

# Module: Overview of EU and UK Pharmaceutical Regulatory Affairs

Date: 14<sup>th</sup> – 16<sup>th</sup> 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, 14<sup>th</sup> April 2026

Time	Activity	Speaker
08:15 – 08:45	<b>Registration</b>	
08:45 – 09:00	<b>Opening and Introduction - Setting the scene</b>	<b>Sacha Lynch</b> Module Lead
09:00 – 10:00	<b>Lecture 1: Overview of MAA and Legal Basis</b> <ul style="list-style-type: none"><li>Recap on Structure of CTD Modules</li><li>Brief recap on EU and UK Legislation</li><li>Legal basis of applications</li><li>Content of M1</li></ul>	<b>Sacha Lynch</b>
10:00 – 10:15	<b>Refreshment Break</b>	
10:15 – 11:15	<b>Lecture 2: Module 4 Non Clinical</b> <ul style="list-style-type: none"><li>First Necessary first trial of man</li><li>Further preclinical data for the MAA and the link to the SmPC</li></ul>	<b>David Jones</b> Consultant
11:15 – 11:30	<b>Refreshment Break</b>	
11:30 – 12:30	<b>Lecture 3: Module 5 Clinical Development</b> <ul style="list-style-type: none"><li>Overview of clinical development</li><li>Phase I, II, III trials</li><li>Clinical Regulatory strategy and impact of HTA</li><li>Clinical pharmacology data (PD &amp; PK)</li><li>Clinical efficacy and safety data</li></ul>	<b>Esther Nougier</b> Boehringer
12:30 – 13:30	<b>Lunch</b>	
13:30 – 14:30	<b>Lecture 4: EU Clinical Trial Authorisations</b> <ul style="list-style-type: none"><li>The Clinical Trial Regulation</li><li>Clinical Trials Information System</li><li>The application process</li><li>Clinical Trial Publication requirements</li><li>Modifications and Notifications</li></ul>	<b>Shalini Gupta</b> Boyd Consultants
14:30 – 15:30	<b>Lecture 5: UK Clinical Trials Landscape</b> <ul style="list-style-type: none"><li>Overview of the differences from the EU CTR process</li><li>The UK CTR process</li><li>Route A and Route B modifications</li><li>UK Transparency considerations</li></ul>	<b>Bilal Bham</b> Amodaia Ltd
15:30 – 16:00	<b>Refreshment Break</b>	
16:00 – 16:30	<b>Quiz</b>	<b>Module Lead</b>
16:30 – 17:00	<b>End of day 1 wrap up and final questions</b>	<b>Module Lead</b>

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**Day 2: Wednesday, 15<sup>th</sup> April 2026**

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

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**Day 3: Thursday, 16<sup>th</sup> April 2026**

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