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EU JOINT CLINICAL ASSESSMENT

JCA and associated activities – Cogentia

Mark Orchard +44 (0) 1223 967276 mark.orchard@cogentia.co.uk cogentia.co.uk

RUNNING IN PARALLEL TO THE EMA ASSESSMENT, THE JCA IS A CRITICAL FIRST STEP TO POSITIVE NATIONAL P&R PROCEDURES

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2025 → ONCOLOGY PRODUCTS, ATMPs & MEDICAL DEVICES

2028 → ORPHAN DESIGNATION PRODUCTS

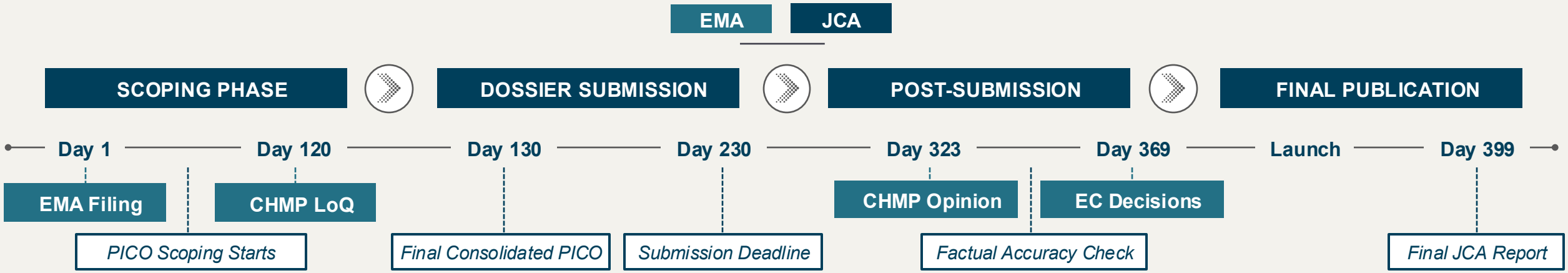
2030 → ALL MEDICAL PRODUCTS

JOINT CLINICAL ASSESSMENT

The JCA is an EU-wide regulation, that aims to provide a streamlined, standardised way to evaluate the relative clinical effectiveness of new medicinal products and devices, with several objectives for member states:

1. **Increase efficiency**: reduce duplication of efforts
2. **Enhance quality**: provide reliable and consistent information for local P&R procedures
3. **Strengthen collaboration between member states**: harmonise approaches and reduce inconsistencies
4. **Provide faster patient access**: as a result of increased efficiency and harmonised procedures

Ultimately, the economic evaluation and decision to reimburse products at the national level remains with national payers. However, they must give due consideration to the published JCA reports



CHMP, Committee for Medicinal Products for Human Use; EC, European Commission; EMA, European Medicines Agency; JCA, Joint Clinical Assessment; PICO, Population, Intervention, Comparator, Outcomes LoQ, List of Questions.

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JCA: KEY CHALLENGES AND CONSIDERATIONS FOR MANUFACTURERS

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As manufacturers prepare to engage with the JCA process, there are a number of key challenges, and mitigation strategies to optimise outcomes

KEY CHALLENGES	KEY MITIGATION STRATEGY
Tight timelines Companies will only have 100 days from receiving the final scope to develop and submit their JCA dossiers	**Initiate drafting early** Manufacturers should have a full draft of the JCA dossier ready at the time of final scope, with the final 100 days used to adapt & add rationale for deprioritised PICOs
Adapting internal process Conventionally 'HTA'-style dossiers are managed by country teams. For the JCA, internal leads are typically at the global level, requiring a change in process	**JCA training & playbook** JCA training for core and wider teams to support understanding of their roles, as well as a JCA playbook that can help internal leads prepare for the JCA process
Managing internal resource The JCA process will run in parallel to the EMA process, resulting in intensive burden for cross-functional teams, including biostatistics, regulatory, HEOR and medical	**Strong centralised project management** A single point of contact to manage involvement of cross-functional teams, to facilitate availability of key individuals and functions at critical stages (e.g. reviews, clarification)
Addressing the needs of all member states The myriad requirements of EU member states, both in terms of PICOs and methods for estimating relative effectiveness can impose a substantial burden on manufacturers	**PICO consolidation & objection handler** Use of a PICO consolidation framework to prioritise evidence generation activities, and a robust objection handler to provide rationale for non-prioritised PICOs
Maximising the output of the JCA report Member states are obliged to give due consideration to the JCA report. The extent to which they do so is contingent on submitting a robust JCA dossier	**Affiliate workshops & rollout sessions** Affiliate involvement in dossier preparation & initial PICO consolidation. Rollout of JCA materials and key learnings & considerations workshop following JCA report publication

