

THE FUTURE OF
CLINICAL DEVELOPMENT



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Worst CDISC Implementation Processes – How to Avoid Some Very Basic Mistakes in SDTM, ADaM, Define.xml and Reviewer's Guide Production

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Define.xml and Reviewer's Guide Production

- Data package content
 - SDTM datasets (XPT,SAS-files), Define.xml, SDRG
 - ADaM datasets (XPT, SAS-files), Define.xml, ADRG

STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AELT	AELLTCD	AEDECOD
MR308-1501	AE	MR308-1501-1584005	1	HEAD DISCOMFORT	Head discomfort	10019194	Head discomfort
MR308-1501	AE	MR308-1501-1584015	1	ALOPECIA	Reynolds	10011760	Reynolds
MR308-1501	AE	MR308-1501-1584015	2	DIZZINESS	Dizziness	10013573	Dizziness
MR308-1501	AE	MR308-1501-1584015	3	HYPERHIDROSIS	Hyperhidrosis	10020642	Hyperhidrosis
MR308-1501	AE	MR308-1501-1584015	4	NAUSEA	Nausea	10028113	Nausea
MR308-1501	AE	MR308-1501-1584019	1	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	2	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	3	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	4	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	5	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	6	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	7	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	8	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	9	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	10	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	11	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	12	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	13	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	14	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	15	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	16	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	17	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	18	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	19	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	20	CONSTIPATION	Constipation	10010774	Constipation
MR308-1501	AE	MR308-1501-1584019	21	CONSTIPATION	Constipation	10010774	Constipation

Tabulation Datasets for Study CDISC01 (SDTM-IG 3.1.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xpt
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt
SE	Subject Elements	SPECIAL PURPOSE	One record per actual Element per subject	Tabulation	STUDYID, USUBJID, SESTDTC, SEENDTC, TAETORD, ETCD	se.xpt
SV	Subject Visits	SPECIAL PURPOSE	One record per actual visit per subject	Tabulation	STUDYID, USUBJID, SVSTDTC, VISITNUM	sv.xpt
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CHSTDTC, CMENDTC, CMCAT, CMTRT, CHDOSTXT, CMDOSE, CHINDOC, CHDOSFRQ	cm.xpt
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXSTDTC, EXENDTC, EXTRT, EXDOSE	ex.xpt
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD, AESTDTC	ae.xpt
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSSTDTC, DSSTXT, DSCAT, DSDECOD	ds.xpt

Study Data Reviewer's Guide

SDRG, Inc.
Study SDRG-001A
Version 2014-08-06



Define.xml and Reviewer's Guide Production

Day 1-28

STUDYID	Study Identifier	text	10			Protocol	Yes	Identifier	
DOMAIN	Domain	text	2	DOMAIN		Assigned	Yes	Identifier	
	Abbreviation								
USUBJID	Unique Subject Identifier	text	30		raw.dose.pt	Assigned	Yes	Identifier	Site Identifier is 'XX' Subject Identifier: concatenate '000' with subjid (for example: '000101')
EXSPID	Sponsor-Defined Identifier	text	1			Derived	No	Identifier	sort raw.suelup (whenever the variable up01 ~= blank) by PT and UDDTC and assign number per subject by UDDTC
EXTPT	Planned Time Point Name	text	15	TPT	raw.dose.time point	CRF Pages 17, 22, 45	No	Timing	Use the compiled macro map_vis_tp, using the visit tab as input



