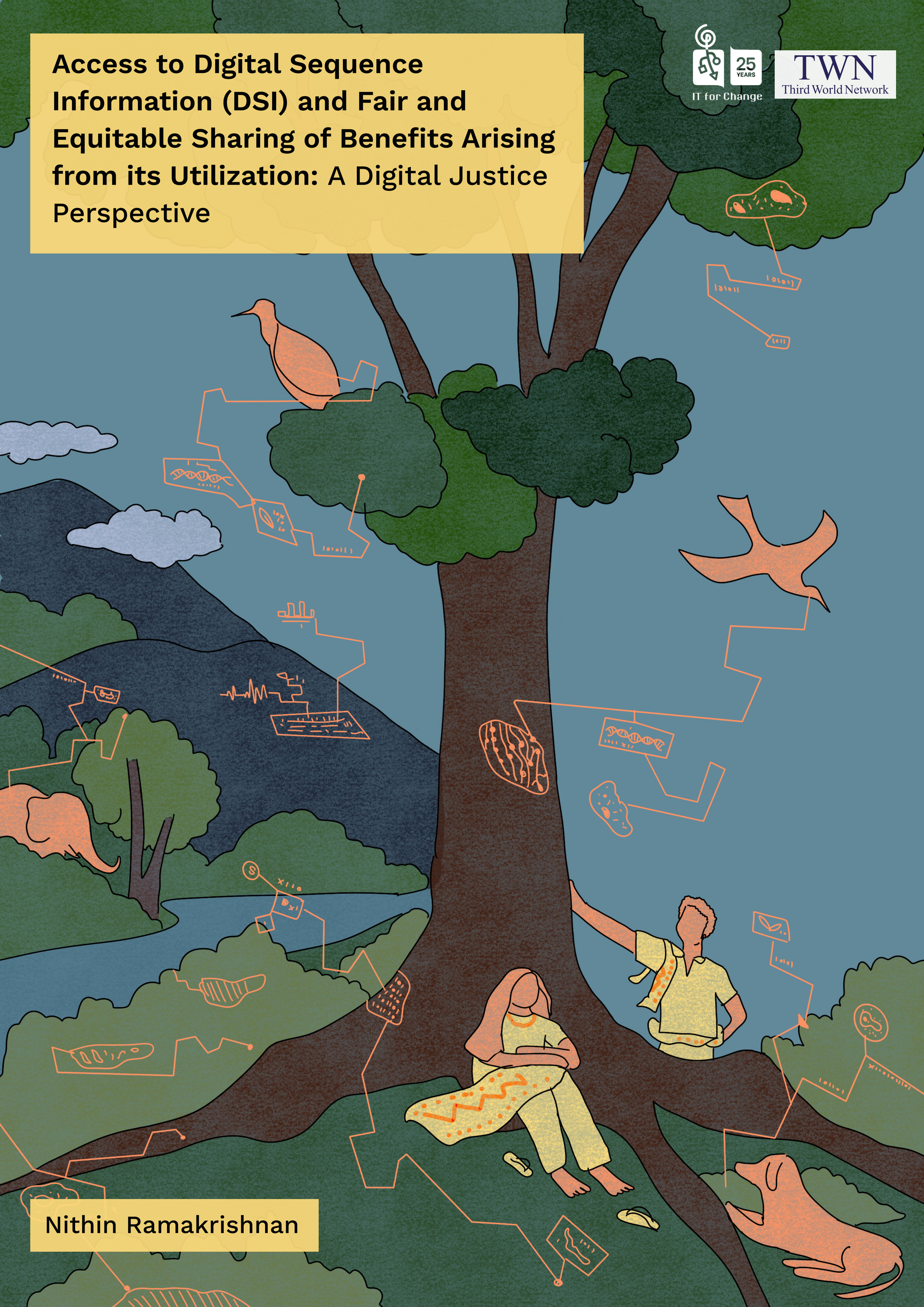

Access to Digital Sequence Information (DSI) and Fair and Equitable Sharing of Benefits Arising from its Utilization: A Digital Justice Perspective

25 YEARS
IT for Change
TWN
Third World Network

Nithin Ramakrishnan

Acknowledgements

This report is part of a research collaboration between IT for Change and Third World Network (TWN) under the Centering Equity and Justice in Global Data Governance project, a collaborative initiative anchored by IT for Change, with support from the Fair Green and Global Alliance (FGG) and the Centre for Global Digital Justice (CGDJ). The project aims to advance sector-specific, contextually grounded data justice principles rooted in Global South perspectives, developed in collaboration with progressive civil society organizations and people's movements. Through this engagement, the project examines the impacts of digitalization and datafication in critical domains— including public health, biodiversity, food sovereignty, and climate change mitigation and adaptation— to articulate justice-oriented approaches to data governance.

About IT for Change

Founded in 2000, IT for Change is a Southern NGO rooted in feminist principles and committed to advancing digital justice through the democratization of digital technologies. It holds Special Consultative Status with the United Nations Economic and Social Council (ECOSOC).

About Third World Network

TWN is a not-for-profit international policy-oriented research organization founded and established in Malaysia. TWN's mission is to bring about a greater articulation of the needs and rights of the peoples of developing countries, a fair distribution of world resources, and forms of development that are ecologically sustainable and fulfil human needs.

About the Fair Green and Global Alliance

Fair, Green and Global Alliance is a consortium of eight global organisations whose goal is to expand civil society voices to make trade and global supply chains just and fair in Global South contexts.

About the Center for Global Digital Justice

The Center for Global Digital Justice (CGDJ) is a policy resource center that aims to further Global South visions of digital governance and technological innovation.

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Executive Summary

This study examines the governance practices of selected Digital Sequence Information (DSI) databases from the perspective of biodiversity justice, sovereignty, human rights, and fair and equitable benefit-sharing under international law. It analyses how current DSI-sharing practices affect the enjoyment of human rights and the implementation of the Convention on Biological Diversity (CBD), the Nagoya Protocol, and emerging international frameworks on DSI governance.

Advances in sequencing technologies, bioinformatics, synthetic biology, and artificial intelligence have transformed the use of genetic resources. Increasingly, research and development are conducted through access to digital genetic sequence data rather than physical biological materials. This shift has enabled researchers and commercial actors to utilize genetic resources while bypassing access and benefit sharing (ABS) obligations traditionally associated with access to physical materials. The study argues that this has created conditions for “digital biopiracy”, where sequence data derived from biodiversity-rich countries and Indigenous Peoples and local communities (IPLCs) are utilized using digital technologies without fair and equitable sharing of benefits.

The report undertakes a comparative analysis of selected databases and platforms frequently referenced in international ABS discussions, namely the Genbank (based on International Nucleotide Sequence Database Collaboration policy), Global Initiative on Sharing All Influenza Data (GISAID), and the Global Biodiversity Information Facility (GBIF). It evaluates their practices across fourteen elements from the DSI data life-cycle, including data submission requirements, due diligence, user identification, data access conditions, benefit-sharing obligations, jurisdiction, audit rights, access guarantees, and consistency with the UNESCO Recommendation on Open Science 2021.

The study finds that despite differences in institutional design, the examined databases follow broadly similar governance approaches that externalize responsibility for legality and benefit-sharing to data providers and national authorities, while the databases themselves assume little responsibility for ensuring accountability or equitable use. In particular, the study identifies several systemic governance concerns:

- absence of meaningful checks on whether data uploaders possess lawful authority or consent from rights holders;
- anonymous access to DSI;
- lack of enforceable benefit-sharing obligations on users;
- absence of effective mechanisms linking DSI to the country of origin and original biological materials;

- limited transparency and accountability of database operators;
- inadequate safeguards against digital biopiracy;
- absence of data audit rights for competent authorities;
- discriminatory or unequal access conditions;
- biosecurity and cyber-biosecurity risks associated with unrestricted sharing of sensitive sequence information; and
- concentration of digital infrastructure and governance power in a small number of developed countries and institutions.

The report argues that prevailing claims equating anonymous access with “open access” are inconsistent with the UNESCO Recommendation on Open Science 2021. Open Science, properly understood, requires accountability, transparency, responsible governance, and equitable sharing of benefits. Open access to DSI could be subjected to all these requirements. The study contends that current DSI-sharing systems often promote the extraction of data from developing countries without reciprocal scientific, technological, or economic gains, thereby reinforcing structural inequalities in the bioeconomy.

The paper further demonstrates that unregulated DSI-sharing practices undermine several internationally recognized human rights, including:

1. the right to sovereignty over natural resources;
2. the right to self-determination;
3. the right to development;
4. the right to enjoy the benefits of scientific progress;
5. the right to enjoy natural resources;
6. and the rights of Indigenous Peoples and local communities.

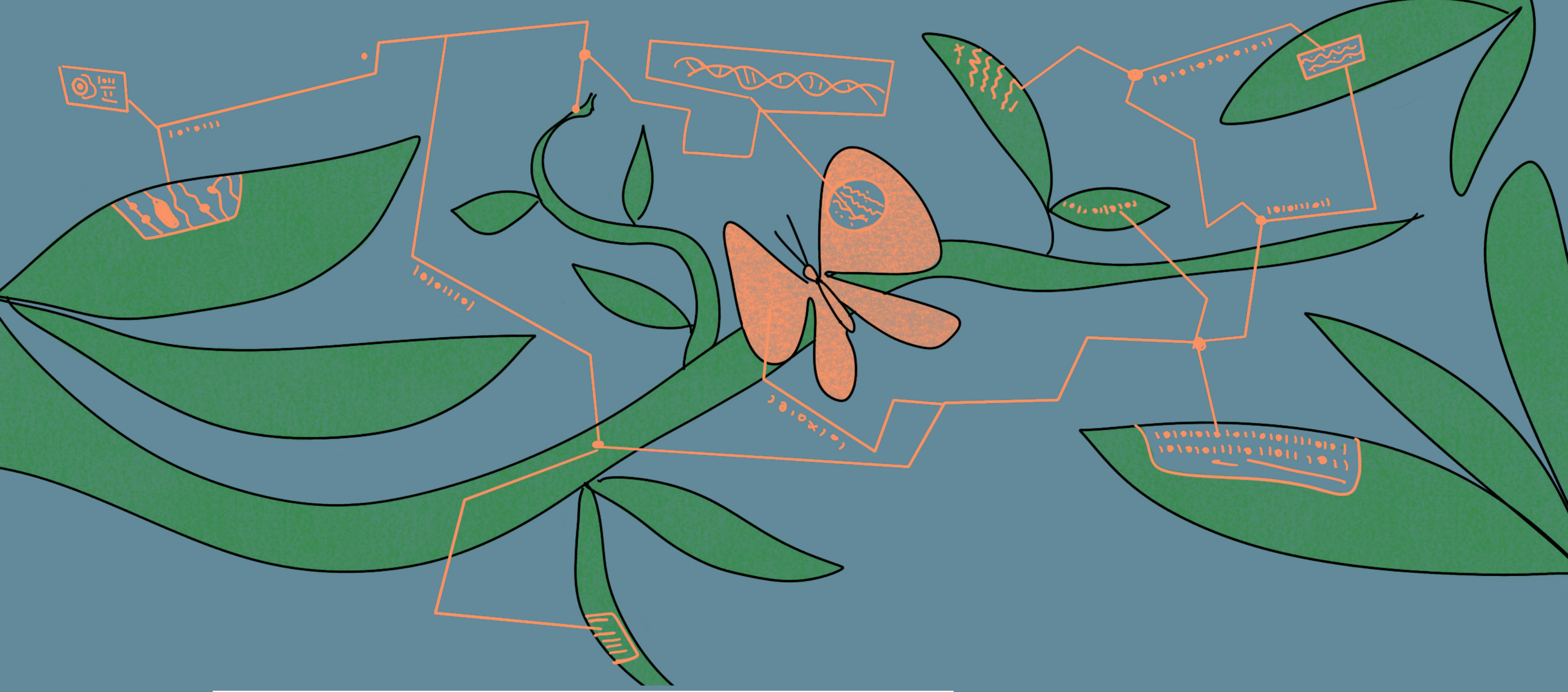
Drawing on international environmental law, such as the Convention on Biological Diversity, the Nagoya Protocol, international human rights law, the CBD COP Decision 16/2, and emerging global debates on data governance, the study argues that States possess clear legal authority to regulate the generation, storage, sharing, and utilization of DSI. It further argues that States hosting or supporting DSI databases have international responsibilities to ensure that such infrastructures do not undermine the sovereign rights and legal interests of provider countries and communities.

The report concludes that current DSI governance models are inadequate to address the legal, ethical, developmental, and security implications associated with the growing digital bioeconomy. It therefore calls for the development of a DSI-sharing environment that is accountable, transparent, respectful of provider rights, and consistent with international law.

To this end, the study proposes the development of a multilaterally accountable database infrastructure and recommends minimum requirements for DSI databases, including:

i. verified user registration and prohibition of anonymous access;
ii. legally binding data access and use agreements;
iii. compliance with national ABS laws;
iv. due diligence and traceability measures;
v. recognition of provider rights and country-of-origin information;
vi. no perpetual retention rights for databases;
vii. maintenance of user logs and audit rights;
viii. non-discriminatory access guarantees;
ix. safeguards against biosecurity risks;
x. interoperability between accountable databases;
xi. obligations to support fair and equitable sharing of both monetary and non-monetary benefits;
xii. legal clarity on policies, such as on intellectual property claims and termination; and
xiii. cooperation with competent legal authorities.

Ultimately, the study argues that accountable governance of DSI is not incompatible with scientific progress or open science. Rather, accountable governance is necessary to ensure that scientific advancement contributes to equity, human rights, biodiversity conservation, public trust, and global justice.



I. Introduction and Context

The Convention on Biological Diversity (CBD) addresses biodiversity conservation, the sustainable use of its components, and access to genetic resources. It also establishes obligations for the fair and equitable sharing of benefits arising from their use. Genetic resources support research and development across sectors of global importance, including for product developments in fields such as medicines and agriculture. Studies published in 2023 estimate that industries dependent on these resources could generate nearly four trillion USD in global value by 2030.[1] At the same time, genetic resources are vulnerable to misuse, including in bioterrorism and biowarfare.[2]

The CBD reaffirms that Parties have sovereign rights over their natural resources. They may regulate access and require benefit sharing by applying terms and conditions, while facilitating access for environmentally sound purposes.[3] States can develop a variety of benefit sharing regimes varying from multilateral to bilateral, international to domestic, or even specialised regimes for specific fields of research like public health and agriculture.[4] The details of building such regimes are elaborated in the Nagoya Protocol to the Convention.

