

ARE NICE ACHIEVING THEIR TIMELINES FOR REVIEWING HIGHLY SPECIALIST TECHNOLOGIES (HST) IN ENGLAND?

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Introduction/objective

- In 2012, the National Institute for Health and Care Excellence (NICE) introduced the Highly Specialised Technology (HST) program in England to enable patient access to medicines for rare diseases, which would struggle to meet the assessment standards of the single technology appraisal (STA) program
- Changes were made to the HST program in March 2017 in order to speed patient access to innovative treatments
- The HST process should take 168 days from submission, with draft recommendations published within 4 months of marketing authorisation (MA)¹.
- This research aims to determine whether NICE is becoming more efficient in evaluating medicines and treatments through the HST process. Specifically, the research aims to compare the length of assessment time between HST's conducted before and after the March 2017 update

Methods

- All completed HST evaluations published by NICE between November 2014 and July 2021 were included.
- Fifteen HST evaluations were analysed to understand the process timing, from preparation of the scope to the publication of the final guidance, as well as the publication of Evaluation Consultation Documents (ECDs) (Figure 1)
- To understand whether NICE has become more efficient in this process over time, the 15 HST evaluations were split between those with final scope published before and after the March 2017 update.

Figure 1: Methods flow diagram



Results

Figure 2: HST Process:



- NICE's HST process evaluates the use of highly specialised medicines and treatments indicated for very rare conditions within the NHS in England. The HST process is described in Figure 2
- The analysis showed that all 15 HST products have received a positive recommendation at the end of the appraisal process (Chart 1)
- For the HST process, the median time from the publication of the final scope to the publication of the final evaluation determination (FED) document was 348 days, with the range being from 234 to 1169 days. This is over twice as long as NICE's stated timelines for the HST (168 days) (Chart 2).

- For HST guidance prior to August 2017, the median days from final scope to FED was 352 days (range 312 - 944 days), compared to 302 days (range 234 - 1169 days) for HST guidance with the final scope published after March 2017 (Chart 2)
- Of the six pre-March 2017 HST guidance's, three required the publication of more than one ECD, compared to 0 in the post-March 2017 HST guidance process. This is shown in Chart 3, which lists the HST's in order of final scope publication date (oldest to newest).

