

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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Objectives & Deliverables	Timelines
Review current company practices	Q1 2022
Develop conference abstract	Q2 2022
Draft paper	Q3 2022
Conference slides	Q4 2022
Final White Paper ready for Public Review	Q4 2022
Publish White Paper	Q1 2023

CURRENT STATUS Q2/3 2022

- Meeting on a regular basis to gather information for the White Paper
- Sub-teams have been formed

Project Members	Organisation
Alexandra Cochinaire	Johnson & Johnson
Ann M Pennington	Pfizer
Arman Sabbaghi	Purdue University
Armin Schueler	Merckgroup

Project Members	Organisation
Liping Sun	FDA
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Matt Baldwin	Amgen
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Samson Ghebremariam	Novartis
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Shahida Tamboli	Labcorp
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Steve Gilbert	Pfizer
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Dan Checketts	Jazz Pharmaceuticals
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Helle Lynggaard	Novo Nordisk
Jennifer, Britt	Gilead
John Scott	FDA
Jonathan Siegel	Bayer
Jozef Aerts	XML4Pharma
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Kevin Liu	Pfizer
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