endTB Data Sharing Initiative: Data Access Guidelines

The Data Access Committee ("DAC") will follow these Guidelines when evaluating applications to access data held by the endTB Data Sharing Initiative ("eDSI Data"). All approved applications will have a Data Access Agreement signed by the Data Requestor and the eDSI hosts (Medecins Sans Frontieres France, Partners in Health, Interactive Research and Development Global Limited) before the data are made accessible.

Application

Each Data Requestor will submit a Data Access Request.

Presumption of Approval

If an application complies with these Guidelines, there are no concerns about scientific value or ethics, and the application does not meet criteria for Steering Committee review, then there is a rebuttable presumption that the application will be approved by the DAC.

The eDSI Data Access Process

- All applications will be processed by the Administrator and the DAC in accordance with their terms of reference.
- There is no fee or other cost for Data Requestors to access the eDSI Data.
- The DAC will make it's best efforts to respond within 2 months (via the Administrator).
- The DAC may seek the opinion of independent experts to inform their decision. In the case that this extends the review period, the Data Requestor shall be informed.
- The DAC (and its Request Review Subgroups) can decide to:
  (i) approve the application,
  (ii) approve the application subject to caveats (including the need for any ethical review/approval);
  (iii) submit the application to further review by full DAC or SC (per specified criteria);
  (iv) request further clarification or amendment from the applicant;
  (v) recommend collaboration with other groups proposing overlapping work; or
  (vi) reject the application.

Ultimately all requests must receive a final decision of (i), (ii), or (vi). The DAC will provide written justification for all rejected applications.

- Rejected applications and those for which amendments are requested will be reconsidered if the issues raised by the DAC are addressed in a subsequent application. Disputes and/or appeals regarding the data access decisions will be managed by the Data Access Committee in the first instance and, if required, may be referred to the Steering Committee for final decision.
- The DAC defines the scope of data sets to be released.

eDSI Data Protection

Only pseudonymized data will be made available to Data Requestors.

Review considerations

Applications will be evaluated according to the following criteria:

Scientific value

The DAC will ensure that the proposal has scientific value by verifying that the scientific question:
- addresses a knowledge gap and avoids duplication without added value and unnecessary competition,
- benefits the wider public health community.

Plans to publish and disseminate the research results must enable access to the results by DR-TB-affected communities.

Scientific Validity

The eDSI Data requested must be capable of answering the research question. The methodology proposed to answer the research question must be sound.

Applications to the Platform must not request more than the minimum eDSI Data necessary to answer the research question – each variable requested must be required for the successful completion of the research.[1]

Capacity building and equity

eDSI strongly encourages (e.g. does not oblige) applicants to promote equity or capacity-building, through some or all of the following:

- the application is led by, or includes collaborative partnerships with, the research community in countries contributing data to eDSI,
- the application develops research capacity in country-ies with high burdens of DR-TB,
- the application includes community involvement,
- the applicants are supporting an appropriate capacity building initiative in an area related to the application.

Data Requestors

Access to eDSI Data is limited to Data Requestors working in a field relevant to DR-TB and with a formal affiliation with a health, research, humanitarian, government, inter-government, non-governmental or academic institution with legal status.

Research must not be for commercial purposes or in the promotion of a commercial enterprise and/or its products or services. Any Research that is commercial should be referred to and discussed directly (outside eDSI) with the relevant data contributors, depending on the dataset(s) requested.

The Data Requestor will attest that sufficient funding to perform the proposed research has been secured or is being sought for this purpose.

The Data Requestor will not have previously violated the terms of the eDSI Data Access Agreement.

Ethics

The DAC must be satisfied that there are no concerns with respect to the ethical aspects of the application.

Approvals

All required scientific and ethical waivers or approvals must be obtained before the Data Transfer Agreement is signed and before any eDSI Data is shared with the Data Requestor.

If approvals are received from other study countries to add data to the eDSI data repository, researchers already granted access to data can reach out to the eDSI administrator to ask to receive data from these additional countries. This only applies to data from the same endTB study that the researchers were already granted access to. The DAC should prioritize the review of such additional request in a reasonable timeline. In case of agreement, the Data Transfer Agreement should be amended to include the additional data before a new updated dataset is shared.

eDSI Data Access Agreement

Before any eDSI Data is disclosed, Data Requestors will be required to enter a standard Data Access Agreement imposing obligations on the Data Requestor that are intended to ensure compliance with the key principles underpinning the eDSI.

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[1] These requirements fulfill principles of proportionality and minimization.