Scoping study on potential future commercial use of digital sequence information on genetic resources

UN environment programme WCMC

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Executive summary

Introduction

In decision 15/9, the CBD COP agreed that the benefits from the use of digital sequence information on genetic resources (DSI) should be shared fairly and equitably. It was also decided to establish a multilateral mechanism for benefit-sharing from the use of DSI, including a global fund. Technologies that use DSI and the products that derive from them are evolving at a rapid pace. This could have future implications for the multilateral mechanism. The UN Environment Programme World Conservation Monitoring Centre (UNEP-WCMC), in collaboration with the CBD Secretariat, has prepared this scoping study as a contribution towards discussions on the multilateral mechanism. A key focus of this scoping study is to highlight forward-looking aspects that may affect the potential use of DSI and, thereby, the further development and future effective functioning of the multilateral mechanism.

From its generation, DSI can be applied across value chains to develop innovative products and services. This scoping study examines how the technologies that use and rely on DSI, as well as their applications in various fields, are evolving. This will provide a better understanding of potential implications that this may have for the commercial use of DSI. In the past few years, increasingly advanced technologies and tools have expanded the potential range of the technological applications that use biological systems, living organisms, or derivatives to make or modify products or processes. Many of these, fall within the scope of biotechnology as defined by the CBD (see also Box 2). DSI is deeply interrelated with many of these technologies, including synthetic biology and DNA barcoding, and plays a key role in their application in industrial, medical, and agricultural contexts.

This scoping study highlights how selected technological applications using DSI are evolving as a way to illustrate the potential for commercial use of DSI in the coming years and decades. It is important to note that the selected technological applications represent only a few examples of the many potential applications of DSI and related technologies and tools. Moreover, the selected technological applications are interrelated and may be used in in multiple industrial sectors, including food, health, chemicals, cosmetics and materials, often in an overlapping way. Nevertheless, looking at the trends in industrial, medical and agricultural biotechnology, as well as noting some other disruptive technologies and technological applications, provides initial insights on the breadth of potential trends and applications of DSI in commercial products and services, for further research and consideration.

Methods

This scoping study aims to provide initial insights from experts and practitioners on trends in the use of DSI, identifying areas for further research and discussion. The scoping study is based on responses received to a survey sent out to experts and practitioners, complemented by a high-level review of the literature. This information was used to identify future trends in how technologies and technological applications are likely to evolve, how their development and use may spread globally, and what new types of products and services are likely to result in the coming years, across a range of sectors. We reached out to 270 experts and practitioners, receiving 48 responses from 35 different institutions from around the world. Out of the responses 48, 42% were from people whose institution is based in a developing country and out of the 35 institutions included, 51% are based in a developing country.

Key findings

The survey and literature review reveal several key trends in technologies and technological applications utilizing DSI. New and enhanced industrial biotechnology techniques are set to broaden and improve both new and existing processes, cutting costs and environmental impacts. In medical biotechnology, innovations promise to drive precision diagnostics and treatments, potentially transforming healthcare for difficult-to-treat diseases. Agricultural biotechnology is advancing towards creating customized crops with better nutrition and resilience, while 'molecular farming' opens new avenues for producing diverse non-food products for healthcare and energy. Advances in synthetic biology, bolstered by artificial intelligence (AI) and cell-free environments, are poised to revolutionize product development and production methods across sectors. The rise of portable sequencing tools and DNA barcoding technologies is facilitating real-time environmental monitoring and forensic applications. Additionally, emerging technologies, such as DNA-based data storage, may extend DSI's potential beyond traditional uses, with AI accelerating the development and diversification of new products.

Considerations

The transformative potential of DSI lies in enabling broader and more rapid access to data and driving innovative technologies and products. The direction is moving towards increased data, cheaper and easier to implement technologies, and a wider range of products. However, the potential benefits of these innovations will not necessarily result in increased accessibility across countries, or fair and equitable sharing of the benefits resulting from the use of DSI.

This scoping study describes the fast pace of development of DSI-related technologies and technological applications and outlines many of the remaining known unknowns in the future use of DSI. Its findings suggest that the following considerations may be helpful when thinking about a benefit sharing mechanism:

Access to data

It is important to consider who will be able to access the increasing amounts of DSI data. Cheaper and easier-to use technology could potentially enable local expertise to collect and upload data to global DSI databases. Less centralized generation of DSI data could feed into global and automatic data systems, providing users with more complete data and eventually enabling local stakeholders and companies to better manage biodiversity. However, intellectual property rights and the "race for data", while driving innovation at the moment, may create future barriers to innovation and equitable access, exacerbating existing disparities in access to technology and hindering collaborative efforts.

By enabling mass analysis of DSI databases, AI will transform innovation in biotechnology. It will likely become unfeasible to track which individual DSI contributed towards an AI derived product. As DSI databases become larger, and the value of DSI lies within the dataset as a whole, it must be considered how the value of an individual piece of DSI will change over time. In addition, advances in synthetic biology and AI may also reduce our reliance on DSI derived from genetic resources. It will become increasingly difficult to determine whether DSI derives from a naturally occurring genetic resource or not.

Access to technologies and products

Technological advances are making tools that use DSI more affordable and easy-to-use. An important question arises around who will actually own and have access to these technologies. DSI that underpins many technologies often derives from developing countries and increasing research and investment is being focused on developing regions. However, the majority of technology companies are currently based in developed countries. It is uncertain if technological advances will narrow the technology gap between developed and developing countries, or widen it. There are also important questions around which companies will be producing these products, where they will be located, and if the products will be affordable and accessible to those in developing countries.

Potential implications

Experts consulted highlighted the continuing and rapid pace in innovation on DSI-related technologies and technological applications. In principle, as they develop and mature, technologies become more affordable and accessible. In practice, however, high initial costs, fast rate of technological turnover, intellectual property and skills and knowledge required often mean technologies do not become widely or evenly spread. A "future-proof" multilateral mechanism for benefit-sharing from the use of DSI should consider this uncertainty in its modalities and operationalization. Some options currently on the table for the multilateral mechanism focus on the value-addition steps of the value chain, rather than at the point of access to DSI. The importance of fair and equitable sharing of non-monetary benefits, such as technology transfer and technical and scientific cooperation, has also been discussed during deliberations on DSI. If frameworks for sharing non-monetary benefits for specific sectors are developed, it would be relevant to consider the aspects that affect access to data and use of technologies mentioned in this study. Furthermore, the role of intellectual property rights (IPR) and how it might limit access to benefits arising from future technologies and products should also be considered. This is especially critical given the significant public policy benefits that DSI-derived technologies can provide. Further to the information included in this scoping study, it proposes other relevant areas of research. For example, the impact of the development of technologies that use DSI on groups including indigenous peoples and local communities, women and youth is an important consideration, as well as the role private DSI databases will play going forward.

List of acronyms

AHTEG on DSI: Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources

AI: artificial intelligence

CBD: Convention on Biological Diversity

COP: Conference of the Parties

CRISPR: clustered regularly interspaced short palindromic repeats

DNA: deoxyribonucleic acid

DSI: digital sequence information on genetic resources

GMO: genetically modified organism

IPBES: Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services

IPR: intellectual property rights

NGS: next-generation sequencing

OECD: Organisation for Economic Co-operation and Development

PCR: polymerase chain reaction

RNA: ribonucleic acid

UNEP-WCMC: United Nations Environment Programme World Conservation Monitoring Centre

WHO: World Health Organization

Glossary

Antibody: a protein produced by the immune system in response to the presence of a foreign substance ('**antigen**')

Antigen: any substance that triggers the body to make an immune response.

Artificial intelligence (AI): there is no consensus on the definition of AI. Within the context of this scoping study, AI refers to the OECD definition:[1] "an AI system is a machine-based system, that for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment".

Biofuel: liquid or gaseous fuels that are made from biomass (e.g. bioethanol, timber, animal waste, etc.).

Bioreactor: an apparatus or vessel that provides controlled and optimal conditions to grow organisms to carry out a biochemical reaction.

Biosensor: devices that detect and produce a signal in the presence of a particular chemical, molecule or organism.

Biotechnology: any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.[2]

Commercial use of DSI: the commercial sale of products or services which contain DSI or involve the use of DSI in their development.

CRISPR-Cas9: A genome editing tool. CRISPR-Cas9 (clustered regularly interspaced short palindromic repeats), enables precise and localized modifications directly to the genomes of living organisms, resulting in altered gene functions. DSI provides the exact DNA sequence of the gene or genomic region that needs to be edited. This information then directs the enzyme Cas9 to the location within the genome that requires editing.[3] Note that since the advent of CRISPR-Cas9, other technologies that work in similar ways have been developed that are loosely referred to as CRISPR.

Digital sequence information on genetic resources (DSI): In Decision 14/20, it is noted that 'the term "digital sequence information" may not be the most appropriate term and that it is used as a placeholder until an alternative term is agreed'.[4] There is some consensus that DSI includes nucleic acid sequencing data, but the scope of this term could be extended to include other types of data, such as protein sequence data and other dematerialized genetic resources.[5]

Enzyme: "An enzyme is a biological catalyst and is almost always a protein. It speeds up the rate of a specific chemical reaction in the cell. The enzyme is not destroyed during the reaction and is used over and over."[6]

Gene: "the basic physical and functional unit of heredity. Genes are made up of DNA, and occupy a fixed position (locus) on a chromosome. Genes achieve their effects by directing the synthesis of proteins."[7]

Genetic engineering: "the artificial manipulation, modification, and recombination of DNA or other nucleic acid molecules in order to modify an organism or population of organisms"[8]

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[1] OECD. AI Principles overview. Available at: https://oecd.ai/en/ai-principles (Accessed on 30 July 2024)
[2] Convention on Biological Diversity, 1992. Text and annexes. Article 2. Available at: https://www.cbd.int/doc/legal/cbd-en.pdf
[3] Samal D, Murthy MK, Malaviya S and Khandayataray P, 2023. Synthetic Biology: A Scientific Review of Current Developments and Future Perspectives. *The International Journal of Science, Mathematics and Technology Learning,* 31(2), 633.
[4] CBD/COP/DEC/14/20. Available at: https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-20-en.pdf
[5] CBD/DSI/AHTEG/2020/1/3. Available at: https://www.cbd.int/doc/c/fef9/2f90/70f037ccc5da885dfb293e88/dsi-ahteg-2020-01-03-en.pdf
[6] National Human Genome Research Institute. Available at: https://www.genome.gov/genetics-glossary/Enzyme
[7] IPBES (2019). Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Available at: https://www.ipbes.net/global-assessment
[8] IPBES (2019). Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Available at: https://www.ipbes.net/global-assessment

Genetically modified organism: "organism in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. [9] [10]

Genetic resources: "genetic material of actual or potential value."[11]

Genomics: "Genomics is the study of the complete set of genes (the genome) of organisms, of the way genes work, interact with each other and with the environment".[12]

Macromolecule: a large molecule made up of smaller chemical structures (e.g. a protein).

Metabolism: all of the chemical reactions that occur within an organism and that provide the organism with energy.

Metabolic pathway: a series of chemical reactions that occur within a cell, beginning with a starting substrate and finishing with an end product.

Metabolite: a product (intermediary or final) of the metabolism.

Microorganism: a small organism not visible to the naked eye (e.g. bacteria).

