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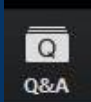
Reflecting on the NICE technical
engagement process – is it working?
What does it mean for you?

BresMed Health Solutions



BresMed™

Webinar housekeeping

- All participants will be on mute for the duration of the webinar
- We will be presenting our findings for approximately 45 minutes
- There will be interactive polls throughout the presentation
- We will use the last 10–15 minutes for a Q&A session
- Please use the webinar's Q&A functionality  to ask questions, and use the 'like' functionality to help prioritize the questions of most interest to you
- We will follow-up with responses to the Q&A to all participants

Your presenters



Dawn Lee
Chief Scientific Officer



Annie Barnes
Director, Consulting and Management

Special thanks to Tingting Qu, Grant McCarthy, Robert Kidd, Sam Taylor, Cameron Lilley and Hannah Dawson of BresMed

Objective of this webinar

To share our review of the first 20 STAs that have been through the new NICE technical engagement process, and present:

- The evidence we have gathered on whether the changes to the process is resulting in more efficient decision making (as was intended)
- Our learnings, insights and implications for how companies plan future appraisals

The five things you should do if you are a manufacturer planning ahead for a future appraisal

1 Be prepared!

2 Acknowledge the additional time and resources required upfront

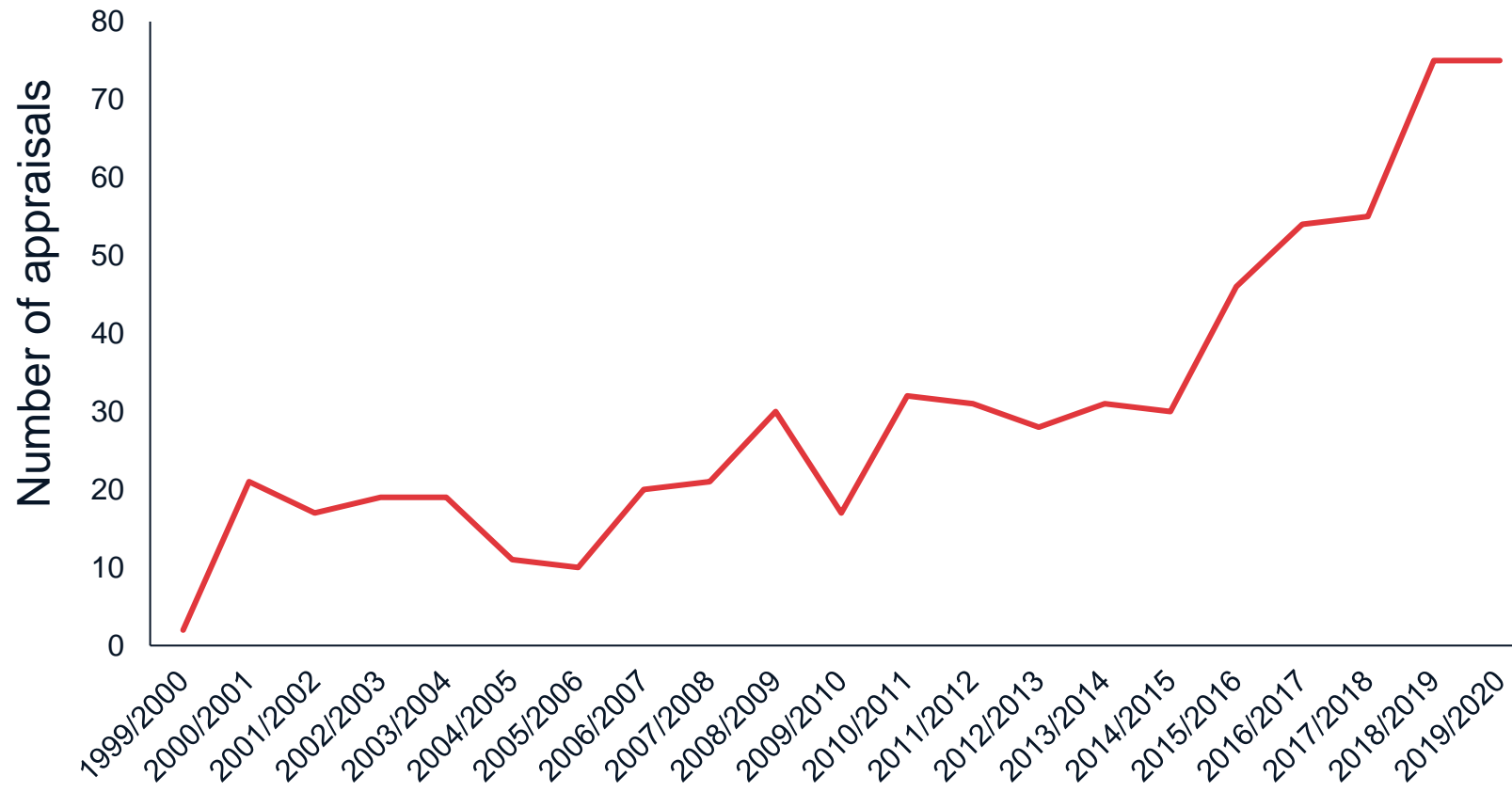
3 Push for correct attendees to be present at the technical engagement call

4 Take the opportunity to consider pricing

5 Expect the unexpected

The need for change...

The NICE TA programme produced an average of 30 appraisals per year before 2014–15.
There were 55 appraisals endorsed in 2017–18



Key: NICE, National Institute for Health and Care Excellence; TA, technology appraisal.

Source: <https://www.health-ni.gov.uk/articles/nice-endorsed-technology-appraisals-20172018>

During the consultation, the need for change was acknowledged by NICE...

During the consultation, NICE noted that the number of annual appraisals was anticipated to rise to 75 topics per year, due to:

- Regulatory approval for products at an earlier stage of development
- Personalized medicine resulting in multiple indications for new drugs
- Requirement for timely access to clinically effective and cost-effective technologies

NICE also noted that:

- An increasing number of topics require > 2 committee discussions
- Approximately 80% of final NICE guidance is positive, while 60% of draft recommendations are negative

Getting to the right decision at the right time

Deliver increased output without more committee meetings



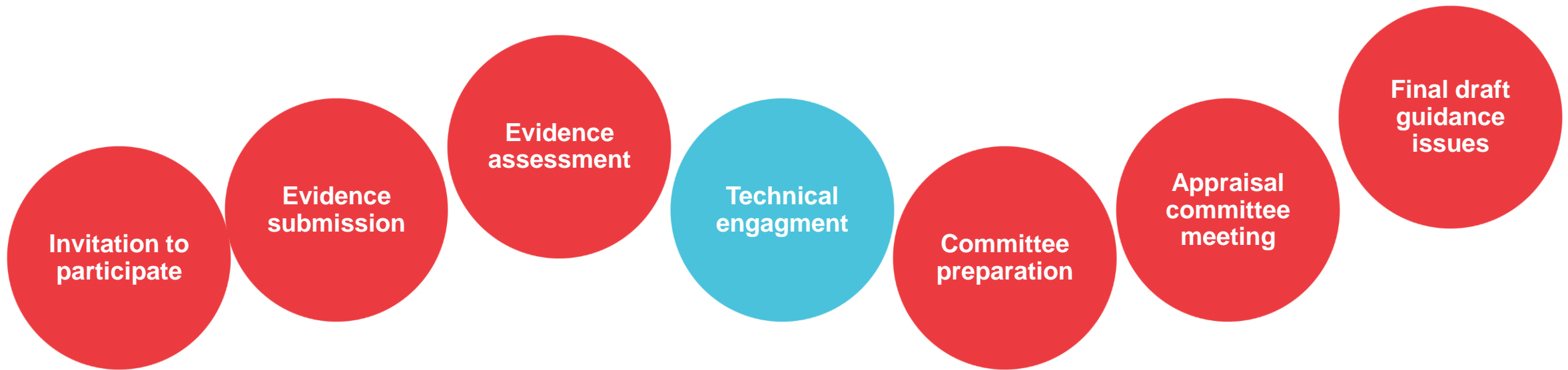
Adjust the process so that more work is completed before reaching the committee



