



MTP Connect

MedTech and Pharma Growth Centre

Precision Medicine Roundtable White Paper

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Precision Medicine and its potential to deliver personalised care to a patient has the power to be transformative; to bring about significant changes for patients, carers and health professionals. MTPConnect's White Paper canvasses the key issues, connects stakeholders and stimulates discussion around how best to integrate Precision Medicine into the Australian healthcare system.



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Executive Summary

MTPConnect is a not-for-profit organisation aiming to accelerate the rate of growth of the medical technologies, biotechnologies and pharmaceuticals sector to increase commercialisation, collaboration and establish Australia as an Asia-Pacific hub for MTP companies. Part of MTPConnect's role is to anticipate challenges associated with highly innovative healthcare technologies and assist the Australian life sciences industry in addressing these challenges.

The recent Australian Council of Learned Academies (ACOLA) report, "The Future of Precision Medicine in Australia", is just one of many recent publications from Australian academic and research institutions, State and Federal governments and independent companies where the potential of genomics in Precision Medicine in Australia is explored in context of the challenges faced in implementing it to the Australian healthcare system. Australia has a well-established system to provide universal healthcare and the complexity of integrating evolving new technologies into the health system with current regulatory and reimbursement processes will be challenging.

MTPConnect has recognised that in the current discussion around Precision Medicine (beyond genomic technologies), the broader MTP sector has not been fully involved, yet its contribution is pivotal to the evolution and implementation of Precision Medicine in Australia. To address this and foster broad engagement, MTPConnect facilitated a roundtable bringing together stakeholders in the sector to explore the key issues around technology, regulation and reimbursement, commercialisation and implementation. The aim of the roundtable was to extend and feed into the national dialogue across the diverse industry sectors, and to identify key challenges and potential recommendations so that MTPConnect can support the sector in implementing Precision Medicine into the Australian healthcare system and contribute as a sector to the national strategy.

There was clear agreement at the roundtable that a common language for Precision Medicine is required to facilitate dialogue between a broad base of relevant stakeholders including researchers, physicians, policy makers, industry, patients and the general public, for whom this White Paper is intended.

For the purposes of this White Paper we are using the following broad description of Precision Medicine as used in the ACOLA report: *"Precision Medicine has a broad remit, encompassing genomics and other omics (metabolomics, microbiomics, proteomics and transcriptomics), epigenetics (associated with gene-environment interaction), gene editing technologies (such as CRISPR) and the development of targeted therapies specific to an individual's disease profile. Advances in Precision Medicine, and the technologies that support it, are poised to reshape healthcare, invigorate biotechnology and ripple out to fields such as agriculture, environmental science, defence and beyond."*

The opportunities of Precision Medicine were well accepted and there was general acknowledgement that this would range from improving diagnoses and providing more tailored treatments (e.g. medication, devices or gene therapies) to screening programs, and general healthcare improvement.

Discussion centred on the following needs:

- Health System Infrastructure needs to support cross-disciplinary practice of Precision Medicine and provide equitable access to appropriate care for all Australians irrespective of socio-economic and geographical position.
- Broad education of the workforce, as well as the public, to build understanding of the benefits, limitations and risks of Precision Medicine, as well as the ethical, legal and societal impacts.
- Strong and clear Data Governance systems, especially related to data ownership, security, privacy, and consent.
- Regulatory and reimbursement processes need to be fit for purpose. Given the complexity and pace of evolution of technologies, Precision Medicines will challenge current legislative and regulatory structures. A central issue was the generation of evidence to support regulatory and reimbursement submissions as these would be challenged by changes in clinical trial design, availability of real-world data and increased integration of artificial intelligence and algorithms into analysis and interpretation of data and therefore clinical practice.
- Ensuring Australian practices are harmonised with international practices and maintain Australia's position as an active and valued player in research and innovation from universities, research laboratories and the clinical and medical research industry.

Underpinning the above discussion was:

- The cost of the change needed to include Precision Medicine in current practice
- The challenge of collaborating across different health sectors

This paper collates the insights from the broad and diverse stakeholders in the MTP sector around the potential challenges of integrating Precision Medicine into the Australian healthcare system. These insights can be used to facilitate discussion and change within the sector and nationally. It must be recognised that this change will need to be both physically (infrastructure, collaboration and process) as well as culturally driven, as Precision Medicine speed and complexity and personalised approach to care is significantly different to the current practice. Building public trust will be critical and this will require active community engagement.

Precision Medicine and Emerging Technologies



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The practice of Precision Medicine delivers personalised medical care to a patient. Precision Medicine encompasses the tailoring of diagnostic processes, prevention, treatment and monitoring based on a patient's genetic makeup, environment and lifestyle. The concept of Precision Medicine isn't new; there are many examples of Precision Medical practices integrated into standard clinical practice e.g. blood transfusions are donor matched to reduce the risk of complications. However, the rapid and transformational technological advances, together with the sequencing of the human genome, the expansion of bioinformatics capabilities and the increased data storage capacities, have led to the expansion of medical technologies, providing more precise medical interventions.

The impact of Precision Medicine on health areas will vary as both technology and clinical insight evolves, however, changes will be much more substantive than a shift towards more complex diagnostic testing. Precision Medicine practices will affect every part of medical technology development from basic benchtop research practices, clinical trial design, evidence collation, regulatory and reimbursement requirements and include ethical, legal and societal impacts. The improved capacity for data storage has enabled genome sequencing data to be stored, shared and analysed by international teams, providing insights on a multitude of disease states and biological processes. This, in turn, has influenced research focus, encouraged collaboration and supports ongoing development of tailored treatments and new technologies. Clinical trial design is evolving to respond to patient populations identified and treated by molecular data and not only by traditional signs and symptoms of disease or anatomical sites. Collation of relevant evidence to support the safety and efficacy assessment of new technologies and interventions is complex due to the rapid technological advances, comparative nature of analysis and clinical analytical skill needed to interpret the data. Internationally, regulatory and reimbursement authorities are grappling with the complex task of adapting assessment processes to ensure patients get access to new safe and effective medical advances in a timely way. Even though the medical, technology and pharmaceutical industries and healthcare professionals work within a strong ethical and legal structure there is a need for ongoing revision and review of this in light of new technologies such as gene therapies.

In Australia, a review of the "National Health Act 1953" has been proposed in response to the evolving nature of healthcare. The collation of data to provide clinical insights will play a key part in the success of Precision Medicine due to the need to compare data to determine genetic drivers and variances. Therefore, patients will have personal health information collected and shared, often internationally. As seen in the recent "My Health Record" debate, as Precision Medicine becomes more mainstream this may raise considerable concerns for patients, healthcare practitioners and the health system. The societal impact of Precision Medicine should not be underestimated.

As outlined above, healthcare policy and practice will need to respond and adapt to the changing technologies, methodologies and evidentiary needs, and this will challenge Australia's current approach to delivery of universal care. A recent example of this was the Therapeutic Goods Administration's "Proposal for regulation of IVD (in vitro diagnostics) Companion Diagnostics" requesting industry comment on the legal definition of a companion diagnostics and insights on an appropriate regulatory approach. A key part of this consultation is to ensure that new processes and procedures are harmonised with international regulatory authorities such as Food and Drug Administration and European Union.

Precision Medicine will bring about significant changes to how and when healthcare is delivered. This will bring change for patients, carers and health professionals and challenges for the infrastructure supporting the healthcare system. It is timely that MTPConnect engages with a broad and diverse range of stakeholders to identify key challenges and potential recommendations so that it can support the sector in implementing Precision Medicine into Australian the healthcare system and contribute as a sector to the national dialogue.

Regulatory and Reimbursement Challenges

Despite the rapid evolution of Precision Medicine technologies and significant efforts to bring these into clinical practice, limited progress has been made delivering Precision Medicine to the market to date, with success achieved mostly in the oncology field.

Regulators and payers need robust evidence that Precision Medicine delivers improved patient outcomes compared to the intervention they are replacing or supporting, through comparison of existing evidence and new generated

evidence to support evidence-based decision-making. Based on the context of the technology, demonstrating Clinical Utility is complex and includes establishing analytical and clinical validity first. Figure 1 provides an overview of these concepts (perhaps more clearly applicable to genetic tests than genomic tests). One challenge is that specificity and sensitivity both for analytical and clinical validity varies based on the context of the test (disorder and setting). This makes it a complex environment for regulators and payers to navigate. In addition, ethnic diversity must also be considered in the Australian context.

