

# Systemic anti-cancer therapy dataset

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Escalation process for non-compliance

## About the NDRS

The National Disease Registration Service (NDRS) is part of NHS Digital (NHSD). Its purpose is to collect, collate and analyse data on patients with cancer, congenital anomalies, and rare diseases. It provides robust surveillance to monitor and detect changes in health and disease in the population. NDRS is a vital resource that helps researchers, healthcare professionals and policy makers make decisions about NHS services and the treatments people receive.

The NDRS includes:

- the National Cancer Registration and Analysis Service (NCRAS) and
- the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)

Healthcare professionals, researchers and policy makers use data to better understand population health and disease. The data is provided by patients and collected by the NHS as part of their care and support. The NDRS uses the data to help:

- understand cancer, rare diseases, and congenital anomalies
- improve diagnosis
- plan NHS services
- improve treatment
- evaluate policy
- improve genetic counselling



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Improving lives with data and technology – NHS Digital support NHS staff at work, help people get the best care, and use the nation's health data to drive research and transform services.

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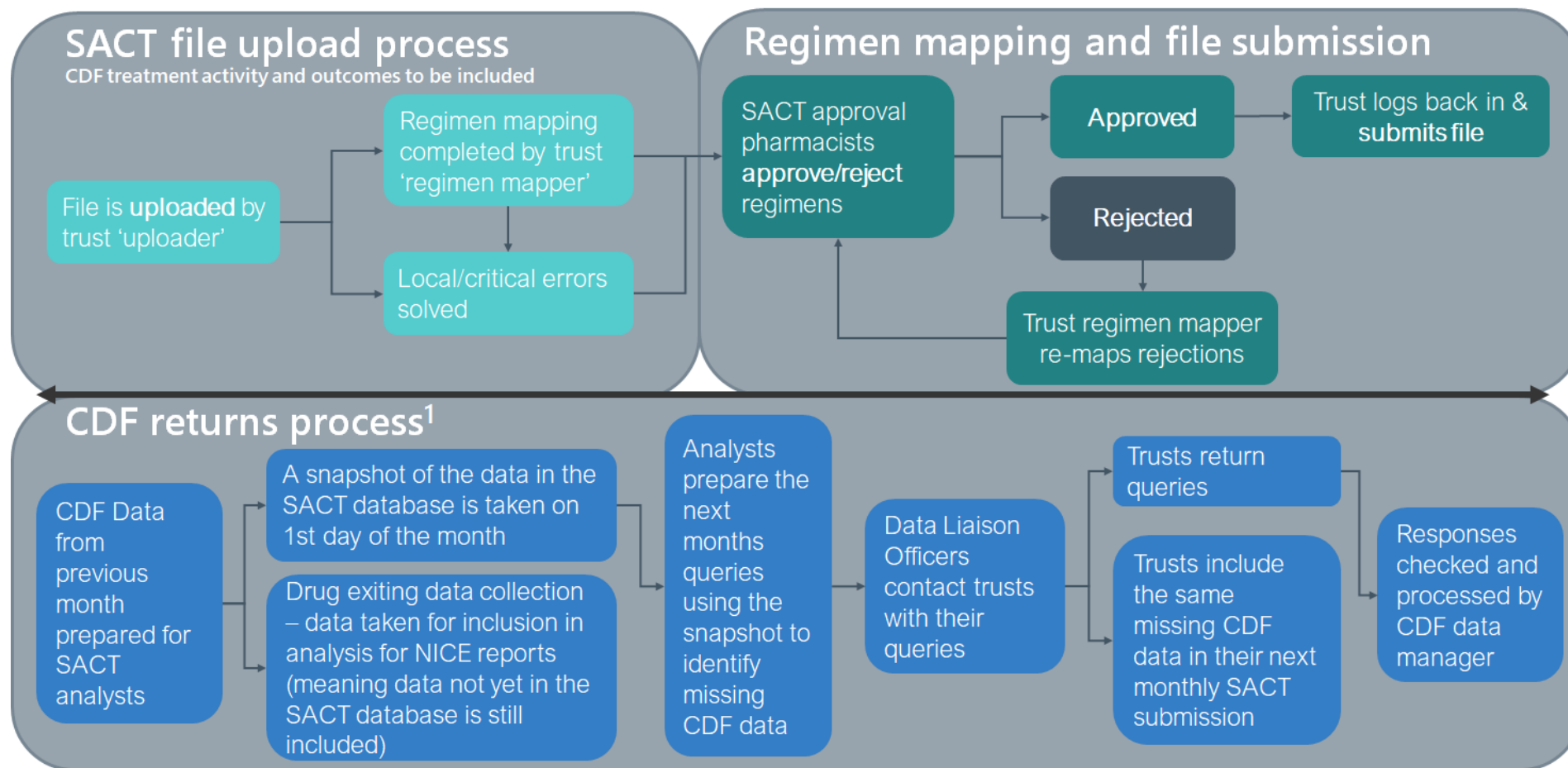
## 1. Background

The systemic anti-cancer treatment (SACT) dataset is the national collection of all disease modifying cancer treatments delivered by NHS trust providers. Monthly submission of SACT data has been mandatory for all NHS trusts since April 2014 ([www.chemodataset.nhs.uk/home](http://www.chemodataset.nhs.uk/home)) and is detailed within the NHS Standard Contract ([www.england.nhs.uk/nhs-standard-contract/](http://www.england.nhs.uk/nhs-standard-contract/)). Submission of SACT data provides a comprehensive database allowing us to understand treatment patterns and outcomes on a national scale. Failure of NHS trusts to submit SACT data undermines this potential and represents contractual non-compliance.

