

# European Statistical Forum

## Application of Causal Inference in Drug Development

Date  
**16 November 2021**

Language  
  
**English**

Location  
**Online**  
Virtual Conference

### MEDIA PARTNERS



### ABOUT

In 2020 the revision of ICH E9 has become effective in the ICH regions. Beyond the immediate operational consequences in terms of study documentation development, it has become clearer and clearer that the introduction of the Estimand framework may require methodological solutions which were not common practice in drug development when the revised guidance was released.



In this context, causal inference, or the problem of causality in general, has received a lot of attention in recent years. It appears to provide a suitable methodological framework for tackling some of these challenges.

Five years from now the event touched on Estimands. In this year's edition, the ESF goes back to Estimands to better understand the implications of the introduction of the ICHE9 (R1) guidance in terms of how the traditional approach of statistical inference may be affected in its fundamentals of sample size, testing, and estimation by the arrival of causal inference.

The conference will focus, among others, on the following areas:

- Regulatory perspective on study design development based on causal inference methods
- Operational implementation of causal inference methods
- Novel approaches based on causal inference methodologies
- Real case studies and practical approaches

### Scientific Board

Jens-Otto Andreas - *Project Lead Statistician* at UCB Biosciences GmbH

Lisa Comarella - *Director Biostatistics* at CROS NT

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?

The conference is addressed to statisticians, pharmacometricians, physicians, regulators, academia and other experts interested in the field belonging to: Pharmaceutical, and Biotechnology companies, CROs, Universities/Hospitals, Academic Research.

## PROGRAMME

All the below mentioned times are CET

16 November 2021	
10:00 am 10:15 am	Welcome
10:15 am 10:55 am	<b>Causal inference in drug development - a regulatory perspective</b>  <b>Theodor Framke</b> Seconded National Expert at European Medicines Agency
10:55 am 11:25 am	<b>An information-theoretic approach for the evaluation of surrogate endpoints based on causal inference</b>  <b>Ariel Alonso Abad</b> Professor at KULeuven



11:25 am 11:40 am	<b>Break</b>
11:40 am 12:10 pm	<b>Rephrasing Least Squares Means as a causal quantity</b>  <b>Christian Pipper</b> Senior Statistical Advisor at LEO Pharma A/S
12:10 pm 12:40 pm	<b>Hypothetical estimands in clinical trials - a unification of causal inference and missing data methods</b>  <b>Jonathan Bartlett</b> Reader in Statistics at University of Bath
12:40 pm 1:40 pm	<b>Lunch break</b>
1:40 pm 2:30 pm	<b>Principal Stratum Estimands in Drug Development</b>  <b>Björn Bornkamp</b> Senior Director Statistical Consultant at Novartis Pharma AG  <b>Baldur Magnusson</b> Senior Director Biostatistics at Novartis Pharma AG
2:30 pm 3:00 pm	<b>Treatment effect estimation with missing values</b>  <b>Julie Josse</b> Senior Researcher at Inria
3:00 pm 3:15 pm	<b>Break</b>
3:15 pm 4:05 pm	<b>Round Table: Application of Causal Inference in Drug Development</b>  <b>Ariel Alonso Abad</b> Professor at KULeuven  <b>Jonathan Bartlett</b> Reader in Statistics at University of Bath  <b>Björn Bornkamp</b> Senior Director Statistical Consultant at Novartis Pharma AG  <b>Theodor Framke</b> Seconded National Expert at European Medicines Agency  <b>Baldur Magnusson</b> Senior Director Biostatistics at Novartis Pharma AG  <b>Christian Pipper</b> Senior Statistical Advisor at LEO Pharma A/S



4:05 pm  
4:15 pm

## Conclusions

## SPEAKERS



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



*Scientific Board*  
**Lisa Comarella**  
Director Biostatistics at CROS NT



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



*Scientific Board*  
**Marc Vandemeulebroecke**  
Global Group Head for Dermatology at  
Novartis Biostatistics



*Speaker*  
**Ariel Alonso Abad**  
Professor at KULEuven



*Speaker*  
**Jonathan Bartlett**  
Reader in Statistics at University of Bath



*Speaker*  
**Björn Bornkamp**  
Senior Director Statistical  
Consultant at Novartis  
Pharma AG



*Speaker*  
**Theodor Framke**  
Seconded National Expert at European  
Medicines Agency



