COVAX

CEPI Gavi The Vaccine Alliance unicef World Health Organization

Manufacturing Taskforce

May 12, 2021

Where we are today

“Novavax to start shipping COVID-19 vaccines to COVAX program in third quarter”
(Reuters, May 6)

“Moderna commits up to 500M vaccine doses to COVAX”
(Politico, May 3)

“Covax has reserved 500 million doses of the J&J vaccine”
(New York Times, March 12)

Supply and manufacturing challenges remain

“Export controls of input supplies threaten to hinder global vaccine production”
(The Economist, April 24)

“The next big COVID-19 bottleneck? A shortage of trained vaccine workers”
(Fierce Pharma, April 23)

“Syringe shortage hampers Japan's COVID-19 vaccination roll out”
(Reuters, Feb 16)

The Manufacturing Taskforce has set an impact-ambition along four workstreams

PRELIMINARY

Workstream	Aspiration		Convener
1 **Immediate COVAX Response** CEPI: N. Lurie & M. Downham	Create partnership to enhance **visibility on input supplies** Accelerate **export permits/custom clearance** for critical SKUs Expand **fill & finish match making** mechanisms	**Short-term COVID impact** *(1-3 months)*	CEPI
2 **Mid-Term COVAX Response** CEPI: N. Lurie & M. Downham Gavi: D. Maugeais & H. Kettler	Create **overview of global manufacturing capacities** Better **utilize existing capacities**, e.g., voluntary tech transfer Develop **regulatory & manufacturing workforce**	**Mid-term COVID impact** *(Until end of 2022)*	CEPI Gavi The Vaccine Alliance
3 **Long-Term Sustainable Manufacturing** WHO: M. Friede & R. Long BMGF: D. Robinson	**Expand capabilities of existing manufacturers in LMICs**: grow existing capabilities and strengthen the know-how of existing manufacturers **Establish sustainable capacity** in regions with no significant capacity	**Long-term COVID-19 and beyond impact**	World Health Organization Bill & Melinda Gates foundation
0 **Shared fact base / Task Force Coordination Office**	Create aligned **supply baseline** Conduct supply and manufacturing **ecosystem mapping** Maintain an integrated view of **funding requirements** across workstreams	**Enabling baseline of information**	CEPI Gavi The Vaccine Alliance World Health Organization unicef Bill & Melinda Gates foundation

Workstream 0: Shared fact base / Task Force Coordination Office

PRELIMINARY

Initial achievements

- Launched **manufacturing taskforce**
- **First draft of ecosystem mapping** (~ 30 organizations, 130 ongoing initiatives)
- F**irst view of supply data**

Priorities for next weeks

- **Finalize ecosystem mapping** and disseminate further
- Ensure **taskforce is up and running** and whole group convened
- Develop **supply baseline and test assumptions**

Key milestones going forward

- Develop **supply outlook** *(first version end of May)*
- Publish aligned **ecosystem mapping** *(first version end of May)*
- Create overview of immediate **enabling resources needs** *(end of May)*
- Have **Taskforce Coordination Office** up and running (end of May)

Workstream 1: Immediate COVAX Response

PRELIMINARY

Initial achievements

- Validated supplier and manufacturer interest in **input supply marketplace** and detailed marketplace design
- Identified first set of pain points and solutions for **free flow of goods**
- Identified key intervention areas for improving **Fill & Finish matchmaking**
- **Engaged key governments** and stakeholders (e.g., USG, EC)

Priorities for next weeks

- **Finalize the charter/terms of participation** to ensure legal compliance and confidentiality
- **Onboard partners** to marketplace and prepare for launch
- **Detail list of critical SKUs** and export permit acceleration solutions
- **Implement intervention** areas identified

Key milestones going forward

- **Launch** initial input supply marketplace *(June)*
- **Launch** free flow of goods interventions *(June)*
- **Launch** of Fill & Finish matchmaking interventions *(June)*

Workstream 2: Mid-Term COVAX Response

PRELIMINARY

Initial achievements

- Identified and accessed key sources of data for existing **capacity mapping**
- Started framing of key **challenge areas & potential solutions**
- **Identified interdependencies** with other taskforce workstreams

Priorities for next weeks

- Continue **data collection/ consolidation** for mapping
- Finalize assessment and mapping of priority **problems and potential mid-term solutions**
- **Develop draft solutions** in partnership with manufacturers based on the identified pain points

Key milestones going forward

- **Finalize pain points and capacity mapping** and share with key partners *(June)*
- ***Share proposed solutions/ COVAX value proposition*** *to address mid-term capacity challenges with key partners (June)*

Workstream 3: Long-Term Sustainable Manufacturing

PRELIMINARY

Initial achievements

- Initial **EOI** issued by WHO for mRNA hub
- Aligned on **3 design choices** for expanding & creating vaccine manufacturing in LMICs
- Defined initial **program structure** (working groups, deliverables, timeline) for detail design and implementation
- Shared **draft concept note** for input from partners

Priorities for next weeks

- Conduct info call on **concept note**, address feedback and confirm optimal go-forward **design model**
- Complete high-level **costing estimate**
- Refine **working groups** and identify participants/leads
- Continue to synthetize **EOI responses & evaluation**

