



2025 Annual Report

This report was adopted by the Coordination Group at its 18th meeting on 12 February 2026. This document has not been endorsed by the European Commission and may not in any circumstances be regarded as stating a position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

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List of abbreviations

Abbreviation	Definition
ATMP	Advanced Therapy Medicinal Product
CG	Coordination Group
EHT	Emerging Health Technologies
EMA	European Medicines Agency
HAG	Heads of HTA Agencies
HTA	Health Technology Assessment
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
MPG	Methodological and Procedural Guidance
PLEG	Post Licensing Evidence Generation
RBAC	Role Based Access
SME	Small and Medium-Sized Enterprises
SN	Stakeholder Network

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1 Introduction

1.1 Scope of the report

[Regulation \(EU\) 2021/2282](#) on health technology assessment (HTA) entered into application on 12 January 2025, three years after its adoption. It creates a legal framework for the cooperation of Member States on the clinical assessment of medicinal products and medical devices at Union level.

The HTA Regulation is implemented via a Member State Coordination Group on HTA (Coordination Group), which met for the first time on 21 June 2022.

At its 2nd meeting on 28 November 2022, the Coordination Group decided to establish four different subgroups tasked with carrying out a specific set of activities under the HTA Regulation: joint clinical assessments, joint scientific consultations, identification of emerging health technologies, development of methodological and procedural guidance. The subgroups first met on 24 and 25 April 2023.

Article 6(4) of the HTA Regulation requests that the Coordination Group adopts its annual report of work carried out in the preceding year at the latest by 28 February of the following year. This provision applies as of January 2025.

This document provides the first annual report, covering the main activities of the Coordination Group and its subgroups in 2025.

2 Governance

2.1 Member State Coordination Group on Health Technology Assessment

All 27 EU Member States, as well as Norway, Iceland and Liechtenstein, have designated their member organisations in the Coordination Group, which in turn appointed their representatives. The complete list of members in the Coordination Group and its four subgroups is available on the Commission [Europa website](#), together with the names and declarations of interests of its representatives.

At its second meeting on 28 November 2022, the Coordination Group decided to operate in a joint configuration until 2025. Its meetings would cover both medicinal products and medical devices under the leadership of a Chair assisted by two Co-Chairs: one with expertise on medicinal products and one with expertise on medical devices.

On the same date, the Coordination Group elected **Roisín Adams** (National Centre for Pharmacoeconomics, Ireland) as Chair, **Niklas Hedberg** (Dental and Pharmaceuticals Benefits Agency, Sweden) as Co-Chair with expertise on medicinal products and **Marco Marchetti** (National Agency for Regional Healthcare Services, Italy) as Co-Chair with expertise on medical devices.

The Coordination Group renewed this decision at its 15th meeting on 25 September 2025, when Member States agreed to continue operating in a joint configuration for an additional three years, and to renew the mandate of the current Chair and Co-Chairs until end 2028.

In 2025, the Coordination Group met six times: on 28 February, 22 May, 30 June, 25 September, 23 October and 28 November. On 20 March 2025, the members of the Coordination Group met informally online to discuss the national consultations of stakeholders' organizations during the scoping process.

The final agenda and flash reports from the official meetings are published on the [Europa website](#) after each meeting, while the summary minutes are published after their adoption at the next meeting.

The Coordination Group Chair and Co-Chairs also met on a monthly basis online with the Chairs and Co-Chairs of all subgroups and the European Commission in an informal "Joint Chairs" format, to discuss cross-cutting issues relevant to the implementation of the HTA Regulation.

In its 13th meeting on 22 May 2025, the Coordination Group introduced a second Co-Chair in the governance of the subgroups for joint clinical assessments and joint scientific consultations.

2.1.1 The subgroup for joint clinical assessments

All 27 EU Member States and Norway have designated their members and representatives in the Subgroup for joint clinical assessments (JCA Subgroup).

The JCA Subgroup is chaired by **Judith Fernandez** (Haute Autorité de Santé, France), and co-chaired by **Anne Willemsen** (National Health Care Institute, Netherlands) and **Sari Ormstad** (Norwegian Medical Products Agency). Camille Thomassin (Haute Autorité de Santé, France) and Andrea Beelen (National Health Care Institute, Netherlands) assisted Sari Ormstad in her duties during the temporary leave of Judith Fernandez (July-present) and Anne Willemsen (July-October).

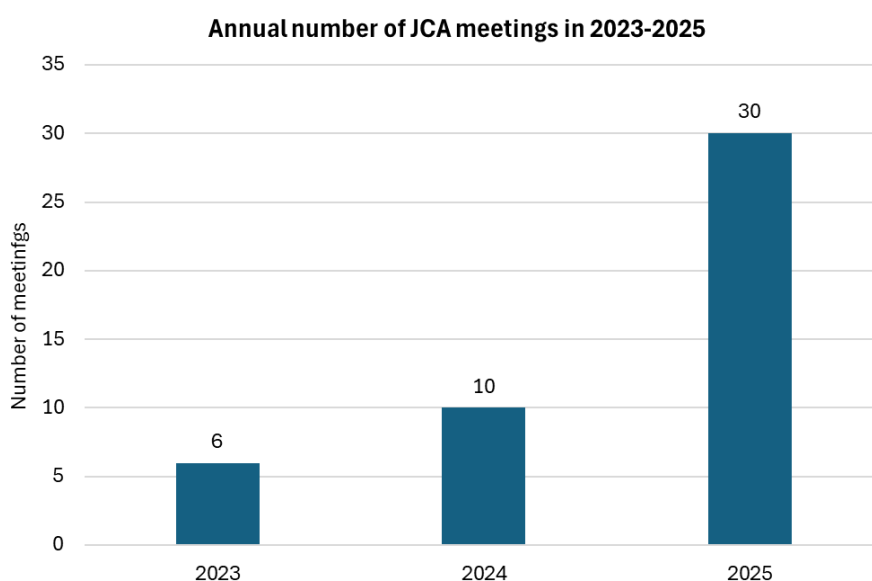


Figure 1: Annual number of JCA meetings 2023-2025

(the number for 2025 includes both subgroup meetings and case specific meetings)

2.1.2 The subgroup for joint scientific consultations

26 EU Member States and Norway have designated their members and representatives in the Subgroup for joint scientific consultations (JSC Subgroup).

