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BENEFIT-SHARING IN THE DIGITAL ERA

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Introduction

The advent of Digital Sequence Information (DSI) on genetic resources has revolutionized the fields of biology, biotechnology, and environmental science by providing unprecedented access to genetic data. However, this shift has introduced new challenges related to the governance, benefit-sharing, and ethical use of genetic resources. The traditional Access and Benefit-Sharing (ABS) frameworks, such as the Nagoya Protocol, were designed around the physical access to genetic resources. With the rise of synthetic biology and advanced computational tools, which utilize digital data to create novel genetic sequences and products, these traditional models face significant obstacles.

Scientists can now design and manipulate biological systems without directly accessing the physical genetic material. While beneficial for scientific progress, this complicates the application of ABS mechanisms. Key challenges include the bypassing of physical access to genetic resources, unclear ownership and jurisdiction over newly created sequences, including unchecked cross border data transfers, lack of accountability and transparency in usage, and the consequent potential circumvention of ABS rules. All these challenges are amplified by existing DSI databases, established before the full implementation of ABS principles and outside the framework of the Convention on Biological Diversity (CBD), and which often lack mechanisms for effective benefit-sharing and compliance monitoring.

To address these challenges, a CBD-managed DSI database is proposed. This database would not only complement existing international databases but also address their limitations in benefit-sharing, data governance, and tracking. By including adequate accountability and transparency measures, the proposed database aims to prevent unauthorized use and enhance traceability. It would also support the scientific community to provide information about scientific advancements and ongoing research paradigms, providing for better opportunities and avenues for technology transfer and capacity building, as well as equitable participation of developing country scientists in global scientific efforts.

1. Understanding Digital Sequence Information (DSI)

In a strict sense, Digital Sequence Information (DSI), refers to the digital representation of genetic data obtained through sequencing technologies and subsequent bioinformatics analyses. This includes various types of genetic sequences, such as DNA, RNA, and protein sequences, as well as data related to biological processes like gene expression, metabolic pathways, and regulatory networks. DSI provides crucial insights into the molecular mechanisms underlying organismal function and evolution. However, legally the terminology could also cover metadata, knowledge and information about gene-environment interactions, etc.

The information contained in DSI can be leveraged to understand and manipulate various biological processes, including:

- **Gene Regulation and Expression**: Analyzing how genes are activated or suppressed in response to environmental or internal stimuli. This information is valuable for applications in biotechnology, genetic engineering, and disease research.
- **Protein Synthesis**: Deciphering the amino acid sequences that constitute proteins and their folding patterns. This knowledge is essential for understanding cellular functions and developing targeted therapies.
- **Metabolic Pathways**: Tracing the biochemical pathways through which organisms convert nutrients into energy and other vital molecules through a series of chemical reactions. This can enhance our understanding of metabolism and inform efforts in biotechnology and medicine.
- **Evolutionary Relationships**: Investigating genetic sequences to uncover the evolutionary relationships among species. This information is pivotal for biodiversity research and conservation strategies.
- **Metagenomic Assessment**: Analyzing sequences obtained from environmental samples to represent the collective genetic material of all microorganisms present in a habitat. Metagenomic data offer insights into microbial diversity, community structure, and functional potential.

In the ongoing negotiations around Digital Sequence Information (DSI) under the CBD, the term "DSI" is often used as a placeholder to maintain a level of constructive ambiguity. This ambiguity allows for continued discussions and progress despite the lack of consensus on a clear, universally accepted definition of what constitutes DSI. By not defining the term too narrowly or broadly, negotiators are able to keep the talks open and avoid potential roadblocks, especially as developed and developing countries hold differing views on the scope of DSI. This strategic vagueness allows for flexibility in the negotiation process, while the Parties work toward a process for sharing benefits from the use of DSI that addresses the various interests and concerns involved.

The flipside of this approach is that Parties to the CBD might be soon facing arguments from the users of DSI that they haven't used DSI per se, and hence cannot be compelled to share benefits arising from the use of DSI. The problem could be resolved, to an extent, through careful language around the users' access to information from DSI databases and committing them, when they register with and access a database, to share benefits in accordance with CBD and Nagoya Protocol decisions.

