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When science meets sovereignty: Pathogen digital sequence information between state control and commons-oriented access and benefit-sharing

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ABSTRACT

The rapid and reliable sharing of pathogen digital sequence information (DSI) is essential for genomic surveillance and the development of health products. Such sharing occurs largely through specialized databases governed by their own policies. However, in the absence of agreed international rules, an increasing number of states have sought to assert sovereign control over DSI via domestic Access and Benefit-Sharing (ABS) legislation. As pathogen DSI governance gains prominence, the rules governing its use are poised for change. The recently agreed WHO Pandemic Agreement and multilateral mechanism under the UN Convention on Biological Diversity aim to balance open access to DSI with fair and equitable benefit-sharing.

The advancement and reduced costs of sequencing technologies, coupled with limitations of existing international legal framework, prompt a reevaluation of principles best suited for the regulation of pathogen DSI and benefit-sharing. In this article, I first conceptualize sovereignty and commons-oriented approaches to DSI regulation. I map out and compare international ABS frameworks applicable to pathogens. I describe policies of the leading pathogen DSI databases, INSDC and GISAID. Drawing on a review of 14 domestic ABS laws, I identify common patterns and divergent approaches to regulating pathogen DSI.

I argue that the concept of sovereignty is ill-adapted to govern large-scale transboundary data flows and that a joint stewardship model is needed. I propose commons-oriented design elements for a future multilateral ABS system: providing standardized downstream benefit-sharing obligations, metadata disclosure and notification requirements, proportionate traceability, preserving interoperability of databases, and clear scope, conflict, and enforceability rules to reduce fragmentation across legal regimes.

1. Introduction

The global sharing of pathogen digital sequence information (DSI) is essential for pandemic preparedness, genomic surveillance, and the development of health products.[1] The ongoing technological advancements and decreasing costs of sequencing technologies continue to accelerate scientific progress and facilitate the widespread exchange of pathogen data.[2] Notably, the sharing of SARS-CoV-2 DSI has enabled an unprecedentedly fast response to the pandemic.[3] Such sharing occurs on specialized databases subject to their respective policies and national legislation. However, the rules governing pathogen DSI are poised for change, given the topic's prominence in the reform efforts under the WHO Pandemic Agreement (adopted in 2025) and the UN Convention on Biological Diversity (CBD) (1992).

Accompanying the reforms are questions about core concepts of international law. Access and Benefit-Sharing (ABS) is rooted in and reproduces the concept of state sovereignty over genetic resources, which underpins the logic of exchange between providers and users of genetic

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[1] World Health Organization, Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032, WHO, Geneva, 2022. https://iris.who.int/items/bc6fd912-a689-4ca5-b552-572173fdba3f (accessed 27 December 2025); World Health Organization, Considerations for developing a national genomic surveillance strategy or action plan for pathogens with pandemic and epidemic potential, WHO, Geneva, 2023. https://iris.who.int/items/61143d77-0390-4f9e-ba67-8940ed073797 (accessed 27 December 2025).

[2] J.M. Heather, B. Chain, The sequence of sequencers: the history of sequencing DNA, *Genomics* 107 (2016) 1. https://doi.org/10.1016/j.ygeno.2015.11.003

[3] World Health Organization, Report of the Review Committee regarding amendments to the International Health Regulations (2005), A/WGIHR/2/5, Geneva, 2023. https://apps.who.int/gb/wgihr/pdf_files/wgihr2/A_WGIHR2_5-en.pdf (accessed 27 December 2025)

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materials and data.[4] Existing international ABS agreements have been negotiated with genetic material (such as pathogen samples) in mind. Their ongoing reforms are grappling with how to reconcile the principle of sovereignty with practical realities of data sharing. The large-scale flow of pathogen DSI can bypass sovereignty-based national legal regimes by transcending borders, 'dematerializing' genetic resources, and potentially undermining existing ABS commitments.[5] Furthermore, the proliferation of ABS instruments has revived longstanding debates about fragmentation of international law and the costs of navigating the multitude of normative frameworks. As observed by Morgera, 'the proliferation of references to benefit-sharing has been accompanied by a remarkable lack of conceptual clarity, to the point that it has been rightly asked whether there is just one concept of benefit-sharing or many.'[6]

The growing importance of pathogen DSI warrants a re-evaluation of the concepts and institutions that structure its regulation. To that end, I first reexamine the concepts of sovereignty and research commons and their application to pathogen DSI under international law. Secondly, I map and compare international instruments relevant for pathogen DSI sharing: the CBD, Nagoya Protocol on Access and Benefit-Sharing (2010), WHO Pandemic Influenza Preparedness (PIP) Framework (2011), and the WHO Pandemic Agreement. Consequently, I discuss the evolution of scientific norms concerning genetic data sharing and examine database policies of the International Nucleotide Sequence Database Collaboration (INSDC) and Global Initiative on Sharing All Influenza Data (GISAID) which govern pathogen DSI sharing. I then study the sovereign claims over pathogen DSI invoked by states in their national legislation. Drawing on a review of 14 domestic ABS laws, I identify common patterns and divergent approaches to regulating pathogen DSI.

I argue that governing pathogen DSI through sovereign, point-of-access control is ill-suited to large-scale, transboundary data flows, risking high transaction costs and potentially impeding timely sharing in health emergencies. Instead, I propose legal design principles for governing a shared pathogen DSI commons through enforceable, low-friction obligations focused on downstream use (such as publication, patenting, and product development/commercialization) rather than restricting access to pathogen DSI. This implies a distinction between benefit-sharing rules applicable to pathogen genetic material (to be governed by legally binding and standardized contracts, as envisaged under the Pandemic Agreement) and the user-facing norms for the sharing of DSI. The latter's design should feature proportionate traceability, building on widely used identifiers and mandatory metadata disclosures, supported by notification mechanisms akin to those found in selected domestic ABS jurisdictions. It requires preserving interoperability across databases and platform governance consistent with WHO guidance on pathogen genome data sharing.[7] I argue that the parallel reforms necessitate legal ordering and anti-duplication mechanisms, including harmonized certificates of compliance, to reduce fragmentation and 'stacking' across the Pandemic Agreement, CBD and other bilateral or national DSI benefit-sharing regimes. Consideration must be given to how to incentivize participation and bring within scope users who are not party to PABS/CBD systems agreements, so that key research and product-development pathways are not outside of the system. My proposal thus can be read as a move from sovereignty as control to commons-oriented conceptualization of sovereignty as joint stewardship.

2. Between sovereignty and the commons

ABS under international law seeks to address equity issues surrounding some of the most prominent challenges of our time, including sustainable use of biodiversity, climate change, and pandemics.[8] It rests on the premise that states, exercising sovereign control over genetic resources within their jurisdiction, will make those resources available to facilitate global research and development (R&D), including efforts aimed at pandemic prevention, preparedness, and rapid response. In exchange for access, users—including scientists and industry—are expected to share a portion of the benefits arising from utilization, which may include publications, research outputs, technology transfer and capacity-building, and, where relevant, product development and commercialization.[9] However, absent standardized international rules, the incentives for Parties to enter and comply with ABS transactions can diverge sharply on a case-by-case basis. For example, a state may be reluctant to share a virus sample that will be used to develop a vaccine that it cannot afford to purchase.[10] Conversely, a firm may engage in forum shopping to obtain comparable materials from jurisdictions that impose fewer ABS conditions.[11]

ABS is therefore a particularly fertile site for reproducing a foundational tension in international legal discourse between, on the one hand, the 'apology' for discretionary actions of individual states and, on the other hand, the 'utopia' of a common rules-based international legal order.[12] The ABS regimes have also been criticized for their transactional logic and the implicit assumption that market competition will result in a fair and equitable distribution of resources through trickle down economics.[13] Before turning to an analysis of pathogen ABS rules, it is worth discussing the concepts of sovereignty and the commons, which structurally shape the legal debates surrounding ABS.

2.1. Sovereignty and international law

In 1928, the Permanent Court of Arbitration found that sovereignty

[4] See the Preamble and Arts. 3 & 15.1 CBD.

[5] Heather and Chain (n 2); A.-R. Hampton, Pathogen dematerialization and the ABS loophole, *J. Law Biosci.* 10 (2023) lsad002. https://doi.org/10.1093/jlb/lsad002.

[6] E. Morgera, *Fair and Equitable Benefit-Sharing in International Law*, Oxford University Press, 2024, 4. She further notes that benefit-sharing has been interpreted as a right under Arts 15(7) and 8(j) of the CBD and Art. 5 of the Nagoya Protocol and alternately as a mechanism under Art. 140 of UNCLOS, Art. 10 of the Nagoya Protocol and Art. 10 of the ITPGRFA.

[7] World Health Organization, Attributes and Principles of Genomic Data-Sharing Platforms Supporting Surveillance of Pathogens with Epidemic and Pandemic Potential, WHO, Geneva, 2025. https://pandemichub.who.int/publications/i/item/attributes-and-principles-of-genomic-data-sharing-platforms-supporting-surveillance-of-pathogens-with-epidemic-and-pandemic-potential (accessed 27 December 2025).

[8] Morgera (n 6).

[9] S. Laird, R. Wynberg, M.F. Rourke, F. Humphries, M.R. Ruiz Muller, C. Lawson, Rethink the expansion of access and benefit sharing, *Science* 367(6483) (2020) 1200–1202, doi:10.1126/science.aba9609.

[10] M.F. Rourke, Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of "Viral Sovereignty" and the Mark It Left on the World, in: M. Eccleston-Turner, I. Brassington (Eds), *Infectious Diseases in the New Millennium: Legal and Ethical Challenges*, Springer, Cham, 2020, pp. 167–191, doi:10.1007/978-3-030-39819-4_8.

[11] Covington & Burling LLP, The Impact of the Nagoya Protocol on Global Pathogen-Sharing: Study on Global Disease Surveillance and Pathogen-Sharing, 2023.

[12] M. Koskenniemi, *From Apology to Utopia: The Structure of International Legal Argument*, Cambridge University Press, Cambridge, 2006.

