# Systemic Anti Cancer Therapy (SACT) data set

## Change Specification

# About the NDRS

The National Disease Registration Service (NDRS) is part of NHS England. 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

NDRS
NATIONAL DISEASE REGISTRATION SERVICE

National Disease Registration Service
The Leeds Government Hub
7&8 Wellington Place
Leeds
LS1 4AP

NHS
England

For queries relating to this document, please contact:
NDRSenquiries@nhs.net

# Contents

| | | | |
|---|---|---|---|
| Title | SACT Change Specification | | |
| DAPB Reference | DAPB1533 Amd 20/2025 | | |
| Sponsor | Sarah Stevens | Status | Final |
| Senior Responsible Officer | Dr Martine Bomb | Versions | SACT v4.0 |
| Lead Developer | Andrew Murphy | | |
| Business Lead | Wayne Brown | | |
| Author(s) | Andrew Murphy | Version Date | 29 July 2025 |

**Amendment history:**

| Version | Date | Amendment History |
|---|---|---|
| SACT v4.0 | 14 May 2025 | Final edited version for publication |
| | | |
| | | |
| | | |

**Approvals:**

The data set has been approved by the following overarching boards:

| Name | Responsibility | Date | Version |
|---|---|---|---|
| SACT Senior Team | Cross organisational group, responsible for reviewing and approving all changes to SACT | 19/02/2025 | SACT v4.0 |

# Executive summary

The purpose of this document is to provide guidance intended to support providers of cancer services and developers (both in-house and commercial system suppliers), to prepare for the implementation of the Systemic Anti Cancer Therapy (SACT) data set v4.0 from April 2026.

This document outlines changes to the data set and highlights new data items verses those that have been amended, moved, or deleted.

This is an update to an existing information standard DCB1533 Amd 80/2018. This is required to ensure that the data set still meets the business objectives, scope, and content of the standard and continues to be clinically accurate and relevant.

To maintain the clinical accuracy, it is important to regularly review SACT with clinical experts from across the NHS. Occasionally, other information standards have specific data items which interact with SACT. Where this happens, the Head of Cancer Datasets has consulted with the developers of those standards, to ensure all data items remain accurate and are updated.

These changes have continued the work done in previous reviews and will have a huge effect on the future formulation of SACT.

# Introduction

## Background

SACT data collection in England commenced in April 2012 and is a major part of cancer treatment, with new types of drugs being introduced capable of targeting individual cancers. Historically the recording of SACT activity was held within individual patients' notes. Systemic anti-cancer therapies have been proven to be increasingly successful as a treatment but are ever more complex and expensive. Accurate, timely and complete data collection is a priority and supported through electronic clinical data collection.

The SACT Information Standard addresses the requirement to standardise the recording of SACT treatment and outcomes through electronic systems. Version 4.0 is an extension to the standard, introducing new data, correcting existing data (for better analysis) and removing redundant data to reduce the burden of data collection wherever possible.

## Summary of changes

This new data set version (SACT v4.0), continues the work started in previous versions around reducing the burden of data collection and processing. This is achieved by only requesting data that is vital for the SACT team within the National Disease Registration Service (NDRS), our analytical team or that of our data partners.

Periodically we need to revise the SACT data set to ensure that we meet the current information requirements for the NHS. Therefore, changes were required to make the data set clinically accurate.

New data items have been added or removed after a rigorous 9-month clinical review and a further 4-week consultation.

These reviews allowed the data set to be clinically assessed, validated, and updated by subject matter experts in all fields of oncology, and provides a clinically sound set of data to be collected from 2026 onwards. Occasionally, the same data item is used in different sections of the data set, in these circumstances they are only counted once.

