



High-level launch event for the second EDCTP programme

Strengthening the partnership for
fighting poverty-related diseases in Africa

Proceedings



2 December 2014
Cape Town, South Africa



Towards the second EDCTP programme

The EDCTP high-level launch event for the second EDCTP programme is the last meeting in a series of high-level meetings planned to contribute to the shaping of the strategy and funding approach of the second EDCTP programme. These proceedings document the third high-level meeting dedicated to establishing the second EDCTP programme. The first meeting took place in Cape Town, South Africa on 5 November 2012 and the second meeting was in Dakar, Senegal, on 21 October 2013.

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EDCTP was created in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases (PRDs) of HIV/AIDS, tuberculosis and malaria. Under its first programme EDCTP is a partnership between 16 European countries, the European Union and sub-Saharan African countries. The second programme under the European research framework programme Horizon 2020 is implemented by EDCTP as a partnership of 13 European and 13 African countries that govern EDCTP as members of the EDCTP Association. The aim of the programme remains to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics for HIV/AIDS, tuberculosis and malaria as well as neglected and emerging infectious diseases in collaboration with the pharmaceutical industry and like-minded product development partners and development agencies.

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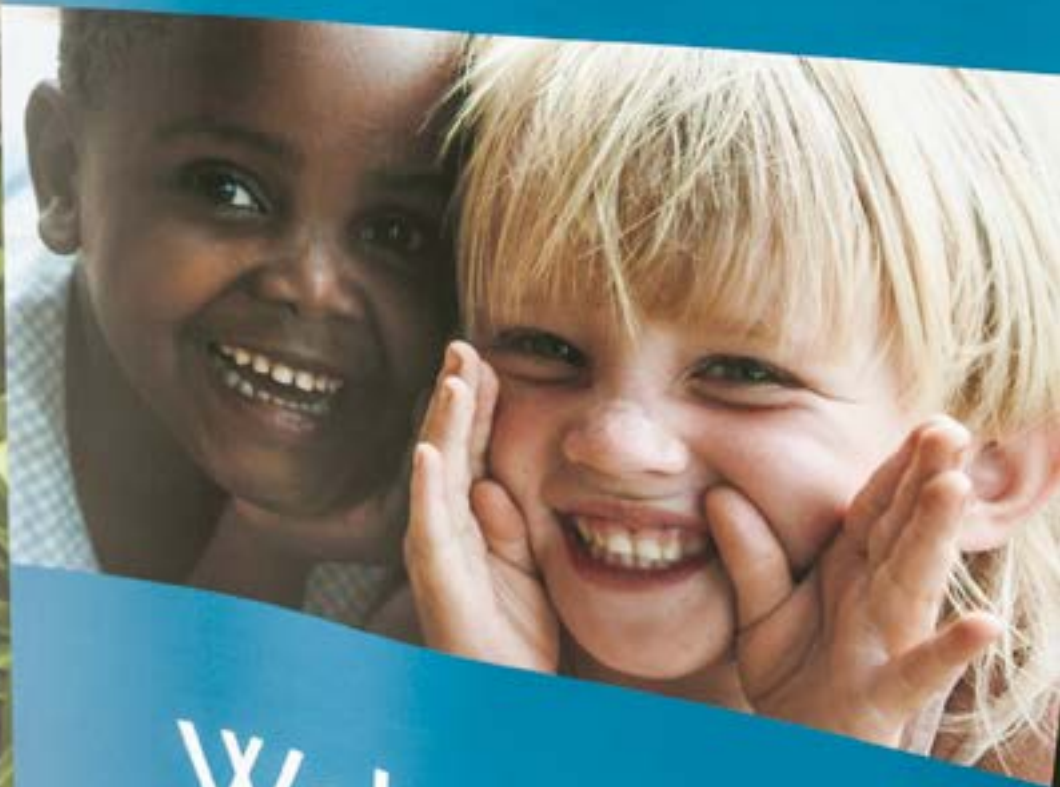
Acronyms and abbreviations

AfroCAB	African Community Advisory Board
ANDI	African Network for Drugs and Diagnostics Innovation
ARV	anti-retroviral (drug)
AU	African Union
EC	European Commission
EFPIA	European Federation of Pharmaceutical Industries and Associations
EIB	European Investment Bank
EU	European Union
EVIPNet	Evidence-informed Policy Network
FAPMA	Federation of African Pharmaceutical Manufacturers Associations
FEAPM	Federation of East African Pharmaceutical Manufacturers
Gates Foundation	Bill & Melinda Gates Foundation
GHIA	Global Health Innovation Accelerator
EDCTP	European & Developing Countries Clinical Trials Partnership
EDCTP ₁	first phase of the EDCTP programme (2003-2013)
EDCTP ₂	second phase of the EDCTP programme (2014-2024)
MDR	multi-drug resistant
MRC(UK)	Medical Research Council of the United Kingdom
MRC(SA)	Medical Research Council of South Africa
NEPAD	New Partnership for Africa's Development
NID	neglected infectious disease
NoEs	EDCTP's Networks of Excellence
PMPA	Pharmaceutical Manufacturing Plan for Africa
SADEC	Southern African Development Community
WHO	World Health Organization
WHO-AFRO	World Health Organization, African Regional Office



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Welcome

2 December 2014
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1. Executive summary

Four speakers addressed the meeting during its **opening session**. Ruxandra Draghia-Akli, Director, Health Research, European Commission (EC) said more African countries were taking ownership of the programme, demonstrating a higher level of commitment. Naledi Pandor, Minister of Science and Technology, South Africa said that while Africa had ‘ramped up’ its investment in research much more remained to be done; also of concern is Africa’s low expenditure on health care. Three exciting aspects to the second EDCTP programme (EDCTP₂) were: the inclusion of neglected infectious diseases (NIDs) and more trial phases, the continuation of capacity strengthening, and the increased commitment of African nations. Robert-Jan Smits, European Commission (EC) Director-General for Innovation and Research, said EDCTP₁ had played a key role in accelerating progress towards the Millennium Development Goals on health. EDCTP₂ retains the same priorities – addressing health challenges through partnership and building Africa’s research capacity. The increase in the size of the budget will be crucial, as will the extension of the programme’s remit. It is hoped that EDCTP will also receive more private sector investment. Georg Schütte, State Secretary, Federal Ministry of Education and Research, Germany said progress could only be made against the worldwide threat of infectious diseases through collaboration; EDCTP helps German researchers collaborate with others in Europe and Africa.

The first of three **keynote addresses** was given by Rose Leke, Professor Emeritus of Immunology and Parasitology, and Chair of the Board of the Cameroon National Medical Research Institute, who summed up the achievements of EDCTP₁, saying that it had redefined North–South collaboration and shown South–South collaboration to be both possible and sustainable. However, she was concerned that some of EDCTP’s activities had

been confined to a small number of African countries; she called for a geographical, rather than a national, approach. In her view, six areas critical for the success of EDCTP₂ would be to:

1. Consolidate the achievements of EDCTP₁
2. Reach parts of Africa not yet included
3. Foster a culture of innovation throughout the bench-to-bedside chain
4. Ensure that NIDs receive adequate attention
5. Ensure commitment from African governments and the private sector
6. Involve women scientists and the African scientific diaspora.

Peter Piot, Professor of International Health and Director of the London School of Hygiene & Tropical Medicine spoke of the ‘global health momentum’ (health improvements, optimism in disease elimination and growing political support) and of ‘the globalisation of global health’ – global health institutions are no longer located exclusively in the North. He referred to the challenges posed by both infectious and non-communicable diseases and by the ‘globalisation of risks’. He outlined a number of ‘what if’ scenarios in which global health could deteriorate. He advocated a move from projects to products, continued funding for capacity building, ‘innovation for impact’, and maintaining the focus on partnerships and synergies. Innovation is needed not just in research but in the ‘delivery of innovation’. Effective policy making requires reliable data. EDCTP should think ‘beyond infectious disease organisations in looking for potential partners’.

Paul Stoffels, Worldwide Chairman of Janssen Pharmaceutical Companies of Johnson & Johnson described his work, as a young doctor, during polio and Ebola fever epidemics. Such experiences have led him and others in the pharmaceutical industry to focus their efforts on such diseases. He discussed his work at Janssen with regard to HIV/AIDS, tuberculosis, Ebola, polio, filariasis and helminthiasis.

Collaboration with EDCTP is proving very helpful; he praised EDCTP's role in capacity building, and its success in building strong partnerships. He stressed the need for urgency in conducting research; innovation, collaboration and citizenship will also be crucial.

There followed three Roundtable sessions in which speakers were asked to address specific areas of interest.

Roundtable 1 focused on the positioning of EDCTP to address global and national health challenges. Presentations were heard from representatives from four African countries, one EU country, the World Health Organization (WHO), and one national medical research council. The achievements of EDCTP so far were enthusiastically endorsed, particularly with regard to:

- The advances made in infectious disease research in Africa
- The partnership approach and equality within the partnership
- North–South and South–South collaboration and synergies
- Achievements in capacity building
- Training and long-term support for African researchers
- Development of ethical and regulatory capacity
- The Networks of Excellence (NoEs).

Features of EDCTP2 identified as being of particular importance included:

- The major increase in the size of the budget
- The broader remit: inclusion of NIDs, all trial phases and health services optimisation research
- The focus on supporting development of new products from bench to bedside – ‘the full value chain’
- The higher level of commitment from African countries: increased ownership and

recognition of the responsibilities that come with ownership

- The intention to broaden support from the private sector (including charitable foundations).

