Information Standards Board for Health and Social Care			
Title	SACT Dataset - Specification v1.2.docx		
Document ID	ISB 1533 Amd 24/2013		
Sponsor	Sean Duffy	**Status**	Final
Developer	Trish Stokes	**Version**	1.2
Author	Systemic Anti-Cancer Therapy Project Team	**Version Date**	24/09/2013

Systemic Anti-Cancer Therapy Dataset - Specification v1.2

Amendment History:

Version	Date	Amendment History
0.1	05/01/11	First draft for comment
0.2	21/02/11	Amendments following discussion with ISB
0.3	19/04/11	Further amendments and additions
0.4	03/05/11	Full stage submission
0.5	10/06/11	Amendments following ISB appraisal
0.6	28/06/11	Final amendments before ISB meeting
1.0	21/09/11	Publication
1.1	19/09/13	Amended to include dataset changes as shown in SACT dataset v2.0
1.2	24/09/13	Updated following comments received following the ISB appraisal

Approvals:

Name	Organisation	Version	Date
CIU Board	CIU Board	1.1	27/08/2013
CIU Board	CIU Board	1.2	20/09/2013

Glossary of Terms:

Term	Acronym	Definition
Cancer		For the purposes of this standard the term ‘cancer’ is used throughout the standard and related documents to cover all conditions registerable by the UK and Ireland Association of Cancer Registries.
Chemotherapy Intelligence Unit	CIU	Team responsible for supporting SACT.
Chemotherapy Planning Oncology Resource Tool	C-PORT	Resource management tool
Commissioners		Organisations that plan, purchase and monitor services to meet the health needs of their local population.
The Health and Social Care Information Centre	HSCIC	The Health and Social Care Information Centre is England's central, authoritative source of health and social care information for frontline decision makers, which builds upon the Health and Social Care Act 2012.
International Statistical Classification of Diseases and Related Health Problems	ICD	A medical classification list for the coding of diseases, signs and symptoms, abnormal findings, complaints, social circumstances and external causes of injury or diseases, as maintained by the World Health Organization (WHO). (The title is followed by the revision number, e.g. ICD10 is the tenth revision.)
International Classification of Diseases for Oncology	ICD-O	An extension of the ICD coding system used principally in tumour or cancer registries for coding the site (topography) and the histology (morphology) of neoplasms. (The title is followed by the revision number, e.g. ICD-O-3 is the third revision.)

Improving Outcomes: A Strategy for Cancer	IOSC	The overarching strategy for cancer services in England.
Information Standard	IS	A measure that ensures that information is managed in a consistent manner across health and social care, both by the computers and the staff.
Multi-disciplinary team	MDT	Clinical team that determines patient management
National Cancer Intelligence Network	NCIN	A UK-wide initiative, working to drive improvements in standards of cancer care and clinical outcomes by improving and using the information collected about cancer patients for analysis, publication and research.
National Cancer Registration Service	NCRS	National Cancer Registration System is the merger of the 8 English Cancer Registries into a single organisation, under one director, using a single system (Encore).
The National Institute for Health and Care Excellence	NICE	The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care.
Office of Population Censuses and Surveys	OPCS	OPCS is a procedural classification for the coding of operations, procedures and interventions performed during in-patient stays, day case surgery and some out-patient attendances in the National Health Service (NHS).
Payment by Results	PbR	Commissioning mechanism used to provide a transparent, rules-based system for paying Providers in which efficiency will be rewarded, patient choice supported and activity for sustainable waiting time reductions is encouraged.
Providers		Organisations that provide health services.
Public Health England	Public Health England	Public Health England is an executive agency of the Department of Health in the United Kingdom, taking up its full powers from 1 April 2013 Its role is protecting and improving the nation's health and well being and to reduce inequalities.
Review of Central Returns	ROCR	The Review of Central Returns (ROCR) process is concerned with supporting the Department of Health (DH) and its Arm's Length Bodies (ALBs) to implement the government's policy in 'Reducing the burden' of data collections from the NHS.
Systemic Anti-Cancer Therapy	SACT	The national collection of all cancer chemotherapy data in the NHS in England, which covers all solid tumour and haematological malignancies. This includes all adult and paediatric cancer patients, those in clinical trials, and covers acute inpatient, daycase, outpatient and community settings.
United Kingdom Association of Cancer Registries	UKACR	A body aimed at promoting and developing cancer registration in England, Wales, Scotland, Northern Ireland and the Republic of Ireland.
XML Schema		The documentation, definitions and descriptions required to enable the production and transmission of data for a specific XML language.

