

EXECUTIVE INSIGHTS

Creating a Vibrant Ecosystem for Precision Medicine: A Prescription for Success

The success of precision medicine — the tailoring of disease prevention and treatment that considers differences in people's genes, environments and lifestyles — relies on a complex ecosystem that puts the patient's experience and outcomes at its centre.

But there are many stakeholders contributing to this ecosystem, and the framework that supports them must be effective, robust and flexible. Critical to this is understanding what 'success' looks like, to ensure the ecosystem will flourish and stakeholders can operate efficiently and profitably as a result.

Precision medicine's profile and its applications have made considerable strides in recent times. As an example, the use of biomarkers to improve the efficiency of clinical trial activity has become almost routine over the past five years, with biomarker identification now comprising over 70% of new clinical trial starts.

At present, techniques like biomarker detection represent much of the current focus around precision medicine applications. But this is only the beginning: precision medicine techniques can be applied to the full spectrum of patient care, from pre-diagnosis through to treatment and monitoring, as outlined in the diagram (see Figure 1)

More advanced precision medicine applications can identify individuals at risk of hereditary conditions, find early signs of disease in asymptomatic populations, and help diagnose, treat and monitor patients as they move from acute treatment to remission.

These advanced therapies are being supported by research and development initiatives, particularly from pharmaceutical companies that are developing applications that include gene therapies, cell therapies and advances in mRNA technology.



Patient diagnosis, treatment and monitoring Symptomatic Pre-symptomatic Actively Tx-treated Remission Diagnosed Predisposition/ Minimal residual risk-**Early** Diagnosis/ **Therapy** Therapy assessment disease/active detection monitoring prognosis guidance (Risk) surveillance Problem addressed · Identify at-risk • Find early signs Diagnose Guide Tx Monitor Tx Find/measure patients - e.g. of disease in disease, management residual response asymptomatic including strategy and/or disease after diseases (BRCA/breast population differential Dx <u>resistance</u> <u>curative</u> cancer) <u>treatment</u> e.g. surgery potential rate (solid)/CAR-T of progression (liquid) Active uses Established for · Ramping in Established use Evidence Numerous Increasingly some colorectal moat in CDx, including in NSCLC (e.g. standard in T790M) hereditary cancer (EXAS) breast comprehensive liquid tumours (e.g. FMI) (BRCA) (OncotypeDx) Pan-cancer Growing use in Ramping Trials evidence as Many (e.g. Grail) Lengthy trials, including pilot-stage potentially prospective increasingly Natera, initiatives with unlocks (outcome-bas deploying input/output Guardant drive TxG-guided uncertain ed) trials may Ionaitudinal response use in solid tumour trials outlook screening in limit broad drugs in monitoring healthy (neo)adjuvant use population

Figure 1

Advanced precision medicine across the clinical landscape

*Dx=diagnosis; Px=prognosis; Tx=therapy; TxM=therapy monitoring; NSCLC=non-small cell lung cancer Source: L.E.K. IP, interviews, research, and analysis

But to ensure precision medicine continues to advance as 'the way of the future', the various stakeholders involved in precision medicine's current environment need to be part of an ecosystem that supports and enhances their individual roles in delivering precision medicine to the patient at the centre of their efforts.

A well-constructed ecosystem, with the right stakeholders, is critical

Ideally, there are many stakeholders in a successful precision medicine ecosystem, with the patient — and his or her outcomes — at the centre of a complex network. This will include primary and secondary healthcare providers, clinical trial and R&D researchers, digital healthcare and data collection organisations, funding providers, regulators, and, of course, the patient's friends and family (see Figure 2).

