K21 Clinical Trial Administration - Beyond the Basics

29th June 2021

The Institute of Clinical Research

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

K21 Clinical Trial Administration - Beyond the Basics

10 CPD POINTS

29th June 2021

K21

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

Course Information

The Course

Clinical Trial Administrators are at the heart of any project team and play an essential role in the clinical trial process. This course gives an in-depth look into some of the aspects of clinical trials. It aims to give an understanding of the history and evolution of clinical research.
Delegates will be guided through the essential documents required at each stage of the clinical trial process and their respective functions, an outline of the key roles and functions, and explores how the role of the CTA fits into the clinical trial process.
The course also gives further insight into the EU legislation governing trials, ethics committees, audits and inspections, using and creating SOPs, auditing and archiving.
The course will utilise trainer input, exercises, and delegate interaction.

Learning Objectives

- Summarise the impact of the EU Directives on clinical research working practices
- Outline the ethics committee submission process
- Describe the function of SOPs and outline the process for creating one
- Identify essential documents and their respective functions
- Describe the key issues in preparing for and participating in an audit/regulatory inspection

Course Outline

- Review of ICH GCP
- EU Clinical Trials Directive & UK Legislation
- The EU Data Protection Act
- Ethics Committees & Submissions
- Standard Operating Procedures - Their management & writing them
- The wider role of the CTA
- CTA Key customers & interactions
- Essential Documents
- Regulatory aspects of Archiving
- Key Documents & Version Control
- Tracking systems
- Data management, data flow & audit trails
- Audits & Inspections

Who would benefit

Those new to the CTA role and those with experience who would like a more in depth look at clinical trials process

Course Fees

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

Your Trainers

Hanna Preus

Dr Hanna Preus is a Global Quality & Compliance and Business Strategies expert with more than 15 years of versatile quality and operational excellence experience in clinical trials – including creating and overseeing quality and business processes across multidisciplinary business units (project management, clinical operations, quality assurance etc.)

An expert in internal external and systems audits/controls, Dr Preus has a strong knowledge and wide practical experience in GxP requirements, Standard Operating Procedures (SOPs), global and local regulatory requirements.

Dr Preus is the author of research on socio-economic determinants of clinical trial systems (the doctoral dissertation), engaging pharmaceutical companies, CROs, sites (hospitals) – Principle Investigators and Sub Investigators, Study, Nurses, and patients.

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Pre-Course Questionnaire - To be completed by all delegates

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

Course Title: K21 Clinical Trial Administration - Beyond the Basics

Date: 29 June 2021

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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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.

Training Location

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.

Registration Form

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: K21 Clinical Trial Administration - Beyond the Basics **Course Date:** 29 June 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

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Declaration

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

Method of Payment

Please not 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:** .....