The EU HTA Regulation,

its implementation and lessons learnt

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EU Regulation on Health Technology Assessment

In application since **12 January 2025**

Common **framework and procedures** for cooperation of Member States on health technologies at Union level

High-quality, **evidence-based** decision-making

Transparency and **inclusiveness** (stakeholders' engagement)

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Joint work driven by EU Member States

Joint Clinical Assessment

One single report on the relative clinical effectiveness and safety of new medicinal products and certain high-risk medical devices

Joint Scientific Consultations

Advice to health technology developers on clinical study designs that generate appropriate evidence

Identification of emerging health technologies

Identify, at an early stage, promising health technologies, to help health systems prepare for them

Methodologies and procedures

Common methodological guidance and procedures developed to conduct the joint work

Involvement of patients/carers and clinicians

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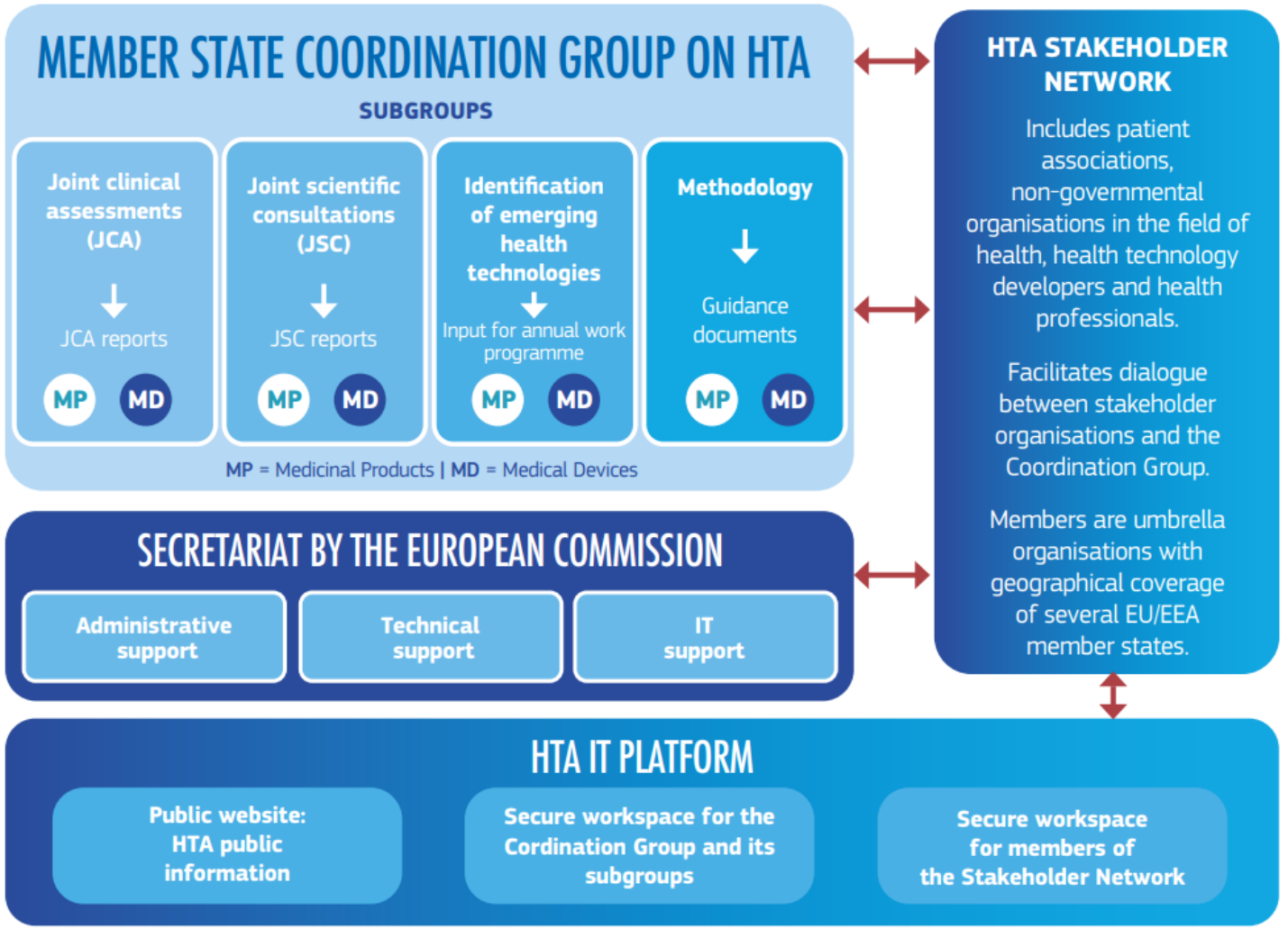
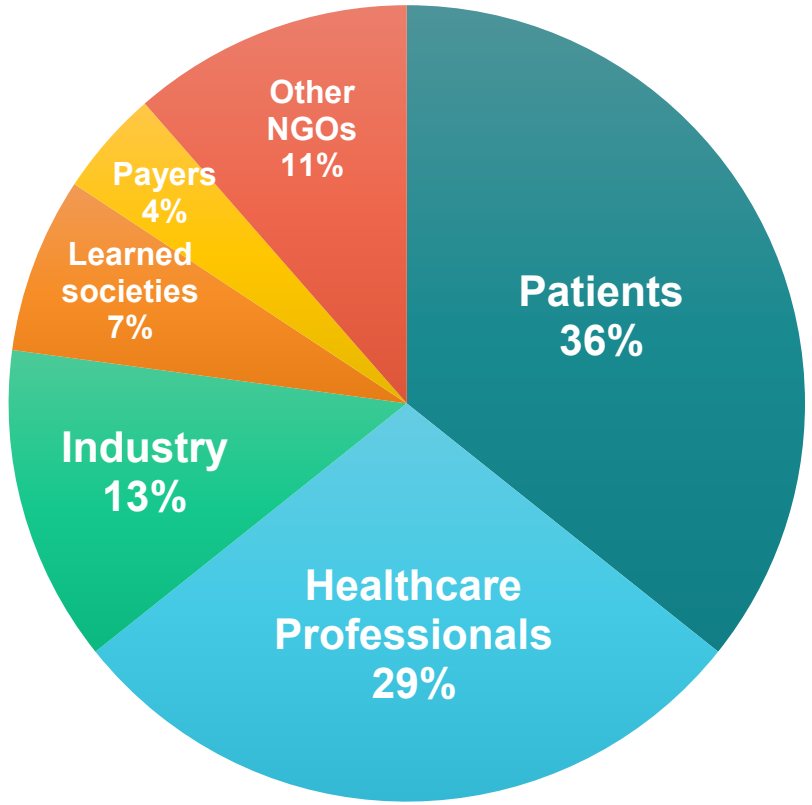
Governance of EU HTA Framework



