

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
CENTRE FOR HEALTH TECHNOLOGY EVALUATION

Technology Appraisals Programme

Specification for Cancer Drugs Fund data collection arrangements

1 Introduction

1.1 A cancer drug can be formally identified for entry into the Cancer Drugs Fund (CDF) at several time points during a technology appraisal:

- The first time point is when the company sends its evidence submission to NICE for a technology appraisal, and includes a proposal for data collection in this submission, covering details set out below. Identification of potential candidates for the CDF at this time point allows NICE and NHS England time to develop the potential data collection arrangements before the appraisal committee meeting;
- A second time point is during the assessment phase, at which time NICE may indicate that a drug could be a CDF candidate;
- The last time point is at the first appraisal committee meeting when the committee identifies that a drug is a CDF candidate;

In exceptional circumstances, it is possible that entry into the CDF could be formally identified at other time points (for example, after an appeal).

Companies may also informally signal to NICE early in the process that a treatment is a potential CDF candidate (for example, during scoping).

2 Possible data collection sources

2.1 There are two main options for collecting further data in the context of the CDF. Both options are potentially complementary to each other. These options are:

- [Systemic Anti-cancer Therapy](#) (SACT) dataset collection, which is mandated by NHS England as part of the Health and Social Care Information Standards and collated by Public Health England. The specific information on SACT can be integrated with other relevant forms of data collection operated by the National Cancer Registration and Analysis Service at Public Health England,

including the Cancer Outcomes and Services Dataset and the Radiotherapy dataset, as well as be linked to other databases such as the Hospital Episodes Statistics (see section 5 for further details);

- Clinical studies:
 - Ongoing studies (for example, further follow-up of Phase II and III trials, or Phase IV or pharmacovigilance studies);
 - Setting up a new study/ data collection.

Theoretically, other established tumour registries could be used as data sources.

The specific arrangements and steps to be taken may differ for each of these options and they are outlined in the subsequent sections of this document.

2.2 Collecting outcome data on an intervention and relevant comparators (if appropriate) in NHS England patients via the available data sources in the National Cancer Registration and Analysis Service at Public Health England, including SACT, will always occur even if other data sources are also used for the CDF data collection. All hospitals providing systemic anti-cancer therapy services are contracted within the NHS Standard Contract to submit key data to SACT.

2.3 SACT is strongly preferred for any data collection of routine chemotherapy practice in England, because the existing infrastructure (including data protection and information governance) is already established, data are already being collected and progress can easily be monitored. Further details are provided in section 5 below.

3 Committee considerations

3.1 The appraisal committee will use published methods to determine whether a drug should enter the CDF (see [Guide to the processes of technology appraisal](#) and its [addendum](#)). When considering whether a drug is a suitable candidate, the appraisal committee will define and describe the specific area(s) of clinical uncertainty. It will make judgements about the feasibility of new CDF data collection (either as the sole data source for addressing the key issues of uncertainty or to complement other data sources):

- This includes establishing the minimum timeframe for providing meaningful data, the duration of which will be determined on a case by case basis. The time frame will be as short as possible, normally up to 2 years, but could be longer depending on the issues of uncertainty, the rarity of the cancer and whether the CDF data collection will be the sole source of data to address the issues of uncertainty;
- The expected population size and treatment duration will be considered using data on current relevant drug use and epidemiology of the disease in England. The appraisal committee will receive advice from the company, NHS England and Public Health England on the nature of the data already being collected through existing studies or routine population-based datasets.

3.2 The committee will consider the ethical issues raised by the Citizens Council report [Using anonymised data derived from personal care records](#), including confidentiality, privacy and data security, transparency, the public benefit of research and good scientific practice.

3.3 When the committee decides that a drug should enter the CDF, it agrees the content of either the final appraisal determination (FAD), which sets out its final recommendations, or the appraisal consultation document (ACD), which sets out its preliminary recommendations.

