International Collaboration on Cancer Reporting

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ANNUAL REPORT
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ICCR International Collaboration on Cancer Reporting

Index

1. MESSAGE FROM THE PRESIDENT

2021 is the tenth anniversary of the formation of the International Collaboration on Cancer Reporting (ICCR) and it is an opportunity to reflect on the progress that has been made across the decade.

Membership

From its inception in 2011 with four members - the Colleges of Pathology of the USA, UK and Australia and the Canadian Association of Pathologists-Association Canadienne des Pathologists (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC) - the ICCR has grown to become a not-for-profit corporation with 18 sponsoring members, covering six continents and representing a pathology community which services several billion people. In 2021 we welcomed four new organisations – Russian Society of Oncopathology, Chinese Society of Pathology, Swiss Society of Pathology and the Arab Division of the International Academy of Pathology.

Membership in the ICCR not only provides much needed funding for its work, but also enables the ICCR to reach out to more pathologists and to better understand the needs of pathologists worldwide.

Succession planning

With ICCR's expanded membership, the importance and reliance on key organizational roles was recognised. Therefore, during the past year several important changes have been progressed. Firstly, to increase the term of office for the ICCR's President and Vice-President from one year to two and secondly to create a President-elect position to ensure adequate continuity in the ICCR executive and provide a stable transition of executive roles.

In addition, member organisations were asked to consider terms of office for their representatives and to facilitate the inclusion of younger pathologists with interest in structured reporting and informatics onto the Board, via the appointment of observers to assist and support directors.

This important work is coordinated by the Dataset Steering Committee (DSC). We are indebted to Professor Tim Helliwell who has brilliantly chaired the DSC for the last three and a half years during which time 35 datasets and 8 updates have been completed. We are also delighted that Professor Sigurd Lax has agreed to chair the DSC going forward.

Core business – standards development

The development of internationally harmonised cancer pathology datasets and reporting guides incorporating contemporary morphologic and molecular standards from partner organizations including 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 and specialty societies is ICCR's core business.

At the end of 2015, the ICCR set an ambitious goal to develop 50 datasets by the end of 2021. This target was to incorporate the most commonly diagnosed cancers world-wide. As at November 2021, the ICCR has 56 datasets published and more than 40 articles related to the ICCR datasets or work of the ICCR in peer-reviewed journals. All ten, most common solid tumours, accounting for approximately 90% of all reported cancers, are included in this list of publications.

Workstreams

Looking ahead to the new decade, at the end of 2020, the ICCR identified two additional workstreams:

- To translate datasets into multiple languages.
- To transform the dataset standards into machine readable formats and to facilitate their electronic implementation.

Translation of the datasets into six priority languages – French, Spanish, Portuguese, German, Chinese and Russian was considered to be an essential next step to advance adoption and uptake of the datasets around the world, in particular in low and middle income countries (LMIC). This is especially important given that the WHO Classification of Tumours is not being translated. In addition to the six languages identified above, we will be working with countries such as Japan and Italy, to facilitate translation into other national languages.

Since 21 datasets were translated into Spanish, French and Portuguese in 2018 through the kind support of the American Society for Clinical Pathology (ASCP), lack of funding has hampered further efforts in this area. Dataset translation will be a key focus in 2022 and we will seek input from our sponsoring and affiliated organizations to advance this agenda.

In addition to providing ICCR datasets in other languages, access to electronic structured reporting tools was considered to be a key resource for pathologists. The ICCR have established the Structured Reporting Implementation Committee (SRIC) to support our electronic goals and are pleased to have Dr. George Birdsong, with his wealth of experience, chair this group.

In many developed parts of the world there are commercially available Laboratory Information Systems (LIS) or middleware solutions. 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. In this case, the availability of electronic representations for each dataset and applicable terminology are all that is needed to ensure accurate and reliable reporting according to the ICCR standard. However, in LMIC there is little or no access to electronic structured reporting tools. Reporting remains paper based or at best done on a standalone PC using word processing software. Therefore, the ICCR has commenced work in two areas:

- ICCR has entered into memoranda of understanding with Smart Reporting, a German Anatomical LIS vendor, which provides them a non-exclusive licence to include the ICCR datasets in its application. Discussions with other interested parties are underway.
- Identification of a low-cost structured reporting web-based application, specifically for LMIC but which will also serve as a model for other LIS wishing to implement ICCR Datasets. Five trial datasets are currently in development using this application.

Sustainability

While membership fees have been adequate in ensure that ICCR's core dataset business, it is recognized that more substantial funding would be required to undertake the other two 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.

A new corporate brochure and logo were accepted in late 2020 and have commenced roll out in 2021. A new website will also be launched in early 2022. With the fresh branding and Ms Meredith's guidance, the ICCR will be seeking additional funding opportunities in 2022. In particular we will be approaching international philanthropic organisations.

