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

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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 ADaM v1.2 (e.g., bidirectional toxicity)
- Developing new Oncology document

**What to Expect**
- Oncology material is included in upcoming ADaM 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!

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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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