DIA Learning

Clinical Statistics for Nonstatisticians

30-31 October 2018
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, and who must present results of clinical trials. The course is aimed for non-statisticians and those who need to refresh their statistical knowledge.

Participants should have a basic understanding of statistics (either through professional experience or studies) roughly equivalent to an introductory statistics course.

FACULTY

Kerry Gordon
(Course Director)
Senior Director, Biostatistics,
Japan, China, Europe and North America
IQVIA, UK

Julie Anne Anderson
Director Statistics
Glaxosmithkline, UK

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 WELCOME AND COURSE OBJECTIVES

Kerry Gordon and Julie Anne Anderson

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 Julie Anne Anderson

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 Julie Anne Anderson

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 Julie Anne Anderson

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 Julie Anne Anderson

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 Julie Anne Anderson

17:15 NETWORKING RECEPTION

18:15 END OF DAY ONE

DAY 2

08:30 SESSION 5

RECAP

Kerry Gordon and Julie Anne Anderson

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 Julie Anne Anderson

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 Julie Anne Anderson

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 Julie Anne Anderson

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 Julie Anne Anderson

16:15 END OF TRAINING COURSE

Training Course Venue

HOLIDAY INN KENSINGTON FORUM

97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9100
Email: reservations@hikensington.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 28 to 31 October 2018 at the rate of GBP 165.00 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".

The room rate is available until 28 September 2018 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.

SwAPP Swiss Association of Pharmaceutical Professionals

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted 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 only available for the industry rate.

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 to DIA.

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

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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

Clinical Statistics for Nonstatisticians # 18532
30-31 October 2018 | Holiday Inn London Kensington | London, UK

DIA Learning

REGISTRATION FEES

Registration fee includes refreshment breaks, lunches and electronic access to training course material. 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	NON-MEMBER
INDUSTRY	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑

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

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

A special discount for SMEs on the standard fee is available for a limited number of places. To proof your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.

DIA MEMBERSHIP

All non-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click here. If you want a membership, please indicate your preference below.

❑ **I would like to receive a one year complimentary DIA membership at no additional cost**

The DIA 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: 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 Fax 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 #18532 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