

Call for Experts: EDCTP Strategic Advisory Committee

Background

The European & Developing Countries Clinical Trials Partnership (EDCTP) aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV, tuberculosis and malaria in sub-Saharan Africa. EDCTP supports multicentre projects that combine clinical trials, capacity building and networking.

Preparations are underway for a proposed second phase of the EDCTP Programme (EDCTP2), which is expected to start in 2014 as part of [Horizon 2020](#), the European Union's (EU) new funding programme for research and innovation for the period 2014-2020. Horizon 2020 brings together all existing Union research and innovation funding, including the Framework Programme for Research, the innovation-related activities of the Competitiveness and Innovation Framework Programme and the European Institute of Innovation and Technology, into a single programme. This funding programme provides for the renewal of the EU's financial commitment to the EDCTP. Whilst retaining a major focus on HIV, tuberculosis and malaria; phase II and III clinical trials; and sub-Saharan Africa, an expanded scope is proposed for EDCTP2 to include:

- All clinical trial phases (I-IV) including implementation research on optimisation of health services
- Neglected Infectious Diseases (NIDs)
- Closer collaboration with industry, like-minded organisations, product development partners and development agencies
- Collaborative research with other developing countries outside sub-Saharan Africa when possible and desirable.

Scope of the Call

The Strategic Advisory Committee (SAC) is the principal advisory group to EDCTP, providing strategic and scientific advice to the EDCTP General Assembly and the Executive Secretariat (SEC), as well as oversight of the scientific integrity of the EDCTP programme. The SAC will assist the SEC in ensuring that EDCTP2 programme operational business plan is developed in the context of global activities, taking into account the dynamic state of product development pipelines, African and European participating member states national plans, needs and priorities.

EDCTP is calling on high level experts from across multiple fields and sectors to apply to become members of the SAC from January 2014. SAC members shall serve in their personal capacity, representing a broad range of disciplines encompassing all aspects of clinical trials in poverty related and neglected diseases (PRNDs) in sub-Saharan Africa within EDCTP mandate.

Experts should have skills, knowledge, expertise and standing in one or more of the following fields:

- **Malaria**
- **HIV**
- **Tuberculosis**
- **NIDs**
- **Ethics/Clinical regulatory affairs**
- **Industry product development experience**
- **Post registration safety and effectiveness programmes**
- **Health services and implementation research**
- **Public health (including epidemiology, biostatistics, health economics and planning)**
- **Social and behavioural sciences within the disease remit of EDCTP2**
- **Research capacity strengthening and training.**

Mandate of the SAC

As the scientific and strategic advisory body to EDCTP, the SAC will prepare an annual Strategic Research Agenda (SRA). This SRA underpins and forms the basis for the SEC to propose the annual work programme of the following year to the General Assembly (GA) for approval.

The SAC may operate as a single forum and as specialist subgroups to develop strategy and to advise on implementation plans. The SAC will be supported by the SEC and will report to the GA.

The main mandate of the SAC shall be as follows:

Strategic planning

- Assist in the designing of the strategic and scientific framework of the EDCTP programme
- Contribute to 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 and evaluation

- Support and provide input on the monitoring and evaluation framework of the EDCTP programme
- 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.

A key role of the SAC will be to assess the state of global product development pathways and the critical paths for future product development. The SAC will work with the Secretariat to identify opportunities to coordinate calls in specific fields as products become available or to hold initiatives to broker activities based on the state of the field.

Composition of the SAC

One (1) SAC Chairperson

Two (2) SAC Vice Chairpersons

Up to nine (9) SAC Ordinary Members

SAC observers (non-voting):

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

In as far as possible, the SAC shall 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 and other expertise relevant to the EDCTP remit; and gender.

Appointment

Appointments to the SAC are approved by the EDCTP General Assembly based on the following criteria:

- Track record and achievements in fields of relevance to EDCTP
- Commitment to the goals and objectives of EDCTP
- Experience and expertise in cross-cutting issues, including capacity building, research ethics, regulatory affairs, collaborative programmes (north-south, north-north, south-south)
- The need to achieve a balanced membership in terms of north-south representation with preference for European and African researchers; professional affiliation; disease specialisation relevant to the EDCTP remit; expertise across multiple sectors; age and gender (without calling into question the necessary level of expertise and insight).

The SAC will comprise up to 12 members (The Chair, Two Vice-Chairs and up to nine ordinary members). Appointments to the SAC are for a three-year period, which may be extended once for a further two years.

Individuals shall be appointed in their personal capacity – i.e. experts with outstanding knowledge in their areas acting independently and in the public interest, who cannot represent collective interests nor being affiliated with private organisations which may benefit from the work of the Committee

Terms of participation

The SAC will meet at least twice per year. Candidates should be prepared to attend meetings consistently, examine and provide comments on documents under discussion, contribute actively to discussions in the committee and where necessary contribute to drafting of working documents and act as "rapporteurs" on an ad-hoc basis. Candidates should also take into account that preparatory work is required prior the meetings. The working language of the SAC is English. SAC members shall adhere to the EDCTP internal regulations and to [EDCTP policy on Conflict of Interest and Confidentiality](#).

EDCTP will make public relevant information and documents on its website, while excluding confidential information. Personal data will be collected, processed and published in accordance with the Personal Data Protection Act of The Netherlands.

Application procedure and deadline for registration

Applicants are requested to download and complete the [Application Form](#) and submit it to applications@edctp.org by **30 August 2013**. Applications received after this date may be considered for the replacement of resigning experts and renewal of SAC membership.

Selection

EDCTP will take the following criteria into account when assessing the registered candidates individually:

- Proven competence and experience of the individual candidate in areas of relevance to the EDCTP2 programme
- Scientific track record and commitment to promoting clinical research in sub-Saharan Africa
- Experience in clinical research or clinical trials, capacity building, health research ethics, public health, health economics and networking.

For achieving a balanced membership in each group, the following selection criteria will be taken into account:

- The need to strike a balance within the SAC in terms of representativeness of stakeholders, gender, age and geographical origin (without compromising the excellence in the required expertise).

Logistical and operational aspects

SAC meetings are normally held at the EDCTP offices in The Hague, The Netherlands or Cape Town, South Africa, or in another location announced in accordance with the procedures and schedule established by EDCTP. SAC members receive an honorarium, in addition to travel and subsistence expenses incurred in relation to activities conducted under SAC membership.

For further information and enquiries please contact [applications\[at\]edctp.org](mailto:applications[at]edctp.org)