Molecular farming: this is the practice of using genetically modified plants to manufacture pharmaceuticals, biofuels and other molecules. It may also be spelled molecular 'pharming'.[13]

Nucleic acids: large molecules essential to life (e.g. DNA, RNA, etc.). The are formed of long chains of nucleotides. Each nucleotide contains a phosphate group, a five-carbon sugar, and a nitrogenous base.

PCR: Polymerase Chain Reaction (PCR) is a laboratory technique that is used to amplify DNA sequences, making millions of copies from a small initial sample.

Personalized medicine: the practice of medicine that uses the genome of a person to guide decisions regarding prevention, diagnosis and treatment of disease. Sometimes also referred to as 'precision medicine'.[14]

Silicon chip: a piece of silicon containing electronic circuits that can perform electronic functions as part of an integrated circuit in computers, smartphones etc.

Sequencing (of DNA): The laboratory process by which the exact order of nucleotides in a DNA molecule is determined. This involves identifying the sequence of the four bases (adenine [A], cytosine [C], guanine [G], and thymine [T]) in a strand of DNA.

Stem cell: Stem cells are self-renewing cells that can differentiate into the different types of cells that make up the body (e.g. liver cells, muscle cells, etc.).

Value chain: "a series of consecutive steps or activities conducted by stakeholders which add or derive value from DSI and are required to bring a product or service from conception through to distribution to consumers".[15]

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[9] IPBES (2019). Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Available at: https://www.ipbes.net/global-assessment

[10] Note that the terms, GMO and LMO (living modified organism) are used interchangeably, but that GMO is the most prevalent term found within the literature review and used by the experts consulted. The Cartagena Protocol on Biosafety defines 'living modified organism' as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

[11] Convention on Biological Diversity, 1992. Text and annexes. Article 2. Available at: https://www.cbd.int/doc/legal/cbd-en.pdf

[12] World Health Organization, 2024. Available at: https://www.who.int/health-topics/genomics#tab=tab_1

[13] Adapted from Buyel J, Glössel J, and Stöger E, 2024. Using plant molecular farming to increase regional biomanufacturing capacity. Science-Policy Brief for the Multistakeholder Forum on Science, Technology and Innovation for the SDGs. Available at: https://sdgs.un.org/sites/default/files/2024-05/BUYEL_~1.PDF

[14] Adapted from WHO, 2023. Health technologies. Available at: https://www.who.int/europe/news-room/fact-sheets/item/health-technologies

[15] CBD/WGDSI/2/INF/1. Available at: https://www.cbd.int/doc/c/58d2/cd87/2ef418ccca31155fb8d0a4f5/wgdsi-02-inf-01-en.pdf

1 Introduction

Digital sequence information on genetic resources in the context of the Convention on Biological Diversity

During the 15th meeting of CBD COP (COP15), Parties to the CBD agreed that the benefits arising from the use of digital sequence information on genetic resources (DSI; Box 1) should be shared fairly and equitably and decided to establish, as part of the Kunming-Montreal Global Biodiversity Framework, a multilateral mechanism for such benefit-sharing, including a global fund. Parties also decided to establish a fair, transparent, inclusive, participatory, and time-bound process to further develop and operationalize the mechanism.[16]

Box 1: Definition of "digital sequence information"

The term digital sequence information on genetic resources (DSI) does not have an internationally agreed definition. In the context of discussions under the CBD, it was considered as a "placeholder" until the COP15 - an operational term, rather than a definition with clear concept and scope. This study is aligned with this approach, recognizing that a range of information may fall within the term DSI, from nucleic acid sequences to information on proteins, metabolites and other macromolecules. For more information on what types of data are included under the umbrella of DSI, please refer to the commissioned study by Houssen, Sara and Jaspars, presented at the AHTEG in 2020 (CBD/DSI/AHTEG/2020/1/3). At COP15, the Parties agreed to continue to use the term 'digital sequence information' for further discussions.

Further to the range of information necessary to inform discussions on the operationalization of the mechanism that was identified at COP15, deliberations on DSI have also identified other aspects of relevance for this matter. For example, in its first meeting, the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources noted the need for further consideration of how to ensure the multilateral mechanism is "future proof." That is, the need for the multilateral mechanism to be designed and implemented in a way that it considers and can address technological developments, including in relation to AI, as applied to DSI.[17] The use of AI is expected to accelerate innovation in technologies that use DSI, potentially leading to previously unattainable and unexpected implications. A simplified timeline with key decisions adopted by CBD COP that relate to DSI can be found in Figure 1.

The United Nations Environment Programme World Conservation Monitoring Centre (UNEP-WCMC), in collaboration with the CBD Secretariat, has prepared this scoping study as a contribution to discussions on the multilateral mechanism on DSI, in particular, forward-looking aspects that could affect the potential use of DSI.

Objectives

This scoping study aims to provide initial insights from experts and practitioners on trends in the use of DSI. While not a comprehensive study, it seeks to identify areas for further research and discussion, particularly by focusing on technologies and technological applications known to rely on and value DSI in the form of commercial products and services.

[16] CBD/COP/DEC/15/9. Available at: https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf
[17] CBD/WGDSI/1/3. Available at: https://www.cbd.int/doc/c/24be/09d3/f69b4c05e158925846e0541b/wgdsi-01-03-en.pdf

Figure 1: Timeline of key CBD decisions relating to DSI.

2 Scope

This scoping study is not a comprehensive review, but helps to identify some preliminary trends that may be useful for ongoing discussions on DSI under the CBD. It also identifies areas for further research and discussion, potentially through a longer and more systematic review. It also raises questions regarding potential implications that these trends could have for the design and implementation of the multilateral mechanism for benefit-sharing from the use of DSI.

In that context, this scoping study focuses on the technologies and technological applications that use and rely on DSI for developing and manufacturing commercial products and services, how they are evolving and what the resulting implications may be for innovation in products and services. The focus on technologies and technological applications, rather than, for example, economic sectors, responds to:

1. the cross-cutting technologies and technological applications using DSI, which are used, in often overlapping ways in a range of sectors;
2. the role of evolving technologies and technological applications in driving the innovative use of DSI in commercial products and processes; and
3. the trend for ideas and innovation to occur at the level of technological developments and technological applications, either within research institutions or start-up enterprises, rather than within companies using the resulting inputs or processes to manufacture finished products – even if finished products specifications (e.g. smaller carbon footprint) may create some of the new market opportunities.

In the past few years, increasingly advanced technologies and tools have expanded the potential range of the technological applications that use biological systems, living organisms, or derivatives to make or modify products or processes. These fall within the scope of biotechnology as defined by the CBD (see also Box 2). DSI is deeply interrelated with many of these technologies, including synthetic biology, artificial intelligence and DNA barcoding, and plays a key role in their application in industrial, medical, and agricultural contexts.

This scoping study highlights how selected technological applications using DSI are evolving as a way to illustrate the potential for commercial use of DSI in the coming years and decades. It focuses on industrial, medical and agricultural biotechnologies as technological applications. These were identified by experts and practitioners, as well as by the literature review, and illustrate some of the potential future commercial use of DSI. It is important to note that the selected technological applications represent a few examples of the many potential applications of DSI and related technologies and tools. Moreover, the selected technological applications are interrelated and may be used in in multiple industrial sectors, including food, health, chemicals, cosmetics and materials, often in an overlapping way. For example, medical biotechnology frequently draws on advances from industrial biotechnology. A genetically engineered plant, used to produce vaccine components, may have involved synthetic biology. While recognising these interconnections, for the purposes of this scoping study, technologies and technological applications are presented separately. Such an approach, focusing on trends in industrial, medical and agricultural biotechnology, allows the scoping study to begin to outline the breadth of potential trends and applications of DSI in commercial products and services, for further research and consideration.

DSI is central to biotechnology in its broad definition, and it is used along the entire product development process, across a range of sectors. At the beginning of the DSI value chain, a single genetic resource can give rise to hundreds to millions of individual DSI records depending on what is sequenced from the genetic resource. The initial point of access to DSI occurs when DSI is downloaded from a database. These databases may contain many millions to billions of DSI. The next step in the DSI value chain is research and development based on DSI. A large number of DSI may be consulted during this process. Not all projects will have successful outcomes and many will not progress through the next steps. If research and development is successful, the development and manufacturing of products and processes may take place, followed by marketing, regulatory approval and commercialization of both intermediary products and final products.[18] In this way, products and services may derive from millions, or even billions, of genetic resources and DSI.

Box 2: What is biotechnology?

The CBD defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific uses."[19] This is a broad definition that recognizes that people have for thousands of years been harnessing biological processes for new products and processes – from plant breeding to using microorganisms to make bread, cheese, and alcoholic beverages.

Nevertheless, the term biotechnology also more specifically refers to a narrower, more modern set of technologies that use enzymes and various laboratory techniques to alter and isolate DNA segments. Though such biotechnology dates back to the 1970s, it has more recently evolved at great speed as genomics, proteomics and other disciplines increased the data, information and knowledge on the structure and dynamics of biological systems. The practical application of biotechnology – innovative products and services based on such technologies – is also evolving quickly. Biotechnology is already used to design and make commercial products and processes in a range of economic sectors – from healthcare and agriculture to industrial manufacturing and consumer products – and related technologies. New and evolving technologies will potentially allow for innumerable new applications. For example, the growing ability to collect, digitize, store, and analyse genomes from large numbers of individuals will provide new insights into the relationship between genes, environment and lifestyle and is expected to result in the rise of personalized, precision health care.

Detailed examples of the DSI value chain for several products, including pharmaceutical, cosmetics, crops and laboratory equipment and services were included in the studies commissioned further to decision 15/9 and made available to the second meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources.[20] This scoping study rather looks ahead at how biotechnology is evolving and what this might mean for the potential future commercial use of DSI.

Within this context, it is also important to acknowledge the relationship between DSI and the field of synthetic biology[21] as DSI underpins many technologies utilized within synthetic biology by enabling the design, optimization and implementation of biological systems and processes across multiple sectors, including the three aforementioned types of biotechnology.[22] For example, synthetic biology often relies on a suite of supporting technologies and tools, such as nucleic acid synthesis, next-generation sequencing and bioinformatics, direct evolution, genome editing, engineered gene drives,

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[18] CBD/WGDSI/2/INF/1. Available at: https://www.cbd.int/doc/c/58d2/cd87/2ef418ccca31155fb8d0a4f5/wgdsi-02-inf-01-en.pdf

[19] Convention on Biological Diversity, 1992. Text and annexes. Article 2. Available at: https://www.cbd.int/doc/legal/cbd-en.pdf

[20] CBD/WGDSI/2/INF/1. Available at: https://www.cbd.int/doc/c/58d2/cd87/2ef418ccca31155fb8d0a4f5/wgdsi-02-inf-01-en.pdf

[21] The CBD COP-13 acknowledged the operational definition of synthetic biology developed by the Ad Hoc Technical Expert Group on Synthetic Biology, that is "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", and considered it useful as a starting point for facilitating scientific and technical deliberations under the Convention and its Protocols. (CBD/COP/DEC/XIII/17)

[22] Akpoviri FI, Baharum SN and Zainol ZA, 2023. Digital Sequence Information and the Access and Benefit-Sharing Obligation of the Convention on Biological Diversity. *Nanoethics*, 12(1).