HTA Stakeholder network: 71 organisations



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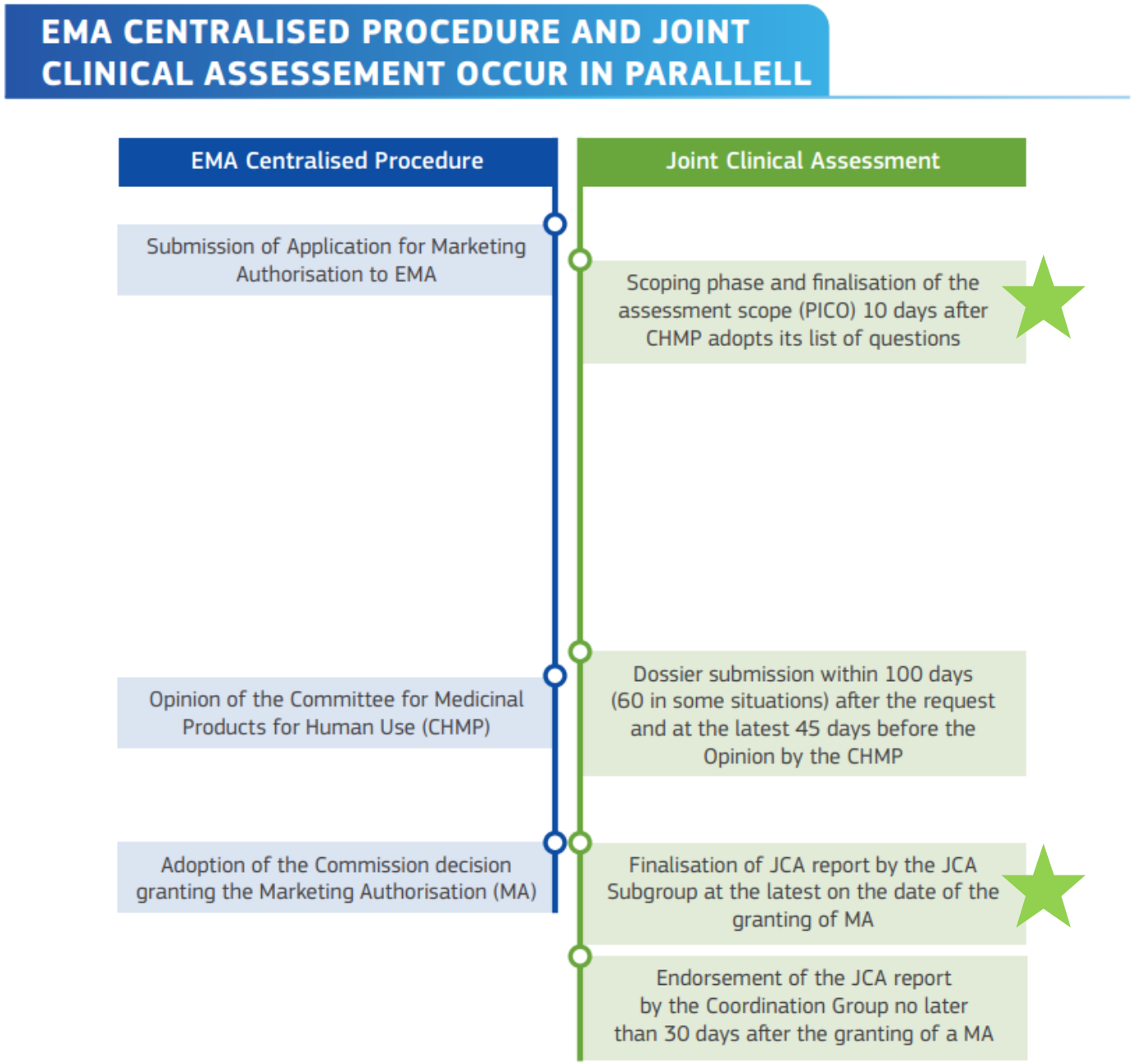
Member State Coordination Group on HTA (HTACG) - European Commission

Joint Clinical Assessments of medicines



consultation of patients and clinicians

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State of play

8 joint scientific consultations initiated in 2026

16 ongoing joint clinical assessments

4 JSC request periods in 2026

4 published JCA and summary reports

Summary indication	ATMP/Onco	Assessor/co-assessor
Non-small cell lung cancer	Onco	Austria/Spain
Respiratory papillomatosis	ATMP	Denmark/Austria
Non-squamous non small cell lung cancer	Onco	Germany/Slovakia
Relapsed or refractory mantle cell lymphoma	Onco	Belgium/Sweden

