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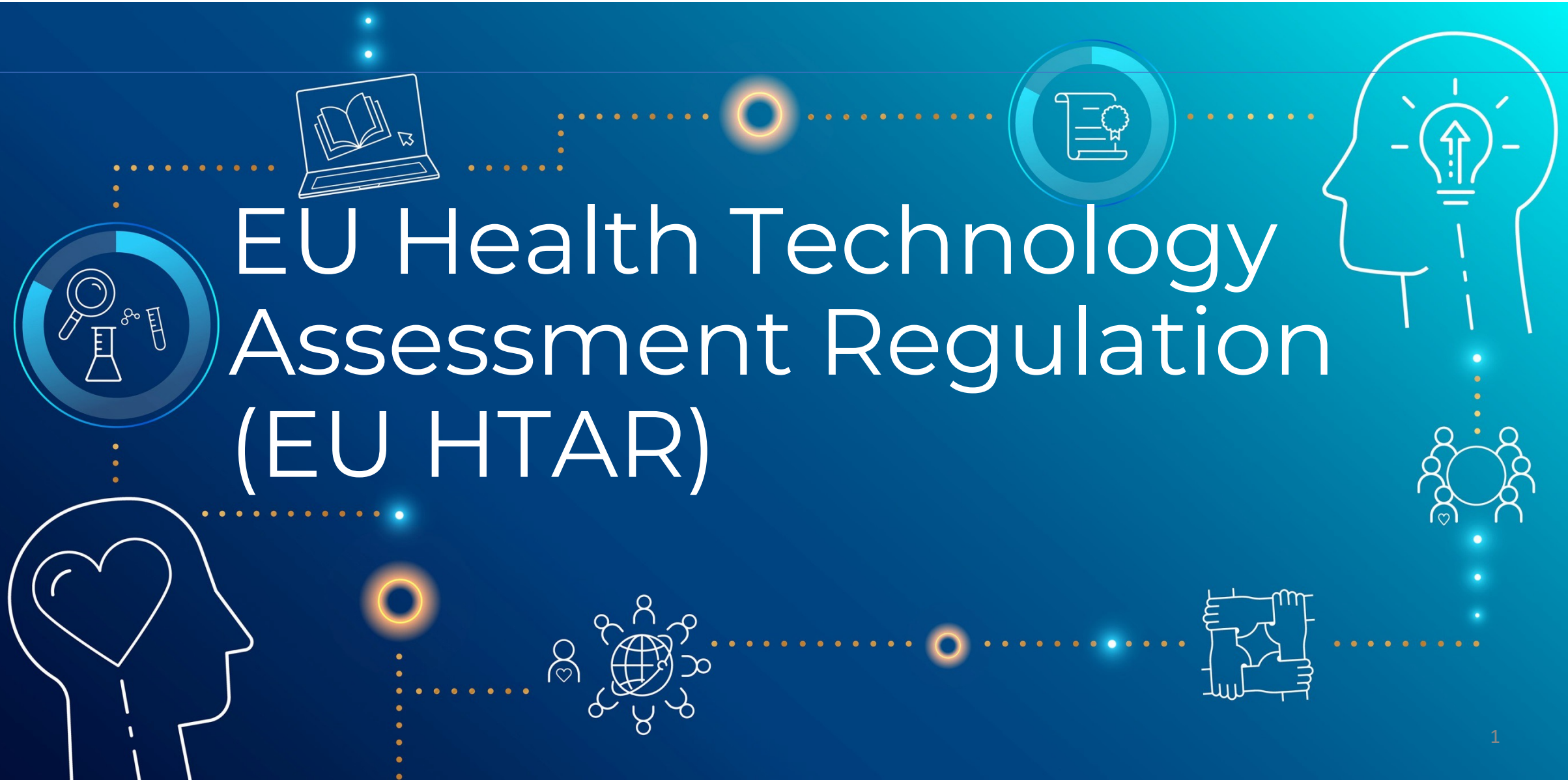

EU Health Technology Assessment Regulation (EU HTAR)

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Disclaimer

These slides are currently under review by EUPATI's Editorial Board. The latest version of these slides will be made available in September 2024.

Click here to learn more: https://eupati.eu/hta4patients/

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Content

- HTA & HTAR
- Governance Structure
- Joint Work
- Methodologies
- Horizon Scanning
- Joint Scientific Consultation
- Joint Clinical Assessment
- IT Platform
- How Can I Get Involved
- Extra Materials/ Further Readings

Online Courses

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Health Technology Assessment (HTA)

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

HTA Domains

Clinical Domains

Health problems and currently used technologies (who is the medicine for and what is the current treatment, e.g. medicines, medical devices, surgical procedures).

Description of health technology under assessment (molecule, pharmacodynamics, pharmacokinetics – what does the medicine do to the body).

Relative clinical effectiveness (how well does the medicine work & how is it measured. It may also include any Patient Reported Outcome (PROs) and Patient Preference Measures (Pref).

Relative safety (toxicology, side effects, risks)

Non-Clinical Domains

Economic evaluation (It is the ONE single aspect that is always being assessed. The EUnethta Core model is suggested as a full structured & standardized assessment.)

Ethical aspects (Traditions, culture and health systems have a great impact on what is considered 'ethical' in the local context.

Social aspects (The impact on the wider society or community, such on other non-healthcare institutions or on carers and family members).

Organizational aspects (It includes changes to the structure of health services & how they are delivered, e.g., when patients recover faster or when a treatment requires specialized staff).

Legal aspects (It refers to national regulation – what healthcare staff is allowed to do and involves ethical considerations, e.g., genomic editing.

Scene Setting

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Regulatory

EMA

- Regulatory approval
- Single licensing system; one EU legislation

Health Technology Assessment

National

- Appraisal phase
  - e.g. cost effectiveness to be added
  - Other considerations?
  - Weighing argument, decision making/reimbursement advice
- JCA should be given due consideration in national decision-making

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Aim of the HTA Regulation

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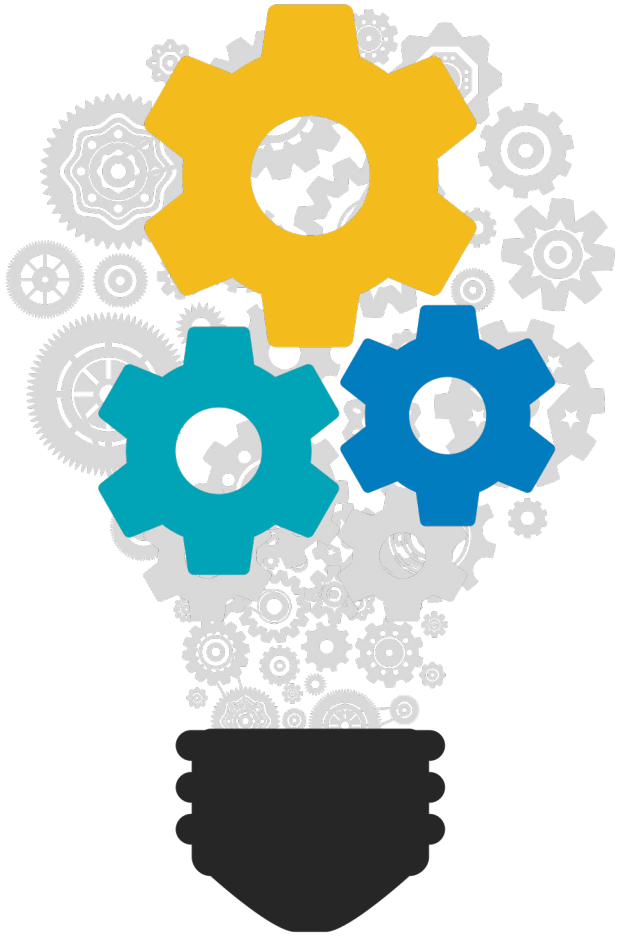
Improve availability of innovative health technologies

Efficient use of resources



Strengthen HTA quality

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Regulatory

EMA

- Regulatory approval
- Single licensing system; one EU legislation

Health Technology Assessment

HTAR

- In JCA relative assessment of Technology X vs. Technology Y (and others)
  - How does it compare to what we already have (*)
- Relative effectiveness and relative safety
- Clinical domain only!
  - No value judgements
  - No conditions or added value or reimbursement
  - Connect methodology and approach

National

- Appraisal phase
  - e.g. cost effectiveness to be added
  - Other considerations?
  - Weighing argument, decision making/reimbursement advice
- JCA should be given due consideration in national decision-making

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Marketing Authorisation & HTAR

Health Technology Assessment Regulation (January 2025 onwards)

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- Unified licensing system
- EU legislation
- Clear and agreed assessment criteria
- **This will lead to marketing authorisation**

European Commission

EU HTA Regulation

National

- Non-clinical domains
- Decision making on pricing & reimbursements
- **This will lead to access to health technologies**

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EU HTAR aim and implementation timeline

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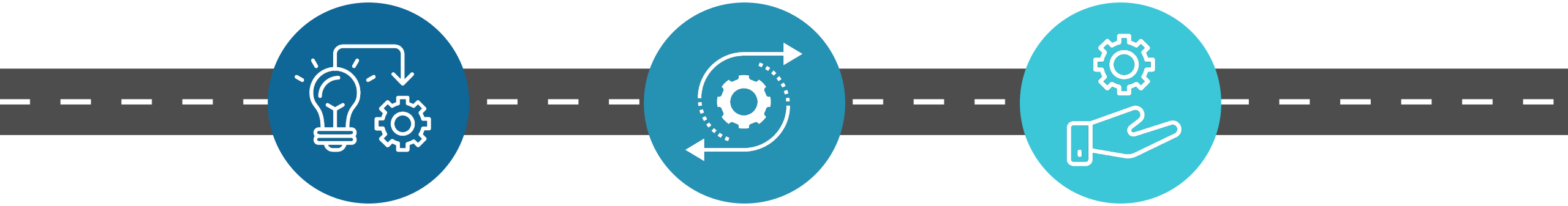
Adoption

December 2021

02

Application

From January 2025



01

Transition period

2022 - 2024

03

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6 Implementing Acts to be adopted by 2025

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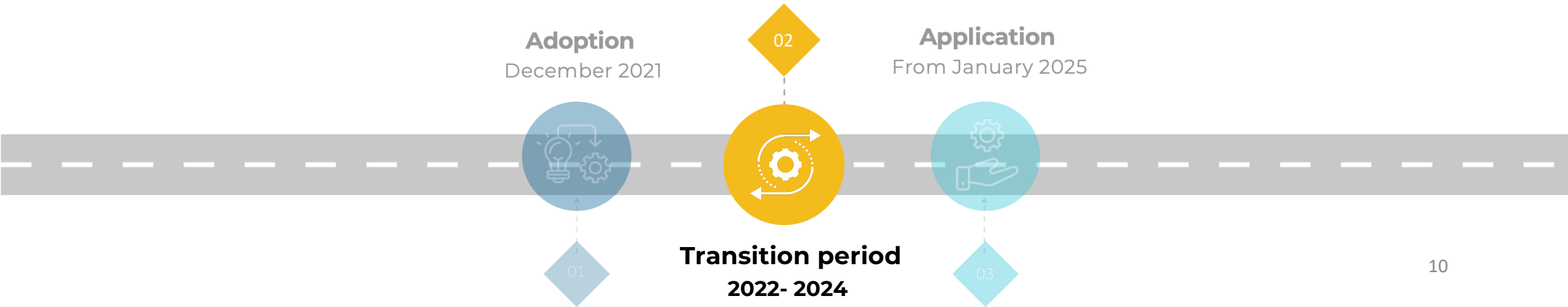
Procedural rules for JCA medicinal products	**Adopted in May**
Procedural rules for the prevention of conflict of interest	**Public consultation until 26 June**
Cooperation by exchange of information with EMA	**Q3 2024**
Procedural rules for JSC medicinal products	**Q3 - Q4 2024**
Procedural rules for JCA medical devices and IVD medical devices	**Q4 2024**
Procedural rules for JSC medical devices and IVD medical devices	**Q4 2024**



2025+ Application

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Medicinal Products

From 2025

New oncology medicines and advanced therapy medicinal products (ATMPs)

From 2028

Orphan medicinal products to be added to the joint work

From 2030

All new medicines will come under the scope of the regulation

Medical Devices

Specific high-risk devices with high impact on patients, public health and EU health systems will be identified by the HTACG to undergo Joint Clinical Assessment.

01 **Adoption**
December 2021

02 **Transition period**
2022 - 2024

03 **Application**
From January 2025

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2025+ Application: National

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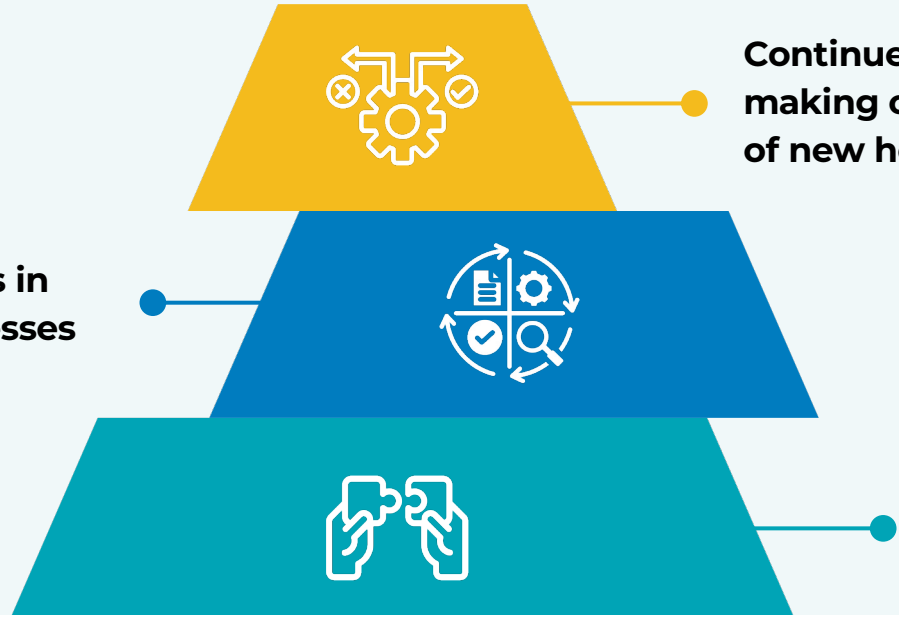

Continue to be responsible for decision-making on pricing and reimbursement of new health technologies.