SACT data is also used to evaluate treatments within the Cancer Drugs Fund (CDF) and submission of treatment activity to the SACT dataset is one of the contractual requirements of CDF funding ([www.england.nhs.uk/cancer/cdf/](http://www.england.nhs.uk/cancer/cdf/)). Failure to submit this activity has the additional consequence of hindering NICE committee decision making when treatments are re-evaluated at the end of the CDF data collection period. CDF data is to be included in monthly SACT data submissions. Due to time constraints, the SACT team follows a process of sending monthly CDF queries to trusts. This ensures CDF data is captured in time, and available for inclusion in analysis used by the NICE committee for decision making. This process does not replace SACT submissions, and data returned in response to monthly queries should also be included when a trust makes monthly SACT data submissions.

An overview of the monthly SACT data collection schedule, including routine SACT submissions and CDF data collection (not yet available in the SACT portal), is outlined in Figure 1.

Figure 1. Monthly overview of SACT data collection



<sup>1</sup> Monthly CDF returns happen in conjunction with the routine submission of SACT data. The purpose of the SACT's team process of collecting CDF data is to ensure that data not yet submitted to the SACT portal can still be included in analysis of CDF data. The process does not replace the need to submit CDF data to the portal.

The SACT data liaison and helpdesk teams with the National Cancer Registration and Analysis Service (NCRAS) at NHS Digital (NHSD) work with trusts to support monthly data submission. Assistance and support are offered through site visits, online and in-person training and email or phone response to ad hoc queries. In addition, the SACT teamwork with e-prescribing system providers to optimise systems for SACT collections and minimise the burden of data submission on NHS trusts.

In some cases, trusts repeatedly fail to submit data despite the efforts of the SACT team. In these cases, an escalation process will be initiated. This document sets out the criteria for escalation and the standard escalation route. It should be noted that trusts are responsible for submission of all data regarding the patients they treat with SACT. Where another trust acts as data host it is the responsibility of the treating trust to ensure their patient data is submitted each month. Where a trust submits data on behalf of the treating trust it is again the responsibility of the treating trust to ensure their patients' data is submitted each month.

## 2. Criteria for initiation of SACT escalation process

The SACT team at NHS Digital support data providers to submit SACT data monthly. The team monitor these submissions to ensure returns are submitted by all trusts and CDF treatment activity is included. For ease of reference, failure to submit refers to data not submitted to registry via the portal. Data uploaded to the portal, but not yet submitted to registry following validation, is considered as outstanding or late. Trusts are responsible for ensuring that SACT data is ready to submit to the registry, and files do not contain any outstanding errors, in line with the SACT upload calendar.

Where trusts fail to submit data, there are several criteria which, if met, initiate escalation for non-compliance. These are:

- Routine SACT data collection
  - Failure to submit any SACT data for **2 or more** consecutive months
  - **4 or more** months of outstanding submission of SACT data
  - repeated requests to re-submit data, for example **3 or more** requests to resubmit data in a 12-month period
- CDF patient data
  - Non-compliance of CDF responses for 3 consecutive months as indicated by SACT deadlines report on CancerStats2. Three months non-compliance is defined as follows:
    - The trust has failed to return three consecutive rounds of routine CDF queries
  - OR
  - The trust has failed to upload details of specified CDF treatments despite multiple requests
- OR

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- The trust has failed to confirm up to date contact details (mandatory prior to sending patient data)

These criteria act as general guidelines. All cases will be assessed on an individual basis and any extenuating circumstances will be considered when initiating an escalation process. Trusts should inform the SACT team at NHSD as soon as possible if they anticipate any issues with data submission.

## **Internal NDRS SACT escalation process**

If data providers meet any criteria for escalation the following escalation process will be initiated. If the issue is satisfactorily resolved at any stage the data provider will exit the escalation process.

The SACT team will be available at all stages of the process to support data providers to meet their contractual obligations. If data providers make efforts to engage with the SACT team and address the issues, the escalation process will be paused. If these efforts do not resolve the issues the escalation process may re-start from this point.

A trust may be escalated to the next stage of the process based on previous communications, without further notification. This action would be based on the severity of the issue.

A summary of the escalation process is summarised in Figure 2.

