Systemic anti-cancer therapy dataset
Escalation process for non-compliance
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, 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.
# Contents

About Public Health England  2  
Contents  3  
1. Background  4  
2. Criteria for initiation of SACT escalation process  5  
3. External NHS England escalation process  8  
4. Next steps  8
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 trust since April 2014 (www.chemodataset.nhs.uk/home) and is detailed within the NHS Standard Contract (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/). 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.

The SACT data liaison and helpdesk teams with the National Cancer Registration and Analysis Service (NCRAS) at Public Health England (PHE) work with trusts to support monthly data submission. Assistance and support is offered through site visits, online and in-person training and email or phone response to ad hoc queries. In addition, the SACT team work 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 patients’ 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 Public Health England 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. 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 consecutive months
  - late submission of SACT data for ≥4 months in a 12-month period
  - repeated requests to re-submit data, for example ≥3 requests to resubmit data in a 12-month period

- CDF patient data
  - CDF patient follow up non-compliance for 3 consecutive months; as indicated by SACT deadlines report of CancerStats2. Three months non-compliance indicates:
    - The trust has failed to respond to three rounds of routine CDF queries
    - The trust has failed to upload details of specified CDF treatments despite multiple requests

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

1. PHE, internal 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.

Trusts entering the escalation process are documented in the SACT team escalation log. This allows the SACT team to track the quality data submission over time and identify corrective actions which help to generate a long-term solution to any problems.

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

Table 1: Organisation contacts for SACT escalation process

<table>
<thead>
<tr>
<th>Stage</th>
<th>Contact</th>
<th>Data Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1: Low</td>
<td>SACT Helpdesk or Data Liaison Officer</td>
<td>SACT Uploader, Lead Pharmacist, Cancer Services Manager</td>
</tr>
<tr>
<td>Stage 2: Moderate</td>
<td>SACT Programme Manager</td>
<td>Cancer Clinical Lead</td>
</tr>
<tr>
<td>Stage 3: High</td>
<td>SACT Governing Board Director of NCRAS, Chair of the Chemotherapy Clinical Information Group</td>
<td>Medical Director</td>
</tr>
</tbody>
</table>

1 Where a specific provider role is given in process, the SACT team reserve the option to substitute with equivalent role within the same organisation.
NCRAS - National Cancer Registration and Analysis Service

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 on 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 reponse 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 reposne is still not received the issue will be escalated to the SACT Governing Board (this includes the Director of the National Cancer Registration and Analysis Service and the Chair of the Chemotherapy Clinical Information Group).

The SACT governing board will report the issue to the Trust Medical Director and request action to resolve the issue.

A response will be requested within 25 working days, 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 PHE internal escalation process.

4. Next steps

If you have any questions or concerns please contact the SACT Helpdesk (SACT@phe.gov.uk) or the NHS England CDF team (england.cdfteam@nhs.net) who will be able answer your queries or put you in touch with a more appropriate contact.