

*Mastering the New Time Pressure
on Human Pharmacology*

4th



EUROPEAN FEDERATION
FOR EXPLORATORY
MEDICINES DEVELOPMENT

Conference

25-26 May 2023, Berlin (Germany)

Pre-Conference Workshop

24 May 2023, Berlin

*The challenges in conducting
human challenge trials:
from COVID-19 and beyond...*

www.eufemed-conference.eu

Preliminary Programme

Status: March 2023, subject to change

Pre-Conference, Wednesday, 24 May 2023

from 12:00 Registration

13:00-18:00 Pre-Conference Workshop

The challenges in conducting human challenge trials: from COVID-19 and beyond...

Day 1, Thursday, 25 May 2023

from 8:00 Registration

8:45 Welcome and Introduction by the President
Tim Hardmann

Session 1 9:00-10:30 How to establish a sound basis for human risk assessment
Chairs **Jan de Hoon**, Belgium; **Rob Zuiker**, The Netherlands

9:00 The pre-clinical perspective
Stephanie Plassmann, Germany

9:25 The ethics review perspective
Joop Van Gerven, The Netherlands

9:50 The clinical perspective
Henri Caplain, France

10:15 Moderated plenary discussion with the speakers

10:30 Break

Session 2 11:00-12:30 Challenges in healthy volunteers and patient recruitment for human pharmacology trials - Experiences and Suggestions
Chairs **Izaak den Daas**, The Netherlands; **Jörg Täubel**, UK

11:00 Studies in healthy volunteers: Evolution in recruitment of healthy volunteer trials, before, during and after the pandemic
Jelle Klein, Belgium

Main challenges for the inclusion of patients in phase I trials
Izaak den Daas, The Netherlands

„Why I took part in a clinical trial“ – Results from a motivation survey amongst Polish healthy volunteers
Agnieszka Kulesza, Poland

Ethical challenges in recruitment for phase I trials
Yves Donazzolo, France

11:45 Moderated plenary discussion with the speakers:
How to improve the situation?

12:30 Lunch-Break

Session 3 14:00-15:30 Posters and Short Presentations on topics of translational
pharmacology
Chairs **Kerstin Breithaupt-Grögler**, Germany; **Erik Mannaert**, Belgium

14:00 6 Selected Short Presentations.
Election of the Winning Short Presentation and Poster

15:30 Break

Session 4 16:00-17:30 Increasing Digitalisation in Human Pharmacology Studies
Management: Helping or Hindering Speeding-up clinical trials?
– Experiences and Suggestions
Chairs **Henri Caplain**, France; **Sybille Baumann**, Germany

Nextgen endpoints for clinical drug development
Kristin Hannesdottir, Switzerland

Handling of digital endpoints
tba

16:40 Moderated plenary discussion

17:30 End of Day 2

17:30 *Get-Together*
with celebration of the 30th Anniversary of AFPT
and interactive Tabletop presentations of innovative
tools and methods

Day 2, Friday, 26 May 202

Session 5 9:00-10:30 Innovative Trial Approaches to Move Efficiently
from FiM to Patient Participants
– Experiences and Suggestions
Chairs **Paul Goldsmith**, UK; **Andreas Kovar**, Germany

9:00 POM - It is all about proof and mechanism
Fabienne Schuhmacher, Germany

- 9:20 From Celecoxib to Gene Editing – Experiences of London based first in human principal investigator a **Jörg Täubel, UK**
- 9:40 Fair consent processes in early phase research – striking a balance between benefits and harms **Hugh Davies, UK**
- 10:00 Moderated plenary discussion
- 10:30 Break

Session 6 11:00-12:00 None fits all: (adaptive) scientific advice formats in the (innovative) pharmaceutical development process - Experiences and Suggestions

Chairs **Ingrid Klingmann, Germany**

- 11:00 Presentation of the new regulatory support toolbox for early (clinical) development and beyond **Bettina Ziegele, Germany**
- 11:30 Moderated plenary discussion: How can these options best be used for innovative early pharmaceutical medicines development by academia, large and small pharma companies?
- 12:00 Lunch

Session 7 13:30-15:10 Ensure Efficiency of Collaboration between Sponsors and Clinical Trial Units under the Clinical Trial Regulation – Experiences and Suggestions

Chairs **Tim Hardman, UK; Jelle Klein, Belgium**

- 13:30 How can CROs support big pharma as well as small biotech companies in their CTR submission **Sybille Baumann, Germany**
- Sponsor and CTU communication during the dossier preparation and trial authorisation process – Experiences from sponsor and site perspectives *tba*
- 14:15 Moderated plenary discussion
- 15:00 Closing Remarks and Farewell from the President Elect **Jan de Hoon, Belgium**
- 15:10 End of the Conference

Scientific and Programme Committee

Sybille Baumann (AGAH), Kerstin Breithaupt-Grögler (AGAH),
Henri Caplain (AFPT), Izaak den Daas (ACRON), Yves Donazzolo (AFPT),
Paul Goldsmith (AHPPI), Tim Hardman (AHPPI), Jan de Hoon (HEALIXIA),
Ingrid Klingmann (AGAH), Jelle Klein (HEALIXIA), Andreas Kovar (AGAH),
Agnieszka Kulesza (POLFEMED), Erik Mannaert (HEALIXIA),
Ewa Urbanczyk (POLFEMED), Rob Zuiker (ACRON)

Conference Dates

24 May 2023, 13:00-18:00 Pre-Conference Workshop

25 May 2023, 8:45-17:30 Day 1

26 May 2023, 9:00-15:00 Day 2

Venue

LANGENBECK VIRCHOW HAUS
Luisenstraße 58/59
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Webpage and online Registration

www.eufemed-conference.eu

Speakers and Chairs

Baumann, Sybille Dr · CRS Clinical Research Services Berlin GmbH · Berlin/DE

Breithaupt-Grögler, Kerstin Dr · -kbr- clinical pharmacology services · Frankfurt/DE

Caplain, Henri Dr · Independent Senior Consultant · Paris/FR

Danjou, Philippe · BioTrial / DANJOU consulting · Rennes/FR

Davies, Hugh · HRA; Specialist Research Ethics Committee · UK

de Hoon, Jan Prof. · UZ Leuven · Leuven/BE

den Daas, Izaak · QPS Netherlands · NL

Donazzolo, Yves Dr · Eurofins Optimed · Grenoble/FR

Goldsmith, Paul · Eli Lilly · UK

Hannedottir, Kristin · NIBR · SW

Hardman, Tim Dr · Niche Science & Technology Ltd. · Richmond/UK

Klein, Jelle Dr · SGS · BE

Klingmann, Ingrid Dr · Pharmaplex bvba · Wezembeek-Oppem/BE

Kovar, Andreas Dr · Sanofi-Aventis Deutschland GmbH · Frankfurt/DE

Mannaert, Erik Dr · Janssen Pharmaceutica N.V. · Merksem/BE

Moerland, Matthijs · Centre for Human Drug Research · Leiden/NL Plassmann,

Stephanie Dr · PreClinical Safety (PCS) Consultants Ltd · Basel/SW

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Täubel, Jörg Dr · Richmond Pharmacology · London/UK

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