SDTM and ADaM Implementation FAQ

WG: Optimizing the Use of Data Standards

EU CSS Introduction

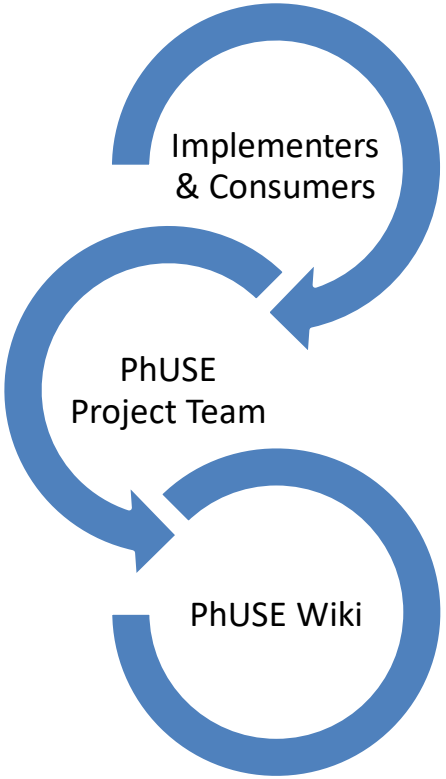
19th June, 2017

SDTM/ADaM Implementation FAQ

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

SDTM/ADaM Implementation FAQ

- A working group was formed to collaborate with CDISC.
  - Additional participants:
    - FDA
    - SDTM/ADaM Implementation SMEs
    - Industry
- Project kick-off was in June 2016
  - Monthly Lead Team Meetings
  - Sub Teams meeting bi-weekly or monthly



Sub-teams

1. SDTM/ADaM IG Nuances
2. Validation/Conformance Rules
3. Data Submissions (SDTM and ADaM)
4. Legacy SDTM Mapping
5. Trial Design Domains
6. Therapeutic Area Specific

Individual Sub-Teams for each topic

1 or 2 Leads, 4-6 team members

Industry, Regulatory, Standards SMEs

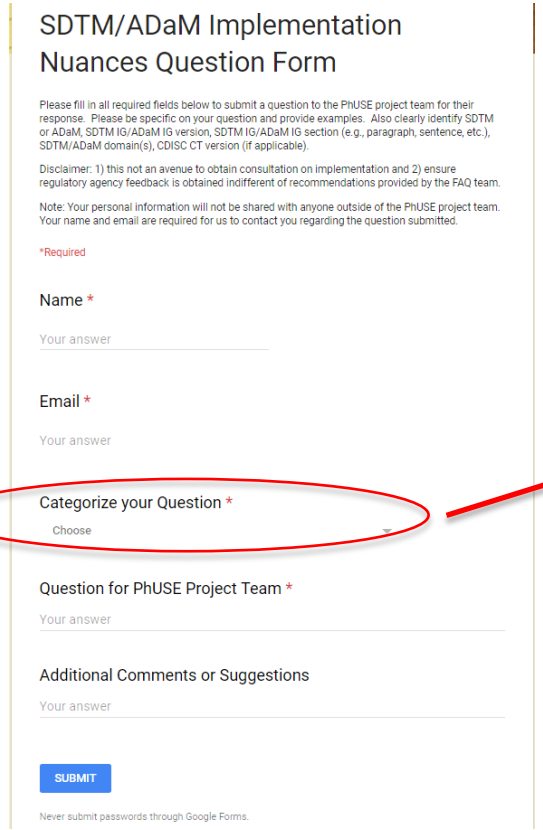
SDTM ADaM Implementation FAQ

- 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

FAQ Process Flow

- Process Flow:
  - Two primary avenues will need to be developed to meet the need for user group frameworks and initial content:
    - A process through which users can submit Question via a form on Wiki.
    - http://www.phusewiki.org/wiki/index.php?title=SDTM_ADaM_Implementation_FAQ
    - A Wiki database where users can go for FAQs and responses for helpful implementation information *(WIP)*

SDTM/ADaM Implementation Nuances Question Form



SDTM/ADaM Implementation Nuances Question Form

Please fill in all required fields below to submit a question to the PhUSE project team for their response. Please be specific on your question and provide examples. Also clearly identify SDTM or ADaM, SDTM IG/ADaM IG version, SDTM IG/ADaM IG section (e.g., paragraph, sentence, etc.), SDTM/ADaM domain(s), CDISC CT version (if applicable).

Disclaimer: 1) this not an avenue to obtain consultation on implementation and 2) ensure regulatory agency feedback is obtained indifferent of recommendations provided by the FAQ team.

Note: Your personal information will not be shared with anyone outside of the PhUSE project team. Your name and email are required for us to contact you regarding the question submitted.

