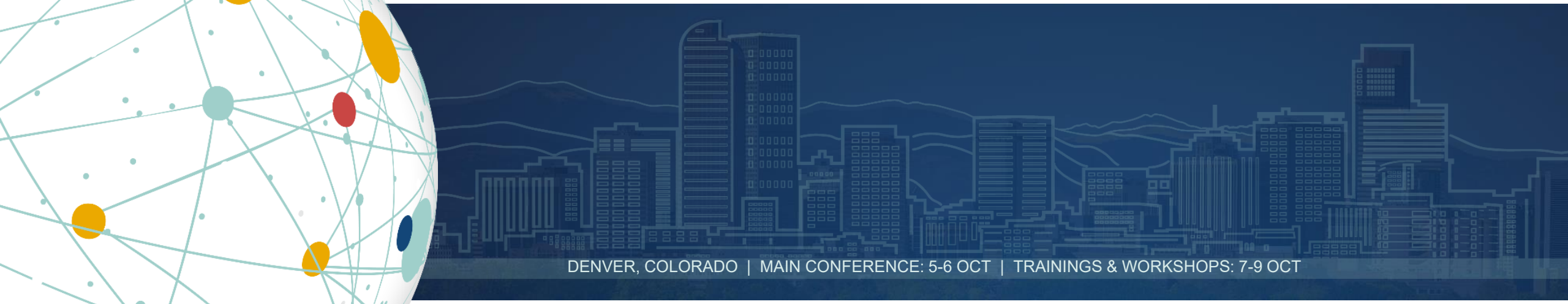


2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



ADaM +IG v3.0: Consolidating the Model & Implementation Guide

ADaM 3.0 Update Series | CDISC 2026 US Interchange

Presenters



ADaM+IG v3.0 Consolidation Sub-team (former) Lead
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Agenda

1. What this session will and will not cover
2. Why consolidation is needed
3. What changed over time
4. What ADaM+IG v3.0 is addressing

What is Covered in this Session

Current Presentation

- General consolidation information

Following Presentations

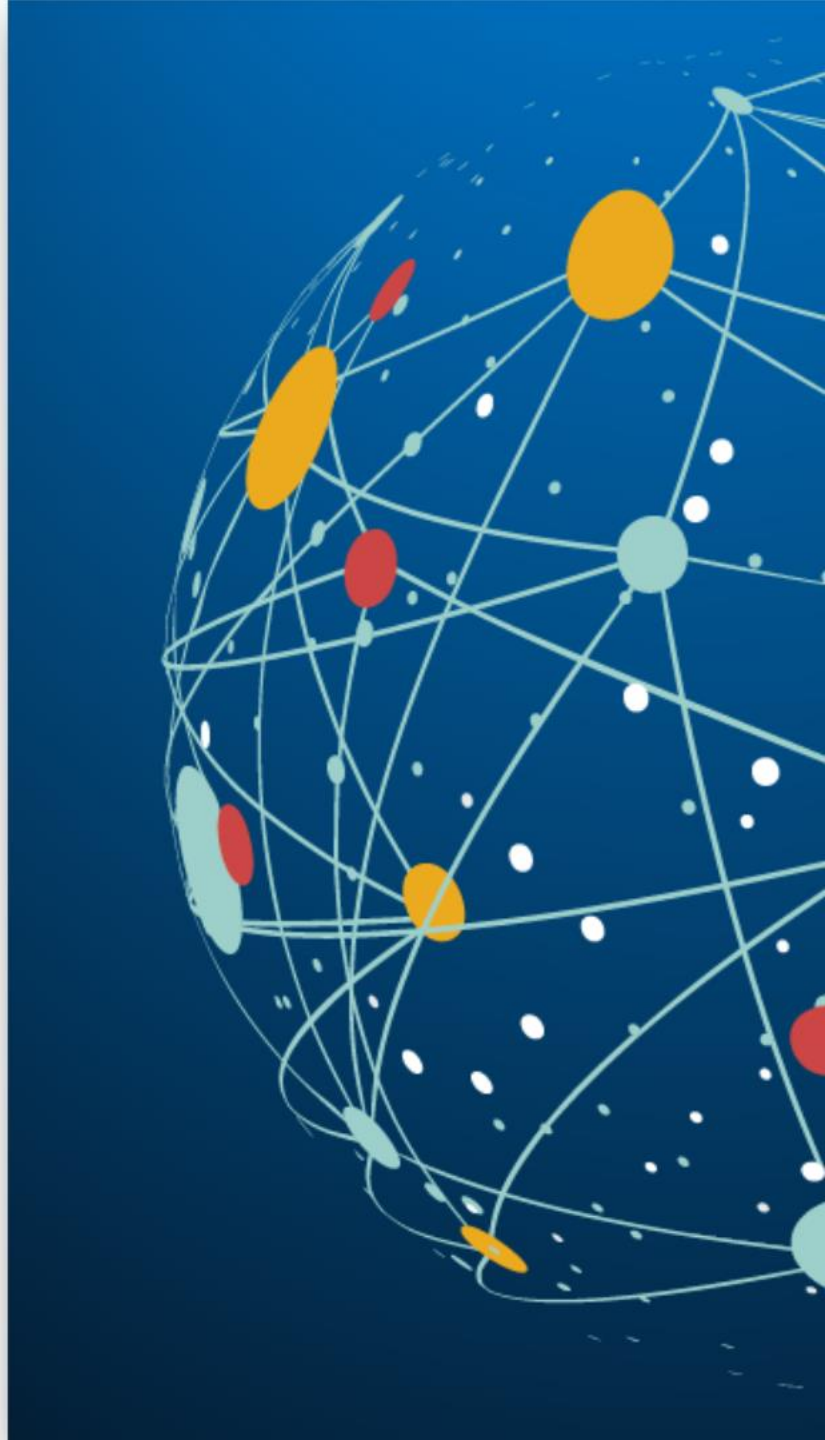
- Examples and supplemental supporting information
- Conformance rules and newly added content

