The EU regulation on health technology assessment: what's in it and why it matters?"

HTA information day, Seville
22 November 2023

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What is health technology assessment?

Health technology assessment (HTA) is the systematic evaluation of the properties, effects, or impact of a health technology in comparison to another technology.

HTA considers evidence about medical, economic, social and ethical issues related to the use of a health technology.

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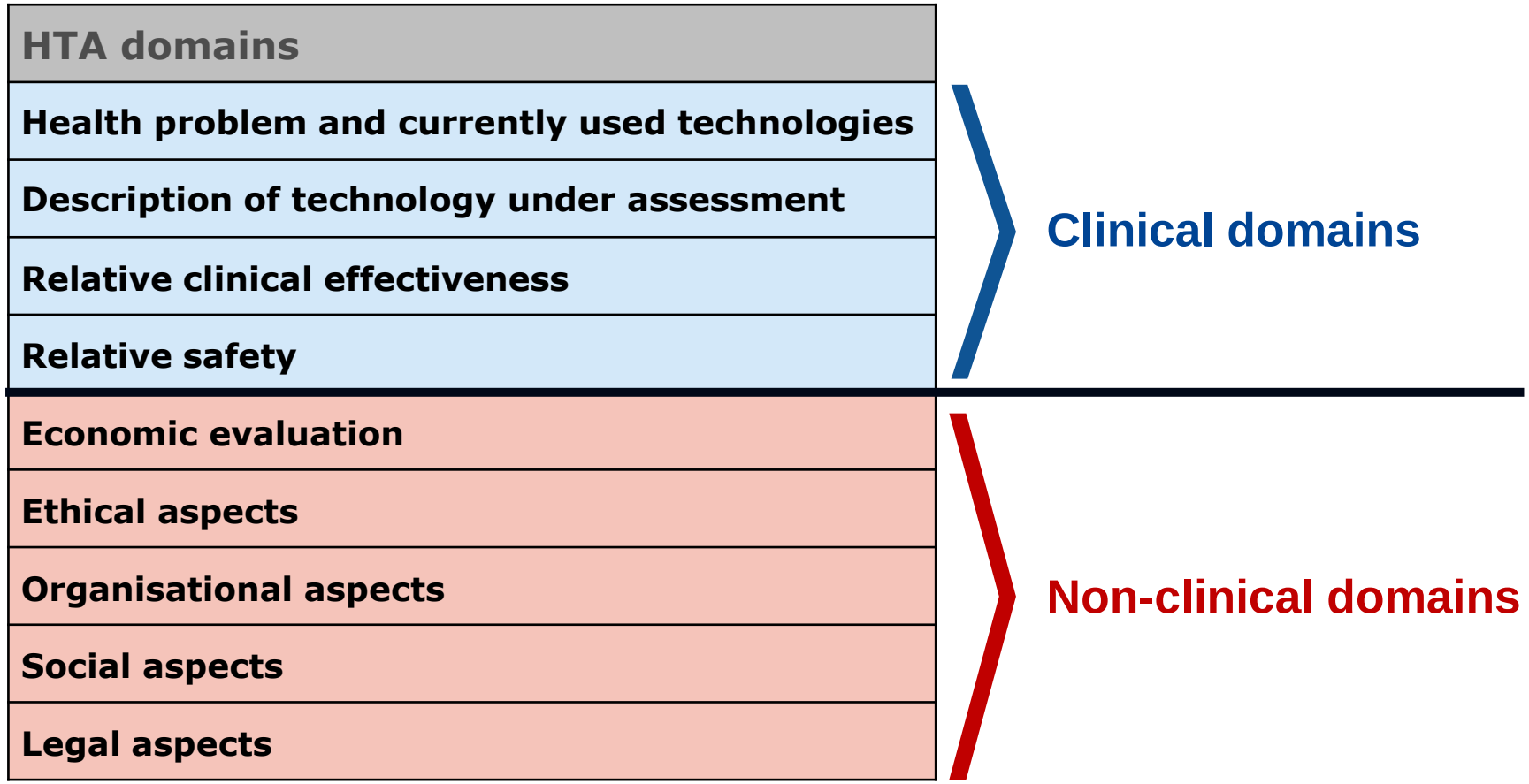
HTA domains


HTA domains
Health problem and currently used technologies
Description of technology under assessment
Relative clinical effectiveness
Relative safety
Economic evaluation
Ethical aspects
Organisational aspects
Social aspects
Legal aspects
Clinical domains
Non-clinical domains

