Public Health England

Protecting and improving the nation's health

Methodologies applied when using the Systemic-Anti-Cancer Therapy (SACT) dataset to evaluate treatments in the Cancer Drugs Fund (CDF)

A working paper on SACT methodologies for CDF funded drugs

Contents

Methodologies applied when using the Systemic-Anti-Cancer Therapy (SACT) dataset to evaluate treatments in the Cancer Drugs Fund (CDF) 1
Contents 2
Introduction 3
Methods 4
CDF applications - identification of the cohorts of interest 4
CDF applications - de-duplication criteria 4
Initial CDF cohorts 4
Timelines for SACT 5
Linking CDF cohort to SACT 6
Data completeness 6
Addressing clinical uncertainties 9
Treatment duration 9
Overall survival 11
Summary 12
References 13

Introduction

The National Institute of Clinical Excellence (NICE) reviews all new and promising cancer treatments which have received a marketing authorisation and make recommendations on their use within the NHS if the clinical and economic evidence, provided by the company, shows that the treatment is not only beneficial to patients but that the drug is cost effective. If there is any clinical uncertainty, and as such, the treatment is not recommended for routine commissioning, but there is enough evidence to say the treatment could be of benefit to patients, then the NICE appraisal committee can recommend a treatment for use in the Cancer Drugs Fund (CDF).

CDF funding allows for a period of manged access whilst additional data is collected to address areas of committee uncertainty. Data may be collected through ongoing clinical trials and/or through real world use of the treatment in the NHS. The Systemic Anti-Cancer Therapy dataset (SACT) is used to collect data on real world treatment use.

This is a working document that details the steps taken to clean and extract data from SACT and applications captured on the NHS England's (NHSE) Blueteq system. It details the methodologies applied to extract these data and analyse outcomes. SACT data are collected for all systemic anti-cancer therapies, regardless of the funding route for the drug, including treatments that are provided through baseline commissioning, the CDF and free of charge as part of an Early Access to Medicines Scheme (EAMS)1.

NHS England and NHS Improvement's Blueteq database captures the Cancer Drugs Fund population. NHS England and NHS Improvement shares Blueteq data with Public Health England (PHE) for the Cancer Drugs Fund evaluation purposes. The lawfulness of this processing is covered under article 6(1)e of the United Kingdom General Data Protection Regulations (GDPR) (processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller). PHE, through the National Cancer Registration and Analysis Service, does have permission to process confidential patient information (without prior patient consent) afforded through Regulation 2 of The Health Service (Control of Patient Information) Regulations 2002. This document will be updated as new methodologies are developed or current methodologies refined.

Methods

CDF applications - identification of the cohorts of interest

NHSE collects applications for CDF treatments through their online Blueteq system. The Blueteq application form can be modified to ensure any essential baseline demographic and clinical characteristics of patients, needed for CDF evaluation purposes, are captured.

Consultants must complete a Blueteq application form for every patient receiving CDF funded treatment. There is a pre-specified list of eligibility criteria for all CDF treatments. As part of the application form, consultants have to confirm that a patient satisfies all eligibility criteria to commence treatment. NHSE pass information to PHE on all patients with an approved CDF application which met the eligibility criteria

CDF applications - de-duplication criteria

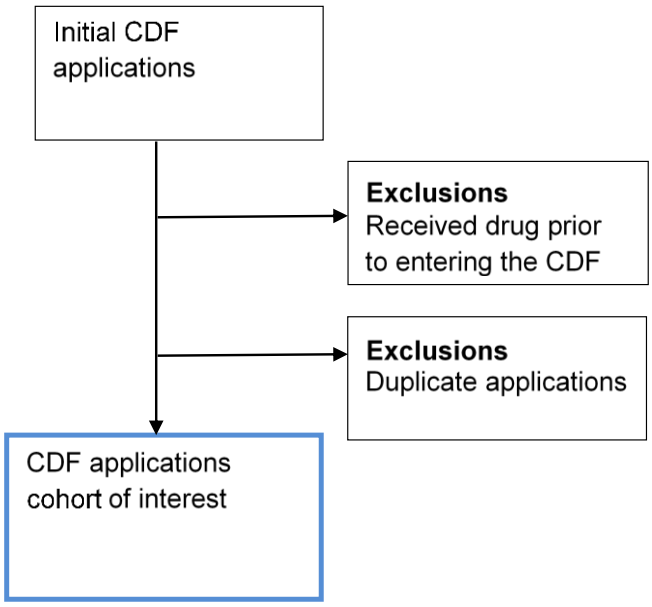
Before conducting any analysis on CDF treatments, the CDF database is examined to identify duplicate applications. The following de-duplication rules are applied.

