Protocol Library

Design, Analyze, Communicate: Working together to improve clinical study outcomes.

Access The Clinical Trial Protocol Registry And Library

Background

A clinical trial protocol is a document detailing key information about a research study, which provides a foundation for the study being carried out.

Sections of a protocol include:

- a background of the topic,
- rationale for carrying out the specific study,
- information on the included study population,
- methods describing exactly what will occur and how,

- a plan for statistical analysis, and
- information on how findings will be disseminated, among others (Chan et al., 2013).

Protocols also incorporate research ethical considerations regarding human subject research, such as safety of subjects, data quality and safe handling, and monitoring (UCLA, 2017).

All protocols must meet quality standards, called Good Clinical Practice, that are in line with regulations concerning human subjects (Cipriani and Barbui, 2010). Prior to the start of research activities, protocols must be reviewed and approved by an Institutional Review Board (IRB) and the Food and Drug Administration (FDA) or the local regulatory authority.

This Protocol Library represents perhaps the largest collection of low- and middle-income country trial protocols. It offers a source of data and potentially a locus of research. The protocols include a number of design decisions, approaches to statistics, recruiting, communication and GCP that might provide ideas for future principal investigators.

Methods

The DAC team performed a search for open access protocols for randomized control trials (RCT) with the criteria below. The search was informal, and included searching Pubmed, Google Scholar, multiple clinical trial registries, as well as direct communication with a number of known LMIC principal investigators. If you would like to suggest an additional study to this Protocol Library, please email: DACTrials@gatesfoundation.org.

Inclusion criteria:

- Full protocol available
- Carried out in low-to-middle income country (LMIC)
- Publication between 2015-2019 of the article describing the study whose design is in the protocol

- Disease areas:
  - Human Immunodeficiency Virus (Folder: HIV)
  - Neglected Tropical Diseases (Folder: NTD)
  - Tuberculosis (Folder: TB)
  - Malaria (Folder: MAL)
  - Maternal, Newborn, & Child Health (Folder: MAT)
  - Nutrition (Folder: NUT)
  - Vaccines (Folder: VAC)
  - Enteric & Diarrheal Diseases (Folder: EDD)
  - Pneumonia (Folder: PNE)
  - Polio (Folder: POL; no files at this time)

Exclusion criteria:

- No full protocol available, defined as protocols less than 45 pages in length
- Published prior to 2015 or after 2019
- Not open access
- Not a randomized control trial
- Full text not available
- Protocol not allowed to be shared publicly
- Disease areas other than indicated
- Trial was not carried out in LMIC

Results

Forty-eight studies were identified to have met inclusion criteria. The majority were carried out in Africa, with the disease areas of HIV, Neglected Tropical Diseases, Tuberculosis, and Malaria making up roughly half of all studies. The mean page count was approximately 150 pages. The range of page counts was 46 to 900.

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Please note: Implementors of studies should also always refer to relevant regulatory standards and guidelines (e.g. FDA, EMA) to assist with study/protocol design.

TOOLS & RESOURCES

DAC Assessment Tool

Resource Database

Protocol Library

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