The following are the major changes to SACT v4.0:

| Key Change | Numbers |
|---|---|
| Deleted Data Items | 11 |
| New Data Items | 27 |
| Data Items with Amendments | 11 |
| Moved Data Items | 5 |

Note, data items with amendments include:

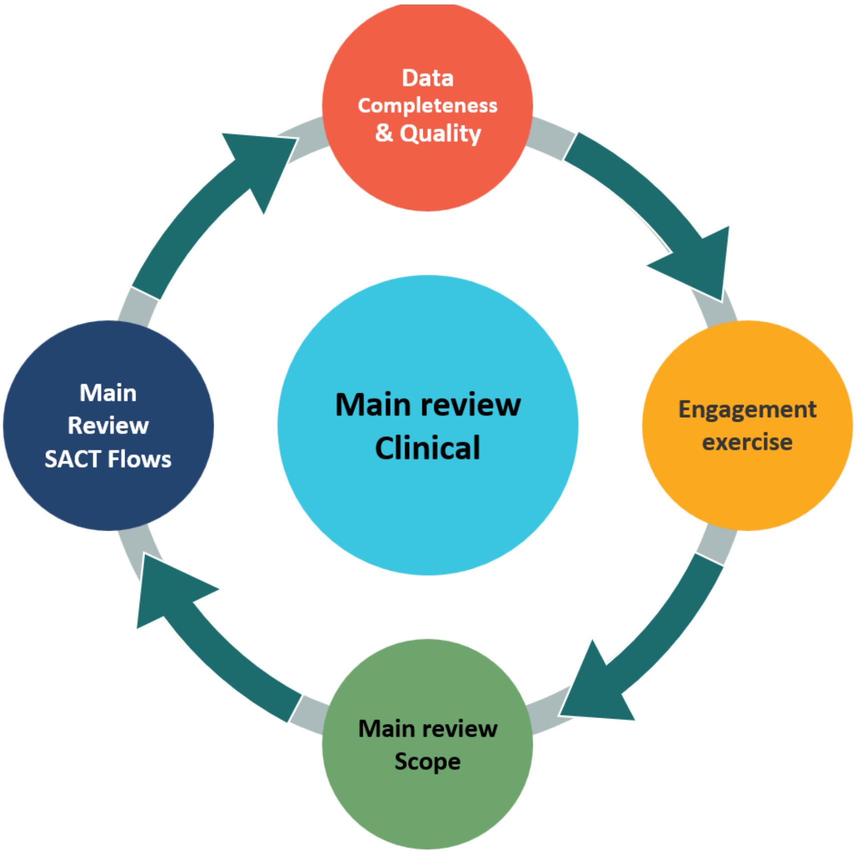
- updated names
- updated descriptions
- new or retired attributes
- schema specification changes.

The data set is now split into the following main sections:

- Linkage - Patient Identity Details
- Demographics and Consultant
- Clinical Status
- Regimen
- Cycle
- Drug Details
- Outcome

It was vital, that the review also worked closely with subject matter experts from across the adult oncology field as well as those who specialise in Children, Teenage and Young Adults (CTYA) and Haematology, as their requirements can be quite different.

The clinical review had four distinct stages as follows:



## Implementation start and full conformance timeline

The revised data set will have an 8-month implementation period for Trusts and suppliers (starting August 2025), to make all the changes required throughout the new standard and do any testing in conjunction with the NDRS/SACT team.

There will be a 3-month phased roll-out from April 2026 (for start of data collection). This is to make allowance for the varied timescales of different software suppliers and in-house developers.

During this 3-month period, data can be submitted as in either SACT v3.0 or v4.0 formats. However, to comply with the standard, data collection using v4.0 only must start by 01 July 2026 at the latest.

## Supporting documents

The following documents will be updated and made available on the 29 July 2025:
NHS England - DAPB1533 SACT:

- requirements specification
- change specification
- implementation guide
- data set v4.0
- technical guidance
- information standard notice

NDRS - SACT webpage:

- SACT v4.0 user guide

These documents are intended to support providers and developers who wish to identify and plan changes to their systems.

# Change specification

This is a complex data set covering all oncology treatments for over 200 diseases, which requires a through periodic review. The latest changes reflect this and are introduced to align with current business needs and clinical practice and to support data quality.

