



PPD[®]

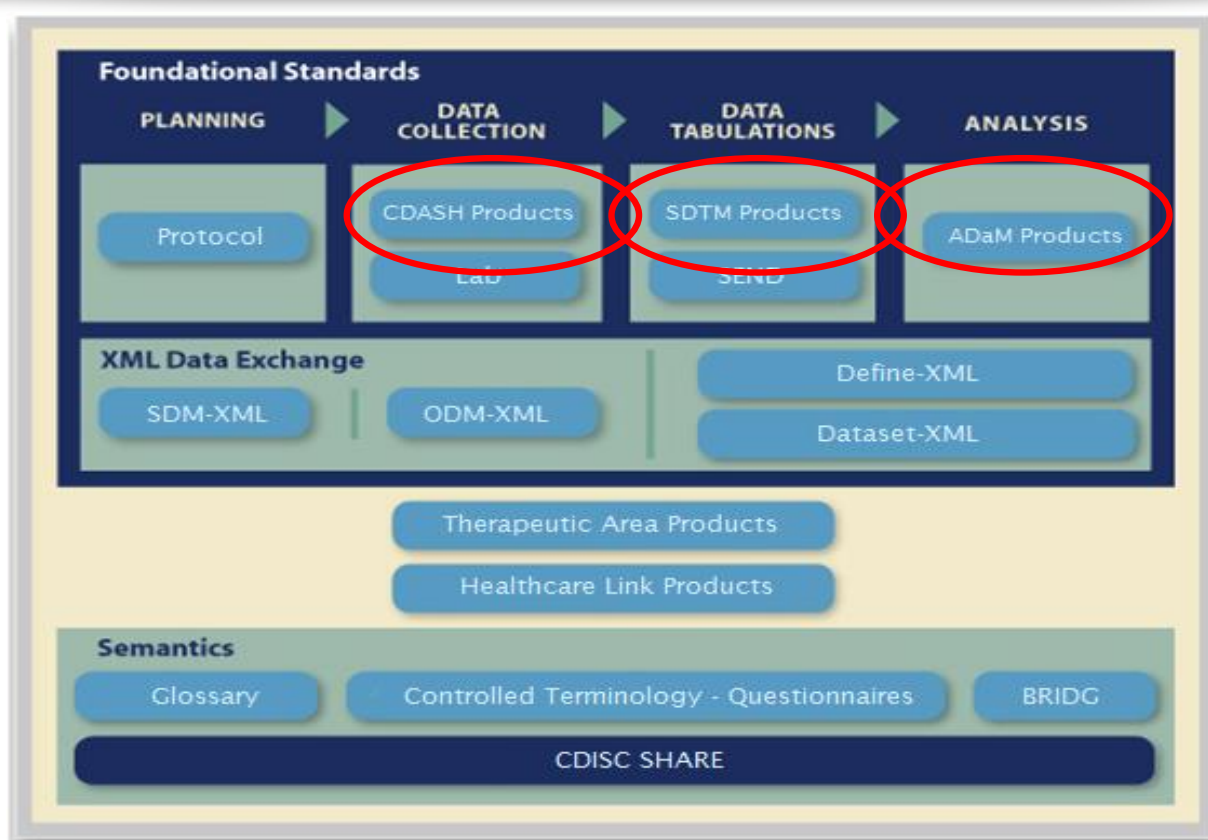
ADaM Standard Overview and Future Outlook -- Zibao Zhang/张子豹 (PPD)

**PhUSE SDE - ADaM and TLF Standardisation
2014-11-28 Shanghai**

Outline

1. Background
2. ADaM overview
3. ADaM examples (a demo)
4. ADaM current status and future
5. Points for discussions
6. Q&A (if time allows)

Background: CDISC Standards



CDISC website www.cdisc.org

ADaM – Past

Year	ADaM (General Cons.)	ADaMIG	Examples
2002	Guideline 1.0 (5 pp) General Considerations (16pp)		
2003			CFB examples CAT examples TTE examples
2005	General Considerations 0.7 General Considerations 1.0		SL 0.2x CFB 0.2x CAT 0.2x
2006	ADaM 2.0 draft ADaM 2.0 final		
2008	ADaM 2.1 draft	ADaMIG 0.1 ADaMIG 1.0 draft	
2009	ADaM 2.1 final	ADaMIG 1.0 final	
2011/ 2012			ADTTE, ADAE Examples, Compliance checks

ADaM – Current

- **ADaM – Analysis Dataset Model**

- **Current ADaM Documents**

- ADaM Model Document 2.1 (2009)
- ADaMIG 1.0 (2009)
- Examples (2011)
- ADTTE (2011)
- ADAE (2012)
- Compliance checks (2011)
- Updated Pilot 1 data (2013)
- ADaMIG 1.1 draft (2014)
- ODS draft (2014)

Analysis Data Model (ADaM)		
Prepared by the CDISC Analysis Data Model Team		
Notes to Readers		
This is Version 2.1 of the Analysis Data Model (ADaM) Document. It includes modifications so that it corresponds to Version 1.0 of the Analysis Data Model Implementation Guide (ADaMIG).		
Revision History		
Date	Version	Summary of Changes
Dec 17, 2009	2.1 Final	Released version reflecting all changes and corrections identified during comment period.
May 30, 2008	2.1 Draft	Draft for comment.
Aug 11, 2006	2.0 Final	Final document.
31 May 2006	2.0 Draft	Incorporate comments from public review.
15 Feb 2006	2.0 Draft	Redesigned from General Considerations v1.0, incorporating Subject-level model, emphasizing requirements and naming and content rules and guidelines.