Regulatory process vs. HTA

- Single licensing system
- Single EU legislation
- Well defined and agreed assessment criteria

- All Member States have different HTA systems
- National legislations and procedures
- Different methodologies and assessment criteria

Regulatory process vs. HTA

- Single licensing system
- Single EU legislation
- Well defined and agreed assessment criteria

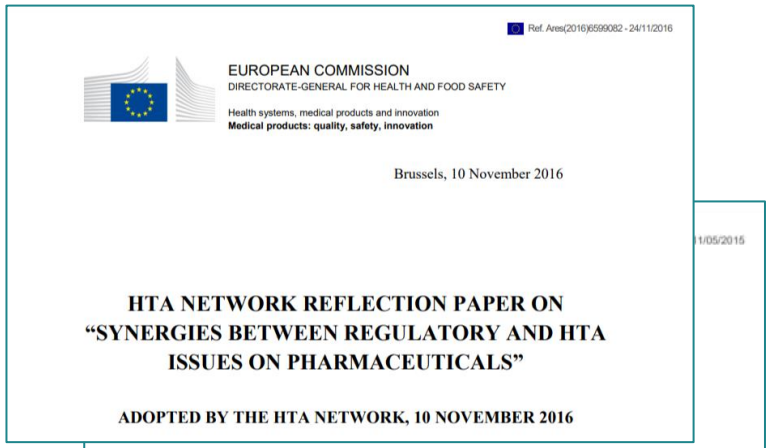
EU HTA regulation

- Joint framework for clinical assessment
- Common methodology and approach for clinical assessments and scientific consultations

NATIONAL

- Use of joint clinical assessment in national decision-making
- Non-clinical assessments
- Decision making on pricing and reimbursements

Strengthening EU HTA cooperation


Ref. Ares(2016)6599082 - 24/11/2016

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Health systems, medical products and innovation
Medical products: quality, safety, innovation

Brussels, 10 November 2016

HTA NETWORK REFLECTION PAPER ON "SYNERGIES BETWEEN REGULATORY AND HTA ISSUES ON PHARMACEUTICALS"

ADOPTED BY THE HTA NETWORK, 10 NOVEMBER 2016

HTA NETWORK REFLECTION PAPER ON "REUSE OF JOINT WORK IN NATIONAL HTA ACTIVITIES"

ADOPTED BY THE HTA NETWORK, APRIL 2015

JA1 (2010 – 2012)
JA2 (2012 – 2015)
JA3 (2016 – 2021)

HTA Regulation

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Regulation (EU) 2021/2282 on HTA

- Adoption 15 December 2021
- Entry into force 11 January 2022
- Entry into application 12 January 2025
- Main objectives: establishing a support framework and procedures for cooperation of Member States on health technologies at Union level; a mechanism for the submission of evidence for joint clinical assessments only once at Union level; common rules and methodologies for joint clinical assessments.

HTA Regulation – Key principles

- **Joint work** on common **scientific, clinical aspects** of HTA
- **Driven by Member State HTA bodies**
- Ensure **high quality, timeliness and transparency**
- Ensure **involvement of stakeholders**
- 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 experts and stakeholders' engagement in joint work**
- **Progressive implementation**

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Joint HTA activities

Joint Clinical Assessments (JCA) on:

- **medicines** first 3 years: cancer medicines and advanced therapy medicinal products

  from January 2028: + orphan medicinal products

  from 2030: full scope
- **a selection of high-risk medical devices and in-vitro medical devices**

Joint Scientific Consultations (JSC)

