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Final Report
Mid-Term Independent Evaluation of the EDCTP Regional Networks 2017-2020

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Key abbreviations and acronyms

ALERRT	African coaLition for Epidemic Research, Response and Training
BHP	TB and Botswana-Harvard AIDS Institute Partnership
BRTI	Biomedical Research and Training Institute
CANTAM	Central African Network for TB, AIDS, and Malaria
CDC	Centres for Diseases Control
CISM	Manhica Health Research Centre
CRA	Clinical Research Associate
CSA	Coordination and support actions
EACCR	East African Consortium for Clinical Research
ECRIN	European Clinical Research Infrastructure Network
EDCTP	European and Developing Countries Clinical Trials Partnership
EP	Evaluation Panel
EU	European Union
GA	General Assembly
GCLP	Good Clinical Laboratory Practice
ICH-GCP	International Conference on Harmonization guidelines for Good Clinical Practice
IEND	Institute of Endemic Diseases
iMTE	independent Mid-Term Evaluation
KEMRI	Kenya Medical Research Institute
MoH	Ministries of health
MoHCC	Ministry of Health and Child Care
NID	Neglected Infectious Diseases
NoE	Networks of Excellence
NTD	Neglected Tropical Diseases

PANDORA-ID-NET	Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics
PAVIA	PharmAcoVigilance Africa
PI	Principal Investigator
PRD	Poverty-related disease
PSIAs	Participating States Initiated Activities
REC	Research Ethics Committee
RN	Regional Network
SAC	Scientific Advisory Board
SADC	Southern African Development Community
SME	Small and Medium Enterprise
SOPs	Standard Operating Procedures
SSA	Sub-Saharan Africa
SU	Stellenbosch University
TESA	Trials of Excellence in Southern Africa
ToR	Terms of Reference
WANETAM	West African NoE for TB, AIDS, and Malaria
WAHO	West Africa Health Organisation
WHO	World Health Organization

Executive summary

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between institutions mandated by EDCTP participating states in Europe and sub-Saharan African, and the European Union. EDCTP supports African institutions to develop their capacity for conducting clinical trials in compliance with good ethical practices, standards and regulations. In 2016, four EDCTP Regional Networks of Excellence (NoEs) were established to promote African co-ownership of the EDCTP projects and strengthens clinical research capacity, scientific leadership and networking in four African regions. The four NoEs: Central African Clinical Research Network (CANTAM2), East African Consortium for Clinical Research (EACCR2), Trials of Excellence in Southern Africa (TESA2) and the West African Network for TB, AIDS and Malaria (WANETAM) involve 63 institutions in 21 African countries. The first interim evaluation of the EDCTP Programme (2014-2016) recommended an independent mid-term evaluation of the EDCTP Regional Networks' performance and impact, and it was in this background that in June 2019, EDCTP commissioned an independent evaluation panel (EP) made up of people with different skills and expertise to carry out the evaluation.

This independent Mid-Term Evaluation (iMTE) is an assessment of the relevance, efficiency, effectiveness, impact and sustainability prospects of the EDCTP-supported regional networks. It provides input for informing future funding strategies and levels of such funding to the networks under the second EDCTP Programme EDCTP2 (2014-2014). The methodology used to achieve this evaluation was informed by the Terms of Reference (ToR) and EDCTP's 'mission to support collaborative research that accelerates the clinical development of new or improved interventions (drugs, vaccines, microbicides and diagnostics) to prevent or treat HIV, tuberculosis, malaria and neglected infectious diseases including emerging and re-emerging infections affecting sub-Saharan Africa'.

Between July and September 2019, the four-member EP developed and deployed a number of procedures including document reviews, interviews, site visits and questionnaire-mediated interactions to gather views from EDCTP personnel and associated committee/assembly members and other stakeholders to explore context-specific insights on the status of the Regional Networks and identify potential areas of improvement for the Networks in particular, and EDCTP in general. This report is the main deliverable from this evaluation, serving, as alluded to before, the dual purpose of an independent status report of the NoEs and as input for informing future funding strategies and levels of such funding to the networks under EDCTP2.

Overall, our findings for each NoE illustrate how, within different operational and contextual constraints, all of the four NoEs have shown relevance for, and commitment towards, the strengthening of capacities for collaborative clinical research in Africa. Steps have been taken towards strengthening and making use of South-South and North-South collaborations between researchers and institutions, as well as promoting dialogue between researchers, communities and policy makers. We have established that EDCTP is playing a major role in ecosystem capacity building in Africa. While there were variations in performance against deliverables across the NoEs, the NoEs have emerged as a strong brand with increasing goodwill. With a balance between expectations and what is achievable, the NoEs can play the envisaged key role of developing and availing much needed capacities for clinical research in Africa. We established that there are active and on-going collaborations, coordination and partnerships within all the Networks as evidenced by publications, annual meeting, consortia work plans, communication strategies, North-South and South-South collaborations. Some challenges regarding contribution and commitment from some partners were noted for the latter, and specific suggestions are made on how to deal with the

challenge. The evaluation also confirmed that the NoEs have made some progress towards contributing to professional development and scientific leadership in clinical trials, and improved quality of clinical laboratories and research management. The NoEs are at different levels in establishment of ICH-GCP-compliant clinical trial capabilities, training of clinical research associates and clinical trial monitors, as well as training and mentorship programmes for researchers, research leaders and research managers. These were seen to be at various stages of progress due to reasons such as operational challenges in transfer of funds, staff changes, lengthy recruitment and ethics approval processes. There have been delays in starting activities in some regions, while the issues of resource insufficiency (e.g. for tuition and bench fees as well as web platforms), Network visibility, utilisation of available capacities, alignment with changing disease patterns, leadership and succession planning, links with national health systems and other key stakeholders all need attention across the regions. Regarding resources, while the issue of inadequacy was noted, there are flexibilities that Networks have to reallocate funds to where they are needed, and such flexibilities could be utilised to address some of the gaps.

Specific details on each of the points above and related others have been discussed and recommendations made on how the NoEs can leverage their current achievements to address challenges and harness opportunities for them to meet targets. Overall, this evaluation confirms that forming and running networks of this nature and magnitude efficiently in Africa requires time and sustained funding with clear medium- and long-term goals. Therefore, we recommend, among others that in order to sustain the achievements they have made to date, it is important at this stage that EDCTP continues to financially and operationally support, and politically advocate for the NoE sustainability. Increasing funding would strengthen clinical trials and researcher support, networking of the Networks, as well as development and implementation of digital platforms, all of which are important for data generation and sharing. Reducing funding at this stage would limit EDCTP's contribution to generation of big data and health research ecosystems capacity building broadly, which is invaluable for reducing the burden of the diseases targeted by EDCTP, while stopping funding at this stage would reverse the gains of a model that has so far proved useful for clinical trials capacity building in Africa through North-South and South-South collaborations. In addition to some suggestions on how the relevance of the Networks in particular and EDCTP in general can be matched with efficient and effective performance, the EP also suggests that EDCTP should use its Africa Office, High Representatives and members of the Scientific Advisory Committee (SAC) to promote the NoEs among political decision-makers as well as organisations involved in product development for diseases endemic in Africa.

1 Introduction

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between institutions mandated by EDCTP participating states in Europe and sub-Saharan African, and the European Union. EDCTP supports African institutions to develop their capacity for conducting clinical trials in compliance with good ethical practices, standards and regulations. In 2016, four EDCTP Regional Networks of Excellence (NoEs) were established to promote African co-ownership of the EDCTP projects and strengthens clinical research capacity, scientific leadership and networking in four African regions. The four NoEs: Central African Clinical Research Network (CANTAM2); East African Consortium for Clinical Research (EACCR2); Trials of Excellence in Southern Africa (TESA2) and the West African Network for TB, AIDS and Malaria (WANETAM) involve 63 institutions in 21 African countries.

NoEs were established to strengthen connections between researchers and institutions in regions of Africa. As indicated by the acronyms, the four NoEs have focused on TB, HIV/AIDS and malaria, priority infections in the first EDCTP programme (EDCTP 1). To date, they have focused on creating sustainable platforms for multicentre trials and a supportive infrastructure for the human capacity development of research in Africa. Following the first interim evaluation of the EDCTP Programme (2014-2016), an independent mid-term evaluation of the performance and impact of the NoEs was recommended. It was in this background that in June 2019, EDCTP commissioned an independent evaluation panel (EP) made up of people with different skills and expertise to carry out the evaluation.

This report is structured as follows: **Section 3** gives the background, context, purpose and objectives of the evaluation. **Section 4** summarizes the approach and methods deployed to collect and analyse data from different sources in order to fulfil the purpose and objectives of the study. **Section 5** presents and discusses findings of the data collection and analysis processes and presents specific recommendations for each Regional Network. **Section 6** presents conclusions and **Section 7** gives some general recommendations and a roadmap for action points.

2 Background, context, purpose and objectives of this evaluation

EDCTP is a public-public partnership between 16 African and 14 European countries. These 30 countries, also called Participating States, are full members of the EDCTP Association. EDCTP's mission is to support collaborative research that accelerates the clinical development of new or improved interventions (drugs, vaccines, microbicides and diagnostics) to prevent or treat HIV/AIDS, Tuberculosis (TB), Malaria and Neglected infectious diseases, including emerging and re-emerging infections, affecting sub-Saharan Africa. EDCTP funds all phases of clinical trials (I–IV), with a focus on phase II and phase III studies. Post-licensing (phase IV) studies encompass pharmacovigilance and effectiveness studies (pragmatic trials) as well as medicinal product-focused implementation research. In parallel, EDCTP funds strengthening of the clinical research enabling environment in sub-Saharan Africa through grants for training (fellowships) strengthening ethics and regulatory frameworks and internationally collaborative (North-North, South-South and North-South) research networks. The second EDCTP programme (EDCTP2) is implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020.

In 2015, EDCTP launched a call for proposals for EDCTP Regional Networks. The call provided funding for actions that aim to support south-south and north-south networking among sub-Saharan African and European institutions in order to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials in line with the International Conference on Harmonization guidelines for Good Clinical Practice (ICH-GCP). These supported networks are expected to contribute to overcoming the lack of capacity, critical mass and inadequate infrastructures that prevent many African institutions from engaging in high quality clinical research activities. Moreover, these networks should build on results from former EDCTP-funded regional networking actions with the aim of strengthening the scientific and clinical research environment for conducting clinical trials in sub-Saharan Africa.

Specific objectives of the networks include:

- To strengthen collaboration and optimise the use of resources and infrastructures within the network
- To offer training and mentorship aimed at promoting professional development and scientific leadership in clinical trials
- To strengthen South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established institutions in building capacity for conducting high-quality clinical research
- To encourage and promote networking and dialogue between researchers, communities and policymakers to maximise the impact of clinical research in Africa.

In 2016, four NoEs covering geographically defined areas in sub-Saharan Africa, Southern, Eastern, Western and Central Africa, were selected following independent scientific evaluation, and were awarded a 36-month grant worth approximately EUR 3 million each. The EDCTP Regional Networks are shown in Table 1 below:

Table 1: EDCTP Regional Networks

Name of Network	Region Covered	Participating Countries and Institutions
Trials of Excellence in Southern Africa II (TESAII)	Southern Africa	14 institutions from 8 African countries: Angola, Botswana, Malawi, Mozambique, Namibia, South Africa, Zambia, Zimbabwe, and 3 European countries: Spain, The Netherlands, and the United Kingdom
Eastern Africa Consortium for Clinical Research 2 (EACCR2)	East Africa	23 institutions from 6 African countries: Ethiopia, Rwanda, Sudan, Tanzania, Uganda,Kenya and 5 European countries: Belgium, Sweden, Switzerland, The Netherlands, and the United Kingdom.
West African Network for TB AIDS and Malaria (WANETAM)	West Africa	17 institutions in 9 African countries: Burkina Faso, Gambia, Ghana, Guinea Bissau, Mali, Nigeria, Senegal, Sierra Leone, Togo, and 4 European countries: France, Germany, Portugal, and the United Kingdom.
Central Africa Clinical Research Network (CANTAM2)	Central Africa	12 institutions from 5 African countries: Cameroon, Democratic Republic of Congo, Gabon, Republic of Congo, Zambia and 3 European countries: Germany, The Netherlands, and the United Kingdom.

In accordance with the 2015 work plan call text, successful networks that demonstrate satisfactory progress by the end of 36 months may be given an opportunity to apply for an additional 5-year grant. Furthermore, in line with the EDCTP response to the recommendations of the first interim evaluation of EDCTP Programme (2014-2016), EDCTP planned to "commission an independent evaluation of the EDCTP Regional Networks' performance and impact.'' The evaluation would produce a status report of the EDCTP Regional Networks and serve as input for informing future funding strategies and levels of such funding to the networks under EDCTP2.

3 Purpose and objectives of the evaluation

The purpose of the evaluation was to perform an independent assessment of the EDCTP-supported Regional Networks. The objectives of the evaluation were to:

1. Assess the status of the project performance so far, including progress towards agreed deliverables, project management and the likelihood of successful completion
2. Assess the results at outcome and impact level (if applicable) of the four Regional Networks so far, particularly concerning their capacity to conduct clinical research and trials according to ICH-GCP standards
3. Review any other project relevant documentation such as training programmes, Standard Operating Procedures (SOPs), inspection reports from health authorities and any audits conducted at any of the participating institutes
4. Provide recommendations and suggestions for enhanced relevance of the networks to emerging regional priorities and how to foster their engagements with other networks and consortia with or without EDCTP funding
5. Assess the implications of adjusted funding options (increasing, reducing or stopping funding) from EDCTP, on the sustainability and impact of the networks.

4 Key evaluation questions

From the evaluation purpose and objectives above, the EP developed three overarching evaluation questions which later formed the basis of more specific questions in the evaluation questionnaires:

1. To what extent have EDCTP regional networks achieved the deliverables set out in the 2015 work plan?
2. In specific terms, how can the relevance, efficiency and effectiveness of Regional Networks be improved?
3. What are the implications of adjusted funding options (increasing, reducing or discontinuing funding) on the sustainability and impact of the Regional Networks?

Within and across the different evaluation questions and objectives, the iMTE also sought to uncover the propagation of scientific and leadership excellence between the Regional Networks and to/from other non-EDCTP networks or consortia.

5 Conceptual and methodological approach

The EP viewed this iMTE as an assessment of the relevance, efficiency, effectiveness, impact and sustainability prospects of the EDCTP-supported regional networks and at a broader level, an endeavour which would contribute to improved understandings of the health research terrain in the study regions. To these ends, the methodology adopted for this study was informed by the ToR (Annex 1a) and EDCTP's 'mission. EDCTP is intervening in the realm of capacity building, which is a broad concept that has many definitions depending on the context and objectives of development programmes. As an EP, our approach was inspired by and in agreement with Potter and Brough (2004), who argue that it is important to address systemic capacity building through a four-tier hierarchy of capacity building needs which includes (i) structures, systems and roles, (ii) staff and facilities, (iii) skills, and (iv) tools (see Figure 1). Emphasising systemic capacity building would improve programme design and monitoring, and lead to more effective use of resources. EDCTP's initiative of launching NoEs in clinical research in Africa is following the model of systemic capacity development and as such is envisaged to contribute towards the creation of environments that lead to the establishment of structural capacity where decision-making is sound and rational and where processes and quality control are called to account for non-performance. Furthermore, the EDCTP model for capacity building was described in the CARI report (2018) on the Inventory of Clinical and Translational Science Capacity in Africa as an ecosystem-wide intervention by creating networks/partnership at the individual, institutional, intra-regional and inter-regional level with other continents that may have the potential to be impactful. However, this effort will need to be improved upon and taken to scale.

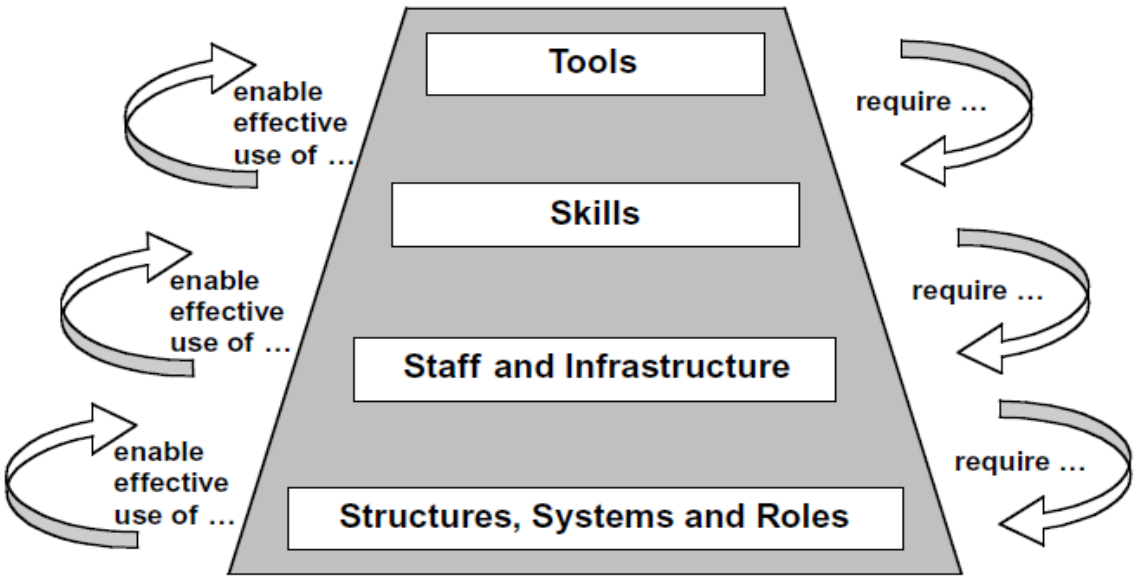

Figure 1: Capacity pyramid depicting the notion of systemic capacity building (Potter C & Brough R, 2004)

The panel's understanding of the dual purpose of the evaluation narrated above draws from the ToR and EDCTP's mission as well as the systemic nature of capacity building illustrated above. Separately and collectively, these dimensions prescribed a multi-method approach in carrying out the iMTE. Hence, the evaluation process was guided by the following conceptual framework (Figure 2).

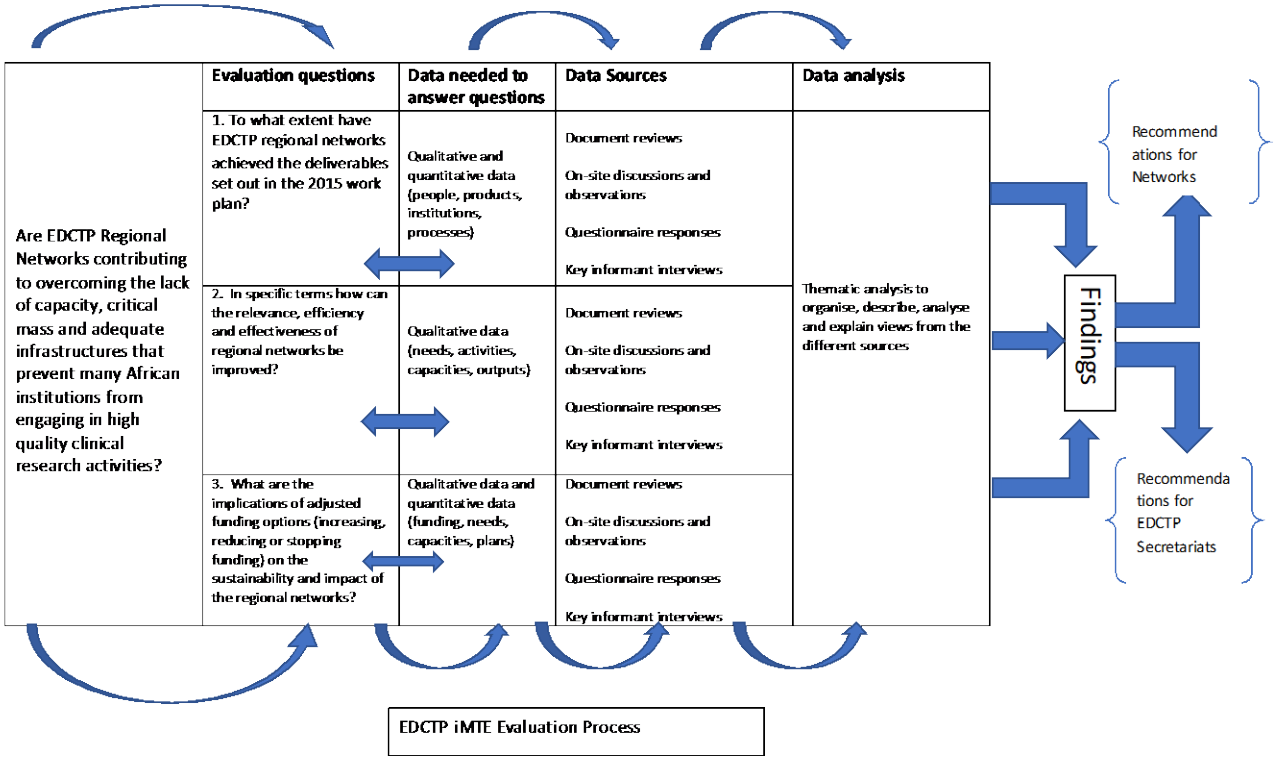

Figure 2: EDCTP iMTE Evaluation Process (framework developed by authors)

This evaluation process framework served as a guide bringing together the key areas of focus for the evaluation and bringing out linkages and rationales between data sources, collection methods and evaluation objectives.

5.1 Scope of the evaluation

Primary and secondary data collections were applied in all the four Regional Networks, namely CANTAM2, EACCR2, TESAII and WANATEM, as well as the EDCTP Secretariat located in The Hague and Cape Town. This iMTE also solicited contributions from key health research and clinical trials stakeholders from the four African regions covered by the networks, representatives of regional economic communities, academic institutions, civil society and other users, as well as current and former EDCTP fellows. In addition, we reached out to representatives of the EDCTP Scientific Advisory Committee (SAC) and General Assembly (GA). As indicated in the evaluation conceptual framework (Figure 2, above), and detailed in the data collection section, we used mixed methods, including document reviews, questionnaires, semi-structured interviews, focus group discussions and observations to gather primary data and for validating secondary data obtained from the desk reviews.

5.2 Data collection and analysis methods

5.2.1 Data collection rationale

This iMTE adopted a case study approach, with the Regional Networks and their linked network activities serving as multiple case studies for careful analysis of the key areas of focus for the evaluation. Desk reviews were conducted against an evaluation checklist based on the evaluation purpose, objectives and key questions, while interviews were conducted using emailed questionnaires and/or semi-structured interview guides for different respondent categories (available in Annex 2a & 2b) to ensure that the questions posed in the ToR were covered in a complete and consistent manner. The EP also kept running notes of any other relevant points made by the various stakeholders during the site visits (Annex 3), or observations they made that were relevant to the evaluation (e.g. of interactions within the Regional Networks or with external parties). The case study approach was best suited for this type of evaluation for the deep and close *in-situ* investigation that could be obtained (Seawright and Gerring, 2008). Interviewees were free not to respond to any questions they felt uncomfortable with, and where feasible and desirable, anonymity was preserved. The identified case studies, primary and secondary data form the basis for the compilation of this Evaluation Report and a PowerPoint Presentation summarising key evaluation findings, conclusions and recommendations, which will be given at the end of the evaluation.

5.2.2 Data collection process

As detailed above and in Figure 2, data for this evaluation was gathered using several complementary methods, namely, emailed questionnaires, document reviews, interviews with some key respondents, site visits and focus group discussions/meetings with the Regional Networks. Below, we present some quantitative details about each data collection method, disaggregated by category of respondents.

