

19<sup>th</sup> – 20<sup>th</sup> of May and 26<sup>th</sup> – 27<sup>th</sup> of May 2025

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

<b>Panel Discussion: Methodological challenges for HTD and assessors.</b>  Mondher Toumi & Steven Simoens			
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\*The schedule may be subject to minor changes