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[1] Grand View Research. (n.d.). Biotechnology market size, share & trend analysis by technology (nanobiotechnology, DNA sequencing, cell-based assays), by application (health, bioinformatics), by region, and segment forecasts, 2024–2030. https://www.grandviewresearch.com/industry-analysis/biotechnology-market

[2] Patrick, S., & Barton, J. (2024, October 16). Mitigating risks from gene editing and synthetic biology: Global governance priorities. Carnegie Endowment for International Peace. https://carnegieendowment.org/research/2024/10/mitigating-risks-from-gene-editing-and-synthetic-biology-global-governance-priorities?lang=en ;

Vinatzer, B. A., Heath, L. S., Almohri, H. M. J., Stulberg, M. J., Lowe, C., & Li, S. (2019, May 15). Cyberbiosecurity challenges of pathogen genome databases. Frontiers in Bioengineering and Biotechnology, 7, 106. https://doi.org/10.3389/fbioe.2019.00106

[3] United Nations, (5 June 1992), Convention on Biological Diversity, Treaty Series, vol. 1760, p.79, Art. 15, https://treaties.un.org/doc/Treaties/1992/06/19920605%2008-44%20PM/Ch_XXVII_08p.pdf.

[4] Convention on Biological Diversity. (2010, October 29). 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. https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

The implementation of these access and benefit sharing (ABS) regimes is increasingly challenged by the CBD's definition of genetic resources, which is framed in terms of physical "materials." Advances in bioinformatics, synthetic biology, and generative biology now allow research to be conducted entirely on digital platforms. Researchers often rely on genetic sequence data (GSD) obtained from databases, without accessing physical samples. This shift enables users to avoid benefit-sharing commitments that would otherwise apply when genetic material is accessed directly.[5] Although the CBD does not distinguish between physical and digital use of genetic resources, certain actors exploit definitional ambiguities to claim that the use of sequence data does not trigger benefit-sharing obligations. This practice undermines the objectives of ABS obligations and contributes to the abridgment of human rights impacts, including on the rights to science, health, food, a healthy environment, and peace. The development of Ebola and COVID-19 vaccines illustrates this concern: although these products relied on genetic sequences shared through databases, access to these health products continues to be a greater challenge for those who need them the most across the globe.[6]

Within the CBD framework, GSD is commonly referred to as Digital Sequence Information (DSI). DSI generally includes genetic data generated by sequencing the DNA or RNA of plants, animals, and microorganisms. When States provide access to genetic material, they are entitled to regulate the extraction and subsequent use of DSI, including any benefit sharing arising from such use.[7] However, many developing countries do not have the bioinformatics capacities or digital infrastructure, such as a national repository to store, manage and share DSI, to fully benefit from this policy space. As a result, sequence data are often deposited in publicly accessible databases located outside the country of origin. These databases are not accountable to provider States or to the CBD.[8]

Researchers and commercial actors can access such data without entering into benefit-sharing arrangements. This weakens the socio-economic justice that underpins ABS regimes. The highly unequal access to COVID-19 vaccines developed using SARS-CoV-2 sequence data highlights this failure. In addition, where national intellectual property laws permit, some users include DSI in patent claims without the consent of the country of origin. Such practices amount to digital biopiracy.[9]

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[5] Ramakrishnan, N., & Rao, C. (2023, March 7). "Open" databases undermine access and benefit sharing [Briefing note]. Third World Network. https://twn.my/title2/biotk/2023/btk230301.htm

[6] Hammond, E. (2020, December). Access and benefit sharing for pathogens: An overview of the issues facing the 2021 World Health Assembly and WHO Executive Board [Briefing paper]. Third World Network. https://twn.my/title2/briefing_papers/twn/ABS%20pathogens%20TWNBP%20Dec2020%20Hammond.pdf

[7] European Commission. (2021, December 1). Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation in the Union. Official Journal of the European Union. Paragraph 2.3.5. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02)

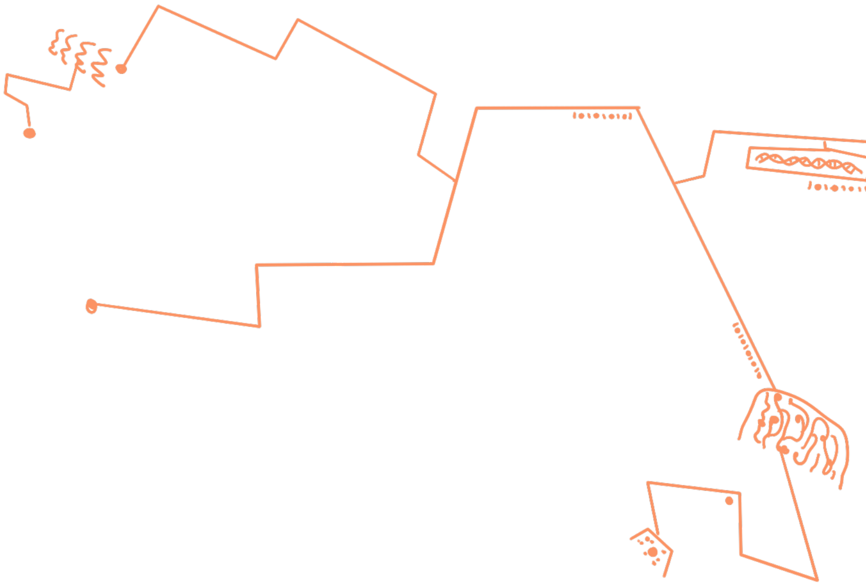
[8] Convention on Biological Diversity, (16 August 2024), Recommendation adopted by the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources, https://www.cbd.int/doc/recommendations/wgdsi-02/wgdsi-02-rec-01-en.pdf. Preambular paragraph in the recommended decision recognizing lack of accountability.

[9] Digital biopiracy refers to the use of digital technologies and infrastructures like sequence databases to bypass prior informed consent (PIC) of the providers of genetic resources and benefit sharing requirements for the use of those genetic resources, and monopolizing R&D outcomes through IP.

In a landmark decision, the sixteenth meeting of the Conference of the Parties to the CBD (COP16) recognized Parties' sovereign rights over DSI and the primacy of national legislation over the use of DSI. It also agreed to establish a multilateral mechanism to share benefits arising from its use.[10] During COP16, developing country Parties to the Convention raised serious concerns relating to the lack of accountability and inclusive governance of current DSI databases. They argued that the practices inconsistent with national and international ABS laws should not continue.[11] These concerns were only partially reflected in the COP16 decision. Resistance from several developed country Parties and certain segments of the scientific community undermined efforts to ensure stronger accountability and equity.

COP16 however agreed to explore new tools and models, including databases, to make DSI publicly available in transparent and accountable ways. The CBD Executive Secretary was requested to commission a study on this issue. The Subsidiary Body on Implementation was also tasked with developing recommendations based on the views of Parties and relevant stakeholders.

This is the context of the present study. It examines existing DSI-sharing practices in selected sequence databases and assesses their implications for fair and equitable benefit sharing.



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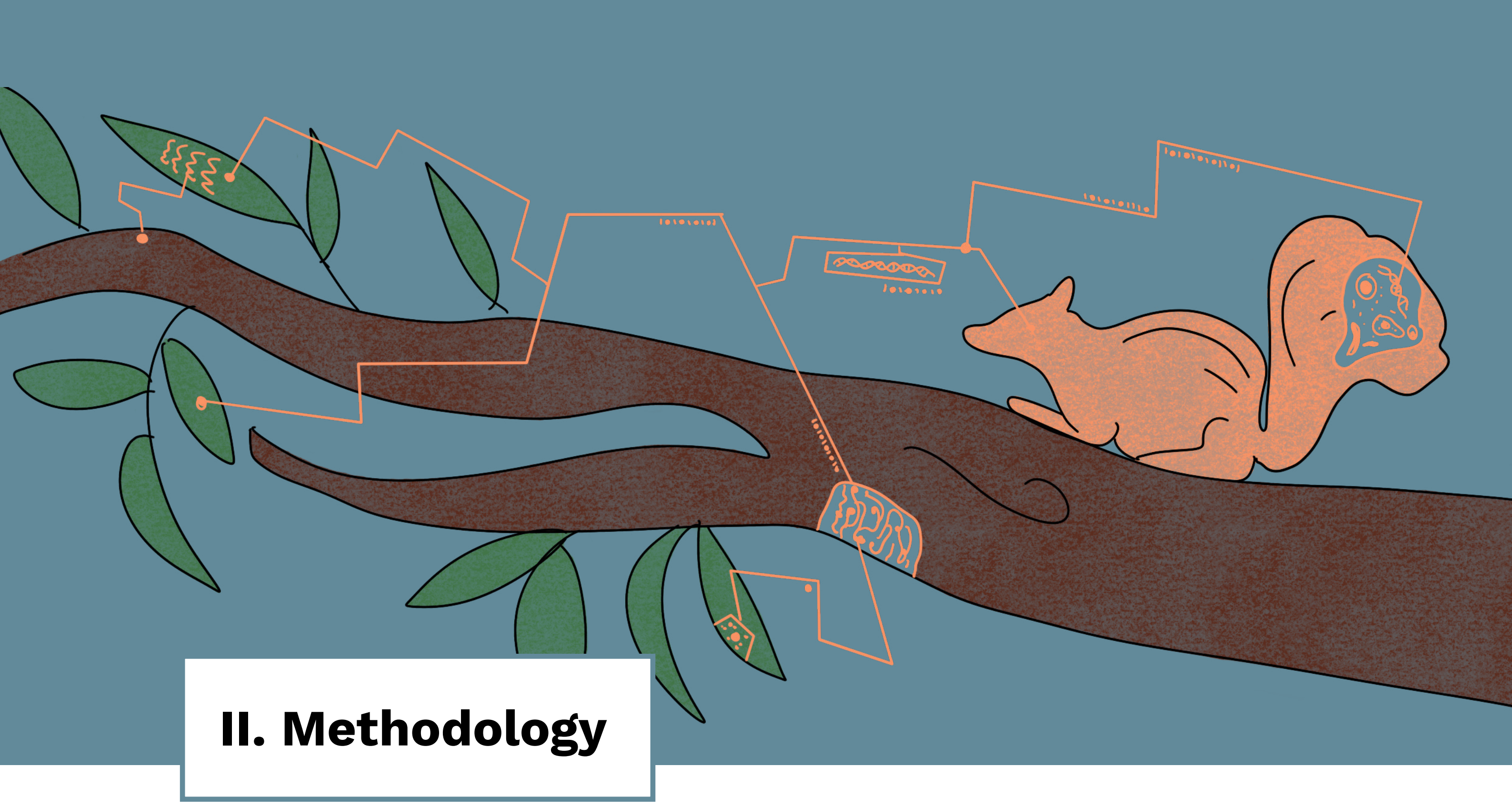
[10] Convention on Biological Diversity, (2024, November 1), Decision 16/2 - Digital sequence information on genetic resources, Annex, https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf;
Arita, M., (2025, February 21) , Data Sovereignty and Open Sharing: Reconceiving Benefit-Sharing and Governance of Digital Sequence Information, Data Science Journal, Vol 24, Page 9, https://datascience.codata.org/articles/10.5334/dsj-2025-009.

[11] Ramakrishnan, N., (2024, August 13) , CBD: Developing countries call for CBD database for DSI and improved data governance, Third World Network, TWN Info Service on Biodiversity and Traditional Knowledge (Aug24/04), https://twn.my/title2/biotk/2024/btk240804.htm;
Ramakrishnan, N., Ching, L.L., (2024, November 19) , COP16: Developing countries struggled to defend sovereign rights over DSI on genetic resources, Third World Network, TWN Info Service on Biodiversity and Traditional Knowledge (Nov24/08), https://twn.my/title2/biotk/2024/btk241108.htm.



II. Methodology

The study was designed to compare certain key databases in terms of various elements relating to the use of DSI, from the data being uploaded, then downloaded, and deleted at the request of the uploader or other competent/rightful persons. The report focuses on the explicit terms and conditions of the databases.

The following three databases were selected based on two criteria. First, whether they are explicitly referenced in international ABS instruments. Second, whether they are frequently cited in international policy discussions on DSI. Genbank and Global Initiative on Sharing All Influenza Data (GISAID), which are recommended in the Pandemic Influenza Preparedness Framework, were selected. Another database, Global Biodiversity Information Facility (GBIF), was actively considered as a multilateral biodiversity database during the negotiations in the informal advisory group to the Co-chairs of the CBD Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources.[12]

In the case of GenBank, the analysis does not rely on GenBank's standalone terms of use. Instead, it examines the terms of the International Nucleotide Sequence Database Collaboration (INSDC), with which GenBank is partnered.[13] INSDC mirrors sequence data across collaborating databases in Japan and Europe. The INSDC website is maintained by the host institution of the European database, the European Nucleotide Archive (ENA), which is operated by the European Molecular Biology Laboratory – European Bioinformatics Institute (EMBL–EBI). INSDC's terms of use refer directly to the EMBL–EBI terms and conditions, which therefore form the basis of this analysis.

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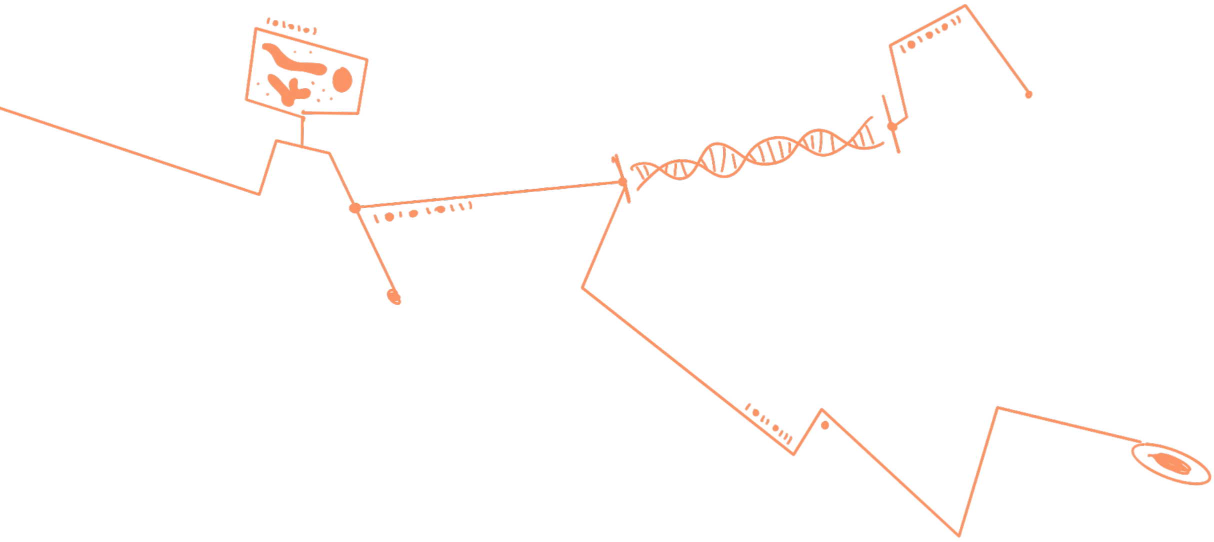
[12] Convention on Biological Diversity (26 July 2024), Report of the Co-Chairs on the outcomes of their informal intersessional work, https://www.cbd.int/doc/c/2d04/c3dd/0ec3bc74cb00f8b9364bcd69/wgdsi-02-inf-02-en.pdf.

