ADaM Conformance Rules

Version 2.0 (Final)

Developed by the
CDISC ADaM Conformance Subteam

Notes to Readers

The conformance rules within this document can be implemented with software to test rules defined within the ADaM Implementation Guide 1.0, ADaM Implementation Guide v1.1, and the ADaM Structure for Occurrence Data v1.

Revision History

Date	Version	Summary of Changes
2010-09-20	v1.0	Final production version based on team review
2011-01-11	v1.1	Maintenance release to correct errors and remove duplicate checks
2012-07-05	v1.2	Maintenance release to correct text, remove checks, and add new checks
2015-03-17	v1.3	Maintenance release to correct text, remove checks, and add new checks for TTE and ADAE
2019-02-20	v2.0 Final	Maintenance release to clarify text, remove checks that are invalid, and add new checks to support ADaMIG v1.1 and OCCDS v1. See details in Appendix B: Revision History.

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1 Introduction

The CDISC Analysis Data Model (ADaM)[1] 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 (ADaMIG) Versions 1.0 and 1.1[2,3], and ADaM Structure for Occurrence Data (OCCDS) Version 1.0[4] include specific guidelines and rules for defining and creating ADaM datasets. CDISC ADaM Conformance Rules may be used to validate datasets against a subset of these rules which are objective and unambiguously evaluable. The conformance rules 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 conformance rules within this document can be implemented with software to test rules defined within the ADaMIG v1.0,[2] ADaMIG v1.1,[3] and the OCCDS v1.0.[4] Future releases of ADaM standard[1] documents will be covered in a subsequent release of this document. The checks are meant to test the structure and certain standardized variable values of the ADaM datasets. These rules are not meant to define the whole spectrum of ADaM compliance including content and well-defined metadata. This version is intended to be used only for single studies. As of the date of publication of this document, no published guidance has been provided for an integrated analysis.

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

- Within Section 4.3.1 of ADaMIG v1.0, the text says, “Include all observed and derived rows for a given analysis parameter.”
- Within Section 4.6.1 of ADaMIG v1.0, the text says, “To identify population-specific analyzed rows, use population-specific indicator variables.”
- Many ADaM variables are conditionally required (i.e., 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.

Although 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 support, coupled with the published conformance rules within this document and the general rules and principles published in the ADaMIG.

3 Description of ADaM Conformance Rules Table

The ADaM conformance rules table contains 9 columns:

- **Check Number**: A unique identifier for the rule.
- **IG Version:** Version of the ADaMIG[2,3] to which the rule is applicable.
- **ADaM Structure Group**: Groups checks based on the ADaM[1] structure to which the requirement relates. In general, a colon indicates a relationship between data structures; a comma is equivalent to the text "and/or” and indicates that a check applies to more than 1 data structure. The groupings are:

  - ALL (applies to any ADaM dataset)
  - ADSL (applies to the standard Subject-Level Analysis Dataset)
  - BDS (applies to Basic Data Structure datasets)
  - OCCDS (applies to Occurrence Data Structure datasets)
  - ADSL:ALL (relationships between the ADSL dataset and any ADaM dataset)
  - ADSL:BDS (relationships between the ADSL dataset and BDS dataset)
  - ADSL:BDS, ADSL:OCCDS (relationships between the ADSL dataset and BDS datasets, and relationships between the ADSL dataset and OCCDS[4] datasets)
  - ADSL:SDTM (relationships between the ADSL dataset and the Study Data Tabulation Model[5] datasets)
  - ALL:SDTM (relationships between any ADaM dataset and the SDTM datasets)
  - BDS, OCCDS (applies to both BDS datasets and OCCDS datasets)
  - BDS:SDTM (relationships between BDS datasets and the SDTM datasets)
  - BDS:SDTM, BDS:ADaM (relationships between BDS datasets and the SDTM datasets, and relationships between BDS datasets and any ADaM dataset)
  - BDS:SDTM, OCCDS:SDTM (relationships between BDS datasets and SDTM datasets, and relationships between OCCDS datasets and SDTM datasets)
  - OCCDS:SDTM (relationships between OCCDS datasets and the SDTM datasets)
- **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.
- **Message Type:**
  - Error. Check is a requirement based on the text from the ADaMIG
  - Warning. Check meets the following criteria:
    - Concept was/will be clarified in a later version of the ADaMIG
    - May not apply to your study
    - Strong recommendations from CDISC
    - Dictionary variables with expected relationships
  - Note. Data quality checks which may require additional investigation to ensure correctness of ADaM dataset
- **Guide:** Published CDISC standard reference document
- **Section:** Section number from the document referenced in the "Guide" column
- **Item:** Numbered item or table within section referenced in the "Section" column
- **Cited Guidance:** Supporting text within the referenced Guide, Section, and/or Item columns

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 2 conditions: (1) there cannot be more than 1 value of TRTAN for each value of TRTA, and (2) there cannot be more than 1 value of TRTA for each value of TRTAN.

In the failure criteria specified in this document, "[*variable name*] is populated" means "[*variable name*] is present in the dataset and [*variable name*] is populated on this row". Similarly, "[*variable name*] is not populated" means "[*variable name*] is present in the dataset and [*variable name*] is not populated on this row".

4 ADaM Conformance Rules

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
1	1.0	ADSL	ADSL dataset does not exist	Error	Model v2.1; ADaMIG v1.0	6; 2.3.1		Model v2.1, Section 6: ADSL and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other analysis datasets are submitted. ADaMIG v1.0, Section 2.3.1: ADSL and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other analysis datasets are submitted.
1	1.1	ADSL	ADSL dataset does not exist	Error	Model v2.1; ADaMIG v1.1	6; 2.3.1		Model v2.1, Section 6: ADSL and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other analysis datasets are submitted. ADaMIG v1.1, Section 2.3.1: ADSL and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other ADaM datasets are submitted.
2	1.0	ALL:SDTM	A variable is present in ADaM with the same name as a variable present in SDTM but the variables do not have identical labels	Error	Model v2.1; ADaMIG v1.0	4.1.2; 3	4 (General Variable Naming Conventions)	Model v2.1, Section 4.1.2: Any ADaM variable with the same name as an SDTM variable is required to be a copy of the SDTM variable, and its label, attributes, and values cannot be modified. ADaM adheres to the principle of harmonization known as "same name, same meaning, and same values." ADaMIG v1.0, Section 3, Item 4

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								(General Variable Naming Conventions): 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. ADaM adheres to a principle of harmonization known as "same name, same meaning, same values."
2	1.1	ALL:SDTM	A variable is present in ADaM with the same name as a variable present in SDTM but the variables do not have identical labels	Error	Model v2.1; ADaMIG v1.1	4.1.2; 3.1.1	3	Model v2.1, Section 4.1.2: Any ADaM variable with the same name as an SDTM variable is required to be a copy of the SDTM variable, and its label, attributes, and values cannot be modified. ADaM adheres to the principle of harmonization known as "same name, same meaning, and same values." ADaMIG v1.1, Section 3.1.1, Item 3: Any variable in an ADaM dataset 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. ADaM adheres to a principle of harmonization known as "same name, same meaning, same values." However, to optimize file size, it is permissible that the length of the variables differ (e.g., trailing blanks may be removed).
5	1.0	ALL	A variable with a suffix of FL has a value that is not Y, N, or null	Warning	ADaMIG v1.0	3	4 (General Flag Variable Conventions); 9 (General Flag Variable Conventions)	ADaMIG v1.0, Section 3, Item 4 (General Flag Variable Conventions): For subject-level character population flag variables: N=no (not included in the population), Y=yes (included). Null values are not allowed.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								ADaMIG v1.0, Section 3, Item 9 (General Flag Variable Conventions): For character flags that are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Table 3.2.6.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags that are not population indicators.
5	1.1	ALL	A variable with a suffix of FL has a value that is not Y, N, or null	Error	ADaMIG v1.1	3.1.4	4; 9	ADaMIG v1.1, Section 3.1.4, Item 4: For subject-level character population flag variables: N=no (not included in the population), Y=yes (included). Null values are not allowed. ADaMIG v1.1, Section 3.1.4, Item 9: For character flags with variable names that end in FL and that are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Tables 3.3.4.2 and 3.3.8.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags with variable names that end in FN and that are not population indicators.
6	1.0	ALL	A variable with a suffix of FN has a value that is not 0, 1, or null	Warning	ADaMIG v1.0	3	5 (General Flag Variable Conventions); 9 (General Flag Variable Conventions)	ADaMIG v1.0, Section 3, Item 5 (General Flag Variable Conventions): For subject-level numeric population flag variables: 0=no (not included), 1=yes (included). Null values are not allowed. ADaMIG v1.0, Section 3, Item 9 (General Flag Variable Conventions): For character flags with variable names

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								that end in FL and that are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Tables 3.3.4.2 and 3.3.8.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags with variable names that end in FN and that are not population indicators.
6	1.1	ALL	A variable with a suffix of FN has a value that is not 0, 1, or null	Warning	ADaMIG v1.1	3.1.4	5; 9	ADaMIG v1.1, Section 3.1.4, Item 5: For subject-level numeric population flag variables: 0=no (not included), 1=yes (included). Null values are not allowed. ADaMIG v1.1, Section 3.1.4, Item 9: For character flags with variable names that end in FL and that are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Tables 3.3.4.2 and 3.3.8.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags with variable names that end in FN and that are not population indicators.
7	1.0	ALL	A variable with a suffix of FN is present but a variable with the same root and a suffix of FL is not present	Warning	ADaMIG v1.0	3	3 (General Variable Naming Conventions)	ADaMIG v1.0, Section 3, Item 3 (General Variable Naming Conventions): The names of all other character flag (or indicator) variables end in FL, and the names of the corresponding numeric flag (or indicator) variables end in FN If the flag is used, the character version (*FL) is required but the numeric version (*FN) can also be included.
7	1.1	ALL	A variable with a suffix of FN is present but a variable with	Warning	ADaMIG v1.1	3.1.1	8	ADaMIG v1.1, Section 3.1.1, Item 8: Variables whose names end in FL are

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			the same root and a suffix of FL is not present					character flag (or indicator) variables with at most 2 possible non-missing values, Y or N (i.e., yes or no). The name of the corresponding numeric flag (or indicator) variable ends in FN. If the flag is included in an ADaM dataset, the character version (*FL) is required but the corresponding numeric version (*FN) can also be included. If both versions of the flag are included, there must be a one-to-one mapping between the values of the 2 variables, as described in Section 3.1.4.
10	1.0	ALL	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	Error	ADaMIG v1.0	3	4 (General Flag Variable Conventions); 9 (General Flag Variable Conventions)	ADaMIG v1.0, Section 3, Item 4 (General Flag Variable Conventions): For subject-level character population flag variables: N=no (not included in the population), Y=yes (included). Null values are not allowed. ADaMIG v1.0, Section 3, Item 9 (General Flag Variable Conventions): For character flags that are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Table 3.2.6.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags that are not population indicators.
10	1.1	ALL	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	Error	ADaMIG v1.1	3.1.4	4; 9	ADaMIG v1.1, Section 3.1.4, Item 4: For subject-level character population flag variables: N=no (not included in the population), Y=yes (included). Null values are not allowed.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								ADaMIG v1.1, Section 3.1.4, Item 9: For character flags with variable names that end in FL and which are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Tables 3.3.4.2 and 3.3.8.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags with variable names that end in FN and which are not population indicators.
11	1.0	ALL	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	Error	ADaMIG v1.0	3	4 (General Flag Variable Conventions); 9 (General Flag Variable Conventions)	ADaMIG v1.0, Section 3, Item 4 (General Flag Variable Conventions): For subject-level character population flag variables: N=no (not included in the population), Y=yes (included). Null values are not allowed. ADaMIG v1.0, Section 3, Item 9 (General Flag Variable Conventions): For character flags that are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Table 3.2.6.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags that are not population indicators.
11	1.1	ALL	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	Error	ADaMIG v1.1	3.1.4	4; 9	ADaMIG v1.1, Section 3.1.4, Item 4: For subject-level character population flag variables: N=no (not included in the population), Y=yes (included). Null values are not allowed. ADaMIG v1.1, Section 3.1.4, Item 9: For character flags with variable names that

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								end in FL and which are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Tables 3.3.4.2 and 3.3.8.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags with variable names that end in FN and that are not population indicators.
12	1.0	ALL	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	Error	ADaMIG v1.0	3	9 (General Flag Variable Conventions)	ADaMIG v1.0, Section 3, Item 9 (General Flag Variable Conventions): For character flags that are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Table 3.2.6.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags that are not population indicators.
12	1.1	ALL	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	Error	ADaMIG v1.1	3.1.4	9	ADaMIG v1.1, Section 3.1.4, Item 9: For character flags with variable names that end in FL and which are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Tables 3.3.4.2 and 3.3.8.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags with variable names that end in FN and that are not population indicators.
13	1.0	ALL	The length of a variable name exceeds 8 characters	Error	Model v2.1; ADaMIG v1.0	4.1.2; 3	5 (General Variable Naming Conventions)	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD[6] guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								total length of the name cannot exceed 8 characters). ADaMIG v1.0, Section 3, Item 5 (General Variable Naming Conventions): To ensure compliance with SAS Transport file and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.
13	1.1	ALL	The length of a variable name exceeds 8 characters	Error	Model v2.1; ADaMIG v1.1	4.1.2; 3.1.1	1	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD[6] guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the total length of the name cannot exceed 8 characters). ADaMIG v1.1, Section 3.1.1, Item 1: To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character

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								variables must be no more than 200 characters in length.
14	1.0	ALL	A variable name does not start with a letter (A-Z)	Error	Model v2.1; ADaMIG v1.0	4.1.2; 3	5 (General Variable Naming Conventions)	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the total length of the name cannot exceed 8 characters). ADaMIG v1.0, Section 3, Item 5 (General Variable Naming Conventions): To ensure compliance with SAS Transport file and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.
14	1.1	ALL	A variable name does not start with a letter (A-Z)	Error	Model v2.1; ADaMIG v1.1	4.1.2; 3.1.1	1	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the total length of the name cannot exceed 8 characters). ADaMIG v1.1, Section 3.1.1, Item 1: To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in

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								length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.
15	1.0	ALL	A variable name contains a character other than letters (A-Z), underscores (_), or numerals (0-9)	Error	Model v2.1; ADaMIG v1.0	4.1.2; 3	5 (General Variable Naming Conventions)	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the total length of the name cannot exceed 8 characters). ADaMIG v1.0, Section 3, Item 5 (General Variable Naming Conventions): To ensure compliance with SAS Transport file and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.
15	1.1	ALL	A variable name contains a character other than letters (A-Z), underscores (_), or numerals (0-9)	Error	Model v2.1; ADaMIG v1.1	4.1.2; 3.1.1	1	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the total length of the name cannot exceed 8 characters).

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								ADaMIG v1.1, Section 3.1.1, Item 1: To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.
16	1.0	ALL	The length of a variable label is greater than 40 characters	Error	Model v2.1; ADaMIG v1.0	4.1.2; 3	5 (General Variable Naming Conventions)	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the total length of the name cannot exceed 8 characters). ADaMIG v1.0, Section 3, Item 5 (General Variable Naming Conventions): To ensure compliance with SAS Transport file and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.

