



OHDSI Workgroup Objectives and Key Results (OKR)

2023 Update

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CTWG Purpose

Objective: To allow adequate representation of clinical trial data represented as CDISC SDTM in OMOP.

Approach: We advocate minimum changes to the OMOP CDM and Standardized Vocabularies because we want to ensure minimum impact on OHDSI tools like Atlas, whilst providing a value-add SDTM-to-OMOP conversion with minimum data loss. We have proposed conventions introducing new concepts and modifiers, but no new CDM tables; and providing guidance for ETL developers where appropriate. Our proposals were originally built on OMOP CDM v6 and the Oncology extension, with v5.3 backward compatibility. In a new v5.4 the additions from the Oncology extension became standard, which made our changes minimal, thereby, making our proposals fully compatible with v5.4.



CTWG Accomplishments

2023: Evaluating a single Vivli clinical study and developing initial high-level conceptual mappings between SDTM-to-OMOP (Persons, Procedure_Occurrence, etc.)

2022: CTWG was given access to 20 Vivli clinical study packages in the SDTM format. The CTWG team is doing an inventory of those study packages in order to prioritize SDTM-to-OMOP mappings. The existing CTWG guidance topics will be further assessed, and new ones identified where necessary.

2021: CTWG did an assessment of clinical trial data providers where SDTM data could be accessed. This eventually led to discussions with Vivli (i.e., general data usage agreements and platform feasibility evaluation).

2020: Used a synthetic representation of the CDISC SDTM data via PHUSE Test Data. Initial guidance topics were codified but require further testing with diverse real world SDTM data. The CTWG proposals submitted to the OHDSI community in July 2020.



CTWG Challenges

- Constraints by WG in accessing clinical study data within the Vivli environment (i.e., limited number of team members)
- Vivli environment time constraints (i.e., free access for one year, then pay for access)
- Installing needed software in the Vivli environment
- Working with obfuscated study data
- Pivoting strategy from mapping-to-execution to simply conceptual mapping guidance
- Access to less restricted SDTM study sources



CTWG OKR

Objective: To define the conceptual mappings and guidance to support CDISC SDTM-to-OMOP conversion

- Key Result #1: Identify ≥ 3 real-world SDTM clinical studies
- Key Result #2: Develop conceptual SDTM-to-OMOP mapping specifications using a prioritized set of common SDTM domains (adverse events, vital signs, demographics, concomitant medications, laboratory test results, medical history, and procedures)
- Key Result #3: Publish draft SDTM-to-OMOP guidance by Q1 2024
 - Conceptual mappings on key domains of interest
 - Topic based best practices format
 - Identified gaps, issues, and challenges



CTWG Ask

- Additional sources of real-world clinical studies in SDTM format
- Any volunteers to support SDTM-to-OMOP high-level concept mappings
- Any organization active working on SDTM-to-OMOP conversions that have lessons learned outcomes