Current & Forthcoming CDISC ADaM Publications: An Overview

Guowei Wu and Cindy Stroupe
CDISC ADaM Team

Meet the Speakers

Guowei Wu, Ph.D.

Title: Sr. Principal Scientist

Organization: Merck & Co., Inc., Rahway, NJ, USA

Has been at Merck & Co., Inc., Rahway, NJ, USA for more than 20 years where he is a standard architect. He is a CDISC ADaM team member since 2012 and participated several sub-teams. Currently, he is the sub-team leader for 'CDISC ADaM FDA technical document and TAUG review team' and 'CDISC ADaM FMQ example team'

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 ADaM Team Lead

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 CDISC.*

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

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Agenda

1. CDISC ADaM Team
2. CDISC ADaM Guiding Principles
3. Current CDISC ADaM Publications
4. Forthcoming CDISC ADaM Publications

CDISC ADaM Team

CDISC ADaM Team:

- Current Team Lead: Cindy Stroupe

- Future Team Lead: Trevor Mankus

- Prior Team Lead: Brian Harris

- Over 150 volunteers participate in at least one ADaM sub-team

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CDISC ADaM Sub-teams

ADPP Examples	FMQ Examples
Oncology Examples	DILI Analysis
CDISC/PHUSE Team - Analysis Datasets to address Lab Table Datasets	ADaM Controlled Terminology
ADA Dataset	ADQRS
ADaM Consolidation	FDA Technical Document and TAUG review
Conformance Rules	Education
Other IGs & TAUGs	Cross-foundational

CDISC ADaM Guiding Principles

Technical Implementation Principles ADaM

Usability	Clarity and Consistency	ADaM documents include metadata	Support End-to-End Data Flow within CDISC	Continuous Improvement of Standards, Focusing on Priorities need to include "Continuous Improvement" below
Statement: ADaM standards are developed to align with analysis needs, enable analysis-ready datasets, and support the needs of reviewers, including traceability back to SDTM. **Rationale:** Study analysis reporting should not need to change in order to be represented in ADaM. Reviewer needs should also be met using ADaM standards. **Key Benefits:** • Enables the standards to be broadly adopted • Allows for reproduction of analysis results • Allows for re-use of programs and automation of metadata-driven processes	**Statement:** ADaM develops clear, consistent, and predictable analysis dataset standards that can be clearly understood and readily implemented. **Rationale:** Consistency and predictability in the data standard aid in both development and the review process. **Key Benefits:** • Eases implementation of the ADaM standard • Fosters communication between users of ADaM datasets *Action Items:* • *Include rules/validation checks as part of development*	**Statement:** ADaM sets the standard for both data and metadata. **Rationale:** Clear communication can be achieved by readable metadata **Key Benefits:** • Metadata aids in clear and unambiguous communication • Allows for representation in SHARE	**Statement:** ADaM standards are developed with the expectation of SDTM data as the source and Define-XML as the standard for delivering metadata. **Rationale:** SDTM, ADaM, and Define-XML are all parts of the CDISC standard **Key Benefits:** • Enables standards to work together • Supports traceability across the CDISC standards	**Statement:** ADaM deliverables are determined and prioritized based on a blend of considerations, including addressing the most commonly occurring analysis needs, regulatory guidance, other CDISC initiatives and developments, and team members' interest. **Rationale:** Deliver what industry needs and we have the skillset to create **Key Benefits:** Provides solutions that are broadly applicable, taking advantage of interest

Current CDISC ADaM Publications

ADaM Documents and Their Applicability to ADaMIG Versions

Document	ADaMIG v1.0	ADaMIG v1.1	ADaMIG v1.2	ADaMIG v1.3
Analysis Data Model	Foundational doc for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaM OCCDS IG v1.1	Not written for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaM OCCDS v1.0	Not written for ADaMIG v1.0	Written for ADaMIG v1.1	Applicable	Applicable
ADaM Data Structure for Adverse Event Analysis v1.0	Written for ADaMIG v1.0	Superseded by OCCDS v1.0	Superseded by OCCDS v1.0	Superseded by OCCDS v1.0
ADaMIG for Non-compartmental Analysis (ADNCA) v1.0	Not written for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaMIG for Medical Devices (ADaMIG-MD) v1.0	Applicable	Applicable	Applicable	Applicable
ADaM Conformance Rules v5.0	Applicable	Applicable	Applicable	Applicable
The ADaM BDS for Time-to-Event Analyses v1.0	Written for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaM Statistical Examples v1.0	Written for ADaMIG v1.0	Applicable	Applicable	Applicable
Define-XML v2.0	Applicable	Applicable	Applicable	Applicable
ARM Specification for Define-XML Version 2 v1.0	Applicable	Applicable	Applicable	Applicable

Other Current ADaM Publications

- Basic Data Structure for ADaM popPK Implementation Guide v1.0

- Associated Example Documents

    o ADaM Metadata Submission Guidelines v1.0

    o ADaM Examples of Traceability v1.0

    o ADaM Examples in Commonly Used Statistical Analysis Methods

- Knowledge Articles and Examples

Forthcoming CDISC ADaM Publications

Forthcoming CDISC ADaM Publications

ADaM v3.0

- Consolidation of most of the ADaM normative documents, 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
- The ADaMIG for Medical Devices will remain as its own document
- Target Publication Date: 2026

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Forthcoming CDISC ADaM Publications

ADaM Implementation Guide for Anti-drug Antibodies (ADADA)

- A BDS-like structure is needed to support proper analysis of ADA.

- ADADA will require specific nominal and actual timing variables.

- 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.

- Target Publication Date: 2025

Forthcoming CDISC ADaM Publications

ADaM Oncology Examples:

- An examples document to support analyses for clinical trials focused on oncology therapies.

- Provide sponsors with a standardized approach for using ADaM for the oncology therapeutic area.

- Details various oncology analysis needs using current ADaM dataset structure

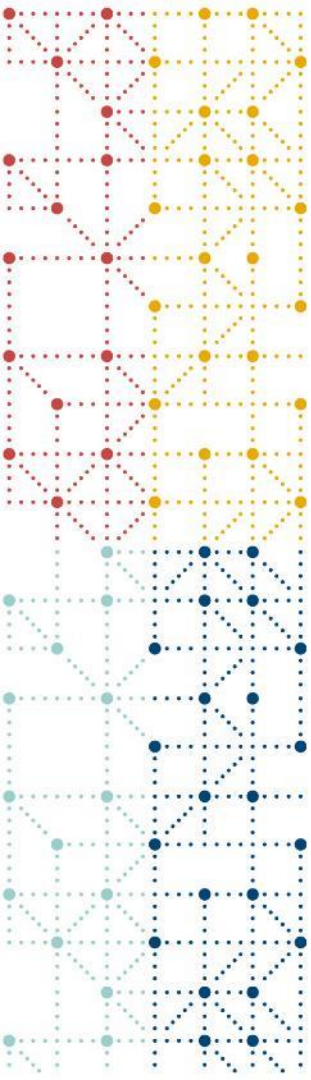- Target Publication Date: 2025

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Other Forthcoming CDISC ADaM Publications

- ADaM FMQ (FDA Medical Query) Examples
- ADDILI – Example Dataset for DILI (Drug-Induced Liver Injury) Analysis included in FDA Standard Safety Tables and Figures
- ADaM Example Datasets for Lab Displays: An examples document containing ADaM-conformant datasets to support some of the lab displays included in the FDA Standard Safety Tables and Figures
- ADQRS supplements
- ADPP – Examples document detailing how to create ADPP using existing variables from the external vendor data as a source

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?

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Thank You!