Swiss TPH Summer Symposium 2018

Clinical Research in Resource Limited Settings: Mission Impossible or Role Model for Future Drug Development?

28 June 2018, University Hospital ZLF Kleiner Saal, Basel, Switzerland

Swiss TPH
Swiss Tropical and Public Health Institute
Schweizerisches Tropen- und Public Health-Institut
Institut Tropical et de Santé Publique Suisse

Associated Institute of the University of Basel

PROGRAMME

Thursday, 28 June 2018

Registration and Welcome

08.30 **Registration**

09:00 **Welcome and Introduction,** Christian Burri, Swiss TPH, Basel, Switzerland

Session 1 – Setting the Stage

Moderator: Daniel Paris, Swiss TPH, Basel, Switzerland

09:15 **Cost of Development of Medicines for Neglected Diseases**, Anna Doubell, Policy Cures Research, Sydney, Australia

09:45 **Quality Framework for Clinical Trials**, Matthias Briel, Clinical Trial Unit, Department of Clinical Research, University of Basel, Switzerland

10:15 **Risk Management in Clinical Trials in Today's ICH-GCP(R2) Framework**, Ingrid Klingmann, European Forum for Good Clinical Practice, Brussels, Belgium

10:45 **Coffee Break**

Session 2 – Clinical Research Worlds – Approaches and Challenges

Moderator: Wiweka Kaszubska, Medicines for Malaria Venture, Geneva, Switzerland

11:15 **The Big Pharma Approach and Future Developments**, Anthony Man, Novartis International AG, Basel, Switzerland

11:45 **Conducting Investigator Initiated Trials in low Resource Settings – the Northern Perspective**, Klaus Reither, Swiss TPH, Basel, Switzerland

12:15 **Conducting Investigator Initiated Trials in low Resource Settings – the Southern Perspective**, Ally Olotu, Ifakara Health Institute, Dar es Salaam, Tanzania

12:45 **Lunch**

Session 3 – Future Trends and Approaches

Moderator: Ingrid Klingmann, European Forum for Good Clinical Practice, Brussels, Belgium

14:00 **Working in a PDP Business Model**, David Reddy, Medicines for Malaria Venture, Geneva, Switzerland

14:30 **The Future of Drug Development**, Djordje Filipovic, Novartis International AG, Basel, Switzerland

15:00 **Coffee Break**

Session 4 – The Partnership approach

Moderator: Christian Burri, Swiss TPH, Basel, Switzerland

15:30 **Approaches, Success Stories and Challenges – the Industry Perspective**, Luc Kuykens, Sanofi, France

16:00 **Approaches, Success Stories and Challenges – the Academia Perspective**, Christian Burri, Swiss TPH, Basel, Switzerland

16:30 **Closing Words**, Jürg Utzinger, Swiss TPH, Basel, Switzerland

17:00 **Close of Day**

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Speaker Profiles

Welcome

Christian Burri, Swiss TPH, Basel Switzerland

Christian Burri, MPharm, PhD, is Deputy Head of the Department of Medicine and Head of the Medicines Implementation Research Unit at the Swiss TPH, as well as Professor of Pharmacy & Clinical Pharmacology at the Department of Pharmaceutical Sciences, University of Basel. For 20 years, he has been involved in the management and conduct of clinical trials on drugs and vaccines against neglected tropical and poverty related diseases, mainly in low income countries. This has led to significant knowledge and capacity building involvement in the areas of quality management, research ethics and regulatory affairs. Burri has significantly contributed to the improved treatment of parasitic diseases with a particular passion for sleeping sickness (human African trypanosomiasis). Burri was trained as a pharmacist at the University of Bern, Switzerland, holds a PhD in medical parasitology from the University of Basel, and received post-doctoral training in molecular pharmacology at Johns Hopkins University in Baltimore, Maryland. Since 2000, he has held a Diploma in Pharmaceutical Medicine of the Swiss Association of Pharmaceutical Professionals (SwAPP).

