

International Collaboration on Cancer Reporting

ABN 69 601 723 960

ANNUAL REPORT 2018





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1. MESSAGE FROM THE PRESIDENT

The primary function of the ICCR is to produce internationally agreed upon and evidence-based datasets, freely available for pathology reporting of cancers worldwide. In the longer term, through iterative development cycles and international collaboration, our goal is to achieve harmonization of pathology reporting datasets worldwide. This will greatly reduce the burden of dataset development and maintenance for ICCR sustaining members and will also allow low and middle income countries to utilize the datasets without having to worry about creating their own content.

As the following report indicates, the ICCR continues to make significant progress in dataset development and is currently coordinating the development of datasets corresponding to the International Agency for Research on Cancer (IARC) / World Health Organization (WHO) 5th Series of tumour classification blue books. Since the ICCR was formed in 2011, we have developed a robust, international, evidence informed system for dataset development:

- The established ICCR development process is rigorous, evidence based, consultative and currently supported by over 250 multi-national and globally recognized content experts on the Dataset Authoring Committees.
- A detailed five-year plan has been developed to continue dataset production in synchrony with IARC/WHO publications. Currently, five of the top 10 solid tumors are not covered by ICCR datasets however as the first 2 bluebooks in series 5 are digestive tract and breast, this deficiency will be rectified over the next year. Datasets on colorectal cancer including polyps, stomach, esophagus, exocrine pancreas and breast will be the focus of our work plan for 2019.
- The ICCR engages with relevant international specialist pathology organizations during dataset development including the ISUP, ISGYP, AAOMP and NASHNP – many of whom have contributed financially as affiliated organizations. We will continue to pursue new affiliated organizations as appropriate for future dataset development.
- Increasingly, with international interest in structured reporting, European and other
 countries are looking to the ICCR as their source of datasets for local use. Our website
 analytics shows significant activity emanating from Russia, India, South America, various
 European countries and Japan along with those countries that are already sustaining
 members of the ICCR.

Several significant developments have occurred over the last year:

1. Strong Collaborative Relationship with IARC:

Under Professor Ian Cree's leadership, the tumor classification group at IARC have embarked upon an ambitious plan to publish a complete suite of WHO blue books over the next 4-5 years. Timely publication of the datasets corresponding to the new blue books is critically important for cancer pathology reporting worldwide. In order to better support this process, a new Memorandum of Understanding between IARC and ICCR, which lays out the principles of the collaboration, has been signed. There is bilateral representation on the ICCR Dataset Steering Committee and the IARC 5th Series Editorial Committee, respectively, along with a plan to coordinate the use of domain expert pathologists to facilitate the timely



production of the blue books and datasets. In 2018, the digestive tract and breast blue books are being finalized and the planning for the bone and soft tissue book has started. The ICCR with the advice of IARC is commencing work on the colorectal, stomach, esophagus, exocrine pancreas and breast datasets. Series champions have been appointed – GI tube (Dr. Iris Nagtegaal), hepatobiliary pancreatic (Dr. Kay Washington), and breast (Dr. Puay Hoon Tan).

The ICCR has also been asked to participate in a new IARC coordinated research initiative entitled, IARC Collaboration on Cancer Classification and Research (IC3R). Professor Tim Helliwell will represent the ICCR at the inaugural meeting in February 2019.

2. Dataset Translation:

With the strong support of the ASCP and the leadership of Drs. James Wisecarver and Dan Milner, the first batch of ICCR datasets have been translated into 3 languages – Spanish, French and Portuguese. This work is being done as part of the ASCP's commitment to the UICC Cancer City Challenge 2025. This program is designed to improve cancer care and cancer outcomes in a large number of cities across the globe with populations greater than one million people. The dataset translations will be featured on the ICCR website under separate tabs. Importantly, not only have the datasets been translated, but also the detailed explanatory notes. This will provide a wonderful source of information to pathologists throughout the world whose primary languages are not English. Having seen this progress, a number of other jurisdictions are showing very strong interest in having the ICCR datasets translated into other important world languages.

