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NHS England

CONSULTATION ON PROPOSALS FOR A NEW CANCER DRUGS FUND (CDF) OPERATING MODEL FROM 1ST APRIL 2016

January

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Introductions & Welcome

Sara Geater

Senior Engagement Manager,

NHS England

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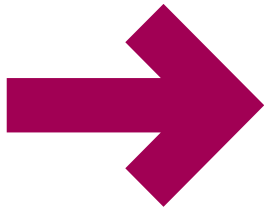
Objectives of the Consultation

- To seek views of the public and other stakeholders on proposals for a new Cancer Drugs Fund operating model from 1 April 2016

Objectives of today:

- To provide an opportunity to learn about, seek clarification and discuss the proposals in order for participants to submit informed responses via the online portal



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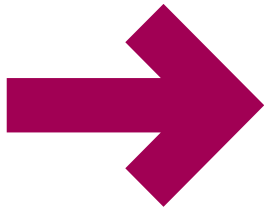
Programme for today's event

- Setting the context
- An overview of the proposals and consultation questions
- What does this mean for NICE?
- Questions from the floor
- Break
- Group discussion
- Plenary
- Close



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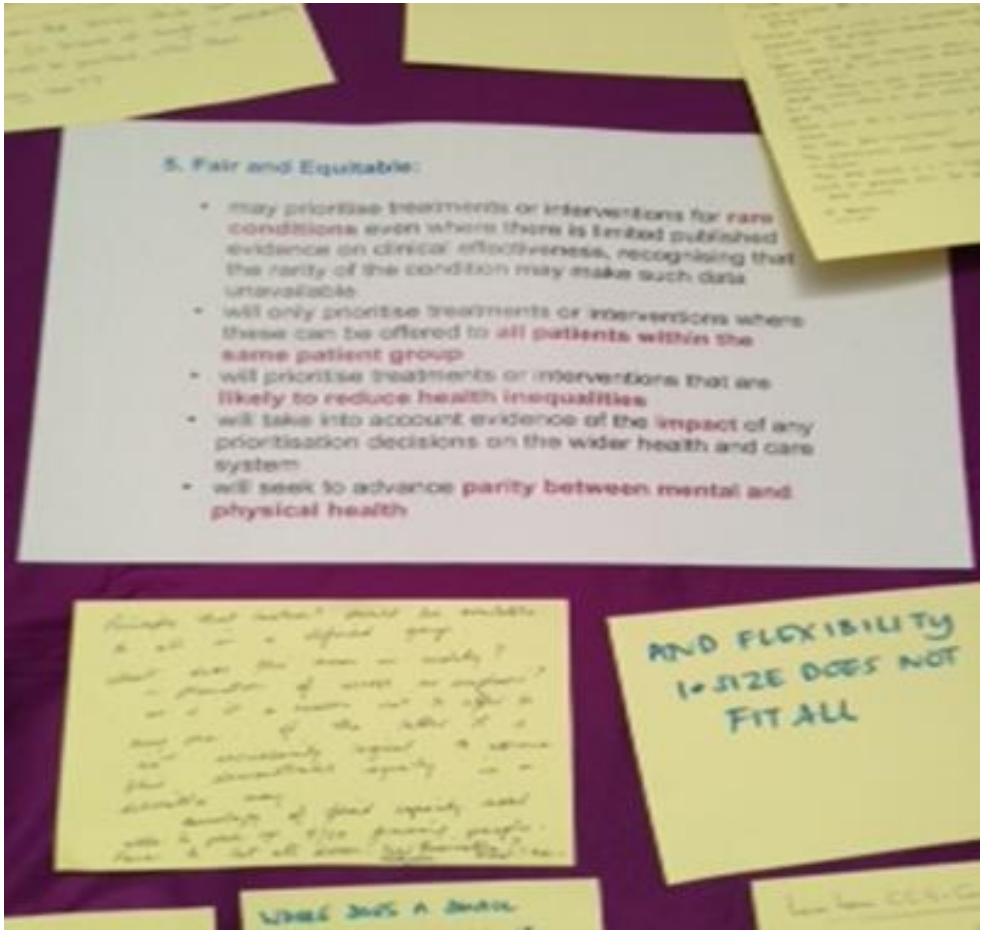
Collecting your views



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Setting the context

Professor Sir Bruce Keogh

National Medical Director

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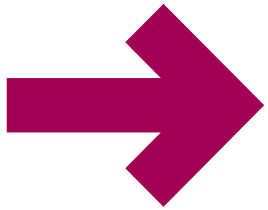
The independent Cancer Taskforce

- Established in January 2015 to produce a new, five-year national cancer strategy for England
- Taskforce report ‘Achieving World Class Cancer Outcomes: A Strategy for England, 2015-2020’, published July 2015
- 96 recommendations, focused on ‘radically’ improving outcomes for people affected by cancer and using resources more wisely.
- Cally Palmer – NHS National Cancer Director, responsible for leading implementation of this strategy.