The JSC Subgroup is chaired by **Stephanie Said** (Federal Joint Committee, Germany), and co-chaired by **Sonia Pulido Sánchez** (Spanish Agency of Medicines and Medical Devices, Spain) and **Alexandra Poulsson** (Norwegian Medical Products Agency).

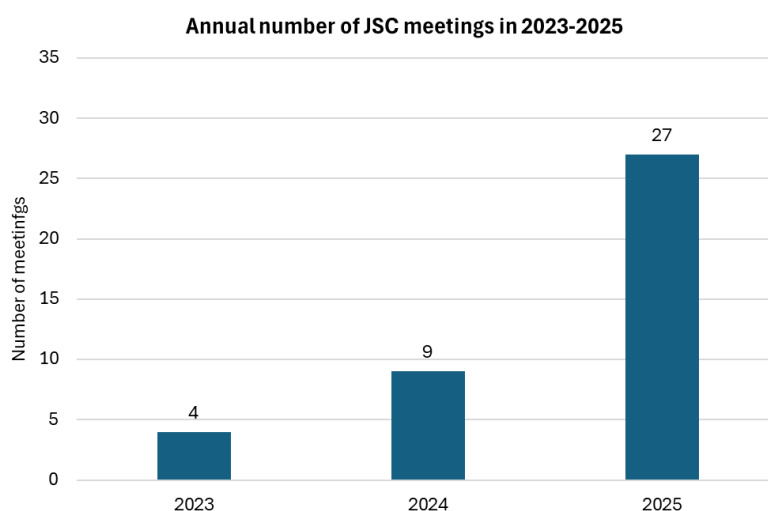


Figure 2: Annual number of JSC meetings 2023-2025

(the number for 2025 includes both subgroup meetings and case specific meetings)

2.1.3 The subgroup for the identification of emerging health technologies

26 EU Member States and Norway have designated their members and representatives in the Subgroup for the identification of emerging health technologies (EHT Subgroup).

The EHT Subgroup is chaired by **Kim Helleberg Madsen** (Danish Medicines Agency) and co-chaired by **Jelena Ivanovic** (Italian Medicines Agency).

In 2025 the EHT Subgroup met regularly every two months: on 23 January, 13 March, 13 May, 10 July, 24 September, and 7 November.

2.1.4 The subgroup for the development of methodological and procedural guidance

26 EU Member States and Norway have designated their members and representatives in the Subgroup for the development of methodological and procedural guidance (MPG Subgroup).

The MPG Subgroup is chaired by **Beate Wieseler** (Institute for Quality and Efficiency in Health Care, Germany), and co-chaired by **Sara Couto** (National Authority of Medicines and Health Products, Portugal).

In 2025 the MPG Subgroup met regularly every two months: on 20 January, 10 March, 12 May, 7 July, 8 September, and 6 November.

2.2 The Stakeholder Network

Pursuant to the HTA Regulation, the Commission established a Stakeholder Network (SN) to support the work of the Coordination Group and its subgroups upon request. Currently, 71 organisations and 2 observers are [members of the network](#), including patients' associations, associations of health technology developers, health professionals' organisations and other non-governmental organisations in the field of health. The European Medicines Agency (EMA) and the NBCG-Med (Notified Body Coordination Group) receive a standing invitation to all SN meetings to ensure the coordination of the work with stakeholders in all related fora.

The Stakeholder Network is chaired by **Maya Matthews**, head of the HTA Unit within the Directorate-General for Health and Food Safety of the European Commission.

The Coordination Group has held joint meetings with the Stakeholder Network twice a year since June 2023. In 2025, they met on 1 July and 24 October. On those occasions, Member States and stakeholders shared their first reflections on the application of the HTA Regulation, discussed the work programme of the Coordination Group for 2026, as well as how the Stakeholder Network will be involved in the preparatory work on the evaluation of the HTA Regulation starting in 2026. The Coordination Group and subgroups' Chairs and Co-Chairs actively participate in these meetings.

In order to support the input of patient and clinical experts in HTA a working group was established within the Stakeholder Network (more information on page 20). In 2025, four meetings of the SN working group on the identification of patients and clinicians (6 March, 29 April, 18 June, 12 September), took place as well as the kick-off meeting of the SN working group on the evaluation on 9 December.

2.3 The European Commission

The HTA Regulation is implemented by **the HTA Unit** within the Directorate-General for Health and Food Safety of the European Commission. The unit facilitates the work of the Coordination Group.

In accordance with Article 28 of the HTA Regulation, the unit supervises the procedures for joint clinical assessments, and provides technical, legal and IT expertise and support. The Unit serves as the HTA secretariat to the Coordination Group and hosts all meetings taking place in person, hybrid and online. The Unit is also responsible for assessing the conflicts of interest of all representatives and experts and ensuring the transparency of the HTA framework including via the publication of documents and information on the Europa website.

The HTA Unit is working closely with **the European Medicines Agency** to ensure the smooth application of the Regulation at the interface with the central marketing authorisation procedure.

3 Key achievements in 2025

3.1 Joint Clinical Assessments

The joint clinical assessment is the core element of the HTA Regulation. It provides a scientific analysis of the the clinical evidence on the relative effectiveness and relative safety of a health technology. This analysis will be used by Member States in their national decisions on pricing and reimbursement.

In line with the staggered approach of the HTA regulation, from 2025-2027 the scope of the joint clinical assessment of medicinal products is focused on new active substances for the treatment of cancer and on advanced therapy medicinal products (ATMPs).*

There is no selection for joint clinical assessments. The joint clinical assessment is performed in parallel to the assessment of the marketing authorisation application at the European Medicines Agency. All products seeking marketing application authorisation (via the European Medicines Agency), and belonging to the above categories, are in scope under the HTA Regulation.

