]
185	S3.0	The lower case letter “y” in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Analysis Parameter Variables	A variable with a prefix of PARCAT has y fragment appended after PARCAT that is not a single-digit integer [1-9]

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
186	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Analysis Parameter Variables	A variable with a prefix of AVALCAT has y fragment appended after AVALCAT that is not a single-digit integer [1-9]
187	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Analysis Parameter Variables	A variable with a prefix of BASECAT has y fragment appended after BASECAT that is not a single-digit integer [1-9]
188	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Analysis Parameter Variables	A variable with a prefix of CHGCAT has y fragment appended after CHGCAT that is not a single-digit integer [1-9]
189	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Analysis Parameter Variables	A variable with a prefix of PCHGCAT has y fragment appended after PCHGCAT that is not a single-digit integer [1-9]

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
190	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Analysis Parameter Variables	A variable with a prefix of R2A and a suffix of LO has y fragment appended after R2A that is not a single-digit integer [1-9]
191	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Analysis Parameter Variables	A variable with a prefix of R2A and a suffix of HI has y fragment appended after R2A that is not a single-digit integer [1-9]
192	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Analysis Parameter Variables	A variable with a prefix of SHIFT has y fragment appended after SHIFT that is not a single-digit integer [1-9]
193	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	BDS	Metadata	Analysis Parameter Variables	A variable with a prefix of CRIT has y fragment appended after CRIT that is not a single-digit integer [1-9]
194	S3.2.4	PARAM and PARAMCD are present and have a one-to-one mapping	BDS	Present/ Populated	Analysis Parameter Variables	PARAM is not present

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
195	S3.2.4	PARAM and PARAMCD are present and have a one-to-one mapping	BDS	Present/ Populated	Analysis Parameter Variables	PARAMCD is not present
196	S3.2.4	PARAM and PARAMCD are present and have a one-to-one mapping	BDS	Present/ Populated	Analysis Parameter Variables	PARAM is not populated
197	S3.2.4	PARAM and PARAMCD are present and have a one-to-one mapping	BDS	Present/ Populated	Analysis Parameter Variables	PARAMCD is not populated
198	S3.2.4	Either AVAL or AVALC must be present.	BDS	Present/ Populated	Analysis Parameter Variables	AVAL is not present and AVALC is not present
199	S3	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label and values must not be modified	ALL:SDTM	Metadata	Data Point Traceability Variables	A variable is present in ADaM with the same name as a variable present in SDTM but the variables do not have identical data types
200	S3	ADaM variables defined in ADaM IG must be the defined type (num, char)	ALL	Valid Value	General	A variable is present in ADaM with the same name as a variable defined in the ADaM IG but the variables do not have identical data types
201	S3.2.2	Any variable beginning with TRTAG and ending in N must have a corresponding variable beginning with TRTAG, and having the same increment.	BDS	Present/ Populated	Treatment Variables	TRTAGyN is present and TRTAGy is not present
202	S3.2.3	APERETM must have corresponding APxxETM value.	ADSL:BDS	Value Consistency	Timing Variables	The value of APERETM when APERIOD is equal to xx is not equal to the value of APxxETM

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
203	S3.2.3	APERSTM must have corresponding APxxSTM value.	ADSL:BDS	Value Consistency	Timing Variables	The value of APERSTM when APERIOD is equal to xx is not equal to the value of APxxSTM
204	S3.1	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified.	ADSL:SDTM	Value Consistency	Subject Demographics	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.AGE is not equal to DM.AGE
205	S3.1	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified.	ADSL:SDTM	Value Consistency	Subject Demographics	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.AGEU is not equal to DM.AGEU
206	S3.1	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified.	ADSL:SDTM	Value Consistency	Subject Demographics	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.SEX is not equal to DM.SEX
207	S3.1	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified.	ADSL:SDTM	Value Consistency	Subject Demographics	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.RACE is not equal to DM.RACE

