Guidelines
for the
Development of ICCR Datasets

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Document history

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Version 0.3	Review by ICCR	October 2012
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Abbreviations

DSC	Dataset Steering Committee
DAC	Dataset Authoring Committee
IARC	International Agency for Research on Cancer
ICCR	International Collaboration on Cancer Reporting
LIS	Laboratory Information System
WHO	World Health Organization
QA	Quality Assurance
CAP	College of American Pathologists
USA	United States of America
RCPath	Royal College of Pathologists
RCPA	Royal College of Pathologists of Australasia
ISO	International Organization for Standardization

1. PURPOSE

The purpose of this document is to describe the development process of International Collaboration on Cancer Reporting (ICCR) cancer datasets. The aim is to ensure that the datasets produced for different tumour types have a consistent style and content, and contain all the parameters needed to guide management and prognostication for individual cancers.

This document will be updated periodically as required in order to maintain its currency and to take advantage of improvements in process which will be achieved as the collaborative process progresses.

2. INTRODUCTION

For a number of years, datasets for the pathology reporting of cancer have been published by many organisations around the world, at national and institutional levels. In the United States of America (USA), the College of American Pathologists (CAP) currently publishes more than 70 'Checklists' for synoptic reporting of all major cancers.[1] In the UK, the Royal College of Pathology (RCPath)[2] publishes cancer datasets and in Australia, the Royal College of Pathologists of Australasia (RCPA) publishes structured protocols for cancer reporting.[3] Moreover, a number of European nations have active programs of a similar nature. These various protocols define the detailed pathology and staging data essential for histological diagnosis, patient management and prognosis with the intention that it is complete, concise, reproducible and in line with international standards and current knowledge. Since all evidence-based cancer protocols are necessarily derived from international peer-reviewed literature, it is inevitable that cancer protocols produced by these various organisations will contain similar data elements, albeit with minor variations.

Recognising that standardised cancer datasets are a prerequisite for national and international benchmarking in cancer monitoring and management, and that pathology reports provide key information on tumour classification, staging and prognostic data, the initial ICCR quadripartite alliance was established to examine the practicability of developing international, evidence-based pathology datasets for all major cancers.

The ICCR recognised that there were benefits that could be gained from international extension of this process:

- Dataset production by a single organisation avoids reduplication of cancer pathology dataset development in many different jurisdictions. Producing datasets is a significant burden upon each country and creates risks for interoperability and international comparison.
- In developing a single international standard it becomes possible to engage international expertise and ensure that there is a common meaning and definition for all data elements with consistent application of value lists.
- The creation of a single, defined, evidence-based dataset for each cancer greatly facilitates electronic implementation by standardising Laboratory Information System (LIS) data structures, terminology bindings and electronic messaging.

Dataset elements

Each cancer dataset comprises a series of elements which are important for the clinical management, staging or prognosis of the cancer e.g., tumour diameter, lymphovascular invasion, or fundamental to the histological diagnosis and conclusion e.g., macroscopic tumour details. Each element is included based on the consensus of the Dataset Authoring Committee (DAC).

An element may be designated as core or non-core by the DAC as described below.

CORE elements

CORE elements are those which are essential for the clinical management, staging or prognosis of the cancer. These elements will either have evidentiary support at Level P2 or above (based on the Hierarchy of Research Evidence for Tumour Pathology[4]). In rare circumstances, where level P2 evidence is not available an element may be made a CORE element where there is unanimous agreement in the DAC. An appropriate staging system e.g., Pathological TNM staging would normally be included as a CORE element.

Molecular and immunohistochemical testing is a growing feature of cancer reporting. However, in many parts of the world this type of testing is limited by the available resources. In order to encourage the global adoption of ancillary tests for patient benefit, International Collaboration on Cancer Reporting (ICCR) includes the most relevant ancillary testing in ICCR Datasets as CORE elements, especially when they are necessary for the diagnosis. Where the technical capability does not yet exist, laboratories may consider temporarily using these data elements as NON-CORE items.

The summation of all CORE elements is considered to be the minimum reporting standard for a specific cancer.

NON-CORE elements

NON-CORE elements are those which are unanimously agreed should be included in the dataset but are not supported by level P2 evidence. These elements may be clinically important and recommended as good practice but are not yet validated or regularly used in patient management.