- in parallel with the European Medicines Agency

Emerging Health Technologies

Methodology for joint HTA work

Voluntary cooperation

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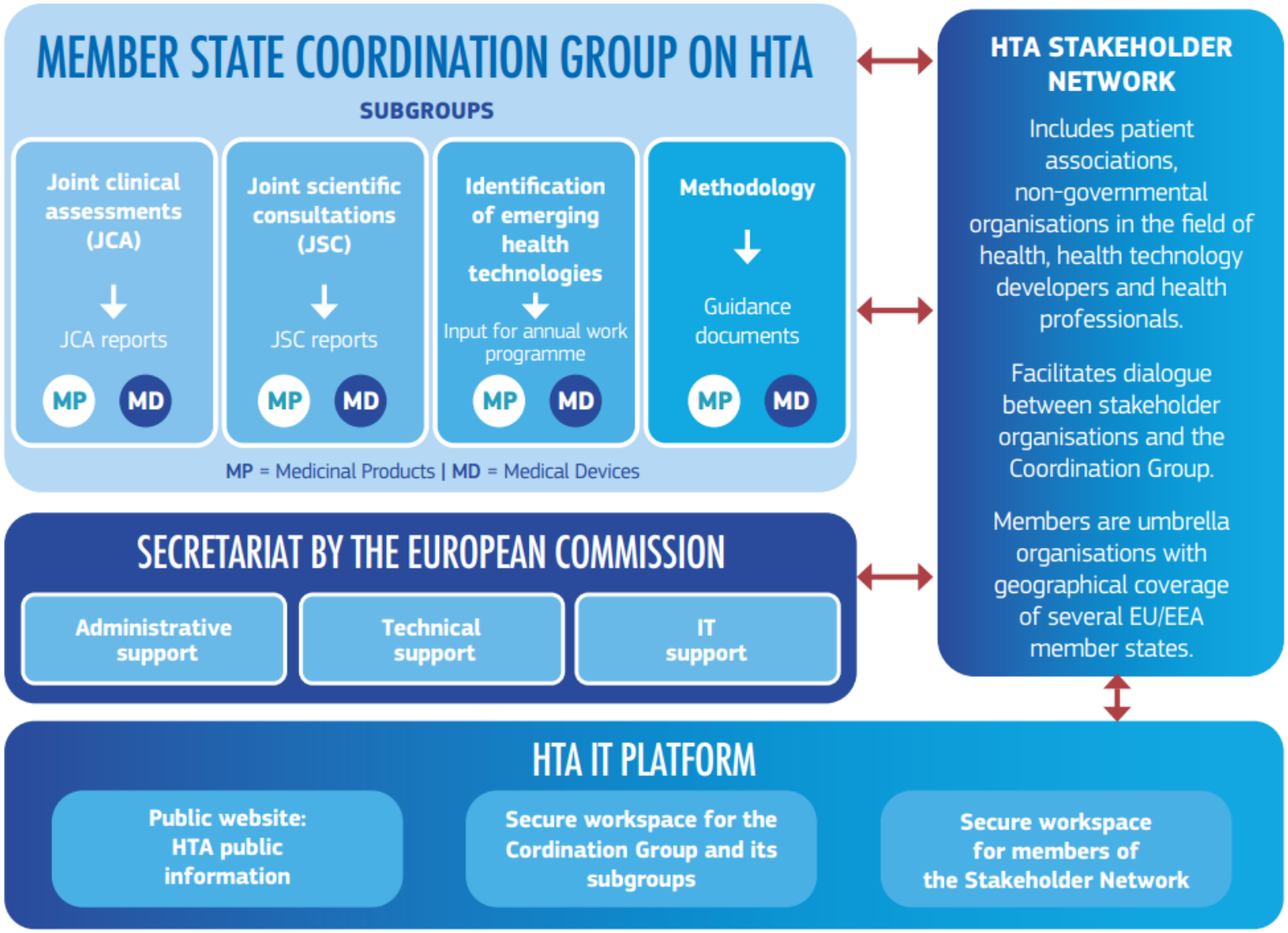
Governance



