International Collaboration on Cancer Reporting

ABN 69 601 723 960

ANNUAL REPORT
2022

ICCR International Collaboration on Cancer Reporting

Index

1. MESSAGE FROM THE PRESIDENT

2022 has been an exceptionally busy year for the International Collaboration on Cancer Reporting (ICCR). The primary focus has been on standards development but work on translation has also been a priority. The BDP (Professional Association of German Pathologists) also was welcomed as a gold sponsor. In addition, there have been a number of key organisational changes that needed to be addressed.

Core business – standards development

The development of standards for pathologists reporting cancers is ICCR's core business. Each dataset incorporates contemporary morphologic and molecular standards from partner organisations that include the International Agency on Cancer Research (IARC), World Health Organization (WHO), the American Joint Committee on Cancer (AJCC) and Union for International Cancer Control (UICC) TNM as well as specialty societies such as International Society of Gynecological Pathologists (ISGyP) and International Society of Urological Pathology (ISUP). The datasets serve as a bridge between the standard setters and the global pathology community.

The ICCR has 57 published datasets to date, including datasets for the top ten solid tumours worldwide. Six ICCR datasets have also been updated in the last 12 months to reflect the latest WHO Classification of Tumours and a further 23 updates are in progress. More than 50 articles related to the ICCR datasets or work of the ICCR in peer-reviewed journals have been published.

This year, ICCR entered into a Memorandum of Understanding with the International Academy of Cytology (IAC) to investigate the development of ICCR Cytopathology datasets, utilizing lung cytopathology as the pilot project. The project is progressing well, and future datasets are being considered.

Translation

The ICCR considers that translation of the ICCR datasets into other languages to be an essential step to advance adoption and uptake of the datasets around the world, in particular in low and middle income countries (LMIC).

Following a translation summit in May of this year, members of the ICCR agreed that to ensure a quality outcome, a two phased approach would be adopted for all translations – the translation itself and a quality assurance (QA) review. Several models of translation were discussed. It was agreed that various models would be trialed if funding were available.

Six priority languages – French, Spanish, Portuguese, German, Chinese and Russian – were identified – these reflecting those languages used in multiple countries or by very large populations. Through the very kind financial support of the American Society for Clinical Pathology (ASCP), the International Society of Breast Pathology (ISBP) and Singapore General Hospital Breast Pathology Course, translation of the new breast suite of four datasets into these six languages and two language variants was undertaken. This was an essential pilot project to explore the various activities, workload and challenges of translation for future planning. The translation work for this pilot project was undertaken by an ISO accredited translation company. They have completed the translations and the QA review by the relevant Societies and Colleges of Pathology is currently underway. A follow-up summit is being planned for the first half of 2023.

Implementation

In 2021 ICCR convened the Structured Reporting Implementation Committee (SRIC) to explore how ICCR might support pathologists through the provision of electronic structured reporting tools.

During 2022, SRIC has been discussing and reviewing various technologies, including those used by organisations around the world including the College of American Pathologists (CAP) and the Pathological Anatomical National Automated Archive of the Netherlands (PALGA).

Education

Recognising the enormous educational value of the datasets, the ICCR has now included a fourth strategic goal and workstream, namely education, to the existing goals of standards development, translation and implementation.

The datasets provide a single authoritative and evidence-based standard that enables pathologists to keep abreast of the latest information relevant to each cancer and also offers pathologists in LMIC with a benchmark and therefore a "ladder" for progression and advancement in cancer reporting as their local capability improves.

ICCR will look at partnering with relevant organisations, such as the World Continuing Education Alliance (WCEA) to deliver educational events in the near future.

Sustainability

Membership in 2022 has been stable and fees paid by our members have been sufficient to ensure that ICCR's core business of dataset development and maintenance continues. It is recognised however that more substantial funding would be required to significantly advance the other three workstreams.

With the kind assistance of Donna Meredith, the Managing Director of Keystone Corporate Positioning, who has offered her services pro-bono, the ICCR Executive has been working on a fundraising strategy and new branding, which included a new corporate brochure, logo and new website (live in July 2022).

With Ms Meredith's guidance, the ICCR will be seeking additional funding opportunities with philanthropic organisations.

Organisational changes

As ICCR's membership has increased over the last several years, so has the size of its Board. Legislative and regulatory changes to companies incorporated in Australia have also changed this year adding an additional layer of bureaucracy for our Directors. Therefore, given these two factors, the ICCR Executive proposed adopting a similar organisational structure to many of its members – that of a having a Board with a small number of Directors, supported by a governing council to which all members would belong. Constitutional changes to reflect this change were proposed and adopted at the Board meeting in October 2022. This change was ratified at the Annual General Meeting in November 2022. The new organisational structure comes into effect immediately.

Thank you

On behalf of the ICCR Executive, I would like to express sincere gratitude to our sponsoring organisations and strategic partners for providing us the resources and intellectual support to accomplish our important goals. We are particularly thankful for the great work done by our Dataset Steering Committee chaired by Sigurd Lax, the Dataset Authoring Committees including series champions, chairs and members, and the Structured Reporting Implementation Committee chaired by George Birdsong. Your tremendous spirit of volunteerism and enthusiasm are greatly appreciated. We are especially grateful to Meagan Judge, our tireless administrative lead who keeps the ship on course and the other dedicated project managers and assistants.

On a personal note, it has been a great privilege to have the opportunity of pursuing an impactful international passion project that has seen the ICCR evolve from concept to reality over the last 13 years. I am truly honoured to have served as your President for the past 5 years.

John Srigley, President ICCR

2. ICCR's Vision and Mission

2.1 Vision statement

Internationally standardised, multilingual and machine readable pathology reports documenting cancer subtype, grade, stage and other morphologic and molecular tumour parameters are necessary to improve patient care and outcomes and to advance cancer control in populations.

2.2 Mission statement

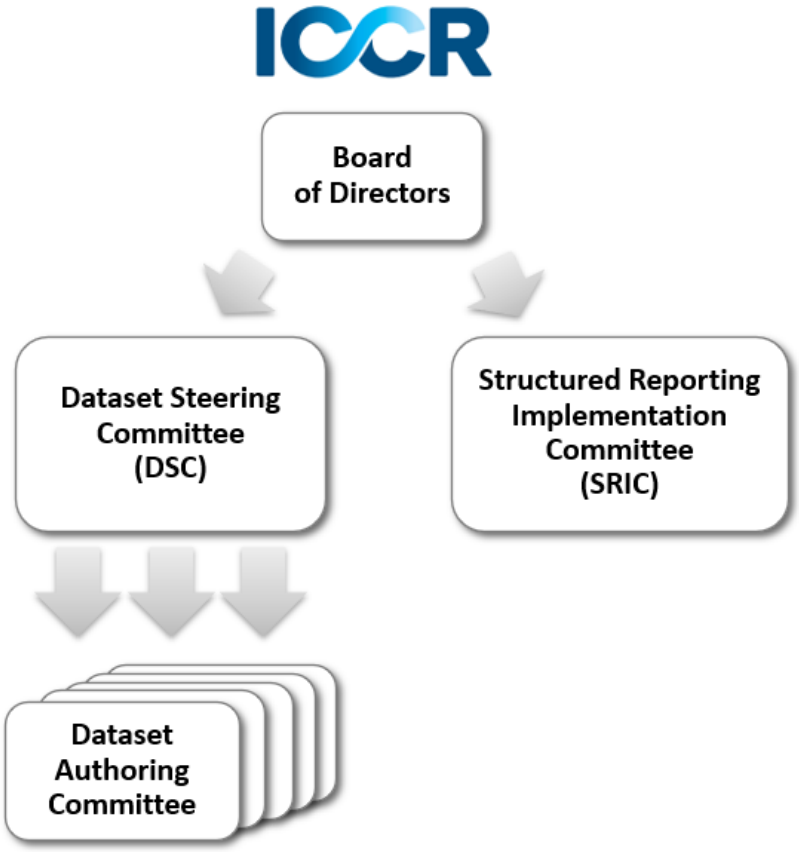
The International Collaboration on Cancer Reporting (ICCR) produces internationally standardised pathology datasets incorporating contemporary morphologic and molecular parameters which are translated into multiple languages and are available in machine readable formats. The datasets are based on strong scientific evidence and are used primarily to improve patient care. High quality data also facilitate population-level cancer control initiatives including cancer registration, epidemiology, quality research, resource planning and education.

3. ORGANISATIONAL OVERVIEW

The ICCR was founded by major pathology organisations from around the world to produce internationally standardised and evidence based datasets for the pathology reporting of cancer. Its goal is to improve cancer patient outcomes worldwide and to advance international benchmarking in cancer management.

The ICCR was incorporated as a not-for-profit organisation in September 2014.

The organisational structure currently is as follows (although it will change in 2023 as the constitutional changes approved at the 2022 AGM are implemented, see below):



The ICCR is supported by membership and sponsorship.

The ICCR currently has three levels of membership:

- Platinum - which provides the member organisation with both Board of Directors (BoD) and Dataset Steering Committee (DSC) representation. Platinum membership entitles the organisation to four votes on the Board. The annual subscription for a Platinum member is $20,000 USD.