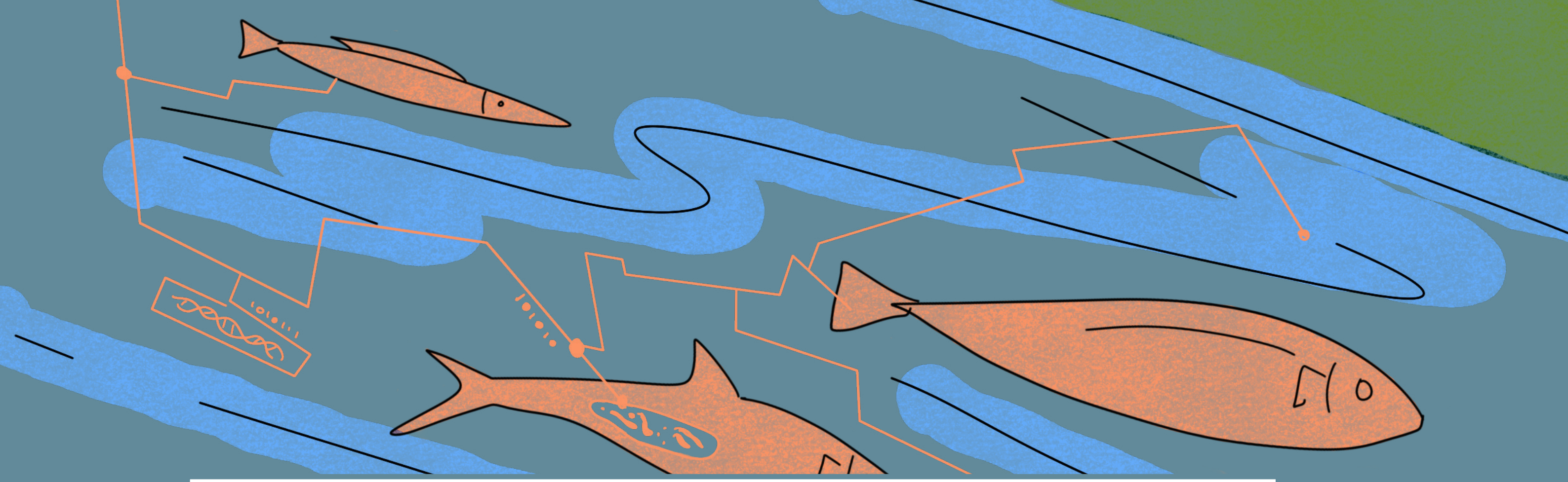
[13] INSDC (n.d.), Members page, https://www.insdc.org/about-insdc/#vf-tabs__section-members

As all the selected databases provide free access, the inclusion of The Arabidopsis Information Resource (TAIR) was initially considered to enable comparison with a subscription-based database. However, TAIR was excluded from this version of the report due to its highly curated nature and its focus on a single species, which would limit comparability.

Fourteen elements in the data life cycle were identified, based on the discussions of various professionals working in the field of bioinformatics and ABS, both in-house and external. These elements form the analytical framework for the comparative assessment presented in the subsequent sections. The elements are:

1. Data submission
2. Due diligence to ensure legitimacy of the submission
3. Action against illegitimate data submission
4. Right to retract data
5. Data access
6. Application of Terms and Conditions
7. Benefit sharing
8. Termination and suspension
9. Personal data disclosures
10. Jurisdiction and the governing law
11. Open access claim
12. Guarantee of access
13. Data audit rights
14. Consistent with UNESCO Recommendation of Open Science





III. Comparative Analysis of DSI Sharing Practices of Selected Databases

Elements	**EMBL-ENA**	**GISAID**	**GBIF**
Data submission	User registration required for data submitter/ publisher.[14]	User registration required for data submitter/publisher.[15]	User registration required. Data publishers must also obtain endorsement from the relevant GBIF Participant country or entity.[16]
Due diligence to ensure legitimacy of the submission	User is exclusively responsible.[17] EMBL–ENA does not verify legality. No requirement to submit an International Recognized Certificate of Compliance (IRCC)[18] as referred to in Nagoya Protocol or national permits.	User solely responsible for determining the legality and appropriateness.[19] IRCC/National permits not required. GISAID acknowledges that it can be liable to the extent provided by any applicable law.[20]	GBIF should ask for reasonable assurance from the data publisher/holder, regarding consistency with applicable laws and requirements for Prior Informed Consent (PIC), in particular when data submitted requires access to biodiversity resources[21]. IRCC/National permits may be considered as reasonable assurance. GBIF also acknowledges there can be liability claims against them.[22]

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[14] European Nucleotide Archive, (n.d.), ENA Documentation, Register a Submission Account, https://ena-docs.readthedocs.io/en/latest/submit/general-guide/registration.html.

[15] GISAID Initiative, (n.d.), Platform Login, https://platform.epicov.org/epi3/frontend#4b1561.

[16] Global Biodiversity Information Facility, (n.d.), Quick guide to publishing data through GBIF.org, https://www.gbif.org/publishing-data.

[17] EMBL-European Bioinformatics Institute. (2024, February 5). Terms of use: Data resources and tools. https://www.ebi.ac.uk/about/terms-of-use/

[18] An internationally recognized certificate of compliance is evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent. Convention on Biological Diversity, (2010, October 29), 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, Art 17, https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

[19] GISAID Initiative. (2011, March 16). GISAID EpiFlu™ database access agreement. https://gisaid.org/terms-of-use/

[20] GISAID Initiative, (2011, March 16), GISAID EpiFlu™ Database Access Agreement, Paragraph on 'Limitation on Liability', https://gisaid.org/terms-of-use/.

[21] Global Biodiversity Information Facility. (2017, August 16). Data publisher agreement. https://www.gbif.org/terms/data-publisher

[22] The Data Publisher Agreement enables GBIF to retract data to avoid such liability. Global Biodiversity Information Facility, (16 August 2017), Data Publisher Agreement, Provisions, https://www.gbif.org/terms/data-publisher.

Elements	**EMBL-ENA**	**GISAID**	**GBIF**
Action against illegitimate data submission	EMBL-EBI may use personal information from its security logs to stop such behaviour and to inform any relevant third party.[23] EMBL also reserves rights (i) to rectify, delete, or restrict access to, content that it judges to be inappropriate, unlawful, infringing third-party rights or inadequately protected, and (ii) to limit or revoke user access.[24]	Any breach of agreement will lead to termination of rights and privileges.[25]	GBIF reserves the right to retract if it has reason to believe continuing to publish the data creates responsibility, until satisfaction.[26]
Right to retract data	EMBL-ENA reserves the right to store permanently,[27] although rights of owners are recognized.	Providers give irrevocable license to GISAID to collect, store, reproduce, access, modify, display, distribute, coordinate, arrange, and otherwise use the data submitted.[28]	Data publishers (submitter) retain the right to withdraw submitted data.[29]
Data access	User registration and login not required for viewing or downloading data.[30]	User registration and login required for download and view.[31]	Views possible without login. User registration and login required for downloading certain data and not mandatory in all cases.[32]

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[23] EMBL-European Bioinformatics Institute, (5 February 2024), Terms of use - Data Resources and Tools, Para 5, https://www.ebi.ac.uk/about/terms-of-use/.

[24] EMBL-European Bioinformatics Institute, (5 February 2024), Terms of use - Data Resources and Tools, Para 10, https://www.ebi.ac.uk/about/terms-of-use/.

[25] GISAID Initiative, (16 March 2011), GISAID EpiFlu™ Database Access Agreement, Paragraph on 'Termination', https://gisaid.org/terms-of-use/.

[26] Global Biodiversity Information Facility, (16 August 2017), Data Publisher Agreement, Provisions, https://www.gbif.org/terms/data-publisher.

[27] EMBL-European Bioinformatics Institute, (5 February 2024), Terms of use - Data, Para 2, https://www.ebi.ac.uk/about/terms-of-use/.

[28] GISAID Initiative, (16 March 2011), GISAID EpiFlu™ Database Access Agreement, Para 2.a., https://gisaid.org/terms-of-use/.

[29] "The power to publish data only belongs to Data Publisher, which can retract Data from publication without giving notice or explanation". Global Biodiversity Information Facility, (16 August 2017), Data Publisher Agreement, Provisions, https://www.gbif.org/terms/data-publisher.

[30] A genbank page on African Rice Genome allows download without registration. National Center for Biotechnology Information, (n.d.), National Library of Medicine - Genome, https://www.ncbi.nlm.nih.gov/datasets/genome/?taxon=4538.

[31] Paragraph 2.d. on licence terms indicates that only "authorized users" (registered users) are supposed to have access. GISAID Initiative, (16 March 2011), GISAID EpiFlu™ Database Access Agreement, Para 2.d., https://gisaid.org/terms-of-use/.

[32] INSDC Dataset download via GBIF annotated archive option requires log in. Global Biodiversity Information Facility, (n.d.), Occurrence Search - Download, https://www.gbif.org/occurrence/download?dataset_key=d8cd16ba-bb74-4420-821e-083f2bac17c2; Downloading the same via darwin core option requires no log in. Global Biodiversity Information Facility, (13 September 2021), INSDC Sequences, https://www.gbif.org/dataset/d8cd16ba-bb74-4420-821e-083f2bac17c2.

Elements	EMBL-ENA	GISAID	GBIF
Application of Terms and Conditions	Terms of data access and use apply through declaration of terms and conditions of the website. Certain data resources may apply specific conditions or licensing agreement.[33] Where human data is involved, it employs data access agreements.	Terms of data access and use are applied through Database Access Agreement.[34]	Mostly through Data User Agreement[35]. Certain options promote free and/or anonymous access, in which case, users are not necessarily bound by agreement.[36] Providers have separate publisher agreements.[37]
Benefit sharing	Mentions data might be subject to the benefit sharing rights.[38] Responsibility of the user to not to infringe such rights.	No mention of benefit sharing rights. User to agree with all applicable laws and regulations.[39]	GBIF MoU and agreements do not alter benefit sharing agreements[40].
Termination and suspension	Database undertakes no responsibility for any temporary or permanent discontinuity in service.[41] Commitment to open science is limited to "all reasonable efforts", there will be an attempt to give notice.[42] No clarity about what happens to data after termination of service.	Users agree to partial or full suspension of access, without prior notice.[43] Database Access Agreement may be terminated on breach. GISAID may also terminate agreement with 30 days' notice without giving any reason. When GISAID terminates access, rights it gained from the data submitter continue to exist, including storage.[44]	GBIF Secretariat cannot guarantee uninterrupted data access services.[45] In this case, participating countries and the governing board have a say. No clarity about what happens to data after termination of service.

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[33] EMBL-European Bioinformatics Institute, (5 February 2024), Terms of use - General, Para 9, https://www.ebi.ac.uk/about/terms-of-use/.

[34] GISAID Registration paper requires every user to accept GISAID EpiFlu™ Database Access Agreement, https://gisaid.org/register/

[35] Global Biodiversity Information Facility, (16 August 2017), Data User Agreement, https://www.gbif.org/terms/data-user.

[36] Global Biodiversity Information Facility, (16 August 2017), Data Publisher Agreement, Provisions, https://www.gbif.org/terms/data-publisher.

[37] Global Biodiversity Information Facility, (16 August 2017), Data Publisher Agreement, Provisions, https://www.gbif.org/terms/data-publisher.

[38] EMBL-European Bioinformatics Institute, (5 February 2024), Terms of use - Data, Para 4, https://www.ebi.ac.uk/about/terms-of-use/.

[39] GISAID Initiative, (16 March 2011), GISAID EpiFlu™ Database Access Agreement, Paragraph on 'Legal Compliance', https://gisaid.org/terms-of-use/.

[40] Global Biodiversity Information Facility, (16 August 2017), Data Publisher Agreement, Annex Para 1, https://www.gbif.org/terms/data-publisher;
Global Biodiversity Information Facility, (16 August 2017), Data User Agreement, Annex Para 1, https://www.gbif.org/terms/data-user.

[41] EMBL-European Bioinformatics Institute, (5 February 2024), Terms of use - Data Resources and Tools, Para 2, https://www.ebi.ac.uk/about/terms-of-use/.

[42] EMBL-European Bioinformatics Institute, (5 February 2024), Terms of use - General, Para 7; read with Terms of use - Data Resources and Tools, Para 2, https://www.ebi.ac.uk/about/terms-of-use/.

[43] GISAID Initiative, (16 March 2011), GISAID EpiFlu™ Database Access Agreement, Paragraph on 'Your rights upon suspension of access', https://gisaid.org/terms-of-use/.

[44] GISAID Initiative, (16 March 2011), GISAID EpiFlu™ Database Access Agreement, Paragraph on 'Termination', https://gisaid.org/terms-of-use/.

[45] "GBIF Secretariat cannot guarantee the quality or completeness of data, nor does it guarantee uninterrupted data access services". Global Biodiversity Information Facility, (16 August 2017), Data User Agreement, https://www.gbif.org/terms/data-user.

