Agenda

• Opening remarks
• Introduction to the WHO BioHub System and its Guiding Principles
• Presentation of meeting objectives
• Moderated discussion
• Closing remarks
Opening remarks

Dr Michael Ryan
Executive Director
WHO Health Emergencies Programme
Meeting objectives

The technical consultation aims to:

• obtain input from various stakeholders to design the WHO BioHub System on the issue of access and benefit sharing
Introduction to the WHO BioHub System and its Guiding Principles
WHO BioHub System: Concept & Elements

Countries
Voluntary sharing of biological materials

Sharing via SMTA 1*

WHO BioHub System
WHO BioHub Facility

Sharing via SMTA 2
Sharing via SMTA 3

Allocation Advisory Group
Prioritizes BMEPP** allocation

Recipients
Qualified entities
Non-commercial use
Commercial use

Global Knowledge & Development of countermeasures

* Standard Material Transfer Agreement
** Biological materials with epidemic or pandemic potential
### Guiding Principles of the WHO BioHub System

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
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<td>A voluntary system for the global public health</td>
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<td>Equity and fairness</td>
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<td>Transparency</td>
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<td>Acknowledgement and co-authorship</td>
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<td>Consistency with applicable ethical regulations, norms, and standards requirements</td>
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<td>Timeliness</td>
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<td>Collaboration &amp; Cooperation</td>
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<td>Best practices for safety and security</td>
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<tr>
<td>Consistency with applicable law</td>
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<td>Sustainability and maximal preservation</td>
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The full text of the Guiding Principles can be found at: [https://www.who.int/initiatives/who-biohub](https://www.who.int/initiatives/who-biohub)
Key Guiding Principle in focus for this thematic session

Equity and fairness

Equity and fairness, as well as public health risk and need, will govern access to BMEPP contributed to the WHO BioHub System, and the research, data, and other materials resulting from the WHO BioHub System.
Key Guiding Principles in focus for this thematic session

Consistency with applicable law

The WHO BioHub System will be established and operated in a manner consistent with applicable law, regulations, rules, and standards, including under legal rules and regulations as well as national and international law.
Key Guiding Principles in focus for this thematic session

**Collaboration & Cooperation**

The WHO BioHub System will promote collaboration and cooperation with existing networks, repositories, and scientific groups to strengthen knowledge and contribute to the advancement of effective, efficient, fair and equitable response to epidemic or pandemic public health events.
Approach to developing the WHO BioHub System

Stream 1
Pilot Testing

Stream 2
System Design

WHO BioHub System
 Paragraph 9.15:

• work together with Member States, the medical and scientific community, and laboratory and surveillance networks,

• to promote early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens of pandemic and epidemic, or other high-risk, potential,

• taking into account relevant national and international laws, regulations, obligations and frameworks, including, as appropriate, the International Health Regulations (2005), the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and the Pandemic Influenza Preparedness Framework and

• the importance of ensuring rapid access to human pathogens for public health preparedness and response purposes;".

WHO is working in accordance with WHA 74.7
Stream 2 – updates on technical consultations with stakeholders

**Research**
Handling research results and appropriate recognition of contributions

Key (technical) stakeholders:
Lab networks, scientists and biorepositories etc

**GSD**
Sharing of Genetic Sequence Data

Key (technical) stakeholders:
Legal experts and civil society and industry, other UN agencies, etc

**IP**
Intellectual Property Rights

Key (technical) stakeholders:
Legal experts and civil society and industry, other UN agencies, etc

**Access to benefits arising from the sharing of BMEPP**
Difference between non-commercial and commercial benefits

Key (technical) stakeholders:
Legal experts esp. on Nagoya, civil society and industry involvement, etc

WHO BioHub System
Type of potential benefits arising from the sharing of BMEPP

**Public health tools and information**

- Public health information and tools to perform risk assessment
- Regular and timely surveillance updates and situation reports
- Access to genetic sequence data (GSD) through one or more relevant, publicly accessible databases
- Timely updated evidence-based medical products recommendations

**Laboratory and capacity strengthening support**

- Reagents and reference biological materials
- Training, mentoring and capacity strengthening (funds or in-kind training towards building laboratory and/or surveillance capacities in developing countries)
- Research – participation and acknowledgement of Provider scientists, especially those from developing countries, in scientific projects

WHO BioHub System
Type of potential benefits arising from the sharing of BMEPP

Medical and other products (options that could be considered)

- **Access to medical** and non-medical countermeasures or **products** (through various modalities)

- Grant to manufacturers in developing countries **licenses on mutually agreed terms** on technology, know-how, products and processes for which it holds IPR for the production of BMEPP medical products.