3.1.1 Assessors and co-assessors

The joint clinical assessment is led by an assessor and a co-assessor from two different countries. These individuals are representatives of a member institution designated to be part of the JCA Subgroup and are appointed by the JCA Subgroup in a meeting or via a written procedure. Fifteen different countries have taken up assessor and/or co-assessor roles for one or more joint clinical assessments.



Figure 3: Countries involved in at least one JCA by 31 December 2025

3.1.2 Phases of the joint clinical assessment of medicinal products

The initiation phase of a joint clinical assessment begins when the European Medicines Agency informs the HTA Unit of the submission of a marketing authorisation application in scope under the HTA Regulation. During this phase, the JCA Subgroup appoints an assessor and a co-assessor for the case.

In the scoping phase, the assessor and co-assessor develop a proposal for the assessment scope. All members of the JCA Subgroup are invited to provide input on this proposal. The assessor and co-assessor consolidate the input received on the assessment scope proposal. Individual experts are invited to provide input on the consolidated assessment scope. Then, the JCA Subgroup finalises the assessment scope.

The dossier preparation phase starts when the health technology developer receives the assessment scope in the Commission’s first request. During this phase, the health technology developer prepares the dossier for the joint clinical assessment of the medicinal product in accordance with the requirements set out in the HTA Regulation and Commission [Implementing Regulation \(EU\) 2024/1381](#) on the joint clinical assessment of medicinal products. Once the dossier is submitted by the health technology developer, the Commission, in consultation with the assessor and co-assessor, verifies whether the dossier complies with the requirements laid down in Article 9(2), (3), and (4) of the HTA Regulation.

During the assessment phase, the assessor and co-assessor draft together the joint clinical assessment and summary reports. The draft reports are reviewed by the JCA Subgroup and subsequently shared with individual experts for their input, as well as with the health technology developer for a factual accuracy check.

Once the revised joint clinical assessments and summary reports have been finalised by the JCA Subgroup, they are shared with the Coordination Group for review and endorsement. The Commission then performs a procedural review of the reports and publishes the procedurally compliant reports on the Europa website.

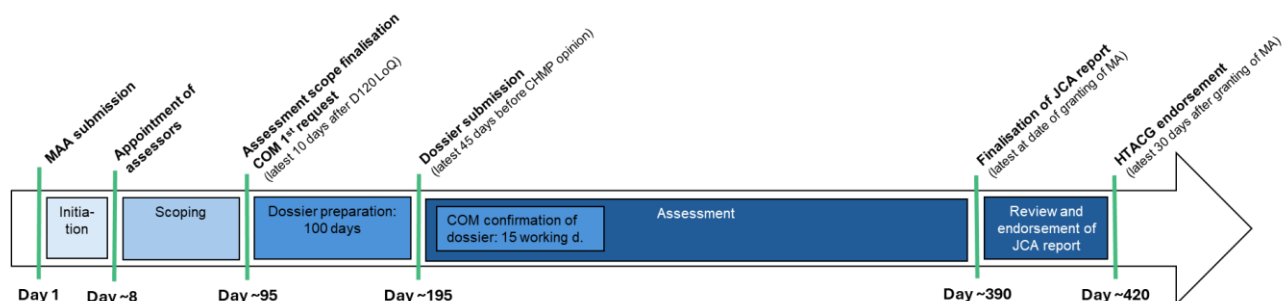


Figure 4: Timeline and phases of the (standard) joint clinical assessment procedure for medicinal products

Abbreviations: CHMP: Committee for Medicinal Products for Human Use; LoQ: list of questions; MAA: marketing authorisation application.

3.1.3 Medicines undergoing joint clinical assessments

The list of ongoing joint clinical assessments is available on the [Europa website](#). It is regularly updated.

In 2025, the JCA Subgroup started 13 joint clinical assessments, including one product with two therapeutic indications.

The 13 joint clinical assessments include ten new oncology products and three advanced therapy medicinal products.

Six products have orphan designation, indicating that nearly half of the ongoing assessments concern medicinal products for rare diseases.

Three joint clinical assessments involve products from small and medium-sized enterprises (SME). One joint clinical assessment involves a product from a research institute.

The table below provides a consolidated overview of the composition of the 13 joint clinical assessments by product type, therapeutic indication, orphan designation, SME involvement, and procedural status.

Table 1: Characteristics of ongoing joint clinical assessments by the end of 2025

International non-proprietary name (INN) / Common name	Type of product*	Therapeutic indication - Summary	Orphan	SME status	JCA status
Tovorafenib	Oncology	Treatment of paediatric low-grade glioma (LGG)	✓		Dossier confirmed
Autologous melanoma-derived tumour infiltrating lymphocytes, ex vivo-expanded	ATMP**	Treatment of melanoma			Dossier in preparation
Sasanlimab	Oncology	Treatment of bladder cancer			Confirmation check of dossier
Lurbinectedin	Oncology	Maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)	✓		Confirmation check of dossier
Onasemnogene abeparvovec	ATMP	Treatment of 5q spinal muscular atrophy (SMA)	✓		Confirmation check of dossier
Tarlatamab	Oncology	Treatment of extensive-stage small cell lung cancer	✓		Dossier in preparation
Camizestrant	Oncology	Treatment of adults with locally advanced or metastatic breast cancer			Dossier in preparation
Catequentinib	Oncology	Treatment of synovial sarcoma or leiomyosarcoma	✓	✓	Dossier in preparation
Senaparib	Oncology	Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer		✓	Dossier in preparation

Relacorilant	Oncology	Treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer	✓		Scoping
Ensartinib	Oncology	The treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)		✓	Scoping
Zopapogene imadenovec	ATMP	Treatment of respiratory papillomatosis in adults	✓		Scoping
Sintilimab	Oncology	Treatment of non-squamous non-small cell lung cancer in adults			Scoping

** ATMP and oncology product.

By the end of 2025, the status of the joint clinical assessments is as follows: one confirmed dossier; three undergoing the European Commission's confirmation check of the dossier; five awaiting the dossier following the European Commission's first request (dossier in preparation); and four in the process of developing the assessment scope.

No joint clinical assessment has arrived at endorsement phase.