Overview: six strategic priorities

Spearhead a radical upgrade in **prevention and public health**

Drive a national ambition to achieve **earlier diagnosis**

Establish **patient experience** on par with clinical effectiveness and safety

Transform our approach to support people **living with and beyond cancer**

Make the necessary **investments** required to deliver a modern, high-quality service

Commissioning, accountability and provision

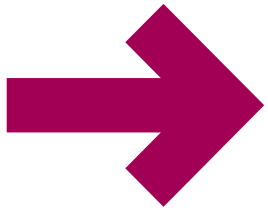
The Independent Cancer Taskforce

- Implementation of the strategy will be overseen by a cross-system Cancer Transformation Board, which will meet for the first time at the end of January.

- Independent Advisory Group, chaired by Dr Harpal Kumar, CEO of CR UK, to be established – ‘holding up a mirror’ to the Transformation Board, and will be reporting in the summer.

Delivering a modern, high-quality service

- The Taskforce recognised that, since its inception in 2010, the CDF has provided access to treatments for more than 72,000 patients.
- However, it also recognised that a modern, high-quality service for patients with cancer required the development, and implementation, of a more sustainable solution for access to new cancer treatments.
- New CDF needs to be properly integrated into a unified cancer programme, and aligned with NICE appraisal processes, - not a ‘bolt on’.



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Overview of the proposed new CDF process

Professor Peter Clark

Chair of the Cancer Drugs Fund

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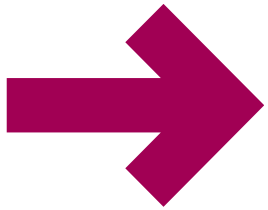
The proposed new CDF process – an overview

- The CDF should become a ‘managed access’ fund for new cancer drugs, with clear entry and exit criteria.

- Enable access to those drugs which appear promising but where NICE indicates that there is insufficient evidence to support a recommendation for routine commissioning.

- These drugs would be given a conditional recommendation by NICE and their use enabled by the CDF for a pre-determined period whilst further evidence is collected. At the end of this period the drug would go through a short NICE appraisal, using this additional evidence.



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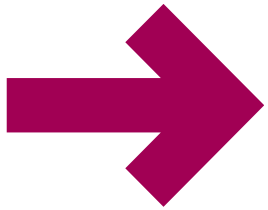
The proposed new CDF process – an overview II

- It would attract either a NICE positive recommendation, at which point it would move out of the CDF into routine commissioning, or a NICE negative recommendation, at which point it would move out of the CDF and become available only on the basis of individual patient funding requests.

- This approach will enable the money in the CDF to be more effectively managed, as well as providing a new pathway for innovative drugs to be assessed and made available to patients.



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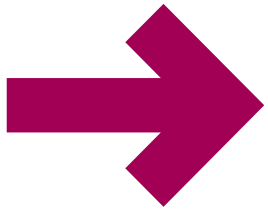
Consultation question:

Do you agree with the proposal that the CDF should become a "managed access" fund for new cancer drugs, with clear entry and exit criteria?



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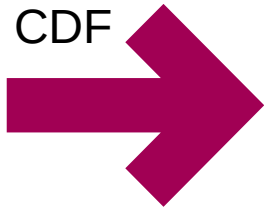
The new CDF model – key features

- NICE will appraise all cancer drugs that are expected to receive a Marketing Authorisation
- NICE will normally issue draft guidance prior to Marketing Authorisation
- NICE will normally publish their final guidance within 90 days of Marketing Authorisation
- NICE will make a recommendation falling into one of 3 categories:
  - Recommended for routine use
  - Not recommended for routine use
  - Recommended for use within the Cancer Drugs Fund
- At the point of Marketing Authorisation, all drugs with a draft recommendation for routine use, or a draft recommendation for conditional use within the CDF will receive interim funding from the CDF budget



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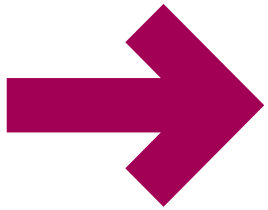
Consultation questions:

Do you agree with the proposal that all new cancer drugs and significant new licensed cancer indications will be referred to NICE for appraisal?

Do you agree with the proposal that the NICE Technology Appraisal Process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant licence extensions for existing drugs?



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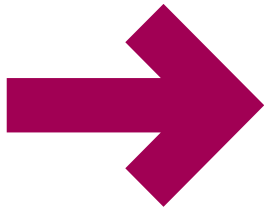
Consultation questions:

Do you agree with the proposal for draft NICE cancer drug guidance to be published before a drug receives its marketing authorisation?

Do you agree with the process changes that NICE will need to put in place in order for guidance to be issued within 90 days of marketing authorisation, for cancer drugs going through the normal European Medicines Agency licensing process?



