STRATEGIC TAKEAWAYS FROM COVID-19 VACCINE DEVELOPMENT

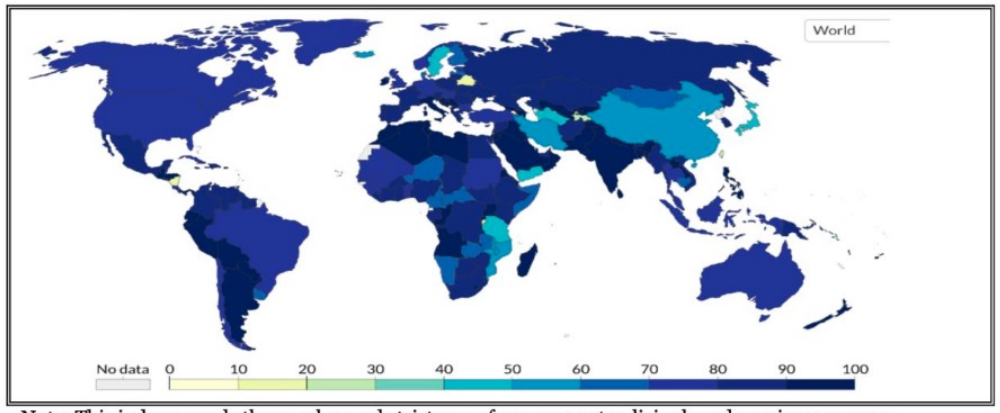
GROUP - 4

BIA 674

INTRODUCTION

With an emphasis on the vaccination supply chain, this report provides a comprehensive overview of the global response to the COVID-19 pandemic. This article examines the challenges of creating, manufacturing, and distributing vaccines, and highlights the importance of vaccine development in light of the global health problem. The talk aims to assess international cooperation projects and emphasize the logistical constraints of ensuring equitable access to vaccines. It outlines national immunization distribution strategies and highlights the role of international organizations like COVAX.

Exhibit 2 *Government Response Stringency Index, April 16, 2020*



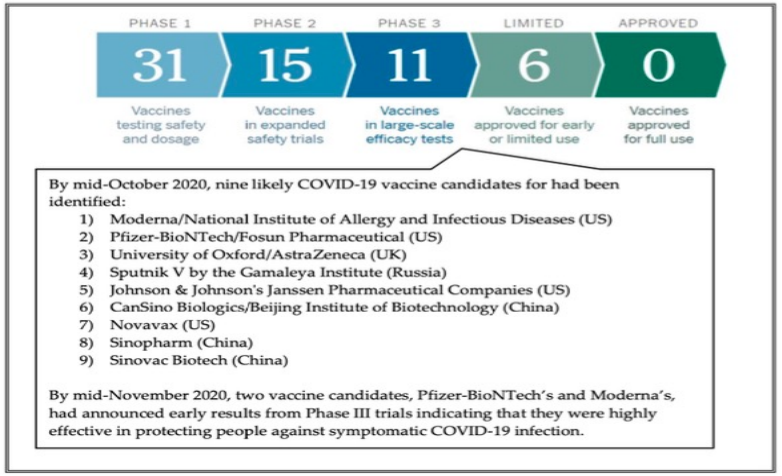
Note: This index records the number and strictness of government policies based on nine response indicators calculated from the strictest sub-region's policies, including school closings, workplace closures and travel bans, and should not be interpreted as a score of appropriateness or effectiveness of a country's response.

Source: The Oxford COVID-19 Government Response Tracker 2020.

