Amendment 1 to the Study Data Tabulation Model (SDTM) v1.2 and the SDTM Implementation Guide: Human Clinical Trials V3.1.2

Prepared by the

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Notes to Readers

This is the first Amendment to Version 1.2 of the Study Data Tabulation Model Document (SDTM) and Version 3.1.2 of the SDTM Implementation Guide: Human Clinical Trials. This document includes additional variables related to human clinical trials added at the request of FDA CDER, and is being posted for implementation prior to the next formal releases of the SDTM and SDTMIG.

Revision History

Date	Version	Summary of Changes
2011-04-05	Version 1.0 Draft	Initial release for comment.
2011-12-14	Version 1.0 Final	Final Release for Implementation.

Note: Please see Appendix A for Representations and Warranties, Limitations of Liability, and Disclaimers.

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1. Additions to the Study Data Tabulation Model

1.1. ADDITIONS TO SECTION 2.2.2: THE EVENTS OBSERVATION CLASS

Add the following variables:

Variable Name	Variable Label	Type	Role	Description	SDTMIG	SEND
Qualifier Variables						
--LLT	Lowest Level Term	Char	Variable Qualifier of --TERM	MedDRA Lowest Level Term.	√	
--LLTCD	Lowest Level Term Code	Num	Variable Qualifier of --LLT	MedDRA Lowest Level Term code.	√	
--PTCD	Preferred Term Code	Num	Variable Qualifier of --DECOD	MedDRA Preferred Term code.	√	
--HLT	High Level Term	Char	Variable Qualifier of --TERM	MedDRA High Level Term from the primary path.	√	
--HLTCD	High Level Term Code	Num	Variable Qualifier of --HLT	MedDRA High Level Term code from the primary path.	√	
--HLGT	High Level Group Term	Char	Variable Qualifier of --TERM	MedDRA High Level Group Term from the primary path.	√	
--HLGTCD	High Level Group Term Code	Num	Variable Qualifier of --HLGT	MedDRA High Level Group Term code from the primary path.	√	
--BDSYCD	Body System or Organ Class Code	Num	Variable Qualifier of --BODSYS	MedDRA System Organ Class code used for analysis.	√	
--SOC	Primary System Organ Class	Char	Variable Qualifier of --TERM	MedDRA primary System Organ Class.	√	
--SOCCD	Primary System Organ Class Code	Num	Variable Qualifier of --SOC	MedDRA primary System Organ Class code.	√	

Variable order should be as follows:

--LLT --LLTCD	In order, after --MODIFY
--PTCD --HLT --HLTCD --HLGT --HLGTCD	In order, after --DECOD
--BDSYCD --SOC --SOCCD	In order, after --BODSYS

1.2. ADDITIONS TO SECTION 2.2.6: THE DEMOGRAPHICS DOMAIN

Add the following variables:

Variable Name	Variable Label	Type	Description
Qualifier Variables			
ACTARMCD	Actual Arm Code	Char	Short name for the actual Arm in which the subject participated during the trial, limited to 20 characters.
ACTARM	Description of Actual Arm	Char	Description of the actual Arm in which the subject participated during the trial.
RFXSTDTC	Date/Time of First Study Treatment	Char	First date of exposure to any protocol-specified treatment or therapy for the subject in ISO 8601 character format.
RFXENDTC	Date/Time of Last Study Treatment	Char	Last date of exposure to any protocol-specified treatment or therapy for the subject in ISO 8601 character format.
RFICDTC	Date/Time of Informed Consent	Char	Date/time of informed consent in ISO 8601 character format.
RFPENDTC	Date/Time of End of Participation	Char	Date/time when subject ended participation or follow-up in a trial, in ISO 8601 character format. Should correspond to the last known date of contact.
DTHDTC	Date/Time of Death	Char	Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database.
DTHFL	Subject Death Flag	Char	Indicates the subject died. Should be Y or null. Should be populated even when the death date is unknown.

Variable order should be as follows:

ACTARMCD ACTARM	In order, after ARM
RFXSTDTC RFXENDTC RFICDTC RFPENDTC DTHDTC DTHFL	In order, after RFENDTC

2. Additions to the SDTMIG

2.1. DEMOGRAPHICS

2.1.1. ADDITIONS TO SECTION 5.1.1: DEMOGRAPHICS - DM

Add the following variables:

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
ACTARMCD	Actual Arm Code	Char	*	Record Qualifier	Code of actual Arm. When an Arm is not planned (not in Trial Arms), ACTARMCD will be UNPLAN. Randomized subjects who were not treated will be given a value of NOTTRT. Values should be "SCRNFAIL" for screen failures and "NOTASSGN" for subjects not assigned to treatment. Restricted to values in Trial Arms in all other cases. ACTARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ACTARMCD is longer than for other short variables to accommodate the kind of values that are likely to be needed for crossover trials.	Req
ACTARM	Description of Actual Arm	Char	*	Synonym Qualifier	Description of actual Arm. When an Arm is not planned (not in Trial Arms), ACTARM will be "Unplanned Treatment". Randomized subjects who were not treated will be given a value of "Not Treated". Values should be "Screen Failure" for screen failures and "Not Assigned" for subjects not assigned to treatment. Restricted to values in Trial Arms in all other cases.	Req
RFXSTDTC	Date/Time of First Study Treatment	Char	ISO 8601	Record Qualifier	First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.	Exp
RFXENDTC	Date/Time of Last Study Treatment	Char	ISO 8601	Record Qualifier	Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing).	Exp
RFICDTC	Date/Time of Informed Consent	Char	ISO 8601	Record Qualifier	Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent.	Exp
RFPENDTC	Date/Time of End of Participation	Char	ISO 8601	Record Qualifier	Date/time when subject ended participation or follow-up in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact. Examples include completion date, withdrawal date, last follow-up, date recorded for lost to follow up, or death date.	Exp
DTHDTC	Date/Time of Death	Char	ISO 8601	Record Qualifier	Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database.	Exp
DTHFL	Subject Death Flag	Char	(NY)	Record Qualifier	Indicates the subject died. Should be Y or null. Should be populated even when the death date is unknown.	Exp

