

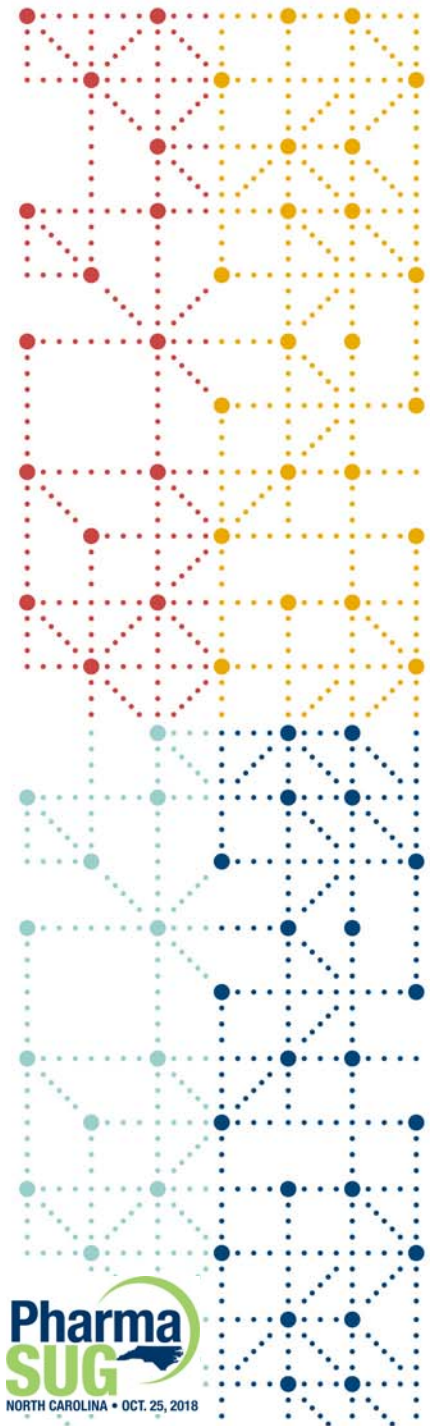


ADaM 2018: What's New and What's Coming

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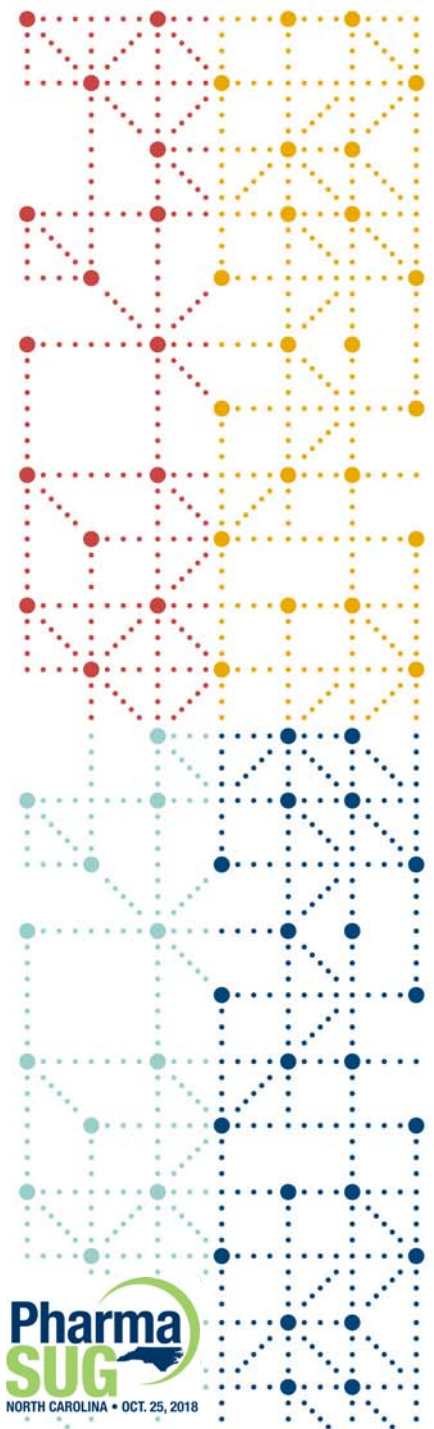
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Agenda

1. Update on ADaM subteams
2. Documents summary
3. ADaM future plans



Subteam Updates



1: ADaMIG v1.2

Description

- Implement updates to the ADaM Implementation Guide and release as a new version in 2018.