Joint work results in national HTA processes

Contribution to the joint work processes including stakeholder involvement

Adoption
December 2021

01

Transition period
2022 - 2024

02

Application
From January 2025

03

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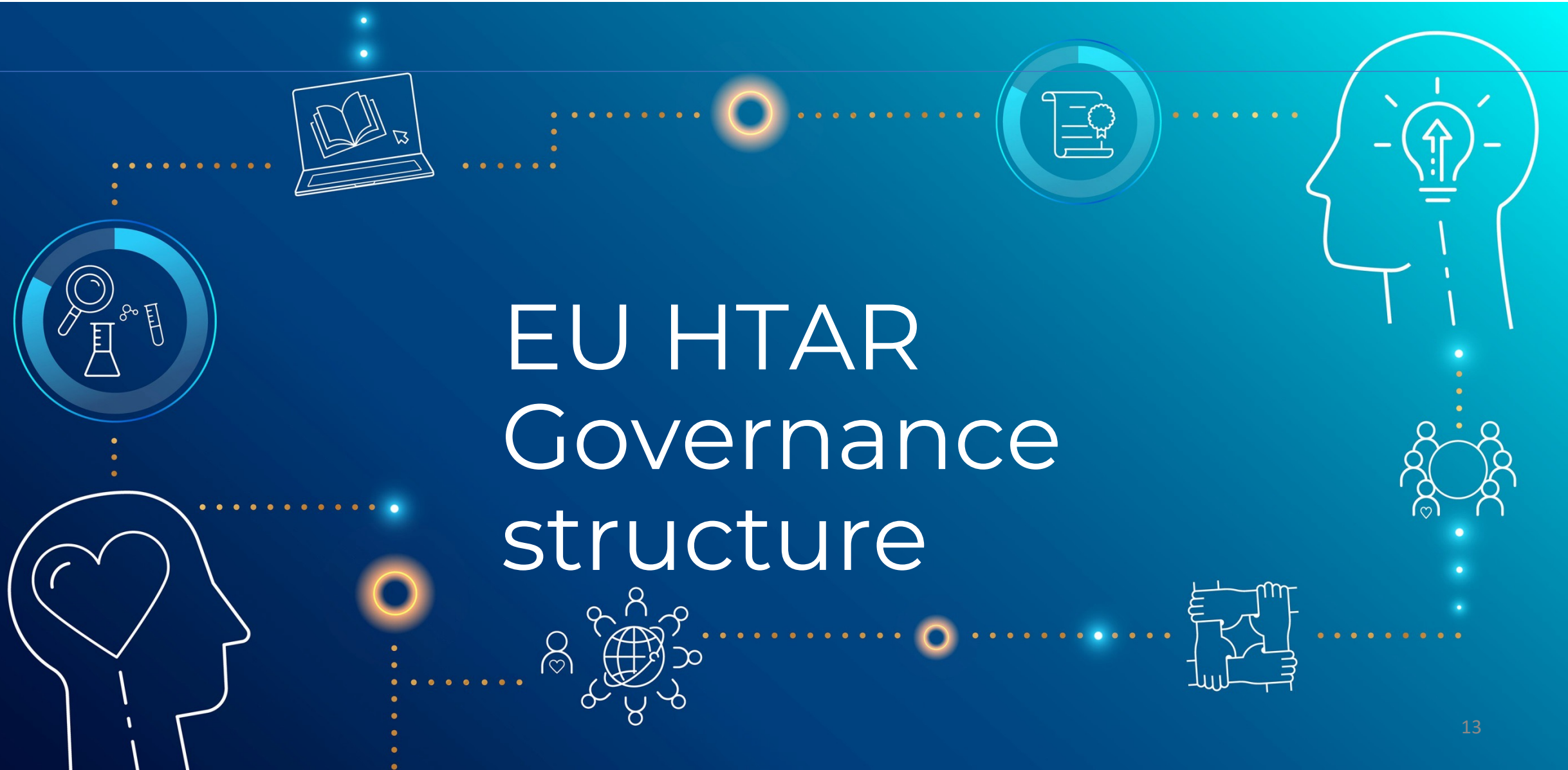

EU HTAR Governance structure

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Governance Structure

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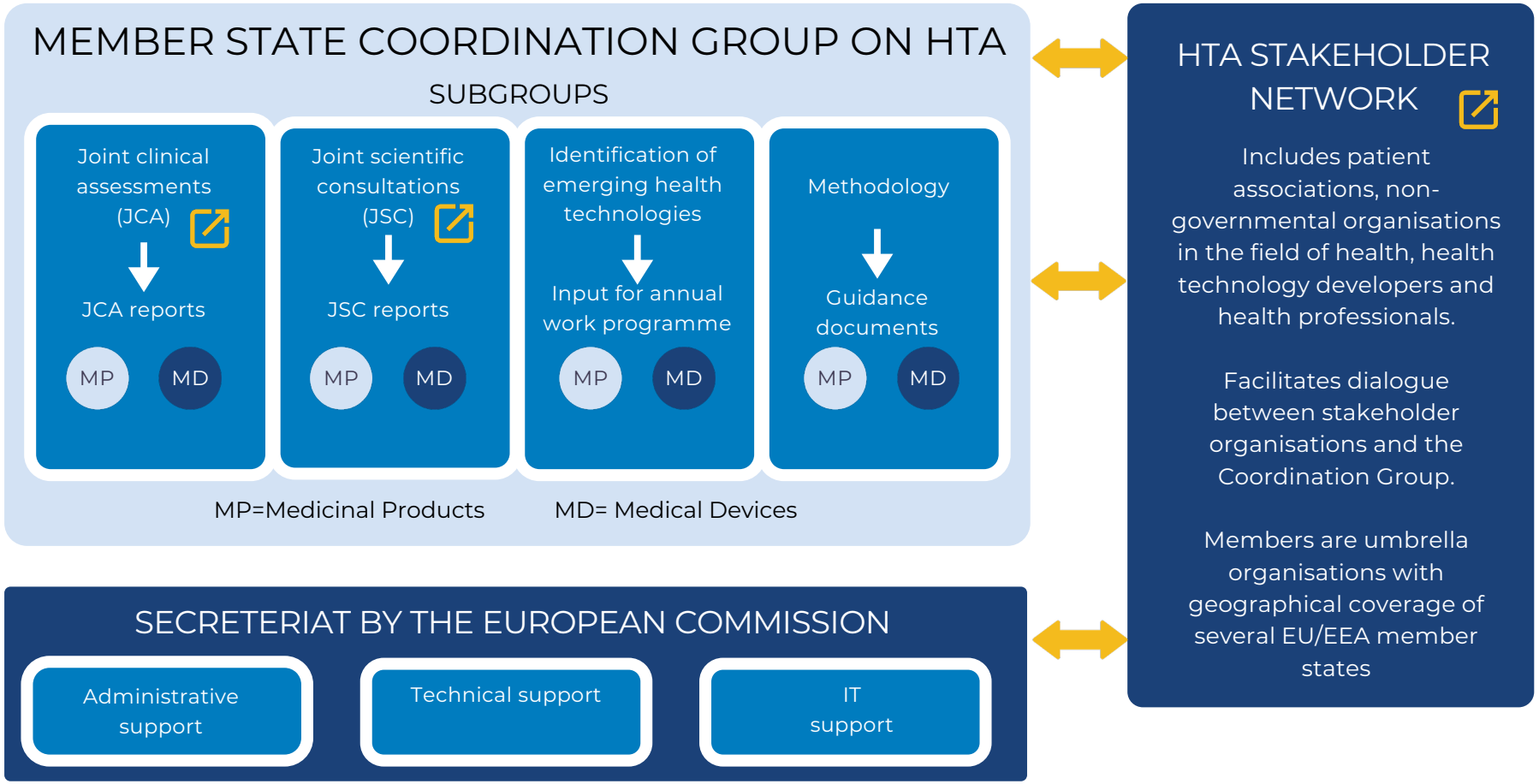

Governance and key elements of the HTAR Source: European Commission, 2023. https://health.ec.europa.eu/document/download/84c1ec8f-9be3-4073-aceb-330764c93152_en?filename=hta_regulation-implementation_factsheet_en.pdf

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HTA Coordination group (HTACG)

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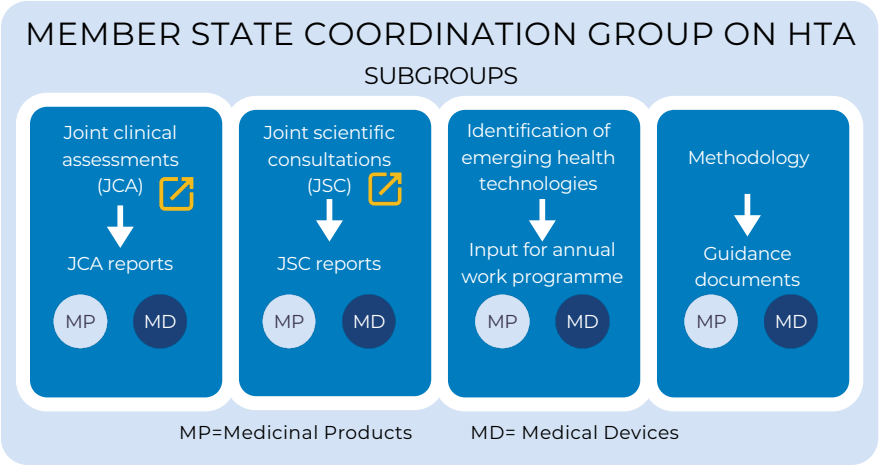

- Members appointed by the EU member states (List at the end)
- The members of the Coordination Group designate their national or regional bodies/authorities to the subgroups and ensure appropriate HTA expertise is available in the subgroups.

Key Tasks of HTACG

Coordination of the subgroups

Identifying emerging health technologies

Creating strategic & methodological guidance documents for subgroups

Specification of procedural steps & timeframes for JCAs, updates of JCAs and JSCs.

Ensuring stakeholder involvement

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HTA Stakeholder Network

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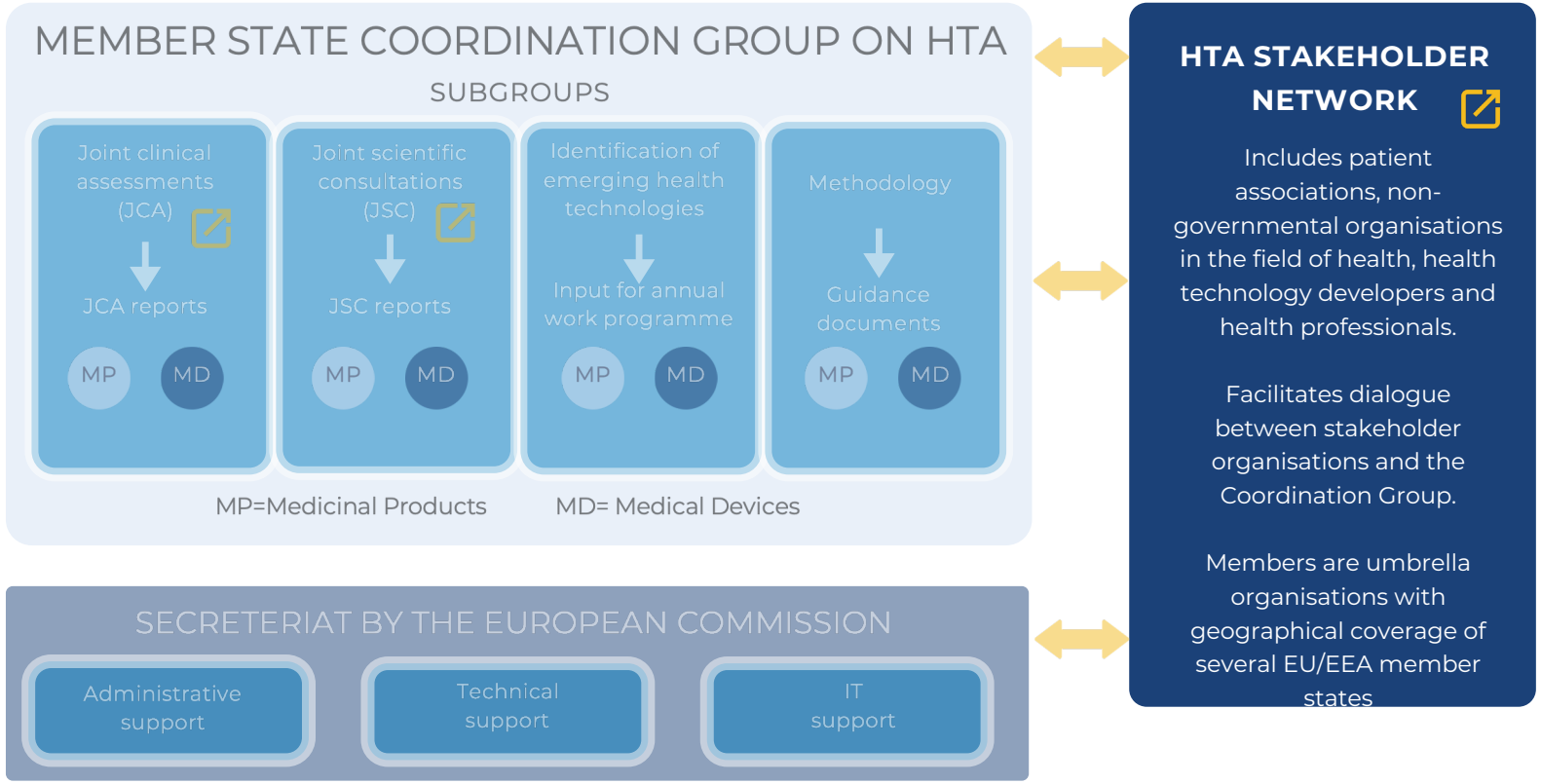

HTA STAKEHOLDER NETWORK

Includes patient associations, non-governmental organisations in the field of health, health technology developers and health professionals.

