Frequency and Variation of Clock-Stop During EMA Assessment for Oncology Products – Implication on JCA Timelines

HPR86

Cervelo Bouzo P[1], Wang T[1], Lara J[1], McAuslane N[1]

[1]Centre for Innovation in Regulatory Science, London, UK

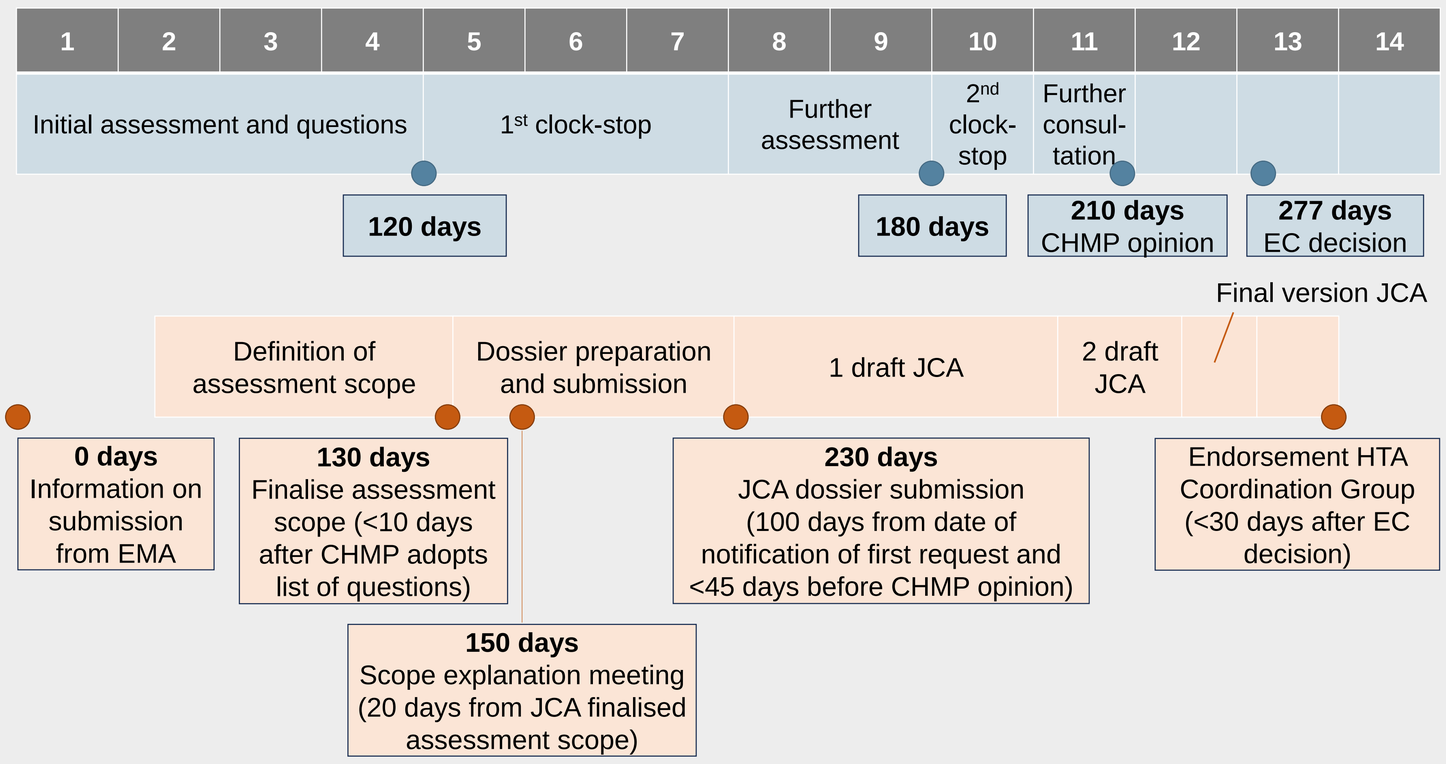
Introduction

The implementation act adopted for the EU HTA regulation defined the timelines of scoping, submission and output of Joint Clinical Assessment (JCA), which will be in parallel with the European Medicines Agency (EMA) timelines.

Objective

This study aims to analyse the breakdown of EMA review cycle time, frequency and variation of clock-stops in the approval process of oncology new active substances (NASs), to understand the variation on company response times and the potential influence on JCA dossier submission and review timelines.

Fig 1. Timeline (months) of EMA assessment (standard review) and JCA process



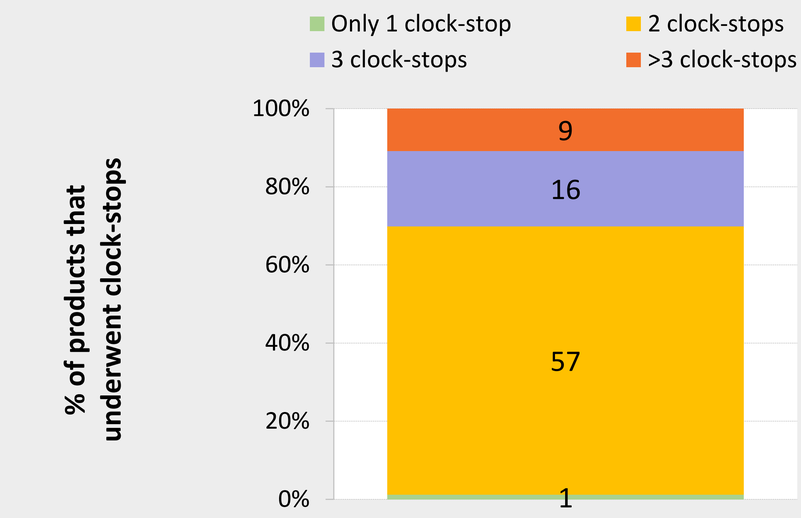
Methods

Data was extracted from EMA reports from oncology NASs approved between 01-Jan-2019 to 31-Dec-2023. Scientific assessment time is calculated by start of scientific assessment to the outcome letter, clock-stop time was calculated as the timing between the release of outcome letters and the response from sponsors from oncology NASs approved for each cycle of communication. All timelines in this study are calendar days.

