From Joint Clinical Assessment to National HTA: Similarities and Divergences Across the EU Member States

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OBJECTIVE

- The European Union (EU) Joint Clinical Assessment (JCA) aims to harmonize the assessment of comparative clinical effectiveness and safety across member states, while preserving national autonomy over pricing and reimbursement decisions
- This study describes the similarities and key differences between JCA requirements and national health technology assessment (HTA) processes across EU member states, with implications for evidence generation and access planning

METHODS

- A comparative policy and methodological review was conducted to map JCA requirements against national HTA expectations across EU member states
- Information was synthesized from the EU HTA Regulation (EU 2021/2282), Implementing Regulation (EU 2022/1107), HTA Coordination Group (HTA CG) procedural[1] and dossier guidance[2], and European Medicines Agency (EMA) procedural documentation[3]
- National HTA frameworks were reviewed across twelve member state agencies: G-BA/IQWiG (Germany), HAS (France), AIFA (Italy), AEMPS/IPT (Spain), ZIN (Netherlands), KCE (Belgium), TLV (Sweden), AOTMiT (Poland), AIHTA (Austria), INFARMED (Portugal), NCPE (Ireland), and DMC (Denmark)
- Areas of alignment and divergence were identified through structured comparison of methodological guidelines and submission requirements

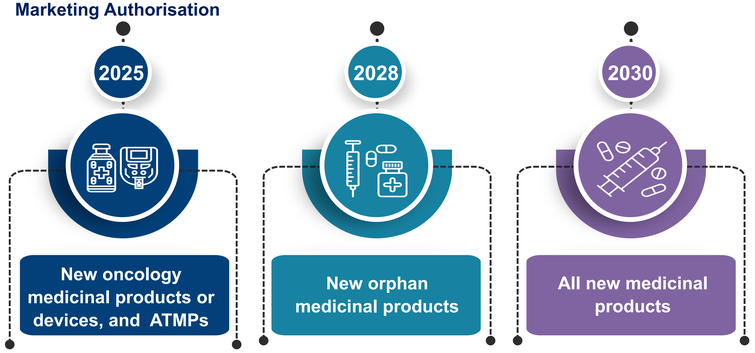
RESULTS

- Since January 2025, the JCA applies to new oncology medicines and advanced therapy medicinal products (ATMPs), will extend to orphan drugs in 2028, and include all newly centrally authorised medicines by 2030 (**Figure 1**). The JCA process spans across five phases over 406 days, aligned with EMA milestones, ensuring that the JCA report is endorsed within 30 days of marketing authorisation (MA) (**Figure 2**)
- Running in parallel with the EMA review, the JCA begins at Day 1 with the population-intervention-comparator-outcome (PICO) scope proposal; following finalisation – occurring 10 days after the Committee for Medicinal Products for Human Use (CHMP) issues the List of Questions, the dossier must be submitted within 100 days of the request and at least 45 days before the CHMP opinion (**Figure 3**). The final report is endorsed by the HTA Coordination Group within 28 days of MA
- **Table 1** summarises the comparison of EU JCA requirements with national HTA bodies across the EU member states
- JCA delivers a single, centralised assessment of comparative clinical effectiveness and safety based on an agreed PICO scope, with no duplication of clinical assessment at the national level. The systematic literature review (SLR) methodology is broadly harmonised - PRISMA reporting, dual screening, and standardised risk-of-bias tools (RoB 2.0, ROBINS-I) are consistently required, alongside mandatory searches in MEDLINE, Embase, CENTRAL, ClinicalTrials.gov, and ICTRP
- It is noteworthy that, substantial heterogeneity persists across member states in downstream HTA requirements. Economic evaluations (cost-effectiveness analyses, CEA/ cost-utility analyses, CUA), budget impact analyses (BIA), incremental cost-effectiveness ratio thresholds, decision criteria, and the interpretation and use of country-relevant subgroup evidence remain within member states competence
- Comparator relevance, subgroup evidence, and real-world evidence acceptance differ markedly, reflecting local practice and payer priorities
- Shorter time window of SLR (3 months) aligns with G-BA but is tighter than other evaluated member states (6 months: HAS, NCPE, ZIN, and TLV; 12 months: AIHTA). Certainty-of-evidence frameworks also varies, with most bodies using GRADE, while IQWiG applies its own system

