Systemic Anti-Cancer Therapy Data Set

User Guidance v.9

Amendment History:

<table>
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<th>Version</th>
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<tr>
<td>0.1</td>
<td>13/05/10</td>
<td>Draft Stage submission</td>
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<td>0.2</td>
<td>14/12/10</td>
<td>Amendments following feedback</td>
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<td>0.3</td>
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<td>Updating of Data Dictionary definitions</td>
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<td>0.4</td>
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<td>Addition of technical guidance section</td>
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<td>0.5</td>
<td>20/04/11</td>
<td>Further amendments and additions</td>
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This version of the guidance incorporates Data Dictionary changes as below.

NHS Connecting for Health

NHS Data Model and Dictionary Service

Reference: Change Request 1158
Version No: 1.0
Subject: Systemic Anti-Cancer Therapy Data Set
Effective Date: 1 April 2012
Reason for Change: Change to Data Standards
Publication Date: 1 July 2011

### Forecast Changes:

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1. Introduction

The Systemic Anti-Cancer Therapy (SACT) Information Standard and phased implementation of national data collection applies to all organisations providing cancer chemotherapy services in or funded by the NHS in England. The standard relates to all cancer patients, both adult and paediatric, in acute inpatient, daycase, outpatient settings and delivery in the community. It covers chemotherapy treatment for all solid tumour and haematological malignancies, including those in clinical trials.

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 i.e. medical and nursing, pharmacy, information, IT and management staff. It is not intended that introduction of the standard should have any direct impact on the delivery of patient care. However, the above groups, which will be involved in the local implementation of the information standard, need to take account of implications of the standard in their work area and develop a strategy to meet its requirements.

1.1 Background

The national collection of all cancer chemotherapy information in the NHS in England will commence in April 2012. This is in line with the requirements of the Department of Health’s policy document Improving Outcomes: A Strategy for Cancer January 2011.

Chemotherapy is now a major part of cancer treatment, with new types of drugs being introduced capable of targeting individual cancers. Historically the recording of chemotherapy has only been held within individual patients’ notes. Despite the considerable costs of cancer chemotherapy, estimated to be in the order of one billion pounds a year, there is currently no comprehensive picture available of the number of patients being treated or details of their care. With the advent of electronic recording of treatment, and in particular electronic prescribing systems, it has now become realistic to commence national collection and analysis of cancer chemotherapy being provided within the NHS. To make this practical, standardisation of the recording of chemotherapy treatment and outcomes is necessary and the SACT Information Standard addresses this requirement.
1.2 Benefits

From April 2012, a staged monthly data collection will be commenced, initially from trusts with e-prescribing systems, though all organisations delivering any chemotherapy for cancer will be expected to provide some information from September 2012. As soon as sufficient data have been quality assured and analysed, initial reports will be issued to contributing providers, leading to a data collection and reporting process from 2013 onwards. Once established, this will be a continuing process and will require careful governance and maintenance.

This is an important new initiative with a wide range of benefits in terms of understanding patterns of clinical management in cancer chemotherapy. This will be very valuable for those providing and commissioning chemotherapy services, ensuring that services are both of high quality and delivered efficiently. Equally importantly, it will support patients and their clinical teams in choosing appropriate care, based on accurate knowledge of current practice and the corresponding benefits and toxicities of treatment. This will, therefore, support patient choice and empowerment in a way that has not previously been possible.

The SACT dataset will also integrate with the other clinical NHS datasets, ultimately enabling the outcome of the complete patient pathway to be understood.

For details of the implementation timetable refer to Appendix 2, pg.63.

1.3 Chemotherapy Intelligence Unit

The national collection of chemotherapy data will be held and analysed by a new Chemotherapy Intelligence Unit, based at the Oxford Cancer Intelligence Unit and responsible to the National Cancer Action Team (NCAT) and the National Cancer Intelligence Network (NCIN). Cancer registries have extensive experience of handling sensitive, confidential information on cancer patients and are bound by Section 251 of the NHS Act 2006.

In order to provide an accurate and complete analysis of clinical practice, the data collected will include information on the patient and their condition, with details of every attendance for chemotherapy. It will also record a summary of the outcome of treatment.

1.4 Clinical Governance

The use of electronic systems to support patient management requires electronic patient identifiable data to be held locally within the provider organisation in order to deliver safe treatment. This is particularly applicable to electronic prescribing systems. It is the responsibility of the provider organisation to inform and obtain the agreement of the patient for the potential secondary uses of the data. Where patients do not consent for their data to be shared, it is the responsibility of the provider organisation to ensure the records of these patients are not included in the data downloads submitted to the Chemotherapy Intelligence Unit.
A process of clinical governance will be maintained by the Chemotherapy Information Group to ensure that any apparent anomalies in clinical activity or practice will be reported back to the provider organisation for investigation and verification before being incorporated into reports.

1.5 Mapping local data to the SACT Information standard

There is no requirement to modify local clinical practices or data recording, however local system managers will be required to map local nomenclature and data formats to that defined in the SACT information standard before transmission. Provider organisations are encouraged to review the content of the standard and consider whether making primary data recording consistent with the standard would benefit their services in terms of safety and efficiency. Examples of this are standardisation of chemotherapy cycle numbering, particularly relevant where patient management is transferred during treatment and the consistent completion of fields summarising the end of treatment.

1.6 Maintenance and updating

Any changes required to improve the functionality and changes required from time to time to ensure that the data standard remains consistent with need, will be co-ordinated through the Chemotherapy Information Group. This group reports to the National Cancer Action Team’s Chemotherapy Implementation Group and the National Cancer Intelligence Network’s Steering Group. Provider organisations are encouraged to submit comments or requests concerning the dataset, its collection and analysis to CIU@sph.nhs.uk for consideration.

Agreed changes or enhancements to the implementation of the data standard will be circulated to all contributors on a regular basis via the Chemotherapy Intelligence Unit.
2. Definitions for the National Systemic Anti-Cancer Therapy Data Set

With the advent of a National Systemic Anti-Cancer Therapy Data Set, it is important that field naming is consistent within hospital systems and the definitions of the fields are unambiguous and applied by all providers.

Where possible, field naming and definitions should either be aligned with those agreed for the Radiotherapy Data Set (ISB 0111) or avoided.

**Definitions**

The term “course” has not been used in the data set. The term is used variably and discussions have highlighted this as a potential risk. The term “regimen” plus the number of cycles has been substituted in the data set. The term programme has been added to mean the whole of a sequence of chemotherapy planned.

The relationships between programmes, regimens, cycles and administration dates are shown in the accompanying graphic and examples of data set structures (pages 9-10).

**Programme:** The key factor in the definition of a programme is that it is a pre-planned sequence of treatment that may include one or more regimens. If the patient’s clinical situation changes, then subsequent treatment constitutes a new programme.

- Where a curative programme is completed successfully but the patient subsequently develops recurrent disease, further treatment will constitute a new programme.

