

**IMPORTANCE OF INVESTMENTS IN ASIA AND THAILAND
FOR VACCINE R&D,
STATE OF THE ART QUALITY TESTING
AND REGULATORY HARMONIZATION
ONGOING INITIATIVES AND OPPORTUNITIES TO CONSIDER**



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Director of National Vaccine Institute



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VACCINE IN EXPERIMENTAL ANIMALS



THAILAND HAS 3 ANIMAL TESTING FACILITIES
for POC, toxicity, and immunogenicity studies



Mahidol University
National Laboratory
Animal Center



Mahidol University
National Laboratory
Animal Center

**National Laboratory
Animal Center
Mahidol University**



**Center for Animal Research
Naresuan University**



**National Primate Research
Center of Thailand
Chulalongkorn University**



VACCINE IN EXPERIMENTAL ANIMALS



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**National Laboratory
Animal Center
Mahidol University**



Scope of Service

- Animal Testing – Toxicity Testing
 - Oral Toxicity Test
 - Skin / Local Tolerance Test
 - Toxicopathology
- Laboratory Analysis
 - Animal Health (Hematology, Serology, Necropsy, Histology, Microbiology, Parasite, Urine analysis)
 - Environment quality for raising animals (Diets, Water, Bedding, Air, Surface Antimicrobial Products (Organic))
- Training courses in laboratory animal science and to provide consultancy service to customer both local and international.

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**Center for Animal Research
Naresuan University**



Scope of Service

- Nonclinical evaluation of vaccines (WHO Technical Report Series)
 - Single Dose Toxicity Study
 - Repeated Dose Toxicity Study and Local Tolerance study
 - Developmental and reproductive toxicity (DART) study
- Nonclinical evaluation of Pharmaceutical Products (EMA, ICH guidelines)
 - Single Dose Toxicity Study
 - Repeated Dose Toxicity Study and Local Tolerance study
- Biological evaluation of medical devices
- Guidelines for Testing of Chemicals
- ABSL1, ABSL2 & ABSL 3 facilities and equipment for rental

VACCINE IN EXPERIMENTAL ANIMALS



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NATIONAL PRIMATE RESEARCH CENTER OF THAILAND
ศูนย์วิจัยไพรเมทแห่งชาติ

**National Primate Research
Center of Thailand
Chulalongkorn University**

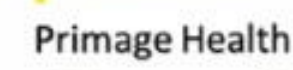


Scope of Service

- Non-clinical drug, vaccine and biopharmaceuticals testing in non-human primates
- Pharmacokinetics
- Safety pharmacology test
- A wide range of services in the area of efficacy and toxicology

The monkeys behind Covid-19 vaccines research

- COVIGEN DNA vaccine: BioNet Asia Co., Ltd
- Baiya SARS-CoV-2 Vax 1, 2 Protein-subunit vaccine: Baiya Phytopharm Co., Ltd
- ChulaCov19 mRNA vaccine: Chula VRC



ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS

WHY ANIMAL TESTING REPLACEMENT IS NEEDED ?

The use of animal testing for quality control has a long history. However, it is now recognized to present **several limitations**,



Delays
in vaccine
availability



**High
variability**
in test results



Potential failure
to accurately reflect
the true quality and
safety of the products





ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS



WHAT IS **WHO** GUIDANCE ON REPLACING ANIMAL TESTING ?

The WHO Guidelines on the replacement or removal of animal tests" mark a pivotal shift in the quality control (QC) of biological products, prioritizing scientific advancement over tradition.



The 3Rs Principle:

Rigorous application of Replacement, Reduction, and Refinement in all testing protocols.



In Vitro Priority:

Non-animal technologies are now recognized as scientifically superior, offering greater robustness and reproducibility.



Removal Goal:

The ultimate objective is to fully replace in vivo animal assays wherever scientifically justified.



World Health Organization

WHO/BS/DRAFT4/PC2/JULY2025
Page 1

WHO/BS/2025/2485
ENGLISH ONLY

Guidelines on the replacement or removal of animal tests for the quality control of biological products



ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS

FROM **WHO** GUIDANCE **TO** STRATEGIC IMPLEMENTATION

STRATEGIC IMPLEMENTATION



Proactive Adoption

Manufacturers are urged to implement non-animal methods immediately. Do not wait for specific WHO product guidelines to be updated before making the switch.