Status

- Wrapping up Public Review comment resolution

What to Expect

- Expected to be finalized late 2018 or early 2019

2: QRS-GDSSF ADaM Supplement

Description

- Develop documents describing how to model questionnaires, rating and scales data in ADaM compliant structures.

Status

- First Questionnaire ADaM supplement has completed public review and is undergoing FDA review

What to Expect

- QRS-GDSSF will be updated based on public review comments and published as “Provisional” as soon as finalized
- Other Questionnaires will be updated using the template developed for QRS-GDSSF
- Hope to finalize by the end of 2018

3: ADaM Compliance Checks

Description

- Revision of ADaMIG v1.0 checks
- Additional checks specific to OCCDS v1.0 and ADaMIG v1.1

Status

- 60-day public review period ends Nov 12, 2018

What to Expect

- Public review comments will need to be resolved before finalizing
- Final document to be published as soon as finalized, early 2019

4: ADaM Medical Devices

Description

- Document describes how to apply the current ADaM standard structures and use new medical-device-specific ADaM structures for analysis of medical device data

Status

- Finalizing preparation for public review

What to Expect

- 60-day public review expected early 2019
- Comments will need to be resolved
- Final document should be published in 2019



5: ADaM Integration

Description

- Document details structures of ADaM datasets to support integrated analysis, including IADSL, IBDS and IOCCDS.

Status

- Internal review planned to begin this month

What to Expect

- Internal review comments resolved end of 2018
- 60-day public review expected in early 2019
- Final document expected in 2020



6: ADaM OCCDS v1.1

Description

- Updates to OCCDS v1.0, including more complex examples

Status

- ADaM full team review is complete, and now preparing for public review

What to Expect

- ADaM review comments will need to be resolved before larger CDISC review
- 60-day public review expected in early 2019
- Final document should be published in 2019



7: ADaM Traceability Examples

Description

- New document with in-depth ADaM examples with an emphasis on providing clear traceability in data and metadata. Examples range from simple to complex data flow scenarios.

Status

- Preparing for ADaM full-team review

What to Expect

- ADaM review comments will need to be resolved before larger CDISC review
- 60-day public review expected in 2019
- Final document should be published in 2019

8: ADaM Education Materials

Description

- Revamp of classroom courses for IACET certification
- Completion of the e-learning classes

Status

- IACET Primer class complete for release at the 2018 US Interchange
- Beginning work on Theory and Application class.
- Rolling e-learning modules (development, review, publishing)

What to Expect

- IACET Theory and Application class update will be released in 2019
- New e-learning modules will be published as finished



9: ADaM PK Analysis

Description

- Develop a model specific to the analysis of pharmaco-kinetic data

Status

- Resolving comments from ADaM Leadership Team review

What to Expect

- Needs ADaM full-team review, then larger CDISC review
- 60-day public review expected in early 2019
- Final document should be published in 2019

10: ADaM Oncology

Description

- Include Oncology structures, variables, and examples in existing ADaM documents and TAUGs
- Create new ADaM docs for Oncology-specific needs

Status

- New material added to ADaMIG v1.2 (e.g., bidirectional toxicity)
- Developing new Oncology document

What to Expect

- Oncology material is included in upcoming ADaMIG v1.2 and TAUGs
- Oncology document in early development, with a goal for public review in 2019



