



## Workshop on Ethical Approval for Controlled Human Infectious Models (CHIM) Clinical Trial Protocols

This is organised within the framework of Chimichurri, Subtopic (ST) 2 of the IHI (IMI) Inno4Vac project

May 30-31, 2023

### Agenda v. 5.5

#### Co-chairs

Katherine LITTLER, World Health Organization, Switzerland

Euzebiusz JAMROZIK, Monach Oxford University

#### Day 1 – Tuesday, May 30, 2023

8:30	<b>Registration</b>
9:00-9:15	<b>Welcome</b> IABS European Vaccine Initiative Public Health Belgium
9:15-9:45	Background on the ethics of CHIM and what are unresolved issues in the context of CHIM <b>Euzebiusz JAMROZIK, Oxford University, United Kingdom</b>
9:45-10:00	Discussion
10:00-10:15	What do we request for production and quality control of CHIM-strains. Should it be GMP or is adherence to GMP acceptable? <b>Wim VAN MOLLE, Sciensano, Belgium</b>
10:15-10:30	Discussion
10:30-10:50	Coffee break
10:50-11:05	UK situation: MHRA's involvement of ethical evaluation of CHIM <b>Janet MESSER, Health Research Authority, United Kingdom</b>
11:05-11:20	Discussion
11:20-11:35	COVID-19 CHIM study: the Imperial College Experience <b>Christopher CHIU, Imperial College London, United Kingdom</b>
11:35-11:50	COVID-19 CHIM study: the ethical committee viewpoint <b>Simon KOLSTOE, University of Portsmouth, United Kingdom</b>
11:50-12:05	COVID-19 CHIM study: the Dutch viewpoint <b>Dimitri Diavatopoulos, Radboud University, The Netherlands</b>
12:05-12:30	Discussion



- 12:30-13:30 Lunch break
- 13:30-13:45 Acceptability of risk of severe AE (e.g. long COVID)  
**Meta ROESTENBERG, Leiden University Medical Centre, Netherlands**
- 13:45-14:00 Discussion
- 14:00-14:15 Evaluation of novel CHIM protocols (Zika as a relevant example)  
**Seema SHAH, Northwestern University Medical School and Director of Research Ethics at Lurie Children's Hospital, U.S.A.**
- 14:15-14:30 Discussion
- 14:30-14:45 Practical experience on Malaria CHIM trial in Germany  
**Benjamin MORDMÜLLER, Radboud University, Netherlands**
- 14:45-15:00 Malaria: the ethical committee viewpoint  
**Wolfram METZGER, Eberhard Karls Universität Tübingen, Germany**
- 15:00-15:15 Discussion
- 15:15-15:35 Tea break
- 15:35-15:55 Experience with Dengue CHIM on ethics  
**Anna DURBIN, Johns Hopkins Bloomberg School of Public Health, U.S.A. v.**
- 15:55-16:10 Ethical considerations,  
**Euzebiusz JAMROZIK, Oxford University, United Kingdom**
- 16:10-16:25 Discussion
- 16:25-16:40 Experience on influenza CHIM  
**Adrian WILDFIRE, CHIMunomics, United Kingdom**
- 16:40-16:55 Influenza: the ethical committee viewpoint  
**Simon KOLSTOE, University of Portsmouth, United Kingdom**
- 16:55-17:10 Discussion
- 17:10-17:35 Report on challenge studies for pandemic preparedness  
**Bridget WILLIAMS, University of Oxford, United Kingdom**
- 17:35-17:50 Discussion
- 17:50-18:00 Rap-up  
**Katherine LITTLER, World Health Organization, Switzerland**  
**Euzebiusz JAMROZIK, University of Oxford, United Kingdom**



18:30-19:30      Networking reception at Marivaux Hotel

### Day 2 – Wednesday, May 31, 2023

8:30-8:45      Welcome

8:45-9:00      Experience on RSV CHIM  
**Bruno SPEDER, hVivo, United Kingdom**

9:00-9:15      RSV: the ethical committee viewpoint  
**Martine DE VRIES, Leiden University Medical Center, Netherlands**

9:15-9:45      Discussion

9:45-10:00     Experience on C. Difficile CHIM  
**Maria VEHRESCHILD, Johann Wolfgang Goethe University Frankfurt am Main, Germany** **v.**

10:00-10:15    Experience on enteric challenge studies, lessons that could be drawn from previous models (typhoid, paratyphoid)  
**Malick Gibani**

10:15-10:35    C. Difficile: the ethical committee viewpoint  
**Martine DE VRIES, Leiden University Medical Center, Netherlands**

10:35-10:50    Discussion

10:50-11:10    Coffee break

11:10-11:25    Experiences with ethical aspects of CTA in Belgium  
**Pierre VAN DAMME, Ilse DECOSTER, University of Antwerp, Belgium**

11:25-12:00    Discussion

12:00-13:00    Round table discussion:  
**Marco CAVALERI, European Medicines Agency, United Kingdom**  
**Martine DE VRIES, Leiden University Medical Center, Netherlands**  
**Euzebiusz JAMROZIK, University of Oxford, United Kingdom**  
**Simon KOLSTOE, University of Portsmouth, United Kingdom**  
**Wolfram METZGER, Eberhard Karls Universität Tübingen, Germany**  
**Catherine LITTLER, World Health Organization, Switzerland**

13:00          Adjourn