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**EDCTP**

The power of sharing science

**EDCTP–Wellcome Trust symposium on  
Challenges and opportunities of conducting clinical trials in  
pregnant women and future infants in resource-limited settings**  
Session 130, 8 November 2017, 08:00-09:45, Room 341/342 (Level 300)



Supported by the EU



Programme book

## About EDCTP

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EDCTP's mission is to contribute to the reduction of the individual, social and economic burden of poverty-related infectious diseases in sub-Saharan Africa. EDCTP is a partnership between 14 European and 15 African countries. The EDCTP programme is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.

We fund collaborative clinical research to accelerate the development of accessible, suitable and affordable medical interventions to identify, prevent or treat these diseases, including neglected infectious diseases. Our approach integrates development of African clinical research capacity.

## About Wellcome Trust

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Wellcome exists to improve health for everyone by helping great ideas to thrive. We're a global charitable foundation, both politically and financially independent. We support scientists and researchers take on big problems, fuel imaginations, and spark debate.

We remain true to the vision and values of our founder, Sir Henry Wellcome, a medical entrepreneur, collector and philanthropist. Our funding supports over 14,000 people in more than 70 countries. In the next five years, we aim to spend up to £5 billion helping thousands of curious, passionate people all over the world explore ideas in science, population health, medical innovation, the humanities and social sciences and public engagement.

# EDCTP–Wellcome Trust symposium

## Challenges and opportunities of conducting clinical trials in pregnant women and future infants in resource-limited settings

8 November 2017, 08:00-09:45, Convention Center - Room 341/342 (Level 300)

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Conducting clinical trials in low- and middle-income countries (LMICs) is essential to deliver new and improved medical interventions that are safe, effective, appropriate and accessible for the affected population. Pregnant women and their unborn children in LMICs are particularly vulnerable to a range of infections that can lead to significant mortality and morbidity to mother and baby. There is a need to develop medical products to prevent and treat infection in pregnancy and that can be implemented effectively in LMICs.

The systematic exclusion, however, of pregnant women from clinical trials conducted by product developers, as well as the challenges (scientific, ethical, social, cultural) of conducting research in pregnant women limit the development, testing and approval of safe, affordable and effective products for pregnant women. Furthermore, such trials can be costly and of long duration where extended infant follow-up post-trial is included. There is a need to maximize the impact of research through collaboration and data sharing from individual trials conducted in pregnant women.

This symposium focuses on the practical challenges faced and lessons learned by researchers conducting clinical trials in pregnant women in LMICs. The presentations will focus on malaria, HIV and Zika infection in pregnant women and will share practical experiences from sub-Saharan Africa (Malawi and Mozambique), Asia (Thailand) and South America (Brazil).

# Learning Objectives

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1. Participants will gain an understanding of the major challenges faced by researchers conducting clinical trials in pregnant women in different LMICs in three continents (Africa, Asia, and South America).
2. Participants will be able to understand some of the social, ethical and cultural challenges in the conduct of clinical trials in pregnant women and how these can be taken into consideration through community engagement.
3. Participants will be able to discuss the problems and potential solutions around public health interventions delivery and clinical trials at community levels in resource-limited settings.

# Agenda

After short introductions of EDCTP and Wellcome Trust, four presentations of 20 minutes each will be given. The symposium will end with a discussion session to summarise recommendations on best practice for conducting clinical trials in pregnant women, including consideration of good participatory practices, ethical and social aspects, as well as how such research can best be conducted in a collaborative network (North and South).

## Chairs

- **Pauline Beattie**, European & Developing Countries Clinical Trials Partnership (EDCTP), The Hague, The Netherlands
- **Mike Turner**, Wellcome Trust, London, United Kingdom

08.00 – 08.10	<b>Brief Introduction to the session, EDCTP and Wellcome Trust</b>
08.10 – 08.30	<b>Social, ethical and legal implications of research in pregnant women during the Zika outbreak</b> Ruth Faden, Berman Institute of Biomedical Ethics, Johns Hopkins University, USA
08.30 – 08.50	<b>Community engagement in the context of clinical trials on reproductive health</b> Khátia Munguambe, Universidade Eduardo Mondlane & CISM, Mozambique
08.50 – 09.10	<b>Practical challenges with implementing studies involving pregnant women in an African setting with high HIV and malaria prevalence</b> Victor Mwapasa, College of Medicine-University of Malawi, Malawi
09.10 – 09.30	<b>Effects of malaria and other tropical infections on maternal and child health</b> Rose McGready, University of Oxford and Shoklo Malaria Research Unit, Thailand
09.30 – 09.45	<b>Discussion</b> led by the Chairs

