Public Health England

Protecting and improving the nation's health

# Cancer Outcomes and Services Dataset (COSD)

Version 8.0

# Specification

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Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge
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# Data Coordination Board

This information standard (DCB1521) has been approved for publication by the Department of Health under section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Coordination Board (DCB), a sub-group of the Digital Delivery Board.

This information standard comprises the following documents:

- Specification
- Implementation Guide
- Change Request.

An Information Standards Notice (DCB1521 Amd 74/2016) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled versions of these documents can be found on the NHS Digital website. Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

Date of publication: 28 September 2017.

| | | | |
|---|---|---|---|
| **Title** | COSD Specification | | |
| **SCCI reference** | DCB1521 Amd 74/2016 version 8.0 | | |
| **Sponsor** | Dr Jem Rashbass | **Status** | Draft |
| **Senior responsible officer** | Professor John Newton | **Version** | 8.0 |
| **Developer** | Andrew Murphy | | |
| **Author(s)** | Andrew Murphy | **Version Date** | 31/05/2017 |

## Amendment history:

| Version | Date | Amendment history |
|---|---|---|
| 8.0 | 31-05-2017 | Draft version for DCB Submission for v8.0 release (Amd 74/2016) |
| 8.1 | 03-07-2017 | Updated version with changes following review and recommendations |
| 8.2 | 21-07-2017 | Updated version with changes following review and recommendations |
| 8.3 | 04-08-2017 | Updated version including expanded Data Quality section as requested |
| 8.4 | 11-08-2017 | Final for Publication (post editorial comments) |

## Approvals:

This document MAY be approved by the following:

| Name | Signature | Title / Responsibility | Date | Version |
|---|---|---|---|---|
| COSD Advisory Board | COSD Advisory Board | COSD Advisory Board | 09-03-2016 | 7.0 |
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| COSD Advisory Board | COSD Advisory Board | Cross Organisation Board | 21-04-2017 | 8.0 |
| COSD Governance Board | COSD Governance Board | Cross Organisation Board, reporting to Professor Chris Harrison, National Clinical Director (NHS England) and Dr Jem Rashbass, Director for National Disease Registration (Public Health England) | 25-04-2017 | 8.0 |

## Glossary of terms:

| Term | Acronym | Definition |
|---|---|---|
| Burden advice and assessment service | BAAS | The Burden Advice and Assessment Service (BAAS)[1] - previously the Review of Central Returns (ROCR)[2] programme offers advice, guidance and support for the health and social care system (both nationally and locally) on minimising the burden and bureaucracy of data collection, freeing up staff time to care, as well as making recommendations to the Data Coordination Board (DCB)[3]. |
| Cancer | | For the purposes of this standard the term 'cancer' is used throughout the standard and related documents to cover all conditions defined by the World Health Organization (WHO) and International Agency for Research on Cancer (IARC) Classification of Tumours[4]. |
| Cancer Centre's | | Organisations which help people to live with, through and beyond cancer by bringing together specialist clinical and professional staff and communities of support. |
| Cancer Outcomes and Services Data set | COSD | The COSD is the national standard for reporting cancer in the NHS in England. It replaced the previous National Cancer Data set and includes the former Cancer Registration data set and additional site specific data items relevant to the different tumour types. |
| Cancer Registration Data Set | CRDS | The data set requirements for cancer registration now incorporated into the COSD. |
| Cancer Registries | | Organisations which exist internationally to collect, process, analyse and disseminate data on cancer patients in their local regions. |

[1] http://content.digital.nhs.uk/baas
[2] https://rocrsubmissions.ic.nhs.uk/Pages/HomePage.aspx
[3] http://content.digital.nhs.uk/isce
[4] http://whobluebooks.iarc.fr/

| | | |
|---|---|---|
| CancerStats Portal | | Online resource that allows Trusts to review specific cancer data submitted as part of the conformance framework. |
| Care Quality Commission | CQC | One of the independent regulators of health and social care in England[5]. |
| Commissioners | | Organisations that plan, purchase and monitor services to meet the health needs of their local population. |
| Diagnostic Imaging Data set | DIDS | Data set containing diagnostic imaging test activity across the NHS, taken from Radiology Information Systems. (See SCCI standard 1577)[6]. |
| Extensible Markup Language | XML | Extensible Markup Language (XML) is a set of rules for encoding documents in machine-readable form. |
| Improving Outcomes: A Strategy for Cancer | IOSC | The overarching strategy for cancer services in England[7]. |
| Information Standard | IS | A document containing standards that relate to the processing of information. |
| 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. |

[5] https://www.qcs.co.uk/
[6] http://content.digital.nhs.uk/isce/publication/scci1577
[7] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/388160/fourth_annual_report.pdf

| | | |
|---|---|---|
| MDT Coordinator | | The Multi-Disciplinary Team (MDT) coordinator is the person(s) responsible for facilitating the MDT meeting. They also have additional duties for collecting and recording information on patients as they pass through the Provider Trust, whilst on a cancer pathway. Sometimes known as a Patient Pathway Coordinator. |
| National Cancer Data set | NCDS | The previous nationally approved reference standard for the collection of cancer data now incorporated into the COSD. |
| 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. The NCIN is now part of Public Health England[8]. |
| National Cancer Registration and Analysis Service | NCRAS | The NCRAS is the National Cancer Registration and Analysis Service for England, collecting cancer data from all NHS Providers of cancer care in England. The NCRAS is a function within the National Disease Registration Service within Public Health England. |
| National Cancer Waiting Times Monitoring Data set | NCWTMDS | The Information Standard (DCB0147)[9] used to monitor the time that patients with suspected and diagnosed cancer have wait for appointments, tests and treatments[10]. |
| NHS Digital | NHS Digital | NHS Digital (previously known as 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. |
| Office of National Stastics | ONS | The UK's largest independent producer of official statistics and the recognised national statistical institute of the UK |
| Providers | | Organisations that provide health services. |

[8] The NCIN is now part of the National Cancer Registration and Analysis Service.
[9] Currently SCCI0147, but next version (expected September 2017) will be DCB0147
[10] http://content.digital.nhs.uk/isce/publication/SCCI0147

| | | |
|---|---|---|
| Public Health England | PHE | 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 wellbeing and to reduce inequalities. |
| Radiotherapy Data Set | RTDS | A standard data set covering every patient treated with radiotherapy in the NHS in the England[11]. |
| Site Specific Clinical Reference Group | SSCRG | A group of experts (at tumour site level) who advise on what data needs to be collected and what analyses conducted[12]. |
| Systemic Anti-Cancer Therapy Data Set | SACT | The national collection of all cancer chemotherapy data in the NHS in England, which covers all solid tumour and hematological malignancies. This includes all adult and paediatric cancer patients, those in clinical trials, and covers acute inpatient, day case, outpatient and community settings[13]. |
| The Royal College of Pathologists | RC Path | A professional membership organisation committed to setting and maintaining professional standards and to promoting excellence in the practice of pathology. |
| United Kingdom and Ireland Association of Cancer Registries | UKIACR | The UKIACR brings together organisations with an interest in developing cancer registration as a resource for studying and controlling cancer in the UK and Ireland[14]. |
| XML schema | | The documentation, definitions and descriptions required to enable the production and transmission of data for a specific XML. |

[11] http://content.digital.nhs.uk/isce/publication/SCCI0111
[12] http://www.ncin.org.uk/cancer_type_and_topic_specific_work/cancer_type_specific_work/sscrgs
[13] http://webarchive.nationalarchives.gov.uk/+/http://www.isb.nhs.uk/documents/isb-1533/amd-24-2013
[14] http://www.ukiacr.org/

# Contents

# 1. Overview

## 1.1 Summary

The table below contains a summary of the information standard.

| **Standard** | |
|---|---|
| Standard Number | DCB1521 |
| Standard Title | Cancer Outcomes and Services Data set |
| Description | The Cancer Outcomes and Services Data set (COSD) is a compiled data set which provides the standard for secondary uses information required to support implementation and monitoring of Improving Outcomes: a Strategy for Cancer (IOSC).<br><br>This standard consists of:<br>• a set of individual data items, with their definitions<br>• the assemblage of these data items into discrete data sets<br>• the means of flowing the data items<br>• compilation of the data items into a single reconciled and verified data set<br><br>COSD incorporates some of the National Cancer Waiting Times Monitoring Data set (NCWTMDS). In v8.0 many of these data items have now been retired as separate complete data sets are available nationally and this reduces the burden of data collection.<br><br>All patients diagnosed with or receiving cancer treatment in or funded by the NHS in England are covered by the standard. This includes adult and paediatric cancer patients.<br><br>Providers of cancer services have been required to provide a monthly return on all cancer patients diagnosed from 1st January 2013 using this data set. Data are collated via the NCRAS local offices, and formal mechanisms for transmission of data from Providers to registries have been extended to carry the COSD data set. |
| Applies to | • cancer centres, cancer units and all other providers of NHS commissioned cancer services<br>• developers and suppliers of electronic systems for use in NHS commissioned cancer centres and NHS provider services<br>• organisations purchasing electronic systems for use in |

| | |
|---|---|
| | NHS commissioned cancer centres and NHS provider services<br>• users of secondary data about cancer at both national and local levels, including:<br>At a national level:<br>• Department of Health (DH)<br>• National Cancer Registration and Analysis Service<br>• other appropriate national information, research and service planning organisations, e.g.<br>○ NHS Digital<br>○ Care Quality Commission (CQC)<br>○ NHS Improvement[15]<br>○ Public Health England (PHE)<br>○ NHS England<br>At a local level:<br>• strategic clinical networks (SCNs)<br>• local cancer service provider networks<br>• local NCRAS offices<br>• commissioners and providers<br>As COSD is for Secondary Care uses, there is no intention for this to be used by Primary Care or Private Hospitals.<br>Note: It is important to note that if a patient is on a NHS pathway, but the treatment is carried out in a private hospital (due to capacity issues or at the request of the NHS Trust), these data must be collected and reported (within COSD) by the NHS Trust, as if the treatment was carried out by them. |
| **Release** | |
| Release Number | Amd 74/2016 |
| Release Title | Version 8.0 |
| Description | This is a change to the Cancer Outcomes and Services Data set (COSD) standard which builds on the work started in v7.0 and introduces:<br>• new data items<br>• amendments to existing data items<br>• deletions where required<br>• realignment of existing data items within the current data set |

