UCL – WHO TB-IPD Data Access Committee Terms of reference

Overview of the TB-IPD Project

This Project involves curating a global individual patient data (IPD) platform for tuberculosis (TB) treatment (TB-IPD). The TB-IPD is a shared platform and collaborative initiative to generate reliable evidence on the drug-resistant TB treatment to inform future tuberculosis treatment guidelines.

Outline and scope of these Terms of Reference (ToR)

Individuals, groups, or organisations who wish to use the data shall first submit a brief application to the **TB-IPD Data Access Committee (DAC)**.

The purpose of this document is to describe the membership, terms of reference, roles, responsibilities, authority, decision-making and relationships of the DAC for this project, including the timing, frequency and format of meetings.

1. Membership and size of the Data Access Committee

The DAC will be composed initially of 6-8 members.

- At least four of the committee members shall be representatives of the Data Contributors.
    - The DAC will be appointed by WHO/UCL from Data Contributors, while reserving at least two seats for people from low- and middle-income countries
    - In addition, up to two members may be appointed who have expertise or represent interests relevant to the IPD
    - The initial DAC members will be appointed for a term of approximately 1 year
    - Before this term ends, the process and membership composition will be reviewed by WHO/UCL, with input from existing Contributors, in terms of developing a longer term view of who should sit on subsequent committees, duration of membership and how they are selected
- The DAC will also include a representative from the WHO Global TB Programme (voting), plus a representative of the Data Curator (non-voting).

Initially, the chair will be from WHO/UCL; this will be reviewed in subsequent meetings and before the end of the first year of the DAC's appointment

2. Other participants in deliberations of the Data Access Committee

<u>Facilitator</u>

The Facilitator will be a member of staff at UCL. The Facilitator will

- be responsible for arranging meetings of the DAC and informing members about procedures
- be responsible for coordinating reports, producing and circulating minutes and action points

- be the central point for all DAC communications between the DAC and other bodies
- be copied into all correspondence between DAC members
- be kept aware of any issues as they arise
- send out initial responses to data requests detailing the next DAC meeting and how to make a formal data request
- keep a central record of all minutes, reports and correspondence by the DAC.

Observers

Observers are not members of the DAC but may be invited to provide expert input or to represent a data requestor; other observers may attend at the discretion of the DAC.

Community, civil society or patient advocates

Representatives may also attend DAC meetings. One representative will be present per DAC meeting (with voting rights).

3. Roles and responsibilities of the Data Access Committee

The DAC is the body which approves data access requests by researchers. Specifically, the DAC will:

- Review formal data access requests and their respective analysis plans
- Make decisions regarding granting access to these requests

DAC members will not be asked to formally sign a contract but should formally register their agreement to join the group by confirming by email (1) that they agree to be a member of the DAC and (2) that they agree with the contents of these ToR. Any potential competing interests should be declared at the same time (see below).

4. Competing interests

All members of the DAC should complete a form declaring of any competing interests, both real and potential. These are not restricted to financial matters
– involvement in trials or intellectual investment could be relevant. Although members may well be able to act objectively despite such connections, complete disclosure enhances credibility. DAC members should not use any data to inform trading in pharmaceutical shares, and careful consideration should be given to trading in stock of companies.

Changes in declarations of real or potential competing interests should be minuted at the start of each meeting, including any conflicts that relate to the applications under discussion.

5. Confidentiality

All members of the DAC and other meeting participants or those involved in deliberations about data requests should sign a confidentiality agreement. All documentation and exchanges with regard to the TB-IPD should be considered confidential unless clearly stated otherwise or made publicly available by the data curator or WHO.

6. Frequency and organisation of meetings

- The DAC will normally meet up to three times per year, unless there are no requests to deal with
- At the request of any member of the DAC, interim meetings may be organised. Some issues may need to be dealt with between meetings, by phone/video or by email, and DAC members should be prepared for such instances
- Efforts will be made to ensure that all members can attend

- If this is not possible, or at short notice any DAC members cannot attend, then the DAC may still meet if at least three voting members, including WHO, will be present, plus also one member from the Data Curator team
- Regular participation from DAC members is expected. If this is not possible, they may be replaced
- The meetings may be divided into closed and open sessions. In closed sessions. presence will be usually limited to the DAC members and the Facilitator. Other attendees may be invited for all or part of the meeting by the DAC
- DAC members not able to attend a meeting may pass comments to the DAC Chair or Facilitator for consideration during the discussions

7. Decision making

The DAC will be responsible for deciding whether the data requests are:

1. granted
2. modifications requested, or
3. rejected

It may be rejected because:

- it is not scientifically sound
- it is not feasible
- the DAC believes it is inconsistent with the purpose or objective of the Project
- it is inconsistent with the conditions listed in the Data Access Request form

The DAC will seek to achieve consensus on every decision. If consensus cannot be reached, then decisions will be made by simple majority. Where there is no majority, the WHO representative will have the casting vote. The Data Curator representative will not vote.

8. Reporting

A written response to each application will normally be provided within 30 days following the DAC meeting. Reasons for rejection (if applicable) will be provided in that response. Suggestions for improvement may also be made if the request is approved, but these are not obligatory.