

Event managed by



European Statistical Forum

Tuesday, **November 13th**, 2018

INNOVATIVE CLINICAL TRIAL DESIGNS

📍 | Copenhagen, Denmark

Copenhagen Marriott Hotel

Kalvebod Brygge 5

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INNOVATIVE CLINICAL TRIAL DESIGNS

Adequately designed clinical trials have always been a cornerstone of clinical development.

Whereas in the past the focus was often on a proper analysis of fixed designs with a clearly defined population, during the last decade there is a huge shift towards a more integrated view. Several innovative clinical trial designs and design features have appeared like adaptive, basket, umbrella, and platform designs as well as innovative methods to the handling of multiplicity issues connected to them. In particular, but not limited to oncology, basket, umbrella, and platform designs are currently considered across academia and the pharmaceutical industry to allow for novel paths of clinical development and subsequent registration. Adaptive designs, for example to reassess sample size, drop treatment arms or to enrich the patient population, are becoming more and more popular. The handling of multiplicity in such designs has become more sophisticated. This was even more enhanced by the publication of the FDA draft guidance on the topic of multiplicity in 2017.

Based on these aspects statisticians but also related functions like medicine, regulatory affairs, market access and pharmacometrics are faced with the challenge to cope with this rapidly evolving field of innovative clinical trial designs and to implement state-of-the-art designs in their development programs

The ninth edition of the [European Statistical Forum](#) is therefore dedicated to innovative clinical trial designs.

This will include presentations focusing on:

- Basket, umbrella, and platform designs and their analysis
- Novel approaches to adaptive designs
- Innovative ways of multiplicity handling
- Regulatory views and status of acceptance regarding above-mentioned designs
- Case studies and practical approaches

The conference aims at promoting the exchange of expertise, bringing together statisticians, physicians, regulators, academia and other experts interested in the field of innovative clinical trial design

Scientific Board



Jens-Otto Andreas

Head Statistical Sciences & Innovation - Bone & New Diseases at UCB Biosciences GmbH



Lisa Comarella

Director Biostatistics at CROS NT Group



Frank Fleischer

Head of Methodology Statistics at Boehringer-Ingelheim



Giacomo Mordenti

Global Biometrics Director at Livanova

Who should attend?

The conference is addressed to statisticians, pharmacometricians, physicians, regulators, academia and other experts interested in the field belonging to:

- Universities/Hospitals
- Academic Research
- Pharmaceutical, and Biotechnology companies
- CROs

NEWS 2018 | Pre-Conference Workshop: Monday, November 12th, 2018

Multiple Testing in Confirmative Adaptive Designs [Please read page 5](#)

INNOVATIVE CLINICAL TRIAL DESIGNS

- 08:00 - 08:30 **Registration and Welcome Coffee**
- 08:30 - 08:40 **Welcome from the Chair**
Jens-Otto Andreas - Head Statistical Sciences & Innovation - Bone & New Diseases at UCB Biosciences GmbH
Lisa Comarella - Director Biostatistics at CROS NT
Frank Fleischer - Head of Methodology Statistics at Boehringer-Ingelheim
Giacomo Mordenti - Global Biometrics Director at Livanova
- 08:40 - 09:20 **Olivier Collignon - Biostatistician at Luxembourg Institute of Health**
A regulator's view on innovative clinical trial designs
- 09:20 - 10:00 **Franz König - Associate Professor at the Section of Medical Statistics at the Medical University of Vienna**
Adaptive designs for confirmatory model based decisions using MCP-Mod
- 10:00 - 10:40 **Ekkehard Glimm - Statistician at Novartis**
An adaptive clinical trial design handling several sources of multiplicity
- 10:40 - 11:10 **Coffee break**
- 11:10 - 11:50 **Andy Grieve - Head of Statistical Innovation Centre of Excellence, Development and Patient Value Practices at UCB**
Patient-Centred Clinical Trial Designs Using Bayesian Decision Analysis
- 11:50 - 12:30 **David Dejardin - Statistical Scientist at Roche**
Decision making in basket trial: A hierarchical weight approach
- 12:30 - 13:30 **Networking Lunch**
- 13:30 - 14:10 **Thomas Zwingers - Senior Director, Consultancy Services at CROS NT**
The use of historical controls from register data in randomized clinical trials in rare diseases
- 14:10 - 14:50 **Charles Gordon - Sr Manager, Quality Statistics and Data Science at LivaNova**
Extrapolation using Bayesian Hierarchical Modeling for a Pediatric Indication
- 14:50 - 15:20 **Coffee break**
- 15:20 - 16:00 **James Matcham - Head of Early Clinical Development Biometrics at AstraZeneca**
Platform Trials in Drug Development
- 16:00 - 16:40 **Tom Parke - Director of Software Solutions at Berry Consultants**
Platform Trials: From Breast Cancer to Ebola, lessons and challenges
- 16:40 - 16:50 **Conclusions**

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HOW TO REACH THE CONFERENCE VENUE

Copenhagen Marriott Hotel

Kalvebod Brygge 5

The hotel is situated in central Copenhagen on Kalvebod Brygge.