[13] M.F. Rourke, Access by Design, Benefits If Convenient: A Closer Look at the Pandemic Influenza Preparedness Framework's Standard Material Transfer Agreements, *Milbank Q.* 97(1) (2019) 91-112; H. Mayrand, From Classical Liberalism to Neoliberalism: Explaining the Contradictions in the International Environmental Law Project, *Rev. gén. droit* 50 (2020) 57–85, https://doi.org/10.7202/1071277ar; M. Eccleston-Turner, Access and Benefit-Sharing Isn't Equity: Why the Pandemic Treaty Won't Change the Status Quo, *VerfBlog*, 5 April 2024, https://verfassungsblog.de/access-and-benefit-sharing-isnt-equity/, https://doi.org/10.59704/6b158671e4376980 (accessed 27 December 2025).

allows states 'to exercise […] to the exclusion of any other State, the functions of a State on their territory.'[14] This function-oriented definition underscores the conceptual problems with defining sovereignty, which is variously understood as embodying qualities both internal and external to law.[15] In international law, sovereignty can be traced back to the writings of Emer de Vattel, who proposed a vision of the law of nations that would apply to equal and independent States as ultimate units of international politics.[16] Later scholars have criticized Vattel for providing an intellectual foundation to the inviolability and subjectivism of the state sovereignty.[17] Brierly called Vattel's individualism a 'disaster' for international law,[18] while Van Vollenhoven went as far as calling Vattel a 'Satan' who presented a 'kiss of Judas' to the works of Grotius.[19] However, Vattel's actual argument rested upon the logical assumption that sovereign states would retain an interest in international order and coexistence.[20] The modern criticism of Vattel as a 'prince of positivists' has instead to be read in the context of early 20th century political debates about the role of international law in preventing interstate conflict.[21]

The 20th century conceptualizations of sovereignty continue to influence our disciplinary imagination. On the one hand, a Schmittian reading of Leviathan would treat sovereignty as a power external to law: one that decides on the state of exception.[22] In an irrational world governed by fear, it falls to various Leviathans to impose meaning by defining what is right or true, leaving little basis for communitarian pursuits of global legal order beyond the occasionally corresponding national interests.[23] State Parties to the covenants are thus the ultimate judges upon their validity and interpretation. Conversely, in Kelsen's pure theory of law, sovereign states are treated as points of attribution within a normative hierarchy,[24] with international law recognizing the claims to authority of different governments.[25]

The structural importance of sovereignty to international law remains evident. Sovereignty helps constitute states as persons of international law and as subjects of rights and duties.[26] It relies on and reproduces a pyramidal ordering of Euclidian space and the presumption of stable borders within which the jurisdiction of the state can be exercised.[27] Historically, it has often been wielded as an exclusionary and violent force. Entities perceived as less developed, fragile, or 'failed,' as well as Indigenous peoples and minority communities were portrayed as unable to assert territorial supremacy and having penetrable, negotiable, and subordinate boundaries and identities, and thus as legitimate objects of foreign sovereign power.[28] Yet the language of sovereignty has also functioned as an emancipatory idiom, particularly during decolonization, when it was mobilized to assert newly independent states' permanent sovereignty over natural resources.[29] This turn was closely associated with the Bandung moment and, later, the New International Economic Order (NIEO), both of which foregrounded claims to economic self-determination and sought to recalibrate global rules governing the control and redistribution of resource-derived wealth.

Contemporary assertions of sovereignty in the ABS space can thus be read as a continuation of this legacy of decolonization, by extending the logic of permanent sovereignty over natural resources to include genetic resources, including pathogens. The absence of regulation and mostly unhindered flow of genetic resources had long accentuated the inequities between developed countries with a strong industrial base and resource-rich developing countries.[30] Oldham and Thambisetty write of a 'colonial era trope whereby developing countries [would] provide raw materials and in return (eventually) receive high value manufactured products.'[31] The international legal response has focused on asserting a sovereign right of states to regulate access to their genetic resources. Yet even where they carry emancipatory potential, sovereign claims over resources remain subjectivist and may be mutually conflicting, often without regard to considerations of any 'common' international good, particularly relevant in the case of preparedness and response to pandemics which, by definition, ignore state borders. I thus turn to the 'commons' as the other pole of my conceptual framework.

2.2. Toward pathogen research commons?

'Commons,' and in particular 'research commons,' are not a single

[14] PCA, Island of Palmas case (Netherlands v. United States), 4 April 1928, 838.

[15] G. Agamben, *Homo Sacer: Sovereign Power and Bare Life*, D. Heller-Roazen (Trans.), Meridian, 1998, 28.

[16] A. Strobeyko, The person of the state: the anthropomorphic subject of the law of nations, *J. Hist. Int. Law* 25 (2022) 36. https://doi.org/10.1163/15718050-bja10076; B. Holland, The moral person of the state: Emer de Vattel and the foundations of international legal order, *Hist. Eur. Ideas* 37 (2012) 438–453. https://doi.org/10.1016/j.histeuroideas.2011.03.001.

[17] Ibid.

[18] J. L. Brierly, *The Law of Nations: An Introduction to the International Law of Peace*, 6th edn, Clarendon Press, 1963, 39.

[19] C. van Vollenhoven, *Die Drei Stufen Des Völkerrechts*, Martinus Nijhoff, 1919.

[20] E. Vattel, *Le Droit Des Gens, Ou Principes de La Loi Naturelle*, Liberty Fund, 1758), Préliminaires §11-14.

[21] Emmanuelle Jouannet, *Emer de Vattel et l'émergence Doctrinale Du Droit International Classique*, A. Pedone, 1998; S. Zurbuchen, Emer de Vattel on the society of nations and the political system of Europe, in: S. Kadelbach, T. Kleinlein, D. Roth-Isigkeit (Eds.), *System, Order, and International Law: The Early History of International Legal Thought from Machiavelli to Hegel*, Oxford University Press, Oxford, 2017, 265.

[22] C. Schmitt, *The Leviathan in the State Theory of Thomas Hobbes: Meaning and Failure of a Political Symbol*, Global Perspectives in History and Politics, Greenwood Press, 1996; C. Schmitt, *Political Theology: Four Chapters on the Concept of Sovereignty*, G. Schwab (Trans.). University of Chicago Press, 2005. Also see: R. Howse, Schmitt, Schmitteanism and Contemporary International Legal Theory, in; A. Orford, F. Hoffmann (Eds.), *The Oxford Handbook of the Theory of International Law,* Oxford University Press, Oxford, 2016, 213–230.

[23] A. Strobeyko, *Specters of man: sovereignty and anthropomorphism of the state*, Geneva Graduate Institute, Geneva, 2023, 68. https://repository.graduateinstitute.ch/record/301148?ln=en.

[24] H. Kelsen, *General Theory of Law and State*, A. Wedberg (Trans.), Harvard University Press, 1945; H. Kelsen, *Die Funktion der Verfassung*, Forum XI (1964) 583–601.

[25] H. Kelsen, *Introduction to the Problems of Legal Theory*, B. Litschewski Paulson, S. Paulson (Trans.), Clarendon Press, 1992, 61.

[26] Strobeyko (n 23); J. d'Aspremont, The doctrine of fundamental rights of states and anthropomorphic thinking in international law, *Cambridge J. Int. Comp. Law* 4 (2015) 501. https://doi.org/10.7574/cjicl.04.03.501.

[27] F. Ost, M. van de Kerchove, *De la pyramide au réseau? Pour une théorie dialectique du droit,* Presses de l'Université Saint-Louis, 2010.

[28] H. Charlesworth, The Sex of the State in International Law in: N. Naffine, R. Owens (Eds.), *Sexing the Subject of Law*, Gaunt & Sons, London, 1997, 263; A. O'Donoghue, 'The admixture of feminine weakness and susceptibility': gendered personifications of the state in international law, *Melbourne J. Int. Law* 19 (2018) 227.

[29] A. Anghie, *Imperialism, Sovereignty and the Making of International Law*, Cambridge University Press, 2005

[30] Morgera (n 6) 50; M.W. Tvedt, T.R. Young, Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD (IUCN Environmental Policy and Law Paper No. 67/2), IUCN, Gland, 2007, https://doi.org/10.2305/IUCN.CH.2007.EPLP.67/2.en.; C.J. Carlson, M. Granados, A. Phelan, N. Ramakrishnan, T. Poisot, The LISTEN principles for genetic sequence data governance and database engineering, *Nature Genetics* 57 (2025) 2099–2105, https://doi.org/10.1038/s41588-025-02270-7.

[31] P. Oldham, S. Thambisetty, The Pandemic Access and Benefit Sharing System: Four Elements of a Trusted System, LSE Legal Studies Working Paper No. 10/2024, 2024, https://doi.org/10.2139/ssrn.4810352 (accessed 27 December 2025).

legal form but a heterogenous governance frame through which communities of users co-define rules for the provisioning, access, and stewardship of shared resources for collective and collaborative use.[32] Use within research commons is participatory: it brings resource providers into the R&D process and feeds results back into the resource pool.[33] Public authorities are not external to this arrangement; they may act as convenors, curators, rule-setters, or enforcers of the rules governing the commons.[34]

In the pathogen ABS context, a research-commons framing differs from Hardin's 'tragedy of the commons'[35] because the central risk is not overuse, but enclosure—of pathogen samples and data—behind sovereign and intellectual property (IP) claims or technical barriers that can fence off research data, raising transaction costs and undermining innovation.[36] The prevailing global IP model and enclosure drives can over-reward monopolization, and call for alternative incentive structures.[37]

Insights from research-commons scholarship are particularly salient for pathogen DSI, given the centrality of sequence data to genomic surveillance and to the R&D of life-saving health products.[38] The literature suggests that a commons-oriented approach could lower transaction costs for non-commercial and public-interest research while preserving downstream benefit-sharing obligations—triggered by publications, patents, or commercialization—and replace bilateral contracts with standardized instruments such as licences.[39]

The regulation of access to genetic commons must also be situated within postcolonial critiques emphasizing that commons are never politically neutral.[40] Thambisetty cautions that invocations of scientific freedom may, in practice, obscure existing forms of control and inequality.[41] A viable research-commons approach therefore has to grapple with the realities of IP rights and contracting practices, develop tools for identifying and tracing use, and embed transparency norms that balance openness with fairness. In that context, the literature increasingly points toward models of joint stewardship that ensure fair recognition of contributors.[42]

Further work is needed to adapt the research-commons frame to pathogen DSI and to identify concrete legal pathways for its implementation. Below, I analyze how the concepts of sovereignty and the commons have featured in the rules governing pathogen DSI sharing, before proposing design elements for its regulation in line with a commons-oriented approach.