2. DSI Products and Services

Products and services based on Digital Sequence Information (DSI) encompass a wide range of applications across various fields, including biotechnology, pharmaceuticals, agriculture, and environmental management. These have to be adequately assessed for potential environmental, human health and socioeconomic risks, which are a matter for other CBD provisions and are not addressed in this paper. Here are some examples:

Pharmaceuticals and Biotech Products

- Drug Development: Using genetic and protein sequence information to identify and develop new drugs and therapies. This includes designing targeted treatments based on specific genetic markers or protein structures.
- Biologics: Developing biologic drugs, such as monoclonal antibodies, which are derived from genetic information and produced using recombinant DNA technology.

• Agricultural Innovations

- Genetically Modified Crops: Creating genetically modified organisms (GMOs) with enhanced traits such as pest resistance, improved yield, or better nutritional content, based on genetic sequence data.
- Crop Breeding: Applying DSI to accelerate traditional breeding programs by identifying genes associated with desirable traits.

• Environmental and Conservation Applications

- Biodiversity Monitoring: Using metagenomic data to assess and monitor biodiversity, including identifying species and tracking changes in ecosystems.
- Conservation Genomics: Applying genetic information to understand and protect endangered species, including genetic rescue and population management strategies.

• Diagnostic and Personalized Medicine

- Genetic Testing: Providing diagnostic services based on DNA sequences to identify genetic disorders, predispositions, or disease risk.
- Personalized Medicine: Tailoring medical treatments and interventions based on an individual's genetic profile, improving efficacy and reducing adverse effects.

• Research and Development Tools

- Bioinformatics Software: Developing software and databases for analyzing and interpreting genetic and protein sequences, facilitating research in various biological and medical fields.
- Genomic Databases: Creating and maintaining repositories of genetic sequences and related data that researchers and developers use to explore biological questions and applications.

• Synthetic Biology Products

- Custom-built Genetic Constructs: Designing and synthesizing novel genetic sequences for applications in synthetic biology, such as creating new metabolic pathways or engineered organisms with specific functions.

• Environmental Health and Safety

- Bioremediation: Using genetically engineered microorganisms to clean up environmental pollutants, based on information about their metabolic pathways and genetic capabilities.

3. Why Access and Benefit-sharing Systems for Use of DSI?

components of biological diversity and conserving them.

Access and benefit-sharing systems for the use of Digital Sequence Information (DSI) are essential for several reasons:

Facilitation of Appropriate Access to and Conservation of Genetic Resources and Diversity:

ABS systems are not systems to trade genetic resources, but serve a greater purpose – i.e. facilitating access to genetic resources in an "appropriate" manner, and ensuring their use is "environmentally sound" and does not run counter to the objectives of CBD. By identifying components of biological diversity and the genetic elements that maintain and promote diversity, recording their access to such elements and their use, and sharing benefits arising therefrom fairly and equitably, ABS systems present sustainable ways of accessing the

• **Equitable Distribution of Benefits:** DSI often stems from genetic resources accessed from specific regions or countries. Benefit-sharing ensures that those who provide these genetic

resources, including their local communities and countries, receive a fair share of the benefits derived from their use. This is aligned with principles of fairness and equity under the Convention on Biological Diversity (CBD) and the Nagoya Protocol, ensuring that those who contribute to the genetic pool are duly compensated.

- **Incentivizing Conservation and Sustainable Use:** By sharing the benefits of DSI, countries and communities are motivated to continue conserving their biodiversity and managing their genetic resources sustainably. This financial and ethical incentive plays a critical role in protecting ecosystems and species, reinforcing global efforts to conserve biodiversity.
- Filling the Financial Gap for Biodiversity Protection: As species continue to face extinction at alarming rates, there is a significant financial gap in funding for biodiversity conservation. Benefit-sharing from the use of DSI provides much-needed financial resources to support the protection of endangered species and habitats, helping to bridge this gap and ensure long-term biodiversity preservation.
- Facilitating Research and Innovation: ABS systems create safe, secure and trustworthy systems for providing access to DSI, that will increase the regular sharing of the DSI promoting research and innovation worldwide and at the same time, can funnel resources back to countries providing genetic resources, supporting research, scientific development, and capacity-building in those regions. This fosters technological advancements and enhances scientific capabilities, contributing to global innovation and the equitable growth of scientific knowledge.
- **Promoting Transparency and Trust:** Clear and fair benefit-sharing mechanisms build trust between the providers and users of genetic resources. By establishing transparent processes, these mechanisms help avoid conflicts and foster cooperation, ensuring that both parties engage in a mutually beneficial relationship.
- Acknowledging Intellectual Contributions: The utilization of DSI often involves significant
 intellectual input from indigenous peoples and local communities as well as researchers across
 the globe. Fair benefit-sharing recognizes and compensates these contributions, ensuring that
 intellectual property and innovations arising from genetic resources are properly valued and
 rewarded.
- Strengthening Legal and Ethical Frameworks: Effective access and benefit-sharing systems reinforce the legal and ethical frameworks governing the use of genetic resources. By adhering to international agreements and national regulations, benefit-sharing promotes responsible and compliant use of genetic information, strengthening global governance of biodiversity.

