

NOVEMBER 2023

GLOBAL PANDEMIC AGREEMENT: WHO COLLABORATING CENTER SUPPORT  
FOR NEW EQUITY AND COORDINATING MECHANISMS

# EMERGENCY COUNTERMEASURE DEVELOPMENT AND DEPLOYMENT

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The O'Neill Institute for National and Global Health Law (O'Neill Institute) was established in 2007 through the generous philanthropy of Linda and Timothy O'Neill to respond to the need for innovative solutions to the most pressing global health concerns. In bringing together experts from both the public health and legal fields, the O'Neill Institute reflects the importance of public and private law in health policy analysis. Housed at Georgetown University Law Center in Washington, D.C., the O'Neill Institute draws upon Georgetown's considerable intellectual resources, and believes that the law is a fundamental tool for solving critical health problems. The O'Neill Institute sees national and global health law as a frontier for collaborative, international, and rights-based approaches to health and well-being for all.

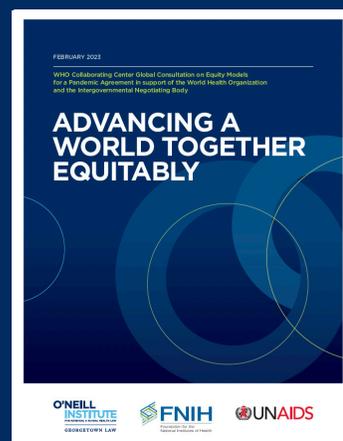
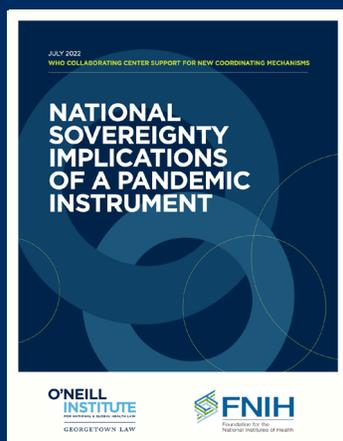
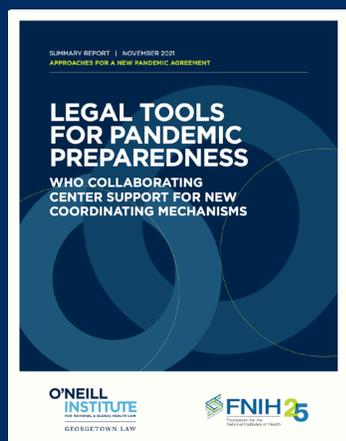
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The Foundation for the National Institutes of Health (FNIH) builds public-private partnerships that connect leading biomedical scientists at the US National Institutes of Health (NIH), life sciences companies, foundations, academia, and regulatory agencies. Through team science, we solve complex health challenges and accelerate breakthroughs for patients, regardless of who they are or what health challenges they face. The FNIH accelerates new therapies, diagnostics, and potential cures; advances global health and equity in care; and celebrates and helps train the next generation of scientists. Established by the US Congress in 1990 to support the mission of the NIH, the FNIH is a not-for-profit 501(c)(3) charitable organisation.

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The University of Cape Town (UCT) is a public research university in Cape Town, South Africa. Established in 1829 as the South African College, it was granted full university status in 1918, making it the oldest university in South Africa and the oldest university in Sub-Saharan Africa in continuous operation. UCT is organised in 57 departments across six faculties offering bachelor's to doctoral degrees. UCT's vision is to be an inclusive, research-intensive African university that addresses the challenges of our time with cutting-edge teaching, research and facilities. As a university we are committed to promoting transformation, to working tirelessly to guarantee the sustainability of our institution, and to ensuring excellence in all we do.

## PREVIOUS O'NEILL-FNIH WHO COLLABORATING CENTER REPORTS



# ABOUT THIS DOCUMENT

**The O’Neill Institute for National and Global Health Law** (O’Neill Institute), a WHO Collaborating Center, in partnership with the **Foundation for the National Institutes of Health** (FNIH) and the **University of Cape Town** (UCT) in an effort to support the World Health Assembly and the Intergovernmental Negotiating Body, convened leading authorities on the development and deployment of emergency countermeasures, namely vaccines, diagnostics, and treatments. These experts, representing every WHO region in disciplines as diverse as global health, law, human rights, biomedical science, financial services, civil society, intellectual property, the life sciences industry, clinical trial design, government, retail health, patient advocacy, the environment, academia, and health equity, collaborated to inform the WHO, policymakers, Member States, and the public as the agreement is negotiated. The list of contributors is provided as Annex 1. The list of our guiding questions is provided as Annex 2.

This report summarises the major themes that arose across the convening for use by policymakers and the international community as they consider how to move forward. The organisers have also incorporated additional context, content from literature that experts submitted along with their follow-on reflections after the convening, case studies that illustrate points made during the meeting, and additional options for the pandemic agreement based on the text the INB released after the convening.

**This summary report is not meant as a consensus document**, but as a compilation of the ideas and diverse perspectives offered by experts who are participating in their individual capacity, not as representatives of their respective organisations. Presenting the landscape of views is intentional and no expert is expected to endorse every single point contained in the report. In fact, it is likely that every expert will disagree with various assertions incorporated herein. Moreover, language included in this document does not imply institutional endorsement by the organisations that participants represent.

All sessions proceeded under Chatham House rules. The O’Neill Institute, the FNIH, and UCT facilitated the discussions. Portions of the project were funded by grants from the FNIH’s Pandemic Relief Fund and the Notkins Biomedical Research Fund through support to the Foundation for the National Institutes of Health. For the avoidance of doubt, this summary does not necessarily reflect the views or positions of the participants, their institutions, the O’Neill Institute, the FNIH, or UCT.

The organisers express their deep gratitude to the experts who provided their insights and advice to this convening, especially so given a short timeline to be responsive to the INB discussion. Each has performed a public service and feels deeply about creating a future where the highest attainable level of health can be realised for all.

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# INTRODUCTION

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**“Accelerating availability of effective, safe, quality medical countermeasures is essential in a public health emergency to save lives and reduce disease spread and severity...[and it is important] to explore and implement expedited pathways to ensure availability of such medical countermeasures in the market.”**

ROLAND ALEXANDER DRIECE, PRECIOUS MATSOSO, et al., *The Lancet*, 29 April 2023.<sup>1</sup>

The need for a “whole-of-government and whole-of-society approach, prioritizing the need for equity” to combat future pandemics was the impetus for establishing an Intergovernmental Negotiating Body (INB) to draft and negotiate a pandemic agreement.<sup>2</sup> A key component of this holistic approach is “greatly enhancing international cooperation to improve, for example, alert systems, data-sharing, research, and local, regional and global production and distribution of medical and public health counter measures, such as vaccines, medicines, diagnostics and personal protective equipment.”<sup>3</sup> While some countermeasures work across many threats, novel pathogens often require new tools. And once developed, these tools must be deployed across the globe to every community, equitably and in a timely way, with particular attention to the most vulnerable everywhere. Speed is crucial, and the COVID-19 pandemic demonstrated the potential for rapid innovation with enough coordination, financing, and know-how. However, shortcomings in preparing for countermeasure development and the subsequent gross inequities in the availability and allocation of them in developing countries has necessitated fresh thinking. As articulated by Africa CDC Director General Jean Kaseya, there is “a collective need to fortify health security and adaptability, extending beyond respective national boundaries.”<sup>4</sup>

Designing effective pandemic preparedness and response governance instruments requires a deeper understanding of what it takes to equitably research, design, manufacture, and deliver countermeasures against novel threats, how other international regimes reinforce or undermine their research and development, availability, and optimal use for public health, and how to widen and accelerate their access, affordability, and uptake. These issues are interconnected, and a breakthrough in the current negotiations could significantly improve pandemic outcomes.

To that end, the O’Neill Institute for National and Global Health Law at Georgetown University, a WHO Collaborating Center, in partnership with the Foundation for the National Institutes of Health and the University of Cape Town, convened an expert group on 2-3 October 2023 representing every WHO region in disciplines as diverse as global health, law, human rights, biomedical science, financial services, civil society, intellectual property, the life sciences industry, clinical trial design, government, retail health, patient advocacy, the environment, academia, and health equity to identify best practices in innovating and delivering technologies and to explore practical ways to balance private incentives for needed research and development with greater accessibility for the most vulnerable. This report captures the reflections and contributions of these global experts and builds upon many of the themes identified in previous O’Neill Institute-FNIH convenings, particularly *Advancing a World Together Equitably: WHO Collaborating Center Global Consultation on Equity Models for a Pandemic Agreement in Support of the World Health Organization and the Intergovernmental Negotiating Body*, which was co-convened with UNAIDS early in 2023.<sup>5</sup>

The 2 June 2023 draft of the accord<sup>6</sup> was the latest text available at the time of the convening. The INB released a negotiating text to Member States on 16 October 2023 and to the public on 30 October 2023.<sup>7</sup> This report generally quotes from the 30 October text.

## SECTION 1

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# COUNTERMEASURE DEVELOPMENT: LEARNINGS FROM CASE STUDIES

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**EXISTING MODELS SERVE AS BOTH FOUNDATIONAL PIECES AND POINTS OF REFLECTION** for the research and development of future countermeasures and the potential for improving quality, access, availability, affordability, and uptake. The successes and shortcomings of the models presented to the meeting provided a means to consider why they did or did not work, how their successful elements could be scaled and enhanced, or how their shortcomings could be mitigated.

## Countermeasure Development in the Current Draft of the Pandemic Agreement

Before reviewing the case studies, it is useful to review the critical places in the negotiating text that address countermeasure development. Article 4 requires State Parties to “develop, strengthen and maintain capacity to carry out integrated public health surveillance, including in respect of infectious diseases in humans, and animals that present significant risks of zoonotic diseases spill-over.”<sup>8</sup> Article 9 would, among other things, commit State Parties to build and sustain research and development (R&D) institutions, particularly in low- and lower-middle income countries (LMICs); promote collaboration, open science, and sustained R&D investment for pandemic products; encourage participation of relevant stakeholders including through knowledge translation and evidence-based communication tools; promote public dissemination of government-funded R&D (and the terms of such funding); and encourage further joint technology ventures and the inclusion of relevant stakeholders.<sup>9</sup>

Relatedly, Article 11 addresses the transfer of technology and know-how to facilitate the production of pandemic-related products. Working through the Conference of the Parties (COP) – the forum for governance that would be created for State Parties to implement the treaty and monitor its compliance—countries would push for technology transfer and know-how through several mechanisms, including the use of waivers of intellectual property protections.<sup>10</sup>

Article 13 would establish a WHO Global Supply Chain and Logistics Network (SCL Network) to estimate the most likely types and amounts of required pandemic products, assess demand for and source raw materials, maintain a dashboard of manufacturers and suppliers, identify purchasing mechanisms and require transparency on terms between manufacturers and governments, maintain countermeasure stockpiles, and facilitate the purchasing and delivery of products.<sup>11</sup> The COP would be charged with developing the “guidelines on modalities and collaboration”<sup>12</sup> and “undertak[ing] the foregoing no later than 31 May 2025.”<sup>13</sup>

## Case Models

### COVAX

COVAX—the vaccine arm of the Access to COVID-19 Tools (ACT) Accelerator—was perhaps the most prominent development and deployment COVID-19 era model on the international stage. Co-led by the Coalition for Epidemic Preparedness Innovations (CEPI); Gavi, the Vaccine Alliance; and the WHO in partnership with UNICEF and the Pan-American Health Organization (PAHO) Revolving Fund, COVAX was created to “accelerate the development and manufacture of COVID-19 vaccines and to guarantee fair and equitable access for every country in the world.”<sup>14</sup> As of August 2023, nearly 2 billion vaccine doses had been allocated and shipped via the programme.<sup>15</sup> However, it fell short in its objective to deliver that quantity by the end of 2021.<sup>16</sup> It suffered supply constraints early on in the pandemic due to low financial headroom and liquidity: it took several months to mobilise financial pledges for COVAX, and then only US\$ 400 million of the US\$ 2.4 billion pledged in 2020 was paid by the end of that year. Meanwhile, high-income countries were able to swiftly purchase the earliest-available supply and used superior liquidity and risk-tolerance to rapidly secure a more diversified portfolio. Later, COVAX’s first procurement partner was temporarily prohibited from exporting vaccines to address domestic need.