RNA-based tools, modelling, artificial intelligence and machine learning, biofoundries and BioBricks, among others, which also depend on DSI.[23]

Under the CBD, synthetic biology was recognized as a rapidly developing, cross-cutting issue with regard to the three objectives of the Convention at COP-14[24] and relevance of DSI for synthetic biology was also acknowledged at CBD COP-15.[25] Thus, to keep track of the developments in synthetic biology and their potential impacts on the three objectives of the Convention, the CBD COP-15 established a process for broad and regular horizon scanning, monitoring and assessment, as well as a multidisciplinary ad hoc technical expert group on synthetic biology to support this work (decision 15/31).[26]

Thus, in light of the above, this scoping study additionally highlights certain cross-cutting technological fields and applications that are proving to be disruptive. They are fundamentally changing the way certain economic sectors operate by introducing new features, capabilities, and efficiencies. These are synthetic biology, artificial intelligence and DNA barcoding. The CBD COP has consistently recognized the role of DNA barcoding in the context of biodiversity and related activities,[27, 28] and artificial intelligence has been part in discussions of the work of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources[29] and was highlighted by the multidisciplinary AHTEG on synthetic biology as one of the prioritized trends and issues in synthetic biology.[30]

A final point on scope is that although this study focuses on commercial applications, these technologies also have a range of non-commercial purposes, including taxonomy, morphology, conservation, or others. As noted in discussions in the context of the CBD and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, this scoping study recognizes that the line between commercial and non-commercial use can sometimes be unclear.

3 Methodology

This scoping study was produced on the basis of data gathered through a survey of experts and practitioners on technologies employed for the commercial use of DSI, as well as a high-level literature review.

The survey was designed to gather information on how technologies that use DSI are evolving, including in relation to the companies and countries that develop and/or use them around the world, as well as new types of products and services that are likely to result from evolving technologies across a range of economic sectors (see Appendix 1).

The survey was sent to more than 270 experts and practitioners working with or on technologies using DSI for commercial purposes. This list included a sample of experts and practitioners from government, academia, business, and other sectors around the world, including those that are part of the Informal Advisory Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources. In total, we received 48 responses (58% from research, 21% from business, 10% from government and 10% categorized as other) from 35 different institutions (we received responses from multiple people for four of the institutions). All 48 responses were considered in the

[23] Secretariat of the Convention on Biological Diversity, 2022. Technical Series No. 100. Available at: cbd-ts-100-en.pdf.
[24] CBD/COP/DEC/14/19. Available at: https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-19-en.pdf
[25] CBD/COP/DEC/15/31. Available at: https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-31-en.pdf
[26] CBD/COP/DEC/15/31. Available at: https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-31-en.pdf
[27] CBD/COP/DEC/14/24. Available at: https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-24-en.pdf
[28] CBD/COP/DEC/14/11. Available at: https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-11-en.pdf
[29] CBD/WGDSI/REC/2/1. Available at: https://www.cbd.int/doc/recommendations/wgdsi-02/wgdsi-02-rec-01-en.pdf
[30] CBD/SBSTTA/26/4. Available at: https://www.cbd.int/doc/c/8cb2/d007/23a9f799fb31180cb353d6e2/sbstta-26-04-en.pdf

analysis undertaken for this scoping study. Of the total number of responses received, i.e. 48, 42% came from people whose institution is in a developing country (see Figure 2). When considering the total number of institutions that have responded to the survey, i.e. 35, 51% are based in developing countries (Figure 3).

The survey was supported by a rapid, high-level review of scientific literature (e.g. peer-reviewed academic journal articles) and grey literature (e.g. reports, newsletters, blogs etc.) that synthesize or review existing knowledge on trends in technologies that use DSI for commercial purposes. This high-level review primarily focused on recent literature available in English, thus providing a broad overview rather than an exhaustive analysis. As a result, the literature review did not encompass all relevant studies relating to the use of DSI. Literature was identified by searching for key terms relevant to DSI and the technologies that use DSI. This approach was also used to identify gaps in knowledge, based on our observation of gaps in the literature, where further research and consultation would be needed to understand future trends. A list of all literature consulted can be found Appendix 2.

Figure 2: Geographical distribution and country economy classification of all survey responses (n= 48).

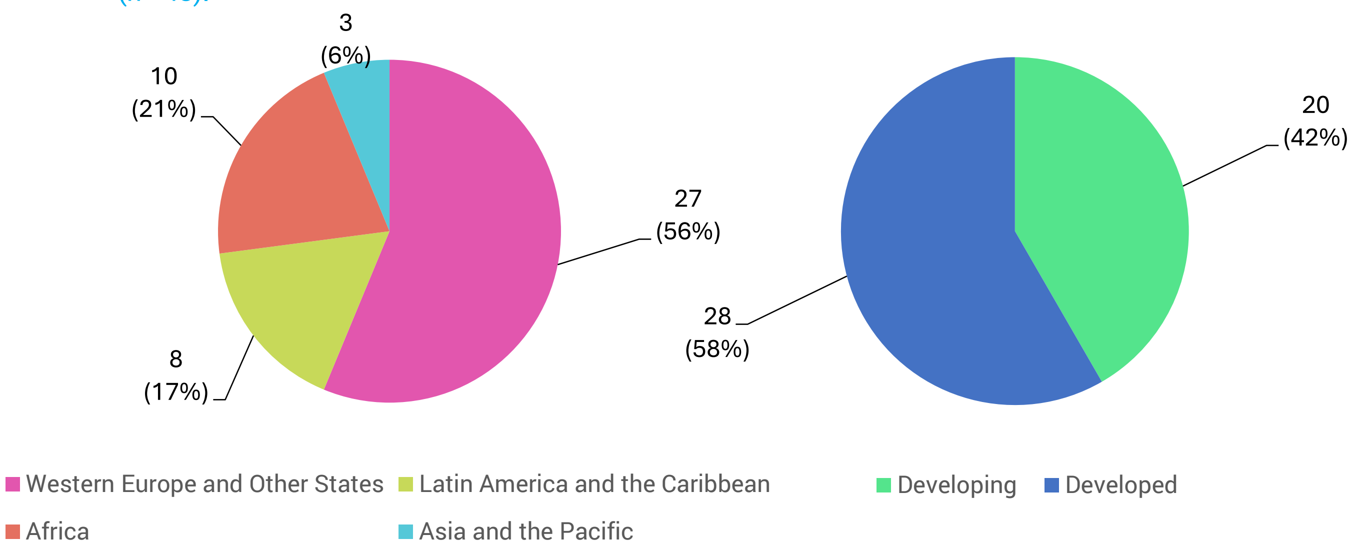
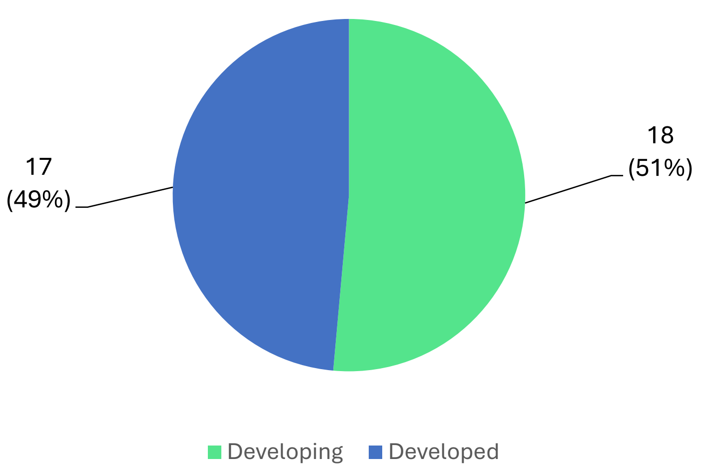


Figure 3: Country economy classification of institutions represented in the responses (n= 35).



4 Limitations and assumptions

This scoping study has several limitations, which are identified below.

Firstly, the scope of this study focused on selected technologies and technological applications, which do not constitute an exhaustive list of technologies or technological applications that are relevant to DSI. While the technological applications selected are wide ranging and commercially important, they may not capture all possible trends. There is no internationally accepted definition of 'technology,' but for the purpose of this scoping study we use the term to refer to tools and methods. Technology may be deployed in various ways and sectors, to solve specific problems, improve efficiencies or provide innovative approaches, which may then be referred to as technological applications. These technological applications will result in various intermediate and ultimately final products along the value chain.

Furthermore, the scoping study relates to DSI on genetic resources, and not specifically covering the traditional knowledge associated with genetic resources and the related information that may be derived. On a related vein, no distinction has been made regarding specific genetic resources, for instance those in the marine realm, or what the future use of DSI may imply in the context of other intergovernmental processes that deal with DSI.

Due to time limitations, a non-exhaustive literature review was carried out. It was limited to studies available in the English language and to high-level review of articles and resources. This limitation may have affected the depth and breadth of the insights and representation of views, as well as the comprehensiveness of the review. For instance, more examples were found of biotechnology companies from developed countries. While this could indicate a trend, further work would be needed to investigate non-English literature and see whether that trend would be confirmed or not.

Linked to the timeframe in which the scoping study was developed, six weeks were provided to receiving responses on the survey. While several reminders were sent to invited participants during this period, the limited period of time to complete the survey may have impacted the number of responses received.

Another important aspect to mention relates to the stakeholders targeted for this work and related geographical representation. During the process for the identification of experts and practitioners, special effort was made in trying to reach out to individuals and organizations from all regions in order to get a geographically balanced sample. Nonetheless, despite these efforts, information was more readily available for the larger biotech centres, which led to a larger proportion of stakeholders from larger companies being contacted. Furthermore, most of the emails were written in the English or Spanish language, which may have limited the responses we received and therefore the representation of views. The study focused on gathering the views of experts and practitioners and in doing so used a targeted approach that did not entail reaching out to all major groups, e.g. indigenous peoples and local communities, women and youth.

Finally, as a means to narrow the scope and simplify the analysis in light of the time available, this scoping study made the assumption of continued technology growth. Nonetheless, in reality, there are many factors at play (e.g. interest rates, risk appetite, disruptive global events etc.), which may impact the growth of DSI technologies in unforeseen ways that are outside the scope of this study.

Despite these limitations, this scoping study provides initial insights on trends in the future use of DSI, offering a starting point for future work. There is therefore an opportunity for further research in this area to focus in addressing the limitations identified.

5 Selected technological applications

This section describes how some technological applications that use DSI are evolving in terms of their use and commercial applications. This is the core of the scoping study and serves as the basis for the concluding thoughts and questions on potential implications in the next section.

The three technological applications selected for this scoping study illustrate trends in technology development and the potential future use of DSI to drive innovation and novel products and services. Table 1 summarises what these technological applications entail, how DSI is used and what are the existing and potential future products and services that result from the use of DSI. These points are further developed in the subsections below. It must be recognized that there is significant overlap between these technological applications, which may be used in multiple industrial several sectors. For example, agricultural biotechnology can be closely linked to medical biotechnology, such as in the production of plant-based vaccines. Focusing on trends in industrial, medical and agricultural biotechnology provides a range of examples on potential trends in novel commercial products and services that may emerge from the use of DSI in the coming decades. It does not provide a comprehensive overview, but seeks to highlight topics and gaps that may merit further consideration.