Overall, benefit-sharing from DSI aims to ensure that the advantages derived from genetic resources are distributed fairly and contribute to broader goals of conservation, research, and sustainable development.

4. DSI Repositories

Digital Sequence Information (DSI) can be accessed through several platforms and resources, depending on the type of data and its intended use. Here are some key sources:

• Genomic Databases

- NCBI GenBank: A comprehensive public database that provides access to DNA sequences from various organisms, including annotations and related information.

- Ensembl: A genome database offering detailed annotations for a wide range of species, including human, model organisms, and various plants and animals.
- DDBJ (DNA Data Bank of Japan): Provides nucleotide sequence data and is one of the major international sequence databases.

• Bioinformatics Platforms

- UniProt: A protein sequence and functional information database that offers detailed protein sequences and annotations.
- PDB (Protein Data Bank): A repository for three-dimensional structural data of proteins, nucleic acids, and complexes.

• Specialized Repositories

- Metagenomics Data Repositories: Platforms like MG-RAST (Metagenomics Rapid Annotations using Subsystems Technology) provide access to metagenomic data, which includes sequence information from environmental samples.
- JGI (Joint Genome Institute): Provides access to high-throughput sequencing data, particularly for environmental and microbial genomics.

• Research Institutions and Consortiums

- European Nucleotide Archive (ENA): Provides nucleotide sequence data and is part of the International Nucleotide Sequence Database Collaboration (INSDC).
- The 1000 Genomes Project: Offers access to a comprehensive dataset of human genetic variation, including high-resolution sequencing data.

• Data Portals for Specific Fields

- TCGA (The Cancer Genome Atlas): Provides access to genomic data related to various types of cancer, including DNA, RNA, and protein sequences.
- OpenSNP: A platform for sharing genetic data from personal genome sequencing projects, focusing on individual genetic variation and related traits.

• Institutional Repositories

- University and Research Institution Repositories: Many universities and research institutions maintain their own databases and repositories where they share DSI generated from research projects.

• Collaborative Platforms

- Biodiversity Information Standards (TDWG): Provides access to data related to biological diversity and taxonomy, often integrating genetic information.
- Biocreative: Offers access to specialized datasets and resources related to biological text mining and DSI.

Access to DSI often requires navigating these databases and platforms to find the specific data needed, which may include searching by species, gene, protein, or environmental sample.

It is estimated that the INSDC databases (GenBank, ENA, and DDBJ) collectively store around 80-90% of all publicly available genomic sequences.

Table 1. Location and brief description of largest databases containing genomic data

	Description	Location
1. GenBank	One of the largest repositories for	National Center for
	nucleotide sequences, containing a vast	Biotechnology
	collection of DNA data across multiple	Information (NCBI),
	organisms. It is one of the key databases	NIH, Bethesda,
	in the INSDC.	Maryland, USA.
2. European Nucleotide	Europe's main nucleotide sequence	European
Archive (ENA)	database, providing open access to	Bioinformatics Institute
	genomic and DSI data. It collaborates with	(EBI), part of EMBL,
	GenBank and DDBJ under the INSDC	Hinxton, United
	framework.	Kingdom.
3. DNA Data Bank of	Asia's largest nucleotide sequence	National Institute of
Japan (DDBJ)	database and works closely with GenBank	Genetics, Mishima,
	and ENA to exchange data within the	Shizuoka, Japan.
	INSDC.	
4. Sequence Read	One of the largest repositories for raw	Managed by NCBI
Archive (SRA)	sequence data from high-throughput	(USA), EBI (UK), and
	sequencing technologies. It contains data	DDBJ (Japan).
	from various genomics projects, including	
	metagenomics and transcriptomics	
	studies.	
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5. MG-RAST	A large repository and analysis platform	Argonne National
(Metagenomics Rapid	for metagenomics data, providing tools	Laboratory, Lemont,
Annotations using	for analyzing and annotating microbial	Illinois, USA.
Subsystems	sequences from environmental samples.	
Technology)		
6. Joint Genome	Provides extensive genomic data, focusing	Lawrence Berkeley
Institute (JGI)	on plant and environmental genomics. It	National Laboratory,
	supports data from large-scale sequencing	Walnut Creek,
	projects and facilitates research into	California, USA.
	energy and environmental sustainability.	

