



## The Quad's contribution to revolutionising biotechnology strategies

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### Key points

- The Quad countries have invested in pharmacology, neuropharmacology and agriculture individually, establishing themselves with a focus on life extension and enhancement using biotechnology.
- The 21st century has introduced significant technologies within biotechnology, including synthetic biology, genetic editing, and genetic engineering. These technologies have wide-ranging social implications, impacting agriculture, medical research, and disease prevention.
- Over the last decade, biotechnology has gained significant attention in three primary application areas: bioinformatics and bioproduction; genetic engineering and synthetic biology; and biosecurity and biosafety. Each contributes to medical advancements, industrial processes, agricultural productivity, and global biosafety.
- The Quad nations play distinct roles in biotechnology. Australia excels in regenerative medicine and agriculture, Japan focuses on the pharmaceutical sector, the United States leads across biotechnology sectors, and India aims to address healthcare and agricultural challenges.

### Policy recommendations

Quad countries should:

- Establish data-sharing guidelines for fair use of data and return on outcomes. This will also encourage increased investment in research and development of bioproduction.
- Leverage their alliance in the WHO to establish standards for genetic engineering and synthetic biology, including by establishing norms for genome editing.
- Revitalise the Australia Group for biosecurity and biosafety to increase focus on global biosafety standards in biosafety labs, especially level 3 and level 4 for biosafety labs (BSL3 and BSL4). Further expand the Australia Group to include more Indo-Pacific countries.

### The biotechnology revolution and biotechnology market

Biotechnology is an interdisciplinary science that combines biology, technological innovation, and engineering to create outcomes ranging from human health, plant and ecology enhancement and environmental impact. The field delineates three areas of focus.<sup>1</sup> The first is the cognitive revolution, highlighting genes and their relationship with observable behaviour. The second, neuropharmacology, is the use and influence of chemicals and drugs on the nervous system for cognitive enhancement and its implications on society. The third area highlighted is

the scope for prolonging life using biotechnology, its innovations, and the implications of this. Alongside these areas, the 21st century has also brought forward synthetic biology, genetic editing, and engineering as technologies with immense social consequences.

In the last decade, biotechnology has garnered the attention of most innovators and technologists in a few key areas, including:

### **Bioinformatics and biocuration**

The intuitive first use in biotechnology is data collection, storage, use and sharing. Bioinformatics refers to biological data and information ranging from DNA to fingerprint scans, while biocuration is the organising, using and sharing of this data.<sup>2</sup> These two have drastically influenced medical research in biodata and biosafety labs.<sup>3</sup>

### **Genetic engineering and synthetic biology**

Genetic engineering and synthetic biology became significant with iterations in cancer research, medical innovation, health augmentation and a greater awareness and control in all disease prevention and life enhancement.<sup>4</sup>

### **Bioproduction and agriculture**

Biotechnology also has applications in agriculture that encompass a wide range of areas to enhance and safeguard plants and animals. This includes the development of animal vaccines, techniques for modifying plants through genetic marker-assisted breeding, and genetic engineering of agricultural species, both plants and animals.<sup>5</sup>

This field offers diverse benefits, including the ability to manufacture new products previously unattainable or delivered at a limited scale, improvements in traditional industrial processes, and advancements in sustainability with reduced environmental impact.

### **Biosecurity and biosafety**

Finally, the last primary sector in biotechnology is biosafety and biosecurity. Biosafety involves efforts and studies to contain biological hazards to prevent accidental exposure of laboratory workers, local communities, and the environment, particularly concerning infectious pathogens. Biosecurity is a large-scale effort to ensure use in good faith for all biotechnology developments and prevention and deterrence against the use of any biological agents for harm.

With the Biological Weapons Convention (BWC) holding its ninth review conference and recent conversations around biosafety labs and their security measures, this area, too, has assumed global importance.<sup>6</sup>

Biotechnology strategies are yet to include these four areas that remain the most significant regarding application areas, scope, and impact.

## **Global biotechnology evolution**

While the term biotechnology revolution has been popularised in the past three decades, the actual growth of the sector has maintained its predicted outcome in market size and growth, specifically in medical research and innovation.<sup>7</sup>

In the contemporary world, popular biotechnology has been deeply rooted in its genetic perspective of disease. Biotechnology already includes other sectors, even if they are derivative of gene engineering with large-scale impacts.<sup>8</sup> One of the biggest contenders in the biotechnology revolution is the European Union (EU), which has been the third-largest market in

the biotechnology sector since 2012.<sup>9</sup> From 2012 till 2018, the EU was responsible for approximately 13 per cent of global medicine production.<sup>10</sup>

Countries such as South Korea, Singapore, and especially China, have significantly invested in their biotechnology sectors. China's rapid growth and large-scale investment in biotechnology have influenced its position as the second most influential global leader in biotechnology.<sup>11</sup> Estimates suggest that Chinese governments have invested over US\$100 billion in life sciences research and development.<sup>12</sup>

## Quad countries and their strategies

Globally, specific guidelines apply to the biotechnology industry and impact all four Quad<sup>i</sup> countries — Australia, the US, Japan, and India. These include the BWC and the Cartagena Protocol for biosecurity.<sup>13</sup> The Convention on Biological Diversity (CBD) and the Nagoya Protocol overlook biodiversity and trade.<sup>14</sup> Further, the World Health Organisation (WHO) has highlighted guidelines on global biobanking, and biological lab safety post the COVID-19 pandemic.<sup>15</sup> Aside from these overarching guidelines, each Quad country has its regulatory approach to the biotechnology revolution.