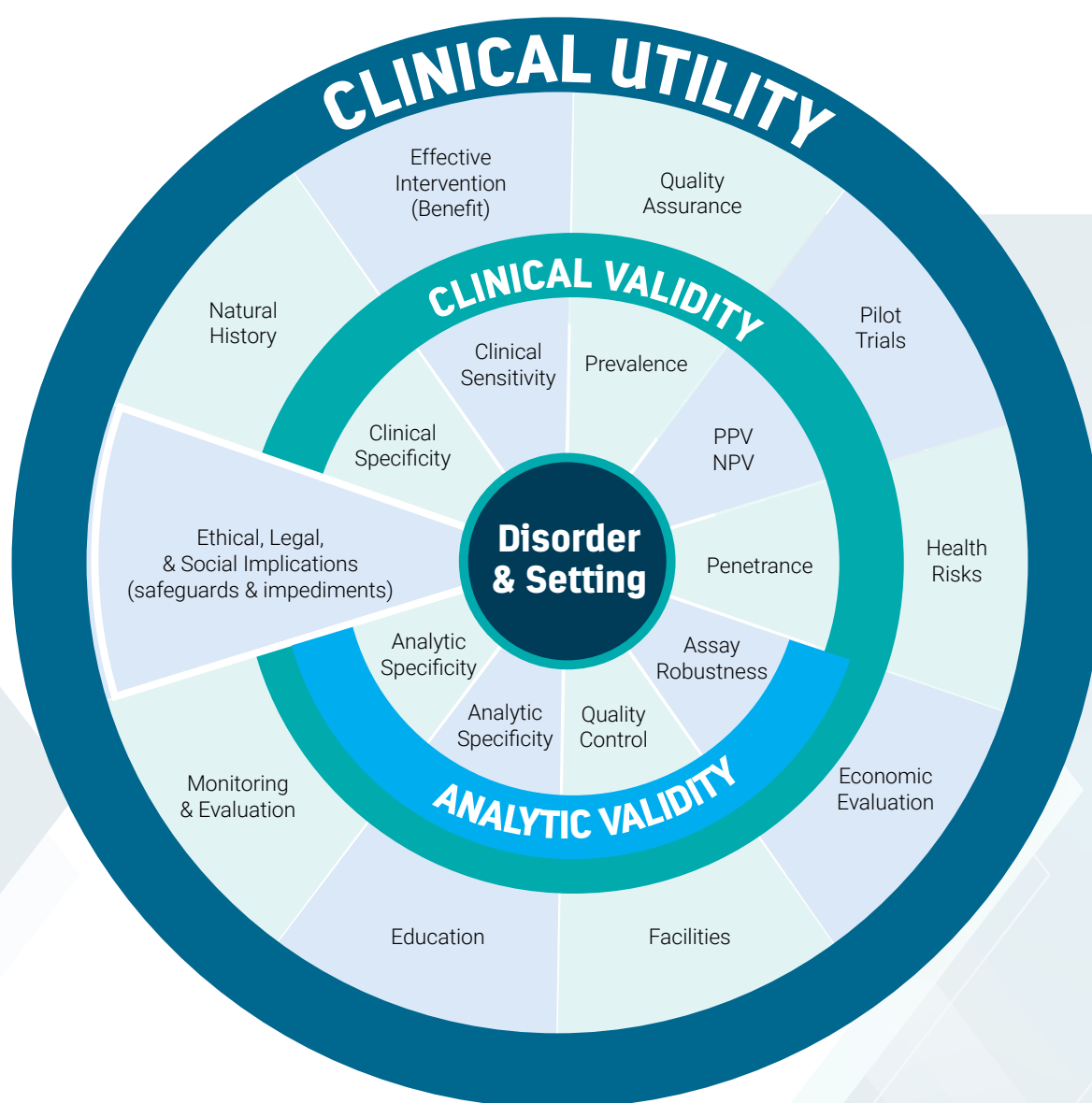


Figure 1 Context Based Clinical Utility Framework

(Modified from: Dr Lyon, President, Association of Molecular Pathology (USA), ISCC Educational Series)

In addition, the technology will be implemented within a healthcare system, where multiple factors impact on the provision of care variation from initial decision to test through to the interpretation of the test results. A key issue

here is the multitude of clinical, algorithm based and non-clinical data that will be available and that will need to be assessed and its relevance determined. See Figure 2.

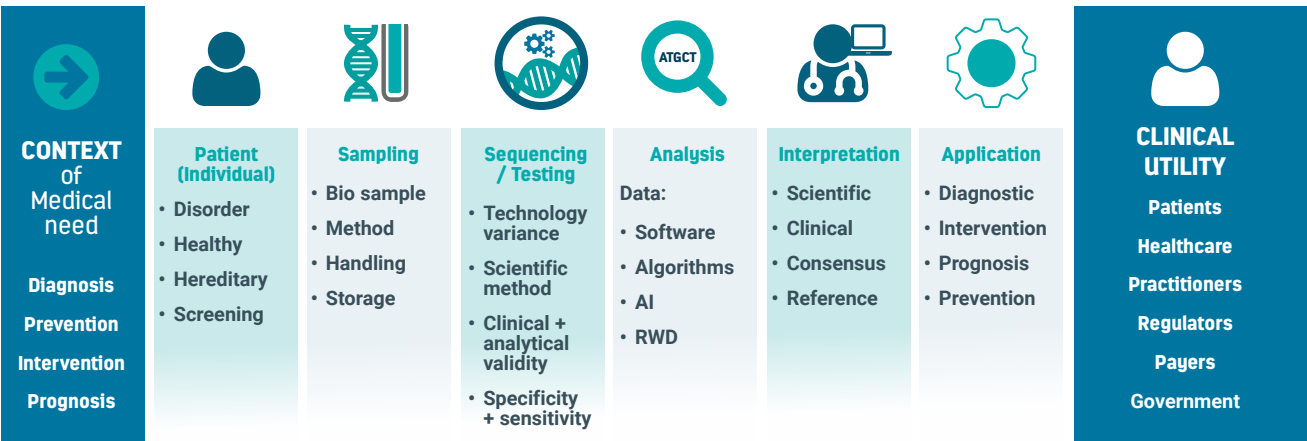
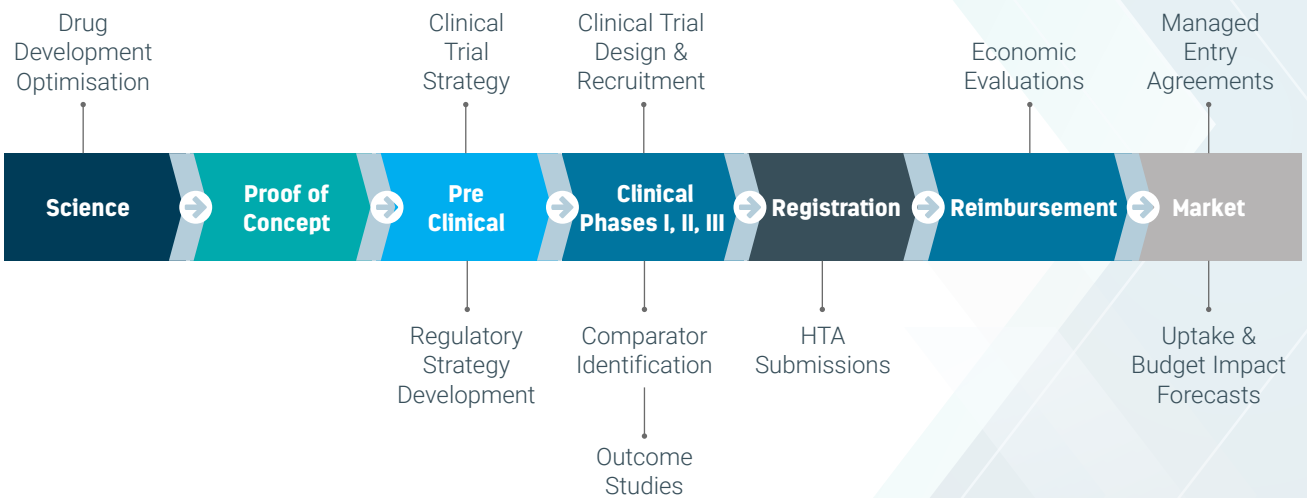


Figure 2 Practice of Precision Medicine

Whilst Precision Medicine undoubtedly has big therapeutic and economic potential, significant scientific and non-scientific 'barriers' in delivering Precision Medicine still remain. These are all underpinned by regulatory uncertainties mostly related to the lack of clarity of requirements and standards across these varied and rapidly evolving technologies.

