

Protecting and improving the nation's health

SACT Dataset V3.0Frequently Asked Questions

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Introduction

The FAQ document is intended to provide extra user support by recording frequently asked questions and providing additional information on the new dataset and dataset items.

For dataset standard and implementation information you must read the following documents..

• Published dataset standard: DCB1533: Systemic Anti-Cancer Therapy Data Set

This FAQ document is designed to be used as an aide only in conjunction with the following documents.

- User guide document DCB1533 SACT User Guide
- SACT dataset V3.0 SACT_Dataset_v3.0_Final
- Technical Guide DCB1533 SACT Technical Guide

This document will cover any frequently asked questions pertaining to the new dataset standard V3.0.

This document will be regularly updated with frequent questions and answers where applicable and the most up to date version will be available on our website.

Version Number	V 4.5
Month of release	July 2019
Information contact	sact@phe.gov.uk
Direct link	http://www.chemodataset.nhs.uk/frequently_asked_questions/

Schema Specification

The mandatory, required, optional or pilot (M/R/O/P) column indicates the requirement for the inclusion of data:

Schema Specification	Description		
M = mandatory	this data item is mandatory; the record cannot be submitted if the mandatory data items are not completed – the file will be rejected if mandatory items are absent and other data items are completed		
R = required	this data item is required as part of NHS business rules and must be included where available or applicable, however, the section can be submitted without completing all the required items		
O = optional	his data item can be included at the discretion of the submitting organisation and their commissioners as required or local purposes		
P = pilot	this data item will not normally be included in the direct submission from cancer service provider organisations unless the provider Trust is part of the specific pilot exercise		

Upload & submission - Frequently Asked Questions

Q. When do I have to submit the new dataset items?

A.Collection of the new dataset will start from September 2019 treatment activity with a 3-month implementation window. Data for treatment activity September-November can be submitted as either SACT V2.0 or SACT V3.0. All providers must submit the new dataset for December 2019 activity onwards.

Q. When will I start to submit the new dataset items?

A.The 2-month timeline for routine submission of SACT data means that SACT treatment activity must be uploaded to the SACT portal within 8 weeks of activity month end.i.e. September activity must be uploaded to the portal by the end of November.

If you plan to implement the new dataset with September 2019 activity - you will upload this data by the end of November 2019

If you plan to implement the new dataset with October 2019 activity - you will upload this data by the end of December 2019

If you plan to implement the new dataset with November 2019 activity - you will upload this data by the end of January 2020

Q. I am concerned I will not be able to make the deadline, what should I do?

A. You should contact the SACT team as soon as possible and a data liaison officer will work with you to provide extra support and to help with planning.

Q; I don't think the new dataset is feasible for us. Can we opt to remain on the old dataset?

A.No, all providers must submit the new dataset for December 2019 activity. It will not be possible to submit data in the old format for activity after this date.

Q. Can I stay on the same upload schedule?

A. The 1-month upload schedule is being phased out and the new dataset standard specifies the 2-month schedule only. This will mean a change for only those currently on the 1-month upload schedule.

Q. Can we submit the new dataset in XML format?

A.The only upload format accepted is .csv format, XML format is not acceptable

Q. If I am not sending optional or pilot items, do I have to include those columns on my upload?

A.Yes, the columns for all fields will need to be present, in correct order and correct header title (see uploadexample.csv). If you are not submitting optional or pilot items then these columns will be blank

Q. Can I use any header row?

A.No,the header must be provided as per the technical specification document only – see link at start of the upload & submission FAQ

Q. Can we introduce the new dataset gradually, ie submit partial data in the new format and partial data in the old?

A.Dual submission of both datasets may be possible during the three month implementation period (September – November 2019) but this would require prior agreement with the SACT team and will only be allowed in exceptional circumstances. Our recommendation is to switch all submissions to the new dataset at one time.

Q. We have two hospitals working separately within the trust. Do we need to both change to the new version at the same time?

A. The portal will allow different hospitals in a trust to submit different versions of the dataset but we would strongly recommend that you switch over as a trust all together.

Q. Can we use any name for our submission file?

A. No. The file MUST be named correctly in accordance with the Technical specification. The new dataset has a Unique UnitID that must be used in the title of all submitted files. Failure to use the unique UnitID will result in the file failing upload.