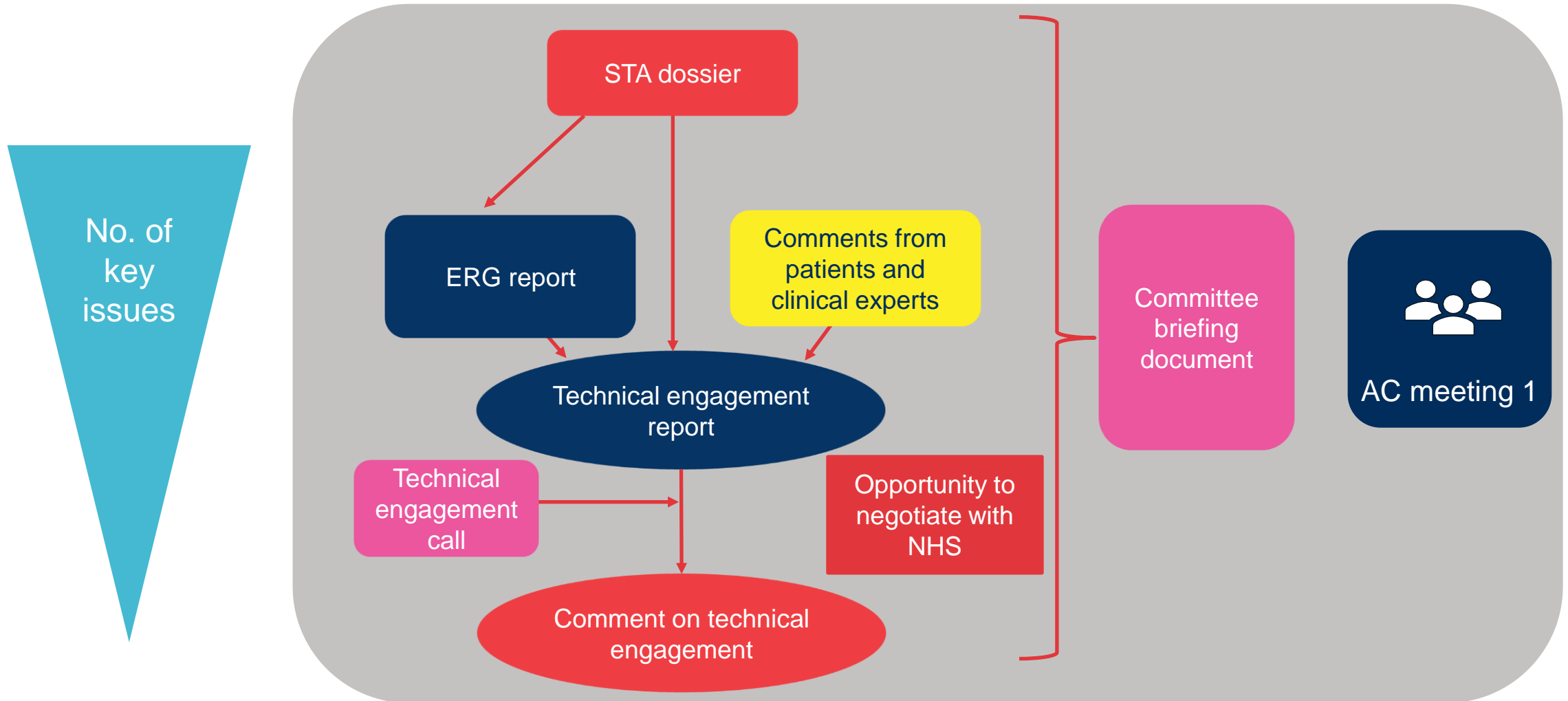
Maximize the ability to decide at the first committee meeting



Key changes in the STA process



Technical engagement allows a further round of consultation before the first appraisal committee meeting



A wider range of stakeholders are involved in technical engagement

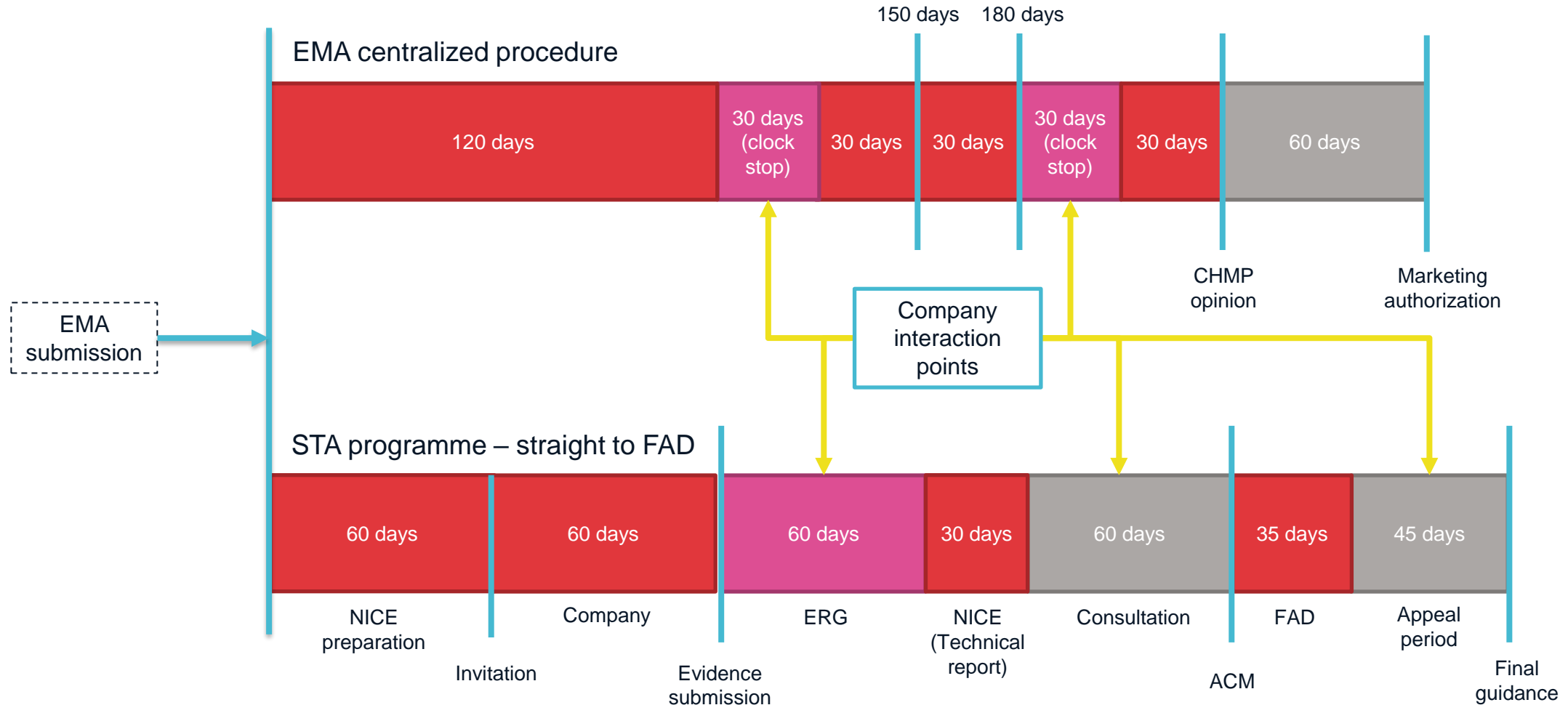


Key: ERG, evidence review group; NHS, National Health Service.

