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)

www.oeslive.pl/eufemed

Preliminary Programme
Status: June 2024

Friday, 20 September 2024

from 8:00	Registration
09:00	Welcome and Introduction ***Jan de Hoon, UZ Leuven, Belgium***
09:10	What does the PI of an early phase clinical trial need from an Investigator's Brochure? ***Jeroen van Smeden, CHDR, Netherlands***
09:40	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 Arndt, PCS, Switzerland***
10:40 – 11:00	Coffee Break
11:00 – 12.15	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;
   N.N. BfArM (invited)

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;
   N.N. late phase investigator Poland (invited)

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 Applied Linguistics
Dobra 55
00-312 Warsaw, Poland

Organizing society

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