Facilitates dialogue between stakeholder organisations and the Coordination Group.

Members are umbrella organisations with geographical coverage of several EU/EEA member states

Purpose of the HTA Stakeholder Network

To facilitate dialogue between stakeholder organizations and the Coordination Group and its subgroups as appropriate.

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HTA Stakeholder Network

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HTA STAKEHOLDER NETWORK

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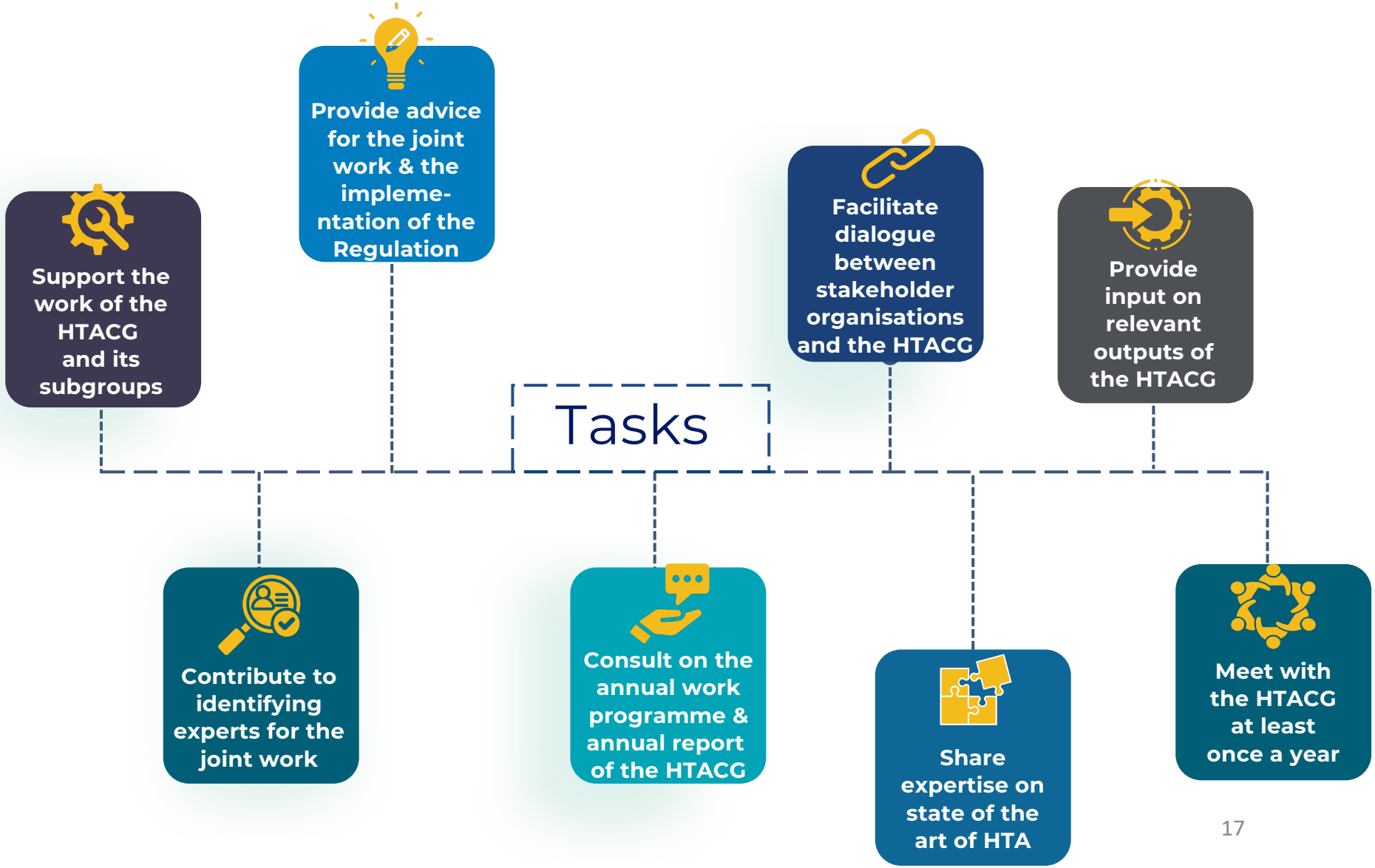

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HTA Stakeholder Network

EUPATI HTA4Patients

HTA STAKEHOLDER NETWORK

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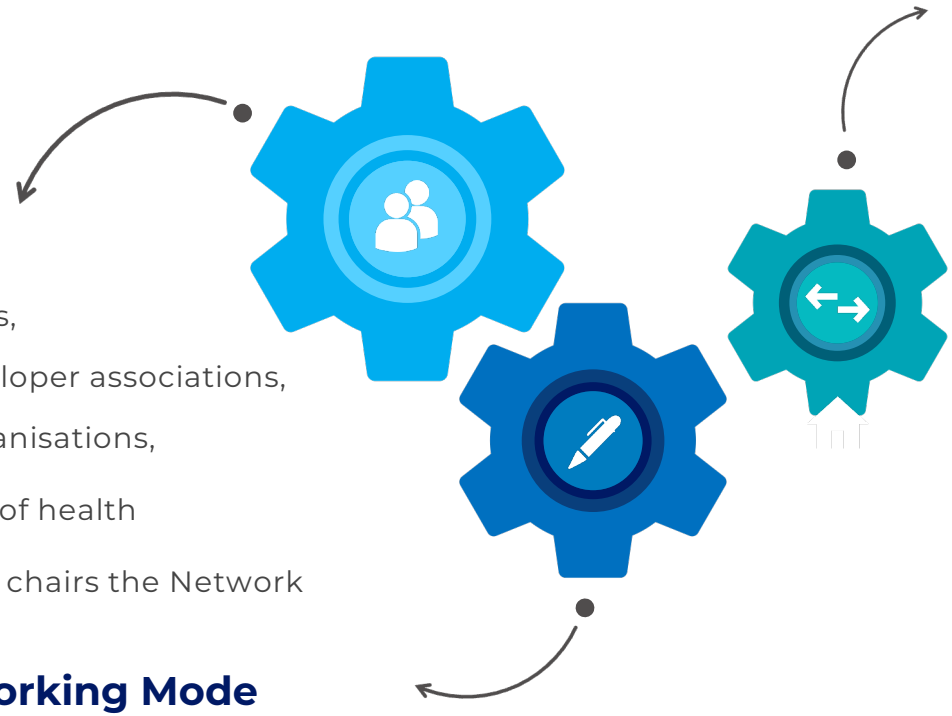
Facilitates dialogue between stakeholder organisations and the Coordination Group.

Members are umbrella organisations with geographical coverage of several EU/EEA member states

Members

- Patient associations,
- Consumer organisations,
- Health technology developer associations,
- Health professional organisations,
- Other NGOs in the field of health

DG SANTE representative chairs the Network



Working Mode

- They meet (at least once a year, with the meeting minutes being publicly available).
- The exchange of information occurs via the IT Platform.

Role

HTA Stakeholder Network:

- Independent function from the JCA and JSC processes.
- Focuses on broader stakeholder engagement and overarching issues.

VS

Stakeholder Involvement:

- The involvement of patients and clinical experts is integrated directly into the **JCA** (providing input on draft reports) and **JSC** (during the preparation of draft joint scientific consultation outcome documents) processes.

See the full list of member organizations here:
https://health.ec.europa.eu/health-technology-assessment/regulation-health-technology-assessment/implementation-regulation-health-technology-assessment/hta-stakeholder-network-declarations_en

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Declaration of Interest

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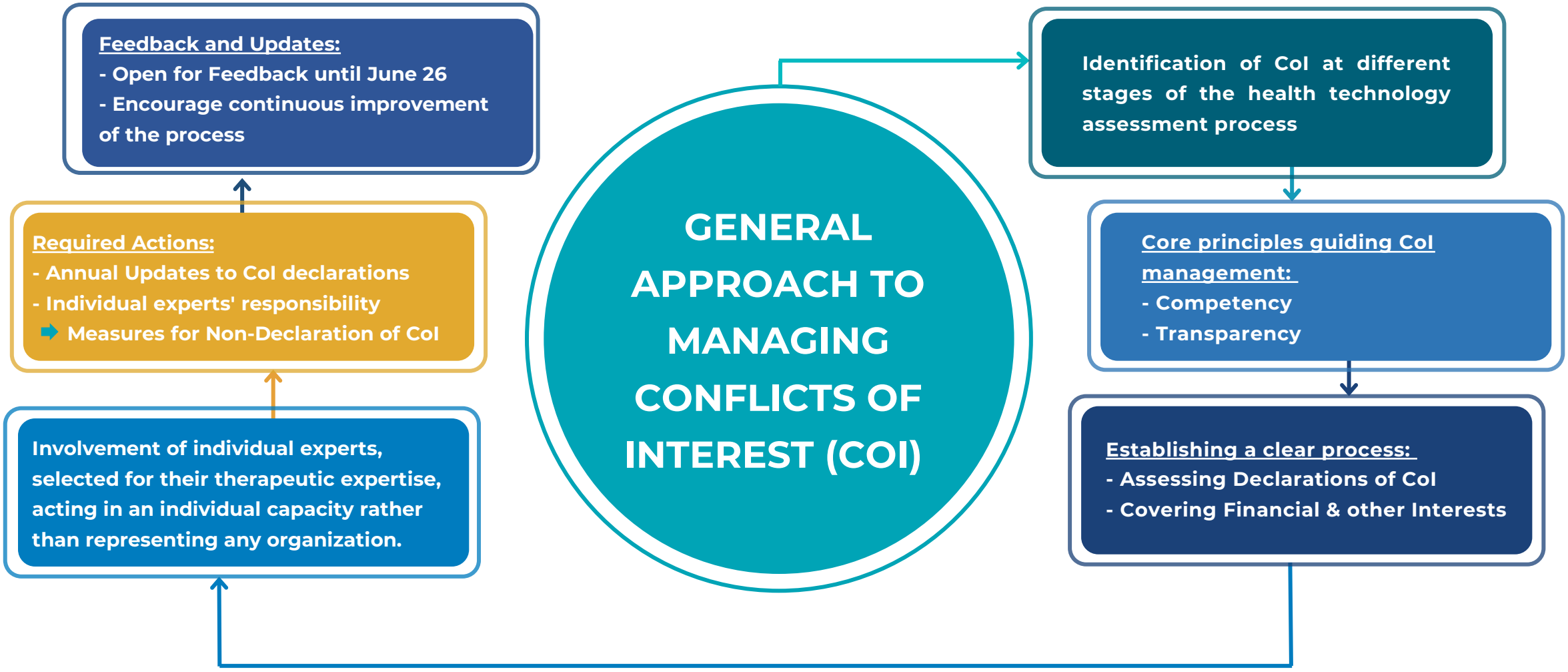

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Conflict of Interest (CoI)

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NATIONAL LEVEL COI MANAGEMENT

General CoI Management:
- Applies to all participants of the joint work

Importance of Consultation:
Involvement of organizations and individual experts

[Link to Draft Implementing Act and DoI Form]

EUROPEAN LEVEL COI MANAGEMENT

Draft Implementing Act:
- Rules for CoI management
- Focus on health technology sector interests

Terminology & Selection
- Definition of individual experts'
- Selection based on therapeutic expertise

HTA Secretariat Responsibilities:
- Manage DoI and CV
- Decide on appearance of DoI

CoI Assessment & Decision:
- Commission assesses CoI
- Determines participation eligibility

Digital Platform & Access:
- Manage CoI process on HTA IT Platform
- Access contingent on CoI assessment

Expert Responsibility:
- Experts responsible for DoI accuracy
- Annual updates required

Public Availability:
- DoI and CV made public (excluding patients)

