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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
10117 Berlin
GERMANY
www.langenbeck-virchow-haus.de

Organizing society

EUFEMED
Rue de l'industrie 4
1000 Brussels
BELGIUM
info@eufemed.eu · www.eufemed.eu

Conference Management and Contact

CSi Hamburg GmbH
PCO Professional Conference Organizer
Goernestraße 30
20249 Hamburg (Germany)
+49 (0)40 30770300 · meetings@csihamburg.de

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Webpage and online Registration

https://eufemed-conference.eu/2023/registration/

Mastering the New Time Pressure on Human Pharmacology

4th EUFEMED onference

EUROPEAN FEDERATION FOR EXPLORATORY MEDICINES DEVELOPMENT

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: April 2023, subject to change

Pre-Conference Workshop, Wednesday, 24 May 2023

13:00-18:00 — *The challenges in conducting human challenge trials: from COVID-19 and beyond...*

Each presentation incl. 10 min Q&Q

13:00 Welcome
Henri Caplain, France

13:10 General introduction: Challenge studies, what's in a name?
Jan de Hoon, Belgium

13:30 Challenge studies with infectious agents
Emma Smith, United Kingdom

14:05 Challenge studies with infectious agents: pro, cons and ethical aspects
Hugh Davies, United Kingdom

14:40 Challenge studies in asthma
Harun Badakhshi, Germany

15:15–15:45 Break

15:45 Challenge studies with immunological stimulants
Matthijs Moerland, The Netherlands

16:20 Challenge agents in target engagement models
Jan de Hoon, Belgium

16:55 (remote presentation)
Challenge studies in pain: the pleasure of applying pain…
Philippe Danjou, France

17:25 General discussion and closing remarks

Day 1, Thursday, 25 May 2023

8:45 Welcome and Introduction by the President
Tim Hardmann, United Kingdom

9:00-10:30 — Session 1

How to assess risk from pre-clinical to clinical research more efficiently | Experiences and suggestions
Chairs: *Jan de Hoon, Belgium; Rob Zuiker, The Netherlands*

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

9:25 The clinical perspective
Henri Caplain, France

9:50 The regulatory perspective
Joop van Gerven, The Netherlands

10:15 Moderated plenary discussion with the speakers

10:30-11:00 Break and visit the industry partnerships

11:00-12:30 — Session 2

Challenges in healthy volunteers and patient recruitment for human pharmacology trials - Experiences and Suggestions
Chairs *Izaak den Daas, The Netherlands; Jörg Täubel, United Kingdom*

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 survery 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?

12:30-14:00 Lunch-Break and visit the industry partnerships

14:00-15:30 — Session 3

Posters and short Presentations on topics of translational pharmacology
Chairs *Kerstin Breithaupt-Grögler, Germany; Erik Mannaert, Belgium*

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

15:30-16:00 Break and visit the industry partnerships

16:00-17:30 — Session 4

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

16:00 Nextgen endpoints for clinical drug development
Jelena Curcic, Switzerland; *Kristin Hannesdottir, USA*

16:40 Digitalisation in early clinical trials: theory and practical examples
Sverre Bengtsson, Sweden

17:05 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

Day 2, Friday, 26 May 2023

9:00-10:30	Session 5
	Innovative Trial Approaches to Move Efficiently from FiM to Patient Participants – Experiences and Suggestions
Chairs	*Paul Goldsmith, United Kingdom; Andreas Kovar, Germany*
9:00	POM - It is all about proof and mechanism *Fabienne Schumacher, Germany*
9:20	From Celecoxib to Gene Editing – experiences of a London based first in human principal investigator *Jörg Täubel, United Kingdom*
9:40	Fair consent processes in early phase research - striking a balance between benefits and harms *Hugh Davies, United Kingdom*
10:00	Moderated plenary discussion
10:30-11:00	Break and visit the industry partnerships
11:00-12:00	Session 6
	None fits all: (adaptive) scientific advice formats in the (innovative) pharmaceutical development process - Experiences and Suggestions
Chairs	*Dick de Vries, The Netherlands; 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?
12:00-13:30	Lunch-Break and visit the industry partnerships
13:30-15:10	Session 7
	Ensure Efficiency of Collaboration between Sponsors and Clinical Trial Units under the Clinical Trial Regulation - Experiences and Suggestions
Chairs	*Tim Hardman, United Kingdom; Jelle Klein, Belgium*
13:30	How can CRO`s 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*

Speakers and Chairs

Badakhshi, Harun Dr · Charité Research Organisation GmbH · Berlin/DE
Baumann, Sybille Dr · CRS Clinical Research Services Berlin GmbH · Berlin/DE
Bengtsson, Sverre · Viedoc · S
Breithaupt-Grögler, Kerstin Dr · -kbr- clinical pharmacology services · Frankfurt/DE
Caplain, Henri Dr · Independent Senior Consultant · Paris/FR
Curcic, Jelena · Novartis Institutes for BioMedical Research (NIBR) · SW
Danjou, Philippe · BIOTRAL / DANJOU consulting · Rennes/FR
Davies, Hugh · HRA Specialist Research Ethics Committee · London/UK
de Hoon, Jan Prof. · UZ Leuven · Leuven/BE
de Vries, Dick · Galápagos Biopharma Netherlands B.V. · Oegstgeest/NL
den Dass, Izaak · QPS Netherlands B.V. · Leeuwarden/NL
Donazzolo, Yves Dr · Eurofins Optimed · Grenoble/FR
Goldsmith, Paul · Eli Lilly · Bishop's Stortford/UK
Hannesdottir, Kristin · Novartis Institutes for BioMedical Research (NIBR) · Boston/USA
Hardman, Tim Dr · Niche Science & Technology Ltd. · Richmond/UK
Klein, Jelle Dr · SGS · Edegem/BE
Klingmann, Ingrid Dr · Pharmaplex bvba · Wezembeek-Oppem/BE
Kovar, Andreas Dr · Sanofi-Aventis Deutschland GmbH · Frankfurt/DE
Kulesza Agnieszka · Biokinetica S.A. · Jozefow/PL
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
Schumacher, Fabienne · Sanofi-Avebtis Deutschland GmbH · Frankfurt/DE
Smith Emma · Imperial College, Department of Infectious Disease · London/UK
Täubel, Jörg Dr · Richmond Pharmacology · London/UK
Van Gerven, Joop Prof. · University of Leiden · Leiden/NL
Ziegele, Bettina · Paul-Ehrlich-Insitut (PAI) · Langen/DE
Zuiker, Rob Dr · Centre for Human Drug Research · Leiden/NL

Call for Abstracts

The abstract submission is open until 7 April 2023.

We would like to invite conference participants to contribute to the scientific programme of the EUFEMED conference 2023 by submitting abstracts that can be considered as poster- and additional short oral prestentation. Abstracts with a focus on Exploratory Medicines Development are highly welcome. Presented topics may be related to the conference topic or may concern other methodological or scientific aspects of translational pharmacology and early phase clinical trials. Click here an read more to start the submission more...

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NEW in this conference and a first time option: service providers and industry/academia sponsors can book a TABLETOP and personally present an innovative tool/technology/methodology at the Get-Together evening.

We invite you to concretely contribute to all our knowledge and progress awareness. At the same time you support EUFEMED as your "European professional family". If you want to support this conference financially, we would like to invite you to sponsor nd early phase clinical trials. Read more...