NICE committees role remains unchanged

Committees are still the ultimate decision makers
in the NICE process

STAs timings were also aligned to regulatory timelines at same time as introducing technical engagement



Key: ACM, appraisal committee meeting; CHMP, Committee for Medicinal Products for Human Use; EMA, European Medicines Agency; ERG, evidence review group; FAD, final appraisal determination; NICE, National Institute for Health and Care Excellence; STA, single technology appraisal.

Interactive poll 1

Have you been involved in the technical engagement process?

Research objective

We undertook a review of recent appraisals to assess whether the changes in process are helping to meet the objectives set out by NICE in making the STA process more efficient:

- Reducing the length of time required for a decision on appraisal
- Reducing the number of appraisal committee meetings required to make a decision
- Reducing the number of issues that need to be considered by committees

Interactive poll 2

Do you consider the technical engagement process to have aided NICE in achieving their goals?

Forty STAs were reviewed for outcomes of key interest

20 STA – pre-technical engagement

20 STA – post-technical engagement

Committee and ERG; length of appraisal; number of AC meetings;
 Data on the number of key issues identified at each stage;
 Stage at which PAS introduced / pricing negotiations take place

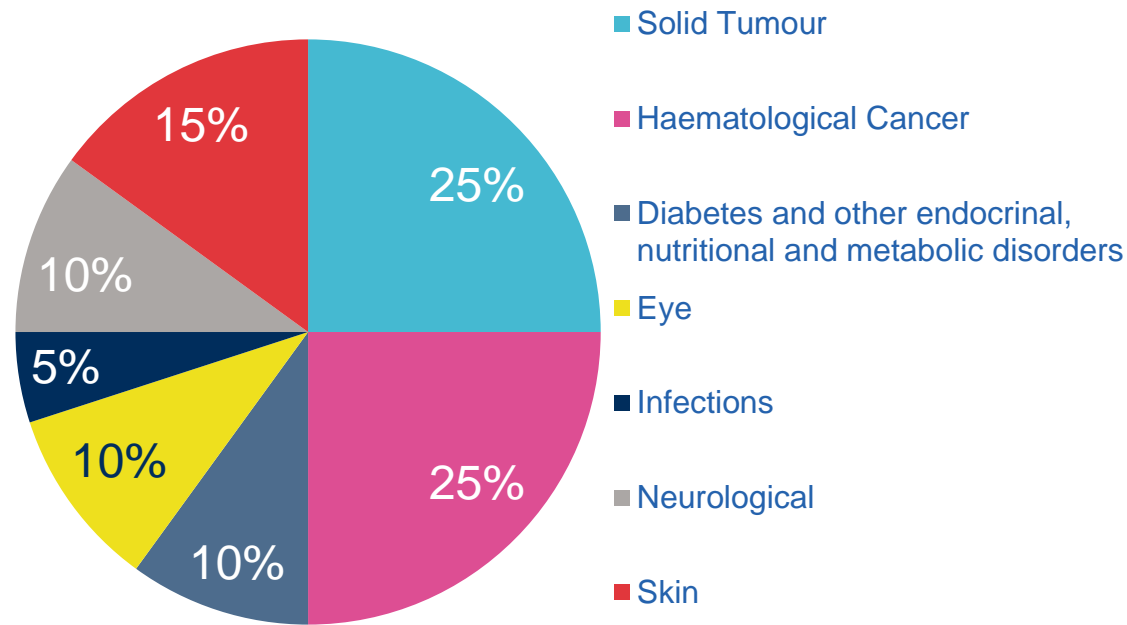
Key: AC, appraisal committee; ERG, evidence review group; PAS, patient access scheme; STA, single technology appraisal.

Limitations

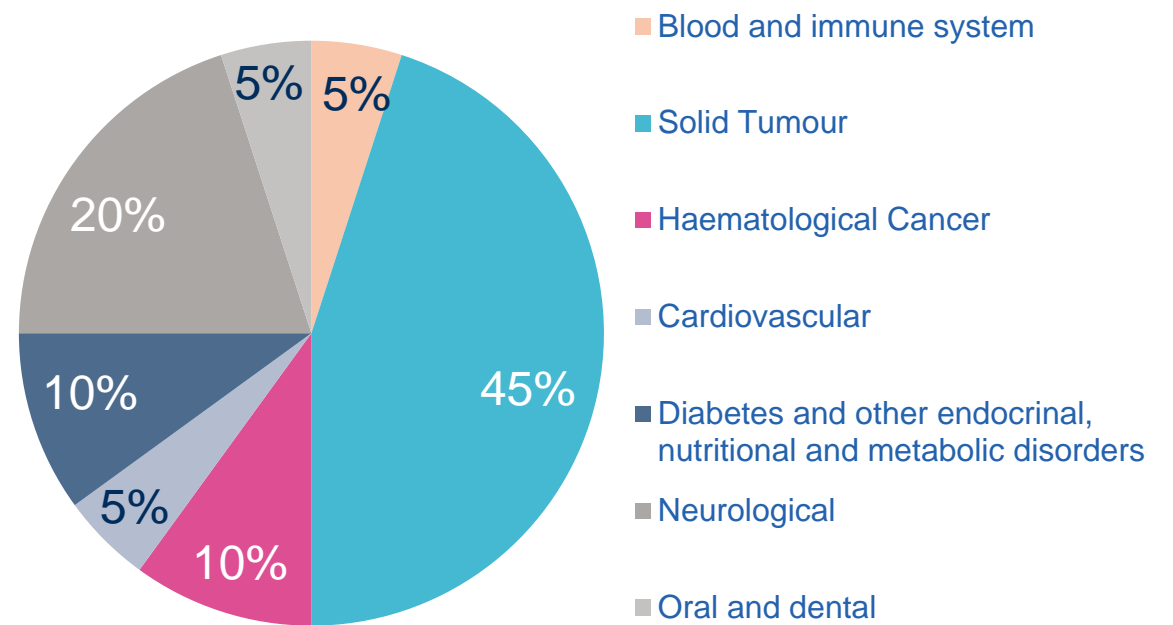
- Small sample size
- Variations within the types of appraisals and committees considering
- Lack of publicly available information on TE calls
- Potential for bias due to timing of analysis
- Inability to point to causality

A higher proportion of treatments for solid tumours and treatments for neurological condition were assessed through the new process

Pre-technical engagement appraisals (n = 20)



