

## **Terms of Reference endTB Data Sharing Initiative (eDSI) Data Access Committee (DAC)**

### **1. Date Approved and Governing Body**

These Terms of Reference (ToR) will be endorsed by the DAC and ratified by the eDSI Steering Committee.

### **2. Purpose**

The endTB Data Sharing Initiative (eDSI) has been established to develop and promote research on treatment and diagnosis of drug-resistant TB. The eDSI fulfills three 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 DAC is to:

- Determine whether requests to access data from the eDSI conform to: the Data Access Guidelines (DAG), Ethics Framework, and Conflict of Interest Policy and/or require Steering Committee or external input (see section 10).
- Communicate decisions to the eDSI administrator for notification to the applicants.
- Define the scope of datasets to be released (e.g. safety, clinical outcomes).
- If necessary, prioritize applications.
- Report to eDSI Steering Committee (SC) on activities of the DAC.
- Provide input to the SC on research priorities, emerging issues in data access and any implications for eDSI strategy and policy.

### **3. Membership**

The DAC shall start with 12 members; it may expand up to 24 members if quantity and frequency of data access requests require it. Membership will include representation from: endTB consortium partners/signatories to the endTB Research Agreement, countries contributing data (target of at least 1/3 of membership), affected communities/patient activist organizations/community advisory boards (target of at least 1/6 of membership). 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. Gender and geographical (notably, resource) imbalances will be avoided. Members will be selected through an open nomination process. Based on the guidance about representation, the administrator will submit membership for validation by the Steering Committee. There can only be one representative per institution and any one individual cannot represent more than one institution.

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

#### *Eligibility*

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Members must agree to abide by the eDSI Charter, Ethics Framework, the Conflict-of-Interest Policy, the Data Access Guidelines, and the present TOR (these documents are collectively referred to throughout as the Governance Framework of the eDSI). Members may serve in an individual or institutional capacity.

#### *Alternate members*

Members who represent institutions and are unable to fulfill their service may nominate a different individual from that institution (who holds similar skills/experience) to serve as an alternate member. The alternate member will retain the voting right of the member they represent and will be subject to the same eligibility requirements. Individual (non-institutional) members may not appoint alternate members.

#### *Membership Term*

The DAC membership is 3 years; members can serve a maximum of 3 consecutive terms. Where possible terms will be staggered to assure continuity of DAC functions.

#### *Resignation*

Members are free to resign their position. Notice of 3 months is preferred though not required. Named alternate members may replace institutional members for the remainder of their term.

#### *Request Review Subgroups*

Subgroups of members will be formed to simplify review of data access requests. Subgroups will comprise 4-6 DAC members. Subgroups will be formed to ensure the inclusion of relevant research expertise, perspective of patient/activist, and perspective of those who reside in countries contributing data to the eDSI. The distribution of these attributes will not necessarily be one per person (e.g. a patient/activist might also hold relevant research expertise).

## **4. Chair**

The DAC shall appoint, through a 2/3 vote, its Chair from among the DAC membership. The term is 3 years and a Chair can serve a maximum of 2 consecutive terms. The Chair will be responsible for dealing with urgent matters that arise between scheduled meetings of the DAC. The DAC does not delegate decision-making responsibility to the Chair. Any urgent action taken by the Chair must be considered and decided upon by the DAC at the first available opportunity.

## **5. External Observers**

External observers/advisors who offer expertise in specific issues relevant to the applications being considered may be invited to provide advice and/or attend meetings as appropriate. External observers will not have voting rights and may be requested to sign non-disclosure agreements as necessary.

## **6. Administration**

The eDSI Administrator will provide administrative services to the Data Access Committee. The administrator will prescreen applications and only pass on to DAC when confirmed to be complete.

They will receive and distribute communications on its behalf and manage and coordinate required meeting activities in accordance with the Administrator Terms of Reference.  
The Administrator will make publicly available, where possible, summaries of minutes and materials online on the endTB website.

## **7. Quorum**

No business shall be transacted at any meeting of the Data Access Committee unless a quorum is present (or responsive, if by email).  
A quorum for review of data access requests is 4 members. Quorum for other business of the DAC is 50% + 1 of the total membership at that 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 DAC shall appoint one of their number to chair the meeting.

## **8. Meeting Frequency**

The DAC aims to hold at least annual, full meetings. Subgroups assigned to review data access requests will aim to meet or otherwise communicate (see item 9 below) within one month of the request, to facilitate a response to the request within 2 months.

## **9. Operations**

The Data Access 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 their ToR. All members will receive a copy of all requests for data access and may comment even though only a subset will be required to review.

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

The Data Access Committee may arrange for collective decision-making by exchange of emails outside of meetings as long as the DAC is satisfied that to do so is appropriate; all Data Access Committee members are contacted and decisions are made under the same thresholds as defined in item 10. Decisions made by exchange of emails and Subgroup decisions on Data Access Requests shall be formally documented at the next meeting.

