



Q&A Panelists

- Nancy Brucken
IQVIA
- Nate Freimark
The Griesser Group
- Brian Harris
AstraZeneca
- Jiannan (Jane) Kang
Merck
- Trevor Mankus
Certara
- Sandra Minjoe
ICON
- Luke Reinbolt
Navitas Data Sciences
- Cindy Stroupe
UCB Pharmaceuticals
- Tatiana Sotingco
Johnson & Johnson
- Guowei Wu,
Merck

ADaM Office Hours

10.10.2023

The logo for CDISC, featuring the lowercase letters "cdisc" in a dark blue font. Above the letter "i" are four small colored dots: red, yellow, green, and light blue.



Documents in publishing

Population Pharmacokinetic
(POPPK) Implementation Guide

ADaM Conformance Rules v5.0



Population Pharmacokinetic Implementation Guide

- Purpose:
 - Provide guidance and rules around dataset structure for use in Population Pharmacokinetic (PK) modeling, a sub-class of the Basic Data Structure (BDS)
- This is an implementation guide
 - An updated version of the ADaM Conformance Rules will be published at the same time this document is published



Documents in Review Cycle

ADaM Oncology Examples

Analysis Results Data Model and
Implementation Guide



ADaM Oncology Examples

- Purpose:
 - Present examples demonstrating how the current version of ADaM can be used to generate analyses that support the review and approval of compounds used in the treatment of oncological disease
 - It is intended to provide examples of how the model can be used but not provide guidance or rules in the application of ADaM
 - No impact on ADaM Conformance Rules
- Current Status:
 - Sub-team is currently resolving public review comments
- Target Publication Date:
 - 1st half of 2024

Analysis Results Data Model

- Purpose:
 - Provide a model and implementation guide for analysis results and associated metadata
 - This will be a model and implementation guide
 - It will have associated conformance rules



Documents in Concept Phase

Implementation Guides

- AD ADA
- ADaM 3.0

Examples Documents (possibly)

- AD DILI
- FMQs



ADADA (Analysis of Anti-Drug-Antibody Results)

- Purpose:
 - Provide guidance on preparing datasets for use in analyzing and modeling Anti-Drug Antibody results
 - This will be an implementation guide, with associated conformance rules
- Current Status:
 - A sub-team has drafted a proposal
- Target Publication Date:
 - 2024

ADaM 3.0

- Purpose:
 - Consolidation of many of the ADaM normative documents, including:
 - ADaM (model document)
 - ADaMIG
 - ADaM Structure for Occurrence Data Implementation Guide
 - ADaMIG for Non-compartmental Analysis Input Data
 - The ADaMIG for Medical Devices will remain as its own document
 - As this is a model & implementation guide, ADaM conformance rules will be updated
- Current Status:
 - Sub-team has created a consolidated table of all ADaM variables and has begun the initial draft
- Target Publication Date:
 - 2025

AD DILI (Analysis of Drug Induced Liver Injury Events)

- Purpose:
 - Provide guidance on preparing datasets for use in analyzing DILI events
 - Team is still deciding if this will be an examples document or an implementation guide – most likely an examples document
- Current Status:
 - A sub-team has just been created to investigate this further
- Target Publication Date:
 - 2024

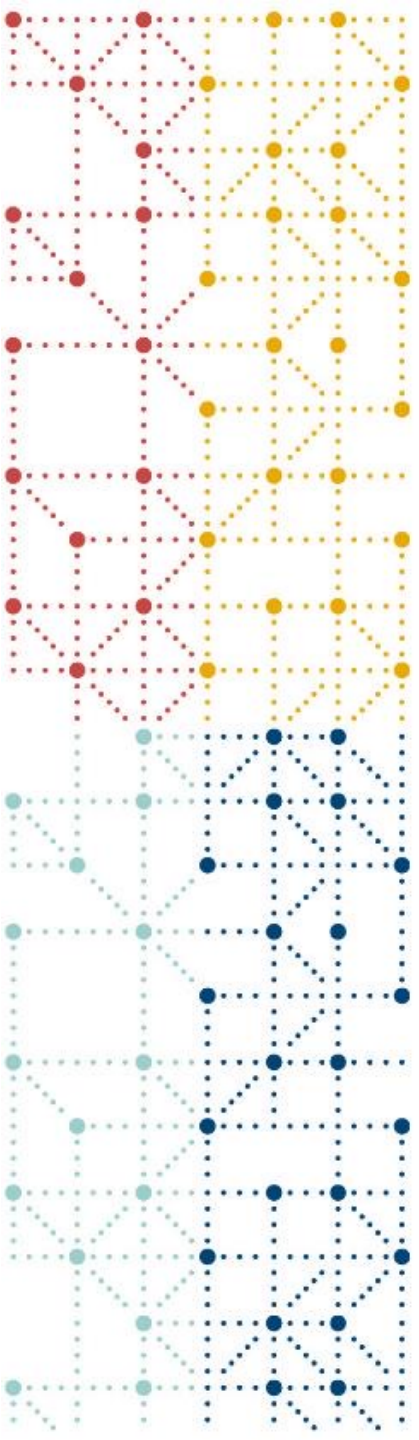
FDA Medical Queries (FMQ) Examples Document

- Purpose:
 - Provide guidance on preparing datasets for any analyses using FMQs
 - The current plan is to create an examples document rather than making any updates to the OCCDS v1.1 document
- Current Status:
 - A sub-team is working on a proposal
- Target Publication Date:
 - 2024



Other

- AD QRS Supplement work is ongoing
- PHUSE/CDISC ADaM collaboration example document supporting FDA Standard Safety Tables and Figures Integrated Guide
- Looking at ways to expand example documents and knowledge articles
- See a gap in the current ADaM standards? Come join the team



**Thank
You!**

cdisc