Contents

1 Overview

1.1 Summary

Standard	
Standard Number	ISB 1533
Standard Title	Systemic Anti-Cancer Therapy Dataset
Description	This standard specifies a dataset for use at both national and local levels to generate secondary uses information about systemic anti-cancer therapy (chemotherapy) to assist in achieving, supporting and monitoring the NHS Operating Framework, specialist commissioning and related policy. All patients receiving cancer chemotherapy in or funded by the NHS in England are covered by the standard. This includes adult and paediatric cancer patients receiving chemotherapy treatment for solid tumours and haematological malignancies, including patients in clinical trials. Providers of cancer chemotherapy services are required to provide a monthly return on all chemotherapy activity using this dataset. There is a phased implementation of these monthly returns from April 2012 to April 2014, depending on the implementation of electronic prescribing within provider organisations. Details of the timetable are included in the standard specification. The standard may also inform design of electronic prescribing and other clinical systems as it defines, for consistent use, terms such as regimen and cycle that are used in chemotherapy prescribing and administration for individual patients. This specification and the accompanying guidance document together comprise the Information Standard and are subject to ISB Information Standards change control processes. The dataset has been approved by the Review of Central Returns Steering Committee – ROCR – reference number ROCR/OR/2110/001MAND.
Applies to	• Cancer centres and all other providers of NHS commissioned cancer chemotherapy services • Developers and suppliers of electronic prescribing systems for use in NHS and NHS commissioned cancer services • Organisations purchasing electronic prescribing systems for use in cancer services • Users of secondary data about chemotherapy services, including providers and commissioners of cancer services, clinical trials bodies, cancer research organisations, the National Cancer Registration Service (NCRS), Public Health England (PHE), Department of Health and relevant Royal Colleges. Does not apply to: • Chemotherapy given to treat patients with a diagnosis other than cancer, e.g. dermatological or rheumatological conditions.
Release	
Release Number	Amd 24/2013

Release Title	SACT Dataset Version 2.0 Updates
Description	As part of the SACT Dataset's on-going implementation and maintenance, a number of changes have been identified: Addition of the following data item in order to comply with general Information Standard rules: • NHS NUMBER STATUS INDICATOR CODE Change of data item name to TNM STAGE GROUPING (FINAL PRETREATMENT) in order to align with the Cancer Outcomes and Services Dataset (COSD). This change affects the following data item: • TNM CATEGORY (FINAL PRETREATMENT) Update data item description for the following data item in order to provide further clarification that this data item corresponds to the term 'line of chemotherapy' expressed in many prescribing systems: • SYSTEMIC ANTI-CANCER THERAPY PROGRAMME NUMBER Addition of a new national code ('D – Disease Modification') to the following data item in order to reflect current clinical practice. Guidance on this national code is included in the SACT User Implementation Guide in which it explains its intended use • DRUG TREATMENT INTENT
Implementation Completion Date	1st April 2014

1.2 Supporting Documents

Ref #	Title
1	SACT Dataset v2.0
2	SACT Dataset – Change Request v1.0
3	SACT Dataset – Implementation User Guide v0.11
4	SACT Dataset - NHS Data Model and Dictionary Change Request 1370

1.3 Related Standards

Ref #	Reference	Title
1	ISB 0149-02	NHS Number for Secondary Care
2	ISB 0021	ICD-10
3	ISB 1521	Cancer Outcomes and Services Dataset

