

Module 23: The EU Paediatric Regulations

12 – 14 May 2025



LOCATION: TOPRA 3RD FLOOR, CITY REACH. 5-6 GREENWICH VIEW PLACE, LONDON, E14 9NN

Module Leader(s): Evgenia Mengou

Day 1 - 12th May 2025

Time	Activity	Speaker
13.30 – 14.00	Lunch and registration	
14.00 – 14.30	Welcome & Introduction to the Module	Evgenia Mengou, <i>EV Pharma Solutions Ltd</i>
14.30 – 15.30	Lecture 1: Ethics of Research in Paediatrics	Harris Dalrymple, <i>ICON plc</i>
15.30 – 16.30	Lecture 2: Overview of Global Legislation and Collaboration Activities in Paediatrics	Evgenia Mengou, <i>EV Pharma Solutions Ltd</i>
16.30 – 17.00	Refreshment break	
17.00 – 18.30	Lecture 3: EU Paediatric Legislation (current and proposed)	Steve Pinder, <i>Envestia Ltd</i>

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Day 2 – 13th May 2025

Time	Activity	Speaker
8.55 – 9:00	Module Lead's Introduction	Evgenia Mengou, <i>EV Pharma Solutions Ltd</i>
9:00 – 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	Melissa Blake
12.00 – 13.00	Lunch	
	Lecture 6: Quality (CMC) development considerations	Christian Maasch, <i>Takeda</i>
13.00 – 14.00	Lecture 7: Non-clinical development considerations	David Jones,
14.00 – 15.00	Lecture 8: Clinical development considerations	Harriet Gray Stephens, <i>Boyd's</i>
15.00 – 15.15	Refreshment Break	
15.15 – 17.30	Case Study	

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Day 3 – 14th May 2025

Time	Activity	Speaker
8.55 – 9:00	Module Lead’s Introduction	Evgenia Mengou, <i>EV Pharma Solutions Ltd</i>
9:00 – 10:00	Lecture 9: Paediatric Clinical Trial Considerations	
10.00 – 10.30	Refreshment Break	
10.30 – 11.15	Lecture 10: PSP vs PIP	
11.15 – 12.15	Lecture 11: Agency Perspective	
12.15 – 13.15	Lunch	
13.15 – 14.15	Lecture 12: Considerations on Under-served (special) Populations	
14.15 – 14.45	Refreshment Break	
14.45 – 15.30	Lecture 13: Modelling, Simulation, and Extrapolation	
15.30 – 16.30	Case study discussion	
16.30	Close and Farewell	