Structured Pathology Reporting of Cancer 2015-16

FINAL Report to
Australian Government
Department of Health

31st July 2016
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# Contents

Document Control.................................................................................................................................. 2  
Contents .................................................................................................................................................. 3  
1. Glossary of terms & acronyms ........................................................................................................ 4  
2. Executive summary ......................................................................................................................... 5  
3. Project statement ................................................................................................................................ 7  
   3.1 Background .................................................................................................................................... 7  
   3.2 The Structured Pathology Reporting of Cancer 2015-16 Project.............................................. 7  
4. Scope ................................................................................................................................................ 9  
   4.1 Purpose .......................................................................................................................................... 9  
   4.2 Meeting objectives ...................................................................................................................... 9  
   4.3 Exclusions ..................................................................................................................................... 9  
5. Governance ...................................................................................................................................... 10  
6. Project Activities ............................................................................................................................. 12  
   6.1 Reporting Requirements ........................................................................................................... 12  
   6.2 Key activity indicators / milestones / KPIs ................................................................................. 12  
   6.3 Review of progress against the Activity Plan ......................................................................... 13  
   6.4 Detailed activity review ............................................................................................................. 18  
   6.5 Issues Register ............................................................................................................................ 29  
   6.5 Documentation summary ........................................................................................................... 29  
7. Project Challenges ............................................................................................................................ 30  
8. Financials ......................................................................................................................................... 30  
9. Appendices ....................................................................................................................................... 31  
   Appendix A - NHMRC Extended levels of evidence.................................................................. 31  
   Appendix B - SPRC Governance Structure .............................................................................. 33  
   Appendix C - SPR Capability matrix ......................................................................................... 34  
   Appendix D - Comparison of terms .............................................................................................. 35  
   Appendix E - Scope .......................................................................................................................... 37  
   Appendix F - ICCR open consultation notification to RCPA fellows ......................................... 38  
10. References ........................................................................................................................................ 40
1. Glossary of terms & acronyms

<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>DETAIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP</td>
<td>Anatomical Pathologists</td>
</tr>
<tr>
<td>CAP</td>
<td>College of American Pathologists</td>
</tr>
<tr>
<td>CAP-ACP</td>
<td>The Canadian Association of Pathologists</td>
</tr>
<tr>
<td>CPAC</td>
<td>The Canadian Partnership Against Cancer</td>
</tr>
<tr>
<td>ESP</td>
<td>European Society of Pathology</td>
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<tr>
<td>FHIR</td>
<td>Fast Healthcare Implementation Resources</td>
</tr>
<tr>
<td>HL7</td>
<td>Health Level 7</td>
</tr>
<tr>
<td>IARC</td>
<td>International Agency for Research on Cancer</td>
</tr>
<tr>
<td>ICCR</td>
<td>International Collaboration on Cancer Reporting</td>
</tr>
<tr>
<td>ISUP</td>
<td>International Society of Urological Pathology</td>
</tr>
<tr>
<td>LIS</td>
<td>Laboratory Information System</td>
</tr>
<tr>
<td>MCU</td>
<td>Online Macroscopic Cut-up manual</td>
</tr>
<tr>
<td>NATA</td>
<td>National Association of Testing Authorities, Australia</td>
</tr>
<tr>
<td>NEHTA</td>
<td>National e-Health Transition Authority</td>
</tr>
<tr>
<td>NPAAC</td>
<td>National Pathology Accreditation Advisory Council, Australia</td>
</tr>
<tr>
<td>PITUS</td>
<td>Pathology Information, Terminology and Units Standardisation</td>
</tr>
<tr>
<td>RCPA</td>
<td>Royal College of Pathologists of Australasia</td>
</tr>
<tr>
<td>RCPPath</td>
<td>The Royal College of Pathologists (UK)</td>
</tr>
<tr>
<td>SPRC</td>
<td>Structured Pathology Reporting of Cancer</td>
</tr>
<tr>
<td>TNM</td>
<td>Tumour– Node-Metastasis</td>
</tr>
</tbody>
</table>
2. Executive summary

This is the Final Report for the: Structured Pathology Reporting of Cancer (SPRC) 2015-16 Project. Over the 10 months of the project the following activities have been completed:

- Reviewed the terms, definitions and dataset development processes of the International Collaboration on Cancer Reporting (ICCR) to ensure that these will provide the core components of the SPRC protocols (ie the required and recommended elements, values and commentary). Any anomalies in definitions/terms/processes have been resolved and reflected in the changes to the SPRC Framework documents.

- RCPA representation was established on the ICCR Dataset Steering Committee to represent local interests.

- Local representatives have been identified to participate in ICCR Dataset Authoring Committees on cervical cancer which has commenced as well as for a future suite of datasets on the head & neck and endocrine. Discussions have progressed regarding a RCPA representative for the ICCR central nervous system datasets. The RCPA representative for the ICCR CNS Dataset Authoring Committee is required in October.

- All RCPA Anatomical Pathology (AP) Fellows were invited to provide comment on the ICCR heart, mesothelioma and thymus datasets during the public consultation period in Sept-October 2015. Local authoring committees were established for heart, mesothelioma and thymus and provided a detailed review of each ICCR dataset during the open consultation phase in anticipation of the development of local versions of the protocols.

- The SPRC protocol development process (Framework documents) have been redrafted to reflect three recent significant initiatives which impact on local protocol development:
  - The availability of international datasets from the ICCR ie the ICCR datasets will provide the foundation for SPRC protocols developed in the future;
  - The publication of the RCPA Macroscopic Cut-up Manual. A revised process synchronising the development of specimen handling and macroscopic information has been established.
  - The development of tissue fixation guidelines by the RCPA.

- The revised Framework has been reviewed and approved by the SPRC Project Group and is now published to the RCPA website.

- The revised Framework documents were used as the foundation to develop a local ovary, fallopian tube, primary peritoneal site protocol as well as three new thoracic protocols – heart, mesothelioma and thymus. The new process has proceeded very well and has clearly demonstrated that the availability of ICCR datasets can significantly speed up the process of development of local cancer protocols. All four local protocols are now published to the RCPA website.

- An educational webinar by Prof Kench on prostate cancer was held on 26th April 2016. It was attended by 60 participants and is available on the RCPA website for download.

- SPRC newsletters for September 2015, December 2015 March 2016 and June 2016 have been distributed to all RCPA Anatomical Pathology (AP) and Haematology Fellows and Trainees.

- A registrar training session on Structured Pathology Reporting of Cancer was undertaken in April 2016 in NSW and additional opportunities are being planned for 2016/17.

- The NPAAC Information and Communication document has undergone a period of public consultation, including references to mandate the use of SPRC. Until this document is finalised by NPAAC, the College has approved a position statement recommending pathologists adopt
level 3 compliance (refer Appendix C) to SPRC. This position statement has been published and circulated to NATA assessors.

- The SPRC Project team continued to work with the Australian Digital Health Agency\(^1\) to develop an information model for colorectal cancer using FHIR. Work has been synchronised with the PITUS-15-16 Project (Working Group 5) who have also engaged with the Australian Digital Health Agency to use HL7/FHIR for outbound transmission of SPRC information to cancer registries.

- The SPRC Project Manager continued to provide advice and assistance to all queries from laboratory system vendors and pathologists on SPRC and SPRC implementation.

\(^1\) Formally NEHTA
3. Project statement

3.1 Background

Studies show that the traditional narrative style of reporting, leads to the omission of essential information necessary for patient management,¹⁻³ and that structured reporting significantly enhances the completeness and quality of data in pathology reports.⁴⁻⁷ Consequently minimum or comprehensive datasets for the reporting of cancer have been developed⁸⁻⁹ around the world. Both the United Kingdom,¹⁰ and United States¹¹ have produced standardised cancer reporting protocols for national use for many years.

In response to the growing body of evidence, the Cancer Institute NSW convened a National Round Table meeting in 2007, drawing together the major representatives in pathology across Australasia. The Round Table meeting documented a number of initiatives in structured reporting in progress around Australia, however, it was apparent that each was being developed in relative isolation creating a concern that each project may end up reporting to a different standard.

The value of a national approach to structured pathology reporting (SPRC) was clearly recognised at that meeting and it was agreed that “Structured or synoptic reporting of cancer cases in anatomical pathology and haematology contribute to better cancer control at the levels of:

- clinical management and treatment planning
- cancer notification and registration
- aggregated analyses, and
- clinical research

and, cancer care in Australia would benefit from the development, publication and adoption of a series of national structured reporting standards for each cancer type”.

In response to the Roundtable recommendation, the Cancer Institute NSW secured funding in February 2008, from the Department of Health and Ageing (Quality Use of Pathology Programs) to work with the RCPA and Cancer Australia to develop an initial 6 reporting datasets (lung, prostate, breast, and colorectal cancers, lymphoma and melanoma) and a framework to guide development of the datasets, in partnership with national clinician and pathologist organisations.

At the conclusion of the first phase of the project, six cancer protocols had been developed in addition to a comprehensive framework for the development of future cancer protocols.