Session 1 – **Setting the Stage**

Daniel Paris, Swiss TPH, Basel Switzerland - *Moderator*

Daniel Paris, MD, PhD, DTMH, is a clinical doctor and researcher who recently joined Swiss TPH in January 2017 in his new role as Medical Director and Head of the Department of Medicine at Swiss TPH. His position incorporates the fusion of two predominantly service-oriented departments into a single medical department, with the addition of clinical translational research and diagnostic methodologies. Paris is a Swiss national clinically trained at the University of Zurich. He spent the past 12 years working in clinical research in Southeast Asia for the University of Oxford, based in Bangkok as coordinator of clinical tropical medicine research with a focus on tropical rickettsial illnesses, diagnostics, clinical trials and causes-of-fever studies.

Anna Doubell, Policy Cures Research, Australia

Anna Doubell joined the global health think tank, Policy Cures Research, in 2015 to pursue a career aligned with her longstanding volunteer commitment to not-for-profits and international development. Doubell uses the modeling and analysis skills she developed over 12 years in investment banking to provide decision-making tools and strategic analysis to those creating new pharmaceutical products for neglected diseases. As Director of Research, she leads the team that, amongst other projects, conducts the annual G-FINDER survey, which tracks and reports on global investments into research and development for neglected diseases. Doubell holds a Master of Public Health, Master of Applied Finance, Bachelor of Science and Bachelor of Commerce.

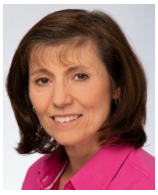
Matthias Briel, Institute for Clinical Epidemiology and Biostatistics, Clinical Research, University Hospital Basel, Switzerland

Matthias Briel has been deputy director of the Basel Institute for Clinical Epidemiology and Biostatistics, Department of Clinical Research, University Hospital Basel since 2012. He is also Assistant Professor (pt) at the Department for Clinical Epidemiology and Biostatistics, McMaster University in Hamilton, Canada since 2009. He holds an FMH title in Preventive Medicine and Public Health. His research focuses on the design and conduct of clinical trials & meta-analyses and quality of clinical research. Briel teaches clinical research methodology and evidence-based medicine to under- and postgraduates. He authored and co-authored over 150 original research articles and is an academic editor with PLoS One and the Cochrane Heart Group.

Ingrid Klingmann, European Forum for Good Clinical Practice, Belgium

Ingrid Klingmann, MD, specialises in General Medicine, Clinical Pharmacology and Pharmaceutical Medicine with over 30 years of experience in various senior medical, operational and managerial functions in pharmaceutical industry, CROs and clinical trial sites focusing on clinical trial design and management, ethical and regulatory aspects. Since January 2003, she has her own pharmaceutical development and site management support consulting company. Klingmann is Chairman of the Board of the European Forum for Good Clinical Practice. Her broad professional background as a physician with experience in patient care, clinical development, site management and patient engagement enables her to bridge the gaps between the interests and skills of various medicines development stakeholders aiming to develop new patient-relevant treatments more efficiently. Klingmann is also President of PharmaTrain Federation, the nfp organisation focussing on global standardisation and improvement of post-graduate training in medicines development sciences. She teaches different clinical research and regulatory affairs topics in diploma and master courses at the University of Bonn, University of Basel, and the Université Libre de Bruxelles.

Session 2 – **Clinical Research Worlds – Approaches and Challenges**



Wiweka Kaszubska, Medicines for Malaria Venture, Switzerland - *Moderator*

Wiweka Kaszubska, PhD, is the Head of Product Development at Medicines for Malaria Venture (MMV) based in Geneva, Switzerland. MMV's mission is to bring new, effective and affordable medicines to malaria endemic countries with an ultimate aim of disease eradication. Kaszubska is responsible for the late stage development portfolio of anti-malarial drugs. Her team works in close partnership with pharmaceutical organizations to develop and register new medicines for malaria endemic countries. Prior to joining MMV in 2012, Kaszubska was Head of Global Product Unit for Autoimmune and Inflammatory therapeutic area at Merck Serono in Geneva. She started her career in Discovery Research at Abbott Laboratories in Chicago in Metabolic Disease area. She has over 15 years global pharmaceutical industry experience across most phases of drug development. Kaszubska holds a PhD in biochemistry from the University of Illinois, and a Bachelor's degree in chemistry from the University of Chicago.

