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PABS 101: FOUNDATIONS OF PATHOGEN ACCESS AND BENEFIT-SHARING UNDER THE PANDEMIC AGREEMENT

Interviews with Gian Luca Burci, Anne Huvos, Luisa Belloni, Timothy Dallman, Stephanie Switzer, Mark Eccleston-Turner, and Michelle Rourke

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LIST OF ABBREVIATIONS

ABBREVIATION	FULL FORM
ABS	Access and Benefit-Sharing
BBNJ	Biodiversity Beyond National Jurisdiction (Agreement)
BM	Biological Material
CBD	Convention on Biological Diversity
COP	Conference of the Parties
DDBJ	DNA Data Bank of Japan
DSI	Digital Sequence Information (in the context of the CBD and BBNJ)
ENA	European Nucleotide Archive
FAO	Food and Agriculture Organization
GISAID	Global Initiative on Sharing All Influenza Data
IHR	International Health Regulations
IGWG	Intergovernmental Working Group
INSDC	International Nucleotide Sequence Database Collaboration
IP	Intellectual Property
IVPPs	Influenza Viruses with Pandemic Potential
IVTM	Influenza Virus Traceability Mechanism
MAT	Mutually Agreed Terms
MLM	Multilateral Mechanism
MLS	Multilateral System
NICs	National Influenza Centres
PA	Pandemic Agreement
PABS	Pathogen Access and Benefit-Sharing
PHEIC	Public Health Emergency of International Concern
PIC	Prior Informed Consent
PIP Framework	Pandemic Influenza Preparedness Framework
R&D	Research and Development
SI	Sequence Information (in the context of the Pandemic Agreement)
SII	Specialized International Instrument
SMTA	Standard Material Transfer Agreement
VTDs	Vaccines, Therapeutics, and Diagnostics
WHA	World Health Assembly
WHO	World Health Organization

PABS 101: FOUNDATIONS OF PATHOGEN ACCESS AND BENEFIT-SHARING UNDER THE PANDEMIC AGREEMENT

INTRODUCTION

In May 2025, after over three years of negotiations, Member States of the World Health Organization (WHO) adopted the Pandemic Agreement (PA) establishing a new legal framework for global pandemic prevention, preparedness and response. However, the Agreement will not open for signature or enter into force until its Annex on Pathogen Access and Benefit-Sharing (PABS) is negotiated by the WHO Intergovernmental Working Group (IGWG) and adopted by the World Health Assembly (WHA). The IGWG met for the first time in July 2025. It is to submit the outcomes of its deliberations to the 79th WHA in May 2026.

This publication was prepared as part of the lead-up to the 5 September 2025 workshop, '*PABS 101: Foundations of Pathogen Access and Benefit-Sharing under the Pandemic Agreement*,' organized by the Global Health Centre (GHC), in partnership with the Permanent Mission of the Federal Democratic Republic of Ethiopia to the United Nations Office and other international organizations in Geneva, the Permanent Mission of the Republic of Indonesia to the United Nations Office and other international organizations in Geneva and the Permanent Mission of the Kingdom of the Netherlands to the United Nations Office and other international organizations in Geneva. This workshop aims to foster a deeper understanding of how Access and Benefit Sharing (ABS) operates in practice and to explore its potential implications for the IGWG discussions. To enhance the discussion and prepare for the event, Global Health Centre staff interviewed the expert speakers invited to the workshop.

THE ORIGINS AND EVOLUTION OF PABS

*Interview with **Gian Luca Burci**, Senior Visiting Professor of International Law, Geneva Graduate Institute, and Academic Adviser, Global Health Centre*

1. What is Pathogen Access and Benefit Sharing and why does it matter?

A perennially thorny issue affecting the global community's ability to manage infectious disease outbreaks is the rapid and reliable international sharing of pathogens, including their sequence information (SI), and related benefits. Such sharing is governed under rules collectively referred to as ABS.

Healthcare workers and researchers often sample and sequence biological materials (e.g. blood, saliva, tissue) from infected persons for medical and research purposes. Global access to pathogen samples and SI is critical for surveillance and understanding of pathogens, as well as development of health products: vaccines, therapeutics, diagnostics (VTDs). Pathogens and VTDs developed from their use are, however, often controlled by different actors (public and private, commercial and non-commercial), in various countries, and with different scientific, industrial, and economic interests. These differences call for a nuanced approach toward pathogen ABS, building on and in conversation with existing international ABS regimes.

2. How is the sharing of benefits governed under international law?

The practice of pathogen ABS globally has been characterized by two developments that have increased its legal, political and practical complexity and are at the origin of the inclusion of the PABS System in the negotiations of the WHO PA.

The first development concerns the politics of pathogen ABS. Since the mid-2000s, cross-border outbreaks of emerging infectious disease have been followed by ABS controversies, which emerged roughly in parallel with the negotiation of the Nagoya Protocol seeking to elucidate benefit-sharing provisions under the Convention on Biological Diversity (CBD).

In 2007, Indonesia suspended international sharing of samples of H5N1 Influenza viruses due to concerns over accessing vaccines developed from their use, citing the CBD's principle of sovereignty over biological resources and the right of contributing countries to regulate access to biological resources under their jurisdiction and to seek benefits in return. This decision prompted the negotiation of the Pandemic Influenza Preparedness (PIP) Framework adopted by the WHA in 2011. Hailed as a milestone in global health governance, the PIP Framework established a system that places fair and equitable benefit-sharing on an equal footing with rapid and timely access to pandemic influenza samples and entrusts WHO to be the manager and stewards of the system. The Nagoya Protocol was negotiated in parallel to the PIP Framework, adopted in 2010, and entered into force in 2014. While the Nagoya Protocol reproduces the CBD's approach to ABS, requiring bilateral negotiations for access to resources, the PIP Framework provides a multilateral system applicable to pandemic influenza samples (see the next section of this discussion paper). As recognized under both instruments, benefit-sharing can include:

1. Academic benefits, such as acknowledgement of source, scientific collaboration, co-authorship and shared research funding between providers and receivers.

