Innovation Policy System Safeguarding the Development of Synthetic Biology Science, Technology, and Industry: Post-Print

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Abstract

In recent years, synthetic biology has witnessed rapid advancement, introducing novel paradigms and methodologies to life science research. This has not only substantially enhanced humanity's comprehension of the fundamental nature of life, thereby catalyzing revolutions in science and technology, culture, and industry, but has also engendered extensive discussions within the synthetic biology community regarding research and development investment, industrial translation, education and training, intellectual property, public perception, as well as ethical and biosafety regulation. This article systematically reviews the policy and governance challenges confronting the development of synthetic biology science, technology, and industry, along with existing strategies and practices. It proposes recommendations including: strengthening top-level design and clarifying regulatory responsibilities; establishing technical standards and regulating market access; emphasizing the construction of platforms for education, training, and science popularization; and building an innovation policy system and comprehensive governance framework that facilitates joint participation from government agencies, the scientific community, the education sector, industry, and the public.

Full Text

Innovative Policy System to Safeguard the Development of Synthetic Biology Science, Technology, and Industry

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Abstract

Synthetic biology is an interdisciplinary field that combines life science and engineering to study the mechanisms of life, with applications spanning energy, chemicals, medicine, environmental protection, and agriculture. This rapidly advancing field raises important public policy issues ranging from R&D investment and commercialization to education and training, biosafety and biosecurity, intellectual property, and public perception. This paper reviews existing policies, strategies, and practices for the development and application of synthetic biology, and proposes recommendations for strengthening top-level design and clarifying regulatory responsibilities, establishing technical standards and market access norms, emphasizing education platforms and science communication, and building an innovative policy and governance system with participation from government agencies, scientific community, education sector, industry, and the public.

Keywords: synthetic biology, policy system, governance system

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In recent years, synthetic biology has developed rapidly, bringing new thinking and methodologies to life science research. This has not only greatly enhanced human understanding of the essence of life and catalyzed revolutions in science, technology, culture, and industry, but has also sparked discussions regarding R&D investment, industrial translation, education and training, intellectual property, public perception, and the oversight of ethics and biosafety. This article systematically examines the policy and management challenges facing the development of synthetic biology science and industry, reviews existing strategies and practices, and proposes recommendations for strengthening top-level design, clarifying regulatory responsibilities, establishing technical standards and normalizing market access, emphasizing education training and science communication platform construction, and building an innovative policy system and comprehensive governance framework with participation from government departments, scientific community, education sector, industry, and the public.

Synthetic biology employs engineering design principles to purposefully design, modify, and even synthesize "artificial life" from scratch, representing an emerging frontier discipline with significant scientific and technological value and application potential. In recent years, synthetic biology has achieved rapid development with continuous major breakthroughs. "Artificial life" breaks through natural laws of life, helping humanity approach the truth of life's origins and evolution. Advances in gene synthesis and design have propelled synthetic biology research from single cells to the activity mechanisms of multicellular complex life systems, and toward quantitative, controllable design and construction of artificial gene circuits and chassis organisms, as well as hierarchical design and functional diversification of artificial cells. This not only greatly enhances human understanding and manipulation of the essence and working principles of life, but will also catalyze a revolution in science, culture, technology, and industry.

Synthetic biology brings entirely new thinking and methods to life science research, representing a revolution compared to traditional "investigating things to acquire knowledge" methodologies. First, it represents a new thinking mode. Unlike the reductionist thinking of traditional life science research that moves from whole to parts, synthetic biology provides a new holistic thinking mode for understanding life through quantitative, design-oriented synthesis. Second, it represents a new research paradigm. Unlike traditional life science research that "reads" information, synthetic biology initiates a qualitative change in the genetic code from "reading" to "writing." Simultaneously, it has moved from traditional experimental science paradigms into the "fourth paradigm" of "data-intensive science." Third, it represents a new scientific revolution. Synthetic biology promotes a giant leap in global science from understanding life to "designing life," hailed as the third revolution in life science following the elucidation of DNA's double helix structure and the Human Genome Project. Fourth, it represents a convergent technology. The development of synthetic biology promotes the integration of life science with physics, chemistry, nanoscience, information science, and other scientific and technological fields. This "convergence" has transcended the original meaning of "interdisciplinary" to become a "convergence" of science, technology, engineering, and even natural sciences with social sciences and management science [1].

