



# Report on Emerging Health Technologies - 2025

*This report was funded by the EU4Health Programme via a service contract with the European Health and Digital Executive Agency, acting under the mandate of the European Commission. 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.*

---

Disclaimer:

The intelligence outlined in this report may be subject to change. Medicinal products, medical devices or in vitro diagnostic medical devices may be added or removed from this overview following the identification of new horizon scanning signals (e.g., company announcements, clinical trial factors etc.). The estimated number of medicinal products provided in this report is subject to much uncertainty. The estimated regulatory submission timelines are also subject to change. Various factors can alter these timelines including company announcements regarding data availability or timelines around regulatory intent to make a marketing authorisation application to the European Medicines Agency.

## Contents

<b>List of abbreviations .....</b>	<b>4</b>
<b>1. Introduction and purpose of the report.....</b>	<b>5</b>
<b>2. Types of Emerging Health Technologies included in the report .....</b>	<b>5</b>
<b>3. Methodology and sources of data.....</b>	<b>6</b>
<b>4. Emerging Health Technologies .....</b>	<b>8</b>
<b>4.1. Medicinal products (oncology).....</b>	<b>8</b>
<b>4.2. Medicinal products (ATMPs).....</b>	<b>8</b>
<b>4.3. Medical devices.....</b>	<b>9</b>

**List of abbreviations**

<b>Abbreviation</b>	<b>Definition</b>
ATMP	Advanced Therapy Medicinal Product
EMA	European Medicines Agency
EMDN	European Medical Device Nomenclature
ENT	Ear, Nose, and Throat
FDA	U.S. Food and Drug Administration
IHSI	International Horizon Scanning Initiative
IVD	<i>In Vitro</i> Diagnostic Medical Device
JCA	Joint Clinical Assessment
MedDRA	Medical Dictionary for Regulatory Activities
PRIME	Priority Medicines

## **1. Introduction and purpose of this report**

In accordance with Article 22 of Regulation (EU) 2021/2282 on Health Technology Assessment (HTA) <sup>(1)</sup>, the HTA Coordination Group (CG) requested the Emerging Health Technologies 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. Whilst retaining some uncertainty, the reports aim to support the HTA Coordination Group in planning its work, particularly in relation to joint clinical assessment (JCA).

This report fulfils the obligation to publish anonymised, aggregated, non-confidential information as referred to in Article 30(3) (m) of the EU HTA Regulation. It also promotes transparency and public awareness of the EU HTA Regulation.

## **2. Types of Emerging Health Technologies included in this report**

### Medicinal products

The Emerging Health Technologies Subgroup has taken into account the scientific specifications of medicinal products subject to JCAs as agreed by the HTA Coordination Group <sup>(2)</sup>. Medicinal products included in this 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 (ATMPs) <sup>(3)</sup>, for which the therapeutic indication is the treatment of any medical condition.

---

<sup>(1)</sup> Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU

<sup>(2)</sup> Scientific specifications of medicinal products subject to joint clinical assessments as agreed by the HTA Coordination Group (HTACG) at its meeting on 10 June 2024.

<sup>(3)</sup> The scientific recommendation on classification of ATMPs at the European Medicines Agency (EMA) is an optional procedure, hence there is a need to identify those ATMPs which have not undergone the voluntary EMA classification process. Potential ATMPs are defined as medicinal products which could fall into the criteria for ATMPs set out in Article 17 of Regulation (EC) No 1394/2007.

This report also highlights where medicinal products have regulatory designations which may be of special interest such as orphan designations from the European Medicines Agency (EMA) and/ or United States Food and Drug Administration (FDA), or Priority Medicines (PRIME) designation from the EMA. Such designations can signify specific regulatory pathways or rare indications, which is of relevance for joint work under the EU HTA Regulation.

#### Medical devices and *in vitro* diagnostic medical devices (IVDs)

Article 7(1) points (c) and (d) of the EU HTA Regulation detail the medical devices and IVDs subject to JCA if selected pursuant to Article 7(4) of that Regulation. Medical devices that are potentially eligible for JCA from 2026 are included in this report. Data limitations prevent the inclusion of IVDs in this report.

### **3. Methodology and sources of data**

The Emerging Health Technologies Subgroup requested horizon scanning intelligence from multiple relevant sources to support the development of this report.

For medicinal products, these included the EMA<sup>(4)</sup>, the International Horizon Scanning Initiative (IHSI)<sup>(5)</sup>, national horizon scanning systems within the Emerging Health Technologies Subgroup, and the HTA Stakeholder Network.

In the end, only data from the EMA and IHSI were used to inform the preparation of this report.

---

<sup>(4)</sup> As per the Implementing Regulation (EU) 2024/2699, the EMA provided data to the Emerging Health Technologies Subgroup. All information was provided by the EMA to the Emerging Health Technologies Subgroup in confidence, and has been anonymised and aggregated for the purposes of this report.