STUDYID	DOMAIN	USUBJID	AESQ	AETERM	AELLT	AELLTD	AELDECOD
MR308-1501	AE	MR308-1501-198405	1	HEAD DISCOMFORT	Head discomfort	10019194	Head discomfort
MR308-1501	AE	MR308-1501-1984015	1	ALOPECIA	Alopecia	10001760	Alopecia
MR308-1501	AE	MR308-1501-1984015	2	DIZZINESS	Dizziness	10013573	Dizziness
MR308-1501	AE	MR308-1501-1984015	3	HYPERHIDROSIS	Hyperhidrosis	10020642	Hyperhidrosis
MR308-1501	AE	MR308-1501-1984015	4	HAIR LOSS	Hair loss	10020313	Hair loss
MR308-1501	AE	MR308-1501-1984019	1	CONJUNCTIVITIS	Conjunctivitis		
MR308-1501	AE	MR308-1501-1984019	2	DIAPHORETTIC	Diaphoretic		
MR308-1501	AE	MR308-1501-1984022	1	INFILTRATION	Infiltration		
MR308-1501	AE	MR308-1501-1984025	1	BAC	BAC		
MR308-1501	AE	MR308-1501-1984025	2	NASAL	Nasal		
MR308-1501	AE	MR308-1501-1984025	3	NAUSEA	Nausea		
MR308-1501	AE	MR308-1501-1984026	1	DRY	Dry		
MR308-1501	AE	MR308-1501-1984026	2	DRY	Dry		
MR308-1501	AE	MR308-1501-1984026	3	DRY	Dry		
MR308-1501	AE	MR308-1501-1984026	4	HEA	Hea		
MR308-1501	AE	MR308-1501-1984030	1	SOMNOLENCE	Somnolence		
MR308-1501	AE	MR308-1501-1984033	1	TENDONITIS	Tendonitis		
MR308-1501	AE	MR308-1501-1984034	1	ORAL	Oral		
MR308-1501	AE	MR308-1501-1984035	1	MUSCLE	Muscle		
MR308-1501	AE	MR308-1501-1984035	2	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	3	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	4	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	5	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	6	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	7	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	8	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	9	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	10	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	11	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	12	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	13	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	14	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	15	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	16	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	17	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	18	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	19	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	20	STIFF	Stiff		
MR308-1501	AE	MR308-1501-1984035	21	STIFF	Stiff		



	STUDYID	DOMAIN	SUBJID	AESQ	AETERN	AELLT	AELLTCD	AEEDECD
MR308-1501	AE	MR308-1501-1894005	1	HEAD DISCOMFORT	Head discomfort		10019134	Head discomfort
MR308-1501	AE	MR308-1501-1894015	1	ALOPECIA	Alopecia		10017780	Alopecia
MR308-1501	AE	MR308-1501-1894015	2	DIZZINESS	Dizziness		10011573	Dizziness
MR308-1501	AE	MR308-1501-1894015	3	HYPERHIDROSIS	Hyperhidrosis		10020542	Hyperhidrosis
MR308-1501	AE	MR308-1501-1894015	4	NAUSEA	Nausea		10022813	Nausea
MR308-1501	AE	MR308-1501-1894019	1	CONSTIPATION	Constipation		10016774	Constipation
MR308-1501	AE	MR308-1501-1894019	2	DIARRHOEA	Diarrhoea		10017275	Diarrhoea
		STUDYID		MDVIDO		SUBKEY		VOID
MR308-1501	AE	1818		MDV_8.0		Subject 1		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 2		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 3		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 4		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 5		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 6		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 7		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 8		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 9		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 10		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 11		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 12		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 13		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 14		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 15		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 16		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 17		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 18		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 19		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 20		SE 01
MR308-1501	AE	1818		MDV_8.0		Subject 21		SE 01

Tabulation Datasets for Study CDISC01 (SDTM-IG 3.1.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.spt
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCDC	te.spt
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.spt
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.spt
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.spt
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.spt
SE	Subject Elements	SPECIAL PURPOSE	One record per actual Element per subject	Tabulation	STUDYID, USUBJID, SESTDTC, SEENDTC, TAETORD, ETCDC	se.spt
SV	Subject Visits	SPECIAL PURPOSE	One record per actual visit per subject	Tabulation	STUDYID, USUBJID, SVSTDTC, VISITNUM	sv.spt
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CMSTDTC, CMENDTC, CMCAT, CMTRT, CMDOSTRT, CDDOSU, CHINDC, CHDSCRQ	cm.spt
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXSTDTC, EXENDTC, EXTRT, EXDOSQ	ex.spt
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD, AESTDTC	ae.spt
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSSTDYD, DSSTDTC, DSCAT, DSDSCOD	ds.spt

