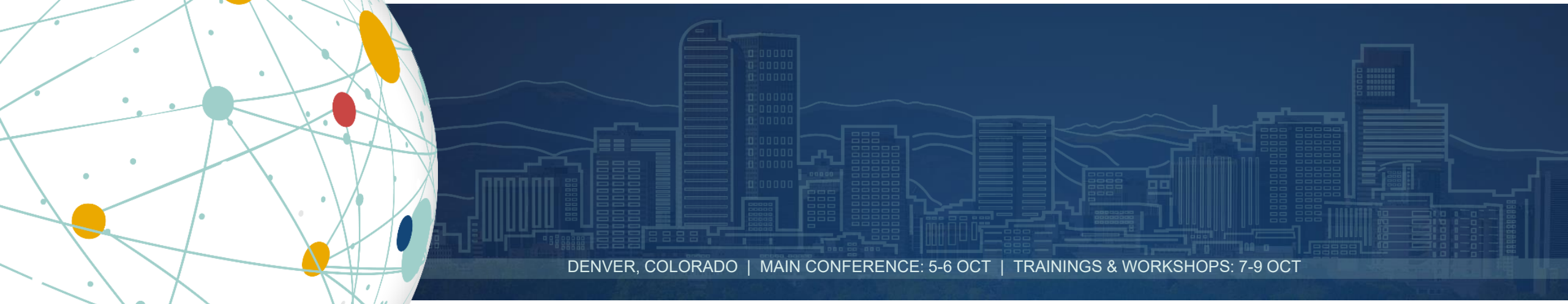


2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Curation of Informative Text as Part of ADaM+IG v3.0 Update

Session 3A: ADaM+IG v3.0 Update Series | CDISC 2026 US Interchange

Brian Harris | 5 October 2026

Presenters

Session 3
Track A

ADaM+IG v3.0 Update Part 2: Curation of Informative Text & Documents



ADaM Informative Document Sub-team Lead
Brian Harris
CDISC ADaM Team

The Consolidation Motivated

A new approach to presenting informative text within normative documents

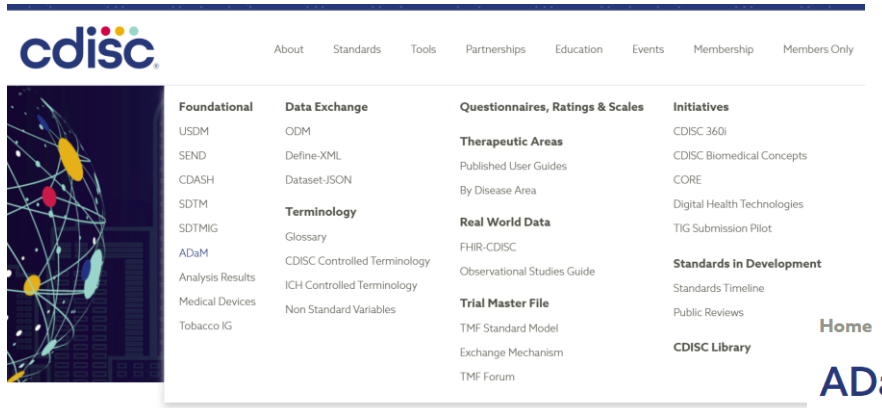
An active curation of the informative documents authored by the ADaM



Navigating ADaM Documents

At present and in the future

How does ADaM present to the community now?





Home / Standards / Foundational / ADaM

ADaM

Description | Versions | Education | Knowledge Base | Archive | Guiding Principles

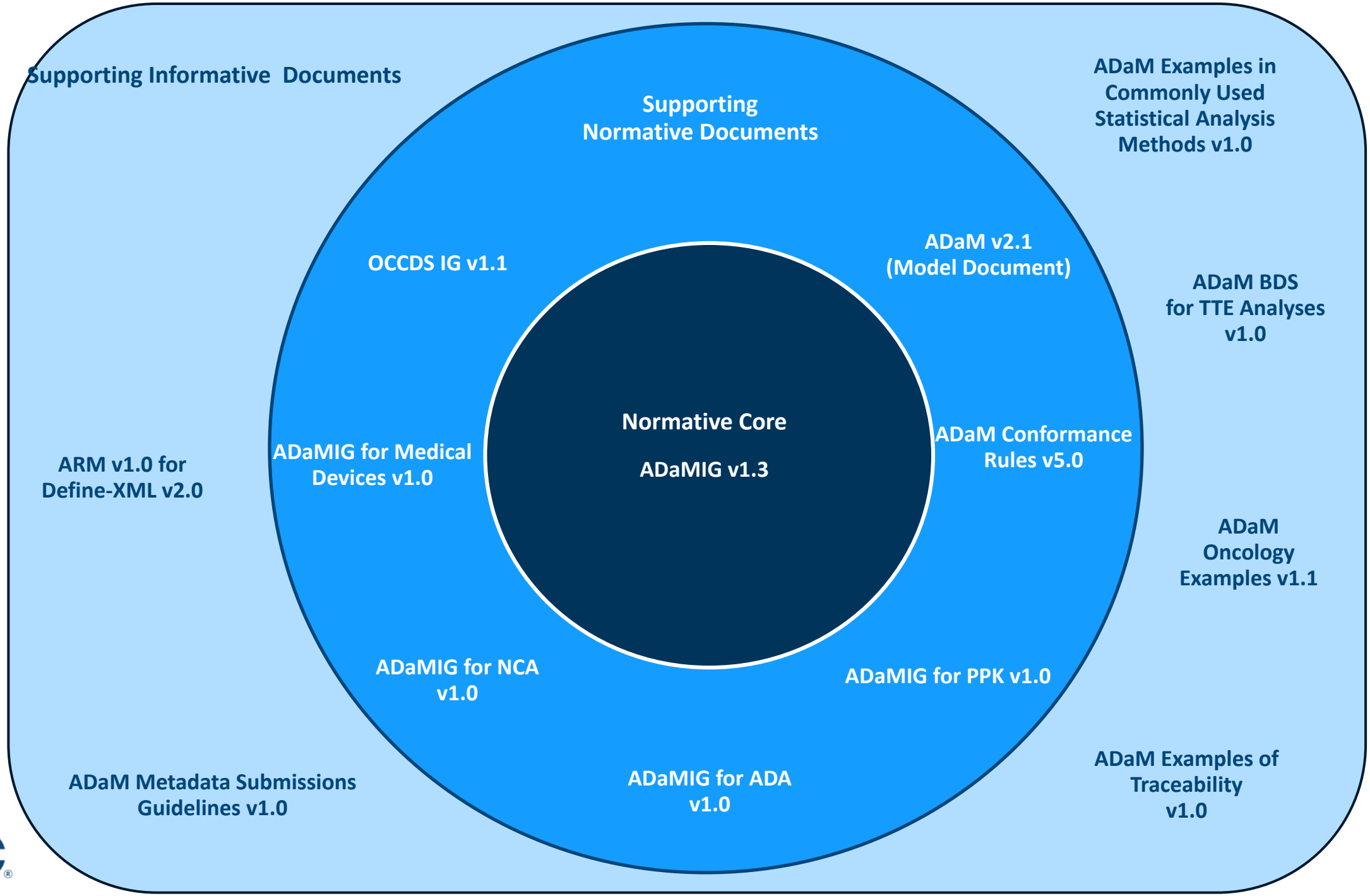
An Analysis Data Model Implementation Guide (ADaMIG) is developed in reference to a specific ADaM model. Currently, all ADaMIGs are supported by the ADaM v2.1 model. Additional ADaM supplements containing normative content for specific analysis use cases have also been developed. The table below lists the documents available at the time of publication of ADaMIG v1.3 and describes their applicability to ADaMIG Versions 1.0, 1.1, 1.2, and 1.3.

