

endTB Data Sharing Initiative

Steering Committee

Terms of Reference

1. Approval and Governing Body

The Steering Committee (SC) shall adopt these Terms of References (ToR) and become active when at least nine SC members have signed the Committee Terms and Conditions.

2. Purpose

The endTB Data Sharing Initiative (eDSI) has been established to promote ethical, equitable and transparent access to endTB data for a range of users who share the common goal of increasing knowledge and disseminating information to improve care for drug-resistant TB patients.

The eDSI has three distinct purposes:

- 1) host curated, cleaned, pseudonymized data on diagnosis and treatment of drug-resistant TB, from the endTB project;
- 2) manage requests for access to endTB datasets;
- 3) promote research performed by people from countries that have contributed the data.

The purpose of the Steering Committee is to define and oversee the eDSI policy, strategic direction, and management.

The members of the Steering Committee will ensure the eDSI works in compliance with the eDSI Charter and Ethics Framework.

3. Membership

The Steering Committee shall comprise 9-12 voting members. It will be constituted from:

- the following three endTB consortium partners/signatories: Medecins sans Frontieres France (MSF), Partners in Health (PIH) and Interactive Research and Development Global Limited (IRD) **(3)**,
- countries contributing data **(3-4)**,
- affected communities/TB activist organizations/community advisory boards **(>=2)**.

Membership will bring a representative balance of skills and expertise in clinical research, data protection and management, ethics in research, benefit sharing and community engagement.

At inception of the eDSI, the Steering Committee shall be constituted by soliciting nominations from TB program leadership (and/or important private-sector partners) of countries contributing the largest number of observations to the datasets and representing a diverse geographical distribution. Nominations for community members will be solicited from organizations of affected communities/civil society. Each organization included in the endTB consortium named above (MSF, PIH, IRD) will nominate representation in the Steering

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Committee. Selection of the initial SC will be made by the eDSI task force set up by MSF, PIH and IRD to establish the Platform.

There can only be one representative per institution and no individual can represent more than one institution. The composition of the Steering Committee will avoid gender and geographical imbalances and work toward broad representation.

Membership will be reviewed based on needs. If changes in membership distribution (e.g., fewer country representatives) occur, the SC shall notify supervising ECs/IRBs.

The names and affiliations of the SC members will be made public on the endTB website.

Eligibility

Members must agree to abide by the eDSI Charter, Ethics Framework and Conflicts of interest Policy, the present ToR, and the rest of the governance framework for the Platform (referred to collectively as the Governance Framework).

Alternate members

A representative may nominate an individual from their country or institution to take his or her place as an alternate member, subject to reasonable efforts to ensure continuity of individuals attending meetings.

Membership Term

The Steering Committee members can hold their position for 3 years. Every effort will be made to rotate members off, and new members on, after a single term. However, members can serve for a maximum of 3 terms. Timing of rotation on and off the Committee will be staggered to ensure continuity of membership where possible. The Steering Committee can appoint new members. Country members will be selected by the Steering Committee through a nomination process that gives priority to countries that contributed data which were not previously represented on the Steering Committee. New community member nominations will be solicited from organizations of affected communities/civil society. Each of the three organizations from the endTB consortium with permanent institutional SC representation (MSF, PIH and IRD) will nominate new representation from their institution under the same principles.

Resignation & revocation of membership

Members are free to resign their position with immediate effect. Notice of 3 months is preferred. Named alternate members may replace institutional members for the remainder of their term.

An individual's membership on the Steering Committee can be revoked by the other members of the Steering Committee for breach of any part of the eDSI Governance Framework. In such a case, the institution/constituency represented would be asked to nominate a replacement.

4. Chair

The Steering Committee shall appoint a Chair. These positions will be held on a 2-year basis. The Chair can be re-elected and can serve a maximum of 2 terms.

The Chair will:

- chair the meetings,
- seek confirmation that the Declaration of Interests of each member is current and up to date,
- manages potential conflicts of interest in accordance with the eDSI Conflict-of-Interest Policy
- coordinate the Steering Committee annual report with the support of the Administrator,
- review and validate the minutes of the Steering Committee meetings taken by the Administrator.

In the event a Conflict-of-Interest involves the Chair, another member of the SC who has no conflict shall be selected by the other members of the SC to manage and resolve the conflict/ potential conflict in accordance with the eDSI Conflict of Interest policy.

5. External Observers

With agreement of the Steering Committee, individuals who are not members of the Steering Committee may attend and participate in any Steering Committee meeting or part of a meeting, but non-members may not participate in decision-making.

6. Administration

The eDSI administrator will provide administrative services to the Steering Committee in accordance with the Administrator Terms of Reference. They will receive and distribute communications on its behalf and manage and coordinate required meetings. They will provide information on eDSI activities to the Steering Committee for its annual report. The Administrator will make publicly available the annual report and, where possible, summaries of minutes and materials online on the endTB website.

7. Quorum

No business shall be transacted at any meeting of the Steering Committee unless a quorum is present. A quorum is at least 50% + 1 of the total voting memberships at the time. The Chair and alternate members shall count toward the quorum.

In the absence of the Chair at a meeting, the present members of the Steering Committee shall appoint one of their number to chair the meeting.

8. Meeting Frequency

The Steering Committee shall meet at least once a year (in person or virtually).

A special meeting may be called at any time (in person or virtually) when requested by the Chair or by at least 2 members of the Steering Committee. At least 2 days' notice of the meeting and matters to be discussed shall be given to the other Steering Committee members.

