A DECADE OF R&D FOR NEGLECTED DISEASES IN AFRICA
Endemic Country Research and Development for Patient Access

CONFERENCE PROGRAMME
Speakers & Chairs
The Road to Regulatory Harmonization for Africa: Accelerating Access to Essential Medicines and Vaccines

Chair: Dr Margareth Ndomondo-Sigonda, Medicines regulatory Harmonization (AMRH) Programme Coordinator, NEPAD Agency

Introduction: Dr Nathalie Strub-Wourgaft, Medical Director, Drugs for Neglected Diseases initiative

Part I: What Has Worked Over the Last Decade?

AVAREF: Accelerating Vaccine Clinical Trial Approvals
Prof. Bartholomew Dicky Akanmori, WHO/AFRO

IEC and NRS Successful Collaboration in Approving Medical Device Clinical Trials: A Product Development Partnership Perspective
Dr Annalene Nel, Medical Director, International Partnership for Microbicides - IPM

Joint Ethics: International Workshop
Dr Samba Cor Sarr, Research Manager, Ministry of Health, Senegal

WHO Pre-Qualification Programme: Facilitating Regional Approval and Patient Access to Treatments
Hiiti B. Sillo, Director General, Tanzania Food & Drugs Authority - TFDA

Article 58: Collaboration Between the European Medicines Agency and WHO
Dr Marie-Hélène Pinheiro, Principal Regulatory Advisor, European Medicines Agency (EMA)

Part II: Towards Standards for Harmonization

Are Current Biological Norms Adapted for Clinical Research in Africa?
Dr Bernhards Ogutu, Senior Clinical Trialist (INDEPTH Network), KEMRI

Priority Areas To Be Addressed in Ethics and Regulatory Reviews in Africa
Dr Michael Makanga, Director South-South Cooperation and Head of Africa Office, EDCTP

Capacity Strengthening Initiatives for Regulatory Authorities in Africa
Esnat Mwape, Director, Pharmaceutical Regulatory Authority, Zambia

Can We Define Essential Technical Standards for Dossiers Necessary for Regulatory Harmonization?
Samvel Azatyan, Manager, Medicines Regulatory Support Programme, World Health Organization (WHO)
### Clinical Research-Related Capacity Strengthening: Best Practices and Lessons Learned

**Chair**

Prof. John Reeder, Director of the Special Programme for Research and Training in Tropical Diseases - TDR

**Strengthening Research Governance: Improving Quality and Research Practice through Ethics Review**

Prof. Bruno Kubata, Co-ordinator of Research for Health & Pharmaceutical Innovation, AU-NEPAD & Member R4HA Team, COHRED

**AMFm Capacity Strengthening for Malaria**

Dr John Amuasi, Komfo Anokye Teaching Hospital (KATH), Ghana and University of Minnesota School of Public Health, USA

**Data Management Centre for LEAP Studies**

Raymond Omollo, Head Data Centre and Statistician, DNDi Africa

**Beyond Clinical Trials: Training of Nurses to Roll Out NECT for Sleeping Sickness While Reinforcing Capacities in the Health System**

Dr Jose Ramon Franco Minguell, Medical Officer, Human African Trypanosomiasis Programme, NTD Department, WHO *(presented by P. Mundidimbi)*

Patrice Kabangu Mundidimbi, Supervisor, East Kasai Provincial Coordination Human African Trypanosomiasis National Control Programme, Ministry of Health, DRC

**An Integrated Approach to Building Health Research Capacity**

Dr Sam Kinyanjui, Head of Training KEMRI-Wellcome Trust

**TDR Career Development Fellowship Programme Building Capacity that Lasts for Product Development and Registration**

Dr Pascal Launois, Scientist, TDR

Dr Wilfried Mutombo, Human African Trypanosomiasis National Control Programme, Ministry of Health, DRC

**NETWORKING COCKTAIL**
The Road to Regulatory Harmonization for Africa: Accelerating Access to Essential Medicine and Vaccines

Dr Margareth Ndomondo-Sigonda
Programme Coordinator, Medicines Regulatory Harmonization (AMRH), NEPAD Agency, South Africa

Dr Margareth Ndomondo-Sigonda leads the African Medicines Regulatory Harmonization (AMRH) Programme, which operationalizes the African Union’s Pharmaceutical Manufacturing Plan for Africa (PMPA), which seeks to enable African countries to fulfill their national obligations to provide all citizens with safe, high-quality and efficacious essential medicines. The NEPAD Agency - as the technical arm of the African Union and in collaboration with partners, is working through the AMRH Programme, to support African Regional Economic Communities (RECs) and countries to lead medicines regulatory harmonization in their respective countries and to respond to the challenges of increasing access to essential medicines.

