

Roles and Responsibilities for the ICCR Dataset Development Process

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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
WHO	World Health Organization
COI	Conflict of interest
UICC	International Union Against Cancer

1. PURPOSE

International Collaboration on Cancer Reporting (ICCR) dataset development involves commitment to a quality process. The *Guidelines for the Development of ICCR Datasets* document outlines the steps to be undertaken:

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 Dataset Authoring Committee(s) (DAC)
 3. Selection of the DAC members
- and for each dataset:
4. Review of relevant, published cancer datasets
 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
 13. Publication of an academic review in peer reviewed journal.

This document outlines the roles and responsibilities of the following participants in the dataset development process:

- ICCR Dataset Series Champion
- Chair, DAC
- ICCR Dataset Steering Committee (DSC) representative
- Domain specialists, DAC.

An ICCR Project Manager is also included as part of every DAC.

Refer to Organisational Chart (Appendix B).

Each of these roles and their responsibilities is discussed in detail below.

2. ICCR DATASET STEERING COMMITTEE (DSC)

The ICCR DSC will:

- Select an appropriately qualified Dataset Series Champion if a suite of datasets is to be developed synchronously for a single anatomical area e.g., Genitourinary, Breast, Bone and soft tissue, Head and Neck, Endocrine etc.
- Select the Chair(s) of the DACs.
- Ratify the Domain specialist nominations. The ICCR DSC will resolve any jurisdictional issues (perceived or real) within the Domain specialists in conjunction with the Chair.
- Nominate one of their membership to participate on each ICCR DAC.
- Review and endorse the final dataset prior to open consultation and publication.
- Review and resolve any conflicts of interest (COI) that arise.

3. ICCR DATASET SERIES CHAMPION

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 engage with all of the ICCR DACs in the series.

The ICCR Dataset Series Champion will have the following responsibilities:

- Sign a COI document and maintain an awareness of any potential COI in relation to the project, and immediately notify the ICCR Project Manager of any potential or perceived COI.
- Provide advice and support to the ICCR DSC on the choice of DAC Chairs.
- Provide advice and support to the Chairs of the DACs within their specific anatomical series to ensure harmonisation across the datasets under development.
- Assist the Chairs of the DACs in the identification and nomination of domain specialists.
- Provide a conduit of communication between DACs within the series and with the ICCR DSC.
- Treat all individuals in the process with respect and professionalism.
- Be positive and supportive of the ICCR process in all communications external to the ICCR.
- Be available and place high priority on the ICCR development process in order to meet the agreed timeframes.
- Assist the Chairs of the DACs in any conflict resolution including dealing with non-responders on the committee.
- Work closely with the ICCR DSC representative and ICCR Project Manager throughout the development of the dataset(s) to ensure adherence to the ICCR process.

4. CHAIR, DATASET AUTHORIZING COMMITTEE (DAC)

The ICCR DSC, having selected a specific cancer dataset or dataset series for development, will invite appropriately qualified expert pathologist(s) 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(s) of the DAC is required to:

- Sign a COI document and maintain an awareness of any potential CIO in relation to the project, and immediately notify the ICCR Project Manager of any potential or perceived COI. For continued participation in the DAC, the signed COI document must be returned prior to the first meeting of the DAC to the ICCR Project Manager.
- Sign 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). For continued participation in the DAC, the signed copyright licence must be returned to the ICCR Project Manager prior to the first meeting of the DAC.
- Nominate on average 8-12 domain specialists (comprising expert pathologists, and where applicable 1 or more clinicians) for review and endorsement by the ICCR DSC. These nominations should, where possible:
 - represent international expertise in this cancer field
 - be geographically and linguistically diverse
 - include reasonable gender distribution
 - include both seasoned experts and up and coming pathologists in the field
 - work effectively as part of a team
 - support structured pathology reporting of cancer
 - be committed to deliver a quality outcome.
- Lead the DAC seeking the best input from all participants.
- Treat all individuals in the process with respect and professionalism.
- Be positive and supportive of the ICCR process in all communications external to the ICCR.
- Be able to author/edit sections of the dataset as required.
- Be available and place high priority on the ICCR development process in order to meet the agreed timeframes. 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.
- Respond in a timely manner to all communications.
- Act as the arbitrator amongst the group and seek consensus.
- Adhere to the definitions of core/non-core elements – ensuring adequate evidence is cited in support of core elements.
- Work closely with the ICCR DSC representative, ICCR Dataset Series Champion (where is applies) and ICCR Project Manager to ensure adherence to the ICCR process.
- Support the ICCR process of harmonisation of element and value names.
- Lead the authorship of an academic article on the ICCR dataset for submission to a peer-reviewed journal or propose a suitable DAC member to undertake this role if they are not able to.