2. Economic benefits, such as access fees, shared ownership, licensing, upfront or milestone payments, salaries and preferential terms, joint ventures, joint ownership of intellectual property (IP) rights, and royalty rights over commercial utilization of pathogens as well as countermeasures.

3. Outbreak-related benefits, such as sharing related data and information and access to countermeasures including vaccines, diagnostics and therapeutics.

4. Systems strengthening benefits, such as capacity building, technology transfer, and infrastructure development.

The second development crucial to ABS is the rapid diffusion and availability of sequencing technology that facilitates widespread exchange of pathogen SI. SI can be shared among researchers or uploaded onto the large number of public or private databases that offer access under different conditions. The most popular databases appear to be the Global Initiative on Sharing All Influenza Data (GISAID)[1] based in Germany, and the International Nucleotide Sequence Database Collaboration (INSDC), a collaboration among GenBank, European Nucleotide Archive (ENA), DNA Data Bank of Japan (DDBJ).[2] SI is not expressly mentioned in the CBD, its Nagoya Protocol, or the PIP Framework, thus creating uncertainty as to its status in international law and raising potentially difficult issues as to the role and status of existing databases. It is also more elusive and difficult to track and regulate than the movement of physical samples, given the large scale of data flows and the complexity of underlying infrastructures. However, it is worth noting the establishment of the benefit sharing mechanism for DSI (Digital Sequence Information, a term which includes pathogen SI) by the CBD Conference of the Parties Decision 16/2 adopted in November 2024.[3] The decision invites companies (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' for disbursement.[4]

3. How do you situate PABS in the context of the Pandemic Agreement? Could you outline the key issues which arose in the context of PABS negotiations?

There is wide consensus within the public health community that the transactional and bilateral model of the CBD and Nagoya Protocol are not appropriate for the needs of outbreak prevention and response, which requires a predictable and sustainable multilateral approach including quick and unimpeded sharing of pathogens and SI as well as fair, timely and equitable sharing of benefits arising from their utilization.

The negotiation of the PA was therefore a unique opportunity to operationalize a dedicated mechanism for the sharing of pathogens (including SI) and benefits tailored to the specific needs of public health. The main principles of the PABS system were included in the working draft submitted to INB2[5] at the outset of the negotiations, and were elaborated in subsequent drafts.

1 https://gisaid.org/.

2 https://www.insdc.org/about-insdc/.

3 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.

4 Adam Strobeyko, 'A New Beginning for International Benefit-Sharing? Harmonising and Complying with Rules on Digital Sequence Information,' CIL Dialogues, February 23, 2025, https://cil.nus.edu.sg/blogs/a-new-beginning-for-international-benefit-sharing-harmonising-and-complying-with-rules-on-digital-sequence-information/.

5 WHO, Draft annotated outline of a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+), Intergovernmental Negotiating Body, Second Meeting, A/INB/2/3, 14 April 2022, available at: https://apps.who.int/gb/inb/pdf_files/inb2/A_INB2_3-en.pdf.

One particular concern that ran throughout the negotiations was to ensure that the PABS system be consistent with Article 4.4 of the Nagoya Protocol, which exempts specialized international ABS instruments consistent with Nagoya Protocol objectives from its obligations.

What eventually became Article 12 proved one of the most controversial provisions largely because of the divergent priorities between developing and developed countries. The main challenge was to balance guarantees of rapid and timely access to pathogens with equally credible guarantees of equitable benefit-sharing without reproducing the transactional approach of the CBD and the Nagoya Protocol. Another related aspect was the role of the industry and how to ensure its participation, commitment and contribution through an international treaty. A particularly controversial aspect of this issue was agreeing on a percentage of the production of pandemic-related health products to be shared with WHO during a pandemic emergency.

The difficulty of agreeing on a detailed text that could be operationalized from the outset, and at the same time the momentum for the conclusion of the Agreement, led to the adoption of a general text in Article 12, which contains guiding principles but mostly sketches the contour of an annex to be negotiated by a newly formed IGWG and eventually adopted by the Health Assembly. Until the annex is adopted, the Agreement cannot be opened for signature and ratification (Article 31). This unusual outcome shows the crucial importance of PABS as the precondition for the implementation of the Agreement as a whole.

Indeed, Article 12 forms an integral part of the cluster of articles (9 to 14) dedicated to pandemic-related health products. These articles are interdependent and, if properly implemented, mutually strengthening, and PABS stands at the centre of this system. For example, a precondition for strengthened and sustained R&D is both the timely and unimpeded availability of pathogens and SI underpinned by Article 12. This in turn forms the basis for more equitable geographical distribution of manufacturing capacities (Article 10), which also requires the transfer of needed technology in particular to developing countries (Article 11). The transfer of technology and granting of non-exclusive licences are also listed among the benefits that can arise from pathogen-sharing (Article 12.8). In other words, the articles in question form a self-sustaining loop with PABS as a precondition for their entry into force.

PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK

*Interview with **Anne Huvos**, Unit Head, Pandemic Influenza Preparedness Framework Secretariat, WHO & **Luisa Belloni**, Project Officer, WHO*

1. How does the PIP Framework operate and what lessons can be drawn from it for PABS?

When The PIP Framework was negotiated by WHO Member States over four years and formally adopted by the World Health Assembly in 2011 under Article 23 of the WHO Constitution. It is not a treaty and therefore not legally binding on Member States. However, it does create legally binding benefit-sharing commitments through its Standard Material Transfer Agreements (SMTAs).

The Framework is implemented by a small Secretariat within the WHO Health Emergencies Programme. WHO implements the PIP Framework in close partnership with Member States, industry, civil society and the public health laboratories of the Global Influenza Surveillance and Response System (GISRS).

The PIP Framework has two objectives that are equally important:

- sharing by WHO Member States of influenza viruses with human pandemic potential with GISRS; and
- equitable access to vaccines, medicines and other products and technologies.

