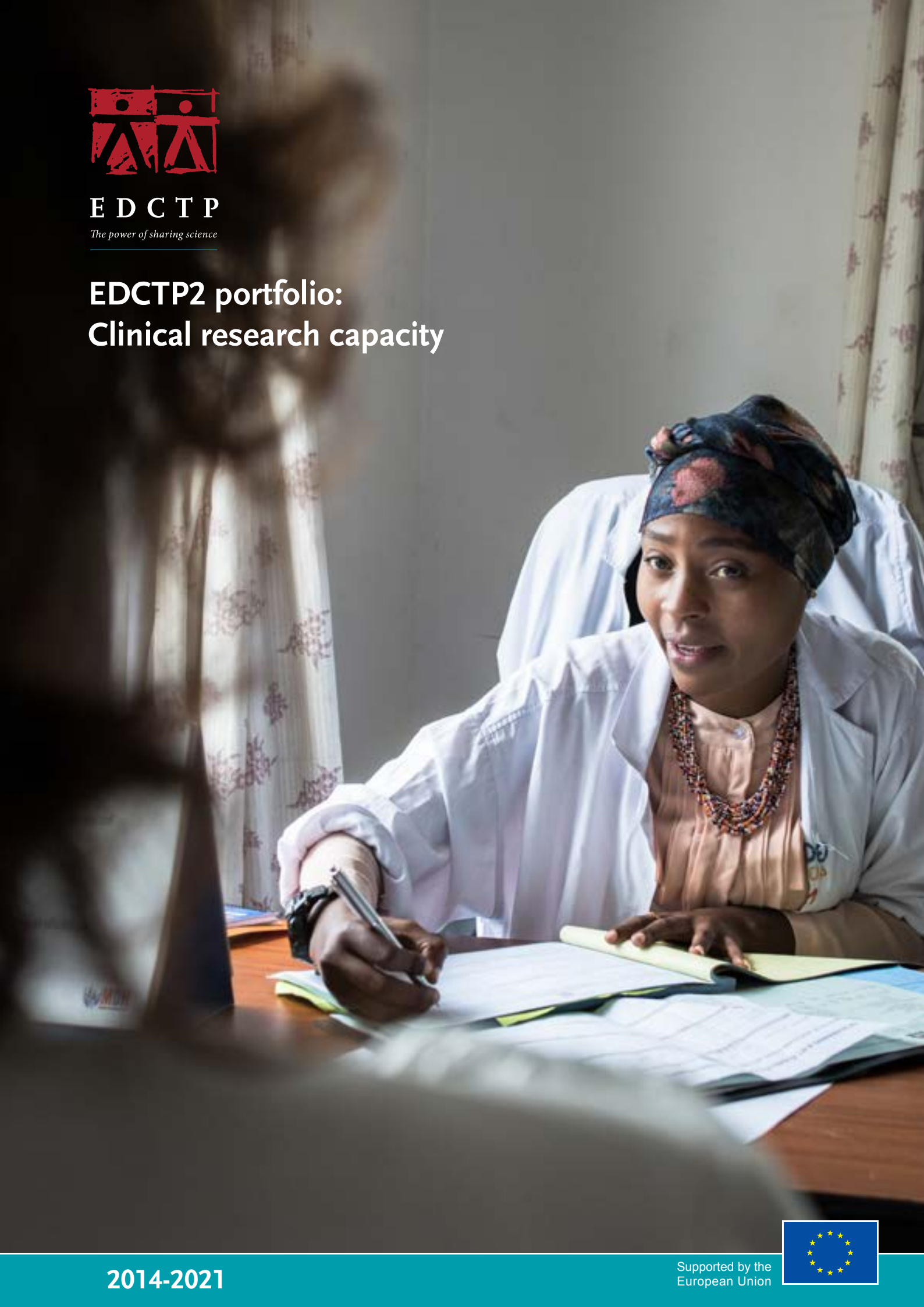




EDCTP

The power of sharing science

EDCTP2 portfolio: Clinical research capacity



2014-2021

Supported by the
European Union



About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership between 14 European and 16 African countries, supported by the European Union.

EDCTP's vision is to reduce the individual, social and economic burden of poverty-related infectious diseases affecting sub-Saharan Africa.

EDCTP's mission is to accelerate the development of new or improved medicinal products for the identification, treatment and prevention of infectious diseases, including emerging and re-emerging diseases, through pre- and post-registration clinical studies, with emphasis on phase II and III clinical trials. Our approach integrates conduct of research with development of African clinical research capacity and networking.

The second EDCTP programme is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation. Cofunding from the Calouste Gulbenkian Foundation (CGF, Portugal), the Carlos III Health Institute (ISCIII, Spain), the Deutsches Zentrum für Luft und Raumfahrt e.V. (DLR, Germany), the Foundation for Science and Technology (FCT, Portugal), the Medical Research Council (MRC, United Kingdom), the Netherlands Organisation for Scientific Research (NWO, Netherlands), the South African Medical Research Council (SAMRC, South Africa), the Swedish International Development Cooperation Agency (Sida, Sweden), and the Special Programme for Research and Training in Tropical Diseases (TDR) for the projects highlighted in this publication is gratefully acknowledged.

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Developing capacity for clinical research in sub-Saharan Africa – the EDCTP contribution

Capacity development is a core EDCTP activity, complementing its support for clinical trials and product-focused implementation research. Effective capacity development requires a long-term perspective, an integrated system-wide approach, and strong partnerships with host countries to ensure sustainability. Guided by these principles, EDCTP is making a lasting contribution to the capacity of countries in sub-Saharan Africa to undertake high-quality clinical research – to the benefit of the research community, ethics and regulatory bodies, policymakers and populations.

The European & Developing Countries Clinical Trials Partnership (EDCTP) exists to advance the development and implementation of new and improved medical interventions against key infectious diseases, through support for collaborations between countries and institutions in Europe and sub-Saharan Africa. Since its launch in 2014, the second EDCTP programme (EDCTP2) has awarded more than €814 M in grants to support landmark studies on vaccines, drugs and diagnostics for TB, HIV/AIDS, malaria, diarrhoeal diseases, respiratory infections, and emerging and re-emerging infections.



Dr Michael Makanga
Executive Director

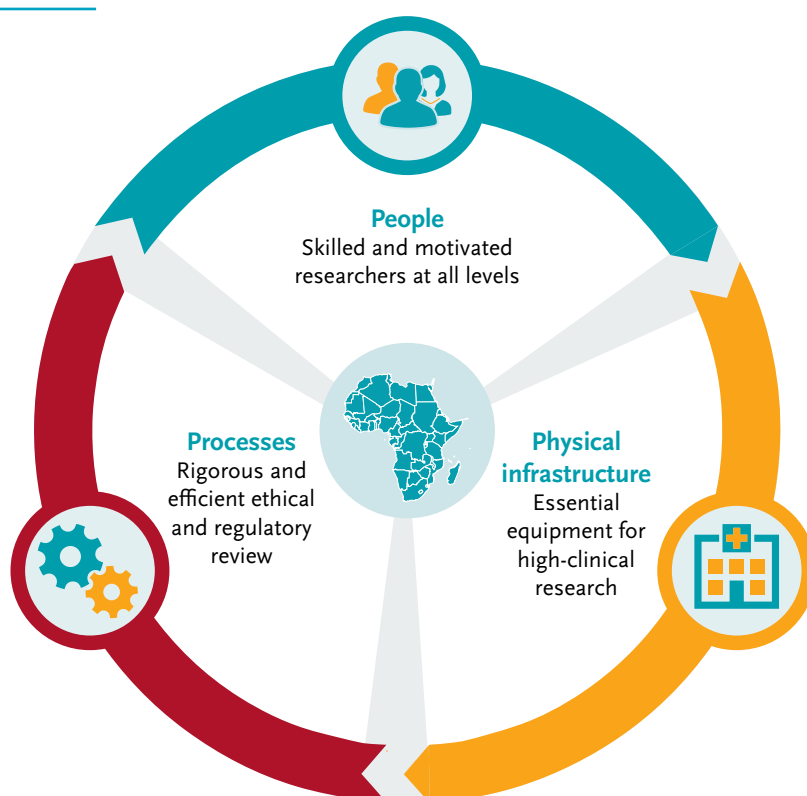
International collaborative clinical trials lie at the heart of EDCTP's work. But a further important goal is to build the capacity of countries in sub-Saharan Africa to carry out clinical research, including international-standard clinical trials. Support for capacity development is embedded within funding for clinical trials, and also the focus of dedicated funding schemes.

Capacity development is critical for a range of reasons. First and foremost, it enables countries, institutions and individuals to participate in clinical studies, including international consortia. More generally, it creates an enabling environment that attracts further studies. It also benefits countries by promoting greater self-reliance in health research, and by building national human scientific capital – a vital national asset to ensure research growth, ownership and leadership. Furthermore, early experience with evaluation of new and improved interventions is associated with their more rapid introduction to benefit health.

EDCTP2 capacity-building funding at a glance

- **305** sub-Saharan African institutions benefiting from enhanced research facilities
- **201** fellows funded in 25 sub-Saharan African countries
- **534** trainees (including 197 Master's and 208 PhD students) funded through EDCTP grants
- **150** epidemiologists and biostatisticians across Africa funded through an EDCTP-Africa CDC joint initiative
- **37** sub-Saharan African countries benefiting from regulatory and ethics review capacity building
- **42** institutions in 27 sub-Saharan African countries participating in Networks of Excellence.

EDCTP integrated capacity development approach



Key aspects of capacity development

Capacity development requires an integrated, systems-oriented perspective. There are many aspects to clinical research capacity, and benefits will not be fully realised unless all are addressed.

Physical infrastructure such as laboratory, clinical facilities, data management and IT equipment is clearly essential. Development of **human capacity** is fundamental to long-term sustainability. Skills development is essential at all levels, from research leaders through up-and-coming researchers, to master's and PhD students at the start of their careers. Equally important are the laboratory support and research administration staff, who make an essential contribution to the research enterprise.

International networking – both North–South and South–South – is fundamental to capacity development. International connections facilitate the diffusion of knowledge and new experimental techniques. Stronger institutions can support the development of those with less experience. Networks facilitate the building of relationships to underpin mentoring and exchange to build research skills.

From a national perspective, high-quality clinical research depends on effective **systems of research regulation and oversight**. Structures and processes for ethical review of research proposals need to be in place to ensure that the interests of participants are protected, without creating unnecessary obstacles that delay research or deter clinical trial sponsors. These elements are important components of wider **national health research systems**, which also include the capacity of policymakers to use research evidence and scientific advice in decision-making in order to build better health care systems.

EDCTP and physical infrastructure

Support for building of physical infrastructure capacity is strongly tied to the needs of clinical research projects. Funding for essential research-ready clinical space, laboratory equipment, data management and other essential tools is embedded within proposals for clinical trial support, with 229 institutions in 38 countries hosting EDCTP-funded activities in sub-Saharan Africa.

Lack of physical infrastructure is one reason why institutions and countries without a strong track record of clinical research may struggle to compete in international funding calls. One role of the four EDCTP regional **Networks of Excellence** is to work with institutions in disadvantaged countries to build physical infrastructure so they are better able to compete for funding.

EDCTP and personal support

EDCTP provides dedicated **fellowship funding** to build human capacity in clinical research. By December 2021, EDCTP had supported 201 fellows, including 45 Senior Fellows, Africa's research leaders, and 125 Career Development Fellows, the research leaders of the future. EDCTP fellowships play a critical role in retaining and attracting back scientific talent. Senior fellowships also include an element of future capacity building, with funding provided for supervision and mentoring of junior researchers, helping to coalesce a critical mass of researchers around leading scientists.

The **EDCTP Alumni Network** and its associated web platform (<https://edctpalumninetwork.org>) encourage continued networking, collaboration and mentoring. Subsidiary networks have been established for each of the disease areas covered by EDCTP.

EDCTP has worked extensively with partners on fellowship support. Calls have been organised with the WHO Regional Office for Africa, WHO's Special Training Programme in Tropical Diseases (TDR), the Africa Centres for Disease Control (Africa CDC), the Africa Research Excellence Fund (AREF), foundations (such as the Fondation Botnar) and the private sector (including Novartis and GlaxoSmithKline). These calls have provided opportunities to build capacity in targeted areas.

The future of clinical research in the region will depend on a continuing stream of young, motivated and talented **trainee scientists**. EDCTP provides extensive support for master's and PhD studentships, embedded with its support schemes. This ensures that young researchers 'learn by doing', and gain research skills within the context of an ongoing major clinical research study, under the wing of a Senior Fellow, or with the supportive infrastructure provided by a regional Network of Excellence. By now,

EDCTP has supported 208 PhD and 197 master's students.

A further important aspect of skills development is **short-term training**. This provides opportunities for researchers to develop new skills, supported by African or European partners. Training is also used to build the capacity of support staff, for example in laboratory management or clinical study management, as well as in practical areas such as research proposal writing and grant management. Currently, 9,091 people have benefited from short-term training through EDCTP support.

EDCTP and ethics/regulatory capacity building

EDCTP has provided specific funding to develop regulatory and ethical review capacity within countries in sub-Saharan Africa, supporting activities in 37 countries. Although the region still hosts relatively few trials in comparison to its disease burden, more clinical research is being carried out in sub-Saharan Africa. Increasing global interest in conducting trials is increasing pressure on poorly resourced regulatory and ethical review bodies. Furthermore, increasingly complex clinical trial design and ethical issues, such as those surrounding research on vulnerable populations, pose major challenges to national regulatory authorities, as well as national and institutional research ethics committees. Moreover, registration of clinical trials in online registries is now internationally recognised best practice. EDCTP funded the establishment of the Pan-African Clinical Trials Registry (PACTR), the only WHO-endorsed clinical trial database in Africa and the premier source of information on African trials.

National systems therefore need the capacity to evaluate increasing numbers of proposals and to monitor active projects, and the skills to consider a wide range of issues. Dedicated EDCTP funding has enabled countries to strengthen their capacity and improve their efficiency through training programmes for members of ethical review committees, implementation of electronic proposal management and monitoring systems, and strengthening of national, regional and international coordination and networking. EDCTP funding has enabled groups of countries to work together to develop and harmonise regulatory and ethical review procedures,

drawing upon links to European partners and African regional bodies such as the African Vaccines Regulatory Forum (AVAREF).

One specific area of focus has been safety monitoring, with several projects building national capacity in **pharmacovigilance**. These activities are essential for ensuring that possible adverse events are identified and investigated in clinical trials and when new interventions are introduced. Effective pharmacovigilance systems protect populations, highlight possible safety issues with new interventions, and help to build public trust in clinical research and health systems.

EDCTP funding has also enabled projects to examine specific issues in regulatory and ethical review. These have included embedding a gender perspective in ethical review and research design, and capacity building specifically in French- and Portuguese-speaking countries.

EDCTP and networking

International networking allows researchers to tap into global networks, facilitating the spread of knowledge and new experimental techniques and providing access to research resources. It provides opportunities for placements and mentoring, as well as transfer of new technologies.

EDCTP clinical studies are based on collaborations between institutions in Europe and sub-Saharan Africa, and increasingly with partners in other high-income countries. These connect 229 institutions in 38 countries in sub-Saharan Africa with 153 institutions in 19 countries in Europe, as well as 14 institutions from other high-income countries beyond Europe.

In addition, South–South networking provides opportunity to share experience and expertise, and to harmonise and coordinate activities, for example through collaborative development of capacity. A key role in South–South networking is played by the four EDCTP regional **Networks of Excellence** – CANTAM in Central Africa, EACCR in East Africa, TESA in southern Africa and WANETAM in West Africa – which collectively span 42 institutions in 27 countries in Africa. Moreover, there is a North–South networking component with 16 European Institutions in 9 European countries. As well as providing routes for the dissemination of knowledge, they provide an important infrastructure for the training of young and upcoming scientists, help to develop

capacity in countries with less mature health research systems, and carry out preparatory studies that can provide the basis for later interventional studies.

Other important EDCTP-funded networks include two major international networks focusing on **epidemic preparedness**, ALERRT and PANDORA-ID-NET. Bringing together teams in multiple African and European countries, the networks are enhancing the capacity of countries to detect, prevent and respond to outbreaks of emerging and re-emerging infectious diseases.

National health research systems

The above examples illustrate how EDCTP is contributing to the development of multiple aspects of research capacity in sub-Saharan African countries. This integrated perspective aligns with the approach taken by the WHO Regional Office for Africa to develop sustainable national health research capacity in the region, and EDCTP and the WHO Regional Office have developed a strategic partnership to advance this agenda.

A series of high-level meetings have been held to discuss benchmarking of national health research systems in the region, using a tool developed by the WHO Regional Office. The most recent survey has revealed promising progress in national capacity development, and EDCTP is providing funding to support collection of data to the region's Health Observatory to facilitate ongoing monitoring of health research capacity.

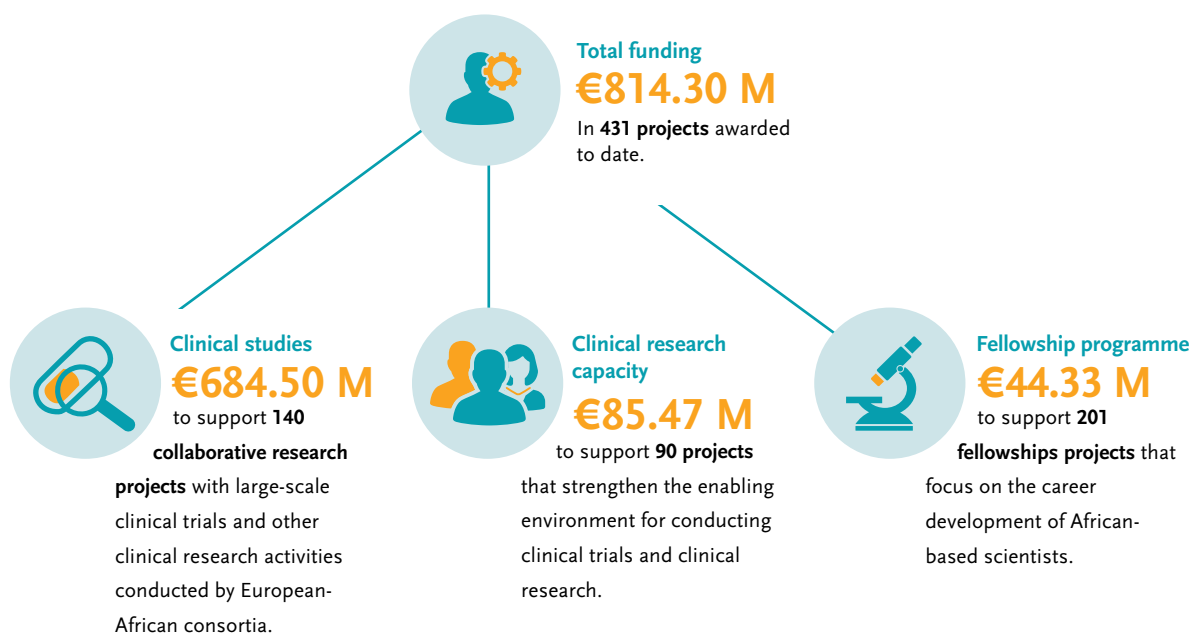
Conclusions

EDCTP grant funding and other activities are contributing to the development of high-quality and sustainable health research systems in sub-Saharan Africa. They are helping to support increasing numbers of clinical trials, and providing a firm foundation to support further extension of clinical research activity – in pursuit of a vision of research conceived, designed and executed in sub-Saharan Africa. This will ensure that countries in the region can identify and enact research agendas shaped by local health priorities, including capacity that can be mobilised to address emerging and re-emerging health challenges – such as Ebola, COVID-19 or whatever threat next emerges.



