Introduction to vaccine R&D, manufacturing, and technology transfer to ramp up capacity

WTO – C19 Vaccines R&D, Manufacturing & Distribution workshop

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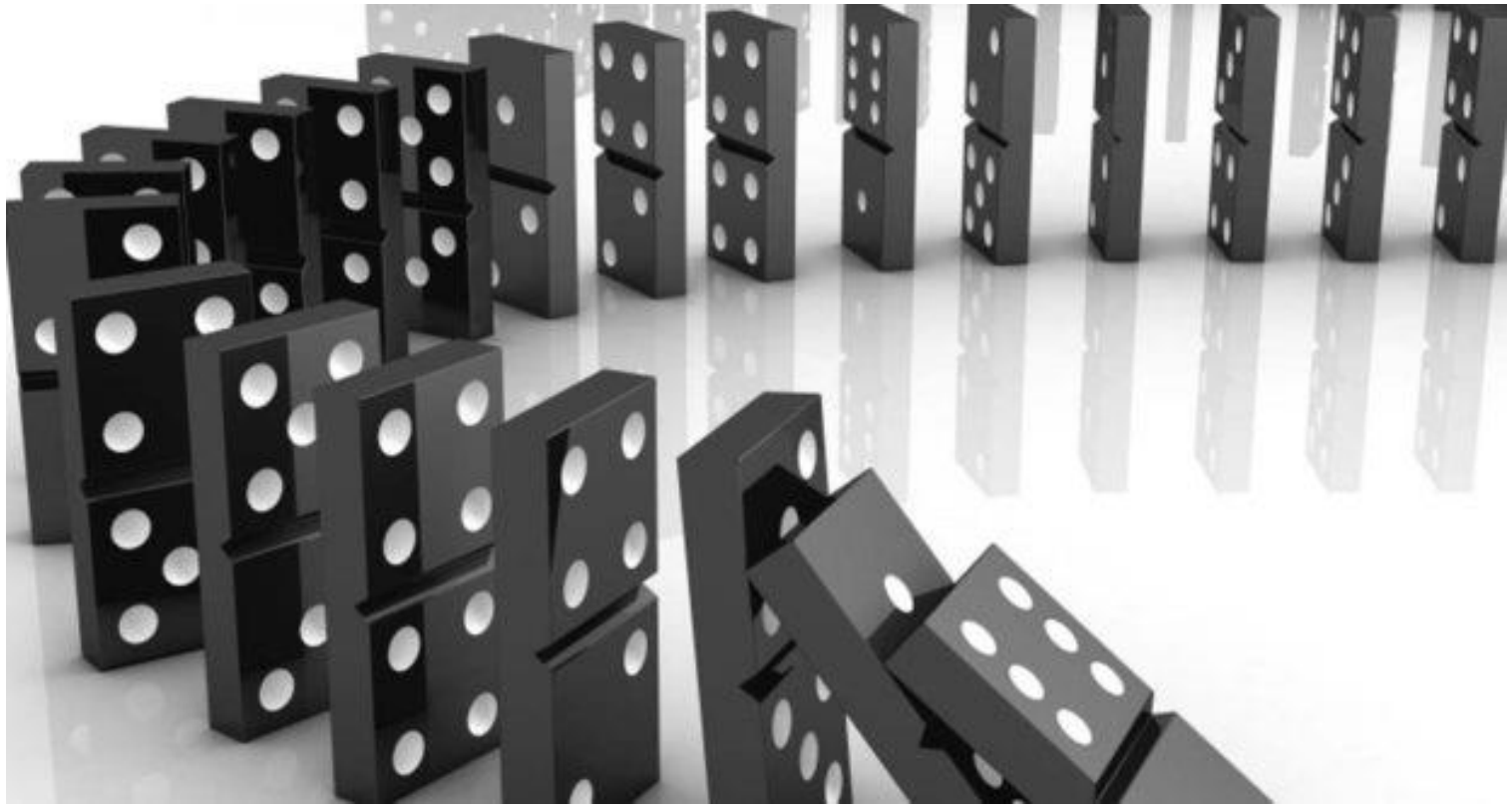
Organisation,