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16	1.1	ALL	The length of a variable label is greater than 40 characters	Error	Model v2.1; ADaMIG v1.1	4.1.2; 3.1.1	1	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the total length of the name cannot exceed 8 characters). ADaMIG v1.1, Section 3.1.1, Item 1: To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.
17	1.0	ALL	The length of a character value is greater than 200 characters	Error	Model v2.1; ADaMIG v1.0	4.1.2; 3	5 (General Variable Naming Conventions)	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the total length of the name cannot exceed 8 characters). ADaMIG v1.0, Section 3, Item 5 (General Variable Naming Conventions): To ensure compliance with SAS Transport file and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed

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								only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.
17	1.1	ALL	The length of a character value is greater than 200 characters	Error	Model v2.1; ADaMIG v1.1	4.1.2; 3.1.1	1	Model v2.1, Section 4.1.2: In developing naming conventions, sponsors should consider the requirements noted in the eCTD guidance document as well as the need to conform to the SAS Transport format requirements (e.g., the total length of the name cannot exceed 8 characters). ADaMIG v1.1, Section 3.1.1, Item 1: To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.
18	1.0	ALL	Labels for ADaM variables do not match the standard labels for ADaM variables listed in the implementation guide that cannot be modified. Exceptions: (1) variables whose names contain indexes “y”, "xx", or “zz” (2) variable labels with	Error	ADaMIG v1.0	3		ADaMIG v1.0, Section 3: In general, the variable labels specified in the tables in Section 3 are required. There are only 2 exceptions to this rule: (1) descriptive text is allowed at the end of the labels of variables whose names contain indexes "y" or "zz"; and (2) asterisks (*) and ellipses (...) in specified variable labels

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			asterisks (*) and ellipses (...) indicated for sponsor-appropriate text					should be replaced by the sponsor with appropriate text.
18	1.1	ALL	Labels for ADaM variables do not match the standard labels for ADaM variables listed in the implementation guide that cannot be modified Exceptions: (1) variables whose names contain indexes "w", “y”, "xx", or “zz” (2) variable labels with asterisks (*), braces ({...}), and ellipses (...) indicated for sponsor-appropriate text	Error	ADaMIG v1.1	3.1.6		ADaMIG v1.1, Section 3.1.6: In general, the variable labels specified in the tables in Section 3 are required. There are only 2 exceptions to this rule: (1) descriptive text is allowed at the end of the labels of variables whose names contain indexes "y" or "zz"; and (2) variable labels containing a word or phrase in brackets (e.g., {Time}) should be replaced by the producer with appropriate text that contains the bracketed word or phrase somewhere in the text (e.g., "the label for a *TM variable is indicated as {Time} in this document") indicating any producer-defined label is permitted as long as the word Time is incorporated in it.
19	1.0	ADSL	COMPLFL is present and has a value that is not Y or N	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
19	1.1	ADSL	COMPLFL is present and has a value that is not Y or N	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
20	1.0	ADSL	FASFL is present and has a value that is not Y or N	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
20	1.1	ADSL	FASFL is present and has a value that is not Y or N	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
21	1.0	ADSL	ITTFL is present and has a value that is not Y or N	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
21	1.1	ADSL	ITTFL is present and has a value that is not Y or N	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
22	1.0	ADSL	PPROTFL is present and has a value that is not Y or N	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
22	1.1	ADSL	PPROTFL is present and has a value that is not Y or N	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
23	1.0	ADSL	SAFFL is present and has a value that is not Y or N	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
23	1.1	ADSL	SAFFL is present and has a value that is not Y or N	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
24	1.0	ADSL	RANDFL is present and has a value that is not Y or N	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
24	1.1	ADSL	RANDFL is present and has a value that is not Y or N	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
25	1.0	ADSL	ENRLFL is present and has a value that is not Y or N	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Population Indicator(s) have a

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								Codelist/Controlled Term value of "Y, N".
25	1.1	ADSL	ENRLFL is present and has a value that is not Y or N	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: Population Indicator(s) have a Codelist/Controlled Term value of "Y, N".
26	1.0	ADSL	COMPLFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
26	1.1	ADSL	COMPLFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included.
27	1.0	ADSL	FASFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
27	1.1	ADSL	FASFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included.
28	1.0	ADSL	ITTFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
28	1.1	ADSL	ITTFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: The values of subject-level population

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included.
29	1.0	ADSL	PPROTFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
29	1.1	ADSL	PPROTFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included.
30	1.0	ADSL	SAFFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
30	1.1	ADSL	SAFFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included.
31	1.0	ADSL	RANDFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
31	1.1	ADSL	RANDFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN,

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								where 0=no and 1=yes) of the population flag can also be included.
32	1.0	ADSL	ENRLFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
32	1.1	ADSL	ENRLFN is present and has a value that is not 1 or 0	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included.
33	1.0	BDS	A variable with a suffix of RFL has a value that is not Y or null	Warning	ADaMIG v1.0	3	6 (General Flag Variable Conventions)	ADaMIG v1.0, Section 3, Item 6 (General Flag Variable Conventions): For parameter-level and record-level character population flag variables: Y=yes (included). Null values are allowed.
33	1.1	BDS	A variable with a suffix of RFL has a value that is not Y or null	Warning	ADaMIG v1.1	3.1.4	6	ADaMIG v1.1, Section 3.1.4, Item 6: For parameter-level and record-level character population flag variables: Y=yes (included). Null values are allowed. Note that the controlled terminology is not the same for these population flag variables as for subject-level population flag variables. Depending on how validation checks are written, this difference could cause an issue for a producer-defined subject-level flag variable with a name that ends in "RFL" or "PFL" if it is copied into a BDS dataset.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
34	1.0	BDS	A variable with a suffix of PFL has a value that is not Y or null	Warning	ADaMIG v1.0	3	6 (General Flag Variable Conventions)	ADaMIG v1.0, Section 3, Item 6 (General Flag Variable Conventions): For parameter-level and record-level character population flag variables: Y=yes (included). Null values are allowed.
34	1.1	BDS	A variable with a suffix of PFL has a value that is not Y or null	Warning	ADaMIG v1.1	3.1.4	6	ADaMIG v1.1, Section 3.1.4, Item 6: For parameter-level and record-level character population flag variables: Y=yes (included). Null values are allowed. Note that the controlled terminology is not the same for these population flag variables as for subject-level population flag variables. Depending on how validation checks are written, this difference could cause an issue for a producer-defined subject-level flag variable with a name that ends in "RFL" or "PFL" if it is copied into a BDS dataset.
35	1.0	BDS	A variable with a suffix of RFN has a value that is not 1 or null	Warning	ADaMIG v1.0	3	7 (General Flag Variable Conventions)	ADaMIG v1.0, Section 3, Item 7 (General Flag Variable Conventions): For parameter-level and record-level numeric population flag variables: 1=yes (included). Null values are allowed.
35	1.1	BDS	A variable with a suffix of RFN has a value that is not 1 or null	Warning	ADaMIG v1.1	3.1.4	7	ADaMIG v1.1, Section 3.1.4, Item 7: For parameter-level and record-level numeric population flag variables: 1=yes (included). Null values are allowed. Depending on how validation checks are written, this difference could cause an issue for a producer-defined subject-level flag variable with a name that ends in "RFN" or "PFN" if it is copied into a BDS dataset.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
36	1.0	BDS	A variable with a suffix of PFN has a value that is not 1 or null	Warning	ADaMIG v1.0	3	7 (General Flag Variable Conventions)	ADaMIG v1.0, Section 3, Item 7 (General Flag Variable Conventions): For parameter-level and record-level numeric population flag variables: 1=yes (included). Null values are allowed.
36	1.1	BDS	A variable with a suffix of PFN has a value that is not 1 or null	Warning	ADaMIG v1.1	3.1.4	7	ADaMIG v1.1, Section 3.1.4, Item 7: For parameter-level and record-level numeric population flag variables: 1=yes (included). Null values are allowed. Depending on how validation checks are written, this difference could cause an issue for a producer-defined subject-level flag variable with a name that ends in "RFN" or "PFN" if it is copied into a BDS dataset.
37	1.0	ALL	There is more than 1 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	Warning	ADaMIG v1.0	3	10 (General Variable Naming Conventions)	ADaMIG v1.0, Section 3, Item 10 (General Variable Naming Conventions): If any combining of the SDTM character categories is done, the name of the derived ADaM character grouping variable should end in GRy and the name of its numeric equivalent should end in GRyN where y is an integer from 1-9 representing a grouping scheme. For example, if a character analysis variable is created to contain values of Caucasian and Non-Caucasian from the SDTM RACE variable that has 5 categories, then it should be named RACEGRy and its numeric equivalent should be named RACEGRyN (e.g., RACEGR1, RACEGR1N). Truncation of the original variable name may be necessary when appending suffix fragments GRy, or GRyN.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								The ADaM Team acknowledges that this cited guidance does not adequately support the creation of a conformance rule; however, we recognize the intent of character and numeric variable pairs and the one-to-one relationships that they must have.
37.01	1.1	ALL	There is more than 1 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, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.1.1	5; 6	ADaMIG v1.1, Section 3.1.1, Item 5: For variable pairs designated as having a one-to-one mapping within a specified scope (e.g., within a parameter, within a study), if both variables are present in the dataset and there exists a row in that scope on which both variables are populated, then there must be a one-to-one mapping between the 2 variables on all rows within the scope on which both variables are populated. The scopes noted in this document should be considered the minimum level for the mapping; this does not preclude the producer from using a broader level of scope. For example, if a one-to-one mapping is specified as within a PARAM, the producer may elect to use the same one-to-one mapping across all PARAMs within the dataset or study. In addition, note that "within a parameter" means "within a parameter within a dataset." ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character; but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5.
38	1.0	ALL	There is more than 1 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	Warning	ADaMIG v1.0	3	10 (General Variable Naming Conventions)	ADaMIG v1.0, Section 3, Item 10 (General Variable Naming Conventions): If any combining of the SDTM character categories is done, the name of the derived ADaM character grouping variable should end in GRy and the name of its numeric equivalent should end in GRyN where y is an integer from 1-9 representing a grouping scheme. For example, if a character analysis variable is created to contain values of Caucasian and Non-Caucasian from the SDTM RACE variable that has 5 categories, then it should be named RACEGRy and its numeric equivalent should be named RACEGRyN (e.g., RACEGR1, RACEGR1N). Truncation of the original variable name may be necessary when appending suffix fragments GRy, or

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								GRyN. The ADaM Team acknowledges that this cited guidance does not adequately support the creation of a conformance rule; however, we recognize the intent of character and numeric variable pairs and the one-to-one relationships that they must have.
38.01	1.1	ALL	There is more than 1 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, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.1.1	5; 6	ADaMIG v1.1, Section 3.1.1, Item 5: For variable pairs designated as having a one-to-one mapping within a specified scope (e.g., within a parameter, within a study), if both variables are present in the dataset and there exists a row in that scope on which both variables are populated, then there must be a one-to-one mapping between the 2 variables on all rows within the scope on which both variables are populated. The scopes noted in this document should be considered the minimum level for the mapping; this does not preclude the producer from using a broader level of scope. For example, if a one-to-one mapping is specified as within a PARAM, the producer may elect to use the same one-to-one mapping across all PARAMs within the dataset or study. In addition, note that "within a parameter" means "within a parameter within a dataset." ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5.
39	1.0	ALL	A variable with a suffix of DTF has a value that is not within Controlled Terminology for DATEFL	Warning	ADaMIG v1.0	3	6 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 6 (General Timing Variable Conventions): Variables whose names end in DTF are date imputation flags. *DTF variables represent the level of imputation of the *DT variable based on the source SDTM DTC variable. *DTF=Y if the entire date is imputed. *DTF=M if month and day are imputed. *DTF=D if only day is imputed. *DTF=null if *DT equals the SDTM DTC variable date part equivalent. If a date was imputed, *DTF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
39	1.1	ALL	A variable with a suffix of DTF has a value that is not within Controlled Terminology for DATEFL	Error	ADaMIG v1.1	3.1.1	1	ADaMIG v1.1, Section 3.1.1, Item 1: As described in Table 3.1.5.1, variables whose names end in DTF are date imputation flags. *DTF variables represent the highest level of imputation of the *DT variable based on the source SDTM DTC variable. *DTF=Y if the year is imputed. *DTF=M if year is present and month is imputed. *DTF=D if only day is imputed. *DTF=null if *DT equals the SDTM DTC variable date part equivalent. If a date was imputed, *DTF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done. Note that the list of examples in Table 3.1.3.1 is not exhaustive.
40	1.0	ALL	A variable with a suffix of TMF has a value that is not within Controlled Terminology for TIMEFL	Warning	ADaMIG v1.0	3	7 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 7 (General Timing Variable Conventions): Variables whose names end in TMF are time imputation flags. *TMF variables represent the level of imputation of the *TM (and *DTM) variable based on the source SDTM DTC variable. *TMF=H if the entire time is imputed. *TMF=M if minutes and seconds are imputed. *TMF=S if only seconds are imputed. *TMF=null if *TM equals the SDTM DTC variable time part equivalent. For a given SDTM DTC variable, if only hours and minutes are ever collected, and seconds are imputed in *DTM as 00, then it is not necessary to set *TMF to "S". However, if seconds are generally collected but are missing in a given value

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								of the DTC variable and imputed as 00, or if a collected value of seconds is changed in the creation of *DTM, then the difference is significant and should be qualified in *TMF. If a time was imputed *TMF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done.
40	1.1	ALL	A variable with a suffix of TMF has a value that is not within Controlled Terminology for TIMEFL	Error	ADaMIG v1.1	3.1.1	2	ADaMIG v1.1, Section 3.1.1, Item 2: As described in Table 3.1.5.1, variables whose names end in TMF are time imputation flags. *TMF variables represent the level of imputation of the *TM (and *DTM) variable based on the source SDTM DTC variable. *TMF=H if the entire time is imputed. *TMF=M if minutes and seconds are imputed. *TMF=S if only seconds are imputed. *TMF=null if *TM equals the SDTM DTC variable time part equivalent. For a given SDTM DTC variable, if only hours and minutes are ever collected, and seconds are imputed in *DTM as 00, then it is not necessary to set *TMF to "S". However, if seconds are generally collected but are missing in a given value of the DTC variable and imputed as 00, or if a collected value of seconds is changed in the creation of *DTM, then *TMF should be set to "S". If a time was imputed *TMF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								imputation in *DTM if imputation was done.
41	1.0	ALL	A numeric variable with a suffix of DT does not have a date format	Error	ADaMIG v1.0	3	1 (General Timing Variable Conventions); 2 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 1 (General Timing Variable Conventions): Numeric dates, times, and datetimes should be formatted so as to be human-readable with no loss of precision. The anchor or reference day from which all other dates are numbered should be clearly identified in the metadata. ADaMIG v1.0, Section 3, Item 2 (General Timing Variable Conventions): Variables whose names end in DT are numeric dates.
41	1.1	ALL	A numeric variable with a suffix of DT does not have a date format	Error	ADaMIG v1.1	3.1.2	1; 2	ADaMIG v1.1, Section 3.1.2, Item 1: Numeric dates, times, and datetimes should be formatted so as to be human-readable with no loss of precision. ADaMIG v1.1, Section 3.1.2, Item 2: Variables whose names end in DT are numeric dates.
42	1.0	ALL	A numeric variable with a suffix of TM does not have a time format, excluding ARELTM and variables with a suffix of DTM	Error	ADaMIG v1.0	3	1 (General Timing Variable Conventions); 4 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 1 (General Timing Variable Conventions): Numeric dates, times, and datetimes should be formatted so as to be human-readable with no loss of precision. The anchor or reference day from which all other dates are numbered should be clearly identified in the metadata. ADaMIG v1.0, Section 3, Item 4 (General Timing Variable Conventions): Variables whose names end in TM are numeric times.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
42	1.1	ALL	A numeric variable with a suffix of TM does not have a time format, excluding ARELTM and variables with a suffix of DTM	Error	ADaMIG v1.1	3.1.2	1; 4	ADaMIG v1.1, Section 3.1.2, Item 1: Numeric dates, times, and datetimes should be formatted so as to be human-readable with no loss of precision. ADaMIG v1.1, Section 3.1.2, Item 4: Variables whose names end in TM are numeric times.
43	1.0	ALL	A numeric variable with a suffix of DTM does not have a datetime format	Error	ADaMIG v1.0	3	1 (General Timing Variable Conventions); 3 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 1 (General Timing Variable Conventions): Numeric dates, times, and datetimes should be formatted so as to be human readable with no loss of precision. The anchor or reference day from which all other dates are numbered should be clearly identified in the metadata. ADaMIG v1.0, Section 3, Item 3 (General Timing Variable Conventions): Variables whose names end in DTM are numeric datetimes.
43	1.1	ALL	A numeric variable with a suffix of DTM does not have a datetime format	Error	ADaMIG v1.1	3.1.2	1; 3	ADaMIG v1.1, Section 3.1.2, Item 1: Numeric dates, times, and datetimes should be formatted so as to be human-readable with no loss of precision. ADaMIG v1.1, Section 3.1.2, Item 3: Variables whose names end in DTM are numeric datetimes.
44	1.0	ALL	A variable with a suffix of TM and a variable with a suffix of DTM with the same root name have different time values	Error	ADaMIG v1.0	3	5 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 5 (General Timing Variable Conventions): If a *DTM and associated *TM variable exist, then the *TM variable must match the time part of the *DTM variable. If a *DTM and associated *DT variable

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								exist, then the *DT variable must match the date part of the *DTM variable.
44	1.1	ALL	A variable with a suffix of TM and a variable with a suffix of DTM with the same root name have different time values	Error	ADaMIG v1.1	3.1.2	5	ADaMIG v1.1, Section 3.1.2, Item 5: If a *DTM and associated *TM variable exist, then the *TM value must match the time part of the *DTM value when the *DTM variable is populated. If a *DTM and associated *DT variable exist, then the *DT value must match the date part of the *DTM value when the *DTM variable is populated.
45	1.0	ALL	A variable with a suffix of DT and a variable with a suffix of DTM with the same root name have different date values	Error	ADaMIG v1.0	3	5 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 5 (General Timing Variable Conventions): If a *DTM and associated *TM variable exist, then the *TM variable must match the time part of the *DTM variable. If a *DTM and associated *DT variable exist, then the *DT variable must match the date part of the *DTM variable.
45	1.1	ALL	A variable with a suffix of DT and a variable with a suffix of DTM with the same root name have different date values	Error	ADaMIG v1.1	3.1.2	5	ADaMIG v1.1, Section 3.1.2, Item 5: If a *DTM and associated *TM variable exist, then the *TM value must match the time part of the *DTM value when the *DTM variable is populated. If a *DTM and associated *DT variable exist, then the *DT value must match the date part of the *DTM value when the *DTM variable is populated.
46	1.0	ALL	A variable with a suffix of DY has a value of 0	Error	ADaMIG v1.0	3	8 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 8 (General Timing Variable Conventions): Variables whose names end in DY are relative day variables. In ADaM as in the SDTM, there is no Day 0. If there is a need to create a relative day variable that includes Day 0, then its name must not end in DY. ADaM relative day variables

