Optimizing the Use of Data Standards Working Group - SDTM and ADaM Implementation FAQ

SDTM ADaM Implementation FAQ

- This project focuses on understanding standards implementation nuances that exist across available SDTM and ADaM versions.
- The deliverables include:
  - A process through which users can submit questions and see previously answered questions – PhUSE collaboration space Teamwork site.
  - A Wiki where users can go for FAQs for helpful implementation information

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- Discussed the CDISC 2017/2018 Roadmap
- Documented and categorized over 25 SDTM/ADaM implementation issues across all sub-teams
- FDA shared how they make use of the standardised study data we submit
- Discussed existing unanswered questions and provided individual perspectives on these
- Explored real submission issues to understand potential reasons for the finding as views on the root cause.

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Areas of particular interest were:

- Business & Validation Rules
- Use of custom domains vs. supplemental qualifier vs. Findings About
- Challenges in creating Trial Design Domains especially for more innovative study designs
- Challenges in adoption of controlled terminology and the impact this has on regulators and sponsors

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