2 Health and Care Organisations

2.1 Requirements

#	Requirement [1]
1	Providers of cancer services **SHOULD** review their clinical services and confirm which areas of the standard apply to their clinical practice. They **SHOULD** also carry out a data mapping exercise to assess how well their existing systems align to the Systemic Anti-Cancer Therapy Dataset specification and develop a plan for alignment if required.
2	An experienced Head of Cancer Services in each provider organisation **SHOULD** guide the service and system review, based on a good understanding of the scope, definitions and rules behind the data items (from the Implementation User Guide (3)).
3	All providers of cancer services **MUST** submit data files to the Chemotherapy Intelligence Unit (CIU) on a monthly basis according to the staged programme defined in section 5.4 below. A schedule for monthly submissions is published annually by the CIU.
4	Where patients have requested that their data is not shared, the provider organisation **MUST** ensure the records of these patients are not included in the data downloads submitted to the Chemotherapy Intelligence Unit.
5	Clinical and operational staff predominantly record data for primary purposes, including data held in electronic prescribing systems, to record clinical events and facilitate medical intervention. Provider organisations **MUST NOT** utilise this dataset for record keeping or to support their clinical and operational data capture. This standard must only be used for secondary uses.
6	Data items **MUST** be submitted in the formats specified in section 3 of the Implementation User Guide (3).
7	Downloads **MUST** be submitted in either CSV or XML
8	Data quality reports that are supplied back to the data supplier **SHOULD** be reviewed and a resubmission **MAY** be made the following month
9	It must be possible for the CIU to reconstitute details of each patient's sequential management from data supplied. Providers of cancer services therefore **MUST** include mandatory data items, otherwise files will be rejected, and required data items, which are part of NHS business rules, where available or applicable.

2.2 Conformance Criteria

Organisation Type	Criteria
Provider	SACT Portal Submission QA • SACT submission files are tested against the agreed business rules; • A 'file validation report' is issued to demonstrate provider compliance; • 80% of the mandatory fields must be compliant in order to submit file; Clinical QA • Feedback on compliance of OPCS 4 Regimen List. • Where anomalies exist the data is reviewed by the

[1] The key words MUST, SHOULD and MAY are defined in the information standards development methodology. They follow RFC-2119.

	Clinical Oncologist and Oncology Pharmacist through an iterative process. Monthly Data Completeness & Compliance Spreadsheet published on www.chemodataset.nhs.uk, which contains details of the degree of Provider compliance of SACT data against expected levels. Regular reports are also published on the website which highlight how the project is progressing so far as a whole.

3 IT Systems Suppliers

3.1 Requirements

#	Requirement [2]
1	Suppliers of Chemotherapy e-prescribing systems or Cancer IT systems **MUST** implement changes in accordance with their local contractual arrangements to enable all specified data items in the SACT Dataset to be captured and extracted in compliance with the Specification and Implementation User Guide (3).

3.2 Conformance Criteria

Criteria
Software suppliers are invited to use the SACT Supplier test portal to validate their amended XML/CSV report extracts. The portal will validate against the file, then against each of the data items to establish compliance. A test report can be produced to confirm compliance.

[2] The key words MUST, SHOULD and MAY are defined in the information standards development methodology. They follow RFC-2119.

4 Scope and Structure

4.1 In scope

The standard covers all patients receiving cancer chemotherapy in England through the NHS directly and care commissioned by the NHS. The dataset 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 patients with solid tumours and haematological malignancies, including those in clinical trials.

It does not apply to chemotherapy given to treat patients with a diagnosis other than cancer, e.g. for dermatological or rheumatological conditions.

4.2 Data definitions

Details of the fields which comprise the SACT dataset, including their Data Dictionary definitions, permissible values and other qualifying descriptions, are contained in the accompanying Implementation User Guide.

The Cancer Outcomes and Services Dataset has some overlapping content with the SACT data standard. Where this occurs, field definitions are consistent to allow data to be interoperable.

4.3 Dataset structure

Chemotherapy is given over a prolonged period of time, often months or years, comprising repeating and sequential elements. The patient may attend two or more providers during the course of treatment. In order to track the patient during treatment the dataset must be capable of linking all the elements of care in a consistent and ordered way.

In order to achieve this, the dataset requires a branching structure which links the initial data fields, which will remain constant during the treatment, with detail of each regimen, cycle and drug administration. Examples of this are shown diagrammatically in the SACT Implementation User Guide

At the completion or cessation of a treatment regimen, the outcome section must link back to all previous fields.

Downloads from providers to the central repository will be in the form of monthly reports of current activity, including regimens started and completed or ceased in that time period. It must be possible for the CIU to reconstitute details of each patient's sequential management from this data.

5 Implementation

5.1 Submission of data

File submission is via the Chemotherapy Intelligence Unit (CIU) web portal in .CSV or XML format – see SACT Implementation User Guide.