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								need not be anchored by SDTM RFSTDTC. When SDTM.RFSTDTC is not the anchor date then the anchor date used must be stored in an ADaM dataset.
46	1.1	ALL	A variable with a suffix of DY has a value of 0	Error	ADaMIG v1.1	3.1.2	8	ADaMIG v1.1, Section 3.1.2, Item 8: Variables whose names end in DY are relative day variables. In ADaM as in the SDTM, there is no Day 0. If there is a need to create a relative day variable that includes Day 0, then its name must not end in DY.
47	1.0	ADSL	SITEID is not present within ADSL	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: SITEID has Core=Req.
47	1.1	ADSL	SITEID is not present within ADSL	Error	ADaMIG v1.1	3.2	Table 3.2.1	ADaMIG v1.1, Section 3.2, Table 3.2.1: SITEID has Core=Req.
48	1.0	ADSL	A variable with a suffix of FL is not present in ADSL	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Per the CDISC Notes for Population Indicators, a minimum of 1 subject-level population flag variable is required for every clinical trial.
48	1.1	ADSL	A variable with a suffix of FL is not present in ADSL	Error	ADaMIG v1.1	3.2	Table 3.2.3	ADaMIG v1.1, Section 3.2, Table 3.2.3: Per the CDISC Notes for ADSL Population Indicator Variables, a minimum of 1 subject-level population flag variable is required in ADSL.
49	1.0	ADSL	AGE is not present within ADSL	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: AGE has Core=Req.
49	1.1	ADSL	AGE is not present within ADSL	Error	ADaMIG v1.1	3.2	Table 3.2.2	ADaMIG v1.1, Section 3.2, Table 3.2.2: AGE has Core=Req.
50	1.0	ADSL	AGEU is not present within ADSL	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: AGEU has Core=Req.
50	1.1	ADSL	AGEU is not present within ADSL	Error	ADaMIG v1.1	3.2	Table 3.2.2	ADaMIG v1.1, Section 3.2, Table 3.2.2: AGEU has Core=Req.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
51	1.0	ADSL	SEX is not present within ADSL	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: SEX has Core=Req.
51	1.1	ADSL	SEX is not present within ADSL	Error	ADaMIG v1.1	3.2	Table 3.2.2	ADaMIG v1.1, Section 3.2, Table 3.2.2: SEX has Core=Req.
52	1.0	ADSL	RACE is not present within ADSL	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: RACE has Core=Req.
52	1.1	ADSL	RACE is not present within ADSL	Error	ADaMIG v1.1	3.2	Table 3.2.2	ADaMIG v1.1, Section 3.2, Table 3.2.2: RACE has Core=Req.
53	1.0	ALL:SDTM	The values of USUBJID are not present in SDTM.DM	Error	ADaMIG v1.0	3	4 (General Variable Naming Conventions)	ADaMIG v1.0, Section 3, Item 4 (General Variable Naming Conventions): 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. ADaM adheres to a principle of harmonization known as "same name, same meaning, same values."
53	1.1	ALL:SDTM	The values of USUBJID are not present in SDTM.DM	Error	ADaMIG v1.1	3.1.1	3	ADaMIG v1.1, Section 3.1.1, Item 3: Any variable in an ADaM dataset 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. ADaM adheres to a principle of harmonization known as "same name, same meaning, same values."
54	1.0	ADSL	Within ADSL there is more than 1 record for a unique value of USUBJID	Error	ADaMIG v1.0	1.3; 2.3.1; 3.1		ADaMIG v1.0, Section 1.3: The ADSL dataset contains 1 record per subject. ADaMIG v1.0, Section 2.3.1: ADSL contains 1 record per subject, regardless of the type of clinical trial design. ADaMIG v1.0, Section 3.1: The structure of ADSL is 1 record per subject,

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								regardless of the type of clinical trial design.
54	1.1	ADSL	Within ADSL there is more than 1 record for a unique value of USUBJID	Error	ADaMIG v1.1	1.3; 2.3.1; 3.2		ADaMIG v1.1, Section 1.3: The ADSL dataset contains 1 record per subject. ADaMIG v1.1, Section 2.3.1: ADSL contains 1 record per subject, regardless of the type of clinical trial design. ADaMIG v1.1, Section 3.2: The structure of ADSL is 1 record per subject, regardless of the type of clinical trial design.
55	1.0	ADSL	SUBJID is not present within ADSL	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: SUBJID has Core=Req.
55	1.1	ADSL	SUBJID is not present within ADSL	Error	ADaMIG v1.1	3.2	Table 3.2.2	ADaMIG v1.1, Section 3.2, Table 3.2.2: SUBJID has Core=Req.
58	1.0	ALL	A variable with a suffix of DT is not a numeric variable	Error	ADaMIG v1.0	3	2 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 2 (General Timing Variable Conventions): Variables whose names end in DT are numeric dates.
58	1.1	ALL	A variable with a suffix of DT is not a numeric variable	Error	ADaMIG v1.1	3.1.2	2	ADaMIG v1.1, Section 3.1.2, Item 2: Variables whose names end in DT are numeric dates.
59	1.0	ALL	A variable with a suffix of TM is not a numeric variable	Error	ADaMIG v1.0	3	4 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 4 (General Timing Variable Conventions): Variables whose names end in TM are numeric times.
59	1.1	ALL	A variable with a suffix of TM is not a numeric variable excluding SDTM variables with a suffix of ELTM	Error	ADaMIG v1.1	3.1.2	4	ADaMIG v1.1, Section 3.1.2, Item 4: Variables whose names end in TM are numeric times.
60	1.0	ALL	A variable with a suffix of DTM is not a numeric variable	Error	ADaMIG v1.0	3	3 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 3 (General Timing Variable Conventions):

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								Variables whose names end in DTM are numeric datetimes.
60	1.1	ALL	A variable with a suffix of DTM is not a numeric variable	Error	ADaMIG v1.1	3.1.2	3	ADaMIG v1.1, Section 3.1.2, Item 3: Variables whose names end in DTM are numeric datetimes.
61	1.0	ADSL:SDTM	SDTM.EX is present and neither TRTSDT or TRTSDTM are present	Warning	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRTSDT and/or TRTSDTM are required if there is an investigational product.
61	1.1	ADSL:SDTM	SDTM.EX is present and neither TRTSDT or TRTSDTM are present	Warning	ADaMIG v1.1	3.2	Table 3.2.6	ADaMIG v1.1, Section 3.2, Table 3.2.6: TRTSDT and/or TRTSDTM are required if there is an investigational product.
64	1.0	ADSL	TRTxxAN is present and TRTxxA is not present	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRTxxA
64	1.1	ADSL	TRTxxAN is present and TRTxxA is not present	Error	ADaMIG v1.1	3.1.1	6	ADaMIG v1.1, Section 3.1.1, Item 6: the secondary variable of the variable pair cannot be present in the dataset unless the primary variable is also present.
66	1.0	ADSL	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	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRxxPGy
66	1.1	ADSL	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	Error	ADaMIG v1.1	3.1.1	7	ADaMIG v1.1, Section 3.1.1, Item 7: The secondary variable of the variable pair cannot be present in the dataset unless the primary variable is also present
70	1.0	ADSL	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	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRxxAGy
70	1.1	ADSL	A variable with a prefix of TR, containing AG with a suffix of	Error	ADaMIG v1.1	3.1.1	7	ADaMIG v1.1, Section 3.1.1, Item 7: the secondary variable of the variable pair

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			N is present and a variable with the same root without a suffix of N is not present					cannot be present in the dataset unless the primary variable is also present
71	1.0	ADSL	ARM is not present within ADSL	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: ARM has Core=Req.
71	1.1	ADSL	ARM is not present within ADSL	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: ARM has Core=Req.
72	1.0	ADSL	ADSL does not contain TRT01P	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: At least TRT01P is required.
72	1.1	ADSL	ADSL does not contain TRT01P	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: At least TRT01P is required
75	1.0	ADSL	TRTxxPN is present and TRTxxP is not present	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRTxxP
75	1.1	ADSL	TRTxxPN is present and TRTxxP is not present	Error	ADaMIG v1.1	3.1.1	7	ADaMIG v1.1, Section 3.1.1, Item 7: The secondary variable of the variable pair cannot be present in the dataset unless the primary variable is also present
76	1.0	ADSL	There is more than 1 value of TRTxxPN for a given value of TRTxxP	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRTxxP
76	1.1	ADSL	There is more than 1 value of TRTxxPN for a given value of TRTxxP, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: One-to-one mapping to TRTxxP within a study
77	1.0	ADSL	There is more than 1 value of TRTxxP for a given value of TRTxxPN	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRTxxP
77	1.1	ADSL	There is more than 1 value of TRTxxP for a given value of TRTxxPN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: One-to-one mapping to TRTxxP within a study

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78	1.0	ADSL	At least 1 TRTxxP is present where xx is greater than 01 and (TRTxxP is present and TRxxSDT is not present)	Warning	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRxxSDT and/or TRxxSDTM is required in trial designs where multiple treatments are given to the same subject, such as a crossover design.
78	1.1	ADSL	At least 1 TRTxxP is present where xx is greater than 01 and (TRTxxP is present and TRxxSDT is not present)	Warning	ADaMIG v1.1	3.2	Table 3.2.6	ADaMIG v1.1, Section 3.2, Table 3.2.6: TRxxSDT and/or TRxxSDTM are only required in trial designs where multiple treatments are given to the same subject, such as a crossover design, but are permissible for other trial designs.
79	1.0	ADSL	At least 1 TRTxxP is present where xx is greater than 01 and (TRTxxP is present and TRxxEDT is not present)	Warning	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRxxEDT and/or TRxxEDTM are required in trial designs where multiple treatments are given to the same subject, such as a crossover design.
79	1.1	ADSL	At least 1 TRTxxP is present where xx is greater than 01 and (TRTxxP is present and TRxxEDT is not present)	Warning	ADaMIG v1.1	3.2	Table 3.2.6	ADaMIG v1.1, Section 3.2, Table 3.2.6: TRxxEDT and/or TRxxEDTM are only required in trial designs where multiple treatments are given to the same subject, such as a crossover design, but are permissible for other trial designs.
80	1.0	ADSL	TRTxxA is present and TRTxxP is not present	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: CDISC Notes for TRTxxP state: "At least TRT01P is required."
80	1.1	ADSL	TRTxxA is present and TRTxxP is not present	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: CDISC Notes for TRTxxP state: "At least TRT01P is required."
81	1.0	ADSL	TRTxxP is present and xx is greater than 01 and TRT{xx-1}P is not present	Warning	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: CDISC Notes for TRTxxP state: "At least TRT01P is required." The ADaM Team acknowledges that this cited text does not adequately support the creation of a conformance rule; however,

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								this may be clarified in a future version of the ADaMIG.
81	1.1	ADSL	TRTxxP is present and xx is greater than 01 and TRT{xx-1}P is not present	Warning	ADaMIG v1.1	3.1.1; 3.2	2e; Table 3.2.4	ADaMIG v1.1, Section 3.1.1, Item 2e: If an indexed variable is included in a dataset, there is no requirement that the preceding variable(s) in the sequence be included. For example, a dataset might include ANL02FL but not ANL01FL. ADaMIG v1.1, Section 3.2, Table 3.2.4: CDISC Notes for TRTxxP state: "At least TRT01P is required." The ADaM Team acknowledges that this cited text does not adequately support the creation of a conformance rule; however, this may be clarified in a future version of the ADaMIG.
84	1.0	ADSL	TRTEDT is not equal to the maximum value of all TRxxEDT variables	Note	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Date of last exposure to treatment for a subject in a study
84	1.1	ADSL	TRTEDT is not equal to the maximum value of all TRxxEDT variables	Note	ADaMIG v1.1	3.2	Table 3.2.6	ADaMIG v1.1, Section 3.2, Table 3.2.6: TRTEDT - Date of last exposure to treatment for a subject in a study
85	1.0	ADSL:ALL	A variable is present with the same name as a variable present in ADSL but the variables do not have identical labels	Error	ADaMIG v1.0	3.2		ADaMIG v1.0, Section 3.2: See Section 3.1 for ADSL variables, any of which may be copied to basic structure datasets to support traceability or enable analysis.
85	1.1	ADSL:ALL	A variable is present with the same name as a variable present in ADSL but the variables do not have identical labels	Error	ADaMIG v1.1	3.3		ADaMIG v1.1, Section 3.3: See Section 3.2 for ADSL variables, any of which may be copied to BDS datasets to support traceability or enable analysis.

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86	1.0	ADSL:ALL	A variable is present with the same name as a variable present in ADSL but the variables do not have identical formats	Error	ADaMIG v1.0	3.2		ADaMIG v1.0, Section 3.2: See Section 3.1 for ADSL variables, any of which may be copied to basic structure datasets to support traceability or enable analysis.
86	1.1	ADSL:ALL	A variable is present with the same name as a variable present in ADSL but the variables do not have identical formats	Error	ADaMIG v1.1	3.3		ADaMIG v1.1, Section 3.3: See Section 3.2 for ADSL variables, any of which may be copied to BDS datasets to support traceability or enable analysis.
88	1.0	ALL	STUDYID is not present	Error	ADaMIG v1.0	3.1; 3.2	Table 3.1.1; Table 3.2.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: STUDYID has Core=Req. ADaMIG v1.0, Section 3.2, Table 3.2.1.1: STUDYID has Core=Req.
88	1.1	ALL	STUDYID is not present	Error	ADaMIG v1.1	3.2; 3.3	Table 3.2.1; Table 3.3.1.1	ADaMIG v1.1, Section 3.2, Table 3.2.1: STUDYID has Core=Req. ADaMIG v1.1, Section 3.3, Table 3.3.1.1: STUDYID has Core=Req.
89	1.0	ALL	USUBJID is not present	Error	ADaMIG v1.0	3.1; 3.2	Table 3.1.1; Table 3.2.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: USUBJID has Core=Req. ADaMIG v1.0, Section 3.2, Table 3.2.1.1: USUBJID has Core=Req.
89	1.1	ALL	USUBJID is not present	Error	ADaMIG v1.1	3.2; 3.3	Table 3.2.1; Table 3.3.1.1	ADaMIG v1.1, Section 3.2, Table 3.2.1: USUBJID has Core=Req. ADaMIG v1.1, Section 3.3, Table 3.3.1.1: USUBJID has Core=Req.
90	1.0	BDS	TRTP is not present	Error	ADaMIG v1.0	3.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2, Table 3.2.2.1: TRTP has Core=Req.
90.01	1.1	ALL	None of the subject-level or record-level treatment variables defined in the IG is present	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: At least 1 treatment variable is required in a BDS dataset. This

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								requirement is satisfied by any of the subject-level or record-level treatment variables (e.g., TRTxxP, TRTP).is allowed to use any treatment variable in analysis of BDS. Any subject-level treatment variable may be copied into the BDS dataset from ADSL.
91.01	1.1	ADSL:BDS, ADSL:OCCDS	A non-missing value of TRTP is not equal to at least 1 value of the character planned treatment variables in ADSL defined in the IG	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: CDISC Notes for TRTP state that although "there is no requirement that TRTP will correspond to the TRTxxP as defined by the record's value of APERIOD, if populated, TRTP must match at least 1 value of the character planned treatment variables in ADSL (e.g., TRTxxP, TRTSEQP, TRxxPGy)."
92	1.0	BDS	There is more than 1 value of TRTPN for a given value of TRTP	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: The numeric code for TRTP. One-to-one map to TRTP.
92	1.1	BDS	There is more than 1 value of TRTPN for a given value of TRTP, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTPN has the numeric code for TRTP. One-to-one mapping within a study to TRTP.
93	1.0	BDS	There is more than 1 value of TRTP for a given value of TRTPN	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: The numeric code for TRTP. One-to-one map to TRTP.
93	1.1	BDS	There is more than 1 value of TRTP for a given value of TRTPN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTPN has the numeric code for TRTP. One-to-one mapping within a study to TRTP.
95	1.0	BDS	There is more than 1 value of TRTAN for a given value of TRTA	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: The numeric code for TRTA. One-to-one map to TRTA.

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95	1.1	BDS	There is more than 1 value of TRTAN for a given value of TRTA, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTAN has the numeric code for TRTA. One-to-one mapping within a study to TRTA.
96	1.0	BDS	There is more than 1 value of TRTA for a given value of TRTAN	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: The numeric code for TRTA. One-to-one map to TRTA.
96	1.1	BDS	There is more than 1 value of TRTA for a given value of TRTAN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTAN has the numeric code for TRTA. One-to-one mapping within a study to TRTA.
97	1.0	BDS	TRTPGyN is present and TRTPGy is not present	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: The numeric code for TRTPGy.
97	1.1	BDS	TRTPGyN is present and TRTPGy is not present	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTPGyN has the numeric code for TRTPGy.
98	1.0	BDS	On a given record, 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	Note	ADaMIG v1.0			There is no guidance in the ADaMIG to support this rule.
98	1.1	BDS	On a given record, 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	Note	ADaMIG v1.1			There is no guidance in the ADaMIG to support this rule.
99	1.0	BDS	On a given record, a variable with a suffix of STDY has a value greater than a value of a variable with the same root and	Note	ADaMIG v1.0			There is no guidance in the ADaMIG to support this rule.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			a suffix of ENDY, and both variables are populated					
99	1.1	BDS	On a given record, 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	Note	ADaMIG v1.1			There is no guidance in the ADaMIG to support this rule.
102	1.0	ADSL:BDS, ADSL:OCCDS	For every unique xx value of APERIOD, there is not an ADSL variable TRTxxP	Error	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: The numeric value characterizing the period to which the record belongs. The value of APERIOD must be consistent with the xx value in TRTxxP, TRTxxA, and all variables whose names begin with TRxx and APxx.
102	1.1	ADSL:BDS, ADSL:OCCDS	For every unique xx value of APERIOD, there is not an ADSL variable TRTxxP	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.2	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.2: APERIOD has APERIOD is a record-level timing variable that represents the analysis period within the study associated with the record for analysis purposes. The value of APERIOD (if populated) must be one of the xx values found in the ADSL TRTxxP variables.
103	1.0	ADSL:BDS	For every unique xx value of APERIOD in BDS datasets, there is not an ADSL variable TRxxSDT	Note	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: The numeric value characterizing the period to which the record belongs. The value of APERIOD must be consistent with the xx value in TRTxxP, TRTxxA, and all variables whose names begin with TRxx and APxx.
103	1.1	ADSL:BDS	For every unique xx value of APERIOD in BDS datasets, there is not an ADSL variable TRxxSDT	Note	ADaMIG v1.1	3.3.3	Table 3.3.3.2	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.2: APERIOD has APERIOD is a record-level timing variable that represents the analysis period within the

