



Legal Frameworks and Data Sharing for Pathogen Genomics

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Legal frameworks for data sharing

History, overview, existing mechanisms



Challenge #1: Pathogen vs patient data



Challenge #2: Data sharing within the country and material and data transfer agreements



Challenge #3: Data sharing across borders

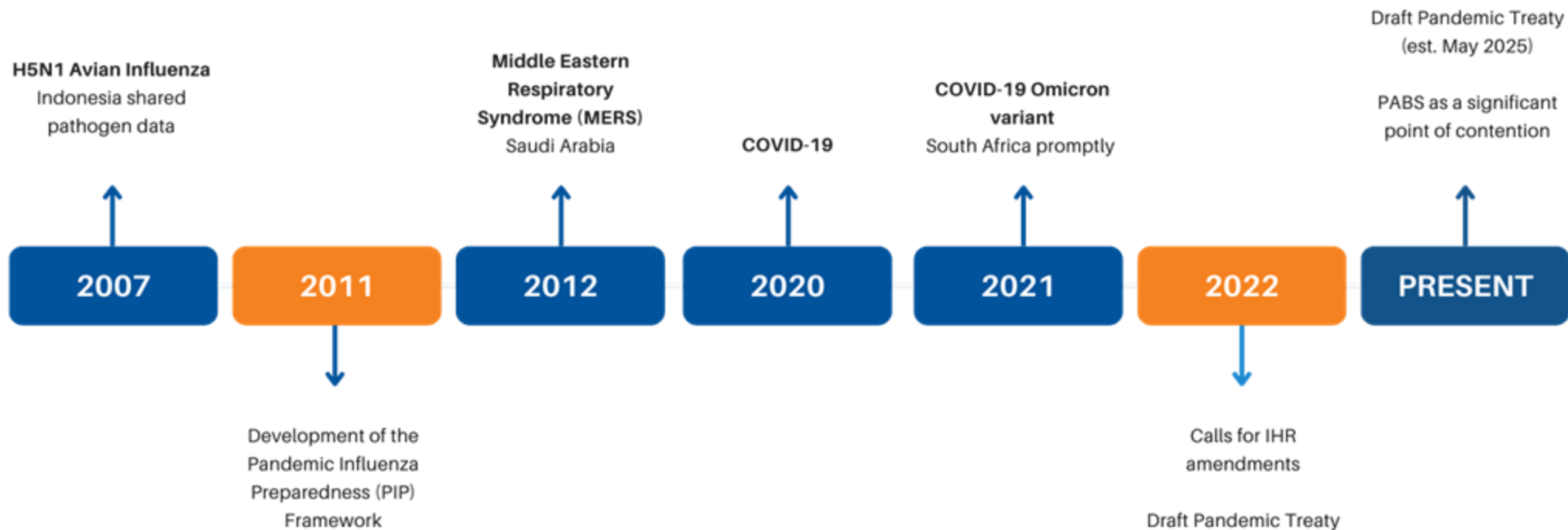


Solutions

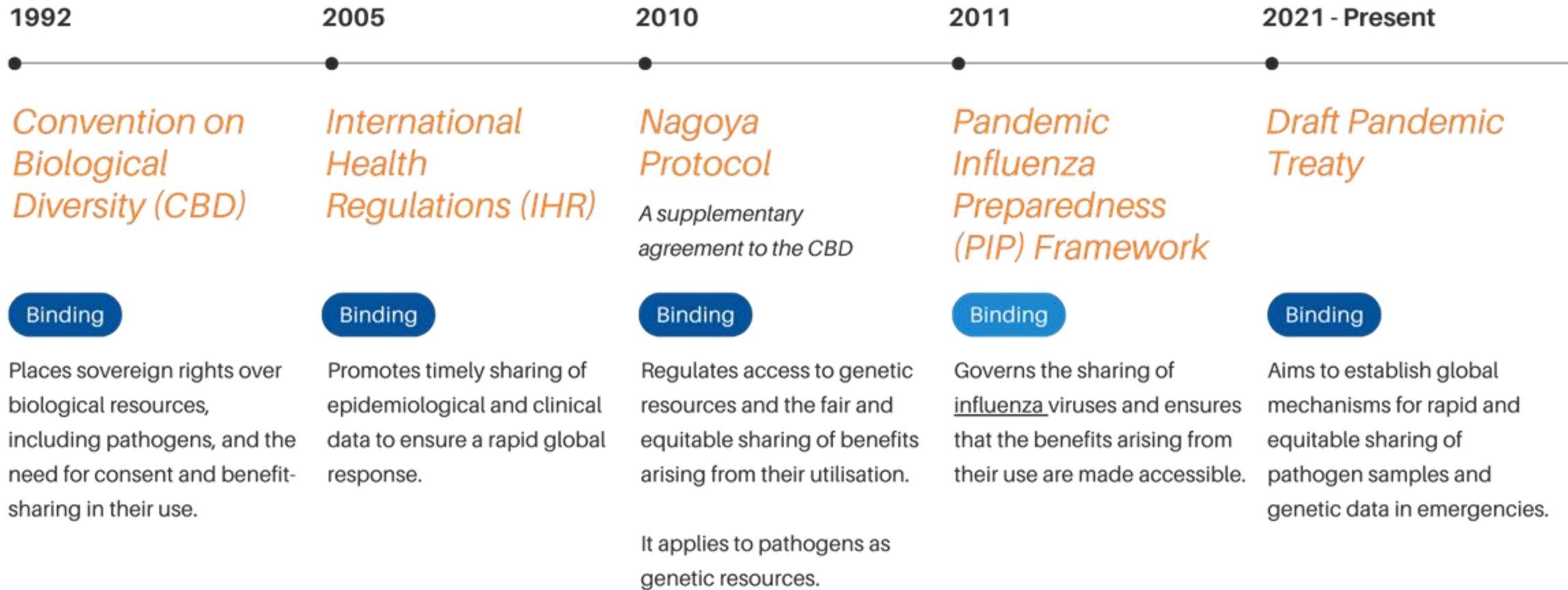


Pathogen access and benefit sharing

A history



Key legal instruments - Global



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2021 - Present

Draft Pandemic Treaty

Binding

Aims to establish global mechanisms for rapid and equitable sharing of pathogen samples and genetic data in emergencies.