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.

ADaM Documents In Progress*

- ADaM metadata **submission guideline**
- Document to cover **multivariate analyses**
- **Compliance checks** to cover ADAE and ADTTE
- **ISS/ISE** Integration

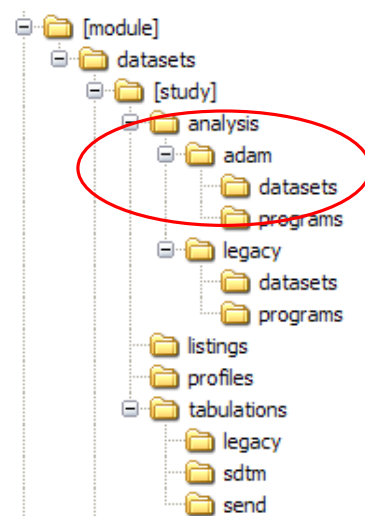
*based on CDISC Webinar in April 2014

Background and Purpose of ADaM

- FDA required data submission

- Analysis datasets
 - ADaM
- Listings
- Profiles
- Tabulations datasets
 - SDTM
 - SEND

<http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>



- FDA's expectations on data standards

- Data from all companies in the same structure
- Allows data to be combined across companies and by therapeutic areas
- Support larger vision of having FDA warehouse repository

ADaM Section 1-2, ADaMIG Section 1

ADaM Overview

- Fundamental principles
- ADaM rules for analysis datasets
- ADaM standard data structure
 - ADSL
 - BDS, e.g. ADEFF, ADTTE
 - ODS, e.g. ADAE
- ADaM standard variables
- ADaM metadata
- ADaM standard solutions to implementation issues

ADaM Fundamental Principles

- Analysis datasets must:
 - facilitate **clear and unambiguous** communication and provide **traceability**
 - be analysis-ready (“**ONE PROC AWAY**”)
 - be accompanied by **metadata**
 - be readily useable by **commonly available software tools**
- **Traceability**
 - The concept of traceability is a **cornerstone** of the Analysis Data Model.

ADaM Section 3.1, ADaMIG Section 2

Demonstration: Traceability

Demog. and Baseline Char. Analysis Dataset (ADSL)

Variable	Label	Type	Controlled Terms or Format
USUBJID	Unique Subject Identifier	text	

Demographics Dataset (DM)

Variable	Label	Type	Controlled Terms or Format	Component
STUDYID	Study Identifier	text		
USUBJID	Unique Subject Identifier	text		
DOMAIN	Domain Abbreviation	text		
SUBJID	Subject Identifier for the Study	text		
RFSTDTC	Subject Reference Start Date/Time	text		
RFENDTC	Subject Reference End Date/Time	text		
SITEID	Study Site Identifier	text		
AGE	Age in AGEU at RFSTDTC	float		
AGEU	Age Units	text	AGEU	Derived
SEX	Sex	text	SEX	Result Qualifier
RACE	Race	text	ADRACE	Result Qualifier
ARMCD	Planned Arm Code	text	ARMCD	Derived
ARM	Description of Planned Arm	text		Derived
COUNTRY	Country	text		Derived
DMDTC	Date/Time of Collection	text		CRF Page 7
DMDY	Study Day of Collection	float	COMP_STUDY_DAY	Timing

DEMOGRAPHICS

Date of birth Not Entered in Database
MM / DD / YY

SEX Sex ☐ Female ☐ Male

RACE Origin ☐ CA Caucasian (European, Mediterranean, Middle Eastern)
☐ AF African Descent (Negro, Black)
☐ EA East/Southeast Asian (Burmese, Chinese, Japanese, Korean, Mongolian, Vietnamese)
☐ AS Western Asian (Pakistani, Indian Sub-continent)
☐ HP Hispanic (Mexican-American, Mexico, Central and South America)
☐ O Other (Mixed-racial parentage, American Indian, Eskimo)

Annotated Case Report Form

Go to the top of the [define.xml](#)

Date of document generation (2007-12-20T11:25:43)

square test for categorical variables.
NOTE: duration of disease is computed as months between date of enrollment and date of onset of the first definite symptoms of Alzheimer's disease.