Some representatives of African nations noted that their governments had not, so far, devoted many resources to medical research but that it was planned for this to change. However, the level of support already given by African nations is often underestimated. The outcomes of EDCTP-supported research will be put to good use by the African governments, which will also take steps to see that EDCTP is promoted internationally.

Representatives from the EU and from WHO placed much value on what could be achieved in global health through collaboration between their organisations and EDCTP (e.g. on regulatory issues, pharmacovigilance and improving access to existing products). The benefits of EDCTP to national research institutions were also noted. Other points made were that Africans should ‘own the science’, and that monitoring the impact of research is essential.

Contributors to **Roundtable 2** were asked to discuss how best to integrate EDCTP activities throughout the entire health innovation chain, ‘from bench to bedside’. Representatives of two African countries, WHO, a patient group, and the African pharmaceutical industry spoke during this session.

Issues identified by speakers included the need to focus more on translational activities, on changing the ‘culture’ of research, and on the delivery of new interventions. Training – not just of scientists – was also seen as a key issue. EDCTP has been willing to take risks in the way it supports young researchers, but gaps remain; expanded funding for researchers could help prevent the brain drain. EDCTP's

funding for health services optimisation research was also welcomed.

Researchers were urged not to undervalue the role of patients participating in their studies; patients and their communities can strengthen the research platform and help create new interventions.

African pharmaceutical manufacturers aspire to meeting the needs of the continent for efficacious and safe drugs and to progress from manufacturing into research and discovery, but companies are presently struggling to survive. The industry and EDCTP should identify areas for collaboration.

Also mentioned was the need for EDCTP to collaborate with a range of other Africa-based organisations (including the African Union and the African Network for Drugs and Diagnostics Innovation) on issues including capacity building, information exchange and drug procurement

In **Roundtable 3**, speakers were asked to focus on the challenge of creating long-term, socially responsible partnerships between governments and the private sector (including pharmaceutical companies, charities, philanthropic donors and product development partnerships). There were presentations on behalf of three funding agencies and from two representatives of the pharmaceutical industry.

Funding agencies are considering new approaches that include:

- Supporting projects that address more than one disease
- Supporting researchers throughout their careers
- Finding new ways to monitor the impact of research
- Programmatic approaches

- Assisting in the development of policies based on locally-generated evidence
- ‘Catalytic’ funding that meets up to 50% of costs
- Support for pharmacovigilance and the local manufacture of generic drugs.

Industry representatives said they valued their links with EDCTP, which they wished to strengthen. EDCTP should seek to form links with organisations and programmes concerned with other disease categories (and also in other business sectors), while remaining focused on what it does best – supporting infectious disease research. EDCTP could also become involved in efforts to improve access to good quality care. The African industry seeks collaboration with EDCTP in the development of new drugs, possibly through co-financing of research studies and assist with technology transfer and capacity development.

Emerging from comments made across all of the Roundtable sessions were a number of recommendations for the future:

- The achievements of EDCTP₁ must be built upon to address the scale of the challenges still ahead
- There is a need to expand in certain parts of Africa; most research has taken place in just a few countries
- Sustainability issues must be addressed – especially regarding difficulties in retaining researchers in their own countries
- Focus on innovation for new products and for their delivery
- A multidisciplinary approach is required
- EDCTP should think broadly in terms of potential partners (e.g. industries outside the pharmaceutical sector)
- The programme should seek more active engagement with patients, the public and health care workers
- Capacity building should include management training

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- EDCTP should seek synergy with Africa's pharmaceutical industry
 - Africa's growing burden of non-communicable diseases and cancer should not be ignored.

The meeting's **closing session** began with a laudation marking the retirement of Pascoal Mocumbi as EDCTP's High Representative; he was thanked for his major contribution and a biennial Pascoal Mocumbi Prize named in his honour was officially announced. Ruxandra Draghia-Akli, said that EDCTP had made 'fantastic progress', which will help towards achievement of the health Millennium Development Goals. Aggrey Ambali, Professor and Head of the NEPAD Science, Technology and Innovation Hub said NEPAD considers itself part of the EDCTP team and sees this relationship becoming stronger. Africa needs a strong culture of science and innovation. He called for a multidisciplinary approach.

Mark Palmer, Chair of the EDCTP General Assembly, said the meeting had seen many senior figures express their commitment to EDCTP2, as a result of which he was confident in the success of the programme. Nevertheless, he cautioned that it is unlikely that any of the diseases targeted by the EDCT2 will be eliminated during the next ten years; most of the challenges will remain. Scientists can only supply the best evidence; EDCTP cannot guarantee new cures, but can promise support for infrastructure to facilitate quality research.

In her closing remarks, Minister Naledi Pandor stressed the need to be very ambitious. It is not right that so many Africans live in such dire conditions but – if we are ambitious – then a similar meeting in ten years' time would be in a different context, where there is no feeling of inequality but one of working together to address the welfare of a significant proportion of the world's people.

Carlos Moedas, European Commissioner for Research, Innovation and Science, speaks at the welcome reception on 1 December 2014



2. Background

The high-level event held in Cape Town, South Africa marked the launch of the second programme of the European & Developing Countries Clinical Trials Partnership (EDCTP) on 2 December 2014. The meeting was jointly organised by the European Commission (EC) and EDCTP, and was hosted by the South African Department of Science and Technology. The objective was to provide an opportunity to discuss the role and strategic vision of EDCTP2, and to explore possibilities for synergies with other international initiatives. The opening session was followed by three keynote addresses from distinguished speakers. There were then three roundtable sessions each focussing on a specific challenge for the second programme:

- The positioning of EDCTP to address global and national health challenges
- Connecting the health delivery chain in order to get research results ‘from bench to bedside’
- Creating socially responsible partnerships for long-term investments in global health.

Roundtable panellists included African ministers, African and European high-level policymakers, as well as representatives from industry, international public and private organisations and a patient organisation.

The event was attended by 156 delegates, including African and European government representatives, major research funders, scientists, industry representatives and other experts.

Participants' registration at the High-Level Launch Event of EDCTP2



3. Opening session

The meeting was opened by **Mr Daan Du Toit**, Deputy Director-General International Cooperation and Resources, Department of Science & Technology, South Africa. Speaking on behalf of Phil Mjawara, Director of the Department who was unable to be present, he said South Africa was fortunate to be the site of EDCTP's African office and was honoured to host this important meeting.

Also welcoming delegates **Dr Ruxandra Draghia-Akli**, Director, Health Research, European Commission (EC) said that, with the launch of EDCTP2, more African countries were taking ownership of the programme and becoming active participants. There was a much higher level of commitment from these countries, both financially and as regarding the achievement of goals.

Dr Naledi Pandor, Minister of Science and Technology, South Africa welcomed ministers and other representatives of countries and institutions participating in the meeting, including Carlos Moedas, the European Commissioner for Research, Innovation and Science, who had been present for discussions the previous day but had since been obliged to

return to Europe. She also thanked researchers for their contributions, which had been central to the success of the first EDCTP programme (EDCTP1). South Africa is proud to play an important part in the EDCTP programme; in addition to hosting the EDCTP Africa office, the country is also the site of many EDCTP-funded research activities.

EDCTP is a flagship of EU-African collaboration, and the launch of EDCTP2 offers an opportunity to further strengthen this collaboration, said Minister Pandor. The discussions taking place at the launch meeting would therefore be of key importance. A highlight of EDCTP2 will be the direct participation of African countries in the governance of EDCTP; there are now eleven African member countries in the EDCTP Association (launched in May 2014), with two more expected to join soon.

Citing Ebola fever as an example, Minister Pandor noted that it costs less to prevent a health crisis than to deal with one. It is therefore encouraging to see the development of Africa's health research capacity. Africa has 'ramped up' its investment in research and the increasing number of research publications from South African institutions has been one of a number of encouraging developments. Nevertheless, there is still much more to be done: while the continent has 2.3% of world GDP, it is responsible for only 0.04% of health research expenditure; and while having 12% of the world's population, it has only 0.01% of the world's scientists. This, she said, should worry us!

Also of concern is the low expenditure on health care; Africa has 25% of the global burden of disease but only 1% of global health expenditure. Access to affordable care therefore remains poor for most Africans.



Dr Naledi Pandor, Minister of Science and Technology, South Africa, at the opening session

There is much to celebrate in what EDCTP has achieved, but many challenges still lie ahead. Minister Pandor contrasted improvements in the HIV situation in South Africa with the failure to make progress against maternal and child mortality. She went on to mention a number of South African initiatives, including Grand Challenges South Africa¹ and the Global Health Innovation Accelerator (GHIA).²

Minister Pandor identified three particularly exciting aspects to EDCTP2 – firstly the inclusion of neglected infectious diseases (NIDs) and more trial phases; secondly the further strengthening of capacity; and thirdly the increased commitment made by African nations themselves, which will allow leverage of further resources from other countries, the private sector and philanthropic organisations.

She expressed her thanks to EDCTP staff in Cape Town and The Hague, and wished well to the programme's second phase, which she said would place Africa in a more favourable position to address its health challenges. Improving the living conditions of its people must be Africa's priority.

Mr Robert-Jan Smits, European Commission (EC) Director-General for Innovation and Research, pointed out that accelerating progress towards the Millennium Development Goals on health was one of the European Union's leading ten priorities. EDCTP will play a key role in the achievement of this aim. Under EDCTP1, the aim of the partnership was to establish a new collaborative model for research on the 'big three diseases' (HIV/AIDS, tuberculosis and malaria), taking the form of trials that follow international guidelines for quality research and have the aim of improving the health of those most in need. There is much to celebrate in the achievements of



Mr Robert-Jan Smits, EC Director-General for Innovation and Research, at the opening session

EDCTP1 but the challenges remain, so the deliberations of the launch meeting would be important in determining the way forward.