1. If 2 trusts submit an application for a CDF treatment, for the same patient (identified using the patient's NHS number), and both applications have the same approval date, then the record where the CDF trust (the trust applying for CDF treatment) matches the SACT treating trust is selected.
2. If 2 trusts submit an application for a CDF treatment, for the same patient, and the application dates are different, then the record where the approval date in the CDF is closest to the regimen start date in SACT is selected, even if the CDF trust (the trust applying for CDF treatment) didn't match the SACT treating trust.
3. If 2 applications are submitted for a CDF treatment and the patient has no regimen start date in SACT capturing when the specific drug was delivered, then the earliest application in the CDF is selected.

Initial CDF cohorts

Analysis is limited to CDF applications made from the date when the drug entered the CDF. Any treatments delivered before the CDF entry date are excluded as they are likely to be patients receiving treatment via an EAMS programme or a compassionate access scheme run by the pharmaceutical company.

Figure 1. Derivation of the cohort of interest from the initial CDF applications made for a specific CDF drug, from the CDF entry date to the data collection end date



Timelines for SACT

SACT is the primary data source when there is no clinical trial, in this situation SACT will be used to answer areas of clinical uncertainty that have been raised at the NICE committee. Where SACT is the primary data source a 4-month reporting period is allowed from the end of the data collection for treatment information to be collected and reported to the SACT dataset. This window ensures the data is as correct and complete as possible. Trusts submit records to the SACT dataset 12 weeks after treatment activity. During the intervening time, trusts upload their initial SACT data for the month to the submission portal, correct all local and critical errors (errors arise if a submission fails to pass validation on the upload portal), map all regimens to national standards and finally submit the data. An additional month is allowed for the SACT submission to pass through the data collection system at PHE before data is available for analysis.

SACT is the secondary source when there is an ongoing clinical trial that will act as the primary data source and answer the clinical uncertainty raised at the NICE committee. Where SACT is the secondary data source SACT follow-up stops 4 months before the end of data collection to allow more rapid delivery of the SACT report after the formal end of data collection.

The SACT snapshot is taken on the first Saturday of every month and made available to analysts, normally by the 20th of the month. At the time of reporting, all patients are sent for tracing to obtain their vital status using the Personal Demographics Service (PDS)2.

Linking CDF cohort to SACT

NHS numbers are used to link SACT records to data in NHSE's Blueteq system for specific drugs in the CDF identified in figure 1. Information on treatments in SACT are examined to ensure the correct SACT treatment records are matched to the CDF application, this includes information on treatment dates (regimen, cycle and administration dates) and primary diagnosis codes in SACT.

Where differences are found between the primary diagnosis in SACT and the primary diagnosis in the CDF the extent of matching is reviewed. If the primary diagnosis code used in each dataset is slightly different but falls within the same tumour group, for example, C82 and C83 are both Non-Hodgkin lymphoma, the difference is not queried further. Where there are significant differences, for example, diagnosis code of C82 against the CDF application and a diagnosis code of C34 (lung) in SACT, the SACT team contact the trust to establish the reason for the difference and confirm if this is a data entry error.

