

Welcome

to the 6th EFSPI

Regulatory Statistics Workshop

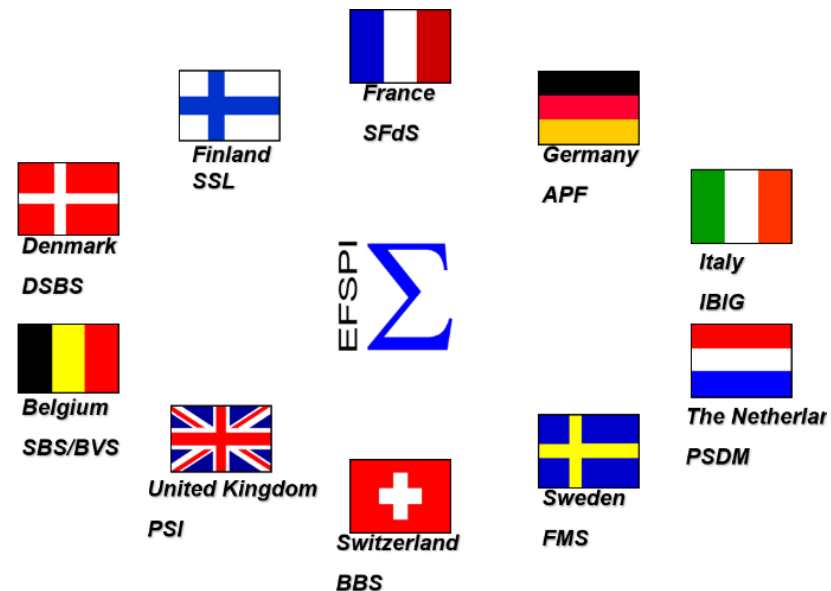
webinar 1: Decentralized trials

Next days to come

- Webinar 2
 - Tuesday, September 14, 2021
 - Complex innovative designs
- Webinar 3
 - Wednesday, September 15, 2021
 - Real-world data

What is EFSPI ?

- EFSPI = European Federation of Statisticians in the Pharmaceutical Industry
- Founded in 1992
- A federation of National European Groups
- Currently 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: www.efspi.org





EFSPI objectives

- To promote professional standards of statistics and the standing of the statistical profession in the pharmaceutical industry
- To offer a collective expert input on statistical matters to national and international authorities and organisations
- To exchange information on and harmonise attitudes to the practise of statistics in the European Pharma Industry and within member groups

Upcoming events with EFSPi involvement

28.09.2021 DIA webinar:

Estimands How and Why - A Real Life Case
Study in Oncology

(co-organized by EFSPi / PSI WG estimands in oncology)

[link](#)

21.10.2021 Joint PSI, EFSPi and ASA BIOP Webinar:
Complex Innovative Designs

[link](#)

Upcoming EFSPi event on Decentralized trials

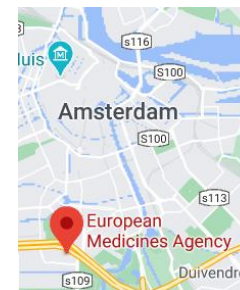
- Meeting to share and discuss **case studies** (from industry) of **statistical issues** associated with DCTs.
- Target: End of October – Early November.
- Three speakers confirmed
- **Question/desire: One or two more speakers**
- If you have any suggestion, please contact:
 - David Wright (david.wright1@astrazeneca.com), or
 - Egbert Biesheuvel (egbert.biesheuvel@danone.com)
- **Thanks!**