Article 3: General Principles

Overarching principles, e.g. solidarity, transparency, and cooperation – applicable to pathogen sharing.

Article 14: R&D

Promote global collaboration in R&D, i.e. developing vaccines, diagnostics, and treatments by sharing genetic sequences and related data.

Article 6: Surveillance and Notification

Outlines obligations for countries to enhance surveillance and notification systems; provisions for sharing pathogen data.

Article 16: Fair and Equitable Benefit Sharing ★

Provisions for equitable distribution of vaccines, diagnostics, and other health products derived from shared pathogen data.

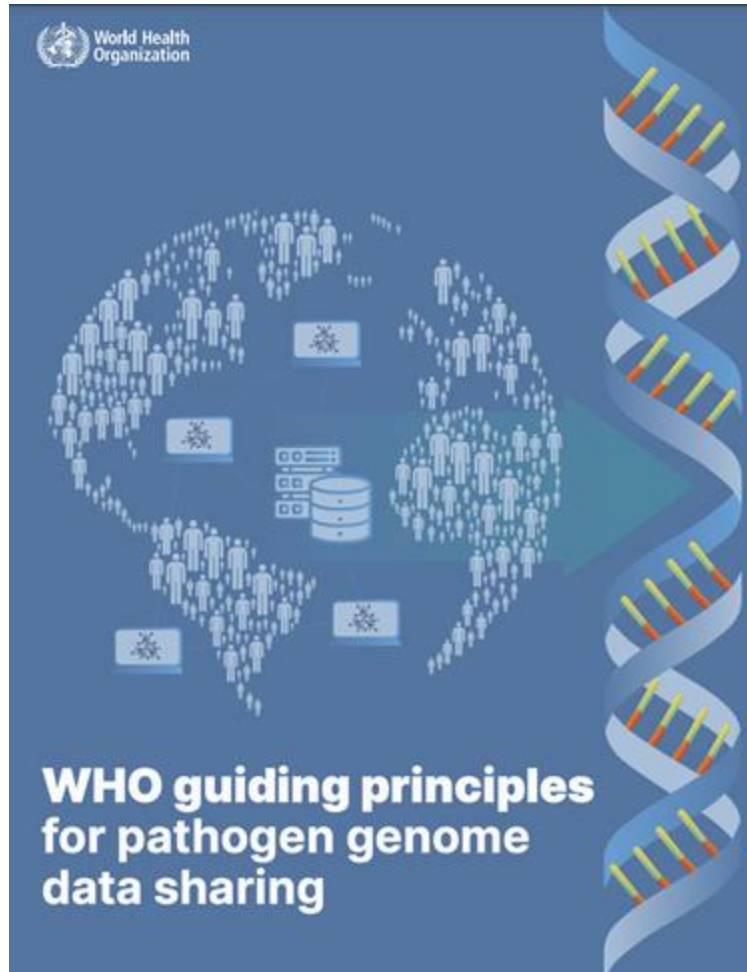
Article 10: Access to Pathogen Samples and Genetic Sequence Data ★