VACCINE DEVELOPMENT & TRIALS

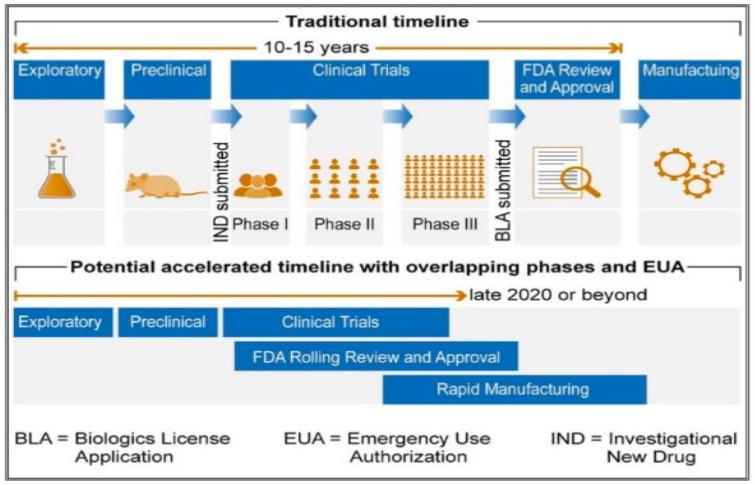
COVID-19 vaccine development and testing proceeded at a rapid speed, exceeding the typical schedule for vaccine development. Within six months of the crisis, there were 137 vaccine candidates in pre-clinical development and 46 in human trials. To speed up the process, certain Phase II trials were combined with bigger Phase III trials with hundreds of patients to evaluate both safety and efficacy. The goal was to provide COVID-19 immunizations in eight months, which is significantly shorter than the previous average of 9.4 years for complex vaccine development.

Exhibit 3 *Coronavirus Vaccine Global Portfolio as of October 16, 2020*



Sources: Corum, Wee, & Zimmer, 2020; Le, Cramer, Chen, and Mayhew, 2020; Loftus et al, 2020.

Exhibit 4 *Vaccine Development Process*



Source: GAO analysis of GAO-20-215SP, FDA, HHS, and Pharmaceutical Research and Manufacturers of America (PhRMA) documentation. GEO-20-583SP.

COVID-19 VACCINE TECHNOLOGIES

The development of COVID-19 vaccines has embraced various technologies, including:

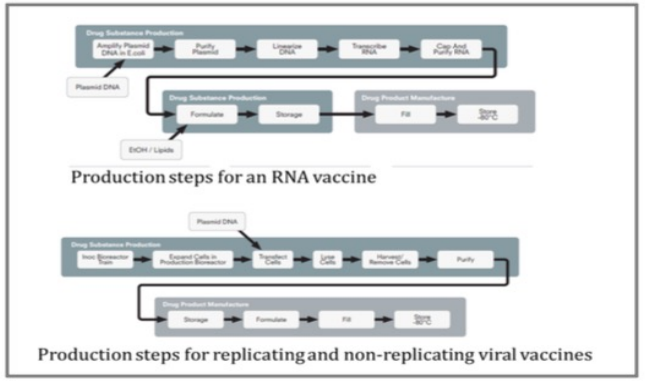
- ***mRNA Vaccines:*** Examples include Pfizer-BioNTech and Moderna vaccines. These vaccines enable rapid development and adaptation to variants but necessitate ultra-cold storage conditions.
- ***Viral Vector Vaccines:*** Such as AstraZeneca-Oxford and Johnson & Johnson vaccines, these vaccines utilize a harmless virus to deliver the vaccine. They have less stringent storage requirements but may evoke immune responses to the vector.
- ***Protein Subunit Vaccines:*** For instance, Novavax vaccine, these vaccines are generally well-tolerated but may require adjuvants for enhanced immunity.
- ***Inactivated or Live Attenuated Vaccines:*** These vaccines employ killed or weakened forms of the virus, providing a stable approach but potentially requiring booster shots.

Each technology presents a balance between efficacy, production speed, and logistical challenges, influencing their suitability for different contexts.

MANUFACTURING: A COMPLEX PROCESS

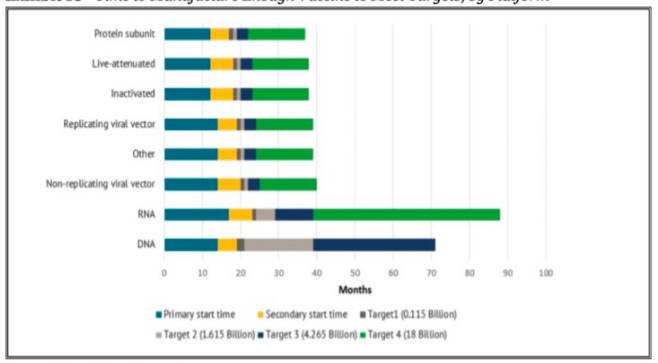
- COVID-19 vaccine manufacture is a complex process that includes drug substance production, formulation, packaging, and storage, all under strict quality control.
- Some of the challenges are controlling the risk of scaling up production in parallel with clinical trials and the requirement for a significant investment to develop or modify manufacturing facilities, especially given the unique nature of some vaccine technologies like mRNA.
- The production process is further complicated by the need to maintain a steady and high-quality supply of raw materials as well as variable temperature requirements for various vaccine types.