New data items have been added or data items removed after extensive consultation with subject matter experts across all oncology specialities, including CTYA and Haematology. Details of the consultation can be found in the consultation summary report, which has been provided as evidence to the Data Governance and Assurance Team (DGAT).

Throughout the data set, choices have been added to help improve data quality and reduce misinterpretation and burden. These are supported by unique sections, which group key data items or specific attributes with a corresponding data item. This removes the error submission and improves data quality.

Linkage data items have been realigned across the data set into the correct ‘higher level’ grouping, improving the structure. This in turn enforces the addition of mandatory data items, improving data quality.

Wherever possible, duplication across the data set has now been removed and full explanations of how to collect these data within the new structure are provided within the user guidance.

# Deleted data items

The following data items were deleted for reasons stated against each item. More detail is available within the change control log of SACT v4.0 (inc. Data Item Numbers) and should be used in conjunction with this document. These deleted data items are grouped by their data set sections:

## Demographics and Consultant Details

- Consultant GMC Code
    - no longer meets national specifications and replaced with the following two data items:
        - Professional Registration Issuer Code - Consultant (Initiating Treatment)
        - Professional Registration Entry Identifier - Consultant (Initiating Treatment)

## Regimen

- Adjunctive Therapy
    - to be replaced with Treatment Context, on the advice of the SACT review team
- Co-Morbidity Adjustment
    - replaced with option in new Dose modification section

## Drug Details

- DM+D
    - no longer required due to inaccurate data submission during pilot phase
- Administration Date
    - data item split to accommodate accurate recording of date vs date/time as specified by the Data Design Authority

## Outcome

- Regimen Modification - Dose Reduction
    - replaced with new choices and sections across the data set, to specifically record Dose modification
- Regimen Outcome Summary - Curative (Completed as Planned)
    - replaced with a single outcome field to allow for a simpler and more accurate recording of a regimen outcome
- Regimen Outcome Summary - Curative (Not Completed as Planned) Reason
    - replaced with a single outcome field to allow for a simpler and more accurate recording of a regimen outcome

- Other - Regimen Outcome Summary - Curative (Not Completed as Planned) Reason
    - replaced with a single outcome field to allow for a simpler and more accurate recording of a regimen outcome
- Regimen Outcome Summary - Non Curative
    - replaced with a single outcome field to allow for a simpler and more accurate recording of a regimen outcome
- Regimen Outcome Summary – Toxicity
    - replaced with toxicity grade for more accurate recording

# New data items

Full details of all the new data items are provided in the SACT v4.0 user guidance. The following is a list of these new data items grouped by their data set sections:

## Demographics and Consultant Details

- Professional Registration Issuer Code – Care Professional (Initiating Treatment)
  - this is an enforced change throughout all new data sets by NHS England's, NHS Data Model and Dictionary Service
- Professional Registration Entry Identifier – Care Professional (Initiating Treatment)
  - this is an enforced change throughout all new data sets by NHS England's, NHS Data Model and Dictionary Service, and replaces the 'Consultant GMC Code'

## Regimen

- Treatment Context
  - to accurately reflect currently clinical practice, and replaces 'Adjunctive Therapy'
- Curative Line of Treatment
  - to allow the recording of each line of curative treatment
  - this has a range of 1-99
- Non-Curative Line of Treatment
  - to allow the recording of each line of non-curative treatment
  - this has a range of 1-99
- Chemoradiation
  - an indication of whether the Systemic Anti-Cancer Therapy Drug Regimen was given as part of Chemoradiation
  - this has been re-introduced from v2 and retains its original data item number (24)
- Regimen Modification
  - this allows for a notification to be recorded if there has been an upfront dose modification or not (Y/N), which modified the regimen
- Reason for Regimen Modification
  - this allows for the recording of the reasons for the upfront modification
- Reason for Regimen Modification – Patient (Clinical) Factors
  - this allows the recording (from a set menu) of clinical factors, which resulted in a dose modification

