

# Mastering increasing complexity in developing innovative therapies

21-23 May 2025



Together in Lamot Conference Centre  
Mechelen, Belgium



22 May 2025

Wednesday, May 21, 2025

## EUFEMED Pre-conference workshop: The most suitable participant for phase 1 clinical trials

13:00 - 13:15	Welcome and Introduction
13:15 - 15:15	<p>The most suitable participant for phase 1 clinical trials - Plenary Session</p> <p>How did the healthy volunteer evolve over the last 10 years? - Thomas Lodeweyckx, SGS, Belgium</p> <p>Which populations should be included in phase 1 clinical trials? Sponsor, investigator, regulator and ethics committee perspectives.</p> <ul style="list-style-type: none"> <li>• The sponsor's perspective – Joachim Höchel, Bayer, Germany</li> <li>• The investigator's perspective – Yves Donazzolo, Eurofins, France</li> <li>• The regulator's perspective – Joop Van Gerven, CCMO, The Netherlands</li> <li>• Ethical perspective and the VolREthics initiative - François Bompart, INSERM Ethics Committee, France</li> </ul> <p>What is the place of patients in First-In-Human trials? - Jan de Hoon, KU Leuven, Belgium</p>
14:45 - 15:15	Coffee break
15:15 - 16:15	<p>Parallel breakout sessions:</p> <ul style="list-style-type: none"> <li>• Who do you consider a healthy volunteer?</li> <li>• What is the population that you would include in phase 1 clinical trials?</li> <li>• Would you include non-oncology/non-ATMP patients in a First-in-Human trial?</li> </ul>
16:15 - 16:45	Coffee break
16:45 – 17:30	Feedback from break-out sessions

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## EUFEMED-HEALIXIA Joint Conference day

9:00 - 9:15	Welcome and introductions – Jan de Hoon, EUFEMED & Erik Present, Healixia
9:15 - 9:45	Keynote Presentation - Genetic medicines: setting the scene for treatments of the future – Olivier Harari, Regeneron Genetic Medicines, USA <i>Session chair: Jan de Hoon</i>
9:45 - 10:45	Medicines Development for innovative therapies: challenges in early and late clinical development <ul style="list-style-type: none"> <li>Challenges faced by the sponsor: lessons learned and hurdles to overcome – Anna Rozova, Chiesi Global Rare Disease, USA</li> <li>Challenges faced by the investigator: focus on the treatment of ALS as a rare disease – Philip Van Damme, KU Leuven, Belgium</li> <li>The patient's perspective as participant in a First-in-Human clinical trial – patient testimony</li> </ul> <i>Session chairs: Jan de Hoon, Nariné Baririan</i>
10:45 - 11:15	Coffee break
11:15 - 12:45	Medicines Development for innovative therapies - challenges in regulation and reimbursement <ul style="list-style-type: none"> <li>Challenges and opportunities from an industry perspective considering current/ upcoming changes – Armand Voorschuur, pharma.be, Belgium</li> <li>Joint Health Technology Assessment (HTA) in Europe: today and tomorrow? – Marc Van de Casteele, RIZIV-INAMI, Belgium</li> <li>Challenges in the development and registration of orphan drugs: a Regulator Perspective - Tim Leest, EMA's Committee for Orphan Medicinal Products (COMP), Belgium</li> </ul> <i>Session chairs: Erik Present, Ingrid Theeuwes</i>



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12:45 – 13:45	Lunch
13:45 - 15:15	<p>Oxford Debate - Diversity YES, but in Phase I? – With Keith Berelowitz, PatientRx Ltd, UK; Henri Caplain, Consultant, France; Liam Eves, h-Bar Consultants, UK; Kerstin Breihaupt-Grögler, independent researcher, UK.</p> <p><i>Session Chair: Tim Hardman</i></p>
15:15 – 15:45	Coffee break
15:45 - 17:15	<p>Parallel session A: The new ethical framework</p> <ul style="list-style-type: none"> <li>Impact of the new versions of the Declaration of Helsinki, ICH-GCP E6 R3 and WHO guidance for the conduct of clinical trials – Varvara Baroutsou, IFAPP, Greece</li> <li>The VolREthics Initiative – What will it change? – François Bompard, INSERM Ethics Committee, France</li> <li>eConsent Done Right: A Fit-for-Purpose Study Framework – Hilde Vanaken, TCS, EFGCP, Belgium</li> </ul> <p><i>Session chairs: Ingrid Klingmann, Yves Donazzolo</i></p> <p>Parallel session B: Real World Data in Belgium: will Phase IV studies become obsolete?</p> <ul style="list-style-type: none"> <li>Secondary use of data as a source of Real World Data/Evidence – Annelies Verbiest, UZA, Belgium</li> <li>The Federated Health Innovation Network: transform healthcare with data – Kim Denturck &amp; Peter De Jaeger, AZ Delta, Belgium</li> <li>The We Are Platform: a sustainable citizen-centric ecosystem for personal health data – Elfi Goesaert, VITO, Belgium</li> </ul> <p><i>Session chairs: Geert Van Gassen, Elke Debie</i></p>
17:30 - 18:00	<p>Closing Keynote Presentation: Evolving a new framework to optimize drug development – Richard Hargreaves, Bristol Myers Squibb, USA</p> <p><i>Session chair: Jan de Hoon</i></p>
19:00 - 22:00	Social Event with dinner at Salons Van Dijck, Mechelen



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## EUFEMED Conference day 2

- 9:00 - 10:30      Update on safety biomarkers in early clinical development
- Interest and use of emerging safety biomarkers in the drug development – Philippe Detilleux, Sanofi, France
  - Kidney safety biomarkers in human and approach to interpret emerging exploratory biomarkers – Emmanuel Krupka & Olivier Roux, Sanofi, France
  - Translational Approach of the Clinical and Nonclinical Evaluation and Qualification of Blood-based Biomarkers of Drug-induced Neurotoxicity: An IMI TransBioLine project – Greet Teuns, Johnson & Johnson, Belgium
  - CNS safety biomarkers in humans and their application in early-phase clinical drug development – Geert Jan Groeneveld, CHDR, The Netherlands
- Session chairs: Rob Zuiker, Erik Mannaert*

10:30 – 11:00      Coffee break

11:00 - 11:45      Research in the spotlight: Poster pitches of selected abstracts and Audience Voting for best presentation award  
*Session chairs: Thomas Lodeweyckx, Elke Debie*

11:45 - 13:15      Artificial Intelligence in Clinical Development: Buzzword, vision, or reality? With confirmed speakers:

- Liesbet Geris, VPH Institute, Belgium
- Cristhyne Leon, Nova in Silico, France
- Flora Musuamba Tshinanu, FAMHP, Belgium

*Session chairs: Joachim Höchel, Tim Weglewski*

13:15 - 13:30      Summary & End of conference – Ingrid Klingmann, EUFEMED

13:30 - 14:00      Farewell lunch

