

# CEPI'21 vaccine manufacturing survey results



# Map 2021 vaccine manufacturing landscape\*

- 29Mar-18Jun'21: request for information - Africa, SE Asia, Latin America, Middle East
- Determine vaccine manufacturing site capacity and capability per region whether:
  - Requiring development to improve epidemic/pandemic preparedness and response options
  - Countries aspiring to establish manufacturing capacity/capability currently absent or limited



## Core Capabilities

- Research & Development
- Drug Substance / Product
- Formulation & Filling
- Packaging & Labelling
- Storage & Distribution



## Platform Technology

- Nucleic: DNA, mRNA
- Viral: live / vector, inactivated / killed
- Lipid nanoparticle
- Protein: recombinant, subunit, conjugate



## Site Capacity

- Formulated vaccines
- Vial, syringe, container
- Vaccine lyophilization
- Cold chain:  $\geq -20^{\circ}\text{C}$  &/or  $\leq -60^{\circ}\text{C}$
- Warehousing, quarantine



## Pathogen

- All per site

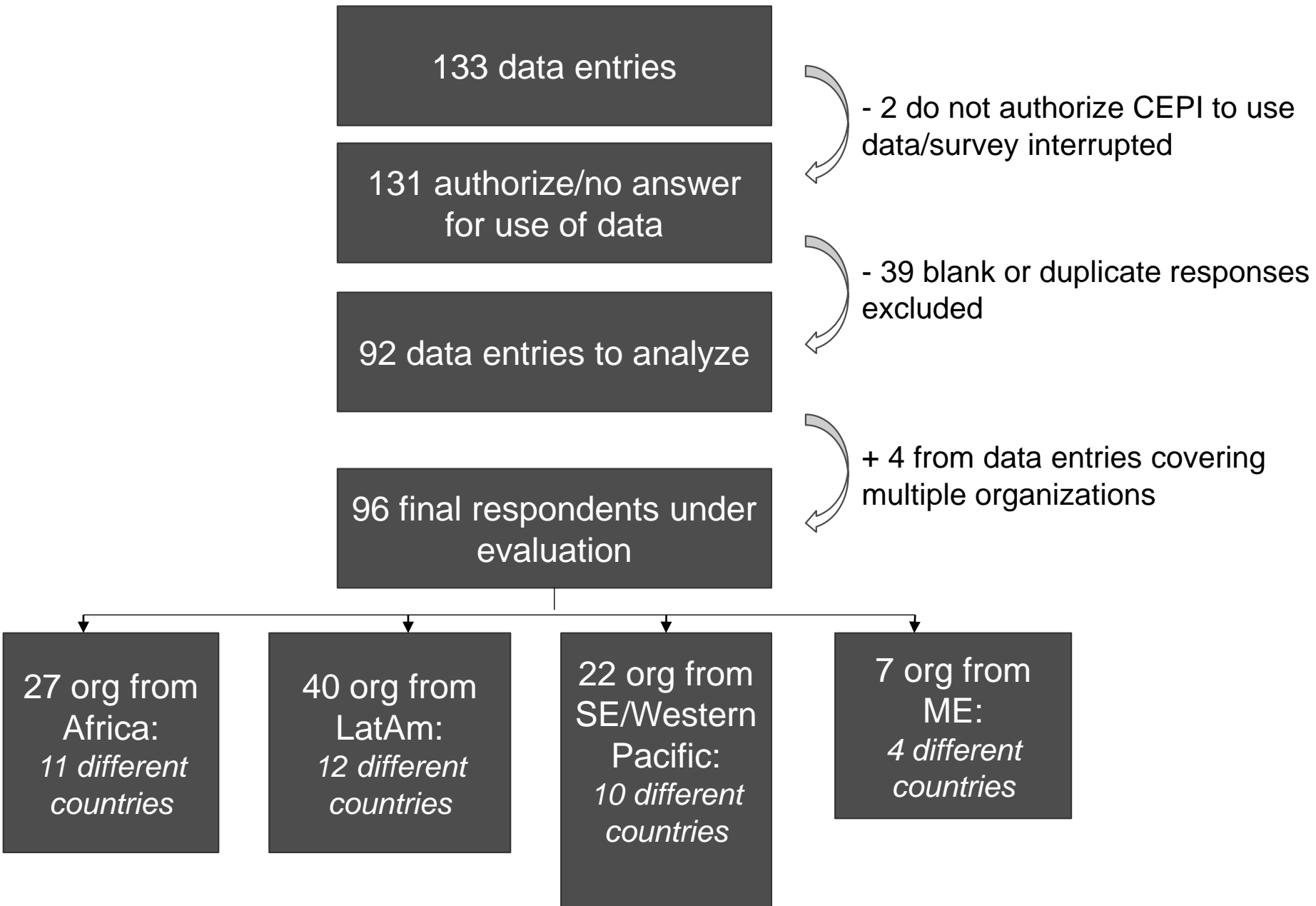
# Executive data review summary

- Totals: 133 data entries → 96 final respondents under evaluation
  - Africa (11 countries), SE Asia (12 countries), Middle East (4 countries) LatAm & Caribbean (10 countries)
- Small/academic R&D labs, MoH facilities, vaccine/pharma manufacturers, vet institutes
- No/minimal R&D – clinical trial &/or DNA / mRNA platform technology focused
- Predominantly drug substance/product through to supply (1→9 vaccines per site)
