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 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 & Sanofi**
12.00	*Lunch Break*
13.00	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

13.30 Panel discussion (part 1) - Prepared statements, statements and questions below

- What are the critical requirements for a viral CHIM to be conducted as outpatient? What are the consequences of not doing a CHIM outpatient?
- Bystander risks: how to incorporate this into the safety assessment of the protocol and how to make sure that this is systematically assessed?
- How do the production dossier and production processes of challenge agents fit into the new CTR regulations and requirements for IMPD's? What if they don't fit – e.g. requirements are scientifically impossible or financially challenging?
- What is the role of community and participant engagement in CHIM-development in Europe?

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**

15:00 *Afternoon Coffee-Break*

15:30 Panel discussion (part 2)

17:00 End of meeting