[15] https://improvement.nhs.uk/

| | |
|---|---|
| | • a revised schema to reflect these amendments<br>• a new 'non-primary cancer pathway' for recording recurrence, progression and transformation<br>• the removal of the older 'recurrence' pathway<br><br>These changes will allow the COSD to continue to meet the business objectives of the standard.<br><br>In addition there are new data to help identify and analyse:<br><br>• risk factors<br>• liver tumours<br>  ○ a new section has been added at the request and guidance of liver specialists<br>• recurrence, progression and transformation, both as part of the 'Primary Cancer Pathway' and within the new 'Non-Primary Cancer Pathway'<br>  ○ the old recurrence pathway has been removed and replaced with a more accurate 'Non-Primary Cancer Pathway'<br>• metastatic disease<br><br>Many data have been realigned across the data set into the correct higher level groupings, especially around children, teenage and young adults (CTYA).<br><br>The data set can now be easily maintained within each Trust, by using one of two subsets (depending on the department responsible for each data collection process):<br><br>• pathology - this was part of the last version of the standard and is now mandated across all Trusts to supply these data in COSD XML directly from their pathology departments<br>  ○ this is different from the patient pathway sub set as there are unique linkages for pathology and therefore requires its own unique schema<br>• patient pathway - this is the data, excluding pathology, which the cancer services teams need to collect. By removing the pathology data from their workload, it reduces their burden of data collection by up-to 30% across the whole data set<br>  ○ as pathology data continues to be collected by the pathologists and reported by the pathology departments (using structured COSD XML), it is not expected that the MDT Coordinators/Pathway Coordinators or cancer services teams will be required to duplicate this 'clinical' data collection |

| | |
|---|---|
| | • this is expected to reduce the burden of data collection for the Cancer Teams at Trusts |
| Implementation start and completion date | • implementation will be between 29/09/2017 and 31/03/2018 (6 months)<br>• data collection will start from 01/04/2018 (with a three month roll-out period between 01/04/2018 and 30/06/2018)<br>• full conformance from 01/07/2018 (reported in the July batch within the September upload) |

## 1.2 Supporting Documents

This Specification should be read in conjunction with the following documents:

| Product | Document Reference | Title |
|---|---|---|
| Change Request | www.content.digital.nhs.uk/isce/publication/dcb1521 | Change Request |
| COSD Data set v8.0 | http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd | COSD data set 8.0 |
| COSD Data set v8.0, Pathology v3.0 | http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd | COSD data set 8.0, Pathology v3.0 |
| COSD v8.0 user guide | http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd | COSD v8.0 user guide |
| COSD v8.0 Pathology data set v3.0 user guide | http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd | COSD v8.0 Pathology data set v3.0 user guide |
| Implementation Guide | www.content.digital.nhs.uk/isce/publication/dcb1521 | Implementation Guide |

## 1.3 Related Standards

This Specification should be read in conjunction with the following standards:

| Ref # | Reference | Title |
|---|---|---|
| DCB0147 | http://content.digital.nhs.uk/isce/publication/DCB0147 | National Cancer Waiting Times Data set |
| SCCI0111 | http://content.digital.nhs.uk/isce/publication/SCCI0111 | Radiotherapy Data set |
| ISB 1533 | http://www.isb.nhs.uk/documents/isb-1533/amd-63-2010/index_html | Systemic Anti-Cancer Therapy Data set |
| SCCI1577 | http://content.digital.nhs.uk/isce/publication/scci1577 | Diagnostic Imaging Data set |
| SCCI0021 | http://content.digital.nhs.uk/isce/publication/SCCI0021 | International Classification of Diseases |
| SCCI0034 | http://content.digital.nhs.uk/isce/publication/scci0034 | SNOMED CT |
| n/a | http://www.rcpath.org/professional-standards | Royal College of Pathologists Standards and Data sets for Histopathology Reporting on Cancers and Tissue Pathways |

## 1.4 Contacts

| **Sponsor** | |
|---|---|
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| Email Address | cosd@phe.gov.uk |

# 2. Health and Care Organisations

## 2.1 Requirements

| # | Requirement |
|---|---|
| 1 | NHS Providers of cancer services (hereinafter referred to as NHS Providers) **MUST** read the Specification and Change Request in conjunction with the Implementation Guidance to identify how the standard is applicable to them. |
| 2 | NHS Providers **MUST** review their system compatibility against this standard to identify any changes required to current practice to ensure that all data items in COSD v8.0 can be flowed electronically by the dates specified in this document. If there are compatibility gaps, then further development is required to meet the standard. |
| 3 | NHS Providers **MUST** submit the data using the XML format for extracts from MDT cancer information management systems. |
| 4 | NHS Providers **MUST** submit the data using the XML format for extracts from pathology systems. |
| 5 | NHS Providers **SHOULD NOT** utilise this data set primarily to support their clinical and operational data capture. |

## 2.2 Conformance Criteria

| Organisational Type | # | Criteria |
|---|---|---|
| Providers | 1 | Data items submitted are as specified in the COSD v8.0 data set and submitted within the defined time period and in the format specified. |
| | 2 | All specified linkage items are required (at record level) to enable linkage of the relevant cancer registration records. |
| | 3 | There is a 25 working day reporting period following the month end, to submit the agreed data items following diagnosis date. |
| | 4 | There is a 25 working day reporting period following the month end, to submit the agreed data items following treatment start date. |
| | 5 | There is a 25 working day reporting period following the month end, to submit any additional or amendments to the data items. |
| | 6 | An agreed method of submission with the NCRAS is required, for all items not flowed as part of the standard extract (e.g. imaging data). |

| | | |
|---|---|---|
| | 7 | Notify the NCRAS (as soon as possible after discovery) of any known reasons for significant variation in the number of new cases submitted monthly in comparison to previous months. |
| | 8 | Monthly feedback from the NCRAS is provided for review, using the CancerStats portal. This will allow cancer teams to assess if the data uploaded meets their expectation, and if not then they should be challenged with the Cancer Services Manager. |
| | 9 | Quarterly feedback reports are provided by the NCRAS to help the auditing of case ascertainment, quality and completeness. NCRAS should be informed of reasons for any discrepancies as soon as possible. |
| | 10 | A minimum of 80% of all expected cases is to be reported by provider Trusts annually by site specific tumour group, as agreed with the NCRAS. |
| | 11 | All data extracted from Trust MDT cancer information management systems is to be reported in XML. |
| | 12 | All data extracted from Trust pathology systems is to be reported in XML. |

Conformance is measured against the COSD Conformance Framework which has been published on the COSD webpage[16]. Basic feedback on conformance is provided to Providers through the NCRAS, COSD CancerStats portal[17].

Additional reporting for the National Prostate Cancer Audit[18] (NPCA), National Lung Cancer Audit[19] (NLCA), Incidence, Survival and Mortality data, are also available on the portal, along with Clinical Headline Indicators (CHI)[20].

Feedback reports are provided to the COSD Governance Board in order to monitor and manage compliance to the information standard.

[16] http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd
[17] https://nww.cancerstats.nhs.uk/users/sign_in
[18] https://www.npca.org.uk/
[19] https://www.rcplondon.ac.uk/projects/national-lung-cancer-audit
[20] www.ncin.org.uk/view?rid=2805

# 3. IT Systems

It would be expected that all Trusts have a service level agreement (SLA), with their system supplier to ensure future development needs are sufficient to meet changes to the standard.

## 3.1 Requirements

| # | Requirement |
|---|---|
| 1 | Trusts **MUST** ensure that cancer IT and pathology systems change in accordance with their local contractual arrangements, to enable all specified data items in COSD v8.0 to be captured and extracted in compliance with the Specification and Implementation Guidance.<br>There will be amendments to the existing COSD schema(s) to support this process and a new schema issued for pathology data. |

## 3.2 Conformance Criteria

| Criteria |
|---|
| The requirement above **MUST** be met.<br>NHS Providers **MUST** submit the agreed data items within 25 working days of the month end following diagnosis or treatment date. The DCB standard provides all the documentation to support this process, including:<br>• Implementation Guide<br>• Change Request<br>• Specification Document<br>• COSD Dataset v8.0<br>• COSD Dataset v8.0 (Pathology v3.0)<br>• Schema(s)<br>• Data set User Guides<br>Each regional NCRAS office has a nominated Cancer Improvement lead who will help and support any Trust struggling to meet the standard. |

# 4. Scope

## 4.1 In scope

The data set relates to all cancer patients, both adult and paediatric, in acute inpatient and outpatient settings. The trigger for data collection is when a diagnosis, or suspected diagnosis of cancer is confirmed. Primarily this diagnosis takes place within secondary care.

The standard covers neoplasms coded within ICD-10 diagnosis codes range C00 – C97, D00 - D48 and E85.9[21]. See Appendix A for list of Mandatory Registerable Conditions.

The Achieving World-Class Cancer Outcomes, A Strategy for England 2015-2020 (Cancer Taskforce Report)[22], produced a series of recommendations which directly impacted upon COSD. The strategy pointed out the need for changes - which have been interpreted and applied to the data set and new data items have been included within v7.0 and v8.0 to support these recommendations.

All changes can be found within the published Change Request document.

The data set can be easily maintained within each Trust, by using one of two subsets (depending on the department responsible for each data collection process):

- pathology - this was part of the last version of the standard and is now mandated across all Trusts to supply these data in COSD XML directly from their pathology departments
    - this is different from the main patient pathway sub set as there are unique linkages for pathology and therefore requires its own unique schema
- patient pathway - this is the data, excluding pathology, which the cancer services teams need to collect, by removing the pathology data from their workload, it reduces their burden of data collection by up-to 30% across the whole data set
    - as pathology data continues to be collected by the pathologists and reported by the pathology departments (using structured COSD xml), it is not expected that the MDT Coordinators, Pathway Coordinators or cancer services teams will be required to duplicate this 'clinical' data collection
        - this is expected to reduce the burden of data collection for the cancer teams at Trusts

[21] *Although Primary amyloidosis (E85.9) is listed as an E ICD code in the World Health Organisation (WHO) disease classification, amongst clinicians it is widely acknowledged and subsequently treated as a cancer, receiving Chemotherapy in cases. Whilst we await the WHO disease classification being updated to reflect this fact, we have extended the scope of the COSD to include this. The United Kingdom and Ireland Association of Cancer Registries (UKIACR) is currently considering its inclusion in the UKIACR Library of Recommendations, which we have referenced in Appendix A.*

[22] http://www.cancerresearchuk.org/about-us/cancer-strategy-in-england

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

Finally, where there were data that are no longer part of a linked national data set (e.g. Royal College of Pathologists), these have also been removed from the data set.