Consequently, synthetic biology has far surpassed traditional biotechnology research paradigms and product application fields, and is considered a disruptive technology that may change future society. Meanwhile, the complexity, novelty, and unprecedented depth and breadth of application scope and scale of synthetic biology technologies and products will bring new issues in organizational structure, funding models, intellectual property, culture, education, and safety regulation.

Strategic Planning and Diversified Investment to Support Science, Technology, and Industry Development

The development of synthetic biology cannot be separated from government strategic guidance and strong support. Over the past decade, both public and private funding in synthetic biology have shown significant upward trends. The scientific community, industry, and government management departments have strived to promote synthetic biology research, application, and industrial translation through strengthened strategic planning and various measures. Multiparty funding support from government, foundations, and enterprises is more conducive to the translation of synthetic biology innovations and large-scale production, promoting the development of related industries.

Currently, synthetic biology technology roadmaps represent a form of forward-looking planning. The European Union was the first to promote the formulation of synthetic biology roadmaps, which serve as both technical and policy roadmaps reflecting the EU's design and planning in synthetic biology from 2008 to 2016. Building upon its 2012 Synthetic Biology Roadmap, the UK released the *UK Synthetic Biology Strategic Plan 2016* in 2016. Guided by these roadmaps and strategic plans, the UK government established the Synthetic Biology Leadership Council (SBLC) [5] and has continuously increased investment and support for synthetic biology. The UK government also supports enterprise-led R&D projects to encourage industrial development. In 2017, the UK government invested £10 million in the Rainbow Development Fund to support the development of synthetic biology spin-off and startup companies. From 2000 to 2016, more than 146 synthetic biology startups were established in the UK, with the number of synthetic biology companies doubling on average every five years [6].

The U.S. government primarily supports basic research and technology development in synthetic biology through federal agencies including the National Science Foundation (NSF), National Institutes of Health (NIH), Department of Agriculture (USDA), and Department of Defense (DOD), with total public funding for synthetic biology reaching approximately $820 million from 2008 to 2014 [7]. Additionally, close collaboration between U.S. research institutions, foundations, venture capital groups, and enterprises has promoted the full-chain development of synthetic biology from basic research to industry. The large-scale production of semi-synthetic artemisinin represents not only a milestone in applying synthetic biology innovations but also the best example of promoting basic research translation through diversified support and investment from government, foundations, and enterprises.

The Chinese government attaches great importance to scientific and technological innovation in frontier interdisciplinary fields and has sustained planning and deployment. Since 2010, the Ministry of Science and Technology's "973" Program has established ten synthetic biology-specific projects, and the "863" Program has also launched major synthetic biology projects. In particular, both the *13th Five-Year National Science and Technology Innovation Plan* and the *13th Five-Year National Basic Research Special Plan* have deployed research on strategic forward-looking major scientific issues and cutting-edge key technologies including synthetic biology.

The enormous industrial prospects of synthetic biology, combined with government support and guidance, have changed the investment landscape. From 2012 to 2016, global investment in synthetic biology enterprises maintained continuous growth, with synthetic biology startups accumulating nearly $4 billion in venture capital. In just the first half of 2018, global fundraising by synthetic biology enterprises reached $1.575 billion. These investments include not only general technology fields such as gene synthesis, computational tool development, and bioengineering platforms, but also applied research fields including medicine and food. Investment methods have also diversified, including startup financing, public offerings, and government investment supporting enterprise R&D [8].

Platform and Infrastructure Construction to Promote Technological Breakthroughs

Engineering platforms and infrastructure for synthetic biology are fundamental guarantees for realizing the "bottom-up" engineering design concept, particularly requiring government top-level design, resource guarantees, and long-term support. On the one hand, governments can establish excellence (innovation) centers to aggregate resources and cultivate talent. On the other hand, the construction of various general and specialized platforms not only provides technical and tool support but also plays important roles in establishing unified norms and standards for synthetic biology.

As early as 2006, the U.S. National Science Foundation invested $20 million to establish the Synthetic Biology Engineering Research Center (SynBERC) with Harvard University, MIT, UC Berkeley, and UC San Francisco. This center not only helped researchers construct biological systems using standardized sensors, effectors, pathways, and logic gate genetic circuits, but also included training engineers in synthetic biology and actively promoting discussions on social and management issues among policymakers and the public. After NSF support for SynBERC ended, the Engineering Biology Research Consortium (EBRC) was established to continue advancing synthetic biology discipline development.