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What changed over time

What Changed Over Time

- Normative guidance began in the Model document and primary ADaM Implementation Guide; later documents (OCCDS, ADNCA, ADPPK) added normative content of their own.
- A separate model document lost value, as it needed a little updating when new classes or subclasses appeared.
- Inconsistencies across the Implementation Guides created ambiguity about how concepts and guidance apply across data classes.
- Subsequent ADaMIG releases added major updates, leaving parts of earlier guidance outdated or superseded.



Why ADaM+IG v3.0?

Background and motivation for consolidation

Why Consolidation is Needed

- Consolidating multiple documents into one comprehensive standard—“one to rule them all.”
- Cover all ADaM classes and subclasses in one authoritative resource.
- Inventory all ADaM variables by class and subclass, with applicability and usage constraints.
- Resolve conflicting guidance across implementation documents.
- Clarify how concepts and variables are used across data classes.
- Create a scalable foundation for future updates.
- Prepare for Analysis Concepts and the Analysis Results Standard while keeping consistency and traceability.

“One to rule them all” (Lord Sauron)

What ADaM+IG v3.0 is Addressing

What ADaM+IG v3.0 Is Addressing

- ADaM IGs and the Model merged into one document
  - Included in the consolidation:
    - ADaM v1.3
    - OCCDS v1.1
    - ADADA v1.0
    - ADNCA v1.0
    - ADPPK v1.0
  - Excluded:
    - Medical Devices Implementation Guide
      - Rationale
        - Different concepts driven by regulatory requirements
        - CDISC is considering a cross-foundational Medical Devices standard, like the TIG

What ADaM+IG v3.0 Is Addressing

- A consolidated variable list with consistent attributes and CDISC notes
  - It shows which variables apply to which dataset class including variables that apply across multiple classes (e.g., ASTDT)

Variable Name	Variable Label	Section	Type ODM	Terminology	Core	CDISC Notes	Technical Notes
ASTDT	Analysis Start Date	Timing	date	encoding: System Date	ALL: Cond AE: Req	Usage: The start date associated with the analysis record. For BDS: Usage: The start date associated with the analysis value. ASTDT and AENDT may be useful for traceability when AVAL summarizes data collected over an interval of time, or when AVAL is a duration. For OCCDS: Origin: Derived= Created from converting XX.--STDTC from character ISO 8601 format to numeric date format, applying imputation rules if specified in the statistical analysis plan (SAP) or metadata.	Formal name: ASTDT Formal label: Analysis Start Date Name normalised: A|(ST)DT Concept Tags: |A|ST|DT| Name pattern: Regular SDTM Variable: Display format: date{fdl}. Recommended Classes: *BDS*OCCDS*OCCDSAE*

What ADaM+IG v3.0 Is Addressing

- Complex sections clarified based on ADaM team implementation experience
  - Clarified when to add derived columns versus derived rows in BDS
  - Created a variable list defining use by class and subclass, etc.
- Related concepts grouped by topic rather than by dataset class
  - All timing variables covered in a single section

What ADaM+IG v3.0 Is Addressing

- Moved larger examples to the Example Documents for easier reference.
- Added and refined smaller examples throughout to improve clarity and precision.
- New variables added to close gaps
  - PARAMXT (formerly PARQUAL)
    - Defined in the IG; extends PARAM
  - AyDY - Analysis Relative Day y
  - R2ANRLO – Ratio to Analysis Normal Range Low
  - Plus, other variables standardizing common concepts

Parts 2 & 3 will cover these topics in detail, so stay tuned!

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Consolidation, Not Reinvention

- The integration of ADaM IG v1.3 and ADaM Model Document v2.1 into ADaM+IG v3.0 primarily reflects document consolidation and restructuring, rather than new requirements.
- Existing guidance is unified and streamlined into one cohesive resource
- Key benefits: clarity, consistency, and usability across the standard
- Version 3.0 is an evolution of the standard: easier to understand, navigate, and implement
- Estimated date for public review is second half of 2027

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Sneak peek at the Consolidation Structure…



- ADaM v3 - Sections
  - 1 Introduction
  - 2 Fundamental Principles of ADaM
  - 3 Analysis Data and Information Flow
  - 4 ADaM Dataset Conventions
  - 5 ADaM Variable Conventions
  - 6 Standard ADaM Variables
  - 7 Examples of Treatment Variables for Common Trial Designs
  - 8 Creation of Derived Columns Versus Creation of Derived Rows in BDS
  - 9 Examples for Inclusion and Identification Records
  - 10 Examples of Bidirectional Lab Toxicity Variables & Shift Variables
  - Appendices

Summary

Summary

- One to Rule Them All
- Consolidation, Not Reinvention

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Questions?

