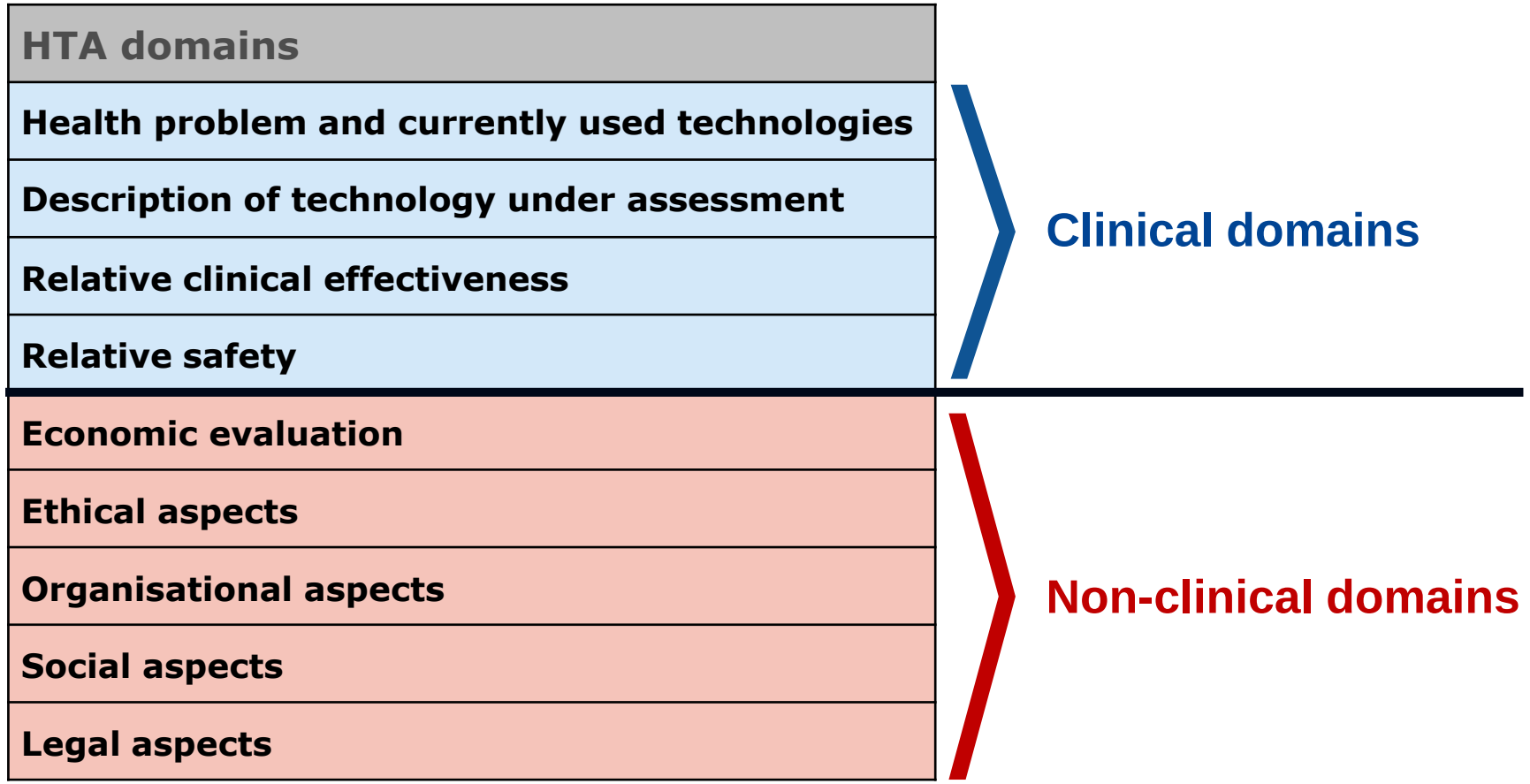
Regulation (EU) 2021/2282 on Health Technology Assessment

Maya Matthews, Head of Unit SANTE C2,

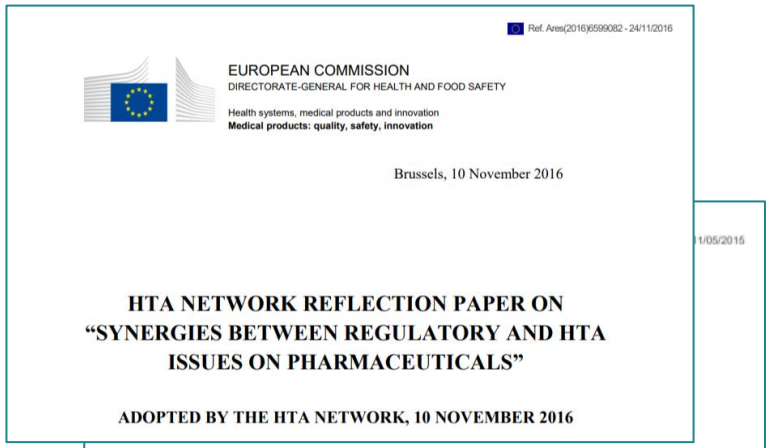
State of Health, European Semester, Health Technology Assessment.

