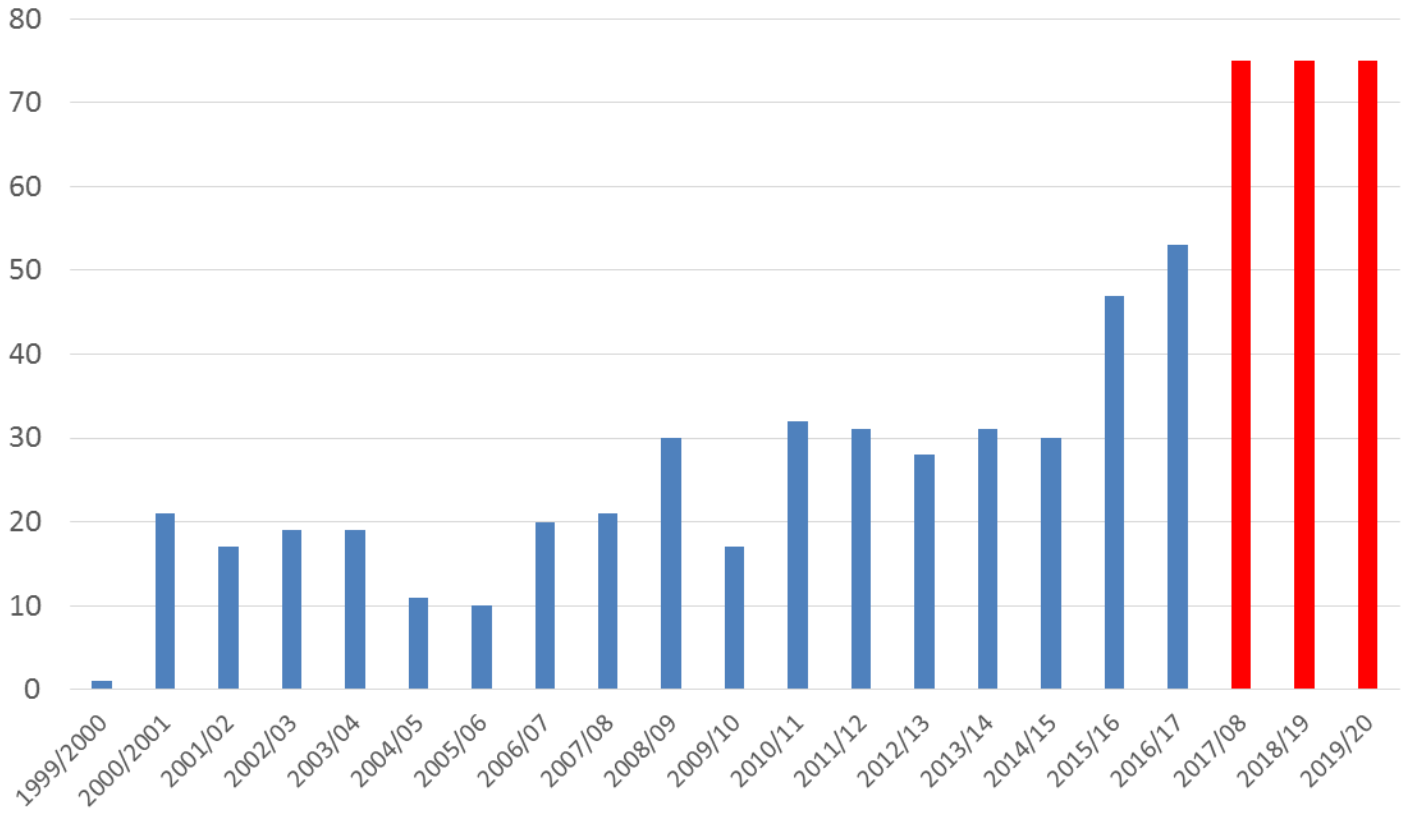
Increasing capacity within the TA programme

Cancer52 Meeting – Wednesday 25 April 2018

NICE National Institute for Health and Care Excellence

Technology Appraisals

The demand for TA guidance is increasing



Proposed solution

Getting to the right decision at the right time

- Approximately 80% of final NICE guidance is positive whilst 60% of draft recommendations are negative.
- The proposed amendments to the process aim to enable us to maximise the ability to reach a final decision at the first committee meeting.

