



# Update from the European Commission on the HTA Regulation

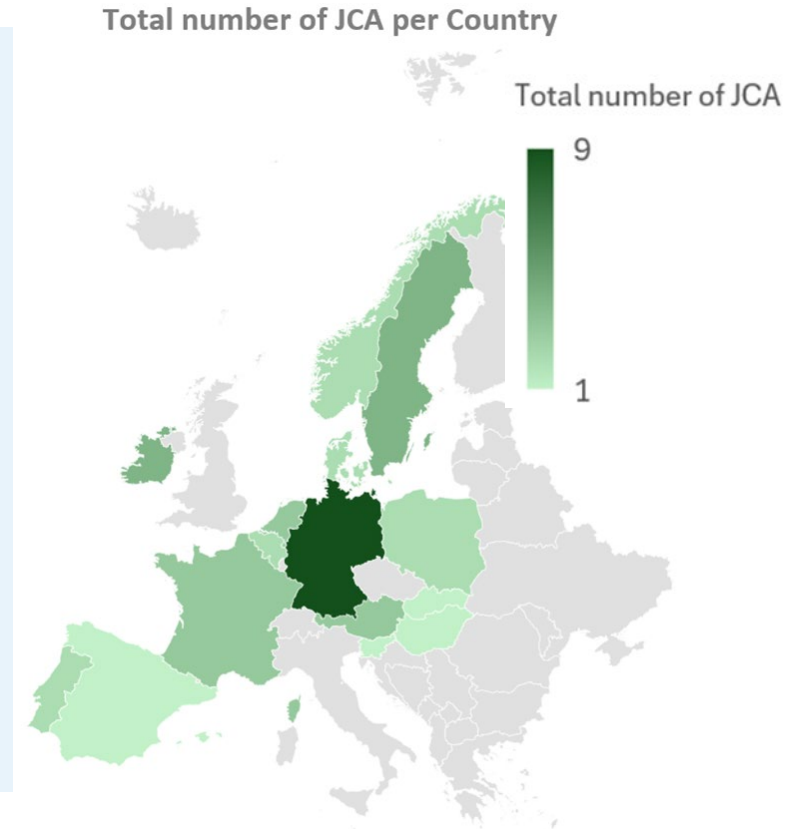
**EMA ISG meeting - 29 June 2026**

*Valentina Barbuto, Policy Officer  
Unit C2 – Health Technology Assessment  
Directorate-General for Health and Food Safety, European Commission*

# State of play: joint clinical assessments

## ✓ 18 Joint Clinical Assessments (JCAs) initiated:

- 1 completed (published on 9 June)
  - 3 discontinued
  - 14 ongoing
- +
- 5 ATMPs, 9 orphan medicines, several SMEs
  - 15 different Member States took assessor and co-assessor roles
  - Anticipate high scaling up in 2026 (based on letters of intent)



## [Joint Clinical Assessments - European Commission](#)

Table with ongoing, discontinued and completed JCAs. Last updated: 24 June 2026

# NEW The first joint clinical assessment!

## Joint Clinical Assessment report on tovorafenib (Ojemda)

BACKGROUND DOCUMENT

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Description

Files

### Details

Publication date 9 June 2026

Author Directorate-General for Health and Food Safety

### Description

JCA report on tovorafenib (Ojemda):

- [JCA report on tovorafenib \(Ojemda\)](#) - PDF
- [JCA summary report on tovorafenib \(Ojemda\)](#) - PDF

Date of endorsement by the Member State Coordination Group on HTA: **30 April 2026**

Date of conclusion of the procedural review by the European Commission: **19 May 2026**

Additional files:

- [Annex – Factual accuracy check by the health technology developer and response by the assessors on the JCA report on tovorafenib \(Ojemda\)](#) - PDF
- [Dossier of the health technology developer for tovorafenib \(Ojemda\)](#) - ZIP(27.28 MB )

❖ Report

❖ Summary report

❖ Dossier of the health technology developer

❖ Comments received during its preparation

The report is available at the following link :