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								study associated with the record for analysis purposes. The value of APERIOD (if populated) must be one of the xx values found in the ADSL TRTxxP variables.
104	1.0	ADSL:BDS	For every unique xx value of APERIOD in BDS datasets, there is not an ADSL variable TRxxEDT	Note	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: The numeric value characterizing the period to which the record belongs. The value of APERIOD must be consistent with the xx value in TRTxxP, TRTxxA, and all variables whose names begin with TRxx and APxx.
104	1.1	ADSL:BDS	For every unique xx value of APERIOD in BDS datasets, there is not an ADSL variable TRxxEDT	Note	ADaMIG v1.1	3.3.3	Table 3.3.3.2	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.2: APERIOD has APERIOD is a record-level timing variable that represents the analysis period within the study associated with the record for analysis purposes. The value of APERIOD (if populated) must be one of the xx values found in the ADSL TRTxxP variables.
105	1.0	BDS, OCCDS	There is more than 1 value of APERIODC for a given value of APERIOD	Error	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: Text characterizing to which period the record belongs. One-to-one map to APERIOD.
105	1.1	BDS, OCCDS	There is more than 1 value of APERIODC for a given value of APERIOD, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.2	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.2: APERIODC has Text characterizing to which analysis period the record belongs. One-to-one mapping within a dataset to APERIOD.
106	1.0	BDS, OCCDS	There is more than 1 value of APERIOD for a given value of APERIODC	Error	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: Text characterizing to which period the record belongs. One-to-one map to APERIOD.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
106	1.1	BDS, OCCDS	There is more than 1 value of APERIOD for a given value of APERIODC, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.2	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.2: APERIODC has Text characterizing to which analysis period the record belongs. One-to-one mapping within a dataset to APERIOD.
109	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of AVISITN for a given value of AVISIT	Error	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: Within a parameter, there is a one-to-one mapping between AVISITN and AVISIT so that AVISITN has the same value for each distinct AVISIT.
109	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of AVISITN for a given value of AVISIT, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.2	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.2: Within a parameter, there is a one-to-one mapping between AVISITN and AVISIT so that AVISITN has the same value for each distinct AVISIT.
110	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of AVISIT for a given value of AVISITN	Error	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: Within a parameter, there is a one-to-one mapping between AVISITN and AVISIT so that AVISITN has the same value for each distinct AVISIT.
110	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of AVISIT for a given value of AVISITN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.2	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.2: Within a parameter, there is a one-to-one mapping between AVISITN and AVISIT so that AVISITN has the same value for each distinct AVISIT.
111	1.0	BDS	ARELTM is present and ARELTMU is not present	Error	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: 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.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
111	1.1	BDS	ARELTM is present and ARELTMU is not present	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.1	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.1: 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.
112	1.0	BDS	ARELTM is populated and ARELTMU is not populated	Note	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: 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.
112	1.1	BDS	ARELTM is populated and ARELTMU is not populated	Note	ADaMIG v1.1	3.3.3	Table 3.3.3.1	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.1: 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.
113	1.0	BDS	ARELTMU is present and ARELTM is not present	Error	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: The units of ARELTM. For example, "HOURS" or "MINUTES" ARELTMU is required if ARELTM is present.
113	1.1	BDS	ARELTMU is present and ARELTM is not present	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.1	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.1: The units of ARELTM. For example, "HOURS" or "MINUTES" ARELTMU is required if ARELTM is present.
117	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of ATPT for a given value of ATPTN	Error	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: Within the same parameter, there is a one-to-one mapping between ATPT and ATPTN.
117	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of ATPT for a given	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.1	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.1: Within the same parameter, there

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			value of ATPTN, considering only those rows on which both variables are populated					is a one-to-one mapping between ATPT and ATPTN.
118	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of ATPTN for a given value of ATPT	Error	ADaMIG v1.0	3.2.3	Table 3.2.3.1	ADaMIG v1.0, Section 3.2.3, Table 3.2.3.1: Within the same parameter, there is a one-to-one mapping between ATPT and ATPTN.
118	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of ATPTN for a given value of ATPT, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.1	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.1: Within the same parameter, there is a one-to-one mapping between ATPT and ATPTN.
121	1.0	ALL	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	Note	ADaMIG v1.0	3	9 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 9 (General Timing Variable Conventions): Names of timing start variables end with an S followed by the 2 characters indicating the type of timing (e.g., SDT, STM), unless otherwise specified elsewhere in ADaMIG Section 3. The ADaM Team acknowledges that this cited text does not adequately support the creation of a conformance rule. See definition of Message Type="Note" in Section 3, Description of ADaM Conformance Rules Table.
121	1.1	ALL	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	Note	ADaMIG v1.1	3.1.2	6	ADaMIG v1.1, Section 3.1.2, Item 6: Names of timing start variables end with an S followed by the characters indicating the type of timing (i.e., SDT, STM, SDTM), unless otherwise specified elsewhere in ADaMIG Section 3. The ADaM Team acknowledges that this cited text does not adequately support the

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								creation of a conformance rule. See definition of Message Type="Note" in Section 3, Description of ADaM Conformance Rules Table.
122	1.0	ALL	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	Note	ADaMIG v1.0	3	10 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 10 (General Timing Variable Conventions): Names of timing end variables end with an E followed by the 2 characters indicating the type of timing (e.g., EDT, ETM), unless otherwise specified elsewhere in ADaMIG Section 3. The ADaM Team acknowledges that this cited text does not adequately support the creation of a conformance rule. See definition of Message Type="Note" in Section 3, Description of ADaM Conformance Rules Table.
122	1.1	ALL	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	Note	ADaMIG v1.1	3.1.2	7	ADaMIG v1.1, Section 3.1.2, Item 7: Names of timing end variables end with an E followed by the characters indicating the type of timing (i.e., EDT, ETM, EDTM), unless otherwise specified elsewhere in ADaMIG Section 3. The ADaM Team acknowledges that this cited text does not adequately support the creation of a conformance rule. See definition of Message Type="Note" in Section 3, Description of ADaM Conformance Rules Table.
123	1.0	BDS	There is more than 1 value of PARAMTYP for a given value of PARAMCD	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: Indicator of whether the parameter is derived as a function of 1 or more other parameters.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
123	1.1	BDS	There is more than 1 value of PARAMTYP for a given value of PARAMCD	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Indicator of whether the parameter is derived as a function of 1 or more other parameters.
124	1.0	BDS	There is more than 1 value of PARCATy for a given value of PARAMCD.	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: A categorization of PARAM. For example, value of PARCAT1 might group the parameters having to do with a particular questionnaire, lab specimen type, or area of investigation.
124	1.1	BDS	There is more than 1 value of PARCATy for a given value of PARAMCD.	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Note that PARCATy is not a qualifier for PARAM. PARAM to PARCATy is a many-to-one mapping; any given PARAM may be associated with at most 1 level of PARCATy (e.g., 1 level of PARCAT1 and 1 level of PARCAT2).
125	1.0	BDS	There is more than 1 value of PARCATy for a given value of PARCATyN	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: There should be a one-to-one relationship between PARCATy and PARCATyN.
125	1.1	BDS	There is more than 1 value of PARCATy for a given value of PARCATyN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: There must be a one-to-one relationship within a dataset between PARCATy and PARCATyN.
126	1.0	BDS	There is more than 1 value of PARCATyN for a given value of PARCATy	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: There should be a one-to-one relationship between PARCATy and PARCATyN.
126	1.1	BDS	There is more than 1 value of PARCATyN for a given value of PARCATy, considering only	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: There must be a one-to-one relationship within a dataset between PARCATy and PARCATyN.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			those rows on which both variables are populated					
127	1.0	BDS	Within a given value of PARAMCD for a subject, BASE is populated and there is not at least 1 record with ABLFL equal to Y	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: 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.
127	1.1	BDS	Within a given value of PARAMCD for a subject, BASE is populated and there is not at least 1 record with ABLFL equal to Y	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: 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.
128	1.0	BDS	Within a given value of PARAMCD for a subject, BASEC is populated and there is not at least 1 record with ABLFL equal to Y	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: Baseline value of AVALC
128	1.1	BDS	Within a given value of PARAMCD for a subject, BASEC is populated and there is not at least 1 record with ABLFL equal to Y	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: BASEC contains the value of AVALC copied from a record within the parameter on which ABLFL="Y".
129	1.0	BDS	Within a given value of PARAMCD for a subject, there is more than 1 value of BASE for a given value of BASEC	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: There must be a one-to-one map between BASE and BASEC within a given PARAM if both are populated.
129	1.1	BDS	Within a given value of PARAMCD for a subject, there is more than 1 value of BASE for a given value of BASEC, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Within a given parameter, if there exists a row on which both BASEC and BASE are populated, then there must be a one-to-one mapping between BASEC and BASE on all rows on which both variables are populated.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
130	1.0	BDS	Within a given value of PARAMCD for a subject, there is more than 1 value of BASEC for a given value of BASE	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: There must be a one-to-one map between BASE and BASEC within a given PARAM if both are populated.
130	1.1	BDS	Within a given value of PARAMCD for a subject, there is more than 1 value of BASEC for a given value of BASE, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Within a given parameter, if there exists a row on which both BASEC and BASE are populated, then there must be a one-to-one mapping between BASEC and BASE on all rows on which both variables are populated.
131	1.0	BDS	Within a given value of PARAMCD, BASETYPE is populated for at least 1 record and is not populated for at least 1 record	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: Required when there are multiple ways that baseline is defined. If used for a given PARAM, should be populated for all records of that PARAM.
131	1.1	BDS	Within a dataset, BASETYPE is populated for at least 1 record and is not populated for at least 1 record	Error	ADaMIG v1.1	3.3.4; 4.2.1	Table 3.3.4.1; 6	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: If used for any PARAM within a dataset, should be non-null for all records of that dataset. ADaMIG v1.1, Section 4.2.1, Item 6: Whenever there is more than 1 definition of baseline, the BASETYPE column is required. BASETYPE identifies the definition of baseline that corresponds to the value of BASE in each row.
132	1.0	BDS	R2BASE is not equal to AVAL divided by BASE	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: AVAL/BASE
132	1.1	BDS	R2BASE is not equal to AVAL divided by BASE	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Ratio to the baseline value. Equal to AVAL/BASE.
133	1.0	BDS	R2AyLO is not equal to AVAL divided by AyLO	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: AVAL/AyLO

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
133	1.1	BDS	R2AyLO is not equal to AVAL divided by AyLO	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Ratio to the lower limit of the analysis range y. Equal to AVAL/AyLO.
134	1.0	BDS	R2AyHI is not equal to AVAL divided by AyHI	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: AVAL/AyHI
134	1.1	BDS	R2AyHI is not equal to AVAL divided by AyHI	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Ratio to the upper limit of the analysis range y. Equal to AVAL/AyHI.
135	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of SHIFTy for a given value of SHIFTyN	Warning	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: SHIFTN has a one-to-one mapping relationship with SHIFT. The ADaM Team acknowledges that this cited text does not adequately support the creation of a conformance rule. The intent of the ADaM Team was clarified in ADaMIG v1.0, Section 3.2.4; ADaMIG v.1.1, Table 3.2.4.1.
135	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of SHIFTy for a given value of SHIFTyN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: SHIFTyN maps one-to-one to SHIFTy within a parameter.
136	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of SHIFTyN for a given value of SHIFTy	Warning	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: SHIFTN has a one-to-one mapping relationship with SHIFT. The ADaM Team acknowledges that this cited text does not adequately support the creation of a conformance rule. The intent of the ADaM Team was clarified in ADaMIG v1.0, Section 3.2.4; ADaMIG v.1.1 Table 3.2.4.1.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
136	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of SHIFTyN for a given value of SHIFTy, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: SHIFTyN maps one-to-one to SHIFTy within a parameter.
137	1.0	BDS	CRITyFL is populated and CRITy is not populated	Error	ADaMIG v1.0	3.2.6	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.4.1: Character indicator of whether the criterion defined in CRITy was met.
137	1.1	BDS	CRITyFL is populated and CRITy is not populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: Required if CRITyFL exists. In some cases, the presence of the text string indicates that the criterion is satisfied on this record and CRITyFL is set to Y, whereas a null value indicates that the criterion is not satisfied or is not evaluable and is accompanied by a null value in CRITyFL. In other cases, the text string identifies the criterion being evaluated and is populated on every row for the parameter, but whether or not the criterion is satisfied is indicated by the value of the variable CRITyFL. ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: Character flag variable indicating whether the criterion defined in CRITy was met by the data on the record.
141	1.0	BDS	There is more than 1 value of PARAM for a given value of PARAMCD	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: There must be a one-to-one mapping with PARAM.
141	1.1	BDS	There is more than 1 value of PARAM for a given value of PARAMCD, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: There must be a one-to-one mapping to PARAM within a dataset.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
142	1.0	BDS	There is more than 1 value of PARAMCD for a given value of PARAM	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: There must be a one-to-one mapping with PARAM.
142	1.1	BDS	There is more than 1 value of PARAMCD for a given value of PARAM, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: There must be a one-to-one mapping to PARAM within a dataset.
143	1.0	BDS	PARAMCD has more than 8 characters in length	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: Values of PARAMCD should follow SAS Version 5 variable naming conventions (8 characters or fewer; starts with a letter; contains only letters and digits).
143	1.1	BDS	PARAMCD has more than 8 characters in length	Error	ADaMIG v1.1	3.1.1; 3.3.4	1; Table 3.3.4.1	ADaMIG v1.1, Section 3.1.1, Item 1: To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length. ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Values of PARAMCD should follow the SAS Version 5 transport file format and Oracle constraints as noted under General Variable Conventions in Section 3.1.1.
144	1.0	BDS	PARAMCD starts with a character other than a letter	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: Values of PARAMCD should

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								follow SAS Version 5 variable naming conventions (8 characters or fewer; starts with a letter; contains only letters and digits).
144	1.1	BDS	PARAMCD starts with a character other than a letter	Error	ADaMIG v1.1	3.1.1; 3.3.4	1; Table 3.3.4.1	ADaMIG v1.1, Section 3.1.1, Item 1: To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length. ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Values of PARAMCD should follow the SAS Version 5 transport file format and Oracle constraints as noted under General Variable Conventions in Section 3.1.1.
145	1.0	BDS	PARAMCD has characters that are not letters, digits, or underscores	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: Values of PARAMCD should follow SAS Version 5 variable naming conventions (8 characters or fewer; starts with a letter; contains only letters and digits).
145	1.1	BDS	PARAMCD has characters that are not letters, digits, or underscores	Error	ADaMIG v1.1	3.1.1; 3.3.4	1; Table 3.3.4.1	ADaMIG v1.1, Section 3.1.1, Item 1: To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in length; start with a letter (not

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								underscore); and be composed only of letters (A-Z), underscores (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length. ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Values of PARAMCD should follow the SAS Version 5 transport file format and Oracle constraints as noted under General Variable Conventions in Section 3.1.1.
146	1.0	BDS	Within a dataset, there is more than 1 value of PARAM for a given value of PARAMN	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: There must be a one-to-one mapping with PARAM.
146	1.1	BDS	Within a dataset, there is more than 1 value of PARAM for a given value of PARAMN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: There must be a one-to-one mapping to PARAM within a dataset.
147	1.0	BDS	Within a dataset, there is more than 1 value of PARAMN for a given value of PARAM	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: There must be a one-to-one mapping with PARAM.
147	1.1	BDS	Within a dataset, there is more than 1 value of PARAMN for a given value of PARAM, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: There must be a one-to-one mapping to PARAM within a dataset.
148	1.0	BDS	PARAMN is not an integer	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: PARAMN must be an integer.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
149	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of AVALC for a given value of AVAL	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: AVALC can be a character string mapping to AVAL, but if so there must be a one-to-one map between AVAL and AVALC within a given PARAM.
149	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of AVALC for a given value of AVAL, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: AVALC can be a character string mapping to AVAL, but if so there must be a one-to-one map between AVAL and AVALC within a given PARAM.
150	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of AVAL for a given value of AVALC	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: AVALC can be a character string mapping to AVAL, but if so there must be a one-to-one map between AVAL and AVALC within a given PARAM.
150	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of AVAL for a given value of AVALC, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: AVALC can be a character string mapping to AVAL, but if so there must be a one-to-one map between AVAL and AVALC within a given PARAM.
151	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of CRITy	Error	ADaMIG v1.0	4.7.1		ADaMIG v1.0, Section 4.7.1: The definition of CRITy can use any variable(s) located on the row and the definition must stay constant across all rows within the same value of PARAM.
151	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of CRITy	Error	ADaMIG v1.1	4.7.1		ADaMIG v1.1, Section 4.7.1: The definition of CRITy can use any variable(s) located on the row, and the definition must stay constant across all rows within the same value of PARAM.
152	1.0	BDS	BASETYPE is present, BASE is populated, and BASE is not equal to AVAL where ABLFL	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: If BASE is populated for a parameter, and BASE is non-null for a

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			is equal to Y for a given value of PARAMCD and BASETYPE for a subject					subject for that parameter, then there must be a record flagged by ABLFL for that subject and parameter.
152	1.1	BDS	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	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: 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.
154	1.0	BDS	Within a given PARAMCD and BASETYPE for a subject, more than 1 record has ABLFL equal to Y	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: Character indicator to identify the baseline record for each parameter, or if there is more than one baseline definition, for each parameter and baseline type (BASETYPE). See BASETYPE in Table 3.2.4.1. ABLFL is required if BASE is present in the dataset. A baseline record may be derived (e.g., it may be an average), in which case DTYPE must also be populated. 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.
154	1.1	BDS	Within a given PARAMCD and BASETYPE for a subject, more than 1 record has ABLFL equal to Y	Error	ADaMIG v1.1	3.3.8	Table 3.3.8.1	ADaMIG v1.1, Section 3.3.8, Table 3.3.8.1: Character indicator to identify the baseline record for each subject, parameter, and baseline type (BASETYPE) combination. See BASETYPE in Table 3.3.4.1. ABLFL is required if BASE is present in the dataset. A baseline record may be derived (e.g., it may be an average), in which case DTYPE must also be populated. If BASE is populated for a

