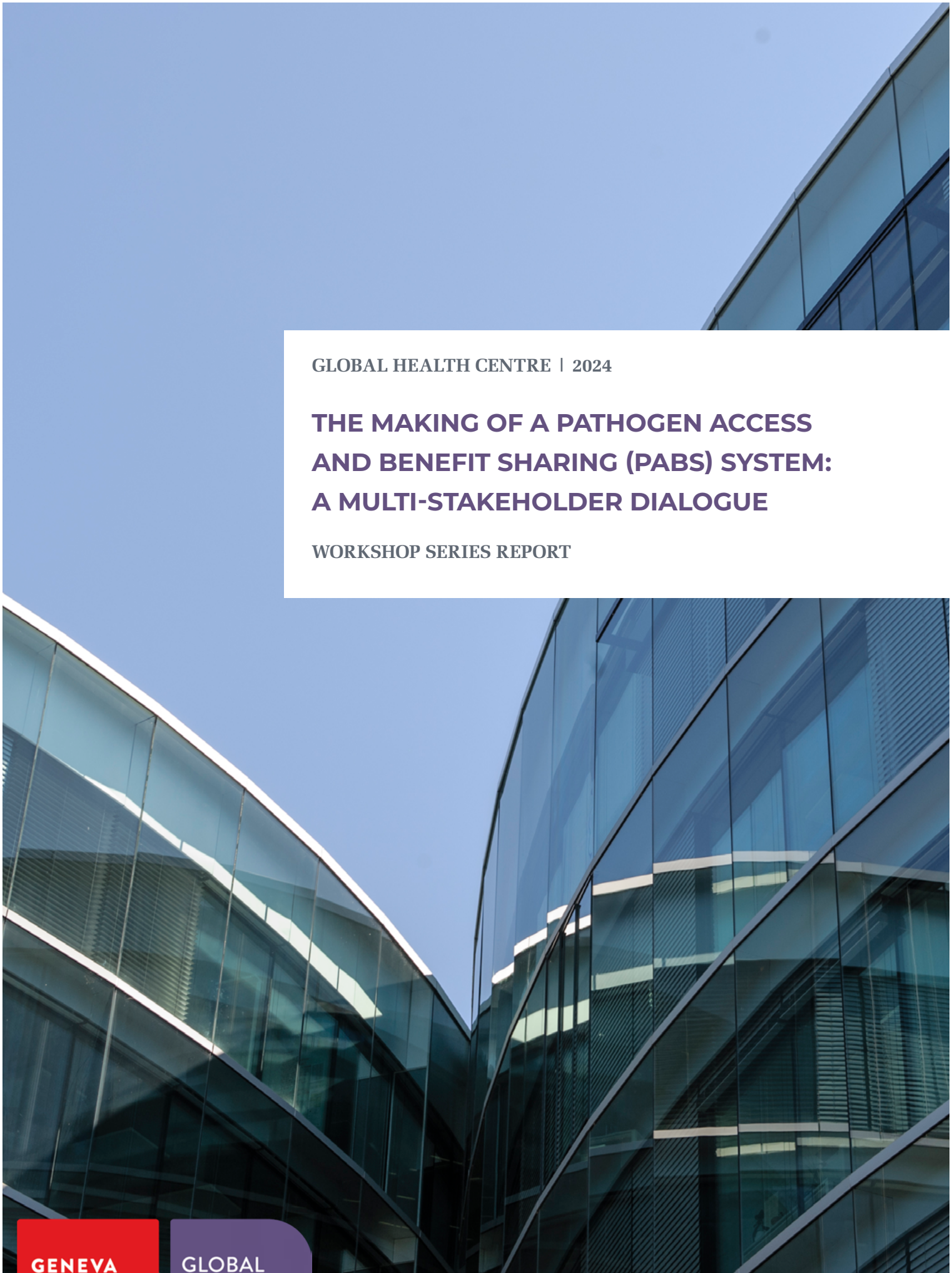

GLOBAL HEALTH CENTRE | 2024

# THE MAKING OF A PATHOGEN ACCESS AND BENEFIT SHARING (PABS) SYSTEM: A MULTI-STAKEHOLDER DIALOGUE

WORKSHOP SERIES REPORT

GENEVA GRADUATE INSTITUTE

GLOBAL HEALTH CENTRE

This publication was developed as the outcome of the workshop “The Making of a PABS System: A Multi-Stakeholder Dialogue” which took place on 14 February 2024 at the Geneva Graduate Institute.