Under the framework of its Synthetic Biology Roadmap, the UK has established seven multidisciplinary synthetic biology research centers and one industrial center through government funding, forming a nationwide integrated research network. These centers have complementary advantages and promote the development of new synthetic biology technologies through resource allocation of equipment and personnel, while also fostering the UK's synthetic biology innovation and industrial culture. Among them, the Synthetic Biology Knowledge and Innovation Centre (SynbiCITE), established through funding for company-led synthetic biology technology development projects, has become the UK's center for technology translation and industrialization. SynbiCITE not only oversees UK synthetic biology entrepreneurship projects but also plays important roles in promoting industrial translation, startup establishment, development funding, and entrepreneurship training courses. In October 2018, SynbiCITE proposed a new five-year strategic plan to create an innovation ecosystem for synthetic biology through new facilities, expanded partnerships, investor alliances, and industry clubs, building an innovation cluster in the UK [9].

Several Chinese universities and research institutes have also recognized the forward-looking significance of synthetic biology and have established relevant research centers (laboratories), gradually building several interdisciplinary research platforms and teams. For example, the Key Laboratory of Synthetic Biology established by the Chinese Academy of Sciences, and related interdisciplinary centers established by Peking University, Tsinghua University, and others. In recent years, governments at all levels have played active roles in synthetic biology infrastructure and innovation platform construction, such as the "National Synthetic Biology Technology Innovation Center" planned to be co-established by Tianjin and the Chinese Academy of Sciences, and the "Synthetic Biology Research Major Scientific Infrastructure" being planned in Shenzhen. These jointly established platform facilities will explore higher-level cooperation mechanisms, provide comprehensive services, and promote new breakthroughs in synthetic biology science, technology, and industry.

Synthetic biology engineering platforms, standard component libraries, and databases are powerful supports for enhancing capabilities in quantitative prediction, precision design, standardized synthesis, and precise regulation. For example, the Registry of Standard Biological Parts (RSBP) established by MIT specifically collects various biological components that meet standardization conditions, providing retrieval by component function, application field, chassis organism, construction method, and contributor. Currently, based on understanding the "design-build-test-learn" engineering cycle, European and American countries have built several synthetic biology engineering platforms. For instance, IBioFAB at the University of Illinois at Urbana-Champaign is the world's first automation center for synthetic biology applications. The DNA synthesis and construction platform established by Imperial College London has set up systematic and standardized operations for the "design-build-test-report-learn" cycle framework, and through cooperation with enterprises under SynbiCITE support, has greatly increased research throughput and speed, providing support for more complex and advanced artificial life R&D.

Promoting Open Intellectual Property Management and Standardization

As related technologies develop and products gradually enter the market, generating enormous economic benefits, synthetic biology involves increasingly complex intellectual property issues. For example, the patent dispute between Jennifer Doudna's team at UC Berkeley and Feng Zhang's team at the Broad Institute over CRISPR-Cas9 lasted for years. When the U.S. Court of Appeals for the Federal Circuit awarded key intellectual property to the Broad Institute on September 10, 2018, and upheld the U.S. Patent and Trademark Office's previous decision [10], shares of Zhang's Editas company surged, with market value increasing by up to 1 billion RMB.

Synthetic biology intellectual property issues primarily involve patents, copyrights, and trademarks [11], as well as database protection and trade secrets. Currently, patent issues receive the most attention. Debates focus on whether naturally occurring substances can be patented and how software patents in synthetic biology can promote knowledge translation. The "synthetic biology IP puzzle" arising from the fundamental contradiction between openness, open-source, and patent protection requires reconsideration and redefinition of the boundaries between intellectual property and the public domain [12]. At the Copenhagen "Synthetic Biology and Intellectual Property" symposium hosted by the European Synthetic Biology Research Network (ERASynBio), participants suggested that government investment institutions, academic institutions, and patent agencies should consider the social value and social responsibility of research activities beyond commercial interests, and proposed developing economical and easy-to-use open-source software tools, using public tools not restricted by intellectual property, improving patent quality and ownership transparency, exploring licensing guidelines and best practices, and legislative and regulatory policy reforms [13].

