





## **SPONSORS**



## **INTRODUZIONE**

The application of big data analytics like machine learning and artificial intelligence holds the potential to transform drug development by means of improved patient outcomes, identification of new treatments and reduction of costs and development time.

This transformation is facilitated not only by the development of the analytical techniques, but also by the ever-expanding availability of data from legacy information, clinical trials, and medical records

from participants in data collection initiatives as well as the even broader "real world". The enrichment of biological, clinical and patient preference large-scale data could enable computational inference relevant to real-world pharmaceutical research, particularly in the areas of:

- Identification of predictive factors for patient response
- More efficient clinical trial management and recruitment
- Supplementing clinical trial data with real world data
- Drug candidate selection and pipeline development
- Orphan drugs, rare diseases and drug repurposing

The 11th edition of the European Statistical Forum is therefore dedicated to understanding if and how these new techniques may be changing the drug development paradigm, to highlighting opportunities and pitfalls, and to exploring how the role of the biostatistician may evolve and interact with these new approaches.

In scope are presentations for example on:

- Regulatory views on the new analytical techniques incorporating data science elements
- Advanced methods for response prediction or subgroup identification
- Novel approaches to trial design incorporating flexible elements for patient stratification
- Innovative ways to incorporate real world data into the clinical study design or analysis
- Early identification of Adverse Drug Reactions
- Real case studies of collaboration between biostatisticians and data scientists
- Opportunities and risks with novel data science methodologies.

The European Statistical Forum conference will be preceded by a seminar / training on data science and machine learning methodology.

## **Scientific board**

Jens-Otto Andreas - *Head Statistical Sciences & Innovation - Bone & New Diseases* 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.

## **PROGRAMMA**

All times indicated are Central Europe Time

9 November 2020

14:00 16:00	Seminar   Machine Learning in clinical drug development
	Markus Lange Senior Principal Statistical Consultant at Novartis AG
	<b>Lorenz Uhlmann</b> Principal Biostatistician at Novartis AG
16:00 16:10	Break
16:10 18:00	Seminar   Machine Learning in clinical drug development
	Markus Lange Senior Principal Statistical Consultant at Novartis AG
	<b>Lorenz Uhlmann</b> Principal Biostatistician at Novartis AG
10 November 2020	
10:00 10:20	Welcome
10:50 11:20	AIML and Statistics: don't get lost in translation
	<b>Graeme Archer</b> VP & Head, Non-Clinical & Translational Statistics at GlaxoSmithKline Pharmaceuticals R&D
10:20 10:50	The challenges and opportunities in using (and regulating) broader data and applied analytics in guidance development and technology assessment in the UK
	Thomas Lawrence Data scientist, Managed Access at NICE
11:20 11:30	Break
11:30 12:00	Challenges and Opportunities of Machine Learning Methods in Biostatistics
	Marietta Kirchner Biostatistician at Institute of Medical Biometry and Biostatistics, University of Heidelberg
12:00 12:30	Drug candidate selection and pipeline development - a data science approach
	<b>Dimitrios Skaltsas</b> Co-founder & Executive Director at Intelligencia
12:30 12:40	Morning Wrap up

12:40 14:00	Lunch break
14:00 14:30	Integrating clinical and genetics data for predicting anti-epileptic drug response
	<b>Johann de Jong</b> Principal Scientist / A.I. Data Scientist at UCB
14:30 15:00	Recent examples of how data science is being used in clinical development. Reflections on lessons learnt
	David Wright Head of Statistical Innovation at AstraZeneca
15:00 15:10	Break
15:10 15:50	<b>ROUND TABLE</b>   Data Science in Drug Development: are we in presence of revolution?
	<b>Graeme Archer</b> VP & Head, Non-Clinical & Translational Statistics at GlaxoSmithKline Pharmaceuticals R&D
	Marietta Kirchner Biostatistician at Institute of Medical Biometry and Biostatistics, University of Heidelberg
	<b>Johann de Jong</b> Principal Scientist / A.I. Data Scientist at UCB
	Thomas Lawrence Data scientist, Managed Access at NICE
	Dimitrios Skaltsas Co-founder & Executive Director at Intelligencia
	David Wright Head of Statistical Innovation at AstraZeneca
15:50 16:00	Conclusion