- Where a palliative treatment programme achieves the desired response but the patient subsequently relapses requiring further treatment this will constitute a new programme. *For example, a patient may receive four months of a taxane and is thought to have stable disease and the treatment is stopped. Two months later progressive disease is identified and the patient is started on Capecitabine, this constitutes a new programme.*

- Where a palliative treatment programme fails to achieve the desired response and is discontinued, with the formulation of a new treatment plan, further treatment will constitute a new programme. *For example, where a patient remains continuously on chemotherapy for a prolonged period, having a sequence of palliative regimens each in an attempt to control disease this would constitute a series of programmes, as it was not a planned sequence.*

In the management of the majority of adult solid tumours, the chemotherapy programme and regimen will be the same. Particularly in the management of haematological and paediatric tumours, two or more recognised regimens may be given concurrently or sequentially and constitute a single chemotherapy programme.
Programme number: Programmes will be numbered sequentially and the option to start from any number must be available to allow for prior management not recorded on the current system.

Regimen: Conventionally this term is used to identify a standard or trial group of drugs given in a specific way and may include other instruction concerning the timing and parameters of treatment. The regimen title will be as agreed by the Oncology Regimen Steering Group and this will inform the OPCS Guidance for Clinical Coders.

In the management of the majority of adult solid tumours, the chemotherapy programme and regimen will be the same. Particularly in the management of haematological and paediatric tumours, two or more recognised regimens may be given concurrently or sequentially and constitute a single chemotherapy programme.

Regimen number: Where a patient has two or more regimens of chemotherapy within a programme, for a given cancer, they should be numbered sequentially, irrespective of intent. If two or more regimens commence on the same day, the regimen planned to be completed first should be given the lower number. The option to start from any number must be available to allow for prior management not recorded on the current system. If a patient develops a second cancer, the numbering will start again.

Cycle: Apart from continuous chemotherapy, 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 chemotherapy.

For continuous, normally oral chemotherapy, it will be necessary to agree an arbitrary equivalent. In order to align with the advice of the Oncology Regimen Steering Group, which informs the OPCS Guidance for Clinical Coders, a cycle will be 28 days from first administration.

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.

Administration date: Consistent terminology is required to identify each contact between the patient and the chemotherapy team when chemotherapy is administered. This will cover initial and subsequent contacts and needs to be recorded for inpatient treatment, chemotherapy clinic attendances, attendances in a primary care setting and domiciliary administration by a specialist service. In the case of infusions, the administration date will be the day the infusion was commenced.

For continuous oral chemotherapy, the administration date will be the first day of the nominal cycle i.e. one administration date per 28 days.

Date of final treatment: This is date of commencement of the final cycle (not the date of final administration).

The dataset table is included as appendix 1, pg.63.
2.1 SACT Data Model

The Data Structures are described below.
Dataset structure - example 1

- chemotherapy programme
- regimen
  - cycle
  - etc.

- administration day
- administration day
- bolus injection/infusion commenced/oral component commenced

Dataset structure - example 2

- chemotherapy programme
- regimen 1
  - cycle 1
  - cycle 2
  - cycle 3
- regimen 2
  - cycle 1
  - cycle 2
  - cycle 3

Dataset structure - example 3

- chemotherapy programme
- regimen 1
  - cycle 1
  - cycle 2
  - cycle 3
- etc.
- regimen 2
  - cycle 1
  - cycle 2
  - cycle 3

- admin. day
3. Data Set Field Descriptions

**Data item number and name**
1. NHS number

**SACT description**
As NHS data dictionary

**NHS data dictionary element**
NHS NUMBER

The NHS NUMBER, the primary identifier of a PERSON, is a unique identifier for a PATIENT within the NHS in England and Wales. This will not vary by any ORGANISATION of which a PERSON is a PATIENT.

**Format**
n10

**Relevant code and /or pick list**
Not applicable

**Purpose**
Main identifier and essential for data linkage

**Source**
Hospital PAS

**Comments**
This is a fundamental field in the data set as the prime identifier.

The NHS NUMBER is 10 numeric digits in length. The tenth digit is a check digit used to confirm its validity. The check digit is validated using the Modulus 11 algorithm and the use of this algorithm is mandatory. There are 5 steps in the validation of the check digit:

**Step 1** Multiply each of the first nine digits by a weighting factor as follows:

**Digit Position**
(starting from the left) Factor:

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<tr>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
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Step 2 Add the results of each multiplication together.

Step 3 Divide the total by 11 and establish the remainder.

Step 4 Subtract the remainder from 11 to give the check digit.

If the result is 11 then a check digit of 0 is used. If the result is 10 then the NHS NUMBER is invalid and not used.

Step 5 Check the remainder matches the check digit. If it does not, the NHS NUMBER is invalid.
Data item number and name
2. Date of birth

SACT description
As NHS data dictionary

NHS data dictionary element
PERSON BIRTH DATE

The date on which a PERSON was born or is officially deemed to have been born.

Format
an10 ccyy-mm-dd

Relevant code and /or pick list
Not applicable

Purpose
This is additional identifier. It also allows analysis of provision by age

Source
Hospital PAS

Comments
This is a secondary identifier. It is generally well collected.
Data item number and name
3. Gender – current

SACT description
As NHS data dictionary

NHS data dictionary element
PERSON GENDER CODE CURRENT

A PERSON's gender currently

Format
an1

Relevant code and/or pick list
0 – not known
1 – male
2 – female
9 – not specified

Purpose
To allow analysis by gender

Source
Hospital PAS system

Comments
Sex at birth would be a more fundamental data item but impractical to collect in some situations, therefore current gender has been included.
Data item number and name
4. Ethnicity

SACT description
As NHS data dictionary

NHS data dictionary element
ETHNIC CATEGORY

ETHNIC CATEGORY is the same as attribute ETHNIC CATEGORY CODE. The 16+1 ethnic data categories defined in the 2001 census is the national mandatory standard for the collection and analysis of ethnicity.

Format
an2

Relevant code and/or pick list
ONS 2001 categories 16+1

Purpose
To allow analysis by ethnic category to reveal potential differences in uptake of treatment or types of treatment

Source
Hospital PAS

Comments
This field is not always well recorded and may be recorded differently by different sources. The incidence of some cancers may vary by ethnic group. This may be due to a combination of genetic, cultural and dietary factors.
Data item number and name
5. Patient postcode

SACT description
As NHS data dictionary

NHS data dictionary element
POSTCODE OF USUAL ADDRESS

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.

Format
max an8

Relevant code and/or pick list
Not applicable

Purpose
This is supportive identifier. It allows analysis by commissioner and geographical area, including generation of treatment rates by population. It allows demonstration of patient flows and provider catchments.

Source
Hospital PAS

Comments
This is an important field, since it is the only field that allows analysis by defined populations. The postcode may change during a patient’s management either because the patient moves house or with changes in postcode allocation.
Data item number and name
6. Registered GP practice code

SACT description
As NHS data dictionary

NHS data dictionary element
The GENERAL MEDICAL PRACTICE CODE (PATIENT REGISTRATION) is an ORGANISATION CODE. This is the CODE of the GP practice that the patient is registered with.

Format
an6

Relevant code and/or pick list
NHS list of code and name

Purpose
To inform commissioning and allow analysis of patterns of care by commissioner

Source
Hospital PAS

Comments
The commissioning system is due to change. GP practice code has been included as this is an established code which can be grouped for commissioning purposes.
Data item number and name
7. Consultant GMC code

SACT description
Code of consultant who initiated SACT programme

NHS data dictionary element
CONSULTANT CODE (INITIATED SYSTEMIC ANTI-CANCER THERAPY)

For the Systemic Anti-Cancer Therapy Data Set, this is the CONSULTANT CODE of the CONSULTANT who initiated the Systemic Anti-Cancer Therapy.