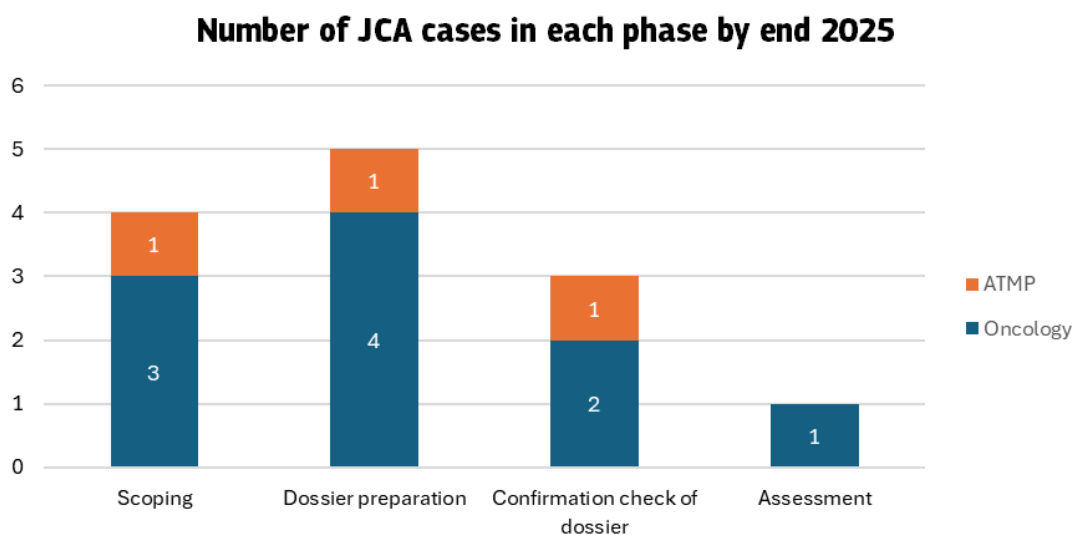


Figure 5: Number of JCA cases in each phase by end 2025

3.1.4 The joint clinical assessment of medical devices and *in vitro* diagnostic medical devices

The joint clinical assessment of medical devices (MDs) and *in vitro* diagnostic medical devices (IVDs) will start in 2026.

In 2025, the JCA Subgroup set up in cooperation with the MPG Subgroup a working group to develop guidance documents for the joint clinical assessment of medical devices and *in vitro* diagnostic medical devices. The guidance developed is listed on page 27.

The JCA Subgroup is responsible for developing a draft recommendation for the selection of medical devices and *in vitro* diagnostic medical devices for joint clinical assessment for Coordination Group. A pilot on the recommendation process was conducted, providing practical experience with the application of the selection criteria, the timeline and the development of a template recommendation for the selection of medical devices and *in vitro* diagnostic medical devices for joint clinical assessment.

The development of the first recommendation started in January 2026.

3.2 Joint Scientific Consultations

The joint scientific consultation provides health technology developers with early scientific guidance on the evidence and data requirements to support a subsequent joint clinical assessment, helping the planning of the clinical studies and clinical investigations of a health technology.

This consultation can streamline evidence preparation for joint clinical assessment and enhance the quality of evidence generation.

Joint scientific consultations in particular provide guidance on the relevant clinical study design aspects, or clinical investigation design aspects, including comparators, interventions, health outcomes and patient populations. It is optional for the health technology developer to raise health economic assessment related questions.

Joint scientific consultations can take place in parallel with the scientific advice from the European Medicines Agency if requested by the developer (“**parallel joint scientific consultations**”).

Joint scientific consultations are a voluntary element under the HTA Regulation and are requested by the interested health technology developer during specific request periods.

There are no fees for the joint scientific consultations under the HTA Regulation. The JSC Subgroup uses the criteria in Article 17(3) of the HTA Regulation to select candidates from the requests received.

3.2.1 Assessors and co-assessors

The joint scientific consultation is led by an assessor and a co-assessor from two different countries. These individuals should be representatives of a member organisation designated to be part of the JSC Subgroup, which appoints them in a meeting or via a written procedure. Nine different countries have taken up assessor and/or co-assessor roles for one or more joint scientific consultations.

When health economic assessment related questions were raised by the health technology developer, pairing of Member States in assessor/co-assessor roles for a joint scientific consultation included a partner with health economics in the remit.



Figure 6: Countries involved in at least one JSC by 31 December 2025

3.2.2 Selected requests

In 2025 the JSC Subgroup opened two request periods:

- From 3 February to 3 March, for medicinal products only;
- From 2 to 30 June, for both medicinal products and medical devices.

In total 17 requests for medicinal products were received in 2025 and seven cases were selected by the JSC Subgroup. Four of the selected cases concerned requests for parallel joint scientific consultations. No request was received from developers of medical devices.

Table 2: Overview of JSC requests received and selected during the 2025 request periods

Request period	Number of JSC requests received	Number of JSCs selected	Parallel HTACG/EMA JSCs selected
1st: 3 February to 3 March 2025	8	3	1
2nd: 2 to 30 June 2025	9	4	3
Total	17	7	4

By the end of 2025, the status of the joint scientific consultations was as follows:

- Four joint scientific consultations were completed.
- One joint scientific consultation was withdrawn by the developer.
- Two joint scientific consultations are ongoing.

Two joint scientific consultations involved products from SMEs.

Four joint scientific consultations involved products seeking an orphan designation and one an advanced therapy medicinal product.

In terms of therapeutic fields:

- 42% (3/7) of the selected joint scientific consultations included a medicinal product for cancer;
- 28% (2/7) of the selected joint scientific consultations included a medicinal product for a neurodegenerative disorder;
- 14% (1/7) of the selected joint scientific consultations included a medicinal product for other therapeutic area: a neuromuscular disorder;
- 14% (1/7) of the selected joint scientific consultations included a medicinal product for another therapeutic area: a neurodevelopmental disorder.