3. Relevant international ABS frameworks

3.1. CBD and Nagoya protocol

The CBD recognizes sovereignty of states over genetic resources and the authority to regulate access to them.[43] Under the CBD, access to such resources is determined bilaterally and contractually, subject to the Prior Informed Consent (PIC) from the relevant domestic authorities of the country providing the resource,[44] and Mutually Agreed Terms (MAT) between the resource provider and the recipient.[45] Benefit-sharing can include contractual provisions on access to and transfer of technologies, scientific collaborations and participation in biotechnological research.[46]

The Nagoya Protocol, adopted in 2010 and with 142 Parties as of 2025, was negotiated to better articulate benefit-sharing under the CBD's and to clarify its enforcement and implementation with regard to genetic resources. It provides a detailed, non-exhaustive list of non-monetary and monetary benefits to be included in contracts, which include access fees, shared ownership, licensing, upfront or milestone payments, salaries and preferential terms, joint ventures, joint ownership of IP rights and royalties over commercialization of health products.[47] However, despite high expectations, the CBD and its Nagoya Protocol failed to generate sufficient benefit-sharing between the pharmaceutical industry and developing states.[48] They have also been

[32] E.C. Kamau, G. Winter (Eds.), Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law, Routledge, Abingdon, 2013; B.M. Frischmann, M.J. Madison, K.J. Strandburg (Eds.), *Governing Knowledge Commons,* Oxford University Press, Oxford, 2014, https://doi.org/10.1093/acprof:oso/9780199972036.001.0001; E. Ostrom, Governing the Commons: The Evolution of Institutions for Collective Action, Cambridge University Press, Cambridge, 2015 (Canto Classics ed.; first published 1990); T. Dedeurwaerdere, P. Melindi-Ghidi, A. Broggiato, Global scientific research commons under the Nagoya Protocol: Towards a collaborative economy model for the sharing of basic research assets, *Environmental Science & Policy* 55 (2016) 1–10, https://doi.org/10.1016/j.envsci.2015.08.006.

[33] G. Winter, Common pools of genetic resources and related traditional and modern knowledge: an overview, in: E.C. Kamau, G. Winter (Eds.), *Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law*, Routledge, Abingdon, 2013, pp. 3–25. doi:10.4324/9780203590881-2.

[34] J.H. Reichman, P.F. Uhlir, A contractually reconstructed research commons for scientific data in a highly protectionist intellectual property environment, *Law and Contemporary Problems* 66(1) (2003) 315–462.; J.L. Contreras, Leviathan in the commons: biomedical data and the state, in: K.J. Strandburg, B.M. Frischmann, M.J. Madison (Eds.), *Governing Medical Knowledge Commons*, Cambridge University Press, Cambridge, 2017, pp. 19–45. doi:10.1017/9781316544587.002.

[35] G. Hardin, The tragedy of the commons, *Science* 162(3859) (1968) 1243–1248. doi:10.1126/science.162.3859.1243.

[36] Reichman and Uhlir (n 34).

[37] D. Baker, A. Jayadev, J.E. Stiglitz, Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century, AccessIBSA: Innovation & Access to Medicines in India, Brazil & South Africa, July 2017. https://cepr.net/publications/innovation-intellectual-property-and-development-a-better-set-of-approaches-for-the-21st-century/ (accessed 27 December 2025).

[38] B.J. Evans, Genomic data commons, in: K.J. Strandburg, B.M. Frischmann, M.J. Madison (Eds.), *Governing Medical Knowledge Commons*, Cambridge University Press, Cambridge, 2017, pp. 74–101. doi:10.1017/9781316544587.005.

[39] Dedeurwaerdere, Melindi-Ghidi and Broggiato (n 32); Kamau and Winter (n 32); Winter (n 33); P.-T. Stoll, ABS, justice, pools and the Nagoya Protocol, in: E.C. Kamau, G. Winter (Eds.), *Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law*, Routledge, Abingdon, 2013, pp. 305–314. https://doi.org/10.4324/9780203590881-20.

[40] A.L. Phelan, M. Sirleaf, Decolonization of global health law: lessons from international environmental law, *J. Law Med. Ethics* 51 (2023) 450–453. https://doi.org/10.1017/jme.2023.78; Carlson and others (n 30).

[41] S. Thambisetty, The unfree commons: freedom of marine scientific research and the status of genetic resources beyond national jurisdiction, *Mod. Law Rev.* 88(2) (2025) 300–332. https://doi.org/10.1111/1468-2230.12923.

[42] F. Humphries, M. Rabone, M. Jaspars, Traceability approaches for marine genetic resources under the proposed ocean (BBNJ) treaty, *Front. Mar. Sci.* 8 (2021) 661313. https://doi.org/10.3389/fmars.2021.661313; A. Mazé, Geographical indications as global knowledge commons: Ostrom's law on common intellectual property and collective action, J. Inst. Econ. 19(4) (2023) 494–510. https://doi.org/10.1017/S1744137423000036; Carlson and others (n 30).

[43] See the Preamble and Arts. 3 & 15.1 CBD.

[44] Art. 15.5 CBD.

[45] Art. 15.4 CBD.

[46] Arts. 16, 18 & 19 CBD.

[47] Art 5.4 and Annex to the Nagoya Protocol. See: A. Rizk, A. Strobeyko, G.L. Burci, S. Moon, What are the options?: pathogen-, GSD- and benefit-sharing in an international instrument, Global Health Centre Discussion Paper, Graduate Institute of International and Development Studies, Geneva, 2022. https://doi.org/10.71609/iheid-es7c-e993.

[48] A. Deplazes-Zemp, S. Abiven, P. Schaber, M. Schaepman, G. Schaepman-Strub, B. Schmid, K.K. Shimizu, F. Altermatt, The Nagoya Protocol could backfire on the Global South, *Nat. Ecol. Evol.* 2 (2018) 917–919. https://doi.org/10.1038/s41559-018-0561-z.

criticized for high transaction costs[49] and for neglecting the specific needs of human and animal health.[50] Their emphasis on case-by-case bilateral access negotiations privileges sovereignty over commons-oriented considerations.

The CBD and the Nagoya Protocol only apply to physical samples of genetic material and not to pathogen DSI, which has the potential of undermining the ABS arrangements.[51] To address this gap, in November 2024, the Conference of the Parties (COP) of the CBD, held in Cali, Colombia, adopted Decision 16/2 establishing a multilateral mechanism for the sharing of benefits resulting from the use of DSI.[52] It applies to DSI that is 'made publicly available, in compliance with national legislation' and not subject to terms precluding its free availability.[53] The decision invites companies[54] (including in the pharmaceutical and biotechnological industries) which benefit 'directly or indirectly' from DSI to contribute either 1% of their profits or 0.1% of their revenue to the 'Cali Fund.' Additional sharing of other benefits, such as capacity-building, technical and scientific cooperation, is also encouraged. The Cali Fund will disburse payments directly to countries and are likely to focus on biodiversity conservation and its sustainable use. At least a half of allocations will be distributed toward the 'self-identified needs of indigenous peoples and local communities.'[55]

The CBD COP decision also indicates that 'public databases, academic, and public research institutions are not expected to make monetary contributions to the global fund.' Nevertheless, it expects entities operating such databases to inform their users of ABS commitments, including the potential requirement to contribute to the Cali Fund in cases of commercial use of DSI, and the relevant national and international laws. The entities operating databases should ensure that information on the DSI's country of origin, associated metadata, and any related traditional knowledge is submitted in alignment with open science principles. They should require DSI submitters to indicate that submitted data is free from restrictions that would prohibit sharing.

The CBD Decision 16/2 creates an ambitious framework and a significant stepping stone for sharing DSI-related benefits. Unlike the traditional approach under the CBD and Nagoya Protocol, which rely on bilateral agreements between resource providers and recipients, Decision 16/2 acknowledges state sovereignty but, in a commons-oriented move, seeks to simplify DSI governance by adopting a sectoral approach and inviting global payments for compliance, irrespective of individual ABS transactions. However, its approach is constrained by the non-binding character of COP decisions in international law and by the absence of dedicated enforcement mechanisms to ensure compliance and payment. Decision 16/2 instead relies on industry willingness and national-level measures to implement its principles. As states continue to regulate access to DSI at the national level, a key advantage associated with international decisions—the ability to establish a single agreed set of rules that enhance legal certainty and clarity for users of data —is undermined. At the time of writing, it remains unclear how double payments under different pathogen DSI benefit-sharing regimes can be effectively avoided. Nonetheless, given Parties' explicit commitment to continue exploring benefit-sharing modalities, Decision 16/2 is best understood as a new beginning for addressing DSI under the CBD, rather than a final word on the topic.[56]

3.2. *WHO pandemic influenza preparedness (PIP) framework*

The idea that states enjoy sovereignty specifically over viruses found in their jurisdiction—so-called 'viral sovereignty'—gained prominence following the 2007 H5N1 influenza dispute, when Indonesia faced obstacles in accessing health products developed using the very samples it had provided.[57] The resulting WHO PIP Framework establishes the only functioning multilateral ABS system for public health purposes by regulating the sharing pandemic influenza virus samples and related benefits. The PIP Framework reaffirms the sovereign rights of states over their biological resources (pathogen samples). It seeks to balance an imperative of rapid access to samples and information during a health emergency and, on an equal footing, access to vaccines and sharing of other benefits.

The sharing of pandemic influenza samples takes place through the WHO's Global Influenza Surveillance and Response System (GISRS). In exchange, companies obtaining these samples from the GISRS laboratories commit to provide, through WHO, benefits related to their use. The PIP Framework was adopted as a World Health Assembly (WHA) resolution and is not a legally binding instrument. Instead, it operates through private law contracts that bind their parties, the so-called Standard Material Transfer Agreements (SMTAs). SMTA1 governs the sharing of materials between laboratories within the GISRS, while SMTA2 applies to transfers outside the network, such as to manufacturers of health products. SMTA2s, negotiated and concluded between the WHO and manufacturers, permit the recipients to claim intellectual property rights on PIP material, but obliges them to share benefits chosen from the list in an annex to the agreement. The benefits may include commitments such as donating or reserving a percentage of real-time health product production at affordable prices for the WHO during an influenza pandemic or granting licenses to manufacturers in developing countries. Additionally, recipient manufacturers agree to make an annual Partnership Contributions, which supports pandemic influenza preparedness and response efforts, as well as the operations of the PIP

[49] Bagley et al. 'Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development' 20 January 2020, CBD Ad Hoc Technical Expert Group on DSI on Genetic Resources. 'In the EU, some users report costs of obtaining PIC/MAT as between EUR 500 to EUR 10,000 per negotiation, requiring up to 500 personnel hours, and taking up to three years to conclude.' In: M. Bagley, De-materializing genetic resources: synthetic biology, intellectual property and the ABS bypass, in: C.R. McManis, B. Ong (Eds.), Routledge Handbook of Biodiversity and the Law, Routledge, Abingdon, 2018, pp. 219–236; Thambisetty (n 41).

[50] M.S. Beato, V. Veneroso, The Nagoya Protocol on access and benefit sharing: the neglected issue of animal health, *Front. Microbiol.* 14 (2023) 1124120. https://doi.org/10.3389/fmicb.2023.1124120; S. Switzer, A. Strobeyko, M. Eccleston-Turner, S. Aubry, M. Rourke, Negotiating Pathogen Access and Benefit-Sharing (PABS): Recommendations and Priority Issues, SSRN (2025). https://doi.org/10.2139/ssrn.5383869. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5383869 (accessed 27 December 2025).

[51] P. Greenfield, Biopiracy row at UN talks in Geneva threatens global deal to save nature, *The Guardian*, 30 March 2022. https://www.theguardian.com/environment/2022/mar/30/cop15-faces-copenhagen-moment-genetic-data-dispute-aoe (accessed 27 December 2025).