EDCTP's investment in research & development

2014-2021



Clinical research capacity

By type

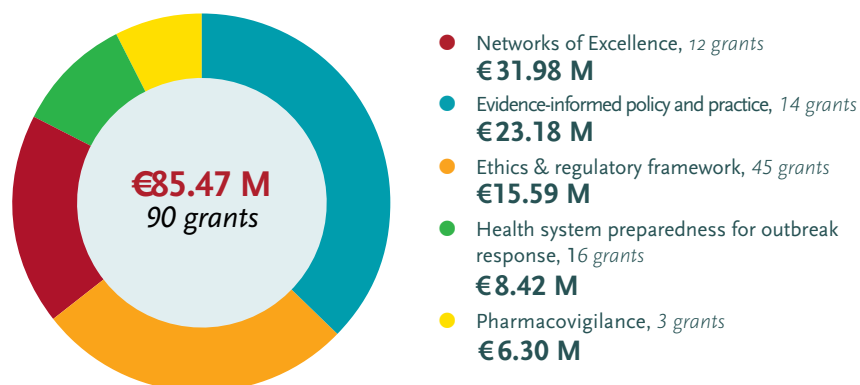
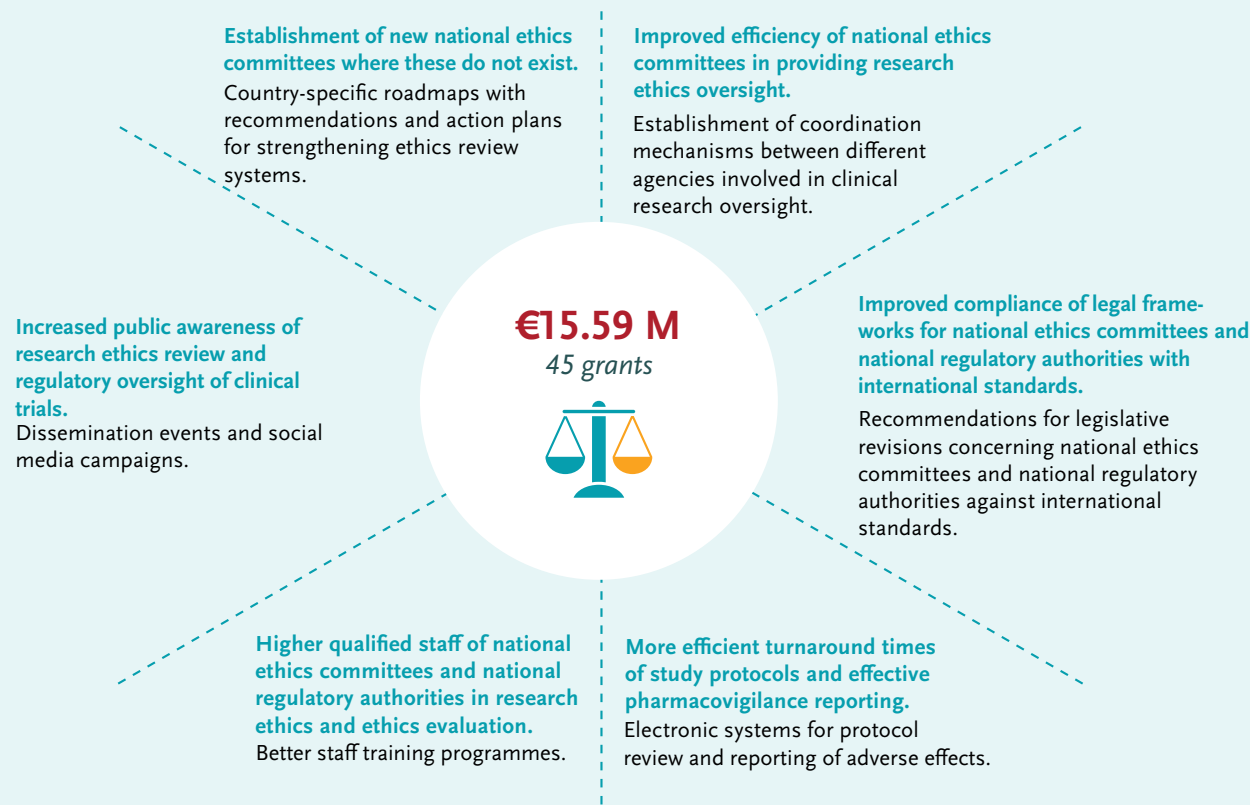




Photo:
A resident of the Kangemi community

2014-2021

EDCTP's contribution towards ethics and regulatory activities in Africa



Enhancing coordination of research oversight in Uganda

The CREDU project has developed systems to strengthen and streamline the activities of regulatory agencies and research ethics committees in Uganda.

The challenge

In Uganda, several bodies are involved in oversight of clinical research. These include the National Drug Authority, Uganda National Council for Science and Technology (UNCST), Uganda National Health Research Organisation, the Office of the President and research ethics committees.

It is important that these bodies protect the interests of research participants, and also operate efficiently to ensure the timely evaluation and implementation of safe and effective medical interventions.

The project

The CREDU project brought together Uganda's research oversight bodies, a key academic centre (the Infectious Diseases Institute at Makerere University) and the Mbale Regional Referral Hospital. It aimed to strengthen the capacity of the individual agencies, improve coordination among them, improve the quality of ethics review, and enhance networking across regulatory, clinical and research communities in Uganda and beyond.

Individual capacity building focused on ethics and regulatory training, exchange visits, and mentoring and placements at institutions outside Uganda. A one-week good regulatory practice course was developed for members of research ethics committees and staff of research oversight bodies.

To promote efficiency and coordination, a shared Clinical Research Information Management System (CRIMS) was developed, for use by research oversight bodies and research ethics committees. An introductory training workshop was attended by more than 100 participants from stakeholder organisations. As well as supporting more harmonised practice, CRIMS provides a convenient point of contact for researchers, providing an interface for data capture, data management, data validation, quality control

Project at a glance

Project: CREDU: Consortium for Clinical Regulation and Ethics Capacity Development in Uganda

Project lead: Ms Winfred Badanga Nazziwa, Uganda National Council for Science and Technology, Kampala, Uganda

Countries involved: Uganda

Target population(s): All

Year funded: 2017

EDCTP funding: €299,406

Project website: www.uncst.go.ug/credu-project

and regulatory compliance with clinical research management processes.

To enhance the quality of ethical review of research proposals, the CREDU project has strengthened the national research ethics committees accreditation system. The national accreditation committee has learned from US models and now plays a more active role in monitoring of ethics committee activities. More than 300 committee members, administrative staff and institutional heads have been trained in research ethics, ethics committee administration and review of research proposals.

Impact

The CREDU project has provided tools to harmonise and coordinate regulatory and ethics review activities in Uganda. As well as strengthening systems to protect the health and wellbeing of those participating in clinical research, the project has helped to generate a more supportive environment for clinical research in Uganda.

Boosting regulatory capacity in Liberia

The Lib-Regul-Trials project is building the capacity of Liberia's national regulatory authority to monitor drug safety and oversee clinical research more effectively.

The challenge

Liberia's national regulatory authority, the Liberia Medicines and Health Products Regulatory Authority (LMHRA) is relatively young, having been established in 2010. It has a particular focus on combating counterfeit drugs, a major problem in West Africa. For example, more than 120,000 children's lives may be lost each year because of substandard antimalarial drugs.

The LMHRA is also responsible for approving clinical trials in Liberia. During the 2014–16 West Africa Ebola outbreak, three major international trials of Ebola vaccines and therapeutics were launched, which highlighted that the LMHRA was ill-prepared to assist, review and oversee ongoing clinical trials in the country. This contributed to the slow start of clinical studies, which only began when the outbreak was nearing its end.

The project

The Lib-Regul-Trials project is strengthening the capacity of the LMHRA to carry out its core functions, including review and oversight of clinical research.

The project is supporting a review and updating of the country's regulatory framework for clinical research. A new electronic system is being introduced to facilitate submission, review and monitoring of clinical trial proposals. The skills of LMHRA staff in clinical research oversight are being developed, in areas such as appraisal of clinical trial applications, Good Clinical Practice, clinical trials monitoring and pharmacovigilance.

Relationships are being strengthened with other regulatory authorities to ensure closer adherence to international standards, and links are being built with institutional review boards and international organisations involved in strengthening and harmonising the work of national regulatory authorities.

Project at a glance

Project: Lib-Regul-Trials project

Project lead: Dr David Sumo, Liberia Medicines and Health Products Regulatory Authority, Liberia

Countries involved: Liberia

Target population(s): All

Year funded: 2017

EDCTP funding: €300,000

Impact

The Lib-Regul-Trials project will build the LMHRA's capacity in drug safety monitoring, a national priority area, and in clinical trial oversight. It will ensure that lessons are learned from the 2014–2016 West Africa Ebola outbreak and that the country is better prepared to respond effectively and rapidly to proposals to carry out research in outbreak settings. This will ensure that it is fully able to protect the health of its citizens through the comprehensive review of clinical protocols and monitoring of ongoing clinical trials.

Sharing ethics learning across Africa

The C2C-TEP project is enabling three countries spanning sub-Saharan Africa to learn from each other.

The challenge

Independent ethical review of research proposals is an essential element of clinical research. Many countries in sub-Saharan Africa have made great strides in strengthening systems for ethical review of clinical research, yet challenges remain in embedding such systems within national regulatory frameworks.

With many countries facing similar challenges, there are opportunities for countries in sub-Saharan Africa to share experiences and learn from each other, as well as from countries with longer-established ethical review systems.

The project

The C2C-TEP project is a South–South collaboration supported by internationally recognised ethics review experts. It links together stakeholders from East and West Africa, specifically Ethiopia, The Gambia and Ghana.

The project is founded on an evaluation of the current strengths and weaknesses of the existing research ethics review systems in the three countries. It has also explored how well national and institutional research ethics committees engage with national regulatory authorities.

These findings have been presented to representatives of stakeholder organisations, such as national ethics committees and research ethics committees/institutional review boards. These analyses will be used to develop strategies and action plans for improving national and institutional review systems.

The consortium aims to monitor implementation of improvement plans, and produce practical guidance that can be used to inform planning in other countries in the region.

Impact

The C2C-TEP project will enable the three countries involved to share experiences and

Project at a glance

Project: C2C-TEP: Coast to Coast Transcontinental Ethics Partnership

Project lead: Dr Jonas Lexow, MRC Unit, The Gambia

Countries involved: Ethiopia, The Gambia, Ghana, UK

Target population(s): All

Year funded: 2017

EDCTP funding: €261,377

Project website: www.mrc.gm/projects-details-others

learn from one another, avoiding duplication of efforts and promoting coordinated approaches to ethical review. As well as strengthening ethical review systems in individual countries, the project should also promote cross-country harmonisation, facilitating multicentre studies spanning the different countries.

Building ethical review capacity in Sudan

The Enhancing Ethics in Sudan project is building national and institutional capacity in ethical review of research.

The challenge

Sudan, the third largest country in Africa by area, has been affected by persistent insecurity in multiple areas, leading to extensive displacement of people and creating highly vulnerable populations. Despite some progress, infectious diseases still account for 30% of deaths in Sudan. In addition, levels of antimicrobial resistance are alarmingly high.

The project

Despite these security challenges and political instability, some health research is conducted in Sudan. The Enhancing Ethics in Sudan project aims to contribute to stronger health research infrastructure by developing national and institutional capacities for ethical review of research. The project focuses on the two main regulatory and ethics authorities in the country, the National Health Research Ethics Committee and the National Medicine Board, as well as Sudan's research ethics committees.

The first part of the project involved the review of the national guidelines that govern research on human participants, which were published by the Federal Ministry of Health in 2007. Through the work of 13 experts in research ethics, updated guidelines were developed, approved by the Federal Ministry of Health, and distributed to all research ethics committees in Sudan.

The project also worked with National Health Research Ethics Committee and the National Medicine Board to clarify their respective roles and responsibilities, including standard operating procedures (SOPs) for each. A template has also been developed to enable state and institutional research ethics committee to establish their own SOPs. A two-day workshop and discussion event was organised for members of the two bodies.

The project has also mapped institutional research ethics committees in Sudan, which identified nine functional committees. The project supported the training of 116 research ethics

Project at a glance

Project: Enhancing Ethics in Sudan

Project lead: Dr Shaza Abbas, University of Khartoum, Sudan

Countries involved: Sudan

Target population(s): All

Year funded: 2017

EDCTP funding: €291,042

Project website: <http://snrec.sd>

committee members from 16 institutes across five states, through a four-day workshop and three-week online course. Members of the project team have also assisted the Federal Ministry of Health in its review and strengthening of the National Health Research Ethics Committee, in the dissemination of updated guidelines, and strengthening of the accreditation system for research ethics committees.

The project has also helped to establish a national network – the Sudanese Network of Research Ethics Committees – linking national regulatory authorities and research ethics committees. This network will help to harmonise and standardise processes and provide a forum for discussion of ethical issues and challenges.

Impact

The project has strengthened national and institutional capacities for ethical review of research, ensuring stronger protection of the interests of human participants in clinical studies. Indirectly, the project also stimulated the Federal Ministry of Health to remind state Ministries of Health of their responsibility to establish state-level research ethics committees. Creation of such committees will further protect the interests of highly vulnerable populations.

Developing ethical review capacities in West Africa

The REECAO project is helping to develop and harmonise the research regulatory activities of three countries in West Africa – Ghana, Guinea and Mali.

The challenge

Increasing numbers of clinical trials are being conducted in sub-Saharan Africa. However, such trials raise a number of context-specific ethical issues, including potential research participant who are illiterate and socio-cultural specificities that raise questions about participants' understanding of how clinical research is conducted.

In addition, countries in West Africa are at risk of infectious disease outbreaks, as illustrated by the devastating 2014–16 Ebola epidemic. In these emergency situations, research needs to be initiated as rapidly as possible, while ensuring that participants' rights and interests are protected.

The project

The REECAO project is building the capacity of three West African countries – Ghana, Guinea and Mali – to provide effective ethics review of complex clinical studies. It aims to enhance the transparency, governance and coordination of ethics committees, thereby facilitating multicentre international studies.

The project brings together key bodies from participating countries, including national ethics committees, research ethics committees/institutional review boards, and national regulatory agencies. As well as these South–South links, expert input is being provided by Lyon Catholic University, France.

The project has established a network uniting national ethics committees and institutional review boards in the three countries, along with an associated website. This includes a bibliographic database updated every three months with key publications. An email hotline in French and English has also been created to enable ethics committee members to seek expert guidance. An online platform has also been established with standardised guidelines and

Project at a glance

Project: REECAO: Renforcement de l'Éthique des Essais Cliniques en Afrique de l'Ouest [Strengthening research ethics of clinical trials in West Africa]

Project lead: Dr Karim Traore, Ministère de la Santé et de l'Hygiène Publique, Mali

Countries involved: France, Ghana, Guinea, Mali

Target population(s): All

Year funded: 2017

EDCTP funding: €299,881

Project website: <http://reecaoafrica.org>

procedures for protocol submission and review.

The project is implementing a training programme for members of national ethics committees and institutional review boards covering ethical issues related to clinical trials and research on human participants. Training sessions, based on the 'train the trainer' model, have been held in each of the three participating countries.

Impact

The REECAO project is ensuring that research ethics committees in the three participating West African countries are equipped to manage complex emerging questions in clinical research, including research in emergency situations. It will enable the countries to respond more effectively and efficiently to clinical research proposals, including those involving international multicentre studies.

Regulatory and ethics capacity-building in Portuguese-speaking countries

The BERC-Luso project is building ethical review and clinical research regulatory capacity in five Portuguese-speaking countries – Angola, Cape Verde, Guinea Bissau, Mozambique and São Tomé and Príncipe.

The challenge

Strong national regulatory and ethics review frameworks for clinical research are essential to protect the interests of research participants and to create a conducive environment for clinical trials. However, many resources to support development of national regulatory and ethics review capacity are in English, disadvantaging Portuguese-speaking countries in the region.

Conversely, there are opportunities for countries to collaborate and coordinate development of regulatory and ethics review frameworks, avoiding duplication of efforts and promoting sharing of experiences across countries.

The project

The BERC-Luso project aims to develop and strengthen national medicines regulatory systems and ethical review of clinical research in five Portuguese-speaking countries – Angola, Cape Verde, Guinea Bissau, Mozambique, and São Tomé and Príncipe. As well as networking between these countries, it is also drawing on the expertise of Portuguese institutions with well-established regulatory systems.

The project is engaging with national ethics committees and national regulatory agencies. One key action has been a comparative analysis of the legislative framework for clinical research and regulatory bodies in the five participating countries. These comparisons, and benchmarking against international standards, were fine-tuned at a specially convened workshop in Lisbon, and have been used to create roadmaps for the development of national legislative frameworks in the participating African countries. The workshop was held immediately before a symposium organised by the project on international best practices in clinical research and the project's work with Portuguese-speaking countries in sub-Saharan Africa.

Project at a glance

Project: BERC-Luso: Biomedical Ethics and Regulatory Capacity Building Partnership for Portuguese-Speaking African Countries

Project lead: Professor Maria do Céu Patrão Neves, Ordem dos Farmacêuticos, Lisbon, Portugal

Countries involved: Angola, Cape Verde, Guinea Bissau, Mozambique, Portugal, São Tomé and Príncipe

Target population(s): All

Year funded: 2017

EDCTP funding: €299,986

Project website: <https://berc-luso.com>

The project will also be working to develop the skills and expertise of members of national ethics committees and national regulatory agencies, through an intensive theoretical and practical education programme and training, including internships in Portuguese institutions to apply knowledge.

The project has created a Portuguese-language website to strengthen networking between sites. This includes a digital repository of documents in Portuguese to support national ethics committees and national regulatory agencies activities.

Impact

The BERC-Luso project is strengthening links between Portuguese-speaking countries, and between these countries and Portugal, accelerating the development of regulatory environments that protect populations and facilitate clinical research for the benefit of local people.

Building ethics review capacity in Nigeria

The DREIN project is strengthening ethics review capabilities in Nigeria, and improving coordination across key national agencies involved in the governance of clinical research in the country.

The challenge

With an estimated population of more than 200 million, Nigeria is the most populous country in Africa. Infectious diseases account for a high proportion of deaths in Nigeria, and in recent years the country has been affected by multiple infectious disease outbreaks, including Lassa fever, yellow fever and meningitis.

To address these challenges, clinical research is essential, and bodies such as the Nigeria Centre for Disease Control are driving forward public health research in the country.

The project

The DREIN project aims to strengthen the environment for clinical research in Nigeria, working in close collaboration with the Federal Ministry of Health of Nigeria and key bodies involved in regulation of clinical research and ethics review of research proposals.

The project incorporates the Nigerian National Health Research Ethics Committee (NHREC), the Nigerian National Food and Drugs Administration and Control (NAFDAC), which jointly regulates clinical trials and manages the Nigerian Clinical Trials Registry with NHREC, and the Center for Bioethics and Research, Ibadan. It is also drawing upon training tools developed by the Council on Health Research for Development (COHRED).

The DREIN project is focusing on short-, medium- and long-term training of administrative and technical staff of research ethics committees in Nigeria. This includes two-month diploma-level training in research ethics coordinated by the Center for Bioethics and Research, as well as master's-level training for key NHREC and NAFDAC staff. Staff at seven high-volume research ethics committees are being trained to RHInNO Ethics, the electronic ethics review software developed by COHRED, and RHInNO Ethics software is being upgraded.

Project at a glance

Project: DREIN: Deepening Research Ethics in Nigeria

Project lead: Professor Clement Adebamowo, Center for Bioethics and Research, Ibadan, Nigeria

Countries involved: Nigeria, Switzerland

Target population(s): All

Year funded: 2017

EDCTP funding: €289,125

Project website: <https://edctp-drein-project.com>

The project is also promoting networking through annual joint training and workshops for the national agencies, whose staff are also being provided with advanced training in research ethics. In addition, it is providing technical assistance to support updating of the Nigerian National Code for Health Research Ethics and for development of sub-codes for research in vulnerable populations.

Impact

The DREIN project will make an important contribution to the strengthening of health research infrastructure in Nigeria as it seeks to address its key infectious disease challenges.

Building regulatory and ethics review capacity in Ethiopia

The SteRN project is promoting interactions between research oversight bodies and the research community to strengthen governance mechanisms for clinical research in Ethiopia.

The challenge

Over recent decades, Ethiopia has made great strides in addressing its health challenges, for example achieving substantial reductions in neonatal and maternal mortality. Its Health Sector Transformation Plan has set ambitious targets for the future. The Plan includes a commitment to research and evidence-based decision-making.

However, although countries such as Ethiopia often have a coherent policy framework for regulation of health research, implementation of policies is often incomplete.

The project

The SteRN project aims to build capacity to accelerate the implementation of policy and processes for the effective oversight of clinical research in Ethiopia. The project will be coordinated by the National Ethical Review Committee, in partnership with the national regulatory authority and research institutions in Ethiopia and other African countries.

The project's activities will be based on a review of clinical trials activity in Ethiopia and a needs assessment to determine development priorities for clinical trials ethics review. A training programme will be established to develop institutional capacity in ethical review, including master's-level education and continuing professional development. An online platform will be introduced to improve the efficiency of research protocol review. The project will also facilitate accreditation by WHO and strengthen monitoring and evaluation.

The project also aims to strengthen networking and coordination of stakeholders with an interest in ethical review of clinical research in Ethiopia.

Project at a glance

Project: SteRN: Strengthening the Capacity of the National Research and Ethics Review Committee and the National Regulatory Authority for Clinical Trials in Ethiopia

Project lead: Mr Yohannes Sitotaw Addisie, Ministry of Science and Higher Education, Ethiopia

Countries involved: Ethiopia, Uganda

Target population(s): All

Year funded: 2017

EDCTP funding: €299,800

Impact

The SteRN project will make a significant contribution to the development of an enabling environment for clinical research in Ethiopia, facilitating the studies that will be needed for it to achieve its ambitious public health goals.

Building regulatory and ethics review capacity in Kenya

The HATUA-Kenya project aims to strengthen capacity for ethical review in Kenya and build a better-connected community of practice.

The challenge

Clinical research activities are growing rapidly in sub-Saharan Africa, with infectious disease a major focus of research. The complexity of clinical studies is also increasing as new types of trial design and new experimental approaches are developed.

For countries to benefit from these innovations, effective systems for regulation of clinical research are required, to protect populations while also facilitating research with the potential to benefit such populations. National systems must have the expertise and capacity to handle growing volumes of increasingly complex research.

The project

The HATUA project (*'hatua'* means 'action' in Swahili) aims to enhance the technical capacity of Kenyan regulatory bodies and selected high-volume institutional research ethics committees. Its goals are to strengthen oversight at a national level and enhance the performance of institutional bodies, as well as to improve coordination between regulators and institutional research ethics committees and across different committees.

