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Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources
Second meeting
Montreal, Canada, 12–16 August 2024
Item 3 of the provisional agenda*
Further development of the multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund

Studies commissioned further to decision 15/9

Note by the Secretariat

1. The Executive Secretary circulates herewith, for information of participants in the second meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources, studies commission pursuant to decision 15/9 on digital sequence information on genetic resources (para. 22 (b) and (c)).

2. In response to the request, and with the generous support of the Government of Norway, the Government of the United Kingdom of Great Britain and Northern Ireland and the European Commission, the Secretariat partnered with the United Nations Environment Programme World Conservation Monitoring Centre (UNEP-WCMC), which collaborated with KPMG UK, in undertaking a study to analyse and model the extent to which a multilateral mechanism for benefit-sharing from the use of DSI, and any other options the Ad Hoc Open-ended Working Group might decide, met the criteria listed in paragraphs 9 and 10 of that decision; and a study on the options for revenue-generating measures at different points along the value chain, the feasibility of their implementation and their costs relative to their potential revenue.

3. Considering the interlinkages between the topics and required expertise for the studies, and to minimize the length of documents, both topics were combined into one compiled study. The executive summary of this work is available as document CBD/WGDSI/2/2/Add.2/Rev.1.

* CBD/WGDSI/2/1.
** The present document is begin issued without formal editing.

Annex

Studies commissioned further to decision 15/9 on digital sequence information on genetic resources

Study A. A study on the options for revenue-generating measures at different points along the value chain of DSI, the feasibility of their implementation and their costs relative to their potential revenue

Study B. A study to analyse and model the extent to which a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, and any other options the ad-hoc open-ended working group may decide, meets the criteria in paragraphs 9 and 10 of decision 15/9

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Acronyms

Set out below is a list of acronyms used throughout this report.

ABS: Access and Benefit Sharing

AHTEG: ad hoc technical expert group

CBD: Convention on Biological Diversity

COP: Conference of the Parties

DSI: Digital sequence information on genetic resources

KMGBF: Kunming-Montreal Global Biodiversity Framework

GBIF: Global Biodiversity Information Facility

GISAID: Global Initiative on Sharing All Influenza Data

IAG: Informal Advisory Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources

INSDC: International Nucleotide Sequence Database Collaboration

IP: Intellectual property

MAT: Mutually Agreed Terms

NGS: Next generation sequencing

PIC: Prior Informed Consent

UNCLOS: United Nations Convention on the Law of the Sea

WHO: World Health Organization

WIPO: World Intellectual Property Organization

Glossary of terms

This section outlines our understanding of terms used in this study in relation to a) terms linked to DSI, and b) terms used to describe the fund generating measures.

General terms linked to DSI

Formal, legal, internationally agreed definitions do not yet exist for many terms used in the context of DSI. For the purpose of these studies, the following terms are used, based on available literature.

Access to DSI: Downloading DSI from a database or repository source, or through generation of DSI from genetic resources (sequencing).

Biological diversity: *'means the variability among living organisms from all sources including, inter alia, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems'*.[1]

Commercialisation of products / services based on the use of DSI: the sale of products or services which contain DSI or involve the use of DSI in their development.

Fund contributions / fund generating measures: ways in which money may flow into a benefit sharing fund.

Disbursement from the fund: disbursement of monetary benefits from the fund with recipients.

[1] Convention on Biological Diversity (1992) - Text of the Convention (cbd.int) accessed 26 April 2024

DSI: In Decision 14/20, the Conference of the Parties to the Convention on Biological Diversity 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'.[2] Decision 15/9 then agrees on the continuing use of the term "digital sequence information" for further discussions.[3] For the purposes of this study, DSI will be considered from non-human sources only, encompassing plants, fungi, animals, and microbes.

Genetic material: *'means any material of plant, animal, microbial or other origin containing functional units of heredity'.*[4]

Genetic resource: *'means genetic material of actual or potential value'.*[5]

Intellectual property: refers to '*creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce*'.[6] In the context of DSI, protection of IP may include patents, copyright, and trade secrets.[7]

Levy: an amount of money, such as a tax or fee, that must be paid.[8]

Modalities: possible elements of a multilateral mechanism.[9]

Mutually Agreed Terms: contractual terms and conditions, which may include benefit sharing.[10]

Net profit: Net profit (also called net income or net earnings) is the value that remains after all expenses, including interest and taxes, have been deducted from total entity income.[11]

Non-monetary benefit sharing: the sharing of benefits which are not monetary such as capacity building and technology transfer. Further examples of non-monetary benefit sharing activities can be found in the Annex of the Nagoya Protocol.[12]

Open access: open availability of research data, including DSI, in the public domain through openly accessible databases.[13,14,15]

Open source licenses: in the context of software, an open source license refers to the terms and conditions that allow anyone to freely use, modify and share the design and code of the software.[16]

Prior Informed Consent: permission required to access a genetic resource.[17]

Profit: The value that remains after a company's expenses have been paid. A non-technical, general definition has been applied where no assumption is being made on the type of profit (gross, operating, net, etc) in question.[18]

Revenue: The total value of all sales of goods and services plus the value of its other income, recognized by a company in a period (revenue and turnover are defined in the same way for this study).

[2] CBD/COP/DEC/14/20. Available at 14/20. Digital sequence information on genetic resources (cbd.int) accessed 20 June 2024
[3] CBD/COP/DEC/15/9
[4] Convention on Biological Diversity (1992) - Text of the Convention (cbd.int) accessed 26 April 2024
[5] Convention on Biological Diversity (1992) - Text of the Convention (cbd.int) accessed 26 April 2024
[6] https://www.wipo.int/about-ip/en/ accessed 02 May 2024
[7] Seitz, C., 2020. Digital sequence information–legal questions for patent, copyright, trade secret protection and sharing of genomic sequencing data. In *IOP Conference Series: Earth and Environmental Science* (Vol. 482, No. 1, p. 012002). IOP Publishing.
[8] https://dictionary.cambridge.org/dictionary/english/levy accessed 27 April 2024
[9] See annex of CBD/COP/DEC/15/9 accessed on 28 March 2024
[10] Article 6, Nagoya Protocol (2010). Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity - Text of the Nagoya Protocol (cbd.int) accessed 24 April 2024
[11] Profit - Overview, Examples of Gross, Operating, and Net Profit (corporatefinanceinstitute.com) Accessed 11 July 2024
[12] Nagoya Protocol (2010). Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity - Text of the Nagoya Protocol (cbd.int) accessed 24 April 2024
[13] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[14] Broggiato, A., Vanagt, T., Lallier, L.E., Jaspars, M., Burton, G. and Muyldermans, D., 2018. Mare geneticum: balancing governance of marine genetic resources in international waters. *The International Journal of Marine and Coastal Law*, *33*(1), pp.3-33.
[15] Soren Brunak, Antoine Danchin, Masahira Hattori, Haruki Nakamura, Kazuo Shinozaki, Tara Matise, Daphne Preuss, 2002.Nucleotide Sequence Database Policies. Science 298 (5597): 1333 15 Nov 2002
[16] Licenses – Open Source Initiative accessed 14 May 2024
[17] Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (2002) Bonn Guidelines on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilization (cbd.int) accessed 14 May 2024
[18] Profit - Overview, Examples of Gross, Operating, and Net Profit (corporatefinanceinstitute.com) Accessed 11 July 2024

Royalties / royalty payments: Royalties, also called royalty payments, are payments made from a licensee to a licensor for the use of their intellectual property under a licensing agreement. The licensee buys the right to use the asset or property for profit in exchange for compensation on products sold under the license.[19]

Sales: the volume of items sold or the value of sales (i.e. the value generated from the sales of products/services only, not inclusive of other income), recognized by a company in a period.

Standardized licences: terms and conditions used in collaborative licensing mechanisms.[20]

Trigger: the event or activity which results in the requirement to share benefits.[21]

Turnover: The total value of all sales of goods and services plus the value of its other income, recognized by a company in a period (revenue and turnover are defined in the same way for this study).

Unlinked to the access, use or commercialisation of DSI: events unrelated to the access, use or commercialisation of DSI which may, for example, trigger benefit sharing e.g., voluntary contributions.[22]

Unlinked to specific DSI: unrelated to the access, use or commercialisation of specific DSI.

Value Chain: a series of consecutive steps or activities conducted by stakeholders which add or derive value from a product and are required to bring a product or service from conception through to distribution to consumers. As an asset moves from one entity in the value chain to another, it is assumed to gain value.[23]

Fund generating measures

Note that the following options (apart from the 1% levy proposal[24]) will involve some form of rate setting to be agreed by Parties. See section 11 for further details.

- **Fee to access DSI and / or related information:** payment associated with accessing DSI from databases, and / or access to related information such as protein structure or function. This may involve a fee to download individual sequences, or could involve a membership fee / subscription to access DSI in databases / cloud-computing spaces.[25,26,27]
- **Payment / levy on services associated with generation and use of DSI:** payment for DSI-related services linked not only to the generation of DSI (DNA sequencing), but also the storage, processing, expertise, and analysis of sequences[28,29]
- **Payment / levy on products associated with use of DSI:** payment on products associated with use or generation of DSI, such as a levy on laboratory equipment linked with the production of DSI[30]

[19] Royalties: Definition & Types of Royalty Payments (contractscounsel.com) accessed 05 July 2024
[20] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[21] Morgera, E., 2016. The need for an international legal concept of fair and equitable benefit sharing. *European Journal of International Law*, *27*(2), pp.353-383.
[22] Annex (A, Option 3 (Payments and contributions)).
[23] Porter, M., 1985. e.(1985) competitive advantage-creating and sustaining superior performance. New York.; Brown, L., 1997. Competitive Marketing, Melbourne: Nelson; Dubey, S., Singh, R., Singh, S.P., Mishra, A. and Singh, N.V., 2020. A brief study of value chain and supply chain. *Agriculture Development and Economic Transformation in Global Scenario*, pp.177-183.
[24] [Global] [multilateral] [solution[s] for sharing of benefits from the use of] digital sequence information on genetic resources (cbd.int) accessed 27 April 2024
[25] Oldham, P. (2020). Digital Sequence Information - Technical aspects. Zenodo (CERN European Organization for Nuclear Research). https://doi.org/10.5281/zenodo.7323632 Accessed 01 May 2024
[26] https://www.cbd.int/abs/DSI-webinar/DSIPolicyOptions2021.pdf
[27] See page 17 where a de-coupled policy approach is described by Scholz, A.H., Hillebrand, U., Freitag, J., Cancio, I., dos S. Ribeiro, C., Haringhuizen, G., Oldham, P., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective. WILDSI
[28] Oldham, P. (2020). Digital Sequence Information - Technical aspects. Zenodo (CERN European Organization for Nuclear Research). https://doi.org/10.5281/zenodo.7323632 Accessed 01 May 2024
[29] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[30] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.

- **Payment at the point of protecting IP:** payment made at the time of protecting IP (e.g., patent registration) associated with use of DSI.
- **Payment at the point of use of DSI:** payment made at the time of conducting research and / or development involving DSI.
- **Licences:** payments made linked to licences, such as standardised licences associated with DSI in open-access databases, or commons licenses as used in the field of open-source software development[31,32]
- **Payment at the point of commercialisation:** payment made at the time of selling products or services which contain DSI / biodiversity, or which involved the use of DSI / biodiversity in their development, or payment made by a sub-sector which sells classes of products or services[33]
- **Payment at some time after commercialisation:** payment made at some specified time after selling products or services which contain DSI / biodiversity, or which involved the use of DSI / biodiversity in their development, or payment made by a sub-sector which sells classes of products or services [34]
- **Fixed royalties:** payment of pre-negotiated, fixed royalties on those who successfully sell products or services which contain DSI, or which involved the use of DSI in their development, or payment made by a sub-sector which sells classes of products or services [35,36]
- **Milestone payments:** payments triggered by an activity or occurrence of an event. For example, this could be tied to the application or exploitation of IP rights[37,38]
- **1% levy on retail sales of products developed from the use of DSI / of products developed using biodiversity:** payment of 1% on the retail price of all commercial income resulting from the sale of products developed from the use of DSI, or of all products developed from the use of biodiversity[39,40]
- **Government contributions:** payments may be based on national gross domestic product or other appropriate United Nations statistics[41,42]
- **Voluntary contributions:** voluntary payments could be made by the private sector, database users, governments, private donors, or others[43,44]

[31] Oldham, P., and Kindness, J., 2022. Sharing Digital Sequence Information. Study for the European Commission. doi: 10.5281/zenodo.6557191
[32] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[33] Global multilateral solution[s] for sharing of benefits from the use of] digital sequence information on genetic resources (cbd.int) accessed 27 April 2024
[34] Global multilateral solution[s] for sharing of benefits from the use of] digital sequence information on genetic resources (cbd.int) accessed 27 April 2024
[35] Vogel, J.H., Ruiz Muller, M., Angerer, K., Delgado-Gutiérrez, D. and Gálvez Ballón, A., 2022. Bounded openness: A robust modality of access to genetic resources and the sharing of benefits. *Plants, People, Planet*, *4*(1), pp.13-22.
[36] Halewood, M., Bagley, M.A., Wyss, M. and Scholz, A.H., 2023. New benefit-sharing principles for digital sequence information. *Science*, *382*(6670), pp.520-522.
[37] Crama, P., Reyck, B., De, Degraeve, Z., 2009. Milestone Payments or Royalties? Contract Design for R&D Licensing. *Operations Res.* 56 (6), 1539–1552. doi: 10.1287/opre.1080.0589
[38] Sirakaya, A., 2019. Balanced options for access and benefit-sharing: stakeholder insights on provider country legislation. *Frontiers in plant science*, *10*, p.476328.
[39] Annotated provisional agenda (cbd.int) accessed 27 April 2024
[40] https://www.cbd.int/doc/c/c064/37f6/d5024789093ef19bf5f84519/wg2020-05-03-en.pdf accessed 27 April 2024
[41] Oldham, P., Chiarolla, C. and Thambisetty, S., 2023. Digital Sequence Information in the UN High Seas Treaty: Insights from the Global Biodiversity Framework-related Decisions. *LSE Law-Policy Briefing Paper*, (53).
[42] Halewood, M., Bagley, M.A., Wyss, M. and Scholz, A.H., 2023. New benefit-sharing principles for digital sequence information. Science, 382(6670), pp.520-522.
[43] DSIPolicyOptions2021.pdf (cbd.int) accessed 27 April 2024
[44] WGDSI-01 - Documents (cbd.int) accessed 24 April 2024
[44] COP-15 - Documents (cbd.int) accessed 24 April 2024

1) Background

This section provides context in terms of the international frameworks relevant to governance of DSI, the scope of DSI considered in this study, how DSI is generated and the key public databases where DSI is stored and accessed.

Access and Benefit Sharing (ABS) Frameworks Governing Genetic Resources and DSI

The Convention on Biological Diversity (CBD, 1992) and its Nagoya Protocol (2010) provide international, legal frameworks governing access to genetic resources and the fair and equitable sharing of benefits arising from their utilization.[45,46] An overview of the ABS framework is provided below.

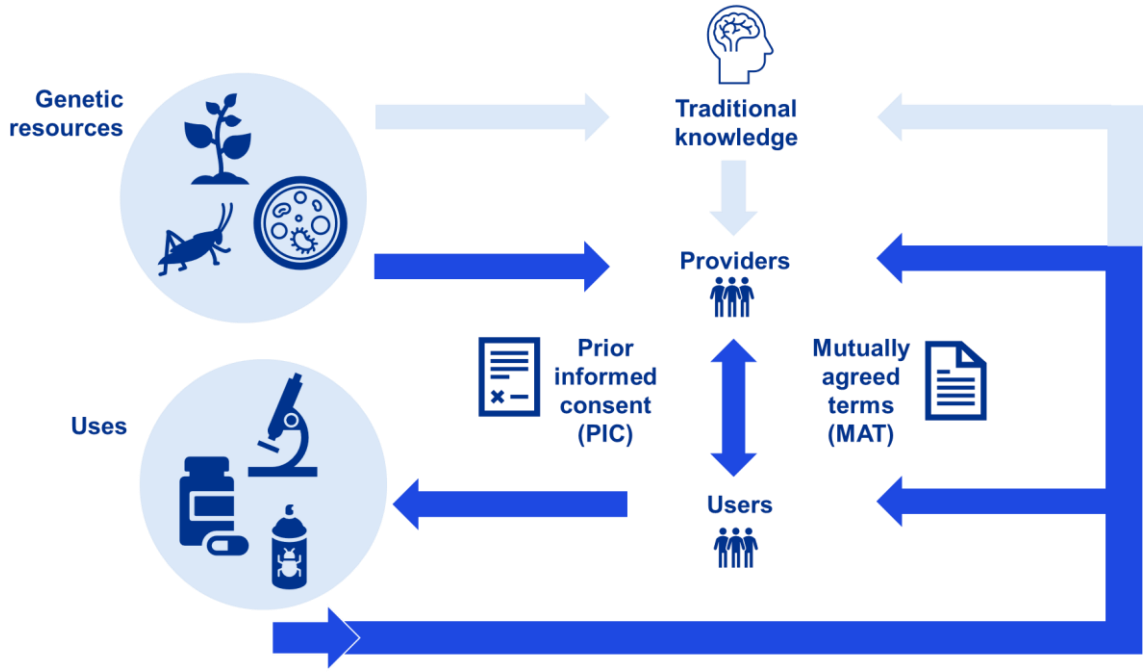

Figure 1: Overview of the ABS framework under the Nagoya Protocol. Adapted from: Factsheet on Access and Benefit-Sharing, Secretariat of the Convention on Biological Diversity, 2010.[47]

The International Treaty on Plant Genetic Resources for Food and Agriculture (also known as the 'Plant Treaty') and the WHO Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits are specialised international ABS instruments governing genetic resources.[48,49] Similarly, the Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (adopted in 2023) will govern benefit sharing arising from activities with respect to marine genetic resources DSI on marine genetic resources of areas beyond national jurisdiction.[50] It is recognized that a solution for international governance of DSI should be mutually supportive of these other ABS instruments. Preambular paragraph 8 indicates that '*any solution for the fair and equitable sharing of benefits from the use of DSI on genetic resources should be mutually supportive of and adaptable to other instruments and fora while recognizing that other fora may develop specialized approaches'*.[51] In addition, paragraph 9(h) indicates that the new

[45] Convention on Biological Diversity (1992) - Text of the Convention (cbd.int) (accessed 24 April 2024)
[46] Nagoya Protocol (2010). Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity - Text of the Nagoya Protocol (cbd.int) accessed 24 April 2024
[47] ABS Information Kit produced and published by the CBD secretariat (2011). Available at: www.cbd.int/abs/awareness-raising/ accessed 23 April 2024
[48] FAO (2001). International Treaty on Plant Genetic Resources for Food and Agriculture. FAO Res. 3/2001, 3 November 2001 (entered into force 29 June 2004) - Texts of the Treaty | International Treaty on Plant Genetic Resources for Food and Agriculture | Food and Agriculture Organization of the United Nations (fao.org) - accessed 25 April 2024
[49] World Health Organization (2011). Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits - pandemic-influenza-preparedness-en.pdf (who.int) – accessed 25 April 2024
[50] BBNJ (2023). Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction - XXI-10 CTC (un.org) accessed 28 April 2024
[51] CBD/COP/DEC/15/9 Available at 15/9. Digital sequence information on genetic resources (cbd.int) accessed 14 May 2024

solution should '*be mutually supportive of other ABS instruments'*.[52] As such, there is an ongoing effort to develop a solution for a DSI multilateral mechanism that is mutually supportive of other ABS instruments.[53]

According to the Report of the multidisciplinary Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment on its second meeting, '*rapid advances in artificial intelligence and machine learning have led to a significant increase in their use for the development of organisms, components and products of synthetic biology*'.[54] Synthetic biology has been described as '*a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems*'.[55] It has the potential to advance developments in many sectors, including pharmaceutical, agricultural and energy applications. The potential benefits associated with synthetic biology include the development of new drugs and therapies, improved crops, conservation applications for threatened species and cleaner energy sources. Potential risks may include the accidental release of harmful organisms, the creation of new pathogens, and the misuse of synthetic biology as well as ethical considerations. Regulation, international agreement on common standards, allocation of research funding, scientific cooperation and technology transfer as well as public education represent policy options available to policy makers to govern synthetic biology.

Defining the scope of DSI for this study

'*Recognizing the different understandings of the concept and scope of digital sequence information on genetic resources, and the range of views regarding the need to define such concept and scope',* the Conference of the Parties (COP) to the CBD '*agrees on the continuing use of the term "digital sequence information" for further discussions*'.[56] In alignment with the conceptual framework reported by the AHTEG on DSI on genetic resources which met in 2020, this study considers DSI within the following[57]:

- Group 1 - DNA and RNA
- Group 2 - DNA, RNA, and proteins
- Group 3 - DNA, RNA, proteins, metabolites, and other macromolecules

A fourth group involving associated information was also considered by the AHTEG but is not addressed within this study. DSI will be considered from non-human sources only, encompassing plant, fungi, animal, and microbes. The focus will be on the use of DSI.

Process of DSI Generation

DSI is generated through a series of steps starting from isolation of genetic material to the analysis and publication of sequence data:

1. **Sample Collection:** A sample of biological material is needed, which is typically collected from plants, animals, or microbial sources. This step may involve access to genetic resources and requires consideration of and compliance with ABS regulations (as described above in **Figure 1**).
2. **Isolation:** Using specific protocols, the molecule of interest — DNA, RNA, or proteins — is isolated. This step ensures that the biological material is purified and ready for analysis.

[52] CBD/COP/DEC/15/9 Available at 15/9. Digital sequence information on genetic resources (cbd.int) accessed 14 May 2024
[53] CBD/COP/DEC/15/9 Available at 15/9. Digital sequence information on genetic resources (cbd.int) accessed 14 May 2024
[54] CBD/SYNBIO/AHTEG/2024/1/3 Report of the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment on its second meeting (cbd.int) accessed on 11 July 2024
[55] CBD/COP/DEC/XIII/17 Synthetic biology (cbd.int) accessed 13 July 2024
[56] CBD/COP/DEC/15/9. Available at https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf accessed on 27 March 2024
[57] Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources (cbd.int) accessed 24 April 2024

3. **Sequencing:** Chemical methods and various machines are employed to determine the biochemistry of metabolites and macromolecules (nucleotides for DNA and RNA, amino acids for proteins) and their precise order in the sequence. See nucleotide sequence in **Figure 2**.

4. **Data Cleaning, Analysis and Characterisation:** The raw data from the sequencing process is then 'cleaned,' which involves removing sequencing errors. The cleaned sequence data is compared with other sequences using bioinformatics tools that include computer algorithms and scientific expertise.

5. **Publication:** The results of the analysis and the cleaned, annotated sequence information are then potentially published in scientific databases, data banks or journals. The publication step makes the data accessible for further research and development activities. [58]

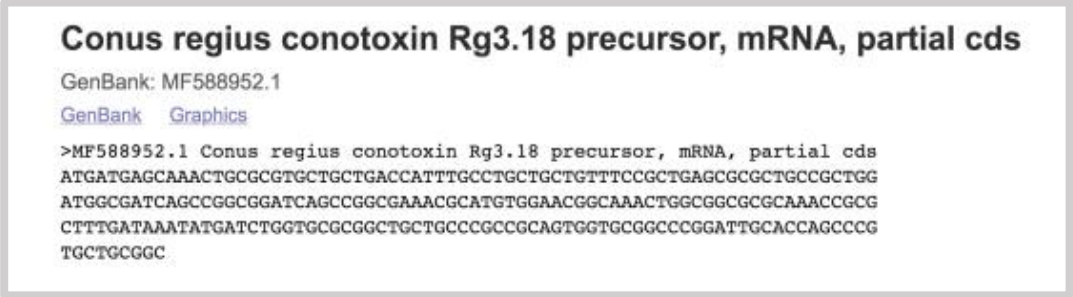

Figure 2: Partial mRNA sequence of the Conus snail published in GenBank (adapted from source: Digital Sequence Information on Genetic Resources).[59]

DSI can include datasets which provide different levels of information, which begin with raw sequences, resulting from the sequencing process. Sequences can be “cleaned”, in which errors are removed, the sequence has been analysed and sometimes annotated, with researchers sometimes providing information relating to gene function, often considered the most valuable metadata for commercial users. The outcome of this process may look similar to the mRNA sequence presented above of the Conus snail (with the extract presented being from GenBank).[60]

Public Databases

The International Nucleotide Sequence Database Collaboration (INSDC) has been the core infrastructure for collecting and providing nucleotide sequence data and metadata for over 30 years.[61] The INSDC currently consists of three partner organizations, the ROIS-NIG's DNA Data Bank of Japan (Japan), NLM-NCBI's GenBank (USA) and the EMBL-EBI's European Nucleotide Archive (international organization with 29 member states, Europe). New and updated data on nucleotide sequences contributed by research teams to each of the three databases are synchronised on a daily basis. The INSDC has a uniform policy of free and unrestricted access to all of the data records their databases contain.[62] Anyone can access these records to plan experiments or publish any analysis or research. Citation of DSI used and new DSI generated for a research project (through unique identifiers in INSDC) is often mandated by scientific journals. Appropriate credit is given by citing the original submission, following the practices of scientists utilising published scientific literature. In addition, data from the Global Biodiversity Information Facility (GBIF) indicates that INSDC has applied creative common's license to their data shared through GBIF.[63]

Data from INSDC forms a major part of research with DSI. As of 2024, the database contained 250 million annotated sequences, being downloaded partially or completely 34 million times per year and

[58] Karger, Elizabeth & Plessis, Pierre & Meyer, Hartmut. (2019). Digital Sequence Information on Genetic Resources (DSI) - An Introductory Guide for African Policymakers and Stakeholders.
[59] Karger, Elizabeth & Plessis, Pierre & Meyer, Hartmut. (2019). Digital Sequence Information on Genetic Resources (DSI) - An Introductory Guide for African Policymakers and Stakeholders.
[60] Jaspars, M. in Laird, S.A. et al (2018). A Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol, 2018. Convention on Biological Diversity. CBD/SBSTTA/22/INF/3 CBD/DSI/AHTEG/2018/1/3.
[61] International Nucleotide Sequence Database Collaboration (insdc.org) accessed 14 May 2024
[62] Brunak, S., Danchin, A., Hattori, M., Nakamura, H., Shinozaki, K., Matise, T. and Preuss, D., 2002. Nucleotide sequence database policies. Science, 298(5597), pp.1333-1333.
[63] https://www.gbif.org/occurrence/search?q=Sars&publishing_org=ada9d123-ddb4-467d-8891-806ea8d94230 accessed 15 July 2024.

used by more than 10–15 million unique users.[64] 99.5% of the 750 downstream sequence databases that pull and push DSI through the scientific ecosystem directly rely on the INSDC system, with 16% of sequences in the INSDC having country of origin information associated with them.[65] The data are linked to a further 1200 databases and hundreds of thousands of publications that, on average, cite 44 sequences per publication. It is important to note that private databases also exist and are used across sectors.

The Global Initiative on Sharing All Influenza Data (GISAID) is another public database which stores DSI.[66] Data from GISAID is widely used in the human health sector by public researchers and industry, particularly in the development of human influenza vaccines. GISAID was also widely recognized as the key resource for COVID sequence data during the pandemic.[67,68] A key difference between INSDC and GISAID is that whilst both databases are public and free to access, GISAID requires users to register before they can download data. This enables GISAID to maintain oversight of who downloads which data but does not place restrictions on what can be done with the data.

[65] As of 2022, only 16% of sequences in the INSDC had country of origin information associated with them. Scholz, A.H., Freitag, J., Lyal, C.H.C. et al, 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nat Commun* 13, 1086. https://doi.org/10.1038/s41467-022-28594-0.
[66] GISAID - gisaid.org accessed 11 July 2024.
[67] Önell, J. and Kinnunen, P., 2022. The importance of databases during pandemics: A study of GISAID during the COVID-19 pandemic.
[68] Oldham, P., and Kindness, J., 2022. Sharing Digital Sequence Information. Study for the European Commission. doi: 10.5281/zenodo.6557191

2) Aims of the studies

This section sets out the aims of the two studies (Study A and Study B) that have been undertaken and are summarised in this report. Given the links between the aims of the studies, the primary research was designed to address both study aims and the findings of the studies are reported together in this document.

The Aim of Study A

This study provides an analysis of options for generating revenue for the global fund across different stages of the value chain, in response to the request for studies outlined in paragraph 22(c) of decision 15/9 from the CBD COP. Specifically, the COP requested the Executive Secretary to the CBD to "*commission a study on the options for revenue-generating measures at different points along the value chain, the feasibility of their implementation and their costs relative to their potential revenue*".[69]

The primary goal of this study is to synthesise critical insights from existing literature and stakeholder consultation regarding revenue generation from DSI. By doing so, the study aims to offer information on leveraging DSI as a resource for generating revenue for the global fund, while considering the operational challenges and financial implications of such strategies.

The Aim of Study B

The aim of this study is to provide an assessment of options for a multilateral mechanism for DSI. This study is in response to the request for studies outlined in paragraph 22(c) of decision 15/9 from the CBD COP. Specifically, the COP requested the Executive Secretary to the CBD to "*commission a study to analyse and model the extent to which a multilateral mechanism from the use of DSI on genetic resources, and any other options the Ad Hoc Open-ended Working Group may decide, meets the criteria in paragraphs 9 and 10 of the present decision*".[70]

At part two of its fifteenth meeting in Montreal in December 2022, the CBD COP adopted the Kunming-Montreal Global Biodiversity Framework (KMGBF, decision 15/4) and several related decisions including decision 15/9 on DSI on genetic resources. In that decision on DSI, the COP agreed that the benefits from the use of DSI on genetic resources should be shared fairly and equitably. The COP also agreed on a set of criteria that a solution for the sharing of benefits arising from the use of DSI should follow (see section 7 below). Additionally, the COP decided to establish a multilateral mechanism from the use of DSI, including a global fund. It also decided to establish a fair, transparent, inclusive, participatory, and time-bound process to further develop and operationalise this multilateral mechanism.

Parties and stakeholders have been proposing options for the sharing of the benefits arising from the use of DSI and worked on compiling those options into policy archetypes (see section 9 below). Closer to COP15, the Informal Advisory Group (IAG) on DSI on genetic resources discussed and reflected on more developed versions on some policy options. The summary can be found in section II.D. of report **CBD/WG2020/5/INF/1**. They also discussed and debated several technical topics related to DSI and policy options, which they compiled in reports.[71]

[69] CBD/COP/DEC/15/9. Available at https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf accessed on 27 March 2024
[70] CBD/COP/DEC/15/9. Available at https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf accessed on 27 March 2024
[71] CBD/WG2020/3/INF/8. Available at https://www.cbd.int/doc/c/079d/1142/339a68fee2d22e95fb2b1c4c/wg2020-03-inf-08-en.pdf accessed on 28 March 2024

3) Methods

This section sets out the methods used in both studies to meet the study aims. Given the links between the aims of both studies, the methods involved techniques which were designed to address the aims of both studies and were undertaken simultaneously.

The studies involved literature reviews, semi-structured interviews, and a survey to gather the required information.

Literature review **-** The literature review was conducted via Google Scholar using keywords (digital sequence information; genetic; genome; nucleotide sequence data; synthetic biology; DNA; RNA; proteins; metabolites and macromolecules) to:

a) Identify the market sectors which use DSI, their respective value chains, and market sizes at present and expected up to 2030. The 2030 timeframe was chosen to align with the set targets of the Kunming-Montreal Global Biodiversity Framework.

b) Research potential fund generating measures and modalities of the multilateral mechanism for benefit sharing (see section 9).

Semi-structured interviews **-** Stakeholder consultation involved semi-structured interviews and a survey. The aim was to better understand stakeholder views on the extent to which potential modalities of the multilateral mechanism meet the criteria of paragraphs 9 and 10 of CBD COP decision 15/9, including potential risks and opportunities. The aim of the interviews was also to better understand stakeholder views on:

a) Implementation of different fund generating measures, at different points in the value chain, and across different sectors.

b) Benefits associated with implementing various fund generating measures.

c) Challenges and potential solutions associated with various fund generating measures.

Semi-structured interview guides were prepared and agreed with the CBD Secretariat. These questions were sent to individuals ahead of the interviews to enable preparation. The questions were used to guide the interview meetings (conducted via Microsoft Teams), but there was also flexibility for diversion and to probe specific areas depending on stakeholder responses. In efforts to foster open candid discussions, stakeholder meetings followed the Chatham House Rule and were not recorded (video or audio). Instead, records of discussion were manually transcribed. Seventeen interviews were conducted (between 15.04.2024 – 29.04.2024) with individuals from each stakeholder group (see list below). These individuals were selected in agreement with the CBD Secretariat. Individuals did not officially speak as representatives of these groups, but these groupings instead are based on their associations with the Parties or organizations and their long-standing engagement as individuals in the process.

Survey **-** A survey was prepared together with the CBD Secretariat and sent to members of the DSI Informal Advisory Group (114 individuals) which represents members across all stakeholder groups (described below) with the aim of gathering their perspectives on the extent to which various modalities meet the required criteria. Forty individuals responded to the survey - see section 10 for further details. Results from these surveys were then collated and used to create a visualisation (see section 10) which provides an overview of the extent to which participants consider various modalities meet the required criteria.

Results from the literature review were coupled with interview notes and survey feedback to create matrices to assess the extent to which modalities meet the criteria (see Appendix). These matrices are summarised in sections 11 - 15.

Stakeholders involved in the interviews

There are many stakeholder groups involved in the field of DSI: government (those responsible for making and implementing policy and regulation); industry (producers and commercial users of DSI);

research community (producers of DSI); civil society; database operators and indigenous peoples and local communities. Individuals associated with the following Parties / organizations were interviewed:

Government / regional economic integration organizations: African Union, European Union, Brazil, Indonesia. **Industry / commercial users:** International Chamber of Commerce, Japan Bioindustry Association, International Seed Federation, International Federation of Pharmaceutical Manufacturers and Associations, Basecamp Research Ltd. **Academic research community / non-commercial users:** DSI Scientific Network - Leibniz Institute DSMZ & Corporación Corpogen Colombia, Consultative Group on International Agricultural Research, One World Analytics, Griffith University, South African National Biodiversity Institute, Lund University. **Civil society:** Third World Network. Database Operators: International Nucleotide Sequence Database Collaboration - GenBank / DNA Data Bank of Japan/ EMBL-EBI, Global Biodiversity Information Facility. **Indigenous peoples and local communities:** International Indigenous Forum on Biodiversity.[72]

By conducting a combination of literature reviews and stakeholder consultation, the aim was to analyse current perspectives on the extent to which a multilateral mechanism for benefit sharing from the use of DSI meets the criteria in paragraphs 9 and 10 of decision 15/9, together with potential reasons for the current assessments and factors which may promote the extent to which criteria are met in the future.

[72] The representative of International Indigenous Forum on Biodiversity consulted with their group ahead of the interview. The answers are therefore representative of indigenous peoples and local communities' views.

4) Limitations

This section outlines the limitations of the research undertaken. In line with best practice, these limitations have been identified and acknowledged to provide context for the conclusions.

The following limitations affected the extent of research and stakeholder consultation conducted, as well as the conclusions that could be reached.

- **Time:** A short timeframe was given to the consultants from initiation of the studies to submission of the first draft. As such, time constraints played a key role in the extent of stakeholder consultation and research that could be conducted.
- **Conceptual Ambiguity:** A challenge encountered in this study was the absence of an internationally agreed definition of DSI. For the purposes of this study, DSI will be considered from non-human sources only, encompassing plants, fungi, animals, and microbes.
- **Stakeholder Engagement:** Some stakeholders may not have had the resources or capability to respond to the survey given the time constraints (ten days). Similarly, interviews and surveys were conducted in English language which may have limited participation. While efforts were made to foster open and candid discussions, and to schedule substantial time with stakeholders, the meetings were limited to 90 minutes and only transcribed manually. These two factors could limit nuance and detail in some arguments or explanations and may affect representativeness of stakeholder groups.
- **Understanding of Terms:** The survey assumes that everyone holds the same interpretation of terms, such as each of the modalities (elements under consideration within potential policy options) and of the accounting terms referred to including turnover, profit and sales**,** and that the criteria are considered as having equal weighting.
- **Access to Information:** The analysis within this study was constrained to information that is publicly available. This limitation may have affected the depth of the insights drawn and comprehensiveness of the review. Similarly, most of the literature reviewed was in English language.
- **Summarised Information**: Key aspects, such as the DSI value chain across market sectors, have been summarised and simplified so that diagrammatic representations of these value chains could be created.

5) DSI value chains

This section describes our understanding of the main value chain steps associated with DSI

In this study, a 'value chain' is defined as 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. As an asset moves from one entity in the value chain to another, it is assumed to gain value, resulting from the investment of human and financial capital.[73] The value chain can be used as a tool to clarify and separate the major activities involved in creation of a finished product or service, thereby enabling the identification of key steps within a product's value chain and the points at which it may generate lower and higher returns for stakeholders.

Potential steps in the DSI value chain may include (but are not limited to) the following:

- Collection of genetic resources from the natural environment
- Access to DSI (through sequencing of a genetic resources, or download from a database)
- Research and development with DSI
- Application for IP rights, if applicable
- Production
- Regulatory approval, if applicable
- Marketing
- Commercialisation

The specific activities involved in a DSI value chain will vary depending on factors such as the market sector and the final product / service in question. There is as yet no decision in relation to the multilateral mechanism on the specific starting point in the DSI value chain – this could (for example) be considered as access to DSI via a database or other sources, or through the sequencing of a genetic resource. For the purpose of these studies, we consider the starting point as the access to DSI via a database.

[73] Porter, M., 1985. e.(1985) Competitive advantage-creating and sustaining superior performance. New York.; Brown, L. (1997). Competitive Marketing, Melbourne: Nelson; Dubey, S., Singh, R., Singh, S.P., Mishra, A. and Singh, N.V., 2020. A brief study of value chain and supply chain. *Agriculture Development and Economic Transformation in Global Scenario*, pp.177-183.

6) Overview of market sectors which use DSI

This section provides an overview of the sectors which use DSI. For each of the five sectors considered in this study (pharmaceutical; cosmetics; plants and animal breeding and agricultural biotechnology; laboratory equipment associated with the use of DSI; and information, technology, and technical services related to DSI) an overview of the sector is provided, a visualisation of the value chain and commercialisation mechanisms, and case study examples of DSI being used in the sector.

Following the advent of gene sequencing technologies, such as high-throughput sequencing and third generation sequencing, and the first complete sequencing of a gene in 1972 (the gene encoding the coat protein of the bacteriophage MS2), it has been possible to generate longer gene sequence reads at progressively faster speeds and lower costs, leading to a huge proliferation in data.[74] For example, INSDC had over 9 petabytes of sequence data maintained in their database in 2020, where one petabyte is equal to 1000 terabytes.[75]

There is potential for DSI to be used across a broad variety of sectors.[76] Potential products / processes developed with the use of DSI may include new medicines, ingredients, new foods and nutritional supplements, health and beauty supplements, cosmetic products, biomaterials (such as bioplastic and other fossil-based alternatives), textiles and feed for animals, but also as co-adjuvants and enhancers in many industrial and manufacturing processes improving their efficiency and reducing their environmental impact.

Key market sectors considered in this study are the following:

- Pharmaceutical
- Cosmetics
- Plant and animal breeding and agricultural biotechnology
- Laboratory equipment associated with the use of DSI
- Information, technology, and technical services related to DSI

These five sectors were selected, in agreement with the CBD Secretariat, after an initial review of the literature led to the understanding that these are the main sectors which currently use DSI.

Descriptors of sectors

1) **Pharmaceutical** – in the pharmaceutical sector DSI is used throughout the development of most health products. The most obvious users of DSI include 1) primary research teams who generate new and updated data on DNA/RNA sequencing information such as those who sequence a pathogen first or more accurately, and 2) translational and applied healthcare researchers and pharmaceutical companies, who utilise DSI in the generation of pharmaceutical products and treatments.
2) **Cosmetics –** consumer demand for new and innovative products drives significant investment in research and development in the cosmetics sector. The need to create new formulations to meet the changing needs and desires of customers has led to the exploration of the use of genetic engineering to design and create biosynthesised ingredients that offer enhanced cosmetic benefits or extend product shelf-life. The proportion of products that result from research involving DSI in this industry is not readily available.
3) **Plant and animal breeding and agricultural biotechnology** – for the purpose of these studies, the plant and animal breeding and agricultural biotechnology sector is broadly defined to encompass the agricultural and aquacultural processing and production activities aimed at

[74] Min-Jou W., Haegeman G., Ysebaert M., Fiers W. Nucleotide sequence of the gene coding for the bacteriophage MS2 coat protein. Nature. 1972;237:82–88
[75] Masanori Arita, Ilene Karsch-Mizrachi, Guy Cochrane, on behalf of the International Nucleotide Sequence Database Collaboration, The international nucleotide sequence database collaboration, *Nucleic Acids Research*, Volume 49, Issue D1, 8 January 2021, Pages D121–D124, https://doi.org/10.1093/nar/gkaa967
[76] Aubry, S., 2019. The future of digital sequence information for plant genetic resources for food and agriculture. *Frontiers in plant science*, *10*, p.1046. accessed 09 July 2024

generating crops and animals for food and feed purposes. This sector is crucial for global food security and economic development.[77] The proportion of products that result from research involving DSI in this industry is not readily available.

4) **Laboratory equipment associated with the use of DSI** – the sector considered here develops and manufactures laboratory reagents and equipment such as those used for sequencing, modifying, or generating genetic material. The sector is considered as benefiting from investment from DSI users, not from the use of DSI.

5) **Information, scientific and technical services related to DSI** – software (i.e. databases and platforms) is used to read, manipulate, model and test or store DSI. Also included are software that support or improve the function of a piece of hardware (i.e. for the automation of a sequencing or bioengineering process). The bioengineering and synthetic biology sectors are particularly reliant on those. This category also includes collectors of genetic resources or environmental DNA (eDNA) and producers of information on DSI, which are then acquired by companies in various sectors, including major cloud services companies (AWS, Azure, and Google) and specialist cloud platforms. It is important to note that due to limited data availability, revenue or net profit figures for this sector are based on the computational biology sub sector.

Table 1 below shows estimates of the current sector revenue (and net profit) generated by each sector as well as forecast sector revenue (and net profit) for 2030. The year 2030 has been used for the forecast to align with the set targets of the KMGBF. The sector revenue shows the relative scale of the different sectors that use DSI which are considered in this study. It is important to note however that not all of a sector's revenue (or net profit), even if linked to research using DSI, would necessarily fall under the new multilateral mechanism. This will depend on the modalities that the COP agree on for contributions to the fund.

Table 1: Total sector revenue and net profit generated by sectors which use DSI (2024 and 2030).