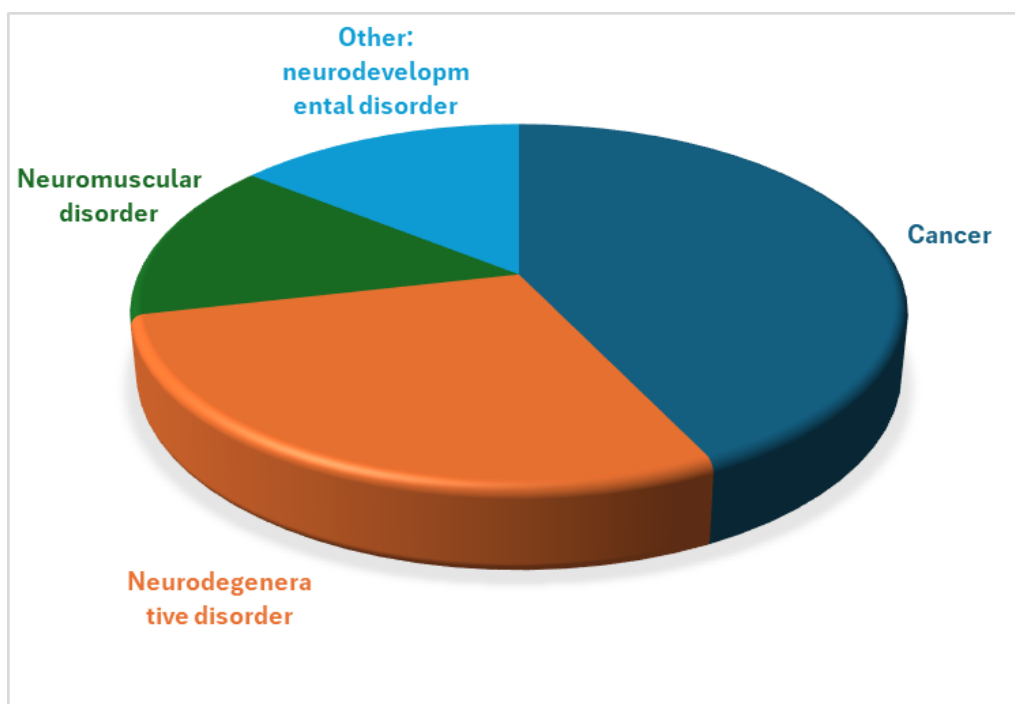


Figure 7: Therapeutic fields of joint scientific consultations in 2025

Regarding the areas of advice requested by the developers: for all requests questions on patient population, comparator, outcomes and study design were asked; advice on the intervention was asked in four cases, questions on health economics were posed five times and in two cases other aspects were raised, namely in relation to safety and PLEG (Post Licensing Evidence Generation).

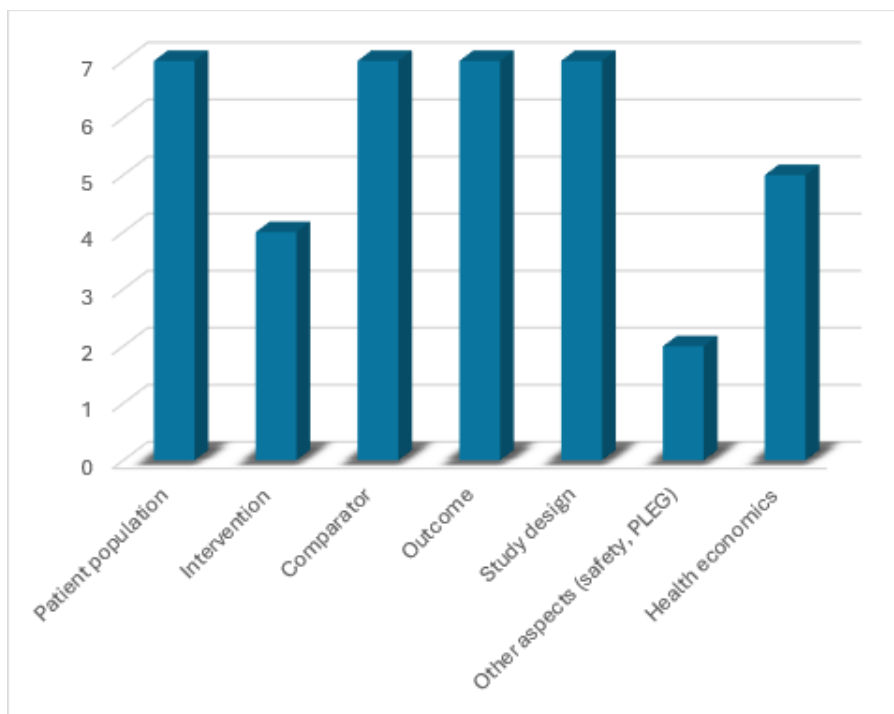


Figure 8: Areas of advice in joint scientific consultations in 2025

3.2.3 Outcome documents finalised

The JSC Subgroup finalised four outcome documents in 2025. All were approved by the Coordination Group via written procedure with no further comments, and sent afterwards to the requesting health technology developer.

The average time for completion of a joint scientific consultation procedure was 140 days (around 4.5 months) for the completed joint scientific consultations at the time this report was adopted, measured from submission of the initial briefing package to sending out of the JSC outcome document to the health technology developer.

3.3 Patients, carers and/or clinicians

The HTA Regulation mandates the systematic involvement of individual experts (patients, carers or clinicians) in each joint clinical assessment or joint scientific consultation. A dedicated webpage for patients, carers and clinicians is available on [the Europa website](#).

The European Commission is tasked with identifying patients, carers and/or clinicians following the rules contained in [Implementing Regulation \(EU\) 2024/1381](#) on the joint clinical assessment of medicinal products, [Implementing Regulation \(EU\) 2024/3169](#) on the joint scientific consultation of medicinal products, and [Implementing Regulation \(EU\) 2024/2745](#) on the management of conflicts of interests.

In February 2025, the European Commission established a working group within the HTA Stakeholder Network to co-create the process for identifying patients, carers and/or clinicians for involvement in joint HTA activities. The working group brings together patient organisations and healthcare professional organisations from the HTA Stakeholder Network, the Chairs and Co-Chairs of the HTA Coordination Group and of the the JCA and JSC subgroups, as well as the European Medicines Agency, and the Brussels Centre for Collaboration in Health (which is responsible for managing expert contracts).