From Copenhagen Airport (CPH) Hotel direction: 4.8 miles SE

This hotel does not provide shuttle service.

Driving directions

Take the Highway E20 in direction of City Centre. Cross Sjællandsbroen and turn right. 2 km further, the Copenhagen Marriott Hotel is located on your right.

By subway

Solution 1) From Copenhagen Airport, take M2 and stop at Kongens Nytorv. Then take M4 and stop at København H (Central Station). It is 850 metres from hotel.

Solution 2) From Copenhagen Airport, take M2 and stop at Christianshavn. It is 1.4 km from hotel.

By bus | Bus Station Nearby Copenhagen Central Station

By train | Train Station Kobenhavns Hovedbanegård (Copenhagen Central Station)
650 metres W from hotel | 480 metres NW from hotel



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OPPORTUNITIES

Sponsor the event and take the chance to network with all attendees!

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Download the **Events Summary 2018**



For further information

Please visit [the conference website](#) or contact the organisational office:

Ilaria Butta Phone: +39 (0)35.4123594 | ilaria.butta@LSAcademy.com

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TO REGISTER FOR THE CONFERENCE YOU CAN:

- **DIRECTLY REGISTER ONLINE:** <https://esf-2018.lscademyevents.it/orders/new>

In this case, you can pay by credit card or by bank transfer.

- **FILL IN AND SEND THE REGISTRATION FORM (PAGE 6) FOR EACH ATTENDEE BY EMAIL**

ilaria.butta@LSacademy.com **OR BY FAX** +39(0)35.4501262. In this case, you can pay by bank transfer.

Registration fee for the Conference [13 November, 1 DAY]

€ 670,00* **Early Bird fee until October 11th, 2018**

€ 790,00* Ordinary fee (after October 11th, 2018)

€ 580,00* Patronage members fee

€ 430,00* Academy, Public Administration, Freelance

***For Italian companies: + 22% VAT**

NEWS 2018: Pre-Conference Workshop

Multiple Testing in Confirmative Adaptive Designs

Listening to your wishes, we are glad to inform you that European Statistical Forum is coming with a new format. The formative - informative conference is strengthened with the Pre-Conference Workshop: Multiple Testing in Confirmative Adaptive Designs on Monday, November 12th, 2018.

This 1/2 day workshop provides an overview of the current state of the art in design and analysis of adaptive clinical trials. Special emphasis is put on multiple hypotheses testing with adaptive designs.

For further information about the workshop, please download the brochure.

Registration fee for the Workshop + Conference [12 November, 1/2 DAY + 13 November, 1 DAY]

€ 1.090,00* **Super Early Bird fee until August 10th, 2018**

€ 1.170,00* **Early Bird fee (until October 11th 2018)**

€ 1.345,00* Ordinary fee (after October 11th, 2018)

€ 990,00* Patronage members fee

€ 630,00* Academy, Public Administration, Freelance

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REGISTRATION FORM

• Registration fee for the Conference (13 November, 1 DAY)

- € 670,00* Early Bird fee until October 11th, 2018
- € 790,00* Ordinary fee (after October 11th, 2018)
- € 580,00* Patronage members fee
- € 430,00* Academy, Public Administration, Freelance

The fee includes: Seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.

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- € 990,00* Patronage members fee
- € 630,00* Academy, Public Administration, Freelance

The fee includes: tuition, teaching materials for the workshop, coffee breaks, lunch, organisational office assistance, certificate of attendance. Seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.

*For Italian companies: + 22% VAT

Surname _____ Name _____
Company _____ Job title _____
Address _____
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Phone _____ Fax. _____
E-mail _____
Special Dietary Requests _____

I wish that my data (name, surname, job position and company) are inserted in the list of attendees distributed the day of the event

Invoicing details

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Terms & Conditions

Terms of payment The registration fee must be paid at the time of registration. Confirmation of event admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants or registrations of roles that are not included in the target of the event.

Cancellation Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the event date. Cancellations will only be valid if made in writing (by email). Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

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Payment by bank transfer

The full amount must be paid on registration to **EasyB S.r.l** by bank transfer. If you pay by bank transfer, please attach proof of payment to the registration form.

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