Implementation of Estimands (ICH E9 (R1)) using Data Standards



Project Scope
Impact assessment of the estimands framework and recommendations/best practices (where applicable) for implementing the framework in the following areas: • Data Collect Design/CDASH • SDTM • ADaM (including handling of intercurrent events, missing data imputation) – Analysis Displays • cSDRG and ADRG Development of new standards is not in scope, and any impact findings that may necessitate new standard development will be shared with CDISC for their consideration. Examples may be created on how to implement the framework by using permitted extensions to the existing data standards.

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CURRENT STATUS **Q1 2024**

- Completed public review of White Paper
- Great interest in paper as received over 400 public comments
- Collaborating with EIWG statisticians to align white paper recommendations
- Poster session at the US Connect and presentation at International Society for Biopharmaceutical Statistics (ISBS) 2024

Objectives & Deliverables	Timelines
Submit abstracts for multiple conferences	Q2 2023
Develop draft White Paper for internal project review prior to PHUSE Working Group Review and Public Review	Q3 2023
Final White Paper	Q1 2024