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

PROVISIONAL AGENDA – OCTOBER 9, 2019

v. OCTOBER 14, 2019

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:

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	Case study: Typhoid/Paratyphoid Andrew POLLARD, University of Oxford, United Kingdom
09:45	Case study: RSV TBC
10:00	Case Study: Shigella TBC
10:15	Discussion
10:40	Coffee break

Session 2 - Regulation – GMP and the Trial Challenge

Chairs:

11:10	Regulation in the U.S. TBC
11:25	European survey of regulation Nele BERTHELS, Federal Agency for Medicines and *Health* Products (FAMHP), Belgium
11:40	Global variation in regulation Pieter NEELS, Chair Human Vaccine Committee, International Alliance for Biological Standardization (IABS)
11:55	Case study: Leishmaniasis Paul KAYE, University of York, United Kingdom
12:10	Case study: Hepatitis C TBC
12:25	Case study: Malaria Robert SAUERWEIN, Radboud University Medical Center, Nijmegen, The Netherlands
12:40	Discussion
13:00	Lunch

Session 3 - Ethics (supported by Medical Research Council Hic-Vac network)

Chairs:

13:45	**Philosophical perspective for HIC and LMIC** **Michael SELGELID, Monash University, Australia**
14:00	**Ethics of human challenge in LMIC** **TBC**
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	**Case study: Neisseria gonorrhoea** **Marcia HOBBS, University of North Carolina, U.S.A.**
15:00	**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

Chairs:

16:15	**Systematic review of Challenge studies involving children** **Kate EMARY, University of Oxford, United Kingdom**
16:30	**Philosophy & ethics of challenging children** **Claudia EMERSON, McMaster University, Canada**
16:45	**Regulatory perspective** **TBC**
17:00	**Discussion**
17:25	**Summary of the day**
17:30	**Drinks & Dinner**

FRIDAY FEBRUARY 7th

07:30	**Breakfast**

Session 5 – Threat to the Community and Environmental Safety Session

Chairs:

08:30	**Challenges in safety of enteric challenge in Asia** **Cherry KANG, Christian Medical College, Vellore, India**
08:45	**Case study: Containment of respiratory viruses** **Adrian WILDFIRE, S.G.S., United Kingdom**

09:00	Case study: Norovirus – Robert Frenck, University of Cincinnati, U.S.A.
09:15	Case study: Zika Philippe MAYAUD, Uganda
9:30	Discussion

Session 6 – Recruitment, engagement, advertising and incentive

Chairs:

09:55	Compensation – how much is the right amount? Alberto Giubilini, University of Oxford, United Kingdom
10:10	Volunteer's experience Blanché OGUTI, University of Oxford, United Kingdom
10:25	Coffee break
10:55	Public engagement in Kenya for malaria challenge Philip BEJON, KEMRI Wellcome Trust Research Programme, Kenya
11:10	Risks and challenges in engagement in LMIC Roma CHILENGI, Center for Infectious Disease Research, Zambia; Cherry KANG, Christian Medical College, Vellore, India
11:25	Discussion

Session 7 – Pre-existing immunity

Chairs:

11:50	Where should we go for our challenge studies? Is pre-existing immunity the thing? Wellcome and BMGF Strategy
12:05	Case study: Malaria case study on the influence of pre-existing immunity Philip Bejon, KEMRI Wellcome Trust Research Programme, Kenya
12:20	Case study: Zika Anna DURBIN, Johns Hopkins Bloomberg School of Public Health, U.S.A.
12:35	Discussion
13:00	Lunch

Session 8 – Clinical, immunological, and microbiological endpoints

Chairs:

14:00	What we should look for as immunological endpoints Prof. 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	Case study: GBS microbiological endpoints Kirsty E.K MEHRING-LE DOARE, Imperial College of London, United Kingdom
14:45	Case study: 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:

15:40	**Summing up – Funding challenges** **Bill & Melinda Gates Foundation, U.S.A.; Wellcome Trust, United Kingdom**
15:45	**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	**Tea and Close**