5.2 Data sources

The data will be provided by all hospitals and providers treating cancer patients with chemotherapy. Collation of data will depend on local system implementation and configuration, for example:

- Patient identifiers, demographics and details of the provider will be derived from existing patient administration systems and should be linked electronically to the e-prescribing systems, where these are in use.

- Details of the patient's clinical picture may also be derived from a variety of hospital systems or may need direct entry into an e-prescribing system.

- Details specific to cancer chemotherapy, regimens, cycles and administration will be recorded in the course of clinical practice and will be derived either from an e-prescribing system or other clinical database.

- Details of the outcome of chemotherapy will also be recorded as part of patient management and will form part of the standard output from an e-prescribing system.

5.3 Approach and timelines

The SACT Information Standard was implemented in England from April 2012 with a staged implementation of national collection of the SACT dataset between April 2012 and April 2014.

The SACT dataset has been designed to mirror the clinical decision making in prescribing chemotherapy. It is divided into six sections (see Appendix 1 of the SACT Implementation User Guide):

1) Demographics – including commissioner and provider initiating treatment
2) Clinical status
3) Programme and regimen – including the factors relevant at commencement of treatment
4) Cycle
5) Drug details
6) Outcome

Currently provider organisations vary in their implementation of electronic prescribing for chemotherapy and the following programme of compliance will apply.

- **Full e-prescribing implementation** – all hospital sites and services administering chemotherapy and all tumour types. These organisations have been required to submit data in all clinical areas that have e-prescribing implemented from **April 2012**. That includes all inpatient, outpatient and community services for all solid tumours, haematological and paediatric malignancy. All administration routes, including oral prescription, are required.

- **Partial e-prescribing implementation** – not all hospital sites and services or not all tumour types. These organisations have been required to submit data in all clinical areas that have e-prescribing implemented from **April 2012.** They have been expected to develop full coverage of all tumour sites and services from **September 2012**.

- **No e-prescribing system but other clinical electronic systems** capable of capturing some information on chemotherapy. These organisations have been required to submit partial data, sections 1-4 & 6 of the dataset, from **September 2012**. They are expected to develop the

functionality to submit full downloads from **April 2014**.

- **No clinical electronic systems** except hospital systems capable of recording demographics, cancer waiting times and commissioning data. These organisations have been required to submit partial data, sections 1-3 & 6 of the dataset, from **September 2012.** They are expected to develop the functionality to submit full downloads from **April 2014**.

5.4 Staged programme of national data submission

Current situation	Sept 2011 – April 2012	April 2012 – Sept 2012	Sept 2012 – April 2013	April 2013 – Sept 2013	Sept 2013 – April 2014	From April 2014 onwards
Providers with fully implemented e-prescribing systems	Preparation including test downloads (voluntary basis)	Start full downloads	Continue full downloads	Continue full downloads	Continue full downloads	Continue full downloads
Providers with partially implemented e-prescribing systems	Preparation including test downloads (voluntary basis)	Start partial downloads	Start full downloads	Continue full downloads	Continue full downloads	Continue full downloads
Electronic clinical system but no e-prescribing		Preparation including test downloads	Start partial downloads, dataset sections 1-4 & 6	Continue partial downloads	Continue partial downloads	Start full downloads
Basic hospital systems only		Preparation including test downloads	Start partial downloads, dataset sections 1-3 & 6	Continue partial downloads	Continue partial downloads	Start full downloads

6 Concept of Operation

6.1 Working Practices

6.1.1 Staff Groups involved

Implementation of the SACT dataset has implications for the skills and training of several staff groups.

- Clerical staff. This staff group need to be aware of the existence of the dataset collection process and may be responsible for inclusion of demographic data from hospital systems. They are not expected to enter clinical data. Briefing on the SACT data standard should be incorporated into their induction training.

- Pharmacy staff. Pharmacy processes are integral with the operation of this information standard, particularly where an e-prescribing system is fully operational. Implementation of the standard does not require any change in their work practices but nomenclature in documentation should be checked to ensure it is consistent with the information standard. This should be disseminated as necessary through the relevant professional bodies.

