Clinical Trials Working Group

Mike Hamidi (co-lead)
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Working Group Update
October 5, 2021
What is the CTWG?

Clinical Trials Working Group

Objective: To allow adequate representation of clinical trial data in OMOP.

First use case: To convert clinical trial data in CDISC SDTM format to OMOP, with a view to allowing trial planning optimization.

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 are built on OMOP CDM v6 and the Oncology extension, with v5.3.1 backward compatibility.

Status:
- Proposals submitted to the OHDSI community In July 2020.
- Currently applying our proposed conventions to the PHUSE database (a synthetic SDTM database).

Membership

WG co-leads: Mike Hamidi, Pfizer, US (Kamir.Hamidi@pfizer.com) Zhen Lin, Robot Bacon, US (Zhen.Lin@ohdsi.org)

Current members

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As of As of 2021-08-07
The Clinical Trials Working Group (CTWG) proposes conventions for the OMOP CDM and Standardized Vocabularies to capture clinical trial specific data.

Our use case is the conversion of clinical trial data in CDISC SDTM format to OMOP, with a view to allowing trial planning optimization. SDTM was chosen as it is a clinical trials’ submission standard that is “required” by the FDA and PMDA, “preferred” by the China NMPA, and “accepted” by the EMA. All our proposals assume the source data is in SDTM format and represent the final set of data from a clinical trial.

We advocate minimum changes to the OMOP CDM and Standardized Vocabularies to minimize impact on OHDSI tools like Atlas, whilst providing a value-add SDTM-to-OMOP conversion with minimum data loss.

Our proposals cover **eight main topics** for which there is currently insufficient support in the OMOP CDM and Standardized Vocabularies. They include introducing new concepts and modifiers, but no new CDM tables. Furthermore, we provide guidance for ETL developers when dealing with some data that is more complicated in nature, or certain scenarios that may be present in clinical trial submitted datasets (e.g., non-unique subject ids).

This document details our proposals for each of those eight topics, built on OMOP CDM v6 and the Oncology extension, with v5.3.1 backward compatibility.
OMOP CDM uses, for example, health records and claims databases. The CDM and vocabulary set is comprehensive to manage multiple data sources and supporting models (e.g., LOINC, SNOMED). SDTM was originally developed to support clinical research use case that are predominantly based on non-RWD terminology (e.g., CDISC, MedDRA, etc.). Although, SDTM can accommodate some aspects of observational-based research, it was not designed for this purpose. However, being able to utilize SDTM for OMOP is not beneficial for researchers but also sponsors.

An academic use case has been identified where OMOP CDM is converted back to SDTM for submission purposes.

Source: Mike Hamidi

*Data standards used for regulatory submissions (e.g., for the US FDA)
CTWG Activities

Clinical Research Topics

- Did the patient complete the trial?
  - Yes: Observation: 4082640 “Completion of clinical trial”
  - No: Observation: 4087967 “Patient withdrawn from trial”
- What is the reason for withdrawal?
  - Decided by patient: Value: 4306655 “Death”
  - Lost to follow-up: Value: 44811247 “Lost to clinical trial follow-up”
  - Serious adverse event: Value: 4586631 “Withdrawn from trial because of serious adverse event”
  - Withdrawn by investigator: Value: 7 “Withdrawn by investigator”

SDTM-to-OMOP CDM Mapping

- Source: usubjid
- qseq
- qtestcd
- qtest
- qscat
- qscat
- qscat
- qsscat
- qsscat
- qsscat
- qsscat
- qsscat
- qsscat
- visitnum
- visit
- qsdtc

Figure 2. Trial outcomes and corresponding mappings.

Taking a conceptual thought...

...into mappings

Source: https://github.com/OHDSI/ClinicalTrialsWGETL/wiki
Some mappings require some additional upfront strategies.
CTWG Next Steps

• Access to additional real-world SDTM data
  • Actively working with **Vivli** and **C-Path** with a likelihood of happening Nov. 2021

• Use additional SDTM data to continue mapping activities
  • Identify gaps and limitations
  • Assess strategies for other topics not listed

• Producing an industry guidance and example package
  • A synthetic SDTM-to-OMOP data set
  • Generalized mappings with associated disclaimers/tips
  • Best practice guidance document

We need data!
Thank you!

Clinical Trials WG

Bridging the gap between clinical trial and observational research

Join us!


Fridays this Fall
7:30AM PT/9:30AM CT/10:30AM ET/3:30PM UK/10:30PM CST

SDTM Tables  OMOP Tables

VS  Measurement
LB  Drug_exposure
EX  Procedure_occurrence
CM  Observation
MH  Condition_occurrence
AE

Pathways for advanced transformation of CDISC SDTM data sets into OMOP CDM, Didden et al., 2020