EDCTP2, he said, retains the same priority – to address health challenges through partnership and to help build Africa's research capacity. An important part of the latter is improving the retention of trained people in their countries. Emerging diseases, including Ebola fever, will be part of the extended remit of EDCTP2. The extension of the remit to include all trial phases will enable the provision of support to all phases of development. The major increase in the size of the budget will also be crucial. It is expected that, in addition, the new programme will receive more investment from the private sector (including charitable foundations), for which the target set is €500 million. It was good to see the private sector well represented at the meeting and he hoped for the signing of agreements soon. Such investment is one of the most effective ways of improving the development of African countries.

Mr Smits paid tribute, as did several subsequent speakers, to the role played by Dr Pascoal Mocumbi who was instrumental in

¹ <http://www.mrc.ac.za/funding/GrandChallenge.htm>

² <http://sites.path.org/southafrica/health-technology-innovation-hub/>

encouraging African countries to commit to and invest in health and health research.

The final opening address was given by **Dr Georg Schütte**, State Secretary, Federal Ministry of Education and Research, Germany, who said he would help to give a European partner perspective. Dr Schütte set out three reasons why Germany had joined and continues to support EDCTP.

The first reason is ‘selfish’; it helps the work of German researchers to have collaboration with excellent partners in Europe and Africa, and EDCTP provides a framework to make this possible. He noted that Germany’s new national centre for infectious disease research (one of six recently established national centres) has already acquired several partners thanks to EDCTP.

The second reason is that progress can only be made against the worldwide threat of tropical diseases through collaboration. He referred to Germany’s three-fold strategic framework for collaboration: at governmental level there is a policy on global health; the Ministry of Education and Research emphasises research collaboration with Africa, and thirdly, poverty-related-neglected tropical diseases are on the German international agenda. (He noted that the latter diseases will also be on the agenda for next year’s G7 meeting, which will be hosted by Germany.) Global problems require global solutions. There were many lessons to be learned from the current West African epidemic of Ebola fever, in particular the need for preparedness in all countries.

Thirdly, EDCTP is an ‘invaluable asset’ that should be supported. Addressing all European partners, he called for a cultural shift which does justice to the global significance of the African continent, which calls for courage, patience and commitment to change. EDCTP is an example of this cultural shift.



Dr Georg Schütte, State Secretary, Federal Ministry of Education and Research, Germany, at the opening session

4. Keynote addresses

Facing new challenges: building on the achievements of EDCTP-1

The first of the three addresses was given by **Professor Rose Leke**, Chair of the Board of the Cameroon National Medical Research Institute and Professor Emeritus of Immunology and Parasitology, Cameroon. She was grateful to be part of such an important meeting. The launch of EDCTP2 was a landmark in progress against infectious diseases.

A recurring question is how best to train scientists to engender the knowledge, skills and tools necessary for the control of infectious diseases. Several strategies have been investigated with support from donors. However, Professor Leke's concern is that these initiatives have taken place in just a few African countries. She favours a geographical, rather than a national, approach.

Summing up the achievements of EDCTP1, she placed particular emphasis on the Networks of Excellence (NoEs), training fellowships, ethics and regulatory projects, clinical trials with integrated capacity building, and the member-state-initiated projects. The NoEs have shown South–South collaboration to be both possible and sustainable. EDCTP has supported over 400 trainees and in most cases grantees have been supported beyond their PhDs. The support for 74 ethics and registration projects has also been commendable. EDCTP1 has been remarkable in redefining North–South collaboration. The programme is now the largest North–South and South–South collaboration, with 13,000 research collaborators in Africa and 750 in Europe. The challenges that still lie ahead include the need for vaccines for HIV/AIDS, tuberculosis and malaria, and more effective treatments – particularly for tuberculosis, for which current treatments are so slow. Ebola fever has also reminded us of the need

for better healthcare systems able to respond to emergencies and to conduct research.



Professor Rose Leke, Chair of the Board of the Cameroon National Medical Research Institute and Professor Emeritus of Immunology and Parasitology, Cameroon, gives her keynote speech

Professor Leke went on to define six areas that will be critical for the success of EDCTP2.

1. Consolidate the achievements of EDCTP1 by maintaining the partnership approach and ensuring the sustainability of the capacity that has been created. However, the number of participating African countries should be increased to achieve a critical mass, and efforts made to ensure the sustainability of the capacity that is created. (Some facilities closed down at the end of EDCTP1 funding; this should not happen.) Every effort must be made to retain African researchers in Africa.
2. The programme should be expanded to reach parts of Africa not yet included.
3. Foster a culture of innovation. Innovation should extend beyond new technologies to the fostering of a culture in which the social context of their delivery is understood and communities are engaged in their implementation. What is required is a

people-centred health system. Professor Leke reaffirmed the importance of the inclusion within EDCTP₂ of the entire ‘value chain’ from lead identification to phase IV studies. The potential of traditional medications and repurposing of existing drugs should also be investigated.

4. The addition of NIDs to the EDCTP programme remit is important. Note that, as a group, they rank second in terms of disease burden, after HIV/AIDS.
5. More commitment is needed from African governments and from the private sector. Ministers should be held to the promise to allocate 2% of health budgets to research, which has seldom been fulfilled. New ways should be found to get governments to respect this commitment.
6. Encourage the participation of women scientists and of the African scientific diaspora. Professor Leke urged African researchers now living and working elsewhere, to ‘Bring home your expertise!’

Professor Leke concluded with thanks to all the partners involved in achieving the ‘tremendous progress’ made in EDCTP₁, which had given hope to African scientists. She urged scientists to ‘dream big, bold and beyond our present horizons’ and to go beyond borders to make an indelible imprint in the fight against infectious diseases. Scientists owe this to those who die and those who live in poverty – they are not just statistics but individuals.

EDCTP₂ and the global health momentum

Professor Peter Piot, Director of the London School of Hygiene & Tropical Medicine began his presentation with reference to his part in an evaluation of EDCTP₁. He had been impressed with the progress achieved, particularly with regard to the focus on equitable partnership,

capacity and infrastructure strengthening, support for African-led projects and the creation of regulatory and ethical frameworks.

Global health is currently dominated by the Ebola fever crisis, the message of which is ‘Act early and you will win’. Referring to AIDS, he urged caution when people claim the end is near – it is not. Nevertheless, we now have a ‘global health momentum’: we are seeing health improvements, there is optimism in disease elimination (most notably polio), and political support is growing. For example, NTDs will be on the next G7 meeting and the G20 has issued a statement on Ebola fever. We are also witnessing ‘the globalisation of global health’; in other words, global health institutions were formerly all located in the North but are now also to be found in the South.



Professor Peter Piot, Director of the London School of Hygiene & Tropical Medicine, gives his keynote speech

Discussing the global burden of disease Professor Piot referred to the challenges posed by both infectious and non-communicable diseases. He went on to discuss the ‘globalisation of risks’; not only pathogens but also unhealthy products (tobacco, alcohol, sugar and cars) are spreading rapidly around the world. He also outlined a number of ‘what if’ scenarios in

which global health could deteriorate. These included drug resistance,³ the emergence of new pandemics, environmental disasters, and the possibility that rates of tobacco use, diabetes and hypertension could get out of control.

In discussing the best ways forward, Peter Piot spoke of the need to think in terms, not of projects, but of products. A focus on adequate funding and capacity building will be essential. Referring to the case of South Africa, an increase in research funding (1998–2008) had led to a marked rise in published research output. The number of scientific papers produced by Africans tripled in the ten years to 2013, reaching over 55,400. However, Africa still only accounts for 2.4% of the world's total output.

He also called for 'innovation for impact' and for a constant search for productive partnerships and synergies. In particular, he regards South–South partnerships as 'a potential game changer in the power structure of research'; at present most institutions in the South have partnerships only with the North and this must change.⁴ Higher education and research are integral building blocks of development; Africa must grow in these fields this or it will remain a 'cash-crop economy'.

A further need is for improved data to enable more effective policy making and more appropriate programmes. Describing global burden of disease data as 'the mother of all estimates', he stressed the unreliability of much of the data now available.

Calling for more thinking outside the box, Professor Piot emphasised that, 'Innovation is needed not just in research but in the delivery of innovation'. As an example, he said that much can be achieved through the use of

mobile phones; if they can change the way people bank, they can be used in health care to aid diagnosis and treatment.

In seeking to develop partnerships, we should remember that, 'No one is rich enough to have nothing to learn and no one is too poor to have nothing to offer'. We should think beyond infectious disease organisations in looking for potential partners.

Professor Piot said EDCTP had promoted not only good science but also new ways of working. It has been part of a move towards 'Global Health 2.0'. This he said would include: a shift from Northern principal investigators to global principal investigators, from study sites to centres of excellence, from biomedical to multidisciplinary approaches, from the delivery of innovation to innovation in delivery, and from a focus on infections and maternal and child health to a broader health agenda.

In conclusion, he said, we owe to those who are dying to help them, and we can help them through innovation.

Supporting health through new science and technology

Dr Paul Stoffels, Worldwide Chairman of Janssen Pharmaceutical Companies of Johnson & Johnson began by describing some of his early experiences as a doctor. These included working with polio cases in the Democratic Republic of Congo, where 2000 children and adults were 'put back on their feet and given their dignity back'. He also saw an early Ebola fever outbreak, in which a number of his friends and colleagues died. He reflected that the same part of Africa has since lost a generation through AIDS. Such experiences have led him and others in the pharmaceutical industry to focus their efforts on the diseases that cause such suffering.

