NDRS
NATIONAL DISEASE REGISTRATION SERVICE

NHS England

Systemic Anti Cancer Therapy (SACT) data set

User Guide v4.0.2

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

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Contents

Version Control

Version	Date	Brief Summary of Change	Editors
Version 4.0.1	11 July 2025	– Final edited version for publication	Andrew Murphy
Version 4.0.2	26 Nov 2025	– Updated PFU description (pg46)	Andrew Murphy
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		–	

Executive summary

This User Guide is one of a suite of documents to aid users in implementing the Systemic Anti Cancer Therapy (SACT) Information Standard (DAPB1533 Amd20/2025). It includes all the data items in SACT v4.0, together with definitions, formats, codes, values and additional guidance on collection and implementation. Find more SACT documents in the 'downloads' section on the NDRS SACT website.

One of the aims of this review was to reduce burden whilst updating the data set so that it remained clinically accurate and meets the business objectives, scope and content of the standard.

In v4.0, there are an additional 16 data items overall, compared with v3.0 and of them, 4 are compulsory due to the change in the way date and consultant codes are now recorded. In addition, most of the other increases were to ensure that 'Regimen', 'Cycle' and 'Dose Modification' as well as 'Cycle Delay' were correctly structured and recorded.

The data is used as an important indicator as to the outcome of drug treatments. Linking the data to other major data sets, also allows for better staging and more accurate mortality data, which are important indicators to the effectiveness of drugs delivered in the treatment of cancer.

Implementation of the Standard is carried out by the National Disease Registration Service (NDRS), technical queries regarding implementation should be raised in the first instance to your regional Data Liaison staff at your local NDRS office.

Contact details for the regional data liaison managers, can be found on the NDRS website under the 'support and feedback' section, on the SACT webpage.

The SACT Information Standard applies to all organisations providing systemic anti-cancer treatment therapies in, or funded by, the NHS in England. The SACT data set collects information reported routinely by NHS Trusts on the treatment of malignant disease in secondary care in England.

This data set relates to all cancer patients, both adult and paediatric, in acute inpatient, day-case and outpatient settings and delivery in the community. It covers systemic anti-cancer treatment for all solid and haematological malignancies, including patients in clinical trials.

Introduction

What is the impact of SACT on clinical services

The impact of the standard will vary, depending on the configuration of hospitals and services and the existing and planned implementation of electronic prescribing and other clinical electronic systems.

The contents of this User Guidance document should be made available to all staff groups involved in responding to the standard, including:

- medical and nursing
- pharmacy
- information
- IT
- management staff

It is not intended that the standard should have any direct impact on the delivery of patient care. However, the above groups, which are involved in the local implementation of the information standard, need to take account of any new changes of the standard in their work area and develop a strategy to fully meet its requirements by the end of the implementation period.

If you are a new provider of systemic anti-cancer therapies; as well as reading the Implementation user guide, please contact the NDRS liaison team.

Other useful recourses to support the collection of the SACT data set, can be found on the NDRS/SACT webpage.

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 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.

The SACT data set community

The SACT data set community was launched on FutureNHS in August 2023. Please note this replaces the previous community on the Knowledge Hub and is only available to NHS staff working within an NHS Trust in England or via a Cancer Alliance. The community offers a space for members to make connections with other NHS Trusts and Alliances and access important guidance and updates from the SACT data set team.

Once registered, users will have access to the community forum which provides a space to ask questions to other members and view or join discussions. They can also access important updates, information, webinar recordings and slide decks. Updates include upcoming events and the SACT data set team's 'What Happened This Month' blog on the community homepage. To request an invitation, please complete our short online form, you will then receive an invitation to join, usually within 2 working days.

NHS England partnership on cancer data and the 'Cancer Drugs Fund'

The SACT data set also underpins the work of the NHSE partnership on 'Cancer Data', and the 'Cancer Drugs Fund'.

This partnership uses National Cancer Registration and Analysis Service (NCRAS) data sets, including the information submitted by Trusts to the SACT data set on current routine care, to inform improvements in service provision and clinical practice.

More information on the work of NDRS partnerships can be found on our work section of the SACT website.

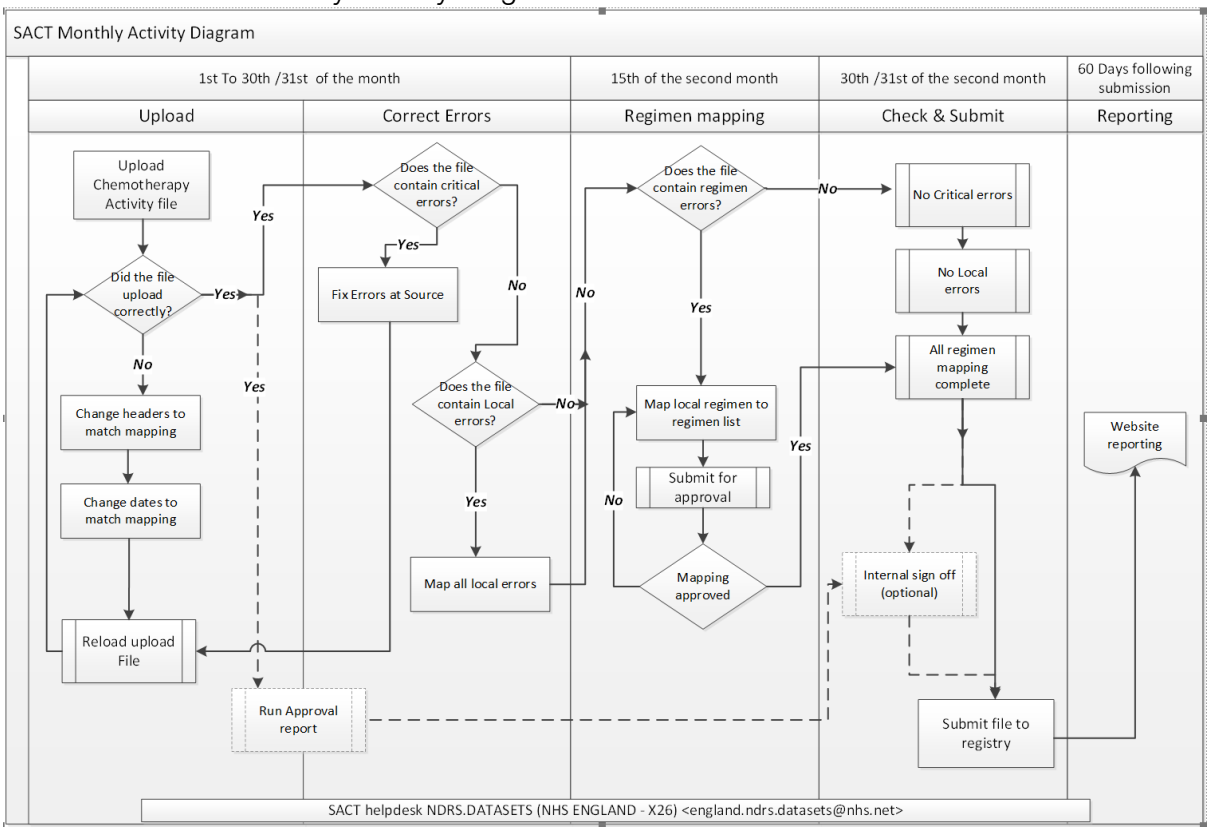
You can find out more about the methodologies applied when using the SACT data set to evaluate CDF treatments using this link.

When should data be submitted?

Data files are required to be submitted monthly, using the 2-month schedule, for example: submissions of September 2025 activity data (01-09-2025 to 30-09-2025) must be uploaded as follows:

- 1 to 30 November 2025
    - files containing September data MUST be uploaded to the portal and all errors on the file MUST be resolved
- by 15 December 2025
    - regimen mapping MUST be completed
    - this process can start at any point once the file has been uploaded
- by 31 December 2025
    - all regimen queries MUST be resolved, and the file MUST be submitted

Below is a SACT monthly activity diagram…



Notes:

- all provider Trusts are advised to upload as early as possible in the month as this will allow more time to fix any errors
- uploading on the last day will mean that there may not be enough time to fix any errors and therefore Trusts may become 'non-compliant' for various measures
- uploading earlier in the month will allow more time for regimen mapping if needed

API upload portal

There are detailed instructions on how to upload your data on the EnCORE API by clicking this link, which will take you to the SACT technical guidance webpage.

This includes information on:

- general submission principals
- data extraction in csv format
- SACT column header convention in csv format
- file submission via the EnCORE API

In addition, there is information on data submissions and file naming convention, such as:

- data items that should be submitted
- validations
- reporting

Why is change needed?

Periodically we need to revise the SACT data set, to ensure that we meet the current information requirements for the NHS.

The 'NHS Long Term Plan' aims to save thousands of lives each year by dramatically improving how we diagnose and treat cancer. The ambition is that by 2028, an extra 55,000 people each year will survive for five years or more following their cancer diagnosis.

The need to have strong cancer data collection, empowers NHS England to enforce this through the mandate of data collections. These data will be the base for cancer analysis and research for the next 5 years.

Benefits of collecting SACT data

Since its conception in 2012, SACT data has been used for a series of important analyses, including 30-day mortality post SACT. In addition, the CancerStats2 portal has now become the home of SACT analysis reporting and contains many additional reports as follows:

- SACT activity
- data completeness and quality reports
- dose branding
- specific CTYA data analysis
- time to first treatment

In addition, there is also analysis and reports around the cancer drugs fund.

To access CancerStats2, you need to be on a Health and Social Care Network (HSCN) and have a valid user account. If you feel you need access to these reports, please speak to your regional data liaison manager and they will support you with this.

Definitions for the SACT data set

Within SACT, it is important that field naming is consistent within hospital systems and the definitions of the fields are unambiguous and applied by all providers.

All field naming and definitions must either be aligned with or approved by the NHSE Data Model and Dictionary Service or by the Data Design Authority. This allows for consistency across the NHS and prevents any unnecessary burden of data collection.

Definitions:

The following are definitions used throughout the SACT data set and user guide:

- the term 'Regimen' is used to identify a standard combination of drugs
- the term 'Cycle' is used to identify treatment intervals within a regimen
- the term 'Administration' is used to identify the physical administration of drugs

The relationships between programmes, regimens, cycles and administration dates are shown in the accompanying graphics and examples of data set structures (pages 10-11)

Regimen:

A SACT regimen identifies a standard for a combination of drugs (or single drug) given in a planned schedule.

A regimen can be:

- standard
- part of a trial
- specifically designed for an individual treatment plan

The SACT drug regimen title will be as agreed by the SACT team and an NHS support pharmacists' group, as they maintain the regimen list, and this will inform the OPCS Guidance (Classification of Interventions and Procedures).

Cycle:

Apart from continuous SACT, a regimen normally contains identifiable repeating elements, and each repeat should be identified and numbered. Some regimens have alternating repeating elements, and some have consecutive sets of repeating elements. In all these cases the term 'Cycle' would be equally valid and help to identify the stage of progress of the patient through SACT.

Cycle number:
These will be numbered sequentially within a regimen and the option to start from any number must be available to allow for prior management not recorded on the current system. The cycle number is now mandatory from v4.0.

Administration date:
In v4.0, the 'Administration Date' has changed after discussions with NHS England's (NHSE) Data Design Authority and the Data Model and Dictionary teams.

From v4.0, the administration date has been split into two distinct choices, each having a different reporting format and at least one must be submitted within the data set record, as follows:

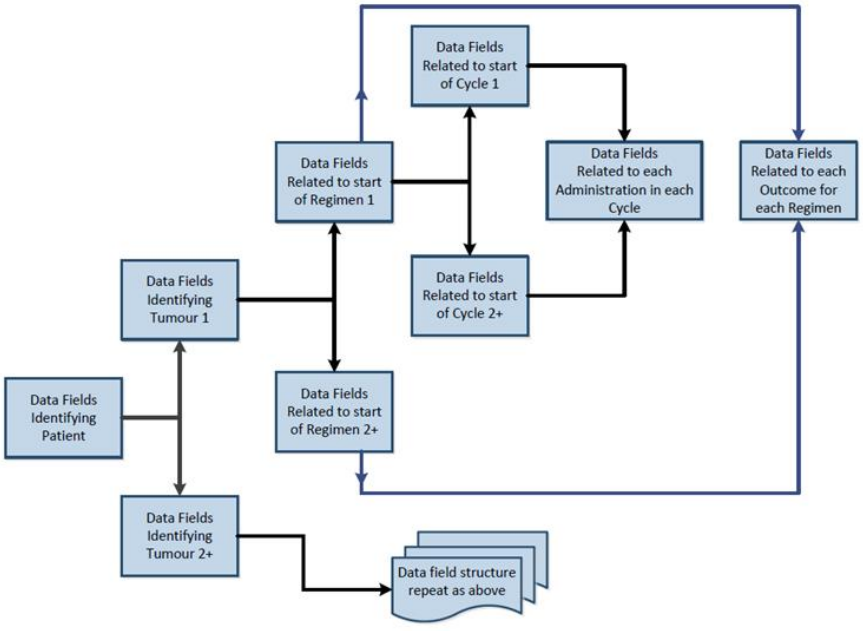
Choice 1:
Administration Timestamp (Infusion):, For recording the date and time when the anti-cancer drug was administered to a patient (an infusion commenced).