Q. What are the different UnitID's that I have to name my files

A. You will need to ensure your file has a UnitID as follows

SACT dataset Version	UnitID
Current version – SACT v2.0	SACT_v2-ccyymmdd-ccyymmdd.csv
New version – SACT v3.0	SACT_v3-ccyymmdd-ccyymmdd.csv
Outcomes Upload only	Outcomes_Upload-ccyymmdd-ccyymmdd.csv

General Dataset - Frequently Asked Questions

You should ensure you have read the following document: DCB1533 SACT - User Guide

Q. Will the SACT team notify my software provider?

A. Yes, the SACT data liaison teams have already began to discuss the new data standard with software providers however it will be up to each trust to ensure their software provider is able to provide them with the system they require for the submission of the new dataset.

Q. Do we have to keep sending the data items in SACT v2.0 that will be retired in SACT v3.0?

A. Yes, the current dataset standard stays in place until you start submitting the new dataset.

Q. Who do I contact if I have questions about the new dataset?

A. Firstly always check our website for the latest version of this FAQ document and see if your question is listed here. If you still have a question, please contact the SACT helpdesk and Data liaison team at sact@phe.gov.uk.

Q: Will we be able to test our submissions before going live as we did when the new portal was introduced?

A: Yes, there will be a test period. More information will be released at a later date.

Q. I notice that some fields have a leading zero and excel removes this from my .csv submission

A. The validation for these fields will allow for data with and without leading zero.

Unlike the previous dataset version there are no conflicts within each field, so if you send "1" instead of "01" we will map automatically.

Q. How do we submit Biosimilars?

A.Biosimilars should be submitted using the drug name field under the brand name (originator drugs should be submitted under the generic name)

SACT Dataset Fields

Section 1

Data Item Section Name: DEMOGRAPHICS AND CONSULTANT

Data Item Section Description: To carry details for the Demographics and Consultant

Dataset Item details

Data Item Name: NHS NUMBER

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 21

Format: n10

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

Q. Can I submit Local Patient Identifier instead of NHS number?

A. Only where a NHS number is not available or cannot be disclosed.

Dataset Item details

Data Item Name: LOCAL PATIENT IDENTIFIER

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 21

Format: min an1 max an20

Schema Specification: Mandatory New Dataset Status: New Item

Frequently Asked Questions

Q. My system does not generate a Local Patient Identifier?

- A. As long as you are able to submit NHS number then NHS number is the preferred data item.
- Q. Both my PAS & eprescibing system generates a different number, which should I submit?
- A. To assist with linking to other NCRAS datasets then the PAS number is preferred.

Data Item Name: NHS NUMBER STATUS INDICATOR CODE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 21

Format: an2

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Dataset Item details

Data Item Name: PERSON FAMILY NAME

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 21

Format: max an35

Schema Specification: Mandatory New Dataset Status: New Item

Frequently Asked Questions

Q. What do we submit if the patient has a protected identity

A. Contact the helpdesk to discuss what "dummy" information can be submitted in special

circumstances

Dataset Item details

Data Item Name: PERSON GIVEN NAME

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 21

Format: max an35

Schema Specification: Mandatory New Dataset Status: New Item

Frequently Asked Questions

Q. What do we submit if the patient has a protected identity

A. Contact the helpdesk to discuss what "dummy" information can be submitted in special

circumstances

Data Item Name: DATE OF BIRTH

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 22

Format: an10 ccyy-mm-dd

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Dataset Item details

Data Item Name: PERSON STATED GENDER CODE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 22

Format: an1

Schema Specification: Required New Dataset Status: Replacement Item

Frequently Asked Questions

Q. Why have the response options changed for this data item?

A. The national code list has been updated in accordance with NHS Digital policy.

Dataset Item details

Data Item Name: PATIENT POSTCODE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 22

Format: max an8

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

Q. What should I do if the patient does not have a postcode or their ID is protected?

A. Please record a dummy postcode for this field e.g. ZZ99 9ZZ

Data Item Name: CONSULTANT GMC CODE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 22

Format: an8

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

Q. Why is the format an8 when the code from the GMC is n7?

A. NHS digital require codes to have an alpha prefix. For the majority of SACT records this will

be a 'C' (for consultant)

