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SYNTHETIC BIOLOGY, AI AND AUTOMATION:
A FORWARD-LOOKING TECHNOLOGY ASSESSMENT

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Abstract

Synthetic biology harnesses and redesigns biological systems to drive innovation across a broad range of sectors, including health, agriculture, and production. It is increasingly integrating with artificial intelligence tools like large language models and robotics to accelerate innovation, improve accessibility, and enable more complex applications. Guided by the OECD Framework for Anticipatory Governance of Emerging Technologies, this report provides a strategic intelligence assessment of this convergence, laying out several concrete cases of where the technology is and how it could develop in the future. It identifies the governance implications (e.g. biosecurity and biosafety, data supply chain, human oversight) with accompanying policy options for each to guide policymakers on potential future actions. The report recommends further analysis on a range of issues due to policy importance and high uncertainty, such as forward-looking monitoring of the technology's development, agile and anticipatory governance, and leveraging spaces for international collaboration.

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This report is compiled by Douglas K. R. Robinson, Daniel Nadal, and Sari Hagimoto of the OECD's Science and Technology Policy Division, with the support of Alessandra Colecchia, David Winickoff and César Barraza-Botet. The authors wish to thank the experts consulted for their invaluable contributions across the in-person workshop, webinar, additional calls, and valuable written input. They have contributed in their personal capacity, and their input does not necessarily represent the views or positions of the organisations with which they are affiliated. A full list of experts is provided in the Annex.

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Note from the Secretariat

Synthetic biology has been identified as one of the key emerging technologies under examination within the Committee for Scientific and Technological Policy's (CSTP) Programme of Work and Budget (PWB) for the 2025–2026 biennium [DSTI/STP(2024)6/REV1], building on the foundations established during the 2023–2024 cycle [DSTI/STP(2023)12].

To advance understanding and policy dialogue in this field, the Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT) has undertaken several important initiatives. These include the May 2023 workshop *Engineering Biology: Scoping Developments and Policy Themes* [DSTI/STP/BNCT(2023)8/REV1], the Global Forum on Technology event *Building Our Biofuture* held alongside the CSTP Ministerial Meeting in April 2024 [DSTI/STP(2024)18], and the flagship report *Synthetic Biology in Focus: Policy Issues and Opportunities in Engineering Life* [DSTI/DPC/STP(2024)7/FINAL].

A key conclusion emerging from these efforts is the need for deeper analysis of the growing convergence between synthetic biology and digital technologies, particularly artificial intelligence (AI) and robotics. This report responds to that need by providing a forward-looking assessment of this convergence—referred to as SynBioxAI—and by exploring its policy implications. It examines the preparedness of existing governance ecosystems and contributes to ongoing reflections within the BNCT Secretariat, including the prospective development of an OECD Recommendation for Responsible Innovation in Synthetic Biology [DSTI/STP/BNCT(2025)2].

The insights presented here aim to equip policymakers with timely strategic intelligence on these rapidly evolving technologies. They support anticipatory governance by helping decision-makers understand emerging trends, assess potential benefits and risks, and identify opportunities to steer innovation towards socially desirable outcomes.

This report represents an initial diagnostic step within the OECD Framework for the Anticipatory Governance of Emerging Technologies, laying the groundwork for future action and policy development in this transformative domain.

Executive Summary

Synthetic biology seeks to harness and redesign biological systems, or compounds derived from them, to advance research and development in fields as diverse as health (e.g. genetically engineering human cells to treat diseases), agriculture (e.g. genetically modifying plants to express desirable traits), and production (e.g. biomanufacturing substances of interest via genetically altered microbial cells). In recent years, synthetic biology has been increasingly integrating AI technologies like Large Language Models (LLMs) and AI-augmented biodesign tools, as well as robotics and automation. This convergence is improving accessibility to the technology, accelerating the pace of innovation by streamlining the Design-Build-Test-Learn cycle, and increasing the complexity of what is possible – resulting in potential benefits and risks.

This report provides a forward-looking strategic intelligence assessment of this convergence between synthetic biology, AI, and automation—collectively referred to in this report as SynBioxAI. The analysis serves as a preliminary diagnosis of this area of convergence, guided by the *OECD Framework for Anticipatory Governance of Emerging Technologies*, with the goal of identifying governance challenges, policy opportunities, and areas that may require further strategic (policy) intelligence.

The report observes a number of trends stemming from SynBioxAI convergence:

- **Technological convergence is accelerating research and innovation:** SynBioxAI is already transforming R&D across sectors and is likely to be further augmented by convergence with automation. This is seen particularly through the development and use of tools such as LLMs, AI-augmented biodesign, automated biological research systems, and biofoundries, which are tackling, or improving response to, existing research bottlenecks and technical challenges.
- **Global challenges are policy drivers to advance biotechnology solutions**: Climate change, health crises, and food security are reinforcing the strategic importance of SynBioxAI for sustainable and resilient systems. The opportunity cost of not engaging with these innovations needs to be balanced with assessing and mitigating potentially negative impacts of their use.
- **Agile governance requires assessment:** Adaptive and proportionate governance is essential to keep oversight and risk mitigation in pace with the speed of innovation (i.e. 'pro-innovation regulation'). Identifying whether there are any overlaps or gaps between synthetic biology and AI regulations, and if so aligning them, could help address risks like dual-use, biosecurity and biosafety. Post-market surveillance may also detect and respond when issues arise, and human-in-the-loop systems are needed to create safeguards for automated research infrastructures.
- **Access and (re)use of high quality aggregated data is essential to develop robust AI models:** Aggregating enough data to avoid bottlenecks calls for addressing fragmentation, promoting high-quality curated datasets with long-term sustainability, and balancing openness with security.
- **Technology sovereignty and research security are an increasing concern:** Securing national innovation capabilities in this competitive and geopolitically sensitive field is key, whilst also mitigating misuse of open-source tools and protecting proprietary technologies from malicious actors.

- **Educational and workforce shifts are inevitable and require management:** New interdisciplinary skills are needed at the intersection of biology, computer science, engineering, and assessment. In addition, science and technology studies, social sciences and humanities can provide vital inputs to policy. Promoting development of these skills (e.g. via job retraining, dedicated curricula, etc.) could help avoid workforce bottlenecks.
- **Many unknowns exist around longer-term foundational research, where additional structured anticipation may be needed.** Potentially transformative research areas include synthetic cells (fully artificially-built living organisms) and digital twins of biological systems. These developments call for anticipatory risk and opportunity assessment as well as public dialogue.

The report provides a number of further actions that could inform and support policy making in, and anticipatory governance of, the convergence of SynBioxAI:

- Initiate **future oriented technology monitoring, assessment and foresight exercises** across value chains to keep abreast of SynBioxAI developments, explore plausible future scenarios of their evolution and implications for the economy, security (research, technological and national), society and the environment.
- Promote **international collaboration** on data-sharing infrastructures and standards (including data interoperability). These remain largely underdeveloped but are urgently needed given the rapid digitisation of biology.
- Support and pilot **agile policy mechanisms** (e.g. regulatory sandboxes) to test adaptive governance approaches that can reduce regulatory bottlenecks and keep pace with the expected rapid development of SynBioxAI.
- Continue improving **biosecurity and biosafety practices**, such as integrating more sophistication in risk management approaches (e.g. nucleic acid screening). Ensure that robust science-based biosafety strategies that anticipate and mitigate potential risks on human and environmental health are in place before considering release of synthetic organisms or their products outside the laboratory. Anticipate on issues related to longer-term research pathways with higher uncertainty trajectories, such as synthetic cells.
- Explore the **(dis)incentive structures for open vs closed research**, AI models, and databases. A better understanding of the trade-offs in different contexts could inform policies, particularly with a view to balancing research and technology security with economic competitiveness, growth and scalability, and fair access across populations and locations.
- Encourage **public and expert dialogues** to assess ethical boundaries and societal values, particularly on the transformative potential of AI-augmented design of functional synthetic organisms.
- Invest in **interdisciplinary education and workforce transformation** to avoid future talent shortages and maximise the potential of SynBioxAI.

Table of contents

Tables

Figures

Boxes

1 Introduction

Synthetic biology promises to revolutionise a range of sectors, and is in fact already providing much needed solutions, from treating infectious and non-communicable diseases in healthcare, to improving food systems security via drought-resistant crops, to enabling industry's shift to sustainable biomanufacturing for environmental sustainability[1]. Innovation in these applications is being further accelerated by synthetic biology's convergence with artificial intelligence tools like machine learning, as well as accompanying digital technologies like robotics and automation, and in the future even with quantum technologies[2] - expanding the boundaries of what is possible.

At the same time, new challenges are arising from the increased democratisation of synthetic biology knowledge via AI tools, greater availability of open-source data and increased reliance on digital tools, and the possibility of automating the research process. Powerful innovations could be more easily leveraged by nefarious actors which increase biosecurity risks, and opaque algorithms and training data sets could enhance existing biases and divides. Future frameworks, such as the planned OECD Recommendation for Responsible Innovation in Synthetic Biology, should recognise and mitigate these risks to ensure the technology develops in a positive direction and fosters a future where all can benefit.

In the *OECD Framework for Anticipatory Governance of Emerging Technologies* (OECD, 2024[1]), there is a recommendation to undertake a preliminary diagnosis before investing in deep-dive strategic intelligence gathering for extended appraisal of technologies with regards to governance. Since off-the-shelf evidence is not directly available yet, this report presents a forward-looking technology assessment to help inform this preliminary diagnosis and to identify avenues of further work.

This report first unpacks the scope of synthetic biology convergence with AI, automation and robotics (SynBioxAI),. Five illustrative examples of SynBioxAI research and technology are selected to showcase the technology's state of play and where it could be heading, grounded in the context in which it is emerging to better flesh out the tensions, obstacles and policy opportunities. These include: accelerating research and development via AI-augmented biodesign tools and biofoundries; embedding into and transforming value chains; education and skills; beyond containment (the release of genetically modified organisms outside of laboratories); and long-term transformative and enabling research.

Seven implications for governance are then identified and unpacked, with accompanying policy options suggested for each to guide policymakers on potential future policy actions. These include: pro-innovation regulation; biosecurity and biosafety; data supply chain (e.g. production, access, use, protection); regional disparities; human oversight; technology sovereignty; and research security.

This is followed by a section dedicated to the "preliminary diagnosis" of the convergence of synthetic biology, AI and automation, mobilising the six dimensions of diagnosis, outlined in the *OECD Framework for Anticipatory Governance of Emerging Technologies* (see Annex A for details). The report concludes with a section identifying key areas potentially in need of further strategic policy intelligence followed by concluding remarks.

What is Synthetic Biology x AI x Automation?

There is no internationally agreed definition for synthetic biology, but it is understood as a **multidisciplinary area of biotechnology that seeks to harness and redesign biological systems,** or compounds derived from them, to fulfil new functions and meet human needs in research and product development[3]. It builds upon well-characterised applications such as human cells genetically engineered to target and treat diseases (Irvine et al., 2022[2]); genetically modified plants expressing desirable traits (Khan et al., 2019[3]), or microbial cells genetically altered to produce chemicals of interest in biomanufacturing settings (Cho et al., 2022[4]); but also goes beyond these, with new-to-nature genetic material and the future creation of new life forms like synthetic cells.

The last two decades of biological research have seen the rise of big data, for example via 'omics technologies': the use of experimental tools like high-throughput sequencing to measure the molecular composition of biological systems like cells and tissues. This includes measure gene data (genomics), proteins (proteomics) and RNA (transcriptomics), as well as integrative omics which combine several measurements for a fuller picture of their interactions (Dahal et al., 2020[5]). This unprecedented level of granularity has provided scientists valuable new insights into cellular mechanics, but making sense of such large amounts of data can be complex (Ahmed et al., 2024[6]).

AI advances like machine learning (ML), including large language models (LLMs), are offering new tools to synthetic biologists to generate new insights from large amounts of data. For example, LLMs can summarise complex research papers or propose experimental lab protocols, whilst AI-augmented biodesign tools can design molecules with novel properties and increased specificity in shorter timeframes. These applications are generally categorised as either **general-purpose technologies** (e.g. LLMs which collect and process vast amounts of existing natural language data) and **specialised biological tools** (e.g. biological design models trained on biological datasets that can make predictions and generate new data).[4] [5] This distinction is not always clear-cut and may be a source of debate, but it is also critical as each poses different technological and governance opportunities and challenges: they may have different levels of market concentration, degree of algorithm openness, or face different constraints in the availability of suitable training data (e.g. natural language data is more widely available than structural protein data).

In combination with **automation tools like robotics and high-throughput (i.e. rapid) technologies,** many steps in the scientific research process are getting closer to becoming highly automated: robots could carry out experimental steps like sample preparation and liquid handling, processing large amounts of samples, and collecting and analysing large volumes of data (Carter et al., 2023[7]). This could help improve speed, accuracy and reproducibility of experiments involving repetitive tasks and reduce human burden. In fact, there are already dozens of biofoundries across the world that aim to integrate these technologies into large-scale modular research facilities to optimize biological research workflows (Global Biofoundries Alliance, 2022[8]). However, it should be noted that technologies progress at different paces: subsets of robotic technologies have been in use for years (e.g. liquid handlers), whilst integration of individual robotic equipment for fully automated processes with no human intervention is still challenging,.

Altogether, these convergences are driving trends of **improved accessibility** (for both specialised and non-specialised users), **accelerated pace of innovation** (streamlining and automating the Design-Build-Test-Learn cycle for reduced time and costs in research and development), and **increased complexity** (creating complex virtual models by processing larger volumes of data).

2 Locating the transformative potential

Five examples of SynBioxAI research and technology are selected to illustrate the state of play and where the technology could be heading in the future. These developments are grounded in the context where they are arising to better map out the opportunities, tensions and obstacles. A brief analysis of the policy drivers directing the evolution of these technologies, namely a series of global challenges, can be found in Annex A.

Accelerating research and development

The integration of AI with synthetic biology is transforming R&D by accelerating design, optimization, and production of biological systems. AI-driven tools facilitate predictive modelling, rapid iteration cycles, and automation, with a potential to significantly reduce experimental costs and time.

AI-Augmented Biodesign Tools

Computational tools are increasingly being used to help predict molecular structures and their interactions at a fraction of the time and cost of traditional methods. Scientists previously relied on extensive wet-lab experimental efforts to understand the structure and behaviour of biological molecules and circuits, and whilst AI cannot yet fully replace them, AI models fed large biological datasets can identify and replicate design patterns in nature. For example, Google DeepMind's AlphaFold can accurately predict the 3D structure of proteins based solely on their amino acid sequence (Jumper et al., 2021[9]), and their latest model can even predict the structures and interactions between proteins and other biomolecules, like DNA and RNA (Google DeepMind and Isomorphic Labs, 2024[10])[6].

AI-augmented tools can design biomolecules with highly targeted and novel functions. They can streamline genetic engineering by allowing researchers to design, simulate, and test biological constructs in silico before physical assembly. For example, Benchling**,** a cloud-based platform, provides an integrated suite for DNA sequence design, annotation, and collaboration, promising to improve efficiency and to reduce human error (Casas, Bultelle and Kitney, 2024[11]). Generative design tools can create sequences to yield molecules with optimised properties (e.g. improved expression rate, compatibility across microorganisms, stability, 3D structure….), including new-to-nature ones[7] - for example, CAMEOS is a computational model that can help researchers design gene sequences with increased stability (Blazejewski, Ho and Wang, 2019[12]). In biomedical applications, this high degree of customisation allows for generated sequences that are personalised to match individual genetic profiles, potentially increasing treatment effectiveness and reducing side effects (Taherdoost and Ghofrani, 2024[13]). However, whilst these computational simulations could help reduce time, costs, and the need for extensive lab work, results still need to be validated experimentally.

Computational models can also help design the cellular processes to generate biomolecules of interest. Genetic circuits and metabolic pathways – the interacting biological elements in a cell that make

it function - are essential for programming cells to generate biomolecules. Optimizing these for efficiency, yield and stability over time is key for product viability, especially if they are to be scaled up for commercial manufacturing. AI tools can help design and test approaches for these desired outcomes. For example, Cello is an open-source software tool that constructs artificial gene circuits leveraging a library of DNA parts as Boolean logic gates (Jones et al., 2022[14]).

AI agents are being developed to become 'artificial assistant scientists' that could support humans throughout the research process. Solutions like FutureHouse are developing AI models that could mine current scientific literature to extract connections between ideas and help human scientists generate new hypotheses, design experiment protocols and help analyse results, automating parts of the research cycle and accelerating the process (Skarlinski et al., 2024[15]).

Biofoundries

A biofoundry is an advanced, automated facility designed to accelerate synthetic biology research and biomanufacturing by integrating high-throughput robotics, automation, and computer-aided design tools (Global Biofoundries Alliance, 2022[8]). These facilities aim to streamline the Design-Build-Test-Learn cycle, to enable the rapid development of engineered microorganisms, genetic systems, and biologically derived products across industries such as healthcare, agriculture, and bioenergy. Biofoundries could be used to advance research that in turn aims to address critical global challenges like pandemics, climate change, and food security by enhancing the speed and scalability of biotechnology innovation. Their key advantages include automation-driven cost reduction, high-throughput scalability, and a collaborative ecosystem that fosters interdisciplinary innovation. Additionally, they aim to democratise access to cutting-edge biotechnology, enabling smaller startups and researchers to leverage advanced infrastructure without massive capital investment (Holowko et al., 2021[16]), although issues such as sustainability (see Box 1.2.) and funding remain.

