3rd Human Challenge Trials in Vaccine Development

Organized by
The International Alliance for Biological Standardization
IABS
Pembroke College Oxford
United Kingdom
February 6-7, 2020

AGENDA – FEBRUARY 3, 2020

Scientific Committee

Andrew Pollard, co-Chair Scientific Committee; University of Oxford, United Kingdom
Robert Sauerwein, co-Chair Scientific Committee, Radboud University Medical Center, Nijmegen
Pieter Neels, Chair Human Vaccine Committee, International Alliance for Biological Standardization (IABS)

Ivana Knezevic	**World Health Organization, Switzerland**
Rebecca Sheets	**International Alliance for Biological Standardization (IABS), U.S.A.**
Claudia Emerson	**McMaster University, Canada**
Marc Gurwith	**PaxVax Inc., San Diego, CA, USA.**
Anna Durbin	**Johns Hopkins Bloomberg School of Public Health, U.S.A.**
William Ripley Ballou	**GlaxoSmithKline, U.S.A.**
Martin Broadstock	**Medical Research Council, United Kingdom**
Helen McShane	**University of Oxford, United Kingdom**
Paul Kaye	**University of York, United Kingdom**
Kirsty E.K Mehring-Le Doare	**Imperial College of London, United Kingdom**
Peter J.M. Openshaw	**Imperial College of London, United Kingdom**
Daniela Ferreira	**Liverpool School of Tropical Medicine, United Kingdom**
Adrian Wildfire	**S.G.S., United Kingdom**

THURSDAY FEBRUARY 6th

08:00	**Registration**
8:30	**Introduction** **Andrew POLLARD, co-Chair Scientific Committee; University of Oxford, United Kingdom** **Robert SAUERWEIN, Radboud University Medical Center, Nijmegen, The Netherlands** **Pieter NEELS, Chair Human Vaccine Committee, International Alliance for Biological Standardization (IABS)**

Session 1 - The Role of Challenge Models

Chairs: Andrew POLLARD, University of Oxford, United Kingdom

09:00	**Overview: What is the role of challenge studies?** **Myron LEVINE, University of Maryland School of Medicine, U.S.A. –**
09:15	**Case study: Group A Streptococcus** **Joshua OSOWICKI, University of Melbourne, Australia**
09:30	**The Role of Challenge Models: case study on Typhoid/Paratyphoid** **Andrew POLLARD, University of Oxford, United Kingdom**
09:45	**Case study: RSV** **Andrew CATCHPOLE, hVIVO, United Kingdom**
10:00	**Development, use and refinement of Shigella controlled human infections** **Chad PORTER, Naval Medical Research Center, Maryland, U.S.A.**
10:15	**Discussion** **Lynda STUART, Bill & Melinda Gates Foundation, U.S.A.**
10:40	**Coffee break**

Session 2 - Regulation – GMP and the Trial Challenge

Chairs: Pieter NEELS, Chair Human Vaccine Committee, International Alliance for Biological Standardization (IABS)

11:10	**European survey of regulation** **Nele BERTHELS, Federal Agency for Medicines and *Health* Products (FAMHP), Belgium**
11:25	**Global variation in regulation** **Pieter NEELS, Chair Human Vaccine Committee, International Alliance for Biological Standardization (IABS)**
11:40	**GMP and the Challenge Agent: Leishmaniasis** **Paul KAYE, University of York, United Kingdom**
11:55	**Case study: Malaria** **Robert SAUERWEIN, Radboud University Medical Center, Nijmegen, The Netherlands**
12:10	**Discussion**
12:25	**Lunch**

Session 3 - Ethics

This session is supported by the Medical Research Council Hic-Vac Network

Chairs: Robert SAUERWEIN, Radboud University Medical Center, Nijmegen, The Netherlands

13:45	**Philosophical perspective for HIC and LMIC** **Michael SELGELID, Monash University, Australia**
14:00	**Controlled infection studies: ethical issues and LMICs** **Susan BULL; Michael PARKER, University of Oxford, United Kingdom**

14:15	**Guidelines for ethics committees in HIC** **Hugh DAVIES, University of Oxford, United Kingdom**
14:30	**WHO Roadmap to ethics** **Katherine LITTLER, World Health Organization (WHO), Switzerland**
14:45	**Experimental human gonococcal infection: Advances and challenges** **Marcia HOBBS, University of North Carolina, U.S.A.**
15:00	**Ethics Case Study: Dengue** **Anna DURBIN, Johns Hopkins Bloomberg School of Public Health, U.S.A.**
15:15	**Case study: Schistosomiasis** **Meta ROESTENBERG, Leiden University Medical Center, The Netherlands**
15:30	**Discussion** **Led by Simon KOLSTOE, University of Portsmouth, United Kingdom**
15:50	**Tea break**

