WITH STANDARDS – UNLOCK THE POWER OF DATA

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2022
EUROPE
INTERCHANGE
27-28 APRIL | VIRTUAL EVENT

20 Minutes to get you aligned with the new ADaM IG (et al)

Presented by Angelo Tinazzi, Senior Director, Statistical Programming,
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Meet the Speaker

Angelo Tinazzi

Title: Senior Director; Statistical Programming

Organization: Cytel Inc

Angelo is a Senior Director in the Statistical Programming Group at Cytel leading the Standards, Systems, CDISC Consulting Team.

Angelo is a CDISC ADaM Authorized Instructor and member of the CDISC European Coordinating Committee where he is also leading Italian speaking User network.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of Cytel*

- *I have no real or apparent conflicts of interest to report.*

Agenda

1. What was released last November 2021?
2. What's New in ADaM IG 1.3
3. What's New in ADaM OCCDS v1.1
4. ADaM Implementation Guidance for Medical Device v1.0
5. ADaM Implementation Guidance for Non-Compartmental Analysis v1.0
6. Conclusions

What was released last November 2021?

ADaM Standard vs ADaM Implementation Guidance

What “makes” ADaM?

Additional Guidance / Source of Recommendations

What was released last November 2021?

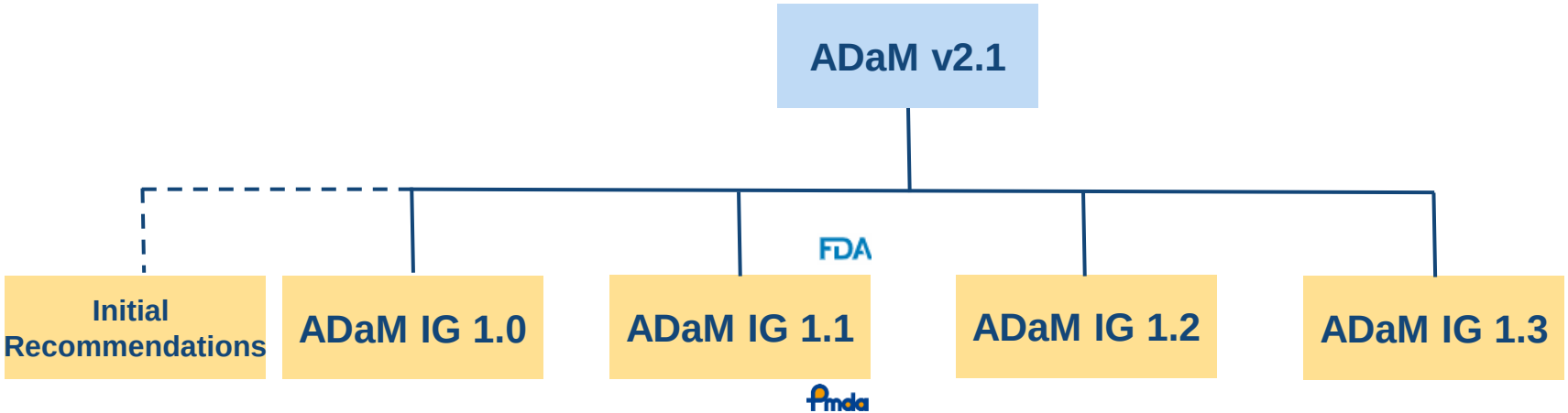
Updated Standards / Documents

- ADaM Implementation Guidance Version 1.3
- ADaM OCCDS Implementation Guidance Version 1.1
- ADaM Implementation Guidance for Medical Device Version 1.0
- ADaM Implementation Guidance for Non-Compartmental Analysis Version 1.0

What was released last November 2021?

https://www.cdisc.org/standards/foundational/adam/adamig-v1-3-release-package

ADaM Standard vs ADaM Implementation Guidance



What “makes” ADaM?

- How do I know which version of the implementation guide I should use?
- Which documents can be used together, and which should not be?
- Which documents are relevant to my needs?
- Do I need to read all these documents?

Ref.:

- ***Why Are There So Many ADaM Documents, and How Do I Know Which to Use?*** *Sandra Minjoe, PRA Health Sciences, CDISC US Interchange 2020*
- **Making Sense of the Various ADaM Documents**, CDISC Knowledge Base Article https://www.cdisc.org/kb/articles/making-sense-various-adam-documents

What “makes” ADaM?