## 4.2 Out of scope

As a 'Secondary Uses' data set, this standard does not define record level data to be used in the delivery of care. The data for COSD should be derived from patient identifiable data, which are already recorded for the purpose of care management.

- general practice - developments in the extraction of data from general practice systems are the subject of other work by NHS Digital, specifically the general practice extraction service (GPES)
    - There are no formal links at present but this is expected to be developed in the future
- radiotherapy - this is subject to an existing standard, the National Radiotherapy Data set (RTDS) - SCCI0111, these data are now collected by the NCRAS and this standard was updated in September 2015
- chemotherapy - this is subject to an existing standard, the Systemic Anti-Cancer Therapy data set (SACT) - ISB1533
- imaging - this is subject to an existing standard, the Diagnostic Imaging Data set (DID) - SCCI1577, however some additional imaging data are required for COSD which is not part of this data set

COSD has been carefully reviewed to support other major data sets wherever possible, to reduce the duplication of data collection. In addition discussions have taken place with other data set owners to refine data items where cross-over is possible, to maximise the clinical relevance and prevent multiple (similar) data being created with different meanings. This work is supported by the NHS Digital, Data Dictionary and Terminology teams.

# 5. Implementation and Use

## 5.1 Guidance

### *5.1.1 High Level View*

This standard, together with the data set, defines the complete set of secondary uses cancer data for reporting and specifies the items which need to be returned directly by NHS Providers.

Other items are either subject to other Standards (such as RTDS), provided from other sources (such as ONS or screening services) or derived (these are clearly distinguished in the data set documentation). Further details are provided in user guidance and the following provides summary information only.

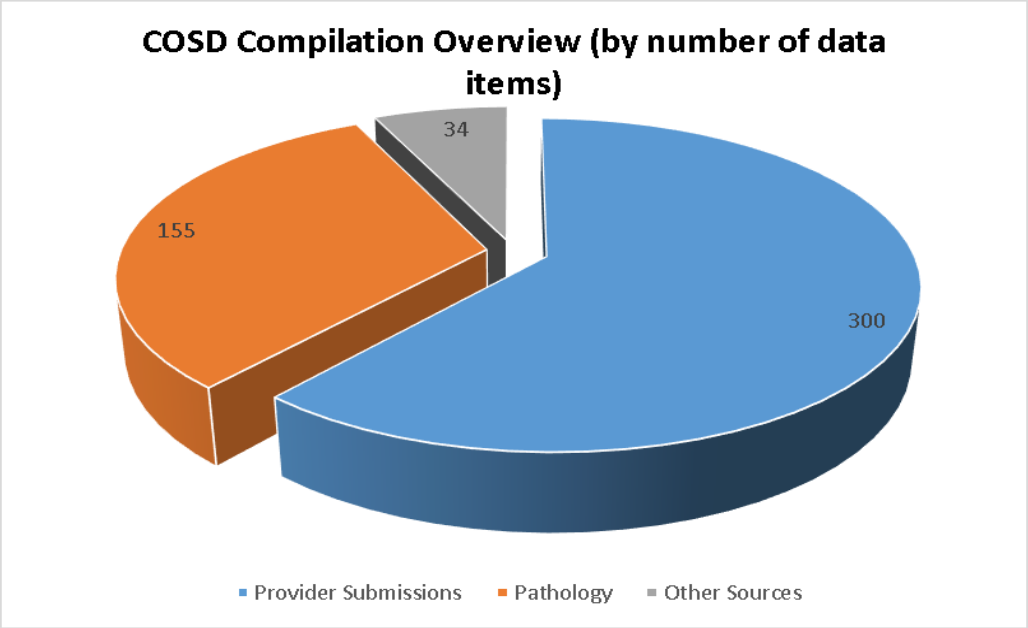


**Fig 1: COSD compilation overview**

**Provider submissions:** The 300 items shown above comprise the subset of the COSD to which the remainder of this specification refers unless otherwise stated. These are the items which are included in the XML schema and are expected to be flowed directly from NHS Providers to the local NCRAS Branch Office, from one or more electronic systems within the Provider organisation.

**Pathology:** Unless otherwise specified, these items are expected to be collected directly from the pathology department and are identified separately within the full data set. These are items which are essential to compile the full data set but are covered by their own schema and data flow.

**Other sources:** Unless otherwise specified (within the data set), these items are excluded from the remainder of this specification document and are identified separately within the full data set. These are items which are essential to compile the full data set but are collected for other information standards. Wherever possible this duplication of data collection has been reduced or removed in v8.0, however sometimes it is essential to report these data in multiple data sets.

### *5.1.2 Model data flow diagram*

The following diagram demonstrates how the full COSD data set will be compiled centrally by local NCRAS offices from data flowing from a number of systems and sources.

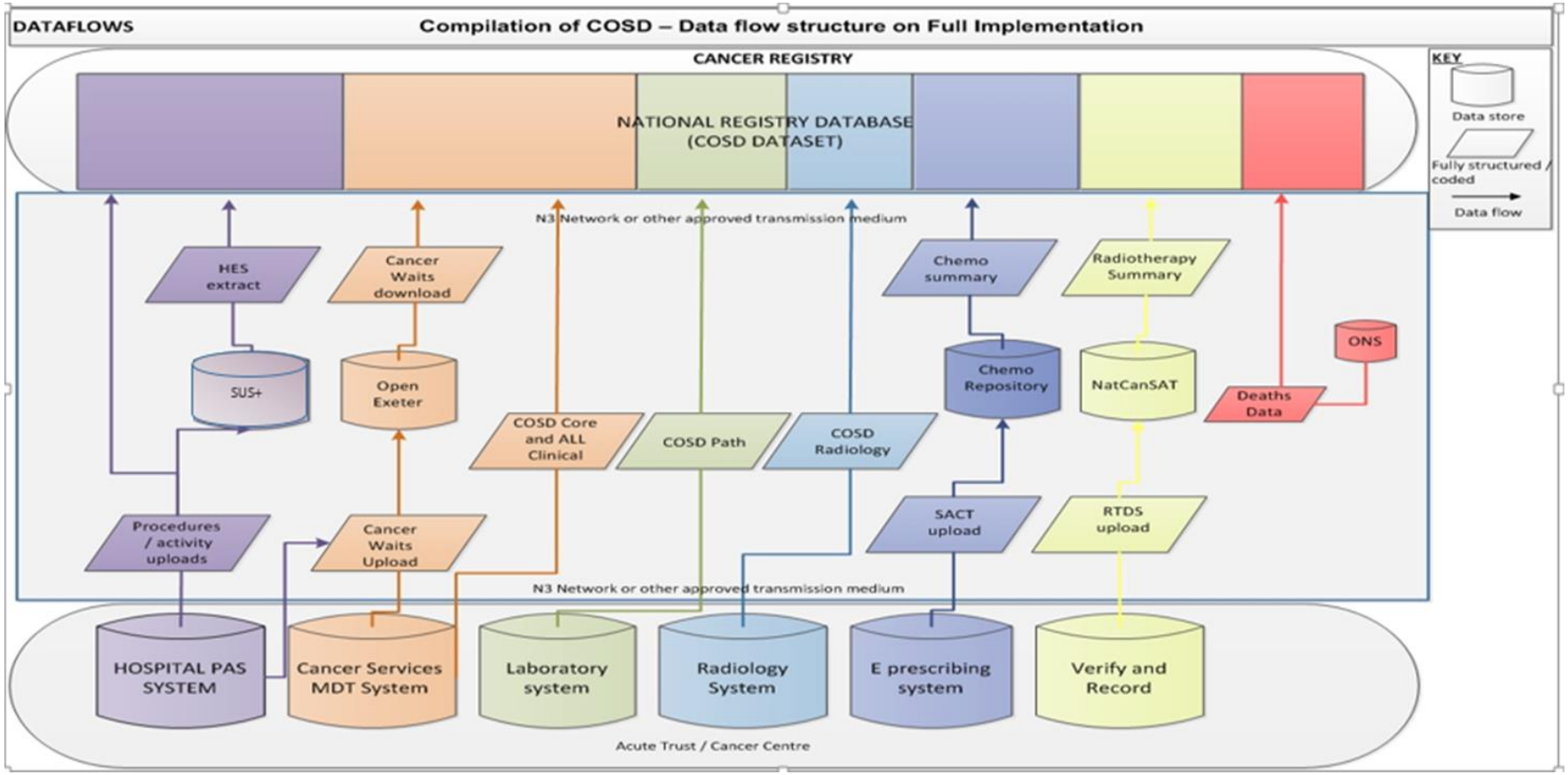


***Fig 2: COSD compilation - Data flow structure on full implementation***

### 5.1.3 Structure of data set - Provider Submissions

There is a core data set, of which most data items are applicable to all cancers recorded, and an additional set of site specific data sets (one for each of the thirteen identified tumour groups). Some of these site specific data sets contain further subsets applicable to individual diseases. Each recorded case will therefore have a core and usually a site specific data set completed.

This would be the same for pathology, where you have a Core and then eleven site specific pathology data sets, although you can submit pathology through both.