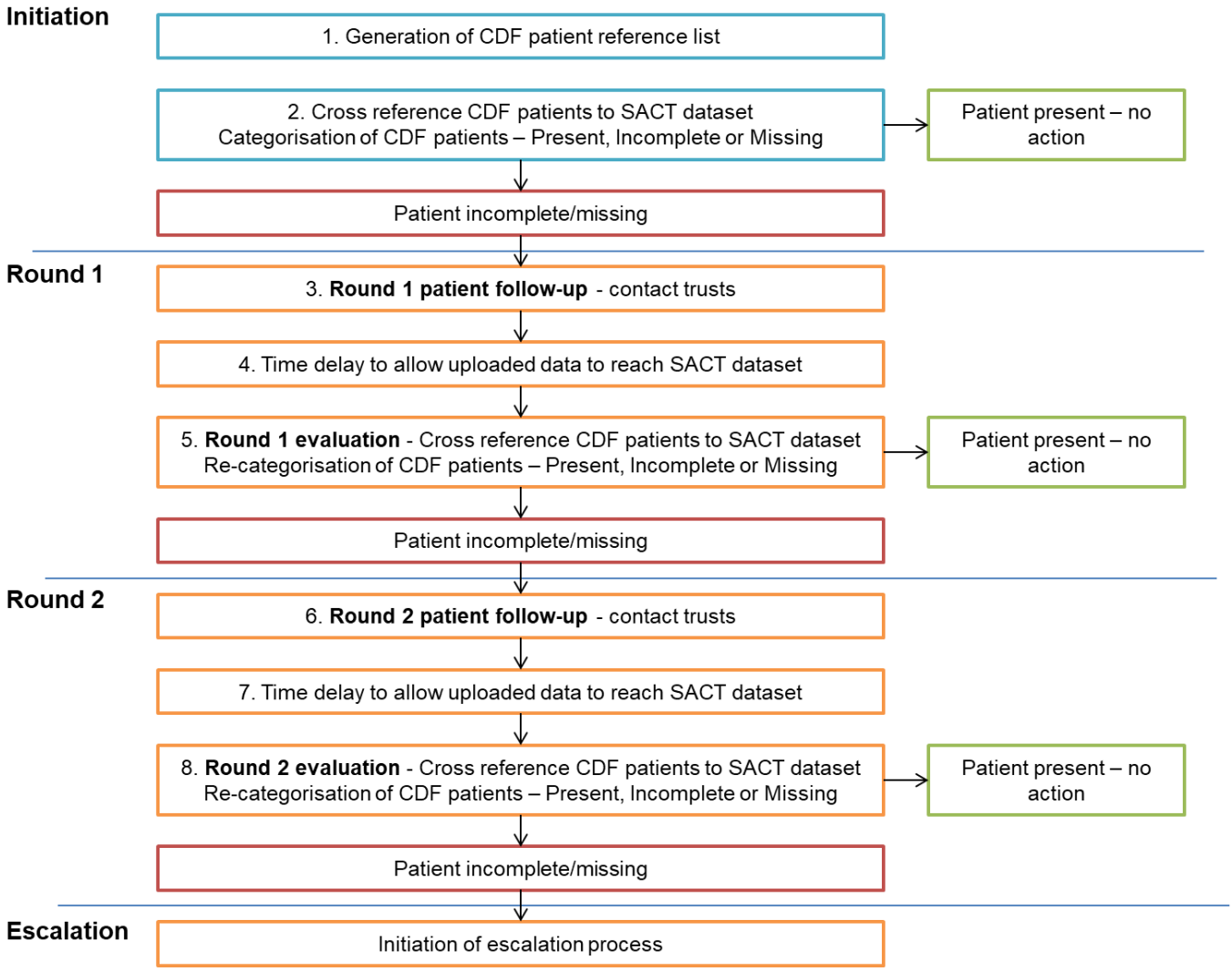
Data completeness

Data completeness of the SACT dataset has improved since its implementation in 2012 with all trusts now submitting their systemic anti-cancer therapies. This improvement is a result of the wider use of e-prescribing systems and the recruitment of several SACT data liaison officers at PHE. PHE also has a dedicated SACT helpdesk that supports trusts in their SACT data submissions.

PHE have started to produce several routine outputs to demonstrate data completeness of SACT data for the submitting trusts. These reports help trusts to review their performance and highlight data gaps. These reports can be found on the Cancerstats2 website3. This website can only be accessed behind the N3 (NHS) network. In addition to routine reports, NHSE in partnership with PHE developed a medicines optimisation (MO) CQUIN4. The CQUIN includes requirements to improve the overall quality and completeness of the SACT data being provided by trusts. It also identifies several SACT data items that are high priority for improvement.

For CDF indications, PHE have set up an additional process in which the SACT data liaison officers follow-up with trusts if any of their CDF treatment activity is missing. As such, the quality of SACT data for CDF applications is higher than general SACT submissions. An overview of the process for patient follow up is provided below (Figure 2 and Table 1).

Figure 2. CDF follow-up overview



Analysts at PHE generate an updated Blueteq reference list on a monthly basis, for the duration of data collection. This list contains patient NHS numbers, date of birth, diagnosis, CDF treatment, requesting consultant, and the Blueteq approval date. The Blueteq reference list of patients is uploaded as a data table into the Cancer Analytical System (CAS) which is used to store and analyse all SACT data.

SACT data uploaded by trusts becomes available to analysts through CAS on the third week in the month. At this stage patient identifiers from the SACT dataset are cross-referenced to the Blueteq reference list and CDF patients flagged as ‘present’, ‘missing’ or ‘incomplete’ based on the following criteria:

Table 1. Criteria to evaluate status of CDF patients in SACT

Patient status	Criteria
Present	Patient with Blueteq application and complete record for CDF treatment in SACT dataset. A 'complete' record is defined as a patient with: • SACT record for the expected CDF treatment • treatment start date less than or equal to 30 days post-Blueteq approval date • treatment activity within the last 3 months • OR no treatment activity for greater han or equal to 3 months but a submitted treatment outcome
Incomplete	Patient with Blueteq application and record for CDF treatment in SACT dataset, missing one of the following fields: • treatment start date less than or equal to 30 days post-Blueteq approval date • treatment outcome summary, if no treatment activity in SACT for greater than or equal to 3 months
Missing	Patient with Blueteq application and no SACT record for CDF treatment

Patients identified as incomplete or missing are flagged for follow up and allocated to the appropriate member of the SACT helpdesk or data liaison team, based on geographic coverage.

