

01. Introduction

When to submit to UK and Irish Health Technology Assessments (HTAs) is a balance. Too soon, and you will duplicate effort and miss key learnings from ongoing HTA decisions. Too late, and there is a missed opportunity for potential revenue, and risks of clinical trial data, systematic literature reviews (SLRs), and relevant comparators being outdated.

This research reviews the typical sequential approach for UK and Irish HTA submissions compared to an optimal timeline, whilst outlining the key decision points and considerations for each HTA agency.

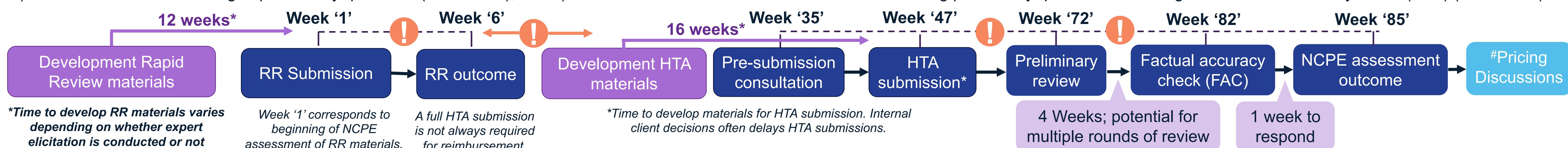
02. Methods

A typical sequential timeline that follows NICE, SMC, and NCPE HTA standard technology submissions, including the development of materials and HTA review/decision times, was first plotted; with submission timelines informed by the respective HTA body websites.

Periods of 'down-time' (!) were highlighted, demonstrating where time can be saved in a streamlined approach. Similar HTA submission requirements were also noted as potential duplications of effort. The sequential HTA timelines were segmented, and re-organised, to demonstrate the optimal workflow.

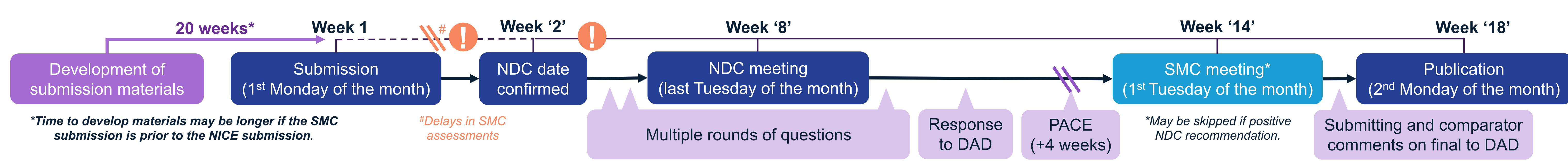
02a. NCPE Reimbursement Process

The average time from rapid review (RR) submission to HTA assessment outcome is 85 weeks (n=86, outcomes published 2022-24).¹ Significant 'down-time' exists between 1) RR outcome and HTA development, 2) HTA submission and issuing of preliminary questions (~25 weeks), and 3) from recommencement of the assessment following preliminary questions to issuing of the factual accuracy check (FAC) (~10 weeks).



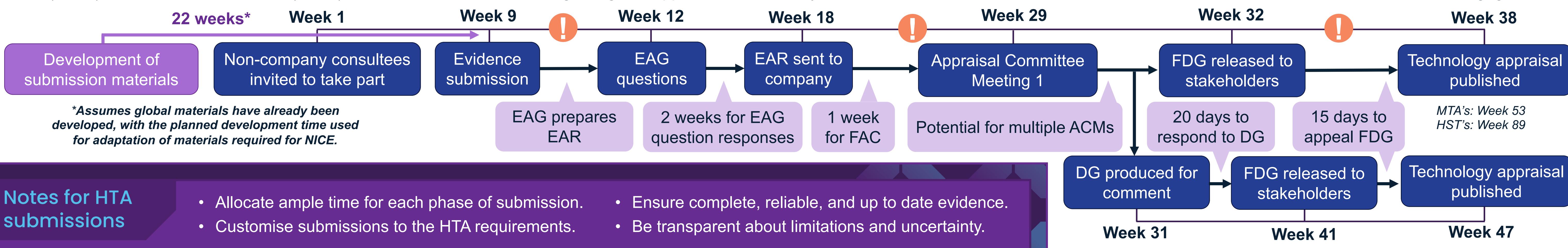
02b. SMC Reimbursement Process

"Ideal" timelines for an SMC assessment is 22 weeks with a Patient and Clinician Engagement (PACE) meeting,² and 18 weeks for Non-PACE. However, timelines are likely extended between the Company's submission and allocation of a New Drugs Committee (NDC) date by 1-2mo.



02c. NICE Reimbursement Process

Milestone dates for submission of materials are set ahead of time,³ with applicants required to adhere to timelines (linked to post-regulatory approval) or incurring fines for late submissions. In the event of multiple ACM's, there may be an opportunity to begin compiling submission materials for NCPE and SMC. For TAs with guidance published from 2024, 52% (40/77) had only one ACM before the final scope was published, 32% (25/77) had two ACMs, and 16% (12/77) had three or more. The average length of appraisal increased by 20 weeks between TAs that had one or two ACMs. Timelines do not consider technical engagement.

