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Current & Forthcoming ADaM Publications

Presented by Cindy Stroupe
UCB, Inc.



Meet the Speaker

Cindy Stroupe

Title: Standards Manager

Organization: UCB

Has been at UCB, Inc. for almost 20 years as a statistical programmer and now as a Standards Manager focusing on analysis standards and end-to-end implementation. Support within the CDISC ADaM team has included participation in the following sub-teams: ADaM Conformance, ADaM Implementation Guide version 1.2, ADaM Implementation Guide version 1.3 and ADaM Library Team. Currently serving as Future ADaM Team Lead, planning to move into the Team Lead role beginning in January 2024.



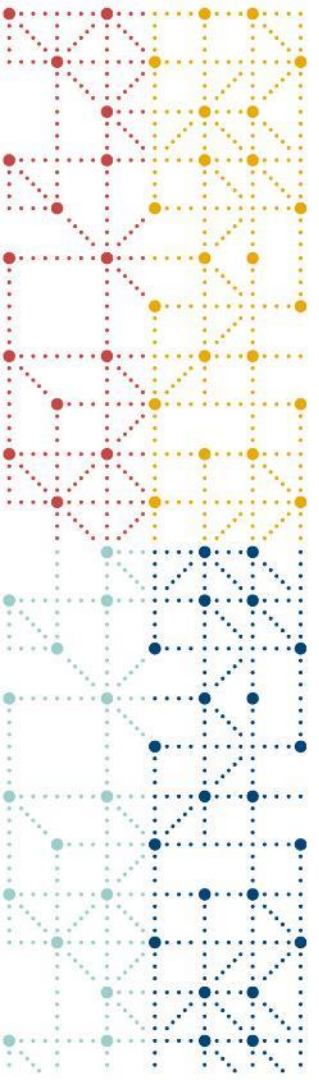
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- *The author have no real or apparent conflicts of interest to report.*



Agenda

1. ADaM Implementation Guide v3.0
2. ADaM Implementation Guide for Anti-drug Antibodies (ADADA) v1.0
3. ADaM Implementation Guide for Population Pharmacokinetic (ADPPK) v1.0
4. Other Current and Forthcoming ADaM Publications



ADaM Implementation Guide

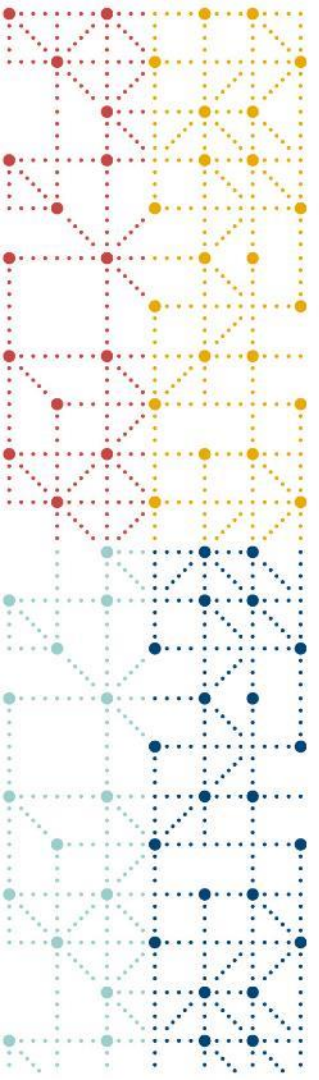
Version 1.3



ADaMIGv3.0

Bring all Implementation Guides (IG) together

- Consolidation of many of the ADaM normative document, including:
 - ADaM (model document)
 - ADaMIG
 - ADaMIG for Non-compartmental Analysis Input Data
 - ADaM Structure for Occurrence Data Implementation Guide
 - ADaM for Population Pharmacokinetic Implementation Guide (when finalized)
- The ADaMIG for Medical Devices will remain as its own document
- Target Publication Date: 2025



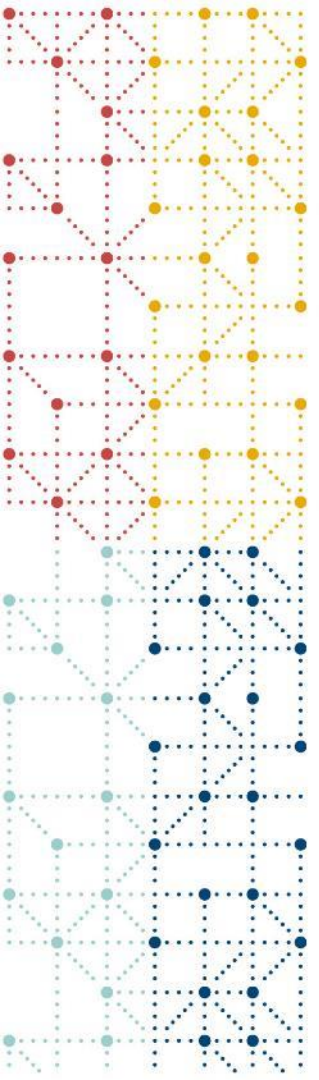
ADaM Implementation Guide for Anti-drug Antibodies (ADADA) Implementation Guide

Version 1.0



ADADA v1.0

- A BDS-like structure is needed to support proper analysis of ADA.
- ADADA will require specific nominal and actual timing variables.
 - First dose – NFRLT & AFRLT
 - Most recent Dose – NRRLT & ARRLT
- The ADADA document will acknowledge BDS and focus on what new pieces need to be added.
- A similar approach was used for ADNCA and ADPPK.



