EGCP2 The ICR Ethics & GCP Forum

27th November 2019

The day will start at 08:45 with registration and coffee for a prompt start at 09:15. We aim to finish by 16:30.

ICR Training

EGCP2 The ICR Ethics & GCP Forum

3 CPD POINTS

27th November 2019

EGCP2

Venue - 33 Queens Square, London

Course Information

The Course

THIS FORUM IS FULLY BOOKED

The ICR Ethics and GCP Forum provides an excellent opportunity to:

- Keep up to date with current ethical and clinical research issues
- Learn about new industry and regulatory initiatives
- Hear key industry figures speak about their specialist fields
- Network with fellow clinical research professionals

Learning Objectives

Pricing

ICR Members - £40

Guests - £50

Course Outline

Ethics Forum Chair: Joan Perou

GCP Forum Steering Committee:

- Janice Hedgecock,
- Stuart Harris,
- Julia DeCesare
- Heidi Chandler
- Helen Buck

UCL Joint Research Office: Helen Cadiou

Who would benefit

Course Fees

Guest	**£50.00**
ICR Member	**£40.00**
ICR Member Academic	**£40.00**

Your Trainers

Kirsty Wydenbach

Dr Kirsty Wydenbach is a Senior Medical Assessor and the Deputy Unit Manager in the Clinical Trials Unit, having joined the MHRA in 2009. She has been involved in the UK regulation of clinical trials across all therapy areas and all phases of development, including trials for chemical and biological products, Advanced Therapy Products and many first-in-man studies. She has also been involved in European discussions aiming to establish an EU harmonised approach to clinical trials, particularly for Developmental Safety Update Reports (DSURs) and Reference Safety Information (RSI). She was also an EMA expert for the update of the First-in-Human guideline.

More recent EU priorities have included the new Clinical Trial Regulation and Kirsty currently sits on the safety subgroup of the Clinical Trials Facilitation Group (CTFG) that is working on how safety reporting aspects will be implemented. Other recent work has included collaboration with external industry groups and regulators regarding adaptive and novel trial designs: she is leading on this aspect for the MHRA in order to implement that aspect of the Life Sciences Industrial Strategy, and was a contributor to the EU CTFG "Recommendation Paper on the Initiation and Conduct of Complex Clinical Trials".

Your Trainers

Paul Strickland

Paul Strickland (Strickland Quality Assurance Ltd)

Paul Strickland founded Strickland Quality Assurance Ltd, a QA consultancy capitalising on his 27 years of experience in Clinical Quality Assurance. As a consultant he has audited across the world, for organisations of all sizes. He has also given GCP training and refresher courses, inspection preparation guidance and support during the inspections themselves.

Paul previously worked for twelve years at Amgen Ltd, most recently as Director of Intelligence and Inspections, and Regional Head of Clinical Auditing. In former years, Paul worked in a GCP auditing capacity with the Wellcome Foundation and with Glaxo. From the beginning, he led the facilitation of many regulatory inspections, both in-house and in the field in Europe, USA and Africa. He also has several years' previous experience in QA of manufacturing with Serono Diagnostics. His first healthcare role was in 1979 with Amersham International.

Paul has been course principal for the RQA GCP auditing course for eighteen years, and was a tutor on the course for a number of years before this. He gained RQA's Diploma in Research Quality Assurance in 1998 and is a Fellow of the Association. Paul was the chair of the Audit Working Party, a subgroup of the EFGCP, from 2005 to 2019. In this role he was a member of the EFGCP Board and an invited member of the MHRA Stakeholder Engagement Meeting.

This will be Paul's last public presentation as he will be retiring at the end of the year.

Your Trainers

Janet Messer

Dr Janet Messer

Janet Messer is Director of Approvals Service at the Health Research Authority. She is responsible for the Research Ethics, Confidentiality Advice, Assessment and Assurance services, alongside the supporting guidance, advice and learning functions. Her team works collaboratively with a wide range of partner organisations to fulfil the HRA's aims to make it easier to do good quality ethical research in the UK. She has a PhD in biochemistry from University of Cambridge and a Masters in Medical Law, along with many years' experience of clinical research in the pharmaceutical industry, NHS R&D and the NIHR Clinical Research Network.

She sits on the NHS Digital Research Advisory Group and is a member of its ethics & streamlining working group. She has presented internationally on use of patient data and the General Data Protection Regulation.

Your Trainers

Lucielle Mansfield

Lucielle Mansfield (Luci) is a Senior Project Manager at QRC Consultants. Luci graduated from the Nottingham Trent University with a PhD in Microbiology and has over 14 years of clinical experience. Luci has managed clinical trials within the UK and EU across a range of therapeutic areas and various phases of development. Luci has experience of working in both a Pharmaceutical company and a Clinical Trial Unit. She is a member of the ICR and HSRAA.

Your Trainers

Keith Summerhayes

A **Senior Medical Device Professional**with significant technical & managerial skills and international experience, gained during the past 35 years, with major US & European 'blue chip' Pharmaceutical, Contract Research and Orthopaedic Medical Device Corporations. Has also obtained significant experience in start-up medical device companies and has run his own Consultancy Company for nearly 11 years. Whilst heavily Clinically focused the past 14 years has included some involvement in Quality & Regulatory Management.

