

Welcome to the Bi annual ICR Ethics & GCP Forum 18th March 2021



Learn more to achieve more

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**With grateful thanks to Jess and Erica
at ICR for systems and event
organisation**

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ICR ETHICS & GCP FORUM COMMITTEES



Joan Perou (HonFICR)
Ethics Forum Chair

Janice Hedgecock (HonFICR)
GCP Forum Chair
Greatspur Clinical Development Ltd

GCP Forum Committee Members

Stuart Harris
Astellas Pharma Ltd

Julia DeCesare
AstraZeneca

Helen Cadiou
University College London

Heidi Chandler
Barking, Havering and Redbridge University
Hospitals NHS Trust

Helen Buck
Freelance Clinical Research Professional

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The ICR and the Ethics & GCP Forum would especially like to express our thanks to today's speakers:

- Kirsty Wydenbach, MHRA Clinical Trials Unit
- Janet Messer, HRA Approvals Service
- Dr Leslie Gelling, Cambridge South Research Ethics Committee
- Lucy Parker and Nicola Johnson, Royal Free Hospital
- Kamal S. Saini, Covance Clinical and Periapproval Services
- Janice Hedgecock, ICR GCP Forum Chair

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- Attendees will be automatically muted throughout the meeting
- Please use the Q & A facility to ask questions of the speakers
- Electronic copies and an audio recording of the presentations will be available on the ICR Website within seven working days (www.icr-global.org)

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ICR EVENTS

Thursday 18th March 2021



Ethics & GCP Forum

Programme

09:30 Online Registration/Dial-in
10:00 Welcome

Ethics Forum

10:10 **MHRA Update incl. Brexit**
Kirsty Wydenbach, Deputy Unit Manager / Expert Medical Assessor, MHRA Clinical Trials Unit

11:20 **Pause**

11:30 **Research Ethics Committee Insights**
Dr Leslie Gelling, Chair, Cambridge South Research Ethics Committee & Principal Academic on Adult Nursing at Bournemouth University

12:15 **Lunch Break**

GCP Forum – Non-COVID studies – continuity

13:00 **The Pandemic and Non-COVID Studies: Restart Experiences**
Lucy Parker, R&D Manager, and Nicola Johnson, Oncology Lead Research Nurse, Royal Free Hospital

13:50 **Pause**

14:00 **The Pandemic and Non-COVID Studies: CRO Insights**
Kamal S. Saini, Executive Medical Director, Covance Clinical and Periapproval Services

14:50 **Pause**

15:00 **Update on HRA Approval and HRA Activity**
Janet Messer, Director of Approvals Service, HRA

15:50 **Pause**

16:00 **Key GCP Updates**
A summary of changes in GCP-related regulations and guidelines since the last Ethics/GCP Forum meeting.
GCP Steering Committee

16:50 **Close**

Ethics & GCP Forum

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

Learning Outcomes

- Learn about the latest information from the HRA
- Learn about the latest updates from the MHRA
- Understand the challenges faces by sponsors and research sites in continuing conduct of non-COVID-19 studies
- 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

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