11: Analysis Results Metadata (ARM) Validation Rules

Description

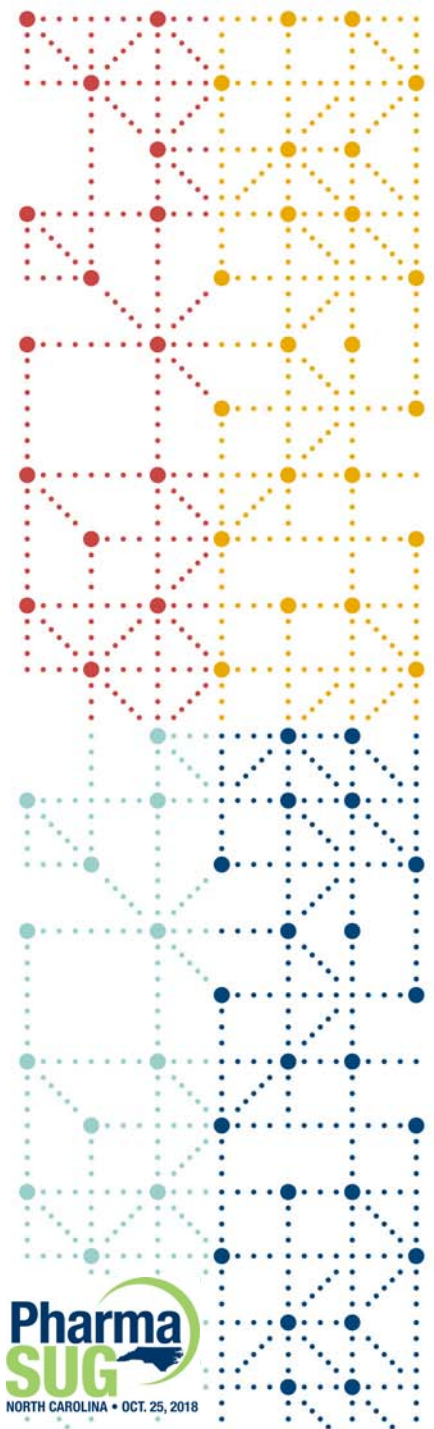
- Developing ARM validation rules to be used for define.xml compliance checks

Status

- Draft discussed within ADaM metadata subteam
- Harmonization with CDISC Define-XML validation rules specifications ongoing

What to Expect

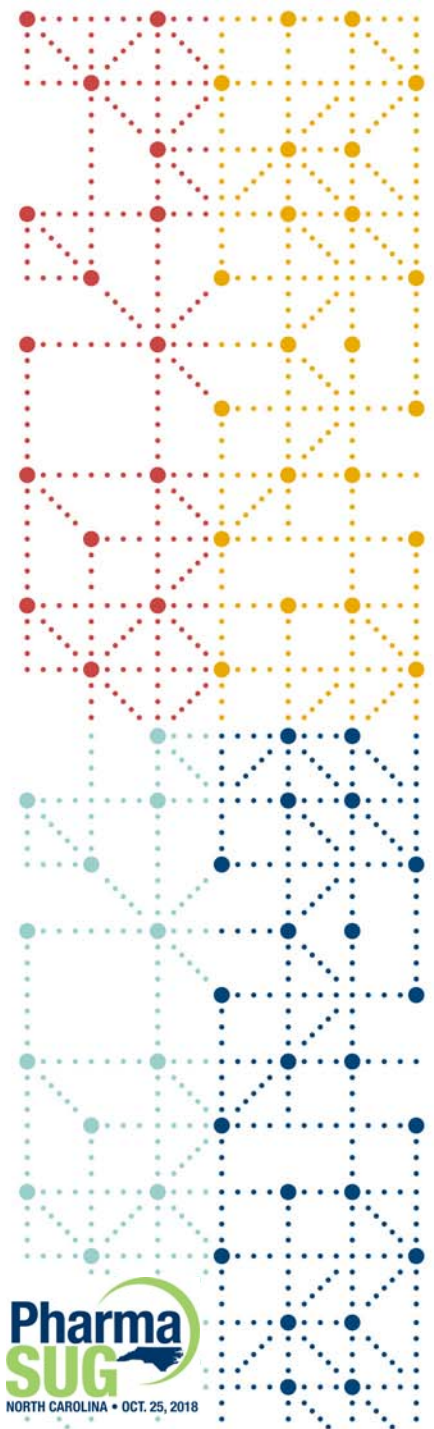
- Final document should be published in 2019



ADaM Documents Summary

Documents Summary: the ADaM Team is busy!

