Introduction of **SDTM and ADaM Implementation FAQ** Project

WG: Optimizing the Use of Data Standards

SDE in Tokyo, Japan

11th May, 2018

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SDTM/ADaM Implementation FAQ

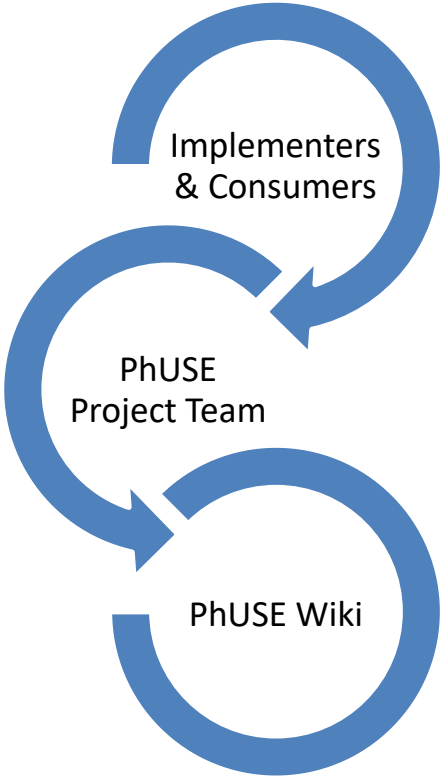
since 2016

- The Standards Implementation Nuances sessions at the Mar 2016 North America CSS and Jun 2016 EU CSS surfaced various common challenges amongst SDTM and ADaM implementers and consumers
- Industry in need of a forum and subsequent knowledgebase (FAQ) to address these challenges

SDTM/ADaM Implementation FAQ

since 2016

- A working group was formed to collaborate with CDISC, FDA, and industry.
- 77 members across 36 organizations (FDA, CDISC, Sponsor companies, and vendors)
- Project team meeting and collaboration once every 2 weeks (Tuesday @ 3:00PM –GMT/SUT, 11:00PM/0:00AM JST)
  - Start date of BST : Sunday of the last week of March
  - End date of BST : Sunday of the last week of October



Computational Science Working Groups

SDTM/ADaM Implementation FAQ

since 2016

Collaboration Tools

- Working with PhUSE Wiki (public)

  http://www.phusewiki.org/wiki/index.php?title=SDTM_ADaM_Implementation_FAQ

  – Submitting Questions (public)

    http://www.phuse.eu/wiki-feedback

  – FAQ Database (public)

    http://www.phusewiki.org/wiki/index.php?title=SDTM_FAQ_Team_Responses

- Walk through project teamwork site (project team members only)
  https://phuse.teamworkpm.net/projects/157138/overview

Examples of the FAQ - Published

- *What are best practices for creating CT for/representing questionnaire responses?*
- *What is the general recommendation/approach for generating/submitting custom domains (e.g. non-standard CDISC SDTM domains) to regulatory agencies?*
- *Does the legacy data in non-CDISC format need to be converted to SDTM for all studies that are part of the FDA or PMDA submissions? If a sponsor has one pivotal study in non-CDISC and the other pivotal study in CDISC, do I need to convert both to CDISC format before submission?*

Examples of the FAQ - Published

- *Will JumpStart (DataFit) services be available for pharma clients before submission? What kind of checks are included in JumpStart?*
- *When will CDISC (SDTM/ADaM) data standards be mandatory for data submission and how does this differ from for each regulatory agency*?
- *Why are Screen Failures and Not Assigned not represented in TA?*
- *How should a subject that is incorrectly dosed be represented in SE (i.e. a subject is randomized to Drug A, but receives Drug B)? Unplanned element?*
- *How to define an unplanned Element in SE? Example: unexpected washout*

Examples of the FAQ – Work in Progress

- *What is the requirement for Clinical Site Data and Subject-level Data Listings for FDA CDER's Inspection Process (also called BIMO submission or OSI Pre-NDA request)?*
- *What goes in the "misc" folder with an m5 eCTD folder structure? For example, a lookup file containing SMQ assignment.*
- *Does the Sponsor need to submit SAS Codes? Does it have to be executable? Is there any guidance on that?*

Questions and Topics from US CSS 2018 (March)

- Integration (ISS and ISE) – integrated SDTM vs. integrated ADaM
- Submission of Analysis Results Metadata (ARM)
- FDA and PMDA submission package
- Next version of IG
- Trial level lookup concept and methods

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