



Go8 Genomics and Precision Medicine Collaboration and Commercialisation Summit – outcomes and summation

Sydney: Thursday 26 July 2018

Introduction:

The **Go8 Genomics and Precision Medicine Collaboration and Commercialisation Summit** comprised Go8 and University of Auckland researchers, investors, government and innovation leaders who came together to discuss the emerging research opportunities and how best to realise them collaboratively.

There were 127 participants.

The formal body of the Go8's commercialisation and engagement directors - the Go8 Innovation and Commercialisation Group - planned the Summit to highlight Go8-specific research expertise and its collaboration capability.

Through *Innovation and Science Australia's* focus on genomics and precision medicine in its '*Australia 2030: Prosperity through Innovation*' plan, this research area was identified as the first in a Summit series.

The Summit heard from Minister for Health, the Hon Greg Hunt MP; the Chair of Innovation and Science Australia, Mr Bill Ferris; the Chair of the Australian Medical Research Advisory Board, Professor Ian Frazer; and the Lead for the Australian Genomic Health Alliance, Professor Kathryn North.

A range of leading researchers provided the scientific basis for the Summit and extended discussion to the practicalities of advancing genomics and precision medicine outcomes. Representatives of venture capital and investment organisations, as well as key pharmaceutical companies, provided their perspectives.

Message from Go8 Chief Executive Vicki Thomson

I would like to warmly thank everyone who gave their valuable time to attend this Summit.

I found the day insightful and welcomed the level of candour and trust in the room.

We can build on that.

There were home truths we needed to hear. There were pointers to a successful collaborative future if we all put in the effort that future deserves.

I very much hope we can repeat the Summit with your involvement and build from this outcomes-focused foundation.

It was with enthusiasm that even before the day had concluded I was informed an infectious diseases collaboration had been mooted. The Go8 is positive this is the first of many!

Again, thank you.

Summit Outcomes

- A large number of benefits and issues have been robustly discussed and highlighted, delivering a benefit to future effective collaboration.
- Two separate collaborations entailing multiple Go8 members and two distinct investors are being developed as a direct result of discussions between parties at the Summit.
- The timing and content of the Summit has been deemed valuable by many participants, panellists and speakers and the opportunity to intensively network was appreciated.

Note:

The Go8 is undertaking a survey of all participants for information on outcomes arising from the Summit that can be shared.

Actions /Next steps

- Go8 to develop and release a capability statement of Go8 in Genomics and Precision Medicine by end third quarter 2018.
- Monitor and support Go8 engagement with others, including investors and industry in Genomics and Precision Medicine, with possibility of a revisit of progress in 12 months, through Go8 formal working groups.
- Go8 to work with others in contributing to and advising key policy development and discussions on genomics such as the implementation of the Genomics Health Futures Mission.
- Go8 to investigate options for two specific actions:
 - Go8 joint equity in the Biomedical Translation Fund; and
 - Go8 role in education, upskilling as identified at the Summit.

Opportunities re genomics identified

- Training and education. Could the Go8 be a combined force in educating the future workforce at the student level?
- Genomics awareness. Could the University of Sydney's approach to introducing genomics across all curricula including science more broadly and the social sciences be duplicated?
 - Extend those involved - include and incorporate philosophers and social scientists.
 - While other 'omics' are not at the same point of maturity, there will be further opportunities and challenges as they develop further.
 - Integration across disciplines is important – i.e. those with autism have a much higher incidence of cancer in later life. Why?
 - Australia must identify and leverage its competitive advantage i.e. from our regional position or our indigenous population. A 100,000 Genome project in South East Asia?
- Researchers should be immersed in taking research to market i.e. through placement or direct involvement in companies.
- Could the Medical Research Future Fund (MRFF) assist i.e. by ensuring reproducibility is assured before researchers engage industry in clinical trials. Commercialisation offices often don't have such funds.

- The Go8 universities may need to target more precisely areas for research and activity. No need to re-invent the wheel in a multicultural country like Australia. Data available from elsewhere in the world could be obtained and used.
- Specific ideas include:
 - A collaborative national effort in identified areas – e.g. pharmacogenetic testing; with a focus on data and samples.
 - The relevance of artificial intelligence and machine learning and ways forward if applicable to genomics and dealing with data of this scale.
 - Using genomics as a tool for monitoring good health rather than (simply) as a disease prevention tool.
 - Thinking beyond the genomics and the genes/DNA to other opportunities such as the role of wearables / heartrate monitors.
 - The possibility of genetic testing across people’s lifetime, and whole genome sequencing over long periods such as 50 years to understand factors that progress to disease.

Funding questions

- Is it possible for industry to put money into projects without expectations of return?
- Can the Go8 (as collective or individual members) put equity into the Biomedical Translation Fund – equity alongside a matching amount from one of the three fund managers.