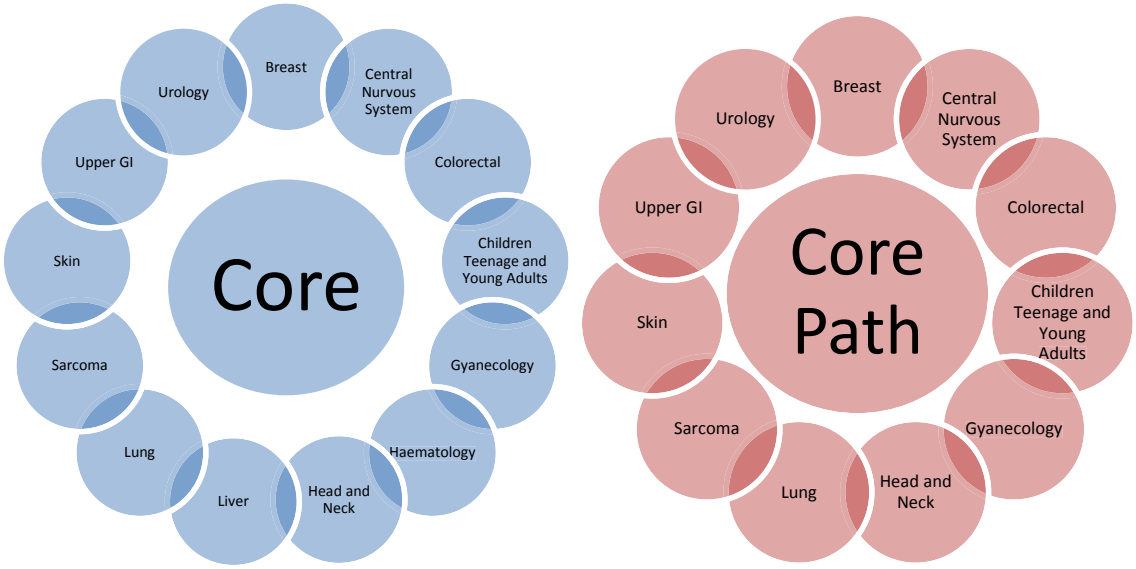


***Fig 3: Structure of COSD***

### 5.1.4 Data set subsections

Within each of the core and site specific data sets, the data items are further grouped according to their stage along the patient pathway as follows:

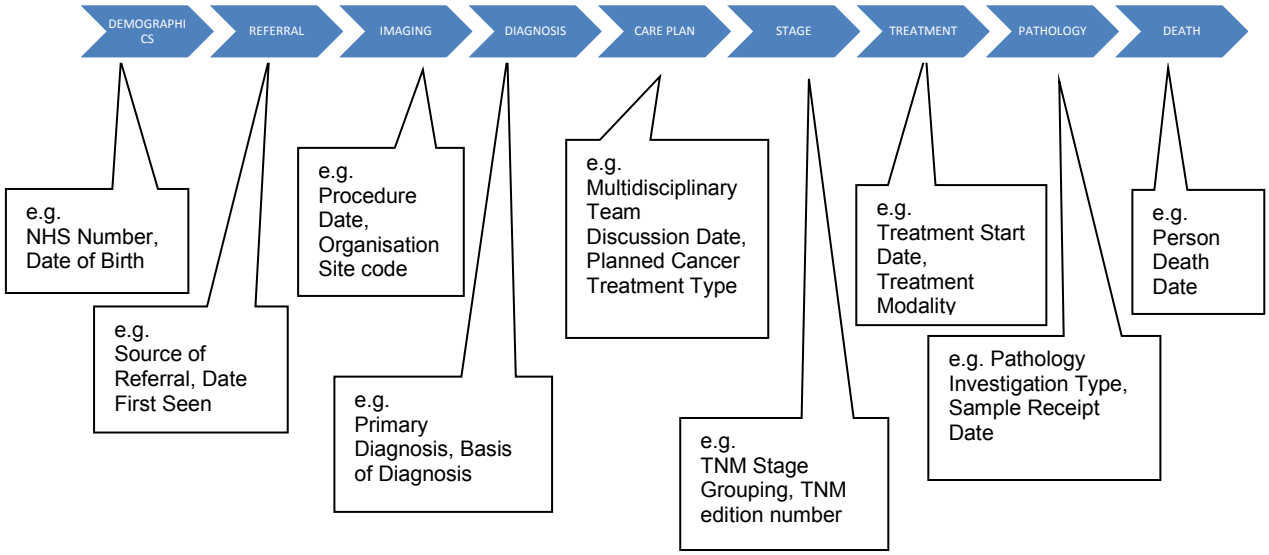


***Fig 4: Data set subsections***

From January 2016, Trusts were mandated to collect pathology directly from their pathology departments, although these data can also be submitted within COSD.

However the recommendation is that (non-clinical) MDT Coordinators should not be expected to transcribe complex free text reports into their local MDT system, if these data are already supplied direct from the pathologist.

## 5.2 Governance

### *5.2.1 Information Governance*

Data collection from all the new sources required to support cancer registration are covered by existing permissions granted by the Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA).

The data set contains sensitive and patient-identifiable information items. The Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA) has confirmed that reporting of patient identifiable data is covered by the NCRAS existing support under the Health Service (Control of Patient Information) Regulations 2002 (see Appendix H for details). Reported data will be managed by the NCRAS where there is long standing expertise in managing large volumes of confidential data.

Although the data items which are flowed to the NCRAS have changed, the data flows (i.e. which organisations will be receiving the data in identifiable form) remain unchanged. 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[23].

To help and support Trusts with this, the NCRAS and Cancer Research UK have developed a patient information leaflet (see Appendix B) that is a useful resource for organisations wanting to develop or revise local information materials. These have been written with the patient in mind and consulted upon to ensure it is easy to understand, and an updated version is expected in September 2017, and these leaflets are provided without cost to all NHS Trusts in England. More information about the review of informed choice for cancer registration can be found on the cancer research website[24].

NCRAS, as part of PHE, comes under the Department of Health's Data Protection Act registration with the Information Commissioner's Office (ICO). The NCRAS has reviewed its information governance policies to correlate them with those of PHE and maintain compliance with NHS Digital information governance toolkit. These policies inform for example:

- access controls of data
- server security
- encryption
- data transfer procedures

[23] http://www.ncr.nhs.uk/patientinfo/
[24] http://www.cancerresearchuk.org/health-professional/review-of-informed-choice-for-cancer-registration

### 5.2.2 Consent Process

Where patients have requested their data are not shared, the provider organisation must ensure that their records are not included in the data downloads submitted to the NCRAS. It is suggested that a dissent (i.e. the proactive expression of dissent by an individual from whom consent has not been obtained) or a similar flag should be provided in the provider organisation systems so that the record can then be omitted from the monthly upload.

The NCRAS has published a Patient Information Leaflet (Appendix B) which explains that individuals have the right to access and have their own data held in the NCRAS removed, and explains the process. This is currently being reviewed and consulted on by partner organisations and a new leaflet is expected to be released in September 2017. If a patient discovers that their information has been uploaded to the NCRAS and they wish for this to be deleted, the requester can email their request to optout@phe.gov.uk or write to the Director of NDR[25] using the address in the patient leaflet. The NCRAS will then, as far as is possible, remove the patient from the NCRAS database.

The NCRAS information for patients wishing to have their information removed as far as possible from the NCRAS database is available on the NCRAS website (http://www.ncras.nhs.uk/patientinfo). See Appendix C for further information.

### 5.2.3 Data Retention

The NCRAS holds data indefinitely, as without this facility accurate mortality and survival data cannot be calculated. If a patient wants their data removed at any point, then this facility is available as explained in 5.2.2 above.

### 5.2.4 Data Disclosure

The NCRAS adheres to the requirements of the Data Protection Act 1998 with regard to the receipt, storage and transfer of information relating to individuals. When releasing data to third parties, all NCRAS offices strictly comply with the approved on the release of patient-identifiable and potentially identifiable information.

Recipients of such data are required to sign a declaration stating that they will protect the information they are entrusted with, use it only for the purpose for which it was supplied and make no attempt to identify information pertaining to particular individuals or to contact individuals. They are also prohibited from presenting any information that may identify an individual. This is also the case with publications produced by NCRAS, which present aggregated data only.

[25] National Disease Registration

The UKIACR policy on Data Disclosure applies to this data and is available (see Appendix D for further information). As the NCRAS is part of PHE, all such requests must be approved by the Office of Data Release (ODR).

### *5.2.5 Subject Access Requests*

Subject Access Requests (SARs) are managed through PHE's Public Accountability Unit, in line with PHE's Data Protection Policy and the Data Protection Act.

For SARs, relating to cancer registration, there is a two stage information release process. This is designed to balance the needs of the individual with our statutory requirement to protect patient confidentiality.

At the first stage, we provide the subject with a summary report known as an "exemplar report". This report contains information about data sources attached to the subject's cancer registration, the date we received them and the originating organisation. The report gives examples of the type of information these sources might contain and a glossary of terms.

Following this, If the subject requires more information, we also offer to send a copy of the actual records attached to the subject's cancer registration to the primary care physician (the General Practitioner) or another clinician who knows the patient. This allows the GP to verify that the data has been sent to the correct person and, because some of the information is quite technical, the recipient also has the opportunity to ask the practice staff to explain anything they may not understand.

All the information is reviewed by the NCRAS' own Caldicott Guardian before being released. Requests are fulfilled within the time periods required by the Data Protection Act.

There is a sample process map attached in Appendix E.

### *5.2.6 Clinical Governance*

This is a secondary uses standard - no direct patient safety hazards were identified for the data set itself. Consultation, piloting, user guidance and validation processes address data quality issues that might have an indirect impact on services, patient care and treatment. The risk that patient identifiable data could be accessed or disclosed inappropriately is addressed in the Implementation Guidance section of this specification and guidance. The risk that the data set could be used to design primary use clinical systems is addressed at number 5 at Section 2.1 (Health and Care Organisations Requirements) of this document.

### *5.2.7 Data Quality*

The two areas for consideration are the quality of data submitted by providers and the data quality processes at the NCRAS offices.

Before and during the review process for COSD v8, previous versions were reviewed in detail and the submitted data assessed to ensure that it was still fit for purpose. In addition it is important that the data being received continues to be of a standard that can influence national analysis and international benchmarking. Examples of how some of the data have improved over time are as follows:

- staging has improved across the country and in 2017 some regions (Dorset) were submitting at >80% for the number of cancers discussed at MDT with a full stage
- performance status has improved across the country by 75% between 2013 and 2017

In addition in 2016, a review of all COSD v6 site specific data was conducted to check for completeness. This information was shared with the SSCRG leads and will be reviewed again in early 2018, looking at Q3 2017 COSD v7 data.

This review process is important as it identifies data that requires clinical review and if necessary either changing, updating or removing from future versions. This can happen due to changes to clinical practice and also the importance of the data for analytical reporting. Priorities change as does the direction of medicine over time, and COSD has to reflect this. This constant review is an important part of the development process.