³ Of particular concern would be resistance to antibiotics, artemisinin and antiretrovirals.

⁴ He cited the African Society of Laboratory Medicine as a fine example of an organisation that through South-South collaboration will encourage innovation.



Dr Paul Stoffels, Worldwide Chairman of Janssen Pharmaceutical Companies of Johnson & Johnson, gives his keynote speech

Dr Stoffels then described his work at Janssen and the important innovations made by this company. This includes HIV/AIDS research and the creation of the biggest database of HIV of drug candidates. Drug resistance is of great concern, particularly with regard to HIV/AIDS. It is essential to use the drugs we have now in an effective way. He stressed the need to improve patient compliance with treatment, which would require the development of simpler drug regimens. Also needed are simple viral load tests to determine when to switch therapies. There is also much that can be achieved through the use of existing technologies; for example, slow-release antivirals on vaginal rings.

Janssen has been working in collaboration with the Bill & Melinda Gates Foundation to develop rilpivirine (a long-lasting drug for HIV-AIDS treatment and prevention) and with the TB Alliance, where identification mycobacterial ATP synthase was identified as a drug target for tuberculosis, leading to a new drug for multi-drug resistant tuberculosis (MDR-TB) – bedaquiline which, he cautioned, should be strictly reserved for use against MDR-TB only.

The company has been working on an Ebola fever vaccine since 2008. This programme has

now been accelerated and – if the vaccine is found to be effective – Janssen expects to produce over one million doses next year, and three to four million in 2016. But close collaboration will be needed with African governments to undertake effective, ethical trials with no delays.

Other Janssen contributions to the battle against infectious diseases include donations of mebendazole to implement the Children Without Worms programme.⁵ The company is also working on a new chewable formulation of this drug. Vaccine research currently in progress includes collaboration with the University Harvard and the US National Institutes of Health on HIV vaccine research, and the development of a highly productive cell line that will lead to an improved polio vaccine. Various avenues are also being pursued in efforts to develop new filariasis treatments, including possible repurposing of existing drugs.

In such work, collaboration with EDCTP is proving very helpful; Dr Stoffels has been impressed by the work of the programme so far and welcomes the launch of its second phase. In particular, he praised EDCTP's focus on specific health care issues in Africa, its support for capacity building, and its success in building strong partnerships.

The pharmaceutical industry has the technology but, said Dr Stoffels, it needs collaboration with other institutions so that trials can be conducted quickly – not just for Ebola but also for malaria and other diseases. He continued to stress the need for urgency; avoiding delays is crucial. Better laboratories are essential to achieve results of good quality, faster. Innovation, collaboration and citizenship will all be crucial in the attainment of progress. Janssen is willing to work to build capacity to achieve the breakthroughs that are needed against infectious diseases in Africa.

⁵ <http://www.childrenwithoutworms.org/>



Participants of the High-Level Launch Event for EDCTP2

4. Roundtable 1

Positioning EDCTP to address global and national health challenges

A major challenge for EDCTP is to create a truly equal partnership of European and African countries. This will require sustained political support from policy-makers and financial support from governments, from both Europe and Africa. In Roundtable 1, representatives of the governments of three African member countries and one aspirant African country nation were asked to address several issues: why their governments had decided to join the partnership; what resources they would be committing; what steps they were taking to promote health research; and how they would promote EDCTP's success and support its positioning at global level. Also contributing to Roundtable 1 were representatives of one European country (France), the World Health Organization and one Medical Research Council (South Africa).

Co-Chair **Dr George Schütte**, State Secretary, Federal Ministry of Education and Research, Germany introduced Roundtable 1 and the speakers. **Professor Nkandu Luo**, Minister of Chiefs and Traditional Affairs, Zambia was the session's other Co-Chair, as well as one of the speakers.

Professor John Gyapong, Pro-Vice Chancellor for Research Innovation and Development of the University of Ghana spoke on behalf of Ghana's Deputy Minister of Health Hon. Victor Bampoe, who was unable to attend. Professor Gyapong began by addressing the question as to why Ghana had opted to become a member country of the EDCTP Association. He said that, because of positive experiences with EDCTP₁, it was thought 'wise' to take the opportunity offered by membership. Ghana already had good knowledge of the partnership and its procedures. Ghana has also decided to contribute its own resources to EDCTP. This reflects the fact that the country's own agenda coincides with the aims of EDCTP. A

contribution of particular importance was the capacity of Ghana's internationally recognised research centres, which are able to handle all trial phases.

Ghana is aware, however, that it has not been devoting sufficient funding to research, even though it has performed better than many other countries in this regard. Action will be taken to address this situation 'pretty soon'. Higher education in particular will receive more support. The target of devoting 1% of the health budget to research will also be reached soon.

Professor Gyapong then considered how EDCTP might contribute to Ghana's national health research priorities and health policies. He cited NIDs as an example of where supported was needed. The current outbreak of Ebola fever, and the inadequate level of the response, has demonstrated the need to develop resources and underlined the importance of effective health systems.

The next speaker was **Professor Nkandu Luo**, Minister of Chiefs and Traditional Affairs, Zambia. She said Zambia had jumped at the chance to become a member of the EDCTP Association. Having been privileged to be involved in discussions in EDCTP's General Assembly and in the former Developing Countries Coordinating Committee (DCCC), Minister Luo said she knew EDCTP to be a unique organisation: its investments are real and it 'walks the talk'. Most other programmes are 'lopsided' but EDCTP offers African countries a chance to take on ownership and the responsibilities that come with ownership. She referred to the legacy of Zambia's recently deceased President Michael Sata, who often spoke of 'doing, not talking', noting that this was also the approach adopted by EDCTP.

As regards resources that Zambia will contribute to EDCTP, she said the country does

have some research infrastructure, though this needs to be improved. She stressed that contributions made by African governments to EDCTP sometimes go unrecognised. For example, governments pay for electricity and staff in the buildings in which research takes place.

Zambia is in a position to promote EDCTP's success and support its positioning at global level, due to its active role in the United Nations, and in the African Union (AU), the New Partnership for Africa's Development (NEPAD) and Southern African Development Community (SADEC). Every opportunity would be taken to make clear how much EDCTP is doing: 'We will say who is really helping us'.

She concluded by highlighting the achievements of EDCTP's Networks of Excellence (NoEs) in facilitating South–South collaboration. Nevertheless, more should be done in this regard, including bringing countries such as Lesotho and Swaziland into the NoEs. North–South partnerships have been successful but a forum is now needed to further develop South–South collaboration.

Mr Marcelino Lucas, Permanent Secretary, Ministry of Health, Mozambique began by explaining his country's decision to join the EDCTP Association. Mozambicans, he said, believe in partnership and the country is already a member of many other international bodies. The government is also well aware of EDCTP and what it has achieved; the programme has helped raise the quantity and quality of health research in Mozambique, the results of which can already be seen. Pascoal Mocumbi, as a former Prime Minister of Mozambique has in addition played a key role.

Mozambique will be able to contribute towards EDCTP through its Ministry of Science and Technology, which was established 10 years ago albeit with limited resources. The government is also encouraging the private sector to

become more involved in research. The government of Mozambique has approved a research for health agenda and is planning to establish a national programme. The outcomes of EDCTP-supported research will be taken note of by the government, which will ensure they are put to good use.

Mozambique will take steps to see that the work of EDCTP and its achievements are known and promoted internationally.

The meeting was then addressed by **Dr Mountaga Tall**, Minister for Higher Education and Research in Mali, a country that is an aspirant member of the EDCTP Association. He listed three reasons why his country wished to join: Mali and EDCTP share common objectives regarding health priorities; they also agree on the importance of biomedical research in solving human problems; and Mali wishes to draw on the support of EDCTP to develop its research capacity and infrastructure, in addition to its ethical and regulatory environment.

Mali is willing to contribute its own resources to EDCTP. 'If you want heaven to help, you must first help yourself', said Minister Tall, stressing that it was important to convey the political will of his government to go beyond talking the talk. It intends to take action to boost health research in Mali and has already established a permanent policy to expand research through training and capacity improvement. There is a fund (\$4m) to which Malian scientists can apply. The government also intends to lift taxes on the import of biomedical equipment, and will aggressively fight the brain drain through the creation of an environment in which young researchers have a good career path.

Minister Tall said EDCTP can contribute to Mali's national health research priorities and health policies through investment in shared priority areas and in the development of

capacity, including ethics and regulatory capacity. It is his intention to showcase the achievements of EDCTP at various international gatherings that he will be attending.

Dr Roger Genet, Director-General for Research and Innovation at the Ministry of Higher Education and Research, France said it is French policy to collaborate with the South. The French agency for AIDS research and other bodies have been enabled through EDCTP. Industrial companies have also become involved. New programmes on the three poverty-related infectious diseases (HIV/AIDS, tuberculosis and malaria) have created a wealth of data, for example, on rates of HIV transmission. He provided several examples of successful research programmes in Africa that had been supported by France.

France has been a member of EDCTP since its inception, and has therefore followed the implementation of the EDCTP_I programme from the European side. One of the objectives – and one of the most difficult challenges – has been to achieve superior coordination and integration of national research programmes at European level, within the remit of EDCTP. France has a wealth of experience of collaboration with African countries and also collaborates with other EU nations. It has set up research fields for NIDs and now Ebola, and it will expand such activities. France is the second biggest contributor to the Global Fund to fight HIV/AIDS, tuberculosis and malaria. It also supports other initiatives.

