• A **CROS Academy** course

Thursday, **10th May** 2018 | 9:00 – 18:00

Understanding Biostatistics Methodology for Successful Regulatory Submissions

Brussels, Belgium

For further information:

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Understanding Biostatistics Methodology for Successful Regulatory Submissions

Introduction

The publication in 1998 of ICH E9 guidance on Statistical Principles in Clinical Trials brought a degree of clarity and harmonization to the statistical requirements of the major regulatory authorities. Since that time the FDA and EMA have issued a further twelve guidance documents and have developed certain standard approaches which are not well-documented.

In this course a statistician experienced in interacting with both the FDA and EMA will identify the key issues of concern to regulatory authorities and will focus on ways to design and analyse clinical trials to avoid or minimize the impact of these issues.

Both the EMA and FDA have introduced new regulatory guidelines in both drug and device development that make the understanding of basic statistical concepts fundamental. The new ICH GCP E6(R2) addendum has also called for a risk-based approach to clinical trials with a bigger emphasis on data analytics. The statistician is playing a larger role in the preparation of regulatory submissions and interpreting feedback from regulatory authorities.

Course Objectives

After this course, participants should be able to:

- Understand the main statistical issues of concern to regulators
- Work with statisticians to Identify ways to design and analyse trials to avoid these issues arising

Official language of the course

English

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For whom is this course designed?

- Medical Directors and Medical Affairs professionals
- Heads of Clinical Operations with limited statistical knowledge
- Clinical professionals in Pharmaceutical, Biotechnology or Medical Device Companies
- Regulatory professionals in Pharmaceutical, Biotechnology or Medical Device Companies
- Biostatisticians with limited knowledge of regulatory activities
- Outsourcing managers

Agenda

08:30 - 09:00	**Welcome and Registration**
09:00 - 09:45	Regulatory Guidance on Statistical Topics
09:45 - 10:30	Objectives of a Study - Primary Outcome, Estimands and the Problem of Multiplicity
10:30 - 10:45	**Morning Coffee Break**
10:45 - 11:30	Dealing with Multiplicity
11:30 - 12:30	Non-Inferiority Trials - Choice of Margin
12:30 - 14:00	**Lunch**
14:00 - 14:45	Analysis Populations- what patients do we include?
14:45 - 15:30	How to handle missing data - including sensitivity analysis
15:30 - 15:45	**Afternoon Coffee Break**
15:45 - 16:30	Subgroup Analyses
16:30 - 17:15	Specific guidance for oncology trials
17:15 - 18:00	**Questions and Answers**

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Lecturer's bio

Thomas Zwingers

Thomas Zwingers is Head of Statistical Consultancy for CROS NT, a global CRO with offices in the UK, Germany, Italy and the US. In his current role, Thomas provides pharma, biotech and medical device companies with statistical methodology advice pertaining to trial design, conduct and reporting including regulatory submission, and has presented statistical findings to the European Medicines Agency on numerous occasions. Thomas has been working in the clinical trial environment since 1980 in project team management and statistical analysis. He specializes in statistical analysis and reporting with particular expertise in Adaptive Trial Design and Non-Inferiority Trials.

Prior to joining CROS NT, Thomas has an independent statistical consultant who ran his own biometrics CRO in Germany for over 20 years. During this time, he gained a considerable amount of experience in Dermatology, Respiratory and Oncology studies, and has particular expertise in applying adaptive designs to oncology trials.

About CROS NT e CROS Academy

As a global Contract Research Organization (CRO), CROS NT enhances clinical trial outcomes and optimizes vendor oversight with data-driven services and solutions. From study design to clinical study reporting, CROS NT's services include biometrics and data science (data management, biostatistics programming and analysis), medical writing, pharmacovigilance, regulatory consultancy and clinical project management and monitoring.

CROS Academy | Established as a specialist biometrics CRO, CROS NT launched CROS Academy as a training branch to provide a series of classroom trainings and webinars in our areas of expertise including biostatistics and clinical data management. We also offer in-house, tailored training for companies with specific needs.

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To register for the course you can fill in and send the **registration form** to crosacademy@crosnt.com or directly **register online** https://2018-understanding-biostatistics-brussels.lsacademyevents.it/orders/new

Registration Fees

- ☐ **Early bird: € 640,00** until 26/04/2018
- ☐ **Ordinary: € 750,00**
- ☐ **Academy – Public Administration: € 450,00**

A discount will be applied for the registration of 3 or more colleagues of the same company. Please contact crosacademy@crosnt.com

The fee includes: tuition, teaching materials, lunches and coffee breaks, organizational office assistance, attendance certificate.

Methods of payment

The full amount must be paid on registration to EasyB s.r.l by bank transfer or by credit card. If paying by bank transfer please attach proof of payment to the registration form.

Bank transfer payable to:

EasyB S.r.l.
Via Roma, 20 - 24022 Alzano Lombardo (BG)
P. **IVA 03633040161**
Banco BPM - Filiale di Carobbio Degli Angeli
IBAN: **IT81 F 05034 53960 000000003450**
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Terms & conditions

Terms of payment The registration fee must be paid at the time of registration. Confirmation of course 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.

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 course date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. CROS NT and the organiser EasyB reserve the right to postpone or cancel an event, to change the location of an event or to alter the lecturer 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.

The course will proceed with a minimum of 6 participants.

Should this number not be reached, the registered participants will be notified at least one week prior to the commencement of the course.

The secretarial office reserved the right not to accept registrations not compatible with the course's target audience (please read the section "For whom is this course designed?" in the leaflet).

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.

Date _____ **Signature** _____

For further information, please contact the secretarial office

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