**Co-convenors of the workshop**: International Geneva Global Health Platform, Global Health Centre at the Geneva Graduate Institute.

The first draft of this report was produced by ChatGPT based on a transcript of the workshop produced by Otter.ai. It was reviewed and lightly edited by Ava Greenup, Suerie Moon and Gian Luca Burci for clarity. All speakers were given the opportunity to comment on the accuracy of an earlier draft of this report. Changes were made in response to comments received and checked against the transcript. Speaker names have been anonymized in this report to facilitate open discussion during the workshop. The report does not necessarily represent the views of any affiliated or co-organizing entity or participant.


CONTACT

Global Health Centre

Maison de la paix
Chemin Eugène-Rigot 2A
Case Postale 1672
CH-1211 Genève 1

graduateinstitute.ch/globalhealth

globalhealth@graduateinstitute.ch

@GVAGrad_GHC

Global Health Centre

@globalhealthcentre

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# EXECUTIVE SUMMARY

The workshop “The Making of a PABS System: A Multi-Stakeholder Dialogue'' took place on 14 February 2024 at the Geneva Graduate Institute. The workshop sought to inform WHO Member States involved in discussions over a Pathogen Access and Benefit Sharing (PABS) system in the context of negotiations towards a Pandemic Agreement and amended International Health Regulations. The two workshop panels consisted of questions from the moderator to and short answers from speakers, followed by discussion and questions from the audience.

In the first panel, “Scope, Samples and GSD,” speakers tackled a range of topics including: the advantages and disadvantages of narrower versus broader scope of pathogens to be included in the system, how decisions should be made on which pathogens should be included, approaches to recognition and coordination of laboratory networks by WHO, defining what it means for a database to be considered "publicly available," ensuring adherence to benefit-sharing commitments, preventing free riding in the PABS system, revenue generation models for financing, and methods for detecting and enforcing breaches of obligations.

In the second panel, “Cross-Cutting Issues,” speakers discussed topics including: understanding relevant developments under the Convention on Biological Diversity, incentivizing private sector participation in the PABS system, implementing real-time supply obligations during pandemics, determining appropriate product set-asides, implications of prohibiting seeking IP rights on unmodified vs modified materials under the PABS System, and ensuring equitable benefit-sharing between and during pandemics.

The workshop closed with brief comments recognizing the challenges but also underscoring the importance of taking into account the range of complexities in designing a workable, equitable PABS system, and the potential utility of further discussion with experts, including those who had participated in the workshop.

# THE MAKING OF A PABS SYSTEM: A MULTI-STAKEHOLDER DIALOGUE

## INTRODUCTION

A multilateral PABS system remains one of the core issues in the negotiations towards a Pandemic Agreement (PA) and amendments to the International Health Regulations (IHR). This was underscored by the creation of a subgroup specifically focusing on facilitating informal consultations on Article 12 of the PA, chaired by Dr Viroj Tangcharoensathien of Thailand, and co-facilitated by Australia, Norway and Ethiopia.

A co-facilitator gave opening remarks summarizing the design elements of a PABS system prepared by the Chair and Co-Facilitators and circulated for discussion in the sub-group, and highlighting the necessity of input from all stakeholders for the development of an effective system. PABS represents a complex area under negotiation, and despite the considerable distance left to be covered, there is a shared commitment among member states to establish a system that strengthens pandemic prevention, preparedness, and response (PPPR) through expedited access to pathogens and associated genetic sequence data (GSD) and equitable access to related benefits. This consensus among stakeholders emphasizes the importance of ensuring that any proposed system aligns with the objectives of the Convention on Biological Diversity (CBD)[1] and the Nagoya Protocol.[2] To this end, proposals aim to ensure legal certainty, maximal participation, simplicity, practicality, and transparency.

The design elements of a PABS system delineate four key elements: coverage, access and benefit sharing, implementation, and governance. Coverage currently includes both biological materials and GSD, targeting pathogens with pandemic potential based on specified criteria. Access commitments include immediate sharing of GSD with WHO, sharing of biological materials with participating labs, and sharing of GSD with WHO-recommended databases. Access and benefit sharing mechanisms entail cooperative frameworks where all users of shared materials and data contribute to benefit sharing. Implementation and governance mechanisms are also under discussion, focusing on simultaneous operationalization of access and benefit sharing provisions and establishing legally binding contracts with manufacturers.