Key limitations of JCA

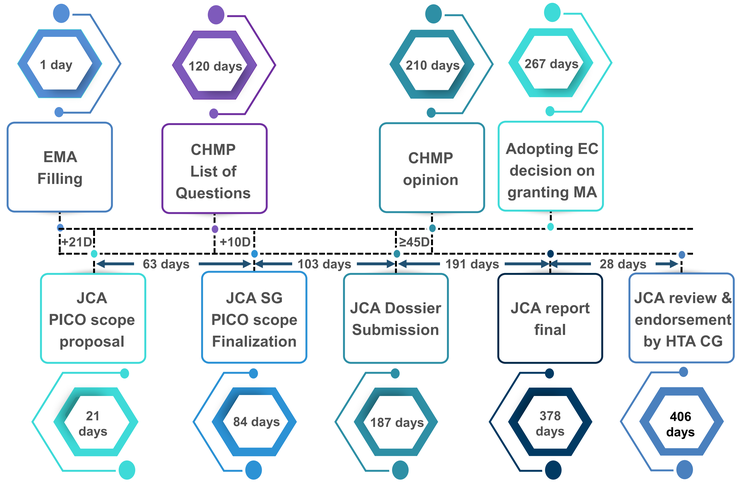
- Aligning internal processes with new JCA requirements
- Allocating resources to handle the increased workload
- Meeting evidence expectations across all EU member states
- Leveraging the JCA report for national submissions
- Addressing multiple PICO scenarios within a single JCA dossier
- Completing dossier and SLR updates within compressed JCA deadlines
- Bridging missing head-to-head data through indirect treatment comparisons

Figure 1: Phased implementation of JCA for medicinal products seeking centralised Marketing Authorisation



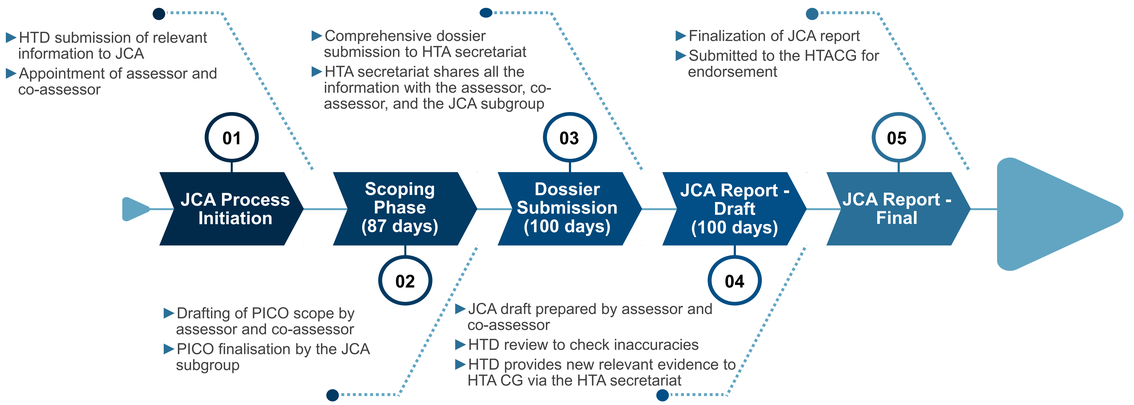
ATMP: Advanced therapy medicinal products; JCA: Joint Clinical Assessment

Figure 3: Overview of key EMA and EU JCA milestones (standard procedure) with associated durations



CHMP: Committee for Medicinal Products for Human Use; D: days; EMA: European Medicines Agency; EC: European Commission; HTA CG: Health Technology Assessment Coordination Group; JCA: Joint Clinical Assessment; MA: Market Authorization; PICO: Population-intervention-comparator-outcome; SG: Subgroup

Figure 2: EU Joint Clinical Assessment process of total duration of 406 days



HTA: Health Technology Assessment; HTA CG: Health Technology Assessment Coordination Group; HTD: Health Technology Developer; JCA: Joint Clinical Assessment; PICO: Population-intervention-comparator-outcome

Table 1: Comparative overview of the EU JCA and national HTA frameworks across EU Member States, summarising regulatory scope, dossier methodology, and SLR/NMA requirements