An effective leader with a broad understanding of clinical research and associated regulatory and quality management issues and business drivers, including the productive management of change, the need to proactively focus on customer perceived needs and the identification & prosecution of opportunities to gain incremental business through the provision of 'added value' services to maximise return and profitability.

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: EGCP2 The ICR Ethics & GCP Forum

Date: 27 November 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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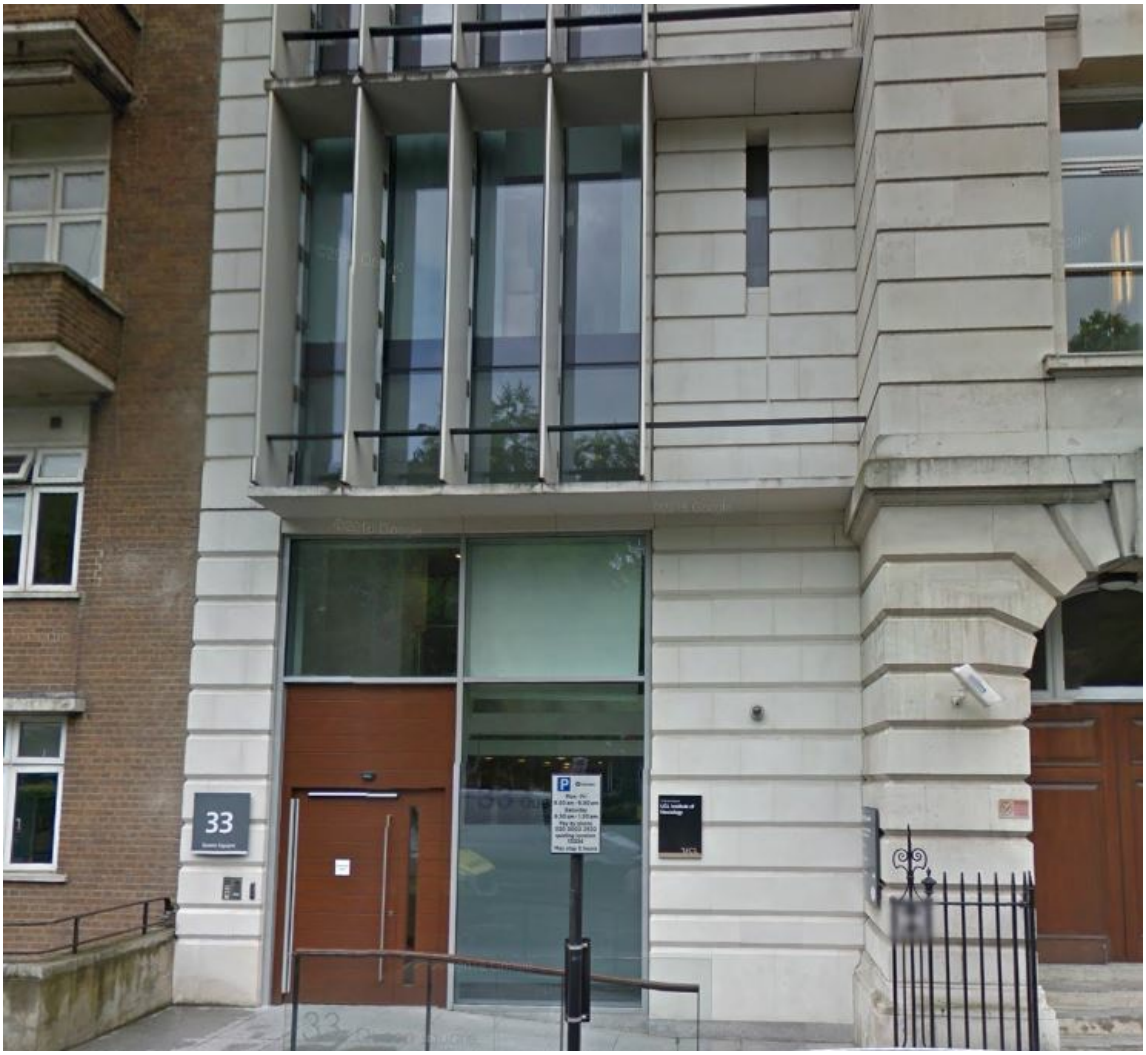
* The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free - however it may not be possible to cover all requests for dietary preferences.

Training Location



Address: 33 Queens Square, University College London, Lower Ground Floor, 33 Queen Square London, GB, WC1N 3BG

33, Queen Square is a short walk from Russell Square tube Station (Piccadilly line) and within 15 mins walk from King's Cross and Euston Stations.

Local Taxi Companies

Addison Lee - 0843 504 0326

Accommodation

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

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Imperial Hotel - www.imperialhotels.co.uk / 020 7837 3655

The Montague on the Gardens - www.montaguehotel.com / 020 7637 1001

Premier Inn London Holborn - www.premierinn.com / 0871 527 9496

The Morton - www.mortonhotel.co.uk / 020 7692 5600

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: EGCP2 The ICR Ethics & GCP Forum **Course Date:** 27 November 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 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:** .....