



K35 Statistics for Non-Statisticians

4th November 2021



**The day will start at 08:45 with registration and coffee for a prompt start at 09:15.
We aim to finish by 17:30.**

ICR Training

K35 Statistics for Non-Statisticians

10 CPD
POINTS



4th November 2021

K35

Venue - The Institute of Clinical Research Training Suite, White Waltham

Course Outline

The Course

Statistics is the art and science of summarising data. Statistics play an essential role in all stages of clinical research from design through to analysis and interpretation.

Clinical Trials generate large volumes of data but most of us are looking for the “punch-line”; Did the new treatment work? Were the two groups being compared the same or different? We rely on statistics to help us design the most appropriate trial to answer our questions, to determine the required sample size and to interpret the results. A poorly designed study wastes time, resources and puts patients at unnecessary risk. A solid understanding of statistical principles is important for all team members, not just the team statistician; however for many of us statistics is nearly a foreign language.

This course is aimed at non-statisticians who work in clinical research and provides an introduction to the statistical methods used for the design, conduct and analysis of clinical trials. The course emphasises the application of statistical concepts to clinical research; aiming to demystify the subject and equipping delegates with the knowledge to read, understand, interpret and communicate data & statistics.

This is an introductory course and no significant mathematical knowledge is required.

Delegates should bring a laptop and calculator to the course.

Learning Objectives

- Define statistical terminology
- Read the statistical parts of a medical journal paper
- Describe the various types of data and how they are summarised
- Outline the process for statistical analysis of clinical trials

Describing Data

- Types of data, types of endpoints
- How are data described and presented
- Important issues relating to graphs, table, diagrams etc.
- Comparing two groups (means, odds ratios, hazard rates/ratio, Kaplan-Meier)

Significance Testing

- What is being evaluated
- Null and alternative hypothesis
- Types of error - P-values and confidence intervals
- Types of test

Power and Sample Size

- What is power?
- Power and sample size
- Determinants of sample size
- Designing clinical trials from statistical perspective
- Statistical sections of protocols

Statistical Reports

- Populations (ITT, per protocol)
- Safety and efficacy presentation
- Describing and understanding statistical significance

Who would benefit

All those working in clinical research, who would like to have a better understanding of statistics.

Course Fees

Guest	£550.00
ICR Member	£450.00
ICR Member Academic	£350.00

David Morgan

David joined the pharmaceutical industry in 1986. He has led both statistics and data management groups in UK and US and spent 9 years in the CRO sector. David joined Ipsen in 2007 as Senior Director of Clinical Development Data Sciences, with global responsibility for data and statistical aspects of clinical development and successful regulatory submissions to FDA and EMA. From 2012 to 2015 he took up a new role as VP / Chief Statistical Scientist for Ipsen – supporting the Chief Medical Officer in ensuring patient safety and data integrity throughout the company. In this role he led Ipsen's initiative on Data Transparency.



Pre-Course Questionnaire - To be completed by all delegates

Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Course Title: K35 Statistics for Non-Statisticians

Date: 04 November 2021

Name:

Company / Hospital:

Position / Job Title:

How much experience of clinical trials do you have? (Years)

.....
.....
.....

What are you hoping to get out of the day?

.....
.....
.....

State one issue/problem you would like discussed at the meeting

.....
.....
.....

Special Dietary Requirements

.....
.....
.....

* The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free - however it may not be possible to cover all requests for dietary preferences.



Address: The Institute of Clinical Research Training Suite, Suite 1, Cedar Court Grove Business Park White Waltham, Berkshire, SL6 3LW

The ICR's training suite is situated near the charming village of White Waltham. Located just off the A404, with connections by road or rail.