Document	IG 1.0	IG 1.1	IG 1.2	IG 1.3
Analysis Data Model (ADaM) v2.1, Dec 2009				
ADaM Examples … v1.0, Dec 20111	Written for			
ADaM Data Structure for AE v1.0, May 2012	Written for	Superseded	Superseded	Superseded
ADaM BDS for Time-to-Event v1.0, Dec 2012	Written for			
define.xml v2.0, Mar 2013				
ARM for define.xml 2.0 v1.0, Jan 2015				
ADaM OCCDS v1.0, Feb 2016		Written for		
ADaM OCCDS v1.1, Nov 2021				
ADaM ADNCA v1.0, Nov 2021				
ADaM IG Medical Devices v1.0, Nov 2021				
ADaM Conformance Rules v4.0, Nov 2021				

ADaM IG section 1.3.1 / Table 1.3.1.1 Other CDISC Documents and Their Applicability to ADaMIG Versions

Additional Guidance / Source of Recommendations

CDISC Therapeutic Area Guidance (TAUGs)

- 2015 ADaM Supplement to the TAUG-DIabetes
- ADaM recommendations provided in 19 of the 41 published TAUGs
- Some examples
  - Use of Intermediate dataset for the calculation of complex TTE endpoint (Breast TAUG)
  - ADSL Examples (Diabetes Therapeutic Area User Guide v1.0 - Supplement for ADaM)

Additional Guidance / Source of Recommendations

Interim ADaM Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic Version 1.0 (Provisional) – June 2021

- Various recommendations on how to address analysis requiring the assessment of COVID-19 Impact
- Pandemic-related variables for both ADSL and OCCDS

Variable Name	Variable Label	Purpose
EPRELFL	Epi/Pandemic Related Population Flag	this variable would be widely used in safety and efficacy analysis, sensitivity analysis
EPSITEFL	Site Trans Related to Epi/Pandemic Flag	This variable would be used in subject and sensitivity analysis
EPDTHFL	Subj Death Related to Epi/Pandemic Flag	This variable would be used in subject analysis
EPDCTFL	Treat Disc Related to Epi/Pandemic Flag	This variable would be used in safety, and sensitivity analysis
EPDCSFL	Study Disc Related to	This variable would be used in safety,

Variable Name	Variable Label	Purpose
--EPRELI	Epi/Pandemic Related Indicator	This variable would be used for traceability and safety analysis
EPAFL	Epi/Pandemic Analysis Flag	This variable would be used for safety and sensitivity analysis
--EPADJI	Epi/Pandemic Related Adjustment Reas Ind	This variable would be used for traceability and safety and sensitivity analysis
EPCMQFL	Epi/Pandemic CMQ Flag	This variable would be used for safety analysis
EPSMQFL	Epi/Pandemic SMQ Flag	This variable would be used for safety analysis

Ref.: "….." ……

What’s New in ADaM IG 1.3

New Variables, Text changes

The concept of Sub-Class

What's New in ADaM IG 1.3

No major changes

- 0 New Variables
- 0 Modified Metadata Attributes

Some wording corrections

- 3 Clarifications
- 5 Modifications
- 4 Corrections

Exploring Changes in SDTMIG 3.4 & ADaMIG 1.3, Pinnacle21 Webinar, https://www.pinnacle21.com/blog/exploring-changes-sdtmig-34-adamig-13

The concept of Sub-Class

- Introduced with define.xml 2.1
- Applicable (for now) to ADaM only
- Available in define.xml CDISC CT since 2019Q4

The concept of Sub-Class

BDSSC - ADaM Basic Data Structure Subclass

C165635

Extensible: No
Submission Value: BDSSC
Definition: Terminology relevant to the subclasses of the ADaM basic data structure.
NCI Preferred Term: CDISC Define-XML ADaM Basic Data Structure Subclass Terminology
Synonyms: ADaM Basic Data Structure Subclass

Filter results

Term	Submission Value	Synonyms	Definition	NCI Preferred Term
C172452	NON-COMPARTMENTAL ANALYSIS	NCA	A dataset containing data that is used for non-compartmental analyses.	Non-Compartmental Analysis Dataset
C165637	TIME-TO-EVENT	TTE	A dataset containing data that is used for Time-to-Event analyses.	Time-to-Event Dataset

The concept of Sub-Class

OCCSC - ADaM Occurrence Data Structure Subclass

C176227

Extensible:	No
Submission Value:	OCCSC
Definition:	Terminology relevant to the subclasses of the ADaM occurrence data structure.
NCI Preferred Term:	CDISC Define-XML ADaM Occurrence Data Structure Subclass Terminology
Synonyms:	ADaM Occurrence Data Structure Subclass

Filter results

	Term	Submission Value	Synonyms	Definition	NCI Preferred Term
	C176265	ADVERSE EVENT		A dataset containing data that is used for adverse event analyses.	Adverse Event Dataset

The concept of Sub-Class

MBDSSC - ADaM Medical Device Basic Data Structure Subclass

C177903

Extensible: No
Submission Value: MDBDSSC
Definition: Terminology relevant to the subclasses of the ADaM device level basic data structure.
NCI Preferred Term: CDISC Define-XML ADaM Medical Device Basic Data Structure Subclass Terminology
Synonyms: ADaM Medical Device Basic Data Structure Subclass