The main emphasis of the process adjustments is on undertaking more work before the topic reaches the committee.

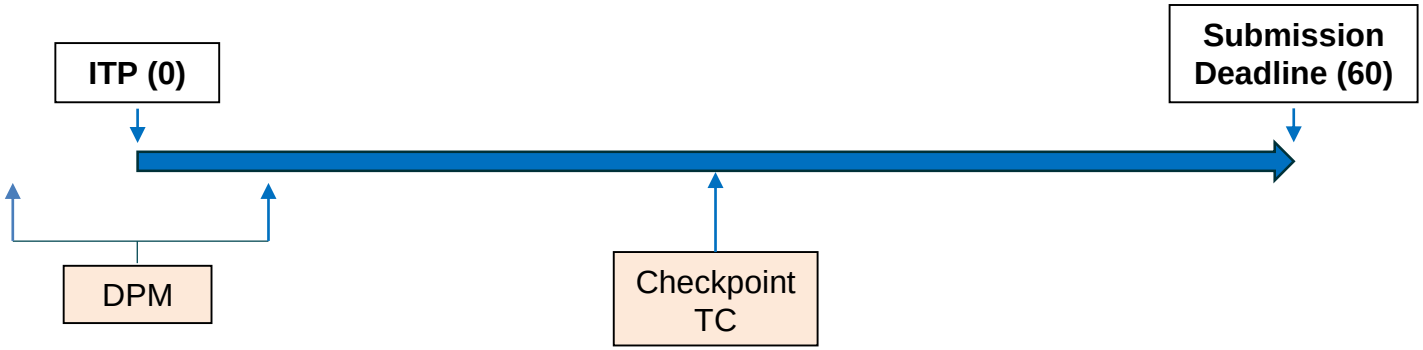
The new process

Changes to the TA process

- Increased engagement earlier in the appraisal process
- Introduction of the Technical Engagement step
- Attendance of clinical experts and patient experts at the appraisal committee – 'opt-out' option
- Releasing committee decisions to C&Cs
- Proceeding to FAD without a second Appraisal Committee Meeting