The Institute of Clinical Research Training Suite

Suite 1, Cedar Court

Grove Business Park

White Waltham

Maidenhead

SL6 3LW

By Car: Join the A404 either via at J5 of the M40, or J8/9 of the M4. Follow the A404 until you reach J9A signposted to Maidenhead/Reading. Turn right at the first roundabout, then continue on that road, going straight across any subsequent roundabouts. Take the second right past the airfield. If you reach the village, you've gone too far.

Once inside Grove Park, turn left at the first mini roundabout, then right at the T junction. Turn right at the red brick building, and we are in the one furthest from the road. Park in the large car park on your right. Please contact the Secretariat using the buzzer by the door - type in 12 and then press the small bell.

By Train: The nearest station is Maidenhead, located on the Paddington - Reading line. We recommend getting a taxi from the station, as bus routes are sporadic. It should take roughly 15 minutes.

Local Taxi Companies

Dot to Dot + 44 01628 200 999

Golden Executive + 44 1628 622955

Imperial +44 1628 771777

Accommodation

The ICR does not specifically recommend any accommodation - however the following are within easy travelling distance of the training venue

Hotel or Bed & Breakfast Name	Contact number	Website	Approximate Distance to The Institute of Clinical Research
Premier Inn Maidenhead	08715 279520	http://www.premierinn.com	4 miles 14 minutes
Taplow House Hotel	01628 670056	https://taplowhousehotel.com	6 miles 16 miles
Bel & The Dragon	01628 521263	https://belandthedragon-cookham.co.uk/	7 miles 18 minutes
CIM Moor Hall	+44 1628 427500	https://moorhall.cim.co.uk/	7 miles 18 minutes

There are also a number of travel websites which may allow you to identify local accommodation and special offers - e.g. expedia

The Small Print

As a matter of policy we do not issue electronic copies of the slides used.

All ICR materials are copyrighted.

All delegates receive a delegate book.

Payment must be received in advance of a training course commencing. The ICR has the right to refuse entry for non-payment. Payment by invoice must be settled within 14 days from the date of invoice.

We understand that occasionally circumstances may change and that you will be unable to attend your chosen course. Notification of cancellation must be made in writing. If you cancel **more than 14 days prior to the event**, we will refund the course less £50 to cover administration costs. If you cancel within 14 days, no refund will be payable, but we will allow you to transfer to another course of your choice.

We will accept a change of delegate at any time without you incurring a penalty. The Institute of Clinical Research reserves the right to cancel any course that is under-subscribed but will give you 7 days notice in writing and will refund your course fees without any liability for any consequential or indirect loss.

At anytime, you may transfer to the same course within 12 months, or to another course of your choice within 6 months; a £25 administration fee will be charged for such transfers.

We may also need to change the venue but will give you 7 days notice in writing of the new location.

Programmes as published are correct, however due to circumstances beyond our control, trainers, speakers and/or the programme may need to be altered occasionally.

The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free – however it is not possible to cover all possible requests for dietary preferences.

Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Registration Form

Please photocopy this form for further registrations

Course Title: K35 Statistics for Non-Statisticians **Course Date:** 04 November 2021

Membership No.: **Title(Dr,Mr,Mrs,etc):** **First Name:**

Surname: **Job Title:**

Company Name:

Email Address:

Confirmation of booking will be sent by email, unless you request here that it is sent by post ☐

Correspondence Address

Address:

Postcode: **Country:** **Telephone Number:**

Special Dietary Requirements

.....

Declaration

I agree to the terms and conditions of booking **Signature:**

Method of Payment

Please note that your place will only be confirmed when payment has been received (please tick as required)

I wish to pay the fee of

☐ I enclose a cheque payable to "The Institute of Clinical Research"

OR

☐ I wish to pay by

☐ VISA ☐ MASTERCARD ☐ DELTA ☐ EUROCARD

Card Number

Start Date **Expiry Date**

Name (as it appears on the card)

Signature of card holder

OR

☐ Please invoice my company using Purchase Order Number Invoices can only be raised when a PO no. is provided

Correspondence Address

Address:

Postcode: **Country:**