

## SHAPING THE QUAD'S DNA: HOW CAN QUAD COUNTRIES MANAGE BIOTECH'S OPPORTUNITIES AND RISKS?

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# About the Quad Tech Network Series

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The Quad Tech Network (QTN) is an Australian Government initiative to promote Track 2 research and public dialogue on cyber and critical technology issues relevant to the Indo-Pacific region.

As part of the initiative, research institutions in Australia (the National Security College at The Australian National University), India (the Observer Research Foundation), Japan (the National Graduate Institute for Policy Studies) and the United States (Center for a New American Security) have commissioned papers on key issues facing the region.

These papers – together, the QTN series – offer analysis and recommendations on shared challenges facing Australia and Indo-Pacific partners in the cyber and technology environment.

The QTN is managed by the National Security College at The Australian National University, with the support of the Australian Department of Foreign Affairs and Trade.

## About the Series Editors

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## Executive Summary

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- **Biotech will be one of the most economically lucrative emerging technologies.** Many health, industrial and agricultural products will be replaced with more effective, cheaper and environmentally friendlier biological equivalents. Some predictions suggest that up to 60 per cent of all products could be made using biotechnology processes.
- **Three Quad governments – Japan, India and the US – have all recognised the need for dedicated bioeconomy or biotechnology strategies.** Each has a dedicated biotechnology and/or bioeconomy strategy with a recognition that this will be a consequential industry. Australia too is devoting significant new resources to develop its life sciences sector.
- **The Quad countries should work together on biotech standards, ethics and joint research infrastructure initially.** The most immediate overlapping national interests on biotech are ensuring that all four nations work together to have access to world class research infrastructure such as laboratories, computing power and gene banks; to develop a mechanism to harmonise technical standards in the rapidly changing sector; and a dialogue for ethics and security considerations in this rapidly changing sector.
- **The Quad can play a role in shaping security discussions on biotechnology.** Biotechnology has the power to cheaply alter the genes of living organisms, from viruses to humans. Biological systems self-replicate and changes to one part of a system can cascade to other parts of the system. The Quad is a small enough grouping of powerful biotech countries with compatible forms of governance to start these difficult conversations about how to regulate this powerful set of technologies.

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## Policy Recommendations

- **The Quad should establish a Biotech Standards Trade Enabling Program,** to facilitate and promote standards harmonisation, technical alignment and regulatory coherence. This program will initially focus on finding areas of commonality. This program will allow for steady harmonisation where possible on emerging biotechnologies. It will also allow the four countries to present a joint position on issues of commonality at global standards organisations.
- **The Quad should establish a dialogue on the security and ethical considerations of new biotechnologies.** This dialogue can help resolve some of the key positions among Quad countries. These initial discussions will need to be broadened out to other countries further down the track.
- **The Quad should establish a Joint Research Infrastructure Sharing Arrangement.** Australia, Japan and India to different degrees struggle to commercialise their research and also face challenges in upkeep of expensive research infrastructure. This arrangement would allow for the infrastructure to be shared across more users.
- **The Quad Vaccine Experts Group should evolve into a dialogue with emerging countries to explore the possibilities for future biotech technology and skills transfer.** Lower- and middle-income countries want to be able to produce vaccines and develop their own biotech sectors. The Quad can transition from a provider of vaccines to an enabler of development.

## The biotech bonanza. What is it? Why does it matter?

Biotechnology is the use of biological materials, such as proteins, antibodies, genes, and cells, to develop new drugs and treatments as well as products beyond medicine. This is a broad definition and what fits exactly under that definition varies. The focus of this paper is large-scale modern biotechnology which can be divided into four segments:

- **Biologics** (also called biopharmaceuticals) – pharmaceuticals which are synthesized from or contain living organisms (mRNA vaccines are an example of a biologic);
- **Genomics, molecular diagnostics, and precision medicine** – the study of the entirety of an individual's DNA sequence information—the genome; molecular diagnostics (the use of DNA or RNA sequences to diagnose a person's propensity for a disease or condition); and precision medicine (the use of genetic information to tailor an individual's health care)<sup>1</sup>;
- **Agricultural biotechnology** – the use of biological products or biological elements to assist agricultural output. For example, plant grafting or plant cloning and plant propagating to molecular biology to gene technology in crops; and
- **Industrial biotechnology** (also called synthetic biology) – the use of biological products to deliver industrial processes such as putting genes into yeast to create silk thread.<sup>2</sup>

While biotechnology has been around for many years, recent breakthroughs in computing power, AI, and humans' ability to quickly and cheaply map the genome of living organisms means that the potential of these technologies is magnitudes more powerful than it was even a decade ago. For example, it would not have been cost effective to develop widespread precision medicine based on an individual's DNA just a handful of years ago.