Dr Ndomondo-Sigonda was previously Director General for the Food and Drug Authority in Tanzania.

Dr Nathalie Strub-Wourgaft
Medical Director, Drugs for Neglected Diseases initiative (DNDi), Switzerland

Nathalie Strub-Wourgaft joined DNDi as Medical Director in February 2009. Dr Strub-Wourgaft, who most recently served as Director of Clinical Development at Trophos, has over 15 years of clinical development experience, including with Pfizer from 2000 to 2003, and Lundbeck from 1995 to 1999. She also served as Medical Director for a contract research organization from 2004 to 2005, and for the French office of Aspreva from 2005 to 2008.

Dr Strub-Wourgaft graduated as Medical Doctor from Necker Hospital, Université René Descartes in Paris, France, in 1983.
Dr Annalene Nel  
**Medical Director, International Partnership for Microbicides, IPM, South Africa**

Annalene Nel qualified as a Medical Doctor in 1984 from the University of Stellenbosch, South Africa. She worked as a Medical Officer in numerous therapeutic areas and lectured in Pharmacology, Pulmonology and Toxicology at the Tygerberg campus of the University of Stellenbosch Medical School. She has worked as an investigator in Clinical Research since 1986, in allergy/pulmonology trials, tuberculosis, adult and paediatric vaccine trials and passed several FDA inspections without any findings. She obtained her B.Sc.Hons in Clinical Pharmacology cum laude in 1986 and her PhD in 1997.

In 1997, she joined Quintiles to be the founder member of the Cape Town office. She was responsible for the general management of the office, clinical operations, feasibilities, medical support and training of staff in all departments in South Africa and business development coordination. She later headed Business Development for Quintiles, Africa.

Dr Nel joined IPM as a Site Development Consultant from August 2005 until March 2006. Since April 2006, she is the Executive Vice President, Chief Medical Officer at IPM, overseeing research centre capacity strengthening and building; clinical program support and operations; and community engagement and safety affairs. She is the Chair of the Dapivirine Vaginal Ring Product Development Committee. She manages and oversees the global Phase III Dapivirine Vaginal Ring program that was initiated 2011.

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Dr Samba Cor Sarr  
**Research Manager, Ministry of Health, Senegal**

After his training in health research management at Laval University of Quebec, Samba Sarr was made responsible for the Sengalese health research system in 2002. He started his mandate by revising the strategic plan of operational health research and worked to install a functional ethical committee.

As Senegalese coordinator, Dr Sarr has been very active in several projects: Enforcement of African health research System, the EDCTP project for strengthening human resources for health research and governance, and the TRREE project for capacity building of evaluation and supervision health research protocol, and is the focal point for the strengthening of the health research system project supported by COHRED and NEPAD.

He further coordinates the scientific committee of the International Expo of Health and Medical Equipment (SISDAK3) organized in Dakar, since 2009, and is an expert of UEMOA on the regulation of clinical trials and pharmacovigilance, as well as an expert of WAHO and WHO health regulation research system and financing. Dr Sarr further participated in the elaboration of Senegalese law on ethical health research and the SOPs of National Ethical Health Research Committee.
Hiiti B. Sillo  
**Director General of the Tanzania Food & Drugs Authority, Tanzania**

Since 2011, Hiiti Sillo is the Director General of the Tanzania Food and Drugs Authority (TFDA) after acting in the same capacity since May 2010. Prior to this, he served the TFDA in several managerial positions including Director of Medicines and Cosmetics between 2008 and 2010.

Mr Sillo was as a quality assessor for the WHO Prequalification of Medicines Programme (WHO) from 2003 to 2010.