The project is working closely with Kenya's national regulatory agency, the Pharmacy and Poisons Board, and the National Commission for Science, Technology and Innovation (NACOSTI), which is responsible for approving all clinical research in Kenya and accreditation of institutional research ethics committees.

The project's focus is on 'three Cs': compliance, capacity building and community building. For compliance, a capacity needs assessment was carried out to inform the development of shared online platforms at national and institutional levels. This has included systems for pharmacovigilance reporting, clinical trial registration, and research institution registration.

Project at a glance

Project: HATUA-Kenya

Project lead: Professor Elizabeth Anne Bukusi, KEMRI, Nairobi, Kenya

Countries involved: Kenya, Switzerland

Target population(s): All

Year funded: 2018

EDCTP funding: €300,000

Project website: <https://www.kemri.org/14-kemri-centres/hatua-kenya-project>

The online RHInno Ethics system for protocol submission and review is being introduced at both national and institutional levels.

Capacity is being built through master's training in bioethics for six students, as well as short-term training for research administrators and staff supporting the work of institutional research ethics committees. Community-building activities have included several workshops and other events organised in collaboration with the Bioethics Society of Kenya, to support sharing of experiences across institutions and discussion of topical ethical issues.

Impact

The HATUA project will strengthen ethical review capacity in Kenya, enabling it to consolidate its position as one of the leading countries for health research in sub-Saharan Africa.

Building capacity for diagnostics regulation in Liberia

The IGORCADIA project has strengthened the capacity of authorities in Liberia to regulate diagnostic use and oversee research on diagnostics.

The challenge

Accurate diagnosis is vital in both clinical practice and research. Diagnostic use can guide choice of therapy in care settings, while accurate diagnosis is essential in research for determining the efficacy of treatments.

National regulatory authorities have responsibility for ensuring the safety and performance of diagnostics, and for overseeing research involving diagnostics. These functions require specific expertise in assessment of diagnostics. However, the health research system in Liberia has limited experience and capacity in diagnostic regulation and oversight of research involving diagnostics.

The project

The IGORCADIA project has successfully built the diagnostics-related capacity of the Liberian Medicines and Health Products Regulatory Authority (LMHRA). It focused on three key areas – LMHRA's capacity to register and license the import and use of diagnostics, its ability to oversee and carry out diagnostics research, and coordination with other agencies.

Specific actions included a revision of Liberia's diagnostics-related regulatory framework, in collaboration with the Liberian Ministry of Health and the National Research Ethics Board. Three LMHRA staff underwent extensive training at the Ghana Food and Drug Authority, a Regional Centre of Regulatory Excellence. International experts also undertook 15 days' training on quality assurance for in vitro diagnostics.

LMHRA staff and those at project partner St Joseph's Catholic Hospital in Monrovia also benefited from five three-day workshops on key topics in diagnostics research. Ten participants went on to participate in a research project on malaria diagnosis in the Hospital.

The project also strengthened links between the LMHRA and St Joseph's Catholic Hospital, consolidating the latter's position as a reference laboratory partner for the LMHRA. Education sessions were organised on new diagnostics

Project at a glance

Project: IGORCADIA: Improved Governance and Research Capacities in Diagnostics for Infectious Diseases of the Liberian Medicines and Health Products Regulatory Authority (LMHRA)

Project lead: Dr Alfredo Mayor Aparicio, Barcelona Institute for Global Health (ISGlobal), Spain

Countries involved: Liberia, Spain

Target population(s): All

Year funded: 2017

EDCTP funding: €299,911

Project website: www.isglobal.org/es/-/igorcadia

technologies and hands-on refresher sessions on quality assurance and other aspects of Good Laboratory Practice and Good Clinical Practice. In addition, the Hospital's General Director spent a week in Spain gaining high-level skills in health facilities and research units.

As well as enhanced networking between the LMHRA and St Joseph's Catholic Hospital, the project also helped to establish a Diagnostic Steering Committee, through which the LMHRA shared progress with national and international stakeholders. In addition, links with the Liberian National Research Ethics Committee were strengthened, with the Committee coordinating training on ethical review and monitoring of diagnostics projects.

Impact

The IGORCADIA project has built regulatory capacity in a specialist and highly dynamic area of health research, diagnostics. Strengthened regulatory capacity will create an environment more able to host research on these infections and ensure use of effective diagnostic products in clinical practice. Furthermore, new and strengthened networks will ensure the longer-term sustainability of the progress made during the project.

Strengthening ethics review in French-speaking countries

The AFREENET project is enabling three French-speaking countries to work together and with European partners to build national ethics review capabilities.

The challenge

Increasing numbers of clinical trials are taking place in sub-Saharan Africa. Furthermore, the complexity of many of these trials is also on the rise. These developments pose a challenge to national ethics committees, which need to stay abreast of emerging ethical considerations as well as ensuring they operate efficiently.

Ensuring that ethics review committees are fit for purpose can be a particular challenge in French-speaking countries, as many support resources and training materials are produced in English.

The project

The AFREENET project is bringing together three French-speaking countries in sub-Saharan Africa – Benin, Côte d'Ivoire and Guinea – to support joint development of national ethics review capacities, drawing on the expertise of French-speaking European partners.

One key aim is to update working practices, with the adoption of revised standard operating procedures and internationally validated working methods. In the first year of the project, new IT and other equipment was purchased and additional support staff were recruited to ensure that the three national ethics committees were better able to carry out their duties.

The project is also undertaking activities to build the capacities of national ethics committees, in areas spanning basic ethics to more specific emerging issues. Extensive training sessions, lasting three and a half days, have taken place in each country, including practical exercises, all delivered in French. New mechanisms are being established to support longer-term training of committee members, including development of a pool of ethics trainers. The project aims to establish a training pathway to systematically build the skills of new committee members.

Project at a glance

Project: AFREENET: Africa Ethics Excellence Network

Project lead: Ms Virginie Pirard, Institut Pasteur, Paris, France

Countries involved: Benin, Côte d'Ivoire, France, Guinea

Target population(s): All

Year funded: 2017

EDCTP funding: €299,956

Project website: <https://research.pasteur.fr/fr/project/afreenet>

The project is also creating national and international networking structures to support greater sharing of experience and expertise. Awareness of the roles and activities of national ethics committees is also being raised among researchers, research institutes, regulators, international agencies and other stakeholders.

Impact

The AFREENET project has supported the collaborative development of national ethics committee capacity in three French-speaking countries, avoiding duplication of efforts and enabling countries to learn from each other as well as from European partners.

Strengthening ethics review in Portuguese-speaking countries

The LusoAfro-BioEthics project is supporting the collaborative development of national ethics review capabilities in three Portuguese-speaking countries.

The challenge

As in other countries in sub-Saharan Africa, clinical research has been on the increase in Portuguese-speaking countries. Research ethics committees have been established in ministries of health, universities and other research institutions to ensure that the interests of people are protected and research conforms to international standards of ethical practice.

However, research ethics committees in these countries have limited expertise and experience in ethics review of clinical research proposals. In addition, they face the drawback that most training materials and other resources are produced only in English.

The project

The LusoAfro-BioEthics project is uniting three Portuguese-speaking countries – Angola, Cabo Verde and Mozambique – and European partners to support joint and collaborative development of ethics review capabilities.

One key aim is to build the knowledge and expertise of ethics committee members, through a series of specialist workshops. The first two workshops, held in Angola and Cabo Verde, were attended by nearly 50 delegates in total. Online educational resources, on priority topics identified through initial consultations, have been produced in Portuguese.

The project has organised a self-assessment survey of research ethics committees in participating countries, to gain a clearer picture of capacity development needs. It is also focusing on developing administrative practices and promoting efficiency. Guidelines and other documentation are being produced in Portuguese in areas such as informed consent, protocol reviews, standard operating procedures, and assessing the procedures of research ethics committees.

Project at a glance

Project: LusoAfro-BioEthics: Strengthening Bioethics Committees in Lusophone African Region

Project lead: Professor João Schwalbach, Comité Nacional de Bioética para a Saúde, Mozambique

Countries involved: Angola, Cabo Verde, Mozambique, Portugal

Target population(s): All

Year funded: 2018

EDCTP funding: €291,496

Project website: <https://www.lusoafro-bioethics.org>

As well as physical meetings, which provide new networking opportunities, an online platform has been developed to support sharing of experience and expertise across the African and Portuguese partners. Notably, the project has also helped to create a new research ethics committee at the University of Cape Verde.

Impact

The LusoAfro-BioEthics project is enabling three Portuguese-speaking countries to jointly develop their research ethics capacities, reducing duplication of efforts, enabling the sharing of experiences, and drawing on the expertise of European partners. It has created a solid platform for the further joint development of capabilities in the three countries.

Strengthening ethics review and drug safety monitoring in Tanzania

The SMERT project is building capacity and strengthening the coordination of ethics review and drug safety monitoring activities in Tanzania.

The challenge

To provide a nurturing environment for clinical research, countries need effective and efficient regulatory and ethics review structures that safeguard the interests of participants in research and also minimise any unnecessary obstacles to clinical research. Effective pharmacovigilance systems to detect and investigate possible adverse reactions to new interventions are a critical aspect of these oversight mechanisms.

As national regulatory landscapes can be complex, effective coordination across stakeholders is also important. In Tanzania, key bodies include the National Institute of Medical Research (NIMR), the Tanzania Medicine and Medical Devices Authority (TMDA) and the National Health Research Ethics Committee.

The project

The SMERT project has focused on developing the technical competence of those involved in ethics review, the efficiency and coordination of administrative processes, and strengthening pharmacovigilance systems for clinical research in Tanzania.

It initially set out to identify the development needs of all stakeholders to inform future activities. The needs assessment covered the National Health Research Ethics Committee and 13 institutional review boards. A bioethics curriculum has been developed at Kilimanjaro Christian Medical University College for all postgraduate medical and biological sciences students, and has been taken up by two other universities in Tanzania. It incorporates several emerging areas of ethical interest, including research during public health emergencies and use of stem cell technologies. A staff member of the National Health Research Ethics Committee was supported to undertake master's training in bioethics, helping to build national bioethics capacity.

A short ethics training course has been developed and completed by 87 members of institutional review boards; it is being refined and will be made available as a free online resource. Following

Project at a glance

Project: SMERT: Streamlining the Health Research Ethics Review Process and Regulatory Framework in Tanzania

Project lead: Dr Nyanda Elias Ntingya, National Institute for Medical Research, Tanzania

Countries involved: Tanzania, the United Kingdom

Target population(s): All

Year funded: 2017

EDCTP funding: €299,949

Project website: www.mmrp.org/projects/interventions/smert-project

training of researchers and ethics committee members, the median time of approval of research protocols was reduced from 120 to 32 days.

In addition, an electronic system has been developed to enable the electronic submission and review of proposals and to deliver feedback to applicants. To improve efficiencies, the NIMR and TMDA have begun to undertake joint monitoring visits. In addition, to enhance pharmacovigilance, an electronic system has also been introduced for reporting of adverse events during clinical trials, and a system for reporting adverse events of licensed medicines has been advanced, leading to a tripling in the numbers of adverse events reported.

Impact

The SMERT project has achieved major improvements in the efficiency and coordination of ethics review activities in Tanzania, leading to measurable changes in performance. The project's activities have fed into the East African Health Research Commission's work on harmonisation of research ethics review and, with the SMERT project's support, the TMDA hosted a forum for East Africa's national medicines regulatory bodies – a first step towards the development of a common set of high-quality standards across the region.

Strengthening ethics review in Kenya

The STReK project is enabling the University of Nairobi to strengthen the capacity of research ethics committees in Kenya.

The challenge

Research ethics committees are essential for reviewing clinical research proposals and ensuring that projects conform to high ethical standards. The growth of clinical research in sub-Saharan Africa, and increasing complexity in the range of ethical issues that need to be considered, is placing strains on many countries' infrastructure for ethics review.

In Kenya, research ethics committees are accredited by the National Commission for Science, Technology and Innovation (NACOSTI), through its National Bioethics Committee. The number of accredited research ethics committees has increased from five in 2009 to 25 in 2018.

The project

Through the STReK project, the University of Nairobi is working in collaboration with NACOSTI and the National Bioethics Committee to improve the efficiency of the Committee and to strengthen the capacity of members of both the National Committee and institutional research ethics committees in the country to undertake ethics review.

The project has facilitated the development of a new strategic plan for the National Bioethics Committee, based on extensive consultation among stakeholders. To support more effective working and streamlining of its operations, the project has helped to develop a set of revised standard operating procedures for the National Bioethics Committee. These will provide templates for use by research ethics committees across the country.

With support from the STReK project, the National Bioethics Committee is also enhancing its IT infrastructure for monitoring research ethics committees and creating a database of committee members to support networking and consultation.

A research ethics training package is being developed and will be delivered to at least 120

Project at a glance

Project: STReK: Strengthening Research Ethics and Review and Oversight in Kenya

Project lead: Professor Walter Jaoko, University of Nairobi, Kenya

Countries involved: Kenya

Target population(s): All

Year funded: 2018

EDCTP funding: €299,736

committee members. A structured mentorship programme is also being introduced, including placements at mentor sites, for 22 research ethics committee members. At the end of the project, NACOSTI will organise a research ethics conference to promote networking, sharing of experience and benchmarking, with invitations extended to other national bioethics committees in East Africa and at least one EU research ethics committee.

Impact

The STReK project is strengthening connections between academia and a key regulatory body in Kenya, to improve the efficiency and quality of ethics review processes in the country. It will help to ensure that the country remains an attractive country in which to carry out clinical research and has the capacity to increase the volume of research undertaken.

Strengthening ethics review and regulatory processes in Zambia

The BUCARERZ project is building the capacity of Zambia's national bioethics committee and local research ethics committees.

The challenge

The Zambia National Health Research Policy of 2010 identified capacity building in ethical conduct of research as a key priority.

The body with overall responsibility for regulating clinical research in Zambia is the National Health Research Authority (NHRA). The NHRA includes a National Health Research Ethics Board (NHREB), which oversees research ethics committees and institutional review boards. However, these committees have limited expertise in ethics review, and the central regulatory bodies lack the full range of expertise necessary to build their capacity.

The project

The BUCARERZ project is enabling the NHRA to build its regulatory oversight capacities and systems, including those for ethics review of clinical research proposals. A research capacity needs assessment has been undertaken, as well as an audit of research ethics activities. These have been used to develop a national research ethics and regulatory capacity-building plan.

Through a 'train the trainer' model, 18 core staff from the NHRA, NHREB and the Zambia Medicines Regulatory Authority have taken part in training courses on various aspects of regulatory function across Africa, including Good Clinical Practice, Good Laboratory Practice and research ethics. Events are being organised to pass on this new knowledge to research ethics committee members, researchers and healthcare workers. NHRA staff will also undertake follow up of a selection of ongoing projects.

A new electronic platform, RHInnO Ethics, is being introduced for review of all proposals and research protocols.

Following the introduction of the new systems, the NHREB has begun to hold monthly meetings to improve efficiency and to manage

Project at a glance

Project: BUCARERZ: Building Capacity for Research Ethics and Regulation in Zambia

Project lead: Dr Godfrey Biemba, National Health Research Authority, Zambia

Countries involved: Zambia

Target population(s): All

Year funded: 2018

EDCTP funding: €297,597

Project website: www.nhra.org.zm/new

an anticipated increase in applications. This has led to a significant reduction in the time taken to review proposals, from an average of 90 days to less than 30 days.

The NHREB has also launched regular interactions with research ethics committees, to discuss emerging ethical issues and to promote harmonisation in procedures. NHRA and NHREB members will also develop international contacts to network and share experience, with partners such as the African Medicines Harmonisation Programme.

Impact

The BUCARERZ project is strengthening consideration of ethical issues in clinical research throughout the entire health research system in Zambia. As well as delivering measurable improvements in ethics review systems and practice, more generally it should also help to stimulate greater interest in clinical research across the country.

In-depth training in regulatory science

The Reg. Science-Fellows project will establish a cohort of individuals in southern Africa with practical experience of regulatory assessment.

The challenge

National regulatory agencies have a complex function to perform, needing to identify the most appropriate regulatory pathways for medicinal products and to carry out sophisticated risk–benefit analyses. In Zimbabwe and many other countries in sub-Saharan Africa, medicines reviewers and regulatory science staff to support these activities are in short supply.

Although some postgraduate training courses do exist, these generally lack a practical dimension and first-hand application of knowledge in regulatory decision-making.

The project

The Reg. Science-Fellows project is addressing this gap by developing a fellowship scheme jointly managed by the Medicines Control Authority of Zimbabwe and the University of Zimbabwe. Its aim is to develop a cohort of medicines reviewers and regulatory science professionals with particular expertise in key areas of product assessment. These include the assessment of new medicines being introduced into southern Africa, of complex biopharmaceutical products, and product licensing applications based on bioequivalence data (data aiming to show that a new product has the same activity as an existing licensed product).

The project is developing three-week competency-based short courses, as well as a two-year fellowship in regulatory sciences, and will undertake annual proficiency testing of Medicines Control Authority staff. Training will be available to other national regulatory agencies.

At least 100 staff will undertake the short courses and up to ten fellows will be supported through the fellowship programme. Fellows will complete the short courses as well as training at the Utrecht WHO Collaborating Centre for Pharmaceutical Policy and Regulation, practical work assignments and case studies, and work on live medicines reviews.

Project at a glance

Project: Reg. Science-Fellows: Competence-based Fellowship for African Medicines Reviewers and Regulatory Science Professionals

Project lead: Ms Tariro Makamure-Sithole, Medicines Control Authority of Zimbabwe

Countries involved: Zimbabwe

Target population(s): All

Year funded: 2018

EDCTP funding: €270,019

In the first 18 months of the project, 102 regulators and regulatory affairs professionals from five Southern African Development Community (SADC) countries undertook three short courses, and eight individuals from Botswana, Eswatini, South Africa, Zambia and Zimbabwe were appointed to the fellowship scheme through a competitive application process.

Impact

The Reg. Science-Fellows will build the capacity of staff at the Medicines Control Authority of Zimbabwe and other national regulatory authorities in the SADC area to undertake increasingly complex medicines reviews. It will also generate a pool of highly qualified experts in regulatory science able to further expand capacity in southern Africa.

Building regulatory capacity in Cameroon

The BREEDSAFCA project will support the development of capacity in ethics review and drug safety monitoring in Cameroon.

The challenge

National regulatory agencies have a critical public health role to play in protecting populations, during clinical trials and when new medicines are licensed and introduced.

In Cameroon, regulation of clinical research is the responsibility of the Division of Health Operational Research in the Ministry of Health. The Division sets up research ethics committees and works closely with the Cameroon National Ethics Committee, which reviews clinical research proposals. The Directorate of Pharmacy, Laboratory and Drugs is responsible for drug safety monitoring (pharmacovigilance). However, although policies and infrastructures exist for regulation of clinical research and pharmacovigilance, these are not widely enforced.

The project

The BREEDSAFCA project is strengthening national systems for ethics review of research and pharmacovigilance in Cameroon. Commissions are being set up to examine and revise existing regulations of ethics review and pharmacovigilance and to suggest new regulations where they are needed. The performance of bodies involved in these areas will be evaluated and plans developed to enhance their activities where required.

The project will support the set up of new ethics committees at two universities in two regions in Cameroon. It will also help to establish pharmacovigilance units for two new health programmes and in one new region of the country.

In the first year of the project, a review was undertaken of existing regulations covering research involving human participants, and a need was identified for two new regulatory guidelines. Key texts relevant to pharmacovigilance have also been collated, and will also be reviewed to identify the need

Project at a glance

Project: BREEDSAFCA: Strengthening the Regulatory Framework to Upgrade Ethical Review of Clinical Research and Drugs Safety Monitoring in Cameroon

Project lead: Dr Jerome Ateudjieu, Ministry of Public Health, Cameroon

Countries involved: Cameroon

Target population(s): All

Year funded: 2018

EDCTP funding: €296,384

for updating. In addition, a questionnaire has been developed that will be used to assess training needs among research ethics committee members, researchers involved in clinical studies in Cameroon, and staff in pharmacovigilance units.

Impact

The BREEDSAFCA project will build capacity in Cameroon in two key areas – ethics review of clinical research protocols and safety monitoring for drugs and other medical interventions, such as vaccines. In doing so, it will strengthen the protection provided to participants in clinical research in Cameroon, and protect public health more generally by improving monitoring and investigation of potential adverse reactions to drugs and vaccines.

Building regulatory and ethics review capacity in Togo

The ERUDIT project will support the introduction of tried-and-tested systems for efficient ethics review of research and drug safety monitoring.

The challenge

Although clinical research is growing in sub-Saharan Africa, French-speaking countries lag behind in the hosting of clinical studies, including clinical trials, and typically have less well-developed systems for ethics review of research proposals.

The Council on Health Research for Development (COHRED) has developed an electronic platform, known as RHInno Ethics (<https://rhinno.net>), which is specifically designed for management and ethics review of research proposals. RHInno Ethics is used by several countries in the region, but countries require support to introduce the system and to gain benefits from it.

The project

The ERUDIT project aims to ensure that the key bodies in Togo responsible for ethics review of clinical research – the national bioethics committee (Comité de Bioéthique pour la Recherche en Santé, CBRS) – and drug safety monitoring (Direction de la Pharmacie, du Médicament et des Laboratoires, DPML) are equipped with the technological tools and skills to operate a high-quality ethics review and regulatory system.