Questionnaires

Table 2: Respondent categories and response rates.

Respondent Category	Number of Questionnaires Sent	Number of Filled Questionnaires Received
EDCTP Staff	10	4[1]
EDCTP Regional Network	40	25
EDCTP Scientific Advisory Committee (SAC)	5	1
EDCTP General Assembly (GA)	5	1
Africa-based stakeholders	11	2
Global partners	6	2
Total	**77**	**35**

[1] Among these, some face-to-face interviews were conducted, guided by the questionnaire

Document Reviews
Below is a summary of the documents that were received and reviewed:

Table 3: Documents reviewed for the iMTE

Document Category	Specific Details of Documents Received
Proposals and Plans	• 2015 EDCTP Call for Proposals • 2014-2024 EDCTP Strategic Business Plan • 2019 EDCTP iMTE Terms of Reference
Agreements	• Regional network specific EDCTP Grant agreements
Progress Reports	• EACCR2 Annual and Interim Report and Supporting Documents • TESAII Annual and Interim Report and Supporting Documents • WANETAM Annual and Interim Report and Supporting Documents • CANTAM2 Annual and Interim Report and Supporting Documents • EDCTP site visits reports for CANTAM2 and WANETAM • EDCTP Annual Report 2017
Evaluation Reports	• First EDCTP Interim Evaluation Report (2014) (by Technopolis)
Others	• EDCTP Strategic Research Agenda

Site visits to Regional Networks
Visits to the coordinating sites of the Regional Networks were conducted in accordance with the schedule below:

Table 4: Schedule for site visits

	East African Consortium for Clinical Research (EACCR2) Entebbe, Uganda	**Central African Network for TB, AIDS, and Malaria (CANTAM2) Brazzaville, Republic of Congo**	**Trials of Excellence in Southern Africa (TESAII)** **Maputo, Mozambique**	**West African Node of Excellence for TB, AIDS, and Malaria (WANETAM) Dakar, Senegal**
Visiting Panel Members	Hassen Ghannem	Hassen Ghannem	Elizabeth Allen and Hassen Ghannem	Juntra Karbwang
Dates	Week 12 August 14-16 August	Week 19 August 19-21 August	Week 26 August 28-30 August	Week 26 August 28-30 August

Prior to the visits, agendas for the mission were drafted, customised and agreed on with the Regional Network coordinators. These agendas included meetings and interactions with different institutions and project teams and visits to research facilities. Details on the total number of meetings and categories of attendees for each meeting will be given in the findings section for each Regional Network.

5.2.3 Data analysis

Qualitative data was analysed thematically, while simple computations and descriptive analyses were used for quantitative data. The analysis was also based on the principle of triangulation of data from the varied sources engaged with, within and between Regional Networks and projects. This evaluation was structured and delivered in a manner based on and informed by NoE activities. The logic of analysis and abstraction did not intend to move too far away from the respondents' narratives. Contributions are not weighted but included based on relevance. The semi-structured nature of the evaluation questionnaire allowed the EP to ensure that all key questions were covered, while also being alert to unexpected information when it came to light. Data from completed questionnaires was extracted into an Excel spreadsheet, by respondent category, with thematic analysis used to draw out and organise emerging views. However, as all respondents' views were considered important, single viewpoints are also presented in the report. The anonymised Excel spreadsheets are available in the Evaluation Report Annexes. Findings in the upcoming sections are disaggregated as appropriate, primarily along the lines of Regional Networks, respondent categories and thematic areas, all taking into consideration the purpose and objectives of the evaluation which included impact beyond the Regional Networks. The findings and recommendations will also show a cross-Regional Networks analysis on specific thematic areas and identify best policy and practice lessons that Regional Networks and countries may adopt.

5.2.4 Limitations and mitigations

Besides a low response rate from some of the stakeholder categories (see Table 2), and the fact that not all targeted respondents had the same level of access to EDCTP documents, there were no major limitations for the evaluation. While the majority of respondents were grant-holders, entailing a potential bias in the findings, the wide range of documents that were reviewed and broad diversity of these respondents (by gender, age, expertise, level of experience, geography, history of engagement with EDCTP) from the Regional Networks and other categories were a key part of the triangulation and mitigation measures for ensuring validity of the findings.

6 Evaluation findings on status of implementation, performance and impact of regional networks

Overall Regional Network performance against set targets

This findings section begins by summarising the status of performance of all the Networks against the deliverables set out when the Networks were launched. This summary is presented in Table 5 below. The results show overall but varied progress among the Networks across the categories of partnerships, expertise development, training, infrastructure and operationalisation of the Networks. Further details for each Network are provided in the sections that follow, and in Annex 4.

Table 5: Progress towards achieving deliverables set out in 2015

Deliverables			progress towards achieving the deliverable			
			CANTAM2	TESAII	WANETAM	EACCR2
Category 1	Partnership	Publish at least three peer reviewed scientific or policy publications as a demonstration of active collaboration and coordination	In progressed and surpassed targets	In progress and surpassed targets	In progress and on track	In progress but delayed
		Organise at least one annual meeting	In progress and on track	In progress and on track	In progress and on track	In progress and on track
		Regular consortia communication (e.g. documented teleconferences)	In progress and on track	In progress and on track	In progress and on track	In progress and on track
		Annual work plans aimed at increased harmonisation of study methods and sharing infrastructures	In progress but delayed	In progress but delayed	In progress but delayed	In progress but delayed
Category 2	Expertise	Initiated at least one ICH-GCP-compliant clinical trial in PRDs funded from other grants,conducted and managed by appropriately qualified individuals within the network.	In progress but delayed	In progress and on track	In progress but delayed	In progress and on track
		Trained or otherwise acquired at least five clinical research associates (CRAs) that are certified to monitor clinical trials and can be contracted by EDCTP, other funders or clinical trial sponsors to monitor the progress and quality of clinical trials.	In progress but delayed	In progress and on track	In progress but delayed	In progress but delayed
Category 3	Training	Comprehensive training and mentorship plans	In progress and on track	In progress but delayed	In progress but delayed	In progress but delayed
		Dedicated courses	In progress and on track	In progress and on track	In progress but delayed	In progress and on track
		Short term staff exchange programs	In progress but delayed	In progress and on track	In progress but delayed	In progress but delayed
		Active rotation process among sites for mentors/trainers and trainees	In progress but delayed	In progress but delayed	In progress but delayed	In progress but delayed
Category 4	Infrastructure	Incorporate at least one fully functional clinical laboratory accredited to GLP to perform clinical trials research	In progress but delayed	In progress and on track	In progress but delayed	In progress and on track
		Develop a functioning data management service	In progress and on track	In progress and on track	In progress but delayed	In progress but delayed
Category 5	Organisation	A robust strategic business plan	In porogress but delayed	In progress but delayed	In progress but delayed	In progress but delayed
		A transparent, fully-functional management and governance structure	In place	In place	In place	In place
		A long-term strategy to ensure the viability, sustainability and progression of the network after the end of the EDCTP funding	In progress but delayed	In progress and on track	In progress but delayed	In progress but elayed
		Communication strategy	In progress but delayed	In progress but delayed	In progress but delayed	In progress but delayed
		A regularly updated website and policies for dissemination data, results and other relevant information	In place	In place	In place	In place

Source: Table developed by EP based on data from document reviews, site visits and questionnaire responses

6.1 Evaluation findings – document reviews, site visits and network member questionnaires

This section summarises key findings on each of the four Regional Networks, drawing from site visits, document reviews and questionnaire responses. Findings from the document reviews and site visit reports were treated as two complementary data sets and thus synthesised and reported together, while questionnaire responses were treated as individual responses and thus analysed and reported separately. All questionnaire responses reported represent what the respondents said (sometimes verbatim!), even if they may differ from others' perceptions and experiences. As alluded to earlier, this evaluation was structured and delivered in a manner based on and informed by NoE activities. The logic of analysis and abstraction did not intend to move too far away from the respondents' narratives. Contributions are not weighted but included on the basis of relevance. Recommendations for each Regional Network are based on a combination of both narratives.

6.1.1 CANTAM2 findings

Synthesis of CANTAM2 document reviews and site visits

The following section summarises key findings on the CANTAM2 Regional Network, drawing from document reviews, meetings, interviews and EP observations during site visits, analysing these against the four key objectives of the Network. Further details on each of the categories can be found in the Evaluation Report Annexes.

Objective 1: To strengthen collaboration and optimise the use of resources and infrastructures within the network

The CANTAM2 Network's different work packages have realised several successes towards this objective. Among these are the more than 15 high-impact publications that have been produced from the work in bothEDCTP1 and EDCTP2, demonstrating continuity, strength and relevance of collaborations. High impact collaborations have also been initiated with policymakers and the private sector locally and regionally, strengthening the visibility and relevance of the Network. Requisite ethics clearances have been obtained, paving the way for timely and ethically-sound use of available resources and infrastructures.

Objective 2: To offer training and mentorship aimed at promoting professional development and scientific leadership in clinical trials

Across the different work packages, a number of achievements have been realised against the set targets for this objective. These include clinical trials that have been initiated and pharmacovigilance activities implemented in Cameroon, Republic of Congo (Brazzaville) and Gabon. Meanwhile, a training platform has been set up to strengthen the Network with tools such as the 3D printing, CRISPR-Cas9 and Diagnostic Tests for NTDs, while two EDCTP career development fellowships and 10 additional grants have been received by CANTAM2. Drug-induced hepatotoxicity analyses were completed in Cameroon and a cohort of TB and TB+HIV patients was established in Gabon to assess molecular epidemiology and resistance patterns of *M. tuberculosis* complex in co-infected patients. Staff training has also been held, for example in Brazzaville, with staff from the NTDs control programme and the national laboratory of public health also trained by the Network. Meanwhile, the SLACK community for early career researchers has been established to foster interaction and collaboration, in the process contributing to other CANTAM2 objectives.

Objective 3: To strengthen South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established institutions in building capacity for conducting high quality clinical research

North-South and South-South collaborations are demonstrated through different activities within and across the work packages. Notable examples include: study protocols developed between Germany, Gabon, Cameroon, Republic of Congo and Democratic Republic of the Congo; study investigations ongoing in Germany with staff exchange from Congo's Fondation Congolaise pour la Recherche Medicale (FCRM) and Cameroon's University of Buea (UB); staff being trained in Germany and at CANTAM2 sites with FCRM, UB, and University of Yaoundé 1 to be added; a CANTAM2 supported Zambian Masters in Medicine researcher who will implement a project on neonatal TB; laboratory upgrade visits conducted in Congo, Cameroon and Gabon; and a 5-day course on TB molecular diagnostics held in Tanzania, July 2019.

Objective 4: To encourage and promote networking and dialogue between researchers, communities and policymakers to maximise the impact of clinical research in Africa

Different methods are being deployed for engagement with different stakeholders within and outside the Network. For example, CANTAM2 has a functional website and social media platforms for engagement with external audiences, and an intranet page for sharing documents between members. Face-to-face interactions were also held, for example, in the period under review, with a successful stakeholder meeting with regulatory authorities in three countries, namely Cameroon, Gabon and Republic of Congo.

Summary of challenges encountered by CANTAM2

Across the different work packages, there were a number of challenges which impinged on attainment of the above objectives, including a lack of adequate support for junior data managers, poor adherence to mentorship programmes by both mentors and mentees, weak international networking, lack of provision for bench fees, English language challenges for French-speaking countries, brain drain and delays with ethics approval processes. Overall, there is a need for recognition that the Network is about system and institutional capacity building, and it takes time for effective coordination among multiple stakeholders to be established. More details can be found in the Evaluation Report Annexes.

Synthesis of CANTAM2 questionnaire responses against iMTE thematic areas

This section summarises key findings on the CANTAM2 Regional Network, drawing from questionnaire responses. The views of the respondents were synthesised and analysed against the main thematic areas set out in the evaluation questionnaire.

The CANTAM2 Network has 12 institutions made up of 5 African countries (namely Cameroon, Republic of Congo, Democratic Republic of Congo, Gabon, Zambia) and 3 European countries (Germany, The Netherlands, United Kingdom).The main objective of the CANTAM2 network is to take advantage of its efforts in the first phase of the network and expand activities beyond malaria, TB and HIV/AIDS to neglected tropical diseases (NTDs) and pharmacovigilance studies, and increase the number of participating countries and partners. The global strategy of CANTAM2 is to strengthen emerging African institutions through training, establishment of career development and mentorship programmes, and improvement of research facilities. The network also aims to strengthen ethical review boards and regulatory authorities serving the collaborating sites as well as establish effective community liaison at each site.

What worked well and how to sustain it, what didn't work well, and adjustments made

Questionnaire respondents indicated that collaboration within CANTAM2 generally worked well when institutions were motivated, internal communications were good, and funds were available, and because of good relationships with central African partners, such as those involved in the Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics (PANDORA-ID-NET) Consortium. CANTAM2 institutions were said to have improved capacities through laboratory renovations, student participation in consortium-led internal and external workshops (e.g. for TB diagnostics and bioinformatics), and visits of PhD students to the UK partner. Respondents suggested that these improvements will be sustained with continuous investment, and engaging local support and pharmaceutical trials, although modest funds availed can support low risk student projects and/or pilot trials such as training platforms. Otherwise, it was felt that there should be an increase in the visibility of activities. Additional funds for postdoctoral (postdoc) students would also limit the brain drain, and women scientists should specifically be supported. The massive up-scaling of joint clinical trial activities was said to be not so successful and this depends on active searches for suitable calls. Some training was also affected by local political instability. Complex institutional funds' disbursement procedures to different partners also caused delays in implementing some activities (as did delays in ethics clearances), but the financial issues should resolve with the creation of one new bank account. It was suggested that the CANTAM2 project manager should encourage partners' compliance with reporting deadlines (or consider setting interim deadlines) and invite them to EDCTP meetings for a better understanding of the reporting rules. The scope of research for the NTDs was considered to be limited and needs to be prioritised, while HIV research activities were unfortunately affected by the deaths of two leaders. It was suggested that better planning of the budget during the EDCTP applications process can prevent partners arguing over funds as has previously been observed.

Relevance, efficiency, effectiveness and impact of the network

The relevance of CANTAM2 was highly rated (an average 9/10) by members responding to the questionnaires, as sites have been consolidated, laboratories equipped, and researchers empowered through skills' enhancement. There are few formal networks between African researchers, so the EDCTP Regional Networks are pertinent for strengthening quality research in the region. Efficiency and effectiveness also rated highly (8/10), with CANTAM2's goals being matched with achievements and clear guidelines and frameworks for activities. However, as mentioned above, grant administration has been problematic and, in addition, CANTAM2 needs to produce more outputs to justify its available budgets. It was mentioned that the will is there, but implementation may be limited due to underestimation of costs, and the complex economic and political instability in this region. To enhance effectiveness, activities such as training could be embedded within a broader strategy (e.g. supporting the best attendees to thereafter apply for scholarships) to help build a critical mass of scientists/leaders, particularly as many projects rely on European Union (EU) partners for data analysis. Impact on capacity development was considered average to strong but could be improved through more training, increased availability of laboratory equipment and postdocs. For local/national problems impact was felt to be average, though generally correlated with regional public health interests. Regional impact was felt to be strong, though beyond the region it was largely weak, aside from existing EU partners; it was recommended that connection to other EDCTP Regional Networks should be reinforced. Moreover, feedback on impact from governance and financial management was varied.

Other ideas from its members for enhancing CANTAM2's relevance, effectiveness, and efficiency include sustaining investment, encouraging inter-Regional Network collaboration, and targeting strategically-located, but weak institutions. Researchers could also be more involved in decision-making and there is room for improved communication, project management training, and delegation of work by Principal

Investigators (PIs) to junior researchers. Organising coordination and collaboration meetings involving all four Regional Network representatives and cross-Regional Network grant calls could help.

How to align/catalyse agendas of national research and EDCTP Participating States
CANTAM2 works closely with national diseases control programmes, with research focal points within national ministries, and aligns with national research and capacity development agendas. It was suggested that meetings with Participating States could be organised to elaborate on a common strategic plan with EDCTP Regional Networks.

Implications of different levels of funding, ideas for adjusted funding
CANTAM2 was considered by these members, on average, 43% ready to sustain itself, with critical factors for this being core funding, retaining trained technical personnel, and encouraging inter-regional activities (e.g. exchange of technologies and human resources, and establishment of 'super' centres of excellence to reduce brain drain and prevent sample exports out of the region). Increasing skills in writing/designing competitive proposals and projects were felt to be key, as is integrating activities in academic curricula and establishing a culture of locally driven research projects. Reduced funding would mean limits to accomplishing the current objectives, but if so, the priorities would be for staff retention and maintaining acquired skills, research on underfunded diseases that contribute to poverty, data management, and mentorship. It was suggested that Regional Networks could be asked to demonstrate how they would achieve more for less, with increased funding available for those demonstrating high levels of productivity. EDCTP should also not be afraid to discontinue funding if a partner has failed to deliver above a certain threshold. Part-time salaries could be capped to a percentage (e.g. 25%) of total personnel costs, to support mostly full-time personnel to drive the agenda. Money could be better spent on activities impacting action rather than in coordination, but, ultimately, if funds were reduced, there would be dramatically fewer research outputs, and young African scientists developing research careers would likely retreat into routine healthcare or teaching or migrate to find jobs outside of Africa. Priorities to pursue with the same level of funding were said to include collection of data on prevalent infectious diseases tied strongly to concrete deliverables. Meanwhile, increased funding would allow retention of trainees and establishment of sustainable platforms for clinical trials, which would also help in developing new ideas and projects.

Excellence in weak institutions, supporting novice investigators and language barriers
Most respondents felt that the strong institutions could support the weaker ones, though one respondent cautioned the former may "*give crumbs to the weak institutions and perpetuate themselves in power*". Otherwise, weaker institutions could be empowered as 'fledgling' trial sites, with clear deliverables for how sites will be developed, and technical staff trained to use core equipment provided. There could be specific calls for weak institutions to enable them to develop capacity for competitive grants – with them providing the ideas and leadership as PIs, and the stronger institutions in a deputy or advisory role. Institutions should be African-led, with EU personnel seconded on equitable conditions to local personnel and rising researchers should partake in network activities at all levels. Already in place within CANTAM2 is a virtual grant office for young investigators to register for assistance in writing projects and applying for financial support. EDCTP should consider having a PhD scholarship programme, with projects in a home and EU partner institute, exploiting biobanks and patient cohorts already involved in EDCTP or elsewhere, for maximal efficiency. There were mixed feelings about language – on the one hand the language of science is English, and it could be cost-effective to teach English or have exchange visits to other language sites. However, there is a place for researchers being allowed to use the language they know. Regardless, it was felt that the networks can be a platform to break language and cultural barriers.

Other partnership/business models for collaborative scientific and trials research
One CANTAM2 respondent suggested strengthening the current model, while others proposed maintaining the current platform but rotating PIs or leadership of the Networks between countries to ensure management experience is shared. Multicentre trials, joint collaborative actions with other funding bodies or Regional Networks, were also proposed, as was a model based on specific subjects – e.g. laboratories in the South and North working on similar topics, to be more productive. All young scientists/students involved with EDCTP Regional Network projects could be signed up on a central platform for idea and knowledge exchange (NB: one such platform, SLACK, already exists – EDCTP could approve appointment of a dedicated administrator, to create relevant content, and facilitate discussion). Such models would largely be complementary.

Knowledge exchange between academia, public and private actors, community engagement and issues not adequately attended to in agendas on trials in sub-Saharan Africa/globally
It was proposed that EDCTP could set up one database of capacities and resources of Regional Network sites for matching with another for Small and Medium Enterprises (SMEs) interested in product development, to accelerate the process of providing evidence for policy change. Programmes to help clinical communities improve quality of care could also be funded, and Africa should consider private competitive research institutions with good business models. It was felt that research in paediatric pneumonia, sepsis, meningitis, viral infections, neonatal health, obstetric issues, and men's health are under-resourced. EDCTP should also add preclinical activities to its portfolio as this will bring more academics into the network. Community/community leader engagement through community advisory boards was considered vital and more social science input is needed to educate and inform communities (and governments) about the necessity of trials.

Training of staff in neglected areas or 'hard to get' specialties like statisticians and monitors is needed, and EDCTP should provide a funding call to bring in personnel to train a critical number of these to then train others. There are some countries with very difficult trial regulations so an effort should be made to train ethical bodies, and build a regional or sub regional ethical body, to help countries ensure populations are well protected.

Peer-review of grant applications can be flawed as it is increasingly difficult to obtain balanced, science- rather than agenda-driven, fair protocol assessments. EDCTP should be represented at regional level to closely follow the networks. There was also a request for a breakdown of budgets assigned to Networks to enable transparency and equity of distribution of funds.

Panel recommendations for CANTAM2
The following is a summary of the key recommendations arising from the EP's analysis and consideration of the findings summarised in the sections above:

- To realise its full potential, the CANTAM budget line for communication/internet and for partner exchanges needs to be increased.
- CANTAM should explore the establishment of gene sequencing capacities locally, including finding ways of sharing available capacities.
- We propose inviting CANTAM2 Advisory Board members to participate in the next annual steering committee meeting and present to the partners their views and road map for the future.
- There are flexibilities in use of budget lines if a partner is not performing according to expectations, which the Regional Network needs to utilize.

- For better management and monitoring of budget expenses by the Network partners, we recommend establishment of a simple platform/oversight committee to assist with of following-up on institutional activities closely and to pinpoint shifts in budget lines.
- As there are limited funds for exchange of training South-South or North-South, we propose an increase in bench fees and additional funds for the mentorship programme and exchange travels. Meanwhile, networking between PhD students could be improved by linking up students with similar topics, allowing them to share proposals, research results and to have joint publication authorships.
- Contacts with regulatory authorities and ethics committees should be strengthened by upgrading the lobbying strategy.
- EDCTP should encourage setting up of an annual conference for all NoEs partners.
- To better address the NTD burden and epidemiology in Central Africa, there is need for substantial funding towards answering many questions that remain unaddressed.

6.1.2 EACCR2 findings

Synthesis of EACCR2 document reviews and site visits

This section of the report highlights the achievements so far realized in the EACCR2 Regional Network, based on desk reviews, site visit meetings, interviews and observations by the EP. These findings are presented after analysis through the lens of the Network's main objectives. The section also presents the challenges encountered. Further details on the views highlighted can be found in the Evaluation Report Annexes.

The general objective of EACCR2 is to leverage, strengthen and sustain an existing EDCTP-funded EACCR to contribute to the new EDCTP2 strategic business plan of promoting regional collaborative research on new or improved interventions to prevent and control poverty-related (HIV, TB, malaria), neglected infectious and emerging/re-emerging diseases in sub-Saharan Africa. The Network has five specific objectives, performance against which is summarised in the following section.

Objective 1: To strengthen the collaboration and optimise the use of shared research infrastructures, other capacity building resources and opportunities

The TB, Malaria and HIV nodes conducted site assessments and identified the infrastructure and human resource capacity of the sister sites to conduct research. This information guided the nodes to draw priorities for infrastructural upgrades at different sites. The infrastructure development and sharing so far includes the improvement of laboratories, upgrade of a health centre and clinic in the new nodes. The five NID node partner countries have already received funding for the infrastructure upgrades. Clinical research compliance with GCP was said to have improved from 20% to 80% as a result of GCP training.

Objective 2: To establish a new node (NID) to manage and establish the needed facilities to conduct clinical trials on neglected, emerging and re-emerging disease that burden the region

The NID node has been established and hosted by IEND. A short-term training course in molecular diagnostics was conducted and five MSc students were recruited. The node focuses on five diseases endemic in East Africa, namely Schistosomiasis, Dengue, Leishmaniasis, Cysticercosis and Hadatosis. Members of the node participated in other node activities/meetings and trainings. However, in early 2019, the leader of this node resigned from the IEND, and it was suggested by the Steering Committee to move the NID coordination to KEMRI.