# **SPEAKERS**



Scientific Board Jens-Otto Andreas Project Lead Statistician 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 Graeme Archer VP & Head, Non-Clinical & Translational Statistics at GlaxoSmithKline Pharmaceuticals R&D



Speaker Johann de Jong Principal Scientist / A.I. Data Scientist at UCB



Speaker Marietta Kirchner Biostatistician at Institute of Medical Biometry and Biostatistics, University of Heidelberg



Speaker Markus Lange Senior Principal Statistical Consultant at Novartis AG



Speaker Thomas Lawrence Data scientist, Managed Access at NICE



Speaker Dimitrios Skaltsas Co-founder & Executive Director at Intelligencia



Speaker Lorenz Uhlmann Principal Biostatistician at Novartis AG



Speaker David Wright Head of Statistical Innovation at AstraZeneca

## 9 November 2020 | 2:00 PM - 6:00 PM CET PRE-CONFERENCE SEMINAR

### Machine Learning in clinical drug development Advanced statistical tools and techniques

### Introduction

There is tremendous interest and excitement surrounding the application of Machine learning (ML) in drug development. Machine Learning (ML) tools can process information much faster, cheaper and more accurately than any human, and some people expect no less than a change to the clinical drug development paradigm.

In this online course, we will get the participants up to speed with the opportunities of ML in drug development. We will discuss the statistical details behind the ideas, the implementation using software (R) as well as the interpretation of the results. Any examples will be inspired by real problems.

### Who should attend?

Recommended for any quantitative scientist seeking an overview of machine learning and artificial intelligence (AI) and its application in the pharmaceutical industry.

#### Programme

Overview of ML in pharma - "match made in heaven" or "it's complicated"?

Discussion of key ML concepts

Key elements and principles for building and assessing supervised machine learning methods (e.g. loss functions, metrics, cross-validation, hold out data, bootstrap)

(Regularized) regression models such as Lasso, Ridge, Elastic Net, GAM

Ensemble methods based on classification and regression trees (e.g bagging, random forest and boosting)

A basic knowledge of Neural Networks and how they lead to deep learning methods

## Type of training

Shared presentation by Markus und Lorenz that aims to provide theoretical background and practical examples. Questions are welcome, we are hoping for lively discussions.

#### Lecturers

Markus Lange, Senior Principal Statistical Consultant - Novartis AG

- Studies of mathematics at the Ruhr-University Bochum
- Doctoral thesis at the Hannover medical school
- More than 5 years of industry experience
- Senior Principal Statistical Consultant at Novartis

Lorenz Uhlmann, Principal Biostatistician - Novartis AG

• Studies of statistics at the LMU Munich

- Doctoral thesis at the Institute for Medical Biometry and Informatics (IMBI), Heidelberg University
- Head of the working group "Statistical Modeling" at the IMBI
- Principal Biostatistician at Novartis

### **Participant experience**

The attendees should have solid knowledge of general statistics (such as generalized linear models). Basic knowledge of R programming is recommended but not required.

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

- understand different types of machine learning (e.g. supervised, unsupervised, re-enforcement) and the types of problems where they might be applied
- identify whether it is appropriate to apply machine learning or artificial intelligence techniques to a drug development problem
- assess and provide guidance on ML and AI solutions proposed by others (e.g. external vendors)
- interpret results from machine learning solutions
- get started if you want to apply the discussed techniques on your own

## **QUOTE ISCRIZIONE**

#### CONFERENCE

€ 590,00\* Early Bird fee until October 30th, 2020
 € 690,00\* Ordinary fee
 € 430,00\* Freelance, Academy, Public Administration

#### **PRE-CONFERENCE SEMINAR**

€ 570,00\* Early Bird fee until October 30th, 2020

€ 665,00\* Ordinary fee

€ 360,00\* Freelance, Academy, Public Administration

PRE-CONFERENCE SEMINAR + CONFERENCE
€ 1080,00\* Early Bird fee until October 30th, 2020
€ 1195,00\* Ordinary fee
€ 670,00\* Freelance, Academy, Public Administration

\* for Italian companies: +22% VAT

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

# **SEDE DEL CORSO**



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.