Dataset Item details

Data Item Name: CONSULTANT SPECIALTY CODE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 22

Format: an3

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Dataset Item details

Data Item Name: ORGANISATION IDENTIFIER (CODE OF PROVIDER)

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 22

Format: min an3 max an5

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Section 2

Data Item Section Name: CLINICAL STATUS

Data Item Section Description: To carry details for Clinical Status

Dataset Item details

Data Item Name: PRIMARY DIAGNOSIS

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 24 & 40

Format: min an4 max an6

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

Q. The patient does not have a primary ICD diagnosis code what should we submit?

A. If there is no primary ICD diagnosis code you must submit either Morphology or SNOMED CT instead.

Dataset Item details

Data Item Name: MORPHOLOGY ICD-O

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 24 & 56

Format: Min an5 - Max an7

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

Q. The patient does not have a morphology diagnosis code what should we submit?

A. If there is no morphology diagnosis code you must submit either ICD primary code or SNOMED CT instead.

Data Item Name: **DIAGNOSIS CODE (SNOMED CT)**

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 25

Format: min n6 max n18

Schema Specification: Optional New Dataset Status: New Item

Frequently Asked Questions

Q. Do I have to supply this dataset item?

A. This item is only optional and does not have to be included if you do not routinely collect this Information – See Schema Specification on page 4

Q. The patient does not have a SNOMED CT diagnosis code what should we submit?

A. If there is no SNOMED CT diagnosis code you must submit either ICD primary code or Morphology instead.

Q. Why was this data item added?

A. This data item was added to comply with NHS digital policy for data coding requirements.

Q. Can this item be mapped automatically from the primary ICD code

A. No. there is no direct mapping available. We have been working with NHS digital coding teams and for each primary ICD there are multiple SNOMED CT options available.

Example:

ICD-10 code	ICD-10 code descriptio n	Number of SNOMED concepts mapped to this ICD-10 code	Sample of corresponding SNOMED concepts (a maximum of 10 examples provided)
C50.9	Malignant neoplasm: Breast, unspecified	53	Malignant neoplasm of ectopic site of female breast (disorder), 188159008 Malignant neoplasm of ectopic site of male breast (disorder), 188168005 Cancer en cuirasse (disorder), 254841008 Inflammatory carcinoma of breast (disorder), 254840009 Carcinoma of breast (disorder), 254838004 Malignant phyllodes tumour of breast (disorder), 254844000 Lobular carcinoma of breast (disorder), 278054005 Malignant neoplasm of male breast (disorder), 372095001 Carcinoma of male breast (disorder), 372096000 HER2-positive carcinoma of breast (disorder), 427685000

Section 3

Data Item Section Name: REGIMEN

Data Item Section Description: To carry details for the Regimen

Dataset Item details

Data Item Name: ADJUNCTIVE THERAPY

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 26

Format: an1

Schema Specification: Required New Dataset Status: New Item

Frequently Asked Questions

Q. Why has this data item been added?

A. This has been updated so that the treatment intent can be more accurately recorded against therapy type. Previously "adjuvant" and "neo-adjuvant" were included as response options within the "Treatment Intent" data item.

Q. What is meant by adjuvant treatment?

Adjuvant therapy, is a therapeutic agent given <u>after</u> a main treatment and is designed to **maximize** the effectiveness of the main treatment

- For example, adjuvant therapy is the additional treatment usually given after surgery to reduce the risk of relapse due to the presence of undetected disease.
- If known disease is left behind following surgery, then further treatment is NOT technically adjuvant.

Neoadjuvant therapy is a therapeutic agent given <u>before</u> a main treatment and is designed to **maximize the effectiveness** of the main treatment

• For example, a neoadjuvant therapy can turn a tumor from untreatable to treatable by shrinking the volume to allow effective surgery.

Not applicable (primary treatment) refers to therapeutic agents which are the main treatment in their own right and are not designed to support the effect of another "main" treatment.

In this context "primary" refers to the "main" and not "first" treatment.

Data Item Name: INTENT OF TREATMENT

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 27

Format: an2

Schema Specification: Required New Dataset Status: Replacement Item

Frequently Asked Questions

Q. Why has this data item changed?

A. The response options for Treatment Intent have been updated to reflect clinical practice and to allow for more accurate recording of intent across all tumour groups.

