



# The Vaccine Program

**KPMG's Point of View**

Advisory

February 2021



# Foreword

The world we live in now is one where coexistence with the COVID-19 virus is a norm. Like every other country tackling the crisis, Malaysia has been fighting hard to overcome this pandemic.

While government and healthcare systems around the world have long been accustomed to distributing vaccines to different segments of their populations, the COVID-19 vaccine will be a first for many not just in scale but also due to the potential impact on the world's health, social and economic wellbeing. It is important to have a trusted, safe, fast and efficient system in place to ensure rapid roll out of the vaccine program.

Immunization programs in Malaysia are to protect against diseases by ensuring accessibility of immunization services to every eligible person. The objective is to ensure everyone has access to quality and safe vaccine, services delivered based on best practices, equity, affordable, efficient, technologically appropriate and are consumer-friendly.

Our honorable Prime Minister released Malaysia's National COVID-19 Immunization Program Handbook on 16 February 2021, outlining the country's strategic plan to inoculate at least 80% of the population or close to 27 million people by the first quarter of 2022. Immunization will be implemented in three phases over a period of 12 months, and the first batch is expected to be vaccinated beginning 26 February 2021.

Given the many complexities currently relating to vaccine distribution requirements, the government has prepared an equitable plan for all Malaysians and non-citizens. The government will need to rapidly implement the plan in a secured and accountable manner. But, the need for extremely rapid implementation will stress the government resources for agility, disaster management, root-cause analysis and accountability. Private sector participants have the expertise and resources to work together with the government for the success of Malaysia's National COVID-19 Immunization Program.

COVID-19 vaccines have been developed, trialed, and approved in record time, and programs are being mobilized and developed at record pace. This pandemic has resulted in the biggest and most rapid vaccination program in human history.

Vaccine programs must strike a balance between public policy, stakeholder cooperation, public engagement and public-private participation over time. It involves multiple stakeholder groups who influence the program development, vaccine production, delivery and administration, each with its own perspective of its roles and activities in program rollout. To yield better success, an integrated approach begins from vaccine production to administration to monitoring population, using technology and strong collaboration between government, manufacturers, logistics, providers and the population.

*'The Vaccine Program: KPMG's Point of View'* dives into building a successful vaccine program which entails 7 key elements; Program Strategy & Policy, Program Management, Public Engagement & Communications, Vaccine Procurement, Distribution Logistics, Provider Capacity and System Ramp-Up and Technology Enablement.

As stakeholders align for delivery, a good patient experience is critical in educating the public, increasing uptake of vaccines in the population, and supporting the stakeholders in delivering and measuring a mass-scale program more effectively and efficiently.



**Lee Yee Keng**  
Head of Healthcare  
KPMG in Malaysia

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## Appendices: KPMG's COVID Efforts, Vaccine Information

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# We have healthcare PPP advisory experience in Malaysia

- Driving the healthcare reform agenda
- Experienced Infrastructure PPP advisor in Malaysia
- Established Hospital Support Services advisor in Malaysia
- Cross-functional, geo perspectives
- Experienced advisor to leading vaccine companies



Pharma 2030



UHC 2030



Prescription for Change

# We are the top firm in healthcare reform in ASPAC



<b>Australia &amp; New Zealand</b>	Driving healthcare reform at the federal and state level, and supporting DoH with procurement optimization of critical supplies during COVID-19
<b>China</b>	Only advisory firm in Bohai think tank; led the Sanming reform that became the national template, and also leading the Beijing commission implementation
<b>Hong Kong</b>	Have supported healthcare reform efforts for years, including with the HKHA;
<b>Japan</b>	Driving healthcare reform at the federal and prefecture level with excellent access to stakeholders; COVID taskforce under Pharma Affairs & Food Sanitation Council
<b>Korea</b>	Designed the NHI scheme, strategic advisory to KHIDI, various national and local transformation programs, supporting KCDC as a reference laboratory
<b>Malaysia</b>	Leading many PPP reforms, including science park build-outs, teaching facilities, investor relations;
<b>Singapore</b>	Considered a leader in shaping healthcare reform, including national costing as well as running the SG Clean program; very close to HSA, ACE, among other peak bodies
<b>Taiwan</b>	Team led by MD/PhD/lawyer with excellent ecosystem connectivity (as proven during recent J&J projects); direct experience in the vaccine pathway
<b>Thailand</b>	Greater connectivity through the private sector healthcare channel
<b>Vietnam</b>	Working with HSPI, World Bank, and Pharma Group to advise on the future of UHC; our efforts include shaping the plans with respect to the COVID situation

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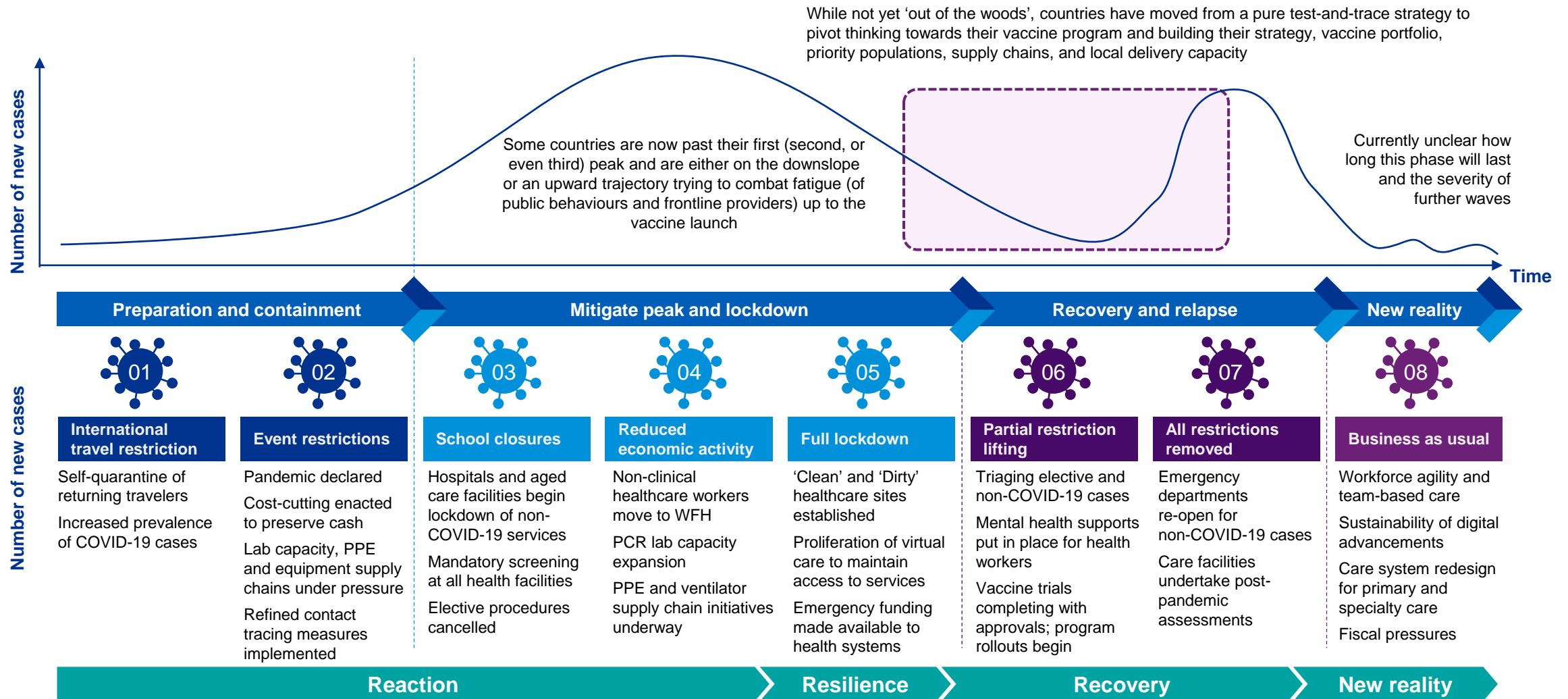
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## Appendices: KPMG's COVID Efforts, Vaccine Information

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# From test-and-trace to vaccinate: where we are now



**Most countries are in the midst of Vaccine Program strategy development, even as first-wave vaccines are being rolled out**



# The Challenge: Vaccine Programs

Vaccines have been developed, trialled, and approved in record time – but also, programs are being mobilized and developed at record-pace; this also introduces the biggest, most rapid vaccination program in human history

## Program Challenges



It is the most massive inoculation scheme ever seen



The situation is dynamic as information becomes available – from supply shocks to adverse events to public uptake



The public may have doubts from misinformation, reducing uptake



Getting a vaccine requires procurement strategy and enhanced handling (from cold storage to last-mile delivery)



Overstretched providers are now being asked to take on a new responsibility



Existing Health IT infrastructure has been built but may not be suitable



## A Tech-enabled, People-empowered Vaccination Program

## Considerations

The program needs to be **strategic based upon supply, priority, risk, and capacity**



A proactive and **data-informed Command Center** is required to monitor the Program



A **transparent and trust-based communication** approach encourages uptake



**Supply chains** – from vaccine manufacturers to distributors need to be diversified, secured, and planned with providers



**Provider execution** needs training, delivery support, investment, and capacity to deliver



How to **link with digital infrastructure** – from patient records to COVID apps



**A vaccination program requires a well-planned, highly-coordinated, and adaptive approach to inoculate the masses**

# Design principles for shaping a vaccine program

Design principles will be essential to support alignment of stakeholders ensuring there is a shared understanding of the problem, the scenarios to be managed and a proposed solution.