FINAL SAP -21-

Analysis	Table 14-2.01 - Summary of Demographic and Subject Baseline Characteristics
Description	Summary statistics for selected demographic and subject baseline characteristics variables, ITT population
Reason	pre-specified in protocol
Data References	Demog. and Baseline Char. Analysis (ADSL) [where ITT='Y']
Documentation	SAP Section 9.2 SAP Template 3

ADaM Rules for Analysis Datasets

- Analysis datasets must:
 - include a subject-level analysis dataset named “ADSL”
 - consist of the optimum number of analysis datasets needed and have enough self-sufficiency to allow analysis and review with little or no additional programming or data processing
 - be named using the convention “ADxxxxxx”
 - use ADaM standard variable names and naming conventions when available
 - maintain the values and attributes of SDTM variables if copied into analysis datasets without renaming (i.e., adhere to the “same name, same meaning, same values” principle of harmonization)
 - apply naming conventions for datasets and variables consistently across studies within a given submission and across multiple submissions for a product

Classes of ADaM Data Structure

- **ADSL** (Subject-level Analysis Dataset)

- Reserved dataset name “ADSL”
- One record per subject

- **BDS** (ADaM basic Dataset)

- Designed with the maximum number of analysis time points (e.g., ADTTE is illustrated in the diagram)

- **ODS** (ADaM Occurrence Dataset)

- general data structure for analysis. Examples include typical analysis of Adverse Events, Concomitant Medications, and Medical History
- one record per each AE recorded in SDTM AE domain (ADAE)

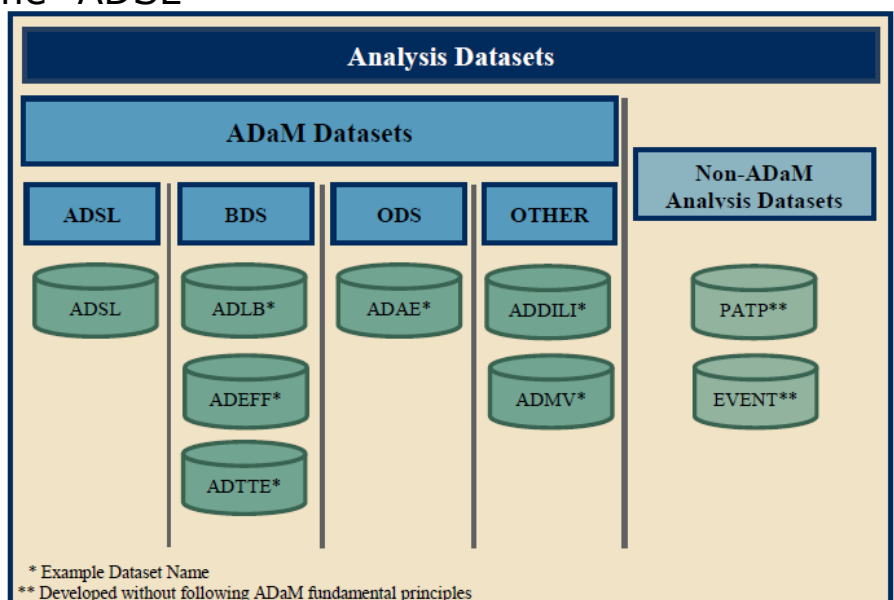


Figure 1.6.1 Categories of Analysis Datasets

ADaM Standard Variables

- General Variable Naming Conventions
 - e.g. ---DT/---TM/---SDT/---EDT
- ADSL Variables
 - e.g. AGE/AGEU/SEX/RACE, TRTxxP/TRTxxA, FASFL/SAFFL/ITTFL
- BDS Variables
 - e.g. PARAM/PARAMCD, AVAL/AVALC, BASE/CHG/PCHG
- ODS Variables (draft, ADAE as first example)
 - e.g. AOCCFL/AOCCIFL/AOCCzzFL

standard **predictable** data structure and variables

ADaMIG Section 3

ADaM Variables Descriptions

Table 3.1.1 ADSL Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
SEX	Sex	Char	(SEX)	Req	The sex of the subject is a required variable in ADSL. If the variable is not a copy of DM.SEX, then an additional differently named variable must be added.
RACE	Race	Char	(RACE)	Req	The race of the subject is a required variable in ADSL. If the variable is not a copy of DM.RACE, then an additional differently named variable must be added.
RACEGRy	Pooled Race Group y	Char		Perm	Character description of a grouping or pooling of subject race for analysis purposes.
RACEGRyN	Pooled Race Group y (N)	Num		Perm	The numeric code for RACEGRy. Orders the grouping or pooling of subject race for analysis and reporting. One-to-one map to RACEGRy.
Population Indicator(s)					
FASFL	Full Analysis Set Population Flag	Char	Y, N	Cond	A character indicator variable is required for every population that is defined in the statistical analysis plan. A minimum of one subject-level population flag variable is required for every clinical trial. Additional population flags may be added. The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
SAFFL	Safety Population Flag	Char	Y, N	Cond	
ITTFL	Intent-To-Treat Population Flag	Char	Y, N	Cond	
PPROTFL	Per-Protocol Population Flag	Char	Y, N	Cond	
COMPLFL	Completers Population Flag	Char	Y, N	Cond	
RANDFL	Randomized Population Flag	Char	Y, N	Cond	
ENRFL	Enrolled	Char	Y, N	Cond	

Values of ADaM “Core” Attribute

- **Req** = Required. The variable must be included in the dataset.
- **Cond** = Conditionally required. The variable must be included in the dataset in certain circumstances.
- **Perm** = Permissible. The variable may be included in the dataset, but is not required.