Commercialisation and Overcoming the Barriers

A typical development pathway of a medicine is long and complex (Figure 3). Given its nature, a Precision Medicine approach may impact all these development segments, consequently requiring adjustment of the development pathway to meet the needs of an individual patient or patient subpopulations.



On the other hand, diagnostic tests and medical devices are also at the core of Precision Medicine, and the development pathway of such products is different and will vary on a global basis. Navigating all these diverse development pathways in the context of Precision Medicine will certainly represent a challenge in the future.

For example, the challenge of commercialisation of diagnostics is reflected in the evolution from the 'research only' market, to the more mature commercial LDTs (Lab-developed tests) with only a small number of fully-fledged IVD (in-vitro diagnostic) kits.

In addition to standardisation and regulatory control of these different segments, there is the challenge of ensuring clinical relevance and utility, potentially tying biology with patient electronic health records and databases.

The need to keep current with international practices and maintain Australia's position as an active and valued player in the medical technology industries and contribute to research and innovation in collaboration with universities, research laboratories, and through clinical and medical research is paramount.

Implementation of Precision Medicine in Practice

The new advances in Precision Medicine will change the way medicine is practiced and implemented, and this raises a variety of concerns not only from the patients, but also from healthcare providers and policy makers perspectives (Figure 2).

Some of the principles that should be considered in order to integrate Precision Medicine into healthcare practice include:

- A better understanding of Precision Medicine concepts and technologies throughout the whole Precision Medicine ecosystem (healthcare providers, payers, employers, policymakers, as well as patients and their families);
- Development of appropriate policies and practices for patient engagement, data governance, including privacy, data safety and other data related ethical, legal and societal issues;
- Development of best practice for collection and dissemination of evidence used to demonstrate Precision Medicine clinical utility; development of best practices for healthcare delivery approaches, ensuring appropriate access to Precision Medicine.

Australian Precision Medicine Sector and Future Opportunities

Genomic testing is currently the most advanced area of Precision Medicine in Australia, with multiple institutions providing their genomic sequencing capabilities as a service to patients. Furthermore, there has also been an increased number of government-supported clinical services and clinical trials developing new Precision Medicine therapies in the space of genomics. Other Precision Medicine areas, such as omic biomarkers and gene editing technologies are currently mostly laboratory-based, in development phase.

The National Health Genomic Policy Framework was established in 2017, to ensure successful integration of genomics into the Australian healthcare system. The key strategic areas for action were:

- "Supporting a person-centred approach;
- Building the workforce;
- Ensuring sustainable and strategic investment;
- And ensuring safety and quality and responsible collection, storage, use and management of genomic data."

As an important reference for implementing the GHFM, the Australian Government announced in its May 2018 budget the establishment of the Genomics Health Futures Mission (GHFM), a 10-year, \$500 million investment in genomics research.

Existing facilities in Australia providing gene sequencing and other genomic services include:

1. The Australian Genome Research Facility (established in 1997 by government in partnership with the University of Queensland and the Walter and Eliza Hall Institute; operating across five Australian states, with most capacity based in Melbourne)
2. The Kinghorn Centre for Clinical Genomics (established in 2012 at the Garvan Institute of Medical Research, with primary focus on genome sequencing)
3. The Ramaciotti Centre for Genomics (established in 2009 at the University of New South Wales, as a consortium of universities)
4. Victorian Clinical Genetics Services (VCGS) (subsidiary of Murdoch Children's Research Institute, provides a fully integrated 'end-to-end' clinical genomics services)
5. Other facilities offering whole genome clinical sequencing service: SA Pathology, PathWest; QIMR Berghofer Medical Research Institute

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This list is not exhaustive. It is also noted that there are both clinical grade and research grade sequencing capabilities and facilities (the former being accredited by the National Association of Testing Authorities).

Additional Stakeholders in the space of Precision Medicine include:

- The Royal College of Pathologists of Australasia (RCPA) which provides a variety of services relevant to Precision Medicine, including developing standards and guidelines for Precision Medicine testing
- The National Measurement Institute which is undertaking several projects related to Precision Medicine (e.g. developing internationally comparable measure of DNA methylation in cancer diagnosis)
- Recently, various initiatives (not exhaustive) have been established to support genomic testing in Australia (Table 1).

Initiative	Description
The Australian Genomics Health Alliance	<ul style="list-style-type: none">• Established in 2014 as a national network of clinicians, pathologists and researchers dedicated to translating genomic approaches into clinical practice• Integrates expertise of various stakeholders: CSIRO, Australian Genome Research Facility, National Computational Infrastructure and state government funded genomics programs.• 78 partner organisations, 30 clinical sites• Four focus areas: national diagnostic and research network; federated data infrastructure; regulatory, economic policy and examination of the barriers to implementation; and education, ethics and workforce
Melbourne Genomics Health Alliance	<ul style="list-style-type: none">• Established in 2013 as a collaboration of ten healthcare and research organisations in Victoria, with a goal to use genomics to improve individual care• Focus on 11 disease conditions, including immune system disorders, genetic heart conditions, neurodegenerative disease and certain cancers
Sydney Genomics Collaborative	<ul style="list-style-type: none">• Established in 2014 at the Garvan Institute of Medical Research in partnership with NSW government• Goal: implementing genomics research into diseases with a genetic component, including cancers• Programs: The Medical Genome Reference Bank (sequencing in health elderly individuals); The NSW Genomics Collaborative Grants program (genome sequencing in melanoma, heart disease and schizophrenia); The Genomic Cancer Medicine Program (genomics in cancer)
Queensland Genomics Health Alliance	<ul style="list-style-type: none">• Established in 2016 with funding from Queensland Government• 4 Clinical Demonstration projects have commenced in lung cancer, melanoma, mature onset diabetes in the young and infectious disease.
CSIRO initiatives	<ul style="list-style-type: none">• e-Health Research Centre (AEHRC) includes high-throughput genomic data analysis and genome engineering• AEHRC is part of CSIRO's Health and Biosecurity Unit• Data61 – research in data management, cybersecurity, artificial intelligence etc.

MTPConnect Roundtable:

Precision Medicine



The MTPConnect Roundtable on Precision Medicine was held on the 23 August 2018 during the ARCS Conference in Sydney, with the aim to:

- Bring together approximately 30 key representative stakeholders from across Australia's MedTech Biotechnology and Pharmaceutical (MTP) sector, including government, regulators, industry organisations, industry, academia and clinicians to discuss opportunities and challenges for precision medicine in Australia; and
- Contribute to the national dialogue and understanding concerning Precision Medicine in Australia for the MedTech Biotechnology and Pharmaceutical (MTP) sector.

For a list of workshop participants representing key stakeholders, see [Appendix 2](#). Participants were divided into three diverse groups and were asked to focus on four key topics in four separate sessions to identify challenges and recommendations emerging from the discussions. Four key discussion topics were as follows:

- 1. Technology**
- 2. Regulation/reimbursement**
- 3. Commercialisation**
- 4. Implementation**

Participants were asked to address a series of questions for each of the four topics, to focus their contributions and subsequent discussion. These questions are listed in the initial section for each topic.

Roundtable: Context of discussion

To facilitate meaningful discussion, the following three categories of Precision Medicine tools that will be used in clinical practice within the next 5 years was presented. Given the diversity of the participants as well as breadth of experience with Precision Medicine, these examples were used amongst the table to stimulate discussion (Figure 4):

1. 'Omics' – based biomarkers

'Omics' technologies are high throughput techniques that generate large amount of data for a particular molecule (e.g. DNA, proteins, metabolites), identifying relevant biomarkers in individuals with a specific medical condition. These can be classified into: diagnostic, prognostic, predictive and predisposition biomarkers (e.g. HER2 protein test predicts response to breast cancer treatment; BRCA1 gene tests indicates risk of breast and ovarian cancer). A general advantage of 'omic' technologies is that they can be specific to time and tissue.