Parameter	Options	EU JCA	G-BA / IQWiG (Germany)	HAS (France)	AIFA (Italy)	AEMPS/IPT (Spain)	ZIN (Netherlands)	KCE (Belgium)	TLV (Sweden)	AOTMiT (Poland)	AIHTA (Austria)	INFARMED (Portugal)	NCPE (Ireland)	DMC (Denmark)
Scope of assessment	Clinical	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Economic	×	×	×	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cost-effectiveness?	CEA	×	×	×	✓	×	×	×	×	×	Limited	✓	×	×
	CUA	×	×	×	×	×	✓	✓	✓	✓	Limited	✓	✓	✓
	BIA	×	×	×	✓	✓	×	×	×	×	Limited	✓	×	×
PICO framework	Country-specific PICO	Multiple PICOs per MS	Single PICO; ACT fixed	Per-indication PICO	PICO + Italian SoC	PICO; Spanish SoC	PICO; Dutch SoC	PICO; Belgian SoC	PICO; Swedish SoC	PICO; Polish SoC	PICO; Austrian SoC	PICO; Portuguese SoC	PICO; Irish SoC	PICO; DMC-defined comparator
Evidence preference	RCT	✓*	✓*	✓ (+PFS)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	RWE	×	×	×	✓	✓	×	×	×	×	×	×	×	×
	Economic	×	×	×	×	×	✓	✓	✓	✓	×	×	✓	✓
SLR mandatory?	Yes	✓ (per PICO)	✓ (per ACT)	✓ (less prescriptive)	✓ (clinical section)	✓	✓	✓	✓	✓	✓	✓	✓	✓ (per methods guide)
Mandatory biomedical databases	Medline	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Embase	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Cochrane	✓	✓	✓	✓	×	✓	✓	✓	✓	×	×	✓	✓
Trial registries	CT.gov	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	ICTRP	✓	×	×	×	×	×	×	×	×	×	×	×	×
	EU CTR	✓	✓	✓	×	×	✓	✓	×	×	×	×	✓	✓
	Sponsor-registry	✓	✓	×	×	×	×	×	×	×	×	×	×	×
Two review screening	Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
SLR cut-off before submission	≤3 months	✓	✓	×	×	×	×	×	×	×	×	×	×	×
	≤6 months	×	×	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓
	≤12 months	×	×	×	×	×	×	×	×	×	✓	×	×	×
Quality assessment tool	RoB	✓ (v2)	IQWiG-specific	✓ (v1/v2)	✓	✓	✓ (v1/v2)	✓ (v1/v2)	✓	✓	✓	✓	✓	✓ (v1/v2)
	ROBINS-I	✓	IQWiG-specific	✓	✓	×	✓	✓	✓	×	×	✓	✓	✓
	NOS	×	IQWiG-specific	×	×	✓	×	×	×	✓	✓	×	×	×
Reporting standard	PRISMA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	CONSORT	✓	✓	✓	✓	×	✓	✓	✓	×	×	×	✓	✓
	Bucher	✓	✓ (strict)	✓	✓	✓	×	×	×	×	✓	×	×	×
ITC method preference	MAIC/STC	✓	×	×	×	×	×	×	×	×	×	×	×	×
	NMA	✓	×	✓	✓	✓	✓ (preferred)	✓ (preferred)	✓ (preferred)	✓ (preferred)	×	✓	✓ (preferred)	✓ (preferred)
NMA framework	Bayesian	✓	×	✓	✓	✓	✓ (preferred)	✓ (preferred)	✓ (preferred)	✓	✓	✓	✓ (preferred)	✓ (preferred)
	Frequentist	✓ (justified)	✓ (preferred)	✓	✓	✓	×	×	×	✓	✓	✓	×	×

*Only hard endpoints in case of randomized controlled trials.
Abbreviations: ACT: Appropriate Comparator Therapy; BIA: Budget Impact Analysis; CEA: Cost-Effectiveness Analysis; CENTRAL: Cochrane Central Register of Controlled Trials; CONSORT: Consolidated Standards of Reporting Trials; CT.gov: ClinicalTrials.gov; CUA: Cost-Utility Analysis; EU CTR: European Union Clinical Trials Register; EU JCA: European Union Joint Clinical Assessment; ICTRP: International Clinical Trials Registry Platform; MAIC: Matching-Adjusted Indirect Comparison; MS: Member State; NMA: Network Meta-Analysis; NOS: Newcastle Ottawa Scale; PFS: Progression Free Survival; PICO: Population, Intervention, Comparator, Outcomes; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCTs: Randomized Controlled Trials; RoB: Cochrane Risk-of-Bias; ROBINS-I: Risk Of Bias In Non-randomized Studies of Interventions; RWE: Real-World Evidence; SLR: Systematic Literature Review; SoC: Standard of Care; STC: Simulated Treatment Comparison.

Conclusion:

- JCA represents a significant shift toward harmonised clinical assessment across Europe, reducing duplication and increasing consistency across markets
- However, national HTA bodies continue to apply distinct requirements, highlighting the need for early and well-planned evidence development
- Aligning global evidence generation with JCA timelines while anticipating country-specific HTA needs is critical to support efficient access pathways across EU Member States

References:
1. Member States Coordination Group on Health Technology Assessment. Procedural guidance for JCA medicinal products. Accessed on 08 May 2026. Procedural guidance for JCA medicinal products - Public Health; 2. Member States Coordination Group on Health Technology Assessment. Guidance on filling in the joint clinical assessment (JCA) dossier template – Medicinal products. Accessed on 08 May 2026. Guidance on filling in the joint clinical assessment (JCA) dossier template – Medicinal products - Public Health; 3. The evaluation of medicines, step-by-step. Accessed on 08 May 2026. The evaluation of medicines, step-by-step | European Medicines Agency (EMA);

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