3. International IT Community:

Under the guidance of A/Prof. W. Scott Campbell from University of Nebraska Medical Centre, the project with SNOMED CT has been flourishing. SNOMED CT International have recognized the importance of terminology binding for the cancer datasets produced by the College of American Pathology (CAP) and the ICCR. Representatives from various countries including Sweden, UK, US, Canada, Netherlands and Australia have been working to help with the encoding of the CAP and ICCR datasets. Furthermore, under the guidance of Scott Campbell, significant progress has been made in the integration of genomics with the foundational cancer pathology data. This is particularly important as we move forward with more molecular oncology biomarkers and individualized precision medicine.

4. ICCR Promotional Activity:

In 2018, there were publications on general aspects of the ICCR and dataset development published in the American Journal of Surgical Pathology, Reports and Reviews¹, and The Pathologist (October 2018 issue). The dataset translation component has been featured in an article by Dr. Dan Milner in the October issue of Critical Values, and the ASCP quarterly journal. A successful symposium was conducted by the European Task Force on Synoptic Reporting and the ICCR at the European Congress of Pathology meeting in Bilbao in September. The meeting was well attended and topics included structured biomarker reporting, formatting of reports for maximum impact and an update on the IARC series 5 blue book project. Several academic papers related to the ICCR datasets have been published

¹ Ellis DW, Judge M and Srigley JR (2018). International Harmonization of Cancer Diagnosis, Staging, and Data Sets for Pathology Reporting—The Role of the International Collaboration on Cancer Reporting. *AJSP: Reviews & Reports* 23(3):109-112.



and were accepted including ones in genitourinary, head neck pathology and central nervous system.

5. Outreach and Sustainability:

The ICCR is having sustainability challenges and without identifying increased revenue sources, we could be in an untenable financial situation by the end of the current business year (June 2019). The leadership has been active in seeking additional sustaining members. Formal invitation have been sent to the Chinese Anti-Cancer Association (CACA) and the Japanese, Brazilian and German Societies. Other organizations are being pursued as well. We are also looking at the possibility of creating different sponsorship tiers in the hope of attracting additional members and revenue. Other sustainability models being investigated include the possibility of licensing the ICCR datasets at a national level and developing funding relationships with industry through novel vehicles such as, "Access Accelerated". The sustainability plan will be a major focus of leadership activities over the next few months.

John Srigley, President ICCR

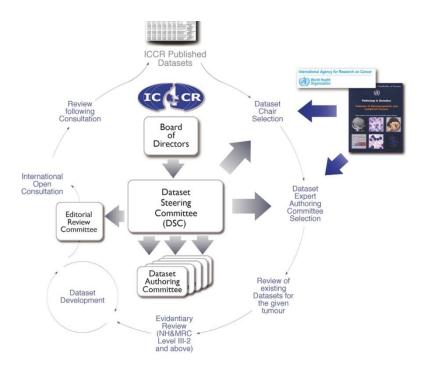


2. ORGANISATIONAL OVERVIEW

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. Three classes of membership have been established:

- 1. Sustaining
- 2. Corporate
- 3. Individual
- 4. Honorary

Sustaining membership provides the principal amount of funding on which the ICCR depends. There are now six sustaining members, which are:

• The European Society of Pathology (ESP),

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- The Royal College of Pathologists UK,
- The College of American Pathologists (CAP),
- The Royal College of Pathologists of Australasia (RCPA),
- The Canadian Association of Pathologists (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC)
- The American Society of Clinical Pathology (ASCP), and
- Royal College of Physicians of Ireland, Faculty of Pathology (RCPI FoP)

Each of the sustaining members is represented on the ICCR Board of Directors (BoD), which has strategic oversight of all ICCR operations and financial and legal responsibility for the running of the ICCR. Each sustaining 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)
- Fred Bosman 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)
- Sanchia Aranda, Chief Executive Officer, Cancer Council Australia; and president, UICC, and
- Kieran Sheahan for the Royal College of Physicians of Ireland, Faculty of Pathology (RCPI FoP)

At the BoD in October 2017, John Srigley was elected President and Tim Helliwell, Vice president. David Ellis stepped down as President and was appointed by the BoD to the position of Executive Officer. In that role Dr Ellis provides advice to the BoD and continuing corporate knowledge.