Rapid and equitable sharing of pathogen samples and genetic sequence data during health emergencies; access to LMICs.

Article 20: Digital Health and Data Infrastructure

Development of digital infrastructures that support the secure and efficient sharing of pathogen data





1. *Capacity development*
2. *Collaboration and cooperation*
3. *High-quality, reproducible data*
4. *Global and regional representativeness*
5. *Timeliness*
6. *Acknowledgement and intellectual credit*
7. *Equitable access to health technologies as a benefit*
8. *As open as possible and as closed as necessary*
9. *Interoperability and relevance for national, regional and global decisionmakers*
10. *Trustworthiness and ease of use*
11. *Transparency*
12. *Consistency with applicable law and ethical regulations*
13. *Compliance and enforcement*



Data Sharing Accord - PHA4GE

Provides a baseline set of conditions for the secondary use of data that are shared openly



1. Attribution



2. Overview of
outputs prior
to publication



3. Onward
sharing of data



4. Host and
phenotype
data



5. Geospatial
data



6. Intellectual
Property



7. Opportunity
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Regional efforts



Pathogen data vs. Patient data

Privacy Risks in Pathogen Data Sharing

☐ Pathogen genome data



☐ Human genome data mixed in and shared



1. Raise awareness and establish baseline practice

2. Curation controls to prevent raw data sharing

☐ Metadata



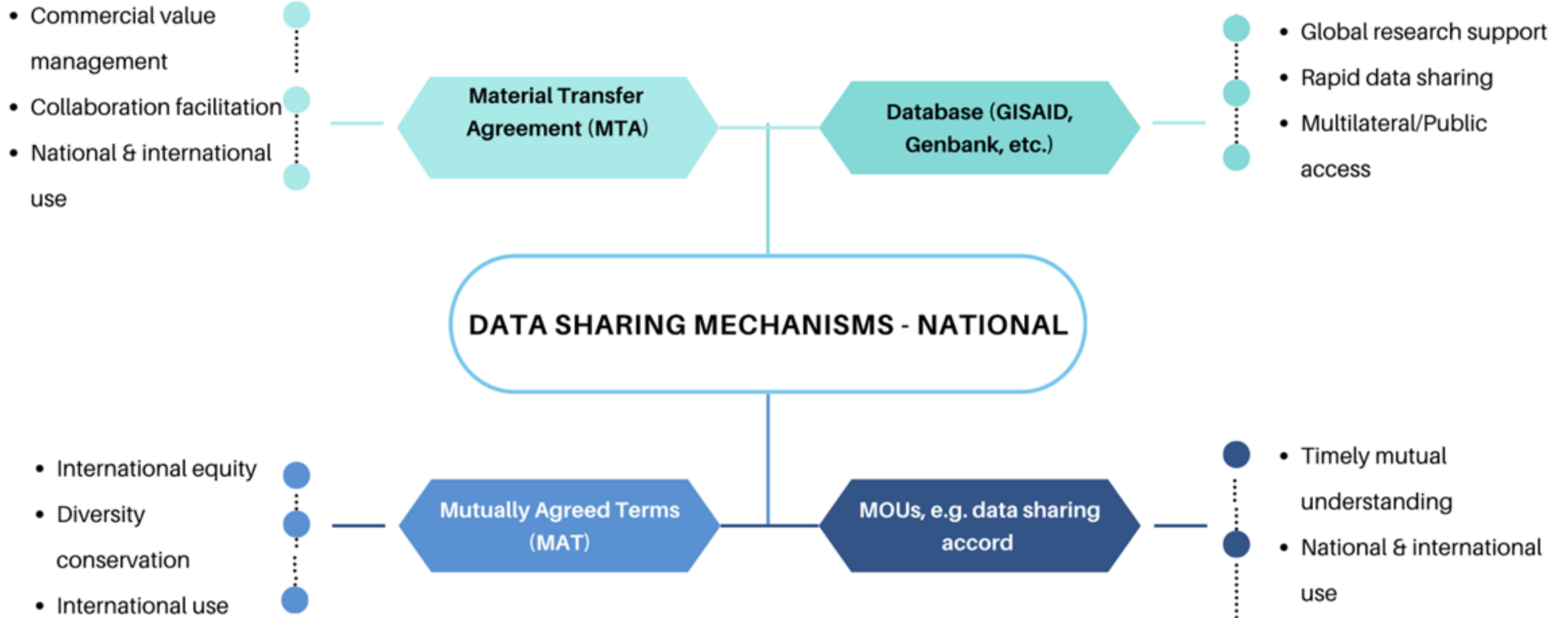
1. Rigorous legal assessment on metadata collection

