



# Stakeholder Meeting on Co-infections and Co-morbidities

13 September 2017

The Hague, The Netherlands





EDCTP

European & Developing Countries  
Clinical Trials Partnership

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Mercure Hotel Den Haag Centraal  
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08:45-09:30	Registration & Coffee/Tea
09:30-09:50	<b>Welcome and introduction to EDCTP</b> <b>Dr Michael Makanga</b> and <b>Dr Ole Olesen</b> (EDCTP, The Netherlands)
09:50-09:55	<b>European Commission investment in the area of co-infections and co-morbidities</b> <b>Dr Alessandra Martini</b> (European Commission)
09:55-10:05	<b>Introduction of meeting chairs, meeting objectives and expected outcomes</b> <b>Dr Maryline Bonnet</b> (Institute of Research for Development, France) <b>Professor John Gyapong</b> (University of Health and Allied Science, Ghana)
10:05-10:45	Keynote address <b>Professor Shabir Madhi</b> (National Institute for Communicable Diseases and University of Witwatersrand, South Africa)
10:45-11:00	Discussion
11:00-11:15	Coffee/Tea
	<b>Challenges and perspectives in the clinical management of co-infections</b>
11:15-11:30	<b>Dr Jorge Alvar</b> (Drugs for Neglected Diseases Initiative (DNDi), Switzerland)
11:30-11:45	<b>Dr Vanessa Christinet</b> (Centre International de Recherches, D'Enseignements et de Soins (CIRES), Cameroon)
11:45-12:15	Discussion <ul style="list-style-type: none"><li>• Dr Victor Mwapasa (University of Malawi, Malawi)</li><li>• Dr Dawit Wolday (Path Medical Services &amp; Mekelle University College of Health Sciences, Ethiopia)</li></ul>





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	<b>Co-morbidities associated with PRDs and NCDs and their treatments</b>
12:15-12:30	<b>Dr Rashida Ferrand</b> (London School of Hygiene & Tropical Medicine, UK; Biomedical Research & Training Institute, Zimbabwe)
12:30-12:45	<b>Mr Ronan L'Heveder</b> (Santé Diabète, France)
12:45-13:15	Discussion <ul style="list-style-type: none"><li>• Mr Simon Chell (GlaxoSmithKline, United Kingdom)</li><li>• Professor Andre Pascal Kengne (Non-communicable Diseases Research Unit, MRC, South Africa)</li></ul>
13:15-14:00	Lunch
	<b>Tools for diagnosis of co-infections and co-morbidities</b>
14:00-14:15	<b>Mr Philippe Jacon</b> (Cepheid, France)
14:15-14:45	Discussion <ul style="list-style-type: none"><li>• Dr Sabine Dittrich (FIND, Switzerland)</li><li>• Dr Sébastien Quesney (Fondation Mérieux, France)</li></ul>
	<b>Development and testing of products used for treatment and prevention</b>
14:45-15:00	<b>Professor Pauline Byakika-Kibwika</b> (Infectious Disease Institute, Makerere University, Uganda)
15:00-15:15	<b>Dr Gerald Voss</b> (Tuberculosis Vaccine Initiative, The Netherlands; Global HIV Vaccine Enterprise, USA)
15:15-15:45	Discussion <ul style="list-style-type: none"><li>• Professor Christine Stabell Benn (Staten Serums Institut, Denmark; Bandim Health Project, Guinea-Bissau)</li><li>• Professor Gary Maartens (University of Cape Town, South Africa)</li></ul>
15:45-16:00	Coffee/Tea
16:00-17:00	<b>Final summing up and recommendations</b>
17:00-17:15	<b>Closing remarks</b>



## Chair and speaker biographies

### Chairpersons



**Dr Maryline Bonnet** is Research Director at the Institute of Research for Development (IRD) in Montpellier, France. Following her medical degree (1992) and a Master's degree in Physiology and Parasitology (1993) at the University of Grenoble, she worked for Médecins Sans Frontières (MSF) from 1994-2003. During this time, she was based in various countries, including Benin, Vietnam and the former Russian states, where she managed MSF tuberculosis programmes. From 2003 she worked at Epicentre, Geneva as an epidemiologist and completed a doctorate in public health at the Pierre and Marie Curie University, Paris in 2009. She took up her post as Research Director at IRD in December 2013. Dr Bonnet is a clinical epidemiologist with considerable experience in the clinical management of tuberculosis and the management and evaluation of tuberculosis control programmes. Moreover, she has served on several review and advisory boards of the ANRS and WHO. She is a member of the EDCTP Scientific Advisory Committee.



