

Module: Overview of EU and UK Pharmaceutical Regulatory Affairs

Date: 14th – 16th April 2026



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

Module Leaders: Grzegorz Kojro and Sacha Lynch

Day 1: Tuesday, 14th April 2026

Time	Activity	Speaker
08:15 – 08:45	Registration	
08:45 – 09:00	Opening and Introduction - Setting the scene	Sacha Lynch Module Lead
09:00 – 10:00	Lecture 1: Overview of MAA and Legal Basis <ul style="list-style-type: none">Recap on Structure of CTD ModulesBrief recap on EU and UK LegislationLegal basis of applicationsContent of M1	Sacha Lynch
10:00 – 10:15	Refreshment Break	
10:15 – 11:15	Lecture 2: Module 4 Non Clinical <ul style="list-style-type: none">First Necessary first trial of manFurther preclinical data for the MAA and the link to the SmPC	David Jones Consultant
11:15 – 11:30	Refreshment Break	
11:30 – 12:30	Lecture 3: Module 5 Clinical Development <ul style="list-style-type: none">Overview of clinical developmentPhase I, II, III trialsClinical Regulatory strategy and impact of HTAClinical pharmacology data (PD & PK)Clinical efficacy and safety data	Esther Nougier Boehringer
12:30 – 13:30	Lunch	
13:30 – 14:30	Lecture 4: EU Clinical Trial Authorisations <ul style="list-style-type: none">The Clinical Trial RegulationClinical Trials Information SystemThe application processClinical Trial Publication requirementsModifications and Notifications	Shalini Gupta Boyd Consultants
14:30 – 15:30	Lecture 5: UK Clinical Trials Landscape <ul style="list-style-type: none">Overview of the differences from the EU CTR processThe UK CTR processRoute A and Route B modificationsUK Transparency considerations	Bilal Bham Amodaia Ltd
15:30 – 16:00	Refreshment Break	
16:00 – 16:30	Quiz	Module Lead
16:30 – 17:00	End of day 1 wrap up and final questions	Module Lead

Day 2: Wednesday, 15th April 2026

Time	Activity	Speaker
08:45 – 09:00	Opening	
09:00 – 10:00	Lecture 6: Common Technical Documentation Module 3 <ul style="list-style-type: none">• Build-up of Module 3• Drug Master File and its implications• Module 3 deficiencies• Stability requirements	Stephane Vranckx GSK
10:00 – 10:15	Refreshment Break	
10:15 – 11:15	Lecture 7: Chemical-Pharmaceutical data from an R&D Perspective <ul style="list-style-type: none">• Importance of pharmaceutical development• Considerations for different formulations• Development: pitfalls and solutions	Rachel Ouannassa Pfizer
11:15 – 11:30	Refreshment Break	
11:30 – 12:00	Lecture 8: Regulatory Operations <ul style="list-style-type: none">• OMS, PMS, SPOR, web-based eAF, eCTD, 4.0, RIMs system etc	Grzegorz Kojro
12:00 – 13:00	Lunch	
13:00 – 14:00	Lecture 9: Common Technical Document Module 2 <ul style="list-style-type: none">• Structure and purpose of Module 2• Content and presentation of quality, non-clinical and clinical and clinical overview and summaries• Consistency and links between documents	Tomáš Radiměřský State Institute for Drug Control, Czechia
14:00 – 15:00	Case Study 1 CMC	Stephane Vranckx GSK
15:00 – 15:30	Refreshment Break	
15:30 – 16:00	Case Study 1 CMC Feedback	
16:00 – 17:00	Lecture 10: Regulatory Strategy <ul style="list-style-type: none">• Global Strategic Considerations for development with EU focus• Health authority interactions (including Scientific/HTA Advice) - when to use and practical advice• Paediatric Development and PIPs• Orphans	Stewart Cole Jazz Pharma
17:00 – 17:15	End of day 2 wrap up and final questions	

Day 3: Thursday, 16th April 2026

Time	Activity	Speaker
08:45 – 09:00	Opening	
09:00 – 10:00	Lecture 11: Centralised Procedure <ul style="list-style-type: none">• When to use the procedure• How to manage the procedure: internally and externally• Practical experience to date including orphan drugs• Implications of using the procedure – public assessment reports & binding decisions• Accelerated pathways	Jenny Horwood Consultant
10:00 – 11:00	Lecture 12: The Mutual Recognition Procedure and the Decentralised Procedure <ul style="list-style-type: none">• A short overview – when to use the procedure• Overview of MR and DC procedures• CMDh referral process• Duplicate licences• Impact on Prescription Status	Andrew Modley TEVA
11:00 – 11:20	Refreshment Break	
11:20 – 12:15	Lecture 13: UK Procedures <ul style="list-style-type: none">• UK ILAP and Early Access Scheme• Overview of International Procedures• Overview of National MAA Requirements	Sacha Lynch
12:15 – 13:15	Lunch	
13:15 – 14:15	Case study 2 Choice of Procedure	Sacha Lynch
14:15 – 14:45	Case study 2 Choice of Procedure Feedback	
14:45 – 15:15	Refreshment Break	
15:15 – 16:15	Lecture 14: Post Approvals – Variations and Renewals <ul style="list-style-type: none">• Variation Regulation• Categorization (Type IA, IA (in), IB, I)• New application Vs variation• Grouping and work-sharing• New legislation on renewals and updates to the variation Reg• Requirements and documents to be provided• Timelines for submission and assessment	TBC
16:15 – 16:30	Closing remarks	Module Lead