Sectors	Sector revenue		Net Profit (at 12.5%)	
	US$ bn, 2024	US$ bn, 2030	US$ bn, 2024	US$ bn, 2030
1) Pharmaceutical	593.24[78]	836.60[79]	74.16	107.95
2) Cosmetics	333.90[80]	474.00[81]	41.74	59.25
3) Plant and animal breeding and agricultural biotechnology	581.62[82]	904.23[83]	72.70	113.03
4) Laboratory equipment	43.36[84]	66.40[85]	5.42	8.30
5) Information, scientific and technical services related to DSI	7.65[86]	22.44[87]	0.96	2.81

[77] Food and Agriculture Organization of the United Nations "Expanding sustainable aquaculture production." < https://www.fao.org/3/cc0461en/online/sofia/2022/expanding-sustainable-aquaculture-production.html> accessed 03 April 2024
[78] Pharmaceutical Manufacturing Market Size USD 863.6 Billion by 2030 (vantagemarketresearch.com) accessed 26 June 2024
[79] Pharmaceutical Manufacturing Market Size USD 863.6 Billion by 2030 (vantagemarketresearch.com) accessed 26 June 2024
[80] Cosmetics Market Size, Share, Trends & Forecast | Report 2030 (kingsresearch.com) accessed 26 June 2024
[81] Cosmetics Market Size, Share, Trends & Forecast | Report 2030 (kingsresearch.com) accessed 26 June 2024
[82] Seed https://www.maximizemarketresearch.com/market-report/global-seeds-market/111623/#:~:text=Seeds%20Market%20size%20was%20valued%20at%20US%24%2084.83,2024%20to%202030%2C%20reaching%20nearly%20US%24%20111.76%20Bn.; aquaculture Aquaculture Global Market Report 2024 - Research and Markets; plant breeding Plant Breeding and CRISPR Plants - Global Strategic Business Report (researchandmarkets.com); agricultural biotechnology Agricultural Biotechnology Market Size & Industry Value By 2030 (databridgemarketresearch.com); livestock (monitoring) [Latest] Global Livestock Monitoring Market Size/Share (globenewswire.com); horticulture Greenhouse Horticulture Market to Hit Revenue of $66.76 Billion by 2032 | Tomatoes to Contribute More than 50% to Greenhouse Produce | Extrapolate (yahoo.com) accessed 26 June 2024
[83] Seed https://www.maximizemarketresearch.com/market-report/global-seeds-market/111623/#:~:text=Seeds%20Market%20size%20was%20valued%20at%20US%24%2084.83,2024%20to%202030%2C%20reaching%20nearly%20US%24%20111.76%20Bn.; aquaculture Aquaculture Global Market Report 2024 - Research and Markets; plant breeding Plant Breeding and CRISPR Plants - Global Strategic Business Report (researchandmarkets.com); agricultural biotechnology Agricultural Biotechnology Market Size & Industry Value By 2030 (databridgemarketresearch.com); livestock (monitoring) [Latest] Global Livestock Monitoring Market Size/Share (globenewswire.com); horticulture Greenhouse Horticulture Market to Hit Revenue of $66.76 Billion by 2032 | Tomatoes to Contribute More than 50% to Greenhouse Produce | Extrapolate (yahoo.com) accessed 26 June 2024
[84] Lab Supplies Market Size, Share & Forecast Report, 2030 (psmarketresearch.com) accessed 26 June 2024
[85] Lab Supplies Market Size, Share & Forecast Report, 2030 (psmarketresearch.com) accessed 26 June 2024
[86] Computational Biology Market Size & Share | Report, 2030 (kingsresearch.com) accessed 26 June 2024
[87] Computational Biology Market Size & Share | Report, 2030 (kingsresearch.com) accessed 26 June 2024

Sectors	Sector revenue		Net Profit (at 12.5%)	
	US$ bn, 2024	US$ bn, 2030	US$ bn, 2024	US$ bn, 2030
Total	**1559.77**	**2330.67**	**194.97**	**291.33**

Note: All sector revenue figures have been estimated for 2024 using the sector revenue available for the most recent year (as per the referenced source) and the sector CAGR in the referenced data sources. Sector revenue estimates for 2030, where not explicitly stated in the external source, were extrapolated from the estimate of 2024 sector revenue, using the CAGR. Net profit was indicatively estimated assuming a 12.5% average net profit across the sectors. However, it should be noted that the figures are indicative only as research suggests that this average net profit margin varies between and within the sectors under consideration. It has not been possible to identify net profit estimates for each sector. The revenue for laboratory equipment captures revenue beyond that which is only used for DSI. The revenue for the computational biology sector was used as a proxy for information, scientific and technical services related to DSI.

The sections below outline the value chains associated with various market sectors related to DSI. However, it is important to note that the majority of research projects across each market sector do not typically reach the final commercial stages, and not all commercial products generate a benefit for the company.

a) Pharmaceutical

Overview

Advances in science and increasingly large DSI datasets have altered biology and ultimately the life science sector, where DSI is used in a wide range of research disciplines including in the development of pharmaceuticals, small molecule, biologics, vaccines, advanced therapy medicinal products, biotechnology-based food and medicines, medical devices, biomedical technologies, nutraceuticals, cosmeceuticals, and other products that improve the lives of organisms. DSI can be used in multiple ways, including via the identification of new molecular targets or better understanding of the mode of action of a disease or treatment. Advances in science and increasingly large DSI datasets have altered the life science sector, where DSI is used in a wide range of research disciplines, including in the development of pharmaceuticals, small molecule, biologics, vaccines, and advanced therapy medicinal products.

The scope of the use of DSI in the pharmaceutical sector can be found throughout the development of a product (see **Figure 3)**. The most obvious users of DSI are 1) primary research teams who generate new and updated data on DNA/RNA sequencing information (such as those who sequence a virus first or more accurately and 2) translational and applied healthcare researchers and pharmaceutical companies, who utilise DSI in the generation of pharmaceutical products and treatments.

Visualization of the value chain and commercialisation mechanisms

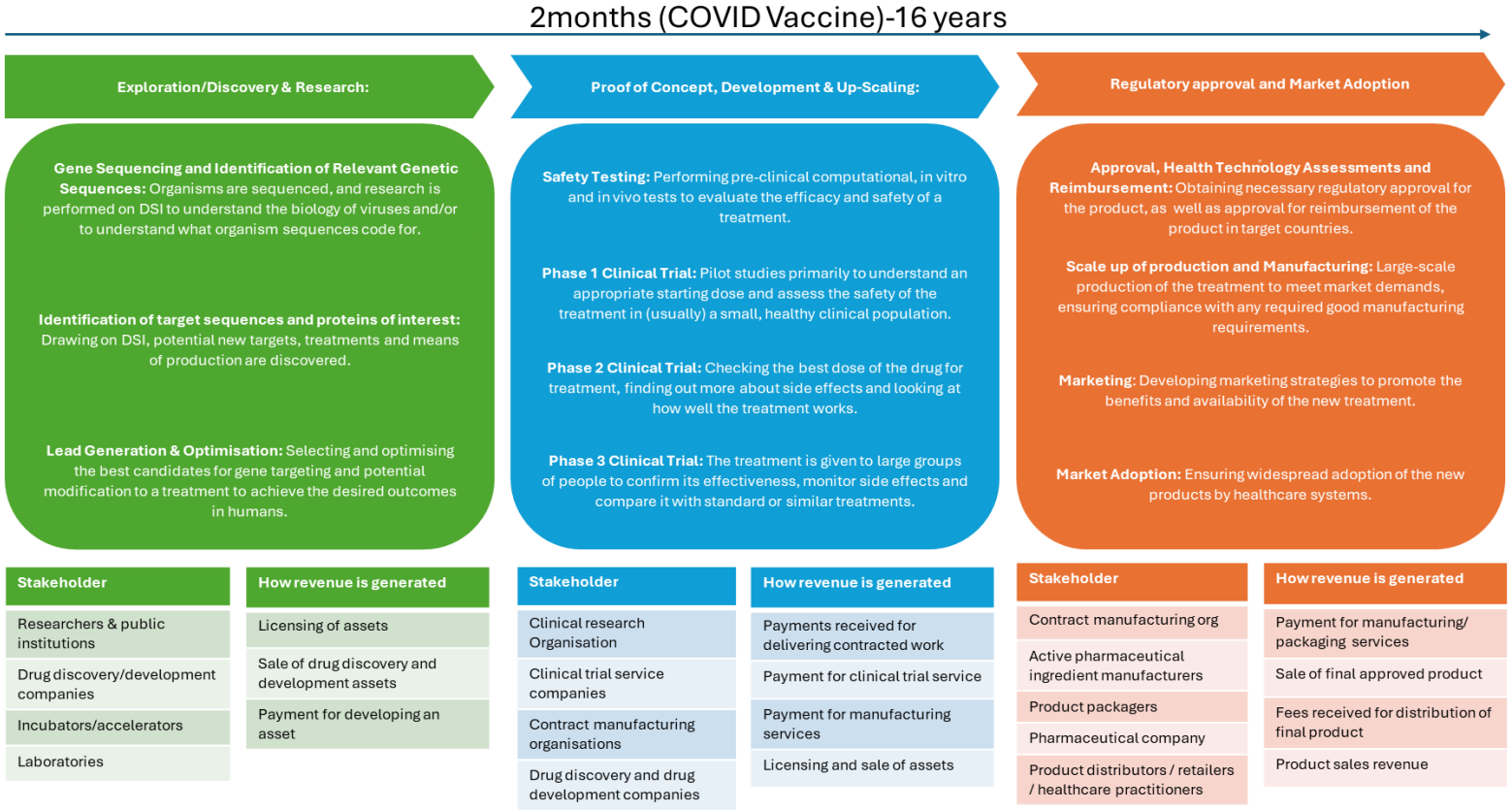

Figure 3: Illustration of a typical value chain in the pharmaceutical sector. It should be noted that not all successful projects go through all phases described.[88,89,90]

[88] Aitken, M., 2016. Understanding the pharmaceutical value chain. *Pharmaceuticals Policy and Law*, *18*(1-4), pp.55-66.
[89] Polack, F.P., Thomas, S.J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J.L., Pérez Marc, G., Moreira, E.D., Zerbini, C. and Bailey, R., 2020. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *New England journal of medicine*, *383*(27), pp.2603-2615.
[90] DSI Scientific Network. (2023). Ebola virus: Developing a life-saving antibody therapy with public DSI. DSI-regeneron-ebola-therapy-factsheet.pdf (dsiscientificnetwork.org) - accessed 23 April 2024.

The sharing of DSI via INSDC participating databases has proved invaluable in the generation of pharmaceutical products including for areas of large unmet medical need. DSI plays an important role in public health research and has a number of human health applications. The development of vaccines in response to pandemic / epidemiological situations is one of the key areas in which the pharmaceutical sector utilised DSI. As outlined in the case studies below, the accessibility and availability of DSI for translational researchers working on infectious diseases, such as Ebola and SARS-COV-2, facilitated a reduced time for development and access to effective diagnostics, therapeutics, and vaccines.

Case studies

COVID-19 Vaccines

It should be noted that this case study illustrates a value chain that was unusually rapid and that most value chains in this sector require a longer timeframe.

During the COVID-19, global pooling of sequence data of the SARS-COV-2 virus facilitated further understanding of the virus, monitoring of the outbreak and the rapid development of diagnostic tests, vaccines, and medicines. The SARS-COV-2 virus was sequenced and shared globally with researchers to help accelerate development of a vaccine. The spike protein gene of the virus was selected by some as a potential target to develop the vaccine candidates, as the spike protein is essential for the virus to attach to the host cell, thereby making it an effective antigen, or target for the immune system to recognize and attack. Pfizer and BioNTech's clinical testing also included vaccine candidates that generated the SARS-CoV-2 receptor-binding domain subunit protein. Some companies also used whole inactivated virus in their development. The genetic sequence was then altered for the vaccine based on years of experience and previous research on other known coronaviruses. Having access to shared DSI for new variants of SARS-COV-2 also allowed researchers to act quickly and respond to new viral variants and to adapt the vaccine if required.

The stabilised (or modified) spike protein was synthetically manufactured and inserted into a plasmid, a small, circular piece of DNA. Plasmids are used in mRNA vaccine production because they are easy to replicate and reliably contain the target gene sequence. This is illustrated in **Figure 4** below. Once a sequence is selected, a new plasmid can be produced within a couple of weeks, allowing new mRNA vaccines to be modified and tested rapidly.

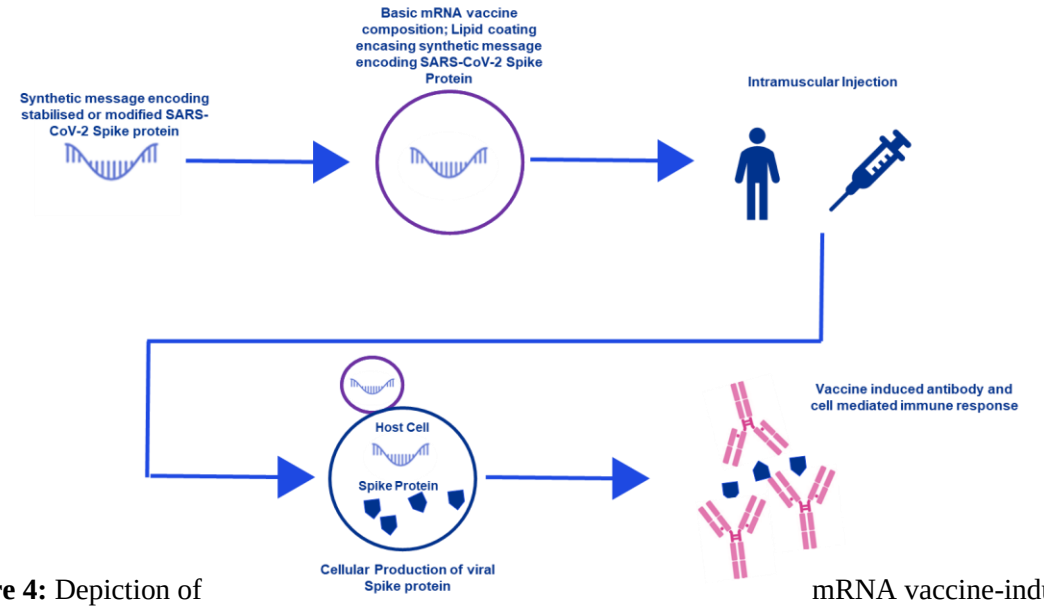

Figure 4: Depiction of mRNA vaccine-induced antibody response against SARS-CoV-2 spike proteins (adapted from the American Society of Microbiology)[91]

[91] Ashley Hagen.COVID-19 Vaccine FAQs (2021) ASM.org. Available at: https://asm.org/Articles/2020/December/COVID-19-Vaccine-FAQs. Accessed 15 May 2024

Section	Details
Case Study Name	mRNA Vaccines developed to prevent COVID-19
Organization involved	Pfizer & BioNTech and Moderna
Sector	Pharmaceutical
Geographical Area	USA
Description of Value Chain	**Pfizer and BioNTech** co-developed the first COVID-19 vaccine that was granted emergency-use authorisation or conditional approval in several regions globally. The development of the vaccine is believed to have been initiated on 10 January 2022, the same day the Chinese Centre for Disease Control and Prevention shared the SARS-CoV-2 genetic sequences.[92] Using this publicly available sequence information, the Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer (see **Figure 5**).[93] The pharmaceutical company **Moderna developed the betacoronavirus mRNA vaccine** to treat COVID-19 in March 2020 (just two months after the WHO declared a public health emergency of international concern). In December 2020, the first vaccine doses were administered.[94] The vaccine was developed based on the publicly available DSI and its patent US-10702600-B1: "betacoronavirus mRNA vaccine, which did not refer to SARS-CoV-2 sequences but rather 176 genetic sequences from several different respiratory viruses, drawn from several countries". [95] In addition, the patent discloses 96 new sequences, which were submitted to public DSI databases alongside the patent.
Stages Involved	Sequencing and sharing of the SARS-COV-2 genome, exploration of publicly available genetic resource / genome sequence and the development and market launch of a COVID-19 vaccine.
Financial Information	Since the launch of their COVID-19 vaccines, Moderna and Pfizer have accumulated **more than US$ 100bn (£83; €94) in global sales**.[96,97]
Other Relevant Information	**Linking genomic and epidemiologic information of COVID-19**: To help analyse the spread and evolution of COVID-19 virus, researchers collated and analysed data related to the viral genome, sequence variations, and locations in temporal and spatial distribution. Information from the Wikipedia web page and published research papers were categorised and mined to extract epidemiological data, which was then integrated with the public dataset. Genomic and epidemiological data were matched with public information, and the data quality was verified by manual curation. Finally, an online database centred on virus genomic information and epidemiological data can be freely accessed at: https://www.biosino.org/kgcov/, which was helpful to identify relevant knowledge and devising epidemic prevention and control policies in collaboration with disease control personnel.

[92] Polack, F.P., Thomas, S.J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J.L., Pérez Marc, G., Moreira, E.D., Zerbini, C. and Bailey, R., 2020. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *New England journal of medicine*, *383*(27), pp.2603-2615.

[93] Thorn, C. R., Sharma, D., Combs, R., Bhujbal, S., Romine, J., Zheng, X., Sunasara, K., & Badkar, A., 2022. The journey of a lifetime - development of Pfizer's COVID-19 vaccine. *Current opinion in biotechnology*, 78, 102803. https://doi.org/10.1016/j.copbio.2022.102803. Accessed 23 April 2024.

[94] A Brief History of Vaccination (who.int) accessed 12 July 2024

[95] DSI Scientific Network. (2023) Using DSI to design an mRNA Vaccine. DSI-covid-vaccines-factsheet.pdf (dsiscientificnetwork.org). Accessed 23 April 2024.

[96] Roy V, 2023. Financing covid-19 mRNA vaccines. *BMJ* 2023; 380 :p413 doi:10.1136/bmj.p413.

[97] Note that Pfizer's COMIRNATY covid-19 sales amounted to $11,220 million in 2023 Pfizer Inc. - Investor Relations - Financials - Annual Reports accessed 12 July 2024

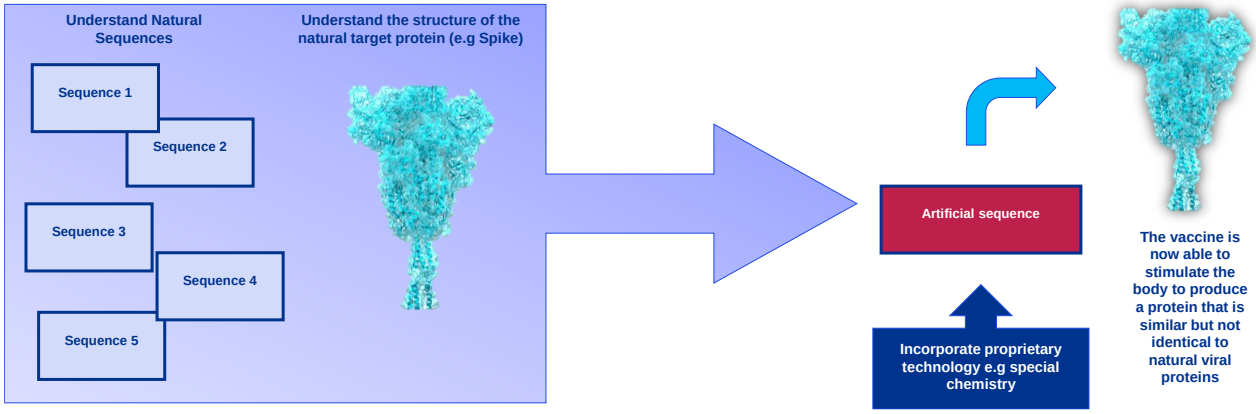

Figure 5: A simplified process for designing an mRNA vaccine. Note that the artificial sequence is 70% identical with the natural spike protein (image adapted from DSI Scientific Network – using DSI to design an mRNA vaccine).[98]

Zaire Ebola antibody therapy

The process of developing Zaire Ebola antibody therapy (Inmazeb / REGN-EB3) has taken several years, and relied on the use of Ebola DSI that was available in public databases, including samples collected during the 2013-16 outbreak in West Africa. The drug was shown to prevent deaths from Ebola during a later outbreak in the Democratic Republic of Congo.[99]

Section	Details
Case Study Name	Ebola Antibody Therapy (REGN-EB3)
Organization involved	Regeneron Pharmaceuticals
Sector	Pharmaceuticals
Geographical Area	USA
Description of Value Chain	Regeneron used a broad panel of Zaire (and other) ebolavirus sequences for screening which enabled selection of the most potent cocktail of antibodies to develop a commercial antibody therapy to Zaire Ebola. The scientific breakthrough and value of DSI in this case study arose from the ability to conduct comparative research within DSI databases. Through comparative research, key characteristics of a virus can be identified to provide information relevant to the development of a successful medicine. Using publicly available sequences in the process of generating antibody therapeutics is standard and prudent practice. If this was not the case, each company would need to individually acquire and sequence physical samples, which would: (i) incur significant cost in terms of time, resources and effort; (ii) substantially slow down the rate of drug discovery; (iii) result in fewer new therapeutics being brought to market; and (iv) in the case of deadly infectious disease, increase risk of inadvertent spread of such diseases. Obtaining individual sequences for such pathogens by individual companies (or academics) is challenging for both biosafety and logistical issues. By leveraging the in-house antibody discovery (VelociGene®, VelocImmune® and VelociMab®) and production technologies and through the support of the U.S. government's Biomedical Advanced Research and Development Authority

[98] DSI Scientific Network. (2023). Using DSI to design an mRNA Vaccine. DSI-covid-vaccines-factsheet.pdf (dsiscientificnetwork.org) - accessed 23 April 2024.
[99] DSI Scientific Network. (2023). Ebola virus: Developing a life-saving antibody therapy with public DSI. DSI-regeneron-ebola-therapy-factsheet.pdf (dsiscientificnetwork.org) - accessed 23 April 2024.

	(BARDA), Regeneron scientists were able to develop and validate the new therapeutic candidate to combat the Zaire Ebola virus.[100]
Stages Involved	Sequence identification, optimization, proof of concept, development, upscaling, and regulatory approval.
Financial Information	The U.S. government has contracted with Regeneron for a supply of the drug over six years, agreeing to pay US$ 10 million in 2021 and an average of US$ 67 million per year through 2026.[101]

b) Cosmetics

Overview

The cosmetics industry is a multi-billion-dollar global industry, where consumer demand for new and innovative products drives heavy investment in research and development. The need to create new formulations to cater to the changing needs and desires of customers, also comes with limitations relating to traditional cosmetic ingredients that may hinder effectiveness, reduce shelf-life or present risks to customers.

It should be noted that some sub-sectors of the cosmetics industry can be reliant on synthetic biology research. The use of DSI in the cosmetics sector can be found in parts of the development, safety and efficacy testing and production of new cosmetic products, as well as the production of existing cosmetic ingredients via alternative production methods (see **Figure 6**). The most obvious users of DSI appear to be 1) primary research teams who generate new and updated data on DNA/RNA sequencing information (such as those who identify and sequence a protein that may form a cosmetic ingredient, or the identification of a bacterial strain for use in a bioreactor ingredient production) and 2) translational and applied cosmetic researchers and cosmetic companies who utilise DSI in the generation of *in vitro* models for assessing cosmetic safety and efficacy testing, as well as the production of cosmetic products and ingredients from genetically modified organisms (GMOs).[102]

[100] Regeneron. Making a Drug You Hope No One Will Ever Need (2018). Available at: https://www.regeneron.com/about/perspectives/making-ebola-drug - accessed 23 April 2024

[101] Ned Pagliarulo. FDA approves Regeneron antibody drug as first Ebola virus treatment (2020) BioPharma Dive. Available at: https://www.biopharmadive.com/news/fda-ebola-drug-regeneron-first-approval/587066/ -accessed 23 April 2024.

[102] Gomes, C.; Silva, A.C.; Marques, A.C.; Sousa Lobo, J.; Amaral, M.H. Biotechnology Applied to Cosmetics and Aesthetic Medicines. *Cosmetics* **2020**, *7*, 33. https://doi.org/10.3390/cosmetics7020033 - accessed 04/ April 2024.

Visualization of the value chain and commercialisation mechanisms

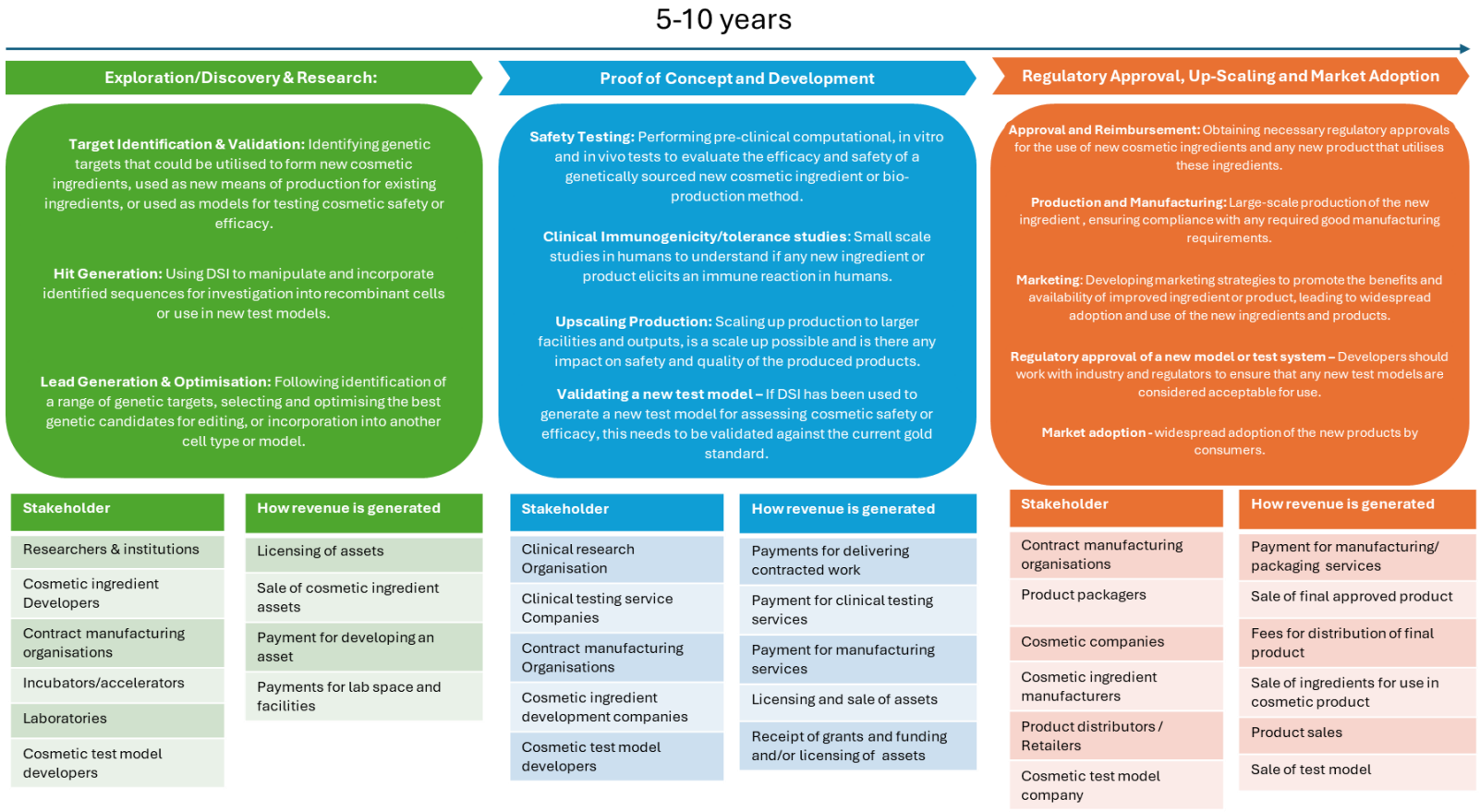

Figure 6: Illustration of a typical value chain in the cosmetics sector involving new ingredient development.[103,104,105]

[103] Gomes, C.; Silva, A.C.; Marques, A.C.; Sousa Lobo, J.; Amaral, M.H. Biotechnology Applied to Cosmetics and Aesthetic Medicines. *Cosmetics* **2020**, *7*, 33. https://doi.org/10.3390/cosmetics7020033 - accessed 04 April 2024.

[104] Nasser H., Eikmanns B.J., Tolba M.M., El-Azizi M., Abou-Aisha K.,2022. The Superiority of Bacillus megaterium over Escherichia coli as a Recombinant Bacterial Host for Hyaluronic Acid Production. *Microorganisms*. 2022;10:2347. doi: 10.3390/microorganisms10122347. accessed 04 April 2024

[105] Cosmetic Industry - Colipa accessed 30 April 2024

Case studies

Section	Details
Case Study Name	Hyaluronic acid (HA) production using modified cells in bioreactors
Organization involved	Cross Sector
Sector	Cosmetics
Geographical Area	Global
Description of Value Chain	HA is used in a range of sectors, with a prominent use in cosmetic formulations. As a result, the global market for HA is expected to undergo growth in the coming years, with a projected value of US$ 16.8 billion by 2030.[106] Bioreactors can be used for the large-scale production of recombinant proteins and secondary metabolites which can be used as cosmetic ingredients. These cell-based culture systems are now regularly used in the commercial production of HA, which is now primarily obtained through microbial fermentation.[107] The development of a modified bacterial HA production method involves the sequence identification of a HA producing gene; insertion of this gene into a bacterial cell that will express the gene; production and sale of HA; and the sale of cosmetics that utilise bioreactor produced HA.[108] Historically HA was obtained commercially from rooster combs, and later from certain strains of group C *Streptococcus* which synthesise this compound naturally.[109,110] However, rooster sourced HA presented an allergy risk, and streptococci can be difficult or prohibitively expensive to ferment, as well as being more challenging to manipulate genetically. Streptococci also have the potential to produce harmful exotoxins.[111] Considering these challenges, a range of other bacterial hosts have been successfully genetically engineered to produce HA, both improving yield and reducing risk of harm to users.[112] By understanding the biosynthetic pathway of HA in other species, and identifying the genes involved, HA can now be produced in genetically engineered bacterial strains with improved safety profiles.[113,114,115,116,117]

[106] Iaconisi GN, Lunetti P, Gallo N, Cappello AR, Fiermonte G, Dolce V, Capobianco L., 2023. Hyaluronic Acid: A Powerful Biomolecule with Wide-Ranging Applications-A Comprehensive Review. *Int J Mol Sci*. 2023 Jun 18;24(12):10296. doi: 10.3390/ijms241210296. PMID: 37373443; PMCID: PMC10299688. Accessed 04 April 2024

[107] Oliveira, J.D.; Carvalho, L.S.; Gomes, A.M.V.; Queiroz, L.R.; Magalhães, B.S.; Parachin, N.S., 2016. Genetic basis for hyper production of hyaluronic acid in natural and engineered microorganisms. *Microb. Cell Fact*. 2016, 15, 119

[108] Ucm, R., Aem, M., Lhb, Z., Kumar, V., Taherzadeh, M.J., Garlapati, V.K. and Chandel, A.K., 2022. Comprehensive review on biotechnological production of hyaluronic acid: status, innovation, market and applications. Bioengineered, 13(4), pp.9645-9661.

[109] Balasz, E. A. February 1979. Ultrapure hyaluronic acid and use thereof. U.S. patent 4,141,973. accessed 04 April 2024

[110] Hascall, V. C., and T. C. Laurent, 1997. Hyaluronan: structure and physical properties. .In V. C. Hascall and M. Yanagishita (ed.), *Science of hyaluronan today*. Seikagaku Corp., Tokyo, Japan. [Online.] www.GlycoForum.gr.jp. Accessed 04 April 2024

[111] Widner B, Behr R, Von Dollen S, Tang M, Heu T, Sloma A, Sternberg D, Deangelis PL, Weigel PH, Brown S., 2005. Hyaluronic acid production in Bacillus subtilis. *Appl Environ Microbiol*. 2005 Jul;71(7):3747-52. doi: 10.1128/AEM.71.7.3747-3752.2005. PMID: 16000785; PMCID: PMC1168996. Accessed 04 April 2024

[112] Iaconisi GN, Lunetti P, Gallo N, Cappello AR, Fiermonte G, Dolce V, Capobianco L., 2023. Hyaluronic Acid: A Powerful Biomolecule with Wide-Ranging Applications-A Comprehensive Review. *Int J Mol Sci*. 2023 Jun 18;24(12):10296. doi: 10.3390/ijms241210296. PMID: 37373443; PMCID: PMC10299688. Accessed 04/04/2024

[113] Chen S.J., Chen J.L., Huang W.C., Chen H.L., 2009. Fermentation process development for hyaluronic acid production by Streptococcus zooepidemicus ATCC 39920. *Korean J. Chem. Eng*. 2009;26:428–432. doi: 10.1007/s11814-009-0072-3. accessed 04 April 2024

[114] Prasad S.B., Ramachandran K.B., Jayaraman G., 2012. Transcription analysis of hyaluronan biosynthesis genes in Streptococcus zooepidemicus and metabolically engineered Lactococcus lactis. *Appl. Microbiol*. Biotechnol. 2012;94:1593–1607. doi: 10.1007/s00253-012-3944-0. accessed 04 April 2024.

[115] Nasser H., Eikmanns B.J., Tolba M.M., El-Azizi M., Abou-Aisha K.,2022. The Superiority of Bacillus megaterium over Escherichia coli as a Recombinant Bacterial Host for Hyaluronic Acid Production. *Microorganisms*. 2022;10:2347. doi: 10.3390/microorganisms10122347. accessed 04 April 2024

[116] Chien L.J., Lee C.K., 2007. Enhanced hyaluronic acid production in Bacillus subtilis by coexpressing bacterial hemoglobin. *Biotechnol. Prog.* 2007;23:1017–1022. doi: 10.1021/bp070036w. Accessed 04 April 2024

[117] Nasser H., Eikmanns B.J., Tolba M.M., El-Azizi M., Abou-Aisha K., 2022. The Superiority of Bacillus megaterium over Escherichia coli as a Recombinant Bacterial Host for Hyaluronic Acid Production. *Microorganisms*. 2022;10:2347. doi: 10.3390/microorganisms10122347 accessed 04 April 2024

Stages Involved	Sequence identification, optimisation, heterologous expression, proof of concept, development, upscaling, commercialization.
Financial Information	The global market for HA is expected to grow in the coming years, with a projected value of US$ 16.8 billion by 2030.[118]
Illustrative Figures	Heterologous HA Production in *Bacillus megaterium* is demonstrated in **Figure 7** below.[119]

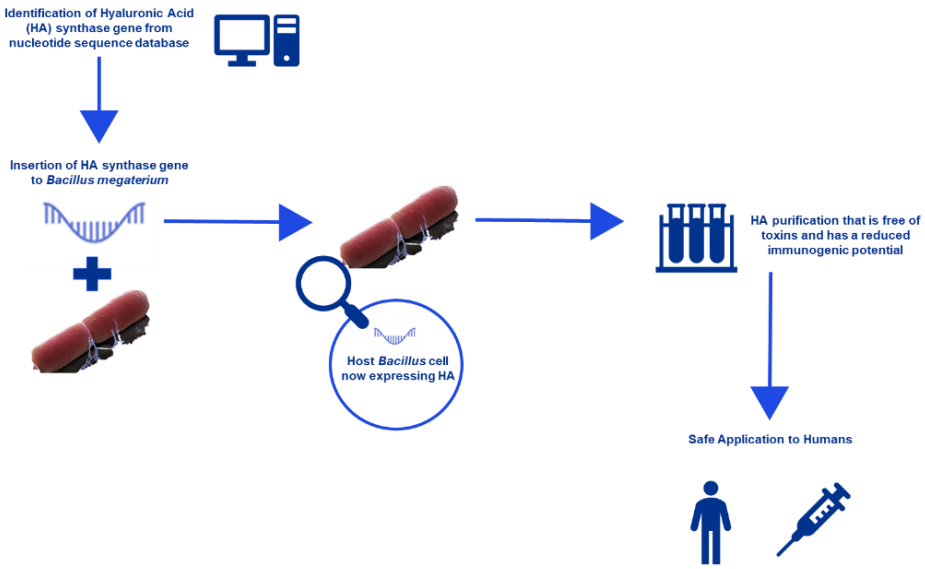

Figure 7: Heterologous HA production in Bacillus megaterium (adapted from "The Superiority of Bacillus megaterium").[120]

c) Plant and animal breeding and agricultural biotechnology

Overview

For the purpose of this report, the plant and animal breeding and agricultural biotechnology sector is broadly defined to encompass the following sub-sectors: seed, aquaculture, plant breeding, agricultural biotechnology, livestock (monitoring) and horticulture. This sector is crucial for global food security and economic development.[121] DSI plays a pivotal role in research enhancing crop production, livestock breeding, and development of disease resistance mechanisms.[122,123] The use of DSI in breeding is a tool to accelerate the steps of traditional breeding research.

DSI is utilised in the plant and animal breeding and agricultural biotechnology sector to drive improvements in yields, nutrition quality and resilience to pests, diseases, and climate change. Through the sequencing and analysis of genetic material from plants and animals, researchers can identify and select for genes responsible for beneficial traits. Some breeding techniques that use DSI do not focus on identification of genes. For example, genomic selection involves a focus on markers associated with breeding values for traits without a focus on genes. This process is used to develop

[118] Iaconisi GN, Lunetti P, Gallo N, Cappello AR, Fiermonte G, Dolce V, Capobianco L., 2023. Hyaluronic Acid: A Powerful Biomolecule with Wide-Ranging Applications-A Comprehensive Review. *Int J Mol Sci.* 2023 Jun 18;24(12):10296. doi: 10.3390/ijms241210296. PMID: 37373443; PMCID: PMC10299688. 04 April 2024

[119] Nasser H, Eikmanns BJ, Tolba MM, El-Azizi M, Abou-Aisha K., 2022. The Superiority of Bacillus megaterium over Escherichia coli as a Recombinant Bacterial Host for Hyaluronic Acid Production. *Microorganisms*. 2022 Nov 28;10(12):2347. doi: 10.3390/microorganisms10122347. PMID: 36557601; PMCID: PMC9787986, accessed 04 April /2024/

[120] Nasser H, Eikmanns BJ, Tolba MM, El-Azizi M, Abou-Aisha K., 2022. The Superiority of Bacillus megaterium over Escherichia coli as a Recombinant Bacterial Host for Hyaluronic Acid Production. *Microorganisms*. 2022 Nov 28;10(12):2347. doi: 10.3390/microorganisms10122347. PMID: 36557601; PMCID: PMC9787986, accessed 04 April 2024/

[121] Food and Agriculture Organization of the United Nations (2022). "Expanding sustainable aquaculture production." https://www.fao.org/3/cc0461en/online/sofia/2022/expanding-sustainable-aquaculture-production.html - accessed on 03 April 2024

[122] Pradeepkiran JA "Aquaculture role in global food security with nutritional value: a review." https://academic.oup.com/tas/article/3/2/903/5487790 - accessed 03 April 2024

[123] Mohamad Nor Azra, Victor Tosin Okomoda, Meisam Tabatabaei, Marina Hassan and Mhd Ikhwanuddin. "The Contributions of Shellfish Aquaculture to Global Food Security: Assessing Its Characteristics From a Future Food Perspective" https://www.frontiersin.org/articles/10.3389/fmars.2021.654897/full accessed on 03 April 2024

improved varieties of crops and breeds of animals significantly faster than traditional breeding. DSI also supports the development of biofortified foods, GMOs, and novel feed enzymes that address specific challenges in food production and contribute to the enhancement of food and feed efficiency.

The figure below (**Figure 8**) underscores the global engagement with DSI through the prism of user interaction with select crop genomics databases. **Figure 8** portrays the distribution and frequency of users accessing MaizeGDB, SoyBase, and the Legume Information System, highlighting the

worldwide reliance on these databases for agricultural research and development.[124] The MaizeGDB reflects the highest user activity, with approximately 5,244 users per month, predominantly in the United States, underscoring maize's significance as both a staple and a commercial crop. SoyBase, with around 2,500 users per month, sees substantial access in the Americas and Asia, regions where soy production and consumption are integral to food and agricultural industries. The Legume Information System, with approximately 2,300 users monthly, exhibits a globally dispersed user base, indicating the universal importance of legumes in agriculture due to their protein value and soil-enhancing properties. The details of this can be seen in **Figure 8.** Note that this figure originates from the US Department of Agriculture (USDA) and therefore only illustrates crops significant in US agricultural activity.

Figure 8: Users by country and by month of crop genomics databases for three illustrative cultures in the USA. This figure should not be interpreted as representative of the global use of DSI in crop genomics (figure compliments of USDA).[125]

The importance of open access to DSI is compelling, particularly in Africa, where the diversity of crops and cropping environments, a burgeoning scientific community, and a rapidly growing population, creates a unique and pressing demand for research and innovation in the plant and animal breeding and agricultural biotechnology sector (See section 8(b) for further context). Access to genomic data can catalyse advancements in agricultural productivity and sustainability, contributing to food security and economic growth within the continent.[126] The geographical distribution of database users also suggests widespread agricultural research. As such, by promoting access to and use of DSI, there is potential to support the bridging of gaps in terms of application of DSI for food and feed purposes, particularly in regions that are underrepresented in data usage (see **Figure 8**).

The value chain for DSI in the plant and animal breeding and agricultural biotechnology sector spans the journey from genetic characterisation, research and targeting, through to commercial distribution of improved agricultural and aquacultural products (see **Figure 9**). Initial stages involve the exploration and identification of genetic sequences that hold the potential to enhance crop traits, such as yield, shelf life, nutritional content, or resilience to environmental stressors. Following the initial discovery, these genetic markers undergo rigorous validation and optimisation to ensure they meet the desired objectives. The development phase then transitions these findings from the lab bench to field trials, where concepts are tested and production methods are refined. The culmination of this value chain is the marketing and selling stage, where the enhanced products are introduced into the market with strategic positioning to ensure adoption and impact. This value chain is not only critical for meeting global food demands but also represents the intersection of scientific innovation and practical

[124] USDA/ARS, United States Department of Agriculture/Agriculture Research Service (USDA/ARS) https://www.ars.usda.gov/ accessed 03 April 2024
[125] Figure produced by Carson Andorf and Lisa Hartman of the USDA/ARS, United States Department of Agriculture/Agriculture Research Service (USDA/ARS)https://www.ars.usda.gov/ accessed 03 April 2024
[126] Aryee, S.N.D., Owusu-Adjei, D., Osei-Amponsah, R., Skinner, B., Sowatey, E. and Sargent, C.A., 2021. Sustainable genomic research for food security in sub-Saharan Africa. *Agriculture & Food Security*, *10*, pp.1-12.

agricultural solutions.[127] In the plant and animal breeding and agricultural biotechnology sector, these stages can encompass stakeholders from academic and research institutions, biotech start-ups and small and medium-sized enterprises, as well as large agribusiness companies. For example, universities and public and private research institutes could be involved in the early stages of discovery and research, start-ups and SMEs typically engage in the development and up-scaling phases, and large companies play a major role in the marketing and selling stage, leveraging economies of scale for production and distribution.

The application of DSI within the plant and animal breeding and agricultural biotechnology sector involves continuous research and development, trials and testing as part of the development of a product and upscaling of production, followed by marketing and market adoption efforts. This process is iterative and cyclical, ensuring that feedback from later stages informs ongoing research and discovery.

[127] Digital sequence information on genetic resources (cbd.int) accessed 27 March 2024

Visualization of the value chain and commercialisation mechanisms

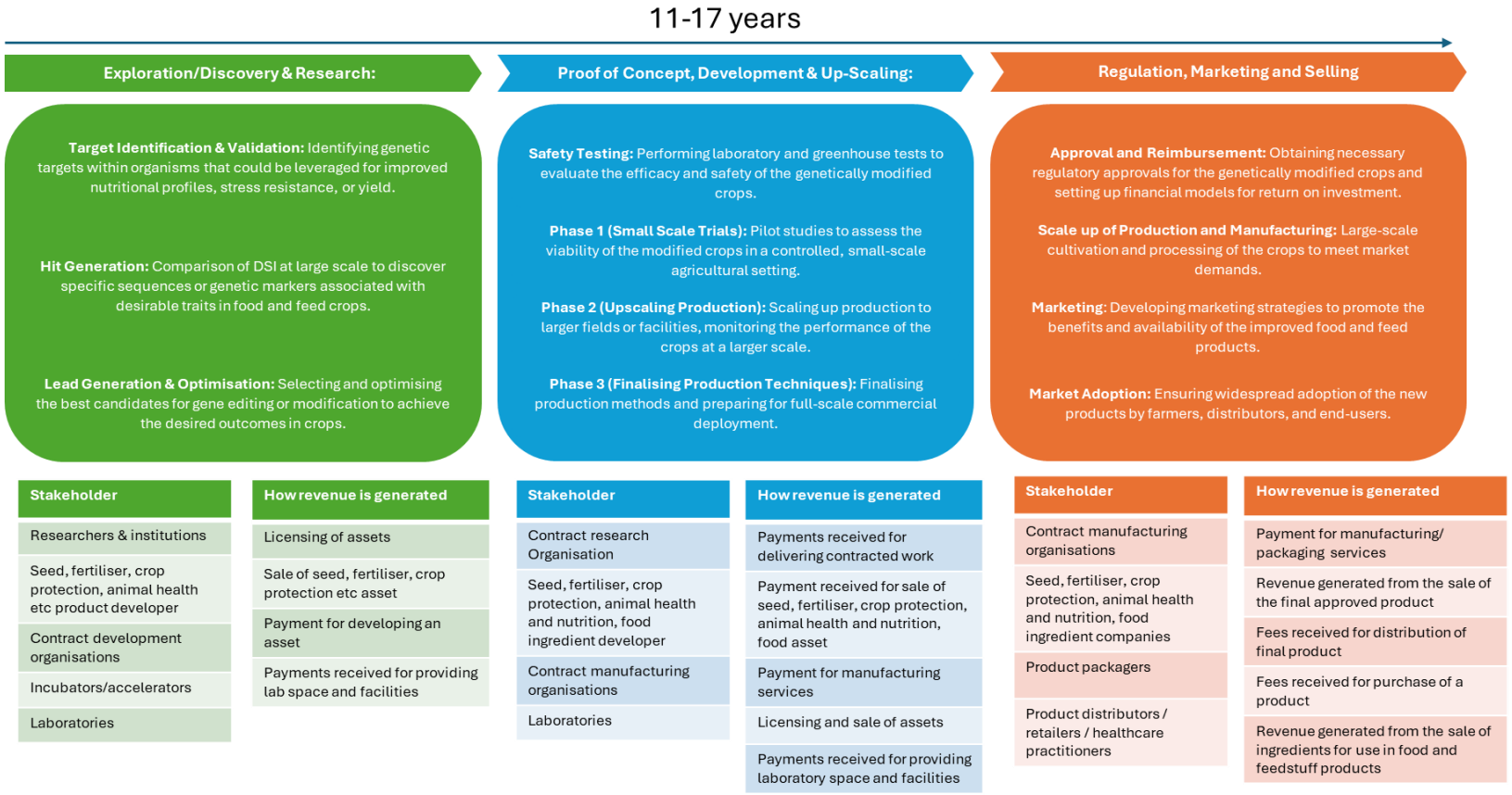

Figure 9: Illustration of a typical value chain involving genetically modified or genome-edited crops – a sub-sector within the plant and animal breeding and agricultural biotechnology sector.[128,129,130]

[128] Digital sequence information on genetic resources (cbd.int) accessed 27 March 2024
[129] Digital Sequence Information: an Evidence Review: Final Report — University of Strathclyde accessed 09 April 2024
[130] Aryee, S.N.D., Owusu-Adjei, D., Osei-Amponsah, R., Skinner, B., Sowatey, E. and Sargent, C.A., 2021. Sustainable genomic research for food security in sub-Saharan Africa. *Agriculture & Food Security*, *10*, pp.1-12.