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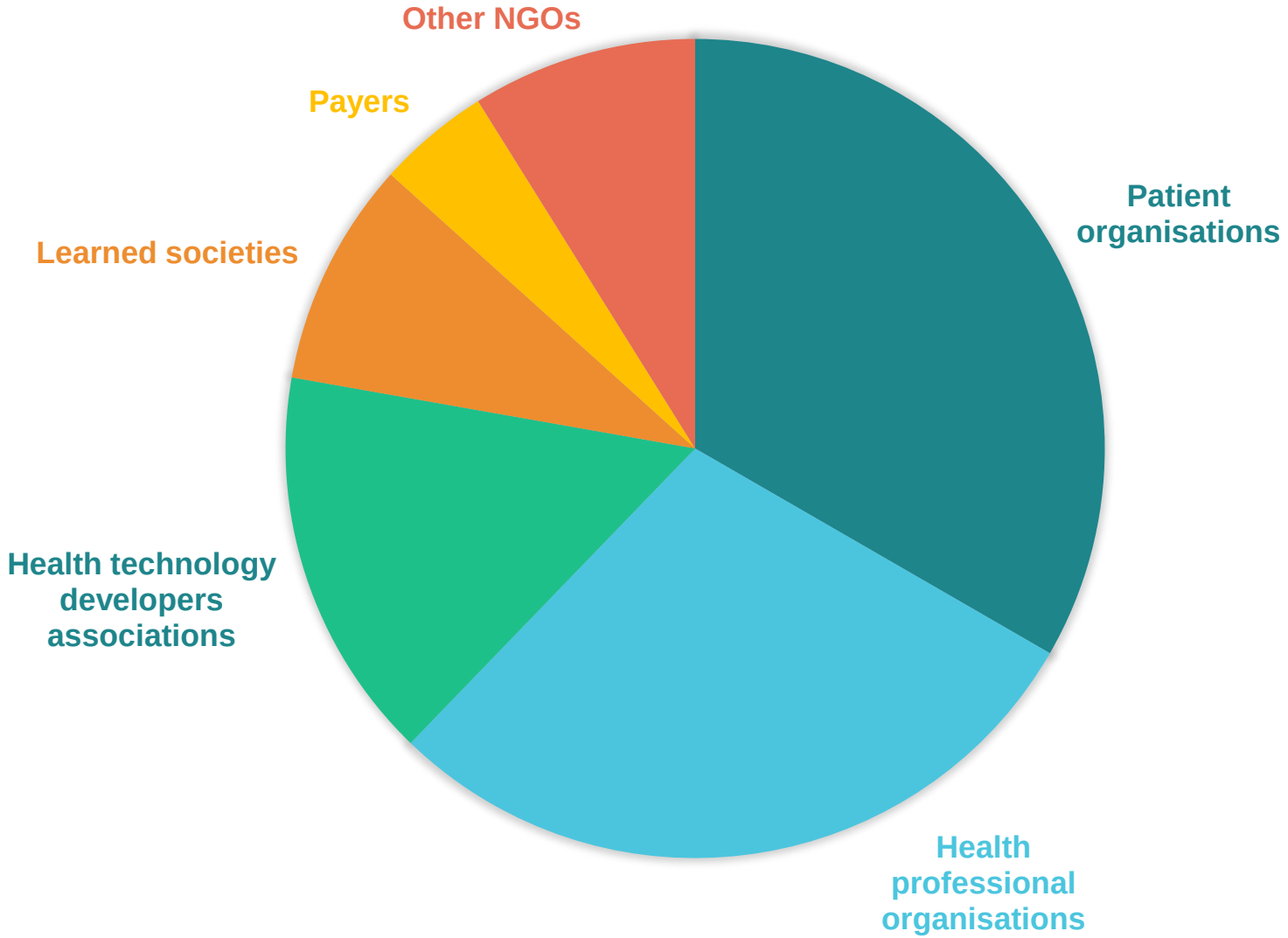
Type of organisations in the HTA Stakeholder Network



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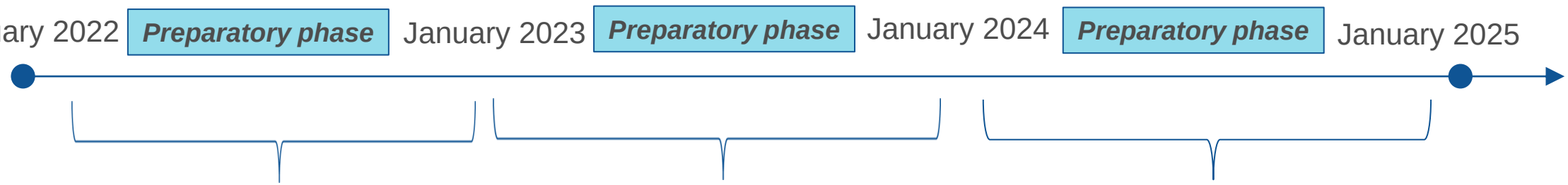
Halfway through the preparatory phase

Adoption
December 2021

Entry into force
January 2022

- **Developing the IT platform (EC)**

Application
January 2025



- **Setting up the Coordination Group (EC)**
- **Drafting implementing acts (EC)**
- **Setting up the subgroups (EC)**
- **Setting up the Stakeholder Network (EC)**
- **Drafting guidance and procedures (CG)**
- **Training and capacity building**
- **Awareness raising, incl. HTA information events (regional)**

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Service contract EUnetHTA21

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Implementing acts to be adopted by 2025