- Current (2021) maximum production capacity (approximate doses): from thousands for CTM to 800MM: pathogen & platform specific
  - Many plan to increase dose supply capacities between 2022 to 2025

## Pathogens

Cholera  
COVID-19  
Diphtheria  
Hepatitis A, B  
Haem. influenzae type b  
HPV  
Intracellular protozoa  
Japanese encephalitis  
Measles  
Meningitis  
Mumps  
Pertussis  
Polio  
Rabies  
Rotavirus  
Rubella  
RSV  
SARS  
Seasonal influenza  
Shingles  
Strep. Pneumococcus  
Tetanus  
Tuberculosis (BCG)  
Typhoid  
Varicella  
Yellow fever

# Flow chart of data selection



# Data assessment categorization and criteria

Category / criteria
<b>Spectrum of core capabilities</b>
Unknown/blank
R&D only
DS or DP only
R&D and DS or DP
End to end capability
<b>Organization dose capacity</b>
Unknown/blank
Small < 50M doses/year
Medium-large >50M doses/year
<b>Years of experience</b>
Unknown/blank
Less than 5 yrs
More than 5 yrs
<b>No. of vaccines supported</b>
None/blank/unknown
1 vaccine
2-3 vaccines
More than 3 vaccines

Category / criteria
<b>Existing international collaborations</b>
No/unknown
Yes
<b>Regulatory status</b>
None/blank/unknown
National approval track record
Approval track record from multiple countries, EMA, FDA, WHO PQ
<b>Profitable vs reliant on Gov/NGO funding</b>
<b>Veterinary vaccine manufacturer (n=5)</b>
<b>Capability per technology</b>
None/blank/unknown
One technology only
More than 1 technology
<b>International support</b>
No/unknown
Yes
<b>Local Gov. support e.g. funding, advisory etc</b>
No/unknown
Yes