In view of this, Gavi worked closely with development finance institutions to develop a suite of innovative financing tools to improve COVAX’s financial flexibility. Examples include the European Investment Bank’s (EIB) Frontloading Facility and the US Development Finance Corporation’s (DFC) Rapid Financing Facility, which together had provided frontloading capacity of US \$2 billion of liquidity by May 2022.<sup>17</sup>

Early in the pandemic, the partners who came together to create the ACT Accelerator needed to rapidly consider what countermeasures could be required, particularly in lower-resource settings. Immediate decisions then needed to be made regarding funding and funding sources, the volume of vaccines required, and locating manufacturing capacity, each of these elements had to be determined with great specificity.

COVAX was cited as an example of a proactive approach to development and contracting arrangements. It was further observed that open science and public-private collaboration were key components. Some experts noted that while the COVAX model remained viable, similar regimes would need to be sufficiently financed by “Day Zero” of the next pandemic so they are prepared to enter into supply agreements sooner. Others would have preferred that WHO Member States and civil society organisations had a larger role in COVAX and for decision-making to have been more transparent. They noted that countries that signed up to procurement through COVAX could also undermine its bargaining power and scoop up early supply by entering into bilateral purchasing agreements with manufacturers. The terms of its procurement contracts, pricing terms, and timelines for delivery remained mostly unknown as well.<sup>18</sup>

### ROLL BACK MALARIA PARTNERSHIP

The Roll Back Malaria (RBM) Partnership is “the largest global platform for coordinated action towards a world free from malaria. It is comprised of over 500 partners from community health worker groups and researchers developing new tools, to malaria-affected and donor countries, businesses, and international organisations.”<sup>19</sup> The WHO has recognised RBM as having “made an important contribution” to the Millennium Development Goal concerning malaria by “helping forge consensus between partners, mobilising resources, and catalysing action.”<sup>20</sup>

RBM's Surveillance, Monitoring, and Evaluation Working Group is chartered to seek alignment and share best practices among the many partners engaged in disease surveillance. As a recent achievement, over the past two years, the Working Group has developed and refined 16 data dashboards that all the partners use to track factors affecting surveillance activities and capabilities, including funding gaps, supply chains, technical support, and weather forecasts. Having a common source of widely available information permits discussions to move from fact finding to taking action to track and address disease burden.

## PRODUCT DEVELOPMENT PARTNERSHIPS—DNDi, UNITAID, CIPLA

A product development partnership (PDP) is a form of public-private partnership where public sector and philanthropic financing are pooled with academic and industry know-how to incentivise the research and development of therapies for neglected diseases.<sup>21</sup> One such PDP between the Drugs for Neglected Diseases initiative (DNDi), a “not-for-profit research organization developing new treatments for neglected patients,”<sup>22</sup> Unitaid, a WHO-hosted institution that “saves lives by making new health products available and affordable for people in low- and middle-income countries,”<sup>23</sup> and Cipla, a publicly listed life sciences company, resulted in the development of a 4-in-1 paediatric antiretroviral treatment for HIV that recently achieved regulatory approval in South Africa, Mali, Uganda, and Kenya.<sup>24</sup> The treatment will not require refrigeration, is better tasting than older paediatric treatments, and will cost less than US \$1 per day.<sup>25</sup>



A group of nurses deliver COVID-19 vaccines to local vaccination points in the Sundarbans, India.

Credit: Gavi/2022/Benedikt v.Loebell

It was noted that a model such as this—one that focuses on a specific product and establishes a multistakeholder strategy to develop it—can yield important and affordable new health technologies in the short or medium terms. Further, building PDPs at scale could provide a reliable and durable avenue to broaden the benefits of innovation that is not dependent on donors or external aid.

## **INSTITUT PASTEUR'S BIOLOGICAL RESOURCE CENTER**

Researchers require pathogenic samples and their genetic sequences to be able to kick-start development of a vaccine or medicine. Biobank networks, such as the one managed at the Institut Pasteur's Biological Resource Center (CRBIP), facilitate collection, storage, and distribution of biological material, including pathogenic specimens. CRBIP states that it will “accept deposits of microbiological materials, lyophilize (i.e. freeze-dry) strains; receive and process human fluid biological materials; characterize the biological materials phenotypically (by physical characteristic), genotypically (according to the unique characteristics of their DNA); and functionally; preserve and distribute microbial and human bioresources; and offer training and expertise.”<sup>26</sup> The research institution requesting samples must generally negotiate a materials transfer agreement (MTA), which governs the conditions under which the biobank will provide the material and the obligations of the receiving institution. MTA requirements can vary widely from biobank to biobank and transaction to transaction and do not consistently address ownership and intellectual property rights comprehensively. This can draw out negotiations and create uncertainty as to whether once a countermeasure is created, there will be a right to deploy it.<sup>27</sup> It was also noted that such restrictions try to balance the speed of innovation with the rights of those that originally provided the material.

## **CORBEVAX**

Corbevax is a subunit vaccine designed at Texas Children's Hospital Center for Vaccine Development and the Baylor College of Medicine in the United States that has been administered in India and Botswana to protect against COVID-19. Motivated by equity considerations, the inventors elected not to pursue a patent on the product so that it could be distributed at reduced cost in lower-resource settings.<sup>28</sup> It was noted that academic institutions, which are often the source of early innovation and are often non-profit entities, could play a larger role in ensuring access through the terms they negotiate for the licensing of their technology, such as requiring access for low-income populations.

## **WHO/MEDICINES PATENT POOL mRNA TECHNOLOGY TRANSFER PROGRAMME**

The WHO/Medicines Patent Pool (MPP) mRNA Technology Transfer Programme is a consortium involving the South African Medical Research Council and life sciences companies Afrigen and Biovac to “build manufacturing capacity in LMICs to produce mRNA vaccines, in an effort to improve health security in LMICs through local and/or regional production of mRNA COVID-19 vaccines, as a primary target.”<sup>29</sup> Afrigen and Biovac had attempted to obtain licenses to pre-existing technology to develop a COVID-19 vaccine but were unable to timely innovate, scale, and distribute a new product at a cost-effective price because the licenses were denied. Ultimately, the WHO/MPP Programme aims to boost local development and manufacturing capacity for mRNA vaccines and other countermeasures, introduce new technologies in the region, improve regulatory capacity, and develop a local workforce. It intends to share the platform with 15 partners in middle-income countries to enable them to produce mRNA technologies and develop a pipeline for other disease targets.

## ADVANCE MARKET COMMITMENT

Relatedly, an Advance Market Commitment (AMC) to support market entry for vaccine manufacturers in Africa is under development.<sup>30</sup> Pioneered by Gavi, an AMC aims to create incentives for life sciences companies to develop and manufacture vaccines through an agreement with Gavi to purchase large quantities at an established price. In return, the company agrees to provide later doses reliably and at a sustainably affordable price. Gavi has created previous AMCs for pneumococcal and COVID-19 vaccines, and it envisions the new AMC as a vehicle that would enable an emerging industry in Africa to overcome otherwise unassailable start-up costs and build trust in their new products. Its designers hope that it can establish a sustainable, regionally diversified supplier base with minimised undesired market distortions, improving pandemic response capacity, supply resilience, and security sovereignty.

## THE BIOMARKERS CONSORTIUM

The Biomarkers Consortium, which is managed by the FNIH, “convenes government, industry, patients and patient advocacy groups, and not-for-profit organizations to address ... the development and the seeking of regulatory approval for disease biomarkers and surrogates.”<sup>31</sup> A biomarker—such as blood pressure—is a measurable characteristic of the body that is an indicator of a disease or condition and helps to identify viable new therapies. The Consortium is a membership organisation that seeks broad stakeholder input and is inclusive in its governance. Its members agree to its “General Intellectual Property and Data Sharing Principles”, which highlights that the Consortium is designed to “promote discovery,” “speed” research, and “make research results and data” coming from its activities “broadly available.”

## ZIKA OUTBREAK RESPONSE

The importance of interagency coordination and timely pandemic declarations in order to spur countermeasure development was highlighted through a review of the US Government’s response to the Zika outbreak. Early in the crisis, the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Biomedical Advanced Research and Development Authority (BARDA), Department of Defense, and others set up internal response units who then liaised with one another via the Executive Office of the President. It was observed that this helped with role allocation and ultimately improved decision-making, including to acknowledge as a matter of law that a pandemic was in progress. This triggered access to legislatively authorised emergency funding, reinforced to the agencies that the crisis was a priority, and permitted the FDA to use an expedited authorisation process for pandemic countermeasures.

It was pointed out that it took time to generate political consensus to ensure an appropriation to fully support this effort,<sup>32</sup> and an expert highlighted that this had forced the US Department of Health and Human Services to reallocate funding from other important efforts, such as Ebola,<sup>33</sup> thus removing incentives for countermeasure producers to continue work on these measures in the context of a market failure. It was further noted that short-term investment and reallocation of funding is not uncommon, and is exacerbated when political attention wanes, increasing the risks for those that invested and putting preparedness at risk.

## LIMITATIONS

Some experts note that most of the models discussed address countermeasure development through *ad hoc* instruments and urged a more fundamental rethinking of how global health equity can be achieved. For example, some mechanisms, such as the MPP, are voluntary, rely

on goodwill, and do not address underlying inequities.<sup>34</sup> These experts highlighted that the right to enjoy the benefits of scientific progress gives citizens a legitimate expectation that their governments will establish policy frameworks aimed at developing scientific capacity for health and disseminating the outcomes of scientific research. Adopting a human rights framing, scientific progress accrues to the benefit of the many and not the few and requires that essential drugs are made accessible to all. They further noted that since equality is at the core of human rights, countries must redress substantive inequality and unequal access to the right to enjoy the benefits of scientific progress.<sup>35</sup> Alternative models, it is therefore argued, must be able to demonstrate that they ensure public goods are protected for public benefit, that private interests do not ultimately determine what is needed for public health, and that there is a verifiable way to hold actors accountable.

## Options for Countermeasure Innovation in the Pandemic Accord

As the convening participants discussed the merits and weaknesses of existing models and the possibilities and imperatives for future approaches, it was observed that many issues are multifaceted, and policymakers have to be mindful of potential trade-offs. For example, how can scientific expertise be broadly shared while promoting personal privacy? How do governments craft and maintain fit-for-purpose regulatory regimes that can cope with crisis timelines while only permitting safe and effective products to make it through to licensure? How can continuous biopharmaceutical and medical device R&D be incentivised in the face of immense uncertainty about whether, when, and in what quantities medical countermeasures



**A healthcare worker administers a COVID-19 vaccination in a government vaccination centre in Islamabad, Pakistan.**

Credit: Gavi/2021/Asad Zaidi

might be needed? What is the right global manufacturing capacity to ensure that it can be appropriately sized outside of health emergencies and surged during them? How can markets and rules-based regimes be enhanced to address these uncertainties? How can local communities be mobilised and empowered while promoting global coordination and solidarity? Equity continues to be the central consideration, and it was broadly noted that new, more innovative models will be needed to improve outcomes during the next pandemic.

## DECENTRALISING DEVELOPMENT CAPABILITIES

Many participants highlighted the urgency of building regional and national capacities in LMICs for R&D, clinical trials, regulatory infrastructure, technical expertise, surveillance, manufacturing, and distribution, alongside continuing efforts to strengthen overall health systems capacities,<sup>36</sup> including via routine immunisation programmes as an efficient and cost-effective health intervention.

R&D capacities are nascent in lower-income countries, and the surge in need for vaccine manufacturing capacity during the COVID-19 pandemic, it was argued, demonstrated the limitations of the global countermeasures manufacturing infrastructure, particularly in light of export restrictions put in place by some countries where large-scale manufacturing is sited. It was noted that, while a few regional organisations, such as the ASEAN Centre for Public Health Emergencies and Emerging Diseases (ACPHEED), have been founded to enhance “preparedness, detection, response and resilience to public health emergencies,”<sup>37</sup> they are thus far underfunded and functionally limited. They must have the scope, mandate, and capital to drive impact and not devolve into a front for political expediency. Investment in these institutions, and how the pandemic agreement can facilitate those investments, is something that could be considered.

