Response to National Health Genomics Policy Framework 2017-2020

Submission from the Clinical Oncology Society of Australia and Cancer Council Australia

March 2017

The **Clinical Oncology Society of Australia** (COSA) is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients.

Cancer Council Australia is Australia's peak national non-government cancer control organisation and advises the Australian Government and other bodies on evidence-based practices and policies to help prevent, detect and treat cancer.

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3. **Are you providing your response on behalf of an organisation?**

   Yes, Clinical Oncology Society of Australia and Cancer Council Australia

4. **If applicable, please specify you and/or your organisation's area of expertise.**

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5. **Do you consent to potentially being contacted to discuss the content of your submission further?**

   Yes Phone Number (Optional): 02 8063 4155

6. **Do you accept the terms specified above about the confidentiality of submissions?**

   Yes

Section of Framework		Question	Response
Glossary	Pg. 2-5	7. Are there other key terms referenced in the Framework which should be added to the glossary? If so, please provide details.	No.
		8. Are the definitions easy to understand? Do any definitions require amendment? If yes, please provide details.	An understanding of scientific terminology is required to comprehend the majority of the definitions within the glossary. The definitions are clear given the audience for this Framework is 'decision and policy makers at national, state and health service level'. We would recommend that the glossary be revised if it was to be used for educational purposes targeted to the general public.
Preamble	Pg. 7-8	9. Does the Preamble provide a sufficient overview of the Framework? If not, please provide further details.	Yes. The purpose and scope are clear and reflect the theoretical content and 'current state of play' within the Framework. The preamble also addresses the limitations of the Framework. It acknowledges that the Framework cannot address specific issues related to genomics and health, however, that the

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			overarching principles can be applied by all health agencies.
		10. Are there linkages with other key frameworks or strategies that should be explicitly referred to in the Preamble? If yes, please provide details.	Developing a Framework to support the quality use of genomic information in practice must acknowledge all social, legal and ethical legislative requirements. Beyond these requirements, the use of genomics in practice for the management of risk, diagnosis and treatment of cancers based on a known genetic marker, requires interaction with best practice standards including evidence based clinical practice guidelines and optimal care pathways to guide the use of genomics in the care of people affected by cancer. These best practice documents are utilised by oncology health professionals in the management of patients, and contain disease specific treatment guidance with the ability to be tailored to an individual patient's circumstances. The National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research,* and *Principles for the Translation of 'omics' – based tests from discovery to health care* must be referenced as governing standards to

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			conduct ethical, and high impact research for application in clinical and psychosocial care. As the Framework evolves, it must link in with current and emerging Commonwealth priorities including; Medicines and Medical Devices Review and changes in the Therapeutic Goods Administration review pathways; review of Medicare Benefit Schedule items by the Medicare Benefits Schedule Taskforce; promotion of My Health Record, integration with Medical Research Future Fund, and work of the National Digital Health Agency, and the work of the Primary Health Care Advisory Group (PHCAG).
		11. Is a three year timeframe sufficient for the Framework? Please explain your answer.	Yes. The understanding of genomes and the application of this information in the diagnosis and treatment of cancer will continue to evolve rapidly. Therefore, the opportunity for the Framework to be reviewed frequently is appropriate. The Framework is based on fundamental principles, and therefore, it remains flexible enough to be adapted or utilised in the local context. However, given the lack of a detailed implementation plan or objectives, there is no accountability or ability to

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			monitor appropriateness of the application of the framework in practice.
Strategic Context	Pg. 10-12	12. Are the most critical international and national activities referenced? If no, please provide details of what may be included and why it is important.	Not all state and territory governments have made financial commitments to advance genomics clinical practice and research. The Framework must ensure there is a consistent, whole of nation approach to reduce unsatisfactory variability. The International Cancer Genome Consortium (ICGC) coordinates a large number of research projects, and generates comprehensive catalogues of genomic abnormalities in tumours from 50 different cancer types and/or subtypes which are of clinical and societal importance across the globe. This data is made available to the entire research community as rapidly as possible, and with minimal restrictions, to accelerate research into the causes and control of cancer. The ICGC facilitates communication among the members and provides a forum for coordination with the objective of maximising efficiency among the scientists working to understand, treat, and prevent these diseases. This is an example of international collaboration advancing genomic knowledge in cancer.