Objective 3: To boost and deliver an Eastern Africa training and mentorship programme promoting an increase and retention of the independent African researchers, research leaders and managers to conduct internationally competitive clinical trials

The activities that support the achievement of this objective are the long-term training programmes, disease-specific and cross-cutting short courses. For long term trainings, a total of 5 post-doc, 5 PhD and 21 MSc students are being supported through EACCR2, and 7 enrolled for an online international Master of Advanced Studies in Vaccinology degree at the University of Lausanne. For short course training, a total of 332 researchers and laboratory staff have been equipped with different skills to conduct an ICH-GCP-compliant trial. These short courses consist of ICH-GCP itself, ICH-GCP training-of-trainers course, training of clinical trial monitors, a refresher course for monitors, financial management, research management, data management and other specific technical training such as malaria microscopy, TB microbiology, molecular diagnostics, basic epidemiology and biostatistics. Three other short courses were in preparation for mid-2019, namely an introductory course on Research Ethics and HIV Immunology and a Genomics course. For mentorship, two participants from Sudan participated in a malaria mentorship programme KEMRI-Wellcome Trust in Kilifi, Kenya. From the document reviews and as observed during the evaluation

visit, the progress in objective 3 has exceeded the planned activities. This, hopefully, will translate into increased numbers of trials in EACCR2.

Objective 4: To strengthen and strategically expand South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established Eastern Africa institutions in building capacity for conducting high quality clinical research
Significant numbers of South-South and North-South collaborations have been established in the past two years. There are several South-South collaborations on writing grant proposals, conducting research to strengthen study sites, and on short-course training. There are also several North-South collaborations on writing grant proposals research and training. For training, an example of this North-South partnership is the enrolment of six MSc students for the Masters course in Vaccinology, conducted in partnership with the University of Lausanne.

Objective 5: To promote networking and dialogue between researchers, communities and policymakers to maximize the use of health research evidence for shared knowledge management, policy change and improved health programming in Eastern Africa
Policymakers from the Ugandan Ministry of Health attended the launch of the EACCR2 Network where a speech by a representative of the ministry emphasised the need for research in poverty-related diseases (PRDs). The Ugandan government also pledged to support the translation of research results into policy within the country. The meeting was also attended by representatives of the ministries of health from the involved EDCTP African member countries, national health research regulatory authorities and the other Regional Networks. Meanwhile, the EACCR2 has a functioning website which details its activities and active social media platforms (Facebook and Twitter) where updates of all activities are posted for the benefit of the external world. A stakeholder meeting was organised in Entebbe in early 2019 to discuss the partnering for Outbreak and Response.

Summary of challenges encountered by EACCR2
Attainment of the above has faced a number of challenges, notably communication and job change/insecurity challenges, which led to relocation of the NID node from Sudan to Kenya; limited PhD and post-doc training opportunities compared to demand; lack of tuition support for MSc or PhD candidates; lengthy processes for registration and certification of Clinical Research Associates (CRAs); and lack of proper recording and coordination of short-term training activities. Further details can be found in the Evaluation Report Annexes.

Synthesis of EACCR2 Questionnaire responses against iMTE thematic areas
The East African Consortium for Clinical Research (EACCR2) is a network of 14 institutions made up of 5 African countries (Uganda, Ethiopia, Tanzania, Sudan, Rwanda) and 5 European countries namely UK, The Netherlands, Sweden, Belgium and Switzerland. This section summarises key findings on this Regional Network, drawing from questionnaire responses. The views of the respondents were synthesised and analysed against the main thematic areas set out in the evaluation questionnaire.

What worked well and how to sustain it, what didn't work well, and adjustments made
EACCR2 members reported that training courses (including for a pool of clinical trial monitors) were successful as they had been allocated a specific budget and networking also helped with sourcing facilitators. It was suggested a curriculum should now be developed for training of monitors. Supporting PhD and MSc students with data collection and analysis is felt to be important, as is covering tuition fees (and travel and accommodation for trips to overseas institutions) to help students commit. Leveraging complementary (rather than competing) institutional strengths was said to be excellent, resuscitating

South-South and North-South collaborations (which have previously been individually driven) and ensuring an optimal use of resources. The network should increase its multi-site proposals to consolidate the roadmap, and funding should extend to studies to use the established capacity until research groups can sustain themselves. The EXIT-TB study was cited as an exemplar of investigators working together towards ending TB. Shared needs-driven infrastructural upgrades were considered successful by some, although others felt funds were too limited, particularly for weaker institutions. Non-funded northern partners were reported as not active as they did not have budgeted activities, though non-funded southern partners could access courses. The network did not bring together researchers and policymakers. However, this is expected in year 3. A communication plan and use of Zoom and WhatsApp have made challenging communications better. However, there were challenges with political instability in Sudan, members changing institutional affiliations interrupting neglected infectious diseases (NID) node work plans, and not all sites have cooperated on network reporting. It was suggested that Sudanese partners should be given an opportunity to catch up. Delays in receiving funds from EDCTP by the NID node in Sudan, due to national banking challenges in the country, were resolved by funds being sent directly to the NID sister sites. The legal transfer of NID node coordination activities from Institute of Endemic Diseases (IEND), University of Khartoum to Kenya Medical Research Institute (KEMRI) will allow more robust coordination.

Relevance, efficiency, effectiveness and impact of the network

EACCR2's relevance was highly rated by its members who responded to the questionnaires, at an average of 9/10. Southern researchers are now writing and conducting research in synergy, leveraging expertise for relevant regional research. Training has allowed for expertise that would otherwise be hired at costly rates (e.g. clinical trial monitoring), and infrastructure upgrades have resulted in laboratory accreditations. The average efficiency rating was 7/10, due to partner roles, budgets and activities ascertained before agreements signed. The annual meeting was well organised, trainings well planned, and sister institutions empowered to procure items, despite some delays in approvals and procurement due to political instability. Effectiveness was rated 8/10; parties were felt to understand their role, though it was felt some issues could have been better anticipated, as could the flow of funds to some nodes. Impact from capacity development (training/mentorship of more than 30 MSc, 280 short course trainees, 5 PhDs and 5 postdocs) was strong, infrastructure development was average and community engagement weak. However, there was little direct funding to research activities since the call is a coordination and support actions (CSA) call which does not allow for clinical research. Impact from regional networking was considered mainly strong with investigators being involved in the African coalition for Epidemic Research, Response and Training (ALERRT) and the Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics (PANACEA), PANDORA-ID-NET, PharmAcoVigilance Africa (PAVIA), PROFORMA and Streamlining ethics review process and regulatory framework in Tanzania (SMERT), and the EXIT TB grant implemented in all TB node sites. Impact beyond the region was, however, felt to have been varied. Impact for governance and financial management was mainly strong- half-year reporting had improved accountability and the various committees were meeting on schedule. There were no disallowable costs in year 1. It was suggested that the Secretariat management could rotate and there should be at least one person fully paid by the network in each partner country to support activities. Hurdles should be investigated in real-time to avoid interruption of activities, and cross-network collaborations within EDCTP would be helpful. It was felt that a line item on communication would also be beneficial (although this may represent as misunderstanding of the CSA which allows for budgeting of such activities).

How to align/catalyse agendas of national research and EDCTP Participating States

It was reported that EACCR2 members are involved in or work closely with ministries of health, with institutional strategic plans aligning with national priorities. However, it was felt that more funds are

needed for meetings with policymakers and regional network activities and those of PSIAs, or EDCTP States should optimise resources for enhanced outcomes with projects showing how they contribute to national or regional agenda. A suggestion was for the EDCTP Africa office to facilitate linking up the Regional Networks with the country representatives of the different countries where needed and help the Regional Network to support the PSIAs in work plan development and reporting.

Implications of different levels of funding, ideas for adjusted funding

This network was considered around 43% able to sustain itself by its members (an average of ratings presented). If funds were reduced, members suggested that networking and writing joint research proposals to seek funding from EDCTP and other agencies could continue, but vital gains would be lost. Clinical trials could be monitored at a subsidised fee and short-term training conducted at home institutions and universities with South-South collaborations on grant applications and shared infrastructure for research. The members felt that the priority activities would be surveys for current data, and cross-regional and continental networking for innovative diagnostics, vaccines and drugs to combat poverty-related infectious diseases. With increased funding, however, there could be theme-related meetings for proposal writing, community engagement and cross-regional networking to harness capacity within the continent for multi-site/country/region or phase 1 studies (providing 'hands-on' experience). More funding would allow for further infrastructure, with gradual focus on priority areas.

Excellence in weak institutions, supporting novice investigators and language barriers

The current model is considered useful but needs strengthening through sustained funding for training, exchange visits, internships and mentorships (possibly paid), all with clear objectives. It was suggested that MSc students could fast track through PhD and postdoc, thereafter being mentored to become standalone researchers. There is twinning between weak and strong institutions, but this needs improved communication, especially in responding to calls, for which they should be co-applicants. Nascent investigators could be attached to established institutions for a year then continue being monitored/mentored on return to their institution. For language barriers, the network could provide training specifically in scientific writing and communication in English, though just bringing players together can help. Translation services during such activities, such as those used at Anglo and Francophone scientific conferences, could be useful. Many trainees are, however, also excited to learn in Kiswahili.

Other partnership/business models for collaborative scientific and trials research

EACCR2 members felt that EDCTP should engage with other partners like the Wellcome Trust, Deltas and the African Academy of Sciences, for joint funding for networks. In addition, cross-regional networks between EACCR2, TESAII, CANTAM2, and WANETAM, with proposals and protocols spanning the continent or small research collaborations focusing on one theme, were suggested.

Knowledge exchange between academia, public and private actors, community engagement and issues not adequately attended to in agendas on trials in sub-Saharan Africa/globally

Useful I suggested for knowledge exchange included EDCTP country meetings, an EDCTP scientific journal and an EDCTP database of research resources. Otherwise, universities should give researchers honorary positions for much closer engagement and allow them to do part-time teaching and spend time at research centres. Calls that promote South-South collaborations should be promoted, as should private-public partnerships, and thematic calls that spur thought and idea generation with a view of bringing together players to build a collaborative environment to address community problems jointly. Within the continent, TESAII may have had the highest exposure to trials which other networks could tap. Communities can be invited to visit research facilities and select key members to interact with the

researchers and respond to community questions and concerns. Pre- and post-trial surveys would holistically evaluate the impact of a trial. Under-represented areas of research were said to include neonatal mortality and premature births with all their related complications, while another important issue raised was publication bias, whereby northern partners/funders use southern research data without adequate acknowledgement. However, it was said that EDCTP is doing a fantastic job in preventing this by stimulating sub-Saharan Africa (SSA) researchers and building SSA capacity; "*many funders/research partners could or actually should learn from the EDCTP model*".

Panel recommendations for EACCR2

- To have agencies/projects to co-fund or co-organise short term training in which EACCR2 trainees at various nodes in different countries can participate. This should also cover training programmes for clinical trial monitors.
- EACCR2 should involve the existing fellows in conducting such courses to reduce the costs of hiring experts (e.g. for basic level courses).
- We recommend pairing of experienced scientists with young scientists to work closely in laboratories in mentorship attachments or in the form of mentorship in scientific writing and writing manuscripts (mentorship level).
- EACCR2 should create forums in which the EDCTP senior fellowship alumni can guide the PhDs and current fellows on existing challenges in their research work.
- Where possible, EDCTP could consider funding to cover full PhD and MSc support including tuition. Relatedly, provision of small grants for postdocs within Regional Networks would create a critical mass of clinical trial experienced scientists able to attract funding from other sources as independent researchers and this could mean a more sustainable Regional Network even with reduced funding in the future.
- There is need for continued partnership and collaboration in grant application for EACCR2 with other networks funded by EDCTP (ALERRT, EXIT-TB, PAVIA) and others not funded by EDCTP.

6.1.3 TESAII findings

Trials of Excellence in Southern Africa (TESAII) is a network that was established with the objective of creating a framework for collaboration, capacity building and training among 14 institutions from 8 different Southern African and 3 European countries. The eight African countries are South Africa, Zimbabwe, Angola, Namibia, Mozambique, Botswana, Malawi, Zambia and the three European countries are UK, Spain and The Netherlands. There are additional partners, who include Logic Trial, LT (South Africa), the HIV Vaccine Virtual Network, Mozambique-South Africa-Swaziland Cross-Border Malaria Initiative (MOSASWA), European Clinical Research Infrastructure Network (ECRIN) and the Africa Research Initiative and Support Network (ARISE). The Network further seeks to strengthen and enhance the capacities for clinical research in Southern Africa built during TESA1, as well as to increase collaboration, North-South and South-South networking activities among member institutions. To achieve this, TESAII focuses its activities around strengthening the capacities among partner sites, promoting professional development, scientific leadership and fostering collaborations to maximize impact.

Synthesis of TESAII document reviews and site visits

This section of the report highlights the achievements so far realized in the TESAII Regional Network based on desk reviews, site visit meetings, interviews and observations by the EP. These findings are presented after analysis through the lens of the Network's four main objectives. The section also presents the challenges encountered. Further details on the views highlighted can be found in the Evaluation Report Annexes.

The general objective is to consolidate the TESAII network and increase its capacity by engaging in innovative trials and interventions and expanding the regional training platform. The Network has four main sub-objectives, and the following is a summary of key achievements on each of these objectives.

Objective 1: To strengthen collaboration and optimise the use of resources and infrastructures within the network

TESAII had a successful kick-off meeting with the attendance of high-level project stakeholders, project sponsors, government representatives from Mozambique, researchers, academics, politicians, civil society and leaders from other EDCTP Regional Networks. A master plan for the 3-year grant was discussed at TESAII board meetings. During the first year: 1) three laboratories were selected to be reference laboratories in the main PRDs research strand i.e. Manhica Health Research Centre (CISM) for Malaria; Stellenbosch University (SUN) for TB and Botswana-Harvard AIDS Institute Partnership (BHP) for HIV/AIDS and 2) a data centre at CISM was to be established for malaria. The BHP HIV reference laboratory has ISO 17025 accreditation (for testing and calibration laboratories) and SUN-TB has already been accredited based on ISO 15189 (quality management system requirements for medical laboratories). CISM has ISO 9001 (also quality management) but has decided to strive for ISO 15189. In the second year, the CISM malaria laboratory underwent technical assessment in October 2018 by the Portuguese Agency IPAC for ISO 15189 and nonconformities are being corrected. Several training courses were conducted to increase the capacity of the data management centre in CISM towards the quality certification.

Objective 2: To offer training and mentorship aimed at promoting professional development and scientific leadership in clinical trials

Training and mentorship programmes are operational in TESAII. The consortium has developed one Mentoring and Training plan together with SOPs for short and long training programme, although there was a delay in delivering the plan. In year 1, 12 short-term training courses and 3 exchange visits were successfully conducted and 150 TESAII members benefitted from capacity building in several subjects such as GCP/Good Clinical Laboratory Practice (GCLP), Bio-informatics, Statistics, ISO Accreditation and

Drug Resistance. In year 2, 8 short-training courses were conducted and benefitted more than 50 staff of the TESAII members. The main areas covered were quality management systems; finance and grant management; drug resistance training; and advanced research ethics training. For long-term training: 12 long-term students (MSc and PhD) have been enrolled in various African universities, with equity in gender. Trainees felt TESAII had created many opportunities for learning, exchanging experiences and interacting with others within and outside their own countries. What was learnt during internships could be applied at their home institutions. Travel had enabled trainees to present their work within the region (e.g. at the regional conference in Botswana), while some were able to present their projects overseas.

Objective 3: To strengthen South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established institutions in building capacity for conducting high quality clinical research

There are a number of good examples of South-South collaboration in TESAII, one being exchange visits between advanced and less developed institutions (e.g. SU and BHP supporting the University of Namibia (UNAM) and the Angola Health Research Centre (CISA). Training courses have also been conducted collaboratively. Establishment of the Low-Income Countries Research Institution Management Courses (LICRIMAC) in English and Portuguese could be an example for other EDCTP Regional Networks (IP and ownership issues to be verified). At the research level, collaboration is operational between the BHP and University of Zimbabwe College of Health Sciences (UZCHS) sites in the development of two point of care Cepheid GeneXpert tests, namely the HIV-1 qualitative test used for early infant diagnosis of HIV-1 and the HIV-1 Quantitative test used for virological monitoring (viral load quantitation) of response to antiretroviral therapy. South-South collaboration is also in place between BHP and Zimbabwe's Biomedical Research and Training Institute (BRTI) on the preparation for the BRTI laboratory ISO accreditation in HIV drug resistance genotyping.

Objective 4: To encourage and promote networking and dialogue between researchers, communities and policymakers to maximise the impact of clinical research in Africa

At a high level, the TESAII Network has worked to align with regional issues/governance, with a joint meeting of EDCTP, SADC and TESAII scheduled to launch the first reference laboratory. Specific projects have also been used to gain policy and political influence. For example, the Ministry of Health and Child Care (MoHCC), Zimbabwe, approved a clinical study being conducted at a primary healthcare centre in Harare. It is hoped that the results from the study may influence policy change in tests to be used for early infant diagnosis of HIV at all of the point of care health centres nationwide. BHP has had a forum to brief MoHCC on some of the research findings in which capacity building activities have been highlighted. For example, on 17 December 2018, BHP presented urgent viral Hepatitis data findings to the deputy permanent secretary to the Minister of Health/Health Services Management. Meanwhile, at the level of research, TESAII members have attended several workshops, local and international conferences in which they have interacted with other members from within and outside the Networks. The TESAII website is functional for knowledge and information exchange within and outside the Network.

Summary of challenges encountered by TESAII

Some challenges have been encountered across the work packages in the implementation of activities towards the objectives above. These challenges range from poor involvement to date of one of the northern partners; confusion regarding the concept of reference laboratories, resulting in delays in their establishment; some work package leaders not delivering on their activities; time allocated to short courses deemed to be too short; courses said to be too theoretical in some instances; limited financial resources to cover travel and accommodation of fellows; language barriers between Anglophone and

Lusophone countries; poor grant management and reporting systems and lack of social media platforms for the Network. Further details can be found in the Evaluation Report Annexes.

Synthesis of TESAII questionnaire responses against iMTE thematic areas

This section summarises key findings on this Regional Network, drawing from questionnaire responses. The views of the respondents were synthesised and analysed against the main thematic areas set out in the evaluation questionnaire.

What worked well and how to sustain it, what didn't work well, and adjustments made

The members of this network felt it has been successful thus far in establishing new collaborations and infrastructure, helped by smooth communications, face to face meetings and efficient coordination. Short courses were popular and have allowed for open-dialogue and networking, also breaking language barriers to some extent, although it was suggested that Portuguese language delivery of courses would help further. In addition, train-the-trainer courses would empower local personnel and reduce travel costs, as would e-Learning. A mismatch between grant cycles versus university calendars had impacted long-term fellowships, which was nevertheless overcome by partial grant support and working with the universities involved. However, postgraduates have had to apply to other organisations to supplement their funds from TESAII, and, while some institutions invited mentees to 3-month training within clinical trials, none were yet able to attend training due to lack of funding. Mentorship and training plans are now in place and slow infrastructure upgrades due to tender processes have improved. It was suggested that a no-cost-extension may help achieve delivery of the Data Centre. However, some institutions were reported to have underperformed, and there has been slow reporting, a situation that the Network's Steering Committee needs to deal with. Policymaker engagement was also felt to have been overshadowed by other activities, although members have been tasked to come up with strategies. Administratively, numerous documents need to be made available in a repository and the newly launched TESAII website should disseminate up to date information about opportunities to reach a wider audience, potentially using a web-based course communication guide already developed. The network must apply for external grants to answer pressing research questions to assure application of skills attained.

Relevance, efficiency, effectiveness and impact of the network

Relevance was rated highly by its members at an average 9/10, as capitalising on each other's strengths will help answer common health challenges in TB, HIV and malaria that disproportionally affect Africa. This is suggested to be a value proposition for sponsors, but ministries of health should also be engaged to address specific important problems, including through implementation research. Efficiency was rated 8/10, as the model reduced duplication and enhanced use of resources. However, more could be done to develop tools to support under-resourced sites be compliant with Network requirements, with site project managers potentially relieving administrative, technical and regulatory work for busy Pis. Some also felt the very different themes may hamper constructive collaboration. Effectiveness was rated high at 8/10 through strong leadership and opportunities to evaluate network activities regularly. Policy engagement and joint protocol writing are however considered to be lagging. Impact from capacity development was said to be strong as a result of the MSc and PhD programmes, short- and long-term attachments and infrastructure development; senior network members have vast expertise from which young researchers can draw from and interactions between sites helps promote knowledge exchange. In addition, by increasing competence and ethics capabilities, the rights, dignity, safety and well-being of participants is more assured. Perceptions on impact for local problems was average to strong as research expertise leads to higher competence and quality research, ultimately improving patient care (although no money for research is available). For regional networking, impact was largely strong, through clinical attachments, network meetings, and establishing reference laboratories. Beyond the regions, it was felt to be more

varied, though North-South collaborations strengthen existing research and development collaborations, including for new joint grant applications relevant to southern African countries. A recommendation was made for more involvement in intergovernmental activities through bodies such as the Southern African Development Community (SADC). Impact from governance and financial management was felt to be strong due to the efficiency of the coordinating institution, though more financial training is needed at sites.

How to align/catalyse agendas of national research and EDCTP Participating States

It was suggested this can be achieved through presenting results at national conferences and more formal interaction with national and regional authorities. There should be active follow-up on regional initiatives and collaboration with strategic national health institutes, government ministries and institutions of higher education to address priorities beyond HIV, TB and malaria. This would assist in transforming significant results into action through policy and practice. Having calls under PSIA can help, and there could be joint training for network members and local policymakers. Participating States must recognise the potential for EDCTP networks to do regional or cross border research or consultancy activities and engage them for such work in collaboration with government or academic institutions. This will develop regional capacity for managing their own affairs using already existing human capital.

Implications of different levels of funding, ideas for adjusted funding

This network was felt to be only 37% ready to sustain itself (average result). If funds were reduced, the focus would be on key activities with the potential to enhance trials (e.g. short-term courses, local mentorship and twinning), promoting capabilities to the global pharma and medical devices industry, and securing co-funding. Priorities would include harmonisation of standards for ethical reviews, specimen and data handling, and strengthening/maintaining the newly established reference laboratories and data management services. International travel would be reduced but short courses and MSc studentships retained. Should current funding be maintained, the network should expand on what has worked and has higher potential for attracting more grant funding; writing disease-specific protocols through the nodes. With increased funding, there is the potential for cross-network trials, implementation science to improve uptake of research results, training of more PhDs, strengthening grants management and reference laboratories. Less developed sites could also be prioritised to accelerate equal opportunities. Money can be channelled into epidemiological studies, implementation research and trials to not only answer research questions and improve health outcomes but as a basis for human resource development; a snowball effect for more grants and long-term sustainability. Funding should be incremental based on achieved targets and TESAII should be pitched as a regional node of excellence for global multi-site trials, offering its data management and lab services to sponsors.