Increased engagement earlier in the appraisal process

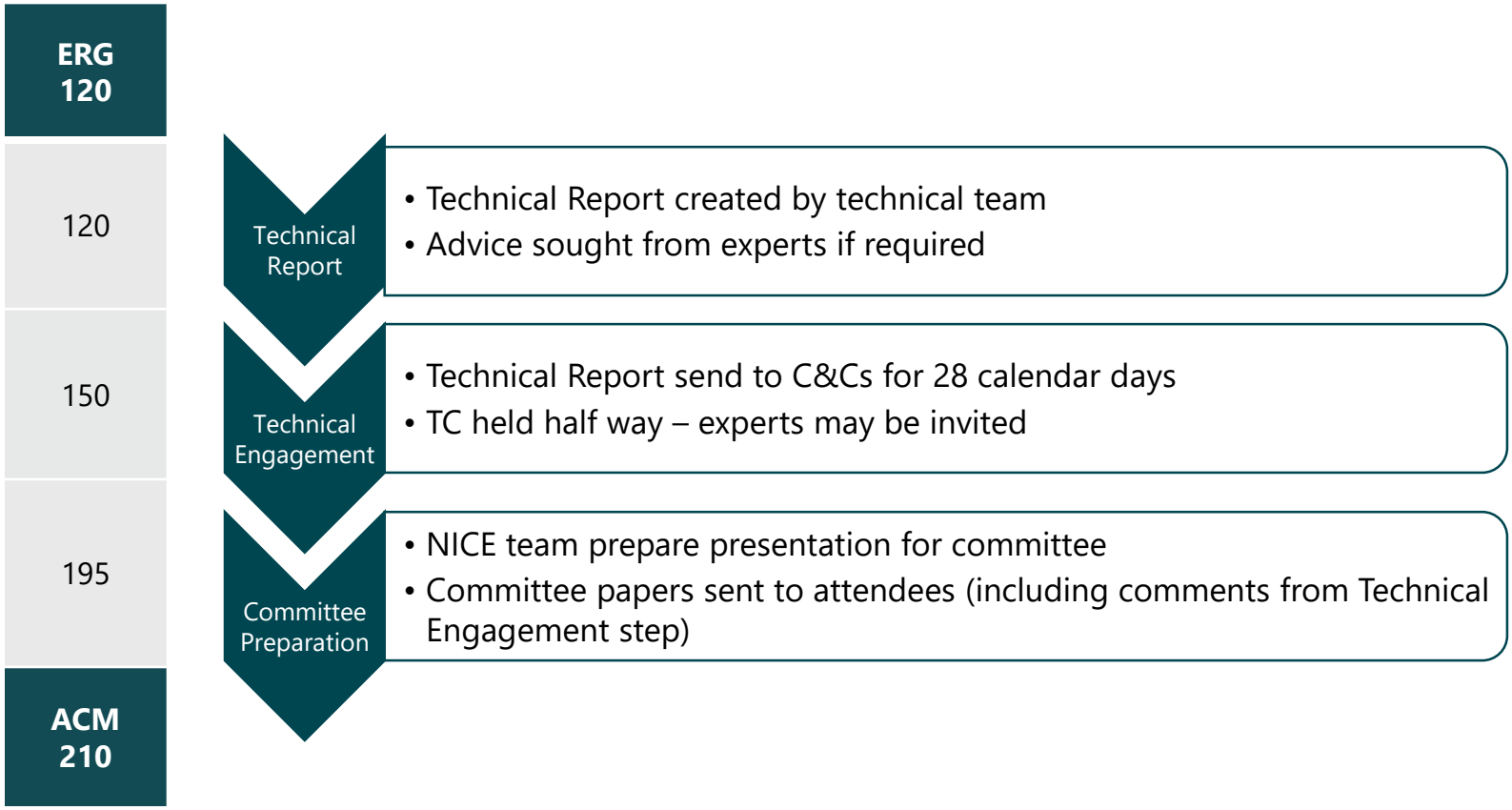
To try to ensure company submission is robust and minimise the need for edits and/or the submission of additional information later on a checkpoint meeting has been introduced.



Clear wording added to the process guide regarding open engagement between Company and NICE throughout the submission stage.

Technical Engagement

- Additional step in the Technology Appraisal process aiming to pull forward consideration of scientific and technical elements prior to committee



Attendance of clinical experts and patient experts at the appraisal committee

We have introduced the option to 'opt-out' of attendance at the meeting when experts feel their views are adequately reflected in the technical report and attendance in person may not add additional benefit.

Our intention is to increase patient and clinical input into the appraisal process at a much earlier point.

We will need to ensure that expert attendance at committee is not regarded as a substitute for input into the technical engagement stage

Releasing committee decisions to Consultees and Commentators

- Top level committee decision will be released to all consultees and commentators 5 working days after the appraisal committee meeting (this included experts)

Proceeding to FAD without a second Appraisal Committee Meeting

- Opportunity for the committee chair to agree that a second face to face committee meeting isn't required after a ACD consultation in the scenario where the committee is clear about its expectations after the first meeting, and where the company responds by making an updated commercial offer only.
- Earlier final guidance publication = earlier access for patients!