5. Advanced Computational Tools and Benefit-sharing Challenges

Generative biology represents a cutting-edge field that combines principles from synthetic biology, computational biology, and artificial intelligence to design, create, and manipulate biological systems. It transcends traditional methods by not just studying or utilizing existing natural sequences but enabling the generation of entirely new genetic sequences, organisms, or biological products. This innovative approach utilizes advanced computational tools such as machine learning, gene synthesis, and computational modelling to simulate and engineer biological systems that may not naturally occur.

These advanced computational tools allow scientists to design novel biological sequences from scratch or modify existing ones, providing unprecedented opportunities in biotechnology, pharmaceuticals, and environmental sustainability. However, the ability to create new sequences

without directly accessing original physical genetic resources also introduces significant challenges to current frameworks for access and benefit-sharing (ABS) of Digital Sequence Information (DSI). By decoupling the use of DSI from physical genetic resources, generative biology and its associated computational tools raise complex legal, ethical, and practical issues, challenging the traditional ABS system and necessitating the development of new policies and mechanisms to ensure fair and equitable benefit-sharing in this rapidly evolving technological landscape.

- Bypassing Physical Access to Genetic Resources: In traditional benefit-sharing models,
 physical access to genetic resources is the basis for the Nagoya Protocol's Access and BenefitSharing (ABS) framework. However, advanced computational tools allow for the creation of new
 organisms or compounds entirely from digital sequences, without needing to access the original
 genetic material in situ. This challenges the established mechanisms for triggering benefitsharing, as no physical resource is exchanged.
- Unclear Ownership and Jurisdiction: Generative biology can design and create genetic sequences using digital information available in DSI databases, raising questions about the ownership of these digital sequences. The countries from the South are disempowered to exercise their jurisdiction on the DSI generated from genetic materials from their territories, even from their native or endemic species, because often these DSI databases do not verify legitimate rights of the uploader to make the information public, they do not label country of origin, and even share data anonymously with users. Cross border data transfers also create jurisdictional issues.
- Lack of Accountability and Transparency: Once DSI is uploaded into global databases like GenBank, ENA, or DDBJ, it becomes accessible to anyone, anonymously. Advanced computational tools can utilize such data to create entirely new sequences, making it extremely difficult to trace which sequences are being used and for what purposes. This lack of accountability and transparency measures complicates efforts to monitor and enforce benefit-sharing agreements.
- Excuse of Derivatives: Generative biology can produce derivatives of DSI, such as synthetic genes, proteins, or organisms, that are functionally similar or entirely novel compared to the original sequence. Often, those who develop these compounds claim that they did not use a single national sequence or natural sequences or they used sequences from several source countries and hence they cannot share benefits. They argue that traditional ABS agreements do not always account for these complex derivatives, and they find it difficult to share benefits with each provider country.
- **Potential for Circumvention of ABS Rules:** There is a risk that companies or researchers could use generative biology to bypass the ABS system entirely. By synthesizing genetic materials from publicly available DSI, they can potentially avoid having to negotiate access or share benefits with the country of origin. This could lead to inequitable use of genetic resources, particularly affecting biodiversity-rich countries that rely on benefit-sharing for conservation and development efforts.
- Challenges to Existing Legal Frameworks: Current international agreements like the Nagoya Protocol and the Convention on Biological Diversity (CBD) are primarily designed around the physical access to genetic resources. The advent of generative biology challenges the implementation of these frameworks, as they are not equipped to deal with the complexities of using digital data to create synthetic organisms or products. This creates an urgent need to develop innovative ABS systems for use of the DSI in the context of generative biology.