Under this Programme, he also worked at WHO HQ in Geneva in 2007 on a rotational position for the WHO Prequalification of Medicines Programme. Mr Sillo is one of the pioneers of the African Medicines Registration Harmonization Initiative for the East African Community (EAC), launched in March 2012. He also served as a representative of the EAC Medicines Regulators to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) during 2011-2012.

Mr Sillo is a pharmacist and holds Bachelor of Pharmacy Degree from the Tamil Nadu Dr M.G.R Medical University in Chennai, India, and a Master of Science in Pharmaceutical Services and Medicines Control from the University of Bradford in the UK. Mr Sillo also serves as a part-time lecturer at the School of Pharmacy of the Muhimbili University of Health and Allied Sciences based in Dar Es Salaam, Tanzania.

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Dr Marie-Hélène Pinheiro  
**Principal Regulatory Advisor, European Medicines Agency (EMA)**

In January 1999, Marie-Hélène joined the European Medicines Agency’s Human Unit Regulatory Affairs Sector and is now principal Regulatory Affairs Adviser. In this capacity, she is responsible for the provision of regulatory advice for vaccines anti-infective, advanced therapies and anti-asthmatic medicinal products within EMA product teams. She is also the regulatory adviser to the Committee for Advanced Therapies medicinal products, Vaccine Working Party, and the EMA innovation task force.

Dr Pinheiro also has the responsibility for coordination of all EMA activities related to ‘Article 58’ medicinal products evaluated by EMA in collaboration with the World Health Organization. Finally, she is a Members of the European Commission representative at Borderline and Classification Medical Devices Expert Group and the EMA Regulatory Affairs representative at the European Commission Notice to Applicants.
Dr Bernhards Ogutu
Chief Research Officer KEMRI, Senior Clinical Trialist INDEPTH Network, Kenya

Bernhards Ragama Ogutu is a Kenyan paediatrician and clinical pharmacologist. He is a Chief Research Officer at the Kenya Medical Research Institute (KEMRI) and Senior Clinical Trialist at the INDEPTH-Network. He is the Scientific Team leader of the Centre for Research in Therapeutic Sciences (CREATES) a consortium of the KEMRI Centre for Clinical Research, Strathmore University, African Centre for Clinical Trials and Council for Scientific and Industrial Research (CSIR), and the South African Strathmore University.

Dr Ogutu received his MBChB, MMed, and PhD from the University of Nairobi. He is a certified Physician Investigator and Facilitator.

Since 1992, Dr Ogutu has held different positions, from practising paediatrics at several hospitals to lead clinical trialist in a number of product evaluation protocols. He has been an external examiner at several universities. Dr Ogutu is a member of several National and International Scientific Committees. His areas of research include clinical trials, disease pathogenesis, clinical therapeutics with a bias in malaria and a keen player in clinical trials capacity development in Africa.

Dr Mickael Makanga
Director of South-South Cooperation and Head of Africa EDCTP Office, South Africa

Dr Michael Makanga is Director South-South Cooperation and Head of Africa Office of the European & Developing Countries Clinical Trials Partnership (EDCTP). He is a Ugandan medical doctor with a Bachelor of Medicine and Surgery from Makerere University, Kampala, Uganda, and a Masters Degree and PhD in Clinical Pharmacology and Therapeutics from the University of Liverpool, United Kingdom.

Dr Makanga has considerable international experience in conducting and management of health research programmes with emphasis in conduct of clinical trials, as well as ethics and clinical regulatory affairs.

He is currently responsible for inter alia overseeing the EDCTP Africa office, fostering close relationship of the partnership with the African scientific, policy making, regulatory and political leadership. He is part of the oversight team involved in the management of scientific matters and advises on capacity development and south-south and north-south networking.
Ms Esnart Mwape  
**Director General, Zambia Medicines Regulatory Authority**

Esnart Mwape is the first Director General of the Medicines Regulatory Authority in Zambia (Formerly Pharmaceutical Regulatory Authority), a position she has held for over six years. Prior to this position, she served as Registrar of the Pharmacy and Poisons Board, which was transformed to Pharmaceutical Regulatory Authority in 2004 (later renamed Zambia Medicines Regulatory Authority).