Other areas of interest

- References to Multiple Technology Appraisal removed from process guide but remains as a process that can be used within the TA programme
- CDF process steps have been added
- Fast Track Appraisal process steps have been added
- Budget Impact Test process steps have been added
- Section 3.1.22 has been amended to clarify how NICE handles confidential comparator discounts
- Removed previous section 6 (Appeals)
- Re-format of process diagrams

Implementation

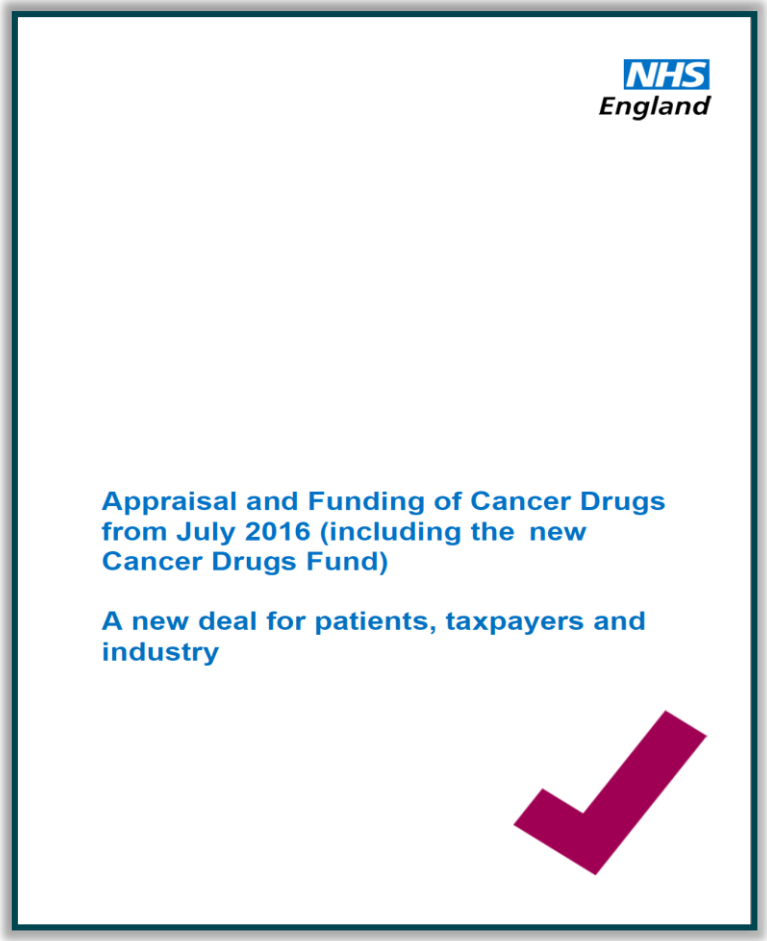
- New process guide published on NICE website 03 April 2018
- Transition of topics onto new process based on Committee Meeting schedules – it will be made clear to stakeholders which process and topic is proceeding on
  - Will inform individual companies and other stakeholders
  - Exploring changes to the website topic pages
- There will continue to be a mixture of 'old' and 'new' process appraisals running for the next year
- Elements of the new process brought into all ongoing appraisal topics

Any questions?

Cancer Drugs Fund

Objectives:

- Faster access to new treatments
- Drive stronger value for money for taxpayers
- Offer a new fast-track route to best and most promising drugs when companies price responsibly