Coordination,

Collaboration,

Synchronisation,

Timing…



Categories of vaccine platform technologies

Oldest → Newest

Category		Technology	Antigen[1] used	Examples
Whole Pathogen Vaccines		Live Attenuated	• Weakened pathogen	• Rotavirus, MMR, Chickenpox, yellow fever
		Inactivated	• Killed/Altered Pathogen	• Polio, whooping cough, Hep-A, rabies
Subunit Vaccines		Recombinant Protein	• Yeast cells containing pathogen DNA	• HPV, Hep-B, Men-B
		Toxoid	• Toxins produced by pathogen	• Diphtheria, tetanus
		Conjugate	• Sugars found on surface of pathogen	• Hib, typhoid conjugate
		Virus like particles	• Molecules resembling virus	• Hep-B, HPV
Viral vector vaccines		Replicating	• Harmless viruses deliver antigen producing code to cells	• Ervebo (Ebola)
		Non replicating	• Same as replicating but viruses cannot reproduce	• Oxford-AstraZeneca COVID-19, J&J COVID-19
Nucleic acid Vaccines		RNA	• mRNA which causes cells to produce antigen	• Pfizer, Moderna COVID-19
		DNA	• DNA which causes cells to produce antigen	• *None approved*[2]

Notes: 1. Antigen: a toxin or other foreign substance which induces an immune response in the body, especially the production of antibodies. 2. Melanoma, West Nile vaccines approved for veterinary use

Source: University of Oxford, Vaccines Europe

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Core stages of vaccine manufacture: CEPI'21 survey*

- Research (i.e. Identification, Investigation, and/or Characterization of novel vaccine candidates)
- Development (i.e. up/downstream processing and analytical development of novel vaccine candidates to support GMP processes and/or clinical trial material supply)
- Drug Substance (i.e. provision of starting seed/initial drug product for bulk manufacture)
- Drug Product (i.e. bulk drug product manufacture)
- Formulation & Filling (i.e. final formula preparation and filling of bulk drug product)
- Packaging & Labelling (i.e. package & label vials of final drug product and/or clinical trial material)
- Storage & Distribution (i.e. storage and supply of vaccine final drug product and/or clinical trial material)

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*CEPI web: Survey launched by CEPI to track multinational vaccine manufacturing capacity for use in future epidemics and pandemics (19May'21) & Vaccine production efforts across key regions mapped in first-of-its-kind study to prepare for future pandemics (27Oct'21)

EoI (Q1/22)* - vaccine development and MfG facilities

Identified against a quorum of eligibility criteria to improve preparedness and response to future epidemics or pandemics

(i) Develop and supply vaccine candidates for use in GMP manufacture (of drug substance/product), QC, formulation & fill, distribution supporting commercial or clinical trial use

(ii) Rapidly provide vaccine emergency counter measures e.g., drug substance/product to LMICs for processing to address epidemic and pandemic threats

(iii) Ability to support transferring vaccine manufacture technologies/processes, analytical methods, innovations, and equipment to LMIC developers, manufacturers &/or CDMOs.

(iv) Be a training provider either at or virtually from the “Facility” and on site at LMIC developer/manufacturer to support strengthening workforce capability and expertise

(v) Evaluate and develop innovative equipment, processes, vaccine presentations to support rapid response to epi-/pandemic outbreaks

(vi) Where applicable, appropriate IP and associated license rights to under-take the required core criteria activities and where mutually agreed, support a technology transfer process to/from other entities in support of CEPI’s Equitable Access goals

(vii) Proven or clear plans to have appropriate quality systems, authority certified GMP readiness (incl. import/export experience) and recorded regulatory experience aligned to the activities described

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***Calls-for-Proposal of interest:**

1. Central Lab Network expansion (Q4/21) to more diseases than SARS-CoV2 vaccine analysis & onboard SH organizations
2. Innovative technologies to improve vaccine thermostability (Q1/22)

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