The vaccine delivery system must be **fair, efficient, and transparent, providing equitable and timely** access to the vaccine for all



The delivery system will facilitate a smooth and orderly vaccination experience **tailored and sequenced to different needs and levels of urgency or priority** while also being cognizant of the overarching outcomes



The vaccine delivery system should maximize the quality of the **on-the-day experience** for each citizen in order to build trust in the process



The vaccine delivery system must be **flexible** to allow for changes in the delivery model as the policy and delivery landscape evolves and adapts to emergent circumstances and risks



The approach will look **to leverage and mobilise the existing and required workforce** to support the managed and timely delivery of vaccine(s) to every citizen, while ensuring the safety, health and wellness of the workforce



The vaccine delivery system needs to monitor, manage and react to **vaccine adoption** as well as **public sentiment**



The vaccination management process should **leverage existing infrastructure and systems** (both public and private) wherever possible



The vaccine delivery system will ensure that population information is managed within **appropriate security, privacy and compliance safeguards**

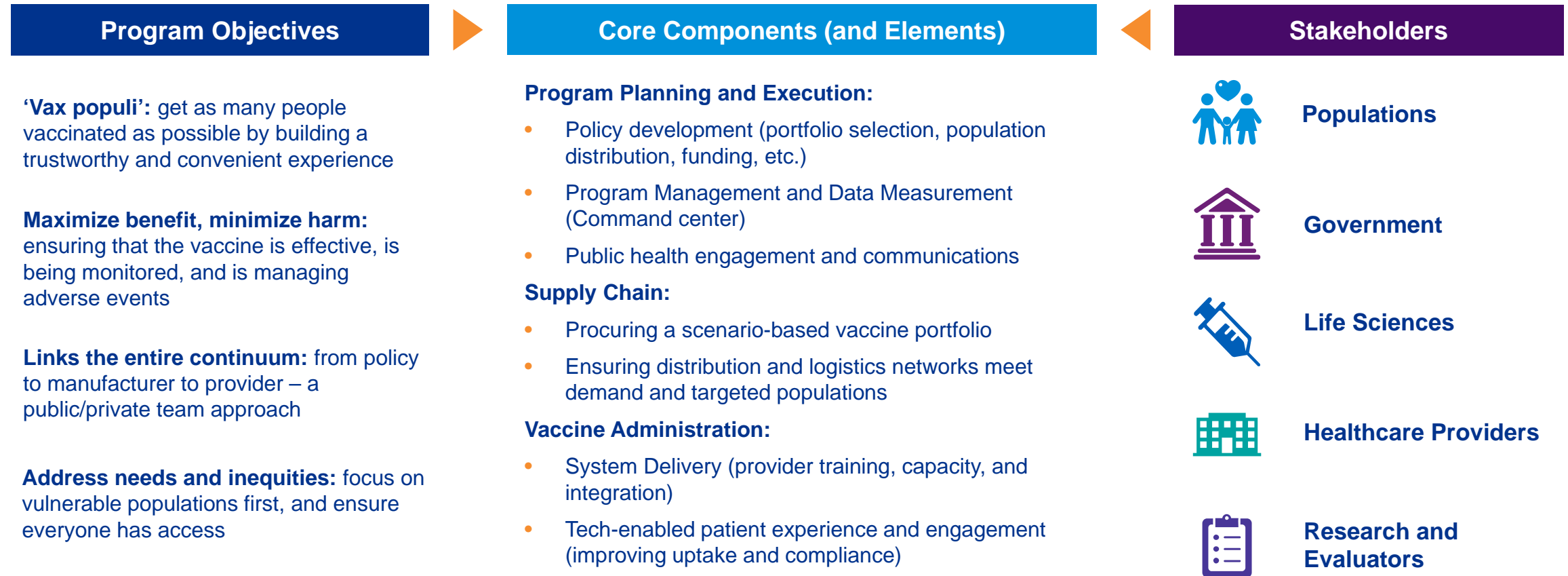


Wherever possible, the solution should **integrate with and build upon the existing systems and processes** in order to provide a holistic view of a citizen's immunization record

**Ultimately, vaccines are a societal good, and a delivery system needs to be built around supporting the people manufacturing, administering, and receiving it.**

# Building a Vaccine Program

Vaccine programs strike a balance between public policy, stakeholder cooperation, and public engagement over time



**Note:** there is no ‘one-size-fits-all’ approach; countries will need to adapt to their stakeholder dynamics, policy environment, and provider infrastructure

# Vaccine Program Key Stakeholders

Illustrative

Vaccine programs involve multiple stakeholder groups who influence the program development, vaccine production, delivery, and administration -- each with its own perspective of its roles and activities in program rollout:

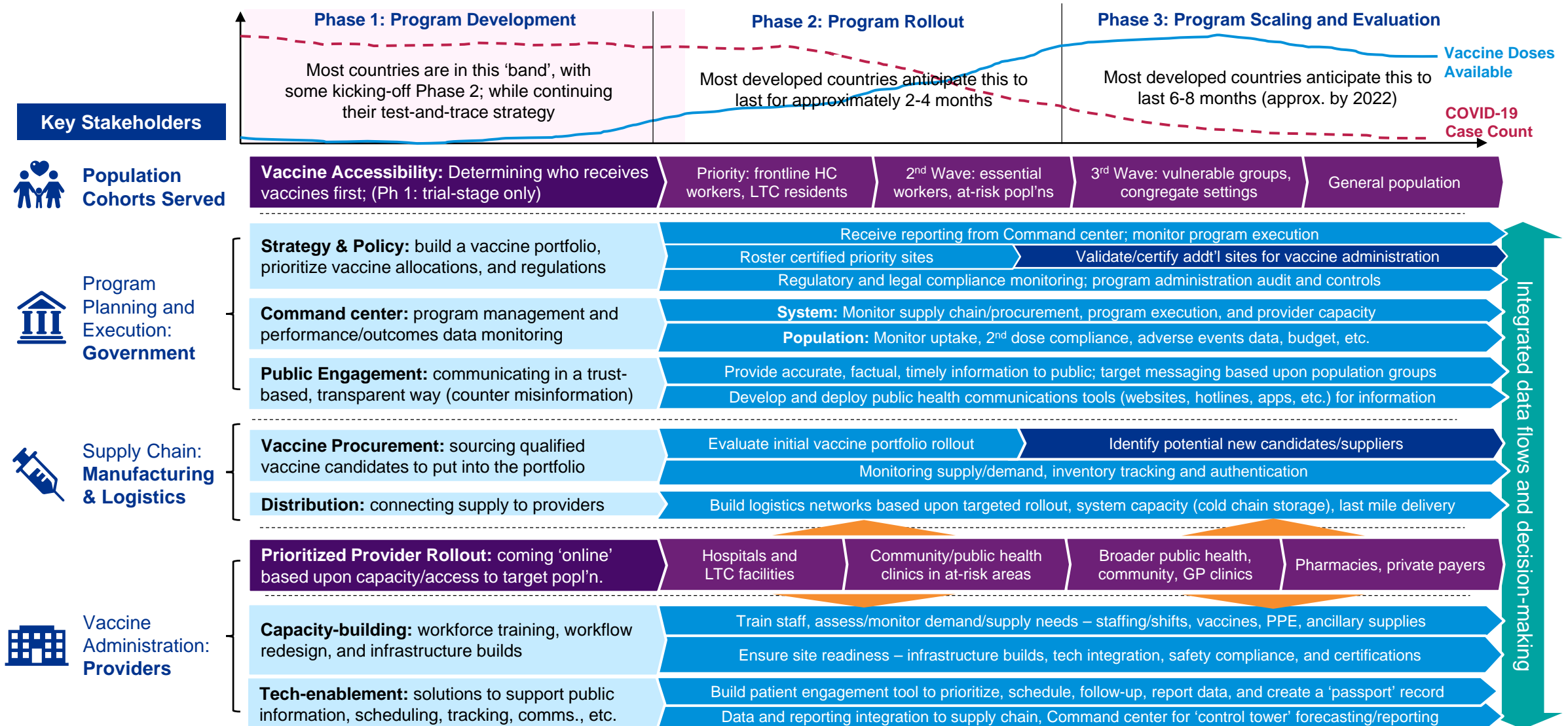


Stakeholder:	Populations	Government (Federal/Prov/Regional)	Manufacturers and Distributors	Providers	Research & Evaluators
Stakeholder Group Constituents	Priority Cohorts – Frontline Occupational Groups and High-Risk	Public Health Policy and Communications	Vaccine Manufacturers	Public Health Units (incl. schools, mobile, workplace)	Researchers (Vaccine Monitoring and Adaptation)
	Secondary Cohorts – At- risk, essential workers	Regulatory & Safety Compliance (Drug Administration)	Ancillary Vaccine Supplies and PPE Manufacturers	Hospitals	International Data Sharing Consortia (e.g., Medicines for Europe)
	General Population – Healthy Adults	Finance	Distributors	Community Clinics	International Public Health Bodies (e.g.,WHO)
		Legal		Long-term Care / Home Care Providers	
		Gov't Procurement and Vendor Selection	Logistics & Warehousing	Private (e.g., insurers, employers)	Oversight bodies (e.g., Ombudsman, Auditor General)
		Cyber & Data Privacy			
		Security (Defense)			
Stakeholder Key Roles:	Recipient	Policy, Management, & Communications	Supply Chain	Vaccine Administration	Program Evaluation



