

The JCA Early Birds: What we know and what to watch out for

Nick Stringfellow, Consultant at Lightning Health explores the key considerations that manufacturers should be aware of and the future lessons that will come following publication of the first JCAs, now that new oncology products and ATMPs are undergoing assessment¹

Since the EU JCA came into effect on 12 January 2025, 14 products have been selected for assessment (see below).² These products represent the JCA 'early birds', navigating uncharted territory and allowing manufacturers to learn from their experience and adapt their JCA strategy accordingly.



Product	Indication	Assessor	Co-assessor
Tovorafenib*	Paediatric low-grade glioma	NCPE, Ireland	IQWiG, Germany
Autologous melanoma-derived tumour-infiltrating lymphocytes*	Treatment of melanoma	HAS, France	AOTMIT, Poland
Sasanlimab	Treatment of bladder cancer	ZIN, The Netherlands	DMC, Denmark
Onasemnogene Apeparvovect	Treatment of SMA	NCPE, Ireland	HAS, France
Lurbinectedin	Treatment of lung cancer	IQWiG, Germany	INFARMED, Portugal
Camizestrant	Treatment of adults with locally advanced or metastatic breast cancer	DVSV, Austria	RIZIV-INAMI, Belgium
Tarlatabamab	Treatment of extensive-stage small cell lung cancer	IQWiG, Germany	NNGYK, Hungary
Catequantinib	Treatment of synovial sarcoma or leiomyosarcoma	TLV, Sweden	NOMA, Norway
Sensiparib	Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer	IQWiG, Germany	JAZMP, Slovenia
Relacoriant	Treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer	INFARMED, Portugal	TLV, Sweden
Ensartinib	The treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)	DVSV, Austria	AEMPS, Spain
Zopapogene imadenovec	Treatment of respiratory papillomatosis in adults	DMC, Denmark	AHTA, Austria
Sintilimab	Treatment of non-squamous non-small cell lung cancer in adults	IQWiG, Germany	NIHO, Slovakia
Sonrotocicax	Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)	NIHDI-INAMI-RIZIV, Belgium	TLV, Sweden

*The first two medicinal products to undergo JCA were announced on the 15 April 2025³

Key considerations for the manufacturers



Evidence generation/synthesis to address diverse MS requirements

The JCA introduces the requirement to submit supporting data for a new therapy in line with PICO requirements across up to 27 European MS. This creates the potential for a high number of PICOs to address through evidence generation/synthesis (particularly for therapy areas where a high level of divergence in clinical practice is expected between EU countries). The role of ITCs and well-constructed RWE studies will likely be imperative to address potential limitations in available RCT data.



Alignment of timelines for the HTA and regulatory strategy

Manufacturers will need to run regulatory and JCA processes in parallel, and will have only 100 days from receiving the final JCA scope (including PICOs) to submit the JCA dossier. This will require close alignment between Regulatory, Medical, HEOR and Market Access functions to anticipate likely data/analysis requirements and ensure this is available in line with stringent EMA/JCA timelines.



Anticipation of implications for country level HTA

With many HTA bodies yet to introduce clear guidance on how the JCA will be incorporated into national processes, the primary aim of HTAR in reducing duplication across markets may not initially be met. Advanced planning will be required to anticipate potential additional analysis/evidence synthesis that could be requested at the MS level (e.g., related to the validation of surrogate endpoints and varying requirements for country specific health economic value demonstration).