1 **CBD "Article 1. Objectives**. The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding." Available: https://www.cbd.int/convention/articles/default.shtml?a=cbd-01

2 **Nagoya Protocol "Article 1. Objectives**. The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components." Available: https://www.cbd.int/abs/text/articles?sec=abs-01

# PANEL 1 DISCUSSION: SCOPE, SAMPLE & GSD

The first panel was moderated by Professor Gian Luca Burci of the Global Health Centre, Geneva Graduate Institute. The moderator posed one question to each of a series of expert speakers, who were asked to provide concise responses. The below report summarizes the response of a specific speaker for each question. After the initial set of questions were posed, speakers were free to respond to each other orally or in the online chat. The interactions in the chat are also summarized here.

### 1. What are advantages and disadvantages to having a narrower vs broader scope of pathogen samples and data to be shared under the PABS?

The speaker advocated for a narrower scope, emphasizing the importance of focusing on pathogens with known pandemic potential, such as coronaviruses and influenza, which is covered under the Pandemic Influenza Preparedness (PIP) framework. A narrower scope would allow for the rapid development and timely access to diagnostics and countermeasures. Whilst acknowledging the potential value of including other pathogens, the speaker advised against broadening the scope to encompass other virus families based solely on virulence or the potential to cause human infection as this would incur substantial volumes of data and thus create a system that would be difficult to manage.

Secondly, the speaker underscored the critical role of GSD in the context of access and benefit sharing. Emphasis was placed on the crucial role of shared GSD in facilitating rapid diagnostics, vaccine development, and the assessment of antiviral drug efficacy. Access to shared viruses is deemed essential for the production of inactivated vaccines and the study of pathogen characteristics, including virulence.

Lastly, the interconnected nature of global health was highlighted, emphasizing the reliance that future public health measures will have on timely sharing of information. This will aid the global community to mitigate delays in access to countermeasures and avoid inequities that occurred during the COVID-19 pandemic.

### 2. Who decides which pathogens fall within the PABS system and how? What are the strengths and weaknesses of a centralized system?

The speaker emphasized the need for agreement on the definition of pathogens with pandemic potential and highlighted that Member States will have the opportunity to deliberate and select between a broader or narrower scope. The current definition being considered for pathogens with pandemic potential is *any pathogen that has been identified to infect a human and that is: novel (not yet characterized); or known (including a variant of a known pathogen), potentially highly transmissible and/or highly virulent and could cause a PHEIC*. Once a consensus is reached, the subsequent process would involve the identification of pathogens through national surveillance systems and detection mechanisms. Upon the detection of a human case, an assessment would be necessary to ascertain whether the pathogen in question is a novel entity or a variant of a known pathogen. This determination would serve to delineate whether the pathogen falls within the purview of the proposed access and benefit sharing system.

The PIP framework, which only applies to samples of influenza virus of pandemic potential, as a precedent for addressing other pathogens with pandemic potential was highlighted. Specific criteria for defining such pathogens were proposed. Advocating against an overly broad approach that could encompass the entire field of microbiology, emphasis was placed on the need for a targeted focus on pathogens with genuine pandemic potential. This approach would streamline efforts and resources towards effectively addressing the most significant public health threats.

### 3. How would WHO approach the recognition and/or coordination of laboratory or database networks?

WHO's engagement with experts and expert institutions can be addressed by relying on the existing Regulations for Study and Scientific Groups, Collaborating Institutions and Other Mechanisms of Collaboration, adopted by the Executive Board at its 69th session, according to the speaker. Those regulations offer flexibility in collaborating with individuals and institutions while safeguarding against conflicts of interest and prioritizing public health interests. Agreements with relevant institutions are crafted based on criteria and standards set by Member States.

Regarding the identification of pathogenic threats, the establishment of a scientific or expert advisory group was suggested. This group would navigate evolving technical and technological landscapes, including synthetic biology

### 4. What does 'publicly available' mean for databases? How can FAIR principles be made consistent with benefit-sharing?