Results

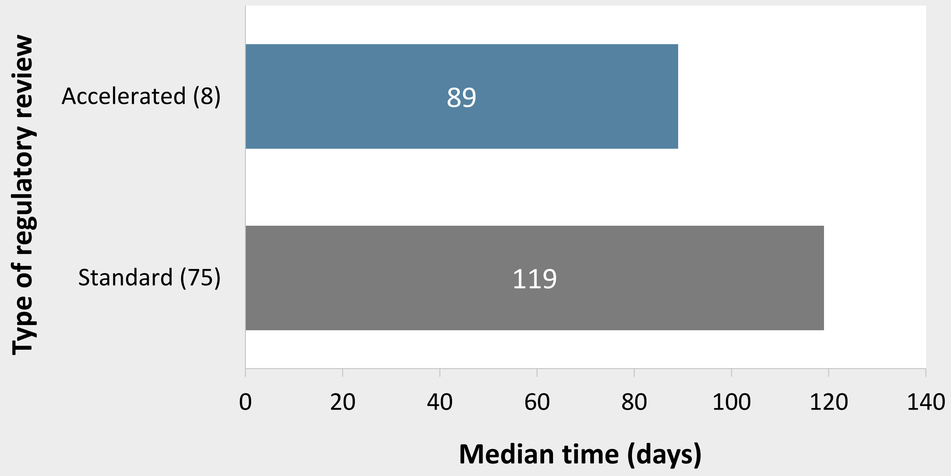
The first clock-stop occurred in 100% (n=83) of the oncology products and only one of these products did not undergo more than one clock-stop (Fig 2). Almost 70% (n=57) of the products underwent 2 clock-stops while the remaining oncology products completed 3 or more than 3 clock-stops.

Fig 2. Proportion of oncology products that underwent clock-stops (EMA approvals between 2019-2023)



The time for the first scientific assessment for standard reviews lasted a median of 119 days (95% CI: 119, 119) and a median of 89 days (95% CI: 89, 89) for accelerated reviews (Fig 3).

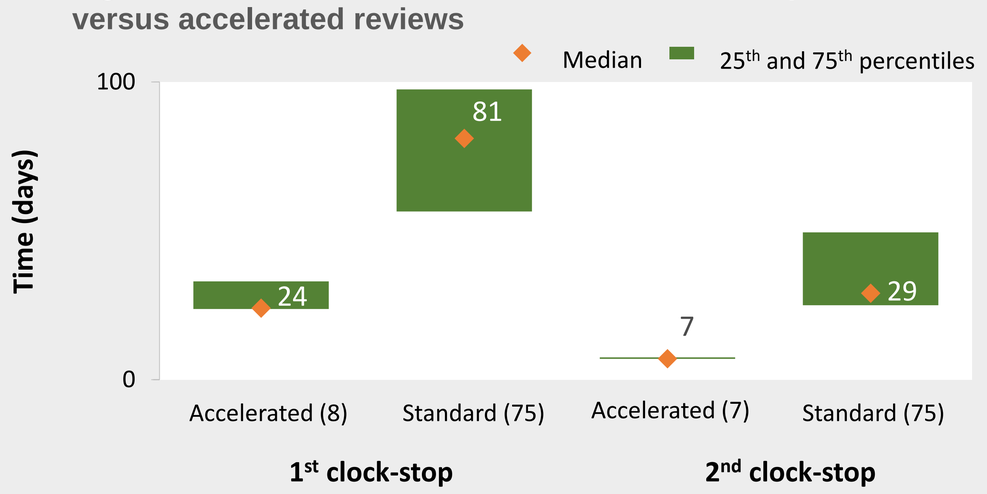
Fig 3. Median time of the 1st scientific assessment in standard versus accelerated reviews



For standard reviews, the first clock-stop had a median duration of 81 days, with a variation ranging from 57 days (25th percentile) to 98 days (75th percentile), followed by the second clock-stop (median time 29, variation 25 to 50) (Fig 4).

The first clock-stop of accelerated reviews lasted a median of 24 days (95% CI: 24, 33) while the second clock-stop lasted a median of 7 days (95% CI: 7, 8).

Fig 4. Variation of duration of 1st and 2nd clock-stops in standard versus accelerated reviews

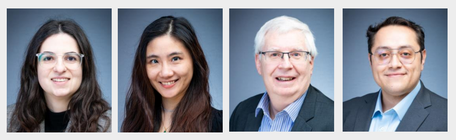


Conclusion

Our analysis demonstrates that both the first and second clock-stops were used in almost all of the oncology products, with a lower likelihood of more than 2 clock-stops occurring. The variation of clock-stop durations builds in variability into the EMA review process, therefore, early awareness and preparation of JCA is required within companies to ensure the parallel process is aligned and efficient.

Center for Innovation in Regulatory Science

Mission: To maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and HTA policies and processes in developing and facilitating access to pharmaceutical products.



Contact: pcervelo@cirsci.org; twang@cirsci.org; jlara@cirsci.org; nmcauslane@cirsci.org

Presented at ISPOR Europe 2024, November 17 – 20, 2024, Barcelona, Spain