Elements	EMBL-ENA	GISAID	GBIF
Personal data disclosures	EMBL-EBI may use personal information from its security logs (IP address etc.) Disclosure will be based on "privacy notice"[46] and "internal policy on data protection."[47] Disclosure to relevant third parties may occur.[48]	Name and institutional affiliation shared amongst all authorized users. Will not disclose personal data to any third party unless required by law or order of court/tribunal in the course of litigation.[49]	Personal data disclosures occur as required by law.[50]
Jurisdiction and the governing law	Governing law not specified in the terms of use. Data controller located in the UK; Data Protection Officer located in Germany.[51]	Disputes involving data providers shall be governed by the local law of the provider.[52] Disputes involving a data user shall be settled under Rules of Arbitration of the International Chamber of Commerce. In this case Place of Arbitration and Applicable laws are mentioned as that of Germany.[53]	Both data publisher and data users' agreements are governed by the laws of Denmark.[54]

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[46] EMBL-European Bioinformatics Institute. (2024, February 5). Terms of use: Data resources and tools. https://www.ebi.ac.uk/about/terms-of-use/

[47] EMBL-European Bioinformatics Institute, (2024, February 5), Terms of use - Privacy, Para 1, https://www.ebi.ac.uk/about/terms-of-use/.

[48] EMBL-European Bioinformatics Institute, (2024, February 5), Terms of use - Data Resources and Tools, Para 2, https://www.ebi.ac.uk/about/terms-of-use/.

[49] GISAID Initiative, (16 March 2011), GISAID EpiFlu™ Database Access Agreement, Paragraph 2.f. on 'Privacy', https://gisaid.org/terms-of-use/.

[50] Global Biodiversity Information Facility, (5 December 2024), Privacy Policy, Section 4, https://www.gbif.org/terms/privacy-policy.

[51] EMBL-European Bioinformatics Institute, (2025, March 10), Data protection: Privacy notice for EMBL-EBI's public website, https://www.ebi.ac.uk/data-protection/privacy-notice/embl-ebi-public-website/.

[52] GISAID Initiative, (2011, March 16), GISAID EpiFlu™ Database Access Agreement, Paragraph on 'Miscellaneous', Clause 'e', https://gisaid.org/terms-of-use/.

[53] GISAID Initiative, (2011, March 16), GISAID EpiFlu™ Database Access Agreement, Paragraph on 'Miscellaneous', Clause 'f', https://gisaid.org/terms-of-use/.

[54] Provisions Section in both agreements specify the laws of Denmark. Global Biodiversity Information Facility, (16 August 2017), Data Publisher Agreement, Provisions, https://www.gbif.org/terms/data-publisher;
Global Biodiversity Information Facility. (2017, August 16). Data publisher agreement. https://www.gbif.org/terms/data-publisher

Elements	**EMBL-ENA**	**GISAID**	**GBIF**
Open access claim	As per INSDC officials in 2021 – INSDC makes no claim of providing open access.[55] As of 20-05-2024, INSDC claims to be "premium pen Access"[56]	Government supporting, and hosting GISAID describes the database as "protected open access" (geschützten offenen Zugang).[57]	To the greatest extent possible, GBIF claims to be an open access facility.[58]
Guarantee of access	No such responsibility undertaken. Accepts no responsibility for the consequences of any temporary or permanent discontinuity in service.[59]	No such responsibility undertaken. Without any limitation based on Database Access Agreement, GISAID can suspend access to all or any part of the GISAID EpiFlu™ Database and/or Data without any prior notice or liability to the user.[60]	No such responsibility undertaken. Nevertheless, the multilateral governance model gives better assurance of access. GBIF Secretariat cannot guarantee the quality or completeness of data, nor does it guarantee uninterrupted data access services. Users employ these data and services at their own risk.[61]
Data audit rights	Not specified.	Not specified.	Not specified.
Consistent with UNESCO Recommendation of Open Science[62]	Not consistent. Neglects the principle that greater openness comes with greater responsibility for all open science actors. Very limited public accountability, and sensitivity to conflicts of interest. Nearly non-existent vigilance as to consequences of research activities.	Not consistent. Nearly non-existent public accountability as the database is managed privately. Very limited sensitivity to conflicts of interest. Offers possibility of limited vigilance against the consequences of research.	Not consistent. Slightly better public accountability than GISAID and INSDC, as databases have some for decentralized governance structure. Very limited sensitivity to conflicts of interest and possibilities of vigilance against the consequences of research.

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55 Arita, M., Karsch-Mizrachi, I., & Cochrane, G. (2020, November 9), The international nucleotide sequence database collaboration, Nucleic Acids Research, 49(D1), D121–D124, https://doi.org/10.1093/nar/gkaa967.

56 The International Nucleotide Sequence Database Collaboration, (n.d.), About INSDC - Mission and Vision, https://www.insdc.org/about-insdc/#vf-tabs__section-mission-vision.

57 Federal Ministry of Health - Germany, (2018, June 9), World's largest database supports research into flu vaccines, https://www.bundesgesundheitsministerium.de/ministerium/meldungen/2018/juni/gisaid.html

58 Global Biodiversity Information Facility, (2017, August 16), Data Publisher Agreement, Annex Para 2, https://www.gbif.org/terms/data-publisher;
Global Biodiversity Information Facility, (2017, August 16), Data User Agreement, Annex Para 2, https://www.gbif.org/terms/data-user.

59 EMBL-European Bioinformatics Institute, (2024, February 5), Terms of use - Data Resources and Tools, Para 2, https://www.ebi.ac.uk/about/terms-of-use/.

60 GISAID Initiative, (2011, March 16), GISAID EpiFlu™ Database Access Agreement, Paragraph on 'Your rights upon suspension of access', https://gisaid.org/terms-of-use/.

61 Global Biodiversity Information Facility, (2017, August 16), Data User Agreement, https://www.gbif.org/terms/data-user.

62 United Nations Educational, Scientific and Cultural Organization, (23 November 2021), Recommendation on Open Science, https://www.unesco.org/en/legal-affairs/recommendation-open-science.

IV. Findings

Despite differences in mandates and governance models, the databases examined display a strikingly similar approach to preventing biopiracy and promoting access and benefit sharing.

In practice, all three adopt a hands-off model. Responsibility is shifted to providers of genetic material from which DSI is derived. Due diligence is also shifted to national authorities that provide access to physical genetic resources. This approach is often justified in the name of open access in international fora like the Conference of the Parties (COP) to the CBD. At the same time, the databases themselves do not assume responsibility to ensure access for all legitimate users on a non-discriminatory basis. The databases do not exercise due diligence with respect to the data they host. They do not verify whether data is submitted by persons with legitimate authority to make such data publicly available. Nor do they assess whether submitters comply with applicable national or international laws. While the databases acknowledge, in principle, that publicly shared data may be subject to national sovereignty and to the rights of Indigenous Peoples and local communities (IPLCs), they take no concrete measures to safeguard these rights. There is little responsibility undertaken to ensure DSI is linked to the original sample and identified with the country of origin. Their sole response is limited to general disclaimers in terms of use, stating that data may be subject to third-party rights.

The databases also very well know that the users have significant potential conflicts of interest when it comes to disclosing the origin of genetic resources from which the DSI is sequenced, and without proper terms and conditions, the users are prone to not disclose the true source. Yet they do not take any measures to prevent the misuse of their platform by data submitters and users, undermining the rights of the provider countries and communities of genetic materials, knowingly or unknowingly.

Given the high commercial and non-commercial value of DSI and the significant stakes for States and IPLCs, the standard of care exercised by these databases is inadequate. In particular, the approach of the International Nucleotide Sequence Database Collaboration (INSDC) in promoting “free and unrestricted access” to anonymous users effectively renders the sovereign rights of states and the rights of IPLCs over DSI meaningless in practice. Governments, mainly from developed countries, that fund, host, or support these databases, which have the least interest in preventing biopiracy and ensuring benefit sharing, have not exercised prudence in this regard.

Until recently, the international community had also not stepped up to address these governance gaps. This began to change with the adoption of CBD COP Decision 16/2 in 2024, which explicitly recognizes the obligations of entities operating databases and other tools that depend on and make DSI publicly available.[63] The decision now places responsibilities on Parties that fund, sponsor, or host sequence databases to ensure that database practices are consistent with CBD decisions.[64]

COP16 also made a historic decision to explore possible new tools and models, such as databases, for making DSI on genetic resources publicly available and accessible in a transparent and accountable manner to all Parties.[65] This marks the first significant effort in several years to address accountability and transparency in DSI sharing. Although the preamble in the draft decision acknowledged the problems of sharing DSI through databases unaccountable to parties, this language was removed from the final text as part of a pragmatic compromise between developed and developing countries, with the understanding that the COP and other CBD bodies would pursue further work to improve accountability.

However, where DSI continues to be shared internationally through online databases controlled by a limited number of governments or entities, without accountability to the wider international community and without binding international legal guidance, serious governance challenges persist.

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[63] Convention on Biological Diversity, (2024, November 1), Decision 16/2 - Digital sequence information on genetic resources, Annex, Para 10, https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf.

[64] Convention on Biological Diversity, (2024, November 1), Decision 16/2 - Digital sequence information on genetic resources, Annex, Para 11, https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf.

[65] Convention on Biological Diversity, (2024, November 1), Decision 16/2 - Digital sequence information on genetic resources, Operative Para 4, 6(b) and 7(b), https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf.

1. Absence of checks by databases on the right holder's consent

Rights over DSI do not vest automatically in any person in possession of the data. They rest with the provider of the genetic material from which the data were derived.[66] Despite this, databases do not verify whether the DSI uploader has the consent or legal authority of the actual rights holder. The problem is aggravated when DSI is uploaded to the databases not accountable to CBD Parties and that share DSI with unidentified persons.

Arguments in favor of unrestricted uploading are often framed as serving open science. However, open science also requires that data should not be extracted inequitably and benefits arising from the use of shared data should reach all.[67] When DSI is uploaded to databases without consent checks and then shared with unidentified persons, both these requirements of open science are not met.

2. Anonymous access

Several databases, including the largest sequence data collaboration, the INSDC, allow anonymous access. Others, such as GBIF, provide both anonymous and registered access, depending on the data publisher's choice. Similarly, some international agricultural research agencies under the CGIAR share sequence data without requiring user registration or identity verification.[68]

Some scientific groups equate "anonymous sharing" with "open access" or as a critical feature of open access.[69] It can clearly be inferred from the UNESCO Recommendation on Open Science 2021 that anonymous access is incompatible with open access.

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[66] European Commission, (1 December 2021), Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, Official Journal of the European Union, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02). / Convention on Biological Diversity, (2024, November 1), Decision 16/2 - Digital sequence information on genetic resources, https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf.

[67] United Nations Educational, Scientific and Cultural Organization. (2021, November 23). Recommendation on open science. https://www.unesco.org/en/legal-affairs/recommendation-open-science

[68] IRRI manages Rice SNP-Seek Database, https://snp-seek.irri.org/index.zul and ICRISAT manages Cicerseq Database Chickpea Genomes. https://cegresources.icrisat.org/cicerseq/

[69] DSI Scientific Network, What does open access to DSI mean for researchers? https://www.dsiscientificnetwork.org/wp-content/uploads/2024/12/DSI-Open-Access-ENG-WEB.pdf; But see Carlson, C., Granados, M., Phelan, A., Ramakrishnan, N., Poisot, T., et al. (2025). The LISTEN principles for genetic sequence data governance and database engineering. Nature Genetics, 57, 2099–2105. https://www.nature.com/articles/s41588-025-02270-7

The Recommendation clarifies that open access data may carry rights and obligations attached to it[70] and such data must be governed in ways that address conflicts of interest, and social and ecological risks emanating from research activities.[71] Realizing these rights and obligations attached to data and the implementation of good data governance requires the identification of users and actors. Therefore, anonymous access weakens data governance and undermines the core principles of open science, rather than promoting them.

3. Absence of benefit sharing with countries of origin and provider communities

Public databases have no system of obligating users to share benefits with the countries of origin or the original provider communities. In the very first place, databases neither seek to know who the actual rights holder is, nor to identify the users accessing the DSI. This situation is exacerbated with limited or no efforts being made to collect, verify, and display country of origin information, and to ensure sequence data files remain permanently linked to original biological samples and country of origin, from which those samples were collected. They also do not use a data access or data user agreement to obligate users to share benefits with the applicable country of origin or provider communities, or deploy tracking tools to ensure benefit sharing.

As a result, neither monetary nor non-monetary benefits are shared by the users of DSI from databases. It must be noted that the databases, on the other hand, do use data user agreements, terms of use of databases, and other tools like tracking IP addresses, etc., to the extent that the interests of database owners are served.

4. Biosecurity and cyber-biosecurity concerns

Anonymous access to DSI also raises serious biosecurity and cyber-biosecurity concerns, particularly when pathogenic sequences are involved.[72] As research and development increasingly rely on sequence databases, these platforms become attractive targets for data manipulation and misuse.[73]

High-risk pathogen sequences, including those of the smallpox virus (Variola major), can be accessed through databases such as the INSDC by anonymous users. Artificial intelligence systems drawing on publicly available DSI have already been shown to generate pathogenic sequences.[74]

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[70] Paragraph 7 of UNESCO Recommendation on Open Science 2021

[71] Paragraph 14(d) ibid

[72] Convention on Biological Diversity, (2018, January 12), 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, https://www.cbd.int/doc/c/b39f/4faf/7668900e8539215e7c7710fe/dsi-ahteg-2018-01-03-en.pdf.

[73] Vinatzer, B. A., Heath, L. S., Almohri, H. M. J., Stulberg, M. J., Lowe, C., & Li, S. (2019, May 15), Cyberbiosecurity challenges of pathogen genome databases, Frontiers in Bioengineering and Biotechnology, Vol 7. https://doi.org/10.3389/fbioe.2019.00106.