***NHS Providers*:**

- each Provider is responsible for ensuring the data submitted to the NCRAS or submitted through other standard NHS routes is of the highest quality and completeness possible, and accurately represents the service provided
- the NCRAS provides a dynamic feedback process from the cancer registration system to Providers
    - this will allow data quality assurance at a field level - with clinical teams given secure access to the data (via the Cancer Stats portal) that their organisation has submitted

***National Cancer Registration and Analysis Service:***

- one of the main roles of the NCRAS is to ensure data quality and consistency
- the eight NCRAS regional offices have now moved to a single online processing system (ENCORE)
- working practices have been standardised with continuous performance monitoring and oversight of the entire NCRAS through Public Health England

In 2016, NCIN became part of the National Cancer Registration and Analysis Service (NCRAS), which is part of Public Health England (PHE). This has

enabled more efficient analysis of cancer data. Specific aspects of data quality are described in Appendix F.

CancerData[26] is a public accessible portal to look at outcomes data for CCG and provider Trusts. This has been specifically released for the public as well as NHS organisations, and is a vital step forward in improving data quality, whilst producing as near-to real-time data analysis from the NCRAS.

Although these data are not drawn exclusively from COSD 'level two' measure this in CancerStats. There are three levels within CancerStats for COSD reporting:

- level one - which measures submissions criteria
- level two - which measure performance of certain data exclusively from the Trust
- level three - which looks at all data reported to and processed on a patients cancer registration record, regardless where the data came from

COSD does form part of the total data used within the NCRAS cancer registration record, and is an important part of data collection across the NHS in England.

### *5.2.8 Demographic Data*

The cancer registration data is dynamic and individual tumour records are updated from numerous disparate data sources. Linkage of some these sources across the NHS is not sufficiently good to allow accurate mapping of new data to existing items without patient-identifiable data.

An example could be when using only NHS Number. There is a risk that a typo could cause the wrong data to be inadvertently added to the wrong patient or a new record created to a patient who does not have cancer. Having additional patient identifiers helps to remove that possibility and provides an invaluable QA process between the Trusts and the NCRAS.

Even once linked, retaining addresses and names remains important; the address stored by the NCRAS is that at the time of diagnosis of the tumour and is essential for cancer cluster analyses possibly many years later, when the patient may have moved. Without patient name, registries could not support genetic and follow-up enquiries made by clinicians who often only have limited information on the index case and possible relatives.

Nevertheless it is registry practice to use pseudonymised or even anonymous (possibly still disclosive) data sets for analysis where patient identity is not needed. Access to identifiable and potentially disclosive data requires

[26] https://www.cancerdata.nhs.uk/index.html

appropriate permissions from the Office of Data Release (ODR). This is a function of the National Disease Registry (NDR) within Public Health England.

For details on how the cancer registry processes deal with linkage and data discrepancies please see Appendix G.

## 5.3 Technical Architecture

### *5.3.1 Implementation overview*

The COSD standard was reviewed and modified the requirements on NHS Providers to submit monthly cancer data returns to the NCRAS by approved NHS secure methods. Providers should therefore have reviewed and revised their previous arrangements to submit monthly returns to their local NCRAS office in relation to the timeframe, content and format of those returns in order to conform to this Specification.

It is recognised that the data items may be recorded in different electronic systems and there is no requirement to send an integrated record of all data items in one file provided the rules for identifying and linking records are followed to enable the data to be recombined by the NCRAS.

Cancer data returns to the NCRAS before COSD covered generic (core) data items only. However, in addition to revising this core data set, the COSD also includes thirteen site specific data sets consisting of data items which have been identified by the Site Specific Clinical Reference Groups (SSCRGs), as essential for the analysis of outcomes and services of the relevant tumour sites, which now only include clinical data items.

Pathology data was moved and re-aligned with Core pathology (in v7.0), keeping their site-specific identity and groupings. This was necessary to enable to correct formatting of the pathology data set, which requires a different set of linkage data-items.

For v7.0, a separate schema was also created by a Technical Modeller, within NHS Digital.

There is a 6 month implementation period to amend local systems to comply with the new standard (DCB1521 Amd 74/2016). The full data set should be submitted using XML format for all new primary cancers, recurrent, metastatic and secondary cancers.

Providers are therefore expected to update their data extraction processes as per the defined standard. All new extracts should be developed using the XML schema provided as part of the standard. All extracts from MDT management and pathology systems should be submitted in XML.

It is recognised that some changes to pre-existing working practices may be required, particularly in relation to the electronic capture of site specific clinical data items by clinical Multi-disciplinary Team (MDT) members in order to

facilitate extraction for COSD. With the collection of pathology data direct from the pathology labs, this reduces the burden of data collection by up-to 30%[27] on the MDT, thus making the collection of these non-pathological data easier to collect.

There are no changes to arrangements for submission of data under other approved standards as a result of implementing this standard.

### *5.3.2 Changes to prior data collection/data flows*

About 40% of the data items to be submitted directly by NHS Providers under COSD are covered by pre-existing data collections and/or pathology. Most of these are collected either monthly or at point of care.

The following summarises the changes to the pre-existing collections and flows:

**Cancer Registration:**

- ***previously*** the cancer registration data was supplemented by COSD monthly submission to NCRAS under national contract, this was extended to include site specific clinical and site specific pathology items, data has been submitted from cancer information management systems in XML since January 2015
- ***new*** consolidation of the pathology data set and subset within COSD, will make collecting data more logical and reduce the burden of data collection for (non-pathological data items) by up-to 30% across the whole data set

**COSD Pathology Data Set:**

- ***previously*** data was submitted from (LIMS) laboratory information management systems in XML from January 2016
- ***new*** revised pathology data set and XML schema, issued by NHS Digital
- ***previously*** RCPath core pathology data sets (data items covered by professional standard minimum data sets)
- ***new*** all data sets within COSD have been aligned to RC Path core data sets and wherever required, out-of-date items removed

**Cancer Waiting Times:**

- ***previously*** cancer waiting times continues to be available to cancer registries monthly, following local validation and central reporting
- ***new*** the developers of both COSD and CWT have worked together to reduce the burden of data collection across both data sets for this

[27] This has been evidenced in the Burden Advice and Assessment Service documentation, which is part of the standard review process.

version change, this is vital to reduce duplication and improve data collection

**National Cancer Audits:**

- ***previously*** it was expected that data items shared with the national audits would continue to be dual flowed until the quality and completeness of these items through the COSD Standard is considered adequate. At this time the audits will be able to obtain the items through the NCRAS service and will no longer need to collect them directly
- ***new*** there are no new data for The National Lung Cancer Audit (NLCA) which remains completely collected within COSD, additional data have been added to COSD v8.0 to support the collection of the National Prostate Cancer Audit (NPCA)

**SACT and RTDS:**

- ***previously*** RTDS is now submitted directly to the NCRAS and both RTDS and SACT have been integrated as direct feeds into cancer registration
- ***new*** wherever possible the collection of these data have been removed from COSD to be solely collected within the parent data set, this will reduce the burden of data collection

### *5.3.3 Actions required*

NHS Providers will need to:

- identify items in COSD which were previously collected electronically and those that require changes to systems in order to collect them
- identify items in COSD which may be received by the NCRAS offices from other routes (e.g. Image Exchange Portal)
- identify electronic source for all data items, this may include (but not limited to): Patient Administration Systems (PAS), MDT software systems, pathology and imaging systems
- identify the items that can be extracted in XML format and submitted by the current NHS compliant methods to the NCRAS
- identify data items which are not recorded in a XML format but could be submitted in other formats until appropriate electronic software is available, this is likely to be pathology/ imaging data items which are included in pathology/imaging reports

A range of supporting documents are available from the COSD pages on the NCIN website[28]. Additional support is available to Providers from the NCRAS Data Liaison Teams.

NCIN has now become part of the National Cancer Registration and Analysis Service (NCRAS), which is part of Public Health England (PHE). The NCIN website has been re-branded to reflect these changes and will continue to publish additional information and updates on the COSD webpages.

### *5.3.4 Data Sources*

Data may be recorded in a variety of systems such as MDT software and patient administration systems (PAS), and therefore multiple data extract files may be submitted from a variety of sources.

The following diagram shows the data flows to complete the full COSD data set as of January 2017. The grey shaded areas are data items in the 'Reference - Other Standards' and 'Other Sources' sections of the data set, which have now been removed in v8.0.

This differs from Fig2 (pg23) as it highlights the flow of data for COSD only.

