

# Has NICE Increased the Speed of Patient Access and Use of Financial Arrangements for New Oncology and Non-Oncology Drugs?

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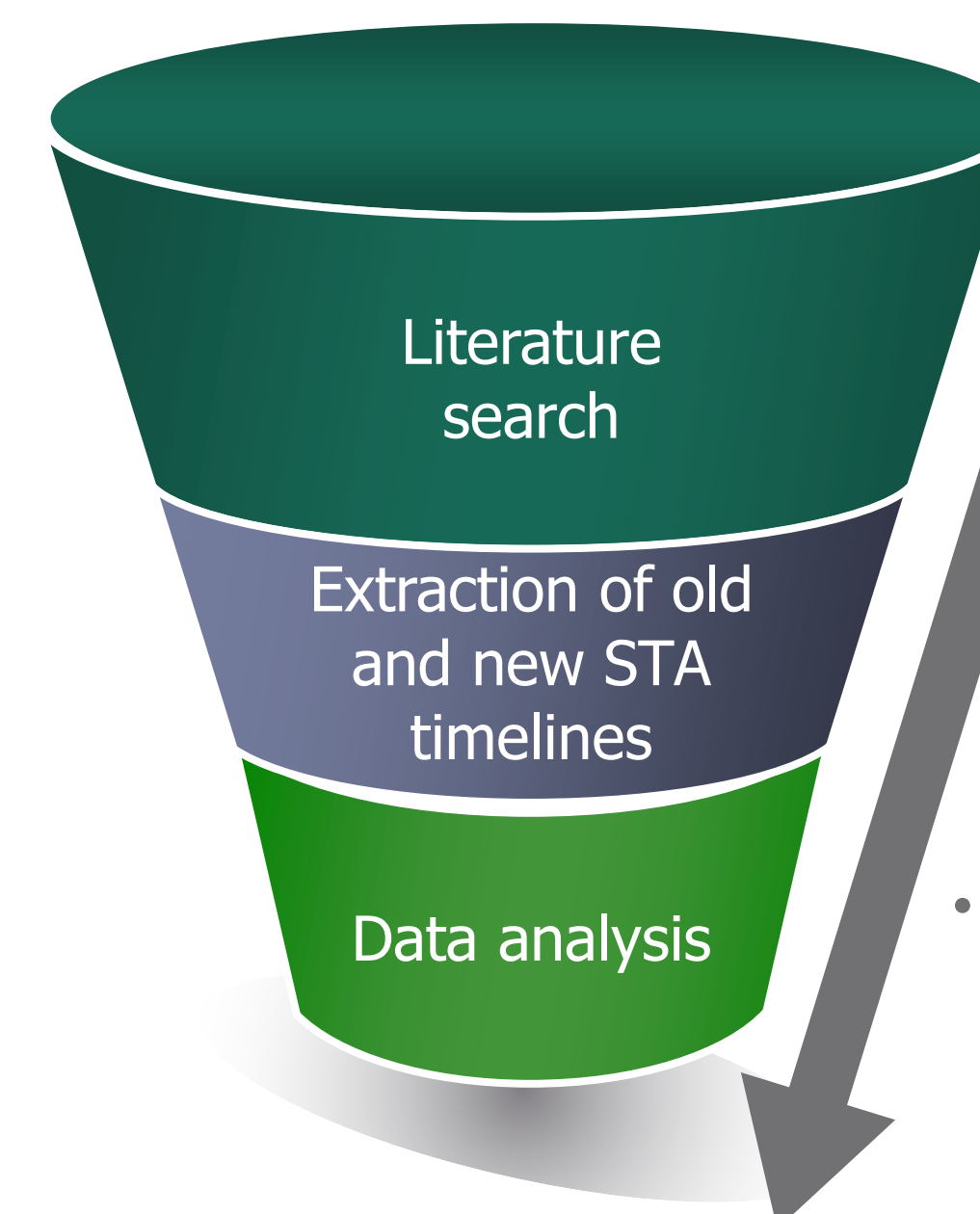


## Introduction/objective

- ▶ The National Institute for Health and Care Excellence (NICE) Single Technology Appraisal (STA) process is the principal route via which new pharmacological technologies are evaluated for a single indication in the English National Health Service (NHS).<sup>1</sup>
- ▶ In April 2018, NICE began the roll-out of a STA review process, which aimed to improve patient access by making the review process speedier.
- ▶ This led to the introduction of a technical engagement phase which resolves any issues within submissions prior to committee meetings and set a target of publishing guidance within 90-days of marketing authorisation (MA).
- ▶ The study was set out to review the timelines and use of financial agreements for products being appraised with the old (pre-April 2018) and new (post-April 2018) STA process.