Choice 2:
Administration Date (Oral Drug Dispensed): For recording continuous oral chemotherapy, the administration date will be the first day of the nominal cycle, or the date on which an oral drug was dispensed to the patient.

For these dates there is no change to the v3.0 format, in that only the date is required, and this must be recorded using the standard date format [ccyy-mm-dd].

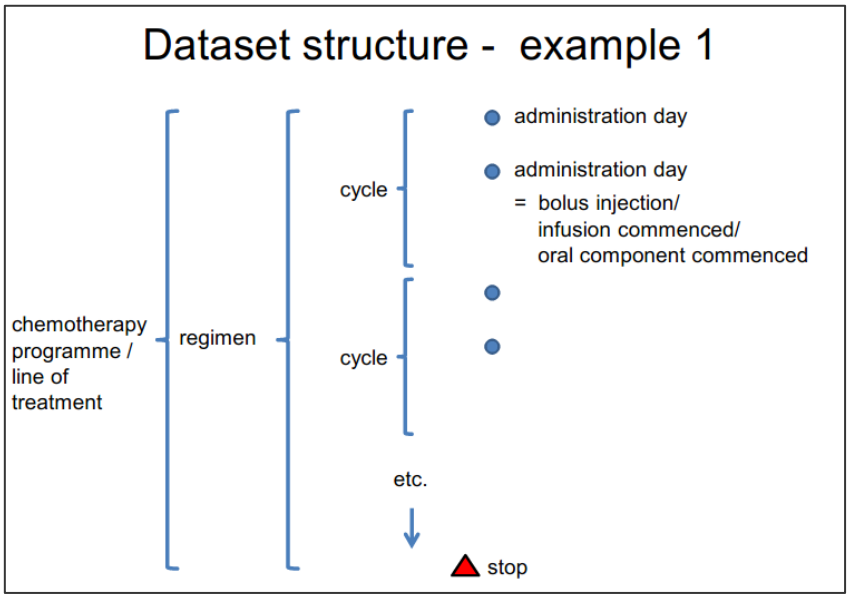
SACT data model

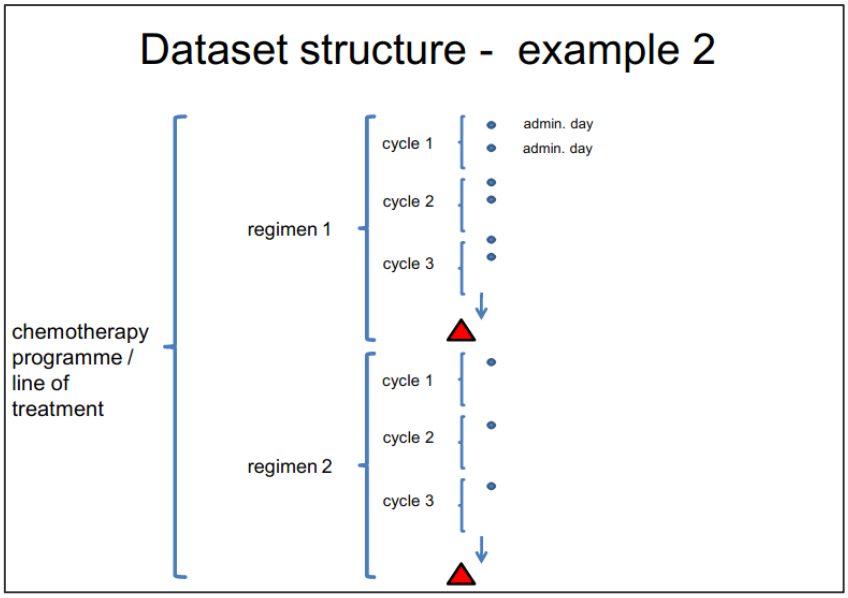
The following data model explains the relationship between the data and the treatment process (Regimen and Cycle), provided to a patient:

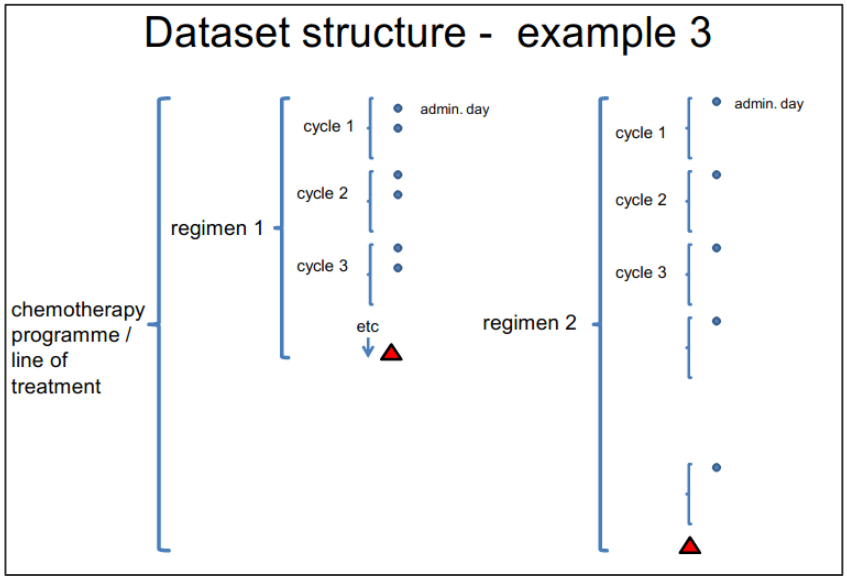


The data structures

The data structures are described below using three examples:







Which diagnoses does SACT apply to?

For the purposes of SACT the term 'cancer' relates to all conditions defined as registerable by the UK and Ireland Association of Cancer Registries (UKIACR) and these are listed in Appendix B.

These are in addition to Appendix A - Cancer Waiting Times ICD10 Codes and Tumour Groups for Primary Diagnoses. SACT requires that all treatments for new diagnoses and secondary/metastatic cancer are recorded.

All treatments for recurrences diagnosed at each Trust must also be included.

Schema specification

As with previous versions of SACT, v4.0 will not be converted to .xml reporting. Therefore, all Trusts should continue to report using the formatted .csv uploads as usual.

Choices

Within v4.0, we have introduced choices throughout the data set, these are to improve the quality of data submitted by the Trust and will be clearly explained within this user guide.

Sections

Within v4.0, we have introduced a series of sections throughout the data set, which link specific data items or defined attributes with their additional linked data item. This improves data quality and allows for the flow of data to be more logical in its approach. These will be clearly explained within this user guide.

Mandatory

The 'Linkage' data items are mandatory and must be submitted for all records. It is vital that these are always available so that the correct information can be linked to the right patient and the correct tumour. A record will not be able to be submitted if any mandatory data item is missing. These records must be added to the main file otherwise the whole file will not pass validation tests.

In some cases, certain data items have been made mandatory within sections to improve the quality of the data submitted. In these cases, no data within that section can be submitted without these mandatory data items being completed. These sections however are required; therefore, a missing section will not affect the submission of all other data.

Required

Most other data-items are set as 'Required'. This means that if they are applicable to the reported tumour or patient pathway, they must be completed and treated as a mandatory item. Not every data-item however will be applicable to every patient, tumour, or treatment pathway. By using 'Required', this allows for a more accurate and inclusive

collection of data. Therefore, all applicable data in each section marked as ‘required’ must be submitted for each record as soon as available.

Optional

Optional data items can be submitted by any Trust, but there is no requirement to enforce this data collection at this point. All optional data-items would remain under review and may change in future version controls of SACT.

Note:

- there are no optional data-items in v4

Meaning of 'Not known' value

'Not known' includes both 'not recorded' and for example 'test not done'. This is usually coded 9 or 99 (depending on the data item format).

Pilot

There are no pilot data items in SACT v4.0.

Cardinality

It is important to remember that each section and data item within the data set is controlled by its own published cardinality rule. This will help you understand the relationship each section or data item has within the overall file. There is a range of cardinality within the data set, these are at both the section and data item level.

Section level cardinality:

- (1..1) this indicates that the section is mandatory and ‘must be one occurrence per record’
- (1..2) this indicates that the section is mandatory and there ‘must be at least one of the following choices per record’
- (0..*) this indicates that the section is required and ‘may be multiple occurrences per submission’
- (0..1) this indicates that the section is required and ‘may be up to one occurrence per record’

Data item level cardinality:

- (1..1) this indicates that the data item is mandatory and must be submitted
- (1..*) this indicates that the data is mandatory and that multiple attributes are allowed to be reported
- (0..1) this indicates that the data item is required/optional
- (0..*) this indicates that the data is required/optional, but that multiple attributes are allowed to be reported

SACT data items

Key to data item tables

All data items are listed as follows:

Data Item Number	The reference number for the SACT data item
Data Item Section	The section in which the data item appears
Data Item Name	The name of the data item. Please refer to the data set for the data dictionary names, (this may be different from the v4.0 data item name).
Format	Format required for submission of the data item
Schema specification (M/R/O/P)	The detailed schema for submission of the data is included in the Technical Guidance. This column identifies whether items are required for the extract to pass validation rules when submitted. M – Mandatory R – Required O – Optional P – Pilot Notes: • items in the 'Linkage' section are Mandatory and must be included for the record to pass validation • all applicable data should be submitted as soon as possible
Moved data items	All data items that have moved within the data set since the last version will be indicated using bullet points following each data item description.

ICD-10 and ICD-O-3 codes

The SACT data items should be collected for all cancers and other registerable conditions where applicable and where systemic anti-cancer therapies have been delivered as a primary or subsequent treatment. See Appendix A to C for the full lists of ICD10 and ICD-O-3 codes.

SACT data items in detail

Linkage - Primary identity details

Data linkage

These items are mandatory for every record, to enable NCRAS to accurately link patient records. To ensure that records submitted can be linked appropriately, key data fields must be completed for each record submitted.

There will be one linkage section completed each time the record is submitted. This is a new section for SACT v4

Primary identity details

Must be one occurrence per record (1..1)

Linkage Identifier Choice Choice 1..2

Choice 1

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
1	NHS Number	n10	M*

End of choice 1

Choice 2

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
44	Local Patient Identifier	min an1 max an20	M*

End of choice 2
End of Linkage Identifier Choice

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
43	NHS Number Status Indicator Code	an2	M

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
2	Person Birth Date	an10 ccyy-mm-dd	M
9	Organisation Identifier (Code of Provider)	min an3 max an5	M

Linkage identifier choice

* A combination of either 'NHS Number' and/or 'Local Patient Identifier' are mandatory for the schema. This section is classified as [1..2], therefore both can be submitted, but a record cannot be submitted without at least one of these data items.

Notes:

- most patients will have an NHS Number, and this should always be included where available
- for those who do not have an NHS Number, the hospital number (Local Patient Identifier) must be provided
- if both are available, then it is advised to submit both data items

Choice 1

NHS Number

The 'NHS Number' is a unique identifier for a patient within the NHS in England and Wales. This will not vary between any organisations of which a person is a patient.

There are some exceptions though, and these patients will not have a valid NHS Number:

- foreign nationals
- Scottish patient
- some members of the armed forces, including US personnel
- prisoners
- babies under the age of 12 weeks

Choice 2

Local Patient Identifier

The 'Local Patient Identifier' is a number used to identify a patient uniquely within a health care provider. It may be different from the patient's case note number and may be assigned automatically by the computer system.

NHS Number Status Indicator Code

This is a mandatory data item. The 'NHS Number Status Indicator Code' indicates the verification status of the NHS number provided.

National Code	National Code Definition
01	Number present and verified
02	Number present but not traced
03	Trace required
04	Trace attempted - No match or multiple match found
05	Trace needs to be resolved (NHS number or patient details conflict)
06	Trace in progress
07	Number not present and trace not required
08	Trace postponed (baby under six weeks old)

Person Birth Date

This is a mandatory data item. The 'Person Birth Date' is the date on which a person was born or is officially deemed to have been born. This should be automatically linked via your local PAS or EPR system when you create a record for the first time.

