European Statistical Forum
Statistical Reasoning in Drug Development

Data
25 October 2022

Lingua
🇬🇧
Inglese

Location
Barcelona, Spain

SPONSORS

αlgorics

MEDIA PARTNERS

CREATIONKnowledge
HCP insights for leaders in healthcare

INTRODUZIONE

Medical and pharmaceutical statistics have become a highly specialized field with technically advanced methods for exposure and response modeling, dose-finding, adaptive study designs, etc. However, teams sometimes struggle with issues and phenomena that appear much more basic but have a massive impact in practice.

Do we see patterns in data where there are none? Can we distinguish association from causation? How reproducible are subgroup findings, or scientific results in general?

The resolution of these and similar issues is often difficult in interdisciplinary settings, as it requires a blend of statistical, common-sense, and communicative skills.
It is however of vital importance that the results generated from the analyses of the clinical study data is properly understood and interpreted because wrong conclusions can result in a waste of time, effort, increase of costs and can compromise the safety and well-being of patients.

The European Statistical Forum (ESForum) shall include presentations focusing on various aspects of statistical reasoning:

- Reproducibility
- Hidden bias
- Multiplicity (endpoint selection, subgroups, etc.)
- Choice of scales and effect measures
- Prediction, attribution, estimation
- Association vs. causation
- Statistical significance vs. clinical relevance
- Pattern detection
- The interpretation of inferential statistics both in the frequentist as well as in the Bayesian framework.

Methodological approaches to the above issues as well as case studies and practical experiences will be presented.

Scientific Board
Jens-Otto Andreas - *SSI Business Operational Excellence Senior Lead* at UCB Biosciences GmbH
Lisa Comarella - *Director Biostatistics* at Alira Health Biometrics
Giacomo Mordenti - *Head of Biostatistics & Data Management Europe* at Daiichi Sankyo Europe GmbH
Marc Vandemeulebroecke - *Global Group Head for Dermatology* at Novartis Biostatistics

Who should attend?
This statistical conference is addressed to statisticians, pharmacometricians, regulatory affairs specialists, academia and other experts interested in the field belonging to: Pharmaceutical, and Biotechnology companies, CROs, Universities/Hospitals, Academic Research.

PROGRAMMA

25 October 2022	
08:30 **09:00**	**Registration**
09:00 **09:10**	**Welcome from the Scientific Board**
09:10 **09:50**	**Medical Statistics: only science, or also some art?** **Robert Hemmings** Consultant at Consilium Salmonson and Hemmings
09:50 **10:30**	**The Value of Biostatistics in the Interpretation of Clinical Studies** **Hans Ulrich Burger** Senior Director at Hoffmann-La Roche Ltd
10:30 **11:00**	**Coffee break**
11:00 **11:50**	**Cases of Multiplicity in Clinical Development – Same Zoo, Different Animals** **Cornelia Kunz** Methodology Statistician at Boehringer Ingelheim Pharma GmbH & Co. KG **Frank Fleischer** Head of Therapeutic Area and Methodology Statistics at Boehringer Ingelheim Pharma GmbH & Co. KG
11:50 **12:30**	**Planning of Clinical Trials Using Unconditional Probabilities** **Andy P Grieve** Statistical Research Fellow at UCB Pharma
12:30 **13:30**	**Networking lunch**
13:30 **14:10**	**Bayesian Statistics for Rare Diseases: from incorporation of auxiliary data to prediction of disease trajectory** **Bruno Boulanger** Senior Director, Global Head Statistics and Data Science at PharmaLex
14:10 **14:50**	**Generalized Pairwise Comparisons as a Statistical Method for Patient-Centric Medicine** **Vaiva Deltuvaite-Thomas** Research Statistician at International Drug Development Institute, IDDI

14:50 **15:20**	**Coffee break**
15:20 **16:00**	**Use of Bayesian Predictive Power for Interim Decisions with Time-to-Event Endpoints** **Rajat Mukherjee** VP Advanced Statistics and Data Science at Alira Health
16:00 **16:30**	**Round Table: Statistical Reasoning in Drug Development**
16:30 **16:40**	**Conclusions**

SPEAKERS

Scientific Board
Jens-Otto Andreas
SSI Business Operations
Excellence Senior Lead at
UCB Biosciences GmbH

Scientific Board
Lisa Comarella
Director Biostatistics at Alira Health
Biometrics

Scientific Board
Giacomo Mordenti
Head of Biostatistics &
Data Management Europe
at Daiichi Sankyo Europe
GmbH

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Speaker
Bruno Boulanger
Senior Director, Global
Head Statistics and Data
Science at PharmaLex

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Vaiva Deltuvaite-Thomas
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Drug Development Institute, IDDI

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Hans Ulrich Burger
Senior Director at
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Speaker
Frank Fleischer
Head of Therapeutic Area and
Methodology Statistics at Boehringer
Ingelheim Pharma GmbH & Co. KG

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Andy P Grieve
Statistical Research Fellow
at UCB Pharma

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Robert Hemmings
Consultant at Consilium Salmonson and
Hemmings

Speaker
Cornelia Kunz
Methodology Statistician at
Boehringer Ingelheim
Pharma GmbH & Co. KG

Speaker
Rajat Mukherjee
VP Advanced Statistics and Data Science
at Alira Health

QUOTE ISCRIZIONE

€ 670,00* Early Bird fee until 14 October 2022
€ 790,00* Ordinary fee
€ 430,00* Freelance, Academy, Public Administration

Fee includes: seat at the conference, copy of presentations of Speakers who allow the distribution, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.

* for Italian companies: +22% VAT

DURATA E INFORMAZIONI UTILI

The conference will take place at:

H10 Marina Barcelona
Av. Bogatell, 64-68 – E08005 – Barcelona

H10 Marina Barcelona is 10 minutes walk from the beach and 5 minutes away you have the Olympic Village. Closer to the Metro stop, Bogatell: it is just 2 minutes behind the hotel and can take you into the city centre in 15 minutes, or you could even walk in about 30-40 minutes.

100 m from Bogatell metro station (Line 4)
300 m from Marina metro station (Line 1)
15 km from Barcelona-El Prat airport

COVID-19
LS Academy is aware of the evolving impact of COVID-19 and is committed to offering safe and

secure face-to-face courses and conferences. From physical distancing, protect, detect, cleaning and hygiene. LS Academy ensures that all our events are conducted in accordance with official government guidelines and regulations, understanding that these measures may vary and change as the situation evolves.

SEDE DELLA CONFERENZA

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