***** *Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value).*

2.1.2. ADDITIONS TO SECTION 5.1.1.1: ASSUMPTIONS FOR DEMOGRAPHICS DOMAIN MODEL

9. The order of these new variables within the domain should follow the rules as described in Section 4.1.1.4 of the SDTMIG and the order described in Section 1.2 of this document.
10. As described in Section 4.1.4.4 of the SDTMIG, RFSTDTC is used to calculate study day variables. RFSTDTC is usually defined as the date/time when a subject was first exposed to study drug. This definition applies for most interventional studies, when the start of treatment is the natural and preferred starting point for study day variables and thus the logical value for RFSTDTC. In such studies, when data are submitted for subjects who are ineligible for treatment (e.g., screen failures with ARMCD=SCRNFAIL), subjects who were enrolled but not assigned to an arm (ARMCD=NOTASSGN), or subjects who were randomized but not treated (ACTARMCD=NOTTRT), RFSTDTC will be null. For studies with designs that include a substantial portion of subjects who are not expected to be treated, a different protocol milestone may be chosen as the starting point for study day variables. Some examples include non-interventional or observational studies, studies with a no-treatment arm, or studies where there is a delay between randomization and treatment.
11. RFXSTDTC may be the same as RFSTDTC, but it might be different for some studies. An example of the latter would be when RFSTDTC was defined as the date the informed consent was signed. RFXSTDTC should be the same as SESTDTC for the first treatment Element described in the SE dataset.
12. RFXENDTC may often be the same as the SEENDTC for the last treatment Element described in the SE dataset. RFXENDTC may or may not be the same as RFENDTC, the date defined as the reference end for a subject.
13. RFICDTC should correspond to the date of the informed consent protocol milestone in DS, if that protocol milestone is documented in DS. In the event that there are multiple informed consents, this will be the date of the first one.
14. RFPENDTC will be the last date of participation for a subject for data included in a submission. This should be the last date of any record for the subject in the database at the time it's locked for submission. As such, it may not be the last date of participation in the study if the submission includes interim data.

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2.2. ADVERSE EVENTS

2.2.1. ADDITIONS TO SECTION 6.2.1: ADVERSE EVENTS - AE

Add the following variables:

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
AELLT	Lowest Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the Lowest Level Term.	Exp
AELLTCD	Lowest Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the Lowest Level Term.	Exp
AEPTCD	Preferred Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the Preferred Term.	Exp
AEHLT	High Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the High Level Term for the primary System Organ Class.	Exp
AEHLTCD	High Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the High Level Term for the primary System Organ Class.	Exp
AEHLGT	High Level Group Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the High Level Group Term for the primary System Organ Class.	Exp
AEHLGTCD	High Level Group Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the High Level Group Term for the primary System Organ Class.	Exp
AEBDSYCD	Body System or Organ Class Code	Num	MedDRA	Variable Qualifier	Dictionary derived. Code for the body system or organ class used by the sponsor. When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor‘s analyses and summary tables, which may not necessarily be the primary SOC.	Exp
AESOC	Primary System Organ Class	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the primary System Organ Class. Will be the same as AEBODSYS if the primary SOC was used for analysis.	Exp
AESOCCD	Primary System Organ Class Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the primary System Organ Class. Will be the same as AEBDSYCD if the primary SOC was used for analysis.	Exp

2.2.2. ADDITIONS TO ASSUMPTIONS FOR SECTION 6.2.1.1: ADVERSE EVENTS DOMAIN MODEL

9. Variable order in the domain should follow the rules as described in Section 4.1.1.4 of the SDTMIG and the order described in Section 1.1 of this document.
10. The addition of AELLT, AELLTCD, AEPTCD, AEHLT, AEHLTCD, AEHLGT, AEHLGTCD, AEBDSYCD, AESOC, and AESOCCD is applicable to submissions coded in MedDRA only. Data items are not expected for non-MedDRA coding.

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2.3. ASSUMPTIONS FOR DOMAIN MODELS

2.3.1. ADDITION OF SECTION 4.1.2.9 - VARIABLE LENGTHS

Very large transport files have become an issue for FDA to process. One of the main contributors to the large file sizes has been sponsors using the maximum length of 200 for character variables. To help rectify this situation:

- The maximum SAS Version 5 character variable length of 200 characters should not be used unless necessary.
- Sponsors should consider the nature of the data, and apply reasonable, appropriate lengths to variables. For example:
  - The length of flags will always be 1
  - --TESTCD and IDVAR will never be more than 8, so length can always be set to 8
  - The length for variables which use controlled terminology can be set to the length of the longest term.

2.4. CHANGES TO APPENDIX C5: REMOVAL OF STANDARD SUPPLEMENTAL QUALIFIER NAME CODES

The following QNAMs should be removed since they have been replaced by variables in the Events general observation class:

QNAM	QLABEL
--HLGT	High Level Group Term
--HLT	High Level Term
--LLT	Lowest Level Term
--LLTCD	Lowest Level Term Code
--PTCD	Preferred Term Code
--HLTCD	High Level Term Code
--HLGTCD	High Level Group Term Code
--SOCCD	System Organ Class Code

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