Some experts argued that any new manufacturing framework should adopt an end-to-end approach with equity at its centre and be designed with a collective governance and public health purpose. Some stakeholders have called for regional manufacturing hubs that are built on open science principles and implement equity in R&D, reducing reliance of LMICs on donations.<sup>38</sup> How these mechanisms may impact future medical countermeasure innovation is critical to assess.

It was also suggested that smaller outbreaks could be more effectively addressed with improved fit-for-purpose regional capacities. For example, regional and/or national pandemic surveillance centres could be tasked with watching for signals of a pandemic and transmitting critical information to the government agencies, civil society organisations, research institutions, and others involved in countermeasure development. Platform technologies to address a variety of pathogenic threats and create locally relevant vaccines is another potential investment area, particularly since new, built-from-scratch inventions to address every local outbreak may be cumbersome. Experts highlighted that regional manufacturing capacity could be built on the basis of existing novel technologies for countermeasures, such as mRNA technology, which is becoming increasingly valuable since it can be rapidly adapted to new variants and is easy to scale.<sup>39</sup> However, the capabilities of these new platforms to address all potential infectious disease threats has not been tested or established.

Financing for health systems strengthening is also critical and mentioned in Article 20(1)(b) but is only required in line with national fiscal capacities, meaning that countries with debt burdens will not have the capabilities to realise this imperative. Given this, it was noted that development financing institutions and donor governments will need to play a major role in providing critical financial support. And while it is inferred, to whom data from surveillance centres is transmitted and how it is interpreted in a common form could be outlined more lucidly.

## SUPPLY CHAINS

It was observed that innovations are only as strong as the supply chains that produce and deliver them, and substantial space is given in the current agreement to supply chain and logistics (Article 13). There were experts who noted that strong regional supply chains, including distribution systems for the last mile, will be essential to ensure equitable access to countermeasures because the flow of goods across borders may be interrupted in a crisis. It was also mentioned that there is a risk of over-investing in capacity that will sit idle between pandemics. Article 13 contains a lot of potential activities and how they are operationalised will have as much to do with its contribution to improved preparedness and response as the activities that are included. Collaborating with UNICEF Supply Division, Gavi, and similarly experienced institutions is essential to avoid overlap and learn from past experience.

It was also observed that medical countermeasures have highly complex and variable input supply chains, which are often bespoke to the product and manufacturing process. Some participants noted that it would be extremely difficult if not impossible, for a central global body to control or even coordinate supply chains for countermeasures, and by doing so would likely increase production time and decrease volume. The negotiating text states that the SCL Network “will operate within the framework of WHO, in partnership and collaboration with relevant international, regional and other organizations,”<sup>40</sup> and it was suggested by some stakeholders that the World Trade Organization (WTO) has a leadership role to facilitate discussion and negotiation to ensure the rapid, free flow of unfinished and finished goods and materials across the globe.

## MANAGING MISINFORMATION

While global availability and affordability of countermeasures proved to be major barriers to equity during COVID-19, there was also a problem with public acceptance of them, especially vaccines. With misinformation and disinformation rampant and likely to remain a problem in future pandemics, it was observed that clear, consistent communication with the public is essential to ensure uptake of the countermeasures that are so painstakingly developed. It was further noted that it is important for public officials to maintain their credibility with timely and state-of-the-art communications with the public and among each other. Article 18 on “Communication and Public Awareness” contemplates “strengthen[ing] science, public health and pandemic literacy in the population,” combating misinformation, conducting research on how to improve trust in science and adherence to pandemic measures, and “promot[ing] and apply[ing] a science- and evidence-informed approach to effective and timely risk assessment and public communication.”<sup>41</sup>

The June draft contained provisions concerning community engagement, outreach, and social listening<sup>42</sup> that were omitted from this article in the October text. Some experts expressed that such engagement at the local level is critical. In many societies, people are far more trusting of their face-to-face relationships than they are of remote and faceless institutions.

## COOPERATION

A major throughline of the models presented was that countermeasure development and deployment is a team activity, and that end-to-end partnerships that include and align around a well-defined public health goal enhance their chances of improved outcomes.

Article 16 gives voice to this notion, for example by requiring State Parties to, among other things, “promote global, regional and national political commitment, coordination and leadership,” “collaborate and cooperate with competent international and regional intergovernmental organizations and other bodies,” “promote equitable representation on the basis of gender, geographical and socioeconomic status, as well as the equal and meaningful participation of young people and women,” “implement policies that respect, protect and fulfil the human rights of all people,” and “assist developing countries through multilateral and bilateral partnerships that focus on developing capacities for effectively addressing health needs” for pandemic prevention, preparedness, and response (PPPR) in line with the agreement’s requirements concerning implementation capacities and support.<sup>43</sup> Some observed that there is an orientation towards multi- and bilateral assistance aimed at strengthening pandemic-related health security infrastructure, and the agreement could instead address the challenges that countries face with maintaining functional health systems in between pandemics.

Article 17 requires countries to “promote collaboration with relevant stakeholders, including the private sector and civil society.”<sup>44</sup> In particular, partnering with community-based organisations and women’s groups in remote areas can facilitate trust because global nongovernmental organisations may have limited geographic and community reach. Similarly, the development of countermeasures must consider the needs of the affected communities. For example, it was noted that, in the midst of a pandemic, human beings continue to cope with pre-existing health challenges, and so new approaches to innovation need to be built holistically. Facilitating models that empower and engage affected communities is one way the accord could spur innovation while promoting equity.



**Members of the NIH All of Us Research Program, in their efforts to build a diverse health database to accelerate research, collect a blood sample from a participant.**

Credit: All of Us Research Program/US NIH

There was a meaningful difference of opinion among the convenors about the role of the private sector. Some believe its participation is vital and that improved pandemic response must include it as an essential partner. Others are much more hesitant, finding the profit maximisation incentive to be a barrier that should place it at arm's length. One expert suggested that specific actions to build better understanding and cooperation between manufacturers and other public health and pandemic response actors is warranted. It was suggested that the legal and economic pressures commercial organisations face, and their resulting degrees of freedom, may not be well understood, and that opportunities for dialogue and engagement could improve alignment in pandemic response objectives. It was also noted that unless and until the public sector can fully fund biopharmaceutical and diagnostics R&D; own, operate, and maintain the means of production for all medical countermeasures globally; and distribute them to every corner of the globe, the private sector must be a central actor in this enterprise. Some stakeholders indicated that the best approach is that of an ecosystem wherein there is active collaboration between the public, private, and academic spheres, where the private sector should be a critical partner and actively participate.

The principles in the negotiating text are important aspirational commitments, but some observed they lack specificity in the actions they require or how to measure when a country has successfully fulfilled their duties under them. To be sure, too much specificity could make the agreement inflexible or result in an instrument that needs constant updating.<sup>45</sup> But it could provide for a mechanism that would permit countries to align from time to time the targets that would signal progress towards solidarity, equity, transparency, and responsiveness while accounting for their different capabilities.

The agreement could also incentivise governments to consider legislative action to improve the innovation environment. For example, many regulatory regimes are built for “peacetime” but buckle under the weight of their own administration during a pandemic event or lack mechanisms for the review and approval of new products under emergency circumstances. As will be reviewed in the *Clinical Trials* section, there are opportunities for national, regional, and global coordination and learning to harmonise regulatory regimes and make them better.

## FINANCING

Adequate financing is essential for the rapid development and deployment of countermeasures, and must be early, flexible, and at-risk to ensure that the funds are able to be used for critical pandemic response activities needed at that time. For example, it took COVAX 15 months to raise US \$10 billion, and it also had to turn donor pledges into cash in hand, which delayed when it could purchase vaccines and put its orders later in the queue. Having prearranged Day Zero financing that can be immediately tapped into when a pandemic begins would improve the speed of the response. It was noted that financing pandemic prevention requires sustained long-term resources to develop the capacities noted above, as well as pressure-tested tools that can cope with the complexity of emergency countermeasures development, including tools linked to mature finance, risk-tolerant R&D investment, equity-focused delivery support, and legal, procurement, and governance systems.

While more funding for pandemic preparedness would be welcome, providing more *stable and predictable* funding for countermeasures would be a great improvement, and governments are the primary actors with sufficiently concentrated economic clout to make a difference—though some governments certainly have greater capability in this respect. The history of underfunding preparedness between pandemics has led to enormous acute spending for response after a crisis hits. In that spirit, obligations to have in place reserve funds that can be tapped into quickly and continually replenished could provide an element of certainty when pandemic panic sets in.

Some were sceptical that the ideas under consideration at the INB (and currently reflected in Article 20) would, on their own, result in the mobilisation of finance needed to make a meaningful difference. However, the inclusion of the “health, finance, and private sectors” in developing new ideas inferred an openness to explore additional sources of funding beyond development assistance budgets to more innovative mechanisms, a strategy previous O’Neill Institute-FNIH convenings discussed at length.<sup>46</sup> It was also appropriate to address how LMICs could be supported in financing their compliance with the draft agreement.

In view of constrained fiscal environments and competing governmental priorities, some recommend that innovative financial tools continue to play a vital role in providing the necessary funding for pandemic response to “optimize existing response financing for speed, coordination, and at-risk” capabilities, including by adapting existing tools that funded the COVID-19 response.<sup>47</sup> The EIB’s Frontloading Facility, DFC’s Rapid Financing Facility, and International Finance Facility for Immunisation (IFFIm), which each sped up access to liquidity during the COVID-19 response could feature in future pandemics. Many of the aforementioned financing tools are in process of being expanded to accomplish this.

## DATA PRIVACY

Several participants noted the crucial importance of having rapid access to data regarding pathogens in order to commence immediate work on developing countermeasures. Similarly, it was noted that an “open science” approach, making the results of research available for other scientists in a timely manner to build on, is critical to innovation. However, the privacy rights of patients are key considerations too. The use of aggregated or unidentified data can avoid many of the data privacy concerns. One suggestion was crafting a public health use agreement for pathogen sequence data to permit transparent and equitable sharing and use of data while crediting the data owners; for example, data submitters in LMICs should be consulted to understand their needs and ensure appropriate recognition. The continuous management of these interwoven factors is acknowledged in the draft text, and many expect the debate over which factors to prioritise to continue well past the treaty’s ratification.

## INTELLECTUAL PROPERTY

Much of the current model of innovation relies on the proposition that it is largely incentivised by granting intellectual property rights over inventions. According to the World Intellectual Property Organization (WIPO), the “top five patent applicant locations in the field of vaccines are China, the United States of America (US), Germany, the Republic of Korea and the Russian Federation. In the field of therapeutics, China, the United States, the Republic of Korea, India and Germany are the top applicant locations.” It also reported that “[p]atent applicants are distributed almost equally between companies (52 percent of the vaccines and 49 percent of the therapeutics dataset) and universities and research organizations (42 percent of the vaccines and 38 percent of the therapeutics dataset), but with companies accounting for a larger proportion of the two datasets.”<sup>48</sup>

There is already a global legal system for protecting intellectual property through the WTO and its accompanying agreements, particularly the *Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement*.<sup>49</sup> The draft pandemic agreement states that countries shall “make use of [TRIPS] flexibilities”<sup>50</sup> and during pandemics “encourage all holders of patents related to the production of pandemic-related products to waive, or manage, as appropriate, for a limited duration, the payment of royalties by developing country manufacturers”; it would require this of those that “received public financing for their development”.<sup>51</sup>

Issued by government authority, a patent grants to the holder a market exclusivity over the use of an invention for a defined period of time. The basic policy proposition is that inventors will maximise their efforts—and society will enjoy the benefits—if they believe they will be rewarded for their achievements and recoup the costs of their failures.