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								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.
155	1.0	BDS	Within a given PARAMCD for a subject, more than 1 record has ABLFL equal to Y and BASETYPE is not present	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: Character indicator to identify the baseline record for each parameter, or if there is more than one baseline definition, for each parameter and baseline type (BASETYPE). See BASETYPE in Table 3.2.4.1. ABLFL is required if BASE is present in the dataset. A baseline record may be derived (e.g., it may be an average), in which case DTYPE must also be populated. 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.
155	1.1	BDS	Within a given PARAMCD for a subject, more than 1 record has ABLFL equal to Y and BASETYPE is not present	Error	ADaMIG v1.1	3.3.8	Table 3.3.8.1	ADaMIG v1.1, Section 3.3.8, Table 3.3.8.1: Character indicator to identify the baseline record for each subject, parameter, and baseline type (BASETYPE) combination. See BASETYPE in Table 3.3.4.1. ABLFL is required if BASE is present in the dataset. A baseline record may be derived (e.g., it may be an average), in which case DTYPE must also be populated. 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.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
156	1.0	BDS	A variable with a prefix of CRIT, a suffix of FL and containing a 1-digit number is present and a variable with the same root without a suffix of FL is not present	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: Character indicator of whether the criterion defined in CRITy was met. See also CRITy in Section 3.2.4. Required if CRITy exists.
156	1.1	BDS	A variable with a prefix of CRIT, a suffix of FL and containing a 1-digit number is present and a variable with the same root without a suffix of FL is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: Character flag variable indicating whether the criterion defined in CRITy was met by the data on the record. See CRITy for more information regarding how to use CRITy and CRITyFL to indicate whether a criterion is met. Required if CRITy exists.
157	1.0	BDS	A variable with a prefix of CRIT and a suffix of a 1-digit number is present and a variable with the same root with a suffix of FL is not present	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: Character indicator of whether the criterion defined in CRITy was met. See also CRITy in Section 3.2.4. Required if CRITy exists.
157	1.1	BDS	A variable with a prefix of CRIT and a suffix of a 1-digit number is present and a variable with the same root with a suffix of FL is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: Character flag variable indicating whether the criterion defined in CRITy was met by the data on the record. See CRITy for more information regarding how to use CRITy and CRITyFL to indicate whether a criterion is met. Required if CRITy exists.
159	1.0	BDS	AWTDIFF is populated and AWTARGET is not populated	Warning	ADaMIG v1.0	3.2.5	Table 3.2.5.2	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.2: Absolute difference between ADY or ARELTM and AWTARGET
159	1.1	BDS	AWTDIFF is populated and AWTARGET is not populated	Warning	ADaMIG v1.1	3.3.5	Table 3.3.5.2	ADaMIG v1.1, Section 3.3.5, Table 3.3.5.2: Absolute difference between ADY or ARELTM and AWTARGET

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
160	1.0	BDS	AWU is present and both AWLO and AWHI are not present	Note	ADaMIG v1.0	3.2.5	Table 3.2.5.2	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.2: Unit used for AWLO and AWHI
160	1.1	BDS	AWU is present and both AWLO and AWHI are not present	Note	ADaMIG v1.1	3.3.5	Table 3.3.5.2	ADaMIG v1.1, Section 3.3.5, Table 3.3.5.2: Unit used for AWLO and AWHI
163	1.0	BDS	BTOXGR is present and ATOXGR is not present	Error	ADaMIG v1.0	3.2.5	Table 3.2.5.4	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.4: ATOXGR of the baseline record identified by ABLFL
163	1.1	BDS	BTOXGR is present and ATOXGR is not present	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: ATOXGR of the baseline record identified by ABLFL
164	1.0	BDS	BTOXGR is present and ABLFL is not present	Error	ADaMIG v1.0	3.2.5	Table 3.2.5.4	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.4: ATOXGR of the baseline record identified by ABLFL
164	1.1	BDS	BTOXGR is present and ABLFL is not present	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: ATOXGR of the baseline record identified by ABLFL
165	1.0	BDS	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	Error	ADaMIG v1.0	3.2.5	Table 3.2.5.4	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.4: ATOXGR of the baseline record identified by ABLFL
165	1.1	BDS	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	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: ATOXGR of the baseline record identified by ABLFL
166	1.0	BDS	BNRIND is present and ANRIND is not present	Error	ADaMIG v1.0	3.2.5	Table 3.2.5.4	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.4: ANRIND of the baseline record identified by ABLFL

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
166	1.1	BDS	BNRIND is present and ANRIND is not present	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: ANRIND of the baseline record identified by ABLFL
167	1.0	BDS	BNRIND is present and ABLFL is not present	Error	ADaMIG v1.0	3.2.5	Table 3.2.5.4	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.4: ANRIND of the baseline record identified by ABLFL
167	1.1	BDS	BNRIND is present and ABLFL is not present	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: ANRIND of the baseline record identified by ABLFL
168	1.0	BDS	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	Error	ADaMIG v1.0	3.2.5	Table 3.2.5.4	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.4: ANRIND of the baseline record identified by ABLFL
168	1.1	BDS	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	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: ANRIND of the baseline record identified by ABLFL
169	1.0	BDS	The value of CNSR is not a positive integer or 0	Warning	ADaMIG v1.0	3.2.5	Table 3.2.5.3	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.3: It is strongly recommended to use 0 as an event indicator and positive integers as censoring indicators.
169	1.1	BDS	The value of CNSR is not a positive integer or 0	Warning	ADaMIG v1.1	3.3.6	Table 3.3.6.1	ADaMIG v1.1, Section 3.3.6, Table 3.3.6.1: It is strongly recommended to use 0 as an event indicator and positive integers as censoring indicators.
176	1.0	BDS	ABLFL is not equal to Y or null	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: Codelist/Controlled Terms: Y {Y,NULL}
176	1.1	BDS	ABLFL is not equal to Y or null	Error	ADaMIG v1.1	3.3.8	Table 3.3.8.1	ADaMIG v1.1, Section 3.3.8, Table 3.3.8.1: Codelist/Controlled Terms: Y {Y,NULL}

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
178	1.0	BDS, OCCDS	ANLzzFL is not equal to Y or null where zz is a -padded 2-digit integer [01-99]	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: Codelist/Controlled Terms: Y {Y,NULL}
178	1.1	BDS, OCCDS	ANLzzFL is not equal to Y or null where zz is a -padded 2-digit integer [01-99]	Error	ADaMIG v1.1	3.3.8	Table 3.3.8.1	ADaMIG v1.1, Section 3.3.8, Table 3.3.8.1: Codelist/Controlled Terms: Y {Y,NULL}
180	1.0	BDS:SDTM	SRCDOM has a value that is not an SDTM domain name or null	Note	ADaMIG v1.0	3.2.8	Table 3.2.8.1	ADaMIG v1.0, Section 3.2.8, Table 3.2.8.1: The 2-character identifier of the SDTM domain that relates to AVAL or AVALC
180.01	1.1	BDS:SDTM, BDS:ADaM	SRCDOM has a value that is not an SDTM domain name, ADaM dataset name, or null	Error	ADaMIG v1.1	3.3.9	Table 3.3.9.1	ADaMIG v1.1, Section 3.3.9, Table 3.3.9.1: The SDTM domain name or ADaM dataset name that relates to the analysis value (e.g., AVAL or AVALC in a BDS dataset). If the source data is a supplemental qualifier in SDTM, this variable will contain the value of RDOMAIN in SUPP-- or SUPPQUAL.
181	1.0	BDS	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	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: 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.
181	1.1	BDS	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	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: BASE contains the value of AVAL copied from a record within the parameter on which ABLFL="Y".
182	1.0	BDS	BASETYPE is not present, BTOXGR is populated, and BTOXGR is not equal to ATOXGR where ABLFL is	Error	ADaMIG v1.0	3.2.5	Table 3.2.5.4	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.4: ATOXGR of the baseline record identified by ABLFL

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			equal to Y for a given value of PARAMCD for a subject					
182	1.1	BDS	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	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: ATOXGR of the baseline record identified by ABLFL
183	1.0	BDS	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	Error	ADaMIG v1.0	3.2.5	Table 3.2.5.4	ADaMIG v1.0, Section 3.2.5, Table 3.2.5.4: ANRIND of the baseline record identified by ABLFL
183	1.1	BDS	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	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: ANRIND of the baseline record identified by ABLFL
194	1.0	BDS	PARAM is not present	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: PARAM has Core=Req.
194	1.1	BDS	PARAM is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: PARAM has Core=Req.
195	1.0	BDS	PARAMCD is not present	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: PARAMCD has Core=Req.
195	1.1	BDS	PARAMCD is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: PARAMCD has Core=Req.
196	1.0	BDS	PARAM is not populated	Error	ADaMIG v1.0	3.2		ADaMIG v1.0, Section 3.2: The ADaM document introduces the ADaM Basic Data Structure. A BDS dataset contains 1 or more records per subject, per analysis parameter, and per analysis timepoint. Analysis timepoint is conditionally required, depending on the analysis. In

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								situations where there is no analysis timepoint, the structure is 1 or more records per subject per analysis parameter.
196	1.1	BDS	PARAM is not populated	Error	ADaMIG v1.1	3.3		ADaMIG v1.1, Section 3.3: The ADaM model document introduces the ADaM Basic Data Structure. A BDS dataset contains 1 or more records per subject, per analysis parameter, and per analysis timepoint. Analysis timepoint is conditionally required, depending on the analysis. In situations where there is no analysis timepoint, the structure is 1 or more records per subject per analysis parameter.
197	1.0	BDS	PARAMCD is not populated	Error	ADaMIG v1.0	3.2		ADaMIG v1.0, Section 3.2: The ADaM document introduces the ADaM Basic Data Structure. A BDS dataset contains 1 or more records per subject, per analysis parameter, and per analysis timepoint. Analysis timepoint is conditionally required, depending on the analysis. In situations where there is no analysis timepoint, the structure is 1 or more records per subject per analysis parameter.
197	1.1	BDS	PARAMCD is not populated	Error	ADaMIG v1.1	3.3		ADaMIG v1.1, Section 3.3: The ADaM model document introduces the ADaM Basic Data Structure. A BDS dataset contains 1 or more records per subject, per analysis parameter, and per analysis timepoint. Analysis timepoint is conditionally required, depending on the analysis. In situations where there is no analysis timepoint, the structure is 1 or

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								more records per subject per analysis parameter.
198	1.0	BDS	AVAL is not present and AVALC is not present	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: AVAL and AVALC have Core=Req (at least 1).
198	1.1	BDS	AVAL is not present and AVALC is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Either AVAL or AVALC must be present in the dataset.
199	1.0	ALL:SDTM	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	Error	ADaMIG v1.0	3	4 (General Variable Naming Conventions)	ADaMIG v1.0, Section 3, Item 4 (General Variable Naming Conventions): 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. ADaM adheres to a principle of harmonization known as "same name, same meaning, same values."
199	1.1	ALL:SDTM	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	Error	ADaMIG v1.1	3.1.1	3	ADaMIG v1.1, Section 3.1.1, Item 3: Any variable in an ADaM dataset 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.
200	1.0	ALL	A variable is present in ADaM with the same name as a variable defined in the ADaMIG but the variables do not have identical data types	Error	ADaMIG v1.0	3		ADaMIG v1.0, Section 3: This section defines the required characteristics of standard variables (columns) that are frequently needed in analysis datasets. The ADaM standard requires that these variable names be used when a variable that contains the content defined in Section 3 is included in an analysis dataset. In addition, the "Type" column is being used to define whether the variable being described is character or numeric.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								The ADaM Team acknowledges that ADaMIG v1.0 mistakenly indicated 6 variables as character when they should have been numeric. This error was corrected in ADaMIG v1.1. These 6 variables should comply with the correct variable type in ADaMIG v1.1 when they are present in the dataset: TRxxPGyN, TRxxAGyN, ANRLO, ANRHI, AyLO, and AyHI.
200	1.1	ALL	A variable is present in ADaM with the same name as a variable defined in the ADaMIG but the variables do not have identical data types	Error	ADaMIG v1.1	3		ADaMIG v1.1, Section 3: This section defines the required characteristics of standard variables (columns) that are frequently needed in ADaM datasets. The ADaM standard requires that these variable names be used when a variable that contains the content defined in Section 3 is included in an ADaM dataset. In addition, the "Type" column specifies whether the variable being described is character or numeric
201	1.0	BDS	TRTAGyN is present and TRTAGy is not present	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: The numeric code for TRTAGy
201	1.1	BDS	TRTAGyN is present and TRTAGy is not present	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: The numeric code for TRTAGy
204	1.0	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.AGE is not equal to DM.AGE	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: If the variable is not a copy of DM.AGE, then an additional differently named variable must be added.
204	1.1	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.AGE is not equal to DM.AGE	Error	ADaMIG v1.1	3.2	Table 3.2.2	ADaMIG v1.1, Section 3.2, Table 3.2.2: DM.AGE

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
205	1.0	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.AGEU is not equal to DM.AGEU	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: If the variable is not a copy of DM.AGEU, then an additional differently named variable must be added.
205	1.1	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.AGEU is not equal to DM.AGEU	Error	ADaMIG v1.1	3.2	Table 3.2.2	ADaMIG v1.1, Section 3.2, Table 3.2.2: DM.AGEU
206	1.0	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.SEX is not equal to DM.SEX	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: If the variable is not a copy of DM.SEX, then an additional differently named variable must be added.
206	1.1	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.SEX is not equal to DM.SEX	Error	ADaMIG v1.1	3.2	Table 3.2.2	ADaMIG v1.1, Section 3.2, Table 3.2.2: The sex of the subject is a required variable in ADSL; must be identical to DM.SEX.
207	1.0	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.RACE is not equal to DM.RACE	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: If the variable is not a copy of DM.RACE, then an additional differently named variable must be added.
207	1.1	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.RACE is not equal to DM.RACE	Error	ADaMIG v1.1	3.2	Table 3.2.2	ADaMIG v1.1, Section 3.2, Table 3.2.2: The race of the subject is a required variable in ADSL; must be identical to DM.RACE.
208	1.0	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.SUBJID is not equal to DM.SUBJID	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID, and DM.SITEID
208	1.1	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of	Error	ADaMIG v1.1	3.2	Table 3.2.1	ADaMIG v1.1, Section 3.2, Table 3.2.1: DM.SUBJID

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			DM.USUBJID and ADSL.SUBJID is not equal to DM.SUBJID					
209	1.0	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.SITEID is not equal to DM.SITEID	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID, and DM.SITEID
209	1.1	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.SITEID is not equal to DM.SITEID	Error	ADaMIG v1.1	3.2	Table 3.2.1	ADaMIG v1.1, Section 3.2, Table 3.2.1: DM.SITEID
210	1.0	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.ARM is not equal to DM.ARM	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: DM.ARM
210	1.1	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.ARM is not equal to DM.ARM	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: DM.ARM
211	1.0	BDS	ABLFN is not equal to 1 or null	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: Codelist/Controlled Terms: 1 {1,NULL}
211	1.1	BDS	ABLFN is not equal to 1 or null	Error	ADaMIG v1.1	3.3.8	Table 3.3.8.1	ADaMIG v1.1, Section 3.3.8, Table 3.3.8.1: Codelist/Controlled Terms: 1 {1,NULL}
212	1.0	BDS	ANLzzFN is not equal to 1 or null where zz is a -padded 2-digit integer [01-99]	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: Codelist/Controlled Terms: 1 {1,NULL}
212	1.1	BDS	ANLzzFN is not equal to 1 or null where zz is a -padded 2-digit integer [01-99]	Error	ADaMIG v1.1	3.3.8	Table 3.3.8.1	ADaMIG v1.1, Section 3.3.8, Table 3.3.8.1: Codelist/Controlled Terms: 1 {1,NULL}

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
221	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of AVALCATy for a given value of AVAL and y	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: A categorical representation of AVAL and/or AVALC
221	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of AVALCATy for a given value of AVAL and y, where y is a single-digit integer [1-9]	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: A categorization of AVAL or AVALC within a parameter
222	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of BASECATy for a given value of BASE and y	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: A categorical representation of BASE
222	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of BASECATy for a given value of BASE and y, where y is a single-digit integer [1-9].	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: A categorization of BASE or BASEC within a parameter
223	1.0	BDS	Within a given value of PARAMCD for a subject, CHG is populated and is not equal to AVAL - BASE	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: Equal to AVAL-BASE
223	1.1	BDS	Within a given value of PARAMCD for a subject, CHG is populated and is not equal to AVAL - BASE	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Equal to AVAL-BASE
224	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of CHGCATy for a given value of CHG and y	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: A categorical representation of CHG
224	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of CHGCATy for a	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: A categorization of CHG within a parameter

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			given value of CHG and y, where y is an integer [1-99, not -padded]					
225	1.0	BDS	Within a given value of PARAMCD for a subject, PCHG is populated and is not equal to ((AVAL - BASE)/BASE)*100	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: Equal to ((AVAL-BASE)/BASE)*100
225	1.1	BDS	Within a given value of PARAMCD for a subject, PCHG is populated and is not equal to ((AVAL - BASE)/BASE)*100	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: Equal to ((AVAL-BASE)/BASE)*100
226	1.0	BDS	Within a given value of PARAMCD, there is more than 1 value of PCHGCATy for a given value of PCHG and y	Error	ADaMIG v1.0	3.2.4	Table 3.2.4.1	ADaMIG v1.0, Section 3.2.4, Table 3.2.4.1: A categorical representation of PCHG
226	1.1	BDS	Within a given value of PARAMCD, there is more than 1 value of PCHGCATy for a given value of PCHG and y, where y is a single-digit integer [1-9]	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: A categorization of PCHG within a parameter
227	1.0	ADSL	There is more than 1 value of TRTSEQP for a given value of TRTSEQPN	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRTSEQP
227	1.1	ADSL	There is more than 1 value of TRTSEQP for a given value of TRTSEQPN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: One-to-one mapping to TRTSEQP within a study
228	1.0	ADSL	There is more than 1 value of TRTSEQPN for a given value of TRTSEQP	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRTSEQP

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
228	1.1	ADSL	There is more than 1 value of TRTSEQPN for a given value of TRTSEQP, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: One-to-one mapping to TRTSEQP within a study
229	1.0	ADSL	There is more than 1 value of TRTSEQA for a given value of TRTSEQAN	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRTSEQA
229	1.1	ADSL	There is more than 1 value of TRTSEQA for a given value of TRTSEQAN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: One-to-one mapping to TRTSEQA within a study
230	1.0	ADSL	There is more than 1 value of TRTSEQAN for a given value of TRTSEQA	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: One-to-one map to TRTSEQA
230	1.1	ADSL	There is more than 1 value of TRTSEQAN for a given value of TRTSEQA, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: One-to-one mapping to TRTSEQA within a study
231	1.0	ADSL	Within a given value of TRTxxP, there is more than 1 value of TRxxPGy, where xx is a -padded 2-digit integer [01-99] and y is a single-digit integer [1-9]	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRxxPGy: Planned pooled treatment y for Period xx. Useful when planned treatments (TRTxxP) in the specified Period xx are pooled together for analysis according to pooling algorithm y. For example, in Period 2 the first pooling algorithm dictates that all doses of Drug A (TR02PG1="All doses of Drug A") are pooled together for comparison to all doses of Drug B (TR02PG1="All doses of Drug B"). Each value of TRTxxP is pooled within at most 1 value of TRxxPGy.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
231	1.1	ADSL	Within a given value of TRTxxP, there is more than 1 value of TRxxPGy, where xx is a -padded 2-digit integer [01-99] and y is an integer [1-99, not -padded]	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: TRxxPGy: Planned pooled treatment y for Period xx. Useful when planned treatments (TRTxxP) in the specified Period xx are pooled together for analysis according to pooling algorithm y. For example, in Period 2 the first pooling algorithm dictates that all doses of Drug A (TR02PG1="All doses of Drug A") are pooled together for comparison to all doses of Drug B (TR02PG1="All doses of Drug B"). Each value of TRTxxP is pooled within at most 1 value of TRxxPGy.
232	1.0	ADSL	There is more than 1 value of TRxxPGy for a given value of TRxxPGyN, where xx is a -padded 2-digit integer [01-99] and y is a single-digit integer [1-9]	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRxxPGyN: The numeric code for TRxxPGy. One-to-one map to TRxxPGy.
232	1.1	ADSL	There is more than 1 value of TRxxPGy for a given value of TRxxPGyN, where xx is a -padded 2-digit integer [01-99] and y is a single-digit integer [1-9], considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: TRxxPGyN: The numeric code for TRxxPGy. One-to-one mapping to TRxxPGy within a study.
233	1.0	ADSL	There is more than 1 value of TRxxPGyN for a given value of TRxxPGy, where xx is a -padded 2-digit integer [01-99] and y is a single-digit integer [1-9]	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRxxPGyN: The numeric code for TRxxPGy. One-to-one map to TRxxPGy.
233	1.1	ADSL	There is more than 1 value of TRxxPGyN for a given value	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: TRxxPGyN: The numeric code for

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			of TRxxPGy, where xx is a -padded 2-digit integer [01-99] and y is a single-digit integer [1-9], considering only those rows on which both variables are populated					TRxxPGy. One-to-one mapping to TRxxPGy within a study.
234	1.0	ADSL	Within a given value of TRTxxA, there is more than 1 value of TRxxAGy, where xx is a -padded 2-digit integer [01-99] and y is a single-digit integer [1-9]	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRxxAGy: Actual pooled treatment y for Period xx. Required when TRxxPGy is present and TRTxxA is present.
234	1.1	ADSL	Within a given value of TRTxxA, there is more than 1 value of TRxxAGy, where xx is a -padded 2-digit integer [01-99] and y is an integer [1-99, not -padded]	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: TRxxAGy: Actual pooled treatment y for Period xx. Required when TRxxPGy is present and TRTxxA is present.
235	1.0	ADSL	There is more than 1 value of TRxxAGy for a given value of TRxxAGyN, where xx is a -padded 2-digit integer [01-99] and y is a single-digit integer [1-9]	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRxxAGyN: The numeric code for TRxxAGy. One-to-one map to TRxxAGy
235	1.1	ADSL	There is more than 1 value of TRxxAGy for a given value of TRxxAGyN, where xx is a -padded 2-digit integer [01-99] and y is a single-digit integer [1-9], considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: TRxxAGyN: The numeric code for TRxxAGy. One-to-one mapping to TRxxAGy within a study.
236	1.0	ADSL	There is more than 1 value of TRxxAGyN for a given value of TRxxAGy, where xx is a -	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRxxAGyN: The numeric code for

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			padded 2-digit integer [01-99] and y is a single-digit integer [1-9]					TRxxAGy. One-to-one map to TRxxAGy
236	1.1	ADSL	There is more than 1 value of TRxxAGyN for a given value of TRxxAGy, where xx is a -padded 2-digit integer [01-99] and y is a single-digit integer [1-9], considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: TRxxAGyN: The numeric code for TRxxAGy. One-to-one mapping to TRxxAGy within a study.
237	1.0	BDS	There is more than 1 value of TRTPGy for a given value of TRTPGyN, where y is a single-digit integer [1-9]	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: TRTPGyN: The numeric code for TRTPGy. One-to-one map to TRTPGy.
237	1.1	BDS	There is more than 1 value of TRTPGy for a given value of TRTPGyN, where y is an integer [1-99, not -padded], considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTPGyN: The numeric code for TRTPGy. One-to-one mapping within a study to TRTPGy.
238	1.0	BDS	There is more than 1 value of TRTPGyN for a given value of TRTPGy, where y is a single-digit integer [1-9]	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: TRTPGyN: The numeric code for TRTPGy. One-to-one map to TRTPGy.
238	1.1	BDS	There is more than 1 value of TRTPGyN for a given value of TRTPGy, where y is an integer [1-99, not -padded], considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTPGyN: The numeric code for TRTPGy. One-to-one mapping within a study to TRTPGy.
239	1.0	BDS	TRTPGy is present and TRTA is present but TRTAGy is not	Error	ADaMIG v1.0	3.3.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.3.2, Table 3.2.2.1: TRTAGy: Actual pooled

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			present, where y is a single-digit integer [1-9]					treatment y. "y" represents an integer [1-9] corresponding to a particular pooling scheme. Required when TRTPGy is present and TRTA is present. May vary by record within a subject.
239	1.1	BDS	TRTPGy is present and TRTA is present but TRTAGy is not present, where y is an integer [1-99, not -padded]	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTAGy: TRTAGy is the actual pooled treatment y attributed to a record for analysis purposes. "y" represents an integer [1-99, not -padded] corresponding to a particular pooling scheme. Required when TRTPGy is present and TRTA is present.
240	1.0	BDS	There is more than 1 value of TRTAGy for a given value of TRTAGyN, where y is a single-digit integer [1-9]	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: TRTAGyN: The numeric code for TRTAGy. One-to-one map to TRTAGy.
240	1.1	BDS	There is more than 1 value of TRTAGy for a given value of TRTAGyN, where y is an integer [1-99, not -padded], considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTAGyN: The numeric code for TRTAGy. One-to-one mapping within a study to TRTAGy.
241	1.0	BDS	There is more than 1 value of TRTAGyN for a given value of TRTAGy, where y is a single-digit integer [1-9]	Error	ADaMIG v1.0	3.2.2	Table 3.2.2.1	ADaMIG v1.0, Section 3.2.2, Table 3.2.2.1: TRTAGyN: The numeric code for TRTAGy. One-to-one map to TRTAGy.
241	1.1	BDS	There is more than 1 value of TRTAGyN for a given value of TRTAGy, where y is an integer [1-99, not -padded], considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTAGyN: The numeric code for TRTAGy. One-to-one mapping within a study to TRTAGy.

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242	1.0	ADSL	There is more than 1 value of TRTxxAN for a given value of TRTxxA, where xx is a -padded 2-digit integer [01-99]	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRTxxAN: The numeric code variable for TRTxxA. One-to-one map to TRTxxA.
242	1.1	ADSL	There is more than 1 value of TRTxxAN for a given value of TRTxxA, where xx is a -padded 2-digit integer [01-99], considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: TRTxxAN: The numeric code variable for TRTxxA. One-to-one mapping to TRTxxA within a study.
243	1.0	ADSL	There is more than 1 value of TRTxxA for a given value of TRTxxAN, where xx is a -padded 2-digit integer [01-99]	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRTxxAN: The numeric code variable for TRTxxA. One-to-one map to TRTxxA.
243	1.1	ADSL	There is more than 1 value of TRTxxA for a given value of TRTxxAN, where xx is a -padded 2-digit integer [01-99], considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: TRTxxAN: The numeric code variable for TRTxxA. One-to-one mapping to TRTxxA within a study.
244.01	1.1	ADSL:BDS, ADSL:OCCDS	A non-missing value of TRTA is not equal to at least 1 value of the character actual treatment variables in ADSL defined in the IG	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: TRTA: TRTA is a record-level identifier that represents the actual treatment attributed to a record for analysis purposes. TRTA indicates how treatment varies by record within a subject and enables analysis of crossover and other multi-period designs. Though there is no requirement that TRTA will correspond to the TRTxxA as defined by the record's value of APERIOD, TRTA must match at least 1 value of the character actual treatment variables in ADSL (e.g., TRTxxA, TRTSEQA,

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								TRxxAGy). As noted previously, at least 1 treatment variable is required. This requirement is satisfied by any subject-level or record-level treatment variables (e.g., TRTxxP, TRTP, TRTA). Even if not used for analysis, any ADSL treatment variable may be included in the BDS dataset.
252	1.0	OCCDS	AVAL is present or AVALC is present	Warning	OCCDS IG v1.0	1.1		OCCDS IG v1.0, Section 1.1: There is no need for AVAL or AVALC. Occurrences are counted in analysis, and there are typically 1 or more records for each occurrence assessment
252	1.1	OCCDS	AVAL is present or AVALC is present	Warning	OCCDS IG v1.0	1.1		OCCDS IG v1.0, Section 1.1: There is no need for AVAL or AVALC. Occurrences are counted in analysis, and there are typically 1 or more records for each occurrence assessment
254	1.0	OCCDS	PARAM is present	Warning	OCCDS IG v1.0	3.2		OCCDS IG v1.0, Section 3.2: There is no PARAM nor AVAL.
254	1.1	OCCDS	PARAM is present	Warning	OCCDS IG v1.0	3.2		OCCDS IG v1.0, Section 3.2: There is no PARAM nor AVAL.
256	1.0	ADSL:ALL	The values of USUBJID are not present in ADSL	Error	Model v2.1; ADaMIG v1.0	6; 3.1		Model v2.1, Section 6: The structure of the ADSL is 1 record per subject, regardless of the type of clinical trial design. ADSL is used to provide the variables that describe attributes of a subject. This structure allows simple merging with any other dataset, including SDTM and analysis datasets. ADaMIG v1.0, Section 3.1: The structure of ADSL is 1 record per subject, regardless of the type of clinical trial design. ADSL is used to provide the

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								variables that describe attributes of a subject. This section lists the standard variables that are required to be in every ADSL.
256	1.1	ADSL:ALL	The values of USUBJID are not present in ADSL	Error	Model v2.1; ADaMIG v1.1	6; 3.2		Model v2.1, Section 6: The structure of the ADSL is 1 record per subject, regardless of the type of clinical trial design. ADSL is used to provide the variables that describe attributes of a subject. This structure allows simple merging with any other dataset, including SDTM and analysis datasets. ADaMIG v1.1, Section 3.2: Within a given study, USUBJID is the key variable that links ADSL to other datasets (both SDTM and ADaM).
257.01	1.0	OCCDS:SDTM	A variable whose name is 5 characters in length with a suffix of SEQ is not present.	Error	OCCDS IG v1.0	3.2.2	Table 3.2.2.1	OCCDS IG v1.0, Section 3.2.2, Table 3.2.2.1: --SEQ has Core=Req.
257.01	1.1	OCCDS:SDTM	A variable whose name is five characters in length with a suffix of SEQ is not present.	Error	OCCDS IG v1.0	3.2.2	Table 3.2.2.1	OCCDS IG v1.0, Section 3.2.2, Table 3.2.2.1: --SEQ has Core=Req.
258.01	1.0	BDS:SDTM, OCCDS:SDTM	For a value of AD*.USUBJID that is a value of --.USUBJID, a value of AD*.--SEQ is not a value of --.--SEQ	Error	Model v2.1; OCCDS IG v1.0	4.1.2; 1.1		Model v2.1, Section 4.1.2: Any ADaM variable with the same name as an SDTM variable is required to be a copy of the SDTM variable, and its label, attributes, and values cannot be modified. ADaM adheres to the principle of harmonization known as "same name, same meaning, and same values." OCCDS IG v1.0, Section 1.1: The structure for the occurrence analysis dataset is usually 1 record per each

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								record in the corresponding SDTM domain.
258.01	1.1	BDS:SDTM, OCCDS:SDTM	For a value of AD*.USUBJID that is a value of --.USUBJID, a value of AD*.--SEQ is not a value of --.--SEQ	Error	Model v2.1; OCCDS IG v1.0	4.1.2; 1.1		Model v2.1, Section 4.1.2: Any ADaM variable with the same name as an SDTM variable is required to be a copy of the SDTM variable, and its label, attributes, and values cannot be modified. ADaM adheres to the principle of harmonization known as "same name, same meaning, and same values." OCCDS IG v1.0, Section 1.1: The structure for the occurrence analysis dataset is usually 1 record per each record in the corresponding SDTM domain.
259.01	1.0	BDS:SDTM, OCCDS:SDTM	AD*.USUBJID equals --.USUBJID, AD*.--SEQ equals --.--SEQ, and the values of a variable with prefix -- which is present in both datasets are not equal	Error	Model v2.1; OCCDS IG v1.0	4.1.2; 1.1		Model v2.1, Section 4.1.2: Any ADaM variable with the same name as an SDTM variable is required to be a copy of the SDTM variable, and its label, attributes, and values cannot be modified. ADaM adheres to the principle of harmonization known as "same name, same meaning, and same values." OCCDS IG v1.0, Section 1.1: The structure for the occurrence analysis dataset is usually 1 record per each record in the corresponding SDTM domain.
259.01	1.1	BDS:SDTM, OCCDS:SDTM	AD*.USUBJID equals --.USUBJID, AD*.--SEQ equals --.--SEQ, and the values of a variable with prefix -- which is present in both datasets are not equal	Error	Model v2.1; OCCDS IG v1.0	4.1.2; 1.1		Model v2.1, Section 4.1.2: Any ADaM variable with the same name as an SDTM variable is required to be a copy of the SDTM variable, and its label, attributes, and values cannot be modified. ADaM adheres to the principle of

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								harmonization known as "same name, same meaning, and same values." OCCDS IG v1.0, Section 1.1: The structure for the occurrence analysis dataset is usually 1 record per each record in the corresponding SDTM domain.
268	1.0	OCCDS	ADURN is populated and ADURU is not populated	Error	OCCDS IG v1.0	3.2.4	Table 3.2.4.1	OCCDS IG v1.0, Section 3.2.4, Table 3.2.4.1: CDISC Notes for ADURU state: "Conditional on whether ADURN is included."
268	1.1	OCCDS	ADURN is populated and ADURU is not populated	Error	OCCDS IG v1.0	3.2.4	Table 3.2.4.1	OCCDS IG v1.0, Section 3.2.4, Table 3.2.4.1: CDISC Notes for ADURU state: "Conditional on whether ADURN is included."
269	1.0	OCCDS	TRTEMFL is not equal to Y or null	Error	OCCDS IG v1.0	3.2.5	Table 3.2.5.3	OCCDS IG v1.0, Section 3.2.5, Table 3.2.5.3: Code List/Controlled Terms have allowable values of: "Y"
269	1.1	OCCDS	TRTEMFL is not equal to Y or null	Error	OCCDS IG v1.0	3.2.5	Table 3.2.5.3	OCCDS IG v1.0, Section 3.2.5, Table 3.2.5.3: Code List/Controlled Terms have allowable values of: "Y"
270	1.0	OCCDS	PREFL is not equal to Y or null	Error	OCCDS IG v1.0	3.2.5	Table 3.2.5.5	OCCDS IG v1.0, Section 3.2.5, Table 3.2.5.5: Code List/Controlled Terms have allowable values of: "Y"
270	1.1	OCCDS	PREFL is not equal to Y or null	Error	OCCDS IG v1.0	3.2.5	Table 3.2.5.5	OCCDS IG v1.0, Section 3.2.5, Table 3.2.5.5: Code List/Controlled Terms have allowable values of: "Y"
271	1.0	OCCDS	FUPFL is not equal to Y or null	Error	OCCDS IG v1.0	3.2.5	Table 3.2.5.5	OCCDS IG v1.0, Section 3.2.5, Table 3.2.5.5: Code List/Controlled Terms have allowable values of: "Y"
271	1.1	OCCDS	FUPFL is not equal to Y or null	Error	OCCDS IG v1.0	3.2.5	Table 3.2.5.5	OCCDS IG v1.0, Section 3.2.5, Table 3.2.5.5: Code List/Controlled Terms have allowable values of: "Y"

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
272	1.0	OCCDS	A variable with a prefix of AOCC and a suffix of FL is not equal to Y or null	Error	OCCDS IG v1.0	3.2.6	Table 3.2.6.1	OCCDS IG v1.0, Section 3.2.6, Table 3.2.6.1: Code List/Controlled Terms have allowable values of: "Y"
272	1.1	OCCDS	A variable with a prefix of AOCC and a suffix of FL is not equal to Y or null	Error	OCCDS IG v1.0	3.2.6	Table 3.2.6.1	OCCDS IG v1.0, Section 3.2.6, Table 3.2.6.1: Code List/Controlled Terms have allowable values of: "Y"
279	1.0	OCCDS	AESEVN is not equal to 1, 2, 3, or null	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AESEVN state: "Code AE.AESEV to numeric."
279	1.1	OCCDS	AESEVN is not equal to 1, 2, 3, or null	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AESEVN state: "Code AE.AESEV to numeric." Code List/Controlled Terms have allowable values of: "1, 2, 3".
280	1.0	OCCDS	There is more than 1 value of AESEV for a given value of AESEVN	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AESEVN state: "Code AE.AESEV to numeric."
280	1.1	OCCDS	There is more than 1 value of AESEV for a given value of AESEVN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AESEVN state: "Code AE.AESEV to numeric."
281	1.0	OCCDS	There is more than 1 value of AESEVN for a given value of AESEV	Error	ADaMIG v1.0;	3; 3.2.8	9 (General Variable Naming	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
					OCCDS IG v1.0		Conventions); Table 3.2.8.1	are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AESEVN state: "Code AE.AESEV to numeric."
281	1.1	OCCDS	There is more than 1 value of AESEVN for a given value of AESEV, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AESEVN state: "Code AE.AESEV to numeric."
282	1.0	OCCDS	ASEVN is not equal to 1, 2, 3, or null	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ASEVN state: "Code ASEV to numeric." Code List/Controlled Terms have allowable values of: "1, 2, 3".