2. Metadata standardization

Presented with xmind



Data sharing mechanisms - national

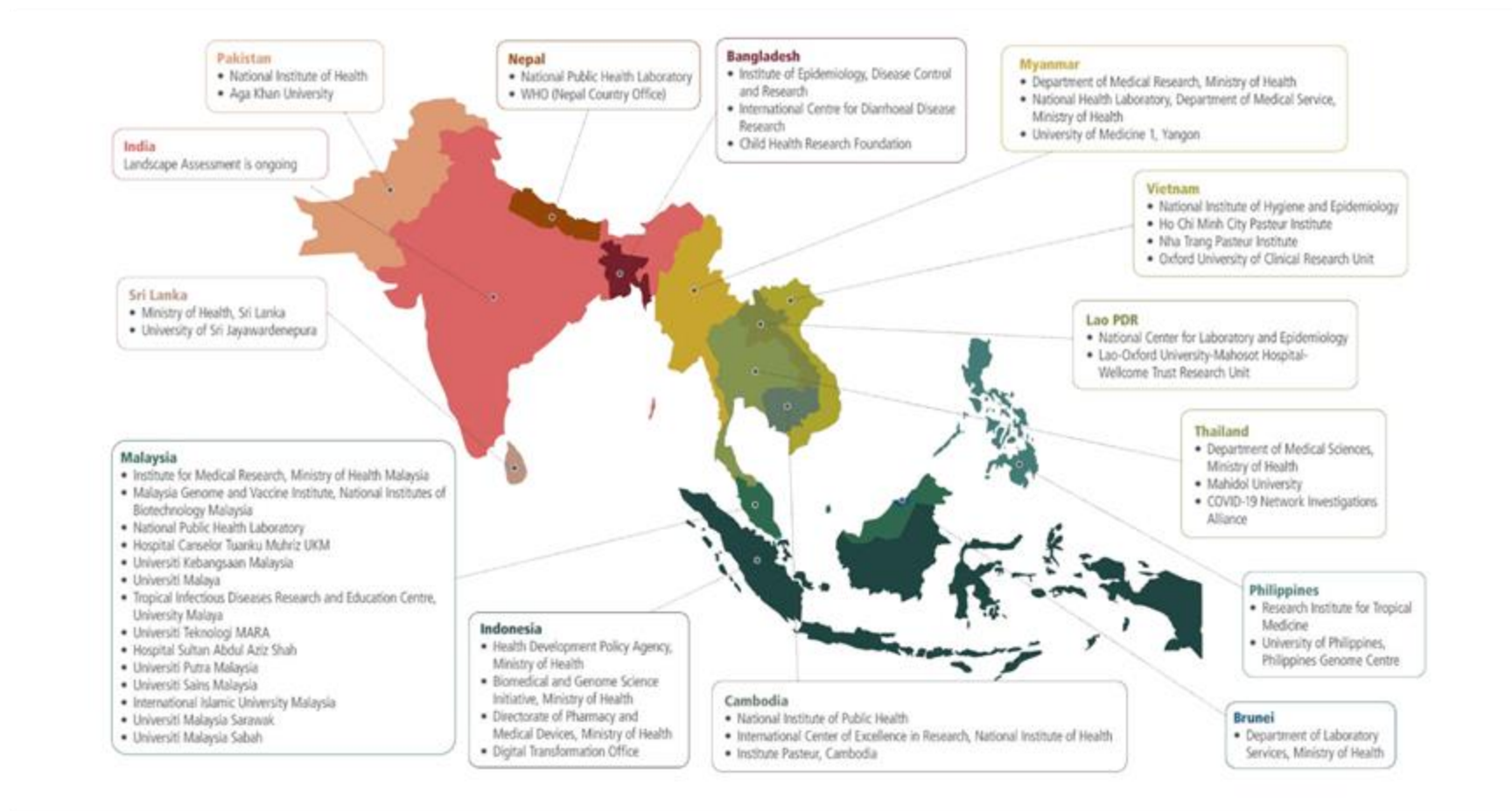


Data sharing platforms

	Benefits	Obstacles	Onward Data Sharing Allowed?
National platforms	<ul style="list-style-type: none">• Tailored to national policies and needs, compliance with local regulations• Data security and sovereignty	<ul style="list-style-type: none">• Limited cross-border data sharing• Inconsistent data formats and standards (e.g. interoperability between agencies)• Risk of data isolation	Restricted
Private platforms e.g. Google, AWS	<ul style="list-style-type: none">• Global reach and infrastructure• Wide range of services (e.g., storage, computing, AI and machine learning)• High scalability and flexibility• Advanced security features	<ul style="list-style-type: none">• Data sovereignty issues• High operational costs• Dependency on a single service provider	Yes, with user control
Global platforms, e.g. GISAID	<ul style="list-style-type: none">• High-quality, curated pathogen data• Trusted platform with wide participation• Promotes global collaboration	<ul style="list-style-type: none">• Restricts onward sharing of data• Limited accessibility to certain user groups• Controversy over data access and governance transparency	No



What can we do as a region?



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TECHNICAL SUPPORT

Legal landscaping, identification of strengths and gaps, webinars, workshops, knowledge exchange

REGIONAL DATA SHARING AGREEMENT

Consensus-building between countries in the region pre-outbreak

ACCESSIBILITY

Offline/online platforms, interoperability

CLOUD PLATFORMS

Sovereign cloud-based computing, private platforms, blockchain

Pakistan

- National Institute of Health
- Aga Khan University

Nepal

- National Public Health Laboratory
- WHO (Nepal Country Office)