Key information other than that which is essential for clinical management, staging or prognosis of the cancer such as macroscopic observations and interpretation, which are fundamental to the histological diagnosis and conclusion e.g., macroscopic tumour details, may be included as either CORE or NON-CORE elements by consensus of the DAC.

Permitted responses

Permitted responses refer to the range of standardised responses that are used to describe an element e.g., present, absent.

Evidence

A review of evidence in the latest peer-reviewed literature is necessary to ensure that the dataset contains the most recent, validated information pertaining to a given cancer. Where applicable, citations must be included to direct the reader to the evidence justifying inclusion of a data item in the dataset.

The World Health Organization (WHO) Hierarchy of Research Evidence for Tumour Pathology published by Colling R, Indave I, et al. 2024[4] is used (Refer to Appendix A).

Where no reference is provided, the authority is the consensus of the DAC.

Commentary

Commentary is explanatory text, diagrams or tables that clarify the elements used to:

- define the way an item should be reported, to ensure clarity and conformity;
- explain why an item is included (e.g., how does the item assist with clinical management or prognosis of the specific cancer);
- cite published evidence in support of the element; and
- state any exceptions or issues.

Commentary is designed to provide contextual guidance to the reporting pathologist.

3. DATASET SCOPE

In general, ICCR datasets cover malignant entities, either alone or in association with other pre-cancerous or non-invasive components.

Dataset scope does not cover non-malignant entities alone except in certain circumstances:

- For anatomical areas such as the heart and central nervous system, benign tumours are included in the scope as even a benign condition has serious prognostic implications.
- Tumours of uncertain malignant potential.
- In cases where in situ neoplasia is relevant the scope may cover both invasive and non-invasive tumour components.

4. DATASET DEVELOPMENT PROCESS

This section explains the process of developing ICCR cancer datasets. The process, described in detail below, involves:

1. Selection of a Dataset Series Champion, for the development of a suite of datasets across a specific anatomical area/organ system
2. Selection of the chair(s) of the DAC
3. Selection of the DAC members and for each dataset
4. Review of relevant, published cancer datasets and key publications
5. Draft a proposed dataset
6. Committee review of the draft dataset to identify areas of agreement and discord, to focus further discussion
7. Undertake a series of committee discussions to agree and finalise the dataset
8. Format the dataset to the ICCR standard
9. ICCR quality review prior to open consultation
10. Open consultation of the dataset
11. Feedback on the dataset
12. Publication of the dataset on the ICCR website following ratification by the ICCR Dataset Steering Committee (ICCR DSC)
13. Publication of an academic review in a peer reviewed journal.

Step 1: Selection of a Dataset Series Champion, for the development of a suite of datasets across a specific anatomical area/organ system

For the development of a suite of datasets in a specific anatomical area that are to be developed synchronously, the ICCR DSC will select an appropriately qualified expert pathologist to the role of Series Champion. The Series Champion will engage with each of the ICCR DACs in the series, as well as provide advice and support to the ICCR DSC on matters relating to the specific anatomical series under development.

Representatives on the DSC committee are requested to provide the ICCR DSC with names of potential candidates. This will include those authors engaged in the relevant International Agency for Research on Cancer (IARC)/WHO Classification of Tumours 'Blue book' series. ICCR DSC members should also consult with relevant organisations and societies during this nomination process. Potential candidate(s) will be circulated to the ICCR DSC for review and a final determination of candidate will be made at the next meeting. The final determination will take into account the desired personal attributes, geographical representativity and position responsibilities as documented below. Once agreed by the committee, an informal approach to the candidate will be made, and following its acceptance, a formal invitation from the ICCR will be sent.

The role of Series Champion is vital to the success of ICCR dataset development and as such the candidate will have the following essential personal attributes:

- have demonstrated leadership and expertise in the specific anatomical area to be developed (proven based upon bibliography);
- have editorial experience;
- be authoritative, interactive and consensual in approach; and
- be available to lead the development process of the dataset suite.