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		13. Does the Strategic Context provide a clear case for improved national consistency in genomics policy? Please explain your answer.	Yes, the strategic context is clear in the need to translate genomic knowledge into health care. However, perhaps implied, the Framework could present greater support for ongoing research investigation to discover health benefits from genomic testing. Australia requires a system that generates continued interest in the use of genomics to solve hard issues especially in rare and less common cancers, and the application of this knowledge to the development of effective treatments and risk management strategies. Beyond research discovery and direct translation into medical services, the strategy also requires a population approach to education, with the ability for information to be tailored depending on an individual's risk of disease.
An Australian Perspective	Pg. 13-14	14. Are there additional barriers, issues or challenges to integrating genomics into the health system that should be included in this section? If yes, please provide details.	Australia does not currently have the capacity or capability to fully integrate genomics into clinical practice. The gap between the supply of available workforce and demand on clinical genomic specialists is widening. The 'Australian Perspective' section fails to recognise psychological and genetic

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			support which a patient and their family need after receiving genetic/genomic test results. It also does not acknowledge the increased pressure this will have on the currently limited genetic counselling workforce. Currently, major genomic facilities supporting cancer research discovery and translation into practice, and service delivery in Australia are based in New South Wales and Victoria. These institutions include: - Garvan Institute for Medical Research (New South Wales) - Kinghorn Cancer Centre (New South Wales) - Australian Genome Research Facility (Victoria) - Centre for Cancer Genomic Medicine (Victoria) Challenges to be explored include: - Insurance coverage: • Testing expenses outside of Commonwealth billing arrangements • Implications for eligibility and coverage of insurance based on presence of genetic marker indicating a predisposition to disease.

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			- Person-centred: • Genomic testing cannot be conducted in isolation, and must incorporate pre and post testing genetic counselling as part of the decision making process. The referring oncology specialist must ensure options can be explored based on whether the test identifies a genomic marker or not. • Integration of supportive care and genetic counselling, as standard referral pathway practice. • Tailored information regarding the outcome of testing and what that means for an individual's health. - Appropriate access to genetic testing: • Require new multidisciplinary models of care which recognise interaction between clinical, genetic and allied health sectors as one continuous pathway. • Address equitable access to genomic services for populations vulnerable to under-servicing and under-utilisation of genomic services including our culturally diverse population and rural and remote Australians.

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			- Require a health system and clinical workforce which is responsive to advances in genomics medicine and technology: • Current Health Technology Assessment process can result in delays to access of genomic testing to identify whether a genomic marker is present which provides eligibility to access the related pharmaceutical product. • Inconsistent reimbursement policies/ subsidy which can impact on equitable access to testing and services. • Level of certainty that the presence of a particular genomic mutation will or will not develop into cancer and/or benefit from the indicated treatment. - Workforce capacity and skill base: • Variable knowledge about genomics and its application in practice across health care professionals. • Uncertainty whether with increased demand genomic information can be analysed and sent back to the referring doctors in a timely way. • Lack of current storage options for individual's genomic information.

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			• Lack of supporting clinical practice and guidance to aid clinicians' decisions to refer for testing, and the communication of the implications to their clients.
A National Health Genomics Policy Framework for the next 3 years	Pg. 15	15. Are the key guiding principles appropriate? Please explain your answer. National; High-level, strategic framework; system focused; person-centred care; evidence-based clinical policy & evidence informed public policy; flexible to keep up with scientific advances and; identify priority areas.	Yes, we agree with the guiding principles and think this is a sensible and logical approach. Ensuring these principles are at the forefront of planning and implementing activities will support equitable and informed access to tests and services based on the genomic information generated. Person-centred care must include the involvement and accessibility of supportive care and psychosocial services throughout a continuous decision making process. There is a large literature base indicating that decision making in this context can be highly stressful, and can raise significant psychosocial issues (such as reintroducing or intensifying bereavement, or causing family conflict when family members differ in their decision-making). There is also strong evidence that effective psychosocial care improves outcomes in this cohort.