<sup>(5)</sup> IHSI is the primary horizon scanning resource for a number of member states and was used to provide horizon scanning intelligence to the Emerging Health Technologies Subgroup. IHSI is a publicly funded body which uses publicly available data only. See <https://ihsi-health.org/>

In order to comply with the requirement to provide aggregated, non-confidential information, this report provides anonymised information at aggregate level using Medical Dictionary for Regulatory Activities (MedDRA) terminology.

The information contained in this report was compiled using available data from September 2025. It is recognised that information on the development of medicinal products is subject to uncertainty, and this should be considered when reading this report. The development of medicines is complex and varied. Readers of this report should be mindful that there is considerable uncertainty associated with predicting when medicines will reach particular developmental and regulatory milestones. International publications describe attrition rates up to 40%<sup>(6)</sup>. However, this can vary considerably depending on the technologies and therapeutic areas. Factors to consider are clinical trial failures, delays, global policy changes, and commercial strategies.

For medical devices, this report also contains anonymised, aggregated, non-confidential information. The information, dated April 2025, was provided by the EMA in accordance with Article 2(2) of Commission Implementing Regulation (EU) 2024/2699<sup>(7)</sup>. No other data source was used. In 2026, the Emerging Health Technologies Subgroup will explore directly how relevant manufacturer associations could provide data via the HTA Stakeholder Network.

---

<sup>(6)</sup> Schuhmacher, A., Hinder, M., Brief, E., Gassmann, O. and Hartl, D., 2025. Benchmarking R&D success rates of leading pharmaceutical companies: an empirical analysis of FDA approvals (2006–2022). *Drug Discovery Today*, p.104291.

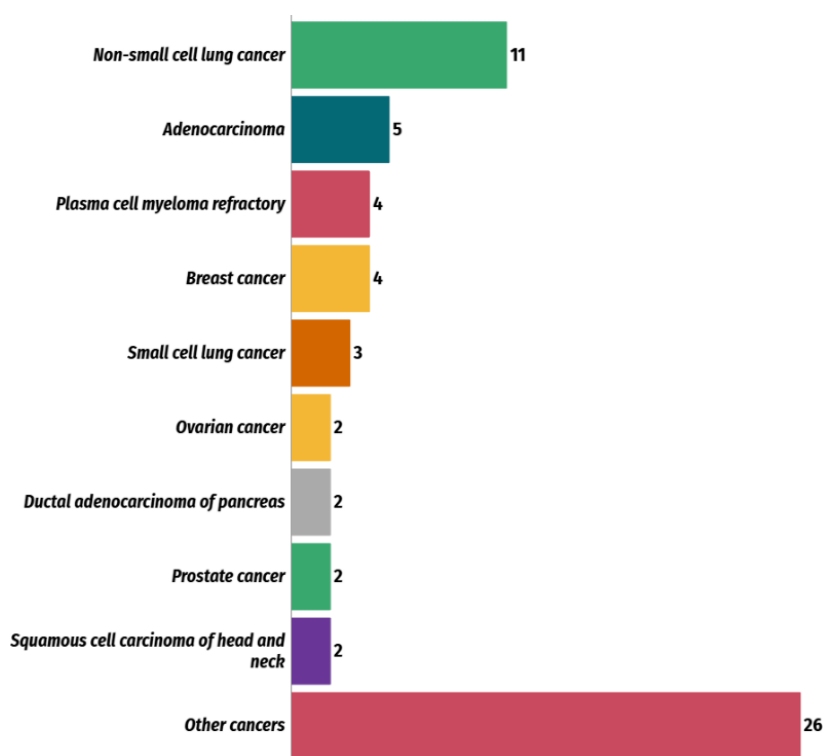
<sup>(7)</sup> Commission Implementing Regulation (EU) 2024/2699 of 18 October 2024 laying down, pursuant to Regulation (EU) 2021/2282 of the European Parliament and of the Council, detailed procedural rules for the cooperation of the Member State Coordination Group on Health Technology Assessment and the Commission with the European Medicines Agency in the form of exchange of information as regards the joint clinical assessment of medicinal products and medical devices and in vitro diagnostic medical devices and as regards the joint scientific consultation on medicinal products and medical devices.

## 4. Emerging Health Technologies

### 4.1. Medicinal products (oncology)

In total 61 medicinal products with unique therapeutic indications for oncology were identified. These products may be eligible for JCA under the EU HTA Regulation in 2026. Of these, 6 have PRIME designation from the EMA, 21 have orphan designation from the EMA and/ or FDA, and 9 may potentially be regulated as ATMPs.