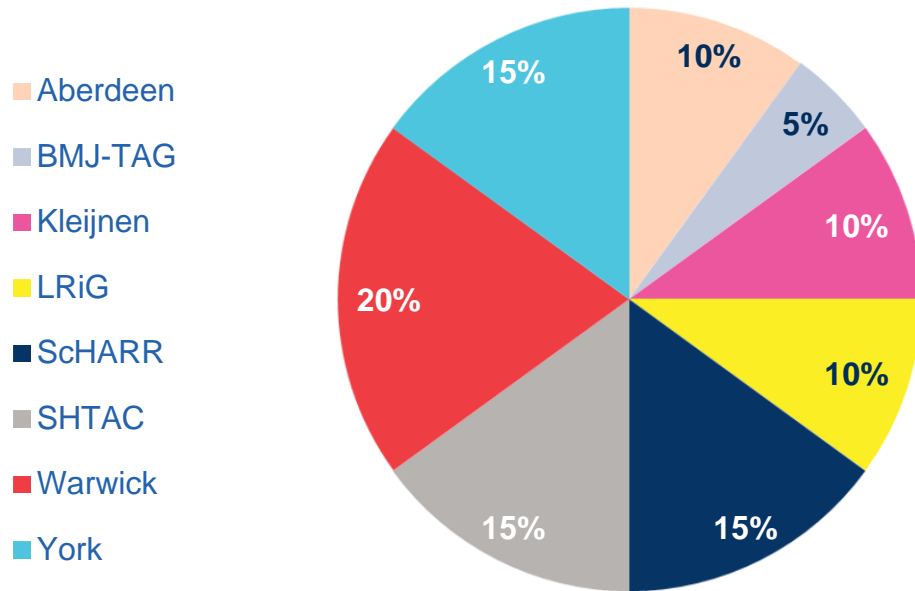
Post-technical engagement appraisals (n = 20)



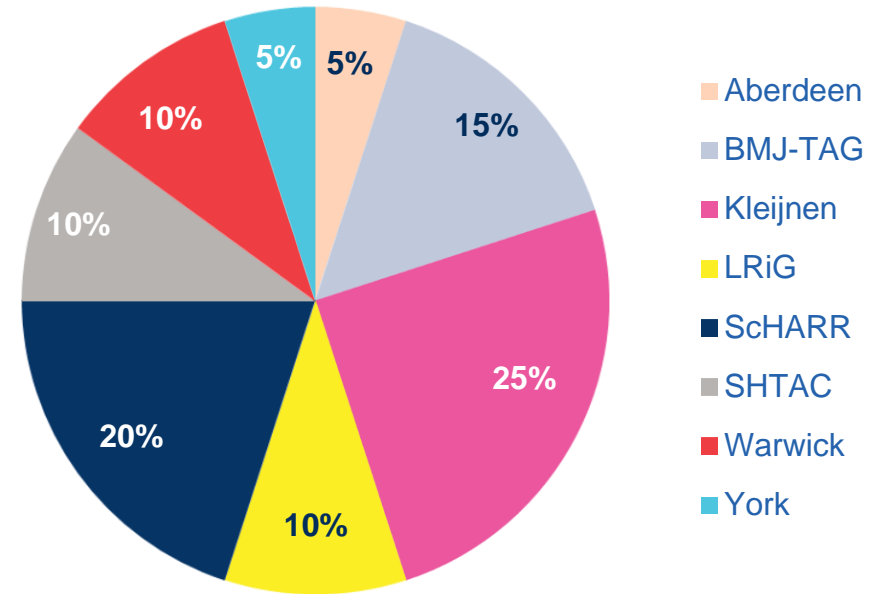
Key: STA, single technology appraisal.

A higher proportion of technical engagement appraisals were assessed by Kleijnen and ScHARR

Pre-technical engagement appraisals (n = 20)

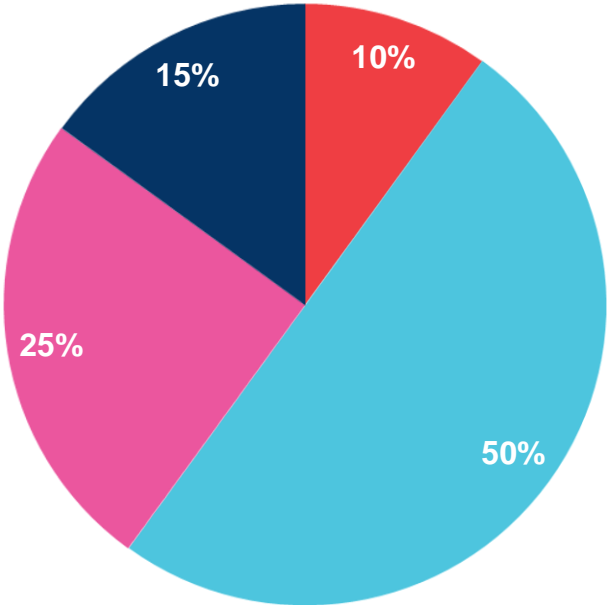


Post-technical engagement appraisals (n = 20)



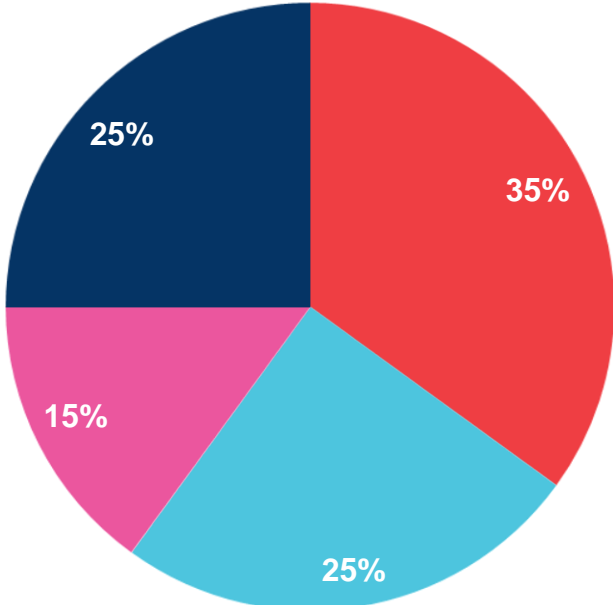
A higher proportion of technical engagement appraisals were assessed by Committee A, whereas Committee B assessed half of the pre-technical engagement appraisals

Pre-technical engagement appraisals (n = 20)



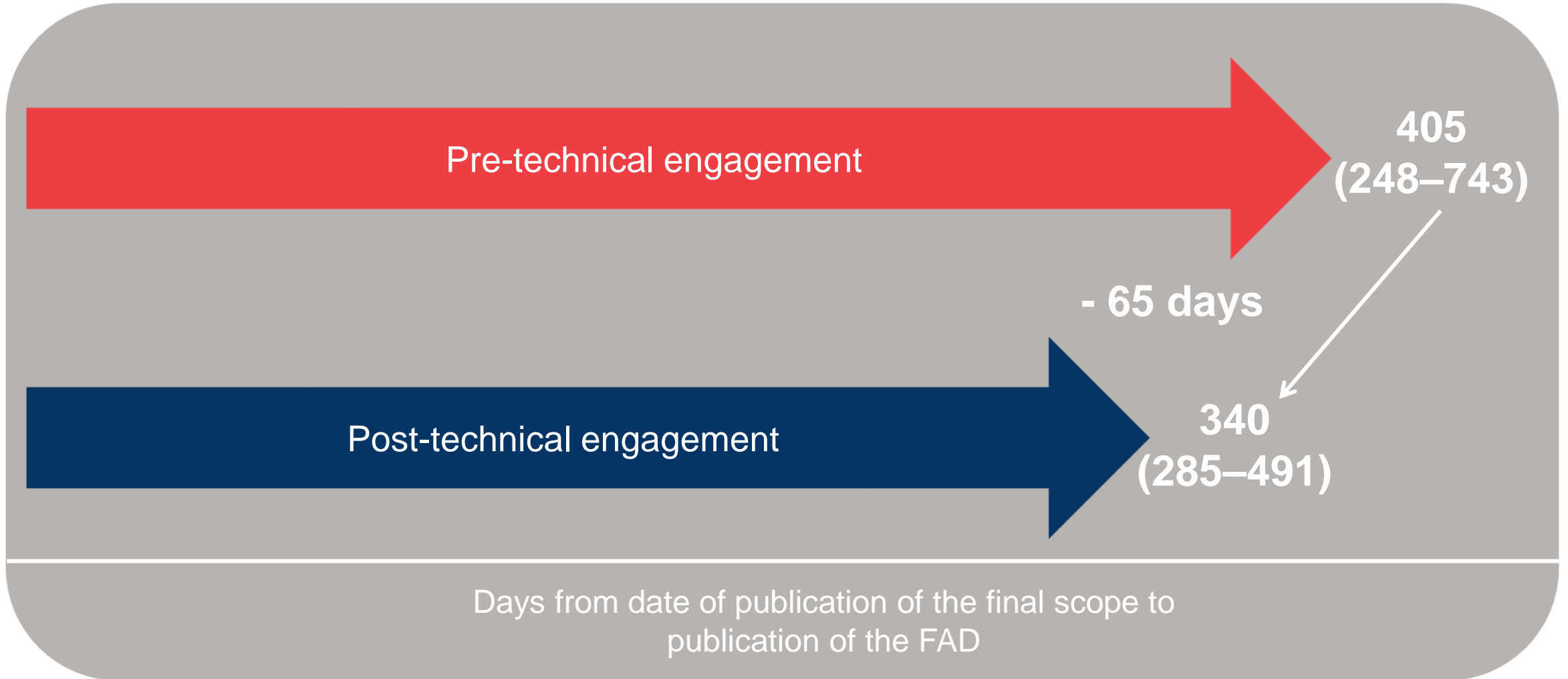
■ Committee A ■ Committee B
■ Committee C ■ Committee D

