

VACCINE

NATIONAL VACCINE DEVELOPMENT ROADMAP







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WHY NVDR

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The emergence of the COVID-19 pandemic has warranted a relook at the need of producing local vaccines and becoming a vaccine producing country.



Aside from the importance of securing the national security and self-sufficiency in vaccines, there should also be a balanced focus in driving the bioeconomy of the country.



As a lesson learnt from the COVID-19 pandemic and the limited supply of vaccines for this pandemic, there is a need to be prepared for future crisis and pandemic through the development of local capabilities in vaccine R&D and manufacturing.



The National Vaccine Development Roadmap will enable stakeholders and government to evaluate and develop capability and capacity of Malaysia towards becoming a vaccine producing country, moving the country from the current state in vaccine manufacturing to achieve a fully developed vaccine ecosystem.



The National Vaccine Development Roadmap is also in line with the National Biotechnology Policy and National Policy on Science, Technology and Innovation (NPSTI) 2021-2030.





Vaccine Fill-and-Finish Manufacturing Vaccine Bulk Manufacturing



To develop a national roadmap that will enable stakeholders and the government to understand the current scenario and gaps within the vaccine industry.

To formulate short-, mid-, and long-term strategic plans to enable Malaysia to become a vaccine-producing country.



Achieve self-sufficiency in vaccine manufacturing and R&D within 10 years



To develop a holistic vaccine manufacturing value chain To have balanced focus on biosecurity and bioeconomy

To spur advancements in R&D, technology, and human capital

To foster

collaboration and alignment between government bodies, agencies, and private sectors

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Malaysia achieves local vaccine manufacturing capability R&D and human capital have become developed enough to proceed to homegrown vaccine production The developed vaccine infrastructure will contribute to the biotechnology ecosystem

Ecosystem and Value Chain of Vaccine in Malaysia

(Current and Proposed Future)



Indicates the gaps

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02. THE WAY FORWARD (HOW DO WE ACHIEVE THE ASPIRATION OF NVDR)

National Vaccine Development Roadmap Key Enablers

VACCINE

The key development enablers, which help to drive the vaccine ecosystem in Malaysia, center on the development of the vaccine development and manufacturing value chain while focusing on both national biosecurity and bioeconomy.

Holistic vaccine manufacturing value chain

Enables vaccine manufacturing and development in Malaysia, including halal vaccine as a niche

- Initial R&D
- Fill-and-Finish
- Bulk Manufacturing

Collaboration between stakeholders

Ensures harmony between the government bodies and agencies involved in the vaccine industry

- Collaboration among research institutes and academia
- Collaboration among researchers and manufacturers

Balanced focus on biosecurity and bioeconomy

Provides the country with vaccine biosecurity while driving its bioeconomy

- National Vaccine Stockpile
- Development of vaccines with local and global demand

Advancements in R&D, technology, and human capital

Prepares the ecosystem for indigenous vaccine development

- Technology transfer and acquisition
- Development of human capital

National Vaccine Development Roadmap Strategy Framework

> The National Vaccine Development Roadmap aims to prepare Malaysia to be self-sufficient in vaccine manufacturing and R&D within 10 years. To develop Malaysia's vaccine ecosystem, strategies for six key areas and critical pathways have been formulated, along with five inter-pillar strategic activities.

Proposed Strategy Framework Concept





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03. MALAYSIA GENOME AND VACCINE INSTITUTE



The establishment of a Malaysia Genome and Vaccine Institute

(MGVI) will support vaccine research for new infectious diseases and vaccinations, boost collaboration and provide wide access to research facilities to cater vaccine research, which is in line with the National Policy on Science, Technology and Innovation (NPSTI) 2021-2030. The governance of the MGVI will be led and centralised under NIBM, while the activities will be conducted in decentralised facilities to leverage on existing capabilities, such as:

 Institute for Medical Research facility to conduct vaccine discovery research (e.g., BSL-3 labs)

 Institute for Clinical Research, Clinical Research Malaysia and Hospitals experience and expertise in conducting clinical trials