Key innovations applicable across biotechnologies

In addition to the trends for specific biotechnologies listed in Table 1 below, there are cross-cutting technological developments that could be applied across all biotechnologies, driving innovation and novel products and services. For example, high-throughput screening and automation enables the rapid screening of large numbers of genetic variants or microbial strains using automated systems. Next-generation sequencing (NGS) offers quicker and more cost-effective sequencing of genomes and transcriptomes. Computational biology and bioinformatics are transforming how biological data is interpreted, using algorithms, modelling, and data analysis tools to predict outcomes and design new biological systems. Similarly, AI and machine learning algorithms are being employed to analyze complex biological data and optimize biotechnological processes. There are also growing capabilities to conduct precision modifications and generate novel synthetic genomes and pathways, increasing the complexity and capability of synthetic biological systems. Integration of biological components into silicon chips and devices is another innovative area, alongside advances in bioreactor design and control systems that enhance the efficiency and scalability of microbial fermentation. Additionally, the application of 3D printing technologies is facilitating the creation of novel biological materials and structures.

Table 1: A summary of how selected biotechnologies are using DSI and the evolving applications, as informed by the survey and high-level literature review.

	What it entails	How DSI is used	Current applications of the technology	Future potential applications
Industrial biotechnology	It is the application of biological systems, such as microorganisms, cells, or enzymes, to industrial processes to produce chemicals, materials, or energy. It leverages biotechnology to develop more efficient or sustainable manufacturing processes.	DNA sequences of microorganisms, plants, and animals, including specific genes responsible for desirable traits; and metabolic pathways information and models, which show the enzyme-catalyzed chemical reactions that occur in a cell. It also involves genome editing tools like CRISPR for precise modifications.	• Biofuels • Bioplastics • Medical devices • Specialty chemicals • Enzymes for detergents • Flavours and additives	Innovations in industrial biotechnology could offer more efficient, sustainable, and versatile options to existing products in a range of sectors, as well as completely novel products. Examples include: • Bio-based materials for electronic devices, biodegradable circuit boards and organic solar cells. • Materials incorporating living cells that can sense and respond to their environment, repair themselves, or perform specific functions • High-value cosmetic and food ingredients, offering enhanced purity and functionality. • Biocatalysts with reduced energy demands for chemical synthesis and reduced need for hazardous chemicals • Biodegradable plastics • Converting waste materials into valuable products such as biofuels
Medical biotechnology	It is the application of biological systems, such as microorganisms and cells, to produce pharmaceutical and diagnostic products to prevent and treat diseases or injuries. It leverages biotechnology to discover and develop new drugs and vaccines.	DSI used includes human, animal, and pathogen genomes; genetic markers for disease; and protein structures. It also involves the use of CRISPR and other gene-editing technologies for targeted treatments.	• Antibodies • Gene therapy • Vaccines • Diagnostic tests	Innovations in medical biotechnology could offer more personalized healthcare treatments and widespread use of instantaneous diagnostics. Examples include: • Direct editing of patient genomes to treat genetic diseases • New vectors that can deliver larger genetic payloads to patients • Reprogrammable stem cells to treat tissue injury • Vaccines less susceptible to the evolutionary adaptation of pathogens • More representative genome assemblies (less focused on particular groups of people or model organisms) • Biosensors to provide instant diagnostics and detect patient vitals in real time, releasing medicines in response • Construction of synthetic genomes
Agricultural biotechnology	It includes modification of living organisms and new genomic technologies to make or modify agricultural products to address challenges in food security, nutrition, sustainability, and environmental impact. It leverages biotechnology to develop more efficient and sustainable crop varieties, animal breeds and chemicals such as fertilizers and pesticides.	DSI used includes genetic information on crops and livestock for trait selection and improvement (e.g. drought resistance, pest resistance, and increased nutritional value). It also involves genome editing tools like CRISPR for precise modifications.	• Disease resistant crops • Crops with enhanced nutrition • Crops resilient to harsh environmental conditions • Biofertilizers • Biopesticides • Livestock with improved traits.	Innovations in agricultural biotechnology have the potential to offer healthier, more sustainable and resilient food products, as well as small molecules for use across a range of sectors: • Climate resilient crops, inspired by indigenous species and varieties • Crops and animals with higher yields, better pest resistance and enhanced nutritional value • Molecular 'farming' of genetically modified crops, producing a range of small molecules, from vaccines to biofuels. • Plant-based or microorganism-based alternatives to animal products and fossil fuels

5.1 Industrial biotechnology

Industrial biotechnology is a broad field that encompasses the use of biological systems to develop products, processes and technologies for industrial purposes.

The applications of industrial biotechnology result in chemicals, materials, and energy that are used in a range of economic sectors. Some of these compounds are already produced through biotechnology on an industrial scale, including ethanol for biofuels, lactic acid for bioplastics, and itaconic acid for resins, paints, and fibres. For example, citric acid, possibly the most important organic acid produced through industrial biotechnology on basis of tonnage, is extensively used in food and pharmaceutical industries. It is produced mainly by submerged fermentation using *Aspergillus niger* or *Candida* species from different sources of carbohydrates, such as molasses.

Role of DSI in industrial biotechnology

DSI plays an important role by enabling the design, optimization and implementation of biological systems and processes for industrial applications. Data and information used may include DNA sequences of microorganisms, plants, and animals, including specific genes responsible for desirable traits; and metabolic pathways information and models, which show the enzyme-catalyzed chemical reactions that occur in a cell. DSI may be used to design genetic modifications that improve or create new metabolic pathways within microbial strains used in industrial processes, such as fermentation. For example, by analysing sequence data, researchers can design and engineer biocatalysts (e.g. enzymes), which are used to activate and speed up specific chemical reactions. Catalysts with improved characteristics, such as higher yields and stability under industrial conditions, are used in various industries, including food and beverage, cosmetics, textiles, and pharmaceuticals. For instance, researchers looking to develop or improve enzymatic detergents, which provide enhanced stain removal, can use data in the Protein Data Bank (PDB), a repository of three-dimensional structural data of large biological molecules, such as proteins and nucleic acids, to analyze the structure of enzymes to optimize their activity and stability under laundry conditions (e.g. varying water pH, temperature).

Future trends in industrial biotechnology

Industrial biotechnology aims to enable companies to increase efficiency, lower costs, and reduce environmental impact of their activities, more increasingly relying on synthetic biology tools and applications to achieve this. For example, industrial biotechnology may be used to replace synthetic plastics with renewable materials and substances. Polylactic acid (PLA), produced from corn, cassava, and other feedstocks currently provides a replacement for synthetic plastics and is competitive on a cost and performance basis. In 2023, NatureWorks LLC, the PLA manufacturer, reported having sold over a billion pounds sterling worth of PLA. Industrial biotechnology may also reduce pressure on biological resources. For example, Veramaris, a joint venture between DSM and Evonik, uses large-scale fermentation of agricultural biomass with a strain of microalgae to produce omega-3-fatty acid rich algal oil that can substitute fish oil as a feed component for aquaculture. In 2023, due to growing demand for sustainable omega-3 fatty acids, Veramaris increased its production volume by 50%.

Technological innovations will be an important driver of industrial biotechnology, Traditionally, the choice of biobased molecules for development has been opportunistic rather than systematic. However, the growing amount of DSI available and development of systems biology tools, machine learning, and cell-free systems, among other technologies, will allow more methodical research and development into industrial technology applications. For example, genomics and other "omics" technologies allow identifying improved enzymes for conversion, elucidation of metabolic pathways and the genetic engineering of production hosts. AI (see Box 3) will make it possible to predict the production of potential and metabolic needs of any microbial strain. Data-driven, cell-free systems – that is, systems where biochemical reactions occur independently of living cells - are also accelerating bio-discovery and design. Finally, traditional catalysts used in industrial biotechnology continue to improve.

In principle, such technological development could take place in companies and institutions around the world. Based on a patent-based analysis, recent studies have found that a diverse group of firms, large and small, is developing new patented products and processes in industrial biotechnology, with new companies steadily entering the field.[31] However, other studies highlight that most biotechnology patents – used as a proxy for technological innovation – are still held by companies in developed countries.[32]

The trend in technological developments is towards industrial biotechnology processes that are increasingly based on data, carried out with more efficiency and reduced costs, and leading towards a wider range of products. Given evolving technologies, experts see many opportunities and few limitations on the substances and materials that could be produced through industrial biotechnology. Of course, product development will ultimately be driven by market demand, costs, and profit margins. It is estimated that the current market will reach USD $852.55 billion over the next decade.[33]

5.2 Medical biotechnology

Advancements in medical biotechnology have revolutionized the field of healthcare, providing innovative solutions for diagnosis, treatment, and prevention of diseases. This branch of biotechnology relies upon many synthetic biology techniques, as well as cell and tissue culture techniques to discover or create therapies, drugs, antibodies, vaccines and personalized treatments. For example, recombinant insulin, produced using genetically modified bacteria, has become a cornerstone in the treatment of diabetes. Additionally, monoclonal antibodies, engineered to target specific cells, are used in cancer therapy and autoimmune diseases, offering targeted and effective treatment options. Moreover, gene therapy and CRISPR-Cas9 technology hold the promise of correcting genetic disorders at their source, potentially curing previously untreatable conditions. Finally, protein-based biologicals are a fast-growing class of pharmaceutical products, manufactured from engineered biological sources, including plants and microbes.

Role of DSI in medical biotechnology

Comparing large number of DSI from databases can help researchers identify genetic mutations associated with different kinds of diseases that may be potential targets for new or existing drugs. DSI can also speed up the testing of potential drugs, as bioinformatic tools and AI can use DSI to model and simulate the structure of target proteins and predict how new drugs will interact with them. Going beyond generic drugs, DSI is also involved in the nascent field of personalized medicine, where treatments are tailored to a specific patient's genome. For example, the genome editing tool CRISPR-Cas9 (clustered regularly interspaced short palindromic repeats) enables precise and localized modifications directly to the genomes of living organisms, resulting in altered gene functions. DSI provides the exact DNA sequence of the gene or genomic region that needs to be

[31] Linton K, Wise J and Stone P, 2008. Patenting Trends and Innovation in Industrial Biotechnology. USITC Staff Research Study Working Paper. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1302904
[32] Grassano N, Napolitano L, M`barek R, Rodriguez Cerezo E and Lasarte Lopez J, 2024. Exploring the global landscape of biotech Innovation: preliminary insights from patent analysis. Publications Office of the European Union, Luxembourg. Available at: https://publications.jrc.ec.europa.eu/repository/handle/JRC137266
[33] Reports and Data, 2024. Materials and Chemicals - Industrial Biotechnology Market. Available at: https://www.reportsanddata.com/report-detail/industrial-biotechnology-market

edited. This information then directs the enzyme Cas9 to the location within the genome that requires editing.[34] DSI is also crucial for the design of new vaccines through identifying effective antigens that produce a strong immune response. The development of diagnostic tests also requires DSI to detect specific biomarkers of pathogens.

There are many types of medical and pharmaceutical biotechnology companies that use DSI. Both large pharmaceutical giants and more focused biotechnology firms use DSI to help discover, develop, and manufacture new drugs, vaccines and treatments. For instance, BixBio, a start-up based in South Africa, is building bioinformatics tools based on artificial intelligence to look at the genetic diversity in Africa's population and discover genetic links to disease and new drug targets. Some companies focus on gene therapy and editing to target specific diseases, while others may focus on diagnostics. Most of these companies will use tools and data provided by genomics companies, which in turn rely upon DSI for their products. For example, the once small enterprise, BioNTech, used DSI extensively in the development of the COVID-19 vaccine. BioNTech used next generation sequencing (NGS) technology, such as that provided by Illumina, and other computational tools to analyze the genome of the virus and identify optimal targets for the vaccine. Then AI-powered machine learning tools, such as those provided by InstaDeep, helped to accelerate the design and optimization of the vaccine candidate. DSI was also used by pharmaceutical giant Pfizer to analyze and interpret vast amounts of clinical trial data for the vaccine, before manufacture and distribution were rolled out.

Future trends in medical biotechnology

Medical biotechnology aims to go beyond generic offerings and enable companies to develop more efficient and tailored treatments and diagnostics at scale. For example, plant systems will be further harnessed to produce a wide range of pharmaceuticals (e.g. vaccines and other small molecules). In particular, production of protein-based therapeutics (such as hormones and antibodies) is the fastest growing area of plant-made pharmaceuticals.[35] Compared to small molecule drugs, protein-based therapeutics can offer higher levels of potency and specificity, with lower toxicity and side effects. In the future, diseases that have been historically challenging to treat with small molecule drugs (such as neurogenerative, cardiovascular and metabolic diseases) could be addressed using antibody products. While single-target antibodies have been available for some time, advancements in protein design, partly driven by AI, will accelerate the development of next generation antibodies, capable of binding to multiple targets.[36, 37]

Another trend with potentially large impacts on global healthcare is the replacement of generic and reactive healthcare with more proactive and personalized healthcare. Rapid and cheap genome sequencing and AI-driven analysis of DSI databases will enable quicker and more targeted research and subsequent product development, while technologies such as CRISPR-Cas9 will be able to make direct corrections to individual patient genomes.

Furthermore, advances in automation technology will likely reduce the time and manual effort required for diagnostics and treatments. For example, chronic conditions currently require frequent testing, monitoring and treatment, all of which are time consuming, costly and require manual effort. This process could be transformed by the integration of biological processes onto silicon devices,

[34] Samal D, Murthy MK, Malaviya S and Khandayataray P, 2023. Synthetic Biology: A Scientific Review of Current Developments and Future Perspectives. *The International Journal of Science, Mathematics and Technology Learning,* 31(2), 633.
[35] Zahmanova G, Aljabali AAA, Takova K, Minkov G, Tambuwala MM, Minkov I, Lomonossoff GP, 2023. Green biologics: harnessing the power of plants to produce pharmaceuticals. *International Journal of Molecular Sciences*, 24,17575. Available at: https://doi.org/10.3390/ijms242417575
[36] Keri D, Walker M, Singh I, Nishikawa K and Garces F, 2024. Next generation of multispecific antibody engineering. Antibody Therapeutics, 7(1), 37-52.
[37] BIO RAD, 2024. The antibody saga: key milestones and big predictions. Available at: https://www.bio-rad.com/en-uk/applications-technologies/exploring-latest-trends-antibody-therapeutics?ID=a75a5fba-560b-295f-b90b-6582dddb6e7e

removing the need for hands on treatment. New products will include devices that act as internal delivery systems, altering cellular processes at the gene level, in real time. For example, 'biosensors' that detect heat rates, presence of pathogens or release insulin in response to glucose levels.

Traditionally, medicine has often taken a reactive approach, relying on symptoms to diagnose and treat diseases, as well as treating acute conditions rather than focusing on prevention. New technologies emerging in the medical biotechnology space are looking to remove chance from the equation and provide tools to make the human genome invulnerable to disease. For example, the Human Genome Project-write focuses on building entire, synthetic genomes of humans and commercial species so that human genomes, and that of commercially valuable species, can be made vulnerable to viruses.[38]

Advances in medical biotechnology may also help mend some biases in the medical research market. Traditionally, medical products are developed using DSI from a few model organisms or ethnic groups, but rapid and cheap DNA sequencing could encourage sampling from a broader segment of the human population. This could lead to more effective and a broader range of treatments.

All these technological advances in precision and targeted medicines will lead to a much larger range of products than ever before, addressing so far unmet medical needs and transforming healthcare. For pharmaceutical companies, this represents more than just the potential launch of new products, but a fundamental shift in their role in the healthcare sector.[39] Changes to business models may see more and more companies take the opportunity to switch to service provision first and product provision second. However, it remains to be seen how these innovative technologies, products and services will be distributed and accessed across the world. Currently, regional coverage of medical and pharmaceutical biotechnology is concentrated in those countries with the fastest growing economies. However, there are indications that this is starting to shift, with research and production of pharmaceuticals increasing in developing countries such as Bangladesh, Brazil, Colombia, Cuba, Egypt, India, Iran, Kenya, Malaysia, Mozambique, South Africa and Uganda.[40, 41] Ultimately, where products are developed and who will be able to access them will be driven by market and political forces. The global market of pharmaceutical biotechnology is expected to increase from USD $304 – $448.1 billion to USD $566 – $745.1 billion over the next 10 years.[42]

5.3 Agricultural biotechnology

Agricultural biotechnology uses biological systems to improve plants, microbes, animals and agricultural processes to address challenges in food and agriculture, including food security, nutrition, sustainability, and environmental impact.

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[38] The Center of Excellence for Engineering Biology. Home of GP-write. https://engineeringbiologycenter.org/

[39] Paschalidis K, 2024. The Future of Personalized Medicine Hinges on Pharma Executives Revolutionizing Business Models. PharmExec. Available at: https://www.pharmexec.com/view/the-future-of-personalized-medicine-hinges-on-pharma-executives-revolutionizing-business-models

[40] Fane B, Campbell A and Wastl J, 2023. A tale of two pharmas – Global North and Global South. Perspectives on funding and collaboration, and the localisation of SDGs in the pharmaceutical industry. *Digital Science*. Available at: https://www.digital-science.com/tldr/article/a-tale-of-two-pharmas-global-north-and-global-south/#new-geography-of-the-pharma-industry

[41] Vieira M, Andi T, Karim O, Srishti SA, Pineda SA, Ruiz AA, Large K, Liu Y, Moon S, Naher N, Siddiqui A and Ahmed SM, 2023. Rising pharmaceutical innovation in the Global South: a landscape study. *Journal of Pharmaceutical Policy and Practice*, 16(155), 1–19.

[42] Prescient & Strategic Intelligence, 2024. Biopharmaceuticals Market Size & Share Analysis - Trends, Drivers, Competitive Landscape, and Forecasts (2024 - 2030). Available at: https://www.psmarketresearch.com/market-analysis/biopharmaceuticals-market#:~:text=Get%20Sample%20Pages-,Biopharmaceuticals%20Market%20Data,reach%20%24745.1%20billion%20by%202030

The applications of agricultural biotechnology result in new and improved crop varieties and animal breeds, as well as agrochemicals, fertilizers, supplements and other inputs in the agriculture, food and feed sector. For example, there are over 15 genetically modified, herbicide tolerant crop species approved for commercial use,[43] and genetically modified soybean now dominates the world soybean market, with 600,000,000 metric tonnes expected to be sold by 2026.[44] Other examples of products resulting from agricultural biotechnology include insect resistant corn, canola with augmented nutrition, salmon that mature faster, and cattle that are resistant to mad cow disease. Many of these products have been developed by collaborations involving research institutions and companies in developing countries. For example, Mahyco, an Indian company founded in 1964, was the first seed company worldwide to successfully commercialize certain types of genetically modified cotton. It was also the first private enterprise in India to produce and market hybrids in sorghum, pearl millet, wheat and sunflower.

Initially, agricultural biotechnology focused on agricultural needs, but it is increasingly also considering consumer needs and preferences. For example, UK-based food ingredient company Moolec is using a novel molecular farming technique to produce soybeans with high levels of pork protein, as a meat substitute.[45]

Role of DSI in agricultural biotechnology

With the help of bioinformatic tools and AI, researchers use DSI to identify and characterize the genes and mutations responsible for desirable traits in crop or animal species. Researchers can analyze sequence data, using tools and data provided by genomics and agricultural biotechnology companies, to design and develop genetic modifications to enhance the yield and nutritional value of crops and animals, such as engineering a plant to produce a specific vitamin or increase protein content. Crop and animal breeding companies also use DSI to enhance traditional breeding techniques. By analysing detailed genetic maps and markers, researchers better understand which breeding pairs will produce better results for their product. For example, researchers from the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) have identified the molecular markers for iron and zinc content in sorghum,[46] which could result in sorghum varieties that help reduce malnutrition in sorghum-consuming countries. In addition, biotechnology techniques can also be used to design fertilizers, pesticides, vaccines for plants and microorganisms that promote soil health.

Future trends in agricultural biotechnology

Agricultural biotechnology has the potential to enable companies to produce a diverse array of products for food and agriculture. Conventional agriculture largely relies on traditional farming practices, which includes selective breeding, crop rotation, and the use of natural fertilizers and pesticides. These methods can be considered time-consuming and potentially limited in their ability to significantly improve crop yields or resistance to pests and diseases. Increasing amounts of available DSI and development of synthetic biology tools, machine learning and other technologies will allow more methodical research and development into how to optimize the growth of crops and the products that derive from them. Biotechnology, including synthetic biology, could thus be a tool in transforming food systems to become more efficient and climate resilient. For example, research

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[44] Fact.MR, 2024. GMO soybean market. Available at: https://www.factmr.com/report/426/gmo-soybean-market#:~:text=According%20to%20Fact.MR%2C%20the,the%20world%20by%202026%2Dend.

[45] Moolec, 2024. Available at: https://moolecscience.com/

[46] Halewood M, Lopez Noriega I, Ellis D, Roa C, Rouard M and Sackville Hamilton R, 2018. Using genomic sequence information to increase conservation and sustainable use of crop diversity and benefit-sharing. *Biopreservation and Biobanking,* 16(5), 368 – 376.

is increasingly focusing on indigenous varieties and wild crop relatives that may be naturally more resilient to local conditions than commercial cash crops.[47] AI-driven technology, utilising DSI databases, will accelerate precision agriculture to optimize breeding programs, improve crop yields and enhance resistance to diseases and climate change. For example, the African Orphan Crops Consortium is working to sequence and analyze the genomes of neglected African crops such as amaranth, African eggplant, and finger millet, which are naturally rich in vitamins, to improve their climate resilience, pest resistance and productivity.[48] In addition to nutritional and economic benefits, people can benefit from widespread use of pest resistant crops. Around 25 million farm workers are thought to be victims of pesticide poisoning each year.[49] While only a dozen or so genetically engineered crops have been approved for use so far, research and development are increasing due to reduced costs and advances in biotechnology, with many projects developed in low-income countries (especially Africa) through collaborations with agriculture corporations, public institutions and philanthropic organizations. Another growing industry is 'molecular farming', where crops are genetically engineered to grow and produce a particular product, analogous to miniature bioreactors.[50] Molecular farming will potentially have low start-up costs and scalable productions. Agricultural biotechnology will also be relevant for other types of biotechnology and economic sectors, as, for example, plants can be genetically engineered to produce a range of high value molecules for use in pharmaceuticals, as well as alternatives to animal-based products, biofuel alternatives to fossil fuels and other consumer products. The diversity of products, and relative ease at which producers could switch the products being manufactured by plants, has the potential to improve supply chain sustainability. The size of the agricultural biotechnology market is valued to be around USD $40 - $80 billion and is expected to grow to USD $60 - $312 billion over the next decade.[51, 52]

6 Technological fields and applications

This section describes certain cross-cutting technological fields and applications that are changing the way certain economic sectors operate by introducing new features, capabilities, and efficiencies. Focusing on trends in synthetic biology, artificial intelligence and DNA barcoding provides a range of examples on potential trends in novel commercial products and services that may emerge from the use of DSI in the coming decades.

