Q&A Summary

**Question 1: Has there been progress in Indonesia to ensure access to global vaccines and therapeutics derived from data provided by Indonesia?**

Ronald Eberhard Tundang: I think Indonesia has made two significant moves in the last few years. In 2022, Indonesia became part of the WHO mRNA tech transfer program. One of Indonesia’s state-owned enterprises, Big Pharma, has been designated to receive the benefits of this technology and is currently working on developing mRNA vaccines not only for COVID-19 but also for other diseases. Last year, the same enterprise entered a 10-year partnership with the Coalition for Epidemic Preparedness Innovations (CEPI) to increase production capacity, aiming to establish Indonesia as a regional hub in Southeast Asia. I believe this is one example of an industrial policy that the government of Indonesia is pursuing to enhance its capacity. Additionally, since Indonesia has a relatively high burden of tuberculosis, the government announced this year plans to conduct clinical trials for TB vaccines, in collaboration with GlaxoSmithKline and cansino biologics, a Chinese company. With all these examples, I think Indonesia is taking more steps in industrial policy to increase its pharmaceutical manufacturing capacity. I’ll stop there, just to provide those examples.

**Question 2: Thanks for the presentation. I am Dr. Myat Htut Nyunt from Myanmar. I agree that data sharing is important and increasingly popular. However, when multiple platforms are available for data sharing, what considerations should guide the selection of one over the others? Additionally, should we share all databases or focus on just one? If someone shares the same data across multiple databases, what impact might this have?**

Nicki Tiffin: This is a great question, and I think it highlights the need to move away from the idea that there’s only one way to share data, which is simply handing it over. I think the answer depends—while “it depends” may not sound helpful, the factors it depends on are important. For example, consider what you’re comfortable with regarding how the data will be used going forward. If you’ve collected data from participants, you might have concerns. For me, a real issue arises when people map out the locations of individuals with specific infectious diseases. So, it's about reflecting on what you consider ethical for the onward use of the data and, in terms of equity, how much involvement you want in its further use. Then, check the conditions you’re agreeing to when you upload to a database.

I think it’s essential to read the fine print and confirm what rights or oversight you retain. Match this with the level of oversight you wish to maintain. Sometimes, you may not need any oversight for onward use, and that’s fine. In such cases, the data's location is less relevant. However, at times, you may have concerns. For example, the misuse of pathogen data could negatively impact public health messaging if it’s misinterpreted, especially if subsequent research yields inaccurate results. It’s crucial to consider your requirements for onward data use. This is also part of your ethical responsibility as a researcher: weighing potential benefits against possible harms. I believe this is a process to work through. Personally, I don’t see any harm in storing data in multiple locations. A reliable database should allow you to link to access IDs from other platforms, so there’s no harm in maintaining data in multiple places. It might increase your workload slightly if you’re involved in sharing the data, but ultimately, it’s a matter of assessing the ethical considerations of each situation.

**Question 3: When the ABS discussions in health began, it was due to “big pharma” (typically from the global north) developing products that were not being made available at affordable prices to the lower-income countries. Now as countries like India, Indonesia, South Korea, and others in the region slowly build their own powerhouse pharma R&D and manufacturing capabilities, access to sequences and biological materials will become increasingly more important to these companies. Are these pharma companies positioned to abide by the ABS regulations that are being set by their own countries, and navigate the complicated ABS requirements of other countries in the region?**

Kashish Aneja: I think it's a really good question because you're right. When initial ABS discussions happened, times were different. And right now, we’re seeing much more local manufacturing capacity in LMICs, especially in India. Specifically, to your question, I am honestly less concerned about the ability of pharma companies to comply with the regulations. I think they have enough resources, both human and financial, to actually comply with the regulations - often having the right incentive would help in complying.

I’m more worried and concerned about those regulators having the intent to enforce the actual laws and policies. We’ve seen—for example, in India—that countries with local manufacturing capacities are less inclined to withhold access to data because withholding access often goes against their own interests when they have the capacity to regulate. They would rather provide open access to data and use that leverage to negotiate better prices or IP rights. For instance, during the COVID-19 pandemic, Bharat Biotech received the pathogen sequence from the Indian government and manufactured a vaccine. The Indian government did not impose any ABS regulations, at least as far as is publicly known. We’ve seen a shift between countries with extensive manufacturing capacities and those without such capacities are generally more hesitant about sharing data without attaching terms and conditions.