- Gold - which provides the member organisation with both BoD and DSC representation. Gold membership entitles the organisation to two votes on the Board. The annual subscription for a Gold member is $10,000 USD.

- Silver - which provides the member organisation with DSC representation only. The annual subscription for a Silver member is $5,000 USD.

Membership provides the principal amount of funding on which the ICCR depends.

As at November 2022 the ICCR has two Platinum members, which are:

- Royal College of Pathologists of Australasia (RCPA) and
- American Society of Clinical Pathology (ASCP).

These members have provided additional contributions above their membership fees and were recognised with elevation to Platinum membership at a 50% discount.

As at November 2022, ICCR has fifteen Gold members, which are:

- European Society of Pathology (ESP),
- Royal College of Pathologists United Kingdom (RCPath),
- College of American Pathologists (CAP),
- Canadian Association of Pathologists (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC),
- Royal College of Physicians of Ireland, Faculty of Pathology (RCPI FoP),
- German Society of Pathology (DGP),
- Brazilian Society of Pathology (SBP),
- Hong Kong College of Pathologists,
- Austrian Society of Pathology/Austrian Division of the International Academy of Pathology (ÖGPath/IAP Austria),
- Japanese Society of Pathology (JSP),
- Italian Society of Pathological Anatomy and Cytology (SIAPEC),
- Swiss Society of Pathology (SSP),
- Russian Society of Oncopathology (RSOP),
- Chinese Society of Pathology (CSP), and
- Professional Association of German Pathologists (BDP).

Each of the Platinum and Gold member organisations is represented on the ICCR BoD which has strategic oversight of all ICCR operations and financial and legal responsibility for the operation of the ICCR.

As at November 2022, there are two Silver members, which are:

- French Society of Pathology (FSP) and
- International Academy of Pathology – Arab Division.

At the BoD meeting held on 13 January 2022, John Srigley was re-elected as President and James Kench was elected as Vice-president of the company. Tim Helliwell was appointed as Executive Officer.

The ICCR DSC has responsibility for all activities relating to the development of ICCR datasets. The DSC invites representation from all sustaining members, as well as strategic partners such as the IARC and the European Organisation for Research. Sigurd Lax of the Austrian Society of Pathology/Austrian Division of the International Academy of Pathology holds the position of Chair of the DSC.

Dataset Authoring Committees (DACs) are convened as needed for the development of specific datasets. DAC members are recognised as honorary contributors to the ICCR for the lifetime of the datasets on which they contributed.

The ICCR SRIC was convened in 2020. Its purpose is to provide guidance to the BoD on matters relating to the implementation of ICCR cancer datasets, and to advance the detailed technical aspects impacting the efficient implementation of standardised cancer datasets such as electronic representation. Structured reporting options for Low Middle Income Countries (LMIC) and terminology binding. George Birdsong has been appointed Chair, SRIC.

The BoD, DSC, DAC and SRIC members are all volunteers that provide their expertise and time altruistically.

3.1 Constitutional change

The ICCR is registered as a business in Australia. The Australia Business Registry Services (ABRS) governs the process of business registrations in that jurisdiction and they have dictated that all Directors of companies, registered in Australia need an identification number (Director ID or DIN). The intention is to help prevent the use of false or fraudulent Director identities.

The process to obtain a Director ID is reasonably straightforward for Australian residents as they have a tax file number which assists with the identification criteria. However, for non-Australian members the requirements are more difficult – involving certified copies of identification papers and official translations of same (if the original is not in English). Therefore, the ICCR executive, having considered the matter in detail, proposed a change to the constitutional structure of the ICCR. The change involved forming a small BoD that would include the President and Vice-president and up to three additional Directors (five Directors in all) with all members included in a governing Council. The Council would undertake most of the current responsibilities of the BoD in relation to the strategic direction of the company. The BoD retains responsibility for the budget and other occupational health and safety requirements, as these cannot be delegated according to Australian law.

Changes to the constitution were drafted by Norton Rose solicitors and the constitution was circulated for review and discussion at BoD meetings on July 7 and October 25 2022.

The revised constitution was put to the Annual General Meeting held on 8 November 2022 as a special resolution and ratified, effective immediately.

As a result, the ICCR BoD now has the following Directors:

- James Kench – ICCR President,
- Kerryn Ireland-Jenkin, representing the RCPA,
- Nga Yin Annie Cheung, representing the Hong Kong College of Pathologists, and
- Kieran Sheahan representing the RCPI FoP.

Nominations for and appointment of a Vice-President has been deferred until 2023.

3.2 Workstreams

The ICCR has four workstreams:

- Standards development
- Translation
- Implementation
- Education.

Each of these is discussed in more detail below.

4. STANDARDS DEVELOPMENT

The development of reporting standards for pathologists reporting cancers is ICCR's core business.

The ICCR dataset development follows an agreed process that is outlined in *Guidelines for the Development of ICCR Datasets* (http://www.iccr-cancer.org/datasets/dataset-development), which is reviewed and updated annually by the ICCR DSC. The process is summarised in Figure 1.

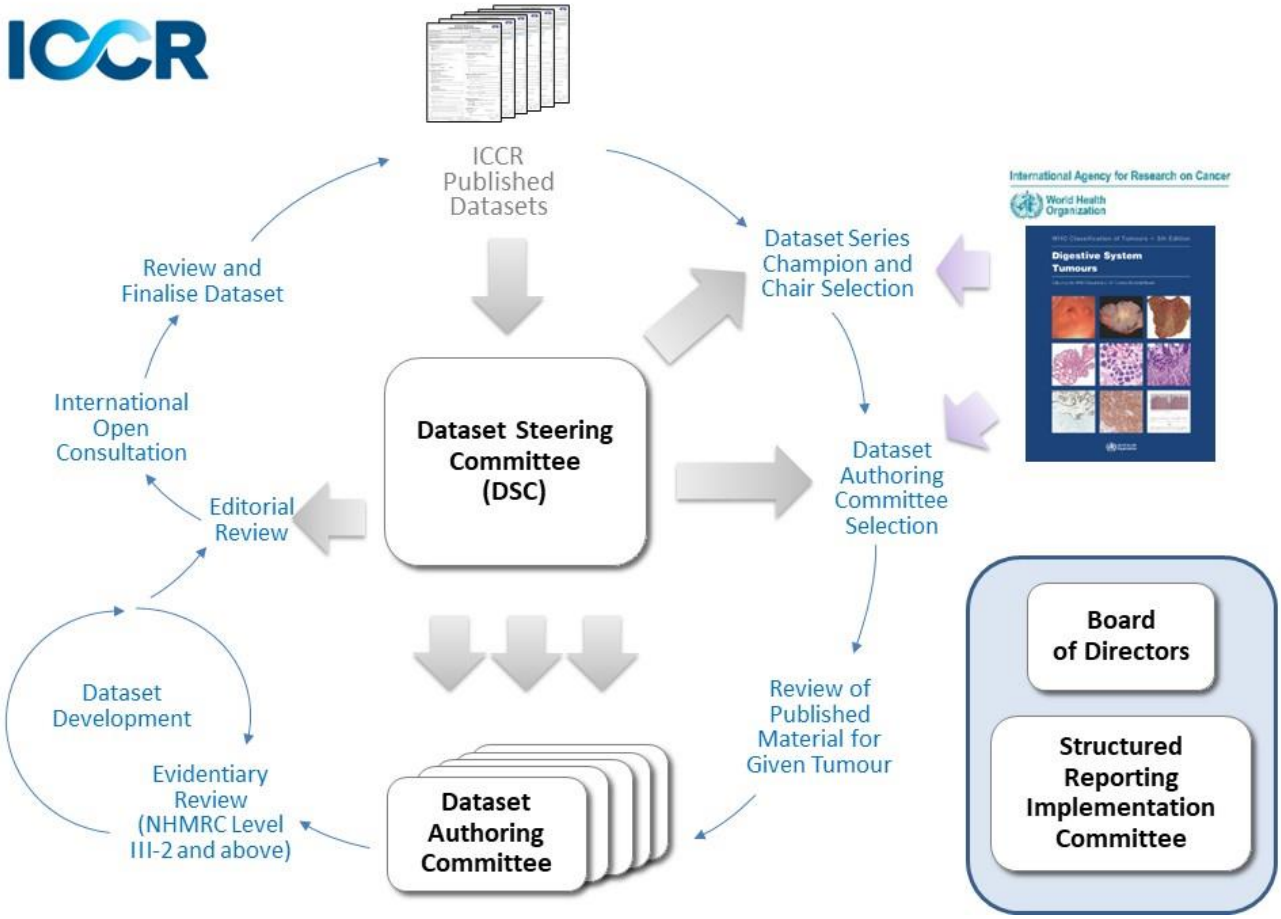


Figure 1: ICCR dataset development process.

The ICCR develops datasets in synchrony with the WHO Classification of Tumours updates. Dataset work commences close to the publication of the revised classification. The 5th edition of the WHO is currently underway.

For the development of a series of datasets, the ICCR appoints a Series Champion who acts in an advisory role to the DSC to assist in the nomination of qualified candidates for the Chair and DAC roles. In addition, the Series Champion oversees the development process, supports the work of the dataset Chairs, and ensures harmonisation across the series. The responsibilities for each of the roles in a DAC are described in *Roles and Responsibilities for the ICCR dataset development process* (http://www.iccr-cancer.org/datasets/dataset-development). This document is reviewed and updated annually by the ICCR DSC.

For the development of each dataset, the DSC appoints appropriately qualified expert pathologist(s) to take on the role of Chair of the DAC. The Chair(s) are supported in the development process by a Project Manager and a representative from the ICCR DSC.

4.1 Published datasets

As at November 2022, the ICCR has published 57 datasets. All published datasets are compliant with the latest 8th edition TNM staging, where applicable.

See Appendix 9.1 for all published ICCR datasets.

4.1.1 International Standard Book Numbers (ISBN)

International Standard Book Numbers (ISBN) have been assigned to each ICCR dataset published from July 2017. Datasets published before this date will be assigned an ISBN as they are updated.

4.2 Datasets in progress

The IARC/WHO 'blue books' are integral to all cancer datasets and as such the ICCR is committed to developing harmonised international datasets in synchrony with IARC/WHO. ICCR have a five year forward plan, 2018-2023, synchronising dataset development with IARC/WHO 'blue book' updates. Given IARC/WHO and ICCR utilise similar experts for the authorship of their documents, IARC and ICCR have agreed a process of resource allocation and timing to avoid over burdening the authorship pool.

There are 28 ICCR datasets currently in progress:

4.2.1 Thoracic

There are four datasets in the Thoracic series: Lung Cancer Resections, Thymic Epithelial Tumours, Mesothelioma in the Pleura, Pericardium and Peritoneum, and Heart, Pericardium and Great Vessels. The datasets for Thymic Epithelial Tumours, Mesothelioma in the Pleura, Pericardium and Peritoneum, Heart, and Pericardium and Great Vessels have been updated and published.

Wendy Cooper, from Australia, is the appointed Series Champion.

The ICCR is finalising the update of the Lung cancer – resection specimens dataset, (4th edition) (Chair: Andrew Nicholson).

4.2.2 Cytology

In May 2020 the International Academy of Cytology (IAC) entered into a Memorandum of Understanding (MoU) with IARC to work on cytopathology books as an additional resource to the WHO 5th Edition Classification of Tumours. In October

2021, ICCR entered into discussions with IAC with a view to potential collaboration on a series of cytopathology datasets.

An MoU between ICCR and IAC was signed in March 2022 agreeing to work on a joint project to develop a dataset for the cytopathology reporting of lung cancer. The ICCR Lung cancer DAC had previously recommended that ICCR consider the development of a dataset for small diagnostic samples of lung cancer. Therefore, it was agreed to expand the scope of this dataset to incorporate cytopathology.

The joint project is administered by a Cytopathology Steering Committee (CSC) that includes representation from ICCR and IAC and reports to the ICCR DSC. Chairs representing both parties were appointed - Andrew Nicholson for the ICCR and Andrew Field for IAC.

The Lung cancer DAC was expanded to include cytopathologists and the dataset is progressing well.

4.2.3 Paediatrics

In synchrony with the updates to the WHO Classification of Paediatric Tumours, the ICCR is developing four new paediatric datasets as follows:

1. Hepatoblastoma (Chair: Dolores López-Terrada)
2. Nephroblastoma (Chair: Elizabeth Perlman)
3. Neuroblastoma (Chair: Jason Jarzembowski)
4. Rhabdomyosarcoma (Chair: Rita Alaggio)

Miguel Reyes-Múgica, from United States of America (USA), is the appointed Series Champion.

4.2.4 Genitourinary

In synchrony with the updates to the WHO Classification of Urinary and Male Genital Tumours, the ICCR is planning updates to 12 existing datasets as follows:

1. Carcinoma of the bladder - cystectomy, cystoprostatectomy and diverticulectomy specimen (update of 1st edition)(Co-Chairs: Eva Compérat and Toyonori Tsuzuki)
2. Carcinoma of the penis (update of 1st edition)(Chair: Isabel Alvarado-Cabrero)
3. Carcinoma of the renal pelvis and ureter - nephroureterectomy and ureterectomy specimen (update of 1st edition)(Co-Chairs: Eva Compérat and Toyonori Tsuzuki)
4. Carcinoma of the urethra - urethrectomy specimen (update of 1st edition)(Chairs: Eva Compérat and Toyonori Tsuzuki)
5. Invasive carcinoma of renal tubular origin (update of 1st edition)(Co-Chairs: Holger Moch and Sean Williamson)

6. Neoplasia of the testis - orchidectomy specimen (update of 1st edition)(Chair: Daniel Berney)

7. Neoplasia of the testis - retroperitoneal lymphadenectomy specimen (update of 1st edition)(Chair: Daniel Berney)

8. Prostate cancer - radical prostatectomy specimen (update of 2nd edition)(Co-Chairs: James Kench and Gladell Paner)

9. Prostate cancer - transurethral resection and enucleation specimen (update of 1st edition) (Co-Chairs: James Kench and Gladell Paner)

10. Prostate - core needle biopsy (update of 1st edition)(Co-Chairs: James Kench and Gladell Paner)

11. Renal biopsy for tumour (update of 1st edition)(Co-Chairs: Holger Moch and Sean Williamson)

12. Urinary tract carcinoma - biopsy and transurethral resection specimen (update of 1st edition)(Co-Chairs: Eva Compérat and Toyonori Tsuzuki)

John Srigley, from Canada, is the appointed Series Champion.

4.2.5 Central nervous system

In synchrony with the updates to the WHO Classification of Central Nervous System (CNS) Tumours, the ICCR is planning to update the Tumours of the CNS dataset (update of 1st edition)(Chair: Pieter Wesseling)

4.2.6 Head and neck

In synchrony with the updates to the WHO Classification of Head and Neck Tumors the ICCR is planning updates to 9 existing datasets as follows:

1. Carcinomas of the nasal cavity and paranasal sinuses (update of 1st edition)(Chair: Justin Bishop)

2. Carcinomas of the hypopharynx, larynx and trachea (update of 1st edition)(Chair: Nina Zidar)

3. Carcinomas of the oral cavity (update of 1st edition)(Chair: Susan Müller)

4. Carcinomas of the nasopharynx and oropharynx (update of 1st edition)(Chair: Rebecca Chernock)

5. Carcinomas of the major salivary glands (update of 1st edition)(Chair: Alena Skalova)

6. Malignant odontogenic tumours (update of 1st edition)(Chair; Edward Odell)

7. Ear and temporal bone tumours (update of 1st edition)(Chair: Ruta Gupta)

8. Mucosal melanomas of the head and neck (update of 1st edition)(Chair: Michelle Williams)

9. Nodal excisions and neck dissection specimen (update of 1st edition)(Chair: Martin Bullock)

Lester Thompson, from USA, is the appointed Series Champion.

4.3 Datasets in planning

The following dataset series are currently being considered for a development start in 2023:

- Endocrine
- Skin
- Ophthalmic.

4.4 TNM staging

8th edition

The 8th editions of the AJCC and UICC TNM Classification of Malignant Tumours were published in late 2016. Given that the UICC TNM is widely used in Europe, United Kingdom and other parts of the world, while AJCC TNM is used extensively in the North America and Australia, the ICCR was keen to be bipartisan in its approach. Ostensibly these versions are harmonised, however on a more detailed review a number of differences were noted. Some of these issues are significant, particularly in relation to testicular cancer where the pT staging category may actually be recorded differently depending on which version of TNM is used.

Having investigated the issue, the ICCR decided to use UICC TNM 8th edition in cases where there is concordance between the versions but use the AJCC TNM 8th edition in cases where the AJCC version more accurately reflects the most contemporary and scientifically validated information.

In 2020, the AJCC adopted a new approach to publication of its TNM staging system, moving from an edition-based model to a versioning approach or 'rolling updates'. In this model, the various anatomic sites will be updated individually and published separately.

At this stage the UICC has agreed to consider publishing errata to align with AJCC updates. They have reported that a 9th edition TNM staging will be published in late 2023.

ICCR will continue to work with both organisations choosing the best approach for each of its datasets series.

4.5 Peer-reviewed publications

A key step in the development of ICCR datasets is the production of an accompanying article submitted to a peer-reviewed journal. To date, more than 50 dataset related articles have been published.

See Appendix 9.2 for all ICCR dataset related peer-reviewed publications.

5. TRANSLATION

The ICCR considers that translation of the ICCR datasets into other languages is an essential step to advance adoption and uptake of the datasets around the world, in particular in LMIC especially as the WHO Classification of Tumours are not being translated.

Several models of translation have been discussed and various trials are underway to gather information to inform future efforts.