In the context of access and benefit sharing of pathogens, the FAIR principles, which stands for Findable, Accessible, Interoperable, and Reusable were discussed. While making data Findable, Accessible, and Reusable are relatively simple concepts for non-specialists, the speaker highlighted that "Interoperable" is perhaps less intuitive.

Interoperability entails enabling machine-actionable movements and enhancing computational systems' capacity to find, access, interoperate, and reuse data with minimal human intervention. This is crucial due to the exponential growth of data sets in the big data fields, including the life sciences, making it challenging to manage and utilize information effectively.

Emphasis was placed on the significance of interoperability in facilitating seamless data exchange across thousands of databases and data types, enabling complex biological inquiries to be addressed effectively in an integrative manner.

Additionally, the significance of openly available databases, which play a pivotal role in facilitating research endeavors was highlighted. The speaker encouraged negotiators to look briefly at open databases in order to gain a better understanding of what openness and interoperability mean. Despite the substantial costs involved in maintaining these databases, the speaker emphasized that their accessibility is paramount for scientific advancement.

### 5. How can PABS be protected from free riders who benefit from the system but don't contribute to it?

One significant concern in the realm of pathogen access and benefit sharing is the issue of "free riders," referring to countries or entities that may not fully participate or contribute to international agreements and regulations while reaping their benefits. This poses challenges in negotiations, especially if key players fail to ratify the PA, potentially gaining an advantage without fulfilling their obligations.

To address this, the speaker emphasized that establishing a rules-based system is essential. Such a system should provide clear terms and conditions governing access to pathogen materials and sequence data, offering legal certainty and encouraging responsible sharing practices. The system could also mitigate free riding by imposing obligations on entities accessing materials or information, ensuring fair distribution of benefits.

Additionally, implementing verified user accounts and data access agreements can help monitor access to pathogen materials and sequence data, promoting transparency and accountability. Moreover, there may be a presumption that products developed in response to pandemic potential or health emergencies have been derived from the shared system, placing the burden of proof on accessing entities to ensure compliance.

Furthermore, regulatory authorities play a crucial role as checkpoints in the development and approval process of medical countermeasures, and could safeguard against free riding and ensure adherence to established regulations and standards.

### 6. How can breaches of obligations be detected and enforced?

The speaker emphasized that a crucial aspect of any system concerning access and benefit sharing of pathogens is the establishment of binding terms and conditions of use. These terms govern the sharing of materials with laboratories and other entities, ensuring compliance and accountability. Drawing from experiences like the PIP framework, where non-compliance can lead to suspension or removal of designation, it underscores the importance of such terms in fostering adherence.

Moreover, when sharing with entities outside laboratories, particularly with manufacturers, it is imperative to have binding terms and conditions to address concerns like hesitancy in sharing benefits. The WHO Secretariat's role in raising awareness and facilitating discussions, as seen in the PIP framework, demonstrates the significance of ensuring compliance with agreed obligations.

Regarding data sharing, principles of good governance such as user verification, data access agreements, transparency and accountability to WHO Members are paramount. These principles are aligned fostering an environment conducive to open science practices.

To ensure detection and compliance, it is crucial to design the system without gaps or loopholes, providing legal certainty and equal treatment to all parties involved. Member states' active involvement in detailing the terms and conditions adds confidence and motivation for compliance among material/data providers and users, according to the speaker.

### 7. How can effective revenue generation models be created to finance an ABS system? What are relevant experiences from other regimes, including in the UN Biodiversity Beyond Areas of National Jurisdiction Treaty (BBNJ)?

A critical aspect regarding revenue generation models for international instruments, gleaned from past experiences, is the necessity of adopting a diverse mix of approaches rather than relying solely on one method, according to the speaker. This lesson is evident from the FAO Plant Treaty's implementation, where the reliance on Member State contributions and anticipated revenue from commercial users proved inadequate. Recognizing this, different approaches were taken to accommodate these issues in the recent BBNJ Treaty, considering insights from the CBD COP 15.

The BBNJ Treaty could encompass various revenue generation options, including contributions from parties, milestone payments, a percentage of sales from commercial products, and a tier-based fee structure. Furthermore, provisions empower the competent authority to explore alternative revenue generation measures based on recommendations from the Access and Benefit Sharing Committee, enhancing future flexibility.