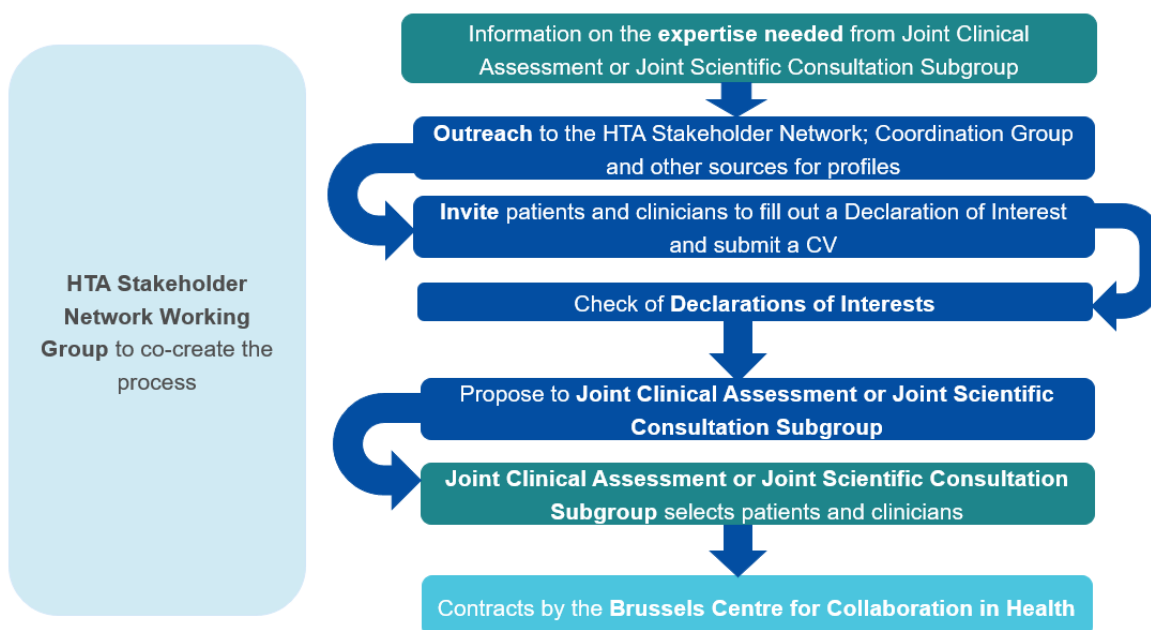


Figure 9: Process for identifying and selecting patients, carers and clinicians

Following input from the JSC or JCA subgroups on the expertise required, the European Commission identifies suitable patients, carers and/or clinicians in accordance with the implementing legislation mentioned above. Potential sources include members of the HTA Stakeholder Network, the European Reference Networks for rare and complex diseases and their corresponding European patient advocacy groups, Orphanet, national contact points for

clinical trials designated under Article 83 of [Regulation \(EU\) No 536/2014](#), and the experts' database of the European Medicines Agency. Where initial requests do not yield a sufficient number of profiles, the Commission may consult additional databases or directories or seek support from the Coordination Group, and other relevant EU and international organisations.

The Commission has identified more than 300 patients, carers and/or clinicians to participate in joint clinical assessments or joint scientific consultations. All of them are required to submit a Declaration of Interests, which is assessed by the HTA Unit. Patients, carers and/or clinicians with declared interests are not automatically excluded from joint work and may participate where those interests are not relevant for the specific case for which they are being considered. In exceptional circumstances, the Commission may propose patients, carers and/or clinicians with conflicts of interest.

After being identified by the HTA Unit, the patients, carers and/or clinicians are selected by the JCA or JSC Subgroups in a meeting or via a written procedure.

Patients, carers and/or clinicians in joint clinical assessments

At least one patient (or carer) and one clinical expert were selected by the JCA Subgroup for each case. By end 2025, 38 patients, carers and/or clinicians were involved in joint clinical assessments.

In the joint clinical assessment, the experts are asked to provide input on the consolidated assessment scope, and the revised draft joint clinical assessment and summary reports. In addition, their early engagement in the process is recommended. To support their contributions, templates and additional guidance documents have been developed.

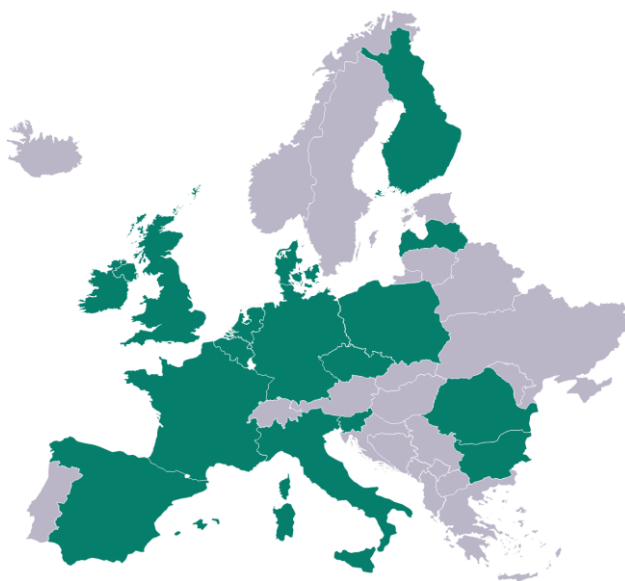


Figure 10: Geographical coverage of selected patients, carers and/or clinicians in JCAs by 31 December 2025 (based on country declared in their declaration of interest)

Patients, carers and/or clinicians in joint scientific consultations

One patient (or carer) and one clinical expert were selected by the JSC Subgroup in every case. By end 2025, 10 patients, carers and/or clinicians were involved in joint scientific consultations.

In the joint scientific consultation, the experts are asked to provide input during the joint scientific consultation and are also invited to the discussion meeting with the health technology developer.