*Required

Name *

Your answer

Email *

Your answer

Categorize your Question *

Choose

Question for PhUSE Project Team *

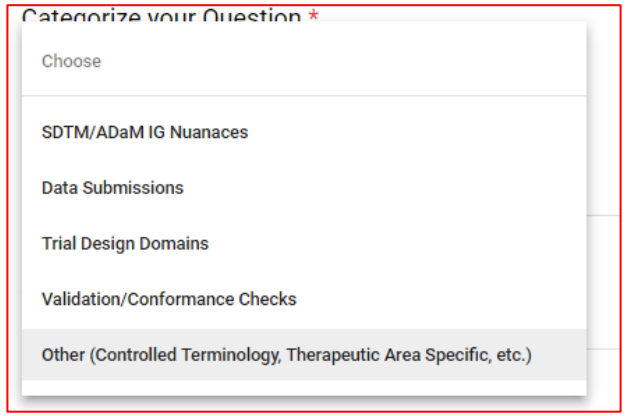
Your answer

Additional Comments or Suggestions

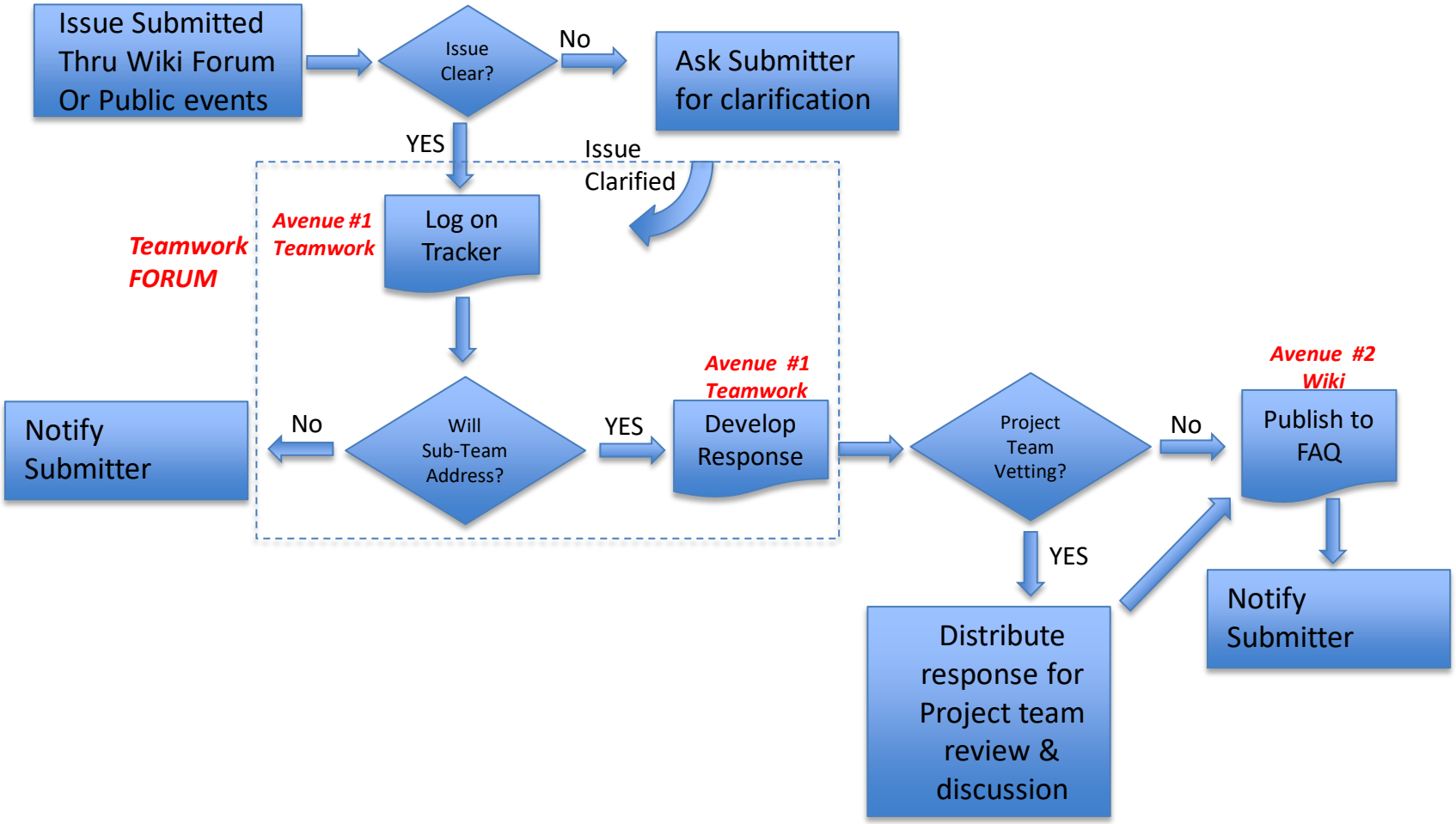
Your answer

SUBMIT

Never submit passwords through Google Forms.



