

4° CONGRESSO NAZIONALE GIRF

GRUPPO ISPOR ROMA FOR FUTURE

FIRENZE

30 giugno • 1 luglio 2025

HTA-R e JCA: Percorsi di adattamento alla nuova normativa

*Evoluzione delle modalità di lavoro e
collaborazione a sei mesi dall'implementazione*

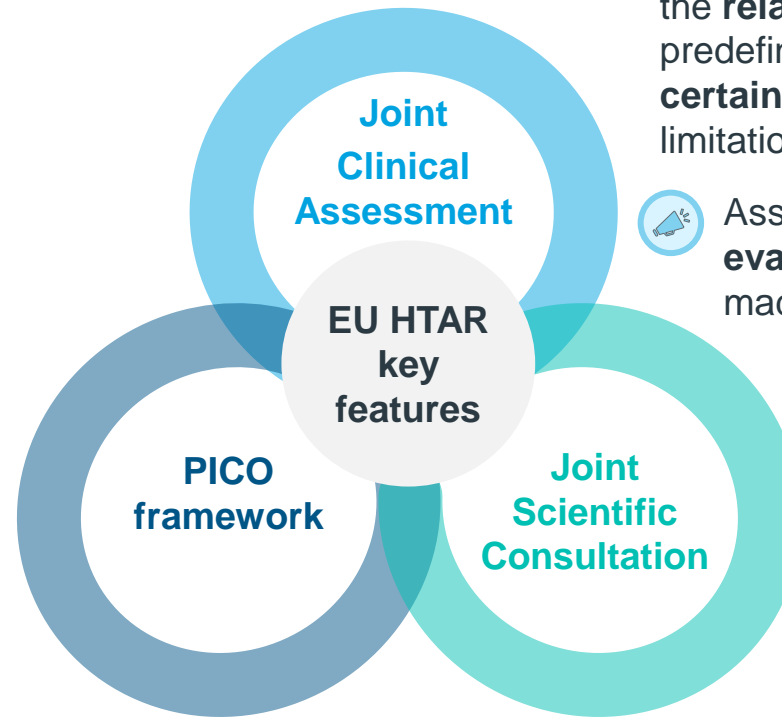
Dott.ssa Gloria Lombardi – Associate Principal, EU HTA Lead, IQVIA RWS

It has arrived! EU HTA-R is now in effect, introducing Joint Clinical Assessment (JCA) and Joint Scientific Consultation (JSC)

Methodological framework for specifying research questions in scope for JCA

Based on three parameters (besides intervention in scope, I):

- **Population (P)**: all relevant population(s) and subpopulation(s)
- **Comparator (C)**: all relevant available comparator(s)
- **Outcomes (O)**: endpoints and outcomes of interest



Mandatory health technology assessment evaluating the **relative efficacy and safety** of a drug against predefined comparator(s), focusing on the **degree of certainty of results** considering strengths and limitations of available evidence



Assessment of '**added-value**' and **economic evaluations** are not part of JCA and will still be made at national level

Elective scientific advice on the **study design** and the **evidence generation plan** to improve the quality and appropriateness of data produced by the HTD in view of **future JCA assessment**

Source: Regulation (EU) 2021/2282

HTA-R – Health technology assessment regulation; HTD – Health technology developer; JCA – Joint Clinical Assessment; JSC – Joint Scientific Consultation; PICO – Population Intervention Comparator Outcomes