- Q. Can I select more than one option?
- A. Yes, this is a 'repeating field' meaning that you can supply multiple options from the list, if multiple options are completed they should be submitted in the .csv file as follows "1;2;4"
- Q. What is the maximum number of response options I can select?
- A. You can select one `Curative` intent or up to four `Palliative intents`, we would not expect to receive a combination of both `Curative` & `Palliative` Intents.
- Q. From the selection of Palliative intents, is there a preferred (hierarchy) response?
- A. No. You should select all response options which apply. There are multiple options and you should select all which are relevant

Dataset Item details

Data Item Name: REGIMEN

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 27

Format: max an150

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

- Q. Can I only submit nationally recognised names?
- A. No, local names can be submitted and mapped to national names using the SACT portal. For unknown trial regimens these can be mapped to group name: 'Trial Unspecified'.
- Q. Is there a national regimen list available?
- A. Currently the only regimen list is available through TRUD. Regimen List available through TRUD

Data Item Name: HEIGHT AT START OF REGIMEN

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 28

Format: n1. max n2

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

Q. Do we need to submit this for all treatment types i.e. Oral

A. Yes, this data item must be submitted for all treatments to meet NHS England requirements.

Dataset Item details

Data Item Name: WEIGHT AT START OF REGIMEN

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 28

Format: max n3.max n3

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

Q. Do we need to submit this for all treatment type i.e. Oral

A. Yes, this data item must be submitted for all treatments to meet NHS England requirements.

Dataset Item details

Data Item Name: PERFORMANCE STATUS AT START OF REGIMEN - ADULT

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 28

Format: an1

Schema Specification: Required New Dataset Status: Replacement Item

Frequently Asked Questions

Q. Why was this changed?

A. The new dataset standard only requires performance status to be submitted for adult patients.

Q. We do not treat adults, so do I have to submit this item?

A. No, performance status is only required for adults.

Data Item Name: CO-MORBIDITY ADJUSTMENT

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 28

Format: an1

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

Q. Should I complete this item if a patient has any co-morbidity?

A. This data item is designed to capture when co-morbidities are a significant factor in deciding on regimen, or in varying the dose or treatment interval

Dataset Item details

Data Item Name: DATE DECISION TO TREAT

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 28

Format: an10 ccyy-mm-dd

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Dataset Item details

Data Item Name: **START DATE OF REGIMEN**

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 29

Format: an10 ccyy-mm-dd

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Data Item Name: CLINICAL TRIAL

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 29

Format: an2

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

Q. Has this item changed?

A. The terminology in the description has changed. We only want to know when a patient is enrolled in an active Systemic Anti-Cancer Therapy Trial at time of treatment.

Section 4

Data Item Section Name: CYCLE

Data Item Section Description: To carry details for the drug Cycle

Dataset Item details

Data Item Name: CYCLE NUMBER

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 30

Format: max n3

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Dataset Item details

Data Item Name: START DATE OF CYCLE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 30

Format: an10 ccyy-mm-dd

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Data Item Name: WEIGHT AT START OF CYCLE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 30

Format: max n3.max n3

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

Q. Do we need to submit this for all treatment type i.e. Oral

A. Yes, this data item must be submitted for all treatments to meet NHS England requirements.

Dataset Item details

Data Item Name: PERFORMANCE STATUS AT START OF CYCLE - ADULT

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 31

Format: an1

Schema Specification: Required New Dataset Status: Replacement Item

Frequently Asked Questions

Q. Why was this changed?

A. The new dataset standard only requires Adult performance status to be submitted for SACT

Q. We do not treat adults, so do I have to submit this item?

A. No, performance status is only required for adults.

Section 5

Data Item Section Name: DRUG DETAILS

Data Item Section Description: To carry the drug Details for the patients treatment

Dataset Item details

Data Item Name: **DRUG NAME**

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 32

Format: max an55

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

Q. Can we submit our own local drug names?

- A. Currently you are able to submit local drugs names, however they may be a future requirement to map these to BNF or standard groupings.
- Q. How should we be submitting Biosimilars?