[74] Service, R.F., (2023, June 14), Science, Could chatbots help devise the next pandemic virus?, https://www.science.org/content/article/could-chatbots-help-devise-next-pandemic-virus

Experts such as Kevin Esvelt, who have developed CRISPR technology, have warned that unrestricted online publication of viral genomes could contribute to future pandemics and warned members of the U.S. Congress in December 2021 that posting the genetic sequences of viruses could lead to a global pandemic.[75] Scholars opine that technology has evolved since 2004, when scientists argued that open access to pathogen genomes should be promoted.[76]

While this issue is often ignored as a pathogen-specific concern, risks are no longer limited to pathogenic sequences. The 2013 Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids in the US states the following, marking a shift from biosecurity regimes focused solely on listed pathogens and toxins toward risk assessment of sequences of concern and all synthetic genetic materials with equal care:

> … regulated pathogens and toxins do not represent the entirety of the potential risks to public health, agriculture, plants, animals, animal or plant products, or the environment that could arise from the misuse of synthetic nucleic acids. Non-regulated pathogens and toxins, as well as other novel types of nucleic acid sequences, may also pose significant risks if they are misused. To minimize these risks, a shift is needed from relying solely on lists of regulated pathogens and toxins to also assessing the risks associated with other nucleic acid sequences that may contribute to pathogenicity or harm if introduced into new genetic frameworks (i.e., Sequences of Concern [SOCs]). Also, modern molecular biological techniques allow the conversion between different types of nucleic acids (e.g., RNA to DNA, and vice versa), so it has become necessary to treat all types of synthetic genetic materials with equal care. Additionally, benchtop nucleic acid synthesis equipment is increasingly common in modern laboratories, which changes the commercial landscape for synthetic nucleic acid…[77]

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[75] Willman, D., & Warrick, J. (2024, April 10). Research with exotic viruses risks deadly outbreak, scientists warn. The Washington Post. https://www.washingtonpost.com/investigations/interactive/2023/virus-research-risk-outbreak/ United States Senate Homeland Security and Governmental Affairs Committee. (2022, August 3). Credible pandemic virus identification will trigger the immediate proliferation of agents as lethal as nuclear devices: Testimony of Professor Kevin M. Esvelt, Massachusetts Institute of Technology. https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/Esvelt%20Testimony.pdf

[76] Vinatzer, B. A., Heath, L. S., Almohri, H. M. J., Stulberg, M. J., Lowe, C., & Li, S. (2019, May 15). Cyberbiosecurity challenges of pathogen genome databases. Frontiers in Bioengineering and Biotechnology, 7, 106. https://doi.org/10.3389/fbioe.2019.00106 ;
Esvelt, K. M. (2022, November). Delay, detect, defend: Preparing for a future in which thousands can release new pandemics. Geneva Centre for Security Policy.

[77] U.S. Department of Health and Human Services. (2023, October 13). Screening framework guidance for providers and users of synthetic nucleic acids. Federal Register, 88(197). https://www.federalregister.gov/documents/2023/10/13/2023-22540/screening-framework-guidance-for-providers-and-users-of-synthetic-nucleic-acids

In the US, bio-foundries that synthesize genetic materials from sequences are required to perform sequence screening, follow know-your-customer policies, verify the identity of their customers, and follow up further to verify the legitimacy of the order. Similar requirements are not promoted when it comes to sequence data generation, storage, sharing, and processing.

5. Absence of data audit rights for rights holders or competent legal authorities

Data audit rights allow rights holders and competent authorities to examine data logs, storage infrastructure, and data-processing systems. In the context of DSI, governments of CBD Parties should have the authority to conduct such audits, including inspections of physical storage devices and the status of their use. This is not accorded by the above databases.

In contrast, the European Union's 2018 Regulation on the free flow of non-personal data explicitly recognizes the authority of competent bodies within the EU to access premises, equipment, and data-processing infrastructure in accordance with Union or national law.[78] No comparable provisions exist in current international DSI-sharing practices.

6. No guaranteed access: accounts can be terminated

Existing databases do not operate under an inclusive international mandate to guarantee access to DSI for users from all countries and regions, consistent with rights and obligations under the CBD. Most retain unilateral authority to suspend or terminate access, with or without notice. Restrictions may apply to individual users, IP addresses, or entire countries and regions.

It is important for scientists from all backgrounds to have access to DSI, irrespective of distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. However, to achieve this aim, digital infrastructure cannot be left unregulated or left only to a few states. Unregulated access regimes expose users to political discretion and managerial arbitrariness. Scientists to whom access is denied unilaterally by databases – particularly those from developing countries or with limited institutional support – would lack remedies or access to justice. As most major databases are hosted in developed countries, any grievance is typically subject to their jurisdiction, and engaging in litigation or contest is not affordable for scientists from other regions.

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[78] European Parliament & Council of the European Union. (2018, November 14). Regulation (EU) 2018/1807 on a framework for the free flow of non-personal data in the European Union. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1807

Recent developments in the US illustrate these risks. Media reports[79] indicate that thousands of datasets and research papers have been taken down due to revisions in the US government policy. In this context, scientists have also expressed concern about the safety and integrity of genetic sequence information databases, including Genbank,[80] which is part of the INSDC. The National Institutes of Health recently took down access to researchers from China, Hong Kong, Macau, Russia, Iran, North Korea, Cuba, and Venezuela.[81] Access to the Global Invasive Species Database was also denied to users in the Russian Federation; this is footnoted in CBD Decision 16/18.[82] Allowing a small number of governments to control globally shared DSI enables unilateral decisions that can adversely affect access and the national interests of other Parties.

7. Unequal access: discriminatory functionalities

Not all users of databases have equal rights and access. Database governance structures are often non-transparent and non-inclusive, resulting in unequal access among users. Some databases restrict advanced tools or functionalities to paying users, collaborators from affiliated institutions, sponsors, or funder states. Such models widen disparities between well-resourced researchers and those with limited funding.

As a result, sequences sourced from biodiversity-rich developing countries may be more accessible to researchers in developed countries, private companies, or well-funded institutions than to scientists from the countries of origin. In addition, data shared in trust may be accessed or altered by individuals close to database managers,[83] or used without detection for private monetary or non-monetary gain. For instance, the GISAID database also provides differentiated functionalities to different users, according to certain networking surveys.[84]

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[79] Singer, E. (2025, February 2). Thousands of U.S. government web pages have been taken down since Friday. The New York Times. https://www.nytimes.com/2025/02/02/upshot/trump-government-websites-missing-pages.html

[80] Branswell, H. (2025, February 10). Amid shakeup in U.S. science, researchers express alarm over integrity of key genetic databases. STAT. https://www.statnews.com/2025/02/10/genbank-sra-nih-genetic-databases-trump-impact/

[81] Incorvaia, D. (2025, April 8). NIH blocks researchers in China, Russia and other countries from multiple databases. Fierce Biotech. https://www.fiercebiotech.com/research/nih-bans-researchers-china-russia-and-other-countries-multiple-databases

[82] Convention on Biological Diversity. (2024, November 1). Decision 16/18: Invasive alien species. https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-18-en.pdf

[83] Knickmeyer, E. (2025, February 2). Elon Musk's DOGE gets access to classified USAID info after security chiefs tried to block move and then were put on leave, officials say. Fortune. https://fortune.com/2025/02/02/elon-musk-doge-usaid-classified-info-security-chiefs-leave/

[84] Theo Sanderson [@theosanderson], (2023, April 1), Quick survey for GISAID users..., X (formerly Twitter), https://x.com/theosanderson/status/1642065209106767873?s=20.

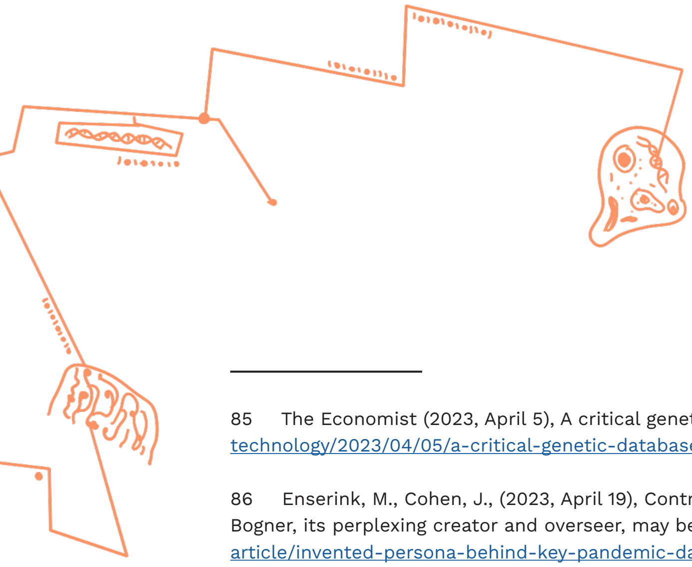
The database management was accused of caprice and lack of transparency by scientists, as reported in The Economist[85] and in Science.[86] Further, there have been several instances where access to DSI has been restricted.[87] It must be noted that scientists from developing countries will have fewer resources to fight against discrimination.

8. Data leaks undermine national laws and/or other benefit sharing regimes

Data leaks happen when sequences and other associated information become available outside of the respective benefit-sharing frameworks. It can happen when somebody uploads data in violation of national laws of the country of origin or material transfer agreements under which they received the data. Such data leakages can also occur if somebody distributes downloaded information against the terms and conditions of a database. Anonymous access exacerbates the risks and dangers of data leaks.

9. Limited access to remedies

Database terms and conditions typically specify the jurisdiction for legal action. Where sequences are hosted or stored in another country, aggrieved states or provider communities must pursue remedies under foreign legal systems. This is the same in cases where researchers' access is suspended unilaterally. It can be seen from the above table in Section III that the most popular databases all mark their jurisdictions in the Global North and apply the laws of developed countries.



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[85] The Economist (2023, April 5), A critical genetic database is under fire, https://www.economist.com/science-and-technology/2023/04/05/a-critical-genetic-database-is-under-fire.

[86] Enserink, M., Cohen, J., (2023, April 19), Control issues: GISAID offers a safe space to post viral genomes. Peter Bogner, its perplexing creator and overseer, may be jeopardizing its future, Science, https://www.science.org/content/article/invented-persona-behind-key-pandemic-database.

[87] Theo Sanderson [@theosanderson], (2023, October 23), I am a researcher studying viruses. I have contributed to the sequencing of more than a million genomes deposited in..., X (formerly Twitter), https://x.com/theosanderson/status/1716463132925657459.

V. Overarching Concerns

1. The lack of multilateral accountability and transparency

Existing sequence databases lack meaningful multilateral accountability and transparency, particularly toward the Parties to the CBD. Thus, none of the major databases analyzed are compatible with emerging CBD Decision 16/2 expectations, with respect to “accountability and transparency to all parties”. CBD Parties, therefore, must work towards building new databases or getting the existing databases to enter into a working relationship with the CBD.

This raises a fundamental governance question: whether one or more databases should be accountable to the CBD and its Parties collectively. The answer is clearly in the affirmative. Multilaterally accountable databases are essential to establish a well-governed open science infrastructure that ensures not only access to data, but also appropriate scientific provenance, attribution of contributions, and fair and equitable sharing of the outcomes of research and innovation, thereby reducing digital biopiracy and serving justice. In contrast, the absence of accountability and transparency undermines monitoring and compliance with the CBD and its Nagoya Protocol, enables digital biopiracy,[88] and undermines fair and equitable sharing of both monetary[89] and non-monetary benefits.[90]

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[88] “vast amounts of what is being called digital sequence information DSI are being used and patented, without permission from the countries that own the genetic resources from which the sequences are derived”. Bagley, M. A. (2022). Just sharing: The virtues of digital sequence information benefit-sharing for the common good. Harvard International Law Journal, 63(1). https://journals.law.harvard.edu/ilj/wp-content/uploads/sites/84/HLI101_crop-3.pdf

[89] Thomas, J., (2024, November 19), UN puts AI Titans on the hook for billions of dollars of biopiracy payments, Scan the Horizon Blog, https://www.scanthehorizon.org/p/un-puts-ai-titans-on-the-hook-for. can provide a fair estimate of the value which is still off the legal hook

[90] Medical Products for Ebola, M-Pox, Avian Influenza, Covid19 Pandemic could have been accessed promptly by the developing countries, had there been proper ABS regulations in place.

Sashikant, S. (2023, June 12). Ebola inequity reinforces need for comprehensive access & benefit sharing mechanism. Third World Network. https://www.twn.my/title2/health.info/2023/hi230602.htm

Rao, C., & Gopakumar, K. M. (2024, April 23). WHO: Monkeypox and avian flu outbreaks stress need for equitable access under IHR. Third World Network. https://www.twn.my/title2/health.info/2024/hi240406.htm

A related question is whether accountability should instead rest with individual states. While in theory national oversight may appear consistent with data sovereignty, in practice it fragments governance of DSI access and use. Such fragmentation creates regulatory gaps that can be exploited for biopiracy or, in extreme cases, bioterrorism. Power asymmetries between database host countries, countries of origin of genetic resources, and countries where researchers and developers are based would also distort governance of DSI further in such a situation. These asymmetries place the implementation of key international ABS instruments, including the Nagoya Protocol, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the Pandemic Influenza Preparedness (PIP) Framework, and the WHO Pandemic Agreement, at the discretion of a small number of powerful governments. For developing countries, this situation is particularly acute, as they neither control nor host the critical digital infrastructure through which DSI is shared and monetized.

As UNCTAD’s Data for Development Report (2024) notes, concerns regarding accountability, transparency of operations, and democratic control over data systems have become pressing:

> While advances in data-driven innovations are built on global collaboration, encompassing contributions from universities, public research institutions, and various global companies, the resultant technologies’ ownership largely remains in the hands of a select group of companies. These market leaders, predominantly situated in a few developed countries, exert overwhelming control in the data economy. By cornering the knowledge and infrastructure essential for refining and capitalizing on the technology, these companies have cultivated dominant market positions, particularly in areas of deep learning and neural networks, both of which are data-intensive domains. The significant concentration of power within a few entities brings forth pressing concerns. Among these are issues of accountability, the transparency of operations, and the overarching question of how democratic control can be asserted over data and AI systems, especially given the profound influence they have on our daily lives.[91]

In the context of DSI, these concerns are even more acute. In the absence of multilaterally accountable databases, there is no guarantee of non-discriminatory access to DSI. Instead, a small group of market-dominant actors, predominantly located in developed countries, monopolize DSI-driven innovations and technologies built with contributions from public universities and public research institutions.

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[91] United Nations Conference on Trade and Development, (2024, May 8), Data for Development, p.54, https://unctad.org/publication/data-development.

In doing so, they also exclude the original providers of genetic resources – the IPLCs who nurture biodiversity – from generating or benefiting from wealth from their own resources.

2. Inequitable extraction of data from developing countries

Limited digital capacity in developing countries, combined with the prevailing academic publishing ecosystem, compels researchers to deposit DSI in databases that are unaccountable to their governments. This practice diminishes their own ability to benefit fairly and equitably from the use of such data, including as contributors of data or as research collaborators. It also weakens the right of their fellow citizens to access DSI derived from the genetic resources of their communities, as most major databases operate under developed country jurisdictions. The same structural imbalance affects their right to a fair share of benefits as provider countries of genetic resources. In addition, the physical storage locations of these databases are rarely disclosed.

As a result, current database practices facilitate inequitable extraction of genetic data from developing to developed countries, in direct contradiction with the UNESCO Recommendation on Open Science. The Recommendation requires Member States to ensure that open science "incorporates the values and principles...to ensure that the benefits of open science are shared and reciprocal, and do not involve unfair and/or inequitable extraction of data and knowledge."[92]

It further recommends that Member States of UNESCO develop policy environments that support the effective operationalization of open science and adopt certification and regulatory measures to prevent vendor lock-in, predatory behavior, and inequitable extraction of profit from publicly funded scientific activities.[93] Open science markets are also required to function "without market dominance by any commercial entity,"[94] given the public interest and role of public funding.