The Data Access 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: Decision-making and responsibilities**

The DAC and its Request Review Subgroups shall endeavor to make decisions by consensus (meaning all those present in the meeting or responsive, if by email, agree). If consensus on any decision cannot be reached, decisions will be submitted to a vote. Each individual member has one vote. Decisions to grant or reject access by a Request Review Subgroup shall be taken by a simple majority (50% + 1 if the number of voting members is even).

In case of appeal by the requestor, the request will be reviewed by the full DAC. DAC decisions shall be taken by a simple majority. In case of a tie, the Chair shall have the deciding vote.

The Data Access Committee shall have the following powers and responsibilities:

- Manage and oversee all applications to use the eDSI data. This includes reviewing, approving and denying applications in accordance with all parts of the eDSI governance framework, and providing written answers to the Administrator for notification to the applicants;
- If deemed useful by DAC Request Review Subgroup, to seek advice from other DAC members;
- If deemed useful by DAC members, to refer the application for external advice by a subject-matter expert (selected by DAC members) to provide an opinion to inform the DAC's decision;
- Evaluate and refer to the Steering Committee requests in the following circumstances:
  - the DAC's decision differs from the specific recommendation of an external expert to approve/deny access;
  - there is a need for input on the prioritization of requests in accordance with the Data Access Guidelines due to an influx of proposals;
  - there is irreconcilable disagreement amongst DAC members;
  - the DAC considers the application needs or would otherwise benefit from Steering Committee input.
- Evaluate requests and do one of the following: (i) approve the application, or (ii) approve the application subject to caveats (including the need for project funding or any ethical review/approval); or (iii) submit to further review by SC (in circumstances described above); (iv) request further clarification or amendment from the applicant, or (v) recommend collaboration with other group proposing overlapping work; (vi) reject the application; ultimately all requests must receive a final decision of (i), (ii), or (vi)
- Refer requestors to resources requested (or identified as necessary by the DAC) to complete the approved use;
- Define the datasets to be released;
- Provide input to the SC on research priorities, emerging issues in data access and any implications for eDSI strategy and policy;
- Report to SC on activities of the DAC.

The Chair of the DAC is responsible for executing the eDSI Conflict-of-Interest policy as it relates to data requests.

Applications will be evaluated by the DAC 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 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.

### Capacity building

Applications must include a credible capacity building plan, which may include some or all of the following:

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

## **11. Accountability**

The DAC will monitor data access requests (both those accepted and rejected) and their management to ensure compliance with the eDSI Governance Framework. This Framework guides compliance with all applicable laws, governmental rules, regulations, good practices and guidelines (including without limitation: (i) of the country where the data have been collected or originate from; and (ii) international best standards and rules) relating to medical confidentiality, medical ethics, privacy, medical research, data protection and data access, including without limitation, the duties to not cause harm to individuals or groups, to respect patients' autonomy, patient confidentiality and the patient's right to informed consent.

The Data Access Committee is an independent decision-making body that operates under the strategic direction of the Steering Committee.

## **12. Interests**

All members of the DAC shall abide by the Platform's Conflict of Interest Policy and declare any interests in advance of joining the committee using the Declaration of Interests form. This will be reviewed annually.

The Chair of the DAC or the administrator will seek verbal (or email) confirmation at the start of any meeting (or data request review) that the Declaration of Interests of each member is current and up to date, and in respect to the items of business on the agenda. It is the duty of each member of the Data

Access Committee to declare interests not only at the start of meetings but as they arise in accordance with the eDSI Conflict of Interest (CoI) Policy.

Should any conflict arise, these shall be managed in line with the procedures outlined in the eDSI Conflict of Interest Policy. Applications for data access by Steering Committee and DAC current and previous members or associated persons, and the current or previous Administrator or associated persons, will be managed in accordance with the eDSI CoI policy. Any DAC member with a (potential) CoI shall be excluded from decisions on the relevant application in accordance with the eDSI CoI Policy.

### **13. Reporting**

The DAC, with the assistance of the Administrator, will provide semi-annual reports and updates to the Steering Committee on activity and eDSI use at least (or within a timeframe agreed by the DAC and Steering Committee), summarizing the applications approved and rejected, recommendations as to publication on the Platform website and any emerging issues in data governance or use.

Institutional members of the DAC shall disseminate minutes and reports of the DAC meetings to the organisation that member represents as appropriate. Individual members may also disseminate minutes and reports to their self-identified constituency as they deem appropriate.

The DAC will cooperate with the Administrator to make available on the eDSI website as soon as reasonably possible for each application:

- Title and date;
- Decisions and category of reasons for rejection;
- Any conditions on approval;
- Recommendations on publication.

The DAC will cooperate with the Administrator to make available on the eDSI website as soon as reasonably possible: updated records of all DAC policies, procedures and membership.

### **14. Conduct**

The Data Access Committee shall keep these Terms of Reference under review.

Any changes to these Terms of Reference may be made with unanimous support of Data Access Committee membership and must be ratified by the Steering Committee.