THE EVOLVING HORIZON OF ONCOLOGY: PREDICTING THE IMPACT OF THE EU HTA REGULATION FOR 2026-2029

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Introduction

In January 2025, the new European Regulation on Health Technology Assessment (HTAR) entered into force, introducing a harmonized framework for the evaluation of medicinal products across Member States. Under this regulation, all oncological New Therapeutic Entities (NTEs) and Advanced Therapy Medicinal Products (ATMPs) submitted for Marketing Authorization (MA) are now subject to mandatory Joint Clinical Assessment (JCA). This requirement also extends to applications for indication extensions of these products.[1]

Following a three-year period, the scope of mandatory JCAs will be expanded to include orphan medicinal products, further broadening the reach of joint evaluations at the European level starting from 2028.[1]

In the initial months of implementation, eight JCAs for oncological products have already been initiated.[2] This marks a pivotal phase in the application of the new regulatory framework, during which Member States and regulatory authorities are still actively preparing to navigate the upcoming shift in the paradigm of clinical evidence evaluation for these products.

Building upon a previous analysis, this study aims to estimate the number of JCAs that may be conducted for oncology medicines in the upcoming phases of HTAR implementation. The projection includes oncological and oncohematological NTEs and indication extensions, expected to submit MA applications between 2026 and 2029.

Methods

To estimate the number of oncological and oncohematological New Therapeutic Entities (NTEs) likely to submit a Marketing Authorization (MA) application between 2026 and 2029, including those undergoing Joint Clinical Assessment (JCA) for indication extensions, an analysis was performed on all active clinical trials involving antineoplastic medicines. Data were retrieved from the IQVIA Pipeline Link database, which tracks pipeline projects across approximately 600 diseases in 75 countries, providing detailed information on disease area, therapeutic class, and regulatory status.

Given the time horizon considered, only phase II and III trials were included, while phase I studies were excluded due to their longer development timelines and lower probability of success in early-stage research.

In accordance with the HTAR,[1] among all oncological and oncohematological medicines in phase II or III of clinical development, the analysis focused on medicines being studied for their first indication. This was done by excluding molecules already approved, those under investigation for additional indications, and biosimilars. For products involved in multiple trials, the study corresponding to the primary indication was identified, selecting either the most advanced phase or the earliest initiated trial.

From this pool, NTEs potentially eligible for MA submission between 2026 and 2029 were identified based on the median time from trial initiation to EMA submission, as derived from historical data from an IQVIA database on Italian negotiation dynamics. Given the Likelihood of Approval (LoA) for oncological and oncohematological NTEs retrieved from literature,[3] the number of products expected to reach EMA evaluation directly from phase II or III trials was calculated. In particular, the likelihood of FDA approval[4] was used as a proxy. It was assumed that these rates would also be applicable to EMA approval, as EMA and FDA reportedly have a high concordance (up to 98%) in their marketing authorization decisions.[4]

Additionally, the number of NTEs currently in phase II that may progress to phase III and submit a MA application by 2029 was estimated by considering the median duration of phase II trials,[5] the Probability of Transition (PoT) to phase III,[3] and the time required for EMA submission.

Lastly, an estimate was made of the number of oncological drugs that may undergo JCA for an extension of indication by 2029. This included both the selected NTEs and those evaluated during the first year of HTAR implementation (n=12, considering that, by September 2025, 8 JCAs for oncological products have been initiated).[2] To inform this estimate, all oncological and oncohematological products with a positive CHMP opinion for their first indication between 2015 and 2020 were analyzed, and the number of additional approved indications within a five-year window was retrieved. This historical trend was used to project the number of future indication extension submissions for the selected NTEs by 2029.

