

Module 23: The EU Paediatric Regulation

12 – 14 May 2025



LOCATION: LINCOLN PLAZA LONDON

2 Lincoln Plaza, Canary Wharf, London E14 9BD

Module Leader: Evgenia Mengou

Day 1 - 12th May 2025, Monday

Time	Activity	Speaker
12.30 – 13.00	Lunch and registration	
13.00 – 13.30	Welcome & Introduction to the Module	Evgenia Mengou , <i>EV Pharma Solutions Ltd</i>
13.30 – 14.30	Lecture 1: Ethics of Research in Paediatrics	Harris Dalrymple , <i>Camden and King's Cross Research Ethics Committee</i>
14.30 – 15.30	Lecture 2: Overview of Global Legislation and Collaboration Activities in Paediatrics	Evgenia Mengou , <i>EV Pharma Solutions Ltd</i>
15.30 – 16.00	Refreshment break	
16.00 – 17.30	Lecture 3: EU Paediatric Legislation (current and proposed)	Steve Pinder , <i>Envestia Ltd</i>



Day 2 – 13th May 2025, Tuesday

Time	Activity	Speaker
08.55 – 09:00	Module Lead's Introduction	Evgenia Mengou, <i>EV Pharma Solutions Ltd</i>
09:00 – 10:30	Lecture 4: PIP Procedure	Mette Due Theilade Thomsen, <i>PIP Adviser</i>
10.30 – 11.00	Refreshment Break	
11.00 – 12.00	Lecture 5: PIP Development	Michelle Blake, <i>DLRC</i>
12.00 – 13.00	Lecture 6: Quality (CMC) development considerations	Christian Maasch, <i>Takeda</i>
13.00 – 14.00	Lunch	
14.00 – 15.00	Lecture 7: Non-clinical development considerations	David Jones, <i>Independent Consultant</i>
15.00 – 16.00	Lecture 8: Clinical development considerations	Harriet Gray Stephens, <i>Boyd's</i>
16.00 – 16.15	Refreshment Break	
16.15 – 18.30	Case Study	



Day 3 – 14th May 2025, Wednesday

Time	Activity	Speaker
08.55 – 09:00	Module Lead's Introduction	Evgenia Mengou, <i>EV Pharma Solutions Ltd</i>
09:00 – 10:00	Lecture 9: Paediatric Clinical Trial Considerations	Angeliki Siapkara, <i>AstraZeneca</i>
10.00 – 10.30	Refreshment Break	
10.30 – 11.15	Lecture 10: Optimizing Drug Development Through Effective Paediatric Strategies	Martine Dehlinger-Kremer, <i>ICON Plc</i>
11.15 – 12.15	Lecture 11: Agency Perspective	Dominik Karres, <i>EMA</i>
12.15 – 13.15	Lunch	
13.15 – 14.15	Lecture 12: Considerations on Under-served (special) Populations	Harris Dalrymple, <i>Camden and King's Cross Research Ethics Committee</i>
14.15 – 14.45	Refreshment Break	
14.45 – 15.45	Lecture 13: Modelling, Simulation, and Extrapolation	Paula Muñoz Piniella Monica Rodrigues <i>CTI</i>
15.45– 16.30	Case study follow-up discussion	
16.30	Close and Farewell	