In 2018 through the kind contribution of the ASCP, 21 of the ICCR datasets were translated into Spanish, French and Portuguese (see section 5.1). However, due to a lack of funding these translated datasets are becoming outdated as further updates to the English language versions are published.

The ICCR held a translation summit in May 2022. Several outcomes were agreed:

1. Translation of the ICCR datasets is a complex process and will be a significant challenge.
2. Six priority languages – French, Spanish, Portuguese, German, Chinese and Russian – were identified – these reflecting those languages used in multiple countries or by very large populations.
3. Certification of official ICCR translations by an ISO 9001:2015 certified translation company was deemed important.
4. Any translation must be undertaken in two steps: The initial translation, and a Quality Assurance (QA) review step.
5. ICCR to develop a list of questions that need to be answered in all proposals for translation.

Various models and challenges were also discussed at the meeting and noted.

5.1 Datasets translated

The following datasets translated into Spanish, French and Portuguese in 2018 are available on the ICCR website:

Group	Dataset
Genitourinary	Carcinoma of the urethra - urethrectomy specimen
	Carcinoma of the renal pelvis and ureter - nephroureterectomy and ureterectomy specimen
	Urinary tract carcinoma - biopsy and transurethral resection specimen
	Carcinoma of the bladder - cystectomy, cystoprostatectomy and diverticulectomy specimen
	Invasive carcinoma of renal tubular origin
	Renal biopsy for tumour
	Carcinoma of the penis and distal urethra
	Neoplasia of the testis - retroperitoneal Lymphadenectomy
	Neoplasia of the testis - orchidectomy specimen
	Prostate cancer - transurethral resection and enucleation specimen
	Prostate cancer - radical prostatectomy specimen
	Prostate - core needle biopsy
Digestive tract	Intrahepatic cholangiocarcinoma, perihilar cholangiocarcinoma and hepatocellular carcinoma

Group	Dataset
Thoracic	Lung cancer
	Thymic epithelial tumours
	Neoplasms of the heart, pericardium and great vessels
	Mesothelioma in the pleura and peritoneum
Gynaecology	Endometrial cancer
	Ovary, fallopian tube and primary peritoneal carcinoma
	Carcinoma of the cervix
Skin	Invasive melanoma

5.2 Pilot projects

Since the Translation summit in May 2022, several pilot projects have commenced as detailed below.

Breast

Four datasets in the Breast Suite are being translated into the six priority languages (French (European), Spanish (European), Portuguese, German, Chinese and Russian) and two variants (French – Quebecois and Spanish – Latin American) as follows:

- Ductal carcinoma in situ, variants of lobular carcinoma in situ and low grade lesions
- Invasive carcinoma of the breast
- Surgically removed lymph nodes for breast tumours
- Invasive carcinoma of the breast in the setting of neoadjuvant therapy.

Translation is being done by IDEM, an ISO accredited translation company from Chicago. A QA process is underway with the various Societies and Colleges of Pathology.

The project is funded through a very generously donation from the ASCP supplemented by smaller donations from the International Society of Breast Pathology (ISBP) and the Singapore General Hospital Breast Pathology Course.

The purpose of the project is to enable the ICCR to explore the various issues and challenges involved in a project of this size which will inform future translation efforts.

Ukrainian

ICCR was approached in July 2022 by a group of Ukrainian pathologists wishing to translate several of the ICCR datasets into the Ukrainian language. As this was a single jurisdiction project not affecting a broader population, ICCR has agreed and is monitoring progress.

Italian

ICCR has had discussions with SIAPEC and the Italian Ministry of Health to consider a project to translate ICCR datasets into Italian for national use. It was agreed that before undertaking a larger project, that a small pilot would be useful. Therefore, a quote from IDEM, the translation company, has been provided to SIAPEC regarding translation of the Breast datasets into Italian, and SIAPEC is also undertaking translation of the same datasets for comparison purposes. Once this is complete, further discussions will take place to agree the best way forward.

German

The German speaking members of the ICCR – Germany, Austria and Switzerland – have put forward a proposal based on the questionnaire developed to pilot the translation of the ICCR datasets. Further discussion is planned between all parties.

5.3 Language specific webpages

Language specific pages have been added to the ICCR website to host the translated datasets. New pages will be added as needed in the future. An example is shown below:

5.4 Future translation

ICCR has 57 published datasets and many more in planning. It represents a large body of work to be translated and there is also the ongoing maintenance of the datasets to be considered. This requires a substantial investment in funding. ICCR will continue to investigate various options for funding as well as different models.

6. IMPLEMENTATION

6.1 Structured Reporting Implementation Committee (SRIC)

ICCR convened the SRIC in 2021 for the purpose of providing guidance to the ICCR on matters relating to the implementation of ICCR cancer datasets and to advance the detailed technical aspects impacting the efficient implementation of standardised cancer datasets.

George Birdsong, Professor in the Department of Pathology and Laboratory Medicine at Emory University School of Medicine, is the current Chair of the SRIC.

Membership of the committee includes those with expertise in electronic dataset development, terminology development, informatics and cancer reporting. The committee meet every 2-3 months.

6.2 Implementation – Memoranda of Understanding (MoU)

There has been a significant increase in requests from Laboratory Information System (LIS) and middleware vendors and jurisdictions wanting to implement the ICCR datasets. This has prompted the development of standard MoU to be used for these requests. Through the kind assistance of the RCPA, the MoU was drafted by Norton Rose solicitors.

The principal clauses in the MoU cover:

- Ownership and Intellectual Property of the ICCR datasets,
- The criteria under which ICCR datasets should be implemented,
- The datasets covered by the agreement,
- Liability and protections for both parties, and the
- Term of the agreement and withdrawal criteria.

This year MoU's have been signed with Celerato AG of Switzerland and Cancer Center Sp. z o.o. of Poland. In addition, the RCPA and RCPath have also signed MoU with ICCR. The purpose of these agreements is for the Colleges to incorporate ICCR datasets into their local cancer protocols.

6.3 Copyright

Drafting of the standard MoU as noted above, drew the ICCR's attention to a specific issue regarding the copyright that ICCR obtains from its DACs. Legal advice suggested that for the ICCR to sublicense the materials to LIS or other organisations, in order for implementations, revisions were required to the copyright letter which each DAC member is asked to sign.

A revised copyright letter was drafted and submitted for BoD approval in October 2020 and has been rolled out since to all current DACs.

Only those datasets covered by the new DAC copyright agreement are included in the MoU.

6.4 Electronic ICCR datasets

To make best use of the ICCR datasets and eliminate the variability that is introduced when using a paper reference document, pathologists need access to structured reporting tools. Use of a reporting tool also facilitates electronic reporting to cancer registries, as well as improving workflow and supporting research through the availability of database searches etc.

In many parts of the world there are commercially available LIS or middleware solutions, which have the facility for structured data entry and storage to support the implementation of cancer datasets. Older LIS, that are currently incapable of electronic structured reporting, are gradually being replaced as they are upgraded, as the importance of structured reporting of cancer is recognised.

However, in many LMIC there is little or no access to electronic structured reporting tools and reporting remains paper based or at best done on a standalone PC using word processing software.

ICCR needs a scalable solution that best serves the needs of locations with varying degrees of IT sophistication. A tiered approach is being discussed.

In 2021 ICCR entered into a MoU with Travis Brown, a pathologist from Australia, who has developed a structured reporting application. As this is very simple to use, and lightweight in regard to required technology, it is proposed to use this application for:

- LMIC with minimal information technology (IT) capability
- Education through webinars, and
- As a demonstration of intent to potential funders.

For mid-level sites, that is, those with reasonable IT capability, who have an existing LIS but lack adequate structured reporting tools, a solution providing user friendly front-end reporting tools is needed. It is proposed that this application would be electronically updateable and cater for multiple laboratory locations.

As noted above, there are laboratories with LIS or middleware solutions, with the facility for structured data entry. These would be classified as sites with a high level of IT capability. For these sites to implement ICCR datasets, they require uploadable files to ensure this is done quickly and efficiently.

Ideally the solution chosen for the mid-level and high-level sites would be the same application. The SRIC is working on building a list of requirements to support this tiered approach.

6.4 Terminology

Coded terminology is very important to any pathology implementation as it reduces the variability of terms to a single unique code. Even common terms have variability e.g., lymphovascular space invasion, lymphovascular invasion, and lymph-vascular invasion. Different languages add another layer of complexity. Coding of elements such as lymphovascular invasion and response values such as ‘not identified’ or ‘present’ with standard clinician terms such as SNOMED CT reduces the variation and allows for advanced computer searches and interoperability.

Early in 2017, work commenced on the development of SNOMED CT content to represent the data elements in cancer datasets. This project is led by Scott Campbell from University of Nebraska Medical Center, USA, under the auspice of the International Pathology and Laboratory Medicine Special Interest Group (IPaLM SIG) of the International Health Terminology Standards Development Organisation (IHTSDO), an international non-profit organisation that owns SNOMED CT. The encoding of cancer synoptic reports, including biomarkers, became an official project with SNOMED International later in 2017, ensuring both support and resources for content creation and publication.