[52] Convention on Biological Diversity (CBD), Digital sequence information on genetic resources. Draft decision submitted by the President (CBD/COP/16/L.32/Rev.1), Cali, Colombia, 1 November 2024. https://www.cbd.int/doc/c/bd4f/2861/9dce4f46d43a637231a442e0/cop-16-l-32-rev1-en.pdf.

[53] Ibid.

[54] Ibid, 'Entities which on their balance sheet dates exceed at least two out of three of these thresholds (total assets: USD 20 million Sales; USD 50 million; Profit: USD 5 million).'

[55] Ibid.

[56] A. Strobeyko, A new beginning for international benefit-sharing? Harmonising and complying with rules on digital sequence information, *CIL Dialogues* (Centre for International Law, National University of Singapore), 23 February 2025. https://cil.nus.edu.sg/blogs/a-new-beginning-for-international-benefit-sharing-harmonising-and-complying-with-rules-on-digital-sequence-information/ (accessed 10 May 2025).

[57] D.P. Fidler, Negotiating equitable access to influenza vaccines: global health diplomacy and the controversies surrounding avian influenza H5N1 and pandemic influenza H1N1, in: E. Rosskam & I. Kickbusch (Eds.), *Negotiating and Navigating Global Health*, vol. 2, World Scientific, 2011, 139. https://doi.org/10.1142/9789814368049_0008

Framework Secretariat and GISRS. While the PIP Framework and its SMTAs only apply to pandemic influenza samples, self-reported use of pathogen DSI can also trigger Partnership Contributions.

The PIP Framework has been described as an innovative instrument involving the pharmaceutical industry in the normative commitments underpinning global pandemic preparedness and response.[58] A study of 14 SMTA2s found that companies preferred donations and reserving of health products over other forms of benefit-sharing, such as licensing or transfer of technologies.[59] The WHO claims to have secured >940 million doses of pandemic vaccine to be sent to countries during the next influenza pandemic.[60] However, the PIP Framework remain untested in the absence of a human influenza pandemic in recent years, making it impossible to predict whether companies will fulfill their obligations during the state of emergency. Moreover, the PIP Framework's reliance on SMTAs raises questions about the viability and transparency of the system and the ability of WHO to enforce their terms against powerful industry and state actors.[61] Rourke's textual analysis of the PIP Framework and its SMTA2s reveals significant legal constraints on the system's operation during an influenza pandemic.[62] In particular, because of the inclusion of *force majeure* and confidential clauses in contracts with manufacturers, it is unclear whether the latter could be held accountable for failing to meet their obligations in the event of a pandemic.

The PIP Framework thus offers an interesting attempt to reconcile a sovereignty-based ABS paradigm with a commons-oriented, multilateral system of participating laboratories. Its relevance for pathogen DSI is, however, limited: it formally applies only to influenza viruses and relies on self-reporting with respect to the use of pandemic influenza DSI. Its effort to standardize contractual terms through a multilateral mechanism, rather than requiring case-by-case PICs and MATs, can also be read as a move toward a commons approach. At the same time, the readers can reasonably ask themselves how 'standard' the SMTAs are in practice, if they still entail case-by-case negotiation, including over commercially confidential clauses.

3.3. WHO pandemic agreement

At the 78th World Health Assembly (WHA) in May 2025, WHO Member States adopted the Pandemic Agreement after more than three years of negotiations.[63] However, according to its Article 31(2), the Pandemic Agreement will be opened for signature only once the WHA adopts an Annex on the Pathogen Access and Benefit-Sharing (PABS) System described in Article 12(2) of the Agreement.

The proposal to establish PABS System for pathogens with pandemic potential and their DSI has been one of the most contentious issues throughout the Pandemic Agreement negotiations. States with major research, development, and manufacturing capacity, and industry actors based there, have tended to prioritise rapid, timely access to pathogen materials and DSI, emphasising non-monetary benefits such as open access to information, scientific recognition, and collaboration.[64] Many low- and middle-income countries, by contrast, have framed PABS as a tool to address structural inequities by requiring comprehensive, enforceable benefit-sharing, including monetary and in-kind contributions.[65]

Article 12 therefore sets out the general architecture and guiding principles for the future PABS System for 'PABS Materials and Sequence Information,' while deferring the detailed rules to the PABS Annex. In line with the CBD/Nagoya approach, Article 12 of the Pandemic Agreement recognises States' sovereign rights over their biological resources and links the sharing and/or utilisation of PABS materials and DSI to the rapid, timely, fair and equitable sharing of benefits.

Article 12 further anticipates that 'participating manufacturers' will be bound, through legally binding contracts with the WHO, to provide rapid access targeting 20% of their real-time production of safe, quality and effective vaccines, therapeutics and diagnostics during a pandemic emergency. At least 10% is to be donated, with the remainder reserved for WHO at affordable prices. Distribution is to be based on public health risk and need, with particular attention to the needs of developing countries, therefore establishing a multilateral system.

At the time of writing, key design features of the PABS System remain unsettled. These include its definitions and scope; the terms, legal nature, and degree of standardization of contracts between WHO and participating manufacturers; the implications for pathogen DSI-hosting databases; modalities for DSI traceability; and the institutional arrangements needed to operationalize the System. The PABS Annex may also provide for additional benefit-sharing options, including capacity-building and technical assistance, R&D cooperation, non-exclusive licensing, and other forms of mutually agreed technology transfer.

The relationship between the PABS System and existing pathogens ABS instruments, including the CBD/Nagoya framework, the PIP Framework, and bilateral ABS arrangements, remains to be clarified to ensure legal coherence and mutual supportiveness and, ultimately, to facilitate rapid and equitable access to pathogens and associated benefits. Absent such coordination, overlapping international and domestic ABS measures risk duplication, increased legal uncertainty, and further fragmentation of the international ABS landscape.

The WHO Pandemic Agreement with its PABS System, once it enters into force, has the potential to reshape global regulation of pathogen DSI. It is expected to apply to DSI and to rely on contractual mechanisms, but the extent to which it will incorporate further design elements (including those relevant to database governance, traceability, and compliance) remains uncertain. I return to these design choices in Section 6.

More broadly, this section has shown that pathogen DSI, as distinct

[58] Rizk and others (n 47) 7; Morgera (n 6) 71.

[59] A. Rizk, A. Bezruki, M. Fallah, J. Sieka, T. Nyenswah, G. Matta, E. Paiva, G. L. Burci, S. Moon, Drivers and barriers to pathogen- and benefit-sharing (PBS): an empirical study of global perceptions and practices and case studies from Ebola in Liberia and Zika in Brazil, *Global Health Governance* 17(1) (2022) 4–36.

[60] World Health Organization, SMTA2 with vaccine & antiviral manufacturers (Category A): SMTA2 negotiating strategy and achievements, World Health Organization, Geneva, 30 March 2026. https://cdn.who.int/media/docs/default-source/pip-framework/smta2/smta2_cata_20221115.pdf?sfvrsn=5f74516c_1 (accessed 14 May 2025).

[61] Rourke (n 13).

[62] Ibid.

[63] World Health Organization, Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response: Report by the Director-General, Provisional agenda item 16.2, A78/10, 14 May 2025. https://apps.who.int/gb/ebwha/pdf_files/WHA78/A78_10-en.pdf (accessed 27 December 2025).

[64] A. Strobeyko, Thematic Text Comparison of Initial Text Proposals from Members of the Intergovernmental Working Group (IGWG) on the WHO Pandemic Agreement (A/IGWG/2), Governing Pandemics, Graduate Institute of International and Development Studies, Geneva, 202. https://docs.google.com/spreadsheets/d/1UMHJ-J0rpKzIOno5e_VZiGrDPK5QTSsc/edit?rtpof=true&sd=true (accessed 27 December 2025); G.L. Burci, A. Strobeyko, D. Morich, Global health law reforms: an update on the amended International Health Regulations and the pandemic agreement negotiations, *ASIL Insight* 28 (2024). https://www.asil.org/insights/volume/28/issue/4/global-health-law-reforms-update-amended-international-health (accessed 27 December 2025).

[65] Upon launching the negotiations of the Pandemic Agreement, WHO Member States emphasised their 'commitment…to develop a new instrument for pandemic prevention, preparedness and response with a whole-of-government and whole-of-society approach, prioritising the need for equity.' World Health Organization, Draft report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies to the special session of the World Health Assembly, A/WGPR/5/2, 12 November 2021. https://apps.who.int/gb/wgpr/pdf_files/wgpr5/A_WGPR5_2-en.pdf. See: Eccleston-Turner (n 13).

from physical samples, has been a blind spot in international legal regulation, one now being addressed by parallel reforms. Existing frameworks are predominantly sovereignty-oriented and include only limited commons features They have been deemed 'woefully inadequate for the digital age' by the former lead negotiator of the Africa Group at the CBD.[66]

In the interim, the policies of DSI-hosting databases continue to play a constitutive role in structuring access, use, and benefit-sharing expectations with regard to pathogen DSI.[67]

4. Database policies

In this section, I review the relevant scientific norms and the policies of the leading pathogen DSI databases. Scientists regularly upload DSI to such databases, with submissions often mandated by grants or journals. Database policies regulate who can access DSI—whether access is fully open or restricted to registered users with institutional affiliation—and what they may do with it, including whether data can be shared outside the database. They also bear on interoperability between databases operating under different policy regimes.

For this article, databases were selected to reflect the range of policy approaches discussed in connection with the WHO Intergovernmental Working Group (IGWG) on the PABS Annex to the Pandemic Agreement. I first outline the development of scientific norms concerning sharing of genomic data. I then describe and situate INSDC's policy of unrestricted open access and GISAID's model of public access with protections.[68]

4.1. Scientific norms

Since the Human Genome Project, the life-science community has treated the immediate, unrestricted release of genetic data as essential for and scientific integrity, reproducibility, and progress. In the Bermuda Principles (1996), leaders from the scientific community agreed on a set of principles requiring sequence information be released in publicly accessible databases within twenty-four hours after generation.[69] Those norms were generalised by the Fort Lauderdale agreement (2003),[70] which framed release of data the as a responsibility of funders, data producers, and users. The Toronto Statement (2009)[71] extended pre-publication access to all large-scale genome and genomics projects. Together with Good Scientific Practice codes, journal data-availability rules and funder open-access mandates, these norms have made deposition of sequence information in the public repositories a near-universal prerequisite.[72] In the context of pathogen DSI, WHO Guiding Principles for Pathogen Genome Data Sharing (2022),[73] call for timely, representative and openly accessible genome data, transparent source attribution, collaboration with originating laboratories and equitable distribution of benefits.