After the initial success of this pilot, a second round of funding from the Department of Health and Ageing (Quality Use of Pathology Programs) was obtained in 2010 to build on the initial project foundation to promote and expand the use of structured reporting of cancer.

A third round of funding to continue both local and international development of cancer datasets was approved by the Department of Health in June 2012 for a further three years.

This report covers progress in the fourth period of funding from August 2015 to June 2016.

3.2 The Structured Pathology Reporting of Cancer 2015-16 Project

The pathology report lays the foundation for a patient’s cancer journey and conveys information which:

- Provides the definitive diagnosis
- Includes critical information for Tumour-Node-Metastasis (TNM) staging
- Evaluates the adequacy of the surgical excision
• Provides morphological and biological prognostic markers which determine personalised cancer therapy

However, the rapid growth in ancillary testing such as immunohistochemistry, flow cytometry, cytogenetics, and molecular studies have made the task of keeping abreast of advances on specific cancer investigations extremely difficult for pathologists. This national initiative in developing structured pathology reporting of cancer has been critical to assist in addressing issues such as these. The use of structured pathology reporting of cancer checklists provides a mechanism to ensure key elements are included in the pathology report specifically those which have clinical management, staging or prognostic implications. The adoption and use of standardised structured pathology reporting of cancer in Australia improves the quality, delivery, and consumption of Medicare funded pathology services through:

• Improvements to the completeness and quality of data provided to clinicians, through consistent formatting and content encouraging better communication and improved safety;
• Development of protocols by expert pathologists to ensure reporting is best practice.
• Adherence to a checklist for cancer reporting which significantly improves the rate of inclusion of crucial features required for patient management;
• The use of mandatory elements (standards) that are differentiated from those that are not mandatory but are recommended (guidelines);
• Improvement to the consistency and speed of reporting by the use of discrete data elements recorded from the checklist.
4. Scope

4.1 Purpose

The objective of the Structured Pathology Reporting of Cancer Project is to further develop, promote and implement standardised National Structured Reporting of Cancer protocols to improve completeness and quality of data provided to treating clinicians and to enhance patient care.

4.2 Meeting objectives

The goal of the QUPP is to achieve improvement in health and economic outcomes from the use of pathology in health care, through the pursuit of better practice amongst requesters (or referrers) and providers of pathology services and knowledgeable and engaged consumers.

This Project addresses the Quality Use of Pathology Program “Quality Pathology Practice”, being to support professional practice standards that meet consumer and referrer needs and provide evidence-based, best practice, quality-assured services that are safe, cost effective and efficient.” This program of work relates directly to improving the standard of pathology reporting for cancer both nationally and internationally through:

- the development of standardised pathology reporting cancer protocols which ensure pathologists use the most current, evidence-based templates
- the inclusion of reporting checklists that ensure pathology reports include complete information
- facilitating the implementation of structured reporting and other e-health cancer-related strategies based on a single, nationally agreed standard, and
- improved communication between clinicians and pathologists by using common meanings and definitions for all data elements

Patient health outcomes are improved by:

- the completeness of cancer reports allowing patients to receive the most effective and timely treatment
- the use of standardised language which reduces miscommunication that may result in delays and mistakes in treatment
- ensuring patient specimens are assessed against the most up to date evidence based standards.

4.3 Exclusions

The following are considered exclusions in delivering this Project:

- The Project funding does not include payment for pathologists and other working group member’s time.
- The Project does not include funding for any associated costs that may be incurred by Australian Digital Health Agency in investigating the use of FHIR for the development of electronic information models based on the SPRC protocols
- The Project does not include funding for any associated cost of implementation of SPRC in laboratories.

2 Formally NEHTA
5. Governance

The governance model established under the initial funding period remains current, and has been updated to incorporate formalised international relationships. This structure provides the mechanism for communication and support, incorporating interconnectivity to international organisations such as College of American Pathologists (CAP) to support long term development and expansion. A diagram of the governance model is included in Appendix B.

There are 5 critical elements to the governance model:

1. CanSAC

Cancer Services Advisory Committee (CanSAC) is a RCPA committee reporting to the RCPA Board of Directors. It was formed in 2008 to provide governance for the SPRC Project and to foster multidisciplinary communication and knowledge sharing to support cancer-related activities and organisations.

It provides leadership in the development, dissemination and preservation of a national structure for useable, evidence-based cancer pathology reporting standards and guidelines.

2. Project Group

The Project Group has representation from each of the parties to the MOU (refer below) as well as clinical involvement and RCPA Executive Team representation.

The project group meets on a 4-6 week basis via teleconference to:

- To monitor project progress
- To review risks and issues
- To provide advice and direction to resolve issues and plan activities

3. Cancer Specific Expert groups

The expert groups have been structured into groupings to align with other international bodies to facilitate communication and participation. The expert groups reflect broad anatomical structures such as Gastrointestinal rather than Colorectal. One or more ‘authorship’ groups are formed in each expert group who are responsible for the development of the cancer protocols eg

4. National Stakeholders

The SPRC communicates with key stakeholders from around Australasia including other cancer related organisations, laboratory systems vendors, medical colleges and IT organisations.
5. **International collaboration**

The SPRC has formalised collaboration internationally via the formation of the International Collaboration on Cancer reporting (ICCR). The Chair of the SPRC Project is the RCPA representative on the ICCR Dataset Steering Committee (DSC) and both the Chair and President of the ICCR are members of CanSAC. The ICCR connects the SPRC Project with other international bodies such as CAP and RCPath via CanSAC membership and is an integral part of the governance structure.

**Memorandum of Understanding**

A Memorandum of Understanding (MOU) between the Royal College of Pathologists of Australasia (RCPA), Cancer Australia and the Cancer Institute NSW was entered into to oversee the SPRC Project in 2008. This was renewed in 2012 and expired in July 2015. As part of the current finding period, this MOU was renewed as at November 2015. The continued participation of the parties under this MOU has facilitated communication with the wider cancer related community.
6. Project Activities

6.1 Reporting Requirements

- September 14th 2015  Detailed activity work plan  Completed on time
- January 15th 2016  First Performance Report  Completed on time
- May 15th 2016  Second Performance Report  Completed on time
- July 31st 2016  Final Report  Completed on time

All reporting requirements have been maintained, and to date have all been met.

6.2 Key activity indicators / milestones / KPIs

The success of this project is measured by the following 4 key performance indicators, a summary of progress against the target is included below and further details are described in Section 6.3.

<table>
<thead>
<tr>
<th>Performance indicator description</th>
<th>Target</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Number of new local protocols developed and published by June 30th 2016</td>
<td>1</td>
<td>The Ovary, Fallopian tube and primary peritoneal site protocol was published in June 2016.</td>
</tr>
<tr>
<td>2 Number of new thoracic local protocols commenced and substantially progressed, ready for public consultation stage by June 30th 2016</td>
<td>3</td>
<td>All 3 thoracic local protocols - Mesothelioma, Thymic Epithelial Tumours and Tumours of the Heart were published in July 2016.</td>
</tr>
<tr>
<td>3 Requests for information from NPAAC, Australian Digital Health Agency and LIS vendors actioned to inform and support the uptake of structured reporting protocols</td>
<td>100%</td>
<td>100% of requests for information have been actioned to date.</td>
</tr>
<tr>
<td>4 Percentage of RCPA Anatomical Pathology Fellows who receive the project newsletter and an invite to participate in the pilot webinar.</td>
<td>100%</td>
<td>100% of RCPA Anatomical Pathology (AP) Fellows were sent the September, December, March and June SPRC project newsletters. All RCPA AP Fellows were invited to the educational webinar held on April 26th.</td>
</tr>
</tbody>
</table>

3 Formally NEHTA
6.3 Review of progress against the Activity Plan

The following table includes the steps outlined in the activity report provided in August 2015, a summary of progress against activities scheduled is included and further details are described below.
### Activity Plan:

<table>
<thead>
<tr>
<th>Contractual activity</th>
<th>Activity steps</th>
<th>Activity Owner</th>
<th>Date Due</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2</strong> Development of NSPRC protocols based on new ICCR datasets</td>
<td>2.1.1 Review of definitions/terms/processes</td>
<td>Project Manager</td>
<td>31&lt;sup&gt;st&lt;/sup&gt; Oct 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>2.1.2 Resolve/agree any anomalies in definitions/terms/processes</td>
<td>SPR Project Group</td>
<td>18&lt;sup&gt;th&lt;/sup&gt; Dec 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>2.1.2 Review of definitions/terms/processes</td>
<td>Project Manager</td>
<td>31&lt;sup&gt;st&lt;/sup&gt; Oct 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>2.1.2 Resolve/agree any anomalies in definitions/terms/processes</td>
<td>SPR Project Group</td>
<td>18&lt;sup&gt;th&lt;/sup&gt; Dec 15</td>
<td>Completed</td>
</tr>
<tr>
<td>2.2 Liaise with the RCPA Fellows in the ICCR development process via expert participation or public consultation.</td>
<td>2.2.1 RCPA involvement in ICCR Dataset Steering Committee</td>
<td>Project Team</td>
<td>Monthly</td>
<td>On going</td>
</tr>
<tr>
<td></td>
<td>2.2.2 Identify local representatives to participate in future ICCR Dataset Authoring Committees for the following areas:</td>
<td>Project Manager/ Clinical Lead</td>
<td>30&lt;sup&gt;th&lt;/sup&gt; Oct 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>o Head &amp; Neck and Endocrine</td>
<td></td>
<td>30&lt;sup&gt;th&lt;/sup&gt; Nov 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>o Cervical</td>
<td></td>
<td>31&lt;sup&gt;st&lt;/sup&gt; Jan 16</td>
<td>In progress – required by ICCR in Oct 2016</td>
</tr>
<tr>
<td></td>
<td>o CNS</td>
<td></td>
<td>30&lt;sup&gt;th&lt;/sup&gt; Jun 16</td>
<td>Not required in 2016 by ICCR.</td>
</tr>
<tr>
<td></td>
<td>o Breast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.2.3 Formulate local authoring committees where none exists:</td>
<td>Project Manager/ Clinical Lead</td>
<td>30&lt;sup&gt;th&lt;/sup&gt; Sep 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>o Thoracic (Heart, mesothelioma and thymus)</td>
<td></td>
<td>31&lt;sup&gt;st&lt;/sup&gt; Jan 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>o Liver</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contractual activity</td>
<td>Activity steps</td>
<td>Activity Owner</td>
<td>Date Due</td>
<td>Status</td>
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</tr>
<tr>
<td>2.2.4 Open consultation – comment by RCPA fellows</td>
<td>Project Manager</td>
<td>23rd Oct 15</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>o Thoracic (Heart, mesothelioma and thymus)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Liver</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Genitourinary</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2.2.4</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2.3 a. Revise the NSPRC protocol development process (framework) to reflect that the core development is via the ICCR (ie the ICCR dataset serves as the foundation of all future NSPRC protocols).</td>
<td>2.3.1 Schedule workshop with RCPA Macroscopic Cut-up Manual Project Team to discuss a revised, synchronised approach</td>
<td>Project Manager/Clinical Lead</td>
<td>29th Sep 15</td>
<td>Completed</td>
</tr>
<tr>
<td>b. Update the NSPRC framework documents which describe the NSPRC protocol development process to reflect the new process.</td>
<td>2.3.2 Draft updates to framework documents</td>
<td>Project Manager</td>
<td>31st Oct 15</td>
<td>Completed</td>
</tr>
<tr>
<td>c. Test and refine this new process through the development of new NSPRC protocols using the Ovary/Fallopian tube/Primary Peritoneal site dataset.</td>
<td>2.3.3 Review and approve draft changes</td>
<td>Project Manager/Clinical Lead</td>
<td>30th Nov 15</td>
<td>Completed</td>
</tr>
<tr>
<td>2.3.4 Draft local ovary, fallopian tube, primary peritoneal site protocol based on the new framework</td>
<td>Project Manager</td>
<td>30th Nov 15</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>2.3.5 Work with local Gynaecological expert co-chairs on draft local ovary, fallopian tube, primary peritoneal site protocol</td>
<td>Project Manager/Protocol Co-Chairs</td>
<td>28th Feb 16</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>2.3.6 Circulate draft local ovary, fallopian tube, primary peritoneal site protocol to local Gynaecology expert committee for review /comment</td>
<td>Project Manager</td>
<td>31st Mar 16</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>2.3.7 Make revisions based on feedback</td>
<td>Project Manager/Protocol Co-Chairs</td>
<td>30th Apr 16</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>Contractual activity</td>
<td>Activity steps</td>
<td>Activity Owner</td>
<td>Date Due</td>
<td>Status</td>
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<td></td>
<td>2.3.8 Open consultation on local ovary, fallopian tube, primary peritoneal site protocol</td>
<td>Project Manager</td>
<td>31st May 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>2.3.9 Publish local ovary, fallopian tube, primary peritoneal site protocol</td>
<td>Project Manager</td>
<td>30th Jun 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>2.3.10 Review and revise framework based on process with Ovary, fallopian tube, primary peritoneal site protocol</td>
<td>Project Manager</td>
<td>30th Apr 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>2.3.11 Present revised framework to SPRC Project Group for review and approval</td>
<td>Project Manager/ SPRC Project Group</td>
<td>30th Jun 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>2.3.12 Present final framework to SPRC Project Group for review and approval</td>
<td>Project Manager/ SPRC Project Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.3.13 Present revised Ovary, fallopian tube, primary peritoneal site protocol to SPRC Project Group for review and approval</td>
<td>Project Manager/ SPRC Project Group</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>2.3.14 Present final Ovary, fallopian tube, primary peritoneal site protocol to SPRC Project Group for review and approval</td>
<td>Project Manager/ SPRC Project Group</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>3 Education/promotion of SPR</td>
<td>3.1 Develop and implement a pilot webinar based on a single NSPRC Project protocol/ICCR dataset.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.1.1 Investigation of webinar tool</td>
<td>Project Manager</td>
<td>30th Sep 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>3.1.2 Review and approve webinar outline</td>
<td>Project Manager/ SPRC Project Group</td>
<td>15th Oct 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>3.1.3 Agree specific topic and set timeframe</td>
<td>Project Manager/ Clinical Lead</td>
<td>30th Nov 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>3.1.4 Advertise webinar</td>
<td>Project Manager</td>
<td>28th Feb 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>3.1.5 Conduct webinar</td>
<td>Project Manager/ Clinical Lead</td>
<td>30th Apr 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>3.1.6 Assess survey results</td>
<td>Project Manager/ SPRC Project Group</td>
<td>31st May 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>3.2 Develop and distribute a NSPRC Project newsletter.</td>
<td>Project Manager</td>
<td>30th Sept 15</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>3.2.1 Develop and distribute quarterly newsletters</td>
<td>Project Manager</td>
<td>20th Dec 15</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>31st Mar 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>30th Jun 16</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>3.3 Undertake promotional activities which include but are not limited to: presentations, fliers and representation at relevant conferences.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>3.3.1 Schedule Registrar training opportunities per state</td>
<td>Clinical Lead</td>
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<td>3.3.2 Deliver registrar presentations at the 2016 NSW Recent Advances and Too Hard Slides lecture series</td>
<td>Clinical Lead/ State representatives</td>
<td>31st May 16</td>
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<td>3.3.3 Pathology Update representation and flier</td>
<td>Project Manager</td>
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<tr>
<td>Contractual activity</td>
<td>Activity steps</td>
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<td>Date Due</td>
<td>Status</td>
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<td>-----------</td>
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<td>3.3.4 Presentation at IAP – Ovary, fallopian tube, primary peritoneal site protocol 3.3.5 Maintaining SPRC website</td>
<td>Protocol Co-Chair Project Manager</td>
<td>30th Jun 16 30th Jun 16</td>
<td>Completed On going</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Facilitate implementation of Structured Reporting into Laboratories</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1 Support, through the NSPRC Project Group, the use of NSPRC.</td>
<td>4.1.1 Mandating level 3 through NPAAC 4.1.1.1 Review of feedback from public comment on the NPAAC Information and Communication document 4.1.1.2 Respond to any queries related to SPRC in the Information and Communication document 4.1.2 Progress the introduction of SPRC into the RCPA curriculum</td>
<td>RCPA representatives to NPAAC Project Manager Project Manager Project Manager/Clinical Lead</td>
<td>30th Sept 15 31st Dec 15 31st Mar 16</td>
<td>Completed None received Completed</td>
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<tr>
<td>4.2 Work with Australian Digital Health Agency(^4) to explore the development of an information model using Fast Healthcare Interoperability Resources (FHIR).</td>
<td>4.2.1 Work with Australian Digital Health Agency on the FHIR information model for colorectal cancer 4.2.2 Participate in PITUS to synchronise HL7/FHIR developments for SPRC</td>
<td>Project Manager Project Manager</td>
<td>30th Jun 16 31st Dec 15</td>
<td>Completed Completed</td>
</tr>
<tr>
<td>4.3 Provide advice and assistance to pathologists and Laboratory Information System (LIS) vendors who are implementing NSPRC in public and private laboratories throughout Australia.</td>
<td>4.3.1 Respond to all queries from LIS vendors and pathologists on SPR and SPRC implementation. 4.3.2 Support the PITUS project in the development of a standards for messaging to Cancer registries</td>
<td>Project Manager Project Manager/Clinical Lead</td>
<td>30th Jun 16 30th Jun 16</td>
<td>On going On going</td>
</tr>
</tbody>
</table>

\(^4\) Formally NEHTA
6.4 Detailed activity review

The Project undertook the following activities as outlined in the Standard Funding Agreement with the Department of Health dated August 2015:

6.4.1 Harmonisation of terms

Project activity: Review the terms, definitions and dataset development processes of the International Collaboration on Cancer Reporting (ICCR) to ensure that these will provide the core components of the SPRC protocols (ie the required and recommended elements, values and commentary) in the future.

