WEBINAR: Controlled Human Infection Challenge Studies: Lessons from Malaria towards COVID-19

Tuesday, 1 SEPTEMBER 2020
13:00 Central European summer time

Since severe acute respiratory infections caused by the SARS-CoV-2 virus have first been reported in December 2019, COVID-19, the disease caused by SARS-CoV-2, has developed in a pandemic posing a major threat to global public health and to societies worldwide. According to WHO, major challenges for the current public health response include a lack of safe, effective vaccines and treatments, and gaps in scientific knowledge regarding pathogenesis, immunity and transmission.

As of mid-July 2020, 23 candidate vaccines are in early clinical development, and 140 candidates in preclinical evaluation. Controlled Human Infection Challenge Studies which involve the deliberate infection of healthy volunteers are well established during the clinical development of vaccines for influenza, typhoid, cholera or malaria. Their aim is to accelerate clinical vaccine development by providing (preliminary) estimates of efficacy and safety and to select the most suitable candidates for further development. In addition, such studies have been used to better understand the immune response processes after infection.

These studies must be based on thorough ethical and scientific principles, and must involve careful community engagement. This webinar will describe these principles, outline the risk mitigation steps taken in previous malaria human challenge studies, explore how this might be applied in the context of COVID-19 vaccine development, and address ethical and practical concerns.

Faculty:

Marco Cavaleri, Head of Office, Anti-infectives and Vaccines, European Medicines Agency (EMA), Amsterdam, The Netherlands

Euzebiusz Jamrozik, Monash Bioethics Centre, Monash University, Melbourne, Australia

Melissa Kapulu, Kenya Medical Research Institute, Nairobi, Kenya

Colin Pillai, CP+ Associates and Pharmacometrics Africa, Basel (Switzerland) and Cape Town (South Africa)
Andrew J Pollard, Professor of Paediatric Infection and Immunity, Director of Graduate Studies, Department of Paediatrics, St Cross College University of Oxford and Children’s Hospital Oxford (United Kingdom)

Bernd Rosenkranz, Fundisa African Academy of Medicines Development, Schwielowsee (Germany) and Cape Town (South Africa)

Getnet Yimer, Regional Director for Global One Health Initiative of the Ohio States University in East Africa, Addis Ababa, Ethiopia

Moderated by:
Craig Rayner, President – Integrated Drug Development, Certara

### PROGRAMME

<table>
<thead>
<tr>
<th>Welcome</th>
<th>Bernd Rosenkranz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>Craig Rayner (Moderator)</td>
</tr>
<tr>
<td>Principles of human challenge studies</td>
<td>Getnet Yimer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Leveraging human infection studies in endemic populations</th>
<th>Melissa Kapulu</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory aspects of human infection challenge studies</td>
<td>Marco Cavaleri</td>
</tr>
<tr>
<td>Practical experience with COVID-19 vaccine development</td>
<td>Andrew Pollard</td>
</tr>
<tr>
<td>Practical and ethical considerations for COVID-19 vaccine development</td>
<td>Euzebiusz Jamrozik</td>
</tr>
<tr>
<td>Facilitated Discussion</td>
<td>Craig Rayner</td>
</tr>
<tr>
<td>Concluding remarks</td>
<td>Colin Pillai</td>
</tr>
</tbody>
</table>
Marco Cavalieri is Head of Office, Biological Health Threats and vaccines strategy. He is the Chair of EMA COVID Task force and responsible for EMA activities for emergent pathogens, vaccines and AMR. Marco Cavaleri is a Pharmacologist who spent several years in industry in R&D mainly in the area of anti-infectives covering different positions in preclinical and clinical development.

In 2005 he joined the EMEA as Scientific Administrator in the Scientific Advice and Orphan Drugs Sector, specifically being in charge of anti-infectives and vaccines scientific advice procedures. In 2009 he was appointed as Head of Section for Anti-infectives and vaccines in the Safety & Efficacy Sector, Human Medicines Development and Evaluation Unit.

