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CENTER FOR VACCINE INNOVATION & ACCESS (CVIA)

10th Policy Actions for COVID-19 Economic Recovery (PACER) Dialogues

Enhancing Readiness for Large-Scale Vaccine Distribution Amid COVID-19

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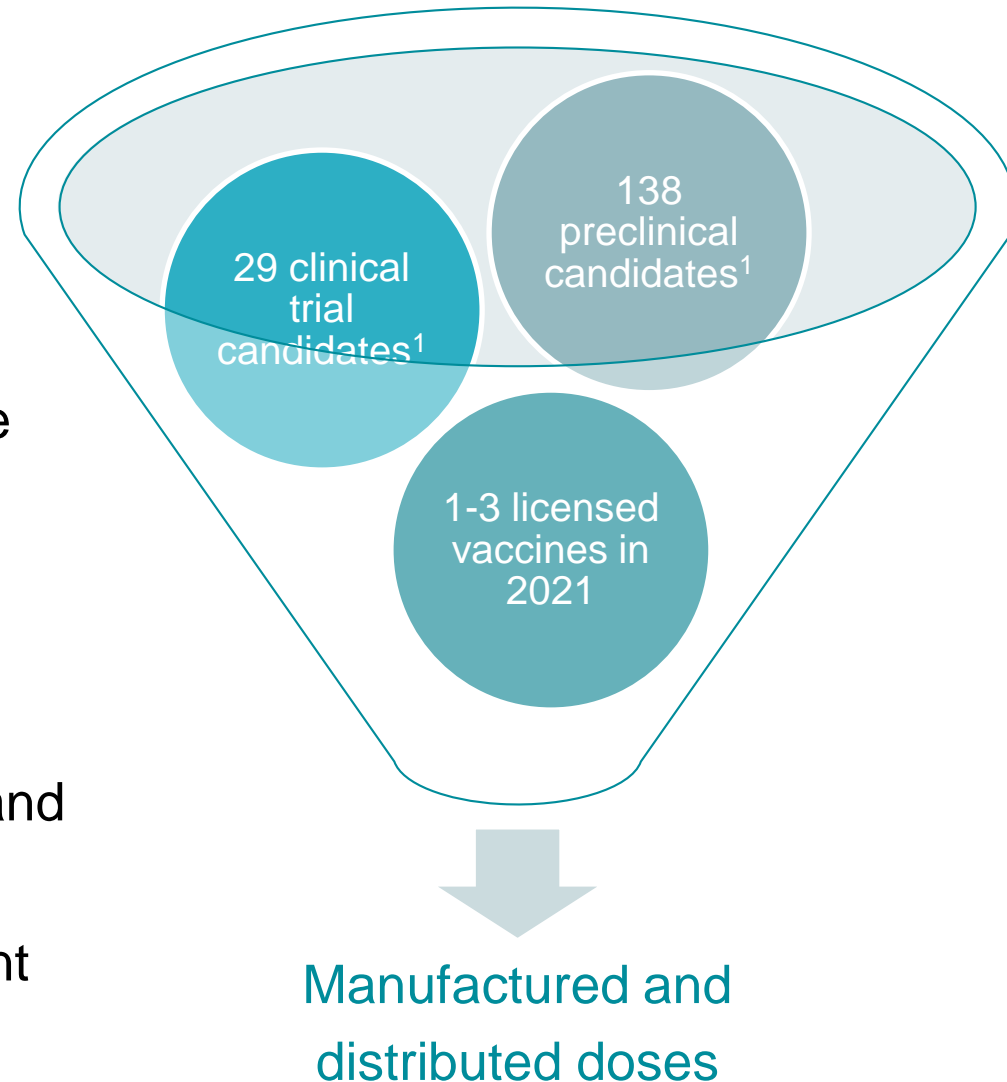
Global supply and access strategies

