

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.

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Objectives & Deliverables	Timelines
Publish responses to questions received under: • Data Submission • SDTM/ADaM IG Nuances • Trial Design Domain • 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