

Clinical Statistics for Non-Statisticians

17-18 October 2017

Holiday Inn London 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 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.

LEARNING OBJECTIVES

At the conclusion of this course, participants will 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

DAY 1

08:00 REGISTRATION

08:30 WELCOME AND COURSE OBJECTIVES

Kerry Gordon and James Matcham

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

Kerry Gordon and James Matcham

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

Kerry Gordon and James Matcham

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

Kerry Gordon and James Matcham

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 BREAK

13:30 SESSION 3 CONTINUED

15:00 COFFEE BREAK

15:30 SESSION 4

MAKING DECISIONS

Kerry Gordon and James Matcham

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

Kerry Gordon and James Matcham

17:15 NETWORKING RECEPTION

18:15 END OF DAY ONE

DAY 2

08:30 SESSION 5

RECAP

Kerry Gordon and James Matcham

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

Kerry Gordon and James Matcham

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

11:30 SESSION 7

META ANALYSIS

Kerry Gordon and James Matcham

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 BREAK

13:30 SESSION 8

CRITICAL LITERATURE REVIEW

Kerry Gordon and James Matcham

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

Kerry Gordon and James Matcham

16:15 END OF TRAINING COURSE

Training Course Venue

Holiday Inn London Kensington Forum

97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9094

www.hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 16 to 18 October 2017 at the rate of GBP 160.00 per standard double room for single use per night including Full English Breakfast, taxes and service fee.

In order to book a hotel room, please contact the hotel directly and quote the booking reference "DIA/RV5".

The room rate is available until 16 September 2017 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Heathrow Airport take the London Underground Victoria line and get off at Gloucester Road. The hotel is located within 3 min walking distance from the station.



Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11 credits.



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For groups of 5 or more individuals, please contact EMEA@DIAglobal.org for a custom group rate.

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REGISTRATION FORM

Clinical Statistics for Non-Statisticians # 17532

17-18 October 2017 | Holiday Inn London Kensington | London, UK



REGISTRATION FEES

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

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 <input type="checkbox"/>	€ 1'605.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 <input type="checkbox"/>	€ 880.00 <input type="checkbox"/>

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Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.

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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

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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

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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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

Attendee email required for course material access

PAYMENT METHODS

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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.**

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Date Signature