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[92] United Nations Educational, Scientific and Cultural Organization, (2021, November 23), Recommendation on Open Science, Paragraph 16(a), https://www.unesco.org/en/legal-affairs/recommendation-open-science.

[93] United Nations Educational, Scientific and Cultural Oranization, (2021, November 23), Recommendation on Open Science, Paragraph 17(i), https://www.unesco.org/en/legal-affairs/recommendation-open-science.

[94] United Nations Educational, Scientific and Cultural Organization, (2021, November 23), Recommendation on Open Science, Paragraph 17(i), https://www.unesco.org/en/legal-affairs/recommendation-open-science.

UNCTAD's Digital Economy Report 2021 warns that developing countries risk becoming "mere providers of raw data to global digital platforms, while having to pay for the digital intelligence obtained from their data".[95] This is exactly what happens when DSI databases are unaccountable and non-transparent, and their users are not obligated to share benefits fairly and equitably.[96]

Further, UNCTAD's Data for Development Report 2024 reconfirms this warning: "The rising value of data has fuelled competition for its collection, resulting in practices that are often unsustainable and inequitable. Such practices can exacerbate power imbalances, putting developing countries at a disadvantage and potentially widening disparities in their access to and control over valuable data resources."[97]

Ownership and control of major DSI databases remain concentrated in a small number of developed countries, which retain the authority to determine access conditions and usage rules. For decades, these databases have resisted external oversight and mandatory "country of origin" metadata requirements. As a result, developed countries effectively control access to information that competent national ABS authorities in developing countries require to implement their domestic legislation.[98]

This lack of oversight has now complicated the fund allocation questions in the Cali Fund, a multilateral fund established for the sharing of monetary benefits from the use of publicly accessible DSI, when no other benefit sharing conditions are attached to it by the providers of the genetic resource from which DSI is extracted. According to CBD COP Decision 16/2 on the Cali Fund, the allocation of money from the fund has to take into account the geographical origin of the genetic resources from which DSI in the database was derived. Yet, due to incomplete or unreliable country of origin data – an issue explicitly acknowledged in the decision itself – allocation decisions are increasingly difficult to operationalize.

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[95] United Nations Conference on Trade and Development. (2021, August). Digital Economy Report 2021. https://unctad.org/system/files/official-document/der2021_en.pdf

[96] Carlson, C.J., Farrell, M.J., Grange, Z., Han, B.A., Mollentze, N., Phelan, A.L., Rasmussen, A.L., and others, (2021, November 8), The Future of Zoonotic Risk Prediction, Philosophical Transactions of the Royal Society B: Biological Sciences, 376, https://pubmed.ncbi.nlm.nih.gov/34538140/: argues in the context of zoonotic risk prediction and benefit sharing, "scientists who gather novel sequence data may rightfully be hesitant to upload unpublished data to online Web tools for zoonotic risk prediction without clear and enforceable protections" and "without appropriate governance, the countries with the highest burden of zoonotic emergence might find their own data (repackaged in an analytic format) sold back to them at a premium by scientists and corporations from high income countries."

[97] United Nations Conference on Trade and Development, (2024, May 8), Data for Development, p.39, https://unctad.org/publication/data-development.

[98] INSDC spatiotemporal metadata – minimum standards update (03-03-2023) still do not ask "country of origin" of biological sample, instead it requires a mention of "country" which is defined as "locality of isolation of the sequenced sample indicated in terms of political names for nations, oceans or seas, followed by regions and localities". This definition is followed with a comment which says this metadata field refers to "the site where the source organism was isolated or sampled". This provides space for interpretation to users and thus cannot lead to disclosure of country of origin, conclusively. From June 2024, this meta data field is changed into "geographic location" meaning here again the same is the case. The International Nucleotide Sequence Database Collaboration, (3 March 2023), INSDC spatiotemporal metadata – minimum standards update (03-03-2023), https://www.insdc.org/news/insdc-spatiotemporal-metadata-minimum-standards-update-03-03-2023/

Further, the Data for Development Report argues, “Power dynamics, imbalanced relationships, and barriers to entry often prevent these countries [referring to developing countries] from actively participating in decision-making processes that shape global data policies. As a result, their voices may be marginalized, and their specific needs and concerns may not be adequately addressed”. In the DSI context, the classic example is the INSDC’s plans to expand membership to new partners, where prospective members will be required to demonstrate eligibility to the founders, in accordance with the criteria established by the founders.[99]

3. Unregulated DSI sharing undermines human rights

Unregulated cross-border sharing of DSI has direct and cumulative impacts on a range of internationally recognized human rights. These include the rights to sovereignty, self-determination, development, enjoyment of the benefits of science, access to and enjoyment of natural resources, equality and non-discrimination, and the rights of Indigenous Peoples and local communities. These impacts arise from the same governance failures identified earlier: lack of accountability, opacity, and the disconnect of DSI from national and community-based ABS frameworks.

(i) Right to sovereignty

The sovereign right of states over natural resources is firmly recognized under Article 3 of the CBD and its Nagoya Protocol, as well as in United Nations General Assembly Resolutions 1515 (XV) of 1960,[100] and 1803 (XVII) of 14 December 1962[101]. Resolution 1803 further clarifies that permanent sovereignty over natural resources is vested not only in states, but in peoples and nations, thereby translating this principle into the domain of human rights.

Resolution 1803 states that “the exploration, development and disposition of such resources, as well as the import of the foreign capital required for these purposes, should be in conformity with the rules and conditions which the peoples and nations freely consider to be necessary or desirable with regard to the authorization, restriction or prohibition of such activities”.[102]

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[99] The International Nucleotide Sequence Database Collaboration, (2025, May 20), INSDC publishes guidance for prospective new members https://www.insdc.org/news/insdc-publishes-guidance-for-prospective-new-members/

[100] Resolution 1515 (XV) of 1960 made the recommendation that the sovereign right of every State to dispose of its wealth and its natural resources should be respected in conformity with the rights and duties of States under international law. United Nations (General Assembly), (15 December 1960), Resolution 1515 (XV) of 1960 - Concerted action for economic development of economically less developed countries, A/RES/1515(XV), Paragraph 5, https://digitallibrary.un.org/record/205871/files/A_RES_1515%28XV%29-EN.pdf.

[101] Referring to the Recommendation from Resolution 1515 (XV) of 1960, the UN Resolution 1803 (XVII) of 1962 on Permanent Sovereignty over Natural Resources says “any measure in this respect must be based on the recognition of the inalienable right of all States freely to dispose of their natural wealth and resources in accordance with their national interests, and on respect for the economic independence of States”

[102] United Nations (General Assembly), (1962, December 14), Resolution 1803 (XVII) of 1962 - Permanent sovereignty over natural resources, A/RES/1803(XVII), Para 2, https://www.ohchr.org/en/instruments-mechanisms/instruments/general-assembly-resolution-1803-xvii-14-december-1962-permanent.

This linkage is reinforced by the common Article 1 of the International Covenants on Civil and Political Rights, and on Economic, Social and Cultural Rights (ICCPR and ICESCR respectively), which affirms that “all peoples have the right to self-determination and may freely dispose of their natural wealth and resources, without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law”[103].

Article 25 of the ICESCR further states that “nothing in the present Covenant shall be interpreted as impairing the inherent right of all peoples to enjoy and utilize fully and freely their natural wealth and resources.” This makes permanent sovereignty over natural resources a sacred right, or a right of special character, not even restricted by the plausible limitations or qualifications indicated in the Common Article 1 of the Covenants, such as obligations arising out of the need for international cooperation or the principle of mutual benefit.[104]

This Article operates as a safeguard against forms of international cooperation that entrench inequality or perpetuate the external dominance of developed countries over developing countries’ resources. In this sense, sovereignty functions not only as protection from unwarranted foreign state interference, but also from control by external private actors and transnational corporations.

When DSI database practices evade or frustrate national ABS laws, and export genetic data outside of the territory of the country of origin of the genetic resource, they sever the legal and factual link between genetic resources and the sovereign authority of the State. Such practices, therefore directly undermine the right to sovereignty as recognized under international law.

(ii) Right to self-determination

The right to self-determination operates as a right to good governance, protecting populations from exploitation by both state and non-state actors. It is undermined when control over natural resources is surrendered to private entities or external actors without ensuring primary benefits for the people, or when transparency and accountability are lacking in the governance and use of public resources.

According to the Committee on Economic, Social and Cultural Rights, “the ability of people to defend their own economic, social and cultural rights depends significantly on the availability of public information. Efforts to ensure accountability and to combat corruption also require such information in order to be effective.”[105]

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[103] United Nations General Assembly. (1966, December 16). International Covenant on Civil and Political Rights. United Nations Treaty Series, 999, 171. https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-civil-and-political-rights s;
United Nations General Assembly. (1966, December 16). International Covenant on Economic, Social and Cultural Rights. United Nations Treaty Series, 993, 3. https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights

[104] Saul, B., Kinley, D.H., Mowbray, J., (2014), The International Covenant on Economic, Social and Cultural rights : Commentary, Cases, and Materials, Oxford University Press, 1ed, p.110.

[105] UN Committee on Economic, Social and Cultural Rights (CESCR), (1997, December 22) UN Committee on Economic, Social and Cultural Rights: Concluding Observations, Azerbaijan, E/C.12/1/Add.20, https://www.refworld.org/policy/polrec/cescr/1997/en/34876.

When DSI is handled or shared through databases that permit anonymous access and use, competent authorities and providers of genetic resources are deprived of the information necessary to implement ABS effectively. As a result, nationals, Indigenous Peoples, and local communities who have contributed to the conservation and sustainable use of the genetic resources from which DSI is extracted are deprived of their right to self-determination regarding the access, use, and benefit sharing with respect to such resources. Practices such as anonymous DSI sharing are therefore directly incompatible with the right to self-determination.

Claims that such practices promote science or innovation cannot override this right, as self-determination underpins both the right to development and the right to science.

(iii) Right to development

The Right to development connects sovereignty and self-determination. According to Article 1 of the UN Declaration on the Right to Development (1986), this human right implies “the full realization of the right of peoples to self-determination”, and “the exercise of their inalienable right to full sovereignty over all their natural wealth and resources”.[106]

Article 2 emphasizes that the human person is the central subject of development and should be the active participant and beneficiary of the right to development. The practices of DSI databases effectively hide the transactions relating to the use of genetic resources, and consequently deny both active participation in the resource management and governance, as well as fair benefits to the contributor communities.

Further, Principle 10 of the UN Rio Declaration on Environment and Development (1992) requires environmental issues to be handled “with the participation of all concerned citizens” with “appropriate access to information concerning the environment” and “opportunity to participate in decision-making processes.”[107]

Current anonymous access to DSI and non-transparent database practices also violates these participatory rights by preventing informed participation of provider communities in genetic resource governance.

Further, effective access to judicial and administrative proceedings, including redress and remedy, will also be compromised when the people lack the necessary information to initiate these proceedings.

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[106] United Nations (General Assembly), (1986, December 4), Resolution 41/128 of 1986 - Declaration on Right to Development, https://www.refworld.org/legal/resolution/unga/1986/en/15508.

[107] Rio Declaration on Environment and Development, Principle 10, June 14, 1992, 31 I.L.M. 874, 876.

(iv) Right to science

The human right to enjoy the benefits of scientific progress is explicitly recognized in Article 27(1) of the Universal Declaration of Human Rights[108] and Article 15(1)(b) of the ICESCR. This right encompasses both access to scientific benefits and the conditions under which science is conducted.

UNESCO's Venice Statement (2009) identifies three core dimensions of the right to science: freedom of scientific research and communication, enjoyment of scientific benefits, and protection from the adverse effects of science.[109] These dimensions reveal two distinct groups of rights holders: scientists and the broader public. Unaccountable DSI database practices undermine the rights of both.

When dominant database managers unilaterally alter policies governing access to DSI and its metadata and share DSI anonymously, they compromise scientific provenance and distort benefit-sharing outcomes by severing the link between genetic resources and DSI, as well as the relationship between providers and researchers. Arbitrary enforcement of terms of use (often inadequate for good governance), coupled with the absence of effective remedies, interferes with researchers' freedom of scientific research and access to information. At the same time, anonymous DSI sharing makes the monitoring of potentially harmful effects of science less inclusive and less effective.

According to the Special Rapporteur on the Right to Science, "Reasons of the importance of the participation of individuals, communities and peoples in science-related decision-making include, in particular (a) the obligation to protect all persons, including marginalized populations, such as indigenous peoples, against the negative consequences of scientific testing or applications on, in particular, their food security, health or environment...Major decisions regarding funding and research priorities, science policies, emerging areas of research, and new technological applications should entail a participatory process."[110]

Effective ABS frameworks can serve as key checkpoints for intervention to monitor scientific risks and ensure public accountability. Recent demands by farmers' groups for contractual obligations on the recipients of genetic resources under ITPGRFA to involve the farmers, especially those who have provided seeds for research in risk assessment and valuation of biosafety, etc., illustrate how ABS mechanisms can operationalize the right to defend against the adverse impact of scientific applications.[111]

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[108] United Nations (General Assembly), (1948,December 10), Resolution 217A(III) of 1948 - Universal Declaration of Human Rights, Art. 27, https://www.refworld.org/legal/resolution/unga/1948/en/11563.

[109] United Nations Educational, Scientific and Cultural Organization, (16-17 July 2009), Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications https://www.unesco.org/en/legal-affairs/recommendation-open-science.

[110] Shaheed, F., (2012, May 12), Report of the Special Rapporteur in the field of cultural rights: The right to enjoy the benefits of scientific progress and its applications, UN Human Rights Council, A/HRC/20/26, https://docs.un.org/en/A/HRC/20/26.

[111] Seedtreaty.org, (n.d.), Protect Your Seeds, Protect Your Future, https://seedtreaty.org/.

(v) Right to enjoy natural resources

The right to enjoy natural resources is enshrined in Article 25 of the ICESCR and reinforced by Articles 1 and 12, which protect subsistence rights and link natural resources to freedom from hunger. Together, these provisions establish a justiciable entitlement for peoples to fully utilize their natural resources.

Article 1 explicitly affirms that no people may be deprived of their means of subsistence, while Article 12 obligates states to improve food production, conservation, and distribution by making full use of scientific and technical knowledge. These provisions highlight the interdependence of natural resources, science, food systems, and human well-being.

