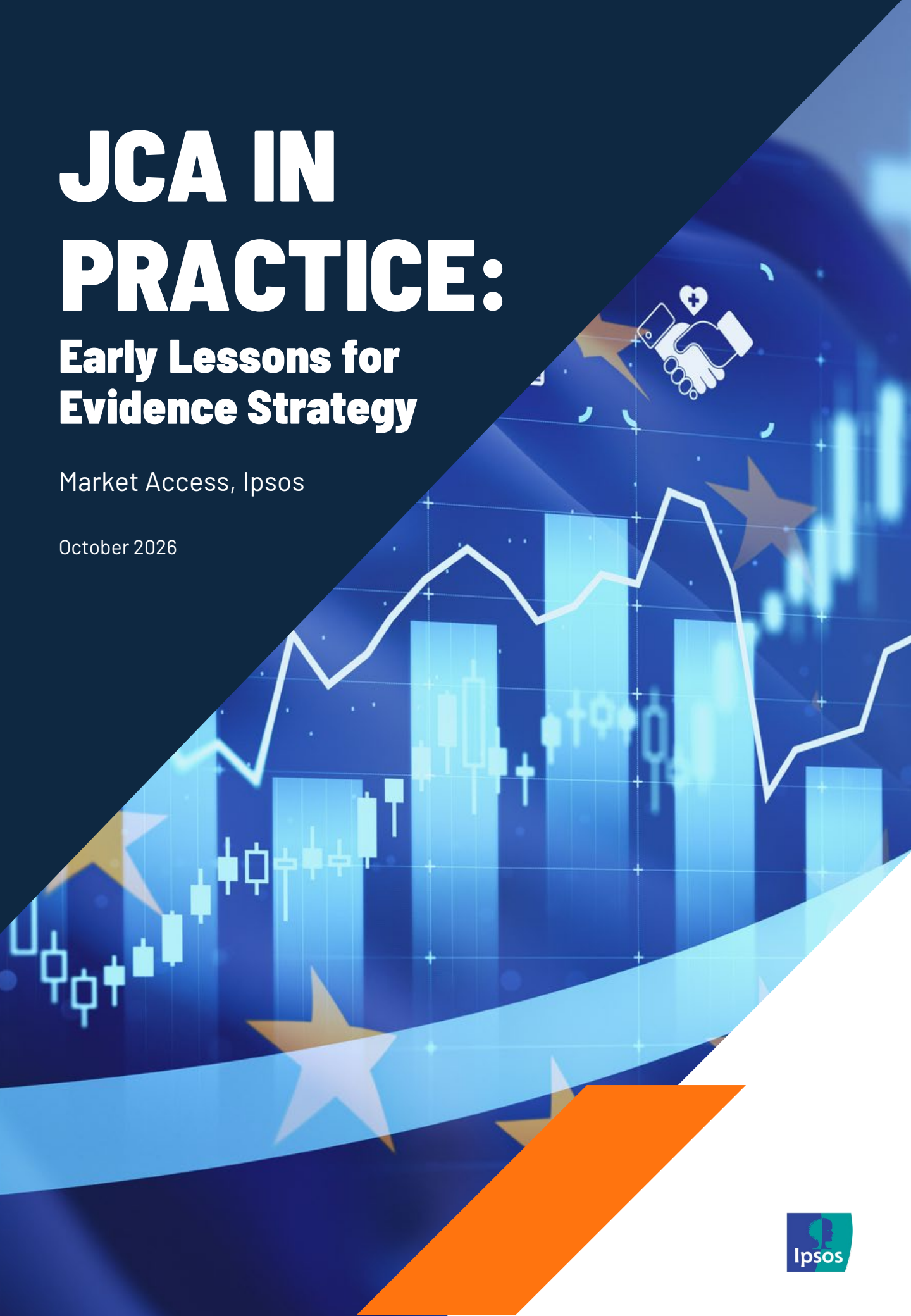
JCA IN PRACTICE:

Early Lessons for Evidence Strategy

Market Access, Ipsos

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INTRODUCTION
WHY THIS MATTERS

European Union's new reality

The JCA framework is reshaping the EU market access landscape, with initial assessments offering early insights into how the process works in practice.

Further lessons will emerge as national HTA bodies integrate JCA outputs into their assessment and decision-making processes.

