Implementation of the Regulation (EU) 2021/2282 on Health Technology Assessment

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Regulation (EU) 2021/2282
Key principles

- **Joint work** on common **scientific, clinical aspects** of HTA
- Joint work **driven by Member State HTA bodies**
- Ensure **high quality, timeliness and transparency**
- Ensure **use of joint work in national HTA processes**
- **Member States** remain responsible for:
  - Drawing **conclusions on added value** for their health system
  - Taking **decisions on pricing & reimbursement**
- **Addresses stakeholders' engagement in joint work**
- **Progressive implementation**

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Regulation (EU) 2021/2282 Governance

- The Regulation on HTA entered into force in January 2022, with application from January 2025.
- Sustainable and transparent framework for EU cooperation on HTA

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HTA Regulation – Joint HTA activities

- **Joint Clinical Assessments/JCA** on:
  - **medicines** (first 3 years: oncology medicines and ATMP;

    following 2 years: + orphan drugs; after 5 years: full scope)
  - **a selection of high-risk implantable medical devices classified as class IIb or III** pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure
- **Joint Scientific Consultations/JSC**
  - HTA only
  - in parallel with regulators
- **Emerging Health Technologies**/Horizon scanning
- **Methodology for joint HTA work**

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HTA Regulation Implementation timeline

Adoption

December 2021

Entry into force

January 2022

Date of Application

January 2025

Joint Clinical Assessment Full Scope

January 2030

Preparatory phase

Implementation phase

Part of rolling Implementation plan

- **Setting up the Coordination Group/HTACG (EC)**
- **Setting up the Stakeholder Network (EC)**
- **Drafting implementing and delegated acts (EC)**
- **Drafting guidance documents (CG)**

eunethta

Service contract EUnetHTA21

Joint Scientific Consultations (JSC)

+

Stepwise build-up of Joint Clinical Assessments (JCA) scope for medicines:

- From Jan. 2025: cancer drugs, ATMPs

(from date of application)

- From Jan. 2028: orphan drugs

(3 years after date of application)

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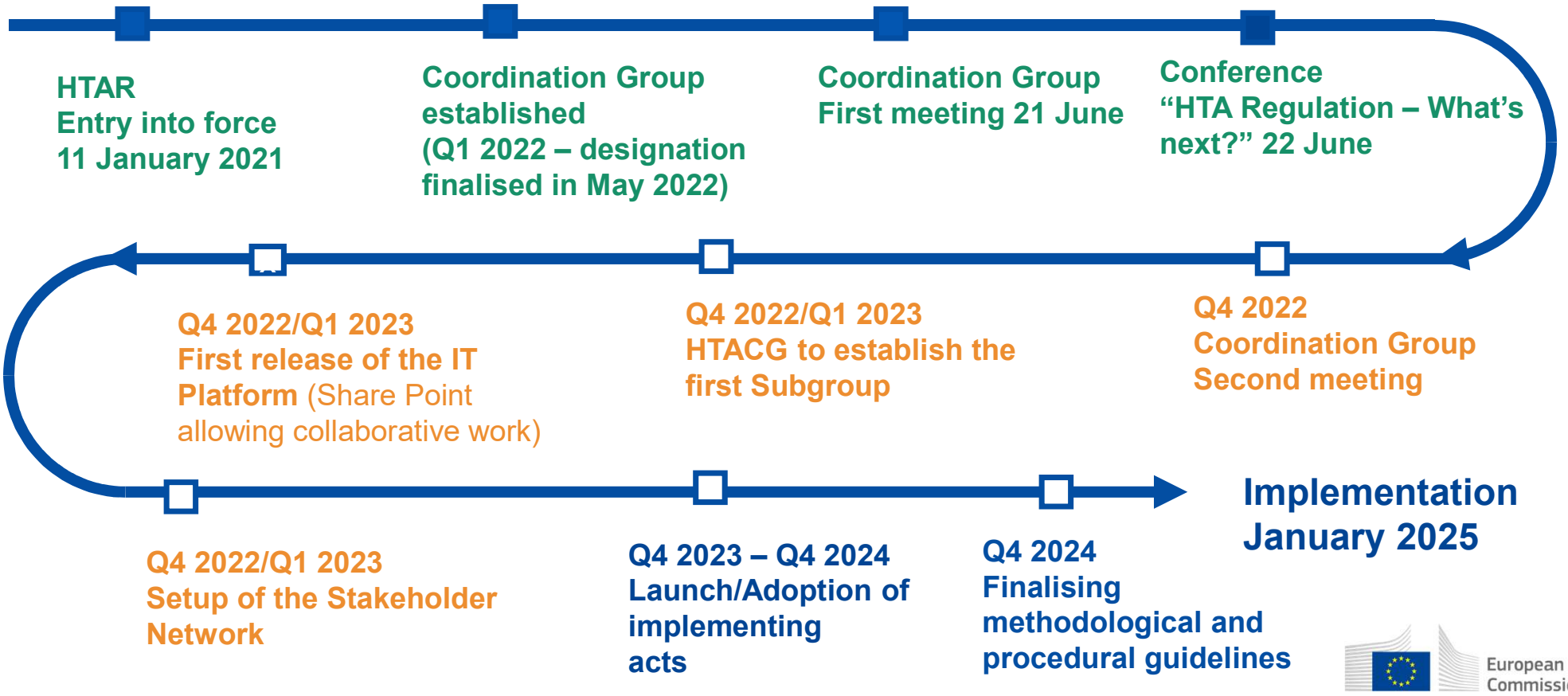
HTA Regulation
Implementation rolling plan