- If the committee's decision to enter a drug into the CDF does not require a consultation, a FAD will be issued. This can occur when the recommendation for use within the CDF is in line with the marketing authorisation or the company's proposed use and the data collection arrangements have been agreed in principle by all parties before the committee meeting. The appraisal committee chair will approve the details of the data collection arrangements before the FAD is released for consideration of appeal.
- If the committee's decision to enter a drug into the CDF does require a consultation, an ACD will be issued (see sections 3.7.26 and 3.7.27 of the [addendum](#) to the Guide to the processes of technology appraisal). The committee will then review the data collection arrangements at its subsequent meeting in light of all comments received on the ACD.

4 Steps for data collection arrangements

- 4.1 After the committee has specified the key clinical uncertainties that need to be addressed through data collection to inform guidance review, a data collection arrangement (DCA) working group is formed. This has representation from NICE, the appraisal committee (normally the chair or vice-chair) and the NHS England CDF clinical lead:
- When the committee has been presented with the company's data collection proposal as part of the evidence submission and agreed this in principle, the DCA group will review the data collection proposal, with independent academic input, and provide commentary to the appraisal committee;
 - When it is the committee that has identified the drug as a potential CDF candidate, the DCA working group will, with independent academic input, translate the committee's key uncertainties related to clinical outcomes into a defined data collection question. This specification might include using results from studies or data sources already in progress plus Public Health England data including SACT data, or by Public Health England data including SACT data collection alone, or by new studies plus Public Health England data including SACT data collection. Public Health England will be involved when the data collection is through Public Health England data sources, and the company will be involved when data collection is from company-run clinical trials.
- 4.2 The population of patients to be treated, the numbers of patients needed for robust analysis in the data collection, comparators (where appropriate), the key outcomes to address the appraisal committee's issues of uncertainty (which will subsequently be used in economic modelling in the appraisal review after the CDF), analysis plan and the timeframe for the studies and/or Public Health England data, including SACT data, will be identified by the DCA working group. Relevant stakeholders, including the company, and clinical and patient experts present at the appraisal committee meeting, will be asked to comment.
- 4.3 The governance arrangements for the analysis or evaluation will be defined and form part of the formal data collection arrangement. It will include information governance and data protection as well as the requirement for

research ethics approval. Key governance points that will be documented include:

- Identification of data controllers and processors;
- Details of patient consent (or specify the circumstances where it is not considered necessary);
- Accountability for protocol;
- Accountability for analysis plans;
- Accountability for data collection platform (database issues);
- Accountability for monitoring and validation;
- Procedures for access to data;
- Data ownership and authorship of any publications;
- Accountability for disseminating results;
- Caldicott Guardian agreement.

These details need to be finalised before the managed access agreement, including the data collection arrangement, is approved by the CDF investment group.

5 Data collection via established registries

Public Health England data sources, including SACT

5.1 Data collection via Public Health England data sources, including SACT will always accompany any other data sources. The Public Health England data outcome collection could be the sole source of outcome data. The SACT data collection process is the preferred option for data collection in the CDF for five main reasons:

- SACT dataset is a mandated dataset as part of the Health and Social Care Information Standards. This is listed as a Schedule 6 national information requirement within the NHS Standard Contract;
- SACT collects data on all systemic treatments (including previous and subsequent therapies);
- The SACT dataset is part of a wider cancer data collection landscape at Public Health England, aiming to provide a complete picture of a cancer patient's pathway from diagnosis through linkage (see section 5.2);

- All necessary governance arrangements through SACT – and other datasets brought together by Public Health England - have been established with trusts and SACT data submission by trusts has been mandatory since April 2014;
- SACT already has experience both in data liaison with trusts and with analysis of NHS outcome data.

5.2 Public Health England's National Cancer Registration and Analysis Service brings together data from more than 500 local and regional data feeds to build an understanding of an individual's treatment from diagnosis. This includes information drawn from histopathology reports, multidisciplinary team meeting decisions, radiotherapy and systemic anti-cancer treatment data (through the SACT database), administrative details such as route of admission and access to imaging information to enable accurate cancer staging. The data can also be linked to other data sets including the Diagnostic Imaging Dataset (DID), Hospital Episode Statistics (HES) and Cancer Waiting Times (CWT).