2. Complex artificial intelligence (AI) – based algorithms

AI-based algorithms use genetic information, electronic health records and sociodemographic data to predict prognosis and optimal treatment choices for individual patient (e.g. Sapientia – complex algorithm which informs treatment decision; or QRISK – risk prediction algorithm).

3. Digital health applications

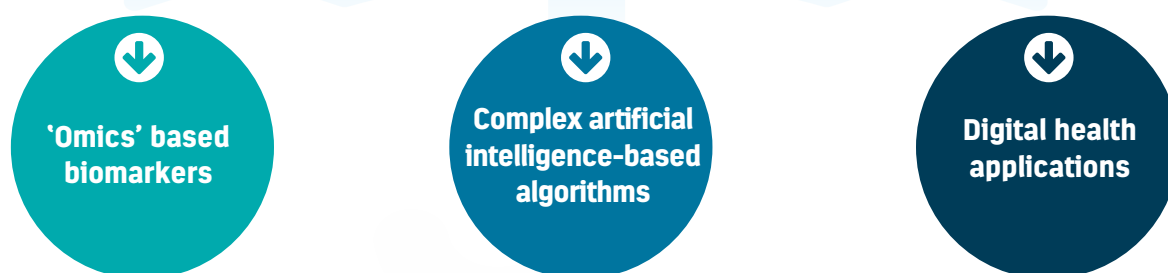
Health applications record and process patient data, including physical activity and physiological data to aid disease management (e.g. MyHeart Counts).

In addition to these three areas, therapeutic interventions via gene therapies are emerging from research into experimental practice. In general, these can be described as:

- Replacing a mutated gene that causes disease with a healthy copy of the gene.
- Inactivating, or "knocking out," a mutated gene that is functioning improperly.
- Introducing a new gene into the body to help fight a disease.

Experimental therapies are being trialled in such diverse areas as haemophilia, various retinal-related causes of blindness and sickle cell anaemia. However, significant ethical, social and legal dimensions exist in these areas and need to be considered.

Three types of precision medicine tools are likely to become more widespread in clinical practice over the next decade:



EXAMPLES		
Tests for prognostic biomarkers e.g. indicate risk of disease progression after prostate cancer diagnosis	Diagnostic services e.g. genetic, genomic and molecular testing services	Test for disease susceptibility markers e.g. BRCA 1 gene indicates risk of breast and ovarian cancer
Gene Therapies	Complex algorithms e.g. Sapientia – combines genomic sequencing with clinical phenotyping to inform treatment decisions	Risk prediction tools e.g. QRISK - static algorithm that determines risk for cardiovascular disease
Tests for predictive biomarkers e.g. HER2 protein test predicts response to breast cancer treatment	Digital health applications e.g. My Heart Counts – records and analyses data on activity, risk factors "and haematology	Patient decision aids e.g. MAGIC – produces dynamic decision aids that update based on published guidelines

Figure 4 Precision Medicine 'Umbrella' – Modified from Love-Koh et al (2018) (Courtesy of Biointelect)

While the rapid development of these tools will evidently deliver more precise and better tailored treatment pathways, it will also present with new challenges in the analysis and validation of the evidence and decision making. Therefore, guidelines and treatment algorithms, as well as the health-

technology assessment and decision-making processes will need be adjusted to robustly and successfully implement these innovative technologies into the healthcare systems.

Roundtable: Discussion

The questions stimulated vigorous discussion of the issues and opportunities associated with the four key topics. The key points from the discussions are reported in the following pages along with recommendations on addressing these issues and opportunities. By its nature, a Roundtable discussion has limitations on the depth and detail that is possible. However, it identified a substantial body of work that will be required to optimise the opportunities for and benefits from Precision Medicine in Australia. While the four key areas provided a useful structure to the discussion, it is clear there is considerable overlap across the topics. In addition, the breadth of technologies and tools under the umbrella term of Precision Medicine provides an additional challenge to optimising this area. For all these reasons, this White Paper should be seen as an important addition to the dialogue that has begun in Australia on Precision Medicine, while recognising that this dialogue will be a lengthy journey with much to be resolved over time.

To further assist in bringing clarity to a complex topic, the following pages utilise graphical representations of the key topic areas. These representations also serve to highlight the overlap and interconnectedness of the issues and opportunities. Each graphic is accompanied by a brief description to assist in understanding how it contributes to the dialogue.

Topic 1 and 4 have been combined due to the extensive cross- over of the topics.

Colour coding was used in the graphics for ease of reference to discussion points/recommendations in the tables provided in Appendix 1 (e.g. grey colour links ‘common language’ as a raised challenge in Figure 5 to specifically noted barriers and recommendations for ‘common language’ in Topic 1 and 4: Technology/ Implementation in Appendix 1).

Topic 1 and 4: Technologies/Implementation

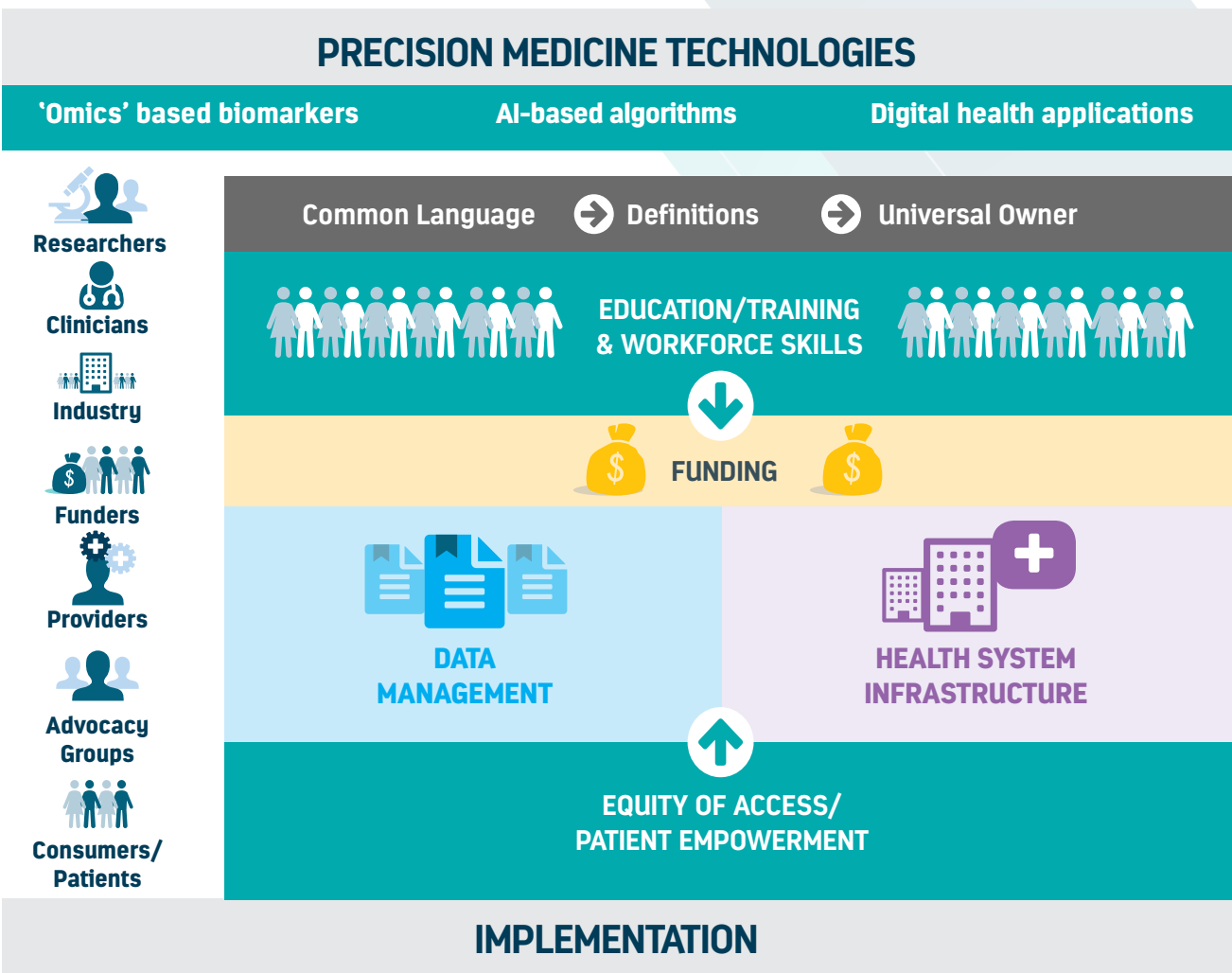


Figure 5 Technologies and Implementation: Summary of Discussion

During the discussion of these two topic areas (technologies and implementation) it became apparent that there is a great deal of commonality to the issues associated with both areas. The breadth of the tools under the overall umbrella of Precision Medicine means that a common language and set of terminology is necessary and this in turn is essential to the education, training and workforce capabilities required. This breadth of tools also brings further challenges to the data management (capture, analysis and access) required, along with the implications for health system infrastructure requirements that will be essential for optimal application of these tools.