The ICCR Dataset Steering Committee (DSC) has responsibility for all activities relating to the development of ICCR cancer datasets. The DSC invites representation from all sustaining members, as well as strategic partners such as the International Agency for Research on Cancer (IARC), the European Organisation for Research and Treatment of Cancer (EORTC), and the International Association of Cancer Registries (IACR).

At the DSC meeting in June 2018, Tim Helliwell, in his position as Vice President, was appointed Chair of the DSC.

The purpose of the ICCR Editorial/Quality Committee (EQ) is to provide an independent review of each ICCR dataset prior to public consultation to ensure it adheres to ICCR standards. Currently this committee's function is undertaken by the DSC.



Dataset Authoring Committees (DACs) are convened as needed for the development of specific datasets.

The BoD, DSC and DAC members are all volunteers that provide their expertise and time altruistically. Administrative support is provided through volunteers from member organisations.

2.1 Honorary membership

At the BoD meeting in February 2017, it was agreed that DAC members would be included as honorary non-voting members of the ICCR for the lifetime of the datasets on which they contributed.



3. 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).

For the development of each dataset, the ICCR Dataset Steering Committee (DSC), appoints an appropriately qualified expert pathologist to take on the role of Chair of the Dataset Authoring Committee (DAC) who is supported in the development by a Project Manager and ICCR representative.

For the development of a series of datasets such as the Head and Neck (H&N) series, 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.

3.1 Published datasets

As at November 2018, the ICCR has 31 published datasets. All published datasets are compliant with the latest 8th edition TNM staging where applicable, with the exception of the dataset for Invasive Melanoma. This dataset is being updated in synchrony with the update to the World Health Organisation (WHO) publication on Classification of Skin Tumours at which time the 8th edition TNM staging will also be incorporated.

The following is a list of published datasets:

Urinary/male genital

- Prostate carcinoma (radical prostatectomy specimens) 2nd edition, which has been developed for radical prostatectomy specimens for prostate carcinoma. Published: August 2017
- 2. Prostate carcinoma (transurethral resection and enucleation specimens) 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 ie 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**, 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, 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 Specimens 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 specimens 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 specimens 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 specimens 1st edition, which has been developed for the reporting of biopsy and transurethral resection (TUR) 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. Biopsy of the kidney is dealt with in a separate dataset. Published: May 2018.

Female reproductive organs

- Endometrial carcinoma 3rd edition, which covers resection specimens of endometrial cancers. It is not applicable for small endometrial biopsy specimens. Published: July 2017
- 2. Carcinoma of the ovary, fallopian tube and primary peritoneal site, 1st 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: March 2015
- 3. Carcinoma of the cervix, 1st 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: March 2017

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 ie 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, 1st 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 May 2016

Digestive Tract

 Intrahepatic, and perihilar cholangiocarcinoma and hepatocellular carcinoma, 1st 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 May 2018.

Skin

1. **Invasive melanoma 1st edition**, which has been developed for reporting of primary cutaneous invasive melanoma. Published: November 2013

Central Nervous System

- 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

- 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.

3.1.1 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 ISBN as they are updated.

3.2 Datasets in progress

There are 14 datasets currently in progress:

3.2.1 Endocrine suite

In synchrony with the publication of the WHO publication on Classification of Endocrine Tumours 4th Series, four datasets are in development:

- 1. Thyroid (Chair: Ronald Ghossein)
- 2. Parathyroid (Chair: Michelle Williams)
- 3. Adrenal cortical gland (Chair: Thomas Giordano)
- 4. Adrenal medulla/ Paraganglioma/ Phaeochromocytoma/Carotid body (Chair: Arthur Tischler)

Dr Anthony Gill, a pathologist from Sydney Australia, who has extensive expertise in Endocrine Pathology, was appointed to be the Series Champion for this ICCR series.