Pharma and MedTech may benefit from reflecting on these early experiences as JCA implementation continues to evolve across markets

The ambition driving JCA

> Introduced to promote HTA convergence, reduce duplication and align clinical assessment more closely with regulatory approval, JCA aims to support timely access to innovative technologies.

Since its 2025 rollout, the first reports have been published, with a growing assessment pipeline and further expansion of scope planned.

JCA Technology Scope and Reports Status *(October 2026)*

Jan 2025

Oncology medicines + Advanced Therapy Medicinal Products (ATMPs)

4 Completed | **16 Ongoing**

Jan 2026

Selected high-risk medical devices (class IIb & III) / In Vitro Diagnostics

0 Completed | **2 Ongoing**

Jan 2028

Expansion to other orphan medicines

Jan 2030

All centrally authorised medicinal products

EXECUTIVE SUMMARY

The first four completed JCAs and the discontinued JCAs provide an early view of how the JCA framework handles markedly different evidence packages.

Each case highlights a distinct readiness dimension for future medical products to consider.

Published JCA reports

	Ojemda® (tovorafenib)	**Imdyllta®** (tarlatamab)	**Zepzelca®** (lurbinectedin)	**Itvisma®** (onasemnogene)
Indication	Previously treated **pLGG**	Previously treated **ES-SCLC**	Post-1L maintenance **ES-SCLC**	**5q SMA** w / biallelic SMN1
Date	9 June 2026	8 July 2026	8 July 2026	7 Sep. 2026
Assessment scope*	**8 PICOs** Populations: 3 Comparators: 7 Outcomes: 13	**7 PICOs** Populations: 4 Comparators: 5 Outcomes: 9	**1 PICO** Populations: 1 Comparators: 1 Outcomes: 12	**12 PICOs** Populations: 6 Comparators: 5 Outcomes: 12
Core evidence	**FIREFLY-1:** Phase II single-arm; indirect comparative evidence via MAIC only	**DeLLphi-304:** Phase III; H2H evidence for 3 PICOs, ITCs[1] for the remaining 4	**IMforte:** Phase III; H2H evidence	**STEER / STRENGTH**: Phase III / Phase IIIb single-arm; direct evidence vs sham, ITCs[2] vs active treatment
Key evidence gap	PICO breadth insufficiently covered	Comparative evidence not robust	Endpoint evidence incomplete / weak	Limited subpopulation representation

Discontinued JCA due to incomplete dossiers

	Tacquell® (autologous TIL therapy)	**Qezzaqar®** (catequentinib)	**Tyvyt®** (sintilimab)
Indication	Melanoma	Soft tissue sarcomas	NSCLC

1L: first-line | ES-SCLC: extensive-stage small-cell lung cancer | H2H: Head-to-Head | MAIC: matching-adjusted indirect comparison | ML-NMR: multilevel network meta-regression | NMA: network meta-analysis | NSCLC: non-small cell lung cancer | pLGG: paediatric low-grade glioma | TIL: tumour-infiltrating lymphocytes | SMA: spinal muscular atrophy | SMN1: survival motor neuron 1.
* Number of Populations, comparators and outcomes that are distinct (de-duplicated) across PICOs;
1- NMA, Bucher, MAIC | 2 - MAICs, ML-NMR



KEY TAKEAWAYS

What **was learned?**

JCA assessments **highlight key evidence gaps** around PICO scoping, comparator evidence, endpoints and subpopulation coverage.

What **remains to be learned?**

In the near term the **practical impact of JCA reports (or that of reported discontinuations), will become clearer** as HTA bodies use its outputs, respond to identified gaps, and shape time to access.

What **next?**

With JCA becoming increasingly important to EU access, **early readiness assessments and adaptive evidence strategies will be key** to mitigating access risks and avoiding inefficient evidence generation.

WHAT HAVE THE FIRST JCAS TAUGHT US?