Biofoundries require significant upfront investment but their long-term operational costs, such as staffing and equipment maintenance, represent the biggest cost. Academic and national biofoundries, like the London Biofoundry or K-BioFoundry, tend to benefit from continued public, institutional and grant funding to maintain their activities. Private biofoundries, on the other hand, may struggle without continuous financial backing and may need to incorporate functions as Contract Research Organizations (CROs): offering paid research services to private or academic institutions looking to accelerate their research (Holowko et al., 2021[16]). Efforts like the Global Biofoundries Alliance and the Global Center for Biofoundry Applications are fostering international partnerships across biofoundries to exchange best practices and develop common metrics and standards, to address common challenges and support scalability (Duncan, 2024[17]).

Box 2.1. Case Study: Shenzhen Biofoundry

Shenzhen Biofoundry is a major project funded and developed by the Shenzhen municipal government and led by the Shenzhen Institute of Advanced Technology (SIAT) in the Chinese Academy of Sciences. Its primary goal is to establish a synthetic biology research platform that supports both academic research and industrial applications (SSBI, 2024[18]). It is structured around three main platforms: design and learning, synthesis and testing, and user testing - the first of which uses AI, bioinformatics, and big data to develop customized experimental solutions (SIAT, 2020[19]). Unlike other biofoundries, such as iBioFAB (University of Illinois) and EGF (University of Edinburgh), which are typically established and operated independently by universities and research institutions, Shenzhen Biofoundry benefits from strong government backing and strategic investment (Guomiao et al., 2023[20]). Like other research institutions in People's Republic of China (hereafter China), Shenzhen Biofoundry may incorporate elements of the "civil-military fusion" concept, which could enable dual-use applications of its technologies in both military and civilian sectors (Weingarten, 2024[21]).

With strong government support, a focus on international collaboration, and the integration of diverse research platforms and data analysis technologies, Shenzhen Biofoundry presents an advanced example of biofoundries' potential. It is a member of the Global Biofoundry Alliance (GBA), collaborating with similar facilities worldwide to advance synthetic biology on a global scale (Global Biofoundries Alliance, 2022[8]).

Source: OECD Research.

Embedding into and transforming value chains

The convergence of AI and synthetic biology is profoundly changing multiple industries, helping enable smarter, faster, and more sustainable production systems. By integrating AI-driven insights and computation modelling with genetic engineering, industries ranging from pharmaceuticals to materials and energy are aiming to optimize efficiency, sustainability, and scalability.

In healthcare, integration of SynBioxAI in drug discovery and development is addressing key inefficiencies in current approaches, potentially helping meet the growing demand for therapeutics and accelerating responses to health crises[8]. The pharmaceutical industry faces significant challenges, including long development timelines, high costs, and high failure rates in clinical trials (Schlander et al., 2021[22])[9] as the complexity of biological systems makes it difficult to predict how effective and safe new drugs will be. AI is helping by analysing vast genetic datasets and compound libraries to predict targets, potential drug-target interactions, and optimising lead compounds, thereby reducing reliance on costly and time-intensive high-throughput screening and expediting the identification of promising drug candidates (Saltonstall, Ross and Kim, 2024[23]) (Schneider et al., 2020[24])[10]. Additionally, AI-driven computational modelling can enhance molecular behaviour predictions (Puniya, 2025[25]) and ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) properties, enhancing drug safety assessments and minimizing late-stage failures (Cáceres, Tudor and Cheng, 2020[26]). These insights can shape the selection and development of drug candidates that can then be produced by synthetic biology, including precision-targeted biologics and cell-based therapies. A recent pioneering example is Insilico Medicine's use of AI to identify both the drug target and drug molecule, taking under 18 months and at a tenth of the cost of conventional programs (Insilico Medicine, 2025[27]) (Fatima, Allami and Yousif, 2023[28])[11].

Food production and agriculture applications of synthetic biology, such as engineered microbes and crops, are being streamlined and accelerated by AI. Genetic engineering has been used to create

nutritionally enhanced food sources - for example, fermentation processes with engineered microbes to produce high-quality, functional ingredients that improve the flavour and nutritional value of various foods (Hyde, 2024[29]) including plant-based meats (Liu et al., 2023[30]), or plants engineered to produce essential nutrients typically found in animal-based foods (Jiang et al., 2024[31]). This not only improves and diversifies food products, but could also potentially contribute to reducing traditional animal farming. Synthetic biology has also been used to create crops with desirable traits (e.g. drought tolerance, improved yield) (Voigt, 2020[32]), and the growing integration of AI to assist these processes has for example helped identify target mutation sites in microbes and crops or predicted outcomes of genetic changes (Zhang et al., 2025[33]).

The materials and chemicals sectors are using SynBioxAI to develop innovative and environmentally sustainable production methods and products. Biocatalysis, which employs engineered enzymes to accelerate chemical reactions, has been advanced by synthetic biology (Currin et al., 2014[34]) and is now being significantly enhanced by AI-driven design to achieve more efficient and sustainable production. For instance, ML-guided enzyme engineering has facilitated the creation of biocatalysts capable of forming amide bonds, a fundamental reaction in green chemistry (Sandalow, 2025[35]). SynBioxAI is also being used to optimize the engineering of microbes and cell-free systems to synthesize products (e.g. platform chemicals, plastics) from biological feedstocks rather than petroleum (Burgos-Morales et al., 2021[36]), including using waste materials (Pirie, 2025[37]), thereby reducing dependence on fossil fuels, decreasing environmental pollution, and contributing to a circular economy.

Box 2.2. Driving a Sustainable Bioeconomy

Synthetic biology is supporting sustainability efforts by fostering a bioeconomy that replaces fossil-based products with biologically derived alternatives - such as fuels, plastics, or chemicals. This transition is crucial in combating climate change, as bio-based materials can significantly reduce carbon emissions and mitigate environmental degradation. Biomanufacturing, accelerated by AI, is rapidly gaining traction as a more sustainable alternative to traditional manufacturing (Ólives, 2024[38]).

However, the high energy consumption by computers running AI models poses a sustainability challenge. Training a single large AI model can emit over 500 metric tons of CO_2, equivalent to five cars' lifetime emissions (Cho, 2023[39]), and in the U.S. AI-related electricity consumption is expected to quadruple by 2030 (Alastair Green, 2024[40]). AI's growing carbon footprint could offset the environmental benefits it could enable in the bioeconomy, but solutions like renewable energy-powered data centres and improvements in algorithmic efficiency are being ideated to mitigate these issues.

Existing initiatives recognise this challenge and illustrate how AI and synthetic biology can work together sustainably. The Biofoundry of Sorbonne University Alliance – one of four sites that make up the Paris Biofoundry – specialises in engineering photosynthetic organisms that use atmospheric CO_2 as the sole source of carbon, leading to a greenhouse gas footprint below neutrality and the claim to be the "*first green biofoundry in the world*" (Paris Biofoundry, 2024[41]).

Source: OECD Research.

Education and skills

AI tools are starting to reshape education and training, making advanced synthetic biology knowledge and techniques more accessible. The use of LLMs to simplify content, develop personalised curricula, answer questions, and draft reports is becoming increasingly common in many education settings. Many academic institutions are embracing the use of AI to assist with learning and enable guided

access to new technologies. However, many teachers still lack training or clear frameworks for integrating AI effectively into curricula. Ethical concerns such as plagiarism, data privacy, and transparency in content generation remain unresolved, while unequal access to digital tools may deepen existing educational inequalities. Furthermore, LLMs can generate inaccurate or biased content that students may struggle to evaluate critically and distinguish from AI hallucinations[12], and overreliance on such tools risks weakening essential thinking, writing, and problem-solving skills[13]. Understanding these technological limitations and which skills still need to be taught is an ongoing process (Samson and Pothong, 2025[42])[14].

AI and automation tools are influencing how laboratories operate, shifting the skills needed by researchers. In some academic research laboratories, there is an increasing shift from using bioinformatics solely in the latter stages of research to analyse results, towards incorporating it in early experiment stages to design or troubleshoot laboratory protocols and components (Götting et al., 2025[43]). This trend could intensify as more advanced AI systems for experimental design and analysis are developed. These developments are changing the skills needed by scientists, requiring further multidisciplinarity: software engineers and life scientists often work together to develop computational tools for synthetic biology, fostering a collaborative culture of recombination across knowledge fields. Experts therefore note a growing need for new profiles, including specialists that can communicate and translate between interdisciplinary teams, but these unique profiles are often developed on the job and may leave a skills gap if they decide to change employers. Governments and regulators may also need to strengthen their expertise to keep policymaking informed by, and in pace with, technology development[15].

To what extent new AI tools will overall lower barriers of entry to synthetic biology is a subject of debate, and the impact will likely be different for general purpose technologies and specialised tools. Publicly available LLMs – and future specialised AI systems designed for scientific research assistance – are increasingly capable of extracting and summarising information from research papers and respond to user questions, which as they become more polished could make scientific information more widely accessible to broader audiences. AI biodesign tools, on the other hand, may still require advanced training to operate and particularly to interpret and implement the design suggestions they generate (e.g. to set up the experimental conditions to produce a chemical of interest). These issues could be discussed as part of broader societal debates on the desired level of bioliteracy.

Beyond containment

Whilst synthetic biology research and deployment has mostly focused on developing microorganisms for contained applications (e.g. vat fermentation for production of specific chemicals or molecules), there have already been some early examples of deliberately-released modified organisms (Robinson and Nadal, 2025[44]). As with the release of any genetically modified organism (GMO) into the environment, robust science-based biosafety strategies that anticipate and mitigate potential risks on human and environmental health are necessary. It is anticipated that in the future, risk analysis and mitigation can be supported by the deployment of AI and digital tools, and the implementation of innovative biocontainment methods.

Regulatory science could benefit from AI models to enhance the speed and robustness of risk assessments. Current GMOs regulations call for risk assessments based on empirical research (such as monitoring applications in the environment or controlled experiments) before unconfined releases to mitigate risks to humans and the environment. However, these empirical assessments can be slow, cumbersome and limited in scope. By leveraging AI's ability to analyse large datasets and predict outcomes, risk prediction models could be developed that better predict the interaction of GMOs in nature and their evolution over time (although this would require further data on environmental interactions). Once developed, such tools could help scientists and regulators make more informed and timely decisions, and develop more effective communication to inform communities potentially impacted by environmental

releases. However, challenges such as limited data availability, algorithmic bias, and building trust in AI-generated results remain to be addressed (Mmbando, 2024[45]).

Biocontainment – strategies for improved safety and control of modified organisms in the environment – could be improved by AI-enhanced foundational research. This research domain has been ongoing for decades, with scientists proposing and testing multiple strategies to act as failsafes and improve risk considerations for modified organisms: genetic kill switches (which trigger organism death in response to selected stimuli or environmental conditions), synthetic auxotrophs (organisms engineered to rely on an externally supplied nutrient to survive) and barcoding (introducing short artificial genetic sequences for monitoring and identification). However, the robustness of these control strategies requires further improvements, as environmental pressure and evolutionary mutations can overcome controls (Mandell et al., 2015[46]). AI can be a tool in further research into more robust solutions, for example through the identification of frequently occurring evolutionary escape pathways, or by optimizing the design of biological circuits using neural networks (Merzbacher, Aodha and Oyarzun, 2023[47])[16].

Biocontainment is relevant not only when synthetic biology products are being intentionally released into the environment by well-intentioned actors complying with existing regulatory frameworks, but also in instances of unintentional release of modified organisms from labs. In this latter case, and also when nefarious actors purposefully release bioweapons as a biosecurity threat to societies, **biosurveillance is one of the first lines of defence against biological threats**: collecting intelligence on potential biological threats, including early detection, to improve our understanding and speed of response, either by security organisations or academic institutions (The White House, 2012[48]). Over the past decades, automated biohazard detection systems have been in use for decades to monitor environmental samples for known harmful biological agents and infectious diseases (for example in hospitals or city water supplies), such as the U.S. BioWatch system or the CDC's National Wastewater Surveillance System (NWSS). These detection systems traditionally relied on local sample collection followed by laboratory assays, necessitating several hours for results (Institute of Medicine and National Research Council Committee on Effectiveness of National Biosurveillance Systems, 2011[49]), whereas modern commercial applications now enable automation, remote sampling and real-time analysis (Kraken Sense, 2024[50]). Further advances in biosensors – living organisms engineered to detect specific chemicals or organisms – driven by AI could allow for faster analysis of more complex data and identification of insights and patterns, which could be further expanded by using other technologies like the Internet of Things (IoT).

Identifying whether a biological threat is natural or man-made could inform response strategies and support accountability. Existing methods to detect bioengineering are limited, costly and time-consuming. New computational tools have the potential to address some limitations. For example, the U.S.'s Intelligence Advanced Research Projects Activity (IARPA) established the Finding Engineering Linked Indicators (FELIX) program with the aim to improve detection capabilities for bioengineered organisms. Two tools were developed to support technicians in detecting such microorganisms within a complex environmental sample, with a 70% accuracy rate (Draper, 2022[51]). They rely on comparing the genomes of sample microorganisms to the species' reference (unmodified) genomes to detect potential signatures of genetic engineering. Further R&D is needed to address technical limitations. In addition, determining a sample has been bioengineered does not necessarily attribute it to an actor or imply it was developed as a bioweapon, and more holistic investigations into real-world circumstances would still be needed (Mullin, 2022[52]), which may call for investment into law enforcement capabilities.

Long-term transformative and enabling research

AI and automation technologies have the potential to accelerate foundational developments in synthetic biology, not only increasing our basic understanding of biological systems but in turn also enabling new applications. Long development time frames and unclear outcomes create a higher degree of uncertainty.

Whilst most current genome editing applications are limited to modifying existing organisms, assembling biological components could generate synthetic cells, creating life from scratch. Although the field is far from developing fully autonomous self-growing and evolving cells, some proto-innovations have already been demonstrated: scientists have mimicked cellular properties of CO_2 fixation in liquid droplets (Miller et al., 2020[53]) and even created vesicles which could produce anticancer proteins inside tumours as therapeutics (Krinsky et al., 2017[54]). There is great foundational knowledge to be gained from understanding how cells, and by extension life, is structured. More practically, artificial cells could be more malleable, expressly designed to perform a single, highly-specific function more efficiently – as opposed to "traditional" engineered cells which still have many unrelated processes in the background[17]. (Adamala et al., 2024[55]). **Beyond this bottom-up approach, synthetic cells could also be built in top-down fashion.** For example, scientists have experimentally replaced a bacterium's genome with a fully chemically synthesised replica of another bacterial species' genome. The modified cells not only survived and self-replicated but also adopted the donor species' features (Gibson et al., 2010[56]). Another top-down approach is minimal cells - systematically knocking out genes to retain only those essential for survival - to better understand genes' functions and the processes that regulate life (Xu, Hu and Chen, 2016[57])[18].

Digital tools could be developed to create virtual models - so-called 'digital twins' - of cells to potentially simulate, predict, and steer their behavior. Large amounts of data points (e.g. multi-omics and high throughput technologies measuring at the resolution of single cells) could be combined with AI and spatial technologies (which map molecular data spatially) to create 3D virtual models of cells that can simulate their functioning. Crucially, these digital models aim to predict not only how a cell would respond to a treatment but also identify the mechanism behind the response (DeepLife, 2022[58]). This work does not limit itself to cells, as researchers have already developed whole-organism digital simulations for the worm model organism *C. elegans* (albeit with model simplifications) (Zhao et al., 2024[59]). Yet organisms are extremely complex, with countless reactions and interactions taking place simultaneously, and there are currently too many knowledge gaps to develop a fully operational digital twin (Wu and Koelzer, 2024[60])[19].

Emerging concepts like mirrored life, which might eventually be accelerated by AI tools, pose critical risks that require anticipatory risk analyses and societal deliberations. Most biomolecules can exist in two mirrored forms, with each chiral image having different properties. Key molecules for all life on Earth have the same chirality: DNA and RNA are "right-handed" whilst amino acids are "left-handed". Scientists have already synthesized alternate chirality molecules to advance our foundational understanding of chirality and in view of developing potential applications like therapeutics, but developing microorganisms that have complete alternate chirality is decades away. Anticipating this future, researchers under the auspices of the *Mirror Biology Dialogues Fund* published an article in 2024 highlighting the risk such organisms could pose to natural ecosystems, food chains, and human health in the event they were not contained in a lab. The group therefore called for a ban on mirrored life research, and going forward are supporting multistakeholder dialogues on this topic to promote understanding of the research's implications and the development of practical governance frameworks that address these challenges (Adamala et al., 2024[61]) (Mirror Biology Dialogues Fund, 2025[62]).