Post-technical engagement appraisals (n = 20)



■ Committee A ■ Committee B
■ Committee C ■ Committee D

On average, there was a reduction of 65 days in the length of appraisal following the introduction of the new process



Interactive poll 3

Do you feel that the technical engagement process has impacted your post-submission workload?

The new process marginally increases the amount of information the committee needs to consider at the first committee meeting

Committee pre-briefing document



567 pages (296–788)

Pre-technical engagement

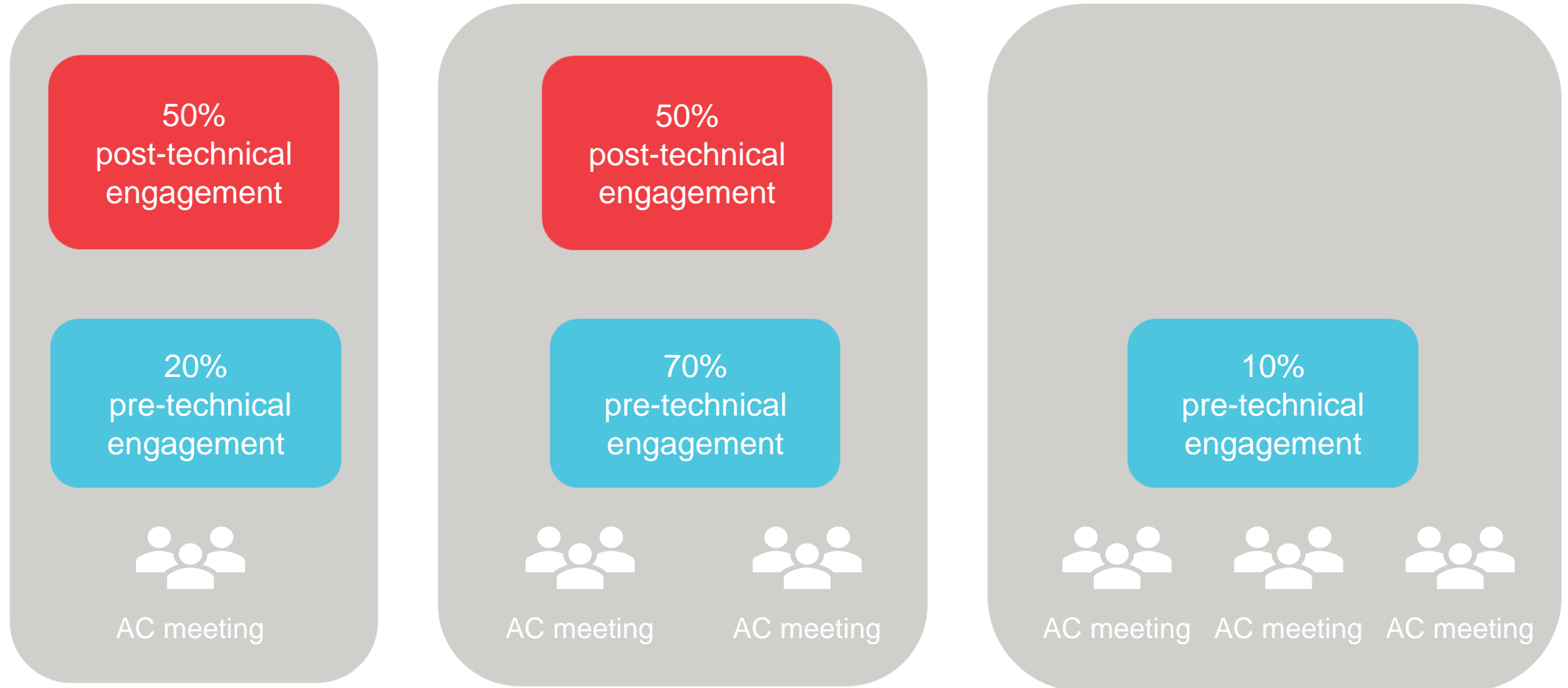
Committee pre-briefing document



590 pages (364–890)