- Grant **royalty-free licenses** to interested manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of BMEPP medical products.

- **Transfer of technology, know-how and/or processes for production** of BMEPP medical products.
PIP Framework Objectives & Scope

Two objectives to be pursued on an equal footing:

Improve sharing influenza viruses with pandemic potential with the WHO Global Influenza Surveillance Response System (GISRS) for risk assessment and vaccine development

Establish more predictable, efficient, and equitable access to vaccines and other life saving products at the time of a pandemic

Scope: Covers only influenza viruses with pandemic potential (IVPP) not seasonal viruses
Two principal benefit sharing mechanisms:

**Standard Material Transfer Agreement (SMTA 2 - PIPF Annex 2)**

- $252 million collected since 2012
- 83 countries (in 2018-current) supported in the preparedness sector

**Partnership Contribution (PC) (PIPF section 6.14.3)**

- $252 million collected since 2012
- 83 countries (in 2018-current) supported in the preparedness sector

WHO BioHub System
Surveillance & risk assessment information

Technical assistance to strengthen key capacities, e.g. pandemic surveillance, risk assessment

Support to strengthen national pandemic influenza response capacities

Equitable access to vaccines, antivirals and other critical pandemic response supplies (smta2)
The ACT-Accelerator – COVID-19 pandemic

The Access to COVID-19 Tools Accelerator (ACT-A) is a partnership structure to drive global collaboration to end the COVID-19 pandemic.

The Access to COVID-19 Tools (ACT) Accelerator was launched at the end of April 2020 and brings together governments, scientists, businesses, civil society, and philanthropists and global health organizations (the Bill & Melinda Gates Foundation, CEPI, FIND, Gavi, The Global Fund, Unitaid, Wellcome, the WHO, and the World Bank). Following the ACT-Accelerator launch, UNICEF and PAHO became delivery partners for COVAX, the vaccines pillar.
COVAX and COVAX Facility

- COVAX’s goal is to **accelerate the development and manufacture of COVID-19 vaccines**, and to **guarantee fair and equitable access** for every country in the world.

- **COVAX Facility** - a **global risk-sharing mechanism for pooled procurement and equitable distribution** of COVID-19 vaccines.
PIP and ACT-A considerations

- As the COVID-19 pandemic is still ongoing, **ACT-A is operating** and lessons learned are to be further collected.

- **PIP** was adopted in 2011 and since then it has been **fully employed** for pandemic influenza **preparedness**. However since 2011 no pandemic influenza occurred, therefore the ‘response’ operational part was not activated and tested in a real-life situation.
Today’s consultation
Meeting objectives

The technical consultation aims to:

• **obtain inputs from various** stakeholders to design the WHO BioHub System on the issue of access and benefit sharing
Learning from previous technical stakeholders' consultations

- Thank you for making the time to participate!
- WHO BioHub System **co-development** relies on your inputs
- We are happy to have **global participation** on all previous editions as well as this one:
  - Theme 1: Research (28 October 2021) – 499 participants
  - Theme 2: Sharing of Genetic Sequence Data (19 November 2021) – 399 participants
  - Theme 3: Intellectual Property (9 December 2021) - 274 participants
Today’s technical consultation rules of engagement

• Please make sure you are registered on Zoom with your Name and Institution (Affiliation) (so that everyone can see who is attending the meeting)

• When you take the floor please introduce yourself - Name and Institution (Affiliation)

• The consultation is inclusive of all stakeholders, we understand there will be divergent opinions but the purpose of the meeting is to gather those diverse views to provide MS with a large range of options for the design
Today’s technical consultation rules of engagement

• The chat function is available, but would be more beneficial to make your comments and ask the questions by taking the floor
• Focus on constructive proposals for the design
• Please do not speak too fast, to enable interpretation
• If you wish, please send detailed input at biohub@who.int
Questions from the concept note to prepare discussions

1. What **type of ABS modalities** should be included as the core components of the WHO BioHub System?

2. If applicable, what are the **benefits that your stakeholder group would find most difficult to provide, or would most wish to receive?**

3. What are potential **access and benefit sharing arrangements** that would advance public health goals in an epidemic or pandemic situation?

4. Are there any **constraints that may affect the design** of a potential BioHub - ABS model, including from the scientific, legal, and/or operational perspective(s)?
Points to touch-on during your intervention

1. **What benefits** should be prioritized?
2. **Who should contribute** to ensure these benefits?
3. **How to arrange** the access and benefit sharing modalities?
Thank you!

www.who.int/initiatives/who-biohub/

WHO Secretariat can be reached for any further inputs at: biohub@who.int