Excellence in weak institutions, supporting nascent investigators and language barriers

Network members suggested that strong institutions can be twinned with weaker ones through a specific call, or seed grant in designing projects, funding applications and joint study implementation through on-the-job mentorships. More funds should then be given to the weaker institutions, although monitoring of defined deliverables is key. Scholarships for training, at any level are critical, as is the participation of young researchers in network meetings. Nascent researchers should be provided with a distinct aim complementary to their field of interest, within a trial spanning several institutions in a network. These 'sub-studies' will provide high impact, first authorship peer-reviewed publications while improving experience and knowledge of researchers. Language is a barrier and a network of countries speaking the same language could impact their own development with their insertion in a more global agenda later. Language barriers can however be helped through joint scientific meetings, and a strong leading institution speaking the same language as its network to interface with others.

Other partnership/business models for collaborative scientific and trials research
Various models were suggested, largely complementing the existing structure. EDCTP could consider piloting an intra-African scientific and trials research colloquium to consolidate African research infrastructures with a view to creating mega scientific nodes to drive agendas on a large scale. Networks need to engage with regional economic and governance groups including the African Union. Pooling of resources by big funders into one basket for similar trials that require multi-country participation will make scientific findings more generalisable and well-established sites could offer services at cost to generate income. Sabbaticals for experts from centres of excellence to weaker sites would help strengthen systems, as could placement of supported postdocs in weaker sites from the centre of excellence to facilitate integration of technology and expertise for both. The disease working groups could also have more autonomy.

Knowledge exchange between academia, public and private actors, community engagement and issues not adequately attended to in agendas on trials in sub-Saharan Africa/globally
The EDCTP bi-annual forum was felt to be a good place to invite external participants, including private and public stakeholders; a key need in Africa is innovation, promotion and partnering with start-ups, promotion of interactions with other Regional Networks and beyond. Networks must be encouraged to take on implementation research for products arising from EDCTP research and other scientific endeavours. Research networks should form solid partnerships with communities through consultative committees to translate research findings, while patient advocacy groups can also be supported to promote access to quality research, transparency, assurance of research ethics and ultimately trust. Under-attended issues include cancer and diarrhoeal research, research not reflecting "one health" and some social and economic aspects. Funding was also inadequate for participation of Northern partners and training on administrative management and there is a need for more attention to adherence to ICH-GCP (including consent and reporting of adverse effects to regulatory authorities). Finally, most big clinical trials funded by international funders take place in the same few countries with historical ties, excluding others which requires attention. One respondent commented that this evaluation is critical, a relevant exercise in terms of continual improvement of the model. It may serve as a good barometer to measure progress and shortfalls to be rectified through corrective action.

Panel recommendations for TESAII

- Regarding networking and coordination, the following actions are recommended: use of software to monitor network and research management; more regular meetings with the network's Scientific Advisory Committee; incorporating more context and background details on Network activities in narrative reports; having experienced network coordinators mentor less experienced sites to coordinate the network in the future and ensure a close follow-up with Northern institutions planned activities; and raising awareness of other EDCTP activities such as the Knowledge Hub and Alumni platform.
- Include the following capacity building and training activities: investment in language skills training in Portuguese for Angolan and Mozambican delegates; more financial support for student travel and accommodation; seed funding for implementing small collaborative projects, not restricted to science; increasing practical relevance of courses (e.g. allowing to bring own data and manuscripts); inclusion of eSwatini (Swaziland) and Lesotho in future and increasing support for Namibia; and 'exporting' successful courses to other Regional Networks.
- On communication and policy dialogues, the network could help sites approach policymakers about aligned activities and goals where needed, including gaining presence in relevant SADC meetings and community engagement forums. There is need to invest more in making the website more lively, up-to-date and clearer on courses offered and other network activities. Increasing media coverage,

starting a newsletter and inclusion of student presentations in annual meetings would also strengthen the network.

6.1.4 WANETAM Findings

This Regional Network has 17 institutions from 9 African countries (Senegal, Mali, Nigeria, Ghana, Togo, Burkina Faso, Gambia, Sierra Leone, Guinea Bissau) and 4 institutions in 4 European countries (UK, France Germany, Portugal).

Synthesis of WANETAM document reviews and site visits

The following section summarises key findings on the WANETAM Regional Network, drawing from document reviews, meetings, interviews and observations during site visits by the EP, and analysing these within the context of the Network's four key objectives. Further details on the views highlighted can be found in the Evaluation Report Annexes.

Objective 1: Strengthen collaboration and optimize use of resources within Network facilities

WANETAM has published five research articles (results from WANETAM funding under EDCTP1), which suggests the continuity of collaborations and interactions of the network members, and two new publications so far in the current WANETAM, which indicates active collaborations. In terms of sharing of resources, WANETAM has two shared laboratories that are available for GCP-compliant trials. Three more laboratories have been selected for further improvement as accredited laboratories which are being supported by experts from the London School of Hygiene and Tropical Medicine. The laboratories will share protocols for sampling, storage and diagnosis among the participating partners for the inter-country helminthic surveillance.

Objective 2: Promote professional development and scientific leadership in clinical trials through mentorship and training

In terms of professional development, malaria and TB Networks, and cross-cutting training, WANETAM has had significant progress despite a delayed start. This has seen 172 scientists trained in various fields to support the conduct of GCP-compliant clinical trials. Furthermore, five scientists are being trained as clinical trial monitors that can be utilised in the region. Training has been successful due to the commitment of countries/work package leaders.

Objective 3: To strengthen South-South and North-South collaborations between researchers and institutions with a specific focus of supporting less established institutions in building capacity

There are various activities of North-South and South-South networking, including networking among the four Regional Networks. An additional four institutions have applied to become WANETAM members and a South-South, West African Paediatric TB Network was established, as was a collaborative network for the improvement of laboratory quality.

Objective 4: To encourage and promote networking and dialogue between researchers, communities and policy makers to maximise the impact of clinical research in Africa

Establishment of the West African paediatric TB Network also contributes towards fulfilment of this objective. There has also been promotion of the Regional Network in the sub-region through broadcast media, establishment of networking with WAHO and the collaboration with the West Africa Global Health Alliance. The WANETAM website is being updated, as is the communication plan, which will be launched upon approval.

Summary of challenges encountered by WANETAM

The main challenge is limited resources for attending international conferences and meetings across the Regional Networks, or to advocate for more South-South networking activities. As a result, the Network remains relatively unknown to external partners in terms of its activities and study sites. The development

of shared tools and shared databases were delayed due to the lack of personnel. There is also limited funding to support the development of laboratories to accreditation; limited to only one where there should be three. There remains poor involvement of some participants in the Network's activities and a lack of focus on linking research to public health. National NTD programmes are not fully involved. Ethics committees exist in every country but competence, as required by GCP, is not assured. With regards to the training and mentorship**,** there have been delays in long-term training of MSc's in various fields, including data management, clinical trials and medical biostatistics, finance, as well as grant and financial management. There are also delays in the exchange of scientists and mentoring arrangements. Meanwhile, though improving, communication remains insufficient within the Network and with other Regional Networks.

Synthesis of WANATEM questionnaire responses against iMTE thematic areas
This section summarises key findings on the WANETAM Regional Network, drawing from questionnaire responses. The views of the respondents were synthesised and analysed against the main thematic areas set out in the evaluation questionnaire.

What worked well and how to sustain it, what didn't work well, and adjustments made
Perceptions of accomplishments against targets ranged from outstanding/strong to satisfactory. Training was felt to have been successful due to the commitment of countries/work package leaders and can be sustained by continued motivation and further funding. Implementation of malaria activities was considered highly successful due to good management, while training on childhood TB and establishment of a West Africa Paediatric TB network should sustain research. South-South collaboration for NTDs was felt to have been a strength, and three more countries are interested to join. Progress with monitor training and support for a regional accredited laboratory has been positive, while recommendations for sustaining gains include standardised protocols, data management/sharing processes, and best practice. However, financial support is crucial.

Many felt communication (particularly within the work packages) did not work well, possibly due to a lack of deputy leadership. A recommendation by the Steering Committee to address communication gaps, launch a website and social media strategy is being implemented. There were also delays in fund transfers affecting South-North training, which is being addressed. It was reported that national NTD programmes are not fully involved, and more advocacy is needed. The likelihood for papers in malaria is low as there is no project and the HIV work package implementation problems were felt to be due to weak work package management and a late start. Other constraining factors included a lack of commitment from some partners (who could be excluded), and issues with organisation, focus and sustainability plans. For the latter, a robust strategic business plan with clear indicators of success is in hand. However, funding is limited and short-term for significant long-lasting impact, so the network should work towards attracting additional funding. Meanwhile, there are very few joint activities with European partners apart from training, so an engagement plan will be developed and training around projects must be encouraged.

Relevance, efficiency, effectiveness and impact of the network
Relevance is considered high by WANETAM members (average 9/10), as the work packages are related to regional needs and EDCTP networks have significantly contributed to capacity building, improved quality of clinical trials and research management. It has allowed for opportunities for multi-institutional collaborations not possible otherwise, and each institution can focus on its strengths while improving weaknesses. The average efficiency rating was 7/10 and related to commitment by members and strong secretariat leadership. Efficiency could be improved, however, by still more effective coordination and enabling sites to keep abreast of milestones. There are few staff available and these are stretched to

capacity with work sometimes organised around individuals, slowing output if they are unavailable. Monitoring must be financed to support weaker sites in funds management. The average effectiveness rating was 7/10; work package leaders are very experienced, and the trainings have had great impact. The overall direction of the WANETAM Network is considered appropriate but sometimes its use of resources is not optimal.

Impact for capacity development was largely considered strong, with scientists trained in novel technologies to conduct quality trials. Impact for local problems was mostly average or strong, with a focus on local health challenges and supporting laboratories. Regional networking impact was mostly strong, with close work with the West Africa Health Organisation (WAHO) on common topics like Ebola and NTDs, although activities are not clear beyond training. Beyond the region, networking was felt to be weak to average, with South-South and North-South networking mentioned as ineffective. However, governance and financial management were rated average to strong, with a request that EDCTP provide financial management software.

Ideas for enhancing relevance, effectiveness and efficacy of WANETAM include review and alignment of its activities in each country and taking advantage of institutions having collaborations with ministries of health. The network can also be improved through better communications, integrating additional high performing institutions, more training on EDCTP procedures, regular monitoring, transparency and improved information sharing.

How to align/catalyse agendas of national research and EDCTP Participating States

There is a need to establish strong collaboration with countries' authorities, with high level discussion by all stakeholders to articulate issues within the sub-region before proposals are drawn up. Research and training activities should be done in collaboration with national programmes, policymakers, regional health organisations such as WAHO, government public health laboratories and NGOs. PSIAs and EDCTP research are aligned but could be enhanced by PSIA's taking part in the annual retreat and advisory committee meetings. Links should also be established between network investigators and their respective country representative at the EDTCP General Assembly.

Implications of different levels of funding, ideas for adjusted funding

This network was felt 50% ready to sustain itself by its members (average rating). With reduced funds the priorities would be for key public health areas, and activities would include mentoring of young scientists (and women), promoting collaborative quality science, building capacities for trials with modern equipment, harmonisation of regulatory requirements, and community engagement. The network would need to seek support from governments and obtain grants beyond EDCTP. There would be fewer meetings and training workshops. If the same funding were available, the network could do more capacity building, including practical applications of skills gained through previous rounds. With increased funding, the priorities are more clinical trials, capacity building, networking, and inter-country proposals. Junior scientists from institutions not currently members could also be included. Funding could be redistributed to areas with more need (e.g. for laboratory accreditation to support trials, networking for young scientists) and paid to institutions of the work package leaders for easier management. Multi-institutional funding has also been somewhat successful.

Excellence in weak institutions, supporting novice investigators and language barriers

A model to support weak institutions should be tailored to their needs as per a gap analysis, as there may not be a one-size-fits-all solution. Talented MSc, PhD and postdocs should be supervised by senior scientists who undergo mentorship training, with mentors and mentees having access to support

materials. Scientists from stronger institutions can write grants with those from weaker ones, with the latter being co-PI. Some calls could also be targeted at weak centres. Funding weak institutions, if well organised, can work with close monitoring of funds and proper supervision with the funding they secure used by themselves, but with the network involved as a partnering structure (not a governing body). Novice investigators could also be given a role to play within the network.

Suggestions to overcome language barriers include mentorship programmes with a focus on non-English speaking scientists spending time in an English-speaking environment, and language classes. WANETAM already rotates activities across partner sites which encourages cohesion and a platform for breaking long-term Anglophone/Francophone language barriers. Aside from language, one person advocated for more training on problem-solving skills, while another felt any attempts to break language barriers may be useless with not many people adhering.

Other partnership/business models for collaborative scientific and trials research
Members suggested an annual event of all Regional Networks to share results, to which policymakers, governmental bodies and funding agencies are invited. Other partnerships may be between public-private or academia-pharma. WANETAM could provide funding for scientists in each work package to build a team with MSc, PhD and postdocs and the senior scientist in a strong institution. Such models should be complementary to the existing network to expand opportunities, with open competition.

Knowledge exchange between academia, public and private actors, community engagement and issues not adequately attended to in agendas on trials in sub-Saharan Africa/globally
Mentorship programmes and scientific visits can augment capacity building and be achieved through Memoranda of Understanding. EDCTP and others may consider the organisation of joint global meetings/conferences/symposia to share more information on collaborative trials. Other actions may include the presentation by EDCTP and others of their initiatives at regional and international meetings. Interactions with the pharmaceutical industry by the network has been minimal which needs to be addressed – opportunities for information and data sharing and advocacy with industry should be explored in a way that is acceptable to both parties. The concept of intellectual property should be developed.

Community engagement was mentioned as crucial to gain trust, especially in Africa where vaccines and new interventions are not always well accepted, and this should start with identifying community and opinion leaders at the initiation of the grant, or even at proposal stage, and continue beyond a trial, including sharing of results. However, good community engagement is a challenge for investigators so strengthening their capacity is a priority. Community engagement was also mentioned as something not attended to in SSA, with the need to understand differences in different cultures and design interventions in consideration of these. More trials will have a cascade effect on health systems; human, economic and infrastructure development. This will also promote research and development, and there is a need for African driven pre-clinical development, while more TB and NTD research is needed.

Panel recommendations for WANETAM

- To provide additional support for better coordination within the Regional Network, among Regional Networks and with partners outside Africa.
- WANETAM should urgently implement better monitoring and coordination protocol. Better monitoring would ensure that MSc's training takes off in time and better coordination would hasten the exchange of scientists and mentoring arrangements. Continued motivation of work package leaders is essential and for this, further funding may be required.

- There is need to expand and make more timely and efficient communication means among stakeholders as well as making links between the on-going research and public health systems. Better coordination among participating researchers in the Network will also help in attaining these and broader targets. Also, key is putting in place mechanisms to ensure competency of the ethics committees in the Network.

7 Views of EDCTP Secretariat, Scientific Advisory Committee, General assembly, steering committee and other stakeholders

This section summarises key findings pertaining to all the Networks, drawing on questionnaire responses and interactions with various categories of key respondents including the EDCTP Secretariat, Steering Committee, SAC, GA as well as other stakeholders in Africa and beyond. The views of the respondents were synthesised and analysed against the main thematic areas set out in the evaluation questionnaire.

What worked well and how to sustain it, what didn't work well, and adjustments made or needed
Respondents in this category were in general agreement that the EDCTP regional networks represent an organised community for outreach and are a core asset of EDCTP. They serve as good sources of credible high-quality scientific data for bodies such as the World Health Organization (WHO). They also serve as a good sounding board for ESSENCE documents, and some consider they should be the first port of call partners for trial grant submissions, particularly EDCTP applications. Regional Networks have spawned many South-South collaborations, in addition to transcending and complementing the historical affiliations in countries, e.g. those along Anglophone, Francophone and Lusophone lines. They are contributing towards the development of excellent health research cadre, in addition to contributing towards staff retention and utilisation through the deployment of research capacities in other new or existing research areas. Non-communicable diseases will outstrip communicable diseases in morbidity shortly and the Networks are well placed in terms of core competence to expand beyond their infectious disease focus in a structured and stepwise manner. A challenge, however, will be to maintain research quality and it is important to consider new technologies. Critical factors for sustaining these Networks include flexibility in membership – integration of new members along given criteria (also allowing smaller entities working on NTDs to profit) and to adapt to epidemiological development. It may also be prudent and timely to operate as one Network of four branches with an annual agenda for cross-network strategic discussions and selected collaborative actions. A common public interactive website could help in this regard, in addition to bringing much needed visibility of the Networks.

Regional Networks have done very well in training (including in GCP, study design, GCLP, financial management) and governance models, and are well on their way to improving infrastructure. They have done particularly well with bringing together institutions (South-South networking) and are no longer working as silos. There is better communication and collaboration in activities and they now share the same vision and mission due to EDCTP being more involved in management and activities in this phase, with frequent catch-up teleconferences and information about opportunities they can take advantage of to grow and promote themselves. EACCR2 and WANETAM are ahead with shared accredited laboratories, while CANTAM2 has the strongest North-South collaboration while EACCR2 has more reciprocal monitors trained. WANETAM2 and EACCR2 are the only Regional Networks with joint projects (WANETAM plus and Exit-TB respectively). All Regional Networks are mentoring students and there are six EDCTP Fellows, five whom are integrated into the Regional Network team. All in all, 55 African institutions have upgraded trial sites and all Regional Network have steering committees and managers.

Exchanges across languages should be a norm for EDCTP, including assisting French-speaking Networks to improve in scientific English and grant writing. Particularly for CANTAM2, from the outside a stagnation is perceived. There are no new partners engaged, and an increasing gap between organisations developing with and without EDCTP. This could be overcome through encouragement, to bring new emerging and promising partners on board. Dynamism in leadership often depends on individuals; there could be more management training and encouragement to delegate and share, as these are important

for sustainable development. The inclusion/participation of centres and organisations is rather biased and based on collaborative preferences. They could have a rethink about what was promised, and what they need to reach their goals (more or different partners).

Despite gains, support to NOEs is a small part of the EDCTP budget and it may be important to develop better platforms and communities of practice that justify sustaining them and help them achieve full potential. Though generally closely linked to national programmes, they may lack focus on linking research to public health – here they could help researchers enhance efforts. On the other hand, full alignment with national agendas may not be optimal, as research needs room for creativity to become successful. More broadly, ethics and knowledge translation are important to enhance knowledge exchange between academia, public and private. The related issues not adequately addressed in agendas on trials in sub-Saharan Africa and globally include integration of teaching about clinical research (content, fascination, regulations, approaches) at an early (and every) stage of education – this mainly applies to physicians, but particularly also for nurses and other life science students.

Relevance, efficiency, effectiveness and impact of the network

Relevance of the networks rated an average 8/10 by respondents in these categories. Building networks and combating diseases of poverty whose epidemiology is constantly shifting, including emergency of epidemics, requires strong research networks in Africa for ensuring country alignment with collective efforts able to enhance capacity for countries left behind because of limited capacity, as opposed to working in silos. They are not recognised as central to research progress in their respective regions. However, there is still more work to be done for them not only to address regional needs but also continental needs. Buy-in from governments/ministries responsible for research is essential. Without this, it will be difficult for Regional Networks to be recognised within each region as key drivers for building research capacity

Efficiency rated 7/10. Significant progress has been made in many regards to efficiency, but there is room for improvement. Smooth coordination among institutions is still limited, and partners are sometimes far removed from activities and/or there is no institutional ownership or buy-in or accountability. At times the Regional Network lead coordinator does not want to delegate activities, which is not productive. Financial management could also be improved

Effectiveness rated higher at 8/10, although some outputs had not been delivered on time. It was recognised that much work has been done over the past 10 years, for example workshops that would have otherwise been out of reach for some and a career pathway developed for most long-term trainees. However, retention of the latter needs to be addressed because most talent is not being absorbed back. The Regional Networks also need to start being innovative in how they address research needs which could lead to impact and success being recognised on a regional and continental level

Impact from capacity development has been strong, for many institutions and individuals. With respect to local problems it has been average/good as the work is country driven and has a focus on PRDs. Impact with respect to regional networking is generally average and closer cooperation with RECs is required. Beyond the region impact is also average, with some strengths such as PANDORA-ID-NET and ALERRT, and weaknesses in that North-South networking is still poor. Financial/governance related impact is average/good. All have good management systems and centres but PIs (coordinators) - very senior research and institutional heads - are overwhelmed with other activities and network managers struggle to direct scientists because many are yet to recognise their pivotal role. They should have greater

authority, and scientists from weaker institutions could have greater coordinating roles with PIs delegating more.

Some activities align with regional needs, however some do not, and one notes duplication of activities and efforts with an improved coordinated approach between Regional Networks and regional bodies needed; the Regional Networks should have a seat at the table of these regional bodies and work more closely with national programmes and WHO country offices so that they are in the know of what is in these agendas and how they can align activities. National plans of involved countries should inform the Regional Network research agendas. EDCTP GA members and ministries of health (MoH) should be actively engaged in Regional Network activities. The following quote from one of the respondents illustrates this view:

> "*(Regional Networks) could help member states within their region identify methods for systematically monitoring research being done in these countries making it easier for member states in Africa to report on PSIAs (a very big challenge at the moment). I think in many of these countries there is no centralised system where this information can be extracted from. For European member states wishing to conduct research in Africa, perhaps they should make contact with the (Regional Network) in the region where they wish to conduct their research and take it from there.*"

European Member States and African Member States should use Regional Networks as instruments for their joint funding. Related to the above, is the need for Networks to learn from each other on this and other issues. For example, while there is evidence of alignment with national/regional research agendas from EACCR2 and CANTAM2, TESAII has a poor/non-existent relationship with SADC. CANTAM2 has been more successful with regards to outreach to communities by improving science among female students and funding from Total Oil for combating malaria and diarrhoeal diseases (corporate responsibility). The level of involvement of communities in trials is generally high, though funded by others, not EDCTP. Platforms for exchanging such experiences should be utilised.

While improving, the visibility of the Regional Networks is however still a problem; they need to work on better packaging and marketing themselves within each region and between regions. While each Regional Network has its own communication strategy, the EDCTP Secretariat should also look at how to strategically communicate about them to member states to ensure they are recognised as flagship projects central to driving the research agenda. There could also be a better link with EDCTP Fellows as many now hold senior positions in home countries institutions and governments; combining the Regional Networks and Fellows will give greater coverage of institutions in Africa and perhaps greater influence. The Regional Networks should also facilitate mentoring of fellowship applications, particularly from countries not applying/failing. Regional Networks have potential to bridge the gap in research capacity by bringing together different countries and should widen their scope to include more countries, particularly more institutions in left behind countries, as some are yet to submit fellowship applications, such as Burundi. There could be a formalised method to work on this established between the Regional Networks and the EDCTP Alumni Network Working Groups. Conversely, a contributory factor in the inability to achieve some deliverables is larger networks carrying inactive/unengaged members. In particular, the inclusion of northern partners in some has not really assisted, with their contribution not being visible. Restricting the networks' sizes could force them to only bring on partners who make a meaningful contribution to form strategic and mutually beneficial partnerships.

Implications of different levels of funding, ideas for adjusted funding

Forming and running new networks efficiently in Africa requires time and sustained funding with clear medium- and long-term goals. Gains can be sustained with continued training, collaboration /networking (both low hanging fruit), dialogue and coordinated efforts across Regional Networks. Access to additional funding and international level infrastructure would however assist them get to the next level, as would strategies on how to how to attract clinical trials to make use of world class facilities. Ability to attract funding should be gradually built within each Regional Network, however, core funding needs to be secured to ensure they do not fail to function between grants. Ideally, this should come from EDCTP member states and local institutions for long term sustainability beyond the duration of EDCTP grants. In the meantime, budget for the next grants should be revised upwards as limited funding is shared amongst many partners. In addition, the mandate of Regional Networks could be diversified to include funding of clinical trials. For alternative funding streams, the Regional Networks should be seen as bringing value to member states, as it may not be clear what exactly they are contributing to their research environment. Until they see tangible outputs, it will be hard to convince them of the potential the Regional Networks have or convince their governments to help fund them beyond the EDCTP grants. This is a critical part of getting buy in at country level.

