Accelerating vaccine development in the UK safely: enhancing Human Challenge Studies to combat infectious diseases

Agenda

Tuesday 6 February 2018, 09.30 – 17.00
Academy of Medical Sciences, 41 Portland Place, London, W1B 1QH (John Newsom-Davis Council Chamber)

Meeting Chairs: **Professor Andrew J Pollard** FRCPCH PhD FMedSci, Professor of Paediatric Infection and Immunity at the University of Oxford, Director of the Oxford Vaccine Group. **Professor Maria Zambon** PhD FRCPath FMedSci, Director of Reference Microbiology at Public Health England.

09.30 – 10.00	**Registration**
Introduction	
10.00 – 10.10	**Welcome from the Chairs**
10.10 – 10.15	**Human challenge studies: the 2005 Academy of Medical Sciences report** **Professor Richard Moxon** FRS FMedSci, Emeritus Professor of Paediatrics at the University of Oxford.
Session 1: The UK environment for human challenge studies	
10.15 – 10.25	**The HIC-Vac network: structure and aims** **Professor Peter Openshaw** FRCP PhD FRSB FMedSci, Director of the HIC-Vac Network and Professor of Experimental Medicine, Imperial College London
10.25 – 10.50	**Funding human challenge studies in the UK** **Dr Charlie Weller**, Head of Vaccines Programme at Wellcome; **Dr Jonathan Pearce**, Head of Infection and Immunity at the Medical Research Council.
10.50 – 11.10	**Developing a human challenge model for TB** **Professor Helen McShane**, Professor of Vaccinology and Wellcome Trust Senior Clinical Fellow at Oxford University.
11.10 – 11.30	**Refreshment break**
Session 2: The ethics and regulation of human challenge studies	
11.30 – 11.50	**Ethical considerations for human challenge studies** **Dr Claudia Emerson**, Director of the Institute on Ethics & Policy for Innovation, McMaster University.
11.50 – 12.10	**Oversight of UK human challenge studies** **Professor Jonathan Montgomery**, Chair, Health Research Authority

12.10 – 12.30	**Human Challenge Trials for vaccine development: WHO approach** **Dr Ivana Knezevic**, Group Lead, Norms and Standards for Biologicals, World Health Organization.
12.30 – 13.00	**Regulatory perspectives on human challenge studies** **Dr Marco Cavaleri**, Head of Anti-infectives and Vaccines, Scientific and Regulatory management Department at the European Medicines Agency. **Dr Graham McNaughton**, Pharmaceutical Assessor at Medicines and Healthcare products Regulatory Agency.
13.00 – 13.45	**Lunch**
Session 3: Developing a model of best practice to ensure safety	
13.45 – 13.55	**Recap of the morning's discussion** Chairs
13.55 – 14.35	**Break-out session 1** In this break-out session, attendees will be split into groups and asked to consider the key issues for: a) the manufacture of agents, b) the oversight of studies, and c) how to maximise the benefits of volunteer challenge studies.
14.35 – 15.00	**Feedback and discussion**
15.00 – 15.15	**Refreshment break**
15.15 – 15.55	**Break-out session 2** In this break-out session, attendees will discuss practical steps that could be taken to improve current best practice and what should be included as guiding principles for ethics committees and investigators.
15.55 – 16.50	**Feedback and discussion**
16.50 – 17.00	**Closing remarks** Chairs
17.00 – 19.00	**Drinks reception**
19.00	**Close**