In 2025, the selected experts provided written input to all consultations, and in four cases this was complemented by interviews. The experts shared insights into how the condition affects daily life, their experiences with currently available therapies, and their expectations of new health technologies. They also provided feedback on the proposed clinical development plans (e.g. trial design), including perceived limitations and expectations. Clinicians contributed with their expertise and day-to-day clinical experience on the proposed clinical trials, including perspectives on target populations, minimum study duration, and comparators. During the discussion meeting, patients, carers, and clinicians were all invited to share their views throughout the agenda. Efforts are underway to further strengthen and enhance their meaningful participation.

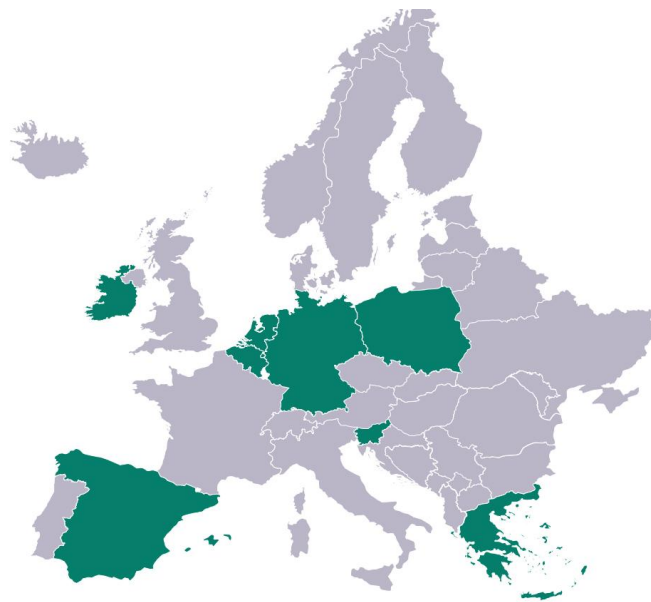


Figure 11: Geographical coverage of selected patients, carers and/or clinicians in JSCs by 31 December 2025 (based on country declared in the declaration of interest)

3.4 Identification of emerging health technologies

One of the main tasks of the Coordination Group is to prepare reports on emerging health technologies expected to have a major impact on patients, public health or healthcare systems, in line with Article 22 of the HTA Regulation.

3.4.1 Mapping of horizon scanning systems

In 2025 the EHT Subgroup continued the mapping of horizon scanning systems and initiatives with a view to identify relevant sources for the 2025 EHT reports on emerging health technology. The EHT Subgroup also completed a pilot project to collect relevant data from SN organisations and organised a related webinar on 17 February 2025 for the Stakeholder Network and Member States representatives.

3.4.2 2025 reports on emerging health technologies

The Coordination Group requested the EHT Subgroup to produce reports on emerging health technologies for those medicinal products and medical devices estimated to fall within the scope of that Regulation in 2026. The reports aim to support the Coordination Group in planning its work, particularly with respect to joint clinical assessments. The public version of the EHT 2025 reports was published on 9 January 2026 on the [Europa website](#).

In preparing its 2025 reports, the EHT Subgroup requested horizon scanning intelligence from multiple relevant sources. For medicinal products, these included the European Medicines Agency, the International Horizon Scanning Initiative (IHSI), national horizon scanning systems within the EHT Subgroup, and the Stakeholder Network. In the end, only data from the European Medicines Agency and IHSI were used to inform the preparation of the reports. For medical devices, the information was provided by the European Medicines Agency in accordance with Article 2(2) of the Commission [Implementing Regulation \(EU\) 2024/2699](#).

Concerning medicinal products, the EHT Subgroup took into account the scientific specifications of medicinal products subject to joint clinical assessments as agreed by the Coordination Group. Medicinal products included in the report are those which:

- Are likely to contain new active substances for which the therapeutic indication is the treatment of cancer;
- Could potentially be regulated as advanced therapy medicinal products for which the therapeutic indication is the treatment of any medical condition.

For medical devices and *in vitro* diagnostic medical devices, the report includes the products covered by Article 7(1) points (c) and (d) of the HTA Regulation which are potentially eligible for joint clinical assessment from 2026.

3.5 Development of methodological and procedural guidance

The development of methodological and procedural guidance is the basis for the work of the Coordination Group on all its joint activities. The guidance follows the international standards of evidence-based medicine and is systematically reviewed and updated.

3.5.1 Methodological and procedural guidance finalised

Following on from the development of the suite of guidance documents on medicinal products developed over 2023 and 2024, in 2025 the MPG Subgroup developed the following methodological guidance on medical devices, together with the JCA Subgroup:

- [Guidance on filling in the joint clinical assessment dossier template – Medical devices and in vitro diagnostic medical devices](#)
- [Procedural Guidance for the joint clinical assessment of medical devices and in vitro diagnostic medical devices](#)
- [Guidance on the HTACG recommendation for the selection of medical devices and in vitro diagnostic medical devices for joint clinical assessment](#)

The MPG Subgroup also collaborated with the JSC Subgroup on the development of the:

- [Guidance for the selection of medical devices and in vitro diagnostic medical devices for joint scientific consultations](#)
- [Procedural Guidance for joint scientific consultations on medical devices and in vitro diagnostic medical devices](#)

With the start of the joint clinical assessments, the MPG Subgroup has set up 3 Supporting Groups (the PICO, the Statistical and the Information Retrieval Supporting Groups) to provide advice and assistance to assessors and co-assessors upon their request. and to generalize the learnings from individual joint clinical assessments for discussion in the MPG and JCA Subgroups, as appropriate. The MPG subgroup also set up a regulatory guidance working group for collaboration with the European Medicines Agency on selected guidance documents. The Supporting Groups, operating within MPG Subgroup, met nine times in 2025.

The MPG Subgroup has developed an approach to provide early learnings from ongoing joint clinical assessments and to answer questions from stakeholders in a timely manner. Generalized learnings and clarification of open questions are discussed and agreed in the MPG and JCA Subgroups, as appropriate. Results from this process are provided in a [Question & Answer document](#) published on the Europa website. This mechanism allows for timely publication of additional information useful for the joint clinical assessment process. Where appropriate, this content will be transferred to guidance documents in the future.

