



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

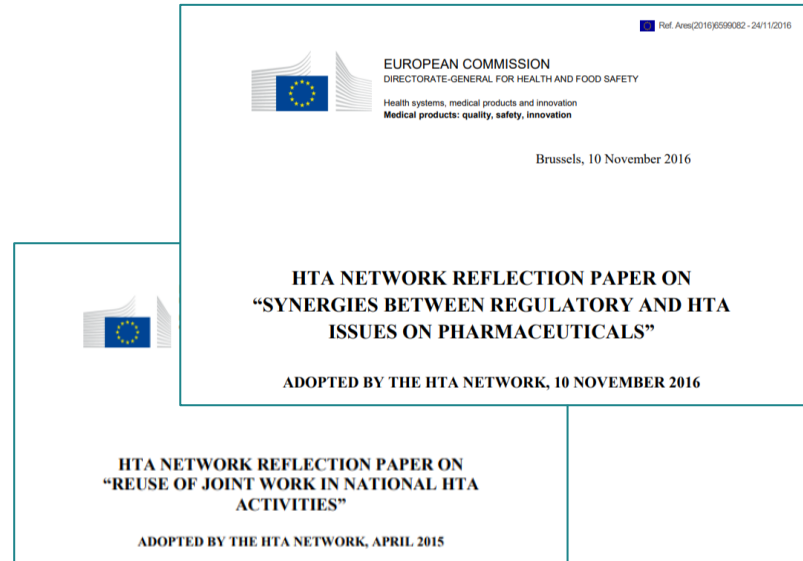
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EMA PCWP/HCPWP annual meeting

15 November 2022

Strengthening EU HTA cooperation



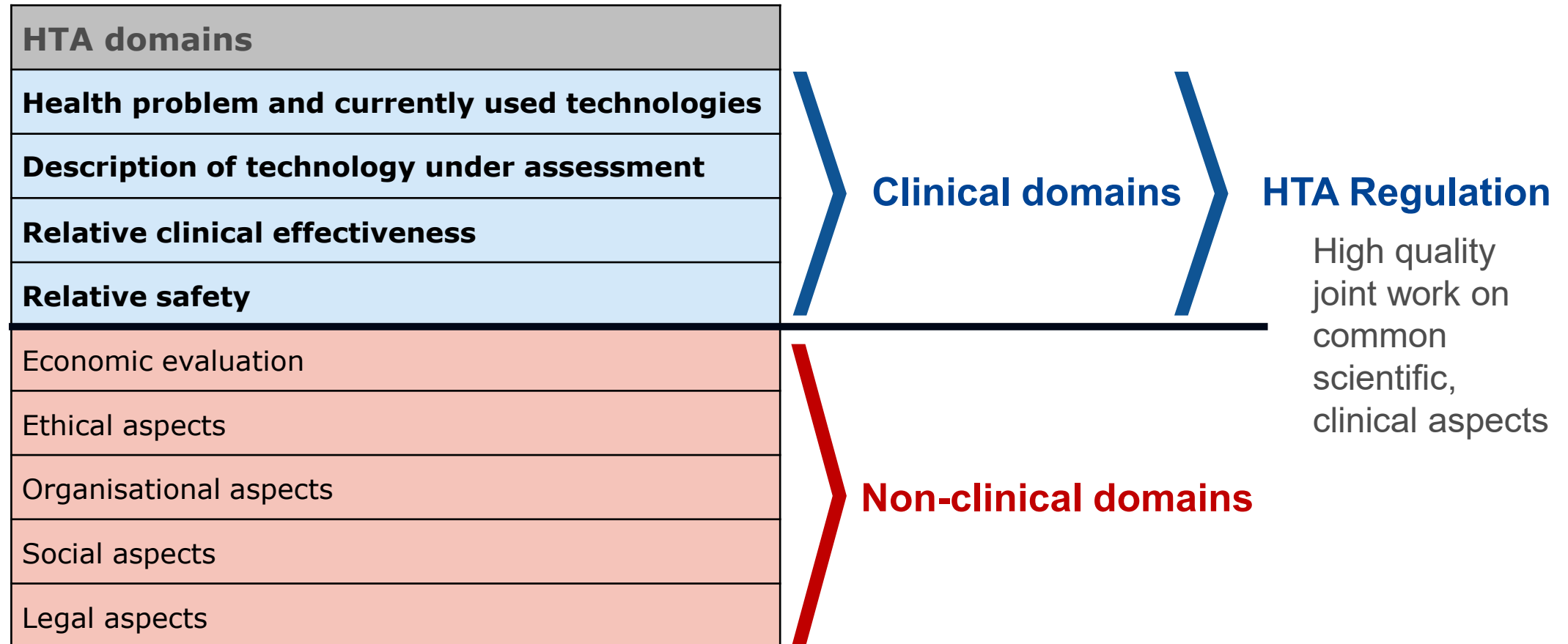
JA1 (2010 – 2012)
JA2 (2012 – 2015)
JA3 (2016 – 2021)