JCA, Joint Clinical Assessment; JSC, Joint Scientific Consultation; PICO, Population, Intervention, Comparator, Outcomes

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A SUCCESSFUL JCA PROCEDURE REQUIRES EARLY PLANNING, WITH ALL KEY ASPECTS IN PLACE AT THE TIME OF FINAL SCOPE

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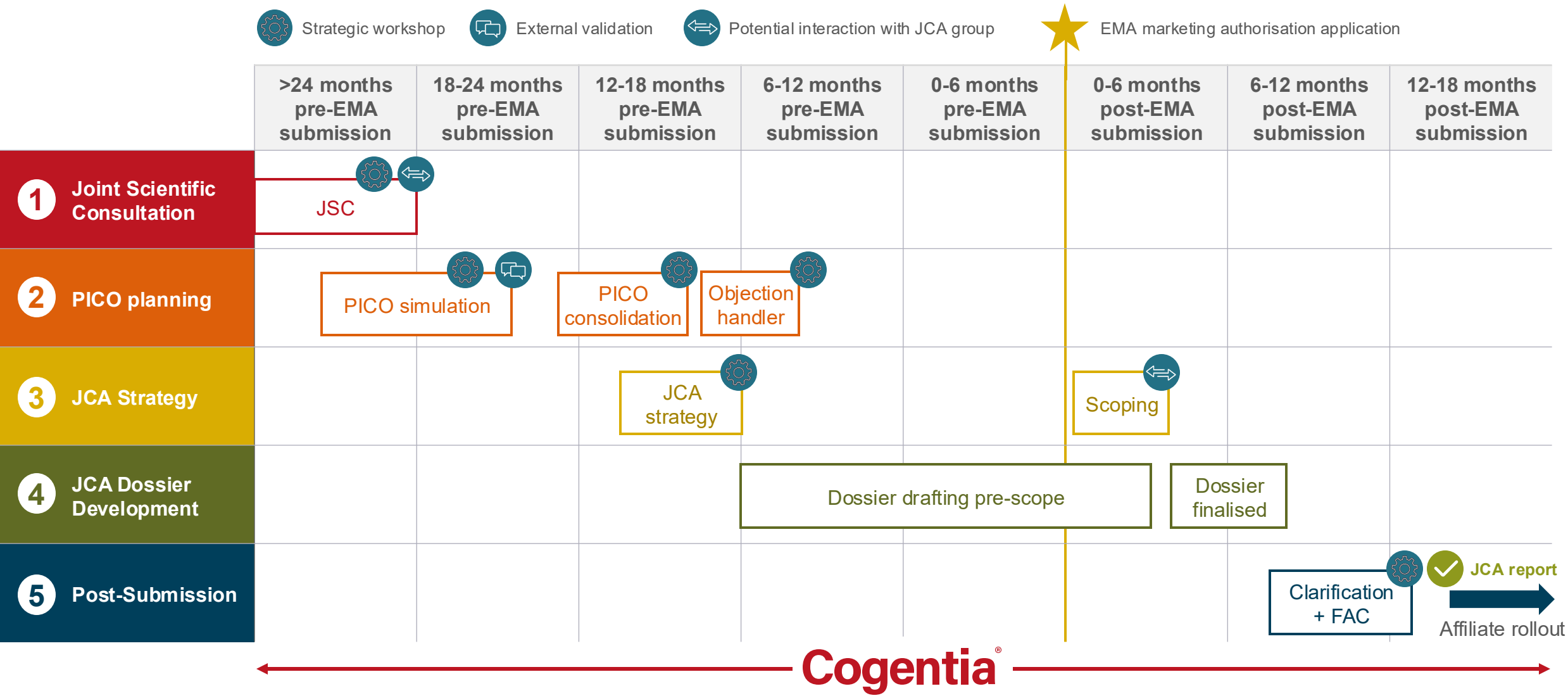

FAC, Factual Accuracy Check; JCA, Joint Clinical Assessment; JSC, Joint Scientific Consultation; PICO, Population, Intervention, Comparator, Outcomes

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THE JCA PROCESS INCLUDES SEVERAL ACTIVITIES, WITH ASSOCIATED CRITICAL SUCCESS FACTORS FOR MANUFACTURERS