Step 2: Selection of the Chair of the Dataset Authoring Committee (DAC)

The ICCR DSC, having selected a specific cancer dataset or datasets for development, will identify, in consultation with the Dataset Series Champion if appointed, an appropriately qualified expert pathologist to take on the role of Chair of the DAC. On occasion two pathologists may be appointed as co-Chair, particularly if more than one dataset is to be developed or updated by the one DAC.

The Chair should:

- have acknowledged expertise and leadership in the specific cancer field;
- have experience in writing academic papers in peer-reviewed journals, or previous experience in the development of structured reporting guidelines for the specific cancer;
- be an advocate of structured reporting;
- be committed to undertaking elements of writing the dataset as necessary within the specified timeframe;*
- be able to manage and lead the development of the dataset; and
- be able to gain consensus.

* It should be noted that in the event that the Chair is experiencing difficulties in meeting development timeframes, a co-Chair may be appointed to assist at the discretion of the ICCR DSC.

Step 3: Selection of the Dataset Authoring Committee (DAC) members

The Chair of the specific DAC will identify potential domain specialists in consultation with the ICCR DSC (refer to Figure 1). The ICCR DSC will consult with the Dataset Series Champion, if appointed, in the discussion and decisions related to the appointment of the DAC.

The domain specialists will consist of pathologists and usually one or more relevant clinicians such as a surgeon, medical oncologist or radiation oncologist. The DAC should comprise approximately 8-12 people, however in some highly specialised areas the group may be smaller.

Identification of domain specialists should take into account the following criteria:

- a level of expertise *in the specific cancer* such as:
    - experience in writing or reviewing academic papers in peer-reviewed journals
    - authorship of relevant WHO or staging publications
    - previous experience in the development of structured reporting guidelines
    - high volume practical experience i.e., subspecialisation in the specific area
    - participation in clinical trials and other published research in the relevant field.
- geographic and linguistic diversity;
- gender diversity; and
- the inclusion of both seasoned experts as well as up and coming pathologists in the field.

In addition, all domain specialists should:

- be committed to structured reporting in pathology.
- be committed to reviewing the dataset during its development process and providing feedback in a timely manner. Feedback must be provided via email or attendance at the first DAC meeting to meet ICCR DAC contribution criteria. Please refer to the procedure for non-responders in section 8 of the *Roles and Responsibilities for the ICCR dataset development process* document.
- be committed to participate in writing of the dataset and associated journal article, as necessary.
- able to work in a culturally diverse team.

Nominations of potential domain specialists by the DAC Chair, Dataset Series Champion or ICCR DSC should include relevant supporting information as to their level of expertise or experience according to the above criteria, if requested by the ICCR DSC.

The ICCR DSC, in consultation with the Dataset Series Champion if appointed, will review and validate the list of nominated domain specialists. Once ratified, invitations will be extended to the domain specialists of the DAC. On agreeing to participate, domain specialists are asked to sign:

a. a conflict of interest document to ensure an impartial participation in the development process, and
b. a license of copyright to the ICCR to allow ICCR to use, copy and publish the dataset. (Note this does not transfer ownership of the copyright in the content which remains with the author).
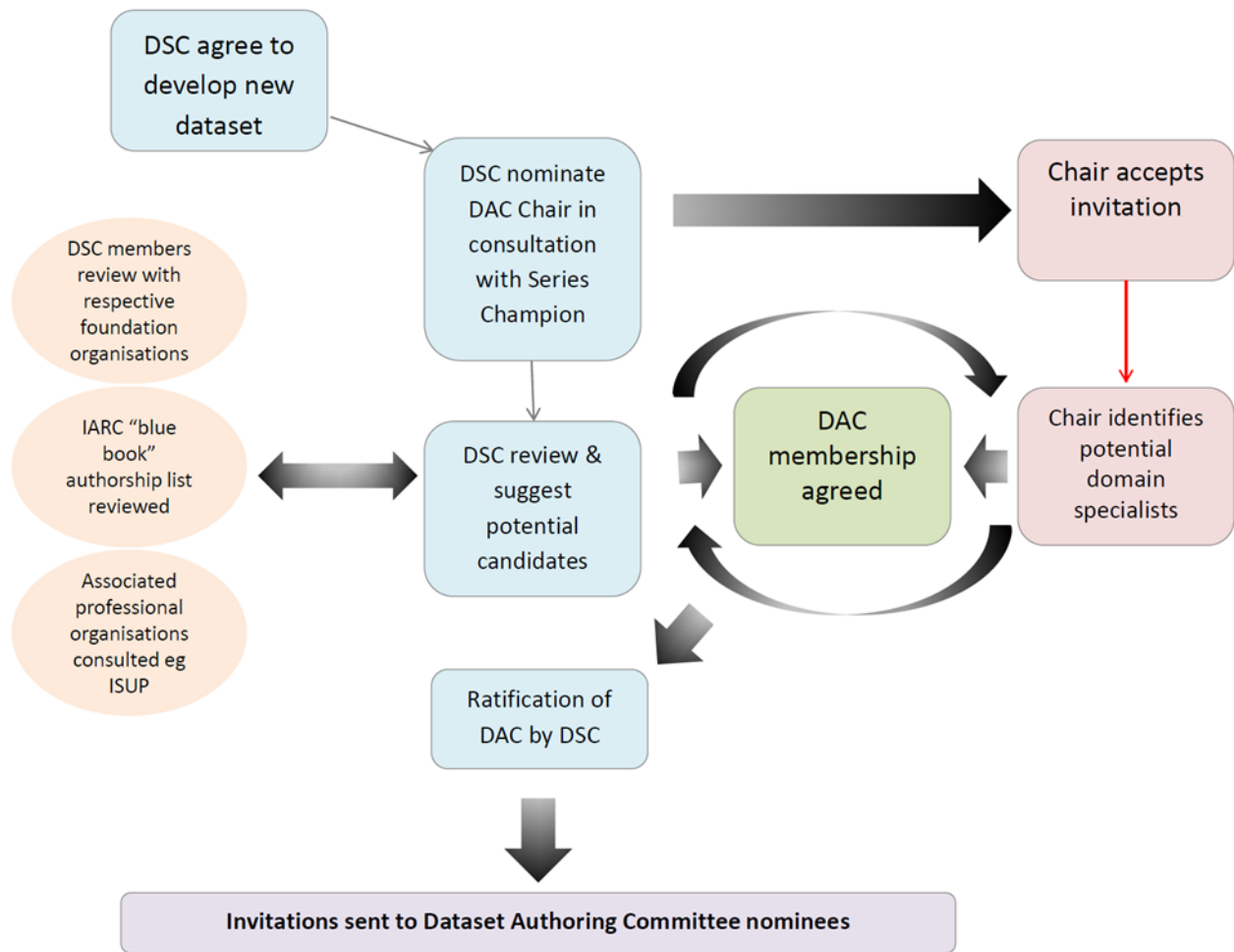
Figure 1: ICCR Dataset Authoring Committee formation.

Step 4: Selection of the ICCR DSC representative

The ICCR DSC representative role is to act as a liaison between the DSC and DAC, to consult the DSC on overarching dataset decisions and ICCR standards; and support the chair with any issues of this nature.

The ICCR DSC representative should:

- provide guidance and support to the Chair as applicable, regarding ICCR standards and authoring committee participation.
- undertake a quality assurance role, overseeing the process specifically around the nomination of core/non-core elements and evidentiary review.
- work with the Project Manager throughout the process to resolve any of the above.

There is particular value for this role in providing representation on issues where DAC members have requested that the DSC review an ICCR standard (such as units of measurement), or the categorisation of elements (such as ancillary testing elements) etc.

Step 5: Review of existing, relevant, published cancer datasets

A search for all published cancer datasets covering the specific cancer to be developed is undertaken by the ICCR Project Manager. This scan includes review of datasets, protocols or checklists published in review articles or other international websites.

This set of cancer datasets forms the foundation for a comparative review in which elements which are core (required) in any one or more of these datasets is extracted for consideration along with all responses and commentary.

Step 6: Draft a proposed dataset

An initial document of proposed elements is developed by the ICCR Project Manager in conjunction with the Chair of the DAC. This document puts forward proposed elements following review and consideration of the mandatory/required/core elements from each of the submitted/published datasets (Step 3). Of particular importance is how each dataset has approached a particular topic (e.g., extent of invasion), what responses have been used and what evidentiary support is provided.