In addition to Models and Implementation Guides, Conformance Rules have been developed, which help to ensure that generated data structures conform to the standards. These rules aim to identify all conformance rules and case logic from ADaM documents, classifying and codifying them in a form that supports quality processes and tool development.

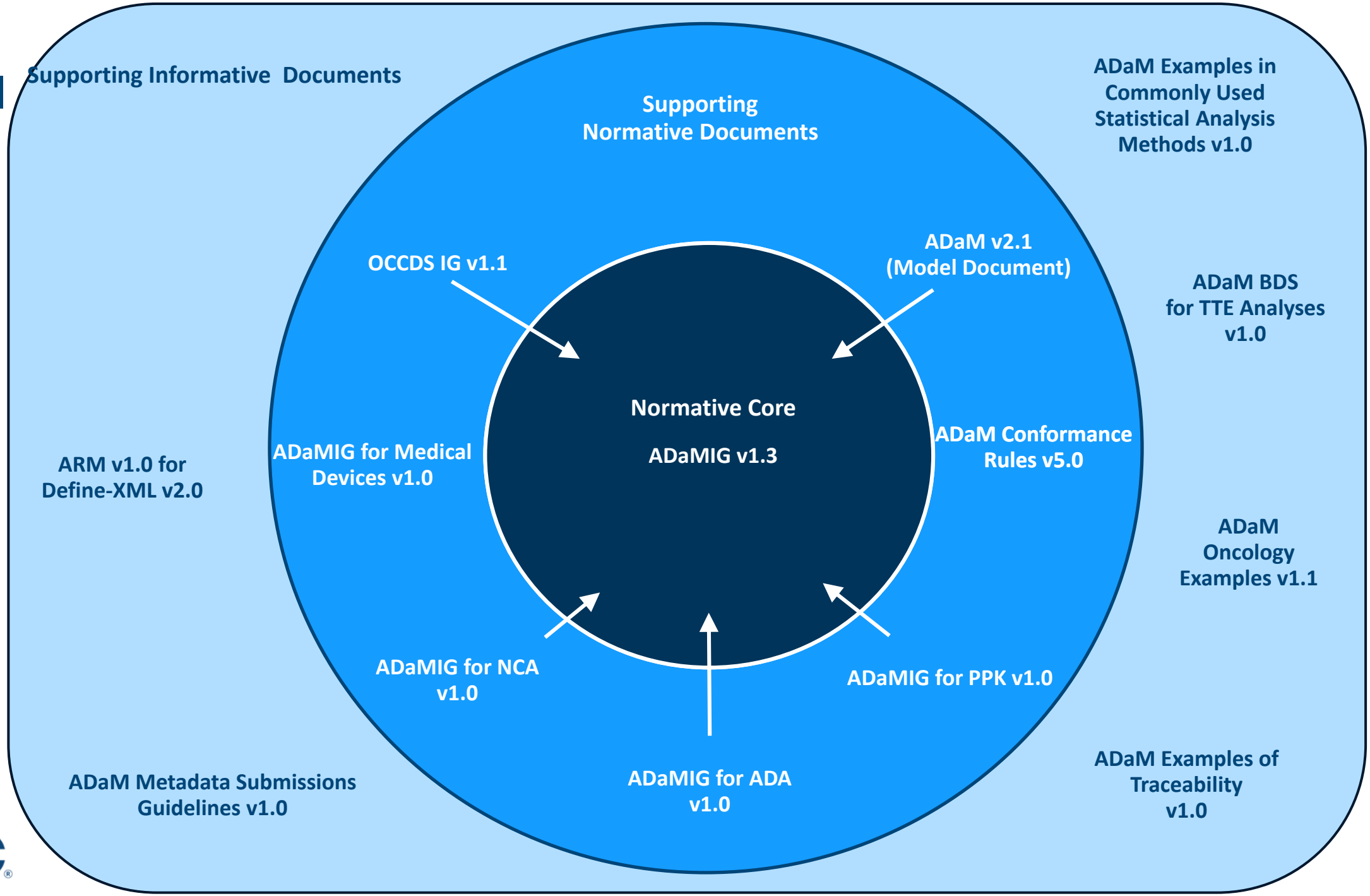
ADaMIG Version	Compatible Model, Rules & Implementation Guide	Associated Examples Documents
ADaMIG v1.3 29 November 2021	ADaM v2.1 ADaM Conformance Rules v5.0 ADaMIG for Medical Devices v1.0 ADaMIG for Non-compartmental Analysis Input Data v1.0 ADaM Structure for Occurrence Data Implementation Guide v1.1 Basic Data Structure for ADaM popPK Implementation Guide v1.0	ADaM Metadata Submission Guidelines v1.0 ADaM Examples of Traceability v1.0 ADaM Basic Data Structure (BDS) for Time-to-Event (TTE) Analyses v1.0 ADaM Examples in Commonly Used Statistical Analysis Methods Analysis Results Metadata (ARM) v1.0 for Define-XML v2.0 ADaM Oncology Examples v1.0