Overall, Esnart has worked for the regulatory authority for close to sixteen years and out of which thirteen years have been at the helm of the medicines regulatory authority. She has wide experience in regulatory matters ranging from medicines policy matters to organization and management of a regulatory authority, and has served on different boards and committees within and outside the Ministry of Health. She has worked with a wide range of bilateral and multilateral partners who have in one way or the other supported the work of the Authority and engaged various stakeholders on a wide range of regulatory matters. She has also taken an active part in the realization of strategic objectives for regional harmonization initiatives within SADC, COMESA, and AU.

Ms Esnart Mwape is a pharmacist by profession and has a Master of Science degree in Pharmacy from Zaporozhye Medical Institute in Ukraine.

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Dr Samvel Azatyan  
**Manager, Medicines Regulatory Support Programme, WHO, Switzerland**

Samvel Azatyan is a clinical pharmacologist, with a PhD degree in clinical pharmacology and medicines regulation from the State Medical University of Armenia. From 1992 until 1999, Dr Azatyan served as a deputy director at the National Medicines Regulatory Authority of Armenia while also teaching clinical pharmacology at the National Institute of Health of Armenia.

In 1999, Dr Azatyan joined the World Health Organization, initially at the WHO Regional Office for Europe, in Copenhagen, Denmark, and in 2003 the WHO Headquarters in Geneva, Switzerland. Currently, he is in charge of the Medicines Regulatory Support Programme (MRS) in the team of Quality Assurance and Safety of Medicines in the Department of Essential Medicines and Health Products. The MRS Programme supports activities involved in assessing national medicines, regulatory authorities/systems (NMRAs) to identify needs, assisting NMRAs in the development of institutional plans of corrective measures, and supporting training and regulatory capacity building. The Programme has also been active in reviewing the regulatory assessment tool, providing feedback on implementation of existing WHO guidance, norms and standards, developing training materials, developing internal procedures, developing and maintaining technical competence of regulatory staff, and enhancing technical cooperation with partners within WHO and outside. The most important areas of work for the Medicines Regulatory Support Programme include supporting and promoting regulatory cooperation and harmonization.
Clinical Research-Related Capacity Strengthening: Best Practices and Lessons Learned

Prof. John Reeder
Director of the Special Programme for Research and Training in Tropical Diseases (TDR), Switzerland

John Reeder has advised numerous international organizations on strengthening health research capacity in least developed countries, such as the United States Fogarty Institute’s global infectious disease research training. He has also provided support to the Multilateral Initiative on Malaria (MIM), the Roll Back Malaria Partnership, and the Global Fund to Fight AIDS, TB and Malaria, and grant guidance to the Wellcome Trust and the Bill & Melinda Gates Foundation.

Dr Reeder began his career in medical microbiology laboratories in the United Kingdom and then moved to health training as a development volunteer in the Highlands of PNG, working with a world-renowned malaria research team at the Walter and Eliza Hall Institute. He made significant contributions to the study of the molecular basis of pathogenesis and the molecular epidemiology of the malaria parasite, and maintains active research interest in malaria and other agents of major global health significance, such as tuberculosis and HIV. He has published over 120 scientific papers that span from basic laboratory research to large community-based field studies.

A naturalized Australian, born and educated in England, he received his PhD in microbiology at the University of Manchester.

Raymond Omollo
Head Data Centre and Statistician, DNDi Africa, Kenya

Raymond Omollo joined DNDi as a Senior Data Manager for the Leishmaniasis East Africa Platform (LEAP) trial projects in February 2007. Currently Head of Data Centre and Statistician for DNDi Africa, Raymond is responsible for the design and development of databases and data capture tools for quality assurance and quality control, data preparation, cleaning and analysis.

For four years, he worked as a Data Manager for an HIV-1 research project at the University of Nairobi’s Department of Paediatrics and Child Health. He was a statistician consultant for the Urban Research and Development Centre for Africa (URADCA) on a global survey by the World Health Organization, on Maternal and Perinatal Health in Africa.

