A CROS Academy course

# Introduction To Adaptive Trial Design

## Flemings Hotel Mayfair

Looking Glass Room
Half Moon Street – Mayfair
London W1J 7BH

Tuesday, 2 December 2014
8:30 – 18:00

Save 30% if you register for **"Understanding the Statistical Elements of a Study Protocol – for Non-Statisticians"** on 1st December in London

FOR ADDITIONAL INFORMATION:

+39 045 820 26 66 crosacademy@crosnt.com www.crosnt.com

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# Introduction to Adaptive Trial Design

## Introduction

In the past few years we have witnessed an exponential increase in costs for drug development. Consequently, the question pharmaceutical companies continue to face is, *"how can we make a study more efficient while maintaining the validity and integrity?"*.

Adaptive Trial Designs offer greater flexibility and the possibility to modify a study in progress based on new information derived from accumulated data. Studies have demonstrated that between 20-30% of clinical studies are using adaptive designs and this number is expected to rise, especially in the exploratory phase of drug development. Study data indicates that the implications of adaptive designs – such as sample size recalculation or early study termination – could potentially save Sponsors between €75 - €150 million euros per year.

An adaptive design approach applies to changes in sample size, criteria for inclusion/exclusion, changes in doses or treatment regiment, study endpoints, the elimination or addition of treatment groups, and the possibility of early closure. Choosing the appropriate statistical method and type of design is crucial to success and allows biostatisticians to make "go/no-go" decisions.

## After this course, you should be able to:

- Discuss the adaptations possible in a trial design and understand decision rules
- Understand basic statistical principles in a study
- Realize the potential risks of adaptive trials
- Realize the benefits of adaptive trials
- Comprehend why oncology is a unique therapeutic area and how adaptive designs can improve efficiency in this area

## From whom is this course designed?

- Heads of Operations with limited or no Statistics knowledge
- Medical Directors
- Clinical Professionals in Pharmaceutical, Biotech or Medical Device companies
- Biostatisticians with limited knowledge on adaptive trial design
- Outsourcing Managers

## About the instructor

### 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 was 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.

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## Agenda

| | |
|---|---|
| 08:30 - 09:00 | Registration |
| 09.00 – 09.45 | Reasons for Using Adaptive Trial Design in a Clinical Trial |
| 09:45 – 10:30 | Overview of Statistical Methods |
| 10:30 – 10:45 | Coffee Break |
| 10:45 – 11:30 | Adaptive designs in different Drug Development Phases |
| 11:30 – 12:30 | Decision rules in different Drug Development phases |
| 12:30 – 14:00 | Lunch |
| 14:00 – 14:45 | Special topics in Oncology |
| 14:45 – 15:30 | Guidelines and Regulations on Adaptive Designs |
| 15:30 – 15:45 | Coffee Break |
| 15:45 – 16:30 | Implications of Adaptive Design on Clinical Project Management |
| 16:30 – 17:15 | Hand-on Exercise on Adaptive Design in a Pase II/III trial |
| 17.15 – 18.00 | Q&A |

## CROS NT & CROS Academy

### CROS NT

In its 22nd year, CROS NT is a global Contract Research Organization (CRO) specialized in clinical data services. With over 1,000 studies completed in a variety of therapeutic areas and indications, CROS NT has remained focused on biometrics including statistical consultancy, analysis and reporting, clinical data management, medical writing and life science technology solutions. We collect, integrate and analyze data from various sources and use processes and technology to ensure excellent project governance, reporting and traceability.

### CROS Academy

Building off CROS NT's strong heritage and expertise in biostatistics and clinical data management, we created CROS Academy which provides a series of webinars and classroom trainings from top statisticians and clinical professionals within the CROS NT organization. CROS NT also offers in-house, tailored training for companies who have specific training needs. Course topics range from biostatistics for non-statisticians, study designs, sample size calculation and Adaptive Trial Design to clinical data management processes. Our expert instructors can personalize trainings to company requests.

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## Registration fee: £ 400

The fee includes: guaranteed seat at the course, copy of presentation material, informative literature, networking lunch and coffee breaks, organizational assistance, certificate of participation for your training records.

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Group Rates apply for registering 3 or more people from your company

## Payment method

The registration fee can be paid either by cheque or wire transfer. If paying via wire transfer, please use the following bank details:

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You can also pay online via credit card using the following link:
**http://events.lsacademy.it/europe**

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## Terms & Conditions

### Cancellation

Please note that refunds (70% refund of the registration fee ) will only be given if cancellation is received before November 24th, 2014. 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. 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.

Date _____ Signature _____

## For additional information:

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