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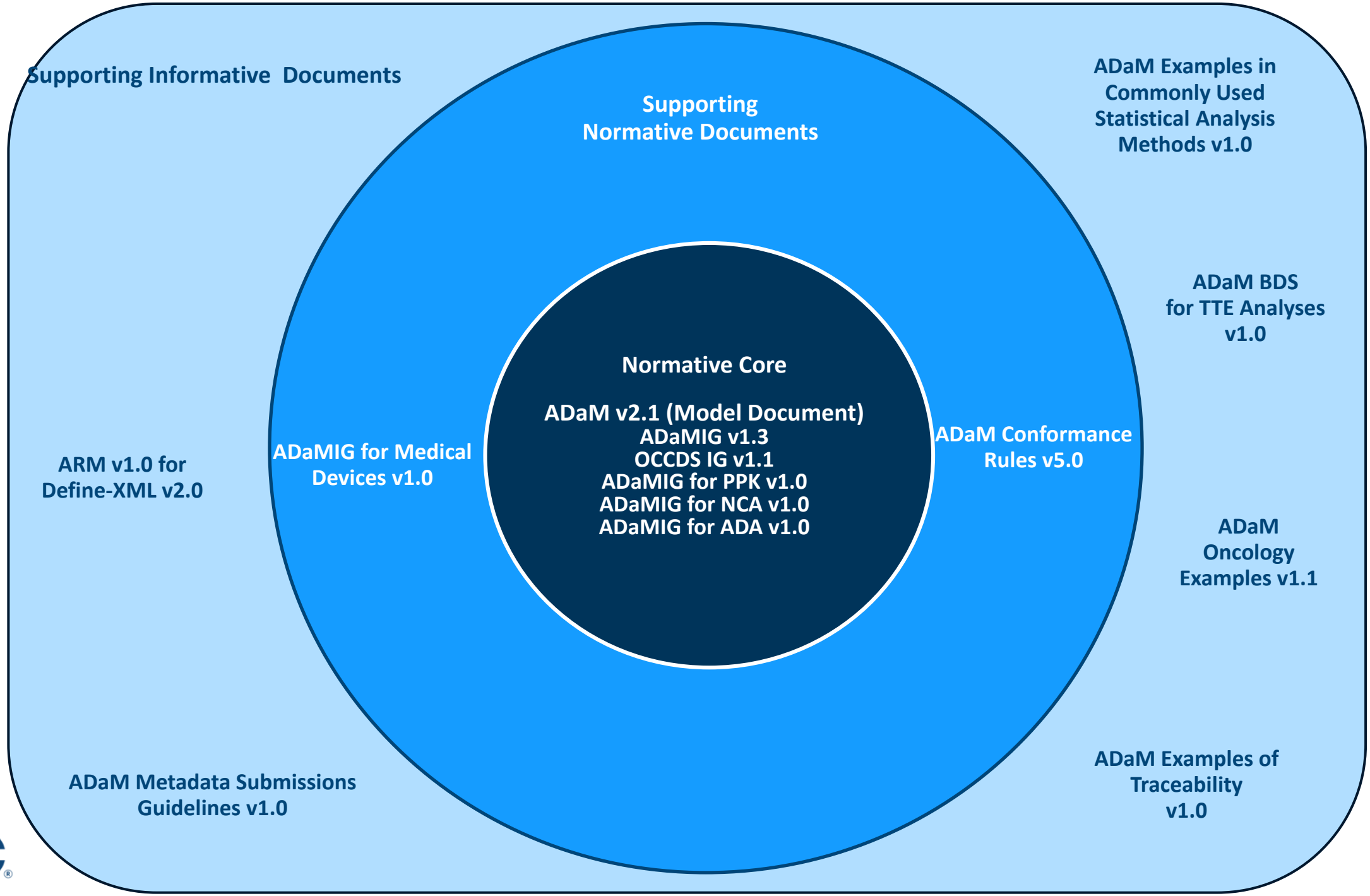
Now


Supporting Informative Documents
Supporting Normative Documents
ADaM Examples in Commonly Used Statistical Analysis Methods v1.0
OCCDS IG v1.1
ADaM v2.1 (Model Document)
ADaM BDS for TTE Analyses v1.0
Normative Core
ADaMIG v1.3
ADaMIG for Medical Devices v1.0
ADaM Conformance Rules v5.0
ARM v1.0 for Define-XML v2.0
ADaM Oncology Examples v1.1
ADaMIG for NCA v1.0
ADaMIG for PPK v1.0
ADaM Metadata Submissions Guidelines v1.0
ADaMIG for ADA v1.0
ADaM Examples of Traceability v1.0

The Proposal



In Progress


Supporting Informative Documents
Supporting Normative Documents
ADaM Examples in Commonly Used Statistical Analysis Methods v1.0
ADaM BDS for TTE Analyses v1.0
Normative Core
ADaM v2.1 (Model Document)
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ADaM Conformance Rules v5.0
ARM v1.0 for Define-XML v2.0
ADaM Oncology Examples v1.1
ADaM Metadata Submissions Guidelines v1.0
ADaM Examples of Traceability v1.0

A New Approach for Informative Text

Motivated by this consolidation effort

Normative text sets the rules; informative text explains them

NORMATIVE

Mandatory

Sets requirements and rules that you must follow to achieve compliance.

COMPLIANCE IMPACT

Required — it creates the obligation.

INFORMATIVE

Explanatory

Provides descriptive background, context, and guidance that help you understand the rules.

COMPLIANCE IMPACT

Not required — it supports understanding.

Key distinction: normative documents have corresponding conformance rules; “Examples” documents do not

Bottom line: normative text defines what you must do; informative text helps explain why and how.

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Write informative text to explain—not prescribe

EXPLAIN WITH EVIDENCE

★ EXPLAIN—DON'T PRESCRIBE

Describe what something is, how it works, or why it matters.

★ STAY FACTUAL AND PRECISE

State verifiable information; name sources, assumptions, and limitations.

★ SEPARATE FACT FROM ADVICE

Label advice as guidance or a recommendation—not an obligation.

★ USE EXAMPLES AND RATIONALE

Illustrate the concept without implying that the example is mandatory.

SIGNAL NON-NORMATIVE STATUS

★ CHOOSE NON-NORMATIVE VERBS

Prefer describes, indicates, may, can, is intended to, or is typically used to.

★ RESERVE REQUIREMENT WORDS

Keep must, shall, required, and prohibited for normative text.

★ LABEL THE CONTENT

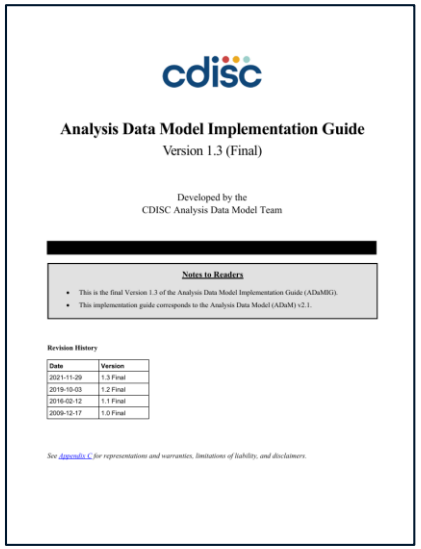
Use headings such as Background, Explanation, Example, or Rationale.