Dr Euzebiusz Jamrozik is a practising physician and bioethicist at the Monash Bioethics Centre. His academic work on infectious disease ethics is focused on vaccines, vector-borne disease, and drug resistance.

Dr Jamrozik is lead author of the report of a Wellcome Trust funded project on ethical and regulatory issues related to human challenge studies in endemic settings (2020, Springer Briefs). He has been a member of WHO Ethics Working Groups on human challenge studies as well as vector-borne diseases and antimicrobial resistance. His other publications include work on ethical issues related to malaria, Zika, drug resistance, and evidence-based medicine. He was a 2018 Brocher Foundation Scholar and co-organised a Brocher Workshop on ethical issues associated with asymptomatic infection.

Dr Melissa Kapulu, MD, PhD is a trained immunologist and vaccinologist based at the KEMRI-Wellcome Trust Research Programme, Kilifi Kenya and Centre for Tropical Medicine and Global Health, University of Oxford, Oxford UK. She holds an MSc degree in Immunology of Infectious Diseases at the London School of Hygiene and Tropical Medicine and a DPhil degree with a project on malaria transmission-blocking vaccines at the University of Oxford. Research experience initially started with investigating oral immune responses to vaccination. This was followed by undertaking epidemiology studies in assessing community infectious reservoirs for malaria. Her current portfolio of work includes and involves Shigella and malaria: using human infection models: to understand naturally acquired immunity, assess vaccine efficacy and correlates of protection; sero-epidemiology studies in children under five years (Shigella) and in cohorts of children and adults (malaria); and vaccine antigen discovery and development (malaria). She is the principal investigator for Shigella human infection studies and co-PI on malaria human infection studies.
Colin Pillai, PhD runs two social ventures that develop scientific capability in drug discovery and development in low- and middle-income countries. Previously, he worked as a pharmacometrician and a senior leader at Roche and Novartis in Switzerland. He acquired his clinical and research experience in hospital and community pharmacy, academia and at the South African Medical Research Council’s Tuberculosis Research programme running Phase 1 clinical trials.

Colin is a Honorary Professor at UCT, a Honorary Fellow of the Royal College of Physicians and a Senior Advisor on capacity development for global health to the Bill and Melinda Gates Foundation.

Andrew J Pollard, BSc MA MBBS MRCP(UK) FRCPCH PhD DIC FHEA FIDSA FMediSci, is Professor of Paediatric Infection and Immunity at the University of Oxford, Honorary Consultant Paediatrician at Oxford Children’s Hospital and Vice Master of St Cross College, Oxford.

He obtained his medical degree at St Bartholomew’s Hospital Medical School, University of London in 1989 and trained in Paediatrics at Birmingham Children’s Hospital, UK, specialising in Paediatric Infectious Diseases at St Mary’s Hospital, London, UK and at British Columbia Children’s Hospital, Vancouver, Canada. He obtained his PhD at St Mary’s Hospital, London, UK in 1999 studying immunity to Neisseria meningitidis in children and proceeded to work on anti-bacterial innate immune responses in children in Canada before returning to his current position at the University of Oxford, UK in 2001. He chaired the UK’s NICE meningitis guidelines development group, the NICE topic expert group developing quality standards for management of meningitis and meningococcal septicaemia. His research includes the design, development and clinical evaluation of vaccines including those for meningococcal disease and enteric fever and leads studies using a human challenge model of (para)typhoid. He runs surveillance for invasive bacterial diseases and studies the impact of pneumococcal vaccines in children in Nepal and leads a project on burden and transmission of typhoid in Nepal, Bangladesh and Malawi, and co-leads typhoid vaccine impact studies at these sites. He has supervised 37 PhD students and his publications includes over 500 manuscripts and books on various topics in paediatrics and infectious diseases. He chairs the UK Department of Health and Social Care’s Joint Committee on Vaccination and Immunisation, is a member of WHO’s SAGE, and chaired the European Medicines Agency scientific advisory group on vaccines (2012-2020). He received the Bill Marshall award of the European Society for Paediatric Infectious Disease (ESPID) in 2013, the ESPID Distinguished Award for Education & Communication in 2015 and the Rosén von Rosenstein medal in 2019 awarded by the Swedish Paediatric Society and the Swedish Society of Medicine. He was elected to the Academy of Medical Sciences in 2016 and is an NIHR Senior Investigator. He made the first British ascent of
Jaonli (6632m) in 1988 and Chamlang in 1991 (7309m) and was the Deputy leader of the successful 1994 British Medical Everest Expedition. He is the Chief Investigator leading the development of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2 (COVID-19).