The project aims to align terminology development and cancer dataset development efforts to truly create computable, interoperable cancer reporting tools for use by all participating nations.

7. FINANCES

7.1 Budget

The ICCR's financial year (FY) runs from 1 July to 30 June.

A budget based on expenses incurred in the previous year and what is anticipated to be needed in the current year was proposed and accepted at the 19 August 2021 BoD meeting for the financial year ending 30 June 2022.

7.2 Income

Income received to the end of the 2021-22 FY was $245, 977 AUD derived from member subscription fees and sponsorship (see section 7.4).

7.3 Expenditure

Planned expenditure for the 2021-22 FY was $255,101 AUD. Actual expenditure was $188,656 AUD.

Items of expenditure are categorised as follows:

Category	Item
Business costs	Insurances
	Auditor
	Bank fees
Meetings	Teleconference/web meetings
Promotion & communication	Web services
	Domain specific email
	Domain name registration
	Business cards
Staffing	Project Managers
	Project Management Officer
	Equipment/expenses
Dataset development	Software
	Medical Illustrator
	Copyright fees
	Open access for publications
Miscellaneous	Stationary etc.
	Stakeholder database rework

7.4 Sponsorship

In addition to membership fees, the ICCR looks for sponsorship to help support the cost of development of datasets. In the FY 2021-22, the ICCR received $2,000 USD from the ISBP and $2,658 USD from the Singapore General Hospital Breast Pathology Course to support the translation of the Breast datasets.

7.5 Audited financial statement

The ICCR financial status is audited yearly by BDO Chartered Accountants. A fully audited financial statement was prepared and tabled at the Annual General Meeting held on 8 November 2022.

In summary, assets exceed liabilities and with continuing support from the member organisations ICCR can meet its financial commitments now and in the foreseeable future.

BDO, in its report, did not raise any matters of concern.

7.6 Sustainability

While the membership and sponsorship provide sufficient funding for the continuation of ICCR's core business which is the development of cancer datasets, it does not allow for the necessary resources to push forward with translation or implementation activities to the extent needed. The ICCR, therefore, has been investigating various potential fund-raising strategies with the kind assistance of Donna Meredith, Managing Director of Keystone Corporate Positioning, Australia. Ms Meredith recommended that as part of ICCR's strategy that a renewed logo and branding was needed to better promote the ICCR to potential funding organisations.

A new logo and corporate profile (brochure) were reviewed and accepted by the BoD at its Strategic Planning meeting in October 2020. The logo was rolled out during 2021 to all ICCR documents and datasets as they were developed.

A new ICCR website was designed in 2021-22 and went live in July 2022.

The new website, logo and corporate profile will help position the ICCR to take advantage of new funding opportunities, especially in the philanthropic domain, in 2023.

8. STAFFING

The ICCR has adopted a dataset development model based on the involvement of a Project Manager.

Although it is possible for pathologists to produce datasets without the input of a Project Manager, the involvement of an ICCR Project Manager streamlines and standardises the dataset development process, reduces individual pathologists' time and effort, expedites the development timeline and ensures implementation of, and adherence to, ICCR standards.

The process of dataset development involves a number of activities which can be divided broadly into two categories:

a. Administrative activities, including meeting organisation, agendas and meeting notes, collation of feedback, stakeholder database management, referencing, formatting of documents, email notifications etc., and

b. Stakeholder/content management including the development and review of draft dataset documents, timeframe management, harmonisation of terms and content, guide development, identification and tracking of issues, reporting to DSC, stakeholder correspondence/support of expert panels etc.

8.1 Project Manager

ICCR Project Managers undertake stakeholder/content management. The ICCR has two Project Managers on a contract basis:

1. Fleur Webster commenced in February 2015 and is employed on a permanent part-time contract via the RCPA for 26.25 hours (~3.5 days) per week, to support dataset development. Ms Webster works from her home office in Albury, Australia.

2. Meagan Judge, whilst working for the RCPA, provided services to the ICCR on a volunteer basis from 2010-18. From January 2019, Ms Judge has been employed 15 hours (~2 days) per week, on a permanent part-time contract via the RCPA, providing operational support for the BoD and DSC. Ms Judge works from her home office in Sussex Inlet, Australia.

8.2 Project Management Officer (PMO)

An ICCR Project Management Officer undertakes administrative activities.

Gina Green commenced in September 2017 and is employed on a permanent part-time contract via the RCPA for 18.75 hours (~2.5 days) per week. Ms Green works from her home office in Sydney, Australia, and works under the supervision of Ms Webster.

8.3 Human Resources Support

The RCPA has provided the human resources infrastructure under which Ms Webster, Ms Judge and Ms Green are employed since 2015 and have invoiced the ICCR quarterly for their salaries. The RCPA has not charged the ICCR for this administrative service.

Following discussions in late 2021 and early 2022, the ICCR entered into an agreement with ICCR to formalise the arrangement of ICCR Human Resources (HR) management. RCPA manage and provide resources to ICCR on a contractual basis.

9 APPENDIX

9.1 Published datasets

The following is a list of ICCR published datasets as at November 2022:

Urinary/male genital

1. **Prostate Cancer - radical prostatectomy specimen, 2nd edition,** which has been developed for radical prostatectomy specimens for prostate carcinoma. Published: August 2017.

2. **Prostate Cancer - transurethral resection and enucleation specimen**, **1st edition,** which has been developed for the examination of transurethral resection and enucleation (suprapubic/simple/open prostatectomy) specimens of the prostate. The elements and associated commentary apply to invasive carcinomas of the prostate gland. Urothelial carcinomas arising in the bladder or urethra are dealt with in a separate dataset, while urothelial carcinomas arising in the prostate are included in this dataset. Published: August 2017.

3. **Prostate - core needle biopsy, 1st edition,** which has been developed for the examination of prostate core needle biopsies. The elements and associated commentary apply to invasive carcinomas of the prostate gland. Urothelial carcinomas arising in the bladder or urethra are dealt with in a separate dataset, while urothelial carcinomas arising in the prostate are included in this dataset. Published: August 2017.

4. **Invasive carcinoma of renal tubular origin, 1st edition,** which has been developed for excision specimens of the kidney. Urothelial carcinoma arising from the upper renal tract, Wilms tumours and other nephroblastic and mesenchymal tumours are not included. This dataset is designed for the reporting of a single laterality of specimen i.e., left or right. Published: July 2017, Updated July 2018.

5. **Renal biopsy for tumour, 1st edition,** which has been developed for core or wedge biopsy specimens for tumour of the kidney. Published: July 2017.

6. **Carcinoma of the penis, 1st edition,** which has been developed for the reporting of specimens from patients with carcinoma of the penis, including resection, biopsy and lymphadenectomy. The protocol applies to primary carcinoma of the penis, as well as distal urethral squamous carcinomas. Melanomas and other urethral carcinomas are not included in the scope of the dataset. Published: August 2017.

7. **Neoplasia of the testis - orchidectomy specimen, 1st edition,** which has been developed for the reporting of both partial and radical orchidectomy specimens from patients with neoplasia of the testis. The protocol applies to all germ cell and sex cord-stromal tumours of the testis. Paratesticular malignancies are excluded. Published: August 2017.

8. **Neoplasia of the testis - retroperitoneal lymphadenectomy specimen, 1st edition,** which has been developed for the reporting of retroperitoneal and other lymphadenectomy specimens as well as visceral metastasis excision specimens from patients with malignant tumours of the testis. The protocol applies to all malignant germ cell and sex cord-stromal tumours of the testis. Paratesticular malignancies are excluded. Published: August 2017.

9. **Carcinoma of the urethra - urethrectomy specimen, 1st edition**, which has been developed for the reporting of resection specimens from patients with carcinoma of the urethra. The protocol applies to primary carcinomas (non-invasive and invasive), with or without associated epithelial lesions. Urothelial tumours diagnosed as papilloma or papillary urothelial neoplasm of low malignant potential are not carcinomas and this dataset does not apply to those diagnoses. Biopsy and transurethral resection specimens are dealt with in a separate dataset. Carcinomas arising in the distal penile urethra (glans region) are included in the Carcinoma of the penis and distal urethra dataset and are not to be reported using this dataset. This dataset is to be used for adenocarcinoma arising in the accessory glands of the urethra (Skene, Littre, Cowper). Published: May 2018.

10. **Carcinoma of the renal pelvis and ureter - nephroureterectomy and ureterectomy specimen, 1st edition**, which has been developed for the reporting of resection specimens from patients with primary carcinoma of the ureter and renal pelvis. The protocol applies to carcinomas (non-invasive and invasive), with or without associated epithelial lesions. Urothelial tumours diagnosed as papilloma or papillary urothelial neoplasm of low malignant potential are not carcinomas and this dataset does not apply to those diagnoses. Biopsy and transurethral resection specimens are dealt with in a separate dataset. For bilateral tumours, complete a separate dataset for each. Published: May 2018.