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Enablers	Pg. 16-17	16. Are there additional enablers that should be included? If yes, please provide details.	We agree with the enablers, and they address some of the earlier points we raised as barriers and challenges. In addition, policy is an enabler to conducting research through funding mechanisms, clinical trials governance and collaborative infrastructure. Funding mechanisms can use eligibility criteria to ensure the translation of research outcomes. Members of the genomic workforce are critical enablers to advocate for service capacity. They can advise on the required skill set and training of existing or emerging professionals in this field. In addition, a willing oncology health professional workforce is an enabler to the success of the Framework. Cancer is a set of complex diseases and develops through the division of cells. Genomics is playing an increasing part in the identification, detection, diagnosis, treatment and ongoing risk management strategies of individual cancer types. Although not all cancer types currently have an identified predictive genetic factor, the research community will continue to make discoveries that change the management of these conditions. Professional bodies and Colleges must integrate

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			genomic training and opportunities for continuous professional development opportunities for the oncology health professional workforce. Flexible models of care such as the introduction of telehealth and teletrials, and integration of genetics into mainstream oncology will continue to evolve to improve patient access to all aspects of cancer management to facilitate access to optimal care.
Strategic Intent	Pg. 16-17	17. Is the Strategic Intent of the Framework appropriate? If no, what would you suggest?	The strategic intent ensures the Framework remains broad in scope to support flexibility as the use of genomics in healthcare becomes more sophisticated. The strategic intent focuses on translation, rather than developing the research base. A focus on translating research into practice must incorporate clinical management of the condition, but equally the supportive elements of person-centred care. The Framework requires defined objectives to determine its impact over time.
Priorities Areas	Pg. 17	18. Are the priority areas appropriate? Please explain why or why not.	Yes, the priority areas are appropriate and relate to the six priority areas outlined in greater detail in the document. However, the Framework significantly lacks an emphasis on the importance of managing a

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		a) Ethical, social and legal (regulatory) issues b) Strong leadership and governance c) A skilled and literate genomics workforce d) Application of genomic knowledge is evidence based, high quality and safe e) Integration of genomic knowledge into person-centred health care, supported by equity of access to services f) Sustainable investment in health genomics g) Effective and appropriate collection, management and utilisation of genomic data	person's psychosocial care needs. Genetic testing can place significant stress on a person prior to testing and also once the results arereceived. The decision to have a genetic or genomic test must be made based on access to quality information, referral from a clinician and with the involvement of a genetic counsellor[i]. More specifically, the following must be addressed within the priority areas: • Guidance for the use of genomic information in treatment decision making pathways (Cancer Clinical Practice Guidelines and Optimal Care Pathways). • Psychosocial management of supportive care needs for people with or at risk of developing cancer. This extends beyond the episode of care to continuous and long term follow up. • Best practice process for the communication of information prior to referring a client for testing, and once the analysis is received. • Continued collaboration between Commonwealth and State and Territory governments and related policies. • Collaborative data collection and analysis.

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Overarching priority – ethical, social and legal (regulatory) issues	Pg. 18-24	19. Is the placement of ethical, social and legal (regulatory) issues as an overarching priority appropriate?	Ethical, social and legal principles must be integrated into all aspects of the Framework. We support the integration of the principles from the *National Statement on Ethical Conduct in Human Research* to ensure the meaningful involvement of people in research and person-centred clinical care.
		20. Should these issues be considered prior to the six priority areas, or after?	It is appropriate to have 'Ethics, social and legal (regulatory) issues' presented prior to the six priority areas given these principles must be embedded uniquely into each priority area. However, the Framework does not explicitly acknowledge ethical, social and legal issues as part of each priority area.
		21. Are there any other broad ethical, legal or social issues that should be addressed under this priority? If yes, please provide details.	<u>Ethical</u>: Careful consideration of the issues around consent is required. With improvement in technology and genomic understanding, it is likely that conditions that weren't identified at the time of initial testing are discovered. This discovery may have implications for living family members which will require that due care is taken to ensure permission to release this sensitive information posthumously is obtained.

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			The definition given to 'incidental findings' in the Framework should be amended. We recommend changing this to '…which are changes in genes unrelated to specific reason/condition/problem bring investigated.' In Australia there is currently no consensus on how to approach incidental findings. If incidental findings are to be reported, the workforce requires guidance on the consent process and how to discuss the possibility of future discovery with patients. Professional agreement must be sought on the ethical principles for communication and reporting of incidental findings. There is currently a lack of published information and educational materials to support fully informed consent. Potential concern that discrimination based on genetic risk could occur. <u>Legal</u>: Medico-legal issues associated with 'direct to consumer' testing. This is when an individual organises their own test, without referral, and then may present the analysis to a healthcare professional. Direct to consumer testing creates uncertainty around the ability of the person to make

