Age, treatment with systemic antibiotics, leukocyte count, serum albumin, and serum creatinine as a measure of renal function (ATLAS)

Clinical Classification Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

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Notes to Readers

This supplement is intended to be used with other CDISC user guides for specific therapeutic/disease areas and follows the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical Trials.

Revision History

Date	Version
2020-05-19	1.0 Final

1 Introduction

This document describes the CDISC implementation of the Age, treatment with systemic antibiotics, leukocyte count, serum albumin, and serum creatinine as a measure of renal function (ATLAS) clinical classification.

CDISC does not modify questionnaires, ratings, and scales (QRS) instruments to meet Clinical Data Acquisition Standards Harmonization (CDASH) case report form (CRF) standards.

The representation of data collected for this clinical classification is based on the Study Data Tabulation Model Implementation Guide (SDTMIG) Disease Response and Clin Classification (RS) domain model, which can be found on the CDISC website at: https://www.cdisc.org/standards/foundational/sdtmig.

These specific implementation details for this clinical classification are meant to be used in conjunction with the SDTMIG. All CDISC QRS documentation packages can be found on the CDISC website at: https://www.cdisc.org/foundational/qrs.

The CDISC Intellectual Property Policy can be found on the CDISC website at: https://www.cdisc.org/about/bylaws.

1.1 Representations and Warranties, Limitations of Liability, and Disclaimers

This document is a supplement to the SDTMIG for Human Clinical Trials and is covered under Appendix F of that document, which describes representations, warranties, limitations of liability, and disclaimers. Please see Appendix F of the SDTMIG for a complete version of this material.

CDISC specifies how to structure the data that has been collected in a database, not what should be collected or how to conduct clinical assessments or protocols.

2 Copyright Status

This instrument is in the public domain. CDISC has included the ATLAS in the CDISC library of QRS data standards supplements. Hence, CDISC developed RSTESTCD and RSTEST for each item based on the actual text on the clinical classification. There may be many versions of this instrument in the public domain or copyrighted. CDISC has chosen to use this version as the data standard.

The CDISC documentation of this instrument consists of: (1) controlled terminology, (2) standard database structure with examples, and (3) CRF(s) annotated with the CDISC SDTMIG variables with submission values.

Note: CDISC Controlled Terminology is maintained by National Cancer Institute (NCI) Enterprise Vocabulary Services (EVS). The most recent version should be accessed through the CDISC website at: https://www.cdisc.org/standards/terminology.

Reference for the Age, treatment with systemic antibiotics, leukocyte count, serum albumin, and serum creatinine as a measure of renal function (ATLAS):

- Miller, M.A., Louie,T., Mullane, K., Weiss, K., Lentnek, A., Golan, Y., et al. (2013). Derivation and validation of a simple clinical bedside score (ATLAS) for Clostridium difficile infection which predicts response to therapy. BMC Infectious Diseases, 13: 148.

3 The RS Domain Model

3.1 Assumptions for the RS Domain Model

All assumptions and business rules described in the SDTMIG RS domain are applicable to this supplement. Additional assumptions specific to the ATLAS are listed below.

ATLAS is a calculated score from 5 clinical and laboratory values collected at the time of *Clostridium difficile* infection (CDI) diagnosis. Each value is scored 0-2 and the total of the 5 scores is used to predict treatment response to CDI therapy.

1. The scale points include a numeric rating (0-2) and a description of what is represented by the rating (e.g., 0 = "< 60 years"). For ATLAS, RSORRES is populated with the text description while the numeric rating is represented in the standardized character and numeric result variables RSSTRESC and RSSTRESN.
2. The ATLAS instrument includes a total score that is considered as captured data on the CRF and is not considered as derived in the example below. This total score is considered as captured data when provided as part of Electronic Data Transfer (eDT) and is not considered as derived in the example below.
    a. If operationally defined by the sponsor, it is the sponsor's responsibility to set the --DRVFL flag based on its eCRF process to derive subtotals and total scores. An investigator-derived score written on a CRF will be considered a captured score and not flagged. When subtotal and total scores are derived by the sponsor, the derived flag (--DRVFL) is set to Y. However, when the subtotal and total scores are received from a central provider or vendor, the value would go into --ORRES and --DRVFL would be null (see SDTMIG Section 4.1.8.1, Origin Metadata for Variables).
3. Terminology:
    a. RSCAT, RSTESTCD, and RSTEST values are included in CDISC Controlled Terminology.
    b. A full list of value sets for the result field is provided in Section 4, SDTM Mapping Strategy.

3.2 Example for the ATLAS RS Domain Model

The following ATLAS example shows the terminology used to implement the instrument in the RS domain. This example shows the data for 1 subject collected at the baseline visit for an ATLAS instrument. The example uses CDISC Controlled Terminology for RSTESTCD, RSTEST, and RSCAT. All original results are represented with preferred terminology in RSORRES. This result is then transformed into the standard numeric score in RSSTRESN and a character representation of the standard numeric score in RSSTRESC.

The table represents the questions from the ATLAS form. The ATLAS score is the sum of all the scale points and is represented in row 6.

rs.xpt

Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	RSSTRESN	RSLOBXFL	VISITNUM	RSDTC
1	STUDYX	RS	STUDYX-123	1	ATLAS101	ATLAS1-Age	ATLAS	60-79 years	1	1	Y	1	2015-05-15
2	STUDYX	RS	STUDYX-123	2	ATLAS102	ATLAS1-Treatment With Antibiotics	ATLAS	Yes	2	2	Y	1	2015-05-15
3	STUDYX	RS	STUDYX-123	3	ATLAS103	ATLAS1-Leukocyte Count	ATLAS	< 16,000	0	0	Y	1	2015-05-15
4	STUDYX	RS	STUDYX-123	4	ATLAS104	ATLAS1-Albumin	ATLAS	26 - 35 g/L	1	1	Y	1	2015-05-15
5	STUDYX	RS	STUDYX-123	5	ATLAS105	ATLAS1-Serum Creatinine	ATLAS	>= 180 umol/L	2	2	Y	1	2015-05-15
6	STUDYX	RS	STUDYX-123	6	ATLAS106	ATLAS1-Score	ATLAS	6	6	6	Y	1	2015-05-15

4 SDTM Mapping Strategy

This section is used for reference regarding the CRF data capture and to understand the alignment of the instrument to the SDTM RS domain. It also provides guidance on how the result variables (RSORRES, RSSTRESC, and RSSTRESN) should be populated.

RSTESTCD = "ATLAS101" RSTEST = "ATLAS1-Age"

RSORRES	RSSTRESC	RSSTRESN
< 60 years	0	0
60-79 years	1	1
>= 80 years	2	2

RSTESTCD = "ATLAS102" RSTEST = "ATLAS1-Treatment With Antibiotics"

RSORRES	RSSTRESC	RSSTRESN
No	0	0
Yes	2	2

RSTESTCD = "ATLAS103" RSTEST = "ATLAS1-Leukocyte Count"

RSORRES	RSSTRESC	RSSTRESN
< 16,000	0	0
16,000 - 25,000	1	1
> 25,000	2	2

RSTESTCD = "ATLAS104" RSTEST = "ATLAS1-Albumin"

RSORRES	RSSTRESC	RSSTRESN
> 35 g/L	0	0
26 - 35 g/L	1	1
<= 25 g/L	2	2

RSTESTCD = "ATLAS105" RSTEST = "ATLAS1-Serum Creatinine"

RSORRES	RSSTRESC	RSSTRESN
<= 120 umol/L	0	0
121 - 179 umol/L	1	1
>= 180 umol/L	2	2

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