3.2.2 Skin datasets

An update to the Invasive cutaneous melanoma dataset, published in 2013 is underway and a new dataset for Merkel Cell carcinoma, chaired by Dr Klaus Busam, has commenced in synchrony with the update of the 4th series WHO Classification of tumours for skin tumours.



3.3 Datasets in planning

The IARC/WHO 'blue books' are integral to all cancer datasets and as such the ICCR is committed to developing harmonized international datasets in synchrony with IARC/WHO. To support this a revised 5 year plan synchronising dataset development with IARC/WHO 'blue book' updates has been developed and agreed. 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.

3.3.1 Digestive tract

The 5th series of the IARC/WHO 'blue books' has now commenced with the Digestive Tract volume already drafted. A series of high priority datasets for the digestive tract have been identified and are being planned with the assistance of two Series Champions - digestive tube - Dr. Iris Nagtegaal, hepatobiliary pancreatic Dr. Mary Kay Washington. A total of 5 datasets in this series will be developed: Colorectal (2 datasets - Resection and Polypectomy/local rewsections specimens), Stomach, Oesophagus, and Exocrine Pancreas.

3.3.2 Breast

IARC/WHO are currently drafting updates to the Breast volume. Planning for a series of 3 datasets for Breast - invasive cancer, DCIS and Sentinel Lymph node specimens has commenced with the appointment of Dr Puay Hoon Tan as Series Champion.

3.4 TNM staging

The 8th editions of the AJCC Cancer Staging Manual and the 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 USA, Canada 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.

3.5 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, 9 dataset related articles have been published:

 Dataset for reporting of carcinoma of the cervix: Recommendations from the International Collaboration on Cancer Reporting (ICCR). McCluggage WG, Judge MJ, Alvarado-Cabrero I, Duggan MA, Horn L-C, Hui P, Ordi J, Otis CN, Park KJ, Plante M, Stewart CJR, Wiredu EK, Rous B, Hirschowitz L. Int J Gynecol Pathol. 2018, 37(3):205-228. doi:10.1097/PGP.00000000000000012



- Dataset for reporting of Thymic Epithelial Tumours: Recommendations from the International Collaboration on Cancer Reporting (ICCR). Nicholson AG, Detterbeck F, Marx A, Roden AC, Marchevsky AM, Mukai K, Chen G, Marino M, den Bakker MA, Yang WI, Judge M, Hirschowitz L. Histopathology. 2017 Mar;70(4):522-538. doi: 10.1111/his.13099. Epub 2016 Nov 28
- Dataset for Reporting of Malignant Mesothelioma of the Pleura or Peritoneum: Recommendations From the International Collaboration on Cancer Reporting (ICCR). Churg A, Attanoos R, Borczuk AC, Chirieac LR, Galateau-Salle F, Gibbs A, Henderson D, Roggli V, Rusch V, Judge MJ and Srigley JR (2016). Arch Pathol Lab Med.[Epub ahead of print]
- Dataset for reporting of ovary, fallopian tube and primary peritoneal carcinoma: Recommendations from the International Collaboration on Cancer Reporting (ICCR). McCluggage WG, Judge MJ, Clarke BA, Davidson B, Gilks CB, Hollema H, Ledermann J, Matias-Guiu X, Mikami Y, Stewart CJR, Vang R and Hirschowitz L. (2015). Mod Path 28(8):1101-1122.
- Dataset for Pathology Reporting of Cutaneous Invasive Melanoma Recommendations From the International Collaboration on Cancer Reporting (ICCR).
 Scolyer RA, Judge MJ, Evans A, Frishberg DP, Prieto VG, Thompson JF, Trotter MJ, Walsh MY, Walsh NMG, Ellis DW. (2013). Am J Surg Pathol. 37(12):1797-814.
- Dataset for Reporting of Lung Carcinomas: Recommendations From International Collaboration on Cancer Reporting. Jones KD, Churg A, Henderson DW, Hwang DM, Ma Wyatt J, Nicholson AG, Rice AJ, Washington MK, Butnor KJ. (2013) Arch Pathol Lab Med. 137(8): 1054-1062.
- Dataset for Reporting of Endometrial Carcinomas: Recommendations From the International Collaboration on Cancer Reporting (ICCR) Between United Kingdom, United States, Canada, and Australasia. McCluggage WG, Colgan T, Duggan M, Hacker NF, Mulvany N, Otis C, Wilkinson N, Zaino RJ and Hirschowitz L (2012).International Journal of Gynecological Pathology 32:45-65.
- Dataset for reporting of prostate carcinoma in radical prostatectomy specimens: recommendations from the International Collaboration on Cancer Reporting. Kench, JG, Delahunt B, Griffiths DF, Humphrey PA, McGowan T, Trpkov K, Varma M, Wheeler TM, Srigley JR. Histopathology 2013, 62, 203–218.
- Ellis DW and Srigley J (2015). Does standardised structured reporting contribute to quality in diagnostic pathology? The importance of evidence-based datasets. Virchows Arch [Epub ahead of print] PMID: 26316184.