Manufacturers of countermeasures reinforce this position. In the Berlin Declaration, which lays out industry's vision to support equitable access in pandemics, pharmaceutical industry actors identified intellectual property protections as a key enabler for innovation in advance of the next pandemic and credited the IP system with their success in rapidly developing and scaling up multiple assured-quality, safe, and effective vaccines and innovative treatments against COVID-19.<sup>52</sup> Relatedly, they have also argued that compulsory IP waivers threaten the innovation ecosystem, for example by removing incentives to explore dual use of therapeutics and vaccine technologies, encouraging proliferation of falsified and substandard medicines, and inhibiting rapid access to quality-assured products.<sup>53</sup>

Others are dubious that an IP-based innovation system can deliver for the public health, particularly during a crisis. They point out that while a corporation's fiduciary duty to maximise shareholder value is not mutually exclusive to public health aims, patent enforcement can stand in the way of building greater resilience and regional autonomy when use of critical technologies for local innovation is prohibited. They point to the inadequacy of the TRIPS Agreement waiver regime to meaningfully identify and act on circumstances when IP rights should give way to broader access.<sup>54</sup> They also argue against granting full patent rights to inventions partially financed with public money,<sup>55</sup> and highlight a perceived lack of public health needs-driven direction in R&D priority-setting,<sup>56</sup> with an IP system that favours wealthier nations with in-country capacity.<sup>57</sup>

The role of IP in public health remains an issue of considerable reflection and debate, with implications that are incredibly broad and that are interconnected with other aspects such as the contribution of publicly funded research to innovation, competition or anti-trust laws, disclosure of contractual terms, and public procurement. Research institutions including those with government funding, are often paid royalties through IP-grounded partners when they license their inventions to others to further development, with the revenue then reinvested into new R&D activities and to support their academic missions. It was also suggested that alternative, workable modes for incentivising R&D could be needed if patent exclusivity regimes were amended, which would also require amending the TRIPS Agreement. Also, several experts stated that how patent holders and governments exercise their rights and the transparency around publicly funded research remain important considerations.

## Summing Up

It was observed that from a people-centred perspective, the COVID-19 pandemic underscores how important it is to swiftly create and guarantee equitable access to a sustainable, reliable supply of countermeasures and that additional factors such as strengthened health systems capacities, credible public information and messengers, and universal health coverage will also impact the effectiveness of any particular model.

## SECTION 2

# PANDEMIC CLINICAL TRIAL CAPABILITIES

**MEDICINES AND VACCINES SHOULD UNDERGO CLINICAL TRIAL TESTING** before country regulators authorise them for use. A lack of established clinical trial capability and capacity for pandemic products was a significant bottleneck in the response to the COVID-19 pandemic. The World Health Assembly,<sup>58</sup> the African Union,<sup>59</sup> and the G7<sup>60</sup> are among those citing improvements in clinical trials, especially trial capacity, as a critical activity.

Article 9 of the negotiating text states that:

*The Parties shall, in accordance with national laws and regulatory frameworks and contexts, take steps to develop and sustain, strong, resilient, and appropriately resourced, national, regional and international research capabilities. To this end, the Parties shall increase clinical trial capacities, including by building and maintaining a skilled research workforce and infrastructure, as appropriate; strengthening clinical trial policy frameworks, particularly in developing countries; investing in the infrastructure and training of clinical research networks and the coordination of clinical trials through existing, new, or expanded clinical trial networks, including in developing countries, to be prepared to provide timely and appropriate responses to pandemics; and identifying and researching supply chain needs to rapidly mount and scale research responses during pandemic emergencies.<sup>61</sup>*

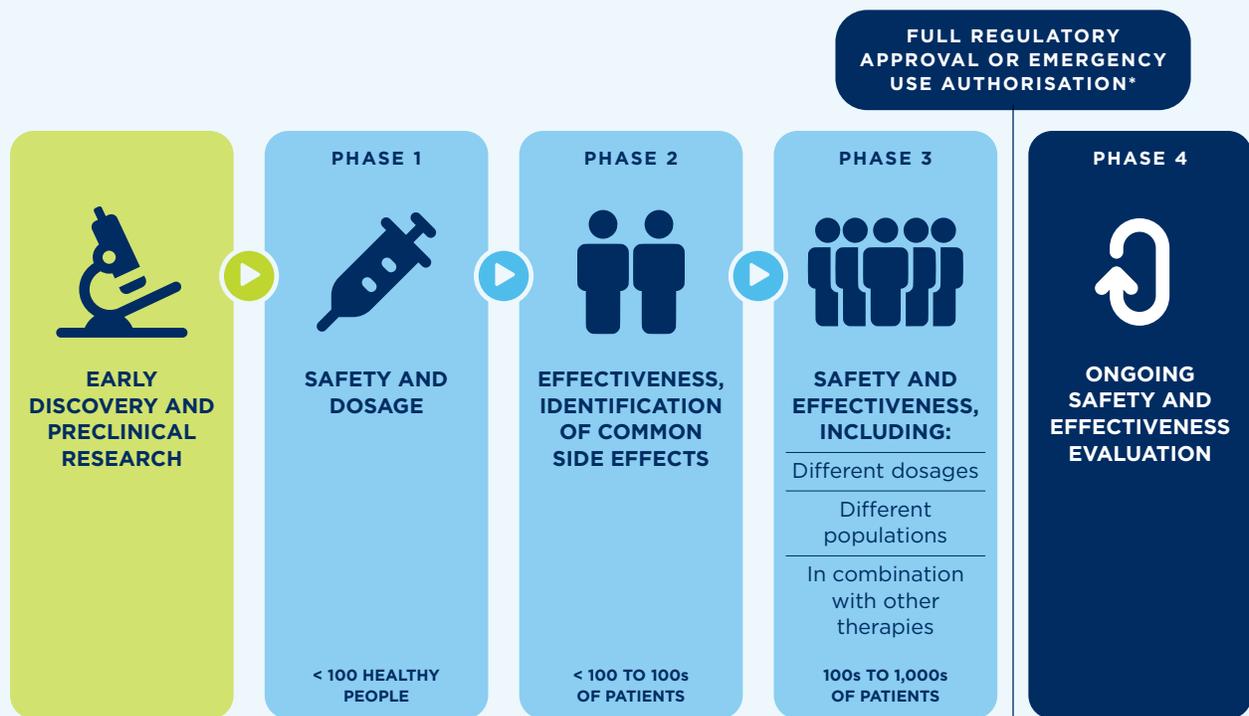
It also requires that “clinical trials have equitable representation, considering racial, ethnic and gender diversity across the life cycle,” and that the State Parties promote sharing of national research agendas and R&D priorities, strengthen international coordination and collaboration, develop policies to share clinical trial protocols and results while protecting sensitive personal health information, and support mechanisms to facilitate rapid reporting and data interpretation.<sup>62</sup> Relatedly, under Article 14, State Parties would be required to “align and, where possible, harmonize technical and regulatory requirements and procedures” as well as “promote and facilitate the use of regulatory reliance and mutual recognition...concerning the quality, safety and efficacy of pandemic-related products.”<sup>63</sup> Whereas the June draft tempered many of the clinical trial capacity obligations with “as appropriate” language, the verbiage in the negotiating text takes a more assertive stance.

The clinical trial capability and capacity challenges encountered as HIV, Ebola, and SARS-CoV-2 emerged provide a rich history from which to consider how to mobilise the resources and structures needed to test countermeasures for future pandemics.

## Clinical Trials: What They Are and How They Work

The WHO defines a clinical trial as “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”<sup>64</sup> Generally, a treatment needs to successfully traverse

three phases before a country's regulatory body will consider approving it. In the first phase, the intervention will be given to a small group of healthy volunteers (usually less than 100) to assess safety, establish a proper dosing range (enough to be effective but not higher), and identify side effects. If progressed to Phase 2, a larger patient population will take the treatment to assess whether it is effective and to identify less common adverse side effects that may not have emerged during the previous phase. Finally, a Phase 3 trial also tests safety and effectiveness, this time among a larger group (hundreds to several thousand patients), and particularly in different populations, at different dosages, and in combination with other therapies. If the treatment receives regulatory approval, it remains subject to ongoing safety and effectiveness evaluation (often termed "Phase 4").<sup>65</sup>



**\*This is the standard clinical trials progression. Phase 4 requirements can be meaningfully different after a countermeasure has received an emergency use authorisation (or in WHO terminology, an “Emergency Use Listing”) than after full regulatory approval.**

The scientific rigour of the clinical trial sequence helps give physicians and the public confidence in the treatment's potential to address the patient's health condition and allows them to evaluate the potential side effects of electing to administer it. The most robust clinical trials are randomised controlled trials (RCTs), which compare the effect of a new therapy to the current standard of care (or placebo if this is a completely new intervention). It is critical that trial design aligns with good clinical practice. The rigour and time involved in designing and executing a trial are both necessary and expensive. A Phase 3 trial can cost tens of millions of US Dollars, though the costs of any particular trial can vary considerably,<sup>66</sup> with the number of patients<sup>67</sup> and disease area<sup>68</sup> being significant variables.

In a pandemic context, rapid availability needs to be considered in tandem with incomplete information concerning a countermeasure's safety and efficacy profile. Some regulatory regimes have an accelerated, conditional use mechanism for emergencies.<sup>69</sup> They establish the circumstances for considering emergency use and decision-making criteria for expeditiously authorising a treatment or quickly terminating it.

## The Challenges

After the Ebola crisis that occurred in West Africa during 2014-2016, the WHO recognised a need for “more efficient ways to conduct clinical trials in times of distress.”<sup>70</sup> While a WHO-commissioned stakeholder survey found that “some capacities and networks have already been expanded in a number of ways,”<sup>71</sup> many challenges remain.

The most frequently cited challenge in this discussion was a highly fragmented and siloed regulatory approach globally. This means that study design and execution need to address the regulatory capacities and laws of each country where the countermeasure may be used. This can take precious time during a crisis. For example, during the acute phase of the COVID-19 pandemic, some trials had finished patient enrolment globally before regulators in some countries with trial sites could complete their reviews and approve them. Complicating matters, clinical trial design tends to be highly bespoke; normally an inventor crafts, and needs to receive regulatory approval of, a trial design “protocol” each time a therapy is to be tested.

Some experts noted that underinvestment in regulatory capacity slowed down the evaluation of tested products. Among the reasons cited were the novelty in assessing the new therapeutic platforms, burdensome bureaucratic processes that lacked the nimbleness needed in an emergency context, and a lack of coordination between agencies with roles in a country's approval process.

Early in the COVID-19 pandemic, there was recognition that little clinical trial capacity for pandemic products existed. Meanwhile, there were hundreds of potential therapies trying to access that limited capacity. Some groups published the results of insufficiently powered trials (meaning too few patients were enrolled to generate a scientifically rigorous conclusion), thereby confusing the public and, when the treatments did not work, sowing distrust.

While participation from the entire population is important, patient or participant collaboration is another area ripe for improvement. There were experts who noted that patient and civil society voices are often peripheral to clinical trial discussions, and that during crises, their perspectives may be omitted entirely. This can lead to misalignment between what therapies get tested and what people most want. The disconnect can also brew a lack of trust which can lead to poor adoption. In addition, communities who participate in clinical trials are often locked out of benefiting from the countermeasures they help validate.

A lack of concerted efforts to engage patients can exacerbate challenges that already exist in patient recruitment and enrolment. In higher-resource environments, 80% of trials are delayed by more than one month due to under-enrolment.<sup>72</sup> In all settings, but in lower-resource environments in particular, it is difficult to connect the right patients to the appropriate trials. In addition, when participants believe a trial is not aligned with their objectives or if contributing becomes inconvenient, it can lead to high attrition. Moreover, testing safety and effectiveness in diverse populations is critical but often hard to achieve, particularly given the scepticism some communities have of researchers' motives due to historical injustices and distrust.<sup>73</sup>

Data management is a complex, complicating factor as well. Trial participants do not have much control over their own data, including how they are responding to the given therapy. While double-blind studies (whereby neither participants nor the investigators know who has been given the agent or a placebo) are scientifically rigorous, they leave patients largely in the dark as to what is going on inside their own bodies. Moreover, such data may yield important insights if later analysed in combination with data from other studies, but it is difficult for patients to give fully informed consent to a hypothetical future use. There were experts who emphasised that trial participants are performing a public service, so the results of the research they are contributing to should be broadly disseminated while also protecting individualised data from disclosure, and they should receive post-trial access to products and fair pricing commitments.