Many of these research paths revolving around creating synthetic life and changing the known structures of life forms raise ethical considerations. The main concerns around synthetic biology - from moral obligations towards engineered and artificial life to the unknown long-term impacts of research – have been described (Kriebisch et al., 2025[63]). The novel long-term foundational advances accelerated by convergence with AI and automation detailed in this section introduce novel uncertainties not yet fully explored and reflected upon by society, and thus likely necessitate transparent communication and re-engagement with stakeholders about desirable goals, the means to achieve them, and the ethical boundaries of large-scale design of nature. These conversations should be informed by historical experiences.

3 Governance Implications and Policy Options

The examples above aim to illustrate where converging SynBioxAI technologies are heading, grounded in their development and application contexts. Enabling the secure and sustainable implementation of these future visions, however, will require identifying the governance implications and addressing the challenges. These are unpacked in this section, with a non-exhaustive series of policy options suggested for each to guide policymakers on potential future actions.

Pro-innovation regulation

Governance of synthetic biology converging with artificial intelligence does not start from zero. Many jurisdictions have had extensive regulation on synthetic biology products for decades (e.g. EU GMO legislation originated in 1990, and other regulatory frameworks for chemicals or biologicals may also be relevant), and a growing number of regulatory initiatives on AI are arising in recent years (from safety institutes to soft law approaches to regulation)[20]. Combined with standards, self-regulation, and other soft law approaches, existing frameworks are likely to cover most foreseeable applications of SynBioxAI, particularly as the use of AI in biotechnologies has been considered in recent policy work: the EU's AI Act includes in its scope applications in drug discovery[21], and the U.S. 'America's AI Action Plan' contains biosecurity provisions like nucleic acid synthesis screening measures[22]. Therefore, to what extent SynBioxAI developments warrant updating existing regulation remains to be examined. Targeted national legal reviews[23] could identify regulatory overlaps, grey zones and gaps to inform future policymaking efforts to avoid duplication, close regulatory gaps, and ensure coherence. These should explicitly consider dual-use risks, the regulation of biological data, and the oversight of relevant AI tools, and more broadly take into account the fragmented approaches pursued in different countries and internationally (e.g. the OECD's AI and biotechnology governance work[24], or that of the UN Convention on Biological Diversity (CBD) on synthetic biology).

At the same time, there may be a challenge in bringing together the different cultures of self-regulation and norms of synthetic biology and AI. AI technologies have developed at breakneck speed in the last few years, developing commercial applications rapidly with limited oversight ("*move fast and break things*"). On the other hand, synthetic biology, as a sector within biotechnology, has a long history of governance and oversight, including self-regulatory initiatives like the moratorium on recombinant DNA research that scientists self-imposed in 1975 (Cohen, 2025[64])[25]. Their convergence will bring these divergent cultures of self-regulation together. This applies, for example, to both investors (used to the rapid development and limited oversight of AI innovations, will be faced with longer timeframes for development and deployment in synthetic biology due to increased regulatory oversight and the less linear nature of R&D) and governments (where environmental safety, health technology assessments, and AI regulators may work separately). Accounting for these diverging cultures may be key to develop robust and workable guidance, soft laws and regulation – and also offers an opportunity for each field to learn from the other.

Recent global trends are include governance approaches that simplify existing regulations to promote technological innovation that aims to support societal goals (Draghi, 2024[65]) (OECD, 2025[66]). In synthetic biology, for example, the UK's Regulatory Horizons Council (RHC) recommends that technologies in early development stages are only governed by self-regulation and flexible soft laws (e.g. standards, guidelines) rather than hard laws in order to not excessively disrupt their evolution (Regulatory Horizons Council, 2025[67]). Whether such approaches underestimate potential safety and security risks for consumers and the environment, or whether these recommendations stem from the accumulated regulatory experience with biotechnology products, is an ongoing debate within the community with no consensus yet among experts and regulators who were involved in the preparation of this report.

In times of polycrises, enabling policy proportionality and directing for societal goals could potentially foster useful technological innovation. Risk identification, management, and mitigation are key to safely develop technologies. It is important to contextualise the benefits and risks with accompanying solutions and safeguards, and note the underlying positive transformative potential of SynBioxAI and thus the opportunity cost of not pursuing it. Hardwiring directionality into R&D to guide technology development towards achieving desirable societal goals, and mitigating any impacts from the technology that might compromise them, is a key ongoing challenge. Concepts like Safe-by-Design, Safer Innovation Approach, and Responsible Research and Innovation are increasingly being adopted[26]. It may also involve embedding proportionality into governance: if applications of SynBioxAI research could help tackle grand global challenges like climate change or pandemics, should streamlined regulatory approval (that also maintains strong safety considerations) be favoured? An example would be the U.S.' 'Operation Warp Speed', which helped speed up the development COVID-19 vaccines by allowing pharmaceutical companies to run parallel studies and leverage additional data sources during regulatory assessment (GAO, 2021[68]).

Agile, adaptive and anticipatory governance processes may offer solutions. These shift the focus from managing downstream risks towards upstream engagement of stakeholders involved in the innovation process itself to anticipate and mitigate issues. Examples such as the Proportionate and Adaptive Governance of Innovative Technologies (PAGIT) (Tait, 2024[69]) or the OECD Framework for Anticipatory Governance of Emerging Technologies (OECD, 2024[1]) may be appropriate. As SynBioxAI convergence matures, it may call for further reflections on its governance architecture: who is engaged, who makes decisions, and who ensures accountability? Regional and international fora (like the OECD) may play a role in facilitating discussions, sharing norms and promoting interoperability across jurisdictions.

Table 3.1. Policy options for pro-innovation regulation

Sub-topic	Policy option	Opportunities	Consideration
Fragmentation	Targeted national legal reviews to map where synthetic biology and AI regulations overlap and where gaps exist	Existing regulations in synthetic biology and AI likely already cover SynBioxAI applications, but reviews could clarify whether updates are necessary to avoid duplication and ensure coherence.	Consider fragmented approaches pursued in different countries, as well as international efforts (e.g. OECD work on AI and biotechnology governance, or the UN CBD on synthetic biology).
Learnings exchange	Create metastructure to collect and share lessons from governance efforts in synthetic biology and AI, perhaps hosted internationally at the OECD or CBD.	Bringing together the differing governance cultures in synthetic biology and AI may at times be a source of tension, but also offers opportunity for each field to learn from the other.	For example, the proliferation of AI safety/security institutes may inspire efforts in synthetic biology to promote research on governance issues and facilitate discussions.
Agility and anticipation	Apply agile and anticipatory governance processes, as well as Safe-by-Design, Safer Innovation Approach, and Responsible Research and Innovation.	Shifting focus from managing downstream risks towards upstream engagement of stakeholders in the innovation process to anticipate and mitigate tech development issues.	Existing examples can be learned from: the Proportionate and Adaptive Governance of Innovative Technologies (PAGIT) and the *OECD Framework for Anticipatory Governance of Emerging Technologies.*

Source: OECD Research

Biosecurity and biosafety

AI tools like LLMs and AI agents promise to democratise synthetic biology knowledge and capabilities, potentially lowering the barriers of entry to the field. While this could support students and researchers in their work, it could also be leveraged by nefarious actors for harmful purposes, such as developing toxins or pathogens with pandemic potential and successfully executing a biological attack (Persaud et al., 2025[70]). It is still a matter of debate how much these biosecurity risks and uplift in capabilities already go beyond those from existing tools like the internet (Peppin et al., 2024[71]), with some studies suggesting interventions may be needed (Brent and McKelvey, 2025[72]) whilst risk assessments from AI developers believing it is not yet enough to warrant drastic concerns (Anthropic, 2025[73]) but still implementing security standards (Anthropic, 2025[74]). This may evolve as AI tools further develop. Fortunately, the implementation of AI-generated synthetic biology designs would still require the transfer of in silico-derived designs into the physical world (i.e. molecules, organisms), requiring laboratory and production infrastructures and financial resources, offering additional opportunities for safeguards.

Safeguards accounting for user intent could assist in better assessing biosecurity risks, for risk management to not impede positive innovation. Some oversight systems may have traditionally focused more on assessing a technology's potential for harm (e.g. if a genetic sequence encodes a toxin) than querying what the end use may be. However, the risk if an order for a genetic sequence is made by a well-known researcher at a public university is likely lower compared to if it were made by an unknown individual with no affiliation, because the intent would be clearer. Similarly, understanding the user's intent when interacting with a generative AI model (e.g. by looking at the original prompt) could provide clarity on the degree of risk. This suggests that more sophisticated frameworks for assessing user intent (such as contextual metadata, behavioural indicators, and credentialing systems for customer screening) could contribute to improving risk management strategies, accounting for privacy and personal data protection considerations. This aligns with recent international guidance[27] which emphasise the importance of combining sequence-based screening with user and order context analysis.

Balancing the degree of openness of AI models for synthetic biology is an ongoing challenge. A biosecurity-by-obscurity approach may suggest closed models that could limit access of sensitive tools to vetted users (or block data on sensitive biological agents) and reduce the risk of nefarious actors using them. At the same time, open-source models can not only encourage transparency and trust, but also collaboration and peer-review that would improve the efficacy of the tools and allow for collaborating in risk identification and mitigation. AlphaFold is a prominent example where its open-source nature helped improve its robustness (Domínguez, 2022[75]). Finding the right balance is a constant challenge for developers but approaches like built-in guardrails and tiered access (e.g. high-risk functionalities accessible only to users with credentials) are being ideated (Carter et al., 2024[76]). It could also depend on the level of risk foreseen for applications via robust risk assessment (i.e. high-risk tools may require additional security features than low-risk ones), but baseline governance criteria for open-source AI models in biotechnology could be defined on traceability, reproducibility, and dual-use mitigation features.

Building a generative culture of responsibility is a key safeguard for biosafety and biosecurity. Whilst every stage of research and development should incorporate safety and security requirements (e.g. lab safety checklists), these 'compliant cultures' alone could prove cumbersome for researchers and leave gaps. Achieving an appropriate level of safety may require these government regulations to be combined with building a generative culture of responsibility, where researchers take initiative to identify and mitigate risks and integrate biosecurity and biosafety into design considerations. Strengthening this culture would also support robust biorisk management, which is critical for addressing risks such as laboratory leaks or unintended environmental release[28]. This approach can be more effective but more difficult to achieve, and would likely require a balance of bottom-up and top-down efforts, and even rely on engagement from a broad range of partners. For example, industry procurement guidelines could require buying supplies only from companies confirmed to follow certain security guidelines.

Nucleic acid synthesis screening

Nucleic acid synthesis can be considered the interface between the digital and physical realms of synthetic biology, and thus a key target for biosecurity policies. Many efforts are underway to support screening of gene synthesis orders, including private and governmental efforts, and ranging from voluntary frameworks to guidance and mandatory requirements[29]. Current approaches tend to rely on homology of requested sequences to known dangerous sequences, to identify when a suspicious order is being placed. However, it is not as straightforward, as sequences from dangerous agents can be used for benign applications and sequences from benign agents can be hazardous.

AI-powered biodesign tools pose new risks for synthesis screening, as they could design genetic sequences with low homology to known sequences that still produce proteins with similar structure and function to knowns dangerous proteins, thus evading existing screening systems. This calls for training such tools to overcome heightened risks of AI-generated sequences[30]. Since no screening technique is infallible, and as AI-powered tools increase in complexity and capability, holistic ecosystem-wide strategies (e.g. incorporating customer screening measures, engaging new players like manufacturers of benchtop synthesizers, etc.) may be needed to raise sufficient barriers against misuse and ensure maximum safety (Wittmann et al., 2024[77]). Although difficult to achieve in practice, in the future more sophisticated approaches could focus on identifying "functions of concern" that consider the environmental and cellular contexts in addition to the genetic sequence for more informed decision-making (EBRC, 2025[78]).

Policy efforts may consider diverging national ecosystems and legal frameworks. Not all countries have nucleic acid synthesis providers within their borders; purchasing structures may be different; and regulations may be more or less prescriptive – all of which impact the reach of governance solutions. Further mapping of these divergences could inform future discussions, building on existing work such as the Global Health Security Index[31]. Another area for review and modernisation could be import and export controls, which could for example also become more sophisticated in assessing the actual risks posed by genetic sequences, but this may call for further technical guidance on biosecurity screening of AI models. Furthermore, differences between national regulatory regimes are causing confusion for researchers on whether a sequence or pathogen is regulated, and further clarity from export control authorities could make safeguards more aligned and therefore robust whilst maintaining support for innovation (Jacob, 2024[79])[32].

Table 3.2. Policy options for biosecurity and biosafety

Sub-topic	Policy option	Opportunities	Consideration
Risk management	Incorporate more sophistication in assessing user intent to more accurately determine risk level.	Could involve developing harmonized guidelines, including baseline requirements for provider due diligence, and sharing best practices in customer screening and 'know your customer' approaches.	Institutional affiliation is one potential metric of intent – likely lower risk from orders made by well-known researchers than individuals with no affiliation – but not the only parameter.
Responsibility	Build a generative culture of responsibility by growing researcher awareness.	As it is difficult to oversee every researcher, a generative biosecurity and biosafety culture aims to empower individual researchers' to be aware of security and safety concerns and favours proactive safeguards on their end.	Engagement of professional societies, funding agencies and institutional leadership will be critical to balance bottom-up and top-down approaches. Considered as a complement to regulation, not a replacement.
Biosafety	Invest in regulatory capacity (e.g. funding, public-private partnerships) to future-proof risk assessment	Ensures expertise for robust risk analysis of speedy and complex innovation, fit-for-purpose regulatory exercises, and supporting deployment of safe, beneficial innovation.	Could involve exchanges and mutual learning between regulators and innovators, shaping innovation development from design stage to facilitate its regulation.
Nucleic acid synthesis	Establish holistic, ecosystem-wide strategies for sequence- and customer- screening guidelines, which account for novel risks posed by AI.	Creates a set of best practices that countries should adopt to provide clarity and guidance to relevant actors	Account for countries having different regulations and infrastructures for purchasing nucleic acids (no one-size-fits-all approach); for all players in the ecosystem (e.g. benchtop synthesis device manufacturers, biofoundry alliances); and incentives for companies to

			comply. Use existing regulations and frameworks as lessons.[33]

Source: OECD Research.

Data supply chain

Training AI algorithms for synthetic biology requires large amounts of high-quality curated biodata, but this is currently a major bottleneck. Although increasing digitalisation and automation of the field are increasing the amount of data generated, the data is often fragmented in silos (across government projects, private research institutions and industry), under different ownership, annotation, standards, and with varying levels of security.

Supporting data generation, aggregation and use is key and is underpinned by common data sharing infrastructures and standards[34]. Infrastructures are composed of common hardware, software and guidelines that enable researchers to share and reuse data. Currently, these are often small and independently developed and housed by government bodies, private institutes or NGOs, each following different standards (what data, in what format…) developed in-house. Because of this fragmentation, data collected is not interoperable between structures and is of varying degrees of quality, making it harder to aggregate for training AI models (NSCEB, 2024[80])[35]. Beyond developing structures for aggregating data, it may also be useful to improve curation: training better models does not always require more absolute data but rather more high-quality, curated datasets. Engaging researchers to identify which subsets of data would be most promising and focusing on standardising those may be most efficient path forward.

Lessons can be learned from previous infrastructure successes, like the Protein Data Bank and the ensuing protein structure prediction tool AlphaFold. Its development was only possible thanks to the large amounts of aggregated and expertly curated structural data in the Protein Data Bank (PDB), the accompanying standards, its global and open access nature, and the scientific journals' requirement for researchers to make their data publicly accessible in the PDB (Callaway, 2024[81]). This masterclass in data set creation was a long-term (originally ideated in the 1960s) and expensive government-funded initiative (although generating a return on investment of over 1,500 times the federal funding) (Sullivan, Brennan-Tonetta and Marxen, 2017[82]), which has been difficult to replicate for other applications. Whilst there are a lot of data types available (e.g. genetic data), they do not exist in the same highly curated and standardized format as the PDB, and it is difficult to predict which will be the most successful. Instead of burdening the organisations hosting them with complex funding applications, policymakers may wish to develop a mechanism to identify promising efforts and proactively support them. Furthermore, not all applications are equal: AI for structural biology is arguably easier to develop (e.g. collect protein structure data, develop a data set, train a model, compare against clear benchmark) than more complex applications like virtual twins of cells. This highlights the continued need for foundational and practical research[36].

Novel technological approaches could help tackle the data bottleneck, but are still in their infancy. Synthetic data – artificial data generated by AI models to complement real world datasets – could help increase the necessary amount of data for training models in a cost-effective manner and with reduced privacy implications[37]. It could even be developed with purposefully improved diversity so as to reduce bias of trained models (Oren and Di Cerbo, 2024[83]), but the risk of artifacts and bias remains, and thus its long-term positive impact on AI models may be limited (Shumailov et al., 2024[84])[38]. As with any emerging technology, it would be responsible to consider the danger of progressing too quickly down a research route and being locked in[39].