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
208	S3.1	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified.	ADSL:SDTM	Value Consistency	Subject Demographics	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.SUBJID is not equal to DM.SUBJID
209	S3.1	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified.	ADSL:SDTM	Value Consistency	Subject Demographics	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.SITEID is not equal to DM.SITEID
210	S3.1	Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified.	ADSL:SDTM	Value Consistency	Subject Demographics	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.ARM is not equal to DM.ARM
211	S3.2.6	ABLFN must have a value of 1 or null	BDS	Controlled Terminology	Flag Variables	ABLFN is not equal to 1 or null
212	S3.2.6	ANLzzFN must have a value of 1 or null	BDS	Controlled Terminology	Flag Variables	ANLzzFN is not equal to 1 or null
213	S3.0	The lower case letter “y” in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	ADSL	Metadata	Subject Demographics	A variable with a prefix of SITEGR has a y fragment appended after SITEGR that is not a single-digit integer [1-9]

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
214	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	ADSL	Metadata	Subject Demographics	A variable with a prefix of SITEGR and a suffix of N has y fragment appended after SITEGR that is not a single-digit integer [1-9]
215	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	ADSL	Metadata	Subject Demographics	A variable with a prefix of RACEGR has y fragment appended after RACEGR that is not a single-digit integer [1-9]
216	S3	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	ADSL	Metadata	Subject Demographics	A variable with a prefix of RACEGR and a suffix of N has y fragment appended after RACEGR that is not a single-digit integer [1-9]
217	S3	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	ADSL	Metadata	Treatment Variables	A variable with a prefix of TRxxPG has y fragment appended after TRxxPG that is not a single-digit integer [1-9]

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
218	S3.0	The lower case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization, an analysis criterion, or an analysis range, and is replaced with a single digit [1-9].	ADSL	Metadata	Treatment Variables	A variable with a prefix of TRxxAG has y fragment appended after TRxxAG that is not a single-digit integer [1-9]
221	S3.2.4	AVALCATy must have the same value for all records within a parameter for a given value of AVAL.	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD there is more than one value of AVALCATy for a given value of AVAL and y.
222	S3.2.4	BASECATy must have the same value for all records within a parameter for a given value of BASE.	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD there is more than one value of BASECATy for a given value of BASE and y.
223	S3.2.4	If populated, the value of CHG must be equal to AVAL-BASE.	BDS	Valid Value	Analysis Parameter Variables	Within a given value of PARAMCD for a subject, CHG is populated and is not equal to AVAL - BASE.
224	S3.2.4	CHGCATy must have the same value for all records within a parameter for a given value of CHG.	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD there is more than one value of CHGCATy for a given value of CHG and y
225	S3.2.4	If populated, the value of PCHG must be equal to ((AVAL-BASE)/BASE)*100.	BDS	Valid Value	Analysis Parameter Variables	Within a given value of PARAMCD for a subject, PCHG is populated and is not equal to ((AVAL - BASE)/BASE)*100
226	S3.2.4	PCHGCATy must have the same value for all records within a parameter for a given value of PCHG.	BDS	Value Consistency	Analysis Parameter Variables	Within a given value of PARAMCD there is more than one value of PCHGCATy for a given value of PCHG and y

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
227	S3.1	TRTSEQPN must be a one-to-one match to TRTSEQP	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRTSEQP for a given value of TRTSEQPN
228	S3.1	TRTSEQPN must be a one-to-one match to TRTSEQP	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRTSEQPN for a given value of TRTSEQP
229	S3.1	TRTSEQAN must be a one-to-one match to TRTSEQA	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRTSEQA for a given value of TRTSEQAN
230	S3.1	TRTSEQAN must be a one-to-one match to TRTSEQA	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRTSEQAN for a given value of TRTSEQA
231	S3.1	TRxxPGy must have the same value for all records for a given value of TRTxxP.	ADSL	Value Consistency	Treatment Variables	Within a given value of TRTxxP there is more than one value of TRxxPGy.
232	S3.1	TRxxPGyN must be a one-to-one match to TRxxPGy	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRxxPGy for a given value of TRxxPGyN
233	S3.1	TRxxPGyN must be a one-to-one match to TRxxPGy	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRxxPGyN for a given value of TRxxPGy
234	S3.1	TRxxAGy must have the same value for all records for a given value of TRTxxA.	ADSL	Value Consistency	Treatment Variables	Within a given value of TRTxxA there is more than one value of TRxxAGy.
235	S3.1	TRxxAGyN must be a one-to-one match to TRxxAGy	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRxxAGy for a given value of TRxxAGyN
236	S3.1	TRxxAGyN must be a one-to-one match to TRxxAGy	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRxxAGyN for a given value of TRxxAGy