# Vaccine Program: Gov't. POV Placemat

Illustrative



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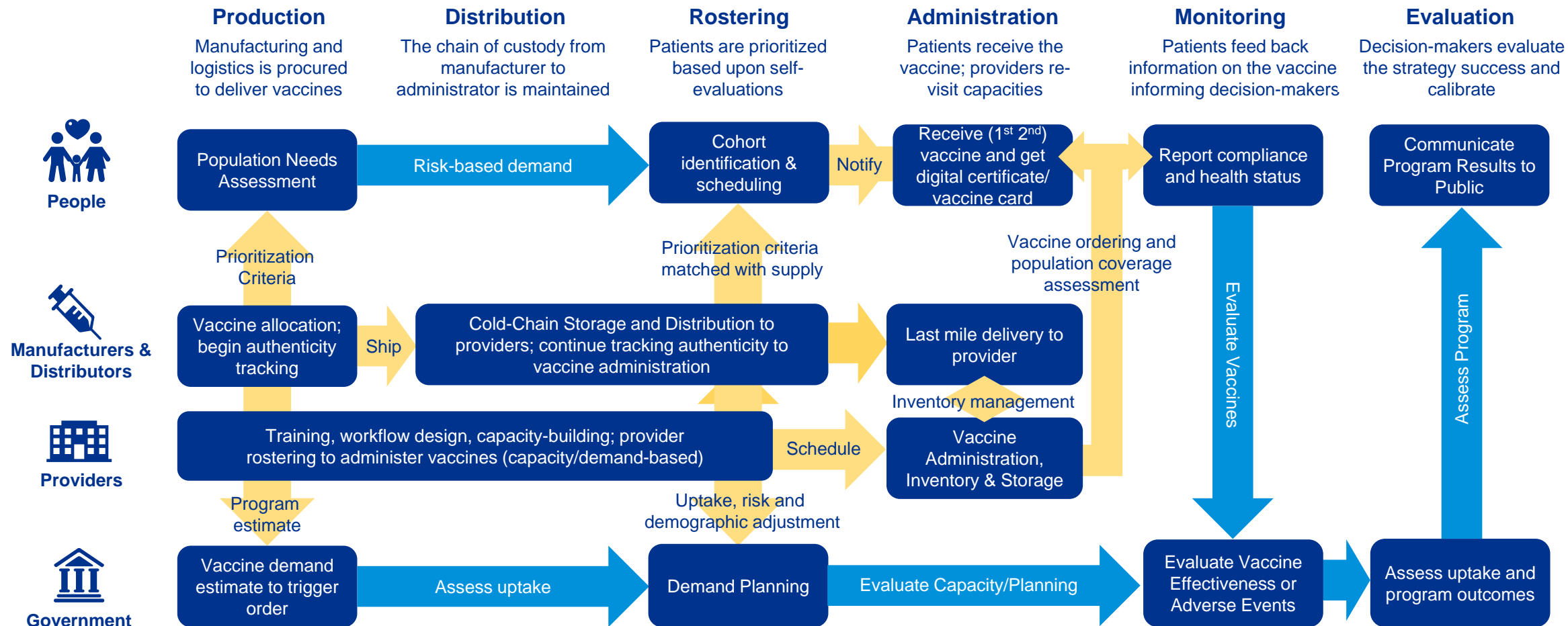
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# Envisioning An Integrated Approach

Illustrative

An integrated approach begins from vaccine production to administration to monitoring population-level uptake; using technology and strong collaboration between government, manufacturers, logistics, providers, and populations – programs can yield better success

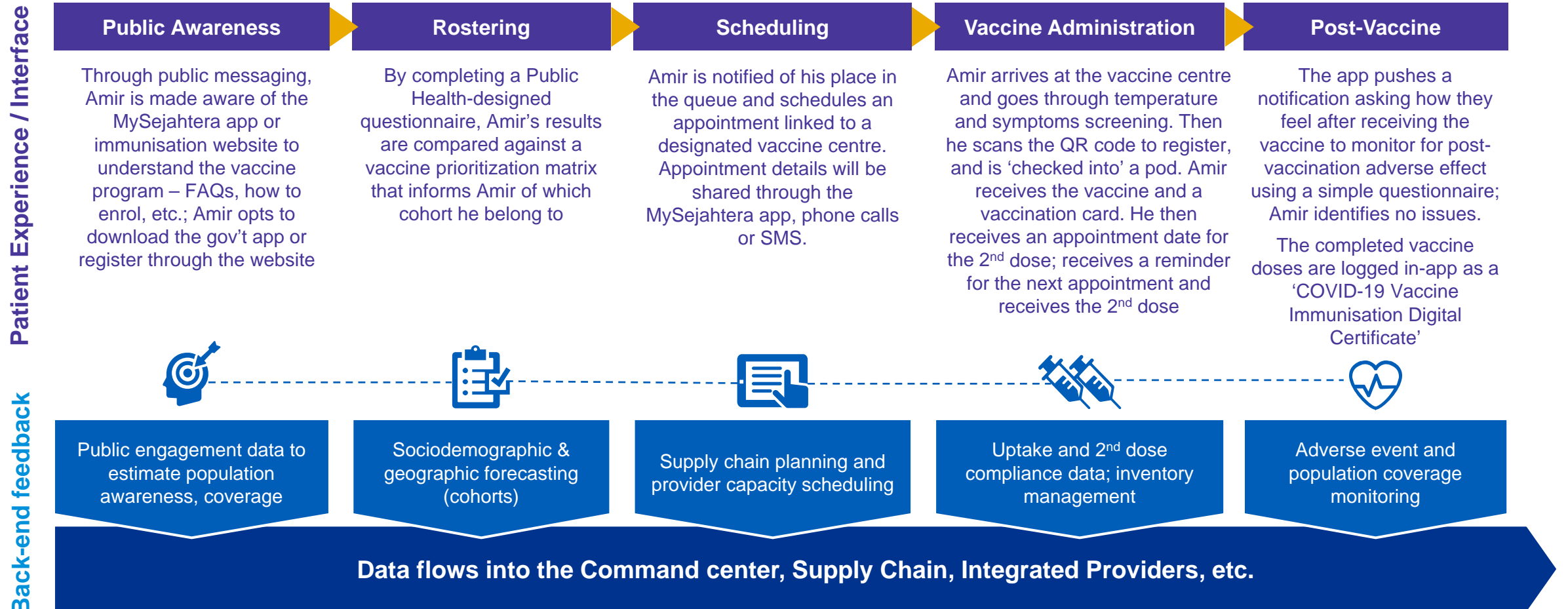




# Envisioning The Patient Journey through Digital Platform

Illustrative

As stakeholders align for delivery, a good patient experience is critical in educating the public, increasing uptake of vaccines in the population, and supporting the stakeholders in delivering and measuring a mass-scale program more effectively and efficiently