# Global survey respondents support pandemic vaccine preparedness to respond

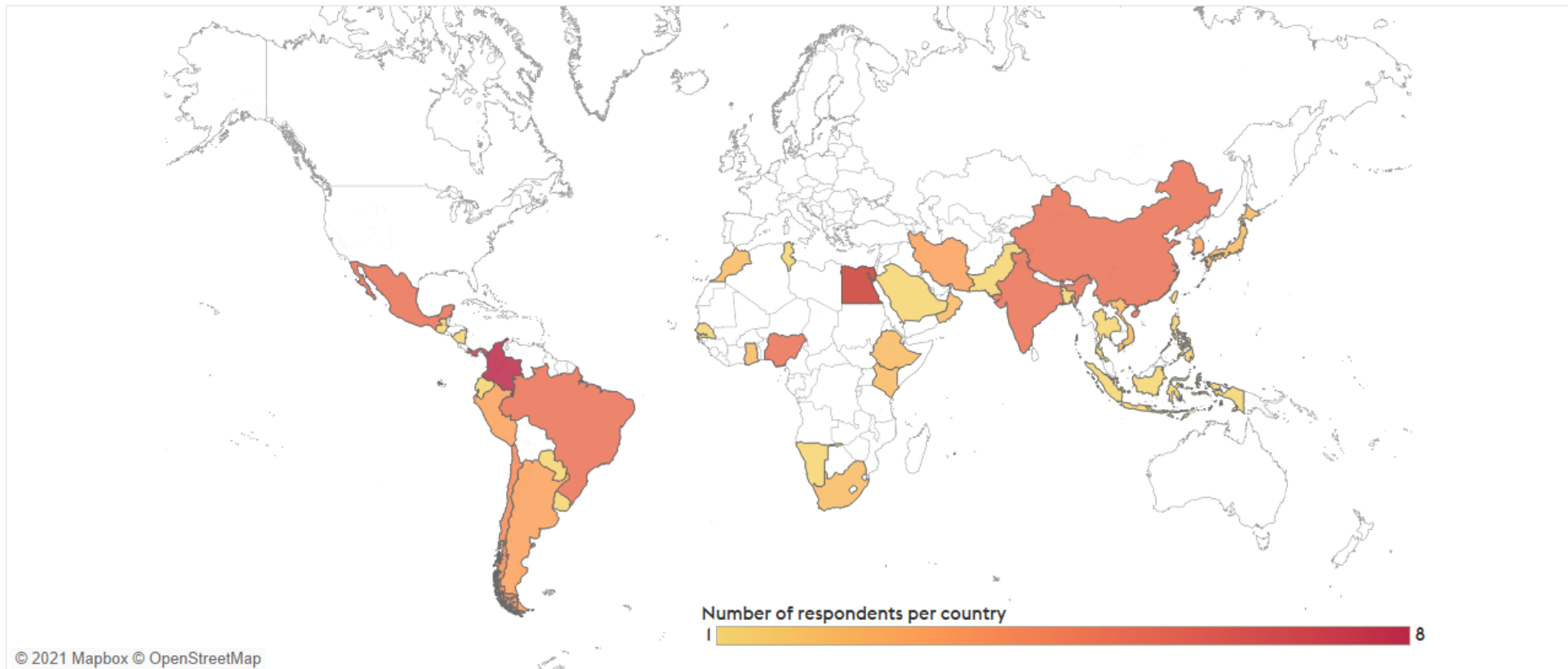
Supporting pandemic vaccine preparedness

	Africa	LatAm	Middle East	South East/ Western Pacific	Grand Total
Extremely Willing	20	19	6	16	61
Might Be Willing	2	10		3	15
No Willingness To Support		3			3
Unknown / No response	5	8	1	3	17

Supporting future pandemic vaccine responses

	Africa	LatAm	Middle East	South East/ Western Pacific	Grand Total
Extremely Willing	22	21	5	16	64
Might Be Willing		10	1	3	14
No Willingness To Support		2			2
Unknown / No response	5	7	1	3	16