It is bringing together multiple national and international partners to introduce the RHInno Ethics platform into Togo, and to train key CBRS and DPML staff in its use. To enhance associated working practices, the project is also helping to develop and implement standard operating procedures for operation of the CBRS.

COHRED is coordinating implementation plans for RHInno Ethics, while project partner TCD eClinical Solutions is supporting its technical installation and support, PharmaEthics is overseeing development of standard operating procedures, and Pharmedics is providing French-language support across the full range of

Project at a glance

Project: ERUDIT project: Enhancing Togo's Ethical Review and Regulatory Competencies for Health Research

Project lead: Professor Mireille Prince David, Ministry of Health and Social Protection, Togo

Countries involved: Togo

Target population(s): All

Year funded: 2018

EDCTP funding: €300,000

Project website: <http://sante.gouv.tg/node/563>

clinical research review, auditing and inspection functions. Implementation of RHInno Ethics will also provide the CBRS and DPML with access to the many resources developed for the system.

The project will also support development of websites for the two organisations, introduction of electronic document management systems, and for drafting of a code covering the ethics of human participation in research, which is currently not part of the Code de Santé Publique in Togo.

Impact

The ERUDIT project will provide Togo's key ethics review and pharmacovigilance bodies with access to well-established technical infrastructure for managing clinical research applications, as well as support for its introduction and to enhance associated working practices. It will therefore help to develop sustainable and robust national capacity for efficient and high-quality ethical review.

Building ethics review and regulatory capacity in Senegal

The SEN-ETHICS project is enabling Senegal to strengthen and harmonise its regulatory processes for clinical research.

The challenge

Effective regulatory systems and ethics review processes are essential to protect populations participating in clinical research, including clinical trials, and those receiving medical interventions. Their importance is reflected in their inclusion as one of WHO's six building blocks of health systems – ensuring access to medical products of assured quality, safety and efficacy.

In Senegal, key regulatory bodies include the National Council for Ethics and Health Research (CNER) and the Department of Pharmacy and Medicine. While basic systems are in place, there is a need to constantly review and enhance procedures in light of developments in medicine and evolving ethical challenges.

The project

The SEN-ETHICS project aims to strengthen the capacity of Senegal's national ethics committee and national regulatory authority to support better governance of clinical trials and other regulatory functions. A situational analysis has been undertaken in the areas of regulation and ethics, identifying gaps and development needs. A roadmap has been developed for the implementation of recommendations at the CNER.

In the first year of the project, two regulatory workshops were organised, and during the course of the project 160 staff members will be trained on ethical and regulatory evaluation systems. Tools and procedures will be reviewed and updated as required, and also harmonised to improve collaboration across agencies.

The project has also begun work on the creation of a new institutional review board at IRESSEF, a recently launched national health and epidemiological research institute in Senegal.

To promote harmonisation and adherence to

Project at a glance

Project: SEN-ETHICS project: Upgrading National Ethics Review Systems and Regulatory Bodies in Senegal

Project lead: Dr Samba Cor Sarr, Ministry of Health and Social Action, Senegal

Countries involved: Senegal

Target population(s): All

Year funded: 2018

EDCTP funding: €293,922

Project website: www.cners.sn

good practices, the project is being undertaken in collaboration with key regional bodies, including the African Vaccine Regulatory Forum, the Developing Countries Vaccine Regulators Network, and the African Medicines Regulatory Harmonisation Programme and its 11 Regional Centres for Regulatory Excellence. It is also coordinating activities with the EDCTP-funded BCA-WA-ETHICS project, which is working to mainstream gender perspectives into ethics review processes.

Impact

The SEN-ETHICS project will enhance the capacity, efficiency and coordination of regulatory and ethics review processes in Senegal, to ensure consistency with the highest international standards.

Building regulatory and ethics review capacity in Zimbabwe

The ZERCaP initiative is enabling Zimbabwe to upgrade its policies and processes related to oversight of clinical research.

The challenge

Following several years of socio-economic turmoil, Zimbabwe has entered a period of relative stability. Until recently, the country's economic difficulties have led to little investment in health systems and health research, but this situation is beginning to change.

The Medical Research Council of Zimbabwe (MRCZ) is responsible for ensuring the ethical conduct of research in the country. Following several years of uncertainty and high staff turnover, it is now stabilising and looking to upgrade its oversight systems and processes, to provide a foundation for an expansion of health research in Zimbabwe.

The project

ZERCaP is enabling the MRCZ to address the key challenges facing its health research governance systems. For example, the country has not had a standardised clinical trials and health research oversight system, while research ethics committees are at different levels of maturity. Research proposals are still submitted manually, and tools for developing proposals for ethical approval and for conducting site visits are not harmonised.

In collaboration with the Medicines Control Authority of Zimbabwe, which is responsible for monitoring drug safety, and key research ethics committees at higher education institutions, the MRCZ is harmonising policies and guidelines covering oversight of clinical research. A development programme will ensure that new MRCZ staff are better able to support research ethics committees, leading to the creation of at least three centres of excellence in research ethics review.

In addition, an electronic system for receiving, reviewing and approving research proposals is being introduced. This will enhance access to clinical trial information across stakeholders, and

Project at a glance

Project: ZERCaP: Zimbabwe Ethics and Regulatory Capacity Project

Project lead: Mr Tendayi Kureya, Medical Research Council of Zimbabwe

Countries involved: Zimbabwe

Target population(s): All

Year funded: 2019

EDCTP funding: €290,000

feed into a wider database and online platform for sharing health research information.

Impact

The ZERCaP initiative will help to reinvigorate ethical oversight systems in Zimbabwe, creating a platform for future enhancements to ensure consistency with the highest international health research oversight standards. In doing so, it will establish a stronger foundation for the expansion of high-quality and ethically conducted clinical research to address the country's health challenges.

Building regulatory and ethics review capacity in Ghana

The STREC-Ghana project is enhancing coordination across the bodies involved in clinical research oversight in Ghana.

The challenge

Ghana has a relatively strong science base and a well-respected regulatory system for clinical research – it is, for example, a designated Regional Centre of Regulatory Excellence. Nevertheless, it faces increasing demands as the number of national and international clinical research proposals increases. In addition, it continues to face major infectious disease threats, including Ebola outbreaks.

The Council for Scientific and Industrial Research (CSIR-Ghana) is responsible for coordinating and regulating scientific research in Ghana. Its other key regulatory agency is Ghana's Food and Drugs Authority (FDA), which has a mandate to coordinate, approve and certify all clinical trials.

The project

The STREC-Ghana project is improving coordination across Ghana's regulatory bodies and its 17 accredited research ethics committees. It is also undertaking a systematic assessment of its regulatory, ethics and structural capacity, in order to identify key gaps and development needs.

The project is based on a partnership between CSIR-Ghana and the FDA, as well as with the Council on Health Research and Development (COHRED, headquartered in Switzerland), Pharmalys (Senegal) and Pharma Ethics (South Africa). This collaboration will enable a detailed review to be undertaken of capacity, based on a stakeholder participatory approach, to inform the development of plans to create a strengthened and more responsive system.

Based on this situational analysis, specialist and targeted technical training will be provided to those involved in the coordination, regulation and monitoring of clinical trials. The tried-and-tested RHInno Ethics online ethics review system (<https://rhinno.net>) will also be introduced, with support of the project partners,

Project at a glance

Project: STREC-Ghana project: Strengthening Regulatory and Ethics Capacity in Ghana

Project lead: Dr Mike Yaw Osei-Atweneboana, Council for Scientific and Industrial Research, Ghana

Countries involved: Ghana, Senegal, South Africa, Switzerland

Target population(s): All

Year funded: 2019

EDCTP funding: €300,000

to improve efficiency and the consistency of processes, and to enhance coordination across stakeholders.

Impact

The STREC-Ghana project will ensure that Ghana maintains its commitment to continuing quality improvements in its regulatory systems, with more efficient processes and greater coordination across sectors. Ultimately, it will enable Ghana to maintain and enhance its favourable environment for high-quality clinical research.

Building regulatory capacity in southern Africa

The SPaRCS project is enabling four countries in southern Africa to collaborate on strengthening regulatory systems for clinical research and drug safety monitoring.

The challenge

As increasing numbers of medical products are evaluated in clinical trials and introduced in African countries, there is a growing need to ensure that effective systems are in place to regulate clinical studies and to monitor for potential adverse events. To date, these aspects of health systems have not received the attention they merit.

Similar challenges are faced by all countries, and there are opportunities for different countries to share experiences, learn from each other and coordinate efforts to develop their national regulatory systems.

The project

The SPaRCS project is supporting coordinated development of regulatory capacity in four southern African states – Eswatini, Namibia, South Africa and Zimbabwe. It has a particular focus on regulation of clinical trials and drug safety monitoring (pharmacovigilance).

The project is encouraging collaborations between regulatory agencies and academia and across the four countries, helping to establish sustainable relationships and a community of practice that will last beyond the project. In the first phase of the project, regulatory structures, personnel, activities and reporting systems are being mapped in each of the countries, using a participatory approach.

The results of this mapping exercise will feed into a second phase exploring opportunities for mutual learning across the four national regulatory authorities, including exchange visits and topic-specific workshops. In the final phase, local experts and education institutes will be involved in the development of educational materials to enhance the capacity of health professionals in pharmacovigilance and adverse event reporting.

Project at a glance

Project: SPaRCS project: Strengthening Pharmacovigilance and Regulatory Capacities in Four Southern African Countries

Project lead: Dr Hazel Bradley, University of Western Cape, South Africa

Countries involved: Eswatini, Namibia, South Africa, Zimbabwe

Target population(s): All

Year funded: 2020

EDCTP funding: €299,896

Impact

The SPaRCS project will enhance the personnel and institutional capacities of the national regulatory authorities in the four countries, through increased connectivity, reciprocal learning and a community of practice that will support further reflective practice and collaborative learning into the future.

Building regulatory and ethics review capacity in Sierra Leone

The SERCLe project is enabling EU–Africa collaborations to strengthen ethics review and regulatory systems for clinical research in Sierra Leone.

The challenge

The number of applications for clinical research has risen nearly tenfold in Sierra Leone over the past decade. The complexity of applications has also increased, with research proposed on vulnerable populations, high-risk pathogens, and novel therapeutics and diagnostics.

At the same time, Sierra Leone is still recovering from the impact of the 2014–16 West Africa Ebola outbreak, and has limited capacity to manage these increasing demands effectively.

The project

The SERCLe project is strengthening ethics and regulatory governance and practice in Sierra Leone, focusing on its national ethics committee, the Sierra Leone Ethics and Scientific Review Committee, and its national regulatory authority, the Pharmacy Board of Sierra Leone.

The project is undertaking a baseline assessment of institutional capacities, which will be used as the basis for the development of collaborative action plans to address key gaps. Priority areas will include governance mechanisms, including policy, guidelines and standard operating procedures, improving collaboration between the Ethics and Scientific Review Committee and the Pharmacy Board, strengthening links with regional and international organisations, developing the technical capacity of individuals, and building institutional capacity to undertake additional training in ethics review and regulatory oversight of clinical research.

The project will also extend links to other sources of expertise, including the Regional Centre of Regulatory Excellence in Ghana, the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden, the Council on Health Research for Development (COHRED), and the African Vaccines Regulatory Forum (AVAREF).

Project at a glance

Project: SERCLe project: Strengthening Ethics and Regulatory Capacity in Sierra Leone

Project lead: Mr Andy Leather, King's College London

Countries involved: Sierra Leone, UK

Target population(s): All

Year funded: 2020

EDCTP funding: €299,990

Impact

The SERCLe project will build upon existing successful collaborations between Sierra Leone and Europe, drawing on European and African centres of excellence to strengthen the ethics review and regulatory capacity of Sierra Leone. Alongside other capacity-building initiatives, it will create a more favourable environment for research on Ebola and other priority infectious diseases.

Building ethics review capacity in Liberia

The LiberHetica project is building an EU–Africa collaboration to strengthen ethical review of clinical research in Liberia.

The challenge

Liberia was badly affected by the 2014–16 West Africa Ebola outbreak. As well as the immediate loss of life, the outbreak also had a devastating economic impact and led to major disruption in Liberia's health systems. These setbacks undid much of the progress in Liberia achieved after the end of more than a decade of civil unrest in 2003.

As well as Ebola, the country faces the threat of multiple existing and emerging infectious disease threats, emphasising the need for strong health research systems, including regulatory and ethics review capacity.

The project

The LiberHetica project is establishing a collaboration between the EU and Liberia in order to strengthen ethics review practices. A key focus is on the institutional review board of the University of Liberia–Pacific Institute for Research and Evaluation, Liberia's leading site for infectious disease research, and the National Research Ethics Board of Liberia.

As well as working with these individual bodies, the project is also developing an ethics capacity improvement strategy to be presented to the Ministry of Health, Liberia for nationwide implementation.

The project aims to enhance links between Liberia and national ethics committees in Europe and other European organisations involved in oversight of clinical research. It will also build and strengthen links with African ethics networks and projects, including the EDCTP-funded REECAO project and ALERRT pandemic preparedness network.

The project is also improving collaboration and consistency of practice across other bodies in Liberia involved in ethics review, by developing and implementing standardised guidelines and operating procedures. Through subregional networks and engagement with surrounding

Project at a glance

Project: LiberHetica project: Increasing the Capacity of Oversight for Clinical Trials in Liberia by Establishing European–African Collaborations that Facilitate the Implementation of Efficient Processes, Harmonised Procedures, Standardised Guidelines and Educative Training Programmes

Project lead: Mr Jemee Tegli, University of Liberia–Pacific Institute for Research and Evaluation, Liberia

Countries involved: Liberia, UK

Target population(s): All

Year funded: 2019

EDCTP funding: €300,000

countries, the project will develop collaborations and promote adoption of harmonised ethics procedures. It will also address the balance of gender, expertise and representation of vulnerable populations on ethics review bodies.

Impact

The LiberHetica project will create a sustainable European–African collaborative network that will support the development and introduction of more efficient procedures, standardised guidelines, and ethics training programmes. Its activities will help to establish a stronger framework for clinical research in Liberia and a foundation for future capacity development.

Building regulatory capacity in Central Africa

The Africlinique project is drawing on a collaborative approach to strengthen the regulatory systems for clinical research in countries in Central Africa, starting with Cameroon and the Republic of the Congo.

The challenge

Despite the size of its population, sub-Saharan Africa hosts only a small proportion of the world's clinical trials. Even within sub-Saharan Africa, countries in Central Africa carry out relatively little clinical research.

Several initiatives have aimed to build capacity for clinical trials in Africa, and in Central Africa specifically. The EDCTP-funded Central African Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM) network (<http://www.cantam.org>), for example, has done much to develop individual and institutional capacity for research. However, further progress is being held back by limited regulatory and ethics review capacity in Central African countries

The project

The Africlinique project is strengthening the capacity of the national regulatory authorities of Cameroon and the Republic of the Congo. It is based on the creation of a collaborative network encompassing Central African and European national regulatory authorities as well as CANTAM and bodies such as the African Vaccine Regulatory Forum (AVAREF).

Through the project, the partners will collectively develop an action plan for implementation of new standard operating procedures, harmonised guidelines, training programmes and drug safety monitoring mechanisms. The network will also facilitate ongoing communication and education across partners.

The project is also developing a joint advocacy campaign highlighting the opportunities for clinical research in Central Africa, to raise awareness of the economic and societal benefits of clinical trials in the region, and to encourage clinical research organisations to consider Central Africa as a site for studies.

Project at a glance

Project: Africlinique project: A European–African Network for Strengthening the Regulatory Capacity for Clinical Research and Pharmacovigilance in Central Africa: Implementation of Harmonised Procedures, Efficient Guidelines and Training Programmes

Project lead: Professor Francine Ntoumi, Fondation Congolaise pour la Recherche Médicale, Republic of the Congo

Countries involved: Cameroon, Republic of the Congo, UK

Target population(s): All

Year funded: 2019

EDCTP funding: €300,000

Impact

The Africlinique project will create a sustainable European–African collaborative network that will strengthen regulatory and pharmacovigilance capacity in Central Africa, and establish efficient and harmonised approaches for regulation. It will help to nurture a more attractive environment for clinical research initially in Cameroon and the Republic of the Congo, and potentially also in other Central African countries which have the opportunity to join the collaboration.

Strengthening community engagement in Uganda

The SCINE-U project is enhancing the capacity of community advisory boards to feed into ethics review processes.

The challenge

Increasing numbers of clinical trials are being conducted in sub-Saharan Africa, making it ever more important that the interests of participants and wider communities are protected.

Through various initiatives, the ethics review capacities of the Uganda National Council for Science and Technology (UNCST) and institutional research ethics committees have been significantly strengthened in recent years. However, one area that has not been addressed to date is community engagement, for example through community advisory boards. There is currently limited guidance on engagement with such boards, so activities are dependent on the commitment of individual researchers.

The project

The SCINE-U project is supporting activities to enhance community input into national ethics review processes in Uganda. A situational analysis is being undertaken across the 19 institutions carrying out clinical research in Uganda to identify the routes through which communities currently feed into ethical review of research proposals. Consultations will take place with community advisory boards, participants, research ethics committees, national ethics regulators, researchers and other key stakeholders.

Based on the findings of the situational analysis, as well as a review of similar documentation used in other settings and interviews with key stakeholders, policies and guidelines on engagement with community advisory boards and operating manuals for such bodies will be developed.

The project will also develop an education programme and training materials to build the capacity of community advisory boards to provide input into ethics review activities, with training and mentoring of board members. An

Project at a glance

Project: SCINE-U project: Strengthening Community Structures in Clinical Research to Improve Oversight Role of National Ethics Regulatory Bodies in Uganda

Project lead: Mr Andrew Ojok Mijumbi, The AIDS Support Organization (TASO), Uganda

Countries involved: Uganda

Target population(s): All

Year funded: 2020

EDCTP funding: €294,286

online management information system will also be developed so that the UNCST can keep track of the involvement of community advisory boards in ethics review activities nationally. A monitoring and evaluation framework will be developed so that the functionality of boards can be tracked over time.

Impact

The SCINE-U project will close a key gap in ethics review activities in Uganda, strengthening links between national research oversight bodies and community advisory boards. It will also build the capacity of community advisory boards to play a meaningful role in clinical research ethics review and project monitoring activities. This will ensure that community advisory boards are better able to protect the interests of local communities and ensure that research adheres to sound ethical practices.

Strengthening regulatory and ethical review capacity in Rwanda

The BRECOR project is enhancing the capacity of key bodies in Rwanda involved in regulatory and ethics review of clinical research.

The challenge

For sub-Saharan African countries to develop and implement a health research agenda responsive to their needs, they need to ensure that they sustain an environment conducive to high-quality clinical research.

Given the increasing number and complexity of clinical research proposals, it is essential that countries have sufficient numbers of individuals with the expertise to review clinical research proposals, across all relevant disciplines.

The project

The BRECOR project is bringing together a range of international partners from Europe and sub-Saharan Africa to enhance the human and infrastructural capacity for regulation and ethical review of clinical research proposals in Rwanda. It will work with the key bodies involved in such review, including institutional review boards, which carry out an initial assessment of proposals, and the Rwanda National Ethics Committee, which approves all clinical trials in the country, as well as the Rwanda Food and Drug Authority (FDA).

As well as strengthening core national ethical review functions, the project will deliver hands-on training to ensure that members of Rwanda's eight institutional review boards have sufficient breadth of expertise and skills to effectively review the design, plans and feasibility of proposed clinical studies.

The project also aims to improve the efficiency of national systems, for example by introducing into the National Ethics Committee the RHInnO Ethics (<https://rhinno.net>) online system for submission, review and approval of protocols, as well as a paperless document and information management system. It also aims to improve oversight of ongoing projects through training of staff from the National Ethics Committee, institutional review boards and the FDA on

Project at a glance

Project: BRECOR project: Building the Regulatory Capacities of Rwanda

Project lead: Dr Jean-Baptiste Mazarati, Ministry of Health, Rwanda

Countries involved: Rwanda, Senegal, South Africa, Switzerland

Target population(s): All

Year funded: 2019

EDCTP funding: € 300,000

clinical trial assessment and monitoring by clinical quality assurance experts.

Impact

The BRECOR project will strengthen regulatory and ethics review capacity in Rwanda, ensuring effective protection of the interests of participants and providing a supportive environment for clinical studies addressing key local health issues.

Strengthening ethics review capacity in Eswatini

The ERECIS project is enhancing the capacity of key bodies in Eswatini involved in ethics review of clinical research.

The challenge

Since 2006, Eswatini has had informal structures in its Ministry of Health dedicated to safeguarding the interests of participants in clinical research.

With clinical research protocols becoming increasingly complex and often spanning multiple countries, Eswatini has a need to formalise and modernise its ethics review capabilities and ensure consistency with international best practice. In particular, there is a need to equip its national research ethics committee, the National Health Research Review Board (NHRRB), to better fulfill its national oversight role and to build the capacity of institutional research ethics committees so they are better able to assess clinical study protocols and monitor ongoing clinical studies.

The project

The ERECIS project is bringing together a range of international partners from Europe and sub-Saharan Africa to enhance the ethical review capacity of the NHRRB and institutional review boards in Eswatini. It will work with the country's key bodies involved in clinical research oversight, including the NHRRB, the Eswatini Ministry of Health and its Medicine Regulatory Authority.

