

How to Navigate the Parallel HTA and EMA Processes in the EU

15 March 2027 | 11:00-18:00 CET | Basel, CH



Overview

The first Joint Clinical Assessment (JCA) submissions under the HTA Regulation are underway. For new cancer medicines and ATMPs, since January 2025 the Regulatory submissions through the centralised procedure to the European Medicines Agency (EMA) will also trigger the JCA process. Both processes will run in parallel and the new legislative framework for exchange of information between regulators and HTA will take effect. The new process will require a close collaboration between the regulatory and HTA/market access teams at company level.

This course will discuss regulatory preparedness for the JCA process, explain the interface between regulators and EU HTA Coordination Group and which information is shared by the two.

It will inform you about practical strategic and operational challenges and how to solve them. Preparation early on in development is key, hence two workshops in small groups will focus on the role of prospective evidence planning/Joint Scientific consultation and the operational aspects of writing and submitting the JCA dossier.

The instructors have been very close to the HTA Regulation implementation activities in companies and with the policymakers.

Learning Objectives

- Understand the JCA process and how it links to the marketing authorisation process
- Regulatory documents or information shared to inform scoping process and JCA timelines
- Reducing the risk of the regulatory process to impact the JCA process
- Preparing and aligning internally
- Understand the role of prospective evidence planning/Joint Scientific consultation
- The operational aspects of writing and submitting the JCA dossier

Who Will Attend

- Regulatory strategy leads
- Regulatory authority members
- Clinical development professionals
- CROs
- Consultants involved in EMA's approval processes

Faculty

Niklas Hedberg (invited)

Chair of the EUnetHTA Executive Board

Thomas Ecker

Independent JCA Expert

Inka Heikkinen

Regulatory Policy Lead
Lundbeck

Nadege Le Roux

Regulatory Policy Senior Director
Bristol Myers Squibb

Isabelle Stoeckert

Independent Regulatory Science Expert

Anke van Engen

Global Category Leader, Health Economics,
HTA, Value and Access
IQVIA

Schedule-At-A-Glance

10:30 REGISTRATION

11:00 WELCOME AND INTRODUCTION

11:15 SESSION 1 PART 1

JCA LEGISLATIVE FRAMEWORK AND GUIDELINES

Inka Heikkinen

- Introduction to HTA Regulation and implementing acts
- The HTA JCA process and how it relates to EU Marketing Authorisation Application process
- Rules for exchange of information between the EMA and EU HTA Coordination Group, and its subgroups

12:00 SESSION 1 PART 2

JSC FRAMEWORK AND PROCESS

Inka Heikkinen

- JSC regulatory framework
- Application process and tips for the application form
- Learnings from previous parallel advice

12:30 SESSION 2

IMPLICATIONS FOR REGULATORY STRATEGY AND ENGAGEMENT PLAN

Isabelle Stoeckert

- Regulatory relevant aspect of the JCA dossier (PICO concept and dossier content)
- Label considerations and scenario planning
- Narrative alignment and managing the parallel process
- Transparency of the JCA dossier and potential implications

13:15 LUNCH BREAK

14:00 SESSION 3

INTERNAL ALIGNMENT AND COMMUNICATION AS THE CORNERSTONE FOR SUCCESS

Nadege Le Roux

- Reducing uncertainties through close communication of timelines, anticipated questions and final indication

14:45 SESSION 4

JCA DOSSIER - WHAT GOES IN IT?

Thomas Ecker

- Specifications of the JCA dossier
- Similarities with the AMNOG dossier
- Common and different elements to the regulatory dossier
- Guidances

15:30 SESSION 5

EVIDENCE GENERATION - ADDRESSING THE POSSIBLE GAPS

Anke van Engen

- Learnings from the PICO simulations & required evidence
- Overview of non-direct evidence approaches and acceptable methods

16:15 COFFEE BREAK

16:30 SESSION 6

PANEL DISCUSSION WITH NIKLAS HEDBERG, CHAIR OF THE EUNETHTA EXECUTIVE BOARD

Moderator: Inka Heikkinen

The Panel of Presenters will be joined for this last session by Niklas Hedberg, Chair of the EUnetHTA Executive Board, and Participants will have the opportunity to discuss topics of relevance on how to best prepare for these processes. Participants are invited to formulate their questions beforehand.

- First experience with the JCA procedure, Niklas Hedberg, Chair of the EUnetHTA Executive Board
- Group discussion and Q&A

17:45 CLOSING OF THE COURSE

RECAP FROM THE DISCUSSIONS

18:00 END OF THE TRAINING COURSE

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DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China



Venue Information

Congress Center Basel

Messeplatz 21, 4058 Basel, Switzerland

Tel: +41 58 206 28 28

Email: basel@messe.ch



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How to Navigate the HTA and EMA Processes # 27590

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ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

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