Bangladesh

- Institute of Epidemiology, Disease Control and Research
- International Centre for Diarrhoeal Disease Research
- Child Health Research Foundation

Myanmar

- Department of Medical Research, Ministry of Health
- National Health Laboratory, Department of Medical Service, Ministry of Health
- University of Medicine 1, Yangon

Vietnam

- National Institute of Hygiene and Epidemiology
- Pasteur Institute
- Institute of Clinical Research Unit

India

Landscape Assessment is ongoing

Sri Lanka

- Ministry of Health
- University of Sri Lanka

Malaysia

- Institute for Medical Research
- Malaysia Genome Centre
- Biotechnology Research Centre
- National Public Health Laboratory
- Hospital Canselor
- Universiti Kebangsaan Malaysia
- Universiti Malaysia Sarawak
- Tropical Infectious Diseases Research and Education Centre, University Malaysia
- Universiti Teknologi MARA
- Hospital Sultan Abdul Aziz Shah
- Universiti Putra Malaysia
- Universiti Sains Malaysia
- International Islamic University Malaysia
- Universiti Malaysia Sarawak
- Universiti Malaysia Sabah

Indonesia

- Health Development Policy Agency, Ministry of Health
- Biomedical and Genome Science Initiative, Ministry of Health
- Directorate of Pharmacy and Medical Devices, Ministry of Health
- Digital Transformation Office

Cambodia

- National Institute of Public Health
- International Center of Excellence in Research, National Institute of Health
- Institute Pasteur, Cambodia

Philippines

- Research Institute for Tropical Medicine
- University of Philippines, Philippines Genome Centre

Brunei

- Department of Laboratory Services, Ministry of Health



In your country, what challenges have you encountered when trying to share pathogen data regionally or internationally, and how have you addressed these challenges?





Thank you

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