The core idea of synthetic biology is designing new biological functions based on standardized biological components. Through standardization, the biological components needed to design and modify biological systems can be defined, and their functions characterized and abstracted. The best solution for component storage, assembly, and adaptation issues is also to establish standards. BioBrick is the earliest standardized biological component concept, and the BioBrick Foundation (BBF) established thereby leads the BioBrick Public Agreement (BBPA). This agreement legally allows individuals, companies, and research institutions to develop standardized biological components and share them openly under this agreement framework. The BioDesign Automation Facility (BIOFAB) is an organization specialized in biological design and construction created by MIT based on the International Genetically Engineered Machine (iGEM) competition. It supports R&D in academic and commercial institutions by maintaining and respecting intellectual property rights. Additionally, since many synthetic biology research institutions and laboratories lack a "standard exchange format," hindering seamless linking of different biological component libraries, reproducibility of biological design results, and ultimately leading to incomplete and inaccurate literature information, the "Synthetic Biology Open Language" (SBOL) developed by over 30 institutions and organizations has established unified regulations and requirements for the definition, description, and even schematic symbols of biological components, enabling researchers to accurately share information and reproduce results .

Education and Training for Interdisciplinary Talent Development

The convergent development model of synthetic biology requires innovative talent cultivation and educational models. Research teams should form interdisciplinary research groups and echelons, emphasizing the integration of discipline construction and talent cultivation. The iGEM competition is the most representative synthetic biology-related competition, gradually becoming well-known to the public worldwide. Its main purpose is to design, construct, and test innovative and diverse new biological systems using standard biological components.

iGEM attracts student teams from numerous universities and even high schools globally, with participating teams increasing year by year from 5 in 2004 to 313 in 2017. Through years of development and optimization, iGEM has not only continuously practiced and improved synthetic biology concepts, strategies, techniques, and tool systems, but also cultivated young synthetic biologists for the future and promoted the gradual maturation of this emerging discipline.

With the continuous development of synthetic biology, the demand for interdisciplinary talent is increasing. In recent years, European and American countries have gradually established synthetic biology discipline education systems through implementing related education programs [15]. For example, MIT not only offers graduate courses integrating multiple disciplines but also establishes synthetic biology education programs for high school students. The education program funded by SynBERC targets not only students but also teachers and public science education. Imperial College London offers synthetic biology courses at both undergraduate and graduate levels. Chinese university teachers and students also actively participate in iGEM activities and have achieved excellent results. Participating teams increased from 4 in 2007 to 97 in 2017, with Chinese university teams winning 30 gold medals in 2017 alone [16]. Some Chinese universities and research institutes have also offered synthetic biology-related lectures or courses for undergraduates and graduates, and have attempted to compile synthetic biology textbooks suitable for Chinese students, building platforms for cultivating students and enhancing their research quality.

Risk Prevention and Regulation for Healthy Development

While the rapid development of synthetic biology brings enormous benefits to medicine and health, industrial and agricultural production, environmental protection, human life, and social progress, it may also pose potential risks to ecological environments and human health. On the one hand, artificial design and modification endow synthetic organisms with special capabilities beyond natural organisms, meaning they could potentially cause tremendous destructive effects [17]. On the other hand, synthetic biology's greater emphasis on compatibility of technical standards and open sharing of data and materials compared to other life science fields increases biosafety hazards and social risks, while also challenging existing biosafety policies and regulations.

The OECD, UK Royal Society, and U.S. National Academy of Sciences launched discussions on synthetic biology safety issues under the Convention on Biological Diversity framework at their joint meeting on "Opportunities and Challenges in the Emerging Field of Synthetic Biology" in July 2009. The U.S. National Science Advisory Board for Biosecurity (NSABB) pointed out in its 2010 report that synthetic biology faces potential biosafety risks. Under NSABB's advocacy, the U.S. government promulgated the *Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, clearly requiring regular review of all life sciences research receiving federal funding to identify potential threats from dual use research of concern (DURC) and implement oversight [18].

Additionally, the U.S. government commissioned the National Academies of Sciences, Engineering, and Medicine to conduct research on oversight of "future biotechnology" and bi defense vulnerabilities in synthetic biology, proposing risk assessment frameworks and regulatory systems [19,20]. The U.S. NIH has also revised its *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines) originally issued in 2002, with revisions in 2013 and 2016. The new NIH Guidelines stipulate that biosafety-related research must undergo risk assessment by institutional biosafety committees or biosafety officers and implement appropriate biosafety protection measures before initiation .