Conversely, to achieve optimal implementation of these tools, patient engagement will be essential, especially to achieve equity of access to potentially complex applications. Achieving that will in turn require clarity around data (collection, privacy and security) and health system infrastructure (how to access the required tools), plus appropriate and timely education of both the public and specific patient populations.

The different funding models that apply in primary care and secondary/tertiary care also represent a challenge to optimal implementation. Similarly, there will need to be a consideration of the which tests might be offered in the public sector versus those that the private sector might chose to make available.

Topic 2: Regulation and Reimbursement

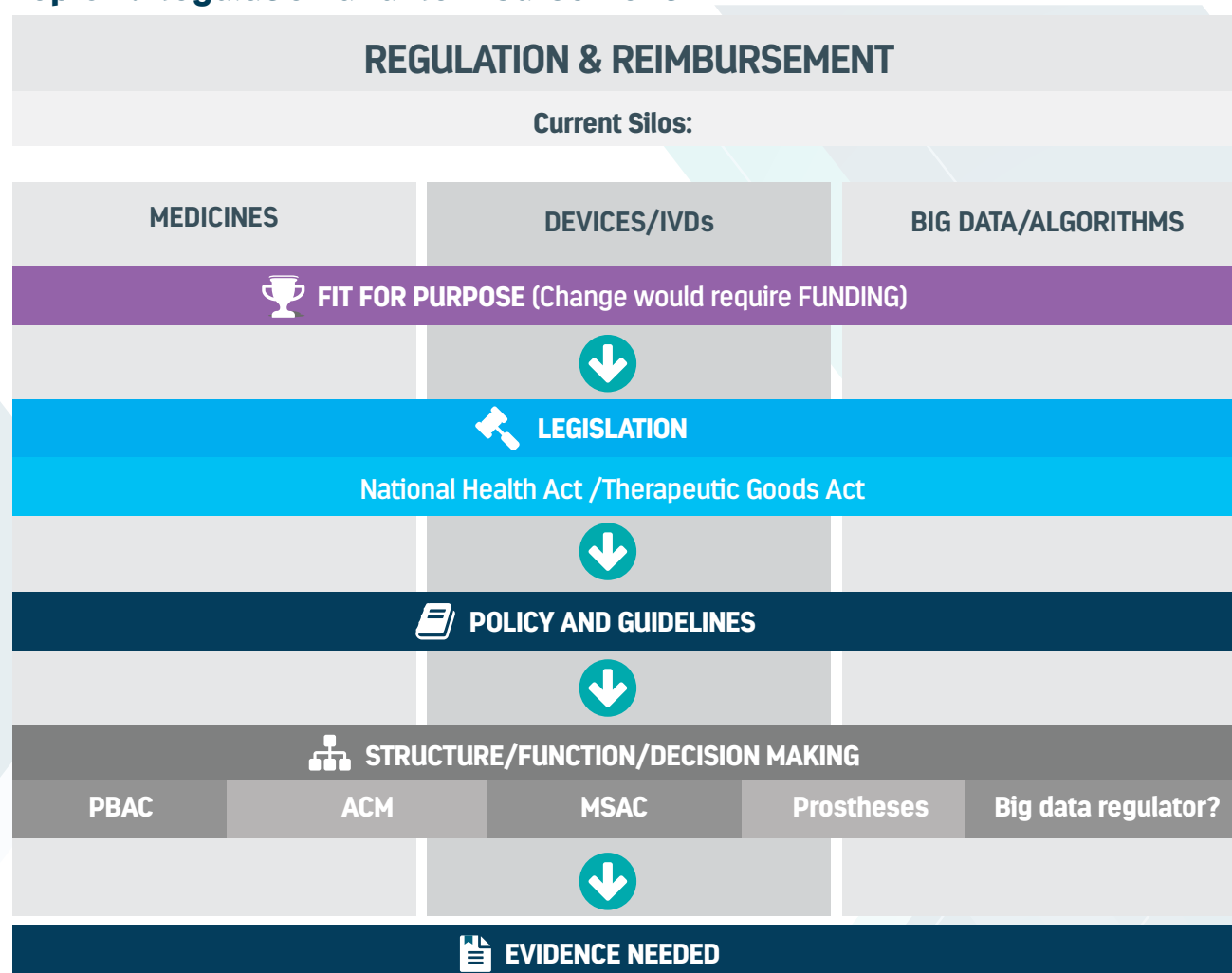


Figure 6 Regulation & Reimbursement: Summary of Discussion

A key issue to resolve is the safety and regulation of tests offered directly to the consumer. The Roundtable acknowledged that regulation and reimbursement are separate but closely connected processes. Both have legislative underpinnings that were established prior to Precision Medicine becoming a reality, leading to lack of specificity that would assist the subsequent development of policies and guidelines for Precision Medicine technology and tools. For example, there is no definition of companion diagnostics in legislation governing regulation of health technologies in Australia. Similarly, in the health technology

assessment and reimbursement area, while efforts have been made to align aspects of these processes across medicines and diagnostics, Roundtable participants reported that this was still suboptimal. Challenges to health technology assessment include the evaluation of tests that have the potential for self-improvement (as more clinical data is collected). When newer Precision Medicine technologies and tools are added into the mix (e.g. CRISPR, gene therapies, medicine / device combinations and AI algorithms) the need for better aligned and connected processes becomes very apparent.