Journal articles for Liver, Renal, Prostate - Core/Needle Biopsies/TURP, Prostate Radical Prostatectomy and CNS tumours are all well progressed with planning underway for articles on testes, urinary tract and penile carcinomas. A suite of Head and Neck journal articles has also been accepted for publication in Archives of Pathology & Laboratory Medicine.



4. TRANSLATION

Translation of 17 ICCR datasets into Spanish, French and Portuguese has been completed through the kind contribution of the American Society of Clinical Pathology (ASCP), a sustaining member of the ICCR.

The translation work is critical as the IARC/WHO Classification of Tumours "Bluebooks" are not being translated, so having the datasets available in other languages will be very important to advance adoption of standardised reporting in the future.

The ASCP, engaged the services of an ISO 9001:2015 certified company to undertake the translations.

The initial translation process has been a useful pilot and further refinement of the process and change control between the ICCR and ASCP/ISO translation company is being planned to ensure a streamlined procedure in the future.

4.1 Datasets translated

The following translated datasets are posted to the ICCR website:

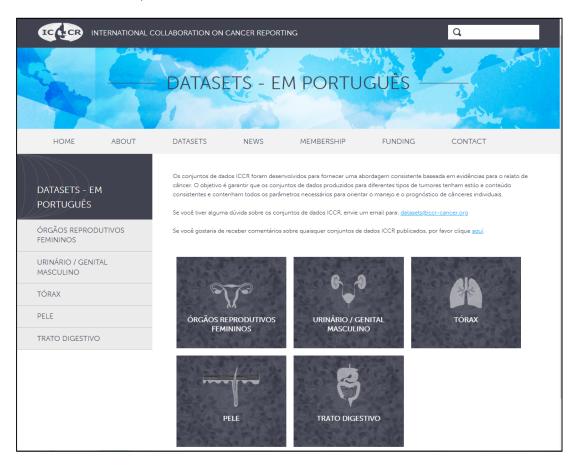
Group	Dataset
Genitourinary	Urethrectomy
	Ureterectomy and Nephroureterectomy
	Urinary bladder - Transurethral resection and Biopsy
	Urinary Bladder
	Kidney
	Kidney biopsy
	Penis
	Testicular cancer - RPLND
	Testicular cancer
	Prostate - Transurethral resection
	Prostate - Radical Prostatectomy
	Prostate - Core/needle Biopsy
	Liver - Intrahepatic & Perihilar Cholangiocarcinoma and
Digestive tract	Hepatocellular
Thoracic	Lung
	Thymic Epithelial Tumours
	Heart, Pericardium and Great Vessels
	Mesothelioma in the Pleura and Peritoneum
Gynaecology	Endometrium
	Ovary, Fallopian Tube & Primary Peritoneal Site
	Cervix
Skin	Invasive Melanoma

Translations into Spanish, French and Portuguese for the Head and Neck dataset suite and the CNS dataset are planned.