Case studies

Example 1

Sub1 rice varieties, developed using DSI, have a gene that confers tolerance to flooding. This innovation is crucial for rice-growing regions prone to seasonal floods, enhancing crop resilience and ensuring food security for millions.[131]

Section	Details
Case Study Name	Identification and utilization of gene Sub 1 rice that confers flood tolerance[132,133,134,135,136,137,138]
Organization involved	International Rice Research Institute in collaboration with national agricultural research systems and the Bill & Melinda Gates Foundation
Sector	Food and feed (agriculture)
Geographical Area	Primarily South and Southeast Asia, including Bangladesh, India, Nepal, and the Philippines.
Description of Value Chain	The value chain begins with the identification, characterisation and sequencing of the Sub1 gene, followed by breeding to introgress this gene into popular local rice varieties. The process involves laboratory research, field testing, regulatory approval, and eventually dissemination to farmers through seed distribution networks. More specifically this work encompasses DNA and RNA, with a direct focus on the gene itself (DNA) and its expression (RNA), leading to the production of specific proteins that provide the desired trait.
Stages Involved	1. Genomic identification 2. Breeding and development of Sub1 varieties 3. Field testing and validation 4. Regulatory approval 5. Seed production and distribution 6. Farmer adoption and cultivation
Financial Information	Funded by grants from the Bill & Melinda Gates Foundation; specific financial details vary by project phase and location. The development and distribution of Sub1 rice have been supported by multi-million-dollar investments aimed at improving food security and resilience to climate change.
Other Relevant Information	Sub1 rice varieties have shown to improve yield stability in flood-prone areas by as much as 1-3 tonnes per hectare compared to non-Sub1 varieties. This improvement significantly impacts the livelihoods of smallholder farmers and contributes to regional food security.

[131] Agronomy | Free Full-Text | Novel Sequencing and Genomic Technologies Revolutionized Rice Genomic Study and Breeding (mdpi.com) accessed 27 March 2024
[132] Rice Breeding Innovations (irri.org) accessed 09 April 2024
[133] Digital Sequence Information: an Evidence Review: Final Report — University of Strathclyde accessed 09 April 2024
[134] Agronomy | Free Full-Text | Novel Sequencing and Genomic Technologies Revolutionized Rice Genomic Study and Breeding (mdpi.com) accessed 09 April 2024
[135] Sub1 Rice: Engineering Rice for Climate Change (cshlp.org) accessed 09 April 2024
[136] 'Green revolution' dwarf gene sd1 of rice has gigantic impact | Briefings in Functional Genomics | Oxford Academic (oup.com) accessed 09 April 2024
[137] Physiological and antioxidant responses associated with Sub1 gene introgressed rice (Oryza sativa L.) lines under complete submergence | Physiology and Molecular Biology of Plants (springer.com) accessed 09 April 2024
[138] Thinking beyond the SUB1 gene: Making rice varieties that can survive longer floods and produce higher yields - Rice Today (irri.org) accessed 09 April 2024

Example 2

Golden Rice is genetically modified to produce beta-carotene in its edible parts, addressing vitamin A deficiency. This project exemplifies the application of DSI for nutritional enhancement of crops, aiming to mitigate public health issues in regions dependent on rice as a staple food.

Section	Details
Case Study Name	Golden Rice[139,140,141]
Organization involved	International Rice Research Institute, in collaboration with Syngenta and Helen Keller International, among others.
Sector	Food and feed (agriculture)
Geographical Area	Targeted towards countries with high rates of vitamin A deficiency, including in Asia, Africa, and Latin America[142]
Description of Value Chain	The value chain for Golden Rice involves genetic engineering to incorporate genes responsible for beta-carotene production, followed by breeding with local rice varieties. This includes lab research, field trials for efficacy and safety, regulatory review and approval, and ultimately the distribution of seeds to farmers. More specifically, this project goes beyond just the DNA and RNA to include the metabolic pathways and the resulting metabolites (beta-carotene) in the edible parts of the rice. Public health initiatives to monitor the impact on vitamin A deficiency rates in the population are also part of the value chain.
Stages Involved	1. Genomic identification 2. Genetic engineering 3. Cross-breeding with local varieties 4. Field trials and safety testing 5. Regulatory approval and compliance 6. Seed production and distribution 7. Adoption by farmers and purchased by the general population
Financial Information	Funding includes contributions from public, private, and philanthropic sources, with significant investment for research, development, and field trials. The rice sector is estimated at US$ 306.85 billion in 2023, it is expected to reach US$ 317.28 billion in 2024, with a CAGR of 3.4% to US$ 387.76 billion by 2030.[143] The 10-year delay of approval associated with the introduction of Golden Rice in India alone was estimated to cost the country's gross domestic product approximately US$199 million per year over a decade.[144]
Other Relevant Information	Golden Rice has been a subject of debate regarding GMOs' role in food and agriculture. However, it remains a pioneering example of how genetic engineering can address critical nutritional deficiencies.

Example 3

Section	Details
Case Study Name	Enhancing Cassava for Disease Resistance and Nutritional Quality
Organization involved	International Institute of Tropical Agriculture (IITA) National agricultural research organizations in Africa Bill & Melinda Gates Foundation

[139] Golden rice | Description, GMO, Genetic Engineering, Controversy, History, & Facts | Britannica accessed 09 April 2024
[140] Golden Rice: instructions for use | Agriculture & Food Security | Full Text (biomedcentral.com) accessed 09 April 2024
[141] More rice research collaboration between IRRI and Syngenta - Rice Today accessed 09 April 2024
[142] Golden Rice | International Rice Research Institute (irri.org) accessed 09 April 2024
[143] Rice Market Size, Share, Growth, Trends Analysis, & Forecast 2030 (beyondmarketinsights.com) accessed 09 April 2024
[144] Golden Rice, Part 4: Cost-effective GMO crop can save lives and dramatically boost developing economies - Genetic Literacy Project accessed 09 April 2024

Sector	Food and feed (Agriculture)
Geographical Area	Sub-Saharan Africa, with emphasis on Nigeria, Tanzania, Uganda, and Ghana
Description of Value Chain	This project's value chain encompasses the genomic sequencing of cassava to identify genes conferring resistance to diseases like cassava mosaic disease and cassava brown streak disease, as well as genes enhancing nutritional content. The process involves comparative analysis of genetic resource samples, gene identification, breeding, field trials, regulatory approval, seed production, and distribution.
Stages Involved	1. Use of DSI to comparatively analyse genetic resource samples to identify the relevant genes 2. Genomic sequencing and functional genomics research 3. Breeding for disease resistance and nutritional enhancement 4. Field trials for efficacy and environmental safety 5. Regulatory approval and compliance 6. Seed distribution and farmer adoption
Financial Information	The development and dissemination of these cassava varieties are supported by significant funding from philanthropic organizations and government research grants. As of 2022, the cassava market size was valued at US$ 175.9 billion. Projections indicate that the industry will continue to expand, reaching US$ 254.28 billion by 2032 with a CAGR of 4.18% during that period.[145]

d) Laboratory equipment associated with the use of DSI

Overview

Genomic sequencing technology has advanced rapidly over recent years, particularly since the advent of synthetic biology. As such, the equipment involved in sequencing, modifying, and DNA synthesis has become faster, cheaper and more precise. Laboratory equipment development has been greatly influenced by advances in computer technology and the "data revolution", with sequencing technology as an example being exponentially cheaper and faster. [146]

The scope of companies considered in this sector includes organizations which develop and manufacture lab reagents or make machinery for the purpose of sequencing, modifying, or generating genetic sequences. The organizations are considered as benefiting from the use of DSI but are not necessarily directly involved in the use of DSI itself to generate their products / services, although they may be involved in offering commercial services that support the use of DSI (see **Figure 10**). Examples of laboratory equipment developers include Illumina, ThermoFisher, Agilent Technologies PacBio, Oxford Nanopore and Qiagen. It is important to note that companies referred to in this sector do also develop tools and technologies for sequencing human genetic resources. As such, financial information presented in this section is not necessarily representative of exclusively non-human uses of their equipment.

Sequencing technologies

In the past, unravelling the genetic information contained in living organisms was a slow and expensive process. According to the US National Human Genome Research Institute, once significant human genome sequencing began for the Human Genome Project, a 'draft' human genome sequence was produced over a 15-month period (from April 1999 to June 2000) at an estimated cost of

[145] Cassava Market Trends, Size, Share, and Industry Analysis, 2032 (marketresearchfuture.com) accessed 09 April 2024
[146] Cremin, C.J., Dash, S. and Huang, X. (2022) 'Big data: Historic advances and emerging trends in biomedical research', Current Research in Biotechnology, 4, pp. 138–151. Available at: https://doi.org/10.1016/j.crbiot.2022.02.004 accessed 24 April 2024.

approximately US$ 300 million.[147] By late 2015, a human genome could be sequenced for less than US$ 1,500.[148] Today, there are companies working to reduce this cost to less than US$ 100.[149]

Automation of library preparation for next generation sequencing (NGS)

As NGS technology has evolved, the throughput of machines has steadily increased while sequencing costs per base have decreased. Regardless of the underlying principles of the respective sequencing method, all modern sequencing technologies require dedicated sample preparation to yield the sequencing library loaded onto the instrument. In bioinformatics, the handling of big data generated by high-throughput NGS requires considerable IT resources – comprehensive analysis solutions are still under development. During library preparation, three major challenges can be observed: complexity of protocols, contamination, and cost.

The recent automation of protocols now reduces error rates and increases reproducibility. Many well-established protocols for different sequencing platforms require similar steps and result in the same automation demands. Five potential automation processes have been identified:[150]

1.Mechanical fragmentation

2.Enzymatic reactions

3.Size selection and clean-up

4.Amplification

5.Quantification

Examples of Automation solutions developed for NGS library preparation:

- Zephyr G3 (Perkin Elmer, 2019)
- Biomek platform: NXp (Beckman Coulter)
- AB Library Builder system (Thermo Fisher Scientific)
- Bravo (Agilent)

Bioreactors and bioprocessing equipment

Bioreactors are vessels or tanks in which whole cells or cell-free enzymes transform raw materials into biochemically produced by-products for sale and further use.[151] They are used widely for agricultural, environmental, industrial and medical applications, with ever-increasing use in bioengineered recombinant biological species including bacteria, yeast and mammalian cells. Recombinant protein production represents a multibillion-dollar market and the equipment developed as part of this process is imperative to its function.[152] The development of this technology when used with recombinant cells is reliant on the use of DSI and is now utilised in the production of bio-produced products. For example, mammalian cell lines have been used for a large number of approved recombinant therapeutics, though the 'target DNA' can have other origins. A study from 2018 showed that in the preceding 3-4 years, 62 of the 71 new biopharmaceutical active ingredients in the market were recombinant proteins, and of those 52 (84%) were from mammalian cells, one from a transgenic system, five from *E.coli* and four from *S.cerevisiae*.[153] The generation and processing of recombinant organisms, requires a range of equipment which can only be developed using a combination of genetic resources and DSI. It should be noted that the equipment required are not

[147] Wetterstrand, K. (2021) The Cost of Sequencing a Human Genome, Genome.gov. National Human Genome Research Institute. Available at: https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost accessed 23 April 2024.
[148] SITNFlash (2017) Strength in Numbers: genetic sequencing of large populations is shaping the future of medicine, Science in the News. Available at: https://sitn.hms.harvard.edu/flash/2017/strength-numbers-genetic-sequencing-large-populations-shaping-future-medicine/ accessed: 23 April 2024
[149] Genetic testing for rare diseases company | 3billion (2022) 3billion.io. Available at: https://3billion.io/blog/whole-genome-sequencing-cost-2023#:~:text=New%20companies%20are%20also%20trying accessed: 23 April 2024
[150] J.F. Hess et al 'Library preparation for next generation sequencing: A review of automation strategies' (2020) Biotechnology Advances, 41, p. 107537. Available at: https://doi.org/10.1016/j.biotechadv.2020.107537 accessed 04 April 2024
[151] Schaechter, M. (2009) Encyclopedia of Microbiology | ScienceDirect, www.sciencedirect.com. Available at: https://www.sciencedirect.com/referencework/9780123739445/encyclopedia-of-microbiology.
[152] Vandermies, M., & Fickers, P. (2019). Bioreactor-Scale Strategies for the Production of Recombinant Protein in the Yeast Yarrowia lipolytica. Microorganisms, 7(2), 40. https://doi.org/10.3390/microorganisms7020040 accessed 04 April 2024
[153] Walsh G. (2018). Biopharmaceutical benchmarks 2018. 36, 1136–1145. 10.1038/nbt.4305

necessarily designed only for the purposes of recombinant DNA based products. Similarly, sequencing systems are not used only for producing DSI for manufacturing processes, but also for detection and identification purposes.

Visualization of the value chain and commercialisation mechanisms

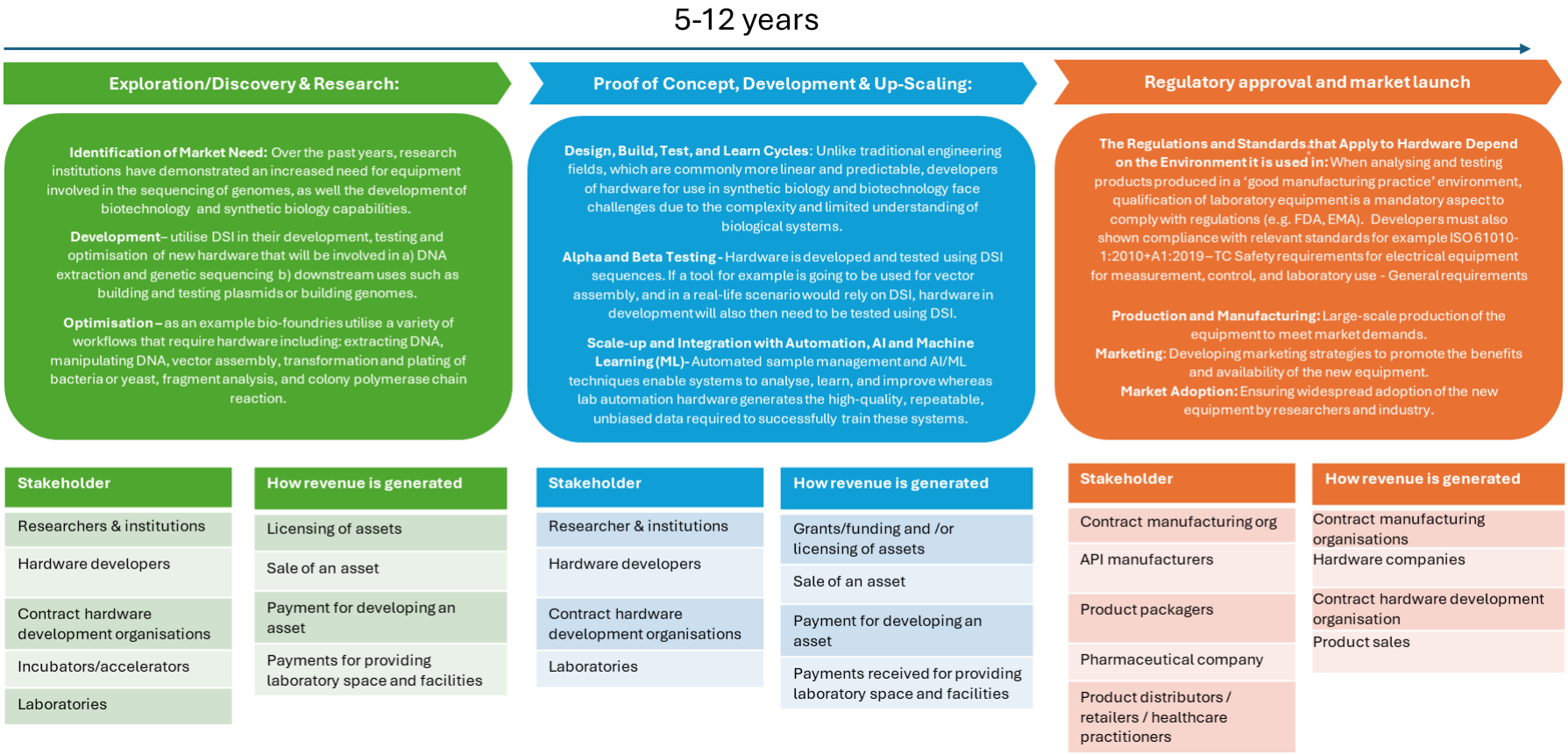

Figure 10. Illustration of a typical value chain for laboratory equipment associated with the use of DSI.[154,155]

[154] Vandermies, M., & Fickers, P. (2019). Bioreactor-Scale Strategies for the Production of Recombinant Protein in the Yeast Yarrowia lipolytica. Microorganisms, 7(2), 40. https://doi.org/10.3390/microorganisms7020040 accessed 04 April 2024

[155] J.F. Hess et al 'Library preparation for next generation sequencing: A review of automation strategies' (2020) Biotechnology Advances, 41, p. 107537. Available at: https://doi.org/10.1016/j.biotechadv.2020.107537 accessed 04 April 2024

Case study

Section	Details
Case Study Name	Sequencing Technologies – NovaSeq X Series
Organization involved	Illumina
Sector	Laboratory Equipment (hardware)
Geographical Area	Global
Description of Value Chain	Illumina is the leading provider of sequencing services and sells both instruments and reagents for genome sequencing and controls over 80% of the sequencing market.[156] Llumina's new generations of sequencers use a method called "sequencing by synthesis" to decipher DNA. This process first requires that DNA strands, which are usually in double-helix form, be split into single strands. The DNA is then broken into short fragments that are spread onto a flow cell. When a flow cell is loaded into the sequencer, the machine attaches color-coded fluorescent tags to each base: A, C, G, and T. Each of the DNA fragments gets copied one base at a time, and a matching strand of DNA is gradually made, or synthesised. The value chain involves an exploration and discovery stage for a new piece of equipment, moving to proof of concept and development. Following this, there would be a required scale up, marketing and finally sale of the product to users. The value chain would include all of the various companies involved in these steps.
Stages Involved	1) Identification of market need 2) Development design, build, test, and learn cycles 3) Scale-up and integration with automation, AI and machine learning 4) Compliance with regulation and standards 5) Marketing 6) Commercialisation
Financial Information	llumina annual company revenue for 2023 was US$ 4.504bn[157]

e) Information, scientific and technical services related to DSI

Overview

The generation of DSI has given rise to the development of bioinformatic computational programmes for the characterisation, manipulation, and testing (amongst other functions) of DSI. Bioinformatics refers to the application of computational tools and analyses that allow the capture and interpretation of biological data.[158] It is an interdisciplinary field which harnesses computer science, mathematics, physics, and biology, and is considered essential for the management of data in modern biology and medicine.

The Human Genome Project in 2003 led to the sequencing of the whole human genome after 13 years of research.[159] With the advent of whole genome sequencing and the exponential increase in genetic sequence information available (including its subsequent digitalisation) the bioinformatic tool industry has developed. This means that now, anyone with access to a bioinformatic programme (paid for or free) can discover the genetic composition of a range of biological species and molecules.

[156] Franklin Carpenter. Top 10 Gene Sequencing Companies by Revenue (2022). BioSpace. Available at: https://www.biospace.com/article/top-10-gene-sequencing-companies-by-revenue/. Accessed: 23 April 2024
[157] Illumina Revenue 2010-2022 | ILMN (2023) www.macrotrends.net. Available at: https://www.macrotrends.net/stocks/charts/ILMN/illumina/revenue#:~:text=Illumina%20revenue%20for%20the%20twelve accessed 30 April 2024
[158] Bayat A. Science, medicine, and the future: Bioinformatics. BMJ. 2002 Apr 27;324(7344):1018-22. doi: 10.1136/bmj.324.7344.1018. PMID: 11976246; PMCID: PMC1122955, accessed 11 April 2024.
[159] The Human Genome Project. Available at: www.genome.gov/human-genome-project (accessed 16 July 2024).

Over the last two decades, digital transformation across multiple sectors has advanced the way data is utilised and stored globally. The rapid expansion of data generation, use, and storage has gone hand in hand with the dawn and expansion of cloud computing, which allows for the storage of large volumes of data and the use of computer capacity housed in remote data centres rather than on individual computers or local networks or servers.[160] These data centres, when considered together, form worldwide networks with varying degrees of integration and communication between them. The use of cloud computing is commonly described as a set of three services:[161]

- Infrastructure as a service (hardware)
- Platforms as a service (framework applications), e.g. databases
- Software as a service (user end products), e.g. digital genetic manipulation software

A typical value chain within this sector is illustrated below in **Figure 11**.

[160] Oldham, P. and Kindness, J. (2022) 'Sharing Digital Sequence Information', Zenodo (CERN European Organization for Nuclear Research) [Preprint]. Available at: https://doi.org/10.5281/zenodo.6557191 accessed 04 April 2024
[161] Oldham, P. and Kindness, J. (2022) 'Sharing Digital Sequence Information', Zenodo (CERN European Organization for Nuclear Research) [Preprint]. Available at: https://doi.org/10.5281/zenodo.6557191 accessed 04 April 2024

Visualization of the value chain and commercialisation mechanisms

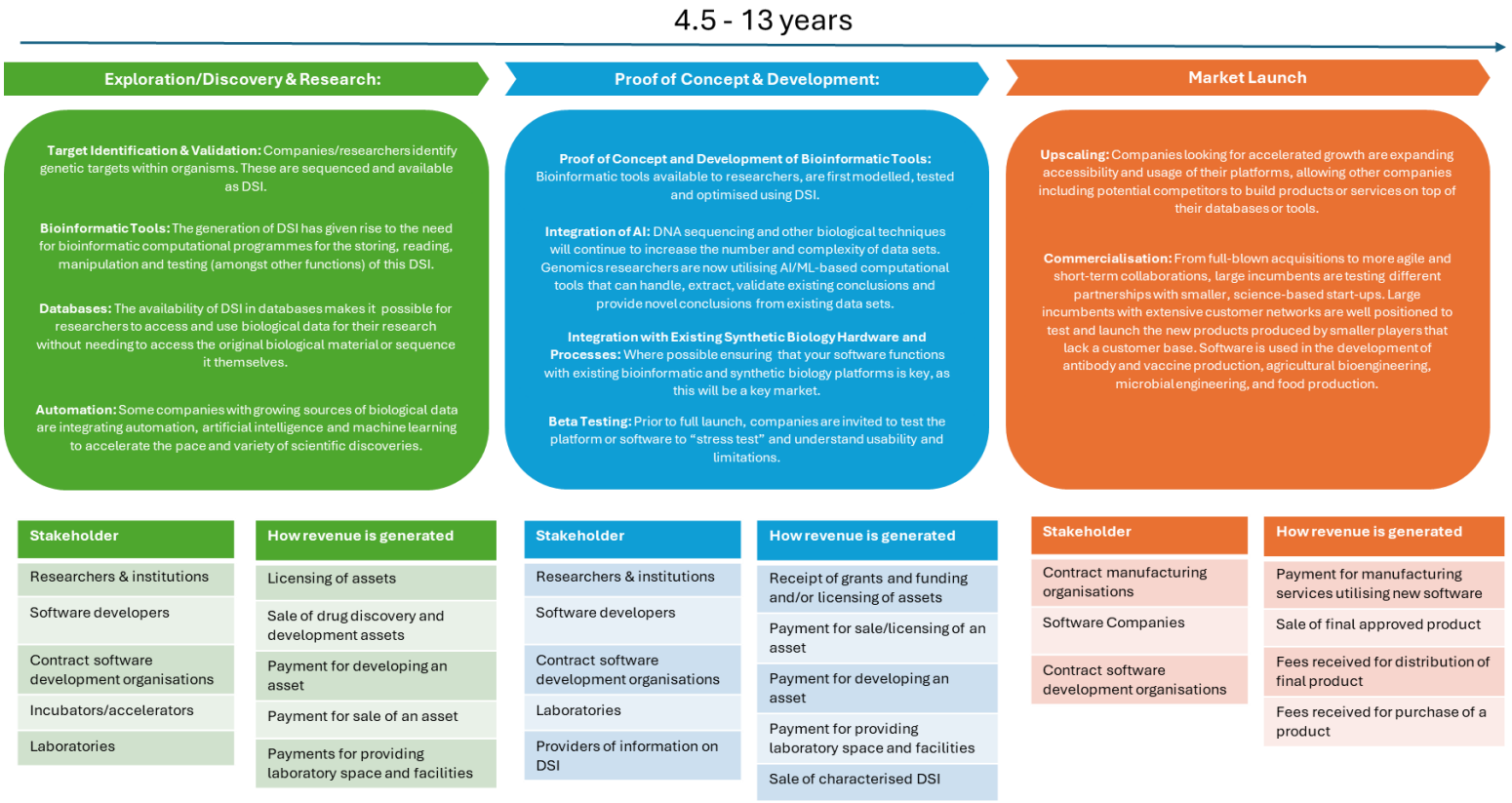

Figure 11: Illustration of a typical value chain for information, scientific and technical services related to DSI.[162,163,164]

[162] Bayat A. Science, medicine, and the future: Bioinformatics. BMJ. 2002 Apr 27;324(7344):1018-22. doi: 10.1136/bmj.324.7344.1018. PMID: 11976246; PMCID: PMC1122955, accessed 11 April 2024.
[163] Fleischmann RD, Adams MD, White O, Clayton RA, Kirkness EF, Kerlavage AR, et al. Whole-genome random sequencing and assembly of Haemophilus influenzae Rd. Science. 1995;269:496–512 4
[164] Oldham, P. and Kindness, J. (2022) 'Sharing Digital Sequence Information', Zenodo (CERN European Organization for Nuclear Research) [Preprint]. Available at: https://doi.org/10.5281/zenodo.6557191 accessed 04 April 2024

The scope of the use of DSI in the IT sector includes the development of software that is used in: generating; reading; modifying; and testing (amongst other functions) DSI. The stakeholders who use DSI in the IT sector are 1) those involved in the development and maintenance of paid for and free bioinformatic software and software related to DSI use in bioengineering and synthetic biology, 2) open source and free access genetic sequence/DSI databases and repositories such as INSDC. This category also includes producers of information on DSI, which may be considered as third parties or intermediaries between the point of access to genetic resources and users of DSI. These intermediaries may, for example, sell characterised DSI to a variety of market sectors. These organizations are considered as benefiting from the use of DSI, in contrast with other sectors that directly use DSI in their products and processes. An additional point to consider is also the inclusion of software that supports or improves the function of a piece of hardware (for example software involved in the automation of a sequencing or bioengineering process).

Case studies

Data banks

Data banks allow access to DSI from an original sequence of a genetic resource as well as its associated information, which varies depending on the DSI, the database and in some cases the user. Open access databases are usually accessed by public and private sector entities. In the case of the INSDC, the dataset was downloaded partially or completely 34 million times in 2020, with 10–15 million unique users, and 99.5% of the 750 downstream sequence databases that pull and push DSI through the scientific ecosystem directly.[165] DSI can also be found in private databases which can be categorised into two general subgroups: 1) 'in-house databases', which contain DSI for use internally by a company and 2) 'commercial databases', which are available to paying members.[166] Other examples of open access genetic resource databases include BioBricks, iGEM and Open Source Drug Discovery.[167,168] These databases allow access to all potential users at a very low cost.

Further along the value chain commercial small- and medium-size enterprises offer software and storage solutions for both academic and commercial partners to access, manipulate (via proprietary software) and store computationally manipulated material either for a license fee or for free.[169]

Bioinformatic Tools

Outside of databases there exists a large range of software and storage solutions for both academic and commercial partners to access, manipulate and store DSI. This software is particularly prominent in synthetic biology, where it facilitates and accelerates all the steps of the 'design, build, test' cycle.[170] These approaches are iterative to product development where learning takes place throughout the creation of a product or system. Tools to support each of the stages of this cycle in synthetic biology are illustrated below.

[165] Rohden, F., Huang, S., Dröge, G. & Scholz, A. H. Combined study on digital sequence information in public and private databases and traceability. Report No. CBD/DSI/AHTEG/2020/1/4 https://www.cbd.int/doc/c/1f8f/d793/57cb114ca40cb6468f479584/dsi-ahteg-2020-01-04-en.pdf (2020). Accesssed 12 April 2024/

[166] Rohden, F., Huang, S., Dröge, G. & Scholz, A. H. Combined study on digital sequence information in public and private databases and traceability. Report No. CBD/DSI/AHTEG/2020/1/4 https://www.cbd.int/doc/c/1f8f/d793/57cb114ca40cb6468f479584/dsi-ahteg-2020-01-04-en.pdf (2020). Accesssed 12 April 2024

[167] GMO data banks, such as Biosafety Clearing House, are also of relevance BCH | Biosafety Clearing-House (cbd.int) accessed 12 July 2024

[168] iGEM accessed 12 July 2024

[169] Sarwade, S. (2023) 25 Bioinformatics Tools for Easy and Effective Data Analysis, Geekflare. Available at: https://geekflare.com/bioinformatics-tools/ (Accessed: 24 April 2024).

[170] Carbonell, P., Currin, A., Jervis, A. J., Rattray, N. J., Swainston, N., Yan, C., Takano, E., & Breitling, R. (2016). Bioinformatics for the synthetic biology of natural products: integrating across the Design-Build-Test cycle. Natural product reports, 33(8), 925–932. https://doi.org/10.1039/c6np00018e. Accessed 12 April 2024.

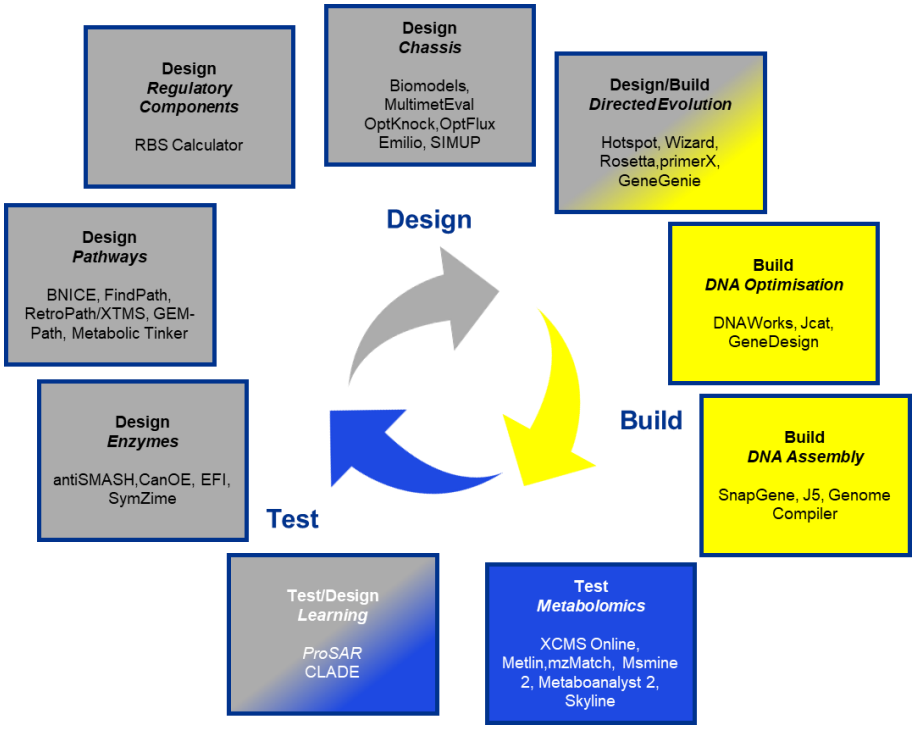

Figure 12: Examples of bioinformatics tools and associated tasks for the Design/Build/Test cycle in synthetic biology (image adapted from bioinformatics for the synthetic biology of natural products) [171]

The use of computational design tools is necessary for the effective identification of combinations of enzymes, pathways, cellular regulatory components and chassis/host organisms that can be used in synthetic biological cells and systems.[172] Software and tools for the mining of databases for candidate genetic sequences have become important for genetic development, with examples including antiSMASH software, which is used to identify and annotate sequenced microbial genomes for relevant biosynthetic gene clusters involved in the production of natural products.[173]

Once an engineered pathway is to be introduced into a host organism, a range of software is available to ensure that, at each step, synthetic genes are expressed successfully in the given host species. At this stage, several steps are necessary, namely organism-specific codon-optimisation, alleviation of secondary mRNA structure, as well as removal of intrinsic regulation (transcriptional and translational), repeating sequences, and other regulatory elements e.g. prokaryotic homopolymeric tracts. A range of free and commercial tools are available for those steps, and these can be combined in automated pipelines.[174] Some examples of free to access software can be found in

Figure 12 (above). Many commercial gene synthesis vendors also offer their own optimisation algorithms. These companies include Gen9, Thermofisher's GeneArt, and GenScript, and allow for further genetic and cellular system optimisation in the synthesis methodology.[175]

Other commercial users of bioinformatic tools and DSI include genetic service companies who offer services to the agricultural sector. For example, companies offer services to assess seed quality, seed and plant health, genetic and trait purity (e.g. understanding pesticide resistance/stress), molecular

[171] Carbonell, P., Currin, A., Jervis, A. J., Rattray, N. J., Swainston, N., Yan, C., Takano, E., & Breitling, R. (2016). Bioinformatics for the synthetic biology of natural products: integrating across the Design-Build-Test cycl
[172] Carbonell, P., Currin, A., Jervis, A. J., Rattray, N. J., Swainston, N., Yan, C., Takano, E., & Breitling, R. (2016). Bioinformatics for the synthetic biology of natural products: integrating across the Design-Build-Test cycle. Natural product reports, 33(8), 925–932. https://doi.org/10.1039/c6np00018e. Accessed 24 April 2024
[173] Weber T., Blin K., Duddela S., Krug D., Kim H. U., Bruccoleri R., Lee S. Y., Fischbach M. A., Müller R., Wohlleben W., Breitling R., Takano E., Medema M. H. Nucleic Acids Res. 2015;43:W237–W243.
[174] Carbonell, P., Currin, A., Jervis, A. J., Rattray, N. J., Swainston, N., Yan, C., Takano, E., & Breitling, R. (2016). Bioinformatics for the synthetic biology of natural products: integrating across the Design-Build-Test cycle. Natural product reports, 33(8), 925–932. https://doi.org/10.1039/c6np00018e (accessed 24 April 2024)
[175] Carbonell, P., Currin, A., Jervis, A. J., Rattray, N. J., Swainston, N., Yan, C., Takano, E., & Breitling, R. (2016). Bioinformatics for the synthetic biology of natural products: integrating across the Design-Build-Test cycle. Natural product reports, 33(8), 925–932. https://doi.org/10.1039/c6np00018e (accessed 24 April 2024)

breeding (for the identification and introduction of favourable genetic traits), or a genetic assessment of animal health.[176] The availability of such services often involves the development of proprietary platforms of computational programmes that accelerate animal and seed breeding/selection, allowing users to predict the future traits of the progeny.

[176] Eurofins BioDiagnostics (2024) Eurofins BioDiagnostics. Available at: https://www.eurofins-biodiagnostics.com/ (accessed 24 April 2024).

Case Study

Section	Details
Case Study Name	Geneious Prime[177]
Organization involved	GraphPad Software, LLC
Sector	Software
Geographical Area	Global
Description of Value Chain	Geneious Prime is a cloud based molecular biology and bioinformatic platform. Geneious Prime is used by researchers and translational scientists to support several areas related to DSI usage including molecular biology, genetic engineering and synthetic biology. Geneious subscriptions are offered with personal yearly subscriptions ranging from a personal student subscription of US$200 through to a multi-user corporate subscription of $22,500. [178]
Stages Involved	Exploration and Discovery, Research, Proof of concept, Development, Market Launch and Commercialization.
Financial Information	Geneious Prime was purchased by Dotmatics in 2022 for an undisclosed amount.

f) Comparing and contrasting market sectors

Across the market sectors reviewed above, the value chains follow a generally sequential approach from research and discovery through to product development and finally product commercialization, with various stakeholders intersecting each stage to generate revenue. Whilst the specific details associated with use of DSI and revenue generation do vary, there are many parallels. For example, many stakeholders are involved in each stage and generate value of DSI in a variety of ways. Whilst the timelines and use of DSI along the value chains may vary, the access to and use of DSI are the most aligned between the pharmaceutical, cosmetics and plant and animal breeding and agricultural biotechnology sectors.

The case studies illustrate that DSI may be used in different ways throughout the value chain of product development. Following genetic sequencing, DSI is analysed and characterised.[179] DSI can be used to identify or confirm the presence of favourable genes for breeding programmes in the seeds, plants, livestock or in transgenic species.

In the hardware and software sectors, equipment and computational programmes are developed to sequence and generate DSI as well as use, model, test and store DSI. The development timelines for these products tends to be shorter and their use cross-sectoral. For example, hardware in the form of sequencing technology is required for the sequencing of genetic resource while software is used to analyse those genomic properties. See section 11e for an overview of the potential points in the value chains across market sectors which may trigger the requirement to pay into the fund.

Note on scope of DSI

In many market sectors, particularly the pharmaceutical, cosmetics, and plant and animal breeding and agricultural biotechnology, the use of DSI is linked to the broadest scope group described by the AHTEG. The other two sectors (laboratory equipment associated with the use of DSI and information, scientific and technical services related to DSI) are tied more specifically to the use of sequences. It is important to note that the scope of DSI will have an impact on the sectors that may be included in the multilateral mechanism. For example, the nutritional supplement sector (not included in this study) do not use sequence data but rely instead on metabolite data.

[177] Features | Geneious Prime (2024) Geneious. Available at: https://www.geneious.com/features/. (accessed 25 April 2024).
[178] Pricing | Geneious Prime (2024) www.geneious.com. Available at: https://www.geneious.com/pricing/ (accessed 25 April 2024).
[179] Claudia Manzoni, Demis A Kia, Jana Vandrovcova, John Hardy, Nicholas W Wood, Patrick A Lewis, Raffaele Ferrari, Genome, transcriptome and proteome: the rise of omics data and their integration in biomedical sciences, Briefings in Bioinformatics, Volume 19, Issue 2, March 2018, Pages 286–302, https://doi.org/10.1093/bib/bbw114. Accessed: 29 April2024

g) Emerging and novel market sectors

The above sectors are not exhaustive and there are emerging applications for DSI that will likely grow in coming years. Below are some examples of these emerging technologies:

DNA data storage: This is the concept of encoding and decoding binary data using DNA as a storage medium. This technology has the potential to bridge the current gap between information production and the ability to store data.[180]

Environmental DNA (eDNA) services: Environmental DNA can be collected from water, soil, air, skin, or stomach to cite a few, and is increasingly being utilised within the field of environmental assessments or medicine as it can be used to identify the organisms (including microscopic organisms) present in a sample. These services can be used to support organizations with meeting their nature-related reporting and disclosure requirements.[181,182] The environmental monitoring market was valued at US$14.5 billion in 2021 with growth of 4.5% CAGR expected to 2026.[183]

Artificial Intelligence (AI) derived datasets: AI systems are complex models designed to analyse large volumes of data with the purpose of recognising patterns and making predictions, among other use cases. The past 5 years have seen a rapid increase in the accuracy and sophistication of these models, driven by increased availability to computer processing power and wider availability of structured and unstructured data.[184] The global market size of AI amounts to US$200bn in 2023 with this predicted to rise to US$1.8tn by 2030.[185] DSI form a rich dataset for AI models to draw from, with an open data landscape providing rich training datasets for these models. One view on the potential challenge of AI, as Halewood et al., (2023) notes, is the *"output of AI is based on multiple streams of biological data, none of which belongs to a single country or United Nations forum, making attribution of DSI-based commercial outcomes to individual countries inconceivable*". Given this, "*benefit sharing tied to access would no longer occur to any meaningful extent***".** [186]

Key Points:

- DSI value chains follow a generally sequential approach from research and discovery through to product development and finally commercialisation of products / services.
- Whilst the timelines and use of DSI along the value chains may vary, the points of access to, and the use of DSI are fairly aligned between the pharmaceutical, cosmetics and the plant and animal breeding and agricultural biotechnology sectors. The laboratory equipment (hardware) and information technology and computational programmes / platforms (software) including producers of information on DSI, follow slightly different value chain stages to the three above.
- Emerging and novel market sectors include those linked to DNA data storage, eDNA and AI derived datasets.

[180] Ceze, L., Nivala, J. & Strauss, K. Molecular digital data storage using DNA. *Nat Rev Genet* **20**, 456–466 (2019). https://doi.org/10.1038/s41576-019-0125-3

[181] https://www.naturemetrics.com/species-detection accessed 15 July 2024

[182] https://www.spygen.com/technologies/edna-barcoding/ accessed 15 July 2024

[183] https://www.marketsandmarkets.com/Market-Reports/environmental-monitoring-market-216846315.html?utm_source=Pulse&utm_medium=AV?utm_source=Pulse&utm_campaign=AV accessed 02 May 2024

[184] https://data.europa.eu/en/publications/datastories/open-data-and-ai-symbiotic-relationship-progress

[185] https://www.statista.com/outlook/tmo/artificial-intelligence/worldwide#:~:text=Artificial%20intelligence%20(AI)%20worldwide%20%2D%20statistics%20%26%20facts&text=The%20market%20for%20AI%20technologies%20is%20vast%2C%20amounting%20to%20around,trillion%20U.S.%20dollars%20by%202030 accessed 02 May 2024

[186] Halewood, M.; Bagley, M.A.; Wyss, M.; Scholz, A.H. New benefit-sharing principles for digital sequence information. Benefit sharing should be decoupled from access. *Science* 2023, *382*, 520–522

7) Criteria of paragraphs 9 and 10 of CBD decision 15/9

This section outlines the criteria of paragraphs 9 and 10 of CBD decision 15/9, against which options for a multilateral mechanism for DSI (see section 9 for a description of the options) are assessed.

At part two of the fifteenth meeting of the CBD COP, decision 15/9 on DSI was adopted.[187] In that decision, the COP agreed that the benefits from the use of DSI on genetic resources should be shared fairly and equitably. The COP also agreed on a set of criteria that a solution for the sharing of benefits arising from the use of DSI should follow. Additionally, the decision established a global multilateral benefit sharing mechanism from the use of DSI, including a global fund.

Paragraphs 9 and 10 of CBD COP decision 15/9 are relevant to this study as is the annex to the decision listing issues for further consideration.[188] In paragraph 9 of the decision, the COP agreed that a solution for fair and equitable benefit-sharing on DSI on genetic resources should, inter alia:

(a) Be efficient, feasible and practical.

(b) Generate more benefits, including both monetary and non-monetary, than costs.

(c) Be effective.

(d) Provide certainty and legal clarity for providers and users of DSI on genetic resources.

(e) Not hinder research and innovation.

(f) Be consistent with open access to data.

(g) Not be incompatible with international legal obligations.

(h) Be mutually supportive of other ABS instruments.

(i) Take into account the rights of indigenous peoples and local communities, including with respect to the traditional knowledge associated with genetic resources that they hold.