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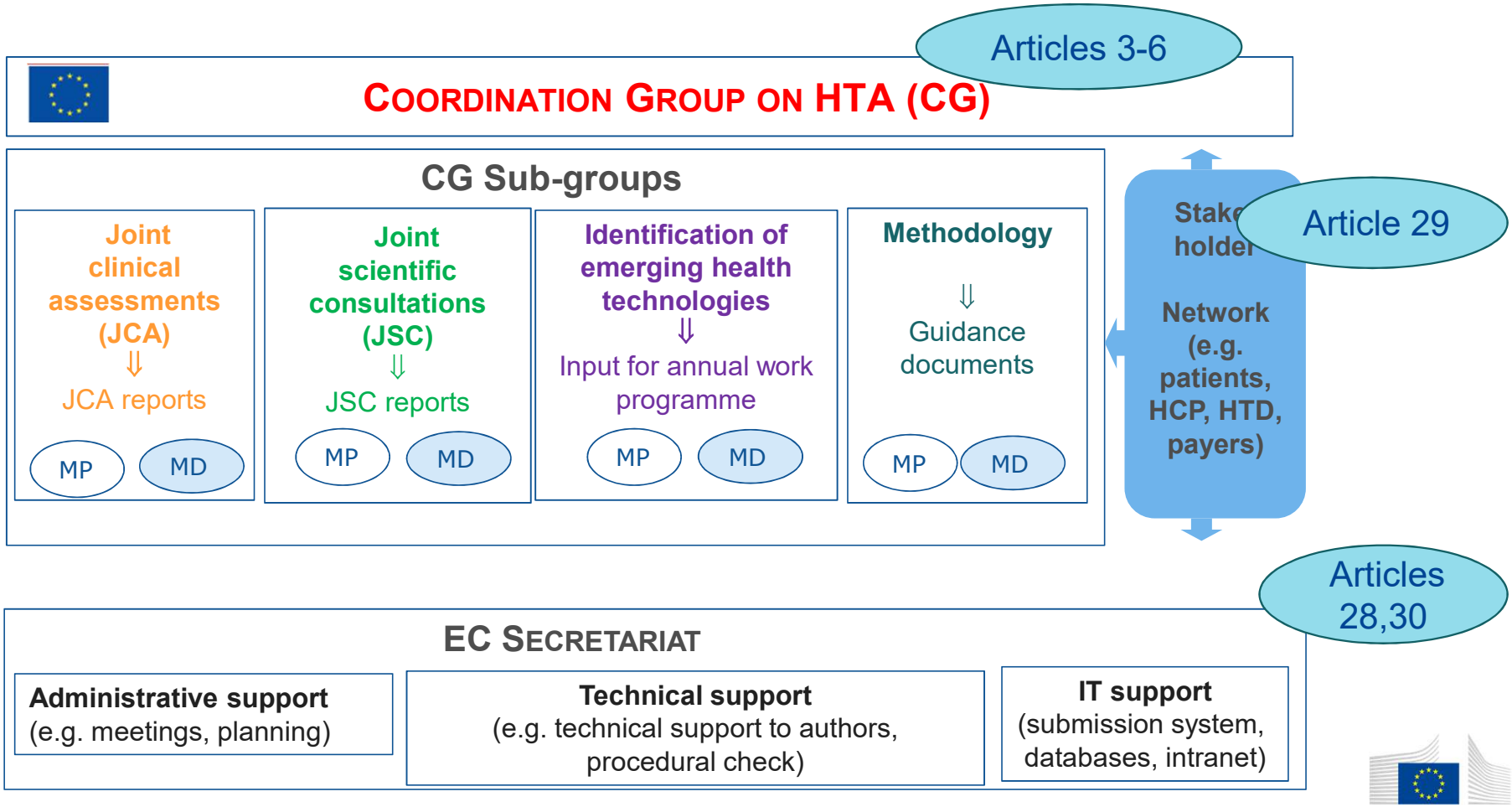
HTA Regulation
MS Coordination Group on HTA



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MP = medicinal products, MD = medical devices, HCP = healthcare professionals, HTD = health technology developers

Conclusions

- Implementation of the HTAR is a priority for the Commission
  - Establishing governance and operational structures
  - Drafting and adoption of implementing legislation
  - Ensuring continuity of key joint activities until implementation date through the EunetHTA21 contract
- Commitment of Member States and stakeholders is essential to secure smooth implementation

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Thank you

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