Unless otherwise specified, all ADaM variables are populated as appropriate, meaning nulls are allowed.

ADaM Standard Variables

- General Variable Naming Conventions
- ADSL Variables
- ADaM BDS Variables
 - PARAM/PARAMCD, AVAL/AVALC
- ADaM ODS Variables

General Variable Naming Conventions

- In a pair of corresponding variables, the primary or most commonly used variable have no suffix or extension
 - e.g., **TRTP** and TRTPN, **AVAL** and AVALC
- Lower case letters “xx”, “y”, and “zz”
- ---GRy: grouping variables, y refers to the grouping scheme or algorithm, e.g. SITEGR1
- SDTM character variables to numeric variables
 - with an “**N**” suffix added, e.g. RACEN

General Timing Variable Conventions

- ---DT: numeric dates
- ---DTM: numeric datetimes
- ---TM: numeric times
- ---DTF: date imputation flags
- ---TMF: time imputation flags

- ---SDT, ---STM etc: timing start variables
- ---EDT, ---ETM etc: timing end variables

General Flag Variable Conventions

- **---FL, ---FN**: character and numeric flag variables
- Subject-level ---FL and ---FN variables:
 - N = no (not included), Y = yes (included). Null values are not allowed.
 - 0 = no (not included), 1 = yes (included). Null values are not allowed.
- Parameter-level and record-level: ---PFL, ---PFN, ---RFL, ---RFN variables:
 - Y = yes (included). Null values are allowed.
 - 1 = yes (included). Null values are allowed.

ADaM Standard Variables

- General Variable Naming Conventions
- ADSL Variables
 - e.g. AGE/AGEU/SEX/RACE, TRTxP/TRTxA, FASFL/SAFFL/ITTFL
- BDS Variables
 - e.g. PARAM/PARAMCD, AVAL/AVALC, BASE/CHG/PCHG
- ODS Variables (draft, ADAE as first example)
 - e.g. AOCCFL/AOCCIFL/AOCCzzFL

ADSL (Analysis Data Subject Level)

- Contains **important information about a subject**
- **Structured as one record per subject**
 - Allows for merging with any other file (ADaM or SDTM)
 - Regardless of clinical trial design
- Used as a source for
 - Variables required in **other analysis datasets**
 - **Denominator value** for populations of interest
- Required variables with **standards names and attributes** (loaded into FDA Repository)
 - Will allow tools to be developed

ADSL Standard Variables

- Required variables
 - Study and Subject Identifiers
 - Subject Demographics, e.g. AGE/SEX/RACE
 - Population Indicator (s), e.g. FASFL
 - Treatment Variables, TRTxxP
 - Trial Dates (conditionally required)
 - Permissible variables
 - Numeric equivalents of flags
 - Stratification variables
 - Treatment duration and compliance variables
 - Other key visit dates and durations
 - Protocol specific event information, such as death/survival
- ADaM Section 6, ADaMIG Section 3.1**

ADaM Standard Variables

- General Variable Naming Conventions
- ADSL Variables
 - e.g. AGE/AGEU/SEX/RACE, TRTxP/TRTxA, FASFL/SAFFL/ITTFL
- BDS Variables
 - e.g. PARAM/PARAMCD, AVAL/AVALC, BASE/CHG/PCHG
- ODS Variables (draft, ADAE as first example)
 - e.g. AOCCFL/AOCCIFL/AOCCzzFL

ADaM BDS – Basic Data Structure

- A **predictable structure** will bring some benefits:
 - communication, metadata, software development, etc
- Designed to be flexible for **majority of analyses**
- **One or more records per subject per analysis parameter, per analysis time points** (if applicable)
- BDS PARAM/PARMACD can contain **any type of data**
 - An event, a finding, or an intervention, or
 - A derived or combined
- Allow **flexibility to add supporting columns** as needed

ADaM BDS Variables

- Study and Subject Identifier
- Treatment Variables
- Timing Variables
- Analysis Parameter Variables
- Analysis Descriptor Variables
- Indicator Variables, e.g. population flags
- Analysis-Enabling Variables
- Data Point Traceability Variables
- SDTM Variables (Traceability)

ADaM BDS: Analysis Parameter Variables

- Variables to describe what is being analyzed
- “Topic” variables in ADaM BDS (required)
 - **PARAM**: description of the analysis parameter
 - **PARAMCD**: short name of the analysis parameter in PARAM
- Other permitted variables
 - PARAMN
 - PARAMTYP
 - PARCATy
 - ...