The bioeconomy refers to “the set of economic activities relating to the invention, development, production and use of biological products and processes.”<sup>3</sup> Life sciences are the set of sciences that deal with living organisms (such as biology) that contribute the fundamental research for biotech breakthroughs.

Across most sectors of biotech, the potential for economic growth is enormous. A McKinsey report argues that as much as 60 percent of the physical inputs to the global economy could, in principle, be produced biologically—about one-third of these inputs are biological materials (wood or animals bred for food) and the remaining two-thirds are nonbiological (plastics or fuels) but could potentially be produced or substituted using biology.<sup>4</sup> Therefore, it is possible that bio innovations could impact up to 60 percent of physical inputs, although attaining that full potential is a long way off. Even modest progress toward it could transform economies, societies, and our lives, including what we eat and wear, the medicines we take, the fuels we use, and how we construct our physical world.

The same report argues that, in human health, at least 45 percent of the current global disease burden could be addressed using biological science that is conceivable today (although the report does not put a time frame on it).<sup>5</sup> Potentially 30 percent of all private sector R&D will be in biology-related industries. Even if only a fraction of that comes to pass, the size of the global bioeconomy will be trillions of dollars annually above where it is now.<sup>6</sup>

Biotech is not just growing rapidly, it also eating into the market share of synthetic medicine. For example, in the US biologics' share of the pharmaceutical industry grew from 30 per cent in 2014 to 42 per cent in 2018.<sup>7</sup> The research pipeline for biologics in the US is strong across most therapy areas and so it quite probable this trend will continue.<sup>8</sup>

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**The point being that countries which lead in traditional pharma will need to re-tool their skill set. Biological takeover will gradually happen to many industries over the next few decades.**

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This is true for Japan too, which is a traditional pharmaceuticals powerhouse. Seventeen of the world's top 100 pharmaceuticals companies are in Japan, accounting for 9 per cent of global revenue, greater than India and China combined, but well behind both the US and the EU.<sup>9</sup>

Biotech is fundamentally different in four ways to most other technologies at the front line of China-US competition such as semiconductors, critical minerals, battery technology, artificial intelligence, advanced communication technology, smart manufacturing, new materials, and robotics manufacturing.<sup>10</sup> First, the set of products within the biotech industry is much broader than say semiconductors or battery technology in which each production stage and key technology is concentrated in small number of companies. Each biotech product has vastly different supply chains – a drought resistant crop and a biologic will have different supply chains. Second, the world is probably in earlier stages of both development of the technology and also regulating use of the technology than many other key emerging technologies. Third, the data sensitivities are different. The transfer of personal data is always sensitive. But biodata includes genetic information which can allow for the identification of family members and in the future will potentially also allow the holder of the data to know the appearance of the person. This will pose serious challenges to the anonymization of such data. Finally, the technologies go to some of the most fundamental elements of life – treatments for sick individuals, the food that we eat. This inherently makes the acceptance of failure lower in biotechnology than in some other technologies.

## Biotech in the Quad

Of all the key emerging technologies, biotech may be the most economically consequential in the medium to long-term. Biotech will impact a wider range of products than other emerging technologies, from gene sequencing technology to biological industrial processes.

The main questions for all countries in the Quad are:

1. How to secure a slice of the economic prosperity promised by the biological revolution?
2. How to manage the significant extant security concerns and difficult-to-predict outcomes of these technologies?
3. How to regulate the general use and international transfer of traditional health data and genomic data?
4. How to manage the ethical concerns of the biological revolution as distinct from the security concerns?

The Quad nations have different yet somewhat symbiotic roles in the biotech sector. Australia has a strong R&D sector which struggles with commercialisation (despite recent improvements). Australia's biotech industry is predominately composed of SMEs and research institutions.<sup>11</sup> Its areas of strength are in agricultural biotechnology and regenerative medicine.