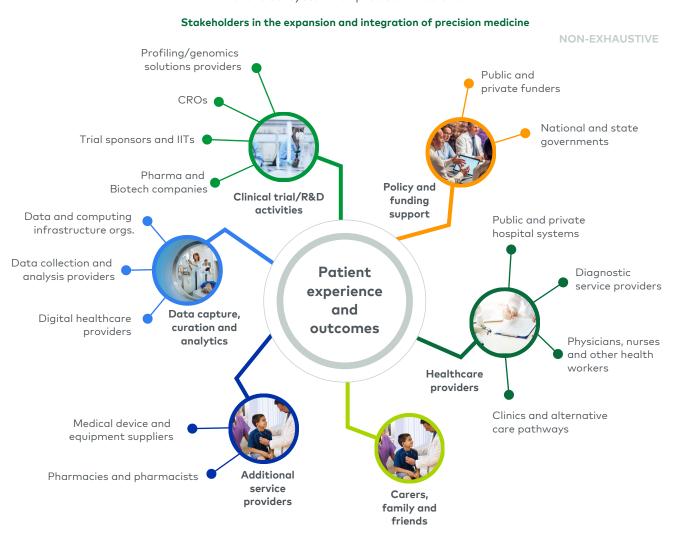


Figure 2
A vibrant ecosystem for precision medicine

*CROs=contract research organisations; IITs=Investigator initiated trials Source: L.E.K. IP, interviews, research, and analysis

Figure 2 provides an overview of the precision medicine ecosystem, but behind this framework lie other, more subtle interconnections between stakeholders. The moving parts across the patient pathway include stages of referral and consent, biospecimen collection and genomic sequencing, variant analysis and clinical trial matching, and patient follow-up and reporting. Each stakeholder must manage their role to ensure the right activity is carried out in the right way, at the right time, so that each stage proceeds smoothly and efficiently.

An integrated, multidisciplinary effort involving all stakeholders is key to this effort. Up until now, the stakeholders most involved in precision medicine initiatives across the Asia-Pacific (APAC) region have been local governments. Singapore, Thailand and Japan have all created individual initiatives to drive the use of precision medicine in genomic sequencing of their various populations, aiming to grow local knowledge and support precision medicine capabilities in their countries.

Precision medicine also has strong support in Australia, but with a difference from the largely government-driven approach of these other examples. In Australia, precision medicine's ecosystem has seen much more of a public-private partnership across the relevant stakeholders — a unique combination in comparison to other overseas initiatives.

One example is Australian Genomics, a collaborative group of 80 government and commercial organisations that includes research institutions and clinical care providers, established by the Australian government in 2021. Australian Genomics supports the integration of genomic medicine as a standard of healthcare in Australia, advising the government on how to roll out and manage its decade-long AUD \$500 million genomics programme, as part of the government's Medical Research Future Fund.

A related initiative involves Omico, an Australian government-backed national network of researchers, clinicians and related industry partners. Omico's Precision Oncology Screening Platform Enabling Clinical Trials (PrOSPeCT) initiative is an AUD \$185 million genomic medicine project involving the government, global pharmaceutical companies like Roche and Bayer, social impact investors, and other research institutes and clinical care providers. Uniquely, it is a true public-private partnership, with state and federal governments joining forces with industry and not-for-profit organisations to deliver a national programme.

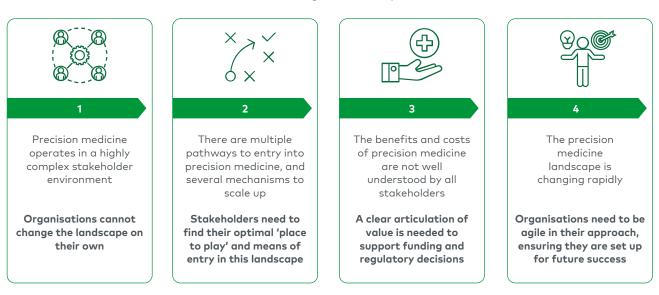
PrOSPeCT is intended to bring precision oncology trials to the Australian public by linking genomic technology to trials of new therapeutic products. It will sequence the genes of 20,000 Australian cancer patients to help develop new treatment paths across Australia for people with difficult-to-treat cancers.

PrOSPeCT builds on the impressive results that Omico has achieved through the Molecular Screening & Therapeutics (MoST) study, which has successfully screened over 7,000 cancer patients, recommending treatment to almost 4,000 and referring over 600 to clinical trials. It is estimated that PrOSPeCT will deliver AUD \$525 million in new direct investment in locally based clinical trials, create 650+ new highly skilled jobs in two years and deliver \$135 million of savings in healthcare costs through avoided health interventions, including medicines, tests and additional hospital costs.

There are challenges to consider in getting to 'success'

PrOSPeCT also demonstrates the importance of having the right business models and structures in place to ensure long-term funding and stakeholder support across the life of the project. The initiative, and other examples like it, showcases both the opportunities and challenges in scaling precision medicine applications to enable widespread access to patients and improved health outcomes (see Figure 3).