Analysis Parameter Variables – An example

Row	PARAM	PARAMCD	AVISIT	AVISITN	VISITNUM	ABLFL	AVAL	BASE	CHG	PARAMTYP
1	Weight (kg)	WEIGHT	Screening	-4	1		99	100	.	
2	Weight (kg)	WEIGHT	Run-In	-2	2		101	100	.	
3	Weight (kg)	WEIGHT	Baseline	0	3	Y	100	100	0	
4	Weight (kg)	WEIGHT	Week 24	24	4		94	100	-6	
5	Weight (kg)	WEIGHT	Week 48	48	5		92	100	-8	
6	Weight (kg)	WEIGHT	Week 52	52	6		95	100	-5	
7	Log10(Weight (kg))	L10WT	Screening	-4	1		1.9956	2	.	DERIVED
8	Log10(Weight (kg))	L10WT	Run-In	-2	2		2.0043	2	.	DERIVED
9	Log10(Weight (kg))	L10WT	Baseline	0	3	Y	2	2	0	DERIVED
10	Log10(Weight (kg))	L10WT	Week 24	24	4		1.9731	2	-0.0269	DERIVED
11	Log10(Weight (kg))	L10WT	Week 48	48	5		1.9638	2	-0.0362	DERIVED
12	Log10(Weight (kg))	L10WT	Week 52	52	6		1.9777	2	-0.0223	DERIVED

Two parameters:

Weight (kg) - observed

Log10(Weight(kg)) - derived

ADaM BDS: Analysis Parameter Variables – Analysis Values

- Variables that contain char or num values used for analysis
 - AVAL**: Numeric analysis value described by PARAM
 - AVALC**: Character analysis value described by PARAM
 - AVALCATy**: A categorical representation of AVAL and/or AVALC

– ...

Row	PARAM	PARAMCD	AVISIT	AVISITN	VISITNUM	ABLFL	AVAL	BASE	CHG	PARAMTYP
1	Weight (kg)	WEIGHT	Screening	-4	1		99	100	.	
2	Weight (kg)	WEIGHT	Run-In	-2	2		101	100	.	
3	Weight (kg)	WEIGHT	Baseline	0	3	Y	100	100	0	
4	Weight (kg)	WEIGHT	Week 24	24	4		94	100	-6	
5	Weight (kg)	WEIGHT	Week 48	48	5		92	100	-8	
6	Weight (kg)	WEIGHT	Week 52	52	6		95	100	-5	
7	Log10(Weight (kg))	L10WT	Screening	-4	1		1.9956	2	.	DERIVED
8	Log10(Weight (kg))	L10WT	Run-In	-2	2		2.0043	2	.	DERIVED
9	Log10(Weight (kg))	L10WT	Baseline	0	3	Y	2	2	0	DERIVED
10	Log10(Weight (kg))	L10WT	Week 24	24	4		1.9731	2	-0.0269	DERIVED
11	Log10(Weight (kg))	L10WT	Week 48	48	5		1.9638	2	-0.0362	DERIVED
12	Log10(Weight (kg))	L10WT	Week 52	52	6		1.9777	2	-0.0223	DERIVED

ADaM BDS: Analysis Parameter Variables – Others

- BASE
- BASEC
- BASECATy
- BASETYPE
- CHG
- CHGCATy
- PCHG
- PCHGCATy
- R2BASE
- R2AyLO
- R2AyHI
- SHIFTy (BASECATy vs AVALCATy)
- SHIFTyN
- CRITy
- ...

ADaM BDS – Example 2

Analysis Parameter				Indicator Variable		Analysis Parameter				Population Flag		
Row	PARAM	AVISIT	AVISITN	VISITNUM	VSSEQ	ABLFL	AVAL	BASE	CHG	DTYPE	ITTRFL	PPROTFL
1	Weight (kg)	Screening	-4	1	1164		99	100	.		Y	Y
2	Weight (kg)	Run-In	-2	2	1165		101	100	.		Y	Y
3	Weight (kg)	Baseline	0	3	1166	Y	100	100	0		Y	Y
4	Weight (kg)	Week 24	24	4	1167		94	100	-6		Y	Y
5	Weight (kg)	Week 48	48	5	1168		92	100	-8		Y	Y
6	Weight (kg)	Week 52	52	6	1169		95	100	-5		Y	
7	Weight (kg)	Endpoint	9999				93.5	100	-6.5	AVERAGE	N	
8	Weight (kg)	Endpoint	9999				93	100	-7	AVERAGE		Y
9	Log10 (Weight (kg))	Screening	-4	1	1164		1.9956	2	.		Y	Y
10	Log10 (Weight (kg))	Run-In	-2	2	1165		2.0043	2	.		Y	Y
11	Log10 (Weight (kg))	Baseline	0	3	1166	Y	2	2	0		Y	Y
12	Log10 (Weight (kg))	Week 24	24	4	1167		1.9731	2	-0.0269		Y	Y
13	Log10 (Weight (kg))	Week 48	48	5	1168		1.9638	2	-0.0362		Y	Y
14	Log10 (Weight (kg))	Week 52	52	6	1169		1.9777	2	-0.0223		Y	
15	Log10 (Weight (kg))	Endpoint	9999				1.9708	2	-0.0292	AVERAGE	Y	
16	Log10 (Weight (kg))	Endpoint	9999				1.9685	2	-0.0315	AVERAGE		Y
		ADaM Timing		SDTM Variable		Analysis Descriptor						

ADaM
Timing

SDTM
Variable

Analysis
Descriptor

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- General Variable Naming Conventions
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- ODS Variables (draft, ADAE as first example)
 - e.g. AOCCFL/AOCCIFL/AOCCzzFL

ADaM ODS – Occurrence Data Structure

- ODS describes the general data structure and content typically found in **occurrence analysis**.
 - counting of subjects with a record or term, and often includes a structured hierarchy of dictionary coding categories.
- Examples: typical analysis of **Adverse Events, Concomitant Medications, and Medical History**.
- **no need for AVAL or AVALC**.
- Occurrences are counted in analysis, and there are typically one or more records for each occurrence (**event level to subject level**).