- Nursing staff. This staff group have the major role in the administration of chemotherapy to the patient and in the recording of detailed information of the patient's progression through treatment. New staff need to be briefed initially, as a normal part of their induction process, but "hands on" training on e-prescribing systems is necessary to ensure efficient and accurate recording of data. This training is required wherever an e-prescribing system is in operation.

- Medical staff. This staff group is primarily responsible for initiating the prescription, monitoring the patient's clinical progress, making adjustments to the prescription as required and summarising the treatment episode. Familiarisation with electronic prescribing will be incorporated into post graduate training with the co-operation of the Royal Colleges. Junior doctors will also need "hands on" experience in using the local system. Consultants are expected to personally prescribe chemotherapy treatment as agreed by the MDT and to be responsible for completing the end of treatment summary in the e-prescribing system.

- IT staff are required to have the necessary skills and training to maintain the functionality of e-prescribing systems. This now includes the creation of extracts for submission to the SACT data repository. Details of this are covered in the SACT Implementation User Guide.

All groups require access to appropriate user guidance in electronic and paper form. There are supplier specific "user forum" arrangements already in existence and these provide a route to offering additional support on incorporating updates and any practical issues arising from the introduction of the SACT information standard.

6.1.2 User Guidance

Please refer to the SACT Implementation User Guide. It is preferable for local user guidance to be grafted seamlessly into that already provided for users of electronic prescribing systems, either by system suppliers or local teams. This must be consistent with the SACT Information Standard but also system specific and tailored to the architecture and graphic interface of individual suppliers' systems.

6.2 Information Governance

The dataset contains sensitive and patient-identifiable information items. The NHS Health Research Authority has confirmed that reporting of patient identifiable data to the CIU is covered by the National Cancer Registration Service existing support under the Health Service (Control of Patient Information) Regulations 2002. Reported data will be managed by the CIU, which is part of the National Cancer Registration Service where there is expertise in managing large volumes of

confidential data.

In compliance with the fair processing requirement within the Data Protection Act, provider organisations are expected to inform patients of this purpose for reporting their information and of the potential use of the information for service development, analysis and statistical research.

Where patients have requested that their data is not shared, the provider organisation must ensure that their records are not included in the data downloads submitted to the CIU. It is suggested that a 'no consent' or similar flag is provided in local systems so that the record can then be omitted from the monthly upload.

If a patient discovers that their information has been uploaded to the central repository and they wish for this to be deleted, the organisation must complete a Subject Deletion Request form (available on the Chemotherapy Upload Portal) and send this to the CIU to action. The CIU will then delete the record from the database along with any backup files. An updated Patient Information Leaflet is currently under development which will explain that individuals have the right to access and have their own data held by the National Cancer Registration Service deleted, and the process by which to do this. The NCRS are currently in the process of drafting the new leaflet and are looking to consult with patient groups on its content in October 2013. A final version of the leaflet will be tested with focus groups and made available to stakeholders for comment prior to a final version being published in early 2014.

