



WORKSHOP

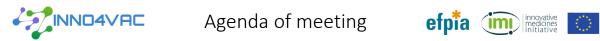
REFINING THE REGULATORY CONTEXT OF CONTROLLED HUMAN INFECTION MODELS

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





NN□4∨A⊏ Agenda of meeting







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

Panel discussion (part 2)

End of meeting 17:00

15:45