ADaM ODS Variables

- ADSL Variables
- Identifier Variables
- Dictionary Coding and Categorization Variables
- Timing Variables
- Indicator Variables
- Occurrence Flag Variables
- Treatment/Dose Variables
- Descriptive Variables
- Standardized MedDRA Query Variables
- Original or Prior Coding Variables

ADaM ODS: Occurrence Flag Variables

- Occurrence flags typically created by sorting the data in the required order and then flagging the first treatment emergent record.
 - **AOCCFL**: 1st Occurrence of Any XX Flag
 - **AOCCIFL**: 1st Max Sev./Int. Occurrence Flag
 - **AOCCzzFL**: 1st Occurrence of

...

Row	STUDYID	USUBJID	AESEQ	AETERM	AEDECOD	AEBODSYS	TRTEMFL	AOCCFL	AOCCSFL	AOCCPFL
1	XYZ	XYZ-001-001	1	HEADACHE	Headache	Nervous system disorders				
2	XYZ	XYZ-001-001	2	CHRONIC BACK PAIN	Back pain	Musculoskeletal and connective tissue disorders				
3	XYZ	XYZ-001-001	3	NOSE BLEEDING RIGHT NOSTRIL	Epistaxis	Respiratory, thoracic and mediastinal disorders				
4	XYZ	XYZ-001-001	4	PROBLEMS OF HYPOTENSION	Hypotension	Vascular disorders	Y	Y	Y	Y
5	XYZ	XYZ-001-001	5	HEADACHE	Headache	Nervous system disorders	Y		Y	Y
6	XYZ	XYZ-001-001	6	HEADACHE	Headache	Nervous system disorders	Y			
7	XYZ	XYZ-001-001	7	LOOSE STOOL	Diarrhoea	Gastrointestinal disorders	Y		Y	Y
8	XYZ	XYZ-001-001	8	ABDOMINAL DISCOMFORT	Abdominal discomfort	Gastrointestinal disorders	Y			Y
9	XYZ	XYZ-001-001	9	DIARRHEA	Diarrhoea	Gastrointestinal disorders	Y			

ADaM Overview

- Fundamental principles
- ADaM rules for analysis datasets
- ADaM standard data structure
 - ADSL
 - BDS, e.g. ADEFF, ADTTE
 - ODS, e.g. ADAE
- ADaM standard variables
- ADaM metadata
- ADaM standard solutions to implementation issues

ADaM Metadata

- Analysis dataset metadata
- Analysis variable metadata
- Analysis parameter value-level metadata
- Analysis results metadata

Analysis results metadata

Table 5.3.1.2 Analysis Results Metadata for the Pairwise Treatment Comparisons in the Statistical Display in Figure 5.3.1.1⁶

Metadata Field	Definition of field	Metadata
DISPLAY IDENTIFIER	Unique identifier for the specific analysis display	Table 14-3.01
DISPLAY NAME	Title of display	Primary Endpoint Analysis: ADAS Cog (11) - Change from Baseline to Week 24 - LOCF
RESULT IDENTIFIER	Identifies the specific analysis result within a display	Pairwise treatment comparisons
PARAM	Analysis parameter	ADAS-Cog (11) Total Score
PARAMCD	Analysis parameter code	ACTOT11
ANALYSIS VARIABLE	Analysis variable being analyzed	CHG
REASON	Rationale for performing this analysis	Primary efficacy analysis as pre-specified in protocol
DATASET	Dataset(s) used in the analysis.	ADQSADAS
SELECTION CRITERIA	Specific and sufficient selection criteria for analysis subset and / or numerator	ITTFL='Y' and AVISIT='Week 24' and PARAMCD='ACTOT11'
DOCUMENTATION	Textual description of the analysis performed	Linear model analysis of ADAS-Cog(11) total score change from baseline at Week 24 for pairwise treatment comparisons and adjusted means; missing values imputed using LOCF, Efficacy population. Used randomized treatment as class variable; site group as class variable; and baseline ADAS-Cog score in model.
PROGRAMMING STATEMENTS	The analysis syntax used to perform the analysis	PROC GLM; CLASS SITEGR1 TRTP; MODEL CHG = TRTP SITEGR1 BASE; ESTIMATE 'H VS L' TRTP 0 1 -1; ESTIMATE 'H VS P' TRTP -1 1 0; ESTIMATE 'L VS P' TRTP -1 0 1; LSMEANS TRTP / OM STDERR PDIF CL; RUN;

Standard Solutions to Implementation Issues

- Treatment variables for common trial designs (sect 4.1)
- Creation of derived columns vs rows (sect 4.2)
 - Rule #1 to Rule#6
- Inclusion of all observed and derived records for a parameter versus the subset of records used for Analysis (sect 4.3)
- Inclusion of supportive data (sect 4.4)
- Identification of rows used for analysis (4.5)
- Identification of population-specific analyzed rows (sect 4.6)
- Identification of records which satisfy a pre-defined criterion for analysis purposes (sect 4.7)
- Other issues to consider (sect 4.8)

Standard Solutions – An example

- Creation of derived columns vs rows (sect 4.2)
 - Rule 1. A **parameter-invariant** function of AVAL and BASE on the same row that does not involve a transform of BASE should be added as **a new column**.
 - Rule 2. A **transformation of AVAL** that does not meet the conditions of Rule 1 should be added as **a new parameter**, and AVAL should contain the transformed value.