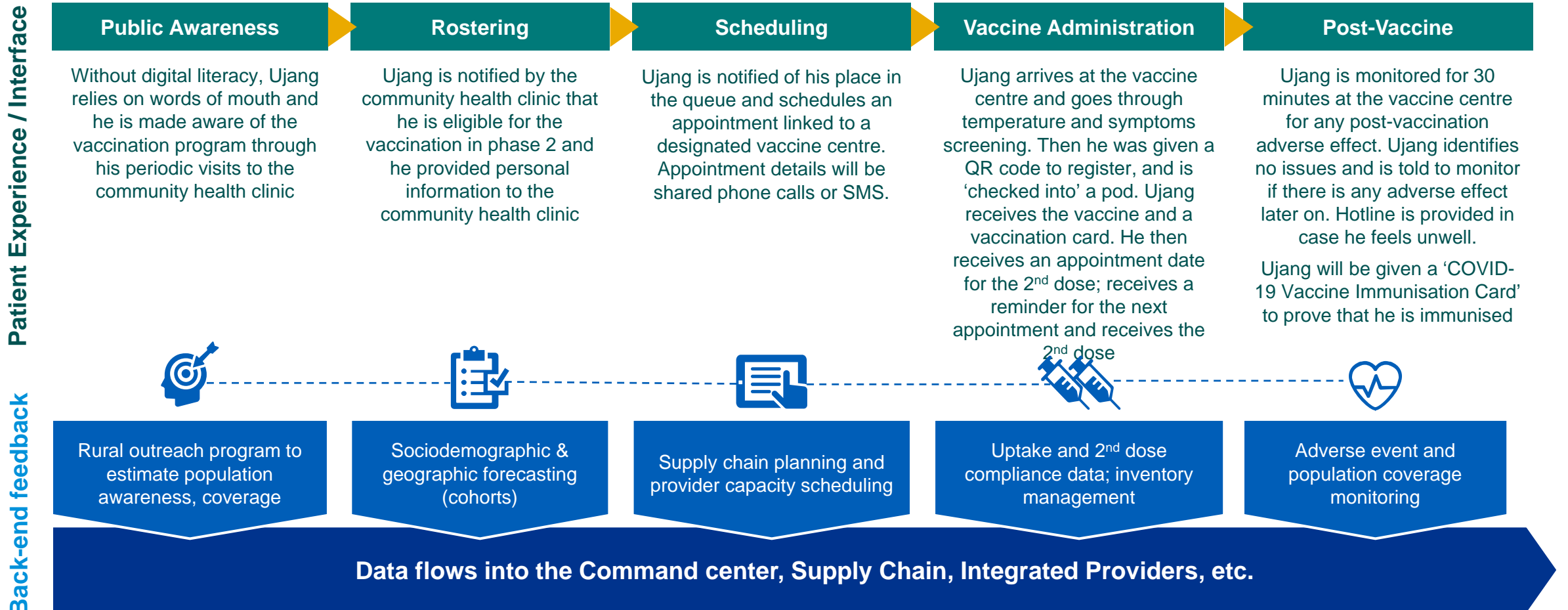




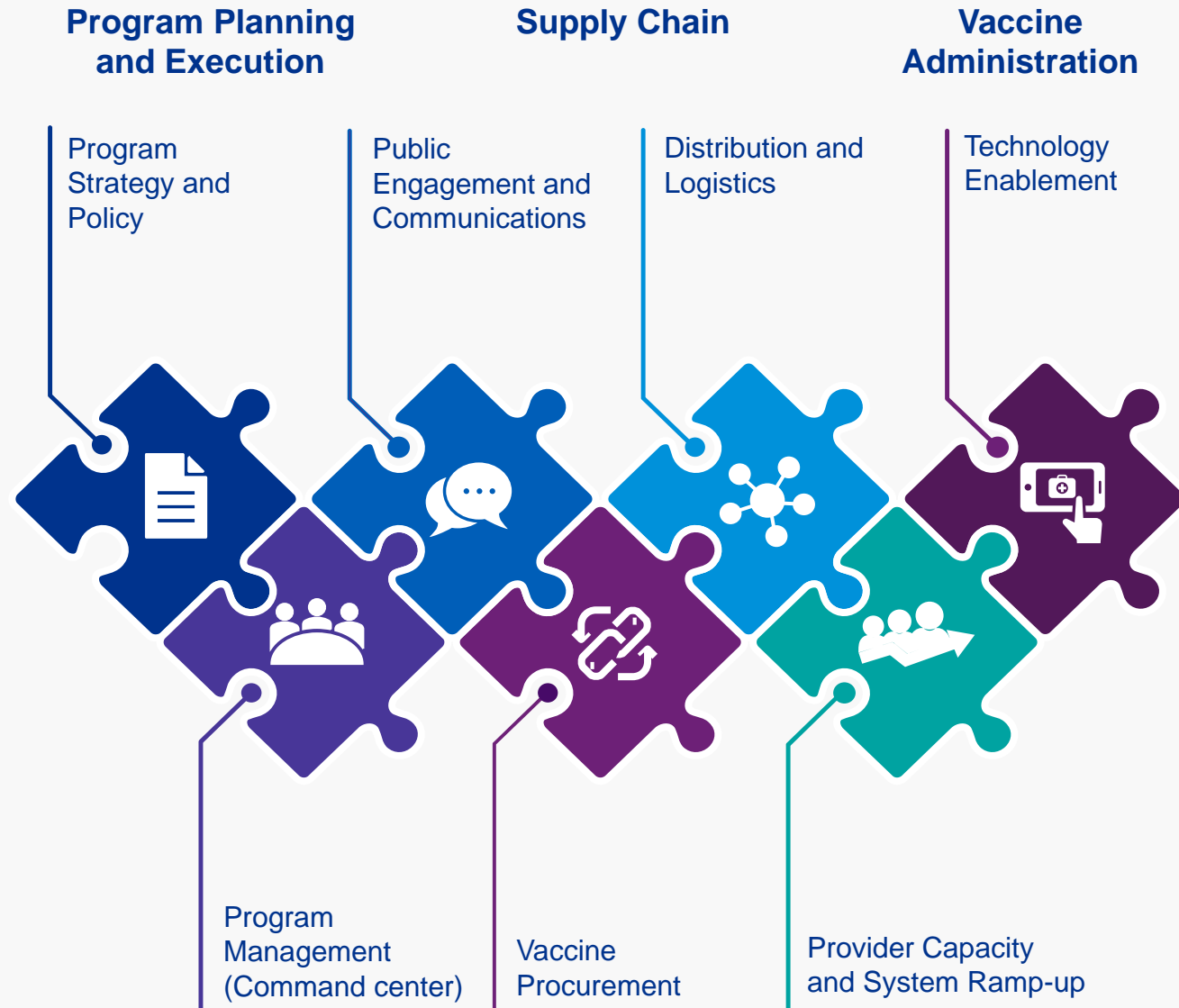
# Envisioning The Patient Journey through Manual Process

Illustrative

For people who do not have access to MySejahtera app or online platform, the enrolment of vaccination will be done through scheduling either via hotline, community health clinic or rural outreach program



# The Seven key elements of a Vaccine Program





# 1. Program Policy and Strategy

Governments will need to set policies around vaccines in a resource-and-time constrained environment; identifying and selecting vaccine candidates, building a scenario plan, and determining which populations are recipients of limited supplies of the vaccine.

## Capabilities

What we can Support

1

**Vaccine Portfolio Development:** a scenario-based strategy that factors safety, efficacy, availability, handling and administration traits, etc. of candidates

2

**Prioritizing Populations:** a data-based risk classification identified at the individual level (exposure, outcome, and determinants); to inform allocation/distribution of vaccines to jurisdictions

3

**National Registration:** contemplating who can administer vaccines (provider registration), how vaccinations are documented, and what it enables

4

**Program Funding and Funds Flow:** translating demand/supply data into understanding budget allocations, local provider funding, and procurement

5

**Regulatory and Legal Compliance:** ensuring stakeholder compliance with public health, legal, and regulatory (e.g., drug administration) rules



## An example of where we are helping our clients

### Vaccine Rollout Design & Implementation, Scotland

**Client issue:** Scottish Government requested support with developing possible roadmaps for the design and implementation of vaccination roll out to 5 million citizens. Included developing scenarios for different available vaccines and distribution.

**Approach:** Mobilize a program to design, develop and roll out vaccinations to all citizens by developing:

- Scenario models,
- Forecasting models,
- A service delivery framework, and
- A national plan for delivery.

It also includes helping define the digital architecture and solutions to support mass vaccinations.



## 2. Program Management (Command Center)

With multiple stakeholders delivering the vaccine to an entire population, managing a vaccine program is complex, requires significant coordination, and is resource-intensive. Program management through a 'Command Center' ensures program execution, timely issue management, and progress reporting.

### What we can Support

#### Capabilities

- 1 Program Governance Design:** developing the organizational/reporting structure among stakeholders (including Government leadership/agencies, providers)
- 2 Day-to-day Management:** facilitating and coordinating the multiple stakeholders to manage issues, gather reporting, execute the strategy and program
- 3 Program Analysis:** using analytics to inform system planning for decision-makers and public communications – including uptake progress, adverse events, compliance to adapt program tactics/strategy
- 4 Dashboards and Reporting:** consolidating data from multiple sources to get a local and systemwide view of program progress



#### An example of where we are helping our clients

##### COVID-19 Lab Network, Canada

**Client issue:** Ontario's Ministry of Health needed help to rapidly expand COVID-19 testing in the community and reduce backlog.

**Approach:** After a rapid diagnosis, the below plan was implemented:

- A collaborative network operated by provincial agencies, hospitals, and the private sector which enabled a rapid and sustained growth in testing capacity
- A coordinated approach to procure and implement new testing infrastructure, including human resources
- A consistent approach to network operations and management that established clear service expectations and allowed for high utilization of available infrastructure with improved turnaround times



## 3. Public Engagement and Communications

Critical to a successful vaccine program is its public uptake (and compliance with 2<sup>nd</sup> dose); given the extremely rapid development/approvals of vaccines, massive impact of COVID-induced behavioural changes, some in the public are skeptical. Transparency leads to trust, and trust leads to uptake.

### What we can Support

#### Capabilities

1

**Communications Planning and Strategy:** a coordinated plan is required to deliver a trust-and-transparency based plan with the public – including which methods, messages, and population groups to engage

2

**Stakeholder Engagement:** managing on an ongoing basis the expectations, moods, and reactions of stakeholders through sentiment analysis to help form and adapt program execution

3

**Accessible Resources:** building multimedia channels (e.g., online chatbots, apps, hotlines, multilingual material, etc.) that help dispel misinformation, promote public uptake, and ensure that underserved communities are engaged and informed



#### An example of where we are helping our clients

##### COVID-19 support for vulnerable populations, USA

**Client issue:** COVID-19 is having an outsized impact on racial and ethnic minorities in the US. The Morehouse School of Medicine (MSM) needed support to fight COVID-19 in racial and ethnic minority, rural, and socially vulnerable communities.

**Approach:** The three-year program will require:

- Managing a strategic network of national, state, territorial, tribal, and local organizations – known as the National COVID-19 Resiliency Network – to deliver COVID-19-related information to communities hit hardest by the pandemic; and
- Building and managing a platform that will host targeted messaging and support the COVID-19 local response.