4.2. International nucleotide sequence database collaboration (INSDC)

Since the 1980s, advancements in sequencing technology have prompted the scientific community to call for databases to manage the increasing volumes of DSI. Small, dispersed databases gradually evolved into a large, interconnected system, leading to the establishment of the INSDC database infrastructure. INSDC is an international collaboration between three public databases: GenBank in the United States, the European Nucleotide Archive (ENA) in the United Kingdom, and the DNA Data Bank of Japan (DDBJ).

The INSDC is 'the core database infrastructure' for publicly available DSI and scientific research.[74] A constellation of 3000 other open databases exchange back and forth with the INSDC repositories.[75] Submission to INSDC is also a prerequisite for publication in scientific journals. Consequently, INSDC databases have tens of millions of users distributed across every sovereign state.[76] They host hundreds of millions of sequences and effectuate tens of millions of searches every month.[77] 95% of non-human pathogen DSI databases analyzed by Rohden et al. (705 out of 743) directly link to or download pathogen DSI from INSDC. The remaining 5% also relies on the use of unique identifiers—so-called Accession Numbers—issued by the INSDC. The exchange between databases is often fully automated and occurs at the backend, through machine-to-machine pipelines. Given the sheer volume of data exchange, Rohden et al. highlight the technical infeasibility of comprehensively tracking and tracing all pathogen DSI, which can be easily downloaded, reproduced, and modified by users.[78] Instead, additional disclosures could be required and, in 2023, introduced mandatory spatiotemporal metadata requirements.[79]

INSDC thus provides the global scientific community with a large-scale, open public infrastructure for DSI sharing, including pathogen DSI.[80] It operates under a policy of a 'free and unrestricted' open access, allowing anonymous access to pathogen DSI, forbidding any downstream licensing or use restrictions on DSI records. It thus guarantees permanent public availability of submitted records. However, this approach also comes with limited editorial control and terms of use,

[66] P. du Plessis, Simple plan could raise the billions needed to stem biodiversity loss, *New Scientist*., 21 October 2024. https://www.newscientist.com/article/2452598-simple-plan-could-raise-the-billions-needed-to-stem-biodiversity-loss/ (accessed 27 December 2025).

[67] Rizk and others (n 47); M. Rourke and others, Policy opportunities to enhance sharing for pandemic research, *Science* 368 (2020) 716. https://doi.org/10.1126/science.abb9342.

[68] S.A. Laird, R.P. Wynberg, A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol, Secretariat of the Convention on Biological Diversity (CBD), Montreal, 2018.

[69] Wellcome Trust, Summary of the report of the Second International Strategy Meeting on Human Genome Sequencing, 1997. https://www.genome.gov/25520385/online-education-kit-1997-bermuda-meeting-affirms-principle-of-data-release (accessed 27 December 2025).

[70] Wellcome Trust, Sharing data from large-scale biological research projects: a system of tripartite responsibility, 2003. https://www.genome.gov/Pages/Research/WellcomeReport0303.pdf (accessed 27 December 2025).

[71] Toronto International Data Release Workshop Authors, Prepublication data sharing, *Nature* 461 (2009) 168. https://doi.org/10.1038/461168a.

[72] F. Rohden and others, Combined study on digital sequence information (DSI) in public and private databases and traceability, Secretariat of the Convention on Biological Diversity (CBD), Montreal, 2020. CBD/DSI/AHTEG/2020/1/4; Rizk and others (n 47).

[73] World Health Organization, Guiding principles for pathogen genome data sharing, World Health Organization, Geneva, 2022. https://apps.who.int/iris/bitstream/handle/10665/364222/9789240061743-eng.pdf?sequence=1&isAllowed=y (accessed 27 December 2025).

[74] Rohden and others (n 72).

[75] DSI Scientific Network, Mapping the landscape of DSI databases: a large, interconnected, and ever evolving DSI data ecosystem, 2024. https://www.dsiscientificnetwork.org/wp-content/uploads/2024/12/DSI-Database-landscape_WEB.pdf (accessed 27 December 2025).

[76] Rohden and others (n 72); Laird and Wynberg (n 68).

[77] E.W. Sayers, M. Cavanaugh, L. Frisse, K.D. Pruitt, V.A. Schneider, B.A. Underwood, L. Yankie, I. Karsch-Mizrachi, GenBank 2025 update, *Nucleic Acids Res.* 53(D1) (2025) D56–D61. https://doi.org/10.1093/nar/gkae1114.

[78] Rohden and others (n 72).

[79] International Nucleotide Sequence Database Collaboration (INSDC), INSDC spatiotemporal metadata – minimum standards update (03-03-2023), INSDC, 3 March 2023. https://www.insdc.org/news/insdc-spatiotemporal-metadata-minimum-standards-update-03-03-2023 (accessed 27 December 2025).

[80] Rohden and others (n 72).

raising some concerns about data quality and benefit-sharing.[81] As sovereign claims over pathogen DSI intensify, the open access model may collide with states' efforts to assert jurisdiction or levy benefit-sharing obligations on identifiable users. Pandemic Agreement negotiations have featured tensions between states favouring an open-access model and those seeking mandatory user registration.

4.3. The global initiative on sharing all influenza data (GISAID)

Launched at the 61st World Health Assembly in 2008, GISAID was created to facilitate the rapid sharing of influenza pathogen DSI. It was designed to address challenges associated with open databases, particularly the concerns about the fair distribution of benefits and the risk of scientists being 'scooped'—a situation where rival teams could use shared data to publish research without properly acknowledging the original source.[82] To mitigate these concerns, GISAID requires users to create accounts and identify themselves and their affiliations. These accounts are visible to other users, promoting communication and scientific collaboration. By registering, users agree to the Database Access Agreement. This grants them a license to access the pathogen DSI on GISAID, but also obligates them to acknowledge data originators, collaborate with them, and refrain from sharing data outside of GISAID. Violations of these terms can result in the suspension or termination of access.

GISAID is much smaller than the INSDC infrastructure described above, with tens of thousands of users. Nevertheless GISAID's targeted and account-based approach, data curation, and emphasis on academic benefit-sharing have proved especially attractive to many laboratories in low- and middle-income countries.[83] It played a crucial role in the response to the COVID-19 pandemic by hosting the largest collection of SARS-CoV-2 genome sequences and was hailed as a 'game-changer' by the then WHO Chief Scientist Soumya Swaminathan.[84] However, GISAID has also faced criticism for its policy of not allowing data to be openly replicated outside the database. Proponents of open science argue that this restriction can hamper comparative analyses and slow down research.[85] As a non-profit foundation led by a controversial philanthropist reported to have multiple personas and to have acted arbitrarily toward researchers and their submissions, GISAID has faced governance criticisms.[86] Despite these concerns, GISAID illustrates how a tailored, trust-based sharing regime can elicit rapid data deposition from providers who might otherwise be hesitant to share data on fully open repositories.

The case of publicly accessible INSDC and of GISAID (accessible upon registration) show that pathogen DSI databases have been built largely along research-commons lines and the scientific principles of open sharing, prioritizing shared provisioning, wide access, and norms of reciprocal contribution. Yet, these databases operate in the shadow of sovereignty and are increasingly shaped by it. First, key components of the global DSI infrastructure are institutionally embedded in the state: GenBank and DDBJ are hosted by public authorities, and even where repositories are formally 'scientific' in orientation, their governance is conditioned by national legal and political constraints. Second, database rules and technical standards evolve in response to sovereign claims and distributional concerns. The 2023 move within INSDC to require country-of-origin metadata illustrates how provenance can be made legible to state interests without abandoning an open-access model. Moreover, GISAID policy model can be read as an infrastructure-level response to sovereignty-adjacent concerns about control, recognition, and unequal capture of value: its identity-based access, attribution and collaboration expectations, and limits on onward redistribution seek to create trust and to secure non-monetary benefit-sharing for data providers. The choices concerning database interoperability and linkage with other repositories are not merely technical issues.[87] They are inscribed in wider scientific and political debates concerning open science, traceability, and benefit-sharing.[88] Taken together, these developments suggest that DSI databases function not as sovereignty-free spaces but as hybrid governance sites, where commons-oriented scientific norms are continuously negotiated against demands for jurisdiction, traceability, recognition, and, increasingly, benefit-sharing. Such demands are evident when looking at the national ABS legislation applicable to DSI.

5. National legislation regarding access to pathogen DSI

Invoking sovereign rights over genetic resources, sometimes explicitly grounded in constitutional provisions,[89] states increasingly regulate access to pathogen DSI within their territories. To this end, they may adopt specific national legislation and/or interpret the CBD and its Nagoya Protocol as extending to pathogen DSI. A report commissioned by the pharmaceutical industry and prepared by the law firm Covington & Burling LLP identified 'at least 100 distinct ABS laws around the world' including 39 that apply or are likely to apply to pathogen DSI.[90] A comprehensive review of national legislation by Ljungqvist et al. found 104 legally enforceable ABS policies, with 22 countries having adopted a codified position on pathogen DSI.[91]

Building on and expanding the 2020 CBD expert study on the topic,[92] the above-mentioned Covington report and the findings of Ljungqvist et al.,[93] we can distinguish the following national approaches:

1. States where pathogen DSI is subject to bilaterally negotiated access through PICs and MATs.[94]
2. Other compliance-related measures, such as permits.[95]

[81] Covington & Burling LLP, Global sharing of pathogen genetic sequence data: Study on global disease surveillance and pathogen-sharing, 2023.
[82] S. Elbe, G. Buckland-Merrett, Data, disease and diplomacy: GISAID's innovative contribution to global health, *Glob. Challenges* 1 (2017) 33. https://doi.org/10.1002/gch2.1018; Rohden and others (n 34).
[83] Covington & Burling LLP (n 81).
[84] R. Van Noorden, Scientists call for fully open sharing of coronavirus genome data, *Nature* 590 (2021) 195. https://doi.org/10.1038/d41586-021-00305-7.
[85] Ibid; J.P. Kamil, How a dispute over sharing coronavirus genomes is threatening a vital tool for tracking variants, *Bull. At. Sci.*, 3 May 2022. https://thebulletin.org/2022/05/how-a-dispute-over-sharing-coronavirus-genomes-is-threatening-a-vital-tool-for-tracking-variants/ (accessed 27 December 2025).
[86] M. Enserink, J. Cohen, Control issues: GISAID offers a safe space to post viral genomes. Peter Bogner, its perplexing creator and overseer, may be jeopardizing its future, *Science* 380 (2023) 332. https://doi.org/10.1126/science.adi4114.
[87] R. Bellanova, G. Glouftsios, Controlling the Schengen Information System (SIS II): the infrastructural politics of fragility and maintenance, *Geopolitics* 27 (2022) 160. https://doi.org/10.1080/14650045.2020.1830765.
[88] A. Maxmen, Why some researchers oppose unrestricted sharing of coronavirus genome data, *Nature* 593 (2021) 176–177. https://doi.org/10.1038/d41586-021-01194-6; Van Noorden (n 84).
[89] For example, Article 66 of the Peruvian Constitution establishes that natural resources are national patrimony and that the state is sovereign in their utilisation.
[90] Covington & Burling LLP (n 11).
[91] G. V Ljungqvist and others, Global patterns in access and benefit-sharing: a comprehensive review of national policies, *BMJ Public Health* 3 (2025) e001800. https://doi.org/10.1136/bmjph-2024-001800.
[92] Bagley and others (n 49).
[93] Covington & Burling LLP (n 81); Ljungqvist and others (n 91).
[94] E.g. Bhutan, Colombia, Kenya, Malawi, Malaysia, Namibia, Peru, South Africa.
[95] E.g. Costa Rica, India, Uruguay.