The incorporation of the ICCR in September 2014 and publication of ICCR development processes and definitions have provided the basis for a review of definitions/terms/processes between RCPA and ICCR. This review was undertaken to assess any differences, and the organisations agreed upon relevant modifications to the SPRC Framework to ensure future synchrony.

The ICCR dataset development process documented in the Guidelines for the development of ICCR Datasets, was originally drafted by the SPRC Project Manager and largely based on the development of the RCPA SPRC Protocol Framework. The same key steps include:

- the initial selection of a lead author, then
- the selection of an expert authoring committee, which is determined by the SPRC clinical lead, together with the lead author (Chair),
- an initial draft of the protocol/dataset developed by the Project Manager, which is then tailored with the Chair,
- the protocol/dataset is sent out for comment to the expert committee,
- rounds of teleconference discussion with the expert committee
- a period of open consultation,
- formatting the document and publication.

This process flow was designed with the longer term view that the ICCR datasets would form the foundation of future local Australian protocols. While the original process has been refined to reflect the international setting of the ICCR datasets, the basic flow has been retained and therefore remains synchronous with the RCPA development process.

The ICCR production of datasets has moved from early pilot and trial phases, necessary for the refinement of the development process, to an agreed production schedule based on the publication of key documents such as the World Health Organisation (WHO) Classification of tumours and staging documents as well as a continual cycle of review. With the maturation of the ICCR development process and schedule, it was time to revise the process/framework for the development of RCPA protocols, this is discussed in more detail below.

The original ICCR definitions for required (Mandatory) and recommended (Optional) elements were also based on the RCPA Framework. However, it was later agreed that the definition of a required element at an international level should be supported by a level of evidence. At the suggestion of the RCPA representatives to the ICCR, the NHMRC table\(^\text{12}\) was reviewed and a level of evidence of III-2 or above was agreed to be the benchmark for required elements. Level III-2 evidence is now used to determine MOST required elements (there are some exceptions) within ICCR datasets.
A comparison of the definitions between the RCPA Standards and Guidelines and the ‘equivalent’ ICCR Required and Recommended Elements highlighted the more robust definition used by the ICCR with the inclusion of the NHMRC level of evidence, (a comparison table is included in Appendix D). After discussion at the Structured Pathology Reporting Cancer Project Group meeting in Sept 2015, the definitions for the local Project were amended to synchronise with the ICCR definitions based on the NHMRC level of evidence table (refer revised Framework – Attachments A and B V2.2 Framework Guidelines and v2.4 Framework Template) This will alleviate any potential conflict in the future and ensures that the ICCR elements can be adopted ‘as is’ into the RCPA protocols.

During the comparison process, it was noted that the ICCR datasets are developed according to a defined scope however the SPRC Project did not originally define an overarching protocol development scope. It was agreed to review and adopt the ICCR scope for local protocol development at the SPRC Project Group meeting in October 2015 (refer Appendix E). The revised definitions have been incorporated into the updated Framework documents and the scope has been published to the RCPA website.

Different spelling and terminology necessitated the development of a harmonisation of terms and the adoption of spelling according to the World Health Organisation (WHO) given the number of countries involved in the ICCR. This is ideal in relation to local development as the WHO use UK spelling for common terms such as tumour, as does Australia.

In recent months, the ICCR defined the dataset revision process, describing what triggers a new revision and also the different types of updates needed – major (requiring public consultation), minor (not requiring public consultation) and errata. A change in the MBS schedule for RAS testing, necessitating an update to the local Colorectal cancer protocol, prompted a review of the local update process which comprised a new edition update (requiring public consultation), and errata. On review of the required changes to the colorectal cancer protocol, the SPRC Project Group agreed that the local process could benefit from the inclusion of a ‘minor update’ process similar to that of the ICCR. The SPRC Project Manager circulated a revised update process, modelled on the ICCR, to the SPRC Project Group and this was endorsed. The Release strategy document which describes the local revision process was then updated and republished to the RCPA website.

### 6.4.2 Harmonisation of terms

**Project activity:** Liaise with the RCPA Fellows in the ICCR development process via expert participation or public consultation.

RCPA involvement in the ICCR Dataset Steering Committee (DSC) where matters relating to dataset structure and development processes are discussed and agreed are vital to ensure local interests are represented and local protocol development remains in synchrony with the ICCR. Currently, the DSC meetings are held monthly and include two RCPA representatives: A/Prof David Ellis, ICCR President and Prof James Kench, Clinical Lead Structured Pathology Reporting of Cancer Project. In addition, the SPRC Project Manager attends each DSC meeting and undertakes the secretariat function.

The ICCR DSC undertakes planning of all new datasets and therefore when expert committee representatives are required for a new dataset, RCPA representatives are available to suggest suitably qualified local candidates.

Over the next 12 months, based on the ICCR development schedule, RCPA candidates will be required for:

- A suite of 6-7 head & neck datasets
- A suite of 6-7 endocrine datasets
- A cervical cancer dataset
- Datasets for tumours of the central nervous system (CNS)
- Datasets for breast cancer.

A RCPA candidate to participate in the international expert committee for the development of a cervical cancer dataset was submitted to the ICCR for consideration and was subsequently ratified by the DSC in November 2015. Candidates to participate in the development of the head & neck and endocrine dataset were submitted for ICCR consideration and subsequently the ICCR Head and Neck dataset Authoring Committees have been established and include several Australian pathologists. The nominees for the Endocrine datasets are being considered by the ICCR. Suitable Australian candidates to participate in the Central Nervous System dataset development are currently being considered by the SPRC Project Group and will be required by last quarter in 2016. The ICCR Breast Cancer dataset has been deferred and therefore local nominations are not required at this point.

The ICCR undertake a review of nominated candidates to participate in dataset development and consider the following criteria before ratification:

- representation of key stakeholder groups
- geographic and linguistic diversity
- level of expertise in the specific cancer such as:
  - experience in writing or reviewing academic papers
  - authorship of relevant World Health Organisation or staging publications
  - previous experience in the development of structured reporting guidelines
  - high volume practical experience ie subspecialisation in the specific area
  - participation in clinical trials and other detailed research in the relevant field
- a commitment to structured pathology reporting of cancer
- a willingness to review the dataset during its development process and to provide feedback in a timely manner, to undertake research (literature review) and to participate in writing the dataset and associated journal article as necessary.

Participation by RCPA in the ICCR expert committees is merit based and in a few cases of rarer cancers such as heart neoplasm, expertise, according to the above criteria, is not available in Australia due to the very low number of cases of this nature.

It is essential to ensure that the RCPA provides feedback during the public consultation process as the ICCR datasets are developed. In some cases local expert committees for specific cancers such as thymic carcinoma have not previously been formed and therefore new committees must be convened prior to the ICCR consultation stage to ensure adequate expert feedback. Four new local committees were anticipated to be required in this funding period for thymic, mesothelioma, heart and liver.

During this funding period, three of the four required new local expert committees were convened for thymic, mesothelioma and heart and provided feedback to the ICCR during the consultation period for these datasets. Where possible, the RCPA representative on the ICCR Dataset Authoring Committee (DAC) is also represented on the local committee to provide guidance on ICCR elements and to act as a conduit for the ICCR expert committee. For example, Prof Doug Henderson is on both the local and ICCR mesothelioma expert committees.

Chairs of the three new local expert committees for thymic, mesothelioma and heart were inducted in September and these committees convened in October 2015.

The importance of local feedback during the ICCR open consultation period was emphasised to each committee. Open consultation for the three thoracic datasets - thymic, mesothelioma and heart, closed in late October 2015 and feedback from the local committee was compiled, circulated
within the local expert committee and reviewed by the chair of each committee prior to submission to the ICCR. In most cases the feedback was congruent, however there were a few contradictory suggestions; e.g. a request to make ancillary studies mandatory by one expert committee member and recommended (optional) by another. Review of the feedback by the SPRC Project Manager identified any anomalies and a decision for submission was reached by the Chair of the relevant local expert committee. All comments were recorded and those not actioned by the ICCR were included for discussion in the local protocol (provided these did not contravene ICCR elements).

Nominations for a local expert committee for liver cancer are complete. Open consultation phase for the ICCR liver cancer dataset is expected to commence in July after a delay of approximately 12 weeks.

In addition to the feedback from the local expert committees, the RCPA Anatomical Pathology (AP) Fellows are also invited to provide feedback during the consultation period. Requests for feedback are circulated via direct email and the SPRC newsletter (see Appendix F).

### 6.4.3 Revision of SPRC Framework

**Project activities:**

1. **Revise the SPRC protocol development process (framework) to reflect that the core development is via the ICCR (i.e. the ICCR dataset serves as the foundation of all future SPRC protocols).**

2. **Update the SPRC framework documents which describe the SPRC protocol development process to reflect the new process.**

3. **Test and refine this new process through the development of new SPRC protocols using the ovary/fallopian tube/primary peritoneal site dataset.**

Each SPRC protocol was developed under a quality framework which detailed how protocols look as well as what should be included. The Framework documents consist of a word template and a general guideline document.