## 4. Vaccine Procurement

Securing a diverse portfolio of vaccine manufacturers is critical to a resilient vaccine program; with rapid approvals and a fiercely competitive market – procuring the right vendors on the right terms and prices is key to ensure a reliable supply of vaccines to meet demand.

### What we can Support

#### Capabilities

- 1 Procurement Policy Development:** developing a framework, policies and model for assessing candidate vaccines and their suitability for inclusion in your portfolio/scenario plan
- 2 Vendor Management Support:** managing the supply chain (including contract management, negotiations, and evaluation) to ensure no disruption to supply chain
- 3 Capacity Management:** modelling supply/demand based upon systemwide data and linking it into vaccine/PPE/supplies procurement and logistics



#### An example of where we are helping our clients

##### Supply Chain Modelling, Australia

**Client issue:** Support one of the state's COVID-19 taskforce and work with key central agencies in managing the Personal Protective Equipment (PPE) supply chain.

**Approach:** The engagement involved:

- Advanced analytics and predictive modelling of demand and supply of critical PPE, intensive care and other COVID-19 supplies and services
- Visualization of the outputs and engagement with clinicians & health service executives to support policy makers to allow decision making (i.e. movement of critical supplies, etc.)
- Logistics and broader options for tracking of supplies and determining appropriating stockpiling arrangements



## 5. Distribution and Logistics

Once a portfolio of vaccines are identified, getting them to providers requires significant planning, effort, and communications to ensure that supply meets demand, wastage through mishandling is minimized, and that the security/integrity of the shipments are maintained

### Capabilities

What we can Support

1

**Logistics Planning:** analyzing the geographic footprints of providers and the provider network capacities to determine where vaccines will be received, transported, warehoused, and delivered (especially up to the 'Last Mile')

2

**Vendor Procurement Support:** building a strategy that creates an integrated, reliable network with sufficient redundancies to adapt to any issues in the supply chain or in vaccine administration

3

**Supply Security and Authentication Solutions:** with limited supply and high demand for vaccines, risks ranging from theft, to cyber-attacks, to counterfeiting are ever-present; real-time tracing, cyber solutions, and blockchain-based ledger solutions can counter those threats



### An example of where we are helping our clients

#### Procurement Support, Australia

Provided procurement and supply chain expertise, coupled with market and supplier insight to quickly understand and forecast demand requirements, and develop innovative methods to accelerate the supply of essential goods and services from industry.

#### Logistics & Process Improvement, Spain

Supported logistics, process improvement and management of furloughs on grounds of force majeure (Covid-19) for a local authority. Also supported the systematization of information management and creation of a reporting system for all local offices of the a regional government.





## 6. Provider Capacity and System Ramp-up

Providers are under significant capacity constraints – from time, available resources, room for change; a successful vaccine program requires support to providers in adapting to change – from assessing their capacity gaps, workforce training, new workflows, and other insights

### What we can Support

#### Capabilities

- 1 Provider System Capacity Analysis:** assessing providers' infrastructure, technology, workforce, inventory, storage & handling, to identify gaps and build-up capacity
- 2 Workforce Training:** design and deploy training that complies with safe administration (to patient/provider), while instilling trust and efficiency
- 3 Workflow Design:** using patient journeys combined with provider infrastructure, design patient-and-provider-centric archetypes for vaccine administration (from registration to administration to follow-up)
- 4 Enterprise Insights:** a 'Control Tower' to monitor inventory, scheduling, and capacity planning based upon demand/supply data, etc.



#### An example of where we are helping our clients

##### Virtual Care Implementation, Canada

**Client issue:** Niagara Health (NH), as it faced the COVID-19 global pandemic, required a strategy and a solution to expand their current capabilities in virtual care to continue to serve their patients outside of the four walls of the hospital.

**Approach:** The virtual care solution was selected and deployed through a two-phased approach:

- Based on a rapid assessment, Microsoft Teams was selected as a viable solution to support remote work and virtual care in an outpatient setting.
- A high-level privacy assessment to help identify potential privacy concerns and developed a proposed governance framework for NH as they continued to roll-out the solution





# 7. Technology Enablement

Technology can make a major impact to the success of a vaccine delivery program through creating better patient/user experiences (improving uptake) as well as providing the data that helps inform program decision-making, forecast demand, monitor uptake, and identify any adverse reactions

## What we can Support

### Capabilities

1

**Immunization Information System:** record and track vaccination information (including who has been vaccinated, by which vaccine, how many doses have been administered, reactions, etc.)

2

**Patient Engagement and Vaccine Administration Solution:** a solution that provides tailored public health information, processes eligibility, prioritization, scheduling, reminders, patient on-site processing, documentation, and outcome self-reporting

3

**Supply Chain and Inventory Management:** a 'Control Tower' to plan, manage, and optimize vaccine, PPE, and supplies stocks to reduce waste and align to demand at the provider or system level



### An example of where we are helping our clients

#### ICT Support for Vaccine Rollout, Ireland

Establish necessary Information and Communications Technology (ICT) solution for the roll-out of the COVID-19 in Ireland. Solutions to support – Infrastructure, Applications, Reporting & Analytics, Cyber Security, etc.

#### Vaccine Data Solution, Australia

A solution will be developed using Arwin and Origins, Azure based platforms to:

- Inform targeting of public policy interventions,
- Enable operational decisions through insights, and
- Inform interventions to reduce wastage / improve efficiency at administration sites

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# Global healthcare network

Healthcare systems around the world are facing unprecedented challenges that require policymakers, payers, providers, and suppliers to rethink how they work.

With deep industry experience, KPMG firms are uniquely positioned to provide guidance and support to clients.

KPMG health specialists help them to successfully navigate this rapidly changing environment to transform the way that healthcare is provided.



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Practices in  
KPMG firms



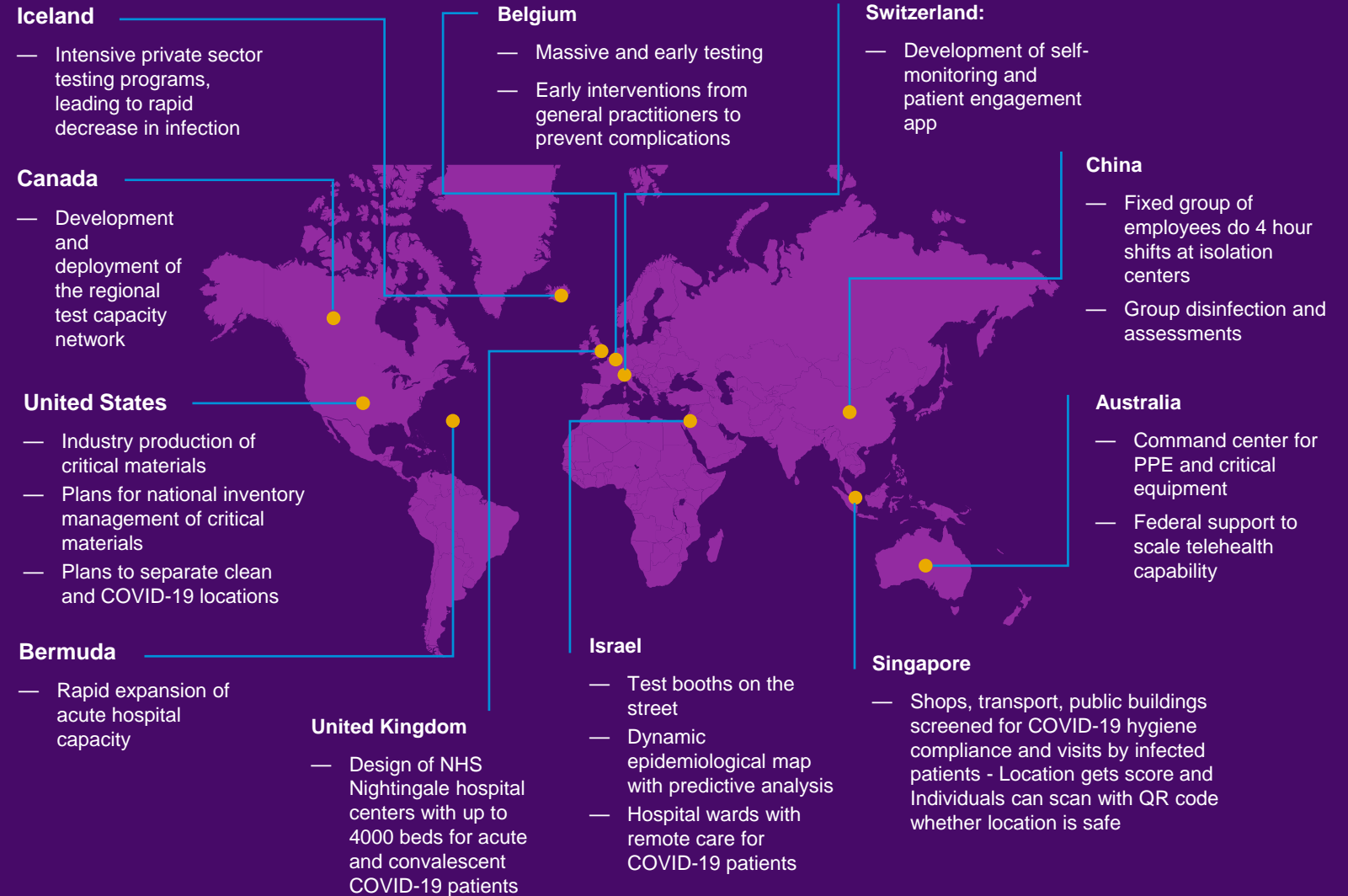
4,500+

KPMG partners and staff  
work in healthcare



Equipped and  
experienced advisory  
teams across the  
global organization

Over 100 projects globally delivered/ in-delivery to support the COVID-19 response



# We've brought digital solutions to the COVID-19 effort globally



# Vaccine programs: what we've learned so far

## Lessons Learned



End to end maps are essential to solution design & consumer centricity



A 'scenario framework' is essential to managing vectors of uncertainty



Robust scenario planning is essential in supporting system preparedness



Real time, agile matching between demand and supply is increasingly important

## Where we've learned from



### Scottish Government Vaccination Programme Design

- Mobilising a programme to design, develop and roll out vaccinations to all citizens.
- This high profile engagement included the development of scenario models, forecasting models, a service delivery framework and a national plan for delivery, alongside support to define the digital architecture and solutions to support mass vaccinations.