Guidance explains; it does not establish a compliance obligation.

Bottom line: make informative status explicit in the wording, structure, and labels.

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Currently, Examples at End of Normative Documents



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Analysis Data Model Implementation Guide

Version 1.3 (Final)

Developed by the
CDISC Analysis Data Model Team

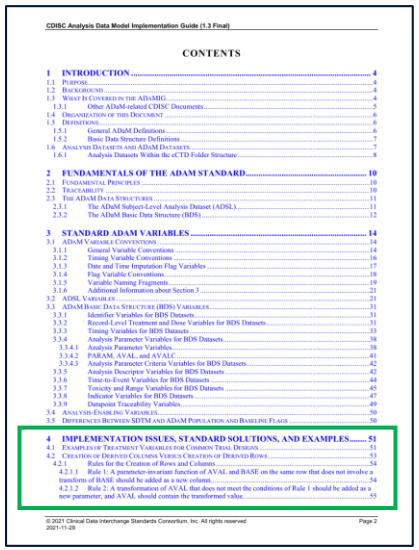
Notes to Readers

- This is the final Version 1.3 of the Analysis Data Model Implementation Guide (ADaMIG).
- This implementation guide corresponds to the Analysis Data Model (ADaM) v2.1.

Revision History

Date	Version
2021-11-29	1.3 Final
2019-10-03	1.2 Final
2016-02-12	1.1 Final
2009-12-17	1.0 Final

See Appendix C for representations and warranties, limitations of liability, and disclaimers.



CDISC Analysis Data Model Implementation Guide (1.3 Final)

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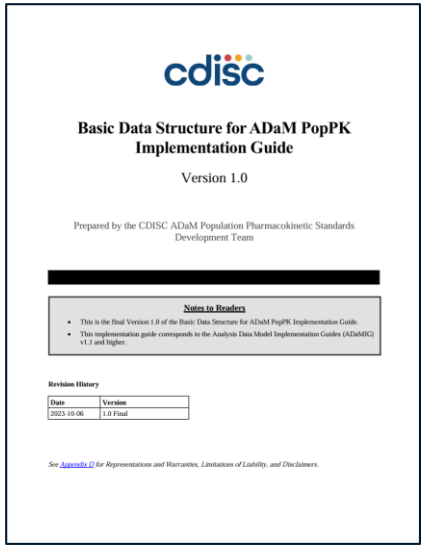
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CDISC Analysis Data Model Implementation Guide (1.3 Final)

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Basic Data Structure for ADaM PopPK Implementation Guide

Version 1.0

Prepared by the CDISC ADaM Population Pharmacokinetic Standards Development Team

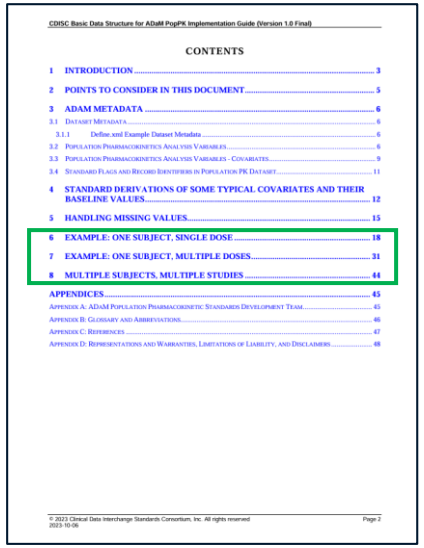
Notes to Readers

- This is the final Version 1.0 of the Basic Data Structure for ADaM PopPK Implementation Guide.
- This implementation guide corresponds to the Analysis Data Model Implementation Guides (ADaMIG) v1.3 and higher.

Revision History

Date	Version
2023-10-06	1.0 Final

See Appendix D for Representations and Warranties, Limitations of Liability, and Disclaimers.

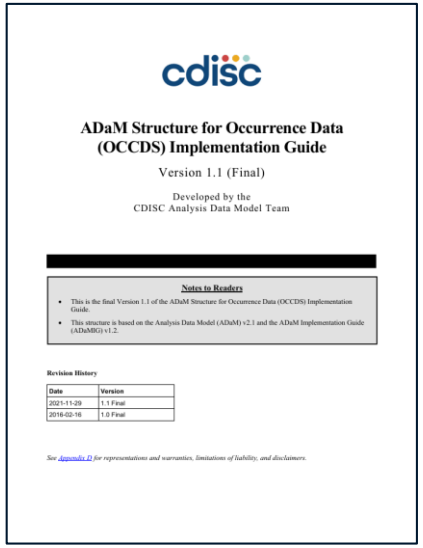


CDISC Basic Data Structure for ADaM PopPK Implementation Guide (Version 1.0 Final)

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ADaM Structure for Occurrence Data (OCCDS) Implementation Guide

Version 1.1 (Final)

Developed by the
CDISC Analysis Data Model Team

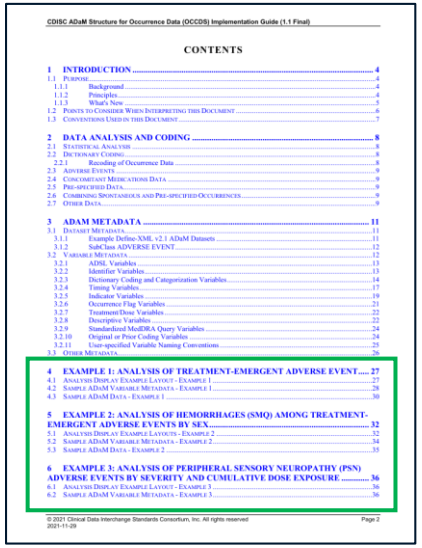
Notes to Readers

- This is the final Version 1.1 of the ADaM Structure for Occurrence Data (OCCDS) Implementation Guide.
- This structure is based on the Analysis Data Model (ADaM) v2.1 and the ADaM Implementation Guide (ADaMIG) v1.2.

