

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

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DAY 1

07:30	REGISTRATION
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08:30	WELCOME AND COURSE OBJECTIVES
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09:00	SESSION 1
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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
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10:30	SESSION 2
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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
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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
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13:30	SESSION 3 (CONTINUED)
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STUDY DESIGN

15:00	COFFEE BREAK
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15:30	SESSION 4
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MAKING DECISIONS

This session illustrates how to set up hypotheses and test them. In addition, we will discuss the characteristics of decision 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
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17:15	DRINKS RECEPTION
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18:15	END OF DAY ONE
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DAY 2

08:30	SESSION 5
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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
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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
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10:30	SESSION 6 (CONTINUED)
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INTERPRETING STATISTICS

11:30	SESSION 7
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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
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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

KNOWLEDGE CHECK

16:30

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/>

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