Evaluation and hardware also present limitations to synthetic biology and AI convergence. Common quantitative and qualitative benchmarks provide valuable feedback on the performance of AI models and help identify the most promising ones. For example, the regular Critical Assessment of protein

Structure Prediction (CASP) competitions were instrumental in showcasing the accuracy of AlphaFold in comparison to competing models (Stevens and He, 2022[85]). Whilst there are small-scale competitions for other applications like protein design, they are not yet as widespread. They also open questions around the best approaches for evaluating models: who would be responsible and involved, and how they could affect model development in the long-term (e.g. narrowing down innovation paths, impacting via web scraping). In addition, there are still limitations from hardware to be improved upon. For example, AI can rapidly generate new genetic sequences, but these still need to be physically produced and are experimentally limited in length to around 200 nucleotides (Song et al., 2021[86])[40].

The success of any data policy in synthetic biology hinges on enforceability, and public and political support. There are already many policies in place to promote the accessibility and freedom of data – for example, researchers receiving public funds often must make their data public - but these may not always be strongly enforced or impact private sector research[41]. Furthermore, whilst government funds have great power in that they can be conditional on supporting societally desirable outcomes (e.g. building public data banks), funding agencies need to balance that with achieving their core funding missions (e.g. supporting cancer research). The trade-off between the two also depends on the level of political support for these parallel objectives, which can be influenced by public and provider trust in the technology. This in turn can be shaped by whether these applications are perceived to be in the public interest, and how this is defined and operationalised[42]. Beyond setting and enforcing policies, there is an important role for measuring impact - for example tracking whether publicly shared data is being accessed and by who, to identify and tackle bottlenecks.

Open vs closed data sets and models

Open versus closed access to biodata and derived algorithms is a trade-off driven by a combination of factors, from biosecurity to economic competition. Closed models may more easily prevent misuse by nefarious actors, as well as protect intellectual property interests and maintain profitability that drives innovation. However, open models may be more trusted, support broad validation and thus be robust and competitive. AlphaFold, for example, was open source which helped it become more accurate than alternative models (Domínguez, 2022[75]). **Promoting transparent and inclusive datasets is not only beneficial for innovation but also to ensure responsibility.** Opaque data sets and algorithms can create a problem if they are not representative of all populations and thus could enhance biases. The potential rise of biodata monopolies that control access to crucial biodata could potentially dictate research and limit paths. Presently, existing large datasets in the synthetic biology space (e.g. ELIXIR and EMBL-EBI) tend to be public and following FAIR[43] principles, but this may not always be the case as AI's different culture and norms become more present, and may need to be preserved as a governance objective.

How innovators can balance transparency and building trust in their solutions whilst maintaining biosecurity and profitability that drives innovation is an ongoing discussion. There shouldn't be an assumption that open source is by default the most desired option by users; some will prioritise having a tool that works well over being able to access its code. Companies are trying to find the balance by, for example, maintaining some secrecy over intellectual property but still publishing white papers on new algorithms and working collaboratively, and keeping open the possibility of wider release in the future. Data labels are another option, endorsing that data sets or algorithms meet a series of criteria (e.g. inclusive, fair return of benefits, high quality, etc.), which could either be adopted voluntarily by private actors or mandated in public projects.

Table 3.3. Policy options for data

Sub-topic	Policy option	Opportunities	Consideration
Aggregation	Support efforts and develop incentives for data generation, aggregation and use, including common data sharing infrastructures (e.g. data from publicly funded projects to be shared into a government-run, accessible repository)	Targeting data silos is key to obtain enough high-quality data to train AI models. Learn from successful experience of the Protein Data Bank which enabled AlphaFold.	Obligations can be set on publicly funded projects but sharing of privately funded data may require incentives. Engage researchers to identify which subsets of data would be most useful and focusing standardization of those may be most efficient path forward.
Standards and benchmarks	Encourage international standards (e.g. ISO) for data formats and benchmarks for evaluation of AI models in synthetic biology (e.g. protein structure prediction, sequence design…).	Internationally agreed data standards would support aggregation and sharing, whilst quantitative benchmarks would facilitate comparison between models to support the most successful ones.	Learn from successful examples in other fields (e.g. DICOM for medical imaging)[44]. Standards can also lead to restriction towards certain innovation paths, so consider (e.g. who is included) when developing.
Open vs closed models	Landscape examples of open and closed datasets and models to compare differing incentives and outcomes	Mapping drivers could help policymakers understand incentives and policy levers available to them.	Factors affecting decision over open vs closed models (e.g. IP, biosecurity, trust...) will be different for different models.

Note: Additional suggestions to policymakers on promoting the sharing, (re)use, and governance of data can be found in several OECD Council Recommendations, such as: Recommendation of the Council on Enhancing Access to and Sharing of Data [OECD/LEGAL/0463]; Recommendation of the Council concerning Access to Research Data from Public Funding [OECD/LEGAL/0347]; Recommendation of the Council on Health Data Governance [OECD/LEGAL/0433], etc.
Source: OECD Research.

Regional disparities

Countries are at different stages of maturity of SynBioxAI research, development, assessment and governance, and will likely need to follow different development paths. Some areas of the world are still focused on developing their nascent synthetic biology ecosystems, much less moving towards convergence with AI. For example, synthetic biology in some developing countries is still primarily limited to academic environments. There are thus still efforts needed to support basic synthetic biology education, research, and private investment that form the foundation for SynBioxAI technologies and governance to develop in the future. Furthermore, current AI ecosystems are concentrated within developed economies (Yu, Rosenfeld and Gupta, 2023[87]), and their infrastructure cannot easily be replicated worldwide (e.g. meeting their high computing and energy needs). Equity in this dimension is also critical to ensure the transition to more digital and AI-enhanced synthetic biology does not further limit access to scientific research in developing economies. This suggests countries may wish to pursue different paths, including potentially leapfrogging some stages. Understanding how this could be done in practice would require further comparative research on different regional approaches, unique opportunities and challenges[45].

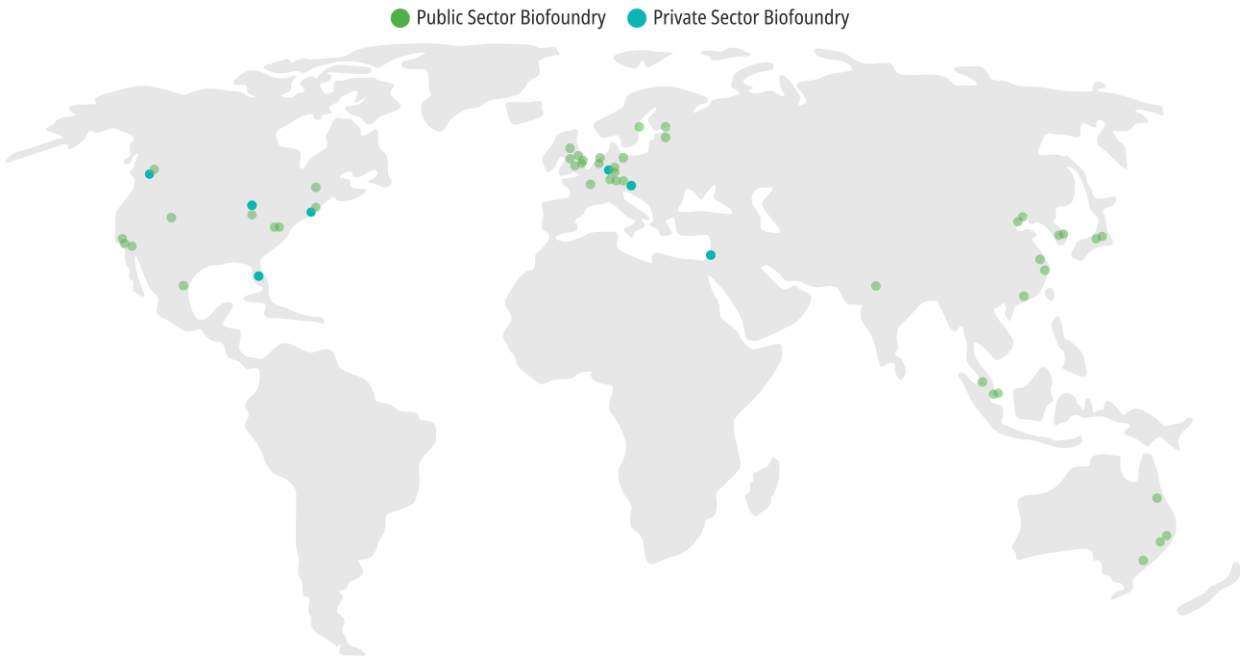
Analysing the reasons for diverging capacities between and within countries, as well as what factors lead to innovation clusters, offers valuable lessons. Biofoundries, largely absent in the low- and middle-income economics, provide an example of technological divides in the synthetic biology and AI sectors. Five interdependent factors have been identified in the literature that lead to capacity differences in biofoundry infrastructure:

1. **Investment levels** play a critical role, as countries with higher public and private investments in biotechnology tend to have more advanced and numerous biofoundries (Hillson et al., 2019[88]). For example, the U.S., U.K., and China lead in biofoundry presence due to robust funding initiatives and long-term R&D commitments.
2. **Entrepreneurial culture** significantly impacts biofoundry development. Nations like the U.S. have well-established venture capital infrastructures that encourage risk-taking and support the

commercialisation of biofoundry-related innovations, whereas risk-averse economies may lag. (François Candelon, 2022[89]))

3. **Critical density of expertise**, as biofoundries thrive in areas with a high concentration of skilled professionals in synthetic biology and related disciplines. Proximity to leading research institutions creates hotspots of innovation (e.g. London, Boston, and Shenzhen) (French, 2019[90]).
4. **Conducive policy and regulatory environments**, with supportive government policies, streamlined regulatory requirements that do not impair safety and security, and initiatives like tax incentives promoting biofoundry development. Conversely, countries with complex bureaucratic hurdles often struggle to build or scale biofoundries (Watkins et al., 2023[91]).
5. **Geopolitical and socioeconomic factors**. High-income nations benefit from economic and geopolitical stability that enable sustained investments, whereas developing economies may face difficulties in allocating resources for synthetic biology infrastructure. Additionally, conflict-free societies with strong trade links and international partnerships often create environments conducive to scientific collaboration, and technological advancement, whilst regions experiencing political instability might struggle to attract investment and expertise (Dixon et al., 2022[92]).

Figure 3.1. Global distribution of biofoundries



Source: OECD

Funding and investment are a major challenge. Developing countries and smaller economies have limited funds to build and maintain R&D infrastructures, often making them more risk averse and dependent on second hand knowledge and equipment. Finding ways to maximise returns on limited amounts of money and scaling institutions efficiently is key. It could involve finding and exploiting niches in the global synthetic biology and AI sectors, leveraging unique local attributes, fostering regional partnerships, or creating enabling policy environments (e.g. risk-based safety and containment requirements to lower costs). In addition, the investment cultures in synthetic biology and AI are very different, with the former requiring more patient financing to reach commercial stage and compounded by synthetic biology being perceived as a higher risk investment[46].

Indigenous knowledge and rights, as well as benefit sharing, need a space in an AI-enhanced bioeconomy. Biological data used to train algorithms should be broadly representative (e.g. include data from developing economies and indigenous communities) to ensure models can benefit them and are not biased against them. At the same time, those who generate this data deserve to be fairly rewarded for it - especially if an AI model goes on to make profit. Data ownership and fairness are complex and political issues, and call for cross-border and multistakeholder engagement on disparities in access, capacity, and influence in innovation. Discussions on the topics of access and benefit-sharing and digital sequence information on genetic resources (as well as broader synthetic biology issues) have been ongoing in several international fora, including the UN CBD and its Nagoya Protocol[47]. Their worldwide representation, multistakeholder expertise and institutional memory make them the appropriate setting for these discussions and policymakers may wish to dedicate enough resources to advance them.

Table 3.4. Policy options for regional disparities

Sub-topic	Policy option	Opportunities	Consideration
Disparities	Continue fostering foundational synthetic biology research and education in countries with nascent SynBioxAI ecosystems.	Opportunity for countries to 'leapfrog' but need to better understand how this can be done in practice.	Include research and education on governance, risk assessment and regulation. Consider limitations from AI infrastructure needs (e.g. energy demand).
Local innovation clusters	Landscape successful policy incentives for regional development e.g. smart specialisation strategies. Collect best practices on developing Centres of Excellence.	Innovation clusters facilitate collaboration and pushing tech frontiers. Supportive policy environments (e.g. meeting infrastructure needs, regulation) are needed to foster them.	Clusters arise from a variety of factors described above and therefore take years to develop, but countries may develop roadmaps based on successful examples.
Biofoundries	Foster collaboration and best practice sharing between established biofoundries and LMICs wishing to develop them.	Supporting more geographical diversity in biofoundry distribution would allow countries to find niches to contribute to the global economy and increase supply chain resilience.	Issues in developing biofoundries are often more about limitations of local resources and infrastructure, so increased knowledge sharing would not be a silver bullet.
Indigenous knowledge and rights	Political support to UN CBD process on benefit sharing and indigenous knowledge and rights.	Leverages existing fora with global representation and multistakeholder expertise, and builds on years of existing discussions and relationships.	Maintaining a broad array of perspectives represented is crucial.

Source: OECD Research.

Human oversight

Convergence between synthetic biology and digital tools could lead to fully automated labs with limited human supervision. Whilst much innovation is still needed to achieve this future vision, one could envision biological facilities where computational tools and robotics drive the entire Design-Build-Test-Learn cycle: LLMs could identify hypotheses by analysing research papers and design the experiments; biodesign tools could design the biological components; robotic arms and high-throughput equipment could run experiments and collect data; which could then be analysed by AI algorithms. From a technical perspective, human input in such an infrastructure may only be needed to supply external resources (e.g. reagents) and provide maintenance. Whilst keeping humans out of these systems may allow for greater pace and even complexity of research, there are limitations and risks to be aware of and mitigated.

Human-in-the-loop systems aim to find the best balance between full automation and targeted integration of human input. Below is an illustrative, non-exhaustive list of possible sites for human intervention, building on existing literature (Price, Crootof and Kaminski, 2023[93]).

- **Legal liability and moral accountability** - If an AI system were to cause harm, it would not be the algorithms or robots that would be held legally and morally accountable, but rather the human

actors involved in the AI system's lifecycle (i.e. those developing, deploying and operating AI). This aims to ensure that those who design or run systems consider safety precautions. However, for the human-in-the-loop to not simply be a designated scapegoat, they must be well-informed of algorithmic decisions and have the authority to approve or override them to avoid harm[48].

- **Resilience and cyberbiosecurity** – In case of emergencies like natural disasters or malfunctions, humans could act as a failsafe to pause systems. Similarly, in the context of a hijacking to produce nefarious substances, humans-in-the-loop could be part of a broader cyber firewall to detect and stop malignant behaviour.
- **Transparency** – Understanding the reasoning behind algorithmic decisions is not always straightforward, which raises ethical questions. Human involvement could seek, interpret and provide justifications for AI decisions. This may be technically difficult (e.g. in black box models) and care should be taken so that the human does not become a simple mouthpiece [49].
- **Ethics and value judgement** – Humans-in-the-loop could help enforce ethical considerations and that agreed-upon values are respected throughout automated processes. Such oversight could ensure algorithms do not objectify humans and preserve dignity. For example, AI systems trained on biased data sets may inadvertently show biased results, and it may be up to human oversight to identify and correct this. By deliberately slowing down research (playing a 'friction role') humans can stop dangerous undesirable research paths before they are taken.
- **Provide directionality** – Even if all practical research steps can be delegated to algorithms and robotic parts, the actual aims of the research can still be set by humans. They can provide the context for why innovation is needed, linking it to broader societal goals and limitations. Researchers' time could be less spent on daily technical tasks and more focused on big-picture thinking, enabling an accelerated pace.
- **Driving societal acceptance** – Research decisions understood, corroborated and guided by humans could be more trusted by society, thus less likely to face opposition, and whose applications may be more likely to be taken up.

Supporting society-wide deliberations and bringing in the unique impacts on synthetic biology research will be key to foster a responsible transition. As the integration of AI and automation in synthetic biology research and industrial applications is still developing, the impacts are not yet fully understood. They will also not affect everyone in the same way: technicians' work may be more easily replaced by automation than managerial positions; early-career researchers coming up in a digital environment could adapt more easily than senior ones. Whilst there will likely be unique considerations in the field of synthetic biology, much will echo broader societal debates related to the roles of humans in more digitalised and autonomous societies (e.g. autonomous driving) - how to ensure responsible retraining, how these systems can complement researchers' work rather than replace it, and how to leave space for human dignity and fulfilment.