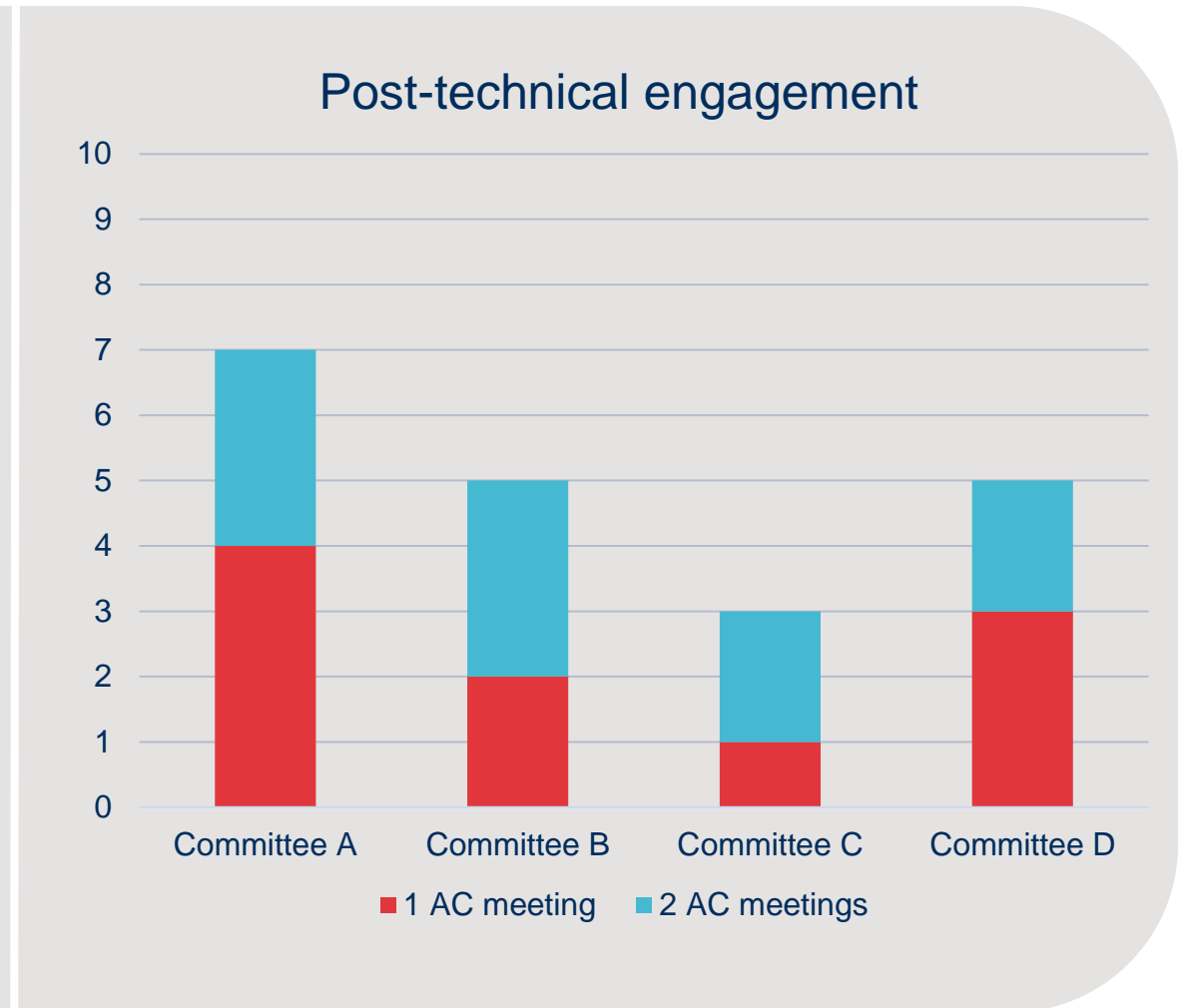
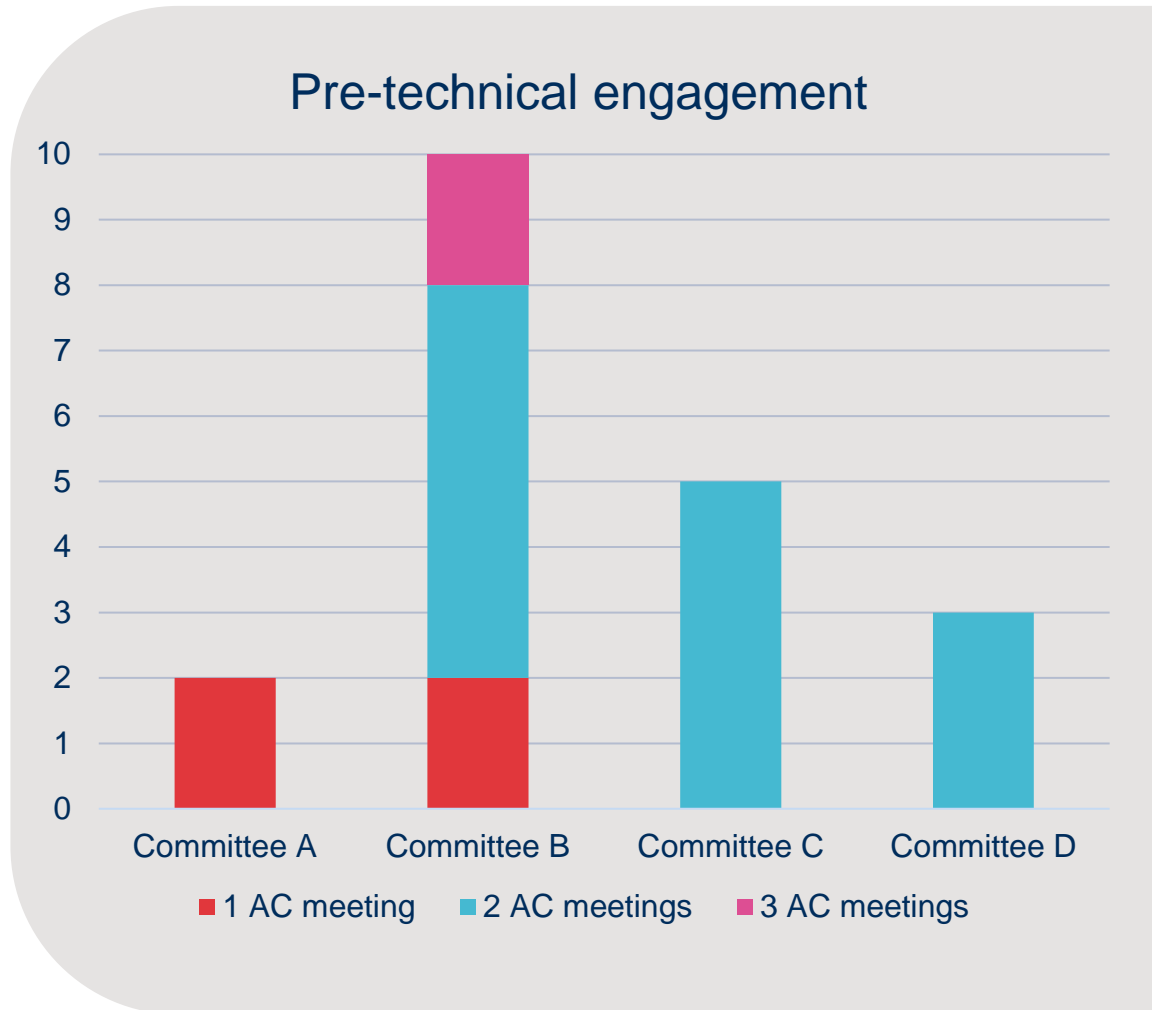
Post-technical engagement

Prior to the change in process, 80% of the assessed TAs required more than one AC meeting – the introduction of the new process reduced this to 50%



Key: AC, appraisal committee; TA, technology appraisal.

Following the introduction of technical engagement, Committees C and D increased the number of appraisals requiring only one meeting



Key: AC, appraisal committee.

Interactive poll 4

Do you think that the increased engagement with clinicians/patients prior to the AC meeting has helped decision making at the AC meeting?

What impact do you think technical engagement has had on the issues raised during the appraisal process?

Technical engagement resolved on average three key issues prior to ACM1

Technical engagement reports highlighted an average of 8.5 key issues (4–18)



An average of 2.7 (0–8) issues were resolved during technical engagement (n = 19)

Of note, there were three out of the 19 appraisals*, it was highlighted in the FAD that no key issues were resolved at technical engagement

Key: ACM1, appraisal committee meeting 1; FAD, final appraisal determination; TA, technology appraisal.

Resolution was determined by information within the FAD for n=14, tracking of issues technical engagement report to ACM1 slides n=5

Notes: * There were no committee slides or information in the FAD for TA 622 to determine the number of issues resolved.