Addressing clinical uncertainties

Treatment duration

Treatment duration is one of the main analyses provided in CDF annual and final reports. The methodology currently applies to non-oral drugs only. A separate methodology is in development to calculate treatment duration for oral drugs.

Start date is defined as the date the patient started their CDF treatment. This date is identified in the SACT dataset as the patient's earliest treatment date for the treatment of interest. Data items used to determine a patient's earliest treatment date are:

1. Start date of regimen – SACT data item #22.
2. Start date of cycle – SACT data item #27.
3. Administration date – SACT data item #34.

The earliest of these dates is used as the treatment start date.

The same SACT data items (#22, #27, #34) are used to identify a patient's final treatment date. The latest of these 3 dates is used as the patient's final treatment date.

Additional explanation of these dates is provided below:

Start date of regimen

A regimen defines the drugs used, their dosage and frequency of treatment. A regimen may contain many cycles. This date is generally only used if cycle or administration dates are missing.

Start date of cycle

A cycle is a period of time over which treatment is delivered. A cycle may contain several administrations of treatment, after each treatment administration, there will be a delay before the next treatment administration. For example; a patient may be on a 3-weekly cycle with treatment being administered on the 1st and 8th day, but nothing on days 2 to 7 and days 9 to 20. The patient's next cycle would start on the 21st day.

Administration date

An administration is the date a patient receives treatment, using the above as an example the administrations for a 3 weekly cycle would be on the first and eighth day and then again on the 21st day, which would be the first day of their next cycle.

The interval between treatment start date and final treatment date is the patient's time on treatment.

All patients are then allocated an ‘administration interval’ which is a set number of days to the end of their final treatment date to allow for the fact that they are effectively still ‘on treatment’ until the next administration. The number of days assigned is the number of days between their cycle administrations. If a patient dies between administrations, then their censor date is their date of death and these patients are deemed to have died on treatment unless an outcome summary is submitted to the SACT database confirming the patient ended treatment due to disease progression or toxicity.

Adding a number of days to a patient’s final treatment date ensures we do not underestimate treatment duration or the number of deaths on treatment. See Appendix A for the number of days added for each drug. The number of days detailed in appendix A are based on the administration schedule recommended by the drug manufacturer and cross referenced with the observed cycles or administrations captured in SACT. The appendix will be updated as new drugs enter the CDF.

Treatment duration

Treatment duration is calculated for each patient as:

Treatment duration (days) = (Final treatment date – Treatment start date) + prescription length (days).

This date would be the patients censored date, unless a patient dies in between their last treatment and the prescription length added, in this case, the censored date would be the patients date of death.

Once a patient’s treatment duration has been calculated, the patient’s treatment status is identified as one of the following:

No longer receiving treatment (event), if:

1. The patient has died.
2. The outcome summary, detailing the reason for stopping treatment has been completed:

    - SACT v2.0 data item #41
    - SACT v3.0 data item #58 - #61

3. There is no treatment record in SACT for at least 3 months.

Otherwise, if none of the above apply, the patient is assumed to still be on treatment and is censored.

Overall survival

Overall survival is calculated from the CDF treatment start date, not the date of a patient's cancer diagnosis. To calculate survival from the treatment start date we use the patient's earliest treatment date, as calculated above, to the patient's date of death or the date the patient was traced for their vital status.

All patients in each cohort of interest are submitted to the PDS to check their vital status (dead or alive). Patients are traced before any analysis takes place. The date of tracing is used as the date of follow-up (censoring) for patients who have not died.

Overall survival is calculated for each patient as:

Interval between the earliest treatment date where a specific drug was given to the date of death or date of follow-up (censoring).

The patient is flagged as either:

Dead (event):

- At the date of death recorded on the PDS

Alive (censored):

- At the date patients were traced for their vital status as we know patients were still alive on this date.

And overall survival is calculated as:

Overall survival (days) = Date of death (or follow up) – Treatment start date

Summary

This document represents standard methodologies used for SACT analysis of CDF treatments. Bespoke methodologies will be developed as required to support treatment evaluation and will be documented as appropriate. This document will be reviewed and updated as methodologies are developed.

References

1. Early Access to Medicines Scheme. GOV.UK: 2016

2. The Personal Demographics Service (PDS). NHS Digital: 2018

3. Cancerstats2. CS2: 2018

4. The NHS England medicine optimisation (MO) CQUIN. SACT: 2018

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000

Website: www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

Published: June 2021
PHE gateway number: GOV-8619

PHE supports the UN Sustainable Development Goals

SUSTAINABLE DEVELOPMENT GOALS