In paragraph 10 of the decision, the COP recognized that '**the monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit indigenous peoples and local communities.**'

[187] CBD/COP/DEC/15/9. Available at https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf accessed 02 May 2024

[188] From the annex to CBD/COP/DEC/15/9 accessed on 28 March 2024

8) Considerations when reviewing modalities and criteria of paragraphs 9 and 10 of CBD decision 15/9

This section sets out considerations that are relevant when reviewing the options for the modalities (see section 9) and criteria (see section 7). This includes the characteristics of data as an economic good, and the potential impact on open access to data, research and innovation, track and trace of DSI, and DSI infrastructure costs.

a) Data as an economic good

DSI is data, and data has certain characteristics which are unlike other assets such as genetic resources. Therefore, these characteristics need to be taken into account when developing fund generating options. Specifically, data such as DSI is:[189,190]

1. **Non-rivalrous in consumption** – This means that the use of DSI by one person/ business does not prevent someone else/ another business using it at the same time, or reduce the amount available to them. This contrasts with physical assets which are usually rivalrous in consumption. While some goods may only be non-rivalrous up to a certain point – the point at which congestion occurs – data does not become congested.

2. **Excludable in consumption** – This means that it is possible to exclude a person/ business from accessing and/ or using data through technical means or by charging for it. For example, if the charge for accessing or using DSI is set too high, or access is only granted to certain users, it may exclude some potential users from being able to use it.

3. **Non-depletable** – Data does not run out or become exhausted; it can be used repeatedly without reducing the amount available.

4. **Changes in value over time** – Different types of data depreciate at different rates. While data that describes information that does not change over time depreciates slowly e.g. personal information, data describing information that changes depreciates faster e.g. location data. Some DSI may depreciate slowly if it is not expected to change over time, while some, such as COVID DSI or other pathogens may depreciate very quickly. In addition, if higher quality data (such as more accurate or granular data) becomes available, the current DSI could depreciate in value over time. It is also important to note that DSI may appreciate in value, if the genetic resource from which the DSI is derived decreases in volume over time, for example.

5. **Increasing returns from combining data** – Bringing together different data, potentially from different sources, increases the value that can be derived from it, as value could be added through analysis undertaken through the aggregation process as combined datasets can be used for new purposes. For example, healthcare researchers and pharmaceutical companies can use DSI combined with other data sources in the generation of new products and treatments. As noted previously, analysis of sequences can only be done by comparing them to all other DSI – the value from any single sequence may be limited.[191]

6. **Decreasing returns to data volume** – The marginal value of additional data within the same data set declines as a larger volume of data in the same data set is less likely to provide new and valuable insights. This is because additional data in the same data set may provide similar information to that in the initial data set.

7. **Externalities** – Data can produce both positive and negative externalities (i.e. impacts on third parties arising from the use of the data).[192]

[189] What is the value of data? A review of empirical methods - Coyle - Journal of Economic Surveys - Wiley Online Library accessed 15 May 2024
[190] Data as an economic good, data as a commons, and data governance (tandfonline.com) accessed 15 May 2024
[191] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[192] WEF_Articulating_Value_from_Data_2021.pdf (weforum.org) accessed 15 May 2024

In addition to the above characteristics which DSI broadly shares with other data, DSI has some unique characteristics. In particular, DSI, in contrast to other types of data, is a representation of compounds and can be translated back into physical form.[193] The provenance of DSI is also especially complex, and it has been argued that establishing appropriate indigenous provenance is key to protecting the interests of indigenous peoples and local communities and to enhance benefit sharing.[194]

Goods are typically defined along two dimensions; rivalrous in consumption and excludability. This is typically to recommend strategies to improve upon market outcomes; to move towards the provision of the optimal quantity and quality of the good.

Data has traditionally been defined as a 'club' good i.e. you can restrict use of data to a 'club' of people/ businesses. This is because use of data by one person/ business does not reduce the amount available to someone else in the 'club', but it is possible to exclude people/ businesses outside the 'club' using it, either through technical means like encryption, or by charging for it.[195]

Table 2: Classification of goods.

	Rivalrous	**Non-rivalrous**
Excludable	Private goods	**Club goods**
Non-excludable	Common resources	Public goods

However, this view of data as a club good has been criticised in some literature for considering data in isolation of its context i.e. where the data comes from and the impact of extracting and processing the data.[196] Hence if the aim is to make sure there is sufficient quality and quantity of data to enable innovation, data needs to be viewed as an economic resource in order to create the right governance structure to incentivise data production and availability. In addition, although data may be viewed as a club good, it is not congestive like other club goods (such as roads), and therefore intervention to prevent congestion (such as toll charges in the case of roads) is not needed. The volume of data and number of users may however incur costs for the maintenance of the infrastructure that hosts the data.

There is a growing body of literature which suggests data should be considered as a common good, requiring management as a common-pool resource. This literature does not focus on the two dimensions defined in neo-classical economics and so is outside this matrix. One of the arguments put forward is that restricting access to data inhibits innovation and new ideas, and rather the focus should be on managing data to achieve societal goals.[197] This therefore needs to be considered when considering and designing fund generating options; as different options will have differential impacts on the incentives to use DSI for research and innovation. Indeed, this is the approach adopted by Oldham (2020) where DSI is treated as a knowledge based common pool resource using the framework developed for analysing sustainable social-ecological systems.

b) Open access to data

There has been a shift towards open government data policies internationally. Open government data policy has in the past emphasised increasing access to public sector information, but the awareness of the need to enable a culture of value creation has helped target the release of valuable data (rather than just focusing on volume).[198] The potential benefits of open data include:[199]

[193] Oldham, P. (2020). Digital Sequence Information - Technical aspects. Zenodo (CERN European Organization for Nuclear Research). https://doi.org/10.5281/zenodo.7323632 Accessed 01 May 2024
[194] Frontiers | Benefit sharing: Why inclusive provenance metadata matter (frontiersin.org) accessed 15 July 2024
[195] Full article: Data as an economic good, data as a commons, and data governance (tandfonline.com) accessed 15 May 2024
[196] Full article: Data as an economic good, data as a commons, and data governance (tandfonline.com) accessed 15 May 2024
[197] Full article: Data as an economic good, data as a commons, and data governance (tandfonline.com) accessed 15 May 2024
[198] Open Government Data Report, OECD (2018) accessed 3 July 2024
[199] The benefits and value of open data | data.europa.eu accessed 15 May 2024

- Equity and fairness – globally, not all regions have the same resources available for research and innovation, particularly for non-commercial uses. Open and free data guarantees that all have access to the data.

- Economic growth and development – Open data can be a source for developing new products and services, and contributes to creating new business models. It can also help individuals and organizations (both public and private) improve their efficiency by making better-informed decisions and better use of resources, thereby driving productivity gains.

- Societal benefits – Open data i) enables citizens to contribute more to policy making by allowing citizens to analyse data, ii) creates opportunities for collaboration between the public and private sectors to work on challenges together, and iii) facilitates inclusion of marginalised groups.

- Greater transparency – Open data enables increased transparency and scrutiny of government actions thereby improving accountability.[200]

The shift to open data more broadly (i.e. beyond government data) is also evident due to the potential benefits from research and innovation. For example, Horizon Europe mandates open access to scientific publications and for research data to be made "as open as possible, as closed as necessary", and the African Union's 10-year Science, Technology and Innovation Strategy which acknowledges the role of open data in achieving socio-economic development.[201]

Measures which couple access to DSI with the requirement to immediately share monetary benefits may have a negative impact on open access. For example, limitations imposed on open access to data (e.g. through an access fee – see section 11b) could hinder research and innovation if prior users of the now restricted data can no longer leverage it.[202] [203] Not only could this limited access and contrast with the principle of open science, but it could also impact the ability of the database itself to secure future funding from government sources, given databases are often funded through government grants on the condition of maintaining open access to data. [204] [205]

Maintaining open and unrestricted access to public databases could be a way to encourage collaborative studies between nations. The impact of restricting access to data may be felt more by countries and research groups with less access to financial resources.

c) Research and innovation

Open access to data has been viewed as a cornerstone of the scientific process.[206] There is concern amongst stakeholders that measures which couple access to DSI with the requirement to immediately share monetary benefits (e.g. with an access fee) may isolate data or reduce effectiveness of databases, particularly for non-commercial research.[207] If access to data is restricted, this could have a negative impact on the analytical capabilities, data infrastructures and academic systems that depend on these open databases and would disincentivize collaboration with researchers based in countries that enforce DSI-related restrictions.[208,209,210,211] Analysis of sequences can only be done by comparing them to all other DSI – the value from any single sequence may be limited. As such, they have no

[200] analytical_report_n9_economic_benefits_of_open_data.pdf (europa.eu) accessed 15 May 2024
[201] Open access: a technical assessment for the debate on benefit-sharing and digital sequence information (zenodo.org)
[202] Rourke, M., Eccleston-Turner, M., Phelan, A. & Gostin, L. Policy opportunities to enhance sharing for pandemic research. Science 368, 716–718 (2020)
[203] Aubry, S., Frison, C., Medaglia, J.C., Frison, E., Jaspars, M., Rabone, M., Sirakaya, A., Saxena, D. and Van Zimmeren, E., 2022. Bringing access and benefit sharing into the digital age. *Plants, People, Planet*, *4*(1), pp.5-12.

[204] 8 Pillars of Open Science | Library Services - UCL – University College London Accessed 12 July 2024
[205] Research at Defra: open access policy for publications - GOV.UK (www.gov.uk) Accessed 12 July 2024
[206] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[207] Laird, S. and Wynberg, R., 2018, February. A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol.
[208] Klünker, I. and Richter, H., 2022. Digital Sequence Information between Benefit-Sharing and Open Data. *Journal of Law and the Biosciences*, *9*(2), p.lsac035.
[209] Prathapan, K. D. et al. When the cure kills—CBD limits biodiversity research. Science 360, 1405–1406 (2018)
[210] Laird, S. et al. Rethink the expansion of access and benefit sharing. Science 367, 1200–1202 (2020)
[211] Ribeiro, C. et al. How ownership rights over microorganisms affect infectious disease control and innovation: A root-cause analysis of barriers to data sharing as experienced by key stakeholders. PLoS ONE 13, e0195885 (2018)

value in isolation.[212] The Natural History Museum and partners argue: *"The 100 million search jobs run annually are not generating 100 million finance-generating outputs. Putting even a very small financial penalty on reading a sequence (were it to be possible) would outweigh the benefits generated and, given the number of sequences being seen, be unduly costly both for users and to implement"* (NHM et al, 2017).[213] As above, research and innovation would likely be hindered if limitations are imposed on open access by an access fee (or similar).[214,215] Furthermore, scientists require open access to DSI to conduct research on biological diversity e.g. to fulfil the aims of the KMGBF and United Nations Sustainable Development Goals.[216,217,218]

For businesses, undertaking research and innovation activity is inherently risky and when decisions are made by businesses in relation to investment in research and development, the expected return on that investment needs to be considered (taking in to account the potential risk of failure). There are already some challenges in terms of achieving the socially optimal level of research and innovation activity. As noted in the Evidence for the UK Innovation Strategy, while innovation benefits innovators through potentially increased revenues, investors do not take account of the spill-over benefits to other businesses and society.[219] Therefore, research and innovation activity with high social value will be underfunded and, if left only to market forces, innovation investment will be below the socially optimal level. This is one of the reasons why governments make funding available for research. By adding an additional charge to access/ use of DSI required for the research process, this increases the cost of the research/ innovation activity, thereby lowering the potential rate of return. Depending on the scale of the payment, at the margin this may mean some activity undertaken by businesses no longer exceeds the required hurdle rate. If a charge to access/ use DSI is implemented, consideration may be required as to how this will be paid for by publicly funded researchers – for example, could it be a reimbursable expense.

d) Track and trace of DSI

Track and trace of DSI is considered as meaning the ability to identify where specific DSI is or has been used within a value chain and where it originates from. Implementation of a track and trace system may facilitate the identification of points in the value chain where DSI is used or commercialised, thereby enabling the triggering of benefit sharing at those stages. However, the wide range of DSI data which can be downloaded from public data bases and then used in various ways means implementing singular and universal processes for tracking this data is not feasible in all situations.[220] Also, the sheer volume of this data means tracking it may negatively impact research output given the time and resource required to do so effectively.[221] Additionally, DSI is often not unique to an individual organism or species, or geographical origin. This means, even if a sequence is identified, it is difficult to trace where it originated and how it was used, without considerable resources and costs.[222] Fundamentally, any track and trace process put in place would require the development and management of new technology and infrastructure, which could be complex and financially and environmentally costly to build and maintain.[223] As such, the process of tracking and

[212] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[213] Laird, S. and Wynberg, R., 2018, February. A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol.
[214] Rourke, M., Eccleston-Turner, M., Phelan, A. & Gostin, L. Policy opportunities to enhance sharing for pandemic research. Science 368, 716–718 (2020)
[215] Aubry, S., Frison, C., Medaglia, J.C., Frison, E., Jaspars, M., Rabone, M., Sirakaya, A., Saxena, D. and Van Zimmeren, E., 2022. Bringing access and benefit sharing into the digital age. *Plants, People, Planet*, *4*(1), pp.5-12.
[216] https://www.un.org/sustainabledevelopment/blog/2021/07/a-new-global-framework-for-managing-nature-through-2030-1st-detailed-draft-agreement-debuts/ accessed 29 April 2024
[217] https://sdgs.un.org/goals accessed 29 April 2024
[218] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)
[219] Evidence for the UK Innovation Strategy (publishing.service.gov.uk) accessed 15 May 2024
[220] Scholz, A. H, (2019), Combined Study on digital sequence information in public and private databases and traceability, p. 21
[221] Digital sequence information - POST (parliament.uk) Accessed 15 May 2024
[222] https://www.cell.com/molecular-plant/pdf/S1674-2052%2821%2900080-0.pdf Accessed 15 May 2024
[223] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.

tracing DSI is considered as 'not practical' (see CBD COP Decision 15/9) and may be cumbersome and administratively challenging to implement.[224]

e) DSI infrastructure costs

The operating cost of the INSDC is estimated to be $50 million annually, while the full operating cost of all DSI databases is estimated to be around $500 million globally on an annual basis.[225,226] The cost effectiveness of any of the modalities needs to consider this financial cost. In particular, if a paywall is imposed on DSI databases it is possible that governments would no longer fund DSI databases with public money and therefore the revenue generated into the global fund would need to cover these costs.

Key Points:

- Data, such as DSI, is unlike other assets and has certain characteristics which need to be taken into account when developing fund generating options. There is a growing body of literature which suggests data should be considered as a common good, requiring management as a common-pool resource.
- There has been a shift to open government data and to open data more broadly given the potential economic and social benefits. The options for fund generation therefore need to be considered in the context of this global movement.
- Implementation of a track and trace system may facilitate the identification of points in the value chain where DSI is used. However, it would require the development and management of new technology and infrastructure, which could be complex and costly.
- Investment decisions in research and development are based on the expected rate of return. Any additional charge to access/ use DSI increases the cost of the research, thereby lowering the potential rate of return. Depending on the scale of the payment, at the margin this may mean some activity no longer exceeds the required hurdle rate.

[224] CBD/COP/DEC/15/9. Available at https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf accessed on 27 March 2024

[225] Rohden, F., Huang, S., Dröge, G. & Scholz, A. H. Combined study on digital sequence information in public and private databases and traceability. Report No. CBD/DSI/AHTEG/2020/1/4 https://www.cbd.int/doc/c/1f8f/d793/57cb114ca40cb6468f479584/dsi-ahteg-2020-01-04-en.pdf (2020). Accessed 12 April 2024/

[226] ICF, I., Smith, E., Switzer, S. and Morgera, E., 2020. Digital Sequence Information: an Evidence Review.

9) Modalities of the multilateral mechanism

This section outlines the modalities for a DSI multilateral mechanism which were considered in this study (contribution to the fund; disbursement of the funds; non-monetary benefit sharing; governance; other policy options) and options within those modalities. These options were assessed by survey respondents in terms of the extent to which they meet the criteria of paragraphs 9 and 10 of CBD decision 15/9 (see section 7 for the list of criteria and section 10 for survey results).

In 2021, the IAG on DSI proposed several policy options for the governance of DSI (see Appendix).[227] These options were considered at CBD COP 15 and a decision was made to fairly and equitably share benefits arising from the use of DSI on genetic resources and to establish a multilateral mechanism and global fund. As a result of that decision, options 0, 1 and 5became obsolete. As such, these options fell away when the multilateral mechanism decision was made. The remaining options (2, 3, 4 and 6), together with newer proposed options linked to voluntary contributions and payment for access to DSI were reviewed, together with the Report of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of DSI with the aim of identifying key options still under consideration for the multilateral mechanism.[228] In addition, the 'Synthesis of views pursuant to decision 15/9' (2023)[229], presented in the first meeting of the Working Group on Benefit-Sharing from the Use of DSI, was reviewed in combination with proposals from CBD COP 15 to identify potential multilateral mechanism options. [230,231,232] These options are listed and described in the tables below.

When assessing the options, it is best practice to follow a transparent, structured approach. An example of a structured framework for identifying and filtering a long list of options is set out in the UK HM Treasury Guide to Developing the Project Business Case.[233] Similar tools for filtering options are widely used by countries around the world. This suggests that choices need to be made in relation to the what (the operational scope), how (i.e. how the service will be delivered), when (i.e. the time path for delivery), who (i.e. who will provide the service e.g. in-house, outsourcing, etc.) and funding (i.e. how will the service be funded e.g. public or private capital or a mixed arrangement). This would likely involve combining different elements of the 'modalities' described below.

a) Contribution to the fund

In the context of ABS, the term 'trigger' is considered as meaning the event or activity which triggers the sharing of benefits.[234] Under existing ABS systems, the requirement to share benefits is linked to legal access to genetic resources, or the commercialisation of products or services resulting from its use.[235,236,237238] In the context of DSI, the trigger point has not yet been agreed and could either be tied to access to DSI or tied to other events / activities such as use or commercialisation of DSI. Alternatively, it could be unlinked to DSI. A 'payment' is considered as a fee or sum of money which will flow into the multilateral fund.[239] By 'scope of products / services' we mean the variety of products / services to which potential fund generating measures may apply. Our understanding of the meaning of various modalities linked to contribution to the fund is described below in **Table 3**. See

[227] Section II.A.4 of CBD/WG2020/3/INF/8 accessed on 28 March 2024
[228] Annotated provisional agenda (cbd.int) accessed on 18 April 2024
[229] Synthesis of views pursuant to decision 15/9 (cbd.int) accessed 24 April 2024
[230] See statement by Japan in the opening plenary WGDSI-01 - Documents (cbd.int) accessed 24 April 2024
[231] COP-15 - Documents (cbd.int) accessed 24 April 2024
[232] [Global] [multilateral] [solution[s] for sharing of benefits from the use of] digital sequence information on genetic resources (cbd.int) accessed 24 April 2024
[233] Guide to developing the Project Business Case (publishing.service.gov.uk) accessed 14 May 2024
[234] Morgera, E., 2016. The need for an international legal concept of fair and equitable benefit sharing. *European Journal of International Law*, *27*(2), pp.353-383.
[235] Nagoya Protocol (2010). Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity - Text of the Nagoya Protocol (cbd.int) accessed 24 April 2024
[236] FAO, 2001. International Treaty on Plant Genetic Resources for Food and Agriculture. FAO Res. 3/2001, 3 November 2001 (entered into force 29 June 2004) - Texts of the Treaty | International Treaty on Plant Genetic Resources for Food and Agriculture | Food and Agriculture Organization of the United Nations (fao.org) - accessed 25 April 2024
[237] World Health Organization (2011). Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits - pandemic-influenza-preparedness-en.pdf (who.int) accessed 25 April 2024
[238] Note that countries such as Brazil and Costa Rica have implemented national ABS legislation which governs DSI.
[239]CBD/WG2020/REC/5/2, [11] and Annex (A, Options 2.1 and 2.2 (Standard mutually agreed terms/licence at the national/international level)). Available at: https://www.cbd.int/doc/recommendations/wg2020-05/wg2020-05-rec-02-en.pdf) accessed 14 May 2024

Section 11 for an assessment of options for the contribution to the fund (outlined here) against the criteria set out in section 7.

Table 3: Description of options linked to contributions to the fund.

Options		**Description**
Trigger Points	Access to DSI	Downloading DSI from a database
	Use of DSI	Research and / or development involving DSI
	Commercialisation of DSI	Selling of products or services which contain DSI, or involved the use of DSI in their development
	Unlinked to DSI	Unrelated to the access, use or commercialisation of DSI and / or unrelated to specific DSI[240]
Payment	Fee to access DSI and / or related information	Payment associated with accessing DSI from databases, and / or access to related information such as protein function. This may involve a fee to download individual sequences, or could involve a membership fee / subscription to access DSI in databases / cloud-computing spaces[241,242]
	Payment or levy on products or services associated with use of DSI (lab equipment and IT)	Payment for DSI-related services linked not only to the generation of DSI (DNA sequencing), but also the storage, processing, expertise and analysis of sequences[243] Payment on products associated with use or generation of DSI, such as a levy on laboratory equipment linked with the production of DSI[244]
	Percentage turnover of DSI products / services	Payment based on the percentage of revenue (as per glossary definition) generated by a business related to DSI products/ services over a specified timeframe.
	Percentage sales of DSI products / services	Further clarification is needed as to how this would be calculated; this could refer to a payment based on the percentage of sales (i.e. the value generated from the sales of products/ services only, not including other income) or a fee based on sales volume (i.e. the number of units of a product/ service sold)
	Percentage profit of DSI products / services	Payment based on the percentage of profit made by a business related to DSI related products/ services over a specified timeframe.
Scope of products / services	Products / services containing DSI	Products / services resulting from the use of DSI or benefiting from its use
	Wider array of products / services	Products / services resulting from the use of DSI / biodiversity, or benefitting from the use of DSI / biodiversity e.g. biodiversity-based products / services[245]
Voluntary contributions		Voluntary payments could be non-legally binding contributions made by the private sector, database users, countries, private donors, or others. These contributions could be made according to a formula agreed by the COP. Alternatively, these contributions could be viewed as donations where entities pay whatever sum they are prepared to pay.[246]

[240] Annex (A, Option 3 (Payments and contributions)).
[241] https://www.cbd.int/abs/DSI-webinar/DSIPolicyOptions2021.pdf accessed 27 April 2024
[242] Scholz, A.H., Hillebrand, U., Freitag, J., Cancio, I., dos S. Ribeiro, C., Haringhuizen, G., Oldham, P., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective. WILDSI
[243] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[244] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[245] Digital Sequence Information on Genetic resources (cbd.int) accessed 27 April 2024
[246] DSIPolicyOptions2021.pdf (cbd.int) accessed 27 April 2024

It should be noted that options within each modality are not necessarily mutually exclusive and could be combined in some cases.

b) Disbursement of the funds

Funds (monetary benefits) may be shared with different types of recipients, to fund the attainment of different objectives, and disbursed on the basis of various factors. Our understanding of the meaning of various modalities linked to disbursement of the funds is described below in **Table 4**. See section 12 for an assessment of options for disbursement of the funds (outlined here) against the criteria set out in section 7.

Table 4: Description of options linked to disbursement of the funds.

Options		**Description**
Funds go to	Government (Global South)	Monetary benefits shared with governments in the Global South
	Indigenous peoples and local communities (South, Potentially North too)	Monetary benefits shared with indigenous peoples and local communities in the Global South, and potentially in the Global North too
	Mix of Government and indigenous peoples and local communities	Monetary benefits shared with a combination of government and indigenous peoples and local communities
Funds used to invest in	Government priorities	Monetary benefits will be used to fund priorities as determined by government
	Biodiversity conservation & sustainable use	Monetary benefits will be used for the conservation and sustainable use of biodiversity
Funds shared on the basis of	Projects	Monetary benefits will be shared on the basis of the amount needed to fund specific agreed projects. This may involve submissions of applications for funding on a competitive basis[247]
	Allocations	Monetary benefits will be shared on the basis of pre-agreed allocations. Various factors could be used to determine the level of funding[248]

c) Non-monetary benefit-sharing

Non-monetary benefits may be shared on the basis of supporting attainment of objectives linked to the conservation and sustainable use of biodiversity, and, inter alia, indigenous peoples and local communities, and / or closing the gap between Global North and Global South in terms of generating, accessing, using, analysing and storing of DSI. The activities to be included within the scope of non-monetary benefit sharing have not yet been decided, and have been suggested as a topic for further discussion by the Ad Hoc Open-ended Working Group on Benefit Sharing from the Use of DSI on Genetic Resources.[249] Our understanding of the meaning of various modalities linked to non-monetary benefit sharing is described below in **Table 5.** See section 13 for an assessment of options for non-monetary benefit-sharing (outlined here) against the criteria set out in section 7.

It is noted that non-monetary benefit sharing may still entail costs for the parties seeking access/ use of the DSI. The sharing of non-monetary benefits does not necessarily mean it is without financial costs to these parties.[250]

[247] International Treaty on Plant Genetic Resources for Food and Agriculture. The Benefit-Sharing Fund. https: //www.fao.org/plant-treaty/areas-of-work/benefit-sharing-fund/bsf-makingprocess/en/ accessed 27 April 2024
[248] Annotated provisional agenda (cbd.int) accessed 27 April 2024
[249] See Section C Annotated provisional agenda (cbd.int) accessed on 18 April 2024
[250] OptionsforNon-MonetaryBenefitSharing.Pistoriusetal..pdf accessed on 18 April 2024

Table 5: Description of options linked to non-monetary benefit sharing.

Options	Description
Non-monetary benefit sharing addresses the broad needs for the conservation and sustainable use of biodiversity	Non-monetary benefit sharing options which support the conservation and sustainable use of biodiversity will be implemented
Non-monetary benefit sharing supports closing the gap to generate, access, use, analyse and store DSI	Non-monetary benefit sharing options which support closing of the gap between Global North and Global South in terms of generating, accessing, using, analysing and storing of DSI will be implemented

d) Governance

Operation of the multilateral mechanism and of the fund may involve various degrees of independence, party representation and membership. Our understanding of the meaning of various governance modalities is described below in **Table 6.** See section 14 for an assessment of options for governance (outlined here) against the criteria set out in section 7.

Table 6: Description of options linked to governance.

Options		Description
Degree of independence	Under the authority of the COP	The multilateral mechanism and/or the fund will operate under the authority of the COP
	Operational autonomy	The multilateral mechanism and/or the fund will operate with operational autonomy
Party representation	Regional balance – 5 United Nations regions	Party representation will include a regional balance across the 5 United Nations regions: • African Group • Asia-Pacific Group • Eastern European Group • Latin American and Caribbean Group • Western European and Others Group
	North/South balance	Party representation will include balance across the Global North and Global South
Other members	Indigenous peoples and local communities as observers	Indigenous peoples and local communities will participate in governance of the multilateral mechanism and / or the fund as observers
	Indigenous peoples and local communities as full members	Indigenous peoples and local communities will participate in governance of the multilateral mechanism and/or the fund as full members
	Private sector as observers	Private sector will participate in governance of the multilateral mechanism/ or and the fund as observers
	Private sector as full members	Private sector will participate in governance of the multilateral mechanism/ or and the fund as full members
	Other stakeholders as observers	Other stakeholders will participate in governance of the multilateral mechanism/ or and the fund as observers
	Other stakeholders as full members	Other stakeholders will participate in governance of the multilateral mechanism/ or and the fund as full members

e) Other policy options

Whilst not necessarily reflective of the full potential range of other policy options (including those that may not yet have been defined), our understanding of other approaches and systems of the DSI multilateral mechanism is described below:

- In parallel to the multilateral mechanism, a list of species and/or geographic areas from which the DSI was extracted will operate under a bilateral mechanism consisting of a standardised MAT
- Parties may opt out of the multilateral mechanism and instead operate their own ABS legislation, which includes DSI

See section 15 for an assessment of these other options (outlined here) against the criteria set out in section 7.

10) Summary of stakeholder perspectives on modalities of the multilateral mechanism

This section summarises the findings from the survey which asked stakeholders about the extent to which they thought the options (as set out in section 9) met the criteria of paragraphs 9 and 10 of CBD decision 15/9 (see section 7).

Forty individuals responded to the survey, including sixteen representatives from government in the Global North, fifteen from government in the Global South, four from industry, one representing indigenous peoples and local communities, one representing database operators, two representing the academic research community and one representing civil society. Survey results were collated into one master spreadsheet. Results are presented in **Figures 13-17** below.

Survey respondents raised a number of comments on the survey, including the possibility for various criteria and options to be interpreted differently by different people (see section 4), as well as questions around how criteria could be measured.

The grey segments below reflect either the difficulty of knowing whether criteria are met and / or to reflect the fact that a modality may not be applicable to the criteria. See the appendix for a tabulated breakdown of the extent to which modalities of the multilateral mechanism meet the required criteria.

Despite the limitations described above and in the limitation section (section 5), it is important to note that the criteria were not designed to provide a framework for detailed economic analysis. Instead, these criteria are valuable in the sense that they have been agreed by 196 Parties as a helpful foundation for operationalising the benefit sharing mechanism.

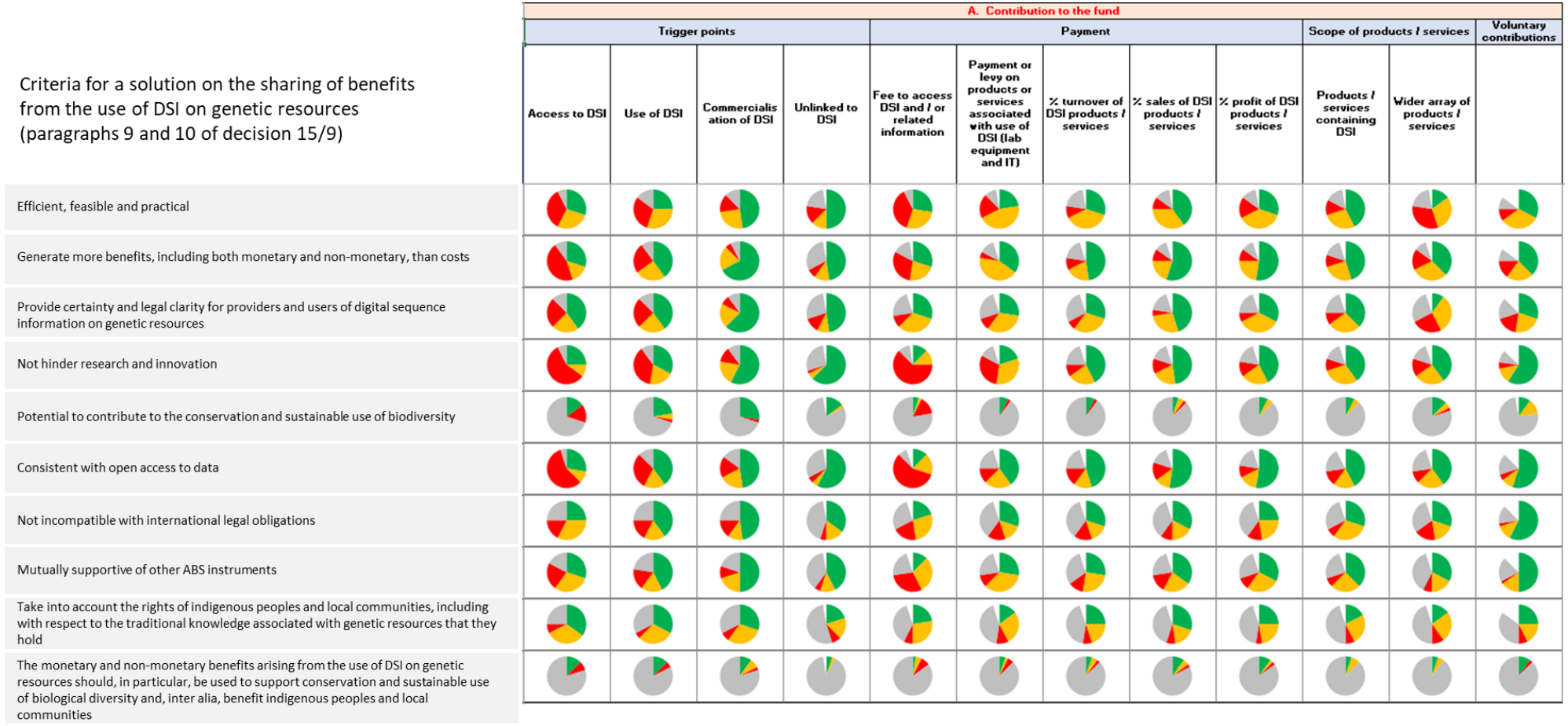

Figure 3: Visualization of scores given by survey respondents indicating the extent to which modalities linked to **contribution to the fund** (x axis) meet the required criteria (y axis). The pie charts show the proportion of respondents who agree that the option; '**very much meets the criteria**' (green), '**somewhat meets the criteria**' (orange), '**does not meet the criteria**' (red), or '**do not know / not applicable**' (grey), and white is no response / no data.

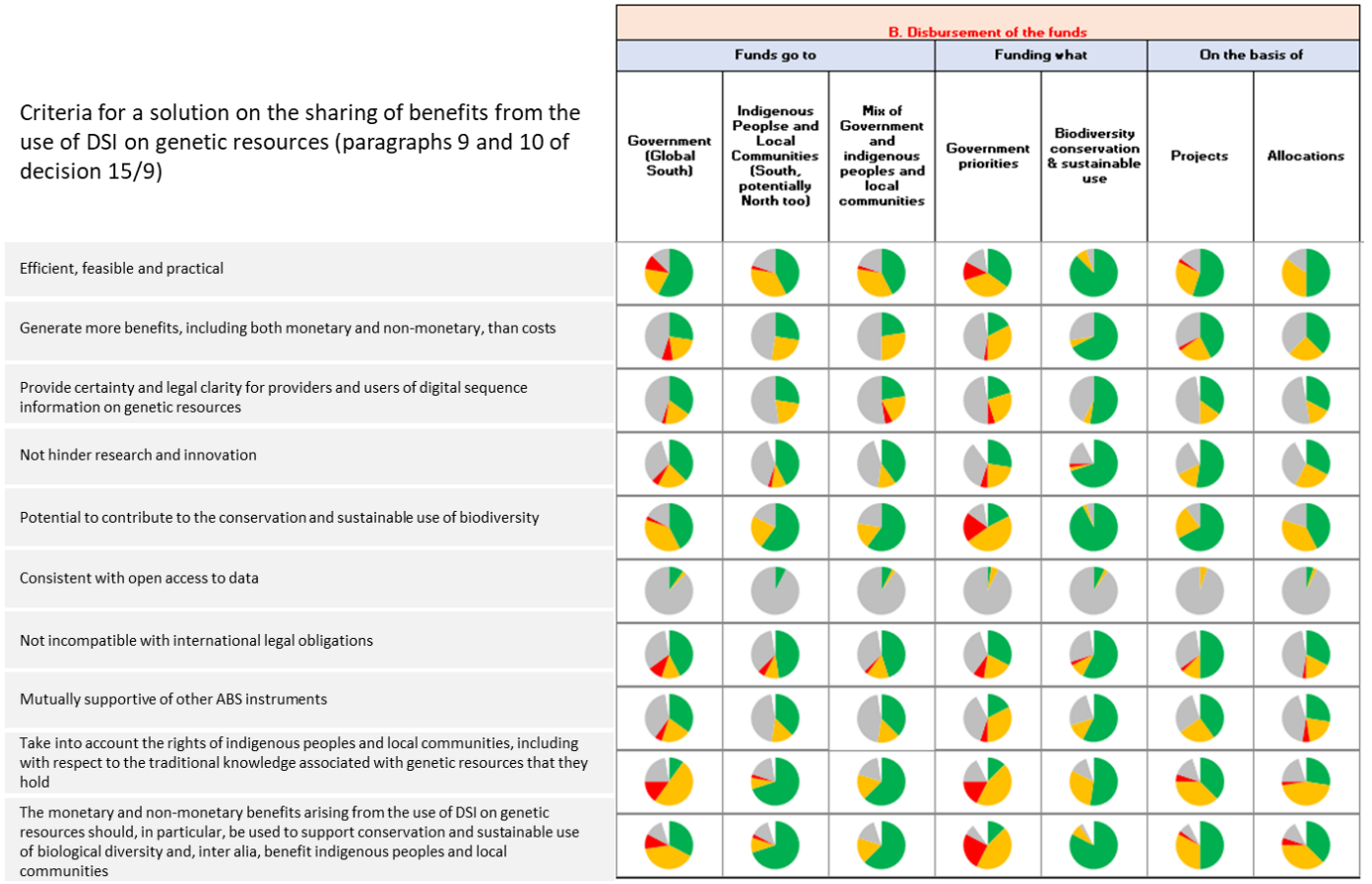

Figure 4: Visualisation of scores given by survey respondents indicating the extent to which modalities linked to **disbursement of the funds** (x axis) meet the required criteria (y axis). The pie charts show the proportion of respondents who agree that the option; '**very much meets the criteria**' (green), '**somewhat meets the criteria**' (orange), '**does not meet the criteria**' (red), or '**do not know / not applicable**' (grey), and white is no response / no data.

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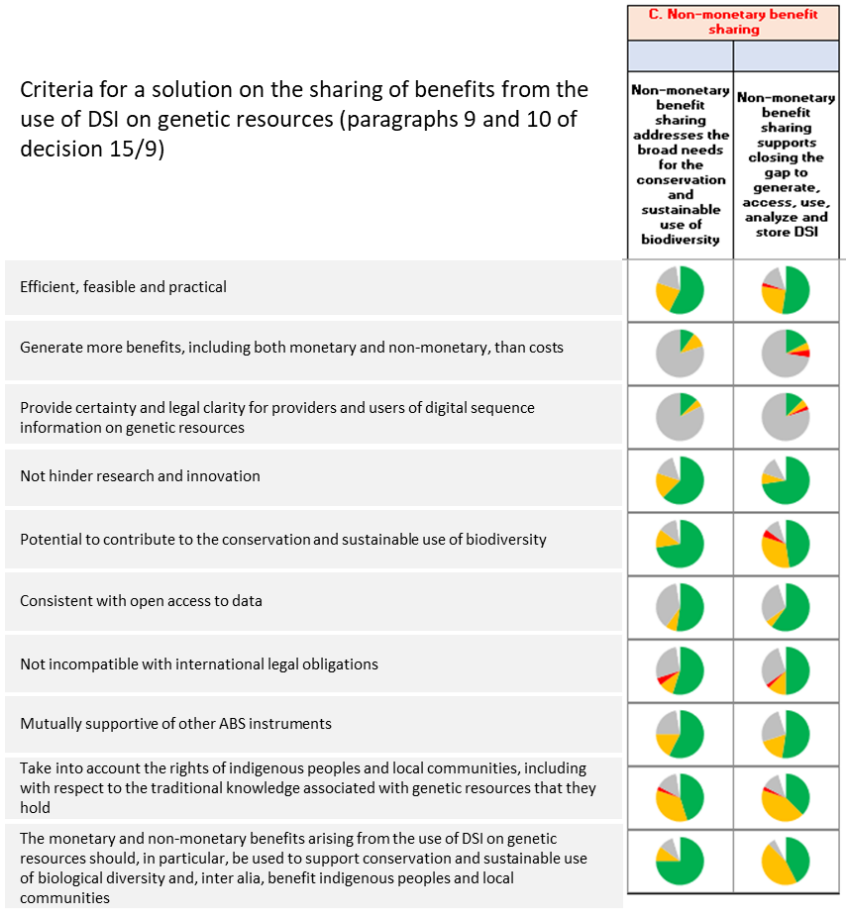

Figure 15: Visualization of scores given by survey respondents indicating the extent to which modalities linked to **non-monetary benefit sharing** (x axis) meet the required criteria (y axis). The pie charts show the proportion of respondents who agree that the option; '**very much meets the criteria**' (green), '**somewhat meets the criteria**' (orange), '**does not meet the criteria**' (red), or '**do not know / not applicable**' (grey), and white is no response / no data.

Figure 5: Visualization of scores given by survey respondents indicating the extent to which modalities linked to **governance** (x axis) meet the required criteria (y axis). The pie charts show the proportion of respondents who agree that the option; '**very much meets the criteria**' (green), '**somewhat meets the criteria**' (orange), '**does not meet the criteria**' (red), or '**do not know / not applicable**' (grey), and white is no response / no data.

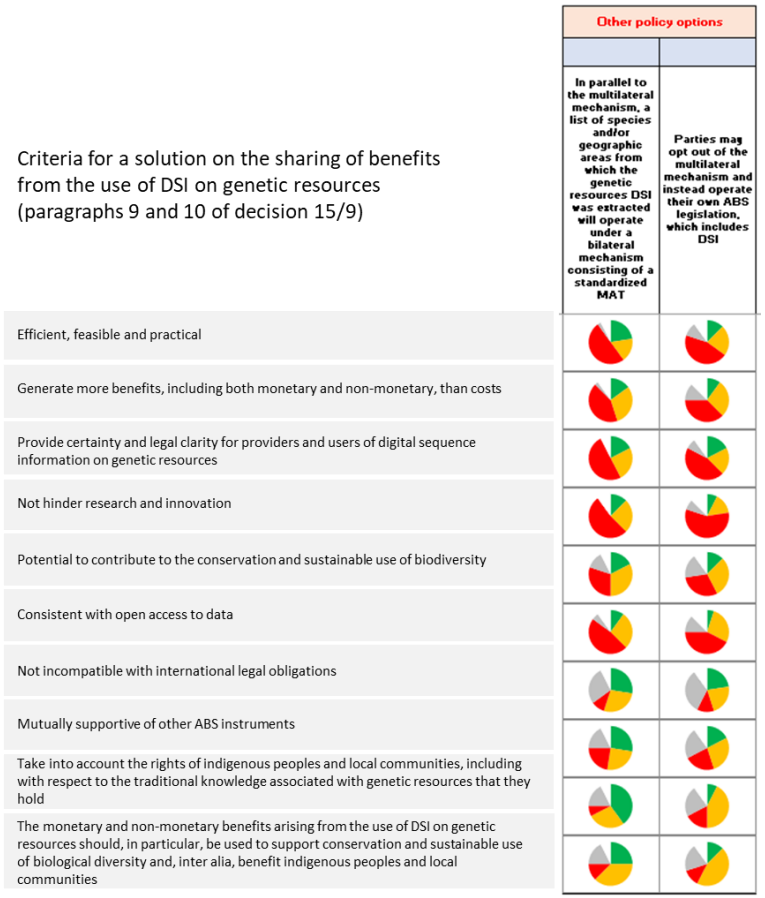

Figure 6: Visualization of scores given by survey respondents indicating the extent to which modalities linked to **other policy options** (x axis) meet the required criteria (y axis). The pie charts show the proportion of respondents who agree that the option; '**very much meets the criteria**' (green), '**somewhat meets the criteria**' (orange), '**does not meet the criteria**' (red), or '**do not know / not applicable**' (grey), and white is no response / no data.

11) Contribution to the Fund

This section assesses the options for the contribution to the fund outlined in section 9a, against the criteria set out in section 7. Options for revenue-generating measures at different points along the value chain are also considered.

This review of contributions to the fund is developed with the understanding that many key parameters remain unclear or unknown. The feasibility of implementing, risks, opportunities and scale of potential funding generated will vary depending on, but not limited to, the following factors: which stakeholders would pay (users of DSI or broader scope, e.g. if voluntary contributions are considered), when, how much, whether associated benefit sharing is on a voluntary or mandatory basis, and whether a single or a combination of measures are implemented.

How to determine the value of data and the potential payment to the fund

There are a several ways in which the value of DSI, and hence the potential payment to the fund, could be calculated. The appropriate method will depend on the specific policy objectives. Existing methods to value data can broadly be divided into market, income, and cost-based approaches. However, attributing a value to data is challenging and a limitation of all the methods is that they omit the value generated from the externalities (both positive and negative) associated with data, such as, for example, the benefits to society of an innovation using DSI.[251] Hence, there is emerging literature which tries to capture these wider, spill-over impacts.

Market-based approaches – This method involves determining the market value of the data by looking at traded prices between buyers and sellers in the market (where such a market exists). This may be considered the best way to identify the value of the data but relies on information that might not be available for DSI. Given active markets for data are still relatively rare, the ability to apply a market-based approach may be limited.[252]

Non-market-based approaches – Where there is no market price, established techniques to derive non-market valuations can be used, such as revealed preference and stated preference techniques.[253] Revealed preference techniques involve inferring the price placed on something by looking at consumer behaviour in a related market. Stated preference techniques involve carrying out specially designed questionnaires to elicit estimates of consumers' willingness to pay (WTP) to obtain a particular outcome, or the compensation to accept a loss – willingness to accept (WTA). In relation to DSI, this would involve asking users of DSI about their willingness to pay for access and/ or use of DSI, or how much they would need to be compensated for a lack of access to DSI. Using a WTP approach is likely to be very complex for DSI data given that WTP is likely to differ across user groups and within user groups, as well as across data sets. A user's WTP may also vary at different times they want to access/ use the data which would need to be considered in the calculation, therefore adding further complexity. Bias is also likely to be an issue as respondents would be incentivised to give low estimates of their WTP if they know this is going to, in turn. be used to determine the payment amount for access/ use.

Income-based approaches – This method measures the revenue or cost savings associated with the use of the data. By comparing the revenue or costs of an organization with and without the data (i.e. the counterfactual), the incremental revenue or marginal reduced costs can be calculated. This method is most feasible when the revenue or cost savings can be easily attributed to the access and use of the data. Given it is often hard to predict the additional revenue or costs savings associated with the use of the data specifically, this method is usually used retrospectively. Revenue may be generated from a product/ service using DSI that is commercialised for many years. The relevant time period therefore needs to be determined such that the present value of the incremental revenue or reduced costs can be calculated, or the time period for which a payment is required would need to be determined (e.g. 5 years), or the payment required until the product/ service using DSI is withdrawn from the market.

[251] What is the value of data? A review of empirical methods - Coyle - Journal of Economic Surveys - Wiley Online Library accessed on 15 May 2024
[252] What is the value of data? A review of empirical methods - Coyle - Journal of Economic Surveys - Wiley Online Library accessed on 15 May 2024
[253] The Green Book (2022) – GOV.UK (www.gov.uk) accessed on 15 May 2024

Cost-based approaches – This method involves identifying the fixed and marginal costs associated with the data, including the costs of storing, processing and providing access to the data to estimate the exchange value, which cannot be observed through market transactions. The estimate "is assumed to give a reasonable lower-bound estimate of the value of the data, under the assumption that an asset will generally have an expected value at least as great as its cost".[254] In the case of DSI, the payment could be set at an amount to achieve cost recovery, or be set higher in order to achieve a return on the data, or lower if the cost is subsidised from elsewhere. If the payment is based on the cost, then it is likely that early users of DSI would face higher costs, but the fixed cost component would fall when spread among a greater number of users.

Externalities-based approaches – This method examines the impact on third parties arising from the use of the data. There are negative externalities associated with data, such as from data breaches and positive externalities, such as research and innovation facilitated through data access. The WTP and WTA methods enable these externalities to be considered in the valuation of data. The approach involves varying the attributes of the data, with the price, to determine consumers' preferences. Difficulties of this approach include cognitive overload for survey respondents and the risk of poorer quality data from surveying a wider population to understand the value they place on the data.[255] This may be particularly complex in the case of DSI as it is likely that different pieces/ categories of data may be valued differently and therefore the method would need to be implemented across all pieces/ categories of the data.

Across each of these methods, it will also be important to consider: i) the absolute scale of the payment, ii) the equity impact, and iii) the potential for cost pass-through in the form of higher prices for end-consumers and/ or businesses in the value chain.

The absolute **scale of payment** to the fund will create incentives and disincentives that should be considered when setting the charge. If the charge is linked to access to DSI and the scale of payment is set too high, then it may deter access and use of the data. Potential users will decide whether to access and use the data by comparing the cost and simplicity of access/ use (private costs) with the potential benefits that they will realise (private benefits). Therefore, if the charge is too high, such that it exceeds the potential benefits for users, it may discourage use, and stifle research and innovation. In addition, at a certain point the scale of the payment may encourage users to create alternative data sources or replicate existing data, to avoid the cost of access. This would lead to inefficiencies.

The principle of **equity** is a guiding design principle for the payment options. A flat fee, independent of user's income (or an organization's revenue or sales), could potentially be regressive. This means users with low incomes may pay proportionately higher rates as a percentage of their income, disproportionately affecting smaller organizations and therefore may be considered inequitable.

Cost pass-through is when businesses change the price of goods/ services they sell following an increase in the cost of producing them.[256] Whether a cost increase for organizations facing payment to the fund is passed on to consumers in full or in part, depends on factors including, but not limited to, competitive conditions and the expected consumer response. All else being equal, the more inelastic the demand (such that the quantity demanded of the relevant goods/ services is unresponsive to a change in price), the greater the likely extent of cost pass-through.

a) Trigger points

The payment into the fund could be required or 'triggered' at various points in the DSI value chain. Set out below is a summary assessment of these trigger points against the criteria (set out in section 7). The feasibility of using different methods for setting the potential payment (as described above varies depending on the trigger point for payment. An assessment of the feasibility of the different methods for different trigger points is also discussed below.

[254] What is the value of data? A review of empirical methods - Coyle - Journal of Economic Surveys - Wiley Online Library accessed 15 May 2024
[255] What is the value of data? A review of empirical methods - Coyle - Journal of Economic Surveys - Wiley Online Library accessed 15 May 2024
[256] Microsoft Word - 524 OFT Cost Pass-Through Final R.docx (publishing.service.gov.uk) accessed 15 May 2024

Trigger point at access to DSI

This option assumes that access to DSI triggers a requirement to share money into the global fund. Since the point of accessing DSI is relatively straightforward to identify, this option could provide certainty and legal clarity for all stakeholders. Identification of the point of access to DSI does not require track and trace, whereas identification of the point of use or commercialisation might (see section 10a on track and trace).[257] As such, implementation of access to DSI as a trigger point may be simpler, more efficient and practical than at the points of use or commercialisation, particularly if decoupled from the requirement to share benefits, and also therefore potentially more cost-effective.[258,259] However, information would need to be captured about those who access DSI in databases, which would require new systems to be implemented at the database level, which may involve additional administrative complexity and cost. [260] This option would also require cooperation of database operators across jurisdictions. In addition, some interviewees suggested that it is unclear what legal route could be taken to implement this trigger at the database level.

If this trigger is coupled with the requirement to immediately share monetary benefits (e.g. in the form of a fee) this may deter access. It is unclear however, the extent to which access may be deterred depending on whether the trigger is coupled with the requirement to share benefits or decoupled with the requirement to share benefits (i.e. benefits could be shared upstream of DSI generation, or downstream of use). Interviewees suggest that if this trigger is coupled with the requirement to immediately share non-monetary benefits (e.g. through a notification regarding opportunities for joint research partnerships) this may be costly, but perhaps less costly than the requirement to immediately share monetary benefits. However, if a party is accessing DSI to develop a new product/ service, it is likely that there are commercial sensitivities and potentially competitive considerations to sharing non-monetary benefits. It is therefore unclear whether the requirement to share non-monetary benefits would be more or less costly than the requirement to share monetary benefits.

If access to DSI is coupled with the requirement to immediately share monetary benefits (e.g. in the form of a fee) this may be inconsistent with the principle of open access to data and could have potentially adverse impacts on research and innovation, which some interviewees suggest may be inequitable. This option may also not support conservation and sustainable use of biodiversity to the degree other triggers could if access to DSI triggers the requirement to immediately share benefits. Scientists require open access to DSI to conduct research on biological diversity e.g. to fulfil the aims of the KMGBF and United Nations Sustainable Development Goals (see section 8c on research and innovation).[261,262,263] However, if the access trigger is decoupled from the requirement to share benefits, the impact on research and innovation may be less severe.

The extent to which a trigger linked to access to DSI is compatible with international legal obligations, is mutually supportive of other ABS instruments, and considers the rights of indigenous peoples and local communities, including with respect to the traditional knowledge associated with genetic resources that they hold, remains unclear.

If access to DSI is coupled with the requirement to pay into the fund, a cost-based approach to determining the payment amount is likely to be most feasible as the data will not yet have been used and hence the impacts of use not yet realised (which would be required for an income-based / externalities-based approach to be used). To determine a set access fee upfront, an estimation of the number of times the data will be accessed or downloaded and the volume of use over a specified time

[257] Paul Oldham and Jasmine Kindness2022 Sharing Digital Sequence Information. Study for the European Commission. doi: 10.5281/zenodo.655719

[258] Halewood, M., Bagley, M.A., Wyss, M. and Scholz, A.H., 2023. New benefit-sharing principles for digital sequence information. *Science*, *382*(6670), pp.520-522.

[259] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.

[260] Laird, S. and Wynberg, R., 2018, February. A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol. In *Montreal: Secretariat of the Convention on Biological Diversity* (pp. 2-79).

[261] https://www.un.org/sustainabledevelopment/blog/2021/07/a-new-global-framework-for-managing-nature-through-2030-1st-detailed-draft-agreement-debuts/ accessed 29 April 2024

[262] https://sdgs.un.org/goals accessed 29 April 2024

[263] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)

period, will be needed in order to estimate the cost of provision given that the fixed costs of provision would need to be allocated across expected accessors. Doing this may be challenging. Although a non-market-based approach to estimate payments may be feasible, e.g., using a WTP assessment, users may not fully understand the potential benefits for their research before using the data, and hence WTP is difficult to ascertain, with a risk to underestimate it.

Trigger point at use of DSI

This option assumes that the use of DSI triggers a requirement to share money into the global fund. There will likely be more benefits available to share at this stage in the value chain, compared to the point of access (but less than at the point of commercialisation), particularly in terms of non-monetary benefits such as research results. However, identification of the point of use of specific DSI may require track and trace (see section 8d). As such, implementation of use of DSI as a trigger point could be financially and administratively costly to implement and may be less feasible, less practical and less effective than at the point of access or unlinked to DSI, both of which are less likely to require track and trace of specific DSI. [264]

In addition, since the point of use of DSI is not straightforward to identify, this option may not provide a strong degree of certainty or legal clarity for stakeholders. If the use of DSI trigger is complicated to understand, and costly or cumbersome to comply with, this may disincentivise research and innovation linked to DSI. This could drive away users who are able to find a legal alternative to using the multilateral system e.g. by sourcing DSI from countries which have implemented national ABS measures (if they do not become incorporated into the multilateral mechanism).[265]

If this trigger is coupled with the requirement to immediately share monetary benefits (e.g. in the form of a payment) this could hinder research and innovation by virtue of the administrative and financial burden. However, the difference in the extent of the deterrence of use of DSI, depending on whether the trigger is coupled with the requirement to share benefits or not, is unclear.

Like the trigger at the point of access to DSI, it is unclear whether the requirement to share non-monetary benefits at the point of use would be more or less costly than the requirement to share monetary benefits, due to the potential commercial sensitivities around sharing non-monetary benefits. One interviewee suggested that for non-commercial users, the requirement to immediately share non-monetary benefits (e.g., in the form of a notification regarding opportunities for joint research partnerships) may be less costly than the requirement to immediately share monetary benefits.

It is important to consider the scope of DSI covered by the ‘use’ trigger and whether this would apply only to the case where DSI is contained in the final products/services, or the case where DSI is used in the research process. If the latter, this may include whole databases within the scope of the ‘use’ trigger. BLAST (Basic Local Alignment Search Tool) searches are the key bioinformatic tool for sequence comparison and retrieval from databases.[266] These searches are a basic requirement for DSI research, particularly during the early stages in the value chain.[267] Some interviewees noted that analysis of sequences can only be done by comparing them to all other DSI in the entire INSDC database (see section 8c).

Regardless of when the requirement to share monetary benefits is triggered (i.e. the trigger point), any requirement to make a payment may not be in line with the principle of open access to data and may also therefore hinder research and innovation. However, the degree to which research and innovation may be impacted may vary. All else being equal (including the level of payment), if the requirement to make payment is at an earlier stage of the research and innovation cycle (i.e. at the point of access or use) it might be more of a barrier to research and innovation, and especially early stage research which is by its nature more risky, compared to the requirement to make payment at a later stage (i.e.

[264] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[265] International Seed Federation (2015); https://www.fao.org/3/ca4962en/ca4962en.pdf accessed 29 April 2024
[266] Kerfeld, C.A. and Scott, K.M., 2011. Using BLAST to teach “E-value-tionary” concepts. *PLoS biology*, 9(2), p.e1001014.
[267] Laird, S. and Wynberg, R., 2018, February. A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol.

at the point of commercialisation) due to the benefits of the research and innovation already being generated (and risks being reduced).

If use of DSI is coupled with the requirement to pay into the fund, a cost-based approach to determining the payment amount is most likely to be feasible, as no income or externalities would yet have arisen from the use of the data to allow income or externalities-based approaches. A non-market-based approach may also be feasible e.g., through a WTP approach, given that users would have a better understanding at this point of the value they place on being able to use the data, compared to when they first access the data. However, as noted above, it is likely that significant uncertainty will remain over the commercial value associated with the use, particularly in early-stage research and innovation processes. Additionally, commercialization is not guaranteed at this stage of the value chain and may drive WTP estimates down. In addition, if the payment amount is only calculated at this point, then the uncertainty regarding the payment amount may deter use of the data or drive away users who are able to find a legal alternative to using the multilateral system.

Specific use case – micro-levy on the sequencing of genetic resources

It is useful to explore specific use cases to better understand the feasibility of this trigger point. For example, a levy could be applied for the sequencing of genetic resources.[268] This would cause no change to open access to DSI, and the income generation could be dissociated from access. Furthermore, this type of system could give scalability and offer better future proofing than other mechanisms. In addition, if this trigger is considered as the sole period relevant to fund generation, it could be more welcomed by industry versus others given a levy on a specific use case alleviates risk of double payment and could provide financial clarity with a consistent approach. By decoupling payments from the point of direct access to DSI and applying them to another, broader stage of the value chain, then free and open access to data is maintained and a stream of funds which is not only predictable, but potentially also significant, could be created.

However, both the literature and some stakeholders interviewed note that micro-levies require national legislation to implement and can be unpopular domestically.[269] Despite the potentially small individual cost, a high volume of research could still result in costs that are material for ongoing research efforts, particularly in low-income countries. When, and on what, the levy would apply across the whole lifecycle of 'use' could also be difficult to agree globally. If a definition on the scope of products or services to which a micro-levy applies is implemented only by some Parties, then there is a risk that jurisdictional shopping may develop.[270] There is also uncertainty over the reliability and scale of funds that could be derived from this use case. Whilst a deep pool of benefits is thought to be available, Scholz, et al., (2020) suggests that '*a micro-levy appears to work best if it is not adopted as the sole method to generate funds, but in combination with other policy options*.[271]

A separate option is to consider micro-levies on machinery such as NGS machines. At the point of writing, there are at least 1892 NGS machines in the world (notably with 90%+ in Northern America, Europe and Eastern Asia combined).[272] Of these, over 85% were listed as Illumina machines which cost between US$ 128,000 and US$ 654,000 (with costs for NGS machines generally ranging from US$ 80,000 to US$ 695,000).[273,274,275] It would be feasible to apply a levy over the purchase of these machines, although to understand the scale of revenue generated for the fund, a view would need to be

[268] Scholz, A. H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T., & Van Zimmeren, E. (2020). Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective. Accessed 30 April 2024

[269] Scholz, A. H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T., & Van Zimmeren, E. (2020). Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.

[270] Scholz, A. H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T., & Van Zimmeren, E. (2020). Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.

[271] Scholz, A. H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T., & Van Zimmeren, E. (2020). Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.

[272] NGS Mapped - Enseqlopedia. accessed 01 May 2024

[273] Quail, M. A., Smith, M., Coupland, P., Otto, T. D., Harris, S. R., Connor, T. R., ... & Gu, Y. (2012). A tale of three next generation sequencing platforms: comparison of Ion Torrent, Pacific Biosciences and Illumina MiSeq sequencers. BMC genomics, 13, 1-13.

[274] Quail, M. A., Smith, M., Coupland, P., Otto, T. D., Harris, S. R., Connor, T. R., ... & Gu, Y. (2012). A tale of three next generation sequencing platforms: comparison of Ion Torrent, Pacific Biosciences and Illumina MiSeq sequencers. BMC genomics, 13, 1-13.

[275] NGS Mapped - Enseqlopedia. accessed 01 May 2024

formed on the estimated number of new machines per year which could be partly informed through the growth rate which is identified as 10.3% and the percentage levy applied to each new machine.[276] However, in comparison to other mechanisms (such as commercialisation-linked mechanisms), levies on NGS machines is expected to contribute fewer funds. In addition, it is important to note that there is a risk that applying micro-levies on machinery may include machines which are used for unknown purposes e.g. research or patientcare.

Specific use case – patents

An alternative is for payments to be made at the point of applying for intellectual property protection associated with novel applications of DSI / inventions involving DSI.[277] Unlike with micro-levies on specific uses or actions related to DSI research, linking payments to patent application could offer a system linked to a well-established legal process with clearly identifiable points in the value chain. The recent WIPO agreement on the disclosure of origin of genetic resources in patents could be relevant to DSI where DSI is sequenced from the utilization of genetic resources.[278]

Like the application of micro-levies, this approach could be complicated by variations in patent law globally, which could make agreeing the specific points at which to require the sharing of benefits difficult. Some global sectors do not use patent processes at all and rely on industrial secrecy. Traceability of DSI use through patents could also be a challenge. For example, a lack of data regarding country of origin of the DSI might make the disclosure of geographical origin in some patents impossible. When the relevant information is available and included, the variety and volume of information that could be relevant could present operational complexities and have a high resource cost for tracing specific DSI use for a patent.[279] The reference and subsequent monitoring of DSI use in a patent in itself, and in the context of a placeholder term with no agreed definition (DSI) could represent a challenge. One significant unintended consequence might be the delay in granting patents due to the difficulty or impossibility to provide this data (i.e. the use of DSI) in the patent application.

Fundamentally, the existence of a patent does not necessarily indicate any current (or future) financial value associate with DSI. All patent applicants pay the same fees regardless of subsequent revenue. As such, linking of payments to the IP system may not be feasible, because patents are not always associated with the generation of revenue. To mitigate this, the benefit-sharing obligation could be triggered when a patent is registered, but only enforced after the successful commercialisation of the product or service, including licencing, developed using DSI.[280] However, there is limited certainty that such mitigations would ensure specific uses such as this (patents) are pursued. Similar to the micro-levies, Smith., et al (2020) suggests that *"this option may need to be combined with other potential measures for accrual of funds to ensure such stability"*.[281]

Finally, royalties could also be a point of revenue in relation to patents. Interviewees suggested it is important to have clear, standard terms and definitions of triggers and fees to promote compliance and legal certainty. [282]

Estimating potential revenue generated for the global fund through a fee on patents linked to DSI

Akin to micro-levies applied to the use of DSI, there is a lack of clarity on the relative financial contribution that could be derived from a patent-based 'use of DSI' mechanism, given the uncertainty over the number of patents that are or will be registered and involve use DSI.

Table 7 below illustrates the range of potential revenue that could be generated for the global fund annually through the application of a fee per patent (ranging from $100 to $5000) applied at the point of patent registration. The patent fees shown are illustrative only and are not examples of existing

[276] https://www.medicaldevice-network.com/analyst-comment/ngs-ivd-market-growth/
[277] C Seitz (2020), Digital sequence information – legal questions for patent, copyright trade secret protection and sharing of genome sequencing data, https://iopscience.iop.org/article/10.1088/1755-1315/482/1/012002/pdf) Accessed 3rd May
[278] WIPO Member States Adopt Historic New Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge accessed 12 July 2024
[279] Oldham, P. (2020). Digital Sequence Information - Technical aspects. Zenodo (CERN European Organization for Nuclear Research). https://doi.org/10.5281/zenodo.7323632 Accessed 01 May 2024
[280] https://www.cbd.int/doc/c/2e3e/f4c0/1d7922921540d01f0c45fd84/wg2020-05-crp-07-en.pdf Accessed 29 April 2024
[281] Smith, E., Switzer, S. and Morgera, E., 2020. Digital Sequence Information: An Evidence Review. https://strathprints.strath.ac.uk/77801/1/Smith_etal_ICF_2020_Digital_sequence_information_an_evidence_review.pdf Accessed 01 May 2024
[282] Vogel, J.H., Ruiz Muller, M., Angerer, K., Delgado-Gutiérrez, D. and Gálvez Ballón, A., 2022. Bounded openness: A robust modality of access to genetic resources and the sharing of benefits. *Plants, People, Planet*, *4*(1), pp.13-22.

patent fees. The estimates of the annual numbers of patents registered are based on publicly available data that best matches the definition of the sectors under consideration. As with other fund generating options explored in this study, estimating the revenue attributable to patents derived from DSI is challenging and would either require track and trace or a mandatory disclosure at registration. As such, the potential revenue that could be generated for the global fund is illustrated for two scenarios, assuming i) 10% and ii) 50% of patents are derived from DSI. In addition, the numbers of patents below may include those linked to human and non-human DSI. The analysis presented is for illustrative purposes of the potential revenue that could be generated, in the absence of data on patents generated per sector derived from use of DSI.

Table 7. Estimated annual funding that could be generated at the point of patent registration per sector (assuming 10% or 50% of patents are attributable to DSI).

		Assumed proportion of patents derived from DSI (Millions of US$)					
		10%			50%		
Sector	**Annual number of patents registered (000s)**	**$100 fee**	**$1000 fee**	**$5000 fee**	**$100 fee**	**$1000 fee**	**$5000 fee**
Pharmaceutical	240 [283]	2.40	24.00	120.00	12.00	120.00	600.00
Cosmetic	29[284]	0.29	2.85	14.26	1.43	14.26	71.31
Plant and animal breeding and agricultural biotechnology	119[285]	1.19	11.86	59.29	5.93	59.29	296.44
Laboratory equipment associated with the use of DSI	9[286]	0.09	0.90	4.50	0.45	4.50	22.50
Information, scientific and technical services related to DSI	9[287]	0.09	0.90	4.50	0.45	4.50	22.50

Notes: The bioinformatics market, which includes hardware and software, registered 18,000 patents in 2022.[288] As this data is not disaggregated between hardware and software, it has been assumed that 50% of these patents relate to software and are therefore relevant to the information, scientific and technical services related to DSI sector, and 50% relate to hardware and are therefore relevant to the laboratory equipment associated with the use of DSI sector.

Trigger point at commercialization of DSI

This option assumes payment is triggered by selling products or services which contain DSI, involved the use of DSI in their development, or benefited from the use of DSI. Additionally, but separately, this option also considers a potential broader scope in terms of products or services which contain biodiversity (biodiversity-based products / services), or which involved or benefited from the use of biodiversity in their development. It should be noted that the mandate of the CBD may potentially

[283] Patent activity in the pharmaceutical industry decreased in Q1 2024 (pharmaceutical-technology.com) taken by multiplying global Q1 pharmaceutical patents by 4.
[284] https://www.just-drinks.com/dashboards/patents/patent-activity-consumer-industry/#:~:text=Most%20patenting%20activity%20has%20been,(2840%2C%20down%2015%25). Total of cosmetics & toiletries and skincare segments (Q3 data) multiplied by 4
[285] https://www.researchgate.net/publication/377813842_Trends_and_Patterns_of_Patent_in_Agriculture_and_Allied_Sector Total of patents filed in animal husbandry, new plants and horticulture categories
[286] https://www.mathys-squire.com/insights-and-events/news/the-rise-of-bioinformatic-related-patents-in-a-data-driven-world/ accessed 01 May 2024
[287] https://www.mathys-squire.com/insights-and-events/news/the-rise-of-bioinformatic-related-patents-in-a-data-driven-world/ accessed 01 May 2024
[288] https://www.mathys-squire.com/insights-and-events/news/the-rise-of-bioinformatic-related-patents-in-a-data-driven-world/ accessed 01 May 2024

limit the inclusion of all biodiversity-based products, but that does not preclude proposals that consider this scope. The basis here is that commercialisation of products or services involving DSI triggers a requirement to share money into the global fund.

Identification of the point of commercialization of DSI may require track and trace which could be financially and administratively costly to implement.[289] However, this requirement may depend on the fund generating measure implemented. If a measure is not tied to the specific DSI used (e.g. 1% levy on biodiversity-based products) then track and trace may not be required, although an understanding of which products are derived through biodiversity would still be needed. If, however, a measure is tied to the DSI used, then track and trace would likely be required (see section 10a on track and trace). As such, implementation of commercialisation of DSI as a trigger point may be less efficient, less feasible, and less practical compared to the access to DSI trigger or those unlinked to DSI which would likely not require track and trace.

Since the point of commercialization of DSI is not straightforward to identify when linked to the specific DSI used, this option may not provide certainty or legal clarity. This could drive away users who are able to find a legal alternative to using the multilateral system.[290] On the other hand, if a track and trace system is not required (when commercialisation is considered based on products / services unlinked to the specific DSI used), this option is more likely to provide certainty and legal clarity.[291]

The benefit realised from DSI at the point of commercialisation is likely to be greater than at the stages of access or use of DSI, due to the fact that there is a monetary benefit realized for those who successfully commercialise their research. As such, there may be the potential to share and hence generate more benefits, including both monetary and non-monetary, at this stage. However, fewer parties will be in scope of making a payment at the point of commercialisation, compared to at the point of access or use, as only a proportion of users of DSI will be successful in commercialisation of their research. Therefore, to achieve the same level of fund contribution, each party in scope of making a payment at the point of commercialisation would have to pay more, compared to at the point of access or use (where there will be more parties in scope of making payment).

If coupled with benefit sharing, commercialisation of DSI as a trigger would be less likely to hinder research and innovation, particularly early-stage research, than the access trigger.[292] Similarly, only entities that generate financial reward from DSI may be within scope of the requirement to pay into the fund. However, there would still be some degree of impact given that the potential benefit sharing at commercialisation stage would still have to be factored into decision making over research and innovation projects that use DSI. In addition, if the commercialisation of DSI trigger is complicated to understand / identify and implement, and overly costly or complicated to comply with, this may disincentivise research and innovation linked to DSI to a degree. In the case of commercialization unlinked to DSI, this is less likely.

If payment into the fund is required at commercialisation stage, an income-based approach to determining the payment amount would be feasible, as the additional revenue from the use of data would start to be realised. An income-based approach is most feasible when applied retrospectively given the difficulties in predicting additional revenue from the use of data. It would also be possible to use a cost-based approach or non-market-based approach at this point, noting the considerations discussed above.

There are several areas that need to be developed in detail to assess the scale of potential revenue associated with a commercialisation trigger (or at some point after commercialisation). For example, whether contributions triggered by commercialisation would be required from all products that have used DSI, or biodiversity or whether this is triggered only over certain thresholds. For example, under

[289] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[290] International Seed Federation (2015); https://www.fao.org/3/ca4962en/ca4962en.pdf accessed 29 April 2024
[291] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[292] Rourke, M., Eccleston-Turner, M., Phelan, A. & Gostin, L. Policy opportunities to enhance sharing for pandemic research. Science 368, 716–718 (2020)

the current Brazilian system's approach, benefit sharing is only triggered if access to genetic resources or DSI has added a large amount of value to the final product. There may conceivably be different commercialisation fees for different products, different sectors as well as different countries with different levels of development. However, it is important to note that calculating benefits that should be shared based on DSI involvement may be impractical and costly. Indeed, Halewood et al., (2023) suggest that '*benefit-sharing should be calculated at an aggregate level'*.[293]

Indicative example of commercialisation-based fee

A royalty fee could be applied to revenue or profit (see also in section 8). The exact percentage of these royalties could vary depending on sector, business size, location or other factors.[294]

Some interviewees indicated that whilst the scope of products and percentage royalties are not easy to determine, agreement on scope would support clarity for implementation. For example, a requirement to pay 0.01% on sales of a rare, blockbuster invention, often understood as a product with annual sales of US$1 billion, would generate US$100,000.[295] Transaction costs would also need to be accounted for. Lessons can also be learned from the International Treaty on Plant Genetic Resources for Food and Agriculture's multilateral ABS system which mandates that commercial users make payments to a fund from the sale of new products if such products are not then made available for further research and breeding.[296] As Halewood et. al (2023) note, "*to date, few commercial users have triggered this benefit-sharing obligation and made royalty payments".* Potential reasons include '*the slow speed of plant breeding, the availability and type of material, alternative sources of materials, the avoidance of Multilateral System of Access and Benefit-sharing material, the imbalance of payment rates between options, and transaction costs for receivers'*.[297] Whilst some seed industry companies and associations have made voluntary contributions to the fund, in general '*few companies have been willing to contribute in the absence of a requirement for others to make such payments, for fear of reducing their competitiveness'*.[298]

Market entry points are diverse but finite within sectors and as such regulatory oversight of many of these types of products could offer checkpoint opportunities.[299] Interviewees did note however that it is important to have clear, standard terms and definitions of triggers and fees to promote compliance and legal certainty.

Specific mechanism – milestone payments

One mechanism that could be utilised across commercialisation triggers (as well as others) is milestone payments. Milestone payments, as with other measures related to commercial success of products / services and associated with licenses, are viewed by some interviewees as having good potential for fund contribution. This is linked to their association with the later parts of the value chain where the financial value of products/services associated with DSI is expected to be greater. It is expected that if a product / service is not commercially successful and does not generate revenue (potentially above an agreed threshold), there would be no requirement to pay the milestone payment. As such, some interviewees suggest that this type of measure could generate large amounts of revenue for the fund, whilst potentially targeting only those entities that benefit from the use of DSI. Clarity in terms of definition of milestones and their payments has been noted as important in the context of the Nagoya Protocol.[300] Whether track and trace is required for milestone payments will depend on the specific milestone the payment relates to, and whether identifying attribution to DSI is needed.

[293] Halewood, M., Bagley, M. A., Wyss, M., & Scholz, A. H. (2023). New benefit-sharing principles for digital sequence information. Science, 382(6670), 520-522.
[294] Oliva, M. J., & Rukundo, O. (2018). A Guide to Intellectual Property Issues in Access and Benefit-Sharing Agreements (Vol. 1052). WIPO. A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements (wipo.int) Accessed 1 May 2024
[295] Vogel, J.H., Ruiz Muller, M., Angerer, K., Delgado-Gutiérrez, D. and Gálvez Ballón, A., 2022. Bounded openness: A robust modality of access to genetic resources and the sharing of benefits. *Plants, People, Planet*, *4*(1), pp.13-22.
[296] Halewood, M., Bagley, M. A., Wyss, M., & Scholz, A. H. (2023). New benefit-sharing principles for digital sequence information. Science, 382(6670), 520-522.
[297] CBD/WGDSI/1/2/Add.2/Rev.1 Executive summary of the compilation of lessons learned from other international funding mechanisms (cbd.int) accessed 13 July 2024
[298] CBD/WGDSI/1/2/Add.2/Rev.1 Executive summary of the compilation of lessons learned from other international funding mechanisms (cbd.int) accessed 13 July 2024
[299] https://www.dsmz.de/fileadmin/user_upload/Presse/WiLDSI_scenarios_DSI_Brussels_March10-11.pdf Accessed 02 May 2024
[300] https://www.cbd.int/doc/c/6920/4e1e/8a6ba925279ea19033eb8ed2/sbstta-26-inf-12-en.pdf Accessed 01 May 2024

Unlinked to the specific use of DSI

This option assumes that other activities / events (unrelated to the access, use or commercialisation of DSI), unlinked to specific DSI, would trigger a requirement to share money into the global fund. For example, if a levy on commercialisation was applied to an entire sector, or a proportion of it, then it would not be linked to any specific activity, use, or product commercialisation, but rather to a recognition that the sector benefits from DSI.

Voluntary contributions are another example of a trigger unlinked to the use of DSI. Survey respondents generally agreed that this trigger met the criteria of decision 15/9 to a greater degree than triggers linked to access or use of DSI (see **Figure 13**). The effectiveness, efficiency, feasibility and practicality of a trigger unlinked to a specific use of DSI is difficult to predict and will depend on the specific option implemented, any alternative triggers, which stakeholders would pay (users of DSI or broader scope), when and how much. Whilst solely voluntary 'donations' are difficult to predict, voluntary contributions (at a level agreed by COP) applied to entire (sub-)sectors could be much more predictable.

It is important to note these unlinked trigger points have the advantage of not requiring track and trace of DSI and presenting potentially less administrative burden for users compared to other triggers since it is not linked to them or their activities. This may help to keep costs of implementation down. However, there is a risk that if a trigger point is unlinked to DSI, e.g. voluntary contributions, this may provide limited certainty (see section below on voluntary contributions) in terms of the potential revenue generated for the fund.[301]

A trigger unlinked to DSI may be seen to be more consistent with the principle of open access to data, than a trigger linked to DSI. However, as discussed previously, any requirement to make a payment, regardless of where the requirement is, may hinder research and innovation. In turn, this may impact conservation and sustainable use of biodiversity.[302]

If payment is unlinked to the use of specific DSI, a cost-based or externalities-based approach is likely to be most feasible for calculating the potential payment into the fund. A non-market-based approach using WTP or willingness to accept methods are unlikely to be feasible as the payment is not related to access or use. An income-based approach is also unlikely to be feasible as this method focuses on measuring the additional revenue or cost saving generated from the use of the data which may not be relevant or may be very difficult to determine at the sector or sub-sector level.

Estimate of revenue generated for the global fund based on a levy on annual sector revenue or annual net profit – unlinked to the specific use of DSI

Table 8 below illustrates the scale of revenue that could be generated for the global fund through a levy on total 2024 and 2030 sector revenues across the sectors considered in the study, or a levy on net profit based on an assumed 12.5% average net profit margin. As shown, to generate a fund contribution of ~$10 billion in 2024, a levy on sector revenue of (~ 0.64%) or on net profit (~5.13%) would likely be required.

Table 8. Illustrative contributions to the global fund based on sector revenue or net profit (2024 and 2030).

Illustrative contributions to global fund based on sector revenue	**US$ bn, 2024**	**US$ bn, 2030**	**Illustrative contributions to global fund based on sector net profit**	**US$ bn, 2024**	**US$ bn, 2030**
Total revenue across relevant sectors	1559.77	2330.67	Total net profit across relevant sectors (assuming average 12.5% net profit margin)	194.97	291.33
Global fund contributions (US$ bn) generated assuming levy on sector **revenue** of:			Global fund contributions (US$ bn) generated assuming levy on sector **net profit** of:		

[301] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.
[302] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)

0.10%	1.56	2.33	1.00%	1.95	2.91
1%	15.60	23.31	10%	19.50	29.13
0.64%	10.00	14.94	5.13%	10.00	14.94
1.28%	20.00	29.88	10.26%	20.00	29.88

Note: Net profit was indicatively estimated assuming a 12.5% average net profit across the sectors. However, it should be noted that the figures are indicative only as research suggests that this average net profit percentage varies between and within the sectors under consideration. It has not been possible to identify net profit estimates for each sector.

Tables 9 and 10 below show the potential contributions per sector considered in this study for 2024 sector revenues and net profits.

Table 9. Illustrative contributions to the global fund based on annual revenue per sector (US $bn 2024).

		Percentage levy on sector revenue						
Sector	**Revenue US$ bn**	**0.10%**	**0.25%**	**0.50%**	**0.64%**	**1.00%**	**1.28%**	**2.00%**
Pharmaceutical	593.24	0.59	1.48	2.97	3.80	5.93	7.61	11.86
Cosmetics	333.90	0.33	0.83	1.67	2.14	3.34	4.28	6.68
Plant and animal breeding and agricultural biotechnology	581.62	0.58	1.45	2.91	3.73	5.82	7.46	11.63
Laboratory equipment	43.36	0.04	0.11	0.22	0.28	0.43	0.56	0.87
Information, scientific and technical services related to DSI	7.65	0.01	0.02	0.04	0.05	0.08	0.10	0.15
Total global fund contributions generated	**1559.77**	**1.56**	**3.90**	**7.80**	**10.00**	**15.60**	**20.00**	**31.20**

Note: as outlined in section 6, figures used for laboratory equipment are not assumed to be specifically related to DSI, as this information is not available. Computational biology is used as a proxy for the Information, scientific and technical services related to DSI.

Table 10. Illustrative contributions to the global fund based on annual net profit per sector (US $bn 2024).

		Percentage levy on sector net profit						
Sector	**Net profit US$ bn**	**1.00%**	**2.00%**	**4.00%**	**5.13%**	**8.00%**	**10.26%**	**16.00%**
Pharmaceutical	74.16	0.74	1.48	2.97	3.80	5.93	7.61	11.86
Cosmetics	41.74	0.42	0.83	1.67	2.14	3.34	4.28	6.68
Plant and animal breeding and agricultural biotechnology	72.70	0.73	1.45	2.91	3.73	5.82	7.46	11.63
Laboratory equipment	5.42	0.05	0.11	0.22	0.28	0.43	0.56	0.87

		Percentage levy on sector net profit						
Information, scientific and technical services related to DSI	0.96	0.01	0.02	0.04	0.05	0.08	0.10	0.15
Total global fund contributions generated	**194.97**	**1.95**	**3.90**	**7.80**	**10.00**	**15.60**	**20.00**	**31.20**

Note: Net profit was indicatively estimated assuming a 12.5% average net profit across the sectors. However, it should be noted that the figures are indicative only as research suggests that this average net profit percentage varies between and within the sectors under consideration. It has not been possible to identify net profit estimates for each sector.

As outlined in section 6, figures used for laboratory equipment are not assumed to be specifically related to DSI, as this information is not available. Computational biology is used as a proxy for the Information, scientific and technical services related to DSI.

Speculative use case – 1% levy on sale of products

The African Group proposed a 1% levy on the commercial sale of products developed using DSI or the use of biodiversity. This is a 1% levy of the retail price of commercial sale of products developed from either the use of DSI, or the use of biodiversity. Some interviewees noted that this was an equitable way of generating funds as it targets revenue generating entities whilst maintaining free and open access to data. Interviewees also suggest that by decoupling access from immediate benefit sharing there would be no need for tracking and tracing of DSI which would limit the additional administrative burden applied to researchers in academia and industry.[303] Interviewees suggest that if a track and trace system is not required, this option could be effective, efficient, feasible and practical. Instead, the levy could be applied to a sector, or an agreed subsection of it. Some even suggest that the 1% levy be applied to entire sectors rather than products or services, further simplifying implementation. However, depending on what products / services are defined as 'in scope' for the 1% levy, an element of tracing may be needed as organizations could still be required to understand which products are derived from biodiversity (albeit this will likely be far simpler than tracing specific DSI).

The impact on research and innovation will depend on the impact on business profits. If businesses face an increase in costs, in the form of the suggested levy on product sales, they can either absorb the cost or pass it on, in part or in full, to customers. Either way, it is likely to reduce business profits either directly by increasing costs, or indirectly through reducing sales, and therefore have a knock-on impact on investment, including in research and innovation.

The 1% levy could generate generally predictable benefits, although the 1% value of the tax or levy could be disputed as to the economic rationale for 1% rather than any other value.[304] In addition, this option would require buy-in by the retail sector and by governments and may be unevenly implemented globally as a result.

The feasibility, effectiveness and clarity of this option will likely depend on the how this is implemented e.g. who would collect the levy (retailers, distributors or companies), how the products of DSI/biodiversity would be decided, the time at which the levy would apply (/at what specific point in the value chain), the percentage rate applied and whether this rate should be universally applied to all consumers.

Speculative use case – government contributions

A separate mechanism that is unlinked to the use of DSI is government contributions. This system puts payment obligations on governments and may be based on national gross domestic product or other agreed-upon formula.[305]

[303] https://www.cbd.int/doc/c/0c79/5954/8ec6714d513ecbd570c0b062/wg2020-05-inf-01-en.pdf accessed 01 May 2024

[304] Klünker, I., & Richter, H. (2022). Digital Sequence Information between Benefit-Sharing and Open Data. Journal of Law and the Biosciences, 9(2), lsac035.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9682569/ accessed 01 May 2024

[305] https://www.cell.com/molecular-plant/fulltext/S1674-2052(21)00080-0?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1674205221000800%3Fshowall%3Dtrue accessed 01 May 2024

This system allows for the decoupling of access from payment into a fund, maintaining free and open access for promotion of research and innovation, and provides a stable and predictable funding source that can underpin other more variable income streams. Depending on the formula utilised, government contributions pose the potential to contribute a large amount of funds.

One publication suggests that government payments could be coupled with access to DSI, where governments would make direct payments to a central fund to allow citizens to access the sequence data openly and freely.[306] This may reduce transaction costs for users, increase certainty and facilitate access. For example, for at least 12 consecutive years, Norway has contributed annually to the benefit sharing fund of the International Treaty on Plant Genetic Resources for Food and Agriculture at the level of 0.1% of the value of annual seed and plant material sales in their national agricultural sector.[307] The Consultative Group for International Agricultural Research recommends that contracting Parties make annual payments to the International Treaty on Plant Genetic Resources for Food and Agriculture's benefit sharing fund based on seed sales within their jurisdictions (like the Norway levy), utilise a fixed royalty rate that corresponds to the value of access to, and use of, both plant genetic resources for food and agriculture and DSI.[308] Parties would then have the option to recoup a portion of that levy payment from commercial users in their jurisdictions.[309,310]

To keep transaction costs at a sustainable level, national governments could agree to make payments, with the option to collect contributions from users in their jurisdictions based on a 'nationally appropriate' formula, at their discretion. Following this approach, the 'trigger point' for payment would be the date upon which contributions from national governments to the fund are due. This approach would not require any tracking or tracing of any use of DSI and would potentially lead to a predictable flow of income to the fund, and not burden commercial users. Since payments would be made by Parties, there would be no need to monitor commercialising entities, no centralised system for monitoring, and all companies would be on the same level-playing field.

However, several interviewees suggested that they do not view government contributions as the most optimal fund generating option and suggest that users of DSI should be responsible for contributing to the global fund. Additionally, further clarification on potential formulas would be required to understand the likely scale of contributions for this modality. Interviewees expressed scepticism with regards to relying on government contributions, arguing it may lead to conflicts between public and private interests, where public funds support private gains.

Separately, governments already receive many competing demands for funding, and this additional demand could possibly have a proportionally more negative affect on lower-income countries than others. In addition, the willingness and ability of governments to pay contributions is dependent on political will and economic stability, which may fluctuate.

A donation-based approach would not require trigger points at all (see section d below)

b) Payment methods

For each of the trigger points there are several payment related considerations regarding practicalities around payments as well as their potential scale.

Fee to access DSI and / or related information

This option assumes that access to DSI and / or related information involves the requirement to pay a fee. This may involve a fee to download individual sequences or could involve a membership fee /

[306] https://www.cell.com/molecular-plant/fulltext/S1674-2052(21)00080-0?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1674205221000800%3Fshowall%3Dtrue accessed 01 May 2024

[307] https://www.fao.org/3/ca8154en/ca8154en.pdf accessed on 15 May 2024

[308] Ebert, A. W., Engels, J. M. M., Schafleitner, R., Hintum, T. V., & Mwila, G. (2023). Critical Review of the Increasing Complexity of Access and Benefit-Sharing Policies of Genetic Resources for Genebank Curators and Plant Breeders-A Public and Private Sector Perspective. Plants (Basel, Switzerland), 12(16), 2992. https://doi.org/10.3390/plants12162992 accessed 02 May 2024

[309] Hamilton, R.S., Halewood, M., López Noriega, I., Rouard, M., Tiambo, C.K., Azevedo, V., Bhattacharjee, R., Cuéllar, W.J., Gisel, A., Hearne, S.J. and Heider, B., 2022. Digital sequence information is changing the way genetic resources are used in agricultural research and development: implications for new benefit-sharing norms.

[310] Ebert, A. W., Engels, J. M. M., Schafleitner, R., Hintum, T. V., & Mwila, G. (2023). Critical Review of the Increasing Complexity of Access and Benefit-Sharing Policies of Genetic Resources for Genebank Curators and Plant Breeders-A Public and Private Sector Perspective. Plants (Basel, Switzerland), 12(16), 2992. https://doi.org/10.3390/plants12162992 accessed 02 May 2024

subscription to access DSI in databases / cloud-computing spaces.[311,312] Survey respondents noted the lack of clarity surrounding the scope of 'related information', and that there could be different considerations depending on the extent of the scope.

Assuming that a route to implementation of an access fee is found, potentially in collaboration with databases, implementation of a fee to access DSI and / or related information may be simpler and more efficient than other payment options. It remains unclear whether the costs associated with implementing an access fee would be more cost-effective than some other payment options which, unlike an access fee, may require implementation of costly track and trace systems (see section 10d on track and trace).[313] A fee to access DSI and / or related information may not necessarily be mutually supportive of other ABS instruments as there is a risk of double payment (stacking), particularly for users in the agricultural / seed sector who frequently use DSI in combination with genetic resources.[314] However, this same consideration applies to all payment options.[315]

To understand the possible scale of revenue that could be generated, it would be necessary to understand the appetite of current database providers to implement fees for access/ use of databases, along with a forecast of expected numbers of users once a paywall is introduced. There is a possible risk that in the absence of major policy changes in some jurisdictions, free databases will continue to exist. For example, DSI could potentially be drawn from 'paid for' databases and then be made freely available to others via the free databases.

Overall, stakeholder consultation and the literature review suggest that an access fee would be costly in terms of the finances and administrative requirements to set up and manage the system and in terms of the impact on open access to databases and knock-on effect for research and innovation (see section 10b on open access to data and section 10c on research and innovation). Some stakeholders felt that this payment option is likely to create an ineffective, impractical and undesirable DSI landscape.[316] However, it may provide a secure source of funding.

