



EDCTP

European & Developing Countries
Clinical Trials Partnership

2017 Annual Report of the EDCTP Scientific Advisory Committee

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Scientific Advisory Committee – Work plan 2018

1 Introduction

The General Assembly (GA) established the Scientific Advisory Committee (SAC) to act as the principal advisory group to EDCTP. The SAC provides scientific and strategic advice to the GA and the Secretariat (SEC), overseeing the scientific integrity of the EDCTP programme.

The SAC comprised the following seventeen members during the 2017 reporting period:

	Name	Gen-der	Nationality	Organisation name and country	Professional expertise
1	Prof Eleni Aklillu	F	Sweden/Ethiopia	Karolinska Institute, Sweden	Pharmacology, TB/HIV, co-infection
2	Dr Maryline Bonnet	F	France	Institute of Research and Development, France	TB, epidemiology, paediatric LRTI
3	Prof Christian Burri	M	Switzerland	Swiss Tropical & Public Health Institute (Swiss TPH) (Switzerland)	Clinical trials operations, Resource limited settings, Neglected diseases, Public Health, Research Ethics
4	Prof. John Gyapong	M	Ghana	University of Health and Allied Sciences (Ghana)	Epidemiology Neglected Tropical Diseases Clinical Trials Implementation Research Research Ethics
5	Prof. Catherine Hankins	F	Canada	Amsterdam Institute for Global Health and Development (The Netherlands)	Biomedical HIV prevention, Research ethics, Emerging pathogens, Good Participatory Practices (GPP)
6	Prof. Stefan Kaufmann	M	Germany	Max Planck Institute for Infection Biology, Germany	Immunology, TB vaccine development (product development/industry experience)
7	Prof. Maria Fraga Oliveira Martins	F	Portugal	Universidade Nova de Lisboa, Instituto de Higiene e Medicina Tropical, Portugal	Biostatistics, health economics
8	Prof. Martin Meremikwu	M	Nigeria	Institute of Tropical Disease Research & Prevention, University of Calabar Teaching Hospital (Nigeria)	Child health Clinical trial Systematic review Tropical infections Bioethics

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9	Prof. Keymanthri Moodley	F	South Africa	Stellenbosch University	Bioethics Clinical trials Africa HIV Research Ethics Capacity Development
10	Dr Juliet Nabyonga-Orem	F	Uganda	WHO (Zimbabwe)	Implementation research; knowledge translation; research capacity strengthening; partnerships and health policy dialogue; public health
11	Dr Jutta Reinhard-Rupp	F	Germany	Merck KGaA	Global / children health, pharma industry, product development, research capacity building
12	Prof. Philippe Sansonetti	M	France	Institut Pasteur, France	Enteric infections, vaccine development
13	Prof. Clara Menéndez Santos	F	Spain	ISGlobal Barcelona Institute for Health, Spain	Malaria, Maternal and Child health, Emerging infections, Epidemiology, Clinical trials
14	Prof. Peter Smith	M	UK	London School of Hygiene & Tropical Medicine, UK	Epidemiology, field trials of diverse interventions, vaccines, malaria, emerging infections, clinical trials methodology; broad experience from other funding agencies and WHO
15	Prof. Marleen Temmerman	F	Belgium	Aga Khan University (Kenya)	HIV, microbicides, Maternal and child health, implementation research, research capacity strengthening and training sub-Saharan Africa
16	Prof. Halidou Tinto	M	Burkina Faso	Institut de Recherche en Sciences de la Santé (IRSS) Unité de Recherche Clinique de Nanoro (Burkina Faso)	Parasitology, Malaria; Clinical Trials; Epidemiology; Ethics & Regulatory affairs
17	Prof. Alimuddin Zumla	M	Zambia/UK	University College London, UK	TB (drugs and diagnostics), LRTI (adults), emerging infections, capacity development.