	Standard	Develop-ment	Internal Review	Public Review Prep.	Public Review	Resolve Public Review Comments	Publication Prep.	Est. Publication Date
1	ADaMIG v1.2					X		Q4 2018
2	QRS-GDSSF ADaM Supplement					X		Q4 2018
3	ADaM Compliance Checks (updates to ADaMIG v1 & new ADaMIG v1.1)				X			Q1 2019
4	ADaM Medical Devices			X				Q2 2019
5	ADaM Integration	X						2020
6	ADaM OCCDS v1.1	X						Q4 2019
7	ADaM Traceability Examples	X						Q3 2019
8	ADaM Education Materials (IACET work)	X						ongoing
9	ADaM PK Analysis	X						Q4 2019
10	ADaM Oncology	X						Q4 2019
11	Analysis Results Metadata (ARM) Validation Rules	X						Q4 2019

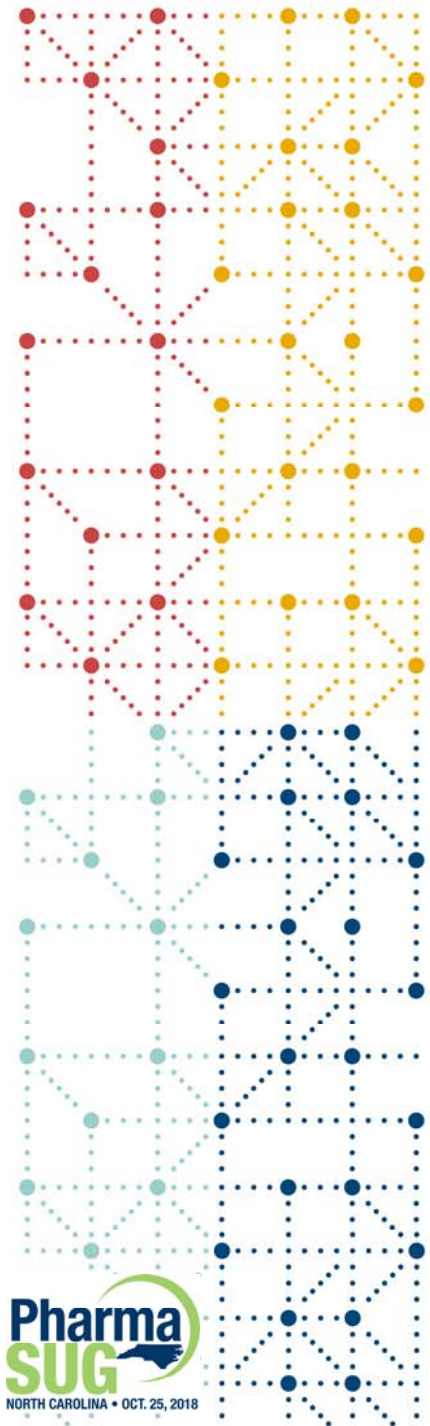


Future ADaM Plans



Future ADaM Plans

- Compliance Checks for ADaMIG v1.2
 - ADaMIG v1.2 team will be adding checks to match the new document
- ADaM components within many TAUGs
 - Ongoing work
- Consolidation of many documents into a single standard document (tentatively ADaM v3.0), to address:
 - Content scattered across multiple documents
 - Duplicated content
 - Content updated in more recent documents but not in older ones
 - Expected to start in 2019, after other “feeder” documents wrap up



Thank You!

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