- Hannah Kettler



Global Development of COVID-19 Vaccines

- Probability of technical and regulatory success²:
 - Preclinical 7%
 - Clinical Trials 17%
- Regulatory agencies agreed to accelerate development, shortening timelines from 7-20 years to 12-18 months
- Manufacturer scale-up and country registrations take time
- 215 countries³ and >7 billion people demand vaccine globally
- Expect a 12- to 18-month supply constraint



¹ WHO, status 18 Aug 2020; ² Pronker et al., PLoS One, 2013 ³ WHO Coronavirus Disease (COVID-19) Dashboard, status July 19, 2020.
PTRS = Probability of Technical and Regulatory Success

COVID-19 Vaccine Pipeline

Candidate	Sponsor	Trial Phase	Institution	Funding
Inactivated vaccine	Wuhan Institute; Sinopharm	Phase 3	Henan Provincial CDC	Ministry of Science and Technology, China
CoronaVac	Sinovac	Phase 3	Sinovac Research and Development Co.	Sinovac Research and Development Co.
mRNA-1273	Moderna	Phase 3	Kaiser Permanente Washington Health Research Institute	Operation Warp Speed; NIAID, BARDA (\$483 million)
BCG live-attenuated vaccine	U Melbourne and Murdoch; Radboud University Med Ctr; Mass Gen Hosp	Phase 2/3	Same as Sponsor	Murdoch Children's Research Institute; UMC Utrecht
AZD1222	The University of Oxford; AstraZeneca; IQVIA	Phase 2/3	The Univ of Oxford, the Jenner Institute	Operation Warp Speed; UK Ministry of Health; The University of Oxford; BARDA
BNT162	Pfizer, BioNTech	Phase 2/3	Multiple study sites in Europe & N Amer	Pfizer; BioNTech
Ad5-nCoV	CanSino Biologics	Phase 2	Tongji Hospital; Wuhan, China	CanSino Biologics
Adjuvant recombinant vaccine	Anhui Zhifei, Institute of Microbiology of the Chinese Academy of Sciences	Phase 2		
BBIBP-CorV	Beijing Institute of Biological Products; Sinopharm	Phase 1/2	Henan Provincial Center for Disease Control and Prevention	Ministry of Science and Technology, China
GX-19	Genexine	Phase 1/2		GenexineGenexine
Gam-COVID-Vac	Gamaleya Research Institute, Acellena Contract Drug Research and Development	Phase 1/2	Various	Gamaleya Research Institute, Health Ministry of the Russian Federation
Self-amplifying RNA vaccine	Imperial College London	Phase 1/2	Imperial College London	UK Secretary of State for Health
LUNAR-COV19	Arcturus Therapeutics and Duke-NUS Medical School	Phase 1/2	Duke-NUS Medical School, Singapore	Arcturus
ZyCoV-D	Zydus Cadila	Phase 1/2	Zydus Cadila	

Source: WHO, <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>, accessed 18 Aug 2020.