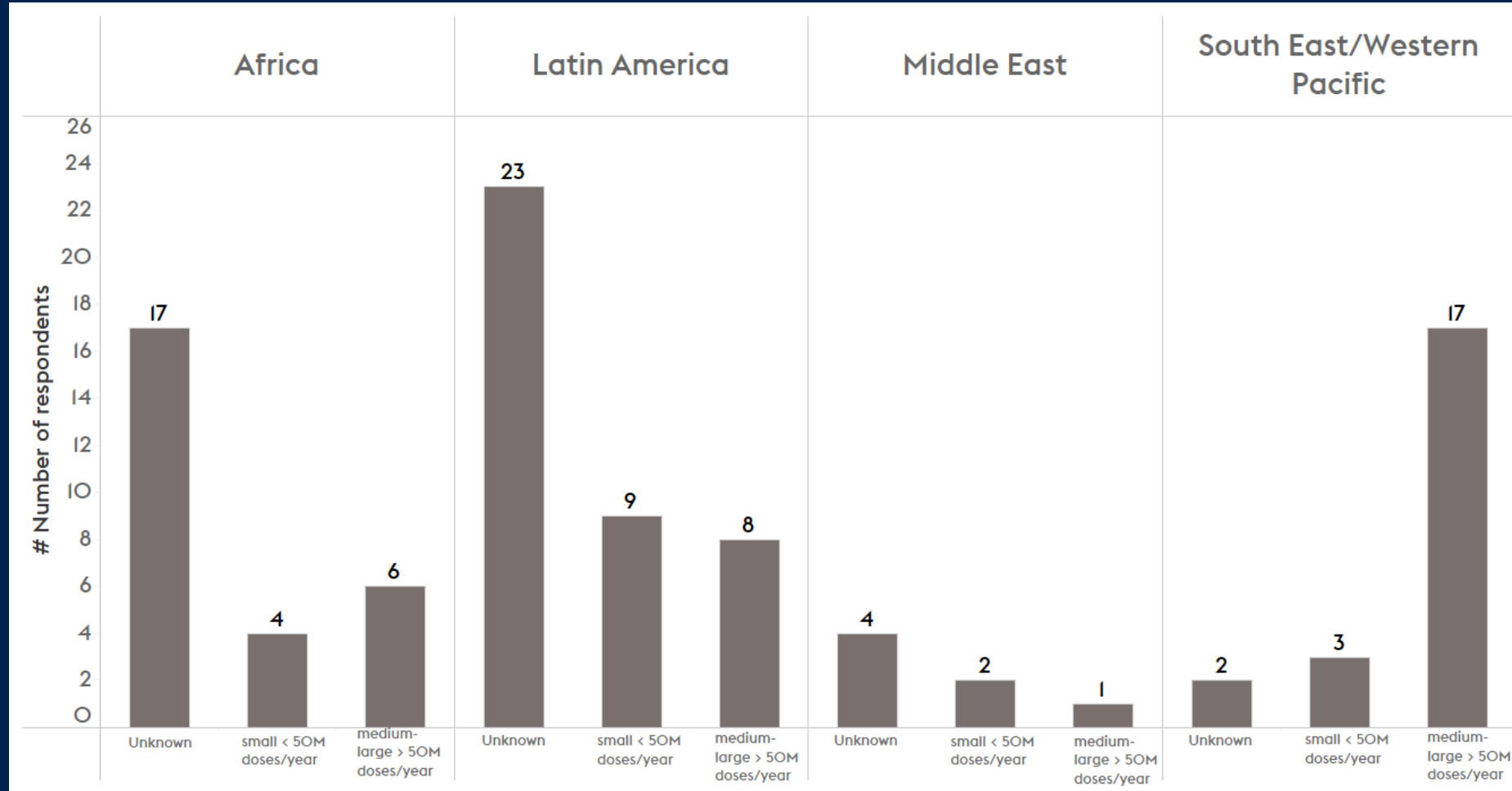
Geographical distribution of the RFI respondents