- Toxicity Grade (Regimen Modification)
    - this allows the recording (from a set menu) of the toxicity score/rating using the Common Terminology Criteria for Adverse Events (CTCAE) version 5

## Cycle Details

- Cycle Modification
    - this allows for a notification to be recorded if there have been any drugs that have been omitted from the cycle (Y/N)
- Reason for Cycle Modification
    - this allows the end user to record the reason if any drugs have been omitted from the cycle
- Reason for Cycle Modification – Patient (Clinical) Factors
    - this allows the recording (from a set menu) of clinical factors, which resulted in modifying the cycle
- Toxicity Grade (Cycle Modification)
    - this allows the recording (from a set menu) of the toxicity score/rating using the Common Terminology Criteria for Adverse Events (CTCAE) version 5
- Cycle Delay
    - this allows the end user to record if the cycle has been delayed (Y/N)
- Reason for Cycle Delay
    - this allows the end user to record the reason for the cycle delay
- Reason for Cycle Delay – Patient (Clinical) Factors
    - this allows the recording (from a set menu) of clinical factors, which resulted in the cycle delay
- Toxicity Grade (Cycle Delay)
    - this allows the recording (from a set menu) of the toxicity score/rating using the Common Terminology Criteria for Adverse Events (CTCAE) version 5

## Drug Details

- Administration Timestamp (Infusion)
    - new data item to accommodate accurate recording of date/time for infusion administered only, as specified by the Data Design Authority
- Administration Date (Oral Drug Dispensed)
    - new data item to accommodate accurate recording of date for oral drug dispensed only, as specified by the Data Design Authority
- Cycle Length in Days
    - required to record the length of the cycle for the drug administered or dispensed
    - this has a range of 1-366

- Number of Cycles Administered (On A Named Day)
    - required to record the number of cycles administered on the named day for the drug administered or dispensed
    - this has a range of 1-20
- Dose Modification
    - this allows the end user to record if there was a modification to the dose (Y/N)
- Reason for Dose Modification
    - this allows the end user to record the reason for any changes to the dose
- Reason for Dose Modification – Patient (Clinical) Factors
    - this identifies (from a set menu) the clinical factors that were a factor in modifying the dose
- Toxicity Grade (Dose Modification)
    - this allows the recording (from a set menu) of the toxicity score/rating using the Common Terminology Criteria for Adverse Events (CTCAE) version 5

## Outcome

- End of Regimen Outcome
    - this allows the reason for completing or stopping the regimen to be recorded

# Amendments to data items

Full details of all the amendments are provided in both the published SACT v4.0 data set (within the ‘change log’ tab), and the user guidance. These documents should be read in conjunction with this change specification. The following is the key to help understand what has changed between versions:

- new or amended data items or text is marked in green highlight
- data items, text or elements of a data item that have been deleted is marked with a ~~red strikethrough~~
- where a yellow highlight has been used, this denotes that the data item has been moved to a new group between SACT v3.0 and SACT v4.0

Amendments were required to ensure that where changes were highlighted through the clinical review, that these changes have been accurately reflected within the new SACT data set. These changes/amendments could be for a variety of reasons as follows:

- Updated Data Item Name
- Updated Description
- Updated Schema Specification
- Retired Attributes
- New Attributes

It is expected that some data will change throughout the lifetime of the data set and these changes will be acknowledged and changes made in the next version review.

In addition, there have been some new sections, which include new choices throughout the data set.

# Appendix A - Uniform Resource Locator (URL) Glossary

This section provides the full URL address, to help and support users who are partially sighted access all links throughout the document.

Page 7 (Supporting documentation):

- ISN publications - https://digital.nhs.uk/data-and-information/information-standards/governance/latest-activity/standards-and-collections/dcb1533-systemic-anti-cancer-therapy-data-set/
- NDRS, SACT website - https://digital.nhs.uk/ndrs/data/data-sets/sact#downloads-and-guides