6.1 Synthetic biology

The field of synthetic biology spans a wide range of sectors, resulting in innovative products, applications and technologies. For instance, synthetic biology uses genetic engineering techniques to create genetically modified organisms, which may be designed to produce biofuels,

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[48] African Orphan Crops Consortium. Available at: https://africanorphancrops.org/
[49] Alavanja MC, 2009. Introduction: pesticides use and exposure extensive worldwide. Reviews on Environmental Health, 24, 303 – 309.
[50] Murad S, Fuller S, Menary J, Moore C, Pinneh E, Szeto T, Hitzeroth I, Freire M, Taychakhoonavudh S, Phoolcharoen W and Ma JK, 2020. Molecular Pharming for low and middle income countries. *Current Opinion in Biotechnology*, 61, 53 – 59.
[51] Data Bride Market Research, 2023. Global Agricultural Biotechnology Market – Industry Trends and Forecast to 2030. Available at: https://www.databridgemarketresearch.com/reports/global-agricultural-biotechnology-market
[52] BCC Research, 2023. Agricultural Biotechnology: Emerging Technologies and Global Markets. Available at: https://www.bccresearch.com/market-research/biotechnology/agricultural-biotechnology-markets-report.html

pharmaceuticals, and other specialty chemicals. This includes, for example, the antimalarial drug artemisinin, which is produced through genetically engineered yeast strains by the company Amyris. Another example is the development of biosensors for environmental monitoring, such as the *E. coli*-based sensors created by Ginkgo Bioworks that detect pollutants in water. The field may also lead to advancements in agriculture, with companies like Bayer utilizing synthetic biology to engineer crops with enhanced traits, such as increased resistance to pests and improved nutritional content.

Role of DSI in synthetic biology

DSI databases, which include DNA sequences of various organisms and specific genes responsible for desirable traits, can be used to identify the functions of specific pieces of DNA, predict protein structures and understand gene regulatory networks. Advancements in bioinformatics and AI (see box 3) further aid in the discovery of gene function through DSI. Functional parts of DNA, known as 'bioparts', can then be combined and optimized to produce devices or 'genetic circuits' that are built into biological systems, such as microbial cells.[53] Researchers use machine learning, AI and DSI to create predictive models, simulating how these genetic circuits will function before they are converted into physical DNA sequences that can be inserted into organisms. These genetically modified organisms can have enhanced characteristics, such as pesticide resistance and higher yields, or new functionalities, such as the ability to synthesize biofuels or vitamins. Researchers also use DSI in the design and development of biosensors.[54] In this context, DSI is used to identify gene sequences that can bind to specific molecular targets. Modified organisms can then be engineered to produce a detectable output when they come into contact with the target. For example, an organism can be engineered to change colour when the cells detect a particular virus, cancer cells, pesticides or chemical agents under various environmental conditions. Because of the wide-ranging applications listed above, researchers are applying synthetic biology to produce a wide range of products across many different sectors, from food and agriculture to health, chemicals, and materials.

A literature review commissioned by the CBD secretariat indicated that the majority of synthetic biology research and innovation currently occurs in developed and industrial countries[55]. Their study showed that publications are concentrated in 10 countries, led by the United States of America and China. This is followed by the United Kingdom, India and Germany, which have a similar level of output. The remaining five countries in the top 10 are Japan, Republic of Korea, Canada, Italy and Australia. However, their analysis of collaboration networks between research groups internationally suggested that there is cooperation between developing and developed nations. The importance of geographic diversity in advancing synthetic biology has also been highlighted by the World Economic Forum's Global Future Council on Synthetic Biology.[56]

Future trends in synthetic biology

Synthetic biology is considered a fast moving, disruptive technology that has the potential to deliver wide-ranging solutions to an equally wide range of challenges, including biodiversity conservation, renewable energy, environment, agriculture, manufacturing and disease prevention, diagnosis and treatment.[57] A comprehensive study commissioned by the CBD secretariat identified 55 different

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[53] Garner KL, 2021. Principles of synthetic biology. *Essays Biochem*, 65(5), 791 – 811.
[54] Gundogdu A, Gazoglu G, Kahraman E, Yildiz E, Candir G, Yalcin D, Koç A and Şen F, 2023. Biosensors: types, applications, and future advantages. *Journal of Scientific Reports-A*, 52, 457 – 481.
[55] CBD/SBSTTA/26/INF/5. Available at: https://www.cbd.int/doc/c/cdd0/47d5/a1c4e03006539ca375b70db4/sbstta-26-inf-05-en.pdf
[56] WEF, 2023. Realizing Geographical Diversity in Synthetic Biology. Available at: https://www3.weforum.org/docs/WEF_Realizing_Geographical_Diversity_in_Synthetic_Biology_2023.pdf
[57] Karoui ME, Hoyos-Flight M and Fletcher L, 2019. Future Trends in Synthetic Biology—A Report. *Frontiers in Bioengineering and Biotechnology*, 7(175), 1 – 8.

trends in synthetic biology, ranging from genetically modified organisms to cyberbiosecurity.[58] The market size of synthetic biology is estimated to be worth somewhere between USD $3.75 - $16.35 billion and is expected to rise to significantly over the next decade, with figures ranging from USD $31.73 - $116.04 billion.[59, 60, 61]

Advances in technology, specifically AI (see Box 3), will be an important driver within synthetic biology, enhancing our ability to extract meaningful insights from complex DSI datasets, improving our efficiency and widening the range of DSI-derived products than can be produced. The integration of artificial intelligence in synthetic biology was also one of the prioritized trends and issues in synthetic biology identified during the horizon scanning process.[62] For example, the development of tailor-made microbial products that once took huge amounts of physical resources, trial and error, time and human input are being shifted towards automatic computer tools that can identify, design and test at a fraction of the time with fewer resources. Ramping up capabilities for design and production will enable researchers to meet new market needs, such as the growing demand for synthetic molecules inspired by biological products. These synthetic alternatives may reduce pressures on wild resources, such as synthetic squalene (traditionally extracted from grains or sharks and used in the beauty and pharmaceutical industry). Synthetic biology techniques, aided by AI, will also facilitate the creation of completely novel genetic resources that are not found in nature, resulting in new functional units and products. For example, a team of scientists have used AI to design a synthetic enzyme that can form carbon-silicon bonds, a chemical reaction that has no biological equivalent.[63] While not a naturally occurring phenomenon, carbon-silicon bonds would be advantageous in the production of biodegradable plastics, silicon-based chemicals and potentially, silicon-based hybrid organisms. Other advances, such as the shift to 'cell-free' production systems will similarly improve efficiency and expand the range of products that can be developed and produced. By assembling cellular machinery onto a silicon chip, researchers will be able to access non-natural materials, increase reaction rates, increase predictability and circumvent toxicity issues encountered in a living cell.[64, 65] For example, researchers have been able to integrate photosynthetic systems onto silicon chips, which could have applications in the biofuel and energy sector.[66] Another example are biosensors for clinical diagnosis that will be able to provide instant diagnoses of cancer from samples of blood and urine.[67] Work has already begun on the development of nanodevices ('nanorobots'), that are small enough to move freely within the body to precisely deliver treatments in situ. This technology could enable companies to provide treatments for tricky to treat conditions, such as the regeneration of neurons in brain-damaged areas or to assist in vitro fertilization.[68]

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[58] CBD/ SBSTTA/26/INF/5. Available at: https://www.cbd.int/doc/c/cdd0/47d5/a1c4e03006539ca375b70db4/sbstta-26-inf-05-en.pdf

[59] Markets and Markets, 2023. Synthetic biology market. BT 2910. Available at: https://www.marketsandmarkets.com/Market-Reports/synthetic-biology-market-889.html

[60] Future Marlet Insights Inc, 2024. Synthetic Biology Market Outlook for 2024 to 2034. Available at: https://www.futuremarketinsights.com/reports/synthetic-biology-market#

[61] Biospace, 2024. Synthetic Biology Market Experiencing Rapid Growth 28.3%. Available at: Synthetic Biology Market Experiencing Rapid Growth 28.3% | BioSpace

[62] CBD/SBSTTA/26/4. Available at: https://www.cbd.int/doc/c/8cb2/d007/23a9f799fb31180cb353d6e2/sbstta-26-04-en.pdf

[63] Kan SBJ, Huang X, Gumulya Y, Chen K and Arnold FH, 2016. Genetically programmed chiral organoborane synthesis. *Nature*, 537(7619), 464-468.

[64] Wang P, Chang AY, Novosad V, Chupin VV, Schaller RD and Rozhkova EA, 2017. Cell-free synthetic biology chassis for nanocatalytic photon-to-hydrogen conversion. *ACS Nano.* 11, 6739–6745.

[65] Koch M, Faulon JL and Borkowski O, 2018. Models for cell-free synthetic biology: make prototyping easier, better, and faster. *Frontiers in bioengineering and biotechnology,* 6(182), 1–6.

[66] Baker SJ, Prasher RD and Lundberg M, 2019. A biohybrid system for artificial photosynthesis on a silicon chip. *Nature Communications*, 10(1), 5237.

[67] Gundogdu A, Gazoglu G, Kahraman E, Yildiz E, Candir G, Yalcin D, Koç A and Şen F, 2023. Biosensors: Types, applications, and future advantages. *Journal of Scientific Reports-A*, 052, 457–481.

[68] Zhang Y, Zhang Y, Han Y, Gong X, 2022. Micro/Nanorobots for Medical Diagnosis and Disease Treatment. *Micromachines (Basel),* 13(5), 648.

Box 3: Role and impact of artificial intelligence (AI) on future trends in commercial use of DSI

Cutting across all technologies that utilize DSI is the growing use of AI to enhance our understanding of and engineering of living organisms. AI uses an iterative cycle of 'design-build-test-learn' to optimize solutions to problems. AI, with its ability to analyse huge amounts of DSI and make predictions, is already beginning to accelerate the discovery of useful variants, drugs and industrial enzymes. For example, Ginkgo Bioworks, a US-based company, is using an AI-driven platform to engineer microbes for industrial applications, primarily in pharmaceuticals, agriculture, and speciality chemicals. Gingko Bioworks has over 2 billion protein sequences in their proprietary DNA database, which allows AI to understand and corroborate structure-function relationships, to then enable the company to design and engineer products tailored to the specifications of clients in different economic sectors. Together with high-throughput screening, which allows up to one million strains to be screened in a single run, AI can guide the selection and optimisation of microbial strains, based on predictive models. In this regard, AI will facilitate the work of synthetic biology researchers to design completely novel sequences, proteins and other molecules, not found in nature.

6.2 DNA barcoding

DNA barcoding uses short genetic sequences form a standardized region of the genome ('barcodes') to identify the species and assess certain aspects present within a biological sample. Barcodes from a sample are compared to libraries containing the barcodes of known species. In this way, DNA barcoding is a technology that relies upon vast amounts of DSI.