**Professor John Gyapong** is the Vice Chancellor of the University of Health and Allied Science in Ghana. Prior to this, he was the Pro-Vice Chancellor for Research Innovation and Development and Professor of Epidemiology at the University of Ghana, and an Adjunct Professor of International Health at Georgetown University in Washington, United States. He is a public health physician and an epidemiologist. His main area of research is infectious disease epidemiology, especially lymphatic filariasis, other neglected tropical diseases (NTDs) and malaria.

Professor Gyapong received his basic medical education in Ghana and later pursued a Master of Science in Public Health in Developing Countries, and a PhD in Epidemiology at the London School of Hygiene and Tropical Medicine, University of London, United

Kingdom. He practised as a doctor in rural Ghana for nine years. He was the Director of Research and Development of the Ghana Health Services for 12 years where was responsible for health systems and implementation research. He was the Representative of the African Ministers of Health/WHO AFRO in the EDCTP General Assembly from 2010 to 2014 and the Ghana Representative in the EDCTP2 General Assembly. Professor Gyapong has served as chair/member of many international board and committees, including the Scientific and Technical Advisory Committee (STAC) for NTDs of WHO-TDR. He is a member and Vice-Chair of the EDCTP Scientific Advisory Committee. He has over 120 publications in peer-reviewed journals and published a book on NTDs in Sub-Saharan Africa.

## Keynote address speaker



**Professor Shabir Madhi** is Executive Director of the National Institute for Communicable Diseases, Professor of Vaccinology and Director of the MRC Respiratory and Meningeal Pathogens Research Unit at University of the Witwatersrand, South Africa. He has been involved in vaccine-related epidemiological and clinical development studies for the past 20 years.

His research has focussed on the leading causes of pneumonia, diarrhoea and neonatal sepsis, which together are responsible for one-third of all under-five childhood deaths globally. Most recently, his research focus has expanded to reducing morbidity and mortality due to infectious causes during early infancy, with a specific focus on maternal immunization as an intervention. He has published over 330 peer reviewed articles, many in leading international journals. He is also the South African Principal Investigator on the Child Health and Mortality Prevention Surveillance (CHAMPS) program, which aims at elucidating the specific causes of stillbirth, neonatal and under-5 mortality, on which he will present provisional data.

He was recipient of the European & Developing Countries Clinical Trial Partnership Scientific Leadership Award in 2016.

## Session speakers



**Dr Jorge Alvar** (DNDi, Switzerland), originally from Granada, Spain, graduated in Medicine and Surgery from the Complutense University of Madrid in 1979, and diploma on Tropical Medicine & Parasitology in Hamburg, Germany. Following this, he obtained his PhD in Medicine before completing a postdoctorate at Cambridge University.

Dr Alvar is the head of the program of Leishmaniasis at Drugs for Neglected Disease initiative (DNDi) from January 2013, and previously (2004-2012) Medical Officer in charge of the Leishmaniasis Control Programme in the Department of Neglected Tropical Diseases at the World Health Organization (WHO), having launched an ambitious strategic plan and specific control programmes in different regions and countries, especially in East Africa. Prior to this he was the director of the National Centre of Tropical Medicine at the Institute of Health Carlos III, Madrid, Spain.

Dr Alvar has considerable expertise in, and has received awards for, his research in leishmaniasis epidemiology, chemotherapy and diagnosis, canine infection, and AIDS co-infection. He has a wide publication record spanning over 30 years and is also member of the editorial board for different journals, and fellow of the Royal Academy of Medicine, Spain.



