EU-HTA for Medical Devices: Risks, Opportunities, and Strategic Implications

Jana Efremova, PhD[1]; Julia Specks, PhD[1]; Alexander Karner, MSc[1]; Johannes Klaus, PhD[1]; Astrid Genet, PhD[1]; Edel Falla, MSc[2]; Sandra Wohlmuther, PhD[1]; Doreen Bonduelle, MSc[1]; Penelope Gallinger, PhD[1]

[1] *IQVIA Commercial GmbH & Co. OHG, Munich, Germany* [2] *IQVIA, London, United Kingdom*

OBJECTIVES

Since 2026, JCA is mandatory for selected high-risk medical devices (MDs) and in vitro diagnostic MDs (IVDs) under the EU HTA Regulation (HTAR), applying pharmaceutical-style evidence expectations to the MD/IVD sector.

This poster assesses how JCA evidence expectations compare with current MD/IVD evidence generation, identifies the resulting gaps and risks, and derives strategic responses for manufacturers.

METHODS

Qualitative review of HTACG guidance on validity and outcomes assessment for JCAs, MDCG guidance on clinical evidence generation for IVDs, and CORE-MD recommendations relevant to medical device evidence requirement

Complemented by reviews of regulatory study-design guidance and peer-reviewed HTAR analyses (2023–2026).

Interpreted through IQVIA's experience with 20 JCA dossiers

RESULTS

EU HTA applies the same evidence expectations to MDs, IVDs and pharmaceuticals. However, evidence generated for MDs and IVDs is typically designed to meet different regulatory requirements, with greater focus on technical performance, diagnostic accuracy, and procedural outcomes, rather than comparative clinical outcomes.

KEY EVIDENCE GAPS:

Comparative evidence: single-arm, historical-control and accuracy studies cannot establish relative effects versus JCA comparators.

Patient-relevant benefit: technical and diagnostic performance may not show clinical added value.

Clinical utility: evidence rarely links surrogate or accuracy outcomes to patient benefit, and it underreports harms from false or delayed results.

Applicability and lifecycle: expert centres, rapid device evolution and short follow-up limit external validity.

THE PATH TO EU MARKET ACCESS

Evidence planning → Joint Scientific Consultation → Joint Clinical Assessment → National reimbursement

CONCLUSIONS

The primary challenge is lifecycle evidence generation to demonstrate comparative, patient-relevant value within the JCA framework.

Early integration of HTA requirements into clinical development is critical so that anticipated PICOs, comparators and outcomes can be addressed.

The JCA does not replace national appraisal: it contains no value judgements; decisions remain with Member States, and impact may be limited where HTA is not a formal reimbursement element.

Opportunity: the HTAR may harmonise evidence requirements; with sufficient evidence, a favourable JCA may support national reimbursement — but may also trigger national (re)assessments.

WHICH MDs / IVDs NEED A JCA?

1. **MDR IIb / III IVDR Class D** — **Risk class** — only MDR Class IIb/III devices and IVDR Class D IVDs are potentially eligible.
2. **Expert panel review** — **Expert panel (ExP) review** — implantable Class III, active IIb drug-delivery devices, Class D IVDs without CS; renewed after significant changes.
3. **HTACG selection** — **HTACG selection** — ≥1 criterion: unmet need, first in class, patient / health-system impact, AI/ML software, cross-border dimension, Union-wide added value.

Eligible does not mean selected: less than 10 MDs were chosen for JCA since the start of the process in June 2026. Selection is discretionary and based on HTACG criteria. Significant product changes can restore eligibility.

TABLE 1: JCA EXPECTATIONS VS. MD / IVD PRACTICE AND JCA RISK

	JCA expectation	Common MD / IVD practice	JCA risk
Comparative evidence	Relative effects vs. relevant comparator	Single-arm, historical-control, accuracy studies	Relative effectiveness not reliably assessable
Patient-relevant benefit	How patients feel, function or survive	Technical, procedural and diagnostic performance	Added value not shown despite technical success
Applicability to practice	Representative populations and settings	Selected patients, expert centres	Limited external validity
Lifecycle evidence	Valid for assessed version; long-term effects	Device changes, short follow-up	May not apply to marketed version
HTA readiness	Addresses anticipated JCA PICOs	Regulatory and HTA planning separate	Missing comparators, outcomes, subgroups

BUILDING BLOCKS FOR MD / IVD MARKET ACCESS

01 **Anticipate PICOs** — Simulate JCA PICOs and comparators early

02 **Build comparative evidence** — Pragmatic, registry-based or randomised designs

03 **Measure patient benefit** — Patient-reported, functional, quality-of-life outcomes

04 **Plan lifecycle evidence** — Version tracking, registries, post-market follow-up

05 **Build organisational readiness** — Cross-functional teams, dedicated resources, pilot dossiers

STRATEGIC RECOMMENDATION

Anticipate PICOs, build comparative patient-relevant evidence, and stay JCA-ready throughout the lifecycle.

Abbreviations: **AI/ML** = artificial intelligence / machine learning; **CORE-MD** = Coordinating Research and Evidence for Medical Devices; **CS** = common specification; **EU** = European Union; **HTA** = Health Technology Assessment; **HTACG** = HTA Coordination Group; **HTAR** = HTA Regulation; **ExP** = expert panel; **IVD** = in vitro diagnostic medical device; **IVDR** = In Vitro Diagnostic Medical Devices Regulation; **JCA** = Joint Clinical Assessment; MDCG = Medical Device Coordination Group; **MD** = medical device; **MDR** = Medical Device Regulation; **PICO** = Population, Intervention, Comparator, Outcome;

Key references: Alshaikh et al. 2025. Value Health. doi:10.1016/j.jval.2025.09.1552. | Alshaikh et al. 2025. Int J Technol Assess Health Care. doi:10.1017/S026646232510319X. | Bralic et al. 2026. | D'Oca et al. 2025. J Mark Access Health Policy. doi:10.3390/jmahp14010003. | Fraser et al. 2025. | Hulstaert et al. 2023. PMID:37491269. | Schnell-Inderst et al. 2025. | Schuster 2024. J Mark Access Health Policy. doi:10.3390/jmahp12020008. | EU HTACG 2024a/2024b. Guidance on Validity of Clinical Studies for Joint Clinical Assessments. | MDCG 2022. Guidance on General Principles of Clinical Evidence for IVDs

ISPOR Europe 2026, Vienna, Austria • Value in Health, Vol. 29, Issue 12S • HTA322

Health Policy & Regulatory | HTA | Medical Technologies

© 2026. All rights reserved. IQVIA® is a registered trademark of IQVIA Inc. in the United States, the European Union, and various other countries.