WHO Member States are expected to share influenza viruses with pandemic potential (IVPPs) with GISRS in a rapid, systematic and timely manner. Such sharing is governed by Standard Material Transfer Agreement (SMTA) 1[6] which establishes the terms and conditions under which Member States, through their GISRS laboratories, share influenza viruses with pandemic potential into, within and out of GISRS.

In addition to serving as a virus sharing platform, GISRS also develops–inter alia–candidate vaccine viruses, and other analyses, materials and information that are shared with Member States and manufacturers of influenza vaccines and other products, such as antivirals and diagnostics.

The Framework establishes two key benefit-sharing mechanisms to strengthen pandemic influenza preparedness and ensure a more equitable response to the next influenza pandemic:

- **An annual Partnership Contribution (PC)**: Influenza vaccine, diagnostic, and pharmaceutical manufacturers that use GISRS collectively provide US$33.7[7] million annually to WHO. These funds are used by WHO to support preparedness and response capacity building activities in countries where they are weak.
- **Advance supply agreements**: Non-GISRS recipients of PIP Biological Materials (PIP BM) must sign an SMTA2 with WHO. Through SMTA2s, WHO secures access, in legally binding contracts, to future pandemic response products such as vaccines, antivirals

6 SMTA1 is found at Annex 1 of the PIP Framework.

7 The level of the annual Partnership Contribution was adjusted in accordance with PIP Framework section 6.14.3, footnote 1, starting in 2025. Previously, the annual Partnership Contribution level was US$ 28 million.

and diagnostics. The SMTA2s ensure that WHO will have access, in real time, to specific percentages of pandemic influenza vaccines, antivirals, and diagnostics, at the time of the next influenza pandemic. A model SMTA2 is found in Annex 2 in the PIP Framework.

Through implementation of the PIP Framework since May 2011, lessons have been learned to address implementation challenges. For instance, in order to ensure that the PIP Framework did not impede the rapid, systematic and timely sharing of IVPPs to entities outside of GISRS, WHO developed an *interim process* to ensure that PIP BM could continue to be shared, in advance of the signature of an SMTA2. This was achieved through the development of a Shipment Notice[8] which is sent to any non-GISRS entity that requests PIP BM. Through the Shipment Notice, the shipping laboratory informs the potential recipient of the PIP Framework and the conditions that will apply if the recipient chooses to move forward with the shipment of PIP BM. All shipments of PIP BM to non-GISRS entities are recorded in the PIP Influenza Virus Traceability Mechanism (IVTM) that was established to record all such transfers of PIP BM, providing the legal and operational foundation for SMTA2 enforcement.

The PIP Framework demonstrates that ABS can be operationalized for public health needs and offers a useful model for future discussions. Its relative simplicity, however, derives from its narrow scope—focusing on a single pathogen with well-defined epidemiological and seasonal dynamics—and from its formal application only to physical virus samples.

2. Even though the PIP Framework formally applies only to physical samples, has it also addressed the sharing of pathogen SI?

PIP was designed for physical virus samples. However, the importance of influenza virus SI was recognized by Member States, who requested the WHO Director-General to consult the PIP Advisory Group on the best processes for further discussion and resolution of issues relating to the handling of genetic sequence data from IVPPs (PIP Framework Section 5.2.4).

While the PIP Framework does not have a *specific* benefit sharing mechanism for benefits arising from the use of IVPP SI only, the concept of 'use of GISRS' which triggers the payment of the Partnership Contribution, has, since 2013, included use of IVPP SI.[9]

WHO itself does not host sequence databases but works closely with GISAID and GenBank. The PIP Advisory Group[10] has done extensive work to explore how to handle SI, including defining the optimal characteristics of IVPP SI databases (timely sharing, quality data, complete data, ease of access, database sustainability and security, source identification and support to regulatory systems).[11] Development of the study included discussions with database managers to determine the feasibility of attaching notices or tags to sequences to alert users to ABS/PIP obligations. The PIP Advisory Group also spearheaded a pilot exercise, conducted by the World Data Center of Microorganisms, which explored linking the use of IVPP SI (as found in publicly available patent filings, regulatory filings, or clinical trial applications), in the development or production of products.[12]

8 PIP BM Shipment Notice, available at pipbm-shipnotice-oct2019.pdf.

9 PIP Framework: Distribution of Partnership Contribution among companies, Page 3, Section II. B), available at pc_distribution.pdf.

10 PIP Framework Advisory Group: https://www.who.int/groups/pip-framework-advisory-group/genetic-sequence-data.

11 PIP Framework Advisory Group Report on Optimal characteristics of an influenza GSD sharing system: https://cdn.who.int/media/docs/default-source/pip-framework/pip-framework-advisory-group/twg_doced1d1fb3-f99e-4797-82f0-60a357a37aee.pdf?sfvrsn=7efec205_1.

12 WHO, Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Report by the Director-General. Document A72/12, 72nd World Health Assembly, Geneva: WHO, 2019. Available at: https://cdn.who.int/media/docs/default-source/pip-framework/governance/wha72-12-op1cde-report-edited-en.pdf.

3. How could the relationship between PABS and the PIP Framework be operationalized in the future?

While awaiting the outcome of PABS negotiations, PIP will likely continue as a stand-alone framework focused on pandemic influenza preparedness. Once PABS is up and running and delivering benefits, Member States will need to decide whether there should be a unitary system covering all pathogens with pandemic potential, including influenza.

To avoid 'double-dipping' or overlapping obligations, influenza-related obligations could be integrated into PABS once it proves effective in securing and distributing benefits. Existing PIP SMTA2 obligations could be converted into PABS commitments, providing quick wins. For example, WHO has already concluded 16 SMTA2s with major vaccine manufacturers. These agreements could be adapted into PABS contracts, immediately assuring access to pandemic vaccines beyond influenza.