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	Objective	Critical success factors	Why Cogentia?
1 **Joint Scientific Consultation**	To obtain feedback on suitability of the proposed evidence package	• Clear articulation of proposed approach and rationale • Optimising pull through from feedback	✓ Wealth of experience in early engagement with G-BA and NICE ✓ Experts in European market access
2 **PICO planning**	To develop a list of potential PICOs, and refine these to priorities for evidence generation	• Efficiency • Robust framework for prioritisation • Rationale for deprioritised PICOs	✓ AI-powered tool for rapid PICO simulation ✓ Proprietary framework for consolidation
3 **JCA Strategy**	To ensure an optimal approach to JCA dossier development	• Expertise in procedural guidance • Consideration of local P&R implications • Stakeholder input	✓ Thorough understanding of all aspects of the JCA process ✓ Experts in multi-stakeholder workshops
4 **JCA Dossier Development**	To develop a high-quality dossier that addresses the requirements of the JCA	• High-quality medical writing • Ability to respond to scope deviation • Management of XF involvement	✓ >150 NICE submissions ✓ Senior project manager throughout ✓ Internal QC prior to 3x rounds of review
5 **Post-Submission**	To clarify any uncertainties in the dossier, and ensure a factually accurate JCA report	• Robust narrative responses • Management of XF involvement • Diligent review of JCA report	✓ Extensive experience in managing & leading on clarification & factual accuracy, through NICE process

AI, artificial intelligence; G-BA, Federal Joint Committee; JCA, Joint Clinical Assessment; JSC, Joint Scientific Consultation; NICE, National Institute for Health and Care Excellence; PICO, Population, Intervention, Comparator, Outcomes; QC, Quality Control; XF, cross-functional.

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COGENTIA: YOUR PARTNER FOR END-TO-END JCA SUPPORT

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Cogentia are your end-to-end JCA partner, from PICO simulation and joint scientific consultation through to scoping and all aspects of JCA pre-and post-submission

Ability to manage complex multi-year, multi-stakeholder projects

- Full support for >150 NICE submissions, often spanning multi-year engagements
- Facilitating involvement of cross-functional teams, including medical, market access, HEOR, biostats, commercial, regulatory

Design, execution, and communication of statistical methods

- Extensive experience in delivery of complex statistical analyses in HTA setting
- Long-standing collaborations with statistical thought-leaders in HTA
- Delivered >50 evidence synthesis projects in the past 5 years

High-quality medical writing team with expertise in dossier development

- Experts in communicating complex scientific data and methodology, with a wealth of experience in HTA and value dossier drafting
- Medical writing team well versed in reporting technical methodologies (e.g. indirect comparisons, SLRs)

As an integrated market access & HEOR agency, with a depth of expertise in strategic market access across Europe, and delivery of multi-year HTA programmes, Cogentia offer an end-to-end programme of support for manufacturers preparing for JCA

HEOR, Health Economics & Outcomes Research; HTA, Health Technology Assessment; JCA, Joint Clinical Assessment; NICE, National Institute for Health and Care Excellence; PICO, Population, Intervention, Comparator, Outcomes; SLR, Systematic Literature Review

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JCA TRAINING

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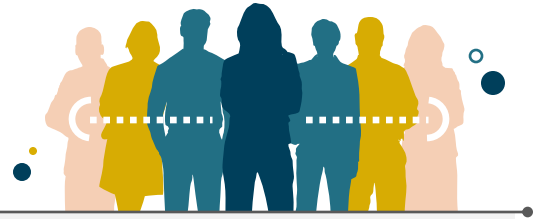
Cogentia offer two programmes of JCA training, one for core teams responsible for leading on JCA procedures, and one for wider teams that need to be sufficiently informed of the process and aware of responsibilities

JCA core team training

Objective: to support JCA leaders in a detailed understanding of the JCA methodology and requirements for manufacturers

- Detailed review of JCA process
- JCA dossier template review
- Scoping & PICO planning review
- Clinical study & evidence synthesis requirements
- Detailed timeline of manufacturer requirements
- Roadmap to a successful JCA procedure

JCA wider team training



Objective: to provide a wider team understanding of JCA, ensuring they factor requirements into their decision-making processes

- JCA process
- High-level overview of the JCA dossier
- Key areas for JCA planning
- Points of engagement for cross-functional teams
- Key considerations for wider team
- Timelines & implications for national procedures

JCA, Joint Clinical Assessment; PICO, Population, Intervention, Comparator, Outcomes.

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If you want to explore how Cogentia can help you with your EU HTA requirements, please contact:

Mark Orchard

Senior Consultant,
JCA Lead

mark.orchard@cogentia.co.uk