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Joint Work

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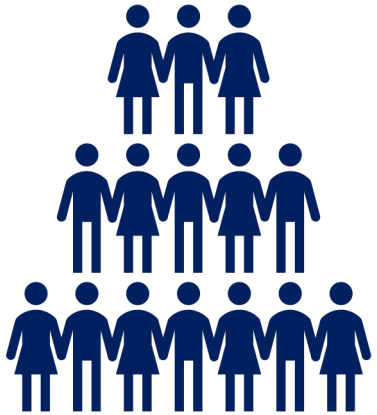
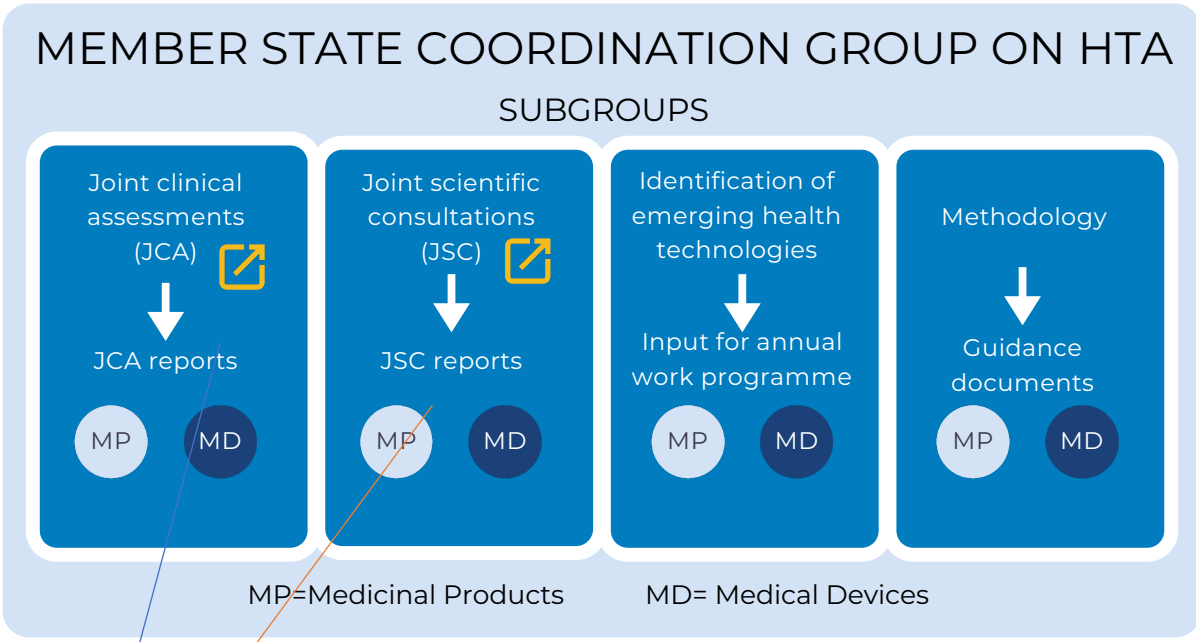
Coordination Group

Subgroup

JSC/ JCA subgroup + external experts





Assessor and co-assessor

For a given health technology, the subgroup appoints an assessor and co-assessor for JSC/JCA.

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HTA4Patients

Horizon Scanning

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What is Horizon Scanning (HS)?

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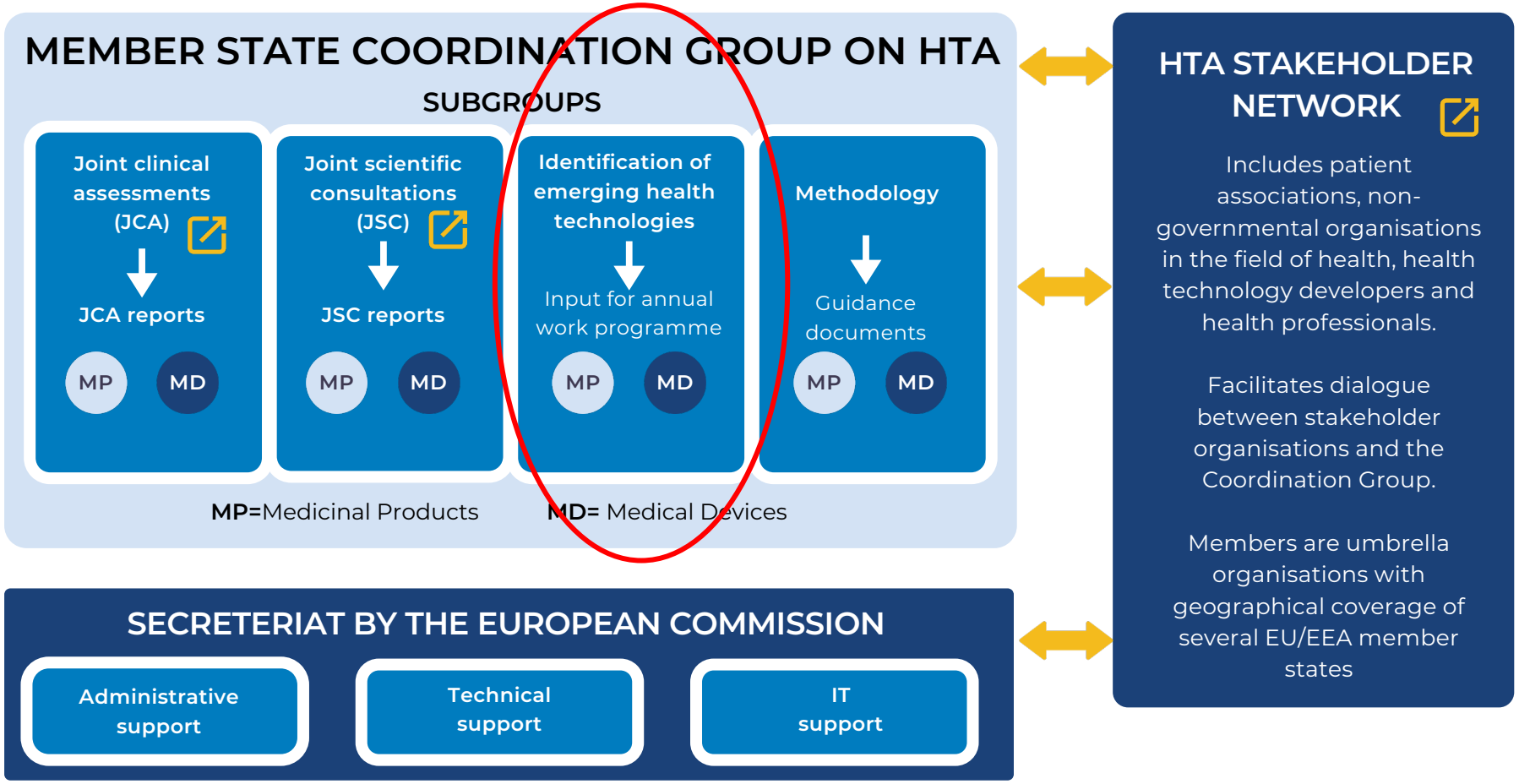

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Benefits of Horizon Scanning

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Identification of new and emerging health technologies, treatments and interventions.

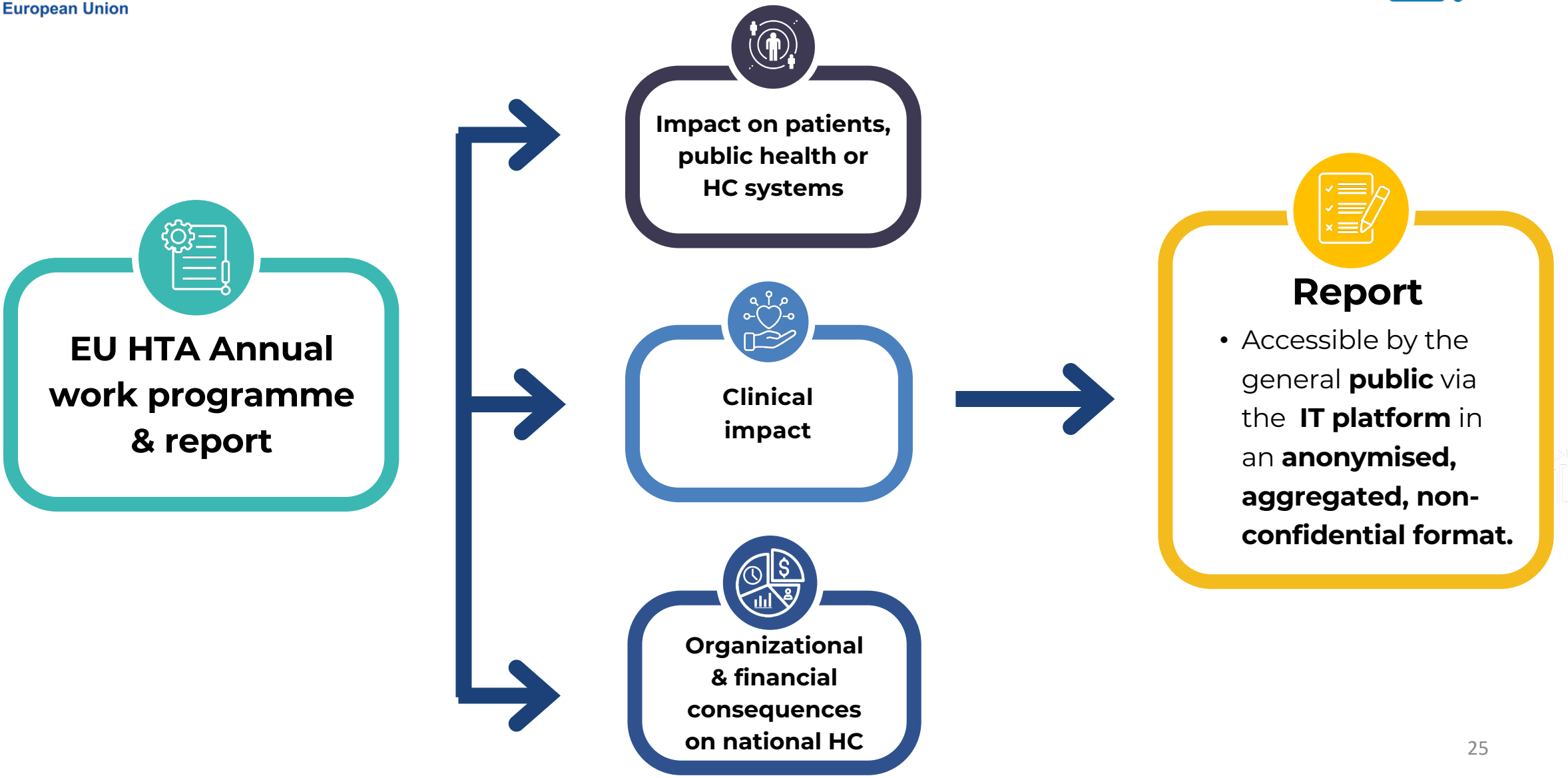
Assessing the potential clinical and economic impact of these technologies.

Anticipating the challenges and opportunities in implementing these technologies.

Supporting evidence-based decision-making in healthcare policy and resource allocation.

Identifying the unmet needs of patients.

HTAR Horizon Scanning process



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Joint Scientific Consultation

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Joint Scientific Consultation

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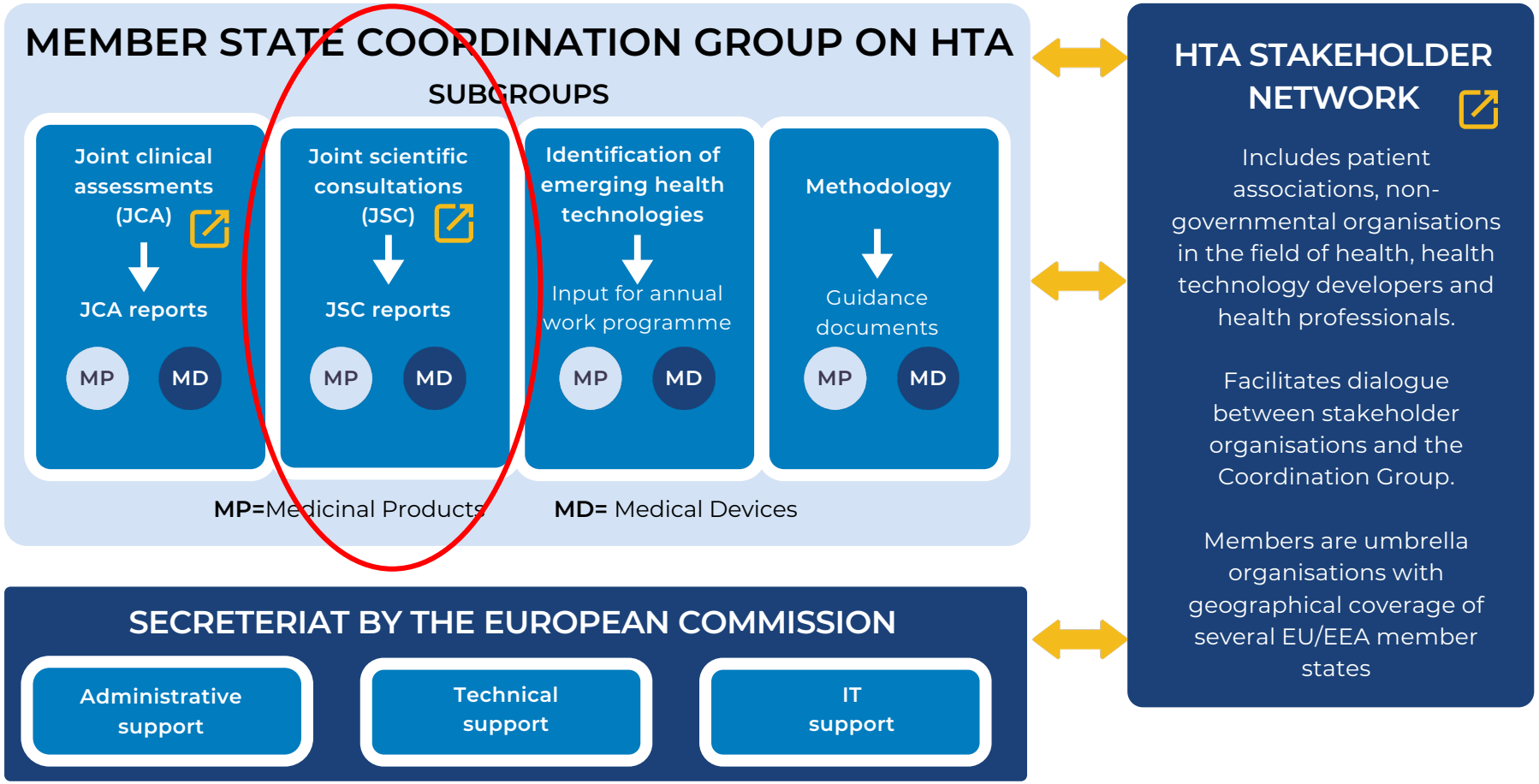

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What is a Joint Scientific Consultation (JSC)?