Early JCAs expose the evidence-readiness challenges that can shape assessment outcomes

PICO breadth can outpace evidence readiness	Ojemda™	**Primary criticism:** A broad assessment scope was met with **very limited comparative evidence**: only 1 of 8 PICOs was supported, relying on an unanchored MAIC with substantial uncertainty.	**Implication: Forecast and stress-test the likely PICO scope** early to identify and mitigate reliance on uncertain indirect comparisons.
Full comparator coverage can still lack robustness	**Imdyltra®**	**Primary criticism:** All 7 PICOs were informed, but **evidence strength varied substantially by comparator** and corresponding comparative method used, with different PICOs relying on direct and indirect approaches.	**Implication:** Establish a **credible comparative evidence pathway** for each anticipated comparator, recognising H2H constraints and the need for methodologically robust ITCs.
Strong trial evidence can still leave endpoint gaps	ZEPZELCA®	**Primary criticism:** Despite complete PICO coverage and direct RCT evidence, **PFS2 was unavailable** and response-based outcomes, PRO and safety outcomes had a high risk of bias	**Implication: Prioritise early KOL / payer validation of critical endpoints**, particularly where HTA precedent and guidelines are limited, to ensure coverage and assess data maturity and robustness expectations.
Population comparability underpins PICO coverage	itvisma®	**Primary criticism:** Despite two RCTs, only 7 of 12 PICOs were informed; **some subpopulations were too small, comparator data were unavailable, and several ITCs were limited by population comparability**.	**Implication:** Anticipate PICO (sub)populations and assess ITC feasibility early to **avoid inefficient evidence generation**, recognising the challenges in generating comparable evidence in small populations
JCA discontinuation is a real risk and may have downstream implications for market access	**Tacquell®** **Qezzaqar®** **Tyvyt®**	**Primary criticism:** The dossiers **did not provide sufficient evidence, methods, documentation, and detailed HTA evaluations** from other agencies to allow assessors to robustly evaluate the full JCA scope, including gaps in PICO coverage, evidence retrieval and indirect comparisons.	**Implication: Get the JCA process right first time** to preserve a common EU evidence base and minimise fragmented national requirements that could slow or complicate access.

H2H: Head-to-Head | KOL: Key Opinion Leader | PFS2: Progression-Free Survival 2 | PRO: Patient-Reported Outcome | RCT: Randomised Controlled Trial

WHAT REMAINS TO BE LEARNED?

National implementation will determine how JCA translates into HTA and access

How will national HTA bodies operationalise and integrate JCA outputs?



Signals: During JCA scoping, some agencies accept manufacturers' proposed PICOs to **inform their national input, without guaranteeing feedback**. JCA integration models also vary: Ireland has demonstrated early reuse of JCA evidence, Germany conducts parallel national assessments before JCA publication, Sweden has embedded JCA outputs nationally, and the Netherlands plans sequential use after JCA completion.

Hypothesis: JCA integration will remain market-specific, with countries embedding EU-level evidence into existing national processes rather than adopting a single model.

Will JCA deliver faster national assessment and access?



Signals: JCA brings HTA-relevant clinical evidence closer to regulatory approval, while **reducing duplication and bring national assessment forward**. In Ireland, Itvisma's early Rapid Review used JCA evidence and was completed on the day of JCA endorsement (~7.5 weeks before publication), suggesting early HTA assessments can leverage JCA evidence ahead of public release.

Hypothesis: JCA may **speed HTA initiation and shorten timelines**, particularly in less resourced agencies and where economic review follows clinical appraisal, by enabling earlier progress.

How will national agencies respond to JCA-identified gaps / uncertainties?



Signals: JCA flags uncertainties, but **national HTA determine how they are addressed.** Germany illustrates this, with the orphan-drug pathway limiting the relevance of some comparator-related gaps. As final national decisions materialise, a key test will be whether agencies continue prioritising their historical evidence review concerns or expand scrutiny to uncertainties flagged by JCA.

Hypothesis: JCA may **highlight evidence gaps**, but national HTA requirements will determine their significance, while expectations for when they should be resolved (e.g. pre-local HTA submission) are evolving.

What will be the next steps for Pharma in case of JCA discontinuation?



Signals: JCA discontinuation does not affect centralised regulatory approval or block national HTA. **Pharma can continue country-level reimbursement discussions** while addressing the evidence gaps that led to discontinuation, which may support JCA re-initiation and restore a common EU clinical assessment for reuse across markets.

Hypothesis: JCA rework is preferable for **addressable gaps, reducing cross-market access risk**, while local HTA and rapid evidence generation offer a pragmatic fallback if discontinued, despite potentially undermining JCA's value.

WHAT SHOULD YOU DO NEXT?

JCA should be embedded within the integrated evidence generation plan, rather than treated as a standalone submission exercise.