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
282	1.1	OCCDS	ASEVN is not equal to 1, 2, 3, or null	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ASEVN state: "Code ASEV to numeric."
283	1.0	OCCDS	There is more than 1 value of ASEV for a given value of ASEVN	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ASEVN state: "Code ASEV to numeric."
283	1.1	OCCDS	There is more than 1 value of ASEV for a given value of ASEVN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ASEVN state: "Code ASEV to numeric."
284	1.0	OCCDS	There is more than 1 value of ASEVN for a given value of ASEV	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ASEVN state: "Code ASEV to numeric."
284	1.1	OCCDS	There is more than 1 value of ASEVN for a given value of ASEV, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ASEVN state: "Code ASEV to numeric."
285	1.0	OCCDS	There is more than 1 value of SEVGRy for a given value of SEVGRyN	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for SEVGRyN state: "Code SEVGRy to numeric."
285	1.1	OCCDS	There is more than 1 value of SEVGRy for a given value of SEVGRyN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for SEVGRyN state: "Code SEVGRy to numeric."
286	1.0	OCCDS	There is more than 1 value of SEVGRyN for a given value of SEVGRy	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for SEVGRyN state: "Code SEVGRy to numeric."
286	1.1	OCCDS	There is more than 1 value of SEVGRyN for a given value of SEVGRy, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for SEVGRyN state: "Code SEVGRy to numeric."
287	1.0	OCCDS	There is more than 1 value of AEREL for a given value of AERELN	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AERELN state: "Code AE.AEREL to numeric."
287	1.1	OCCDS	There is more than 1 value of AEREL for a given value of AERELN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AERELN state: "Code AE.AEREL to numeric."
288	1.0	OCCDS	There is more than 1 value of AERELN for a given value of AEREL	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AERELN state: "Code AE.AEREL to numeric."
288	1.1	OCCDS	There is more than 1 value of AERELN for a given value of AEREL, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., NN for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AERELN state: "Code AE.AEREL to numeric."
289	1.0	OCCDS	There is more than 1 value of AREL for a given value of ARELN	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ARELN state: "Code AREL to numeric."
289	1.1	OCCDS	There is more than 1 value of AREL for a given value of ARELN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ARELN state: "Code AREL to numeric."
290	1.0	OCCDS	There is more than 1 value of ARELN for a given value of AREL	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ARELN state: "Code AREL to numeric."
290	1.1	OCCDS	There is more than 1 value of ARELN for a given value of AREL, considering only those	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
			rows on which both variables are populated					the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ARELN state: "Code AREL to numeric."
291	1.0	OCCDS	There is more than 1 value of RELGRy for a given value of RELGRyN	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for RELGRyN state: "Code RELGRy to numeric."
291	1.1	OCCDS	There is more than 1 value of RELGRy for a given value of RELGRyN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for RELGRyN state: "Code RELGRy to numeric".

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
292	1.0	OCCDS	There is more than 1 value of RELGRyN for a given value of RELGRy	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for RELGRyN state: "Code RELGRy to numeric."
292	1.1	OCCDS	There is more than 1 value of RELGRyN for a given value of RELGRy, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for RELGRyN state: "Code RELGRy to numeric."
293	1.0	OCCDS	There is more than 1 value of AETOXGR for a given value of AETOXGRN	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AETOXGRN state: "Code AETOXGR to numeric."

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
293	1.1	OCCDS	There is more than 1 value of AETOXGR for a given value of AETOXGRN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., NN for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AETOXGRN state: "Code AETOXGR to numeric."
294	1.0	OCCDS	There is more than 1 value of AETOXGRN for a given value of AETOXGR	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AETOXGRN state: "Code AETOXGR to numeric."
294	1.1	OCCDS	There is more than 1 value of AETOXGRN for a given value of AETOXGR, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for AETOXGRN state: "Code AETOXGR to numeric."
295	1.0	OCCDS	There is more than 1 value of ATOXGR for a given value of ATOXGRN	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ATOXGRN state: "Code ATOXGR to numeric."
295	1.1	OCCDS	There is more than 1 value of ATOXGR for a given value of ATOXGRN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ATOXGRN state: "Code ATOXGR to numeric."
296	1.0	OCCDS	There is more than 1 value of ATOXGRN for a given value of ATOXGR	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ATOXGRN state: "Code ATOXGR to numeric."
296	1.1	OCCDS	There is more than 1 value of ATOXGRN for a given value of ATOXGR, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for ATOXGRN state: "Code ATOXGR to numeric."
297	1.0	OCCDS	There is more than 1 value of TOXGGRy for a given value of TOXGGRyN	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for TOXGRyN state: "Code TOXGRy to numeric."
297	1.1	OCCDS	There is more than 1 value of TOXGGRy for a given value of TOXGGRyN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for TOXGRyN state: "Code TOXGRy to numeric."
298	1.0	OCCDS	There is more than 1 value of TOXGGRyN for a given value of TOXGGRy	Error	ADaMIG v1.0; OCCDS IG v1.0	3; 3.2.8	9 (General Variable Naming Conventions); Table 3.2.8.1	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for TOXGRyN state: "Code TOXGRy to numeric."
298	1.1	OCCDS	There is more than 1 value of TOXGGRyN for a given value of TOXGGRy, considering only those rows on which both variables are populated	Error	ADaMIG v1.1; OCCDS IG v1.0	3.1.1; 3.2.8	6; Table 3.2.8.1	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5. OCCDS IG v1.0, Section 3.2.8, Table 3.2.8.1: CDISC Notes for TOXGRyN state: "Code TOXGRy to numeric."
304	1.0	OCCDS	SMQzzNAM is populated and SMQzzCD is not populated	Warning	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
304	1.1	OCCDS	SMQzzNAM is populated and SMQzzCD is not populated	Warning	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
305	1.0	OCCDS	SMQzzNAM is populated and SMQzzSC is not populated	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
305	1.1	OCCDS	SMQzzNAM is populated and SMQzzSC is not populated	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
306	1.0	OCCDS	SMQzzCD is populated and SMQzzNAM is not populated	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
306	1.1	OCCDS	SMQzzCD is populated and SMQzzNAM is not populated	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
307	1.0	OCCDS	SMQzzCD is populated and SMQzzSC is not populated	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
307	1.1	OCCDS	SMQzzCD is populated and SMQzzSC is not populated	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
308	1.0	OCCDS	SMQzzSC is populated and SMQzzNAM is not populated	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
308	1.1	OCCDS	SMQzzSC is populated and SMQzzNAM is not populated	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
309	1.0	OCCDS	SMQzzSC is populated and SMQzzCD is not populated	Warning	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
309	1.1	OCCDS	SMQzzSC is populated and SMQzzCD is not populated	Warning	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: CDISC Notes state: "Conditional on whether SMQ analysis is done."
310	1.0	OCCDS	There is more than 1 value of SMQzzSC for a given value of SMQzzSCN	Error	ADaMIG v1.0	3	9 (General Variable Naming Conventions)	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables.
310	1.1	OCCDS	There is more than 1 value of SMQzzSC for a given value of SMQzzSCN, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.1.1	6	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5.
311	1.0	OCCDS	There is more than 1 value of SMQzzSCN for a given value of SMQzzSC	Error	ADaMIG v1.0	3	9 (General Variable Naming Conventions)	ADaMIG v1.0, Section 3, Item 9 (General Variable Naming Conventions): In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								numeric version of RACE is RACEN. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to date/time variables.
311	1.1	OCCDS	There is more than 1 value of SMQzzSCN for a given value of SMQzzSC, considering only those rows on which both variables are populated	Error	ADaMIG v1.1	3.1.1	6	ADaMIG v1.1, Section 3.1.1, Item 6: In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric, C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable TRTP is character, but it is not named TRTPC. Similarly, in the (APERIOD, APERIODC) pair, the primary variable APERIOD is numeric, but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the 2 variables, as described in ADaMIG v1.1, Section 3.1.1, Item 5.
312	1.0	OCCDS	SMQzzSC is not equal to BROAD or NARROW, where zz is a -padded 2-digit integer [01-99]	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: Code List/Controlled Terms have allowable values of: "BROAD", "NARROW".

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
312	1.1	OCCDS	SMQzzSC is not equal to BROAD or NARROW, where zz is a -padded 2-digit integer [01-99]	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: Code List/Controlled Terms have allowable values of: "BROAD", "NARROW".
313	1.0	OCCDS	SMQzzSCN is not equal to 1 or 2, where zz is a -padded 2-digit integer [01-99]	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: Code List/Controlled Terms have allowable values of: 1, 2.
313	1.1	OCCDS	SMQzzSCN is not equal to 1 or 2, where zz is a -padded 2-digit integer [01-99]	Error	OCCDS IG v1.0	3.2.9	Table 3.2.9.1	OCCDS IG v1.0, Section 3.2.9, Table 3.2.9.1: Code List/Controlled Terms have allowable values of: 1, 2.
320	1.0	ADSL	A dataset is named ADSL and the dataset label is not "Subject-Level Analysis Dataset"	Error	ADaMIG v1.0	2.3.1		ADaMIG v1.0, Section 2.3.1: ADSL contains 1 record per subject, regardless of the type of clinical trial design. ADSL is used to provide the variables that describe attributes of a subject. This allows simple combining with any other dataset, including SDTM domains and analysis datasets. ADSL is a source for subject-level variables used in other analysis datasets, such as population flags and treatment variables. There is only 1 ADSL per study. ADSL and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other analysis datasets are submitted.
320	1.1	ADSL	A dataset is named ADSL and the dataset label is not "Subject-Level Analysis Dataset"	Error	ADaMIG v1.1	2.3.1		ADaMIG v1.1, Section 2.3.1: ADSL contains 1 record per subject, regardless of the type of clinical trial design. The label of the ADSL dataset is "Subject-Level Analysis Dataset".
321	1.0	ADSL	A dataset label is "Subject-Level Analysis Dataset" and the dataset is not named ADSL	Warning	ADaMIG v1.0	2.3.1		ADaMIG v1.0, Section 2.3.1: ADSL contains 1 record per subject, regardless of the type of clinical trial design. ADSL is used to provide the variables that

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								describe attributes of a subject. This allows simple combining with any other dataset, including SDTM domains and analysis datasets. ADSL is a source for subject-level variables used in other analysis datasets, such as population flags and treatment variables. There is only 1 ADSL per study. ADSL and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other analysis datasets are submitted.
321	1.1	ADSL	A dataset label is "Subject-Level Analysis Dataset" and the dataset is not named ADSL	Warning	ADaMIG v1.1	2.3.1		ADaMIG v1.1, Section 2.3.1: ADSL contains 1 record per subject, regardless of the type of clinical trial design. The label of the ADSL dataset is "Subject-Level Analysis Dataset".
322	1.1	BDS, OCCDS	Within a given value of TRTP, there is more than 1 value of TRTPGy, where y is an integer [1-99, not -padded]	Error	ADaMIG v1.1	3.3.2	Table 3.3.2.1	ADaMIG v1.1, Section 3.3.2, Table 3.3.2.1: CDISC Notes for TRTPGy state: "Each value of TRTP is pooled within at most 1 value of TRTPGy."
323	1.1	BDS, OCCDS	Within a study, there is more than 1 value of APHASEN for a given value of APHASE	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.1	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.1: CDISC Notes for APHASEN state: "Within a study, there is a one-to-one mapping between APHASE and APHASEN."
324	1.1	BDS, OCCDS	Within a study, there is more than 1 value of APHASE for a given value of APHASEN	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.1	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.1: CDISC Notes for APHASEN state: "Within a study, there is a one-to-one mapping between APHASE and APHASEN."
325	1.1	BDS, OCCDS	Within a value of APERIOD, there is more than 1 value of ASPER for a given value of ASPERC	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.1	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.1: CDISC Notes for ASPERC state: "One-to-one mapping within a period to ASPER.". CDISC Notes for ASPER

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								state: "Within each APERIOD, the first ASPER is 1 (i.e., it resets to 1 when the APERIOD value changes)."
326	1.1	BDS, OCCDS	Within a value of APERIOD, there is more than 1 value of ASPERC for a given value of ASPER	Error	ADaMIG v1.1	3.3.3	Table 3.3.3.1	ADaMIG v1.1, Section 3.3.3, Table 3.3.3.1: CDISC Notes for ASPERC state: "One-to-one mapping within a period to ASPER." CDISC Notes for ASPER state: "Within each APERIOD, the first ASPER is 1 (i.e., it resets to 1 when the APERIOD value changes)."
327	1.1	BDS	Within a parameter, there is more than 1 value of AVALCATy for a given value of AVALCAyN	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for AVALCAyN state: "There must be a one-to-one relationship within a parameter between AVALCATy and AVALCAyN."
328	1.1	BDS	Within a parameter, there is more than 1 value of AVALCAyN for a given value of AVALCATy	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for AVALCAyN state: "There must be a one-to-one relationship within a parameter between AVALCATy and AVALCAyN."
329	1.1	BDS	Within a parameter, there is more than 1 value of BASECATy for a given value of BASECAyN	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for BASECAyN state: "There must be a one-to-one relationship within a parameter between BASECATy and BASECAyN."
330	1.1	BDS	Within a parameter, there is more than 1 value of BASECAyN for a given value of BASECATy	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for BASECAyN state: "There must be a one-to-one relationship within a parameter between BASECATy and BASECAyN."
331	1.1	BDS	Within a parameter, there is more than 1 value of CHGCATy for a given value of CHGCATyN	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for CHGCATyN state: "There must be a one-to-one relationship within a parameter between CHGCATy and CHGCATyN."

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
332	1.1	BDS	Within a parameter, there is more than 1 value of CHGCATyN for a given value of CHGCATy	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for CHGCATyN state: "There must be a one-to-one relationship within a parameter between CHGCATy and CHGCATyN."
333	1.1	BDS	Within a parameter, there is more than 1 value of PCHGCATy for a given value of PCHGCAyN	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for PCHGCAyN state: "There must be a one-to-one relationship within a parameter between PCHGCATy and PCHGCAyN."
334	1.1	BDS	Within a parameter, there is more than 1 value of PCHGCAyN for a given value of PCHGCATy	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for PCHGCAyN state: "There must be a one-to-one relationship within a parameter between PCHGCATy and PCHGCAyN."
335	1.0	BDS	CRITyFL is present and CRITy is not present	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: CDISC Notes for CRITyFL state: "Required if CRITy exists."
335	1.1	BDS	CRITyFL is present and CRITy is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: CDISC Notes for CRITyFL state: "Required if CRITy exists."
336	1.0	BDS	CRITy is present and CRITyFL is not present	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: CDISC Notes for CRITyFL state: "Required if CRITy exists."
336	1.1	BDS	CRITy is present and CRITyFL is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: CDISC Notes for CRITyFL state: "Required if CRITy exists."
337	1.1	BDS	MCRITyML is present and MCRITy is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: CDISC Notes for MCRITyML state: "Required if MCRITy exists."
338	1.1	BDS	MCRITy is present and MCRITyML is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: CDISC Notes for MCRITyML state: "Required if MCRITy exists."

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
339	1.1	BDS	MCRITyML is populated and MCRITy is not populated	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: CDISC Notes for MCRITyML state: "Required if MCRITy exists."
340	1.1	BDS	Within a parameter, there is more than 1 value of MCRITyML for a given value of MCRITyMN	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: CDISC Notes for MCRITyMN state: "There is a one-to-one mapping between MCRITyML and MCRITyMN."
341	1.1	BDS	Within a parameter, there is more than 1 value of MCRITyMN for a given value of MCRITyML	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.2	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.2: CDISC Notes for MCRITyMN state: "There is a one-to-one mapping between MCRITyML and MCRITyMN."
342	1.1	BDS	Within a parameter, there is more than 1 value of ANRLO for a given value of ANRLOC	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for ANRLOC state: "Within a given parameter, if there exists a row on which both ANRLOC and ANRLO are populated, then there must be a one-to-one mapping between ANRLOC and ANRLO on all rows on which both variables are populated."
343	1.1	BDS	Within a parameter, there is more than 1 value of ANRLOC for a given value of ANRLO	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for ANRLOC state: "Within a given parameter, if there exists a row on which both ANRLOC and ANRLO are populated, then there must be a one-to-one mapping between ANRLOC and ANRLO on all rows on which both variables are populated."
344	1.1	BDS	Within a parameter, there is more than 1 value of ANRHI for a given value of ANRHIC	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for ANRHIC state: "Within a given parameter, if there exists a row on which both ANRHIC and ANRHI are populated, then there must be a one-to-one mapping between ANRHIC and ANRHI on all rows on which both variables are populated."

