



The ethics of alternative clinical trial designs and methods in
low- and middle- income country research

Pullman Bangkok King Power Hotel, 28-29 November 2017

27 November 2017

17:00-19:00	Registration open
18:30-19:30	Planning Committee meeting (Room: Epsilon)

28 November 2017

08:00	<i>Registration</i>
08:30	Welcome and introduction: Nick Day and Phaik Yeong Cheah, Mahidol Oxford Tropical Medicine Research Unit, Thailand
08:45	Keynote presentation: Glenda Gray, President & CEO, South African Medical Research Council
Theme 1 09:15	Cluster randomised trials Chair: Charles Weijer, Western University, Canada
10 min	Introduction to the theme
20 min	Case Study 1: <i>Ethical issues of the PolyIran study: A cluster randomized trial nested within Golestan cohort study</i> Gholamreza Roshandel, Golestan Research Center of Gastroenterology and Hepatology, Iran
20 min	Case Study 2: <i>Lessons from an adaptive multi-arm multi-stage trial of strategies for improving linkage into HIV care or prevention in Malawi</i> Augustine Choko, Malawi-Liverpool Wellcome Trust Clinical Research Programme/ London School of Hygiene & Tropical Medicine, UK
20 min	Discussion
35 min	Breakout group discussion
11:00	<i>Tea/coffee break</i>
Theme 2 11:30	Stepped wedge Chair: Rieke van der Graaf, University Medical Centre Utrecht, Netherlands
10 mins	Introduction to the theme
20 min	Case study 3: <i>'Que Vivan Las Madres': Scaling up an integrated approach to reduce maternal and perinatal mortality in Northern Guatemala – A stepped-wedge cluster randomised trial (SW-CRT)</i> Karla Hemming, University of Birmingham, UK and Guillermo Ambrosio, Epidemiological Research Centre in Sexual and Reproductive Health (CIESAR), Guatemalan Ministry of Public Health
20 min	Case study 4: <i>ATMIYATA: Testing effectiveness of counselling delivered by community volunteers to people with common mental health issues in rural parts of Gujarat, India: Step Wedged Cluster Randomized Trial (SWCRT)</i> Kaustubh Joag, Indian Law Society
20 min	Discussion
35 min	Breakout group discussion
13:15	Poster session
13:40	<i>Lunch</i>



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Theme 3	Adaptive platforms
14:30	Chair: Ross Upshur, University of Toronto, Canada
10 mins	Introduction to the theme
20 min	Case Study 5: <i>The design and implementation of an adaptive platform trial for the treatment of Ebola in West Africa</i> Scott Berry, Berry Consultants, USA
20 min	Case Study 6: <i>Critically ill children and adaptive trials for comparative effectiveness research</i> Srinivas Murthy, University of British Columbia, Canada
20 min	Discussion
15:40	<i>Tea/coffee break</i>
16:10	Breakout group discussion
35 mins	
16:45	Pecha Kucha
30 min	Chair: Barbara Sina, Fogarty International Centre, National Institutes of Health, USA
17:15	<i>Photograph of participants and meeting close</i>
18:00	Meet in the foyer for departure for dinner

29 November 2017

07:30-08:30	Steering Committee meeting (Room: Epsilon)
08:30	Summary – key themes from day 1: Teck Chuan Voo, National University of Singapore and Anant Bhan, Yenepoya Medical College, India
Theme 4	Controlled human infection models
09:00	Chair: Nick Day, Mahidol Oxford Tropical Medicine Research Unit, Thailand
10 min	Introduction to the theme
20 min	Case Study 7: <i>Control of invasive Salmonella in Africa and Asia – Is there a role for establishing controlled human infection models in endemic countries?</i> Meriel Raymond, Oxford University, UK
20 min	Case Study 8: <i>Experiences and perceptions of study participants in a malaria challenge study in Kilifi, Kenya</i> Dorcus Kamuya, KEMRI-Wellcome Trust Research Programme, Kenya
20 min	Case study 9: <i>The case of Zika virus human challenge studies</i> Ricardo Palacios Gomez, Butantan Institute, Brazil
20 min	Discussion
30 min	Breakout group discussion
11:00	<i>Tea/coffee break</i>
Theme 5	Current guidance and regulation: Regional perspectives
11:30	Chair: Mike Parker, Oxford University, UK
10 min	Introduction to the theme
15 mins	Presentation: <i>Current international ethical guidance and regulations on use of alternative research designs</i> Rieke van der Graaf, University Medical Centre Utrecht, Netherlands



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10 mins	Presentation: <i>CHIMS: What does it mean to be a responsible research funder?</i> Katherine Littler, Wellcome, UK
35 mins	Panel response from different regional perspectives and open discussion (practically speaking what problems are faced despite current guidance and regulations?): <ul style="list-style-type: none"> – East Africa - Claude Kirimuhuzya (Kampala International University, Uganda) – Caribbean - Derrick Aarons (Caribbean Public Health Agency, Trinidad and Tobago) – Latin America - Carla Saenz (Pan American Health Organisation, USA) – Southeast Asia - Cristina Torres (Forum for Ethical Review Committees in the Asian and Western Pacific Region, Philippines)
12:40	Poster session
13:00	<i>Lunch</i>
Theme 6 14:00	Current guidance and regulation: Gaps and creative solutions Chair: Katherine Littler, Wellcome, UK
5 mins	Introduction to the theme
15 mins	Presentation: A potential tool to aid decision-making: ' <i>Informing Ethical Evaluations of Adaptive Clinical Trials through Simulation</i> ' Roger Lewis, University of California, USA
40 mins	Panel and open discussion: how well does the current guidance, regulation and tools address the need, what gaps remain and can we identify creative solutions? <ul style="list-style-type: none"> – Rieke van der Graaf, University Medical Centre Utrecht, Netherlands – Roger Lewis, University of California, USA – Phaik Yeong Cheah, Mahidol Oxford Tropical Medicine Research Unit, Thailand – Charles Weijer, Western University, Canada – Patricia Saidon, Instituto de Investigación en Salud Pública, Argentina
15:00	<i>Tea/coffee break</i>
15:30	Panel discussion: Key themes arising from the meeting Chair: Glenda Gray, South African Medical Research Council Panellists: <ul style="list-style-type: none"> – Paul Ndebele, Medical Research Council, Zimbabwe – Anant Bhan, Yenepoya Medical College, India – Carla Saenz, Pan American Health Organisation, USA – Rachel Knowles, Medical Research Council, UK – Mike Parker, Oxford University, UK
16:45	Conclusions, presentation of poster award and GFBR award Chairs: Paul Ndebele, MRC, Zimbabwe and Anant Bhan, Yenepoya Medical College, India
17:00	<i>Meeting close</i>