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
237	S3.2.2	TRTPGyN must have a one-to-one match to TRTPGy.	BDS	Value Consistency	Treatment Variables	There is more than one value of TRTPGy for a given value of TRTPGyN
238	S3.2.2	TRTPGyN must have a one-to-one match to TRTPGy.	BDS	Value Consistency	Treatment Variables	There is more than one value of TRTPGyN for a given value of TRTPGy
239	S3.2.2	TRTAGy is required when TRTPGy is present and TRTA is present.	BDS	Present/ Populated	Treatment Variables	TRTPGy is present and TRTA is present but TRTAGy is not present
240	S3.2.2	TRTAGyN must have a one-to-one match to TRTAGy.	BDS	Value Consistency	Treatment Variables	There is more than one value of TRTAGy for a given value of TRTAGyN
241	S3.2.2	TRTAGyN must have a one-to-one match to TRTAGy.	BDS	Value Consistency	Treatment Variables	There is more than one value of TRTAGyN for a given value of TRTAGy
242	S3.1	Any variable beginning with TRT and ending in AN must have a corresponding variable beginning with TRT, having the same increment and end in A	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRTxxAN for a given value of TRTxxA
243	S3.1	Any variable beginning with TRT and ending in AN must have a corresponding variable beginning with TRT, having the same increment and end in A	ADSL	Value Consistency	Treatment Variables	There is more than one value of TRTxxA for a given value of TRTxxAN
244	S3.2.2	TRTA must match at least one value in TRT01A-TRTxxA	ADSL:BDS	Value Consistency	Treatment Variables	TRTA is not equal to at least one variable with a prefix of TRT, a suffix of A and containing a two digit number

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
245	TTE S1	In these studies, the basis of analysis is the time from a defined starting point to the time of occurrence of the event of interest.	BDS	Present/ Populated	Time to Event Variables	CNSR is present and STARTDT is not present.
246	TTE S1	In these studies, the basis of analysis is the time from a defined starting point to the time of occurrence of the event of interest.	BDS	Present/ Populated	Time to Event Variables	CNSR is present, ADT is not present and ADTM is not present.
247	TTE S4	The original date of risk for the time-to-event analysis. This is generally the time at which a subject is first at risk for the event of interest evaluation.	BDS	Present/ Populated	Time to Event Variables	CNSR is populated and STARTDT is not populated.
248	TTE S4	Analysis date of event or censoring associated with AVAL in numeric format.	BDS	Present/ Populated	Time to Event Variables	CNSR is populated, ADT is not populated and ADTM is not populated.
249	TTE S4	Analysis date of event or censoring associated with AVAL in numeric format.	BDS	Present/ Populated	Time to Event Variables	CNSR is populated and AVAL is not populated.
250	TTE S4	Describe the event of interest or an event that warrants censoring.	BDS	Present/ Populated	Time to Event Variables	EVNTDESC is present and CNSR is not present.

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
251	TTE S4	Describe the circumstance represented by the censoring date if different from the event date that warrants censoring.	BDS	Present/ Populated	Time to Event Variables	CNSDTDSC is present and CNSR is not present.
252	ADAE S1	There is no need for AVAL or AVALC.	ADAE	Present/ Populated	ADAE Variables	AVAL is present or AVALC is present.
253	ADAE S1	The ADAE structure for the standard adverse event safety dataset has at least one record per each AE recorded in SDTM AE domain. However, subjects not analyzed (e.g. screen failures) who have AEs recorded in SDTM AE but not in ADSL do not need to be included in ADAE.	ADSL:ADAE: SDTM	Value Consistency	ADAE Variables	For a value of AE.USUBJID that is a value of ADSL.USUBJID and ADAE.USUBJID, a value of AE.AESEQ is not a value of ADAE.AESEQ
254	ADAE S4.1	There is no PARAM nor AVAL	ADAE	Present/ Populated	ADAE Variables	PARAM is present.
255	ADAE S4.1	A variable should not use the prefix AE unless it is either (1) coming from the SDTM AE or SUPPAE domain or (2) the numeric version of the SDTM variable	ADAE:SDTM	Present/ Populated	ADAE Variables	A variable name begins with "AE" and the variable name or the variable name minus the suffix "n" is not a variable in SDTM.AE or a QNAM in SDTM.SUPPAE, excluding AENDT, AENDTM, AENDTF, AENTMF, and AENDY.
256	S3.1	Invalid USUBJID not found in ADSL data set	ADSL:ALL	Value Consistency	Subject Demographics	The values of USUBJID are not present in ADSL
257	ADAE S4.1.2	Include the identifier variables from SDTM: AESEQ. Required for traceability back to SDTM AE.	ADAE	Present/ Populated	Data Point Traceability Variables	AESEQ is not present