Notes:

- the data item name has been amended in v4, previously 'Date of Birth'
- all dates must be formatted as ccyy-mm-dd
    - SACT will not accept American formatted dates

Organisation Identifier (Code of Provider)

This is a mandatory data item. The 'Organisation Identifier (Code of Provider)' is the organisation identifier of the organisation acting as a health care provider (an6 not applicable to SACT).

This is the 3 or 5-digit code of the organisation submitting the record. This will therefore normally be either the organisation where the referral is received or the treating organisation.

Note:

- this could also include the new ANANA codes, created for new organisations

Demographic and Care Professional details

Demographic and care professional details are required for every record to ensure that the correct patient can be identified, and information can be correctly linked. The Demographics section should be completed by every Provider the first time a record is submitted.

There will only be one demographics and care professional details section completed for each record. Demographic linkage items will be required each time the record is submitted.

It is anticipated that some demographic data items listed below will be collected by every provider with which the patient has contact. Where this information is exchanged, the appropriate data item name should be used.

May be up to one occurrence per submission (0..1).

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
45	Person Family Name	max an35	M
46	Person Given Name	max an35	M
47	Person Stated Gender Code	an1	R
5	Patient Postcode	max an8	M
Start of section – Care Professional (Initiating Treatment)			Section 0..1
Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
62	Professional Registration Issuer Code – Care Professional (Initiating Treatment)	an2	M
63	Professional Registration Entry Identifier – Care Professional (Initiating Treatment)	min an1 max an32	M
End of section – Care Professional (Initiating Treatment)			

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
8	Consultant Specialty Code	an3	R

The following data item has been removed from SACT v4:

- 7 – Consultant GMC Code
    - replaced with two new care professional identification fields within the 'Care Professional (Initiating Treatment)' section

Person Family Name

This is a mandatory data item. The 'Person Family Name' is that part of a person's name which is used to describe family, clan, tribal group, or marital association.

Person Given Name

This is a mandatory data item. The 'Person Given Name' is the forename(s) or given name(s) of a person.

Person Stated Gender Code

The 'Person Stated Gender Code' is the person's gender as self-declared (or inferred by observation for those unable to declare their Person Stated Gender).

National Code	National Code Definition
1	Male
2	Female
9	Indeterminate (Unable to be classified as either male or female)
X	Not known (Person Stated Gender Code not recorded)

Note:

- this may not be the same as their birth 'phenotypic' sex

Patient Postcode

This is a mandatory data item. The 'Patient Postcode' is the postcode of the usual address of the patient at the time of treatment. This is the code allocated by the Post Office to

identify a group of postal delivery points. A code used primarily for the delivery of correspondence to addresses. Postcodes may also be used to define a geographic area.

Notes:

- the following two data items are part of a new section which is required
    - therefore, if you do not know this information, you do not have to submit any data
- however, both data items are mandatory within the section
    - therefore, you cannot submit one without the other

Professional Registration Issuer Code – Care Professional (Initiating Treatment)

The 'Professional Registration Issuer Code – Care Professional (Initiating Treatment)' is a new data item. This is the code which identifies the 'Professional Registration Body' for the consultant or health care professional who is responsible for initiating the treatment.

National Code	National Code Definition
03	General Medical Council
08	Health and Care Professions Council
09	Nursing and Midwifery Council
16	General Pharmaceutical Council

Note:

- this data item must be used in conjunction with 'Professional Registration Entry Identifier – Care Professional (Initiating Treatment)'

Professional Registration Entry Identifier – Care Professional (Initiating Treatment)

The 'Professional Registration Entry Identifier – Care Professional (Initiating Treatment)' is a new data item. This is the registration identifier allocated by an organisation for the consultant or health care professional who is responsible for initiating the treatment.

Note:

- this replaced 'Consultant GMC Code' in v3

Consultant Speciality Code

The 'Consultant Speciality Code' is recorded to report the specialised service of the consultant who initiated the SACT treatment

Clinical Status

This section is required to record more information about the patient's diagnosis.

May be up to one occurrence per submission (0..1)

Diagnosis Choice Choice 1..2
Choice 1

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
10	Primary Diagnosis (ICD-10)	min an4 max an6	M*

End of choice 1

Choice 2

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
11	Morphology ICD-O	min an5 max an7	M*

End of choice 2
End of Diagnosis Choice

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
48	Diagnosis Code (SNOMED CT)	min n6 max n18	R

Diagnosis choice

* A combination of either 'Primary Diagnosis (ICD-10)' and/or 'Morphology ICD-O' are mandatory for the schema. The section is classified as [1..2], therefore both can be submitted, but a record cannot be submitted without at least one of these data items.

Notes:

- all patients will have a Primary Diagnosis (ICD), and this should always be included
- if both are available, then it is advised to submit both data items
    - this is important for Haematological, Sarcoma and CTYA diagnoses

Choice 1

Primary Diagnosis (ICD-10)

The 'Primary Diagnosis (ICD-10)' is normally agreed at the MDT meeting where the patient is discussed, and treatment agreed.

ICD-10 is the International Statistical Classification of Diseases and Related Health Problems (ICD) and is a comprehensive classification of causes of morbidity and mortality. The primary diagnosis is the main condition treated or investigated during the relevant episode of healthcare.

Notes:

- this data item name has been amended, previously 'Primary Diagnosis' and has a new description in v4
- use Appendix A and B for the full list of reportable codes
- all ICD codes must be provided using the full 4-digit code, to allow for accurate analysis and reporting
- where the ICD-10 code only has 3 characters, for example C01, please add "X" as a 'packing digit' to meet the validation rules (such as C01.X, C07.X, C73.X)
    - in addition, the reporting format excludes the decimal CXX.X or DXX.X, all csv reports must be recorded as CXXX or DXXX

Choice 2

Morphology ICD-O

The 'Morphology ICD-O' is the morphology code for the diagnosed cancer as defined by ICD-O-3. This data item must be completed for all Haematological, Sarcoma and CTYA diagnoses.

Notes:

- this data item has a new description in v4
- it is expected that for Haematology cases ICD-O should be used in preference to Primary Diagnosis ICD-10
- please refer to Appendix C for additional support and linkage

Diagnosis Code (SNOMED CT)

The 'Diagnosis Code (SNOMED CT)' is the SNOMED CT concept ID which is used to identify the clinical diagnosis given to the patient.

Notes:

- this data item has a new description and has changed to 'Required' in v4, previously 'Optional'
- please refer to the 'how to find a SNOMED CT diagnosis' for support

Regimen

This section provides additional information about the regimen itself.

May be up to one occurrence per submission (0..1).

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
65	Treatment Context	an2	R
15	Intent of Treatment	an2	R
Line of Treatment Choice			Choice 1..1
Choice 1 – Curative Line of Treatment			
Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
66	Curative Line of Treatment	max n2	M
End of choice 1			
Choice 2 – Non-Curative Line of Treatment			
Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
67	Non-Curative Line of Treatment	max n2	M
End of choice 2 End of Line of Treatment Choice			
Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
16	Regimen	max an150	M
17	Height at Start of Regimen	n1.max n2	R

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
18	Weight at Start of Regimen	max n3.max n3	R
50	Performance Status at Start of Regimen – Adult	an1	R
21	Date Decision to Treat	an10 ccyy-mm-dd	R
22	Start Date of Regimen	an10 ccyy-mm-dd	M
23	Clinical Trial	an2	R
24	Chemoradiation	an1	R

Start of Section –Regimen Modification (0..1)

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
68	Regimen Modification	an1	M
69	Reason For Regimen Modification	an1	R
70	Reason For Regimen Modification – Patient (Clinical) Factors	an1	R
71	Toxicity Grade (Regimen Modification)	an1	R

End of Section – Regimen Modification

The following data items have been removed from SACT v4:

- 49 – Adjunctive Therapy
    - this has been replaced with ‘Treatment Context’
- 20 – Co-Morbidity Adjustment
    - replaced with option in new Dose modification section

Treatment Context

The 'Treatment Context' is a new data item. Treatment context is the context in which the SACT is prescribed, in relation to other treatments the patient has or may receive:

- Neoadjuvant (Before the main therapy)
- Adjuvant (After the main therapy)
- SACT Only, if the treatment has no other element
- CTYA only, where both Neoadjuvant and Adjuvant are applicable

National Code	National Code Definition
01	Neoadjuvant
02	Adjuvant
03	SACT Only
04	CTYA Only (Neoadjuvant and Adjuvant)

Note:

- this data item replaced 'Adjuvant Therapy', as this better reflects current clinical practice

Intent of Treatment

The 'Intent of Treatment' data item has been updated to simplify data recording and reduce burden for front line staff collecting and reporting the data.

National Code	National Code Definition
06	Curative
07	Non-Curative

Notes:

- this data item is no longer a repeating data item and is 'Required' in v4.0
- 01, 02, 03, 04, 05, 98 and 99 have been retired in v4.0
- 06 and 07 are new attributes from v4.0

Line of Treatment Choice

The following two data items form a choice where either the curative or non-curative line of treatment can be recorded. This is a Mandatory [1..1] section, therefore one or the other must be selected depending on the treatment being delivered within this regimen.

Note:

- there can be up-to 99 lines of treatment for either the curative or non-curative treatment, therefore they have a defined range of 1-99

Choice 1

Curative Line of Treatment

The 'Curative Line of Treatment' is a new data item in v4. This is to record the line of "curative" treatment.

Notes:

- curative line of treatment is a Regimen of SACT defined upfront and given with curative intent
    - curative intent refers to therapy aimed at elimination of cancer and preventing its recurrence

Choice 2

Non-Curative Line of Treatment

The 'Non-Curative Line of Treatment' is a new data item in v4. This is to record the line of "non-curative" treatment.

Notes:

- non-curative line of treatment is a regimen of SACT defined upfront and given with non-curative intent
    - non-curative intent refers to therapy aimed at maintaining or improving the quality and/or the quantity of life (for example, inducing "remission") but without the expectation of cure

Regimen

This is a mandatory data item. The 'Regimen' is the acronym derived from the drugs used to identify the Anti-Cancer Drug Regimen.

Notes:

- SACT does not require Trusts to change existing practice or change local regimen names
    - regimen names must refer to a single identifiable regimen, therefore 'bucket codes' must not be used
        - a bucket code is a code that refers to more than 1 regimen, for example 'Chemotherapy'

- once uploaded, local regimen names need to be mapped to a national standard list
    - this is a quick and easy process and can be done via the SACT online mapping tool, pharmacists are usually the best people to do this
        - this is available via the online portal for registered users
- the SACT portal data checker will accept any text that is used in the Regimen column, on upload, all regimen names are checked to the OPCS+ list included on the portal
    - this list is a version of the OPCS Chemotherapy Regimen List, as updated by SACT pharmacists to include new regimens, trials etc
    - if your local name for a particular regimen exactly matches the OPCS+ list, it will be automatically mapped via the portal
- if the regimen name (as it appears on the mapping tool) is truncated or unclear, please contact SACT
- regimens are mapped by Trust, so those uploaded by all the hospitals within your Trust will appear together
    - it may require pharmacists from all hospitals within the Trust to work together to complete all the mapping

Height at Start of Regimen

The 'Height at Start of Regimen' is the height measured in metres at the start of the regimen.

Notes:

- a value of 136cm, must be submitted as 1.36
- local QA should be implemented to ensure any value over 2 metres are reviewed prior to upload

Weight at Start of Regimen

The 'Weight at Start of Regimen' is the weight measured in kilograms at the start of the regimen.

Note:

- height and weight can be used by NDRS to calculate the patients BMI

Performance Status at Start of Regimen – Adult

The 'Performance Status at Start of Regimen – Adult' is the World Health Organisation (WHO) classification indicating a person's status relating to activity/disability.

National Code	National Code Definition
0	Able to carry out all normal activity without restriction
1	Restricted in strenuous activity but ambulatory and able to carry out light work
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
3	Symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden
4	Completely disabled; cannot carry out any self-care; totally confined to bed or chair

Notes:

- this data item is not applicable for Paediatric patients or Skin diagnoses, except for melanoma stage 4
- if a patient is on high dose steroid therapy (for example, dexamethasone), which is clinically considered to have artificially and temporarily improved the patient's performance status, the performance status assessed prior to commencing on steroids should be recorded

Decision to Treat Date

The 'Decision to Treat Date' is the date that the consultation between the patient and the clinician took place and a planned cancer treatment was agreed.

