



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](http://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*

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, AFPMs, 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)***

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 20<sup>th</sup>, 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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## Management and Contact

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## Webpage and online Registration

[www.oeslive.pl/eufemed](http://www.oeslive.pl/eufemed)