5.3 The SACT database collects information reported routinely by NHS trusts in England, on the treatment of malignant disease in four key areas:

- Patient and tumour characteristics;
- Trust and consultant details;
- Treatment characteristics including drug names and drug combinations (regimens);
- 'Outcome' fields.

The full data standard and data dictionary are available [online](#).

5.4 When it has been decided that Public Health England's National Cancer Registration and Analysis Service data are to be used, Public Health England will deliver agreed analyses to support CDF evaluation as part of a wider commissioning agreement with NHS England.

5.5 If a drug has a draft recommendation to enter into the CDF after the NICE first appraisal committee, the DCA working group (see section 4.1) will confirm that the uncertainty identified by the appraisal committee could be answered through the data currently collected through SACT.

If so, the DCA working group will define:

- the data collection question, specifying the required data field(s) whilst in the CDF;
- the data analyses to be provided after the data collection, which will be used when the guidance is reviewed;
- the comparator, if relevant and appropriate, and how to construct analyses when there is little effectiveness data for the comparator;
- the estimated number of patients needed to answer the uncertainty and the specific patient eligibility criteria to match those of the population on which NICE has based its CDF recommendation;
- the timeline for the data collection based on the number of patients needed to answer the data collection question matched against the expected drug uptake and duration of treatment;
- the frequency of analysis updates to check the continuing validity of the timeline;

Based on the areas of uncertainty commonly identified in NICE technology appraisals of cancer drugs, existing Public Health England data sets are expected to be able to cover the vast majority of DCA requirements. However, if the current data fields in Public Health England's datasets are not sufficient to answer the uncertainty, Public Health England has the mechanisms and governance infrastructure in place to collect agreed additional data items deemed feasible within the CDF DCA agreement timeframe.

The terms and conditions of the DCA for any Public Health England data collection will be shared with the company before the second appraisal committee for their review and comments.

Governance of evaluation conduct and data access

- 5.6 Individual patient data will remain within Public Health England premises and there will not be any data sharing of individual patient data outside of Public Health England. Public Health England will be responsible for analysing the data, publishing the methodology used and sharing the results of the data analyses with NICE and NHS England who will then be responsible for sharing them with the company and other relevant stakeholders if necessary. Where Public Health England leads on analyses using established databases within

Public Health England, it is anticipated that no further requirements will need to be put in place. However, this will be reviewed on a case-by-case basis and the necessary arrangements made as applicable and appropriate.

Data ownership

- 5.7 For data held by Public Health England, patients will be the sole data owners. Public Health England will be a data controller as the data constitute personal data.

Accountability for analysis plans

- 5.8 The DCA working group will prepare an analysis plan and timescales that will include interim reporting milestones (e.g. on data quality or accruals). The company should alert NICE if it intends to specify any outcomes not routinely included in Public Health England datasets.
- 5.9 Public Health England will share the full methodology of the analysis and any assumptions with NICE and NHS England, which will then be shared with the company.

Accountability for data collection platform (database)

- 5.10 The accountability for the online data collection platform for Public Health England managed data collections (particularly the SACT portal) lies with Public Health England.

Accountability for monitoring and validation

- 5.11 The accountability for monitoring and validating SACT data in particular submitted to the SACT portal by NHS trusts lies with Public Health England. Updates on patient numbers, completeness and quality of the data, and analysis reporting should be provided at intervals agreed for each appraisal.

Accountability for disseminating results

- 5.12 NICE will publish key evidence and the committee's decision through an ACD or FAD when the original guidance is reviewed at the end of the CDF period. Any Public Health England-led analyses using available data within Public Health England will be part of the committee papers. After the first committee meeting for the guidance review, a FAD will be produced if the drug is

recommended for routine commissioning in line with the original conditions for use in the CDF. In all other circumstances, an ACD will be produced.

Other registries

- 5.13 Other data collection sources outside Public Health England could potentially be used if the company is able to show that this would be feasible (for example, that any information governance issues could be overcome within the limited data collection timeframe). The company's proposal should include the areas listed in sections 5.5–5.12.