- Manage participation of committee members; addressing matters of non-responsiveness or dispute at their discretion and with the assistance and advice of the ICCR Dataset Series Champion and ICCR DSC representative.

The role of Chair is vital to the success of ICCR dataset development. The ICCR DSC maintains the right to remove a Chair who is not able to commit to the above responsibilities, or fails to meet the above expectations during the development process. A Chair will be asked to step down from the role in the event that the Chair:

- Is unavailable for a period of time which delays development for more than 3 months past the agreed timeframe;
- Does not respond in a timely manner to others on the DAC, the ICCR Project Manager or Dataset Series Champion;
- Has a COI which the ICCR DSC deems irreconcilable with the development process; and/or;
- Engages in unprofessional conduct as determined by the ICCR DSC.

5. ICCR DATASET STEERING COMMITTEE (DSC) REPRESENTATIVE

The ICCR DSC will elect a representative to participate on its behalf on an ICCR DAC in the event of a single dataset development or to a dataset series if a suite of datasets in a specific anatomical area are to be developed synchronously.

The ICCR DSC representative is not chosen specifically for their expertise or interest in a specific cancer area, however, this will be taken into consideration.

The ICCR DSC representative will:

- Act as a liaison between the DSC and DAC. This is important because the Dataset Series Champion and/or Chair(s) of the DAC are not usually members of the DSC. DSC members can assist the development process by bringing an understanding of the purpose and goals of the ICCR, its standards, and development directives and expectations regarding committee participation.
- Provide guidance and support to the Dataset Series Champion and/or Chair(s) of the DAC as applicable, regarding ICCR standards and authoring committee participation.
- Represent the DAC on issues that have been referred to the DSC for consideration and decision.
- Undertake a quality assurance role, overseeing the process specifically around the nomination of core/non-core elements and evidentiary review.
- Work closely with the ICCR Project Manager throughout the process to resolve any issues.

6. DOMAIN SPECIALISTS, DAC

Domain specialists on the DAC are required to:

- Sign a COI document to ensure an impartial participation in the development process. For continued participation in the DAC the signed COI document must be returned to the ICCR Project Manager prior to the first meeting of the DAC.
- Sign 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). For continued participation in the DAC the signed copyright licence must be returned to the ICCR Project Manager prior to the first meeting of the DAC.
- Be supportive of the objectives of the ICCR and its goal to encourage structured pathology reporting of cancer.
- Be available and place high priority on the ICCR dataset development process, including the journal article, in order to meet the agreed timeframes. DAC members are required to provide written approval for the draft dataset to be sent for open consultation and publication and for the journal article to be submitted for publication.
- Provide feedback in a timely manner. Feedback must be provided via email or attendance at the first DAC meeting to meet ICCR contribution criteria. If a member fails to meet the contribution criteria they are deemed to have retired and will be removed from the committee (refer to Section 8 Non-responders). Note that substitutions are not permitted to the DAC. If a DAC member is not able to attend a meeting then they should send in comments via email.
- Work cooperatively as part of a team.
- Treat all individuals in the process with respect and professionalism.
- Be able to work in a culturally diverse team.
- As the work of the DAC is in English, a good command of the English language is needed.
- Be able to author/edit sections of the dataset or article for publication as required.
- Where applicable, eligibility for retired professionals to join the DAC should be limited to within one year since retirement.
- Keep the work of the ICCR DAC confidential until such time as public comment is invited. Though DAC members may be members of other key stakeholder groups, they are invited to the ICCR DAC as an individual representing themselves. Other stakeholder groups will be invited to comment on the draft dataset at the open consultation phase.
- Be familiar with the definitions of core/non-core elements.
- Work closely with the ICCR Project Manager and Chair throughout the process.

