

ICR EVENTS

Wednesday 27th November 2019



Ethics & GCP Forum Guidelines and Regulations

Venue: University College London, 33 Queen Square, Lower Ground Floor, WC1N 3BG

Ethics & GCP Forum

Programme

09:00	Registration
10:00	Welcome
	<u>Ethics Forum</u>
10:15	MHRA Update Kirsty Wydenbach, Deputy Unit Manager / Senior Medical Assessor, MHRA Clinical Trials Unit
11:00	Update on HRA Approval and HRA Activity Janet Messer, Director of Research Systems, Standards and HRA Approval Programme
11:45	EMA Trial Master File Guideline Paul Strickland Strickland Quality Assurance Ltd
12:15	Sandwich Lunch
	<u>GCP Forum – Patient Participation</u>
13:30	Data Integrity Lucielle Mansfield QRC Consultants Ltd
14:15	Medical Device Regulation Keith Summerhayes MDCRQ Solutions Ltd
15:00	Comfort Break
15:15	Key GCP Updates A summary of changes in GCP-related regulations and guidelines since the last Ethics/GCP Forum meeting GCP Steering Committee
16:00	Close

Overview

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 Outcomes

- Learn about the latest information from the HRA
- Learn about the latest updates from the MHRA
- Understand the requirements of the EMA TMF Guideline
- Understand the MHRA data integrity guidance and its implications for clinical trials
- Learn about the Medical Device Regulation and the changes for those involved in device clinical trials
- Be aware of recent regulatory changes in clinical research

Organisers

Ethics Forum Chair: *Joan Perou*
GCP Forum Steering Committee:
Janice Hedgecock (Chair), Stuart Harris, Julia DeCesare, Heidi Chandler, Helen Buck
UCL Joint Research Office:
Helen Cadiou

Enquiries (ICR): +44 (0) 1628 501700
office@icr-global.org

Venue

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

<http://www.ucl.ac.uk/ion/contact>

Registration

Visit the ICR Website to book:

Fee: £40 for members, £50 for non-members

(<http://www.icr-global.org/forums/types-of-forum/ethics-and-gcp-forum/>)

Places are limited so please book early!

The programme is subject to change. Please check the ICR Website for the latest version.