Agenda

1 HTA-R: Where are we now?

2 Evolving HQ-affiliates interactions

3 New organizational approaches and challenges

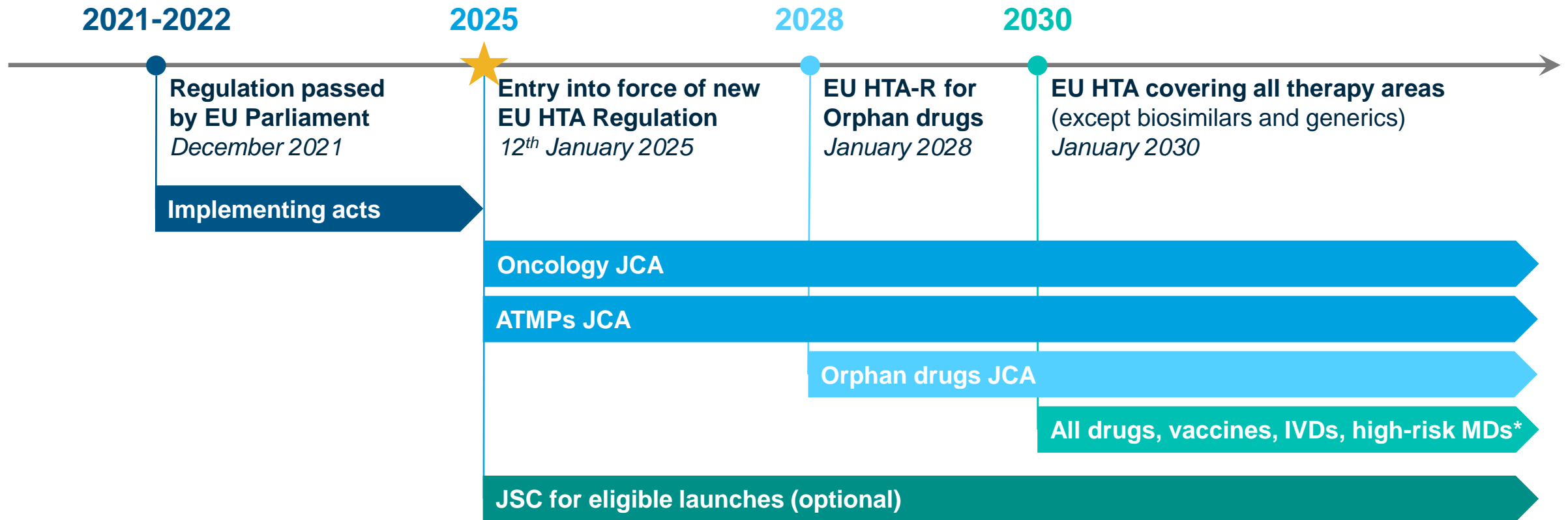
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What is the scope of JCA? Joint Clinical Assessment is implemented for all new oncology drugs and ATMPs, also impacting orphan drugs from 2028