Table 3.5. Policy options for human oversight

Sub-topic	Policy option	Opportunities	Consideration
Human-in-the-loop	Develop legal understanding of legal liability in autonomous models in different jurisdictions.	Unclear legal standing may hinder innovation in the space for fear of future liability issues.	It may take legal challenges for clarification and legal precedents to be set, but a proactive approach could avoid issues.
Societal visions	Organise broad engagement exercise on desirable future roles for humans in AI systems.	Proactively understanding what a broad positive vision of the future is can shape the design stage of new systems.	Need to engage broad range of stakeholders: civil society, bioethics experts, developers, etc.
Ethics	Consider involving independent ethical review boards in development of SynBioxAI tools.	Provides a structured framework for evaluating AI decisions, ensuring compliance with bioethics standards.	Represents additional cost and may be inaccessible to SMEs. Risks slowing down innovation or concentrating it in large companies.

Source: OECD Research and (Price, Crootof and Kaminski, 2023[93]).

Technology sovereignty

Increasing geopolitical strategic competition is impacting technology development and accompanying policies. Given rising geopolitical uncertainties, global conflicts and supply chain disruptions, countries are increasingly seeking to reduce their reliance on others to safeguard their economic and national security. The COVID-19 pandemic and the ensuing supply chain disruptions, for example, showcased how fragile value chains could lead to critical medicine shortages. Scientific and technological innovation, as a motor for societal development and wellbeing, is at the heart of this policy shift to tackle vulnerabilities (OECD, 2023[94])[50].

Both synthetic biology (or related terms like life sciences, biotechnology or engineering biology) **and AI are recurrently listed as critical or key enabling technologies in national strategies and R&D priorities for many major economies[51]**. These explicitly highlight how synthetic biology and AI are essential for countries' economic competitiveness and national security, and thus frame the challenges to their development and the accompanying policy solutions in the context of strategic competition.

Countries building strategically competitive synthetic biology and AI ecosystems face different challenges and opportunities. One of the key promises of synthetic biology is enabling decentralised manufacturing (optimised by AI), where local communities could turn local bio-resources like biomass feedstocks (e.g. sugarcane, cotton) into desirable products (e.g. bio-based chemicals, biofuels). However, not all countries have access to the same resources: countries like Japan or Korea have very advanced biotechnologies, but do not have the same bioresource production capacity of the United States or Brazil. The European Union, for example, has identified the lack of raw materials and thus dependence on external suppliers as a vulnerability for their critical technologies (Ramahandry et al., 2021[95]).[52]

Geopolitical competition is not only arising on technology development, but also on technology governance. Nations naturally strive to be at the forefront of technological innovation as it provides them a competitive edge (e.g. generates lucrative industries, attracts investment) and empowers them to dictate the direction in which a technology develops. However, countries are increasingly making efforts to also lead the establishment of governance mechanisms and shape the narrative. This can take several forms: high-level principles (e.g. Australia's AI Ethics Principles[53]), specialised bodies (e.g. AI institutes in United States, United Kingdom, Japan, Canada and Singapore[54]) and technical components like standards (e.g. the US National Institute of Standards at Technology's work on AI standards[55]). It is noteworthy that equivalent intensive governance efforts did not arise when synthetic biology first developed, perhaps as a reflection of today's increased geopolitical competition, or as a learning from technology experiences since.

Policies for technology sovereignty may be deemed essential at a time of increased geopolitical competition and uncertainty by national governments seeking to reduce dependencies and thus vulnerabilities, but the drawbacks should be noted and where possible mitigated. The globalised world order from previous decades allowed countries to share scientific and manufacturing knowledge, specialise in parts of the ecosystem and take advantage of economies of scale - making innovation and its deployment more efficient. Furthermore, new grand global challenges impacting all countries, from climate change to food and health crises, will most likely require cooperation to develop and implement solutions. A world order more geared towards strategic autonomy will have to find a way to balance strategic independence with the need to collaborate on common challenges (OECD, 2023[94]).

Some elements of technology development are suited for competition whilst others may require international alignment. For topics like industrial policy or data infrastructure, it may be inconsequential or even beneficial for countries to pursue or experiment with different governance approaches as it may provide learnings – whilst keeping in mind that bifurcated or competing governance approaches (e.g. on interoperability or privacy standards) can impact cross-border collaboration, scaling, and innovation. For other topics, like biosafety and biosecurity that regulate activities which could cause irreparable cross-border damage, there may be more of an imperative for internationally harmonised approaches to help

reduce risks. Since this may be difficult in times of geopolitical and economic competition, it may be necessary to leverage non-political actors that can rise above geopolitical tensions to help with international collaboration, such as biosafety federations. It would be useful in future work to unpack which topics within synthetic biology and AI convergence are most in need of cross-border alignment and which fora and actors are most suited for those conversations.

International organisations can play a key role in facilitating the international collaboration needed to govern the convergence of synthetic biology and AI at times of technology sovereignty. The Biological Weapons Convention, for example, has since the 1970s acted as the cornerstone of efforts to prevent the militarization and misuse of biological agents. The CBD, particularly via the 2000 Cartagena Protocol on Biosafety and 2010 Nagoya Protocol, has international agreements on modern biotechnology issues. The OECD has also been a key player: on synthetic biology, the concepts for safety assessment of recombinant DNA, set forward in the OECD's 1986 Blue Book and 1993 Green Book, are credited to have shaped early biotechnology standards and regulations (Matsuo, 2023[96]), whilst on AI it developed the world's first intergovernmental standard on AI[56] and established the OECD AI Policy Observatory to collect relevant data and policies from around the world. On broader emerging technologies, the OECD has developed several legal instruments providing principles and guidelines on how to foster responsible innovation in technology fields (e.g. data sharing[57] and neurotechnology[58]). The OECD's 2024 *Framework for Anticipatory Governance of Emerging Technologies* aimed to equip governments, innovators and societies to anticipate governance challenges and build longer-term capacities to shape innovation[59].

Table 3.6. Policy options for technology sovereignty

Sub-topic	Policy option	Opportunities	Consideration
Critical technologies	Governments to identify key enabling technologies for their societies, the challenges to develop them and thus the accompanying policy solutions.	Each country has unique assets and barriers to developing domestic technology ecosystems (e.g. raw resources, talent, infrastructure). Detailed understanding of these will helps policymakers develop targeted policy interventions.	Many governments have already developed lists of critical technologies, and some even have targeted studies on the challenges and solutions, which may offer valuable lessons to countries in their first attempt to develop these or those updating them.
International cooperation	Map where international collaboration is most needed, and which international fora would be most suited for supporting cross-border collaboration.	International fora provide the opportunity for countries to engage on common challenges and opportunities. Strategically identifying which topics are most ripe for collaboration, and which fora are most suited for those discussions, can help advance progress.	Some organisations have a broad membership whilst others group more like-minded partners. Some are more geared towards fostering conversations and international ties, whereas others have more technical purviews and enforcement power.

Source: OECD Research.

Research security

Research security has emerged as a critical concern for protecting scientific integrity and national interests. While the global research ecosystem can be supported by openness and collaboration, it also faces increasing risks of knowledge leakage, foreign interference, and cybersecurity threats. Safeguarding research infrastructures, controlling access to sensitive knowledge, and ensuring responsible international talent mobility are essential to fostering innovation while mitigating security risks (OECD, 2022[97]).

Whilst the free movement of researchers is vital for scientific progress, it also poses challenges regarding intellectual property protection and potential leakage and misuse of scientific advancements. There are growing concerns about unauthorized knowledge transfer, particularly in dual use fields such as synthetic biology. Several national policies now require stricter disclosures regarding affiliations with foreign entities, with some governments implementing screening mechanisms to assess risks associated with international collaborations. For instance, Japan's 2023 updated research integrity

checklist mandates institutions to independently verify researchers' affiliations (Government of Japan, 2023[98]), while Canada's 'Policy on Sensitive Technology Research and Affiliations of Concern' prohibits funding to researchers with ties to high-risk organizations (Government of Canada, 2024[99]). Although such measures can strengthen research security, international talent exchange can be key to innovation and thus balance with maintaining an inclusive and open research environment would be beneficial. Institutions have thus been advised to implement risk-based evaluation frameworks rather than blanket restrictions that could hinder scientific progress (League of European Research Universities, 2024[100]).

As educational and biological facilities become increasingly digitalised and automated, they become more susceptible to cybersecurity risks. In fact, AI has been recognised to facilitate malicious cyber activity by lowering knowledge barriers for ill-intentioned actors (UK DSIT, 2023[101]). The damage, destruction or theft of research systems or data could hinder scientific research in both public and private settings (OECD, 2022[97]). Furthermore, whilst most complex biofacilities (including those part of larger organisations like universities) generally already follow standard cybersecurity practices, cyberattacks in biological facilities could have disastrous economic, environmental and human health consequences if, for example, they overcame Biosafety Containment Level protections to deliberately release a toxic or infectious agent, or if production of critical substances like medicines was interrupted (Crawford et al., 2023[102]), or if fully automated biomanufacturing hubs were hijacked to produce hazardous agents.

International bodies, national governments, and research institutions are responding to increased cyberbiosecurity threats by developing new policies and guidance. The OECD, for example, has done extensive work in the broader domain of cybersecurity to find common overarching principles and best practices across member states on policy approaches for risk management and the digital security of critical activities, which are applicable to biofacilities among other sectors[60]. The WHO, in their 2024 update to the 2006 'Laboratory Biosecurity Guidance', included new reflections on cyberbiosecurity issues and potential control measures (WHO, 2024[103]). Domestic efforts, like the U.S. National Institute of Standards and Technology (NIST) Cybersecurity Framework or the EU Cyber Resilience Act, already seek to support actors across sectors in detecting, preventing and responding to cyber threats. It is unclear whether biofacilities like biomanufacturing plants require additional tailored technical advice on how to build and implement cybersecurity protections, but further work could aim to answer this. If this were the case, the responsibility and expertise to develop this guidance would lie in technical standards bodies, national cybersecurity agencies, and sectoral regulators, likely in consultation with other stakeholders like industry.

Table 3.7. Policy options for research security

Sub-topic	Policy option	Opportunities	Consideration
Talent security	Consider risk-based evaluation frameworks for research integrity and verifying researchers' affiliations (rather than blanket restrictions).	Blanket restrictions may hinder scientific progress, which has so far been supported by international talent exchange.	Aforementioned examples from Japan and Canada may showcase how policymakers could balance research security with an inclusive and open research environment.
Cyberbiosecurity	Leverage existing resources, principles and guidance to reinforce cyberbiosecurity, and explore whether tailored technical guidelines for biofacilities is needed.	Cyber risks will increase as biofacilities digitalize, which could have disastrous consequences in case of attacks. Identifying whether tailored guidance is needed could guide future work.	Most complex biofacilities likely already follow standard cybersecurity practices. There is already a wealth of resources available, including from the OECD, WHO and cross-sectoral regulation.

Source: OECD Research.

4 Preliminary Diagnosis

As described in the Introduction, the *OECD Framework for Anticipatory Governance of Emerging Technologies* recommends that preliminary diagnosis of the technology area of policy concern should be made to make a first-round assessment of the technology area and to articulate if and where a deeper gathering of strategic intelligence should be made. In this section, the six dimensions of a preliminary diagnosis are mobilised to make this first-round assessment. The next section will identify areas that may require deeper investigation.

Uncertainty

> ***Uncertainty***. *Are the trajectories of development clear? If there is uncertainty, how could it be reduced? A higher degree of uncertainty militates for a greater amount of intelligence gathering, societal engagement and/or upstream governance.*

General purpose AI models, as well as more specialized biodesign tools, are rapidly being rolled out in commercial applications. These are accelerating the pace and complexity of research, but the exact impact on certain areas - such as education and the shifting make-up of research labs - is not yet clear. Further integration of robotics and transitioning to fully automated workflows still requires significant efforts because these technologies are progressing at different paces. Early engagement with innovators and the public could help anticipate and direct that innovation in a desirable direction.

Uncertainty about technology development speed and direction is also being driven by external factors, such as increased global competition and trends towards technological sovereignty, strategic autonomy and resilience. Both synthetic biology and AI are often categorised as critical technologies by national governments, which may lead to protective policies such as limited data sharing or changes to regulatory regimes. This geopolitical competition is not just impacting technology development but also its governance, as countries seek to become first-movers to ensure their approaches are favoured across the globe.

Risk and scale of impact

> ***Risk and scale of impact***. *Despite uncertainties, how would we estimate/evaluate the potential impact of this technology on the foundational and technology-specific values discussed above -- from human rights and liberties to the environment, to human and or animal health and safety? How likely are the potential harms? How severe? How reversible?*

There are many promises to the convergence of synthetic biology and AI, but similar to any emerging technology there are potential risks to be understood and mitigated. These come in addition to well-characterised risks and mitigation measures associated with synthetic biology, such as the uncertainties around releasing GMOs into the environment and the need for risk analysis and management, and new more critical risks like the development of mirrored life. For example, AI tools like LLMs could increase access to synthetic biology knowledge or tools to help students and legitimate researchers, but could also empower nefarious actors and increase biosecurity and bioterrorism risks. Furthermore, as biological

facilities become increasingly digitalised and automated, they become more susceptible to cyberbiosecurity risks. In addition, applications designed for release into the environment would need robust risk assessments to identify and mitigate any biosafety risks.

Balancing openness of AI models with security is an ongoing challenge. More sophisticated safeguards - like better understanding of user intent instead of only assessing a technology's potential for harm - are being pursued that could better assess biosecurity risks whilst not hindering positive innovation. For example, in DNA synthesis screening, there are efforts being taken to improve customer screening practices, as well as better training of AI models to account for novel risks like AI-generated sequences, or trying to align safety frameworks internationally. Ultimately, building a generative culture of responsibility where every actor in the ecosystem feels empowered to ensure security, in combination with safety regulations, would be the most effective safeguard.

Level of public concern or value conflict

> ***Level of public concern or value conflict***. *Is there an increase in public attention in this technology domain? Are there hopes or concerns about the emerging technology field? Are there high political stakes, or political disagreements and controversies? If high public attention warrants a more thorough technology assessment, as well as citizen and stakeholder engagement in governance approaches.*

Both AI and synthetic biology separately have attracted much attention from the public and from governments. Whilst AI technologies developed rapidly and with limited oversight at first, there has been in recent years a flurry of efforts from governments across the world to establish governance frameworks, like safety institutes and even regulations (although approaches have varied across regions). In parallel, there has also been a strong focus from the media on the impact, opportunities, and risks of AI, and thus there is generally broad awareness and deliberations by the public on this technology.

Synthetic biology, on the other hand, remains more obscure and challenging for the citizens to relate to without the support of dedicated citizen engagement mediators. From the early days, biotechnology has seen calls to constrain its development, for example from scientists' self-imposed moratorium on recombinant DNA research prior to the 1975 Asilomar Conference, and to this day there is a degree of public mistrust with regards to GMO products and/or in how public agencies handle this area (Van Baalen, 2021[104]). The broad public debate on AI may be an opportunity to re-engage in the debate on synthetic biology. Engaging the public in co-creating the future, with proactive and transparent science-based information about the promises and risks of synthetic biology and AI to build an educated discussion, could ensure everyone benefits from these technological advancements.

Pace of technology emergence

> ***Pace of technology emergence***. *Is there a rapid expansion in activity? Have developments in this area been accelerating in recent years? Is rapid development desirable? For example, an emerging technology may be perceived as especially promising a societal goal or mission, rendering high-pace development an imperative.*

Converging technologies exacerbate the pacing problem, whereby emerging technology development outpaces the speed of regulatory frameworks. The rapid development of generative AI models is transforming many sectors, including synthetic biology where LLMs are already impacting education, skills and research in the lab. Specialised tools like biodesign software are also being rapidly rolled out, with many commercial applications in the market already and frequently used by labs. Automation tools like robotics and high-throughput technologies have been deployed for longer but will still need time to be integrated into fully automated research workflows, with many biofoundries across the world already heading in this direction.

This convergence is driving improved accessibility to the technology, accelerating the pace of innovation and increasing the complexity of technological solutions, but governance questions such as the role of human oversight in automated systems remain open for societal discussions.

Strategic importance

> ***Strategic importance**. Is the emerging technology featured in national strategic goals such as global competition, response to crises, achieving green transitions?*

Synthetic biology in combination with AI offers many technologies that could be part of a holistic solution to tackle some of the world's global challenges, from the climate crisis and the need to pursue environmental sustainability to improving health and food security. It also promises to help countries tackle new geopolitical strategic trends, such as increased competition, reducing energy costs and fostering more robust and resilient supply chains. This is recognised in many countries' national strategies and R&D priorities, where they are described as essential for countries' economic competitiveness and national security.

Governance gaps

> ***Governance gaps**. Are present governance instruments fit-for-purpose? Are there recognisable (or suspected) regulatory or governance gaps?*

Governance of synthetic biology in convergence with AI does not start from zero, as there are extensive existing frameworks at both national and international levels for synthetic biology and AI separately. These range from hard laws regulating synthetic biology products to softer AI Safety Institutes. Whilst these are likely to already cover most applications of SynBioxAI, a dedicated exercise in identifying overlaps and gaps would help avoid duplication.