The project will ensure that the Eswatini Ministry of Health has an appropriate set of policies and guidelines for clinical research assessment and monitoring, including for ethics review and clinical study monitoring. It will also organise a programme of training to build the capacity of institutional research ethics committees on clinical protocol evaluation and monitoring of clinical trials.

In addition, the project aims to improve the efficiency of ethics review systems, for example by extending use of the RHInno Ethics (<https://rhinno.net>) electronic platform from the NHRRB to three key institutional review boards. It also

Project at a glance

Project: ERECIS project: Enhancing Regulatory and Ethics Capacities in Swaziland [Eswatini]

Project lead: Ms Babazile Shongwe, Ministry of Health, Eswatini

Countries involved: Eswatini, Senegal, South Africa, Switzerland

Target population(s): All

Year funded: 2019

EDCTP funding: €300,000

aims to improve oversight of ongoing projects through training of institutional review board members on clinical trial assessment and monitoring by clinical quality assurance experts, as well as by facilitating use of the RHInno Ethics system for clinical study monitoring.

Impact

The ERECIS project will strengthen ethics review capacity in Eswatini, enabling institutional research ethics committees to play a more active role in clinical protocol evaluation and clinical study monitoring and allowing the NHRRB to play a more strategic role. These changes will build national capacity, improve efficiency, and ensure that ethical and regulatory oversight is consistent with the highest international standards.

Coordinating ethics and regulatory review in Uganda

The SCRECU project is supporting the wider use and evaluation of an information management system specifically designed for clinical research proposals.

The challenge

In recent years, Uganda has significantly strengthened its regulatory and ethics review capacity for clinical research. Regulation of clinical research is the responsibility of the Uganda National Council for Science and Technology (UNCST), which accredits the country's institutional research ethics committees.

However, Uganda also has other important regulatory and ethical review structures, such as the National Drug Authority. Developing submissions for different bodies can be time-consuming and costly, and may deter sponsors of multicentre clinical studies; researchers may also be unsure which regulatory agencies they need to approach. In addition, it has been challenging for different agencies to share information about complex trials, leading to fragmentation and sometimes duplication of efforts.

The project

In the EDCTP-funded CRECU project, an international consortium developed and piloted a new clinical research information management system, known as CRIMS. In the follow-up SCRECU project, CRIMS is being rolled out across a wider range of stakeholders, including the 23 institutional research ethics committees in Uganda.

The CRIMS system provides a common platform supporting the submission, review and approval of clinical research protocols. The project is working with Uganda's institutional research ethics committees to ensure they have the technical infrastructure and skills to implement CRIMS. This will help to ensure a consistency of approach across different agencies and ethics committees, as well as the sharing of information.

Project at a glance

Project: SCRECU project: Scaling up Capacity of Research Ethics Committees in Uganda

Project lead: Dr Maxwell Otim Onapa, Uganda National Council for Science and Technology

Countries involved: Uganda

Target population(s): All

Year funded: 2019

EDCTP funding: €299,901

The project also includes a nested evaluation of CRIMS in different settings, to support further enhancements to the system in light of user experience.

Impact

The SCRECU project will support the scaling up of an online ethics review system across additional stakeholders in Uganda, helping to raise and harmonise standards across institutional research ethics committees and providing a more efficient mechanism for researchers preparing submissions. It will better prepare the country to manage increased numbers of clinical trial applications of increasing complexity, thereby consolidating Uganda's position as an attractive location for clinical studies and trials.

Promoting a gender perspective in ethics review

The BCA-WA-ETHICS project is building the capacity of ethics review committees in Senegal to incorporate a gender perspective into their activities.

The challenge

Sex and gender can have an important influence on the risk of disease and on the appropriateness and effectiveness of treatments. Influences may relate to biological differences between sexes, or sociocultural factors related to sex, gender or gender identity.

In particular, women may be disadvantaged within certain societies, or have particular interests that need to be considered in the design of clinical research studies. It is important that ethics review bodies routinely and systematically consider the specific interests of female participants in research, and more broadly take account of the potential impact of sex, gender and sexual identity.

The project

Through the BCA-WA-ETHICS project, an international consortium is mainstreaming a gender perspective into the activities of Senegal's national research ethics committee (CNERS). It further aims to disseminate good gender-related practice in ethics review more widely across West Africa.

The project will build the capacity of CNERS committee members to systematically consider gender issues in its assessment of clinical research proposals, and whether such proposals have adequately considered and addressed gender issues. Existing tools focused on assessing a gender perspective in protocol evaluation and project monitoring will also be adapted for use in local context.

The project is beginning by mapping the full range of sex- and gender-related issues that need to be considered in Senegal and West Africa more generally. This landscaping activity will be used to inform the development of training plans for CNERS committee members and other key stakeholders.

A subset of trainees will also have the opportunity of internships in Spain to observe

Project at a glance

Project: BCA-WA-ETHICS project: Building Capacities in Gender Mainstreaming for Ethics Committee Members from Senegal to West Africa

Project lead: Assistant Professor Guillermo Martinez-Perez, University of Zaragoza, Spain

Countries involved: Senegal, Spain

Target population(s): All

Year funded: 2019

EDCTP funding: €299,909

how gender-related issues are addressed by Spanish ethics committees. The project will also explore ways to further advance the professional development of individuals involved in initial training. In addition, it will liaise with other EDCTP-funded projects involving the CNERS (such as the SEN-ETHICS project) to promote consideration of gender-related issues.

The project will also build wider networks across West Africa to promote gender mainstreaming in national research ethics committees. The landscaping report will be widely shared, events organised to facilitate discussion and sharing of experience, and a virtual community of practice established to promote networking across stakeholders in West Africa.

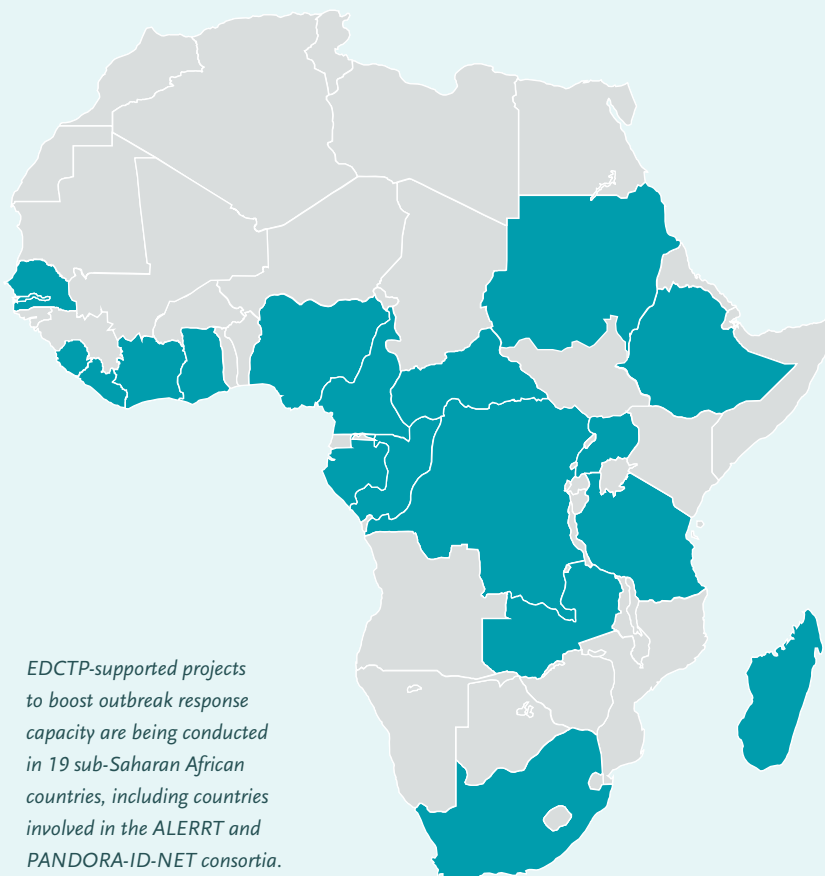
Impact

The BCA-WA-ETHICS project will better enable members of national research ethics committees to consider the gender perspective. Through networking and development of a white paper, the project will also facilitate the development and harmonisation of gender-sensitive policies and practice in ethical review across West Africa more generally. It will also explore barriers to the participation of female scientists in health research and on research ethics committees in West Africa.



Health system preparedness for outbreak response

2014-2020



Building research capacity in Liberia

The SELeCT project has enhanced the capacity of St Joseph's Catholic Hospital in Monrovia, Liberia, to undertake clinical research on Ebola and other infections affecting women and children.

The challenge

The 2014–16 West African Ebola epidemic revealed that the countries affected – Guinea, Liberia and Sierra Leone – were poorly prepared to undertake clinical infectious disease research. As a result, this made it difficult to conduct clinical trials during the outbreak.

In addition, community mistrust and a lack of understanding of clinical research is a significant obstacle to research in such settings.

The project

The SELeCT project had the highly specific aim of developing institutional capacity to conduct biomedical research and undertake clinical trials at St Joseph's Catholic Hospital in Monrovia, home to 30% of the population of Liberia. The Hospital is an NGO providing primary healthcare services to the people of Monrovia, with a particular focus on the care of women and children. The project was led by the Barcelona Institute of Global Health (ISGlobal) and also included the Fundación Juan Ciudad NGO.

Through the project, 14 staff undertook six-month training on Good Laboratory Practice and Good Clinical Practice, through hands-on workshops and an e-learning programme. As part of their training, nine course participants successfully undertook a practical research exercise, to explore the burden of malaria among women attending antenatal care, which generated several research papers. This work found that 12% of mothers had malaria infections, including drug-resistant infections.

In addition, equipment was upgraded in hospital laboratories, and laboratory managers received training in Good Laboratory Practice and development of standard operating procedures.

The project also aimed to strengthen community engagement. Key community stakeholders – ten traditional leaders – were invited to a participatory workshop and provided guidance on Good Clinical Practice and Communication. They were also invited to join a community advisory board, established to provide community and stakeholder input into the design of research projects and to build trust with the local community.

Project at a glance

Project: SELeCT: Strengthening Laboratory Capacities in the St Joseph's Catholic Hospital (Monrovia) for Clinical Trials on infectious diseases

Project lead: Dr Alfredo Mayor Aparicio, ISGlobal, Barcelona, Spain

Countries involved: Liberia, Spain

Target population(s): All, especially women and children

Year funded: 2016

EDCTP funding: €242,917

Impact

The SELeCT project has enhanced the capacity of St Joseph's Catholic Hospital to take part in clinical research during infectious disease outbreaks. It has also stimulated interest in clinical research at the hospital, leading to further grant applications. The project has also helped to build stronger relationships with local communities, which will facilitate future research and inspire community confidence in research.

ISGlobal and the Hospital are also collaborating on the EDCTP-funded IGORCADIA project, a collaboration also involving the Liberian Medicines and Health Products Regulatory Agency, which is building capacity in regulation of diagnostics.

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Building Ebola preparedness in northern Uganda

The ENDORSE project has strengthened the capacity of health workers and institutions to manage infections, including Ebola, in an area at risk of emerging infections.

The challenge

Northern Uganda was the site of the largest Ebola outbreak before the 2014–16 West Africa Ebola epidemic, and remains at risk of further outbreaks.

Healthcare facilities in at-risk areas have a key role to play in the care of people with Ebola or other dangerous infections, but are also important sites for the spread of infections. In addition, health workers are themselves at particular risk of becoming infected.

The project

The ENDORSE project has built health worker capacity in northern Uganda, focusing on epidemic preparedness, biosafety and personal protection from infectious agents in both clinical and laboratory settings.

Following consultations to identify needs, the ENDORSE team developed a package of activities based on the train-the-trainer model. During the first phase of the project, 19 health workers from nine hospitals in northern Uganda received training on infection prevention and control, as well as on methods of adult learning, through theoretical and practical sessions.

In the second phase of the project, the trainers and hospital administrators identified participants who could benefit from training. The training course was delivered to a total of 144 health workers across the nine hospitals, through lectures, group reflection, exercises and practical sessions. The trainers have also begun to cascade training out to other health facilities.

The project concluded with a final conference for participants and other stakeholders, to share experiences and discuss ways to take the initiative forward.

Project at a glance

Project: ENDORSE: Enhancing Individual and Institutional infectious Disease Outbreaks Response Capacities of Healthcare Professionals to Mitigate Infectious Emergencies in the Northern Uganda Region

Project lead: Professor Maria Rita Gismondo, University of Milan, Italy

Countries involved: Ireland, Italy, Uganda

Target population(s): Health workers

Year funded: 2016

EDCTP funding: €194,866

Project website: <http://climvib.eu/portfolio/endorse-edctp-csa-ebola-337/>

Impact

The project has strengthened the capacity of hospitals and other health facilities in northern Uganda to safely handle cases of Ebola and other serious infections. It will enable the centres to offer safer care and take part in research in an area at particular risk of emerging infections, and thereby better contain and prevent infectious disease emergencies in the region.

Building capacity for early-phase clinical trials in Uganda

The Capa-CT project built the capacity of Makerere University College of Health Sciences in Uganda to undertake phase I trials of drugs for infectious disease.

The challenge

Control of the 2014–16 West African Ebola epidemic was held back by the lack of licensed treatments. Similarly, no licensed treatments are available for other viral haemorrhagic fevers with high fatality rates.

However, although the burden of such infections is highest in sub-Saharan Africa, relatively few centres have the specialist facilities and expertise to undertake early-phase clinical research on new therapeutics.

The project

The Infectious Diseases Institute at Makerere University College of Health Sciences in Uganda is a well-established centre of excellence in infectious disease research. The Capa-CT project has built on this foundation, enhancing its capacity to undertake early-phase clinical studies.

To support skills development, the project organised four training workshops on key aspects of clinical management, pharmacokinetic modelling and statistical methods for drug development, delivered to more than 100 local staff. Training was supported by a professor-in-residence initiative. Individual staff received postgraduate training in pharmaceutical medicine and regulatory affairs. One staff member also secured a one-year clinical trial unit placement through a separate EDCTP career development award.

The project also supported upgrading of research facilities and the Institute's research pharmacies. The Institute also identified potential intensive care unit referral sites and suitable patient transfer arrangements. In addition, the project introduced a range of new approaches to build quality management capacities, and catalysed the creation of a new position, a clinical trials quality manager.

Project at a glance

Project: Capa-CT: Enhancing Capacity for Phase I Clinical Trials in Uganda

Project lead: Dr Mohammed Lamorde, Infectious Disease Institute, Makerere University College of Health Sciences, Uganda

Countries involved: Uganda

Target population(s): All

Year funded: 2016

EDCTP funding: €124,512

Project website: <http://capa-ct.idi.co.ug>

Impact

The Capa-CT project has established capacity for phase I clinical trials at a leading site for infectious disease research in Uganda. The skills development also enabled the Institute to join a major international consortium for phase II drug development studies on new interventions for Ebola and Marburg virus infections in an outbreak setting. In addition, the Institute was able to secure further funding for the Capa-CT II project through a later EDCTP Ebola-specific call for proposals.

Building health research capacity in Sierra Leone

The RECAP-SL project identified priorities for health research strengthening in Sierra Leone after the 2014–16 Ebola epidemic.

The challenge

Under-developed health systems in affected countries, including Sierra Leone, were poorly prepared to manage the 2014–16 West Africa Ebola outbreak. The outbreak itself also had a significant damaging impact on health systems in affected countries, adding further to the health consequences of the outbreak.

Development and rebuilding of health systems after shocks such as the Ebola outbreak should be informed by evidence-based policies. However, countries such as Sierra Leone had limited capacity after the outbreak to systematically identify needs and to adopt evidence-informed policy and practice.

The project

The RECAP-SL project aimed to strengthen health research capacity in Sierra Leone, to facilitate the development and implementation of evidence-based policy and practice. It focused on the College of Medicine and Allied Health Services (COMAHS), Sierra Leone's only school of medicine and pharmacy.

The project established a health systems research centre at COMAHS, facilitating the development of a four-year research strategy and an action plan to support the development of institutional research capacity. The strategy has been widely used in COMAHS's discussions with potential research partners.

The project also supported the training of four research fellows in multidisciplinary health systems research, supported by mentors from the Liverpool School of Tropical Medicine, UK, and Sierra Leone. The fellows have received research training, taken part in COMAHS research projects and supported other researchers at COMAHS. Two of the fellows went on to secure PhD scholarships and one was accepted onto the highly competitive three-week intensive Health Systems Global

Project at a glance

Project: RECAP-SL: Institutional Capacity Development for Multidisciplinary Health Research to Support the Health System Rebuilding Phase in Sierra Leone

Project lead: Dr Haja Wurie, College of Medicine and Allied Sciences, University of Sierra Leone

Countries involved: Sierra Leone, UK

Target population(s): All

Year funded: 2016

EDCTP funding: €111,419

Project website: <http://recap.sl>

'Emerging Voices' networking and professional development programme.

In addition, research methodology training was provided to all final-year medical students, and a programme of engagement was undertaken for students at all stages of their studies to raise awareness of research and to encourage interest in research-related activities.

Impact

The project has established a health research centre within Sierra Leone's national medical school, providing a platform for further institutional research capacity strengthening. It has developed staff research capacities and created international connections to support further capacity strengthening. The project has therefore laid the ground for further progress towards the long-term goal of a sustainable fit-for-purpose health system in Sierra Leone.

Building Ebola research capacity in Sierra Leone

The ID-CLINICAL-CAPACITY project has built on an established partnership between Sierra Leone and Europe to strengthen Ebola-related research capacity.

The challenge

An effective response to emergency infectious disease outbreaks requires strong health systems, including the capacity to carry out high-quality clinical research. The 2014–16 West Africa outbreak highlighted significant deficiencies in both these areas in the countries affected.

During the Ebola outbreak, the clinical response in Sierra Leone was strengthened through a long-standing partnership between King's Health Partners in London, UK, and partner institutions in Sierra Leone; 14% of all Ebola cases in the country were treated in units supported by the partnership.

The project

The ID-CLINICAL-CAPACITY project built on this existing Europe–Africa partnership to enhance the capacity for clinical research on Ebola and other regionally important infectious diseases in Sierra Leone. Working with key local academic and clinical partners, the project focused on developing individual research skills, the development of infrastructure to support research, and creation of an enabling environment for clinical research.

Additional material on research was introduced into undergraduate teaching at the College of Medicine and Allied Health Sciences (COMAHS), the only medical and pharmacy school in Sierra Leone. Extracurricular research training was also organised and several students were mentored through research projects.

Building on a widespread desire to play a more significant role in research, workshops, seminars and training were organised for clinicians at key clinical centres, the 34 Military and Connaught Hospitals. Six clinicians received one-to-one mentorship and were supported through successful research projects leading to published outputs.

The project also enabled Connaught Hospital to upgrade its status, so that it was able to

Project at a glance

Project: ID-CLINICAL-CAPACITY: Building research capacity in clinical management of infectious diseases at two main adult government hospitals in Freetown, Sierra Leone

Project lead: Mr Andy Leather, King's College London

Countries involved: Sierra Leone, UK

Target population(s): All

Year funded: 2016

EDCTP funding: €249,000

isolate and treat patients with a wide range of infections. An electronic data management and records system has been introduced, as well as structured assessments and data capture. These systems will facilitate both clinical management and research.

To facilitate drafting of research proposals, the project supported the development of guidelines and templates for clinical research. Members of the partnership have also contributed to technical working groups set up by Sierra Leone's Ministry of Health and Sanitation to integrate research priorities into strategic plans.

Impact

The ID-CLINICAL-CAPACITY project has built on a strong existing partnership between institutions in Sierra Leone and Europe to enhance both clinical and research capacity in facilities central to the responses to outbreaks of Ebola and other infectious disease. It has increased the preparedness of the country to address future outbreaks and to play a more significant role in research undertaken during emergencies.

Enhancing Ebola preparedness in Gabon

The SECC project has strengthened the Ebola-related research capacity of a key institute in Gabon.

The challenge

The Centre de Recherches Médicales de Lambaréné (CERMEL) is a well-respected research institute in Gabon, with a strong track record of participation in clinical trials. It has, for example, contributed to trials of the RTS,S/AS01 malaria vaccine and a phase I Ebola vaccine trial.

However, CERMEL has lacked the capacity to carry out certain laboratory assays, which therefore have had to be outsourced to international partners. Developing the infrastructure and skills base to conduct these assays would extend the range of studies to which the centre could contribute and enable more timely monitoring of study participants.

The project

The SECC project has strengthened the capacity of CERMEL to carry out Ebola-related research. Its biosafety manual has been revised and now includes standards to maintain safety in level 2 and 3 laboratories and for shipping of samples to biosafety level 4 facilities. A biological waste management plan consistent with international standards has been set up and a new biosafety committee established.

Through the SECC project, CERMEL has also introduced laboratory assays for monitoring replication of a virus-based Ebola vaccine, and trained staff in their use. This will allow on-site monitoring of replication of the vaccine virus in trials in children, enhancing safety monitoring.

Other training packages have been used to develop local skills in a range of molecular assays and management of laboratory facilities, including infectious disease surveillance, viral testing and exploratory testing of samples from patients with unidentified infections. This enhanced capacity will enable the centre to contribute to a wider range of research studies.

