DIA Training Course on

Clinical Statistics for Non-Statisticians

Course #14532
23-24 October 2014
Holiday Inn – Kensington Forum, London, UK

Faculty

David Carter
Director
Delta Consulting Ltd, UK

Kerry Gordon
(Course Director)
Executive Director, Biostatistics
Quintiles Ltd, UK

Sara Hughes
Vice President & Head of Clinical Statistics
GlaxoSmithKline, UK

James Matcham
Head, Early Clinical Development Biometrics
AstraZeneca, UK

Instructors onsite will be selected from the full Faculty

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

This course has limited capacity. Register early.

Overview

This course is designed to be an introduction of basic statistical concepts fundamental to clinical research, for professionals who have regular exposure to statistics either through studies or professional experience. The materials cover many key statistical topics, such as the interpretation of odds ratios and hazard ratios, meta-analysis and non-inferiority studies. While the course includes a few formulae for individuals who are interested in computational details, the course emphasises the application of statistical concepts to clinical investigation.

Key Topics

Basic statistical principles pertinent to clinical research.

Who Will Attend

This course will particularly benefit professionals who must understand and work with statistical concepts related to clinical research. It assumes a basic understanding of statistics (either through professional experience or studies) roughly equivalent to an introductory statistics course.

Learning Objectives

At the conclusion of this course, participants should be able to:

- Discuss basic statistical concepts such as variability, confidence intervals, hypotheses testing and P-values
- Use basic statistical terminology with ease
- Distinguish various study designs and identify techniques to avoid bias
- Recognise critical statistical issues in design and analysis
- Differentiate between a superiority and a non-inferiority design and know how each design should be reported

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

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 headquartered 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.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

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THURSDAY | 23 OCTOBER 2014

07:30 REGISTRATION

08:30 WELCOME AND COURSE OBJECTIVES

The objective of this session is to provide an overview of the course objectives and the action plan for the next two days. In addition, the participants have a chance to get acquainted with their course colleagues.

09:00 Session 1

BASIC STATISTICAL CONCEPTS

The objective of this session is to introduce fundamental statistical concepts such as sampling and variability. In addition, we will introduce clinical trial phases and the Intent to Treat Principle.

A. Sampling
B. Influence of sample size
C. Variability
D. Clinical Trial phases
E. Intent to Treat principle

10:00 COFFEE BREAK

10:30 Session 2

TRIAL OBJECTIVES

The objective of this session is to detail different types of primary objectives for trials and review how the results of these trials are assessed.

A. Superiority Trials
B. Non-Inferiority trials
C. Equivalence trials
D. Observational trials
E. Confidence intervals
F. Interpretation of results

11:30 Session 3

STUDY DESIGN

The objective of this session is to review different types of study design, the use of interim analyses and the importance of minimising bias.

A. Parallel group designs
B. Cross-over designs
C. Other common phase 2 designs
D. Choice of the control
E. Treatment allocation
F. Interim analyses
G. Minimising bias

12:30 LUNCH

13:30 Session 3 (continued)

STUDY DESIGN

15:00 COFFEE BREAK

15:30 Session 4

MAKING DECISIONS

The objective of this session will be to illustrate how one can set up hypotheses and test them. In addition, we will discuss the characteristics of decisions rules and how to interpret the testing results.

A. Making decisions in the face of uncertainty
B. Hypothesis tests
C. Type I and type II errors
D. Sample size determination
E. P-values
F. Power
G. Dealing with multiplicity

17:00 WRAP-UP OF DAY ONE

17:15 DRINKS RECEPTION

18:15 END OF DAY ONE

FRIDAY | 24 OCTOBER 2014

08:30 Session 5

RECAP

The objective of this session is to review what we have learned so far.

A. Statistics as an art and science
B. Sampling and variability
C. Confidence interval
D. Types of trial objectives
E. Statistical sense
F. Caution when using statistical terms

09:00 Session 6

INTERPRETING STATISTICS

How to interpret commonly used statistics for continuous, binary and survival data.

A. Means and medians
B. Standard deviation and standard errors
C. Relative risk and odds ratio
D. Kaplan Meier curves
E. Hazard ratios

10:00 COFFEE BREAK

10:30 Session 6 (continued)

INTERPRETING STATISTICS

11:30 Session 7

META ANALYSIS

The objective of this session is to describe how to combine results from different trials. In addition, we will review the limitations of a meta-analysis and how to interpret the results of such an analysis.