Nonetheless, the governance cultures in these two fields are very different, with AI developing rapidly with limited oversight whilst biotechnology and synthetic biology have been strongly regulated from early stages. Being aware of the potential for frictions that may come from converging these norms is key to successfully implementing governance in this converging space. At the same time, it offers an opportunity for each field to learn lessons from the other - a metastructure that collects these learnings and promotes accountability could be useful. Lastly, recent global trends in governance, such as increased geopolitical strategic competition and streamlining of existing rules to foster innovation and economic growth, may shift existing governance norms.

5 Key takeaways and strategic intelligence needs

Whilst there are many policy options relating to the governance implications of synthetic biology, AI and automation convergence throughout the report, a number of areas may require further analysis due to the (a) importance for policy and (b) high uncertainty. These are outlined below.

Countries are at different stages of maturity of synthetic biology and AI ecosystems, and will likely need to follow different development paths. Whilst some countries already boast a large number of advanced biofoundries, some developing countries still need to build a foundation of synthetic biology education, research, and private investment before they can make the most of its convergence with AI and govern it effectively. Countries may wish to pursue different paths to reach this end goal, including leapfrogging stages. This may also be shaped by differences in national bioresource-production capacity.

- ***Potential Action**:* Understanding how this could be done in practice would require comparative research on different regional approaches, indicators to assess the status of the ecosystems that support research and innovation, robust risk assessment on governance in synthetic biology augmented by AI, and the gathering of lessons learned on the drivers for building capacity and innovation clusters.

Governance of synthetic biology, AI and automation convergence does not start from zero, and may be an opportunity for mutual learning and the identification of gaps and loopholes. Synthetic biology, as part of the broader field of advanced biotechnologies, has a long history of regulation and risk analysis and management. AI on the other hand has a much shorter history with an emphasis on soft law, codes of conduct and guiding principles. Thus, there are already governance frameworks and cultures for both synthetic biology and AI, albeit of very different kinds, that could be applicable to most of the novel applications detailed in this report.

- ***Potential Actions**:* To avoid duplication and regulatory overburdening, targeted national legal reviews could identify overlaps and any potential gaps, taking into account fragmented approaches across jurisdictions as well as international initiatives. At the same time, bringing together two quite different governance structures may cause challenges but also provide an opportunity to learn from each other to identify which mix of approaches is suitable for the innovations that are stemming from the convergence of synthetic biology and AI. A metastructure – perhaps facilitated at an international level - could capture the successes and failures from each field's governance and promote cross-learning.

Spaces for international cooperation that balance collaboration and competition in these converging strategic technology areas. Some elements of technology development and governance are suited to support fair competition (e.g. industrial policy) whilst others may require collaboration and international alignment to achieve shared goals, mitigate risks, and manage liabilities (e.g. biosafety and biosecurity). This requires further unpacking which topics within synthetic biology and AI convergence are most in need for cross-border cooperation, where could agreements be most easily found, and which fora would be most suited for these discussions.

- ***Potential Actions:*** International organisations like the OECD have a role to play as forums bringing stakeholders together, knowledge hubs for data and policy analysis, and setting international standards. A key initiative is the planned OECD development of a Recommendation for Responsible Innovation in Synthetic Biology.

Agile and adaptive policies are required to keep pace with the acceleration that could come about through convergence. To leverage the beneficial outcomes of convergence and to steer in desirable directions whilst mitigating risks will require agile approaches. This in turn will require strategic intelligence as evidence to support these policies.

- ***Potential Action:*** Explore agile approaches to strategic intelligence production and use, for example real-time formative evaluation tools and adaptive foresight. How best to connect these approached to decision-making is key, and thus sharing of experiences and best practices across institutions and countries would be advantageous.

Maximising the potential of AI for synthetic biology requires a technical and policy environment that supports generation, aggregation and use of high-quality and curated biodata to train algorithms. Fragmented data sets represent a major bottleneck to AI models for synthetic biology which common data sharing infrastructures and standards could tackle, and which could be informed by best practices in the field like the Protein Data Bank and DICOM. The success of any such policies ultimately hinges on enforceability and the level of political support, and impact should be measured regularly to identify successes and tackle failures.

- ***Potential Action***: Further unpack the emerging and future situation of biodata infrastructures and future convergence industries. Strategic foresight and multi-stakeholder technology assessment could provide key insights.

Ensuring biosecurity and biosafety in the convergence of synthetic biology and AI will require improving sophistication of safeguards and building a culture of responsibility. The convergence of synthetic biology and AI will likely accelerate the move to synthetic biology products that are released in the environment – leading to risk scenarios that require dedicated investigation and the further development of risk assessment and management methods to keep pace with the development. In the longer term, areas that may require specific attention include mirrored life and new-to-nature lifeforms. In the nearer term, AI tools can democratise synthetic biology by lowering entry barriers, which can benefit students and researchers but also pose biosecurity risks if misused by nefarious actors. Existing safeguards with increased sophistication and depth could address these whilst enabling positive benefits from the convergence. Approaches include considering user intent; updating DNA synthesis screening tools to account for AI-generated sequences and adopting internationally harmonised screening standards; or balancing the degree of openness of computational models via tiered access. Robust approaches would be holistic and ecosystem-wide and rely on building a generative culture of responsibility, where researchers proactively identify and mitigate risks and integrate biosecurity and biosafety into design. Nonetheless, these are more difficult to establish than compliant cultures and would likely require a balance of bottom-up and top-down approaches, and buy-in from a broad array of partners in the ecosystem.

- ***Potential Action:*** Building capacity for risk assessment research. Forward-looking risk-benefit scenarios would allow for more informed risk assessment and pro-innovation policies that nurture desirable development whilst mitigating harms. Traditional risk assessment approaches could be combined with in depth foresight activities to enable targeted anticipatory governance, updated regularly and involving multi-stakeholder expert panels to ensure technological and societal relevance, accounting for practical challenges such as resource constraints and uncertainty quantification.

Open versus closed access to biodata and derived algorithms is an ongoing trade-off driven by a combination of factors, from biosecurity to research security to economic security, but biodata

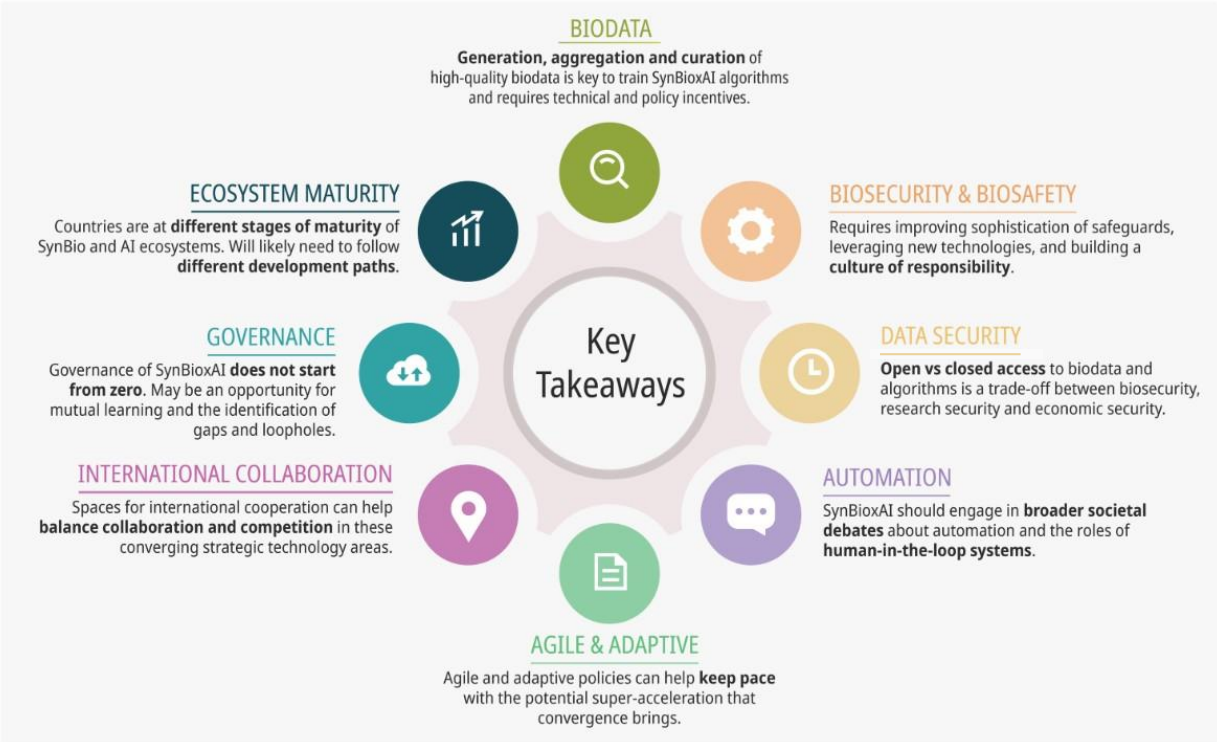
monopolies should be avoided. Closed models may be less likely to be misused by nefarious actors, can help protect intellectual property, and maintain profitability that drives innovation. At the same time, open models may be more trusted, be supported by broad validation that makes them more robust and competitive, and help ensure they are broadly representative and avoid enhancing biases. Whist finding this balance is an ongoing challenge, steps should be taken to avoid the potential rise of biodata monopolies that could control access to crucial biodata and limit research paths and inhibit economic growth in this area.

- ***Potential Action:*** A deeper investigation into the trade-offs between open science and the sharing of data, research and technology security and the need for companies to be able to leverage certain data to create profits.

Synthetic biology should engage in broader societal debates about automation and the roles of human-in-the-loop systems. The convergence of synthetic biology and digital tools could lead to fully automated labs with minimal human supervision, where AI and robotics handle the entire research and development cycle. However, some form of human oversight (i.e. human-in-the-loop system) is essential to mitigate the risks and limitations, for example ensuring legal and moral accountability, resilience and cyberbiosecurity, ethical considerations and providing research directionality. As the impact of automation in synthetic biology will likely echo ethical debates in other areas (e.g. the need for responsible replacement and retraining programmes), it is important for synthetic biology researchers to engage in these society-wide deliberations.

- ***Potential Action:*** Review current and past technology assessment studies on automation, for example in closed-loop deep brain implants, to explore the trade-offs in the spectrum between fully automated and fully human operated systems. This should be followed by a further expert-based technology assessment on the particularities of synthetic biology, AI and automation convergence.

Figure 5.1. Key takeaways and strategic intelligence needs on SynBioxAI



Source: OECD.

6 Conclusion

The convergence of synthetic biology, various forms of AI, and increasingly advanced automation and robotics has the potential to accelerate research and development, opening up new and uncertain possibilities for technological innovations that were previously out of reach.

This forward-looking technology assessment report has scoped the potential developments expected by experts, unpacked the governance implications (identifying 7 key areas), made a preliminary diagnosis of the technology in line with the *OECD Framework on Anticipatory Governance of Emerging Technologies*, and offered some potential pathways forward by identifying potential specific actions that could be taken.

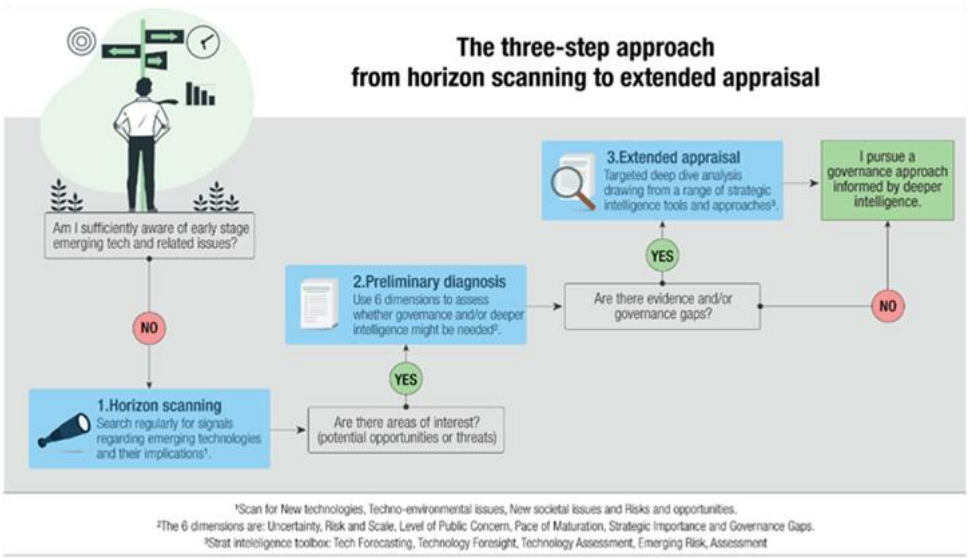
The convergence outlined in this report may accelerate at unprecedented speed the development of novel and transformative innovations, potentially including new-to-nature genetical material and organisms. This dynamic also introduces complex risk scenarios and governance challenges that warrant sustained investigation. Keeping pace with this innovation and steering it in desirable directions will require transparent, inclusive, agile, and adaptive anticipatory governance, supported by continuous evidence-generation processes – strategic intelligence for policymaking. Key to this endeavour is the mutual learning and exchange of lessons and best practices across institutions and countries in both governance of converging technologies and the production of strategic intelligence that remains tailored for, and useable within, agile and adaptive policies.

Annex A. OECD Framework for Anticipatory Governance of Emerging Technologies

The OECD Framework for the Anticipatory Governance of Emerging Technologies aims to equip relevant stakeholders (e.g. policymakers, private sector, and societies) to get ahead of governance challenges brought about by emerging technologies to shape innovation more effectively. It lays out 5 interdependent elements to consider: 1) embedding values; 2) foresight and technology assessment; 3) stakeholder engagement; 4) agile and adaptive regulation; and 5) international collaboration.

This second step of enhancing foresight and technology assessment includes a recommendation to undertake a preliminary diagnosis before investing in deep-dive strategic intelligence gathering for extended appraisal of technologies with regards to governance (see figure X). This report has sought to carry out this process for the convergence of synthetic biology, AI and automation in in 'Section 3: Preliminary Diagnosis', mobilising the six dimensions of diagnosis from the Framework and outlined in Box A A.1. below.

Figure A A.1. Strategic intelligence guidance for anticipatory governance of emerging technologies



Source: *OECD* (2024[105]).

Box A.1. Six dimensions for assessing governance needs of emerging technologies

The OECD Framework for Anticipatory Governance of Emerging Technologies provides guidance on the pragmatic and effective gathering of Strategic Intelligence for informing technology governance. A key step in this approach is the "preliminary diagnosis" step, designed to allow decision makers to make a first, low resource investment, assessment of the focus technology with a view to policy issues, and to help target further work. This preliminary diagnosis is built along the following six dimensions:

- **Uncertainty**. Are the trajectories of development clear? If there is uncertainty, how could it be reduced? A higher degree of uncertainty militates for a greater amount of intelligence gathering, societal engagement and/or upstream governance.
- **Risk and scale of impact**. Despite uncertainties, how would we estimate/evaluate the potential impact of this technology on the foundational and technology-specific values discussed above -- from human rights and liberties to the environment, to human and or animal health and safety? How likely are the potential harms? How severe? How reversible?
- **Level of public concern or value conflict**. Is there an increase in public attention in this technology domain? Are there hopes or concerns about the emerging technology field? Are there high political stakes, or political disagreements and controversies? If high public attention warrants a more thorough technology assessment, as well as citizen and stakeholder engagement in governance approaches.
- **Pace of technology emergence**. Is there a rapid expansion in activity? Have developments in this area been accelerating in recent years? Is rapid development desirable? For example, an emerging technology may be perceived as especially promising a societal goal or mission, rendering high-pace development an imperative.
- **Strategic importance**. Is the emerging technology featured in national strategic goals such as global competition, response to crises, achieving green transitions?
- **Governance gaps**. Are present governance instruments fit-for-purpose? Are there recognisable (or suspected) regulatory or governance gaps?

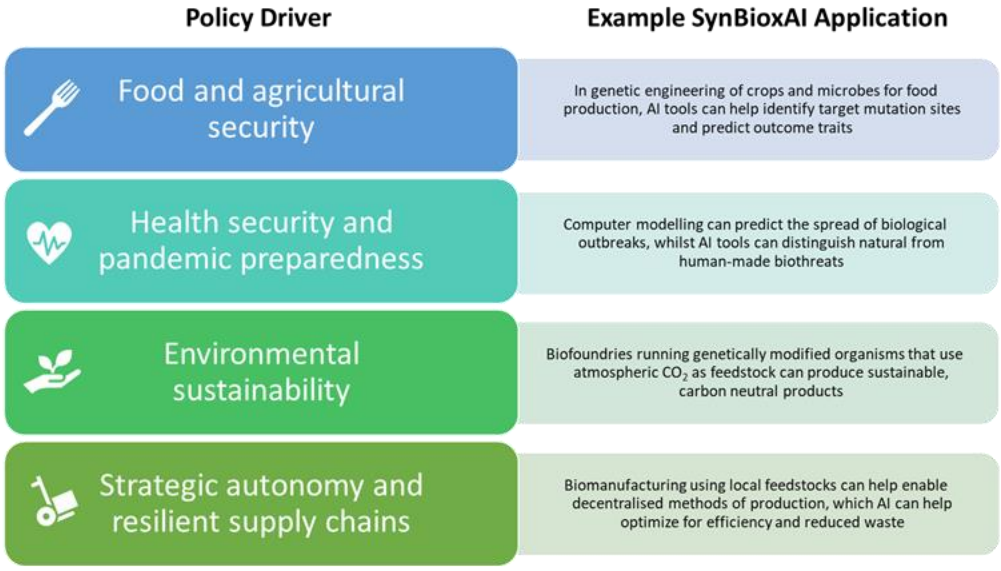
Source: *OECD Framework for Anticipatory Governance of Emerging Technology* (OECD, 2024[1])

Annex B. Policy drivers for new SynBioxAI solutions

Countries around the world are facing common global challenges. The climate crisis poses a planetary-scale threat - changing weather patterns and more frequent destructive weather events like floods and droughts - calling on countries to pursue environmental sustainability and net-zero economies. It is also posing a heightened threat to food and health security in combination with other factors, such as the COVID-19 pandemic. In turn, these are also driving new strategic trends and considerations. For example, higher energy costs in Europe have been steering both industries and general populations to be more energy-efficient, whilst worldwide there has been a move towards more robust and resilient supply chains (e.g. in the form of onshoring critical chains) in the wake of the pandemic and the accompanying supply disruptions.