11. **Carcinoma of the bladder - cystectomy, cystoprostatectomy and diverticulectomy specimen, 1st edition,** which has been developed for the reporting of cystectomy, cystoprostatectomy or diverticulectomy specimens from patients with carcinoma of the bladder. The protocol applies to primary carcinomas (non-invasive and invasive), with or without associated epithelial lesions. Urothelial tumours diagnosed as papilloma or papillary urothelial neoplasm of low malignant potential are not carcinomas and this dataset does not apply to those diagnoses. Biopsy and transurethral resection specimens are dealt with in a separate dataset. Published: May 2018.

12. **Urinary tract carcinoma - biopsy and transurethral resection specimen, 1st edition,** which has been developed for the reporting of biopsy and transurethral resection specimens of the bladder, urethra, ureter and renal pelvis. If biopsies are from different locations then a separate dataset should be completed for each tumour site. The protocol applies to primary carcinomas (non-invasive and invasive), with or without associated epithelial lesions. Urothelial tumours diagnosed as papilloma or papillary urothelial neoplasm of low malignant potential are not carcinomas and this dataset does not apply to those diagnoses. The most distal portion of the penile urethra in the region of the glans penis is not included in this dataset; it is covered in the Carcinoma of the penis and distal urethra dataset. Published: May 2018.

Female reproductive organs

1. **Endometrial cancer, 4th edition,** which covers resection specimens of endometrial cancers. It is not applicable for small endometrial biopsy specimens. Published: August 2021.

2. **Ovary, fallopian tube and primary peritoneal carcinoma, 2nd edition,** which has been developed for resection specimens of primary borderline and malignant epithelial tumours of the ovary, fallopian tubes and peritoneum. It does not include non-epithelial ovarian neoplasms such as germ cell or sex cord stromal tumours or other primary peritoneal neoplasms such as mesothelioma. Published: September 2021.

3. **Carcinoma of the cervix, 4th edition,** which covers pathology reporting of primary cervical carcinomas. Specimens include loop/cone excisions, trachelectomies, simple and radical hysterectomies and exenterations. The dataset applies to epithelial neoplasms only and does not apply to small biopsy specimens. Published: August 2021.

4. **Carcinoma of the vagina, 1st edition**, which has been developed for the pathological reporting of resection specimens of primary carcinomas of the vagina (including carcinosarcomas). Haematopoietic neoplasms, mesenchymal neoplasms, mixed epithelial and mesenchymal neoplasms, malignant melanomas, other non-epithelial malignancies and metastatic tumours are excluded from this dataset. Due to the rarity of primary vaginal carcinomas, there is little published research regarding some of the elements included in this dataset and some of the parameters included are 'extrapolated' from primary cervical and vulval carcinomas and/or represent the opinions and experience of the members of the ICCR Carcinoma of the Vagina DAC. Published: August 2021.

5. **Carcinoma of the vulva, 1st edition**, which has been developed for the pathological reporting of resection specimens of primary carcinomas of the vulva. In some patients with a prior diagnosis of vulval carcinoma (especially squamous), it is not clear whether a 'new' lesion is a recurrence or an independent neoplasm and the dataset can also be used for such tumours, especially when these 'arise' from the surface squamous epithelium. Molecular studies have shown that some of these 'recurrent' neoplasms exhibit similar mutations and are clonally related to the original tumour and are likely to represent true recurrences while others are clonally unrelated with different mutations and are likely to represent new neoplasms. In those rare cases where more than one primary tumour is present, separate datasets should be completed for each neoplasm. These should include all the elements in this dataset, except for lymph node status which does not need to be documented separately for each tumour. Haematopoietic neoplasms, mesenchymal neoplasms, mixed epithelial and mesenchymal neoplasms, malignant melanomas, other non-epithelial malignancies and metastatic tumours are excluded from this dataset. Published: August 2021.

6. **Gestational trophoblastic neoplasia, 1st edition,** which has been developed for the pathology reporting of resection specimens for primary uterine gestational trophoblastic neoplasia which includes invasive hydatidiform mole of either complete or partial type, gestational choriocarcinoma, placental site trophoblastic tumour and epithelioid trophoblastic tumour. The dataset should be used primarily for hysterectomy specimens. This dataset may also be used for rare myomectomy specimens but not all elements will be applicable. The dataset is not intended to be used for extrauterine primary lesions. Non-gestational trophoblastic tumours (germ cell

or somatic origin) and metastatic tumours are excluded from this dataset. Published: August 2021.

7. **Uterine malignant and potentially malignant mesenchymal tumours, 1st edition**, which has been developed for the pathology reporting of resection specimens of the uterus for sarcomas and mesenchymal tumours with potentially malignant behaviour. The dataset is applicable to tumours of the uterine corpus and the uterine cervix. Carcinomas, other non-mesenchymal malignancies and metastatic neoplasms are excluded from this dataset. Carcinosarcoma is also excluded as it is considered to represent a malignant epithelial tumour with divergent mesenchymal differentiation based on clinicopathologic, immunohistochemical and molecular analysis; as such, this entity is included in the ICCR Endometrial Cancer dataset. Published August 2021.

Thorax

1. **Lung cancer, 3rd edition**, which has been developed for resection specimens of lung cancer. It is not applicable for bronchoscopic and transthoracic biopsy specimens. Published: August 2017.

2. **Mesothelioma in the pleura and peritoneum, 3rd edition**, which covers both biopsy and resection specimens. Published September 2022.

3. **Thymic epithelial tumours, 3rd edition**, which applies to resection specimens of the thymus and is applicable for thymoma, neuroendocrine tumours of the thymus and thymic carcinoma but does not cover germ cell tumours, soft tissue tumours, haematolymphoid neoplasms, and other primary thymic neoplasms. Published May 2022.

4. **Neoplasms of the heart, peritoneum and great vessels, 2nd edition**, which covers biopsy and resection specimens for primary tumours of the heart, pericardium and great vessels, including both benign and malignant entities, and excluding haematolymphoid neoplasms and mesothelioma. Published December 2021.

Digestive tract

1. **Intrahepatic cholangiocarcinoma, perihilar cholangiocarcinoma and hepatocellular carcinoma, 2nd edition**, which covers resection specimens of the liver with intrahepatic, and perihilar cholangiocarcinoma and hepatocellular carcinoma. It does not apply to neuroendocrine carcinomas, hepatoblastoma, carcinomas of the extrahepatic bile ducts, gall bladder and benign lesions such as adenomas. Published: November 2020.

2. **Carcinoma of the exocrine pancreas, 1st edition**, which covers resection specimens with carcinomas of the exocrine pancreas, i.e., ductal adenocarcinoma and acinar cell carcinoma. It excludes carcinoma of the ampulla of Vater, common bile duct and duodenum, neuroendocrine neoplasia, lymphoma, sarcoma and secondary tumours. Published: April 2020.

3. **Colorectal cancer, 1st edition**, which covers surgical resection specimens from patients with primary carcinoma of the colon and rectum, including neuroendocrine carcinomas (NECs) and mixed neuroendocrine-non-neuroendocrine neoplasms (MiNENs). It is not applicable to carcinomas of the small intestine, appendix or anus, nor to neuroendocrine tumours (NETs) or non-epithelial malignancies. Primary colorectal carcinomas treated by local excision are not included. Published: April 2020.

4. **Colorectal excisional biopsy (polypectomy) specimen, 1st edition**, which covers local excision specimens from the colon and rectum, including polypectomies, endoscopic mucosal resections (EMR), endoscopic submucosal dissections (ESD), endoscopic full thickness resections (EFTR), transanal submucosal excisions, transanal minimally invasive surgery (TAMIS) and transanal endoscopic microsurgery (TEMS) specimens. Surgical resection specimens from patients with primary carcinoma of the colon and rectum, including NECs and MiNENs, are excluded. Published: April 2020.

5. **Carcinomas of the stomach, 2nd edition**, which covers gastrectomy for gastric carcinomas. Carcinomas involving the oesophagogastric junction (OGJ) with their epicentre >20 mm into the proximal stomach and cardia cancers that do not involve the OGJ are included. These criteria are set by the UICC/AJCC 8th edition Classifications and have been adopted by the WHO to define the diagnosis 'gastric cancer'. For all other tumours involving the OGJ, refer to the ICCR dataset for carcinomas of the oesophagus. NECs and MiNENs (with the exception of mixed adenoma and NETs) are included in this dataset. NETs, non-epithelial malignancies and secondary tumours are excluded from this dataset. Published: December 2021.

6. **Endoscopic resection of the stomach, 2nd edition,** which covers carcinomas involving the oesophagogastric junction (OGJ) with their epicentre >20 mm into the proximal stomach and cardia cancers that do not involve the OGJ are included. These criteria are set by the UICC/AJCC on Cancer 8th edition TNM classifications and have been adopted by the WHO and define the diagnosis 'gastric cancer'. An ICCR dataset for carcinoma of the oesophagus is available for tumours not meeting these criteria. NECs and MiNENs (with the exception of mixed adenoma and NETs) are included in this dataset. NETs, non-epithelial malignancies, and secondary tumours are excluded from this dataset Published: December 2021.