Format
an8

Relevant code and/or pick list
General Medical Council, unique number for each registered medical practitioner

Purpose
It allows identification of consultant team and patterns of management provided.

Source
Hospital PAS or entered directly into prescribing system and code derived

Comments
In some specialty areas, several consultants may work as a team but an individual consultant must be identified as the consultant responsible for initiating the programme of chemotherapy.
**Data item number and name**
8. Consultant specialty code

**SACT description**
Specialty code of consultant who initiated SACT programme

**NHS data dictionary element**
CARE PROFESSIONAL MAIN SPECIALTY CODE

For the Systemic Anti-Cancer Therapy Data Set, this is the MAIN SPECIALTY CODE of the CONSULTANT who initiated the Systemic Anti-Cancer Therapy.

A unique code identifying each MAIN SPECIALTY designated by Royal Colleges. This is the same as the OCCUPATION CODES describing specialties. (Can be derived from consultant code).

**Format**
an3

**Relevant code and/or pick list**
HES item MAINSPEF

**Purpose**
Identifies the specialty under which the patient is being managed.

**Source**
Organisation will derive from consultant code

**Comments**
This field can be derived from the consultant code but should be included as it provides an effective categorisation of clinical activity.
**Data item number and name**

9. Organisational code of provider

**SACT description**

As NHS data dictionary

**NHS data dictionary element**

ORANGISATION CODE (CODE OF PROVIDER)

See the "Organisation Default Codes" in the Default Codes Summary Table at [http://www.datadictionary.nhs.uk/web_site_content/supporting_information/organisation_data_service_default_codes.asp?shownav=1](http://www.datadictionary.nhs.uk/web_site_content/supporting_information/organisation_data_service_default_codes.asp?shownav=1).

**Format**

an3 or an5

**Relevant code and /or pick list**

NHS list of provider code and name. Additional lists will be required for non NHS providers, including home care delivery

**Purpose**

To allow analysis of care by provider and benchmarking between providers.

**Source**

Hospital PAS, other provider codes

**Comments**

This is a critical field in the data set as the provider of chemotherapy must be identified. This field shows the provider responsible for **initiating** the programme of chemotherapy.
Data item number and name
10. Primary diagnosis

SACT description
Primary diagnosis at time of decision to treat

NHS data dictionary element
PRIMARY DIAGNOSIS (ICD AT START SYSTEMIC ANTI-CANCER THERAPY)

For the Systemic Anti-Cancer Therapy Data Set, this is the PRIMARY DIAGNOSIS at the start of the Systemic Anti-Cancer Therapy.

Format
an6

Relevant code and/or pick list
ICD-10

Purpose
To allow analysis by tumour site or group of tumour sites

Source
Several possible sources: PAS, prescribing system, MDT, linked pathology system

Comments This field is essential for solid tumours as it defines the anatomical site of the primary tumour. Where a patient has more than one current cancer diagnosis the diagnosis recorded is the one for which treatment is being given.
Data item number and name
11. Morphology

SACT description
Morphology at time of decision to treat

NHS data dictionary element
MORPHOLOGY (ICD-O AT START SYSTEMIC ANTI-CANCER THERAPY)

This is the PATIENT DIAGNOSIS for the cell type of the malignant disease recorded as part of a Cancer Care Spell.

Format
an6

Relevant code and/or pick list
ICD-O3

Purpose
Identification of morphological subgroups of disease, not defined by ICD-10 e.g. varieties of lung cancer and haematological malignancies

Source
Several possible sources: prescribing system, MDT, linked pathology system

Comments
This field is more appropriate for haematological malignancy which is not primarily based on anatomical site. It also gives added information for some solid tumours e.g. lung and testis. Where a patient has more than one current cancer diagnosis the diagnosis recorded is the one for which treatment is being given.
Data item number and name
12. Stage of disease

SACT description
Stage of disease

NHS data dictionary element
TNM CATEGORY (FINAL PRETREATMENT)

This is the CLINICAL CLASSIFICATION CODE which classifies the combination of tumour, node and metastases into stage groupings where the TNM TYPE is 4, Overall TMN stage and the CANCER TNM STAGING TYPE is 1. final pre-treatment stage.

Format
an5

Relevant code and /or pick list
TNM code. For colorectal and gynaecological tumours Duke’s and Figo staging classification will also be accepted.

Purpose
To allow analysis by stage of disease. Early stage disease will have better outcomes than more advanced disease.

Source
MDT

Comments
This is currently not well recorded in electronic systems but is the basis on which the treatment decision is based and therefore should be recorded. The stage to be recorded is ideally the stage at the decision to treat for the current treatment. The final pre-treatment stage recorded at the patient’s initial treatment may be the only stage information available and this should then be used.
Data item number and name
13. SACT Programme number

SACT Description
Programmes of chemotherapy are numbered according to their chronological order of commencement in the patient’s disease management.

NHS data dictionary element
SYSTEMIC ANTI-CANCER THERAPY PROGRAMME NUMBER
The number of the Systemic Anti-Cancer Therapy Programme.
The SYSTEMIC ANTI-CANCER THERAPY PROGRAMME NUMBER is allocated locally.
Systemic Anti-Cancer Therapy Programmes are numbered according to their chronological order of commencement in the PATIENT’s disease management.

Format
max n2

Relevant code and/or pick list
not applicable

Purpose
To facilitate sequential analysis of patient care

Source
E-prescribing system, local recording, MDT

Comments
In the terminology of the SACT data standard, the programme is the pre-planned sequence of treatment which may include one or more regimens. Please refer to the definitions section. For example, if the patient’s clinical situation changes e.g. from curative to palliative treatment, this would require the commencement of a new programme. Programmes will be numbered sequentially and the option to start from any number must be available to allow for prior management not recorded on the current system. If programme number is not available locally, it will be derived via an algorithm in the SACT data repository.
Data item number and name
14. Regimen number

SACT description
Regimens are numbered according to their chronological order of commencement in the patient’s treatment programme.

NHS data dictionary element
ANTI-CANCER REGIMEN NUMBER

The number of the Anti-Cancer Drug Regimen, for example, Systemic Anti-Cancer Therapy Regimen.

Anti-Cancer Drug Regimens are numbered according to their chronological order of commencement in the treatment programme.

Format
max n2

Relevant code and /or pick list
not applicable

Purpose
To facilitate sequential analysis of patient care

Source
E-prescribing system, local recording, MDT

Comments
Regimens will be numbered sequentially and the option to start from any number must be available to allow for prior management not recorded on the current system. If two regimens within a programme start concurrently, the one due to finish first should be given the lower number.
Data item number and name
15. Intent of treatment

SACT description
Intent of SACT regimen

NHS data dictionary element
DRUG TREATMENT INTENT

A classification of the overall aim of the anti-cancer drug programme.

Format
an1

Relevant code and /or pick list
National codes as below

Purpose
To allow analysis by treatment intent

Source
E-prescribing system, MDT

Comments The list of options for intent has been limited to the four options already included in the data dictionary.