The EU Joint Clinical Assessments



European Commission

Strengthening EU HTA cooperation


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

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

European Commission

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 **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**

Joint HTA activities

Joint Clinical Assessments (JCA) on:

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

  following 2 years (3+2): + orphan medicinal products

  after 5 years: full scope

- **a selection of high-risk medical devices and in-vitro medical devices**

Joint Scientific Consultations (JSC)

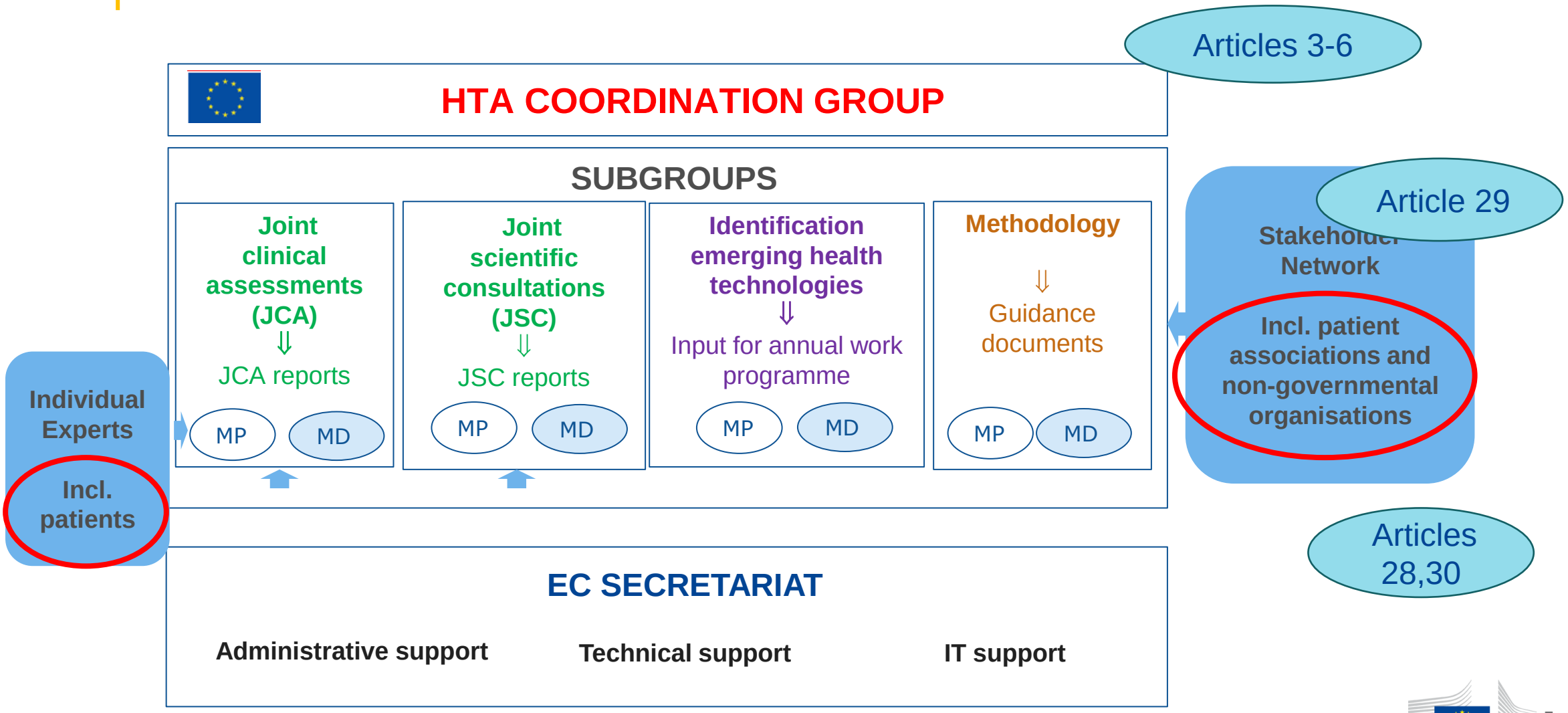
- HTA Coordination Group only
- in parallel with EMA

Emerging Health Technologies

Methodology for joint HTA work

European Commission

MS Coordination Group on HTA



MP = medicinal products, MD = medical devices

HTA Regulation: 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

- **Setting up the Coordination Group and its subgroups (EC)**
- **Setting up the Stakeholder Network (EC)**
- **Drafting the implementing acts (EC)**
- **Drafting the guidance documents (CG)**

Service contract EUnetHTA21

Joint Scientific Consultations (JSC)

+

Joint Clinical Assessments (JCA)

+

Emerging Health Technology reports

+

Methodological and procedural guidance

eunethta

European Commission

Conclusions:
The co-creation of a new system

Inclusiveness and transparency as
key principles of the joint work

Commitment of all stakeholders
essential to secure smooth implementation

Less than two years left until application

European Commission

Thank you for your attention

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European Commission