• **Need for New Monitoring and Reporting Mechanisms:** To adapt to the challenges posed by generative biology, there is a need for new monitoring systems that can track the use of DSI and synthetic biology products. This includes establishing robust digital traceability mechanisms and revising benefit-sharing models to ensure that digital use of genetic information is fairly compensated.

Addressing these challenges requires updating international agreements, improving traceability of DSI usage, and finding new ways to ensure fair and equitable benefit-sharing in the digital age. Hence the CBD DSI Database is suggested.

6. Governance

Data governance refers to the policies, rules, and practices that control how data is managed, accessed, and shared. In public DSI databases, governance frameworks should ensure:

- **Transparency:** Clear guidelines for how DSI is collected, stored, and accessed, ensuring that users understand the terms of use.
- **Accountability:** Mechanisms to track how DSI is used, by whom, and for what purposes, helping providers of genetic resources monitor benefits from the utilization of their resources.
- **Security:** Safeguards to protect sensitive genetic information and ensure compliance with applicable regulations, such as the Nagoya Protocol and/or other ABS regimes.
- **Interoperability:** Enabling integration with other databases while maintaining control over data use and ensuring the equitable sharing of benefits.

Large DSI databases were established to facilitate global research and collaboration by providing free access to genetic information. However, these systems were not designed with benefit-sharing in mind, as they predate the adoption of the Nagoya Protocol and its provisions. Key challenges include:

- Global Access vs. National Sovereignty: The unaccountable access to DSI in these databases conflicts with the rights of countries that want to manage appropriate access to their genetic resources and benefit from their use, in particular countries that lack national bioinformatics capacities. Large database collaborations like INSDC promote free and anonymous use, without ensuring benefit-sharing obligations.
- **Standardization:** The lack of harmonized standards for metadata, access, and benefit-sharing compounds the governance issue, with different databases having different rules and no unified framework to enforce benefit-sharing obligations.

As a result, new governance models are needed to ensure that DSI use aligns with global expectations for fair and equitable sharing of the benefits arising from the use of genetic resources. To address this gap, a unified strategy to ensure that countries providing genetic resources are compensated for the use of DSI, while maintaining the open access nature of these databases.

Key considerations for data governance include:

- **Legal Frameworks**: New policies must be developed to ensure that countries contributing genetic resources retain control over their DSI, even when they are shared in public databases that were not originally designed to enforce such rights.
- **Promotion of Open Science**: Balancing the principles of open access with the need for fair and equitable benefit-sharing is critical to promoting open science, in accordance with the 2021 UNESCO Recommendation on Open Science. Public DSI databases will need to evolve to include mechanisms that create or ensure benefit-sharing obligations while still supporting research.
- **Mandatory Benefit-Sharing**: Establishing enforceable benefit-sharing obligations, for both monetary and non-monetary benefits, through user registration and data access agreements, will ensure that open access can coexist with modern benefit-sharing frameworks, promoting open science objectives.

The integrated approach needs to combine the following:

- a. **Mandatory Monetary Benefit-Sharing:** Requiring sectors that benefited/are benefiting from DSI to contribute to a global benefit-sharing mechanism, recognizing the value derived from the genetic resources linked to the DSI.
- b. **Non-Monetary Benefits:** Promoting non-monetary benefits, such as capacity building, technology transfer, and research collaborations with countries providing genetic resources.
- c. **Institutional Mechanisms:** The creation of a CBD-managed DSI database and system could help ensure that benefit-sharing is ensured when genetic sequences are accessed, addressing the shortcoming of the current databases.

Balancing Diverse Interests

- Holistic Stakeholder Engagement: Addressing the diverse interests of stakeholders—such as indigenous peoples and local communities, industry, and environmental organizations—is crucial. The interests and rights of these groups extend beyond the scientific community, and effective engagement ensures that all relevant voices are heard and respected. It must be noted that the right to science, including the right of everyone to enjoy benefits of scientific progress, is a recognized human right under international human rights law.
- Strategic Approach Needed: A strategic approach is essential to balance these rights and interests in negotiations. This means considering the needs of scientific advancement alongside the rights and benefits of those who provide genetic resources, as well as that of the general public. Policies must reflect this dual responsibility, promoting research while safeguarding genetic heritage.

