Supplementary material for: A Metadata Schema for Data from Experiments in the Social Sciences *

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Additional RCT Metadata Resources and References

The Yale Application for Research Data (YARD) is an open-source web application that structures the process of curating research data for the ISPS Data Archive, a repository for affiliates of the Yale Institution for Social and Policy Studies (ISPS) (ISPS, 2021). YARD uses generic DDI fields to store a self-built vocabulary that can be read by DDI, providing a template for mapping our schema to DDI (Colectica, 2022).

The Registry of Efficacy and Effectiveness Studies (REES) at ICPSR is a registry for causal inference studies, including RCTs, in education research (Anderson et al., 2019).

Ohmann et al. (2017) identify current barriers and propose a set of principles related to sharing and reuse of clinical trial data.

The Clinical Data Interchange Standards Consortium (CDISC) develops data documentation standards for medical research that are used by many regulatory agencies such as the US Food and Drug Administration (National Cancer Institute (2021)).

The World Health organization manages the International Clinical Trial Repository Platform and defines the WHO Trial Registration Data Set, a minimum set of 24 items that a trial must report in order to be considered registered WHO (2021).

Raftery et al. (2015) build a metadata database with 429 data fields containing 125 clinical trials, with very detailed information on study conduct and results (as opposed to the data generated by the study), including e.g. information on adherence to protocol, quality of statistical and economic analyses, and costs.

*All materials for this project can be found on the associated GitHub repository at https://github.com/sakopper/rct_metadata_schema.

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Other platforms aimed at facilitating access to clinical studies harvest registries such as ClinicalTrials.gov: Vivli (2021), the Yoda Project (2021), Duke Clinical Research Institute (2021) and Clinical Study Data Request (CSDR (2021)).

Procedure for Developing Controlled Vocabularies

We followed the procedure of the DDI Controlled Vocabulary working group to make changes to existing and develop new controlled vocabularies. We first defined the coverage of the metadata field, then reviewed existing controlled vocabularies, and finally made changes, such as expanding the available options or creating sub-categories of existing options, or (in some cases) by removing options. CV development was aided by inputs from the working group, multiple J-PAL staff, and the advisory group. We considered CVs from ADA, AidGrade, CESSDA, Clinicaltrials.gov,the Cross-National Equivalent File PSID Codebook, DDI, J-PAL, Gesis Demographic Variables, the IHSN, IPA, REES, and the World Bank. Although all newly developed CVs were tested extensively on the datasets below, we believe further testing with a larger body of data is required to fully cover the universe of values. The current version (version 0.9) of the proposed CVs is therefore hosted on the GitHub repository for this project, and we consider many of them subject to change.

Datasets Included in the Testing Process

Note: Included below are the 26 public datasets that were used in the testing process for version 1.0 of the metadata schema. Three more datasets from ongoing projects will be added once the data are made public.

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