The Framework documents required updating to reflect three recent and significant initiatives impacting local protocol development:

1. **RCPA Macroscopic Cut-up Manual (MCU)**
   
   To date, each SPRC Protocol includes the elements reported during cut-up, as well as detailed specimen handling procedures.

   The SPRC Project highlighted a need for comprehensive, readily accessible macroscopic and specimen handling information and this ultimately led to advocacy for developing the online **RCPA Macroscopic Cut-Up Manual (MCU)**.

   The goal of the online MCU project was to provide an application that allows easy dissemination of cut-up information to pathologists, trainees and scientists. It provides standardised cut-up procedures with an emphasis placed on the capture of structured macroscopic information.

   The **RCPA MCU** is published on the RCPA website and is well established, and provides a level of synchronicity across these two projects; removes any duplicated ‘specimen handling’ information, and provides a single resource for macroscopic dictation information. Macroscopic reporting elements from the SPRC protocols are extracted and formatted into dictation templates which are published on the **RCPA MCU**.

   A workshop between the two projects was held in September 2015 to discuss and agree a draft new process for specimen handling and macroscopic information. The draft process has been incorporated into the revised framework documents (**Attachments A and B**) and was trialled through the development process for the local Ovary/Fallopian Tube and Primary Peritoneal...
2. **Internationally agreed cancer datasets from the ICCR**

The SPRC Project protocol development process now needs to reflect that the core development is via the ICCR i.e. the ICCR dataset serves as the foundation of future SPRC protocol development. To ensure this process runs smoothly, the review of processes, terms and definitions was undertaken (see section 6.3.1) and aligned. These changes have been reflected in the draft revised Framework documents.

3. **CanSAC – Tissue Fixation Guidelines**

Formalin (4% formaldehyde solution in water) is the most commonly used fixative for tissue in histopathology. Originally, optimal morphological preservation was the sole requirement, but in more recent times, with the advent of immunohistochemical typing, antigenic (DNA, RNA) preservation is also required, particularly for cancer related specimens.

Therefore the Cancer Services Committee (CanSAC), in conjunction with the SPRC Project, have developed a set of agreed tissue fixation guidelines which are out for consultation currently and thereafter these guidelines will be published on the MCU section of the RCPA website and a reference included in the SPRC Framework documents. Once approved, these guidelines will be adopted as the Australia standard for Anatomical Pathology laboratories.

**Progress**

The Framework documents were revised to incorporate the ICCR input, the revised specimen handling and macroscopic information process and the upcoming tissue fixation guidelines. These draft Framework documents were reviewed and approved by the Clinical Lead of the SPRC and the SPRC Project Group.

The revised process was trialled through the development process for the local Ovary/Fallopian Tube and Primary Peritoneal Site, Thymic Epithelial Tumours, Mesothelioma of the Pleura and Peritoneum, and Tumours of the Heart, Pericardium and Great Vessels protocols.

All four of the protocols - ovary/fallopian tube and primary peritoneal site, thymic, heart and mesothelioma were drafted based on the revised Framework documents. Once drafted, a comprehensive review was undertaken with the relevant appointed chairs of the local expert committees. This review included a detailed evaluation of the specimen handling and macroscopic information from the RCPA MCU. In the case of the ovary/fallopian tube and primary peritoneal site and thymic protocols this information was reviewed with the RCPA MCU Project Team per the agreed process. As there is no equivalent RCPA MCU for mesothelioma no review meeting was held. In the case of the Heart protocol, a different approach was agreed - in this case the review with the RCPA MCU Project Team was agreed to take place after the protocol was discussed and revised with the expert committee to assess whether this approach was preferred. Evaluating the development process of both options – there was minimal difference between the two and both remain viable options for future development.

Challenges were encountered during the reviews and discussion of the RCPA MCU information due to the differences in the structure of the RCPA MCU versus the protocol/dataset in some cases, eg the RCPA MCU separates information for fallopian tube and ovary and includes peritoneum with ovary, whereas the protocol/dataset encompass all 3 sites together.

The detailed review of the four protocols with the chairs also included a discussion regarding what additional elements to include in the local protocol over and above the ICCR information (the ICCR...
Datasets are intended to be concise rather than comprehensive); whether to upgrade any of the recommended elements in the ICCR dataset to a standard (mandatory) locally and whether any additional commentary that may be useful in the local context was warranted. These additional components were included, final updates made to the ICCR components as they were confirmed by the international committee and the documents circulated for review to the relevant local expert committees.

Teleconferences with each expert committee were held and the protocols discussed in detail. These discussions included a review of ICCR responses to local expert committee feedback. All four protocols were then discussed, revised and circulated for further comment to the expert committees and then posted for a period of public consultation in late May 2016 and are now published to the RCPA website.

The involvement of the RCPA in the ICCR process has enabled the RCPA protocol development to occur as the ICCR datasets are being finalised. This means that local protocols can be published within a short period of time after finalising the ICCR dataset.

The Framework remains a standing topic on both RCPA and the ICCR DSC agendas.

Following the development process of the ovary/fallopian tube and primary peritoneal site, mesothelioma, heart and thymic protocols, the draft Framework documents (Attachments A and B) have been revised, final versions circulated to the Clinical Lead of the SPRC and the SPRC Project Group for endorsement and published to the RCPA website.

**6.4.4 Educational webinar**

**Project activity:** *Develop and implement a pilot webinar based on a single SPRC Project protocol/ICCR dataset.*

In August - September 2015, the SPRC Project Manager undertook an investigation of suitable webinar tools. This included:

- a review of the tools and processes used by the Canadian Partnership Against Cancer (CPAC) who conducted a series of very successful educational seminars via Webex across Canada several years ago, and
- a review of tools available at the RCPA included GoToMeeting which is used commonly for SPRC meetings, and GoToWebinar which is used exclusively for educational sessions held weekly by the Microbiology training network team.

The review assessed and compared features and determined any technical limitations/issues such as:

- the number of potential attendees (GoToMeeting is limited to 25 without substantial additional cost),
- existing software accounts available to the college ie GoToMeeting, GoToWebinar,
- geographic distribution of the potential audience ie availability of toll free numbers etc for regional areas.
- participant technology eg loading of tools and quality of sound
- the presentation tools available in the application eg highlight, pointer
- any online Q&A capability and participant polling,
- registration process and email follow up
- online survey capability
The outcomes of the assessment indicated that GoToWebinar was the preferred option and the SPRC Project Manager undertook a trial of the software during a Microbiology session to gain a better understanding of the process from a participant point of view. The recommendation to use GoToWebinar was agreed by the SPRC Project Group and the following is a summary of the activities undertaken:

- Prof James Kench presented a webinar on “Structured reporting, prostate cancer and the end of Gleason grading”. This topic was relevant to large number of pathologists as recent changes (WHO, ISUP and ICCR) was of interest. It is also in Prof Kench’s area of expertise.
- The webinar presentation was held on 26 April 2016 which coincided with completion of the ICCR development process for prostate and publication of the new WHO classification of tumours.
- 60 participants joined the session which was also recorded and posted to the RCPA website as a resource for review/download.
- A series of promotional activities were advertised in Pathology Today and the SPR Newsletter – 2-3 months and 1 month prior to the session.
- An advertisement for the webinar was included in the December and March SPRC newsletter, as well as in Pathology Today in April.
- A post session survey, posing a series of questions to elicit feedback to assist in planning future webinars. This survey was made available to participants post webinar in a follow up email.
- The results of the survey and feedback received by the Project Manager, and via the post webinar survey, was extremely positive, indicating a desire to see more webinars in the future.

6.4.5 SPRC Newsletter

Project activity: Develop and distribute a SPRC Project newsletter.

A newsletter on SPRC has been developed and distributed quarterly for the last 5 years. The process to produce the newsletter is as follows:

- An initial draft is produced by SPRC Project Manager approximately 5-6 weeks prior to planned distribution. This draft includes a variety of articles such as topics of note from a new protocol; any relevant publications, both local and international; updates from relevant organisations such as the ICCR and TNM cancer staging; topics related directly to SPRC project eg upcoming presentations, open consultation, journal/article publications; and information about related projects eg MCU or PITUS projects.
- This draft is reviewed and edited by SPRC Clinical Lead approximately 3-5 weeks prior to distribution
- It is then circulated to SPRC Project Group for their approval/comment approximately 2-3 weeks prior to distribution
- The approved version is formatted using the College’s online newsletter system, Hartz, and scheduled.
- Approximately 1 week prior to distribution a recipient list is defined. This consists of Anatomical Pathology Fellows and trainees and Haematology Fellows and trainees who are extracted from the College database, IMIS, which ensures the latest contact details
are used. This is added to the contacts of other interested parties from the SPRC stakeholder list.

- Distribution is via online newsletter system Hartz.