A. Biosimilars should be submitted under the brand name (originator drugs should be submitted under the generic name)

Dataset Item details

Data Item Name: DM+D

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 33

Format: min n6 max n18
Schema Specification: Pilot

New Dataset Status: New Item

Frequently Asked Questions

Q. Do I have to supply this pilot item?

- A. Only if you have previously agreed to be part of the pilot scheme with the SACT Team
- Q. Which unique identifier from the dm+d do we need to submit?
- A. The details of this item will be included in the pilot information and will be agreed prior to commencement of the pilot

Data Item Name: ACTUAL DOSE PER ADMINISTRATION

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 33

Format: max n8

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

Q. What dose should we be submitting?

A. The dose should always be submitted as a single dose only (not total dose)

Q. Should I ever submit records with a dose of zero?

A. If at all possible a drug dose should be provided. Records should not be submitted to SACT with a zero dose.

If a drug is not given it should be deleted from your SACT upload. It should not be submitted as a zero dose.

Dataset Item details

Data Item Name: ADMINISTRATION MEASUREMENT PER ACTUAL DOSE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 33

Format: an2

Schema Specification: Required New Dataset Status: New Item

Frequently Asked Questions

Q. Why was this added to the dataset

A. A unit of measurement was added to increase the accuracy of the data analysis.

<u>Dataset Item details</u>

Data Item Name: OTHER - ADMINISTRATION MEASUREMENT PER ACTUAL DOSE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 33

Format: Max an15

Schema Specification: Required New Dataset Status: New Item

Frequently Asked Questions

Q. Do I always have to complete this item?

A. This item only needs to be completed when <u>option 98 (Other)</u> is selected for the previous item Administration measurement per actual dose

Data Item Name: UNIT OF MEASUREMENT (SNOMED CT DM+D)

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 33

Format: min n6 max n18

Schema Specification: Optional New Dataset Status: New Item

Frequently Asked Questions

Q. Do I have to supply this dataset item?

A. This item is only optional and does not have to be included if you do not routinely collect this Information— See Schema Specification on page 4

Q. Why was this data item added?

A. This was added to comply with NHS digital policy for data coding requirements

Dataset Item details

Data Item Name: SACT ADMINISTRATION ROUTE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 33

Format: an2

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Dataset Item details

Data Item Name: ROUTE OF ADMINISTRATION (SNOMED CT DM+D)

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 34

Format: min n6 max n18

CSV Schema Specification: Optional New Dataset Status: New Item

Frequently Asked Questions

Q. Do I have to supply this dataset item?

A. This item is only optional and does not have to be included if you do not routinely collect this Information – See Schema Specification on page 4

Q. Why was this added?

A. This was added to comply with NHS digital policy for data coding requirements

Data Item Name: ADMINISTRATION DATE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 34

Format: an10 ccyy-mm-dd

Schema Specification: Mandatory New Dataset Status: Previous Item

Frequently Asked Questions

Q. What do I submit for Oral treatments as they do not have an admin date?

A. For oral treatments you should use the 'dispensed date' instead of 'administration date'.

Dataset Item details

Data Item Name: ORGANISATION IDENTIFIER OF SACT ADMINISTRATION

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 34

Format: min an3 max an5

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Section 6

Data Item Section Name: OUTCOME

Data Item Section Description: To carry the Outcome Details applicable to the patients

treatment

Dataset Item details

Data Item Name: REGIMEN MODIFICATION - DOSE REDUCTION

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 35

Format: an1

Schema Specification: Required New Dataset Status: Previous Item

Frequently Asked Questions

There are no current questions for this item.

Data Item Name: REGIMEN OUTCOME SUMMARY - CURATIVE (COMPLETED AS PLANNED)

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 35

Format: an1

Schema Specification: Required New Dataset Status: New Item

Frequently Asked Questions

Q. Do I always have to complete this item?

A. This data item should only be completed when the regimen is <u>curative</u> and <u>completed as planned</u>.

Dataset Item details

Data Item Name: REGIMEN OUTCOME SUMMARY - CURATIVE (NOT COMPLETED

AS PLANNED) REASON

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 36

Format: an1

Schema Specification: Required New Dataset Status: New Item

Frequently Asked Questions

- Q. Do I always have to complete this item?
- A. This data item should only be completed when the regimen is <u>curative</u> and <u>not completed as planned</u>.
- Q. Can I select more than one option?
- A. Yes, this is a 'repeating field' meaning that you can supply multiple options from the list, if there are several reasons why a regimen was not completed as planned. If multiple options are selected they should be submitted in the **.csv** file as follows "1;2;4"
- Q. What is the maximum number of response options I can select?
- A. You can select one to four specific reasons as well as an additional `other` option