• Procedural rules for JCA medicinal products	Q4 2023
• Procedural rules for the prevention of conflict of interest	Q1 2024
• Cooperation by exchange of information with the EMA	Q1 2024
• Procedural rules for JSC medicinal products	Q2 2024
• Procedural rules for JCA medical devices and IVD medical devices	Q3 2024
• Procedural rules for JSC medical devices and IVD medical devices	Q4 2024

Preparation, consultation and adoption of implementing acts

Early reflection
The Commission carries out appropriate consultations **during its preparatory work.**

‘**Comitology**’ (examination) **procedure**

HTA Committee provides **opinion** on the draft text

Targeted consultation
Consultations with relevant stakeholders.

Public consultation
Consultations with all stakeholders on Have your Say (4-week feedback period)

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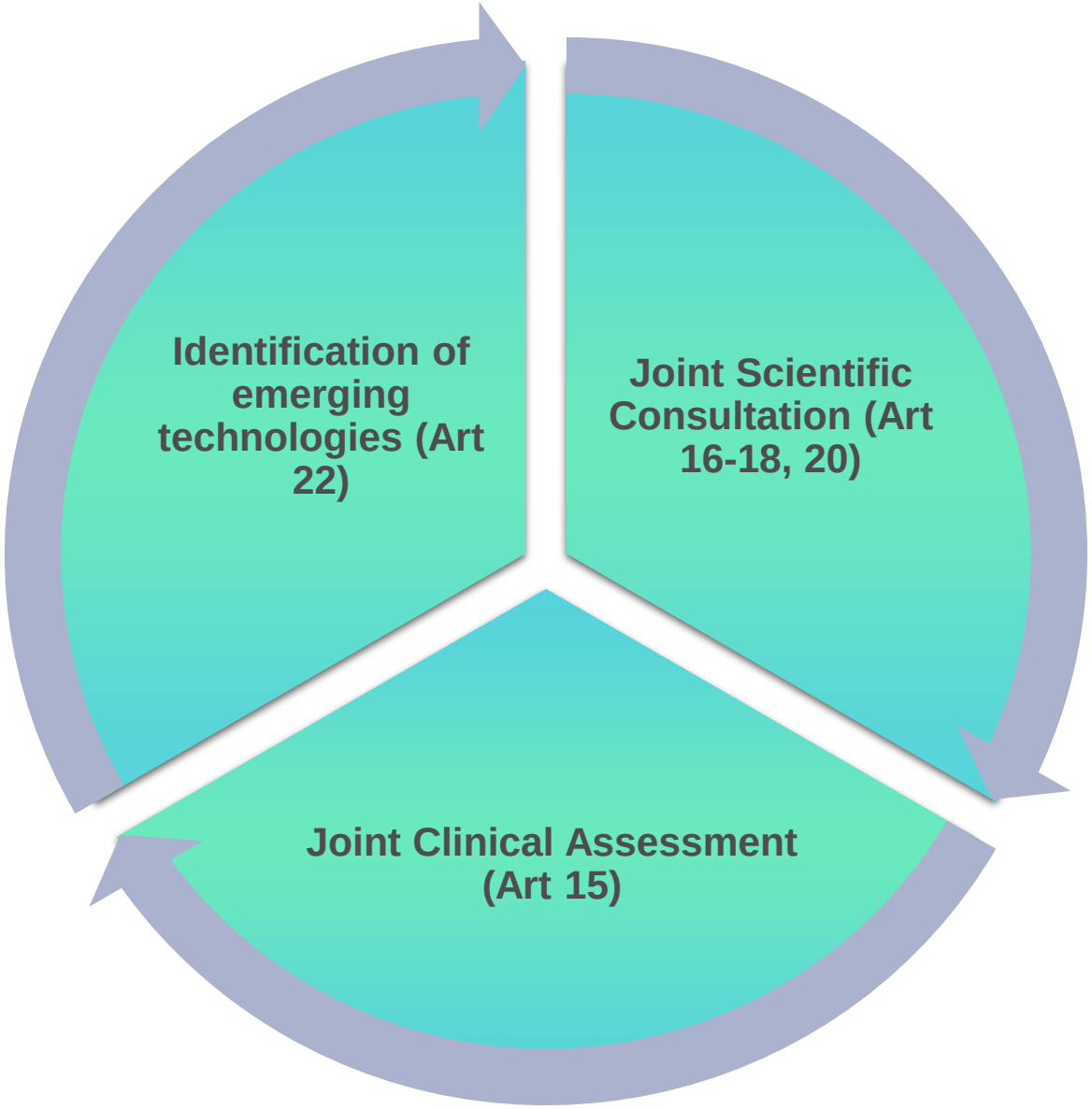
Collaboration with EMA under the HTA regulation