Notes:

- all date formats must be ccyy-mm-dd
- SACT will not recognise or accept American date formats

Start Date of Regimen

This is a mandatory data item. The 'Start Date of Regimen' is the first administration date of the first cycle of a regimen.

Notes:

- all date formats must be ccyy-mm-dd
- SACT will not recognise or accept American date formats

Clinical Trial

The 'Clinical Trial' enables the recording of when a patient is currently in an active SACT trial.

National Code	National Code Definition
01	PATIENT is taking part in a CLINICAL TRIAL
02	PATIENT is not taking part in a CLINICAL TRIAL
99	Not Known

Chemoradiation

This is a new data item in v4. An indication of whether the Systemic Anti-Cancer Therapy Drug Regimen was given as part of Chemoradiation.

National Code	National Code Definition
Y	Yes, part of a combined treatment with radiation
N	No, not part of a combined treatment with radiation

Note:

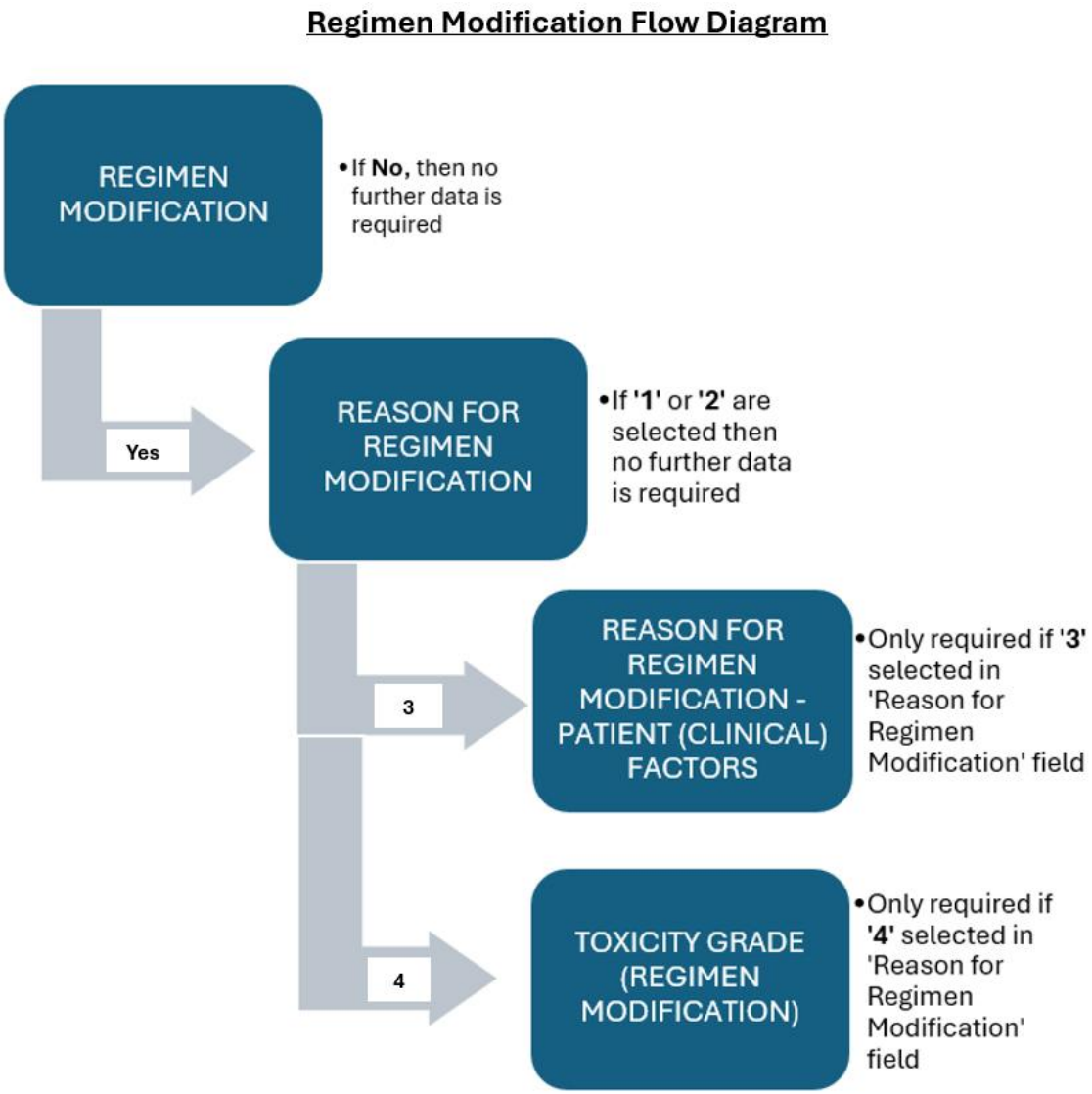
- this data item has been restored from v2 following clinical review, to include its original data item number [24]

Regimen Modification Section

These grouped data items form a section, which identifies if a regimen modification was made.

This is a Required [0..1] section, however the data is important and where applicable must be selected as follows:

- if 'No' is selected, then no further data is required
- if 'Yes' is selected, then additional questions will be asked, and in some cases additional linked data items may also be valid and needs answering:
    - these additional questions are important, and validations will be used as you upload your data onto the NDRS API
    - these are required to improve and enforce data quality and prevent illogical data returns
    - it is important that you implement processes to ensure your data is correct



Regimen Modification

This is a new data item in v4. Record if there has been an upfront dose modification, which modified the regimen.

National Code	National Code Definition
Y	Yes
N	No

Note:

- if you are recording a regimen modification, this data item becomes mandatory within the section

Reason For Regimen Modification

This is a new data item in v4. Record the reason for upfront dose modification. More than one option can be selected, where appropriate.

National Code	National Code Definition
1	Patient choice
2	Organisational (Trust) issue
3	Patient (Clinical) factors
4	Toxicity

Notes:

- 2 - Organisational (Trust) Issues, is where a modification was due to organisational issue such as protocol, capacity, IT & infrastructure
- 3 – Patient (Clinical) Factors, is where a modification was due to Genomics e.g. DPYD variant, Frailty, Comorbidities or Other
- 4 - Toxicity, identifies that toxicity arising from the patient's regimen was a factor in modifying the dose and/or schedule of their regimen

Reason For Regimen Modification - Patient (Clinical) Factors

This is a new data item in v4. Record the clinical factors which resulted in a dose modification.

More than one option can be selected, where appropriate, but can only be selected if '3-Patient (Clinical) factors' is selected in 'Reason for Modification'

National Code	National Code Definition
1	Genomics e.g. DPYD variant
2	Frailty
3	Comorbidities
8	Other

Notes:

- 1 - Genomics e.g. DPYD variant, is the gene encoding the Dihydropyrimidine Dehydrogenase (DPD) enzyme that affects how bodies break down fluorouracil and capecitabine derived chemotherapy drugs
- 2 - Frailty, identifies that the patient's frailty was a factor in modifying the dose and/or schedule of their regimen
- 3 - Comorbidities, identifies that the patient's comorbidities were a factor in modifying the dose and/or schedule of their regimen
- 8 - Other, identifies other reasons that were a factor in modifying the dose and/or schedule of their regimen

Toxicity Grade (Regimen Modification)

This is a new data item in v4. Record toxicity score/rating using the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.

National Code	National Code Definition
1	Grade 1
2	Grade 2
3	Grade 3
4	Grade 4
5	Grade 5

Notes:

- only one grade can be selected, per 'Reason for Regimen Modification'
- this data item must only be selected if '4- Toxicity' is selected in 'Reason for Modification'

Cycle

This section provides additional information about the cycle itself.

Notes:

- the cycle number and start date of cycle are mandatory fields within this section
    - obtaining the weight may not always be possible or appropriate
    - we would expect to receive as much information within this section as possible, as these provide valuable information on the patient's suitability for further treatment
- where patients are part way through their programme, regimen or even cycles, simply record the data for activity in the relevant month
- overtime, we would expect to build a picture of full treatments for each patient, but initially we expect to receive partial data

May be multiple occurrences per submission (0..*).

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
26	Cycle Number	max n3	M
27	Start Date of Cycle	an10 ccyy-mm-dd	M
28	Weight at Start of Cycle	max n3.max n3	R
51	Performance Status at Start of Cycle - Adult	an1	R

Start of Section – Cycle Modification (0..1)

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
72	Cycle Modification	an1	M
73	Reason For Cycle Modification	an1	R
74	Reason For Cycle Modification – Patient (Clinical) Factors	an1	R

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
75	Toxicity Grade (Cycle Modification)	an1	R

End of Section – Cycle Modification

Start of Section – Cycle Delay (0..1)

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
76	Cycle Delay	an1	M
77	Reason For Cycle Delay	an1	R
78	Reason For Cycle Delay – Patient (Clinical) Factors	an1	R
79	Toxicity Grade (Cycle Delay)	an1	R

End of Section – Cycle Delay

Cycle Number

The 'Cycle Number' refers to the cycles numbered sequentially within each regimen.

Note:

- this data item is mandatory in v4.0, previously 'Required'

Start Date of Cycle

This is a mandatory data item. The 'Start Date of Cycle' is the date of the first drug administration in each cycle.

Notes:

- all date formats must be ccyy-mm-dd
- SACT will not recognise or accept American date formats

Weight at Start of Cycle

The 'Weight at Start of Cycle' is the weight measured in kilograms at the start of the cycle.

Performance Status at Start of Cycle – Adult

The 'Performance Status at Start of Cycle – Adult' is the World Health Organisation (WHO) classification indicating a person's status relating to activity/disability.

National Code	National Code Definition
0	Able to carry out all normal activity without restriction
1	Restricted in strenuous activity but ambulatory and able to carry out light work
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
3	Symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden
4	Completely disabled; cannot carry out any self-care; totally confined to bed or chair

Notes:

- this data item is not applicable for Paediatric patients or Skin diagnoses, except for melanoma stage 4
- if a patient is on high dose steroid therapy (for example, dexamethasone), which is clinically considered to have artificially and temporarily improved the patient's performance status, the performance status assessed prior to commencing on steroids should be recorded

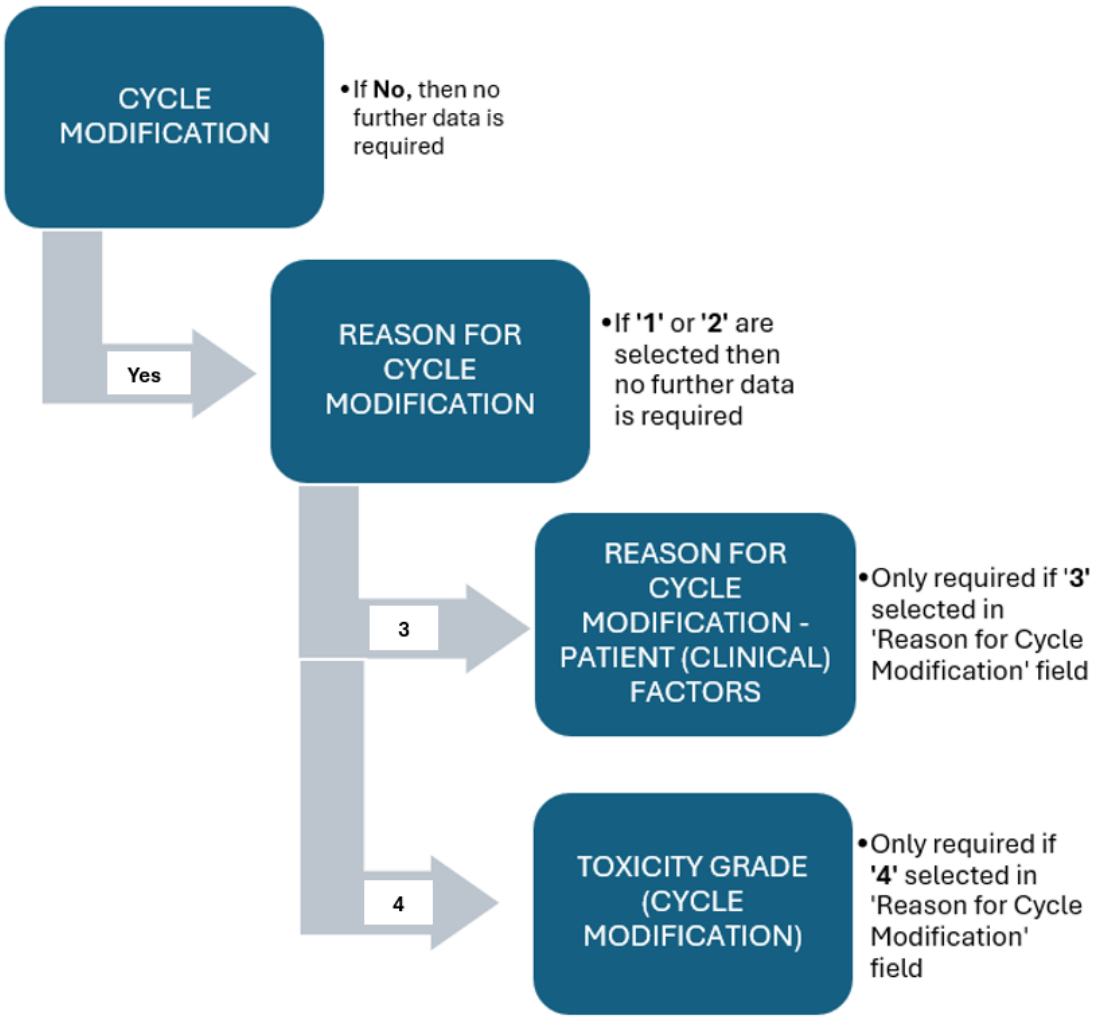
Cycle Modification Section

These grouped data items form a section, which identifies if a cycle modification was made.