**Dr Vanessa Christinet** (CIRES, Cameroon) is currently in charge of a sexual health clinic in Switzerland and a research physician working on a HVTN/HPTN HIV prevention study at the University Hospital of Lausanne. A medical doctor by training, she has clinical experience in general medicine, sexual health, HIV and tropical medicine, which she acquired primarily during her time in northern Cameroon and the University Hospital of Geneva.

Dr Christinet has studied the impact of HIV and immunosuppression on a cohort of

Buruli Ulcer and HIV co-infected patients, and following her interest of HIV-NTD co-infection, she worked on a complete review of all Female Genital Schistosomiasis (FGS) cases published during the last century. This review included the publications studying the link between FGS and HIV.

In the frame of the CIRES association, CIRES in Cameroon was established, which includes a gynecological consultation in a public district hospital, aiming at improving women health with a focus on cervical cancer, sexually transmitted infection and FGS screening.



**Dr Rashida Ferrand** is a clinical epidemiologist and a clinical specialist in HIV Medicine. She is a professor of International Health at the London School of Hygiene and Tropical Medicine and a Wellcome Trust Senior Research Fellow. Over the past 15 years she has been based in Southern Africa leading studies focused on HIV infection among adolescents and young people. Her work led to the recognition globally of the large numbers of perinatally HIV infected adolescent long-term survivors presenting to

health services across southern Africa. Prior to this, it had been assumed that survival beyond early childhood with untreated HIV was exceptional. Her research has highlighted the clinical and psychosocial challenges faced by adolescents with HIV and has been highly influential in drawing attention to the needs of adolescents living with HIV.

Her current work focuses on evaluation of strategies to improve outcomes across the HIV care cascade. One of the key areas of her work is investigation of the impact of longstanding HIV infection among perinatally-infected adolescents, particularly the chronic non-infectious complications of HIV. She is conducting cohort studies investigating the clinical epidemiology and pathogenesis of heart, lung and musculoskeletal disease in HIV-infected older children and adolescents. She has identified a novel form of HIV-associated chronic lung disease that affects up to 20% of children and adolescents in Africa, and is currently conducting an RCT of azithromycin to treat this condition.





**Ronan L'heveder** holds a Master Degree in International Management and a Master Degree in International Politics. He joined the International Diabetes Federation (IDF) in 2005 to organise the World Diabetes Congress in Cape Town and from 2007 to 2015 he built up and managed IDF BRIDGES, a USD 10.000.000 programme dedicated to support translational research in diabetes around the world which funded 41 projects in 36 countries.

Ronan is now working as Senior Advocacy and Communication consultant for the European Region of IDF and he is the Head of external partnerships for the French NGO Santé Diabète.

Santé Diabète is the only French organisation specialised in the prevention and the fight against diabetes in Africa and is member of the Global Coordination Mechanisms on Non Communicable Diseases of WHO. Among all its activities, Santé Diabète is running a project dedicated to the training of healthcare professionals on the management of co-morbidities diabetes/TB and diabetes/HIV in Burkina Faso and in Mali.

[www.santediabete.org/en](http://www.santediabete.org/en)



**Philippe Jacon** joined Cepheid in January 2013. In his role of President, Emerging Markets, he leads the company development in developing and emerging countries, including their HBDC (High Burden and Developing Countries) program, which aims at giving access to a number of Cepheid's state-of-the-art molecular diagnostic tests (Xpert® MTB/Rif, Xpert® HIV-1 VL, Xpert® HIV Qual, Xpert® HCV, Xpert® HPV, etc.) to the populations in need, at concessional prices. All these tests are run on the polyvalent GeneXpert system, that will soon be extended with the new generation portable GeneXpert Omni, allowing further decentralization of molecular testing.