### Australia's Vaccine Connect Solution

- "Digitally-enabling Covid-19 vaccinations for citizens". VaccineConnect is a collaboration between KPMG and 1<sup>st</sup> Group.
- It brings together KPMG extensive experience in complex programme design and implementation for Governments and health systems nationally, with the substantial investment made by 1<sup>st</sup> Group into a market leading platform for connecting consumers and healthcare providers using their existing scheduling systems.

Rapid vaccine program formation is new to the world; it needs to engage multiple stakeholders and be adaptive

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# CDC Playbook Guidance lists 15 considerations for vaccine rollout

1. Pressure test existing vaccine plans for improvement
2. Develop a COVID-19 vaccine program plan
3. Set up an organizational structure and partner involvement
4. Review the phased approach to vaccine distribution
5. Identify prioritized populations
6. Prepare for COVID-19 provider recruitment and enrollment
7. Understanding the jurisdiction's vaccine administration capacity
8. Allocation, ordering, distribution and inventory management
9. Storage and handling
10. Vaccine administration documentation and reporting
11. Second-dose reminders
12. Immunization information system requirements
13. Program communication
14. Regulatory considerations
15. Program monitoring

Source: KPMG US, CDC Interim Vaccine Playbook: [https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim\\_Playbook.pdf](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf)



# EU: Population Prioritization Guidance

Priority groups to consider by member states (in no particular order)	Considerations
Health care and long-term care facility workers	Essential workers with significantly elevated risk of being infected Carry out essential functions to combat the pandemic
People above 60 years of age	Age-based elevated risk of severe disease or death In particular those living in high risk situations such as long-term care facilities
Vulnerable population due to chronic diseases, co-morbidities and other underlying conditions	Elevated risk of severe disease or death Examples of risk factors: obesity, hypertension, asthma, heart conditions, pregnancy
Essential workers outside the health sector	E.g. teachers, child care providers, agriculture and food sector workers, transportation workers, police officers and emergency responders
Communities unable to physically distance	E.g. dormitories, prisons, refugee camps
Workers unable to physically distance	E.g. factories, meat cutting plants and slaughterhouses
Vulnerable socioeconomic groups and other groups at higher risk	E.g. socially deprived communities to be defined according to national circumstances

Source: Preparedness for COVID-19 vaccination strategies and vaccine deployment, European Commission, 15 October 2020

Proposed actions	Timeline
Member States should define a priority list for vaccination, identifying and targeting key population groups and communities, ideally in a tiered/phased approach. Such a list should be flexible to allow for adaptations and updates once details about the vaccine become available and to address epidemiological developments.	Ongoing
Member States should develop and carry out modelling exercises (e.g. for demand planning and vaccine intervention exercises) preferably in a context that allows for cross-European learning and exchange of experiences. The European Centre for Disease Prevention and Control is working on a mathematical model that will support Member States in decision making for planning deployment of COVID-19 vaccines	October to December 2020
Member States should regularly review critical factors, such as the epidemiological situation at national and subnational levels, new evidence about the virus and its impact on human health, actual vaccine uptake and by whom, vaccine storage and supply chain capacities and (human) resources required for vaccination of the population, and define, reassess and adapt COVID-19 vaccination objectives, targets, priorities and strategies accordingly.	Ongoing
Member States should share knowledge and experiences regarding the development and implementation of vaccination strategies, particularly concerning the definition and coverage of priority groups, through the Health Security Committee, coordinated by the European Commission	Ongoing

# EU: Recommended Member State Actions on Vaccines

Proposed actions	Timeline		
Member States should ensure the capacity of vaccination services to deliver COVID-19 vaccines, including a skilled workforce, and medical and personal protective equipment.	October to November 2020	Member States and public health authorities should prepare to undertake studies, independent of industry interests, of vaccine effectiveness and safety:	October to 2022
Member States should ensure easy access to vaccines for target populations, both in terms of affordability and physical proximity.	October to December 2020	<ul style="list-style-type: none"> <li>establishing the necessary networks to collect data and analyse evidence, including if possible, in a statistically representative way, different target populations, such as workers</li> <li>ensure mechanisms to detect, review and respond to vaccine safety events</li> <li>ensure mechanisms for continuous assessment of risk/ benefits</li> <li>via coordination by the European Medicines Agency and the European Centre for Disease Prevention and Control, prepare the participation in large-scale EU-wide effectiveness and safety monitoring studies</li> </ul>	
Member States should prepare for deployment of vaccines with different characteristics and storage and transport needs, and review the required vaccination infrastructure, in particular in terms of cold chain, cooled transport and storage capacities.	October onwards		
Member States should ensure that Immunisation Information Systems and other vaccination registries are updated and ready to process vaccination data.	October onwards		
Member States should ensure clear communication on the benefits, risks and importance of COVID-19 vaccines, thus promoting public trust. <ul style="list-style-type: none"> <li>Member States should identify and share best practices on effective ways to address vaccine hesitancy</li> <li>Member States should work with health professionals as trusted sources on vaccination matters</li> </ul>	October onwards	EU/EEA National Immunisation Technical Advisory Groups collaboration, with European Centre for Disease Prevention and Control coordination, to support national efforts via data and information sharing	Ongoing
Member States should coordinate efforts in tackling the misinformation and disinformation around a possible COVID-19 vaccine, in coordination and collaboration with international bodies and online platforms. The Commission should facilitate these efforts.	October onwards	Member States and public health authorities, with technical support from the European Centre for Disease Prevention and Control, should set up systems for the collection of data on vaccination coverage in target populations and monitor coverage in real-time through individual-based data, incl. through the electronic immunisation register and in accordance with the rules on the protection of personal data.	Ongoing
		Member States should coordinate efforts and responses to the pandemic through the Health Security Committee, coordinated by the European Commission. Cooperation between health authorities and civil protection authorities should be ensured.	Ongoing

Source: Preparedness for COVID-19 vaccination strategies and vaccine deployment, European Commission, 15 October 2020

# Vaccines in Development

Company	Vaccine name	Phase	Notes
Moderna	mRNA-1273	3	Moderna vaccine are made using synthetic messenger RNA. Based on evidence from clinical trials, the Moderna vaccine was 94.5% effective at preventing laboratory-confirmed COVID-19 illness in people who received two doses who had no evidence of being previously infected. Approved for limited or emergency usage in US, Israel, European Union, Qatar, Singapore, United Kingdom, Mongolia, Norway and Canada and full approval in Switzerland. 2 doses required, frozen vaccine (-20 °C)*
Pfizer, BioNTech	BNT162 (Comirnaty)	2/3	Pfizer and BioNTech vaccine are made using synthetic messenger RNA. Based on evidence from clinical trials, the Pfizer-BioNTech vaccine was 95% effective at preventing laboratory-confirmed COVID-19 illness in people without evidence of previous infection. Approved for limited or emergency usage in Argentina, Australia, Canada, Chile, Colombia, Costa Rica, Ecuador, European Union, Iceland, Iraq, Israel, Japan, Jordan, Kuwait, Lebanon, Malaysia, Mexico, Mongolia, Norway, Oman, Panama, Peru, Philippines, Qatar, Serbia, Singapore, Tunisia, UAE, UK and US and full approval in Bahrain, New Zealand, Saudi Arabia, Switzerland. 2 doses required, frozen vaccine ultra-cold (-70 °C)*
The University of Oxford; AstraZeneca; IQVIA	AZD1222	2/3	AstraZeneca and Oxford found out that two doses separated by 12 weeks had an efficacy rate of 82.4%. They would collaborate with the Russian creators of the Sputnik V vaccine, which is also made from adenoviruses, to see if a combination with Sputnik V might increase the efficacy of the Oxford-AstraZeneca vaccine. Approved for limited or emergency usage in Algeria, Argentina, Australia NEW, Bangladesh, Bhutan, Brazil, Chile, Dominican Republic, Egypt, El Salvador, European Union, Iceland, India, Iraq, Kuwait, Maldives, Mexico, Mongolia, Morocco, Nepal, Norway, Pakistan, Philippines, Seychelles, Sri Lanka, South Africa, South Korea, Thailand and United Kingdom 2 doses required, stable in refrigerator for at least 6 months
Gamaleya Research Institute	Sputnik V (Gam-Covid-Vac),	3	Russian scientists estimated that the vaccine demonstrated 91.6 percent efficacy. Approved for limited or emergency usage in Algeria, Argentina, Armenia, Bahrain, Belarus, Bolivia, Bosnian Serb Republic, Gabon, Guinea, Hungary, Iran, Kazakhstan, Lebanon, Mexico, Mogolia, Montenegro, Myanmar, Nicaragua, Pakistan, Palestinian Authority, Paraguay, St. Vincent and the Grenadines, Russia, Serbia, Tunisia, Turkmenistan, United Arab Emirates, Uzbekistan and Venezuela 2 doses required, freezer storage

Source: News Articles



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\* Stability data forthcoming, may change storage and handling requirements

# Vaccines in Development

Company	Vaccine name	Phase	Notes
CanSino Biologics	Ad5-nCoV (Convidecia)	3	<p>On August 12, it was reported they begun conducting phase 3 trials in Saudi Arabia, after completing the first two phases of the human trials in China.</p> <p>On August 17, China had awarded CanSino a patent for their vaccine.</p> <p>Phase 3 trials for CanSinoBIO's candidate, which are planned to involve 40,000 participants in total, have begun enrolling participants in Pakistan, Russia, Mexico and Chile, the latest clinical trial registration data showed. The vaccine trials has recruited over 20,000 people as per the announcement on Dec 21.</p> <p>The vaccine showed 65.7% efficacy in preventing symptomatic cases and a 90.98% success rate in stopping severe disease in an interim analysis of global trials.</p> <p>Approved for limited use in China and emergency use in Mexico and Pakistan.</p> <p>Single dose and requires refrigeration.</p>
Bektop	EpiVacCorona	3	<p>Russia launched a mass vaccination campaign, using EpiVacCorona as well as Sputnik V, an adenovirus-based vaccine. The immune response from EpiVacCorona lasted "for approximately a year." The Vector Institute has yet to release the results of its Phase 3 trial indicating whether the vaccine is effective or not.</p> <p>Approved for limited use in Russia.</p> <p>2 doses required and stable in refrigerator for up to 2 years</p>
Beijing Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	BBIBP-CorV	3	<p>Sinopharm announced that the vaccine had an efficacy of 79.34 percent, leading the Chinese government to give it approval. As concerns grew about new mutations in the coronavirus, Chinese researchers tested BBIBP-CorV against a variant called B.1.351, which was first found in South Africa. They reported that the antibody response created by the vaccine was only modestly weaker against B.1.351.</p> <p>Approval for limited usage in Serbia, Seychelles, Cambodia, Egypt, Hungary, Iraq, Jordan, Nepal, Pakistan and Peru and full approval in China, UAE and Bahrain.</p> <p>2 doses required.</p>
Sinovac	CoronaVac	3	<p>The Sinovac approval comes after the Hong Kong government's expert advisory panel reviewed new data from the drugmaker that showed an efficacy rate of over 62% when two doses are administered 28 days apart. That's higher than the 50.38% efficacy reported last month by Brazil's Butantan Institute, which conducted late-stage trials in the country.</p> <p>Approved for limited usage in China and Hong Kong and emergency use in Azerbaijan, Brazil, Chile, Colombia, Indonesia, Laos, Mexico, Turkey and Uruguay.</p> <p>2 doses required, stable in refrigerator</p>

# Vaccines in Development

Company	Vaccine name	Phase	Notes
Wuhan Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	Inactivated Vaccine	3	<p>The Phase 1/2 trial showed that the vaccine produced antibodies in volunteers, some of whom experienced fevers and other side effects. The Wuhan version of the vaccine is undergoing Phase 3 trials in several countries. In December, Peru briefly paused their Sinopharm trial to investigate neurological problems that one volunteer experienced, but determined that it had nothing to do with the vaccines.</p> <p>With the success of Sinopharm's BBIBP-CorV vaccine created by Beijing Institute, the fate of the Wuhan candidate was not clear.</p> <p>Approved for limited use in China and UAE.</p>
Bharat Biotech	Covaxin	3	<p>The phase 1/2 trial showed that the vaccine didn't cause any serious side effects while producing antibodies to the coronavirus. On Oct. 23, the company announced they were initiating a Phase 3 trial. On Dec. 22, the company announced a partnership with Pennsylvania-based Ocugen to develop Covaxin for the United States market.</p> <p>On Jan. 3, the Indian government granted Covaxin emergency authorization. The authorization came despite no release of Phase 3 data showing the vaccine is safe and effective. On Jan. 26, Bharat researchers reported that antibodies from the Covaxin vaccine can block B.1.1.7, the variant first identified in the United Kingdom in December.</p> <p>Approved for emergency use in India.</p> <p>2 doses required and remain effective at least a week at room temperature</p>
Johnson & Johnson (Janssen)	Ad26.COV2.S	3	<p>The European Union reached a similar deal on Oct. 8 for 200 million doses, and COVAX, an international collaboration to deliver the vaccine equitably across the world, secured 500 million doses. The company is aiming for production of at least a billion doses in 2021.</p> <p>On Nov. 16, Johnson &amp; Johnson announced that they were also launching a second Phase 3 trial to observe the effects of two doses of their vaccine, instead of just one.</p> <p>On Jan. 29, Johnson &amp; Johnson announced the results of the trial: the vaccine had an efficacy of 72% in the United States, 66% in Latin America, and 57% in South Africa.</p> <p>Potentially 1 dose vaccine, stable for two years at -20 °C and up to three months refrigerated at 2-8° C*</p>

Source: News Articles

\* Stability data forthcoming, may change storage and handling requirements

# Vaccines in Development

Company	Vaccine name	Phase	Notes
Zydus Cadila (India-based company)	ZyCoV-D	3	In a Dec. 11 interview, company's chairman Pankaj Patel, the company's chairman, said the company expects to have their vaccine ready for distribution by March 2021. On Jan. 3 the Indian government gave Zydus Cadila permission to advance to a Phase 3 trial with 30,000 volunteers. 3 doses and stable at room temperature for 3 months
Novavax	NVX-CoV2373	3	If its clinical trials succeed, Novavax expects to deliver 100 million doses for use in the United States in 2021. They also have an agreement with other countries, including one to the United Kingdom for 60 million doses and another with Australia for 40 million doses. On Jan. 28, Novavax reported that their United Kingdom trial determined an efficacy rate of 89.3 percent. But in South Africa, the result was just under 50 percent — potentially the result of a new variant there that can evade the antibodies produced by the vaccine. The company is developing a new version of the vaccine that is tailored to the variant. 2 doses required and stable in refrigerator.
AnGes; Osaka University, Takara Bio	AG0302-COVID19	2/3	On June 30, the Japanese biotechnology company AnGes launched a Phase 1 trial to test a DNA-based vaccine, developed in partnership with Osaka University and Takara Bio. The company moved on to a Phase 2/3 trial in December. 2 doses required and store at room temperature
Inovio	INO-4800	2	Inovio are running clinical trials for vaccines against a number of diseases, including HIV, Zika, and several forms of cancer. At the start of the pandemic, Inovio developed a DNA vaccine against the spike protein on the coronavirus. A Phase 1 trial, published in December, did not uncover any serious adverse effects, and measured an immune response in all 38 volunteers. Inovio said that the F.D.A. had given them permission to move forward. They are now running Phase 2 trials in the United States as well as in China and South Korea.
Medicago; GSK	CoVLP	2/3	In July, Medicago launched Phase 1 trials on a plant-based Covid-19 vaccine in combination with adjuvants to boost the immune system's response to the viral proteins. In that study, they found that an adjuvant made by GSK produced promising levels of antibodies in volunteers. On Oct. 23, the company announced it had reached an agreement with the government of Canada to supply 76 million doses. A Phase 2/3 trial of the vaccine began on Nov. 12. 2 doses required and stable in refrigerator

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# Vaccines in Development

Company	Vaccine name	Phase	Notes
Arcturus Therapeutics and Duke-NUS Medical School	LUNAR-COV19 (ARCT-021)	2	Arcturus announced that they had permission to start the Phase 2 portion of the trial in both Singapore and the United States, and will evaluate both single dose and two dose priming regimens of ARCT-021 in up to 600 participants. Singapore reached an agreement with Arcturus to spend up to \$175 million to acquire vaccines when they're ready. They are targeting global Phase 3 study start in Q2 2021 which could allow application for emergency use authorization/conditional approval in H2 2021
University of Melbourne and Murdoch Children's Research Institute; Radboud University Medical Center; Faustman Lab at Massachusetts General Hospital	Bacillus Calmette-Guerin (BCG) live-attenuated vaccine	3	Phase 3 trials in Australia and the Netherlands are both currently recruiting to assess how BCG vaccines impact health care workers' ability to prevent the virus. And Massachusetts General Hospital is evaluating BCG's role in type 1 diabetes and is working to secure funding to examine its effects on COVID-19 in health care workers.
Anhui Zhifei Longcom Biopharmaceutical, Institute of Microbiology of the Chinese Academy of Sciences	ZF2001	3	The Drug Regulatory Authority of Pakistan has given the go-ahead to conduct trials of ZF2001, a drug co-developed by Anhui Zhifei Longcom Biologic Pharmacy Co. Ltd and the Institute of Microbiology of the Chinese Academy of Sciences. Dr Shehnoor Azhar, the spokesperson of UHS, also confirmed the news to Geo.tv and further added that while most vaccines require single or two-doses, the ZF2001 vaccine is instead a three-dose jab.
Genexine (South Korean-based biotechnology company)	GX-19	1/2	Genexine's process to develop the Covid-19 vaccine is being delayed, as the company recently changed its Covid-19 vaccine candidate material in December and received approval for the new plan from the Ministry of Food and Drug Safety.
Sanofi and GSK	Adjuvanted recombinant protein-based vaccine	1/2	On Dec. 11, Sanofi and GSK announced that their vaccine was proving disappointing. While it provided promising levels of antibodies in people under 50, older people did not respond as strongly as they had hoped. They will start a new Phase 2 trial in February with a different formulation. If they can get sufficiently high antibodies with the new vaccine, they will move on to Phase 3 studies. Sanofi and GSK do not expect the vaccine to become available before the end of 2021.