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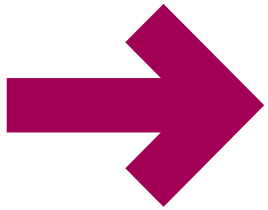
Consultation question:

Do you agree with the proposal that a new category of NICE recommendations for cancer drugs is introduced, meaning that the outcome of the NICE Technology Appraisal Committee's evaluation would be a set of recommendations falling into one of the following three categories:

- *Recommended for routine use;*
- *Recommended for use within the Cancer Drugs Fund;*
- *Not recommended.*



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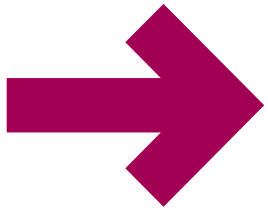
Proposed changes to NICE End of Life criteria

- In order to allow for uncertainty in the clinical benefit of cancer drugs with incremental cost effective ratios in excess of NICE's standard range (£20,000 to £30,000 per QALY gained) to be explored in the context of recommendation for use within the Cancer Drugs Fund, NICE proposes to make the following changes to the End of life criteria:

  - Removing the restriction of the cumulative patient population from the current End of Life criteria to recognise that it has been rarely engaged; and

  - Amendments to emphasise the discretion that exists for NICE Appraisal Committees to interpret the uncertainty criteria when considering a drug for inclusion in the Cancer Drugs Fund.



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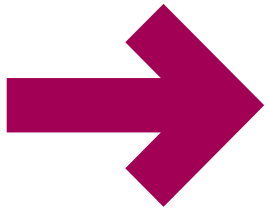
Consultation question:

Do you agree with the proposal that "patient population of 7000 or less within the accumulated population of patients described in the marketing authorisation" be removed from the criteria for the higher cost effectiveness threshold to apply?



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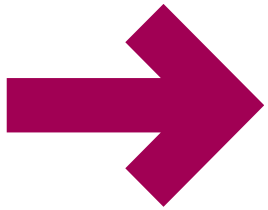
Interim Funding

- Proposed that all drugs that receive a draft recommendation for routine use from NICE will receive interim funding (out of the CDF budget) from the point of marketing authorisation.

- Furthermore, it is proposed that all drugs that receive a draft recommendation for conditional use within the CDF from NICE will also receive interim funding from the point of marketing authorisation.

- Drugs that are not recommended in draft NICE guidance will not receive interim funding.



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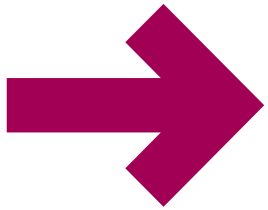
Consultation question:

- *Do you agree with the proposal that all drugs that receive a draft NICE recommendation for routine use, or for conditional use within the CDF, receive interim funding from the point of marketing authorisation until the final appraisal decision, normally within 90 days of marketing authorisation?*



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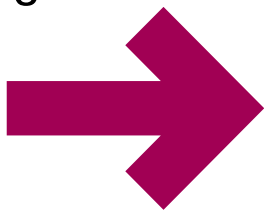
Interim Funding – alternative proposal

- Could provide interim funding for any new cancer drug or indication where the manufacturer has submitted the necessary information to NICE on a timely and comprehensive basis, but where NICE has not been able to make an interim decision at the point of marketing authorisation.

- Disadvantages:
  - potential provision of interim funding for drugs that subsequently receive a draft 'not recommended for routine use' decision from NICE.
  - Potential reduction in the amount of funding available from the fixed CDF budget, for more clinically and cost effective drugs.



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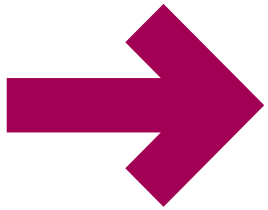
Consultation question:

- *What are your views on the alternative scenario, to provide interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not yet been produced, given that this would imply lower funding for other drugs in the CDF that have actually been assessed by NICE as worthwhile for CDF funding?*



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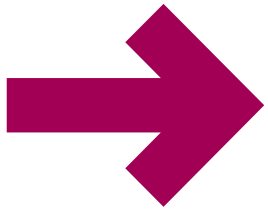
Funding after exit from the fund

- If and when NICE determine that a drug should not be recommended for routine commissioning, that drug will cease to receive funding from the CDF, with the company expected to pay for the drug for those patients who had previously received it. The exception to this will be for those drugs that remain in the CDF as at 31st March 2016.

- Should one of these drugs receive a ‘not recommended’ decision at first appraisal, then funding for existing patients will continue to be met from the CDF budget.



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Off-label cancer drugs

- It is recognised that the potential provision of off-label drugs is an important issue for certain rare cancers, and we wish to invite views, through this consultation, on how this can be addressed.

Consultation question

- *Do you have any comments on when and how it might be appropriate for the CDF in due course to take account of off-label drugs, and how this might be addressed?*

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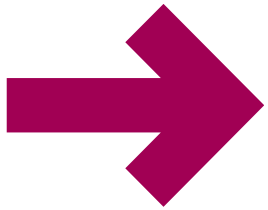
Investment control mechanisms

- To ensure the financial sustainability of the CDF, investment control mechanisms will be put in place to enable it to operate within a fixed budget.
- Propose the introduction of a prospective contingency provision and a cost cap for the total cost of each drug.
-
- As a general principle, the allocation of funds from the CDF to an individual drug/indication will be influenced by the number of patients in the UK necessary to collect the data required by the NICE Appraisal Committee and the cost effective price of the drug implied by the NICE appraisal.
- A CDF Investment Group (a joint committee of NHS England and NICE) will be established, responsible and accountable for ensuring that the CDF is managed within its budgetary limits.