This is a Required [0..1] section, however the data is important and where applicable must be selected as follows:

- if 'No' is selected, then no further data is required
- if 'Yes' is selected, then additional questions will be asked, and in some cases additional linked data items may also be valid and needs answering:
    - these additional questions are important, and validations will be used as you upload your data onto the NDRS API
    - these are required to improve and enforce data quality and prevent illogical data returns
    - it is important that you implement processes to ensure your data is correct

Cycle Modification Flow Diagram



Cycle Modification

This is a new data item in v4. Record if any drugs have been omitted from this cycle.

National Code	National Code Definition
Y	Yes
N	No

Note:

- if you are recording a cycle modification, this data item becomes mandatory within the section

Reason For Cycle Modification

This is a new data item in v4. Record the reason if any drugs have been omitted from this cycle. More than one option can be selected, where appropriate.

National Code	National Code Definition
1	Patient choice
2	Organisational (Trust) issue
3	Patient (Clinical) factors
4	Toxicity

Notes:

- 2 - Organisational (Trust) Issues, is where a modification was due to organisational issue such as protocol, capacity, IT & infrastructure
- 3 – Patient (Clinical) Factors, is where a modification was due to Genomics e.g. DPYD variant, Frailty, Comorbidities or Other
- 4 - Toxicity, identifies that toxicity arising from the patient's regimen was a factor in modifying the cycle

Reason For Cycle Modification - Patient (Clinical) Factors

This is a new data item in v4. Record the clinical factors which resulted in modifying the cycle.

More than one option can be selected, where appropriate, but can only be selected if '3-Patient (Clinical) factors' is selected in 'Reason for Modification'

National Code	National Code Definition
1	Genomics e.g. DPYD variant
2	Frailty
3	Comorbidities
8	Other

Notes:

- 1 - Genomics e.g. DPYD variant, is the gene encoding the Dihydropyrimidine Dehydrogenase (DPD) enzyme that affects how bodies break down fluorouracil and capecitabine derived chemotherapy drugs
- 2 - Frailty, identifies that the patient's frailty was a factor in modifying the cycle
- 3 - Comorbidities, identifies that the patient's comorbidities were a factor in modifying the cycle
- 8 - Other, identifies other reasons that were a factor in modifying the cycle

Toxicity Grade (Cycle Modification)

This is a new data item in v4. Record toxicity score/rating using the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.

National Code	National Code Definition
1	Grade 1
2	Grade 2
3	Grade 3
4	Grade 4
5	Grade 5

Notes:

- only one grade can be selected, per 'Reason for Cycle Modification'
- this data item must only be selected if '4- Toxicity' is selected in 'Reason for Cycle Modification'

Cycle Delay Section

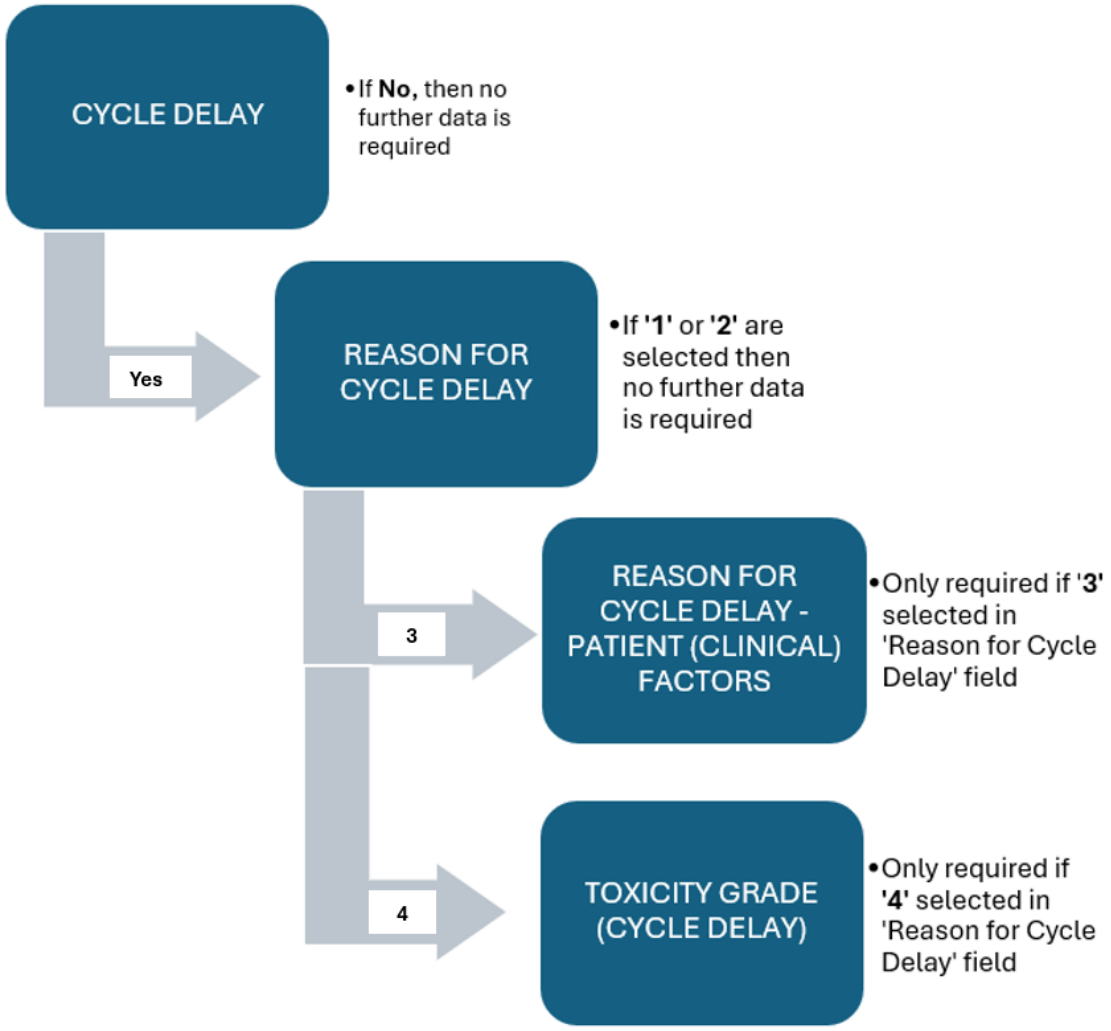
These grouped data items form a section, which identifies if a cycle has been delayed.

This is a Required [0..1] section, however the data is important and where applicable must be selected as follows:

- if 'No' is selected, then no further data is required

- if ‘Yes’ is selected, then additional questions will be asked, and in some cases additional linked data items may also be valid and needs answering:
    - these additional questions are important, and validations will be used as you upload your data onto the NDRS API
    - these are required to improve and enforce data quality and prevent illogical data returns
    - it is important that you implement processes to ensure your data is correct

Cycle Delay Flow Diagram



Cycle Delay

This is a new data item in v4. Record if the cycle has been delayed.

National Code	National Code Definition
Y	Yes

National Code	National Code Definition
N	No

Note:

- if you are recording a cycle delay, this data item becomes mandatory within the section

Reason For Cycle Delay

This is a new data item in v4. Record the reason for the cycle delay. More than one option can be selected, where appropriate.

National Code	National Code Definition
1	Patient choice
2	Organisational (Trust) issue
3	Patient (Clinical) factors
4	Toxicity

Notes:

- 2 - Organisational (Trust) Issues, is where a modification was due to organisational issue such as protocol, capacity, IT & infrastructure
- 3 – Patient (Clinical) Factors, is where a modification was due to Genomics e.g. DPYD variant, Frailty, Comorbidities or Other
- 4 - Toxicity, identifies that toxicity arising from the patient's regimen was a factor in delaying the cycle

Reason For Cycle Delay - Patient (Clinical) Factors

This is a new data item in v4. Record the clinical factors which resulted in the cycle delay.

More than one option can be selected, where appropriate, but can only be selected if '3-Patient (Clinical) factors' is selected in 'Reason for Cycle Delay'.

National Code	National Code Definition
1	Genomics e.g. DPYD variant
2	Frailty
3	Comorbidities
8	Other

Notes:

- 1 - Genomics e.g. DPYD variant, is the gene encoding the Dihydropyrimidine Dehydrogenase (DPD) enzyme that affects how bodies break down fluorouracil and capecitabine derived chemotherapy drugs
- 2 - Frailty, identifies that the patient's frailty was a factor in delaying the cycle
- 3 - Comorbidities, identifies that the patient's comorbidities were a factor in delaying the cycle
- 8 - Other, identifies other reasons that were a factor in delaying the cycle

Toxicity Grade (Cycle Delay)

This is a new data item in v4. Record toxicity score/rating using the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.

National Code	National Code Definition
1	Grade 1
2	Grade 2
3	Grade 3
4	Grade 4
5	Grade 5

Notes:

- only one grade can be selected, per 'Cycle Delay'

- this data item must only be selected if ‘4- Toxicity’ is selected in ‘Reason for Cycle Delay’

Drug Details

This section provides additional information about the drug details.

May be multiple occurrences per submission (0..*).

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
31	Drug Name	max an55	M
32	Daily Total Dose Per Administration	max n8	R
53	Administration Measurement Per Daily Total Dose	an2	R
Start of section - Administration Measurement Per Daily Total Dose			Section 0..1
Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
53	Administration Measurement Per Daily Total Dose	an2	M
54	Other - Administration Measurement Per Daily Total Dose	max an15	M
End of section - Administration Measurement Per Daily Total Dose			
Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
55	Unit of Measurement (SNOMED CT DM+D)	min n6 max n18	R
33	SACT Administration Route	an2	R
56	Route of Administration (SNOMED CT DM+D)	min n6 max n18	R

Administration Date Choice Choice 1..1
Choice 1

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
80	Administration Timestamp (Infusion)	max an25	M

End of choice 1
Choice 2

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
81	Administration Date (Oral Drug Dispensed)	an10 ccyy-mm-dd	M

End of choice 2
End of Administration Date Choice

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
82	Cycle Length in Days	max n3	R
83	Number Of Cycles Administered (On A Named Day)	max n2	R
35	Organisation Identifier of SACT Administration	min an3 max an5	R

Start of Section – Dose Modification (0..1)

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
84	Dose Modification	an1	M
85	Reason For Dose Modification	an1	R
86	Reason For Dose Modification – Patient (Clinical) Factors	an1	R
87	Toxicity Grade (Dose Modification)	an1	R

End of Section – Dose Modification

The following data items has been removed from SACT v4:

- 52 – DM+D
  - no longer required due to inaccurate data submission during pilot phase
- 34 – Administration Date
  - replaced with two new data items

Drug Name

This is a mandatory data item. The 'Drug Name' is the name of the SACT drug given to a PATIENT during an Anti-Cancer Drug Regimen. The name is taken from British National Formulary (BNF).

Notes:

- SACT would like to receive all anti-cancer drugs
  - please note that the term 'anti-cancer drugs' can include BCG, bisphosphonates, biological therapies, and hormonal treatments
- if you happen to include anti-sickness drugs, SACT will accept them
- all anti-cancer drugs by any administration route are included in SACT, but local arrangements may be necessary to add these to the download
- for drugs not yet in the BNF, use the approved name as this will usually be the drug name used by the pharmacy

Daily Total Dose Per Administration

Record the daily dose for the drug administered or dispensed.

