

WELCOME

to the 6th EFSPI Regulatory Statistics Workshop 2021

Webinar 2: Complex innovative designs: Where is their place in drug development?

We have put you on mute We are waiting for other attendees to join We will start soon

6th EFSPI Regulatory Statistics Workshop 13th – 15th September 2021

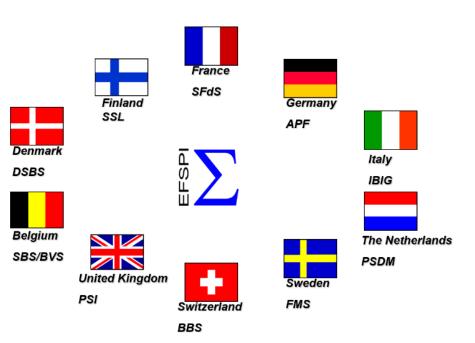
- Three webinar sessions devoted to:
- Yesterday 1. Decentralized trials: What is the impact on evidence generation?
- Today 2. Complex innovative designs: Where is their place in drug development?
- Tomorrow 3. Real-world data using their potential.

- Organization: EFSPI and organizing committees
 THANKS!
- Host: Roche (in particular Kaspar Rufibach) THANKS!



What is **EFSPI**

- EFSPI = European Federation of Statisticians in the Pharmaceutical Industry
- Founded in 1992
- A federation of National European Groups
- Now have 10 national groups
- No individual members
- EFSPI is an "umbrella", non-profit making organisation
- Our national organisations collectively represent 2200 members
- Each organisation has 2 members on the EFSPI Council
- Website: <u>www.efspi.org</u>



6th Regulatory Statistical Workshop!

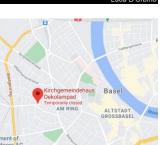
• 2nd time virtual workshop

5 In



• 2022 live meeting???

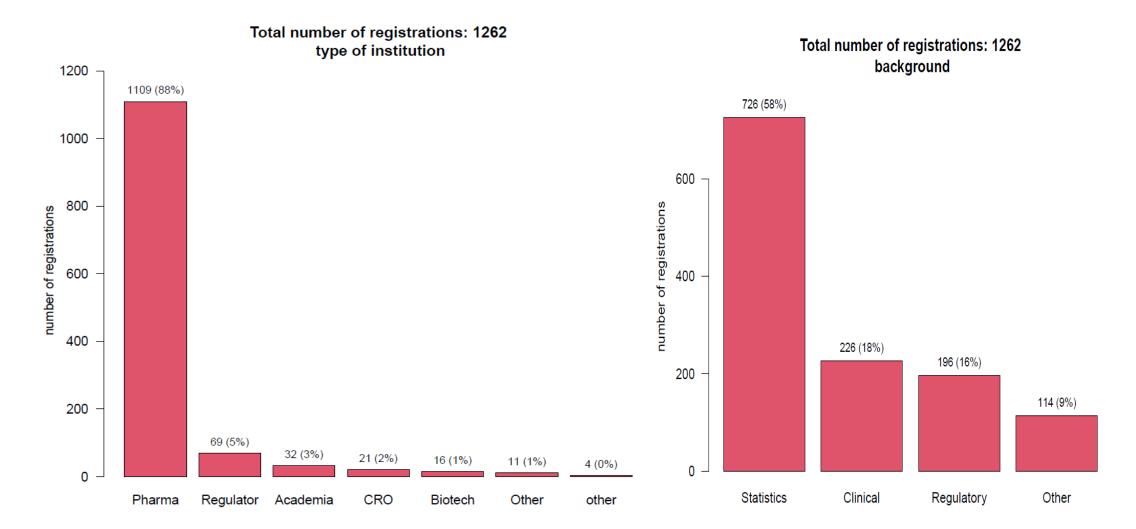




EFSPI

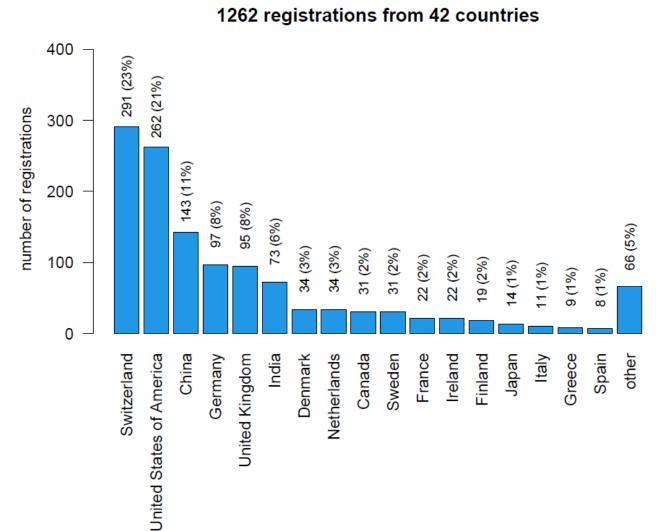
High number of participants

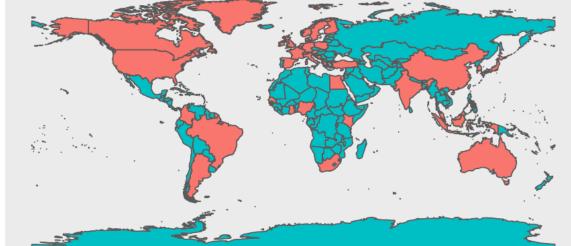
from 200+ live workshop (2019), ≈ 700 people in webinar (2020) More than 1200 participants now!!





Worldwide representation





Big thank you to the organizers!

Local organizing committee

Egbert Biesheuvel (Danone)

Hans Ulrich Burger (Roche)

Christoph Gerlinger (Bayer)

Kaspar Rufibach (Roche)

Emmanuel Zuber (Novartis)

Scientific committee

Elina Asikanius (Finland)

Andreas Brandt (BfArM)

Maria Grünewald (Swedish Medical Products Agency)

Randi Gron (Novo Nordisk)

Cecilia Hedlund (Swedish Medical Products Agency)

Lorenzo Hess (Swissmedic)

Benjamin Hofner (Paul-Ehrlich Institute)

Armin Koch (Medizinische Hochschule Hannover)

Eftychia-Eirini Psarelli (EMA)

Khadija Rantell (MHRA)

Kit Roes (Radboud UMC)

Aldana Rosso (Danish Medicines Agency)

Anja Schiel (Norwegian Medicine Agency)

Steven Teerenstra (Radboud UMC)