Topic 3: Commercialisation

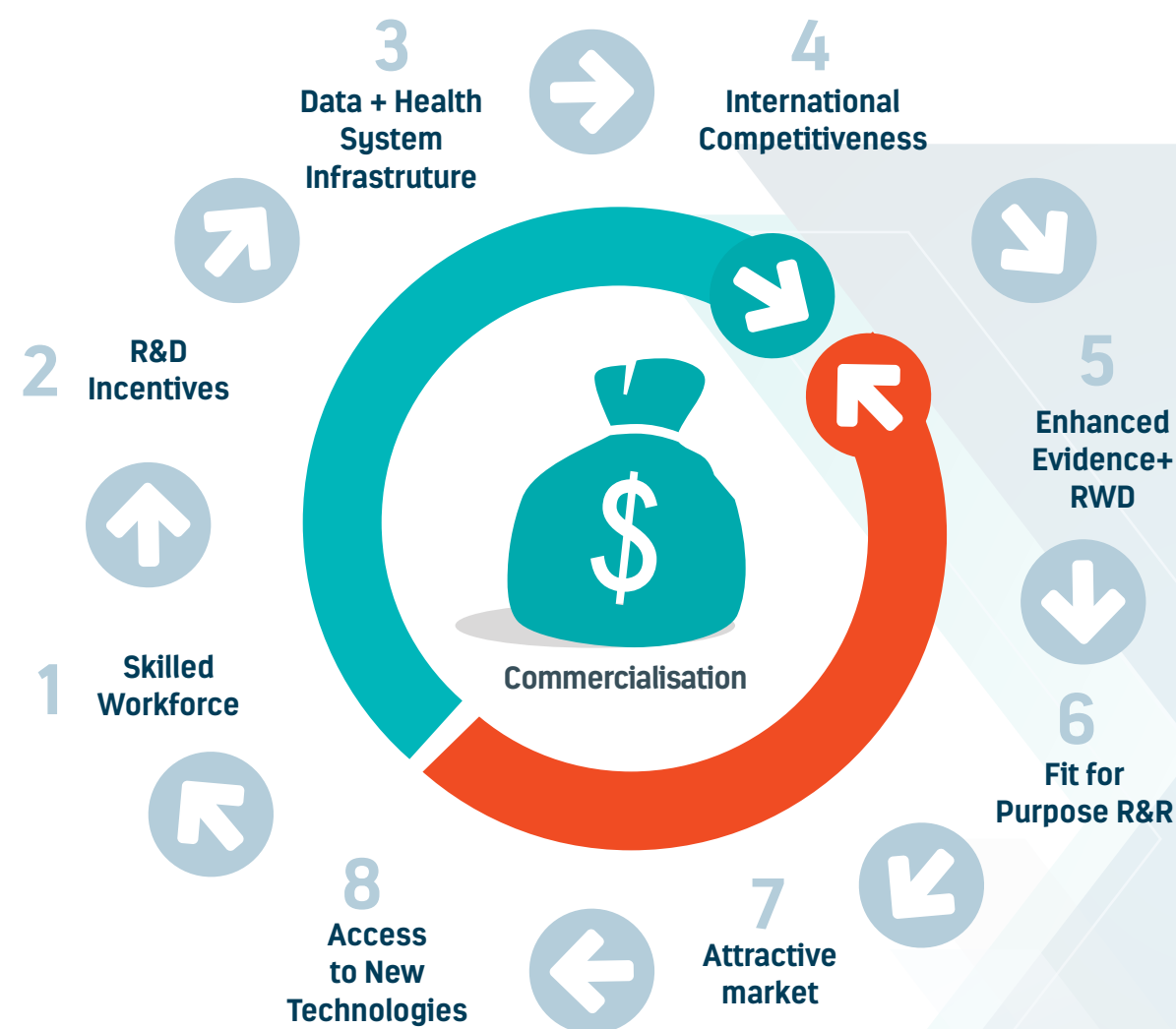


Figure 7 Commercialisation: Summary of Discussion

The discussion on commercialisation highlighted the interplay between multiple factors, all of which need to be aligned if Australia is to succeed as developer and manufacturer of innovative tools and technologies related to Precision Medicine. This overall concept of a 'virtuous cycle' is not new in the overall area of health technology development. However, this is accentuated in this case by the breadth of tools under the broader umbrella of Precision Medicine, the new workforce skills and capabilities required and the importance of health system infrastructure and regulatory/reimbursement clarity. While funding to expand the national dialogue and bring about change is common to all the four topic areas, it is essential here to instil confidence that Australia is serious about achieving a Precision Medicine ecosystem that serves both Australian patients and the health technology development sector.

Roundtable: Conclusion

- There was clear agreement at the Roundtable that a **common language** for Precision Medicine is required to facilitate dialogue and that a **broad base of stakeholders** need to be included in the dialogue - this includes patients as well as the public.

The opportunities of Precision Medicine were well accepted and there was general acknowledgement that this would range from improving diagnoses and providing more tailored treatments (e.g. medication, devices or gene therapies) to screening programs, and general healthcare improvement.

Discussion centred on the following needs:

- **Health System Infrastructure** needs to support cross-disciplinary practice of Precision Medicine and provide equitable access to appropriate care for all Australians irrespective of socio-economic and geographical position.
- Need for **broad education** of the workforce, as well as the public, to build understanding of the benefits, limitations and risks of Precision Medicine as well as the ethical, legal and societal impacts.
- Strong and clear **Data Governance** systems especially related to data ownership, security, privacy, and consent.
- **Regulatory and reimbursement process** needs to be fit for purpose. Given the complexity and pace of evolution of technologies, Precision Medicines will challenge current legislative and regulatory structures. A central issue was the generation of evidence to support regulatory and reimbursement submissions – as these would be challenged by changes in clinical trial design, the availability of real-world data and increased integration of artificial intelligence and algorithms into analysis and interpretation of data and therefore clinical practice.
- The importance of disinvesting in technologies that are replaced by precision medicine, otherwise the claimed efficiencies/benefits will not be realised.
- The need to keep current with international practices and maintain Australia's position as an active and valued player in the medical technology industries and contribute to research and innovation in collaboration with universities, research laboratories, and through clinical and medical research is paramount.

Underpinning the above discussion was the cost of the change needed to include Precision Medicine in current practice and the challenge of working across different health sectors. It is relevant to note that although the ACOLA report on "The Future of Precision Medicine in Australia" was released in 2018, and there are National and State Frameworks for Precision Medicine, there had not been not wide spread review or engagement of these by all stakeholders. This highlights the difficulty in building engagement across sectors.

¹ Governance encompasses the system by which an organisation is controlled and operates, and the mechanisms by which it, and its people, are held to account. Ethics, risk management, compliance and administration are all elements of governance. (Governance Institute of Australia)

MTPConnect: Future commitment to the sector



It is recognised that although the participants at the Roundtable were diverse, there were still key stakeholders who were not able to participate in the discussions due to conflicting events. Efforts have been made to collect and incorporate additional inputs from stakeholders unable to attend the Roundtable. MTPConnect would like to ensure all stakeholders contribute to future dialogue and any additional comments or insights will be welcomed.

Discussions were robust and along with the diversity of background of participants, it was clear that there is a broad range of knowledge and insight into Precision Medicine and the future opportunities and challenges. A common language and broad education across all disciplines of research and development, government and regulatory bodies, and industry is critical to ensure that all can contribute to the implementation of Precision Medicine into the Australian healthcare system. There are significant opportunities that Precision Medicine brings to Australia, not only to improve health outcomes for all Australian, but in building a stronger and more diverse industry that can contribute internationally.

Appendix 1 Roundtable: Questions and collated responses

The questions and collated responses are summarised below. Topic 1 and 4 have been combined due to the extensive cross-over of the topics. Responses have been collated into two columns:

- Challenges raised in the discussion
- Recommendations

The colour coding used in tables relates to the graphics for ease of reference.

Topic 1 and 4: Technology/Implementation

Refer to [Figure 5 Technologies and Implementation: Summary of Discussion](#)



Key questions for discussion - Technology

- What are the implications of this breadth of technology/tools that fall under the umbrella of Precision Medicine (PM)?
- To what extent are various stakeholders operating in siloed approaches rather than addressing/considering the breadth? How can we bridge these silos?
- To what extent are the issues and barriers for the health technology development sector specific to the various specific technology types, or are they broad across the spectrum? Or both?
- Is there a need for more emphasis on a classification/language that would help all stakeholders position the various types of technologies on this spectrum? Should we adopt NIH or genomics England resources/terminology?
- Which of these types of technologies are likely to dominate Precision Medicine in the next 5, 10, 20 years? What are the implications for stakeholders?



Key questions for discussion - Implementation

Education and awareness

- Are we all on the same page regarding terminology and language?
- Is health literacy adequate across all groups?
- Is medical education keeping up with the field?

Patient empowerment

- Are patient consent policies and practices clear and appropriate?
- What are the privacy and security concerns?

Value recognition

- Are evidentiary requirements for reimbursement clear for all types of PM?
- Are diagnostic payments value or process-based?

Infrastructure and information management

- Are policies and procedures related to data collection, analysis and access clear and aligned across the health system?
- Are information technology systems appropriate to cope with the increasing amount of personalised data?
- Is molecular information able to be translated into evidence to support clinical care?

Ensuring access to care

- Is reimbursement of diagnostic tests appropriate and is it facilitating access to improved care?
- Are payment processes and amounts a disincentive to clinicians to practice more personalised medicine?
- How well do clinical guidelines and pathways reflect and incorporate appropriate personalised medicine tools and strategies?



Challenges raised in the discussion

Education around the common language

Discussion around the common language was followed by discussion on the appropriate stakeholder education around the common language in PM.

It can't be assumed all stakeholders understand precision medicine (e.g. it can often be confused with personalised medicine, although there is overlap between the two) and so there should be upfront investment in stakeholder education.