4.2 Website

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.



5. TERMINOLOGY

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) 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 organization that owns SNOMED CT. The ICCR was very keen to participate and a collaborative relationship with the UNMC team commenced. The ICCR and the Cancer Synoptic Working Group (a working group stemming from the IPaLM SIG), agreed to collaborate in an ongoing manner to ensure terminology is developed for cancer reporting such that it meets the needs of the clinical care teams, national registrars and cancer researchers. 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.



6. FINANCIAL REPORT

A budget was proposed and accepted at the 21st and 22nd February 2018 Board of Directors meeting.

The following is a budget summary:

6.1 Projected income

As at 21st/22nd February 2018, the ICCR has a balance of \$148,055.14 AUD with a projected income for 2018 of \$90,083 AUD.

Income is derived from:

- 1. Foundation member fees
- 2. Other donations
- 3. Sponsorship

6.2 Expenditure

Expected expenditure to February 2019 is \$157,874.00 AUD.

Items of planned expenditure are:

Category	Item
Business costs	Legal fees
	Insurances
	Auditor
	Bank fees
Meetings	Teleconference/web meetings
	ICCR DSC face to face meetings*
	Project Manager meetings/update
	Travel to international meetings
Promotion & communication	Web services
	Promotional flier
	Domain specific email
	Domain name registration
	Business cards
Staffing	Project Manager
	Project Management Officer
	Equipment/expenses
Dataset development	Software
	Medical Illustrator
	Copyright fees
	Open access for publications
Miscellaneous	Stakeholder database rework

^{*} Note, this item includes no travel related fees, it relates to costs for room and equipment hire etc for the meetings.



6.3 Sponsorship

In addition to membership fees, the ICCR looks for sponsorship to help support the cost of development of datasets. In the last year, 2 such opportunities have come to fruition:

1. The International Association of Oral and Maxillofacial Pathologists and the British Society of Head and Neck Pathology have both agreed to donate \$1,000USD to support the development of the Head & Neck suite of datasets.

Further opportunities are being sought.

6.4 Audited financial statement

The ICCR financial status is audited yearly. A fully audited financial statement has been prepared and was discussed at the Annual General Meeting held 27th and 28th November. A copy of the audit report is included in Appendix A.



7. 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 standardizes 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 which includes the development and review of draft dataset documents, timeframe management, harmonization of terms and content, guide development, identification and tracking of issues, reporting to DSC, stakeholder correspondence/support of expert panels etc.

7.1 Project Manager

Project Managers undertake stakeholder/content management. The ICCR employs on a contract basis a Project Manager, 24 hours (~3 days) per week, to support dataset development. Ms Fleur Webster started work in February 2015 and is employed on contract via the Royal College of Pathologists of Australasia (RCPA). The RCPA provides the human resources infrastructure under which Ms Webster is employed and invoice the ICCR quarterly for Ms Webster's salary. The RCPA does not charge the ICCR for this administrative service. Ms Webster works from her home office in Thailand.

Ms Webster's current contract concludes in December 2018. It is anticipated that her contract will be extended.

Additional Project Manager services continue to be provided, on a volunteer basis, by member organisations to supplement Ms Webster's contribution.

7.2 Project Management Officer (PMO)

A Project Management Officer undertakes administrative activities.

The ICCR employs 1 PMO on a casual basis, 15 hours (across 3 days) per week under the supervision of Ms Webster. Ms Gina Green started work in September 2017 and is employed via the Royal College of Pathologists of Australasia (RCPA). The RCPA provides the human resources infrastructure under which Ms Green is employed and invoice the ICCR quarterly for Ms Green's salary. The RCPA does not charge the ICCR for this administrative service. Ms Green works from her home office in Sydney.



8. WEBSITE

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

To September 2018, the ICCR website has had 135,038 page views (increased from 72,414 in November 2017); and 38,740 sessions up from 20,987 in November 2017. (A session is the period time a user is actively engaged with the website).