Key milestones going forward (see details on following selected WS3 output pages)

- **Design options** developed and evaluated, incl. high-level costing estimate (*end of May*)
- Target tech & IP landscape initiated, expert panel defined (*end of May)*
- **Concept note** for design phase released (*end of May)*
- **Roadmap for next EOIs** completed *(end of May)*
- **Workstreams launched & detailed planning** of chosen design option conducted *(end of June-end of 2022)*
- **Plans translated into action** and execution initialized (*2022 and beyond*)

WS3 selected output – We defined 3 discrete phases of work for our workstream

Design
Current phase

Detailed Design & Pilot

Build & Implement

Now to end of May

Develop concept & design options, define program structure

- Develop & evaluate design options
- Define program working groups, key milestones and timeline
- Publish concept note v1
- Process EOI responses & prepare for additional EOIs
- Engage with stakeholders for input; identify working group participants
- Conduct initial IP landscaping
- Size high-level costs for subsequent phases

WS 3 leads

June to ~end of 2021

Launch workstreams & conduct detailed planning of chosen design option

- Select technology for transfer
- Design hub and potential affiliate network, select locations
- Develop plan for regulatory & workforce strengthening
- Define hub & recipient governance model
- Refine costing estimates, mobilize funds
- Continue engagement with Member States & other key stakeholders for input
- Issue subsequent EOIs

WS 3 leads

2022 and beyond

Translate plans to action, initiate execution

- Complete facility design & initiate build
- Negotiate & manage any necessary licenses
- Publish normative policy guidance
- Prepare programs for regulatory & workforce strengthening
- Launch initial transfer of selected technology to hub

Key activities

+ other partners as needed to support specific workstreams across build & implementation