Revision History

Date	Version
2021-11-29	1.1 Final
2016-02-16	1.0 Final

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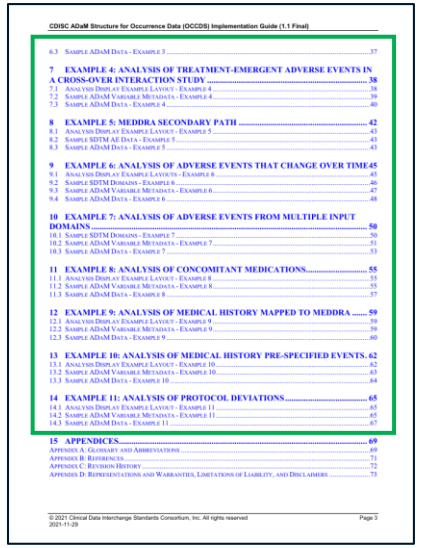


CDISC ADaM Structure for Occurrence Data (OCCDS) Implementation Guide (1.1 Final)

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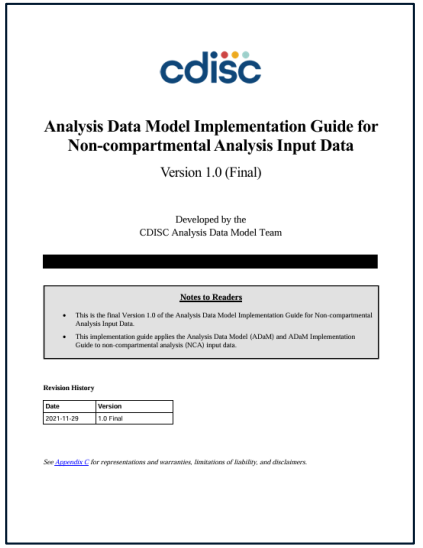
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CDISC ADaM Structure for Occurrence Data (OCCDS) Implementation Guide (1.1 Final)

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Analysis Data Model Implementation Guide for Non-compartmental Analysis Input Data

Version 1.0 (Final)

Developed by the
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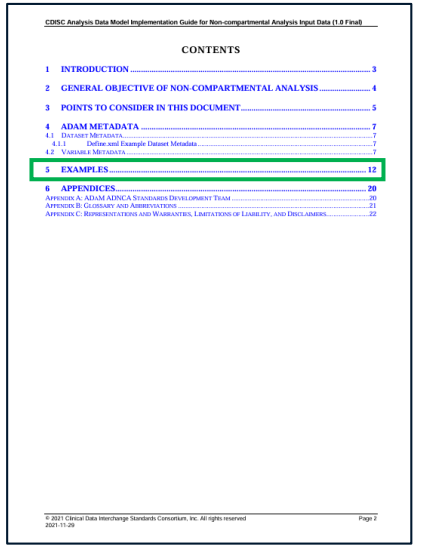
Notes to Readers

- This is the final Version 1.0 of the Analysis Data Model Implementation Guide for Non-compartmental Analysis Input Data.
- This implementation guide applies the Analysis Data Model (ADaM) and ADaM Implementation Guide to non-compartmental analysis (NCA) input data.

Revision History

Date	Version
2021-11-29	1.0 Final

See Appendix C for representations and warranties, limitations of liability, and disclaimers.



CDISC Analysis Data Model Implementation Guide for Non-compartmental Analysis Input Data (1.0 Final)

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Bring examples closer to the ADaM rules they explain

OLD APPROACH

Normative first, Examples later

Requirements appeared at the beginning; informative examples accumulated in a large section at the end.

NORMATIVE TEXT → EXAMPLES AT THE END

Why it did not scale: examples became disconnected from the requirements they supported.

NEW APPROACH

Use right example at the right scale

Small examples stay inline

Insert concise examples directly beside the normative text so context is immediate.

Large examples move to separate documents

Reference dedicated example documents for the extensive examples currently housed in implementation guides.

Example documents are still to be created.

The result: immediate context in the guide, with depth available on demand.

New Approach: Informative Text – Brief & Immediate

Make the informative text readily available (immediate) by embedding the examples in the main body of the ADaM+IG

Keeping the examples within the IG bit-sized & moving larger (more complex) examples outside of the ADaM+IG

Building the story by referencing other examples within the ADaM+IG

Section 5.9.3.2
Record-to-Record Traceability

Another level of traceability which needs to be considered in ADaM is record-to-record (or parameter-to-parameter). Examples of this include:

- Triplicate ECGs – this data would be collected at specific times, but typically are averaged for analysis. The derived average record should point back to the group of triplicate records. Since the SDTM EG.EGSEQ and EG.EGREPNUM will be different on each record of the triplicate, it is useful for traceability to include the SDTM timing variable such as date or timepoint of the ECG to add context to the record. Refer to **Table XXX (8.3.3 as of 12SEP2024)** for example of creating an average.

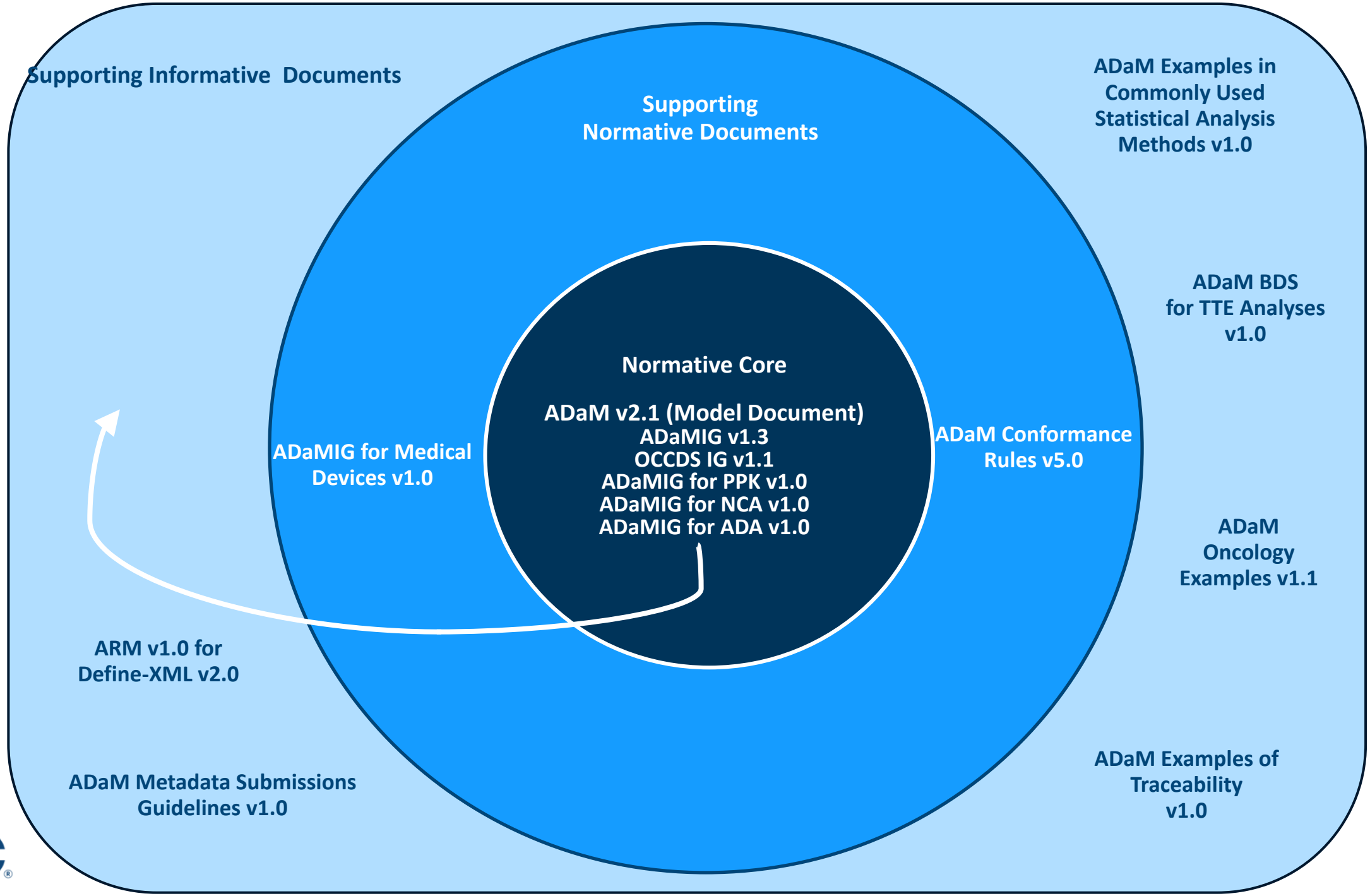
USUBJID	VSSEQ	VISIT	EGREPNUM	EGTESTCD	EGSTRESN	AVAL	DTYPE
ABC-001	1	VISIT 2	1				
ABC-001	2	VISIT 2	2				
ABC-001	3	VISIT 2	3				
ABC-001		VISIT 2					