PATHOGEN AND SEQUENCE INFORMATION SHARING OUTSIDE OF INFLUENZA

*Interview with **Timothy Dallman**, Senior Technical Officer, Emerging Pathogen Intelligence Platforms Unit, WHO Hub for Pandemic and Epidemic Intelligence*

1. In recent health emergencies, including the COVID-19 pandemic, how have pathogen materials (samples) and Sequence Information been shared in practice? Has the sharing been timely and reliable?

The sharing of SI and samples in health emergencies is a critical component of emergency response. However, sharing of such material and data has not been universally timely and reliable. The ability to share is directly linked to the capacity to generate and use SI, and as such, country capacity-building should be at the heart of any guidelines or recommendations for sharing, as per the WHO guiding principles for pathogen genome data sharing.[13] Reliable sharing also requires a robust ecosystem of data platforms and biorepositories that are designed and operated in a way to support public health objectives in both a local and global context.

The COVID-19 pandemic showed the power of data sharing but also highlighted the gaps in both governance and technical frameworks that need to be strengthened to ensure future systems are both reliable and equitable.

2. How has the sharing of pathogen materials between laboratories operated, and what role has the WHO played in supporting that process?

Sharing of pathogen materials has traditionally taken place either through bilateral agreements or within pathogen-specific international networks like the GISRS. In emergencies, WHO has played a key coordination role for many of these networks and coordinated the sharing of material, often via disease-specific WHO collaborating centres, ensuring that laboratories worldwide can access reference strains.

Beyond coordination, WHO also provides technical guidance on the safe handling, transport, and storage of pathogen materials, helping to generate best practice and standardization across diseases and national systems.

Despite this, the sharing landscape remains fragmented, with many bilateral and disease-specific arrangements often resulting in delayed responses to fast-moving emergencies. This fragmentation is one of the major drivers toward a multilateral, standardized system with an appropriate equitable focus.

3. What is the role of the WHO BioHub in that context and how does it operate?

The WHO BioHub was established in 2021 to provide a standardized mechanism for the sharing of pathogens with epidemic or pandemic potential. It operates by providing a secure biorepository where materials can be shared safely with appropriate laboratories under standardized

13 WHO guiding principles for pathogen genome data sharing (2022) https://iris.who.int/bitstream/handle/10665/364222/9789240061743-eng.pdf.

agreements. It aims to reduce reliance on ad hoc bilateral arrangements and ensure a more equitable and transparent material-sharing landscape. It has been used during the recent Mpox public health emergency of international concern to ensure materials from emerging variants could be quickly and safely shared with countries, enabling the refinement of molecular detection and characterization methods.

4. Which databases have been preferred for sharing pathogen Sequence Information, and did those preferences vary by region or type of institution?

A range of platforms support pathogen sequence data sharing, including public domain platforms such as the INSDC databases, which are open access and whose data can be used without restriction; databases that offer structured data governance terms such as Pathoplexus; and those that require user authentication and acceptance of specific data-use terms such as GISAID.

The preference of the submission platform varies by region and institution and has been guided by many factors, including ease of use, disease community preference, added analytical benefits of the platform, as well as considerations around data licensing and recognition.

A key lesson from the pandemic is that it would be valuable for the public health community to agree on a set of common parameters and expected characteristics—such as accessibility, security, governance, contributor recognition, and interoperability—that platforms should aspire to in order to fulfil their public health function. The International Pathogen Surveillance Network (IPSN)[14] is working with partners to define such attributes and principles for genomic data-sharing platforms supporting surveillance of pathogens with epidemic and pandemic potential, with the aim of helping the public health community navigate how to balance local priorities with global public health needs, ensuring that data remains both useful and reusable in emergencies and that data owners have the confidence and trust to participate in such data exchanges.

14 https://www.who.int/initiatives/international-pathogen-surveillance-network

THE ABS LANDSCAPE AND WHAT NEXT FOR PABS

*Interview with **Stephanie Switzer**, Reader in Law, University of Strathclyde, **Mark Eccleston-Turner**, Senior Lecturer in Global Health Law, Department of Global Health and Social Medicine, King's College London & **Michelle Rourke**, Australian Research Council Discovery Early Career Research Award fellow, Griffith Law School, Griffith University*[15]

Introduction

The concept of ABS originates from environmental law, finding expression in the 1992 CBD and its 2010 Nagoya Protocol, which grants states sovereign rights over genetic resources, including pathogens. In essence, access to a country's sovereign genetic resources requires that country's prior informed consent (PIC), unless otherwise determined, and must be accompanied by the fair and equitable sharing of benefits, on mutually agreed terms (MAT), arising from the use of those genetic resources.

A number of specialized multilateral ABS regimes exist in addition to the CBD system, including:

- The PIP Framework, relevant to pathogen sharing on a specific subset of physical influenza pathogens (addressed in section 2 of this paper).
- The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty), which governs those resources via a multilateral ABS system and a benefit-sharing fund.
- The BBNJ Agreement, covering marine genetic resources beyond national jurisdiction, including both physical samples and SI.

The proposed PABS System under the WHO PA aims to create a multilateral ABS regime for pathogens with human pandemic potential. However, its scope remains undefined, raising concerns around a potential overlap with other international ABS instruments, as well as fragmentation, and benefit stacking with existing ABS mechanisms.

Below, we map the existing international ABS mechanisms, their implications for the ongoing negotiations, and outline key design elements and considerations for the PABS system.

1. Charting the conceptual and legal contours of ABS in international Law

ABS and the CBD

Under the CBD, States have sovereign rights over the genetic resources within their jurisdiction, with access to genetic resources to be on MAT and with PIC, unless determined otherwise by

15 This work very much builds on collaboration with colleagues, in particular with Abbie-Rose Hampton, as well as members of the PABS Informal Group, as well as signatories to Stephanie Switzer and others, 'Negotiating Pathogen Access and Benefit-Sharing (PABS): Recommendations and Priority Issues' (7 August 2025) <https://osf.io/9r3g7_v1>. We are extremely grateful for their input in the development of our ideas. Any errors remain the authors' own.

the relevant Party. Where benefit sharing occurs it is to be fair and equitable on MAT. The CBD creates a largely **bilateral** ABS system between providers and users of genetic resources.