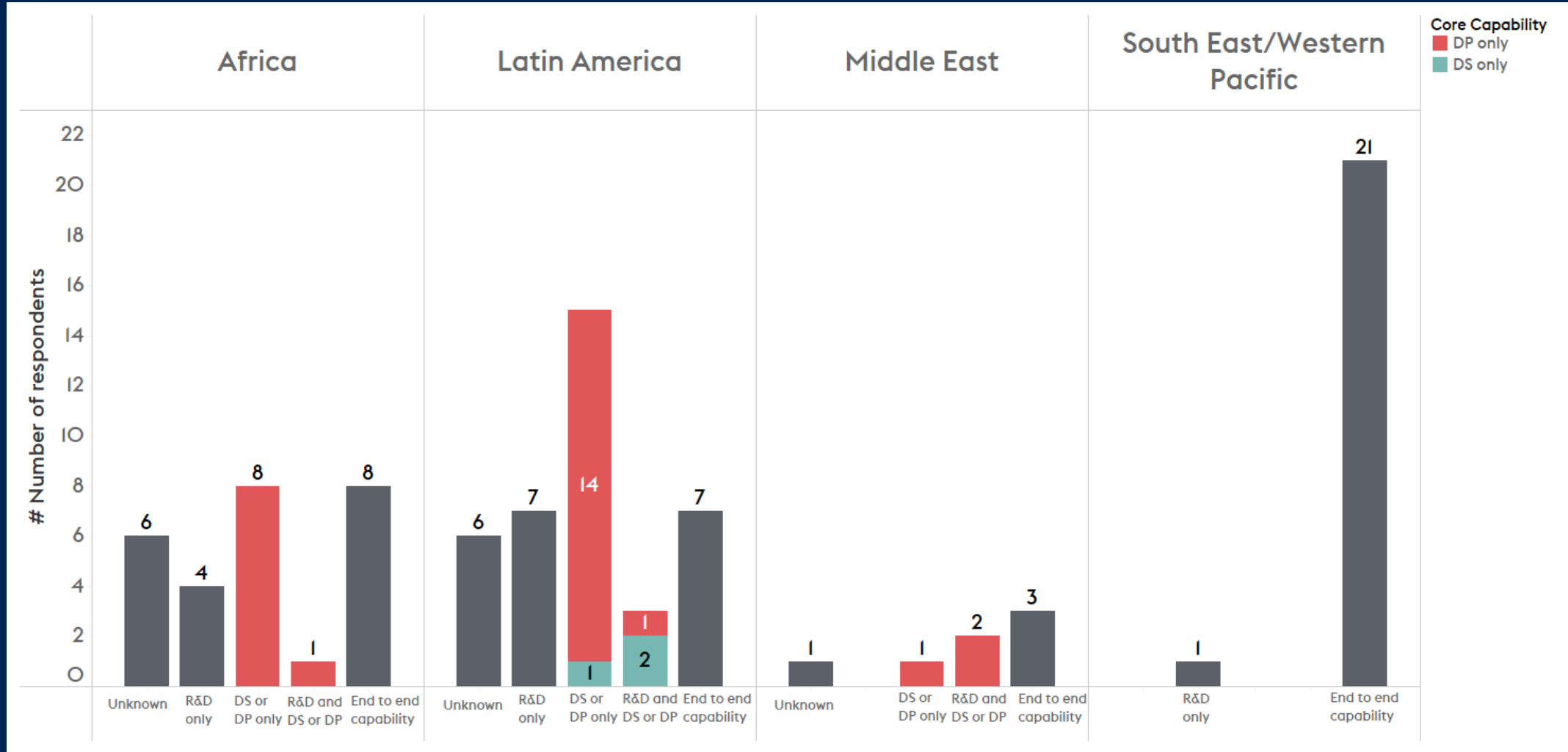
# Vaccine manufacturing capacity predominates in SEA/WP\*

## ➤ Organization size/overall capacity:

- Across regions there are 17 (17.5%) respondents with small manufacturing capacity, whereas 32 (33%) have medium-large scale capacity
- About 50% respondents from Africa and Latin America provided limited information on their manufacturing capacity
- > 70% respondents from South East/Western Pacific have medium-large manufacturing capacity