**Figure 1: Medicinal products for oncology which may be eligible for JCA in 2026**

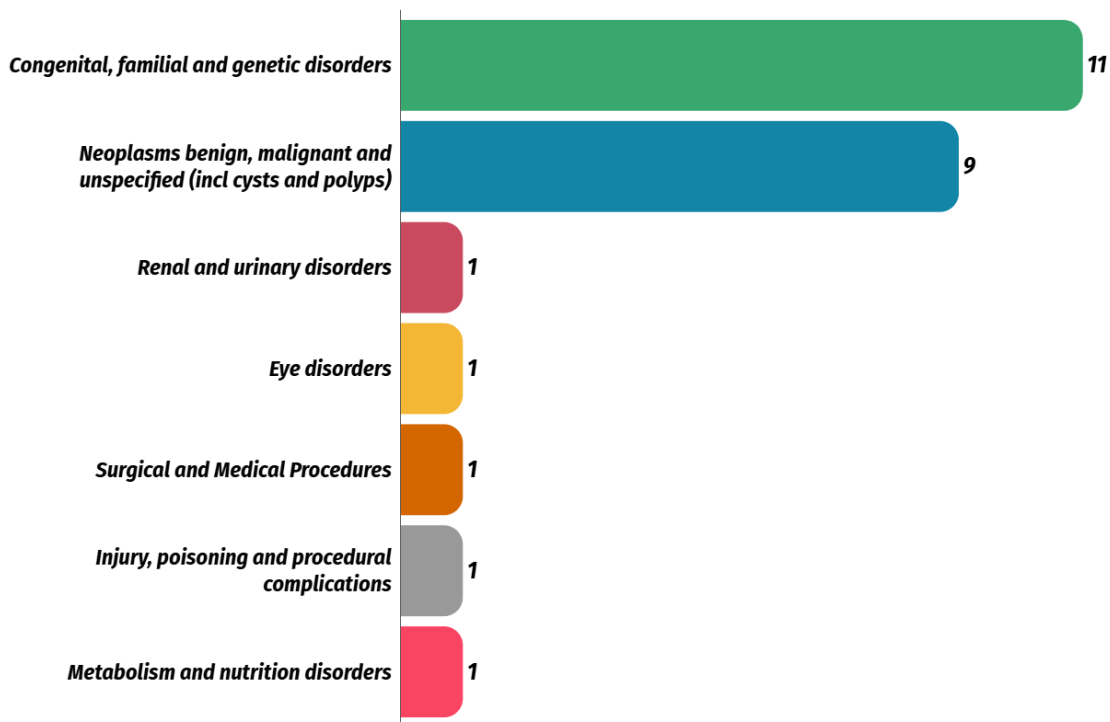


Source: Emerging Health Technologies Subgroup based on data from EMA and IHSI

### 4.2. Medicinal products (ATMPs)

In total 25 ATMPs with unique therapeutic indications were identified. These may be eligible for JCA under the EU HTA Regulation in 2026. Of these, 8 medicinal products have PRIME designation from the EMA, 17 have orphan designation from the EMA and/ or FDA, and 9 are cancer medicinal products.

**Figure 2: ATMPs which may be eligible for JCA in 2026**

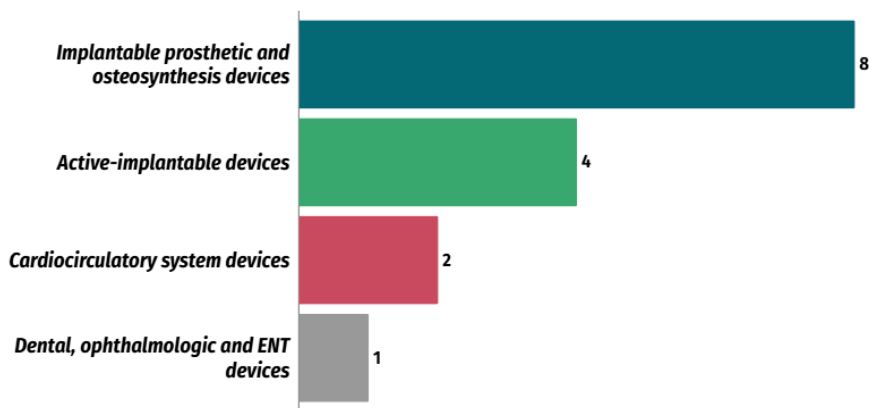


Source: Emerging Health Technologies Subgroup based on data from EMA and IHSI

### 4.3. Medical Devices

Fifteen medical devices have undergone scientific advice with the EMA expert panels over a period of 12 months and may potentially be eligible for JCA as of 2026.

**Figure 3: Overview of medical devices that have benefited from or are currently undergoing scientific advice by the EMA per European Medical Device Nomenclature (EMDN) area, and that may be eligible for JCA from 2026**



Source – Emerging Health Technology Subgroup based on data from EMA