In addition, modern data privacy protection laws built to give individuals more control over how third parties collect, store, and use personal data have stifled cross-border clinical trials. While it was not suggested that such laws are unwise, as they proliferate, the collateral consequences to open science and biomedical discovery will need to be reckoned with.

Conducting clinical trials in resource constrained settings can be done well, but there are unique obstacles. Supply chain failures, financing gaps, and the lack of manufacturing capacity in low-resource settings can limit the opportunities for clinical trial testing in those venues.

There are also significant ethical components. Some experts noted the persisting power asymmetries between higher and lower-income countries and the potential for the former to exercise it in a manner that disadvantages the latter. This asymmetry also involves who owns and controls the tested interventions and the trial data, and the lack of post-trial access commitments for the communities that were involved in the trials. It was cited that less than 20% of clinical trials are conducted in low-income countries,<sup>74</sup> and when they are, often it is to pursue interventions that may be better suited to the needs of higher-resourced populations or to conduct Phase 3 trials in less-regulated environments or save costs. It was also noted that response to drugs varies among populations, and that the safety and efficacy profile of a countermeasure would need to be evaluated in multiple settings.

Some experts emphasised that in lower-resource settings, there are fewer mechanisms to inform and train patients, physicians, and patient groups on their rights and how to provide input on clinical trial design. In addition, LMIC-based trials do not adequately address malnutrition as a confounding factor.

## Pandemic Clinical Trial Case Studies

### ACCELERATING COVID-19 THERAPEUTIC INTERVENTIONS AND VACCINES

The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) programme is a public-private partnership that has sought to “develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines.”<sup>75</sup> Part of ACTIV’s remit was to grow pandemic clinical trial capacity and to evaluate and prioritise the therapies with the highest potential to be tested in fully powered trials. Between March-May 2020, a clinical trial working group developed an inventory of 54 clinical trial networks and 647 trial sites across the world to establish a coordinated mechanism to expedite trials.<sup>76</sup> They also created “innovation playbooks” on electronic clinical outcome assessments (eCOA), ethical electronic consent platform creation, home nursing, remote source data verification (SDV), site training/tools, and an innovations quick reference guide and made them publicly available.<sup>77</sup> To address the bespoke protocol challenge, the partnership designed 11 master

clinical trial protocols, which allowed multiple therapies to be tested under similar conditions. Master protocols to test immune modulators, monoclonal antibodies, and anticoagulants, among others, have permitted 37 agents to be tested with six showing proven efficaciousness against COVID-19.<sup>78</sup> In addition, regulatory agencies from across the world held weekly meetings to consult on how to evaluate the pandemic response products under development.

While the trials commenced in the United States, most expanded to global networks, but not without problems to overcome. For example, some arms of the trial that were planned for LMICs did not open due to supply chain shortages or inability to import therapeutic agents.

## **STRATEGIES AND TREATMENTS FOR RESPIRATORY INFECTIONS AND VIRAL EMERGENCIES**

The Strategies and Treatments for Respiratory Infections and Viral Emergencies (STRIVE) master protocol, which has applied some of the learnings from ACTIV, is built to test therapies that could address a multitude of respiratory pathogens.<sup>79</sup> With nine international coordinating centres encompassing more than 300 trial sites, it will enrol participants living in Australia, Denmark, Mozambique, Singapore, Thailand, Uganda, Ukraine, the United States, and Zimbabwe, among many others. Critically, the international coordinating centres are partnering higher-income country sites with those in LMICs to encourage technical and infrastructure support. Each partnership has a co-lead from each setting to improve collaboration, reduce power asymmetries, and improve readiness for when the next major pathogen emerges.

Notably, when a company is invited to test a therapy through ACTIV or STRIVE, it is informed where the trial sites are located and is evaluated for its willingness to invest in those settings and continually provide access to the treatment there. Some companies were unable to participate because they could not guarantee post-trial access to those communities.

## **WHO COVID-19 SOLIDARITY THERAPEUTICS TRIAL**

The WHO COVID-19 Solidarity Therapeutics Trial is an international collaboration that tested existing therapies for malaria, cancer, and immune system disorders for effectiveness against COVID-19.<sup>80</sup> The Solidarity Trial is also a master protocol and has enrolled more than 14,000 patients at 600 sites in 52 countries, many of which are in low-resource settings. A central “Data and Safety Monitoring Committee” reviews safety and efficacy results and recommends to the WHO whether to open, continue, or close arms of the trial. To improve speed and reduce administrative burden, the WHO approved simplified procedures, including reduced paperwork requirements, and mobilised a cloud-based system to report results and adverse reactions. The Solidarity Trial definitively rejected several therapies that early, insufficiently powered trials had declared were useful to treat COVID-19.<sup>81</sup> Its simplicity and speed may have been particularly important to LMIC decision-making over whether to expend precious resources on treatments that eventually turned out to be ineffective.

## **ADDITIONAL TRIALS**

Other clinical trials of significance but not discussed during the convening include the Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial which successfully recruited patients due to its implementation in routine clinical care settings throughout the United Kingdom,<sup>82</sup> and a prospective COVID-19 treatment study run by the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC), a global federation of clinical research networks.<sup>83</sup>

## Options for the Pandemic Accord

### HARMONISING REGULATORY REGIMES

Harmonising regulatory approval regimes was frequently cited as a critical activity prior to the next emergency. This could provide time and cost savings from trial design to regulatory assessment. By and large, most of the differences from regime to regime are not due to significant policy differences but simply the fact that these systems were built in silos, as well as capacity constraints in most, if not all, countries. For example, the National Academies of Sciences, Engineering, and Medicine explored the benefits of mutual recognition and other reliance activities among regulators. The idea was to share resources and knowledge about regulatory oversight.<sup>84</sup> Also, the European Medicines Agency recognised that its EU-wide Clinical Trial Regulation (CTR)<sup>85</sup> requires more “communication and management efforts to ensure that there is appropriate coordination between the relevant regulatory bodies involved in the implementation of the CTR at national level.”<sup>86</sup>

As noted above, regulators were motivated to work with their cross-border counterparts so the agreement could encourage these collaborations to continue. For example, some noted that the agreement could inspire the construction of regional regulatory networks to review pandemic products efficiently, and these networks could conduct regular “tabletop” exercises to identify process improvements and enhance decision-making. Such collaboration could also help thinly staffed regulatory agencies by bringing to bear the expertise of fellow agencies, particularly when expertise concerning a novel technology is scarce.

A potential risk would be to push for a compulsory one-size-fits-all approach. That would intrude unnecessarily on country preferences (some might, for example, wish to retain population-specific safety requirements) and prolong negotiations indefinitely. Harmonising does not require this. A more common regulatory method—whether a global one or several regional ones—would provide a “centre of gravity” from which countries could deviate, but they would do so while being able to assess the trade-offs of enacting particular requirements. For example, some participants noted that regulatory bodies that primarily oversee generic or biosimilar manufacturers may elect to permit those entities to submit applicable pre-clinical or clinical data on the original medication as part of its approval application.

Even harmonising obvious areas of unnecessary misalignment could speed the generation of data needed to approve therapies that work, dispense with those that do not, and improve the decision-making capabilities of low-, middle-, and high-income country regulatory bodies alike. Treaty text that instructs the Conference of the Parties to create a working group to organise cross-border regulatory coordination, develop a model regulatory statute, and otherwise operationalise Article 14 could be a potential launching point.

### USING MASTER PROTOCOLS

The master clinical trial protocol methods used in the ACTIV, STRIVE, and Solidarity trials could be models to develop adaptable templates for any number of multi-centred trials. No one template will be appropriate in all circumstances, but developing a number of models that could be scaled and tailored to the disease and region could promote faster, more cost-effective testing. Moreover, the templates could contain rigorous patient data protections along with model consent forms that ensure participants understand what data they are providing, how it will be stored, who will have access to it, whether it will be de-identified and whether it is possible to re-identify it, how it will be used, how it could be used in the future in

other research settings, and the rights they have to view it or have it destroyed. Such consent should also be crafted in lay terms and in a manner that could be translated into the language of every community that participates in trials. The agreement could instruct either the WHO or a working group of the COP to facilitate the development of these tools; investments in data architecture to ensure samples, data, and consents are stored together under sufficient encryption; and ongoing community engagement with the clinical research community.

## **BALANCING DATA PRIVACY AND OPEN SCIENCE**

The agreement will need to operate in harmony with the emerging data privacy regimes around the world from the European Union's General Data Protection Regulation (GDPR)<sup>87</sup> to the state of California's Consumer Privacy Act<sup>88</sup> to statutes in other settings that will surely follow. The negotiating text aspires to this,<sup>89</sup> but some experts suggested that it underestimates the degree to which data privacy laws may undermine the activities the treaty is designed to promote. Some experts reflected that it may require negotiators to consult the officials responsible for data privacy regimes to understand the opportunities to support biomedical research without seriously undermining personal data privacy. *Advancing a World Together Equitably* provides additional context and options on this element.<sup>90</sup>

## **IMPROVING STANDING PANDEMIC CLINICAL TRIAL CAPACITY**

Building clinical trial capacity was also cited as both a priority and an inevitability. For some, the question was not whether to pursue improvements but whether there was recognition that if this was not addressed in between pandemics, there would be a scramble to develop it again when a new crisis was underway. Recruiting and enrolling patients, identifying trial sites, training investigators and point-of-care nurses, and other activities are difficult to implement in all settings and especially so in lower-resource environments. The accord could help promote best practices from the ACTIV innovation playbooks and other sources to support planning, start-up, execution, and close-out of studies.

## **PUTTING PATIENTS FIRST**

Finally, centring the patient experience and perspective has important implications for operational success and equitable outcomes. Many access and benefit sharing options that have been considered by the INB link commercial access to a natural resource or genetic sequence found within a political border to that population's ability to obtain countermeasures that were developed as a result of that access. However, some experts suggested that a more durable arrangement would be for communities that participate in clinical studies to receive assurances that they would be able to access the vaccines and medicines developed through those trials. Such linkage, it was noted by some stakeholders, would be consistent with the right to benefit from scientific progress. The models presented above provide evidence and could build momentum to a legal obligation enshrined in the agreement.

## SECTION 3

# ACCESS AND BENEFIT SHARING

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**AT LEAST 140 COUNTRIES** and the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognise health as a human right. The ICESCR also articulates a right to “enjoy the benefits of scientific progress and its applications.”<sup>91</sup> This makes health and well-being through improved availability of pandemic countermeasures an essential component of any new preparedness and response regime.

In his opening remarks to the first meeting of the INB in March 2022, WHO Director-General Tedros proposed “global access and benefit sharing for all pathogens” and “a global policy for the equitable production and distribution of countermeasures” as one of five ways to better prepare the world for pandemics.<sup>92</sup> Since that time, access and benefit sharing (ABS) has evolved to become a fulcrum of the negotiations.

ABS was defined in *Legal Tools for Pandemic Preparedness*, the first O’Neill Institute-FNIH convening, as a “mechanism whereby governments share, or allow the sharing of, biological materials and related genetic sequence information and, in turn, receive benefits like access to technology and know-how that are developed using those resources.”<sup>93</sup> Some stakeholders in that group noted that disparities might be addressed through a multilateral ABS system. For example, some have advocated that the Pandemic Influenza Preparedness (PIP) Framework, presented as a potential solution for the complex issues in the pandemic agreement negotiations, is a model to emulate, while others note that it has limitations that need to be considered, including that it has not been truly means-tested in a pandemic and scaled beyond pandemic influenza.

In *Advancing a World Together Equitably*, it was noted that:

Equitable access to medical countermeasures has been a vexing, persistent, and pervasive challenge. It is a complex issue involving affordability, innovation, fiduciary duty, transparency, and public communication, and it cuts across multiple sectors, notably trade and intellectual property (IP). What occurred during the COVID-19 pandemic is a case in point: inequities in vaccine access manifested shortly after the first diagnostics and vaccines were authorised late in 2020. By mid-March 2022, almost 80% of the population of high-income countries had received a dose of vaccine while the rate in low-income countries hovered at 14%.