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Specific responsibilities of the SAC include:

Strategic planning

- Assist in designing 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 scientific and strategic 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 to the monitoring and evaluation framework of the EDCTP programme
- Provide input to the monitoring of scientific outcomes and strategic impacts of EDCTP-funded grants and programs
- 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 meeting, and the EDCTP Forum
- Advise and assist in the organisation of workshops, meetings, and other relevant events.

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2 Activities for 2017

The SAC work plan for 2017 set out a number of planned activities with specific deliverables. This report summarises the deliverables that have been achieved during the year and the additional activities undertaken by the SAC.

Topic	Deliverable(s) as set out in 2017 work plan	Output
SAC meetings	<ul style="list-style-type: none"> • SAC to meet in two face-to-face meetings in 2017 which will be minuted with clear scientific and strategic recommendations • The SAC Chair to report the outcomes of the SAC meetings to GA • The SAC Chair to report the outcomes of the GA meeting to the subsequent SAC meeting 	<ul style="list-style-type: none"> • During the course of 2017, two face-to-face meetings were held and minuted. The first meeting was held in Amsterdam on 30-31 March 2017 and the second on 14-15 September 2017 in The Hague. • The SAC Chair attended her first GA meeting in May 2017 and provided an update to GA members on SAC activities. During the September SAC meeting, the Chair then updated SAC members on the outcome of the May GA meeting.
Strategic planning	<ul style="list-style-type: none"> • Advise on implementation of the 2017 EDCTP work plan • Provide input into the 2018 work plan, including suggestions for calls for proposals • Update the Strategic Research Agenda • Recommend strategic activities that will require involvement of the EDCTP High-Representatives. 	<p>The SAC provided input and recommendations on the following:</p> <ul style="list-style-type: none"> • 2017 EDCTP work plan <ul style="list-style-type: none"> ○ Stakeholder meeting on co-infections and co-morbidities ○ EDCTP Alumni meeting • Three-year planning cycle (2018-2020) <ul style="list-style-type: none"> ○ Draft EDCTP work plan 2018 including a new funding instrument, portfolio funding • EDCTP Strategic Research Agenda
Monitoring & Evaluation	<ul style="list-style-type: none"> • Submit advice and recommendations to the EDCTP Secretariat on an ad hoc basis • Contribute to the Monitoring and Evaluation of key EDCTP projects involving large consortia with significant investments, such as: <ul style="list-style-type: none"> ○ PanACEA (Networks of Excellence) ○ Epidemics consortium 	<p>The SAC provided input and recommendations on the following:</p> <ul style="list-style-type: none"> • Guiding document for the monitoring and evaluation of the EDCTP2 programme • The Interim Evaluation of EDCTP2: SAC provided detailed comments that were collated by the SAC Chair Prof Hankins. She forwarded this 12-page document to the Evaluation Team and presented the SAC's views in person to the Evaluation

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	<ul style="list-style-type: none"> • Provide input on EDCTP programme indicators • Reports from site visits to major EDCTP trial sites (if applicable). 	<p>Team on April 20, 2017 at a dedicated meeting, prior to the General Assembly meeting with the Evaluation Team in Brussels, which the SAC chair also attended, representing the SAC.</p>
<p>Advocacy and representation at meetings and events</p>	<p>Attendance at meetings and forums as required; membership of organising committees of events to be held.</p>	<ul style="list-style-type: none"> • Suggestions for theme for Ninth EDCTP Forum • Prof Eleni Aklillu attended, on behalf of SAC Chair Catherine Hankins, the EDCTP Participating States workshop on 21-22 March 2017 in Vienna, Austria • Profs Catherine Hankins and Christian Burri represented the SAC at the EDCTP Alumni launch (3-4 October 2017) • SAC Chair Prof Hankins brokered the following bilateral meetings in May and June 2017 to explore potential synergies (details below): <ol style="list-style-type: none"> 1. Executive Director (ED) Dr. Makanga with HIV Research Trust 2. ED Dr. Makanga with the Canadian Institutes of Health Research 3. Thomas Nyirenda and Gabrielle Breugelmans with Fogarty International Center, USA National Institutes of Health