Japan has had a national bioeconomy strategy for nearly two decades.<sup>12</sup> Much of its early strategy focused on biomass, but the government is now pursuing a broader set of biotechnologies. The country has fallen behind China and the US due to its siloed structure which it is now trying to redress. This provides opportunities for international partners to help break some of the research siloes and partner with Japanese organisations. Japan's 2020 strategy update states it wants to "achieve the most advanced bioeconomic society in the world by 2030."<sup>13</sup> Japan has the third largest pharmaceutical market in the world after China and the US.

The US is a leader in almost all sections of biotech. It is an R&D powerhouse with significant pathways to commercialisation plus the largest domestic healthcare, pharma and biologics markets in the world.

India has a rapidly growing biotech sector which is strongly supported by government. India established a Department of Biotechnology in Ministry of Science and Technology in 1986. India faces different development challenges than Australia, Japan and the US. It is seeking to use biotech as a way to overcome some of the immediate health and agricultural challenges that it faces. India is also seeking to establish itself as a bio-manufacturing hub.

## Working together on Shared Quad Biotech Interests

The Fact Sheet from the Quad Leaders' Summit in September 2021 stated "The Quad will monitor trends in critical and emerging technologies, starting with advanced biotechnologies, including synthetic biology, genome sequencing, and biomanufacturing. In the process, we will identify related opportunities for cooperation."<sup>14</sup> The following interests can be an initial area of focus.

First, the Quad should establish a Biotech Standards Trade Enabling Program, to facilitate and promote standards harmonisation, technical alignment, and regulatory coherence.

This can help in harmonising biotech standards between the four markets for these rapidly changing technologies. Biotech standards are the baseline technical guides for all elements of the biotechnology industry such as consumer products, the conduct of experiments, the storage and transfer of biodata, the operation of biobanks among many other items. Biotech standards include technical specifications as well as standards for procedures too. Numerous different bodies set biotechnology standards. Some are UN organisations such as the International Organization for Standardization (ISO). Others are international or American industry standards groups such as ASTM international. There is no one body that sets the standards and competition exists between different standards organisations, companies, and countries to set the standards for new technologies.

This would be in line with India's 2021-2025 biotechnology strategy which states it wants to ensure "quality assurance of Indian products as per international standards." Japan, the US and Australia have significant experience in this area across different biotechnologies and a joint Quad approach could be beneficial. Moreover, standards are being developed at a rapid rate in this field. An ongoing Quad secretariat with members from relevant standards bodies in each country could help solidify positions in which there is commonality of views. The need for greater bilateral standards harmonisation between Australia and India was already identified in the Australian Department of Foreign Affairs and Trade's "An India Economy Strategy to 2035". This program will initially focus on finding areas of commonality. There will naturally be areas of difference, particularly with India, on issues such as intellectual property rights and sharing of biodata. But this program will allow for steady harmonisation where possible on emerging biotechnologies.

The program will allow the four countries to present a joint position on issues of commonality at global standards organisations such as the ISO/TC 276 for biotechnology. Greater standards coordination would involve working together to jointly represent positions in the same leading global groupings. Sometimes, it would involve separately representing the same positions in grouping in which only one or two Quad members are present.<sup>15</sup>

Second, the Quad can establish a dialogue on the security and ethical considerations of new biotechnologies as part of its critical and emerging technology working group. The ability to alter the genetic composition of living organisms - from humans, to viruses, to the food we eat - poses many security challenges, some of which will be unforeseen. Biological systems self-replicate, are self-sustaining, and are highly interconnected. Changes to one part of a system can have cascading effects and unintended consequences across an entire ecosystem or species (including humans). Manipulating biology could unleash lasting – and unforeseen - damage to the health of humans, ecosystems, or both. Many of the materials and tools used are relatively cheap and accessible and becoming more so by the day.

Scientists globally have for the most part sought to conduct biological experiments in ethical ways. The scientific community will remain the most important constituency in this realm.

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**But as the technologies become more widely adopted, more accessible to people beyond the scientific community, more central to every element of our life - we will need stricter government oversight and enforcement in more and more domains.**

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This will be from application of genetic manipulation in humans to the lab-made creation of deadly and highly transmissible viruses.

This dialogue can help resolve some of the key positions among Quad countries. These initial discussions will need to broaden out to other countries over time. Data is vital to enable scientific breakthroughs in biological technology. Enhanced access to data leads to better reproducibility of research results, improved trust in science, and more innovation. The “open-by-default” mantra is steadily being replaced by “as open as possible, as closed as necessary”. That is a much harder mantra to regulate and navigate.