National Codes:
References:
National Cancer Dataset Version 1.3_ISB October 2002
A Adjuvant
N Neo-adjuvant
C Curative
P Palliative
Data item number and name
16. Regimen

SACT description
As NHS data dictionary

NHS data dictionary element
DRUG REGIMEN ACRONYM

The acronym derived from the drugs used in the Anti-Cancer Drug Regimen used to identify the drugs used in the regimen

Format
max an35

NOTE: Non-alphanumeric characters dash – and round brackets () are allowed as these may exist in regimen names. This field is not case-sensitive.

Relevant code and/or pick list
OPCS Classification of Interventions and Procedures version 4.6 and to be consistent with the National Chemotherapy Regimen List (when established)

NOTE: The local acronym may be submitted only where the regimen is currently not included in the OPCS classification or the National Chemotherapy Regimen List (when established).

Purpose
To allow analysis by individual regimen or drug

Source
E-prescribing system or local records

Comments
Connecting for Health in collaboration with the National Cancer Action Team (NCAT) is developing a National Regimen List. A name and number will be allocated for each new regimen. There will be a process through which new and significantly different chemotherapy regimens will be managed. The list will be continually updated by the NCAT lead pharmacist, working with cancer network lead pharmacists and regular updates will be issued via TRUD and published in OPCS Guidance for Clinical Coders. It is planned that there will be an annual main list with 2 or 3 supplementary lists as required during the year.
Data item number and name
17. Height at start of regimen

SACT description
Height in metres at start of SACT regimen

NHS data dictionary element
PERSON HEIGHT IN METRES
A PERSON'S height in metres

Format
n1.max n2

Relevant code and/or pick list
Not applicable

Purpose
To confirm appropriate dose of chemotherapy and dose by metre²

Source
E-prescribing system

Comments
This field is applicable where a drug dose is being calculated on the basis of a patient's height and weight.
Data item number and name
18. Weight at start of regimen

SACT description
Weight in kilogrammes at start of SACT regimen

NHS data dictionary element
PERSON WEIGHT

A PERSON'S weight in kilogrammes

Format
max n3.max n3

Relevant code and/or pick list
Not applicable

Purpose
To confirm appropriate dose of chemotherapy and dose by metre$^2$

Source
E- prescribing system

Comments
This field is applicable where a drug dose is being calculated on the basis of a patient's height and weight.
Data item number and name
19. Performance status at start of regimen

SACT description
A person’s status relating to activity / disability at start of SACT regimen

NHS data dictionary element
PERFORMANCE STATUS FOR ADULTS
PERFORMANCE STATUS CODE FOR YOUNG PERSON

A World Health Organisation classification indicating a PERSON's status relating to activity / disability

The Lansky Play - Performance Scale indicating a young PERSON's status relating to activity / disability. This scale is used for young PERSONS aged 16 years and under.

Format
an1 or an2

Relevant code and/or pick list
WHO categories 0-4: Lansky for children categories 0-100

Purpose
To allow for casemix adjusted analysis. Patients with poor performance status are less likely to tolerate or complete rigorous treatment.

Source
MDT

Comments
WHO categories 1-4 are a match to the ECOG categories and should be used for adults (above 16 years). For birth to 16 years the Lansky scale should be used.
Data item number and name
20. Co-morbidity adjustment

SACT description
Whether or not patient’s overall physical state (other diseases and conditions) was a significant factor in deciding on regimen, or in varying the dose or treatment interval from the start of treatment

NHS data dictionary element
CO-MORBIDITY ADJUSTMENT INDICATOR

An indication of whether a PATIENT’s overall physical state (i.e. other diseases and conditions) was a significant factor in deciding on the type, dose or scheduling of Anti-Cancer Drug Regimen, for example a Systemic Anti-Cancer Therapy Regimen.

Format
an1

Relevant code and /or pick list
Y/N

Purpose
To allow for casemix adjusted analysis. Patients with co-morbidity are less likely to tolerate or complete rigorous treatment.

Source
MDT

Comments
This differs from the full co-morbidity analysis likely to be incorporated in the Clinical Outcomes and Services Data Standard. The field in the SACT data set records whether the chemotherapy treatment chosen has been modified because of the patient’s overall clinical condition. This includes treatment with an alternative regimen, or varying the dose or treatment interval from the start of treatment.
Data item number and name
21. Date decision to treat

SACT description
As NHS data dictionary

NHS data dictionary element
DECISION TO TREAT DATE (ANTI-CANCER DRUG REGIMEN)

The date on which it was decided that the PATIENT required a specific Planned Cancer Treatment.

This is the date that the consultation between the PATIENT and the clinician took place and a Planned Cancer Treatment was agreed.

Format
an10 ccyy-mm-dd

Relevant code and /or pick list
not applicable

Purpose
To allow analysis of wait before start of treatment

Source
GFoCW

Comments
This data field may also be filled from a local system.
Data item number and name
22. Start date of regimen

SACT description
This is the first administration date of the first cycle of a regimen

NHS data dictionary element
START DATE ANTI-CANCER DRUG REGIMEN

Format
an10 ccyy-mm-dd

Relevant code and/or pick list
not applicable

Purpose
To allow analysis by time period

Source
E-prescribing system and GFoCW

Comments
In practice this will be the same date as the start date of the first cycle in a regimen. It is the date of the first administration of chemotherapy.
**Data item number and name**
23. Clinical trial

**SACT description**
As NHS data dictionary

**NHS data dictionary element**
CLINICAL TRIAL INDICATOR

For the SYSTEMIC ANTI-CANCER THERAPY PROGRAMME NUMBER, this identifies if a PATIENT's Chemotherapy treatment is within a CLINICAL TRIAL.

**Format**
an2

**Relevant code and/or pick list**
Y/N

**Purpose**
To identify chemotherapy given within clinical trials

**Source**
E-prescribing system or local records

**Comments**
This field is simply to indicate whether a regimen is within a clinical trial which would not be clear otherwise, if it was the standard arm of the trial.
Data item number and name
24. Chemo-radiation

SACT description
This field identifies regimens which are given as part of a combined treatment with radiation.

NHS data dictionary element
CHEMO-RADIATION INDICATOR
An indication of whether a regimen, such as a Systemic Anti-Cancer Therapy Regimen, is given as part of a combined treatment with radiation.

Format
an1

Relevant code and/or pick list
Y/N

Purpose
To identify use of chemo-radiation only used where this is a recognised treatment regimen

Source
E-prescribing system or local records

Comments
This field is used to record if a regimen is part of a recognised combined treatment, the radiotherapy and chemotherapy may be concurrent or sequential. The regimen name may indicate that it is a combined treatment.
Data item number and name
25. Number of cycles planned

SACT description
The number of cycles specified in the prescription. This may be the number of cycles in the standard regimen or be modified by the prescriber.

NHS data dictionary element
NUMBER OF SYSTEMIC ANTI-CANCER THERAPY CYCLES PLANNED

The number of Systemic Anti-Cancer Therapy Cycles specified in the CHEMOTHERAPY PRESCRIPTION.

This may be the number of Systemic Anti-Cancer Therapy Cycles in the standard Systemic Anti-Cancer Therapy Regimen or be modified by the prescriber.

Format
max n2

Relevant code and /or pick list
Not applicable

Purpose
To allow comparison with number of cycles actually given.