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2.1 New SAC membership for 2017-2020

Three-year membership appointments for EDCTP's SAC (2014-2016) terminated on 31 December 2016. During the SAC meeting on 31 March-1 April 2016, it was agreed that approximately 50% of the membership be retained in order to ensure smooth continuation. Therefore, the call for experts aimed to recruit 8-10 new SAC members. When evaluating membership retention for current SAC members, the EDCTP Secretariat (SEC) considered four criteria:

1. Duration of service
2. Relevance and impact of contribution
3. Voluntary termination of service
4. Change of employment status necessitating termination of service

From these criteria, 7 members were retained from the previous SAC membership. These are:

1. Prof. Eleni Aklilu
2. Dr Maryline Bonnet
3. Prof. Stefan Kaufmann
4. Prof. Maria Fraga Oliveira Martins
5. Prof. Clara Menéndez Santos
6. Prof. Philippe Sansonetti
7. Prof. Sir Alimuddin Zumla

EDCTP launched a call for new SAC members on 11 July 2016, which was announced both on the EDCTP website as well as in The Lancet. The deadline was 10 October 2016. Fifty-two applications were received.

The General Assembly approved 8 new members to join the 7 members who were retained in the membership. These members are:

1. Prof. Christian Burri (Swiss TPH, Switzerland)
2. Prof. Peter Smith (LSHTM, UK)
3. Prof. Halidou Tinto (Institut de Recherche en Sciences de la Santé (IRSS), Burkina Faso)
4. Prof. Marleen Temmerman (Aga Khan University, Kenya)
5. Dr Jutta Reinhard-Rupp (Merck KGaA, Switzerland)
6. Prof. John Gyapong (University of Health and Allied Sciences, Ghana)
7. Prof. Catherine Hankins (Amsterdam Institute for Global Health and Development, The Netherlands)
8. Prof. Martin Meremikwu (Institute of Tropical Disease Research & Prevention, University of Calabar Teaching Hospital, Nigeria)

Professor Catherine Hankins was appointed as Chair.

The EDCTP SEC was tasked to extend the search for two additional new SAC members from the African region to fill expertise gap in the areas of:

- Large-scale field trials and implementation research
- Bio-ethics and legal affairs with patient representative know-how.

On 19 December 2016, EDCTP launched a call for experts in biomedical ethics and implementation research that was announced on the EDCTP website. The deadline was 28 February 2017. As a result, 2 new SAC members were recruited. These members are:

1. Prof. Keymanthri Moodley (Stellenbosch University, South Africa)
2. Dr Juliet Nabyonga-Orem (WHO, Zimbabwe)

Short biographies of all SAC members can be found on the [EDCTP website](#).

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2.2 SAC meetings

SAC members attended two official meetings in 2017. The first meeting was held in Amsterdam on 30-31 March 2017 and the second on 14-15 September 2017 in The Hague. Observers from the European Commission (EC), the WHO Regional Office of Africa (WHO-AFRO), and WHO Geneva were also in attendance.

The SAC Chair, who began her SAC tenure on 1 January 2017, met with the EDCTP2 Interim Evaluation Team in April 2017 and attended her first full GA meeting in May 2017 at which she provided an update to GA members on SAC activities. During the September SAC meeting, the Chair updated SAC members on the comments of the Interim Evaluation Team to SAC's responses on the draft document and on the outcomes of the May GA meeting.

During the first SAC meeting in March, two Vice-Chairs were elected:

1. Prof. Clara Menéndez Santos
2. Prof. John Gyapong

2.3 Strategic planning

During both SAC meetings, members were updated with the progress of the 2017 EDCTP work plan, including the analysis of calls for proposals launched so far. The SAC had provided the EDCTP SEC with advice on speakers and meeting topics for the stakeholder meeting on co-infections and co-morbidities which took place on 13 September 2017. SAC also provided input into the launch meeting of the EDCTP Alumni platform, which aims to enhance networking between EDCTP Fellows funded under both EDCTP programmes.