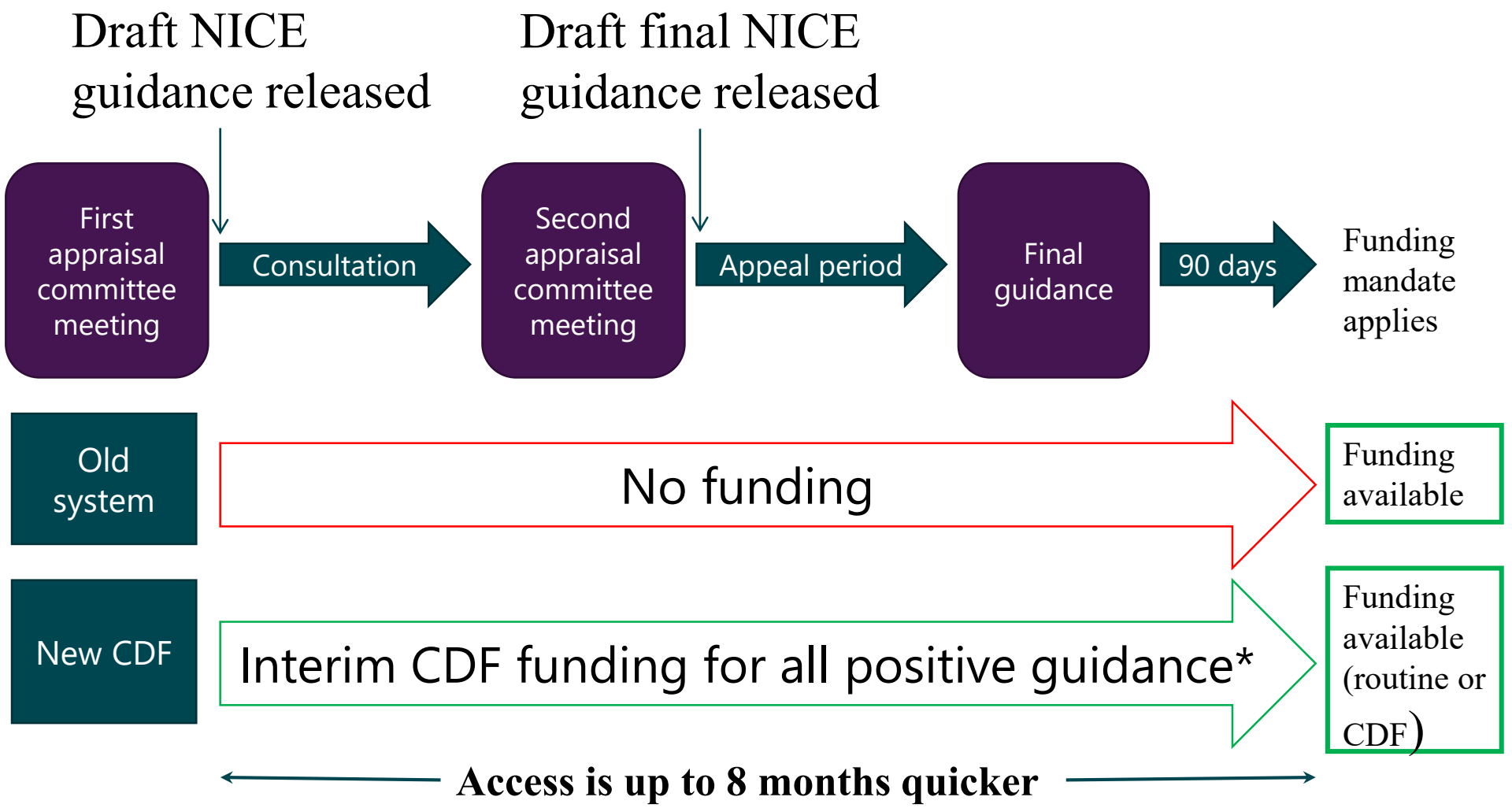


Faster access:
seamless appraisal and commissioning

- Every licensed cancer drug indication to be appraised
- Provisional NICE recommendations before marketing authorisation (MA) and final guidance within 90 days of MA[1]
- Interim CDF funding for all provisional positive NICE recommendations until entry into baseline