He concluded by stressing that there remains ‘a real need’ to avoid duplication and to increase collaboration and synergy between initiatives, as well as between countries.

The World Health Organization (WHO) was represented by **Dr Sarah Louise Barber**, WHO Representative in South Africa. She expressed the regrets of Director General Dr Margaret

Chan, who was unable to be present. WHO remains a strong supporter of EDCTP. Dr Barber highlighted just three of the many areas in which there are mutual benefits to WHO–EDCTP collaboration as they have many shared objectives. Firstly, the findings of EDCTP research are used in the development of WHO’s technical strategies. Also both organisations support capacity building (particularly in tropical disease research), as well as the strengthening of ethical and regulatory capacity. EDCTP is a wonderful platform and can be expanded.

In discussing whether there should be any changes in the cooperation between WHO and EDCTP, she emphasised regulatory issues – for example, finding ways to accelerate regulatory approval of vaccines, particularly in times of emergency. Improving access to existing products is another key area and EDCTP-WHO collaboration may be able to help here, as is the case with improved pharmacovigilance.

Dr Barber called for innovative approaches to improve the delivery of new products from research to remote rural areas; we should bring together all stakeholders to find practical solutions here. She applauded EDCTP₂’s expansion to include other infections but urged the meeting not to forget non-communicable diseases, from which the developing nations bear the biggest burden of premature deaths. Preventive vaccines for cervical cancer are also needed across Africa.

Professor Glenda Gray, President of the South African Medical Research Council (MRC SA) began by discussing how EDCTP and national medical research councils might best coordinate their efforts to address the global challenge of poverty-related and neglected diseases. She said there were similar priorities, making it easy to synergise. Capacity development is seen as a priority in South Africa and the lessons learned here were also relevant to

other countries. South Africa itself could also learn from the experiences of other nations. Nevertheless, she described the budget allocated to capacity development as ‘paltry’.

Professor Gray noted the importance of leverage in obtaining funding. The issue of ownership is regarded as key and equity must be part of ownership.

All the partners involved in EDCTP should share their expertise on developing devices and vaccines. Diagnostics is another important area; South Africa is developing a ‘febrile panel’ and is active in diagnostic work in Sierra Leone. It should not be forgotten that the prevalence of non-communicable diseases is also increasing across Africa.

EDCTP has been a valuable test of concept, Professor Gray said. It has shown we can develop networks and develop capacity. Looking to the future, she said Africans must ‘own the science’. It is also essential to monitor the

impact of the research that is being conducted. Not enough has been said about this so far. How best to measure the impact of research remains a problem. South African researchers have achieved an impressive number of publications, with prevention of mother-to-child transmission of HIV an area of particular success, but more can be done and results must be put into practice. Africans should be ambitious and aim to beat established institutions in terms of publications.

From left to right: Dr Georg Schütte, Prof. Nkandu Luo, Prof. Glenda Gray, Dr Roger Genet, Dr Sarah Louise Barber, Mr Marcelino Lucas, Prof. John Gyapong, Prof. Abdoulaye Djimde (acting as interpreter), and Dr Mountaga Talland, at the roundtable



5. Roundtable 2

From research to people: connecting the health delivery chain

To achieve EDCTP's objectives – raising the health of Africa's people and boosting the continent's healthcare capacities – its activities need to be seamlessly embedded in the health innovation chain from bench to bedside. This will require the involvement of national health policies, national medicines regulations and authorities, and last-but-not-least national and local health systems. Representatives of two African member countries were asked to discuss firstly how they will help EDCTP extend its scope and what their countries hope to gain from their involvement; and secondly the steps they will take to foster engagement of researchers with policy makers, facilitate translation of research into policy and practice, make health care workers aware of new interventions, and improve access to new and improved medicines and technologies. Representatives of WHO, a patient group, and the African pharmaceutical industry also contributed to the Roundtable.

Dr Ruxandra Draghia-Akli, as Co-Chair, reminded the meeting of the expanded remit of EDCTP2 and of the need for a bench-to-bedside approach in research. It was also necessary to involve all stakeholders, including national and local health systems. She then introduced the speakers for Roundtable 2. Professor Hassan Mshinda, Director General of The Tanzania Commission for Science and Technology (COSTECH) and Co-chair/moderator for this roundtable, added that EDCTP1 had 'tested the product' and that he too was looking forward to what could now be achieved under the expanded remit.

Dr Bruno Jean Richard Itoua, Minister of Science, Technology and Innovation, Republic of the Congo (Congo-Brazzaville) and President of the AU's African Ministerial Conference on Science & Technology was the first speaker. He said he supported everything that had

already been said during the meeting, especially regarding the importance of providing support for the development and delivery of new products from bench to bedside ('the full value chain'). However, without ownership and support from African governments themselves, success will not be forthcoming. Congo-Brazzaville is working with UNESCO to develop a new education and research strategy that will include health research. A new National Institute of Health Research has already been established. The biggest challenge is funding but a new national fund has been established with the aim of reaching the target of 1% of total health spending.



Dr Bruno Jean Richard Itoua, Minister of Science, Technology and Innovation, Congo-Brazzaville and President of the AU's African Ministerial Conference on Science & Technology, speaks at the roundtable 2

It is also important to change the research culture. Minister Itoua said Congo-Brazzaville has people with good degrees and their work has been published, but this is not serving the needs of the country. A national health research programme is needed. This will make it possible to extend the scope of EDCTP-supported activities.

Congo-Brazzaville is in a good position to be a part of EDCTP2. In particular, the support for training is welcome.

Minister Itoua also called for close collaboration with the AU, expressing his disappointment that there were no senior AU commissioners present at the meeting. He concluded by urging the adoption of an international, holistic and integrated approach.

Dr Samuel Okware, Director-General of the Uganda National Health Research Organization represented the Ugandan Ministry of Health, the Minister having recently taken on the prime ministership. He reminded the meeting of the many threats to health in Africa, saying, ‘The equator is the epicentre of all diseases’. Uganda started off relatively slowly in its collaboration with EDCTP but several trials are now under way, mainly on malaria and HIV/AIDS. Uganda can facilitate EDCTP2 through the large cohorts it can contribute, which include AIDS and Ebola survivors.⁶

Among the benefits Uganda expects from continued partnership with EDCTP are: technology transfer, improvements in research quality, and enhanced ethical capacity. Fostering the engagement of researchers with policy makers in the health ministry will require a legal framework, which Uganda will establish through a national programme.

In discussing the need to determine the priority areas for research, Dr Okware noted the re-emergence of certain neglected infections and the need to investigate the potential of orphan drugs. The focus must, however, be on the issues facing communities.

Uganda recognises the importance of translational work; an accessible, user-friendly

databank has been set up towards this end. Data must be shared at both local and international levels. Health workers need to be well trained and made aware of effective new interventions. They must also be properly paid and respected. In conclusion, he stressed that ‘Everyone, everywhere should have a minimum quality of life’.

Dr Martin Ota Immunization Research & Development Officer at the WHO Regional Office for Africa (WHO-AFRO) spoke on behalf of Delanyo Dovlo, Director of AFRO’s Health Systems and Services Cluster, who was unable to be present. He reminded the meeting that most African countries are not on target for achieving the health Millennium Development Goals. The investment available through EDCTP offered an opportunity that must be grasped to help remedy this situation. Addressing the issue as to how WHO-AFRO could partner with EDCTP in connecting the health delivery chain, he focused on capacity building and information exchange. For the latter, the knowledge translation platform of the Evidence-informed Policy Network (EVIPNET⁷) will be important but this is currently available in only seven countries. Good procurement of drugs is also a problem that urgently needs attention; IMF loans can sometimes offer a way forward.

Dr Ota described EDCTP as a unique organisation, with an ‘unprecedented’ impact on health research capacity. It had shown that it was willing to take risks, in the way it supports young health researchers. But gaps remain that need to be filled; expanded funding for young researchers could help prevent the brain drain. He also praised EDCTP’s support for health systems research; Ebola has revealed the failings of health systems in the afflicted countries, but it is important to note that there are similar failings elsewhere in Africa.

⁶ Uganda has sent over 100 personnel to West Africa to assist with the current Ebola outbreak.

⁷ <http://global.evipnet.org/>

It is important that health care workers are made aware of effective new interventions; at present they are usually brought on board very late. They should be provided with up-to-date information on research in progress, and provided with system-wide support.

To conclude, he expressed his confidence that EDCTP and WHO can work together to improve the health of the people of Africa.

Professor Leonor Parreira, Secretary of State for Science, Ministry of Education and Science, Portugal said her country had been involved in the work of EDCTP since the programme began; the benefits for researchers have been ‘amazing’. Nevertheless, there is more to be done. A programme has been established to allow African researchers to study in Portugal; the Portuguese Science & Development Programme also supports African students, and the National Development Agency is seeking to make its programmes more effective on the ground. Funding lines have been identified and African colleagues will be assisted in drawing up funding proposals. A significant level of support is also provided in kind by Portuguese researchers. She described investing in people as ‘the best thing we can do’.

Mr Kenly Sikwese, Coordinator of the African Community Advisory Board (AfroCAB), Zambia sought to provide the perspective of people living with AIDS. AfroCAB is part of the international CAB network. CABs have represented the interests of people living with HIV/AIDS on many bodies, in many countries.

Mr Sikwese said it is still easier to find the protocols for research taking place in Europe and North America than to discover what is going on ‘at home’ in Africa. The mind-set of the research community needs to change; perhaps EDCTP can help with this.