The main issues identified:

Workforce and education

- Ensuring the workforce is ready for the genomics revolution.
- Workforce planning and preparedness must extend beyond genomics researchers to other ‘omics’ specialists.
- The rate of skilled people being introduced to the workforce is being outpaced by the rate of change.
- This is also an issue internationally, so that sourcing overseas talent can be limited, while Australian talent could be lured overseas.
- The issue extends past clinicians, health care workers, doctors, and researchers to more trained specialists in data curation.
- Community understanding/acceptance is vital to ensure trust and confidence
 - A workforce and community education model that could be duplicated may be the University of Sydney’s introducing genomics across all curricula including science more broadly and the social sciences.

Identifying Australia’s competitive advantages and positioning

- There is a need to identify and optimise Australian competitive advantage in genomics and precision medicine.
- Our population characteristics - a multicultural community, and our place in the Asia-Pacific region.

- There are huge collected datasets on Caucasian genomics, especially male. Is it strategic for Australia to seek focus on adding to this data?
- Some industry and investors noted disinterest in Caucasian male genomics when operating in Australia.
- One industry representative was seeking a system where unique South Indian, Chinese population data can be accessed.
- The genomics of our indigenous populations is unique and in addressing the needs of Australia's indigenous communities, much could be learned. The University of Auckland noted there were valuable insights for health delivery from Maori peoples, not only in addressing Maori health issues but also those of the wider population.

Sourcing, handling and grappling of data

- There is a pressing need for patient and community literacy – including deep understanding of the facts and implications of genomic based treatment.
- It was noted that patient consent is high – once effective action has been taken to enable appropriate and sufficient understanding by the patient and their support network.
- Such informed consent is vital to the use and reuse of patient genomic data in research.
- National consent frameworks such as discussed by the Australian Genomics Health Alliance are key to progressing a greater community acceptance.
- The concept of dynamic consent – where it's recognised that a patient's repeat consent should be and is sought – should also be embraced.
- An example of an issue to be addressed is how to ensure a patient is appropriately informed, at the same time as being advised of their diagnosis e.g. of cancer, so that a patient can knowledgeably decide to consent.
- Infrastructure is needed to manage and manipulate the data and the complexities of how to interpret numerous and coincidental findings if whole genome sequencing becomes standard
- Large-scale data initiatives like the 100,000 Genomes project in the UK or the UK biobank are seen as positives.
- Global developments are seen as templates - the agreement of GSK and 23andMe to leverage genetic insights to develop novel medicines, with GSK providing \$23 million to 23andMe – an organisation that works to transform understanding of how genes influence health. 83 per cent of those involved consented to their data use. Iceland has DeCode Genetics in which every Icelander is a shareholder.
- Population based screening would result in big datasets that require handling.
- Data integration. The need to collate and derive findings not just from omics data but also patient data including images, MRI scan, longitudinal collections.
- How to obtain further data? More cases in specific areas such as ovarian cancer are needed, but difficult to obtain. In addition, universities can have restrictive material transfer agreements (MTAs) that block sharing.
- New capability such as data skills, data infrastructure, data standards and dictionaries are needed. Reliable networks to promote and confidently share clinical grade data, and to ensure that various sections of the health system are collaborating, are some of the gaps to be filled.

Investor and industry perspectives vary. Researchers may not know what they ideally / realistically want from investors

- Investors and industry have varying expectations:
 - Some investors focus on ‘Valley of Death’ activity and on taking discoveries to drugs; others on patient outcomes while extracting rather than adding to costs.
 - One major pharmaceutical states interest only in basic science – given basic science / discovery is Australia’s strength.
 - Another major pharmaceutical has the opposite business focus - having the largest number of clinical trials in Australia; actively sending medical teams into universities to seek insights and sharing with its own scientists, as well as offering a scientist exchange program.
 - Value in researcher international engagement in genomics (Australia’s role in the international partnership).
 - There was consistent interest by industry and investors in accessing differentiating science that can’t be found ‘in company’, or research differentiating to the degree that it is not found in other key research hubs – especially as Australia is competing on a global stage. Notably, one pharmaceutical panellist noted that to be published in Nature, a researcher doesn’t need to show the research leads to better or is comparable to existing therapy.
- Research is seen as the key element that drives collaboration, centred on the researcher and their ability to provide unique or differentiated research.
- When should investors engage? Some historically go quite early and stay from cradle to maturity. Industry view is no stage too early for researchers to engage.
- Venture capitalists are involved in much more than dollars, it is also about the talent and skills – early understanding and engagement is critical, exposure to IP strategy, repeatable data.
- Should researchers engage with industry/investors earlier? University commercialisation directors have an important role in driving an idea through early engagement and helping researchers with the direction of their research. Researchers would benefit from early industry/investor input.
- Researchers want from investors; ‘your problems’, ‘to address the valley of death in research where it’s funded to a clinical setting’, ‘to enable a researcher to focus on the key issues’.
- Do researchers not understand intellectual property (IP) strategy? They often patent 4-5 years too early – and that this trend to patent early works against them.
- It would be a major benefit for researchers to understand the work that goes into the collaboration, translating, and taking to market process i.e. through direct involvement in a company.

