

Europe



Paul-Ehrlich-Institut



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 Bekerédjian-Ding	Paul-Ehrlich-Institut (PEI), Germany
Wim Van Molle	Sciensano, Belgium

Organizing Committee

Pieter Neels	International Alliance for Biological Standardization (IABS), Belgium
Isabelle Bekerédjian-Ding	Paul-Ehrlich-Institut (PEI), Germany
Christoph Conrad	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 Bkeredjian-Ding, Paul-Ehrlich-Institut, Germany

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

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

- 8:45 PEI-DZIF OSRA, Short presentation,
Christoph Conrad, Paul-Ehrlich-Institut, Germany
- 8:50 Prerequisites for understanding Malaria using CHIM
Peter Kremsner, University of Tübingen, Germany
- 9:15 The view of a clinical assessor licensing a clinical trial
Karen Götz, PEI
- 9:30 Developing CHIM for tuberculosis
Barry Walker, UK
- 10:00 Developing CHIM for drug development in emerging infections
Robert Johnson, BARDA/HHS
- 10:30 **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
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
Meta Roestenberg, Leiden University Medical Center, The Netherlands
- 15:40 An industrial point of view:
Bruno Speder, SGS
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

Saeedeh Fakhrzadeh, Food and Drug Administration, Iran

Wrap-up

16:30

Chairpersons:

Isabelle Bekerdjian-Ding, Paul-Ehrlich-Institut (PEI), Germany

Wim Van Molle, Sciensano, Belgium