International Collaboration on Cancer Reporting

Roles and Responsibilities
for the
ICCR dataset development process

Version: 1.8

Document history

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Version 1.8	Approved changes	March 2019

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1. INTRODUCTION

Cancer dataset development involves commitment to a quality process. The document "Guidelines for the Development of ICCR Datasets" 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 **Dataset Authoring Committee** 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:

- o ICCR Dataset Series Champion
- o Chair, Dataset Authoring Committee
- o ICCR Dataset Steering Committee member
- o Project Manager
- o Domain specialists
- o World Health Organisation (WHO)/International Agency for Research on Cancer (IARC) volume editor (as required)

Refer to organisation chart (Appendix B).

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

2. ICCR DATASET STEERING COMMITTEE

The ICCR Dataset Steering Committee will:

- Select an appropriately qualified Dataset Series Champion if a suite of datasets is to be developed synchronously for a single anatomical area eg Genitourinary, Head and Neck, Endocrine etc
- Select the Chair(s) of the Dataset Authoring Committees
- Ratify the Domain specialist nominations. The ICCR Dataset Steering Committee 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 Dataset Authoring Committee
- Review and endorse the final dataset prior to open consultation and publication
- Review and resolve any conflicts of interest 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 Dataset Steering Committee will select an appropriately qualified expert pathologist to engage with all of the ICCR Dataset Authoring Committees in the series.

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, and
- Be authoritative, interactive and consensual in approach.

The ICCR Dataset Series Champion will have the following responsibilities:

- Sign a conflict of interest document and maintain an awareness of any potential conflict of interest in relation to the project, and immediately notify the ICCR Dataset Steering Committee of any potential or perceived conflict of interest.
- Provide advice and support to the ICCR Dataset Steering Committee on the choice of Dataset Authoring Committees chairs.
- Provide advice and support to the Chairs of the Dataset Authoring Committees within their specific anatomical series to ensure harmonisation across the datasets under development
- Assist the Chairs of the Dataset Authoring Committees in the identification and nomination of domain specialists.
- Provide a conduit of communication between Dataset Authoring Committees within the series and with the ICCR Dataset Steering Committee
- 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 Dataset Authoring Committees in any conflict resolution including dealing with non-responders on the committee.
- Work closely with the ICCR Dataset Steering Committee member and Project Manager throughout the development of the dataset(s) to ensure adherence to the ICCR process.

4. CHAIR, DATASET AUTHORING COMMITTEE

The ICCR Dataset Steering Committee, 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 Dataset Authoring Committees.

The Chair, Dataset Authoring Committee is required to:

- Sign a conflict of interest document and maintain an awareness of any potential conflict of interest in relation to the project, and immediately notify the ICCR Dataset Steering Committee of any potential or perceived conflict of interest.
- 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).
- Nominate 8-10 domain specialists (comprising expert pathologists, and where applicable a clinician) for review and endorsement by the ICCR Dataset Steering Committee. These nominations should:
    o represent the best international expertise in this cancer field
    o be geographically and linguistically diverse where possible
    o work effectively as part of a team
    o support structured pathology reporting of cancer
- Lead the committee 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 Dataset Steering Committee.
- 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 Dataset Steering Committee member and Project Manager to ensure adherence to the ICCR process
- Support the ICCR process of harmonization of element and value names
- Lead the authorship of an academic article on the ICCR dataset for submission to a peer-reviewed journal

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

The role of chair is vital to the success of ICCR dataset development. The ICCR Dataset Steering Committee 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 in the Dataset Authoring Committee
- Has a conflict of interest which the ICCR Dataset Steering Committee deems irreconcilable with the development process
- Engages in unprofessional conduct as determined by the ICCR Dataset Steering Committee

5. ICCR DATASET STEERING COMMITTEE MEMBER

The ICCR Dataset Steering Committee will elect a representative to participate on its behalf, on an ICCR Dataset Authoring Committee 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 Dataset Steering Committee member is not chosen specifically for their expertise or interest in a specific cancer area however, this will be taken into consideration.

The ICCR Dataset Steering Committee member will:

- Provide guidance and support to the Dataset Series Champion and/or Chair(s) of the Dataset Authoring Committee as applicable, regarding ICCR standards and committee participation
- Undertake a quality assurance role, overseeing the process specifically around the nomination of core/non-core elements and evidentiary review.
- Work closely with the Project Manager throughout the process.