6th Regulatory Statistics Workshop

- 2nd time virtual workshop

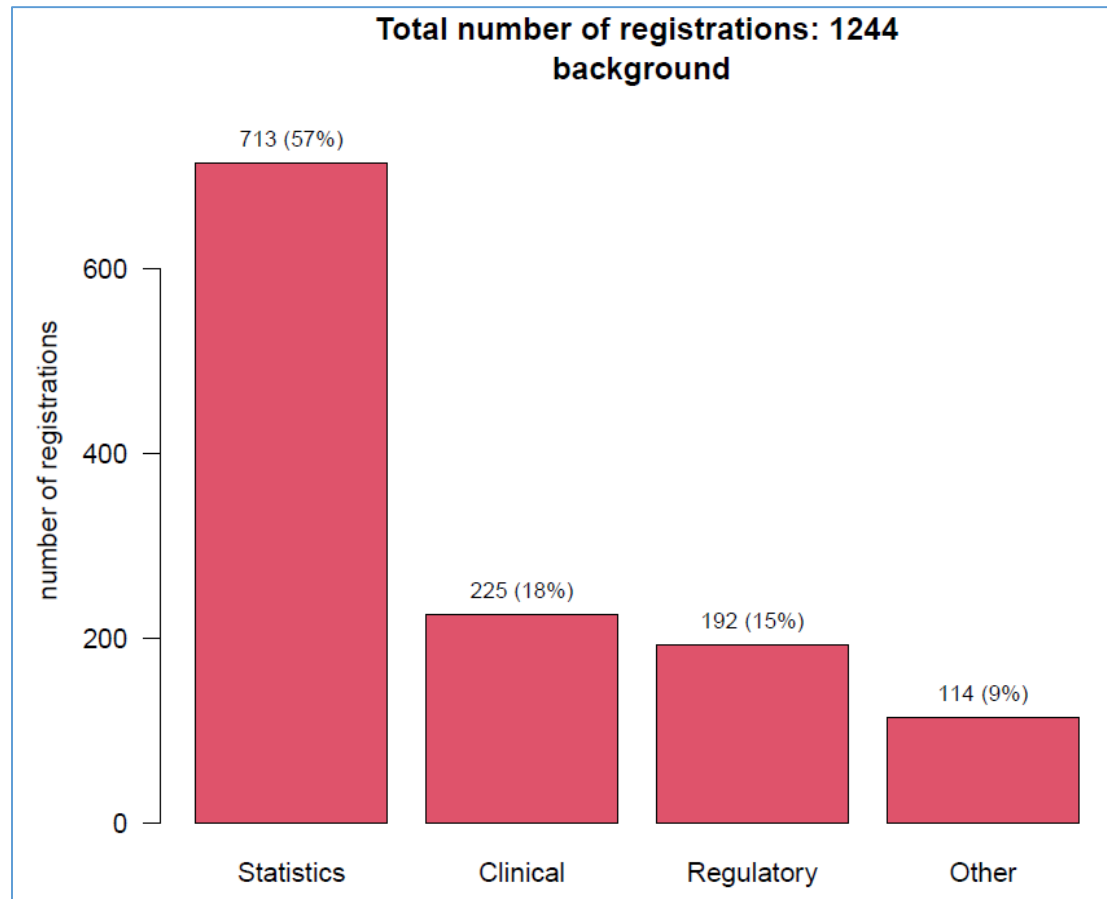
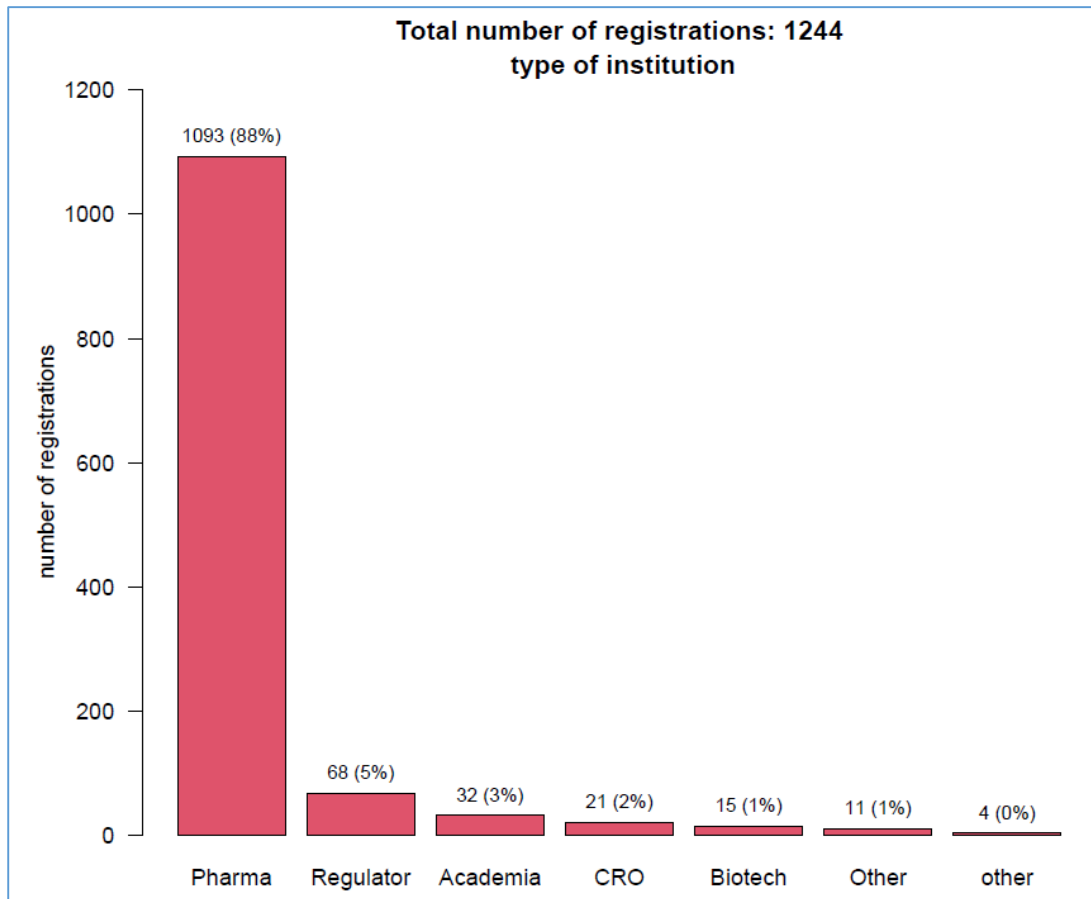