Training & workforce skills

- Furthermore, it was noted that new technologies that incorporate both therapeutic and diagnostic modalities (a device + drug) in a closed-loop feedback are being developed. These developments demonstrate the extremely dynamic nature of the PM field. Therefore, participants emphasized that current workforce knowledge and skills are not well developed and appropriate to manage these new PM technologies.
- All stakeholders, including industry should be involved in the training of the workforce; The rate of change in PM field is getting faster and faster – how do you educate when material quickly becomes dated – industry needs to work together with academia on this closely.

Patient empowerment/awareness

- At was also stated that broad public (including patients and consumers) is not appropriate educated, informed nor engaged.
- 'Patients need to be able to formulate questions before asking'.
- Additional questions: Should government be involved in educating broad public?
- Currently there is no peak body in charge of owning the information and terminology to educate broad public.



Recommendations

- **Stakeholder education should start with basic definitions and agreed language/terms, ideally consistent across the globe**
- **Patient/consumers need to be also involved: terminology and definitions should also be granted to the broader public, not only to researchers, clinicians, payers and providers**
- **Training of the workforce to develop knowledge and skills appropriate for new technologies should involve all stakeholders**
- **Industry and non-industry sector should closely work to achieve most comprehensive training, given that PM field is evolving fast**
- **Identify international models or examples; start with pilot projects and engage non-industry and industry sector**
- **Education (both professional development & public education) is the only way to help mitigate unintended consequences. The baseline level of education amongst the general public must be raised, and academics/experts should conduct 'out-reach' programs to help inform relevant parties**
- **Consumers will likely drive trends in PM, therefore, sophisticated consumer engagement strategies will need to be deployed. Education will also be a key component in driving PM implementation via consumer engagement**
- **There is a potential role of government to identify body to own all the information; define the ways to implement and cascade that down**



Challenges raised in the discussion

Data management

- Participants have noted that data is currently not properly managed (this is an important barrier, given that 'data is the enabler of patient management')
- Data is siloed and not properly coordinated. Entities need to be better geared to 'talk to one another';
- Public perception of privacy: there is a need of better understanding of privacy - risks vs benefits for individual patient;
- Consent around data collection is not well defined: important to answer questions such as: What data will be collected? What will be the collection and integration process? How is data going to be handled?
- States should have integrated data centres rather than individual entities 'hoarding' data for themselves.
- Access to curated, consistently coded national patient data (from MyHealthRecord and other state and national disease registries) is a pre-requisite to realising many of the potential benefits of targeted, personalised healthcare delivery and improvements in clinical research
- A lot of data/potential tools get trapped in research – focus needs to be more on the outcome of the patient not on research



Recommendations

- **Create a data management system in such way that is well-regulated, anonymous and well organised and ideally linked to international management system;**
- **Use stepwise approach - initially focus on PM areas with short-term utility (e.g. pathology)**
- **The public needs to be educated on the benefits of increased data access for developers. Data security capabilities need to be increased to instil public confidence in data collection/analysis.**
- **The use of artificial intelligence might aid the process of collection and data organisation**
- **A national legislative framework needs to be developed**
- **The use of linked datasets (e.g. PHRN datasets), My Health Record and other registries is a potential value resource to improve healthcare delivery both for precision medicine and more broadly by helping to identify patient subgroups and health outcomes over time; Access and use of these data are predicated on making the necessary changes to national privacy legislation and putting in place the required security to facilitate appropriate access to these data.**



Challenges raised in the discussion

Healthcare system infrastructure

- Irrespective of the type of technology that falls under precision medicine, participants noted that there needs to be an appropriate healthcare infrastructure, systems and processes in place to support PM implementation. This does not currently exist.
- There will be common issues and barriers among the different technology types and specific issues/barriers to a particular technology.
- 'Geographical barrier for implementation' – Fragmented healthcare systems like Australia's are not yet ready for Precision Medicine; Australia is a large country with specialist centres dotted around – distance from service, specialist, service labs; rural areas are generally not able to have expertise to deliver, given the lack of dissemination of information.



Recommendations

- **All stakeholders should work closely to establish appropriate healthcare infrastructure systems and processes.**
- **Establish collaborative growth centres that include both developers and manufacturers.**
- **Combination technologies are often complex and will require multi-sectoral collaboration to manage adequately.**
- **Focus on the specific examples and pilot exercises to define all issues for PM implementation – involve all stakeholders: researchers, developers, clinicians, payers etc.**
- **Telemedicine is one part of the solution for education/geography barrier.**

Funding

- All participants agreed that cost is another barrier, overarching for all other barriers.
- In respect to funding of technologies and development of technologies – it was noted that decision will have to be made which technologies are to be funded initially.
- In addition, it was emphasized that long-term funding commitment to implementation of precision medicine is needed.
- **Define technologies that have short-term utility and understand where the biggest issue is for initial funding.**
- **Sufficient resourcing is needed to implement PM properly. Many PM technologies will not be simply an 'add-on', but will instead require long-term support.**
- **Flagship projects could be utilised to demonstrate national successes. These could serve as models to help drive broader initiatives.**

Additional barriers raised in discussion (implementation)

- **Value recognition** – current business models around different technologies might not be appropriate.
- **Ensuring access to care** – current clinical guidelines and pathways do not reflect and incorporate appropriate personalised medicine tools and strategies.
- **Current business models will need to be re-analysed and modified (particular example are diagnostics).**
- **There needs to be cross-sectoral and societal alignment around the practicalities of how different PM technologies are implemented.**

Topic 2: Regulation and Reimbursement

Refer to Figure 6 Regulation & Reimbursement: Summary of Discussion



Key questions for discussion

- Given the breadth of personalised medicine tools and technologies to be regulated, to what extent are regulatory processes adequately defined across the spectrum?
- Regulatory pathways are defined for several technology areas: are they working?
[e.g. Companion diagnostics have laboratory and quality standards defined devices are required to meet relevant quality and manufacturing standards.]
- To what extent must the regulatory environment evolve to accommodate leading edge personalised medicine technologies such as gene therapies? Are the current HTA processes (PBAC and MSAC) sufficiently fit for purpose to assess and recommend technologies across the spectrum?
- Given HTA methods and processes were developed to assess technologies with effects in a broad range of patients, what are the implications when the patient population is expected to be much smaller? Are there concerns with conflicting and unclear evidentiary standards?
- How do evidentiary standards impact on clinical trial design and delivery for personalised medicine? How can regulation/reimbursement incentivise/drive the development of more effective (truly personalised) medicines/devices (through data analytics, AI, etc) by providing a levelled playing field for big pharma/ medtech and innovative SMEs?

Further questions (adapted from ACOLA report):

- How do we ensure that benefits of genetically guided treatment are appropriately shared between the developer of the technology and the taxpayer?
 - How do we design payment arrangements for genetically guided treatment to ensure a fair sharing of risks between the developer of the technology and the taxpayer?
 - How can we build on existing data collection systems to facilitate monitoring for new risk sharing arrangements?
- Are structures available for assessing different types of health outcome, such as the economics of chronic disease prevention or onset delay?
- Who is responsible for the provision of infrastructure associated with genomic technologies (including storage of genetic information and genetic samples)?
- Where should the responsibility for funding of genomic technologies fall, particularly in a mixed public –private health system such as Australia's?
 - Which genomic technologies should be funded or subsidised publicly, and what are the implications of access through the private system in terms of equity and efficiency?



Challenges raised in the discussion



Recommendations

Fit for purpose systems

- It was broadly stated that neither the regulation or reimbursement systems are currently fit for purpose to adequately address PM in the future.
- Systems regulating drugs, devices and IVDs and big data/AI are currently siloed, with little or no communication.

- **Define regulatory pathways for each of the PM technologies in such way that there is a hybrid system of understanding and aligning these**

Legislation

- It was also noted that there are legislative issues around the correct use of information/assessment of economic benefit.
- Current legislation around drugs and medical devices needs to be re-analysed (particularly companion devices – how are they defined and regulated) etc.