Exhibit 7 *Production of Drug Substance and Manufacture of Drug Product for mRNA and Viral Vector Vaccines*



Source: McDonnell et al., 2020

Exhibit 10 *Time to Manufacture Enough Vaccine to Meet Targets, by Platform*



Source: McDonnell et al., 2020.

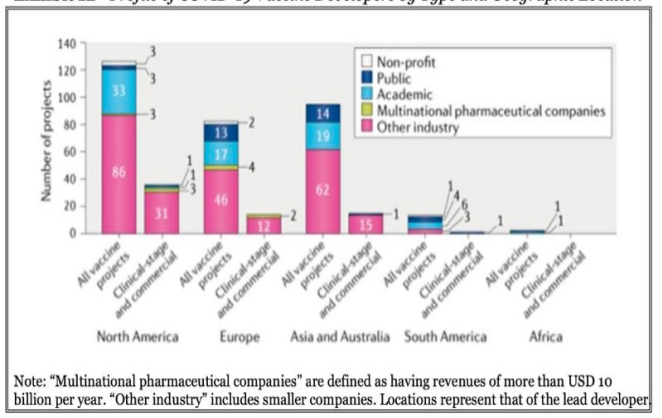
CHALLENGES

- The challenges in distributing COVID-19 vaccines are multifaceted. The sheer scale of reaching billions of people globally, coupled with rising vaccine nationalism, created a complex landscape.
- Distribution strategies varied, with multilateral initiatives like COVAX aiming for equity, while some countries pursued bilateral agreements.
- Vaccine hesitancy, stringent temperature controls, limited infrastructure in certain regions, and the massive volume of shipments further complicated the distribution process.

VACCINE DISTRIBUTION: A GLOBAL OVERVIEW

- Ensuring equal distribution, managing vaccination nationalism and bilateral agreements, and overcoming major logistics and delivery obstacles were all necessary for the global distribution of COVID-19 vaccinations. While nations like the United States launched its own initiatives like Operation Warp Speed, the COVAX Facility spearheaded international efforts, combining funding to procure vaccines for lower-income countries. Additionally, distribution had to deal with logistical obstacles such sustaining cold chain requirements across a range of temperature needs, which had an impact on the handling, storage, and delivery of vaccines worldwide, as well as public vaccine hesitancy.

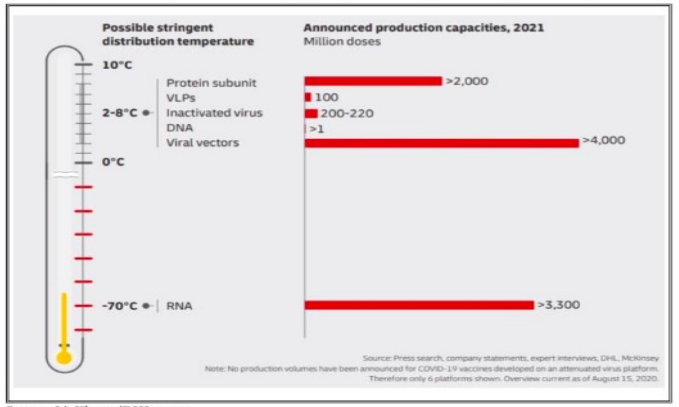
Exhibit 12 *Profile of COVID-19 Vaccine Developers by Type and Geographic Location*



Note: "Multinational pharmaceutical companies" are defined as having revenues of more than USD 10 billion per year. "Other industry" includes smaller companies. Locations represent that of the lead developer.

Source: McDonnell et al., 2020.