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
258	ADAE S4.1.2	Include the identifier variables from SDTM: AESEQ. Required for traceability back to SDTM AE.	ADAE:SDTM	Value Consistency	ADAE Variables	For a value of ADAE.USUBJID that is a value of AE.USUBJID, a value of ADAE.AESEQ is not a value of AE.AESEQ
259	ADAE S4.1.2	Include the identifier variables from SDTM: AESEQ. Required for traceability back to SDTM AE.	ADAE:SDTM	Value Consistency	ADAE Variables	The value of ADAE.USUBJID equals the value of AE.USUBJID and the values of ADAE.AESEQ equals to the value of AE.AESEQ and the values of ADAE.<variable from AE> is not equal to SDTM.AE.<variable from AE>
260	ADAE S4.1.3	Required Variable: AETERM	ADAE	Present/ Populated	ADAE Variables	AETERM is not present
261	ADAE S4.1.3	Required Coding Variable: AEDECOD	ADAE	Present/ Populated	Coding Variables	AEDECOD is not present
262	ADAE S4.1.3	Required Coding Variable: AEBODSYS	ADAE	Present/ Populated	Coding Variables	AEBODSYS is not present
263	S3.2.3	The level of imputation of ASTDT	BDS, ADAE	Value Consistency	Timing Variables	ASTDTF is populated and ASTDT is not populated
264	S3.2.3	The level of imputation of ASTTM	BDS, ADAE	Value Consistency	Timing Variables	ASTTMF is populated and ASTTM is not populated
265	S3.2.3	The level of imputation of AENTM	BDS, ADAE	Value Consistency	Timing Variables	AENTMF is populated but AENTM is not populated

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
266	S3.2.3	The level of imputation of AENDT	BDS, ADAE	Value Consistency	Timing Variables	AENDTF is populated but AENDT is not populated
267	ADAE S4.1.4	ADURU: Conditional on whether ADURN is included.	ADAE	Present/ Populated	Timing Variables	ADURU is populated and ADURN is not populated
268	ADAE S4.1.4	ADURN: Conditional on whether ADURU is included.	ADAE	Present/ Populated	Timing Variables	ADURN is populated and ADURU is not populated
269	ADAE S4.1.5	TRTEMFL must have a value of Y or null	ADAE	Controlled Terminology	Flag Variables	TRTEMFL is not equal to Y or null
270	ADAE S4.1.5	PREFL must have a value of Y or null	ADAE	Controlled Terminology	Flag Variables	PREFL is not equal to Y or null
271	ADAE S4.1.5	FUPFL must have a value of Y or null	ADAE	Controlled Terminology	Flag Variables	FUPFL is not equal to Y or null
272	ADAE S4.1.6	Occurrence flag variables have a codelist of Y or null	ADAE	Controlled Terminology	Flag Variables	A variable with a prefix of AOCC and a suffix of FL is not equal to Y or null
273	ADAE S4.1.6	AOCCzzFL. The lower case letter “zz” in a variable name (i.e., ANLzzFL) is an index for the zzth record selection algorithm where “zz” is replaced with a zero-padded two-digit integer [01-99].	ADAE	Metadata	Flag Variables	A variable with a prefix of AOCC has zz fragment appended after AOCC that is not a zero-padded two-digit integer [01-99], excluding AOCCFL, AOCCSFL, AOCCPFL, AOCCIFL, AOCCSIFL, AOCCPIFL
274	ADAE S4.1.7	DOSEAEON: Conditional on whether DOSAEONU is included.	ADAE	Present/ Populated	Treatment Variables	DOSEAEON is populated and DOSAEONU is not populated