Raymond has an MSc in Applied Statistics (Biometry) and BSc in Statistics from the University of Nairobi. He also obtained a Certificate in Epidemiology and Biostatistics from the University of Washington, Seattle, WA in USA. His areas of research interest are in the design of clinical trials and survival analysis.
Patrice Kabangu Mundidimbi  
**Supervisor, East Kasai Provincial Coordination Human Trypanosomiasis National Control Programme, Ministry of Health, Democratic Republic of Congo**

Patrice Kabangu Mundidimbi is the current supervisor of the East Kasai Provincial Coordination Human Trypanosomiasis National Control Programme of the Ministry of Health in DRC. He holds a graduate degree in nursing.

Mr Mundidimbi has held several nursing positions: Head Nurse of health centres and nursing laboratories, Nurse Responsible and Chief of the Mobile Unit. Always keen on further developments, Mr Kabangu has attended several training courses: UNICEF immunization training and rehydration, PNLTHA and FOMETRO training and testing DIAGNOSIS THA, obstetric emergencies and hospital management training, training on the use of DFMO in South Sudan, Malteser International, WHO, training on Good Clinical Practice by DNDi and SWISS TPH.

His extensive knowledge in nursing has made him a valuable trainer and instructor. He has trained Bonga Yasa DRC nurses with SWISS TPH and DNDi on NECT field, was active as a nursing instructor at the King Baoudouin Hospital (DRC) on the use of NECT, and co-facilitator in nurse training on universal precautions for the DNDi/fexinidazole study.

Dr John Amuasi  
**Komfo Anokye Teaching Hospital – KATH, Ghana and University of Minnesota School of Public Health, USA**

John Amuasi holds a Bachelor’s Degree in human biology, was trained as a medical doctor at the School of Medical Sciences, Kwame Nkrumah University of Science and Technology in Kumasi, Ghana, and worked at the Komfo-Anokye Teaching Hospital in Kumasi. John graduated from the University of Minnesota School of Public Health, USA, with an MPH in Public Health Policy and Administration in 2006. Before returning to Minnesota, where he is currently a PhD candidate, he served as head of the R&D Unit at KATH in Kumasi, Ghana.

Dr Amuasi’s most recent work, funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria, involves leading an evaluation of a malaria treatment program to subsidize costly anti-malaria drugs with the aim of improving accessibility, availability and affordability in his home country Ghana. Dr. Amuasi has consulted with a number of international organizations including the Drugs for Neglected Diseases initiative (DNDi), Medicines for Malaria Venture (MMV), World Health Organization (WHO), Health Action International (HAI) Africa, Dalberg Global Development Partners and the International Centre for Trade and Sustainable Development (ICTSD) on a wide range of issues related to health policy and health systems, specifically related to malaria in Ghana and other parts of Africa. He has also led international malaria research projects in countries that include Burundi and Sierra Leone.

Dr Amuasi currently holds a fellowship at the Interdisciplinary Centre for the study of Global Change, at the University of Minnesota. This fellowship is tailored towards training future leaders in interdisciplinary approaches to understanding and tackling issues of global concern including global health.
Dr Sam Kinyanjui
Head of Training and Capacity Building, KEMRI-Wellcome Trust Programme, Kenya

Dr Kinyanjui began his scientific career in 1994 as a research assistant at the Wellcome Trust Research Laboratories in Nairobi before moving to Kilifi to do a PhD on immunity to malaria and subsequently spent time at the National Institute of Medical Research in London doing postdoctoral research on molecular biology of malaria parasite proteins.

During this period Dr Kinyanjui also developed a keen interest in capacity building for health research in Africa. In 2006 he worked at the African Union Headquarters promoting health research agenda within the Union. In September 2008, Dr Kinyanjui took over the position of head of training at KWTRP. His role is to provide both administrative and strategic guidance on all capacity building activities in the Programme. In the last five years, Dr Kinyanjui has overseen the training of over 25 PhD students and another 40 current students. He is now working with Kenyan universities to develop joint postdoctoral schemes that will provide both a stable career platform and strong research mentorship for the emerging local scientists.

Regionally, Dr Kinyanjui has been involved in advocacy for increased commitment for building research capacity in Africa by both African governments and funding agencies and he sits on the boards of a number of African capacity building initiatives including Consortium for Advanced Research Training (CARTA), Makerere-UVRI Initiative (MUI); the African Doctoral Dissertation Fellowships (ADDRF) and the Malawi Health Research Capacity Strengthening Initiative (HRCSI).