[28] http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd

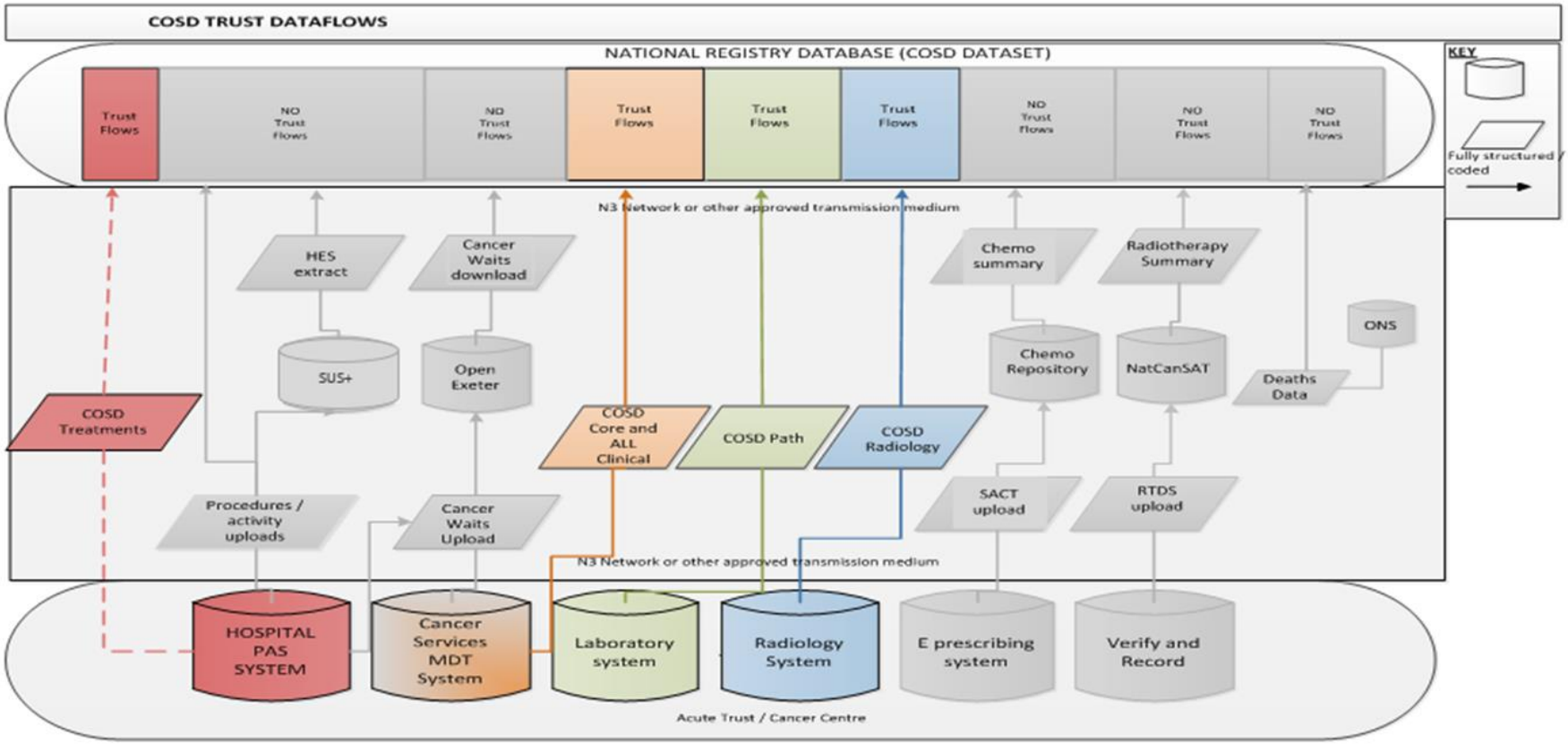


**Fig 5: Example of data flows to complete COSD**

The coloured items show expected data sources for NHS Provider data extracts. There may be some variation in the data sources between providers as configurations of data collection systems are not uniform across the provider community. Please note that SUS has changed to SUS+ and the legacy SUS system ceased to be available from 24th June 2017

### *5.3.5 Submission of Data*

Providers will submit the data to the NCRAS monthly in XML format, using the current NHS approved standards of submission (see Implementation Guidance for further details).

### *5.3.6 XML Format for Submissions*

All Trusts have been required since January 2016 to submit data from MDT Cancer Information Management Systems and Pathology systems in the NHS prescribed XML format.

### *5.3.7 Phased approach to implementation for data set v8.0*

Data extracts from MDT management systems were originally required to be submitted in XML from January 2015, although this was extended to January 2016 on review. This has been a difficult transition for pathology departments and work is ongoing to support Trusts and system suppliers to have compatible systems in place.

The revised data set v8.0 will have a 6 month implementation period for Trusts and suppliers to make and test the changes required throughout the new standard.

Full compliance of the standard must commence by July 2018 at the latest with a phased roll-out from April 2018 (for start of data collection). This is to make allowance for the varied timescales of different software suppliers and in-house developers. During this three month period, data can be submitted in accordance with either data set v7.0 (schema v7.1 Live) or v8.0 (schema v8.0).

Data extracts from pathology systems should be submitted in XML and below is a table of compliance for the COSD data set for v8.0.

| By Date | All Providers |
|---|---|
| **28th September 2017** | **DCB1521 Amd 74/2016 ISN Publication** |
| **29th September 2017** | **Implementation period starts (6 months)** |
| **October 2017 - January 2018** | **Supplier system testing (phase 2)** |
| **January 2018 - February 2018** | **Trust system testing (phase 3)** |
| **31st March 2018** | **Implementation period ends (6 months)** |
| **1st April 2018** | **Start of data collection of the COSD data set (v8.0 Revisions)** |

| | |
|---|---|
| **April 2018 - June 2018** | **Three month roll-out period, to support system developers** |
| **1st July 2018** | **Full Compliance of the COSD data set (v8.0 Revisions). July 2018 data would be uploaded in the September 2018 data submission** |

### *5.3.8 Working Practices*

The implications of the data standard to data providers are as follows:

- all NHS Providers and system suppliers need to include the new and changed data items in their electronic systems
- these organisations may need to amend their transmission methods to enable the new and changed data items to flow and be centrally collated by the NCRAS
- there may be training implications for staff given changes to data item definitions or the implementation of new data items
- provider multi-disciplinary teams may need to adjust their previous processes for capturing data in order to include all the data items in the monthly extracts and ensure accuracy of clinical items

### *5.3.9 Implementation Guidance*

Implementation guidance has been developed to support users, organisations and systems suppliers to implement the standard. Versions of the documentation are available on the NHS Digital standard website[29].

New COSD User Guides has been developed to support the publication of the latest version change and are available on the COSD pages of the NCIN website[30].

[29] http://content.digital.nhs.uk/isce/publication/dcb1521
[30] http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd

# 6 Contact Details

- information, including the COSD data set and COSD User Guide is available on the NCIN website at:
  - http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd
- queries regarding this document should be addressed to:
  - COSDenquiries@phe.gov.uk
    - queries regarding submissions should be discussed with the NCRAS Regional Liaison Managers. Contact emails and telephone numbers are available on the following website: http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd

# Appendix A – Mandatory Registerable Conditions

| ICD 10 | Description of neoplasm |
|---|---|
| C00-C97 | All malignant neoplasms |
| D00-D09 (excluding D04) | All carcinoma in-situ<br>(excluding all D04 in-situ skin cancers) |
| D32-D33<br>D35.2 &<br>D35.3<br>D35.4 | Benign neoplasms of brain & other parts of nervous system<br>Benign neoplasms of pituitary gland & craniopharyngeal duct<br>Benign neoplasms of pineal gland |
| D37-D48 (excluding D47.2) | All neoplasms of uncertain behaviour<br>Neoplasms of unspecified nature of bladder<br>Neoplasm of unspecified nature of brain<br>Neoplasm of unspecified nature of other parts of nervous system & pituitary gland only<br>(Excluding D47.2 Monoclonal gammopathy of undetermined significance (MGUS)) |
| E85.9 | Primary Amyloidosis[31] |

Please see COSD User Guide for full list of Mandatory Registerable Conditions.

[31] Although Primary amyloidosis (E85.9) is listed as an E ICD code in the World Health Organisation (WHO) disease classification, amongst clinicians it is widely acknowledged and subsequently treated as a cancer, receiving Chemotherapy in cases.

# Appendix B – NCRAS/CRUK Patient Information Leaflet
## (v2 - Updated September 2016)

Registry information has shown that 1 in 2 people will now survive cancer for at least 10 years.

Achievements made possible by cancer registration information:

- research showing that there are at least 10 different types of breast cancer, which means treatments can be made more specific for each type
- monitoring whether cancers are becoming more or less common – for example spotting the rapid increase in skin cancer cases has led to prevention campaigns to promote staying safe in the sun and avoiding sun beds
- improvement of the breast cancer screening programme, and the decision to introduce flexible sigmoidoscopy (a technique for examining the bowel) as a method of screening for bowel cancer
- research around when and where patients are diagnosed with cancer, which showed that almost a quarter are diagnosed in an emergency. This has reinforced the importance of finding ways to get more patients diagnosed early

The more information we have in the registry, the easier it is to improve diagnosis and treatment.

What if I don't want my details on the cancer registry?
The benefits of the data collected by the cancer registry have been considerable and we are grateful that nearly everyone with cancer is prepared to share their data with the cancer registry. However, you can ask us to remove all of your details from the cancer registry at any time. These requests won't affect your treatment or care. If you wish to make such a request, you should email **optout@phe.gov.uk** or write to

**Director**
**National Cancer Registration & Analysis Service**
**Public Health England**
**Wellington House**
**London SE1 8UG**

If you have any questions about cancer registration, you can get more information by:

- asking your doctor
- visiting the Cancer Research UK website at **www.cruk.org/cancer-registration** or the cancer registration website at **www.ncras.nhs.uk/patientinfo** where you will find a longer booklet
- and for any questions on cancer, speak to one of Cancer Research UK's nurses on freephone **0808 800 4040** (9am–5pm, Monday to Friday)

Cancer registration is crucial for progress against cancer, and is supported by all the main UK cancer charities and cancer patient groups.

Against Breast Cancer
Bowel & Cancer Research
Bowel Cancer UK
Brain Tumour Research
Brain Tumour Research Campaign
Brainstrust
Breast Cancer Campaign
British Lung Foundation
Core – the Digestive Disorders Foundation
Cancer52
Cancer Research UK
GIST Support UK
It's in the Bag
James Whale Fund for Kidney Cancer
Jo's Cervical Cancer Trust
Skcin – The Karen Clifford Skin Cancer Charity
Leukaemia & Lymphoma Research
Lymphoma Association
Macmillan Cancer Support
Marie Curie Cancer Care
Melanoma Focus
My Name is NOT Cancer
Myeloma UK
Pancreatic Cancer Action
Rarer Cancers Foundation
Sarcoma UK
Shine Cancer Support
Skin Cancer Research Fund
Target Ovarian Cancer
Teenage Cancer Trust
The Pelican Cancer Foundation
The Pink Ribbon Foundation
WMUK

Public Health England

**Cancer Registration** – what it is, the benefits of being on the register, and your options

NHS CANCER RESEARCH UK

We've made great strides in recent years in our understanding of what causes cancer and how best to diagnose and treat it. But we can only continue this progress if we have information about the people who are developing cancer. We collect this information through a process called cancer registration.

Here, we explain why information about you and your cancer is recorded, how this information is used, and how, if you wish, you can see your information or have it removed from the registry.

What is cancer registration?
If you or your child has been diagnosed with cancer, or a condition that can lead to cancer, the medical staff looking after your health will pass information about you on to the National Cancer Registration and Analysis Service.

This will include your name, address, age, sex and date of birth, as well as information about the type of cancer or condition you have, and your treatment.

The Registration Service has the government's permission to collect this information. To get a complete picture we will also link this information to your other health information and to patient surveys about your care, and may share it with the nurses and doctors who are looking after you.

Cancer registration helps scientists investigate possible causes of cancer and improve treatment options.

Your details drive progress in cancer prevention and treatment
Cancer registration is the only way we can keep track of how many people are getting cancer and what types of cancer they have. Healthcare teams use this information to continually evaluate and improve services and treatment options for patients.

Cancer registration also fuels research into cancer, helping scientists investigate possible causes of cancer and improve treatments for the disease. This information is crucial for progress against cancer, and is supported by all the main UK cancer charities and cancer patient groups.

