Clinical Trial Data Conventions for the OMOP CDM

PRESENTERS

Chris Roeder, Katy Sadowski, Maxim Moinat, Philip Solovyev, Sonia Araujo

INTRO

- The current OMOP CDM was created for observational health data.
- A significant gap exists in representing many of the distinctive features of clinical trial data.

METHODS

- We advocate for minimal changes to the OMOP CDM and Standardized Vocabularies whilst providing a value-add SDTM-to-OMOP conversion to capture the unique elements of clinical trial data.
- We are focusing first on converting clinical trial data in CDISC SDTM format.

RESULTS

- We propose to create one observation period record only per clinical trial subject.
- We covered 8 main topics – from trial information and visits, to type concept ids – for which there is currently insufficient support in the OMOP CDM and Standardized Vocabularies.

CONCLUSIONS & NEXT STEPS

- We submitted our proposal to the OHDSI community in July 2020 for review and leadership approval.
- Mapping clinical trial data to the OMOP CDM potentially will add a large volume of data to the OHDSI ecosystem and allow observational and trial data to be combined in analyses.
- We are applying the proposed conventions to a specific clinical trial in CDISC SDTM format to gain further insight into the process of mapping SDTM data to OMOP.
- We welcome new members to this working group!

The OHDSI Clinical Trial Working Group proposes **conventions** to represent **clinical trial specific data** with minimal changes to the existing OMOP CDM

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PROPOSAL SUMMARY

Topic	Proposal Summary
Trial enrollment & trial outcomes	We propose to store these data as an observation for each event related to a person's trial status (e.g., informed consent or completion of trial).
Trial visits	We propose to extend OMOP CDM vocabularies to capture the different trial visit concepts across clinical trial epochs, and to have composite source values to capture time indicators within an epoch (e.g., TREATMENT:WEEK 7).
Seriousness, severity and causality	We propose to link an observation or condition to another record to capture adverse events, along with their seriousness, severity and causality to the trial subject's drug or treatment, via oncology extensions (measurement modifiers) and Observation attributes from OMOP CDM v6.
Study information and arm assignment	We propose storing information about which trial arm the individual trial subjects are in using the COHORT table. We propose storing information about the trial design and trial arms in the COHORT_DEFINITION table.
Novel concepts	Some drugs cannot be standardized as they haven't been "seen" before. For drug concepts, single new concepts can be added without substantial effort at the ingredient level. We propose an improved and simplified process to add clinical drug level drug concepts as RxNorm extensions.
Type concept ids	Type concepts in OMOP give the provenance of a record. We propose to use the newly-added standard type concept for "Case Report Form" to represent trial provenance.
Planned drug dose	To keep administered and planned drug doses in a way that makes comparing them possible, we propose to use a type concept id in the DRUG EXPOSURE table that allows that distinction.
Relative dates	In some clinical trials e.g. when a trial is anonymized, events' timepoints are given as days offset from a subject's informed consent or randomization date. If relative dates are given, we propose to calculate dates using the subject's reference date. The METADATA table can be used to record dates are derived.

AUTHORS

Alexandra Orlova[1], Andrew Williams, PhD[2], Asiyah Yu Lin[3,4], Chris Roeder, MS[5], Cynthia Sung, PhD FCP[6], Emma Vos, MSc[7], Gregory Klebanov, MSc[1], Joshua F. Ransom, PhD[8], Katy Sadowski, BS[9], Maxim Moinat, MSc[7], Michael Kallfelz, MD[1], Mike Hamidi[10], Philip Solovyev, PhD[1], Rhonda Facile, MS[11], Shawn Dolley, MBA[12], Sonia Araujo, PhD[13], Tom Walpole[14], Vojtech Huser, MD PhD[15]

[1]Odysseus, USA; [2]Tufts Institute for Clinical Research and Health Policy Studies, USA; [3]Center for Devices and Radiological Health, FDA, USA; [4]National Center for Ontological Research, USA; [5]University of Colorado, USA; [6]Bill & Melinda Gates Medical Research Institute, USA; [7]The Hyve, The Netherlands; [8]BEKHealth Inc, USA; [9]TrialSpark, USA; [10]CDISC, USA; [11]Elligo, USA; [12]Open Global Health, USA; [13]IQVIA, UK; [14]Trials.ai, USA; [15]National Institutes of Health, USA

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