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Clinical Trials Partnership

**Terms of Reference for the
EDCTP Scientific Advisory Committee (SAC)
for the second phase of the European and Developing Countries
Clinical Trials Partnership programme (EDCTP2, 2014-2024)
undertaken by several Member States under Article 185 of the
Treaty on the Functioning of the EU**



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1 Establishment and function

The General Assembly (GA) shall establish a Scientific Advisory Committee (SAC) comprising fifteen to seventeen members to act as the principal advisory group to EDCTP. The main responsibility of the SAC is to provide strategic and scientific advice to the GA and the Secretariat (SEC) and to oversee the scientific integrity of the EDCTP programme.

Specific responsibilities of the SAC shall include:

Strategic planning

- Assist in the designing of the strategic and scientific framework of the EDCTP programme
- Advise on the development of the EDCTP operational plan and annual workplans for approval by the GA
- Advise on strategies to foster synergies and partnerships with stakeholders in the north and south
- Contribute to the preparation of strategic and scientific documents relevant to EDCTP, as required
- Provide strategic and scientific advice to the GA and the SEC to ensure the successful completion of on-going projects
- Identify strategic needs and priorities for accelerating the development of new or improved clinical interventions, including the required training, networking and capacity building to be undertaken to achieve these objectives
- Review the landscape of Poverty-Related and Neglected Diseases (PRNDs) to identify the role that EDCTP should play in partnership with other stakeholders to accelerate the development or improvement of interventions against these diseases
- Assess the state of global product development pathways and the critical path opportunities for future product development
- Provide advice on the launch and review of any calls for proposals and other programmes.

Reporting and Monitoring & Evaluation

- Support and provide input on the monitoring and evaluation framework of the EDCTP programme
- Provide input in the monitoring of scientific outcomes and strategic impacts of EDCTP-funded grants
- The SAC Chairperson shall prepare an annual report on the previous year's SAC activities and achievements for submission to the GA by 31 January of each year. The report shall include a summary detailing the strategic and scientific advice provided to the SEC throughout the year.

Advocacy and representation at meetings and events

- Participate in EDCTP working groups, stakeholder meetings and the EDCTP Forum
- Advise and assist in the organisation of workshops, meetings and other relevant events

Composition of the SAC

One (1) SAC Chairperson

Two (2) SAC Vice Chairpersons



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Up to fourteen (14) SAC Ordinary Members

SAC observers (non-voting):

- GA Chairperson
- The EDCTP Executive Director (ED) and or his/her representative in the role of SAC Secretary
- EDCTP SEC
- External observers

The SAC members shall serve in their personal capacity, representing a broad range of disciplines encompassing many aspects of product development and clinical trials in PRNDs in sub-Saharan Africa. SAC members should have a demonstrated commitment to the mission and objectives of EDCTP. As far as possible, the SAC should be balanced in terms of north-south representation with preference for European and African researchers; professional affiliation (academia, clinical practice, research institute, government and private sector); disease specialisation relevant to the EDCTP remit¹; other relevant expertise (product development/clinical trials, ethics and regulatory affairs) and gender. Based on EDCTP's strategic requirements during the preparation and implementation of the EDCTP2 programme, the GA Chairperson and the ED, in consultation with the SAC Chairperson, will plan the composition of the SAC membership in accordance with the programme phases.

The SAC may propose to the GA to establish specialist working groups, comprising SAC members and additional co-opted experts, to carry out particular tasks and activities. The need for a working group and the terms of reference for such a working group will be discussed and agreed by the GA prior to its establishment.

2 Appointment and membership

SAC members, including the Chairperson, shall be appointed by the GA, on the recommendation of the Executive Director (ED) in consultation with the GA Chairperson. The ED will propose SAC members for recommendation to the GA on the basis of their qualifications, expertise and ability to contribute to the SAC objectives. The names and institutional affiliations of the SAC members will be published on the EDCTP website.

Appointment to the SAC, including the Chairperson, shall be for a period of three years, which may be extended once for a further period of up to two years. SAC members will elect two Vice-Chairpersons (one from Africa and one from Europe) to serve for three years, with re-election as Vice-Chairperson to serve for an additional two years permitted. The Chairperson or the Vice-Chairpersons may attend GA meetings as non-voting observers. The Vice-Chairpersons shall fulfil the Chairperson's functions during his/her absence.

¹ In the EDCTP2 programme, "poverty-related diseases (PRDs)" include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.



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Proposals regarding renewal or termination of a SAC member's term of office will be made by the ED to the GA. The GA shall renew the appointments of current SAC members at least one month before their previous appointment expires and shall appoint new SAC members at least one month before the expiry of the term of the outgoing members.

On the advice of the ED, the GA can at any time revoke the mandate of any SAC member whose performance is considered inadequate. Membership of the SAC may be terminated for any of the following reasons:

- Failure to attend two (2) consecutive SAC meetings
- A lack of professionalism involving, for example, a breach of confidentiality or repeated failure to conduct assigned tasks
- A change in affiliation resulting in a conflict of interest
- Mutual agreement.

Before terminating a member's appointment, the ED and SAC Chairperson will take due account of the reasons for absence or failure to perform the assigned tasks. After consultation with the SAC Chairperson and other SAC members (including the SAC Vice Chairpersons), the ED can propose to the GA for approval an ad hoc replacement for any SAC member who defaults from his/her duties or resigns before the end of the term of office. The appointment of the ad hoc member shall be for a period of three years.

