WORKSHOP

REFINING THE REGULATORY CONTEXT OF CONTROLLED HUMAN INFECTION MODELS

17th of October, 2025 // 9:30-17:00 (CET)

This workshop will bring together leading researchers, industry representatives, regulators, and ethicists to discuss the evolving regulatory, ethical, and scientific landscape for Controlled Human Infection Models (CHIMs), with a focus on RSV, C. difficile, and influenza trials under the Inno4VAC initiative. CHIM's could be used to decrease the time of development and could give a Proof of Concept or could replace an un-executable phase III trial. But are our regulations and regulatory guidance (CMC, tox, GMO,…) able to execute these trials? Is it ethical to refuse a CHIM trial because of the fact that the documentation of the trial is not 100% in line with GMP? This meeting would like to confront the scientific committee with the question whether all rules and regulations and guidance documents will help to execute a novel innovation CHIM trials that might speed-up a development of highly needed vaccines and/or medicinal products.

Objectives

- Refine our current framework on specific CHIM-related regulatory and practical issues
- Engage on the potential uses for CHIMs in the product development pipeline from the perspective of industry
- Discuss the potential impact of regulatory hurdles for CHIMs and what broader implications this has.

Agenda

09:30 **Opening Remarks**
Pieter NEELS, WP11, IABS-EU Project Leader

09:35 Introduction into Inno4VAC Introduction into C diff and RSV models and issues encountered along the way
Marie-Astrid HOOGERWERF, Leiden University Medical Center

10.00 Presentation of initial results of Inno4VAC trials RSV en C. diff
Annefleur HENSEN, Leiden University Medical Center
Victor CNOSSEN, Centre for Human Drug Research

10.30 Keynote speaker: “To use a CHIM, yes or no?”
Anna DURBIN, Johns Hopkins Bloomberg School of Public Health

11.00 *Morning Coffee-Break*

11.30 Role of CHIM in product development pipeline: vision from industry
GSK

12.00 Role of CHIM in product development pipeline: vision from industry
Sanofi

12.30 *Lunch Break*

13.30 Framework for ethical review from CCMO perspective
Pepijn AL, Utrecht University
Martine DE VRIES, Leiden University Medical Center
Rieke VAN DER GRAAF, Utrecht University Medical Center

14.00-17.00 Panel discussion (part 1) - Prepared statements, statements and questions below
Ethicists panel, participants to be confirmed

- **Meta ROESTENBERG**, Leiden University Medical Center
- **Ingrid DE VISSER-KARMELING,** Centre for Human Drug Research
- Representatives from **GSK**, **Sanofi** and **Regulators**

15:15 *Afternoon Coffee-Break*

15:45 Panel discussion (part 2)

17:00 End of meeting