Genetic resources are defined as 'genetic material of actual or potential value,' meaning any 'material of plant, animal, microbial or other origin containing functional units of heredity.' This definition is generally taken to include pathogens,[16] and as we discuss below, may overlap with the scope and application of the PABS System.

A key recent scientific trend is that of dematerialization via the creation of SI shared mostly through online databases.[17] This has led some to claim this allows the bypassing of ABS by industry, as ABS has typically applied to the use of physical genetic resources.[18]

In recognition of that concern, the CBD COP Decisions 15/9 (2022) and 16/2 (2024) established 'a multilateral mechanism (MLM)' and the voluntary Cali Fund which is directed to receive a proportion of profits or revenue from 'sectors that directly or indirectly benefit from the use of DSI in their *commercial activities*.' Academic institutions and public databases are exempt from monetary benefit-sharing. **Pharmaceuticals** are identified as a sector expected to contribute to the Fund.[19] At the time of writing (August 2025) and nearly 6 months after it became operational, the Cali Fund has received no monetary contributions.

The Nagoya Protocol

The Nagoya Protocol operates as a supplementary Protocol to the CBD, aiming to elucidate benefit sharing under the CBD, as well as the role of Traditional Knowledge. It is largely facilitated through national implementation, resulting in a patchwork quilt of domestic ABS legislation.[20]

Article 8(b) of the Nagoya Protocol (Special Considerations) asks Parties to consider 'present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally' when developing and implementing their ABS laws. However, **this does not suspend ABS requirements in the event of a health emergency**, as is sometimes thought.

As a result, the ABS landscape for pathogens and associated data is a highly mixed picture.

Specialized multilateral ABS instruments

Beyond the CBD, other more specialized ABS instruments seek to capture a different aspect of global genetic heritage.

The **Plant Treaty**, for example, provides a **multilateral**—as opposed to bilateral—ABS regime for 'plant genetic resources for food and agriculture' (PGRFA) that fall within the Plant Treaty's Multilateral System (MLS).[21] The terms for monetary benefit-sharing are set out in a standard material transfer agreement (SMTA) which contains different options as to when such sharing will be triggered and how much is owed when the trigger is activated. Monetary benefits are

16 See Michelle Rourke, 'The History of Accessing and Sharing Human Pathogens for Public Health Research' in Sam Halabi & Rebecca Katz (Eds.), Viral Sovereignty and Technology Transfer: The Changing Global System for Sharing Pathogens for Public Health Research, (Cambridge: Cambridge University Press, 2020) 31, 37 – 38 (discussing the contestation on this issue).

17 Note: DSI is a place holder term without an agreed upon definition.

18 Though certain countries now do seek to provide for ABS in respect of DSI; see Gunnar V. Ljungqvist and others, 'Global patterns in access and benefit-sharing: a comprehensive review of national policies' (2025) BMJ Public Health 2025;3:e001800.

19 CBD COP Decision 16/2 Enclosure 1 sets out indicative sectors that should contribute to the Fund as it is one 'that may benefit directly or indirectly from the use of digital sequence information on genetic resources.'

20 See Gunnar V. Ljungqvist and others (n. 21).

21 These are not just the 64 species listed under the Plant Treaty's Annex 1, but also other non-Annex 1 material that are voluntarily contributed to the MLS and are considered to be within the control of the contracting parties or in the public domain (Article 11.2). It should be noted that the Annex 1 species are not automatically considered to be within the MLS by virtue of being listed. The contracting parties must still agree to share them within the MLS.

pooled within a Benefit-Sharing Fund, for further disbursement according to agreed upon priorities. The monetary benefits that have accrued under the Plant Treaty SMTA are considered to have been insufficient to meet these priorities, with the Benefit-Sharing Fund heavily reliant upon voluntary contributions and donations.[22] Negotiations are ongoing on how to enhance the multilateral system to improve monetary benefit-sharing, and how to encompass DSI within the Plant Treaty's MLS.[23]

The **BBNJ Agreement**[24] applies to 'marine genetic resources in areas beyond national jurisdiction.' Its benefit-sharing arrangements apply to any marine genetic resource (except those collected in the course of fishing activities) and to both DSI and physical resources. ABS is to be achieved via the BBNJ Clearing-House Mechanism,[25] which must be notified prior to any collection and transfer of samples and any efforts to use or commercialize them.[26] The Clearing House is to be established once the BBNJ Agreement enters into force, which at the time of writing has not yet occurred.

More generally, while the Plant Treaty and the BBNJ are unlikely to overlap with the PABS System in terms of their material scope, they form an important part of what may be referred to as the ABS 'regime complex'[27] and accordingly, negotiators of the PABS System may learn important lessons from the negotiation and, in the case of the Plant Treaty, operation of these instruments.

2. How will PABS fit within the existing domestic and international ABS legal frameworks? What should negotiators consider to ensure coherence with existing systems?

Any attempt by the WHO to establish a *multilateral* access and benefit-sharing regime applicable to pathogen sharing will inevitably interact (and potentially overlap) with the Nagoya Protocol/CBD and associated ABS schemes, some of which explicitly encompass pathogens. Concerns have been expressed regarding complexities of these overlaps.[28]

The PA is not ignorant of the challenges posed by the range of countries that apply domestic and regional ABS measures to pathogenic materials and SI that would likely fall within the scope of the PABS system. Article 12(5)(d)(ii) directs that, 'each Party reviews and, as it deems appropriate, aligns its national and/or regional access and benefit sharing measures … so that measures that are contrary to, or inconsistent with, or duplicative of, the PABS Instrument will not be applied.'[29] However, the PABS system also reaffirms sovereign rights of States over PABS material and sequences (see Article 12(1)). The tension between two principles will require clarification by the negotiators of PABS.