These issues are driving the political agenda, and by extension scientific research and development (R&D) being pursued by both public and private actors. Synthetic biology offers many technologies that could be part of a holistic solution to these challenges[61], further accelerated by the convergence with AI. Some examples are highlighted in the infographic below and expanded upon in the next section.

Figure B.1. Policy drivers for technological innovation and example applications of SynBioxAI



Source: OECD Research.

Annex C. List of Biofoundries

Table C.1. List of global biofoundries

Name	City	Country	Public or Private
A*STAR SPARROW	Singapore	Singapore	Public
ACIES BIO	Ljubljana	Slovenia	Private
Agile Biofoundry	Emeryville	USA	Public
Alagene Biofoundry	Herzliya	Israel	Private
Australian Genome Foundry	Sydney	Australia	Public
Australian Institute for Bioengineering and Nanotechnology	Brisbane	Australia	Public
Biofactorial	Vancouver	Canada	Private
Biofoundry India	New Delhi	India	Public
BRIGHT Biofoundry, Technical University of Denmark	Kongens Lyngby	Denmark	Public
Center for Synthetic Biology	Evanston	USA	Private
Colorado Cyberbiofoundry	Colorado	USA	Public
CompuGene, TU Darmstadt	Darmstadt	Germany	Public
Concordia Genome Foundry	Montreal	Canada	Public
CSIRO Biofoundry	Brisbane	Australia	Public
DAMP lab, Boston University	Boston	USA	Public
DTU Biosustain Biofoundry	Lyngby	Denmark	Public
Dyadic	Jupiter	USA	Private
Earlham DNA Foundry	Norwich	UK	Public
Edinburgh Genome Foundry	Edinburgh	UK	Public
Engineering Biology Research Centre, Kobe University	Kobe	Japan	Public
Estonian Biofoundry	Tartu	Estonia	Public
GeneMill	Liverpool	UK	Public
Gingko Bioworks	Boston	USA	Private
iBioFAB -- Illinois Biological Foundry for Advanced Biomanufacturing	Illinois	USA	Public
IBVT	Stuttgart	Germany	Public
IDEA Bio	Queensland	Australia	Public
Jülich Biofoundry, Forschungszentrum Jülich	Jülich	Germany	Private
K-BioFoundry (KAIST and KRIBB)	Daejeon	South Korea	Public
Kobe Biofoundry	Kobe	Japan	Public
Lara, Laboratory Automation Robotic Assistant Biochemistry Greifswald	Greifswald	Germany	Public
Living Measurement Systems Foundry, NIST	Maryland	USA	Public
London Biofoundry, Imperial College London	London	UK	Public
MaxGENESYS, Max Planck Society, MPI for Terrestrial Microbiology	Marburg	Germany	Public
NIST Living Measurement Systems Foundry	Gaithersburg	USA	Public
NSF ExFAB BioFoundry	Santa Barbara	USA	Public
Nucleo de Innovación de Sistemas Biólogicos, NISB	Monterrey	Mexico	Public
Paris Biofoundry	Paris	France	Public
RISE High-throughput Centre		Sweden	Public
SIAT Biofoundry	Shenzhen	China	Public
SJTU Synbio Biofoundry	Shanghai	China	Public
SKy Biofoundry, Sungkyunkwan University	Seoul	South Korea	Public

SYNBIOCHEM	Manchester	UK	Public
SynBiofoundry@TUM	Munich	Germany	Public
SynCTI, Singapore Biofoundry	Singapore	Singapore	Public
SynDNA Lab	Heidelberg	Germany	Public
The Biofoundry at UBC	Vancouver	Canada	Public
Tianjin Biofoundry -- Tianjin Institute of Industrial Biotechnology	Tianjin	China	Public
Tianjin University Biofoundry	Tianjin	China	Public
UCSD Biofoundry	San Diego	USA	Public
UKM Biofoundry	Bangi	Malaysia	Public
VTT Technical Research Centre of Finland	Espoo	Finland	Public
Zhejiang University	Zhejiang	China	Public

Note: This data was compiled in July 2025 and based on desk research collecting, reviewing, and summarizing existing reports, academic papers, and policy documents. It
Source: OECD Research.

Annex D. Methodology

This study used desk research to gather and analyse information on combining synthetic biology and AI. Desk research involves collecting, reviewing, and summarising existing reports, academic papers, and policy documents to get a clear picture of the topic.

The OECD Global Forum on Technology synthetic biology workstream collected the insights from 66 experts (in research, government, academia, non-governmental and industry) from over 30 countries from around the world. The ensuing synthesis report "Synthetic biology in focus: issues and opportunities in engineering life" [DSTI/DPC/STP(2024)7/FINAL] identified the need to anticipate the convergence of synthetic biology with artificial intelligence, automation and robotics. Given the transformative potential of this convergence on the technology and the accompanying governance implications, the OECD could support governments by anticipating technological and socioeconomic issues via forward-looking technology assessments, and use the insights to support future-proofing of governance and innovation policies.

To this end, the OECD Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT) convened a two-day workshop in October 2024 with selected experts from natural and social sciences, governance and foresight, synthetic biology, artificial intelligence, automation and robotics to: (a) discuss the situation of SynBioxAI convergence to date, (b) take a forward-look at potential evolutions of SynBioxAI convergence, identifying potential governance issues and opportunities and (c) explore the readiness of the current synthetic biology governance ecosystem. An online webinar was organized in February 2025 with the original workshop attendants plus additional partners to follow-up on the issues raised and validate the examples and governance implications identified. These insights were complemented by further desk research by the Secretariat and a number of online interactions with around 40 experts between November 2024 and February 2025.

The draft report has been reviewed by OECD delegates to the Working Party on Biotechnology, Nanotechnology and Converging Technologies, the Committee on Scientific and Technological Policy, the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, and the Working Party for the Safety of Novel Foods and Feeds. In addition, the Secretariat in other OECD Directorates reviewed the report and provided feedback: Strategic Foresight Unit of the Office of the Secretary General; Health Division at the Directorate for Employment, Labour and Social Affairs; Health and Safety Division at the Environment Directorate; Digital Connectivity at the Economics and Society Division; and the Artificial Intelligence and Emerging Digital Technologies Division.

Table D.1. Experts engaged across in-person workshop, webinar, online meetings, and written input

Name	Affiliation
Douglas Robinson	OECD Science, Technology and Innovation Directorate
David Winickoff	OECD Science, Technology and Innovation Directorate
Cesar Barraza-Botet	OECD Science, Technology and Innovation Directorate
Carolina Resende Haddad	OECD Science, Technology and Innovation Directorate
Chrystyna Harpluk	OECD Science, Technology and Innovation Directorate
Sari Hagimoto	OECD Science, Technology and Innovation Directorate

Daniel Nadal	OECD Science, Technology and Innovation Directorate
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Dexter Docherty	OECD Strategic Foresight Unit
Uma Kalkar	Centre for the Governance of AI / OECD Strategic Foresight Unit
Adrian Ely	University of Sussex
Alejandra Sierra Aguilera	Universidad del Istmo
Alfonso Jaramillo Rosales	Consejo Superior de Investigaciones Científicas (CSIC)
Alix Pham	Simon Institute for Long-term Governance
Alonso Flores	iGEM
Ana Atanassova	BASF
Ashley Noriega	Center for Future Generations (CFG)
Becky Mackelprang	Engineering Biology Research Consortium
Bianca Garner	National Science Foundation
Buhm Soon Park	Graduate school of STP/ KAIST
Chris Isaac	Nuclear Threat Initiative (NTI)
Christine Lang	MBCC group
Chueh Loo Poh	National University of Singapore
Claudia Vickers	Queensland University of Technology
Conor Griffin	Google DeepMind
Deepak Govindaraj	Council for Scientific and Industrial Research
Delphine Beeckman	BASF
Delphine Thizy	Outreach Network for Gene Drive Research
Diego di Bernardo	University of Naples “Federico II”, Naples, Italy
Diego Oyarzún	University of Edinburgh
Dorothy Zhang	iGEM
Drew Endy	Stanford University
Ediner Fuentes-Campos	National Research System (Sistema Nacional de Investigación - SNI), National Secretariat for Science, Technology, and Innovation (Secretaría Nacional de Ciencia, Tecnología e Innovación - SENACYT) of Panama
Emily Parker	Victoria University of Wellington, New Zealand and the Ministry of Business Innovation and Employment, New Zealand
Emmanuel Dequier	Ministry of Higher Education and Research
Eriko Takano	Manchester Synthetic Biology Research Centre, SYNBIOCHEM
Faouzi Braza	Center for Future Generations (CFG)
Fayza Daboussi	French National Research Institute for Agriculture, Food and the Environment (INRAE)
Fiona Mischel	SynBioBeta
Geoffrey Otim	SynBio Africa
Germán Alejandro Rivas Caballero	Spanish National Research Council (CSIC)
Gilles Truan	French National Centre for Scientific Research (CNRS)
Halima Benbouza	National Council of Scientific Research and Technologies of Algeria
Harald Koenig	Karlsruhe Institute of Technology, Institute for Technology Assessment and Systems Analysis (ITAS)
Ivan R. Jaubert	SynBioBeta
Jean-Loup Faulon	French National Research Institute for Agriculture, Food and the Environment (INRAE)
Jenny Molloy	University of Cambridge
Joyce Tait	Innogen Institute, University of Edinburgh
Kantapich Preedakorn	Office of National Higher Education Science Research and Innovation Policy Council (NXPO)
Kevin Flyangolts	Aclid
Krishna Ravi Srinivas	NALSAR University of Law & Research and Information System for Developing Countries
Lars Friberg	Vinnova
Luis Larrondo	iBio Millennium Institute for Integrative Biology (iBio)- P. Universidad Catolica de Chile
Luis Melo	University of Lisbon
Makiko Matsuo	University of Tokyo
Marc Güell	Pompeu Fabra University

Mariana Marrana	World Organisation for Animal Health (WOAH)
Markus Schmidt	Biofaction
Martin Fussenegger	ETH Zurich (Swiss Federal Institute of Technology, Zurich)
Mary Maxon	Carnegie Sciences
Mauro Magnani	Università degli Studi di Urbino Carlo Bo
Megan Palmer	iGEM Foundation
Michelle Habets	Rathenau Institute
Montserrat Jarquín Cordero	Costa Rican Institute of Technology (ITCR)
Nathan Hillson	Lawrence Berkeley National Laboratory
Nina Youssoufou	French Ministry of European and Foreign Affairs
Pascal Maigne	French Ministry of Higher Education and Research
Patrice Soumillion	Université catholique de Louvain (UCLouvain)
Piers Millett	International Biosecurity and Biosafety Initiative for Science (IBBIS)
Rhys Dubin	US Department of State
Richard Kitney	Imperial College / SynbiCite
Rick Johnson	iGEM Foundation / Business at OECD (BIAC)
Robert Speight	Commonwealth Scientific and Industrial Research Organisation (CSIRO)
Roman Jerala	National Institute of Chemistry
Rory Saitch	UK Government Office for Science
Rosanne Edelenbosch	Rathenau Instituut
Sam Weiss Evans	US National Security Commission on Emerging Biotechnology
Samuli Olilla	VTT Technical Research Centre of Finland
Sophia McCully	Nuffield Council Bioethics
Sophie Peresson	Sciences Po University
Stephen Obol Opiyo	Ohio State University
Tobias Erb	Max Planck Institute for Terrestrial Microbiology
Traci Haddock	Asimov
Urartu Seker	Bilkent University
Vincent Martin	Concordia University
Wataru Mizunashi	New Energy and Industrial Technology Development Organization (NEDO)
Yolanda Schaerli	University of Lausanne
Yorgo El Moubayed	iGEM
Yuhan Bao	iGEM

Note: Affiliations were noted at the time of engagement with experts and may have changed during the drafting and publication process. Furthermore, experts spoke in their personal capacity and did not necessarily reflect the position of their organisations.

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Endnotes

[1] More information on the foundational promises of synthetic biology as well as the accompanying governance and policy implications can be found in the OECD report 'Synthetic Biology in Focus: Policy Issues and Opportunities in Engineering Life'.

[2] More information on quantum technologies, including potential uses in biology, can be found in the OECD working paper 'A quantum technologies policy primer' (https://www.oecd.org/en/publications/a-quantum-technologies-policy-primer_fd1153c3-en.html).

[3]At the time of writing, there is no internationally agreed definition of synthetic biology. Sometimes broadly defined, for example the definition in the Convention on Biological Diversity (https://www.cbd.int/synbio) where it is defined as "A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems". The lack of a standard definition of synthetic biology is seen as a challenge, particularly for developing or adapting legislation (Robinson and Nadal, 2025[44]).

[4] There are many OECD resources providing intelligence on the different types of AI models: including papers on 'AI language models' (https://www.oecd.org/en/publications/ai-language-models_13d38f92-en.html), 'Initial policy considerations for generative artificial intelligence' (https://www.oecd.org/en/publications/initial-policy-considerations-for-generative-artificial-intelligence_fae2d1e6-en.html), 'Is generative AI a General Purpose Technology?' (https://www.oecd.org/en/publications/initial-policy-considerations-for-generative-artificial-intelligence_fae2d1e6-en.html), and the OECD Framework for the Classification of AI systems (https://www.oecd.org/en/publications/oecd-framework-for-the-classification-of-ai-systems_cb6d9eca-en.html).

[5] More information on the unique considerations from each type of AI application is available online in the National Security Commission on Emerging Biotechnology (NSCEB) White Paper Series on AIxBio (https://www.biotech.senate.gov/wp-content/uploads/2024/01/NSCEB_AIxBio_WP3_Risks.pdf).

[6] Protein structures, which are fundamental to their function, were previously only characterizable via expensive and time-consuming experimental efforts (e.g. x-ray crystallography). They are dictated by the interactions of the amino acids that make them up, but these are difficult to calculate manually when proteins can be made up of hundreds of amino acids. Computational models, and in more recent years AI tools like deep learning, can process these large amounts of variables and make predictions with the same accuracy as experimental methods (Service, 2020[116]).

[7] For example, Zymvol helps researchers identify the best existing enzymes for a target application, and its computational models can even identify the necessary mutations to further optimize the enzyme, reducing time costs and the need for experimental lab work (Monza, Gil and Lucas, 2022[115]). Another example is Salesforce's ProGen, a language model that treats amino acid sequences analogously to how natural language models treat sentences, to generate proteins with new functions or proteins with existing functions but with low homology to known sequences (Madani et al., 2023[114]).

[8] The failure rates in clinical trials, particularly during the validation and optimization phases, further contribute to the high cost of drug discovery (Fernald et al., 2024[118]). The rising need for new therapeutics, especially in response to emerging health crises like the COVID-19 pandemic, has underscored the inefficiencies of current drug discovery processes and the urgent need for transformative innovations. Reliance on experimental screening, which explores vast chemical spaces estimated to include over 10^{60} molecules, has limited efficient drug candidate discovery (Huang et al., 2024[119]).

[9] Traditional drug discovery processes are known for being time-consuming, expensive, and often inefficient (Akbar, 2022[127]). On average, the journey to bring a new drug to market takes more than a decade and costs billions of dollars (Schlander et al., 2021[117]) Due to the complexity of biological systems and the difficulty of predicting drug-target interactions, failures in the late stages of development are common, resulting in significant economic losses (Huang et al., 2024[119]).

[10] AI's ability to analyze vast datasets and predict drug-target interactions is revolutionizing the discovery pipeline, reducing reliance on traditional high-throughput screening methods. AI-driven virtual screening methods have been shown to outperform traditional techniques in identifying active drug candidates (Xu et al., 2024[120]).

[11] More information on broader implications of AI in healthcare settings can be found in the OECD policy paper 'AI in Health' (https://www.oecd.org/en/publications/2024/01/ai-in-health-huge-potential-huge-risks_ff823a24.html).

