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

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 11 credits for pharmaceutical medicine. All participants are eligible for these credits.

DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet de Ile-de-France.

DEVELOP, INNOVATE. ADVANCE.

DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

DIAglobal.org
DAY 1
07:30 REGISTRATION

08:30 WELCOME AND COURSE OBJECTIVES

09:00 SESSION 1

BASIC STATISTICAL CONCEPTS
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.

- 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 review 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

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.
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
REGISTRATION FORM

Clinical Statistics for Non-Statisticians # 16532
18-19 October 2016 | Holiday Inn – Kensington Forum | London, UK

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

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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 non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

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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
Email: EMEA@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.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

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.

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.

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Payable in equal instalments with the balance due 30 days after registration.

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