3. Countries adopting measures requiring benefit-sharing from the utilization of pathogen DSI, e.g. through commercialization of health products.[96]
4. Finally, some developed countries do not regulate access to pathogen DSI, seeking to promote its unrestricted sharing and scientific R&D.[97]

This typology reveals a spectrum of approaches to sovereign control over pathogen DSI. Category 1 reflects a direct extension of the CBD's principle of sovereignty over genetic resources and its bilateral access model, now applied to sequence data. In Category 2, regulatory authority over pathogen DSI is exercised through monitoring tools and procedural obligations. For example, countries can check if pathogen DSI originating in their territory is being used in academic publications or patent applications. Category 3 introduces a nuanced model whereby national control is asserted, but benefit-sharing obligations are triggered not at the point of access, but upon commercialization. By contrast, Category 4 represents jurisdictions that deliberately abstain from asserting access requirements over pathogen DSI, aligning instead with open-access models.

While few countries explicitly refer to pathogen DSI in their national ABS legislation, a growing number have extended the sovereign rights originally asserted over physical genetic resources to also cover sequence information.[98] I analyzed ABS legislation from 14 countries that operationalize such control through their national legislation.[99]

At the foundation of these legislative regimes is a clear assertion of state ownership and control. For example, Colombia's Law 165 of 1994, which ratified the CBD, affirms state sovereignty over natural resources found in its jurisdiction.[100] Similarly, Cuba's Law 150/2023,[101] explicitly proclaims sovereignty over genetic resources and their derivatives (Art. 42.1) and affirms continued state ownership even after granting access permissions (Art. 43). Kenya's 2006 Environmental Management and Coordination Regulations state that Kenya retains 'ownership of, and title to, the genetic resource accessed by the user on behalf of Kenyan citizens' (Reg. 9.1).[102] Section 5(1) of Namibia's 2017 ABS laws vest control over genetic resources in the state, regardless any other ownership rights over the land where the resource is found or associated traditional knowledge.[103] We therefore observe that these legislative acts reaffirm the principle of the state's sovereignty and ultimate ownership over genetic resources, which persist even when they overlap with private, communal, or customary rights.

Importantly, many of these legislative acts extend sovereign rights to pathogen DSI, either explicitly or through broader legal constructs such as 'information,' or 'intangible components.' Cuba's Law 150/2023 explicitly includes '*información secuencial genética*' (genetic sequence information) under the sovereign ABS regime (Art. 41.2.).[104] Malawi's ABS Guidelines include 'genetic information or any forms of DNA/RNA sequences or sequence data in any format, including microbiological, digital or synthetic.'[105] Peru's Supreme Decree No. 019-2021-MINAM defines access to genetic resources to include both material and information deposited in digital repositories. It defines derivatives broadly to include biochemical compounds, '*aunque no contenga unidades funcionales de la herencia*' ('even if they do not contain functional units of heredity') and '*componente intangible*' ('intangible components') to include knowledge/innovation/practices associated with the resource.[106] Malaysia's ABS Act 795/2017 applies to genetic resources, microorganisms, derivatives and 'any information relating to' those elements. It also defines 'derivative"' to include biochemical compounds (whether or not containing functional units of heredity) and 'information in relation to derivatives.' Uruguay's Resolution 291/2020 refers to '*secuencias de información genética*' ('genetic sequence information').[107] Colombia's Resolution 1348/2014 confirms that the isolation of 'functional or non-functional units of DNA/RNA' constitutes access to genetic resources.[108] Namibia's Access to Biological and Genetic Resources Act 2/2017 defines a derivative as including any biochemical compound 'even if it does not contain functional units of heredity,' and makes access permits obligatory for 'intangible components, including genetic information or gene sequences.'[109] In a revision of its statutory definitions, India's 2023 Amendment to the Biological Diversity Act (2002) adopts a broad definition of 'derivative' as a naturally occurring biochemical compound/metabolism of biological resources, even if it does not contain functional units of heredity.[110] The 2002 Act explicitly requires prior approval and registration requirements for 'any invention based on any research or information on a biological resource which is accessed from India… including those deposited in repositories outside India.'[111] Definitional techniques such as explicit inclusion, derivative capture, and amendments demonstrate how national lawmakers can extend sovereignty into legal control over pathogen DSI.

A growing number of national ABS laws now treat pathogen DSI as subject to access procedures, such as PICs, MATs, or permits. This is done by addressing pathogen DSI in conjunction with the utilization of a physical genetic resource, or by regulating access to it independently of access to genetic material.[112] The transactional nature of such ABS

96 E.g. Brazil, India, and Malawi.
97 E.g. Australia, EU, Japan.
98 Covington & Burling LLP (n 11) 19; Bagley and others (n 49).
99 Bhutan, Brazil, Cambodia, Colombia, Cuba, India, Kenya, Malawi, Malaysia, Namibia, Nigeria, Peru, South Africa, Uruguay.
100 Colombia, Ministry of Environment & Sustainable Development, Handbook for Access to Genetic Resources and Their By-Products in Colombia, Bogotá D. C., 2021. https://archivo.minambiente.gov.co/images/images/BosquesBiodiversidadyServiciosEcosistemicos/Recursos_Genéticos/Documentos_interes/Manual_de_solicitud_del_contrato_de_Acceso_a_Recursos_Genéticos_y_sus_Productos_Derivados_en_Colombia_Traduccion.pdf (accessed 27 December 2025).
101 Cuba, Ley No. 150, Del Sistema de los Recursos Naturales y el Medio Ambiente, adopted 16 May 2022, published Gaceta Oficial No. 87, 13 Sep 2023. https://www.parlamentocubano.gob.cu/sites/default/files/documento/2023-10/goc-2023-o87.pdf (accessed 27 December 2025).
102 Republic of Kenya, Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations 2016. ww.nema.go.ke/images/Docs/Regulations/Conservationofbiologicaldiversityandresourcesaccesstogeneticres.pdf (accessed 27 December 2025).
103 Republic of Namibia, Access to Biological and Genetic Resources and Associated Traditional Knowledge Act 2 of 2017, signed 9 Jun 2017, in force GN 236/2021, 1 Nov 2021, Government Gazette 6343. https://www.lac.org.na/laws/annoSTAT/Access%20to%20Biological%20and%20Genetic%20Resources%20and%20Associated%20Traditional%20Knowledge%20Act%202%20of%202017.pdf (accessed 27 December 2025).
104 Cuba (n 101).
105 Malawi, Ministry of Natural Resources, Energy & Mining, Guidelines for Access and Benefit Sharing (Lilongwe, Jan 2019). https://ampeid.org/static/d884f0f0434a7499bb723c18f94ef0c0/Malawi_ABS%20Guidelines..pdf (accessed 27 December 2025).
106 Peru, Reglamento de Acceso a los Recursos Genéticos y sus Derivados, Decreto Supremo Nº 019-2021-MINAM, El Peruano, 24 Jul 2021. https://www.gob.pe/institucion/inia/informes-publicaciones/4167935-decreto-supremo-n-019-2021-minam (accessed 27 December 2025).
107 Malaysia, Access to Biological Resources and Benefit Sharing Act 2017, Act 795, Royal Assent 9 Oct 2017, Federal Gazette 17 Oct 2017. https://faolex.fao.org/docs/pdf/mal176890.pdf (accessed 27 December 2025); Uruguay, Ministerio de Vivienda, Ordenamiento Territorial y Medio Ambiente, Resolución Ministerial 291/2020, 14 Feb 2020, Diario Oficial 20 Feb 2020. https://ampeid.org/documents/uruguay/resolution-no-291-020-rm/ (accessed 27 December 2025).
108 Colombia (n 100).
109 Namibia (n 103).
110 Republic of India, The Biological Diversity (Amendment) Act 2023, Act No. 10 of 2023, Gazette of India, 3 Aug 2023. https://egazette.gov.in/WriteReadData/2023/247815.pdf (accessed 14 May 2026).
111 Ibid.
112 Bagley and others (n 49).

relationships reinforces the role of the state as sovereign gatekeeper, including over digital data flows. In India, for instance, foreigners and foreign companies must obtain pre-approval from the National Biodiversity Authority, which is also empowered to oppose foreign intellectual property filings based on Indian genetic resources (s. 18(4) as amended).[113] The 2023 amendments have created a two-track system: strict, permit-based control for foreign access and commercial use, and a lighter-touch registration process with wider exemptions for domestic, non-commercial research. They exemplify linkages between sovereign control over pathogen DSI and industrial policy aiming to strengthen domestic R&D.

Effective implementation of access requirements also relies on the machinery of the state which establishes monitoring mechanisms or dedicated benefit-sharing funds. In Nigeria, the Environmental Standards and Regulations Enforcement Agency monitors quarterly and final reports, maintains a public register of access permits, and can suspend or revoke them for non-compliance.[114] Malaysia's Act 795 creates statutory checkpoints at patent offices, product regulators, and public funding agencies, where permit holders must present ABS documentation (s. 30).[115] Colombia, Peru, and Uruguay similarly assign ABS oversight to IP registries, customs, and funding bodies.[116]

On benefit-sharing, Brazil's Law No. 13.123/2015 establishes a National Benefit-Sharing Fund (Art. 31), into which companies must pay 1% of net revenues (0.1% for small firms) from the commercialization of products based on Brazilian 'genetic heritage,' including sequence data.[117] The fund supports biodiversity conservation, traditional knowledge, and technology transfer, and is governed by a council with Indigenous and community representation. Bhutan and India also maintain tiered biodiversity funds at national and local levels, into which ABS payments are channelled.

