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 person for phase 1 clinical trials

13:00 - 13:15	Welcome and Introduction
13:15 - 15:15	The most suitable person for phase 1 clinical trials - Plenary Session
	How did the healthy volunteer evolve over the last 10 years?
	Which populations should be included in phase 1 clinical trials? Sponsor, regulator and ethics committee perspectives.
	What is the place of patients in First-In-Human trials?
15:15 - 15:45	Coffee break
15:45 - 16:45	Parallel breakout sessions on the above topics
16:45 - 17:00	Coffee break
17:00 - 18:00	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
9:15 - 9:45	Keynote Presentation - Genetic medicines: setting the scene for treatments of the future by Olivier Harari, Regeneron Genetic Medicines, USA
9:45 - 10:45	Medicines Development for rare diseases: challenges in early and late clinical development • Challenges faced by the sponsor: lessons learned and hurdles to overcome (Speaker invited) • 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 (Speaker invited)
10:45 - 11:15	Coffee break
11:15 - 12:45	Medicines Development for rare diseases - challenges in regulation and reimbursement • Joint Health Technology Assessment (HTA) in Europe: today and tomorrow? – Marc Van de Casteele, RIZIV-INAMI, Belgium • Perspective of future marketing authorization holders (Speaker invited) • Perspective or regulators (Speaker invited)
12:45 – 13:45	Lunch

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13:45 - 15:15	Oxford Debate - Diversity YES, but in Phase I? - With Keith Berelowitz, PatientRx Ltd, UK and Henri Caplain, Consultant, France
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 and WHO guidelines for our future performance of clinical trials - Barbara Baroutsou, IFAPP, Greece • The VolREthics Initiative – What will it change? – François Bompart, INSERM Ethics Committee, France • The eConsent Initiative – What It Is, What It Isn't, and Tools to Implement eConsent - Hilde Vanaken, TCS, EFGCP, Belgium
	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 (FHIN): transform healthcare with data (Speaker invited) • The We Are Platform: a sustainable civil-scientific ecosystem for personal health data - Elfi Goesaert, VITO, Belgium
17:30 - 18:00	Closing Keynote Presentation: Evolving a new framework to optimize drug development by Richard Hargreaves, Bristel Myers Squibb, USA
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 - 10:15	Update on safety biomarkers in early clinical development • Interest and use of emerging safety biomarkers in the drug development by Philippe Detilleux, Sanofi, France • Kidney safety biomarkers in human and approach to interpret emerging exploratory biomarkers by Emmanuel Krupka & Olivier Roux, Sanofi, France • CNS safety biomarkers in human and approach to interpret emerging exploratory biomarkers (Speaker invited)
10:15 - 10:45	Coffee break
10:45 - 11:30	Research in the spotlight: Poster pitches of selected abstracts and Audience Voting for best presentation award
11:30 - 13:00	Artificial Intelligence in Clinical Development: Buzzword, vision, or reality? (Speakers invited)
13:00 - 13:15	Summary & End of conference
13:15 - 14:00	Farewell lunch

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