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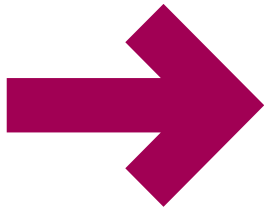
Consultation questions:

- *Do you agree with the proposal to fix the CDF annual budget allocation and apply investment control mechanisms within the fixed budget as set out in the consultation document?*

- *Do you consider that the investment control arrangements suggested are appropriate for achieving transparency, equity of access, fair treatment for manufacturers and operational effectiveness, while also containing the budget? Are there any alternative mechanisms which you consider would be more effective in achieving those aims?*



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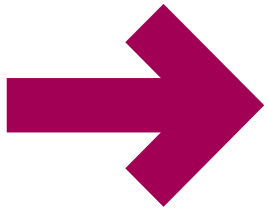
Consultation questions:

- *Are there any other issues that you regard as important considerations in designing the future arrangements for the CDF?*

- *Do you agree that, on balance, the new CDF arrangements are preferable to existing arrangements, given the current pressures the CDF is facing?*

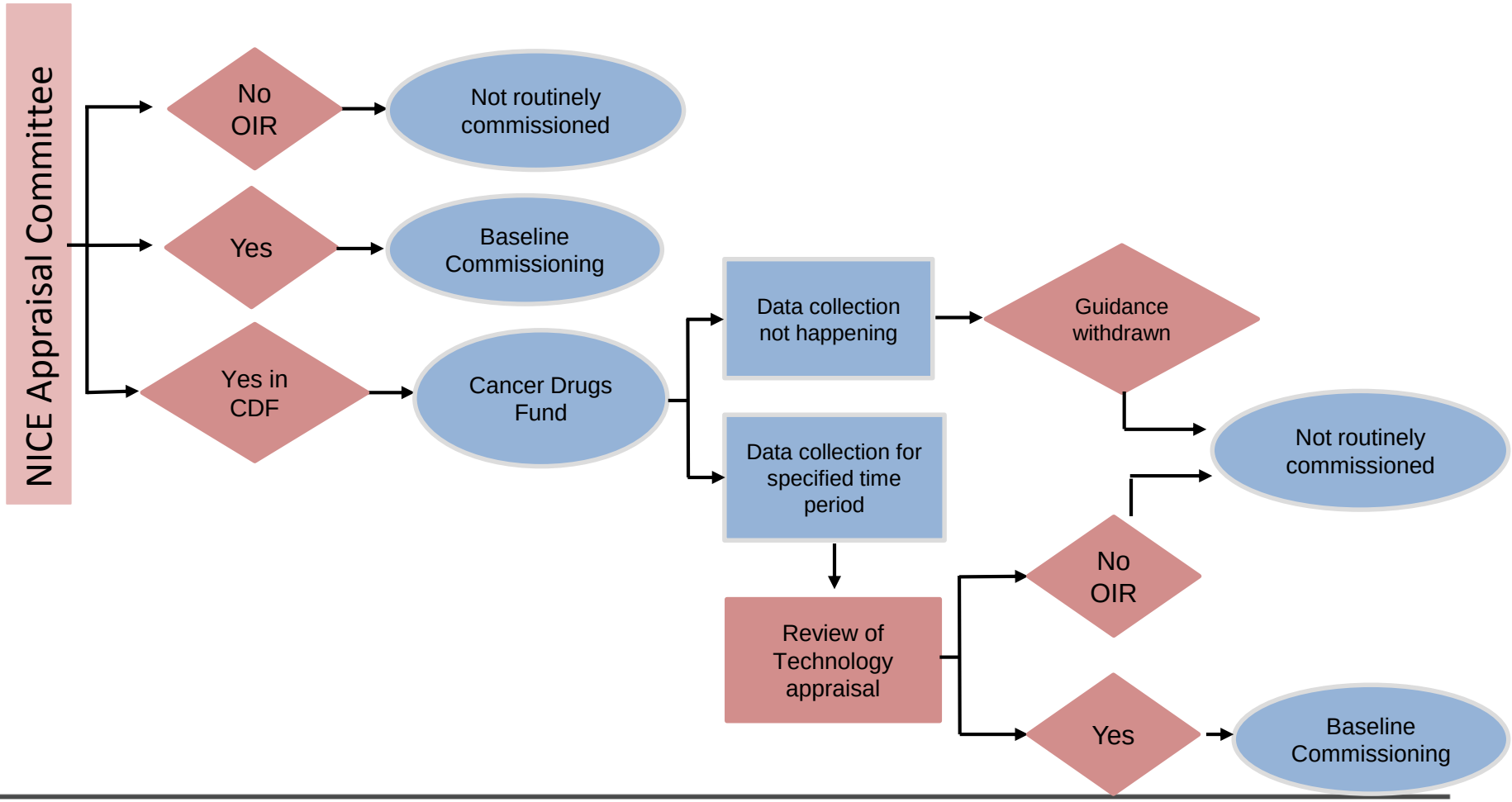


Consultation on proposals for a new operating model for the Cancer Drugs Fund

What does it mean for NICE?

