DIA Learning

Adaptive Design in Clinical Trials

Virtual Live Training Course

29-30 November 2022 14:00-18:30 CET

OVERVIEW

Adaptive designs in clinical trials are by now a well-established tool to efficiently design clinical trials. In some scenarios they offer the flexibility of modifying trials during the trial, after one or more interim analyses, i.e., once partial data are collected.

Using real-world examples from the pharmaceutical industry, this virtual course provides a comprehensive review of the concepts and methods underpinning adaptive clinical designs and examines their application in drug development. It will also provide an overview of data monitoring and regulatory guidance relevant to adaptive designs.

LEARNING OBJECTIVES

- This course will help participants better understand statistical concepts in clinical trial design (such as e.g. randomization or adaptive designs), data analysis and reporting in clinical development
- Participants will also gain insights into the regulatory guidance when applying adaptive designs in clinical development
- This course provides input on how to assess if an adaptive design is appropriate to implement for given research questions and context
- Participants will learn how to communicate to higher management to convince them to switch to the adaptive design
- This course explains what potential statistical and non-statistical resources should participants have available to help plan, run, and report an adaptive clinical trial

WHO WILL ATTEND

This course is for pharmaceutical industry professionals working in:

- Medical affairs
- Regulatory affairs
- Clinical development
- Clinical study project management
- Biopharmaceutical development
- Biostatistics
- Statistical programming

FACULTY

Kaspar Rufibach
Expert Statistical Scientist
Methods, Collaboration, and Outreach Group (MCO)
F. Hoffmann-La Roche AG, Switzerland

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

14:00 INTRODUCTION

14:10 SESSION 1

OVERVIEW OF BASIC STATISTICAL CONCEPTS AND PRINCIPLES

Kaspar Rufibach

- Population and sample
- Hypothesis testing
- Power and significance level

15:10 SESSION 2

RANDOMIZATION AND CLINICAL TRIAL DESIGN

Kaspar Rufibach

- Why do we randomize?
- Ethics of randomization
- How do we specify the sample size in a trial?
- What happens if we do more than one test? Multiple testing
- Issues in the design of clinical trials

16:10 COFFEE BREAK

16:30 SESSION 3

OVERVIEW OF ADAPTIVE CLINICAL TRIALS

Kaspar Rufibach

- Introduction
- Group-sequential and adaptive designs – basic principles using examples

18:30 END OF DAY 1

DAY 2

14:00 SESSION 4

REGULATORY GUIDANCE ON ADAPTIVE DESIGNS

Kaspar Rufibach

- General concerns with adaptive designs
- FDA regulatory guidance on adaptive designs
- EMA regulatory guidance on adaptive designs

15:00 COFFEE BREAK

15:30 SESSION 5

INTERIM ANALYSIS AND DATA MONITORING COMMITTEE (DMC)

Kaspar Rufibach

- Types of trials with interim analyses
- Futility vs. efficacy interim analysis
- iDMC and operational aspects
- Roles and responsibilities of DMC members
- Communication

17:00 SESSION 6

MASTER PROTOCOLS IN DRUG DEVELOPMENT

Kaspar Rufibach

18:00 WRAP-UP AND QUESTIONS AND ANSWERS

18:30 END OF THE VIRTUAL TRAINING COURSE

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership
- You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and does not apply to the already discounted fees for government or charitable nonprofit/ academia.

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

Operating Systems

- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

Minimum System Requirements

- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

Browsers

- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

Internet Connection Speed

- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

Display

- 800x600 pixel resolution or greater (1024x768 pixels recommended).

Follow **@DrugInfoAssn**

Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@DIAglobal.org.

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 7.5 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

REGISTRATION FORM

Adaptive Design in Clinical Trials #22535

29-30 November 2022 14:00-18:30 CET

DIA Learning

REGISTRATION FEES

Registration fee includes full admission to virtal live course and electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER EARLY- BIRD valid until 4 October 2022	MEMBER valid from 5 October 2022	NON-MEMBER
INDUSTRY (OR REPRESENTATIVE)	€ 720.00 ❑	€ 800.00 ❑	€ 985.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 400.00 ❑	€ 585.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.			

All registration fees will be subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership**.

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CET. Tel. :+41 61 225 51 51

Email: Basel@DIAglobal.org Mail: DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click here.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click here. You agree that your personal data will be transferred to DIA in the US.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ Please charge my ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #22535 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. If you have not received your confirmation within five working days, please contact DIA.

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature