



ASIA PGI WEBINAR SERIES

DATA SHARING IN PATHOGEN GENOMICS – WHAT’S THE WAY FORWARD?

3:00 – 4:15 PM SGT
Wednesday, 13 November 2024



ASIA PATHOGEN
GENOMICS Initiative



Centre for
Outbreak Preparedness

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HOST

Elyssa Liu
Lead, Legal
Frameworks, Centre for
Outbreak Preparedness
(COP)



SPEAKER

Ronald Tundang
Consultant, COP &
Universitas Gadjah
Mada



SPEAKER

Kashish Aneja
Consultant, COP

Lead, initiatives in Asia,
O'Neill Institute for
National and Global
Health Law



SPEAKER

Nicki Tiffin
Deputy Director, South
African National
Bioinformatics Institute

Chair, Ethics and Data
Sharing Working
Group, PHA4GE

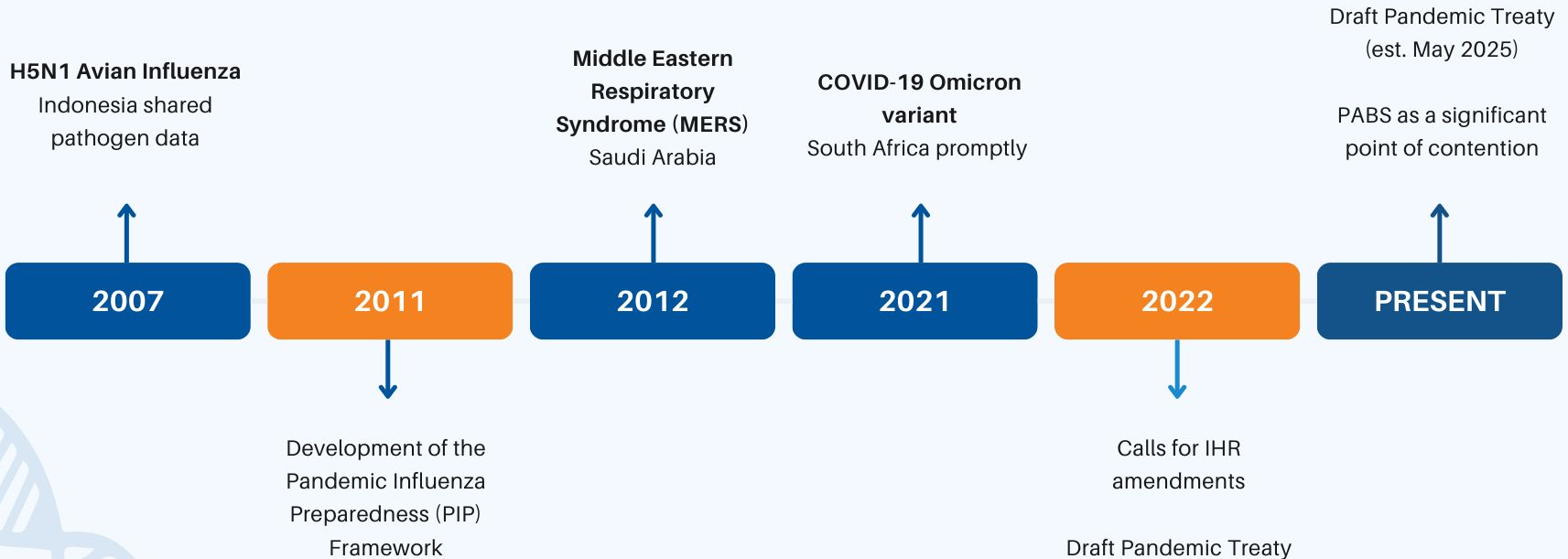


MODERATOR

Yimei Sun
Research Associate,
COP

Pathogen access and benefit sharing

A brief history



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Perspectives from ASEAN and Indonesia

Ronald Tundang

Consultant, Centre for Outbreak Preparedness &
Universitas Gadjah Mada

Associate, International Institute for Sustainable
Development



Enhancing Pathogen Genomic Data Sharing in Southeast Asia: Opportunities and Challenges

RONALD EBERHARD TUNDANG

CONSULTANT, CENTER FOR OUTBREAK PREPAREDNESS, DUKE-NUS MEDICAL SCHOOL

Importance of Data Sharing in Pathogen Genomics

Global Health Implications: How data sharing helps in tracking disease outbreaks (e.g., COVID-19, SARS, H1N1, H5N1).

Benefits for ASEAN: The region's vulnerability to infectious diseases due to high biodiversity and population density

Enhancing response: How shared data can improve outbreak response and preparedness

Current Landscape in ASEAN



Existing Initiatives:

[ASEAN Strategic Framework for Public Health Emergency](#)

[ASEAN Center for Public Health Emergencies and Emerging Diseases](#)

[ASEAN BioDiaspora](#)



Case studies:

[Avian Influenza Control in ASEAN](#)

[Dengue Prevention and Control in ASEAN](#)

Challenges and Barriers

- Policy and Legal Issues:
 - Intellectual property concerns
 - Data sovereignty
- Institutional Issue: Lack of (supra)national body in ASEAN
- Resource Disparities: Variations in funding and infrastructure among member countries

***Recommendations
and Strategies***



Policy Harmonization



Capacity Building



Investments

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Perspectives from India

Kashish Aneja

Consultant, Centre for Outbreak Preparedness

Lead, initiatives in Asia, O'Neill Institute for National
and Global Health Law

Pathogen Genomics Surveillance and Data Sharing: Perspectives from India

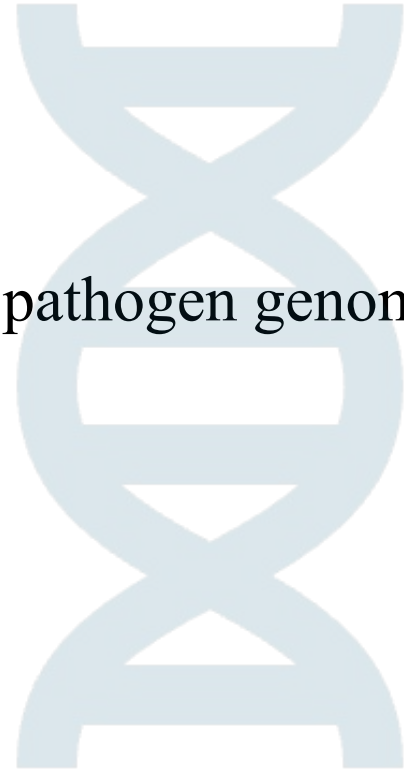
Kashish Aneja

Consultant, Centre for Outbreak Preparedness, Duke-NUS

Lead, Initiatives in Asia, O'Neill Institute for National and
Global Health Law, Georgetown University

Agenda

- Legal, policy and governance landscape of pathogen genomic sequence and data sharing in India
- Key Issues and Gaps
- Looking Ahead



**Law and
Governance
of Pathogen
Genomics
Surveillance
and Data
Sharing in
India**

Access and Benefit Sharing

Storage and Sharing of Biological Data

International Data Sharing

Intellectual Property Rights

Data Protection and Security

Consent

Ethics

Laws facilitating Collaboration & Stakeholder Engagement

Genetic Discrimination

One Health

Public Health Surveillance

Public Health Surveillance

- **Integrated Disease Surveillance Programme (IDSP):** Integration & decentralization of surveillance activities through establishment of surveillance units at Centre, State & District.
- **Indian SARS-CoV-2 Genomics Consortium (INSACOG):**
 - To ascertain the status of Variants of Interest (VoI) and Variants of Concern (VoC) in the country;
 - To establish sentinel surveillance and surge surveillance mechanisms for early detection of genomic variants and assist in formulating effective public health response;
 - To determine the presence of genomic variants in samples collected during super-spreader events and in areas reporting increasing trend of cases/deaths etc.
- **Alliance for Pathogen Surveillance Innovations (APSI)-India:** multi-city consortium backed by the Rockefeller Foundation
- **GenomeIndia Project:** ‘10,000 genome project’
- In 2008, the **Indian Genome Variation (IGV) consortium** was one of the first such initiatives to develop a large-scale database of genomic diversity in India
- **Government Departments/Agencies:**
 - National Centre for Disease Control (NCDC)
 - Department of Biotechnology (DBT)
 - Indian Council of Medical Research (ICMR)
 - Council for Scientific & Industrial Research (CSIR)

Access and Benefit Sharing

- Biological Diversity Act, 2002
- Rules 2004
- Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations (ABS Regulations), 2014
- Amendment, 2023
- The National Biodiversity Authority (NBA), the State Biodiversity Boards (SBBs) and the Biodiversity Management Committees (BMCs) oversee the implementation of the Act and Rules at national, state, and local levels respectively.

Access and Benefit Sharing

- The BDA regulates biological resources, which is defined under the law as *plants, animals, microorganisms, or parts of their genetic material and derivatives (excluding value-added products), with actual or potential use or value for humanity, but does not include human genetic material*
- The law specifically excludes human genetic material from the scope of the definition.
- Microorganisms or pathogens (including vectors of human diseases) found in human body would still be considered as biological resources.
- While the BDA does not include explicit reference to Digital Sequence Information (DSI) or any such terminology, the relevant provisions in the Act can cover in their scope the utilization of DSI. [India's submission on Digital Sequence Information on Genetic Resources in response to CBD notification 2019-012 dated 5 February 2019 pursuant to decisions 14/20 and NP-3/12]
- Legal Status of the person/entity: Indian and non-Indian
- Classifies access and use of biological resources and knowledge associated thereto for certain specific purposes: (i) commercial utilization, (ii) research, and (iii) bio-survey and bio-utilization.

India's submission on Digital Sequence Information on Genetic Resources in response to CBD notification 2019-012 dated 5 February 2019 pursuant to decisions 14/20 and NP-3/12

a) *To clarify the concept, including relevant terminology and scope, of digital sequence information on genetic resources and if and how domestic measures on access and benefit-sharing consider digital sequence information on genetic resources;*

(b) *On benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources.*

Access and Benefit Sharing

PHASE 1: Access by applicant: through approval (constituting PIC) from institutional structures



PHASE 2: Benefit sharing: through signing of MAT and actual sharing with competent authority



PHASE 3: Distribution of benefits: to benefit claimers by competent authority either directly or through biodiversity funds

ABS Implementation in India

Access and Benefit Sharing

Phase 1: Access to Biological Resources

- Approvals to be sought by non-Indians for access
- Approvals to be sought by Indians for access for commercial utilization
- Approvals for international data sharing [transferring ‘results of research’]
- Approvals for seeking intellectual property rights

Access and Benefit Sharing

Phase 2 and 3: Benefit Sharing Mechanisms

*Fair and Equitable
Sharing of Benefits:*

Grant of joint ownership of intellectual property rights to NBA, or where benefit claimers are identified, to such benefit claimers

Transfer of technology

Location of production and R&D units in areas that would facilitate better living standards to the benefit claimers

Association of Indian scientists, benefit claimers and local people with R&D in and bio-survey and bio-utilization

Setting up of venture capital fund for aiding the cause of benefit claimers

Payment of monetary compensation & non-monetary benefits to benefit claimers as suggested by NBA. The ABS Regulations 2014 lists the statutory options available for both monetary and non-monitory compensation.

Access and Benefit Sharing

Phase 2 and 3: Benefit Sharing Mechanisms

Fair and Equitable

Sharing of Benefits

Options [Regulations, 2014]

Monetary benefits options:

- (i). Up-front payment;
- (ii). One-time payment;
- (iii). Milestone payments;
- (iv). Share of the royalties and benefits accrued;
- (v). Share of the license fees;
- (vi). Contribution to National, State or Local Biodiversity Funds;
- (vii). Funding for research and development in India;
- (viii). Joint ventures with Indian institutions and companies;
- (ix). Joint ownership of relevant intellectual property rights.

Non-monetary benefits options:

- (i). Providing institutional capacity building, including training on sustainable use practices, creating infrastructure and undertaking development of work related to conservation and sustainable use of biological resources;
- (ii). Transfer of technology or sharing of research and development results with Indian institutions/ individuals/entities;
- (iii). Strengthening of capacities for developing technologies and transfer of technology to India and/or collaborative research and development programmes with Indian institutions/ individuals/ entities;
- (iv). Contribution/ collaboration related to education and training in India on conservation and sustainable use of biological resources;
- (v). Location of production, research, and development units and measures for conservation and protection of species in the area from where biological resource has been accessed, contributions to the local economy and income generation for the local communities;
- (vi). Sharing of scientific information relevant to conservation and sustainable use of biological diversity including biological inventories and taxonomic studies;
- (vii). Conducting research directed towards priority needs in India including food, health and livelihood security focusing on biological resources;
- (viii). Providing scholarships, bursaries and financial aid to Indian institutions/ individuals preferably to regions, tribes/ sects contributing to the delivery of biological resources and subsequent profitability if any;
- (ix). Setting up of venture capital fund for aiding the cause of benefit claimers;
- (x). Payment of monetary compensation and other non-monetary benefits to the benefit claimers as the NBA

Access and Benefit Sharing

Total Applications Received		8366
Approvals granted and Agreement Signed	Access to Bioresources for Research/ Commercial Purposes [Form I]	746
	Transfer of Research Results [Form II]	45
	Approval for obtaining IPRs [Form III]	4279
	Third Party Transfer [Form IV]	34
	Form B	189
	Total	5293

Storage and Sharing of Biological Data

- **The Indian Biological Data Centre (IBDC)** (also known as Data Repository or National Biological Knowledge, Information and Data Centre)
- **BIOTECH-PRIDE Guidelines (Promotion of Research and Innovation through Data Exchange), July 2021** to facilitate and enable sharing and exchange of biological knowledge, information and data generated through research *conducted within the country through public money/funds (either partly or in whole)*

Type of Data	Data Deposit Timeline
Raw (level 1) Data	Within one year of data-generation
Reference Data Set	Within six months of data-generation
Processed (level 2) Data	Within two years of data-generation
Metadata	To be deposited concurrently with other types of data

Storage Timeline

Storage and Sharing of Biological Data

Data sharing from the Indian Biological Data Centre is **classified** under three categories:

- *Open Access* : under FAIR (findable, accessible, interoperable and reusable) principles
 - *Managed Access* : subject to a written proposal to be provided by the data-requester/use
 - *No access* : access to sensitive data is not permitted, even if generated using public funds
-
- Also permits the **withdraw** of data, provided the data so requested for withdrawal is identifiable in the database
 - **Data User Agreement**: Guidelines mention detailed user terms

Key Issues and Gaps

- 1. Pathogen Genomic Surveillance Infrastructure: Gaps, Strengths**
- 2. Inter-agency Coordination**
- 3. Access and Benefit Sharing (ABS): Policy and Legal Frameworks**
 - a. Ambiguities in Legal Interpretation and Implementation
 - b. Challenges in Applying ABS to Pathogens
 - c. Transparency and Public Accountability in ABS Agreements
 - d. Uncertainty Around Non-Monetary Benefits and Fair Benefit Sharing
- 4. Data Storage and Sharing: Challenges**

Way Ahead

1. Enhancing Pathogen Genomic Surveillance Infrastructure

- a. Develop a National Genomic Surveillance Strategy
- b. Decentralize Surveillance Capabilities
- c. Invest in Workforce Training

2. Improved Inter-agency Coordination

- a. Establish a Statutory, Disease-Agnostic Body
- b. Enhance Real-time Data Sharing Protocols

3. Revisit Access and Benefit Sharing (ABS)

- a. Clarify legal scope and applicability
- b. Develop tailored ABS frameworks for pathogens
- c. Enhance transparency in ABS agreements

4. Strengthen Data Storage and Sharing Mechanisms

- a. Standardize Data Submission Timelines
- b. Enhance Computational Infrastructure
- c. Promote Local Data Control with Global Collaboration

Thank you

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Perspectives from the African region

Nicki Tiffin

Deputy Director, South African National
Bioinformatics Institute (SANBI)

Chair, Ethics and Data Sharing Working Group,
PHA4GE

Pathogen data sharing: Perspectives from Africa

Nicki Tiffin

South African National Bioinformatics Institute
University of the Western Cape, South Africa

Investing in pathogen data to improve health outcomes

- Ensuring maximal use of pathogen genomic data to improve health in Africa and globally
- Prioritising pathogens appropriately
- Accommodating both public health sequence data and research data
- Ensuring African researchers are generators and custodians of African pathogen data, and African populations are beneficiaries



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ADBEx



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Best practices for sharing African pathogen data

Equity

- Benefit sharing
- Full participation by African data generators, equitable sharing agreements

Ethics

- Protecting patients, communities and populations (often ID-related stigma)

Capacity

- Building capacity and skills for research locally

Sustainability

- Leveraging data for onward funding and support

Context

- Harnessing local clinical knowledge for appropriate interpretation of findings

Legislation



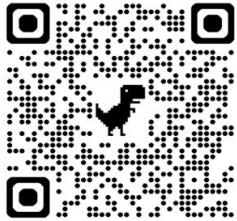
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Where do we start?

What do we mean by data sharing?

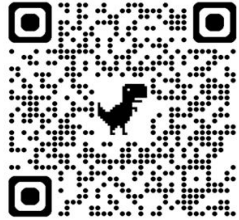


Modes of datasharing
Tamuhla et al. 2023
BMJ Global Health

ADBEx Programme:

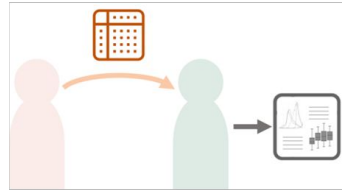
- Moving beyond unidirectional hand-over of data
- Creative ways of data-sharing to support data generators
- Ensuring effective onward use of pathogen data, for maximal benefits

Thinking creatively about models of data sharing

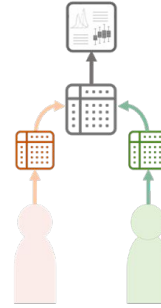


Modes of datasharing
Tamuhla et al. 2023
BMJ Global Health

Direct sharing



Collaborative meta-analysis



Federated analysis



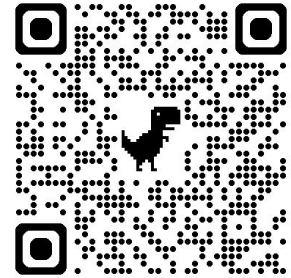
Trusted research environment

What are the baseline rules for pathogen data sharing?

PHA4GE Accord: Establish a baseline, consensus set of rules

- Baseline “etiquette” for sharing microbial data
- Does not replace data-sharing legal agreements/MOUs
- Provides a generally accepted guidance on do’s and don’ts
- Does not replace Data Sharing Agreements/MOUs
- Provides a common, agreed starting base for sharing microbial data
- Opportunity to waive or modify any of the clauses

*e.g. “These data are shared according to the PHA4GE Microbial Data-Sharing Accord, with a waiver on **Clause 9: Invitation to Collaborate**, which is not required.”*



PHA4GE Microbial
Data-sharing Accord
Griffiths et al. 2023
BMJ Global Health



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PHA4GE Microbial Data Sharing Accord

1. Attribution

Acknowledging data generators

2. Overview of outputs prior to publication

Opportunity for data generators to review manuscripts for valid use of data

3. Onward sharing of data

Onward sharing only occurs with explicit agreement of data generator

4. Host and phenotype data anonymization

Protection of individuals from whom microbes/pathogens are sampled

5. Geospatial data

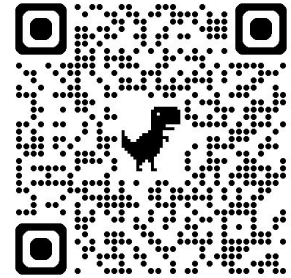
Protection of communities and individuals through responsible mapping

6. Intellectual property

Protected for data generators, transfer of IP only with specific agreement

7. Opportunities for collaboration

Reasonable attempt to invite collaboration



PHA4GE Microbial
Data-sharing Accord
Griffiths et al. 2023
BMJ Global Health

Fit-for-purpose data-sharing agreements

Increase confidence in equitable and ethical data sharing

ADBEx programme, input from PHA4GE:

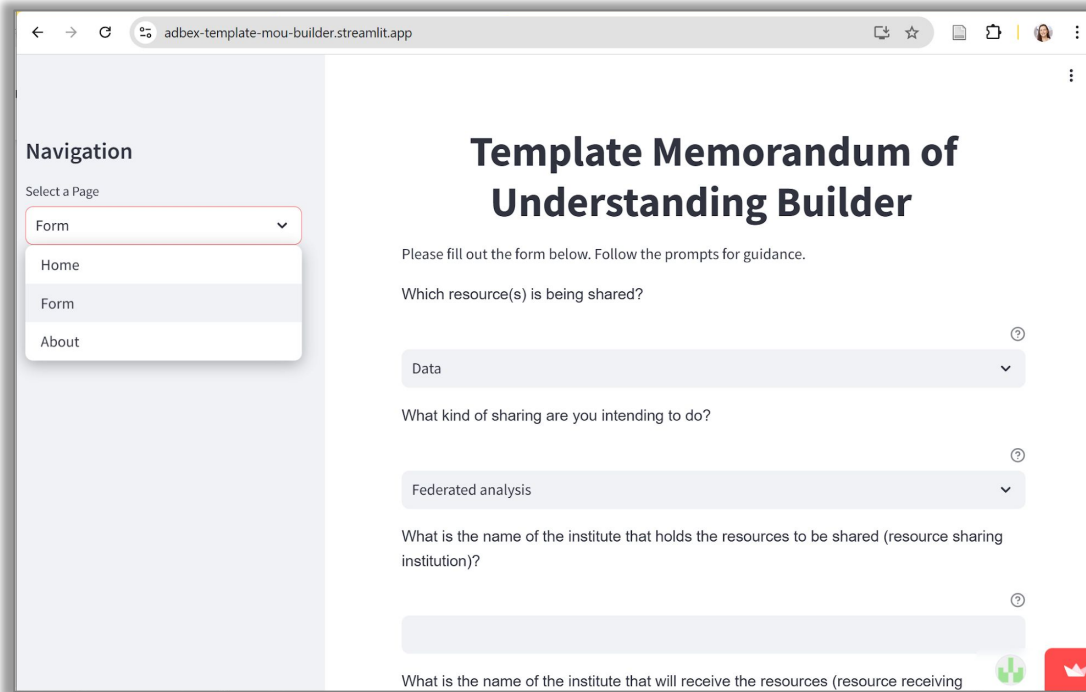
- Online tool for building data-sharing agreements
(also called Memorandum of Understanding, MOU)
- Options for sharing agreements for data or biospecimens
- Options for types of sharing incl. direct, collaborative, federated, TRE and commercial
- ~35 prompts to capture information about the data-sharing plan.
- Modular, with skip logic – specific to biospecimens, data, different sharing models
- Produces Word Document Data-sharing agreement/MOU
- Word document that is generated can be used to draft legal agreements



MOU Builder
T. Tamuhla *et al*
2024, Manuscript in
prep

<https://adbex-template-mou-builder.streamlit.app/>

* If the app is sleeping just wake it up



The screenshot shows a web browser window with the URL `adbex-template-mou-builder.streamlit.app`. The page title is "Template Memorandum of Understanding Builder". On the left, there is a "Navigation" sidebar with a "Select a Page" dropdown menu containing options: "Form" (selected), "Home", "Form", and "About". The main content area contains the following text and form elements:

- Header: "Template Memorandum of Understanding Builder"
- Instruction: "Please fill out the form below. Follow the prompts for guidance."
- Question: "Which resource(s) is being shared?"
- Form field: "Data" (dropdown menu)
- Question: "What kind of sharing are you intending to do?"
- Form field: "Federated analysis" (dropdown menu)
- Question: "What is the name of the institute that holds the resources to be shared (resource sharing institution)?"
- Form field: (empty text input)
- Question: "What is the name of the institute that will receive the resources (resource receiving" (partially visible)
- Form field: (empty text input)

At the bottom right of the form area, there are two icons: a green checkmark and a red crown.



MOU Builder
T. Tamuhla *et al*
2024, Manuscript in prep

Setting an intention for equitable and ethical benefit sharing

The PHA4GE Benefit-Sharing Framework

- Is the research contextually relevant?
- Ethics: Do participants in research see the benefits of the research?
- Equity: Do data generators benefit?
 - develop local capacity
 - recognition of contributions
 - sustainability



Bedeker *et al.* 2022.
BMJ Global Health

Thank you

Health data integration group

Team members – data sharing

Tsaone Tamuhla

Eddie Lulamba

Themba Mutemaringa

PHA4GE collaborators (PI Alan Christoffels)

PHA4GE Ethics and Datasharing WG

Funding:

Bill & Melinda Gates Foundation

- Calestous Juma Fellowship, ADBEx project.
- PHA4GE funding

UKRI/MRC funding, VCAMM project

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Discussion

Please share your questions and comments in
the Q&A chat on zoom

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Thank you for joining us

Please direct questions, comments and feedback to gmsv2070@nus.edu.sg

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