DIA LEARNING

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

Virtual Live Training Course

17-18 September 2025 | 14:00-18:30 CEST

Overview

The first Joint Clinical Assessment (JCA) submissions under the HTA Regulation are underway. For new cancer medicines and ATMPs, since January this year 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

Isabelle Stoeckert
Independent Regulatory Science Expert

Inka Heikkinen
Regulatory Policy Lead, Lundbeck

Nadege Le Roux
Senior Director, Regulatory Policy & Intelligence, BMS

Thomas Ecker
CEO, Ecker + Ecker GmbH

Anke van Engen
Global Category Leader, Health Economics, HTA, Value and Access, IQVIA

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

DAY 1

14:00 WELCOME AND INTRODUCTION

14:15 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

15:00 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

15:30 DISCUSSION AND Q&A

15:45 BREAK

16:00 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

17:00 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

18:00 DISCUSSION AND QUESTIONS

18:30 END OF DAY 1

DAY 2

14:00 WELCOME AND RECAP

14:15 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

15:00 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

15:45 BREAK

16:00 SESSION 6

GROUP DISCUSSIONS

- Group A: JCA DOSSIER AND PICO ANTICIPATION

Moderation: Thomas Ecker and Inka Heikkinen

- Group B: EVIDENCE GENERATION AND ADVICE

Moderation: Anke van Engen and Nadege Le Roux

18:00 CLOSING OF THE COURSE

- Recap from the discussions
- Contribute to a learning system
- Outlook on future development – what can be expected from the policymakers?
- Remaining questions

18:30 END OF THE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

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About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

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

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:
https://www.diaglobal.org/General/System-Requirements

Continuing Education

Please note: Most EU countries accept direct submission, by the participant, of training courses, conferences and other educational opportunities with the aim of obtaining CPD (Continuous Professional Development) points. Please do not hesitate to contact DIA directly if you need any further documentation to conclude your submission.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 7 credits.

REGISTRATION FORM

HTAR | Virtual Live Training Course | # 25590
17-18 September 2025 | 14:00-18:30 CEST

DIA LEARNING

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER EARLY-BIRD valid until 23 Jul 2025	MEMBER valid from 24 Jul 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 900.00 ❑	€ 1'000.00 ❑	€ 1'260.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 500.00 ❑	€ 760.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats are limited.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. Tel. :+41 61 225 51 51

Email: **Basel@DIAglobal.org** Mail: DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy
All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

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

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Attendee email required for course material access

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You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

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Date	Signature