The interaction between PABS and other international ABS frameworks, will depend in part upon its material scope:

22 See e.g. Morten Walløe Tvedt, 'A Contract-law Analyses of the SMTA of the Plant Treaty: Can It Work as a Binding Contract?' (2021) 24 The Journal of World Intellectual Property 83 and CBD, Compilation of lessons learned from other international funding mechanisms.

23 See Stephanie Switzer, Michelle Rourke and Mark Eccleston-Turner, 'Navigating the Global Landscape of Access and Benefit-Sharing (ABS) on Digital Sequence Information (DSI) Regulation: Dealing with Scope Confusion through Mutual Supportiveness' (7 August 2025) <https://osf.io/sdcjb_v1> accessed 21 August 2025.

24 Agreement Under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction ('Biodiversity Beyond National Jurisdiction', BBNJ) 2023, U.N. Doc. A/RES/78/272.

25 See BBNJ, Article 51.

26 BBNJ, Article 12(8).

27 Stephanie Switzer, Michelle Rourke and Mark Eccleston-Turner (n. 23).

28 WHO, 'Implementation of the Nagoya Protocol and pathogen sharing: public health implications - Study by the Secretariat' (2017) https://cdn.who.int/media/docs/default-source/documents/nagoya-protocol/nagoya-full-study-english.pdf?sfvrsn=ec2ab49d_12&download=true.

29 Pandemic Agreement, Article 12(5)(d)(ii).

Options for the material scope of PABS

Ultimately a goldilocks approach to material scope is required; one that is neither too broad so that the system gets overburdened (if everything is shared), nor too narrow so that the system misses 'disease X.' One potential solution could be to adopt an approach similar to that of the International Health Regulations Annex 2 when State Parties are considering whether a public health event needs to be notified to the WHO as a potential Public Health Emergency of International Concern (PHEIC). A list of pathogens that always required to be shared could be established, with a flow diagram setting out relevant criteria (e.g., transmission rate, mortality rate) for how to deal with other (irregular or emerging) pathogens.

(Adapted from Stephanie Switzer and others, 'Negotiating Pathogen Access and Benefit-Sharing (PABS): Recommendations and Priority Issues' (7 August 2025) <https://osf.io/9r3g7_v1>)

The Pandemic Agreement directs that PABS should not be duplicative of other ABS mechanisms.[30] However, the uncertainty of scope can result in regime overlaps and unpredictability.[31] This leads to the risk of benefit stacking (that is, possible multiple payments), potential confusion around sharing, and fragmentation of the international ABS landscape for pathogens. The IGWG may also need to 'determine whether some animal and environmental pathogens fall within scope, particularly as the majority of emerging infectious diseases are zoonoses.'[32]

Case study

At present, it is anticipated that influenza virus samples with human pandemic potential obtained from human samples will remain under the PIP Framework, but benefit-sharing associated with the use of the DSI derived from some influenza viruses could fall under the new PABS System, and indeed domestic laws … Should influenza virus with human pandemic potential be obtained from an animal specimen, the PIP Framework *might* apply, but the GISRS tends to deal with human samples, while veterinary samples are managed through another system governed by the FAO and the World Organization for Animal Health (WOAH). The DSI associated with such a sample may further be regulated under the CBD's MLM or potentially under the domestic laws of the originating State.

(Extracted and adapted from Stephanie Switzer, Michelle Rourke and Mark Eccleston-Turner, 'Navigating the Global Landscape of Access and Benefit-Sharing (ABS) on Digital Sequence Information (DSI) Regulation: Dealing with Scope Confusion through Mutual Supportiveness' (7 August 2025) <https://osf.io/sdcjb_v1> accessed 21 August 2025).

30 Article 12(5)(d), Pandemic Agreement (2025).

31 Stephanie Switzer, Michelle Rourke and Mark Eccleston-Turner (n. 23).

32 Stephanie Switzer and others, 'Negotiating Pathogen Access and Benefit-Sharing (PABS): Recommendations and Priority Issues' (7 August 2025) <https://osf.io/9r3g7_v1>. See also Rourke, Michelle, One Health and Pathogen Sharing: What's Missing in the Pandemic Treaty's Proposed Pathogen Access and Benefit-Sharing (PABS) System? (September 24, 2024). Cambridge University Press, 2024 (forthcoming), Available at SSRN: https://ssrn.com/abstract=4965622 or http://dx.doi.org/10.2139/ssrn.4965622.

Addressing the interactions between PABS and other ABS mechanisms requires proactive engagement with these other regimes, in line with the principle of mutual supportiveness under international law.[33] For example, CBD COP Decision 16/2 directs the DSI MLM be 'implemented in a way that is *mutually supportive* of and adaptive to other international access and benefit-sharing instruments on digital sequence information on genetic resources, to *avoid the stacking of obligations* and, where appropriate, to streamline processes. The governing bodies of other international access and benefit-sharing instruments are invited to collaborate with the multilateral mechanism (emphasis added).'

CBD COP Decision 16/2, in an attempt to 'defragment' the international ABS system, further directs that the DSI MLM applies to DSI to the extent that other specialized ABS mechanisms do not apply (unless the latter 'opt in').[34] However, absent agreement on DSI's definition and uncertainty surrounding the scope of PABS, the distinction may be difficult to make in practice. PABS negotiations concerning pathogen SI will thus require significant coordination and collaboration with the CBD.

A related issue to the above is the extent to which any PABS system will be considered a specialized international instrument (SII) under Article 4(4) of the Nagoya Protocol such that the latter does not apply. Pursuant to Article 4(4), the 'Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.' The Parties to the Nagoya Protocol have yet to reach agreement on the criteria - and procedure - for determining whether an international ABS instrument constitutes an SII, and close coordination and collaboration will be required to ensure that the PABS System is indeed recognized as an SII. This need is identified in Article 12.4 of the Pandemic Agreement.