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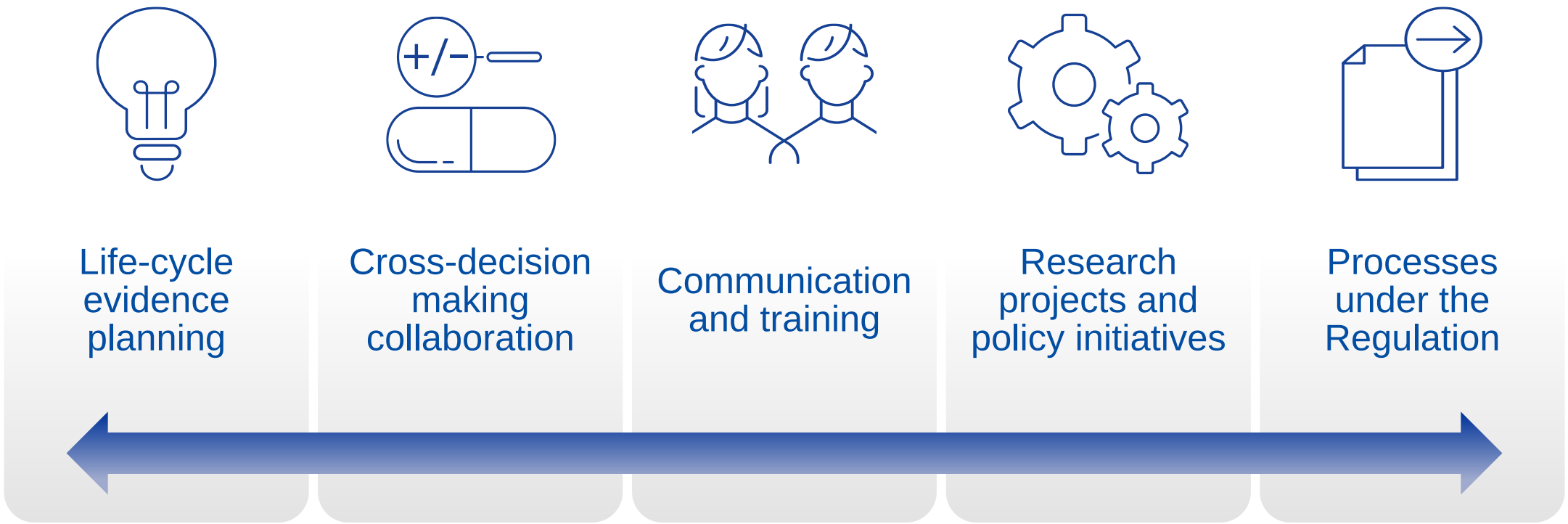

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Rolling plan regularly updated

IMPLEMENTATION ROLLING PLAN

2023-2024

REGULATION (EU) 2021/2282 ON HEALTH TECHNOLOGY ASSESSMENT

This rolling plan contains a list of key activities that the Commission has carried out or intends to carry out in preparation for the implementation of Regulation 2021/2282 on Health Technology Assessment (the "HTAR"). The plan is subject to regular review to provide national authorities and stakeholders with the most updated information.

The HTAR entered into force on January 11, 2022. It will be applicable as of January 12, 2025.

Latest update: June 2023

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Member State Coordination Group on Health Technology Assessment (HTACG) HTAR Article 3				
Fourth meeting of the HTACG	HTAR Article 3		**13 June 2023**	In preparation
Third meeting of the subgroup on methodological and procedural guidance			6 July 2023	In preparation
Third meeting of the subgroup on Joint Clinical Assessments			7 July 2023	In preparation
Third meeting of the subgroup on Joint Scientific Consultations			6 October 2023	In preparation

https://health.ec.europa.eu/health-technology-assessment_en

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Awareness raising – HTA information events

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Conclusions: Co-creation of a new system

Inclusiveness and transparency as key principles of the joint work

Commitment of all Member States and all stakeholders is essential to secure smooth implementation

16 months left until application

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Thank you for your attention

Any question?

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