The point at which issues are resolved in the technical engagement process was unclear from our analysis



Technical engagement
call

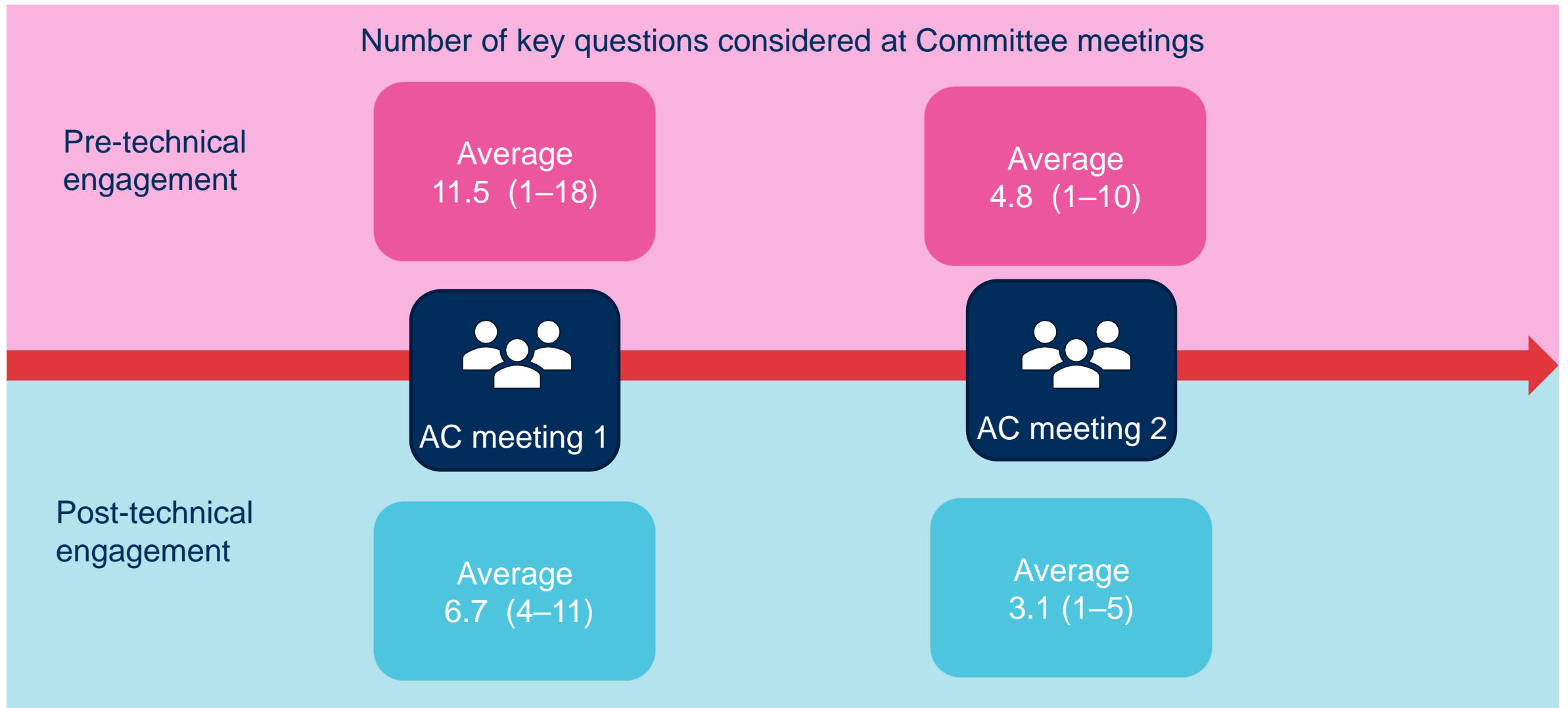


Technical engagement
responses

Companies are engaging with the technical engagement process as an opportunity to provide new data/analyses

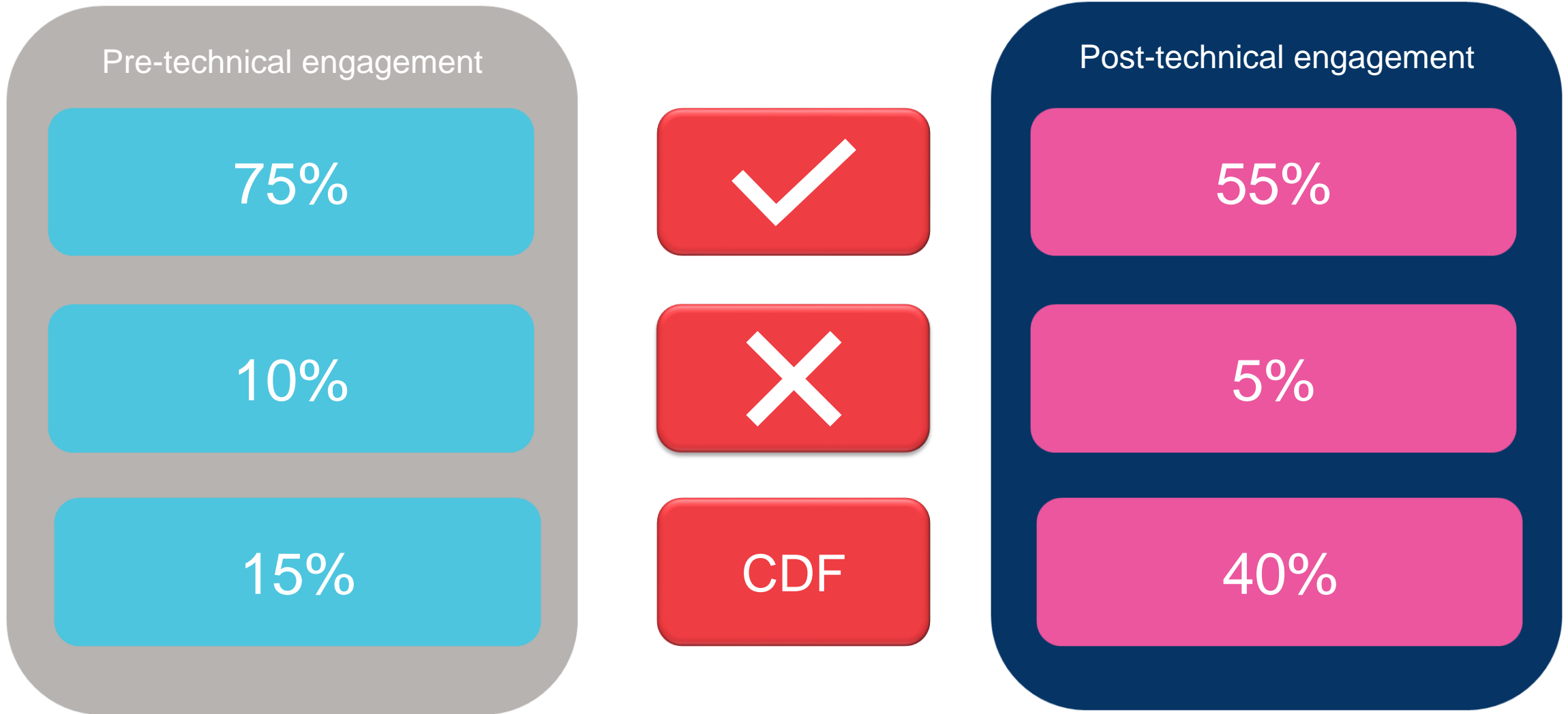


Technical engagement reduces the number of questions that committees consider at AC meetings



Key: AC, appraisal committee.