Estimating revenue generatable through a membership fee / subscription to access DSI in databases / cloud-computing spaces

Oldham and Kindness (2022) examined the potential scale of funds that could be generated by a cloud computing subscription-based model of users of DSI, as shown in **Table 11**.[317]

Table 11. Indicative estimates of potential revenue that could be generatable from a cloud computing subscription-based model of DSI.

DSI user number assumption	User count per year (millions)	Daily per user fee ($)	Yearly revenue ($bn)
ELIXIR 2019	2.867	0.1	0.07
	2.867	1	0.69
NCBI 2018	4.500	0.1	0.11
	4.500	1	1.08
GenBank (Rohden et al 2019)	5.800	0.1	0.14
	5.800	1	1.39
INSDC median (Rohden et al 2019)	12.500	0.1	0.30
	12.500	1	3.00
	500.000	0.1	12.00

[311] https://www.cbd.int/abs/DSI-webinar/DSIPolicyOptions2021.pdf

[312] Scholz, A.H., Hillebrand, U., Freitag, J., Cancio, I., dos S. Ribeiro, C., Haringhuizen, G., Oldham, P., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective. WILDSI

[313] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.

[314] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.

[315] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.

[316] Scholz, A.H., 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), p.giab085.

[317] Oldham, P., & Kindness, J. (2022). Sharing digital sequence information. In Zenodo (CERN European Organization for Nuclear Research). https://doi.org/10.5281/zenodo.6557191. Accessed 29th April 2024

Global (Rohden et al 2019)	500.000	1	120.00

When considering the potential revenue estimates set out in **Table 11**, it is important to note that the authors acknowledge several issues with the user data. These include reliability concerns over using IP addresses to equate to unique user access, general lack of public data and the use of rough estimates by the underlying external sources. Stakeholders interviewed as part of this study also highlighted the difficulty in estimating the number of users. They highlighted that underestimations of the number of users can occur as many cross-sector companies use gateway IP addresses to cloak the actual number of users and pharmaceutical companies are known to regularly download the entire dataset so as not to leave a trace of their target genes or proteins. Equally, using IP addresses may overestimate the number of unique users as singular users can access databases using multiple addresses.

Overall, Oldham and Kindness note that the potential revenue generated by a subscription model underpinned by charges on users is not trivial (and within the context of the cloud computing scope detailed in the article), but also highlight that estimated revenue is not necessarily representative of the potential full scale of revenue that could be generated from DSI.

Based on more up to date data derived from the EMBL-EBI's database, which received 107 million requests a day for access to data from 41 million unique IP addresses in 2022, potential yearly revenue generatable for the fund could be in the range of the below, with the same assumptions as per Oldham and Kindness' study (i.e: based on a daily charge for each of an assumed 240 working days per year):[318]

DSI user number assumption	User count per year (millions)	Daily per user fee ($)	Yearly revenue ($bn)
EMBL-EBI	41	0.1	0.98

Estimating revenue generated through a fee to download individual sequences

It is difficult to estimate the revenue that could be generated by charging a fee based on the number of downloads of individual sequences due to the lack of reliable data on the volume of downloads. Data on downloads is only available for the INSDC. **Table 12** below illustrates the potential revenue that could be generated for the global fund through a fee on downloads, using the INSDC as an example, for which there were 34 million annual downloads in 2020.[319] In line with Oldham and Kindness' review, a levy of $0.1 and $1 per download has been assumed.

This is an illustrative estimate of the potential revenue generatable and should not be considered an estimate for all databases potentially containing accessible and downloadable DSI.

Table 12 Estimated revenue generatable for the global fund based on a fee on downloads of DSI from INSDC.

DSI user number assumption	Estimated no. of downloads per year (millions)	Fee per download ($)	Yearly revenue ($bn)
INSDC	34.0	0.1	0.003
	34.0	1	0.034

Payment or levy on products or services associated with use of DSI (lab equipment and IT)

This option assumes a requirement to make payment for products / services associated with use (and potentially generation) of DSI. This could separate and decouple access to DSI from the payment. This could be implemented by introducing a charge either upstream (e.g. for DNA sequencing) or downstream (e.g. for software to analyse or store DSI) from access.

This option would require national legislation to implement and may be unpopular domestically. Implementing national legislation may take some time and therefore revenue into the fund may not be

[318] https://www.embl.org/documents/wp-content/uploads/2023/06/EMBL-EBI-highlights-2022-digital.pdf Accessed 29 July 2024

[319] Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation (nature.com) accessed 03 July 2024

realised in the immediate term.[320,321,322] In addition, companies may choose not to use such services, or to use them to a minimal extent. Similarly, levies may limit capacity of users in certain jurisdictions due to financial resource constraints.

Receipt of payment for products / services associated with use (or generation) of DSI could provide certainty in terms of ensuring compliance.[323] Legal clarity will depend on a clear understanding of the scope of products / services (e.g. lab reagents, equipment, cloud-computing space) that this option may encompass.
This option would require a system to identify where genetic resources are sequenced, or where it is used, which could potentially be costly.

Income-based payments

There are various income-based payment approaches that are considered below; specifically, payments based on a percentage of turnover, sales or profit (as defined in the glossary). Across each of these options a key challenge will be determining the amount of turnover, sales, or profit that can be attributed to the use of the DSI, compared to other contributing factors. It is likely to be highly complex and difficult to attribute a proportion of turnover, sales or profit to specific DSI inputs but taking a broader approach based on turnover, sales or profit of all products/services containing the use of any DSI would fail to capture:

- the complexity of the research and innovation process,
- the value added to the data inputs by the organization using it, and
- the multiple other inputs, processes and innovation contributing toward the turnover generated

In addition, it will be necessary to determine who should undertake the assessment of attribution – whether it should be done by users themselves or independently, and at what geographical level – global, regional or national.

Percentage turnover of DSI products / services

Any reporting of turnover is highly unlikely to be at the product / service level and would not attribute a specific share, or level, of turnover to DSI access / use specifically. Identification of the turnover of products / services associated with the use of DSI may therefore require implementation of a track and trace system, which would be costly. However, this may depend on the scope of DSI products / services considered (see section 11c Scope of Products below). For example, if the percentage turnover is applied to a category of products / services or a sector (i.e. broader than application to products / services containing DSI), track and trace may not be required. This may therefore be more feasible and more practical to implement.

Since the point of use of DSI is not straightforward to identify, this option may not provide a strong degree of certainty or legal clarity for stakeholders. This is particularly true at the global level, for example if a single product is manufactured and commercialised by different legal entities in different legal jurisdictions.

A payment based on the percentage of turnover of DSI related products/ services may also have significant impacts on innovation (as discussed in section 8c). This is because adding a charge on the turnover associated with DSI related products, reduces the benefits of the research/ innovation activity and therefore lowers the rate of return, potentially reducing research/ innovation activity with a loss of the benefits to society that result from that activity. It could also have wider spill-over impacts to society, especially if costs are passed through to consumers (as discussed in section 11a) - this would increase prices and therefore reduce demand (at least to some extent depending on the elasticity of demand i.e. how responsive demand is to a change in price) and therefore reduce the benefits

[320] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[321] Oldham, P. and Kindness, J. (2022) 'Sharing Digital Sequence Information', Zenodo (CERN European Organization for Nuclear Research) [Preprint]. Available at: https://doi.org/10.5281/zenodo.6557191 accessed 04 April 2024
[322] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[323] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective

associated with these products/ services. Since the scope of turnover is broader than sales or profit (per the glossary definitions in this report), if the same percentage is set across each of these options, all else being equal using turnover may generate more money for the fund.

Percentage sales of DSI products / services

Further clarification is needed as to how this payment method would work in practice.

If a payment is based on the percentage of sales (i.e. which captures the value derived from the sales of products/ services and not other income) then the same considerations as detailed above under a payment based on a percentage of turnover would still apply.

If instead the payment is based on the volume of sales (i.e. the quantity of products/ services sold), the payment could be a flat fee charged per unit sold where the product/ service developed can be attributed to the DSI. However, it is likely to be very complex to determine whether a product/ service can be attributed to the use of DSI in a binary way, given the other factors contributing to the product/ service development process. Even if this was possible, determining the appropriate flat fee would be challenging. In addition, a flat fee may be considered inequitable because it does not take into account users' ability to pay.

It is too early to consider the extent to which option meets the other criteria.

Percentage profit of DSI products / services

Similar considerations as detailed above under a payment based on a percentage of turnover would apply to a payment based on a percentage of profit of DSI related products/ services. The aspect of fairness towards industries with low profit margin should be considered. In addition, this payment option is likely to affect investment incentives. The theory for this is similar to that of the impact of corporation tax on firms' incentives to invest. Economic theory suggests profit maximising firms will invest until the 'cost of capital' (i.e. the cost of financing the investment) exceeds the expected rate of post-tax profit from an investment. A charge levied on data users' profits (akin to corporation tax) will affect investment incentives by affecting the post-tax profitability of a given investment. It will lower the post-tax profit a user may receive from its investments, therefore lowering the benefits and ultimately disincentivising investment.[324]

It may be harder to determine levels of profit against specific products/ services (given the need for often complex cost allocations), compared to determining turnover attributed to products / services. Therefore, it may be more challenging to implement a payment based on profit.

A payment based on a percentage of profit of DSI products/ services, will also have a differential impact on different types of data users. While businesses – who are profit motivated – will face a payment charge, other data users such as charities and non-profit organizations may not.

The extent to which this option meets the other criteria remains unclear.

Estimating revenue generated for the global fund based on a levy on sector revenue or sector net profit derived from DSI

The tables below illustrate the revenue that could be generated for the global fund through a levy on the sector revenue or net profit attributable to DSI for each sector considered in this study.

The revenue for each sector was estimated based on publicly available information for sectors that aligned most closely with those under consideration in this study. Each sector revenue figure was uprated to 2024 values using the CAGR for the sector where the 2024 was not already stated. A 12.5% average net profit margin across the sectors was assumed given it has not been possible to identify exact net profit estimates for each sector (research also suggests margins vary between and within the sectors under consideration).

The proportion of sector annual revenue or net profit derived from DSI is unknown and a range of 20% to 80% attributable to DSI is used to reflect this uncertainty. To illustrate the potential revenue contribution to the global fund, a range of percentage levies (0.2% to 5% for sector revenue, and 1.6% to 40% for net profit) applied to attributable sector revenue or net profit have been used.

[324] The economic effects of full expensing (obr.uk) accessed 14 May 2024

The range of fund contributions illustrated for the ***percentage levy on sector revenue derived from DSI*** are calculated using 2024 sector revenue, assuming a proportion of that sector revenue is attributable to DSI and then applying the relevant levy to that proportion of sector revenue to calculate the contribution to the global fund.

The range of fund contributions illustrated for the ***percentage levy on net profit derived from DSI*** are calculated using an estimated 2024 net profit (assuming a 12.5% average net profit margin), assuming a proportion of that net profit is attributable to DSI and then applying the relevant levy to that proportion of net profit to calculate the contribution to the global fund.

However, it is important to note that the tables below illustrate the revenue that could be generated for the global fund based on a range of assumptions and are therefore indicative and illustrative.

Table 13. Illustrative annual revenue generated for the global fund based on a levy on a proportion of annual sector revenue or net profit derived from DSI: Pharmaceuticals ($bn).

Sector revenue 2024 ($bn)	593.24[325]
Net Profit 2024 ($bn)	74.16

	Percentage levy on revenue derived from DSI	**0.2%**	**0.5%**	**1.0%**	**2.0%**	**3.0%**	**4.0%**	**5.0%**
	Percentage levy on net profit derived from DSI	**1.6%**	**4.0%**	**8.0%**	**16.0%**	**24.0%**	**32.0%**	**40.0%**
Percentage of pharmaceutical sector revenue or net profit derived from DSI	20%	0.2	0.6	1.2	2.4	3.6	4.7	5.9
	50%	0.6	1.5	3.0	5.9	8.9	11.9	14.8
	80%	0.9	2.4	4.7	9.5	14.2	19.0	23.7
	100%	1.2	3.0	5.9	11.9	17.8	23.7	29.7

As shown in **Table 13** above, if 50% of the pharmaceutical sector revenue is attributed to DSI, and a 2.0% levy on this sector revenue is imposed, this will generate around $5.9bn in contributions for the global fund. If 50% of the pharmaceutical sector net profit is attributed to DSI, and a 4% levy on this net profit is imposed, this will generate around $1.5bn in contributions for the global fund.

Table 14. Illustrative annual revenue generated for the global fund based on a levy on a proportion of annual sector revenue or net profit derived from DSI: Cosmetics ($bn).

Sector revenue 2024 ($bn)	333.90[326]
Net Profit 2024 ($bn)	41.74

	Percentage levy on **revenue** derived from DSI	0.2%	0.5%	1.0%	2.0%	3.0%	4.0%	5.0%
	Percentage levy on **net profit** derived from DSI	1.6%	4.0%	8.0%	16.0%	24.0%	32.0%	40.0%
Percentage of cosmetics	20%	0.1	0.3	0.7	1.3	2.0	2.7	3.3

[325] Pharmaceutical Manufacturing Market Size USD 863.6 Billion by 2030 (vantagemarketresearch.com) accessed 26 June 2024
[326] Cosmetics Market Size, Share, Trends & Forecast | Report 2030 (kingsresearch.com) accessed 26 June 2024

sector revenue or net profit derived from DSI	50%	0.3	0.8	1.7	3.3	5.0	6.7	8.3
	80%	0.5	1.3	2.7	5.3	8.0	10.7	13.4
	100%	0.7	1.7	3.3	6.7	10.0	13.4	16.7

As shown in **Table 14** above, if 50% of the cosmetics sector revenue is attributed to DSI, and a 2.0% levy on this sector revenue is imposed, this will generate around $3.3bn in contributions for the global fund.

Table 15. Illustrative annual revenue generated for the global fund based on a levy on a proportion of annual sector revenue or net profit derived from DSI: Plant and animal breeding and agricultural biotechnology ($bn).

Sector Revenue 2024 ($bn)	**581.62**[327]
Net Profit 2024 ($bn)	72.70

	Percentage levy on **revenue** derived from DSI	0.2%	0.5%	1.0%	2.0%	3.0%	4.0%	5.0%
	Percentage levy on **net profit** derived from DSI	1.6%	4.0%	8.0%	16.0%	24.0%	32.0%	40.0%
Percentage of plant and animal breeding and agricultural biotechnology sector revenue or net profit derived from DSI	20%	0.2	0.6	1.2	2.3	3.5	4.7	5.8
	50%	0.6	1.5	2.9	5.8	8.7	11.6	14.5
	80%	0.9	2.3	4.7	9.3	14.0	18.6	23.3
	100%	1.2	2.9	5.8	11.6	17.4	23.3	29.1

As shown in **Table 15** above, if 50% of the plant and animal breeding and agricultural biotechnology sector revenue is attributed to DSI, and a 2.0% levy on this sector revenue is imposed, this will generate around $5.8bn in contributions for the global fund.

Table 16. Illustrative annual revenue generated for the global fund based on a levy on a proportion of annual sector revenue or net profit derived from DSI: laboratory equipment ($bn).

Sector revenue 2024 ($bn)	43.36[328]
Net Profit 2024 ($bn)	5.42

[327] Seed https://www.maximizemarketresearch.com/market-report/global-seeds-market/111623/#:~:text=Seeds%20Market%20size%20was%20valued%20at%20US%24%2084.83,2024%20to%202030%2C%20reaching%20nearly%20US%24%20111.76%20Bn.; aquaculture Aquaculture Global Market Report 2024 - Research and Markets; plant breeding Plant Breeding and CRISPR Plants - Global Strategic Business Report (researchandmarkets.com); agricultural biotechnology Agricultural Biotechnology Market Size & Industry Value By 2030 (databridgemarketresearch.com); livestock (monitoring) [Latest] Global Livestock Monitoring Market Size/Share (globenewswire.com); horticulture Greenhouse Horticulture Market to Hit Revenue of $66.76 Billion by 2032 | Tomatoes to Contribute More than 50% to Greenhouse Produce | Extrapolate (yahoo.com) accessed 26 June 2024

[328] Lab Supplies Market Size, Share & Forecast Report, 2030 (psmarketresearch.com) accessed 26 June 2024

	Percentage levy on **revenue** derived from DSI	0.2%	0.5%	1.0%	2.0%	3.0%	4.0%	5.0%
	Percentage levy on **net profit** derived from DSI	1.6%	4.0%	8.0%	16.0%	24.0%	32.0%	40.0%
Percentage of laboratory equipment sector revenue or net profit derived from DSI	20%	0.0	0.0	0.1	0.2	0.3	0.3	0.4
	50%	0.0	0.1	0.2	0.4	0.7	0.9	1.1
	80%	0.1	0.2	0.3	0.7	1.0	1.4	1.7
	100%	0.1	0.2	0.4	0.9	1.3	1.7	2.2

As shown in **Table 16** above, if 50% of the laboratory equipment sector revenue is attributed to DSI, and a 2.0% levy on this sector revenue is imposed, this will generate around $0.4bn in contributions for the global fund. The revenue for laboratory equipment captures revenue beyond that which is related to DSI.

Table 17. Illustrative annual revenue generated for the global fund based on a levy on a proportion of annual sector revenue or net profit derived from DSI: Information, scientific and technical services related to DSI ($bn).

Sector revenue 2024 ($bn)	7.65[329]
Net Profit 2024 ($bn)	0.96

	Percentage levy on **revenue** derived from DSI	0.2%	0.5%	1.0%	2.0%	3.0%	4.0%	5.0%
	Percentage levy on **net profit** derived from DSI	1.6%	4.0%	8.0%	16.0%	24.0%	32.0%	40.0%
Percentage of information, scientific and technical services sector revenue or net profit derived from DSI	20%	0.00	0.01	0.02	0.03	0.05	0.06	0.08
	50%	0.01	0.02	0.04	0.08	0.11	0.15	0.19
	80%	0.01	0.03	0.06	0.12	0.18	0.24	0.31
	100%	0.0	0.0	0.1	0.2	0.2	0.3	0.4

As shown in **Table 17** above, if 50% of the information, scientific and technical services sector revenue is attributed to DSI, and a 2.0% levy on this sector revenue is imposed, this will generate

[329] Computational Biology Market Size & Share | Report, 2030 (kingsresearch.com) accessed 26 June 2024

around $0.08bn in contributions for the global fund. The revenue for the computational biology sector was used as a proxy for information, scientific and technical services related to DSI.

Income-based approach unlinked to products / services containing DSI

The key challenge of a payment based on the percentage of turnover, sales or profit related to DSI products/ services is determining the amount that can be attributed to the use of DSI compared to other contributing factors. To avoid this challenge, a payment based on the percentage of turnover, sales or profit may be unlinked to the products/ services developed using DSI, and rather, for example, applied to a broad product class or sub-sector. This has the advantage of avoiding the need for a complex and difficult attribution task. However, it requires the determination of the scope of products/ services to be included which may be difficult as articulating an objective set of criteria to identify such products/ services would likely be challenging.

c) Scope of products / services

The scope of products / services that may potentially captured by the multilateral mechanism could be relatively narrow e.g. encompassing those which contain DSI, or could be broader e.g. including a wider array of products / services. In this section we review both the narrower and broader scopes.

Products / services containing DSI

Here we consider products / services resulting from the use of DSI or benefiting from its use. Identification of products / services containing DSI may involve the requirement to track and trace DSI. If track and trace technology is required, this could be very financially and administratively costly to implement.[330] There is a risk that if the payment linked to products / services containing DSI is overly costly or complicated to comply with, this may disincentivise research and innovation linked to DSI. This could drive away users who are able to find a legal alternative to using the multilateral system.[331] As such, interviewees suggest that this scope may be less efficient, feasible and practical to implement than other options for scope of products / services. However, interviewees suggest that if a track and trace system or other monitoring arrangement is not required (e.g. if the scope of products / services is unlinked to the specific DSI used), this option could be efficient, feasible and practical.

Wider array of products / services

The mandate of the CBD may potentially limit the inclusion of all biodiversity-based products, but that does not preclude proposals that consider this scope. As such, a broad scope of products / services is considered in this study.

A wider array of products / services (e.g. biodiversity-based products or cloud storage space) may be simpler to identify than a narrower scope encompassing only products / services containing DSI.[332,333] This is because identification of products / services containing DSI may involve the requirement to track and trace specific DSI, whereas consideration of a broader scope, such as biodiversity-based products or potentially applying to entire (sub-) sectors of industry or categories of products, would not.[334] This list of categories considered within scope could evolve as DSI use evolves in research and innovation. In addition, this option could provide more certainty (than the narrower scope of products / services) that funds would be generated and legal clarity in terms of identifying the products affected by the requirement to pay. As such, this scope may be more effective, efficient, feasible and practical to implement. Therefore, this option may generate more benefits relative to the option for payments

[330] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[331] International Seed Federation (2015); https://www.fao.org/3/ca4962en/ca4962en.pdf accessed 29 April 2024
[332] Halewood, M., Bagley, M.A., Wyss, M. and Scholz, A.H., 2023. New benefit-sharing principles for digital sequence information. *Science*, *382*(6670), pp.520-522.
[333] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[334] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.

for products / services containing DSI.[335] However, this depends on and assumes that agreement can be reached on the extent of the products / services to be governed.

This option is consistent with open data access. Furthermore, interviewees suggests that a broader scope of products / services captured by the requirement to pay into the fund may support a more level playing field in terms of incentivising / not hindering research and innovation involving DSI or biodiversity.

d) Voluntary contributions

Voluntary contributions are an example of a trigger unlinked to the use of DSI and work by entities and / or individuals contributing funds on a voluntary basis. This model promotes a collaborative investment in the stewardship of DSI and genetic resources, underpinning the spirit of the CBD and fostering a shared responsibility. Non-legally binding, voluntary contributions rely on incentives such as a recognition of an organization's delivery on corporate social responsibility and improved positive public relations from closer alignment with sustainable and ethical business practices. At the first Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of DSI on Genetic Resources, Japan proposed this option for the multilateral fund.

There are prominent examples of voluntary contribution models that succeed in generating funds and making subsequent impactful investments. The Lion Share Fund, which encourages advertisers to contribute a percentage (0.5%) of their advertising spend to wildlife conservation, has seen large commercial players such as Mars Inc. and Gucci become funders and have made critical investments into animal conservation efforts on a global scale.[336] As another prominent example, contracting Parties to the International Treaty on Plant Genetic Resources for Food and Agriculture and other stakeholders have voluntarily contributed US$30 million to date.[337]

There are benefits for companies and organizations that contribute if they can effectively communicate this to their customers. Gen Z and Millennial consumers are 27% more likely to buy from brands that prioritise their impact on society and the environment, compared to previous generations, and are forecasted in the United States to dominate purchasing power by 2030.[338] Given the prevalence of DSI use across a vast range of consumer products, voluntary contributions that speak to an entity fulfilling its corporate social responsibility objectives, and clearly committing to biodiversity protection could not only enhance consumer trust but also drive tangible economic benefit in the long term. Another potential incentive for voluntary contributions may be legal certainty, i.e. the certainty that users that contribute voluntarily to the fund are not subject to bilateral benefit sharing claims.

Voluntary contributions are a long-standing funding model. Voluntary contributions also benefit from a low burden of development and so could be established relatively quickly under existing frameworks.[339] Some interviewees noted that a voluntary framework could be established in the short term and then a more detailed or mandatory system could be established in the future. Other key delivery factors for such a mechanism include effective and consistent monitoring and evaluation of contributions and continued advertisement of the fund's existence to those who could contribute to it – both resource intensive activities.

It was noted in interviews that a voluntary contribution system is most likely to obtain the support of the larger economically advanced countries who dominate the market for DSI and without which any global fund would likely fail.

Interviewees noted that the fundamental risks posed by a voluntary model include the unpredictable levels of contributions and the likelihood that contributions would be too small to deliver impactful investments. Indeed, the success of a fund depends on its ability to pool enough resources to make a large difference. The Lion's Share Fund's impact is contingent on substantial contributions from many

[335] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[336] The Lion's Share Fund (undp.org) accessed 2 May 2024
[337] Halewood, M., Bagley, M.A., Wyss, M. and Scholz, A.H., 2023. New benefit-sharing principles for digital sequence information. *Science*, *382*(6670), pp.520-522.
[338] Research: Consumers' Sustainability Demands Are Rising (hbr.org) Accessed 2 May 2024
[339] https://blogs.manchester.ac.uk/mioir/2024/01/26/discussions-on-benefit-sharing-and-data-governance/ accessed on 03 May 2024

advertisers, but its current value is only US$ 6m.[340] If contributions to a DSI fund are low, it may struggle to support the goals of the CBD. The volume and number of contributions could also be largely influenced by economic downturns, shifts in corporate priorities, changes in management, or even evolving public perceptions of the cause. This volatility makes it challenging to plan long-term strategies, budget for ongoing projects, and ensure consistent support for the initiatives the fund and the CBD aims to support. Overall, it is important to note that voluntary contributions may not raise the necessary funds or meet the characteristics of fair distribution.

If voluntary contributions in the context of DSI would operate in a similar manner and with a similar rate of contribution to existing voluntary contribution models, this option would likely not provide funding certainty (in regularity or amount generated). As such, whilst likely feasible and practical to implement, this option is not likely to be as efficient or effective as other options.

Equally, the efficiency of voluntary contributions will depend on a complex and unpredictable myriad of associated elements, such as which stakeholders could pay (users of DSI or broader scope), whether there are any associated limitations or requirements (e.g. annual voluntary contributions) and whether other measures are implemented in combination. Purely voluntary contributions may lead to the requirement for more national legislation on DSI, given this unlinked (to DSI) trigger's lack of legal clarity, which may create a costly and uncertain regulatory landscape.[341] As an unlinked trigger however, it does have the advantage of not requiring track and trace processes, reducing the impact on users compared to other triggers. It is also consistent with open access to data, thus limiting hindrance to research and innovation.[342]

Overall, voluntary contribution models could generate considerable funds under the right conditions and could be an effective short-term lever in the absence of any other substantial funding mechanisms. However, the effectiveness, efficiency, feasibility and practicality of a trigger unlinked to a specific use of DSI is generally difficult to predict. The success of a voluntary contribution model will thus depend on the specific modality implemented, any alternative trigger, which stakeholders would pay (users of DSI or broader scope), when how much and whether associated benefit sharing is on a voluntary or mandatory basis. Ultimately, until the option is better defined, it is difficult to consider whether more benefits will be generated than costs.

e) Mapping of each sectors value chain to payment triggers

For each of the sectors in scope a mapping has been undertaken to ascertain the components of the value chain at which each fund contribution mechanism could generate funds. These are set out below in **Figures 18-22**.

[340] The Lion's Share Fund (undp.org) Accessed 2 May 2024
[341] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.
[342] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)

Pharmaceutical

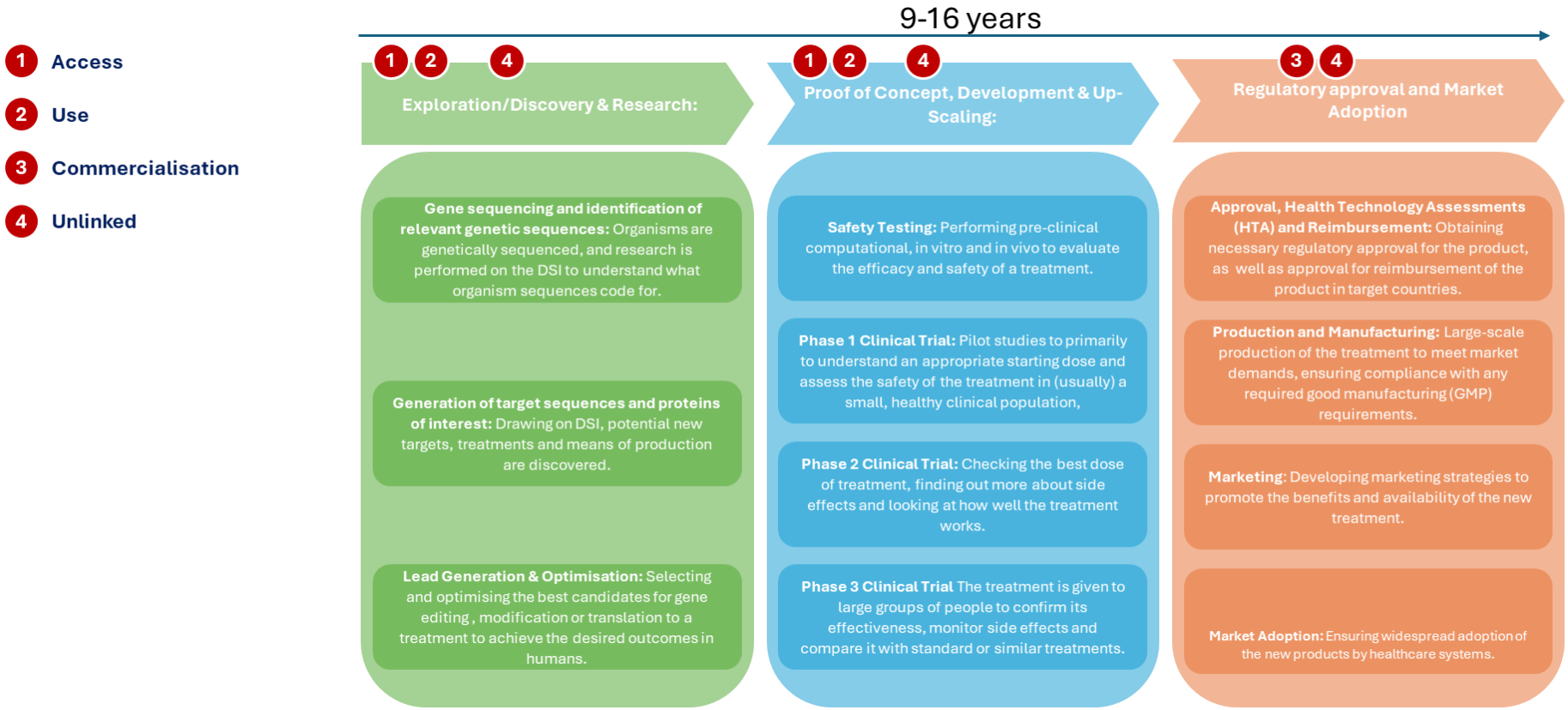

Figure 18. Points in the pharmaceutical value chain where different fund generating measures may apply.

Cosmetics

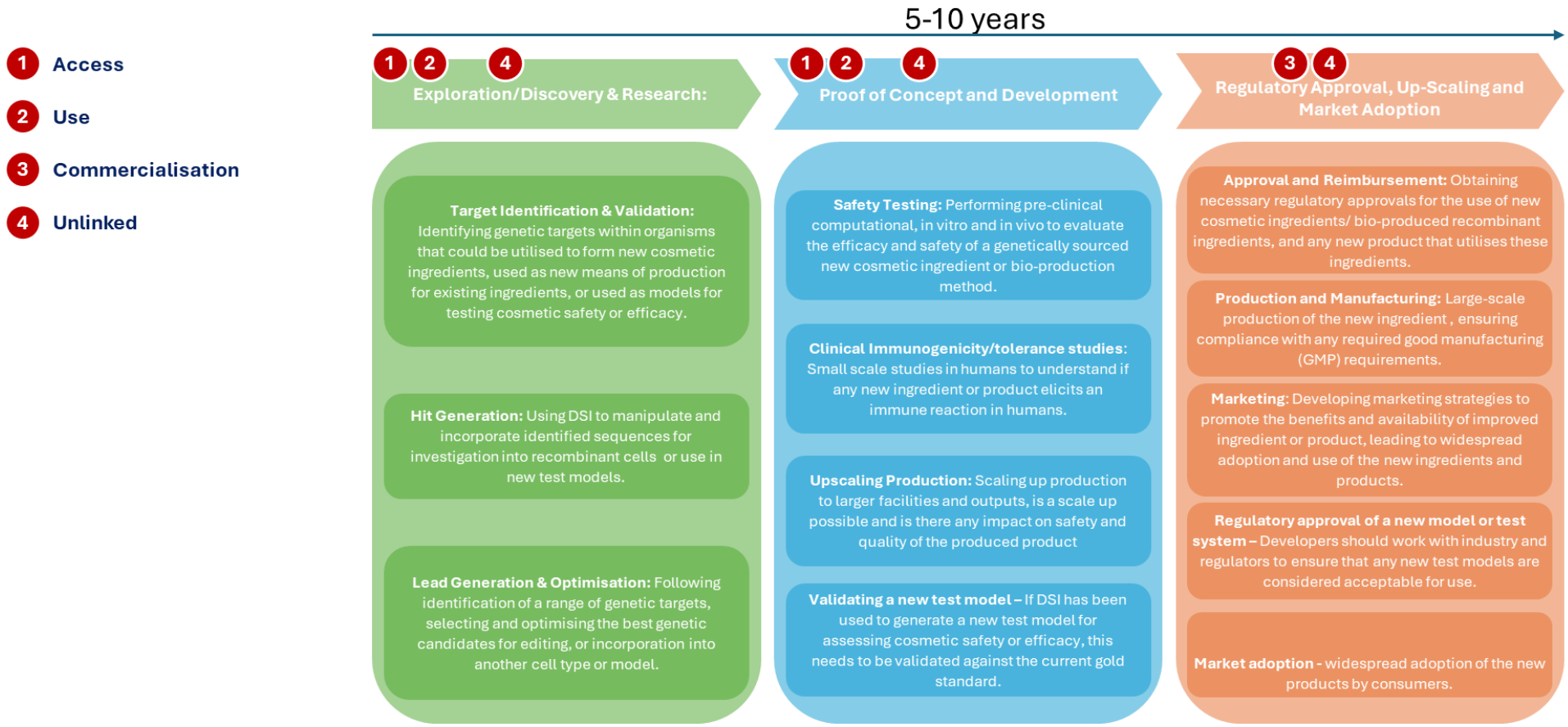

Figure 19. Points in the cosmetics value chain where different fund generating measures may apply.

Plant and animal breeding and agricultural biotechnology

Figure 20. Points in the food and feed value chain where different fund generating measures may apply.

Laboratory equipment associated with the use of DSI

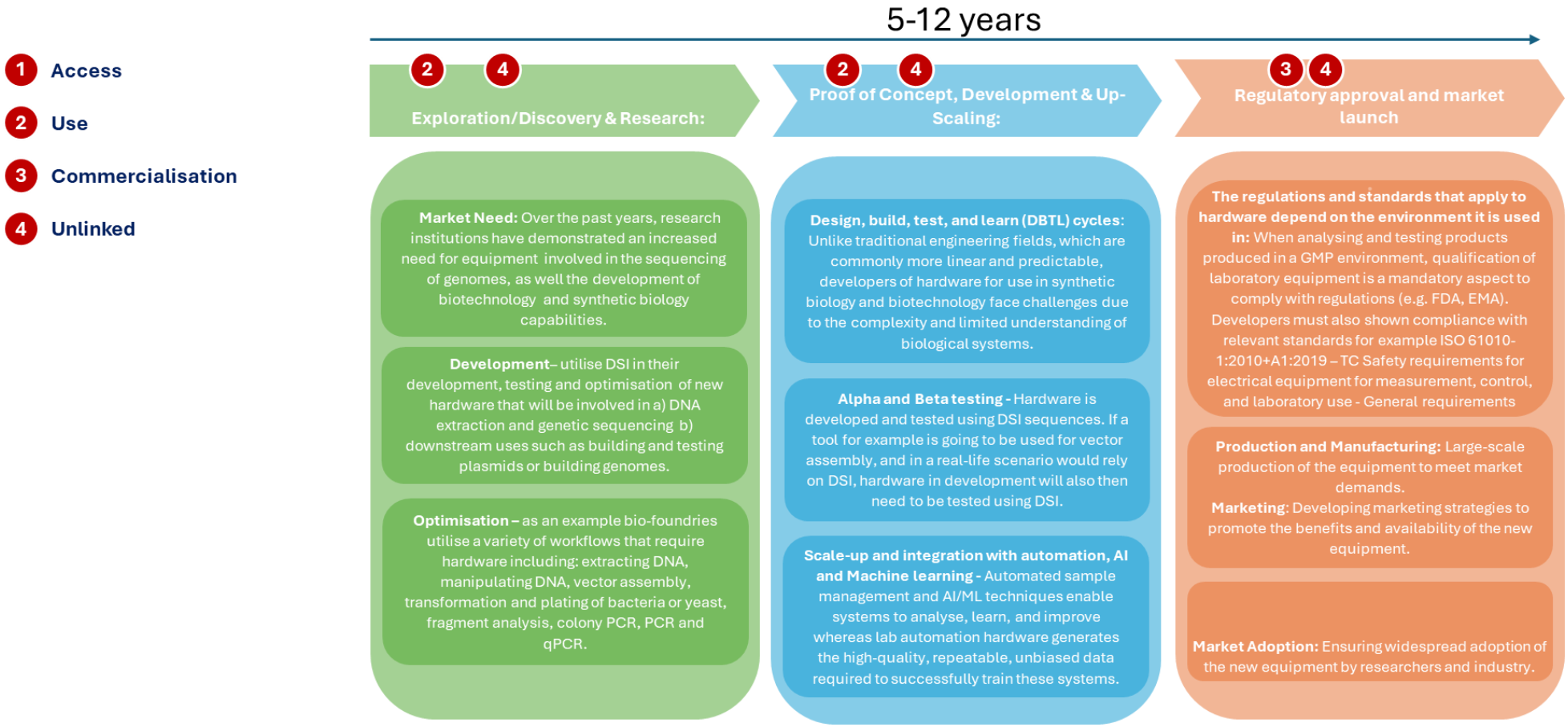

Figure 21. Points in the laboratory equipment value chain where different fund generating measures may apply.

Information, scientific and technical services related to DSI

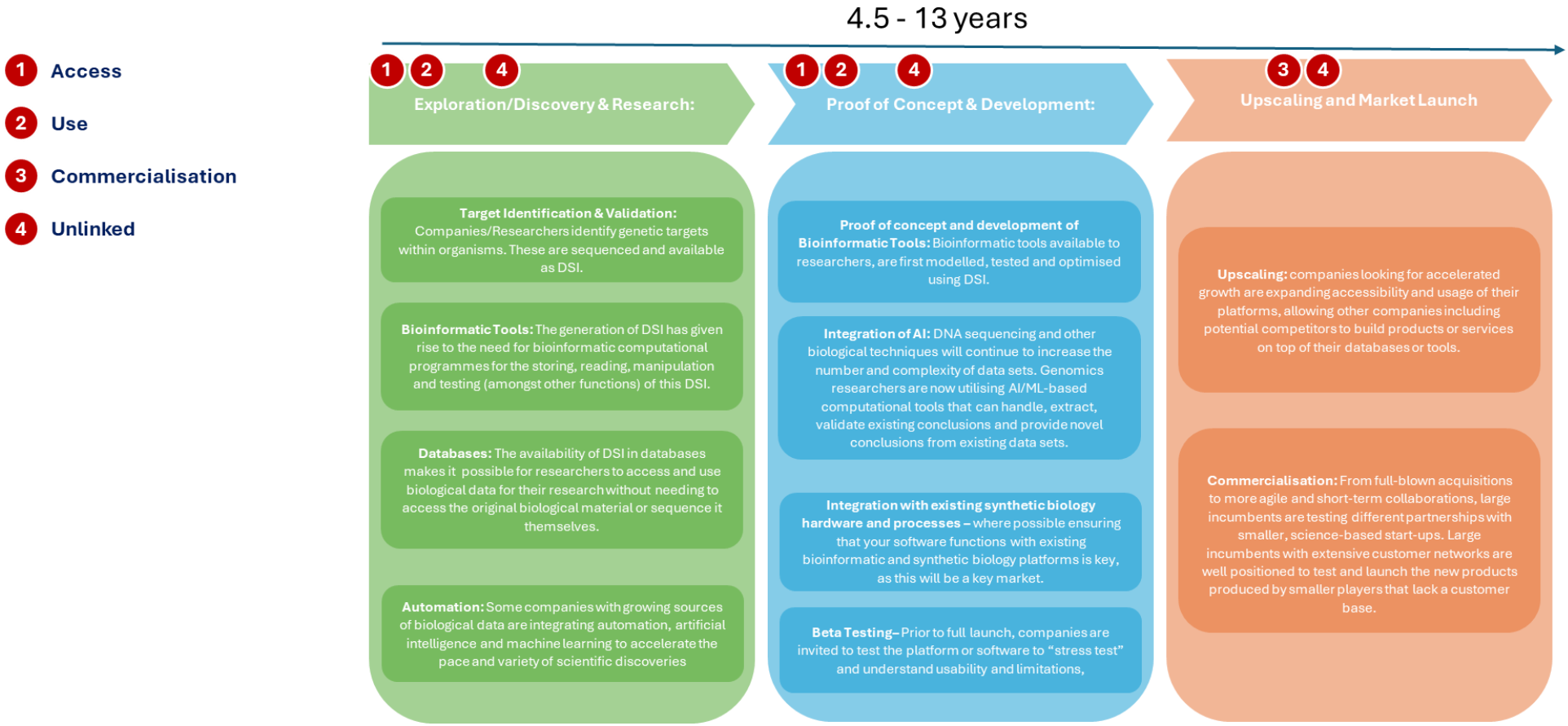

Figure 22. Points in the Information Technology programmes / platforms (software) and commercial producers of information on DSI value chain where different fund generating measures may apply.

Key Points:

- Interviewees and survey respondents suggest that there is a need to clarify the following factors when considering contributions to the fund: which stakeholders would pay (users of DSI or broader scope), when, how much, whether associated benefit sharing is on a voluntary or mandatory basis, and whether a single or a combination of measures are implemented.
- There is concern around implications of fund generating measures and potential negative impacts on open access to data and research and innovation. There is also concern regarding the cost and administrative complexities associated with potentially implementing and managing a track and trace system for DSI.
- Access to DSI, or triggers unlinked to DSI, may provide options which do not require track and trace. Interviewees suggest that it may be useful to consider a system that decouples the requirement to share monetary benefits from the point of access.
- The effectiveness of triggers unlinked to DSI will depend on and assumes that agreement can be reached on the extent of the specific products / services or (sub-) sectors that would be governed.

12) Disbursement of the Funds

This section assesses the options for the disbursement of the funds outlined in Section 9b, against the criteria set out in Section 7.

The way funds are disbursed will depend in part on where the funds are held and how they are governed. According to interviewees, the fund dispersal mechanism should consider which ever route that can meet the objectives (including the conservation and sustainable use of biodiversity). However not all the criteria are relevant for the disbursement of funds modality – not hindering research and innovation and being consistent with open access to data.

It could be more efficient to allow states to decide how they use the funds rather than attempting to prescribe how they should be used. However, this assumes that states would disperse funds to indigenous peoples and local communities who safeguard a large proportion of biodiversity. Interviewees suggest it would likely be challenging and potentially costly (both financially and administratively) to track and prove how funds are being used.

Some interviewees and survey respondents suggest that benefit sharing should be decoupled from where genetic resources originate or from where the genetic resources are sequenced given that this does not directly correlate to where there is need. Instead, it was suggested that funds should be distributed to where conservation is needed. Some survey respondents indicated that whilst there can be separation of 'projects' and 'allocations', depending on how monetary benefits are passed to countries, there may also be overlap between the two. An allocation could also mean a proportion of the fund is spent on different types of projects or using different criteria.

a) Options of where funds go

Government (Global South)

Disbursement of funds to government in the Global South is likely to be feasible and practical, according to some survey respondents. However, survey respondents suggest that this option may be less likely to meet various criteria based on the interpretation that this means all funds should only go to the Global South. Some survey respondents provided comments which indicated that they see it is critical that indigenous peoples and local communities in both the Global North and the Global South should be able to access funding. There is also concern from some stakeholders about indigenous peoples and local communities' access to funds in countries that do not recognize their rights. The link between this modality and the other criteria remains unclear.

Indigenous peoples and local communities (South, potentially North too)

Disbursement of funds to communities (in the Global South, potentially the Global North too) is likely to be effective, efficient, feasible and practical. By disbursing funds directly to communities, there may be greater potential to respect the rights of indigenous peoples and local communities, including their traditional knowledge associated with genetic resources that they hold. As such, survey respondents suggested that this option may be effective at supporting conservation and sustainable use of biodiversity. This is because indigenous peoples and local communities manage areas that hold large proportions of the Earth's biodiversity.[343,344] In practice, it may not be straightforward to find competent accredited entities to manage funds for indigenous peoples and local communities and it may necessitate capacity building. This could increase the costs of this option but would help to better ensure that funds reach the intended beneficiaries.

The link between this modality and the other criteria remains unclear.