3. Operationalization of PABS: principles and elements that need to be addressed by the IGWG

Legal issues concerning the operationalization of PABS

Several design questions remain unresolved around the operationalization of the PABS system. Article 12 directs that all elements should come into force simultaneously, yet sample/SI sharing and benefit provision may not be operational at the same pace. Benefit-sharing is to be implemented through legally binding contracts with the WHO, but these instruments do not yet exist and will require careful drafting to ensure that obligations can be effectively enforced.[35] The potential coexistence of bilateral transfers alongside PABS also raises concerns: while consistent with state sovereignty, such transfers could encourage free-riding and weaken incentives to participate in a multilateral system.

Traceability poses another challenge. While physical samples may be easier to track, tracing sequence information is far more complex and should not undermine existing scientific infrastructures.[36] Questions also persist about the temporal scope of benefit-sharing obligations, including whether countermeasures developed before PABS enters into force would be covered. Additional uncertainties include how disbursement criteria such as 'public health risk and need'

33 Riccardo Pavoni, 'Mutual Supportiveness as a Principle of Interpretation and Law-Making: A Watershed for the 'WTO-and-Competing-Regimes' Debate?' (2010) 21 European Journal of International Law 649.

34 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. Annex, para. 1(c) 'For which the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources is not provided for under other international instruments on access and benefit-sharing, unless the multilateral mechanism is chosen for that purpose under those instruments'.

35 Stephanie Switzer and others, 'Negotiating Pathogen Access and Benefit-Sharing (PABS): Recommendations and Priority Issues' (7 August 2025) <https://osf.io/9r3g7_v1>.

36 Ibid.

will be defined and who will make such determinations.[37] IP rights over PABS materials and potential export restrictions during health emergencies could undermine equitable access. Finally, negotiators must recognize that enforceability and compliance require more than normative clarity: they demand technical capacity, institutional support, and mechanisms robust enough to translate legal commitments into tangible benefits.[38]

Key principles and elements for consideration by IGWG could include:

- A commitment to **legal certainty**,[39] and treatment of **enforcement** as a separate item, including the creation of a **dispute settlement system** catering to the hybrid public/private nature of the PABS system;

- A commitment to **effectiveness**, and ensuring that **PABS deliver more benefits than costs**, and that such **benefits must be delivered predictably and sustainably**;

- A commitment to **reflexivity, learning, review, and the iterative, flexible development of the system, supported by independent monitoring and review**. This could involve the creation of a science-policy interface to 'facilitate the iterative and evidence-based ongoing development of the PABS system'[40] and a **Steering Committee** to discuss policy developments and make proposals for reform based on experiences under PABS. A **Benefit-Sharing Committee** could be created to ensure the effectiveness of benefit-sharing arrangements.

- A commitment to **fairness and equity, and solidarity in the distribution of medical countermeasures**;

- **Transparency** to build trust;

- **Financing the operationalization of the PABS** including shipping costs, insurance and associated indemnification and liability costs.[41]

- A **commitment to other principles of international law** such as good faith, the protection of legitimate expectations and effectiveness.[42]

37 Ibid.

38 See discussion in Julia Schutz Veiga and Henrique Marcos, 'A Digital Infrastructure for Ocean Biodiversity: Reimagining the BBNJ Clearing-House Mechanism' (18 August 2025) Cambridge International Law Journal. https://cilj.co.uk/2025/08/18/a-digital-infrastructure-for-ocean-biodiversity-reimagining-the-bbnj-clearing-house-mechanism/

39 Note: legal certainty in respect access to genetic resources and traditional knowledge is highly likely to form a core criterion of a specialised international instrument under Article 4 (4) of the Nagoya Protocol; see Specialized international access and benefit-sharing instruments in the context of Article 4, paragraph 4, of the Nagoya Protocol

40 Stephanie Switzer and others (n. 35).

41 Ibid.

42 Ibid. Note: these principles are also likely to be to the fore in the determination of whether the PABS System will constitute a specialised international ABS instrument.

WORKSHOP CONCLUSION

Presentations at the '*PABS 101: Foundations of Pathogen Access and Benefit-Sharing under the Pandemic Agreement*' workshop, which took place on 5 September 2025, highlighted several key themes. These inform the concluding reflections below.

On the basis of her experience with the PIP Framework, Luisa Belloni's presentation highlighted that multilateral ABS for pathogen samples can be operationalized through standardized contracts and predictable benefit streams administered by a dedicated secretariat and embedded in laboratory networks. PIP's legally binding SMTAs, its Partnership Contribution, and practical tools such as the shipment notice may offer design cues for PABS, even as PABS must extend beyond pandemic influenza and address more complex issues of pathogen SI. The presentation showed that PIP has continued to evolve to address technological challenges. Its Advisory Group consulted databases housing IVPP sequence information and observed that benefit-sharing aims may be achieved by monitoring products generated using IVPP SI and by informing users of relevant ABS obligations.[1] In line with this approach, the PIP Secretariat worked with the World Data Center for Microorganisms to develop a prototype search engine for scientific publications, patents, regulatory filings, in order to help identify entities developing commercial pandemic influenza products using IVPP SI.[2]

Beyond influenza, the International Pathogen Surveillance Network (IPSN), a global network of pathogen genomic actors, brought together by the WHO Hub for Pandemic and Epidemic Intelligence, is developing common principles and practical guidance for databases and data-sharing standards, and recognition for data generators. In this context, Timothy Dallman emphasized linking equitable, timely sharing with the infrastructures and norms that make sharing reliable. Platform governance, interoperability, transparent licensing, compliance with data-use terms, and links to benefit-sharing are coalescing through WHO-led work[3] and the IPSN.[4] These should be translated into lean, fit-for-purpose PABS requirements that respect open science, he argued. His presentation outlined that databases are moving toward diverse exchange models, including federated systems, and PABS should allow multiple technical pathways to compliance. Capacity building should be integral to data sharing, with quality and reliability norms, and support to generate, curate, and analyze data treated as core benefits to ensure durable data flows and equitable returns.

