

Module 5: Regulatory Control of Clinical Operations
Date: 7-9th July 2026



Location: TOPRA Office: 3rd Floor, City Reach 5, Greenwich View Place, London, E14 9NN

Module Leaders: Shaila Choi and Pierre-Frédéric Omnes

Day 1: Tuesday 7th July 2026

| Time | Activity | Speaker |
|---------------|--|---|
| 10:00 – 10:30 | Registration Welcome & Introduction to the Module | Chairperson: Shaila Choi Azafaros AG |
| 10:30 – 11:30 | Lecture 1: GCP: The platform for clinical research <ul style="list-style-type: none">• Objective• History• Quality & Compliance• Audits and Inspections | Bob Ibbotson Shionogi |
| 11:30 – 12:30 | Lecture 2: GCP Inspections – Agency Experience | Rachel Mead or Michelle Gabriel MHRA |
| 12:30 – 13:30 | Lunch | |
| 13:30 – 14:30 | Lecture 3: Legal aspects of clinical trials <ul style="list-style-type: none">• Product Information and Informed Consent• Data Protection• Enforcement and Sanctions• Liability• Clinical Study Contracts | Adela Williams Arnold & Porter (remote) |
| 14:30 – 15:30 | Lecture 4: Understanding the need for Non-Clinical studies <ul style="list-style-type: none">• Purpose of non-clinical studies in support clinical development• Requirements for different stages of clinical Development | Chris Powell Cambridge BioPharma Consultants Ltd |
| 15:30 – 16:00 | Refreshment Break | |
| 16:00 – 17:00 | Lecture 5: The successful IMPD <ul style="list-style-type: none">• Contents of the IMPD• Pitfalls• Updates | Graham Bell ICON |
| 17:00 | Close | |

Day 2: Wednesday 8th July 2026

| Time | Activity | Speaker |
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| 09:00 – 09:10 | Introduction to Day 2 and review of Day 1 | Chairperson Shaila Choi , Azafaros AG |
| 09:30 – 10:30 | Lecture 6: Regulatory requirements for clinical trials: Medicines <ul style="list-style-type: none">• Current Legislation Requirements• The Clinical Trial Regulation and its Impact• CTA applications / Medical Devices• Ethics Committee Submissions• Reporting of clinical trials.• Industry experience | Pierre-Frédéric Omnes TransPerfect |
| 10:30 – 11:00 | Refreshment Break | |
| 11:00 – 12:00 | Lecture 7: Regulatory requirements for clinical trials of medical devices | Deepa Subramaniyan Roche (remote) |
| 12:00 – 13:00 | Lunch | |
| 13:00 – 13:45 | Lecture 8: Regulatory requirements for clinical trials - Japan <ul style="list-style-type: none">• Legislation requirements• Clinical Trial Notifications• Japanese Regulatory Authorities Consultations• GCP | Mohamed Oubihi Yakumed (remote) |
| 13:45 – 15:00 | Lecture 9: Regulatory requirements for clinical trials – US, Canada, UK <ul style="list-style-type: none">• Legislation requirements• CTA and IND applications & maintenance• Ethics Committee• GCP & Enforcement | Sarah Roberts ICON (remote) |
| 15:00 – 15:30 | Refreshment Break | |
| 15:30 – 16:45 | Case Study <ul style="list-style-type: none">• Introduction (5 min)• Case Study Discussions (1 hour)• Presentations & Feedback (10 mins) | Pierre-Frédéric Omnes TransPerfect |
| 16:45 – 17:45 | Lecture 10: Ethics Committee Perspective | TBC |
| 17:45 | Close | |

Day 3: Thursday 9th July 2026

| Time | Activity | Speaker |
|---------------|--|---|
| 09:00 – 09:10 | Introduction to Day 3 and Review of Day 2 | Chairperson Shaila Choi Azafaros AG |
| 09:10 – 10:15 | Lecture 11: Pharmacovigilance & adverse event reporting in clinical trials <ul style="list-style-type: none">• Adverse Event Reporting - -General requirements and definitions• Safety reporting in the EU• Pharmacovigilance• Future Proposals | Sam Tomlinson Vertex |
| 10:15 – 10:45 | Refreshment Break | |
| 10:45 - 12:00 | Lecture 12: GMP considerations <ul style="list-style-type: none">• Manufacturing authorisation and importation requirements,• Role of the QP• Clinical trial supplies management• | Stefan Crediet Pfizer |
| 12:00 – 13:00 | Lunch | |
| 13:00 – 14:30 | Case Study <ul style="list-style-type: none">• Introduction (10 min)• Case Study Discussions (1 hour)• Presentations & Feedback (10 mins) | Shaila Choi Azafaros AG |
| 14:30 – 14:45 | Refreshment Break | |
| 14:45 – 15:45 | Lecture 13: A GRL's perspective <ul style="list-style-type: none">• Study design• Choice and provision of comparators, populations, SOC• Considerations for study conduct• Scientific advice• How regulatory interacts with clinical in clinical development• Open label extension studies, Named patient supply, Early access programs, Compassionate use | Sonia Rodrigues Astrazeneca |
| 15:45 | Close | |