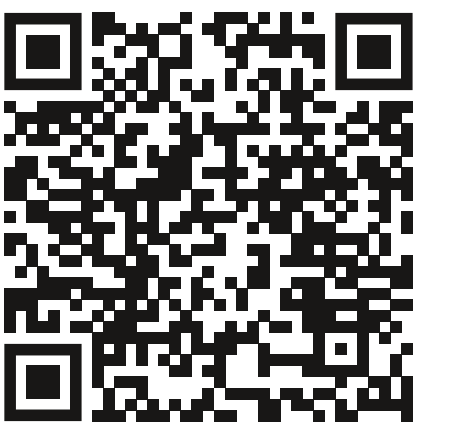


M. Groneberg, K. Ritz-Jansen, S. Stengel, T. Ecker, J. Leismann
Ecker + Ecker GmbH, Hamburg, Germany



Download
Poster

Organizational Readiness for EU HTA: Early Learnings and Key Considerations for Successful Market Access

Background

- The implementation of the EU Health Technology Assessment (HTA) Regulation¹ marks a fundamental shift in evidence generation, planning, and cross-country coordination.
- For Health Technology Developers (HTDs), the new framework introduces the complexity of managing parallel regulatory and HTA processes, which necessitates significant organizational adaptation and strategic foresight. Beyond procedural alignment, companies are required to restructure internal processes and resource allocation to meet evolving evidence demands and compressed timelines.
- Early EU HTA pilots provide first-hand insights into operational readiness, strategic alignment, and practical challenges for companies.

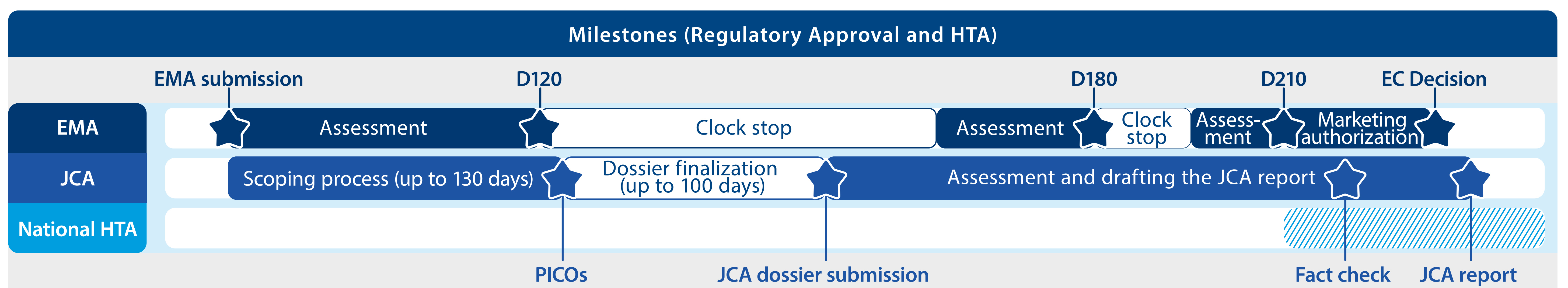
Objectives

- To identify early learnings from initial EU HTA projects.
- To identify the organizational enablers and key success factors needed to achieve readiness for Joint Clinical Assessments (JCA).
- To provide practical recommendations for industry on aligning global, EU, and local Market Access strategies.

Methods

Insights derived from:

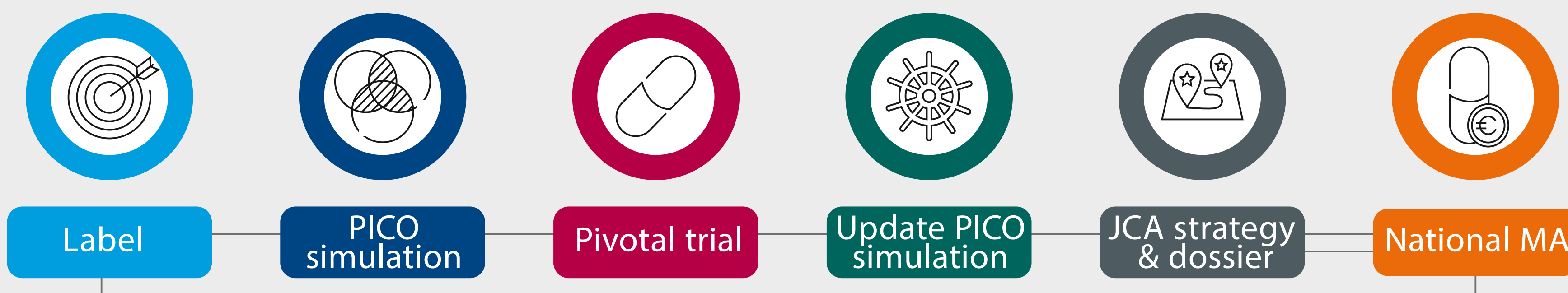
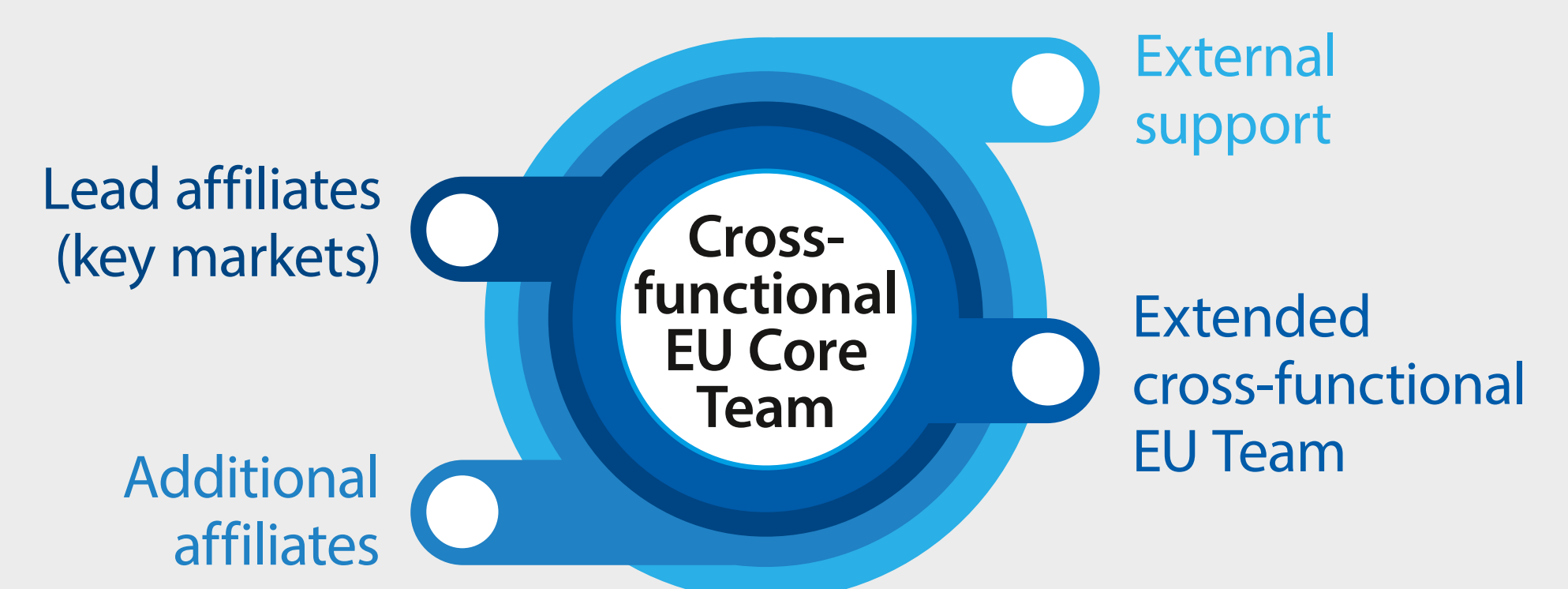
- Early EU HTA pilots (PICO simulations, dossier preparation, mock assessments).
- Organizational readiness programs (roadmaps, RACI charts, governance models).
- Strategic readiness initiatives.