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
345	1.1	BDS	Within a parameter, there is more than 1 value of ANRHIC for a given value of ANRHI	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for ANRHIC state: "Within a given parameter, if there exists a row on which both ANRHIC and ANRHI are populated, then there must be a one-to-one mapping between ANRHIC and ANRHI on all rows on which both variables are populated."
346	1.1	BDS	R2AyLO is present and AyLO is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for R2AyLO state: "AyLO must exist in the ADaM dataset."
347	1.1	BDS	Within a parameter, there is more than 1 value of AyLO for a given value of AyLOC	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for AyLOC state: "Within a given parameter, if there exists a row on which both AyLOC and AyLO are populated, then there must be a one-to-one mapping between AyLOC and AyLO on all rows on which both variables are populated."
348	1.1	BDS	Within a parameter, there is more than 1 value of AyLOC for a given value of AyLO	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for AyLOC state: "Within a given parameter, if there exists a row on which both AyLOC and AyLO are populated, then there must be a one-to-one mapping between AyLOC and AyLO on all rows on which both variables are populated."
349	1.1	BDS	R2AyHI is present and AyHI is not present	Error	ADaMIG v1.1	3.3.4	Table 3.3.4.1	ADaMIG v1.1, Section 3.3.4, Table 3.3.4.1: CDISC Notes for R2AyHI state: "AyHI must exist in the ADaM dataset."
350	1.1	BDS	Within a parameter, there is more than 1 value of AyHI for a given value of AyHIC	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for AyHIC state: "Within a given parameter, if there exists a row on which both AyHIC and AyHI are populated, then there must be a one-

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								to-one mapping between AyHIC and AyHI on all rows on which both variables are populated."
351	1.1	BDS	Within a parameter, there is more than 1 value of AyHIC for a given value of AyHI	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for AyHIC state: "Within a given parameter, if there exists a row on which both AyHIC and AyHI are populated, then there must be a one-to-one mapping between AyHIC and AyHI on all rows on which both variables are populated."
352	1.1	BDS	AyIND is present and AyLO, AyHI, AyLOC, and AyHIC are all not present.	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for AyIND state: "Indicates relationship of AVAL to the analysis range variables AyLO and/or AyHI, or the relationship of AVALC to the analysis range variables AyLOC and/or AyHIC."
353	1.1	BDS	BASETYPE is present, ByIND is populated, and ByIND is not equal to AyIND where ABLFL is equal to Y for a given value of PARAMCD and BASETYPE for a subject	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for ByIND state: "AyIND of the baseline record identified by ABLFL."
354	1.1	BDS	BASETYPE is not present, ByIND is populated, and ByIND is not equal to AyIND where ABLFL is equal to Y for a given value of PARAMCD for a subject	Error	ADaMIG v1.1	3.3.7	Table 3.3.7.1	ADaMIG v1.1, Section 3.3.7, Table 3.3.7.1: CDISC Notes for ByIND state: "AyIND of the baseline record identified by ABLFL."
355	1.1	ADSL	There is more than 1 value of REGIONy for a given value of REGIONyN	Error	ADaMIG v1.1	3.2	Table 3.2.1	ADaMIG v1.1, Section 3.2, Table 3.2.1: CDISC Notes for REGIONyN state: "One-to-one mapping to REGIONy within a study."

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
356	1.1	ADSL	There is more than 1 value of REGIONyN for a given value of REGIONy	Error	ADaMIG v1.1	3.2	Table 3.2.1	ADaMIG v1.1, Section 3.2, Table 3.2.1: CDISC Notes for REGIONyN state: "One-to-one mapping to REGIONy within a study."
359	1.1	ADSL	There is more than 1 value of DTHCAUS for a given value of DTHCAUSN	Error	ADaMIG v1.1	3.2	Table 3.2.8	ADaMIG v1.1, Section 3.2, Table 3.2.8: CDISC Notes for DTHCAUSN state: "Must have a one-to-one mapping to DTHCAUS."
360	1.1	ADSL	There is more than 1 value of DTHCAUSN for a given value of DTHCAUS	Error	ADaMIG v1.1	3.2	Table 3.2.8	ADaMIG v1.1, Section 3.2, Table 3.2.8: CDISC Notes for DTHCAUSN state: "Must have a one-to-one mapping to DTHCAUS."
361	1.0	ALL	The value of ASTDT is greater than the value of AENDT, considering only those rows on which both variables are populated	Note	ADaMIG v1.0	3	9 (General Timing Variable Conventions); 10 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 9 (General Timing Variable Conventions): Names of timing start variables end with an S followed by the 2 characters indicating the type of timing (e.g., SDT, STM), unless otherwise specified elsewhere in ADaMIG Section 3. ADaMIG v1.0, Section 3, Item 10 (General Timing Variable Conventions): Names of timing end variables end with an E followed by the 2 characters indicating the type of timing (e.g., EDT, ETM), unless otherwise specified elsewhere in ADaMIG Section 3.
361	1.1	ALL	The value of ASTDT is greater than the value of AENDT, considering only those rows on which both variables are populated	Note	ADaMIG v1.1	3.1.2	6; 7	ADaMIG v1.1, Section 3.1.2, Item 6: Names of timing start variables end with an S followed by the characters indicating the type of timing (i.e., SDT, STM, SDTM), unless otherwise specified elsewhere in ADaMIG Section 3 ADaMIG v1.1, Section 3.1.2, Item 7: Names of timing end variables end with

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								an E followed by the characters indicating the type of timing (i.e., EDT, ETM, EDTM), unless otherwise specified elsewhere in ADaMIG Section 3.
362	1.0	ALL	The value of ASTDTM is greater than the value of AENDTM, considering only those rows on which both variables are populated	Note	ADaMIG v1.0	3	9 (General Timing Variable Conventions); 10 (General Timing Variable Conventions)	ADaMIG v1.0, Section 3, Item 9 (General Timing Variable Conventions): Names of timing start variables end with an S followed by the 2 characters indicating the type of timing (e.g., SDT, STM), unless otherwise specified elsewhere in ADaMIG Section 3. ADaMIG v1.0, Section 3, Item 10 (General Timing Variable Conventions): Names of timing end variables end with an E followed by the 2 characters indicating the type of timing (e.g., EDT, ETM), unless otherwise specified elsewhere in ADaMIG Section 3.
362	1.1	ALL	The value of ASTDTM is greater than the value of AENDTM, considering only those rows on which both variables are populated	Note	ADaMIG v1.1	3.1.2	6; 7	ADaMIG v1.1, Section 3.1.2, Item 6: Names of timing start variables end with an S followed by the characters indicating the type of timing (i.e., SDT, STM, SDTM), unless otherwise specified elsewhere in ADaMIG Section 3 ADaMIG v1.1, Section 3.1.2, Item 7: Names of timing end variables end with an E followed by the characters indicating the type of timing (i.e., EDT, ETM, EDTM), unless otherwise specified elsewhere in ADaMIG Section 3.
363	1.0	ALL	ONTRTFL is not equal to Y or null	Error	ADaMIG v1.0	3.2.6	Table 3.2.6.1	ADaMIG v1.0, Section 3.2.6, Table 3.2.6.1: Code List/Controlled Terms for

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								ONTRTFL have allowable values of: "Y"
363	1.1	ALL	ONTRTFL is not equal to Y or null	Error	ADaMIG v1.1	3.3.8	Table 3.3.8.1	ADaMIG v1.1, Section 3.3.8, Table 3.3.8.1: Code List/Controlled Terms for ONTRTFL have allowable values of: "Y"
364	1.1	OCCDS	DOSEON or DOSCUMA is present and DOSEU is not present	Error	OCCDS IG v1.0	3.2.7	Table 3.2.7.1	OCCDS IG v1.0, Section 3.2.7, Table 3.2.7.1: CDISC Notes for DOSEU state: "Conditional on whether DOSEON and/or DOSCUMA are included."
365	1.0	ADSL:SDTM	SDTM.EX is present and neither TRTEDT or TRTEDTM are present	Warning	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: TRTEDT and/or TRTEDTM are required if there is an investigational product.
365	1.1	ADSL:SDTM	SDTM.EX is present and neither TRTEDT or TRTEDTM are present	Warning	ADaMIG v1.1	3.2	Table 3.2.6	ADaMIG v1.1, Section 3.2, Table 3.2.6: TRTEDT and/or TRTEDTM are required if there is an investigational product.
366	1.0	ADSL	RANDDT is not present when RANDFL is equal to Y for at least 1 record.	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: CDISC Notes for RANDDT state: "Required in randomized trials."
366	1.1	ADSL	RANDDT is not present when RANDFL is equal to Y for at least 1 record.	Error	ADaMIG v1.1	3.2	Table 3.2.8	ADaMIG v1.1, Section 3.2, Table 3.2.8: CDISC Notes for RANDDT state: "Required in randomized trials."
367	1.1	ADSL:SDTM	The value of ADSL.USUBJID is equal to the value of DM.USUBJID and ADSL.ACTARM is not equal to DM.ACTARM	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: DM.ARM
368	1.0	ADSL	TRxxAGy is not present and both TRxxPGy and TRTxxA are present.	Error	ADaMIG v1.0	3.1	Table 3.1.1	ADaMIG v1.0, Section 3.1, Table 3.1.1: Required when TRxxPGy is present and TRTxxA is present.
368	1.1	ADSL	TRxxAGy is not present and both TRxxPGy and TRTxxA are present.	Error	ADaMIG v1.1	3.2	Table 3.2.4	ADaMIG v1.1, Section 3.2, Table 3.2.4: Required when TRxxPGy is present and TRTxxA is present.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
369	1.0	BDS, OCCDS	*DTF is populated and neither *DT nor *DTM is populated	Error	ADaM IG v1.0; OCCDS IG v1.0	3; 3.2.4	6 (General Timing Variable Conventions); Table 3.2.4.1	ADaM IG v1.0, Section 3, Item 6 (General Timing Variable Conventions): Variables whose names end in DTF are date imputation flags. *DTF variables represent the level of imputation of the *DT variable based on the source SDTM DTC variable. *DTF = Y if the entire date is imputed. *DTF = M if month and day are imputed. *DTF = D if only day is imputed. *DTF = null if *DT equals the SDTM DTC variable date part equivalent. If a date was imputed, *DTF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done. OCCDS IG v1.0, Section 3.2.4, Table 3.2.4.1: CDISC Notes for ASTDTF state: "Conditional on whether any imputation is done for the start date."
369	1.1	BDS, OCCDS	*DTF is populated and neither *DT nor *DTM is populated	Error	ADaM IG v1.1; OCCDS IG v1.0	3.1.3; 3.2.4	1; Table 3.2.4.1	ADaM IG v1.1, Section 3.1.3, Item 1: As described in Table 3.1.5.1, variables whose names end in DTF are date imputation flags. *DTF variables represent the highest level of imputation of the *DT variable based on the source SDTM DTC variable. *DTF = Y if the year is imputed. *DTF = M if year is present and month is imputed. *DTF = D if only day is imputed. *DTF = null if *DT equals the SDTM DTC variable date part equivalent. If a date was imputed, *DTF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								imputation in *DTM if imputation was done. OCCDS IG v1.0, Section 3.2.4, Table 3.2.4.1: CDISC Notes for ASTDTF state: "Conditional on whether any imputation is done for the start date."
370	1.0	BDS, OCCDS	*TMF is populated and neither *TM nor *DTM is populated	Error	ADaM IG v1.0; OCCDS IG v1.0	3; 3.2.4	7 (General Timing Variable Conventions); Table 3.2.4.1	ADaM IG v1.0, Section 3, Item 7 (General Timing Variable Conventions): Variables whose names end in TMF are time imputation flags. *TMF variables represent the level of imputation of the *TM (and *DTM) variable based on the source SDTM DTC variable. *TMF = H if the entire time is imputed. *TMF = M if minutes and seconds are imputed. *TMF = S if only seconds are imputed. *TMF = null if *TM equals the SDTM DTC variable time part equivalent. For a given SDTM DTC variable, if only hours and minutes are ever collected, and seconds are imputed in *DTM as 00, then it is not necessary to set *TMF to "S". However if seconds are generally collected but are missing in a given value of the DTC variable and imputed as 00, or if a collected value of seconds is changed in the creation of *DTM, then the difference is significant and should be qualified in *TMF. If a time was imputed *TMF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done.

Check Number	IG Version	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type	Guide	Section	Item	Cited Guidance
								OCCDS IG v1.0, Section 3.2.4, Table 3.2.4.1: CDISC Notes for ASTTMF state: "Conditional on whether any imputation is done for the start time."
370	1.1	BDS, OCCDS	*TMF is populated and neither *TM nor *DTM is populated	Error	ADaM IG v1.1; OCCDS IG v1.0	3.1.3; 3.2.4	2; Table 3.2.4.1	ADaM IG v1.1, Section 3.1.3, Item 2: As described in Table 3.1.5.1, variables whose names end in TMF are time imputation flags. *TMF variables represent the level of imputation of the *TM (and *DTM) variable based on the source SDTM DTC variable. *TMF = H if the entire time is imputed. *TMF = M if minutes and seconds are imputed. *TMF = S if only seconds are imputed. *TMF = null if *TM equals the SDTM DTC variable time part equivalent. For a given SDTM DTC variable, if only hours and minutes are ever collected, and seconds are imputed in *DTM as 00, then it is not necessary to set *TMF to "S". However if seconds are generally collected but are missing in a given value of the DTC variable and imputed as 00, or if a collected value of seconds is changed in the creation of *DTM, then *TMF should be set to "S". If a time was imputed *TMF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done. OCCDS IG v1.0, Section 3.2.4, Table 3.2.4.1: CDISC Notes for ASTTMF state: "Conditional on whether any imputation is done for the start time."

5 Appendices

Appendix A: References

1. CDISC Analysis Data Model Team. Analysis Data Model (ADaM) 2.1. https://www.cdisc.org/standards/foundational/adam. Published December 17, 2009.
2. CDISC Analysis Data Model Team. Analysis Data Model (ADaM) implementation guide 1.0. https://www.cdisc.org/standards/foundational/adam. Published December 2009.
3. CDISC Analysis Data Model Team. Analysis Data Model (ADaM) implementation guide 1.1. https://www.cdisc.org/standards/foundational/adam. Published February 12, 2016.
4. CDISC Analysis Data Model Team. ADaM Structure for Occurrence Data (OCCDS) 1.0. https://www.cdisc.org/standards/foundational/adam. Published February 16, 2016.
5. CDISC. Study Data Tabulation Model (SDTM). https://www.cdisc.org/standards/foundational/sdtm
6. FDA. Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064994.htm. Published April 24, 2018.

Appendix B: Revision History

The table below summarizes changes between the previous release of the compliance checks and the current release.

Changes from ADaM Validation Checks v1.3 to ADaM Conformance Rules v2.0

- Formatting changes include:
  - Removal of ADaM IG Section Number and Text from ADaM IG columns
  - Addition of Guide, Section, Item, and Cited Guidance columns
  - Removal of Functional Group column
  - Removal of ADaM Variable Group column
  - Compliance check workbook now includes 1 row per rule per IG version, allowing the use of auto-filter on IG Version column to select rules specific to an implementation guide version.
  - Addition of Message Type column; see Section 3, Description of ADaM Conformance Rules Table for definition of "Error," "Warning," and "Note."
- Definition of"Type of Change"
  - Addition: New Rule
  - Revision: Major change to a rule from v1.3 which affects the overall meaning of the rule
  - Modification: Minor change which does not affect overall meaning of the rule
  - Deletion: Ruleis no longer valid

Check Number(s)	Type of Change	Description of Change
37.01	Revision	Revisionof existing Rule #37 and adapted to support ADaMIG v1.1.
38.01	Revision	Revision of existing Rule #38 and adapted to support ADaMIG v1.1.
90.01	Revision	Revision of existing Rule #90 and adapted to support ADaMIG v1.1.
91.01	Revision	Revision of existing Rule #91 and adapted to support ADaMIG v1.1.
180.01	Revision	Revision of existing Rule #180 and adapted to support ADaMIG v1.1.
244.01	Revision	Revision of existing Rule #244 and adapted to support ADaMIG v1.1.
257.01	Revision	Revision of existing Rule #257 and adapted to support ADaMIG v1.0 and v1.1.
258.01	Revision	Revision of existing Rule #258 and adapted to support ADaMIG v1.0 and v1.1.
259.01	Revision	Revision of existing Rule #259 and adapted to support ADaMIG v1.0 and v1.1.
320-356, 359-370	Addition	Added rules which were missing from previous releases found in ADaMIG v1.0, ADaMIG v1.1, or OCCDS v1.0.
3-4, 62-63, 65, 68, 73-74, 83, 87, 91, 94, 100-101, 107-108, 114-116, 153, 158, 161-162, 170-175, 179, 184-193, 202-203, 213-218, 244-251, 253, 255, 257-267, 273-278, 299-303, 314-319	Deletion	Removed checks due to either (1) lack of cited guidance in supporting documentation or (2) inability to be machine-testable.

Changes from ADaM Validation Checks v1.3 to ADaM Conformance Rules v2.0		
18, 37, 38, 41-43, 59, 72, 76-77, 81, 92-93, 95-96, 102, 105-106, 109-110, 117-118, 125-126, 129-131, 135-136, 141-142, 144, 146, 147, 149-150, 169, 178, 180, 212, 221-222, 224, 226-243, 280-298, 310-313	Modification	Modified the machine-testable failure criteria to add clarity or further define the scope of when the rule is appropriate.

Summary of Changes for Each Version of the Conformance Rules						
ADaM Validation Checks Version	IG Version	Number of Checks	Checks Deleted	Rules Added	Rules Modified	Rules Revised
v2.0	1.0	234	90	15	24	3
	1.1	272	N/A	N/A	N/A	N/A

Summary ofDifferences between IG Versions in v2.0					
ADaM Conformance Rules Version	IG Version	Checks Deleted	Rules Added	Rules Modified	Rules Revised
v2.0	1.0 to 1.1	1*	37	68	6

*Check #148 is valid for ADaMIG v1.0 but has been deleted from ADaMIG v1.1.

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