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<thead>
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The latest newsletter from June 2016 is included as Attachment C – Newsletter Jun 16

### 6.4.6 Promotional activities

**Project activity:** Undertake promotional activities which include but are not limited to: presentations, fliers and representation at relevant conferences.

**Presentations/educational events**

During this funding period, the following presentations/informational events were undertaken:

- Pathology Update, Melbourne - February 2016, which includes a session on the recently published cytology thyroid SPRC protocol.
- A registrar training opportunity was conducted in NSW and further training opportunities are planned as part of ongoing training programs.
- International Academy of Pathology, Australasian division - June 2016 at which a presentation on the ovary/fallopian tube and primary peritoneal site protocol was conducted.

A report on the College’s activities in relation to cancer was submitted to the Annual Report of the Clinical Oncological Society of Australia (COSA) and an update provided for publication to the August 2016 Marrayalan (COSA newsletter), both submissions include sections on the SPRC Project and ICCR. (A copy of these reports are available from the RCPA Project Management Office.)

**RCPA Website**

With the changes to the Framework described in section 6.4.3 the SPRC web pages have now been updated with the revised documents and other agreed changes.

Since the launch of the website in November 2013, the Structured Pathology Reporting of Cancer section has received a total of 34,713 pageviews*, and 30,327 of these were unique pageviews**. On average, this section of the website has received 1,011 unique pageviews per month (over 30 months).

The top five landing pages within the Structure Pathology Reporting of Cancer section of the RCPA website were:

1. Cancer Protocols
2. Macroscopic Reporting
3. Public Consultation
4. Implementation
5. Protocol Development

The majority of users (64%) were from Australia, and a further 13% were from New Zealand. The remaining 23% were dispersed across a number of international countries.

* Pageviews is the total number of pages viewed. Repeated views of a single page are counted.
** Unique Pageviews is the number of sessions during which the specified page was viewed at least once. A unique pageview is counted for each page URL + page Title combination.

6.4.7 Support the use of SPRC

Project activity: Support, through the SPRC Project Group, the use of SPRC.

Despite the availability of 30 cancer protocols and having taken the lead in international efforts for standardisation, Australia still lags behind the progress achieved in other countries, as adoption of the SPRC cancer protocols remains voluntary.

However, there are three main areas of progress to report:

1. NPAAC “Requirements for Information Communication” document. In 2014, the National Pathology Accreditation Advisory Council (NPAAC) convened a working party to revise their “Requirements for Information Communication” document. The RCPA and SPRC Project Group members who participated worked to include wording to mandate reporting of all cancers according to the RCPA SPRC protocols.

At the time of this report, the “Requirements for Information Communication” document has undergone a period of open consultation and further feedback from specific organisations sought. However, publication of this document has been delayed due to issues relating to HL7 organisational changes impacting the HL7 messaging standards development process. RCPA will continue to communicate with HL7 and NPAAC about progress of this document.

If the mandate requirements sought are successful, this document will require cancer reports to include all the data elements in the SPRC protocols and display them in a structured format, however it does not go to the extent of requiring the data be stored or transmitted electronically between systems in a discrete manner (Level 3 on the compliance matrix in Appendix C). Mandating implementation of structured reporting at this level will be a significant step forward and will enable Australia to improve the completeness, conciseness, conformity and clarity of cancer reports with subsequent improvements in patient outcomes.

The SPRC Project will continue to provide any clarification or support required to further mandate SPRC via the “Requirements for Information Communication” document. To date, no queries related to SPRC in the Information and Communication document have been received.

2. RCPA position statement. As an interim measure, prior to mandating the RCPA SPRC protocols as discussed above, a position statement and implementation guide were developed and published to the RCPA website in the last funding period.

The Position Statement was intended as ‘moral encouragement’ and support of universal adoption of structured reporting (to at least Level 3 on the compliance matrix in Appendix C). The implementation guide included a set of simple guidelines against which laboratories and assessors are able to measure compliance with the structured reporting standards.

The SPRC Project informed NATA of the publication of the Position Statement in August 2015 and in response an email with a copy of the new Position Statement was sent to all medical testing lead assessors. The intention is that assessors will advise laboratories of the Position Statement, and encourage laboratories towards compliance.
3. **Trainee portfolio.** In September 2015 a letter was written and sent to the Anatomical Pathology (AP) Co-Chief Examiners and the College Registrar formally requesting the inclusion of SPRC in the Trainee Portfolio requirements and Assessment Matrix. Initial discussions with the AP Co-Chief Examiners were very promising. The matter was subsequently discussed and agreed at a meeting with the Board of Education and Assessment. Confirmation has been received that a requirement for Anatomical Pathology trainees to have a minimum of 10 reports, covering at least 3 different organ systems in their portfolio over the 5 years of training has been included in the curriculum. These requirements have been reflected in the 2016 Anatomical Pathology Curriculum Handbook. The success of this process will raise the awareness of the importance of SPRC in AP reporting.

6.4.8 **SPRC Information model**

**Project activity:** Work with the Australian Digital Health Agency\(^5\) to explore the development of an information model using Fast Healthcare Interoperability Resources (FHIR).

In order to promote consistent presentation, conformance with the SPRC protocols, and to facilitate interoperability, archetypes are needed. Archetypes are detailed information models that are a way of representing the checklist from the protocols so that it can be used by Laboratory Information System (LIS) vendors to facilitate implementation and ensure that the SPRC Protocols are faithfully reproduced in each different LIS.

Various options have been investigated to date such as a joint development in 2010-11 with the Australian Digital Health Agency and Ocean informatics using OpenEHR and a pilot project to develop 3 checklists with the College of American Pathologists (CAP). In each case the complexity and cost involved has limited progress.

In 2014, the SPRC Project initiated further discussions with the Australian Digital Health Agency to assess current opportunities. After an initial investigation, the Australian Digital Health Agency suggested in February 2015, that Fast Healthcare Interoperability Resources (FHIR) may offer a mechanism for building archetypes for the RCPA protocols. Australian Digital Health Agency agreed to undertake a pilot project to explore the use of FHIR for the colorectal (CRC) protocol.

The Australian Digital Health Agency\(^6\) noted that progress in developing the RCPA cancer protocols with FHIR may be somewhat slow initially as a result of the continuous development of FHIR. FHIR is a very recent development and while it is gaining a lot of international momentum, it is a times an unstable platform to work with and the tools available to develop FHIR products are in their infancy. However, a discussion with the Australian Digital Health Agency in August 2015 was highly promising as the Australian Digital Health Agency offered to engage Grahame Grieve, who is the main FHIR developer, to assist with the RCPA archetype development.

Using CRC as the example, the Australian Digital Health Agency developed the protocol checklist as an information model in an excel file). To ‘test’ the model and understand how the RCPA protocols are used, the Australian Digital Health Agency requested example reports. A body of reports were provided and a series of calls to work through issues of standardisation, terminology and interdependency of fields was undertaken. These calls have dealt with a series of questions covering the handling of multiple specimens, multiple tumours, the capture of macroscopic data and clinical information/request information as well as ‘translating’ the often difficult cancer related terms and processes used that are difficult for IT personnel to understand.

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\(^5\) Formally NEHTA

\(^6\) Formally NEHTA
**PITUS-15-16** The possible use of FHIR resources as an information model, also raised opportunities regarding its use for system interoperability and as such the SPRC Project goals have intersected with the objectives of the PITUS Project which is also administered by the RCPA with funding provided by the Department of Health (DOH).

The goal of the PITUS-15-16 Project is “to continue the development of standards for information in pathology requests and reports and to facilitate uptake by pathology practices and to allow safer and better quality use of pathology for customers”. Under this project there are five working groups, one of which has direct involvement with the SPRC Project: Working Group 5 (WG5).

FHIR resources can be used for both purposes ie to:

1. develop the knowledge structure or the actual cancer report checklist ie directing the information to be captured, which is the goal of the SPRC Project, as well as,
2. drive the export of standardised report content ie actual cancer report data to be sent outbound from the LIS to the cancer registry which is the intent of the PITUS project.

Therefore to ensure synchrony between the two projects, PITUS Working Group 5 (WG5) includes the Australian Digital Health Agency and the SPRC Project team – Project Manager and the SPRC Clinical Lead.

Currently, the Australian Digital Health Agency in conjunction with PITUS 15-16 Project and the SPRC Project are working through the assignment of terminology – LOINC and SNOMED CT on both the CRC model and a prostate cancer information model.

The PITUS and SPRC projects are working together on a trial implementation of structured cancer reporting in order to specify a standard for messaging structured cancer reporting information via the new HL7 Standard, FHIR. The development of the HL7 Standard FHIR is continuing and the current body of work can be accessed on the HL7 Australia FHIR site at: [HL7 Standard link](#).

The trial implementation involves both NSW Health Pathology, and Sonic (representing public and private pathology) who are currently engaged in the implementation of SPRC data entry tools.

### 6.4.9 Supporting implementation

**Project activity:** *Provide advice and assistance to pathologists and Laboratory Information System (LIS) vendors who are implementing SPRC in public and private laboratories throughout Australia.*

Without the advantages of archetypes/electronic implementation tools, implementations of structured reporting in Australia have been undertaken on an ad hoc basis. Each implementer is required to review and assess paper checklists in the published protocols and make determinations as to how these should be represented for customers.