Of a total of 160 countries accessing the ICCR website, the top 10 countries are:

- 1. United States
- 2. Australia
- 3. India
- 4. Russia
- 5. United Kingdom
- 6. Brazil
- 7. Canada
- 8. France
- 9. Italy
- 10. Germany

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

Consideration will be given to registering users (gratis) to enable better engagement with users worldwide, and to provide better metrics regarding dataset utilization.



APPENDIX A: AUDITED FINANCIAL STATEMENT

International Collaboration on Cancer Reporting Limited ABN 69 601 723 960

FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2018

INDEX	PAGE	
Statement of Profit or Loss and Other		
Comprehensive Income	1	
Statement of Financial Position	2	
Statement of Cash Flows	3	
Notes to the Financial Statements	4	
Directors' Declaration	6	
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Independent Auditor's Report	8	

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2018

		30 June 2018 \$	30 June 2017 \$
Cub a suistinu mauranus	Notes	70.400	405 447
Subscription revenue		76,196	105,117
Interest revenue	_	530	880
Total revenue	_	76,726	105,997
Labour hire costs		101,906	69,112
Stationery and other supplies		4,843	-
Insurance expense		5,410	5,857
Meeting expenses		1,463	6,307
Website development and maintenance		1,265	1,755
Travel and accommodation		5,171	4,093
Audit of financial report		1,500	1,500
Photography		-	208
Copyright		16,370	5,671
Bank charges		156	194
Sundry expenses		323	480
Total expenses	_	138,407	95,177
Profit/(loss) before income tax		(61,681)	10,820
Income tax expense	1a	-	-
Profit/(loss) after income tax	_	(61,681)	10,820
Other comprehensive income:			
Other comprehensive income for the year, net of income tax		-	-
Total comprehensive income for the year	_	(61,681)	10,820

STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2018

	Notes	30 June 2018 \$	30 June 2017 \$
CURRENT ASSETS Cash and cash equivalents		56,834	108,866
Trade and other receivables Prepayments		4,725 2,826	17,232 3,069
	_		
TOTAL CURRENT ASSETS	_	64,385	129,167
TOTAL ASSETS		64,385	129,167
CURRENT LIABILITIES Trade and other payables	_	1,595	4,696
TOTAL CURRENT LIABILITIES		1,595	4,696
TOTAL LIABILITIES	_	1,595	4,696
NET ASSETS		62,790	124,471
HEI AGGETO	_	02,700	127,771
EQUITY Retained earnings	_	62,790	124,471
TOTAL EQUITY	_	62,790	124,471

STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2018

	Notes	30 June 2018 \$	30 June 2017 \$
CASH FLOWS FROM OPERATING ACTIVITIES			
Receipts from subscriptions and donations Interest received Payments to suppliers	-	102,830 530 (155,392)	96,612 880 (132,881)
Net cash (used in)/provided by operating activities	_	(52,032)	(35,389)
Cash flows from investing activities	_	<u>-</u>	
Cash flows from financing activities	_	-	
Net (decrease)/increase in cash and cash equivalents	_	(52,032)	(35,389)
Cash and cash equivalents at the beginning of the period	_	108,866	144,255
Cash and cash equivalents at the end of the period	_	56,834	108,866

NOTES TO THE FINANCIAL STATEMENTS FOR THE FINANCIAL YEAR ENDED 30 JUNE 2018

1. Significant Accounting Policies

The financial report of International Collaboration on Cancer Reporting Limited ("ICCR") for the financial year ended 30th June 2018 was authorised for issue in accordance with a resolution of Directors, dated 28th November 2018.

The financial report has been prepared in order for ICCR to comply with the requirements of its constitution.

The financial report is presented in Australian Dollars which is ICCR's functional and presentational currency.

The financial report has been prepared on an accruals basis and is based on historical costs and does not take into account changing money values or, except where stated, current valuations of non-current assets. Cost is based on the fair values of the consideration given in exchange for assets. The financial report has been prepared on a going concern basis.