Rationalized Testing

Eliminate redundancy by testing only once at a critical manufacturing step. Streamlined strategies reduce animal use while maintaining safety standards.



Regulatory Shift

These new guidelines explicitly supersede animal testing requirements found in older WHO documents, establishing a new global norm for biologicals.



ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS



WHO

GUIDANCE ON REPLACING ANIMAL TESTING IN VACCINE QUALITY CONTROL

**ADVENTITIOUS
AGENT TESTING**

**PYROGENICITY AND
ENDOTOXIN TESTING**

**NEUROVIRULENCE
TESTING**

**POTENCY
TESTING**

**SPECIFIC TOXICITY
TESTING**

**INNOCUITY
TESTING**

ADVENTITIOUS AGENT TESTING

IN VIVO ADVENTITIOUS AGENT TESTING,

- Tests for haemadsorbing & hemagglutinating viruses
- Tests for mycobacteria,
- Tests for avian viruses

HISTORICALLY



Animal-based



WHO RECOMMENDS



✓ Replacing these with molecular methods such as **PCR** or **High-Throughput Sequencing** (HTS).



When molecular methods yield a positive result ✓



Confirmation using **a cell-based culture test** is advised instead of animal testing.



ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS



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AGENT TESTING**

**PYROGENICITY AND
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**POTENCY
TESTING**

**SPECIFIC TOXICITY
TESTING**

**INNOCUITY
TESTING**

HISTORICALLY

**PYROGENICITY
TESTING**



Rabbit (a risk-based approach)



**ENDOTOXIN
TESTING**



Horseshoe crab blood (LAL/TAL assays)



WHO RECOMMENDS

Monocyte Activation Test (MAT)

Recombinant Factor C/F
(rFC/rCR) assays



ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS



WHO

GUIDANCE ON REPLACING ANIMAL TESTING IN VACCINE QUALITY CONTROL

**ADVENTITIOUS
AGENT TESTING**

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TESTING**

**POTENCY
TESTING**

**SPECIFIC TOXICITY
TESTING**

**INNOCUITY
TESTING**

NEUROVIRULENCE TESTING

Performing between manufacturing steps and during quality control for several vaccines, including

- yellow fever vaccine,
- oral poliomyelitis vaccine,
- mumps vaccine, and
- other viral vaccines.

HISTORICALLY



Animal-based



WHO RECOMMENDS



- ✓ Replacing these with molecular methods such as **High-Throughput Sequencing (HTS)**.



ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS



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**ADVENTITIOUS
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TESTING**

**SPECIFIC TOXICITY
TESTING**

**INNOCUITY
TESTING**

POTENCY TESTING

- Performing in-process and on final products.
- For biologicals, especially vaccines, potency using in vivo assays

HISTORICALLY



Animal-based



WHO RECOMMENDS



Replacing
these with
VITRO ASSAYS



- ✓ Strategies, such as
 - + Gaining a thorough understanding of the product's critical quality attributes (CQAs),
 - + Applying the consistency approach, combining antigen content with functional assays for potency determination, and
 - + Supporting the development of product-specific in vitro methods.



ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS



WHO

GUIDANCE ON REPLACING ANIMAL TESTING IN VACCINE QUALITY CONTROL

ADVENTITIOUS
AGENT TESTING

PYROGENICITY AND
ENDOTOXIN TESTING

NEUROVIRULENCE
TESTING

POTENCY
TESTING

**SPECIFIC TOXICITY
TESTING**

INNOCUITY
TESTING

SPECIFIC TOXICITY TESTING

Performing during
production or
on final vaccine's products

- Diphtheria,
- Tetanus
- Acellular pertussis
- Oral cholera
- BCG vaccine

HISTORICALLY 



Animal-based



WHO RECOMMENDS 

Replacing
these with
VITRO ASSAYS



- ✓ Needs to be specific and at least as sensitive as the existing animal model,
- ✓ May be based on the use of a toxin-sensitive cell line or on the use of one or more assays that specifically target parameter(s) known to be essential for toxicity in vivo



ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS



WHO

GUIDANCE ON REPLACING ANIMAL TESTING IN VACCINE QUALITY CONTROL

**ADVENTITIOUS
AGENT TESTING**

**PYROGENICITY AND
ENDOTOXIN TESTING**

**NEUROVIRULENCE
TESTING**

**POTENCY
TESTING**

**SPECIFIC TOXICITY
TESTING**

**INNOCUITY
TESTING**

INNOCUITY TESTING

Performing during
final product for

- Biological product
licensing
- Quality control

HISTORICALLY



Animal-based

The test design
VARIES across
pharmacopoeias &
international standard

Having faced long-standing
SCRUTINY for scientific value
and relevance.