Mix of government and indigenous peoples and local communities

Disbursement of funds to a mix of government and communities is likely to be more efficient, feasible and practical than the previous two options, according to survey respondents.[345,346] By disbursing funds directly to communities when possible and desirable, there may be greater potential to consider the rights of indigenous peoples and local communities, including with respect to the traditional

[343] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.
[344] https://www.thegef.org/what-we-do/topics/indigenous-peoples accessed 01 May 2024
[345] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.
[346] https://www.thegef.org/what-we-do/topics/indigenous-peoples accessed 01 May 2024

knowledge associated with genetic resources that they hold. This in turn could support more effective conservation and sustainable use of biodiversity.

The link between this modality and the other criteria remains unclear.

b) Options of what is funded

Government priorities

Interviewees suggest that the channelling of funds into government priorities is likely to be efficient, feasible and practical and effective as this will help to support attainment of existing objectives, e.g. to fulfil the aims of the KMGBF and United Nations Sustainable Development Goals.[347,348,349] The extent to which this option meets the requirement for benefits to be used to support conservation and sustainable use of biodiversity and benefit indigenous peoples and local communities will depend on the government priorities. Effectiveness will also depend on government priorities. In the case of unstable governments, governments with high levels of corruption, countries engaged in conflict, or facing other urgent needs, the money may be more likely to be diverted away from conservation and sustainable use applications thereby reducing effectiveness. However, we note that paragraph 10 of CBD COP Decision 15/9 states that monetary benefits should be used for the purpose of conserving and sustainably using biodiversity. Paragraph 16 from the First Open Ended Working Group report outlines that there was convergence from Parties that '*funding should be directed towards activities that support the conservation and sustainable use of biodiversity and the implementation of national biodiversity strategies and action plans, especially in developing countries, in particular the least developed countries and small island developing States, as well as countries with economies in transition*.'[350]

This option is likely to provide some degree of certainty in terms and legal clarity, but the link between this modality and the other criteria remains unclear.

Biodiversity conservation & sustainable use

Overall, survey results indicate that disbursement of funds for biodiversity conservation and sustainable use generally meet the required criteria to a greater extent than funding of government priorities. Efficiency, feasibility and practicality of funds being used for biodiversity conservation and sustainable use will depend on the way these funds are used, and any associated terms and conditions. Interviewees suggested that if a monitoring system is required to check that funds are used for conservation and sustainable use purposes, whilst this may promote effectiveness in terms of ensuring that funds are used for the intended purpose, it may be costly. If there is a monitoring system, then there is potentially greater certainty in terms of the way funds are administered and managed. The link between this modality and the other criteria remains unclear.

c) Options of how funding is disbursed

Projects

Survey results indicate that finding based on projects meets most criteria to a greater extent than funding based on allocations. The effectiveness, efficiency, feasibility and practicality of a system required to decide which projects should receive funding will depend on how such a system is organised.[351] This may be contingent in part on the selection criteria used to assess project proposals and determine the fund disbursements.[352] According to survey data, project-based funding is likely to provide a slightly greater degree of certainty and legal clarity than allocations. This certainty may depend on the selection process. Project-based funding is mutually supportive of the International Treaty on Plant Genetic Resources for Food and Agriculture which also involves distribution of funds

[347] https://www.un.org/sustainabledevelopment/blog/2021/07/a-new-global-framework-for-managing-nature-through-2030-1st-detailed-draft-agreement-debuts/ accessed 29 April 2024
[348] https://sdgs.un.org/goals - accessed 29 April 2024
[349] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)
[350] CBD/WGDSI/1/3 wgdsi-01-03-en.docx (live.com) accessed 15 July 2024
[351] E. Tsioumani, Exploring Fair and Equitable Benefit-Sharing from the Lab to the Land (Part I): Agricultural Research and Development in the Context of Conservation and the Sustainable Use of Agricultural Biodiversity (2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2524337 accessed 02 May 2024
[352] Morgera, E., 2018. Fair and equitable benefit-sharing in a new treaty on marine biodiversity: a principled approach towards partnership building?. *Forthcoming in Maritime Safety and Security Law Journal, BENELEX Working Paper*, (16).

on the basis of projects.[353,354] However, some interviewees suggested there is a risk that some countries will not receive any funds if these are shared on the same competitive basis as they are under the International Treaty on Plant Genetic Resources for Food and Agriculture. This may undermine faith in the system.

It is important to note that the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture may decide on different modalities for the allocation of funding from the benefit sharing fund. The competitive model may be changed in the future and this flexibility could be considered when developing the functioning of the multilateral mechanism.[355]

Over half of all survey respondents agree that funding based on projects is likely to support conservation and sustainable use of biodiversity, and to a greater degree than allocations. The link between this modality and the other criteria remains unclear.

Allocations

Some survey respondents suggested that the distribution of funds based on allocations is likely to promote effective, efficient, feasible and practical use of funding, but may depend on the criteria for allocation. In addition, comments shared by survey respondents indicate that allocations are likely to provide certainty and legal clarity for recipients due to the predictable nature of funding.[356,357,358] Several interviewees indicated that the Global Environment Facility (GEF) Secretariat use a STAR method for allocating resources – the System for Transparent Allocation of Resources – and that a similar approach could be applied in the context of DSI. Interviewees suggested that if a guarantee can be made that countries will receive some minimum level of funding (perhaps in the form of means-tested allocations) this could go a long way to promoting faith in the system. In addition, the predictable nature of allocations in the sense of having allocated funding for a certain time may support conservation and sustainable use of biodiversity and take into consideration the rights of indigenous peoples and local communities, as it may enable planning to a greater extent than projects funded on a competitive basis. [359]

Greater clarity is needed on the definition of 'allocations', including consideration of how much money each government would receive, how much each government would be required to spend on certain thematic areas and who would decide these allocations e.g. centrally decided by the Secretariat for the CBD or would each government decide for themselves.

The link between this modality and the other criteria remains unclear.

[353] Chiarolla, C., 2013, November. Benefit sharing in the food and agriculture sector under the FAO International Treaty on Plant Genetic Resource for Food and Agriculture. In *Workshop on 'Models and Incentives for Benefit Sharing* (Vol. 4, p. 5).
[354] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.
[355] See Resolution 3/2019, Annex 2, Operations Manual: Benefit-Sharing Fund; available at: https://openknowledge.fao.org/server/api/core/bitstreams/40256592-9663-45cc-892a-3cd451b93d28/content accessed 14 July 2024
[356] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.
[357] https://www.thegef.org/sites/default/files/publications/GEF_STAR_A4_april11_CRA.pdf accessed 30 April 2024
[358] Barbut, M., 2017. The Global Environment Facility: Our Catalytic Role to Sustain Biodiversity. In *Biodiversity and Ecosystem Insecurity* (pp. 221-231). Routledge.
[359] Barbut, M., 2017. The Global Environment Facility: Our Catalytic Role to Sustain Biodiversity. In *Biodiversity and Ecosystem Insecurity* (pp. 221-231). Routledge.

Key Points:

- Interviewees and comments provided by survey respondents suggested that it would likely be challenging and potentially costly (both financially and administratively) to track / prove that funds are being used for the purposes of conservation and sustainable use of biodiversity.
- By disbursing funds directly to indigenous peoples and local communities, there may be greater potential to take into account the rights of indigenous people and local communities, including with respect to the traditional knowledge associated with genetic resources that they hold.
- Disbursement of funds based on projects is likely to be mutually supportive of the International Treaty on Plant Genetic Resources for Food and Agriculture which also involves distribution of funds based on projects. However, distribution of funds based on allocations is likely to provide certainty and legal clarity for recipients due to the predictable nature of funding. Interviewees suggested that if a guarantee can be made that countries will receive some minimum level of funding (perhaps in the form of means-tested allocations) this could go a long way to promoting faith in the system.
- There should be transparency regarding how the funds are used.

13) Non-monetary benefit-sharing

This section assesses the options for non-monetary benefit-sharing outlined in section 9c, against the criteria set out in section 7.

As described in the annex of the Nagoya Protocol, non-monetary benefits can include a variety of options.[360] Non-monetary benefits may include but are not limited to the sharing of research and development results; collaboration, cooperation and contribution in scientific research and development programmes; participation in product development; capacity-building; technology transfer; and food and livelihood security benefits.[361]

a) Non-monetary benefit sharing addresses the broad needs for the conservation and sustainable use of biodiversity

Non-monetary benefit sharing for the purpose of addressing the broad needs for conservation and sustainable use of biodiversity is likely to include a broad scope of options, ranging from capacity building through to sharing of research results and promoting joint research-partnerships. [362] Survey respondents shared comments which indicate that this option may include a wider array of non-monetary benefit sharing than non-monetary benefit sharing for supporting closing the gap to generate, access, use, analyse and store DSI. As such, non-monetary benefit sharing addressing the broad needs for conservation and sustainable use of biodiversity may consider the rights of indigenous peoples and local communities more than the narrower scope of the modality below by virtue of the broader scope of included options. Many interviewees recognized the important role that indigenous peoples and local communities play in the stewardship of biodiversity.[363,364] By considering indigenous peoples and local communities, survey results indicate that this option may meet the criteria of biodiversity conservation and sustainable use more than the option below.

If building on current best practices, interviewees suggest this option may be relatively straightforward to implement and likely to contribute towards the objective of supporting conservation and sustainable use of biodiversity. However, it remains unclear how non-monetary benefit sharing will be governed, whether on a multilateral / bilateral or voluntary / mandatory basis. In addition, the specific activities that would be encompassed by non-monetary benefit sharing are also still under discussion. The extent to which this option will meet the other criteria remains unclear.

b) Non-monetary benefit sharing supports closing the gap to generate, access, use, analyse and store DSI

Non-monetary benefit sharing for the purpose of closing the gap to generate, access, use, analyse and store DSI is likely to include a broad scope of options, many of which will be similar (if not the same) as the option described above for the purpose of addressing the broad needs of conservation and sustainable use of biodiversity. However, interviewees indicated that this option may potentially be narrower in scope than the previous option, and therefore may not consider the rights of indigenous peoples and local communities as much as the option above.

Survey respondents suggested that without further clarity on how non-monetary benefit sharing will be governed, the extent to which this option may meet other criteria is unclear.

Key Points:

- If building on current best practices, non-monetary benefit sharing options may be relatively straightforward to implement.
- It remains unclear how non-monetary benefit sharing will be governed, whether on a mandatory / voluntary or bilateral / multilateral basis.
- Non-monetary benefit sharing addressing the broad needs for conservation and sustainable use of biodiversity is likely to include a broad scope of options, ranging from capacity building through to sharing of research results and promoting joint research-partnerships – potentially broader in scope

[360] Nagoya Protocol (2010). Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity - Text of the Nagoya Protocol (cbd.int) accessed 24 April 2024
[361] Nagoya Protocol (2010). Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity - Text of the Nagoya Protocol (cbd.int) accessed 24 April 2024
[362] Annotated provisional agenda (cbd.int) accessed 27 April 2024
[363] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.
[364] https://www.thegef.org/what-we-do/topics/indigenous-peoples accessed 01 May 2024

	than non-monetary benefit sharing to support closing the gap to generate, access, use, analyse and store DSI.

14) Governance

This section assesses the options for governance outlined in Section 9d, against the criteria set out in Section 7.

Interviewees and survey respondents were generally unsure of the extent to which different governance options would meet the required criteria. There was also a lack of clarity surrounding the practical difference between 'observer' and 'full member' status.

a) Degree of independence

Under the authority of the COP

Survey respondents viewed COP authority more favourably than an independent authority when rated against many of the criteria. The main discussions under the CBD and Nagoya Protocol take place in the specific COP and MOP. However, there is broader reach for many of the issues discussed, often spilling over into other fora e.g. WHO, WTO and WIPO. [365]

Operational autonomy

Operational autonomy was rated lower by survey respondents than COP authority on all the criteria and was substantially lower on most.

b) Party representation

Regional balance – 5 United Nations regions

Survey respondents viewed a regional balance as more favourable than a North/South balance when rated against many of the criteria.

North/South balance

North/South balance was rated lower by survey respondents than regional balance on most criteria. This North-South terminology reflects generalised negotiating positions of CBD Contracting Parties. The original framing of discussions of the CBD is viewed by some as a contest between the technologically advanced Global North and the biodiversity-rich Global South. As such, it would likely be expected that continuation of these discussions should include North/South representation of Parties in a balanced manner.[366] However, this North-South framing is considered by some interviewees and some survey respondents to be too simplistic, since other key stakeholders should be considered too e.g. private sector, indigenous peoples and local communities, and non-governmental organizations.[367] Whether these other stakeholders should be considered as observers, full members or in some other capacity is not clear.

c) Other members

Indigenous peoples and local communities as observers or as full members

Survey data indicated that respondents believe that observer and full member status of indigenous peoples and local communities would rate well against many of the criteria, with full member status meeting the criteria of conservation and sustainable use of biodiversity to a slightly greater extent than observer status. Interviewees and survey respondents suggested that the option of indigenous peoples and local communities as observers would play an important role in taking into account the rights of indigenous peoples and local communities, but possibly not to the same extent as if indigenous peoples and local communities were given full member status with a voting voice, or one vote per socio-cultural region. The extent could vary depending in part on the size of the governing board and the different numbers of individuals that could be considered – if large, observer status may enable greater participation. If small, then a smaller number of representatives could be members.

Some survey respondents shared comments which suggested that a greater level of participation should be considered for indigenous peoples and local communities due to their role as a special group in the CBD as rightsholders, of the right to self-determination in the case of indigenous peoples, their disproportionate contribution to biodiversity conservation and sustainable use, and their status as

[365] Lawson, C., Rourke, M. and Humphries, F. eds., 2022. *Access and Benefit Sharing of Genetic Resources, Information, and Traditional Knowledge*. Routledge.
[366] Lawson, C., Rourke, M. and Humphries, F. eds., 2022. *Access and Benefit Sharing of Genetic Resources, Information, and Traditional Knowledge*. Routledge.
[367] Lawson, C., Humphries, F. and Rourke, M., 2024. Challenging the existing order of knowledge sharing governance with digital sequence information on genetic resources. *Journal of Intellectual Property Law & Practice*, p.jpad129.

likely key beneficiaries of project funding. In turn, since indigenous peoples and local communities are considered as stewards of biodiversity, their inclusion as observers or full members would have a positive impact on the conservation and sustainable use of biodiversity.[368]

Private sector as observers or as full members

Survey respondents viewed observer status of the private sector as meeting many of the criteria to a greater extent than full member status. Some survey respondents suggested that the private sector should be involved in the governance process, but whether as observers or full members is unclear. One interviewee noted that much of the so-called 'benefits' that could be shared as part of an ABS system are held by private non-state Parties and are potentially beyond the reach of Global North contracting Parties to control.[369,370,371] Other respondents considered that the private sector may already be represented in the governance process by governments. As users of DSI, the private sector forms part of the regulated portion of the mechanism. Some survey respondents noted that the private sector has expressed their concerns and challenges with the Nagoya Protocol.[372]

Other stakeholders as observers or as full members

Interviewees highlighted the importance of key stakeholder groups in the context of international DSI discussions, including indigenous peoples and local communities, the private sector and non-governmental organizations.[373] However, the degree to which these, or other stakeholder groups, should be considered as observers or as full members was not clear. The survey data indicate that observer status was rated more highly than member status on most criteria. Member status was not rated more highly than observer status for any single criterion.

Key Points:

- Survey respondents viewed COP authority more favourably than an independent authority when rated against many of the criteria.
- Survey respondents viewed a regional balance in terms of representation as more favourable than a North/South balance when rated against many of the criteria.
- In terms of other members, survey data indicated that respondents believe that observer and full member status of indigenous peoples and local communities would rate well against many of the criteria, with full member status meeting the criteria of conservation and sustainable use of biodiversity to a slightly greater extent than observer status. Observer status of the private sector was considered by survey respondents as meeting many of the criteria to a greater extent than full member status. With regards to other potential members, survey data indicate that observer status was rated more highly than member status on most criteria.
- Many survey respondents recognized the importance of involving indigenous peoples and local communities.

[368] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.
[369] Fran Humphries, 'Technology Transfer of Aquatic Genetic Resources under the Convention on Biological Diversity and the Nagoya Protocol: "Sponging" off Patent Law Defences' (2016) 39 University of New South Wales Law Journal 234, 239
[370] Lyle Glowka, Françoise Burhenne-Guilmin, Hugh Synge et al., A Guide to the Convention on Biological Diversity (IUCN, 1994) p. 82.
[371] Charles Lawson, 'Implementing an Objective of the Convention on Biological Diversity – Intellectual Property, Access to Genetic Resources and Benefit Sharing in Australia' (2005) 22 Environmental and Planning Law Journal 130, 154–57
[372] Benryane M. A., Belqadi L., Bounou S., Birouk A. (2023) Role and Expectations of the Private Sector in the Implementation of the Nagoya Protocol in Morocco, Afr. J. Manag. Engg. Technol., 1(1), 47-65.
[373] Lawson, C., Humphries, F. and Rourke, M., 2024. Challenging the existing order of knowledge sharing governance with digital sequence information on genetic resources. *Journal of Intellectual Property Law & Practice*, p.jpad129.

15) Other policy options

This section assesses two further policy options, outlined in section 9e, against the criteria set out in section 7.

a) In parallel to the multilateral mechanism, a list of species and/or geographic areas from which the genetic resources DSI was extracted will operate under a bilateral mechanism consisting of a standardized mutually agreed terms (MAT)

Survey respondents and many interviewees expressed their concern that exemptions for a list of species and / or geographic areas could lead to, or enable, the development of a so-called hybrid approach to the governance of DSI. Such a system is viewed as being inefficient, impractical, and unfeasible. Exemptions could create uncertainty and may undermine benefit sharing by preventing researchers from including data from specific countries / areas / species in datasets with data from genetic resources originating in other countries. This would likely not be consistent with open access to data and may hinder research and innovation. To support attainment of certainty and legal clarity, and to promote participation in the multilateral mechanism, interviewees suggested that a simple, harmonised approach is required.

Survey respondents also indicated that this option would be unlikely to generate more benefits than costs. This perspective may be built on experience linked to implementation and compliance with other bilateral ABS instruments such as the Nagoya Protocol.[374] As Bagley (2022) explains *'the costs of complying with Nagoya Protocol legislative requirements has far exceeded what many users and governments anticipated. In the EU, some users report costs of obtaining PIC/MAT as between EUR 500 to EUR 10,000 per negotiation, requiring up to 500 personnel hours, and taking up to three years to conclude. Such delays to research projects can be costly in the fast-paced environment in which many therapeutics, cosmetics, and even agricultural products are developed. Given these kinds of concerns, user reluctance to engage with the Nagoya Protocol bilateral scheme, let alone expand it to DSI, seems eminently understandable'.* [375,376,377] These challenges, combined with limited evidence to date of benefit sharing under the Nagoya Protocol, provide support for the view expressed by survey respondents indicating that the costs of a bilateral component may outweigh the benefits.[378] In addition, one survey participant stated that if the CBD mandates a standardised MAT where everyone must agree to use the exempt DSI, this will likely result in international obligation violations e.g. by potentially forcing the assignment of IP rights, or requiring mandatory technology transfer.

Some interviewees and survey respondents, however, indicated that exemptions of a list of (endemic and / or sacred) species could be supportive of indigenous peoples and local communities' rights, including with respect to the traditional knowledge associated with the genetic resources that they hold. Provider countries and indigenous peoples and local communities are more likely to view exemptions (and / or a potential bilateral approach component to the multilateral mechanism) as in their interests, at least in situations where specific genetic resources can be identified.[379] This is potentially linked to their consideration of the intrinsic, holistic value of resources. As such, interviewees suggest that a 'world heritage list' or a 'sacred species registry' could be considered, potentially in combination with labelling to help track provenance and to promote collaboration. This could enable users of DSI to know more clearly when specific rules apply in a few cases.

b) Parties may opt out of the multilateral mechanism and instead operate their own ABS legislation, which includes DSI

Many interviewees suggested that a DSI landscape involving the requirement to navigate both a multilateral mechanism and bilateral ABS mechanisms for DSI would not be efficient, feasible or

[374] Bagley, M.A., 2022. " Just" sharing: The virtues of digital sequence information benefit-sharing for the common good. *Harv. Int'l LJ*, *63*, p.1.
[375] Bagley, M.A., 2022. " Just" sharing: The virtues of digital sequence information benefit-sharing for the common good. *Harv. Int'l LJ*, *63*, p.1.
[376] https://environment.ec.europa.eu/topics/nature-and-biodiversity/sharing-natures-genetic-resources_en accessed 03 May 2024
[377] Laird, S., Wynberg, R., Rourke, M., Humphries, F., Muller, M.R. and Lawson, C., 2020. Rethink the expansion of access and benefit sharing. *Science*, *367*(6483), pp.1200-1202.
[378] Bagley, M.A., 2022. " Just" sharing: The virtues of digital sequence information benefit-sharing for the common good. *Harv. Int'l LJ*, *63*, p.1.
[379] Bagley, M.A., 2022. " Just" sharing: The virtues of digital sequence information benefit-sharing for the common good. *Harv. Int'l LJ*, *63*, p.1.

practical. As such, a simple, harmonised approach would be preferable. However, additional comments shared by survey respondents indicated that an opt-out option could potentially be feasible if it does not affect data in public databases (i.e. Parties who opt out should prevent publishing on public databases) and if the mechanism is not expected to enforce domestic legislation (i.e. no hybrid system). As with the previous option, provider countries and indigenous peoples and local communities are more likely to view an opt out option (which enables them to instead create their bilateral mechanism) as in their interests, at least in situations where specific genetic resources can be identified. [380]

Key Points:

- Many interviewees suggested that a DSI landscape involving the requirement to navigate both a multilateral mechanism and bilateral ABS mechanisms for DSI would not be efficient, feasible or practical – concern around a potential 'hybrid' approach. Exemptions could create uncertainty. As such, a simple, harmonised approach would be preferable.
- However, some interviewees suggest that a list of (endemic) species could be supportive of rights of indigenous people and local communities.
- An opt-out option could potentially be feasible if it does not affect data in public databases (i.e. Parties who opt out should prevent publishing on public databases) and if the mechanism is not expected to enforce domestic legislation (i.e. not a hybrid system), this approach may be workable.

[380] Bagley, M.A., 2022. " Just" sharing: The virtues of digital sequence information benefit-sharing for the common good. *Harv. Int'l LJ*, *63*, p.1.

16) Conclusion

Based on the above discussions, and recalling the limitations of the studies, the following conclusions have been identified:

a) On fund contributions:

i) Any requirement to share benefits, at any point, may hinder research and innovation. However, all else being equal, if the requirement is at an earlier stage (e.g., at access or use) it might be more of a barrier as benefits of the research aren't yet realised;

ii) Any modality that involves a track and trace system raises concerns in terms of feasibility, cost and administrative complexities. Triggers at the point of access to DSI, on the use of DSI by entire sectors, or those unlinked to DSI do not require track and trace;

iii) Payment triggers related to commercialization and the use of DSI at a sectoral level – but unlinked to specific use of DSI – were considered more positively by stakeholders compared with those related to access to DSI and upstream use of DSI as trigger points;

iv) Such payment triggers, set in the range of 0.1 to 1 per cent of revenue, are estimated to have the potential of generating contributions to the fund in the order of 1 billion to 10 billion United States dollars per annum.

For such payment triggers, however, it would be necessary, to identify the specific products or services or the sectors or subsectors that would be included, with the identification of products and services being more complex than the identification of sectors or subsectors.

b) On fund disbursement:

i) Project-based approaches would provide oversight of what the funds are spent on but would be administratively costly and might increase the gap between Parties able to participate in those competitive processes;

ii) Disbursing funds directly to indigenous peoples and local communities could help to recognize the rights of indigenous people and local communities, including with respect to the traditional knowledge associated with the genetic resources that they hold;

iii) Across all modalities, transparency on how the funds are used is very important;

c) On non-monetary benefit-sharing:

i) Non-monetary benefit-sharing could address conservation and sustainable use of biodiversity or the current capacity gap with respect to generating, accessing, using, analysing and storing DSI, or a combination of both.

Regarding governance arrangements, most of the respondents who expressed a view noted that the multilateral mechanism should operate under the authority of the Conference of the Parties to the Convention on Biological Diversity and with regional balance regarding governance arrangements. The majority recognized that indigenous peoples and local communities as well as other stakeholders should be involved in the work of the governing body.

Overall, a simple, transparent, cost-effective harmonized approach to the multilateral mechanism would promote participation by stakeholders. A structured, incremental approach could enable feedback, review and updating the measures of the fund for generating funds and effective fund disbursement.[381,382,383]

[381] XXI-10 CTC (un.org) accessed 03 May 2024
[382] https://www.nature.com/articles/s41467-022-28594-0 accessed 02 May 2024
[383] iucn-bbnj-treaty-policy-brief.pdf accessed 02 May 2024

1) Appendix A

Interviews - Digital Sequence Information (DSI)

A study on the options for revenue-generating measures at different points along the value chain, the feasibility of their implementation and their costs relative to their potential revenue

Aims:

- To gather stakeholder perspectives on feasibility of implementing different revenue generating measures at different points in the value chain
- To analyse the potential capacity and willingness of various industries to pay, and benefits to pay, as well as challenges and potential solution.

A study to analyse and model the extent to which a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, and any other options the ad-hoc open-ended working group may decide, meets the criteria in paragraphs 9 and 10 of decision 15/9

Aims:

- To gather stakeholder perspectives on effectiveness of different options in meeting the required criteria
- To analyse the financial mechanisms for collecting revenue from DSI into a global fund, and for sharing such revenue equitably in line with the criteria in the annex, and (more broadly) in line with the resource mobilization strategy adopted at COP15

Key terms:

- **Revenue generating measures:** measures which lead to revenue flowing into organizations
- **Fund contributions / fund generating measures:** measures which lead to money flowing into a global multilateral benefit sharing mechanism

1) Please provide a brief overview of how DSI impacts your sector. What is your area of expertise / how do you feel you can contribute towards these studies?
2) What are the different ways in which DSI currently generates revenue in (your) industry?
3) Are there any novel or emerging revenue generating measures you see within your sector? If so, when do you expect these will reach market?
4) Roughly what portion of your sectors' revenue today relies on DSI?
5) Do you think revenue generated through use of DSI will be similar in 2030 and 2040 to today? If not, what scale do you expect this will be at respectively in 2030 and 2040?
6) Do you think the portion of revenue generated from the utilization of DSI will increase by 2030 and 2040 respectively? If so, can you give an estimated portion?
7) Please review our **value chain overview diagrams**. Are there any aspects you feel we have missed or should edit?
8) Do you think there are any **additional measures for generating funds to feed into the global benefit sharing fund** (beyond those we have compiled below) linked to the utilization of DSI that could be considered?
    - Access fee – fee to access individual DSI
    - Access fee – membership fee / subscription to access DSI
    - Access fee – fee to be paid on the data associated with DSI e.g. protein function

- Payment for a DSI-related service e.g. storage, processing and analysis of sequences
- A levy on products or services associated with DSI e.g. micro-levy on lab equipment linked with production of DSI, or cloud-computing space
- Payment of x at the point of utilization of DSI
- Payment of x at the point of protection of IP associated with utilization of DSI
- Payment of x at time of commercialisation
- Payment of x at some time after commercialisation of a product derived from the utilization of DSI (e.g., 5 years)
- Biodiversity bonds
- Marketing programme
- Patent registration
- Licences
- Fixed royalties
- 1% levy on retail sales of product developed from the use of DSI
- Government contributions
- Voluntary contributions

9) **What factors do you feel influence how feasible** it is to implement different fund generating measures linked to use of DSI? I.e. what factors influence workability / functionality of these kinds of measures?

10) What do you feel is the impact on feasibility of implementing revenue generating measures at **different points in the value chain** (i.e. early vs middle vs late)? I.e. do you think it will be more feasible to implement revenue generating measures at the beginning vs middle vs end of the value chain? What factors would be important to consider and why?

11) Of the **fund generating measures above**, which measures do you feel would be **most and least feasible** to implement? Why?

12) What are any **pros and cons of each fund generating measure** listed above that we've not already covered?

13) What do you feel are the **costs (of sharing funds) relative to the potential funding generated for the fund** for the different fund generating measures? How can these be considered or determined?

14) What do you think are the **potential benefits to industry** of paying into the global fund?

15) What do you think is the **capacity and willingness** of industries to pay into the global fund? Do you think this will vary across industry sectors? What factors would be important to consider and why?

16) How do you envision the **modalities of the global multilateral benefit sharing mechanism** for DSI?

17) **Which modalities** do you feel **meet the criteria in paragraphs 9 and 10 of decision 15/9 the most / least?** Why?

18) What do you think could be done to **enhance the extent** to which the different modalities meet the criteria?

19) Based on what we have covered in this meeting, is there anything else you think we should discuss for the purpose of this report?

2) Appendix B

Potential Policy Options for a Multilateral Benefit Sharing Mechanism or DSI

In 2021, the Informal Advisory Group on DSI proposed several policy options for the governance of DSI[384]. These options are described below.

Option 0: Status Quo

Under this option it is recognized that some Parties have adopted domestic measures that regulate access to and use of DSI, however, there is still a divergence of views among Parties regarding benefit sharing from the use of DSI.

Option 1: Digital sequence information on genetic resources fully integrated into domestic Access and benefit sharing measures.

In this case, DSI is subject to each Party's ABS legislation. It is the traditional bilateral approach to ABS. Access is regulated similarly to how genetic resources are accessed under the Convention on Biological Diversity and the Nagoya Protocol, meaning that depending on the national legislation in place, access to DSI could be subject to PIC and MAT (i.e., essentially, GR = DSI). The utilization of DSI is to be regulated by mutually agreed terms (MAT), as are benefit-sharing obligations, and MATs are negotiated for each DSI access. According to the study on ABS measures made available for the consideration of the AHTEG on DSI, some countries are already including DSI within the scope of their national ABS measures, and more are planning to do so in the near future.

Under this option, a tracking and tracing system would be required to not only determine the country of origin of each DSI record uploaded to the database but also how the DSI was being utilized and by whom so researchers could comply with that country's ABS obligations.

Option 2: Standard mutually agreed terms.

This more general grouping of options enables benefit-sharing from the use of DSI, but it is decoupled from access to DSI (MAT but no PIC). Access is therefore not restricted, but benefit-sharing is determined by some type of standard MAT/license/standard multilateral transfer agreement/terms and conditions. The fact that the MAT is standardized implies that there is no need for individual negotiation of a contract for each DSI utilization, but one or a limited number of standard contracts could be utilised. This alternative requires downstream monitoring of DSI use for implementation or enforcement, and monitoring. The difference between the two sub-options is the way that MATs are dealt with, one at the national level and the other at the international level.

Option 2.1: Standard mutually agreed terms/licence at the national level.

In this scenario, each Party establishes a policy system with one or a limited number of standard MAT/licences in their domestic ABS legislation with which users need to comply. This system goes through each country's domestic legislation. Triggers can occur at **commercialization**, for example, and the benefits would be shared bilaterally. In a similar policy, benefit-sharing obligation is triggered **when a patent is registered** and starts after **successful commercialization of a product developed using DSI**. Researchers whose activity is subject to such national legislation must comply with the national system and trace the DSI back to the country of origin of the genetic resource. If a researcher uses multiple DSI from different countries, they are required to potentially comply with several MAT/licences, depending on which standard MAT/licence the country has decided upon for their DSI.

Option 2.2: Standard mutually agreed terms/licence at the international level.

This option addresses benefit-sharing at the international level, as opposed to going through each country's national system as presented under option 2.1. One or more **standard licences** are agreed upon and adopted by Parties, in which the **terms and conditions depend on the licence attached to the DSI**. The benefits from the use of DSI are handled by an international system that redirects them **to the country of origin** of the genetic resource. This means that the researcher/user does not have to approach each country individually. This option offers the **possibility to integrate the licences in the DSI database itself**, and the terms and conditions are communicated to the user upon access (for example, obligations for commercial and non-commercial uses of a particular DSI). Another possibility is the **integration of the terms and conditions or licences in the**

[384] Section II.A.4 of CBD/WG2020/3/INF/8 accessed on 28 March 2024

intellectual property system (for example, when seeking intellectual property protection, based on a disclosure requirement on the use of DSI). In this option, benefits consist of **pre-negotiated fixed royalties on the successful commercialization of a product.**

A **collaboration with journals, patent offices, databases, or any other point along the value chain** of DSI should help enforce the reporting back to the DSI provider. In this case, the user is responsible for complying with the licence terms and conditions, and a downstream **utilization tracking/monitoring mechanism** will ensure the enforcement of these ABS measures.

Option 3: No prior informed consent, no mutually agreed terms.

This general grouping of options involves a **payment or contribution** to go into a multilateral fund. It avoids the need for tracing the origin of the genetic resource from which the DSI was extracted, or the need to monitor the downstream utilization of the product or service derived from DSI. This option includes various possible forms of payments and contributions, with one sub-option being linked to the DSI itself, and the other being separate from the information itself.

Option 3.1: Payment for access to digital sequence information on genetic resources

Here, the principle of a **payment for access** to the sequences itself is central and can be set up in several ways. One way is to collaborate with databases to help introduce a **membership fee/subscription to access DSI**. **This fee** can be determined following pre-negotiated criteria, such as, but not limited to **research application, sector of research, revenue, or a flat rate annual fee.** Another way is to introduce a **very small payment for access to individual DSI in the database**. An account is created, and each sequence download results in a **pre-determined fee** being charged to the account. Finally, a different arrangement is to provide **free access** to the sequence data itself, including some minimal data around it, such as species name, but introduce a **fee to be paid on the associated data** resulting from the analysis and processing of the data, such as protein function or gene association, as this associated data is estimated to be valuable for research and development. The BioSample database[385] currently links sequence data with other data associated with the sequence itself, or the genetic resource from which it comes. In this policy sub option, a collaboration with the BioSample database would lead to a charge for access.

Option 3.2: Other payments and contributions

Several ways in which payments and contributions can be established to be paid into a multilateral fund for benefit sharing from the use of DSI have been proposed in the literature, all stemming from agreements with external entities. One proposal includes **payment for a DSI-related service**, such as **storage, processing, expertise, and analysis of the sequences**, offered in return for a payment. Another proposal imposes **a levy on products or services associated with DSI**. One example is the imposition of a micro-levy on laboratory equipment linked with the production of DSI, while another is on the cloud-computing space rented for the purpose of sequence storage and/or processing. Yet, another proposal revolves around **biodiversity bonds**, as experiences from other fields, such as payments for the use of wildlife images, or climate change green bonds could be used to inform options for DSI. Another option involves a **marketing programme** whereby a label or badge is used on products to boost their sale and convey an idea around biodiversity conservation, while the **companies selling these products would redirect a negotiated percentage of benefits to a multilateral fund**. Finally, **voluntary contributions** could fuel a multilateral fund and come from the private sector, database users, countries, private donors, sub-national governments, or observers etc.

Option 4: Enhanced technical and scientific capacity and cooperation

Under this option, **systematic and mandated technical and scientific cooperation and capacity development related to DSI are promoted**. Enhanced capacity support for developing countries will democratize the access and use of DSI, making it more equitable so that each country has improved/expanded capacity and opportunity to generate, access and use DSI to its full potential. This could take the form of **research collaborations, training, knowledge platforms, technology transfer, technology co-development, database satellites, database infrastructure, and more**. This option is almost always presented **in combination with other policy options.**

Option 5: No benefit-sharing from digital sequence information on genetic resources

[385] Home - BioSample - NCBI (nih.gov) accessed on 28 March 2024

This option entails that the international community decides that no explicit benefit-sharing is necessary from the use of DSI from genetic resources and, thus, no additional mechanisms are proposed for benefit-sharing to be implemented.

Option 6: 1 per cent levy on retail sales of genetic resources

Under this option, a multilateral fund would be established and financed through a **1 per cent levy on all retail sales of goods in developed countries arising from the utilization of genetic resources** in cases where the bilateral PIC and MAT system is not implementable or practicable. **Funds would be distributed through a competitive project-based approach for conservation and sustainable use by indigenous peoples and local communities and others**, guided by scientists and governed by the multilateral governing body.

Additional options received through submissions

The following two hybrid options were received through the call for submissions through notification 2021-063.

(a) The **first hybrid option** is a combination of options **1 and 2.2** presented above. Under this arrangement there would be three alternatives that would depend on whether single or multiple DSI was used and whether the country of origin of the genetic resources from which the DSI was derived from is known:

(i) For single or multiple genetic sequences that come from a known single country of origin that acts also as the provider country of the genetic resource from which the DSI was obtained: PIC and MAT should be negotiated directly with the provider country of the genetic resource from which the DSI is obtained;

(ii) When using multiple genetic sequences that come from different but known countries of origin that act also as the providers of the genetic resource from which the DSI were obtained: no PIC should be negotiated and the benefits from the use of DSI are handled by an international system that directs benefits to the countries of origin. In this case, an internationally standardized MAT is used;

(iii) When using single or multiple genetic sequences where the country of origin of the genetic resources from which the DSI were obtained is not known: no PIC should be negotiated and the benefits from the use of DSI are handled by an international system and used for global projects for the conservation and sustainable use of biodiversity.

(b) The second option is also a hybrid option that would facilitate open access to sequences with some terms and conditions in case the genetic sequences are being used for commercial purposes. Similar to the option above, this alternative would employ internationally standardized MATs when the country of origin of the genetic resources from which the sequences are derived is not known and the benefits would go into a multi-lateral fund. In the case where the country of origin is known the benefits must be shared with the provider countries including indigenous peoples and local communities.

Option 7: multilateral mechanism based solely on voluntary contributions

This option was proposed at the Open-ended Working Group on Benefit-sharing from the Use of DSI at its first meeting.[386]

Option 8: automated big data model

This option was proposed by Oldham and Kindness.[387]

[386] See statement by Japan in the opening plenary WGDSI-01 - Documents (cbd.int) accessed 24 April 2024
[387] Sharing nature's genetic resources - European Commission (europa.eu) accessed 03 April 2024

Analysis of the extent to which modalities of the multilateral mechanism meet the required criteria

A) Contribution to the Fund

The following review of contributions to the fund is on the basis that the following remains unknown, and the extent to which criteria are met will vary depending on, but not limited to, the following factors: which stakeholders would pay (users of DSI or broader scope), when, how much and whether associated benefit sharing is on a voluntary or mandatory basis.

i. Trigger Points

Whilst a detailed cost benefit analysis of trigger points has not yet been conducted, the below presents a largely relative review of each option compared to the other.

Access to DSI

This option involves the assumption that access to DSI triggers a requirement to share money into the global fund.

Table 1. The extent to which access to DSI as a trigger point meets the required criteria.

Criteria	Comments
Be efficient, feasible and practical	• Identification of the point of access to DSI does not require track and trace, whereas identification of the point of use or commercialisation likely would.[388] As such, implementation of access to DSI as a trigger point may be simpler, more efficient and practical than at the points of use or commercialisation, particularly if decoupled from the requirement to share benefits[389] • Whilst technically feasible, this option may clash with open access policies and it is unclear what legal route could be taken to implement this trigger at the database level[390] • In terms of access to DSI as a trigger to immediately share monetary benefits (e.g. in the form of a fee or subscription) this may be less practical due to the potential negative impact on open access to data and potential adverse impact on scientific research using DSI
Generate more benefits, including both monetary and non-monetary, than costs	• To capture new information about users who access DSI in databases, new measures will need to be implemented at the database level. This may involve additional administrative complexity and cost. However, access to DSI as a trigger could be more cost-effective than triggers linked to use or commercialisation of DSI which may require implementation of costly track and trace systems[391] • If the access trigger is decoupled from the requirement to share benefits (I.e. benefits could be shared upstream of DSI generation, or downstream of use, e.g. a user fee on biodiversity-based goods), this could generate more benefits than costs • If this trigger is coupled with the requirement to immediately share monetary benefits (e.g. in the form of a fee or subscription) this may deter access to such a degree that costs outweigh the benefits, particularly taking into consideration the necessary administrative costs to implement such a payment system at this stage

[388] Paul Oldham and Jasmine Kindness2022 Sharing Digital Sequence Information. Study for the European Commission. doi: 10.5281/zenodo.655719
[389] Halewood, M., Bagley, M.A., Wyss, M. and Scholz, A.H., 2023. New benefit-sharing principles for digital sequence information. *Science*, *382*(6670), pp.520-522.
[390] Klünker, I. and Richter, H., 2022. Digital Sequence Information between Benefit-Sharing and Open Data. *Journal of Law and the Biosciences*, *9*(2), p.lsac035.
[391] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.

	• If this trigger is coupled with the requirement to immediately share non-monetary benefits (e.g. in the form of a potential notification regarding opportunities for joint research partnerships) this may be costly, but perhaps less costly than the requirement to immediately share monetary benefits
Be effective	• If a route to implementation of an access trigger is found, potentially in collaboration with databases, then it could be effective. In particular, access to DSI as a trigger could be more cost-effective than use or commercialisation of DSI which may require implementation of costly track and trace technology[392]
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Since the point of accessing DSI is relatively predictable and straightforward to identify, this option could provide certainty and legal clarity for all stakeholders
Not hinder research and innovation	• If the access trigger is decoupled from the requirement to share benefits, this option may not significantly hinder research and innovation • If this trigger is coupled with the requirement to immediately share benefits, this may negatively impact open access to data. Open access to data is viewed as a cornerstone of the scientific process[393][394]. If open access to data is taken away, this would have a negative impact on the analytical capabilities, data infrastructures and academic systems that depend on these open databases and would disincentivize collaboration with researchers based in countries that enforce DSI-related restrictions.[395][396][397][398] As such, this could hinder research and innovation.[399]
Be consistent with open access to data	• In order to capture new information about users who access DSI in databases, new measures will need to be implemented at the database level. Whilst this may not necessarily significantly harm open access to data (e.g. if decoupled from the requirement to share benefits), this could still have some impact open access • If coupled with the requirement to share benefits, access to DSI as a trigger point would be inconsistent with open access to data. This is because an access fee or subscription to access DSI is viewed as in conflict with the principle of open access.
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• May be supportive of other ABS instruments which consider access to genetic resources as the trigger point for specific obligations e.g. the Nagoya Protocol
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear

[392] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[393] Klünker, I. and Richter, H., 2022. Digital Sequence Information between Benefit-Sharing and Open Data. *Journal of Law and the Biosciences*, *9*(2), p.lsac035.
[394] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[395] Klünker, I. and Richter, H., 2022. Digital Sequence Information between Benefit-Sharing and Open Data. *Journal of Law and the Biosciences*, *9*(2), p.lsac035.
[396] Prathapan, K. D. et al. When the cure kills—CBD limits biodiversity research. Science 360, 1405–1406 (2018)
[397] Laird, S. et al. Rethink the expansion of access and benefit sharing. Science 367, 1200–1202 (2020)
[398] Ribeiro, C. et al. How ownership rights over microorganisms affect infectious disease control and innovation: A root-cause analysis of barriers to data sharing as experienced by key stakeholders. PLoS ONE 13, e0195885 (2018)
[399] Rourke, M., Eccleston-Turner, M., Phelan, A. & Gostin, L. Policy opportunities to enhance sharing for pandemic research. Science 368, 716–718 (2020)

The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• This option could promote conservation and sustainable use of biodiversity if decoupled from the requirement to share benefits. • If access to DSI triggers the requirement to immediately share benefits, this option may not support conservation and sustainable use of biodiversity to the degree that DSI otherwise could. This is linked to the likely negative effect on open access to DSI and consequential negative impact on scientific research involving DSI. Scientists require open access to DSI to conduct research on biological diversity e.g. to fulfil the aims of the Global Biodiversity Framework and UN Sustainable Development Goals[400][401][402]

Use of DSI

This option involves the assumption that use of DSI triggers a requirement to share money into the global fund.

Table 2. The extent to which use of DSI as a trigger point meets the required criteria.