The project also supported the organisation of a four-day African Congress for Clinical Trials, which has the potential to become a regular

Project at a glance

Project: SECC: Vaccine Trials and Deployment Towards Sustainability of Ebola Virus Disease Control

Project lead: Dr Selidji Agnandji, Centre de Recherches Médicales de Lambaréné, Gabon

Countries involved: Gabon, Germany, UK

Target population(s): All

Year funded: 2016

EDCTP funding: €18 M

Total project funding: €20,000

Project website: www.africancct.org/description-eng

scientific conference for all those involved in clinical trials in Africa.

A final aim of the project was to develop a decision-making framework to expedite responses to an Ebola outbreak. Following revision of the national Ebola preparedness and response plan, an evidence review board has been set up as a self-sustainable not-for-profit organisation to review scientific evidence of new strategies and interventions for Ebola and to recommend actions in case of an Ebola outbreak.

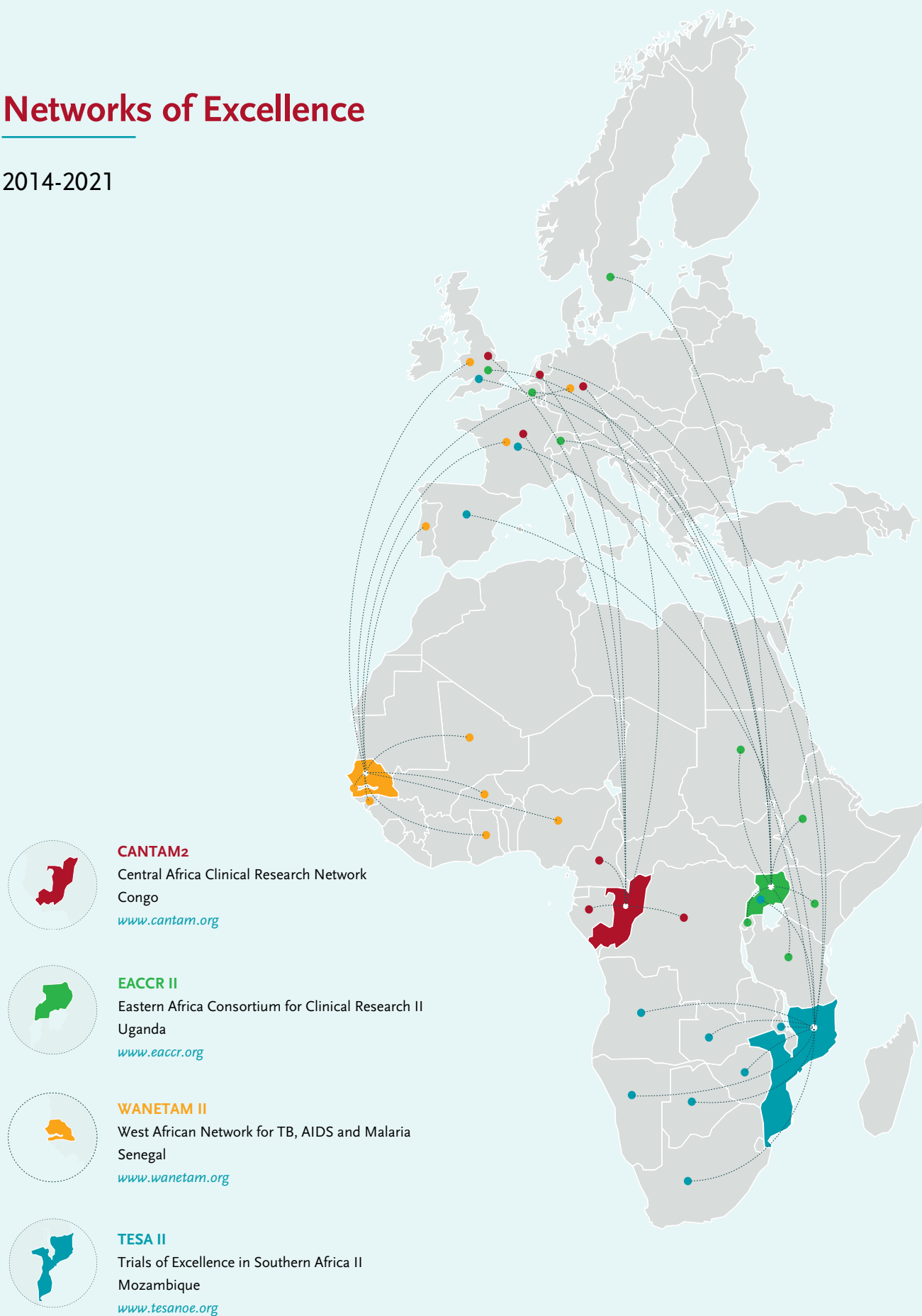
Impact

The SECC project has strengthened the capacity of CERMEL, Gabon's leading health research institute, to carry out research on Ebola and other viruses of epidemic potential. In addition, the principal applicant went on to secure a follow-on EDCTP fellowship. The project has also created a structure to promote evidence-based responses to new Ebola outbreaks.



Networks of Excellence

2014-2021



CANTAM2: Central African Network on Tuberculosis, HIV/AIDS and Malaria

The CANTAM network is drawing on South–South and North–South collaborations to strengthen clinical trial capacity in less-developed centres in Central Africa.

The challenge

Countries in Central Africa are badly affected by poverty-related infectious diseases. Furthermore, many of these countries have limited capacity to carry out international standard clinical trials and other clinical studies on these infections.

Nevertheless, centres of research excellence do exist in Central Africa and have the potential to disseminate knowledge and good practice through networking, taking advantage of their links to academic institutions in Europe.

The project

CANTAM was established in 2009 with EDCTP funding. It initially encompassed seven institutions in three countries – Cameroon, Republic of Congo and Gabon – and had the specific aim of developing the capacity of institutions in Cameroon and the Republic of Congo, drawing on an established research centre in Gabon.

Initial funding enabled the institutions to establish the CANTAM network and to connect to other regional and international networks. It provided a platform for training of multiple master's and PhD students in collaboration with European partners, as well as extensive short-term training. The network also carried out epidemiological studies characterising the prevalence, genotypes, and drug resistance profiles of HIV, malaria and TB pathogens in Cameroon and the Republic of Congo to provide a baseline for future intervention studies.

In follow-up CANTAM2 funding, the network is expanding to include additional African and European partners, including the Democratic Republic of the Congo, France, Switzerland and the UK, with Zambia as a collaborator. The scope of research has been expanded to include co-infections, including neglected infectious diseases, and co-morbidities.

Project at a glance

Project: Central African Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM)

Project lead: Professor Francine Ntoumi, Fondation Congolaise pour la Recherche Medicale, Republic of Congo

Countries involved: Cameroon, Republic of Congo, Democratic Republic of the Congo, Gabon, Germany, The Netherlands, UK, Zambia

Target population(s): All

Year funded: 2017

EDCTP funding: €2.98 M (CANTAM2)

Project website: www.cantam.org

CANTAM2 continues to have a focus on capacity-building, helping to build skills in conduct of clinical trials as well as the capacity of ethics review boards and regulatory authorities. A mentorship plan has been established to support the development of early-career researchers and to promote women in science. It is also strengthening laboratory capacity in participating institutions, including a new molecular biology and parasitology laboratory in the Republic of Congo and upgraded biobanks in the Republic of Congo and Cameroon, and establishing community liaison at each site to provide baseline data in advance of intervention studies.

Studies will have a particular focus on monitoring for adverse reactions to treatments, genetic characterisation of drug resistance, and analysis of drug–drug interactions. One specific project is a multicentre pharmacovigilance study of the Pyramax antimalarial treatment. Other studies will characterise the prevalence of co-morbidities and co-infections with soil-transmitted helminths and other neglected infectious diseases in local populations.

Impact

CANTAM is extending the number of institutions and number of health research staff able to take part in multicentre clinical trials in Central Africa. Baseline data on key pathogens will provide an important resource ahead of intervention studies. CANTAM is also reaching out to new partners, for example to offer assistance to ministries of health and regulatory agencies, and formed part of the PANDORA-ID-NET Consortium funded by the EDCTP to develop preparedness for outbreaks of emerging and re-emerging infectious diseases.

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EACCR: East African Consortium for Clinical Research

The EACCR network is building capacity for research into key poverty-related, neglected and emerging infectious diseases affecting East Africa.

The challenge

East Africa has a high burden of poverty-related infectious diseases and is at risk of outbreaks of Ebola and other viral haemorrhagic infections. The prevalence of TB, HIV/AIDS and malaria is high and co-infections are common; drug resistance is a growing threat.

Several countries in East Africa have well-established clinical research bases and strong links to European research collaborations. Networking provides opportunities to coordinate activities, share experiences, and build the capacities of less well-developed research sites.

The project

The EACCR was established in 2009 with EDCTP funding, initially with 17 institutions in five countries. Its core focus was on capacity building, through long-term (master's and PhD) and short-term training, as well as strengthening of laboratory capacities. Following needs assessments, the EACCR completed infrastructure upgrades at more than 20 sites. It enabled more than 200 researchers to attend ten short-term courses, conducted a wide range of research skills workshops, and supervised 30 postgraduate research fellows.

The EACCR also developed an innovative reciprocal monitoring scheme, generating a pool of experienced clinical trial monitors able to provide independent high-quality oversight of clinical trial activities. Trainee monitors are paired with experienced monitors so that they gain hands-on experience of clinical trial monitoring, raising awareness of quality management and increasing the pool of expertise able to perform monitoring activities in the region.

In follow-up EACCR2 funding, the network is expanding to cover neglected infectious diseases as well as Ebola. It has grown in size, now encompassing 23 African institutions in six countries and eight European partners from

Project at a glance

Project: East African Consortium for Clinical Research (EACCR)

Project lead: Professor Pontiano Kaleebu, Uganda National Health Research Organisation, Uganda

Countries involved: Belgium, Ethiopia, Kenya, The Netherlands, Rwanda, Sudan, Sweden, Switzerland, Tanzania, Uganda, UK

Target population(s): All

Year funded: 2017

EDCTP funding: €3 M (EACCR2)

Project website: <https://eacccr.org>

five countries. EACCR is also a part of the two EDCTP-funded epidemic preparedness consortia, ALERRT and PANDORA-ID-NET.

Thematic nodes of excellence have been established for malaria, TB, HIV/AIDS and neglected infectious diseases (primarily focusing on dengue, schistosomiasis, leishmaniasis, cysticercosis and Ebola), with a cross-cutting training node. Each area has a strong focus on collection of epidemiological, entomological and clinical data that will provide necessary background information to support interventional studies.

The network is also continuing its reciprocal monitoring scheme. It has reached agreement with projects being carried out at EACCR2 institutions to carry out monitoring activities. Network members and other partner institutions have successfully applied for additional EDCTP support, for example for the EXIT-TB study which is promoting new approaches to identify cases of TB that are currently being missed. The EACCR is also supporting four PhD projects associated with the Weltel trial, exploring the impact of weekly phone messaging on retention in a prevention of mother-to-child transmission trial.

Each node is coordinating needs assessments

and upgrading of infrastructure for clinical trial sites, and exploring opportunities for development of joint research protocols, including multi-disease studies to examine the impact of co-morbidities. The network is also continuing to organise a wide range of training opportunities for researchers and research support staff at all levels.

Impact

The EACCR2 project is supporting the development of clinical research capacity across a wide area in East Africa, and coordinating the development of joint multicentre research proposals. It is upgrading clinical research skills and infrastructure, and enabling a wider range of institutions to contribute to research into the poverty-related infectious diseases affecting East Africa.

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TESA: Trials of Excellence in Southern Africa

The TESA network is integrating clinical research capacity building into clinical trials organised in the southern Africa region.

The challenge

Southern Africa has some of the world's highest burdens of poverty-related infectious diseases, particularly HIV/AIDS and TB. Co-infections are common and drug resistance is a growing threat.

On the other hand, the sub-region has a number of internationally recognised research centres, and generates a significant proportion of sub-Saharan Africa's research outputs. These centres of excellence provide opportunities to act as foci to build capacity in less well-developed institutions.

The project

TESA was established in 2009 with EDCTP funding, initially with nine institutions from six countries. Its key aim was to develop and promote collaborations to support capacity building and training in participating institutions. During phase I funding, more than 80 students and clinical research staff received short-term training, 30 courses were organised, and 11 master's, eight PhD and one postdoctoral fellowship were awarded.

In addition, multiple laboratory sites were upgraded, baseline epidemiological studies carried out and consistent standard operating procedures were introduced.

In follow-up TESA II funding, the network has expanded to include 15 institutions from eight Southern African countries, one East African country and four European countries. Four institutions have been selected to act as reference centres, one for each specific disease area (HIV/AIDS, TB and malaria) while one institution acts as the reference data management centre. Reference laboratories have been established for each of the disease areas. The reference centres provide support to other sites in the network, as well as conducting training and capacity development in their respective areas.

Project at a glance

Project: Trials of Excellence in Southern Africa (TESA)

Project lead: Dr Eusebio Macete, Fundacao Manhica, Mozambique

Countries involved: Angola, Botswana, France, Malawi, Mozambique, Namibia, The Netherlands, South Africa, Spain, Uganda, UK, Zambia, Zimbabwe

Target population(s): All

Year funded: 2017

EDCTP funding: €3 M (TESA II)

Project website: www.tesano.org

Short-term training and exchange visits are being organised for researchers and research support staff. Events are also being organised to strengthen relationships with policymakers and support greater evidence-informed decision-making.

Impact

TESA II is drawing on existing centres of excellence in Southern Africa, links to European institutions, and ongoing clinical studies to build clinical research capacities in less well-developed research centres. It is also strengthening collaborations with other networks with similar aims and with policymakers to coordinate activities and achieve greater impact.

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WANETAM: West African Network for Tuberculosis, AIDS and Malaria

The WANETAM network is strengthening clinical research capacity across English-, French- and Portuguese-speaking countries in West Africa.

The challenge

West Africa was badly affected by the 2014–16 Ebola outbreak, and has a high burden of poverty-related infectious diseases. Although HIV is not as prevalent as in other sub-regions, progress in prevention and rollout of antiretroviral therapy has been relatively slow.

Collaboration across research centres in West Africa is challenged by language barriers. However, several strong research institutions exist in West African countries and have established productive relationships with European partners.

The project

WANETAM was established in 2009 with EDCTP funding, initially with 14 institutions in seven countries; additional African and European partners joined later. WANETAM's core focus was on capacity building, organising long-term and short-term training, as well as strengthening of laboratory capacities; stronger institutes in the network developed clinical trial units and secured international accreditation.

Initial funding also provided an opportunity to establish surveillance activities to provide baseline data for future studies. These included work on physiological measures in human subjects as well as antimalarial drug monitoring.

In follow-up WANETAM II funding, the network is expanding to cover neglected infectious diseases as well as Ebola. Thematic nodes of excellence have been established for each area, complemented by a cross-cutting structured training and collaboration programme. Training covers key areas including project-based training to build research leadership, hands-on clinical studies, platform development to support collaboration, and research support functions. Training will be provided for the full

Project at a glance

Project: West African Network for Tuberculosis, AIDS and Malaria (WANETAM)

Project lead: Professor Souleymane Mboup, Réseau Africain de Recherche sur le SIDA, Senegal

Countries involved: Burkina Faso, France, The Gambia, Germany, Ghana, Guinea Bissau, Mali, Nigeria, Portugal, Senegal, Sierra Leone, Togo, UK

Target population(s): All

Year funded: 2017

EDCTP funding: €3 M (WANETAM II)

Project website: <https://wanetam.org>

range of staff, including skills development and mentoring for senior staff, master's-level online courses, and professional development courses and internships.

Training will focus on three priority scientific areas: surveillance, diagnostics and resources to support clinical trial activities.

In the area of TB, work will focus on diagnosis and management of childhood TB, as well as monitoring of TB drug resistance. Malaria studies will include community-based interventions to interrupt transmission, monitoring of insecticide resistance and evaluation of new insecticides, evaluation of new treatments and vaccines, and introduction of a controlled human malaria challenge model.

HIV/AIDS research will cover the development of a unified database across study populations, rollout of viral load assays, and enhancing drug resistance testing. Work on neglected infectious diseases will focus on molecular diagnostics and monitoring of soil-transmitted helminths as well as clinical, laboratory and public health

preparedness for rapid outbreak responses.

Impact

WANETAM is strengthening clinical research capacities across multiple West African countries, enhancing coordination of activities and helping to overcome language barriers. It will facilitate large-scale multicentre trials on the key infectious disease threats in the sub-region, and enhance coordinated and rapid responses to outbreaks of emerging diseases such as Ebola.

Key references

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Cotimoxazole Pro Adults Living with

Eligibility Criteria:-

- All HIV infected adults with
- Asymptomatic HIV infection
- CD4 > 250 cells/mm³

• Pregnant women

• Past history of TB

When

- 8 pills
- 250mg

ALBENDAZOLE

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APR 2017

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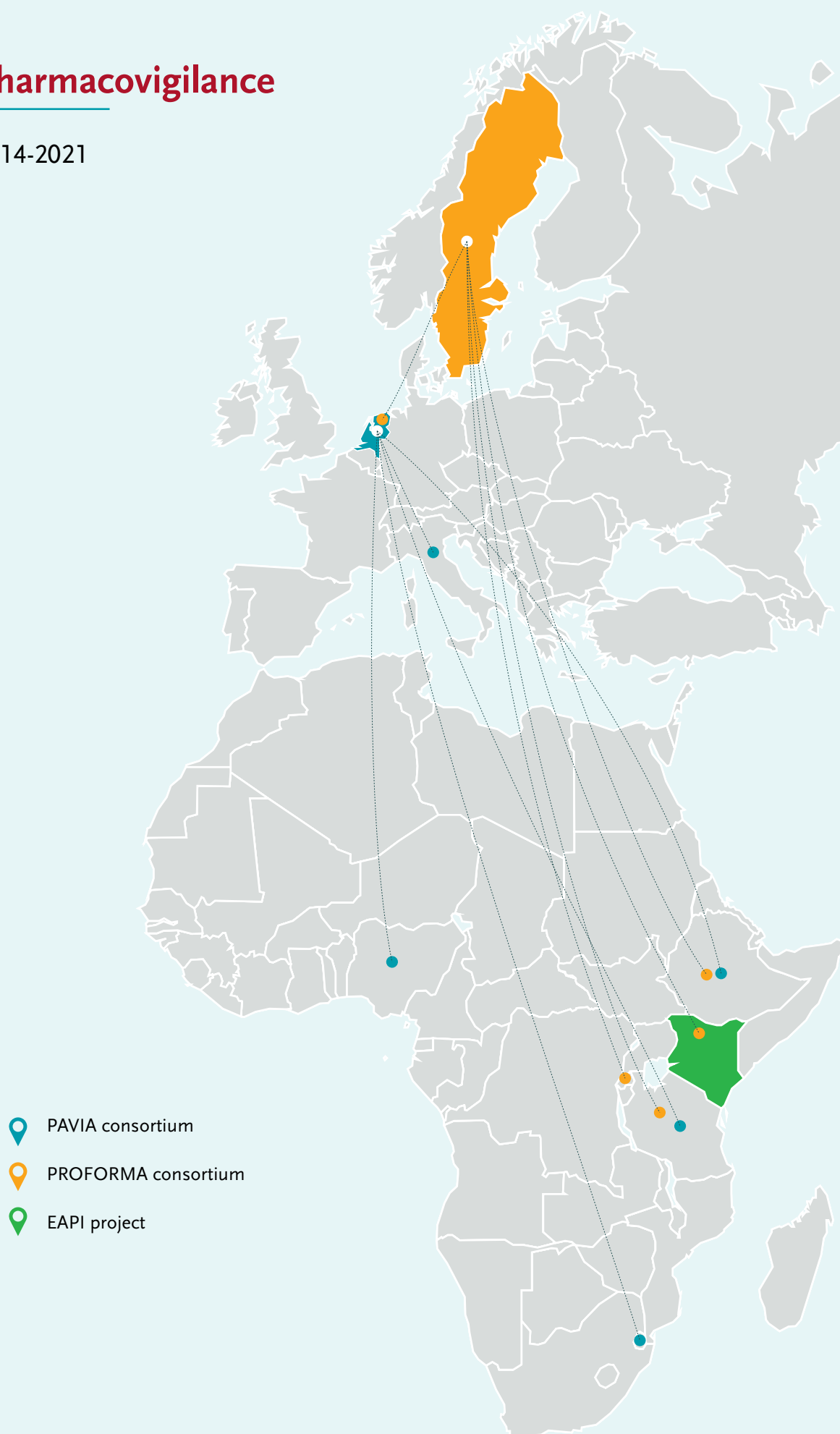
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Pharmacovigilance

2014-2021



Enhancing drug safety monitoring

The PROFORMA project is developing the drug safety monitoring capacities of four East African countries.

The challenge

Increasing numbers of medicines are being developed, and access to new medicines in Africa is increasing. However, these positive trends are creating challenges for national regulatory agencies responsible for processing new drug registrations and monitoring the safety of drugs after they have been introduced.

With mass drug administration campaigns, large-scale immunisation programmes and increasing numbers of clinical trials, effective safety monitoring (pharmacovigilance) is increasingly essential.