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
275	ADAE S4.1.7	DOSECUM: Conditional on whether DOSECUMU is included.	ADAE	Present/ Populated	Treatment Variables	DOSECUM is populated and DOSECUMU is not populated
276	ADAE S4.1.7	DOSAEONU: Conditional on whether DOSEAEON is included.	ADAE	Present/ Populated	Treatment Variables	DOSAEONU is populated and DOSEAEON is not populated
277	ADAE S4.1.7	DOSECUMU: Conditional on whether DOSECUM is included.	ADAE	Present/ Populated	Treatment Variables	DOSECUMU is populated and DOSECUM is not populated
278	ADAE S4.1.8	AESER is Required in ADAE	ADAE	Present/ Populated	ADAE Variables	AESER is not present
279	ADAE S4.1.8	AESEVN must have a value of 1, 2, or 3.	ADAE	Controlled Terminology	ADAE Variables	AESEVN is not equal to 1, 2, 3, or null
280	ADAE S4.1.8	AESEV & AESEVN 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of AESEV for a given value of AESEVN
281	ADAE S4.1.8	AESEVN & AESEV 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of AESEVN for a given value of AESEV
282	ADAE S4.1.8	ASEVN must have a value of 1, 2, or 3.	ADAE	Controlled Terminology	ADAE Variables	ASEVN is not equal to 1, 2, or 3
283	ADAE S4.1.8	ASEV & ASEVN 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of ASEV for a given value of ASEVN

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
284	ADAE S4.1.8	ASEVN & ASEV 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of ASEVN for a given value of ASEV
285	ADAE S4.1.8	SEVGRy & SEVGRyN 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of SEVGRy for a given value of SEVGRyN
286	ADAE S4.1.8	SEVGRyN & SEVGRy 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of SEVGRyN for a given value of SEVGRy
287	ADAE S4.1.8	AEREL & AERELN 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of AEREL for a given value of AERELN
288	ADAE S4.1.8	AERELN & AEREL 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of AERELN for a given value of AEREL
289	ADAE S4.1.8	AREL & ARELN 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of AREL for a given value of ARELN
290	ADAE S4.1.8	ARELN & AREL 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of ARELN for a given value of AREL
291	ADAE S4.1.8	RELGRy & RELGRyN 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of RELGRy for a given value of RELGRyN
292	ADAE S4.1.8	RELGRyN & RELGRy 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of RELGRyN for a given value of RELGRy
293	ADAE S4.1.8	AETOXGR & AETOXGRN 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of AETOXGR for a given value of AETOXGRN

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
294	ADAE S4.1.8	AETOXGRN & AETOXGR 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of AETOXGRN for a given value of AETOXGR
295	ADAE S4.1.8	ATOXGR & ATOXGRN 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of ATOXGR for a given value of ATOXGRN
296	ADAE S4.1.8	ATOXGRN & ATOXGR 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of ATOXGRN for a given value of ATOXGR
297	ADAE S4.1.8	TOXGGRy & TOXGGRyN 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of TOXGGRy for a given value of TOXGGRyN
298	ADAE S4.1.8	TOXGGRyN & TOXGGRy 1:1 map	ADAE	Value Consistency	ADAE Variables	There is more than one value of TOXGGRyN for a given value of TOXGGRy
299	ADAE S4.1.9	SMQzzNAM. The lower case letter “zz” in a variable name (i.e., ANLzzFL) is an index for the zzth record selection algorithm where “zz” is replaced with a zero-padded two-digit integer [01-99].	ADAE	Metadata	MedDRA Query Variables	A variable with a prefix of SMQ and a suffix of NAM has zz fragment appended after SMQ that is not a zero-padded two-digit integer [01-99]
300	ADAE S4.1.9	SMQzzCD. The lower case letter “zz” in a variable name (i.e., ANLzzFL) is an index for the zzth record selection algorithm where “zz” is replaced with a zero-padded two-digit integer [01-99].	ADAE	Metadata	MedDRA Query Variables	A variable with a prefix of SMQ and a suffix of CD has zz fragment appended after SMQ that is not a zero-padded two-digit integer [01-99]