Study Data Reviewer's Guide

SDRG, Inc.
Study SDRG-001A
Version 2014-08-06



Define.xml and Reviewer's Guide Production

Variable	Label	Key	Type	Length	Derivation/Comment
EXDOSE	Dose per Administration	6	integer	2	IF tabl >10 set to 4, else if Table not missing, set to 6. else set to table X 12
EXDOSU	Dose Units		text	2	Derived from ARM, ARMCD - equal to mg
EXDOSFRM	Dose Form		text	7	

Variable	Label	Type	Length / Display Format	Controlled Terms or Format	Source/Derivation/Comment
AWRANGE	Analysis Window Valid Relative Range	text	9		
AWTARGET	Analysis Window Target	integer	8		
AWTDIFF	Analysis Window Diff from Target	integer	8		
AWLO	Analysis Window Beginning Timepoint	integer	8		
AWHI	Analysis Window Ending Timepoint	integer	8		



Define.xml and Reviewer's Guide Production

5.2.2 ADTTE – Time to Event Analysis Dataset

The time to event dataset was used to support the primary study endpoints.

5.2.3 ADLBCHEM – Chemistry Results Analysis Dataset,

These laboratory datasets were used primarily to support shift table analysis based on toxicity grade.

4.2 Issues Summary

Dataset	Diagnostic Message	Severity	Count	Explanation
AE	EPOCH value not found in 'Epoch' extensible codelist	Warning	28	
AE	Missing End Time-Point value	Warning	3	
AE	Model permissible variable added into standard domain	Warning	1	
AE	Permissible variable with missing value for all records	Warning	6	
AE	No Treatment Emergent info for Adverse Event	Warning	28	
CM	CMDOSFRQ value not found in 'Frequency' extensible codelist	Warning	1	



Solution

- Produce and QC the define.xml content parallel to dataset production
- Set up a structure to collect information for the Reviewer's Guide

Variable	Label	Type	Length	Codelist / Controlled terms	Source	Origin	Mandatory (Yes/No)	Role	Comments	Additional comments
STUDYID	Study Identifier	text	10			Protocol	Yes	Identifier		
DOMAIN	Domain Abbreviation	text	2	DOMAIN		Assigned	Yes	Identifier		
USUBJID	Unique Subject Identifier	text	30		raw.dose.pt	Assigned	Yes	Identifier	Study identifier, site identifier, and subject identifier, concatenated and separated by hyphens.	Site Identifier is :XX' Subject Identifier: concatenate '000' with subjid (for example: '000101')
EXSPID	Sponsor-Defined Identifier	text	1			Derived	No	Identifier	Sequential number identifying records within each USUBJID for supplemental dosing data	sort raw.suelup (whenever the variable up01 ~= blank) by PT and UDDTC and assign number per subject by UDDTC
EXTPT	Planned Time Point Name	text	15	TPT	raw.dose.time point	CRF Pages 17, 22, 45	No	Timing		Use the compiled macro map_vis_tp, using the visit tab as input



Postponing Resolving Issues





Postponing Resolving Issues

Issue Summary					
Source	Pinnacle 21 ID	Publisher ID	Message	Severity	Found
ADAE					
	AD0042	42	*TM does not have the ADaM required SAS time format	Error	2
	AD0269	269,270,271	TRTEMFL flag value is not Y or null	Error	111
	AD0279	279,282	AESEVN value != 1, 2, 3, or null	Error	235
ADEG					
	AD0018	18	Variable label mismatch between dataset and ADaM standard	Error	5
	AD0047	47,49,50,51,5	Required variable is not present	Error	1
	AD0110	110	Inconsistent value for AVISIT	Error	149
	AD0256	256	USUBJID value does not exist in the ADaM ADSL domain	Error	21561
ADLB					
	AD0018	18	Variable label mismatch between dataset and ADaM standard	Error	4
	AD0047	47,49,50,51,5	Required variable is not present	Error	1
	AD0110	110	Inconsistent value for AVISIT	Error	196
	AD0141	141	Inconsistent value for PARAM within a unique PARAMCD	Error	1531
	AD0146	146	Inconsistent value for PARAM	Error	1531
	AD0185	185	Illegal variable name: y is not in [1-9] for PARCATy(N)	Error	1
	AD0192	192	Illegal variable name: y is not in [1-9] for SHIFTy(N)	Error	1
	AD0196	196,197	Required PARAM value is null	Error	260
	AD0196	196,197	Required PARAMCD value is null	Error	260