Exhibit 21 *Announced Production Capacities and Possible Distribution Temperatures*

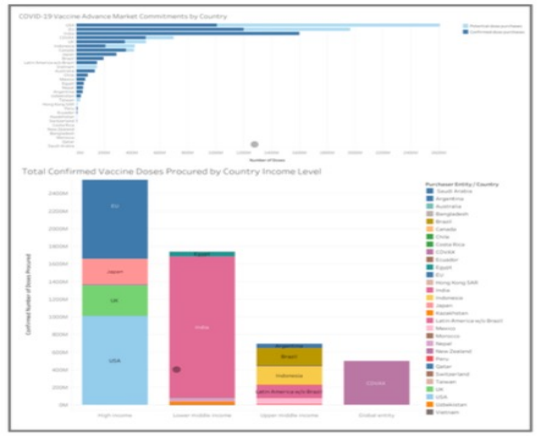


Source: McKinsey/DHL 2020.

VACCINE NATIONALISM V/S GLOBAL EQUITY

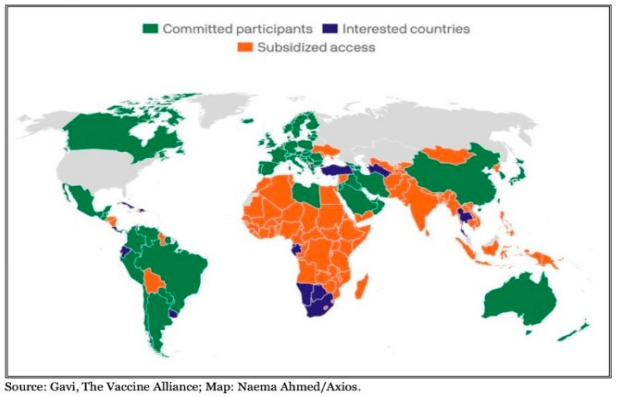
As nations focused on obtaining COVID-19 vaccine doses for their own populations, frequently through bilateral agreements with manufacturers, vaccine nationalism emerged, raising the possibility of unequal vaccine access for lower-income nations. On the other hand, worldwide equity initiatives, supported by the COVAX Facility, sought to combine resources and purchasing power to guarantee just and equal vaccination distribution throughout all countries, irrespective of economic status. However, some wealthier countries negotiated separate accords, casting doubt on COVAX's effectiveness and delivery capabilities and possibly undercutting the objective of fair worldwide access.

Exhibit 13 *COVID-19 Vaccine Advance Market Commitments by Country*



Source: Duke Global Health.

Exhibit 15 *COVAX Vaccine Initiative Participants*



Source: Gavi, The Vaccine Alliance; Map: Naema Ahmed/Axios.

CAPACITY FOR THE FUTURE

- Systems must be built to manage changeovers swiftly and safely in order to increase vaccine manufacturing capacity in the future. This can be a challenging and expensive procedure, particularly when working with novel vaccine technology.
- Though some may not make it through clinical testing, investments in production and capacity for the most promising prospects need to be made speculatively.
- This strategy makes sure that production can ramp up for effective vaccines, but it also requires incentives to counteract the risk of large financial loss.

CONCLUSION

The paper "Building the Supply Chain for COVID-19 Vaccines" offers a thorough understanding of the historically difficult task of creating, producing, and distributing COVID-19 vaccinations on a worldwide scale. It draws attention to the remarkable rate of vaccine development, which is fueled by creative scientific cooperation and large financial commitments.

In order to provide equitable access everywhere, the paper also clarifies the logistical nuances of distribution and the complexity of manufacture. It emphasizes the difficulties caused by vaccine nationalism, the need for fair and open distribution plans, and the practical difficulties associated with storing and transporting vaccines.

OPTIMIZING VACCINE ACCESS

- Improving vaccine supply chain speed from production to distribution can reduce the establishment of viral variations and mutations.
- Governments must weigh the benefits and drawbacks of pre-approval purchase agreements for pharmaceutical corporations while also making sure that vaccine manufacturing facilities are flexible enough to adjust in response to new evidence of efficacy.
- Lastly, when the likelihood of pandemics rises due to factors like population expansion, climate change, and global mobility, lessons acquired from the current pandemic response will guide future preparedness.