The proposal aims to incorporate the best approach of each of the protocols/datasets/proformas in as simple a manner as possible. Each proposed element includes a recommendation as to whether the element should be core or non-core, the proposed responses; evidentiary support for those elements proposed as core and any commentary to assist in conformance and understanding of the element.

Step 7: DAC review of the proposed dataset to identify areas of agreement and discord, to focus further discussion

In this step the proposed elements from Step 5 including responses, evidentiary support and commentary are formatted into an interactive document (e.g., active PDF), which is circulated to the DAC who are asked to provide the following feedback on each proposed element:

- Whether or not they agree to the element name with the opportunity to comment on any issues they feel are important to document and which will direct further discussion.
- Whether or not they agree with the response type and values for the proposed element with the opportunity to propose alternative or amended responses.
- Whether the element should be core or non-core. A review of the evidentiary support (at Level P2 evidence or greater) included for any core element should be undertaken and expanded where possible.
- Any commentary deemed essential for inclusion with the element, to ensure conformity in measurement or meaning of the element may be included at this step or may be added following DAC discussion in a later step.
- Whether there are additional elements not described in the proposed dataset which should be considered by the DAC.

Step 8: Undertake a series of committee discussions to agree and finalise the draft dataset

The DAC will usually require around three meetings (by teleconference/web meeting) to produce a robust draft of the dataset. During the calls individual elements are discussed and notes are recorded. Selected members may be asked to provide further information or undertake additional investigation of the evidence.

Step 9: Formatting the dataset to the ICCR standard

The cancer datasets are published in a specific format called a REPORTING GUIDE ('guide') which includes the elements, responses and all explanatory text.
The potential users of the datasets may not have continued access to the internet and, therefore, the English version of each guide is published in three formats as follows:

1. A hyperlinked guide to be viewed online (a valid internet connection is required). Explanatory text associated with an element is available by clicking on the 'open book' icon.
2. A bookmarked guide which can be downloaded and viewed on screen or printed. When printed, the notes can be looked up manually. When viewed on screen the bookmarked notes enable navigation to the explanatory text.
3. A MS Word document which includes the dataset content to assist with implementation.

Different text characteristics are used to visually differentiate 'core' elements from 'non-core' elements in both guides.

The ICCR Project Manager will develop the guides from the final draft dataset document produced in Step 7. Development includes:

- Seeking permissions to include copyright material in the dataset e.g., Figures, Tables, TNM staging, WHO Classification of Tumours etc.
- Check for errata of any co-dependent publication (such as TNM staging, WHO classification) and include the latest errata publication date in the dataset.
- Review of the elements and responses against the *ICCR Harmonisation Guidelines* document to ensure conformance to standard terminology across all of the ICCR datasets.
- Citing all references.

The draft guide is circulated to the DAC for final review and approval to proceed to open consultation. All members of the DAC must give their approval of the draft guide before the ICCR can proceed to open consultation.

Step 10: ICCR quality review prior to open consultation

Once finalised, the draft guides are reviewed by the ICCR DSC.

ICCR draft datasets are circulated to the ICCR DSC as a quality assurance review for the purpose of:

- Ensuring a quality process has been followed and the resultant dataset meets the standards of the ICCR as determined by the ICCR DSC.

- The number and type of elements (core and non-core) are reasonable and not onerous.
- The dataset is suitably formatted for public review.
- The dataset content is:
  - not contradictory,
  - matches between the guide and the notes,
  - fully referenced.

ICCR DSC members may circulate the draft dataset to their organisation/committees for review. However, any comments received will be considered alongside those received during open consultation.

A minimum of 50% of member organisations represented on the ICCR DSC is required to proceed to open consultation of any given dataset/suite of datasets.

The DSC Quality Assurance (QA) sub-committee provides an in depth review of the draft dataset at this time.

Feedback on the draft dataset from the ICCR DSC and/or the DSC QA sub-committee may necessitate amendments, in agreement with the Chair of the DAC.

Step 11: Open consultation of the dataset

Once approved to proceed to open consultation, the guides are posted as draft documents to the ICCR website for a period of eight weeks. Notifications are sent out to key ICCR stakeholders with the link and instructions for review and feedback.