Figure 2. SACT escalation process





A summary of the contacts for each stage of the escalation is provided in Table 1.

**Table 1: Organisation contacts for SACT escalation process**

Stage	Details	Responsible Contacts <sup>1</sup>	
		NDRS	Data Provider
<b>Stage 1: Low</b>	When a trust meets the criteria for escalation, the Helpdesk or regional Data Liaison Officer will contact the trust to inform them of the non-conformance. A deadline will be agreed, in most cases trusts will be asked to become compliant within 8 weeks, depending on the severity of the situation.	<ul style="list-style-type: none"> <li>• SACT Helpdesk</li> <li>• Regional Data Liaison Officer</li> </ul>	<ul style="list-style-type: none"> <li>• SACT Uploader</li> <li>• Lead Pharmacist</li> <li>• Cancer Services Manager</li> </ul>
<b>Stage 2: Moderate</b>	If the trust does not resolve issues to a satisfactory standard in the given time frame, they will be escalated to stage 2. Where the SACT Programme Manager will contact the Cancer Clinical Lead at the trust to report the issue, highlighting that this represents an escalation for non-compliance.	<ul style="list-style-type: none"> <li>• SACT Programme Manager</li> </ul>	<ul style="list-style-type: none"> <li>• Cancer Clinical Lead</li> </ul>
<b>Stage 3: High</b>	If a satisfactory response is still not received the issue will be escalated to the SACT Steering Group, who will report the issue to the Trust Medical Director and request action to resolve the issue.	<ul style="list-style-type: none"> <li>• SACT Steering Group</li> <li>• Director of NDRS</li> <li>• Chair of the SACT Clinical Leads Group</li> </ul>	<ul style="list-style-type: none"> <li>• Medical Director</li> </ul>

<sup>1</sup> Where a specific provider role is given in process, the SACT team reserve the option to substitute with equivalent role within the same organisation.

## **Stage 1: Low level**

The SACT Helpdesk monitor data submission by trusts and will generally be the first to identify trust non-compliance for “routine SACT data collection”. The data liaison team follow up CDF patients missing from SACT and will identify non-compliance for “CDF patient data”.

Where non-compliance is identified the Helpdesk or Data liaison team will formally contact the Trust SACT Uploader, Lead Pharmacist and Cancer Services Manager (if known) to document the issue. The SACT team will highlight to the trust that this represents initiation of the escalation process and is in addition to routine communications.

The Helpdesk/ Data liaison team will discuss with the trust any support that may be needed. They will outline the response criteria required and a response deadline. The deadline will depend on the severity of non-conformance but generally issues should be resolved within 8 weeks (x2 monthly submission cycles).

The response request may include a requirement for the provider to supply a formalised plan of actions to address issue(s) including timescales. A regular update is required from the provider on progress and upon completion of actions to become compliant.

The SACT team will determine if the received response is satisfactory based on the level of escalation and requested response criteria.

If a satisfactory response is received the trust will exit the non-conformance process.

## **Stage 2: Moderate level**

If a satisfactory response is not received the issue will be escalated to the SACT Programme Manager.

The SACT Programme Manager will contact the Cancer Clinical Lead at the trust to report the issue, highlighting that this represents an escalation for non-compliance.

The SACT Programme Manager will document the attempts made by the SACT team to resolve the issue, together with the response criteria and a response deadline.

If a satisfactory response is received the trust will exit the escalation process.

### **Stage 3: High level**

If a satisfactory response is still not received the issue will be escalated to the SACT Steering Group.

The SACT Steering Group will report the issue to the Trust Medical Director and request action to resolve the issue.

A response will be requested within 3 weeks, detailing specific actions to be undertaken by the provider to become compliant.

## **3. External NHS England escalation process**

Where none of these steps resolves the issue, trusts will be referred to the appropriate regional supply manager at NHS England.

In these cases, NHS England may issue an Information Breach Notice detailing the nature of the breach and expected course of action.

Normally the data provider will be expected to correct the breach in their next SACT submission and confirm in writing the action taken to rectify the breach.

Failure to rectify this Information Breach may result in a withholding of 1% of the Actual Monthly Value, in line with Service Condition 28.15.

The provider will then need to remain breach free for a further 3 months to fully rectify this breach to the commissioner's satisfaction. This is in line with information provided within the NHS England Standard Contract.

NHS England will be responsible for imposing any / all consequences of non-conformance direct with the provider organisation.

The SACT programme lead can include NHS England in any ongoing discussions at their discretion during any phase of the escalation process.

If a trust has already been through the escalation process and this represents a second breach the trust may be referred directly to NHS England following Stage 2 of the NHSD escalation process.

## 4. Next steps

If you have any questions or concerns, please contact the SACT Helpdesk ([ndrs.datasets@nhs.net](mailto:ndrs.datasets@nhs.net)) or the NHS England CDF team ([england.cdfteam@nhs.net](mailto:england.cdfteam@nhs.net)) who will be able answer your queries or put you in touch with a more appropriate contact.