

19th – 20th of May and 26th – 27th of May 2025

Monday, 19 th	Tuesday, 20 th	Monday, 26 th	Tuesday, 27 th
09:00–09:30	09:00–09:45	09:00–10:30	09:00–09:30
Introduction to the course Mira Pavlovic & Mondher Toumi	Stakeholders duties and MS readiness. Mondher Toumi & Lylia Chachoua	Critical review of ITC guidance and implication for indirect evidence development. Samuel Aballea & Piotr Wojciechowski	Impact of JCA report on MS HTA recommendations. Mondher Toumi
Break	Break	Break	Break
09:45–10:45	10:00–11:00	10:45–11:30	09:45–10:30
From EUnetHTA to EU-HTA Regulation. Mira Pavlovic	Communication mapping between stakeholders. Mondher Toumi & Lylia Chachoua	SLR JCA guidance and implications for developers. Mondher Toumi & Beata Smela	Joint Scientific Consultation (JSC) Asma Jouini
Break	Break		Break
11:00–12:00	11:15–11:45	11:30–12:15	10:45–12:15
Review of EU-HTA Regulation process. Mondher Toumi & Lylia Chachoua	Overview of different groups' profiles. Anna Kapusniak	Learning from PICO developed by JCA. Aleksandra Caban & Beata Smela	EUREKA Part 1 Ola Caban & Piotr Wojciechowski & Beata Smela
Lunch Break	Lunch Break	Lunch Break	Lunch Break
13:00–14:00	12:45–14:30	13:15–14:15	13:15–14:45
Critical review of EU-HTA Regulation. Mondher Toumi & Lylia Chachoua	Analysis of JCA validity guidance documents: limits and implications for dossier development. Mondher Toumi	Templates' analysis and implications for JCA development. Mondher Toumi	EUREKA Part 2 Ola Caban & Piotr Wojciechowski & Beata Smela
Break	Break	Break	Break
14:15–14:45	14:45–15:45	14:30–15:30	15:00–16:00
Case study: single arm trials Krzysztof Kloc	Panel Discussion: Country readiness and impact of JCA report on national decision. (Hungary & Poland) Mondher Toumi & David Danko	Why EU HTA may fail or succeed? Mondher Toumi	Panel Discussion: Key performance indicator for EU HTA Regulation. Mondher Toumi & Jörg Ruof & Frank Ulrich Fricke
Break	Break		Break
15:00–15:30	16:00–17:00		16:15–16:45
Case study orphan drug & ATMPs Krzysztof Kloc & Mondher Toumi	Panel Discussion: Country readiness and impact of JCA report on national decision. (France & Germany & Italy) Mondher Toumi & Mira Pavlovic & Antje Behring & Renato Bernardini	Break	Conclusion, discussion and key take home. Mondher Toumi
Break		15:45–16:45	
15:45–16:45			
Panel Discussion: Methodological challenges for HTD and assessors. Mondher Toumi & Steven Simoens		Q&A session Mondher Toumi	

*The schedule may be subject to minor changes