[12] The OECD has developed the Truth Quest Survey to assess whether AI-generated content is more easily distinguishable as false or misleading than human-generated content, identify how people interact with false and misleading content, and aims to shape media literacy strategies (OECD, 2024[125]).

[13] More information on the general impact of AI in education can be found in the OECD working paper 'The potential impact of Artificial Intelligence on equity and inclusion in education' (https://www.oecd.org/en/publications/the-potential-impact-of-artificial-intelligence-on-equity-and-inclusion-in-education_15df715b-en.html).

[14] More information on this issue is available in OECD reports on 'Introducing the OECD AI Capability Indicators' (https://www.oecd.org/en/publications/introducing-the-oecd-ai-capability-indicators_be745f04-en.html) and 'What skills and abilities can automation technologies replicate and what does it mean for workers?' (https://www.oecd.org/en/publications/what-skills-and-abilities-can-automation-technologies-replicate-and-what-does-it-mean-for-workers_646aad77-en.html).

[15] Developments in automation will also have an impact on the future workforce. Projections estimate that unless the manufacturing talent pipeline is reformed to train additional people, there will be a shortfall of 2.1 million unfilled jobs by 2030, with a cost to the economy of $1 trillion (Wellener et al., 2021[106]). Successful existing initiatives include BioMADE, which is supporting innovative education by for example raising awareness of biotechnology careers in early schooling, aligning student curricula with needed

industrial competencies (e.g. data analysis), and reskilling workers from other industries to meet demand – more information is available online at https://www.biomade.org/education-workforce-development.

[16] It should be noted that these control issues are currently not encountered with GM crops, as containment measures for performing field trials before commercialisation and experience with risk assessments for environment release have been in place for 30+ years (National Academy of Sciences, 2016[107]) (Goodman, 2024[108]).

[17] In the future, they could also allow scientists to increase the ceiling of existing biological constraints and open new opportunities, like expanding beyond foundational chemicals and reactions that all life follows, like respiration from glucose.

[18] The smallest minimal cell, 'JCV-syn3', only has 473 genes, but the function of around 30% of these is still unknown (Hutchinson 3rd et al., 2016[109]).

[19] The 'Billion Cells Project' by the Chan Zuckerberg Initiative (CZI) is creating an open database of single-cell snapshots to aggregate enough standardized data at scale to train AI models in better understanding cellular mechanics and develop virtual cell models (Chan Zuckerberg Initiative, 2025[122]).

[20] The OECD has launched 'GAIIN: The Global AI Initiatives Navigators' as a live repository of over 2,000 AI strategies and policies from over 70 jurisdictions (https://oecd.ai/en/dashboards/overview).

[21] At the same time, in the context of a risk-based framework like the EU AI Act, it is worth flagging that some SynBioxAI applications may not be as easily categorised as drug discovery, and innovators may face difficulties in assessing where their tools fit. The Centre for Long Term Resilience has attempted to categorise 50 AI biological models based on the definitions of 'general purpose AI' and 'systemic risk' from the legislation but identified assessment limitations based on differing interpretations and lack of benchmarks (Moulange, Wünn and Nelson, 2025[121]).

[22] Previously, the Executive Order on "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence" had also called for developing frameworks to assess and manage biorisks stemming from AI (accessible here: https://bidenwhitehouse.archives.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/) but was revoked in January 2025 (see https://www.whitehouse.gov/presidential-actions/2025/01/removing-barriers-to-american-leadership-in-artificial-intelligence).

[23] National legal reviews may be complemented by comparative approaches, such as those outlined in the OECD reports: 'The state of implementation of the OECD AI Principles four years on' (https://www.oecd.org/en/publications/the-state-of-implementation-of-the-oecd-ai-principles-four-years-on_835641c9-en.html), 'Advancing accountability in AI' (https://www.oecd.org/en/publications/advancing-accountability-in-ai_2448f04b-en.html), and 'Common guideposts to promote interoperability in AI risk management' (https://www.oecd.org/en/publications/common-guideposts-to-promote-interoperability-in-ai-risk-management_ba602d18-en.html).

[24] More information: on OECD's work on AI (https://www.oecd.org/en/topics/policy-issues/artificial-intelligence.html) (including the OECD Recommendation on AI at https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449), on biosafety (https://www.oecd.org/en/topics/biosafety-novel-food-and-feed-safety.html) on synthetic biology

(https://www.oecd.org/en/topics/sub-issues/synthetic-biology.html), and on the United Nations' Convention on Biological Diversity (https://www.cbd.int/synbio).

[25] Another example could be the OECD '*Recommendation of the Council concerning Safety Considerations for Applications of Recombinant DNA Organisms in Industry, Agriculture and the Environment*', adopted in 1986.

[26] The notions of Safe-by-Design, Safer Innovation Approach, and Responsible Research and Innovation are relevant as well. These are defined and already being considered in the OECD for the development of advanced materials (https://www.oecd.org/en/topics/sub-issues/nanomaterials-and-advanced-materials/safer-and-sustainable-innovation-approach-ssia-nano-enabled-and-other-emerging-materials.html) and neurotechnology (https://www.oecd.org/en/topics/sub-issues/responsible-innovation.html), and in the Danish National Institute for Public Health and the Environment on biotechnology (https://biotechnologie.rivm.nl/safe-by-design).

[27] For example, both the ISO 20688-2:2024 ('*Requirements for the production and quality control of synthesized gene fragments, genes, and genomes'*) and the U.S. Department of Health and Human Services (HHS) 2023 Screening Framework Guidance call for assessing customer legitimacy. In addition, the OECD AI Recommendations calls for "*AI actors should implement mechanisms and safeguards, such as capacity for human agency and oversight, including to address risks arising from uses outside of intended purpose, intentional misuse, or unintentional misuse in a manner appropriate to the context and consistent with the state of the art*" (Principle 1.2) and "*AI systems should be robust, secure and safe throughout their entire lifecycle so that, in conditions of normal use, foreseeable use or misuse, or other adverse conditions, they function appropriately and do not pose unreasonable safety and/or security risks*" (Principle 1.4) (OECD, 2024[113]).

[28] Advances in biosurveillance and biothreat detection detailed in the *"Beyond containment"* section can also complement formal risk assessments. Further ideation and investment may be needed to improve regulatory capacity, develop future-proof risk assessment methodology, and determine whether any precautionary measures would be needed while such methodology and data are developed.

[29] Starting in October 2024, the United States Framework for Federal Scientific Integrity Policy and Practice requires that researchers receiving federal funds can only use these to purchase synthetic DNA from providers that follow best practices in sequence and customer screening. More information is available online: https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf. In the United Kingdom, the Department for Science, Innovation and Technology (DSIT) has released guidance for users and providers of gene synthesis on sequence and customer screening, identifying suspicious transactions, compliance with export controls…. More information is available online: https://www.gov.uk/government/publications/uk-screening-guidance-on-synthetic-nucleic-acids/uk-screening-guidance-on-synthetic-nucleic-acids-for-users-and-providers. Existing non-governmental frameworks include ISO 20688-2:2024 (https://www.iso.org/standard/75852.html) and the International Gene Synthesis Consortium' guidelines (https://genesynthesisconsortium.org/wp-content/uploads/IGSC-Harmonized-Screening-Protocol-v3.0-1.pdf.

[30] A December 2024 study between several nucleic acid synthesis companies and synthesis screening providers found that not all traditional nucleic acid screening tools could detect AI-developed synthetic sequences encoding harmful proteins. However, the same study developed "patches" that could markedly improve detection rates (up to 97%), suggesting it is possible to adapt current tools to account for AI-

generated risks. It points to lessons learned in the past, such as previous adaptations made when other technological developments (like codon engineering) became widespread.

[31] The Global Health Security (GHS) Index is an assessment and benchmarking of health security and related capabilities across 195 countries. It aims to provide metrics to inform change in national health security and improve international capability to address infectious disease outbreaks. The first two editions of the GHS Index were published by the Nuclear Threat Initiative (NTI) and the Johns Hopkins Center for Health Security at the Bloomberg School of Public Health, working with Economist Impact. The third edition also includes the Brown University Pandemic Center. More information can be found online: https://ghsindex.org.

[32] The work of the Australia Group – a group of countries informally aligning their export control regimes to avoid the proliferation of biological and chemical weapons - could serve as a learning opportunity.

[33] Starting in October 2024, the United States Framework for Federal Scientific Integrity Policy and Practice requires that researchers receiving federal funds can only use these to purchase synthetic DNA from providers that follow best practices in sequence and customer screening. More information is available online: https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf. In the United Kingdom, the Department for Science, Innovation and Technology (DSIT) has released guidance for users and providers of gene synthesis on sequence and customer screening, identifying suspicious transactions, compliance with export controls…. More information is available online: https://www.gov.uk/government/publications/uk-screening-guidance-on-synthetic-nucleic-acids/uk-screening-guidance-on-synthetic-nucleic-acids-for-users-and-providers. Existing non-governmental frameworks include ISO 20688-2:2024 (https://www.iso.org/standard/75852.html) and the International Gene Synthesis Consortium' guidelines (https://genesynthesisconsortium.org/wp-content/uploads/IGSC-Harmonized-Screening-Protocol-v3.0-1.pdf.

[34] The 2021 OECD Recommendation on Enhancing Access to and Sharing of Data provides a set of guidelines for public and private actors on how to foster responsible access and sharing of data. (https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0463).

[35] Some OECD Recommendations aim to address this issue: OECD Recommendation of the Council on Enhancing Access to and Sharing of Data (https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0463) and OECD Recommendation on Health Data Governance (https://legalinstruments.oecd.org/public/doc/348/348.en.pdf).

[36] In terms of standards, a successful example to draw upon is the Digital Imaging and Communications in Medicine (DICOM) standard. Its development in the 1980s by associations of healthcare users and professionals transformed the field of medical imaging by standardising previously disparate procedures. Thanks to the standardization of medical images it enabled, it has facilitated clinical practice and foundational research (Larobina, 2023[110]).

[37] Another relevant technology is privacy-enhancing technologies (PETs), which the OECD has more information on: https://www.oecd.org/en/publications/emerging-privacy-enhancing-technologies_bf121be4-en.html.

[38] Similarly, solutions like informed machine learning – where ML models are trained on both data and prior knowledge (e.g. logic rules, algebraic equations, human feedback) – may be able to develop algorithms with fewer data (von Rueden et al., 2023[111]).

[39] Additionally, the integration of more digital tools into the research process will in turn generate more data that can be fed back to improve the models. The challenge there is that the most advanced and automated facilities will generate the most data and gain leverage in better models, which could reward big players over smaller ones, fostering monopolies.

[40] In automation, microfluidic droplet technologies can still improve in throughput and productivity (Mashiyama et al., 2024[112]).

[41] Another example, from the health and clinical sector, would be anti-information blocking (practices hindering the access, sharing and use of data) legislation like the 2016 Cures Act (HealthIT.gov, 2024[124]).

[42] Existing efforts at the OECD, such as the Recommendation on Health Data Governance and the policy paper 'Facilitating the Secondary Use of Health Data for Public Interest Purposes Across Borders' (OECD, 2025[126]) from June 2025 reflect on the need to define and operationalise 'public interest' to better co-ordinate review and oversight across organisations, and on the value of public and provider consultation.

[43] Findability, Accessibility, Interoperability, and Reusability.

[44] In terms of standards, a successful example to draw upon is the Digital Imaging and Communications in Medicine (DICOM) standard. Its development in the 1980s by associations of healthcare users and professionals transformed the field of medical imaging by standardising previously disparate procedures. Thanks to the standardization of medical images it enabled, it has facilitated clinical practice and foundational research (Larobina, 2023[110]).

[45] The work of the International Advisory Council on Global Bioeconomy could be highly relevant, especially their global mapping of national policy strategies and roadmaps. More information available online: https://gbs2020.net/wp-content/uploads/2021/04/GBS-2020_Global-Bioeconomy-Policy-Report_IV_web-2.pdf.

[46] Data generation, sharing, and infrastructure are key bottlenecks in developing countries. This is due to a number of issues: limited infrastructure (many regions lack the laboratory facilities for synthetic biology experimentation and data collection), connectivity gaps (poor digital and physical infrastructure restricting access to global data-sharing networks), and expertise shortages (lack of trained professionals limits the ability to manage and interpret data effectively) (Hillson et al., 2019[88]). Several strategies to address these data gaps in developing countries have been ideated. From a technological perspective, low-cost solutions such as mobile labs, affordable sequencing technologies, and simplified bioinformatics platforms could overcome resource limitations, and global open-access databases could increase data availability by leveraging data from other countries. Capacity building and knowledge sharing could build more lasting bottom-up change. Partnerships with developed nations for technical support and training, as well as sharing of best practices and open-source technologies by successful biofoundry projects (e.g. the Global Biofoundry Alliance) could be effective.

[47] More information on the Convention on Biological Diversity's activities on synthetic biology can be found here (https://www.cbd.int/synbio). Furthermore, the discussions in the following multistakeholder fora may also be relevant: the WHO Pandemic Influenza Preparedness (PIP) Framework, the FAO International

Treaty on Plant Genetic Resources for Food and Agriculture, and the Biodiversity Beyond National Jurisdiction (BBNJ) agreement.

[48] This is in line with the OECD Recommendation on AI, where Principle 1.4 states "*Mechanisms should be in place, as appropriate, to ensure that if AI systems risk causing undue harm or exhibit undesired behaviour, they can be overridden, repaired, and/or decommissioned safely as needed*." (OECD, 2024[113]).

[49] This is in line with the OECD Recommendation on AI, where Principle 1.3 states "*AI Actors should commit to transparency and responsible disclosure regarding AI systems. To this end, they should provide meaningful information, appropriate to the context, and consistent with the state of art: i.to foster a general understanding of AI systems, including their capabilities and limitations, [...] iii. where feasible and useful, to provide plain and easy-to-understand information on the sources of data/input, factors, processes and/or logic that led to the prediction, content, recommendation or decision, to enable those affected by an AI system to understand the output, and, […]"* as well as Principle 1.5 *"b) To this end, AI actors should ensure traceability, including in relation to datasets, processes and decisions made during the AI system lifecycle, to enable analysis of the AI system's outputs and responses to inquiry, appropriate to the context and consistent with the state of the art"* (OECD, 2024[113]).

[50] New policies driving this push for technology sovereignty have been categorised as: protecting innovation (e.g. reducing flow of technology outside of borders such as export controls), promoting national capacity (e.g. strengthening domestic research and manufacturing ecosystems via industrial policies) or strengthening alliances with like-minded partners (e.g. technical standards and common research agendas) (OECD, 2023[94]).

[51] For example: United States, United Kingdom, Australia, Japan, Korea, European Union.

[52] Technology sovereignty policies can impact many of the aforementioned policy areas. For example, increased protection of national resources may lead to stricter data sharing policies or prioritisation of proprietary data sets and algorithmic models over more open-source versions, to ensure the benefits of data aggregation stay within national borders. A more competitive environment for international funding may also impact intellectual property and regulatory regimes to attract business investment.

[53] https://www.industry.gov.au/publications/australias-artificial-intelligence-ethics-principles/australias-ai-ethics-principles.

[54] More information on AI Safety Institutes is accessible online: https://oecd.ai/en/wonk/ai-safety-institutes-challenge.

[55] More information is accessible online https://www.nist.gov/artificial-intelligence/ai-standards.

[56] The "OECD AI principles" in 2019 and updated in 2024 (OECD, 2024[113]).

[57] OECD Recommendation of the Council on Enhancing Access to and Sharing of Data:

https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0463.

[58] The OECD Recommendation of the Council on Responsible Innovation in Neurotechnology was adopted in 2019 as the first international standard in this domain, and consists of 9 guiding principles. More information is accessible online: https://legalinstruments.oecd.org/en/instruments/oecd-legal-0457, and a Toolkit to support its implementation is accessible here:

https://www.oecd.org/content/dam/oecd/en/topics/policy-sub-issues/emerging-technologies/neurotech-toolkit.pdf.

[59] More information is accessible online: https://www.oecd.org/en/publications/framework-for-anticipatory-governance-of-emerging-technologies_0248ead5-en.html.

[60] This includes the OECD Recommendation on Digital Security Risk Management (https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0479), the OECD Recommendation on the Digital Security of Critical Activities (https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0456), the OECD Recommendation on the Digital Security of Products and Services (https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0456), the OECD Recommendation on the Treatment of Digital Security Vulnerabilities (https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0456) and the policy paper 'Key concepts and current technical trends in cryptography for policy makers' (https://www.oecd.org/en/publications/key-concepts-and-current-technical-trends-in-cryptography-for-policy-makers_29d9fbad-en.html).

[61] In April 2025, the U.K. Government Office for Science published the report 'Engineering Biology Aspirations Foresight' which highlights five real-world examples of how synthetic biology is being used to tackle global challenges: bio-synthetic fuels, nitrogen-fixing cereals, fashion materials and processes, lab-grown blood, and microbial metal factories (Government Office for Science, 2025[123]).