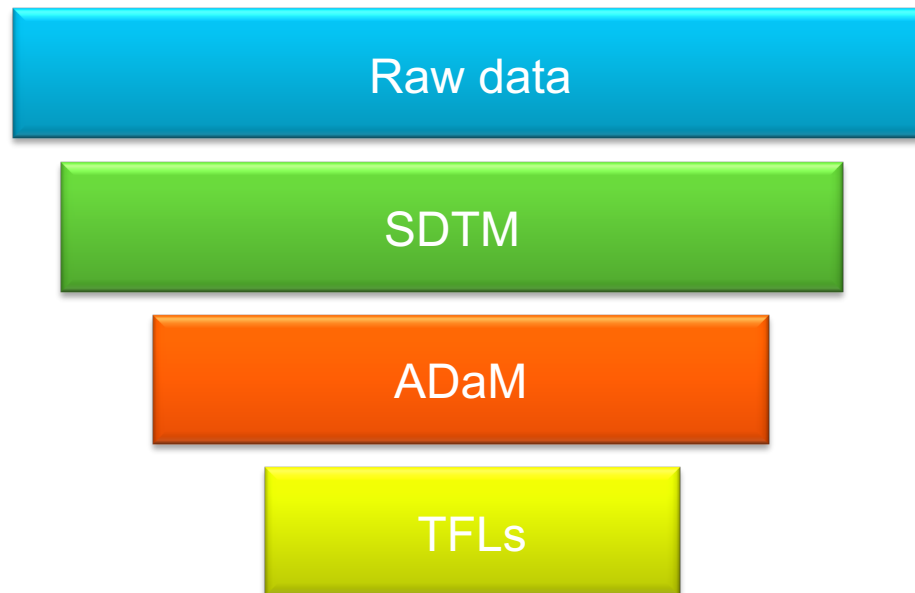


- Solution
 - Separate data issues from programming issues
 - Run compliance checks on every completed domain (i.e., Pinnacle 21)
 - QC define.xml content together with the SDTM or ADaM dataset

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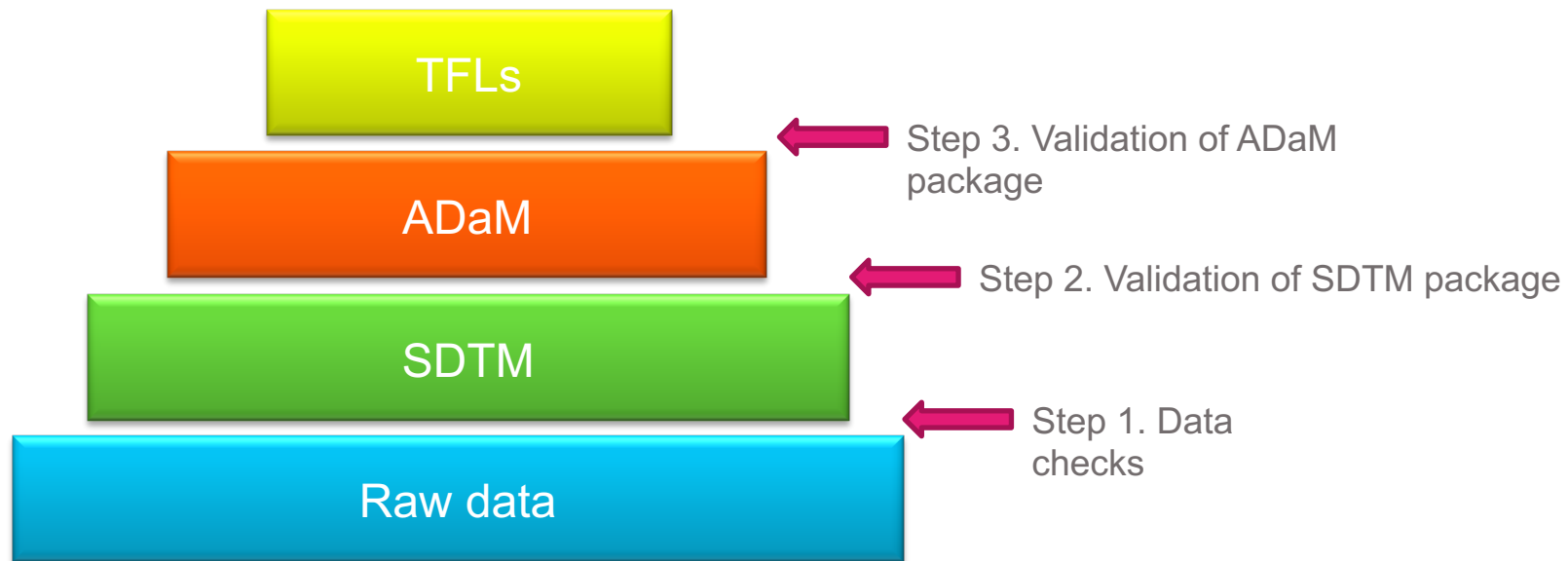
When to sign off what?