*Speaker*  
**Julie Josse**  
Senior Researcher at Inria



*Speaker*  
**Fabrizia Mealli**  
Professor of Statistics, Director of the  
Florence Center for Data Science at  
University of Florence



+39 035.515684 |



info@LSacademy.com

www.LSacademy.com



*Speaker*  
**Baldur Magnusson**  
Senior Director Biostatistics  
at Novartis Pharma AG



*Speaker*  
**Christian Pipper**  
Senior Statistical Advisor at LEO Pharma  
A/S

## TRAINING

---

**Pre-Conference Training**  
**15 November 2021**

**2.00 pm to 6.00 pm CET - Online**

**An Introduction to Causal Inference in Experimental and Observational Settings - *Theory and practice***

### **Introduction**

Most scientific questions are causal in nature. It is therefore necessary to introduce a formal causal language to help define causal effects and spell out the assumptions required to infer such effects from experimental and observational data.

### **Programme**

The potential outcome approach to causal inference will be introduced and statistical methods for inferring causal effects from randomized experiments or observational studies will be presented. Examples and practical sessions will be based on case studies in biostatistics, epidemiology, and public health.

- Introduction to causal inference from the potential outcome perspective.
- Design and analysis of randomized experiments: Fisher's exact p-values, estimators of average causal effects, regression, imputation-based approaches.
  - Practical session 1: Analyzing an RCT on the effect of statins on cholesterol
- Design and analysis of observational studies under confoundedness: the role of the propensity score; matching, weighting, regression estimators.
  - Practical session 2: Analyzing an observational study on the effect of statins
- Beyond RCTs. Intercurrent events: challenges and opportunities. Presentation of a case study with discussion.

*Lecture notes, slides, data, articles and other reading material will be distributed before the course. Practical sessions will be in R but no a priori knowledge of R is required.*

### **Participant experience**

Statistical inference, multivariate analysis.

### **Who should attend?**



The course is addressed to Statisticians, health professionals with statistical background, master and PhD students.

### Teaching methods

Lectures with some practical sessions/examples.

### Lecturer

**Fabrizia Mealli** - *Professor of Statistics, Director of the Florence Center for Data Science at University of Florence*

Fabrizia Mealli is Professor of Statistics. Her research focuses on causal inference, program evaluation, estimation techniques, simulation methods, missing data, and Bayesian inference, with applications to the social and biomedical sciences. She held visiting positions at Harvard University, UCLA, LISER Luxembourg. She serves as coordinator of the Statistics track for the PhD program in Mathematics, Computer Science, Statistics of the University of Florence, and sits the Steering Committee of the European Causal Inference Meeting. She is Elected Fellow of the American Statistical Association, and currently an associate editor of "The Annals of Applied Statistics" and "Observational Studies".

### At the end of the training, you will be able to ...

... develop expertise to assess the credibility of causal claims and the ability to apply the relevant statistical methods for causal analyses.

*Main reference:*

*Imbens G., Rubin D.B. (2015) Causal Inference for the Statistics, Social and Biomedical Sciences: An Introduction, Cambridge University Press*

## REGISTRATION FEE

---

### Pre-Conference Training + Conference:

€ 795,00\* **Super Early Bird fee until 31 August 2021**

€ 835,00\* **Early Bird fee until 02 November 2021**

€ 1.150,00\* **Ordinary fee**

€ 495,00\* **Freelance, Academy, Public Administration**

**Fee includes:** access to the virtual training and conference, organizational support, certificate of attendance, slide presentations in pdf format provided post course and conference.

### Pre-Conference Training:

€ 440,00\* **Early Bird fee until 02 November 2021**

€ 590,00\* **Ordinary fee**

€ 265,00\* **Freelance, Academy, Public Administration**

**Fee includes:** access to the virtual training, organizational support, certificate of attendance, slide presentations in pdf format provided post-course.



**Conference:**

€ 490,00\* **Early Bird fee until 02 November 2021**

€ 630,00\* **Ordinary fee**

€ 290,00\* **Freelance, Academy, Public Administration**

**Fee includes:** access to the virtual conference, organizational support, certificate of attendance, slide presentations in pdf format provided post-conference.

\* *for Italian companies: +22% VAT*

## CONFERENCE VENUE

---



Virtual conference with presentations, slots for Q&A and discussion among delegates.

*LS Academy will provide the link to join the conference some days before.*



+39 035.515684 |



info@LSacademy.com

www.LSacademy.com