Unaccountable DSI sharing undermines this interdependent framework. When genetic sequence data derived from farmers' varieties are digitized without attribution and shared without safeguards to ensure fair and equitable benefit sharing, national measures such as those established under the ITPGRFA are effectively circumvented. As a result, benefit sharing mechanisms both under the ITPGRFA and the national laws are weakened, undermining food sovereignty, food security, and seed sovereignty.[112]

(vi) Rights of Indigenous People and local communities

The rights of Indigenous Peoples and local communities are central to the governance of genetic resources and have direct legal correlation with the application of all the rights discussed above. Article 8(j) of the CBD obliges parties to respect, preserve, and maintain Indigenous and local knowledge, and to ensure equitable sharing of benefits arising from its use, with the approval and involvement of knowledge holders.[113]

Even though the above requirement is diluted by clauses like "subject to national law", "as far as possible" and "as appropriate", the provision explicitly recognizes that Indigenous Peoples and local communities have the right to self-determination, with regard to wider application of their knowledge, innovation and practices relating to biodiversity resources. The inter-relationship between genetic resources and traditional knowledge, and their inseparable nature for indigenous and local communities, is also very well recognized under the Nagoya Protocol.[114]

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[112] SAM, TWN and African Centre for Biodiversity (2025), The Plant Treaty and the Proposed Amendments: What Every Farmer Needs to Know - An Explainer, https://twn.my/title2/books/Plant_Treaty_Explainer.htm

[113] United Nations, (1992, June 5), Convention on Biological Diversity, Treaty Series, vol. 1760, p.79, Art. 8(j), https://treaties.un.org/doc/Treaties/1992/06/19920605%2008-44%20PM/Ch_XXVII_08p.pdf.

[114] Convention on Biological Diversity, (2010, October 29), 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, Preamble, https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

Article 31 of the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) explicitly recognizes Indigenous Peoples' rights to maintain, control, protect, and develop genetic resources and their associated sciences, and requires States to act in partnership with Indigenous Peoples to protect those rights.[115] Article 32(2) of UNDRIP requires free, prior, and informed consent for resource development projects, with the UN Special Rapporteur affirming that any interference with Indigenous rights must meet higher standards than ordinary property restrictions.[116]

Although not widely ratified, ILO Convention No. 169 explicitly recognizes Indigenous Peoples' rights over natural resources pertaining to their lands.[117] Article 15 requires that these rights be specially safeguarded and affirms Indigenous Peoples' entitlement to participate in the use, management, and conservation of such resources. It further obliges states to undertake meaningful consultation to determine whether, and to what extent, Indigenous interests may be prejudiced before authorizing any exploration or exploitation activities. Indigenous Peoples are also entitled to participate in the benefits arising from such activities and to receive fair compensation for any damages sustained.

Current DSI database operations fundamentally violate these frameworks by creating a complete disconnect between traditional knowledge providers and research innovation centres. The anonymous sharing of genetic sequence data without due diligence checks prevents reasonable assessment of prejudicial impacts and effectively eliminates opportunities to participate in the research as well as seek benefits. Interviews with indigenous peoples at CBD COP meetings reveal that in most cases, there is no consultation about DSI generation, storage methods, potential uses, benefit arrangements, or third-party sharing permissions. This is nothing but a systematic violation of their fundamental rights to control and benefit from their ancestral genetic resources.[118]

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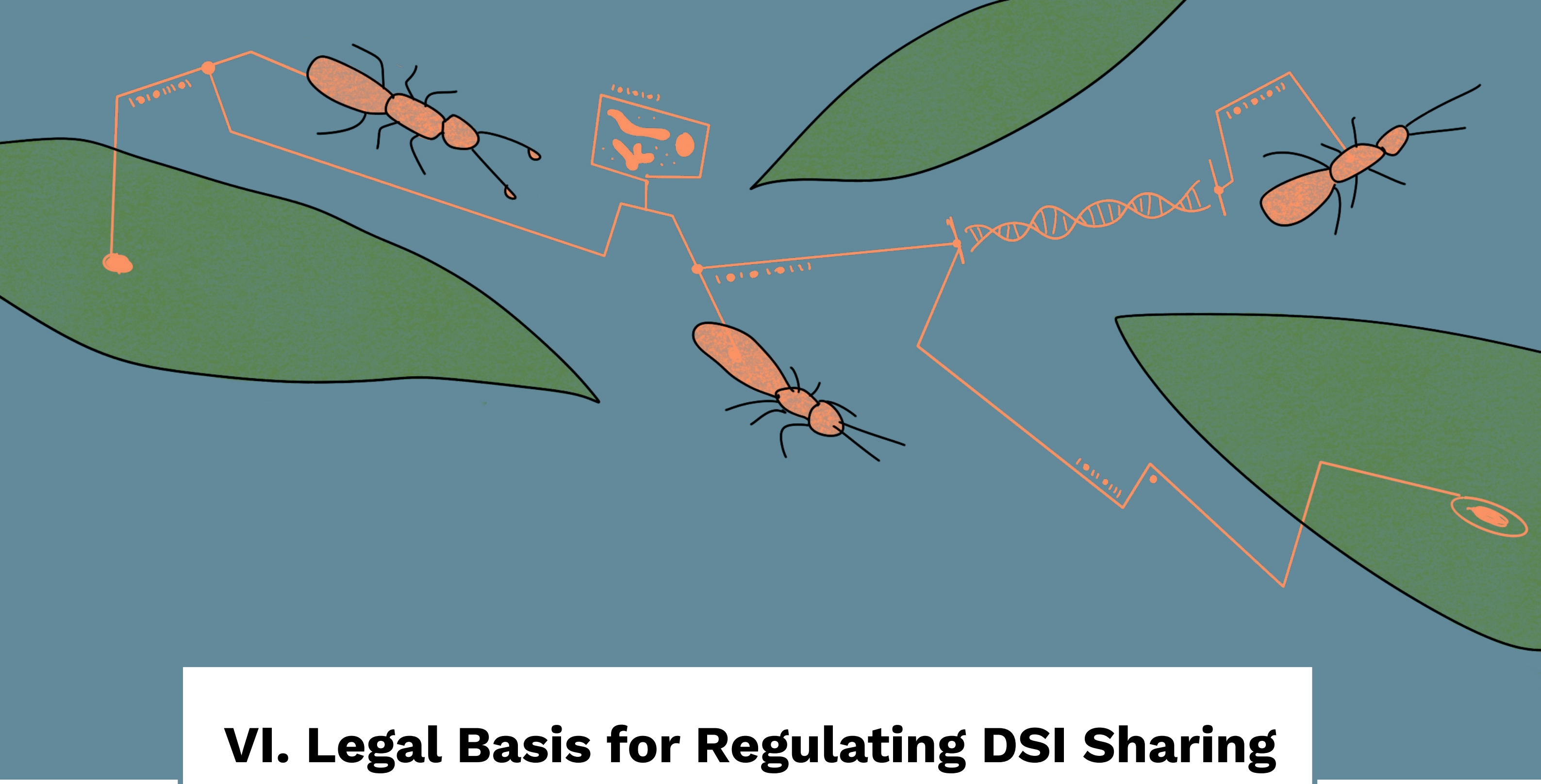
[115] United Nations (General Assembly), (2007, September 13), Resolution 61/295 of 2007 - United Nations Declaration on the Rights of Indigenous Peoples, https://www.un.org/development/desa/indigenouspeoples/wp-content/uploads/sites/19/2018/11/UNDRIP_E_web.pdf.

[116] Centre For Minority Rights Development and Another v Kenya (Communication 276 of 2003), (2009, November 25), ACHPR 102, Para 212, https://africanlii.org/akn/aa-au/judgment/achpr/2009/102/eng@2009-11-25.

[117] International Labour Organisation, (1989, June 7), Indigenous and Tribal Peoples Convention, 1989 (No. 169), https://normlex.ilo.org/dyn/nrmlx_en/f?p=NORMLEXPUB:12100:0::NO::P12100_ILO_CODE:C169.

[118] These interviews are more of informal conversations with the IPLCs representatives whom the author met in person during the CBD COP meetings.



VI. Legal Basis for Regulating DSI Sharing

The free and unregulated cross-border flows of DSI cannot serve people or the planet when the value generated is overwhelmingly captured by a small number of corporations and research institutions concentrated in developed countries. Left unchecked, such flows facilitate digital biopiracy, allowing genetic information to be extracted and exploited without respect for human rights, transparency, accountability, or fair and equitable benefit-sharing under international law.

Addressing this requires an enforceable international data governance framework that: (i) recognizes national sovereignty over DSI; (ii) protects the rights of Indigenous Peoples and local communities; and (iii) enables developing countries to use DSI for their own innovation and development priorities. The legal foundations for such a framework already exist in international law.

At the core lies Article 15(1) of the CBD, which recognizes states' "sovereign rights over natural resources." This provision establishes a bundle of rights that includes the authority to determine access conditions not only to genetic materials but also to data generated from those materials, including DSI. It is widely accepted that access conditions may specify terms governing data generation, storage, sharing, publication, and subsequent use.

This understanding is explicitly reflected in the European Commission's guidance on access and benefit sharing, which recognizes that the use or publication of genetic sequence data may be covered by conditions set out in mutually agreed terms for access to genetic materials and requires those conditions to be respected.[119]

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[119] European Commission, (1 December 2021), Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, Official Journal of the European Union, Paragraph 2.3.5., https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02).

The guidance further clarifies that users who generate sequence data must comply with agreed access conditions and inform subsequent users of any rights and obligations attached to that data. Comparable approaches are reflected in instruments such as the Swiss Academy of Sciences' Agreement on Access and Benefit Sharing for Non-Commercial Research, which contains general terms governing the use of data generated from genetic materials.[120]

CBD COP Decision 16/2 reinforces this legal interpretation. In establishing modalities for operationalizing the multilateral mechanism for fair and equitable benefit-sharing from the use of DSI, the Decision affirms that parties are entitled to determine terms of use for DSI, including benefit-sharing obligations, at the time of granting access to genetic materials.[121] The Decision further recognizes that parties have and can have national legislation that regulates DSI.[122] This national legislation may cover generation, storage, third-party sharing, including through publicly accessible mediums, subsequent use, deletion of data, or taking down of data from certain mediums, portals, or information systems.

Above all, it must be noted that access to genetic resources can be provided through several methods; one of them is by providing access to the genetic sequence information.[123] This reinforces the view that DSI can be regulated as a genetic resource.

While national regulation provides a direct legal basis for governing DSI, COP Decision 16/2 also establishes a clear foundation for international regulation. Through its Modalities set for the CBD Multilateral Mechanism for DSI, the COP sets out expectations for databases within the context of the Multilateral Mechanism. Paragraph 10 of the Modalities annexed to the Decision require entities operating DSI-dependent databases to: (i) inform users about benefit-sharing obligations; (ii) notify data submitters of applicable national and international ABS laws; (iii) require disclosure of country of origin and relevant metadata, including traditional knowledge; (iv) align data governance with principles such as Findable, Accessible, Interoperable, and Reusable (FAIR), Collective benefit, Authority to control, Responsibility, Ethics (CARE), Transparency, Responsibility, User focus, Sustainability and Technology (TRUST), and UNESCO Open Science principles; and (v) ensure data submitted is not subject to restrictions prohibiting its lawful sharing.

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[120] Biber-Klemm, S., Martinez, S.I., Jacob, A., Jevtic, A., (2010, September), Agreement on Access and Benefit Sharing for Non-commercial Research, Swiss Academy of Sciences, https://www.cbd.int/abs/doc/protocol/icnp-1/swiss-academy-science-en.pdf

[121] Convention on Biological Diversity, (2024, November 1), Decision 16/2 - Digital sequence information on genetic resources, Annex, Para 1(a-c), https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf.

[122] Convention on Biological Diversity, (2024, November 1), Decision 16/2 - Digital sequence information on genetic resources, Annex, Para 1, https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf
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[123] Morgera, E., Tsioumani, E., and Buck, M., (2014, July), Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity, Brill | Nijhoff Publications, p.140, https://library.oapen.org/bitstream/handle/20.500.12657/38174/9789004217188_webready_content_text.pdf?sequence=4&isAllowed=y.

Crucially, the decision places corresponding duties on states. CBD Parties that fund, sponsor, or host sequence databases are required to ensure effective implementation of these obligations under Paragraph 11, while other governments (not parties which is only the US, as a sovereign state that signed but did not ratify) are invited to take similar measures under Paragraph 12. Read together, the relevant provisions of Decision 16/2 establish emerging international norms governing DSI sharing. In particular, the requirement that DSI sharing comply with the national laws of provider countries effectively obliges databases to respect the laws of countries of origin, not merely those of the database host state.

General international law supports this approach. International law does not restrict states' sovereign authority over databases operating within their territory or under their control, except to the extent that states must ensure their digital infrastructure is not used in ways that violate jurisdictional limits or cause extraterritorial harm.[124] Accordingly, states in whose territories databases are located, managed, or controlled have a duty to ensure that such databases do not harm the material or legal interests of other states.

Articles 15 and 16 of the Nagoya Protocol obligate its parties to establish appropriate, effective, and proportionate legislative, administrative, or policy measures to ensure that genetic resources utilized within their jurisdiction have been accessed in accordance with prior informed consent and mutually agreed terms. The same applies to storage and utilization of DSI when it is subject to mutually agreed terms. Where database operations undermine the sovereign rights of other states, or the rights of Indigenous Peoples and local communities over genetic resources – including the right to fair and equitable benefit sharing – the host state bears international responsibility to prevent such conduct and to remedy any harm resulting from such conduct which they failed to prevent.[125]

These obligations are reinforced by international human rights law. Given the broad participation in the International Covenants on Human Rights, failure to regulate DSI databases in a manner that respects sovereignty and benefit-sharing triggers State responsibility irrespective of whether a state is party to the CBD or the Nagoya Protocol. The common Article 1 of the Covenants affirms the right of peoples to freely dispose of their natural resources on the basis of mutual benefit and international law, imposing corresponding duties on States and the international community.[126]

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[124] Schmitt, M. (Ed.) (2013), Tallinn Manual on the International Law Applicable to Cyber Warfare, Cambridge University Press, https://www.onlinelibrary.iihl.org/wp-content/uploads/2021/05/2017-Tallinn-Manual-2.0.pdf.