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			an informed decision whether to have the test. It removes the opportunity for genetic counselling prior to a genetic/genomic test and creates uncertain results as the clinician may not have all of the information to judge the test's clinical validity. Genomic literacy in health care practitioners is important as they have a responsibility to communicate a patient's options and respond to any questions or concerns. Improved communication and information tailored to a particular condition and situation to improve confidence in informed decision making is important. <u>Social</u>: Increasingly, the classification, diagnosis and treatment of cancer is based on the molecular composition of the tumour. Improved accuracy of diagnosis and treatment is associated with the presence or absence of a genetic biomarker. The relationship between a particular biomarker and predicting the treatment outcome has seen an increase in positive tumour responses as well as a reduction in toxicity and side effects associated with traditional chemotherapy. Increasingly cancer medicines are also targeting the immune system to

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			manipulate particular protein pathways, such as inhibiting expression, to fight the cancer cells. The use of targeted therapeutic products requires the identification of the corresponding biomarker in order to access the corresponding product registered on the Australian Register for Therapeutic Goods and/or the Pharmaceutical Benefits Scheme. The Medical Services Advisory Committee (MSAC) assess the co-dependent technology required to identify the presence of the biomarker. Therefore, multiple regulatory processes are required in the provision of access to the diagnostic service and treatment. This can impact on the timeliness of access, and also a shift in the assessment of clinical efficacy as trial design and outcomes have a higher level of uncertainty that traditional, large randomised studies. The Medicare Benefits Scheme item descriptors and eligibility criteria must support the optimal and appropriate use of diagnostic services.
Priority Area 1 – Strong leadership and governance	Pg. 25-26	22. With regard to *Priority Area 1 – Strong leadership and governance*, is anything missing or what should change, for:	Achieving strong leadership and governance to support the success of genomic health policy requires a multi-stakeholder advisory structure. This must integrate the interests of all priority areas, and

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		(a) the current situation; (b) why is this important; (c) opportunities for improvement; and/or (d) what the future looks like?	represent jurisdictions and stakeholders involved in health care delivery. Priority areas require individual governance arrangements. National consistency is critical to achieve equal access to services and the appropriate allocation of resources. National leadership, in conjunction with state and territory governments, can address service delivery requirements at each level of the health system. • National billing services and reimbursement models to support service delivery: MSAC reviews applications for the introduction and subsidy of services involved in the identification, diagnosis and ongoing monitoring of cancer. The Pharmaceutical Benefits Advisory Committee (PBAC) assesses applications for government subsidy from sponsors of therapeutic products to make these products available at an affordable price. Increasingly, in the area of cancer treatment, use of a product requires evidence of the presence of a genomic abnormality. This is based on research demonstrating that the probability of a positive

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			health outcome is improved by targeting the genetic abnormality. Unfortunately, as the MSAC and PBAC reviews are two individual regulatory pathways, a delay from MSAC to approve the co-dependent technology will flow on to delay the PBAC's recommendation whether to subsidise the product. Examples of cancer treatments used with the presence of a genomic indicator include: Keytruda is an immune based treatment indicated for the treatment of melanoma for patients who express PD-1 pathway on T cells. Vemurafenib attaches to the BRAF mutation directly which is the most common genetic mutation associated with melanoma. The ability to target genetic mutations or use the immune system to accurately target the treatment of cancer improve outcomes, including reduction of severe side effects and exposure to toxic chemotherapy.

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			• Role of non-Government organisations in disseminating educational information for the community and oncology health professionals: There is increased public awareness about the role of genomics in the risk of developing cancer. This has a flow on effect for the demand of genetic testing services, and importantly increases the need for access to quality information for both the health professional, and the consumer. Disease specific peak bodies and societies have a role in providing and promoting education and information resources to their constituents. Professional groups such as, the Clinical Oncology Society of Australia, have multidisciplinary memberships actively seeking to remain informed, engaged in continuous education opportunities, and share information with their colleagues. • Healthcare professionals are required to maintain registrations with their professional college. The condition of ongoing registration requires members to engage in continuous professional development activities and the use of best