Cooperation EUnetHTA-EMA
(2 work plans 2012-2015; 2017-2021)

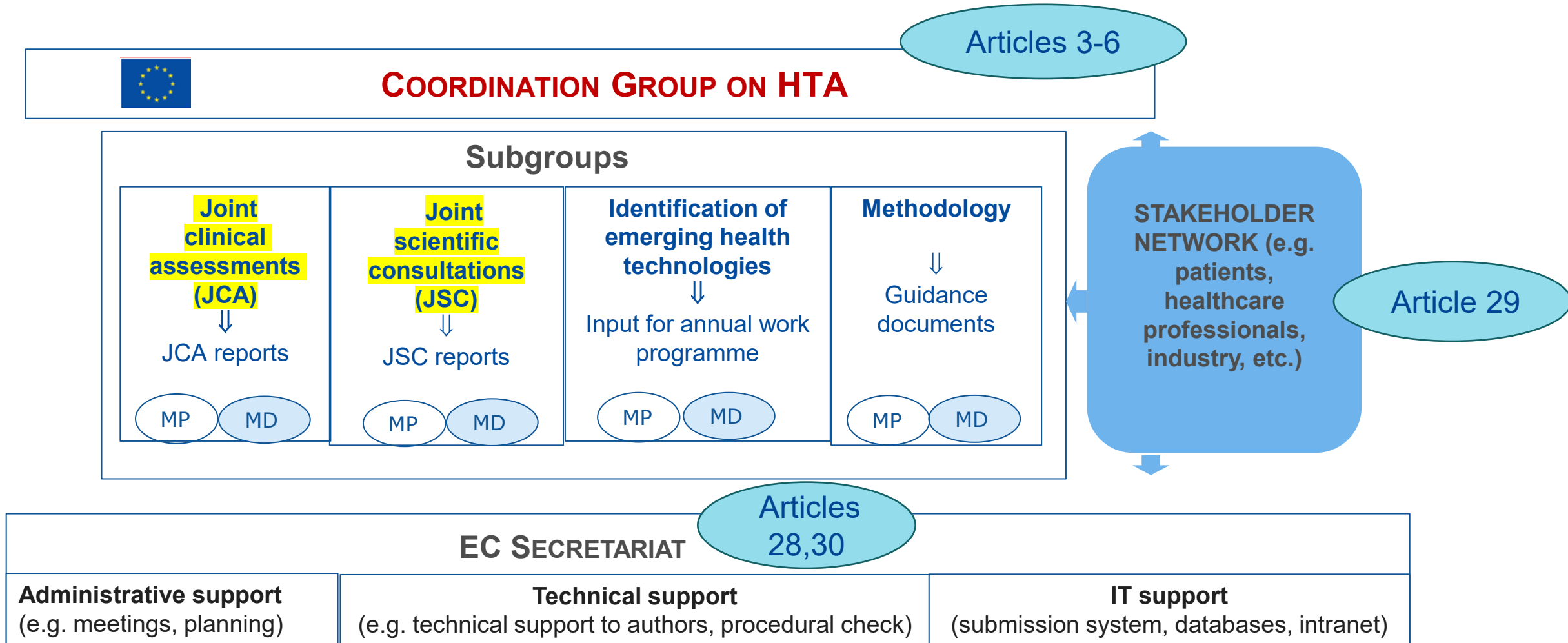


HTA Regulation

EU assessment vs NATIONAL appraisal



HTA Regulation: driven by Member States HTA bodies



HTA Regulation – Joint HTA & engagement with patients and healthcare professionals

1. Joint Clinical Assessments on:

- **medicines** (first 3 years: oncology medicines and ATMPs; following 2 years: + orphan drugs; after 5 years: full scope)
- **a selection of high-risk implantable medical devices**