- Log-transformations – If a record is transformed, deriving AVAL from exactly one record as the source, then we can keep the value of the SDTM --SEQ and all timing variables from the record on the derived/transformed row. In order to aid review, the original non-transformed value can also be present in the dataset, in a record (unique parameter) or a variable (e.g., --STRESN), even if it is not used for analysis. Refer to **Section 8.2.1, Rule 2: Example 1,** for an example of a Log transformation.
- Cholesterol Ratio Derivation – When Total Cholesterol and High-Density Lipoprotein Cholesterol are collected as two unique tests in SDTM LB, and derived Total Cholesterol:HDL-C ratio uses both of these SDTM rows as source input, it would **not** be appropriate to have either SDTM LBSEQ value populated on the derived ratio parameter. However, it would be useful to include the common source timing variables (e.g. VISIT), which were used to merge/join the Total Cholesterol and HDL-C content from those source records. Refer to **Section 8.2.2, Rule 2: Example 2**, for an example of a derived Cholesterol:HDL-C ratio.
- Total Scores on a Questionnaire – In a questionnaire BDS dataset, each individual question could be present as a unique parameter, even if not used for analysis. Then, on the row for the derived total score parameter, it would be useful to include the applicable timing variables in order to show the values from the same timepoint together.

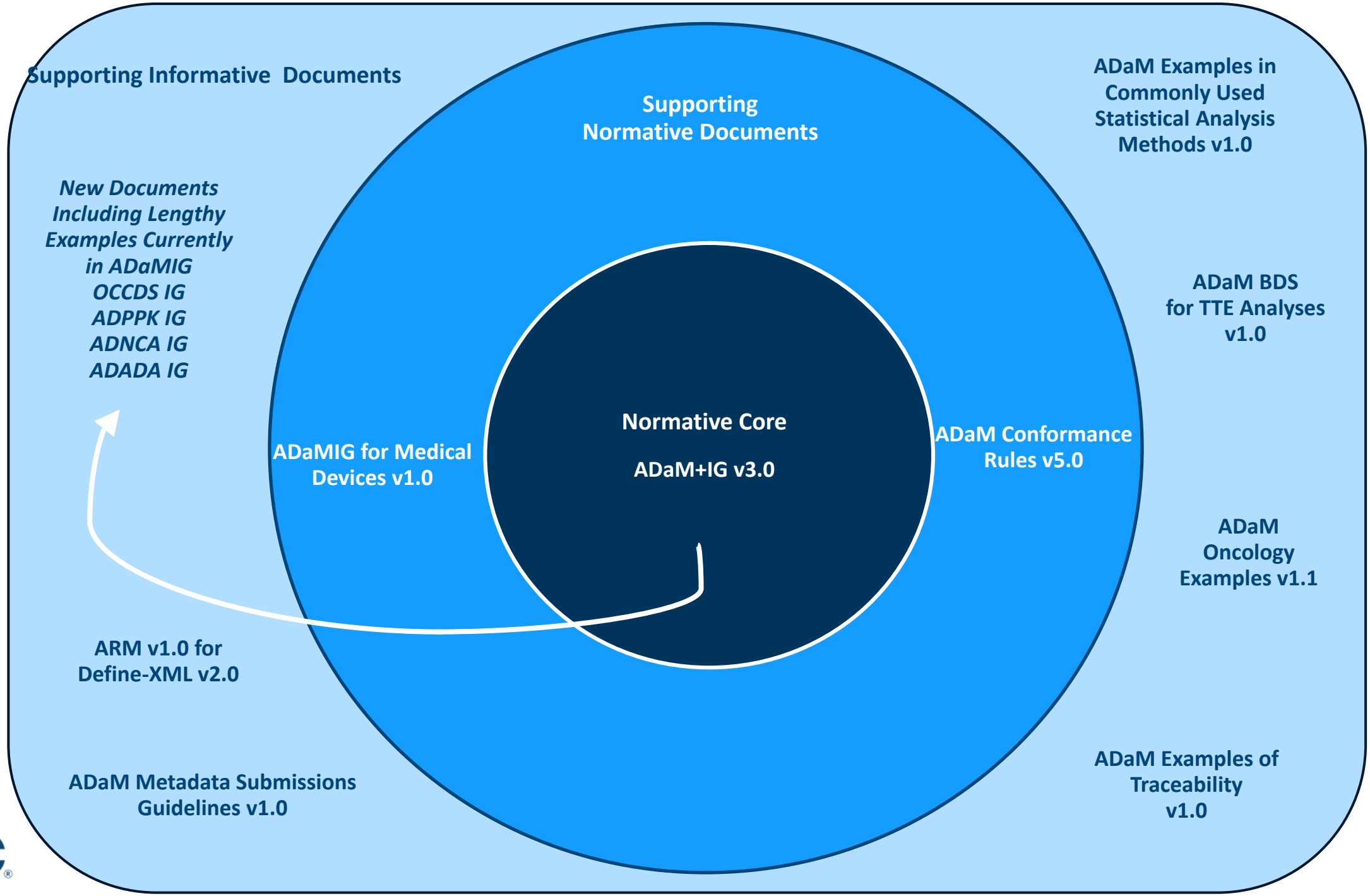
USUBJID	QSSEQ	QSDTC	ADT	VISIT	AVISIT	PARAMCD	PARAM	AVAL
ABC-001	1	2024-03-01	01MAR2024	WEEK 1	Week 1	QS0101	QS01 – Item 1	3
ABC-001	2	2024-03-01	01MAR2024	WEEK 1	Week 1	QS0102	QS01 – Item 2	2
ABC-001	3	2024-03-01	01MAR2024	WEEK 1	Week 1	QS0103	QS01 – Item 3	4
ABC-001	4	2024-03-01	01MAR2024	WEEK 1	Week 1	QS0104	QS01 – Item 4	3
ABC-001		2024-03-01	01MAR2024	WEEK 1	Week 1	QS01TOT	Total Score	12

- Derived Analysis Timepoints - Collected SDTM timing variables, such as VISIT and --TPT, may not be appropriate for analysis. When an analysis timepoint, such as lowest post-baseline value, is needed in addition to the collected timepoint, a new row for the lowest post-baseline is added as described in Section 8. SDTM values on the collected row, such as --SEQ and VISIT, can be copied to the new analysis timepoint row to add traceability. Refer to **Example 2 in Section 9.3.3, Identification of Post-Baseline Conceptual Timepoint Records**, for an example of derived analysis timepoints of Minimum and Maximum.
- Intermediate Parameters – Complex derivations can be split apart to multiple parameters, even if the intermediate parameters will not be summarized. This facilitates validation and review of the final analysis parameter by allowing the calculations of each parameter to be more easily documented and confirmed. See **Section 8.4, Rule 4: A function of multiple rows within a parameter should be added as a new parameter**, where the CD4AUC parameter is an intermediate parameter that is not summarized but is used to create parameter CD4AUCMB. Refer to **ADaM Basic Data Structure for Time-to-Event Analyses v1.0 Table 7.2.2** for an additional example, where intermediate parameters T2HBeAg and T2HBeAb are not summarized but are used to create parameter T2SERO.

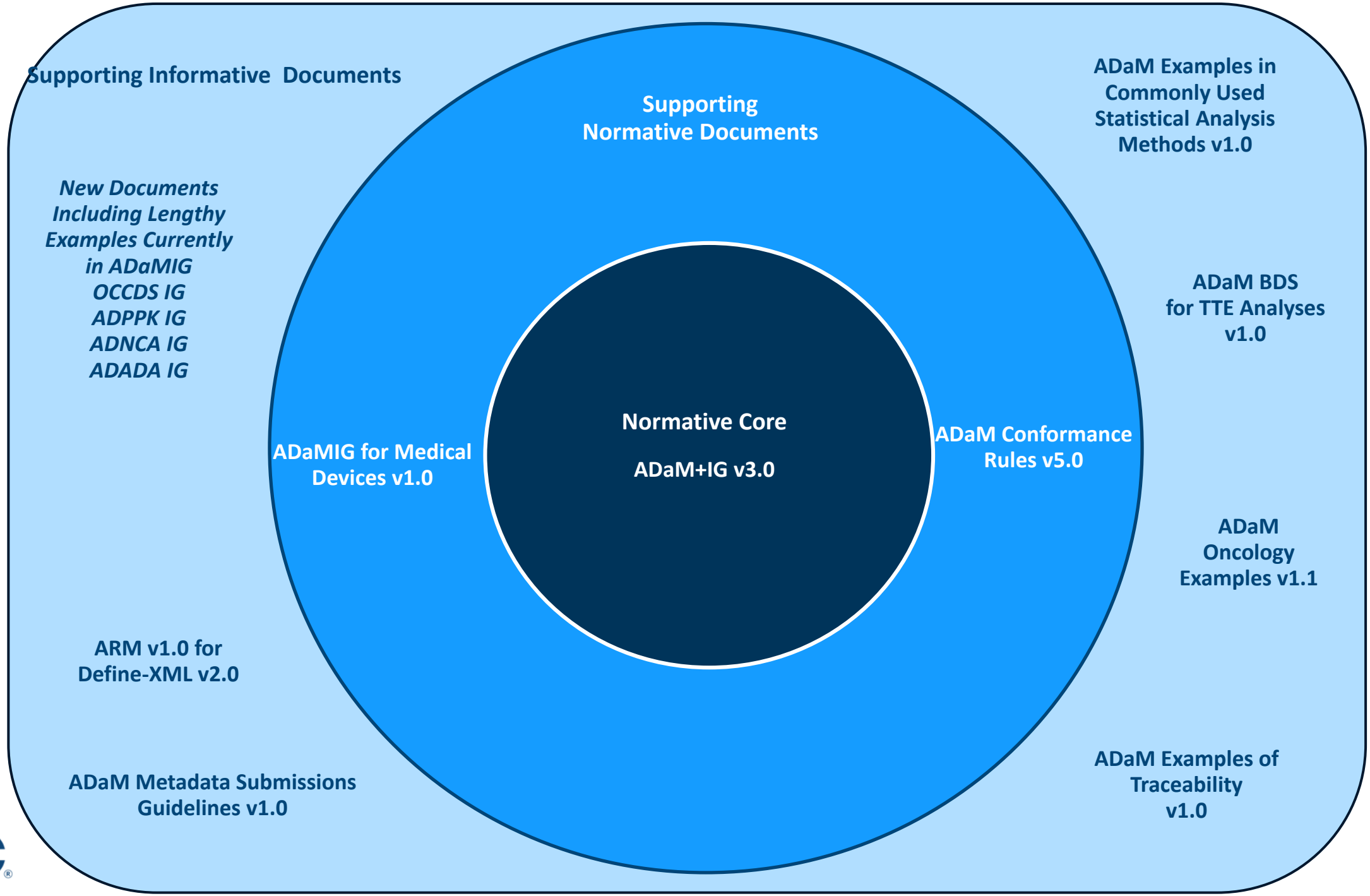
In Progress


Supporting Informative Documents
Supporting Normative Documents
ADaM Examples in Commonly Used Statistical Analysis Methods v1.0
ADaM BDS for TTE Analyses v1.0
Normative Core
ADaM v2.1 (Model Document)
ADaMIG v1.3
OCCDS IG v1.1
ADaMIG for PPK v1.0
ADaMIG for NCA v1.0
ADaMIG for ADA v1.0
ADaMIG for Medical Devices v1.0
ADaM Conformance Rules v5.0
ADaM Oncology Examples v1.1
ARM v1.0 for Define-XML v2.0
ADaM Metadata Submissions Guidelines v1.0
ADaM Examples of Traceability v1.0

