EDCTP – Organigram and Governance

Introduction

This document presents a structured overview of the organizational governance and decision-making bodies within the EDCTP Consortium, as defined in the Consortium Agreement. It aims to clearly outline the composition, responsibilities, and operational rules of each committee and board involved in the project's management and oversight. This structured format is intended to facilitate understanding and serve as a practical reference for all consortium members and stakeholders.

1. Organigram of the Consortium

The following list summarizes the key bodies that form the governance structure of the EDCTP Consortium:

- General Assembly
- Project Coordination Committee (PCC)
- Buruli Ulcer Trial Management Team (BU TMT)
- Leprosy Trial Management Team (Lep TMT)
- Project Advisory Committee (PAC)
- Community Advisory Board (CAB)

2. General Assembly

This section describes the General Assembly, the highest decision-making body of the consortium.

The General Assembly shall be responsible for the following decisions:

a. Material Changes to the Consortium Plan;
b. Modifications or withdrawal of Background in Attachment 1 (Background Included);
c. Entry of a new Party to the Project and approval of the settlement on the conditions of the accession of such a new Party;
d. Withdrawal of a Retiring Party from the Project and the approval of the Mitigation Plan;
e. Proposal to the EDCTP3 JU for a change of the Project Coordinator or Scientific Coordinator;
f. Proposal to the EDCTP3 JU for suspension of all or part of the Project;
g. Proposal to the EDCTP3 JU for termination of the Project and the Consortium Agreement;
h. Identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement;
i. Transfer of tasks of a Party pursuant to Section 5.4.2 or 5.5.2;

j. Declaration of a Party to be a Defaulting Party and remedies to be performed by such Defaulting Party; and
k. Termination of a Defaulting Party's participation in the consortium and measures relating thereto.

Members:
- One representative from each consortium member.

Chair:
- Project Coordinator (FRF), responsible for convening meetings, preparing agendas, and issuing minutes.

Meeting frequency:
- At least once every twelve months.

Decision-Making Quorum:
- Two-thirds (2/3) of the members present.
- Must include the project coordinator, scientific coordinator, and compound contributor.

Decision-making requirements:
- Approval by at least two-thirds (2/3) of the members present.

3. Project Coordination Committee (PCC)

The project coordination committee oversees the day-to-day coordination of the project and supports decision-making processes.

The Project Coordination Committee shall be responsible for the overall execution of the Project, alignment across all Work Packages, decision making and the initial finding of amicable solutions for any disputes between the Parties relating to the execution of the Project. It will ensure the smooth operation of the Project and guarantee that all efforts are focused towards the Project objectives and deliverables. It will also ensure that all Parties are regularly updated on the scientific progress.

Members:
- Project Coordinator (FRF)
- Scientific Coordinator (KNUST)
- Compound Contributor (TB Alliance)
- LSTM

Permanent Advisors:
- AHRI
- MSHCPMU
- Min Ben
- ITM

Ad Hoc Advisors:
- Specific experts invited by the chair as needed for particular agenda items.

Other Participants:
- Any interested consortium member may attend as an advisor after notifying the chair.

Chair:
- FRF

Meeting Frequency:
- Every two months.

Decision-Making Quorum:
- All PCC members must attend or be represented.

Decision-Making Requirement:
- Strive for consensus.
- If consensus cannot be reached, decisions require approval by two-thirds (2/3) of members present or represented.