Chart 1: Outcomes of HST evaluations

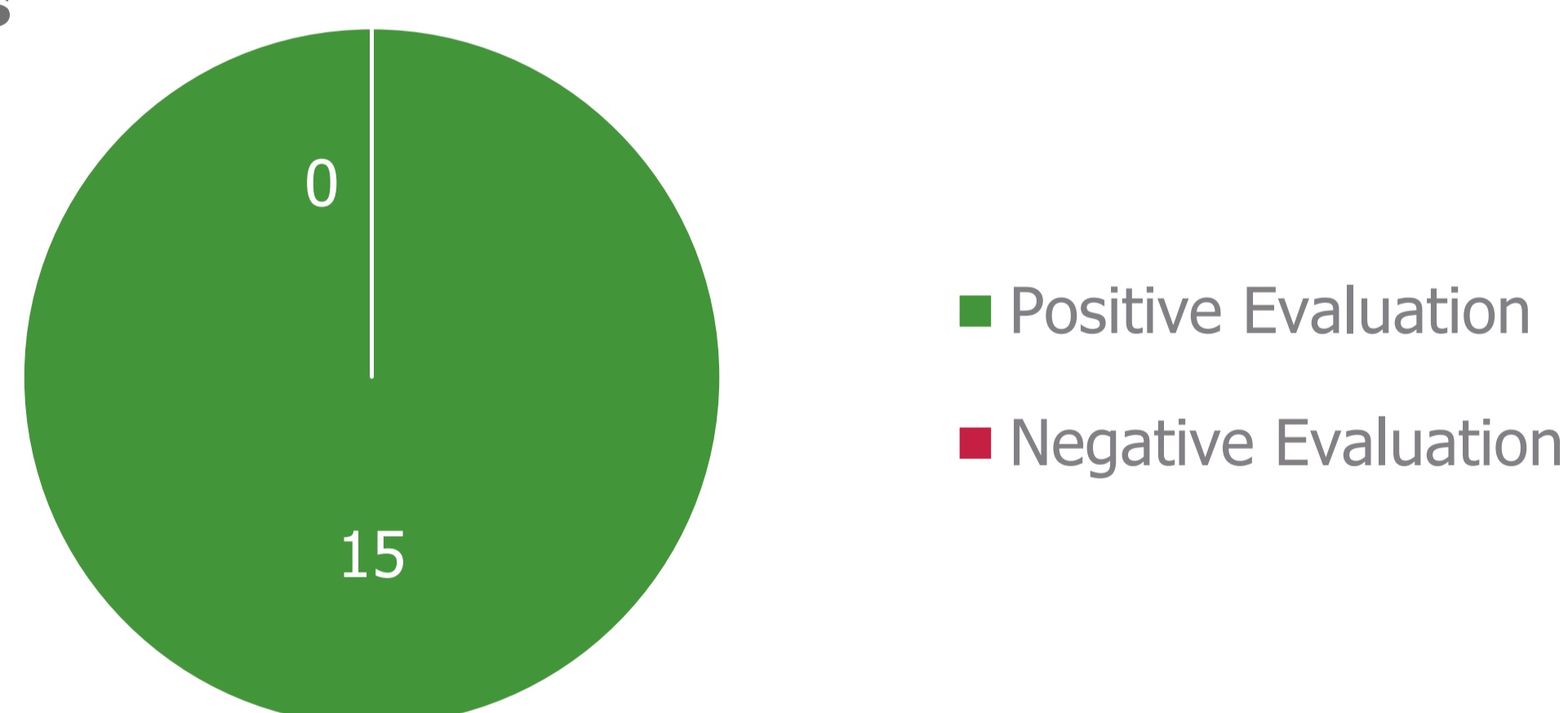


Chart 2: Median time (days) from final scope to FED

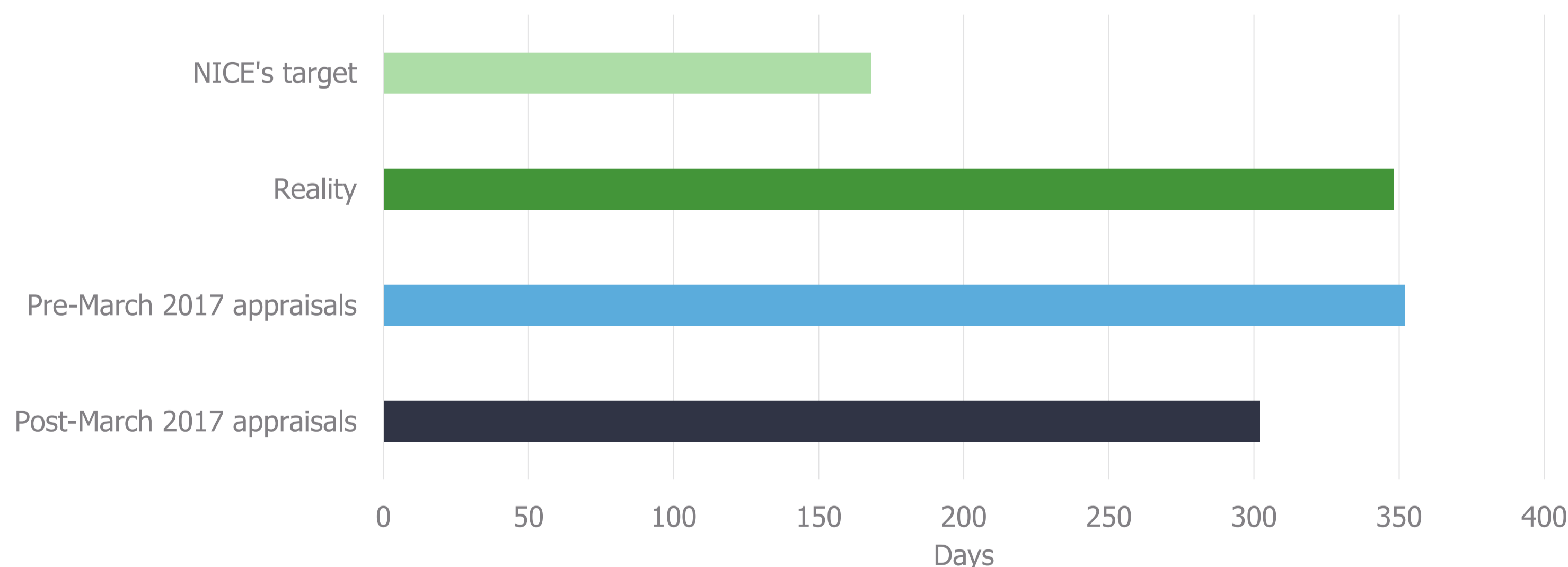
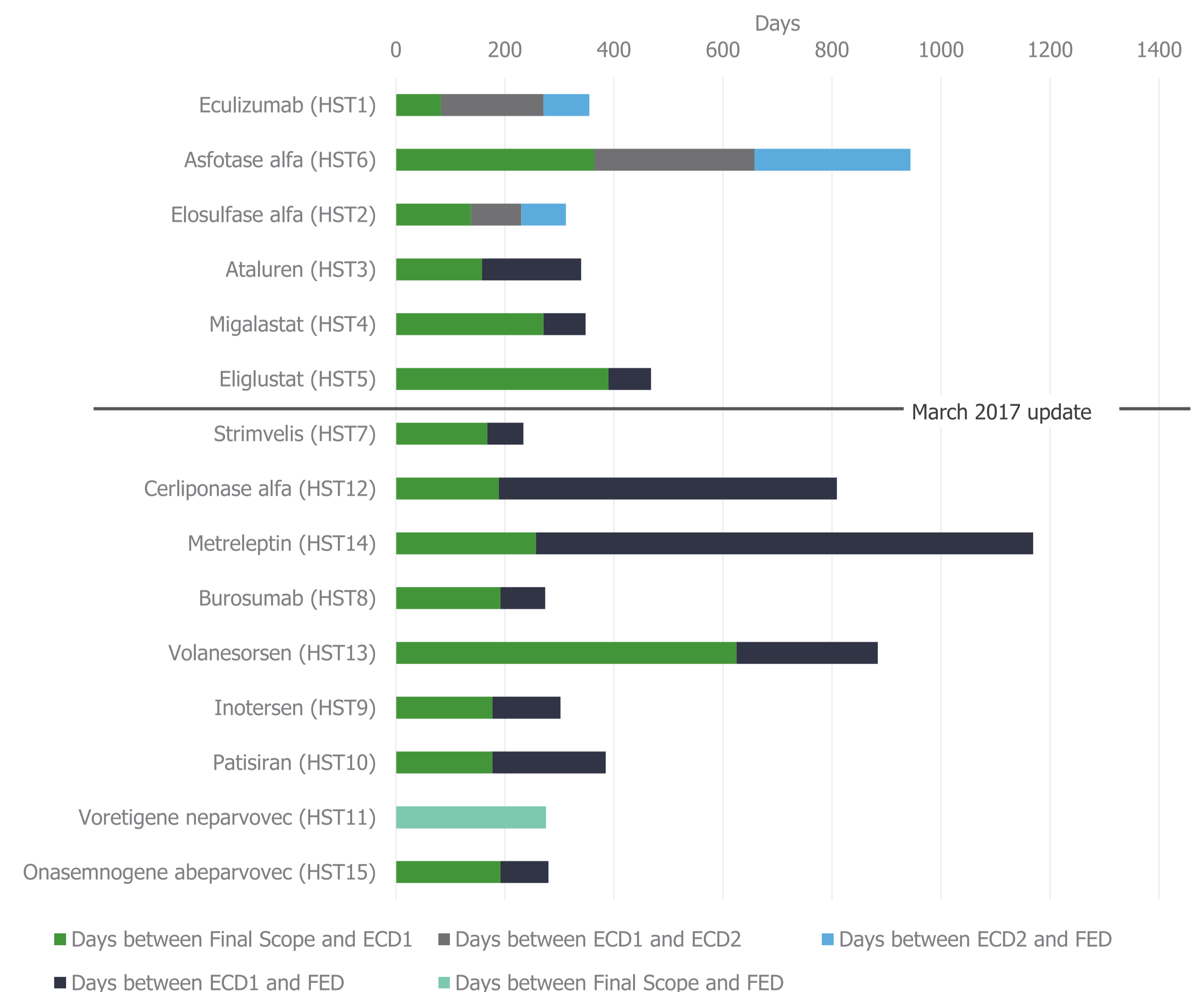