FAQ Process Flowchart



Response Guidelines

- Facts
  - Start with the facts first with explicit references to the source and its location (section, page, etc.), where applicable. This will ensure awareness to the inquirer on how a final opinion by team is made.
  - References should be official sources of documentation used for the purpose of standards development and its corresponding supporting guidance. Some examples include, but not limited to: CDISC, FDA and PMDA.
  - Need to be very cautious when referencing articles that are deemed opinions of other person(s) or organizations and/or deemed as an unofficial secondary/tertiary source.
  - Need to be cautious in responding with assumptions around regulatory agency submission impact. Do not interpret regulatory guidances.
- Opinion
  - End with an opinionated response based on the aforementioned facts.

Response Guidelines

- Team Collaboration
  - Review the question and prior responses to ensure an understanding of the full chain of thought.
  - End goal may include multiple responses to cover the full gamut of possibilities.
  - Identify missing references to posters.
  - Ensure adequate spelling and grammar is present.
  - Identify the final responses to be published (e.g., a reply message identifying the person/date of prior responses deemed necessary for a final response)
- Final Response
  - Project lead to compile a final response based on team collaboration input.
  - Responses will be placed into a consistent template via Notebook publication location.

Collaboration Tools

- Working with PhUSE Wiki

  http://www.phusewiki.org/wiki/index.php?title=SDTM_ADaM_Implementation_FAQ
- Walk through project teamwork site
  https://phuse.teamworkpm.net/projects/157138/overview
- Review SEND Implementation Wiki site

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

Current SDTM/ADaM Implementation FAQ

Collected FAQs (CSS: NA and EU)

Response Document, working draft

Agenda – Monday 19th June

Time	Topic
11:00 – 12:30	Introduction to Optimizing Data Standards Working Group CDISC 2017/2018 Roadmap
12:30 – 13:30	Lunch
13:30 – 15:00	Round table – *I need help with...* • SDTM/ADaM IG Nuances • Validation/Conformance Rules • Data Submissions (SDTM and ADaM)
15:00 – 15:30	Break
15:30 – 17:00	Round table – *I need help with...* • Legacy SDTM Mapping • Trial Design Domains
17:00 – 20:00	• Networking Session

Agenda – Tuesday 20th June

Time	Topic
09:00 – 10:30	Regulators & Industry Discussion • Common Issues Regulators Encounter • What are the causes of these issues • What can we do to resolve these
10:30 – 11:00	Break
11:00 – 12:30	FAQ Breakout Summary & Next Steps
12:30 – 13:30	Lunch
13:30 – 15:30	Panel Discussion, Wrap-up & Closing Remarks

Answered Questions

Answered Questions

FAQ Responses -
June 2017

Open Questions

Open Questions

- FDA business and validation rules are recently released. How does that differ from CDISC SDTM validation conformance rules?
  - how does industry work to ensure they are compliant with both?
  - We have heard FDA using P21 but does the tool cover everything that is expected?
  - FDA is working with CDISC to make them consistent but what does industry do in the meantime?

Open Questions

- Use of custom domain vs. SUPPxx (supplemental) or FAxx (findings about). There is no standard approach to it but what does good practice look like?
- There is lot of details about traceability report in the FDA technical conformance guide
  - Are Sponsors ready for this?
  - Is this something regulatory agencies are requesting?
  - How are Sponsors handling this?

Open Questions

- Trial design domains are expected to be submitted by the FDA per the TCG (especially TS domain).
  - What are the challenges faced in putting this together?
  - Are Sponsors unware of its inclusion?

Open Questions

Data Submission
FAQs

1. FDA business and validation rules are recently released. How does that differ from CDISC SDTM validation conformance rules?
2. Trial design domains are expected to be submitted by the FDA per the TCG (especially TS domain). What are the challenges faced in putting this together?
3. Use of custom domain vs. SUPPxx (supplemental) or FAxx (findings about). There is no standard approach to it but what does good practice look like?

1. For studies I submit with SDTM datasets, what is the FDA's recommendation for including non-SDTM datasets? (e.g., custom domains) How should I submit data mapped to SDTM domains included in later versions
2. Which TSPARMCDs are required in the TS domain? CT list vs. List in IG
3. There were several variables added in SDTM v1.3, e.g., TSVALNF, TSVALCD, TSVCDREF, and TSVCDVER. Should all be submitted for older versions of SDTM

1. How should compliance checks for a study be handled if some domains are based on SDTM IG version 3.1.3, but some domains (oncology specific domains) are based on SDTM IG version 3.2? Which version should be stated when running compliance checks?
2. Is SDTM/ADaM only a U.S. requirement?
3. Does the term 'treatment emergent' only applies to AEs and would not apply to any other datasets (Labs, Vitals, Conmeds, CE etc.)? Other than ADAE, which datasets should the flag be generated?

1. Are there guidelines or recommendations for how to shorten eligibility criteria to fit in the 200 character limit in TI?
2. What is best practice to support Part A vs Part B Analysis
   - Option #1 : Generate two set of SDTM and two set of ADaM
   - Option #2 : Generate one set of SDTM and two set of ADaM (apply subset of Part A vs Part B at ADaM level)
   - Option #3 : Generate one set of SDTM and one set of ADaM
3. Is it acceptable to store randomization or study continuation criteria (which are additional to initial screening criteria) in TI and manage it as you do original criteria?

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