4. Trial Management Teams

Responsibilities

Each Trial Management Team will manage the activities at the relevant Trial site and will monitor the progress of the Trial against deliverables and specified endpoints

Each Trial Management Team shall be responsible, for their respective Trial, for the following:

a. Overall coordination of the Trial activities;
b. Ensuring that the activities and reporting at the Trial sites are synchronized and consistent with each other;
c. Supporting data management at the Trial sites;
d. Oversight of monitoring of GCP and regulatory standards of the Trial and Trial sites;
e. Major clinical/regulatory documents (including but not limited to, protocol, informed consent forms, monitoring and data management plans, clinical study reports and the form of data output);
f. Coordination of patient enrollment and randomization; and
g. Oversight of drug management safeguards, quality assurance activities and laboratory/pharmacy manuals and adherence at Trial sites

Each Trial Management Team may establish sub-teams to perform part of/support the responsibilities as listed above. The Trial Management Team may include Parties, which are not part of the Trial Management Team in such sub-team(s). The Trial Management Team shall define the scope of responsibilities in each such sub-team as well as the decision-making process thereof.

a. Buruli Ulcer Trial Management Team | BU TMT

The BU Trial Management Team focuses on managing and monitoring Buruli Ulcer trial activities.

Members:
- Project Coordinator (FRF)
- Scientific Coordinator (KNUST)
- Compound Contributor (TB Alliance)
- LSTM

Permanent Advisors:
- MSHCPMU
- Min Benin

Ad Hoc Advisors:
- Specific experts invited by the chair as needed for particular agenda items.

Other Participants:
- Any interested consortium member may attend as an advisor after notifying the chair.

Chair:
- KNUST, responsible for convening meetings, preparing agendas, and issuing minutes.

Meeting frequency:
- At least two months.

Decision-Making Quorum:
- All BU TMT members must attend or be represented.

Decision-Making Requirement:
- Strive for consensus.
- If consensus cannot be reached, decisions require approval by two-thirds (2/3) of members present or represented.

b. Leprosy Trial Management Team | Lep TMT

This section covers the structure and responsibilities of the Leprosy Trial Management Team.

Members:
- Project Coordinator (FRF)
- Scientific Coordinator (KNUST)
- Compound Contributor (TB Alliance)

Permanent Advisors:
- AHRI
- MSHCPMU
- ITM
- Min Benin

Ad Hoc Advisors:
- Specific experts invited by the chair as needed for particular agenda items.

Other Participants:
- Any interested consortium member may attend as an advisor after notifying the chair.

Chair:
- FRF , responsible for convening meetings, preparing agendas, and issuing minutes.

Meeting Frequency:
- At least every two months.

Decision-Making Quorum:
- All Lep TMT members must attend or be represented.

Decision-Making Requirement:
- Strive for consensus.
- If consensus cannot be reached, decisions require approval by two-thirds (2/3) of members present or represented.

5. Project Advisory Committee (PAC)

The PAC provides expert guidance to support decision-making across consortium bodies.

The Project Advisory Committee (PAC) will be appointed and steered by the Project Coordination Committee. The Project Advisory Committee shall provide non-binding advice to the Project Coordination Committee, General Assembly and Trial Management Teams upon their request as decision-making support.
The Project Coordinator will ensure that an advisory agreement is executed on behalf of all Parties and each PAC member.

Objective:
- Provide nonbinding advice to the General Assembly, PCC, and TMTs upon request to support decision-making.

Members:
- External experts appointed and guided by the PCC.

Convener:
- FRF

Meeting Frequency:
- Ad hoc

Note:
- Replaces the “Technical Expert Panel (TEP)” mentioned in the initial project proposal.

6. Community Advisory Board (CAB)

The CAB facilitates community engagement and advisory input into trials and project governance.

The Community Advisory Board shall provide non-binding advice to the Project Coordination Committee, General Assembly and Trial Management Teams upon their request as decision-making support.

Objective:

- Provide nonbinding advice to the General Assembly, PCC, and TMTs upon request to support decision-making.

Members:

- Trial site experts appointed by the relevant TMTs and coordinated by the PCC and TMTs.

Conveners:

- KNUST (BU)
- FRF (Lep)

Meeting frequency:

- Ad hoc

Conclusion

This document summarizes the organisational framework and governance structure of the EDCTP Consortium, ensuring transparency and clarity regarding the roles, decision-making processes, and interactions between various committees and advisory bodies. It is designed as a practical reference for all parties involved to promote efficient coordination and collaboration throughout the duration of the project.