Thank you

On behalf of the Executive Team, 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 Authoring Committees, Series Champions, Chairs and members and especially our dedicated Project Managers who keep the whole process alive. In particular, we are indebted to Meagan Judge, our Senior Project Manager, whose talent, dedication and hard work have allowed the ICCR to thrive over the last decade.

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

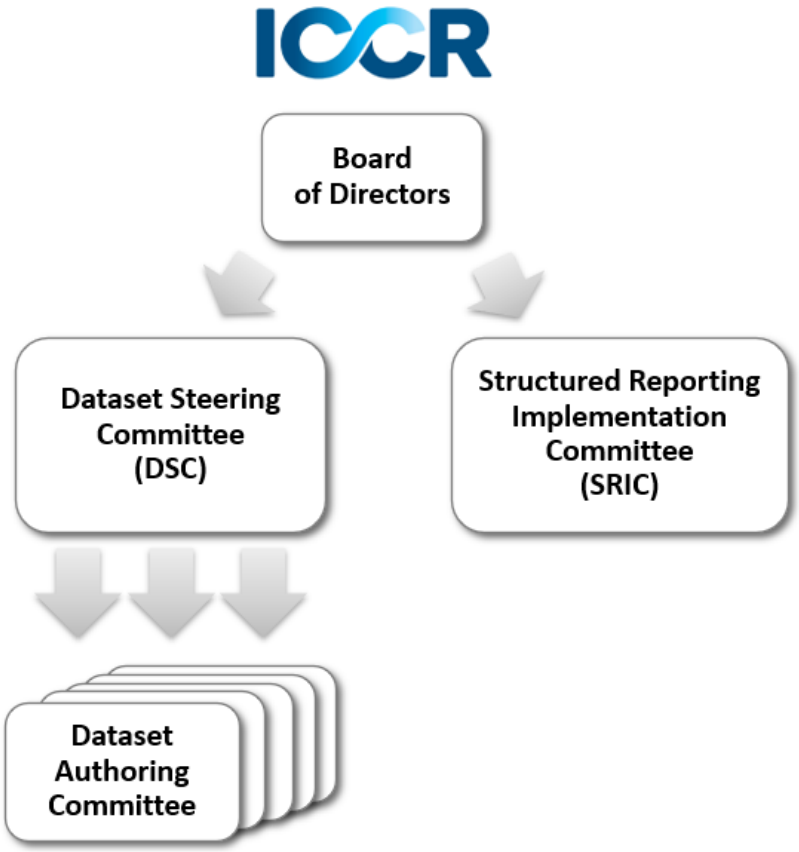
The ICCR produces internationally standardised pathology datasets incorporating contemporary morphologic and molecular parameters which are translated into multiple languages and are available in machine readable formats. The datasets are based on strong scientific evidence and are used primarily to 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 International Collaboration on Cancer Reporting (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 is as follows:



The ICCR is supported by membership and sponsorship.

The ICCR 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 US$20,000.

- 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 US$10,000.

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

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

As at November 2021, the ICCR has two PLATINUM members, which are:

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

Both these members were reconfirmed as Platinum members at the June 2021 BoD meeting. 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 2021, ICCR has twelve GOLD members, which are:

- European Society of Pathology (ESP),
- Royal College of Pathologists UK (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) and
- Chinese Society of Pathology (CSP).

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 running of the ICCR. Each member has nominated directors as follows:

- John Srigley for the Canadian Association of Pathologists - Association Canadienne des Pathologistes (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC),
- Tim Helliwell for The Royal College of Pathologists UK (RCPath),
- James Kench for the Royal College of Pathologists of Australasia (RCPA), and Sanchia Aranda, the second Australian director as per constitutional requirements,
- Marta Cohen for the European Society of Pathology (ESP),
- Thomas Wheeler for the College of American Pathologists (CAP),
- James L Wisecarver for the American Society of Clinical Pathology (ASCP),
- Kieran Sheahan for the Royal College of Physicians of Ireland, Faculty of Pathology (RCPI FoP),
- Peter Schirmacher for the German Society of Pathology (DGP),
- Katia Ramos Moreira Leite for the Brazilian Society of Pathology (SBP),
- Nga Yin Annie Cheung for the Hong Kong College of Pathologists,
- Gerald Hoefler for the Austrian Society of Pathology/Austrian Division of the International Academy of Pathology (ÖGPath/IAP Austria),
- Atsushi Ochiai for the Japanese Society of Pathology (JSP),
- Anna Sapino for the Italian Society of Pathology and Cytology (SIAPEC),
- Vyacheslav Grinevich for the Russian Society of Oncopathology (RSOP) and
- Zhiyong Liang for the Chinese Society of Pathology (CSP).

(Note, the SSP has not yet nominated a representative to the BoD).

As at November 2021, there are two SILVER members, which are:

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

At the BoD on 1st February 2021, John Srigley was re-elected as President and Tim Helliwell was re-elected as Vice-president of the company. David Ellis was re-affirmed as Executive Officer. In that role Dr Ellis provides advice to the BoD and continuing corporate knowledge as Past President.

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, the European Organisation for Research and Treatment of Cancer (EORTC), and the International Association of Cancer Registries (IACR). Tim Helliwell, Vice-president of the ICCR, held the position of Chair of the DSC from January to November 2021, at which time he handed over chair responsibilities to Sigurd Lax of the Austrian Society of Pathology/Austrian Division of the International Academy of Pathology.

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 Structured Reporting Implementation Committee (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. Dr 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

In response to the recommendations of the Strategic Meeting held in October 2020, changes to the ICCR constitution were proposed as follows:

1. Extend the Term of Office for the President and Vice-president

   Previously the President and Vice-president (ICCR Office bearers) were elected by the Board for a period of one year and could be re-elected.

   This was considered to be too brief a period and a tenure of two years was agreed at the Board meeting held on 1st February 2021.

2. Adopt a President-elect position

   Previously, the President and Vice-president (ICCR Office bearers) were elected by the Board following a call for nominations. A person voted to the position of Vice-president was under no expectation or obligation to accede to the position of President.

   At the Strategic meeting held in October 2020 there was proposal to adopt a President-elect position to provide a means of maintaining continuity and prevent the loss of corporate knowledge in the ICCR executive. This was discussed and agreed at the Board meeting held on 1st February 2021.

   In summary, a Vice-president is elected per the usual procedure. The Vice-president becomes the President-elect twelve months prior to the end of the incumbent President's term of office. The President-elect only becomes President if the incumbent President is not re-elected.

   If the Vice-president is unable to undertake the role of President-elect, for whatever reason, another Board member would be elected to take their place as President-elect.

Changes effecting the above two points were drafted by Norton Rose solicitors and the constitution was circulated for review and approval at the BoD on 2nd November 2021. They were put to the Annual General Meeting held on 16th November 2021 as a special resolution and ratified, effective immediately.

4. DATASET DEVELOPMENT STATUS

The core business of the ICCR is to develop internationally validated and evidence-based pathology datasets for cancer reporting for use around the world.

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.

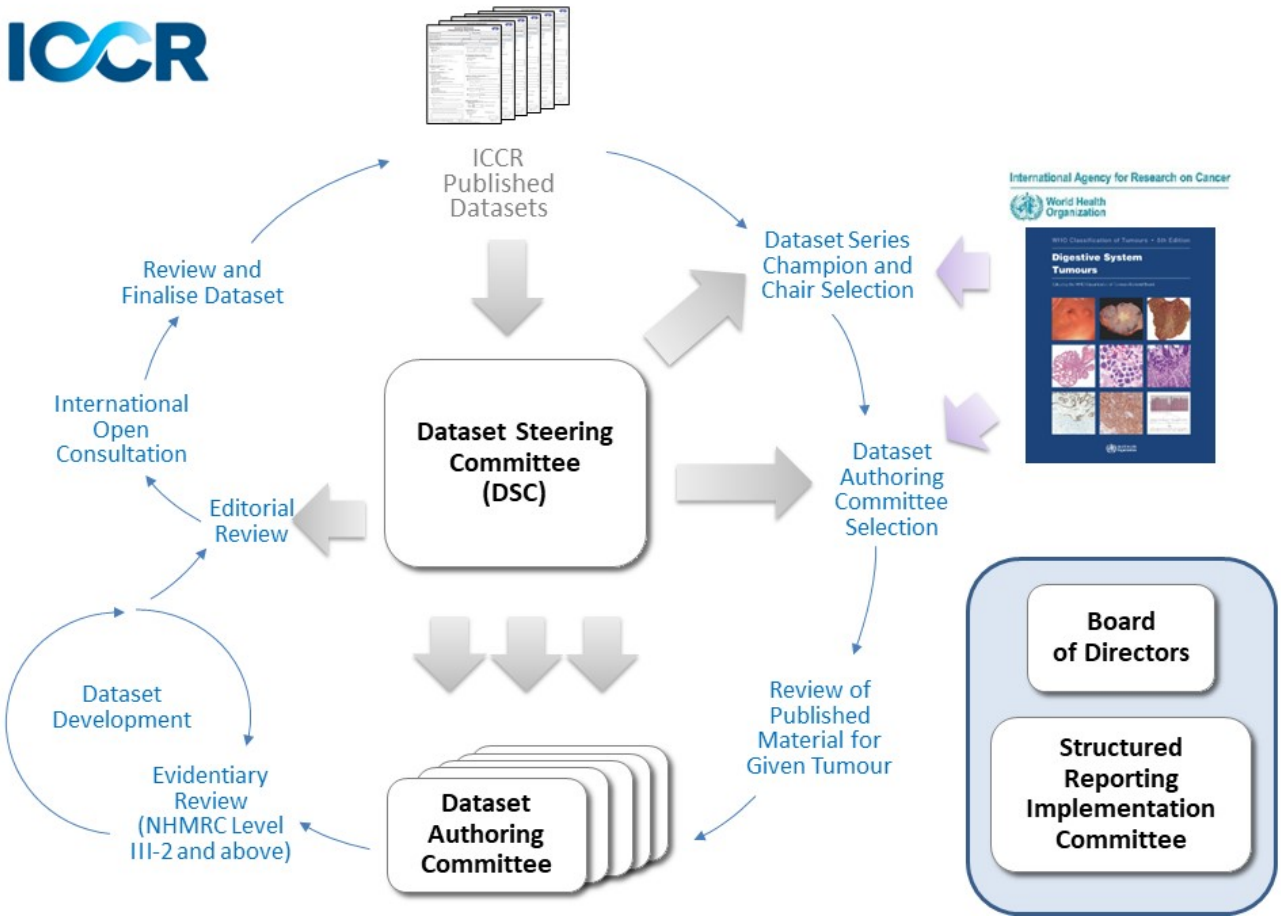


Figure 1: ICCR dataset development process.

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 additionally appoints a Series Champion. The Series Champion 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).

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 ICCR DSC representative.

4.1 Published datasets

As at November 2021, the ICCR has published 56 datasets. All published datasets are compliant with the latest 8th edition TNM staging, where applicable.

See Appendix 10.1 for all published 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 23 datasets currently in progress:

4.2.1 Breast

In synchrony with the publication of the 5th series of the IARC/WHO 'blue books' on Breast cancer, the ICCR has commenced developing a new dataset, Invasive Breast in the post neoadjuvant therapy setting (Chair: Ian Ellis).

This dataset is the fourth in the Breast suite. Three other Breast datasets are already published, refer to Appendix 10.1 for published datasets.

Puay Hoon Tan, from Singapore, is the appointed Series Champion.

4.2.2 Thoracic

The ICCR is in the process of updating four existing datasets as well as developing a new dataset in the Thoracic suite as follows:

1. Lung cancers (update of 3rd edition) (Chair: Andrew Nicholson)
2. Thymic epithelial tumours (update of 2nd edition) (Chair: Anja Roden)
3. Neoplasms of the heart, pericardium and great vessels (update of 1st edition) (Chair: Joseph Maleszewski)
4. Mesothelioma in the pleura and peritoneum (update of 2nd edition) (Chair: Sonja Klebe)

5. Lung biopsy/small diagnostic specimens (1st edition) (Chair: Andrew Nicholson)

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

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 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)(Chairs: Eva Comperat 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)(Chairs: Eva Comperat and Toyonori Tsuzuki)
4. Carcinoma of the Urethra - Urethrectomy Specimen (update of 1st edition)(Chairs: Eva Comperat and Toyonori Tsuzuki)
5. Invasive Carcinoma of Renal Tubular Origin (update of 1st edition)(Chairs: Brett Delahunt 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)(Chairs: James Kench and Gladell Paner)
9. Prostate Cancer - Transurethral Resection and Enucleation Specimen (update of 1st edition) (Chairs: James Kench and Gladell Paner)

10. Prostate - Core Needle Biopsy (update of 1st edition)(Chairs: James Kench and Gladell Paner)

11. Renal Biopsy for Tumour (update of 1st edition)(Chairs: Brett Delahunt and Sean Williamson)

12. Urinary Tract Carcinoma - Biopsy and Transurethral Resection Specimen (update of 1st edition)(Chairs: Eva Comperat 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 existing dataset: Tumours of the CNS dataset.

4.3 Datasets in planning

The following dataset series are currently being considered for a development start in 2022:

- Head and neck
- Endocrine and Neuroendocrine.

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, UK 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 stage 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.

It is not clear at this stage how the UICC will respond to the AJCC 'rolling update' model and whether the two editions will diverge in the future.

Further discissions with both organisations are planned to map out a path forward.

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, 40 dataset related articles have been published.

See Appendix 10.2 for all ICCR dataset related peer-reviewed publications.

5. TRANSLATION

Translation of 21 ICCR datasets into Spanish, French and Portuguese was completed in 2018 through the kind contribution of the American Society of Clinical Pathology (ASCP), a sustaining member of the ICCR. However, further translations have been stymied by a lack of funding and these translated datasets are becoming outdated as further updates to the English language versions are published.

The translation work is critical as the IARC/WHO Classification of Tumours 'blue book' are not being translated, so having the datasets available in other languages will be very important to advance adoption of standardised reporting around the world and greatly assist pathologists practising in LMIC.

The ICCR has agreed that translation of the datasets into six languages - Spanish, French, Portuguese, Chinese, Russian and German is a high priority once funding is secured.

The initial translations into Spanish, French and Portuguese were completed through the services of an ISO 9001:2015 certified company to undertake the translations. The ICCR has discussed adopting a similar model for future translations as this ensures consistency (via objective translation), quality, and scheduled delivery dates, through formal contracts. However, ICCR have agreed that this model requires an additional step to the process. That is, to engage with ICCR's member societies to undertake a quality assurance check of the translated datasets to ensure scientific fidelity.

However, there is a large bolus of datasets to be translated and the ongoing maintenance and upkeep of the datasets will need a substantial investment in funding. Therefore, other models for translation for the six priority languages as well as translation for national languages such as Japanese or Italian are also being considered.

5.1 Datasets translated

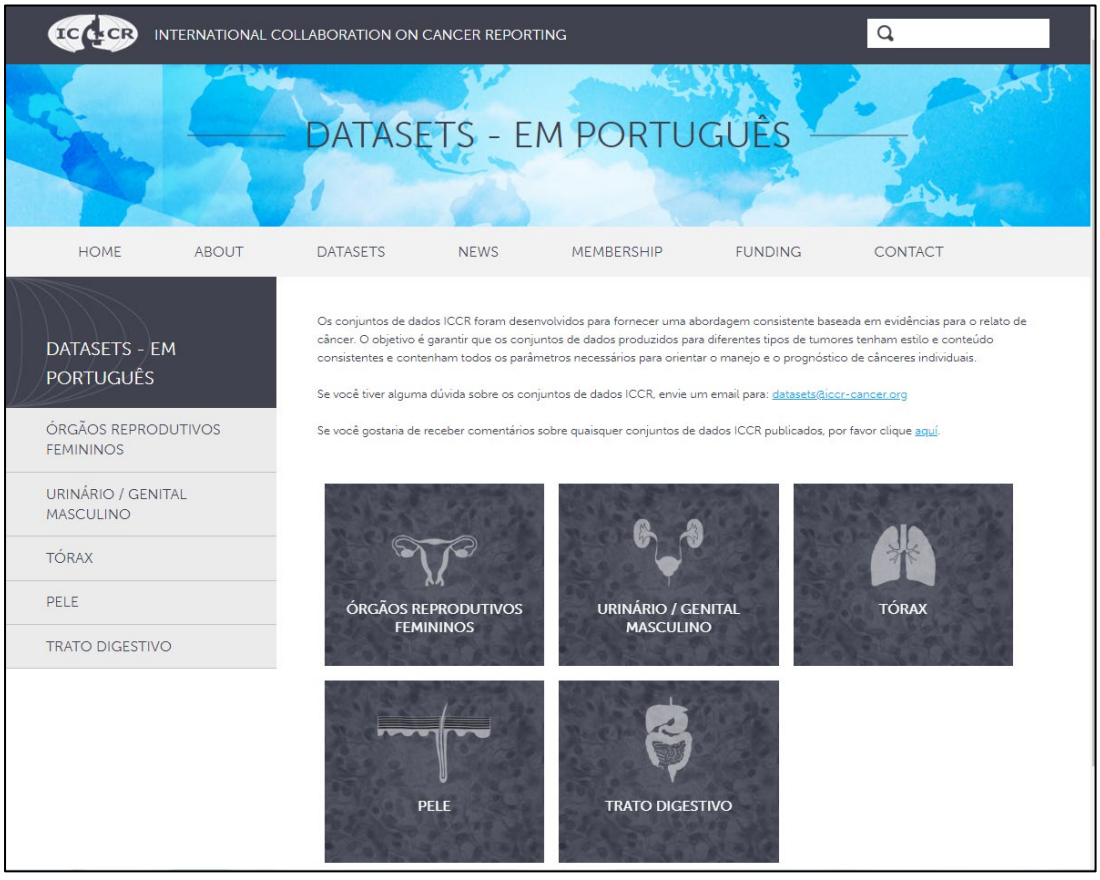
The following Spanish, French and Portuguese translated datasets are available from the ICCR website:

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
Thoracic	Lung cancer

Group	Dataset
	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 Language specific webpages

Language specific pages have been added to the ICCR website to host the translated datasets. An example is shown below:



New pages will be added as needed in the future.

6. IMPLEMENTATION

6.1 Implementation – Memoranda of understanding

There has been a significant increase in requests from Laboratory System and middleware vendors and jurisdictions wanting to implement the ICCR datasets. This has prompted the development of standard memoranda of understanding (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 Smart Reporting, a Munich based company and Wemedoo, a Swiss based company.

6.2 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 DAC's. Legal advice suggested that for the ICCR to sublicense the materials to LIS or other organisations, as would be needed for implementations, revisions were required to the copyright letter which each DAC member is asked to sign.

A revised letter was drafted and submitted for BoD approval in October 2020 and has been rolled out in 2021to all current DACs.

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

6.3 Electronic ICCR Datasets

In order 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 parts of the world 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. Therefore, ICCR is looking at options to provide a low-cost structured reporting solution for LMIC.

There is enormous interest in rolling out this type of tool for particular problem areas such as cervical cancer in South America and Africa, where the capture of essential data is vital to

providing the information necessary for cancer monitoring and management and planning of services. Such a tool would also provide a foundation for educational opportunities through organisations such as the ASCP and the International Gynecolgical Cancer Society (IGCS).

The goal would be to maximise the functionality for LMIC with the minimum of resource requirement and cost.

Over the last few years, the ICCR has investigated several options including a pilot project with IBM, ASCP and INCAN (Paraguay) on the development of a prototype and the option of utilising a third party vendor with an existing and well-established application. However, both these models had issues of cost, quality and the ability for ICCR to integrate the development of the electronic datasets with the existing dataset development process.

Earlier this year, ICCR commenced discussions with a pathologist from Adelaide, Dr Travis Brown, who was developing a simple structured reporting application. Dr Brown was very keen to work with the ICCR on developing his application, especially for use in LMIC.

On review, this application had a number of attractive features:

- Flexibility
- Potential integration into the ICCR dataset development process
- Cost
- Ownership

It was agreed that ICCR would enter into a collaboration agreement with Dr Brown to develop the application piloting an initial five datasets (colorectal, polypectomy, ovary, endometrium and cervix). The collaboration agreement is drafted and is expected to be signed before the end of 2021.

The ICCR is looking to use the application to:

1. Develop any conditional logic, calculations, feasibility ranges etc that are not evident from the paper version with the assistance of content specific e-datasets Quality Assurance (QA) Committees. These additional content related specifications will be made available as supplemental information with the dataset on the ICCR website.
2. Illustrate the characteristics of an electronic version of the ICCR datasets, which will inform other vendors and organisations how the ICCR datasets *should* function when implemented, and
3. Provide a tool that pathologists can use when reporting, particularly in LMIC.

Two e-datasets QA Committees – Colorectal and Gynaecological – have been convened to address any content related questions per point 1 above, as well as to test the application and provide feedback on improvements and corrections that may be needed.

Testing of the first of the electronic datasets is expected to commence before the end of the 2021.

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, LVI, lymphovascular invasion, 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 Dr Scott Campbell from University of Nebraska Medical Center (UNMC), 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. With the 31st October 2021 SNOMED International release, there are a further 600-750 cancer related concept definitions added to SNOMED CT and available worldwide.

6.5 Structured Reporting Implementation Committee (SRIC)

With the increasing global interest in implementing ICCR datasets the various technical aspects noted above need to be worked through in detail. This has prompted the convening of a new committee, the SRIC, whose purpose is to provide guidance to the BoD on matters relating to the implementation of ICCR cancer datasets and 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, accepted the position of Chair of the SRIC in late 2020. Professor Birdsong has previously chaired the CAP Pathology Electronic Reporting Taskforce (PERT) for many years and brings a wealth of experience to the ICCR.

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

7. FINANCES

7.1 Budget

A budget based on the Australian Financial Year (FY) – 1st July 2020 to 30th June 2021 was proposed and accepted at the 19th August 2020 BoD meeting.

7.2 Income

Income received to the end of the 2020-21 FY was $183,853 AUD derived from member subscription fees and sponsorship (see 7.4).

7.3 Expenditure

Planned expenditure for the 2020-21 FY was $218,502 AUD. Actual expenditure was $185,868 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 2020-21, the International Society of Gynaecological Pathology (ISGyP) donated $6,000 USD for the development of the Gynaecological 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 16th November 2021.

In summary, the ICCR was able to increase membership revenue in 2020-21 and the income derived from this all but equalled expenses. 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 Ms Donna Meredith, Managing Director of Keystone Corporate Positioning. 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 has been rolled out during 2021 to all ICCR documents and datasets as they are developed.

Included in the rebranding strategy is a new ICCR website design. As at the date of this report, the website design has been completed and an implementation strategy agreed. The new website is expected to be operational in early 2022.

The new-look website, logo and corporate profile will help position the ICCR to take advantage of some new funding opportunities, especially in the philanthropic domain in 2022.

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 organization, 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 employs two Project Managers on a contract basis:

1. Ms Fleur Webster commenced in February 2015 and is employed on 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. Ms 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 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)

A Project Management Officer undertakes administrative activities.

Ms 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 on this arrangement, in November 2021, RCPA has drafted a formal agreement to outline the services RCPA provide to ICCR. This agreement is slated for discussion at the January 2022 BoD meeting.

9. WEBSITE

The ICCR launched its website, www.iccr-cancer.org, in July 2015.

A summary of progress is outlined below:

Year	Users	Sessions*	Pageviews**	Countries	Top 10 users by country
2016	4,965	6,951	23,442	116	Russia, Australia, USA, Brazil, UK, India, Canada, Japan, Spain, Germany
2017	7,346	10,898	37,127	134	USA, Russia, Australia, UK, India, Canada, Germany, Spain, Italy, Brazil
2018	9,814	15,135	53,425	155	USA, India, Australia, UK, Canada, France, Brazil, Italy, Germany, Spain
2019	17,584	23,554	80,530	177	USA, India, Brazil, Australia, UK, France, Spain, Canada, Germany, Italy
2020	23,270	31,895	109,131	187	USA, India, Brazil, UK, Australia, France, Spain, Germany, Canada, Japan
2021	32,451	47,666	142,201	170	USA, India, UK, Brazil, China, Australia, Italy, Spain, Japan, Germany

* A session is the period time a user is actively engaged with the website.
** Pageviews is the total number of pages viewed. Repeated views of a single page are counted.

Top pages utilised in the last 12 months are:

- female-reproductive-organs,
- breast,
- digestive-tract.

The ICCR continues to monitor these statistics to ensure its continued usefulness to the global audience.

As noted, the ICCR website is undergoing a major redesign to reflect the new logo and branding. It is expected to launch in early 2022.

10. APPENDIX

10.1 Published datasets

As at November 2021, the ICCR has 56 published datasets. All published datasets are compliant with the latest 8th edition TNM staging where applicable.

The following is a list of published datasets:

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 Dataset Authoring Committee 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, 2nd edition**, which covers both biopsy and resection specimens. Published August 2017.

3. **Thymic epithelial tumours, 2nd edition**, which covers resection specimens of the thymus i.e., thymoma, neuroendocrine tumours of the thymus and thymic carcinoma but excludes germ cell tumours and other primary thymic neoplasms. Published September 2017.

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 November 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: April 2017, updated 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 neuroendocrine carcinomas (NECs) and mixed neuroendocrine-non-neuroendocrine neoplasms (MiNENs), are excluded. Published: April 2020.

5. **Carcinomas of the stomach, 1st edition**, which covers gastrectomy specimens for gastric carcinomas. Carcinomas involving the oesophagogastric junction (OGJ) with their epicentre >20 millimetres (mm) into the proximal stomach and cardia cancers that do not involve the OGJ are included, as are neuroendocrine carcinomas (NECs) and mixed neuroendocrine-non-neuroendocrine neoplasms (MiNENs) (with the exception of mixed adenoma and well differentiated neuroendocrine tumours (NETs). Endoscopic resections of the stomach, well differentiated NETs, non-epithelial malignancies and secondary tumours are excluded. Published: November 2020.

6. **Endoscopic resection of the stomach, 1st edition**, which covers carcinomas involving the oesophagogastric junction (OGJ) with their epicentre >20 millimetres (mm) into the proximal stomach and cardia cancers that do not involve the OGJ as well as neuroendocrine carcinomas (NECs) and mixed neuroendocrine-non-neuroendocrine neoplasms (MiNENs) (with the exception of mixed adenoma and well differentiated neuroendocrine tumours (NETs)). Well differentiated NETs, non-epithelial malignancies, and secondary tumours are excluded. Published: November 2020.

7. **Carcinomas of the oesophagus, 1st edition**, which covers resection specimens of the oesophagus, including carcinomas involving the oesophagogastric junction (OGJ) with tumour epicentre ≤20 mm into the proximal stomach. Neuroendocrine carcinomas (NECs) and mixed neuroendocrine-non-neuroendocrine neoplasms (MiNENs) of the oesophagus are included. Endoscopic resections of the oesophagus, well differentiated neuroendocrine tumours (NETs), non-epithelial malignancies such as melanoma, and secondary tumours are excluded. Published: November 2020.

8. **Endoscopic resection of the oesophagus and oesophagogastric junction, 1st edition**, which covers endoscopic resection of pre-malignant and malignant lesions of the oesophagus and oesophagogastric junction (OGJ) including neuroendocrine carcinomas (NECs) and mixed neuroendocrine-non-neuroendocrine neoplasms (MiNENs) of the oesophagus. Well differentiated neuroendocrine tumours (NETs), non-epithelial malignancies such as melanoma, and secondary tumours are excluded. Published: November 2020.

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 World Health Organization (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 World Health Organisation (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 & 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. Gastrointestinal stromal tumour (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. Gastrointestinal stromal tumour (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, 1st edition**, which was developed for the reporting of resection specimens from patients with invasive carcinoma of the breast, with or without ductal carcinoma in situ (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. Phyllodes tumours and needle biopsies are not covered in this dataset. Published: June 2021.

3. **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.

10.2 Peer-reviewed publications

- Dataset for reporting Carcinoma of the Stomach in Gastrectomy: Recommendations from the International Collaboration on Cancer Reporting. Shi C, Badgwell BD, Grabsch HI, Gibson MK, Hong SM, Kumarasinghe P, Lam AK, Lauwers G, O'Donovan M, van der Post RS, Tang L, Ushiku T, Vieth M, Selinger CI, Webster F, Nagtegaal ID. Archives of Pathology & Laboratory Medicine. 2021. Accepted for publication.