To enforce compliance, national laws also rely on sanctions. In Namibia, violations—such as accessing pathogen DSI without a permit—can trigger fines up to NAD 150,000 and/or 10 years in prison, with possible forfeiture of assets.[118] In Malaysia, violations involving pathogen DSI or associated data carry fines, along with possible imprisonment (s. 15(7), 28(5), 31(2)).[119] India has replaced criminal penalties with administrative fines, now reaching ₹ 1 crore for continuing violations (new s.5 5A), and has introduced adjudicating officers and appeal rights to the National Green Tribunal.[120]

States may also introduce emergency exceptions to their ABS systems. For example, Uruguay's Resolution 291/2020 allows for a simplified access procedure through a special permit during public health emergencies (Art. 14). However, such exceptions remain rare and primarily facilitate rather than waive ABS requirements. They confirm rather than undermine the principle of sovereignty: it is the State, not the user, who decides when and how ABS rules may be eased.[121]

In conclusion, the ultimate authority to regulate pathogen DSI resides with national governments. While approaches to national regulation differ, many jurisdictions replicate the logic of sovereignty—understood as hierarchical, top-down control within territorial borders—and extend it to encompass DSI. However, the logic of sovereignty is ill-adapted to the governance of data. The sheer volumes of the pathogen DSI being exchanged,[122] coupled with the relative ease of use of sequencing and database technologies, pose a challenge to an order based on presumption of stable borders and top-down control. Overregulation risks raising transaction costs and deterring international scientific cooperation, particularly during emergencies. In the absence of legal clarity, researchers and companies may engage in forum shopping, seeking jurisdictions with weaker or unclear ABS rules. Thus, while sovereignty over pathogen DSI is increasingly recognized in national legal regimes, its operationalization poses a challenge for international law. This leads me to propose design principles for the future multilateral ABS solutions.

6. Design principles for the multilateral ABS system for pathogen DSI

The challenges and opportunities associated with designing and implementing a multilateral ABS system for pathogen DSI are profound. We have seen that the regulation of pathogen DSI operates across three interacting levels: international frameworks, database policies, and national ABS legislation. These levels do not operate in isolation. National laws should formally adhere to international ABS obligations, yet in practice frequently exceed or diverge from them. Database policies—though not legally binding under international or domestic law—set the operative conditions under which pathogen DSI is deposited and accessed, shaping behaviour and expectations of resource providers and users before any formal legal trigger. The emerging PABS System will need to navigate these three levels simultaneously: by being consistent with CBD and Nagoya Protocol, capable of disciplining national legislative divergence, and enabling co-existence of different database policy models. The risk is not merely fragmentation of international law, but structural misalignment that risks hampering scientific R&D. However, the ongoing reforms also present an opportunity to streamline ABS rules and provide legal certainty to both providers and users.

The system's eventual configuration will shape both the conditions under which pathogen DSI is accessed and the modalities through which benefits are generated and shared. Drawing from the literature, case studies, and international legal developments, several principles can be identified to guide the design of ABS for pathogen DSI in the public interest.[123] I argue that this effort should be seen not as a choice between 'open' and 'closed' systems, but as an exercise in governing a shared socio-technical infrastructure through enforceable, low-friction rules.

6.1. *Rethinking sovereignty: from national access regimes to global commons*

International and national legal instruments reaffirm state sovereignty over genetic resources. The assertion of sovereign claims over data poses serious practical and normative challenges. The Pandemic Agreement and PABS System discussions have to navigate between the logic of sovereignty and commons-oriented ABS. Drawing from the CBD experience with regulating DSI, it appears neither technically possible

[113] India (n 110).
[114] Nigeria, National Environmental (Access to Genetic Resources and Benefit Sharing) Regulations 2009, S.I. No. 30 (Official Gazette No. 62, 9 Oct 2009). https://archive.gazettes.africa/archive/ng/2009/ng-government-gazette-dated-2009-10-09-no-62.pdf.
[115] Malaysia (n 107).
[116] Colombia (n 100); Peru (n 106); Uruguay (n 107).
[117] Brazil, Lei nº 13.123, de 20 de maio de 2015 (Access to Genetic Heritage, Protection and Access to Associated Traditional Knowledge, and Benefit Sharing) Diário Oficial da União 21 May 2015. https://www.wipo.int/wipolex/en/legislation/details/15741.
[118] Namibia (n 103).
[119] Malaysia (n 107).
[120] India (n 110)
[121] Covington & Burling LLP (n 11).
[122] INSDC contains '228 million annotated sequences (1.5 billion reads…). The dataset is downloaded partially or completely 34 million times per year, used by >10–15 million unique users' A.H. Scholz, J. Freitag, C.H.C. Lyal, R. Sara, et al., Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation, *Nature Communications* 13 (2022) 1086. https://doi.org/10.1038/s41467-022-28594-0.
[123] I follow the approach taken by Halewood et al. in thinking about overarching design principles. See: M. Halewood, M. Bagley, M. Wyss, A. Scholz, New benefit-sharing principles for digital sequence information, *Science* 382 (2023) 520–522. https://doi.org/10.1126/science.adj1331.

nor desirable from a research perspective to wall off pathogen DSI in a closed regulatory regime.[124] An approach based on national sovereignty and control over data risks high transaction costs, impediments to scientific progress and, in the worst scenario, a breakdown in the sharing of data in emergencies.[125]

Instead, the concepts of global scientific research commons and common pools of genetic resources can help us address the provision of public goods such as information needed for preparation and response to emergencies. Global commons are defined as research assets governed under non-exclusive use conditions by a group of information producers and users.[126] Resources are provided by resource holders for common, collaborative use by their recipients.[127] In the pathogen DSI context, this commons comprises infrastructure of databases, identifiers, standards and rules governing access, use, attribution, compliance and dispute resolution.

As discussed in Section 2.2, the conventional way of addressing the problem of free riding and cooperation in this context consists of introducing an external public authority with a view of establishing rules that protect collective interest in the long-term.[128] The PABS Secretariat, modeled after PIP Secretariat, could play a role of a public authority by ensuring the continuous functioning of the pathogen DSI-sharing infrastructures, establishing legal relations with their users, monitoring compliance, and building the necessary scientific and legal capacity. The Pandemic Agreement COP could establish a science-policy interface as a subsidiary body, within the meaning of Art 19.4 of the treaty, which would allow the PABS system to stay up to date with regard to scientific information and rapidly changing technology. To address participation concerns, such bodies should institutionalize joint stewardship by providing space for geographically representative scientific and database expertise, clear procedures for compliance and rule changes.

Crucially, ABS is unlikely to succeed if it is primarily focused on controlling access to pathogen DSI. A commons-oriented approach prioritizes governance of use rather than access: standardized conditions and downstream triggers along the R&D chain—at publication, patenting, and commercialization—that keep access low-friction while preserving benefit-sharing obligations. As the 'directing and co-ordinating authority on international health work,'[129] the WHO, with its unique claim to global political legitimacy and representation, should serve as the forum where disputes regarding the system and its evolution are examined in the public interest.[130] While recognizing national sovereignty over genetic resources, such an approach would allow the states to pool information together and facilitate buildup of national capacities for pandemic prevention, preparedness, and response. It also allows traceability to be designed proportionately through widely used identifiers, metadata disclosures and reporting, rather than through an unrealistic ambition of comprehensive tracking of all DSI flows.[131]

6.2. Pathogen DSI databases as research commons: standardizing regulation and tools

Pathogen DSI databases exist as research commons infrastructure in relation to millions of users and thousands of downstream databases that reproduce their data and identifiers.[132] They underpin and rely on scientific journals, laboratories, sequencers, cloud storage, and the funding ecosystem for life-sciences. They are characterized by their public nature: anyone can use them and access the data (subject to prior registration and identification in the case of GISAID).[133] Scientific infrastructure such as the INSDC and GISAID form the backbone of global genomic surveillance. These systems are more than repositories: they represent socio-technical assemblages shaped by evolving community norms.[134]

Academic literature suggests building on policies of INSDC or GISAID for the purposes of new ABS instruments.[135] Seeing databases as research commons underscores the need to balance competing interests of their users for their long-term viability.[136] As a first step, this would mean ensuring that the PABS database ecosystem is future-proof and can adapt to quickly evolving scientific and political knowledge and practices, with an important role for a science-policy interface with geographically representative participation from scientists, database managers, and innovators. We have already seen that the policies of databases have evolved as a result of academic discussions about best practices in the sharing of pathogen DSI for the sake of integrity and replicability of science. I propose turning the focus toward establishment of norms among, and with the participation of, database managers and the scientific community, who share a common interest in the proper functioning of these infrastructures.

Participants in production of knowledge commons are often driven by reputational and academic motivations rather than commercial incentives, which underscores the need for scientific acknowledgment and collaborations as benefits to be shared.[137] Attribution and recognition should therefore be treated as a core, non-monetary benefit-sharing modality, not an ancillary norm. This could be achieved by informing users of the PABS benefit-sharing requirements and standardizing acknowledgment of data origin and of data submitters. Following the agreement found in the CBD Decision 16/2, databases could also be invited to inform their users of relevant ABS commitments, as well as the disclosure of relevant metadata, country of origin, and the use of traditional knowledge. Pathogens DSI submitters could be credited for their contributions on their academic profiles. The use of Digital Object Identifiers (DOIs) could be considered to acknowledge the work of laboratories and researchers sequencing and uploading the data (e.g., by linking their contributions to their ORCID profile).

Preserving interoperability between different databases is crucial for

[124] Rohden and others (n 72).
[125] Halewood and others (n 123).
[126] Dedeurwaerdere, Melindi-Ghidi and Broggiato (n 32).
[127] Kamau and Winter (n 32).
[128] Hardin (n 35).
[129] Art. 2(a), WHO Constitution, 1948.
[130] A. Strobeyko, C.A. Atuire, R. Faden, C.W.L. Ho, V. Ido, M. Kamal-Yanni, et al., Equitable access to pandemic products demands stronger public governance, *Lancet* 404(10467) (2024) 2030–2032. https://doi.org/10.1016/S0140-6736(24)02258-X.
[131] A.S. Haas and others, Threading the needle on Traceability within the PABS System – Promoting Equity and Science, Zonodo (2026). doi:10.5281/zenodo.18493678.
[132] B. Kingsbury, N. Maisley, Infrastructures and Laws: Publics and Publicness, *Annual Review Law and Social Science* 17 (2021) 353–373. https://doi.org/10.1146/annurev-lawsocsci-011521-082856. https://www.iilj.org/publications/infrastructures-and-laws-publics-and-publicness/ (accessed 27 December 2025).
[133] J.-C. Plantin, C. Lagoze, P.N. Edwards, C. Sandvig, Infrastructure studies meet platform studies in the age of Google and Facebook, *New Media & Society* 20(1) (2018) 293–310. https://doi.org/10.1177/1461444816661553.; Kingsbury and Maisley (n 131).
[134] G. Sullivan, Law, technology, and data-driven security: infra-legalities as method assemblage, *Journal of Law and Society* 49(S1) (2022) S31–S50. https://doi.org/10.1111/jols.12352; Kingsbury and Maisley (n 132); Plantin and others (n 133).
[135] Scholz and others (n 122); P. Oldham, S. Thambisetty, The pandemic access and benefit sharing system: four elements of a trusted system, LSE Legal Studies Working Paper No. 10/2024, 2024. https://doi.org/10.2139/ssrn.4810352 (accessed 27 December 2025).
[136] Kingsbury and Maisley (n 132).
[137] Dedeurwaerdere, Melindi-Ghidi and Broggiato (n 32); C.M. Schweik, R. English, Preliminary steps toward a general theory of internet-based collective-action in digital information commons, *Int. J. Commons* 7 (2013) 234; P.A. David, J.S. Shapiro, Community-based production of open-source software: what do we know about the developers who participate?, *Empir. Issues Open Source Softw.* 20 (2008) 364.