- **Re-analyse current legislation and adapt it to incorporate PM technologies in further policies and guidelines**

Policy and guidelines

- Policies and Guidelines are yet to incorporate Precision Medicine technologies

- **Incorporating PM into policies/guidelines will follow legislative adaptation**
- **However, developing guidelines might take too long – organise temporary body of experts in the meantime. Define a pilot project – e.g. high cost of immune-agents for paediatrics where there are no other options – gather people around that theme and start the process. Also, involve third party payer in the discussion**



Challenges raised in the discussion

Structure, function and decision making

- Current regulation/reimbursement pathways are fragmented, and are developed to address broad population, not an individual; there are separate pathways to address drugs, medical devices and IVDs, gene technologies etc;
- Big data/Algorithms – who is the regulator?
- There are difficulties for the traditional regulation and reimbursement pathways to handle a ‘product + process’ technology.
- Payer structures (PBAC, MSAC & Prostheses) are currently not designed to manage the broad array of technologies that constitute Precision Medicine (i.e. device/drug combinations, apps etc).
- Concept of focus and need of pilot projects (with understanding of the governance – who decides? Is it a body of experts? Who is involved in discussion?).
- In addition, we also need to consider how both public and private health systems in Australia can fund PM technologies – e.g. what framework, information/evidence needs are required/appropriate; where can duplication be avoided (between TGA needs for access decisions and payer needs for access decisions).
- Private Health Insurers are another important stakeholder with regards to being part of the broader discussion/further consultation on how to best meet patient’s needs; Prostheses List arrangements (Private Health Insurer reimbursement of devices) won’t apply to a personalised device if is not included on the ARTG (typical). PL arrangements need to evolve to accommodate applications for personalised devices.



Recommendations

- **Reorganise and adapt current regulation/reimbursement pathways.**
- **There will have to be an adaptive approval process and adaptive pricing for PM.**
- **Agile reimbursement structures such a ‘pay for performance’ are needed.**
- **There needs to be a more flexible approach to trial design – including better use of RWE. Streamlined/parallel processing may help address this issue.**
- **Product + process technologies could utilise a ‘principles-based framework’ in which safety, quality and clinical effect are included. Flexible trial design with ‘pseudo-endpoints’ were also suggested as a possible solution.**



Challenges raised in the discussion



Recommendations

Evidence needed

- What evidence to implement PM is needed? – from the regulatory perspective and the payer evidence perspective.
 - The patient population for clinical studies will be much smaller - this needs to be accepted more broadly ('a need for philosophical change from the society in general').
 - Especially within PM for appropriately assessing these technologies/drugs/diagnostics a societal perspective is the only right perspective to take to fully take all the effects into account. Currently, the PBAC for example uses a healthcare perspective).
 - Public also needs to be educated and involved in the discussion on what is the risk/requirements from their perspective on using PM.
- **Define the levels of evidence and what is the evidence; this will require a deep understanding among all stakeholders of the requirements to support Precision Medicine).**
 - **New evidence generation models are needed – RWE.**
 - **Early engagement with patients / regulators is crucial. This will help ensure necessary patient groups are included and facilitate equity of access for patients with potentially rare indications that could benefit from PM.**

Topic 3: Commercialisation

Refer to [Figure 7 Commercialisation: Summary of Discussion](#)



Key questions for discussion

- Are there specific legal and financial barriers/incentives related to commercialisation? How important are the differences for medtech, biotechs vs large pharma and diagnostic companies?
- Is enough thought being given to ethical considerations and privacy concerns in the development and commercialisation phases?
- Some stakeholders regard the policy push to provide funding and incentives as overtaking the need for development of quality evidence of effectiveness and clinical utility: Is this a problem in Australia?
- Are there tensions between the goals of PM to provide stratified, smaller populations of patients with tailored therapies versus standard clinical trial designs, which examine efficacy in a large and generalisable patient populations?
- Does this result in higher costs for PM clinical trials?
[For example, regulators may require both biomarker-positive and negative participants in clinical trials, thus reducing or nullifying any potential savings for the trial sponsor]
- How important are subgroup analyses of standard RCTs in developing/understanding Precision Medicine approaches? Is 'real world evidence' more or less important for the commercialisation of precision medicine?



Challenges raised in the discussion



Recommendations

1. R&D Incentives

- Managing early innovation and development – there is a skill and knowledge gap to mentor small biotech; development is the part of ecosystem and we have excellent development around the country, but it is fragmented.
- Biomarkers and companion diagnostics – development of these will be critical and will raise questions such as: Are they patented or just a test that developer of therapeutic is doing? Need to define the approach to deliver these.
- Interdisciplinary collaboration between engineers, scientist, clinicians and technologists should be incentivised. Many new technologies cut across disciplines and a narrow, 'specialist' focus will not adequately address the rapid changes in the sector.
- 1, 2, 4 were further discuss in Topic: Technologies/ Implementation.

2. Skilled Workforce

4. International Competitiveness

- **Mentoring people going down innovation pathways from basic science;**
- **Blur more the division between industry and research – this could be difficult, solution: encourage more international exchange – bring people with skills; keep indicators for academics; KPIS for translational research.**
- **Medical schools should focus on preparing clinicians for the changing nature of medicine (genomics, AI software). The focus should be on the augmentation of clinical practice with future technologies, rather than a replacement model.**

3. Data + Health System Infrastructure

5. Enhanced Evidence + RWD

6. Fit for Purpose R&R

- Trial design – every patient has its own trial;
- Given that the major interest is the outcome of the individual patient - natural consequence of PM is cost driver for trial design – not a typical clinical trial design for broad population; There is also a question of how we will recruit and stratify patients.
- In the absence of typical clinical trials, Reg/HTA agencies may need to make greater use of observational data/'real world evidence' - which traditionally is considered limited due to the potential for confounding/bias;
- Existing infrastructure is not be fit-for-purpose.
- How we evaluate PM ultimately needs to answer the question of whether patient outcomes are improved. It's a key 'guiding principle'. Data collection frameworks need to 'measure what matters to patients'.
- Evidence can be generated 'precisely' but once approved, it may be applied in a non-precise manner. Unnecessary tests/treatment adds additional costs to the healthcare system.
- Disruptive technology can create a disincentive for clinical adoption. Machine-learning software for diagnostic imaging is a major threat to multiple clinical specialists.
- 3, 5, 6 were further discussed in Topics: Technologies/ Implementation and Regulation & Reimbursement
- **Develop flexible trial design - not classical randomised controlled, placebo controlled (adaptation of clinical trials as you go – 'learning curve').**
- **Sponsors and regulators need to work closely together to develop innovative mechanisms of evidence-generation. Industry also needs to be rewarded for truly innovative therapies or treatment regimes.**
- **There needs to be a realistic 'skills stocktake' for data competency, analytics etc in Australia. Data aggregation and linkage also needs to be addressed.**
- **Evidence generation: it may be that both RCT/subgroup analyses and RWE is needed to show the value of Precision Medicine technologies and this may vary according to stakeholder (e.g. HCP, payer) needs.**



Challenges raised in the discussion



Recommendations

1. R + D Incentives

2. Skilled Workforce

4. International Competitiveness

- Precision Medicine decreases both market size and commercial incentives for development due to extreme patient stratification.
- General unawareness that PM has a great potential to improve health of patients and populations IF/When these new advanced technologies become available to all.

Appendix 2: List of Precision Medicine Roundtable Participants in alphabetical order

Organisation/Body	
AbbVie Australia	Medicines Australia (MA)
AusBiotech	Medical Services Advisory Committee (MSAC)
Australian Council of Learned Academies (ACOLA)	Medical Technology Association of Australia (MTAA)
Australian Genomics Health Alliance (AGHA)	MedTechnique Consulting
Bellberry Limited	MSD Australia
Certara	Pfizer
Commonwealth Scientific and Industrial Research Organisation (CSIRO)	Pharmaceutical Benefit Advisory Committee (PBAC)
Department of Health	Pharmsite Pty Ltd
Eli Lilly	Roche
Genea Biocells	Specialised Therapeutic
Illumina	Stryker
Janssen	Therapeutic Goods Administration (TGA)
Johnson & Johnson	University of Sydney Clinical Trials Centre
	Walter and Eliza Hall Institute of Medical Research (WEHI)

Several other organisations kindly contributed ideas and suggestions following the Roundtable. These included: Pharmsite Pty Ltd, AbbVie, CRC Australia and Medtronic.

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is available at www.business.gov.au/industrygrowthcentres