- Pathology Reporting of Gastric Endoscopic Resections: Recommendations from the International Collaboration on Cancer Reporting (ICCR). Shi C, Webster F, Nagtegaal ID; Dataset Authoring Committee for the development of the ICCR Dataset for Gastric Endoscopic Resections. Gastroenterology. 2021. Accepted for publication.

- Pathology Reporting of Esophagus Endoscopic Resections: Recommendations from the International Collaboration on Cancer Reporting. Lam AK, Nagtegaal ID; Dataset Authoring Committee for the development of the ICCR Dataset for Endoscopic Resection of the Esophagus and Esophagogastric Junction.Gastroenterology. 2021 Oct 13:S0016-5085(21)03622-2. doi: 10.1053/j.gastro.2021.09.069. Epub ahead of print.

- Dataset for the reporting of carcinoma of the exocrine pancreas: recommendations from the International Collaboration on Cancer Reporting (ICCR). Verbeke C, Webster F, Brosens L, Campbell F, Del Chiaro M, Esposito I, Feakins RM, Fukushima N, Gill AJ, Kakar S, Kench JG, Krasinskas AM, van Laethem JL, Schaeffer DF, Washington K. Histopathology. 2021 Aug 11. doi: 10.1111/his.14540. Epub ahead of print.

- Dataset for Pathology Reporting of Colorectal Cancer: Recommendations from the International Collaboration on Cancer Reporting (ICCR). Loughrey MB, Webster F, Arends MJ, Brown I, Burgart LJ, Cunningham C, Flejou JF, Kakar S, Kirsch R, Kojima M, Lugli A, Rosty C, Sheahan K, West NP, Wilson RH, Nagtegaal ID. Ann Surg. 2021 Jul 7. doi: 10.1097/SLA.0000000000005051. Online ahead of print.

- Dataset for the reporting of carcinoma of the oesophagus in resection specimens: recommendations from the International Collaboration on Cancer Reporting. Lam AK, Bourke MJ, Chen R, Fiocca R, Fujishima F, Fujii S, Jansen M, Kumarasinghe P, Langer R, Law S, Meijer SL, Muldoon C, Novelli M, Shi C, Tang L, Nagtegaal ID. Hum Pathol. 2021 Aug;114:54-65. doi: 10.1016/j.humpath.2021.05.003. Epub 2021 May 13.

- Pathology Reporting of Colorectal Local Excision Specimens: Recommendations from the International Collaboration on Cancer Reporting (ICCR). Rosty C, Webster F, Nagtegaal ID; Dataset Authoring Committee for the development of the ICCR Dataset for Pathology Reporting of Colorectal Excisional Biopsy. Gastroenterology. 2021 Aug;161(2):382-387. doi: 10.1053/j.gastro.2021.04.066. Epub 2021 May 4.

- Data set for reporting of carcinoma of the adrenal cortex: explanations and recommendations of the guidelines from the International Collaboration on Cancer Reporting. Giordano TJ, Berney D, de Krijger RR, Erickson L, Fassnacht M, Mete O, Papathomas T, Papotti M, Sasano H, Thompson LDR, Volante M, Gill AJ. Hum Pathol. 2021 Apr;110:50-61. doi: 10.1016/j.humpath.2020.10.001. Epub 2020 Oct 12.

- Data set for reporting carcinoma of the thyroid: recommendations from the International Collaboration on Cancer Reporting. Ghossein R, Barletta JA, Bullock M, Johnson SJ, Kakudo K, Lam AK, Moonim MT, Poller DN, Tallini G, Tuttle RM, Xu B, Gill AJ. Hum Pathol. 2021 Apr;110:62-72. doi: 10.1016/j.humpath.2020.08.009. Epub 2020 Sep 10.

- Pathology data set for reporting parathyroid carcinoma and atypical parathyroid neoplasm: recommendations from the International Collaboration on Cancer Reporting. Williams MD, DeLellis RA, Erickson LA, Gupta R, Johnson SJ, Kameyama K, Natu S, Ng T, Perren A, Perrier ND, Seethala RR, Gill AJ. Hum Pathol. 2021 Apr;110:73-82. doi: 10.1016/j.humpath.2020.07.008. Epub 2020 Jul 17.

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- Dataset for the reporting of urinary tract carcinoma - biopsy and transurethral resection specimen: recommendations from the International Collaboration on Cancer Reporting (ICCR). Varma M, Srigley JR, Brimo F, Compérat E, Delahunt B, Koch M, Lopez-Beltran A, Reuter V, Samaratunga H, Shanks JH, Tsuzuki T, van der Kwast T, Webster F, Grignon D. Mod Pathol. 2020 Apr;33(4):700-712. doi: 10.1038/s41379-019-0403-9. Epub 2019 Nov 4.

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