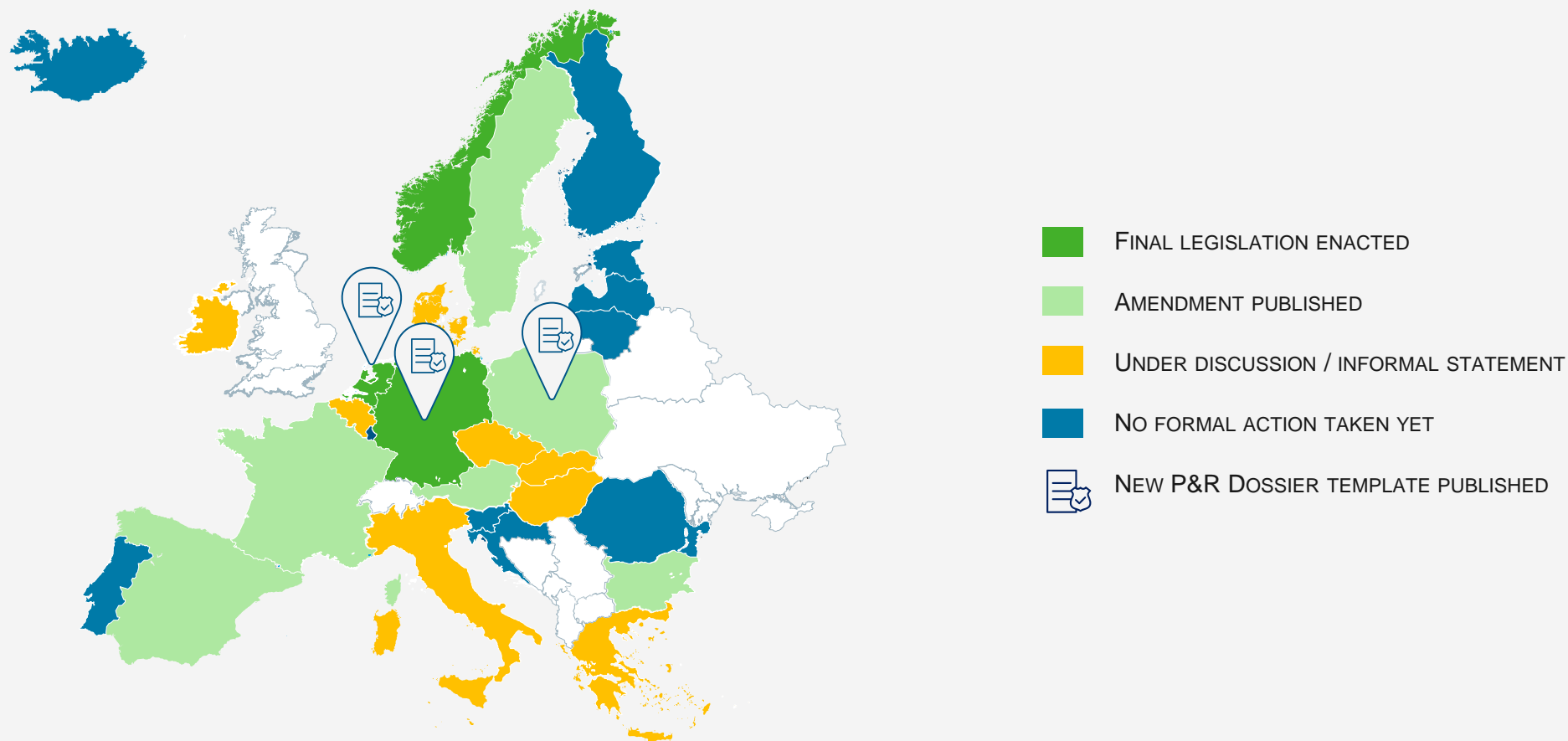


*Select medical devices will be in scope from 2026.

ATMPs – Advanced therapy medicinal products; EU – European Union; HTA-R – Health technology assessment regulation; IVD – In-vitro diagnostics; JCA – Joint Clinical Assessment; JSC – Joint Scientific Consultation; MD – Medical devices.

What has been done so far? Progress of adaptation to the new HTA regulation is still heterogeneous across Member States

EU HTA REGULATION IMPLEMENTATION BY COUNTRY



*Countries which have published a new template include: the Netherlands, Germany and Poland.
HTA-R – Health technology assessment regulation; P&R – Price and reimbursement

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What changes? JCA impacts Market Access activities for both headquarters and affiliates

HTDs must include in the JCA Dossier evidence of comparative clinical effectiveness based on the PICO framework with an EU scope

NEW REQUIREMENTS

Development of JCA Dossier based on PICO(s)



Limited information on **PICO(s)** discussed during the formal scoping process generates the need for **proactive PICO(s) simulations**

Evidence generation



Evidence requirements introduced by the JCA generate the need for comprehensive **evidence generation programs by HTDs**

NEW WAYS OF WORKING

Evolving relationship with HQs



Local affiliates **need to engage with HQs** to inform **national PICO(s) components** and align evidence generation to **local needs**