9. Operations

The Committee may regulate its own procedures subject to the provisions of these Terms of Reference.

The Administrator shall notify and record meeting activities and disseminate information according to the ToR of the Administrator.

Any member wishing to place an item on the agenda for a Steering Committee meeting must provide details to the Administrator in advance of the meeting.

The Steering Committee may arrange for collective decision-making by exchange of emails outside of meetings as long as the SC is satisfied that to do so is appropriate. Decisions made by exchange of emails shall be formally documented at the next meeting.

The Steering Committee may create and dissolve committees or subgroups of its members and shall determine the terms of reference of any such committee subject to the provisions of the eDSI Governance Framework.

Each party will execute its duties in good faith.

10. Duties:

The Steering Committee shall have the following powers and responsibilities:

- Oversight of the eDSI and its strategy, policies, management, internal procedures and activities, in compliance with the eDSI Ethics Framework;
- Oversight, development and promotion of plans and activities to embody the following principles of CIOMS: equitable distributions, community engagement, capacity building and collaborative partnerships;
- Ensure transparency of the eDSI operations and governance and effective communication about the eDSI: review and approve significant public communication of materials;
- Election of new SC members, removal of SC members and changes to SC membership;
- Validation of Data Access Committee membership;
- Support Data Access Committee activities (as per the Data Access Committee Terms of Reference); Review requests that require SC input. Resolve any data access appeals in accordance with the Data Access Guidelines;
- Ensure implementation of the Conflict-of-Interest policy. Resolve any Conflict-of-Interest appeals;
- Ensure implementation of the Committee Member Terms and Conditions with respect to eDSI projects;
- Review performance of eDSI (e.g. through self assessment tool/checklist or customer satisfaction surveys).
- Produce an annual report on the eDSI activities that will be made public on the endTB website.

- Agree on potential expansion of the eDSI (new partnerships or new datasets beyond original scope).
- Consider and agree on dissolution of eDSI, as necessary;
- Agree on changes to the governance structure of the eDSI (e.g. Ethics Framework, Data Access Committee ToR, Steering Committee ToR, eDSI Charter) before notification to ethical review boards who supervise the eDSI;

Subject to the provisions of paragraph 11 below (Accountability):

- Two-thirds of those present (or of those who respond by email) are required to make most decisions.
- For decisions on expansion or dissolution of the eDSI, and decisions on the eDSI governance, unanimity of the voting members is required to make decisions.
- Each individual member has one vote.

11. Accountability

The Steering Committee is accountable to the endTB consortium and to the institutions and/or constituencies that members represent. The SC may be requested to report on project compliance/progress to the institutions/constituencies.

MSF, PIH and IRD have founded the Platform, they also take legal responsibility for the data within the Platform as joint data controllers, and are the legal signatories to the Data Access Agreements with researchers. As such, each of MSF, PIH and IRD acting together or independently have the right to veto the decisions and duties of the SC outlined in these ToR that are not inline with their legal and ethical responsibilities. MSF, PIH and IRD shall also have the responsibility for the Platform hosting and administration activities outlined in the Appendix.

12. Costs

Each SC member pays all the costs it incurs in the implementation of their role. Any given expense/cost can only be committed in writing and in advance by approval from the Administrator. In no case can SC members commit an expense on behalf of themselves or the Platform, without the Administrator's prior written consent.

13. Interests of Steering Committee Members

The Chair of the Steering Committee will seek verbal confirmation at the start of any meeting that the Declaration of Interests of each member is current and up to date, with particular attention to the items on the agenda for that meeting. It is the duty of each member of the Steering Committee to declare interests not only at the start of meetings but as and when they arise in accordance with the Conflict-of-Interest Policy.

14. Reporting responsibilities

Each member of the Steering Committee shall disseminate minutes and reports of the Steering Committee meetings to the institution or constituency that member represents.

The annual report of eDSI activities and summaries of Steering Committee decisions shall be available on the endTB website.

Appendix

MSF, PIH and IRD Platform Hosting and Administration Responsibilities

- Designing, hosting and maintaining the server that holds the Platform, including all Platform data;
- Preparing the datasets to be made available to the Researchers (once approved by the Data Access Committee) and for signing Data Access Agreements with researchers;
- Signing any new Data Contributor Agreements for new data accepted into the Platform (following Steering Committee approval);
- Maintaining and keeping up to date the Platform's Website, reviewing and agreeing to public communication materials and taking a proactive role in ensuring effective communication about the Platform, publishing on the endTB Website descriptions regarding the research projects supported by the Platform and other Platform activities;
- Engagement and communication with third parties to support the Steering Committee and overall Platform development;
- Supporting work to secure long-term funding, sustainability plans and future running costs and, where possible, for methodological and research capacity strengthening and support for Researchers using the Platform;
- Resolution of issues and oversight of enforcement of data access terms, including development of a practical, transparent and fair enforcement strategy to deal with data breaches;
- Defining and performing security tests, audits and reports to be carried out and provided (including frequency) for the Platform;
- Reviewing the ethics approvals and privacy impact assessment of the Platform periodically to ensure frameworks and policies are kept up to date with the current purpose of the Platform, data protection legislation and best practice for information governance and research ethics;
- Performing the Administrator role for the Platform as per Administrator Terms of Reference;
- AOB pertaining to hosting, maintaining and running of the Platform.