# Regulation (EU) 2021/2282 on HTA
# Key principles and next steps

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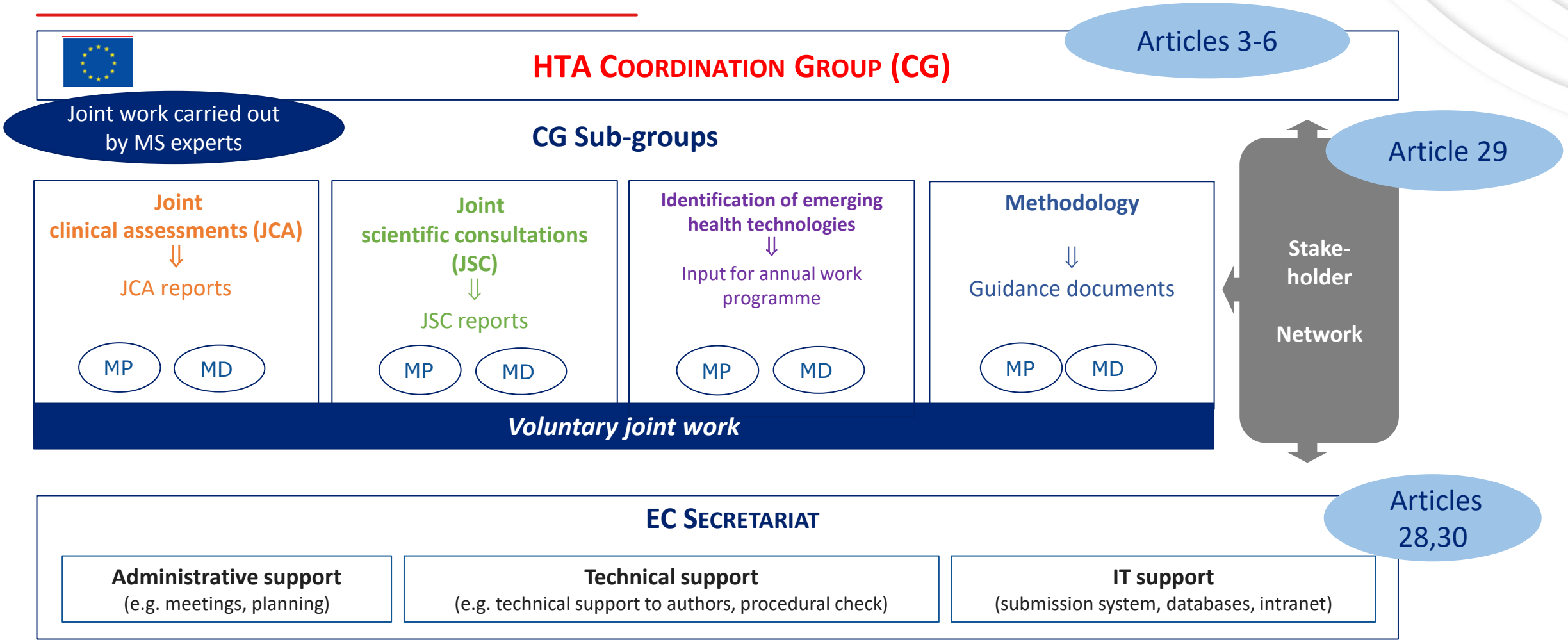
# HTA Regulation - Key principles

- **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**

# HTA Regulation - Governance

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# HTA Regulation - Timeline of implementation

Adoption
***December 2021***

Entry into force
***January 2022***

**Setting up of EC Secretariat**

Date of application
***January 2025***

Full Joint Clinical Assessment scope
***January 2030***

3 years

5 years

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

**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)*

**Joint Clinical Assessments (JCA) scope for Medical devices**

(selection for high risk classes subject to scrutiny procedure)

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Service contract EUnetHTA21

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