

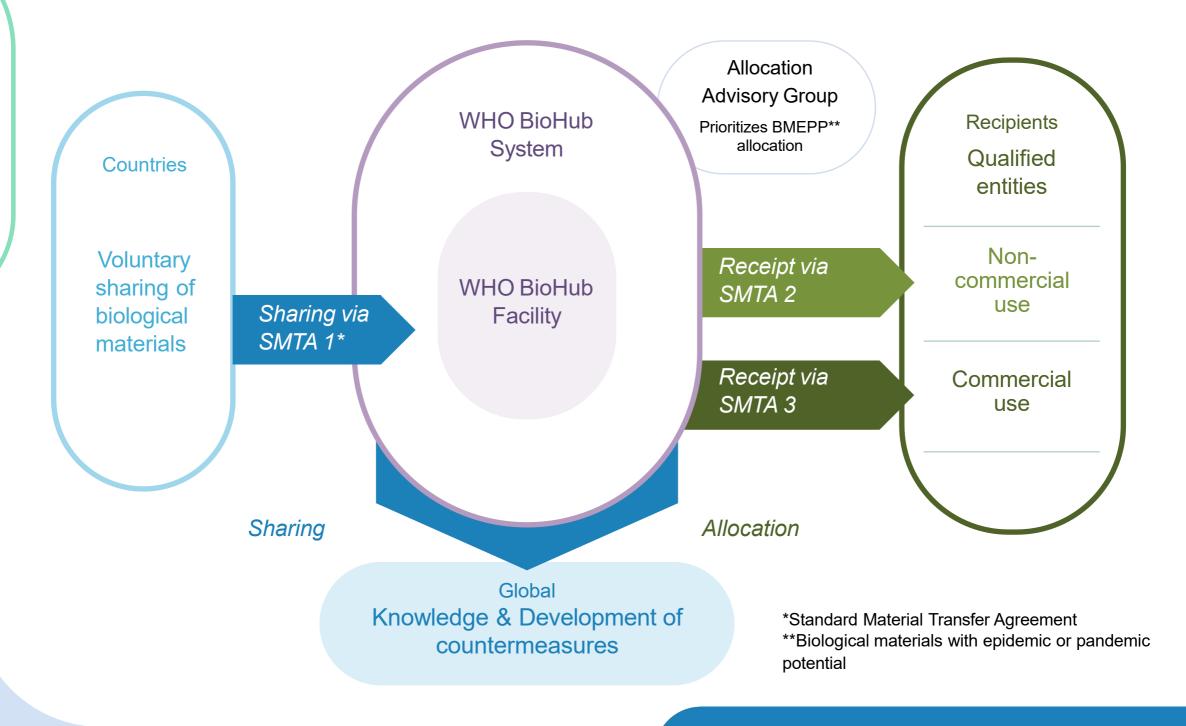
WHO BioHub System

WHO Technical MS Briefing Stream 2 – System Design

7 October 2021



WHO BioHub System: Concept & Elements



Objectives of the WHO BioHub System

- Only applies to BMEPP biological materials with epidemic or pandemic potential;
- Objectives:
 - Promote timely sharing of BMEPP;
 - Facilitate rapid access and analysis of BMEPP to enable:
 - risk assessment and
 - development of effective and safe countermeasures including diagnostics, vaccines and therapeutics; and
 - Ensure fair and equitable access to such products by all countries, based on public health needs.



- It is not replacing existing and future sharing systems (e.g. GISRS for Influenza, bilateral agreements, or viral archives/biobanks)
- It aims to be complimentary with other mechanisms
- We need to design the WHO BioHub System to be better prepared for the next pandemic.



Progress to date

September 2021

Stream 1: Simplified SMTAs for pilot testing for non-commercial sharing ready and available at https://www.who.int/ initiatives/who-biohub



June 2021
Stream 1:
SMTA drafts sent

for discussion





Stream 1 and 2: Two MS Briefings to introduce the project & conceptual approach



June 2021

Stream 1 and 2: MS Briefing to provide updates and prepare for first testing shipments



May 2021

Stream 2: MoU with Switzerland signed to designate the Spiez Laboratory as first BioHub Facility

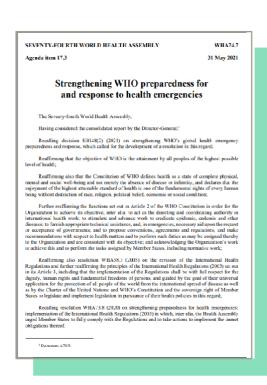
WHA74.7, Agenda item 17.3
31 May 2021 - Strengthening
WHO preparedness for and
response to health
emergencies



WHO will advance work 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
- Ensure availability of a pathogen sharing system that can be rapidly activated in the event of Disease X



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;".



Engagement approaches with MS (until EB 150)



Stream 1Pilot Testing

Through COVID-19
Thursday MS Briefings
– as it involves SARCOV-2 sharing.



Through:

Technical MS Briefings

Technical consultations with all stakeholders

MS will be asked to advise on the process involving all MS and relevant stakeholders.



Stream 2 - MS engagement approach



Proposed consultations' format

Background documents prep

documents on that particular theme

Stakeholders' Consultations

Virtual consultation with key stakeholders depending on the theme

MS Further Input

Report back to MS on the stakeholders' inputs through:

Technical MS Briefings

Web posting of reports

Direct communication with WHO BioHub Secretariat

WHO Secretariat reporting

Implement MS feedback and prepare text for WHA reporting



Proposed topics for technical consultations with stakeholders



Research and links with other biorepositories

Handling research results and appropriate recognition of contributions Key (technical) stakeholders: Lab networks, scientists and biorepositories etc



IPR and GSD

Intellectual
Property Rights
and
Sharing of Genetic
Sequence Data

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



MS Engagement Dates

Oct 2021



First Technical MS Briefing – 7 Oct – 9:30-11:00



Tentative dates for the technical consultations with stakeholders (GVA time) – we may have 'doubling sessions' to accommodate time difference:

- Theme 1 (Research and links with other repositories): 28 October 2021 (15:00 17:00)
- Theme 2 (Intellectual Property Rights and Sharing of Genetic Sequence Data): 17 November 2021 (14:00 16:00)
- Theme 3 (Access to benefits arising from the sharing of BMEPP): 7 December 2021 (14:00- 16:00)

Dec 2021



Second Technical MS Briefing – tentative 16 December 2021

Mar 2022



Third Technical MS Briefing in March 2022 (date TBC).

Regular updates on Stream 1 – Pilot Testing will be given during the MS COVID-19 Information Sessions (Thursdays)



Today's discussions

Do you agree with the proposed engagement plan?

Are the proposed technical consultation with stakeholders' themes in line with the issues you see most important?

Are the proposed stakeholders' categories agreeable?

Stakeholders as per WHA 74.7:

- Medical and scientific community
- Laboratory and surveillance networks

As per existing global frameworks:

- Civil society
- Industry (manufacturers and commercial entities)



THANK YOU

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

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