A crucial aspect of the October 2023 Pandemic Accord Negotiating Text lies in ensuring appropriate contributions from recipients of both physical material and genetic sequence data. While specifics remain ambiguous, leveraging standardized batch identifiers and linking them to standard terms and conditions could facilitate user awareness of their responsibilities.

Regarding Article 20 of the Negotiating Text, the speaker noted that the outlined measures appear promising, but there is room for greater flexibility in language. For instance, funds from recipients could be directed solely to a Capacity Development Fund, but allowing for broader flexibility might also be beneficial.

Lastly, drawing from lessons learned from the CBD, independent assessment and modeling of revenue generation options are crucial. This approach provides parties with an evidence-based foundation for decision-making, fosters trust, and mitigates the risk of adopting ineffective approaches, as witnessed with the FAO Plant Treaty.

Another speaker noted that a compilation of lessons learned from other ABS financing mechanisms had been produced for the CBD working group on DSI.[3]

## DISCUSSION, COMMENTS, QUESTIONS AND ANSWERS

The discussion highlighted the need for a targeted focus on pathogens with genuine pandemic potential to optimize resource allocation and incentives. Clarifying an earlier point, a speaker commented that broadening the scope to include many families of pathogens would increase the complexity greatly (more scientific groups, more pharmaceutical companies) and that would slow down the number of and process of agreements. Many pathogen families do not have animal reservoirs from which novel pathogens can be introduced into humans (pandemic potential). The urgency around sharing of organisms and data for pandemic pathogens would be diluted by increasing the complexity of the process and broadening to include pathogens that do not have known or likely pandemic potential.

In addition, the importance of strategic sequencing and clinical data linkage for effective surveillance and response was emphasized. Participants underscored the need to understand the impact of collected data on public health outcomes. While data sharing is essential, it must be accompanied by clear terms and conditions to avoid wastage of resources and ensure accountability.

Concerns were raised regarding the compatibility of open data principles with benefit sharing. A speaker suggested that open access to data can provide non-monetary benefits, such as research collaboration and knowledge dissemination, but it is not designed to require – and may not be capable of – providing for the sharing of monetary benefits or mandating equitable vaccine access. The fundamental dilemma is that open data allow for maximum scientific enquiry but allow for zero oversight. For a PABS system, finding a balance between data openness, which dominates the status quo in the life sciences and database ecosystem, and monetary benefit-sharing, which might need to constrain or distance itself from open models, is one of the most outstanding challenges.

Another speaker highlighted that access to pathogens and GSD currently does not translate into the pharmaceutical products needed by developing countries to address critical public health needs during emergencies, referring to the inequities that emerged during COVID-19. The discussion also touched upon the challenges posed by current database models, with some suggesting a need to reevaluate the transparency and accountability to WHO MS of existing systems.

3 Compilation of lessons learned from other international ABS funding mechanisms https://www.cbd.int/doc/c/81e4/aa04/71d526871fe0aa306f61ec50/wgdsi-01-inf-01-en.pdf

Regarding revenue generation, various models were proposed to fund the operational requirements of an international system, including micro-levies, subscription-based pricing, and royalty rates. While revenue generation is necessary, some argued that the primary focus should remain on improving access to and sharing of countermeasures, rather than solely generating revenue streams.

There was also an active discussion regarding whether access to data on current databases required or could reasonably implement user registration. Speakers noted that there was variation by database, with some databases requiring user registration and acceptance of a data access agreement that contained terms and conditions of use, while others did not. There could also be variation within a database, with user registration and acceptance of an agreement required for some types of data access (e.g. programmatic) but not others. Another key question concerned how user information might be shared by a database with a third party.

In addition, a question was raised about the legal feasibility of excluding digital sequence information (DSI) from a pathogen access and benefit-sharing (ABS) framework. One speaker emphasized that the CBD parties have agreed to establish a multilateral mechanism for benefit-sharing from DSI under the CBD COP15/9 decision.[4] Another emphasized the critical importance of sharing DSI/GSD for pandemic prevention and response, while another speaker argued that equitable benefit-sharing would not be feasible if GSD were to be excluded from a PABS system, as companies could produce countermeasures using historical material and access to data from new outbreaks.