Figure 1. ***Number of estimated JCA processes between 2026 and 2029 for NTEs***

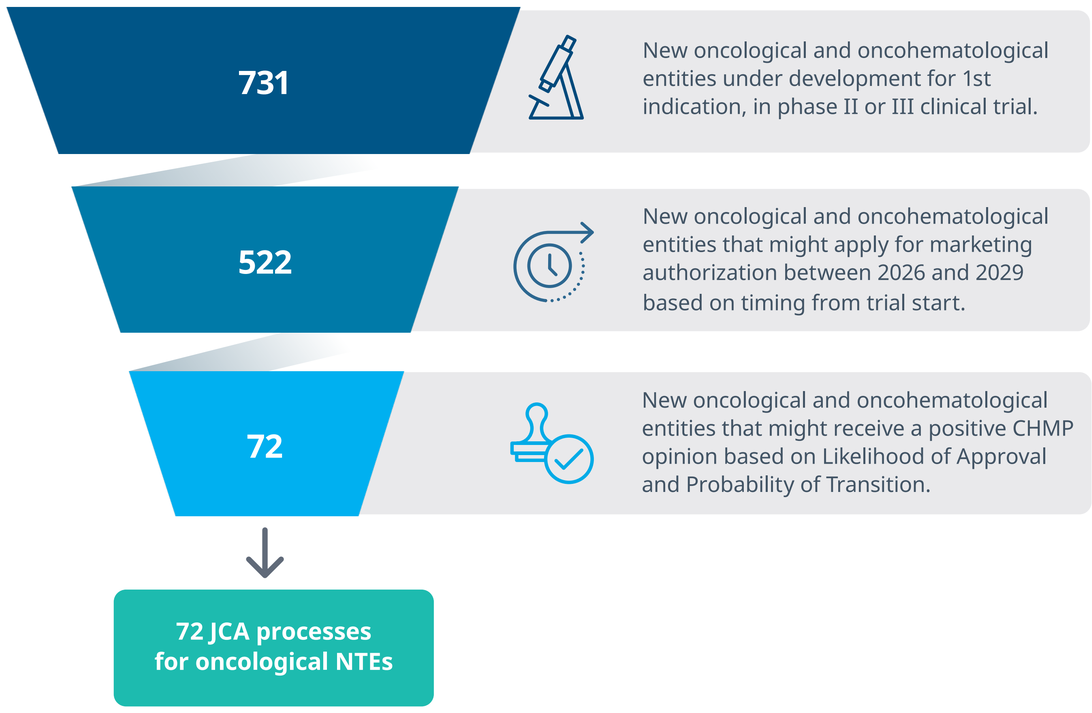
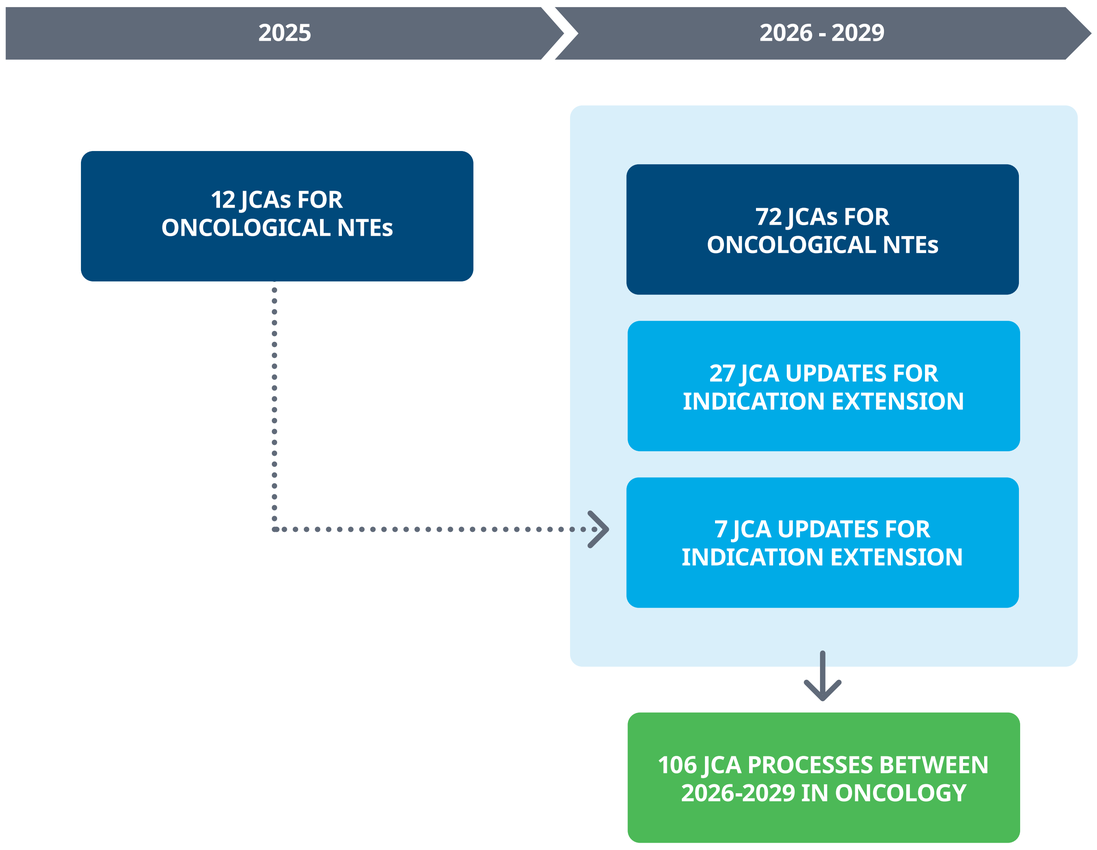