A. Literature searches
B. Methods for combining results
C. Study-level vs patient-level analyses
D. Interpretation
E. Use in indirect comparisons

12:30 LUNCH

13:30 Session 8

CRITICAL LITERATURE REVIEW

The objective of this workshop-based session is to provide participants with a systematic approach to assessing the statistical aspects of published articles, including the reporting of results, and to be able to identify potential statistical failings.

A. Study objectives
B. Study design and sample size
C. Statistical methodology
D. Statistical interpretation of results
E. Study conclusions
F. Workshop

15:45 WRAP-UP AND FEEDBACK

16:00 COURSE ASSESSMENT

16:30 END OF TRAINING COURSE

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following hotel:

Holiday Inn London – Kensington Forum
97 Cromwell Road
SW7 4DN London
United Kingdom

Tel.: +44 207 341 8000
Website: http://www.hikensingtonforumhotel.co.uk/

at the rate of:
GBP 165.00 per room/night inclusive of breakfast and VAT.

In order to make your reservation, please contact the hotel directly at + 44 (0) 207 341 3355 and quote the booking reference: ZO1.

IMPORTANT: The room rate is available until 22 September 2014 or until the group block is sold-out, whichever comes first.

DIA EUROPE CONFERENCES AND WORKSHOPS 2014-2015

- **DIA/EFPIA Information Day on ICH**
  28 March 2014 | Vienna, Austria | ID 14114
- **7th European Conference on Rare Diseases & Orphan Products and Exhibition**
  8-10 May 2014 I Berlin, Germany | ID 14106 | www.rare-diseases.eu
- **8th European Forum for Qualified Person for Pharmacovigilance (QPPV)**
  13-15 May 2014 | London, United Kingdom | ID 14104
- **Achieving Improved Regulatory Efficiency within the current Framework: Les sons from the Escher Project – jointly organised by DIA and TOPRA**
  Mid-September 2014 | Brussels, Belgium
- **8th Annual European Medical Information and Communication Conference and Exhibition**
  23-24 September 2014 | London, United Kingdom | ID 14103
- **Clinical Trials Workshop I – Translating the New Clinical Trials Regulation into Practice**
  23-24 September 2014 | London, United Kingdom | ID 14111
- **Clinical Trials Workshop II – Translating the New Transparency Requirements into Practice**
  24-25 September 2014 | London, United Kingdom | ID 14116
- **Joint DIA/FIP European Workshop Biorelevant Performance Testing of Orally Administered Dosage Forms**
  24-25 September 2014 | Amsterdam, the Netherlands
- **EFGCP/DIA/EMA Annual Conference on Better Medicines for Children – Ex ploring ways to enhance collaboration between key players**
  30 September – 1 October 2014, EMA Headquarters, London, UK
- **Joint DIA/ICOS Conference on Cardiac Toxicity Resulting from Cancer Chemo therapy: Strategies for Early Detection, Risk Mitigation and Clinical Prevetion and Exhibition**
  9-10 October 2014 | Prague, Czech Republic | ID14108
- **4th African Regulatory Conference and Exhibition**
  22-23 October 2014 | Dakar, Senegal | ID 14105
- **Workshop on HTA and Access to Medicines Status and Future**
  End October 2014 | location to be confirmed
- **Joint DIA/AEMPS Statistics Workshop**
  10-11 November 2014 | Barcelona, Spain | ID 14107
- **MAGHREB Regulatory Conference and Exhibition**
  November 2014 | Algiers, Algeria | ID 14113
- **DIA/ISPE Workshop on Computer Science Compliance "Maintain Data Intrity to Reduce Risk for the Patient**
  November 2014 | Basel, Switzerland | ID 14112
- **15th Conference on European Electronic Document Managment (eDM) and Exhibition**
  November/December 2014 | Berlin, Germany | ID 14110
- **Biosimilars Conference**
  Q4 2014 | Berlin, Germany | ID 14115
- **27th Annual EuroMeeting and Exhibition**
  13-15 April 2015 | Paris, France | ID 15101
- **8th Annual Clinical Forum**
  14-15 April 2015 | Paris, France | ID 15103

REGISTRATION FORM

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ID #14532

FEES

	Member*	Non-Member*
Industry	€ 1'420.00 ❑	€ 1'550.00 ❑
Academia/Charitable/Government/Non-profit (Full-time)	€ 710.00 ❑	€ 840.00 ❑
Join DIA now to qualify for the member rate	€ 130.00 ❑	

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

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and training course material.

TOTAL AMOUNT DUE: _____

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

ATTENDEE DETAILS

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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 # 14532 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 Europe.**

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

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days 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
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe 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 Europe office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52 **Web** www.diaeurope.org **Mail** DIA Europe, Kuechengasse 16 4051 Basel, Switzerland