

COVAX

CEPI



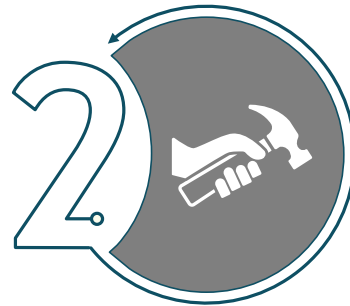
COVAX Manufacturing Taskforce – Workstream 3

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



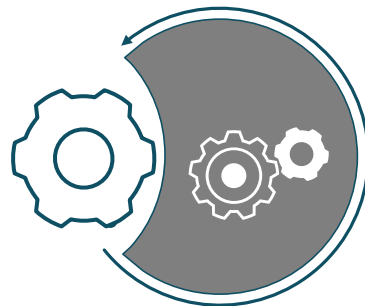
Objective 1

Expand capabilities of existing manufacturers in LMICs



Objective 2

Establish sustainable capacity in regions with no significant capacity

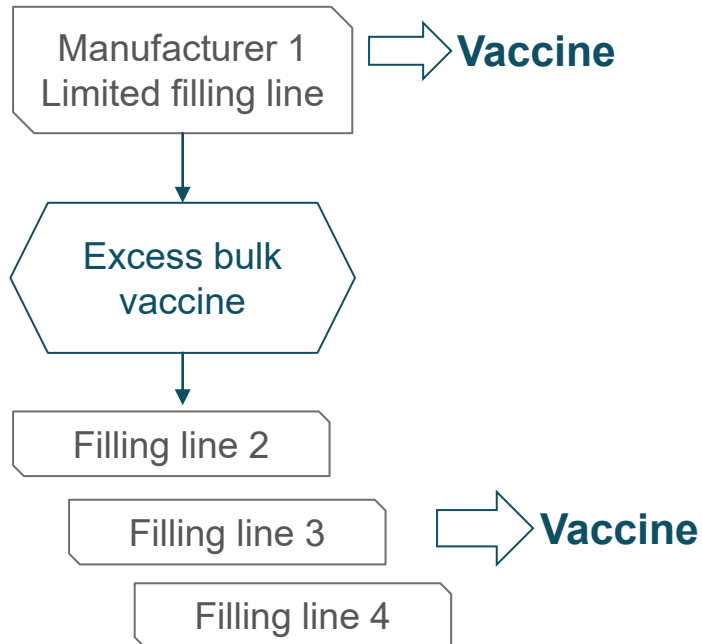


Enablers

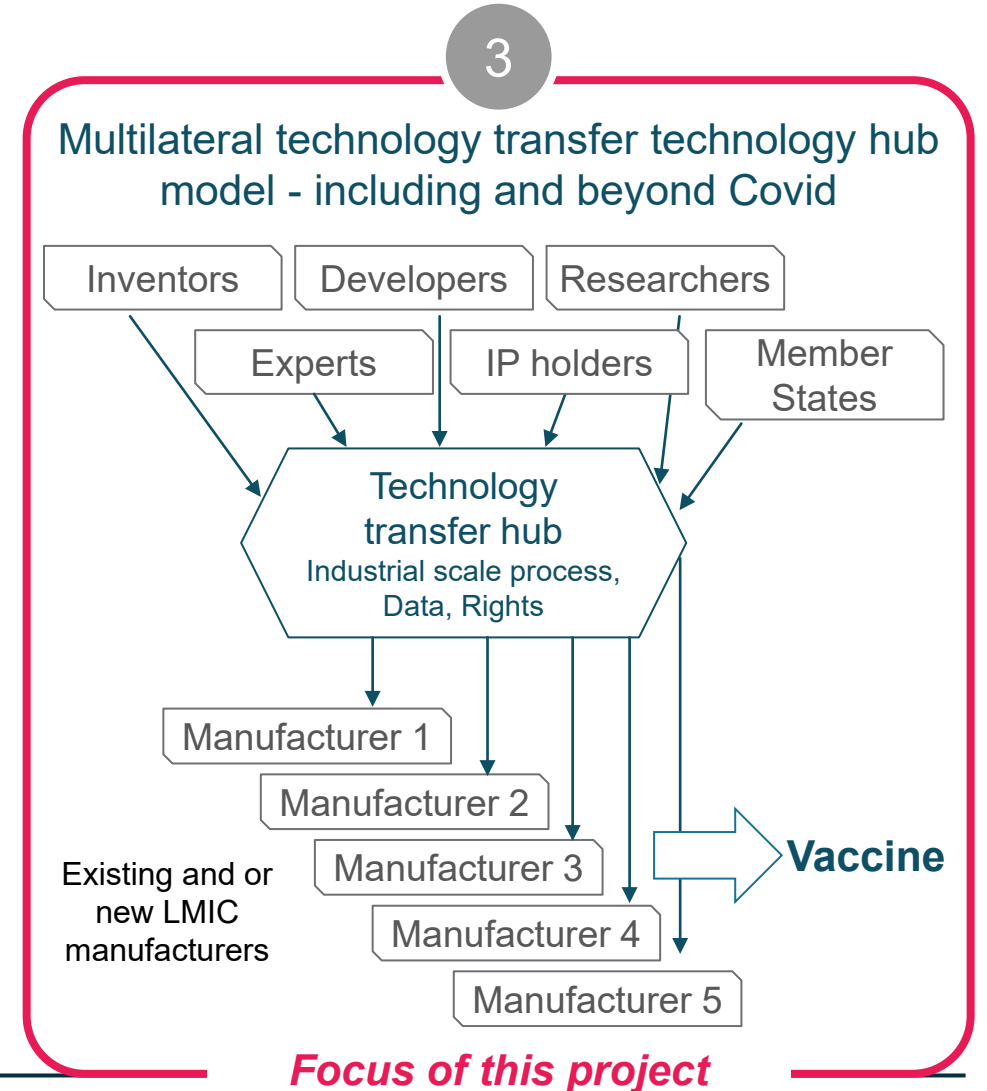
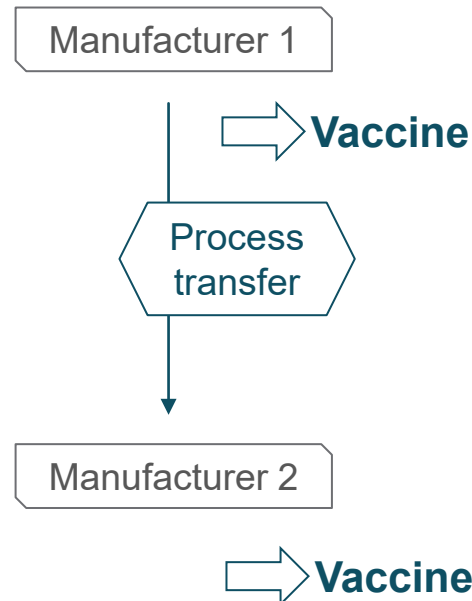
Identify & implement innovations and develop normative frameworks

3 potential approaches for capacity connector identified, with WHO-led WS3 focusing on multilateral TT hub model

1 Fill-finish



2 Bilateral technology transfer



EOI call for mRNA tech hub has been launched in mid-April

Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub



World Health
Organization

16 April 2021 | Call for experts

Given the urgent need for low- and middle-income countries (LMICs) to be able to respond to the COVID-19 pandemic, and the current critical shortage of COVID-19 vaccines in these countries, WHO and its partners are seeking to expand the capacity of LMICs to produce COVID-19 vaccines and contribute to the success of the global vaccination campaign nationally, regionally and globally. Through this new initiative, WHO will facilitate the establishment of (one or more, as appropriate) technology transfer[1] hub(s) which will be able, using a hub and spoke model (REF), to transfer a comprehensive technology transfer package and provide appropriate training to interested manufacturers in LMICs. This initiative will initially prioritize the mRNA-vaccine technology[2] but will expand this call to other technologies in the future, as appropriate.

Ideally such hubs should be able to establish the production process at an industrial or semi-industrial level permitting training in production processes and provision of all necessary SOPs for production and quality control. It is essential that the technology used is either free of intellectual property constraints in LMICs, or that such rights are made available to the technology hub and the future recipients of the technology through a non-exclusive license to produce, export and distribute the COVID-19 vaccine in LMICs, including through the COVAX facility. Preference will be given to applicants who have already generated clinical data in humans, as such clinical data will contribute to accelerated approval of the vaccines in LMICs.