Critical factors for sustainability of the Regional Network will include conducting joint activities with relevant regional entities (ethics committees, Africa Centres for Diseases Control [CDC] Regional Collaboration Centres) and demonstrating value addition by generating and disseminating data that informs national and regional guidelines and policies. Collaboration with ministries of health is also important to ensure country relevant R4H data is up to date in national health observatories. Networks should develop a long-term business strategy, with a strong financial model, innovativeness, and maintenance of world class infrastructure for world class research with tangible outputs to demonstrate impact. Long-term funding, inclusion of institutions left out in the first two cycles and bringing on board stronger partnerships from the north are important. The networks were, however, rated only an average of 37% possible to sustain themselves. To cope with reduced funding, they would need to consolidate ongoing activities (though they are already struggling to conduct current activities as funding is split across 10-16 partners). Priorities would be promoting harmonisation of SOPs and guidelines for national ethics committees, informing preparedness agenda for public health emergencies and attracting research investments, especially from industry. The Regional Network should work with the EDCTP Africa Office to negotiate cooperative agreements with RECs and Africa CDC to include Regional Network linkages with regional entities. With increased funding, they could undertake joint activities with regional entities and work with MoHs to increase National Health Research System barometer scores above 50% for all countries in the respective regions. They would be able to further improve infrastructure and strengthen systems already in place, by employing additional people to have a fully-fledged secretariat within the coordinating institution to run the specific Regional Network. Less money at this point may lead to more focus on project delivery (visibility and kudos) versus improved processes and standards and there is a risk of a fall in quality of data. However, Networks might be tempted to compete against each other to retain funds rather than pool resources and co-create common benefits or contract and focus on bigger institutes at the detriment of smaller ones or those needing capacity building.

Excellence in weak institutions, supporting novice investigators and language barriers

Achieving excellence for weak institutions involves organisational and workforce development through continuous technical support (including interactive training), empowerment and promoting leadership skills with proper and fair resource allocation. Twinning can be achieved but a clear system needs to be in place on how this will be facilitated, with clear and concrete deliverables. It is undoubted that good leadership and coordinated efforts can go a long way in ensuring the networks achieve their targets.

Some have maintained the same coordinating site which at times is not welcome by some parties, so rotation of network coordination and leadership should be considered. It would be important to encourage buy-in from the administration of institutions and governments (i.e. advocacy). Novice investigators meanwhile need mentorship and access to resources and a formal system should be created for the Regional Networks and Alumni network where novices or prospective fellows can be directed to the most appropriate person(s) for assistance through Regional Network project managers and chairs/secretaries of the alumni network working groups. Exchange programmes can help break language barriers within regional scientific communities. Though as the language of science is English, providing support to allow applicants to write better proposals in English is probably most beneficial. As such, prospective applicants can be linked with members of Regional Networks or network linked Fellows who speak French or Portuguese to assist. Otherwise, long-term exchange programmes and establishing language courses as part of clinical research capacity building are suggested. This would also contribute towards ensuring that partnerships are expanded, research is better coordinated and that expertise within the Regional Networks is fully utilized on a regional and continental level.

Additional considerations

Partnerships built on trust and a sense of community ownership need to be developed, with communities around the Regional Network feeling involved and part of decision making with information exchange through community advisory boards. Regular newsletters from the Regional Network to various stakeholders and broad partnerships strategies would also be beneficial to catalyse, manage, enhance knowledge exchange, as would fundraising and aligning with governments' agendas for more local ownership. Pan-African collaborations (inter-networking collaborations) would enhance the current Regional Networks to establish an extra level of inter-network networking.

A related and important dimension will be to identify the unique value of these partnerships over others, and what the overall EDCTP effort would gain - do they also serve as a connection point with Networks in Europe or elsewhere? There are different models to consider, but what does EDCTP want to achieve and how does this fit with its overall programme? There should be a clear link to the EDCTP programme and how partners fit and/or reinforce core EDCTP work. Large scale consortia/collaborative grants may in fact have the same impact. A mix of models could also work; pairing of weak with strong institutes and collaborative training (a "buddy system") or identify as network the most important skill at a weaker institute and take a multi-stakeholder regional network approach over a short period ("SWAT team" approach) such as for an epidemic outbreak. Funding weak institutions may help spread excellence, but new partners need to demonstrate rapid learning and full engagement. They should be included in activities, with mandatory exchanges, and mandatory inclusion of NTD institutions. Twinning could be a requirement along certain criteria – the weaker partner must have basic infrastructure and knowledge, but may have less impact in publications, or be working in a field with less impact factor. Exchanges or secondment of research fellows and/or increase use of on-line training by video conference or remote technology will help. The EU has very successful, albeit with difficulty, favoured EU's Seventh Framework Programme for Research (FP7) grants with participation of institutions of less developed countries. Selection of promising researchers from all diseases and broad selection of institutions for career development grants (and others) will help develop new researchers.

8 Conclusions

This evaluation set out to establish at a broad level, the extent to which EDCTP Regional Networks are contributing to overcoming the lack of capacity, critical mass and inadequate infrastructures that prevent many African institutions from engaging in high quality clinical research activities. Put in another way, this independent evaluation sought to assess EDCTP Regional Networks' performance and impact. Over the course of three months between July and September 2019, the four-member EP developed and deployed several techniques including document reviews, interviews, site visits and questionnaire-mediated interactions to gather views from EDCTP personnel and associated committee/assembly members and other stakeholders to explore context-specific insights to help identify potential areas of improvement for the Regional Networks. This report is the main deliverable from this evaluation, serving the dual purpose of an independent status report of the EDCTP Regional Networks and as input for informing future funding strategies and levels of such funding to the networks under EDCTP2.

This section draws out the main conclusions from the evaluation. Taking into consideration findings from the different sources accessed and assessed, this evaluation makes the following broad conclusions:

1. **To what extent have EDCTP regional networks achieved the deliverables set out in the 2015 work plan?**

As described in detail for each Regional Network, all the Networks have established significant foundations towards achieving the targets set out in the 2015 work plan. There have been delays in starting activities in some regions, while the issues of resource sufficiency, visibility, utilisation of available capacities, alignment with changing disease patterns, links with national health systems and other key stakeholders are all important and vary across the regions. Specific details on each of these points and related others have been discussed and recommendations made on how Networks can leverage their current achievements to address challenges and harness opportunities for them to meet targets. The Networks are a strong brand with increasing goodwill, which, with a balance between expectations and what is achievable, can maintain their key role in developing and availing much needed capacities for clinical research in Africa. Through these Regional Networks initiative, the EP confirms that EDCTP is playing a major role in ecosystem capacity building in Africa as mentioned in the CARI report.

2. **In specific terms how can the relevance, efficiency and effectiveness of regional networks be improved?**

The relevance, efficiency and effectiveness of Regional Networks were generally rated between moderate and high. In particular, respondents noted significant improvements across all these aspects from EDCTP1, as a result of, but not limited to the coordination and administration arrangements now in place. Robust internal monitoring and quality control systems need to be developed and sustained because they are key for the integrity, credibility as well as sustainability of the Networks.

3. **What are the implications of adjusted funding options (increasing, reducing or stopping funding) on the sustainability and impact of the regional networks?**

The Networks will need more resources in order to be able do more particularly with respect to communication facilities and infrastructure, and equally, in order to be able to sustain the achievements they have made to date. Different ways of developing and utilising capacities, partnerships, diversification options and facilitatory roles as levers for dealing with adjusted funding have been suggested. There is increasing political and collective will which provide a good background and foreground for sustaining the Networks through further funding from EDCTP and other potential partners.

9 General recommendations

Taking into consideration our findings and conclusions, and in the backdrop of the evaluation objectives, the EP advances the following general recommendations, which are in addition to the specific recommendations given for each Regional Network. The EP took the extra step of engaging with and consulting some of the key users, including Network members and EDCTP Secretariat, while drafting these recommendations, in order to ensure buy-in and a common understanding.

For EDCTP

1. At this critical stage of capacity building for the Regional NoEs, we strongly encourage EDCTP to continue supporting these Networks in order to further strengthen the capacity development phase already achieved and to sustain them in the future.
2. EDCTP is playing an important role in building systemic capacities for health research ecosystems through supporting development of infrastructures, structures, skills, tools and systems. We recommend that network leadership and succession planning be an integral part of capacity building within- and across-NoEs.
3. We would suggest increasing the financial resources available to the Regional Networks to strengthen and consolidate at the institutional level those fragile and undeveloped institutions. We also suggest for EDCTP to work closely with Networks to identify partners not delivering on their objectives so that those funds may be used elsewhere.
4. We encourage EDCTP to monitor network activities more closely and preferably by an external oversight committee (in collaboration with the project officer in charge and the monitoring and evaluation officer) who would act as a link between the networks to create a collaborative dynamic between them for an efficient use of resources.
5. We encourage EDCTP to use its influence in Africa to introduce and publicise Networks to the political decision-making world and vice versa by encouraging networks to also publicise the achievements of the EDCTP initiative among decision-makers, organisations involved in development in Africa and the scientific world in general.
6. We encourage regular evaluation of the Regional Networks and their reporting according to the performance criteria in consortia agreements.

For Regional Networks

1. An overall recommendation is for Networks to adhere to the envisaged plans and deliverables for each Network and to provide timely contextual details on deviations from the plans.
2. We recommend that the Networks rationalise the use of financial resources made available to them in order to improve efficiency using ideas proposed by the respondents during this evaluation.
3. We advise the Networks to better coordinate the management of teams and partners involved to identify early dysfunctions and implement the necessary corrective measures in a timely manner.
4. Leadership, succession planning and EDCTP alumni are important for capacity building and sustainability of the Networks. There should be clear plans within Networks and consortia on how these issues will be implemented and/or leveraged.
5. We encourage the Networks to develop an efficient communication policy in the involved countries to make known the activities and achievements undertaken in terms of capacity building (success stories, successful people, funded projects, high-calibre and impact factor publications, interactions with policymakers and influence on public policies) through clearly visible online platforms (preferably harmonised).
6. We recommend the Networks to publicise their capacities in conducting GCP clinical trials to external partners outside Africa. One key external partner who supports clinical trials in Africa stated that

Regional Networks were not known to them in terms of activities and study sites that can conduct GCP clinical trials.

7. Relatedly, we recommend that the Networks be proactive in their engagements with regional economic communities, national health ministries and other public health actors, as well as other initiatives such as the Africa CDC. These engagements would help in showcasing the Network's activities and enhancing the relevance and contribution of EDCTP's work to national and regional health agendas.
8. We suggest that the Networks should urgently ensure the competence of Ethics Committees for biomedical research as required by GCP. Clinical trials for product development require competent Ethics Committees based on GCP requirements.
9. We encourage the use of the Networks in place to prepare for the new challenges to Africa's public health, especially non-communicable diseases.

10 Roadmap for short and long-term actions for EDCTP

Short-term

1. Improve Regional Networks' management and follow-up of progress reports by contracting a third party (could be an oversight committee) having this duty as a specific assignment and by increasing the time allocation of the EDCTP officer in charge of Regional Networks.
2. Conduct a needs' assessment of weak institutions in terms of infrastructure, training and grant applications and keep them onboard if they are delivering their duties or replace them with other institutions from countries not involved in the EDCTP initiative in coordination with the NoEs management.
3. Ensure close follow-up and appraisal of contribution and commitment of northern institutions, for example through a clear roadmap of activities and deliverables for the remainder of the grant period in coordination with the NoEs management.

Medium and long-term

1. Revisit inclusion criteria for Regional Networks' renewal to target institutions that delivered well on previous workload and expand to new countries not already involved.
2. Limit the number of involved weak institutions but have a reasonable budget available to make an impact on their infrastructure and capacity building. Relatedly, EDCTP could provide seed funding towards strengthening proposal development and applications by weak institutions.
3. Improve the interaction and exchange between Regional Networks for students, faculty and trial monitors. The creation and use of e-Learning platforms could help in this regard.
4. Alternate the EDCTP forum organisation between North (Europe) and South (Africa) to better embed capacities and disseminate the activities and results of the EDCTP initiative.
5. Elaborate a roadmap for all sub-Saharan Africa countries involvement in EDCTP activities to spread science and excellence to the whole continent.

Acknowledgments:
The Evaluation Panel is grateful to the European and Developing Countries Clinical Trials Partnership (EDCTP) for the opportunity to carry out this evaluation. Gratitude is also due to EDCTP Networks of Excellence, research partners and colleagues in Network countries and other stakeholders for agreeing to set aside time to contribute to this evaluation. The iMTE panel members also acknowledge the contribution of Isayvani Naicker in reviewing the final report and making suggestions based on her participation in the inception phase of the evaluation (see Annex 1a).

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Annex 1a

iMTE Inception Report

Inception Report
Mid-term independent evaluation of the EDCTP Regional Networks 2017-2020

Submitted 31 July 2019

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Acknowledgments
The Evaluation Panel is grateful to the European and Developing Countries Clinical Trials Partnership (EDCTP) for the opportunity to carry out this evaluation. Gratitude is also due to EDCTP Networks of Excellence, research partners and colleagues in network countries for agreeing to set aside time to contribute to this evaluation.

List of Abbreviations and Acronyms

CANTAM	Central African Network for TB, AIDS, and Malaria
EACCR	East African Consortium for Clinical Research
EDCTP	European & Developing Countries Clinical Trials Partnership
EP	Evaluation Panel
ICH-GCP	International Conference on Harmonization guidelines for Good Clinical Practice
iMTE	independent Mid-Term Evaluation
NoE	Networks of Excellence
PSIAs	Participating States Initiated Activities
RN	Regional Network
SSA	Sub-Saharan Africa
SOPs	Standard Operating Procedures
TESA	Trials of Excellence in Southern Africa
TOR	Terms of Reference
WANETAM	West African NoE for TB, AIDS, and Malaria

1 Introduction

1.0 Background and Introduction

This Inception Report for the **Independent Mid-term Evaluation of the EDCTP Regional Networks 2017-2020** (iMTE) describes how the Evaluation Panel (EP) will fulfil the Terms of Reference (ToR – Annex 1a). This is the first output from the evaluation and is based on both an initial document review and preliminary consultations with selected EDCTP staff. It lays the foundation for the remainder of the evaluation by providing key information on the proposed scope and focus of the evaluation, the planned methodology, and the way in which the evaluation will be organised. It includes some data collection instruments which are a key part of the methodology. Preliminary findings of document reviews will be presented in a separate report mid-August in accordance with discussions in the evaluation start-up meeting.

As detailed out in the ToR, the main purpose of this evaluation is to perform an independent assessment of EDCTP-supported Regional Networks in Africa to establish, among others, the relevance, efficiency, effectiveness, as well as impact and sustainability prospects of the four regional networks. The EP will therefore access and evaluate evidence from a number of different sources towards fulfilling this purpose.

This Inception Report has been compiled following literature reviews, stakeholder mapping and preliminary discussions with some key EDCTP staff. The same activities also provided key elements for the research instruments which are attached as Annex 2. A draft list of interviewees targeted for the evidence-gathering phase of the evaluation is attached as Annex 3.

2 Timescale and Scope of the iMTE

2.0 Timescale

It was initially envisaged in the ToR that the iMTE would be conducted over a 5-month period between 30 April and 30 September 2019. However, the timing of the evaluation has slipped, and the study will now take place over 3 months between 1 July and 30 September 2019. While this compressed timeframe will undoubtedly impact the evaluation process, the EP will minimise any negative impact by running some activities concurrently, e.g. document reviews, data collection, analysis and report-writing. Table 1 below shows the timeline for the evaluation.

Table 1: EDCTP NoE iMTE Timescale

Evaluation phase	Activity/Deliverable	Meetings/Presentations	Responsible	By when
Evaluation design and desk study	Desk review (collection and/or analysis) of available data and documentation	Fortnightly EP teleconferences and regular email exchanges	EP	By 31 July, 2019
	Refining methodological approach			
	Submission of inception note (draft and final)			
	Submission of desk review findings synthesis			By 16 Aug, 2019
Data collection, analysis and reporting	Data collection and analysis	Fortnightly EP teleconferences and regular email exchanges	EP	By 13 Sept, 2019
	Submission of draft report			
	Management response		EDCTP	By 30 Sept, 2019
	Submission of final report		EP	
Dissemination and follow-up	Preparation and delivery of PowerPoint Presentation	Concluding presentation meeting at EDCTP in The Hague	Panel Chair and Rapporteur	By 30 Sept, 2019

2.1 Scope of the Study

Primary and secondary data collections will be done in all the four Regional Networks, namely West African NoE for TB, AIDS, and Malaria (WANETAM); East African Consortium for Clinical Research (EACCR); Central African Network for TB, AIDS, and Malaria (CANTAM); Trials of Excellence in Southern Africa (TESA); and EDCTP Secretariat departments in The Hague and Cape Town. This iMTE will also encompass as contributors and beneficiaries, key health research and clinical trials stakeholders from the study regions, representatives of regional economic communities, academic institutions, civil society and other users, as well as current and former EDCTP fellows. As detailed in the methodology section, we will use mixed data collection methods, including document review, questionnaires, and semi-structured interviews with key informants in the Regional Networks to gather primary data and for cross-checking secondary data obtained in the desk studies.

3 Evaluation Methodology

3.0 Methodological approach

The EP sees this iMTE as both an assessment of the relevance, efficiency, effectiveness, impact and sustainability prospects of EDCTP-supported regional networks and an endeavour to contribute learning to the health research arenas of the study regions and beyond. To these ends, the methodology adopted for this study is informed by the ToR (Annex 1a) and EDCTP's 'mission to support collaborative research that accelerates the clinical development of new or improved interventions (drugs, vaccines, microbicides and diagnostics) to prevent or treat HIV, tuberculosis, malaria and neglected infectious diseases including emerging and re-emerging infections affecting sub-Saharan Africa'. The ToR and EDCTP mission both prescribe a multi-method approach in carrying out the iMTE.

3.1 Objectives

The evaluation methodology further draws from the following objectives as set out in the Terms of Reference, which are to:

1. Assess the status of the project performance so far, including progress towards agreed deliverables, project management and the likelihood of successful completion
2. Assess the results at outcome and impact level (if applicable) of the four Regional Networks so far, particularly concerning their capacity to conduct clinical research and trials according to ICH-GCP standards
3. Review any other project relevant documentation such as training programmes, Standard Operating Procedures (SOPs), Inspection Reports from Health Authorities and any audits conducted at any of the participating institutes
4. Provide recommendations and suggestions for enhanced relevance of the networks to emerging regional priorities and how to foster their engagements with other networks and consortia with or without EDCTP funding
5. Assess the implications of adjusted funding options (increasing, reducing or stopping funding) from EDCTP, on the sustainability and impact of the networks.

3.2 Key Evaluation Questions

The iMTE methodology will seek to address the following overarching evaluation questions which will be broadened into more specific questions in the evaluation checklist:

- to what extent have EDCTP regional networks achieved the deliverables set out in the 2015 workplan?
- how best can the relevance, efficiency and effectiveness of regional networks be enhanced?
- what are the implications of adjusted funding options (increasing, reducing or stopping funding) on the sustainability and impact of the regional networks?

Within and across the different evaluation questions and objectives, the iMTE will also uncover the extent of spread of excellence between the regional networks and to/from other non-EDCTP networks or consortia.

3.3 Conceptual Framework

We have constructed a conceptual framework for the evaluation drawing from the objectives and key evaluation questions above to bring together key evaluation topics, indicative questions and key methods that we will use to explore each topic:

Table 2: EDCTP iMTE Key Evaluation Topics, Indicative Questions and Data Collection Methods

Topic	Indicative Evaluation Questions	Desk Research	Internal Interviews	External Interviews	Site visits	Case studies
Partnerships	To what extent is there interaction or collaboration within the network and/or between regional networks?	X	x	X	x	X
	To what extent is there sharing the use of resources and infrastructures within the network and/or between regional networks?	X	x		x	
	To what extent is there collaboration between the South-South (S-S) and/or North-South (N-S) to enhance capacity to conduct high quality research?	X	x	X	x	X
Expertise	To what extent is there expertise to conduct clinical trials based on ICH GCP standards?	X	x	X	x	
	To what extent is there competitiveness for research funding, especially for clinical trials?	X	x	X	x	
	To what extent is there capacity to monitor clinical studies within the network and/or other regional networks?	X	x	X	x	X
Training	To what extent is there formal training and mentorship within the network and/or between regional network to promote professional development and scientific leadership in clinical trials? Relatedly, what evidence is there of training and/or mentoring of less established institutions and novice researchers	X	x		x	
Infrastructure	To what extent is there capacity for laboratories to participate in clinical trials within networks and/or across regional networks?	X	x	X	x	
	To what extent is there capacity of data management to perform in the clinical trials within network and/or regional networks	X	x	X	x	
	To what extent is there study site physical infrastructure to conduct clinical trials?	X	x	X	x	
Organisation, Governance & Financial management	What communication/interaction process and information sharing has been used within the network (researcher, community, policy maker, and regulatory authorities) to maximise the impact of clinical research in Africa?	X	x		x	
	Are the current governance and financial management processes effective and efficient?	X	x		x	X

Research	How relevant is the research undertaken to the population of the countries in which the research is undertaken?	X	x			X
	How many health products have been generated from research undertaken in the network? What is the contribution of research data towards registration of new product(s)	X	x			X

Source: Developed by EP based on ToRs

This evaluation framework above serves as a guide bringing together the key areas of focus for this evaluation and how they will be assessed individually and collectively to form an objective basis for feasible priorities and future targets for the regional networks and EDCTP. Table 3, to follow, builds on this framework to elaborate on links and rationale between data sources, collection methods and evaluation objectives.

3.4 Data collection and analysis methods

Data collection

This iMTE adopts a case study approach, with the RNs and their projects serving as case studies for careful analysis of the key areas of focus for the evaluation. Desk reviews will be conducted against an evaluation checklist based on the conceptual framework above, while interviews will be conducted using emailed questionnaires and/or semi-structured interview guides for different respondent categories (Annexes 2a and 2b) to ensure that the questions posed in the ToR are covered in a complete and consistent manner. The EP will also keep running notes of any other relevant points made by the various stakeholders during site visits, or observations they make that are relevant to the evaluation (e.g. of interactions with the RNs or with external parties). Using the case study approach is best suited for this type of evaluation for the deep and close in-situ investigation that we will be able to obtain. Informed consent will be sought from interviewees and, where feasible and desirable, anonymity will be preserved. The identified case studies, primary and secondary data will form the basis for compilation of a detailed Evaluation Report and a PowerPoint Presentation summarising key evaluation findings, conclusions and recommendations.

Data analysis

We will analyse the qualitative data using thematic analysis and tabulation and statistical analysis for quantitative data sets. Analysis will be based on the principle of triangulation of data from varied sources. The triangulation will be undertaken within and between Regional Networks. The semi-structured nature of the study instrument will allow the EP to ensure on one hand that all key questions are covered, and on the other that the team is alert to unexpected information when it comes to light. Data will be disaggregated as appropriate, primarily along the lines of Regional Networks, but also taking into consideration the purpose and objectives of the evaluation which include impact beyond the networks. We will also do a cross-RNs analysis on specific thematic areas and identify best policy and practice lessons that RNs and countries may adopt. Meanwhile, Table 3 below, builds on the conceptual framework to show the link between interviewee categories, data collection methods and evaluation questions, while Table 4 shows the EP members' roles in the evaluation.