A question was also raised on whether the 2021 UNESCO recommendation on open science[5] would be applicable to PABS and its possible impact. A speaker responded that the UNESCO recommendation represents the current international consensus on what open science is and the factors that need to be considered in sharing data, and therefore would be applicable. The speaker also flagged the OECD Recommendation on Enhancing Access to and Sharing of Data[6] as very useful on practical considerations and issues that need balancing when sharing data, and noted that both the UNESCO and OECD norms were referenced in the COP 15/9 decision.

Finally, a question was raised as to whether allowing open access to pathogen data could raise biosecurity or biosafety concerns. A speaker responded that data alone was not enough to generate a biosecurity threat, but would need to be coupled with other technologies to generate such a threat, but that the broader issue of biosecurity and biosafety remained an important challenge for policy. It was also noted that biosecurity and biosafety issues extended beyond pathogen data and are relevant to other types of biological data (e.g. cyanobacteria and fungi).

4 CBD.2022. Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity 15/9. Digital sequence information on genetic resources: https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf

5 UNESCO. 2021. Recommendation on Open Science. https://www.unesco.org/en/open-science/about

6 OECD. 2021. Recommendation of the Council on Enhancing Access to and Sharing of Data. https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0463

# PANEL 2 DISCUSSION: CROSS-CUTTING ISSUES

The second panel was moderated by Professor Suerie Moon of the Global Health Centre, Geneva Graduate Institute, and followed the same format as the first panel. Each speaker's response to the question is summarized below, as well as the discussion, including inputs from the chat.

**1. What developments are relevant for the health community to understand in the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources (WGDSI) under the CBD?**

A concise overview of recent developments regarding Decision 15/9 under the Convention on Biological Diversity (CBD) was provided. The decision's ambition was to ensure fair and equitable benefit-sharing from DSI on genetic resources, and established a new mechanism via the establishment of a multilateral system and a global fund.

Furthermore, key principles guiding this mechanism (para. 9), such as promoting research and innovation, ensuring open access to data, and respecting the rights of indigenous communities were highlighted. The ongoing process leading to COP 16, including the work of an open-ended working group and an advisory group comprised of diverse stakeholders was outlined. Discussion about forthcoming policy appraisals of revenue-generating mechanisms and lessons learned from other multilateral funding mechanisms was emphasized, underscoring the comprehensive approach that may be required to navigate the complexities of benefit-sharing in the context of pathogen access and benefit sharing.

Pathogens are in scope of the CBD and their DSI will require multilateral benefit-sharing under Decision 15/9 unless they are brought under the PABS system. All pathogens that are not under PABS will thus have their DSI benefits shared multilaterally under CBD.

**2. How can we effectively encourage private companies and institutions to participate in the PABS system? What strategies or incentives would be most feasible and effective in fostering active engagement and compliance with potential benefit-sharing obligations, including but not limited to legal certainty?**

In the context of enhancing surveillance and response mechanisms, the integration of diverse private funding sources and strategic collaboration are paramount objectives, according to the speaker. It is crucial to recognize that benefit sharing encompasses more than mere financial contributions, as access to essential supplies and technical expertise also play pivotal roles. Industry and the private sector can significantly bolster surveillance efforts through their agility and technical proficiency.

Unfortunately, the PIP framework has become the only known model of private sector engagement in surveillance strengthening and pandemic preparedness, but it is far from perfect. Moreover, challenges persist, particularly concerning the rigid nature of existing systems and the potential hurdles in expanding these frameworks to encompass diverse pathogens. Additional surveillance systems must be established to complement existing structures and facilitate seamless collaboration, particularly within the realm of public health.

Efforts to foster collaboration within the private sector and with established systems are instrumental in advancing surveillance capabilities. The pandemic accord offers a new opportunity for building healthy public private partnerships to leverage both catalytic funding and in-kind contributions. Emphasizing the importance of data accessibility and community-driven scientific collaboration, it is imperative to create inclusive environments that encourage knowledge sharing and mutual learning. This bottom-up approach can ensure the effective utilization of resources and fosters a culture of trust and cooperation among stakeholders.