Prior to Cepheid, Philippe Jacon held the position of CEO of the Foundation for Innovative New Diagnostics (FIND). Philippe Jacon joined FIND from EDMA (European

Diagnostic Manufacturers Association) where he acted as the Director General *ad interim*. Philippe is still on the Board and the Operating Management Committee of Medtech Europe.

Prior to EDMA, he spent most of his career with BD (Becton Dickinson and Co) in various positions and locations. Most notably, he was Worldwide President of BD Diagnostics-Diagnostic Systems and Worldwide President of BD Diagnostics - Microbiology Systems, both positions based in Baltimore, MD.

Philippe Jacon has a Microbiologist Engineer degree from the Université de Bretagne Occidentale in France.



**Professor Pauline Byakika-Kibwika** is a physician and Professor of Internal Medicine and Epidemiology at the Department of Internal Medicine, School of Medicine of Makerere University College of Health Sciences. She is a result-oriented, well-rounded leader with close to twenty years of experience in clinical care, research, teaching, capacity building, project development and management. Her overarching

aspiration is to reduce morbidity and mortality from communicable and non-communicable diseases in Africa and beyond through wellness initiatives, clinical care, research and training. She received her doctorate in clinical pharmacology from Trinity College, Dublin and is an accomplished writer with over 40 published articles in peer reviewed journals. Pauline has worked as consultant on projects for the Uganda Ministry of Health (MoH) and partners for Malaria and HIV Control, the East African Community, Tullow Oil Uganda Operations and other community initiatives. Pauline is a Commissioner on the East African Health Research Commission, where she contributes to decision making on matters of health and health related research and findings necessary for knowledge generation, translation, technological development, policy formulations, practices and related matters.



**Dr Gerald Voss** is the interim Director of the Global HIV Vaccine Enterprise, an organization dedicated to accelerating the development of HIV vaccines. He also serves as a Scientific Advisor to the TuBerculosis Vaccine Initiative and is the Executive Director of SciPeo, a consultancy in vaccines, global health and coaching.

He was previously with GSK Vaccines, leading the vaccine R&D projects for diseases of the developing world, and more recently serving as Director of external R&D. During his tenure, Gerald established and managed several product development partnerships with non-profit organizations in HIV, TB, malaria and in global health R&D.

Gerald holds a Ph.D. in Biology from Göttingen University and received his post-doctoral training at Harvard Medical School.

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## **EDCTP Stakeholder Meeting on Co-infections and Co-morbidities**

### **BACKGROUND**

#### **Stakeholder meeting on co-infections and co-morbidities**

Co-infections with several pathogens are frequent in sub-Saharan Africa and represent an important public health problem in many areas due to accelerated and/or complicated disease progression, resulting in increased mortality and morbidity. These co-infections can result in unique challenges in diagnosis, treatment and prevention of disease, including increased toxicities and/or decreased efficacy of interventions. The rise in incidence of non-communicable diseases (NCDs) in sub-Saharan Africa and the necessity for long-term management of some poverty-related diseases (PRDs) and NCDs, often concurrently, adds to these complexities. There is therefore an urgent need to generate research evidence in this area, in order to inform the development of new/improved products and optimisation of existing regimens for the effective diagnosis, treatment, management and prevention of co-infections and co-morbidities. Given EDCTP's disease remit and the overlapping distribution of these diseases in countries where EDCTP funds research, EDCTP is well positioned to impact the fields of co-infection and co-morbidities in sub-Saharan Africa.

The purpose of a thematic stakeholder meeting is to contribute to EDCTP's strategic research agenda, funding approach and strategic alignment with other partners involved in clinical development of interventions against PRDs.

The stakeholder meeting on co-infections and co-morbidities of 13 September 2017 has the following objectives:

- To review the research landscape, including the key clinical research questions and barriers to progress in sub-Saharan Africa
- To discuss the available interventions and products in development with the major partners working in this field
- To reach out to stakeholders involved in this field to collaborate with in the execution of future EDCTP activities
- To identify priority areas for EDCTP in terms of disease, research and intervention priorities for both the short- and medium-term.

In discussing the possibilities for the development of EDCTP's strategy and priorities, the following aspects should be considered:

1. **Review of the product development landscape** Optimising the impact of interventions across the range of treatment, prevention, diagnostics and implementation research, while ensuring new products take into account potential consequences of co-infections and co-morbidities on their effectiveness in target populations.
2. **Disease burden and need for appropriate interventions** Prioritising the development and optimisation of appropriate products for these diseases, taking into consideration the overlapping burden/prevalence of PRDs and NCDs in sub-Saharan Africa.
3. **Emerging opportunities for EDCTP to add value**  
Seizing opportunities arising from product development including post-registration programmes, including effectiveness studies and pharmacovigilance.
4. **Balance between immediate, medium and long-term priorities and clinical trial phases**  
Balancing investment according to long-, medium- and short-term priorities and/or clinical trial phase is important to ensure a robust development pipeline and a steady flow of products.

Participation at the meeting is by invitation only. Meeting delegates will include representatives from academic and research institutions, funding agencies, product development partnerships (PDPs), industry and others. The outputs from the meeting will be made publicly available through a report with recommendations on focus areas for EDCTP activities, including calls for proposals.

EDCTP regularly organises thematic stakeholder meetings. In previous years stakeholder meetings were held on [malaria](#), [HIV](#), [tuberculosis and other mycobacterial infections](#), [neglected infectious diseases](#), [lower respiratory tract infections](#), [diarrhoeal diseases](#), [ethics & regulatory affairs](#), and [capacity development](#).

## **About EDCTP**

EDCTP is a public-public partnership between countries in Europe and sub-Saharan Africa and the European Union, dedicated to combating poverty-related diseases.

The mission of EDCTP is to reduce poverty in sub-Saharan Africa through improved health by funding collaborative research to accelerate the clinical development of new or improved medical interventions against poverty-related and neglected infectious diseases.

The disease scope of the second EDCTP programme (EDCTP2) includes HIV, malaria, tuberculosis; the following neglected infectious diseases (NIDs): dengue, rabies, human African trypanosomiasis (sleeping sickness), leishmaniases, cysticercosis/ taeniasis, dracunculiasis (guinea-worm disease), echinococcosis, foodborne trematodiasis, lymphatic filariasis, onchocerciasis (river blindness), schistosomiasis, soil-transmitted helminthiasis, Buruli ulcer, leprosy (Hansen disease), trachoma, yaws, mycetoma; as well as diarrhoeal infections, lower respiratory infections, and emerging infectious diseases of particular relevance for Africa, such as Ebola and yellow fever.

EDCTP2 runs from 2014 to 2024. The partnership aims for a €2 billion programme budget, having already secured €1.36 billion in pledges. This includes a commitment of up to €683 million from the European Union to match the contributions from the European countries that are members of the EDCTP Association. Additional funding is sought from public and private third parties. EDCTP actively seeks collaboration with industry, like-minded product development partners and development agencies to achieve its objectives.

EDCTP2 is implemented by the EDCTP Association as part of the European Union Framework Programme for Research and Innovation, [Horizon 2020](#). The programme supports all phases of clinical trials (with a focus on phase II and III), advanced testing and field validation of new diagnostic tools as well as product-focused post-registration operational and implementation research studies. These activities are integrated with or supported by capacity development for clinical trials and closely related research in sub-Saharan Africa.

In order to achieve its mission, the programme has the following five specific objectives:

1. To accelerate the development of new or improved medical interventions for poverty-related and neglected infectious diseases
2. To strengthen cooperation between European and sub-Saharan African countries, in particular to build the latter's capacity for conducting high quality innovative clinical research consistent with fundamental ethical principles and international and national regulatory standards
3. To better coordinate, align and, where appropriate, integrate relevant national programmes to increase the impact and cost-effectiveness of European investments in health research on poverty-related and neglected infectious diseases
4. To work with a broad range of public and private partners to maximise the impact of research, to attract additional investment, and to fully exploit the opportunities for high-quality clinical research offered by EDCTP's integrated approach
5. To increase impact through collaborations with other EU initiatives, particularly those related to development assistance.