[1]For cancer drugs referred from April 2016

Changes in cancer drugs funding

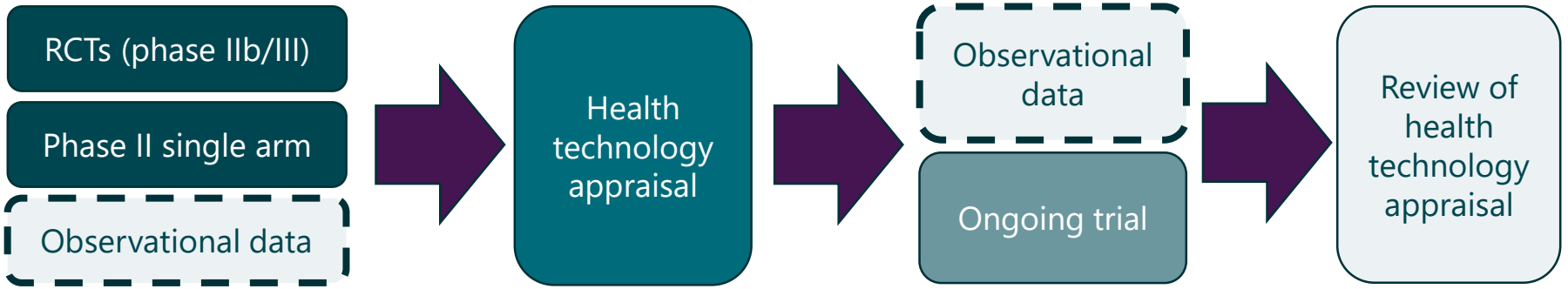


NICE National Institute for Health and Care Excellence

*When any eligible cancer treatment is recommended. Funding mandate applies sooner if consultation is not required, and for EAMS drugs (30 days after publication)

NICE's decision-making about medicines: Evolving evidence needs

- Regulatory world is changing
  - Earlier licensing
  - Less certain evidence base
- Treatments for rare diseases now routinely appraised