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
301	ADAE S4.1.9	SMQzzSC. The lower case letter "zz" in a variable name (i.e., ANLzzFL) is an index for the zzth record selection algorithm where "zz" is replaced with a zero-padded two-digit integer [01-99].	ADAE	Metadata	MedDRA Query Variables	A variable with a prefix of SMQ and a suffix of SC has zz fragment appended after SMQ that is not a zero-padded two-digit integer [01-99]
302	ADAE S4.1.9	SMQzzSCN. The lower case letter "zz" in a variable name (i.e., ANLzzFL) is an index for the zzth record selection algorithm where "zz" is replaced with a zero-padded two-digit integer [01-99].	ADAE	Metadata	MedDRA Query Variables	A variable with a prefix of SMQ and a suffix of SCN has zz fragment appended after SMQ that is not a zero-padded two-digit integer [01-99]
303	ADAE S4.1.9	CQzzNAM. The lower case letter "zz" in a variable name (i.e., ANLzzFL) is an index for the zzth record selection algorithm where "zz" is replaced with a zero-padded two-digit integer [01-99].	ADAE	Metadata	MedDRA Query Variables	A variable with a prefix of CQ and a suffix of NAM has zz fragment appended after CQ that is not a zero-padded two-digit integer [01-99]
304	ADAE S4.1.9	If SMQzzNAM is populated then SMQzzCD must be populated	ADAE	Present/ Populated	MedDRA Query Variables	SMQzzNAM is populated and SMQzzCD is not populated

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
305	ADAE S4.1.9	If SMQzzNAM is populated then SMQzzSC must be populated	ADAE	Present/ Populated	MedDRA Query Variables	SMQzzNAM is populated and SMQzzSC is not populated
306	ADAE S4.1.9	If SMQzzCD is populated then SMQzzNAM must be populated	ADAE	Present/ Populated	MedDRA Query Variables	SMQzzCD is populated and SMQzzNAM is not populated
307	ADAE S4.1.9	If SMQzzCD is populated then SMQzzSC must be populated	ADAE	Present/ Populated	MedDRA Query Variables	SMQzzCD is populated and SMQzzSC is not populated
308	ADAE S4.1.9	If SMQzzSC is populated then SMQzzNAM must be populated	ADAE	Present/ Populated	MedDRA Query Variables	SMQzzSC is populated and SMQzzNAM is not populated
309	ADAE S4.1.9	If SMQzzSC is populated then SMQzzCD must be populated	ADAE	Present/ Populated	MedDRA Query Variables	SMQzzSC is populated and SMQzzCD is not populated
310	ADAE S4.1.9	SMQzzSC & SMQzzSCN 1:1 map	ADAE	Value Consistency	MedDRA Query Variables	There is more than one value of a variable with a prefix of SMQ and suffix of SC has zz fragment appended after SMQ for a given value of a variable with a prefix of SMQ and a suffix of SCN has zz fragment appended after SMQ
311	ADAE S4.1.9	SMQzzSCN & SMQzzSC 1:1 map	ADAE	Value Consistency	MedDRA Query Variables	There is more than one value of a variable with a prefix of SMQ and suffix of SCN has zz fragment appended after SMQ for a given value of a variable with a prefix of SMQ and a suffix of SC has zz fragment appended after SMQ

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
312	ADAE S4.1.9	SMQzzSC must have a value of BROAD or NARROW	ADAE	Controlled Terminology	MedDRA Query Variables	The value of a variable with prefix of SMQ and suffix of SC with zz fragment appended after SMQ is not equal to "BROAD" or "NARROW"
313	ADAE S4.1.9	SMQzzSCN must have a value of 1 or 2	ADAE	Controlled Terminology	MedDRA Query Variables	The value of a variable with prefix of SMQ and suffix of SCN with zz fragment appended after SMQ is not equal to 1 or 2
314	ADAE S4.1.10	The suffix “y” represents an integer [1-9] corresponding to a previous version: DECDORGy, BDSYORGy, HLGTORGy, HLTORGy, LLTORGy, LLTNORGy	ADAE	Metadata	Coding Variables	A variable with a prefix of DECDORG has y fragment appended after DECDORG that is not a single-digit integer [1-9]
315	ADAE S4.1.10	The suffix “y” represents an integer [1-9] corresponding to a previous version: DECDORGy, BDSYORGy, HLGTORGy, HLTORGy, LLTORGy, LLTNORGy	ADAE	Metadata	Coding Variables	A variable with a prefix of BDSYORG has y fragment appended after BDSYORG that is not a single-digit integer [1-9]
316	ADAE S4.1.10	The suffix “y” represents an integer [1-9] corresponding to a previous version: DECDORGy, BDSYORGy, HLGTORGy, HLTORGy, LLTORGy, LLTNORGy	ADAE	Metadata	Coding Variables	A variable with a prefix of HLGTORG has y fragment appended after HLGTORG that is not a single-digit integer [1-9]