**3. From the perspective of the pharmaceutical industry, how do you envision the implementation of real-time supply obligations in times of pandemic/PHEIC within a PABS system – e.g. the proposal to supply 20% of production in real time to WHO? What challenges and opportunities do you foresee in meeting these obligations?**

The speaker underscored the biopharmaceutical sector's commitment to making legally binding equitable access commitments, emphasizing readiness to implement pre- and during-pandemic measures, including real-time product allocation and equity-based tiered pricing. Acknowledging the necessity for flexibility in pandemic response frameworks to accommodate diverse epidemiological contexts and national capacities, the critical importance of rapid and unimpeded access to pathogens and genetic sequence data for effective pandemic response was highlighted. Citing past experiences, such as the swift response to the 2009 flu pandemic, facilitated by timely access to virus strains, the pivotal role of data sharing in pandemic mitigation was emphasized.

Key challenges include the need for regulatory agility, robust distribution networks, and secure supply chains to ensure effective pandemic response. Moreover, ensuring the availability of critical medications for existing indications amidst repurposing efforts was highlighted as a priority. This should include the development of simple, reasonable, and effective response mechanisms to prevent hindrances to research and development efforts.

There is potential for leveraging lessons from the COVID-19 pandemic to develop streamlined and effective response frameworks. Highlighting the industry's demonstrated commitment through swift private-public agreements during the pandemic, deeper engagement with industry stakeholders to incentivize their participation in equitable access agreements should be encouraged.

**4. How to determine appropriate product 'set-asides' that allow for flexibility based on actual needs and demands?**

Three key dimensions regarding the allocation of resources for pandemic prevention and response were outlined: the "What," "How much," and "When." Addressing the "What," it was asserted that specific resource allocation will depend on the nature of the emerging pathogen and its associated countermeasures. Regarding the "How much," allocating resources to two main groups was prioritized: the health workforce and other essential or high-risk populations, suggesting a minimum allocation of 10% for each group to ensure comprehensive coverage. In terms of the "When," emphasis was placed on the importance of real-time access to allocated resources to facilitate immediate deployment in affected populations, thereby minimizing transmission and mortality rates.

Furthermore, the critical role of GSD in PPPR was underscored by the speaker, emphasizing that GSD is indispensable for effective and systematic intervention strategies. An argument was put forward to include GSD in resource allocation plans, stating that it is fundamental to achieving the objectives of PPPR.

**5. What does it mean to prohibit seeking IP rights on unmodified vs modified materials and GSD provided under the PABS System? What are the pros and cons of each approach?**

The issue of data access and benefit sharing was discussed, drawing parallels with past initiatives such as the Human Genome Project, which had concerns regarding gene and sequence capacity and the safeguarding of free access to information derived from the project while also discouraging/preventing individual patent claims. The speaker made references to publications by the OECD and the US Patent and Trademark Office, highlighting these efforts to ensure free access to genetic sequence information while discouraging proprietary control. The HapMap project[7] was highlighted as it implemented click-through contracts to regulate access to sequence data and limit patent-seeking behavior.

Acknowledging the importance of rapid data access during health emergencies, concerns about proprietary restrictions hindering research and development efforts were expressed. A balance between open access to data and incentivizing private investment in product development was advocated for. Additionally, exploring collaborative financing models to support systems promoting open data access and commercial innovations was suggested.

**6. How does your company engage day-to-day in access and benefit-sharing? How do you ensure equitable benefit-sharing in your contractual agreements?**

The company is actively engaged in constructing a comprehensive database of natural biodiversity, aiming to facilitate protein discovery and provide sustainable solutions to the life science industry, according to the speaker. Central to this endeavor is their biodiversity program, which emphasizes access and benefit sharing associated with the samples collected and processed. Rights to samples are secured through research permits and biodiversity collaborations.

The approach varies depending on the legal framework of the countries involved. In regions where benefit sharing is not mandated, the company secures permits solely for access authorization. However, in countries where benefit sharing is obligatory, engagement in biodiversity collaborations ensures that the legal framework supports their commercial research activities.

The process involves assessing legal feasibility, identifying suitable partners for sample collection and processing, and obtaining prior informed consent from landowners and communities. All necessary authorizations and permissions are secured from competent national authorities.

The company offers various benefits to its partners, including provision of a DNA Mobile Research Laboratory, training, funding for research activities, support for proposed research priorities, assistance with publications and data sharing, and royalties on net revenues derived from samples.