# Presentations

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1. **Ruth Faden**, *Berman Institute of Biomedical Ethics, Johns Hopkins University, USA*  
**“Social, ethical and legal implications of research in pregnant women during the Zika outbreak”**
  - Pregnant women and biomedical research- the evidence gap
  - ZIKV- protecting the rights and interests of pregnant women in vaccine development
  - The Ethics Working Group on ZIKV Research and Pregnancy - Methods
  - Ethics guidance on priorities, inclusion and evidence generation
2. **Khátia Munguambe**, *University Eduardo Mondlane & Centre for Health Research of Mozambique (CISM), Mozambique*  
**“Community engagement in the context of clinical trials on reproductive health”**
  - The context of clinical trials and pilot interventions on reproductive health in LMICs
  - Legal framework, inclusion of pregnant women, infants and children in trials, challenges of informed consent, complex decision-making processes
  - Role of community before trial initiation and after trial completion
3. **Victor Mwapasa**, *College of Medicine-University of Malawi, Malawi*  
**“Practical challenges with implementing studies involving pregnant women in an African setting with high HIV and malaria prevalence”**
  - The context of clinical trials in HIV-positive pregnant women
  - The dimension of the malaria co-infection problem in HIV- positive pregnant women
  - Study design and targeted population, inclusion/exclusion criteria
  - Legal framework, inclusion of HIV-positive pregnant women in trials, handling confidentiality and stigma issues around HIV status
4. **Rose McGready**, *University of Oxford and Shoklo Malaria Research Unit, Thailand*  
**“Effects of malaria and other tropical infections on maternal and child health”**
  - The context of common tropical infections in pregnant women
  - Study design and targeted population, inclusion/exclusion criteria
  - Legal framework, inclusion of pregnant women and infants in trials
  - The dimension of the co-infection problem, e.g. malaria-coinfection



**Ruth Faden, PhD, MPH**

Dr Ruth Faden's research focuses on global justice theory and on ethical challenges food and agriculture, learning health care systems, health systems design and priority setting, and access to the benefits of global investments in biomedical research. She is also a co-founder of the Second Wave Initiative which focuses on the responsible inclusion of pregnant women in biomedical research. Dr Faden is the founder of the Johns Hopkins Berman Institute of Bioethics.



**Khátia Munguambe, PhD**

Dr Khatia Munguambe is a researcher in Social Behavioural Sciences, with a focus on the interface between public health interventions and the potential beneficiaries at community level. Her research interests are centred on assessing the feasibility of interventions, and implementing community engagement strategies to maximize intervention uptake. Her current research cuts across a broad range of public health problems, including under-5 mortality, maternal and child health, HIV, TB, and Malaria in LMICs.



### **Victor Mwapasa, MD, MPH, PhD**

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Professor Mwapasa is a public health expert, research scientist and professor in Epidemiology and Public Health at the University of Malawi, College of Medicine. His research interests cover the efficacy and safety of antimalarial and antiretroviral drugs in pregnant women, children and other vulnerable populations. He also conducts community-based studies to identify strategies for increasing the utilization of health services, in general, and access and adherence to antimalarial and antiretroviral therapy. He recently completed a cluster-randomized trial assessing the impact of integrated mother-infant pair clinics and SMS-message reminders in improving retention of HIV-positive mothers and their children enrolled in prevention of HIV mother-to-child transmission programmes.



### **Rose McGready, MD, PhD**

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Professor McGready has conducted many prospective longitudinal cohort studies, commencing in early pregnancy, through to childbirth and follow of the child to the end of the first year of life. Her work with marginalised populations in rural areas on the Myanmar-Thailand border has increased our understanding of malaria and antimalarials particularly in relation to the drug class of artemisinins. She has studied other tropical infections in pregnancy common in South-East Asia to determine their effect on pregnancy outcome, including dengue, scrub and murine typhus, and leptospirosis and soil transmitted helminths. Common medical problems such as anaemia, nutrition in the first 1,000 days of life, the quality and practice of care by skilled birth attendants, have been part of her life's work.





**Mike Turner, Wellcome Trust**

Professor Turner is Head of Infection and Immunobiology at the Wellcome Trust. His research interests focussed on the cell biology, immunology, genetics, genomics and population biology of trypanosome parasites that cause African sleeping sickness in humans and Nagana in livestock. He has also worked on the genomics of malaria parasites and the immunoepidemiology of schistosomes.



**Pauline Beattie, EDCTP**

Dr Beattie is the Operations Manager at EDCTP. She joined the EDCTP management team in August 2011, where she heads the Calls & Grants department. She is responsible for the management and oversight of the grant application process, from the development of calls for proposals, management of peer review, through to post-award evaluation. Dr Beattie has a Masters and DPhil in Parasitology, with a focus on malaria research.



**Jean Marie Vianney Habarugira, EDCTP**

Mr Habarugira is a Project Officer at EDCTP since 2010. He has a Master of Science in Pharmacy (Russia, 2006) and a Masters in Pharmacovigilance and Pharmacoepidemiology (Eu2P, 2014), with a focus on safety reporting from clinical trial conducted in resource-limited settings. Prior to joining the EDCTP Calls and Grants team, he carried out drug development-related research projects at the KNCV Tuberculosis Foundation in The Netherlands, the Dutch Medicines Evaluation Board and EDCTP.

## Colophon

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