The most sensitive data is genomic data. Many people will not want their genomic data shared in certain circumstances. It is feasible in the future that some types of genomic data can be used to identify family members, one's ethnicity and potentially a person's appearance as well genetic traits and potential health issues.<sup>16</sup> Individuals will desire different levels of privacy on this matter.

There is a bigger picture data issue. Even anonymised genomic data can be used to perform population-wide genomic surveys which can then be used to develop bio-surveillance capabilities. China's largest genetic testing firm BGI has been transferring anonymised genomic data from pre-natal tests conducted overseas to China's National GeneBank.<sup>17</sup> A lack of transparency over usage of that material in China makes it difficult to assess the risks. The principles behind the management of bio-data in each Quad country are not the same and probably never will be. In fact, many countries are still working out regulations for general cross-border data transfers, let alone genomic data. It is still a worthwhile exercise to try to form areas of bio-data consensus where feasible. It could help pave the way for better collaboration

using each country's biodata resources. This can form a platform for later discussions with Comprehensive and Progressive Agreement for Trans-Pacific Partnership countries, the EU, and the US-Asia digital pact. Once again, discussion on these issues with China should be welcomed if feasible.

Finally, the Quad can contribute to international research funding and infrastructure sharing mechanisms.

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**For most countries, the capacity to undertake cutting-edge biotech research and development will be the most consequential variable in deciding how much of the biotech pie they get.**

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In Australia and likely Japan and India, there is a real challenge to keep research infrastructure up to date. There may be capacity to share or jointly develop research infrastructure. Japan in its 2020 update to its bioeconomy strategy recognises that its once strong position is now relatively weaker due to a fall in its basic research in the area plus being too slow to share network and critical research infrastructure and data.<sup>18</sup> The challenge is also elucidated in an Australian government report on Australia's Medical Research Commercialisation environment:

“Investment in fundamental research infrastructure is extremely important, as is investment to keep this infrastructure up to date and leading edge, and the coordination of, and access to, this infrastructure. Examples of research infrastructure are genomic infrastructure, biobanking, and high-performance computing facilities. Research infrastructure in Australia is fragmented and duplicated in institutional silos. Access to research infrastructure can be restricted. For example, researchers may not be able to access state funded infrastructure that exists in another state. There may be funding to establish research infrastructure, but there may not be funding to maintain it.”<sup>19</sup>

The Quad is an opportunity to redress this underfunding and also to make it easier to share access to the research infrastructure which is siloed within and between countries. The Biden administration is preparing to spend huge sums of money on biotech research (as well as other sectors) through bills that are currently in different stages of the US legislative process. There is room for small amounts of this to be directed toward the Quad in a pilot program for both basic research and commercialisation which is something that all non-US Quad members seek.

Other forums could be considered for all three of these proposals. The relatively small member group and the strong capabilities in biotech of the Quad however makes it an ideal size for these kinds of activities. If similar structures were set up in say ASEAN + 3 or APEC, they would possibly grind to a bureaucratic and political halt. The other major player in the region is China and we should welcome frank discussions on all these issues with Beijing. However, China's willingness to directly discuss these issues with the Quad or individual members of the Quad is limited. If China in the future wishes to have dialogue on these issues, then it should be welcomed.



# Management of Competing Industrial Policies

There are clear areas in which Quad countries will be in competition. One of the most significant will be biopharma manufacturing. The US review of supply chain preparedness explicitly mentioned active pharmaceutical ingredients as a key input.<sup>20</sup> According to the review:

“China and India are estimated to control substantial parts of the supply chain where there have been issues with shortages due to a range of disruptions that have impacted supply as well as quality and safety. The drive toward lower costs as well as unfair trade practices have led to a hollowing out of domestic production. A new approach is needed to ensure more resilient supply chains that includes improving transparency, building emergency capacity, and investing in domestic production.”

At this stage many of the pharmaceuticals produced in China and India are small molecule (not biological), but China and India are rapidly developing biological pharmaceutical production, particularly in biosimilars which is the biologics version of a generic medicine. Because of the economy of scale in China and India too, biosimilar production will likely remain cheaper in those countries. United States Trade Representative Katherine Tai and other US officials have spoken of protecting labour rights in low-wage countries.<sup>21</sup> This will be seen as a wage burden in India and will make them wary of signing up to any US guidelines.

