



Clinical Trials Workgroup Community Update

November, 2022



Workgroup Objectives

Transform CDISC SDTM Formatted Clinical Trials Data to OMOP CDM

- Propose Conventions
- Generate Mappings
- Publish Guidelines



Challenges

- Data are currently collected according to CDISC SDTM Standard and require ETL definitions/mappings to convert into OMOP CDM
- Privacy concerns make it difficult to access data for testing
- Clinical Trials data are specialized type of medical record often requiring custom vocabularies



Our Approach

- Document Proposed Conventions
 - <https://github.com/OHDSI/ClinicalTrialsWGETL/wiki>
- Collect a set of SDTM formatted source data that adequately represents a breadth of data elements
 - Across different Phases and Therapeutic Areas
- Data Sources
 - PhUSE
 - Vivli
 - CPath
 - TrialTwin



Our Approach - Continued

- Produce ETL definitions and field mappings for source data
 - <https://github.com/OHDSI/ClinicalTrialsWGETL/tree/master/docs>
- Proof of Concept
 - Perform data transformations using definitions & mappings in a protected environment



Key Results & Progress

- Apply our approach to PhUSE (synthetic trial data)
 - Completed (2020-2021)
 - Validated proposed conventions
 - Initial ETL definitions and mappings generated
 - Data not comprehensive enough for large scale use
- Apply our approach to Vivli sourced data (actual trial data)
 - Ongoing since 2021 - Getting approval to access the data has taken time
 - Summer of 2022: Gained access to ~5 SDTM formatted data sets through the Vivli platform
 - Fall of 2022: Gained access to secure implementation enclave to perform data transformation



Key Results & Progress - Continued

- Apply our approach to Vivli sourced data (actual trial data)
 - Currently ongoing: Validating existing ETL mappings and generating new mappings to support conversion of Vivli sourced datasets to OMOP CDM
 - Team members volunteer to produce mappings for specific SDTM domains and/or OMOP CDM output tables
 - During Bi-Weekly Friday meetings, work on mappings as a team and work through and problems/questions
- Going forward
 - Perform transformations for as many Vivli data sets as we can
 - This should get easier as our set of mappings becomes more robust
 - Publish/update mapping definitions on github



Join Us!

- Strong Team
 - 273 Registered Members
 - Consistent member participation every meeting
 - Various backgrounds represented: Pharma, Regulatory, Standards Orgs, Vendors, Technology Advocates
- Contact Us
 - Workgroup Leads: Mike Hamidi, Zhen Lin
 - Kamiar.Hamidi@pfizer.com
 - Zhen.Lin@ohdsi.org
 - We use Microsoft Teams for communication (email for an invite!)
- Resources
 - Workgroup Page: <https://www.ohdsi.org/web/wiki/doku.php?id=projects:workgroups:clinicalstudy>
 - Github Repo: <https://github.com/OHDSI/ClinicalTrialsWGETL>
 - Proposed Conventions: <https://github.com/OHDSI/ClinicalTrialsWGETL/wiki>