In the post-technical engagement STAs reviewed, a higher number of appraisals were recommended through the CDF



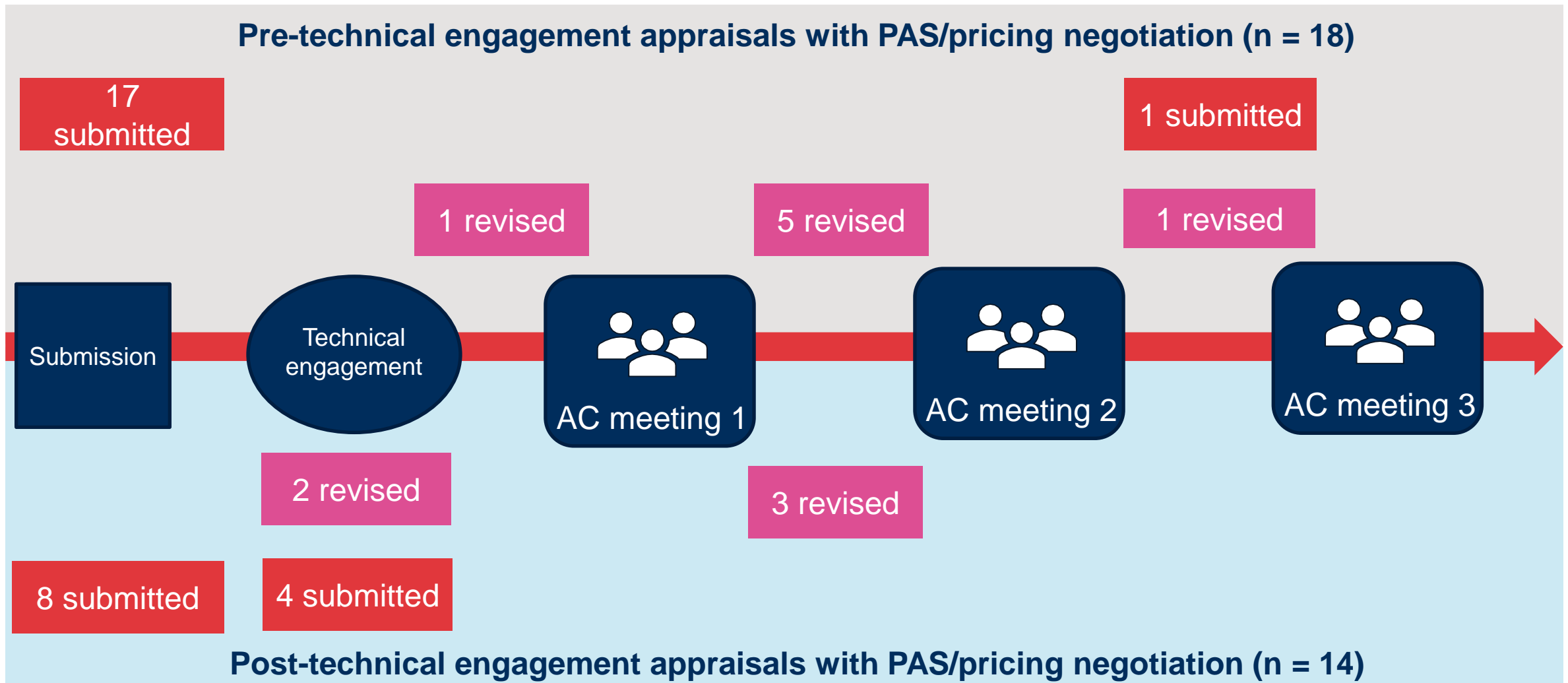
Key: CDF, Cancer Drugs Fund; STA, single technology appraisal.

Interactive poll 6

Do you think technical engagement has lead to an increased willingness to reconsider pricing strategy before committee meeting?

Technical engagement provides a formal opportunity for pricing discussions prior to the first appraisal committee meetings

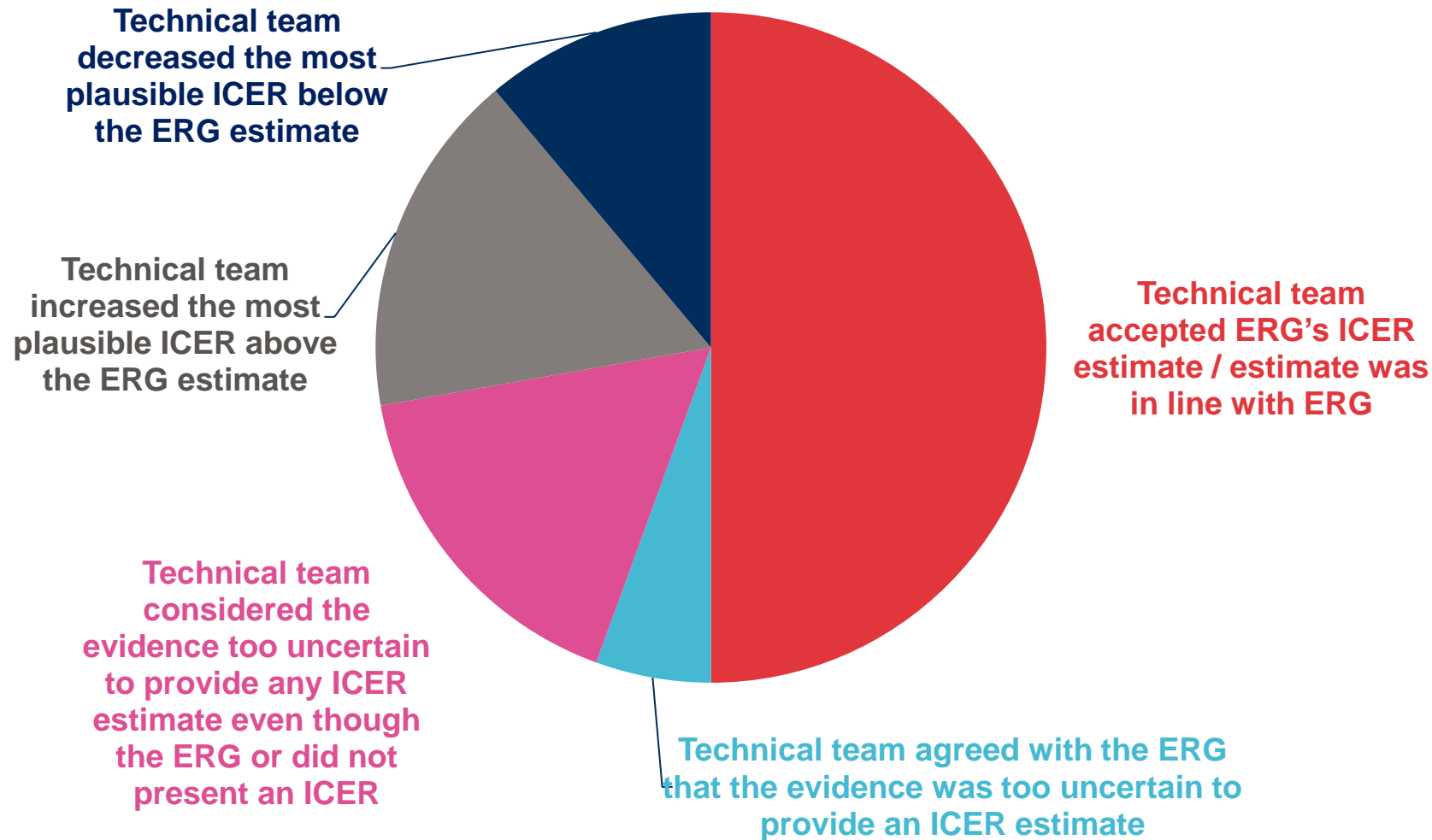
Some evidence companies are using the technical engagement to determine price – but fewer PASs submitted upfront



Key: AC, appraisal committee; NICE, National Institute for Health and Care Excellence; PAS, patient access scheme.

Notes: This is from publicly available information – there may have been additional negotiations that are not clearly identifiable from NICE documents.

The technical team's influence on the ICER evaluation varied in our sample STA



Key: ERG, evidence review group; ICER, incremental cost-effectiveness ratio; STA, single technology appraisal.

Notes: n = 18. ICERs were redacted in two technical engagement reports.

Conclusions

- The duration of appraisals has reduced, albeit not dramatically
- Approximately one third of issues were resolved at technical engagement step
- Reduction in the number of meetings required for decisions, however 50% of appraisals still require more than one committee meeting
- Increased volume of appraisals deemed too uncertain for routine commissioning
- The price negotiation step does not appear to be used by many in the manner intended
- The question of whether the process changes have led to improved decision making remains to be seen

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Q&A



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Thank you!



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