[Joint Clinical Assessment report on tovorafenib \(Ojemda\) - Public Health](#)



# NEW on publication of a JCA



## Guiding Principles on Data Transparency

Adopted on 14 May 2026 by the HTA CG, pursuant to Article 3(7), points (c) and (h), of Regulation (EU) 2021/2282 on Health Technology Assessment

[Health Technology Assessment – Member State Coordination Group adopts guiding principles on data transparency - Public Health](#)

[New - Frequently asked questions about the publication of the Joint Clinical Assessment report - Public Health](#)



# NEW frequently asked questions



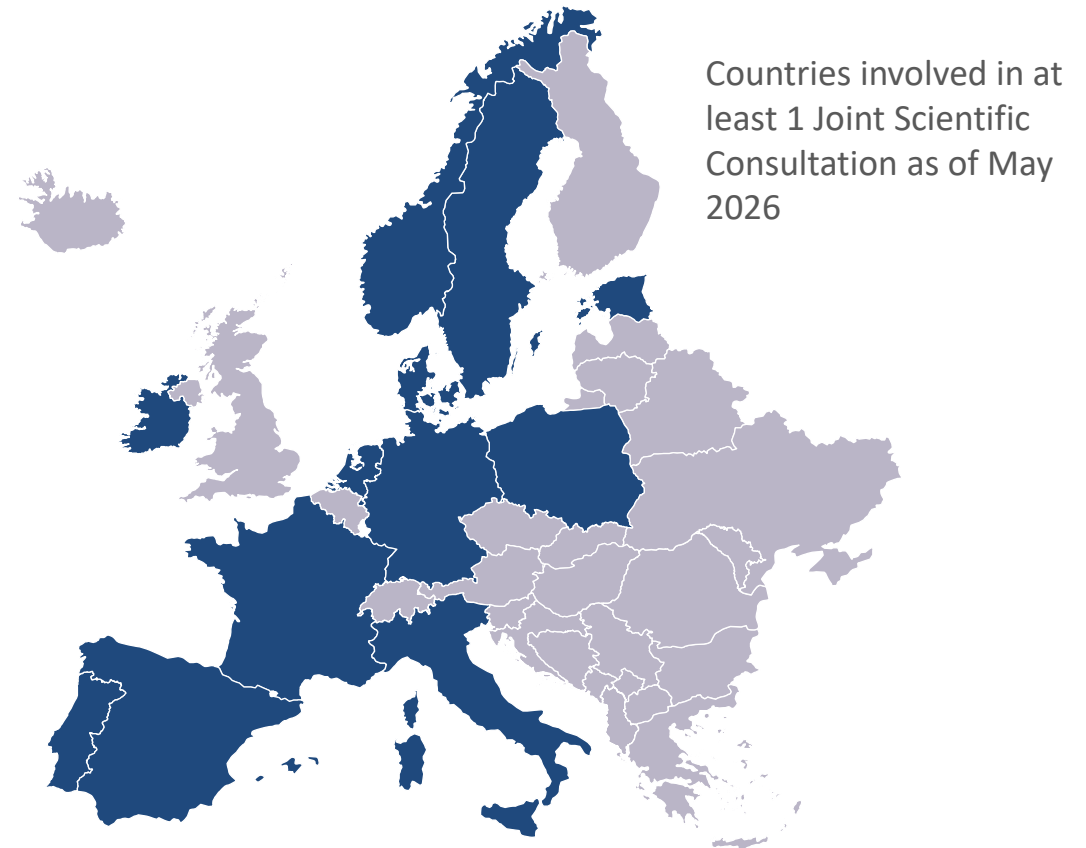
**Questions & Answers**  
on general methodological and procedural issues  
for joint clinical assessments

[Updated - Questions and Answers on general methodological and procedural issues for joint clinical assessments - Public Health](#)