Check Number	ADaM IG Section Number	Text from ADaM IG	ADaM Structure Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria
317	ADAE S4.1.10	The suffix "y" represents an integer [1-9] corresponding to a previous version: DECDORGy, BDSYORGy, HLGTORGy, HLTORGy, LLTORGy, LLTNORGy	ADAE	Metadata	Coding Variables	A variable with a prefix of HLTORG has y fragment appended after HLTORG that is not a single-digit integer [1-9]
318	ADAE S4.1.10	The suffix "y" represents an integer [1-9] corresponding to a previous version: DECDORGy, BDSYORGy, HLGTORGy, HLTORGy, LLTORGy, LLTNORGy	ADAE	Metadata	Coding Variables	A variable with a prefix of LLTORG has y fragment appended after LLTORG that is not a single-digit integer [1-9]
319	ADAE S4.1.10	The suffix "y" represents an integer [1-9] corresponding to a previous version: DECDORGy, BDSYORGy, HLGTORGy, HLTORGy, LLTORGy, LLTNORGy	ADAE	Metadata	Coding Variables	A variable with a prefix of LLTNORG has y fragment appended after LLTNORG that is not a single-digit integer [1-9]

5 References

- CDISC Analysis Data Model Team. "Analysis Data Model (ADaM) Implementation Guide 1.0". December, 2009.
- CDISC Analysis Data Model Team. "Analysis Data Model (ADaM) 2.1". December, 2009.
- CDISC Analysis Data Model Team. "The ADaM Basic Data Structure for Time-to-Event Analysis 1.0". April, 2012
- CDISC Analysis Data Model Team. "Analysis Data Model (ADaM) Data Structure for Adverse Event Analysis". May, 2012

Appendices

Appendix A: Revision History

Change from ADaM Validation Checks 1.2 to 1.3

Check Number	Type of change[1]	Description of change
39	Text Change	Updated variable name
40	Text Change	Updated variable name
53	Text Change	Reworded to make text consistent with similar rules
58	Text Change	Updated ADaM Structure Group
59	Text Change	Updated ADaM Structure Group
60	Text Change	Updated ADaM Structure Group
69	Deletion	Removed because no rule exists requiring a numeric variable when character version is present
85	Text Change	Updated ADaM Structure Group
86	Text Change	Updated ADaM Structure Group
87	Text Change	Updated ADaM Structure Group
94	Text Change	Reworded to make text consistent with similar rules
105	Text Change	Updated ADaM Structure Group
106	Text Change	Updated ADaM Structure Group
154	Text Change	Reworded to make text consistent with similar rules
163 – 168	Text Change	Updated ADaM Structure Group
175	Text Change	Correction in text for ADaM IG reference
177	Deletion	Removed duplicate of check 154
178	Text Change	Updated ADaM Structure Group
182 - 183	Text Change	Updated ADaM Structure Group
213	Text Change	Reworded to make text consistent with similar rules
214	Text Change	Reworded to make text consistent with similar rules
215	Text Change	Reworded to make text consistent with similar rules
216	Text Change	Reworded to make text consistent with similar rules
219	Deletion	Removed duplicate of check 94
220	Deletion	Removed duplicate of check 184
245 - 251	Addition	Added TTE Checks
252 - 319	Addition	Added ADAE Checks

[1] Changes were classified as follows: “Text Change” is an update which affects the text but does not change the meaning or implementation of a check; “Rule Change” is an update which changes the implementation of a check; “Deletion” is the removal of a check; and “Addition” is a new check.

Summary of Changes for Each Version of the Validation Checks

ADaM Validation Checks Version	Number of Checks	Checks Deleted	Rules Added	Rules Modified	Text Changes
1.0	180				
1.1	174	9	3	5	30
1.2	233	2	61	0	13
1.3	304	4	75	0	27

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