Ronald Eberhard Tundang: On the question of access and benefit sharing, I’d like to highlight a few points. First of all, it’s obviously essential, but I think one of the missing elements here is how to ensure that ABS is actually implemented at a practical level. From what we’ve seen in the industry, it hasn’t been widely implemented. So, I think what needs to be done is to provide incentives. What kinds of incentives should governments put in place to ensure that ABS is honored? I think this would also encourage countries to share data across borders and help build trust, fostering a more collaborative environment.

We have the rules, the protocol, and of course, the ongoing pandemic treaty agreement. But based on experiences not only with the Nagoya Protocol but also with the PIP Framework, the main challenge is at the practical level—how to ensure that pharmaceutical companies truly comply and that governments provide incentives without significantly increasing the operational costs for these companies to manufacture. I think I’ll leave it there for now.

**Question 4: While the discussion centers on pathogens of pandemic potentials, there are also other pathogens (AMR bacteria, fungi, etc.) that are of significant burden but are not necessarily visible in the agenda. Can these be used as platforms to initiate and sustain regional data sharing? And would the un-urgency of these pathogens affect willingness and policy framework on sharing? Thank you.**

Nicki Tiffin: So, obviously, since we recently had a pandemic, and before that the Ebola crisis in West Africa, it has really woken everyone up to the fact that we need to be better prepared. But I think, as people working in this space and as researchers, we should definitely leverage this opportunity to create better processes across the board. Equally, we don’t know which of these relatively low-profile endemic pathogens might cause the next crisis. So, I think we need to avoid tunnel vision around specific microbes and ensure we develop solutions that can be generalized. You’re absolutely right that, when we’re not dealing with an immediate crisis from a particular microbe or pathogen, it’s the ideal time to focus on setting up effective, robust systems. This way, we can be prepared across the board rather than reacting in an emergency situation.Thanks.

**Question 5: Excellent panel of speakers - thank you! There is an increasing proportion of digital sequence data produced by government-funded diagnostic and public health genomics laboratories rather than research entities. Researchers are inherently keen to publish their research and share their data so the governance of health service data could be different to research data. Would be good for panel members to reflect on that. - Vitali Sintchenko, University of Sydney, Australia**

Kashish Aneja: I’ll just give a quick answer to that since it flows from the presentation. There is genuine confusion across different countries regarding the applicability of their domestic laws on DSI. For example, in 2019, India stated at the UN that DSI is regulated under the ABS mechanism in India. I think each regulator needs to clarify their position on DSI domestically to make things clearer for everyone. So, I definitely think that’s needed.

Nicki Tiffin: I think it's quite a tricky area to navigate. I’m a researcher, but I have also worked in the health service. In our context, I’m not sure researchers are particularly sensitive to the requirements of public health laboratories within the health service. What we also see is that public health laboratories sometimes lack, for example, bioinformatics capacity to conduct extended research, as they are focused on health service delivery. So, I think there’s a real opportunity for collaboration, where the research environment can support the public health environment, and the public health environment can generate data useful for research. However, this will only work if researchers are aware that health service delivery is the primary goal of public health laboratories. Researchers need to understand, firstly, that public health laboratories are not doing this to publish papers—they’re doing it to deliver health services. Secondly, public health laboratories have a significant responsibility to generate accurate data, analyses, and messaging, as any inaccurate messaging from a public health lab can create a major crisis—a crisis of public confidence or even issues within the health service. The checks and balances in public health service delivery are very different from those in research. So, researchers need to be mindful of this, respectful of these differences, and approach collaboration with public health laboratories carefully and collaboratively.

Ronald Eberhard Tundang: I don’t have much to add, but one key element here is the need for harmonization. If DSI is applicable in one jurisdiction, then when data is transferred from one country to another, there needs to be a set protocol in place to avoid increasing compliance costs for pharmaceutical companies or laboratories. One of the complexities here is that if we have different formats for DSI, companies will face increased compliance costs, which will then burden the industry. Again, incentives will need to be put in place to encourage the application of DSI. I'll stop there.