The principal regulations in the field of biotechnology in Australia begin from the need to govern bioprospecting<sup>ii</sup>, and oversee gene technologies and environmental impact. Like Australia, India has also established good governance in the fields of genetic enhancement and engineering, environmental impact and pharmaceutical production.<sup>16</sup> In 2022, India also established its first mobile biosafety lab.<sup>17</sup> Japan, similarly, has well-established governance for its pharmaceutical sectors, and the US has led the global biotechnology industry consistently for the last decade.<sup>18</sup>

Overall, each Quad nation plays a distinct role in biotechnology. Australia excels in agricultural biotechnology and regenerative medicine, but requires help in commercialisation. Japan has a national bioeconomy strategy and aims to become a global leader, while the US is already a dominant force in biotech across various sectors. India is rapidly expanding its biotech sector, focusing on healthcare and agricultural challenges, and becoming a bio-manufacturing hub.<sup>19</sup>

## Recommendations for enhancing the biotechnology revolution

The Quad countries are well-established in biotechnology and have comprehensive regulations. Specific areas can use more attention to enhance this status and achieve more significant growth in the biotechnology revolution, these include:

### Data sharing for the bioeconomy

The first recommendation is in the fundamentals of the biotechnology sector, that is, data use and sharing. While the Quad countries are all undersigned in the CBD and the Nagoya Protocol, they can establish data-sharing guidelines that ensure equitable representation of the global South in the sharing of biological data, the fair use of this data and the return of research outcomes or sharing of profits with the sources of biological data.<sup>20</sup>

Data sharing — which will help foster research, development, and bioproduction data — requires increased investment. Increasing the capacity for bioproduction can directly influence the bioeconomy of each country.

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<sup>i</sup> The Quadrilateral Strategic Alliance

<sup>ii</sup> Bioprospecting is commercialising new products based on biological resources, such as medicines and agrichemicals.

Bioproduction is also heavily inclusive of genetic engineering, including modified crops and animals to increase the longevity of life and resistance to disease for the two. Bioproduction and agriculture involve the application of biotechnology in enhancing agricultural practices and improving industrial processes. Genetic modification of crops plays a substantial role in increasing agricultural productivity. The global agricultural biotechnology market size in 2022 stood at US\$32.1 billion and is set to reach US\$77.4 billion by 2032, nearly doubling in under a decade.<sup>21</sup>

Data sharing is very closely linked to bioproduction and agriculture, and enhancing this field through the Quad's platform will help grow the vertical beyond its current trajectory. Government incentives, industry-academia collaboration, and intellectual property protection can help achieve this goal. Creating scope for international trade, knowledge-sharing, and cooperation can further enhance this.

### **Establishing standards for genetic engineering and synthetic biology**

In the last decade, with the introduction of automation, artificial intelligence (AI), and machine learning (ML), genetic engineering has advanced to include rapidly generated chemical compounds that save on workforce and work hours, data storage solutions such as DNA storage, organoid intelligence, and even manufactured organisms like Xenobots.<sup>22</sup>

In 2018, the WHO established an Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing and, in 2021, launched a governance framework for genome editing.<sup>23</sup> The Quad can leverage its alliance to represent common interests to the WHO and create guidelines in genome editing to make a foundation for global genome editing norms, and ethical guidelines that allow for equitable benefit sharing and research in medical applications and innovation.

### **Revitalising the Australia Group for biosecurity and biosafety**

Finally, there is a need to include biosecurity and biosafety more explicitly in global norms and guidelines. The Australia Group already represents all four Quad countries, and many others undersigned in the BWC, Cartagena Protocol, and Nagoya Protocol. The same group can also add to its focus a need for global biosafety standards in biosafety labs, especially level 3 and level 4 for biosafety labs (BSL3 and BSL4). Additionally, the Australia Group can grow to include other Indo-Pacific countries, including Indonesia, Vietnam, South Korea and others. This will help address a significant global gap faced by the biotechnology research sector due to the non-participation of countries leading in the biotechnology field, like China, giving smaller countries in the Quad a more significant platform, enhancing existing standards set by the WHO and ISO for the private sector.<sup>24</sup>

## Notes

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## About the author

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## About this paper

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## About the Quad Tech Network

The Quad Tech Network (QTN) is an initiative of the NSC, delivered with support from the Australian Government. It aims to establish and deepen academic and official networks linking the Quad nations – Australia, India, Japan, and the United States – in relation to the most pressing technology issues affecting the future security and prosperity of the Indo-Pacific.

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