Criteria	**Comments**
Be efficient, feasible and practical	• Identification of the point of use of DSI would likely require track and trace. Track and trace may be cumbersome and administratively challenging to implement. This would involve the development and management of new, potentially very complicated track and trace technology and infrastructures. As such, implementation of use of DSI as a trigger point may be less efficient, less feasible and less practical than at the points of access or unlinked to DSI which would likely not require track and trace of DSI
Generate more benefits, including both monetary and non-monetary, than costs	• Use of DSI as a trigger for the sharing of benefits may be more practical than at the point of access (but less than at the point of commercialisation) because there will likely be more benefits available to share at this stage in the value chain, particularly in terms of non-monetary benefits such as research results. • However, if track and trace technology is required, this could be very financially and administratively costly to implement. [403] These high costs may outweigh the benefits, and could drive away commercial users who are able to find a legal alternative to using the multilateral system[404] • If the use trigger is decoupled from the requirement to share benefits (I.e. benefits could be shared upstream of DSI generation, or downstream of use, e.g. a user fee on biodiversity-based goods), this could generate more benefits than costs (assuming that the point of use is straightforward to identify)[405] • If this trigger is coupled with the requirement to immediately share monetary benefits (e.g. in the form of a payment) this may deter use to such a degree that costs outweigh the benefits, particularly taking into consideration the necessary administrative costs to implement such a payment system at this stage

[400] https://www.un.org/sustainabledevelopment/blog/2021/07/a-new-global-framework-for-managing-nature-through-2030-1st-detailed-draft-agreement-debuts/ accessed 29 April 2024
[401] https://sdgs.un.org/goals - accessed 29 April 2024
[402] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)
[403] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[404] International Seed Federation (2015); https://www.fao.org/3/ca4962en/ca4962en.pdf accessed 29 April 2024
[405] Scholz, A.H., 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), p.giab085.

	• If this trigger is coupled with the requirement to immediately share non-monetary benefits (e.g. in the form of a potential notification regarding opportunities for joint research partnerships) this may be costly, but perhaps less costly than the requirement to immediately share monetary benefits
Be effective	• If implementation of a trigger at the point of use of DSI requires the development and management of expensive and administratively costly track and trace technology, this option may not be very effective[406]
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Since the point of use of DSI is not straightforward to identify, this option may not provide a strong degree of certainty or legal clarity for stakeholders
Not hinder research and innovation	• If this trigger is coupled with the requirement to immediately share benefits, this may hinder research and innovation by virtue of the administrative and financial burden. If the use of DSI trigger is complicated to understand and implement, and costly or complicated to comply with, this may disincentivise research and innovation linked to DSI. This could drive away users who are able to find a legal alternative to using the multilateral system[407] • However, in comparison with the trigger linked to access to DSI, the use of DSI is more consistent with the principle of open access to data, and imposes less of a barrier to research in that regard.
Be consistent with open access to data	• Use of DSI as a trigger is consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• This option could promote conservation and sustainable use of biodiversity, in part by supporting open access to data which is required to conduct research on biological diversity[408] • However, if the benefits generated do not outweigh the costs, this option may not support conservation and sustainable use of biodiversity to the degree that DSI otherwise could (e.g. if benefit sharing was triggered at use or commercialisation of DSI, or if benefit sharing is decoupled from the use). This is linked to the availability of funds to help support fulfilment of

[406] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[407] International Seed Federation (2015); https://www.fao.org/3/ca4962en/ca4962en.pdf accessed 29 April 2024
[408] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)

	biodiversity targets, e.g. linked to the aims of the Global Biodiversity Framework and UN Sustainable Development Goals[409][410][411]

Commercialisation of DSI

This option involves the assumption that commercialisation of DSI triggers a requirement to share money into the global fund.

Table 3. The extent to which commercialisation of DSI as a trigger point meets the required criteria.

Criteria	Comments
Be efficient, feasible and practical	• Identification of the point of commercialisation of DSI may require track and trace. Track and trace may be cumbersome and administratively challenging (if not impossible) to implement. However, this requirement may depend on the fund generating measure implemented. If a measure is not tied to the DSI (e.g. 1% levy on biodiversity-based products) then track and trace may not be required. If, however, a measure is tied to the DSI used, then track and trace would likely be required. This would involve the development and management of new, potentially very complicated track and trace technology and infrastructures. As such, implementation of commercialisation of DSI as a trigger point may be less efficient, less feasible and less practical than at the points of access or unlinked to DSI which would likely not require track and trace of DSI
Generate more benefits, including both monetary and non-monetary, than costs	• The financial value of DSI at the point of commercialisation would be greater than at the stages of access or use of DSI. As such, there may be greater potential to generate more benefits, including both monetary and non-monetary, than costs at this stage. • However, if track and trace technology is required, this could be very financially and administratively costly to implement. [412] These high costs may outweigh the benefits, and could drive away commercial users who are able to find a legal alternative to using the multilateral system[413]
Be effective	• If implementation of a trigger at the point of commercialisation of DSI requires the development and management of expensive and administratively costly track and trace technology, this option may not be very effective[414] • However, if a track and trace system is not required and an alternative solution is found, this option could be effective.
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Since the point of commercialisation of DSI is not straightforward to identify, this option may not provide a strong degree of certainty or legal clarity for stakeholders. • However, if a track and trace system is not required and an alternative solution is found, this option could provide certainty and legal clarity

[409] https://www.un.org/sustainabledevelopment/blog/2021/07/a-new-global-framework-for-managing-nature-through-2030-1st-detailed-draft-agreement-debuts/ accessed 29 April 2024
[410] https://sdgs.un.org/goals accessed 29 April 2024
[411] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)
[412] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[413] International Seed Federation (2015); https://www.fao.org/3/ca4962en/ca4962en.pdf accessed 29 April 2024
[414] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.

Not hinder research and innovation	• Commercialisation of DSI as a trigger for benefit sharing would be much less likely to hinder research and innovation than the access trigger.[415] This is because the commercialisation of DSI as a trigger is consistent with the principle of open access to DSI. • However, if the commercialisation of DSI trigger is complicated to understand / identify and implement, and costly or complicated to comply with, this may disincentivise research and innovation linked to DSI. This could drive away users who are able to find a legal alternative to using the multilateral system[416]
Be consistent with open access to data	• Commercialisation of DSI as a trigger is consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• If commercialisation of DSI is used as a trigger for benefit sharing and generates more benefits than costs, these benefits could be used to further promote the conservation and sustainable use of biodiversity and benefit IPLCs. • This option could promote conservation and sustainable use of biodiversity, in part by supporting open access to data which is required to conduct research on biological diversity[417][418].

Unlinked to DSI

This option involves the assumption that other activities / events (unrelated to the access, use or commercialisation of DSI) triggers a requirement to share money into the global fund.

Table 4. The extent to which a trigger point unlinked to specific use of DSI meets the required criteria.

Criteria	**Comments**

[415] Rourke, M., Eccleston-Turner, M., Phelan, A. & Gostin, L. Policy opportunities to enhance sharing for pandemic research. Science 368, 716–718 (2020)
[416] International Seed Federation (2015); https://www.fao.org/3/ca4962en/ca4962en.pdf accessed 29 April 2024
[417] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)
[418] Klünker, I. and Richter, H., 2022. Digital Sequence Information between Benefit-Sharing and Open Data. *Journal of Law and the Biosciences*, *9*(2), p.lsac035.

Be efficient, feasible and practical	• The efficiency, feasibility and practicality of a trigger unlinked to DSI is difficult to predict and will depend on the option implemented, the alternative trigger (e.g. voluntary contributions), which stakeholders would pay (users of DSI or broader scope), when, how much and whether associated benefit sharing is on a voluntary or mandatory basis
Generate more benefits, including both monetary and non-monetary, than costs	• Until the option is better defined, it is difficult to consider whether more benefits will be generated than costs as this will depend on the details of how an unlinked trigger is designed. • There is a risk that if a trigger point is unlinked to DSI (e.g. voluntary contributions) this could generate more costs than benefits[419]
Be effective	• If implementation of a trigger unlinked to DSI does not require track and trace, this could promote effectiveness • However, it is difficult to consider effectiveness more clearly until potential triggers unlinked to DSI are proposed
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• If implementation of a trigger unlinked to DSI does not require track and trace, this could promote certainty and legal clarity • However, it is difficult to consider certainty and legal clarity more clearly until potential triggers unlinked to DSI are proposed and an indication of the scale of funding generated is provided
Not hinder research and innovation	• Assuming that a trigger unlinked to DSI is consistent with open access to data, this option will likely not hinder research and innovation
Be consistent with open access to data	• A trigger unlinked to DSI will likely be consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Until there is greater clarity around the extent to which this trigger can meet the other criteria above, it remains unclear whether a trigger unlinked to DSI could support the conservation and sustainable use of biodiversity to the extent that other trigger can • Assuming that a trigger unlinked to DSI is consistent with open access to data, this option may promote conservation and sustainable use of biodiversity by not hampering research on biological diversity[420]

[419] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.
[420] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)

ii. Payment

Fee to access DSI and / or related information

This option involves the assumption that access to DSI and / or related information involves the requirement pay a fee. Survey respondents noted the lack of clarity surrounding the scope of 'related information' – there could be different considerations depending on the extent of the scope.

Table 5. The extent to which a payment involving a fee to access DSI and / or related information meets the required criteria.

Criteria	Comments
Be efficient, feasible and practical	• Identification of the point of access to DSI does not require track and trace.[421] As such, implementation of a fee to access DSI and / or related information may be simpler and more efficient than other payment options. • However, whilst technically feasible, this option would clash with open access policies and it is unclear what legal route could be taken to implement this fee at the database level • The requirement to pay a fee to access DSI and / or related information may be less practical than other payment options due to the negative impact on open access to data and potential adverse impact on scientific research using DSI[422]
Generate more benefits, including both monetary and non-monetary, than costs	• To capture new information about users who access DSI in databases, new measures will need to be implemented at the database level. This may involve additional administrative complexity and cost. However, fees to access DSI and / or related information could be more cost-effective than other payment options which may require implementation of costly track and trace systems[423] • Given the likely negative impact that an access fee would have open access to data and on scientific research, it is unlikely that this option would generate more benefits, both monetary and non-monetary, than costs.
Be effective	• If a route to implementation of an access fee is found, potentially in collaboration with databases, then it could be effective in comparison with other payment options. However, considering the likely impact on open access to data, this payment option as a whole is likely to be create an ineffective and undesirable DSI landscape.[424]
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Since the point of accessing DSI is relatively predictable and straightforward to identify, a fee administered at the point of accessing DSI and / or related information could provide certainty and legal clarity for all stakeholders. However, the degree of legal clarity will depend on the scope of related information considered.
Not hinder research and innovation	• A fee to access DSI and / or associated information is inconsistent with open access to data. Open access to data is viewed as a cornerstone of the scientific process[425]. If open access to data is removed, this would have a negative impact on the analytical capabilities, data infrastructures and academic systems that depend on these open databases and would

[421] Paul Oldham and Jasmine Kindness2022 Sharing Digital Sequence Information. Study for the European Commission. doi: 10.5281/zenodo.655719

[422] Bagley, M., Karger, E., Perron-Welch, F., Thambisetty, S., Souza, L.D., Frere, T., Frison, C., Humphries, F., Khalaf, N., Lawson, C. and Medaglia, J.C., 2020. Fact-finding study on how domestic measures address benefit-sharing arising from commercial and non-commercial use of digital sequence information on genetic resources and address the use of digital sequence information on genetic resources for research and development. *Ad hoc Technical Expert Group on Digital Sequence Information on Genetic Resources*, *10*.

[423] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.

[424] Scholz, A.H., 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), p.giab085.

[425] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.

	disincentivize collaboration with researchers based in countries that enforce DSI-related restrictions.[426][427][428][429] Analysis of sequences can only be done by comparing them to all other DSI. As such, they have no value in isolation[430]. Therefore, limitations imposed on open access by an access fee would likely hinder research and innovation.[431]
Be consistent with open access to data	• A fee to access DSI and / or associated information is inconsistent with open access to data. This is because an access fee is viewed as in conflict with the principle of open access.[432]
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• May not necessarily be mutually supportive of other ABS instruments as there is a risk of double payment (stacking), particularly for users in the agricultural / seed sector who frequently use DSI in combination with genetic resources[433]
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• This option may not support conservation and sustainable use of biodiversity to the degree that other payment options could. This is linked to the likely negative effect on open access to DSI and consequential negative impact on scientific research involving DSI. Scientists require open access to DSI to conduct research on biological diversity e.g. to fulfil the aims of the Global Biodiversity Framework and UN Sustainable Development Goals[434][435][436]

Payment or levy on products or services associated with use of DSI (lab equipment and IT)

Table 6. The extent to which a payment or levy on products or services associated with use of DSI (lab equipment and IT) meets the required criteria.

Criteria	**Comments**

[426] Klünker, I. and Richter, H., 2022. Digital Sequence Information between Benefit-Sharing and Open Data. *Journal of Law and the Biosciences*, *9*(2), p.lsac035.
[427] Prathapan, K. D. et al. When the cure kills—CBD limits biodiversity research. Science 360, 1405–1406 (2018)
[428] Laird, S. et al. Rethink the expansion of access and benefit sharing. Science 367, 1200–1202 (2020)
[429] Ribeiro, C. et al. How ownership rights over microorganisms affect infectious disease control and innovation: A root-cause analysis of barriers to data sharing as experienced by key stakeholders. PLoS ONE 13, e0195885 (2018)
[430] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[431] Rourke, M., Eccleston-Turner, M., Phelan, A. & Gostin, L. Policy opportunities to enhance sharing for pandemic research. Science 368, 716–718 (2020)
[432] Paul Oldham and Jasmine Kindness 2022 Sharing Digital Sequence Information. Study for the European Commission. doi: 10.5281/zenodo.655719
[433] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.
[434] https://www.un.org/sustainabledevelopment/blog/2021/07/a-new-global-framework-for-managing-nature-through-2030-1st-detailed-draft-agreement-debuts/ accessed 29 April 2024
[435] https://sdgs.un.org/goals - accessed 29 April 2024
[436] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)

Be efficient, feasible and practical	• The requirement to pay for products / services associated with use (and potentially generation) of DSI would separate and decouple access to DSI from the payment. This could be by introducing a charge either upstream (e.g. DNA sequencing) or downstream (e.g. software to analyse or store DSI) from access. Whilst this would require national legislation to implement and may be unpopular domestically, it would preserve open access to data. As such, this option may be more feasible and practical than an access fee, though potentially not as efficient to implement (at least initially)[437][438]
Generate more benefits, including both monetary and non-monetary, than costs	• A payment or levy on products or services associated with use of DSI is likely to encompass a broad spectrum of products / services involved in the DSI value chain. This, coupled with being supportive of open access to data, indicates that more benefits could be generated than costs, particularly when compared with the access fee option. • However, new infrastructure may be required and may be costly[439]
Be effective	• This option has potential to be start accumulating funds in the short-mid-term, which suggests a good degree of effectiveness [440]
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Receipt of payment for products / services associated with use (or generation) of DSI could provide certainty.[441] Legal clarity will depend on a clearer understanding of the scope of products / services (e.g. lab reagents, equipment, cloud-computing space) that this option may encompass
Not hinder research and innovation	• By maintaining open access to data, this payment option would not hinder research and innovation. However, there is a risk that if costs for products / services are too high this could disincentivize research.
Be consistent with open access to data	•
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• May not necessarily be mutually supportive of other ABS instruments as there is a risk of double payment (stacking), particularly for users in the agricultural / seed sector who frequently use DSI in combination with genetic resources[442]
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of	• If new infrastructure is not required (or is not costly), then the benefits accrued from payments for products / services associated with use of DSI may outweigh the costs. These benefits could be used to promote the conservation and sustainable use of biodiversity and benefit IPLCs.

[437] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[438] Paul Oldham and Jasmine Kindness 2022 Sharing Digital Sequence Information. Study for the European Commission. doi: 10.5281/zenodo.655719
[439] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[440] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[441] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective
[442] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.

biological diversity and, inter alia, benefit IPLCs	

% turnover of DSI products / services

Table 7. The extent to which a payment involving % turnover of DSI products / services meets the required criteria.

Criteria	Comments
Be efficient, feasible and practical	•
Generate more benefits, including both monetary and non-monetary, than costs	• Since the scope of turnover is broader than sales or profit, this option may generate more money for the fund than % sales or % profit.
Be effective	•
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Limited certainty or legal clarity because information related to turnover is less easy to obtain in the public domain than other information linked to the use of DSI e.g. it is more straightforward to find information regarding access to DSI (downloads from databases)
Not hinder research and innovation	•
Be consistent with open access to data	•
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• May not necessarily be mutually supportive of other ABS instruments as there is a risk of double payment (stacking), particularly for users in the agricultural / seed sector who frequently use DSI in combination with genetic resources[443]
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• If new infrastructure is not required (or is not costly), then the benefits accrued from payments for products / services associated with use of DSI may outweigh the costs. These benefits could be used to promote the conservation and sustainable use of biodiversity and benefit IPLCs.

[443] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.

% sales of DSI products / services

Table 8. The extent to which a payment involving % sales of DSI products / services meets the required criteria.

Criteria	Comments
Be efficient, feasible and practical	•
Generate more benefits, including both monetary and non-monetary, than costs	• Since the scope of sales is broader than profit, this option may generate more money for the fund than % profit of DSI products / services.
Be effective	•
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Limited certainty or legal clarity because information related to sales is less easy to obtain in the public domain than other information linked to the use of DSI e.g. it is more straightforward to find information regarding access to DSI (downloads from databases)
Not hinder research and innovation	•
Be consistent with open access to data	•
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• May not necessarily be mutually supportive of other ABS instruments as there is a risk of double payment (stacking), particularly for users in the agricultural / seed sector who frequently use DSI in combination with genetic resources[444]
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• If new infrastructure is not required (or is not costly), then the benefits accrued from payments for products / services associated with use of DSI may outweigh the costs. These benefits could be used to promote the conservation and sustainable use of biodiversity and benefit IPLCs.

% profit of DSI products / services

Table 9. The extent to which a payment involving % profit of DSI products / services meets the required criteria

[444] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.

Criteria	Comments
Be efficient, feasible and practical	•
Generate more benefits, including both monetary and non-monetary, than costs	• Since the scope of profit is narrower than turnover or sales, this option may generate comparatively less money for the fund than % turnover or %sales of DSI products / services.
Be effective	•
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Limited certainty or legal clarity because information related to profits is less easy to obtain in the public domain than other information linked to the use of DSI e.g. it is more straightforward to find information regarding access to DSI (downloads from databases)
Not hinder research and innovation	•
Be consistent with open access to data	•
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• May not necessarily be mutually supportive of other ABS instruments as there is a risk of double payment (stacking), particularly for users in the agricultural / seed sector who frequently use DSI in combination with genetic resources[445]
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• If new infrastructure is not required (or is not costly), then the benefits accrued from payments for products / services associated with use of DSI may outweigh the costs. These benefits could be used to promote the conservation and sustainable use of biodiversity and benefit IPLCs.

iii. Scope of Products / Services

Products / services containing DSI

Table 10. The extent to which scope of products / services containing DSI meets the required criteria

Criteria	Comments

[445] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.

Be efficient, feasible and practical	• Identification of products / services containing DSI may involve the requirement to track and trace DSI, which may be cumbersome and administratively challenging (if not impossible) to implement. As such, this scope may be less efficient, feasible and practical than other options for scope of products / services. • If track and trace is not required, this option could be efficient, feasible and practical
Generate more benefits, including both monetary and non-monetary, than costs	• If track and trace technology is required, this could be very financially and administratively costly to implement. [446] These high costs may outweigh the benefits, and could drive away commercial users who are able to find a legal alternative to using the multilateral system[447]
Be effective	• If track and trace of DSI is required, this option may not be very effective
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Likely to provide a low degree of certainty and legal clarity if track and trace is required
Not hinder research and innovation	• There is a risk that if the payment for products / services containing DSI is overly costly or complicated to comply with, this may disincentivise research and innovation linked to DSI. This could drive away users who are able to find a legal alternative to using the multilateral system[448]
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• If track and trace technology is required, this could be very financially and administratively costly to implement. [449] These high costs may outweigh the benefits, and therefore provide little support for the conservation and sustainable use of biodiversity. • However, if a track and trace system (or similar monitoring technology) is not required, then the benefits accrued from payments for products / services containing DSI may outweigh the costs. These benefits could be used to promote the conservation and sustainable use of biodiversity and benefit IPLCs.

[446] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[447] International Seed Federation (2015); https://www.fao.org/3/ca4962en/ca4962en.pdf accessed 29 April 2024
[448] International Seed Federation (2015); https://www.fao.org/3/ca4962en/ca4962en.pdf accessed 29 April 2024
[449] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.

Wider array of products / services

Table 11. The extent to which a wider array of products / services meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• A wider array of products / services (e.g. biodiversity-based products or cloud storage space) may be simpler to identify than a narrower scope encompassing only products / services containing DSI[450][451]. This is because identification of products / services containing DSI may involve the requirement to track and trace DSI, whereas consideration of a broader scope (e.g. biodiversity-based products) would not[452]. As such, this scope may be more efficient, feasible and practical to implement. However, this depends on and assumes that agreement can be reached on the extent of the products / services to be governed.
Generate more benefits, including both monetary and non-monetary, than costs	• Since payments for a wider array of product / services would likely not require implementation of a track and trace system, this option may generate more benefits than costs in comparison with the option for payments for products / services containing DSI[453]
Be effective	• This option may be more effective than the scope of products / services containing DSI
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• This option could provide more certainty (than the narrower scope of products / services) that funds would be generated and legal clarity in terms of identifying the products affected by the requirement to pay
Not hinder research and innovation	• A broader scope of products / services captured by the requirement to pay into the fund may support a more level playing field in terms of incentivizing / not hindering research and innovation involving DSI or biodiversity.
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in	• The benefits accrued from payments for a wider array of products / services has potential to outweigh the costs. These benefits could be used to promote the conservation and sustainable use of biodiversity and benefit IPLCs.

[450] Halewood, M., Bagley, M.A., Wyss, M. and Scholz, A.H., 2023. New benefit-sharing principles for digital sequence information. *Science*, *382*(6670), pp.520-522.
[451] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.
[452] Scholz, A.H., Hillebrand, U., Freitag, J., Devanshi, S., Seitz, C., Thiele, T. and Van Zimmeren, E., 2020. Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective.
[453] Scholz, A.H., Freitag, J., Lyal, C.H., Sara, R., Cepeda, M.L., Cancio, I., Sett, S., Hufton, A.L., Abebaw, Y., Bansal, K. and Benbouza, H., 2022. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, *13*(1), p.1086.

particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	

iv. Voluntary Contributions

Table 12. The extent to which voluntary contributions meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• Voluntary contributions will likely be feasible and practical to implement, but as a single measure for generating funds this option may not be as efficient as other options. The efficiency of voluntary contributions will depend on associated elements such as which stakeholders could pay (users of DSI or broader scope) and whether there are any associated limitations or requirements (e.g. annual voluntary contributions)
Generate more benefits, including both monetary and non-monetary, than costs	• Drawing on lessons learnt from the Plant Treaty (another multilateral ABS system), it is unlikely that voluntary contributions alone would generate more benefits than costs[454]
Be effective	• It is unlikely that voluntary contributions as a single fund generating measure would be effective
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Voluntary contributions as the only measure for generating funds would promote certainty and legal clarity from the point of view of a user in terms of understanding when payments could be made. However, from the perspective of generating funds, this option would not provide certainty or legal clarity that sufficient funding would be generated to meet the required criteria e.g. for the conservation and sustainable use of biodiversity • A purely voluntary system may lead to more national legislation on DSI, which may create a costly and uncertain regulatory landscape for DSI
Not hinder research and innovation	• Unlikely to hinder research and innovation
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear

[454] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.

The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• This option could promote conservation and sustainable use of biodiversity, in part by supporting open access to data which is required to conduct research on biological diversity[455] • However, if the benefits generated do not outweigh the costs, then voluntary contributions may not support conservation and sustainable use of biodiversity to the degree that other payment options could. This is linked to the availability of funds to help support fulfilment of biodiversity targets, e.g. linked to the aims of the Global Biodiversity Framework and UN Sustainable Development Goals[456][457][458]

B) Disbursement of the Funds

According to interviewees, the fund dispersal mechanism should consider which ever route that can meet the objectives (including the conservation and sustainable use of biodiversity). Politically, it would be sensible to allow states decide how they do this. In addition, it would be challenging and potentially costly (both financially and administratively) to track / prove how funds are being used.

Benefit sharing should be decoupled from where genetic resources originate or from where the genetic resources are sequenced – this doesn't impact need. We should distribute funds where conservation is needed.

i. Funds go to

Government (Global South)

Table 13. The extent to which funds going to Government (Global South) meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• Likely efficient, feasible and practical • However, survey respondents suggest that this option may be less likely efficient, feasible and practical based on the interpretation that this means all funds should only go to the Global South
Generate more benefits, including both monetary and non-monetary, than costs	• No link
Be effective	• Likely effective
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Likely to provide certainty and legal clarity • However, survey respondents suggest that this option may be less provide less certainty and legal clarity based on the interpretation that this means all funds should only go to the Global South
Not hinder research and innovation	• Unlikely to hinder research and innovation

[455] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)
[456] https://www.un.org/sustainabledevelopment/blog/2021/07/a-new-global-framework-for-managing-nature-through-2030-1st-detailed-draft-agreement-debuts/ accessed 29 April 2024
[457] https://sdgs.un.org/goals - accessed 29 April 2024
[458] IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. Zenodo https://doi.org/10.5281/zenodo.5517154 (2019)

Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Survey respondents suggest that this option may not take into account the rights of all IPLCs (i.e. those based in the North) if all funds should only go to the Global South
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Survey respondents suggest that this option may be less supportive of conservation and sustainable use of biodiversity if all funds should only go to the Global South • Some survey respondents indicated that they see it is critical that IPLCs in both the Global North and the Global South should be able to access funding.

Communities (Global South, potentially north too)

Table 14. The extent to which funds going to Government (Global South, potentially North too) meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Likely efficient, feasible and practical
Generate more benefits, including both monetary and non-monetary, than costs	• No link
Be effective	• Likely effective
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Likely to provide certainty and legal clarity
Not hinder research and innovation	• Unlikely to hinder research and innovation
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear

Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• By disbursing funds directly to communities, there may be greater potential to take into account the rights of IPLC, including with respect to the traditional knowledge associated with genetic resources that they hold. • Some survey respondents indicated that they see it is critical that IPLCs in both the Global North and the Global South should be able to access funding.
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• By disbursing funds directly to communities, there may be greater potential to take into account the rights of IPLCs, including with respect to the traditional knowledge associated with genetic resources that they hold. As such, survey respondents suggest that this option may be effective at supporting conservation and sustainable use of biodiversity. This is because IPLCs manage areas that hold approximately 80% of the Earth's biodiversity.[459][460]

Mix of Government and communities

Table 15. The extent to which funds going to a mix of Government and communities meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• Likely to be more efficient, feasible and practical than the previous two options, according to survey respondents. This is because a mixture could promote greater allocations to IPLCs who manage areas that hold approximately 80% of the Earth's biodiversity.[461][462]
Generate more benefits, including both monetary and non-monetary, than costs	• Likely some positive impact
Be effective	• Likely effective
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Likely to provide certainty and legal clarity
Not hinder research and innovation	• Unlikely to hinder research and innovation
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear

[459] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.
[460] https://www.thegef.org/what-we-do/topics/indigenous-peoples accessed 01 May 2024
[461] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.
[462] https://www.thegef.org/what-we-do/topics/indigenous-peoples accessed 01 May 2024

Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• By disbursing funds directly to communities, there may be greater potential to take into account the rights of IPLC, including with respect to the traditional knowledge associated with genetic resources that they hold. • Some survey respondents indicated that they see it is critical that IPLCs in both the Global North and the Global South should be able to access funding.
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• By disbursing funds directly to communities, there may be greater potential to take into account the rights of IPLCs, including with respect to the traditional knowledge associated with genetic resources that they hold. As such, survey respondents suggest that this option is likely to be more effective than the previous two options at supporting conservation and sustainable use of biodiversity. This is because IPLCs manage areas that hold approximately 80% of the Earth's biodiversity.[463][464]

ii. Funding what

Government priorities

Table 16. The extent to which funds being used for Government priorities meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Likely efficient, feasible and practical
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Likely effective as will support attainment of existing objectives
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Likely to provide certainty and legal clarity
Not hinder research and innovation	• Unlikely to hinder research and innovation
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear

[463] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.
[464] https://www.thegef.org/what-we-do/topics/indigenous-peoples accessed 01 May 2024

Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Likely
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Will depend on the Government priorities, but likely to support conservation and sustainable use of biodiversity, and benefit IPLCs

Biodiversity conservation & sustainable use

Table 17. The extent to which funds being used for biodiversity conservation and sustainable use meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Efficiency, feasibility and practicality of funds being used for biodiversity conservation and sustainable use will depend on the manner in which these funds are used. If an enforcement or monitoring system is required to ensure that funds are used for conservation and sustainable use purposes, this may be administratively and financially costly, potentially leading to an inefficient and impractical system
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Effectiveness of funds being used for biodiversity conservation and sustainable use will depend on the manner in which these funds are administered and used, and any associated terms and conditions. If a monitoring system is required, whilst this may promote effectiveness in terms of ensuring that funds are used for the intended purpose, the costs may outweigh and undermine the benefits, rendering the system less effective than a system where funds are used freely by Government to support their own priorities
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• The manner in which funds are administered and used, and any associated terms and conditions, will have an impact on certainty and legal clarity.
Not hinder research and innovation	• Unlikely to hinder research and innovation

Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Likely
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Likely to support conservation and sustainable use of biodiversity, and benefit IPLCs, to some degree

iii. On the basis of

Projects

Table 18. The extent to which funds being distributed on the basis of project meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• Distribution of funds on the basis of projects is likely to promote efficient, feasible and practical use of funding. However, this may depend in part on the selection criteria used to assess project proposals.[465] In addition, the efficiency, feasibility and practicality of the system required to decide which projects should receive funding will depend on how such a system is organised.[466]
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear

[465] Morgera, E., 2018. Fair and equitable benefit-sharing in a new treaty on marine biodiversity: a principled approach towards partnership building?. *Forthcoming in Maritime Safety and Security Law Journal, BENELEX Working Paper*, (16).

[466] E. Tsioumani, Exploring Fair and Equitable Benefit-Sharing from the Lab to the Land (Part I): Agricultural Research and Development in the Context of Conservation and the Sustainable Use of Agricultural Biodiversity (2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2524337 accessed 02 May 2024

Be effective	• Distribution of funds on the basis of projects is likely to be effective[467]. However, interviewees suggest there is a risk that some countries will not receive any funds if these are shared on the same competitive basis as they are under the Plant Treaty. This may undermine faith in the system.
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Likely to provide certainty and legal clarity[468]
Not hinder research and innovation	• Unlikely to hinder research and innovation
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Mutually supportive of the Plant Treaty which also involved distribution of funds on the basis of projects[469]
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Likely to support conservation and sustainable use of biodiversity

Allocations

Table 19. The extent to which funds being distributed on the basis of allocations meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Distribution of funds on the basis of allocations is likely to promote efficient, feasible and practical use of funding, but will depend on the criteria
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear

[467] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.
[468] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.
[469] Chiarolla, C., 2013, November. Benefit sharing in the food and agriculture sector under the FAO International Treaty on Plant Genetic Resource for Food and Agriculture. In *Workshop on 'Models and Incentives for Benefit Sharing* (Vol. 4, p. 5).

Be effective	• Distribution of funds on the basis of allocations is likely to be effective
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Likely to provide certainty and legal clarity due to the predictable nature of funding[470][471][472] • Interviewees suggest that if a guarantee can be made that countries will receive some minimum level of funding (perhaps in the form of means-tested allocations) this could go a long way to promoting faith in the system.
Not hinder research and innovation	• Unlikely to hinder research and innovation
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Likely supportive
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Interviewees suggest that if a guarantee can be made that countries will receive some minimum level of funding (perhaps in the form of means-tested allocations) this could go a long way to promoting faith in the system. In addition, the predictable nature of allocations is likely to support conservation and sustainable use of biodiversity and take into consideration the rights of IPLCs.[473]
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Likely to support conservation and sustainable use of biodiversity[474]

C) Non-Monetary Benefit-Sharing (NMBS)

i. NMBS addresses the broad needs for the conservation and sustainable use of biodiversity

Table 20. The extent to which NMBS addressing the broad needs for conservation and sustainable use of biodiversity meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• It remains unclear how NMBS will be governed, whether on a multilateral / bilateral basis or voluntary / mandatory basis. As such, it is unclear whether it will be efficient, feasible or practical

[470] Gullotta, G., Engels, J.M. and Halewood, M., 2023. What plant genetic resources for food and agriculture are available under the Plant Treaty and where is this information?. *Plants*, *12*(23), p.3944.
[471] https://www.thegef.org/sites/default/files/publications/GEF_STAR_A4_april11_CRA.pdf accessed 30 April 2024
[472] Barbut, M., 2017. The Global Environment Facility: Our Catalytic Role to Sustain Biodiversity. In *Biodiversity and Ecosystem Insecurity* (pp. 221-231). Routledge.
[473] Barbut, M., 2017. The Global Environment Facility: Our Catalytic Role to Sustain Biodiversity. In *Biodiversity and Ecosystem Insecurity* (pp. 221-231). Routledge.
[474] Barbut, M., 2017. The Global Environment Facility: Our Catalytic Role to Sustain Biodiversity. In *Biodiversity and Ecosystem Insecurity* (pp. 221-231). Routledge.

Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• It remains unclear how NMBS will be governed, whether on a multilateral / bilateral basis or voluntary / mandatory basis. As such, it is unclear whether it will be effective
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• It remains unclear how NMBS will be governed, whether on a multilateral / bilateral basis or voluntary / mandatory basis. As such, it is unclear whether it will be provide certainty or legal clarity
Not hinder research and innovation	• Interviewees suggest that if this builds on current best practice, this is unlikely to hinder research and innovation
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Likely supportive
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Survey respondents indicate that this option may include a wider array of NMBS than NMBS for supporting closing the gap to generate, access, use, analyse and store DSI. As such, this option may take into account the rights of IPLCs more than the modality below
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Many survey respondents and interviewees recognized the important role that IPLCs play in the stewardship of biodiversity.[475][476] By taking into account IPLCs, this option may meet the criteria of biodiversity conservation and sustainable use more than the option below.

ii. NMBS supports closing the gap to generate, access, use, analyse and store DSI

Table 21. The extent to which NMBS supporting closing the gap to generate, access, use, analyse and store DSI meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• It remains unclear how NMBS will be governed, whether on a mandatory / bilateral basis or voluntary / mandatory basis. As such, it is unclear whether it will be efficient, feasible or practical

[475] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.
[476] https://www.thegef.org/what-we-do/topics/indigenous-peoples accessed 01 May 2024

Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• It remains unclear how NMBS will be governed, whether on a mandatory / bilateral basis or voluntary / mandatory basis. As such, it is unclear whether it will be effective
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• It remains unclear how NMBS will be governed, whether on a mandatory / bilateral basis or voluntary / mandatory basis. As such, it is unclear whether it will be provide certainty or legal clarity
Not hinder research and innovation	• Interviewees suggest that if this builds on current best practice, this is unlikely to hinder research and innovation
Be consistent with open access to data	• Consistent with open access to data
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Likely supportive
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Survey respondents indicate that this option may include a slightly narrower array of NMBS than NMBS for addressing the conservation and sustainable use of biodiversity. As such, this option may take into account the rights of IPLCs less than the modality above
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Likely to support conservation and sustainable use of biodiversity

D) Governance

i. Degree of independence

Under the authority of the COP

Table 22. The extent to which governance under the authority of the COP meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Unclear

Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Unclear
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear
Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• The main discussions under the CBD and Nagoya Protocol take place in the specific COP/MOPs. However, there is broader reach for many of the issues discussed, often spilling over into other fora e.g. WHO, WTO and WIPO[477]
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear

Operational autonomy

Table 23. The extent to which governance under operational autonomy meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Unclear
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Unclear

[477] Lawson, C., Rourke, M. and Humphries, F. eds., 2022. *Access and Benefit Sharing of Genetic Resources, Information, and Traditional Knowledge*. Routledge.

Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear
Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear

ii. Party representation

Regional balance – 5 UN regions

Table 24. The extent to which party representation with a regional balance (5 UN regions) meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Unclear
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Unclear
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear

Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear

North/South balance

Table 25. The extent to which party representation North/South balance meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• Unclear
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• This North-South terminology reflects generalized negotiating positions of CBD Contracting Parties. The original framing of discussions of the CBD is viewed by some as a contest between the predominantly technologically advanced Global North and the biodiversity-rich Global South. As such, it would likely be expected that continuation of these discussions should include North/South representation of parties in a balanced manner.[478] • However, this North-South framing is considered by many interviewees and survey respondents to be too simplistic, since other key stakeholders should be considered too e.g. private sector, IPLCs, and non-governmental organizations.[479]

[478] Lawson, C., Rourke, M. and Humphries, F. eds., 2022. *Access and Benefit Sharing of Genetic Resources, Information, and Traditional Knowledge*. Routledge.
[479] Lawson, C., Humphries, F. and Rourke, M., 2024. Challenging the existing order of knowledge sharing governance with digital sequence information on genetic resources. *Journal of Intellectual Property Law & Practice*, p.jpad129.

Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear
Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Likely mutually supportive[480][481]
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear

iii. Other members

IPLCs as observers

Table 26. The extent to which IPLCs as observers meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• Survey respondents suggest that a greater level of participation should be considered for IPLCs due to their role as a special group in the CBD as rightsholders of the right to self-determination in the case of indigenous peoples, their disproportionate contribution to biodiversity conservation and sustainable use, and their status as likely key beneficiaries of project funding.
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Likely effective at taking into account the rights of IPLCs and supporting conservation and sustainable use of biodiversity

[480] Lawson, C., Rourke, M. and Humphries, F. eds., 2022. *Access and Benefit Sharing of Genetic Resources, Information, and Traditional Knowledge*. Routledge.
[481] Ulrich Brand, Christoph Görg, Joachim Hirsch and Markus Wissen, Conflicts in Environmental Regulation and the Internationalisation of the State: Contested Terrains (Routledge, 2008) pp. 68–77

Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear
Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Interviewees and survey respondents suggest the option of IPLCs as observers would play an important role in taking into account the rights of IPLCs, but possibly not to the same extent as if IPLCs were given full member status. The extent could vary depending in part on the size of the governing board and the different numbers of individuals that could be considered – if large, observer status may enable greater participation. If small, then a smaller number of representatives could be members.
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Interviewees and survey respondents suggest the option of IPLCs as observers would play an important role in taking into account the rights of IPLCs. In turn, since IPLCs are considered as stewards of biodiversity, this could have a positive impact on the conservation and sustainable use of biodiversity.[482]

IPLCs as full members

Table 27. The extent to which IPLCs as full members meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Survey respondents suggest that a greater level of participation should be considered for IPLCs due to their role as a special group in the CBD as rightsholders of the right to self-determination in the case of indigenous peoples, their disproportionate contribution to biodiversity conservation and sustainable use, and their status as likely key beneficiaries of project funding.
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Likely effective at taking into account the rights of IPLCs and supporting conservation and sustainable use of biodiversity

[482] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.

Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear
Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Interviewees and survey respondents suggest the option of IPLCs as full members could play an important role in taking into account the rights of IPLCs, potentially to a greater extent than the option of IPLCs as observers (but this will depend on the size of the governing board).
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Interviewees and survey respondents suggest the option of IPLCs as full members would play an important role in taking into account the rights of IPLCs. In turn, since IPLCs are considered as stewards of biodiversity, this could have a positive impact on the conservation and sustainable use of biodiversity.[483]

Private sector as observers

Table 28. The extent to which private sector as observers meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Some survey respondents consider the private sector as already represented in the governance process by Governments
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Unclear
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear

[483] Wynberg, R. and Laird, S., 2022. Access and Benefit Sharing and Biodiversity Conservation: The Unrealised Connection. In *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (pp. 50-70). Routledge.

Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• As users of DSI, the private sector form part of the regulated portion of the mechanism. Some survey respondents note that the private sector has expressed their concerns and challenges with the Nagoya Protocol. [484] This may be considered as not mutually supportive of other ABS instruments.
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear

Private sector as full members

Table 29. The extent to which private sector as full members meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• Some survey respondents consider the private sector as already represented in the governance process by Governments
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Unclear
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear
Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear

[484] Benryane M. A., Belqadi L., Bounou S., Birouk A. (2023) Role and Expectations of the Private Sector in the Implementation of the Nagoya Protocol in Morocco, Afr. J. Manag. Engg. Technol., 1(1), 47-65.

Be mutually supportive of other access and benefit-sharing instruments	• As users of DSI, the private sector form part of the regulated portion of the mechanism. Some survey respondents note that the private sector has expressed their concerns and challenges with the Nagoya Protocol. [485] This may be considered as not mutually supportive of other ABS instruments.
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear

Other stakeholders as observers

Table 30. The extent to which other stakeholders as observers meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Interviewees and survey respondents highlighted the importance of key stakeholder groups in the context of international DSI discussions, including IPLCs, the private sector and non-governmental organizations.[486] However, the degree to which these, or other stakeholder groups, should be considered as observers or as full members was not clear.
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Unclear
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear
Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear

[485] Benryane M. A., Belqadi L., Bounou S., Birouk A. (2023) Role and Expectations of the Private Sector in the Implementation of the Nagoya Protocol in Morocco, Afr. J. Manag. Engg. Technol., 1(1), 47-65.
[486] Lawson, C., Humphries, F. and Rourke, M., 2024. Challenging the existing order of knowledge sharing governance with digital sequence information on genetic resources. *Journal of Intellectual Property Law & Practice*, p.jpad129.

Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear

Other stakeholders as full members

Table 31. The extent to which other stakeholders as full members meets the required criteria

Criteria	Comments
Be efficient, feasible and practical	• Interviewees and survey respondents highlighted the importance of key stakeholder groups in the context of international DSI discussions, including IPLCs, the private sector and non-governmental organizations.[487] However, the degree to which these, or other stakeholder groups, should be considered as observers or as full members was not clear.
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Unclear
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unclear
Not hinder research and innovation	• Unclear
Be consistent with open access to data	• Unclear
Not be incompatible with international legal obligations	• Unclear

[487] Lawson, C., Humphries, F. and Rourke, M., 2024. Challenging the existing order of knowledge sharing governance with digital sequence information on genetic resources. *Journal of Intellectual Property Law & Practice*, p.jpad129.

Be mutually supportive of other access and benefit-sharing instruments	• Unclear
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear

E) Other Policy Options

Exemptions could create uncertainty, and may undermine benefit sharing by preventing researchers from including data from these countries / areas / species in datasets with data from genetic resources originating in other countries, which may hinder research

i. In parallel to the multilateral mechanism, a list of species and / or geographic areas from which the genetic resources DSI was generated / extracted will be exempt (of the multilateral mechanism) and operate under a bilateral mechanism consisting of a standardized MAT

Table 32. The extent to which, in parallel to the multilateral mechanism, a list of species and / or geographic areas from which the genetic resources DSI was generated / extracted will be exempt (of the multilateral mechanism) and operate under a bilateral mechanism consisting of a standardized MAT meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Many interviewees suggest that exceptions which lead to, or enable, the development of a hybrid approach would lead to creation of a system which is not efficient, feasible or practical • Some interviewees and survey respondents indicate that exceptions for a list of (endemic) species could be a good idea
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Unclear
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Exemptions are likely to have a negative impact on the potential certainty and legal clarity of the mechanism. To meet these criteria, interviewees suggest that a simple, harmonised system is required.
Not hinder research and innovation	• Unlikely

Be consistent with open access to data	• Unlikely
Not be incompatible with international legal obligations	• Likely
Be mutually supportive of other access and benefit-sharing instruments	• Survey respondents suggest that if the CBD mandates a standardized MAT that everyone must agree to use the exempt DSI, this would likely result in international obligation violations e.g. potentially by forcing the assignment of IPR, or requiring mandatory technology transfer.
Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Likely
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear

ii. Parties may opt out of the multilateral mechanism and instead create their own bilateral mechanism for benefit sharing from the use of DSI

Table 33. The extent to which an option in which Parties may opt out of the multilateral mechanism and instead create their own bilateral mechanism for benefit sharing from the use of DSI meets the required criteria

Criteria	**Comments**
Be efficient, feasible and practical	• Survey respondents suggest that an opt-out option could be feasible if it does not affect data in public databases i.e. Parties who opt out should prevent publishing on public databases), and if the mechanism is not expected to enforce domestic legislation (i.e. no hybrid system) • Many interviewees suggest that a DSI landscape involving the requirement to navigate both a multilateral mechanism and bilateral ABS mechanisms for DSI would not be efficient, feasible or practical
Generate more benefits, including both monetary and non-monetary, than costs	• Unclear
Be effective	• Unclear
Provide certainty and legal clarity for providers and users of DSI on genetic resources	• Unlikely
Not hinder research and innovation	• Unlikely
Be consistent with open access to data	• Unlikely
Not be incompatible with international legal obligations	• Unclear
Be mutually supportive of other access and benefit-sharing instruments	• Unclear

Take into account the rights of IPLCS, including with respect to the traditional knowledge associated with genetic resources that they hold	• Unclear
The monetary and non-monetary benefits arising from the use of DSI on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit IPLCs	• Unclear