Is my information confidential?
Making sure your personal information is private and confidential is very important. Without your consent or a strict approval process, information that can be used to identify you will only be released to those providing your care, such as your hospital and doctor.

If you would like to see the information we have about you on the registry, we can give this to your doctor for them to share with you.

How will it benefit me?
There is no guarantee that having your information on the cancer registry will directly benefit you. However, we know that registry information is continually leading to improvements and new information on the prevention, diagnosis and treatment of cancer and so can help future generations.

In order to give each person the best possible care, we need to know how different cancers respond to different treatments – this information is held in the registry.

The registry could also make it easier for your doctor to see whether you could enrol in any clinical trials. If you have a family history of cancer, doctors can use the registry to find out what treatments worked best for your relatives and tailor your care accordingly.

Registry information is sometimes also used to find out which patients have had a particular treatment. This helps doctors identify any patients they need to contact about the treatment.

- the cancer registration leaflet can be downloaded from the following website: http://www.ncras.nhs.uk/patientinfo/
    - as updated versions are created, they will always be available here for anyone to download
    - all NHS Provider Trusts are supplied with these leaflets and re-supply is monitored and recorded within the NCRAS

## Appendix C – Patient Opt Out Request Form

# Patient Opt Out Request Form

This form is for use by patients to request that their personal information be excluded from processing onto the National Cancer Registration Service's cancer registration database.

The personal information collected on this form is needed so that we can process your request correctly. It will only be used in connection with carrying out this request.

*To be completed by the patient. Please complete as fully as possible.*

| **My Details** | |
|---|---|
| My name | |
| My address | NHS number |
| | Date of birth |
| | Sex |
| | Telephone number |
| | Place last treated |
| Post code | Date last treated |

**My request**

I wish the cancer registration system in England to stop adding information about me to the cancer registration database and either

☐ Delete everything except for 'My Details'

Remove, as far as possible all clinical information relating to me but **retain** my NHS number and the information I have provided in the 'My Details' section above in the 'watch list', so that any further information received about me will not be processed by the national cancer registration system.

Or:

☐ Delete everything

Remove, as far as possible all clinical and personal information relating to me **including** my NHS number and the information I have provided in the 'My Details' section above. I understand the registry will not keep any record of my details, so, will not know that any information received about me in the future should not be processed.

We will send you a copy of the leaflet, '*Cancer Registration – what it is, the benefits of being on the register, and your options*'', in the hope that you may

change your mind about opting out. If you do change your mind then please contact us as soon as you can.

Signed _____ Date _____

Please return to: Dr Jem Rashbass
Director,
National Cancer Registration Service
Public Health England
Wellington House
London
SE1 8UG

**Patient advice**

The Health Service (Control of Patient Information) Regulations 2002[32] permits the National Cancer Registration and Analysis Service (NCRAS) to collect information on all cancer patients in England.

All patient have the right to opt out of cancer registration. The first stage of opt out is usually a discussion with a clinician. The clinician will ensure that you are fully aware of the value of your information to research and for improving cancer treatments.

If you still want to opt out and have your details removed from the cancer registration data, you must apply in writing preferably by using the "Patient Opt-Out Request" form above.

The NCRAS will then add your NHS number to an 'exemption list'. By adding your details to this list, the NCRAS can ensure that it will not collect any incoming information about you.

The NCRAS will search all cancer registration files and records and as far as is practicable delete any existing information relating to you that it may already have.

The NCRAS will also check whether it has sent any identifiable information to other permitted organisations such as the Office for National Statistics, and if so as far as is practicable contact that organisation and instruct them to delete the information.

The NCRAS will complete its actions within 20 days of receiving the written request and will confirm this in writing to you.

You may also request removal from the exemption list and the NCRAS will act on this request. However if your details are removed from the exemption list, the NCRAS will not be able to guarantee that your data are not added in future.

[32] http://www.legislation.gov.uk/uksi/2002/1438/made

# Appendix D – UKIACR policy on Data Disclosure

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## UKACR Disclosure Policy

## UKACR Policy on disclosure of identifiable data by cancer registries – guidance on implementation within England and Wales

### Background

Regulation 2 of the Statutory Instrument (SI) on confidentiality – No. 1438, The Health Service (Control of Patient Information) Regulations 2002 – permits cancer registries to receive patient identifiable data [note 1] without the need for informed consent and it permits registries to process said data for the medical purposes stipulated in regulation 2. The regulation was made under Section 60 of the Health and Social Care Act 2001 and continues to have effect under Section 251 of the NHS Act 2006. The approval has been subject to annual review by the Patient Information Advisory Group (PIAG). The functions of PIAG have now been taken over by the Ethics and Confidentiality Committee (ECC) of the National Information Governance Board (NIGB).

**When dealing with requests for patient identifiable data registries must assess each request carefully and on merit, to ascertain whether or not patient identifiable data are really necessary. If not, anonymised data must be supplied, following the relevant UKACR guidelines. This is an important principle that registries must apply, even if patient identifiable data have been provided for similar requests in the past.**

The UKACR guidance is informed by the Disclosure Review for Health Statistics (referred to as the Health Review) developed by the Office for National Statistics and approved by ministers as policy in England. The health review provides detailed guidance on how to decide whether or not data are identifiable, and is the standard reference for publishing health data.

**Summary**

Cancer registries in England and Wales can release patient identifiable data legally only to those organisations specified in items 1) a), 1) b), 1) c), 1)d) and 1) e. All other organisations or individuals need approval from the Ethics and Confidentiality Committee of the National Information Governance Board, unless they have informed consent from patients. This policy must be implemented by all organisations listed in Appendix 1. This policy will be subject to annual review.
All requests for patient identifiable data must be made using the UKACR request form for patient identifiable or potentially identifiable data or the registry's host organisation's standard request form for identifiable data [note 2].

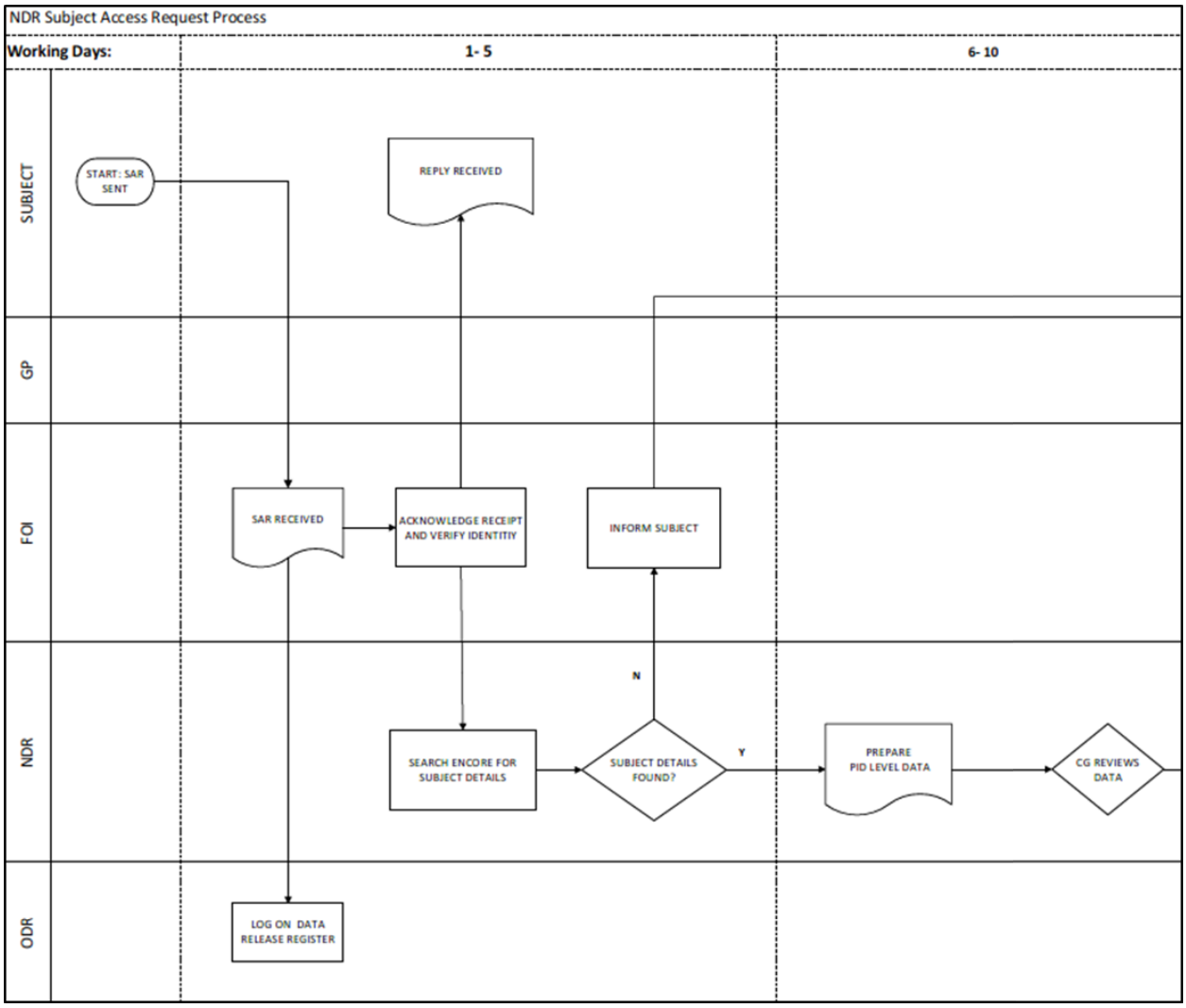
**Chris Carrigan**, National Cancer Registration Co-ordinator, England
**Monica Roche**, Co Chair, United Kingdom Association of Cancer Registries

[note 1] Defined in the Health and Social Care Act 2001 as "For the purposes of this section, patient information is "confidential patient information" where:
(a) the identity of the individual in question is ascertainable:
(i) from that information, or
(ii) from that information and other information which is in the possession of, or is likely to come into the possession of, the person processing that information, and
(b) that information was obtained or generated by a person who, in the circumstances, owed an obligation of confidence to that individual.
Data will be regarded as identifiable if it includes any of the following data items: name, address, postcode, date of birth, date of death, NHS number, hospital number.
[note 2] Registry specific versions of the UKACR request form for patient identifiable or potentially identifiable data are available at: (http://www.ukacr.org/confidentiality).