Source
E-prescribing system or local records

Comments
Many regimens are prescribed with a stated number of cycles; this may be specified in a protocol but may be varied by the prescriber. Some prescriptions will not have a fixed number prescribed at the outset; this is particularly the case with some palliative treatments.
Data item number and name
26. Cycle number

SACT description
Cycles numbered sequentially within each regimen

NHS data dictionary element
ANTI-CANCER DRUG CYCLE IDENTIFIER

A unique identifier for an Anti-Cancer Drug Cycle within an Anti-Cancer Drug Regimen.

Anti-Cancer Drug Cycle is a CLINICAL INTERVENTION where the CLINICAL INTERVENTION TYPE is National Code 02 'Anti-Cancer Drug Cycle'.

Format
max n2

Relevant code and/or pick list
Not applicable

Purpose
Indicates a patient’s progress through the regimen and to support analysis between years

Source
E-prescribing system

Comments
Cycles 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.
**Data item number and name**
27. Start date of cycle

**SACT description**
Date of first drug administration in each cycle

**NHS data dictionary element**
START DATE (SYSTEMIC ANTI-CANCER DRUG CYCLE)

The date of the first drug administration in each Systemic Anti-Cancer Therapy Cycle.

**Format**
an10 ccyy-mm-dd

**Relevant code and /or pick list**
Not applicable

**Purpose**
To identify treatment patterns and to support analysis between years.

**Source**
E-prescribing and local records

**Comments**
No additional comment
**Data item number and name**
28. Weight at start of cycle

**SACT description**
A PERSON’S weight in kilogrammes at start of cycle

**NHS data dictionary element**
PERSON WEIGHT

A PERSON’S weight in kilogrammes

**Format**
max n3.max n3

**Relevant code and/or pick list**
Not applicable

**Purpose**
Where relevant to confirm appropriate dose of chemotherapy

**Source**
E- prescribing system

**Comments**
This is only relevant where weight change during a regimen triggers a change in drug dosage.
**Data item number and name**
29. Performance status at start of cycle

**SACT description**
A person’s status relating to activity / disability at start of cycle

**NHS data dictionary element**
PERFORMANCE STATUS FOR ADULTS
PERFORMANCE STATUS CODE FOR YOUNG PERSON

A World Health Organisation classification indicating a PERSON’s status relating to activity / disability

The Lansky Play - Performance Scale indicating a young PERSON’s status relating to activity / disability. This scale is used for young PERSONS aged 16 years and under.

**Format**
an1 or an2

**Relevant code and /or pick list**
WHO categories 0-4: Lansky for children categories 0-100

**Purpose**
To assess the patient’s suitability for further treatment.

**Source**
E-prescribing system

**Comments**
WHO categories 1-4 are a match to the ECOG categories and should be used for adults (above 16 years). For birth to 16 years the Lansky scale should be used. This field is only relevant in some patients where the performance status changes during the chemotherapy treatment.
Data item number and name
30. OPCS procurement code

SACT description
As NHS data dictionary

NHS data dictionary element
PRIMARY PROCEDURE (OPCS)

OPCS-4 code of an OPERATIVE PROCEDURE

Format
an4

Relevant code and/or pick list
OPCS 4.6

Purpose
To allow analysis by cost group

Source
Payment by Results (PbR) – local systems or e-prescribing system

Comments
No additional comment
**Data item number and name**
31. Drug name (this is repeated for each anti-cancer drug in the regimen)

**SACT description**
BNF or trial name

**NHS data dictionary element**
SYSTEMIC ANTI-CANCER DRUG NAME

The name of the Systemic Anti-Cancer Therapy drug given to a PATIENT during an Anti-Cancer Drug Regimen. The name is taken from British National Formulary chapter 8.

**Format**
max an35

**Relevant code and/or pick list**
BNF, VTM list

**Purpose**
To identify drug usage

**Source**
E-prescribing system or local record

**Comments**
This is the approved name in the BNF. This is equivalent to the VTM name in SNOMED. Drug names may be held as code within e-prescribing systems.
Data item number and name
32. Actual dose per administration

SACT description
Dose in mg or other applicable unit for each administration in a SACT cycle.

NHS data dictionary element
CHEMOTHERAPY ACTUAL DOSE
The actual Chemotherapy dose given in milligrams or other applicable unit for each administration in a Systemic Anti-Cancer Therapy Cycle.

Format
max n7

Relevant code and/or pick list
Not applicable

Purpose
To allow cumulative analysis of drug use by patient and global analysis

Source
E-prescribing system

Comments
This will normally be in milligrams but a small number of drugs may be prescribed using other units. This is the daily dose for oral regimens.
Data item number and name
33. SACT Administration route

SACT description
The prescribed method of delivery for each administration in a SACT cycle

NHS data dictionary element
SYSTEMIC ANTI-CANCER THERAPY DRUG ROUTE OF ADMINISTRATION

The prescribed method of delivery for each administration in a Systemic Anti-Cancer Therapy Cycle.

Format
an2

Relevant code and /or pick list
National codes should be used for this data but the SNOMED preferred term has been matched to this along with the corresponding SNOMED code to facilitate future change to SNOMED CT coding.

<table>
<thead>
<tr>
<th>National Codes</th>
<th>Routes of administration</th>
<th>Definition</th>
<th>SNOMED Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Topical</td>
<td>Administration of a medicinal product to the skin and/or cutaneous wounds and/or nails and/or hair in order to obtain a local effect.</td>
<td>6064005</td>
</tr>
<tr>
<td></td>
<td>Cutaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>06</td>
<td>Intraarterial</td>
<td>Injection of a medicinal product into an artery.</td>
<td>58100008</td>
</tr>
<tr>
<td>12</td>
<td>Intradermal</td>
<td>Injection of a medicinal product into the dermis.</td>
<td>372464004</td>
</tr>
<tr>
<td>10</td>
<td>Intratumour Intraleisional</td>
<td>Administration by injection or any other means of a medicinal product directly to a lesion.</td>
<td>372466002</td>
</tr>
<tr>
<td>04</td>
<td>Intramuscular</td>
<td>Injection of a medicinal product into muscular tissue.</td>
<td>78421000</td>
</tr>
<tr>
<td>07</td>
<td>Intraperitoneal</td>
<td>Injection of a medicinal product into the peritoneal cavity.</td>
<td>38239002</td>
</tr>
<tr>
<td>03</td>
<td>Intrathecal</td>
<td>Injection of a medicinal product through the dura to the subarachnoid cavity.</td>
<td>72607000</td>
</tr>
<tr>
<td>01</td>
<td>Intravenous</td>
<td>Injection of a medicinal product into a vein.</td>
<td>47625008</td>
</tr>
<tr>
<td>09</td>
<td>Intra-Vesicular Intravesical</td>
<td>Administration of a medicinal product to the urinary bladder.</td>
<td>372471009</td>
</tr>
<tr>
<td>02</td>
<td>Oral</td>
<td>Taking a medicinal product by means of swallowing.</td>
<td>26643006</td>
</tr>
<tr>
<td>05</td>
<td>Subcutaneous</td>
<td>Injection of a medicinal product directly underneath the skin.</td>
<td>34206005</td>
</tr>
</tbody>
</table>

Purpose
To allow analysis by route of administration and identify critical areas e.g. intrathecal chemotherapy

Source
E-prescribing system or local record

Comments
The list above is the list currently agreed by the Chemotherapy Information Group
Data item number and name
34. Administration date

SACT Description
The date on which the anti-cancer drug was administered to a patient, an infusion commenced, or an oral drug initially dispensed to the patient

NHS data dictionary element
SYSTEMIC ANTI-CANCER THERAPY ADMINISTRATION DATE

The date on which the Systemic Anti-Cancer Therapy drug was administered to a PATIENT, an infusion commenced, or an oral drug was initially dispensed to the PATIENT.