NOWADAYS

With **GMP**, validated processes, and proper quality control



The test is now deemed unnecessary



National Regulatory Authorities &
Pharmacopoeias have **removed** it from
their requirements.





ANIMAL-BASED TESTING IN VACCINES AND BIOLOGICAL PRODUCTS

ANIMAL TESTING REPLACEMENT in THAILAND



As of 2025, the **Institute of Biological Products, Department of Medical Sciences**, has ongoing projects focused on developing alternative methods to replace animal testing for finished biological products, as follows:

TESTING	PRODUCTS	HISTORICALLY	REPLACEMENT	STATUS
Safety	Recommended biological products	Rabbit pyrogen	Cell-based assay	Research funded (2026–2027)
		Endotoxin (LAL)	rFC	In progress
Potency	Rabies vaccine	Challenge test	Glycoprotein content by ELISA*	Preparing standard material
	HBsAg vaccine	In vivo potency (Ab titer in mice)	HBsAg content by ELISA*	Completed
	Pertussis vaccine	Intracerebral-challenge Mouse Protection Test (MPT)	In vitro ELISA	Feasibility under consideration
	Tetanus Immunoglobulin	Mice immunization	ELISA*	Completed
	Tetanus antitoxin	Mice immunization	ELISA	Completed
	Snake antivenin	Mice immunization	ELISA	In progress

REMARKS: In a **DCVMN** collaborative study to replace the intracerebral Mouse Protection Test for whole-cell pertussis vaccine with the ELISA-based Pertussis Serological Potency test.



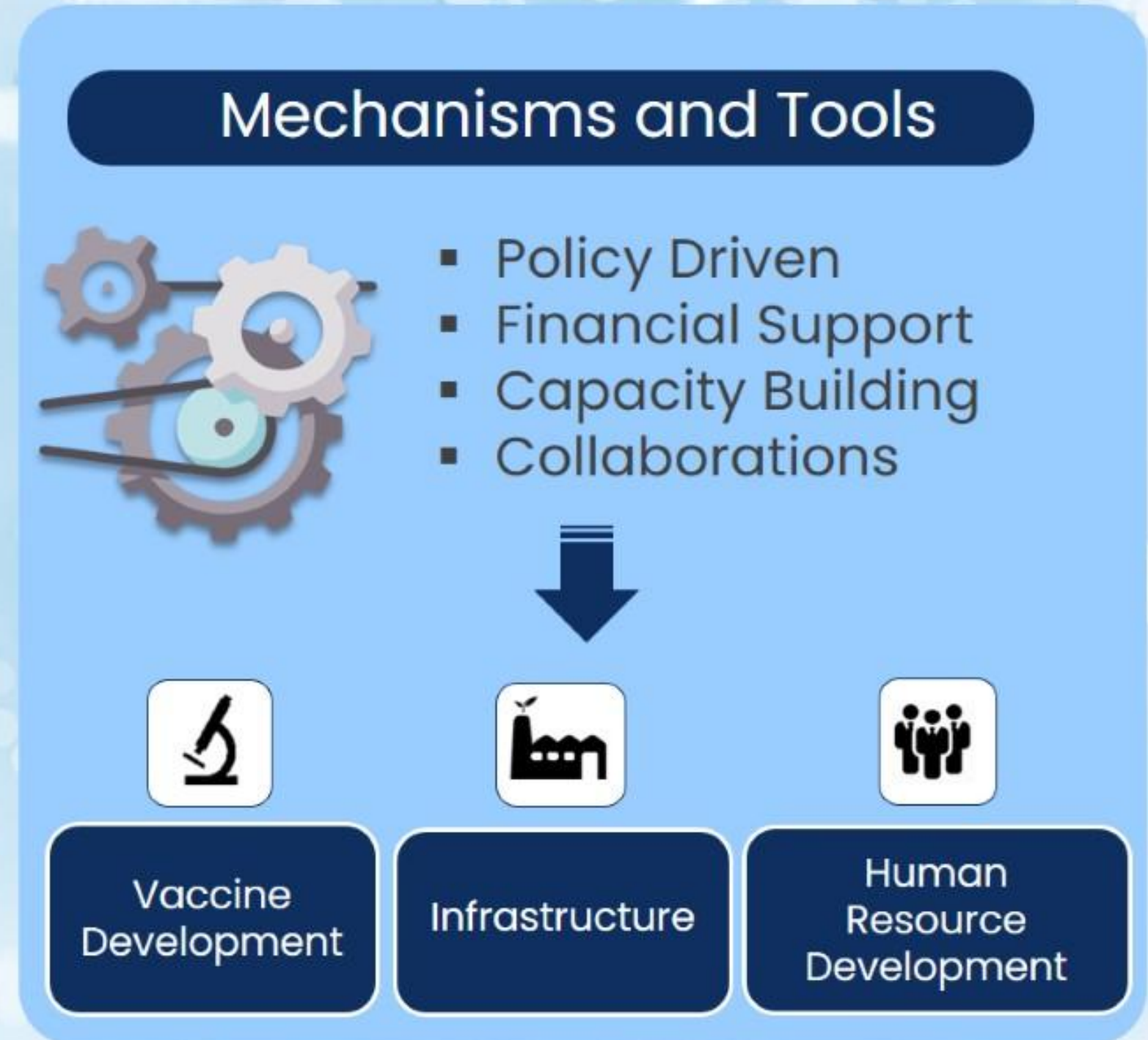
THAILAND'S VACCINE DEVELOPMENT ECOSYSTEM

