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

Steven Solomon
Principal Legal Officer
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

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

- A voluntary system for the global public health
- Equity and fairness
- Transparency
- Acknowledgement and co-authorship
- Consistency with applicable ethical regulations, norms, and standards requirements
- Timeliness
- Collaboration & Cooperation
- Best practices for safety and security
- Consistency with applicable law
- Sustainability and maximal preservation

The full text of the Guiding Principles can be found at: https://www.who.int/initiatives/who-biohub
Key Guiding Principles in focus for this thematic session

Timeliness

To enable an effective public health response, the end-to-end system from sample collection to shipping and generation of scientific information must function with urgency. Data and analyses will be made publicly available in a timely manner, while respecting all applicable WHO, international, and national regulations and standards, and communicated promptly to decision-makers in the affected countries as well as more broadly to all WHO Member States to support effective and timely response measures.
Key Guiding Principles 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

Consistency with applicable ethical regulations, norms, and standards requirements

The WHO BioHub System will be established and operated in a manner consistent with applicable WHO, international, and national ethical regulations, norms, and standards.
Approach to developing the WHO BioHub System

Stream 1
Pilot Testing

Stream 2
System Design

WHO BioHub System
WHO is working in accordance with WHA 74.7

WHO is aiming to:
- Serve the request from MS made in WHA74.7, Agenda item 17.3 31 May 2021
- Establish a pathogen sharing system that can be rapidly activated

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 BioHub System
Topics for 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
WHO BioHub System: Concept & Elements

Voluntary sharing of biological materials

Sharing via SMTA 1*

WHO BioHub System

WHO BioHub Facility

Global Knowledge & Development of countermeasures

Sharing

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Meeting objectives

The consultation aims to:

• obtain input from various stakeholders to design the WHO BioHub System

• engage different stakeholder communities early on, in the design of the System, to ensure its smooth global functioning, to bring global benefits and to advance public health goals
Discussion

1. What do you consider to be the most important factors and considerations relating to IP vis-à-vis the BioHub project?

2. What are your views on the three identified “entry points” for IP linked to the WHO BioHub System:
   1. IP and the physical BMEPP provided to a BioHub Facility
   2. IP developed by a BioHub Facility
   3. IP developed by a Recipient (Qualified Entity) using BMEPP

3. How, should the WHO BioHub System address each of these three “entry points” in terms of a standardized vs a more customized approach?

The background paper for this thematic session can be found here:
Thank you!

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

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