US industrial policy focused on developing domestic biopharma manufacturing capabilities will come into direct competition with India and even Japan. For example, India’s 2021-25 biotechnology strategy states “With the current growth trajectory of the sector we are confident that India will be within the top 5 countries globally and be recognized as a Global Biomanufacturing Hub by 2025, with the Sector growing exponentially to achieve

a growth of \$150 Billion.”

Competing industrial policies will be an ongoing challenge for the Quad Technology Network across numerous technologies. In many cases, there will be little that can be done. For biotech, it will be important to develop mutually agreed standards for biopharma manufacturing. This can be done through the Trade Enabling Program suggested in this paper. The program could also later become a forum for industrial policy alignment (where possible).

China will be another competitor for these Quad countries. It is a leading manufacturer of biosimilars, a leading contract research provider, and a major source of academic research across the biotech spectrum. Chinese firms are now beginning to deliver cutting-edge biopharma products that will be first-in-class globally.<sup>22</sup>

China also has the largest agricultural market and the second largest healthcare market in the world, with expectations that its healthcare sector will be the fastest growing in the world over the next decade (among major economies) due to an ageing population that is becoming wealthier. Firms in Quad countries are going to want access to the Chinese market. For example, Japanese healthcare firms are heavily reliant on their large, yet stagnant, domestic market. Japan’s 2020 bio-strategy states “we should steadily promote what we can do to build a global supply chain with a view to penetrating overseas markets on a mid- to long-term basis.”<sup>23</sup> Here is the crux of the issue for Japan. It wants to build a global supply for an international environment in which China offers the biggest growth potential. Yet, its political relationship with China is increasingly fraught. Access to Chinese markets will often require manufacturing in China for both political and economic reasons.

## Technology Sharing Beyond the Quad

**The Quad faces a clear choice. Is it going to share technology among members only or will it begin to find pathways to transfer elements of technology to other countries?**

Much attention has been paid to vaccine diplomacy. The Quad combined has committed to produce and distribute over 1 billion vaccines in the region by the end of 2022 which is on top of bilateral and COVAX commitments from Quad countries.<sup>24</sup>

However, COVID has revealed that countries with emerging economies want access to production capacity, not just vaccines themselves. China has promised to help countries in the region to develop vaccine manufacturing capacity (although not mRNA facilities) as well as construction of biotech parks in several countries.<sup>25</sup> Given that the Quad is committing to vaccine distribution already, a natural next step should be for the Quad Vaccine Experts Group to evolve into a dialogue with emerging countries to explore the possibilities for future biotech technology and skills transfer.<sup>26</sup> There will be limits because of intellectual property protections for US biotech firms, but this is next step in helping countries in the region to be better prepared for the next pandemic and the coming biotech revolution.

## Policy Recommendations

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- **The Quad should establish a Biotech Standards Trade Enabling Program**, to facilitate and promote standards harmonisation, technical alignment and regulatory coherence. This program will initially focus on finding areas of commonality. There will naturally be areas of difference, particularly with India, on issues such as IPR and sharing of biodata. But this program will allow for steady harmonisation where possible on emerging biotechnologies. It will also allow the four countries to present a joint position on issues of commonality at global standards organisations.
- **The Quad should establish a dialogue on the security and ethical considerations of new biotechnologies.** The ability to alter the genetic composition of living organisms from humans, to virus to our food raises security challenges, some of which will be unforeseen. All Quad countries have identified this as a rapidly changing major security challenge. This dialogue can help resolve some of the key positions among Quad countries. These initial discussions will need to be broadened out to other countries further down the track.
- **The Quad should establish a Joint Research Infrastructure Sharing and Joint Research Funding Arrangement.** Australia, Japan, and India to different degrees struggle to commercialise their research and also face challenges in upkeep of expensive research infrastructure. This arrangement would allow for the infrastructure to be shared across more users. The joint funds would help to bolster biotech research ties between the Quad countries.
- **The Quad Vaccine Experts Group should evolve into a dialogue with emerging countries to explore the possibilities for future biotech technology and skills transfer.** Lower- and middle-income countries want to be able to produce vaccines and develop their own biotech sectors. The Quad can transition from a provider of vaccines to an enabler of development.

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