

WORKSHOP

**REFINING THE REGULATORY CONTEXT
OF CONTROLLED HUMAN INFECTION MODELS**

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

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 CNOSEN, 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
Ricardo PALACIOS, GSK & **Pedro FOLEGATTI**, 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
- 13:45** Q&A session
- 14:00** Ethics of controlled human infection studies
Seema SHAH, Lurie Children’s Hospital of Chicago
- 14:30** *Afternoon Coffee-Break*



15:00

Panel discussion

Chair: Marie-Astrid HOOGERWERF, Leiden University Medical Center

- 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?

Panelists:

Meta ROESTENBERG, Leiden University Medical Center**Ingrid DE VISSER-KARMELING**, Centre for Human Drug Research**Simon KOLSTOE**, University of Portsmouth**Seema SHAH**, Lurie Children's Hospital of Chicago**17:30**

End of meeting