The project

Many national regulatory agencies lack the skilled workforce required to lead and manage pharmacovigilance systems. Furthermore, few have systematic processes in place for monitoring safety after drugs have been licensed for use. The PROFORMA project is therefore bringing multiple international partners together to strengthen pharmacovigilance systems in four East African countries – Ethiopia, Kenya, Rwanda and Tanzania.

The project is connecting pharmacovigilance experts from WHO Collaborating Centres in Pharmacovigilance, five medical universities, four national regulatory agencies and two Regional Centres of Regulatory Excellence in East Africa.

Using standardised WHO pharmacovigilance indicator tools, the project has mapped current pharmacovigilance systems in the four East African countries, identifying current strengths and gaps. These will be used to develop tailored interventions to build capacity in priority areas in each country. 'Train the trainer' models will be used to develop sustainable training programmes, taking advantage of expertise in local academic institutions.

The project aims to develop a cohort of pharmacovigilance-trained individuals across the multiple sectors involved in drug safety data collection and analysis. The project will train 12 postgraduate students (four PhD and

Project at a glance

Project: PROFORMA project: Pharmacovigilance Infrastructure and Post-Marketing Surveillance System Capacity Building for Regional Medicine Harmonisation in East Africa

Project lead: Professor Eleni Aklillu, Karolinska Institute, Sweden

Countries involved: Ethiopia, Kenya, Rwanda, Sweden, Tanzania

Target population(s): All

Year funded: 2018

EDCTP funding: €3 M

Total project funding: €6 M

Project website: <http://proforma.ki.se>

eight master's students) at European and African academic centres, in order to build regional pharmacovigilance expertise and local postgraduate programmes in pharmacovigilance. It will have a particular focus on clinical trials regulation and mass drug administration and immunisation programmes, and is working with national programmes to embed pharmacovigilance in ongoing campaigns.

Impact

The PROFORMA project is enhancing the capacity of the four countries to monitor the safety of new interventions being tested in clinical trials and after they have been introduced into routine use. As well as identifying potential adverse reactions for investigation, enhanced pharmacovigilance activities will help to maintain public confidence in large-scale health programmes such as vaccination and mass drug administration. By ensuring close integration with WHO and regional regulatory harmonisation initiatives, the project is also establishing a sustainable platform for developing national pharmacovigilance capacity.

Enhancing drug safety monitoring

The PAVIA project is building collaborations to enhance drug safety monitoring capacities across four sub-Saharan African countries, with an initial focus on TB.

The challenge

Effective monitoring of clinical trials requires that systems are in place to monitor and investigate potential medical safety issues. Such pharmacovigilance activities are also essential when new drugs are introduced and are used by greater numbers of people.

However, many national regulatory agencies in sub-Saharan Africa, which have responsibility for drug safety, lack the expertise, critical mass and infrastructure to monitor drug safety effectively during clinical trials and after licensing.

The project

The PAVIA project is developing a model for strengthening of pharmacovigilance systems in four sub-Saharan African countries – Eswatini, Ethiopia, Nigeria and Tanzania – based on enhanced cross-sectoral collaboration. It is helping to build bridges between disease-focused public health programmes, national regulatory agencies and medical research institutions. This triangular arrangement will create a channel for identifying and investigating potential safety signals, with medical research institutions acting as a source of clinical expertise.

Capacity at national pharmacovigilance centres will be gradually developed, focusing on data collection, analysis, safety signal identification and investigation. The model is being developed with an initial focus on multidrug-resistant TB. A blueprint will be developed to facilitate extension of the model to other national public health programmes, such as those for malaria and HIV, and potentially adoption by other countries.

National assessments have been undertaken to identify development priorities and to inform country-specific and locally owned capacity-development roadmaps. The project will also work with local ministries of health and other key stakeholders to emphasise the critical importance of pharmacovigilance. Early progress has included the creation of ‘pharmacovigilance triangles’ in

Project at a glance

Project: PAVIA project: Pharmacovigilance Africa

Project lead: Professor Frank Cobelens, Stichting Amsterdam Institute for Global Health and Development, The Netherlands

Countries involved: Eswatini, Ethiopia, Italy, The Netherlands, Nigeria, Tanzania

Target population(s): All

Year funded: 2018

EDCTP funding: €3 M

Total project funding: €12.8 M

Project website: www.pavia-project.net

each country to enhance coordination across different agencies.

In addition, the project has established an international advisory board to ensure coordination and alignment with regional and global pharmacovigilance initiatives. Links have been established with the EDCTP-funded PROFORMA project, which has similar aims, with the EXIT-TB project and with the East African Network of Excellence (EACCR2). It has also engaged with the African Union Development Agency, AUDA-NEPAD, to promote wider policy coherence.

Impact

The PAVIA project will establish a collaborative cross-sectoral model for pharmacovigilance, with clear roles and responsibilities, as well as enhanced national infrastructures for reporting of drug safety data. With an initial focus on TB, by identifying enablers and barriers to implementation, it will facilitate the expansion of pharmacovigilance systems to other disease areas. In doing so, it will enhance the capacity of health systems to absorb new interventions for poverty-related infectious diseases.

Enhancing drug safety monitoring

The EAPI project is building pharmacovigilance capacity in Kenya by strengthening links between academia and national regulatory agencies.

The challenge

Clinical trials are critical for ensuring the safety of new drugs (and safe new use of existing drugs). However, clinical trials can never be big enough to detect rare but significant side effects. Therefore, systems are needed to monitor adverse reactions to new drugs after they have been introduced (pharmacovigilance).

In addition, patients are at risk from harm from poor quality and counterfeit medications. This issue is of particular concern in Africa, which accounts for more than 40% of global reports of substandard and fake medical products.

Strong national regulatory agencies are required to ensure participant safety through clinical trials and after licensing, as well as to combat counterfeit medications. However, national regulatory agencies often lack the resources and expertise to perform these functions effectively.

The project

The EAPI project was established to strengthen pharmacovigilance systems in Kenya. EAPI is a partnership between the Pharmacy and Poisons Board – the national regulatory agency in Kenya – and the University of Nairobi. Jointly, the two bodies have been designated a Regional Centre of Regulatory Excellence for Pharmacovigilance by the African Union Development Agency.

Drug regulatory agencies in sub-Saharan Africa have limited budgets and face shortages of appropriately trained staff. Academics can fill gaps but require practical training to fulfill a role as part-time drug evaluators.

The EAPI project therefore developed e-learning material to support a master's in pharmacovigilance and a pharmacoepidemiology programme at the University of Nairobi, open to pharmacists in Kenya and beyond. A total of 14 modules were converted for online use, opening up much wider access to high-quality materials. The project also developed short courses to build the skills of national ethical committees and

Project at a glance

Project: EAPI project: East African Pharmacovigilance Initiative

Project lead: Dr Kefa Bosire, University of Nairobi, Kenya

Countries involved: Kenya

Target population(s): All

Year funded: 2017

EDCTP funding: €300,000

Project website: <http://eapi.uonbi.ac.ke>

regulatory agencies in pharmacovigilance and other key areas.

The University of Nairobi has also helped the Pharmacy and Poisons Board to develop an innovative coding system to facilitate 'track and tracing' of pharmaceutical products, with integrated pharmacovigilance reporting. Following piloting, the new system could have a major impact on how the Board operates.

Through its website and other activities, the EAPI project is also raising awareness among stakeholders, including the general public, of the importance of pharmacovigilance.

Impact

The EAPI project has established a mechanism for enhancing the capabilities of Kenya's national regulatory agency across all stages of clinical evaluation, including 'phase IV' pharmacovigilance. Its virtual training tools could potentially also help to develop capacity across other countries in East Africa.





Evidence-informed policy and practice

2014-2020

WISH <i>United Kingdom</i>	 	EXIT-TB <i>Tanzania</i>	 	UPTAKE <i>Kenya</i>	 
IMPP-ACT <i>United Kingdom</i>	 	ADAM <i>Mozambique</i>	 	BlockRabies <i>Switzerland</i>	 
TRIP <i>Tanzania</i>	 	INTEGRATED HIV/HTN <i>Uganda</i>	 	SAVING <i>Ghana</i>	 
IMPACT <i>United Kingdom</i>	 	FEX-g-HAT <i>Switzerland</i>	 	Revive IPTp <i>Kenya</i>	 
TWENDE <i>United Kingdom</i>	 	OPT-SMC <i>Senegal</i>	 		

Intervention	Other	Disease	
 Drugs	 Product-focused implementation research	 HIV and HIV-associated infections	 Emerging diseases
 Diagnostics	 Behavioural and social sciences	 Tuberculosis	 Lower respiratory tract infections
 Vaccines	 Capacity building/training	 Malaria	 Diarrhoeal diseases
		 Neglected infectious diseases	

Enhancing sexual and reproductive health care

The WISH study is taking advantage of a research clinic in Kigali, Rwanda, to explore key questions in women's sexual and reproductive health, including better detection of sexually transmitted infections.

The challenge

Sexually transmitted infections (STIs) are a major challenge in sub-Saharan Africa. As well as their direct impact, they can also increase the risk of HIV infection, while HIV can increase the risk of other STIs. In Rwanda, for example, almost 1% of HIV-negative women but nearly 5% of HIV-positive women are infected with syphilis, and certain groups are particularly vulnerable to infection.

In most low-resource settings, including Rwanda, STIs are treated through syndromic management. Treatment is based on clinician assessment of symptoms, without confirmatory diagnosis. Although simple, this can lead to both over-treatment, use of antibiotics that are not needed, and under-treatment. In women, under-treatment is a particular challenge as most STIs are asymptomatic but can have multiple long-term health consequences.

The project

Since 2004, the Rinda Ubuzima NGO in Kigali, Rwanda, has operated a research clinic and laboratory specialising in women's sexual and reproductive health. Rinda Ubuzima has hosted several EDCTP projects.

The WISH project took advantage of this newly established research capacity to explore the potential for improved diagnosis and management of STIs in women. An increasing number of point-of-care diagnostic tests are now available for key STIs, including HIV, *Trichomonas vaginalis*, *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, syphilis and bacterial vaginosis (disruptions to vaginal bacterial ecosystems).

The WISH project recruited 705 women from the community at risk of STIs, who were assessed by standard WHO approaches to diagnosis

Project at a glance

Project: WISH project

Project lead: Professor Janneke van de Wijgert, University of Liverpool, UK

Countries involved: Belgium, Rwanda, UK

Target population(s): Women, including women living with HIV

Year funded: 2016

EDCTP funding: €494,158

Project website: www.liverpool.ac.uk/infection-and-global-health/research/diagnostics-challenge/wish/

and specially developed WISH algorithms. Participants were also tested for *T. vaginalis* and bacterial vaginosis, and high-risk women were additionally screened for *N. gonorrhoeae* and *Chlamydia*. All samples underwent gold standard laboratory testing.

The results revealed that the prevalence of urogenital infections was high in the study population. Rwandan and WHO syndromic algorithms performed poorly, illustrating that reported symptoms and signs do not reliably predict the presence of urogenital infections. The performance of WISH algorithms was significantly better, although improved point-of-care tests are needed, particularly for vaginosis and candidiasis. Testing was also acceptable to both service providers and users.

Impact

The results were shared with policymakers at a workshop in Rwanda. The consensus was that use of diagnostic testing was desirable, programmatically feasible and acceptable to communities. However, the costs of diagnostic tests remain a significant obstacle to implementation.

Key references

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Preventing malaria in pregnancy

The IMPP-ACT study is helping policymakers select the most appropriate approach for preventing and managing malaria in pregnant women.

The challenge

Globally, 85 million women every year become pregnant in areas of *Plasmodium falciparum* malaria transmission. Without interventions, malaria infections have the potential to cause 900,000 low-birth-weight deliveries, leading to the deaths of 200,000 newborn babies and 10,000 mothers.

To prevent these adverse outcomes, WHO recommends a range of measures, including preventive treatment with antimalarial drugs and use of insecticide-impregnated bednets. However, across sub-Saharan Africa malarial parasites are increasingly developing resistance to the main drug combination used to prevent infections, sulphadoxine–pyrimethamine (SP).

The project

For countries in sub-Saharan Africa, it can be challenging to identify the most appropriate approach to prevent and manage malaria. Whether to use diagnostic screening and choice of drug depends on a range of factors, particularly the intensity of malaria transmission and local levels of resistance to SP.

During the past decade, the Malaria in Pregnancy (MiP) Consortium has carried out a range of important studies in sub-Saharan Africa examining the effectiveness of SP and alternative forms of chemoprevention for use alongside bednets, as well as the potential utility of screening for malaria during pregnancy.

The Consortium's work fed into WHO policymaking on malaria prevention in pregnancy, which recommended tailored strategies for areas according to their levels of SP resistance and malaria transmission intensity. In the IMPP-ACT project, the MiP Consortium is building on its previous work to support evidence-based policymaking and implementation to minimise the impact of malaria in pregnancy.

The team has developed tools to enable health policymakers to identify and deploy the safest

Project at a glance

Project: IMPP-ACT study

Project lead: Dr Jenny Hill, Liverpool School of Tropical Medicine, UK

Countries involved: The Gambia, Kenya, Malawi, Mali, UK

Target population(s): Pregnant women

Year funded: 2016

EDCTP funding: €487,463

Project website: www.lstmed.ac.uk/research/collaborations/imppact

and most cost-effective strategies based on local patterns of disease and SP resistance. It has also undertaken work exploring national decision-making processes in four focus countries (The Gambia, Mali, Kenya and Malawi), and provided technical expertise to countries to support changes in policy and implementation of new policies. Regional meetings have been held in East Africa and West Africa to communicate its findings, with technical support offered to national policymakers and technical agencies involved in policy development and implementation.

Impact

The project ensured that national policymaking and programmatic activities in multiple malaria-endemic countries have been informed by the latest findings on malaria prevention in pregnancy, helping to protect the health of both pregnant women and their unborn children. It also generated important insight into the processes involved in the translation of research evidence into national policies and implementation plans.

Key references

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Extending screening for fungal infections

The TRIP implementation study has guided the wider introduction in Tanzania of a new approach to HIV care including screening for opportunistic fungal infections.

The challenge

People with advanced HIV disease are at high risk of death. Cryptococcal infections are a particular challenge, accounting for up to a quarter of deaths of people with HIV.

Early screening for cryptococcal infections, followed by prompt treatment with fluconazole for those testing positive, has been shown to be a highly effective way at reducing mortality in those with advanced HIV disease. In the EDCTP-funded REMSTART trial, cryptococcal screening plus home visits for four weeks to encourage adherence to treatment reduced mortality by 28%.

Findings from this trial informed WHO guidelines on management of late-stage HIV infection in Africa. Even so, take up of cryptococcal screening and home support has been limited.

The project

To promote greater uptake, the REMSTART team is undertaking an implementation study in Tanzania, based on a modified version of the approach used in the original REMSTART trial. Although economic analyses suggested that the REMSTART model would be cost-effective, travel for home visits represented a major proportion of the costs of the intervention and could be logistically challenging. Text messaging could represent an even more cost-effective alternative.

The TRIP study is evaluating the implementation of cryptococcal screening and fluconazole treatment plus text messaging – weekly for the first month then monthly for the next three months – at 24 rural and urban sites in Tanzania. It will generate key data on lives saved when the intervention is introduced into routine practice in these two settings, on its cost-effectiveness, and on the practical barriers to its introduction

Project at a glance

Project: TRIP: Translating Research into Practice

Project lead: Dr Godfrey Sayoki Mfinanga, National Institute for Medical Research, Tanzania

Countries involved: Tanzania, UK

Target population(s): People living with HIV

Year funded: 2016

EDCTP funding: €499,434

Project website: <https://tripproject.org>

Impact

The project has maintained close contact with the Ministry of Health in Tanzania and a range of implementing partners, including UNITAID's Clinton Health Access Initiative (CHAI). The project's experience has informed the development of a national plan for cryptococcal screening, which is now being implemented at additional sites by the Ministry of Health, CHAI (which has taken over the TRIP project's study sites) and other implementing partners.

The project also contributed to the Global Advanced HIV Disease Toolkit, which will support the introduction of the tools evaluated by the TRIP project in other countries. Through UNITAID's CHAI project, the intervention is already being implemented in seven countries in Africa. The project is therefore helping to reduce the burden of one of the leading causes of death in people with HIV infections.

Key references

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Safer dosing of antimalarials

The IMPACT study is generating key data on the safety of a new antimalarial medication, as well as the most appropriate dosing schedules for young children and people being treated with antiretroviral drugs.

The challenge

The antimalarial drug combination dihydroartemisinin–piperaquine (DHA-PPQ) is a highly efficacious treatment for uncomplicated malaria. Due to its long half-life, it is a good option for chemoprevention, as it should offer long-lasting protection against infection.

However, DHA-PPQ has a relatively narrow therapeutic range – concentrations at which it is both effective and safe. This creates a therapeutic challenge. There are concerns that young children or people on antiretroviral drugs are being under-dosed, while some groups may be at risk of cardiac side effects from PPQ if doses are too high. One solution for children would be complex weight-based dosing regimens, but these would make it less easy to use DHA-PPQ in large-scale control programmes.

The project

The IMPACT study is collating data on the links between PPQ dosage and drug concentrations and the risk of cardiac side effects. This work includes data collected in previous EDCTP-funded safety trials, the ADAPT and ADJust studies, which informed the WHO's Evidence Review Group (ERG) on the Cardiotoxicity of Antimalarials, published in 2017.

Members of the IMPACT project team contributed to the identification of global evidence gaps and research priorities, highlighting the importance of standardised collection of cardiac safety data in antimalarial trials. This led to the development of guidelines on cardiac monitoring, published in collaboration with the Worldwide Antimalarial Resistance Network (WWARN). The project also worked with WWARN to develop guidelines on how ECG and other data will be curated by WWARN, to facilitate sharing and synthesis of cardiac safety data from antimalarial trials.

In clinical studies, the IMPACT project team found that people living with HIV on antiretroviral

Project at a glance

Project: IMPACT study

Project lead: Dr Anja (DJ) Terlouw, Liverpool School of Tropical Medicine, UK

Countries involved: Malawi, South Africa, UK

Target population(s): Children, people living with HIV

Year funded: 2016

EDCTP funding: €499,294

Project website: www.lstmed.ac.uk/research/collaborations/impact-improving-the-impact-of-existing-malaria-products—acts

therapy were not at increased risk of DHA-PPQ-related adverse events. However, levels of PPQ were markedly lower in those on efavirenz-based regimens, which could compromise the effectiveness of antimalarial treatment. By contrast, people on nevirapine-based regimens were exposed to elevated levels of PPQ, raising potential safety concerns.

To assess the clinical significance of these findings, a trial of DHA-PPQ safety and efficacy was carried out in Malawi and Mozambique. This found that neither efavirenz- nor nevirapine-based regimens affected the efficacy of DHA-PPQ. Some changes to cardiac function were seen, but they were relatively minor, spontaneously resolved and had no clinical impact; they may have been linked to the resolution of fever rather than to DHA-PPQ.

The project has also used modelling to identify age-based therapeutic windows for primaquine, another antimalarial with potential for use in chemoprevention campaigns. These were adapted for particular regional settings, including Africa, through use of regional weight-for-age growth references. The findings provide a basis for establishing suitable age-based dose regimens for sub-Saharan Africa.

Impact

The IMPACT project has generated important data on antimalarial efficacy and safety in people living with HIV on antiretroviral therapy, and helped to establish a global platform for monitoring cardiac safety in antimalarial trials. It has also illustrated how modelling can identify appropriate age-based antimalarial dose regimens. At the national level, the IMPACT team has been working with national stakeholders in Malawi, including the National Malaria Control Programme, to raise awareness of the importance of antimalarial dose optimisation and the need for pharmacovigilance in certain populations.

Key references

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Extending use of new TB diagnostics

The TWENDE study has been exploring the barriers to the introduction of molecular tests for TB, and developing structures to promote more rapid translation of research into practice.

The challenge

TB kills around 1.5 million people a year. In 2018, 24% of TB cases occurred in sub-Saharan Africa; with 608,000 deaths, the region accounts for 40% of global TB mortality.

Diagnosis of TB is challenging. The most commonly used method, smear microscopy, is not particularly accurate, and laboratory culture is slow and requires special facilities.

New rapid molecular tests have been developed and are recommended by WHO. These include the Xpert MTB/RIF platform and the so-called line probe assay. However, these tools are often not available at frontline health facilities in low-income settings.

The project

The TWENDE team – ‘twende’ means ‘let’s go’ in Swahili – has developed a new method for detecting *Mycobacterium tuberculosis* (Mtb) and for assessing responses to treatment, based on detection of Mtb-specific RNA. In EDCTP-funded research related to this technique, known as the molecular bacterial load assay, the team began to explore the practical and health systems factors affecting the introduction of molecular tests for TB.

The TWENDE study has extended this work, used surveys and interviews with multiple stakeholder groups to identify barriers to the implementation of molecular TB diagnostics. Key factors included inadequate financing, procurement difficulties and insufficient human resources. The study developed a model identifying health system, socioeconomic, cultural and other barriers to translation, which will be of wider relevance to the uptake of innovations into health systems.