People living with AIDS have been asked for their views on researchers. One comment was, ‘Researchers look on us like we are “apps” – i.e. people living with AIDS are something that can simply be added on and then easily deleted. Researchers, he said, often forget that those who participate in research are central to the process. This must change.

Despite being an HIV/AIDS activist for many years, he had only recently heard of EDCTP. It is the belief of the CAB network that trial volunteers can strengthen the research platform. Researchers should not undervalue them as partners who can help create new interventions that can save lives.

To conclude, Mr Sikwese told the meeting, ‘If you want to go far you must take everyone with you, including your communities’.

Dr Paul A Lartey, President and CEO of the La Gray Chemical Company, and Chair of the Pharmaceutical Association of Ghana, said he was grateful to have been asked to give the perspective of the African pharmaceutical industry. He began with a few words about the development of the Federation of African Pharmaceutical Manufacturers Associations (FAPMA). African manufacturers aspire to meeting the needs of the continent for quality, efficacious and safe drugs, and FAPMA seeks the creation of an Africa-wide, sustainable industry that can go from raw materials to final product. This is entirely possible, Dr Lartey said, but ‘a little push’ is needed and EDCTP could play an important part here.

At present, however, the industry’s biggest problem is survival! It suffers from competition from cheap imports. (He noted that South Africa was in a rather different situation in this respect.) To progress from manufacturing into research and discovery is a further challenge. This needs a lot of money. Candidate drugs have been identified but taking them through

to a new product is a huge undertaking. The industry needs support of some kind from government – tax incentives for example. The growth of the industry has been stunted for so long that it is easy to believe it will never achieve its objectives, but FAPMA hopes to address this negative thinking.

Now is the time for FAPMA to get involved with EDCTP and identify the opportunities available for cooperation. In particular, it is important to create bridges for technology transfer. This will enable the industry to move seamlessly up to full production. EDCTP should also partner with African manufacturers to make medicines readily available to all who need them.

Other potential partners included the African Network for Drugs and Diagnostics Innovation (ANDI) and the Pharmaceutical Manufacturing Plan for Africa (PMPA).

From left to right: Prof. Hassan Mshinda, Dr Samuel Okware, Dr Bruno Jean Richard Itoua, Dr Martin Ota, and Prof. Leonor Parreira at the Roundtable 3



6. Roundtable 3

Socially responsible partnerships for long-term investments

EDCTP recognises the risk that new tools for disease prevention and treatment may not be developed quickly and sufficiently. Part of the problem is limited private investment and lack of health research capacities within developing countries. There is a need to increase investment and improve health research capacities to undertake clinical trials in disease endemic regions. This is a long-term commitment that requires partnership between governments, private sector, including pharmaceutical companies, charities, philanthropic donors and public-private-partnership, such as product development partnerships (PDPs). Roundtable 3 examined these issues, with contributions from three funding agencies and two representatives of the pharmaceutical industry. They were requested, in particular, to discuss how they might collaborate with EDCTP to address these challenges.

Professor Tumani Corrah, Emeritus Director, UK Medical Research Unit in The Gambia was Chair of this session, handing over to Dr Bernadette Murgue, Deputy Director, Institute of Infectious Diseases, France, who introduced the Roundtable 3 speakers.

Professor Trevor Mundel, President, Global Health Programme, Bill & Melinda Gates Foundation, USA made the first presentation. EDCTP is unusual in its willingness to provide researchers with long-term funding. But this is still a short time in a researcher's career. The Gates Foundation is now asking how young researchers might be supported throughout their careers.

He noted that its support so far has generally been 'unidimensional' – i.e. funding for projects addressing just one disease or issue. The intention now is to move towards a more multidimensional approach; programmes including several diseases (perhaps not just infectious

diseases) will be considered for support. Quality surveillance to monitor the progress of studies will be regarded as a priority.

What happens, he asked, when one study finishes? We have to see that support does not then dry up. Secondary questions always arise and ways must be found to ensure they are also investigated. By working with partners like EDCTP, the Gates Foundation hopes to ensure that medical research programmes in Africa are sustainable. He noted that the Foundation works closely with product development partnerships (PDPs) and can help establish links between these and EDCTP.

Dr Isabel Mota, Member of the Board of Trustees, Calouste Gulbenkian Foundation, Portugal then addressed the meeting. The Calouste Gulbenkian Foundation is a private Portuguese institution, established in 1956, aiming to raise quality of life through arts, science and education. It has been active in Portuguese-speaking African countries since 1960s. It seeks to help in the core activities required for poverty reduction.

Within the last year, the approach of the Foundation has changed from grant giving to the adoption of a 'programmatic model' that is more focused on training, human resources and boosting institutional capacity. Research is combined with intervention in the field. Isabel Mota said this seems to fit in with what previous speakers here have said about the importance of focusing on Africa's needs. It has worked with a number of other foundations in the EFINTD initiative (European Foundations Initiative for African Research into Neglected Infectious Diseases) to provide training in infectious diseases to African researchers.

Foundation initiatives have facilitated the sharing of experiences, for example with the Health Research Centre of Angola (Centro de investigação em saúde de Angola [CISA]).

Other activities have helped staff retention and the development of policies based on locally-generated evidence.

The Foundation maintains a strong belief in strengthening both North-South and South-South collaboration. Thus its aims and strategy have much in common with EDCTP, with which it will sign a memorandum of understanding regarding strengthening of ethics and regulatory authorities which is crucial in ensuring best practice. Capacity building is only the first of many steps. Transparency is a core principle for the Foundation and will be needed in the creation of a broader partnership that can influence the global health agenda.

Dr William Mwatu, Director of Medical & Regulatory Affairs at GlaxoSmithKline, Kenya has just completed his term as Chair of the Federation of East African Pharmaceutical Manufacturers (FEAPM⁸). In Africa, he noted, local products are often regarded as inferior. An important aim for the pharmaceutical industry has, therefore, been to improve and maintain quality. This has taken precedence over diversification of products, although that has begun to change.

The industry welcomes collaboration with EDCTP. Co-financing of research studies is one area for such collaboration. EDCTP could also help with technology transfer and capacity development.

So far, the African industry's activities in research and development have been restricted to formulation. It now needs to move on to the development of new drugs, but this will need considerable strengthening of capability.

Commenting on how EDCTP might raise and promote its profile, so that it can attract other funders, Dr Mwatu said that communication should be improved. People have a genuine

interest in what scientists are doing, but researchers usually wait for 10 years (i.e. till after a project has finished) before telling the public. 'We should talk beyond ourselves', he said, in order to bring people in.

The African pharmaceutical industry needs some quick successes – hence the need to identify the 'low-hanging fruit' – as well as long-term programmes that generate momentum. People want to be associated with successful ventures. Dr Mwatu urged the meeting to look at businesses in other sectors for support – citing the booming mobile phone companies of Kenya as an example.

The perspective of the global pharmaceutical industry was presented by **Dr Francois Bompert**, Chair of the Global Health Initiative at the European Federation of Pharmaceutical Industries and Associations (EFPIA), and Vice-President and Medical Director of Access to Medicines at Sanofi. Dr Bompert applauded the launch of EDCTP2. In addition to advancing infectious disease research in Africa, EDCTP2 will strengthen health systems and make private sector collaboration more readily achievable. EFPIA already has regular – but informal – contact with EDCTP and is now seeking to move towards a more formal relationship that will extend across the whole spectrum of drug development – candidate identification to registration.

EDCTP has already done a lot to promote its profile, in order to attract other funders. However, it should also now form links with organisations and programmes concerned with other disease categories, while remaining focused on what it does best – i.e. supporting infectious disease research. Another area where EDCTP can help is in monitoring the safety of new products.

Universal health coverage is an important goal, to which EFPIA is strongly committed, and

⁸ <http://feapm.com/>

EDCTP could become involved in efforts to improve access to good quality care.

Dr Shiva Dustdar, Head of Research, Development and Innovation Advisory at the European Investment Bank (EIB), Luxembourg spoke on behalf of the EIB, which she said was a bank ‘not just for Europe’; it is already at work all over Africa.

EIB looks for innovation as well as providing investment. Its current investment strategy is not appropriate for supporting research in the areas dealt with by EDCTP. However, EIB is now looking for ways in which this might be changed. It is hoped to present a tangible strategy next year, which may include funding for expensive, late-stage clinical trials.

Dr Dustdar said the EIB role would be ‘catalytic’ with the aim of meeting up to 50% of costs. Several other areas, such as pharmacovigilance, are also under consideration for

possible support. The Bank looks forward to maintaining a close relationship with EDCTP.

There was time for some very brief questions from the floor. The importance of project management was raised and EDCTP was urged to consider supporting management training. Trevor Mundel agreed this was a key area; effective management can be the difference between success and failure. Shiva Dustdar was asked whether EIB would have the appetite to consider funding the local manufacture of generic drugs. She replied that the Bank did have the mandate to look at this and would welcome applications from Africa.

From left to right: Prof. Tumani Corrah, Dr Bernadette Murgue, Prof. Trevor Mundel, Dr Isabel Mota, Dr William Mwatu, Dr François Bompard and Dr Shiva Dustdar, at the roundtable 3



7. Closing session

The final session of the High-Level Launch for the Second EDCTP Programme was Chaired by Dr Naledi Pandor, Minister of Science & Technology, South Africa.

Laudation for Pascoal Mocumbi and announcement of The Pascoal Mocumbi Award

The laudation was undertaken by **Dr Mark Palmer**, MRC (UK) and Chair of the EDCTP General Assembly. Dr Palmer, who has been associated with EDCTP since 2002, said the search for a High Representative for the Partnership had taken two years but the right person had been found in Pascoal Mocumbi.

