DIA Training Course on

Clinical Statistics for Non-Statisticians

Course #15532
15-16 October 2015
Holiday Inn – Kensington Forum, London, UK

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 through their work settings. The syllabus covers 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 without going off on mathematical tangents.

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.

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.

FACULTY

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

James Matcham
Head, Early Clinical Development Biometrics
AstraZeneca, UK

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.

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DAY 1

07:30 — **REGISTRATION**

08:30 — **WELCOME AND COURSE OBJECTIVES**

09:00 — **SESSION 1**

BASIC STATISTICAL CONCEPTS

This session is to introduces fundamental statistical concepts such as sampling and variability. In addition, we will introduce clinical trial phases and the "Intent to Treat" Principle.

- Sampling
- Influence of sample size
- Variability
- Clinical Trial phases
- Intent to Treat principle

10:00 — **COFFEE BREAK**

10:30 — **SESSION 2**

TRIAL OBJECTIVES

This session details different types of primary objectives for trials and review how the results of these trials are assessed.

- Superiority Trials
- Non-Inferiority trials
- Equivalence trials
- Observational trials
- Confidence intervals
- Interpretation of results

11:30 — **SESSION 3**

STUDY DESIGN

This session is to reviews different types of study design, the use of interim analyses and the importance of minimising bias.

- Parallel group designs
- Cross-over designs
- Other common phase 2 designs
- Choice of the control
- Treatment allocation
- Interim analyses
- Minimising bias

12:30 — **LUNCH**

13:30 — **SESSION 3 (CONTINUED)**

STUDY DESIGN

15:00 — **COFFEE BREAK**

15:30 — **SESSION 4**

MAKING DECISIONS

This session illustrates how to set up hypotheses and test them. In addition, we will discuss the characteristics of decisions rules and how to interpret the testing results.

- Making decisions in the face of uncertainty
- Hypothesis tests
- Type I and type II errors
- Sample size determination
- P-values
- Power
- Dealing with multiplicity

17:00 — **WRAP-UP OF DAY ONE**

17:15 — **DRINKS RECEPTION**

18:15 — **END OF DAY ONE**

DAY 2

08:30 — **SESSION 5**

RECAP OF DAY ONE

This session reviews what we have learned so far.

- Statistics as an art and science
- Sampling and variability
- Confidence interval
- Types of trial objectives
- Statistical sense
- Caution when using statistical terms

09:00 — **SESSION 6**

INTERPRETING STATISTICS

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

- Means and medians
- Standard deviation and standard errors
- Relative risk and odds ratio
- Kaplan Meier curves
- Hazard ratios

10:00 — **COFFEE BREAK**

10:30 — **SESSION 6 (CONTINUED)**

INTERPRETING STATISTICS

11:30 — **SESSION 7**

META ANALYSIS

This session describes 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.

- Literature searches
- Methods for combining results
- Study-level vs patient-level analyses
- Interpretation
- Use in indirect comparisons

12:30 — **LUNCH**

13:30 — **SESSION 8**

CRITICAL LITERATURE REVIEW

This workshop-style session provides 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.

- Study objectives
- Study design and sample size
- Statistical methodology
- Statistical interpretation of results
- Study conclusions
- Workshop

15:45 — **WRAP-UP AND FEEDBACK**

16:00 — **END OF TRAINING COURSE**

COURSE VENUE

Holiday Inn London – Kensington Forum
97 Cromwell Road
SW7 4DN London
United Kingdom
Tel.: +44 207 341 8000
Website: http://www.hikensingtonforumhotel.co.uk/

DIA has blocked a limited number of hotel rooms for the course participants from 13 to 17 Octobert 2015 at the rate of GBP 168.00 per single room per night including Full English Breakfast, taxes and service fee. In order to book a hotel room, please call the hotel directly and quote the booking reference "P9J". The room rate is available until 1 September 2015 or until the room block is sold-out, whichever comes first. Cancellations received after 1 September 2015 will be subject to cancellation fee of 100% of the booking value.

REGISTRATION FORM

Clinical Statistics for Non-Statisticians # 15532 | 15-16 October 2015 | London, UK

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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and training course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'420.00 ❑	€ 1'580.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 710.00 ❑	€ 870.00 ❑
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Payment is due 30 days after registration and must be paid in full by commencement of the course.

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52
Email: diaeurope@diaeurope.org Mail: DIA EMEA, Küchengasse 16, 4051 Basel, Switzerland Web: www.diahome.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa 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
- Tutorial cancellation € 50.00

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.
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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.

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 in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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 Fax Number

email (Required for confirmation)

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 # 15532 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, Middle East and Africa.**

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.diahome.org/EUTerms

Date	Signature