Soon


Supporting Informative Documents
Supporting Normative Documents
ADaM Examples in Commonly Used Statistical Analysis Methods v1.0
New Documents Including Lengthy Examples Currently in ADaMIG
OCCDS IG
ADPPK IG
ADNCA IG
ADADA IG
ADaM BDS for TTE Analyses v1.0
Normative Core
ADaM+IG v3.0
ADaMIG for Medical Devices v1.0
ADaM Conformance Rules v5.0
ADaM Oncology Examples v1.1
ARM v1.0 for Define-XML v2.0
ADaM Metadata Submissions Guidelines v1.0
ADaM Examples of Traceability v1.0

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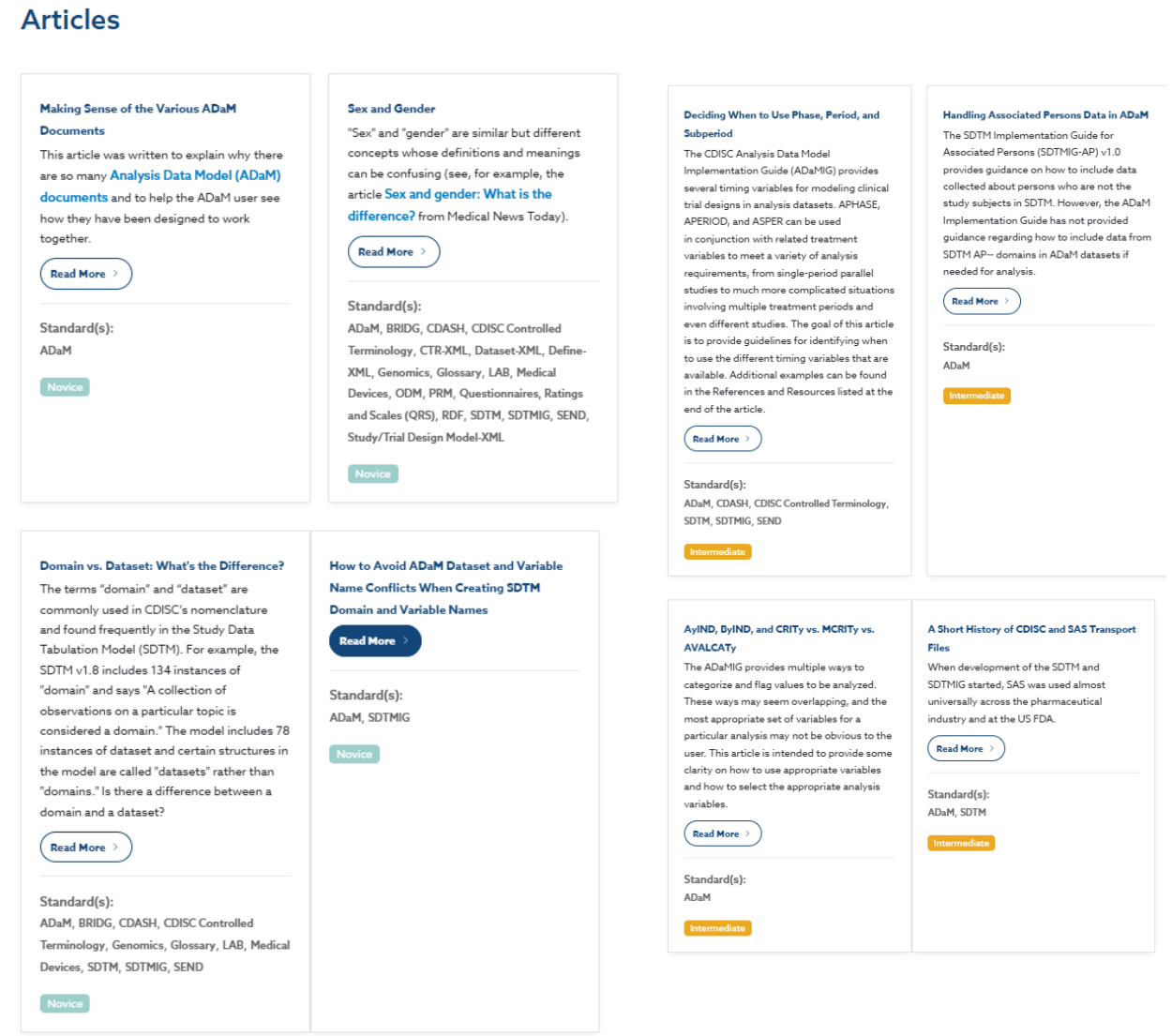
New Active Curation of Informative Docs

Motivated by this consolidation effort

CDISC Knowledge Base

ADaM Knowledge Article

- Dashboard
- Articles
- Examples Collection
- Known Issues
- eCRF Portal
- eTFL Portal
- QRS Portal
- DHT Portal



Creating Knowledge Articles in the Age of AI

AUTHOR FOR RETRIEVAL

ONE TOPIC

Keep each article atomic. A single, distinct topic improves retrieval precision and usage tracking.

COMPLETE CONTEXT

Put required context in the article. Avoid link-dependent meaning and vague pronouns; repeat key nouns.

PREDICTABLE STRUCTURE

Use clear HTML headings, subheadings, bullets, and numbered step-by-step instructions.

AUTHOR FOR TRUST

DESCRIBE ALL MEDIA

Add alt text and captions for screenshots, diagrams, and video because AI cannot interpret visuals alone.

ENRICH METADATA

Use tags, labels, and structured tables to strengthen categorization and semantic retrieval.

GOVERN THE LIFECYCLE

Audit, update, or retire content; use feedback flags to correct inaccurate grounding paths.

Design each article as a complete, machine-readable source of truth.

Bottom line: atomic + structured + self-contained content gives generative AI reliable grounding.

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Knowledge Articles Potentially Coming in the Future

Origin Type & Source in ADaM define.xml

Flag Variables for BDS Datasets

Using SRCDOM, SRCVAR, SRCSEQ when multiple input source area used

How to use DTYPE in addition to metadata

Difference between AVAL & AVALC

Variables used to derive other variables (eg, AWTARGET for AWTDIFF)

What not to put in DTYPE

What to SDTM Content to Retain on a Derived ADaM row

A Brief Overview of the ADaM Standard aimed at those coming with primarily SDTM experience

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Summary

- Creating a clear distinction between the Normative Core and Supplemental Documents
- Taking a new approach to informative text within normative documents
- Actively curating informative documents within and without the CDISC Knowledge Bawse

Questions?