Notes:

- this data item has an updated name and description in v4
- SACT will accept the dose entered by the clinician, to represent the dosage up to a maximum of 8 digits.
    - specify the correct unit as specified in the following data items

Administration Measurement Per Daily Total Dose

Record the actual unit of measurement used for the daily dose of each administration in a SACT cycle.

National Code	National Code Definition
01	mg
02	Mcg
03	g
04	Units
05	Cells
06	x10^6 PFU
07	x10^8 PFU
99	Not Known

Notes:

- this data item has an updated name and description in v4
- PFU is the acronym for Plaque-Forming Unit

Additional notes:

- the following two data items are part of a new section which is required
    - therefore, if you do not know this information, you do not have to submit any data
- however, both data items are mandatory within the section
    - therefore, you cannot submit one without the other

Administration Measurement Per Daily Total Dose

Record 'other' if there is another unit of measurement used for an administration in a SACT cycle, which is not in the list above.

National Code	National Code Definition
98	Other

Note:

- this data item has an updated name and description in v4

Other - Administration Measurement Per Daily Total Dose

Record the other unit of measurement for the total daily dose of each administration in a SACT cycle if not available within [administration measurement per actual dose] field. This must be completed if 98 - Other is selected

Note:

- this data item has an updated name and description in v4

Unit of Measurement (SNOMED CT DM+D)

Record the SNOMED CT® concept ID from the NHS Dictionary of Medicines and Devices, which is used to identify the unit of measurement.

Notes:

- this data item is 'Required' in v4, previously 'Optional'
- You can use the support at the end of the user guide to find the correct SNOMED CT unit of measurement

SACT Administration Route

Record the prescribed method of delivery for each administration in a SACT cycle.

National Code	National Code Definition
01	Intravenous
02	Oral
03	Intrathecal
04	Intramuscular

National Code	National Code Definition
05	Subcutaneous
06	Intraarterial
07	Intraperitoneal
08	Other intracavity Intracavernous
09	Intravesical (Intra-Vesicular)
11	Cutaneous (Topical)
12	Intradermal
13	Intratumour
14	Intralesional
98	Other

Route of Administration (SNOMED CT DM+D)
Record the SNOMED CT® concept ID from the NHS Dictionary of Medicines and Devices which is used to identify the route of administration.

Note:
- this data item is 'Required' in v4, previously 'Optional'

Administration Date Choice
The following two new data items, form a choice where either the drug infusion or drug dispensed details can be recorded. This is a Mandatory [1..1] section, therefore one or the other must be selected depending on the treatment being delivered.

Choice 1:
Administration Timestamp (Infusion): If selected, this is a mandatory data item. Record the date and time when the anti-cancer drug was administered to a patient (an infusion commenced).

These data can be entered using separate 'user friendly' fields as follows:

- **Administration Date (Infusion Administered):** The date of the infusion must be recorded, and this can be obtained from the clinic date where the infusion was administered.
- **Administration Time (Infusion Administered):** The time of the infusion must be recorded, and this can be obtained from the clinic (appointment) time where the infusion was administered, seconds can be recorded/defaulted as :00. If the time is not known, then a default code can be used as detailed below.
    - Examples of valid formats are:
        - 08:15:30 or 15:35:00

For developers: A time must always be submitted; a default time can be set to 00:00:00.

For reporting, the date and time must be combined and include the correct British Summer Time (GMT + 1 Hour), or Greenwich Mean Time addition. It would not be expected that service users would be required to input these additional variables (only the time as indicated above).

Example of a valid reporting format:

- 2024-09-01T10:15:00+(time zone offset either 01:00, 00:00, or Z)

Choice 2:
Administration Date (Oral Drug Dispensed): If selected, this is a mandatory data item. For continuous oral chemotherapy, the administration date will be the date on which an oral drug was dispensed to the patient or prescription issued.

Notes:

- for this date there is no change to the v3.0 format, in that only the date is required, and this must be recorded using the standard date format:
    - all date formats must be ccyy-mm-dd
    - SACT will not recognise or accept American date formats

Cycle Length in Days
This is a new data item for v4. Record the length of the cycle (in days) for the drug administered or dispensed. This has a range of 1-366 days (which covers a leap year).

Number of Cycles Administered (On A Named Day)
This is a new data item for v4. Record the number of cycles administered on the named day for the drug administered or dispensed. This has a range of 1-20.

Organisation Identifier of SACT Administration
Record the 'Organisation Identifier' of the organisation for each administration in a SACT cycle. This is the 3 or 5-digit code of the organisation.

Note:

- this could also include the new ANANA codes, created for new organisations.

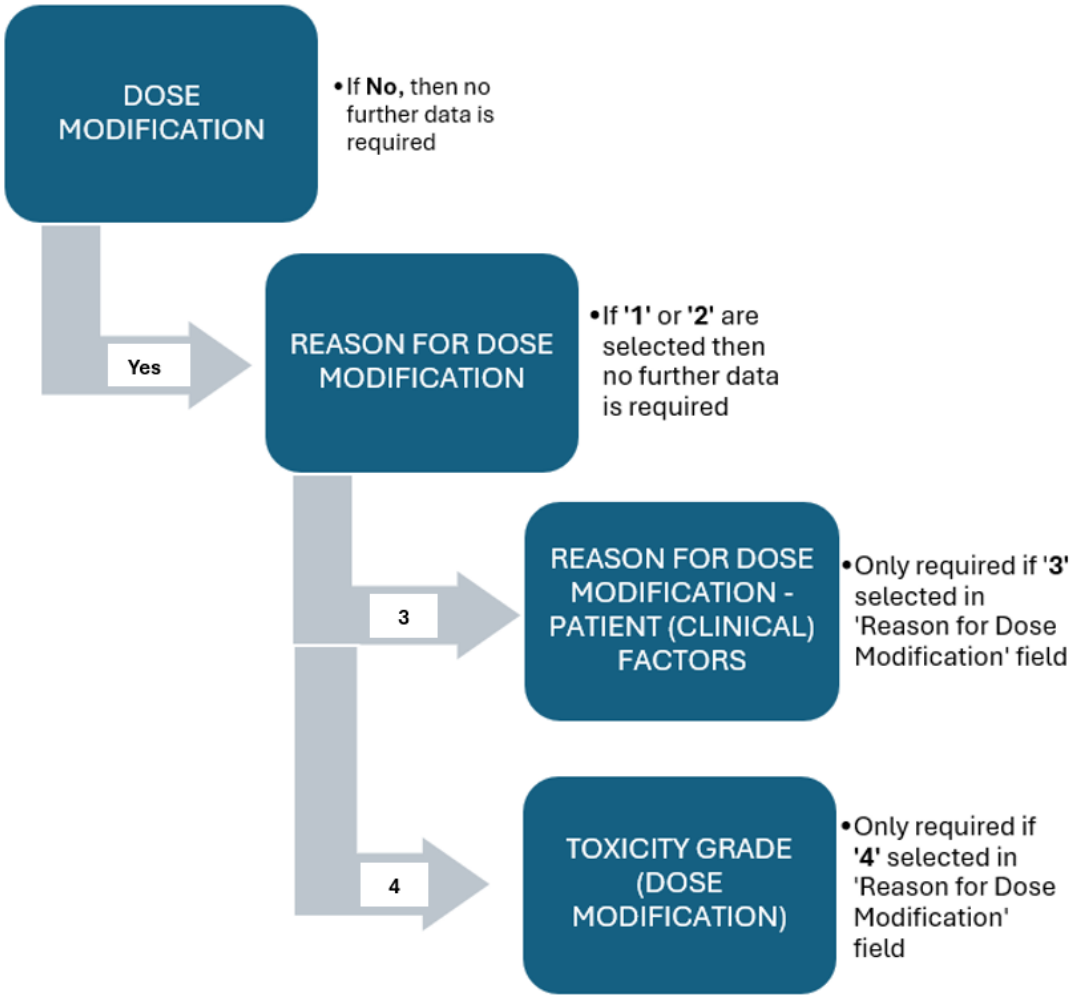
Dose Modification Section

These grouped data items form a section, which identifies if there was modification to the dose.

This is a Required [0..1] section, however the data is important and where applicable must be selected as follows:

- if 'No' is selected, then no further data is required
- if 'Yes' is selected, then additional questions will be asked, and in some cases additional linked data items may also be valid and needs answering:
    - these additional questions are important, and validations will be used as you upload your data onto the NDRS API
    - these are required to improve and enforce data quality and prevent illogical data returns
    - it is important that you implement processes to ensure your data is correct

Dose Modification Flow Diagram



Dose Modification

This is a new data item in v4. Record if there was a modification to the dose.

National Code	National Code Definition
Y	Yes
N	No

Note:

- if you are recording a dose modification, this data item becomes mandatory within the section

Reason For Dose Modification

This is a new data item in v4. Record the reason for any changes to the dose. More than one option can be selected, where appropriate.

National Code	National Code Definition
1	Patient choice
2	Organisational (Trust) issue
3	Patient (Clinical) factors
4	Toxicity

Notes:

- 2 - Organisational (Trust) Issues, is where a modification was due to organisational issue such as protocol, capacity, IT & infrastructure
- 3 – Patient (Clinical) Factors, is where a modification was due to Genomics e.g. DPYD variant, Frailty, Comorbidities or Other
- 4 - Toxicity, identifies that toxicity arising from the patient's regimen was a factor in modifying the dose and/or schedule of their regimen

Reason For Dose Modification - Patient (Clinical) Factors

This is a new data item in v4. Record the clinical factors that were a factor in modifying the dose.

More than one option can be selected, where appropriate, but can only be selected if '3-Patient (Clinical) factors' is selected in 'Reason for Dose Modification'

National Code	National Code Definition
1	Genomics e.g. DPYD variant
2	Frailty
3	Comorbidities
8	Other

Notes:

- 1 - Genomics e.g. DPYD variant, is the gene encoding the Dihydropyrimidine Dehydrogenase (DPD) enzyme that affects how bodies break down fluorouracil and capecitabine derived chemotherapy drugs
- 2 - Frailty, identifies that the patient's frailty was a factor in modifying the dose and/or schedule of their regimen
- 3 - Comorbidities, identifies that the patient's comorbidities were a factor in modifying the dose and/or schedule of their regimen
- 8 - Other, identifies other reasons that were a factor in modifying the dose and/or schedule of their regimen

Toxicity Grade (Dose Modification)

This is a new data item in v4. Record toxicity score/rating using the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.

National Code	National Code Definition
1	Grade 1
2	Grade 2
3	Grade 3
4	Grade 4
5	Grade 5

Notes:

- only one grade can be selected, per ‘Reason for Dose Modification’
- this data item must only be selected if ‘4- Toxicity’ is selected in ‘Reason for Dose Modification’

Outcome

This section provides additional information about the regimen outcomes.

May be multiple occurrences per submission (0..*).

Data Item Number	Data Item Name	Format	Schema Specification (M/R/O/P)
88	End of Regimen Summary	an1	R

The following data items have been removed from SACT v4:

- 38 - Regimen Modification - Dose Reduction
  - replaced with new section to specifically record Dose modification
- 57 - 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
- 58 - 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
- 59 - 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
- 60 - Regimen Outcome Summary - Non-Curative
  - replaced with a single Outcome field to allow for a simpler and more accurate recording of a regimen Outcome
- 61 - Regimen Outcome Summary – Toxicity
  - replaced with toxicity grade for more accurate recording

End of Regimen Summary

This is a new data item for v4. Reason the reason for completing or stopping regimen. More than one option can be selected, where appropriate.

National Code	National Code Definition
1	Completed pre-determined number of cycles
2	Disease Progression
3	Toxicity

National Code	National Code Definition
4	Patient choice to stop treatment
5	Organisation (Trust) issues/reason
6	Minimal residual disease (MRD) negativity
7	Death of patient
8	Other

Notes:

- 1 - Completed pre-determined number of cycles
    - identifies that the patient completed the pre-determined number of cycles, and the regimen has been completed as planned
- 2 - Disease Progression
    - identifies that the regimen was discontinued primarily because of disease progression
- 3 - Toxicity
    - identifies that the regimen was discontinued because of treatment related toxicity without evidence of disease progression
- 5 - Organisation (Trust) issues/reason
    - identifies that the regimen was discontinued primarily because of organisational issue
- 6 - Minimal Residual Disease (MRD) negativity
    - MRD negative is when no cancer cells are detected, during or after treatment, on either a blood draw or a bone marrow aspiration.