Meindert Boysen
Technology Appraisals

The proposed new CDF - NICE



Implications for NICE

1. Appraise all cancer drugs
2. Amend the End of Life criteria
3. Allow for a different approach to uncertainty
4. Publish final guidance for cancer drugs within 90 days of Marketing Authorisation
5. Apply shortened timelines when updating guidance for cancer drugs on the CDF for 24 months
6. Re-consider drugs currently funded through the CDF (transition)

1. Appraise all cancer drugs

- Automatic formal referral of all cancer drugs to the Technology Appraisal work programme
- Setting up of dedicated CDF project team
- Increase technical and Committee capacity to accommodate increase in cancer topic appraisals

2. Amend the End-of-Life Criteria

Current

- 24 months life expectancy
- 3 month life extension
- Small population
- Robust evidence

Proposed

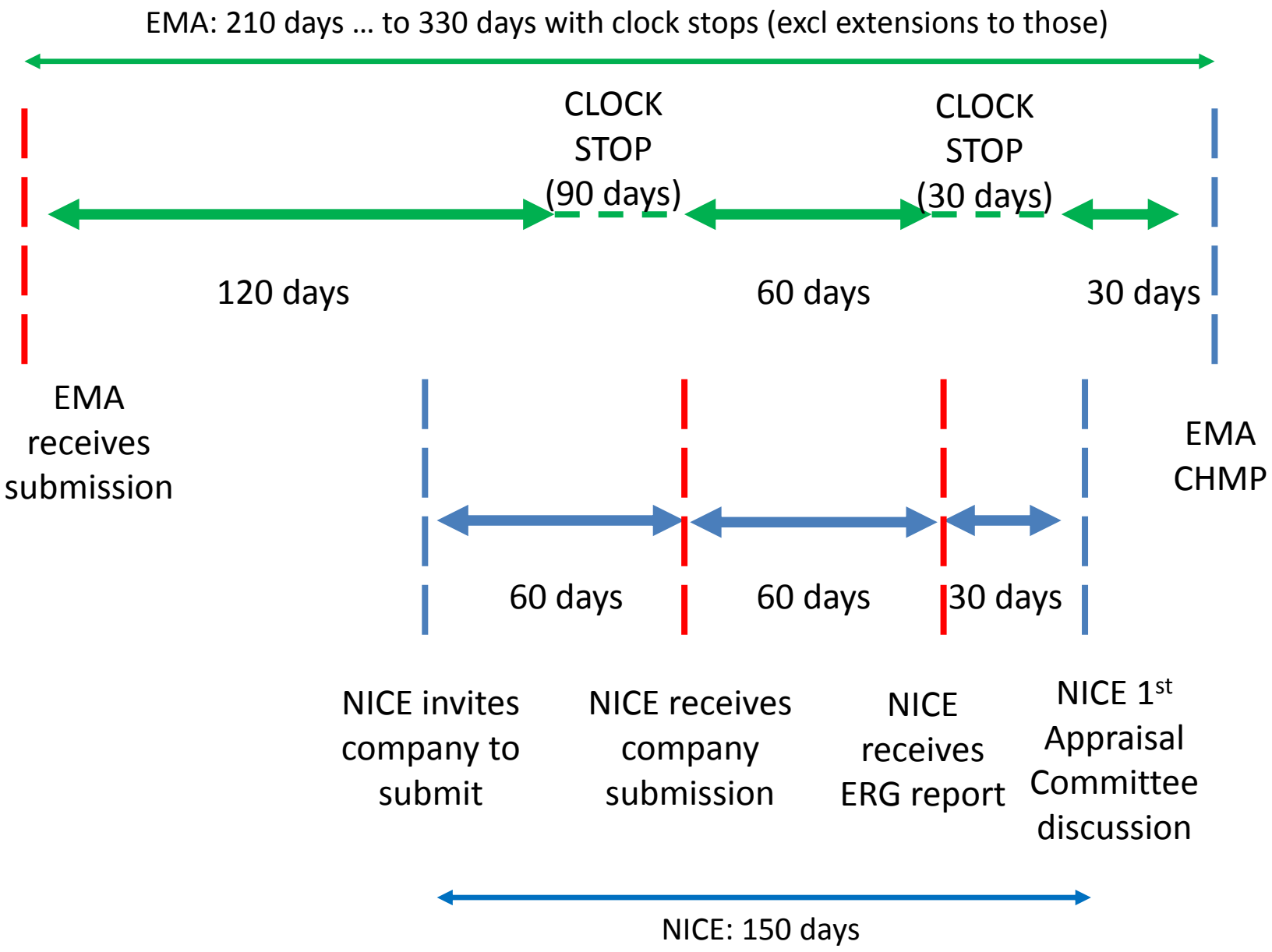
- 24 months life expectancy
- 3 month life extension
- Ensure that Committee understands that they have the flexibility to accept shorter life extension benefits for patients with very short life expectancy by applying the notion of '**normally**' already included in the methods (but now **highlighted**)
- Robust evidence