15 May 2026

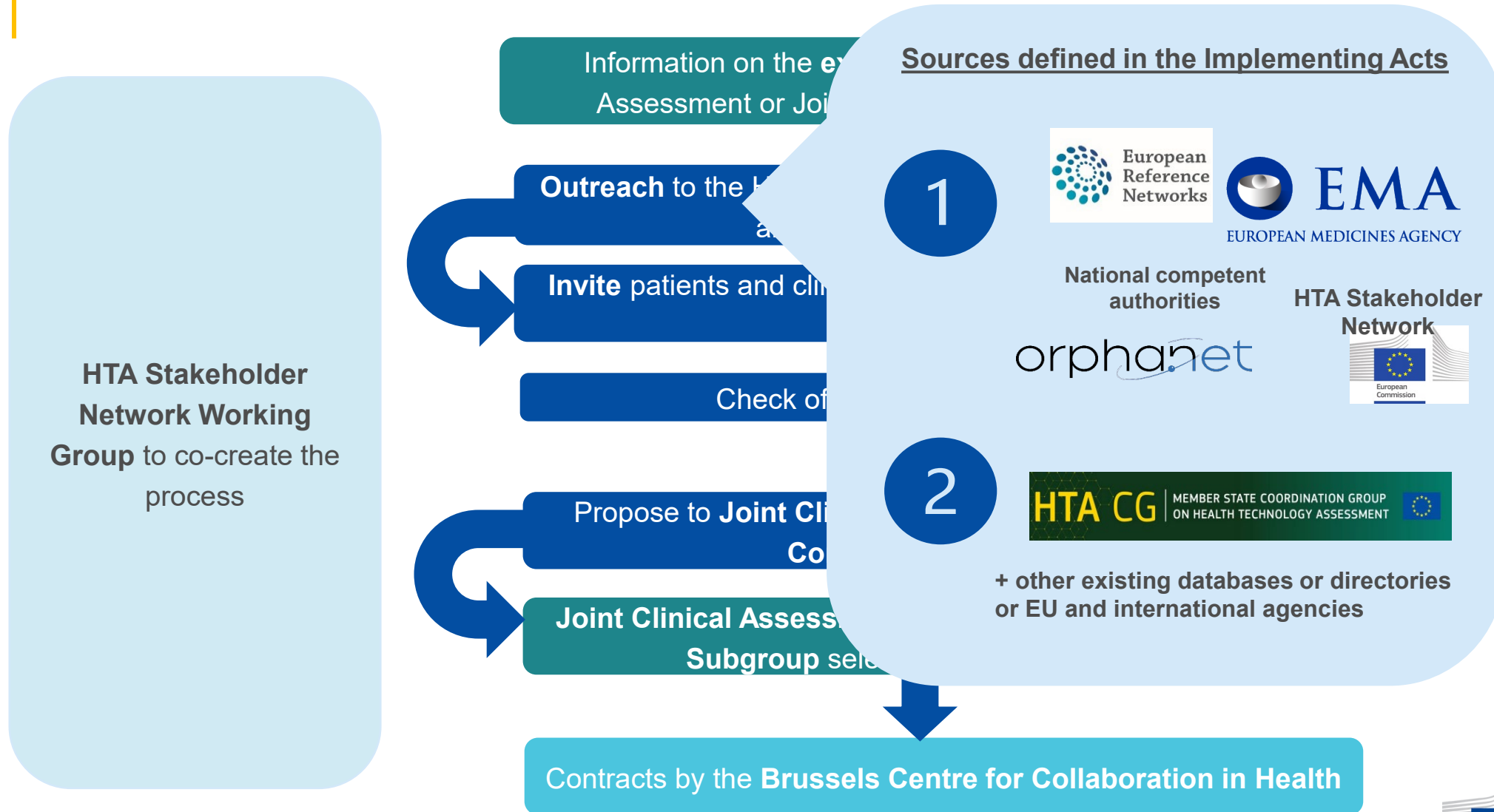
# State of play: joint scientific consultations

- ❖ 7 joint scientific consultations started in 2025 and all completed
- ❖ 7 new joint scientific consultations started in 2026 (2 parallel)
- ❖ **4 requests periods in 2026** (3<sup>rd</sup> ongoing until 1 July)
- ❖ 12 different MS took assessor and co-assessor role