Table 3: EDCTP NoE iMTE interviewees, contribution to the study and proposed data collection methods

Stakeholder Category	Data Collection Methods[2]	Contribution to Evaluation Objectives, Questions and Findings
Regional Networks	Document reviews Key informant interviews	• to what extent have EDCTP regional networks achieved the deliverables set out in the 2015 workplan? • how best can the relevance, efficiency and effectiveness of regional networks be enhanced? • what are the implications of adjusted funding options (increasing, reducing or stopping funding) on the sustainability and impact of the regional networks?
EDCTP Secretariats	Document review Key informant interviews Feedback forums	• to what extent have EDCTP regional networks achieved the deliverables set out in the 2015 workplan? • how best can the relevance, efficiency and effectiveness of regional networks be enhanced? • what are the implications of adjusted funding options (increasing, reducing or stopping funding) on the sustainability and impact of the regional networks?
Regional Economic Communities	Document reviews Key informant interviews	• to what extent have EDCTP regional networks achieved the deliverables set out in the 2015 workplan? • how best can the relevance, efficiency and effectiveness of regional networks be enhanced?
Academic Institutions	Document reviews Key informant interviews	• to what extent have EDCTP regional networks achieved the deliverables set out in the 2015 workplan? • how best can the relevance, efficiency and effectiveness of regional networks be enhanced? • what are the implications of adjusted

[2] We are aware that some of these methods may not be feasible to deploy for a number of reasons, but it is our intention to ensure that we use a wide array of methods to ensure that we access and triangulate our data sources.

		funding options (increasing, reducing or stopping funding) on the sustainability and impact of the regional networks?
EDCTP Fellows	Key informant interviews	• to what extent have EDCTP regional networks achieved the deliverables set out in the 2015 workplan? • how best can the relevance, efficiency and effectiveness of regional networks be enhanced? • what are the implications of adjusted funding options (increasing, reducing or stopping funding) on the sustainability and impact of the regional networks?
Donors, civil society and beneficiaries	Key informant interviews Document reviews	• to what extent have EDCTP regional networks achieved the deliverables set out in the 2015 workplan? • how best can the relevance, efficiency and effectiveness of regional networks be enhanced? • what are the implications of adjusted funding options (increasing, reducing or stopping funding) on the sustainability and impact of the regional networks?

Table 4: EDCTP NoE iMTE Evaluation Panel Member Expertise & Role

Name	Expertise and Role
Hassen Ghannem	Panel chair. A Medical Doctor with a Masters Degree in Community Health from the University of Montreal, Canada and is currently Professor of Community Medicine at the Faculty of Medicine of Sousse and Head of the Epidemiology Department at the Farhat Hached University Hospital in Tunisia. He was Senior Advisor to the Council on Health Research for Development COHRED for North Africa & Middle East
Julius Mugwagwa	Rapporteur. A biotechnologist with a research focus on the development and governance implications of technologies and innovations, particularly the role of health policy and governance structures in providing an enabling environment for health research. He is based at University College London, United Kingdom where teaches and researches on innovation and development.
Elizabeth Allen	Panel member. A pharmacist with post-graduate degrees in Public Health (Epidemiology) and Clinical Pharmacology. Head of Clinical Research at the Collaborating Centre for Optimising Antimalarial Therapy at the University of Cape Town, South Africa
Juntra Karbwang	Panel member. A Medical Doctor with a PhD in Clinical Pharmacology from University of Liverpool, UK and is currently Professor and Head of Clinical Product Development at Nagasaki University, Japan

3.5 Limitations of the methodology

There a few limitations to the proposed evaluation methodology, which the EP will take into consideration in the process of carrying out the evaluation and interpreting its findings. The first limitation is that some patchiness in the findings is expected due either to unavailability of data for some historical dimensions of the evaluation, or to lack of access to respondents even for some contemporary issues. The EP will use triangulation and proxies to deal with these envisaged challenges. The second and related limitation concerns availability of quantitative and qualitative data, with the former being harder to find at the right levels of currency and consistency, especially if it is financial data. Where quantitative measures are missing but desirable for supplementing qualitative data, we will create categories or Likert-scored scales from the qualitative data. The third limitation relates to low response rates from the targeted respondents, which we will mitigate by utilising EDCTP secretariats in setting up appointments and gaining access to respondents.

3.6 Quality Assurance

Apart from employing conceptually, methodologically and ethically-sound evaluation approaches, further quality assurance mechanisms for the evaluation will include:

a) Triangulation of data and findings through the use of a range of methods as detailed in section 3.5;
b) Continuous engagement with EDCTP to ensure that the evaluation scope and process are still in line with the ToR and EDCTP's mission. This will in no way compromise the independence of the evaluation as set out in the ToR;
c) Leveraging our extensive and transferable knowledge of the clinical trials and health research arena in Africa and globally to ensure accuracy and validity of findings.

Meanwhile, given the currency, relevance and importance of the clinical trials and health research health agenda in Africa broadly, there are no significant risks envisaged for the evaluation which the adopted methodological approach and quality assurance mechanisms would not be able to deal with.

Terms of Reference

1. Evaluation Background and Context

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between 16 African and 14 European countries. These 30 countries, also called the Participating States (PSs), are full members of the EDCTP Association. EDCTP's mission is to support collaborative research that accelerates the clinical development of new or improved interventions (drugs, vaccines, microbicides and diagnostics) to prevent or treat HIV, tuberculosis, malaria and neglected infectious diseases including emerging and re-emerging infections affecting sub-Saharan Africa. EDCTP funds all phases of clinical trials (I–IV), with a focus on phase II and phase III studies. Our post-licensing (phase IV) studies encompass pharmacovigilance and effectiveness studies (pragmatic trials) as well as medicinal product-focused implementation research. In parallel, EDCTP funds strengthening of research enabling environment in sub- Saharan Africa through grants in training (fellowships), strengthening ethics and regulatory frameworks and internationally collaborative (north-north, south-south and north-south) research networks. The second EDCTP programme (EDCTP2) is implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020.

In 2015, EDCTP launched a call for proposals for EDCTP Regional Networks (Annex 1). The call provided funding for actions that aim to support regional networking in sub-Saharan Africa and Europe in order to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials in line with the International Conference on Harmonization guidelines for Good Clinical Practice (ICH-GCP). These networks are expected to contribute to overcoming the lack of capacity, critical mass and adequate infrastructures that prevent many African institutions from engaging in high quality clinical research activities. Moreover, these networks build on results from former EDCTP-funded regional networking actions with the aim of strengthening the scientific and clinical research environment for conducting clinical trials in sub-Saharan Africa.

Specific objectives of the networks also include:

- To strengthen collaboration and optimise the use of resources and infrastructures within the network
- To offer training and mentorship aimed at promoting professional development and scientific leadership in clinical trials
- To strengthen South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established institutions in building capacity for conducting high quality clinical research
- To encourage and promote networking and dialogue between researchers, communities and policy makers to maximise the impact of clinical research in Africa.

Four networks covering four geographically defined areas in sub- Saharan Africa; Southern, Eastern, Western and Central Africa; were selected following independent evaluation and were awarded a 36-month grant worth approximately EUR 3 Million. The EDCTP Regional Networks are:

- Trials of Excellence in Southern Africa II – TESAII
- Eastern Africa Consortium for Clinical Research 2 – EACCR2
- West African Network for TB AIDS and Malaria – WANETAM
- Central Africa Clinical Research Network – CANTAM2.

In accordance with the 2015 work plan call text, successful networks that demonstrate satisfactory progress by the end of 36 months may be given an opportunity to apply for an additional 5-year grant. Furthermore, in line with EDCTP Response to the Recommendations of the 1st Interim evaluation of EDCTP Programme (2014-2016), EDCTP will "Commission an independent evaluation of the EDCTP Regional Network's performance and impact ". It is therefore against this backdrop that EDCTP seeks to appoint an evaluation panel to perform an independent assessment. The evaluation will produce a status report of the EDCTP Regional Networks and serve as input for informing future funding strategies and levels of such funding to the networks under EDCTP2.

2. Evaluation purpose and objectives

The purpose of the evaluation will be to perform an independent assessment of the EDCTP supported Regional Networks. The objectives of the evaluation will be to:

- Assess the status of the project performance so far, including progress towards agreed deliverables, project management and the likelihood of successful completion
- Assess the results at outcome and impact level (if applicable) of the four regional networks so far, particularly concerning their capacity to conduct clinical research and trials according to ICH-GCP standards
- Review any other project relevant documentation such as training programmes, Standard Operating Procedures (SOPs), Inspection Reports from Health Authorities and any audits conducted at any of the participating institutes
- Provide recommendations and suggestions for enhanced relevance of the networks to emerging regional priorities and how to foster their engagements with other networks and consortia with or without EDCTP funding
- Assess the implications of adjusted funding options (increasing, reducing or stopping funding) from EDCTP, on the sustainability and impact of the networks.

3. Evaluation scope, approach and methodology

The assessment will cover the four projects awarded under the EDCTP Regional Networks call for proposal (Annex 1) which entered implementation in the third and fourth quarter of 2017. EDCTP will appoint an evaluation panel comprising four to five independent experts with complementary expertise. Each Panel member will be appointed based on meeting at least one of the following criteria:

- Substantial expertise in managing and conducting evaluations of projects/programmes in health research and/or (health) research capacity building supported by the EU
- Thematic expertise regarding global health, poverty-related diseases, including neglected ones, and/or clinical trials, including legal and other regulatory aspects, especially from low-income countries in Africa
- Strong experience in research capacity building, especially from low-income countries in Africa
- Experience in conducting interviews/surveys, conducting desk reviews of documents, and drafting evaluation reports in English
- Knowledge in the field of Horizon 2020's societal challenge "health, demographic change and wellbeing", and in mission-oriented research and research funding.

The methodology to be used must be identified and elaborated by the experts in the inception note, but will include, at a minimum the following qualitative and quantitative elements:

1. Desk review of relevant EDCTP documents, including but not limited to:

- EDCTP2 Strategic Business Plan (2014 – 2024)
- First interim evaluation report of the EDCTP2 programme (2014-2016)
- Call text EDCTP Regional Networks
- EDCTP2 Grant Agreements with the four regional networks
- EDCTP2 Regional Network first technical progress reports
- Most recent status technical updates from each network.

2. Interviews to be conducted by the experts with selected:

- EDCTP Secretariat staff
- Representatives of regional economic communities in which the regional networks are situated, or research ministries and health ministries in countries with participating institutions in networks.
- Network end-users/beneficiaries such as heads of research institutes, students and support staff.
- A selection of EDCTP fellows (current and former) that are actively involved in EDCTP Alumni working groups.

Other relevant stakeholders.
The interviews can be conducted through face-to-face meetings (including site visits of the network coordinating sites), by phone, by videoconference, or by email. EDCTP will make relevant documents and data available to the expert panel. However, the experts are also expected to independently collect data, or documents, when deemed suitable and necessary. The collective tasks of the experts will be the following:

Follow the Terms of Reference as the basis for the evaluation

- Study relevant background documents
- Devise a detailed methodology and plan for conducting the evaluation, including the method of working and distribution of responsibilities within the group of experts, as well as the identification of further information that is required to conduct the evaluation
- Collect information and conduct interviews
- Analyse the acquired information
- Deliver an evaluation report with recommendations that are prioritised, targeted and feasible to implement.

4. Reporting requirements and timelines

The following should be delivered by the experts:

- Inception note (not exceeding 10 pages excluding annexes) which describes preliminary findings of document review, methodological approach, evaluation questions and indicators as well as data collection tools/sources as well as list of persons to be interviewed.
- Evaluation Report (should not exceed 50 pages excluding annexes) containing full evaluation findings, conclusions and recommendations
- PowerPoint Presentation summarising key evaluation findings, conclusions and recommendations.

The experts should deliver their final evaluation report no later than 30 September 2019.

Annex 2a

Emailed questionnaire/Interview Guide for EDCTP Regional Networks, Local, Africa and Global Partners

Independent Mid-Term Evaluation of EDCTP Regional Networks of Excellence

Background

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between 16 African and 14 European countries. These 30 countries, also called the Participating States (PSs), are full members of the EDCTP Association. EDCTP's mission is to support collaborative research that accelerates the clinical development of new or improved interventions (drugs, vaccines, microbicides and diagnostics) to prevent or treat HIV, tuberculosis, malaria and neglected infectious diseases including emerging and re-emerging infections affecting sub-Saharan Africa. EDCTP funds all phases of clinical trials (I–IV), with a focus on phase II and phase III studies. In 2015, EDCTP launched a call for proposals for EDCTP Regional Networks. The call provided funding for actions that aim to support regional networking in sub-Saharan Africa and Europe in order to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials in line with the International Conference on Harmonization guidelines for Good Clinical Practice (ICH-GCP). These networks are expected to contribute to overcoming the lack of capacity, critical mass and adequate infrastructures that prevent many African institutions from engaging in high quality clinical research activities.

Independent Evaluation of Regional Networks

In accordance with the 2015 call for proposals and recommendations of the 1st Interim evaluation of the EDCTP Programme (2014- 2016), EDCTP has commissioned an independent evaluation to assess EDCTP Regional Networks' performance and impact. This independent assessment will produce a status report of the EDCTP Regional Networks and serve as input for informing future funding strategies and levels of such funding to the networks under EDCTP2.

Purpose of this questionnaire and interview

This questionnaire/interview seeks to gather views from ECDTP Regional Networks of Excellence, participating organisations and other key stakeholders to identify context-specific insights to help explore potential areas of improvement for Regional Networks. These interviews will complement observations, discussions and questions of/with EDCTP personnel, advisory committee and general assembly members. Together, the information gathered is expected to provide information to the supervising bodies of research entities (EDCTP Secretariats) and development partners to help them make management or funding decisions based on the findings of the evaluation. We seek your contribution to this endeavour through completing this questionnaire either by email or through a conversation. All responses will be anonymised in the analysis and evaluation reports, with particular care taken where there are few people in a specific role). You do not have to answer any question that you feel is not relevant to you or that you would prefer not to answer. You will be included in the distribution lists for the evaluation outputs which are due in early 2020.

1.0 Respondent details

1.1 Your name (optional): ……..
1.2 Your country: ……
1.2 Your organisation: ……
1.3 Position in own organisation: …… ……..
1.4 EDCTP Regional Network(s) that you are affiliated to:……
1.5 Role in the Regional Network(s):……

2.0 Status and performance of Regional Networks or Partner Organisations

- Please state the main activities of your Regional Network or organisation according to the 2015 work plan?
- How would you describe the level of accomplishment of these activities against set targets? **(See performance indicators checklist)**
- What has worked well and why?
- In your view, how best can these be sustained?
- What has not worked well and why?
- Explain any adjustments that have been made to address the situation?
- Are there any (other) constraining factors/challenges currently and in the future?
- How can these be resolved?
- What overall lessons can be learnt from previous and current EDCTP activities in your region or country?

3.0 Relevance, efficiency and effectiveness of Regional Networks

- On a scale of 1 to 10, how would you rate the relevance (*appropriateness)* of the work of Regional Networks?
- Give reasons for your rating
- On a scale of 1 to 10, how would you rate the efficiency *(doing things right)* of the work of Regional Networks?
- Give reasons for your rating
- On a scale of 1 to 10, how would you rate the effectiveness *(doing the right things)* of the work of Regional Networks?
- Give reasons for your rating
- Using descriptors such as weak, average or strong, how would you describe the impact of the Regional Network(s) with respect to?
    - Capacity development. (e.g. curriculum development/training, mentorship, regulatory, ethical, infrastructure, community engagement)
    - Research to address local problems
    - Regional networking activities
    - Networking beyond the region
    - Governance and financial management
    - Other (specify)
- Please give examples for each description and category
- How best can the relevance, effectiveness and efficiency of the Regional Networks be enhanced?
- How can your Regional Networks ensure (or have they ensured) that their activities align with and catalyse national research agendas, activities, policies and programmes?
- Please suggest ways for Participating States Initiated Activities (PSIAs) or EDCTP Participating States research to bridge/align with the Regional Networks activities?

4.0 Adjusted funding options and implications for sustainability and impact of the Regional Networks

- In your opinion, what are the 3 or 4 critical factors for sustainability of the Regional Network(s)?
- In percentage terms, how ready is the Regional Network you are associated with, to sustain itself?

- What would the Regional Network be able to do in the next 5 years with reduced funding?
- What would it not be able to do and why?
- What priorities should be pursued?
- How about with the same level of funding?
- Or with increased funding?
- If adjustments in funding were to be embarked on, how best should they be done?
- What role is your organisation playing in ensuring impact and sustainability of the Regional Network?

5.0 Supporting under-reached researchers and institutions

- What model of capacity development do you think would fit better for spreading excellence in weak institutions around the Regional Network 'headquarter', if at all?
- How do you envision that strong institutions will engage in twinning less established institutions to respond to call for research proposal or career development fellowships in the future?
- Do you think that funding weak institutions under the leadership of established Regional Networks will lead to spreading excellence in science & research in Africa?
- What are your suggestions for engaging with, and supporting novice investigators through the Regional Network(s)?
- How do you envision the Regional Networks may be used as a platform to break language barriers within regional scientific communities?

6.0 Beyond current Regional Networks, are there other forms of partnership that are useful and effective?

- Can you suggest other forms of partnership or business models that should be considered for collaborative scientific and clinical trials research?
- Would they be replacing or complementing current RNs? Reasons for your suggestion
- Thinking about EDCTP and other key others in collaborative clinical trials research, please suggest some actions that you think they should take to catalyse, manage and enhance knowledge exchange between academia, public and private actors in this area of health.
- What issues do you think are not being adequately attended to in the agendas on clinical trials in Sub-Saharan Africa and globally?
- Finally, do you have any other thoughts to share relating to this evaluation of EDCTP Regional Networks?

Annex 2b

Emailed questionnaire/Interview guide for EDCTP 'Personnel'

Independent Mid-Term Evaluation of EDCTP Regional Networks of Excellence

Background

As you may know, in accordance with the 2015 call for proposals and recommendations of the 1st Interim evaluation of the EDCTP Programme (2014- 2016), EDCTP has commissioned an independent evaluation to assess EDCTP Regional Networks' performance and impact. This independent assessment will produce a status report of the EDCTP Regional Networks and serve as input for informing future funding strategies and levels of such funding to the networks under EDCTP2. In anticipation of this evaluation, you will have been sent the latest reports from the Regional Networks.

Purpose of this questionnaire/interview

This questionnaire seeks to gather views from ECDTP personnel and associated committee/assembly members and other stakeholders to identify context-specific insights to help identify potential areas of improvement for Regional Networks. Responses from these questionnaires will complement observations, discussions and questions of/with those working within or alongside Regional Networks. Together, the information gathered is expected to provide information to the supervising bodies of research entities (EDCTP Secretariats) and development partners to help them make management or funding decisions based on the findings of the evaluation. We seek your contribution to this endeavour through responding to this questionnaire. All responses will be anonymised in the analysis and evaluation reports. with particular care taken where there are few people in a specific role). You do not have to answer any question that you feel is not relevant to you or that you would prefer not to answer. You will be included in the distribution lists for the evaluation outputs which are due in early 2020.

1. Respondent details

1.1 Name (optional):.....

1.4 Role in EDCTP Regional Networks(s): Secretariat □ General Assembly □

2. Status and performance of Regional Networks or Partner Organisations

- What is your opinion of the level of accomplishment of the Regional Network(s) against set targets? Please reflect on specific targets as appropriate **(see performance indicators checklist)**.
- What has worked particularly well and why?
- In your view, how best can these gains be sustained?
- What has not worked well and why?
- Do you feel the Regional Network(s) made adjustments to address the situation?
- Are there any (other) constraining factors/challenges currently and in the future that may prevent the Regional Network(s) achieving their targets?
- How can these be resolved?
- What overall lessons can be learnt from previous and current EDCTP activities in the Regional Networks?

3. Relevance, efficiency and effectiveness of Regional Networks

- On a scale of 1 to 10, how would you rate the relevance of the work of Regional Networks, and why?
- Do the activities align with regional research needs?

- On a scale of 1 to 10, how would you rate the efficiency of the work of Regional Networks, and why?
- On a scale of 1 to 10, how would you rate the effectiveness of the work of Regional Networks, and why?
- Using descriptors such as weak, average or strong, how would you describe the impact of the Regional Network(s) with respect to?
    - Capacity development. (e.g. curriculum development/training, mentorship, regulatory, ethical, infrastructure, community engagement)
    - Research to address local problems
    - Regional networking activities
    - Networking beyond the region
    - Governance
    - Other (specify)
- Please can you give any examples for each description and category
- How best do you think the relevance, effectiveness and efficiency of the Regional Networks may be enhanced?
- How will the Regional Networks ensure or have ensured that their activities align with and catalyse national research agendas, activities, policies and programmes?
- How do you think, or can you suggest ways PSIAs or EDCTP Participating States research can bridge/align with the Regional Networks activities?

4. Adjusted funding options and implications for sustainability and impact of the Regional Networks

- In your opinion, what are the 3 or 4 critical factors for sustainability of this Regional Network(s)?
- In percentage terms, how ready is/are the network(s) to sustain itself/themselves?
- What would the network(s) be able to do in the next 5 years with reduced funding?
- What would it/they not be able to do and why?
- What priorities should be pursued by the network(s)?
- How about with the same level of funding?
- Or with increased funding?
- If adjustments in funding were to be embarked on, how best should they be done?

5. Supporting under-reached researchers and institutions

- What model of capacity development do you think would fit better for spreading excellence in weak institutions around the Regional Network 'headquarter', if at all?
- How do you envision that strong institutions will engage in twinning less established institutions to respond to call for research proposal or career development fellowships in the future?
- Do you think that funding weak institutions under the leadership of established Regional Networks will lead to spreading excellence in science & research in Africa?
- What are your suggestions for engaging with, and supporting novice investigators through the Regional Network(s)?
- How do you envision the Regional Networks may be used as a platform to break language barriers within regional scientific communities?

6. **Beyond the current Regional Networks, are there other forms of partnership that would be useful and effective?**
    - Can you suggest other forms of partnership or business models that should be considered for collaborative scientific and clinical trials research?
    - Would they be replacing or complementing current Regional Networks? Reasons for your suggestion
    - Thinking about EDCTP and other key others in collaborative clinical trials research, please suggest some actions that you think they should take to catalyze, manage and enhance knowledge exchange between academia, public and private actors in this area of health.
    - What issues do you think are not being adequately attended to in the agendas on clinical trials in Sub-Saharan Africa and globally?
    - Finally, do you any other reflections or thoughts you wish to share in relation to this evaluation?