Format
an10 ccyy-mm-dd

Relevant code and/or pick list
Not applicable

Purpose
Defines the date of actual administration.

Source
E-prescribing system

Comments
No additional comment
Data item number and name
35. Organisational code of provider (for each administration)

SACT description
Code of provider for each administration in a SACT cycle

NHS data dictionary element
ORANGISATION CODE (CODE OF PROVIDER)

See the "Organisation Default Codes" in the Default Codes Summary Table at http://www.datadictionary.nhs.uk/web_site_content/supporting_information/organisation_data_service_default_codes.asp?shownav=1.

Format
an3 or an5

Relevant code and /or pick list
NHS list of provider code and name. Additional lists will be required for non NHS providers, including home care delivery

Purpose
To allow analysis of care by provider and benchmarking between providers

Source
Hospital PAS, other provider codes

Comments
This is a critical field in the data set as the provider of chemotherapy must be identified. Patients may move between providers during their chemotherapy treatment.
Data item number and name
36. OPCS delivery code

SACT description
Delivery code for each administration

NHS data dictionary element
PRIMARY PROCEDURE (OPCS)

OPCS-4 code of an OPERATIVE PROCEDURE

Format
an4

Relevant code and/or pick list
OPCS 4.6

Purpose
To allow analysis by cost group

Source
Payment by Results (PbR) – local systems or e-prescribing system

Comments
No further comment
Data item number and name
37. Date of final treatment

SACT Description
The date of the start of the final cycle of SACT treatment within a regimen

NHS data dictionary element
START DATE (FINAL SYSTEMIC ANTI-CANCER THERAPY)

The Start Date of the final cycle of Systemic Anti-Cancer Therapy within a Systemic Anti-Cancer Therapy Regimen. This is the End Date of the Systemic Anti-Cancer Therapy treatment.

Format
an10 ccyy-mm-dd

Relevant code and /or pick list
Not applicable

Purpose
To register the completion or stopping of a regimen.

Source
E-prescribing system or local records

Comments
This has been made consistent with the definition in the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report 2008 www.ncepod.org.uk. It is the most practical date to record.
Data item number and name
38. Regimen modification – dose reduction

SACT Description
Identifies if a regimen was modified by reducing the dose of any anti-cancer drug administered at any point in the regimen after commencement of the regimen.

NHS data dictionary element
SYSTEMIC ANTI-CANCER THERAPY REGIMEN MODIFICATION INDICATOR (DOSE REDUCTION)
An indication of whether a Systemic Anti-Cancer Therapy Regimen was modified by reducing the dose administered.

Format
an1

Relevant code and/or pick list
Y/N

Purpose
To allow a measurement of regimen toxicity

Source
E-prescribing system or local record

Comments
This field may also be generated automatically and is one of three fields recording changes in the regimen.
Data item number and name
39. Regimen modification – time delay

SACT Description
Identifies if a regimen was modified by extending the time between administration dates at any point in the regimen after commencement of the regimen.

NHS data dictionary element
SYSTEMIC ANTI-CANCER THERAPY REGIMEN MODIFICATION INDICATOR (TIME DELAY)

An indication of whether a Systemic Anti-Cancer Therapy Regimen was modified by extending the time between Systemic Anti-Cancer Therapy Administration Dates. *Note: Time delays of 5 days or fewer are discounted to allow for bank holidays or other incidental interruptions not related to drug tolerance.*

Format
an1

Relevant code and/or pick list
Y/N

Purpose
To allow a measurement of regimen toxicity

Source
E-prescribing system or local record

Comments
This field may also be generated automatically and is one of three fields recording changes in the regimen. Time delays in any cycle of 5 days or fewer should be discounted to allow for bank holidays or other incidental interruptions not related to drug tolerance.
Data item number and name
40. Regimen modification – stopped early

SACT Description
Identifies if a regimen was modified by reducing the administration days below the number planned.

NHS data dictionary element
SYSTEMIC ANTI-CANCER THERAPY REGIMEN MODIFICATION INDICATOR (DAYS REDUCED)

An indication of whether a Systemic Anti-Cancer Therapy Regimen was modified by reducing the administration days below the number planned.

Note: This is only applicable where a fixed number of cycles were specified at the start of treatment.

Format
an1

Relevant code and/or pick list
Y/N

Purpose
To allow a measurement of regimen toxicity

Source
E-prescribing system or local record

Comments
This field is one of three fields recording changes in the regimen. It is only applicable where a fixed number of cycles were specified at the start of treatment.
Data item number and name
41. Regimen outcome summary

SACT description
To record the immediate outcome of the treatment

NHS data dictionary element
PLANNED TREATMENT CHANGE REASON

An indicator of whether the treatment within an Anti-Cancer Drug Programme was completed as planned, and if not, the reason why.

Format
an1

Relevant code and /or pick list
National Codes:
0 Treatment completed as prescribed

Treatment not completed
1 PATIENT died
2 Progressive disease during chemotherapy
3 Acute chemotherapy toxicity
4 Technical or organisational problems
5 PATIENT choice (stopped or interrupted treatment)

Purpose
To allow outcome analysis

Source
E-prescribing system or local records

Comments
This is a fundamental field required by the National Chemotherapy Advisory Group (NCAG) Report August 2009 “Chemotherapy Services in England: Ensuring Quality and Safety” www.ncat.nhs.uk. Although this field is available in e-prescribing systems, there is frequently a failure to complete the field.
Data item number and name
42. Date of death

SACT description
As NHS data dictionary description

NHS data dictionary element
PERSON DEATH DATE

The date on which a PERSON died or is officially deemed to have died.

Format
an10 ccyy-mm-dd

Relevant code and /or pick list
Not applicable

Purpose
To estimate 30-day mortality or analyse survival after chemotherapy

Source
ONS

Comments
This field will only be filled directly if a patient dies in hospital or the hospital is informed by the GP. Otherwise the field will be filled retrospectively from ONS data.
4. Technical Guidance for data extraction and submission

Use of XML for Chemotherapy Data Transmission

The NHS will move towards XML as a standard for data transmission in the future and the SACT data set and systems using it will need to be able to make this transition. The Chemotherapy Intelligence Unit (CIU) will be able to handle both CSV files and XML data in parallel from the outset but initially it is anticipated that the vast majority of returns will be in CSV format.

XML data can be imported easily into the existing database structure though cost and timescales for suppliers being able to output XML are likely to vary considerably. The system will therefore be able to handle both CSV and XML files in parallel for some time.

An XML schema will be published as part of the development of the SACT data set application and is expected to be ready in October 2011.

Timescales
XML schema tested between pilot Site (Addenbrookes) and CIU database September 2011
XML schema published October 2011
Suppliers to confirm SACT XML is available December 2011: dependency that some suppliers may need to plan this in to their development schedules.

