



## H20 Data Management for Clinical Researchers

11th June 2019



**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

H20 Data Management for Clinical Researchers

10 CPD  
POINTS



11th June 2019

H20

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

Course Outline

## The Course

This Course has been cancelled. Please contact the Office for more information.

Are you a clinical researcher who has to review and approve data management plans, but find yourself struggling to know what you should be looking for? Do you have to select a Data Management vendor but don't know how to evaluate their capabilities? In this course we will explore data management terminology, data management plans, coding and (e)CRFs so that you can work more effectively with data management specialists.

## Learning Objectives

- Understand clinical data management terminology
- Have a good understanding of data management plans, coding and design of (e)CRFs
- Communicate effectively with data management specialists within a clinical project team

### Data Management basics

- Objectives of data management
- Regulatory background
- Quality of data
- Computer systems

### Data capture

- Design of (e)CRFs
- Data standards – CDISC / CDASH
- External data – labs, Serious Adverse Event data

### Data Management plans

- Flow of data (paper and electronic)
- Data validation – queries
- Links to risk-based monitoring

### Coding of medical terminology

- Purpose of coding
- Adverse events – MedDRA
- Concomitant medications
- Medical history

### Further topics

- Data privacy
- Submission data sets
- Data sharing
- The future of data management

## Who would benefit

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

## Course Fees

<b>Guest</b>	<b>£550.00</b>
<b>ICR Member</b>	<b>£450.00</b>
<b>ICR Member Academic</b>	<b>£350.00</b>

## 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](mailto:training@icr-global.org) or fax to +44 01628 501 709

Course Title: H2O Data Management for Clinical Researchers

Date: 11 June 2019

**Name:** .....

**Company / Hospital:** .....

**Position / Job Title:** .....

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

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.....  
.....

**What are you hoping to get out of the day?**

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.....  
.....

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

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**Special Dietary Requirements**

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.....  
.....

\* 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 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.

**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 10 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

Book Airport Taxi Cabs +44 1494 372 003

## 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 279 520	<a href="http://www.premierinn.com">http://www.premierinn.com</a>	4 miles 14 minutes
The Olde Bell	01628 825881	<a href="http://www.theoldebells.co.uk/">http://www.theoldebells.co.uk/</a>	5 miles 13 minutes
Holiday Inn Maidenhead	0871 527 9326	<a href="http://www.holidayinn.com">http://www.holidayinn.com</a>	3 miles 8 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](mailto:training@icr-global.org) or fax to +44 01628 501 709

## Registration Form

Please photocopy this form for further registrations

**Course Title:** H20 Data Management for Clinical Researchers      **Course Date:** 11 June 2019

**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

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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:** .....