When to sign off what?

Solution





What CDISC version?

CDISC compliant or FDA/PMDA compliant?



Analysis Data Model (ADaM) Implementation Guide

Prepared by the
CDISC Analysis Data Model Team

[Redacted]

Notes to Readers
This Implementation Guide is Version 1.0 (V1.0) and corresponds to Version 2.1 of the CDISC Analysis Data Model.

Revision History

Date	Version	Summary of Changes
Dec. 17, 2009	1.0 Final	Released version reflecting all changes and corrections identified during comment period.
May 30, 2008	1.0 Draft	Draft for Public Comment



Analysis Data Model Implementation Guide Version 1.1

Prepared by the
CDISC Analysis Data Model Team

[Redacted]

Notes to Readers
This Implementation Guide is Version 1.1 and corresponds to Version 2.1 of the CDISC Analysis Data Model.

Revision History

Date	Version	Summary of Changes
2016-02-12	1.1 Final	Released version reflecting all changes and corrections identified during comment period.
2014-05-23	1.1 Draft	Draft for Public Comment
2009-12-17	1.0 Final	

Note: Please see [Appendix C](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.



What CDISC version?



Analysis Data Model (ADaM) Implementation Guide

Prepared by the
CDISC Analysis Data Model Team

Notes to Readers

This Implementation Guide is Version 1.0 (V1.0) and corresponds to Version 2.1 of the CDISC Analysis Data Model.

Revision History

Date	Version	Summary of Changes
Dec. 17, 2009	1.0 Final	Released version reflecting all changes and corrections identified during comment period.
May 30, 2008	1.0 Draft	Draft for Public Comment



Analysis Data Model Implementation Guide Version 1.1

Prepared by the
CDISC Analysis Data Model Team

Notes to Readers

This Implementation Guide is Version 1.1 and corresponds to Version 2.1 of the CDISC Analysis Data Model.

Revision History

Date	Version	Summary of Changes
2016-02-12	1.1 Final	Released version reflecting all changes and corrections identified during comment period.
2014-05-23	1.1 Draft	Draft for Public Comment
2009-12-17	1.0 Final	

Note: Please see [Appendix C](#) for Representations and Warranties; Limitations of Liability, and Disclaimers.



What CDISC version?

Variable label mismatches

SRCDOM	Source Data	Char		Perm	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 SUPQUAL.
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SRCDOM	Source Domain	Char		Perm	The 2-character identifier of the SDTM domain that relates to AVAL or AVALC.
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ADEC					
	AD0018	18	Variable label mismatch between dataset and ADaM standard		Error 4
	AD0047	47,49,50,51,52,53	Required variable is not present		Error 3



What CDISC version?