Results: Key Learnings

1. Organizational Readiness & Cross-Departmental Coordination

- New governance structures are required, including cross-functional EU HTA taskforces.
- Alignment across Global, EU, and Affiliate teams ensures coherent strategies and avoids duplication.
- Clear accountability (via RACI charts) reduces ambiguity and improves decision-making.

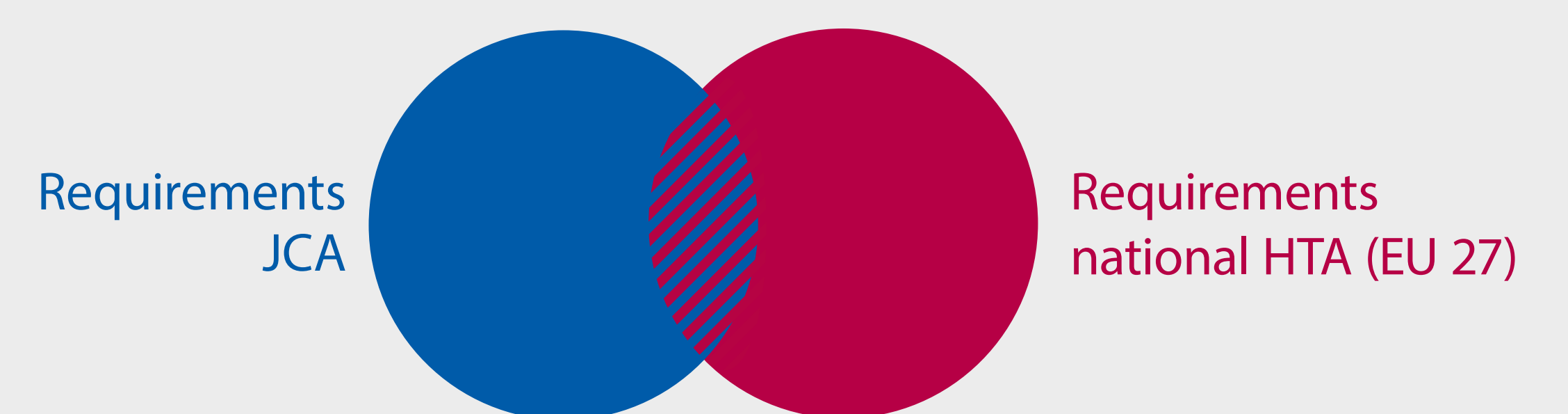


2. Early Market Access Planning

- Market Access considerations must begin before pivotal trials and label finalization.
- PICO simulations are critical to anticipate assessor expectations and align with national payers.
- Evolving label scenarios introduce uncertainty, requiring flexible resource allocation.

3. National & Methodological Considerations

- National HTA bodies diverge on methodological preferences, for example regarding the methods used and the acceptance of indirect evidence.
- JCA dossiers must balance EU-level requirements² with local evidence needs.
- Trade-offs are often required to address regulatory, EU HTA, and national payer expectations simultaneously.



Conclusions & Recommendations

- Organizations must realign their operations to enable the seamless implementation of the JCA.
- Establish a robust operating model – ensure end-to-end coordination of JCA submissions, supported by strong EU Market Access leadership.
- Clarify roles and responsibilities – align Global, Regional, and Affiliate functions through clear RACI structures and accountability.
- Standardize with fit-for-purpose tools – leverage EU HTA-specific templates and project plans to streamline processes.
- Foster cross-functional collaboration – enhance coordination across HEOR, Clinical, Biostatistics, and Market Access through joint workflows.
- Support with training and guidance – provide tailored implementation materials and role-specific training to strengthen affiliate readiness.

References

1. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU
2. Guidance on filling in the JCA dossier template (V1.0; 8 October 2024)