- 2022 live meeting???



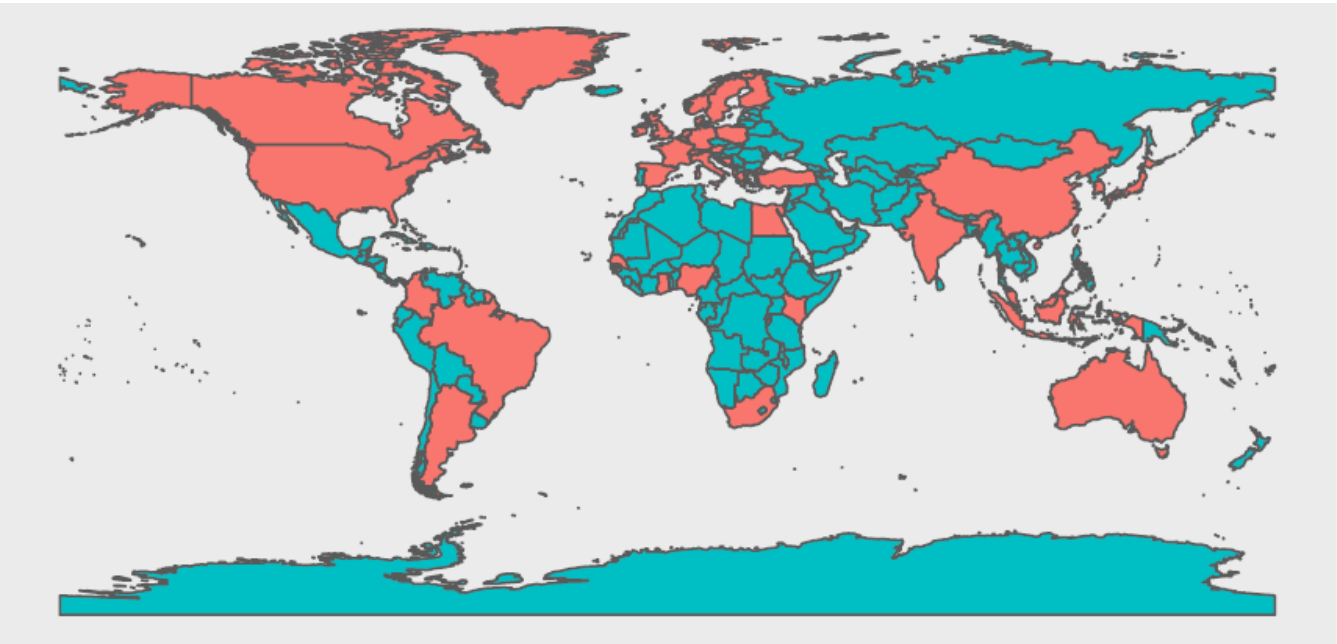
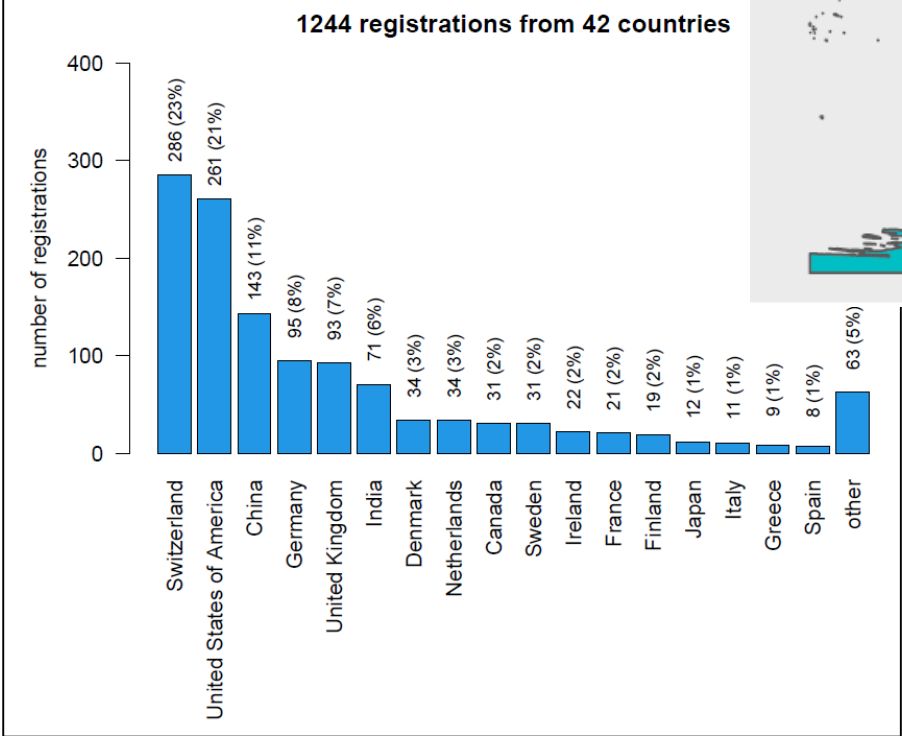
“Every disadvantage has its advantage”

large number of participants !



- 200+ in live workshops before Covid-19
- 800+ in 2020 virtual workshop

worldwide participation !



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)



And now swiftly to today's webinar

- Day 1 webinar
- EMA intro
- Decentralized trials: What is the impact on evidence generation?
- Moderators:
 - Emmanuel Zuber
 - Khadija Rantell