[125] International Law Commission, (2001), Responsibility of States for Internationally Wrongful Acts, Art.28, https://legal.un.org/ilc/texts/instruments/english/draft_articles/9_6_2001.pdf: International Law Commission talks about legal consequences of international wrongs, while Chapter II, Part I provides for several types of attribution of conduct, which could be applicable in the cases referred above.

[126] United Nations Human Rights Committee, (1984, March 13), CCPR General Comment No. 12: Article 1 (Right to Self-determination) The Right to Self-determination of Peoples, Para 5. https://www.refworld.org/legal/general/hrc/1984/en/11735.

It is very clear that entities like INSDC, because they expose economically as well as biologically sensitive information, without effective due diligence, are harming both commercial and security interests of numerous states and peoples. The current practice continues to harm such material interests, and states funding, hosting, or sponsoring such databases need to take action. These states are not only responsible towards the states that provide genetic resources, but also to their peoples comprising indigenous populations and local communities whose rights are distinctly identified.

The states that provide genetic materials are also, in another sense, internally responsible towards their populations for not taking explicit actions to introduce better standards, rules, norms, and discipline in DSI sharing. Several developing countries, however, have expressed a lack of capacity and expertise to manage sequence databases and the application of sequencing technologies, and it is for this reason that they proposed a Database under the CBD.[127] African countries, in particular, have called for digital infrastructure under the CBD multilateral mechanism that could support both global benefit sharing and national ABS implementation where domestic capacity is lacking.

Persistent resistance by some developed countries to these proposals, while simultaneously funding or hosting unaccountable databases, is difficult to reconcile with longstanding international commitments. General Assembly Resolution 626 (VII) of 1952 on the Right to Freely Exploit Natural Wealth and Resources calls on states to refrain from acts designed to impede the exercise of sovereignty over natural resources.[128] Similarly, the Charter of Economic Rights and Duties of States obliges all states to cooperate in eliminating obstacles to resource mobilization, ensuring full participation of its people in the process and benefits of development (Article 7) and to assist developing countries in ways that respect sovereign equality and do not undermine their national control over resources (Article 17).[129]

Thus, regulating DSI sharing or building a multilaterally governed database, as proposed by the African countries during the 2024 CBD negotiations on DSI, is not only important but also legally feasible. For any right to have genuine meaning, it should empower the states (in this case, developing countries) with the agency to exercise such rights thoughtfully, and without undue constraints. Therefore, the international community should take into account the digital divide faced by developing countries and develop safe and secure digital infrastructure, as well as robust legal norms and standards to promote developing country interests. It must be noted that the digital divide is not only limited to internet connectivity but also extends to digital infrastructure like data centres.[130]

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127 Convention on Biological Diversity, (2024, August 16), Recommendation adopted by the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources, Operative Para 2, https://www.cbd.int/doc/recommendations/wgdsi-02/wgdsi-02-rec-01-en.pdf.

128 United Nations (General Assembly), (1952, December 21), Resolution 626 (VII) of 1952 - Right to exploit freely natural wealth and resources, https://digitallibrary.un.org/record/211441/files/A_RES_626%28VII%29-EN.pdf

129 United Nations (General Assembly), (1974, December 12), Resolution 3281 (XXIX) of 1974 - Charter of Economic Rights and Duties of States, https://digitallibrary.un.org/record/190150?ln=en&v=pdf.

130 United Nations Conference on Trade and Development, (2024, May 8), Data for Development, https://unctad.org/publication/data-development: As per numbers quoted in the report, while there are ~3 data centres per million people in North America, the ratio drops to ~0.8 per million in South Asia. Around 65% of the cloud computing market has been cornered by just three firms, Amazon, Google, and Microsoft.

VII. Recommendations

1. Building a DSI sharing environment respectful of the sovereignty of states, human rights, and international law

A DSI sharing environment that respects state sovereignty, human rights, and international law is urgently needed to prevent the continued perpetuation of digital biopiracy as a continuum of physical biopiracy, and to advance socio-economic justice. Such an environment should support multiple databases offering diverse services across the data life cycle, while ensuring respect for the rights of genetic resource providers.

Regulation should be workable: it must not be so prescriptive as to stifle scientific progress, nor so permissive as to allow unaccountable data extraction. This requires a combination of top-down and bottom-up approaches,[131] the former meaning governments take steps to ensure that digital infrastructure remains governed, and the latter meaning allowing digital infrastructure to adjust and adapt itself to good governance standards.

Under a top-down approach, states should develop international rules for DSI sharing that safeguard the rights of provider countries, Indigenous Peoples, and communities. Complementarily, the bottom-up approach should foster an enabling ecosystem in which databases continuously improve governance practices in response to legal, ethical, and scientific expectations. This will provide a certain transition period for existing databases to review their current practices, adopt a transition plan, and to report any non-remediable deviations affecting data collected and shared until the transition is effective.

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[131] United Nations Conference on Trade and Development, (2024, May 8), Data for Development, https://unctad.org/publication/data-development. The report also suggests a combination of both approaches can provide data governance inclusiveness and effectiveness.

States may establish, designate, or authorize one or more databases that are accountable to states individually and collectively through international agreements. These authorized databases should comply with agreed international minimum standards while retaining flexibility to adopt additional protocols consistent with their specific mandates. They could provide core infrastructure functions, including primary data storage, mirroring, and non-discriminatory access, and may serve as initial upload points depending on national policy choices.

Other databases could operate through formal agreements with authorized databases, adopting comparable protocols to create a safe, secure and trusted digital infrastructure and contributing specialized services such as sector-specific curation.

A tiered ecosystem could thus emerge: databases that are authorized by competent authorities; databases fully integrated into the accountable infrastructure through formal agreements; and databases operating with comparable standards to that authorized databases, without formal agreements. Existing databases may upgrade themselves into any of these types based on their own interests and policies of competent authorities. A prescribed transition period would give such databases to plan and adapt to appropriate standards. Beyond the transition period, States could prescribe measures for transition or take other appropriate legal remedies.

In addition, States should pay attention to govern the “first point of upload of data” as it is very critical and is the best interface point at which States and/or international authorities can set a minimum benchmark for data governance. After successful verification of metadata, national law compliance, and attaching of an accession number and/or other identifiers, access can be provided to all registered users with verified accounts, via a login system and subject to the users agreeing to a set of standard legally binding terms and conditions of access. Terms of access to the data from these databases should contain the terms of access as applicable based or relevant ABS and anti-biopiracy laws.

While national databases are ideal, many States lack the capacity to establish and maintain such infrastructure. In this context, international entities such as the CBD, WHO, and FAO are well placed to support the development of multilaterally accountable digital infrastructure. The CBD is also uniquely positioned to host or facilitate DSI databases serving both the multilateral mechanism and national ABS implementation, because the CBD deals with genetic resources in general. The WHO and FAO may also build curated or specialized DSI databases to facilitate research, development, and benefit sharing with respect to genetic or biological materials they manage.

The CBD database proposed by the Africa Group during the 2024 negotiations could serve at least two functions: acting as a repository for DSI within the scope of the CBD multilateral mechanism, and providing developing countries with facilities to store and share DSI under nationally determined terms. Without such infrastructure, States lacking digital capacity cannot meaningfully exercise sovereignty over their genetic resources.

The terms and conditions of the CBD database can take into account the digital divide between developing and developed countries, including in the provision of services and facilities, and aim to bridge that divide. For example, they should stipulate a commitment in data access and use agreements to maximize collaboration with developing country researchers, including by locating research and development processes in provider developing countries. Databases with their establishments and storage facilities in developing countries and that demonstrate active promotion of the skills of the people of developing countries in data management and digital interfaces could also be given special status and consideration under the CBD.

While no governance system can entirely eliminate misuse, these recommendations reject the assumption that the scientific community is unwilling to engage in accountable and transparent DSI sharing practices as well as in fair and equitable benefit sharing. There are scientists who are willing and more than happy to cooperate with systems that offer more accountability and transparency for promoting benefit sharing and avoiding biopiracy.[132] But they should be given clear guidance and facilities such as accountable digital infrastructure to share not only DSI, but also information about their research outcomes. Whereas currently the dominant DSI databases fail to do both.

2. Core minimum standard terms and conditions suggested for DSI databases

Based on analysis of existing database practices and relevant legal instruments, the following minimum standards are proposed to maximize legal certainty, prevent digital biopiracy, and guarantee non-discriminatory access. Governments acting individually or jointly could adopt such minimum standards for databases to promote both access to DSI and the sharing of benefits from the use of DSI.

While no single database currently incorporates all these elements, similar principles have been articulated by scholars under the Licensed, Identified, Supervised, Transparent, Enforced, and Non-exclusive (LISTEN) framework.[133]

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[132] For instance, around 300 scientists called for better benefit sharing obligations under the PABS system in the WHO Pandemic Agreement and called for WHO to establish its own repository or clearinghouse for genetic sequence data and samples: Carlson, C., Becker, D., Happi, C., and others, (23 February 2024), Save lives in the next pandemic: ensure vaccine equity now, Nature, https://www.nature.com/articles/d41586-024-00545-3;

Further bioinformaticians from 10 different countries from 5 different continents came to create a database called Pathoplexus, sharing and analysis of human viral pathogen genomic data and they made a commitment to comply with, endorse and adhere to consensus-driven, international efforts aimed at decreasing disparities and improving equitable global benefits from pathogen sequence sharing: Pathoplexus (n.d.), Pathoplexus Values, Art. 4, https://pathoplexus.org/about/governance/values#article-4-beneficial-sharing.

[133] Carlson, C., and Granados, M., Phelan, A., Ramakrishnan, N., and Poisot, T., (2024, November 16) Engineering data equity: the LISTEN principles, https://ssrn.com/abstract=5022896.

i. **Zero anonymous usage:** All users – natural or legal persons – uploading or accessing data, including via machine-based tools, must be identifiable. Access restricted to verified users is compatible with open science and consistent with UNESCO's Recommendation, as it enhances accountability and governance. Existing models of protected open access demonstrate the feasibility of this approach.[134]

ii. **Zero discrimination:** All data services should be made available to "all verified users" without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.[135]

iii. **Verified and interoperable accounts:** Databases should commit to timely account verification and mutual recognition of verified accounts across interoperable systems, reducing duplication.[136] Verification may be supported by trusted intermediaries such as public authorities, research institutions, or digital identity providers.

iv. **Compliance with national law on data upload:** Uploaders must ensure and declare compliance with applicable national laws, including ABS laws and biosafety and biosecurity requirements. Evidence of compliance should be provided, or uploads routed through authorized publishers, as practiced by some existing platforms. The Global Biodiversity Information Facility uses a similar approach of "endorsement" for data publishers.

v. **Legally binding data access and use agreements:** Users must accept enforceable agreements governing data use, designed to prevent biopiracy and ensure benefit sharing in accordance with applicable ABS regimes.[137]

    (a) Prevent biopiracy: Third-party data sharing should be limited to verified users within accountable systems. Researchers should be discouraged from depositing DSI in databases that disregard provider rights.

    (b) Benefit sharing: Databases must inform users of applicable benefit-sharing regimes, whether under the CBD multilateral mechanism, national ABS laws, and/or other international ABS regimes, as well as bind users accordingly.[138]

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[134] GISAID is a database that provides some sort of "verified login accounts", and is recommended by WHO and has received grants including from the European Commission. The German Federal Ministry of Agriculture, Food and Regional Identity recognizes the same as protected open access("geschützter offener Zugang"), Federal Ministry of Agriculture, Food and Regional Identity (2022, March 17), World's largest database supports research into flu vaccines, https://www.bmleh.de/DE/ministerium/forschung/gisaid2018.html

[135] United Nations Educational, Scientific and Cultural Organization, (2021, November 23), Recommendation on Open Science, https://www.unesco.org/en/legal-affairs/recommendation-open-science.

[136] ORCID IDs are a comparable idea used currently: Open Researcher and Contributor ID, (n.d.), About ORCID, https://info.orcid.org/what-is-orcid/.

[137] GISAID, Gisaid Epiflu™ Database Access Agreement, https://www.epicov.org/epi3/frontend#187559
So does GBIF: Global Biodiversity Information Facility, (2017,August 16), Data User Agreement, https://www.gbif.org/terms/data-user.

[138] EMBL-ENA terms of use shows the possibility of specific data access agreements being attached to specific datasets or participating databases: EMBL-European Bioinformatics Institute, (2024, February 5), Terms of use, https://www.ebi.ac.uk/about/terms-of-use/.

vi. **Maintenance of user logs:** Databases should maintain user logs in accordance with legal standards and retention periods.[139]

vii. **No perpetual retention:** Databases should not claim perpetual rights over data. Uploaders or competent authorities must retain the right to delete or withdraw data, except where retention is mandated by the database's legal mandate.[140]

viii. **Intellectual property policy:** The issue of intellectual property (IP) should also be addressed under the terms and conditions of the databases. It is especially important that IP is not claimed or asserted in a manner that in any way limits access to or use of DSI, by the very countries from whose genetic materials DSI was made available.[141]

ix. **Facilities to showcase outcomes of R&D:** Users should be provided with facilities to showcase their research outcomes using DSI from the databases, and such facilities could reference links back to relevant DSI in use.[142] With a view to promote non-monetary benefit sharing, users of databases should be obligated to showcase certain types of outcomes that they derive from the use of the DSI.

x. **Termination of services:** In the event of database closure, operators must cooperate with competent authorities and other databases to ensure data remains accessible.[143]

xi. **Cooperation with, and accountability to, competent legal authorities:** Databases must cooperate with competent national and international authorities, including by providing access to relevant data and logs, and by recognizing data audit rights in accordance with law.[144] Accessible grievance redressal mechanisms should be made available to the users of databases in cooperation with such legal authorities.

xii. **Use of appropriate advanced technologies:** Advanced technologies may be used, according to capacities, such as artificial intelligence tools to improve accountability and transparency, consequently promoting the realization of objectives mentioned in this section.

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[139] Genbank provides user logs in the user dashboard itself. Almost every online activity is archived for the purposes of the user.

[140] EU GDPR law shows the possibility of the right to delete one's own data from databases. Similar rights exist for the States with regard to the data of their biological resources that are uploaded without the compliance of national laws, where applicable. GBIF also provides such rights.

[141] Most of the databases mention their policy regarding IP in their terms of use.

[142] GBIF has a literature tracking programme, which identifies research uses and citations of biodiversity information accessed through GBIF's global infrastructure. Similar programmes combined with facilities where researchers and users can update their outcomes of research is important.

[143] INDSC Founders and Membership Arrangements have similar arrangements.

[144] This requirement is also consistent with EU Regulation on free flow of non-personal data.

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