Step 12: Feedback on the dataset

Feedback from open consultation is collated and reviewed by the DAC. Responses are formulated and amendments made to the dataset. Final approval by all members of the DAC is required to progress publication of the dataset.

All feedback received and responses from the DAC are anonymised and made available on the website when the datasets are published.

A final review of errata of any co-dependent publication, such as TNM staging and WHO classification, will be undertaken and the errata publication date updated in the dataset.

Step 13: Publication of the dataset on the ICCR website

The datasets are finalised after Step 11 and are submitted to the ICCR DSC for ratification and then published on the ICCR website. A minimum of 50% of member organisations represented on the ICCR DSC is required to proceed to publication of any given dataset/suite of datasets.

Each dataset is published in English as two guides (described in Step 9), and in addition, to facilitate implementation, a MS Word version of the information is provided.

On publication, the bookmarked versions of those datasets scheduled for translation are provided to an International Organization for Standardization (ISO) accredited organisation capable of translating the datasets into other languages. Once approved for publication, these are published to the appropriate language pages on the ICCR website.

Step 14: Publication of an academic review in peer reviewed journal

The final step in the process is for the DAC to produce an article for peer review publication in a journal on the dataset explaining the rationale behind the dataset elements.

Authorship of the manuscript should be confined to the DAC membership to ensure concurrency with the dataset.

Authorship of the manuscript will generally be in the order of chair of the group/lead author, followed by DAC members in alphabetic order, with the Series Champion last. In some cases, the ICCR DSC representative is included (if they have been an active contributor to the development). The ICCR Project Manager is included in the authorship list, most usually as second author.

Manuscripts are submitted to applicable peer review journals as recommended by the Chair and Series Champion (where applicable).

The ICCR DSC will retain oversight of the development of any article produced from this process.

5. PERMITTED MODIFICATIONS

Core and Non-core elements

The use of the terms core and non-core, are based on the availability of the evidence in support of the element. Implementation of these terms may vary between organisations.

Additional elements

The ICCR has initially focused on the needs of clinicians defining those reporting elements which are core and non-core for the clinical management, staging or prognosis of cancer.

However, there are other elements which are not included in the ICCR datasets but which users may wish to include in their local datasets. These elements fall into three categories:

1. Additional core or non-core elements which are necessary to reflect the complete diagnostic picture.
2. Those elements which are important to be *recorded* but not necessarily included in a report. This assumes that there is the capability in the LIS in use to record data elements which may or may not be included in the actual report and that the report can be tailored according to the intended audience.

3. Those elements which are required for national or local reporting or research.

Use of the ICCR datasets does not preclude recording any of the above elements as part of the reporting process.

6. UPDATES TO DATASETS

Datasets will be scheduled for update in synchrony with revisions to the WHO Classification of Tumours.

Additional updates may also be undertaken as a result of harmonisation of datasets within a series, an error, changes to dependent publications, such as staging systems or significant changes in clinical or diagnostic evidence, or management related to a specific cancer.

New edition

A new edition of a dataset is categorised as either a *minor* or *major* revision depending on the type of modifications required.

Minor revision

 A minor revision may be initiated by such changes as:

1. The addition of a new non-core element;
2. Rewording of commentary which does not change the meaning of an element, but further clarifies it;
3. A change to the name of an element (for example, Tumour Dimensions to Maximum Tumour Dimension or a response that does not substantially change its meaning (for example, changing a response from 'absent' to 'not identified'); or
4. The downgrading of a core element to a non-core element.

Major revision

A major revision is generated by such changes as:

1. Updates to dependent publications such as to:
    a. The WHO Classification of Tumours; and/or
    b. Staging systems e.g., International Union Against Cancers (UICC), American Joint Committee on Cancer (AJCC), and International Federation of Gynecology and Obstetrics (FIGO).
2. Upgrading of a non-core element to a core element.
3. The addition of a core element e.g., as a result of new scientific evidence, evidence-based changes in cancer management, or new ancillary tests.
4. The deletion of any element (core or non-core).
5. A change in the commentary which alters the meaning of the element, the response/s or the way in which the response is recorded. If a value/response is changed by the description provided in the commentary or the way in which a calculation or measurement must be made, this requires a major revision.

Public consultation

A minor update will <u>not</u> require a period of public consultation before publication.

