# SDTM ADaM Implementation FAQ


**Project Scope**

The Standards Implementation Nuances sessions at the March North America 2016 CSS and June EU 2016 CSS surfaced various common challenges amongst SDTM and ADaM implementers and consumers. In addition, there were many questions discussed related to data submissions requirements by various regulatory agencies around the world (e.g. FDA, PMDA, NMPA). It became very clear that the Industry is in need of a forum and subsequent knowledge-base (FAQ) to address these challenges. This project team was formed in June 2016 to collaborate with Subject Matter Experts (SMEs) from the industry, CDISC, and the FDA. The goal of this project team is to:

1. Collect frequently asked questions (FAQs) from Industry. If you have a question for the team, email workinggroups@phuse.global.
2. Assess the appropriateness of a question, develop & review a response, collaborate with CDISC/FDA for clarity if required.
3. Publish the FAQ and responses on Advance Hub database for helpful implementation/strategy information.

| Project Leads | Email |
|---|---|
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| Objectives & Deliverables | Timelines |
|---|---|
| Publish responses to questions received under:<br>• Data Submission<br>• SDTM/ADaM IG Nuances<br>• Trial Design Domain<br>• Validation/Conformance Rules | Ongoing |

CURRENT STATUS **Q1 2024**

- Continue to receive, review and answer questions, the responses are published to the PHUSE Advance Hub
- Have advertised for questions via PHUSE communications.

| Published Deliverables | Date |
|---|---|
| Integration Strategies in Support of ISS/ISE Submissions: Version 1.0 | 27-Oct-2020 |
| Best Practices for Submissions of Event Adjudication: Version 1.0 | 02-Dec-2019 |