

ADaM

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What is it and what's next?

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Statistical Programming

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ADaM in a Nutshell

- ✓ Analysis-ready datasets
 - "one statistical procedure away"
- ✓ Metadata similar as known for SDTM
 - Plus optional analysis results metadata
- ✓ TRACEABILITY
 - Communicate data flow from CRF to analysis result and vice versa
- ✓ Standard Data Structures
 - Subject-Level Analysis Dataset (ADSL)
 - Basic Data Structure (BDS)
 - (Adverse Events Analysis Dataset (ADAE))
 - Option of OTHER unspecified data structures

A Common Process Flow

ADaM Specifications →

- Analysis datasets

Seq No	Dataset Name	Variable Name	Variable Label	Type	Length	Default	Source	Computational Method
1	ADSL	TRTSEQ	Treatment Sequence	Char	1		TRTSEQ	
2	ADSL	SDSD	Study Site	Char	2		SDSD	
3	ADSL	SDSD	Study Site	Num	4		SDSD	
4	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	
5	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	
6	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	
7	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	
8	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	

= dataset templates

- Analysis results

Analysis	Dataset Name	Variable Name	Variable Label	Type	Length	Default	Source	Computational Method
1	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	
2	ADSL	SDSD	Study Site	Char	2		SDSD	
3	ADSL	SDSD	Study Site	Num	4		SDSD	
4	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	
5	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	
6	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	
7	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	
8	ADSL	TRTSEQ	Treatment Sequence	Char	4		TRTSEQ	

source for define.xml

SDTM

SAP

Datasets creation programs

ADaM

Results creation programs

Analysis results (TLGs)

define.xml (ADaM)



red: (potential) esubmission deliverables

ADSL Example

	Subject Identifiers				Treatment Variables			Std. Treatment/Trial Dates		
Row	STUDYID	USUBJID	SUBJID	SITEID	ARM	TRT01P	TRT01PN	RANDDT	TRTSDT	TRTEDT
1	X1	X1-01-01	01-01	01	DRUG X	Drug X	2	2009-11-02	2009-11-02	2009-11-09
4	X1	X1-01-02	01-02	01	PLACEBO	Placebo	1	2009-11-13	2009-11-13	2009-11-20

	Demographic Variables							Subject-Level Population Flags				
Row	HTBL	WTBL	AGE	AGEU	SEX	RACE	RACEN	COUNTRY	RANDFL	SAFFL	ITTFLL	PPROTFL
1	178	91.4	50	YEARS	M	WHITE	1	USA	Y	Y	Y	Y
4	170	58.8	62	YEARS	F	OTHER	9	USA	Y	Y	Y	Y

	Trial specific Trial Dates			Baseline Characteristics		
Row	ICDT	DEATHDT	RUNINSDT	GLBL	GLBLGR1	GLBLGR1N
1	2009-10-02		2009-10-09	12.2	Medium	2
4	2009-10-13		2009-10-20	20.5	High	3

- ✓ Structure: one record per subject
- ✓ Standard Dataset Name: ADSL
- ✓ Contains req., cond. and perm. standard variables and non-standard variables
- ✓ Follows variable naming rules (e.g., DT suffix for numeric dates)
- ✓ Source for "Core" variables in other ADaM datasets

BDS Example

Subject Identifier Variables	Parameter Identifier Variables		Analysis Timing Variables		Analysis Variables			Analysis-enabling Variables	
USUBJID	PARAM	PARAMCD	AVISIT	AVISITN	AVAL	BASE	CHG	DTYPE	
Unique Subject Identifier	Unique Description of the Analysis Parameter	Short Name for PARAM	Analysis Visit	Analysis Visit (N)	Analysis Value	Baseline Value	Change from Baseline	Derivation Type	Additional variables for treatment variables, population flags, covariates, etc...
X1-01-01	Weight (kg)	WT	Baseline	1	100	100	0		
X1-01-01	Weight (kg)	WT	Day 8	8	92	100	-8		
X1-01-01	Weight (kg)	WT	Day 15	15	92	100	-8	LOCF	
X1-01-01	BMI (kg/m**2)	BMI	Baseline	1	31.56	31.56	0		
X1-01-01	BMI (kg/m**2)	BMI	Day 8	8	29.04	31.56	-2.52		
X1-01-01	BMI (kg/m**2)	BMI	Day 15	15	29.04	31.56	-2.52	LOCF	

- ✓ Structure: one or **more** record per subject per analysis parameter per analysis visit
- ✓ Generic Data Structure to handle any type of analysis parameters
 - ✓ May contain collected or derived parameters
- ✓ Dataset Naming Convention: ADxxxxxx
 - ✓ Strive for optimum number of datasets for programming and reviewing
- ✓ Req., cond. and perm. standard variables to be used whenever possible

ADaM Updates - Current Status

- ✓ Draft ADaM IG 1.1
 - Feedback from SRC review needs to be implemented
 - Release for public review in spring 2014 (hopefully)
- ✓ Separate Draft Appendix Document: "Occurrence Data Structure (ODS)"
 - Feedback from SRC review needs to be implemented
- ✓ Update of ADaM model document in preparation
 - Not yet shared/discussed within the full ADaM team
- ✓ Define-XML 2.0 - Analysis Results Metadata in preparation
 - Not yet shared/discussed within the full ADaM team

Expected ADaM IG Changes

- ✓ New timing variables for phase, subperiod
- ✓ New index w (subperiods) on top of xx, y and zz
- ✓ Allow index y (e.g. as in SITEGRy) to go from 1-99
- ✓ Allow flexibility for some variable labels
- ✓ Additional permissible standard variables for ADSL
- ✓ Retirement of variables
 - APxxSDTF, APxxSTMF, APxxEDTF, APxxETMF, PARAMTYP
- ✓ New variable naming fragments

Expected ADaM IG Changes (continued)

- ✓ Modified treatment variable requirements for BDS
 - TRTP req. => any one of the possible TRT variables req.
- ✓ New perm. BDS variable ASEQ
- ✓ Clarification when certain timing variables should be included in ADSL vs. BDS
- ✓ New BDS Analysis Multi Response Criterion variables
- ✓ Corrected errors (e.g. type of ANRLO, ANRHI, AyLO, AyHI)
- ✓ General clarifications/edits
 - e.g. stressing the definition "as needed for analysis"

What is Next?

- ✓ Work on ADaM IG V1.2 should also start in 2014
- ✓ Some topics under discussion
 - Allow for different PARCATs for a PARAMCD?
 - Real time variable(s) for plotting
 - Function of multiple rows columns/variables?
 - Multiple treatments at the same time
 - One record per subject datasets besides ADSL
 - PK variables/section
 - Integration issues

Q&A

- ✓ Is there anything specific that bugged you about ADaM?
- ✓ Use cases of struggles with implementing ADaM?
- ✓ Interest in joint review of ADaM IG V1.1?
- ✓ Interest in more regular ADaM discussions?
 - If yes, possible formats
 - Specific topic at the next F2F?
 - TCs?
- ✓ Interest in creating some output as a team?
 - If yes, possible deliverables
 - Specific samples?
 - Volunteers for a lead of this effort?