 University Research Centres expertise to conduct vaccine R&D Malaysia Genome and Vaccine Institute facility to conduct vaccine discovery research and supporting R&D (e.g., genome sequencing)

 IPharm, Institute for Medical Research, SIRIM and Veterinary Research Institute facility and capabilities to conduct preclinical studies on small animals (to be expanded to large animals)

Manufacturers facility to contribute to process development

These existing

facilities can be grouped in several Centre of Excellences which is critical for vaccine development. MIDA and TDA may assist to develop the Centre of Excellences in the National Vaccine Research Centre through the Industrial Collaboration Programme by attracting and engaging with foreign manufacturers to develop R&D capabilities, production facilities and processes as well as the human capital.



04. PHA Develo	ASES OF OPMENT	
NVDR Str Timeframe Development Themes	ategy Present Day (T=0) Responding to Pandemic Threats by Increasing Capacity	Short Term (1-3 years) Developing the Foundations and Obtaining Quick Wins
Strategies/ Initiatives	 Malaysia achieves fill-and-finish capacity-approval granted Vaccine research through grants provided to research institution and universities funded by Malaysia Some private sector interest in imports and conducting fill-and-finish activities 	 Export-oriented policy Halal certification of vaccines Enhancement of regulations Focus on low-hanging fruit Development of the National Vaccine Research Centre
Expected Outcome	Gain experience in manufacturing	 Exportation of till-and-finish vaccines Provision of halal certification for fill-and-finish vaccines Minimal human capital skills required for the manufacture of vaccines through transfer of technology Partnerships with raw materials providers and R&D on halal alternatives for raw materials National Vaccine Institute (by Year 1) Vaccine Preclinical Animal Facility (by Year 2) Vaccine Process Development Center (by year 3)
Vaccine Production		Clinical trials and production of COVID-19 vaccine candidate by IMR, UPM and VRI

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The National Vaccine Development Roadmap is divided into three phases for a 10-year span. Several key strategies and expected outcomes will take place in respective phases, eventually enabling Malaysia to achieve self-sufficient homegrown vaccine production.





ate by AIMST University and USM

Vaccine diplomacy
 Technology acquisition
 Development of supporting ecosystem

• R&D for growth (e.g., process development and improvement of manufacturing technology) • Central vaccine stockpile

05. THE IMPACT OF NATIONAL VACCINE DEVELOPMENT ROADMAP

DIRECT IMPACT

- Gain **self-sufficiency** and achieve biosecurity
- Establish a sustainable ecosystem for vaccine development to cater to global demand
- Enable Malaysia to position itself as a halal vaccine manufacturing and certifying hub
- Enable the cultivation of **talent pools** across various vaccine therapeutic areas / platforms
- Drive vaccine innovation by providing a conducive ecosystem for start-up and university research to flourish

INDIRECT IMPACT

- Contribute to the bioeconomy growth by bridging the biotechnology infrastructure and resource gaps in Malaysia
- Enable **job creation and opportunities** for graduates and returning local experts
- Enable opportunities for **on-the-job experience** for students and young scientists to **ensure talent retention**
- Position Malaysia as a clinical trial hub across all phases
- Attract MNCs to invest and establish facilities in Malaysia due to its sustainable and developed ecosystem
- Boost the adjacent industries (e.g., medical tourism, real estate, and food and beverages (F&B))

06. CONCLUSION



At the moment Malaysia does not have a human vaccine development capability that enables the end-to-end development of indigenous vaccines.

It is imperative that Malaysia looks at a more pragmatic approach towards balancing the need of biosecurity and building local vaccine ecosystem, by focusing on vaccine manufacturing first without neglecting the importance of the development of a holistic vaccine ecosystem, which also includes R&D capabilities and supporting industry players. However, some local players have embarked in the manufacturing of developed vaccines such as the fill-and-finish.

The action plan includes using the public-private-partnership (PPP) model to develop vaccine manufacturing capabilities, collaboration with global network for ease of market entry and identification of vaccine in demand, as well as developing halal certification capabilities.

The roadmap will help Malaysia produce its own high quality, effective and safe vaccines. One of the key challenges that Malaysia had faced during the pandemic was the inability to react with a vaccine production line.



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