3.6 IT Platform

The Coordination Group operates via a dedicated IT platform set up and maintained by the European Commission. This secure intranet allows the exchange of confidential information between the Coordination Group and its subgroups, as well as with the Stakeholder Network, the health technology developers and the experts participating in the joint work, and with the European Medicines Agency, via secure work spaces. It encompasses the information workflows for the declarations of interests and the joint work.

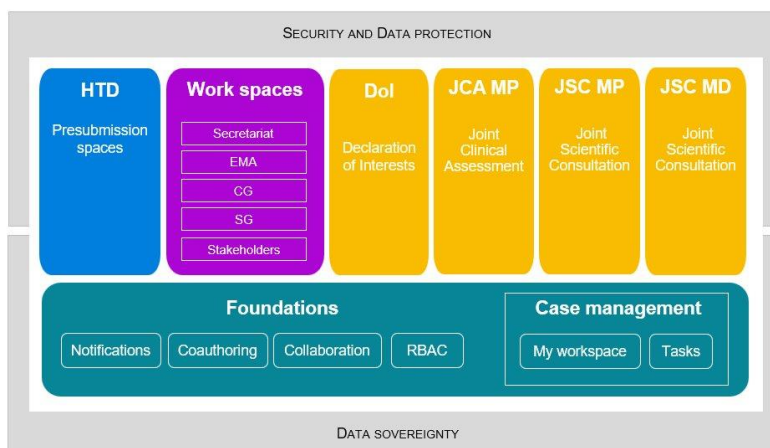


Figure 12: Structure of HTA-IT-Platform (Dec. 2025)

The figure below illustrates the increased activity during the past 12 months and before the application of the HTA Regulation. Other activity data: 1) Number of new spaces for health technology developers: 86, 2) Number of provided training sessions: 11 sessions, 3) Number of completed declarations of interest: 485.

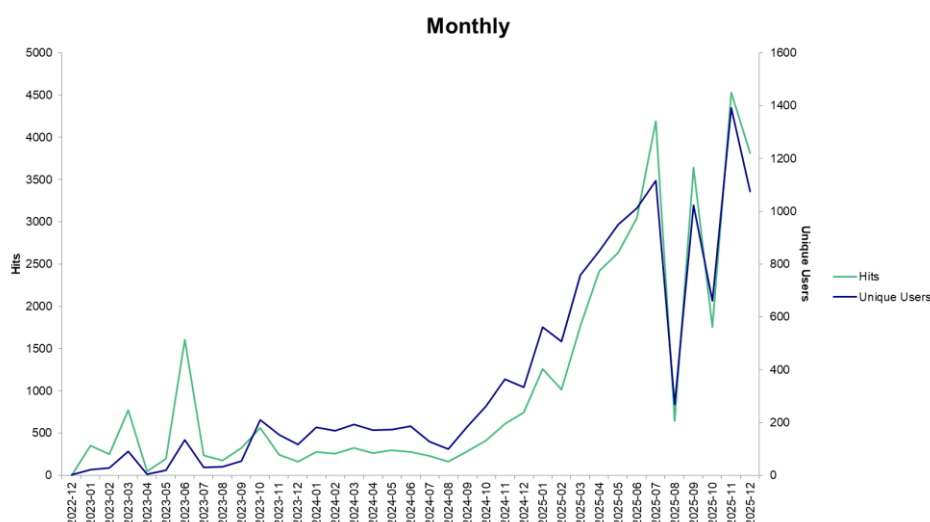


Figure 13: HTA-IT-Platform monthly users, from the opening in December 2022 until December 2025

3.7 Knowledge exchange and dissemination

3.7.1 Communication material

The Commission's dedicated HTA page on [the Europa website](#) is the Coordination Group main communication outlet. All updates, events, and key documents are published on this website.

3.7.2 Heads of HTA Agencies Group

The Coordination Group Chair and/or Co-Chairs attends the Heads of HTA Agencies Group (HAG) meetings at least twice a year to ensure that there is a smooth communication directly with the Heads. An information point on the HAG is regularly included in the Coordination Group meetings' agendas. In addition, the Chair and Co-Chairs of the Coordination Group meet regularly with the HAG Chair and Vice-Chairs.

3.7.3 Major conferences

The Coordination Group and subgroups Chairs and Co-Chairs, as well as several of its representatives, regularly attend and speak at major EU and international events on the implementation of the HTA Regulation. In 2025 this also included the 2nd ASEAN (Association of Southeast Asian Nations) HTA Harmonization Workshop bringing together HTA experts from across the Asia-Pacific region (12-13 November 2025).

On 2 July 2025, the Commission organised a high level conference on the HTA Regulation to mark the beginning of the application period. The Coordination Group and its subgroups Chair and Co-Chairs delivered keynote speeches, moderated and actively participated taking stock of the implementation of the HTA Regulation half-way into its first year of application.

3.7.4 Webinars for health technology developers and individual experts

The Coordination Group, with the collaboration of the European Commission, holds regular webinars to raise awareness on the implementation of the HTA Regulation, in particular within the health technology developer community. The registration is opened with a news announcement on the [Europa website](#), where presentations and video recordings are also available after each event.

After a first one on 15 November 2024, in 2025 the Coordination Group organised three additional webinars for health technology developers of medicinal products (24 January, 21 March, 17 October), one for health technology developers of medical devices (12 December), one for patients and clinical experts (16 May).

3.7.5 Meetings with health technology developers' associations

In 2025 the joint chairs started meeting with the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) to discuss operational issues related to the implementation of the HTA Regulation. The first such meeting was held within Commission premises on 22 October 2025.

3.8 External representation in other bodies

The Coordination Group has designated its representatives on other key initiatives relevant to HTA. Niklas Hedberg is the representative for the Darwin EU advisory board, the World Health Organization (WHO) Europe Access to Novel Medicines Platform, and the Heads of Medicines Agencies/European Medicines Agency (HMA/EMA) Joint Network Data Steering Group. Beate Wieseler (Institute for Quality and Efficiency in Health Care, Germany) is the representative in the ACT-EU (Accelerating Clinical Trials in the EU) multi-stakeholder platform advisory group.