Workstream 3 ambition is to improve long-term LMIC health security via two key objectives and enablers:

1. **Objective 1**
   - Expand capabilities of existing manufacturers in LMICs

2. **Objective 2**
   - Establish sustainable capacity in regions with no significant capacity

**Enablers**
- Identify & implement innovations and develop normative frameworks
3 potential approaches for capacity connector identified, with WHO-led WS3 focusing on multilateral TT hub model

1. **Fill-finish**

   - Manufacturer 1 Limited filling line
   - Excess bulk vaccine
     - Filling line 2
     - Filling line 3
     - Filling line 4

2. **Bilateral technology transfer**

   - Manufacturer 1
   - Process transfer
     - Manufacturer 2
     - Vaccine

3. **Multilateral technology transfer technology hub model - including and beyond Covid**

   - Inventors
   - Developers
   - Researchers
   - Experts
   - IP holders
   - Member States
   - Technology transfer hub
     - Industrial scale process, Data, Rights
     - Manufacturer 1
     - Manufacturer 2
     - Manufacturer 3
     - Manufacturer 4
     - Manufacturer 5
     - Vaccine

**Focus of this project**
EOI call for mRNA tech hub has been launched in mid-April

Call issued on April 16 to seek seeking expressions of interest from

1. **Possible Hubs:** Small/middle-size (public or private) manufacturers of medical products (drugs, vaccines or drug substances) which could host a COVID-19 mRNA hub

2. **Possible Tech Providers:** Owners (public or private) of technology and/or Intellectual Property Rights (IPR) willing to contribute to a technology transfer hub
50+ EOI received from potential candidates for tech transfer hubs & recipients

AS OF 07JUNE2021

20+ Responses from potential tech donors and/or sites for hubs

30+ Responses from countries/manufacturers more likely to be possible recipients

- Potential tech donor only (based in China, UK, USA)
- Potential tech donor & hub site (based in Belgium, India, South Africa, Thailand)
- Potential hub site only (based in Argentina, Belgium, Canada, Chile, Colombia, Italy, Nigeria, Paraguay, Senegal, South Korea, Taiwan)

Potential interest for establishing recipient site (based in Argentina, Bangladesh, Brazil, Chile, Colombia, Cuba, Egypt, India, Indonesia, Kenya, Morocco, Nicaragua, Nigeria, Pakistan, Paraguay, Peru, Philippines, Rwanda, Senegal, South Africa, Thailand, Tunisia, Uganda, Uruguay, Venezuela, Vietnam)

Preliminary – answers still under review
Detailed due diligence process is ongoing, based on several technical criteria

We developed several criteria to assess potential hub / tech donor and issued a detailed questionnaire to be filled by respondents

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<th>Hub criteria</th>
<th>Tech criteria</th>
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Few questions for illustration purpose

- Does the technology have clinical data to prove it works?
- Which lipid / formulation is used? How does this affect price, yield, immunogenicity, FTO?
- Are reagents readily available?
- Is formulation scalable?
- Thermostability?
- Is there freedom to operate?
- Doses / sq metre facility?
- Are recipients able to operate independently? (Open access?)
- Is the tech licensed / free?
Appendix
Context | Our effort sits within the broader COVAX Manufacturing Taskforce as the Workstream 3

Workstream 0
- Shared Fact Base / Task Force Coordination Office
  - Create aligned supply baseline
  - Conduct supply and manufacturer ecosystem mapping
  - Document and share lessons learned across focus areas

Workstream 1
- Immediate COVAX Response
  - Create voluntary input supply visibility partnership
  - Accelerate export permits/custom clearance for critical SKUs

Workstream 2
- Short- and Mid-Term COVAX Response
  - Expand fill & finish match making mechanisms
  - Create overview of global manufacturing capacities
  - Better utilize existing capacities, e.g., voluntary bilateral tech transfer
  - Develop regulatory & manufacturing workforce

Workstream 3
- New & expanded sustainable capacity in LMICs
  - Expand capabilities of existing manufacturers in LMICs
  - Establish sustainable capacity in regions with no significant capacity
  - Enablers: Develop normative policy frameworks, stimulate manufacturing innovations & investments
During initial design phase, WS3 explored a range of options and aligned on a hybrid model for tech transfer hub

1. **Decentralized & flexible**

- Hub(s) at 1+ existing sites, recipients are other existing "partner" sites, gain TT & know-how for novel tech
- Easy and fast to implement
- Low cost, empowers existing LMIC manufacturers
- Low capacity & capability add
- Slower TT process during pandemics and lower chances of success

2. **Centralized & normative**

- 1 hub & several new, identical "affiliate" sites; affiliates receive normative tech transfer & broader capability training
- Adds significant new capacity
- Enables rapid responses during pandemics and more control on network
- Most challenging / longer to implement
- Highest cost
- Low agency for LMICs in approach

3. **Optimized model**

- Preferred option
- Build 1 hub & some new "affiliate" sites; recipients are both partner & affiliate sites; hub offers distinct training module for each
- Combines pros of both models and ensures flexibility
- Pragmatic, case-by-case approach to determine best model by country/region
- Requires robust governance to handle 2 types of "recipients"

"Hub" = center for multilateral TT & training (plus semi- to full-manufacturing scale production in Options 2 & 3); "Partner" site = existing LMIC manufacturer that receives TT; "Affiliate" site = newly built facility affiliated with hub & recipient of TT; TT = Tech Transfer
Manufacturers with approved products and bilateral tech transfers could be leveraged to accelerate pathway

Lever 1: Leverage manufacturer with approved product for 1 or more tech

- Select the techs (mRNA, VV, Proteins EOI)
- Build Hub
- Initial Tech Transfer to Hub, scale-up, develop SOPs/training
- Conduct Ph I/II/III trials at the hub
- Select & transfer tech and know-how to recipients
  - Either new build (affiliates) or expanding capacity of existing manufacturers (partners)
- Support long term sustainability with other routine Vx and Tx transfers
- Expanded and New sustainable manufacturing capacity in LMICs

Lever 2: Prioritized manufacturers having received TT

- Bilateral deals conducted in LMICs within context of COVAX/WS2, or bilateral deals outside of this context can be prioritized as partners and benefit from Hub training, network and sustainable model

Need strong connection between WS2/3 to map bilat. TT and offer long term COVAX continuity/support
Due Diligence process | Criteria assessed for potential hubs

Vaccine know-how
- Previous works on mRNA vaccines
- Vaccines currently in development

Infrastructures
- Key infrastructures
- Existing pilot facilities
- Approximate cost per year to allocate a pilot plant to mRNA training
- Suitability for industrial scale production

Tech transfer exp.
- Experience in tech transfers

Workforce & training
- Number and expertise
- Possibility to allocate staff to establishing and maintaining a technology transfer hub

Regulatory
- Regulatory department
- Recent filings for clinical studies and/or approval
- Site qualification

Access to regional markets & Equity gap
- Accessibility to regional populations in order to sustain inter-pandemic demand
- Exportations to other markets

Ecosystem & financing
- Accessibility to funds
- Sustainability of funding
- Partnerships with relevant public or private sector players
# Due Diligence process | Criteria assessed for potential tech donors

### Development stage
- Approach used (e.g., mRNA, self-amplifying RNA)
- Clinical trial number(s) and summary data
- Data demonstrating efficiency of vaccines
- Pros & Cons of the tech.

### Intellectual property
- Patent number if any
- Requirement to access any other IP

### Mfg. Process
- Manufacturing process
- Largest scale at which production has been implemented (DS\(^2\) and DP\(^3\))
- Scalability to larger scale
- Predicted cost of goods at full manufacturing scale
- Estimated size of DS facility

### Mfg. Inputs
- Required reagents
- Supply constraints (e.g., proprietary)

### Deliverability
- Route of delivery
- Current and final intended presentation for DS/DP/other container
- Thermostability

### Access & incentives
- Ability to provide access to the tech.
- Type of agreement needed
- Licensing of the tech. to other recipients

### Mfg. Plants
- Interest in serving as a tech. training center
- Ownership of a GMP facility
- Ownership of a facility suitable for industrial scale production
- Ownership of staff able to provide training

### Tech transfer exp.
- Experience in tech transfers

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1. Intellectual Property  2. Drug Substance  3. Drug Product  4. For 50M doses per year on a campus with existing water, utilities, analytical labs, etc.