**Question 6: COP16 agreed to establish a multilateral benefit-sharing mechanism from the use of Digital Sequence Information (DSI), which involves establishing a global fund to support biodiversity conservation that industry pays into for utilizing DSI. How do you foresee this multilateral mechanism impacting national ABS regulations (as it relates to human health) in South and Southeast Asia? —Ruvani Chandrasekera, Global Health Security Advisor (Independent)**

Kashish Aneja: We are seeing similar developments regarding the establishment of a multilateral ABS mechanism in the Pandemic Treaty, specifically in Article 12. They are essentially trying to achieve the same goal, which concerns me a bit as these efforts are happening in parallel. Even with Article 12 in the Pandemic Treaty, you’ll see that there is a requirement to provide annual monetary compensation to the overall system, quite similar to what you pointed out in the COP. If this mechanism is realized, domestic laws would require updates to align with either system, whether it is related to the Pandemic Treaty or the COP. However, there's a big "if" because we’ve seen significant backlash against Article 12 in the Pandemic Treaty—whether the system should be voluntary, what percentage should go towards benefit sharing, and whether non-exclusive licensing and manufacturing capacities should be part of this mechanism. The language of the multilateral system will be very important, and how it is adapted domestically is equally important in this context.

Ronald Eberhard Tundang: I'll just circle back to the argument that, obviously, when industries are required to contribute to the Global Fund, it increases their compliance and operational costs for producing a drug. This might create new challenges where government intervention could become necessary, especially since, in many developing countries, domestic industries may struggle to compete with international companies if these contributions affect their pricing structures. This is where incentives will need to be implemented. For example, many developed countries have heavily invested in resources and development subsidies. Developing countries could take a cue from this approach to determine how best to set up subsidies and which companies to target to support their industries, as competing with big pharma already poses enormous challenges. The increased cost of complying with DSI requirements will add another challenge for small and medium-sized companies in developing countries.

Kashish Aneja: Just to add to what Ronald just said, I feel that we are moving into a time when, if one country refuses to share pathogen data, you can always look to another country that would be willing to share the data. Therefore, incentivising the industry to choose a better system is definitely important. Personally, I’m more in favor of technology transfer as an idea, rather than the ABS mechanism itself, as it would yield much more results, I would say.

**Question 7: To Nicki: Wondering why equitable access to benefits is not included in the “baseline rules” you’ve developed? To Kashish: Let’s say I’m an academic scientist working in a lab in India, and I share the pathogen data with a colleague — do I need to get approval under the BDA for such scientific collaboration?**

Nicki Tiffin: With the microbial data-sharing accord, we tried to consider the baseline factors that are relevant in every sharing arrangement. For example, imagine a situation where someone has uploaded their data to a database with open access, and someone else has downloaded that data for further use. In such an environment, it’s not really possible to have a benefit-sharing arrangement. Obviously, that’s what we would like to see, but it’s not a practical expectation for the person who downloaded the open-access dataset. On the other hand, the other seven clauses are reasonable in terms of where those things can, where possible, be achieved. So, in the MOU Builder and the data-sharing agreement builder, as well as the specimen-sharing agreement builder, there’s a section that prompts users to ask if they have a benefit-sharing plan. In that prompt, we also reference the framework so that if people think, “Well, I don’t have a benefit-sharing plan, but I should,” they actually have a tool they can use to think about what benefit-sharing might work. While we’d like it to be a requirement, I think it would be an unfair ask as a baseline for every sharing interaction. That’s the thinking behind it—it's not always implementable, given the different ways we share. And I just want to comment on the question that was asked by Kashish: even if you don’t need approval under the BDA, there’s this fantastic online MOU builder that you and your colleague can use for that interaction.

Kashish Aneja: Thanks for this question. So, as for the law, strictly speaking, if you're in India and you want to share pathogen data with a colleague, it first depends on where your colleague is located. If they are in India or outside India, the requirements differ. If they are in India, you don’t need any approval from the BDA to ‘share’ the data. However, if they are outside India, any international transfer requires approval from the BDA. As far as your colleague is concerned, unless they intend to commercialize the research in India, they don’t need approval. But if they are in India and want to commercialize it or apply for intellectual property rights, they need to seek approval from the BDA. At the time of each approval, the authority will impose certain terms and conditions, which will form part of the ABS agreement.

**Question 8: Is there any social media account maintained by ASEAN Centre for Public Health Emergencies and Emerging Diseases (ACPHEED), so that we can follow updates from and activities organized by the center?**

Ronald Eberhard Tundang: I don't think they have one currently. But you can check some updates here:

* [ASEAN Centre for Public Health Emergencies and Emerging Diseases (ACPHEED)](https://jaif.asean.org/whats-new/asean-center-for-public-health-emergencies-and-emerging-diseases-acpheed/)
* [Japan to Invest Rp743 Billion in ACPHEED - ASEAN Indonesia 2023](https://asean2023.id/en/news/japan-to-invest-rp743-billion-in-acpheed)