To help overcome barriers to the translation of research into practice, the TWENDE study has established knowledge transfer centres at four partner institutions in Kenya, Uganda and Tanzania. More than 25 early-career researchers received training on the translation of research into practice, public communication, and commercialisation of research findings. In

Project at a glance

Project: TWENDE study

Project lead: Dr Wilber Sabiiti, University of St Andrews, UK

Countries involved: Kenya, Tanzania, Uganda, UK

Target population(s): All

Year funded: 2016

EDCTP funding: €439,047

Project website: <http://med.st-andrews.ac.uk/infection/sabiiti/twende/>

addition, six events were held to promote dialogue with regional policymakers.

The team has also secured further funding to evaluate implementation of the molecular bacterial load assay in programmatic settings.

Impact

The TWENDE project has generated key data on the reasons for the slow implementation of molecular testing for TB. It has also created an infrastructure that will more generally create stronger links between policymaking and research communities, and promote the uptake of research into practice.

Key references

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Rooting out hidden TB

The EXIT-TB project is aiming to mainstream a range of interventions to identify TB patients being missed by conventional screening approaches.

The challenge

TB remains the leading infectious cause of death. More than a quarter of all TB deaths occur in sub-Saharan Africa; 417,000 people died in 2016, while 2.5 million fell ill with TB.

The high burden of TB in the region is due in part to low rates of detection and delayed diagnosis, providing opportunities for the disease to spread. Unfortunately, TB is difficult to diagnose, and it is becoming clear that clinical signs such as long-term cough and even commonly used microscopy 'smear' tests are not a reliable guide to infection. Much more aggressive approaches to case detection are therefore required.

The project

The EXIT-TB project, connecting institutions in Ethiopia, Kenya, Sudan, Tanzania and Uganda, aims to promote the introduction into routine practice of a range of measures that have been shown in research settings to improve the detection of TB cases. It will serve as an exemplar of projects accelerating the translation of research into policy and practice.

Four specific approaches are being promoted. One is intensified TB case finding through screening of all patients reporting to outpatient departments with a cough of any duration. TB case finding is also being integrated into reproductive and child health clinics and diabetes clinics.

Further cases are being identified through screening of all patients living with HIV who attend care and treatment centres, irrespective of their symptoms. The final strand is targeted contact tracing for all TB patients with child household members, who are at significant risk of infection.

The project is spearheading and evaluating the implementation of this package of interventions at multiple centres in four sub-Saharan African countries, including both rural and urban facilities. It will explore the feasibility of implementation and

Project at a glance

Project: EXIT-TB project

Project lead: Dr Esther S Ngadaya, National Institute for Medical Research, Tanzania

Countries involved: Ethiopia, Kenya, Norway, Sudan, Tanzania, Uganda, UK

Target population(s): All

Year funded: 2016

EDCTP funding: €2.92 M

Total project funding: €5.85 M

Project website: www.exit-tb.org

identify barriers to implementation and challenges that health systems face in delivering the EXIT-TB package in the different settings; it will also undertake a cost-effectiveness analysis.

Impact

The EXIT-TB project will provide essential data on the impact of the package of interventions on TB case detection, as well as on the practical challenges associated with its introduction into routine practice. It will inform revision of guidelines in integrated care at HIV/AIDS, reproductive and child health clinics, and diabetes clinics, and provide evidence to support wider introduction within participating and other sub-Saharan African countries.

Towards malaria elimination in Mozambique

The ADAM project is supporting the implementation of mass drug administration strategies to eliminate malaria in low-transmission areas of Mozambique.

The challenge

Malaria is the second biggest killer in Mozambique, with an estimated nine million cases every year and more than 14,000 deaths.

In past decades, a range of elimination projects have been organised in the south of the country, where transmission is lowest. Although the number of cases has fallen, elimination has not been achieved. With elimination part of the Global Technical Strategy for Malaria up to 2030, elimination in this area could be a stepping stone to national elimination in Mozambique.

The project

In 2015–2018, the Magude project evaluated a malaria elimination package comprising intensified vector control and six-monthly mass antimalarial drug administration for two consecutive years. This averted three-quarters of expected cases of malaria. Follow-up reactive targeted mass drug administration increased the number of cases averted still further, to 79.1%. The results suggest that time-limited mass drug administration reduced transmission sufficiently to enable initiation of more targeted (focal) mass drug administration, as recommended by WHO.

Based in part on these findings, the Mozambique National Malaria Control Programme has included the goal of elimination of malaria in areas of low transmission intensity in its national malaria strategic plan for 2017–2022.

The ADAM project is supporting the National Malaria Control Programme, one of the three project partners, in development of guidelines for use of the mass drug administration strategy. Through consultation with key stakeholders, it is developing a delivery strategy and monitoring plan for introduction of population-wide and follow-up targeted mass drug administration into routine programmes. It is also developing data collection and visualisation systems to facilitate monitoring of activities.

Project at a glance

Project: ADAM project

Project lead: Dr Pedro Aide, Fundação Manhica, Mozambique

Countries involved: Mozambique, Spain

Target population(s): All

Year funded: 2020

EDCTP funding: €2.2 M

In addition, the project is piloting implementation of the new approaches in programmatic contexts to identify practical barriers and enablers. It is also supporting the development of policy and guidelines in consultation with Mozambique's Malaria Elimination Technical Working Group.

Impact

The ADAM project is supporting the introduction into routine programmatic use of a malaria elimination strategy that has proven highly effective in reducing the incidence of malaria. It will act as a demonstration project, generating learning that will facilitate the wider rollout of the strategy across Mozambique. In doing so, it will further lower the burden of one of the country's leading causes of death.

Blood pressure control in people living with HIV

The Integrated HIV/HTN project is supporting implementation of integrated care for people living with HIV and hypertension.

The challenge

Hypertension, high blood pressure, is the single biggest risk factor for death worldwide. It is more common in sub-Saharan Africa than in any other region – affecting an estimated 30% of adults.

Owing to the wider use of antiretroviral drugs, more people living with HIV in sub-Saharan Africa are surviving into middle age and beyond, when their risk of hypertension increases significantly. Hypertension is poorly diagnosed and controlled in the region, but HIV treatment clinics may provide a way to deliver integrated care for the two conditions.

The project

The SEARCH trial recently evaluated an integrated model of care for HIV and hypertension in Uganda and Kenya that led to improved control of both conditions. The model included one-stop care for both conditions, provision of 12-week drug supplies, flexible appointments and phone access to providers. A hypertension toolkit was developed for service providers, including a diagnostic and treatment algorithm, patient register, hypertension job aids and patient information.

The Integrated HIV/HTN project is now aiming to build on this demonstration by supporting and evaluating the introduction of an integrated model into routine care in 26 districts of western Uganda. The care model is being introduced in collaboration with national disease programme directors and middle-level health managers. Training will be provided to health workers at district level and in primary care facilities, while a text messaging system will be introduced to provide real-time feedback on performance at the district and clinic level.

As well as monitoring health outcomes, the project will explore the barriers to and enablers of integrated care through engagement with policymakers, providers and patients. The cost implications of the new model will also be analysed.

Project at a glance

Project: Integrated HIV/HTN project

Project lead: Ms Jane Kabami, Infectious Diseases Research Collaboration Ltd, Uganda

Countries involved: Uganda, UK

Target population(s): Adults living with HIV

Year funded: 2020

EDCTP funding: €2.25 M

Impact

The Integrated HIV/HTN project will accelerate the introduction of a more patient-centred and integrated model of care for people living with HIV. It should also highlight factors that could facilitate the wider rollout of integrated models of care. Ultimately, the project should lead to changes in policy and practice, and to improvements in the health of people living with HIV and hypertension in western Uganda. More generally, the project will enhance national coordination and the capacity to translate research evidence into practice.

Expanding access to a new drug for sleeping sickness

The FEX-g-HAT project is supporting introduction of fexinidazole, a highly effective new drug for sleeping sickness, human African trypanosomiasis.

The challenge

Infection with the single-celled parasite *Trypanosoma brucei*, human African trypanosomiasis, can be deadly without effective treatment. Enormous gains have been made in control of human African trypanosomiasis in recent decades, and the disease has been targeted for elimination as a public health threat by 2020.

Nearly all cases of human African trypanosomiasis are caused by *T. brucei gambiense*, one of two human-infecting subspecies of *T. brucei*. Treatment of severe cases has until recently relied on intravenous drug infusions, requiring specialist care facilities. However, the Drugs for Neglected Diseases Initiative and its partners have developed a highly effective new treatment, fexinidazole, that can be given orally. Fexinidazole was given a positive scientific opinion by the European Medicines Authority in 2018 and gained marketing authorisation in the Democratic Republic of the Congo (DRC), the worst affected country, in the same year.

The project

Now recommended by WHO, fexinidazole represents a significant shift in clinical practice. Although much easier to administer, new procedures need to be introduced to ensure it is used effectively. For example, it needs to be administered with a meal to ensure adequate uptake. The FEX-g-HAT project aims to accelerate the introduction of fexinidazole by ensuring health systems and health workers in affected countries are able to make the treatment widely available to those who could benefit from it.

The main focus of the project will be on capacity building at national and local levels, drawing on recently updated WHO guidelines. Health workers are being trained and systems are being strengthened for monitoring of potential adverse reactions to the new treatment. As well as the DRC, the project is working with other African

Project at a glance

Project: FEX-g-HAT project

Project lead: Dr Florent Mbo, Drugs for Neglected Diseases Initiative, Switzerland

Countries involved: Belgium, Democratic Republic of the Congo, France, Guinea

Target population(s): All

Year funded: 2020

EDCTP funding: €2.25 M

Project website: <https://dndi.org/research-development/portfolio/fexinidazole-tb-rhodesiense/>

countries with a heavy burden of human African trypanosomiasis, such as Angola, Central African Republic, Guinea and South Sudan. The project will draw upon an existing network, the HAT Platform, which is supporting clinical training across more than 120 institutions in the region and promoting access to treatment. Longer-term follow-up will be taken on by WHO.

Impact

Fexinidazole represents a major step forward for treatment of human African trypanosomiasis, particularly severe disease, reducing the need for challenging procedures such as lumbar puncture and intravenous injection. The FEX-g-HAT project will reduce delays in the implementation of this new treatment and ensure that people in sub-Saharan Africa benefit from fexinidazole as rapidly as possible.

Promoting use of seasonal malaria chemoprevention

The OPT-SMC project is driving forward greater use of pre-emptive drug treatment to prevent malaria in children at times of year when they are most at risk.

The challenge

The sub-Saharan Africa region accounts for 94% of all malaria deaths. Following many years of progress, control of malaria in the region has slowed. Revitalised efforts are required to lower further the malaria burden, and to protect vulnerable populations such as children and pregnant women.

One strategy known to be effective is seasonal malaria chemoprevention (SMC). In areas where transmission is greatly affected by weather conditions, such as high rainfall, children can be given regular doses of antimalarial drugs to ensure they are not infected at times of high transmission. Although this strategy is recommended by WHO, it is not fully implemented in the region – less than 50% of eligible children had access to SMC in 2017.

The project

The OPT-SMC project aims to both widen and strengthen implementation of SMC in sub-Saharan Africa. It is strengthening the capacity of national malaria control programmes to plan effectively and to procure and distribute drugs efficiently to target populations. It is also strengthening capacity for implementation research so national programmes can gain insight into and overcome programmatic barriers. A further aim is to improve the ability of national control programmes to monitor and evaluate performance of SMC campaigns, with new tools being developed to support planning, monitoring and evaluation.

The project is being coordinated by centres in Senegal, Switzerland and the UK, which are building on an existing partnership of 14 countries, 12 of which are already using SMC and two that have plans to introduce it. Enhanced collaboration between partners will support sharing of expertise and experience. The project is also receiving input from WHO (through TDR)

Project at a glance

Project: Optimising the Impact of Seasonal Malaria Chemoprevention (OPT-SMC): Improving delivery and building capacity for evaluation

Project lead: Professor Jean Louis Ndiaye, University of Thies, Senegal

Countries involved: Benin, Burkina Faso, Cameroon, The Gambia, Ghana, Guinea, Mali, Niger, Nigeria, Senegal, Switzerland, Togo, UK

Target population(s): Children

Year funded: 2020

EDCTP funding: €2.25 M

and the Medicines for Malaria Venture, as well as academic support from partners in Senegal and the UK.

Impact

The OPT-SMC project will increase use of a simple intervention with proven life-saving potential, preventing children's deaths from malaria and reducing its clinical, social and economic impact.

Capturing user views on HIV prevention

The UPTAKE project is ensuring that the development of new methods for HIV prevention takes account of the preferences of women and young girls.

The challenge

Women are disproportionately affected by HIV. In sub-Saharan Africa four out of five new HIV infections in people aged 10–19 are among girls. Globally, of every five new infections among young people aged 15–24 years, three are in young women.

As a result, there is great interest in the development of interventions that prevent infection in young women, and also in combining interventions for HIV prevention and contraception. However, the success of these interventions will depend not only on the efficacy of their medical components but also on their acceptability to and use by target populations.

The project

The UPTAKE project aims to strengthen the connections between new product developers and vulnerable user communities, such as female sex workers and at-risk adolescents and young women. By ensuring that the preferences of such groups are factored into early product development, the project will make it more likely that new products are used and successfully reduce transmission of infection.

The project has a particular focus on pre-exposure prophylaxis, PrEP, use of antiretroviral drugs to prevent infection, particularly injectable and implantable long-acting PrEP. PrEP has been convincingly shown to significantly reduce the risk of HIV infection, but daily drug taking imposes a high treatment burden on young people, limiting its effectiveness in practice. The project will also explore the potential of combination interventions that combine long-acting PrEP with long-acting contraceptives.

Based on an innovative collaboration of academic, public health and product development organisations, the UPTAKE project is using behavioural research to explore the attitudes and preferences of key target groups, to understand the likely facilitators of and obstacles to the use

Project at a glance

Project: UPTAKE project: Universally Accessible HIV Prevention Technologies for African Girls and Young Women through Knowledge Applied from Behavioral Economics

Project lead: Dr Anatoli Kamali, Stichting International AIDS Vaccine Initiative, The Netherlands

Countries involved: Kenya, Uganda, UK

Target population(s): Young women

Year funded: 2020

EDCTP funding: €2.4 M

of new devices. It will also develop and evaluate interventions to promote use of existing long-acting contraceptives, to inform approaches used when long-acting PrEP and combination devices are introduced. It will also carry out cost-effectiveness studies based on integration of long-acting PrEP into sexual and reproductive health services.

Impact

The UPTAKE project will accelerate the introduction of novel products for HIV prevention in vulnerable groups by catalysing innovative collaborations between product developers, policymakers and user communities.

Smart technology to prevent rabies

The BlockRabies project is using innovative blockchain technology to increase access to preventive treatments for rabies, by enhancing coordination across groups involved in rabies control.

The challenge

Rabies contracted following bites by infected dogs still kills 60,000 people a year. This is despite the existence of a highly effective treatment, post-exposure prophylaxis, in which a rabies vaccine is administered soon after a bite from an infected animal.

The cost of post-exposure prophylaxis is a major barrier to its use in low-income settings. To overcome this barrier, Gavi, the Vaccine Alliance, is willing to make funds available to support procurement of rabies vaccine by Gavi-eligible countries. However, effective systems are required in countries to ensure post-exposure prophylaxis can be introduced effectively.

The project

Major obstacles to the use of post-exposure prophylaxis include inadequate supply chains and poor communication between public and animal health bodies. The BlockRabies project aims to overcome these barriers using innovative blockchain technology, which enables information to be captured electronically and stored securely and shared among collaborating groups.

The project is engaging with European stakeholders to develop blockchain-based approaches to ensure adequate supplies of rabies vaccine in Mali and Cote d'Ivoire. Blockchain requires only simple tools to use, such as mobile phones, but provides a powerful way to coordinate and manage supply chains so that stocks are always available where they are needed. Blockchain approaches are also being used to promote the sharing of information and alerts between health providers and health and veterinary authorities.

The project will also drive forward use of a streamlined protocol for intradermal post-exposure prophylactic vaccine use for all rabies-suspected bite victims, which has been recommended by WHO but has not been widely

Project at a glance

Project: BlockRabies project

Project lead: Professor Jakob Zinsstag, Swiss Tropical and Public Health Institute, Switzerland

Countries involved: Cote d'Ivoire, France, Mali, Switzerland

Target population(s): All

Year funded: 2020

EDCTP funding: €2.25 M

adopted in sub-Saharan Africa.

Other activities include promoting wider implementation of rabies diagnostic testing in animals. Adherence to treatment and clinical outcomes will be monitored through use of mobile technologies and health centre visits. The project will also undertake an economic analysis to determine the financial implications of the new approach.

Impact

The BlockRabies project will establish a model for treatment of suspected rabies with the potential to be scaled nationally and adapted by other countries. It will provide a mechanism to deliver the Gavi rabies strategy, and contribute to global goals to reduce human deaths from rabies to zero by 2030.

Accelerating new vaccine use in Ghana

The SAVING project is helping to create an environment able to rapidly introduce new vaccines into Ghana.

The challenge

Ghana was one of three countries in sub-Saharan Africa selected to host a pilot implementation project for the RTS,S/AS01 malaria vaccine. The pilot project is anticipated to be a stepping stone towards a wider national rollout, which is likely to present significant practical challenges.

More generally, with increasing numbers of vaccine products and associated technologies likely to become available over the next decade, there is a need to strengthen the capacity of key health systems bodies – such as the Ghana Foods and Drug Authority, Ghana's Ministry of Health, and the Ghana Health Service – to identify and address implementation challenges.

The project

The SAVING project is making use of a framework (value chain) provided by the Access and Delivery Partnership. This recognises the importance of multiple aspects of health system function that must be systematically addressed if populations are to gain timely access to new medical interventions, such as regulatory processes, the national policy and regulatory environment, health technology assessment, procurement and supply chain management, delivery and implementation research, and monitoring for adverse events.

The project has adopted an approach based on implementation research to address these critical areas. It is therefore building implementation research capacity in partner institutions in Ghana, as well as capacity to apply evidence-based decision-making. At least two implementation research projects will be undertaken, on deployment of a mobile application and a patient information system, to gather evidence on implementation challenges and to learn lessons for future introductions.

Project at a glance

Project: SAVING project: Building Capacity to address Implementation Challenges for Sustainable Access and Delivery of New Vaccines in Ghana

Project lead: Professor Margaret Gyapong, University of Health and Allied Sciences, Ghana

Countries involved: Ghana, Switzerland

Target population(s): All

Year funded: 2020

EDCTP funding: €2.13 M

Impact

The SAVING project will strengthen the capacity of the health system in Ghana to evaluate and implement new health interventions in a timely fashion, accelerating the introduction not just of the new malaria vaccine but also of other health interventions.

Promoting malaria prevention in pregnancy

The Revive IPTp project is building the capacity of the health systems in Kenya to deliver malaria-prevention services to pregnant women.

The challenge

Pregnant women are particularly vulnerable to the effects of malaria. Infections can lead to anaemia, and are a common cause of spontaneous abortion, stillbirth, pre-term delivery, and low birth weight, with long-term implications for infant health and development.

To reduce the risk of malaria infections during pregnancy, WHO recommends preventive use of antimalarial drugs, an approach known as intermittent preventive treatment of malaria in pregnancy (IPTp). WHO recommends that antimalarial drugs are provided during antenatal visits. However, in Kenya, although use of antenatal care is very high, only 25% of pregnant women receive three or more doses of IPTp.

The project

The IPTp project aims to use a policy implementation framework to achieve increased use of IPTp in Kenya, in line with national health policy, by engaging with a range of national stakeholders. It is increasing the understanding of IPTp among programme implementers and service providers, as well as their capacity to promote IPTp use among service users. It is also undertaking community engagement to raise awareness of IPTp and promote self-care more generally in pregnant women. Finally, it is strengthening the capacity of county authorities to deliver and monitor IPTp use.

The project brings together a range of stakeholders with a common interest in prevention of malaria in pregnancy. These include the Population Council Kenya, Kisumu Medical and Education Trust, the Midwives Association of Kenya, county health management teams, the National Malaria Control Programme, and the Reproductive Maternal Health Services Unit.

The recent decentralisation of Kenya's health system provides an opportunity to achieve sustainable change at the county level. The project is initially focusing on the two high-prevalence

Project at a glance

Project: Revive IPTp project

Project lead: Dr Harriet Birungi, Population Council Kenya

Countries involved: Kenya

Target population(s): Pregnant women

Year funded: 2020

EDCTP funding: €2.25 M

malaria-endemic counties in Kenya with the lowest uptake of IPTp.

Impact

The Revive IPTp project will reinvigorate efforts to deliver a proven intervention to a vulnerable group experiencing some of the worst impacts from malaria. Lessons learned from the project will support the introduction of similar approaches in other counties and potentially in other malaria-endemic countries where use of IPTp is suboptimal.



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Europe Office

Postal address
P.O. Box 93015
2509 AA The Hague
The Netherlands

Africa Office

Postal address
P.O. Box 19070
Tygerberg 7505, Cape Town
South Africa

Visiting address

Anna van Saksenlaan 51
2593 HW The Hague
The Netherlands

Visiting address

Francie van Zijl Drive,
Parowvallei 7505, Cape Town
South Africa

Phone: +31 70 344 0880/0897

Phone: +27 21 938 0690

Fax: +27 21 938 0569

Email: info@edctp.org

Web: www.edctp.org

Twitter: @EDCTP

YouTube: edctpmedia

Writer:

Ian Jones

Concept and design:

Daniela Pereira

Photography:

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