# Vaccine manufacturing capabilities vary across regions

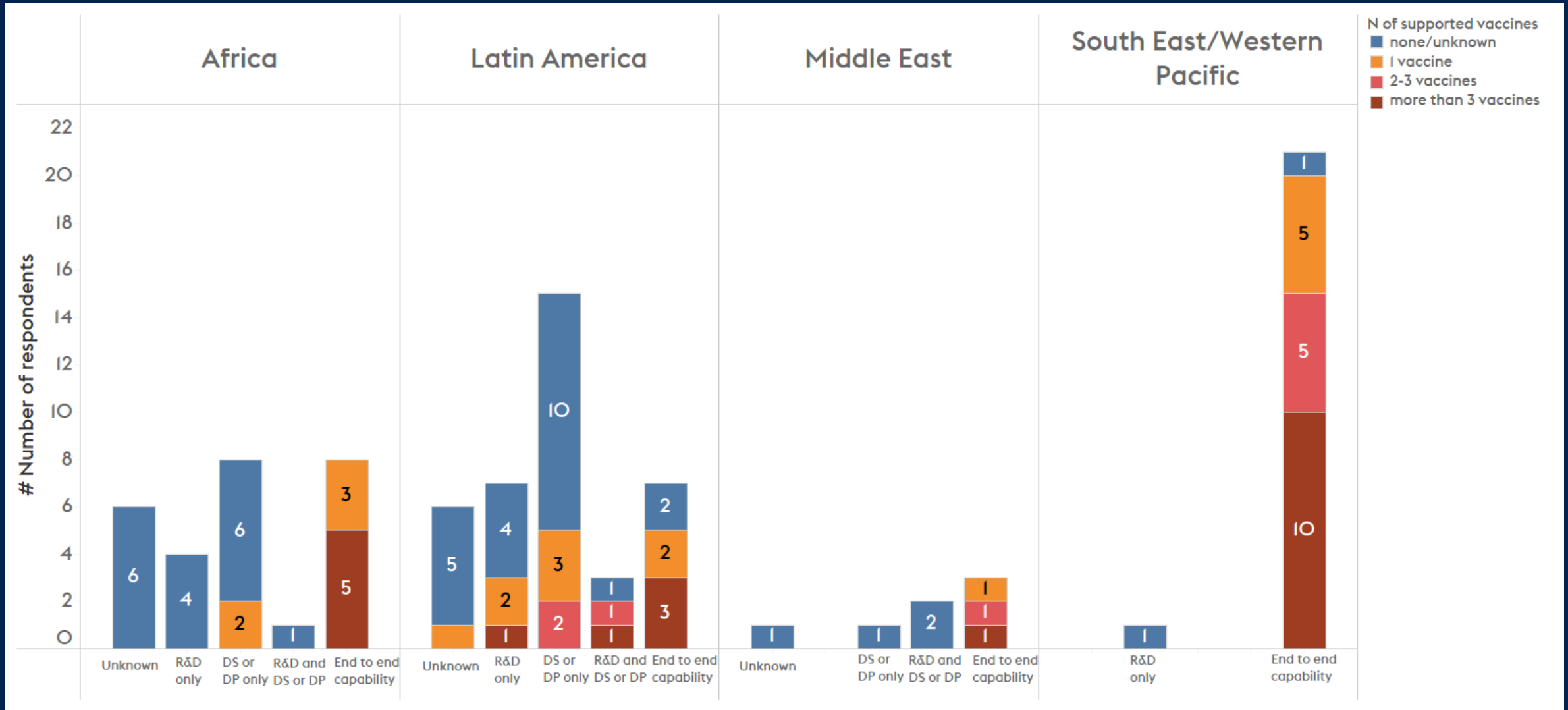


## Key take-aways

- South East/Western Pacific with most of end to end capability
- Existing vaccine manufacturing landscape in Africa, Middle East and Latin America is mostly focused on DP and fill / finish