Various pathways to market; none are easy

- There are a number of ways to get from the research end of the pipeline to the patient (doctor/patient relationship). One is invention to product, and that path can be financed by capital. Other paths might be more direct conversion to health care services.
- A key challenge is how the technology is adapted to a model suited to the Australian system – including who should drive this?

- Clinical trials are many, expensive and not overwhelmingly fruitful.
 - Hundreds of approvals are needed on average for clinical trials – with approximately 50-60 trials from phase 1 to phase 2, only one or two are seriously under consideration.
 - Clinical trials are important but may not result in a drug.
- Reproducibility of results is a key issue, with some studies finding that even original researchers cannot reproduce results (in the United States). This is compounded when industry must validate the results and have the reproducibility tested. This takes time and costs, to the extent that some industry focus only on discovery not clinical trials.
- Running trials on a shoestring budget is also an issue. Potentially fully funding a few trials rather than too many is a strategy.

Community engagement and communication

- A pressing need for patient and community literacy – understanding the facts and implications of genomic based treatment.
- Patient consent is high – once they and their support network have been given sufficient knowledge.
- Informed consent is vital to the use and reuse of patient genomic data
- National consent frameworks such as discussed by the Australian Genomics Health Alliance are key to progressing greater community acceptance.
- The concept of dynamic consent – where a patient’s repeat consent should be sought – should be embraced.
- The complexity in ensuring a patient has the required information to consent at the same time as being advised of a diagnosis e.g. cancer
- The need to improve communication methods – reducing the deluge of consent documentation; effective information sheets; and effectively demonstrating the risks.
- Lessons from the higher level of community openness in Europe and UK, and ready acceptance there of people to participate in large community projects – such as the UK biobank
- The need to ensure fairness and equity of access for diverse populations – cost should not be a barrier to genomics treatment beyond core or mainstream populations.
 - Engagement with indigenous people, and with other cultural and ethnic groups, must be part of the picture.
 - Cultural viewpoints are important when seeking to collect genomic data.
- A role for philosophers, humanities researchers and social scientists to play in helping promote greater understanding and awareness, including in acknowledging and addressing behavioural and cultural considerations.

Ethical considerations paramount, as are legal implications and economics

- These cross over with consent issues and extend for example to considerations such as what to disclose to patient, and around use and re-use of findings.
- Ethical considerations may both reflect existing concerns by non-consenting patients i.e. whether their diagnosis may be used to their detriment by their life or health insurers and may extend to future unknown scenarios such as use in paternity cases.

- The benefits (and cost-savings) can vastly outweigh the input cost i.e. in the case of intellectual disability, the use of genomic research to assess throughout life as a basis for further findings and treatment. But there is a poor ratio of successful to non-successful and unfulfilled clinical trials.

Keynote addresses:

The Minister for Health, the Hon Greg Hunt MP

The Minister presented the Government's strong support for genomics and precision medicine, and his own commitment as Minister.

He noted that colleagues overseas considered Australia had the paramount relationship between academia, clinicians and industry – a view echoed by companies around the world. He commented that Australians were harsh in their self-observations regarding the level of collaboration that exists here, and in the past three to five years, those relationships have been strengthened. A key message was 'Translation is about individual people's lives. This community is driven by those human outcomes.'

Minister Hunt noted the four critical pillars in his and the Government's approach:

- Primary care
- Support and hospitals and private health
- Support for mental health, a gap left too long
- Research

He pointed to the Government's investment in the Biomedical Translation Fund, along with matching support from the three fund managers appointed to the fund. He suggested that additional co-funds could be provided by the Go8 – either collectively or by its individual member universities.

Minister Hunt also spoke about the Medical Research Future Fund and its four key themes, noting the expectation the MRFF would reach \$20 billion and the expected disbursements rising to \$650 million in its fourth year of operation.

The four key themes discussed by the Minister were Patients – rare cancers, rare diseases and clinical trials, Research Driven Programs, the Translation pillar and Mission. He noted the desire to **focus on** clinical trials that make Australia a global destination and called for universities to work with the Department of Health to expedite clinical trials.

In Q&A engagement, the themes that emerged were: the need for State governments to follow the Federal lead as a basis for success, and the relationship between universities and hospitals and if different ownership or governance models were needed.

- The Minister noted that Missions such as the Brain Cancer Mission and national plans, such as on endometriosis, provided the mechanism for State-Federal relations, as well as the role of the Australian Genomics Health Alliance in bringing parties together.
- Regarding university-hospital relations, the Minister pointed to clinical trials as one-stop shops and the role of the Australian Health Research Translation Centres in driving those connections, along with the Genomics Mission.

Note: the Minister did not use speech or notes



Links to the following presentations can be found [here](#):

[The Chair of Innovation and Science Australia \(ISA\) Mr Bill Ferris AC](#)

[The Chair of the Australian Medical Research Advisory Board, Professor Ian Frazer AC](#)

[The Lead for the Australian Genomic Health Alliance, Professor Kathryn North AM](#)