Kubata Bruno Kilunga
Coordinator of Research for Health & Pharmaceutical Innovation, AU-NEPAD, Kenya

Kubata Bruno Kilunga is a citizen of DRC. He did his undergraduate studies at Galatzi University in Romania and his graduate studies at Gifu University, Japan, where he completed his MSc and PhD in Microbiology and Biochemistry (Biotechnology). Thereafter, he spent five years of post-doctoral training in Molecular Parasitology at Osaka Bioscience Institute, Osaka, Japan, where he continued his career as a senior research scientist for ten years.

In 1994-95 he was appointed as a lecturer at the Department of Microbiology and Biochemistry of Orange Free State University in Bloemfontein, South Africa, before returning to Japan for his post-doctoral studies. Upon his return to Africa, he served for three years at the US Army Medical Research Unit Kenya/Walter Reed Army Institute of Research in Nairobi, where he was a senior fellow of the American National Research Council (NRC)/Ellison Medical Foundation USA (2003-2006). In 2006, he was appointed as the Director of the NEPAD regional centre, Biosciences Eastern and Central Africa Network (NEPAD/BecANet) and he established regional capacity building (MSc and PhD training) and scientific research programmes in East and Central Africa.

Bruno is also a Professor of Molecular Biology and Molecular Parasitology at the Department of Biology, School of Science of Kinshasa University in the Democratic Republic of the Congo. Now based in Nairobi, Kenya, he is the Coordinator of Research for Health & Pharmaceutical Innovation at the African Union-NEPAD Agency.
Dr Pascal Launois
UNICEF/UNDP/World Bank/WHO/Special Programme for Research and Training in Tropical Diseases (TDR), Switzerland

Pascal Launois completed his MD in Reims, France in 1988. After a specialization in Immunology and Microbiology, he joined the International Network overseas of the Institute Pasteur. He obtained his PhD in 1997 from the University Claude Bernard in Lyon, France. His postdoctoral work, conducted at the University of Lausanne, focused on the murine model of infection with Leishmania major. He was then nominated as Professor ad honoram at the University of Lausanne (Switzerland) and head of the WHO-Immunology Research and Training Centre (WHO-IRTC), located in the Biomedical Research Centre in Epalinges (Lausanne, Switzerland) between 2003 and 2008. The WHO-IRTC carried out a training programme in the fields of immunology, vaccinology and biotechnology applied to infectious diseases.

Since 2003, he is a scientist at the UNICEF/UNDP/World Bank/WHO/Special Programme for Research and Training in Tropical Diseases (TDR). In charge of the implementation of a new research capacity strengthening strategy within the context of shifting from individual research-based training to a broader and more comprehensive leadership capacity building at individual, institutional and national levels in developing countries, Dr Launois focuses on establishing a continuous monitoring of fellowship programmes for research capacity strengthening, operational regional training centres and training programmes to strengthen national health research systems in DECs. He has over 20 years of experience in capacity building and human development.

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Dr Wilfried Mutombo Kalonji
Medical doctor, Human African Trypanosomiasis National Control Programme (PNLTHA), Ministry of Health, DRC

Wilfried Mutombo received his medical degree at Mbuji-Mayi University in the Democratic Republic of the Congo. Since 2006, he works as a medical doctor at the PNLTHA, working on clinical trial projects for human African trypanosomiasis (HAT). He participated as local investigator for the NECT project – a treatment which was included in the WHO Essential Medicines List. Dr Mutombo also participated in the NECT Field project, which consolidated the results of NECT in real-life conditions.

Dr Mutombo participated in the TDR Career Development Fellowship Programme, benefitting from a year-long internship in clinical development, which he carried out both at Sanofi and at DNDi. He participated in several clinical trial site evaluation and selection visits in collaboration with DNDi, Swiss TPH, and the HAT Platform in DRC, CAR, and South Sudan. He has participated in many training courses and international conferences on HAT and clinical trials.

Wilfried is currently the Coordinating Investigator for the DNDi fexinidazole trial for HAT, which is a clinical Phase II/III trial for the treatment of late stage T.b gambiense HAT. He is also a member of the HAT Platform, which aims at reinforcing clinical research capacities in HAT endemic countries.