7. WORLD HEALTH ORGANISATION (WHO)/INTERNATIONAL AGENCY FOR RESEARCH ON CANCER (IARC) VOLUME EDITOR

World Health Organization (WHO)/International Agency for Research on Cancer (IARC) may nominate an appropriate representative to liaise with the DAC(s) and advise on synchronisation with IARC publications if deemed appropriate by the ICCR DSC.

8. NON-RESPONDERS

‘Non-responders’ are defined as those DAC domain specialists who have accepted the ICCR invitation to participate but with whom no communication on the dataset content is received up to and including the first meeting in the development or update process.

It is the responsibility of the ICCR Project Manager to identify potential non-responders and to ensure adequate follow-up and reminders are provided to maximise the opportunities for response, including escalation to the DAC Chair, Series Champion and Chair of the ICCR DSC. In the event that this is unsuccessful, the DAC Chair or Series Champion, will be asked to send an email to the non-responder advising them they have failed to meet the contribution criteria for DAC members and they are deemed to have retired and are removed from the DAC and authorship of the dataset.

9. DATASET AUTHORIZING COMMITTEE (DAC) TASKS

A DAC is responsible for the development of a cancer dataset. The goal of the DAC is to create a practical dataset that can be used for a broad audience, including lower and middle income countries.

Each dataset will contain the following components:

1. 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 Pathology¹). 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.

2. 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.

3. Commentary

Commentary is based on a review of the current literature and comprises explanatory text, diagrams or tables that clarify core and non-core elements. It is used to:

- define the way an element should be reported, to ensure clarity and conformity
- explain why an element 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
- state any exceptions or issues.

Commentary is essential for core elements and optional for non-core elements.

Commentary is designed to provide contextual guidance to the reporting pathologist. It is implemented in the ICCR guides as contextual help linked to each element to assist the reporting pathologist. For this reason, consideration should be given as much as possible to diagrammatic images wherever these might assist.

4. References for cited evidence

Citations of published literature must be included where applicable.

Evidence

The DAC must apply levels of evidence wherever possible. A review of evidence in the latest peer-reviewed literature is necessary to ensure that the dataset is up to date with the most current evidence-based information.

Core elements based on consensus alone should be avoided unless they are essential for staging, management or prognosis.

The World Health Organization (WHO) Hierarchy of Research Evidence for Tumour Pathology published by Colling R, Indave I, et al. 2024¹ is used (Refer to Appendix A). Where no reference is provided, the authority is the consensus of the DAC.

Third party Copyright

During the writing process, care should be taken to note where permission needs to be sought for the use of diagrams, tables, or blocks of text from copyrighted material which is to be included in the dataset e.g., International Union Against Cancer (UICC) TNM. It is essential that copyrighted material be identified during the process because permission needs to be sought to use the material prior to publication of the dataset.

Authoring notes

- The rendering, formatting and informatics relating to the developed cancer datasets are outside the scope of the DAC.
- Similarly, patient-specific details, demographics and clinical content will not be considered as inclusion of these items in datasets varies in different countries.
- The naming conventions for elements and value lists will be subject to a harmonisation process so that the specific style or spelling need not be considered, e.g., tumor versus tumour, lymphovascular invasion versus lymph-vascular invasion. ICCR follows the *WHO Style Guide 2nd edition* for spelling.