3. Appraising 'uncertainty'

- If the ……estimates of the extension to life are not sufficiently robust such that the uncertainty in the clinical and cost effectiveness data is too great to recommend the drug for routine use, the Committee can consider a recommendation for use within the Cancer Drugs Fund if the following criteria are met:
  - ✓ The ICERs presented have the plausible potential for satisfying the criteria for routine use, taking into account the application of the EoL criteria where appropriate
  - ✓ It is possible that the clinical uncertainty can be addressed through the collection of outcome data from patients treated in the NHS
  - ✓ It is possible that the data collected (including for research already underway) will be able to inform a subsequent update of the guidance

4. Guidance within 90 days of marketing authorisation

- First Appraisal Committee meeting held before an opinion CHMP has been published
- First Appraisal Committee will meet in private, as no regulatory decision will have been made
- ACD or FAD released only when the CHMP has published a positive opinion
- Where a second Appraisal Committee meeting is needed (when an ACD has been issued), it will be held when the product has received its Marketing Authorisation (in public)


EMA: 210 days … to 330 days with clock stops (excl extensions to those)
CLOCK STOP (90 days)
CLOCK STOP (30 days)
120 days
60 days
30 days
EMA receives submission
EMA CHMP
60 days
60 days
30 days
NICE invites company to submit
NICE receives company submission
NICE receives ERG report
NICE 1st Appraisal Committee discussion
NICE: 150 days

5. Update of guidance

- The guidance review will be undertaken through a shortened technology appraisal process, which will normally take a maximum of 6 months. The company will have 4 weeks to submit the new evidence from data collection, and the ERG will have 4 weeks to critique the new evidence (see table 8).
- The CDF guidance review will take into account the data that have become available since the original appraisal, together with any change to the patient access scheme or commercial access arrangement proposed by the company. No changes to the scope of the appraisal will be considered.
- Companies must provide an evidence submission to support the CDF guidance review. The managed access agreement signed at the time of the original appraisal will include this obligation.

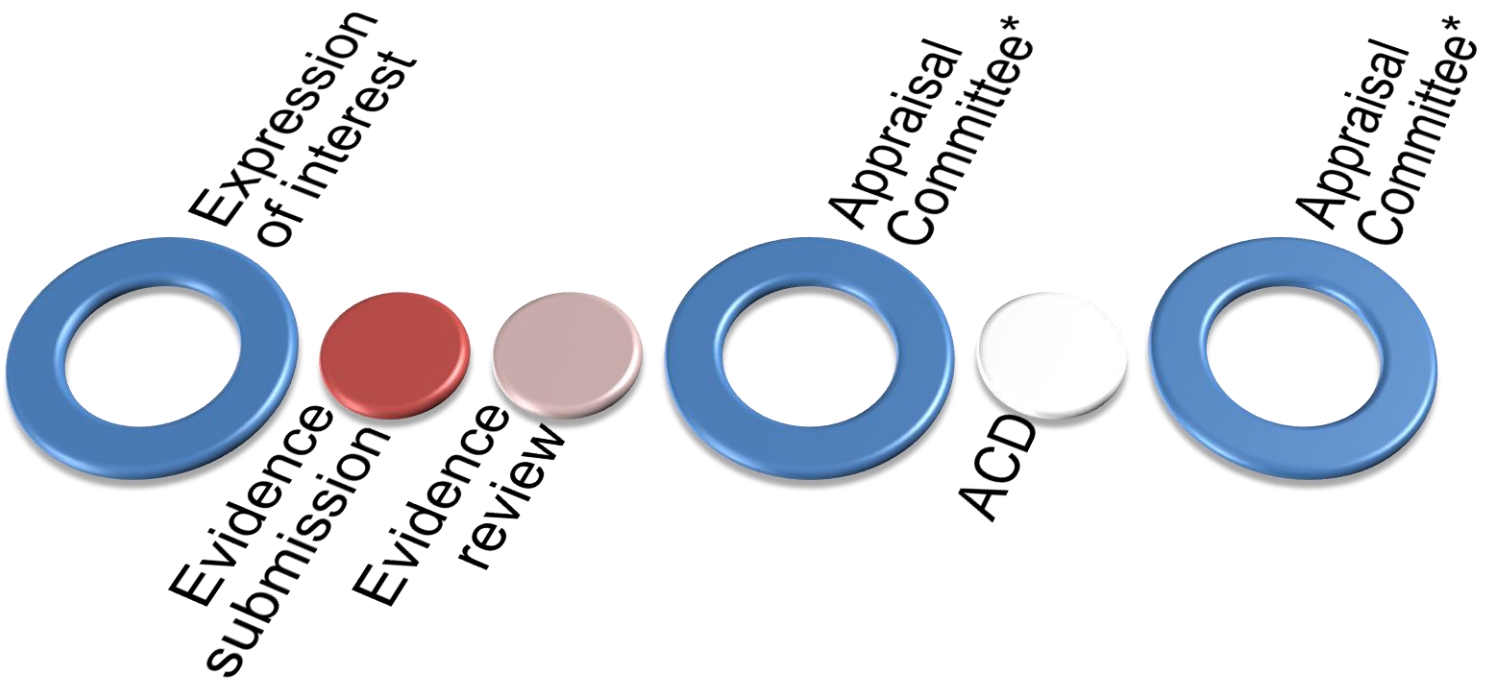
6. Re-consideration of drugs currently funded through the CDF (Transition)