Regional Vaccine Manufacturing

COVID-19 Vaccine Pipeline in Asia

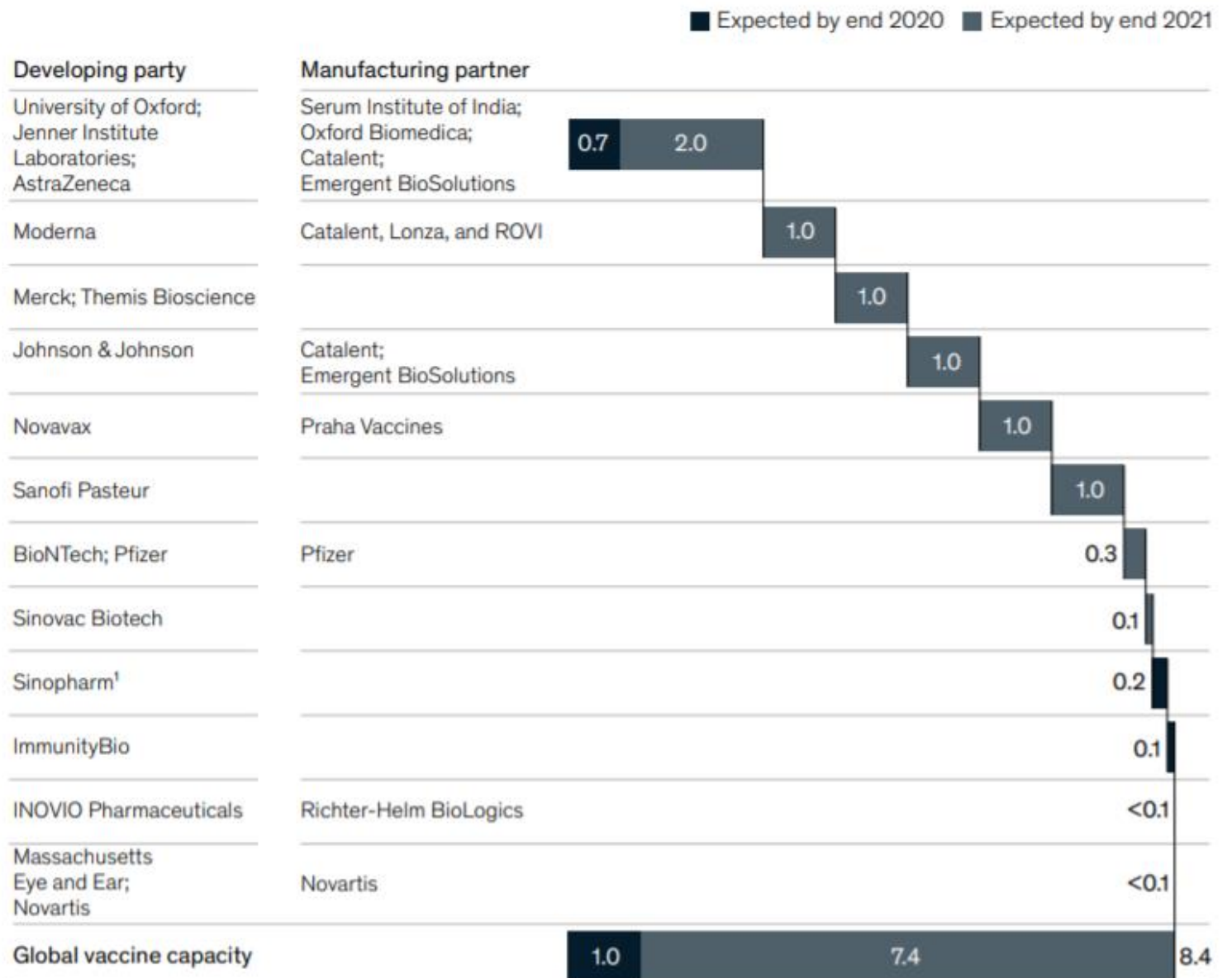
Candidate	Sponsor	Trial Phase	Country of Origin
Inactivated vaccine	Wuhan Institute of Biol Prod; China National Pharma Group (Sinopharm)	Phase 3	China
CoronaVac	Sinovac	Phase 3	China
Ad5-nCoV	CanSino Biologics	Phase 2	China
Adjuvant recombinant vaccine candidate	Anhui Zhifei Longcom Biopharma	Phase 2	China
BBIBP-CorV	Beijing Institute of Biological Products; Sinopharm	Phase 1/2	China
ZyCoV-D	Zydus Cadila	Phase 1/2	India
Gam-COVID-Vac	Gamaleya Research Institute, Acellena Contract Drug Research and Development	Phase 1/2	Russia
GX-19	Genexine	Phase 1/2	South Korea
Covaxin	Bharat Biotech; National Institute of Virology	Phase 1	India
Molecular clamp vaccine	CSL; The University of Queensland	Phase 1	UK, Australia
SCB-2019	GlaxoSmithKline, Sanofi, Clover Biopharma, Dynavax and Xiamen Inovax	Phase 1	USA/EU/China/Australia
mRNA-based vaccine	Chulalongkorn University	Pre-clinical	Thailand

- Several COVID-19 vaccines are in development in Asia.
- Other countries have vaccine manufacturing capabilities (e.g. Indonesia, Japan, Singapore, Vietnam).
- Countries should evaluate the timelines, financial and human resource investment needs, regulatory requirements, and technical risks associated with manufacturing biologics prior to exploring technology transfer options.











