European Access Academy

# EAA Fall Convention

## *EU HTA – Procedural Insights & First Learnings*

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Université Paris Cité & Virtual

## Impulse Presentation

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**Title of the Talk: Involvement of Experts and HTA Bodies**

*Update from the Coordination Group Subgroup JCA*

**Abstract**

**The Regulation (EU) 2021/2282 on health technology assessment (HTAR) entered into force on 11 January 2022 and applies from 12 January 2025.**

This new and permanent EU-framework introduces a single EU-level submission file for joint clinical assessments (JCAs) in order to ensure pooling of resources at the EU level and strengthening the scientific quality of HTA across the EU while avoiding duplication of assessments at national level. It also establishes faster procedures requiring JCAs to be completed within 30 days after the authorisation of the medicine. At last, it implies the systematic consultation of patients and clinicians during the preparation of the assessments as well as the involvement and consultation of the HTA stakeholders.

**As a first step, Joint Clinical Assessments (JCAs) cover marketing authorisation applications for a new cancer medicine or an advanced therapy medicinal product (ATMP). The scope will be extended to orphan medicines in January 2028 and will as of 2030 cover all new medicinal products. Selected high-risk medical devices will also be assessed as of 2026 (see also the factsheet Implementing the EU Health Technology Assessment Regulation). In that respect the implementing act on the JCAs for MDs received a positive opinion from the HTA Committee on 19 September 2025.**

The product specific joint work under the HTA regulation has started in January 2025, and **as of September 30, nine JCAs have been initiated for medicinal products. The list of ongoing JCAs is publicly available on the European Commission website.** The Joint Scientific Consultations (JSCs) have also started, with the first and second request periods launched respectively in February and June 2025.

**The HTA authorities are fully invested in the joint work, whether as assessor or coassessor for the ongoing JCAs, or as Member States representatives in the JCA, JSC, Methodological and Procedural Guidance and/or Emerging Health Technologies subgroups of the HTA Coordination Group.**

**Co-creation of effective patient and clinical expert involvement is key and thus** a working group on the identification of patients and clinical experts was launched within the **Health Technology Assessment Stakeholder Network (HTA SN)**, as reported **during the fifth meeting of the SN held on 1 July 2025 in Brussels. It was also acknowledged during this meeting to improve interactions with Health Technology Developers in the pre-submission stage.**