EUROPEAN FEDERATION
FOR EXPLORATORY
MEDICINES DEVELOPMENT

EUFEMED Workshop

"Making the Investigator's Brochure truly fit for purpose in early medicines development"

September 20, 2024, Warsaw, Poland

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Programme

Friday, September 20, 2024

from 8:00	Registration
9:00	Welcome and Introduction ***Jan de Hoon, UZ Leuven, Belgium***
9:10	What does the PI of an early phase clinical trial need from an Investigator's Brochure? ***Jeroen van Smeden, CHDR, Netherlands***
9:40	What does a Regulator authorizing an early phase clinical trial need from an Investigator's Brochure? ***Sandrine Tinton, AFMPS, Belgium***
10:10	What are the challenges of pre-clinical and translational experts in interpreting, risk-assessing and explaining the so far existing results? ***Daniela Guckelberger, PCS, Switzerland***
10:40 – 11:00	Coffee Break
11:00	Break-out sessions I

1. Preclinical Aspects: e.g., what data need to be included, how to present this data, risk benefit for first-in-human.
   Stephanie Plassmann, PCS, Switzerland
   Thijs van Iersel, ICON, Netherlands

2. Clinical / life cycle IBs: e.g., update of IB during drug cycle, how to keep the IB understandable and ´short´, updates of risk-benefit, substantial amendments.
   Henri Caplain, France
   Nariné Baririan, Chiesi, Italy

3. Regulatory Aspects: e.g., what is needed for correct reviews, how to present data clearly, when to make amendments, input from different countries.
   Sandrine Tinton, AFMPS, Belgium
   Ingrid Klingmann, Pharmaplex, Belgium
   Claudia Riedel, BfArM, Germany

4. Investigator / end-user Aspects: e.g., needs for interpreting safety of participants, difference early / late phase investigators
   Yves Donazzolo, Eurofins Optimed, France
   Jeroen van Smeden, CHDR, The Netherlands
   Ronald Koning, Biokinetica, Poland

12:15 – 13:00 Lunch Break

13:00 *Break-out sessions 2*

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14:00 Reports with discussion from the Break-out Sessions
Moderator: Ingrid Klingmann, Pharmaplex, Belgium

15:30 – 15:45 Coffee Break

15:45 Discussion and decision on concluding recommendations for the early phase IB guideline
Moderator: Jelle Klein, SGS, Belgium

16:30 End of the Workshop

Workshop Date and Time

Friday, September 20th, 2024
9:00 – 16:30

Venue

University of Warsaw, Faculty of Modern Languages
Dobra 55 (entrance from Browarna Street)
00-312 Warsaw, Poland

Organizing society

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