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			practice models of care. Colleges play a critical role in the ongoing training of registered healthcare professionals and the integration of genomics into standards of care.
Priority Area 2 – A skilled and literate genomics workforce	Pg. 27-29	23. With regard to *Priority Area 2 – A skilled and literate genomics workforce*, is anything missing or what should change, for: (a) the current situation; (b) why is this important; (c) opportunities for improvement; and/or (d) what the future looks like?	There are two important categories of 'workforce' which require different approaches to develop skills and knowledge in genomics. 1. Skilled and literate <u>genomic</u> workforce: Includes professionals directly involved in genomic healthcare which are listed within the Framework. 2. <u>Healthcare</u> workforce skilled and literate in use and application of genomic information: Includes all healthcare professionals involved in the care of the community, such as primary care, medical oncology, and allied health services. Integrating genetic services into mainstream oncology requires upskilling of trained oncology health professionals[ii]. Additional resources to aid decision making, referral and communication with clients can assist oncology health professionals to

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			discuss the implications of genomic testing. The integration of genetic services into the oncology multidisciplinary team improves accuracy and communication of test results[iii]. The Framework does not adequately recognise the divide between the anticipated increase in demand for genomic activities and capacity of existing clinical health services. The Framework acknowledges that training is required to create a genetically literate and skilled health workforce, however, feedback from our genetic workforce colleagues indicates that the available positions for genetic counsellors are already less than those who are currently enrolled in genetic counselling courses. Widespread implementation of genomics will require substantial funding and investment into new specialist services and training. In cancer care, access to specialist services and a strong relationship with a primary care physician reduces psychological distress for the consumer. Women with increased familial risk of breast cancer identified that confidence in their general practitioner, availability of tailored information, and access to a familial breast cancer specialist as key

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			components to positively support the process of psychosocial adaptation to familial risk[ivv]. Clinical staff also require the involvement of a genetic counsellor or psychologist to meet the emotional needs of the consumer. 36% of non-genetic specialist medical practitioners who regularly order genetic testing reported difficulty in effectively communicating and managing the emotions associated with genetic testing[vi]. In addition, integrating use of genomic testing into cancer specific clinical practice guidelines and new models of care will support national consistency of cancer care delivery. Medicare Benefit Scheme item numbers can be used to encourage the routine integration of best practice genomic investigation into practice (testing and consultations). <u>Linkages with clinical guidelines:</u> eviQ is a point of care clinical information resource that provides health professionals with current evidence based, peer reviewed, best practice cancer treatment protocols and information. A national network of Cancer Genetic experts came together to provide consensus and evidence-based guidelines for genomic testing and management. The eviQ

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			model should be applied to other sub-disciplines of Genetics. The development of clinical practice guidelines and the endorsement of eviQ guidelines, and the integration of genomics into optimal care pathways, should be essential components to this Framework. <u>Opportunities for improvement:</u> Based on feedback and anecdotal evidence from our professional allies within the cancer genomic workforce, we disagree with the statement 'essentially, the clinical genomics workforce is well funded and has the capacity to manage the growing demand for clinical genomic services.' The system must build more capacity into the delivery of training programs for geneticists and genetic counsellors as more positions are required in these fields. Additional opportunities should be explored such as training nurses and specialists to be more genomic literate through recognised programs.
Priority Area 3 – Application of genomic knowledge is evidence	Pg. 30-31	24. With regard to *Priority Area 3 – Application of genomic knowledge is evidence based, high quality and safe*, is anything missing or what should change, for:	It is the role of the MSAC, to review technologies, and the PBAC to review therapeutic products that align with standards of safety, quality and efficacy. The successful use of targeted therapy is linked to the ability of a companion diagnostic to correctly

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based, high quality and safe		(a) the current situation; (b) why is this important; (c) opportunities for improvement; and/or (d) what the future looks like?	identify patients most likely to benefit from treatment. The proposed products recommended by the PBAC must demonstrate a clinical utility beyond market available products. Genomic knowledge in cancer care must be embedded into disease specific treatment and management pathways in clinical practice guidelines and optimal care pathways. These documents are considered best practice in the delivery of cancer care and guide decision making based on the disease profile and patient circumstances. National cancer screening programs are targeted to people for whom there is evidence that the screening test can find a cancer at a stage when treatment is more effective. Management strategies for ongoing monitoring of progression to disease can be amended based on genomic or familial risk. Amendments to current ethics and governance arrangements would improve the ability for researchers to generate evidence to inform continuous improvements in the delivery of care. Evidence must inform the development of genetic testing guidelines for particular known genetic and genomic markers.