- Drugs on CDF as of Nov 2015
  - Published NICE guidance
  - Ongoing NICE appraisal
  - Never appraised by NICE
- Starting the re-consideration of current CDF drugs imminent to meet timelines from consultation paper
- Any arrangements and activities have to be provisional and subject to change if the proposed CDF arrangements are amended after the consultation
- A rapid review facility will be used to allow consideration of new patient access scheme or commercial access agreement proposals for drugs with published NICE guidance

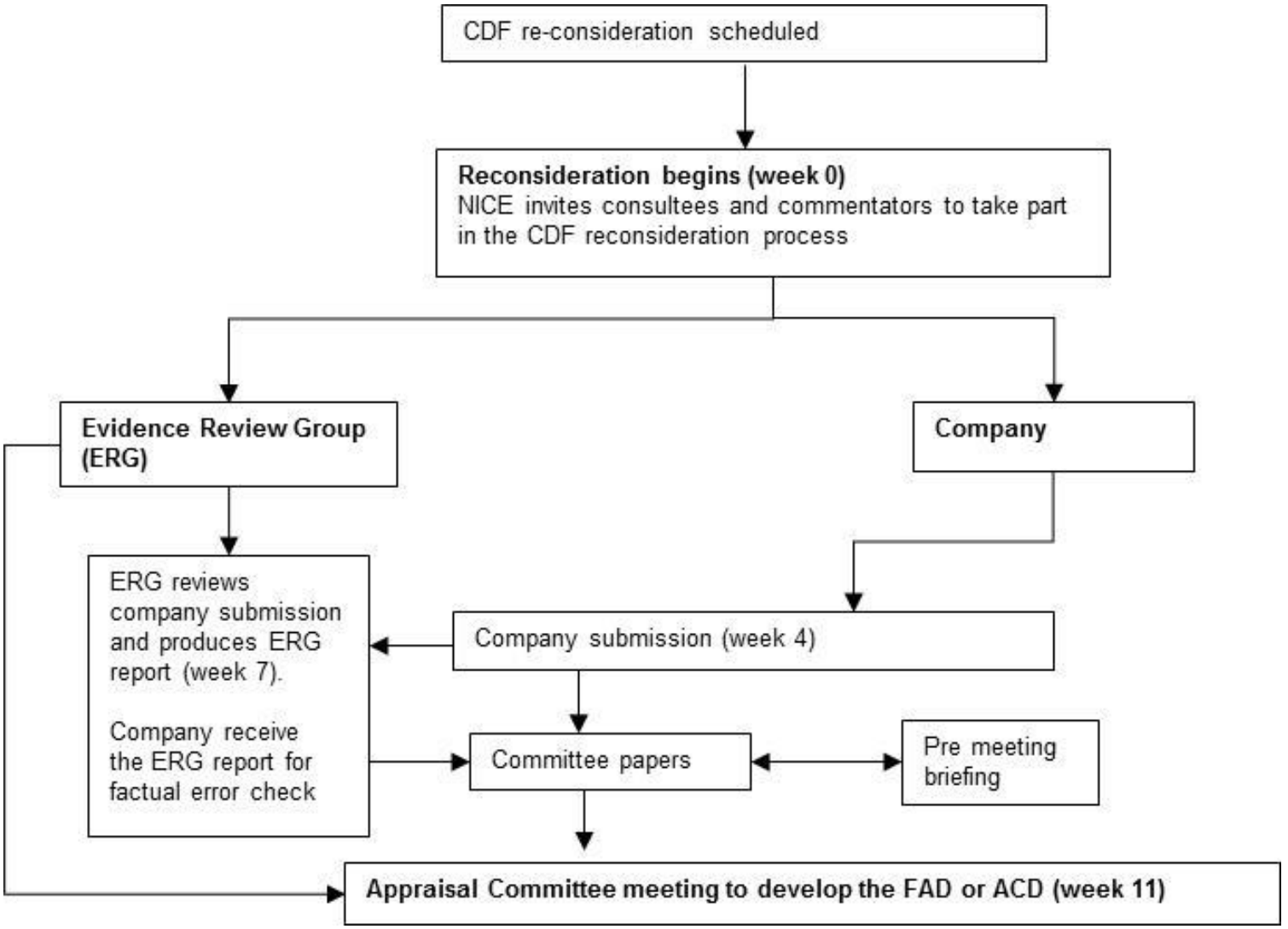
6. Re-consideration of drugs currently funded through the CDF (Transition) cont. 1

- The company evidence submission must
  - focus on cost effectiveness analyses using the assumptions in the economic model determined by the Appraisal Committee in the published NICE documents to be most plausible, and the new costs for the drug. Only in exceptional circumstances and with prior agreement with NICE should new clinical evidence be included.
  - take account of the proposed changes to NICE's methods of technology appraisal set out in the CDF consultation, in particular those concerning the appraisal of life-extending products at the end of life.
- Any commercial access arrangement or patient access scheme must be formally agreed by the time the Appraisal Committee meets.
- Companies will have the opportunity to change their evidence submissions to NICE in case substantial changes are required to the proposals currently included in the CDF consultation.