7. A DSI-related CBD-managed database

A CBD-managed database would address the current shortcomings in DSI governance in accordance with the above-mentioned considerations and promote fair benefit-sharing, and enhance global scientific collaboration, benefiting both the scientific community and the countries providing genetic resources. The database would help the following:

• Leveraging International Databases and Complementing Existing Systems:

The landscape of Digital Sequence Information (DSI) is becoming increasingly intricate. Most DSI is currently stored in international databases, many of which are based in a country that is not a Party to the Convention on Biological Diversity (CBD). This situation presents a challenge as these databases operate outside the CBD framework, making it difficult to ensure compliance

with the principles of Access and Benefit-Sharing (ABS). To navigate this complexity, we need effective leverage points to influence these entities to align with our goals of fair and equitable benefit-sharing. The proposed CBD DSI database could serve as a strategic tool to achieve this.

The proposed CBD DSI database would complement rather than replace existing international databases. It would address critical gaps in areas like benefit-sharing, data governance, and monitoring. This strategic tool would leverage international databases to promote fair and equitable use of genetic resources, influencing non-CBD parties to align with global biodiversity goals.

• Preventing Unauthorized Use:

A major concern is the sequencing of genetic resources obtained through illegal means and their subsequent inclusion in public databases without the knowledge or permission of the relevant national authorities. To address this issue, we propose establishing a DSI permit database containing essential information. Whenever a sequence is uploaded to an international database, it should be cross-referenced with this permit database on the CBD platform.

However, Parties to the CBD and Nagoya Protocol should take active steps in ensuring the databases they fund, sponsor or host participate in this arrangement. This approach would enhance traceability and accountability and reduce unauthorized use. Although governments might not directly track these sequences, the database would enable observatories, activists, NGOs, and other stakeholders to monitor and ensure compliance, thereby fostering greater oversight and adherence to regulations.

Addressing Unauthorized Sequencing by Ex Situ Repositories

Instances have been observed where ex situ collection repositories sequence genetic resources and subsequently share or deposit this data into public databases without proper authorization. To mitigate this issue, a CBD-complementary database could function as a regulatory checkpoint. By mandating that public databases include a field for cross-referencing the certificate of compliance or permit records, such as recording the permit reference number and the issuing department (e.g., in South Africa), this measure would significantly bolster compliance and prevent unauthorized use of genetic resources.

• Supporting the Scientific Community and Capacity Building:

The proposed CBD DSI database would be a valuable asset to the scientific community, offering extensive support for technology transfer, capacity building, and development. It could facilitate these processes by enabling efficient matchmaking, searching, and filtering of research opportunities, training programs, and bibliographic data. Moreover, the database could highlight the needs and opportunities of various parties, serving as a conduit for channelling non-monetary benefits effectively. This approach would not only advance scientific research but also promote inclusive and equitable participation in the global DSI ecosystem.

• Enhancing Global Participation and Scientific Collaboration:

The proposed CBD DSI database has the potential to significantly increase global participation and foster scientific collaboration, especially for countries with limited resources or concerns about being excluded from current public databases. By providing a secure and inclusive

platform, the database would allow these countries to contribute and manage their DSI on their own terms. This approach would encourage broader engagement in global scientific efforts and facilitate the sharing of a larger volume of genetic sequences. Enhanced inclusivity would enrich the global pool of scientific data, accelerate research advancements, and promote collaborative efforts. Ultimately, this would ensure that the benefits derived from scientific discoveries are equitably shared among all stakeholders.

Conclusion

The emergence of generative biology and the complexities surrounding DSI highlight the need for a robust and adaptive governance framework. The proposed CBD-managed DSI database offers a strategic solution to address the gaps in existing systems, ensuring fair and equitable sharing of benefits derived from genetic resources. By integrating accountability measures, enhancing traceability, and promoting inclusivity, this database aims to guarantee both open access as well as fair and equitable benefit-sharing.

This approach not only supports the scientific community by facilitating collaboration and capacity building but also addresses the rights and interests of countries, and the general public, including of the communities providing genetic resources. The creation of such a database represents a critical step towards aligning global scientific practices with true open science approaches, by putting in place legally-enforceable benefit-sharing frameworks, ensuring that the advantages of digital and synthetic biology advancements are enjoyed by everyone, in a fair and equitable manner.

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