It is anticipated that WHO will work with funders and donors to mobilize financial support to establish the hub(s) and, as it(they) is(are) being established, to support the transfer of technology to selected manufacturers in LMICs, taking into consideration the need to establish permanent vaccine production capacity in regions where this is currently essentially absent. This broader objective will ensure that all WHO regions will be able to produce vaccines as essential preparedness measure against future infectious threats.

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

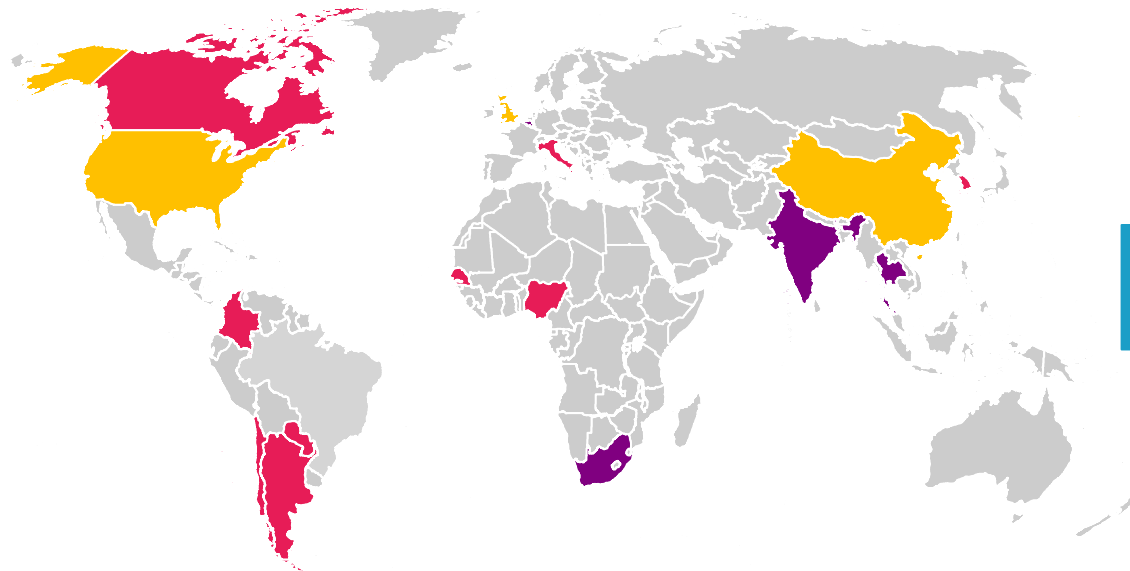
- 1 Possible Hubs: Small/middle-size (public or private) manufacturers of medical products (drugs, vaccines or drug substances) which could host a COVID-19 mRNA hub
- 2 Possible Tech Providers: Owners (public or private) of technology and/or Intellectual Property Rights (IPR) willing to contribute to a technology transfer hub