THE ROLE OF NVI IN THAILAND'S VACCINES DEVELOPMENT

Driven Mechanisms Objectives

Collaborations between network partners in both the public and private sectors are essential for developing the ecosystem of vaccine development in Thailand.

These partnerships ensure readiness to cope with various situations that affect vaccine development



THAILAND'S VACCINE DEVELOPMENT ECOSYSTEM

Upstream Research &
Research Utilization



Common
Infrastructure



Viral vector



Nucleic acid



Inactivated



Subunit



**Universities/
Research organization**

COVID-19, Influenza,
vaccine, BAT etc.
development (TRL 1-3)

**Animal Testing
Facilities**



POC, Toxicity,
Immunogenicity study

Pilot plant



- CDMO
- DS Manufacturing

Industrial plant



Fill and Finish

NSTDA

- Candidate Discovery



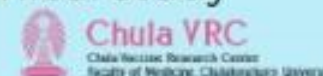
Siam Bioscience

- Manufacturing of
Viral Vector Vaccine and
Monoclonal antibody



Chula VRC

- mRNA/DNA candidate
vaccine development
- Clinical study



BioNet-Asia

- DNA vaccine
development
- Manufacturing of
DNA, mRNA and
bacterial vaccine
(acellular pertussis)



GPO

- Manufacturing of
inactivated egg-based
recombinant vaccine
- Scale Up and
Manufacturing of egg-
based vaccine (Seasonal
Flu, Pandemic Flu)
- Process development
(Cell-based Flu vaccine)