(a) Income Tax

ICCR is classified as a scientific and educational institution by the Australian Taxation Office and therefore, in accordance with section 50-5 of the *Income Tax Assessment Act 1997*, is exempt from paying income tax.

2. Entity Limited by Guarantee

ICCR is limited by guarantee under the *Corporations Act 2001*. The amount of capital, which is capable of being called up, in the event of, and only for the purpose of a winding up of the company, is not to exceed \$100 per member by virtue of ICCR's Constitution.

3. Remuneration of Directors

The Directors of ICCR received no remuneration or benefits during the financial period.

The Directors listed below held office from 1 July 2017 to the date of this report unless otherwise stated.

David William Ellis (resigned Feb 2018) Timothy Richard Helliwell Thomas Wheeler Sanchia Aranda

James Kench (appointed Feb 2018)

John Robert Srigley Fredrik Theodoor Bosman Richard Scolyer (resigned Feb 2018) James Wisecarver Kieran Sheahan (appointed Mar 2018)

DIRECTORS' DECLARATION

In the directors' opinion:

- the attached financial statements and notes thereto comply with the accounting policies described in Note 1;
- the attached financial statements and notes thereto give a true and fair view of the company's financial position as at 30 June 2018 and of its performance for the financial year ended on that date; and
- there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of directors made pursuant to section 295(5)(a) of the Corporations Act 2001.

On behalf of the Directors

Dr John R. Srigley President/Director

Dated this 28th day of November 2018



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DECLARATION OF INDEPENDENCE BY GILLIAN SHEA TO THE DIRECTORS OF INTERNATIONAL COLLABORATION ON CANCER REPORTING LIMITED

As lead auditor of International Collaboration on Cancer Reporting Limited for the year ended 30 June 2018, I declare that, to the best of my knowledge and belief, there have been:

- 1. No contraventions of the auditor independence requirements of the Australian professional accounting bodies in relation to the audit; and
- 2. No contraventions of any applicable code of professional conduct in relation to the audit.

Gillian Shea

Partner

BDO East Coast Partnership

Sydney, 28 November 2018



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INDEPENDENT AUDITOR'S REPORT

To the members of International Collaboration on Cancer Reporting Limited

Report on the Audit of the Financial Report

Opinion

We have audited the financial report of International Collaboration on Cancer Reporting Limited (the Entity), which comprises the statement of financial position as at 30 June 2018, the statement of profit or loss and other comprehensive income and the statement of cash flows for the year then ended, and notes to the financial report, including a summary of significant accounting policies, and directors' declaration.

In our opinion the accompanying financial report presents fairly, in all material respects, the financial position of the Entity as at 30 June 2018 and of its financial performance and its cash flows for the year then ended in accordance with the basis of accounting described in note 1.

Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the Financial Report* section of our report. We are independent of the Entity in accordance with ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of matter - Basis of accounting

We draw attention to Note 1 to the financial report, which describes the basis of accounting. The financial report has been prepared to assist the Entity to meet the requirements of the company's constitution. As a result, the financial report may not be suitable for another purpose. Our opinion is not modified in respect of this matter.

Responsibilities of management and those charged with governance for the Financial Report

Management is responsible for the preparation and fair presentation of the financial report, and have determined that the basis of preparation described in Note 1 is appropriate to meet the requirements of the company's constitution and for such internal control as management determines is necessary to enable the preparation and fair presentation of a financial report that is free from material misstatement, whether due to fraud or error.



In preparing the financial report, management is responsible for assessing the Entity's ability to continue as a going concern, disclosing, as applicable, matters relating to going concern and using the going concern basis of accounting unless management either intends to liquidate the Entity or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Entity's financial reporting process.

Auditor's responsibilities for the audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website (http://www.auasb.gov.au/Home.aspx) at:

http://www.auasb.gov.au/auditors_responsibilities/ar4.pdf

This description forms part of our auditor's report.

BDO East Coast Partnership

BDO

Gillian Shea Partner

Sydney, 28 November 2018