



L22 Process Thinking in Clinical Trials

21st September 2022



**The day will start at 09:45 with registration and coffee for a prompt start at 10:15.
We aim to finish by 18:30.**



The Course

ICH E6 (R2) has emphasized the importance of risk management in relation to ensuring subject safety and rights as well as data integrity in clinical trials. Understanding, oversight and improving clinical trial processes, is a fundamental way of managing these risks. This course demonstrates ways to map processes, how to measure them and to understand how they might fail. It provides a tool kit for root cause analysis and provides approaches to improve processes so as to minimize risk. Throughout, examples are used from clinical trials and participants are encouraged to practise the skills they learn.

Learning Objectives

By the end of this course, you will be able to...

- Understand the relevance of process thinking in clinical trials
- Learn how to map processes
- Learn how to review processes for potential weaknesses and develop preventive actions
- Practise a method of root cause analysis that goes beyond the normal "Five Whys" approach
- Understanding different types of actions and how to develop actions to help prevent recurrence of issues (CAPA)
- Understand how metrics can be used to monitor processes

- ICH E6 (R2) - Process understanding and risk
- How to map a process
- Assessing to process for risk
- What to do when a process goes wrong - corrections and root cause analysis
- Preventing further failures (CAPA)
- Monitoring process health

Who would benefit

Anyone with a role and interest in understanding and improving processes such as:

- Project Managers, Directors
- Clinical Operations Managers, Directors
- Project Management Office
- Data Managers, Directors
- IT Managers, Directors
- Process Improvement Specialists, Directors

Course Fees

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

Keith Dorricott

Keith Dorricott is the Director of Dorricott Metrics & Process Improvement Ltd. He worked in R&D, process development, packaging technology and manufacturing whilst at Kodak Ltd. In 2005 he moved industry into the area of clinical trials and worked for two major CROs leading corporate process improvement. He qualified as a Black Belt in Six Sigma in 2002 and a Master Black Belt in Lean Sigma in 2007. He assists the Metrics Champion Consortium (MCC) by facilitating work groups on centralized monitoring, central lab metrics, vendor oversight, Data Management, and by developing tools to assist with risk assessment and control. He received the MCC Champion Award in 2016 for making significant contributions to advancing the MCC mission to improve the efficiency, quality and effectiveness of clinical trials. Keith regularly presents at conferences such as DIA and SCOPE on the definition and use of metrics as well as the practicalities of quality risk management and risk-based monitoring. Keith is on the approved list of MCC industry consultants ready to assist your organisation with performance metrics and process improvement and has recently launched a novel approach to assist with critical thinking in clinical trials - DIGR-ACT.



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: L22 Process Thinking in Clinical Trials

Date: 21 September 2022

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 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: L22 Process Thinking in Clinical Trials **Course Date:** 21 September 2022

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:**