Performance Indicators Checklist

Topic	Evaluation Questions/Areas	Indicators	Data Sources
Partnership	Evidence of interaction or collaboration within and between regional networks	# of cross-NoEs publications done • Since the initial launch of the NoE. • Since the renewal of the NoE	**Documents** -Approved applications -Technical Progress reports - site visit reports **Interviews**
		# and reports of scientific conferences/ meetings # of shared laboratories, CRAs etc	
	Sharing of resources and infrastructures within and between regional networks	# of shared laboratories for GCP trials	
		# of shared resources – experts etc.	
	Evidence and extent of collaboration between South-South (S-S) and/or North-South (N-S) to enhance capacities to conduct high quality research	# and strength of S-S collaborations on GCP clinical trials	
		# and strength of N-S collaborations on GCP clinical trials	
Expertise	Availability of capacity to conduct clinical trials based on ICH GCP standard	# of GCP trials managed by network with other funding	
	Capacity and competitiveness for research fund bidding, especially for clinical trials	# of grant received for research • Since the initial launch of the NoE. • Since the renewal of the NoE	
	Evidence of capacity to monitor clinical studies within the network and/or other regional networks	# of well-trained CRAs that have been utilized by other organisations	
Training	Evidence of formal training and mentorship within the network and/or between regional networks to promote professional development and scientific leadership in clinical trials	# Formal training course • Clinical trial Study design • GCLP lab training • Financial Management	
		# Mentors	
		# Fellows • Since the initial launch of the NoE. • Since the renewal of the NoE	
		# Fellows who were integrated into the NoE team as part of career path • Since the initial launch of the NoE. • Since the renewal of the NoE	
		• # Trainees • Since the initial launch of the NoE. • Since the renewal of the NoE	

Infrastructure	Existence of laboratories equipped and able to participate in clinical trials within or across regional networks	# Accredited Labs since the launch of the NoE	
	Availability and contribution of data management systems to clinical trials within and/or networks	# of functional data management frameworks	
	Evidence of capacity for study site to conduct clinical trials	# of new or ungraded clinical trial sites (GCP standards)	
		# of functional ethics committees established	
Governance	Availability and use of communication/interaction processes and information sharing arrangements within the network (researcher, community, policy maker, and regulatory authorities) to maximise the impact of clinical research in the network countries and beyond	Overview of communication activities and outputs for: • Researchers • Communities • Policy makers/regulators	
	Evidence of effective and efficient network governance and management processes.	• Overview of governance structure • Costs of different management structures • Judgment (scale 1-10) on effectiveness and efficiency of the process	
	Evidence of effective and efficient financial management processes.	• Overview of financial plans and budget allocations to different activities • Judgment (scale 1-10) on accuracy and optimization of the operational and financial planning	
Research	Evidence of relevant research undertaken in response of needs of target populations.	• Publications (academic and policy) • Link to national and regional research agendas • Judgement (scale 1-10) on the health needs and research undertaken	
	Availability and use of health products generated from research undertaken in the network. Evidence of contribution of research data towards registration of new products.	# of drugs or vaccines or diagnostic tools	

Annex 3

1. **Site visits schedule (Mid - End August 2019)**

	East African Consortium for Clinical Research (EACCR) Entebbe	Central African Network for TB, AIDS, and Malaria (CANTAM) Brazzaville	Trials of Excellence in Southern Africa (TESA) Maputo	West African NoE for TB, AIDS, and Malaria (WANETAM) Dakar
Visiting Panel Members	Julius Mugwagwa & Hassen Ghannem	Julius Mugwagwa & Hassen Ghannem	Elizabeth Allen & Hassen Ghannem	Juntra Karbwang & Isayvani Naicker
Dates	Week 12 August 14-16 August	Week 19 August 19-21 August	Week 26 August 28-30 August	Week 26 August 28-30 August

2. **List of stakeholders from which interviewees will be drawn**

EDCTP Regional Networks

East African Consortium for Clinical Research (EACCR) (Uganda)

- Uganda National Health Research Organisation (UNHRO) (coordinator and Project manager)
- The Chancellor, Masters and Scholars of the University of Oxford
- National Institute of Medical Research (NIMR)
- University College London (UCL)
- University of Khartoum (UofK)
- Good Samaritan Foundation -Kilimanjaro Christian Medical Centre (KCMC)
- University of Rwanda (UR)
- Addis Ababa University (AAU)
- Karolinska Institutet (KI)
- Centre Hospitalier Universitaire Vaudois (CHUV)
- Institute Voor Tropische Geneeskunde (ITG)
- Amsterdam Institute for Global Health and Development (AIGHD)
- Kenya Medical Research Institute (KEMRI)
- Stitching Katholieke Universteit- Radboudumc (RUMC).

Central African Network for TB, AIDS, and Malaria (CANTAM) (Congo Brazzaville)

- Fondation Congolaise pour la Recherche Médicale (FCRM) (coordinator and project manager)
- University of Buea
- Academisch Medisch Centrum Universiteit van Amsterdam (AMC)
- Centre de Recherches Medicales de Lambarene (CERMEL)
- Centre International de Recherches Médicales de Franceville (CIRMF)
- Centre for Research and Filariasis and other Tropical Diseases (CRFiLMT)
- HerpeZ Limited (HerpeZ)
- University College London (UCL)
- Eberhard Karls Univeritat Tubingen (EKUT)
- University of Yaounde I (UYI)
- Unite De Pharmacologie Clinique et Pharmacovigilance (UPC-PV)

- La Faculte de Médicine universite des Sciences de la Santé (DPM-USS-LIBREVILLE).

Trials of Excellence in Southern Africa (TESAII)
- Fundação Manhiça (FM-CISM) (coordinator)
- Botswana-Harvard AIDS Institute Partnership (BHP)
- Amsterdam Institute for Global Health and Development (AIGHD)
- University of Zimbabwe, College of Health Sciences (UZCHS)
- Stellenbosch University (SU)
- LT Clinical Research (Pty) Ltd
- Fundacion Privada Instituto de Salud Global Barcelona (ISGLOBAL)
- Health Research Centre of Angola (CISA)
- Biomedical Research and Training Institute (BRTI)
- Blantyre Health Research & Training Trust (BHRTT)
- University College London (UCL)
- University of Cape Town Lung Institute (Pty) Ltd
- University of Namibia (UNAM)
- University Teaching Hospital (UTH)
- European Clinical Research Infrastructure Network (ECRIN-ERIC)
- Uganda National Health Research Organisation (UNHRO).

West African NoE for TB, AIDS, and Malaria (WANETAM)
- Institut de Recherche en Santé, de Surveillance Epidémiologique et de Formation (RARS/IRESSEF)
- Université Cheikh Anta Diop
- SEN-ETHICS
- ERUDIT
- Pharmalys
- DIAMA Coordinator
    - Institut Pasteur de Dakar (IPD)Medical Research Council (MRC) Unit, The Gambia
    - Nigerian Institute of Medical Research (NIMR)
    - Centre Muraz, Burkina Faso
    - University of Ibadan
    - National Public Health Laboratory NPHL
    - Instituto Nacional de Saude Publica (INASA)
    - Université des Sciences, des Techniques et des Technologies de Bamako
    - London School of Hygiene and Tropical Medicine, (LSHTM)
    - Universidade Nova de Lisboa
    - Institut de Recherche pour le Développement (IRD)
    - Forschungszentrum Borstel Leibniz-Zentrum für Medizin ud Biowissenschaften (FZB)
    - University of Ghana
    - Université Cheikh Anta Diop de Dakar
    - Noguchi Memorial Institute for Medical Research (NMIMR)
    - Programme National de Lutte contre la Tuberculose (PNLT – Togo)
    - Jos University Teaching Hospital (JUTH)
    - University of Sierra Leone
    - Institute of Human Virology Nigeria (IHVN)
    - Institut Pasteur Dakar (IPD)

EDCTP

- EDCTP The Hague
- EDCTP Africa
- EDCTP Scientific Advisory Committee
- EDCTP General Assembly.

Key Partners/Stakeholders in Africa

- African Academy of Sciences
- NEPAD
- CDC Africa
- WHO AFRO
- IAVI
- ANDI
- Strategic Health Innovation Partnership of the South African Medical Research Council
- ECSA
- OCEAC
- WAHO.

Key Partners/Stakeholders outside Africa

- WHO-TDR/ESSENCE
- DNDi
- MMV
- Technopolis.

Some key documents

- Money & Microbes: Strengthening Clinical Research Capacity to Prevent Epidemics: International Vaccines Taskforce
- CARI: Development of an inventory of clinical and translational science capacity in Africa: Report on the Inventory of Clinical & Translational Science Capacity in Africa
- ESSENCE on Health Research: Mechanism for review of investments in research capacity strengthening in low- and middle-income countries
- Senegal Site Visit Report, 26-30 November 2018
- Central Africa Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM), Republic of Congo, Brazzaville, Site Visit Report, 29 – 31 October 2018
- 2015 Call for Proposals - EDCTP Regional Networks
- CANTAM2 Periodic report of action (1 July 2017 – 30 June 2018)
- Eastern Africa Consortium for Clinical Research 2 – (periodic report of action, 1st September 2017 – 30th August 2018)
- TESA II Periodic report of action (1st September 2017 – 31st August 2018)

Annex 4

Performance of the Regional Networks Against Targets

A: CANTAM2

Partners: 12 institutions made up of 5 African countries (Cameroon, Republic of Congo, Democratic Republic of Congo, Gabon, Zambia) and 3 European countries (UK, Germany, Netherlands).

General Objective: To consolidate the CANTAM network and increase its capacity by engaging in innovative trials and interventions, and expanding the regional training platform

Specific Objectives:

1. To accelerate the increase of local mass of health researchers by expanding the training platform including establishment of career development/mentorship programmes.
2. To investigate HIV, malaria and antiretroviral drug-drug interactions in different country cohorts.
3. To strengthen networking activities and local financial support from governments, private sector, and multilateral development partners and establish a robust research governance and support structures, and promote effective leadership.
4. To further develop laboratory and clinical trials capacity to take forward new interventions (diagnostics, treatments, including a range of host-directed therapies, vaccines and biomarkers) on EDCTP priority diseases relevant for the region including new and re-emerging infectious disease threats.

The main objective of the CANTAM2 network is to take advantage of efforts in the first phase of the network's activities to expand its courage beyond Malaria, TB and HIV/AIDS to NTDs and pharmacovigilance studies and increasing the number of participating countries and partners. The global strategy of CANTAM is to strengthen emerging African institutions through training, establishment of career development, mentorship programmes, and improvement of research facilities within the network. The network also aims to strengthen ethical review boards and regulatory authorities serving the collaborating sites as well as establishing effective community liaison at each site.

Objective 1: The mentorship programme has expanded to extramural institutions and places particular emphasis on female mentoring by encouraging female mentor-mentees pairing relationship. The career development grantees are progressing with the implementation of their research. Their research projects confine to HIV, TB or HIV-TB co-infection. The 21 students (13 PhD and 8 master) selected for capacity development are working in different institutions with a communication facility to exchange ideas. Several training workshops have been carried out to strengthen the capacity of university curricula, regulatory authorities, ethics committees, researchers as well as health care workers. In addition, online training on Good Clinical Practices, Good Clinical Laboratory Practice and Ethics in Research is now available.

Objective 2: Protocols of various epidemiological studies, pharmacovigilance of pyronaridine-artesunate antimalarial, host directed therapies for tuberculosis capacity development and magnitude of onchocerciasis and soil transmitted helminthiasis have been submitted for Ethics Committees and received approval in most study sites. All PhD and MSc students selected in Objective 1, have been enrolled as trainees in these studies. The capacity of laboratories was developed as well as personnel across the NoE. Generally, the activities are proceeding in a manner consistent with the project plan, although some study sites experienced some delays in obtaining certificates of approval from ethics committees.

As part of the drug-drug interaction research activity, the network obtained external funding through PYRAMX clinical trial studies which is bIII/IV Clinical trial, funded by MMV. These studies are being carried out in the Cameroon, Republic of Congo (RoC) and Gabon sites. The infectious diseases research centre was established in response to the need for a laboratory facility in RoC that can handle investigations of new and re-emerging infectious diseases. RoC is the only country in the region that did not have such a facility. The research centre is being used for clinical trials of emerging and re-emerging pathogens in RoC. The laboratory hosts 4 laboratory technicians and several MSc and PhD students. UCL, a CANTAM partner, is responsible for developing the centre by providing guidance on the ISO accreditation process.

Objective 3: There were several trainings and workshops carried out in CANTAM2 countries with guest lecturers from USA, Germany etc to facilitate the exchange of knowledge and experience. Stakeholders meetings with regulatory authorities on pharmacovigilance were held in RoC and Cameroon to agree on future activities and to get national support and develop ownership (Jun 2018 in Cameroon; July 2018 in RoC). The meetings were also to prepare for the training workshop on pharmacovigilance that will be held in year two. The network also organised the 2018 World TB Day Conference (22, 24 Mar 2018) to bring together the various CANTAM TB members and collaborators working on TB, scientists, physicians, invited researchers and the national Tuberculosis Control Programmes, Master Degree students and Doctorate Degree students. In addition, the network also organised the 2019 World TB Day Conference and World Malaria day. The website and newsletter have been developed ways to enhance visibility and to disseminate information to stakeholders.

Objective 4: CANTAM2 now supports fully functional institutional biobanks: -80°C freezers have been purchased for CANTAM institutions that needed the equipment as a standard to facilitate the transfer of biological material. The Material Transfer Agreement (MTA) has been designed and is in the process of being validated by the network. CANTAM2 has initiated accreditation of selected laboratories in Cameroon, Gabon and RoC and establishment of a laboratory capacity in Roc which can allow investigation of new and emerging infectious disease threats.

CANTAM 2 Performance against the specific objectives

Deliverables/Activities	WP Concerned	Projected Delivery	Actual Delivery	Ontime/ Delayed
Objective 1: To accelerate the increase of local mass of health researchers by expanding the training platform including establishment of career development/mentorship programmes				
1.2 Mentorship programme plan: • Mentorship plan has been elaborated and validated (July 2018)	WP1	Month 9	Month 12	Delayed
1.3 Junior career grants awarded: • The career development fellowships have been awarded to fellows from Cameroon (one female) and Republic of Congo (three females)	WP1	12	15	Delayed
1.4 Career grant plan of activities done by the awardees: • Awardees have outlined their Gantt charts with activities for the two years and first year report	WP1	18	On going	
1.5 Training plan document for MSC & PhD:	WP1	9	22	Delayed
1.6 Enrolment and academic training of 14 MSC, 7 PhD graduates: • 21 students (13 PhD and 8 master) have been selected for capacity development	WP1	36	On going	
1.8 5 targeted training workshops: • Regional workshop on Laboratory Methods for the Diagnosis of Tuberculosis, Kilimanjaro-Tanzania (8-12 Jul 2019) • Diagnostic techniques on NTDs with related surveys methods, Brazzaville (4-6 Apr 2019)	WP1	30		
1.11 Strengthen 3D printing for the lab/TRend workshop: • 3D printing training to facilitate the molding of laboratory accessories for research work has been conducted (6-8 Feb 2018; 16 attendees)	WP1	12	8	Ontime
1.13 Finance and Project management Workshop: • Completed during site visits to Cameroon (22-24 Jan 2019), Gabon and DRC (Aug 2019)	WP1	24	26	Delayed
1.14 Trained ethics review committees:	WP1	19		Delayed
•				
1.18 Free E-learning courses tailored for CANTAM:	WP1	24		Delayed
3.2 Pharmacovigilance workshops: • The training workshop with selected skilled individuals in the RoC, Cameroon and Gabon on Pharmacovigilance, will be organised before the end of the month of July 2019, under the leadership of UPC-PV.	WP3	18		Delayed
4.2 Capacity building needs assessment report (for clinical trials on Host-Directed Therapies:	WP4	12	18	Delayed

	• Professor McHugh and Dr Julio Ortiz C. visited the CANTAM programme in the Congo-Brazzaville and submitted report on their assessment areas where UCL identified capabilities and needs that need further development and training with research support				
	4.4 Health care workers awareness training:	WP4	24		Delayed
	Online training on Good Clinical Practices (Mar 2019)	WP1	OK		
	Online training on Good Clinical Laboratory Practices (Mar 2019)	WP1	OK		
	Online training on Ethics in Research (Mar 2019)	WP1	OK		
	14th Annual African Vaccinology Course (AAVC) organised by Vaccine for Africa (VacFA) (10-17 Nov 2018)	WP1	OK		
	Workshop on Vaccinology in Africa 2019 (29 Apr- 6 May 2019)	WP1	OK		
	Training on Good Clinical Practice at Biotechnology Centre, Nkolbisson Yaounde, Cameroon (6-7 Mar 2019; 30 attendees)	WP1	OK		
	Workshop on "Fighting Malaria with CRISPR/Cas9: Ethical Implications" was organised in Brazzaville, with the main focus on eliminating malaria with this new gene technology (20 Feb 2018; 38 attendees)	WP1	OK		
Objective 2: To investigate HIV, malaria and antiretroviral drug-drug interaction in different country cohorts					
	5.2 Approved study protocol, ethics clearance obtained: • The study's twenty copies of protocols have been developed and submitted to the national ethical committee. The majority of the study protocols got favorable feedback from the Ethic committee while some are still awaiting.	WP2, WP3, WP5	15	On-going	
	5.3 Ethics approval certificate for all investigations conducted within CANTAM	WP2, WP3, WP5	12	20	Delayed
	As part of the drug-drug interaction research activity, the network obtained external funding through PYRAMX clinical trial studies which is bIII/IV Clinical trial, funded by MMV. These studies are carried out in Cameroon, RoC, and Gabon sites				
Objective 3: To strengthen networking activities and local financial support from governments, private sector, and multilateral development partners and establish a robust research governance and support structures, and promote effective leadership					
	1.9 Southern and Northern Universities exchanges: • The University of Utah (USA), Centre Pasteur and University of Yaounde1 organised the Advance Course on Immunology (YACI) with ISHReCA as the event facilitator The YACI course brought together selected students and lecturers from	WP1	36		

	different institutions with CANTAM students participating in the workshop • The Interfaculty Graduate Programme in Infection Biology (IGIM) in Tubingen had one student from RoC trained for 3 months in Germany and they are working on her manuscript for publication • Abstract submitted at the ASTMH annual conference, New Orleans, USA (Nov 2018) • Training on "Introduction to the numerical modelling of biological systems", Brazzaville, coordinated by Dr Adelaide RAGUIN from Université Heinrich-Heine de Dusseldorf (12 & 20 Dec 2018) • Training in TB diagnostics and clinical trials by UCL (3-14 Jun 2019) • Workshop on Immunology, organised by the Department of Biochemistry of the University of Yaounde in collaboration with the University of Utah and the Centre Pasteur of Yaounde (9-10 May 2019)				
	3.1 Stakeholders meeting on pharmacovigilance in CANTAM countries: • A Stakeholders meeting with regulatory authorities on pharmacovigilance in Congo-Brazzaville and Cameroon was held to agree on future activities and to get national support and develop ownership (Jun 2018 in Cameroon; July 2018 in RoC). The meeting was also to prepare for the workshop training on pharmacovigilance that will be held in year two	WP3	4	Partial	Delayed
	1.15 Stakeholders meetings for regulatory authorities for Central Africa: stakeholder meetings were held with regulatory authorities in the RoC, Cameroon and Gabon on Pharmacovigilance. This meeting was to evaluate the gaps that prevent these partners from being on the same level as DRC which is the only country in central Africa that has a pharmacovigilance system.	WP1	24		Delayed
	5.1 Stake holder meeting on onchocerciasis for preparing the investigation in RoC and Cameroon: • Held on 4 Apr 2019 in RoC (14 attendees)	WP5	3	20	Delayed
	Organised 2018 World TB Day Conference (22, 24 Mar 2018)	-	OK		
	Organised 2019 World Malaria Day Conference (26 Apr 2019)				
	Organised 2019 World TB Day Conference (23 Mar 2019)				
	Developed CANTAM website on Mar 2018	-	OK		

Objective 4: To further develop laboratory and clinical trials capacity to take forward new interventions (diagnostics, treatments -including a range of host-directed therapies, vaccines and biomarkers) on EDCTP priority diseases relevant for the region including new and re-emerging infectious disease threats					
	1.16 Fully functional institutional biobanks: • -80° freezers have been purchased for CANTAM institutions that need the equipment as a standard to facilitate the transfer of biological material The Material Transfer Agreement (MTA) has been designed and is in the process of being validated by the network	WP1	32	On-going	
	4.3 Accreditation of Laboratory – Quality management systems development – Establishment of remerging and re-emerging pathogen lab in RoC: • RoC provided with extensive support to upgrade one of their cat 2 laboratories to cat 3 using a reputable company • Implementation of SLIPTA accreditation system	WP4	36	On-going	
Project Management & Dissemination of Results					
	1.19 Y1 Annual general meeting or CANTAM Kick off meeting: • Held on October 2017	-	3	4	Delayed
	1.20 Y2 annual general meeting:	-	13	20	Delayed
	1.22 Strategic Business and communication plan	-	6	12	Delayed
	1.23 Scientific publications from all research activities in peer reviewed journal: • 4 Publications arising from CANTAM/UCL collaborations and one with EDCTP-NoEs investigations were published in year 1 • 7 publications were published in year 2	-	12, 24, 36	12, 24	Ontime
	• Developed CANTAM website on Mar 2018	-	OK		

B: EACCR2

Partners: 14 institutions made up of 5 African countries (Uganda, Ethiopia, Tanzania, Sudan, Rwanda) and 5 European countries (UK, Netherlands, Sweden, Belgium, Switzerland).

General Objective: To leverage, strengthen and sustain an existing EDCTP-funded EACCR (www.eaccr.org) to contribute to the new EDCTP2 strategic business plan of promoting regional collaborative research on new or improved interventions to prevent and control poverty-related, neglected infectious and emerging/re-emerging diseases in sub-Saharan Africa.

Specific Objectives:

1. To strengthen the collaboration and optimize the use of shared research infrastructures, other capacity building resources and opportunities.
2. To establish a new node (NID) to manage and establish the needed facilities to conduct clinical trials on neglected, emerging and re-emerging disease that burden the region.
3. To boost and deliver an Eastern Africa training and mentorship programme promoting an increase and retention of the independent African researchers, research leaders and managers to conduct internationally-competitive clinical trials.
4. To strengthen and strategically expand South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established Eastern Africa institutions in building capacity for conducting high quality clinical research.
5. To promote networking, and dialogue between researchers, communities and policy makers to maximize the use of health research evidence for shared knowledge management, policy change and improved health programming in Eastern Africa.

Objective 1: In order to achieve this objective, EACCR2 must have a strong network of the participating institutions to share training facilities and resources for GCP training, data management and technical training in areas such as genomics, a mentorship programme and a shared database. The success of this objective is associated with the deliverables of WP1, WP3 and WP4. The TB node, Malaria node and HIV node conducted site assessments and identified the infrastructure and human resource capacity needs for sister sites to conduct research. This information guided the nodes to draw priorities for infrastructural upgrades at the different sites. Infrastructure development and sharing so far includes the improvement of the hospital research ethics committees, laboratories and upgrading of the health centres and clinics in the new nodes. The 5 NID node partner countries have already received the funding for the infrastructure upgrades.

Objective 2: The success of this objective is associated with the deliverables of WP1 to WP5. The NID node was established and initially hosted by the Institute of Endemic Diseases, University of Khartoum (IEND). In early 2019, the leader of this node resigned from the IEND, it was suggested from the Steering Committee to move the NID to Kenya Medical Research Institute under the leadership of Dr Eric Muok. This change will involve the action from the EDCTP secretariat. Meanwhile, a short-term training course in molecular diagnostic was conducted. Five MSc were recruited. The node focuses on five diseases endemic in East Africa: Schistosomiasis, Dengue, Leishmaniasis, Cysticercosis and hadatosis. Members of the node also participated in other node activities/meetings and trainings.

Objective 3: The activities that support the achievement of this objective are the long-term training programme, disease specific and cross-cutting short courses. For long term training, a total of 5 post doc, 5 PhD and 21 MSc students are being supported through EACCR2, and 7 are enrolled for online

international Master of Advanced Studies in Vaccinology, Lausanne. For short course training, a total of 332 researchers and laboratory staff have been equipped with different skills to conduct GCP trials. These short courses consist of ICH GCP, GCP training of trainers' course, clinical trial monitors, refresher courses for clinical monitors, financial management, research management, data management and specific technical trainings such as Malaria microscopy, TB microbiology, molecular diagnostics, basic epidemiology and biostatistics. Three other short courses were in preparation for 2019 at the time of the evaluation, namely, introductory course on Research Ethics and HIV immunology and Genomics course. For mentorship, 2 participants from Sudan participated in a malaria mentorship programme at KEMRI-Wellcome Trust in Kilifi, Kenya. The progress in objective 3 has exceeded the planned activities.