6 Data collection via clinical trials

Ongoing studies

- 6.1 Data collection via ongoing clinical studies is another useful source for the CDF. It can be assumed that the protocol (including analysis plans), governance arrangements and data ownership have already been established by the company, MHRA or academic group sponsoring the study. This would potentially enable the immediate start of data collection (depending on additional ethics approval for the use of the data in the CDF).

New study

- 6.2 Data collection can also be undertaken through a newly designed study but timelines would need careful consideration in light of the time-limited nature of managed access agreements within the CDF. The study can be established by the company or other organisation. If the latter, the study sponsor* will need to provide details to NICE on the points below.

Study protocol

- 6.3 The company or study sponsor should submit the study protocol at the earliest possible stage to NICE which should include details on:
- Monitoring and validation of data collection;
 - Planned analyses, including primary endpoints and any subgroup analysis;

* As defined by the NHS Health Research Authority: "The sponsor is the individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting.

- Data ownership (see below on access to data);
- Planned dissemination of data.

Research governance

6.4 The study sponsor must submit confirmation to NICE that there are appropriate arrangements in place for the following aspects of research governance:

- Ethical approval, including patient information and consent procedures;
- If using NHS data collection sites, NHS Research and Development (R&D) management review at each site;
- Information governance, including data sharing arrangements.

If any of these procedures require modification in view of the use of data as part of CDF, the study sponsor is responsible for receiving the necessary approvals and submitting them to NICE.

Access to data

6.5 To ensure that the appraisal process is as transparent as possible, NICE considers it essential that key evidence on which the appraisal committee's decisions are based is publicly available. For details of NICE's approach to information handling during an appraisal, see section 3 of the [Guide to the processes of technology appraisal](#). The principles outlined in the guidance on [implementing the European Medicines Agency's policy](#) on publishing clinical data should also be taken into account.

6.6 When the guidance is reviewed after data collection has been completed, information marked as confidential should be kept to an absolute minimum in the company submission. Unpublished data should be made available for public disclosure where possible; this will include any analyses by Public Health England. Data that underpin and are included in the economic analyses informing the guidance review should be made available.

7 Timing of data collection arrangements

7.1 For any cancer drug appraisal, NICE will proactively schedule CDF-related meetings of the DCA working group to begin shortly after the first appraisal committee meeting as part of the appraisal-specific timelines. Should a cancer

drug be recommended for routine commissioning or not recommended at the first appraisal committee meeting, these CDF-specific meetings will be cancelled.

- 7.2 When the appraisal committee decides that a drug enters the CDF, it will specify the uncertainty and indicate the general nature of the data that need to be collected. For data collection via established registries where the company has provided a CDF proposal with its evidence submission, the DCA working group will review and confirm that the arrangements in the proposal are fit for purpose. For data collection via established registries where the company hasn't provided a CDF proposal with its evidence submission, the DCA working group will develop the data collection question(s) and outline the analyses that are needed, as well as the duration of data collection (see section 4.2). For data collection via clinical trials, the duration will depend on the expected reporting date.
- 7.3 During the data collection period, NICE will schedule the committee meetings required for the respective CDF guidance review, to ensure as timely review of guidance as possible (for further details, see section 6 of the [addendum](#) to the Guide to the processes of technology appraisal).