BAIYA

- Plant-based subunit
vaccine development
- Clinical study



← **NRA, HRD Capacity** →

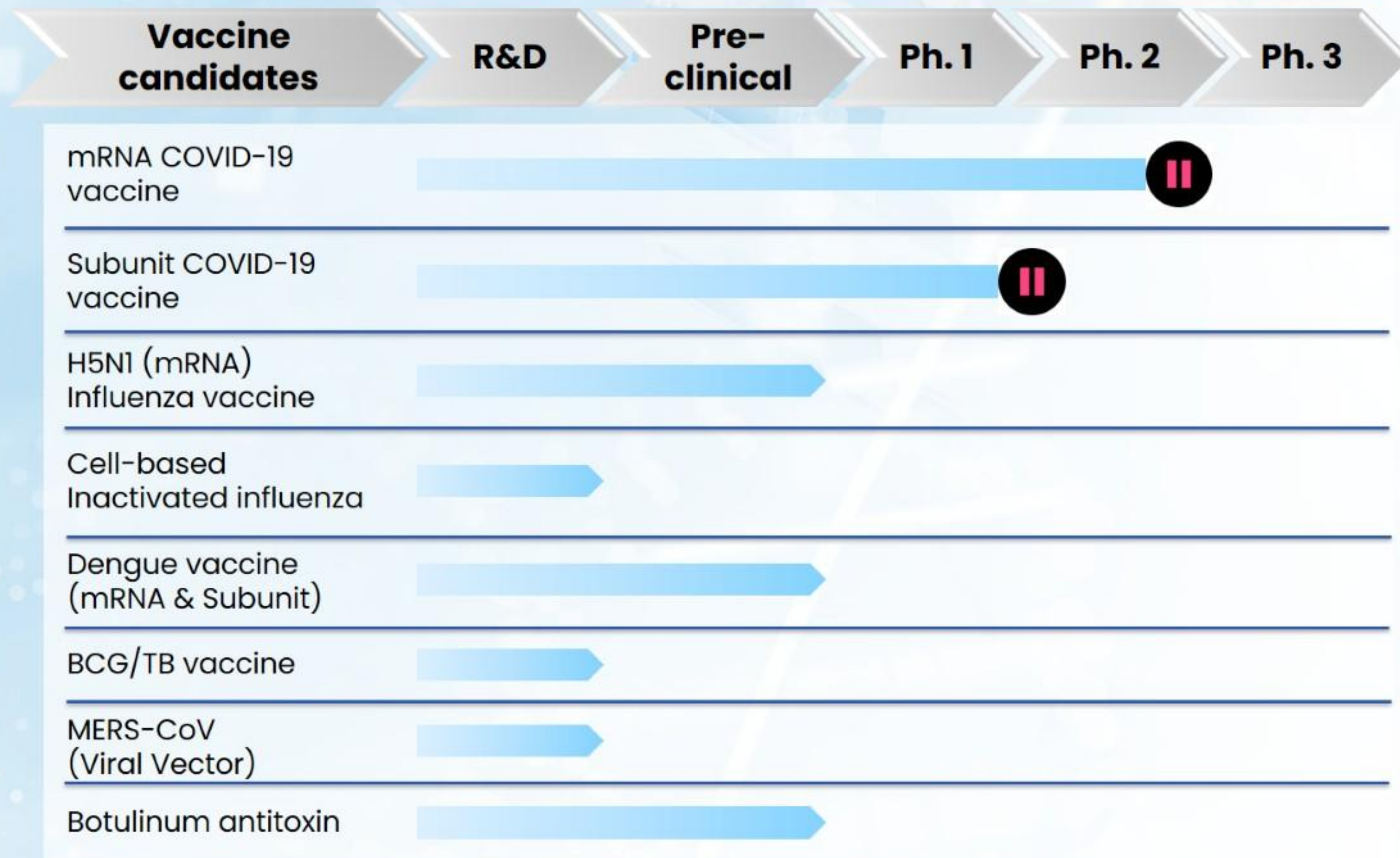
VACCINE CAPACITY BUILDING: R&D AND PRODUCTION

Vaccines and biological materials under R&D



Registered Vaccine by TFDA

- COVID-19
- aP, TdaP,
- BCG
- Japanese encephalitis
- Rabies
- Trivalent Influenza (egg-based)





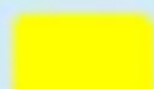
CURRENT VACCINE PRODUCTION POTENTIAL OF THE COUNTRY (AS OF MAY 2024)



Pilot Scale



Industrial Scale

 = On-going

Organization	GMP certificate	BSL level	Technology platforms/Products
MU-Bio Innovation (MU-Bio), Mahidol university	-	BSL-1	• Fermentation technology
National Biopharmaceutical Facility (NBF)	GMP compliance	BSL-2	• Fermentation technology • Cell-based technology
Government Pharmaceutical Organization (GPO) Thailand	GMP compliance	BSL-2+	• Fermentation technology • Egg-based technology • Cell-based technology
Government Pharmaceutical Organization (GPO) Thailand	GMP compliance	BSL-2+	Egg-based technology (NDV-HXP-S, Influenza)
Queen Saovabha Memorial Institute (QSMI-TRCS)	GMP compliance	BSL-2	Up to Down (BCG, immunoglobulins, Rabies) Fill& Finish (JE (Inactivated), Rabies)
Global Biotech Products Co., Ltd (GBP)	GMP compliance	BSL-2	Mid to Down (Influenza, chimeric JE, Rabies)
BioNet-Asia Co., Ltd	GMP compliance	BSL-2	Up to Down (aP, TdaP) mRNA
Siam Bioscience Co., Ltd	GMP compliance	BSL-1	Up to Down Viral Vector technology (COVID-19)

VACCINE CLINICAL TRIAL CENTERS



Chula Clinical Research Center (Chula CRC)

- All-in-one clinical research facility houses
 - Multidisciplinary clinical research team
 - Pharmacokinetics center
 - Data management center
 - Clinical research laboratory
- Experienced in conducting phase 1-4 clinical trials
- Successfully completed over 300 clinical studies.