For a major update that is limited to changes directly related to modifications to dependent publications, a period of public consultation may not be required.

A major update which includes changes related to modifications to dependent publications as well as one or more criteria listed above may require a period of public consultation.

The final decision as to whether a major update requires a period of public consultation will be made by the ICCR DSC, in consultation with the Series Champion, Chair of the relevant DAC and ICCR Project Manager.

Update process

For all revisions, a Chair will be appointed by the ICCR DSC to oversee the update process. This may be the Chair of the original DAC or a new Chair. The Chair, in conjunction with the Series Champion, will recommend domain specialists to participate in the DAC. This may include members of the original DAC, as well as new members. Once the process of dataset revision is completed, the dataset will be approved by the ICCR DSC for publication on the ICCR website.

Those datasets scheduled for translation will be provided to the designated translating organisation for translation of the update into other languages. Once approved for publication, these updated datasets will be published to the appropriate pages on the ICCR website.

ICCR errata

This form of update is used to correct minor errors within a published dataset, such as corrections of spelling, punctuation or typography, or to update cited references that have moved from 'in press' to being published.

An errata update will be undertaken as needed. The ICCR DSC will appoint a ICCR Project Manager to oversee the update. The ICCR Project Manager will liaise with the original Chair of the DAC, where necessary. Once completed, the dataset will be published to the ICCR website.

Errata and updates to co-dependent publications

Staging and classification systems are integral to ICCR Datasets. However, these systems are subject to continued review, periodic revision and publication of errata.

To ensure accuracy in ICCR datasets, each dataset which includes a staging or classification system will include the date of the errata/corrigenda that was reviewed and incorporated into the dataset.
In addition, a yearly review of staging errata and corrigenda, and any updates or revisions to staging and classification systems that have occurred in the previous year, will be undertaken and discussed by the ICCR

DSC. Those modifications deemed important to include in the datasets will be identified and updates to affected datasets scheduled.

Numbering

Each revision of a specific dataset, whether categorised as minor or major, will be denoted by an incremental number e.g., ICCR Lung Cancer Dataset 2.0 denoting the 2nd published edition of the Lung Cancer Dataset. It is also represented by a new ISBN and publication date.

An errata revision, as it is minor in nature, is represented by an incremental update to the revision number of the dataset e.g., ICCR Lung Cancer Dataset 2.1 denotes an errata update to the 2nd published edition of the Lung Cancer Dataset. The publication date for an errata revision remains the same as the publication date of the edition, as does the ISBN.

7. PATIENT IDENTIFICATION

The following are the agreed minimum patient identification data included in the datasets:

- Given Name (forename)
- Family Name (surname, last name)
- Date of Birth
- Patient identifier e.g., medical record number, national identification number etc.
- Request date
- Accession/Laboratory Number.

Local and National requirements may influence the configuration of these elements and necessitate the inclusion of additional elements or the replacement of some of these elements. Use of the ICCR dataset does not preclude any of these changes and the patient demographic list above is provided as a guide only.

8. ICCR HARMONISATION GUIDELINES

As part of the ICCR process, harmonisation of the cancer data element names as well as the responses is undertaken to ensure consistency across all datasets. Common cancer elements e.g., tumour site, margin status and response terms e.g., 'absent' versus 'not identified', are defined and recommended uses and groupings of responses are documented for application across all datasets. The ICCR Harmonisation Guidelines are not a comprehensive list of all possible terms but rather seek to describe common terms and may differ with specific use cases.

9. IMPLEMENTATION CONSIDERATIONS

Successful implementation of the ICCR cancer datasets requires consideration of the following elements:

- Local and national pathology reporting standards
- Interdisciplinary communication
- Electronic implementation
- Change management
- Governance.

10. STAKEHOLDERS

Lead organisations will be used to disseminate notifications for open consultation. Stakeholders may include:

- Pathologists and their professional organisations
- Clinicians and their professional or subspecialist organisations
- Cancer registries
- Patients and their organisations
- Special interest groups.

REFERENCES

1   College of American Pathologists (2025). *Cancer protocols and checklists.* Available from https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates (Accessed 13th January 2025).