Figure 2. ***Estimated JCA processes update for indication extensions between 2026 and 2029***



Results

The analysis of the IQVIA Pipeline Link database identified a total of 6,583 ongoing clinical trials at the time of data extraction, with oncological and oncohematological studies representing 44% (2,884) of the total. Of these, 954 phase II and 472 phase III clinical studies were in progress.

Among all oncology and oncohematology products under investigation, 731 NTEs were identified as being in development for their first indication, with about 30% involved in phase III and 70% involved in phase II clinical studies.

Elaborating on an IQVIA database on Italian negotiation dynamics, a median duration of 3.7 years from pivotal trial initiation to EMA submission was observed for anticancer drugs. This led to the identification of 522 NTEs that could potentially reach EMA evaluation between 2026 and 2029, including 441 oncology and 81 oncohematology medicines.

Based on the likelihood of approval (LoA) for phase II oncological (6.3%) and oncohematological (13.1%) drugs, it was estimated that 13 oncology and 5 oncohematology NTEs may proceed directly to EMA evaluation from phase II trials by 2029. Additionally, 62 products were projected to transition from phase II to phase III. Considering all phase III products – both those already in phase III and those expected to transition from phase II – and applying LoA rates for phase III oncology (27.3%) and oncohematology (45.4%) drugs, it was estimated that 54 oncology and 18 oncohematology NTEs could potentially undergo EMA evaluation from phase III trials by 2029.

In total, 72 new oncological entities are expected to undergo the JCA process between 2026 and 2029 (*Figure 1*).

Lastly, by applying historical trends in the rate of indication extensions for cancer drugs, an additional 34 JCA processes for indication extensions were projected by 2029. This results in an estimated total of 106 JCA processes to be conducted between 2026 and 2029 (*Figure 2*).

Conclusions

Our analysis estimates that approximately 100 JCA processes will be conducted for oncological medicinal products between 2026 and 2029. The estimated trend of JCA processes in the 2026–2029 period is higher than in 2025, reflecting both the increasing routinization of the process, and the expansion of the JCA requirement to additional therapeutic indications as foreseen by the HTA Regulation.

The implementation of HTAR introduces a new regulatory framework that will progressively impact local evaluation practices, data collection, and evidence generation. As the scope of joint assessments expands, continuous monitoring and strategic planning will be essential to anticipate changes and ensure alignment with evolving requirements.

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