This is a time consuming process and to avoid misinterpretations, the SPRC Project has provided advice and support via teleconference, presentation and emails to those implementing or planning to implement the structured reporting of cancer protocols. In the funding period this has included:

- **Voicebrook.** A US based vendor who is pursuing several contracts with their Anatomical Pathology application in Australia. Voicebrook are very keen to understand both the regulatory environment and the RCPA protocols. Calls were scheduled periodically.

- **NSW Health Pathology** are planning to mandate use of SPRC at Level 3 and have agreed to participate in the pilot of SPRC reporting and electronic submission to the Cancer Institute NSW via a joint project of the SPRC Project and PITUS 15-16 Project. At the time of this report, NSW Health Pathology are implementing a middleware solution to support the data entry of SPRC.

- **Dr Travis Brown,** a registrar from Victoria, is undertaking development of a web based application reflecting the RCPA SPRC protocols. The SPRC Project previously worked with Dr Brown on the development of his electronic form application in 2012. The e-forms were
used quite successfully in his local environment. Dr Brown submitted his beta version of the web-based application for review by the SPRC Project Manager – further updates and testing opportunities have been discussed.

Ad-hoc questions and emails are also submitted. The SPRC Project Manager responds to each as they arise.

### 6.5 Issues Register

<table>
<thead>
<tr>
<th>Issue</th>
<th>Source</th>
<th>Impact</th>
<th>Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty maintaining a schedule of delivery on protocols and datasets using volunteer expert committees</td>
<td>Reliance on volunteers to provide the input and editing of local protocols and international datasets.</td>
<td>Delays in the development of new protocols</td>
<td>Schedule regular check point meetings to ensure traction and delivery.</td>
</tr>
<tr>
<td>Lack of progress with ICCR datasets due to lack of Project Management expertise</td>
<td>Adequately skilled people cannot be hired.</td>
<td>Dataset production will slow or cease.</td>
<td>Continued RCPA representation on ICCR dataset steering committee to facilitate planning and progress</td>
</tr>
<tr>
<td>ICCR datasets are not developed due to lack of funding.</td>
<td>ICCR requires independent sources of funds to hire the Project Management expertise it needs</td>
<td>Dataset production will slow or cease.</td>
<td>Identify and investigate multiple funding sources through sponsorship, strategic alliances with key organisations in business plan</td>
</tr>
<tr>
<td>Lack of progress on mandating SPRC.</td>
<td>NPAAC does not publish the standard to implement SPRC to Level 3</td>
<td>Implementation of SPRC will be limited and benefits will not be achieved</td>
<td>Continue to work with NPAAC, NATA and the RCPA to promote mandating SPRC.</td>
</tr>
</tbody>
</table>

### 6.5 Documentation summary

The 30 published SPRC Project protocols and the developed guides, forms, request information sheets, macroscopic templates and MS Word templates are available on [RCPA Structured Pathology Reporting of Cancer website](https://www.rcpa.org.au).
7. Project Challenges

The SPRC Project has not encountered difficulties in the funding period to date.

8. Financials

The RCPA annual audit is currently underway and an audited financial report for this project will be forwarded at the conclusion of the RCPA audit.
9. Appendices

Appendix A - NHMRC Levels of evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Intervention 1</th>
<th>Diagnostic accuracy 1</th>
<th>Prognosis 1</th>
<th>Aetiology 1</th>
<th>Screening intervention 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>I*</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
</tr>
<tr>
<td>II</td>
<td>A randomised controlled trial</td>
<td>A study of test accuracy with an independent, blinded comparison with a valid reference standard; among consecutive persons with a patient clinical presentation</td>
<td>A prospective cohort study</td>
<td>A prospective cohort study</td>
<td>A randomised controlled trial</td>
</tr>
<tr>
<td>II-1</td>
<td>A quasi-randomised controlled trial (i.e., alternate allocation or some other method)</td>
<td>A study of test accuracy with an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation</td>
<td>All or none 1</td>
<td>All or none 1</td>
<td>A quasi-randomised controlled trial (i.e., alternate allocation or some other method)</td>
</tr>
<tr>
<td>II-2</td>
<td>A comparative study with concurrent controls • Non-randomised, observational study • Cohort study • Case-control study • Interrupted time series with a control group</td>
<td>A comparison with reference standard that does not meet the criteria required for Level II or II-1 evidence</td>
<td>Analysis of prognostic factors amongst patients in a single arm of a randomised controlled trial</td>
<td>A retrospective cohort study</td>
<td>A comparative study with concurrent controls • Non-randomised, observational study • Cohort study • Case-control study</td>
</tr>
<tr>
<td>II-3</td>
<td>A comparative study without concurrent controls • Historical control study • Two or more single arm studies • Interrupted time series without a parallel control group</td>
<td>Diagnostic case-control study</td>
<td>A case-control study</td>
<td>A comparative study without concurrent control • Historical control study • Two or more single arm studies</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>Case series or other pre-test/ post-test outcomes</td>
<td>Study of diagnostic yield (no reference standard)</td>
<td>Case series, or cohort study of patient subgroups at different stages of disease</td>
<td>Case series, or cohort study or case series</td>
<td>Case series</td>
</tr>
</tbody>
</table>

Explanatory notes

1 Definitions of these study designs are provided on pages 7-8 How to use the evidence: assessment and application of scientific evidence (NHMRC 2000b) and in the accompanying Glossary.

2 These levels of evidence apply only to studies of assessing the accuracy of diagnostic or screening tests. To assess the overall effectiveness of a diagnostic test there also needs to be a consideration of the impact of the test on patient management and health outcomes (Medical Services Advisory Committee 2005, Sackett and Haynes 2002). The evidence hierarchy given in the ‘Intervention’ column should be used when assessing the impact of a diagnostic test on health outcomes relative to an existing method of diagnosis/comparator test(s). The evidence hierarchy given in the ‘Screening’ column should be used when assessing the impact of a screening test on health outcomes relative to no screening or alternative screening methods.

3 If it is possible and/or ethical to determine a causal relationship using experimental evidence, then the ‘Intervention’ hierarchy of evidence should be utilised. If it is only possible and/or ethical to determine a causal relationship using observational evidence (e.g. cannot allocate groups to a potential harmful exposure, such as nuclear radiation), then the ‘Aetiology’ hierarchy of evidence should be utilised.

4 A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence. Systematic reviews of level II evidence provide more data than the individual studies and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review quality should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome/result, as different studies (and study designs) might contribute to each different outcome.

5 The validity of the reference standard should be determined in the context of the disease under review. Criteria for determining the validity of the reference standard should be pre-specified. This can include the choice of the reference standard(s) and its timing in
relation to the index test. The validity of the reference standard can be determined through quality appraisal of the study (Whiting et al. 2003).

Well-designed population based case-control studies (eg, population based screening studies where test accuracy is assessed on all cases, with a random sample of controls) do capture a population with a representative spectrum of disease and thus fulfill the requirements for a valid assembly of patients. However, in some cases the population assembled is not representative of the use of the test in practice. In diagnostic case-control studies a selected sample of patients already known to have the disease are compared with a separate group of normal/healthy people known to be free of the disease. In this situation patients with borderline or mild expressions of the disease, and conditions mimicking the disease are excluded, which can lead to exaggeration of both sensitivity and specificity. This is called spectrum bias or spectrum effect because the spectrum of study participants will not be representative of patients seen in practice (Mulherin and Miller 2002).

At study inception the cohort is either non-diseased or all at the same stage of the disease. A randomised controlled trial with persons either non-diseased or at the same stage of the disease in both arms of the trial would also meet the criterion for this level of evidence.

All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus; and clear proof of the causal link has come from the disappearance of smallpox after large-scale vaccination.

This also includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (ie. utilise A vs B and B vs C, to determine A vs C with statistical adjustment for B).

Comparing single arm studies ie. case series from two studies. This would also include unadjusted indirect comparisons (ie. utilise A vs B and B vs C, to determine A vs C but where there is no statistical adjustment for B).

Studies of diagnostic yield provide the yield of diagnosed patients, as determined by an index test, without confirmation of the accuracy of this diagnosis by a reference standard. These may be the only alternative when there is no reliable reference standard.

**Note A:** Assessment of comparative harms/safety should occur according to the hierarchy presented for each of the research questions, with the proviso that this assessment occurs within the context of the topic being assessed. Some harms (and other outcomes) are rare and cannot feasibly be captured within randomised controlled trials, in which case lower levels of evidence may be the only type of evidence that is practically achievable; physical harms and psychological harms may need to be addressed by different study designs; harms from diagnostic testing include the likelihood of false positive and false negative results; harms from screening include the likelihood of false alarm and false reassurance results.

**Note B:** When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question eg. level II intervention evidence; level IV diagnostic evidence; level III-2 prognostic evidence.