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The aim of a JSC is to ensure that health technology developers understand what evidence will be required in future health technology assessment.

JSC is performed by a subgroup under the Coordination Group.

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Joint Scientific Consultation (JSC)

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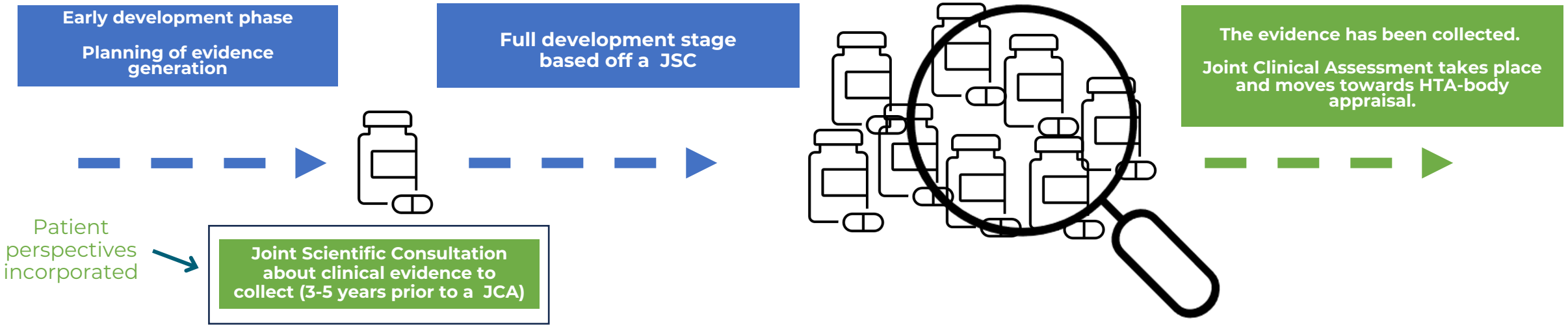
A JSC takes place and the health technology developer receive non-binding advice and guidance from JSC subgroup (representatives of the HTACG) on necessary evidence to generate for a Joint Clinical Assessment.



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JSC Process – How does it work?

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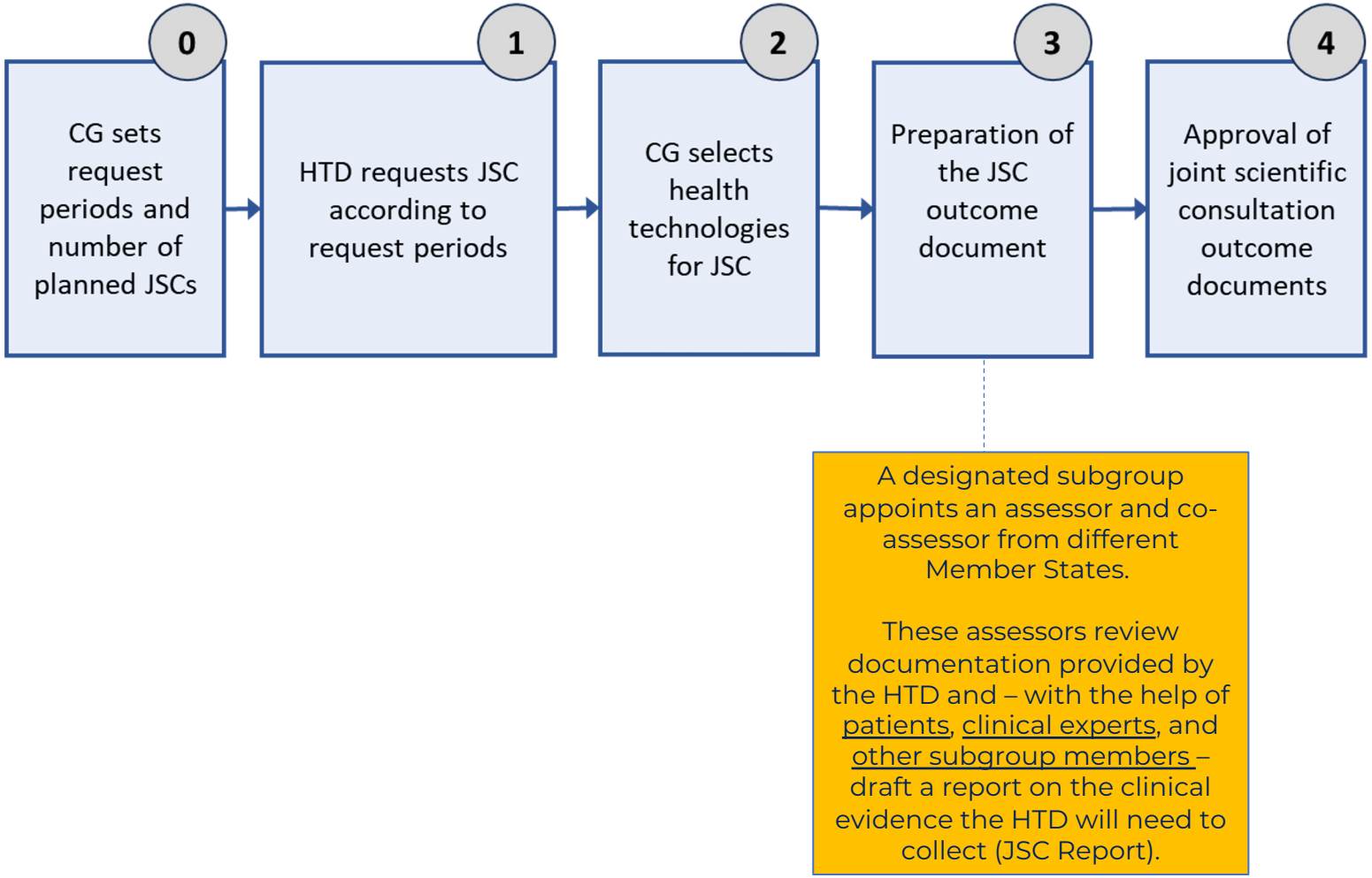

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How can patient perspectives be incorporated in a JSC?

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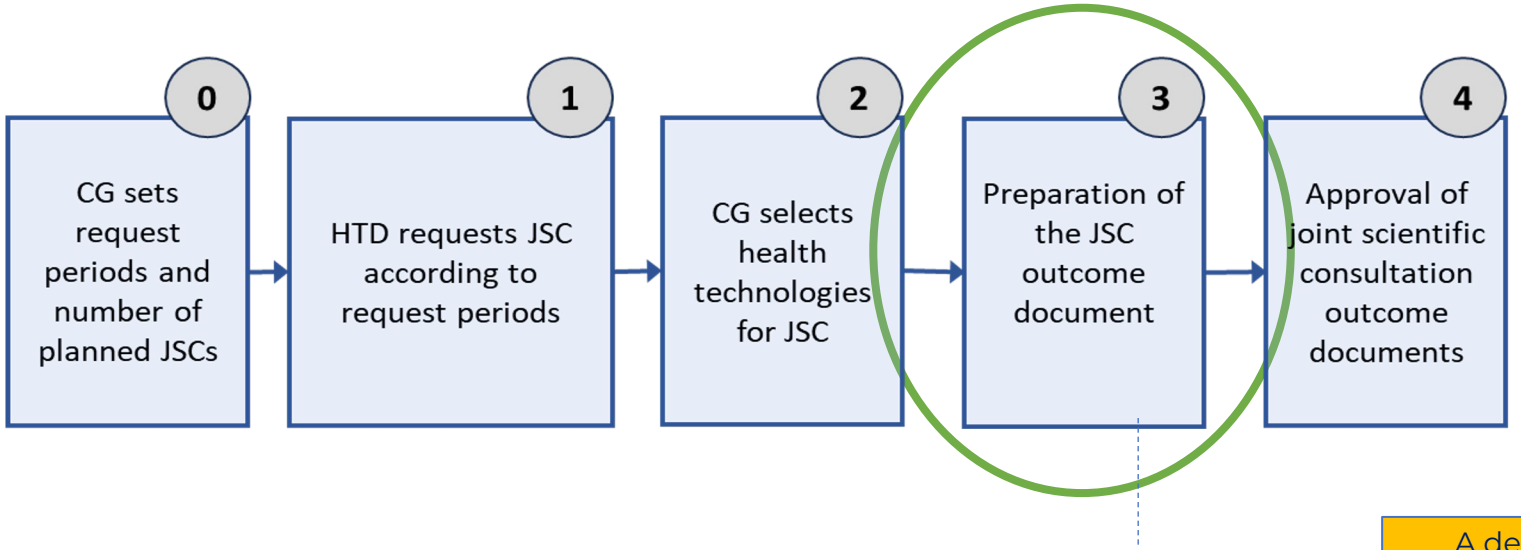

Step **3** is where patient perspectives come in.

Patients will be invited by the subgroup to provide input during the preparation of the draft JSC report.

A meeting (face-to-face or virtual) will take place between the HTD, subgroup members, **patients**, and clinical experts to discuss the health technology in question.

A designated subgroup appoints an assessor and co-assessor from different Member States.

These assessors review documentation provided by the HTD and – with the help of patients, clinical experts, and other subgroup members – draft a report on the clinical evidence the HTD will need to collect (JSC Report).

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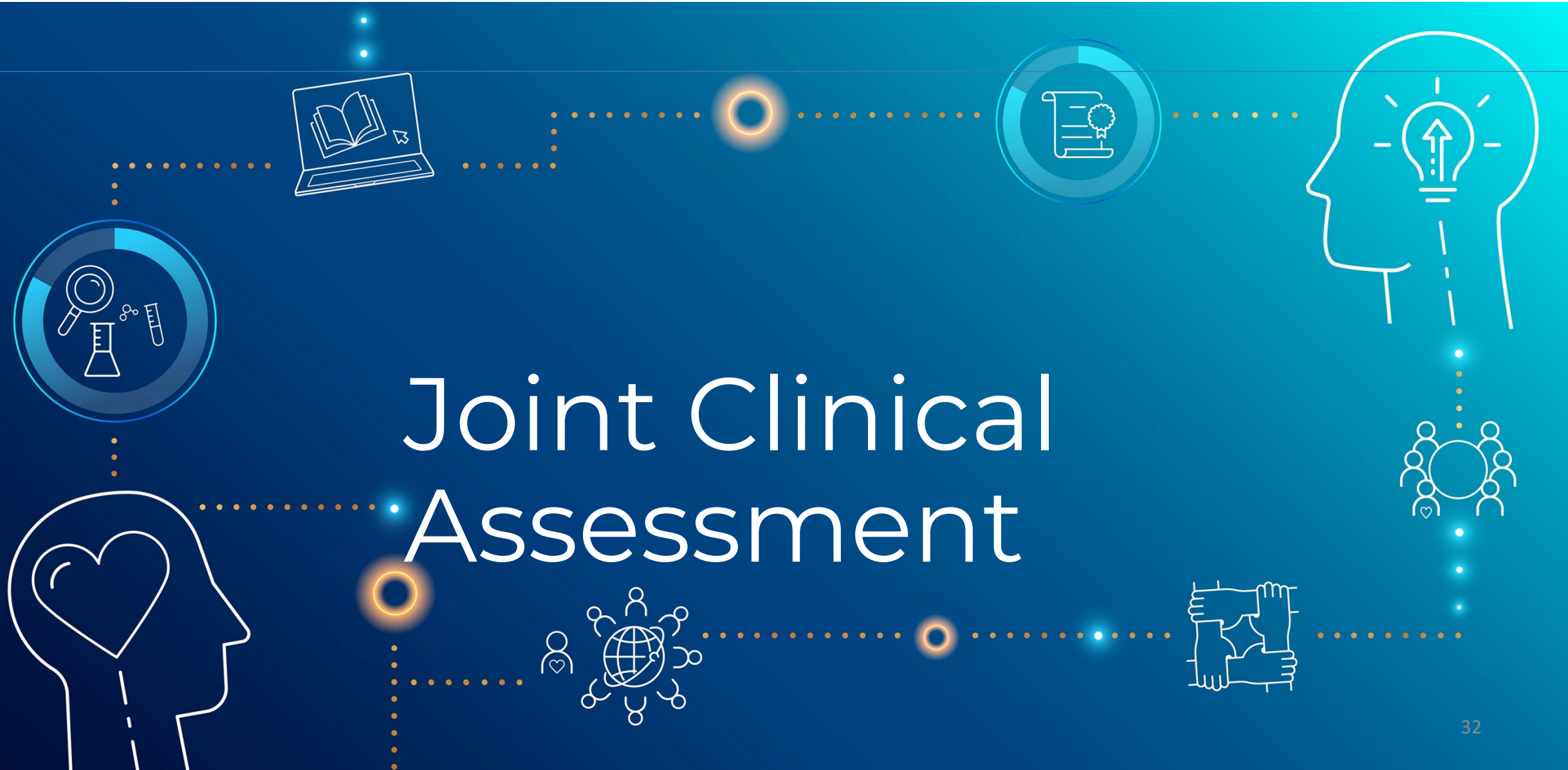