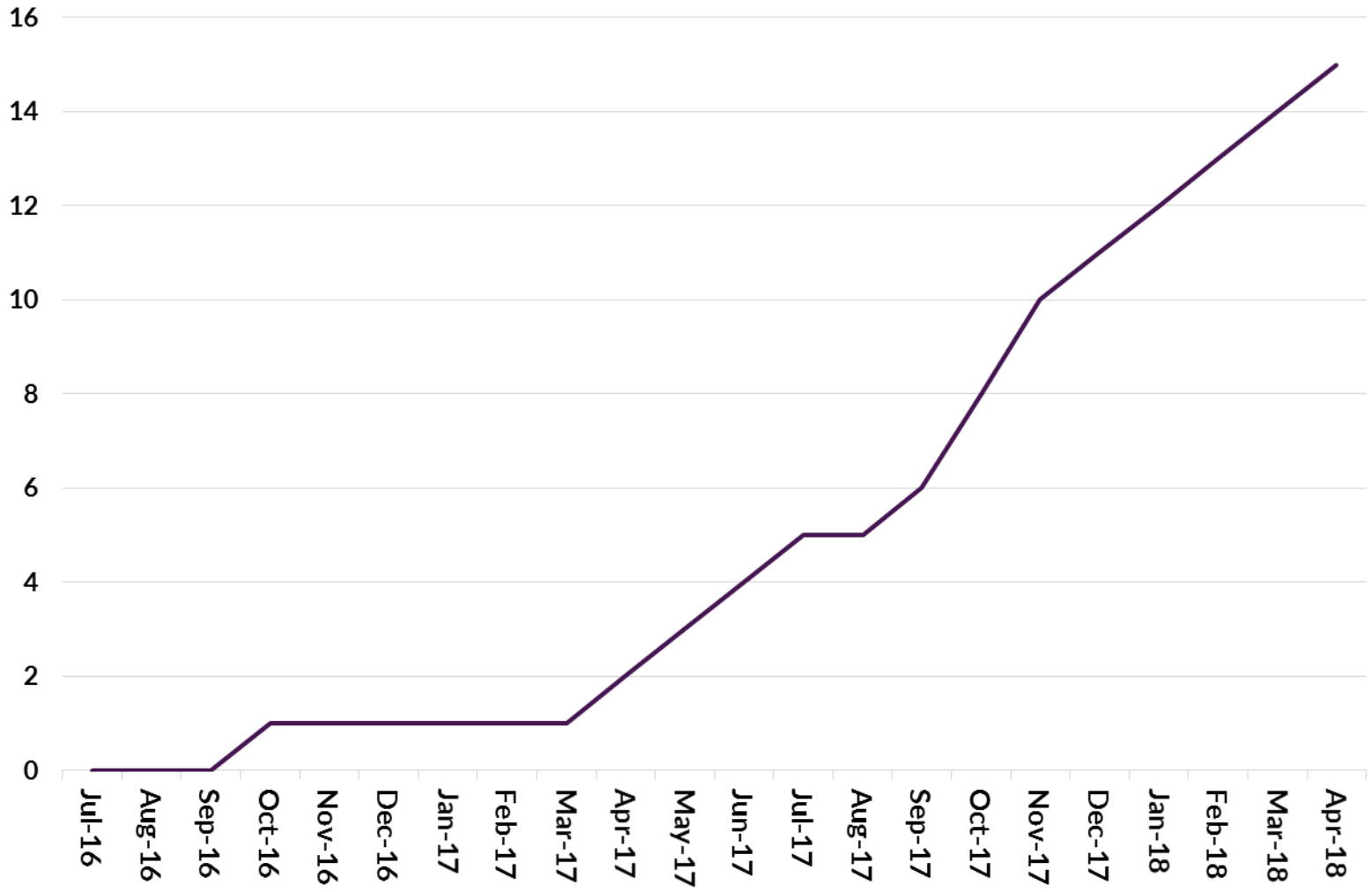


What did this mean for NICE?

- Partnership with NHS England to deliver earlier access
- New option for committee decision-making from 1 April 2016
- More appraisals…

Access to treatment and funding even when there is significant clinical uncertainty

The number of promising treatments recommended for use in the CDF is increasing



Which treatments have been recommended for the CDF so far?

Topic	Primary data source
Osimertinib for NSCLC	Ongoing clinical trial
Brentuximab for Hodgkin's lymphoma	Retrospective study (questionnaire)
Pembrolizumab for NSCLC (1L)	Ongoing clinical trial
Olaratumab for soft tissue sarcoma	Ongoing clinical trial
Obinutuzumab for follicular lymphoma	Ongoing clinical trial
Nivolumab for NSCLC (squamous)	Ongoing clinical trial
Nivolumab for NSCLC (non-squamous)	Ongoing clinical trial
Ibrutinib for Waldenstrom's macroglobulinaemia	SACT dataset
Venetoclax for CLL	SACT dataset (prospective/retrospective)
Nivolumab for SCCHN	Ongoing clinical trial
Atezolizumab for urothelial cancer (1L)	Ongoing clinical trial
Ixazomib for treating multiple myeloma	Ongoing clinical trial
Daratumumab for multiple myeloma	SACT dataset

CLL, chronic lymphocytic leukaemia; NSCLC, non-small cell lung cancer; SCCHN, squamous cell carcinoma of the head and neck

But

are

we

making

a

difference?