Process steps

- Each DAC will be supplied with:
 - a. Relevant cancer specific published datasets from a variety of jurisdictions (if applicable).
 - b. A proposed dataset document. This document puts forward proposed elements following review and consideration of the core and non-core elements from the various submitted cancer datasets and how they have approached a particular topic e.g., extent of invasion. The proposal aims to incorporate the best of each of the available/published protocols/proformas in as simple a manner as possible. Each proposed element will also include proposed responses and to assist in decision making, evidentiary support for elements where possible.
- Each DAC will be asked to review the proposed elements in the proposed dataset document and to provide feedback. This will include:
 - Whether or not each committee member agrees to the element name response type and values for the proposed element with the opportunity to propose alternate or amended responses.
 - Whether the element should be core or non-core. Evidentiary support (at Level P2 evidence or greater) provided for any core element should be reviewed and expanded on where possible.
 - Any commentary deemed essential for explanation of the element. This is particularly important to ensure conformity in measurement or meaning of the element.
 - Whether there are additional elements not described in the draft dataset document which should be considered by the committee.
- The DAC member will be asked to respond within a specific period of time and the responses will be compiled and circulated to the committee.
- A series of web/conference calls (usually three), will then be organised for the DAC to discuss the feedback provided.

- A final draft document will be circulated and will include:
 - Core and non-core elements
 - Response type and value lists for each element
 - Evidentiary support for core elements at a minimum
 - Commentary where necessary to ensure clarity and conformity.
- The information will then be reformatted into the structure of ICCR guides.

Once the draft datasets are finalised they will undergo a quality review process followed by a period of international open consultation. After the open review period, the DAC will formally review the comments in conjunction with the ICCR Project Manager and changes will be made as deemed appropriate by the DAC. Following this, all submissions from the open consultation period will be anonymised and published on the ICCR website together with the responses from the DAC.

REFERENCES

- 1 Colling R, Indave I, Del Aguila J, Jimenez RC, Campbell F, Chechlińska M, Kowalewska M, Holdenrieder S, Trulson I, Worf K, Pollán M, Plans-Beriso E, Pérez-Gómez B, Craciun O, García-Ovejero E, Michałek IM, Maslova K, Rymkiewicz G, Didkowska J, Tan PH, Md Nasir ND, Myles N, Goldman-Lévy G, Lokuhetty D and Cree IA (2024). A New Hierarchy of Research Evidence for Tumor Pathology: A Delphi Study to Define Levels of Evidence in Tumor Pathology. *Mod Pathol* 37(1):100357.

APPENDIX A HIERARCHY OF RESEARCH EVIDENCE FOR TUMOUR PATHOLOGY

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

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	<i>Systematic reviews*</i>	<i>Systematic reviews*</i>	<i>Systematic reviews*</i>	<i>Systematic reviews*</i>	<i>Systematic reviews*</i>	<i>Systematic reviews*</i>
Level P2	<i>Population-based descriptive studies Prospective cohort studies Randomised-controlled trials</i>	<i>Prospective cohort studies Studies derived from randomised-controlled trials</i>	<i>Case-control studies Diagnostic agreement/reproducibility studies Diagnostic test accuracy studies Prospective cohort studies Studies derived from randomised-controlled trials</i>	<i>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</i>	<i>Prospective cohort studies Studies derived from randomised-controlled trials</i>	<i>Prospective cohort studies Randomised-controlled trials Studies derived from randomised-controlled trials</i>
Level P3	<i>Case-control studies Retrospective cohort studies Other cross-sectional studies</i>	<i>Case-control studies Mechanistic clinical studies Other cross-sectional studies Retrospective cohort studies</i>	<i>Consensus studies Other cross-sectional studies Retrospective cohort studies</i>	<i>Case series Consensus studies Other cross-sectional studies Retrospective cohort studies</i>	<i>Case-control studies Observational trials Other cross-sectional studies Retrospective cohort studies</i>	<i>Case-control studies Retrospective cohort studies</i>
Level P4	<i>Case series</i>	<i>Animal studies Case series Mechanistic laboratory studies Molecular database studies Observational trials</i>	<i>Case series</i>	<i>Clinical laboratory test validation studies</i>	<i>Diagnostic test accuracy studies Population-based descriptive studies</i>	<i>Diagnostic test accuracy studies</i>
Level P5	<i>Case reports</i>	<i>Case reports</i>	<i>Case reports</i>	<i>Not used</i>	<i>Case reports Case series</i>	<i>Case reports Case series Mechanistic clinical studies</i>

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.

International Collaboration on Cancer Reporting