**Note C:** Each individual study that is attributed a “level of evidence” should be rigorously appraised using validated or commonly used checklists or appraisal tools to ensure that factors other than study design have not affected the validity of the results.
Appendix B - SPRC Governance Structure

** National Stakeholders**

Structured Pathology Reporting Project Group:
- James Kehoe (chair), Debra Graves, Paul McKenzie, Meagan Judge, David Ellis, Cleo Anderle, Michael Legg, David Rodol, Sandra O'Toole, Claire Cook-Yarborough, Jane Dahlstrom, DHOI representatives.

Royal College of Pathologists of Australasia
- Fellows
- Council
- Executive committee

Cancer Services Advisory Committee (Cancer Advisory Committee)
- Chair: Dr. Sandra O'Toole

Skin & Adnexal Expert Group
- Chair: R. Netter

Gastrointestinal Expert Group
- Chair: J. Brown

Pulmonary and Mediastinum Expert Group
- Chair: J. McWraith

Breast Expert Group
- Chair: G. Farvid

Gynaecological Expert Group
- Chair: J. Amer

Head & Neck & Endocrine Expert Group
- Chair: J. Dodds

Neurological Expert Group
- Chair: M. Rodriguez

Bone & Soft Tissue Expert Group
- Chair: C. Domarco

Paediatric Tumours Expert Group
- Chair: S. Araki

Ocular Expert Group
- Chair: A. Kline

Liaison with other committees as appropriate e.g. Anatomical Pathology Advisory Committee, Haematology Advisory Committee and Pathology Professional Activities Committee

Representation on CAP cancer committees.

** Incorporating the Round Table attendees, Round Table working party and other interested stakeholders.

# Those in red are the executive committee empowered to make decisions on a day to day basis.
# Appendix C - SPRC Capability matrix

<table>
<thead>
<tr>
<th>Entry Level</th>
<th>Goal State</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Entry</strong></td>
<td></td>
</tr>
<tr>
<td>Level 1: Narrative only</td>
<td>Level 6: Use of a structured format</td>
</tr>
<tr>
<td><strong>Content</strong></td>
<td></td>
</tr>
<tr>
<td>Non-RCPA protocol compliant</td>
<td>RCPA protocol content compliant</td>
</tr>
<tr>
<td><strong>Data Storage</strong></td>
<td></td>
</tr>
<tr>
<td>Data stored as a single text field or as a text field per reporting segment eg macroscopic</td>
<td>Individual data elements stored in discrete data fields</td>
</tr>
<tr>
<td><strong>Coding</strong></td>
<td></td>
</tr>
<tr>
<td>No coding</td>
<td>SNOMED CT or other coding enabled</td>
</tr>
<tr>
<td><strong>Messaging</strong></td>
<td></td>
</tr>
<tr>
<td>Discrete data elements are not sent via HL7 messaging</td>
<td>Discrete data elements sent via HL7 messaging</td>
</tr>
</tbody>
</table>


* Health Level 7 is a not-for-profit organisation defining interoperability and standards in healthcare information technology.
## Appendix D - Comparison of terms

<table>
<thead>
<tr>
<th>Original RCPA Framework definitions</th>
<th>ICCR Guidelines definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mandatory elements</strong></td>
<td></td>
</tr>
<tr>
<td>Standards are mandatory, as indicated by the use of the term 'must'. Their use is reserved for core items essential for the clinical management, staging or prognosis of the cancer and key information (including observations and interpretation) which is fundamental to the diagnosis and conclusion. These elements must be recorded and at the discretion of the pathologist included in the pathology report according to the needs of the recipient of the report. The summation of all standards represents the minimum dataset for the cancer.</td>
<td>Required elements are those which are essential for the clinical management, staging or prognosis of the cancer. These elements will either have evidentiary support at Level III-2 or above (based on prognostic factors in the NHMRC levels of evidence document – see Appendix A). In rare circumstances, where level III-2 evidence is not available an element may be Required where there is unanimous agreement in the expert committee. An appropriate staging system eg Pathological TNM staging would normally be included as a required element. The summation of all REQUIRED elements is considered to be the minimum reporting standard for a specific cancer.</td>
</tr>
<tr>
<td><strong>Non-mandatory elements</strong></td>
<td></td>
</tr>
<tr>
<td>Guidelines are recommendations; they are not mandatory, as indicated by the use of the word 'should'. Guidelines cover items that are not essential for clinical management, staging or prognosis of a cancer, but are recommended. Guidelines include key observational and interpretative findings that are fundamental to the diagnosis and conclusion. Such findings are essential from a clinical governance perspective, because they provide a clear, evidentiary decision-making trail. Guidelines are not used for research items.</td>
<td>Recommended elements are those which are unanimously agreed should be included in the dataset but are not supported by level III-2 evidence. These elements may be clinically important and recommended as good practice but are not yet validated or regularly used in patient management. Key information other than that which is essential for clinical management, staging or prognosis of the cancer such as macroscopic observations and interpretation, which are fundamental to the histological diagnosis and conclusion eg macroscopic tumour details, block identification key, may be included as either required or recommended elements by consensus of the Dataset Authoring Committee.</td>
</tr>
<tr>
<td><strong>Commentary</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Commentary is text, diagrams or photographs that clarify the standards and guidelines, provide examples and help with interpretation, where necessary (not every standard or guideline has commentary). Commentary is used to:  
  - define the way an item should be reported, to foster reproducibility  
  - explain why an item is included (e.g. how does the item assist with clinical management or prognosis of the specific cancer)  
  - cite published evidence in support of the element | Commentary is explanatory text, diagrams or tables that clarify the elements used to:  
  - define the way an item should be reported, to ensure clarity and conformity  
  - explain why an item is included (e.g. how does the item assist with clinical management or prognosis of the specific cancer)  
  - cite published evidence in support of the element |
<table>
<thead>
<tr>
<th>Original RCPA Framework definitions</th>
<th>ICCR Guidelines definitions</th>
</tr>
</thead>
</table>
| management or prognosis of the specific cancer).  
- cite published evidence in support of the standard or guideline  
- state any exceptions to a standard or guideline. | • state any exceptions or issues  
Commentary is designed to provide contextual guidance to the reporting pathologist. |
Appendix E - Scope

ICCR Scope adopted by the SPRC project:

In general, the protocols cover malignant entities, either alone or in association with other pre-cancerous or non-invasive components.

Protocols do not cover non-malignant entities alone except in certain circumstances:

- For anatomical areas, such as the heart and central nervous system, benign tumours may be included in the scope of the protocol as even benign conditions have serious prognostic implications.
- Tumours of uncertain malignant potential.
- In cases where in-situ neoplasia is relevant, both invasive and non-invasive tumour components may be included.
Appendix F - ICCR open consultation notification to RCPA fellows

Email notification

Dear RCPA members,

I am writing to invite you to review and provide comment on the draft datasets for pathology reporting of Mesothelioma, neoplasms of the Heart and Thymic epithelial tumours developed by the International Collaboration on Cancer Reporting (ICCR).

The ICCR, a collaboration of the European Society of Pathology (ESP), the Royal College of Pathologists UK, the College of American Pathologists (CAP), the Royal College of Pathologists of Australasia (RCPA) and the Canadian Association of Pathologists (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC), has been formed to develop common, internationally standardised and evidence-based cancer datasets for surgical pathology specimens. Using the best international approaches, and leveraging the knowledge and experience of world-leading pathologists, the ICCR aims to ensure that all cancer reports, will be of the same high quality; ensuring completeness, consistency, clarity, conciseness and above all, clinical utility.

The ICCR has published five cancer datasets to date. These datasets are posted to: ICCR datasets link

Your comment on the draft datasets is invited. They are posted to the following website:

ICCR datasets comments link

The documents will be available for comment until 30th October 2015. Feedback on the documents will be via an electronic form posted on the website.

We would greatly appreciate you disseminating this notification to any other interested parties.

If you have any questions or have any issues accessing any documents or completing the online form, please contact me on the details below.

Regards

Meagan

Newsletter – under ICCR progress section.

The following datasets are now available for public comment:

- Mesothelioma in the pleura and peritoneum (biopsy and resection specimens)
- Thymic epithelial tumours (resection specimens of the thymus ie thymoma, neuroendocrine tumours of the thymus and thymic carcinoma but excluding germ cell tumours and other primary thymic neoplasms)
- Neoplasms of the heart, peritoneum and great vessels (biopsy and resection specimens. Includes primary tumours of the heart, pericardium and great vessels, both benign and malignant entities, but excludes haematolymphoid neoplasms and mesothelioma)

Your feedback on the draft datasets is very important as these datasets will form the foundation of local Australasian structured reporting protocols on these topics.

ICCR datasets comments link

The datasets will be available for comment until 30th October 2015.
Feedback on the documents will be via an electronic form posted on the website or you can email any comments to: MeaganJ@RCPA.EDU.AU
10. References


10. RCP (Royal College of Pathologists) (2015). Datasets and tissue pathways. Available from: [RCP datasets and tissue pathways link](#).
