

## Programme and Organisation Committee Members

Kerstin Breithaupt-Grögler<sup>2</sup> (AGAH), Henri Caplain<sup>1</sup> (AFPT),  
Yves Donazzolo<sup>1,2</sup> (AFPT), Tim Hardman<sup>1</sup> (AHPPI), Jan de Hoon<sup>1</sup> (Healixia),  
Ingrid Klingmann<sup>1,2</sup> (AGAH), Andreas Kovar<sup>1</sup> (AGAH),  
Erik Mannaert<sup>1</sup> (Healixia), Jens Rengelshausen<sup>1</sup> (AGAH),  
Hildegard Sourgens<sup>2</sup> (AGAH), Bettina Ziegele<sup>1</sup> (AGAH)

## Conference Dates

Day 1 28 April 2021, 12:30-17:30 CEST  
Day 2 29 April 2021, 12:30-18:00 CEST  
Day 3 30 April 2021, 12:30-17:40 CEST

## Contact and further information

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

The **European Federation for Exploratory Medicines Development** - EUFEMED - was founded in 2015 as a result of an ongoing, informal collaboration between several European societies active in the area of human pharmacology. The founding associations included: the Belgian Association for Phase-I Units (BAPU, Belgium), Club Phase I (France), the Association for Applied Human Pharmacology (AGAH, Germany) and the Association for Human Pharmacology in the Pharmaceutical Industry (AHPPI, United Kingdom).

## Conference Management and Contact

CSi Hamburg GmbH  
PCO Professional Conference Organizer  
Goernestraße 30  
20249 Hamburg (Germany)  
+49 (0)40 30770300 · eufemed2021@csihamburg.de



## Webpage and online Registration

www.eufemed-conference.eu

## Speakers and Chairs

Abdul-Ahad, Ajad Dr · Niche Science & Technology Ltd. · Richmond/UK  
Breithaupt-Grögler, Kerstin Dr · -kbr- clinical pharmacology services · Frankfurt/DE  
Caplain, Henri Dr · Independent Senior Consultant · Paris/FR  
Chiu, Christopher Dr · Imperial College London · London/UK  
Davies, Elin Haf Dr · aparito · Wrexham/UK  
Dewland, Peter Dr · MAC Clinical Research · Manchester/UK  
van Dijkman, Sven MD, PhD · GlaxoSmithKline · London/UK  
Donazzolo, Yves MD, Msc · Eurofins Optimed · Grenoble/FR  
Galm, Oliver Prof. Dr · Grünenthal GmbH · Aachen/DE  
van Gerven, Joop Prof. Dr · Universiteit Leiden · Leiden/NL  
Gosselin, Alice · Sanofi · Paris/FR  
Hardman, Tim Dr · Niche Science & Technology Ltd. · Richmond/UK  
de Hoon, Jan Prof. Dr · UZ Leuven, Center for Clinical Pharmacology · Leuven/BE  
Jones, Trevor M. Prof. · UK  
Klingmann, Ingrid MD, PhD · Pharmaplex bvba · Wezembeek-Oppem/BE  
Kovar, Andreas Dr · Sanofi-Aventis Deutschland GmbH · Frankfurt/DE  
Lioznov, Dmitry MD · Ministry of Health of the Russian Federation · St. Petersburg/RU  
Llinares Garcia, Jordi Dr · European Medicines Agency · HS Amsterdam/NL  
Mannaert, Erik Dr · Janssen Pharmaceutica N.V. - CPU · Merksem/BE  
Musch, Greet Dr · federal agency for medicines and health products · Brussels/BE  
Neyts, Johan Prof. Dr · Rega Institute, KU Leuven · Leuven/BE  
Petit, Caroline · Sanofi · Paris/FR  
Pfleiderer, Michael Dr · Biopharma Excellence GmbH · Munich/DE  
Rengelshausen, Jens Dr · Grünenthal GmbH · Aachen/DE  
Schacke, Katharina · SocraMetrics GmbH · Oberursel/DE  
Schug, Barbara Dr · SocraMetrics GmbH · Oberursel/DE  
Seimetz, Diane Dr · Biopharma Excellence GmbH · Munich/DE  
Sourgens, Hildegard Prof. Dr · Consultant · Munich/DE  
Sudhop, Thomas Prof. Dr · BfArM · Bonn/DE  
Taubel, Jorg Dr · Richmond Pharmacology Ltd. · London/UK  
Widler, Beat Dr · Widler & Schiemann AG · Basel/CH  
Wydenbach, Kirsty · Medicines and Healthcare Products Regulatory Agency MHRA · London/UK  
Ziegele, Bettina · Paul-Ehrlich-Institut · Langen/DE



**Exploratory Development  
of Novel Therapeutic Approaches -  
Focused strategies based on  
lessons learned in the pandemic**