During the first SAC meeting in March, the EDCTP SEC presented the three-year planning cycle that was prepared in consultation with SAC. The centrally-managed EDCTP2 activities are implemented by the EDCTP Association on the basis of the EDCTP strategic business plan and the EDCTP2 annual work plans. However, to support its medium-term planning, the EDCTP SEC developed a 3-year strategic plan for the period of 2018-2020. The 3-year strategy consists of three elements, namely 1) a comprehensive situation analysis of each disease area of EDCTP2, 2) an overview of EDCTP opportunities and priorities in the next three years, and 3) a proposed plan for addressing the priorities.

Based on the discussions stemming from the three-year planning cycle, SAC provided input into the draft 2018 EDCTP work plan and the proposed new funding instrument called portfolio funding.

SAC also provided an update to the Strategic Research Agenda (SRA). This document is updated annually and provides the basis for the SEC to propose the annual work programme of the following year to the General Assembly for approval. The SRA outlines the key research and capacity gaps for diseases within the EDCTP scope, and ranks them in terms of priorities.

2.4 Monitoring & Evaluation

During the September meeting, the SAC was presented with the results of the meeting of the GA with the team leading the interim evaluation of the EDCTP2 programme, a requirement from the delegation agreement between EDCTP and the European Commission. Several recommendations were put forward in the report, one of which is strengthening results' measurement at EDCTP, both the long-term results of the EDCTP1 and EDCTP2 programmes. Based on these recommendations, the SEC prepared a framework for results-based monitoring and evaluation of the EDCTP2 programme. SAC provided input into this framework.

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2.5 Advocacy and representation at meetings and events

During the March SAC meeting, members provided feedback on the theme of the Ninth EDCTP Forum, which will take place in Q3/Q4 of 2018.

On 21-22 March 2017, Prof Eleni Aklillu attended, on behalf of SAC Chair Prof Catherine Hankins, the EDCTP Participating States workshop in Vienna, Austria. This workshop brought together representatives from EDCTP Participating States to discuss better alignment of Participating States Initiated Activities (PSIAs). The meeting was organised by representatives from Germany, France, and Austria.

On April 20, 2017, SAC Chair Prof. Catherine Hankins presented the SAC members' comments on the draft EDCTP2 Interim Evaluation Report to the Evaluation Team in Brussels. Later that day, she attended the Team's presentation of their findings to the GA.

In May 2017, the SAC Chair Prof. Catherine Hankins SAC brokered three bilateral meetings with research funders to explore potential synergies:

- Executive Director Dr Makanga and Professor Ian Weller of the HIV Research Trust (conference call June 8, 2017)
- Thomas Nyirenda, South-South Networking and Capacity Development Manager; Gabrielle Breugelmans, North-North Networking Manager, and Peter Kilmarx, Deputy Director of the Fogarty International Centre, USA National Institutes of Health (in-person meeting, May 19, 2017 at INTEREST 2017 in Lilongwe, Malawi).
- Executive Director Dr Makanga; Stephen Hoffman, Scientific Director, Institute of Population and Public Health; Elizabeth Paget, Assistant Director, Institute for Infection and Immunity; and Jennifer Gunning, Manager, International Relations & Executive Support, Office of the President, Canadian Institutes of Health Research (conference call May 30, 2017)

On 3-4 October 2017, Profs Catherine Hankins and Christian Burri represented the SAC at the launch of the EDCTP Alumni Network. The network aims to bring together Fellows funded under both EDCTP1 and 2 programmes to enhance collaborations, thereby protecting local innovations, and reduce attrition in scientific leadership in sub-Saharan Africa.

Regarding the stakeholder meeting on co-infections and co-morbidities, SAC members provided input to the agenda, made suggestions to the delegate list, and chaired the meeting (Prof. John Gyapong and Dr Maryline Bonnet). Some SAC members also were in attendance.