Row	PARAM	PARAMCD	AVISIT	AVISITN	VISITNUM	ABLFL	AVAL	BASE	CHG	PARAMTYP
1	Weight (kg)	WEIGHT	Screening	-4	1		99	100	.	
2	Weight (kg)	WEIGHT	Run-In	-2	2		101	100	.	
3	Weight (kg)	WEIGHT	Baseline	0	3	Y	100	100	0	
4	Weight (kg)	WEIGHT	Week 24	24	4		94	100	-6	
5	Weight (kg)	WEIGHT	Week 48	48	5		92	100	-8	
6	Weight (kg)	WEIGHT	Week 52	52	6		95	100	-5	
7	Log10(Weight (kg))	L10WT	Screening	-4	1		1.9956	2	.	DERIVED
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9	Log10(Weight (kg))	L10WT	Baseline	0	3	Y	2	2	0	DERIVED
10	Log10(Weight (kg))	L10WT	Week 24	24	4		1.9731	2	-0.0269	DERIVED
11	Log10(Weight (kg))	L10WT	Week 48	48	5		1.9638	2	-0.0362	DERIVED
12	Log10(Weight (kg))	L10WT	Week 52	52	6		1.9777	2	-0.0223	DERIVED

ADaM Examples – CDISC Pilot Study

- A real study to show:
 - Metadata (4 levels)
 - Datasets (3 classes)
 - ADSL (ADSL class)
 - ADVS (BDS class)
 - ADAE (ODS class)
 - Traceability by define.xml

ADaM Current status and issues

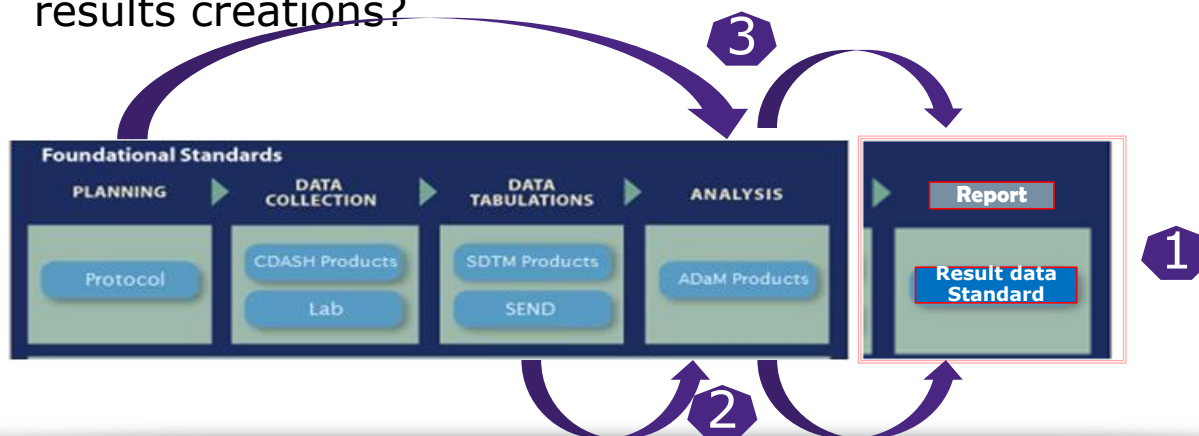
- Agencies requests or are interested in adopting ADaM, e.g US FDA, Japan PMDA
- Increasingly (and sometimes inconsistently) used in the industry, e.g. ADaM datasets used to
 - create all tables/listings/figures
 - create only tables/figures
 - create only statistical tables
- Flexibility vs compliance, clarity of solutions
- Commercial tools are not (widely) available

ADaM Future – short/medium term

- ADaM continue to evolve to be stable?...
 - Solutions to common issues
 - Addition of ODS or other new classes
 - TA standard development including ADaM
 - Cover new study designs, analysis methods, derivation and reporting
- Well accepted by more agencies and by the whole industry?
- Available commercial tools to automatize the creation process (SDTM ->ADaM->TLFs) for some areas, e.g. safety data?

Points for Discussion – long term

1. Standardize TLF outputs/shells, e.g. baseline, common safety and specific efficacy outputs?
2. Standardize the common derivations from SDTM to ADaM, and then to Report when stable in specific area?
3. Streamline using protocol, when standard and database-able, to drive (or via SAP/shells) the ADaM and analysis results creations?