Across the world, DNA barcoding is used to monitor biodiversity and environmental changes by analyzing DNA from water and soil samples (environmental DNA) in real time. For example, Project VigiLife was initiated in 2011 by SpyGen, a French biotechnology company specializing in molecular ecology with the objective of building a worldwide network for monitoring global biodiversity, with the long-term monitoring of thousands of sites around the world and partnerships with organisations around the world, including many developing countries. There are many companies which offer DNA sequencing services tailored to species identification, as well as reference databases, which contain large quantities of DNA barcodes (see Box 4 on data storage). For instance, Thermo Fisher Scientific provides various DNA barcoding solutions for species identification and environmental monitoring. Similarly, Qiagen offers DNA extraction and sequencing kits designed for biodiversity assessments. Illumina provides sequencing technology that powers many DNA barcoding projects, supporting extensive reference databases like the Barcode of Life Data Systems (BOLD). While DNA barcoding has clear benefits for conservation and taxonomy research, it is increasingly used as a method for commercial measurement and monitoring of biodiversity to meet regulatory requirements. As companies seek to measure, disclose and reduce their impacts on nature, environmental DNA samples are increasingly used as a source of on-the-ground data. For example, companies with direct impacts on nature, such as mining or forestry companies, are increasingly employing environmental consultancies to collect, sequence, analyze and monitor biodiversity present at their sites using DNA barcodes.

In addition, barcoding techniques can be used in quality control and forensics, to authenticate the species used in natural ingredients or food products.[69] For example, research using barcode data has shown that up to 30% of seafood products are mislabelled.[70] Mislabelling and associated potential fraud has worldwide implications, but barcoding technologies are helping to address the issue. Companies like Clear Labs are utilizing DNA barcoding to investigate food fraud and ensure accurate labelling. Barcoding technology is also being increasingly used for wildlife forensics and

[69] Mahima K, Kumar KNS, Rakhesh KV, Rajeswaran PS, Sharma A and Sathishkumar R, 2022. Advancements and future prospective of DNA barcodes in the herbal drug industry. *Frontiers in Pharmacology*, 13.
[70] Pardo M Á, Jiménez E and Pérez-Villarreal B, 2016. Misdescription incidents in seafood sector. *Food Control*, 62, 277–283.

marketplace product authentication.[71] For example, the African Centre for DNA Barcoding (ACDB) is using these technologies to combat wildlife crime and verify the authenticity of products in the market.

Future trends in DNA barcoding technologies

Consumers are increasing their demands for traceability and quality for food, cosmetics, and other products. Advances in barcoding technologies, making them cheaper and more accessible, will enable more and more companies to strengthen their transparency and security of their supply chains. Barcoding will also spur innovation in various sectors, shedding light on newly discovered species and allow further research into their unique properties and characteristics, which may go on to have commercial value and use. This will be especially true for fungi and lichen, which require specialists to identify due to the presence of common traits amongst species. The properties of these new species may lead to new and unexpected products for cosmetics, food and pharmaceuticals. Bioprospecting in the field is likely to become a reality with the development of easy to use, handheld sequencing devices, opening up the technology to new users and locations. With the necessary technology transfer and resources there is great potential for DNA barcoding to be available locally and at scale across developing countries. Examples of companies developing these technologies include Oxford Nanopore Technologies, which provide portable sequencing solutions and Basecamp Research, which uses such new technology to pioneer off-grid metagenomic DNA analysis to deliver tailor-made genomics and proteomics to companies in various sectors, and collaborate with countries, such as Cameroon, for their wide deployment.

As technology advances, barcoding may allow for a range of commercial biodiversity-related services. For example, it may be possible for companies to perform assessments of all species present at a site or in an ecosystem, rather than focusing on priority species. Companies measuring biodiversity may take a step further and use these new technologies to monitor genetic variation within a population, a component of biodiversity that is not currently addressed in many environmental impact and other assessments. There is potential for DSI to feed into future national, regional and global biodiversity monitoring systems, allowing near real-time analysis of biodiversity trends. Such a system could alert companies and local authorities to invasive and alien species threats, track changes in species composition due to climate change and other pressures, aid decision making on priority areas. Companies may use this information to help develop more effective nature-based solutions and restoration activities. Companies are also increasingly looking towards biodiversity credits (tradeable units of biodiversity being protected or restored that can be bought and sold on a voluntary credit market) as a way of investing in biodiversity. Accurate assessments and tracking of species provided by barcoding technologies and associated analyzes will allow companies to offer higher integrity biodiversity credits.

Going beyond species identification, a nascent field is exploring the use to barcodes to track individual cell lines. Cell-lineage specific barcodes, which are passed down from each cell replication, may one day allow researchers to identify and track every cell within an organism, opening new frontiers in cellular research and medical diagnostic products and services.[72]

[71] Adamowicz SJ, Boatwright JS, Chain F, Fisher BL, Hogg ID, Leese F, Lijtmaer DA, Mwale M, Naaum AM, Pochon X, Steinke D, Wilson J, Wood S, Xu J, Xu S, Zhou X, and van der Bank M, 2019. Trends in DNA barcoding and metabarcoding. *Genome*, 62(3), v-viii.

[72] Fasullo M and Dolan M, 2022. The continuing evolution of barcode applications: Functional toxicology to cell lineage. Experimental Biology and Medicine, 247(23), 2119 – 2127.

Box 4: Role of data storage in commercial use of DSI

Cutting across all biotechnologies that utilize DSI is the need for adequate storage solutions. Vast amounts of DSI are stored within various public and private databases. Public repositories include databases such as 'GenBank', the 'DNA the Data Bank of Japan' and 'EMBL-EBI' (European Bioinformatics Institute). These are accessible to researchers, companies and the public, usually without fees or restrictions. Other databases are private, commercial enterprises, requiring a subscription or license for access, such as 'Proteome Discoverer' by Thermo Fisher Scientific. These databases are developed and maintained by biotechnology companies or specialized data providers and often provide advanced tools and service for analyzes, integration and interpretation of DSI data. Some databases specialise in a particular organism or group, such as 'FlyBAse' for the model organism *Drosophila melanogaster*. Databases can also specialise in a particular type of DSI, such as 'BOLD' (Barcode of Life Data System) for barcodes or 'UniProt' for protein sequences. As more and more DSI is generated, the market for data storage is poised for significant expansion. Currently worth around USD 74 – 76 million, the DSI data storage market is expected to reach USD $21.4 - $3.3 billion over the next decade.[73, 74] This growth underscores the increasing importance of DSI across various sectors.

6.3 'DNA of things'

The sections above capture the main current commercial applications of DSI, but there may be other technologies that do not fit neatly under these categories, as well as emerging technologies that are not yet widely researched.

For example, DSI may be used more and more by material science researchers. There are initial findings that DNA can be used as a storage architecture to create materials that have embedded memory.[75] This so called 'DNA of things' could enable companies to store data within objects, for medical or everyday use, as well develop machinery that contains its own blueprints for replication. Unique properties of DNA mean that there are multiple advantages to storing data within DNA over conventional magnetic and optical methods. DNA can be replicated with high accuracy, it is a relatively stable and cheap system, and it has a high storage capacity (DNA uses a quaternary rather than binary code). In addition, it is possible that DNA data storage will have a smaller environmental impact. However, current prototypes indicate that scaling such technology to industrial scale will take time.

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[73] Research Nester, 2024. DNA Digital Storage Market. Report ID 3082. Available at: https://www.researchnester.com/reports/dna-digital-data-storage-market/3082#:~:text=DNA%20Digital%20Data%20Storage%20Market%20size%20was%20over%20USD%2074,evaluated%20at%20USD%20106.4%20Million..

[74] Markets and Markets, 2024. DNA Storage Market. Report code SE 8840. Available at: https://www.marketsandmarkets.com/Market-Reports/dna-data-storage-market-68300978.html

[75] Koch J, Gantenbein S, Masania K, Stark WJ, elrich Y and Grass RN, 2020. A DNA-of-things storage architecture to create materials with embedded memory. *Nature Biotechnology,* 38, 39–43.

7 Conclusions and potential considerations

Discussions on DSI and the fair and equitable sharing of benefits resulting from its use have covered a range of issues including the governance of databases that make DSI available. At the sixteenth meeting of the CBD COP, to take place in Cali, Colombia in October 2024, it is expected that a decision on the modalities for the operationalization of the multilateral mechanism for benefit-sharing from the use of DSI is adopted.

In light of the analysis above and the ongoing process in the context of the CBD, this section explores the implications of advances in technologies and technological applications that use DSI. For example, in terms of ensuring wide availability of DSI and the fair and equitable sharing of the benefits resulting from its use, innovative products, new business opportunities, and novel revenue streams.

Over the next few decades, biotechnology, largely based on DSI, will revolutionize a range of economic sectors. It is expected that DSI will continue to be a major foundation of biotechnology and synthetic biology research and development across the globe, with lowered costs, technological advances and acceleration of AI all contributing towards DSI growing as a tool for commercial product development.

As discussed in the sections above, advances in biotechnology promise to enhance the efficiency of product design and development, opening up possibilities for entirely new solutions that will transform healthcare, agriculture, industry and the environment. The most transformative potential of DSI lies in enabling broader and more rapid access to data, technologies and products. The direction is moving towards more data, cheaper and easier to implement technologies, and a wider range of products. However, the potential benefits of these innovations will not necessarily equate to increased accessibility across countries, considering the current capacity gap, or that there will be fair and equitable sharing of the benefits resulting from its use.

7.1 Access to data

A key principle in DSI discussions has been the importance and availability of free to use DSI and DSI-derived data. This information is available online and often stored within public databases. Advances in technologies and technological applications that use DSI would potentially provide new and additional opportunities for researchers in developing countries, whom would have access to data and information from around the world, at no cost. Research has shown that the biggest users of DSI produced by lower middle-income countries (LMIC) are researchers within LMIC’s themselves, which indicates that the flow of DSI from developing countries is both to developed countries and other developing countries.[76] However, there is a component of proprietary data owned and restricted by private entities, which may become more significant. Organizations, companies, and countries are already striving to collect, analyze, and capitalize on biological and genetic information in a “race for data”. Moreover, scientific and technical services related to DSI, including software, artificial intelligence, storage capacity for big data and technologies to harness DSI for commercial products and services are also much more limited in their accessibility. This could create barriers to innovation and equity, as only those who can afford to, will be able to access and benefit from DSI, exacerbating - rather than addressing - disparities in access to technology, hindering collaborative

[76] Scholz AH, Lange M, Habekost P, Oldham P, Cancio I, Cochrane G and Freitag J, 2021. Myth-busting the provider-user relationship for digital sequence information. *GigaScience,* 10(12), giab085.

efforts, and further concentrating the capabilities and technologies for research and product development.

Additionally, the increase in cheaper and more user-friendly technology means that individuals could potentially identify biodiversity in the field instantaneously, cheaply and with little training. Researchers will no longer need to undertake costly trips around the world when local expertise has already collected and uploaded the data to global DSI databases. Less centralized generation of DSI data could feed into global and automatic data systems, providing users with more complete data and eventually enabling local stakeholders and companies to better manage biodiversity.

