

**The European Statistical Forum
is pleased to announce its 7th Annual Conference:
ESTIMANDS and MISSING VALUE**

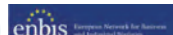


Berlin, Germany
Courtyard Berlin City Center
Axel Springer Strasse 55 - Berlin

Monday,
November 14th, 2016
9:00 - 18:00

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ESTIMANDS and MISSING VALUE

The topic of estimands is an important and relatively new one in clinical development.

Its concept goes to the heart of the design of a clinical trial as an estimand reflects what is to be estimated to address the scientific question of interest on the relevant population. This is in contrast to an estimator, which defines the specific rule how to estimate the estimand.

In the context of treatment benefit, an estimand may address either efficacy or effectiveness aspects. Defining the estimand of interest is an essential step to take before deciding on trial design and primary analysis. The choice of estimand has impact on various other factors to be considered during any clinical trial's planning phase.

A concept that is closely related to estimands is the handling of missing values. Lack of adherence to the study protocol and missing data are often unavoidable in clinical trials, and both increase the need to differentiate between the ideal treatment effect if the medication is taken as planned (de jure) and the treatment effect in presence of the actual adherence pattern (de facto).

The importance of the estimands concept is also emphasised by the fact that the International Conference on Harmonisation (ICH) issued a concept paper titled 'Choosing Appropriate Estimands and Defining Sensitivity Analyses in Clinical Trials' (dated 22 October 2014). An ICH E9 working group is in place aiming for the development of an addendum (Revision 1) to the ICH E9 guidance document.

The seventh edition of the European Statistical Forum is therefore dedicated to the topic of estimands which is closely linked to handling of missing values and sensitivity analyses. This will include presentation focusing on:

- Methodological aspects of estimands
- Proposed estimands and their implications on key attributes like data collection and handling, analyses as well as missing value imputation
- The role of sensitivity analyses and missing value handling techniques
- Regulatory views and status of implementation
- 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 estimands and missing values.

Scientific Board:

Jens-Otto Andreas, *Head EU & East Asia Biostatistics*, UCB Biosciences

Lisa Comarella, *Director Biostatistics*, CROS NT Group

Frank Fleischer, *Principal Methodology Statistician*, Boehringer-Ingelheim

Giacomo Mordenti, *Global Biometrics Director*, Livanova

Who should attend the conference?

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

European Statistical Forum (ESForum) aims to face statistical topics focusing on the most advanced methodological, regulatory and operational characteristics to support the drug and medical devices development.

Pre-Conference Dinner

The dinner will provide an opportunity for you to network informally with your industry peers.

Berlin - Sunday, November 13th, 7:30 PM (the meeting is set for 7:15 PM at the restaurant)

Restaurant "Zur Gerichtslaube"

Poststraße 28, D-10178 Berlin

Please confirm your interest on the registration form or during the registration online

START OF THE REGISTRATION: 8:20
START OF THE CONFERENCE: 8:50
END OF THE CONFERENCE: 16:55

AGENDA

- 08:20 - 08:50 **Registration and welcome coffee**
- 08:50 - 09:00 **Welcome from the Chair**
Jens-Otto Andreas - *Head EU & East Asia Biostatistics, UCB Biosciences*
Lisa Comarella - *Director Biostatistics, CROS NT*
Frank Fleischer - *Principal Methodology Statistician, Boehringer-Ingelheim*
Giacomo Mordenti - *Global Biometrics Director, Livanova*
- 09:00 - 09:45 ***A regulatory view on estimands and their influence on trial planning***
Ann-Kristin Leuchs - *Biostatistician, BfArM*
- 09:45 - 10:30 ***ICH E9(R1): new ICH Guidance on Estimands and Sensitivity Analyses***
Christine Fletcher - *Executive Director Biostatistics, Amgen Ltd*
- 10:30 - 11:00 **Coffee break**
- 11:00 - 11:35 ***Clinical Perspectives on estimands***
Thue Johansen - *Director Medical Anchor-Clinical Pharmacology & Trial Execution, Novo Nordisk*
- 11:35 - 12:10 ***Information Anchored Sensitivity Analysis: some theory and examples***
James Carpenter - *Professor of Medical Statistics and Programme Leader in Methodology, MRC Clinical Trials Unit, London school of Hygiene & Tropical medicine*
- 12:10 - 13:10 **Networking lunch**
- 13:10 - 13:45 ***Choosing Estimands in Clinical Trials with Missing Data***
Craig Mallinckrodt - *Research Fellow, Eli Lilly and Company*
- 13:45 - 14:20 ***Estimands and their role in clinical trials***
Mouna Akacha - *Senior Expert Statistical Methodologist, Novartis Pharma AG*
- 14:20 - 14:55 ***Determining trial objectives, estimands and statistical methods to handle missing data in confirmatory analgesic trials***
Georg Kralidis - *Sr. Principal Statistician, Grünenthal GmbH*
- 14:55 - 15:25 **Coffee break**
- 15:25 - 16:00 ***Estimands for time-to-event endpoints***
Kaspar Rufibach - *Biostatistician, Methodology, Collaboration & Outreach Group, Roche*
- 16:00 - 16:45 **ROUND TABLE: Benefits and Challenges of the Estimands Concept**
Mouna Akacha
Christine Fletcher
Georg Kralidis
Ann-Kristin Leuchs
Craig Mallinckrodt
Kaspar Rufibach
- 16:45 - 16:55 **Conclusions**