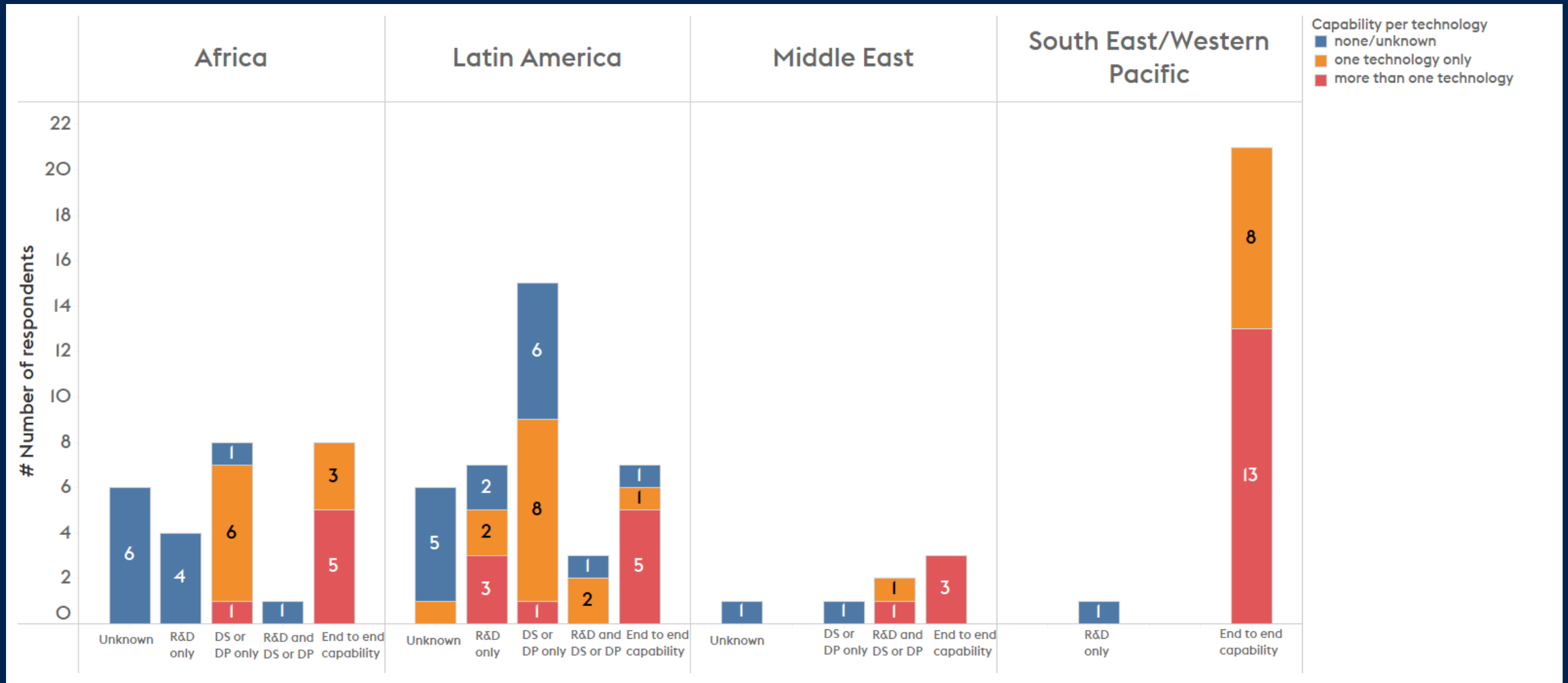
# Wide manufacturing capability linked to highest number of vaccines



## Key take-aways

- Most of respondents with end-to-end capability supports manufacturing of multiple products
- Veterinary Institutes participating to the survey are included (3 in Africa and 4 in Latin America)

# Protein and viral vaccines predominate, limited mRNA across regions



## Key take-aways

- Technology capabilities are mostly focused on: Live Attenuated or Vector; Recombinant, Subunit, Conjugate or toxoid; Inactivated vaccines

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- Experience with mRNA technology is currently limited across all regions

# Aspirational plans focus on delivery through to 2025

Most survey respondent aspirational plans focus on:

- Expanding existing human vaccine manufacturing DS/DP &/or fill-finish capacity
- Create vaccine manufacturing capacity at existing pharma companies or veterinary institutes to support local demand
- Build new capacity (multi-product facility) in countries where there is currently no human vaccine manufacturing capacity/capability
- Technical capability diversification predominantly to technical transfer in DNA / mRNA &/or viral vaccine platforms
- Aspirational plans often linked with international consortia including organizations from HICs
  - Investment often identified and supported by private investors
  - Government endorsement / coordination often critical

# Regional vaccine manufacturing workshop scope

- Review RFI'21 data, discuss gaps and opportunities
- Focus on solutions to establish manufacturing capacity and capability
- Instigate developing a road map to improve or establish sustainable vaccine manufacturing capacity and capability
- Leverage collaborative partner networks e.g. “*Centers of Excellence*” and regional manufacturing sites
- Improve epidemic/pandemic preparedness and response
- Facilitate public health security through a diversified global vaccine manufacturing network



# Roadmap requirements to establish / expand vaccine manufacturing capacity and capability

- ✓ A “*champion*” for oversight and leadership to deliver objectives per region / country
- ✓ “*Local ownership*” of vaccine manufacturing facility capacity and capability within a collaborative partnership association / network
- ✓ Applicable “*business models*” and public-private “*investment*” initiatives
- ✓ Assured manufacturing facility “*sustainability*” in inter-pandemic periods
- ✓ The required “*infrastructure*” e.g. workforce training, quality requirements, regulatory processes, public-private partnerships...

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