scientific R&D. In that context, PABS could build on existing identifiers and metadata/API standards.[138] The WHO's recent work on the attributes and operational principles of pathogen genomic data-sharing platforms is particularly pertinent, as it specifies benchmarks spanning governance and transparency; infrastructure and security; data scope, submission, curation and provenance; access; interoperability; data use and benefit-sharing; analytical and reporting capabilities; and sustainability.[139]

A further commons-oriented design move is to reduce transaction costs by standardizing legal relations upstream. One way to do it would be to provide fully standardized contracts without the need to negotiate commercial-in-confidence clauses with each manufacturer. Proposals such as a 'Sovereign Commons Licence' for DSI go further by pooling sovereignty to combine open access with reputational and financial benefit-sharing incentives.[140] This approach aims to connect physical samples and associated DSI, provide terms of use that are machine- and human-readable to function as a notice and licensing device that preserves low-friction access while making obligations legible across databases, publications, and (where relevant) product-development pipelines.[141] However, the Pandemic Agreement anticipates benefit-sharing being operationalized through legally binding contracts with participating manufacturers, meaning identifier- or licence-based approaches are more likely to complement rather than displace contracts as the primary legal tool. The question of how to capture users of pathogen DSI not party to contracts with WHO, and thus outside of the PABS system, will therefore require further consideration.

6.3. Drawing from the best practices at the national level

In this article, I have reviewed nationalized legislation which operationalized sovereignty by imposing rules on the access to pathogen DSI. However, other approaches are conceivable and preferable over imposition of conditions upon the point of access.

The Brazilian model of pathogen DSI regulation illustrates how benefit-sharing can be decoupled from point of access and linked to downstream use, particularly commercialization. Under Brazil's Law 13.123/2015, any user may access pathogen DSI without seeking a permit in advance.[142] However, they must register the activity in the online National System for the Management of Genetic Heritage and Associated Traditional Knowledge (SisGen) and update it upon processing of pathogen DSI. This system allows benefit-sharing to be linked to successful subsequent commercialization of products. A monetary royalty of 1% of the company's annual net revenue obtained from the finished product (with up to 75% reduction if the user opts for certain conservation or social investments) is paid only once the product commercialization starts. Alternatively, the user may negotiate non-monetary benefits (such as technology transfer or capacity-building) with the Ministry of the Environment or, where traditional knowledge is involved, directly with the Indigenous or traditional community, and register the agreement in SisGen. All monetary contributions flow into the federal ABS Fund, which finances biodiversity conservation, restoration and bio-innovation programs throughout Brazil. This system provides its users with a degree of legal certainty concerning the scope of benefits to be shared, applies them to commercialized products, and incentivizes notification of pathogen DSI use.

Another example is provided by the Swiss Nagoya Ordinance,[143] which implements ABS requirements into national law. It imposes due-diligence obligations on users regarding the provider country from which the resource was obtained, alongside 10-year record-keeping and transmission of key information to downstream users. It also requires notification to the Federal Office of the Environment before market authorization or, where no authorization is required, before marketing a product developed from utilized genetic resources. Intentional breaches of notification duty or false statements are subject to fines.

An international PABS Register could draw lessons from these systems, by providing open access to pathogen DSI, while requiring notification of use and triggering specific benefit-sharing obligations at the commercialization stage. Alternatively, downstream monitoring could be conducted at the national level in accordance with the principles agreed in the PABS instrument. Building on mechanisms in place, search engines could use the metadata and digital identifiers to link pathogen DSI with relevant legal information. Other categories of benefits, such as partnership contributions (e.g. from participating companies or WHO Member States) could also flow continuously to enable the functioning of the system.

6.4. Linking to other instruments: providing legal clarity and coherence

In this article, I have highlighted the growing complexity of ABS normative frameworks, spanning international instruments, as well as an increasing number of national laws that address pathogen DSI. These developments have contributed to a fragmented legal landscape in which transaction costs risk outweighing the benefits the system was meant to deliver.

To reduce that complexity, the PABS instrument must define its scope with precision. One practical option is an agreed, regularly updated list of pathogens (or pathogen families) covered by PABS. Such a list could draw on the WHO R&D Blueprint's current priority pathogens: COVID-19, Crimean-Congo haemorrhagic fever, Ebola virus disease and Marburg virus disease, Lassa fever, MERS-CoV and SARS, Nipah and other henipaviral diseases, Rift Valley fever and Zika.[144] Simultaneously, through the science-policy interface described above, it should reserve the ability to address the pandemic threat of an as-yet-unknown 'Disease X.' Temporal clarity (*ratione temporis*) is equally important: from the legal perspective, PABS obligations can apply only to sequence data entered into the system after the instrument's date of entry into force. Thus, the openness of the system would facilitate inclusion of the 'old' data into its scope.

A related issue concerns membership in the Pandemic Agreement and its relation to other ABS laws. It is of utmost importance to attain universal application of the PABS system to ensure its proper functioning. However, with the US's exit from the WHO, this prospect appears more distant than ever. Nevertheless, states continue to have an interest in rapid and reliable exchange of pathogen DSI for their pandemic preparedness and response. The Pandemic Agreement frames PABS as complementary and non-duplicative and anticipates alignment of national ABS measures applicable to PABS materials and sequence information once all elements of the system are operational. The Pandemic Agreement Parties should seek to operationalize PABS as *lex specialis* vis-à-vis both the CBD and national ABS laws for the priority

[138] See Haas and others (n 131).
[139] World Health Organization (n 7); Strobeyko (n 64).
[140] Oldham and Thambisetty (n 135); P. Oldham and S. Thambisetty, The Sovereign Commons Licence, SSRN, (2025). https://doi.org/10.2139/ssrn.5194900. https://ssrn.com/abstract=5194900 (accessed 27 December 2025)
[141] S. Thambisetty, Is There a Third Way? Lessons for PABS from Parallel Treaty Contexts, *Geneva Health Files*, (26 November 2025). https://genevahealthfiles.substack.com/p/is-there-a-third-way-lessons-for-pathogen-access-benefit-sharing-pandemic-agreement-biodiversity-beyond-national-jurisdiction-bbnj-cali-fund-siva-thambisetty (accessed 27 December 2025).
[142] Brazil (n 117).
[143] Switzerland, Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Ordinance, NagO) of 11 December 2015 (Status as of 1 January 2017).
[144] World Health Organization, Prioritizing diseases for research and development in emergency contexts, WHO 2025. https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts (accessed 27 December 2025).

pathogens identified in its Annex, ensuring legal certainty across jurisdictions. By carving those pathogens out of the CBD's benefit-sharing system, PABS can enable health-specific arrangements—such as in-kind donations of medical countermeasures, scientific acknowledgements and collaborative research—while safeguarding rapid access to data.[145]

Coherence requires practical mechanisms to avoid 'stacking' and duplication across DSI regimes, in particular vis-à-vis the CBD's new multilateral mechanism and the Cali Fund.[146] Building on models such as Nagoya Protocol Internationally Recognized Certificates of Compliance (IRCCs) and the CBD Decision 16/2 certification concept, Parties could establish a PABS certificate (or comparable proof-of-compliance) that is mutually recognized under international and domestic ABS laws, alongside clearer inter-secretariat coordination and transparency around the enforceability of WHO–manufacturer contracts.

7. Conclusion

In this article, I have examined the emerging regulation of pathogen DSI at the intersection of sovereignty claims and the governance of research commons. In the absence of internationally agreed rules, the de facto regulation of pathogen DSI is increasingly shaped by a patchwork of international and national ABS rules and database policies, each seeking to extend control and benefit-sharing expectations to pathogen DSI.

An increasing number of states have begun to assert sovereign control over pathogen DSI through domestic ABS legislation. While the national approaches differ in scope and implementation, they are united by a common ambition: to extend the logic of sovereign rights to sequence information. I have argued that classical sovereignty-based, transactional ABS models are ill-suited to the scale and velocity of pathogen DSI flows. Where access is conditioned on individualized permissions or walled off by technical or legal barriers, the likely outcome is higher transaction costs, incentives for forum shopping, and the risk of delayed sharing in a public health emergency. Conversely, open access without credible benefit-sharing pathways can reproduce the distributive inequities that 'viral sovereignty' claims originally sought to contest.

The regulation of pathogen DSI stands at a critical juncture. The adoption of the WHO Pandemic Agreement represents a historic opportunity to establish a coherent international legal framework that reflects both scientific practice and the need for fairness. However, its practical significance will depend on the design of the PABS Annex, including how it standardizes obligations, supports interoperability across databases, and coordinates with parallel ABS frameworks, such as the CBD's multilateral benefit sharing mechanism on DSI. These processes offer the potential to move beyond fragmented, transactional models toward a multilateral approach that decouples access from benefit-sharing and recognizes the collective nature of pathogen DSI.

I conclude that a commons-oriented approach offers a defensible public interest frame for legal design. It treats pathogen DSI as a shared scientific resource essential to global genomic surveillance and R&D, while making benefit-sharing legible, enforceable, and low-friction for users. For PABS, this implies pooled, standardized modalities that reduce upstream negotiation costs; recognition of the infrastructural role of key databases; and shared metadata/identifier standards to preserve interoperability. It necessitates clear scope, dispute settlement rules, and enforceability to curb fragmentation across international and domestic regimes.

Striking the right balance between openness and equity is essential. A well-designed regime can preserve rapid, universal access to high-quality data while embedding fair benefit-sharing mechanisms, including contributions from commercial users, improved access to health technologies, and scientific benefits. Such a framework would help secure public trust, ensure sustained investment in open data infrastructures, and enhance global pandemic preparedness and response. A failure to reach agreement on these issues risks entrenching legal fragmentation, creating disincentives for data sharing, and undermining the scientific collaboration on which global health security depends. It could lead to the imposition of restrictive access regimes, burdensome compliance requirements, and the erosion of the very infrastructures that have proven vital during past health emergencies.

The future of pathogen DSI regulation thus hinges on the international community's ability to reconcile the principle of sovereignty with the global public interest. Achieving it will require legal imagination, institutional coordination, and sustained political commitment. What is needed is a shift from a conception of sovereignty centred on control to one grounded in stewardship: a form of scientific sovereignty that respects the legitimate expectations of data providers while safeguarding the shared scientific commons upon which we all depend.

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The author certifies that he has no competing interests to declare.

[145] Strobeyko (n 56).

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