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 LITTLE, World Health Organization (WHO), Switzerland
14:45  Experimental human gonococcal infection: Advances and challenges
       Marcia HOBBBS, 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 FRENCCK, 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 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