Data Item Name: OTHER - REGIMEN OUTCOME SUMMARY - CURATIVE (NOT COMPLETED AS PLANNED) REASON

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 36

Format: Max an55

Schema Specification: Required New Dataset Status: New Item

Frequently Asked Questions

Q. Do I always have to complete this item?

A. A. This data item should only be completed when <u>option 5</u> (Other) is selected for previous item Regimen outcome summary - Curative (not completed as planned)

Dataset Item details

Data Item Name: REGIMEN OUTCOME SUMMARY - NON CURATIVE

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 36

Format: an1

Schema Specification: Required New Dataset Status: New Item

Frequently Asked Questions

- Q. Do I always have to complete this item?
- A. This data item should only be completed when the regimen is Non Curative
- Q. This item indicates if a patient has derived from some benefit from treatment. Can you give some guidance on the definition of "patient benefit"?
- A. "Patient benefit" should be identified by the judgement of the treating team. This data item is designed to capture regimen outcomes which are consistent across all diseases and tumour groups.

We are unable to provide a list of possible option but our guidance would be:

- offered any advantage to the patient
- Assessment is based on the opinion of the treating clinician

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Data Item Name: REGIMEN OUTCOME SUMMARY - TOXICITY

Description: For full details check the user guide MDCB1533 SACT - User Guide - Page 36

Format: an1

Schema Specification: Pilot New Dataset Status: New Item

Frequently Asked Questions

Q. Do I have to supply this Pilot item?

We are encouraging all trusts to submit this data item if this is possible based on trust systems.

Q. If I am included in the pilot should I complete this item for all patients?

A. This data item should only be completed if a patient's regimen has been modified. In these cases responses should indicate if toxicity played a part in the modification. If a patient's regimen has NOT been modified, this item does not need to be completed.

Examples of modification could include time delay, dose change etc.

The treatment scope of SACT

SACT is designed to capture all systemic anti-cancer therapies that are given with the aim of being 'disease modifying'. By this, we mean systemic therapy that aims to control cancer by killing cancer cells, preventing or reducing or delaying cancer growth, development or metastasis. Consequently, depending on clinical context, this therapy given with the intention of improving survival, delaying further cancer progression or development, improving disease free or progression free survival.

Alongside, we define 'supportive therapies' are those therapies that are commonly, but not exclusively, given alongside disease modifying systemic therapy to improve symptom control/improve quality of life or reduce or prevent treatment-related toxicity.

To better support trusts with submitting their data, and to have a clearer overview of what data should be included in the mandated SACT dataset, we have put together the following draft list of therapies. We are interested in further feedback on the proposed inclusions and exclusions of therapy types.

The following is intended to be a guide only. If you are in doubt then you can still submit /include the items marked as `No - Outside scope`. SACT will exclude certain treatment types from reporting where applicable.

Main Treatments	Include	Exclude	Notes
Standard Chemotherapy	Yes - Within core scope		
Oral	Yes - Within core scope		
Immunotherapy	Yes - Within core scope		
Targeted (inc Biological)	Yes - Within core scope		
Bisphosphonates	Some - Within scope		Only where treatment matches
			main SACT criteria
Bladder Washouts		No - Outside scope	
Surgical Chemotherapy		No - Outside scope	Example: Carmustine Wafers
Endocrine therapy	Yes - Within core scope		
TACE	Yes - Within core scope		
Radioisotope therapy for Cancer		No - Outside scope	Captured by other dataset
CAR (Chimeric Antigen Receptor)	Yes - Within core scope		
T-cell therapy			

Supportive /Other treatments	Include	Exclude	Notes
G-CSF		No - Outside scope	
Steroids	Some - Within scope		Only where treatment matches main SACT criteria
Anti Emetics		No - Outside scope	
Cardioprotective		No - Outside scope	
Erythropoietin (EPO)		No - Outside scope	

Treatment Type	Include	Exclude	Notes
biosimilars	Yes - Within core scope		To allow comparative analysis
			of clinical effectiveness.