CDF by numbers

Since the new CDF began, approximately **19,700** patients have benefited from **58** drugs treating **97** different cancer indications

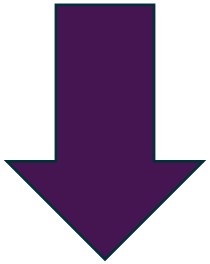
3,700 patients have accessed promising new treatments via a managed access agreement

5,900 patients have had new treatments sooner than they would have had before

Data from 20/11/17

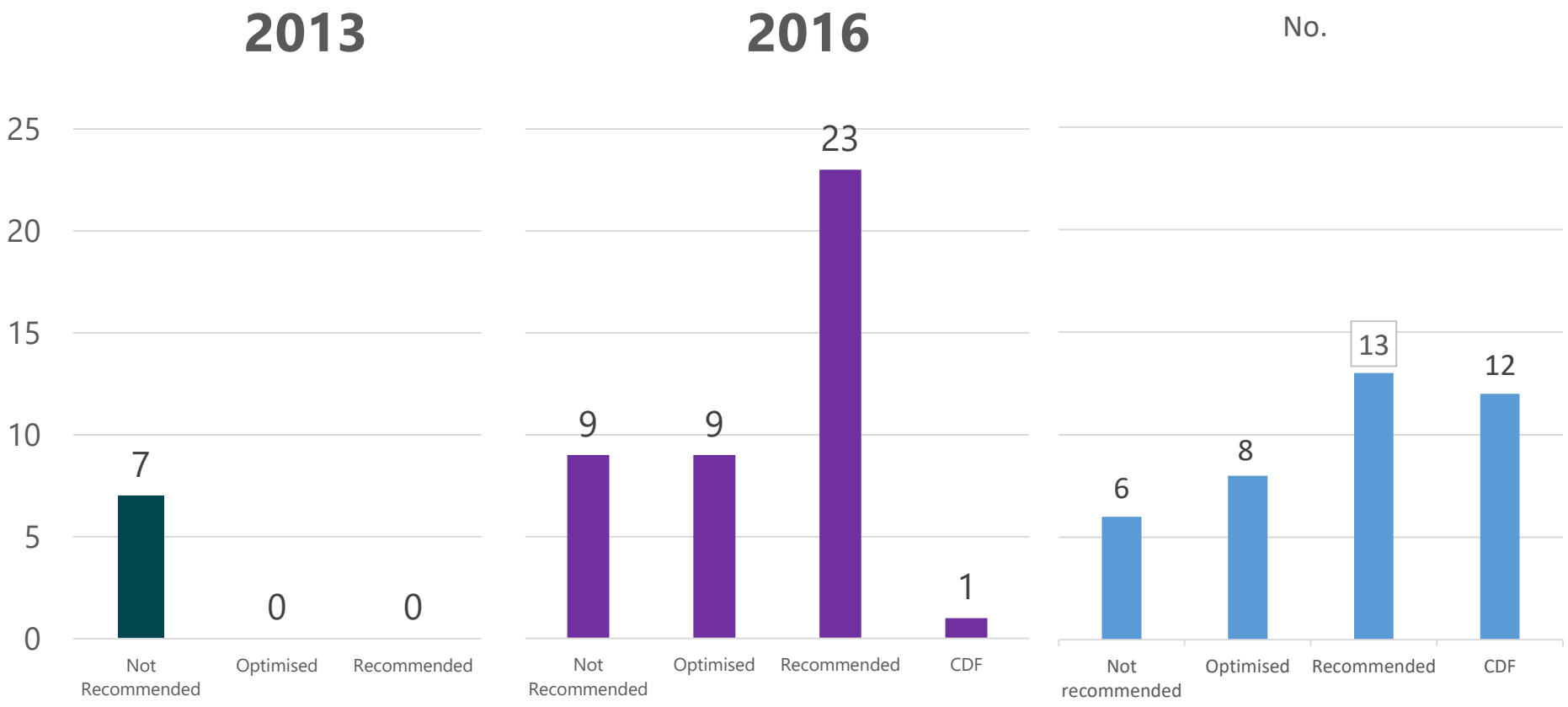
CDF budget (2016-18)

CDF within budget for the first time since 2012-13



Expenditure control mechanism will not be operated

Positive NICE recommendations increasing since adopting the new CDF model



Numbers refer to recommendations for cancer treatments in final guidance. Excludes terminated appraisals

Any questions? (Part 2)