Chart 3: Timelines of HST publications



Discussion and conclusions

- The research showed that NICE are clearly far from their 168-day target for the HST process, with the reality being 107% higher than the target duration. It is questionable whether such a target will ever be achievable given the high complexity of the assessments accepted for the HST program
- Since the most recent HST methods update in March 2017, which were proposed to "benefit patients by providing access to the most effective and cost-effective new treatments more quickly"², the change in speed to patient access has been limited despite the reduced need for the publication of multiple ECD's. There is an obvious negative health consequence for patients, whose access to potentially life-changing medicines is still not optimal
- The primary change in the upcoming HST process update appears to be the proposal that the inclusion criteria is reduced from seven to four. Without clear changes proposed to address the current inefficiencies of the HST program, this could be a missed opportunity.

Abbreviations: ECD: Evaluation consultation document; FED: Final evaluation determination; HST: Highly Specialised Technologies; HTA: Health technology assessment; NICE: National Institute for Health and Care Excellence; STA: Single Technology Appraisal
 References: 1. NICE. 2021. NICE highly specialised technologies guidance. Available at: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-highly-specialised-technologies-guidance>; 2. NICE. 2017. Consultation on changes to technology appraisals and highly specialised technologies. Available at: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/consultation-on-changes-to-technology-appraisals-and-highly-specialised-technologies>