The presentation by Mark Eccleston-Turner situated PABS within a wider landscape of ABS instruments and warned of overlaps with the CBD/Nagoya system, the PIP Framework, and more

1 World Health Organization, *Best Process to Handle Genetic Sequence Data from Influenza Viruses with Human Pandemic Potential (IVPP GSD) under the PIP Framework: Options to Monitor the Use of Genetic Sequence Data from Influenza Viruses with Human Pandemic Potential (IVPP GSD) in End-products,* draft paper, September 29, 2015, https://cdn.who.int/media/docs/default-source/pip-framework/pip-framework-advisory-group/ag-and-gsd/gsdoptionspaper.pdf?sfvrsn=69e03b5_5&ua=1&utm.

2 World Health Organization, *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Decision WHA72(12), Paragraphs 1(c), (d) and (e), Report by the Director-General* (Geneva: World Health Organization, March 2020), https://cdn.who.int/media/docs/default-source/pip-framework/governance/wha72-12-op1cde-report-edited-en.pdf?sfvrsn=8f8bfb33_30&utm.

3 World Health Organization, WHO Guiding Principles for Pathogen Genome Data Sharing (Geneva: World Health Organization, November 8, 2022), https://www.who.int/publications/i/item/9789240061743.

4 World Health Organization, Attributes and Principles of Genomic Data-Sharing Platforms Supporting Surveillance of Pathogens with Epidemic and Pandemic Potential, public consultation draft (Geneva: World Health Organization, 2025), https://cdn.who.int/media/docs/default-source/ipsn/public-consultation-attributes-and-principles-for-pathogen-genomic-data-sharing-platforms.pdf?sfvrsn=e1e36a0f_5.

indirectly with the Plant Treaty, and BBNJ. He called for clear scope and mutual supportiveness of PABS to govern interfaces with other ABS regimes, as well as pursuit of recognition as a SII under Nagoya Article 4(4) to deliver predictable, non-duplicative rules.

The presentation identified the core operational choices the Annex must address: a material scope that neither overloads the system nor misses Disease X, clear temporal coverage of benefits, enforceable WHO-administered contracts, and reliable financing for collection, shipment, data curation, compliance, and liability. Mark Eccleston-Turner also flagged the challenge posed by Article 12's simultaneity requirement, the risk that parallel bilateral transfers could enable free-riding. Open questions remain on who sets and applies allocation criteria based on public-health risk and need, whether SI traceability can support open science, and how to prevent intellectual property claims and export controls during emergencies from eroding equitable access.

Mark Eccleston-Turner called for legal certainty, transparency (including of contracts), a fit-for-purpose dispute-settlement mechanism, and reflexive governance through regular review, independent monitoring, and a science–policy interface. He highlighted the need for sustained institutional capacity and financing in turning norms into predictable benefits and guiding PABS by general principles of international law such as good faith, protection of legitimate expectations, and effectiveness.

Drawing on her experience as Malawi's ABS National Focal Point and co-chair of the CBD's open-ended process on DSI, Mphatso Martha Kalemba emphasized the need for a functioning multilateral system - particularly for DSI, which is difficult to govern bilaterally. She highlighted the value of robust informal and intersessional processes under the CBD, where multiple expert groups and studies convened biodiversity experts/negotiators and scientists alongside economists and lawyers to define problems and craft solutions. For the PABS system, she stressed commissioning targeted studies on allocation methodologies and scope, with structured involvement of diverse expertise.

Mphatso Martha Kalemba advocated for the Parties to the Pandemic Agreement to start by locking in the end goal—ensuring benefits flow back to provider countries—and working backward to operational choices that advance that goal. Agreement on a few areas of convergence can keep negotiations moving while detailed methods are developed. A principal deliverable should be legal clarity for researchers, companies, and provider states alike. She argued that a well-designed system can facilitate technology transfer, mobilize resources for health and innovation, and enhance access to biological materials by rebuilding trust. Clear, credible benefit-sharing rules encourage timely sharing rather than restriction, and support more pathogen research. Malawi's ABS practice illustrates this direction: pathogens are already covered under its national ABS regime, contracts are used for pathogen-related materials, and procedures are being streamlined to increase efficiency and predictability while ensuring mutual supportiveness with other regimes.

Mphatso Martha Kalemba highlighted the interdependence of access and benefit sharing and argued that ABS should not hinder research, but act as a bridge that enables equitable benefit-sharing. In the context of health, benefits are not only monetary but concern sharing of vaccines and diagnostics and contributing to the SDGs and the global health agenda.

A recurring theme in the workshop was the importance of process and participation. The IGWG could enable it through inclusive, intersessional engagement that brings together different expertise. Structured studies and stakeholder input would help ensure that the PABS System is technically sound, legitimate, and implementable, and that it builds the trust needed for timely access to pathogen samples and SI as well as fair and equitable benefit-sharing.

LIST OF SPEAKERS

Speakers	Organization	Role
Suerie Moon	Co-Director, Global Health Centre, Professor of Practice in International Relations & Political Science, Geneva Graduate Institute	Welcome and Closing remarks
Daniela Morich	Senior Manager and Advisor, Geneva Graduate Institute	Moderator
Adam Strobeyko	Legal Advisor, Global Health Centre, Geneva Graduate Institute	Moderator
Gian Luca Burci	Senior Visiting Professor of International Law, Geneva Graduate Institute, and Academic Adviser, Global Health Centre	Speaker
Timothy Dallman	Senior Technical Officer, Emerging Pathogen Intelligence Platforms Unit, WHO Hub for Pandemic and Epidemic Intelligence	Speaker
Luisa Belloni	Project Officer (PIP Framework), World Health Organization	Speaker
Mark Eccleston-Turner	Senior Lecturer in Global Health Law, Department of Global Health and Social Medicine, King's College London	Speaker
Mphatso Martha Kalemba	Chief Environmental Officer, Environmental Affairs Department, Malawi	Speaker

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