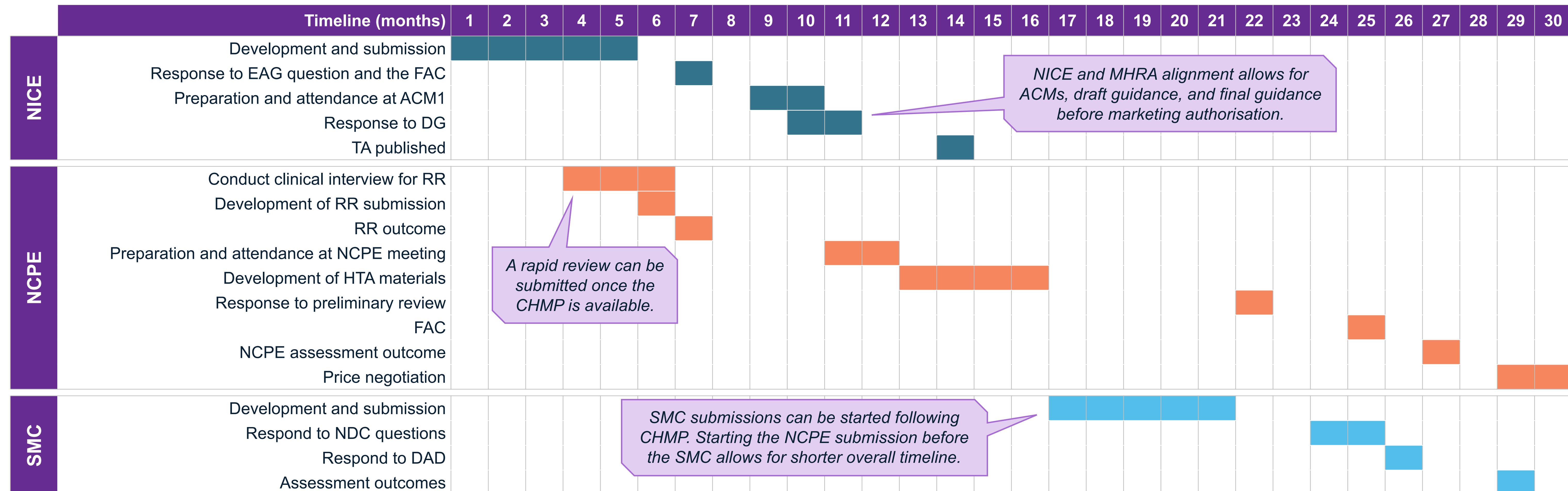


03. Results

In a sequential timeline, the sum of the time to reimbursement decision for all the three HTA agencies is approximately 4 years; this does not account for any delays in the SMC assessments, or multiple NICE ACMs. Given the requirements for each HTA agency to ensure use of the latest available clinical trial data, inclusion of relevant comparators, and SLRs searches to be within 6 months of the submission (not a requirement for the SMC), a **sequential timeline** involves duplication of effort and increased cost to update materials; projects that span several years may also involve personnel changes and a loss project knowledge. There is also a missed opportunity for potential revenue in the later HTA markets, specifically for Ireland where the NCPE submission process may span 2 years from RR submission and is often the last of the three HTA agencies a company submits too.

Mapping all three HTA submission as one continuous project in a **simultaneous timeline**, which considers both the highlighted 'down-time' and peaks of the projects, may reduce the project timelines from approximately 4 years to 2.5 years; a saving of 1.5 years. Estimated timelines includes development time, and the average time to HTA submission for standard technology appraisals.

Note, each HTA agency requires submissions to be relevant and up to date. This means expert opinion and advisory boards are required to be country specific or included representatives from the specified country. SLR searches need to be up to date, and each submission must include the latest available data and country-specific inputs.



04. Conclusions

- A sequential timeline is straightforward but is less efficient in time and resources (e.g. SLRs, CIs).
- A simultaneous timeline provides a more strategic approach and a faster overall time to HTA outcome across the three jurisdictions, once the specific requirements for each HTA body are fully met.
- Starting the NCPE submission process early is important given the longer full HTA submission processes and time between key dates, compared to NICE and the SMC.

Acronyms

ACM, Appraisal Committee Meeting; CHMP, Committee for Medicinal Products for Human Use; CI, clinical interviews; DAD, Detailed Advice Document; DG, Draft Guidance; EAG, Evidence Assessment Group; EAR, External Assessment Report; FAC, Factual Accuracy Check; FDG, Final Draft Guidance; NICE, National Institute for Health and Care Excellence; NDC, New Drugs Committee; PACE, Patient and Clinician Engagement; SMC, Scottish Medicines Consortium.

References

- National Centre for Pharmacoeconomics, Ireland (NCPE). Available at: ncpe.ie
- SMC Workshop, 2024.
- Single technology appraisal (STA) timeline, National Institute for Health and Care Excellence (NICE). 2025. Available at: nice.org.uk