At issue is the tension between incentivising and speeding innovation with equitable distribution of the resulting benefits from that innovation. What is essential is to find equity mechanisms that incentivise scientific sharing and innovation, while also ensuring equitable distribution and access to lifesaving medical resources.<sup>94</sup>

Moreover, some stakeholders pointed out that equitable access cuts across multiple sectors involving health system capability and infrastructure, timely funding, public understanding and confidence in clinical trials and vaccination, and trade restrictions. The latter was noted as a major factor as highlighted by the export restrictions placed on COVAX’s first supplier thus redirecting vaccine made for LMICs to that country’s domestic supply.

The present convening, which included ABS proponents and sceptics, along with experts in relevant disciplines who were evaluating these mechanisms for the first time, considered the ABS options present in the June draft of the accord; models that had been implemented in other areas of human activity; the pros, cons, implications, and collateral consequences of different ABS designs, including the linkage between access to pathogens and genomic sequence data (GSD) and benefit sharing obligations; the nexus with intellectual property regimes; and whether other options for improving and financing innovation and equity were favourable to, or could complement, an ABS mechanism.

The following mosaic of insights provides a landscape view for policymakers to consider. One throughline to this discussion is that those who had deep expertise on ABS, no matter their support or scepticism of particular models or principles, found that their definition of what ABS entails can differ in critical ways from others. The principal takeaway from that discovery is that policymakers must ensure their discussions are grounded in a common definition, so they do not “negotiate past each other.” Further, should the INB submit a treaty to the World Health Assembly with obligations under the ABS heading, it should be very clear to country delegates how it is similar to, and how it differs from, ABS models that already exist so those negotiations are also grounded in a common set of facts, assumptions, and equity.



**A healthcare provider finishes administration of an influenza vaccine to a pregnant patient.**

Credit: US CDC/Robin Spratling

## Understanding Access and Benefit Sharing

### ACCESS VS. BENEFITS

**Access.** The development of strain-specific vaccines and other countermeasures relies on the research community's rapid access to pathogen samples and associated GSD. This is the "access" referred to when designing and implementing an ABS system for pathogens. Similarly, "access" under the *Convention on Biological Diversity* (CBD)<sup>95</sup> and its associated *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization*,<sup>96</sup> which contains the default and most prominent ABS regime in operation, refers to access to genetic resources. Of course, "access" is a term also used in reference to patients and governments accessing countermeasures,<sup>97</sup> but that usage will be avoided in this discussion to avert confusion.

**Benefits.** "Benefits" denotes both monetary and non-monetary benefits. The potential scope of non-monetary benefits is wide. Discussions in the INB have largely used "benefits" to describe countermeasures developed as a result of research institutions' access to pathogens and GSD. But the term could describe a range of other benefits including co-authorships, grants, collaboration, and other forms of recognition for the originating laboratory, as well as technical assistance, capacity-building (e.g., research, regulatory, manufacturing), licenses, and technology transfer.<sup>98</sup>

### ACCESS AND BENEFIT SHARING IN THE NEGOTIATING TEXT

On 16 October 2023, the INB released its new proposal for an ABS regime, called the WHO Pathogen Access and Benefit-Sharing System (PABS System).

Applying the takeaways from older ABS systems that will be reviewed below, the text states that implementation should be undertaken "in a manner to strengthen, expedite and not impede research and innovation; at all times, both during and between pandemics; in a manner to ensure mutual complementarity with the [PIP] Framework; and with governance and review mechanisms, to be determined by the Conference of the Parties."<sup>99</sup>

Parties who discover pathogens with pandemic potential, or who have genetically sequenced them, must share these with WHO collaborating laboratories and public databases. In turn, the laboratories would grant researchers and others access to them via a Standard Material Transfer Agreement (SMTA) approved by the State Parties that, among other things, sets out the PABS System's benefit sharing obligations,<sup>100</sup> as follows:

- In the event of a pandemic, recipients of the material would commit to providing the WHO with a minimum of 20% of the products produced as a result of their access—10% as a donation, 10% at affordable prices to the WHO. If a recipient has manufacturing facilities to create the countermeasures inside the border of a State Party, that government is obligated to facilitate exports to the WHO.<sup>101</sup>
- Recipients would provide an annual financial contribution to a capacity development fund<sup>102</sup> designed to help State Parties, and developing countries in particular, to meet their pandemic accord obligations.<sup>103</sup>

State Parties would also commit to exploring how to encourage collaboration between industry in higher- and lower-resource settings, tiered-pricing mechanisms of product purchasing, and boosting the involvement of scientists from developing countries in the WHO coordinated laboratory network.<sup>104</sup>

The draft also requires State Parties to enforce participation in the system, for example to require manufacturers without an SMTA to provide benefits.<sup>105</sup> It also commits to further discussion on how to allocate the resources the WHO receives and make the system operational by 31 May 2025.<sup>106</sup> It also self-identifies as a specialised international ABS instrument under Article 4(4) of the Nagoya Protocol.<sup>107</sup>

The most significant change from the June draft is that the benefit sharing obligations are relatively specific and compulsory. It was noted during our convening that while the June draft's access requirement was clear and strict, the benefit sharing obligations were less defined or voluntary. Some experts pointed out the potential for power asymmetries and that clear obligations on both ends of the equation would engender more trust and certainty.

## Access and Benefit Sharing Models

Article 12 specifically notes that the PABS System will conform to the CBD and its Nagoya Protocol. An explanation of these models, and others in operation, could help inform whether an ABS programme is viable and the range of possibilities that could be fit-for-purpose.

### THE CONVENTION ON BIOLOGICAL DIVERSITY AND ITS NAGOYA PROTOCOL

The CBD entered into force in 1993 and has near-universal membership with 196 State Parties. The CBD promotes three objectives: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.<sup>108</sup> Prior to the CBD's adoption, genetic resources, including pathogens, were transferred on an *ad hoc* basis.

With its adoption, the CBD ushered in a significant shift, clarifying that genetic resources are the sovereign resources of their country of origin.<sup>109</sup> Article 15 of the CBD sets out basic rules on access and benefit sharing for genetic resources. Users must normally obtain the prior informed consent of the country of origin and come to mutually agreed terms.<sup>110</sup> The aim of this is to share “in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the [originating] party.”<sup>111</sup>

The CBD's Nagoya Protocol was concluded in 2010 to spell out the Convention's ABS provisions and “create greater legal certainty and transparency for both providers and users of genetic resources by establishing more predictable conditions for access to genetic resources [and] helping to ensure benefit-sharing when genetic resources leave the country providing the genetic resources.”<sup>112</sup> It entered into force in October 2014 and has 140 State Parties to date.<sup>113</sup> It has sought to promote fairer and more equitable sharing of benefits arising from the use of genetic resources, including by the transfer of technologies and appropriate funding, and the channelling of benefits into biodiversity conservation.<sup>114</sup>

The Protocol obligates State Parties to create a more certain legal environment in which to operate its ABS requirements. It establishes an ABS “Clearing-House...as a means for sharing of information related to access and benefit-sharing”, and except for “the protection of confidential information, each Party shall make available to the...Clearing-House any information required by this Protocol.”<sup>115</sup> It also requires State Parties, among other things, to create ABS legislation and enforce adherence with it.<sup>116</sup>

The Protocol notably leaves space for the development of specialised international ABS instruments with respect to particular genetic resources. The Protocol states that where a specialised international ABS instrument applies that “is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this 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.”<sup>117</sup> And indeed, Article 12 of the pandemic accord’s draft text self-identifies as a specialised instrument.

Complicating matters is who gets to decide whether the Nagoya Protocol and a self-identifying specialised instrument are in harmony, as the former’s text is silent on this. It was noted that this risks stacking obligations, leading to confusion and disincentives to invest in products. Parties to the Nagoya Protocol have developed draft indicative criteria for specialised international ABS instruments; however, they have not yet been able to reach an agreement on this matter. One of the outstanding issues is whether other instruments can self-identify as specialised international ABS instruments or whether it is for the governing body of the Protocol (the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol or “COP-MOP”) to decide what constitutes a specialised international ABS instrument.<sup>118</sup> Consequently, the legal effect of the draft pandemic accord’s self-identification is unclear.

Multiple experts in the convening raised concerns that the CBD and its Nagoya Protocol do not deliver on their own objectives, much less can serve as an appropriate foundation for an ABS regime governing pathogenic material. They noted that the CBD had not generated reasonable benefits, with limited evidence that the bilateral ABS transactions have protected biodiversity. Another concern raised by some stakeholders was that parties to these transactions do not enter into negotiations on equal footing, with originating country parties potentially being less well-financed than those accessing the resource.

With regard to rapid access to pathogens, while there is nothing in the Nagoya Protocol that would require its parties to delay access, some in the convening cited evidence of the ABS mechanism producing that result. For example, one expert raised the case study of the Zika virus, whereby US researchers sought samples from Brazil, which had enacted domestic ABS legislation though had not yet ratified the Nagoya Protocol. By the time Brazilian and US negotiators sorted the terms for the transfer of material and sharing of benefits, the virus had spread into Puerto Rico, a US territory,<sup>119</sup> rendering the deal moot. While this is not necessarily a case that directly implicates a deficiency in the Nagoya Protocol, it can demonstrate that in cases where a virus spreads quickly, the benefit-seeking party’s leverage dissipates in short order.

Some experts were concerned that an ABS regime that requires extensive negotiation adds critical lost time in the early days of emergency countermeasure development.<sup>120</sup> For instance, an expert noted that a one-month delay in the sharing of SARS-CoV-2 samples could have led to an additional 400,000 lives lost during the COVID-19 pandemic. Other experts noted that some commercial users of pathogen samples can circumvent Nagoya altogether by basing their seasonal flu R&D activities on strains originating from non-Nagoya countries. Another stakeholder highlighted the delays faced in accessing pathogen samples in early 2021 when it was unclear whether Cambodia’s ABS laws permitted the use of a genetically and antigenically distinct H3N2 influenza strain<sup>121</sup> for vaccine R&D. Due to legal uncertainty, some entities switched to a Tasmanian strain while others proceeded “at risk.” One manufacturer reported that the delays and switch resulted in a 40% reduction in vaccine production.<sup>122</sup>

Some experts noted the tremendous variability in domestic ABS laws among Nagoya parties. For example, one participant noted that at least 77 countries expressly include pathogens in the scope of their domestic ABS systems, meaning that they may or may not restrict access to them, and of those, 39 restrict access to pathogen GSD as well. That possible leverage point is balanced by the possibility that countermeasure creators that wish to avoid ABS negotiations will craft products more suited to the environments willing to provide material for free.

A recent development is the decision by the Conference of the Parties to the CBD (and associated decision by the COP-MOP to the Nagoya Protocol) to establish a multilateral mechanism governing “Digital sequence information on genetic resources.”<sup>123</sup> As opposed to a bilateral regime, where the terms are negotiated in a bespoke manner each time a transaction is contemplated, a multilateral system can provide default terms and obligations for access and benefits as circumstances arise. The detailed ABS option under consideration in the pandemic accord would also be multilateral in nature. To avoid the high risk of duplication and confusion and allow for one streamlined system, some reasoned that benefit sharing related to GSD should be addressed under the CBD.

While recognising there are learnings to glean from the CBD’s history, some experts noted that pandemic accord negotiators have no control or influence over how the CBD and its Nagoya Protocol are implemented. They pointed out that the CBD is designed to conserve biodiversity whereas a pathogen ABS is meant to halt the spread of vicious agents. Some participants therefore felt that ABS was not a mechanism that can be considered fit-for-purpose in the public health space. Others believed that the specialised instrument carve-out in the Nagoya Protocol effectively separates the pandemic accord from that regime, so deficiencies concerning the CBD’s fitness to achieve its objectives are peripheral to an ABS system specifically designed to contribute to countermeasure development and deployment, at least for countries that are parties to the Nagoya Protocol and that also ratify the pandemic accord once it is finalised.

## PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK

In 2007, claiming sovereign authority over human pandemic influenza pathogens in its territory further to the CBD, the Indonesian government refused to share H5N1 influenza samples with the WHO’s network of collaborating laboratories without its prior informed consent and an agreement concluded on mutually agreed terms. This framing of pathogens as sovereign genetic resources subject to ABS exchanges led the World Health Assembly to adopt the PIP Framework in 2011.<sup>124</sup>

The PIP Framework is a non-binding WHO instrument whose objective is to create a “fair, transparent, equitable, efficient, effective system” for sharing flu viruses with human pandemic potential, and “access to vaccines and sharing of other benefits.” However, while it contemplates sharing associated GSD with WHO laboratories, it does not attach benefit sharing requirements. It also does not cover *seasonal* influenza nor non-flu pathogens with pandemic potential.<sup>125</sup>

WHO-designated influenza laboratories possessing flu viruses with human pandemic potential and other material enumerated in Section 4.1 of the PIP Framework agree, among other things, to the onward transfer of that material to other laboratories in the WHO Global Influenza Surveillance and Response System (GISRS) on the same terms as those in the Standard Material Transfer Agreement within the WHO GISRS (SMTA 1).<sup>126</sup> Those laboratories also agree to the onward transfer of those materials to *other* recipients, for example life sciences companies and manufacturers, if those recipients complete a separate agreement

(dubbed SMTA 2) with the WHO<sup>127</sup> whereby the recipient agrees to share certain benefits with the WHO.<sup>128</sup> Some noted that legally binding SMTA2s are burdensome however, particularly for small- and medium-sized enterprises that lack resources, and that they do not address the complexities of additional contract and ABS laws in different jurisdictions.

The PIP Framework installs the WHO as the entity responsible for flowing benefits to countries “according to public health risk and need.” Benefit sharing options include donating or selling at low-cost 10% of real-time vaccine production to the WHO and royalty-free licenses to manufacturers in developing countries.<sup>129</sup> Some experts highlighted that the PIP Framework was an attempt to formalise previously *ad hoc* materials transfer and position the WHO as the steward of associated benefits, with equity as its governing principle.

LMICs have long pursued reforms incorporating ABS principles to remediate the persisting effects of historic and ongoing exploitation and extraction of genetic resources to develop products that are designed for, and disproportionately benefit, citizens in wealthy nations.<sup>130</sup> Accordingly, the ABS system in the PIP Framework was also an attempt to achieve fairer, more equitable outcomes recognising the contributions of these communities and to bring order to an environment that consistently delivered unfair results. At the same time, it was noted that some countries have withheld pathogen samples, affecting the development of medical countermeasures, resulting in access challenges and the loss of vaccine production capacity, with the 2007 H5N1 and 2021 H3N2 circumstances as examples.



**A researcher at work in her laboratory, one way in which local laboratory capacity can be built up to quickly respond during a disease outbreak.**

Credit: US CDC

While it has not yet been tested in a pandemic context, the PIP Framework is regularly cited as a specialised ABS mechanism that could be emulated to rapidly facilitate access to samples and share benefits equitably.<sup>131</sup> Some experts viewed it as a prototype ABS mechanism even if its objectives are less than fully realised. They argued that it as a model for a singular multilateral system of benefit sharing that could, with improved enforcement mechanisms and better role clarity, achieve equitable outcomes more effectively than extant systems that rely on unfettered markets and an often-impermeable intellectual property regime. They also noted that it has played a critical role in fairer distribution of influenza vaccine and highlighted that the WHO has signed agreements to secure approximately 420 million doses as of August 2020.<sup>132</sup>

Other experts noted that the PIP Framework's practical effectiveness and scalability in a real-world pandemic response are uncertain. For example, its benefit sharing obligations do not explicitly apply to GSD, and as technology advances, influenza samples can be dematerialised, shared, and then rematerialised without having to complete the SMTA with the WHO that would obligate them to benefit sharing.<sup>133</sup> Second, they note that SMTAs are not fully standardised, so more powerful negotiators can extract more favourable terms. Third, countries and manufacturers can continue to enter bilateral agreements without the WHO's involvement and its role as an intermediary and benefits distributor. Fourth, SMTAs do not mitigate export restrictions, which were a barrier to equitable access during the COVID-19 pandemic, and global supply chains rely on hundreds of ingredients sourced from upwards of potentially 20-30 countries. Finally, they noted that the PIP Framework's financing mechanism—the Partnership Contribution model—does not lend itself to immediate scaling and duplication in a broader context.

## OTHER INTERNATIONAL LEGAL MODELS

Other ABS arrangements offer lessons for a new pathogen ABS system. The UN Food and Agriculture Organisation's (FAO) *International Treaty on Plant Genetic Resources for Food and Agriculture* (Seed Treaty or Plant Treaty)<sup>134</sup> adopts a multilateral ABS system facilitating access to 64 enumerated plant genetic resources for research, breeding, and training for food and agriculture. One of the Seed Treaty's objectives is the fair and equitable sharing of the benefits arising from the use of plant genetic resources. Benefits include access to, and transfer of, technologies, capacity-building, and the monetary and other benefits of commercialisation.<sup>135</sup> Benefits are shared multilaterally among parties, with special consideration given to developing countries.

The Seed Treaty does not self-identify as a specialised agreement, but it was suggested that countries have treated it as such. Its parties that desire access to plant genetic resources sign a standardised contract setting out the conditions for use and benefit sharing. Payments from the SMTA are directed to a benefit sharing fund that FAO administers supporting conservation and sustainable use in LMICs. Nevertheless, critics posit the Seed Treaty has failed to generate sufficient benefits and entities have found ways to circumvent its requirements.

The new *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*<sup>136</sup> creates a mechanism for the fair and equitable sharing of benefits arising from the use of marine genetic resources located outside domestic sea borders. Non-monetary benefits include access to samples, digital sequence information, marine technology transfer, capacity building, and scientific cooperation, while monetary benefits are to be distributed through a special financing mechanism supporting conservation.<sup>137</sup> Its impact will be closely watched.

Also, while not an ABS regime, COVAX's purchasing model, and its shortcomings, offer lessons for ABS construction. COVAX, like Gavi's core programme for routine purchasing, raised capital to procure vaccines for lower-income countries, with the intention that pooled, committed financing would improve bargaining and purchasing power heading into negotiations with manufacturers. However, countries and companies remained free to contract, and in the pandemic context, by the time COVAX had raised its financing base and commenced purchasing negotiations, wealthy countries had already closed agreements for early supply, thus positioning themselves at the front of the queue.

## DESIGNING ABS SYSTEMS

The cases used above demonstrate a variety of methodological choices. In sum, while the CBD and Nagoya Protocol assume bilateral, tailored transactions as their principal mode, the PIP Framework is multilateral, with a central institution (in its case, the WHO) that would organise the flow of materials and benefits via a streamlined transactions method (should it be tested) that, nevertheless, does not prevent public and private entities from entering into bilateral agreements. It was noted that the Seed Treaty operates similarly.<sup>138</sup> These are imperfect models and challenges remain, and some observed that there has been limited success in conditioning equitable access with complex restrictions and requirements.

Convening participants held a diversity of views concerning the elements that might be needed to make an ABS system meaningful. There was no consensus on the correct constellation of elements, but the following were ones that various stakeholders brought forth.

Some noted that an ABS system needed to be inclusive, remarking that most if not all 194 WHO Member States must be committed to the sharing of pathogens and GSD and the sharing of benefits on equal footing whether access and benefit sharing are linked or delinked. Some noted that an ABS system should provide those who use it with legal certainty, for example receiving early recognition from the parties to the Nagoya Protocol that the pandemic agreement's system qualifies as a specialised instrument. Some experts to the *Advancing a World Together Equitably* convening had recommended that officials from other treaty regimes be included in negotiations. Advanced legal certainty is also important to manufacturers, as uncertainty is often priced into their products and factored into other decisions. And for countries providing access, guarantees that benefits will be shared is perhaps most important of all.

Accountability was another element identified by some experts, which would permit evaluation and continual reassessment of the system.<sup>139</sup> Some participants mentioned a desire for timing clarity for when benefit sharing obligations are triggered and the desirability of real-time sharing of products with the WHO for distribution on the basis of public health need. Some reflected on whether benefit sharing obligations should be linked to formal pandemic declarations or some other criteria. Some stakeholders emphasised that the system must be rapid and efficient in order to improve equitable access, and that tying access to benefit sharing would cause unfortunate delays. They noted the accord might instead contain separate articles on equitable access to samples and benefit sharing of countermeasures.

There was also discussion on how and whether a pathogen ABS system should incorporate One Health principles. One Health is defined in the current draft as "an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems."<sup>140</sup> Experts in the *Advancing a World Together Equitably* convening had noted as a general matter that One Health "provided an important opportunity to put in place missing governance at the international level between regimes."<sup>141</sup> Here, some noted that taking

this approach to ABS would encompass the mandates of the WHO's fellow Quadripartite agencies—the World Organisation for Animal Health (WOAH), the FAO, and UN Environmental Programme (UNEP)—and implicate the Nagoya Protocol's “traditional knowledge” provisions.

The October negotiating text's Article 5 concerning One Health makes a direct connection to ABS that is not present in the June document. For example, it states that “the Parties shall promote and enhance synergies between multisectoral and transdisciplinary collaboration at the national level and cooperation at the international level and conduct risk assessments at the interface between human, animal and environment ecosystems, while recognizing their interdependence, and with applicable sharing of the benefits, per the terms of Article 12 [on Access and Benefit Sharing]” and recognises the harmony needed “with other relevant instruments.”<sup>142</sup> Some experts thought this may underscore the utility of involving officials from fellow international organisations in a pathogen ABS system's design and construction.

## Transactional Linkage vs. De-linkage

Under the ABS model, linkage is interpreted as a transaction where countries provide pathogen samples to potential users in *exchange* for medical countermeasures, or an opportunity to receive them.<sup>143</sup> There are a multiplicity of views as to whether linking access measures and benefit sharing obligations effectively fulfils equity aspirations and the extent to which there could be collateral consequences to public health security.

### *Arguments for a strong linkage*

LMICs are often in favour of ABS systems as a defence against formidable and sometimes exploitive practices used against them.<sup>144</sup> Contributing resources found within their borders constitutes a significant component in the development of any end product, and especially medical countermeasures. The population of any country should expect, if not demand, that their governments will seek benefits for this contribution.

Some experts also noted that a choice not to link access to benefit sharing effectively gives away one of the few leverage points that countries with fewer resources have to protect their citizens during a crisis. Some participants said that a viable alternative would need to emerge before countries that have experienced delayed access to countermeasures could be expected to willingly settle for the system as it is currently constructed. Given this, they argued that delinking access to pathogens from the sharing of benefits, without strengthening core obligations and accountability for the latter, would require reliance on voluntarism to countermeasure deployment, and the COVID-19 pandemic demonstrated that reliance on voluntarism during a public health emergency does not work.

They also noted that ABS mechanisms stand as a rules-based way to balance the rights of nations that share genetic resources with those of inventors, which are governed under the TRIPS Agreement. That instrument contains IP waiver provisions that are meant to expedite benefit sharing in emergency situations. Those provisions have been rarely exercised. Some felt that countermeasures are treated as something to be traded rather than a right, and that the linkage response to this dynamic is an attempt to remedy the inequalities LMICs face in accessing them.

Some experts are favourably inclined to try a multilateral mechanism like the PABS System, which does not require delay-inducing bilateral transactions to operate. It was also felt that a mechanism's feasibility would be correlated with the extent to which it is inclusive, permits real-time sharing of countermeasures with the WHO, provides legal certainty, and has timing clarity.

### *Arguments for de-linkage*

Some experts, while sensitive to the objectives of an ABS mechanism, were less convinced that one would deliver the outcomes envisioned. The ability to conduct routine R&D and prepare for pandemics requires rapid, efficient, and legally certain access to pathogens and genetic information. They stated that to achieve this and protect the health of the world, the agreement should prioritise equitable access to countermeasures without conditioning pathogen access to benefit sharing obligations.

First, some experts argued it could introduce unhelpful market dynamics into a relationship between parties that would otherwise have a common interest in preventing a pandemic. De-linkage would instead direct targeted solutions to two related but independent public goods: the need for scientists to have rapid access to novel pathogen samples and associated GSD and the need for equitable distribution of lifesaving countermeasures in a pandemic.

Some reinforced that a transactional approach to pathogen ABS would likely delay access to the material needed for swift development of medical countermeasures in a crisis. In any event, as shown in the Zika case, the leverage enjoyed by access providers would be short-lived as pathogens cross borders quickly, thus incentivising accessing institutions to simply wait for circumstances to evolve.