Figure 3
Four common issues that challenge the use of precision medicine at scale



Source: L.E.K. IP, interviews, research, and analysis

The four key issues outlined in Figure 3 all affect the potential for precision medicine to grow its footprint across the APAC region:

- 1. Precision medicine operates in a **highly complex stakeholder environment**. Organisations cannot change the landscape on their own: stakeholders need to be aligned on their purpose and expectations around their involvement and be clear on what is likely to result, in terms of investment returns and other benefits.
- 2. There are multiple pathways to entry into precision medicine, and several mechanisms for stakeholders to scale up their involvement once they have entered the sector. But stakeholders must carefully consider how to get involved: where is their best 'place to play' in the precision medicine landscape and their most effective entry point into this ecosystem?
- **3.** The benefits and costs of precision medicine **are not well understood** by all stakeholders. Those stakeholders looking to grow their involvement in the area, through additional funding and enabling regulation, need to be very clear on the value proposition.
- **4.** The **precision medicine landscape is a fast-changing one**. Stakeholders must be agile in their approach and ready to innovate around their offerings and business structures, to ensure they are best positioned for future success.

Clear steps to building a successful ecosystem

So what does success look like, in the face of these factors? Our work with clients operating in the precision medicine sector has given us a clear view of what must form the building blocks for success in this area (see Figure 4).

Figure 4
Delivering a successful ecosystem in APAC: how to meet the four challenges



1

Success requires an engaged, connected health system

- Precision medicine requires new and expanded links between healthcare providers, ensuring the health system is set up to collaborate to improve patient outcomes from initial screening to treatment and maintenance
- This also requires a healthcare workforce adept with digital health solutions to supplement existing treatment pathways



2

Success requires a range of new or modified healthcare services

- Organisations must exist across the value chain to fulfil diagnostic, treatment and management requirements for precision medicine
- Precision medicine requires advanced data capture and management systems, data platforms for the safe storage of patient data
- Precision medicine requires adapted supply chain and logistics systems



3

Success requires a supportive regulatory and reimbursement regime

- Appropriate public and/or private reimbursement pathways for new diagnostic and treatment approaches (and R&D) will be needed to expand access to precision medicine
- Adapted, targeted mechanisms of trialling solutions will require revision of stringent regulatory frameworks to realise full benefits



4

Success requires future-ready organisations and systems

- The mechanisms of delivering precision medicine solutions are continually evolving as the science behind precision medicine is explored
- New ways of working and critical consideration of partnerships in this industry will be necessary to enable success (e.g. CAR-T delivery requires partnering of diagnostic clinics, pharma companies and hospitals)

*APAC=Asia-Pacific; CAR-T= Chimeric Antigen Receptor-T cell therapy Source: L.E.K. IP, interviews, research, and analysis

Figure 4 shows the roadmap to success: an engaged and connected framework of providers that includes new or modified healthcare services alongside existing ones. This ecosystem is underpinned by an effective regulatory and reimbursement regime, and it involves providers who are 'future-ready' and who can embrace new technologies and flexible operating models.

For more information, please contact strategy@lek.com.

About the Authors



Manoj Sridhar

Manoj Sridhar, a Partner in L.E.K. Consulting's Life Sciences and Healthcare practice, is based in the Melbourne office. He has deep expertise in strategy development, performance improvement and organizational design, and has advised pharmaceutical, medical technology and government clients on a range of strategy and M&A projects in Australia. Prior to joining L.E.K. in 2017, Manoj led a national research centre developing early-stage immunotherapies and building academia-pharma partnerships to commercialize attractive technologies. He holds a doctorate in physics from Vanderbilt University in the U.S. and an MBA from Melbourne Business School.



Stephanie Newey

Stephanie Newey is the Managing Partner, Head of L.E.K. Consulting Australia and coleader the Australian Healthcare and Life Sciences practice. She has more than 20 years of experience in strategy and consulting, with experience across biopharmaceuticals, life sciences, med tech and healthcare services. Stephanie's expertise is in working closely with organisations to design and deliver transformational growth strategies and performance improvement outcomes. Stephanie's insights into biopharmaceuticals and healthcare are supported by experience working in a multinational pharmaceutical companies. Stephanie graduated from the University of Technology Sydney with a degree in accounting and finance and was awarded a University Medal.

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