



WORKSHOP

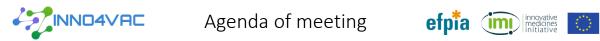
REFINING THE REGULATORY CONTEXT OF CONTROLLED HUMAN INFECTION MODELS

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 |





Agenda of meeting efpia (im) innovative







- 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