*3<sup>rd</sup> EUFEMED Conference, virtual*

**28-30 April 2021**

**Preliminary Programme**

Status April 2021, subject to change

## Day 1, Wednesday, 28 April 2021

from 12:30	Dial-in
12:45	Welcome by the EUFEMED President and get-together <i>Yves Donazzolo, France</i>
<b>Session 1</b>	<b>How to better prepare European early medicines development for future pandemics</b>
Chairs	<i>Yves Donazzolo, France;</i> <i>Tim Hardman, United Kingdom</i>
13:15	<i>Keynote Lecture:</i> Drug discovery and early development strategies for prevention and treatment of virus infections (including repurposing) <i>Johan Neyts, Belgium</i>
13:45	Innovative EU marketing authorisation strategies in times of a pandemic <i>Jordi Llinares Garcia (EMA), The Netherlands</i>
14:15	The role of early phase data in the UK approach to market authorisation for SARS-CoV-2 vaccines <i>Kirsty Wydenbach (MHRA), United Kingdom</i>
14:45	Panel & Open Forum discussion with speakers and the audience
15:15	Break and Networking with your colleagues and exhibitors
<b>Session 2</b>	<b>Technology support to reduce the risks of pandemic effects on Phase1/2 trial performance</b>
Chairs	<i>Henri Caplain, France</i> <i>Jorg Taubel, United Kingdom</i>
16:00	Technologies in trial conduct (including tracing, testing, remote technologies for trials) <i>Elin Haf Davies, United Kingdom</i>
16:30	Covid-19 the tipping point in GCP: From reactive to prospective and proactive quality and compliance management <i>Beat Widler, Switzerland</i>
17:00	Panel & Open Form discussion with speakers and the audience
17:30	End of Day 1

## Day 2, Thursday, 29 April 2021

from 12:30	Dial-in
12:45	Introduction into the day's programme <i>Hildegard Sourgens, Germany</i>
Moderator	This Conference Day is dedicated to getting updates from researchers and service providers on particularly relevant innovations in early medicines development and on exchange of own experiences with colleagues in parallel sessions.
13:00	<i>Parallel interactive Break-out Sessions, Round 1</i>
Room 1	<b>Benefit-risk evaluation of Advanced Therapy Medicinal Products (ATMPs) - short- and long-term aspects</b> <i>Henri Caplain, France; Oliver Galm, Germany</i> <i>Bettina Ziegele (PEI), Germany</i>
Room 2	How will working and training change after the COVID-19 experiences with travel and meeting restrictions? <i>Kerstin Breithaupt-Grögler, Germany</i> <i>Tim Hardman, United Kingdom</i>
Room 3	Early phase clinical trials under the Clinical Trials Regulation: procedures and timelines <i>Yves Donazzolo, France; Katharina Schacke, Germany;</i> <i>Barbara Schug, Germany; Thomas Sudhop (BfArM) Germany</i>
Room 4	<b>SARS-CoV2 vaccine development experiences - Example of CanSino vaccine</b> <i>Ayad Abdul-Ahad, United Kingdom; Dmitry Lioznov, Russia</i>
14:30	Break
<b>Session 3</b>	<i>Poster Presentations</i>
Chairs	<i>Eric Mannaert, Belgium; Jens Rengelshausen, Germany</i>
14:35	Poster presentations and discussions
Chairs	<i>Parallel track:</i> scientific and methodology presentations from exhibitors <i>Hildegard Sourgens, Germany</i>
15:45	Break and Networking in the virtual exhibition
16:05	<i>Parallel interactive Break-out Sessions, Round 2</i>  (repeat of Round 1, Room 1-4)
17:35	“Participants’ Apéro” Welcome by the President and incoming President Meet your colleagues and exhibitors virtually

## Day 3, Friday, 30 April 2021

from 12:30	Dial-in
12:45	Introduction into the day's programme <i>Ingrid Klingmann, Belgium</i>
Moderator, Chair	
12:50	<b>OXFORD Debate</b> - Do we really need placebo in single ascending dose studies? <i>Peter Dewland; Sven Van Dijkman, United Kingdom</i>
13:35	Break and Networking with your colleagues and exhibitors
<b>Session 4</b>	<b>Trends in clinical trial designs</b>
Chairs	<i>Jan de Hoon, Belgium; Andreas Kovar, Germany</i>
13:55	How can extrapolation between populations improve decision-making and speed-up early phase development using biostatistics? <i>Alice Gosselin; Caroline Petit, France</i>
14:25	Preclinical and early clinical design challenges in ATMP development <i>Diane Seimetz, Germany</i>
14:55	SARS-CoV-2 viral challenge study in healthy volunteers <i>Christopher Chiu, United Kingdom</i>
15:25	Panel & Open Forum discussion with speakers and the audience
15:45	Break and Networking with your colleagues and exhibitors
<b>Session 5</b>	<b>Regulatory experiences with COVID-19 trials and authorisations</b>
Chairs	<i>Joop van Gerven (CCMO), The Netherlands</i> <i>Kirsty Wydenbach (MHRA), United Kingdom</i>
16:05	Fast track clinical trial authorisation today and under the Clinical Trial Regulation <i>Greet Musch (FAMHP), Belgium</i>
16:35	Current status of COVID-19 antiviral therapeutics and plans for antivirals for future pandemic preparedness <i>Trevor M. Jones, United Kingdom</i>
17:05	Success and failures in early vaccine development, experience with COVID-19 vaccines <i>Michael Pfleiderer, Germany</i>
17:35	Panel & Open Forum discussion with speakers and the audience
17:55	Closing remarks from the board