List of ongoing JCAs updated regularly on Europa website

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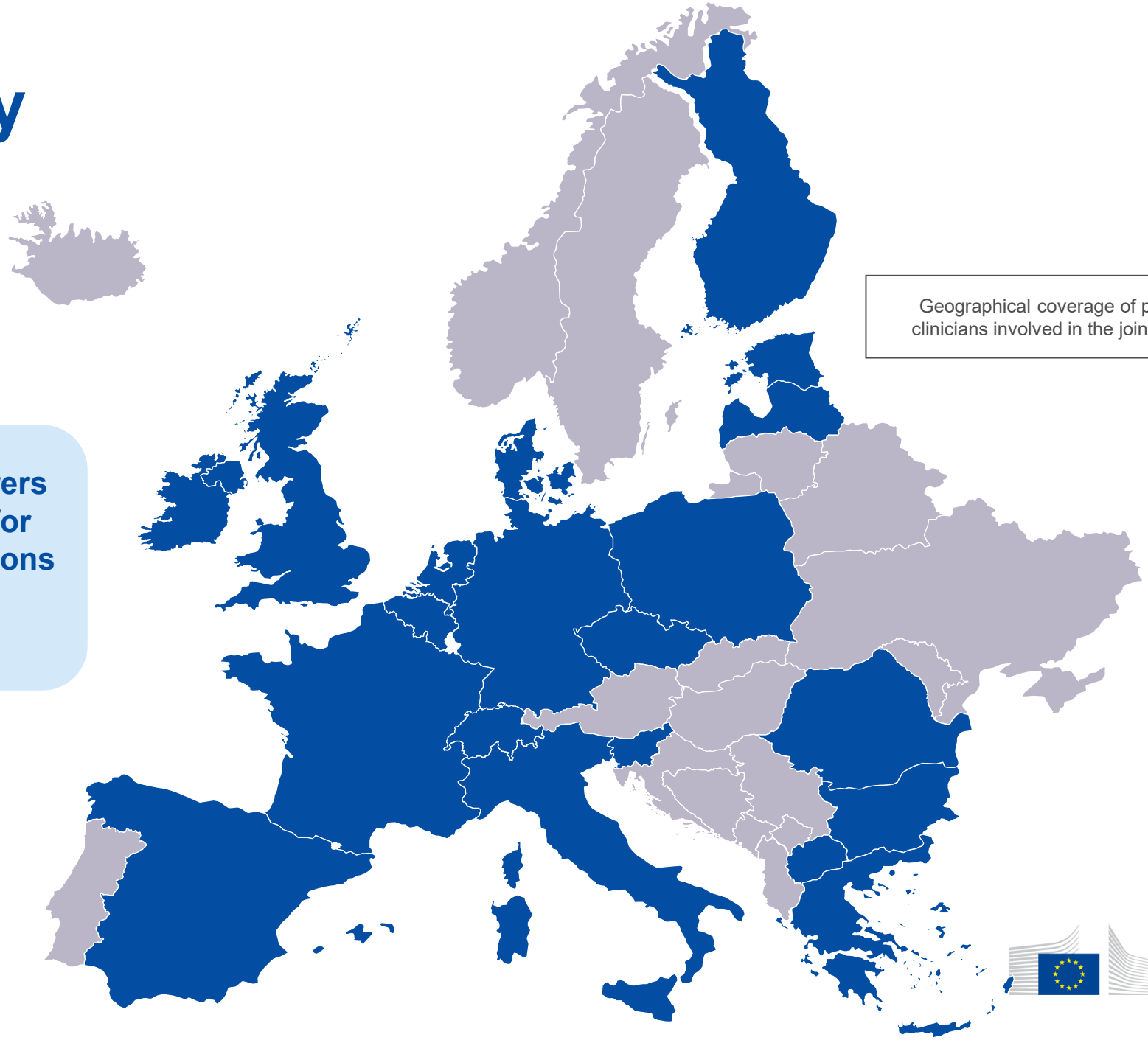
State of play

More than 90 patients/carers and clinicians selected for Joint Scientific Consultations and Joint Clinical Assessments



Geographical coverage of patients and clinicians involved in the joint work so far

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Lessons learnt

- **Trust** – governance, transparency, confidentiality
- **Timing** – EMA and regulatory process deadlines
- **Training** – capacity building
- **Scalability**









Looking ahead



- Upcoming evaluation of the implementation of the Regulation (incl. added value for MS, non duplication of information requests, functioning of the support framework)
- Awareness raising and communication
- Uptake, integration and use of JCA reports

Thank you

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