CIU ready to receive XML files and Guidance available February 2012.
CSV file format no longer accepted 1st April 2014

Data extraction in CSV format

Data files will be required to be submitted monthly, within 7 working weeks of the end of the calendar month, e.g. submissions of April 2012 chemotherapy data (01/04/2012 - 30/04/2012) to be uploaded to CIU by 15th June 2012. It is anticipated that a realistic timetable for monthly data submissions would be around the 15th of each calendar month. The CIU will provide an annual timetable for data submissions to all providers which will contain exact dates, once the data set becomes mandated from 1st April 2012.

Data will be extracted from electronic prescribing and other electronic systems by system software suppliers working with local IT staff in constructing extraction routines.
The database import process requires files to be in a consistent format as outlined below:

Extracted data files should be a single Comma Separated Values (CSV) only, with a .csv file extension. A CSV file template will be available from the Chemotherapy Intelligence Unit (CIU) for data suppliers and software system developers. Note that CSV files must be of the windows type rather than Unix, with carriage returns at the end of each line as well as linefeeds.

None of the data required is case sensitive.

CSV files should be saved with a text delimiter set to the double-quote character in order to allow the use of commas in data values.

The first row of the CSV file should consist of the Column Headers with the column names in exactly the format shown (i.e. including underscore characters). CSV files should not be compressed or packaged in any way.

CSV files should contain only, and all of, the following column headers in the following order, regardless of the data items that can be supplied. The mapping to data set items is shown by the Column Number.

<table>
<thead>
<tr>
<th>Column Header</th>
<th>Column Number/data set Item number</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS_number</td>
<td>1</td>
</tr>
<tr>
<td>Date_of_birth</td>
<td>2</td>
</tr>
<tr>
<td>Gender_current</td>
<td>3</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>4</td>
</tr>
<tr>
<td>Patient_postcode</td>
<td>5</td>
</tr>
<tr>
<td>Registered_GP_Practice_Code</td>
<td>6</td>
</tr>
<tr>
<td>Consultant_GMC_code</td>
<td>7</td>
</tr>
<tr>
<td>Consultant_speciality_code</td>
<td>8</td>
</tr>
<tr>
<td>Organisational_code_of_provider</td>
<td>9</td>
</tr>
<tr>
<td>Primary_diagnosis</td>
<td>10</td>
</tr>
<tr>
<td>Morphology</td>
<td>11</td>
</tr>
<tr>
<td>Stage_of_disease</td>
<td>12</td>
</tr>
<tr>
<td>Programme_number</td>
<td>13</td>
</tr>
<tr>
<td>Regimen_number</td>
<td>14</td>
</tr>
<tr>
<td>Intent_of_treatment</td>
<td>15</td>
</tr>
<tr>
<td>Regimen</td>
<td>16</td>
</tr>
<tr>
<td>Height_at_start_of_regimen</td>
<td>17</td>
</tr>
<tr>
<td>Weight_at_start_of_regimen</td>
<td>18</td>
</tr>
<tr>
<td>Performance_status_at_start_of_regimen</td>
<td>19</td>
</tr>
<tr>
<td>Comorbidity_adjustment</td>
<td>20</td>
</tr>
<tr>
<td>Date_decision_to_treat</td>
<td>21</td>
</tr>
</tbody>
</table>
File submission via the Chemotherapy Intelligence Unit (CIU) web portal
When a CSV file is ready for submission to the national database, staff at the treatment supplier will connect to the CIU chemotherapy web portal using one of Internet Explorer version 6.0 or higher or Firefox version 2.0 or higher.

The URL for the web portal is https://www.chemodataset.nhs.uk. Note this will be live by September 2011.

The portal requires each registered user to agree to the site’s terms and conditions (which will be drafted by the CIU). User logins are held within the repository database along with encrypted passwords for authentication.

Once users have logged in to the portal they will be presented with links to a choice of pages:

- Upload data page
- Validation and data quality reports pages
- User support pages and contact details

Data submission and file naming
The following file naming convention is to be used for submissions:

```
UnitID-yyyyymmdd-yyyyymmdd.CSV
```
Where UnitID is an agreed unique identifier for the supplying chemotherapy provider and matches the user login’s unit code and yyyymmdd is the start date of the data (date of earliest treatment) followed by the end date (date of final treatment).

The name of the file will be created by the user on the web site during the submission process regardless of what the file is called locally on the treatment provider’s computers.

Date picker controls will allow the user to select the date range of the file’s data based on drug administration dates. The unit’s unique identifier will be taken from the user’s login credentials held in the database. The web portal will then display the proposed filename for user approval preventing user errors in file naming. Upload instructions will be available on this page for users.

Files are transferred using the secure web based HTTPS/SSL encrypted protocol, which is used on a daily basis for online shopping, online banking, etc. No extra action is required at the data suppliers end to establish this apart from being on an N3 network connection.

**File Validation and Data Quality Reports**

Files submitted are processed one at a time. The web portal should be able to provide validation results for any uploaded file within one hour of submission. This will be via a report generated for the data supplier on the web portal using logged validation data from the database.

File validation reports will be available for each file uploaded by the treatment supplier. Users will only be able to view reports related to their own data. Each report should display the following information for each file uploaded and processed:

<table>
<thead>
<tr>
<th>Column name</th>
<th>Description of column</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filename</td>
<td>The name of the file that has been validated/uploaded</td>
</tr>
<tr>
<td>Uploaded By</td>
<td>The portal username who uploaded the file</td>
</tr>
<tr>
<td>Date range</td>
<td>The date and time of the extract.</td>
</tr>
<tr>
<td>Date uploaded</td>
<td>The date and time that the file was uploaded</td>
</tr>
<tr>
<td>Total Records</td>
<td>The count of non-blank records in the file</td>
</tr>
<tr>
<td>Valid</td>
<td>The count of successfully validated records in the file</td>
</tr>
<tr>
<td>Invalid</td>
<td>The count of invalid records in the file</td>
</tr>
<tr>
<td>Load%</td>
<td>The percentage of records loaded (i.e. valid records divided by number of records)</td>
</tr>
<tr>
<td>DQ%</td>
<td>The data quality percentage (i.e. number of records with no errors or warnings divided by number of records)</td>
</tr>
<tr>
<td>Error counts</td>
<td>Error counts by rule</td>
</tr>
<tr>
<td>Warning counts</td>
<td>Warning counts by rule</td>
</tr>
<tr>
<td>Informational errors</td>
<td>Informational error counts by rule</td>
</tr>
<tr>
<td>File Status</td>
<td>The current status of file – validated, rejected or loaded</td>
</tr>
</tbody>
</table>
Note that if the file fails validation of mandatory fields above a certain threshold it will be rejected and therefore not reach the data quality checks. Therefore the warning and informational counts will be empty.
Chemotherapy Data monthly activity