Regional Offices

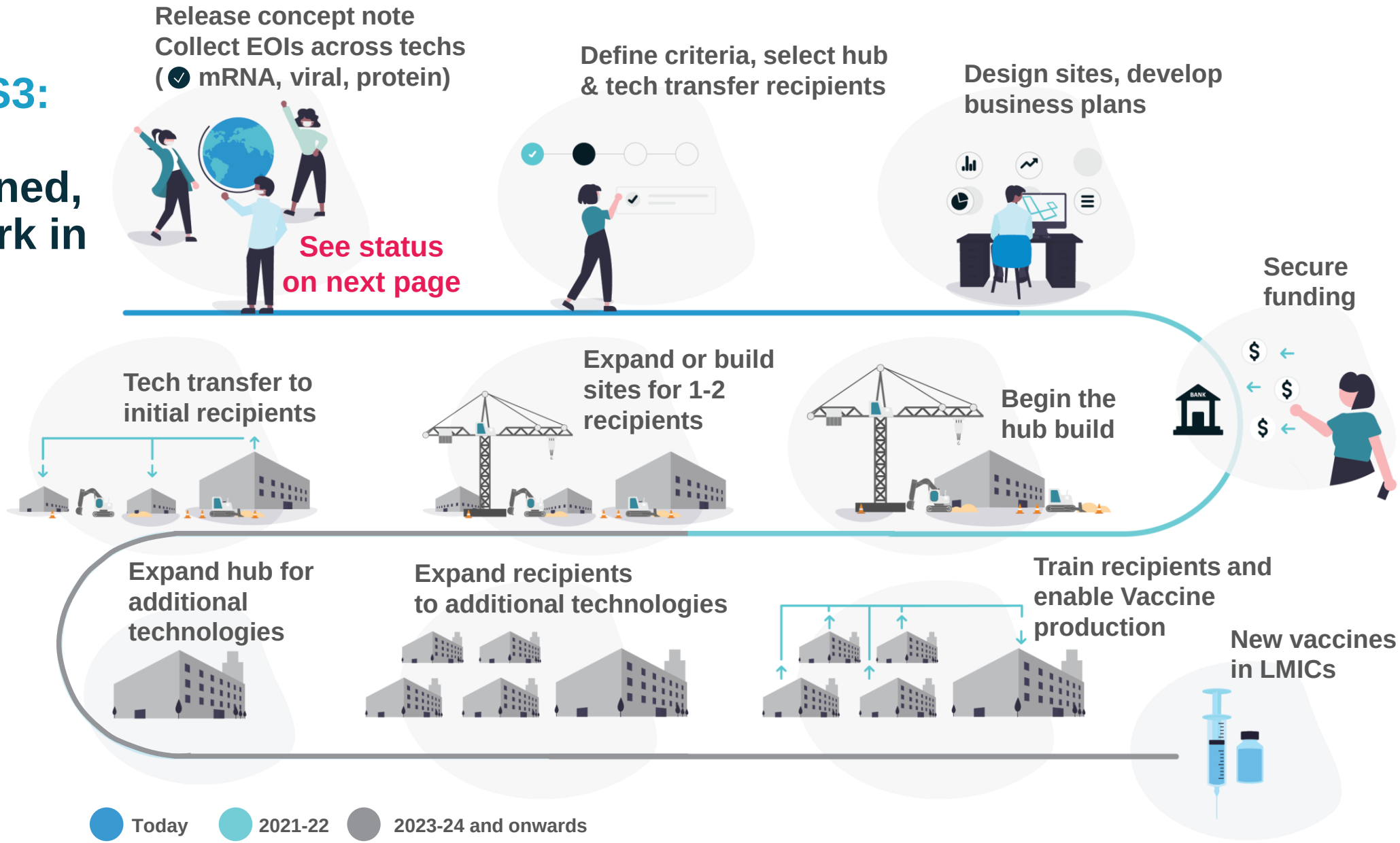
USG

+ others TBD

Note: Exact timeline TBC

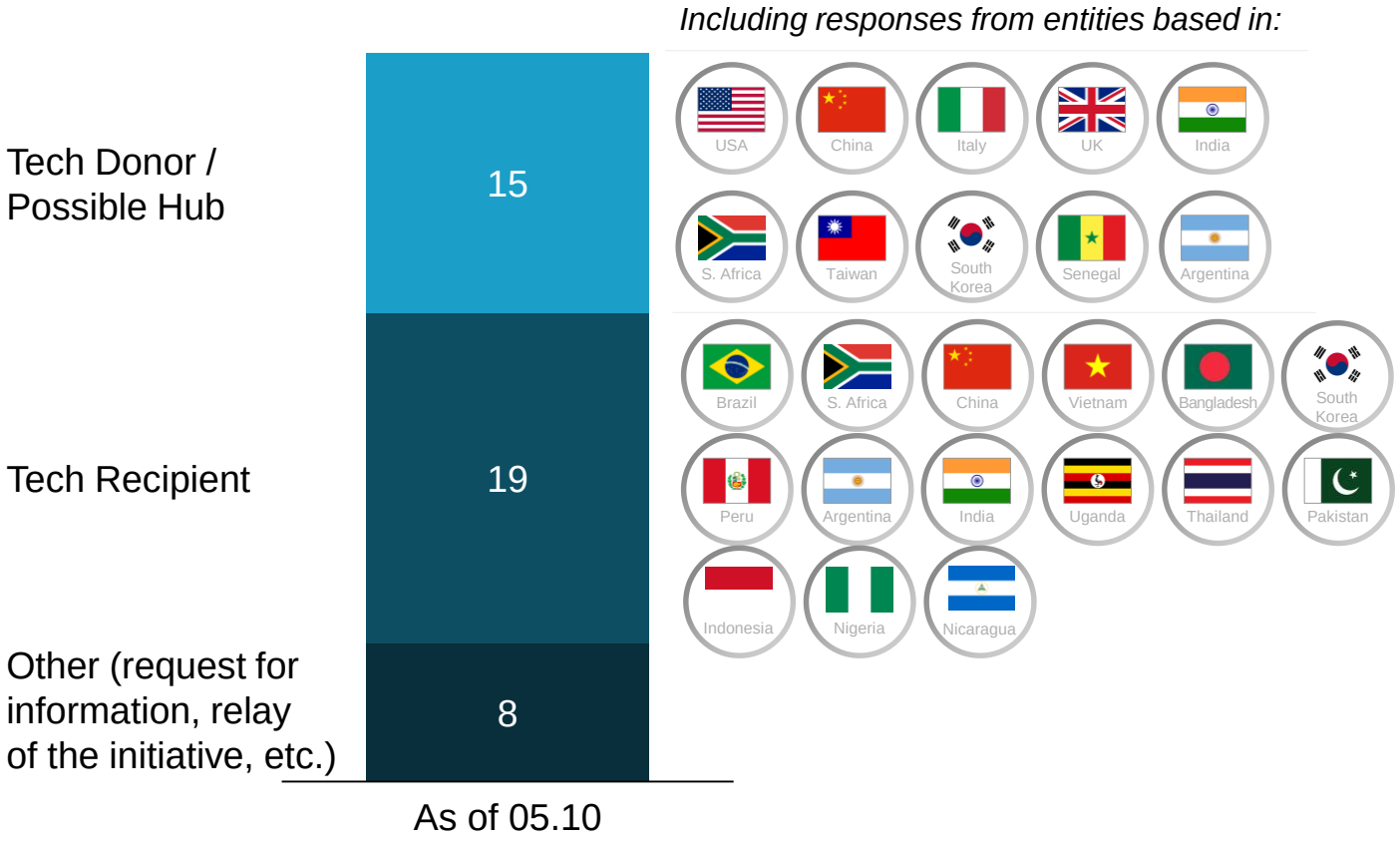
Vision for WS3:

Once design Model is defined, we will embark in a multi-year journey to establish the LMIC network



WS3 selected output – Zoom: Currently processing mRNA EOI responses and identifying possible Donors/Recipients

42 responses to date spanning across many regions - preliminary



Current activities

- Replied to all respondents to acknowledge submission
- Scheduling calls with promising respondents for additional details
- Reaching out to other entities / countries to complement initial responses
- Defining initial criteria to assess fit with overall network and began donors/recipients assessment

Path forward

- Refine selection of doners/recipients
- Synthesize findings & recommendations
- Prepare for & launch EOIs for other techs in late summer

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Thank you