**Reference documents**

- Health and Social Care Act 2001
  (www.legislation.gov.uk/ukpga/2001/15/contents

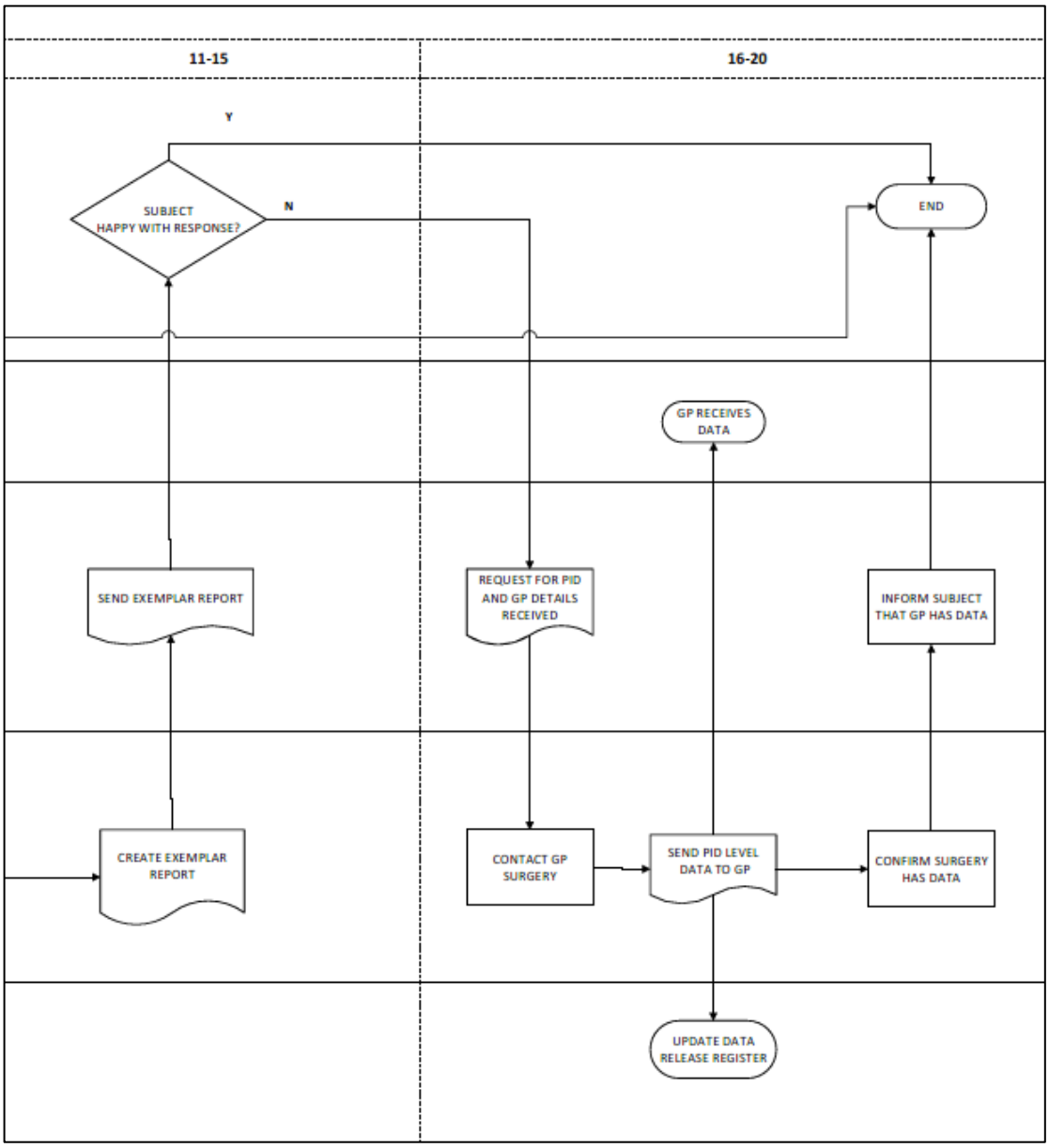
# Appendix E - Subject Access Request Process Map




**FOI days 1-5 and 6-10**

***Note: Process Map document is available upon request***

# Subject Access Request Process (continued)




**(FOI days 11-15 and 16-20)**

***Note: Process Map document is available upon request***

# Appendix F – NCRAS Data Quality Controls

**Automated Quality Control**

The data files submitted through the NCRAS data clearing house are subject to a wide range of validation rules to ensure that the data files and data within fields is consistent, as follows:

**Batch tracing of all cases:**

- all patient-identifiable electronic records are sent to the Demographics Batch Service for tracing against the NHS Spine, where discrepancies are identified, investigated and whenever possible reconciled
- it is not anticipated that this will place any additional load on either the Personal Demographic Service (PDS) or Batch Tracing facilities, however the impact will be monitored by the NCRAS as the project progresses with any significant increase being brought to the attention of the COSD Governance Board

**Use of multiple data sources:**

- the quality of cancer registration relies upon the use of multiple independent data sources to ensure high ascertainment and cross validation, the ENCORE system automates much of the data linkage between the disparate sources - highlighting inconsistencies that can be further investigated

**Cancer registration staff:**

- the National Cancer Registration and Analysis Service employs tumour registration staff at the local registries, these registration staff have considerable expertise in cancer coding and classification and spend much of their time quality assuring the electronic data sources and cases recorded at the registry. In some cases cancer registration officers work in a local provider organisation, but all registries maintain very close contacts with the clinical teams

**Data feedback to clinical teams:**

- rapid feedback to the provider clinical teams, usually through the MDT provides an important process of data validation, the NCRAS uses secure web-based systems to deliver reports at a field-level on the completeness of individual data items

**Data quality audit:**

- the UKIACR has developed a large number of performance metrics covering the process of data collection by registries, these performance metrics have been integrated into the new ENCORE system and will, where appropriate form the basis of daily updates on the data quality and completeness of records held in the NCRAS

# Appendix G – Data Linkage and Data Discrepancies

### *Linkage*

Linkage is a complex issue, which has become far simpler in recent years with the rollout in use of the NHS Number. Registries use different linkage methods according to the type of data which is available. In essence, the more data that is available, the more confident that linkage is correct.

In fact linkage comprises two parts; blocking and weighting. Blocking takes an incoming record and uses a range of search criteria, determined by the incoming records content, to identify a series of possible matches in the database. Where the NHS Number is available, that is used, but other blocking is usually also applied. In a manual context, these blocks tend to be sequential, but in an automated setting they tend to run consecutively, with all potential matches passing to the second stage, weighting.

Weighting can be simple. Deterministic weighting is used for NHS Number matching, but this is always augmented with at least one other identifier. Probabilistic techniques use a wider set of data matches, and are usually used when the NHS Number is not available on either the source record or the blocked record. It looks for the ”commonness” of the data value in the overall database, and then uses that to weight up or down based on a series of random control matches. Probabilistic weighting is a well-defined science, with robust methodologies, however it is used far less than in past years.

### *Data Discrepancies*

The fundamental principle of cancer registration is that it relies on multiple sources of data. When dealing with multiple sources, many of which may contain a common item, there is likelihood that two sources will give different values for a particular item of data.

The technical design of the registration schema is such that multiple sources and multiple data values are held against the summarised registration record. Registration clerks are trained to identify and deal with data discrepancy. This usually starts with some basic data checking with the source data supplier, but where conflicting data exists there are clear rules by which registry staff undertake this. At no stage is any source data overwritten or lost, and regular checks are included in the registration practice to examine random sets of records as part of the standard QA built into registration practice over many years.

# Appendix H – Approval under Health Service (Control of Patient Information) Regulations 2002

**Study title:** **National Cancer Registries Database**
**CAG reference:** **PIAG 3(a)/2001**

Thank you for the provision of an annual review report, submitted for approval under Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State for Health and Health Research Authority on whether an application should be approved, and if so, any relevant conditions. The purpose of the annual review is to provide an update against the conditions of approval where applicable, confirm progress of the activities, review the need to process confidential patient information, and ensure the minimum amount of identifiable information is being used.

**Secretary of State for Health and Health Research Authority approval decision**

1. The Secretary of State for Health and Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has approved the continued processing of those activities taking place under reference PIAG 03(a)/2001 under Regulation 2 of the Regulations. This is subject to the requests for clarification and compliance with the standard conditions of support.

Context

This annual review was provided on behalf of Public Health England and the national cancer registration service, operating under Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002. It set out an update on activities, justification for continuing support and progression against conditions of support. Members were asked to consider the review and confirm whether they were satisfied to provide a positive recommendation to the Secretary of State for Health (for the non-research aspects) and the Health Research Authority (for activities related to medical research), and if there were any further points for comment or clarification. This item was considered at the CAG meeting on 31 October 2016.

**Confidentiality Advisory Group advice**

The annual review confirmed on 18th Nov 2016 the following:

- the report confirmed that there had been no change to the need to continue processing confidential patient information for the specified purposes within Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002
- the need to process multiple identifiers where NHS Number was not present was set out in addition to why anonymised information would not be sufficient to enable the relevant linkages
- the Public Health England Information Governance Toolkit reviewed submission had been published (version 13) as satisfactory
- the eight cancer registries that had been subsumed within PHE had been renamed to the National Cancer Registration and Analysis Service (NCRAS)
- the two conditions of support indicated in 2015 had been satisfactorily addressed through evidence submission
- sharing of information with third parties was set out, in addition to a link to the relevant cancer data releases
- the engagement with the National Data Guardian review was noted, in addition to the future plans indicated within this review in relation to the cancer registries, such as seeking to improve the obtaining of consent, where appropriate, at point of registration
- two requests for patient objection had been made
- no data breaches or 'Serious Incident Requiring Investigation' had been reported in the previous 12 months in relation to this specific application reference

Members agreed that there was a high public interest in these activities continuing and that PHE had satisfactorily addressed the previous conditions and had provided a suitable annual review that set out the benefits to the activities.

Members also particularly welcomed the public engagement that had been undertaken as part of broader activities and welcomed the proposals that included producing, revising and disseminating patient information leaflets and other materials to meet the needs of different cancer patient groups, and working with professionals to help better explain cancer registration benefits to patients.

Full details of the following pdf documents are available upon request if required:

- PIAG 03(a) 2001 National Cancer Registries Database annual review 2016
- PIAG 03(a) 2001 2016 annual review final outcome (Nov 2016)