50+ EOI received from potential candidates for tech transfer hubs & recipients

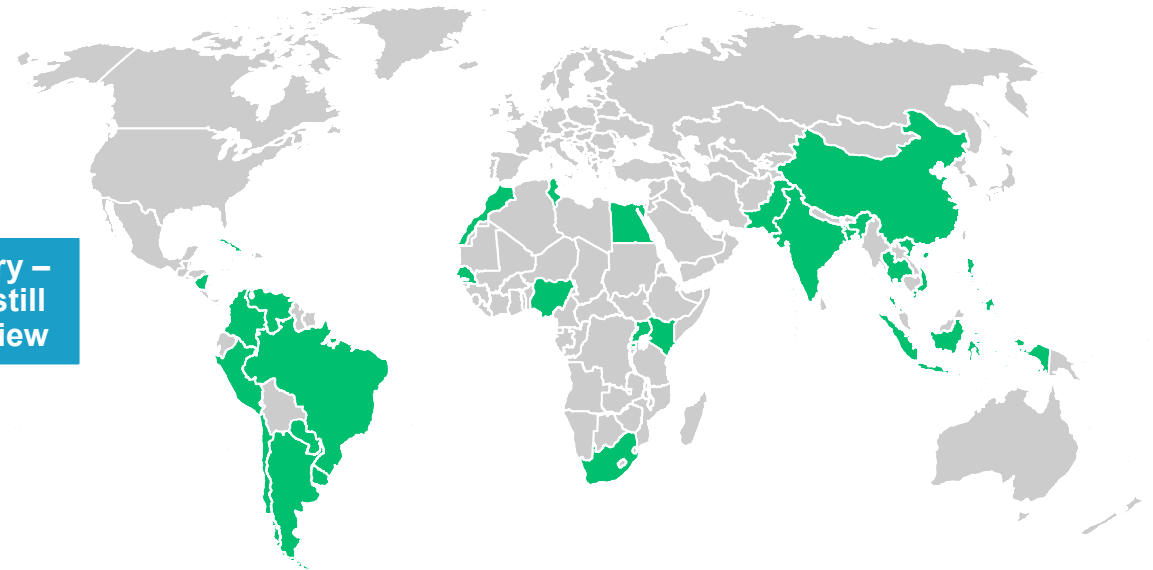
AS OF 07JUNE2021

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

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



Preliminary – answers still under review



- 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)

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

Hub criteria



Tech criteria



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

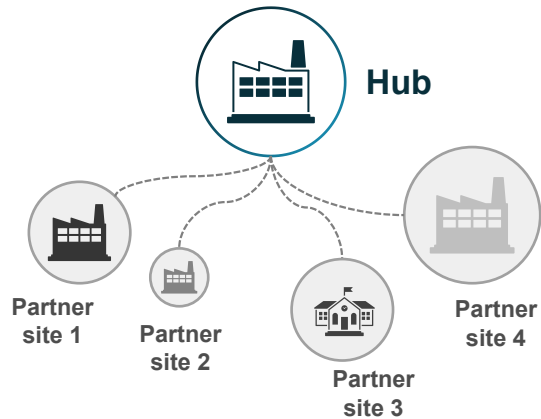


New & expanded sustainable capacity in LMICs

- 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

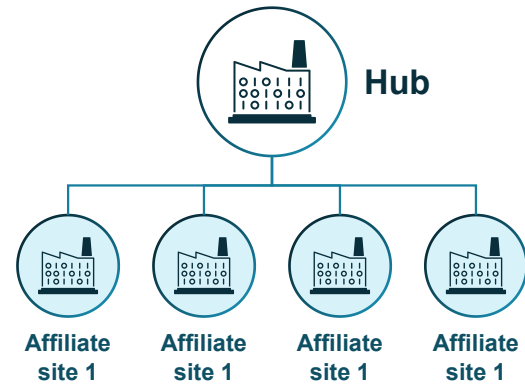


Hub(s) at 1+ existing sites, recipients are other existing "partner" sites, gain TT & know-how for novel tech

- + 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

VS

2 Centralized & normative

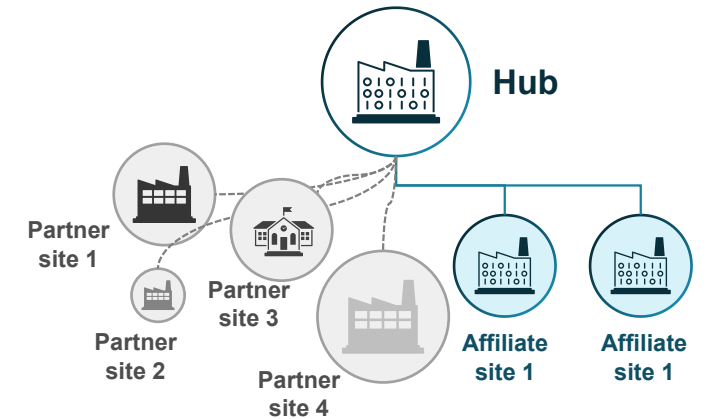


1 hub & several new, identical "affiliate" sites; affiliates receive normative tech transfer & broader capability training

- + 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

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3 Optimized model Preferred option