## Methods

- ▶ STAs published by NICE between January 2017 and June 2020 were searched and identified on NICE's website.

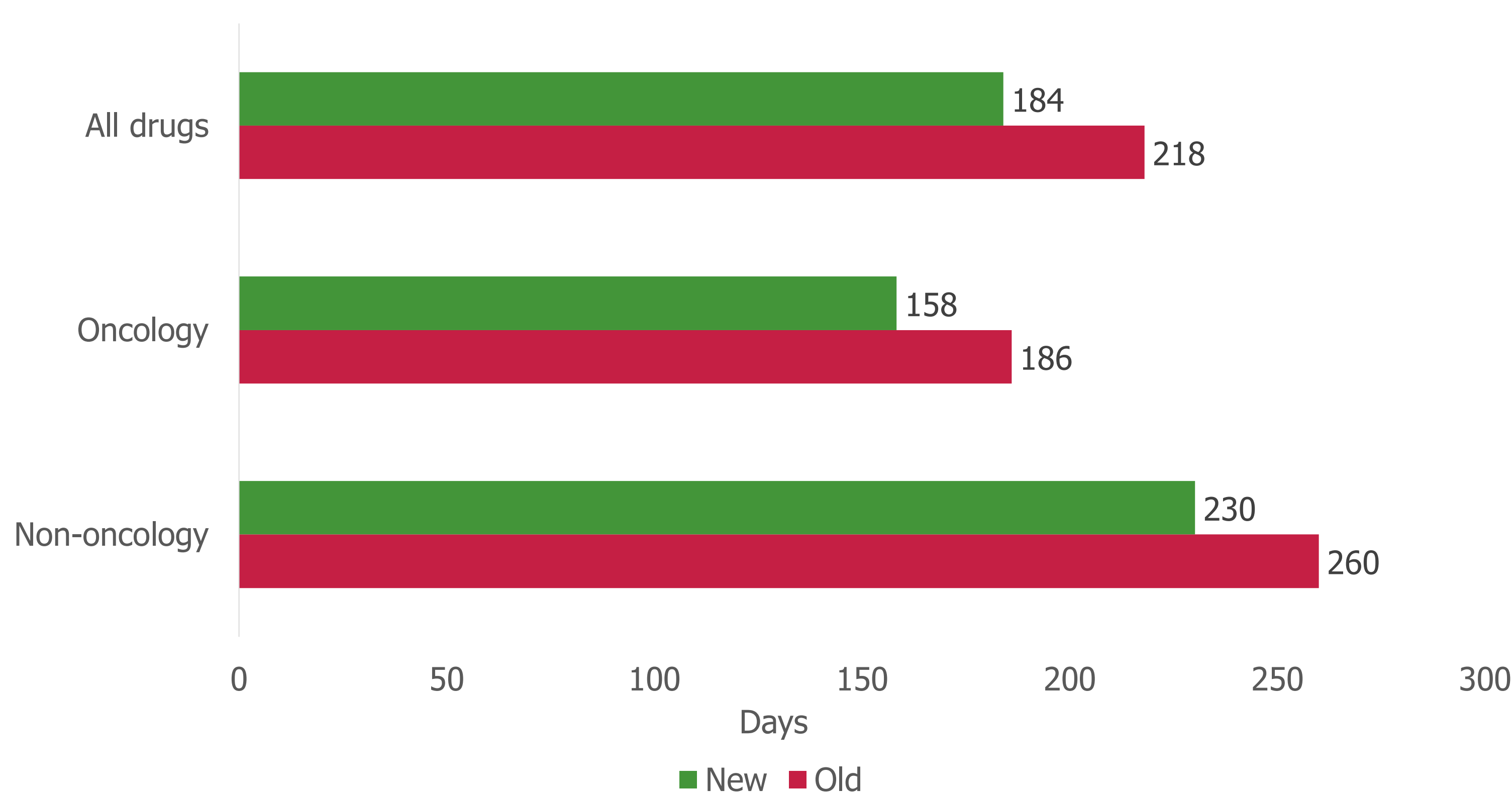


- A review of the available publications from all STAs between January 2017 and June 2020 was conducted on NICE's website.
- For each appraisal, data were extracted on timelines from MA to final appraisal determination (FAD), outcomes and use of financial arrangements.
- Data on oncology and non-oncology technology appraisals (TAs) were then analysed and compared for products subject to the old and new appraisal process, respectively.