Key changes since version 3.0

This updated version of the User Guide includes new data-items, re-alignment of data structure, amendments and contains corrections, for example where there were errors in previous versions and updates where clinical practice has changed from SACT data set v3.0 and should be used to help data collection.

Throughout the data set there are now a series of choices which will make collecting and reporting data easier to understand and will be supported by the new technical document.

In addition, there are some key new sections to link potentially orphaned data items throughout the data set.

The proposed changes can be divided into the five key areas:

- deleted data items
- new data items
- data items with amended attributes
- moved data items
- schema specification changes

Note:

- in some cases, 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 Amended Attributes	11
Moved Data Items	5
Schema Specification Change	7

In v4.0, there are an additional 16 data items overall, compared with v3.0 and of them, 4 are compulsory due to the change in the way date and consultant codes are now recorded. In addition, most of the other increases were to ensure that ‘Regimen’, ‘Cycle’ and ‘Dose Modification’ as well as ‘Cycle Delay’ were correctly structured and recordable.

Clinical terminology integration within SACT

Why are we integrating clinical terminologies within SACT?

The data set can benefit significantly from implementing clinical terminologies within the data model:

- using SNOMED CT to capture outcome measures can reduce the need for individual tables for each measure
- a single table can capture multiple measures using a common structure
- the data set can respond more quickly to changes in clinical practice and information requirements
- terminology is updated at regular intervals and the data set automatically can capture the latest terms without the need for changing the data set through the DAPB process
- all NHS healthcare providers in England must now use SNOMED CT for capturing clinical terms within electronic patient record systems
- the use of SNOMED CT simplifies exchanging clinical information between systems

It is important to note that there is limited use of SNOMED CT within SACT, however this will be reviewed and may capture more clinical terminology within future versions. All SNOMED CT data items have now become 'Required' in v4.0.

What is SNOMED CT

SNOMED CT is the standard clinical terminology for the NHS to support recording of clinical information, in a way that supports data management and analysis to support patient care, while enabling data extraction and data exchange.

SNOMED CT provides a comprehensive set of clinical phrases or terms; this is called a terminology. SNOMED CT is much more than just a set of clinical phrases, for example it also includes groups with relationships between terms. It is the most comprehensive international terminology currently available and can be used across all care settings and all clinical domains.

SNOMED CT is managed and maintained internationally by SNOMED International and in the UK by the UK National Release Centre (part of NHS England). SNOMED CT is specified as the single terminology to be used across the health system.

Find out more about the UK National Release Centre on the NHS England website.

Benefits of using SNOMED CT

As the NHS moves to paperless, and the aspiration to exchange data electronically across the NHS, it is critical that all systems share the same clinical vocabulary. If every system uses its own vocabulary, then interoperability is reduced to simply moving readable documents around the system and clinicians having to repeatedly transcribe data they need to be within their system, thus introducing errors.

The use of an international terminology enables system suppliers to design their system to a common terminology that can be implemented with less country specialisation across a number of countries. The last few years has seen a shift by suppliers from developing country specific solutions to global solutions with local configuration.

Further resources on SNOMED CT

More information about SNOMED CT can be found on the NHS England website - this includes information about the following.

Licensing:

- the UK is a SNOMED International member country
- use of SNOMED CT in the UK is free; however, the use of SNOMED CT does require a license
- SNOMED CT licencing enquiries can be sent to

Training:

- NHS England offer a range of ways for individuals to learn more about SNOMED CT and its uses
- NHS England provide a number of training and education resources about SNOMED CT, including an overview of SNOMED CT, pre-recorded webinars, case studies, brochures and technical guidance
- for system suppliers, you may also be interested in the more technical guidance provided through the recorded webinars

Searching for concepts within SNOMED CT

NHS England have developed a SNOMED CT Browser that can be accessed online.

The NHS England SNOMED CT Browser provides ways to browser and search the SNOMED CT UK Edition. The SNOMED CT UK Edition is currently released twice per year and consists of the International Edition plus the UK-specific content provided within the UK Clinical Extension as well as the UK Drug Extension including maps to ICD-10 and OPCS-4.

This is for use in the UK only.

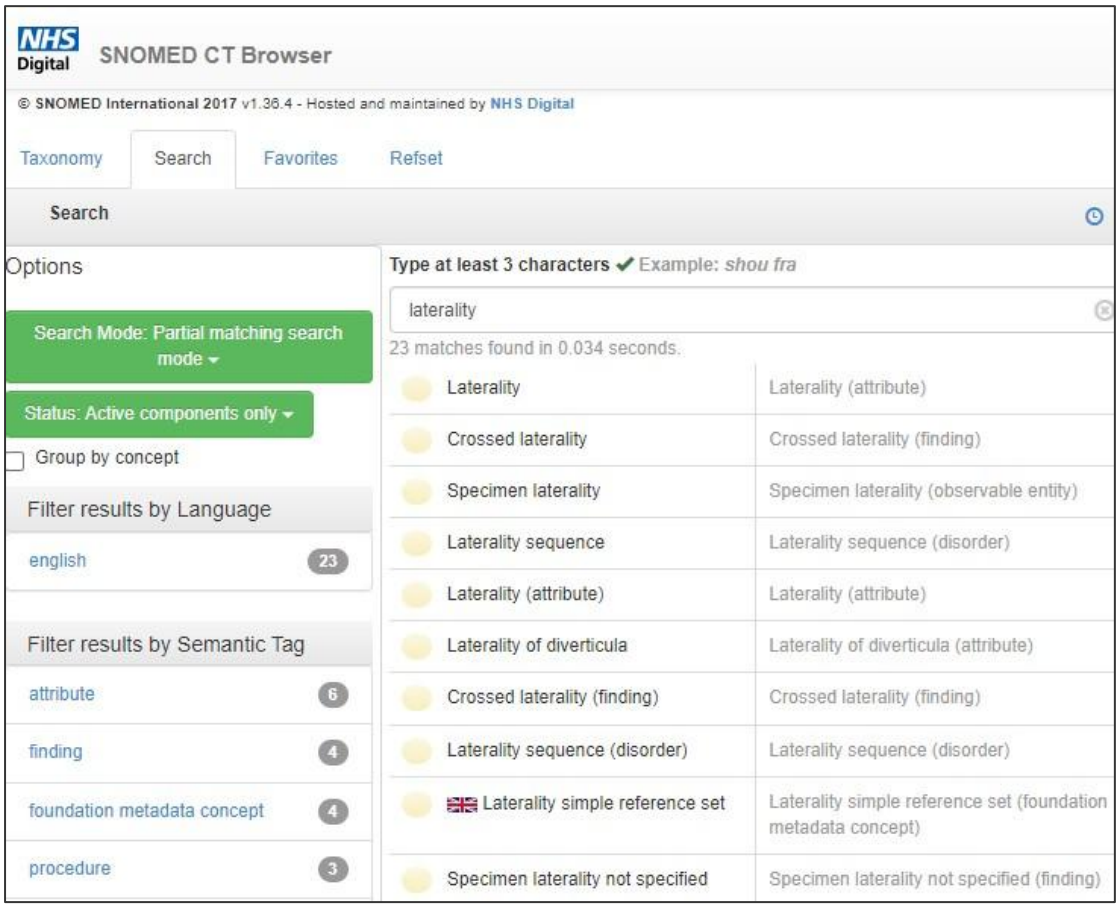
A list of the SNOMED CT releases contained in the browser is maintained and can be viewed on the NHS England website.

The Browser is provided by NHS England to anyone for reference purposes. The interface and REST APIs are not to be used as part of production systems in health care settings.

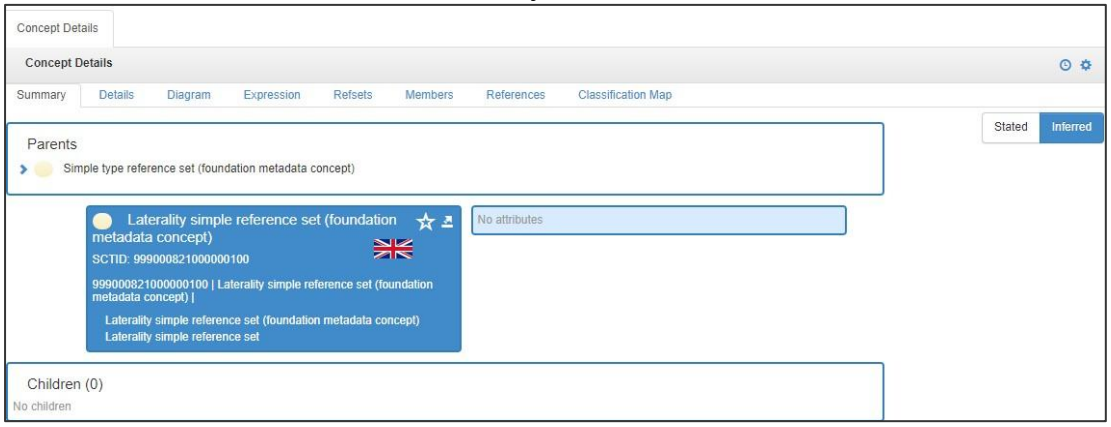
How to use termbrowser

The following provides a useful guide on how to use termbrowser, when searching for SNOMED CT codes:

- go to the termbrowser website
- click the 'Go Browsing' button
- click 'Search'
- enter the known ID or start typing the term required and all available concepts and reference sets will appear below



- select one of the search results - on the right will be the concept ID and information for the item you have selected

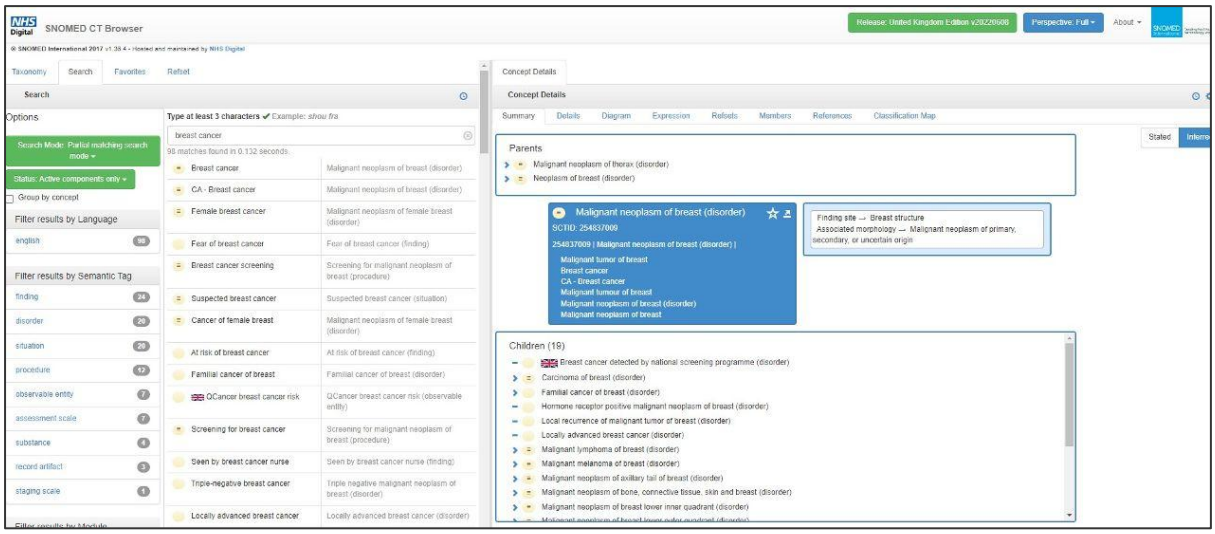


- if this is a reference set - select the members tab from the right-hand window to view all member concepts and their ID's

How to find a diagnosis

When searching for a diagnosis, ensure that you use the (disorder) hierarchy, which will be in brackets at the end of the 'Fully Specified Name' field.

For example, if you search for ‘Breast Cancer’ a long list of available types of breast cancer diagnoses will appear for you to choose as follows:



You can select the more granular level from the children list (on the right) and then cross reference your diagnosis by using the ‘Classification Map’ to ICD10.

