Program for Human Challenge Trial Workshop: Focus on Quality Requirements for Challenge Agents

October 22, 2019

Paul-Ehrlich-Institut, Germany

Scientific Committee

Name	Organization
Isabelle Bekeredjian-Ding	Paul-Ehrlich-Institut (PEI), Germany
Wim van Molle	Sciensano, Belgium

Organizing Committee

Pieter Neels	International Alliance for Biological Standardization (IABS), Belgium
Isabelle Bekeredjian-Ding	Paul-Ehrlich-Institut (PEI), Germany
Christoph Conad	Paul-Ehrlich-Institut (PEI), Germany
Wim van Molle	Sciensano, Belgium
Nele Berthels	Federal Agency for Medicines and Health Products (FAMHP), Belgium
Richard Rupp	University of Texas Medical Branch, U.S.A.
William Ripley Ballou	GlaxoSmithKline, U.S.A.

Provisional AGENDA

8:30 Registration

8:40 Welcome
Pieter Neels, Chair, Human Vaccine Committee, IABS, Belgium
Isabelle Bekeredjian-Ding, Paul-Ehrlich-Institut, Germany

Session 1 – Important choices in the selection of pathogens for CHIM

Chairpersons: Isabelle Bekeredjian-Ding, Paul-Ehrlich-Institut (PEI), Germany

8:45 PEI-DZIF OSRA**,** Short presentation,
Christoph Conrad, Paul-Ehrlich-Institut, Germany

8:50 Historical and ethical aspects of CHIM
Wolfram Metzger, University of Tübingen, Germany

9:05 Prerequisites for understanding Malaria using CHIM
Peter Kremsner, University of Tübingen, Germany

9:25 The view of a clinical assessor licensing a clinical trial
Karen Götz, PEI

Discussion

9:40 Developing CHIM for tuberculosis
Barry Walker, UK

10:10 Developing CHIM for drug development in emerging infections
Robert Johnson, BARDA/HHS

10:40 **Coffee break**

Session 2 – Current regulatory context and quality requirements for infectious agents in CHIM / HCT

Chairperson: Wim Van Molle, Sciensano, Belgium

11:00 Perspective - FDA
Scott Stibitz, Food & Drug Administration (FDA), U.S.A.

11:20 Perspective – NCA
Nele Berthels, Federal Agency for Medicines and Health Products (FAMHP), Belgium

11:40 Perspective - AVAREF
Nyam Yakubu Beno, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria

Session 3 – Practical experiences with viral strain selection and production

Chairperson: Yves Levy, Vaccine Research Institute, France

12:00 **Vaccine Research Institute** – Short presentation and introduction to the session topic
Yves Levy, Paris, France

12:05 Influenza
Daniel Hoft, St. Louise, MO, USA

12:30 Dengue
Stephen Thomas, State University of New York, Syracuse, USA

13:00 Lunch

Session 4 – Bacterial strain selection and production

Chairperson: Richard Rupp, University of Texas Medical Branch, U.S.A

14:00 **Sealy Institute for Vaccines Sciences**, Short presentation and introduction to the session topic

14:05 Choice of strains in HCT for enteric infections
Kawsar Rasmy Talaat, Baltimore, USA

14:25 Safety aspects in CHIM/HCT for tuberculosis (remote)
Sarah Fortune, Harvard Medical School, Boston, US

14:45 Choosing and manufacturing the right Pertussis agent for CHIM
Andrew Gorringe, Public Health England, Porton Down, Salisbury

Session 5 – PROs and CONs discussion on GMP

Chairperson: Nele Berthels, Federal Agency for Medicines and Health Products (FAMHP), Belgium

15:05 A regulatory point of view:
Taking control of bacterial agents – what is the role of NGS?
Oleg Krut, Paul-Ehrlich-Institut (PEI), Germany

15:20 An academic point of view:
GMP Production of Schistosoma for CHIM
Angela van Diepen, Leiden University Medical Center, The Netherlands

15:40 An industrial point of view:
Adrian Wildfire, SGS Belgium
GMP manufacturing of RSV challenge strain – discussions with regulators

Session 6 – Panel discussion on quality requirements and regulatory aspects

Chairperson and Moderator: Pieter Neels, International Alliance for Biological Standardization (IABS)

16:00

Scott Stibitz, Food & Drug Administration (FDA), U.S.A.
Volker Öppling, Paul-Ehrlich-Institut (PEI), Germany
Nyam Yakubu Beno, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria

Wrap-up

16:30 **Chairpersons**:
Isabelle Bekeredjian-Ding, Paul-Ehrlich-Institut (PEI), Germany
Wim van Molle, Sciensano, Belgium