## Results

- ▶ Overall, 148 appraisals were identified in the timeframe of interest. Of them, 18 (12%) were assessed by the new and 130 (88%) by the old STA process.
- ▶ On average, the time between MA and FAD publication was 34 days shorter for all products undergoing the new STA process compared to the old one, with an average duration of 184 vs 218 days, respectively (Figure 1).
- ▶ Timelines were 28 and 30 days shorter for oncology and non-oncology drugs with the new and old process, respectively.

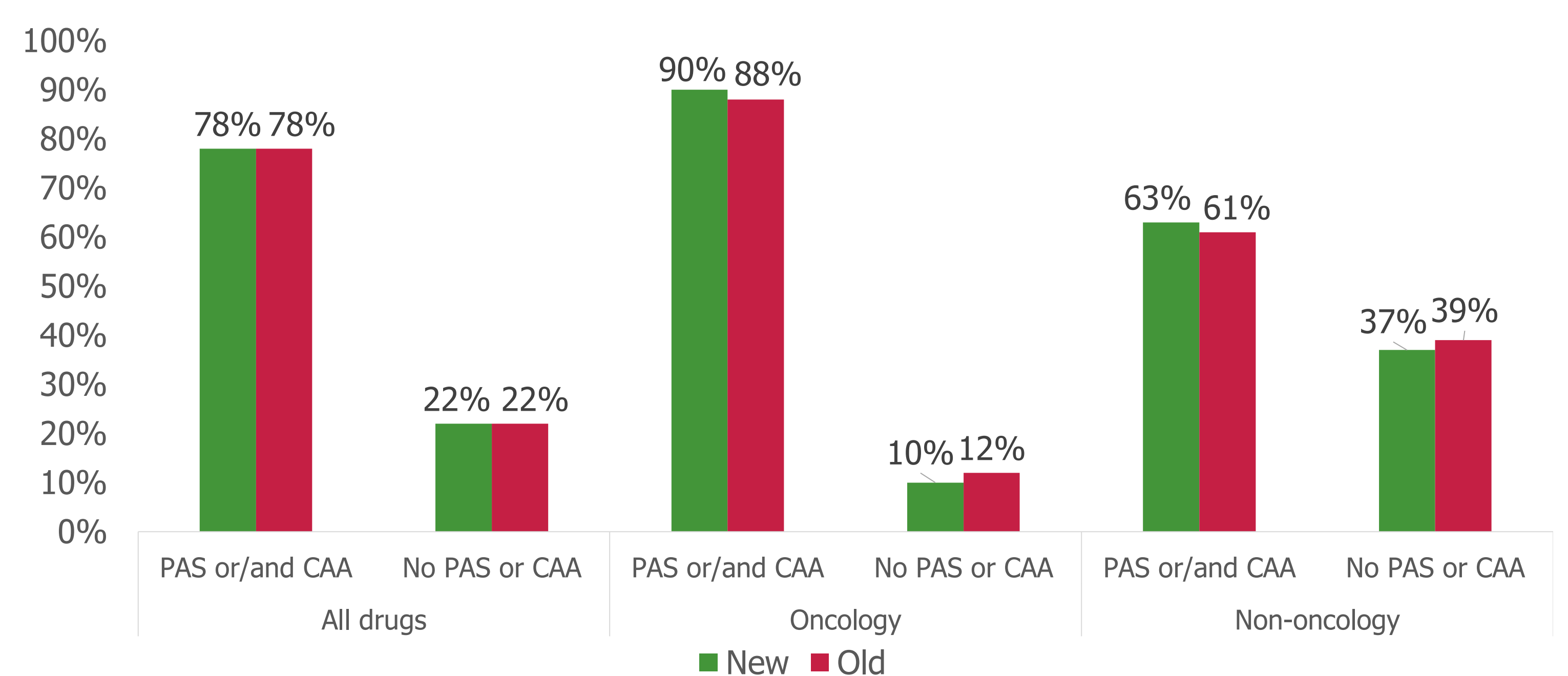
**Figure 1: Time from MA to FAD across oncology and non-oncology drugs with the old and new STA process by NICE<sup>2</sup>**