Overall, a transactional approach where states share pathogen or GSD in direct exchange for guaranteed benefits has been critiqued. Rather, a multilateral system that encourages both rapid sharing of scientific information and equitable distribution of benefits was cited as a preferred approach. The WHO, or another trusted intermediary, would allocate medical countermeasures according to ethics, equity, and need.

Also, it was argued that pathogen sample and pathogen GSD sharing does not necessarily or routinely lead to the development of products or intellectual property, or that a specific product, profit, or windfall to be shared would result. In many cases, risk is assumed, and losses are accrued, as was the case in COVID-19 where numerous therapeutic and vaccine candidates received significant investment but did not reach technical success.

Finally, some participants highlighted that access to countermeasures is part of the human right to health and the right to the benefit of scientific research, which should not be made contingent on providing access to pathogens. To protect the health of the world, these experts believed that the agreement should prioritise equitable access to countermeasures without conditioning pathogen access to benefit sharing obligations.

## **Complementary or Alternative Mechanisms to Promote Equitable Deployment**

Additional modes to proliferate benefit sharing are worth exploring regardless of whether ABS is part of the concluded accord given the view furthered by some experts that it would be unjust and unreasonable to expect LMICs to support an instrument without mechanisms that are reasonably calculated to improve outcomes. They articulated that it was incumbent on

higher-income states to bring actionable ideas that build trust, nurture inclusivity and equity, are anchored in sound governance and accountability, and could be sustainably financed.

There were experts that warned of path dependency with regard to some of the policies and mechanisms under consideration. For example, some urged that negotiators not be so devoted to ABS that complementary measures or alternatives are not fully debated. Other participants encouraged policymakers to consider adjustments to an IP infrastructure that they argue benefits wealthier nations and their economic interests and can produce inequities in a pandemic. A number of considerations were explored in the *Countermeasure Developments* section. These are some additional options presented to our convening.

### **PABS+**

Some experts proposed an enhancement to the PABS system in Article 12. This “PABS+” model would require State Parties to fulfil binding up-front contingent contributions to an LMIC response fund according to a fair and equitable negotiated formula.<sup>145</sup> This, it is argued, would remediate a shortcoming experienced by the PIP Framework’s Partnership Contribution model. All LMIC contingent funding would be supported through grants and concessional financing by multilateral development banks. In turn, State Parties would be obligated to make pathogenic material and GSD available to the WHO’s laboratories to develop countermeasures. This could provide a more concrete exchange on both sides of the equation. To work, it was posited that the response fund would need to have at least US\$ 5 billion prior to the next emergency.

### **COMMON GOOD GOVERNANCE AND REASSERTING THE ROLE OF PUBLIC MEDICINE**

Some argued for a return to an older model where the public sector relied less on the private sector to advance breakthroughs for products that could be considered global public goods. For example, it was noted that many countries, including some in Europe, had public vaccine R&D and manufacturing prior to the 1980s. They also pointed to innovation-sharing models that apply open science principles that are worth emulating and to “common good governance” that can build on a broad range of examples from the area of cooperatives or publicly owned firms producing medicines, diagnostics, and vaccines; Butantan in Brazil and BioFarma in Indonesia were cited as examples, though it was also noted that these firms face many of the same realities as other companies.

Some noted that scientific or technological policies should be established through participatory and transparent processes and be implemented with accompanying transparency and accountability mechanisms.<sup>146</sup> This is not to say that the private sector should be excluded from innovating but to posit that the public sector should not be as dependant on the private sector as it has become. Public-private partnerships could be designed with public health outcomes as the objective to which all partners commit, with heightened awareness of how the partners share the benefits and risks.

### **BENEFIT SHARING FOR ACCESS TO CLINICAL TRIAL NETWORKS**

As articulated in WHO’s Guidance for Managing Ethical Issues in Infectious Disease Outbreaks,<sup>147</sup> and as demonstrated in the ACTIV clinical trials, individuals and communities participating in research should enjoy the benefits derived from their participation. There were stakeholders who thought this arrangement could be a more durable way to promote a better

balance in the access and benefit sharing equation. If incorporated into the accord, ensuring those who join a clinical trial can enjoy the benefits of their participation provides a firmer foundation and more proof of concept for a benefit sharing arrangement.<sup>148</sup>

## **PRIMARY HEALTH CARE AND UNIVERSAL HEALTH COVERAGE**

The importance of the right to health and a commitment to universal health coverage and primary health care are addressed throughout the draft accord. Developing these programmes and adequately financing them remain evergreen challenges. However, it was argued that having them in place during an infectious disease outbreak produces at least three broad classes of tangible benefits to individuals and communities. First, the treatment of patients produces clinical data that is useful in understanding the pathophysiology of disease, improving diagnosis and management, and enhancing public health surveillance. Second, collection of samples provides sequence data for humans and viruses, which are useful in the development of surveillance technologies, diagnostics, and medical interventions. Third, the use of experimental interventions in outbreaks provides information and tangible products such as vaccines and therapeutics. Some posited that broadening the discussion around pathogen sharing and access to countermeasures must include strengthening basic primary health care and including availability of benefits at the clinical level. Finally, it was argued that many people are more likely to trust the advice of public health authorities who are perceived as presiding over a functional and people-centric health system. This is important in ensuring public health guidance on prevention and treatment, and to promote uptake of new technologies.

# CONCLUSION

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**ALL EXPERTS IN OUR CONVENING** emphasised that we are in this together and that solutions are needed to achieve solidarity around making a fairer, more equitable world. Reinforcing this notion, on 20 September 2023, country leaders adopted a *Political Declaration of the United Nations General Assembly High-Level Meeting on Pandemic Prevention, Preparedness and Response* whereby they committed to make a “collective effort to strengthen developing countries capacity for increased innovation,” recognised “the critical role of international collaboration and cooperation in research and development and innovation, particularly in vaccine clinical trials,” and agreed to promote “the fair, equitable and timely sharing of benefits arising from the use of pathogens, sequences or any other materials.”<sup>149</sup>

These aspirations must take a whole-of-society approach, and as Professor Danwood Chirwa<sup>150</sup> reflected to our convening, “we need to come up with relevant, acceptable, and effective countermeasures in a timely manner. Implementation has to be participatory and collaborative. Because of the complexities that we are dealing with, it’s a balancing act in how we think about the opportunities and the challenges presented.”

# GLOSSARY/ACRONYMS

<b>ABS</b>	Access and Benefit Sharing
<b>ACPHEED</b>	ASEAN Centre for Public Health Emergencies and Emerging Diseases
<b>ACT Accelerator</b>	Access to COVID-19 Tools Accelerator
<b>ACTIV</b>	Accelerating COVID-19 Therapeutic Interventions and Vaccines
<b>Africa CDC</b>	Africa Centres for Disease Control and Prevention
<b>AMC</b>	Advance Market Commitment
<b>BARDA</b>	United States Biomedical Advanced Research and Development Authority
<b>CBD</b>	Convention on Biological Diversity
<b>CDC</b>	United States Centers for Disease Control and Prevention
<b>CEPI</b>	Coalition for Epidemic Preparedness Innovations
<b>COP</b>	Conference of the Parties
<b>COP-MOP</b>	Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol
<b>COVAX</b>	COVID-19 Vaccines Global Access
<b>CRBIP</b>	Centre de ressources biologiques de l'Institut Pasteur (Biological Resource Center of the Institut Pasteur)
<b>CTR</b>	Clinical Trial Regulation of the European Union
<b>DFC</b>	United States Development Finance Corporation
<b>DFI</b>	Development finance institutions
<b>DNDi</b>	Drugs for Neglected Diseases
<b>eCOA</b>	Electronic clinical outcome assessments
<b>EIB</b>	European Investment Bank
<b>FAO</b>	United Nations Food and Agriculture Organisation
<b>FDA</b>	United States Food and Drug Administration
<b>FNIH</b>	Foundation for the National Institutes of Health
<b>G7</b>	Group of Seven
<b>Gavi</b>	Now called "Gavi, the Vaccine Alliance", Gavi originally stood for the Global Alliance for Vaccines and Immunisation
<b>GDPR</b>	General Data Protection Regulation of the European Union
<b>GISRS</b>	Global Influenza Surveillance and Response System
<b>GSD</b>	Genomic Sequence Data
<b>ICESCR</b>	International Covenant on Economic, Social and Cultural Rights
<b>IFFIm</b>	International Finance Facility for Immunisation
<b>INB</b>	Intergovernmental Negotiating Body

<b>IP</b>	Intellectual property
<b>LMICs</b>	Low- and lower-middle income countries
<b>MPP</b>	Medicines Patent Pool
<b>MTA</b>	Materials Transfer Agreement
<b>O'Neill Institute</b>	O'Neill Institute for National and Global Health Law
<b>NIH</b>	United States National Institutes of Health
<b>PABS System</b>	Pathogen Access and Benefit Sharing System
<b>PAHO</b>	Pan-American Health Organization
<b>PDP</b>	Product development partnership
<b>PHEIC</b>	Public Health Emergency of International Concern pursuant to the International Health Regulations emic or public health emergency of international concern
<b>PIP Framework</b>	Pandemic Influenza Preparedness Framework
<b>PPPR</b>	Pandemic prevention, preparedness, and response
<b>R&amp;D</b>	Research and development
<b>RBM</b>	Roll Back Malaria Partnership
<b>SCL Network</b>	Supply Chain and Logistics Network
<b>SDV</b>	Source data verification
<b>SMTA</b>	Standard Materials Transfer Agreement
<b>STRIVE</b>	Strategies and Treatments for Respiratory Infections and Viral Emergencies
<b>TRIPS Agreement</b>	Trade-Related Aspects of Intellectual Property Rights Agreement
<b>UCT</b>	University of Cape Town
<b>UNEP</b>	United Nations Environmental Programme
<b>UNICEF</b>	United Nations Children's Fund
<b>WHO</b>	World Health Organization
<b>WIPO</b>	World Intellectual Property Organization
<b>WOAH</b>	World Organisation for Animal Health
<b>WTO</b>	World Trade Organization

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## ANNEX 1

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## ANNEX 2

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# DISCUSSION QUESTIONS

- 1. Innovation Models:** What case studies are you aware of that provide good models to emulate for innovating and delivering pandemic countermeasures? Why do they work and why are stakeholders incentivised to make them work? How can they be scaled? How could they be enhanced, or their shortcomings mitigated?
- 2. Clinical Trial Capacity:** The lack of clinical trial capacity was cited by the World Health Assembly, the African Union, the Fogarty Center at the US National Institutes of Health, and others as a significant bottleneck. What have various pandemics over the last half century (HIV-AIDS, Ebola, COVID-19) taught us about what needs to be addressed to tamp down this risk? What are the reasons clinical trial capacity has not been readily available and are there models that could be proposed?
- 3. Pathogen and Innovation Sharing Models:** What are some existing models you are aware of that (formally or informally) govern pathogen access and benefit sharing that could be deployed, expanded, or amended in the international governance of pandemics? What are the successes, limitations, and opportunities presented by these models? How are they financed?
- 4. Coupling Development and Deployment:** What are some of the trade-offs to acknowledge in coupling, or decoupling, activities related to the development and deployment of emergency countermeasures? What are the advantages and disadvantages of a singular, multilateral system to facilitate pathogen access and benefit sharing? If the INB were to delink pathogen access and benefit sharing, how could it do so while ensuring lower-income countries still have reliable, equitable access to countermeasures and other benefits? Please identify any case studies that offer effective models to emulate.
- 5. Nexus with the CBD:** The draft accord states that an access and benefits system shall be “consistent with, supportive of, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol.” See Article 12. The Nagoya Protocol states that “where a specialised international access and benefit-sharing instrument applies that is consistent with, and does not run counter to, the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialised instrument in respect of the specific genetic resource covered by and for the purpose of the specialised instrument.” See Article 4.4. Given this, what flexibilities does the INB have to craft an innovative, fit-for-purpose ABS regime covering biological material with epidemic and pandemic potential and associated genetic sequence data? Conversely, how constrained is the INB to follow the particularised detail of the Convention and Protocol notwithstanding Article 4.4 (or other provisions)?

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