Anthony Man, Novartis Pharma AG, Switzerland

Tony Man, MD, is Therapeutic Area Head Anti-Infectives at Novartis Pharma AG in Basel. He qualified in biochemistry and medicine at Nottingham University and completed his postgraduate training in Internal Medicine and Medical Oncology. After 7 years of academic hospital practice, he moved to the pharmaceutical industry to pursue a career in clinical research in 1986. Prior roles include Global Head of Oncology at Roche, Head of Translational Oncology at Ciba/Novartis, Chief Executive Officer at Basilea Pharmaceutica and Head of Drug Development Novartis Greater China. Mann has been involved in over 20 successful NDA submissions in different disease areas and is currently involved in the development of new antivirals, anti-bacterials and anti-parasitic drugs at Novartis. Mann is a teaching faculty member for The European and Chinese Courses in Pharmaceutical Medicine (ECPM, CCDRS) and serves as R&D technical advisor to the European and Developing Countries Clinical Trials Partnership.

Klaus Reither, Swiss TPH, Basel Switzerland

Klaus Reither, MD, MSc, PhD, is the Head of the Clinical Research Unit at Swiss TPH. His responsibilities include the supervision and coordination of clinical research projects at Swiss TPH and international partner institutes. His scientific focus is on clinical tuberculosis research, mainly for the clinical development of new TB drugs, TB diagnostics and TB vaccines.

Ally Olutu, Ifakara Health Institute, Tanzania

Ally Olotu, MD, PhD, is a research scientist at the Ifakara Health Institute in Tanzania. He has over 10 years of experience as an investigator in phase I, II and III malaria clinical trials in different settings in Africa. Olotu received his medical degree from the University of Dar es Salaam in 2001, and worked as a resident medical officer for two years before moving to research. He worked on GSK's RTS,S candidate vaccine in KEMRI-Wellcome Trust Programme, Kenya for six years before moving to Equatorial Guinea in 2014 where he coordinated the first ever clinical trial in the country to evaluate the whole sporozoite malaria vaccine PfSPZ manufactured by Sanaria. In 2017 he received an MRC African Research Leadership award to investigate the safety and immunogenicity of RH5, a blood-stage malaria vaccine candidate in malaria exposed adults, children and infants in collaboration with the University of Oxford.

Session 3 – **Future Trends and Approaches**

David Reddy, Medicines for Malaria Venture, Switzerland

David Reddy, PhD, is CEO of the Medicines for Malaria Venture (MMV). This not-for-profit research foundation has brought forward seven new antimalarial drugs to malaria-endemic countries and broadened its malaria drug pipeline to include ten novel compounds in clinical trials. MMV is guided by a board and donor-approved 5-year strategy to develop and deliver new anti malarials to meet the needs of vulnerable populations. Over the last 6 years, David and the MMV team have raised over $450 million to support this strategy, whose ultimate goal is the elimination and eventual eradication of the disease. Reddy has 20 years of experience in the development and commercialization of medicines for the treatment of infectious diseases. His resume includes successful leadership of drug development teams, licensing and alliance management, market analytics and business planning, product and disease area management, and interfacing with Governments, NGOs and patient advocacy groups around access to medicines for priority diseases including HIV/AIDS and pandemic influenza. David has a PhD in Cellular and Molecular Biology from the University of Auckland, New Zealand.