How to reach the conference venue

Courtyard Berlin City Center
Axel Springer Strasse 55 - Berlin

From Berlin-Tegel Airport - TXL

Take the bus X9 and get off at the Zoological Garden. Change to the subway U2 towards Pankow and get off at Spittelmarkt. Cross Seydelstrasse and turn right. The hotel will be on the right.

This hotel does not provide shuttle service.

Bus service, fee: 2.6 EUR (one way)

Subway service, fee: 2.6 EUR (one way)

Estimated taxi fare: 25 EUR (one way)

From Berlin-Schoenefeld International Airport - SXF

Take the bus SX1 to Südkreuz. Then change to bus 248, direction 'S+U Bahnhof Alexanderplatz' and get off at Lindenstrasse/Oranienstrasse. Turn right into Axel-Springer-Strasse, direction Axel-Springer building. The hotel is located at the very end of the street on the left hand side.

This hotel does not provide shuttle service.

Bus service, fee: 3.1 EUR (one way)

Subway service, fee: 3.1 EUR (one way)

Estimated taxi fare: 40 EUR (one way)

OTHER TRANSPORTATION

Download here the plan of public transportations:

<http://www.marriott.com/hotelwebsites/us/b/bermt/pdfs/Berlin%20S-Bahn%20Netz.pdf>

Bus Station

Spittelmarkt 0.1 miles N

Subway Station

Spittelmarkt 0.1 miles E

Train Station

Hauptbahnhof 3.1 miles NW

Parking

On-site parking, fee: 2 EUR hourly, 20 EUR daily


For further information please

visit the website

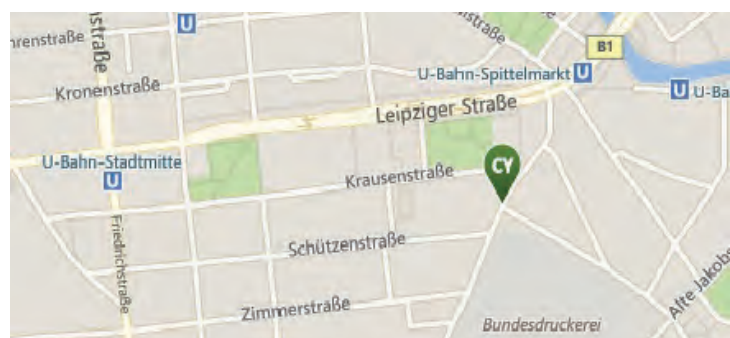
www.esforum.eu

or contact the organization offices:

Stefania Sarga

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Sponsorship opportunities

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Exclusive benefits and high impact branding before, during and after the conference.

For further information, please contact:

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Download the Events Summary:

<http://www.esforum.eu/2016/documents/Events%20Summary%202016.pdf>

TWO WAYS TO REGISTER:

- **Online:** please register here <http://esf-2016.eventify.it/orders/new>
In this case, you can choose to pay by credit card or by bank transfer.
- **By email or fax:** please fill the registration form below for each attendee and send it by email: info@esforum.eu or by fax: +39(0)35.4501262
In this case, you can pay by bank transfer.

REGISTRATION FEE FOR THE CONFERENCE

- € 610,00* **Early Bird fee** until 26th October 2016
- € 705,00* ordinary fee (after 26th October 2016)
- € 550,00* Patronage members fee
- € 370,00* for Academy, Public Administration, Freelance
- *For Italian companies: + 22% VAT

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

REGISTRATION FEE FOR THE CONFERENCE + PRE-CONFERENCE DINNER

- € 645,00* **Early Bird fee** until 26th October 2016
- € 740,00* ordinary fee (after 26th October 2016)
- € 585,00* Patronage members fee
- € 405,00* for Academy, Public Administration, Freelance
- *For Italian companies: + 22% VAT

The **fee includes:** pre-conference dinner (Sunday, November 13th) seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, welcome coffee, networking lunch, two coffee breaks, organisational office assistance, certificate of attendance.

For any additional information, please contact:

Stefania Sarga: info@esforum.eu Phone: +39(0)35.515684

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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.

Information collection and use

Participants information is collected and utilised by EasyB S.r.l. and sponsor companies in accordance with Italian Legislative Decree 196/2003. Data collected will be used and communicated to third parties for the purposes of event organisation and may be used to communicate future similar initiatives. Participants may at any time verify the accuracy of the information and request changes or deletion.

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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