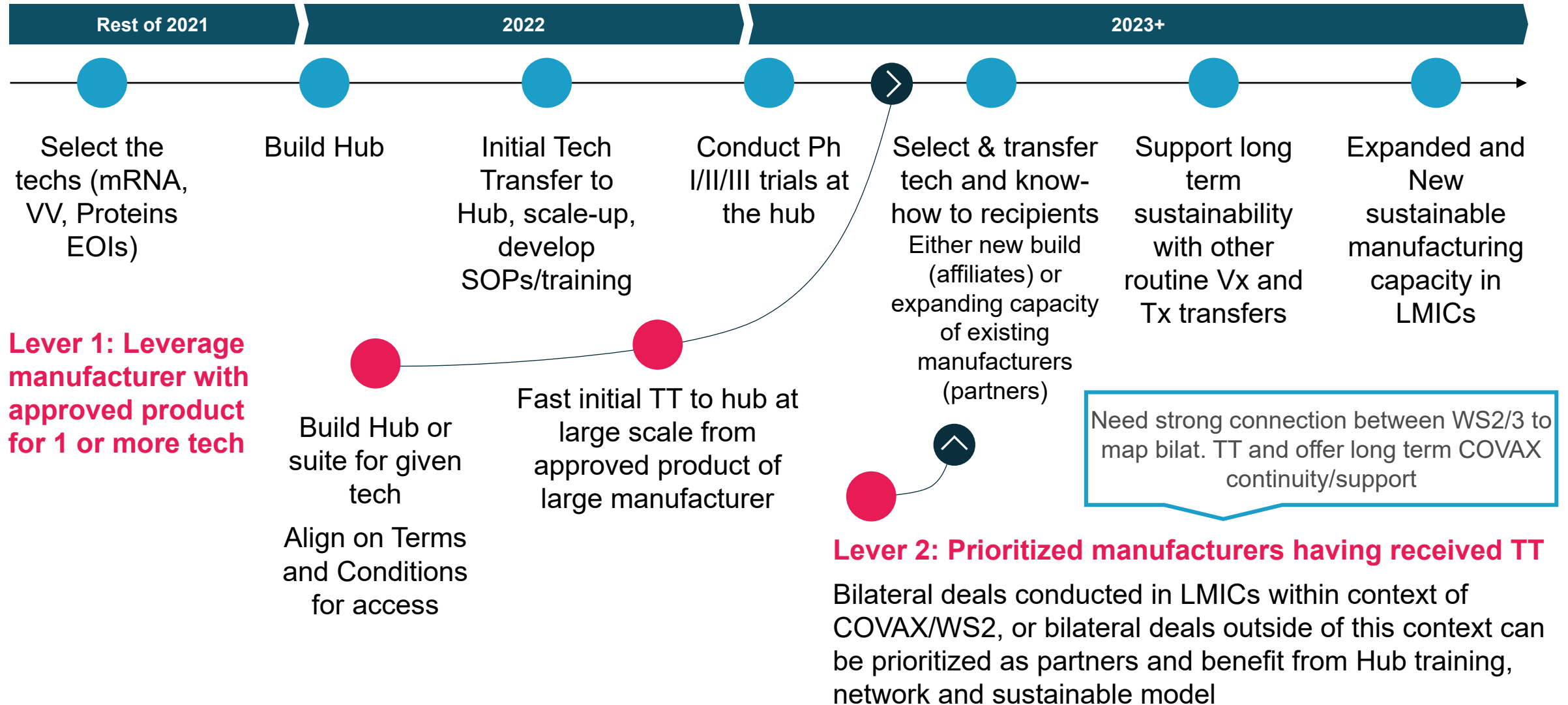


Build 1 hub & some new "affiliate" sites; recipients are both partner & affiliate sites; hub offers distinct training module for each

- + **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



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 IP¹



Mfg. Process

- Manufacturing process
- Largest scale at which production has been implemented (DS² and DP³)
- Scalability to larger scale
- Predicted cost of goods at full manufacturing scale
- Estimated size of DS facility⁴



Mfg. Inputs

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



Deliverability

- Route of delivery
- Current and final intended presentation for DP/final filled 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

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.