Importantly, DSI is treated equivalently to physical genetic material, extending all benefits to DSI as well. A meticulous track and trace protocol is maintained for all samples and commercial outputs, ensuring transparency and accountability throughout their operations.

7 The International HapMap Project, by The International HapMap Consortium Nature 18 December 2003, volume 426, pages 789–796 (2003) https://www.nature.com/articles/nature02168

## DISCUSSION, COMMENTS, QUESTIONS AND ANSWERS

The discussion began by focusing on incentives and barriers to promoting research and development (R&D) using open data. Emphasis was placed on the widespread interest in information sharing for countermeasure development whilst also highlighting the existing incentives for privatizing knowledge and data. To address this, a proposal was made for the establishment of an open-source dividend system where commercial product developers contribute a proportion of revenues to those who openly shared the inputs. This approach could even extend beyond sequence data to include various shared resources such as manufacturing know-how. An example of how this could be implemented was referenced.[8]

Another speaker highlighted that research and development of countermeasures is largely paid for with public funds, and de-risked with large advance purchase agreements. A different speaker highlighted that R&D conducted by firms is largely paid for by those firms.

Another speaker argued that a multilateral PABS system would be in the interests of smaller R&D firms and help even the playing field with larger firms, as the smaller firms could access samples and data without lengthy negotiations with governments. It would also build the capacity of countries to gather samples, sequence data and analyze them, and cover some of the costs of doing so, contributing to surveillance and innovation.

The discussion then shifted to creating an environment conducive to incentivizing collaboration among diverse stakeholders. Emphasis was placed on the importance of strong surveillance systems for both public and private sectors, suggesting a model where immediate data access incurs a cost for industry but remains freely accessible for validated public health authorities. It was suggested that this model could balance industry's need for rapid access with the long-term public good.

Further discussions delved into the financing levels and operational scope of initiatives like the PIP framework. The need for incentives for both industry and provider countries was emphasized, stressing the importance of equitable benefit sharing, good governance to facilitate rapid data flow and the need to encourage industry and others to innovate.

Intellectual property (IP) considerations were also raised, with concerns expressed about the appropriation of shared research for patent claims. Prevalence of broad patent claims and the potential for creating patent thickets were highlighted, suggesting a need for closer examination of how IP will be handled in a PABS system.

The discussion concluded with reflections on the challenges of financing and incentivizing R&D, particularly in scenarios where only a fraction of projects reach the market. Risk-sharing models, such as those implemented by government incentives, were proposed as potential solutions to encourage private sector investment in R&D.

8 An example of how an open source dividend might be implemented at the national level was referenced in Section 11 of this US proposed legislation. https://www.congress.gov/bill/115th-congress/senate-bill/495/text

# CONCLUSION

The workshop closed with brief comments recognizing the challenges but also underscoring the importance of taking into account the range of complexities in designing a workable, equitable PABS system, and the potential utility of further discussion with experts, including those who had participated in the workshop.

# ANNEX

## ANNEX 1. SPEAKERS

| Speakers | Organization | Role |
|---|---|---|
| Suerie Moon | Geneva Graduate Institute | Moderator |
| Gian Luca Burci | Geneva Graduate Institute | Moderator |
| Charlotte Germain-Aubrey | Convention on Biological Diversity | Speaker |
| Amber Scholz | Leibniz Institute DSMZ | Speaker |
| Leif Christoffersen | Basecamp Research | Speaker |
| Cédric Mahé | Foundation for Influenza Epidemiology | Speaker |
| Nirmalya Syam | South Centre | Speaker |
| Sangeeta Shashikant | Third World Network | Speaker |
| Kanta Subbarao | The Peter Doherty Institute for Infection & Immunity | Speaker |
| Beverly Taylor | CSL Seqirus | Speaker |
| Paul Oldham | One World Analytics | Speaker |
| Anne Huvos<br>Steven Solomon | World Health Organization | Speaker |
| James Love | Knowledge Ecology International | Speaker |

GENEVA GRADUATE INSTITUTE

GLOBAL HEALTH CENTRE

Global Health Centre
Maison de la paix
Chemin Eugène-Rigot 2A
Case Postale 1672
CH-1211 Genève 1
graduateinstitute.ch/globalhealth

globalhealth@graduateinstitute.ch
@GVAGrad_GHC
Global Health Centre
@globalhealthcentre