<table>
<thead>
<tr>
<th>1&lt;sup&gt;st&lt;/sup&gt; – 15&lt;sup&gt;th&lt;/sup&gt;</th>
<th>16&lt;sup&gt;th&lt;/sup&gt; – 20&lt;sup&gt;th&lt;/sup&gt;</th>
<th>21&lt;sup&gt;st&lt;/sup&gt; – 30&lt;sup&gt;th&lt;/sup&gt;</th>
<th>30 days after QA reports publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checking and submission of data</td>
<td>Data quality snapshot</td>
<td>Clinical QA</td>
<td>Website reporting</td>
</tr>
<tr>
<td>Check data against business rules</td>
<td>Data quality report to sites</td>
<td>CLINICAL QA Clinical Oncologist / Oncology Pharmacist</td>
<td>Clinical quality reports &amp; feedback to sites</td>
</tr>
<tr>
<td>Submission 100% correct?</td>
<td>DATA QUALITY - Completeness - De-duplication - Rationalisation - Sequence</td>
<td>- Regimen review and input - Prescription review and input</td>
<td>Website reporting</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Do anomalies exist?</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>Load good data</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Do anomalies exist?</td>
<td>No</td>
</tr>
<tr>
<td>Is data 80% compliant?</td>
<td>Yes</td>
<td>Review / update / refer</td>
<td>Review / update / refer</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Is data 80% correct?</td>
<td>Is data 80% correct?</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>Retain bad data for correction</td>
<td>Retain bad data for correction</td>
</tr>
<tr>
<td>Correct bad data by 15&lt;sup&gt;th&lt;/sup&gt; of the month</td>
<td>No</td>
<td>Data quality report to sites</td>
<td>Clinical quality report to sites</td>
</tr>
<tr>
<td>Remaining incorrect data to be corrected by following month’s submission</td>
<td>Yes</td>
<td>Data quality report to sites</td>
<td>Clinical quality report to sites</td>
</tr>
</tbody>
</table>

Recommended initial threshold, subject to review based on data quality issues encountered between April 2011 and April 2012. The threshold will increase over time.

CHEMOTHERAPY INTELLIGENCE UNIT (CIU) HELP DESK AND SUPPORT
Clinical quality report to sites
Chemotherapy data monthly activity

Continuous help desk support will be provided by the Chemotherapy Intelligence Unit (CIU). Note the footnote above anticipates, based on the SACT pilot, that as suppliers become more familiar with their monthly SACT data quality submission issues their success rate in having their monthly submission accepted first time (Submission 100% correct) will increase.

- **1st to 15th day of the month**
  
  o **Objectives** –
    
    - To test the data against the agreed business rules and ensure that mandatory fields are completed.
    - To ensure that data in all fields satisfies the required format and size.
    - Where requirements are satisfied to submit the data through the secure portal for data quality assurance.

  o **Testing data against business rules** –
    
    - Where the data tested is 100% correct it may be submitted through the secure portal.
    - Where at least 80%¹ of the data satisfies the business rules, the correct data may be submitted through the portal. The remaining data is retained for correction.
    - Where less than 80%¹ of the data satisfies the business rules, all of the data is retained for correction.
    - Sites should aim to correct bad data by the 15th day of the month to be able to submit data through the secure portal.
    - Where incorrect data remains, the data should be corrected in time for the following month’s submission.

- **16th to 20th day of the month**
  
  o **Objectives** –
    
    - To ensure that the data submitted satisfies completeness and sequential requirements.
    - Where necessary rationalise and remove duplicate records.
    - To submit the qualified data for clinical quality assurance.

  o **Data quality process** –

¹ Assuming a successful pilot project.
- Where the data which has been quality assured is 100% correct it may be submitted through for clinical QA and a data quality report sent to the site.
- Where anomalies exist, the data is to be reviewed and updated. This will include the correction of obvious errors, rationalisation of data and de-duplication.
- A data quality report will be returned to the site highlighting any changes.
- Where the data is at least 80% correct, the correct data may be submitted for clinical QA. The remaining data is retained for correction by the site.
- Where less than 80% of the data is correct, the data is retained for correction by the site.
- A data quality report is generated and sent to the site.
- The incorrect data is returned to the site for correction in time for the following month’s submission.

21st to 30th day of the month

- Objectives –
  - The quality assurance of all submissions for the regimen and prescription against diagnosis.
  - A review of all data by Clinical Oncologist and Oncology Pharmacist.
  - Generation and provision of clinical QA reports to all sites.
  - Submission of data for analysis and report generation.

- Clinical quality assurance process –
  - Where no anomalies exist the data is forwarded for analysis and the generation of the CIU reports.
  - Feedback reports on clinical quality generated and sent to sites
  - Where anomalies exist the data is reviewed by the Clinical Oncologist and Oncology Pharmacist through an iterative approach involving the treatment site where necessary.
  - If at least 80% of the data is correct, the correct data may be submitted for analysis and report generation.
  - Incorrect data is retained for correction and referred back to the treatment site for correction in time for the following month’s submission.
Appendix 1: Systemic Anti-Cancer Therapy Dataset

The Mandatory, Required or Optional (M/R/O) column indicates the recommendation for the inclusion of data.
M = Mandatory: this data element is mandatory; the message will be rejected if this data element is absent
R = Required: data is required as part of NHS business rules and must be included where available or applicable
O = Optional: the flow of this data is optional. It should be included at the discretion of the submitting organisation and their commissioners as required for local purposes.

In the case of fields 10 and 11, the requirement will be satisfied by one of the two fields being completed.

See attached link for SACT dataset v.15.

## Appendix: 2 Implementation timetable

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<tbody>
<tr>
<td>Trusts with fully implemented e-prescribing systems</td>
<td>Preparation including test downloads (voluntary basis)</td>
<td>Start full downloads</td>
<td>Continue full downloads</td>
<td>Continue full downloads</td>
<td>Continue full downloads</td>
<td>Continue full downloads</td>
</tr>
<tr>
<td>Trusts with partially implemented e-prescribing systems</td>
<td>Preparation including test downloads (voluntary basis)</td>
<td>Start partial downloads</td>
<td>Start full downloads</td>
<td>Continue partial downloads</td>
<td>Continue full downloads</td>
<td>Continue full downloads</td>
</tr>
<tr>
<td>Electronic clinical system but no e-prescribing</td>
<td>Preparation including test downloads</td>
<td>Start partial downloads, dataset sections 1-4 &amp; 6</td>
<td>Continue partial downloads</td>
<td>Continue partial downloads</td>
<td>Start full downloads</td>
<td></td>
</tr>
<tr>
<td>Basic hospital systems only</td>
<td>Preparation including test downloads</td>
<td>Start partial downloads, dataset sections 1-3 &amp; 6</td>
<td>Continue partial downloads</td>
<td>Continue partial downloads</td>
<td>Start full downloads</td>
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</thead>
<tbody>
<tr>
<td>System Construction and testing.</td>
<td>50% of trusts supplying SACT compliant data</td>
<td>Embedding requirements and practices for data capture, management at submission. Provide feedback reporting on data quality and changes for improvement</td>
<td></td>
<td></td>
<td></td>
<td>Consolidate on best practices for data capture and submission. Consolidate feedback to sites. Consolidate reports and publications.</td>
</tr>
<tr>
<td>Data Submission from pilot sites and issue resolution.</td>
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<td>ISB submission approval.</td>
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<tr>
<td>Identification and communication with Cancer Chemotherapy prescribing sites</td>
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</tr>
<tr>
<td>Remaining 50% of trusts supplying partial data</td>
<td>Embedding requirements and practices for data capture, management at submission. Provide feedback reporting on data quality and changes for improvement</td>
<td></td>
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</tr>
<tr>
<td>Management of delays, technical and systems support to trusts encountering difficulties or delays</td>
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</tr>
</tbody>
</table>

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