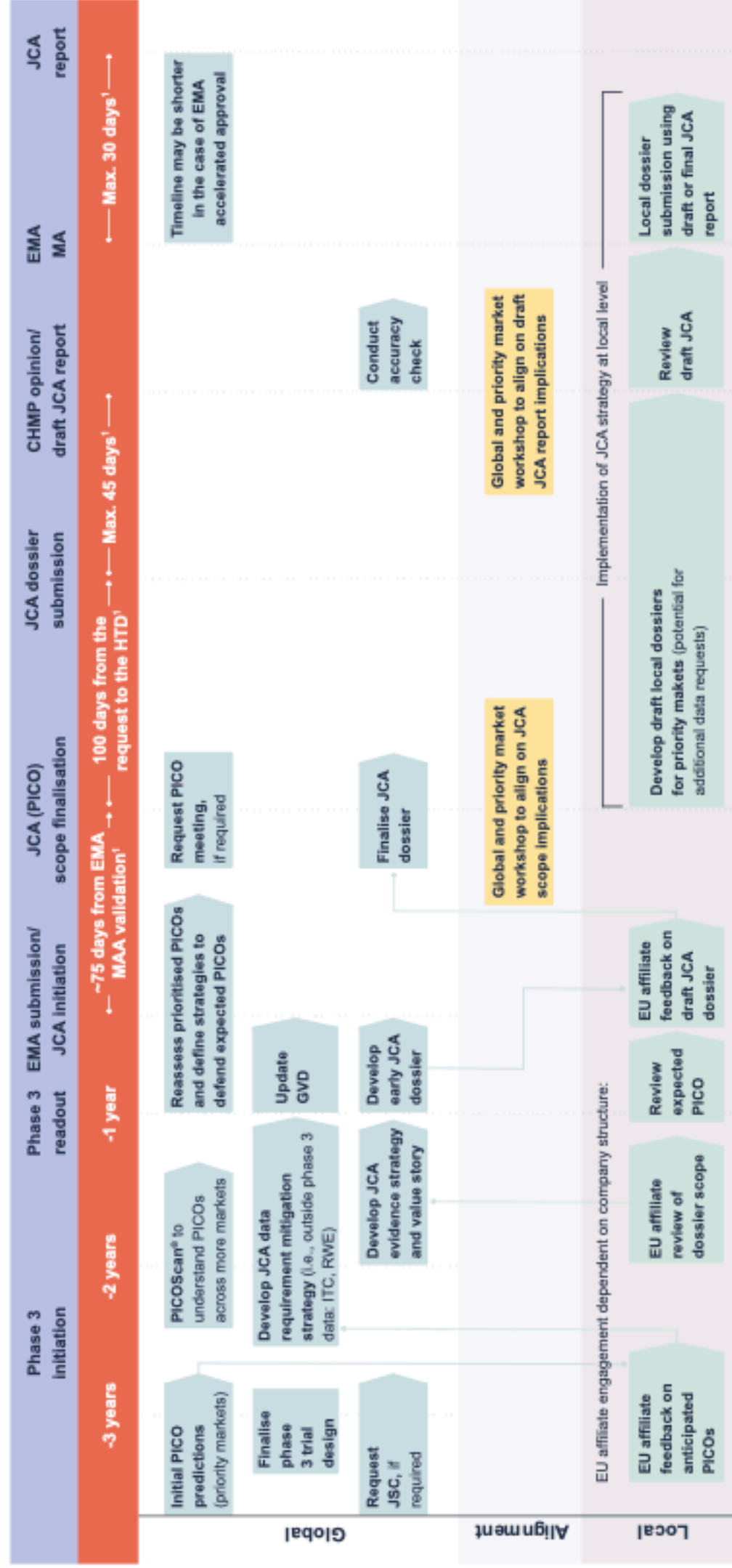


Alignment of global and country level workflows ahead of the JCA

One thing we can be certain of is that preparation for the JCA will require a collaborative approach between global and local leadership teams, leveraging each levels expertise to ensure value demonstration across Europe (see next page).

References. 1. https://health.ec.europa.eu/document/download/c0d81150-f1e1-472d-85eb-a06891dd707e_en?filename=hta_hiar_factsheet-jca_en.pdf. 2. https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en. 3. <https://ec.europa.eu/newsroom/sante/newsletter-archives/62551>.





What to watch out for

2026 represents an exciting time for European market access with the long-awaited publication of the first JCA reports. Key points to look out for will be:

- The number of PICO requests requested for products under assessment, including the level of pragmatism in rationalising potentially high numbers of PICO requests across MS, and accommodating the challenges for manufacturers to address a large number of PICO (that may not be feasible through an RCT, ITC or RWE collection)
- Practical application of the stated timelines for the JCA report publication, including the possible requirement for flexibility if there is variation between the indication requested by the manufacturer and the EMA approved patient population(s)
- Incorporation of the JCA report into national level HTA processes, including potential requests for additional data/analysis not submitted in the JCA report and possible areas of divergence (e.g. for the validation of surrogate endpoints and/or methods used to conduct ITCs)

If you are looking to explore your JCA strategy or further your knowledge on the challenges that must be overcome, speak to a member of the Lightning Health team or drop us an email at enquiries@lightning.health