Joint Clinical Assessment

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Joint Clinical Assessment

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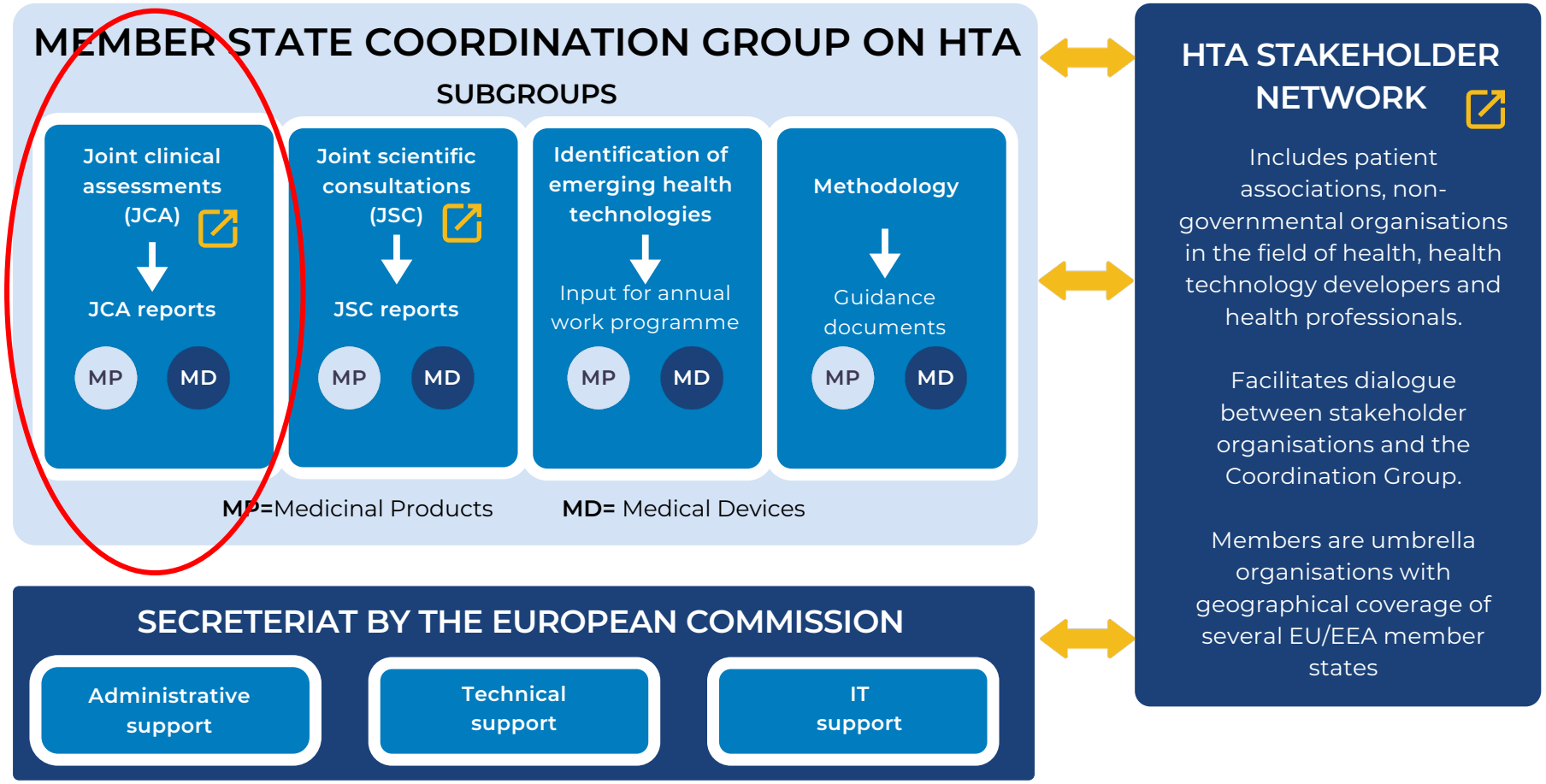

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What is EU Joint Clinical Assessment

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Clinical Domains

Health problems and currently used technologies (who is the medicine for and what is the current treatment, e.g. medicines, medical devices, surgical procedures).

Description of health technology under assessment (molecule, pharmacodynamics, pharmacokinetics – what does the medicine do to the body).

Relative clinical effectiveness (how well does the medicine work & how is it measured. It may also include any Patient Reported Outcome (PROs) and Patient Preference Measures (Pref).

Relative safety (toxicology, side effects, risks)

- A standardised assessment of the **clinical aspects** of a health technology
- **Medicinal products** and medical devices are in scope
- Evaluates the **relative clinical effectiveness**
- **Compare** to standard treatments across member states to establish **relative effectiveness**

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Joint Clinical vs. National Assessment

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Joint Clinical Assessment
by JCA subgroup

National Assessment
by national HTA body and/or payers

Clinical Domains

Health problems and currently used technologies (who is the medicine for and what is the current treatment, e.g. medicines, medical devices, surgical procedures).

Description of health technology under assessment (molecule, pharmacodynamics, pharmacokinetics – what does the medicine do to the body).

Relative clinical effectiveness (how well does the medicine work & how is it measured. It may also include any Patient Reported Outcome (PROs) and Patient Preference Measures (Pref).

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Legal aspects (It refers to national regulation – what healthcare staff is allowed to do and involves ethical considerations, e.g., genomic editing.

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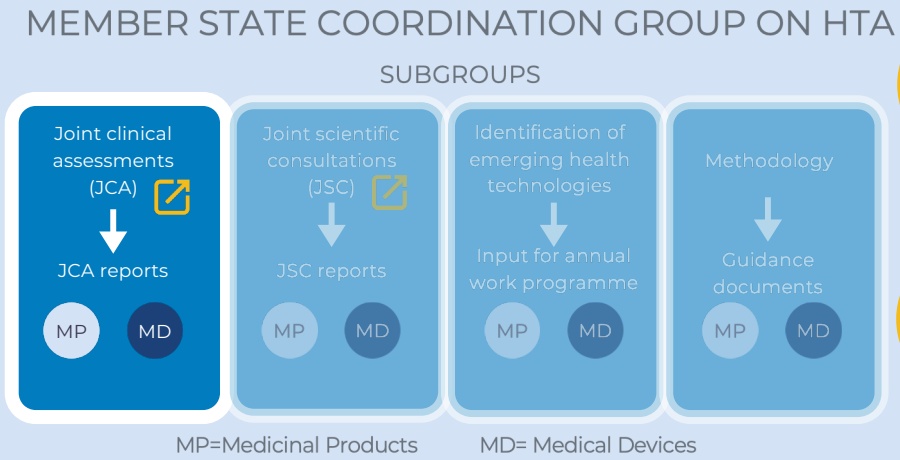
JCA Sub-group tasks



- To assist the HTACG in conducting & updating joint clinical assessments, by overseeing the conduct of the JCAs on its behalf.
- To assist the HTACG in the preparation of guidance on the appointment of assessors and co-assessors for joint clinical assessments.
- **To ensure scientific consistency & performance coherence through collaboration with the subgroups for methodological guidance, for JSCs, and for emerging health technologies.**
- To facilitate cooperation with relevant Union bodies under Regulations (EC) No 726/2004, (EU) 2017/745, and (EU) 2017/746 on JCAs and legislation implementation HTA matters.
- To promote knowledge-sharing and best practices in the field of joint clinical assessments.

Source: JCA Subgroup - Terms of Reference

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JCA scoping - defining what to assess

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Clinical Domains

- Health problems and currently used technologies (who is the medicine for and what is the current treatment, e.g. medicines, medical devices, surgical procedures).
- Description of health technology under assessment (molecule, pharmacodynamics, pharmacokinetics – what does the medicine do to the body).
- Relative clinical effectiveness (how well does the medicine work & how is it measured. It may also include any Patient Reported Outcome (PROs) and Patient Preference Measures (Pref).
- Relative safety (toxicology, side effects, risks)

PICO

- Patient population
- Intervention
- Comparator(s)*
- Outcome(s)

*HTA Stakeholder Network meeting summary. 17 November 2023

For more info on PICOS: https://learning.eupati.eu/mod/page/view.php?id=1145

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JCA Process

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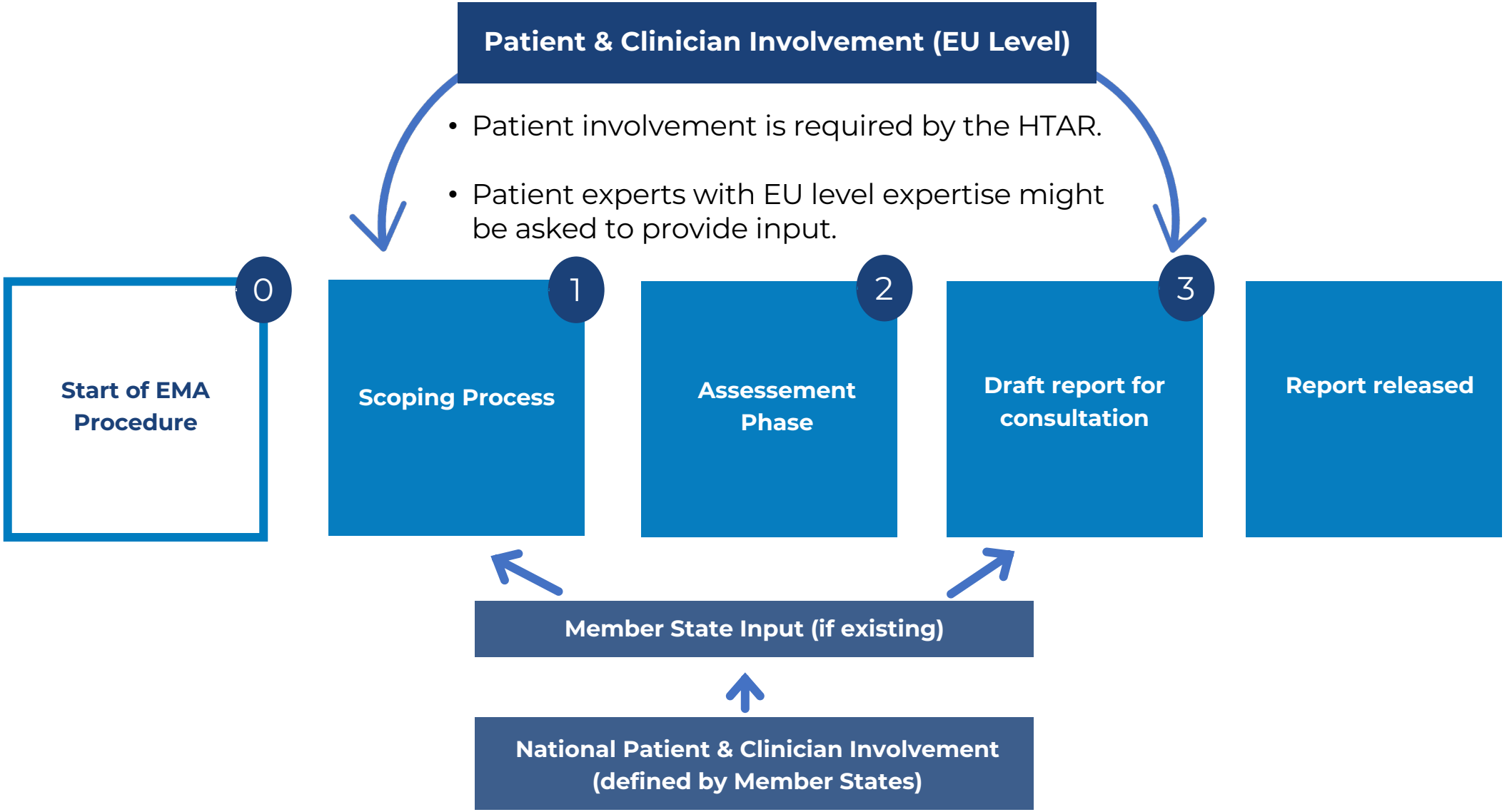