For more information, see EDCTP's [Strategic Business Plan](#).

### **Co-infections and co-morbidities in low and middle income countries**

According to WHO statistics (2015), lower respiratory infections are globally responsible for approximately 2.7 million deaths; tuberculosis (TB) for 1.8 million; HIV for 1.1 million; diarrhoeal diseases for 0.5 million (in children <5 years of age) and malaria for 438,000. Most of these deaths are in low-income countries, particularly in sub-Saharan Africa where the burden of infectious diseases is highest and where a high percentage of people are affected by multiple pathogens. Co-infections may weaken immune systems and complicate treatment, whilst also presenting challenges at initial diagnosis. Furthermore, NCDs account for 28 million deaths annually in low- and middle-income countries. The rise of NCDs, combined with the persistent problem of infectious disease, has created a dual burden of disease in sub-Saharan Africa that presents unique challenges and opportunities for impact.

There are limited data available on co-infections, and mostly for TB, malaria and/or HIV. Additional research is urgently needed, especially in relation to co-infections of NIDs with HIV, TB, malaria, diarrhoeal and/or respiratory infections. It is also necessary to explore ways in which to harness existing investments in communicable diseases research to better address the multitude of NCDs that now confront low- and middle-income countries.

### **R&D investment**

Several member countries of the EDCTP Association support R&D and capacity development in the area of co-infections and co-morbidities through their Participating State Initiated Activities (PSIAs). Their portfolio includes projects in the areas of coinfections between TB-HIV, HIV-NIDs, HIV-HPV, HIV-Hepatitis B, HIV-cryptococcal meningitis, malaria-helminth and other malaria-NID coinfections. Such projects are being funded through the UK Medical Research Council (MRC-UK), the French Agency for Research on AIDS and Viral Hepatitis (ANRS), the Italian Ministry of Health, the Swedish International Development Cooperation Agency (Sida) and Leiden University Medical Center (LUMC) in the Netherlands. In 2017 MRC-UK, the South African MRC, and GlaxoSmithKline (GSK) joined forces under the Newton Fund to support research projects seeking to tackle NCDs in Africa. EDCTP is launching a joint call in 2017 on Senior Fellowships for co-morbidities between PRDs and NCDs.

The US National Institutes of Health (NIH) supports a comprehensive portfolio of biomedical, behavioural, and social science research on HIV and its associated co-infections, co-morbidities, and other complications. High priority topics of research include: addressing the impact of HIV-associated co-morbidities, including tuberculosis; malignancies; cardiovascular, neurological, and metabolic complications; and premature aging associated with long-term HIV disease and antiretroviral therapy.

Unitaid recently announced that its board had endorsed the expansion of Unitaid's portfolio to include co-infections and co-morbidities, with short-term new investments focusing on advanced HIV disease, cervical cancer (HPV) and Hepatitis. More details on funding opportunities are expected to be announced later in 2017.

### **Recommended background reading from speakers**

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Useful websites on vaccine development:

<http://www.who.int/hiv/topics/tb/en/>

<http://hivinsite.ucsf.edu/InSite?page=kb-05-01-06>

<https://www.usaid.gov/what-we-do/global-health/hiv-and-aids/technical-areas/stopping-syndemic-hiv-and-tb-co-infection>

[http://www.who.int/tb/challenges/hiv/convergence\\_of\\_basic\\_and\\_implementation\\_tb\\_and\\_hiv\\_research - are we missing opportunities.pdf?ua=1](http://www.who.int/tb/challenges/hiv/convergence_of_basic_and_implementation_tb_and_hiv_research_-_are_we_missing_opportunities.pdf?ua=1)

[http://www.avac.org/sites/default/files/resource-files/HIV VAX research update sep 2016 web.pdf](http://www.avac.org/sites/default/files/resource-files/HIV_VAX_research_update_sep_2016_web.pdf)

<http://www.aeras.org/pages/global-portfolio>

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