Drugs on CDF with published NICE guidance

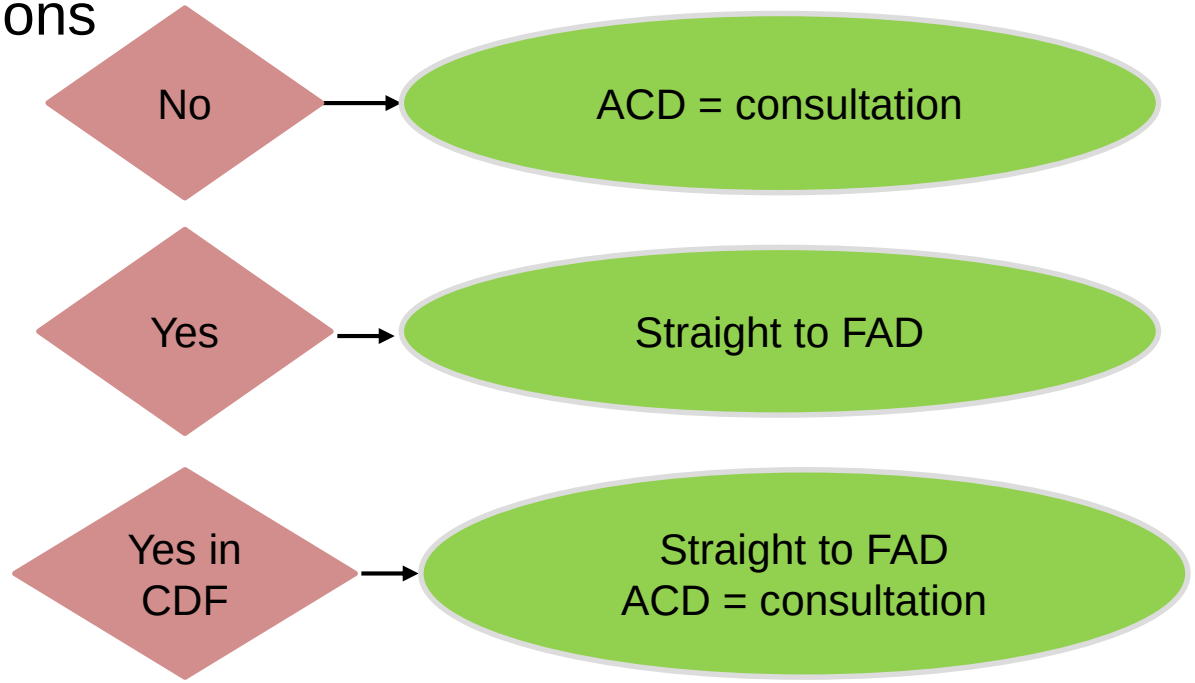


CDF rapid reconsideration process



6. Re-consideration of drugs currently funded through the CDF (Transition) cont. 2

- Appraisal Committee in public as much as possible, patient and clinical experts, company representatives attending
- The Appraisal Committee can make one of the following recommendations



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Q&A on what you've heard so far

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Group Discussions

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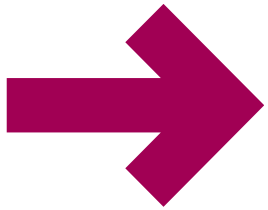
Group Discussions

- Your group number is written on your badge

- Group discussions can help to draw out further areas for clarification, identify areas of complexity or ambiguity.

- Identify 2 key issues that you want to raise:
  - Points that require greater clarification
  - Key themes that consideration needs to be given to



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Feedback on key themes

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Summary and Closing Comments

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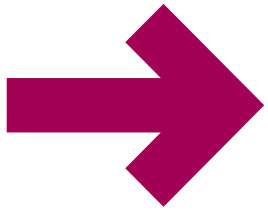
How to make your views known

-
- The consultation launched on **19th November 2015** and closes on **11th February 2016**
- The consultation document and feedback questionnaire can be found at: **https://www.engage.england.nhs.uk/consultation/cdf-consultation/consult_view**
- We are organising face-to-face events and webinars during the consultation period, providing opportunity for stakeholders to hear about the proposals, seek clarification and ask questions.
- For further information, contact: **england.futurecdfconsultation@nhs.net**

Post-consultation

- All feedback received during consultation will be analysed
- A short report, setting out the consultation feedback, will be published on the NHS England website. This will incorporate key messages from today
- NHS England and NICE will make a decision whether or not to approve the proposals, with or without amendments.




NHS
England
Thank you for coming – Don’t forget to submit a response