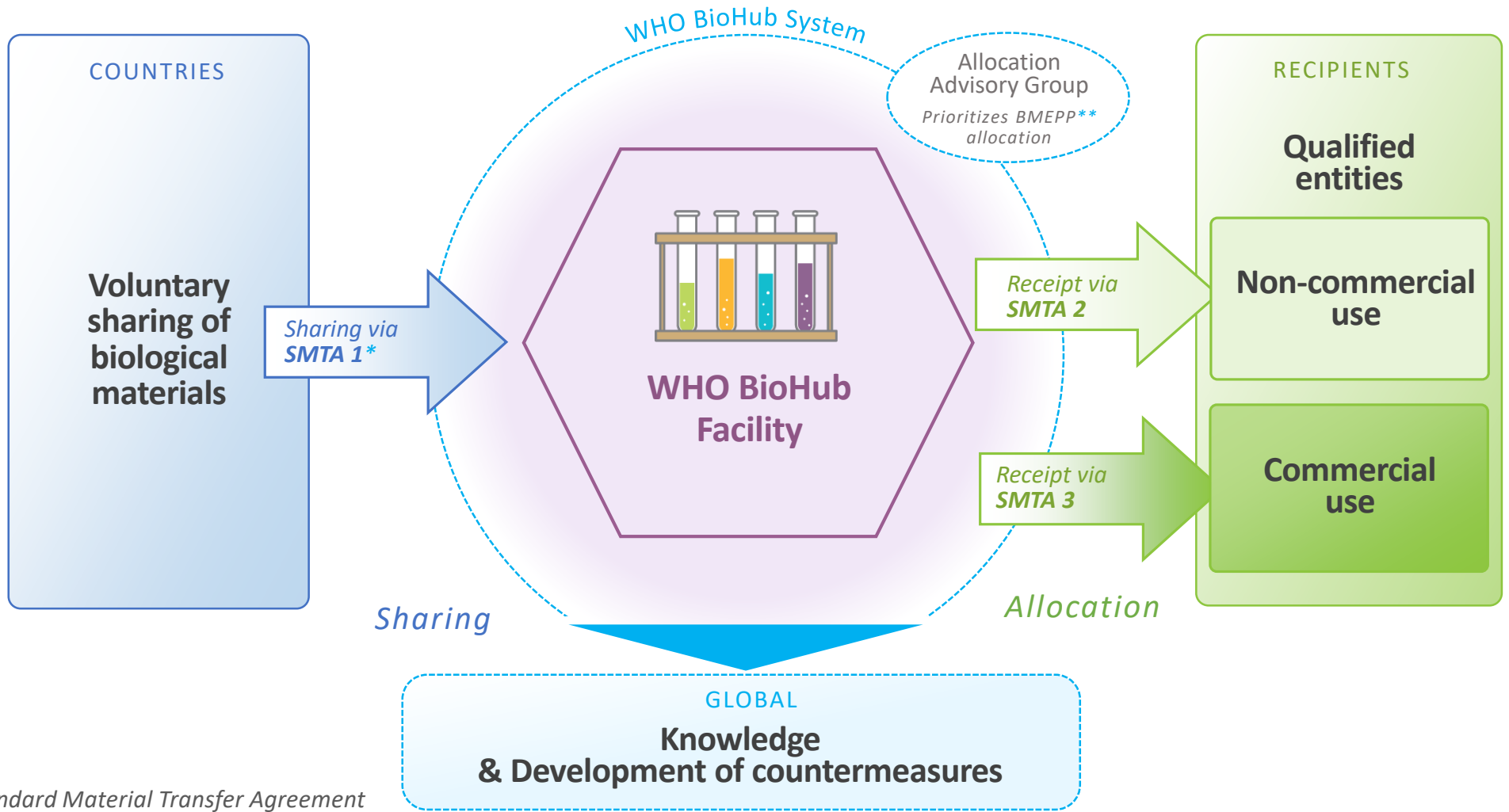

BioHub System



WHO BioHub System MS COVID-19 Briefing 23 September 2021

WHO BioHub System: Concept & Elements



* Standard Material Transfer Agreement

** Biological materials with epidemic or pandemic potential

Progress to date

September 2021

Stream 1:

- **Simplified SMTAs** for pilot testing for non-commercial sharing ready



July 2021

Stream 1 and 2:

- **MS Briefing** to provide updates and prepare for first testing shipments



June 2021

- **Stream 1: SMTA drafts sent for discussion**



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](#)



March and April 2021

Stream 1 and 2:

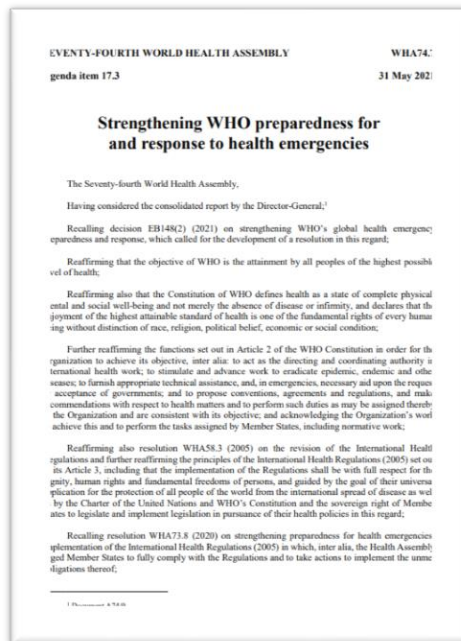
- **Two MS Briefings** to introduce the project & conceptual approach



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;”

MS 5th July Briefing Outcomes:

- Presented drafts SMTAs and the tool /database to track BMEPP shipments
- MS requested more engagement in the development of the WHO BioHub System
- Comments were also sent after the meeting by email

- Follow up from WHO:
 - Review of SMTAs for pilot phase
 - Plan for MS and stakeholder engagement

Engagement approaches with MS (until EB 150)

STREAM 1 PILOT TESTING

Through **COVID-19 Thursday MS Briefings**
– as it involves SAR-COV-2 sharing.

STREAM 2 SYSTEM DESIGN

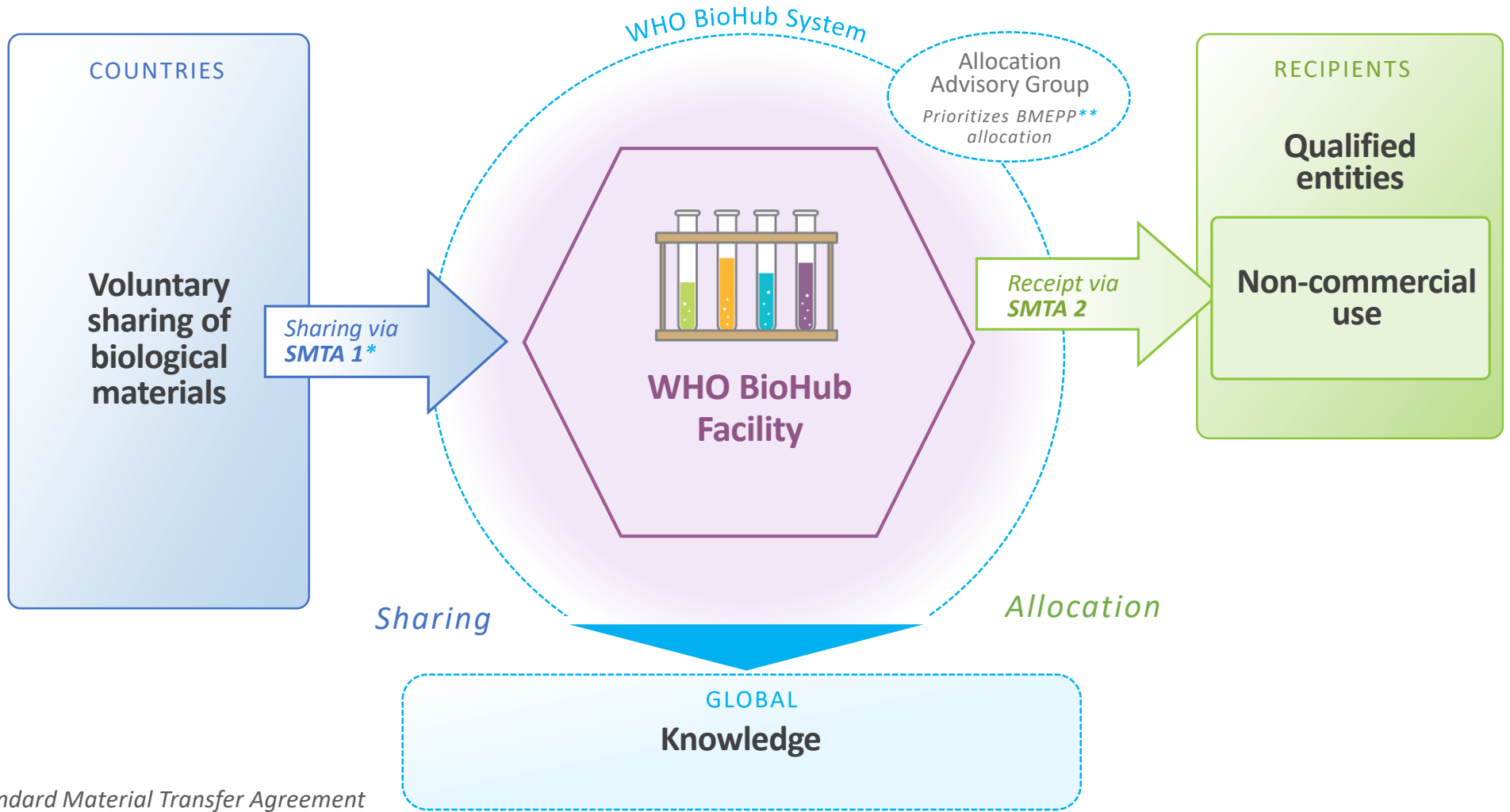
Through:

- **MS Briefings**
- **Technical consultations.**

- *MS will be asked to advise on the process during an upcoming MS Briefing (date TBC - Oct).*
- *WHO will be proposing a process involving all MS and relevant stakeholders.*



WHO BioHub System: Concept & Elements – Pilot-testing



* Standard Material Transfer Agreement

** Biological materials with epidemic or pandemic potential

Pilot-testing update

- To date 7 countries have volunteered to be participate in the pilot-testing phase:



- SMTAs specific to this pilot-testing phase** have been developed for non-commercial sharing of SARS-CoV-2
- MS that wish to be involved and participate in the pilot-testing / access BMEPP should write to biohub@who.int

PILOT TESTING – WHO BIOHUB SYSTEM – STREAM 1
UNTIL MAY 2022

WHO BioHub System

The following package of two documents is to be used for the WHO BioHub System pilot testing (Stream 1) to demonstrate proof of concept of the project and to inform potential further discussions of the WHO BioHub initiative. It aims at enabling voluntary sharing of SARS-CoV-2 BMEPP (Biological Material with Epidemic and Pandemic Potential) into and from a WHO BioHub Facility for non-commercial purposes only, during the period of the Pilot Testing Phase, as detailed in the figure below. Outcomes of the Pilot Testing Phase will be discussed with all Member States and relevant stakeholders and reviewed accordingly.

SMTA 1 | **SMTA 2**
Standard Material Transfer Agreement (SMTA) 1 | Standard Material Transfer Agreement (SMTA) 2
Annex 1 to SMTA 1 - Guiding Principles of the WHO BioHub System | Annex 1 to SMTA 2 - Guiding Principles of the WHO BioHub System
Annex 2 to SMTA 1 - Voluntary Transfer Form | Annex 2 to SMTA 2 - Request Form

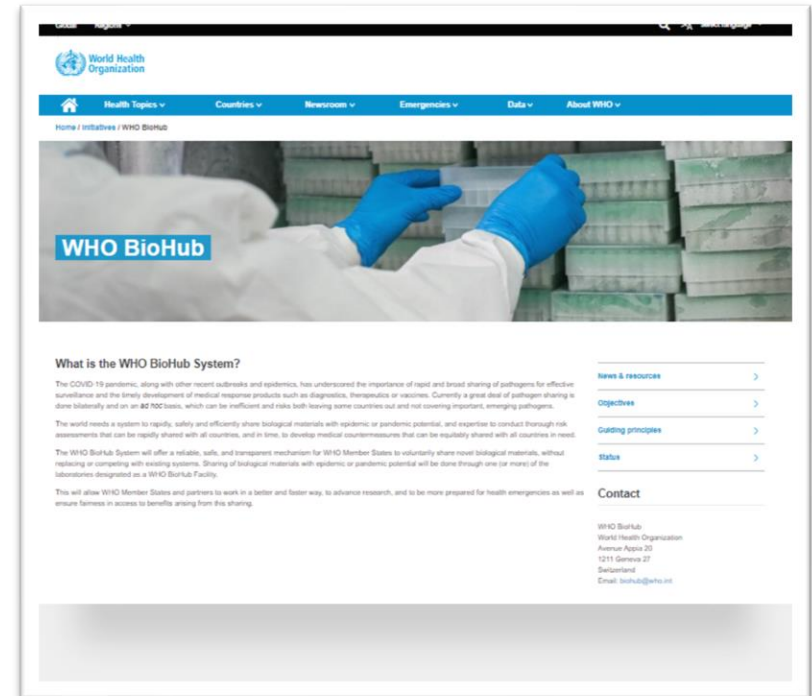
For information on the WHO BioHub System please visit: <https://www.who.int/initiatives/who-biohub/>

SMTA 1 working version for 2021-2022 Pilot Testing Phase – Stream 1 – dated 8 Sept. 2021

WHO BioHub Webpage

- All the documents including:
 - SMTA pilot-testing package,
 - Tracking tool and
 - BMEPP catalogwill be available on the BioHub website:

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



Next steps

STREAM 1 PILOT TESTING

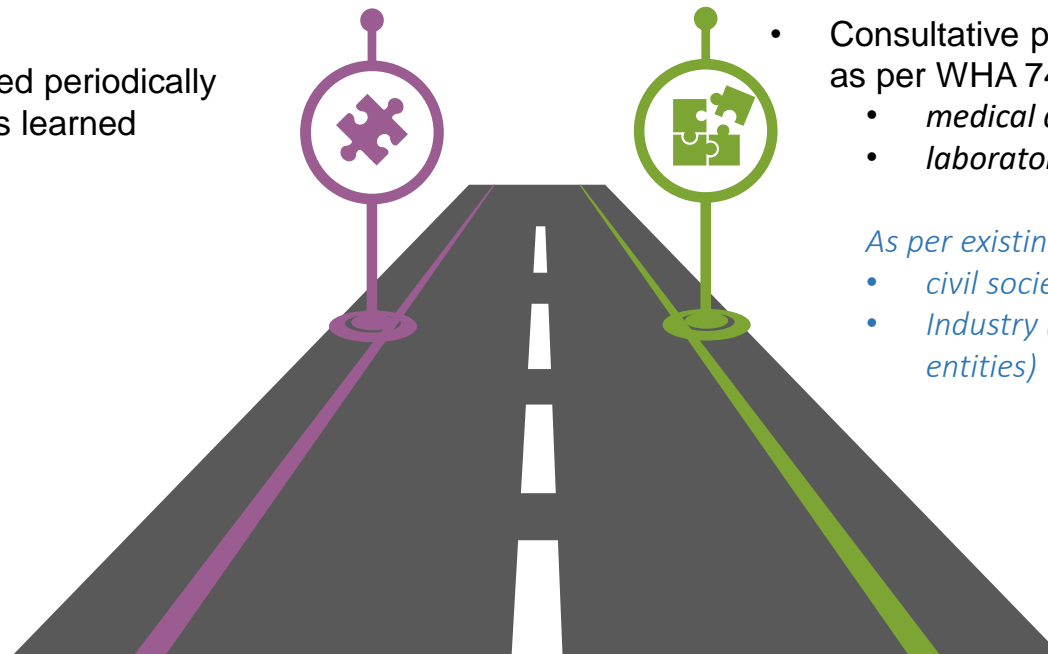
- Start shipping samples in and out of the WHO BioHub Facility, measuring the KPI such as timeliness
- All MS will be updated periodically on progress and lessons learned through Thursday COVID-19 MS Briefings.

STREAM 2 SYSTEM DESIGN

- Dedicated MS Briefing (tentatively October, December, March).
- Consultative processes with all 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