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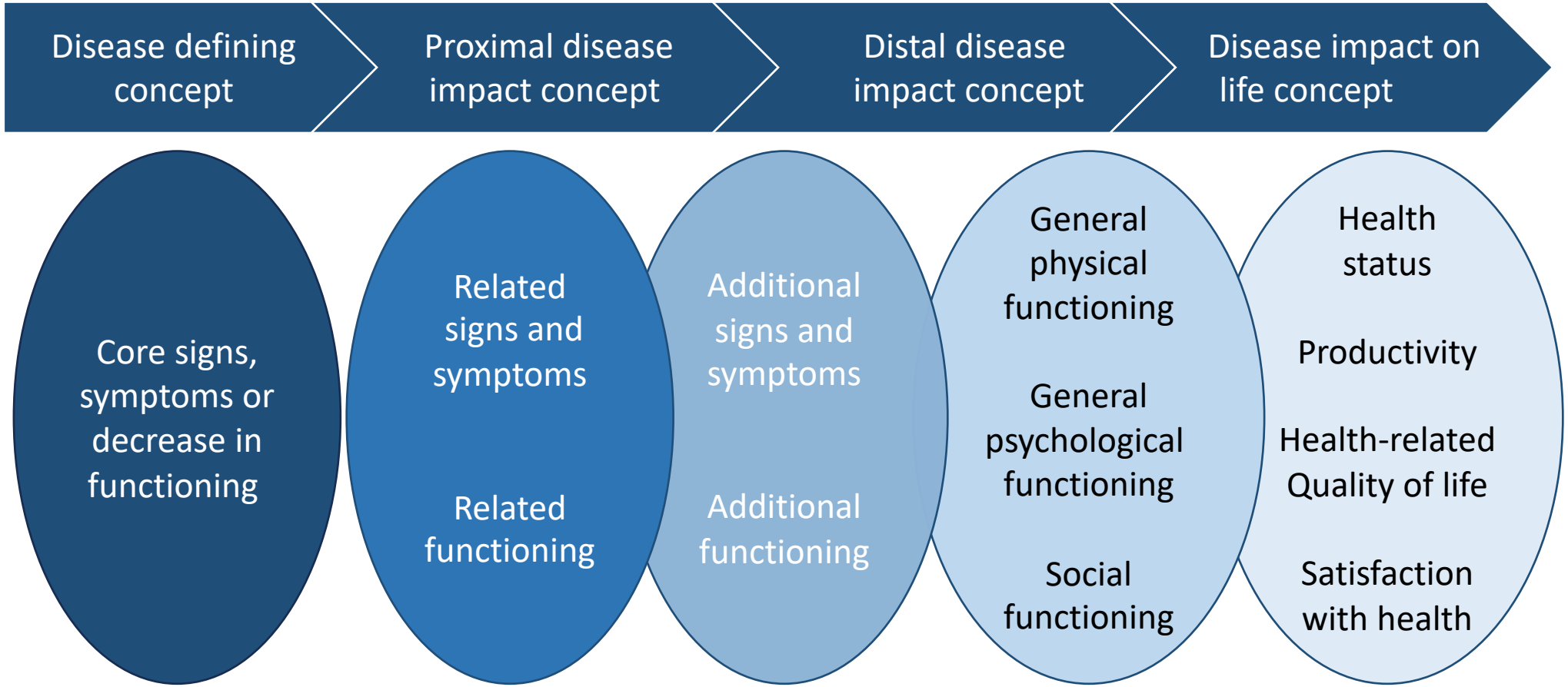
JCA – Measurement categories



Classic clinical domains: Survival, side effects

Patient Reported Outcomes (EUPATI COURSE)

Quality of life factors
Patient-reported outcomes (e.g., burden)

JCA report

A draft report produced by the subgroup

At the EU level:

The assessor and co-assessor will then invite patients and experts to provide their feedback.

National level:

Member state HTA bodies are responsible for collecting comments from patients and other experts via their appropriate means.

The JCA report is available to the public on the IT platform

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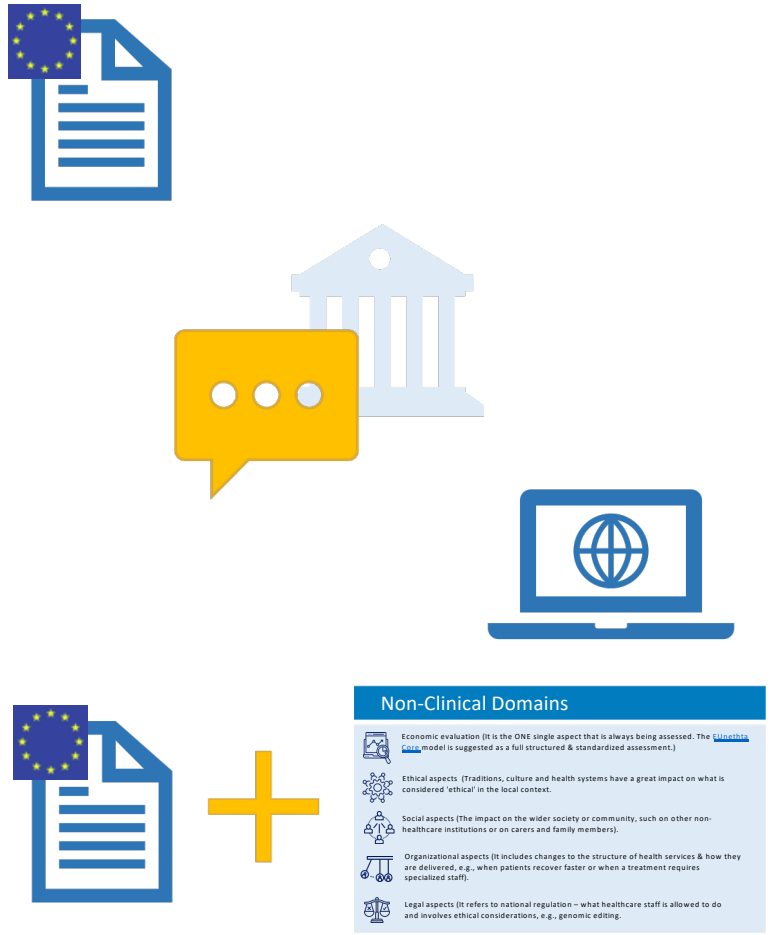

*Day 80 Assessment Report - Clinical template with Guidance - Rev.04.24 Revamp. Assessment templates and guidance | European Medicines Agency (europa.eu)

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Use of the JCA report

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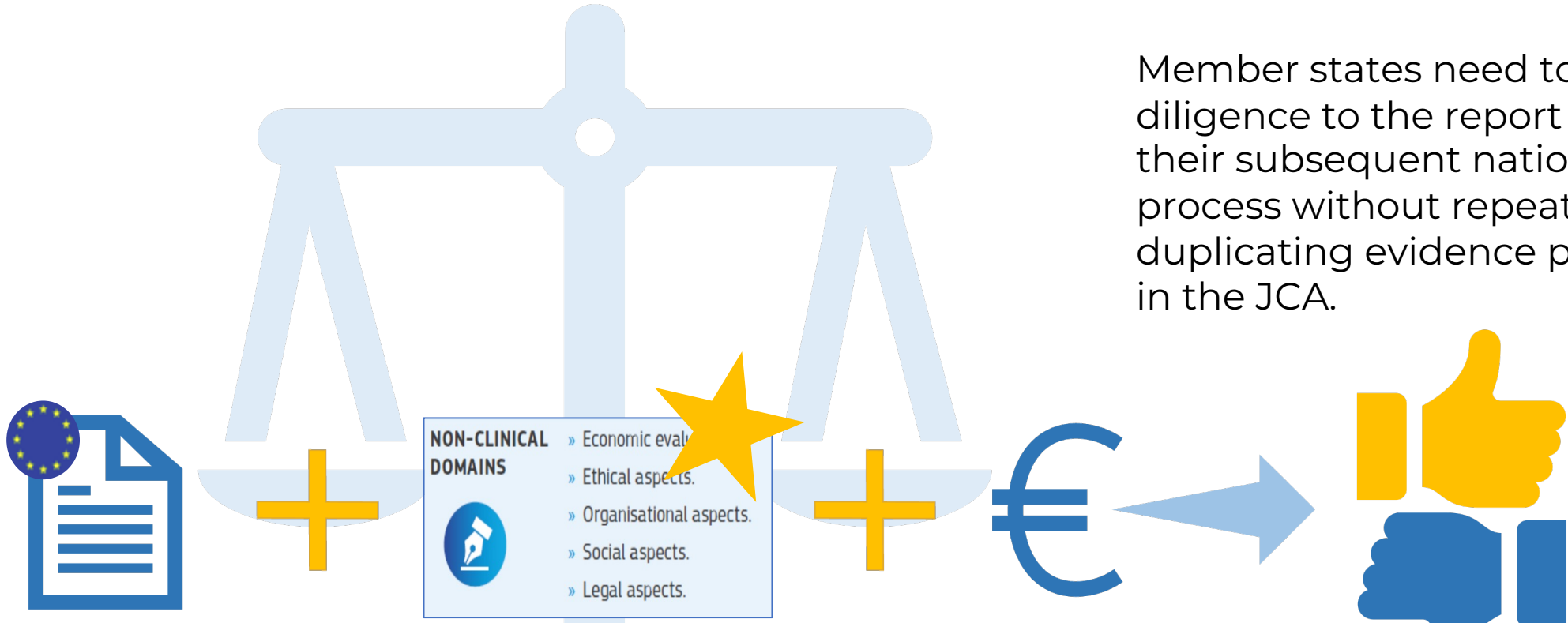
Member states need to give due diligence to the report within their subsequent national process without repeating/ duplicating evidence produced in the JCA.



EU assessment of clinical aspects (JCA Report)

National assessment of ethical, social aspects

National assessment of cost-utility

Medication granted/not granted national approval

JCA in the context of Marketing Authorisation

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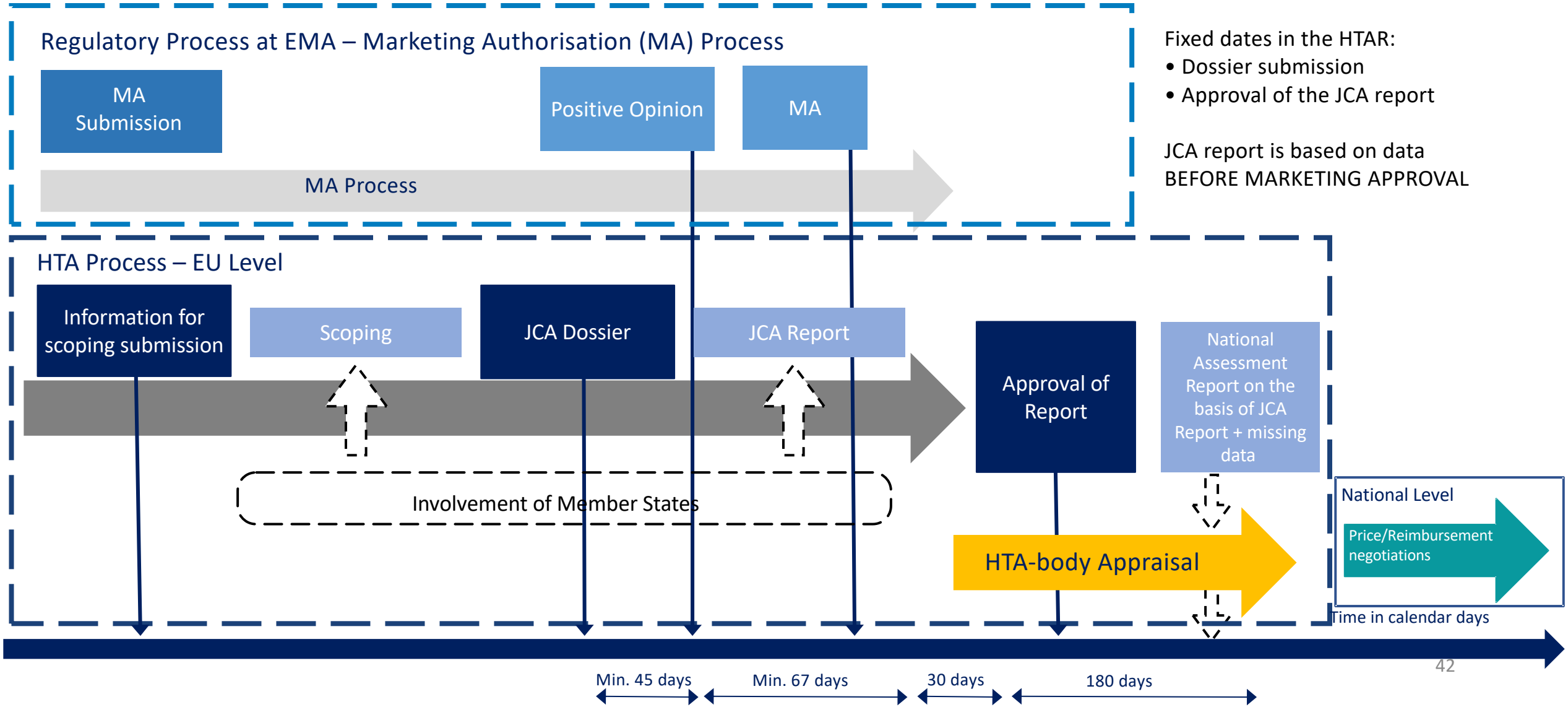