Manufacturing Scale-up Plans

- Manufacturers in Phase 2/3 publicly shared vaccine capacity estimates.
- Global supply volumes assessment assumes all candidate vaccines meet clinical, regulatory, and CMC milestones.
- 1 billion doses contingent on licensure and scale-up by end of 2020 and an additional 7.4 billion doses by end of 2021.¹
- Historical attrition rates in vaccine development **indicate only ~25% of these candidates will be approved.**²

Announced manufacturing capacity for vaccine candidates, billions of doses



The ACT Accelerator (ACT-A)

Tool	Objective	Facilitation Council
Vaccines	2 billion doses by end of 2021	  
Therapeutics	245 million courses to LMICs by mid-2021	  
Diagnostics	500 million tests to LMICs by mid-2021	 
Health Systems Connector	Alignment of delivery efforts/systems/partners	 

LMICs = lower-middle-income countries

COVAX Pillar

Organization

Role

The logo for CEPI (Coalition for Epidemic Preparedness Innovations) consists of the letters 'C', 'E', and 'P' in a blue, sans-serif font, with a red dot above the 'I'.

Development and Manufacturing

- Research and preclinical development
- Manufacturing and capacity building
- Clinical development and operations



Policy and Allocation

- Vaccine strategy and policy
- Access and allocation
- Ethics guidelines



Procurement and Delivery at Scale

- Covax Facility, AMC
- Country readiness and delivery
- Monitoring and evaluation

Overarching Goals

- Create and actively manage a diverse portfolio of vaccine candidates
- Accelerate manufacturing scale-up through at-risk investments
- Prioritize frontline workers and high-risk cohorts to maximize vaccine impact while supply constrained
- Strive for equitable vaccine access and fair allocation
- Create demand and market assurance via advanced purchase commitments
- Prepare countries for successful introduction

COVAX Facility Overview

COVAX Facility Activities

- Pool capital investment to catalyze at-risk scaling of manufacturing facilities
- Negotiate 5-10 advance purchase agreements at highest possible volume and most reasonable price for vaccine candidates meeting technical threshold criteria
- Procure 2 billion doses of licensed vaccine by end 2021
- Provide fair and equitable allocation of vaccine to participating countries

Benefits for participating countries

- Access a portfolio of vaccines, increasing likelihood of receiving doses
- Contribute towards scaling manufacturing at risk, increasing speed and affordability of successful vaccines
- Potential access to emergency buffer (10% of doses) for humanitarian use
- Accelerate progress towards ending the acute phase of the pandemic

Obtaining Vaccine and Financing Options

- Ideally countries obtain vaccine via pooled procurement regionally or globally to leverage multiple vaccine options and pool purchase power.
- Gavi-eligible LMICs and ODA-eligible countries will have access to the COVAX AMC fund with possible co-pay.
- HIC/UMICs interested in joining COVAX will be required to contribute some percent of eventual procurement amount up front to support the facility's ability to negotiate supply agreements with companies and a speed premium.

ADB Southeast Asia member country COVID-19 vaccine financing options and current epidemiology situation

Regional Member	AMC Eligible	WB Income Category	COVID-19 Cases/1M population
Philippines	Yes	LMIC	1,310
Indonesia	Yes	UMIC	477
VietNam	Yes	LMIC	9
Myanmar	Yes	LMIC	7
Cambodia	Yes	LMIC	16
Timor-Leste	Yes	LMIC	19
Laos	Yes	LMIC	3
Thailand	No	UMIC	48
Singapore	No	HIC	9,460
Malaysia	No	UMIC	281
Brunei	No	HIC	324

LIC = low-income country; LMIC = lower-middle-income country; UMIC = upper-middle-income country; HIC = high-income country