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Priority Area 4 – Integration of genomic knowledge into person-centred health care, supported by equity of access to services	Pg. 32-33	25. With regard to *Priority Area 4 – Integration of genomic knowledge into person-centred health care, supported by equity of access to services*, is anything missing or what should change, for: (a) the current situation; (b) why is this important; (c) opportunities for improvement; and/or (d) what the future looks like?	There is increased awareness of treatment-focused genetic testing in the community. In cancer care, this requires more complex testing, and increases demand for services and particularly panel testing to identify various indications for targeted therapies[vii]. A critical component of patient-centred care, particularly in the use of genomic tests, is the need for access to counselling and support services to assist with coping with a diagnosis, or managing distress and uncertainty. Person-centred cancer care is supported by: - Tailored information based on disease and patient circumstances, including the patient's genomic risk profile[viii]. - Health services that support informed decision making at all stages. This requires a relationship between client and oncology health professional, with the involvement of a genetic counsellor. - As genomic testing is integrated into mainstream oncology services, the development of new approaches to the delivery of information is critical.

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			- Conversations with consumers must involve the disclosure of the cost of testing, implications of potential outcomes such as risk management strategies, treatment options, supportive care options, and where there is a familial risk, the impact on broader family unit. - Development of alternative care models to ensure flexibility and equitable access to best practice services, such as the delivery of telephone based genetic counselling. Embedding genetic services into mainstream oncology facilitates a coordinated approach to patient care, and ensure that's the most up to date information, testing technology and access to clinical trials are incorporated across both specialities. Examples include: • Pre- and post-counselling services, delivered by a trained genetic counsellor, co-located and delivered simultaneously with mainstream oncology care provided by a trained genetic counsellor[ix].

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			• Co-location of genetic services in a large cancer centre also supports integration of genetics into the multidisciplinary team. The genetic counsellor reduces psychosocial morbidity associated with genetic testing by being able to address patient and family concerns, insurance, and uncertainty[x]. Adjusting to a mutation-positive response either associated with or without a family history requires professional and peer support to meet emotional and information needs[xi]. Integrating supportive care in the provision of genomic services is a high priority for our two organisations. Access to specialist counselling must be offered beyond the time of considering whether to be tested and the disclosure of results. For many people there will be ongoing issues related to adjustment, family conflict, decision regret, and the dilemma of whether to disclose this information to other family members. Outcomes of genomic testing can change personal circumstances such as recommendation for high risk screening, surveillance, prophylactic procedures and fertility options, which can be highly distressful.

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Priority Area 5 – Sustainable investment in health genomics	Pg. 34-35	26. With regard to *Priority Area 5 – Sustainable investment in health genomics*, is anything missing or what should change, for: (a) the current situation; (b) why is this important; (c) opportunities for improvement; and/or (d) what the future looks like?	Sustainable access to genomic health services requires commitment from the Commonwealth and all jurisdictions. This partnership must ensure ease of transfer of patient information between health services, reduce duplication of effort and collaboration to efficiently utilise genomic infrastructure and expertise across the country, and conduct health services research to ensure optimal capacity of quality services. The proportion of high cost cancer drugs associated with the targeted treatment of cancer, places pressure on the PBAC to recommend products that demonstrate substantial value and clinical utility. Increased consideration should be given to the development of alternative care delivery models such as the use of e-technologies, and telehealth models. These mechanisms could assist to meet increasing demand for genomic services and address equitable access for underserved populations. However, this does not address the immediate workforce limitations or infrastructure planning required to support the expansion of genomic services.

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Priority Area 6 – Effective and appropriate collection, management and utilisation of genomic data	Pg. 36-38	27. With regard to *Priority Area 6 – Effective and appropriate collection, management and utilisation of genomic data,* is anything missing or what should change, for: (a) the current situation; (b) why is this important; (c) opportunities for improvement; and/or (d) what the future looks like?	Links to research comments under *Priority Area 5 – Sustainable investment in health genomics.* Require national ethics and governance structures to support the application of genomic research in the detection, diagnosis and treatment of cancer. In the rare and less common cancer space, where many of these diseases have genomic links, multicentre, potentially teletrial models, and international collaboration is required to increase certainty of research findings. Utilisation of large data sets will undoubtedly aid future discovery of the benefits of genomics in health. The Framework only considers molecular data. However, importance must be placed on capturing clinical data alongside molecular data to ensure the reported benefits influence practice. Integration of clinical data, phenotyping, sharing of data and match-making ability are crucial to the interpretation of molecular information and improvement in diagnostic rates.
Implementing the Framework	Pg. 39	28. Is the suggested approach to implementing the Framework reasonable and appropriate? Please	We agree that an accompanying Implementation Plan is a critical component to the success of the

