

EUnetHTA 21

European Network for Health Technology Assessment

EC Service Contract | 2021-2023

HTA Regulation (EU) Implementation timeline

Adoption

December 2021



Entry into force

January 2022

Preparatory phase

Date of Application

January 2025

Implementation phase

Joint Clinical Assessment
Full Scope

January 2030

- Setting up the Coordination Group/HTACG (EC)
- Setting up the Stakeholder Network (EC)
- Drafting implementing and delegated acts (EC)
- Drafting guidance documents (CG)

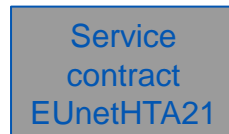
Part of rolling
Implementation
plan

Joint Scientific Consultations (JSC)

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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)



European HTA Structures

EU HTA Coordination
Group (HTAR)

Heads of HTA Group
(HAG)

Regional Collaboration
(FiNoSE, BeNeLuxA)

National (sub-national) HTA bodies

HTAR and RWE

RWE not directly included in HTAR

Joint Scientific Consultations (JSC)

Art.23 Voluntary Cooperation

Parallel - Joint Scientific Consultations



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Parallel EMA/EUnetHTA 21 Joint Scientific Consultations (JSC)

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RWE and HTA

- RW:**
- transparency
 - predictability
 - cost of RW generation
 - burden for Health Care system

emphasis on E:

- Uncertainty influences decision making