3 Other terms of membership

Upon appointment to the SAC and subsequently on an annual basis, members shall complete an EDCTP Conflict of Interest (CoI) and Confidentiality Declaration as per the attached form (Annex 1 #86291). Furthermore, members shall be required to declare CoIs in relation to any item under discussion at a SAC meeting (Annex 2 #93243). Any member with a CoI shall be excluded from the discussion or decision on the issue, and shall not receive the documents relating to that item. Any member who fails to declare a CoI, which subsequently becomes evident, may be expelled from the SAC on the recommendation of the GA, taking into consideration the circumstances of the CoI and its impact on the decision-making process.

In accordance with the EDCTP Code of Conduct and Conflict of Interest Policy (#67098), all documents and discussions at SAC meetings are confidential, unless stated otherwise, and must not be disclosed.

The SAC has no executive function and SAC members are not EDCTP employees. The SAC's role is solely to provide advice and recommendations to the ED and GA via the governance framework of EDCTP, including provision of advice on urgent matters outside of the scheduled SAC meetings. SAC members who are approached by non-EDCTP sources for their views, comments and statements on matters of public health concern and asked to state the views of EDCTP shall refer such enquiries to EDCTP.



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4 Quorum

Decisions or recommendations will, in principle, be taken by consensus. The SAC shall have a quorum when a minimum of two thirds of the members are present. If decision-taking requires voting, the SAC members including the Chairperson will have a vote and a simple majority will decide. The SAC Chairperson shall have a casting vote in the case of a draw, even if the draw arises as a consequence of the SAC Chairperson voting initially. Dissenting opinions, including the reasons for dissent, shall be recorded in the minutes.

5 SAC meetings and operational procedures

The SAC will convene a minimum of two (2) and a maximum of four (4) times per year, scheduled to take place prior to GA meetings. All SAC meetings will be planned and agreed with the ED. EDCTP will cover the costs of up to four (4) meetings of the SAC annually. Costs covered by EDCTP are limited to usual and reasonable travel and subsistence, according to the terms contained in the SAC contracts. Additional meetings or teleconferences may be called by mutual consent of the ED, the SAC Chairperson and the GA Chairperson. Additional meetings or other costs relating to the SAC require prior approval of the ED or the GA Chairperson.

On the invitation of the SAC Chairperson and in consultation with the ED, Observers [i.e. GA Chairperson, other GA members, EDCTP High Representatives and external observers (i.e. representatives from WHO, EC and any other entity approved by the GA)] may be invited to participate in the meetings without voting rights.

In the event that a conflict arises between the SAC and the SEC, the GA Chairperson shall mediate in the event. If mediation is unsuccessful, the matter shall be resolved by the GA.

The SAC Chairperson and ED are responsible for the SAC meeting agenda. A copy of the approved agenda will be sent to the GA Chairperson for information in advance of a SAC meeting. Official notification of each meeting, confirming the date and venue, will be sent to each SAC member, and to any other person required to attend, no later than fourteen (14) days before the meeting date. The papers for the meeting will be made available ten (10) days before the meeting.

As part of monitoring and evaluation, SAC members without conflict of interest may be called upon to advise EDCTP in the scientific outcome and strategic impact of EDCTP-funded grants. In particular, advice may be specifically sought for grants with substantial EDCTP investment and grants with a high level of complexity where there is a significant risk that outputs may be compromised. EDCTP reserves the right to accept or reject any SAC advice relating to the monitoring and evaluation of its grants.

The SEC shall summarise the business and discussions at the SAC meeting via written minutes, circulated to the members. Approval of the minutes will be the first item on the agenda at the subsequent meeting of the SAC. Any objections or amendments to the minutes will be recorded and the originals of the approved minutes, signed by the Chairperson, shall be archived at the SEC. A public version of the minutes will be made available on the EDCTP website.



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6 Honorarium

Time spent on SAC activities and remuneration shall be stated in the contract between SAC members, including the Chairperson, and the SEC and approved by the GA.

7 Liability

EDCTP shall not be liable for any ill health, injury, accident, damage or loss of property of any SAC member during the execution of SAC tasks, including travel and meetings. SAC members shall be personally responsible for insurance coverage in so far as it is not covered by the current insurance policy taken out by the SEC.

The EDCTP Association shall hold the members of the SAC harmless from any liability (claim) directly arising from the actions of the EDCTP in general and the SAC in particular, in so far as it is not due to misconduct or negligence.

8 Communication between the SAC and the GA

Requests and recommendations shall be communicated between the GA and the SAC via the SEC, which reserves the right to edit the documents in an appropriate format without substantially altering their content.

The SAC shall submit strategic and annual plans to the GA via the SEC at least fifteen (15) calendar days prior to the GA meetings where these plans are to be approved. When the GA requests a specific recommendation from the SAC, the SAC shall deliver this to the GA via the SEC normally within two (2) months.

With the agreement of the SAC representatives in the GA, the GA may make minor amendments to the SAC proposals without requesting new recommendations. These amendments, and the justification for them, will be recorded in the minutes.

In cases where the GA does not approve a strategic plan or proposal from the SAC, the reasons for non-approval will be recorded in the minutes and communicated to the SAC. The SAC may be requested to present a revised plan or proposal that incorporates the comments and recommendations of the GA within two (2) months for approval by the GA.

In the event that the SAC has not provided a requested proposal or revision within two (2) months, or a revised proposal is not approved, the GA may take on the responsibility for the relevant action.

In the event of any objection to or disagreement with the advice of the SAC, the GA may make a new request for advice or seek a new recommendation. The objections and disagreements will be recorded in the GA minutes.