2   Royal College of Pathologists (2025). *Cancer datasets and tissue pathways.* Available from: https://www.rcpath.org/profession/guidelines/cancer-datasets-and-tissue-pathways.html (Accessed 13th January 2025).

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APPENDIX A HIERARCHY OF RESEARCH EVIDENCE FOR TUMOUR PATHOLOGY

Table 1: World Health Organization Hierarchy of Research Evidence for Tumour Pathology.[4]

WCT topics:	Etiology		Clinical features, Radiology, Localisation, Macroscopy, Histopathology, Immunohistochemistry, Cytology	Diagnostic molecular pathology Diagnostic immunohistochemistry	Prognosis, Staging	Prediction
	Epidemiology, Prevalence, Incidence, Risk factors	Mechanisms & Pathogenesis				
Research focus:	Population	Cellular, molecular & genetic biology	Pathological characterisation and diagnosis of the tumor	Diagnostic tests (accuracy) and reproducibility (precision)	Prognostics	Predictive biomarkers
Example questions:	How common is this tumour? What factors influence the probability of developing this tumour? Who is at risk?	What are the molecular alterations in this tumor? What mechanisms cause this tumor?	What are the key features of this tumor? How to we define the tumor?	How well does this test confirm the diagnosis?	What features influence five-year survival?	Can this marker predict treatment?
Level P1	*Systematic reviews**	*Systematic reviews**	*Systematic reviews**	*Systematic reviews**	*Systematic reviews**	*Systematic reviews**
Level P2	*Population-based descriptive studies* *Prospective cohort studies* *Randomised-controlled trials*	*Prospective cohort studies* *Studies derived from randomised-controlled trials*	*Case-control studies* *Diagnostic agreement/reproducibility studies* *Diagnostic test accuracy studies* *Prospective cohort studies* *Studies derived from randomised-controlled trials*	*Case-control studies* *Diagnostic agreement/reproducibility studies* *Diagnostic test accuracy studies* *Prospective cohort studies* *Randomised-controlled trials (of diagnostic tests)* *Studies derived from randomised-controlled trials*	*Prospective cohort studies* *Studies derived from randomised-controlled trials*	*Prospective cohort studies* *Randomised-controlled trials* *Studies derived from randomised-controlled trials*
Level P3	*Case-control studies* *Retrospective cohort studies* *Other cross-sectional studies*	*Case-control studies* *Mechanistic clinical studies* *Other cross-sectional studies* *Retrospective cohort studies*	*Consensus studies* *Other cross-sectional studies* *Retrospective cohort studies*	*Case series* *Consensus studies* *Other cross-sectional studies* *Retrospective cohort studies*	*Case-control studies* *Observational trials* *Other cross-sectional studies* *Retrospective cohort studies*	*Case-control studies* *Retrospective cohort studies*
Level P4	*Case series*	*Animal studies* *Case series* *Mechanistic laboratory studies* *Molecular database studies* *Observational trials*	*Case series*	*Clinical laboratory test validation studies*	*Diagnostic test accuracy studies* *Population-based descriptive studies*	*Diagnostic test accuracy studies*
Level P5	*Case reports*	*Case reports*	*Case reports*	*Not used*	*Case reports* *Case series*	*Case reports* *Case series* *Mechanistic clinical studies*

The hierarchy is arranged at the top level to map to the various sections of the World Health Organization Classification of Tumours, that is, matching chapter headings/subheadings as far as possible to cover all topics discussed in the series. The various headings are grouped into similar research topics of interest, such as tumour characteristics, prognostics, and so forth. The levels presented below are in order of robustness, that is, level P1 having the greatest confidence and level P5 the lowest. Each P level for each subsection contains the list of evidence types that rank at that level (in alphabetical order, no intralevel ranking implied). Most types of evidence can be thought of as 'studies' but not all. Studies of rare tumours (defined here as those with an incidence of <1/million population/annum) are automatically upgraded to 1 level. This would include case reports that may be the only unique diagnosis of its type in the literature. Large sample size level P2 studies should be upgraded to level P1. This table should be used in conjunction with the glossary (Supplementary File 2) as the terms used may be different from those that some readers may be used to. * Systematic reviews predominantly including level P2 studies. Systematic reviews of predominantly level P3-P5 studies are placed in level P2. Rapid reviews are placed in level P2.