In addition to government-led oversight and management, the industry has also proposed self-regulatory principles. The International Gene Synthesis Consortium (IGSC) established in 2009 unites major gene synthesis institutions to establish standard procedures for screening gene/DNA order sequences and verifying customer qualifications to reduce potential threats from gene synthesis.

Policy Recommendations for Promoting Synthetic Biology Science, Technology, and Industry Development

Facing a highly integrated future technology like synthetic biology requires comprehensive consideration from multiple levels including forward-looking planning, strategic guidance, key investment, innovative talent cultivation, engineering technology platform construction, and industry-academia-research innovation value chain construction. To further promote the development of China's synthetic biology science, technology, and industry, the following recommendations are proposed based on China's actual development situation and national conditions:

(1) **Strengthen top-level design and formulate science, technology, and industry development roadmaps.** Focus on major national needs, strengthen strategic research and top-level design, and formulate roadmaps for China's synthetic biology science, technology, and industry development. Identify strategic directions and key breakthrough points to achieve multi-level, phased rapid and stable development from basic research to technological innovation, from engineering platform construction to product development and industrial translation. In line with international research trends, further strengthen basic research, conduct frontier exploration and key technology R&D, strive for more original achievements, and form more internationally leading directions in China's synthetic biology science and technology field to support the development of strategic emerging bio-industries. Strengthen the construction of new R&D institutions, innovation platforms, and databases in synthetic biology, establish professional, integrated, and open-sharing infrastructure, and build a platform-supported, enterprise-managed, and market-oriented scientific and technological innovation model. Improve evaluation systems oriented toward innovation, R&D, and achievement transformation that

are suitable for research entities and directions of different natures. Use policies to encourage enterprises to utilize disruptive technologies, promote the integration of R&D, capital, industry, and other elements, and facilitate the development of strategic emerging bio-industries.

(2) **Clarify regulatory principles and establish scientific and efficient management systems.** Conduct scientific and reasonable analysis and evaluation of synthetic biology-related technologies and products, and identify problems, loopholes, and gaps in existing management policies. According to the characteristics of synthetic biology technologies and products, clarify corresponding competent authorities, clarify responsibilities and rights, and establish scientific, rational, effective, and feasible management principles. Formulate supporting policies and normative systems for R&D, production, and application links and their connections. Strengthen synthetic biology intellectual property (including standardization) protection and management to promote open sharing of resources. Organize relevant departments and experts to research and formulate technical/scientific standards, environmental/safety standards, and reproducible measurement standards for processes, and strengthen exchanges and cooperation with international standards organizations. Clarify declaration and approval pathways (responsible departments) for new products, establish market access norms, unify access standards and review systems, and promote more new products entering the market.

(3) **Emphasize discipline and education system construction to cultivate interdisciplinary talent teams.** According to interdisciplinary needs, carefully design education plans to enhance students' innovative abilities, fully reflect relevant chemistry, physics, mathematics, computer science, and engineering concepts and cases in life science courses, and teach the concepts and methods of "convergent" research to lay a solid multidisciplinary foundation for the growth of innovative synthetic biology talents. Support interdisciplinary education and training for undergraduates, graduate students, researchers, and faculty, and gradually establish a systematic interdisciplinary training system for synthetic biology by coordinating multi-party educational resources [22]. In combination with national and local talent programs, actively introduce talents and focus on cultivating a group of strategic scientists, technological innovation talents, and engineering development talents. Advocate interdisciplinary teamwork and cultivate high-level research echelons.

(4) **Strengthen risk assessment and regulation, and build science communication platforms.** Vigorously conduct research on synthetic biology-related ethics, biosafety, and biosecurity issues, support theoretical and methodological research on technical safety risks, improve technical guidelines and guiding documents, and perfect safety assessment and review systems [23]. Understand Chinese public perception and acceptability of synthetic biology and corresponding science communication

needs, establish public understanding and science communication platforms through professional communication teams, foster a rational scientific culture, and guide social cognition and understanding of synthetic biology technologies through scientific and orderly public opinion guidance to promote the healthy development of synthetic biology science, technology, and their industrial and social applications.

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Note: Figure translations are in progress. See original paper for figures.