Dr Mocumbi came to Europe from Mozambique to train in medicine in the 1960s, studying in Portugal, France and Switzerland. His specialty was obstetrics and gynaecology. Returning to work as a doctor in Mozambique, he later became Minister of Health, then Minister of Foreign Affairs and finally Prime Minister (1994–2004), after which he took on his role with EDCTP.

Mark Palmer said Dr Mocumbi had opened doors for EDCTP that no one else could have opened. On the Partnership's behalf he has spoken to ministers, the AU, NEPAD, and many global health bodies. It had not been an easy ride as for many years EDCTP was a hard organisation to sell, said Dr Palmer, noting that The Lancet had published articles in 2005 and 2007 suggesting that the organisation was in peril. Dr Mocumbi's passion and determination was crucial in surviving this difficult phase. It is gratifying that at the end of his term of service he was able to witness the signing of the Association agreement in May 2014. Prior to and during the EDCTP2 launch meeting, Mocumbi had received many messages of thanks and there has been a dinner to mark his

official standing down as High Representative. But on this occasion Dr Palmer was pleased to announce the launch of The Pascoal Mocumbi Prize, which will be presented biennially. The precise details will be announced elsewhere, but the prize will involve a trophy and an award of 50,000 euro.

Dr Mocumbi said a few words in reply. It had been his pleasure to witness the launch of the EDCTP Association and of EDCTP2. The entry of African countries to the Association is a historic step that will enhance both African ownership and contributions. EDCTP, thanks particularly to its capacity building efforts, is contributing to the development of the continent through the promotion of health and health systems. It will benefit the health of African people and have an impact across the world. He was proud and very moved to be able



Dr Mark Palmer and Dr Pascoal Mocumbi at the closing session

to witness all this happening.

Minister Pandor then introduced the three panellists who would wind up the meeting.

Dr Ruxandra Draghia-Akli, EC Director of Health Research reminded the meeting that health and disease are truly global issues. Clinical trials are expensive and a single entity cannot do them alone. Dr Draghia-Akli hopes that ‘little by little’ EDCTP will help bring effective treatments to all who need them.

The current West African Ebola fever epidemic has demonstrated what happens if health threats are ignored. The epidemic has, however, led to increased recognition of the infectious disease challenges faced by Africa and to new funding. The European Union quickly mobilised €240M to support 13 urgently needed Ebola fever research projects, including vaccine trials. This has shown what can be achieved in response to a crisis. In the early days of EDCTP, countries, organisations and individuals had to learn to work together. This has now been achieved and ‘fantastic progress’ has been made, which will benefit all those involved and help towards achievement of the health MDGs. She thanked all those involved for their work. In conclusion, she stressed that ‘innovation is a two-way street’; too often innovation has been seen as starting in the North but it can also begin in the South.

Professor Aggrey Ambali, Professor and Head of the NEPAD Science, Technology and Innovation Hub gave the congratulations of NEPAD to all those who had made EDCTP a success. He thanked the EU for its support, and also all other bodies that had made contributions. NEPAD was pleased to consider itself part of the EDCTP team and sees its relationship with the programme growing and becoming stronger during its second phase. It will work with EDCTP in building centres of excellence and improving regulatory capability. The programme is already strong in east Africa, is developing well in southern Africa, and is now making progress in west Africa. He stressed the need to build a strong culture of science and innovation on the African continent. It

was necessary to go beyond microbiology, molecular biology and other individual specialities towards a multidisciplinary approach. Referring to the Ebola fever epidemic, he said that new health challenges were emerging, so EDCTP2 was being launched at the right time.

Dr Mark Palmer, speaking as Chair of the EDCTP General Assembly emphasised the importance of this launch of the second phase of the programme. He found it heart-warming that so many senior figures had expressed their commitment, as a result of which he was confident that EDCTP2 would be a success. The first call under the new programme (for diagnostics research) was already on the website and more would follow within a few days.

He reminded the meeting that the programme’s expanded remit will include emerging infections (for example, Ebola fever) and diarrhoeal diseases. More trial phases, diagnostics and microbicides are amongst the other new areas. Training programmes will be strengthened, including joint work with the UN’s Special Programme for Research and Training in Tropical Diseases (TDR). Ethics and regulatory support will also be expanded. Nevertheless, it is the building of partnerships and trust that is perhaps the most important feature. Eleven African countries have now become members, since EDCTP became an association under Dutch law, and three more are likely to do so soon.

Dr Palmer paid special tribute to Charles Mgone who will step down as EDCTP’s Executive Director in 2015.

Before long, he anticipated that it would be time to make plans for EDCTP3! He hoped that much progress would have been made by then, though it was unlikely that any of the diseases targeted by the programme would have been eliminated and most of the same challenges would remain. The part of scientists can only

be as suppliers of the best evidence. EDCTP cannot guarantee to develop products or cures, but can promise support for infrastructure that



From left to right: Dr Naledi Pandor, Prof. Aggrey Ambali, Dr Mark Palmer and Dr Ruxandra Draghia-Akli at the closing session

will facilitate excellent research.

In her concluding remarks, Minister Naledi Pandor heartily took issue with Mark Palmer's modest realism, stressing she wanted to be very ambitious in addressing the problems that continue to beset Africa. She went on to propose some targets: by the time EDCTP2 concludes in ten years' time, there should be at least two African countries producing new drugs; and all African countries should be providing their people with excellent health care. She called for a strong focus on outcomes that would make a positive difference for Africa. The character of Africa should be changed; it is not right that so many Africans live in such dire circumstances. If we are ambitious then we will meet in ten years in a different context, where there is no feeling of inequality but one of working together to address the welfare of a significant proportion of the world's people. We can and must do better.

Annex 1 Conference programme

Monday 1 December 2014

Foyer, Camphor (Level 1)

16:00-19:00 **Registration**

Splash Café

19:00-20:00 **Welcome reception**

Tuesday 2 December 2014

Foyer, Camphor (Level 1)

08:00-08:30 **Registration**

Camphor 1-3

08:30-11:00 **Opening session**

CHAIRS

Phil Mjwara, Director-General, Department of Science & Technology, South Africa

Robert-Jan Smits, Director-General for Research and Innovation, European Commission

08:30-10:00 **Opening addresses**

Naledi Pandor, Minister of Science & Technology, South Africa

Carlos Moedas, European Commissioner for Research, Innovation and Science

Georg Schütte, State Secretary, Federal Ministry of Education and Research, Germany

10:00-11:00 **Keynote addresses**

Facing new challenges, building on achievements of EDCTP1

10:00-10:20 **Rose Leke**, Chair of Board of Cameroon National Medical Research Institute (IMPM) and Professor Emeritus of Immunology and Parasitology, Cameroon

10:20-10:40 **Peter Piot**, Director, London School of Hygiene and Tropical Medicine and Professor of Global Health, United Kingdom

10:40-11:00 **Paul Stoffels**, Worldwide Chairman, Janssen Pharmaceutical Companies of Johnson & Johnson, Belgium

11:00-11:30 **Coffee and tea break**

11:30-13:00 **Roundtable discussion**

Positioning EDCTP to address the global and national health challenges

CHAIR

Georg Schütte, State Secretary, Federal Ministry of Education and Research, Germany

MODERATOR

Sinata Koulla-Shiro, Secretary General, Ministry of Public Health, Cameroon

PANELLISTS

Victor Bampoe, Deputy Minister of Health, Ghana

Nkandu Luo, Minister of Chiefs and Traditional Affairs, Zambia

Judith Macgregor, High Commissioner to South Africa, United Kingdom

Marcelino Lucas, Permanent Secretary, Ministry of Health, Mozambique

Mountaga Tall, Minister for Higher Education and Research, Mali

Roger Genet, Director-General for Research and Innovation, Ministry of Higher Education and Research, France

Sarah Louise Barber, World Health Organisation (WHO) Representative in South Africa

Glenda Gray, President, South African Medical Research Council

13:00-14:00	Lunch
14:00-15:30	Roundtable discussion From research to people: connecting the health delivery chain
	CHAIR Ruxandra Draghia-Akli , Director of Health Research Cooperation, European Commission Moderator Hassan Mshinda , Director General, Tanzanian Commission for Science and Technology (COSTECH), Tanzania
	PANELLISTS Bruno Jean Richard Itoua , Minister of Science, Technology and Innovation, Congo-Brazzaville Aaron Motsoaledi , Minister of Health, South Africa Ruhakana Rugunda , Minister of Health, Uganda Leonor Parreira , State Secretary for Science, Ministry of Education and Science, Portugal Delanyo Dovlo , Director Health Systems and Services Cluster, WHO Regional Office for Africa Paul A. Lartey , President and CEO of LaGray Chemical Company, and Chair of the Federation of African Pharmaceutical Manufacturers Associations, Ghana Kenly Sikwese , Coordinator of the African Community Advisory Board (AFRO-CAB), Zambia
15:30-16:00	Coffee and tea break
16:00-17:00	Roundtable discussion Socially responsible partnerships for long-term investments
	CHAIR Tumani Corrah , Emeritus Director, MRC Unit in The Gambia and Chair of the EDCTP Scientific Advisory Committee
	MODERATOR Bernadette Murgue , Deputy Director of the Institute of Microbiology and Infectious Diseases (INSERM), France
	PANELLISTS Trevor Mundel , President, Global Health Programme, Bill & Melinda Gates Foundation, USA Isabel Mota , Trustee of the Board, Calouste Gulbenkian Foundation, Portugal William Mwatu , Managing Director, Tried Approach Limited, Kenya, and Former Chair of FEAPAM François Bompart , Chair of the Global Health Initiative at the European Federation of Pharmaceutical Industries and Associations (EFPIA), and Vice-President and Medical Director of Access to Medicines at Sanofi, France Shiva Dustdar , Head of Research, Development and Innovation Advisory at the European Investment Bank, Luxembourg
17:00-18:00	Closing session
	CHAIR Naledi Pandor , Minister of Science & Technology, South Africa
17:00-17:15	Laudation for Pascoal Mocumbi and announcement of Pascoal Mocumbi Award
17:15-17:30	Conclusions and next steps