Missing TRTP in BDS datasets

TRTP	Planned Treatment	Char		Cond	TRTP is a record-level identifier that represents the planned treatment attributed to a record for analysis purposes. TRTP indicates how treatment varies by record within a subject and enables analysis of crossover and other designs. Though there is no requirement that TRTP will correspond to the TRTxP as defined by the record's value of APERIOD, if populated, TRTP must match at least one value of the character planned treatment variables in ADSL (e.g., TRTxP, TRTSEQP, TRxxPGy). As noted previously, <u>at least one treatment variable is required even in non-randomized trials. This requirement is satisfied by any subject-level or record-level treatment variables (e.g., TRTxP, TRTP, TRTA).</u> Even if not used for analysis, any ADSL treatment variable may be included in the BDS dataset.
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TRTP	Planned Treatment	Char		Req	TRTP is a record-level identifier that represents the planned treatment attributed to a record for analysis purposes. TRTP indicates how treatment varies by record within a subject and enables analysis of crossover and other designs. TRTxP (copied from ADSL) may also be needed for some analysis purposes, and may be useful for traceability and to provide context.
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ADEG					
AD0018	18	Variable label mismatch between dataset and ADaM standard			Error 4
AD0047	47,49,50,51,52,53	Required variable is not present			Error 3



What CDISC version?



ADaM Structure for Occurrence Data (OCCDS) Version 1.0

Prepared by the
CDISC Analysis Data Model Team

Notes to Readers

This Analysis model uses the principles, structures and standards described in the CDISC Analysis Data Model Version 2.1 and Implementation Guide v1.1 documents.



What CDISC version?

Invalid data structure

ADaM 1.0: ADSL, BDS and ADaM OTHER

ADaM 1.1 also includes OCCDS

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
General Observation Class	ADAM OTHER		An analysis dataset that doesn't conform to a pre-defined ADaM dataset structure (e.g. ADSL, BDS or OCCDS).	CDISC Other ADaM Dataset
General Observation Class	BASIC DATA STRUCTURE	BDS	An ADaM BDS dataset contains one or more records per subject, per analysis parameter, per analysis time point. Variables include the value being analyzed (e.g., AVAL) and the description of the value being analyzed (e.g., PARAM). Other variables in the dataset provide more information about the value being analyzed (e.g., the subject identification) or describe and trace the derivation of it (e.g., DTYPE) or support the analysis of it (e.g., treatment variables, covariates).	CDISC Basic Data Structure Dataset
General Observation Class	INTEGRATED BASIC DATA STRUCTURE	IBDS	IBDS is the ADaM Model for the Integrated Basic Data Structure. The structure includes per pool as defined in the integrated SAP when multiple records per subject are included in integrated ADSL.	CDISC Integrated Basic Data Structure Dataset
General Observation Class	INTEGRATED OCCURRENCE DATA STRUCTURE	IOCCDS	IOCCDS is the ADaM Model for Integrated Occurrence Data structure. The structure includes per pool as defined in the integrated SAP when multiple records per subject are included in integrated ADSL.	CDISC Integrated Occurrence Data Structure Dataset
General Observation Class	INTEGRATED SUBJECT LEVEL	IADSL	IADSL is the ADaM Model for Integrated Subject Level Analysis Dataset. The structure is one record per subject per pool as defined in the integrated SAP. Multiple records per subject are required in an integrated ADSL dataset when any subject's data is used in more than one pool and the values for subject-level variables differ across pools.	CDISC Integrated Subject Level Dataset
General Observation Class	OCCURRENCE DATA STRUCTURE	OCCDS	The Occurrence Data Structure (OCCDS) is the ADaM data structure for occurrence analysis. Occurrence analysis is the counting of subjects with a record or term, and often includes a structured hierarchy of dictionary coding categories.	CDISC Occurrence Data Structure
General Observation Class	SUBJECT LEVEL ANALYSIS DATASET	ADSL	The Subject-Level Analysis Dataset (ADSL) is a one-record-per-subject dataset which contains variables that describe subject demographic characteristics and group the subjects for analysis. ADSL is the primary source for subject-level variables included in other analysis datasets such as population flags and treatment variables.	CDISC Subject Level Analysis Dataset

DEFINE				
DD0022		Invalid Standard Version value '2.1' for 'CDISC ADaM'	Error	1
DD0055		Invalid Class value	Error	11
DD0084		Referenced File is missing	Error	1



What CDISC version?

Solution

- Understand your companies expectations
- Understand your client needs
- Make use of the newest implementation guides but keep your data package compliant with FDA and PMDA standard catalogues