7. **Carcinomas of the oesophagus, 2nd edition**, which covers resection specimens of the oesophagus. Carcinomas involving the OGJ with tumour epicentre ≤20 mm into the proximal stomach are included. A separate ICCR dataset is available for endoscopic resections of the oesophagus and oesophagogastric junction. NEC and MiNEN of the oesophagus are included. NET, non-epithelial malignancies such as melanoma, and secondary tumours are excluded. Published: December 2021.

8. **Endoscopic resection of the oesophagus and oesophagogastric junction, 2nd edition**, which covers endoscopic resection (ER) of pre-malignant and malignant lesions of the oesophagus and OGJ. Surgically resected specimens are covered in a separate ICCR dataset. NEC and MiNEN of the oesophagus are included. NET, non-epithelial malignancies such as melanoma, and secondary tumours are excluded. Published: December 2021.

Skin

1. **Invasive melanoma, 2nd edition**, which has been developed for reporting of primary cutaneous invasive melanoma. The second edition of this dataset includes changes to align the dataset with the TNM Pathological staging 8th edition and the WHO Classification of Tumours, Pathology and Genetics of Skin Tumours (2018), in addition to other revisions as listed in the scope section of the dataset notes. Published: October 2019.

2. **Merkel cell carcinoma, 1st edition**, which covers primary cutaneous Merkel cell carcinoma (MCC) in excision (resection) specimens containing tumour. Published December 2019.

Central nervous system

1. **Tumours of the central nervous system (CNS), 1st edition,** which is split into three sections:

   a. Histological assessment of CNS specimens. It is intended that this section should be used in conjunction with the other sections. A full diagnosis of CNS tumours should ideally conform to the 2016 WHO Classification of Tumours of the CNS which requires integration of elements from histological and ancillary analyses. However, the majority of 2016 CNS WHO entities can be diagnosed solely on the basis of histological features and in this situation only this section needs to be completed.

   b. Molecular information for CNS specimens. This section is not needed for those tumours in which molecular information is not captured for diagnostic purposes.

   c. Final integrated report/diagnosis for CNS specimens. In many situations, 2016 CNS WHO diagnoses integrate histological and molecular information and this section is intended for the capture of that final diagnosis.

   Published: August 2018.

Head and neck

1. **Carcinomas of the nasal cavity and paranasal sinuses, 1st edition**, which has been developed for the reporting of resection and biopsy specimens of mucosal malignancies originating in the nasal cavities and paranasal sinuses. Neuroectodermal neoplasms (including melanoma) and sarcomas are not included. Bone, soft tissue and lymphoma protocols are separately listed. Neck dissections and nodal excisions are dealt with in a separate dataset, and this dataset should be used in conjunction, where applicable. Published: September 2018.

2. **Carcinomas of the hypopharynx, larynx and trachea, 1st edition**, which has been developed for the reporting of resection and biopsy specimens of mucosal malignancies of the larynx, hypopharynx and trachea. The protocol applies to all invasive carcinomas of the larynx, hypopharynx and trachea (including the supraglottis, glottis, and subglottis). Salivary-type malignancies arising from mucosal glands of the hypopharynx and larynx should be recorded in this dataset. Mucosal melanoma is presented in a separate dataset. Lymphomas and sarcomas are not included. Malignancies arising at other sites in the head and neck region, and neck dissections and nodal excisions are dealt with in separate datasets which may be used, as appropriate, in conjunction with this dataset. Where more than one anatomically or histologically distinct primary tumours occur, a separate dataset should be completed for each tumour. Published: September 2018.

3. **Carcinomas of the oral cavity, 1st edition**, which has been developed for the reporting of resection and biopsy specimens of invasive carcinomas of the oral cavity, including lip and tongue. Mucosal melanoma, lymphomas and sarcomas are not included. Published: September 2018.

4. **Carcinomas of the nasopharynx and oropharynx, 1st edition**, which has been developed for the reporting of resection and biopsy specimens of the nasopharynx and oropharynx. The protocol applies to all invasive carcinomas of the nasopharynx and oropharynx including the base of tongue, tonsils, soft palate, posterior wall, and uvula. Lymphomas and sarcomas are not included. Published: September 2018.

5. **Carcinomas of the major salivary glands, 1st edition**, which has been developed for the reporting of resection and biopsy specimens of malignant neoplasms and associated carcinoma in situ arising from the major salivary glands. The protocol applies to all carcinomas of the parotid, submandibular and sublingual glands. Melanomas, lymphomas, and sarcomas are dealt with in separate datasets. Minor salivary gland malignancies arising in the oral cavity, nasal cavity and paranasal sinuses, trachea, nasopharynx, oropharynx and hypopharynx and odontogenic specimens are staged according to their anatomical sub-site and are dealt with in separate datasets. Published: September 2018.

6. **Malignant odontogenic tumours, 1st edition**, which has been developed for the reporting of biopsy and resection specimens for malignant primary odontogenic tumours. Malignant neoplasms arising in the nasal cavity and paranasal sinuses, oral cavity, salivary glands, trachea, pharynx and larynx are dealt with in separate datasets. Bone, soft tissue and lymphoma protocols will be separately listed. Published: September 2018.

7. **Ear and temporal bone tumours, 1st edition**, which has been developed for the reporting of resection and biopsy specimens of the ear and temporal bone. It includes ONLY primary tumours of the external auditory canal, middle and inner ear, including both benign and malignant entities (specifically due to anatomic confines and management alternatives which may require significant, destructive or disfiguring surgery). By definition, all malignancies of the external ear (pinna, concha, scaphoid, lobe, etc., such as squamous cell carcinoma, basal cell carcinoma, atypical fibroxanthoma, Merkel cell carcinoma and melanoma) are separately covered by the dermatopathology datasets. Published: September 2018.

8. **Mucosal melanomas of the head and neck, 1st edition**, which has been developed for the reporting of resection and biopsy specimens of mucosal melanoma arising in the nasopharynx, oropharynx, larynx, hypopharynx, oral cavity, nasal cavity and paranasal sinuses. All other malignancies and tumour categories are dealt with in separate datasets, specifically cutaneous melanoma is separately reported. Direct extension of a cutaneous primary into a mucosal site should be excluded and would not be reported in this dataset. Metastasis to a head and neck mucosal site is also excluded. Published: September 2018.

9. **Nodal excisions and neck dissection specimen, 1st edition**, which has been developed for the reporting of lymph node resections from patients with carcinomas and melanomas of the head and neck. This excludes nodal resections for lymphoma and sarcomas. It is not intended for use in reporting lymph node core biopsy or fine needle aspirations. Carcinomas covered by the dataset include squamous cell carcinomas, sinonasal carcinomas, salivary and non-salivary type adenocarcinomas and neuroendocrine tumours. Pathologists may also apply the dataset to metastatic non-Merkel cutaneous squamous cell carcinomas and other cutaneous carcinomas. This dataset is to be used in conjunction with other datasets in the Head and Neck Series. Published: September 2018.

Endocrine

1. **Carcinoma of the adrenal cortex, 1st edition**, which covers malignant adrenal cortical resection specimens, borderline (low-malignant potential lesions), and paediatric adrenal cortical carcinomas. It excludes neuroblastoma, sarcoma, lymphoma, core needle biopsies, benign lesions and tumours and metastasis, and Tumours of the adrenal medulla (e.g., phaeochromocytoma). Published: December 2019.

2. **Parathyroid carcinoma and atypical parathyroid neoplasm, 1st edition**, which covers parathyroid resection specimens when the diagnosis is atypical parathyroid neoplasm (atypical parathyroid adenoma or carcinoma. But excludes biopsies, sarcoma, lymphoma and metastasis. Published: December 2019.

3. **Phaeochromocytoma and paraganglioma 1st edition**, which covers adrenalectomy/partial adrenalectomy specimens for phaeochromocytoma, other excisions for paragangliomas and biopsies of related specimens. It excludes sarcoma, lymphoma and metastasis to the adrenal medulla, neuroblastoma, ganglioneuroblastoma and adrenal cortical tumours. Published: December 2019.

4. **Carcinoma of the thyroid, 2nd edition**, which covers thyroid resection specimens for carcinoma, but excludes core needle biopsies and metastasis to the thyroid gland, invasive follicular thyroid neoplasm with papillary-like nuclear features (NIFTP), tumours of uncertain malignant potential (UMP), thyroid carcinomas arising from struma ovarii, thyroid carcinomas arising in thyroglossal duct cysts, sarcoma and lymphoma. Published: June 2020.

Soft tissue and bone

1. **Primary tumour in bone - biopsy specimens, 1st edition**, was developed for the pathology reporting of biopsy specimens of primary tumour in bone. Ewing sarcoma and related round cell sarcomas with primary bone presentation are also covered by this dataset. A separate dataset is available for reporting of resection specimens of primary tumour in bone. Some types of soft tissue sarcoma may on rare occasion arise primarily in bone and should be reported using the primary tumour in bone dataset, rather than the soft tissue sarcoma dataset. If biopsies are taken from multiple tumour nodules at different sites, these should be documented separately. Haematologic malignancies and metastatic specimens are excluded from this dataset. Published: April 2021.