ADaM Implementation Guide for Population Pharmacokinetic (ADPPK)

Version 1.0

ADaM ADPPK v1.0: New Sub-class of BDS

Details the typical dataset that can be submitted to create PPK parameters:

Table 4.1 Data Structure

Data Structure Name	Data Structure Description	Class of Dataset	Subclass of Dataset	CDISC Notes
ADPPK	Basic Data Structure Population Pharmacokinetic Analysis	BASIC DATA STRUCTURE	POPULATION PHARMACOKENTIC ANALYSIS	Dataset designed to support PPK. Sourced from SDTM (e.g., PC, DM, EX, LB) and ADaM (e.g., ADSL and ADEX datasets).

The Data Structure Name, Data Structure Description, and CDISC Notes are intended to provide information to assist producers in preparing their datasets and are not intended to be metadata submitted in define.xml.



Other Current & Forthcoming Publications

1. Other Current Publications
2. ADaM Questionnaire Supplements (ADQRS)
3. ADaM Oncology Examples
4. ADaM Traceability Examples
5. Other future publications

Other Current ADaM Publications

The following are companions to the above publications:

- ADaM Model Document v2.1
 - ADaM v2.1 was released December 2009 and, although most of the content in the document still applies today, an important considerations document has been created to aid the ADaM user, outlining developments not described in ADaM v2.1
- ADaM Implementation Guide v1.3
 - ADaM IG v1.3 was released in November 2021 and is the latest ADaM Implementation Guide. The documents under development are using the variables and concepts in this document as a base.
- ADaM Conformance v5.0
 - Contains rule sets for each version of the ADaMIG and incorporates all conformance rules from above publications

Current/Forthcoming: ADaM Questionnaire Supplements

- National Early Warning Score (NEWS2) – Close to publication
- Hamilton Depression Rating Scale (HAMD-17) – Preparing to be sent for public review
- Acute Physiology and Chronic Health Evaluation II (APACHE II) – Preparing for internal CDISC review
- Pain Index (PI) – preparing for internal sub team review
- WPAI – just beginning



Forthcoming: ADaM Oncology Examples

- Details various oncology analysis needs using current ADaM dataset structure
- First version of Document is close to being sent out for public review
 - Adverse Events
 - Biomarkers
 - Blood Transfusions
 - Survival Analysis
 - Including PARQUAL
- Subsequent versions will include additional topics



Forthcoming: ADaM Examples

- ADPP – Examples document detailing how to create ADPP using existing variables from the external vendor data as a source
- PDILI – Examples document detailing an example of how to create the data need for potential drug induced liver injury and Hy's Law

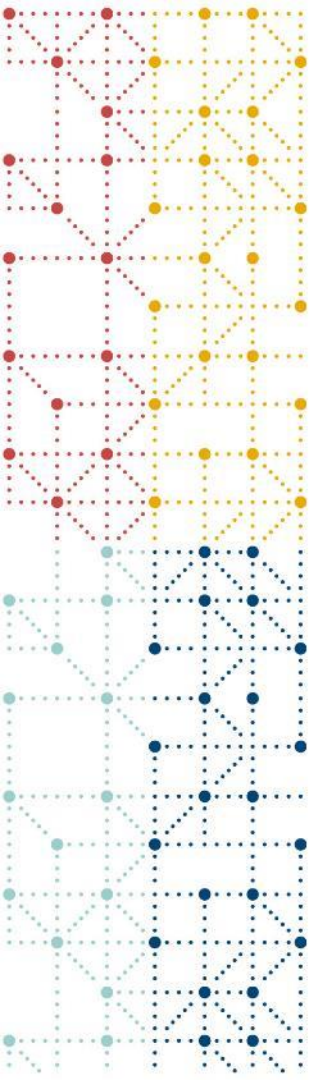


Future of ADaM Documents

- Can we provide additional implementation guidance?
- Should all or some of the publications be combined?
- Can we improve internal consistency within ADaM?
- Can we better serve the user community?

Acknowledgements to Team Leads

- Nancy Brucken
ADQRS
- Liana Forman
COVID-19 Guidance
- Luke Reinbolt
ADPPK IG
ADPP Example
- Jane Kang
ADADA IG
- Paul Slagle
Oncology Examples.
- Tatiana Sotingco
ADaM Team Lead
- Wayne Zhong
Traceability Example
- Amanda Johnson
PDILI Example



Thank You!

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