6. DOMAIN SPECIALISTS

Domain specialists are required to:

- Sign a conflict of interest document to ensure an impartial participation in the development process

- 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).
- Work cooperatively as part of a team
- Be supportive of the objectives of the ICCR and its goal to encourage structured pathology reporting of cancer
- Treat all individuals in the process with respect and professionalism
- Be able to author/edit sections of the dataset or article for publication as required
- Be available and place high priority on the ICCR development process in order to meet the agreed timeframes. Please note that a lack of response to a specific communication during the project will be interpreted as tacit approval of the proffered dataset item/document.
- Provide feedback in a timely manner. Feedback must be provided via email or attendance at the 1st DAC meeting to meet ICCR DAC contribution criteria. Those not responding according to this criteria will be removed from the committee.
- Be familiar with the definitions of core/non-core elements
- Work closely with the Project Manager throughout the process

7. WHO/IARC VOLUME EDITOR

WHO/IARC may nominate an appropriate representative to liaise with the Dataset Authoring Committee(s) and advise on synchronization with IARC publications if deemed appropriate by the Dataset Steering Committee.

8. DATASET AUTHORING COMMITTEE TASKS

A **Dataset Authoring Committee** is responsible for the development of a cancer dataset. The goal of the committee is to create a practical dataset that can be used for a broad audience, including countries that do not have advanced medical care.

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 III-2 or above (based on prognostic factors in the NHMRC levels of evidence[1] document – see Appendix A). In rare circumstances, where level III-2 evidence is not available an element may be made a CORE element where there is unanimous agreement in the expert committee. An appropriate staging system eg Pathological TNM staging would normally be included as a CORE element.

   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 III-2 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 eg macroscopic tumour details, may be included as either CORE or NON-CORE elements by consensus of the Dataset Authoring Committee.

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 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**

Evidence

The **Dataset Authoring Committee** 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.

Citations must be included where applicable.

The extended NHMRC levels of evidence published by Merlin T, Weston A, et al. 2009[1] provides a guide for authors (Appendix A). Where no reference is provided, the authority is the consensus of the expert group.

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 eg AJCC cancer staging definitions. 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 **Dataset Authoring Committee**.
- 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, eg. tumor vs tumour, lymphovascular invasion vs lymph-vascular invasion.

Process steps

- Each **Dataset Authoring Committee** will be supplied with:
    a. Relevant cancer specific datasets from a variety of jurisdictions.
    b. A Proposed Dataset document. This document puts forward proposed elements following review and consideration of the key/core elements from the various submitted cancer datasets and how they have approached a particular topic eg. 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 **Dataset Authoring Committee** will be asked to review the proposed elements in the Proposed Dataset document and to provide feedback. This will include:
    o 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.
    o Whether the element should be CORE or NON-CORE. Evidentiary support (at Level III-2 evidence or greater) provided for any CORE element should be reviewed and expanded on where possible.
    o Any commentary deemed essential for explanation of the element. This is particularly important to ensure conformity in measurement or meaning of the element.

- o Whether there are additional elements not described in the PDF document which should be considered by the committee.
- The committee 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 will then be organised for the committee to discuss the feedback provided.
- A final draft document will be circulated and will included:
  - o CORE and NON-CORE Elements
  - o Response type and value lists for each element
  - o Evidentiary support for CORE elements at a minimum
  - o Commentary where necessary to ensure clarity and conformity.
- The information will then be reformatted into the structure of ICCR Guides.

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

APPENDIX A   NHMRC EVIDENCE HIERARCHY

Additional File 1   NHMRC Evidence Hierarchy: designations of 'levels of evidence' according to type of research question (including explanatory notes)

Level	Intervention [1]	Diagnostic accuracy [2]	Prognosis	Aetiology [3]	Screening Intervention
I [4]	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard,[5] among consecutive persons with a defined clinical presentation[6]	A prospective cohort study[7]	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard,[5] among non-consecutive persons with a defined clinical presentation[6]	All or none[8]	All or none[8]	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: • Non-randomised, experimental trial[9] • Cohort study • Case-control study • Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case-control study
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single arm study[10] • Interrupted time series without a parallel control group	Diagnostic case-control study[6]	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: • Historical control study • Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)[11]	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

APPENDIX B   ORGANISATIONAL CHART