Djordje Filipovic, Novartis International AG, Switzerland

Djordje Filipovic, PhD, is accountable for the businesses of Alcon, Sandoz, Pharmaceuticals & Oncology and upgrading the Novartis cross-divisional presence in Iran. He is a member of the Australia, Asia, Middle East, Africa (AMAC) Executive Committee and member of Global Leadership. Previously, Filipovic was the Franchise Head and General Manager Immunology & Dermatology for the AMAC Region. During his 20 years of experience in the Pharmaceutical industry, Filipovic held positions in Research, Development, Legal, Quality Assurance, Project Leadership, Marketing & Sales in Basel, the U.S. and Germany at global, regional and local levels. Filipovic was Global Head for Zometa, Xolair and Glivec and member of the Novartis Cell and Gene Therapy Executive Committee. Filipovic lead the Novartis Oncology global Project & Portfolio Management organization and served as Chairman of the Novartis Oncology Portfolio Management Board. Prior to joining the Research Division of Sandoz in 1992, he worked in the field of Protein Engineering at the University of Illinois and Battelle Labs with the U.S. Department of Energy. He holds a PhD in Biochemistry and Biophysics from the Swiss Federal Institute of Technology in Zürich and currently lectures at Basel University European Center of Pharmaceutical Medicine (ECPM) on Portfolio Management, Trends in Drug Development and Leadership. Filipovic is a member of the Advisory Board of the ECPM and the Scientific Counsel of the Swiss Academy of Technical Sciences.

Session 4 – **e Partnership Approach**

Ingrid Klingemann, Swiss TPH - *Moderator* - see above

Luc Kuykens, Sanofi, France

Luc Kuykens, MD, is the current Head of Sanofi Global Health Programs. He started his career in public health in 1987, when he worked in leprosy and tuberculosis control in the D.R. of Congo, was chief medical officer for Sierra Rutile Ltd. in Sierra Leone, and Executive Director of the Albert Schweitzer Hospital in Deschapelles, Haiti. Kuykens joined the vaccine industry in 1997 as associate director of regulatory affairs for Merck, then moving to Sanofi Pasteur, the human vaccines global business unit of Sanofi as vice president regulatory affairs for North America in December 2001. He gradually increased his scope of responsibility and was nominated to the Sanofi Pasteur Chief Medical Officer position in 2011. He received his medical degree from the

University of Antwerp in 1986, a Diploma in Tropical Medicine from the Institute for Tropical Medicine in Antwerp in 1987 and a Master's degree in Public Health from the Johns Hopkins University in Baltimore, USA in 1992. Kuykens is a member of a number of regulatory and public health professional societies.

Christian Burri, Swiss TPH – *See above*

***Closing Words*: Jürg Utzinger**, Swiss TPH, Switzerland

Jürg Utzinger, PhD, is Director of Swiss TPH and Professor of Epidemiology at the University of Basel. He obtained his MSc in environmental sciences from the Swiss Federal Institute of Technology in Zurich, and his PhD in epidemiology from the University of Basel. He pursued several years of postdoctoral research in demography and epidemiology at Princeton University in the USA. Before his appointment as Director of Swiss TPH, Utzinger headed the Ecosystem Health Sciences unit of the Department of Epidemiology and Public Health at Swiss TPH. His research, teaching and training interests pertain to the epidemiology and integrated control of neglected tropical disease and health impact assessment of large footprint projects in low- and middle-income countries.

Upcoming Symposia

Swiss TPH Winter Symposium 2018

One Health for Humans and Animals - How Do We Get Zoonoses under Control?

6-7 December, 2018, Parterre Rialto, Basel, Switzerland

More than 60% of human infectious diseases have an animal origin. Join us to explore, learn and share with international zoonoses research experts on the causes and responses to animal-human transmission.

Take part in a rich and intellectually stimulating program of lectures, discussions and debates ranging from the molecular to the global level, from deadly pathogens to health systems, from patients to populations and their socio-economic environments.

- Disease elimination strategies
- Syndromic surveillance and response
- Diagnostic tests
- Molecular epidemiology
- Clinical research
- Patient management
- Control and intervention financing

For more information visit: www.swisstph.ch/events

10th Rudolf Geigy Award

7 December 2018, 16:30-18:30, Parterre Rialto, Basel, Switzerland

Since 2000, the R. Geigy Foundation presents two awards to distinguished scholars in the field of tropical and neglected diseases and/or public health who combine laboratory and field research in novel ways. To mark the occasion, the awardees briefly present their research at a ceremony held in Basel every two years.

The award is to commemorate the spirit and the achievements of Rudolf Geigy, the founder of the Swiss Tropical and Public Health Institute, born in Basel on 20 December 1902. For more information on the Geigy Foundation visit: www.geigystiftung.ch/en

To register for the Geigy event visit: www.swisstph.ch/en/about/events/winter-symposium-2018