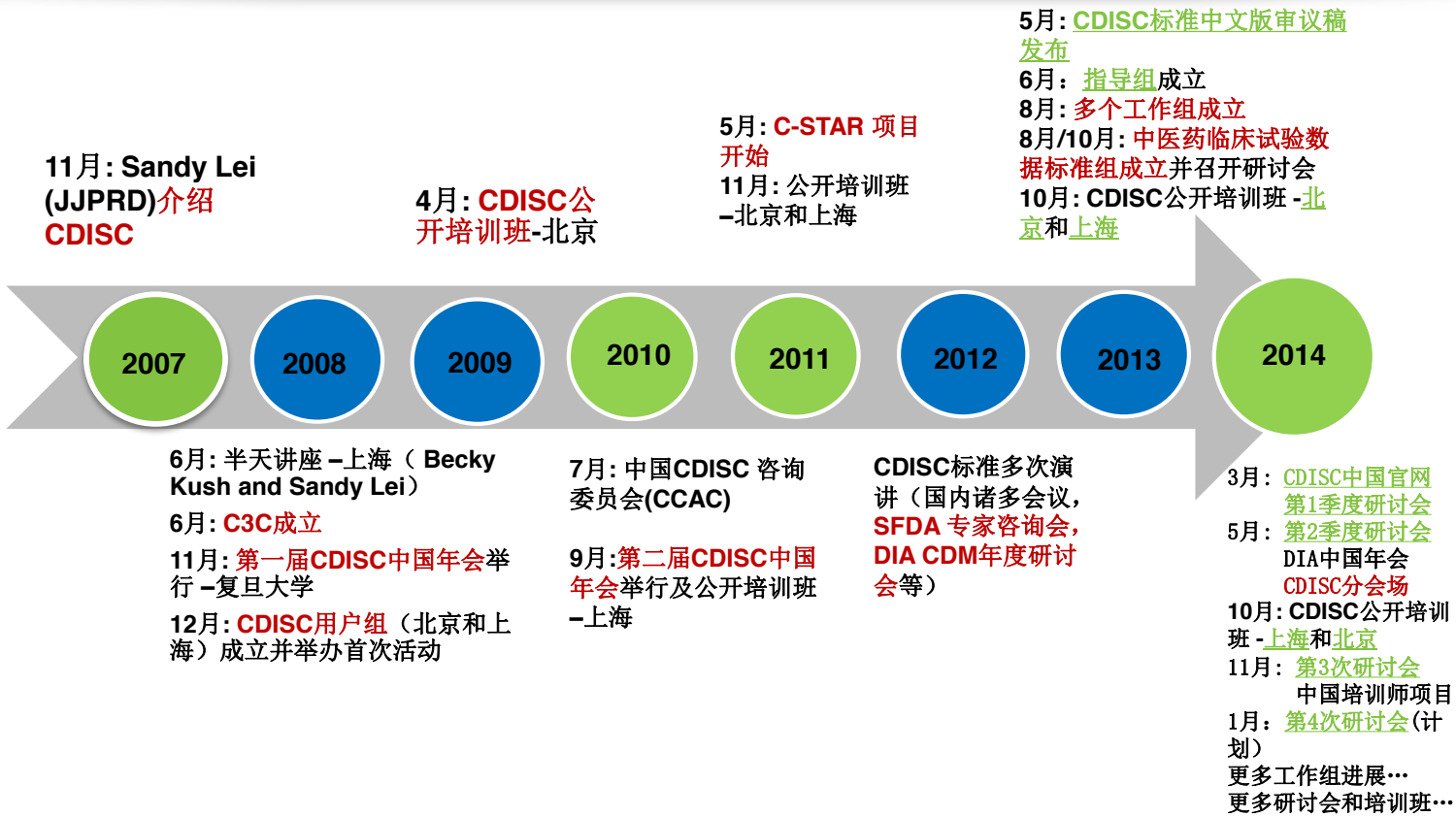
Thank You!

Contact

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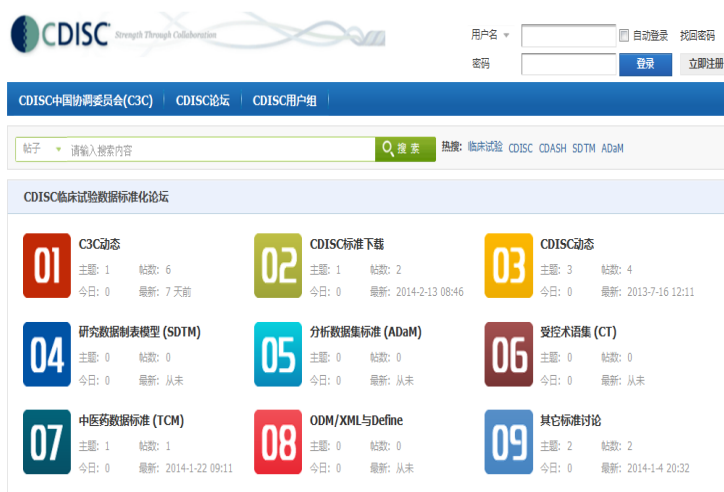
Backup slides

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