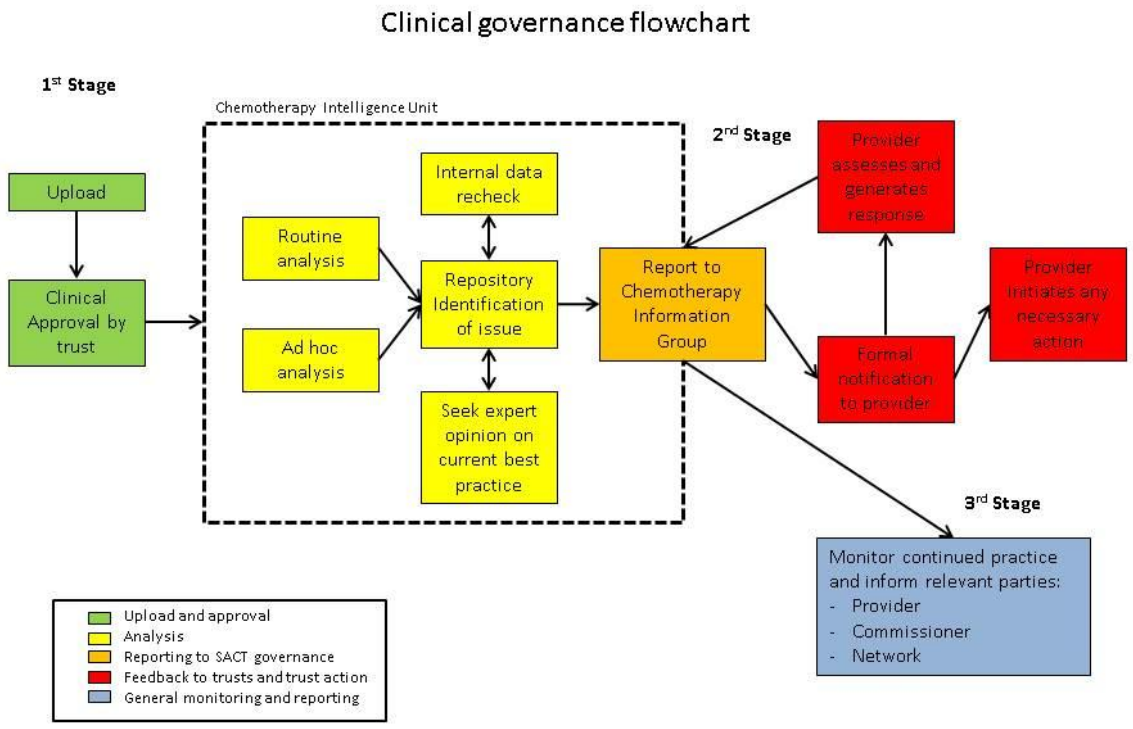
6.3 Clinical Governance

Analysis of the clinical content of the data collected will provide previously impossible insights into the patterns of cancer chemotherapy being delivered by individual providers and to individual patient groups and communities.

The format and content of reporting will be matched to the reasonable requirements of the various recipients of the data and reports, and the confidence intervals applying to each analysis made clear. When an apparently unacceptable variation in clinical practice is revealed by analysis a formal staged process of investigation must be undertaken. This process will determine the following:

- Is this an issue of variation within acceptable range but with limited patient choice?
- Is this an acceptable practice but worrying trend?
- Is this an issue which requires action within an agreed timescale?
- Is this an issue of immediate clinical concern?

This will decide the urgency of appropriate action which will be managed by the Chemotherapy Information Group. The process to be undertaken is presented in the following diagram.



6.4 Data Quality

The SACT dataset has complex and interrelated content, so it is essential that data errors are eliminated to prevent corruption of sometimes complex analyses dependent on many disparate data elements. Conformance criteria are listed in Sections 2 & 3 above and further detail is provided in section 4 of the SACT Implementation User Guide.

Initial quality assurance reports will be issued to providers of data immediately following submission. Once initial data quality standards have been achieved, a suite of standard clinical activity reports will be generated. These will cover defined time periods sufficient to be assessed meaningfully, and circulated to providers, with the request that they are reviewed by clinically competent staff in each provider organisation, to eliminate possible errors in clinical content.

When technical, coding and clinical errors have been corrected, the data will be released for the generation of a full range of analysis and reporting. This process runs in parallel with the clinical governance process in section 6.3 above.

6.5 Maintenance Arrangements

The Chemotherapy Intelligence Unit (CIU) was established on 1st April 2011. It is the conduit for all routine communications relating to the establishment and maintenance of the national chemotherapy dataset and data collection. Any changes required to improve the data collection process and changes required from time to time to ensure that the Information Standard remains consistent with need, will be co-ordinated through the Chemotherapy Clinical Information Group (CCIG). This group reports to the National Cancer Intelligence Network's (NCIN) Steering Group. Organisations and suppliers are encouraged to submit comments or requests concerning the dataset, its collection and analysis to the CIU ciu@sph.nhs.uk / ciu@phe.gov.uk to initiate this process.

A need for changes to the Standard and the User Guidance (which is part of the Standard) may be

identified through this route or during planned evaluation of the implementation of the Standard. Such changes will be subject to consultation, testing, formal approval and notification according to the change process requirements of the Information Standards Board. Agreed changes or enhancements to the implementation approach will be circulated to all contributors on a regular basis via the Chemotherapy Intelligence Unit. The NCIN will continue to be responsible for overall strategy.

7 Supporting Information

Further information from:
https://www.chemodataset.nhs.uk

Help desk email:
ciu@sph.nhs.uk / ciu@phe.gov.uk