For example, if you select ‘Malignant neoplasm of breast (disorder)’ the classification map will show three ICD10 codes:

Concept Details

Concept Details

Summary | Details | Diagram | Expression | Refsets | Members | References | Classification Map

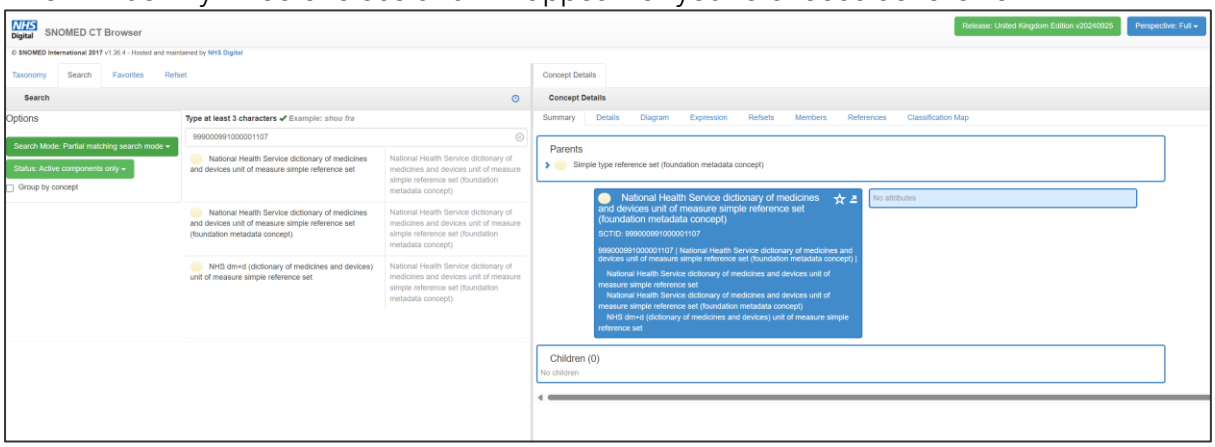
Malignant tumor of breast (disorder)
254837009
ICD10

Map Entries		Rule	Advice
1/1/1	C44.5 Malignant neoplasm: Skin of trunk	ALTERNATIVE	ADDITIONAL CODE POSSIBLE
1/1/2	C50.0 Malignant neoplasm: Nipple and areola	ALTERNATIVE	ADDITIONAL CODE POSSIBLE
1/1/3	C50.9 Malignant neoplasm: Breast, unspecified	TRUE	ADDITIONAL CODE POSSIBLE

How to find a Unit of Measurement (SNOMED CT DM+D)

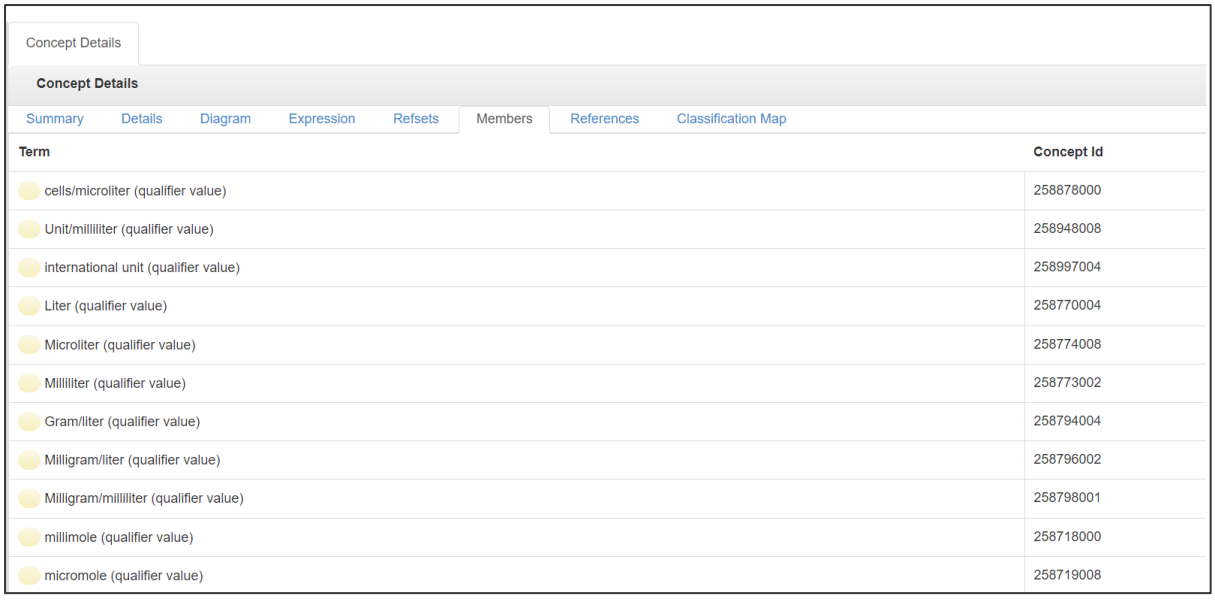
When searching for a unit of measurement (SNOMED CT DM+D), ensure that you use the following concept ID (SCTID) 999000991000001107.

This will identify three choices and will appear for you to choose as follows:



You will notice that it does not matter which option you use you go to the same location. For the purpose of this exercise, we will choose option three [NHS dm+d (dictionary of medicines and devices) unit of measure simple reference set].

Now if you select the members tab from the right of the screen, you will be presented with a large list (around 187) units of measure, each having their own Concept ID.



Concept Details

Concept Details

Summary | Details | Diagram | Expression | Refsets | Members | References | Classification Map

Term	Concept Id
cells/microliter (qualifier value)	258878000
Unit/milliliter (qualifier value)	258948008
international unit (qualifier value)	258997004
Liter (qualifier value)	258770004
Microliter (qualifier value)	258774008
Milliliter (qualifier value)	258773002
Gram/liter (qualifier value)	258794004
Milligram/liter (qualifier value)	258796002
Milligram/milliliter (qualifier value)	258798001
millimole (qualifier value)	258718000
micromole (qualifier value)	258719008

For the data set, enter the correct concept id that maps to the name of the measurement you want to use. If the unit of measurement you want is not in the list, you can request it to be added, by emailing information.standards@nhs.net.

Feedback and queries

This User Guide provides additional information to support the SACT 'Requirement Specification' and should also be used in conjunction with the SACT 'data set v4.0', the 'Implementation Guide' and 'Technical Guidance' documents.

The SACT team at NDRS are here to help and values feedback and suggestions for improvements to SACT data set and collection processes.

Our team provides tailored support to NHS Trusts with any issues around submitting data and to support improvements in data quality and completeness. If you would like to contact the team, then please speak to your regional data liaison manager in the first instance and they will triage your request.

CancerStats2

Feedback reports for the data submitted are available through the Cancer Stats website.

Please note that this platform requires an HSCN secure network connection. To ensure the best user experience, we encourage the use of modern web browsers such as Google Chrome, Mozilla Firefox, or Microsoft Edge to access the platform. A small number of platform users have reported issues when opening reports using Internet Explorer.

This provides feedback on the completion for some key data items across multiple data sets including:

- Systemic Anti-Cancer Therapy (SACT)
- Radiotherapy (RTDS)
- Cancer Outcomes and Services Data set (COSD)
- Cancer Alliance Data, Evaluation and Analysis Service (CADEAS)
- access to population level Incidence, Mortality and Survival data
- Living With and Beyond Cancer (LWBC)
- Rapid Cancer Registration Data set (RCRD)

Acknowledgements

We would like to express thanks to all those who have participated and continue to provide support and guidance in the development of this information standard.

Appendix A - Cancer waiting times ICD10 codes and tumour groups for primary diagnoses

Please refer to the downloadable documents on our website for full details of the ICD-10 codes used within SACT

These are registerable conditions for the purposes of Cancer Waiting Times and used within Cancer Registration, such as NCRAS mandatory fields.

Notes:

- the table lists all the registerable diseases by ICD10 code, together with the expected data set to be completed and the potential stage
- this table provides general guidelines only as not all permutations can be covered and there will always be exceptions, local clinical input is essential to identify and complete the appropriate stage
- further guidance is available from your local cancer registration service office

Appendix B - Mandatory registerable conditions

Please refer to the downloadable documents on our website for full details of the ICD-10 codes used within SACT

Further details to be provided regarding applicable data fields for each disease. These are additional Cancer Registration, for example, NCRAS mandatory registerable conditions.

Notes:

- the table lists are all the registerable diseases by ICD10 code, together with the expected data set to be completed and the potential stage
- this table provides general guidelines only as not all permutations can be covered and there will always be exceptions, local clinical input is essential to identify and complete the appropriate stage
- further guidance is available from your local cancer registration service office
- although primary amyloidosis (E85.9) is listed as an E ICD code in the World Health Organisation (WHO) disease classification, amongst clinicians it is widely acknowledged and subsequently treated as a cancer, receiving chemotherapy in some cases
- whilst we await the WHO disease classification being updated to reflect this fact, it's inclusion as a registerable condition requiring collection via the SACT has been agreed with the National Disease Registration Service

Appendix C - WHO classification of tumours of haematopoietic and lymphoid Tissue

Please refer to the downloadable documents on our website for full details of the codes and groupings

Group numbers have been assigned for ease of reference as used in ICD Codes and WHO Disease Groups in the Haematological section of the User Guide. (WHO Classification does not distinguish Groups 7 and 8 as separate disease groups).

Notes:

- where a suffix has been added, this should be used consistently as shown to ensure that diseases with the same ICD-O-3 code can be correctly distinguished
- to ensure that consistent coding continues to be applied nationally, please advise the SACT team if you identify potential changes or additional coding requirements
- for visual clarity, the ICD-O-3 codes in the table are formatted differently from the specification, records should be submitted according to the format in the specification, either “MXXXXX”, or “MXXXXXX” with suffix
- where marked as “CORE ONLY” there is no disease specific data set so only the core data set will be completed. Please also note that every record must include the relevant ICD-O-3 code
    - this applies only to COSD

Appendix D - Timetable for implementation of v4.0:

Submissions are accepted as follows for SACT versions 3.0 and/or v4.0

Diagnosis month	data set	Accepted MDT system submission format
January 2026	v3.0	csv only
February 2026	v3.0	csv only
March 2026	v3.0	csv only
April 2026	v3.0 or v4.0	csv only
May 2026	v3.0 or v4.0	csv only
June 2026	v3.0 or v4.0	csv only
July 2026	v4.0	csv only
August 2026	v4.0	csv only
September 2026	v4.0	csv only
October 2026	v4.0	csv only
November 2026	v4.0	csv only
December 2026	v4.0	csv only

Appendix E - Uniform Resource Locator (URL) Glossary

This section provides the full URL address, to help and support sight impaired users access all links throughout the document.

Page 4:

- downloads page on the NDRS, SACT website
  - https://digital.nhs.uk/ndrs/data/data-sets/sact#downloads
- NDRS data liaison manager
  - https://digital.nhs.uk/ndrs/data/data-sets/cosd#help-and-feedback

Page 5:

- NDRS SACT website
  - https://digital.nhs.uk/ndrs/data/data-sets/sact

Page 6:

- FutureNHS, website
  - https://future.nhs.uk/
- online FutureNHS access form
  - https://forms.office.com/e/YXsU6sQjTV
- NDRS programme and partnership page
  - https://digital.nhs.uk/ndrs/our-work
- SACT, CDF methodologies page
  - https://digital.nhs.uk/ndrs/data/data-sets/sact/sact-cdf-methodologies

Page 7:

- SACT technical guidance
  - https://digital.nhs.uk/ndrs/data/data-sets/sact/sact-data-set-v4-documentation/sact-data-set-v4-technical-guidance

Page 8:

- CancerStats2 website
  - https://cancerstats.ndrs.nhs.uk/sact

Page 45:

- British National Formulary website
  - https://bnf.nice.org.uk/

Page 57:

- UK National Release Centre for SNOMED CT
  - http://digital.nhs.uk/services/terminology-and-classifications/snomed-ct

Page 58:

- SNOMED CT resource website
  - http://digital.nhs.uk/services/terminology-and-classifications/snomed-ct
- SNOMED CT case studies
  - SNOMED CT Case Studies - Delen: Home - NHS England
- Termbrowser
  - https://termbrowser.nhs.uk/?

Page 59:

- NHS England's 'Delan' home page
  - https://nhsengland.kahootz.com/t_c_home/grouphome

Page 60:

- Termbrowser
  - https://termbrowser.nhs.uk/?

Page 64:

- CancerStats2 website
  - https://cancerstats.ndrs.nhs.uk/sact

Page 65:

- NDRS, ICD 10 Appendix
  - https://digital.nhs.uk/ndrs/data/data-sets/sact/sact-data-set-v4-documentation/sact-user-guide-v4/appendix

Page 66:

- NDRS, registerable conditions appendix
  - https://digital.nhs.uk/ndrs/data/data-sets/sact/sact-data-set-v4-documentation/sact-user-guide-v4/appendix

Page 67:

- NDRS, WHO classification appendix
  - https://digital.nhs.uk/ndrs/data/data-sets/sact/sact-data-set-v4-documentation/sact-user-guide-v4/appendix