Evolving national HTA processes

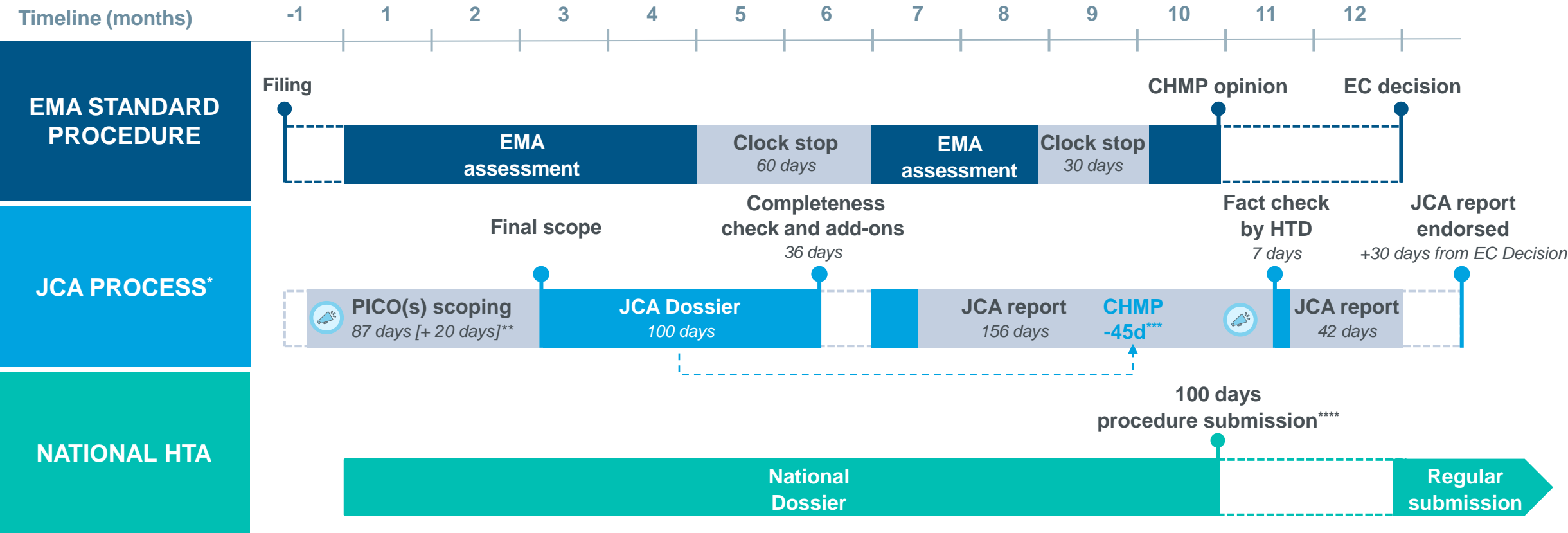


Local affiliates need to learn how navigate **new opportunities and challenges** deriving from centralized assessment

*Including 27 EU Member States, Norway, Iceland and Lichtenstein.

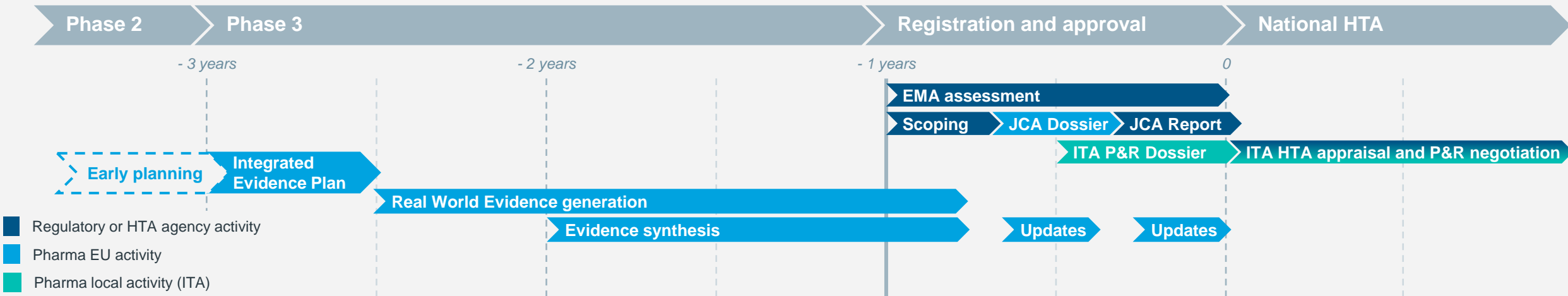
Abbreviations: EU – European Union; HTA – Health technology assessment; HTDs – Health technology developers; HQ – Headquarters; HTA-R – Health technology assessment regulation; JCA – Joint Clinical Assessment; P&R – Price and reimbursement; PICO – Population Intervention Comparator Outcomes; RWE – Real-world evidence.