Dr Bernd Rosenkranz, FFPM
Prof Emeritus Bernd Rosenkranz has a medical degree and is board certified Pharmacologist and Clinical Pharmacologist in Germany and South Africa and Fellow of the Faculty of Pharmaceutical Medicine (FFPM). He worked in the pharmaceutical industry in Germany, France and USA and was Professor/Chief Specialist in Pharmacology and head of the Division of Clinical Pharmacology, Stellenbosch University, where he established the postgraduate programme in Pharmaceutical Medicine / Medicines Development. He is President of the Fundisa African Academy of Medicines Development, guest scientist at the Institute for Clinical Pharmacology and Toxicology, Charité, Berlin, Finance Chair of the 3rd World Conference on Pharmacometrics (held in Cape Town in 2022) and convener of a sub-team involved in preparing the South African COVID-19 Country Report. Bernd Rosenkranz is active member of several professional clinical pharmacology/pharmaceutical medicine organisations, Associate Editor of Frontiers in Pharmaceutical Medicine and Outcomes Research, reviewer for several journals and for the South African National Research Foundation.

Getnet Yimer, MD, PhD, a physician scientist and consultant medical specialist, is a Director for Global One Health initiative of the Ohio State University in Eastern Africa, Prior to this, he has served as a Director for Research and Technology Transfer at the College of Health Sciences, Addis Ababa University for 5 years. For over 7 years, he has worked as consultant for WHO-TDR in charge of leading and coordinating RCTs in 6 African countries namely, Tanzania, Zambia, Uganda, Nigeria, South Africa, and Ethiopia. Getnet is a Chair of the AHRI-ALERT Ethics Review Committee and also a member of the Ethiopian National Health Research Ethics Review Committee at the Ministry of Science and Higher Education. He has served as a PI for a number of big projects funded by; CDC-PEPFAR (1U2GGH001477-01), Swiss National Foundation (R01 MH922731), USAID, EDCTP, Novartis and GSK and as a co-PI for NIH D43- TW010143-01 (MEPI), HRSA-T84HA21124-05-01 (iRIM), World Bank (CDT-Africa), EDCTP, and Astra Zeneca funded projects. Getnet has have published over 60 international peer reviewed publications and a book chapter.
Dr Craig Rayner, President – Integrated Drug Development, Certara

Dr Rayner is President of Certara’s Integrated Drug Development and Strategic Consulting Services. In this capacity, he supports a global team of clinical and quantitative pharmacologists, pharmacometricans, regulatory strategy and drug development scientists who create value for clients across the drug development ecosystem and ultimately accelerate patients’ access to medicines.

Craig has extensive global experience in early and late development of therapeutics, regulatory interaction experience with all major global health authorities, multiple filings and accountability for numerous due diligences, active support of negotiations, deal making and integration activities.

Previously, Craig was the Co-founder and CEO of d3 Medicine. Prior to that, Craig’s appointments included leadership roles in Clinical Pharmacology and Early development (Roche), Clinical development (CSL-Behring), in Business Development/Licensing as Global Due Diligence Director (Roche), and in clinical pharmacology and infectious disease research (Monash University).

Craig holds an Adjunct Associate Professorship in Pharmaceutical Science (Monash University), is a Distinguished Alumni of the Faculty of Pharmacy and Pharmaceutical Sciences (Monash University), has broadly published in clinical pharmacology and also infectious diseases.