Overview: Procedural steps for CDF data collection arrangements

Draft data collection agreement in place before first committee meeting

Week	Action
0	<ul style="list-style-type: none"> Appraisal committee recommends that a cancer drug should enter the CDF after reviewing a draft data collection proposal developed before the first committee meeting
3	<ul style="list-style-type: none"> Where applicable, the DCA working group (including NICE, the appraisal committee chair or vice-chair and the NHS England CDF clinical lead) confirms the research question, including the population, comparator(s), outcomes and necessary analyses Comments are requested from the company and clinical patients experts Where applicable, NICE liaises with Public Health England to ascertain the availability and feasibility of data collection Where applicable, ACD issued to consultee and commentators then published on the NICE website 5 working days later
5	<ul style="list-style-type: none"> Where an ACD is not produced because the committee is fully satisfied with the company's draft data collection agreement, FAD issued to consultee and commentators for appeal and published on the NICE website 5 working days later
7	<ul style="list-style-type: none"> In response to consultation on the ACD, amendments to the draft data collection arrangements are made for consideration by the committee
8/9	<ul style="list-style-type: none"> After consultation, appraisal committee content with data collection arrangements If through 2nd committee meeting: FAD with yes in CDF
10	<ul style="list-style-type: none"> If ACD was issued, data collection arrangements amended in line with committee's preferences expressed at the second committee meeting
11	<ul style="list-style-type: none"> Data collection arrangements finalised¹
14	<ul style="list-style-type: none"> Where an ACD has previously been produced, FAD issued to consultee and commentators for appeal and published on the NICE website 5 working days later.
<p>¹CDF investment control group signs off the data collection arrangements as part of the managed access agreement. Exact timings for this step may vary</p>	

No draft data collection agreement proposed before first committee meeting: committee proposes inclusion in the CDF

Week	Action
0	<ul style="list-style-type: none"> • Appraisal committee considers the treatment has potential to be a CDF candidate. • Committee requests the company prepares a data collection proposal for inclusion in the CDF
2	<ul style="list-style-type: none"> • The DCA working group (including NICE, the appraisal committee chair or vice-chair and the NHS England CDF clinical lead) defines the research question, including the population, comparator(s), outcomes and necessary analyses • Comments on the data collection proposals are requested from the company and clinical patients experts
3	<ul style="list-style-type: none"> • DCA working group agrees the most appropriate source for data collection • Where applicable, NICE liaises with Public Health England to ascertain the availability and feasibility of data • ACD issued to consultee and commentators (published on the NICE website 5 working days later)
5	<ul style="list-style-type: none"> • Company drafts data collection arrangements as appropriate for the respective source for data
7	<ul style="list-style-type: none"> • Draft data collection arrangements prepared for committee meeting/ agreement/ comment
8/9	<ul style="list-style-type: none"> • After consultation, appraisal committee content with data collection arrangements and instructs NICE to prepare a FAD for the treatment to be recommended in the CDF
10	<ul style="list-style-type: none"> • Draft data collection arrangements amended in line with committee agreement
11	<ul style="list-style-type: none"> • Data collection arrangements finalised¹
14	<ul style="list-style-type: none"> • FAD issued to consultee and commentators for appeal and published on the NICE website 5 working days later.
<p>¹CDF investment control group signs off the data collection arrangements as part of the managed access agreement. Exact timings for this step may vary</p>	

No draft data collection agreement proposed before first committee meeting and not recommended in ACD, but subsequent proposal for entry to the CDF is received

Week	Action
0	<ul style="list-style-type: none"> Appraisal committee does not recommend a cancer drug where there is clinical uncertainty because it does not meet other CDF decision-making criteria (for example, the drug does not show plausible potential for cost effectiveness at its current price).
3	<ul style="list-style-type: none"> ACD issued to consultee and commentators (published on the NICE website 5 working days later)
5	<ul style="list-style-type: none"> Company request permission from NICE to submit additional evidence on the form of a CDF proposal Company drafts data collection arrangements as appropriate for the respective source for data
6/7	<ul style="list-style-type: none"> Company submits in its consultation response a draft CDF data collection proposal plus, where relevant, any financial components of a managed access agreement
7	<ul style="list-style-type: none"> Draft data collection arrangements prepared for committee meeting/ agreement/ comment
8/9	<ul style="list-style-type: none"> Appraisal committee content with data collection arrangements and instructs NICE to prepare a FAD for the treatment to be recommended in the CDF Note a third committee meeting may be required if the committee is not fully satisfied by the company's proposal
10	<ul style="list-style-type: none"> Draft data collection arrangements amended
11	<ul style="list-style-type: none"> Data collection arrangements finalised¹
14	<ul style="list-style-type: none"> FAD issued to consultee and commentators for appeal and published on the NICE website 5 working days later.
¹ CDF investment control group signs off the data collection arrangements as part of the managed access agreement. Exact timings for this step may vary	