CONFERENCE

Mastering increasing complexity in developing innovative therapies

21-23 May 2025 | 10 years of EUFEMED | Together in Lamot Conference Centre Mechelen, Belgium | 5 years of Healixia | 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	The most suitable participant for phase 1 clinical trials - Plenary Session
	How did the healthy volunteer evolve over the last 10 years? - Thomas Lodeweyckx, SGS, Belgium
	Which populations should be included in phase 1 clinical trials? Sponsor, investigator, regulator and ethics committee perspectives. • The sponsor's perspective – Joachim Höchel, Bayer, Germany • The investigator's perspective – Yves Donazzolo, Eurofins, France • The regulator's perspective – Joop Van Gerven, CCMO, The Netherlands • Ethical perspective and the VolREthics initiative - François Bompart, INSERM Ethics Committee, France
	What is the place of patients in First-In-Human trials? - Jan de Hoon, KU Leuven, Belgium
14:45 - 15:15	Coffee break
15:15 - 16:15	Parallel breakout sessions: • Who do you consider a healthy volunteer? • What is the population that you would include in phase 1 clinical trials? • Would you include non-oncology/non-ATMP patients in a First-in-Human trial?
16:15 - 16:45	Coffee break
16:45 – 17:30	Feedback from break-out sessions

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Thursday, May 22, 2025

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 *Session chair: Jan de Hoon*
9:45 - 10:45	Medicines Development for innovative therapies: challenges in early and late clinical development • Challenges faced by the sponsor: lessons learned and hurdles to overcome – Anna Rozova, Chiesi Global Rare Disease, USA • Challenges faced by the investigator: focus on the treatment of ALS as a rare disease – Philip Van Damme, KU Leuven, Belgium • The patient's perspective as participant in a First-in-Human clinical trial – patient testimony *Session chairs: Jan de Hoon, Nariné Baririan*
10:45 - 11:15	Coffee break
11:15 - 12:45	Medicines Development for innovative therapies - challenges in regulation and reimbursement • Challenges and opportunities from an industry perspective considering current/ upcoming changes – Armand Voorschuur, pharma.be, Belgium • Joint Health Technology Assessment (HTA) in Europe: today and tomorrow? – Marc Van de Casteele, RIZIV-INAMI, Belgium • Challenges in the development and registration of orphan drugs: a Regulator Perspective - Tim Leest, EMA's Committee for Orphan Medicinal Products (COMP), Belgium *Session chairs: Erik Present, Ingrid Theeuwes*

12:45 – 13:45	Lunch
13:45 - 15:15	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, Germany. *Session Chair: Tim Hardman*
15:15 – 15:45	Coffee break
15:45 - 17:15	Parallel session A: The new ethical framework • 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 • The VolREthics Initiative – What will it change? – François Bompart, INSERM Ethics Committee, France • eConsent Done Right: A Fit-for-Purpose Study Framework – Hilde Vanaken, TCS, EFGCP, Belgium *Session chairs: Ingrid Klingmann, Yves Donazzolo*
	Parallel session B: Real World Data in Belgium: will Phase IV studies become obsolete? • Secondary use of data as a source of Real World Data/Evidence – Annelies Verbiest, UZA, Belgium • The Federated Health Innovation Network: transform healthcare with data – Kim Denturck & Peter De Jaeger, AZ Delta, Belgium • The We Are Platform: a sustainable citizen-centric ecosystem for personal health data – Elfi Goesaert, VITO, Belgium *Session chairs: Geert Van Gassen, Elke Debie*
17:30 - 18:00	Closing Keynote Presentation: Evolving a new framework to optimize drug development – Richard Hargreaves, Bristol Myers Squibb, USA *Session chair: Jan de Hoon*
19:00 - 22:00	Social Event with dinner at Salons Van Dijck, Mechelen

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Friday, May 23, 2025

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

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