Objective 4: Significant numbers of S-S and N-S collaborations have been established in the past 2 years. There are several S-S collaborations on writing grant proposals, conducting research to strengthen study sites, and on short-course training. There are also several N-S collaborations on writing grant proposals, forming new networks, research and training.

Objective 5: Policy makers from the Ugandan Ministry of Health attended the launch of the EACCR2 Network. Through the speech of the representative of the minister for Health of Uganda, emphasis was made of the need for research in the PRDs and support was pledged for translation of research results into policy within the country. The meeting was also attended by representatives from ministries of health from the EDCTP African member countries, national health research regulatory authorities and the other networks of excellence. The EACCR2 has a functioning website which details the EACCR2 activities; active social media platforms (Facebook and Twitter) where updates of all activities are posted for the benefit of the external world. A stakeholders meeting was held in Entebbe early 2019 to discuss partnering for Outbreak and Response.

EACCR2 Performance against the Objectives

Deliverables/Activities	WP Concerned	Projected Delivery	Actual Delivery	On time/ Delayed
Objective 1: To strengthen the collaboration and optimize the use of shared research infrastructures, other capacity building resources and opportunities				
1.1 Active Regional EACCR2 consortium	WP1	Month 3	Month 1	Month
1.2 Recruitment and establishment of the 5 node committees (NID, HIV, Malaria, TB and Training) and Terms of references available	WP1	3	1 and 5	
1.3 EACCR 2 consortium restructured and launched	WP1	15	5	
1.4 Report (s) on annual scientific /networking meetings	WP1	15/22	12/ 4.1	
1.5 Minutes of node meetings and quarterly reports month	WP1	5/ 10/ 15/ 20/ 25/ 34	2/ 8/ 11/ 12	
1.6 Revised EACCR2 strategic plan available	WP1	15		Delayed to 25
3.0 Training plan for all short-term malaria related training and mentorship attachments	WP3	9	10	Delayed
3.1 Hospital data collection questionnaire designed and shared, *(expected to be developed by Malaria Node – Dec 15, 2019)*	WP3	16		Not yet developed
Objective 2: To establish a new node (NID) to manage and establish the needed facilities to conduct clinical trials on neglected, emerging and re-emerging disease that burden the region				
2.1 Reports HIV node site assessment (15) surveys	WP2	9	Partial	Delayed to 22
2.1.1 User manual on HIV epidemiology database (expected to complete by Dec 15, 2019)	WP2	9		Not yet developed
2.2 Report on completed preliminary regional data on ADR profiles	WP2	32	On-going	
2.3 Ethical approval for HIV clinical randomised trial/hot spots obtained (HIV pharmacovigilance study approval obtained but not for WELTEL)	WP2	18		Delay for WELTEL
2.5 Ethical clearance of the prevalence of malaria/Epi and Entomological studies obtained		18	All Approved	
2.6 Ethical reviews/approvals on epi studies by NID node to be obtained		15		Delayed
2.7 Ethical reviews/approvals epi studies/hot spots by TB node obtained		15	6 Three studies approved	One study delayed
2.9 Host directed therapy clinical protocols and documentation on study initiation		16		Delayed
Objective 3: To boost and deliver an Eastern Africa training and mentorship programme promoting an increase and retention of the independent African researchers, research leaders and				

managers to conduct internationally-competitive clinical trials					
	3.0 Training plan for all short-term malaria related training and mentorship attachments		9	Partial, awaiting one staff	Delayed
	3.1 Hospital data collection questionnaire designed and shared (expected Dec 2019)		16		Not yet developed
	3.2 Training plan for 6 MSc students supported by NID node		9	10	
	3.3 Post doc, PhDs, MScs to work with TB Clinical Research recruited		17	7	
Objective 4: To strengthen and strategically expand South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established Eastern Africa institutions in building capacity for conducting high quality clinical research					
	4.1 Finalised plan for HIV and NID prioritised upgrades in 15 sites		12	10	
	4.2 Data sharing management guidelines finalise		7		Delayed to 12
	4.3 Plans to support laboratories to achieve WHO/ ISO Accreditation finalized		22		No information
	4.4 Shared online Database available (*no data entries yet so not yet shared*)		24	11	
	4.5 Strengthened Bioequivalence unit		30		
Objective 5: To promote networking, and dialogue between researchers, communities and policy makers to maximize the use of health research evidence for shared knowledge management, policy change and improved health programming in Eastern Africa					
	5.1 EACCR2 communication plan and brochure finalized		4	Partial	
	5.2 Shared inter-NoE portal/space(URL) and annual newsletters		6	Partial	
	5.3 Reports on the year 3 annual scientific and networking EACCR2 consortium meeting		30		
	5.4 EACCR website online wikis/blogs and African AIDS Vaccine Virtual Network		4	5 Partial	
	5.5 Policy reports and briefs presented to Ministries of Health in Eastern Africa region		12/ 24/ 34	5/ 11/ 12	On time
	5.6 Minutes and reports from coordinator(s) [HIV/ TB/Malaria &NID] involvement in national disease programmes / public health committee meetings		12/ 24/ 34	HIV: 5, 9, 11/ Malaria: 3, 12/ NID: 2, 4, 7, 9	Not done yet
	2.4 Peer review publication/abstract on HIV randomized clinical trial		16/ 20/ 30	Baseline data submitted for pub. in June	

				2019	
	2.8 Conference presentations abstracts and from all EACCR 2 publications		6/ 12/ 18/ 24/ 30	Dec 2018, May 2019	

C: TESA2

Partners: 14 institutions made up of 8 African countries (S. Africa, Zimbabwe, Angola, Namibia, Mozambique, Botswana, Malawi, Zambia), 3 European countries (UK, Spain, The Netherlands) and additional partners Logic Trial, LT (South Africa), the HIV Vaccine Virtual Network, Mozambique-South Africa-Swaziland Cross-Border Malaria Initiative (MOSASWA), European Clinical Research Infrastructure Network (ECRIN) and the Africa Research Initiative and Support Network (ARISE).

General Objective: To consolidate the TESA network and increase its capacity by engaging in innovative trials and interventions, and expanding the regional training platform.

Specific Objectives:

1. To strengthen collaboration and optimize the use of resources and infrastructures within the network.
2. To offer training and mentorship aimed at promoting professional development and scientific leadership in clinical trials.
3. To strengthen South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established institutions in building capacity for conducting high quality clinical research.
4. To encourage and promote networking and dialogue between researchers, communities and policy makers to maximize the impact of clinical research in Africa.

Trials of Excellence in Southern Africa (TESA2) network was established with the objective of creating a framework for collaboration, capacity building and training among 14 institutions from 8 different Southern African and 3 European countries. The objective is to strengthen and enhance the capacities for clinical research in Southern Africa built during TESA 1, as well as to increase collaboration and North-South and South-South networking activities among member institutions. To achieve this, TESA2 focuses its activities around strengthening the capacities among partner sites, promoting professional development and scientific leadership and fostering collaborations to maximize impact.

Objective 1: TESA2 had a successful kick-off meeting with the attendance of high-level project stakeholders, project sponsors, government representatives from Mozambique, researchers, academics, politicians and civil society and leaders from other EDCTP regional Networks of Excellence. A Master Plan for the three years of the grant was discussed at the TESA board meetings. During the first year: 1) 3 labs were selected to be reference labs in the main poverty related diseases ie. CISM Malaria, SUN–TB and BHP-HIV/AIDS. 2) the establishment of data centre in CISM Malaria. The HIV BHP reference lab has ISO 17025 accreditation and SUN-TB has already been accredited based on ISO 15189. For CISM it was initially ISO 9001 and they later decided to strive for ISO 15189. In the second year, the CISM malaria lab underwent technical assessment in October 2018 by the Portuguese Agency IPAC for ISO 15189 and nonconformities are being corrected. Several trainings were conducted to increase the capacity of the data management centre in CISM towards the quality certification.

Objective 2: The consortium has developed one Mentoring and Training plan together with SOPs for short and long training programmes. There was a delay in delivering the plan.
For short-term training: **Year 1**, 12 short-term training courses and 3 exchange visits were successfully conducted and 150 TESA members benefitted from capacity building in several subjects such as GCP/GCLP, Bio-informatics, Statistics, ISO Accreditation and Drug Resistance. **Year 2**, 8 short-training courses were conducted, benefitting more than 50 staff of the TESA members. The main areas covered

were: quality management systems, finance and grant management, drug resistance training and advanced research ethics training.
For long term training: 8 MSc, 1 PhD and 1 Nurse Research student recruited and registered

Objective 3: South-South collaboration was established between the BHP (Botswana) and UZCHS (Zimbabwe) sites on the preparation for two POC Cepheid GeneXpert tests, namely the HIV-1 Qualitative test used for early infant diagnosis of HIV-1 & the HIV-1 Quantitative test used for virological monitoring (viral load quantitation) of response to antiretroviral therapy. S-S collaboration also established between BHP and BRTI (Zimbabwe) institutions on the preparation for the BRTI HIV DR genotyping lab ISO accreditation.

Objective 4: The Ministry of Health Child Care (Zimbabwe) approved the clinical study being conducted at a primary healthcare centre in Harare. It is hoped that the results from the study may influence policy change in tests to be used for early infant diagnosis of HIV at all the point of care health centres nationwide. BHP had a forum to brief MoHCC on some of the research findings in which capacity building activities have been highlighted. For example, on the 17 Dec 2018, BHP presented urgent viral Hepatitis data findings to the deputy permanent secretary of the MoHCC and Health Services Management board. TESA II members have attended several workshops and international conferences in which they have interacted with other members from various sites.

TESA2 Performance against objectives

Deliverables/Activities	WP Concerned	Projected Delivery	Actual Delivery	Ontime/ Delayed
Objective 1: To strengthen collaboration and optimize the use of resources and infrastructures within the network				
1.1 Kick-Off Meeting – report: • Held in Mozambique on 30-31 Oct 2017	WP1	Month 2	Month 2	On time
1.2 General Assembly Y1 Minutes: • Y2 Network Action Plan developed and approved by the consortium	WP1	13	13	On time
1.3 General Assembly Y2 Minutes:	WP1	23		Delayed
1.4 Long-term Strategy Plan: • Three board meeting were conducted under TESA project to (1) discuss and develop the consortium Master Plan for the three years grants (17 Nov 2017); (2) ensure the project deliverables outputs and supervise the accomplishment of work package objectives (6 Apr 2018); and (3) discourse and access implementation challenges and address GAPs (12 Jul 2018) • face-to-face meeting was conducted by TESA with EDCTP office in Cape Town to discuss and seek advice on some activities related to the Labs accreditation process and exchange visits activities (24 Aug 2018)	WP1	36	On-going	
1.6 Accredited Lab to perform CT: • Technical assessment of ISO 15189 compliance conducted at CISM laboratory of Malaria (Mozambique) in October 2018, the nonconformities are being corrected. before the next IPAC accreditation audit planned for September 2019.	WP1	36	On-going	
1.7 Certified Data Management Centre: • workshop was conducted to increase the clinical capacity and the training of sites in Bioinformatics topics.	WP1	34	On-going	
1.8 TESA Consortium Strategic Business Plan: • TESA Workshop in Finance and Grant Management was hosted on the 15th of April 2019 at BHP-Botswana • Quality Management System course was jointly conducted by BRTI and BHRTT at BHRTT in Malawi on the 13th -17th May 2019	WP1	36	On-going	
Objective 2: To offer training and mentorship aimed at promoting professional development and scientific leadership in clinical trials				
2.1 Mentorship Plan: •	WP2	6	18	Delayed
2.2 TESA Consortium: Training Plan: • In year 1, 12 short-term training courses in GCP / GCLP, Bio-informatics, Statistics, ISO Accreditation and Drug Resistance • In year 2, 8 short-training courses were conducted to cover: Bio-informatics, HIV Drug resistance, QMS, Human Research Ethics, GIS/GPS and Clinical	WP2	8	18	Delayed

	attachment • Human Research Ethics training course was conducted by B Compliant consultant, from 16th to 17th April 2019				
	2.3 MSc and PhDs: • 8 MSc, 1 PhD and 1 Nurse Research student recruited and registered with TESA local Universities	WP2	36	On-going	
	2.4 Clinical Research Associate Monitor:	WP2	20		Delayed to 27
	2.5 Clinical Trial Sponsor Contract:	WP2	24		
	2.6 Approval letter from IRB:	WP2	30		
Objective 3: To strengthen South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established institutions in building capacity for conducting high quality clinical research					
	South-South collaboration between the BHP and UZCHS for the preparation for two POC Cepheid GeneXpert tests	WP1	On going		
	Discussion of S-S collaboration between BHP and BRTI institutions are underway for the preparation of BRTI HIV DR genotyping lab ISO accreditation in HIV DR genotyping	WP1	On going		
Objective 4: To encourage and promote networking and dialogue between researchers, communities and policy makers to maximize the impact of clinical research in Africa					
	3.1 Communication Strategy: • The TESA website was developed (www.tesanoe.org)	WP3	7	On-going	Delayed to 26
	3.2 National conferences and workshops attended: • Attended the joint Congress between The Pan African Thoracic Society (PATS) and The South African Thoracic Society (SATS), held in April 2018 in Durban, South Africa • Attended the 2018 Pulmonology Update Conference for researchers and clinicians at Groote Schuur Hospital (6-8 Jul 2018) • Attended the 13th INTEREST Conference 14th -17th May 2019, Accra, Ghana	WP3	12	8	On time
	3.3 International conferences attended: • Attended the Annual Conference on Global Health (24 Mar 2018) • Collaboration for TB vaccine discovery Presentation (Seattle, USA) on the research work by Dr AG Loxton (18 Jun 2019)	WP3	12	8	Ontime
	3.4 Joint applications submitted:	WP3	34		
	3.5 Policy-makers & researchers workshop held: • FM-CISM organised Annual Conference on Global Health - 9th Edition in Maputo-Mozambique during the celebrations World Tuberculosis Day (24 Mar 2018) • Dr Junior Mutsvangwa from BRTI was sponsored to attend the World TB day on the 29th of March 2019 where she managed to engage with the Provincial TB team in the presents of the Zimbabwe National TB Programme (NTP) Manager	WP3	18	16	On time
	3.6 Participate in public health regional/national advisory committee meetings:	WP3	20	16	On time
	3.7 TESA Social networks profiles Local media	WP3	24		

	participation etc:				
	3.8 All partners publications related with EDCTP objectives – Annually compiled and reported: • 7 publications published in year 1 • 3 publications published in year 2	WP3	12, 24, 36	12, 24	Ontime

D: WANETAM

Partners: 17 institutions in 9 developing countries (Senegal, Mali, Nigeria, Ghana, Togo, Burkina Faso, Gambia, Sierra Leone, Guinea Bissau), 4 institutions in 4 European countries (UK, France Germany, Portugal)

General Objectives: Build capacity at regional, national, institutional and individual levels to conduct GCP clinical trials (TB, HIV, Malaria, NTD and Ebola)

Specific Objectives:

1. Strengthen collaboration and optimize use of resources within Network facilities.
2. Promote professional development and scientific leadership in clinical trials through mentorship and training.
3. To strengthen S-S and N-S collaborations between researchers and institutions with a specific focus of supporting less established institutions in building capacity.
4. Encourage and promote networking and dialogue between researchers, communities and policy makers to maximize the impact of clinical research in Africa.

Activities towards these objectives include training and collaboration through thematic nodes of excellence: TB, Malaria, HIV/AIDS, and NTD and Ebola. The strategy uses project-based training to build research leadership and cross-cutting training to enhance professional development and scientific competence in clinical trials and research supports. The network is governed by the management group and advised by a steering committee and an advisory board. The performance of WANETAM during the first year was below expectation as demonstrated by delays in most activities (See table below). The TB, HIV, NTD/Ebola NoE activities started in year 2. The year-one activities were confined mainly to management and networking.

Objective 1: For this objective, the significant activity is the capacity building of laboratory infrastructure. Assessment and evaluation of laboratories has been performed, 3 laboratories have been selected (Ghana, Benin and Mali) for further improvement towards accreditation in 2020. Many planned activities that serve this objective still need to be implemented.

Objective 2: In terms of professional development, malaria and TB activities, and cross-cutting training have made significant progress despite the delay start. More than 100 scientists have been trained in various fields to support the conduct of GCP clinical trials.

Objective 3: There are various activities of N-S, S-S networking, including networking with the other NoEs. An additional 4 institutions applied to become members of the WANETAM network. There was also establishment of a S-S West African Pediatric TB network as well as a collaborative network for the improvement of laboratory quality.

Objective 4: Most of the activities are delayed in implementation. The website should be active and communication between stakeholders should be improved.

Performance of WANETAM against objectives

Activities	Delivered On time	Delayed to	Not yet delivered
Objective 1: Collaboration & Optimize use of resources			
1. Establishment of the West African Pediatric TB network (10 Sites)- 10-11 June 2019	OK		
2. Clinical and Epidemiological Data Output Monitoring		Q4 2016 Q2 2017 Q3 2018 Q2 2019	
3. Develop and share data on ART-Acquired and ART-Transmitted resistance in transmitted resistance in the treatment programme		Q3 2017	
4. Validation of in-house HIV-1/HiV-1 RT-PCR VL assay and viral Load POCs evaluation		Q3 2017 Q1 2018	
5. Implementation of Viral Load assay		Q4 2016	
6. Epidemiological surveillance and building database of helminth prevalence			Not yet started
7. Monitoring and evaluation of the development of anthelmintic resistance			Not yet started
8. A data sharing committee was setup to prepare a data sharing plan and provide guidance and advice to the network	OK		
9. Develop and share data on ART-Acquired and ART-Transmitted resistance in the treatment		Q3 2017	
10. Three laboratories were pre-selected to improvement toward accreditation (Dec 2018-Jan2019)		Q3 2017	
11. Monitoring visit to assess Lab in Bissau (1-15 May 2019)		Q 3 2017	
12. CRF Template for unified data resource entry form (*in progress)*			Month 24
Objective 2: S-S, N-S networking			
1. S-S West African Pediatric TB network		OK	
2. N-S collaboration: Malaria work-initiated action with LSHTM and Radboud University		OK	
3. N-S collaboration: HIV work; 1 scientist from RARS with training in New Generation Sequencing at IRD Montpellier		OK	
4. S-S collaboration visit to Bissau (1-15 May 2019) to strengthen the lab and personnel		OK	
5. S-S meeting with regional institution (WAHO) held in Dakar from (19-21 April 2018)		OK	
6. N-S visit the Institute of Tropical Medicine Lisbon and meeting with Dep. Director of Tropical Medicine, in U of Lisbon to discuss exchange programme (20 Sept 2018)	OK		
7. S-S 4 new institutions applied to become members of WANETAM network		OK	
Objective 3: Professional Development and leadership			
1. Training in Childhood TB (26 pediatricians trained) (10-11 June 2019)		Q3 2017	
2. Training to facilitate the Rolling out novel diagnostics for children and adults – the use of GeneXpert		Q3 2018	
3. Training in TB Genomics (skills for drug susceptibility testing) (10-15 Dec 2018)			
4. Training workshop for PI on study design (Plan for Jan 2020)		Q3 2017	Jan 2020

			Q1 2018 Q1 2018	
	5. Training in the diagnostic of malaria infections with molecular technique (plan for Nov 2019)		Q2 2017	Nov 2019
	6. Training in implementation of community-based cluster randomized trials (12-22 Nov 2018)-8 trained		Q2 2017	
	7. Training on malaria-specific trial design and grant writing (3-7 Mar 2019)-20 trained		Q2/3/4 2017	
	8. Training on entomological characteristics and profiles-Applying Field Technique insecticide resistance (13 Trained: Aug 27- Sept 6, 2018)		Q2 2017	
	9. Training on insecticide resistance (Aug 27- Sept 6, 2018) second group planned for Aug 2019)		Q4 2017 Q2 2018	Aug 2019
	10. Hands-on training on a study on susceptibility of Gambian Adults to PfSPZ-Challenge infection in Controlled Human Malaria Infection (Mar-June 2018)	Q3 2018		
	11. Open clinical including Quality Control and Validation		Q1 2017	
	12. Training Attachment for drug resistance test		Q2 2017	
	13. Training in HIV viral load assay techniques (25-29 Mar, 2019) -20 trained		Q2 2017	
	14. Epidemiological Field training 2 MSc students (on going)		Q3 2017	
	15. Training workshop on innovative tools for helminths diagnostic (19 trained; 3-10 Sep 2018)		Q3 2017	
	16. Training the trainer's workshop on Biosafety and biosafety - <u>postponed to June 2019</u>		Q3 2017	June 2019
	17. Post-Doctoral Mentorship		Q1 2018	
	18. Master training (*on going recruitment*)		Q4 2018	
	19. Training in Epidemiological evaluation of vaccines at the LSHTM from 2-13 July 2018 (Dr. Sophia Osakwe from IHV in Abuja)		Q3 2016	Q2 2019
	20. Training in Epidemiological evaluation of vaccines (1-12 July 2019) (Dr. Barry)		Q3 2018	
	21. Training in CT Monitoring (5 persons – May 2019)		Q3 2016 Q3 2018	Q2 2019
	22. The IATA online run course for biological sample handling and shipment		Q3 2017	
	23. Project management – Prince 2 course (4-8 Feb 2019) – 9 trained		Q3 2016 Q3 2018	Q2 2019
	24. M&E for development Programmes (1-15 June 2019) (2 trained)			
	25. Laboratory quality Assurance training (28 Feb – 30 Sept 2018)		4 mons	
	26. Finance and grant management internship (candidate selected)		Q3 2017	

Objective 4: Promote networking and dialogue between researchers, communities and policy makers				
	1. Communication tool kit for Ebola to be used by clinicians for policy makers and the community			Not yet started M18
	2. Establishment of Ethics Board (Nov 2018)		M1	

	3. Live WANETAM website			M4-36
	4. Network newsletter			M6, M12, M18, M24
	5. High level meeting plan			M24
Project management and networking				
	1. Kick off, yearly meeting and SC meeting, teleconference	OK		
	2. Fund raising – industry representative invited to annual retreat in Bamako in Feb 2019		M24	
	3. Network Business plan (*in progress*)			Q3 2017
	4. Network newsletter (*in progress*)			
	5. International annual meeting for Research Administrators 14-18 Oct 2017, Vancouver, Canada (Mr. Dembo Kantec from MRCG at LSHTM)	OK		
	6. Networking for Research Management (INOEMS) in Edinburg, UK 4-7 June 2018	OK		
	7. Networking for younger scientist (19th ICASA 2017: 4-9 Dec 2017, Abidjan, Cote d'Ivoire) (WP3)	OK		
	8. Coordination of the participation of the 4 EDCTP NoEs in 9th EDCTP Forum held in Lisbon from 17-21 Sept 2018	OK		
	9. International annual meeting for Research Administrators 14-18 Oct 2017 Vancouver, Canada	OK		
	10. Workshop to develop a manual of procedures for ECOWAS Regional Lab Network organised by WAHO/OOAS in Dakar from 19-21 Apr 2018	OK		
	11. Steering committee meeting in Dakar 31 July-1 Aug 2019	OK		
	12. Communication - Website improvement - HIV work package periodic conference call	OK		
	13. Accra retreat held in Jan 2019: revision of training plan for HIV, NTD/Ebola and cross cutting work packages	OK		