Fixed dates in the HTAR:
- Dossier submission
- Approval of the JCA report

JCA report is based on data BEFORE MARKETING APPROVAL

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HTA4Patients

Methodologies

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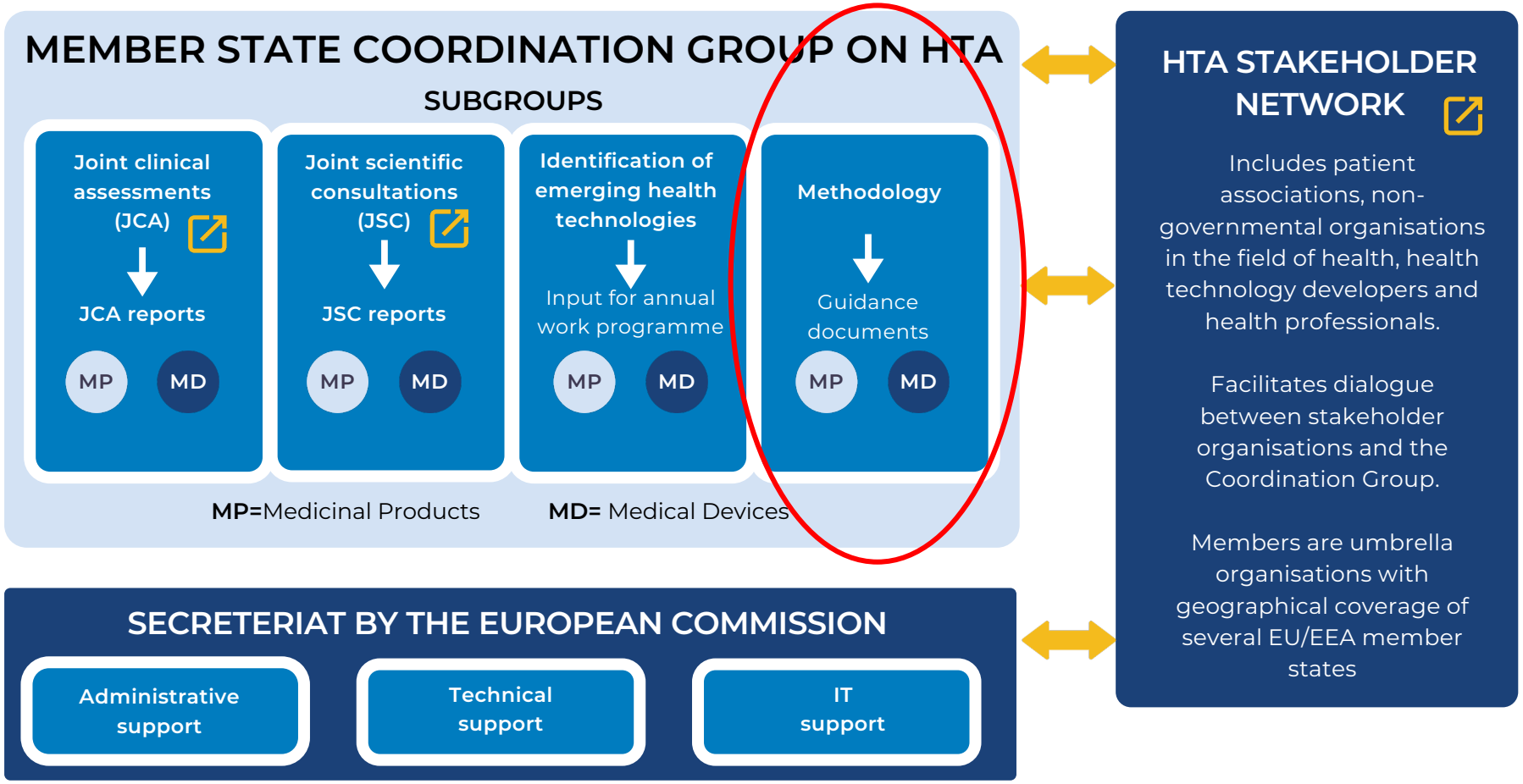
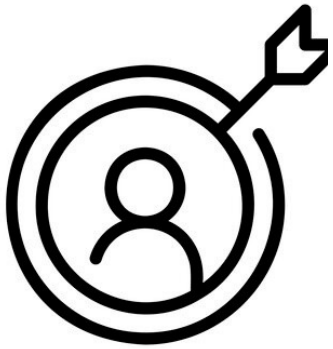
Methodologies



IT platform

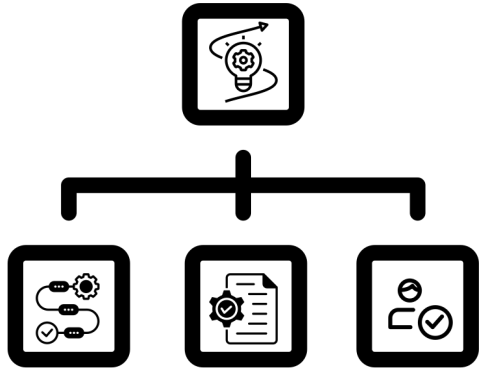
Publicly accessible

Website under development



Secure system for the exchange of information between:

- **The Coordination Group and its subgroups**
- **Members of the stakeholder network**
- **Health technology developers and experts (joint work)**
- **The European Medicines Agency**



Several relevant features and documentation on:

- **Member lists and qualifications**
- **Rules of procedure and meeting summaries**
- **Clinical assessment documentation and reports**
- **Horizon Scanning reports**
- **Stakeholder eligibility and network details**

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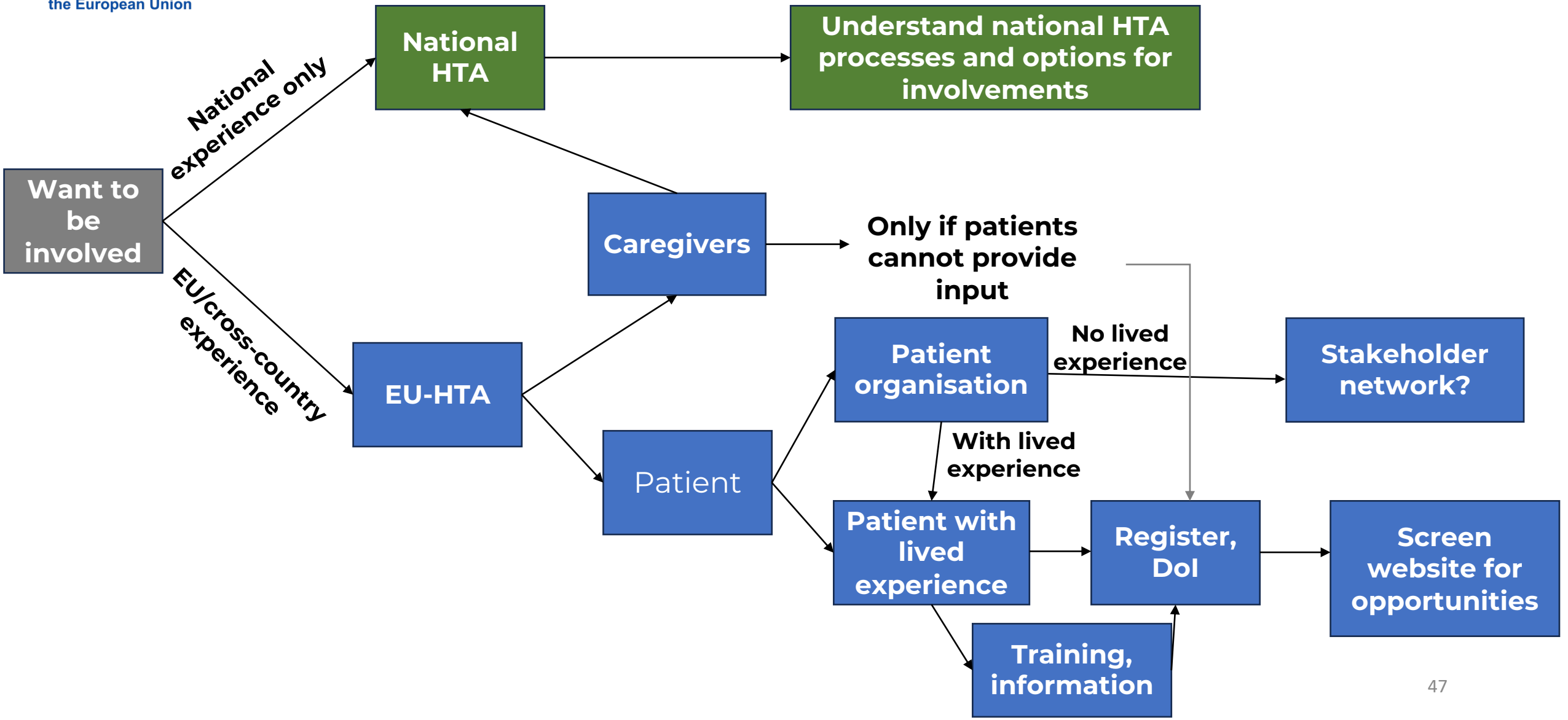
How to get involved

How to become involved?



I am an individual patient- how can I get involved

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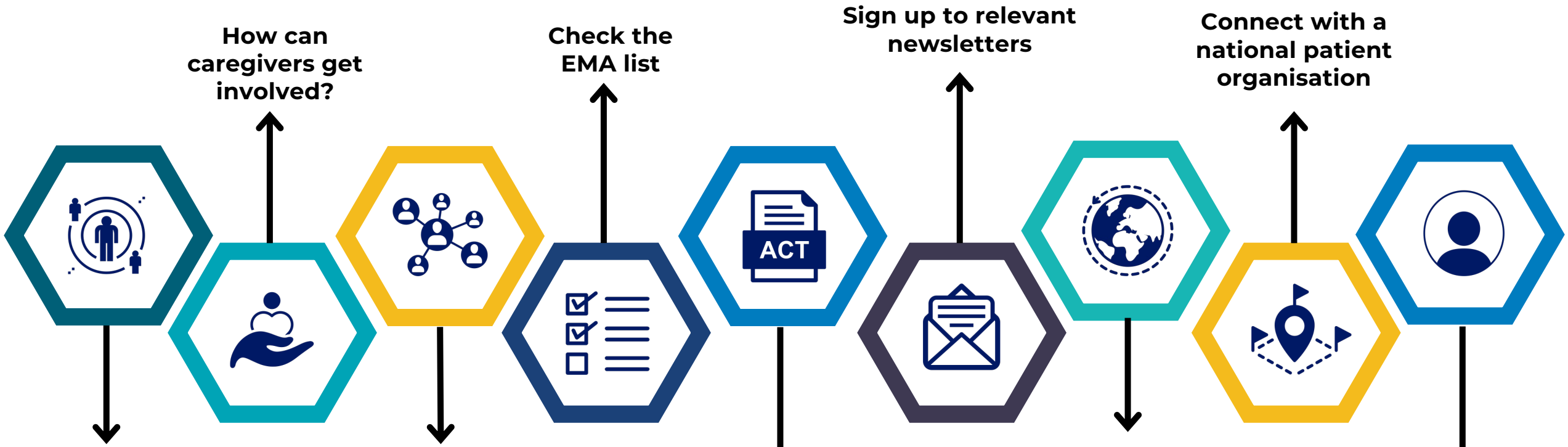

I am an individual patient- how can I learn more

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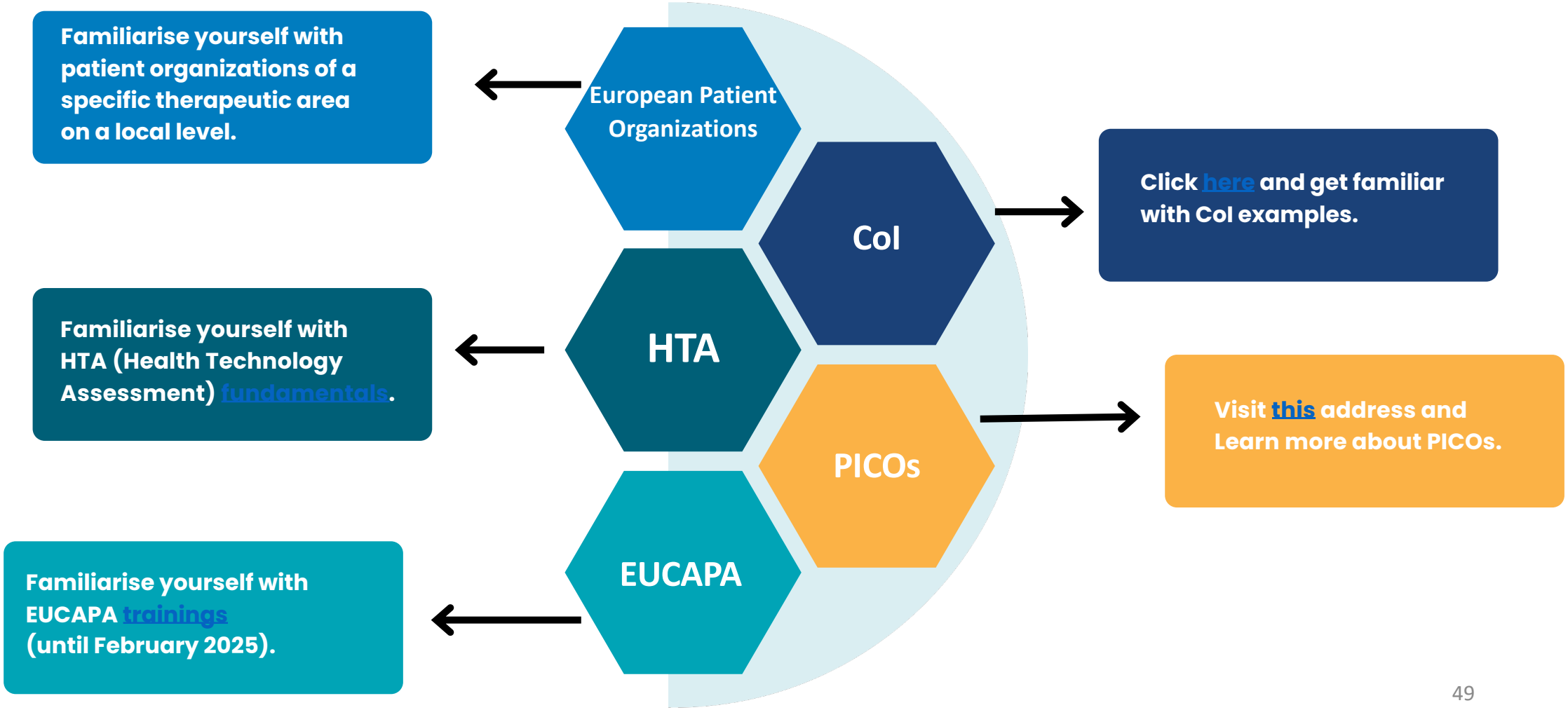

I am a patient organization- how can I get involved

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Check who is in the Stakeholder Network

Connect with EUPATI national platforms

Check the EMA list

Participate in public consultation on IAs

Sign up to relevant newsletters

Organise trainings for patient experts

Familiarise yourself with HTA fundamentals

Learn more about PICOs

Connect with a Stakeholder Network member

Connect with a European organisation

Get familiar with CoI examples

Familiarise yourself with EUCAPA trainings

DICE Pilot Feedback form