A further consideration to how DSI is used and how benefits from its use are shared is the impact of AI and synthetic DSI in biotechnology. Advances in AI technology and the shift to cell-free environments mean that research will no longer be limited to the genetic material found in nature. The creation of novel, synthetic genetic resources will expand the products that we can produce with wide ranging and potentially unlimited possibilities. This becomes an important dimension to be considered as Parties advance in the development of modalities for the operationalization of the multilateral mechanism for benefit sharing from the use of DSI. The fact that AI technologies ingest data from multiple large scale DSI datasets brings some considerations to bear in mind regarding the use of DSI and resulting sharing of benefits:

- When the value of DSI lies in the dataset as a whole, there is a need to consider how the value of any one piece of DSI is likely to decrease as these databases become larger over time. AI uses these databases of DSI to train models, involving several rounds of learning, re-design and directed evolution of sequences. Resulting products are likely to have used DSI from multiple countries and sources, confounded by convergent evolution directed by the AI. For an intermediary or finished product or service, it would be difficult to determine the contribution that any one particular sequence of DNA may have had.
- In addition, trends suggest that researchers will decreasingly rely on DSI from naturally occurring genetic resources to solve a problem or meet a demand. The technology to design synthetic DNA sequences from scratch to produce novel proteins with novel properties is being accelerated through AI. In the future, products may no longer be directly based on DNA that has been extracted from a genetic resource. An important question to consider will be how a product, based entirely on synthetic DNA, would fit within a potential benefit sharing mechanism, and how would it be determined if a DNA sequence is naturally occurring or the product of AI. While AI generated sequences may lessen the requirement to acquire real world samples in the future, experts believe that AI technologies will still likely require DSI from real biological samples to train their models. The Working Group, when developing the draft modalities for operationalizing the multilateral mechanism for the fair and equitable sharing of benefits from the use of DSI, including a global fund, included several aspects that entities operating public databases might need to consider in relation to DSI. Some of these refer, for example, to the provision of information on the country of origin of the genetic resources, or principles to be applied when operating an open access database.

Although AI has potential to enhance our understanding of living organisms and expand product ranges, it is worth noting that some experts are observing a potential slowing of the pace of innovation.[77] Increasingly advanced AI models require larger amounts of higher quality DSI for training, and there is a strong relationship between model performance and training data quality. Public databases of DSI, while instrumental to the progress achieved to date in biotechnology, may lack the size, quality and diversity needed for future AI models to reach their full potential. How AI-

[77] Vince O, Gowers G and McGibbon S, 2024. The Natural Future for AI in Biotech: The Next Generation of Machine Learning Demands Partnership with Biodiversity. GEN Biotechnology, 4(4), 220–227.

driven demand for data will impact DSI supply chain partnerships between countries that provide and use DSI is a relevant consideration.

7.2 Access to technology and products

The trend is towards technologies that use DSI becoming cheaper, more efficient and easier to use with fewer resources and little training. For example, gene editing tools such as CRISPR-Cas9 have increasingly lower barriers to entry, in terms of start-up costs and training needed, and could empower people to harness biotechnology for their own use. An important question to consider relates to who will actually own and have access to these technologies in the future. Some experts are concerned that, rather than narrowing the technology gap between developed and developing, DSI could in fact widen it.[78] Although the DSI that underpins many technologies derives from developing countries, currently biotechnology companies are concentrated in developed countries. Even if data is made open and technology is made accessible to many, consideration needs to be given to which companies will be producing these products. This includes where they are from and where they are located, and if these products will be affordable and accessible to those in developing countries. While it is true that increasing research and investment is focused on developing regions, if technologies continue to be developed and patented by developed countries, then the issue of their access and use will have implications of relevance for the multilateral mechanism.

7.3 Potential implications

Unprecedented advancements are expected in the coming years regarding technologies that use DSI. How and if these technologies, and their resulting products, will be accessible and reach countries equally is less certain. For a "future-proof" multilateral mechanism for benefit-sharing from the use of DSI, this uncertainty should be taken into account in its modalities and operationalization, for example in relation to the ability to use and benefits from DSI, and access to new technologies and products derived from it. Some options currently on the table for the multilateral mechanism focus on the value-addition steps of the value chain, rather than at the point of access to DSI.[79]

Based on the recommendation that the Working Group prepared for consideration at CBD COP16, the multilateral mechanism and its fund will operate according to the principles of inclusivity, equity and transparency. In light of these, it would be important that the elements and questions presented in this study inform what the application of those principles would imply in practice.

Furthermore, the importance of fair and equitable sharing of non-monetary benefits has also been extensively discussed during deliberations on DSI. These might include capacity-building and development, knowledge-sharing, technology transfer, and technical and scientifical cooperation, among others, to support the generation of, access to and use and storage of DSI. According to the recommendation developed by the Working Group, CBD COP16 may decide that specific frameworks for sharing non-monetary benefits for specific sectors are developed. When doing so, a wide range of aspects affecting access to and use of knowledge and technologies derived from DSI, some of which have been presented in this scoping study, would be relevant.

Finding a balance in future policies to incentivize innovation while promoting accessibility and equity would benefit from further consideration. This is especially critical given the significant public policy benefits that DSI-derived technologies can provide, such as advancements in global healthcare and environmental sustainability.

[78] Halewood M, 2024. New rules for sharing benefits from the use of digital sequence Information. *The Nucleus*, 67, 5–9.
[79] CBD/WGDSI/REC/2/1 https://www.cbd.int/recommendations/wgdsi?m=wgdsi-02

This scoping study has been conceived with the intention to complement the work that has been carried out so far on DSI in the context of the CBD and support further negotiations on this matter. These findings may therefore be useful in informing discussions relating to the operationalization of the multilateral mechanism for benefit-sharing from the use of DSI so that its set up is aligned with current and future developments of technologies that use it.

Further to the information included in this scoping study regarding elements that might be considered if designing a "future-proof" multilateral mechanism on benefit-sharing from the use of DSI, it proposes some areas that could be considered for further research in the field of DSI and the potential impacts of its use. For example, the impact on indigenous peoples and local communities, women and youth of future developments in technologies that use DSI is an important consideration that should be investigated. Another area of potential future work could explore more fully the role of private DSI databases and how their business models may or may not change in the future.

Appendix 1

The following survey was sent out to all contacts.

Potential future use of digital sequence information on genetic resources

Working in collaboration with the Secretariat for the Convention on Biological Diversity, the United Nations Environment Programme World Conservation Monitoring Centre (UNEP-WCMC) is conducting a scoping study on the potential future use of digital sequence information on genetic resources (DSI).

In the context of discussions under the CBD and its Nagoya Protocol, the term "DSI" is considered as a placeholder, rather than a term with clear concept and scope (further information on the term DSI can be found here: https://www.cbd.int/doc/c/fef9/2f90/70f037ccc5da885dfb293e88/dsi-ahteg-2020-01-03-en.pdf)

This scoping study, in looking at potential use of DSI, focuses on uses of commercial potential, and covers genomic, transcriptomics, proteomic, and metabolomic data compiled in databases or other data collections for developing new or improved products and services.

As an expert and/or practitioner in companies, research institutions, government agencies or other entities working with such data and related technologies, we'd like to invite to you complete this short survey, which aims to support ongoing discussions on a practical and effective multilateral mechanism for the sharing of benefits from the use of DSI.

Your participation will be treated as confidential, but we ask for your name and contact details for any clarification or additional information that may be required for our study. Responses to the survey will be anonymized and aggregated in a manner that will not allow for the identification or attribution of individual respondents.

The report of the scoping study results will be shared with all the participants afterwards.

We would also greatly appreciate it if you could kindly forward this email to any colleagues or relevant mailing lists that might be interested in completing this survey. Thank you!

1. Name
2. Job Title
3. Organization/Company
4. Your contact email address
5. Sector of your work
6. Where would you position your work in the value chain for DSI-based products and services? [can select multiple]
    a. Extracting DSI from biological material
    b. Storing DSI
    c. Developing tools to process DSI
    d. Processing DSI to develop new knowledge
    e. Processing DSI to develop products or services with commercial applications

    f. Using products or services based on DSI to develop, manufacture, or sell consumer products
    g. Other

7. Which are the key sources of DSI for your work? [can select multiple]
    a. Public database, providing DSI only
    b. Public database, providing DSI and related bioinformatic tools
    c. In-house, corporate databases, with data only for internal use
    d. Commercial databases, offering curated DSI, bioinformatic tools and other services to customers
    e. Other
8. What are the DSI-based technologies used for your work? [can select multiple]
    a. Synthetic biology, including DNA synthesis, gene editing, and metabolic engineering
    b. Industrial biotechnology, including genomics, functional metagenomics, and metabolomics
    c. Medical and pharmaceutical biotechnology, including genomics, transcriptomics, and proteomics
    d. Agricultural biotechnology, including transgenetics, gene editing, and marker assisted selection
    e. Barcoding
    f. Other technologies, including DNA metadata
9. Please describe how your work uses DSI and related technologies to develop products or services. Please provide as much detail as you can.
10. Which are key public and private sector partners in your work? In which countries are they located? Please provide as much detail as you can.
11. What are the types of products that currently derive from your work? [can select multiple]
    a. Pharmaceutical products
    b. Medical and laboratory products and services
    c. Household and personal care
    d. Food and beverages
    e. Crops
    f. Agrochemicals
    g. Animal health and nutrition
    h. Bioenergy
    i. Industrial chemicals
    j. Bioremediation
    k. Leather and textiles
    l. Pulp and paper
    m. Carbon capture

n. Other

12. How do you envision your work evolving in the coming decades? Please consider how the types of data, technologies, and partners may change. Please provide as much detail as you can.
13. How do you think AI might impact the use of DSI?
14. What do you think might be the type of products and services available in the market, which may be developed based on your work in the future, say in 5-20 years' time? Please provide as much detail as you can.
15. What would you say are the implications of such changes and evolving technologies for the adaptability of a multilateral mechanism for the sharing of benefits from the use of DSI so that they remain valid and operational over time (sometimes referred to as "future-proof")? Please provide as much detail as you can.
16. Are there other ways you envisage DSI could be used in the future (next 10 years) either in your field of practice, or any other sector?

Appendix 2

This appendix compiles all of the literary resources accessed in the literature review.

Adam J, 2024. The trends that will shape the biotech industry in 2024. Labiotech. Available at: https://www.labiotech.eu/in-depth/biotech-trends-2024/

Adamowicz SJ, Boatwright JS, Chain F, Fisher BL, Hogg ID, Leese F, Lijtmaer DA, Mwale M, Naaum AM, Pochon X, Steinke D, Wilson J, Wood S, Xu J, Xu S, Zhou X, and van der Bank M, 2019. Trends in DNA barcoding and metabarcoding. *Genome*, 62(3), v–viii.

African Orphan Crops Consortium, 2024. Available at: https://africanorphancrops.org/

Akpoviri FI, Baharum SN and Zainol ZA, 2023. Digital Sequence Information and the Access and Benefit-Sharing Obligation of the Convention on Biological Diversity. *Nanoethics*, 12(1).

Alavanja MC, 2009. Introduction: pesticides use and exposure extensive worldwide. *Reviews on Environmental Health*, 24, 303–309.

Allied Market Research, 2023. Plant-Based Biologics Market Size, Share, Competitive Landscape and Trend Analysis Report, by Product Type, by Source, by Target Disease: Global Opportunity Analysis and Industry Forecast, 2021–2031. Available at: https://www.alliedmarketresearch.com/plant-based-biologics-market-A74549

Baker SJ, Prasher RD and Lundberg M, 2019. A biohybrid system for artificial photosynthesis on a silicon chip. *Nature Communications*, 10(1), 5237.

BCC Research, 2023. Agricultural Biotechnology: Emerging Technologies and Global Markets. Available at: https://www.bccresearch.com/market-research/biotechnology/agricultural-biotechnology-markets-report.html

Benvenuto E, Broer I, D'Aoust MA, Hitzeroth I, Hundleby P, Menassa R, Oksman-Caldentey KM, Peyret H, Salgueiro S, Saxena P and Stander J, 2023. Plant molecular farming in the wake of the closure of Medicago Inc. *Nature biotechnology,* 41(7), 893–894.

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