Individual patient experts and clinical experts

2. Joint Scientific Consultations

- HTA only
- in parallel with regulators



Individual patient experts and clinical experts

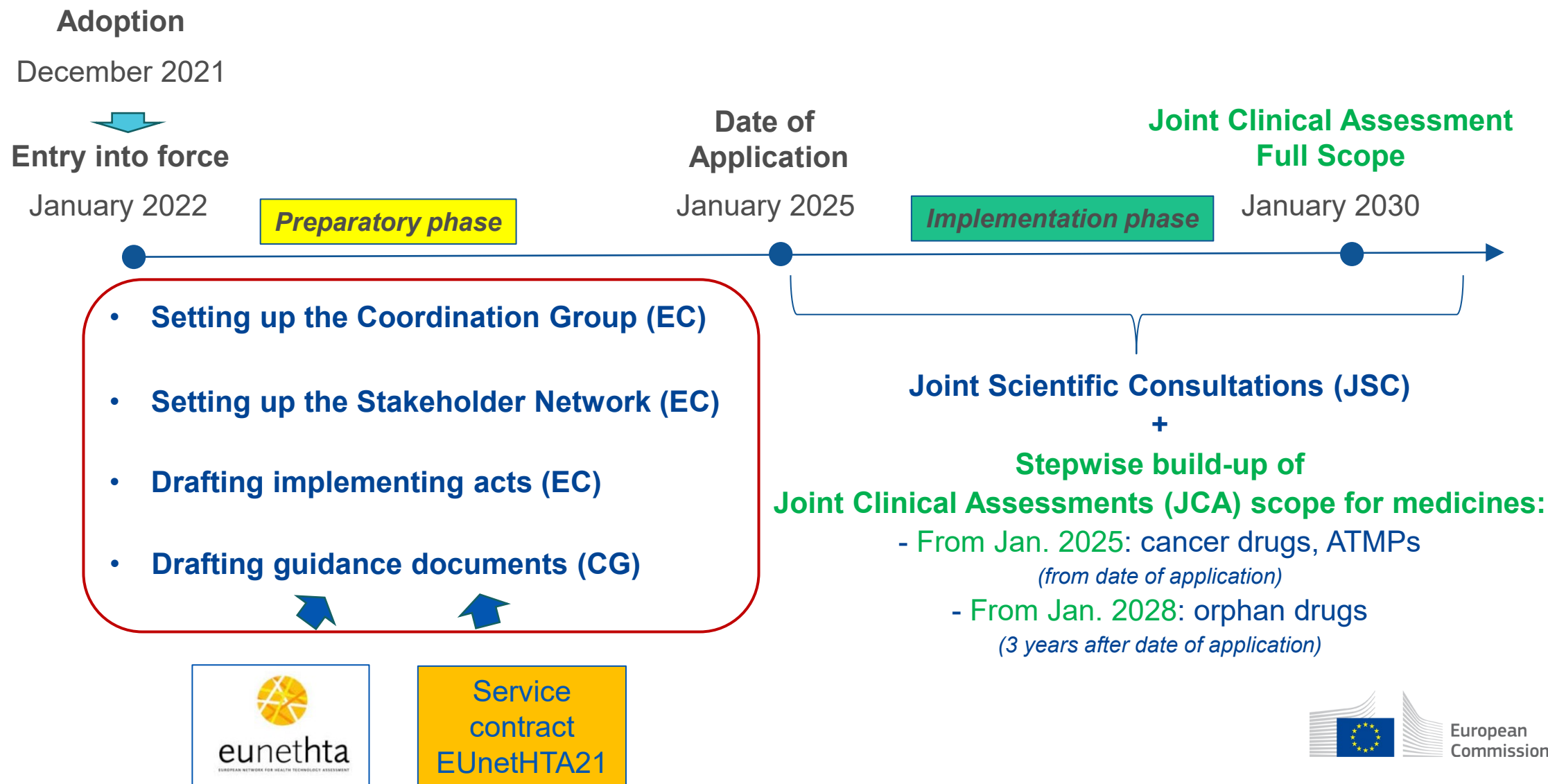
3. Emerging Health Technologies

4. Methodology



Patient organisations
Healthcare professional organisations

HTA Regulation: timeline



HTA Regulation: adoption of procedural rules

Joint Clinical Assessment (JCAs)

- Interaction with **patients, clinical experts and other relevant experts** during JCAs and updates.

Article 15.1c

- Selection and consultation of **patients, clinical experts and other relevant experts** in JCAs.

Article 25.1b

Joint Scientific Consultations (JSCs)

Selection and consultation of **patients, clinical experts and other relevant experts** in JSCs.

Article 20.1b

Implementing acts EC

HTA Regulation: The Stakeholder Network

Open call for applications

to all eligible stakeholder organisations,
incl. patient associations, consumer organisations,
health professionals, non-governmental organisations

Eligibility criteria:

- proof of engagement in HTA
- relevant professional expertise
- geographical EU coverage
- communication and dissemination capabilities

Organisations

to declare their
membership and
sources of funding

Representatives

to declare any
financial or other
interest

The co-creation of a new system

Inclusiveness and transparency as key principles of the joint work

Commitment of patients and healthcare professionals essential to secure smooth implementation

- **STAKEHOLDER ORGANISATIONS** can apply to the stakeholder network
- **INDIVIDUAL EXPERTS** will provide input on JCAs and JSCs

Only two years left until application

Thank you for your attention!

Questions?

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