2. **Primary tumour in bone - resection specimens, 1st edition**, which was developed for the pathology reporting of resection specimens of primary tumour in bone. Ewing sarcoma and related round cell sarcomas with primary bone presentation are also covered in this dataset. A separate dataset is available for reporting of biopsy specimens of primary tumour in bone. Some types of soft tissue sarcoma may on rare occasion arise primarily in bone and should be reported using the primary tumour in bone dataset, rather than the soft tissue sarcoma dataset. Haematologic malignancies and metastatic specimens are excluded from this dataset. Published: April 2021.

3. **Gastrointestinal stromal tumour (GIST) - biopsy specimens, 1st edition**, was developed for the pathology reporting of biopsy specimens for GIST. Metastatic GIST specimens are excluded from this dataset. Published: April 2021.

4. **Gastrointestinal stromal tumour (GIST) - resection specimens, 1st edition**, which was developed for the pathology reporting of resection specimens for GIST. Metastatic GIST specimens are excluded from this dataset. Published: April 2021.

5. **Soft tissue sarcoma - biopsy specimens, 1st edition**, which was developed for the pathology reporting of biopsy specimens for soft tissue sarcomas. Adult rhabdomyosarcoma is also included in this dataset. A separate ICCR dataset is available for reporting of resection specimens for soft tissue sarcomas. Some soft tissue tumours which rarely arise primarily in bone should be reported using the ICCR primary tumour in bone datasets. Lymphoma, uterine sarcoma, paediatric

rhabdomyosarcoma and metastases are excluded from this dataset. GIST are also not included in this dataset as GIST displays a number of unique features which warrant its separate consideration; separate ICCR datasets for GIST are available. Published: April 2021.

6. **Soft tissue sarcoma - resection specimens, 1st edition**, was developed for the pathology reporting of resection specimens for soft tissue sarcomas. Adult rhabdomyosarcoma is also included in this dataset. A separate ICCR dataset is available for reporting of biopsy specimens for soft tissue sarcomas. Some soft tissue tumours which rarely arise primarily in bone and in this case should be reported using the ICCR primary tumour in bone datasets. Lymphoma, uterine sarcoma, paediatric rhabdomyosarcoma and metastases are excluded from this dataset. GIST are also not included in this dataset as GIST displays a number of unique features which warrant its separate consideration; separate ICCR datasets for GIST are available. Published: April 2021.

Breast

1. **Ductal carcinoma in situ, variants of lobular carcinoma in situ and low grade lesions, 1st edition**, which was developed for the reporting of resection specimens for ductal carcinoma in situ (DCIS) of the breast. The protocol applies to cases of DCIS and for where microinvasion (≤1 mm) is present. It also covers other in situ lesions including pleomorphic and florid variants of lobular carcinoma in situ (LCIS), as well as encapsulated papillary carcinoma and solid papillary carcinoma in situ. This dataset may also be used in those rare cases of DCIS removed at core biopsy but without evidence of residual DCIS in a subsequent excision specimen. This protocol should only be used for re-excisions when they contain the largest extent of DCIS. A separate dataset should be completed for bilateral DCIS and for each excision specimen in unilateral disease. DCIS (with or without microinvasion) diagnosed on needle core biopsies only, and residual DCIS post neoadjuvant therapy are outside the scope. Separate ICCR datasets cover DCIS associated with invasive breast carcinomas and breast resections in the neoadjuvant setting. Surgically removed lymph nodes are covered in a separate ICCR dataset which may be used, as appropriate, in conjunction with this dataset. Published: June 2021.

2. **Invasive carcinoma of the breast, 2nd edition**, which was developed for the reporting of resection specimens from patients with invasive carcinoma of the breast, with or without DCIS. DCIS without invasive carcinoma and microinvasive carcinoma (≤1 mm) are dealt with in a separate ICCR dataset. Ipsilateral multifocal disease should be dealt with in a single report. For bilateral invasive breast tumours, a separate dataset should be completed for each side. Surgically removed lymph nodes are dealt with in a separate ICCR dataset which may be used, as appropriate, in conjunction with this dataset. Invasive breast cancer for the post neoadjuvant setting is also dealt with in a separate ICCR dataset. Published: June 2022.

3. **Invasive carcinoma of the breast in the setting of neoadjuvant therapy, 1st edition,** developed for the reporting of resection specimens after neoadjuvant therapy from patients with invasive carcinoma of the breast with or without DCIS. This dataset is for post-treatment surgical specimens. Core needle biopsies are not included. Published June 2022.

4. **Surgically removed lymph nodes for breast tumours, 1st edition**, which was developed for the reporting of surgically removed ipsilateral lymph nodes (including lymph node dissection, targeted axillary surgery, nodal sampling and sentinel node biopsy

specimens) for breast tumours. It is not intended for use in reporting core biopsy or fine needle aspiration of lymph nodes. The assessment of ipsilateral lymph nodes is part of nodal staging of breast cancer, whereas the rare contralateral lymph node involvement is currently interpreted as distant metastasis and is not part of the dataset. The reporting of invasive breast cancer and in situ disease (ductal carcinoma in situ, pleomorphic and florid lobular carcinoma in situ, encapsulated papillary carcinoma and solid papillary carcinoma in situ) are dealt with in separate ICCR datasets which may be used, as appropriate, in conjunction with this dataset. Published: May 2021.

9.2 Peer-reviewed publications

- Reporting of Surgically Removed Lymph Nodes for Breast Tumors: Recommendations From the International Collaboration on Cancer Reporting. Cserni G, Brogi E, Cody HS, Deb R, Farshid G, O'Toole S, Provenzano E, Quinn CM, Sahin AA, Schmitt F, Weaver DL, Yamaguchi R, Webster F, Tan PH. Arch Pathol Lab Med. 2022 Nov 1;146(11):1308-1318. doi: 10.5858/arpa.2022-0060-RA.

- International Collaboration on Cancer Reporting (ICCR) Gynecological Cancer Datasets: A Move Towards International Standardization. McCluggage WG. Int J Gynecol Pathol. 2022 Nov 1;41(Suppl 1):S1-S2. doi: 10.1097/PGP.0000000000000872. Epub 2022 Oct 24.

- The International Collaboration on Cancer Reporting (ICCR): 10 Years Progress in the Development of Cancer Pathology Datasets. Helliwell TR, Judge MJ, Birdsong GG, Ellis DW, Srigley JR. Int J Gynecol Pathol. 2022 Nov 1;41(Suppl 1):S3-S7. doi: 10.1097/PGP.0000000000000899. Epub 2022 Aug 11.

- Data Set for the Reporting of Carcinomas of the Vulva: Recommendations From the International Collaboration on Cancer Reporting (ICCR). Hoang L, Webster F, Bosse T, Focchi G, Gilks CB, Howitt BE, McAlpine JN, Ordi J, Singh N, Wong RW, Lax SF, McCluggage WG. Int J Gynecol Pathol. 2022 Nov 1;41(Suppl 1):S8-S22. doi: 10.1097/PGP.0000000000000900. Epub 2022 Oct 10.

- Data Set for the Reporting of Carcinomas of the Vagina: Recommendations From the International Collaboration on Cancer Reporting (ICCR). Wong RW, Webster F, Bosse T, Focchi G, Gilks CB, Hoang L, Howitt BE, McAlpine J, Ordi J, Singh N, Lax SF, McCluggage WG. Int J Gynecol Pathol. 2022 Nov 1;41(Suppl 1):S23-S33. doi: 10.1097/PGP.0000000000000883. Epub 2022 May 20.

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- Dataset for the Reporting of Merkel Cell Carcinoma: Recommendations From the International Collaboration on Cancer Reporting (ICCR). Busam KJ, Judge MJ, Bichakjian CK, Coit D, Kutzner H, Requena L, Scolyer RA, Stefanato CM, Wood BA, Walsh NM. Am J Surg Pathol. 2022 Nov 1;46(11):1583-1591. doi: 10.1097/PAS.0000000000001959. Epub 2022 Aug 25.

- Dataset for the Reporting of Gestational Trophoblastic Neoplasia: Recommendations From the International Collaboration on Cancer Reporting (ICCR). Hui P, Webster F, Baergen RN, Buza N, Cheung ANY, Kaur B, Ronnett BM, Shih IM, Seckl MJ, Lax SF, McCluggage WG. Int J Gynecol Pathol. 2022 Nov 1;41(Suppl 1):S34-S43. doi: 10.1097/PGP.0000000000000876. Epub 2022 Oct 24.

- Data Set for the Reporting of Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma: Recommendations From the International Collaboration on Cancer Reporting (ICCR). Gilks CB, Selinger CI, Davidson B, Köbel M, Ledermann JA, Lim D, Malpica A, Mikami Y, Singh N, Srinivasan R, Vang R, Lax SF, McCluggage WG. Int J Gynecol Pathol. 2022 Nov 1;41(Suppl 1):S119-S142. doi: 10.1097/PGP.0000000000000908. Epub 2022 Oct 24.

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