Filter results

	Term	Submission Value	Synonyms	Definition	NCI Preferred Term
	C177920	MEDICAL DEVICE TIME-TO-EVENT	MDTTE	A dataset containing data that is used for medical device Time-to-Event analyses.	Medical Device Time-to-Event Dataset

What’s New in ADaM OCCDS v1.1

New Variables

Added New Naming Conventions

Sub-Class ADVERS EVENT

OCCDS New Examples

ADaM Structure for Occurrence Data (OCCDS) 1.1

New variables e.g.,

- **TREMxxFL**, where there are multiple periods analysis needs (example 4, Analysis of Treatment-emergent Adverse Events in a Cross-Over Interaction Study)

New Naming Conventions when multiple sources

- "U" for "unmodified" e.g., **U**BODSYS when combining AE (AEBODSYS) and CE (CEBODSYS)

ADaM Structure for Occurrence Data (OCCDS) 1.1

SubClass=ADVERSE EVENT

- Impact on some “Core” definition e.g., Core=“Req” for –STDTC and –ENDTC when SubClass=**ADVERSE EVENT**

ADaM Structure for Occurrence Data (OCCDS) 1.1

Three additional examples

- Analysis of Adverse Events that Change over Time
- Analysis of Adverse Events from Multiple Input Domains
- Analysis of Protocol Deviations

ADaM Implementation Guidance for Medical Device v1.0

CDISC for Medical Devices

New Classes, ADDL vs ADSL

CDISC for Medical Devices

SDTMIG-MD V1.0 | **SDTMIG-MD V1.1** | **ADaMIG-MD V1.0** | **SDTMIG-MD V2.0**

2012 ----------> 2019 ----------> Nov 2021 ……

SPDEVID
Sponsor Device Identifier

New Classes

- Three new standard ADaM classes
  - ADDL for ADSL
  - MDBDS for BDS
    - MDTTE sub-class
  - MDOCCDS for OCCDS
- Needed when subjects are exposed to multiple devices during the course of the study
- Many concepts are similar to other standard classes

New Classes – ADDL vs ADSL

- ADSL is conditionally required in MD studies
  - When subjects data are collected and analyzed
- ADDL is same as ADSL, but for device information
- Typical source of ADDL can be DI, DR, PR, DX from SDTM
- SPDEVID – Required
- USUBJID – Conditionally Required
- SITEDID - Required

2022 EUROPE INTERCHANGE

CDISC VIRTUAL CONFERENCE

27-28 APRIL

3:30 PM - 5:00 PM CEST on Wednesday, April 27

16:00 - 16:30

ADaM Implementation in Medical Device Clinical Trials - From Theory to Practical Applications

Roxane Debrus, Terumo Europe NV

"ADaM Implementation Guide for Medical Devices" CDISC EU Interchange 2021, Julia Yang, Karin LaPann, Silvia Faini

ADaM Implementation Guidance for Non-Compartmental Analysis v1.0

What is a “Non-Compartmental Analysis”

BDS sub-class

New Variables

ADaM Implementation Guidance for Non-Compartmental Analysis (ADNCA) v1.0

- Non-Compartmental Analysis is one the mathematical method used to calculate Pk Parameters
- No new classes
- **ADNCA**
  - Not a standard name
  - Class=BDS Sub-Class=**NON-COMPARTMENTAL ANALYSIS**
  - SDTM PC and supplemented by information from the EX, EC, or other relevant domains
  - New variables e.g.,
    - Flags to identify records not included in the analysis
    - Treatment/Time Intervals
    - Specific dosing variables
    - DOSEA, DOSEU and AVISIT are “Req” variables

Conclusions

Recap

ADaM Team 2022 Plans

Conclusions / Recap

- Several ADaM sub-teams currently working on a number of different initiatives
- Several guidance / documents available for ADaM Implementation
- Different Versions and Different documents to consider
- Working Progress (https://www.cdisc.org/standards/in-development)

Standard ▲	Release Notes	Projected Publication
ADaM Examples of Traceability	Preparing for Publication.	Q2 2022
ADaM Oncology Examples	In Development.	2022
ADaM popPK Implementation Guide v1.0	In Development.	Q4 2022
Analysis Results Standard v1.0	In Development.	2023

Thank You!

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Abstract

With SDTM and ADaM new IG both released last November 2021, CDISC had an explosive end of 2021. In one single day CDISC was able to release for both SDTM, and ADaM a new Implementation Guidance (IG) along with other related documents, and also a new version of the standard for SDTM.

The focus of this presentation will be on ADaM update:

- ADaM Implementation Guidance Version 1.3

- ADaM OCCDS Implementation Guidance Version 1.1

- ADaM Implementation Guidance for Medical Device Version 1.0

- ADaM Implementation Guidance for Non-Compartmental Analysis Version 1.0

The ADaM CDISC Team had other updates targeted for 2022 such as the "ADaM Examples of Traceability," and "ADaM Oncology Examples." A preview from this planned new guidance will be also presented.