When does JCA take place? The centralized HTA evaluation runs in parallel to the existing EU regulatory process



*Shorter timelines for accelerated assessment & type II variations **After 87 days scoping is shared with HTD, after which there are 20 days for assessment scope explanation meeting. ***Potential +89 days extension granted by HTA Secretariat with justification. ****If HTDs wish to submit the P&R Dossier at CHMP Opinion, JCA report will not be available.
CHMP – Committee for Medicinal Products for Human Use; EMA – European Medicines Agency; HTD – Health technology developer; HTA – Health technology assessment; JCA – Joint Clinical Assessment; EC – European Commission; PICO – Population Intervention Comparator Outcomes

New pathways of activities emerge following JCA implementation



What are the new pathways for Pharma Companies?

Anticipate

Ensure **prioritization of relevant national PICO(s)** in JCA preparation

Integrate, without duplicating

Ensure alignment of evidence plans to **national evidence requirements**

Repurpose

Leverage available evidence and JCA outputs for **effective P&R negotiation**

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Global teams are adapting to EU JCA by creating new ways of working with affiliates, based on number of impacted assets and preexisting structures



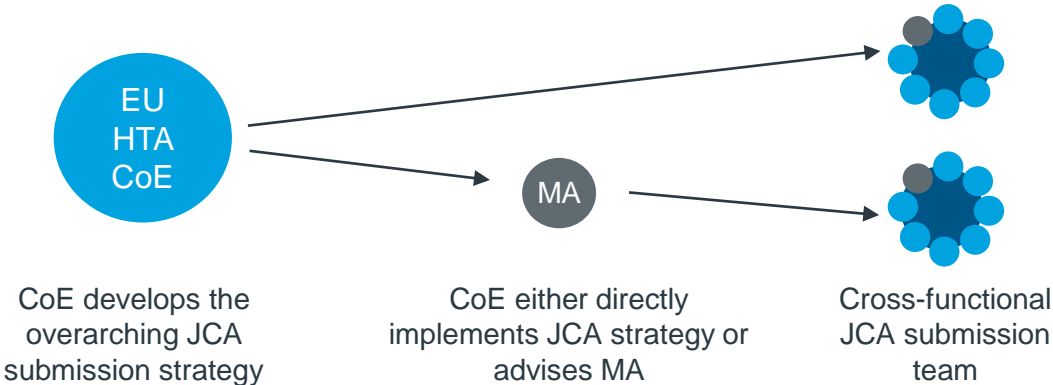
Global MA embedded within asset teams developing asset-specific EU JCA strategies with cross-functional input



- Global MA individual/team
- Other global functions



CENTRAL EU HTA team working across portfolio, implementing EU JCA submissions directly or advising MA



Single asset undergoing EU JCA

Several assets undergoing EU JCA

CoE – Center of excellence; EU – European Union; HTA – Health technology assessment; JCA – Joint Clinical Assessment; MA – Market access; R&D – Research and development

Cross-functional collaboration will become even more relevant for implementing JCA strategy

Market Access & HEOR

Integrate JCA strategy into pricing and access planning to facilitate downstream reimbursement, ensuring national HTA requirements are fulfilled

Biostatistics teams also play a key role in the process, **implementing JCA SAPs**



Medical Affairs

Lead the **generation, interpretation, and communication of clinical and real-world evidence** to meet increasing evidence expectations

Regulatory Affairs

Ensure **alignment between EMA and JCA** processes and timelines and anticipate the impact of possible **EMA label changes** on JCA scope

EMA – European Medicines Agency; HTA – Health technology assessment; JCA – Joint Clinical Assessment; RWE – Real world evidence; SAP – Statistical analysis plan

Please, contact us for more information!

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OUR SOURCES & EXPERTISE:



*Insights briefs
and whitepapers*

*2024 Value in Health
publication on PICO
simulation*



*18 EU HTA posters at
ISPOR Europe 2024*

*EU HTA solutions
factsheet*