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		explain your answer.	Framework however, without further detail we cannot provide any formal endorsement.
Overarching questions (Relates to the entire Framework)	Pg. 39	29. Is the structure of the Framework appropriate and easy to follow? Please explain your answer.	The Framework reads as a scoping document. It presents the current issues, opportunities and based on trends, how the application of genomic knowledge will evolve over time. It outlines the issues and potential solutions without advising how services could apply the Framework in their clinical setting. The Framework would benefit from the development of specific objectives for each priority to guide activities, measurement in practice and outcomes achieved within a set period of time. Content within the Framework does not provide service administrators with adequate guidance on how to embed these priorities into their service. There is general repetition across the document and it would benefit from a restructure to reduce duplication of 'background/setting the scene' information to focus on the objectives and outcomes under each priority area.

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			Overall, the Framework should focus on objectives, and this may require staging timeframes depending on the enablers that need to be in place.
		30. How could the review and evaluation of the Framework be strengthened?	Besides the note that that Framework will be reviewed every three years, there was no detail provided about *how* the Framework would be reviewed and against what objectives it would be evaluated. This is not clear given the lack of objectives, outcomes and targets within the Framework. The Framework requires an implementation plan to guide an assessment of its impact, use and relevance.
		31. Do you have any other feedback on the Framework?	The Framework significantly lacks a focus on psychosocial care. This is critical in the communication of genomic knowledge, and in the decision making process, both pre and post genomic testing. Known genomic markers indicate an increased risk of developing a particular cancer, can accurately diagnosis the condition, or can predict the outcome a related treatment has on disease progression. Once genetic predisposition is established then the oncology health professional and the client can discuss a course of action based on the genomic information and other patient

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			circumstances. Best practice demonstrates that this must involve access to a genetic counsellor[xii]. Counsellors often feel a disconnect between the provision of information (cancer risk, test results, screening recommendations) and the broader counselling role involving issues such as decision-making, coping with the result (and results of other family members), decision regret, and uptake of screening recommendations. Clinical psychologist's express concerns regarding the focus on information provision but limited decision support for people in that situation. Within a genetic counselling session, a counsellor has the professional experience to respond to emotional cues and reduce distress. Educational materials for health professional and ongoing training and professional development opportunities must support the implementation of this Framework. The emphasis of the Framework is on technology as opposed to the implications of increased technological output, particularly how genomics will

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			impact on clinical health services, including supportive care.
		32. Are there any issues you would like covered at the stakeholder consultation forums in February 2017?	Thank you for the invitation to participate in the Sydney forum.
Genomics Framework One Page Outline and the Companion Document		33. Do you have any feedback on the Genomics Framework One Page Outline (noting that it provides a summary of the Framework) or the Companion Document?	The Companion Document provides a good introduction to the topic and intention of the Framework. The One Page Outline provides clarity to the Framework and it would be useful as an annex to the Framework.

[i] C. Jacobs, et al., Key messages for communicating information about *BRCA1* and *BRCA2* to women with breast or ovarian cancer: Consensus across health professionals and service users.
[ii] M. Kentwell, et al., Mainstreaming cancer genetics: A model integrating germline BRCA testing into routine ovarian cancer clinics, Gynecol Oncol (2017).
[iii] M. Kentwell, et al., Mainstreaming cancer genetics: A model integrating germline BRCA testing into routine ovarian cancer clinics, Gynecol Oncol (2017).
[iv] L. Heiniger, et al., Facilitators and challenges in psychosocial adaption to being at increased familial risk of breast cancer, J Genet Counsel (2015) 24:890-907.
[v] E. Steel, et al., How does genetic risk information for Lynch syndrome translate to risk management behaviours? Hereditary Cancer in Clinical Practice (2017) 15:1
[vi] K. Dourma, et al. Non-genetic health professionals' attitude towards knowledge of and skills in discussing and ordering genetic testing for hereditary cancer, Fam. Cancer (2016)15:341-350
[vii] M. Kentwell, et al., Mainstreaming cancer genetics: A model integrating germline BRCA testing into routine ovarian cancer clinics, Gynecol Oncol (2017).
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