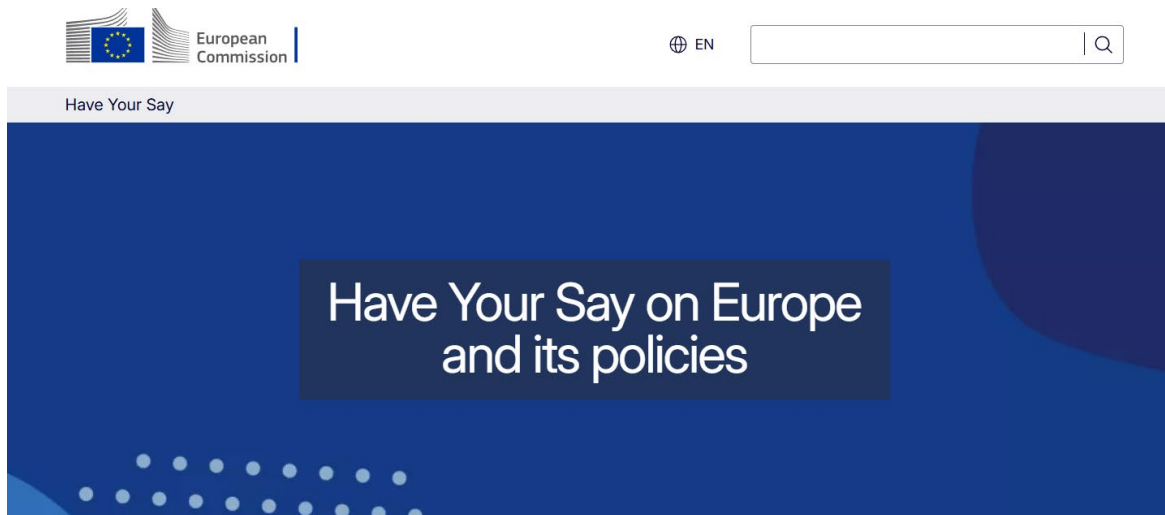
[Joint Scientific Consultations - Public Health - European Commission](#)

# Identification and selection of patients and clinicians in joint work



Dedicated page [Opportunities for patients, carers and clinicians - Public Health](#)

# NEW The evaluation of the HTA Regulation



Health technology assessment – evaluation of EU rules

Have your say - Public Consultations and Feedback > Published Initiatives > Health technology assessment – evaluation of EU rules

### In preparation

- Upcoming**
- Call for evidence**  
Feedback: Upcoming
- Public consultation**  
Planned for Fourth quarter 2026  
Feedback: Upcoming
- Commission adoption**  
Planned for Fourth quarter 2027

### About this initiative

**Summary**

This initiative aims to assess the performance of the EU rules on health technology assessment. This includes how Member States use joint assessments in their decision-making.

The EU health technology assessment framework supports Member States in the joint clinical assessment of new medicines and medical devices, reducing duplication of work for national authorities and industry. It aims to contribute to improving patient access to innovative treatments.

**Topic** Public health

**Type of act** Report

**Category** Evaluation

### Call for evidence

Feedback: Upcoming

### Public consultation

Feedback: Upcoming

The evaluation page is live on *Have your Say*:

[Health technology assessment – evaluation of EU rules](#)

Classified as public by the European Medicines Agency

# To conclude:

- ❖ Two additional JCA publications expected over summer
- ❖ Upcoming: **JCA eligibility checker** / dedicated webpage for developers
- ❖ Please contact [SANTE-HTA@ec.europa.eu](mailto:SANTE-HTA@ec.europa.eu) for any general question and to share information on upcoming submissions (incl. on variations!)
  
- ❖ You have time until 1 July 2026 to apply for a JSC in this request period
- ❖ The next one will open on 23 Sept for about one month
  
- ❖ Prepare for the publication of the call for evidence (4 weeks / Jul-Sept) and public consultation (12 weeks / end 2026) on *Have your Say*

# Thank you

Contact of HTA team:

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