The first assessments have exposed risks around PICO scoping, comparator evidence, endpoint robustness and subpopulation representativeness, reinforcing the need to anticipate areas of scrutiny and mitigate gaps early.

This should begin early in clinical development and be revisited at key milestones as the anticipated JCA scope and landscape evolve.

As national HTA bodies integrate JCA outputs, Pharma and MedTech companies should prioritise JCA readiness early in evidence planning and monitor country-specific implementation, moving beyond gap identification to prioritise risks, assess mitigation options and act while evidence-generation decisions remain flexible.

1 ASSESS

Anticipate JCA Evidence Risks Early
(Phase II, ~3-5 years pre-EMA submission - while evidence plans can still change)

Assess whether your evidence-plan is fit for evolving landscapes and disease complexity, and forecast priority PICOs to inform trial design, evidence generation and JSC engagement.

2 ACT

Address critical evidence risks
(Phase II–III)

Prioritise and mitigate gaps threatening PICO coverage through trial adjustments, additional analyses, ITCs or RWE, avoiding low-value evidence generation.

3 REFINE

Refine JCA evidence for submission
(Phase III)

Reassess PICO coverage as landscape evolves, finalise evidence generation and synthesis, and address uncertainties or justify residual gaps.

4 ALIGN

Prepare for national HTA implications
(Parallel / Post-JCA)

Track emerging patterns in how HTA agencies integrate and use of JCA outputs to inform market-specific evidence, engagement and access strategies.

JSC: Joint Scientific Consultation

HOW IPSOS CAN HELP YOU

Ipsos can help you navigate these challenges through a JCA evidence assessment tool and targeted analyses, including Ipsos Compass tools, to rapidly identify evidence vulnerabilities and inform practical actions to strengthen your evidence strategy.

1 ASSESS

Anticipate JCA evidence risks early (Phase II)

Ipsos support:

JCA Evidence Assessment Tool + **PICO Compass** to anticipate priority PICOs, score evidence readiness and identify vulnerabilities early.

2 ACT

Address critical evidence risks (Phase II–III)

Ipsos support:

ITC Compass + **RWD Compass** + **Payer Pulse Pro** to assess feasibility, validate payer expectations and prioritise evidence, saving time and avoiding unnecessary costs.

3 REFINE

Refine JCA evidence for submission (Phase III)

Ipsos support:

JCA Evidence Assessment Tool + **Ipsos JCA Experts** to strengthen analyses, address residual gaps and optimise dossier readiness.

4 ALIGN

Prepare for HTA implications (Parallel / Post-JCA)

Ipsos support:

HTA Monitor + **Payer Pulse Pro** + **Market Access Advisory** to track national HTA expectations, gather payer insights and tailor local access strategies.

Take the next step towards JCA readiness. Gain an early view of how evolving JCA expectations could impact your evidence strategy and identify where preparation may strengthen future submissions. Contact Chitresh Kumari to continue the conversation.

ABOUT HEALTHCARE AT IPSOS

One of the world's leading providers of healthcare insights, evidence and guidance. Ipsos Healthcare works in partnership with healthcare sector clients, empowering them to align commercial success with what matters most: improving patients' lives.

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THANK YOU



João Ataíde
Senior Market Access Consultant, Ipsos
Joao.Ataide@ipsos.com

João closely follows developments in the evolving JCA environment and has contributed to related research showcased at industry conferences.

He brings extensive European market access experience, managing payer research, pricing and access strategy projects across multiple markets.



Andrew Ballantyne
Head of UK Market Access, Ipsos
Andrew.Ballantyne@ipsos.com

Andrew has extensive global pricing experience developing pricing policies, pricing governance, innovative contracting and value solutions and has a deep knowledge of launch sequencing and price referencing.

Previously, Global Price & Market Access Director at AstraZeneca leading price and access strategy for top eight markets (EU4 + UK, US, JPN & CHN).



Chitresh Kumari
Principal, Market Access, Ipsos
Chitresh.Kumari@ipsos.com

Chitresh has extensive expertise in evidence generation by developing robust evidence-generation strategies, assessing evidence gaps, and aligning clinical development programmes with payer and HTA expectations.

Drawing on deep experience across therapeutic areas, Chitresh helps clients strengthen comparative evidence packages, and optimise evidence plans to support successful market access and anticipate assessment risks.