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# Vaccine Procurement Status - Malaysia

Vaccine	Pfizer/BioNtech	Oxford / AstraZeneca	SINOVAC	CanSino	Gamaleya (Sputnik V)
Country origin	U.S.	U.K.	China	China	Russia
Local Distributor	Pfizer (Malaysia) Sdn Bhd	AstraZeneca Sdn Bhd	Pharmaniaga Bhd	Solution Biologics Sdn Bhd	Duopharma
Expected Shipment	21 February 2021	1H 2021	April 2021	April 2021	March 2021
Doses purchased (million)	32	12.8	12	3.5	6.4
Doses required	2	2	2	1	2
Storage Temperature (°C)	-75	2 - 8	2 - 8	2 - 8	-20
Efficacy Rate (%)	95	62 - 90	50.4 – 91.25	65.7	91.6
Price per dose	Malaysia: <RM 100 U.S.: ~USD 39.5	Malaysia: Non-profit U.S.: < USD 4	Malaysia: Unknown Indonesia: USD 13.60	Unknown	Malaysia: Unknown International: <USD 10
Population Coverage (%)	50	20	18.75	10.9	10
Population Coverage (million)	16	6.4	6	3.5	3.2
Total coverage	~ 35.1 million, equivalent to > 109% of population (32 million)				

Updated based on publicly available information as on 17 Feb 2021.



# Vaccine issues roundup

## Vaccine Efficacy

Some of vaccines i.e. Pfizer may provide some early protection starting 12 days after the first dose. Based on a study published, the vaccine efficacy between the first and second doses was ~52% and rose to 95% seven or more days after the second dose. It is possible that the efficacy of the vaccine in the real world may decrease as it will be used in more diverse populations and over longer time periods.

## Immunity Duration

There is no concrete report published to prove the immunity duration upon vaccination. Experts are inclined to believe that Covid-19 vaccinations will be recurring, perhaps annually, rather than a one-off event.

## Side effect

Generally, Covid-19 vaccines can cause side effects such as fever, chills, headache, swelling or tiredness for a few days, which are normal signs that the body is building protection. However in rare cases, certain individuals may have anaphylaxis (serious allergic reaction), which is an immune system reaction that can block breathing and cause blood pressure to drop.

## Virus mutation

Recent variants of the Covid-19 virus that emerged in the U.K., South Africa and Brazil seem to be more contagious which may lead to more cases, hospitalizations and deaths. Future mutations could undermine the efficacy of current vaccines.

## Temperature sensitivity

Certain vaccines i.e. Pfizer requires extremely low storage temperatures (-75°C). Once the vaccine thaws in a normal refrigerator, it has a shelf life of up to 5 days to be used. Hence, improper handling or logistics may compromise the effectiveness of the vaccine due its high sensitivity to temperature changes. This is expected to be a huge challenge especially in the rural areas.

## Vaccination hesitancy

Some people are concerned about the quick speed of Covid-19 vaccines approval despite assurances of vaccine developers and regulators. Misinformation and rumours about the vaccine could be circulated widely on social media and messaging platforms. This could cause raise levels of vaccine hesitancy among people and cause unnecessary delays in getting vaccinated.

# Vaccine Programme Key Stakeholders

Illustrative

Vaccine programs involve multiple stakeholder groups who influence the program development, vaccine production, delivery, and administration - each with its own perspective of its roles and activities in program rollout:

Stakeholder:	Populations	Government (Federal/Prov/Regional)	Manufacturers and Distributors	Providers	Research & Evaluators	
Stakeholder Group Constituents	<b><u>Priority Cohorts</u></b> <ul style="list-style-type: none"><li>Frontline Occupational Groups (Healthcare personnel &amp; police force)</li><li>High-Risk Citizens (Citizens that have underlying conditions)</li></ul>	<b><u>Public Health Policy and Communications</u></b> <ul style="list-style-type: none"><li>Ministry of Science, Technology and Innovation</li><li>Ministry of Health Malaysia</li><li>MCMC</li><li>Majlis Keselamatan Negara, Jabatan Perdana Menteri (MKN)</li></ul>	<b><u>Vaccine Manufacturers</u></b> <ul style="list-style-type: none"><li>Pfizer-BioNTech</li><li>Oxford-AstraZeneca</li><li>Sinovac</li><li>Covax (WHO)</li><li>Cansino</li><li>Gamaleya</li></ul>	<b><u>Hospitals</u></b> <p>Public Hospitals e.g.:</p> <ul style="list-style-type: none"><li>Hospital Kuala Lumpur</li><li>Hospital Permai, Johor</li><li>Hospital Pulau Pinang</li></ul> <p>Private Hospitals e.g.:</p> <ul style="list-style-type: none"><li>Subang Jaya Medical Centre</li><li>Hospital Pakar KPJ, Johor</li><li>Hospital Lam Wah Ee, Penang</li></ul>	<b><u>Researchers</u></b> <ul style="list-style-type: none"><li>The Centre for Clinical Epidemiology (CCE)</li><li>Institute for Medical Research</li></ul>	
	<b><u>Secondary Cohorts</u></b> <ul style="list-style-type: none"><li>At-risk, essential workers (Teachers, food industry, finance, water and energy sectors)</li></ul>	<b><u>Regulatory &amp; Safety Compliance</u></b> <ul style="list-style-type: none"><li>Ministry of Health Malaysia</li><li>National Pharmaceutical Regulatory Agency</li></ul>	<b><u>Ancillary Vaccine Supplies and PPE Manufacturers</u></b> <ul style="list-style-type: none"><li>Isolation Board – LKL Bhd</li><li>Gloves - Top Glove Corp Bhd &amp; Supermax</li><li>Face Mask – SCGM Bhd</li></ul>	<b><u>Public Health Units</u></b> <ul style="list-style-type: none"><li>University Malaysia</li><li>Hospital Putrajaya</li><li>Mobile vaccination centres / mobile clinics</li><li>Schools</li></ul>	<b><u>International Data Sharing Consortia</u></b> <ul style="list-style-type: none"><li>Medicines for Europe</li><li>World Health Organization</li></ul>	
	<b><u>Rest of population</u></b> <ul style="list-style-type: none"><li>Healthy Adults</li><li>Children (once vaccine is deemed safe for children)</li></ul>	<b><u>Finance</u></b> <p>Ministry of Finance Malaysia</p>	<b><u>Distributors</u></b> <ul style="list-style-type: none"><li>Pfizer (M) Sdn Bhd</li><li>AstraZeneca Sdn Bhd</li><li>Pharmaniaga Bhd</li><li>Duopharma Biotech Bhd</li><li>Solution Biologics Sdn Bhd</li></ul>	<b><u>Community Clinics:</u></b> <p>Main City Clinics e.g</p> <ul style="list-style-type: none"><li>Klinik Kesihatan Kuala Lumpur</li><li>Klinik Penang</li><li>Klinik Johor</li></ul>	<b><u>International Public Health Bodies</u></b> <ul style="list-style-type: none"><li>World Health Organization</li><li>Centers for Disease Control and Prevention</li></ul>	
		<b><u>Legal</u></b> <p>Attorney General's Chambers of Malaysia</p>		<b><u>Community Clinics e.g</u></b> <ul style="list-style-type: none"><li>Klinik Kayu Ara Damansara</li><li>Klinik Gombak Permai</li><li>Klinik Kesihatan Sri Merdang, Terengganu</li></ul>	<b><u>Oversight bodies</u></b> <ul style="list-style-type: none"><li>Ministry of Health Malaysia</li><li>National Pharmaceutical Regulatory Agency</li><li>Majlis Keselamatan Negara, Jabatan Perdana Menteri (MKN)</li></ul>	
		<b><u>Gov't Procurement and Vendor Selection</u></b> <p>Special Vaccine Supply Access Guarantee Committee (JKJAV)</p>		<i>Note: Cold chain logistics limitations should be considered to store / transport vaccines to remote areas.</i>		
		<b><u>Cyber &amp; Data Privacy</u></b> <p>MCMC (MySejahtera)</p>				
		<b><u>Security (Defense)</u></b> <ul style="list-style-type: none"><li>Malaysian Armed Forces</li><li>Royal Malaysia Police</li></ul>				
<b>Stakeholder Key Roles:</b>	<b>Recipient</b>	<b>Policy, Management, &amp; Communications</b>	<b>Supply Chain</b>	<b>Vaccine Administration</b>	<b>Programme Evaluation</b>	



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