Session 4 – Children

This session is supported by the Medical Research Council Hic-Vac Network

Chairs: Claudia EMERSON, McMaster University, Canada

16:15	**Human challenge models in Paediatric populations** **Kate EMARY, University of Oxford, United Kingdom**
16:30	**Philosophy & ethics of challenging children** **Claudia EMERSON, McMaster University, Canada**
16:45	**Regulatory perspective** **Dominique PLOIN, Hospices Civils de Lyon, France**
17:00	**Discussion**
17:25	**Summary of the day** **Chairs**
17:30	**hVIVO - Regulatory guidance for challenge agents** **Alex MANN, hVIVO, United Kingdom**
17:45	**Networking Reception**

FRIDAY FEBRUARY 7th

07:30	**Registration**

Session 5 – Threat to the Community and Environmental Safety Session

Chairs: Adrian WILDFIRE, SGS Life Sciences, Belgium

08:30	**Challenges in safety of enteric challenge in Asia** **Cherry KANG, Christian Medical College, Vellore, India**
08:45	**Containment of respiratory viruses: a case study of unexpected HPIV infection during an A/Belgium/4217/2015 [H3N2] influenza challenge study** **Adrian WILDFIRE, SGS Life Sciences, Belgium**
09:00	**Case study: Norovirus** **Robert FRENCK, University of Cincinnati, U.S.A.**
09:15	**Discussion**

Session 6 – Recruitment, Engagement, Advertising and Incentive

Chairs: Helen McShane, University of Oxford, United Kingdom

09:55	Attitudes towards payment and payment practices in controlled human infection model (CHIM) research Olivia GRIMWADE, University of Oxford, United Kingdom
10:10	Factors influencing participation in controlled human infection models: a pooled analysis from six enteric fever studies Blanché OGUTI, University of Oxford, United Kingdom
10:25	Coffee break
10:55	Community and public engagement for challenge studies in Kenya: Stakeholders, strategies, ethical issues and lessons learnt Primus CHI, KEMRI Wellcome Trust Research Programme, Kenya
11:10	Case study: Influenza; impact of pre-existing immunity on study end points Roma CHILENGI, Center for Infectious Disease Research, Zambia Cherry KANG, Christian Medical College, Vellore, India
11:25	Discussion

Session 7 – Pre-existing Immunity

Chairs: Peter OPENSHAW, Imperial College of London, United Kingdom

11:50	Where should we go for our challenge studies? Shobana BALASINGAM, Wellcome Trust, United Kingdom
12:05	A Controlled Human Malaria Infection study to examine naturally-acquired immunity CHMI – SIKA Study Team Philip BEJON, KEMRI Wellcome Trust Research Programme, Kenya
12:20	Pre-existing immunity case study: Zika virus Anna DURBIN, Johns Hopkins Bloomberg School of Public Health, U.S.A.
12:35	Discussion
13:00	Lunch
13:00 13:20	The Global Health Network – An Introduction to the knowledge sharing hub for human infection studies Trudie LANG, TGHN, University of Oxford, United Kingdom

Session 8 – Clinical, Immunological, and Microbiological Endpoints

Chairs: Anna DURBIN, Johns Hopkins Bloomberg School of Public Health, U.S.A.
Paul KAYE, University of York, United Kingdom

14:00	Immunological endpoints in challenge studies Helen McShane, University of Oxford, United Kingdom
14:15	Case study: RSV immunity and human challenge Peter OPENSHAW, Imperial College of London, United Kingdom
14:30	Microbiological endpoints for a Group B Streptococcal human challenge model Kirsty E.K MEHRING-LE DOARE, St. George's, University of London and MRC/UVRI @LSHTM, Uganda
14:45	Case study: Influenza; impact of pre-existing immunity on study end points Rebecca COX, University of Bergen, Norway
15:00	Case study: Malaria Robert SAUERWEIN, Radboud University Medical Center, Nijmegen, The Netherlands
15:15	Discussion

Session 9 – What is the future

Chairs: Andrew Pollard, co-Chair Scientific Committee; University of Oxford, United Kingdom
Robert Sauerwein, co-Chair Scientific Committee, Radboud University Medical Center, Nijmegen
Pieter Neels, Chair Human Vaccine Committee, International Alliance for Biological Standardization (IABS)

15:40	**Summing up – Funding challenges** **Wellcome Trust, United Kingdom**
15:40	**Summing up – Ethical and regulatory challenges** **Pieter Neels, Chair Human Vaccine Committee, International Alliance for Biological Standardization (IABS)**
15:50	**Final word** **Chairs**
16:00	**Close**