- ▶ For oncology drugs the new STA process resulted in an overall decrease in time between MA and FAD by 38 days, with an average duration of 158 days through the new process vs. 186 days with the old one.
- ▶ Similarly, the average STA process duration for non-oncology drugs was shortened by 30 days with the new STA process with an average duration of 230 days (new process), respectively.

- ▶ Overall, the new STA process by NICE did not result in any change in the utilisation of financial agreements across all treatments. The implementation of any financial agreement was equal (78%) with both processes.
- ▶ Financial agreements were implemented in similar proportions of oncology drugs following the new appraisal process and the old one (90% vs 88%). Proportions of non-oncology drugs subject to financial agreements were also similar: 63% (new process) vs. 61% (old process).

**Figure 2: Implementation of financial agreements across oncology and non-oncology drugs with the old and new STA process by NICE<sup>2</sup>**



- ▶ The implementation of the new STA process did not result in a remarkable change in the utilisation of one type of financial agreement over another (Patient access scheme (PAS) and Commercial access agreement (CAA)). Full breakdown of the financial agreements with the old and new STA process can be seen in Table 1 below.

**Table 1: Breakdown of implementation of PAS and CAA for oncology and non-oncology drugs with the old and new STA process by NICE<sup>2</sup>**

	All drugs		Oncology		Non-oncology	
	New	Old	New	Old	New	Old
Subject to a PAS only (no CAA)	55%	60%	50%	60%	63%	59%
Subject to a CAA only (no PAS)	11%	26%	20%	26%	0%	2%
Subject to a PAS and CAA	11%	1%	20%	1%	0%	0%
No PAS or CAA	22%	12%	10%	12%	38%	39%

## Discussion and conclusions

- ▶ The changes introduced to the STA protocol managed to alleviate delays and inefficient use of committee time for repetitive cost and commercial discussions.
- ▶ Although the new STA process has not met the 90-days post-MA target set by NICE, timelines for products undergoing the new process are approximately one month shorter compared to the old process, enabling earlier patient access. This will be highly beneficial especially for those patients who suffer from life-threatening conditions as it would allow them to gain access to drugs one month earlier.
- ▶ In contrast, there does not appear to be changes in the utilisation of financial arrangements. The same trend can be observed both with the old and the new STA process – PAS and CAAs are more widely implemented for oncology products than non-oncology ones. However, NICE have recognised this, which has resulted in them making further modifications to the new NICE process. The goal of these changes is to refine the Evidence Review Group (ERG) report, hence avoiding clinical experts' concern that they are being repeatedly asked the same questions during engagement.<sup>3</sup>
- ▶ It has been speculated that the changes associated with the new STA process may not significantly impact the overall efficiency of the process because of the small number of appraisals affected and other unexpected complications which often arise during STAs.<sup>1</sup>

Abbreviations: CAA: Commercial access agreement; FAD: Final Appraisal Determination; MA: Marketing Authorisation; NICE: National Institute for Health and Clinical Excellence; PAS: Patient access scheme; STA: Single Technology Appraisal

References: **1.** Walton, M.J., O'Connor, J., Carroll, C., Claxton, L. and Hodgson, R., 2019. A review of issues affecting the efficiency of decision making in the NICE single technology appraisal process. *Pharmacoeconomics-open*, 3(3), pp.403-410.; **2.** NICE. 2020.; **3.** Bresmed.com. 2020. NICE Technical Engagement Process: Navigating The Latest Changes – Bresmed.