Robert-Jan Smits, Director-General for Research and Innovation, European Commission

Ibrahim Assane Mayaki, Chief Executive Officer, New Partnership for African Development (NEPAD)

Mark Palmer, Chair of the EDCTP General Assembly, United Kingdom

Splash Café

19:00-21:30 **Conference dinner**

Wednesday 3 December 2014

09:00-15:30 **Meeting the people and projects:** visits to clinical trial sites supported under the first EDCTP programme

Annex 2 List of participants

Name	Affiliation	Country
Eleni Aklillu	Karolinska Institutet	Sweden
Hannah Akuffo	Swedish International Development Agency (SIDA)	Sweden
Elizabeth Allen	University of Cape Town	South Africa
Aggrey Ambali	NEPAD STI Hub	South Africa
Garry Aslanyan	WHO/TDR	Switzerland
Marieme Ba	Pharmalys	Senegal
Sarah Louise Barber	WHO	South Africa
Abdoulie Barry	EDCTP	The Netherlands
Pauline Beattie	EDCTP	The Netherlands
Isabella Beretta	State Secretariat for Education and Research	Switzerland
Linda Hildegard Bergersen	University of Oslo	Norway
Flora Bertizzolo	European Union Delegation to South Africa	South Africa
Niresh Bhagwandin	Medical Research Council	South Africa
Detlef Böcking	Projekträger im Deutschen Zentrum für Luft- und Raumfahrt e.V. (PT_DLR)	Germany
François Bompert	Sanofi	France
Gabrielle Breugelmans	EDCTP	The Netherlands
Nienke Buisman	European Commission	Belgium
Christian Burri	Swiss Tropical & Public Health Institute	Switzerland
Maria Hermina Cabral	Calouste Gulbenkian Foundation	Portugal
Jose Carbayeda	European Union Delegation to South Africa	South Africa
Ana Lúcia Cardoso	EDCTP	The Netherlands
Chimwemwe Chamdimba	New Partnership for African Development (NEPAD)	South Africa
Tiyani Chauke	Department of Science & Technology	South Africa
Paul Chinnock	EDCTP	United Kingdom
Gavin Churchyard	The Aurum Institute NPC	South Africa
Maja Clausen	Embassy of Germany	South Africa
Tumani Corrah	Medical Research Council Unit	The Gambia
Xavier D'Argoeuves	Consulate of France	France
Rafael de Andrés Medina	Instituto de Salud Carlos III (ISCIII)	Spain
Adélaïde Eléonore De Molouba	Ministère de la Recherche Scientifique et de l'Innovation Technologique	Congo
Patrice Debré	Université Pierre et Marie Curie	France
Jennifer Dent	BIO Ventures for Global Health	United States
Keertan Dheda	UCT Lung Infection & Immunity Unit	South Africa
Alioune Dieye	University Cheikh Anta Diop Dakar	Senegal
M Diop	Embassy of the Republic of Senegal	Senegal

Abdoulaye Djimde	Malaria Research and Training Center	Mali
Natalija Dolya	European Union Delegation to South Africa	South Africa
Ruxandra Draghia-Akli	European Commission	Belgium
Christiane Druml	Medical University of Vienna	Austria
Daan Du Toit	Department of Science & Technology	South Africa
Daniel Du Toit	Tshwane University of Technology	South Africa
Shiva Dustdar	European Investment Bank	Luxembourg
Nuraan Fakier	EDCTP	South Africa
Sindura Ganapathi	Bill & Melinda Gates Foundation	United States
Deby Gassaya	Ministère de la Recherche Scientifique et de l'Innovation Technologique	Congo
Sue Godt	International Development Research Centre	Kenya
Richard Gordon	Medical Research Council	South Africa
Glenda Gray	Medical Research Council	South Africa
John Gyapong	University of Ghana	Ghana
Sakina Habou	Ministère de la Santé Publique	Niger
Laura Harris	Newton Fund	South Africa
Mark Hatherill	South African Tuberculosis Vaccine Initiative (SATVI)	South Africa
Phumelele Higgins	Department of Science & Technology	South Africa
Stéphane Hogan	European Union Delegation to South Africa	South Africa
Suzanne Hoogervorst	EDCTP	The Netherlands
Carel IJsselmuiden	COHRED	Switzerland
David Itier	Institut Pasteur	France
Bruno Jean Richard Itoua	Ministère de la Recherche Scientifique et de l'Innovation Technologique	Congo
Carine Kades	Fondation Congolaise pour la Recherche Medicale	Congo
Christian Kerckhoven	European Commission	Belgium
Kwadwo Koram	Noguchi Memorial Institute for Medical Research	Ghana
Paul Lartey	LaGray Chemical Company	Ghana
Rose Gana Fombaa Leke	National Medical	Cameroon
Pierre Lemonde	Embassy of France	France
Odile Leroy	European Vaccine Initiative	Germany
Glaudina Loots	Department of Science & Technology	South Africa
Nkandu Luo	Ministry of Chiefs and Traditional Affairs	Zambia
Markus Maeurer	Karolinska Institute	Sweden
Michael Makanga	EDCTP	South Africa
Shelton Tendai Mariga	Copenhagen University	Denmark
Francesco Marinucci	Partec GmbH	Germany
Toto Matshediso	Department of Science & Technology	South Africa

Line Matthiessen-Guyader	European Commission	Belgium
Tugela Matubatuba	Department of Science & Technology	South Africa
Souleymane Mboup	University Cheikh Anta Diop	Senegal
Neil McCarthy	Medicines for Malaria Venture (MMV)	Switzerland
Ntombi Mchuba	Department of Science & Technology	South Africa
Helen Mcshane	University of Oxford, Jenner Institute	United Kingdom
Sibusiso Mdlalose	Logic Trials Clinical Research	South Africa
Charles Mgone	EDCTP	The Netherlands
Benoît Miribel	Fondation Mérieux	France
Pascoal Mocumbi	EDCTP	Mozambique
Boitumelo Mokgatla	COHRED	Botswana
Tebogo Mokoma	Department of Science & Technology	South Africa
Mary Moran	Policy Cures Limited	Australia
Isabel Mota	Calouste Gulbenkian Foundation	Portugal
Palesa Motsoeneng	Department of Science and Technology	South Africa
Mountaga Tall	Ministry for Higher Education and Scientific Research	Mali
Hassan Mshinda	Tanzania Commission for Science and Technology	Tanzania
Trevor Mundel	Bill & Melinda Gates Foundation	United States
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Bernadette Murgue	INSERM	France
Tinyiko Mushwana	Department of Science & Technology	South Africa
Najia Musolino	COHRED	Switzerland
Susan Muzite	Research Council of Zimbabwe	Zimbabwe
William Mwatu	Medical & Regulatory Affairs	Kenya
Isayvani Naicker	Department of Science & Technology	South Africa
Michelle Nderu	EDCTP	South Africa
Angelique Ndjoi	University of Health Sciences Libreville	Gabon
Margareth Ndomondo-Sigonda	NEPAD Agency	South Africa
Joseph Ndungu	FIND	Switzerland
Annalene Nel	International Partnership for Microbicides	South Africa
Khalifa Ababacar Sad Niang	Ministère de la Recherche Scientifique et de l'Innovation Technologique	Congo
Leslie Nielsen	IAVI	Uganda
Sirpa Nuotio	Academy of Finland	Finland
Michael Nxumalo	National Research Foundation	South Africa
Thomas Nyirenda	EDCTP	South Africa
Patrick Obel Okeli	Ministère de la Recherche Scientifique et de l'Innovation Technologique	Congo

Samuel Okware	Ministry of Health	Uganda
Ole Olesen	EDCTP	The Netherlands
Martin Ota	WHO Regional Office for Africa	Congo
Nesri Padayatchi	CAPRISA	South Africa
Mark Palmer	Medical Research Council	United Kingdom
Naledi Grace Mandisa Pandor	Ministry of Science & Technology	South Africa
Lara Pandya	EDCTP	The Netherlands
M. Iqbal Parker	International Centre for Genetic Engineering and Biotechnology	South Africa
Leonor Parreira	Ministry of Education and Science	Portugal
Wim Parys	Janssen Pharmaceutica	Belgium
Ricardo Pereira	Foundation for Science and Technology	Portugal
Nkotseng Phahle	Department of Science & Technology	South Africa
Peter Piot	London School of Hygiene & Tropical Medicine	United Kingdom
Armel Lombet Poaty	Ministère de la Recherche Scientifique et de l'Innovation Technologique	Congo
Ana Ponte	Ministry of Education and Science	Portugal
Klaus Reither	Swiss Tropical and Public Health Institute	Switzerland
Eva Rijkers	NACCAP	The Netherlands
Ton Rijnders	TI Pharma	The Netherlands
Morven Roberts	Medical Research Council	United Kingdom
Sigurd Røtnes	Norwegian Directorate of Health	Norway
Olga Rué Clarós	Archival Farma	Spain
Roxana Rustomjee	Medical Research Council	South Africa
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Colophon

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