Vaccine Trial Centre (VTC)

- The VTC is a clinical facility in the Faculty of Tropical Medicine (FTM); Mahidol University
- 37 clinical studies on conducting phase 1-3 clinical trials
- Currently VTC is one of the clinical trial research site of HVTN supported by NIH (MU-CRC, MHRP-CTU, HVTN, DAIDS)..



Siriraj Institute of Clinical Research (SICRES)

- Siriraj Institute of Clinical Research (SICRES) is an academic clinical research institute, operating under the Faculty of Medicine Siriraj Hospital, Mahidol University.
- Conducts cost-effective clinical research
- Full-service clinical trial design and management.
- Precision clinical trial design and management (Phase I to IV)



ASEAN Vaccine Security and Self-Reliance (AVSSR)

ASEAN Vaccine Security and Self-Reliance (AVSSR)

HISTORY



The ASEAN Leaders' Declaration on AVSSR was declared in the 35th ASEAN Summit (November 2019)

2019: The ASEAN Leaders' Declaration on AVSSR was declared

2014: "Workshop among ASEAN Countries on Opportunities for Regional Vaccine Security" in Phuket

2019: COVID-19 Pandemic

2021: AVSSR Strategic and Action Plans 2021-2025 was official endorsed in the ASEAN Health Ministers Meeting

ASEAN Vaccine Security and Self-Reliance (AVSSR)

AVSSR STRATEGIC AND ACTION PLAN 2021-2025

Endorsed by AHMM in 2021

Vision: Towards Realizing Vaccine Security and Self Reliance for All: Ensure healthy ASEAN through timely, equitable access to affordable and quality-assured vaccines

Strategy 1

AVSSR Advancing into global policy level

Strategy 2

Establishing regional pooled procurement & stockpiling mechanisms

Strategy 3

Establishing vaccine information sharing platform

Strategy 4

Capacity Building

Strategy 5

Monitoring & evaluation mechanism

AVSSR Ultimate Goal

Build Security

Ensure continuous and equitable vaccine supply in normal and emergency situations..



Develop Self-reliance

Strengthen regional capacity to produce vaccines with solid infrastructure and readiness.



Create Sustainability

Maintain long-term self-reliance and operational capacity for vaccine

ASEAN Vaccine Security and Self-Reliance (AVSSR)

PROGRESS (2021–PRESENT)



1. AVSSR into global policy level



The 2nd APIC-ADVA Summit on Infectious Diseases & Immunization
On 11–13 February 2025, Singapore



First Regional Consultative Meeting on ASEAN
Diagnostic Security and Self-Reliance (ADxSSR)
17–18 June 2025, Bali, Indonesia



Consultative Workshop on the Research Preparedness
Ecosystem in Asia
On 9–10 July 2025, Bhutan

Organized by 



Sustainable Markets
Convening: Demand-Driven
Solutions Shaping the Future
of Regionalized Vaccine
Manufacturing
On 10 April 2025,
Abu Dhabi, UAE

Organized by  RVMC
Regional Vaccine
Manufacturing Collaboration

Meetings & Conferences

- **2023 Health Cooperation Forum in the Indo-Pacific Region**
 - 📍 13 December 2023, Republic of Korea
- **The 12th National Pharmacy Research & Development Conference 2024**
 - 📍 21 August 2024, Malaysia
- **CEPI's Regulatory Innovations Workshop**
 - 📍 20–22 January 2025, Singapore
- **World Local Production Forum (WLPF) 2025**
 - 📍 8–10 April 2025, Abu Dhabi, UAE
- **World Vaccine Congress**
 - 📍 21–24 April 2025, Washington D.C., USA

And more.....

ASEAN Vaccine Security and Self-Reliance (AVSSR)

PROGRESS (2021-PRESENT)



1. AVSSR into global policy level

By actively presenting the AVSSR initiative on global stages, ASEAN has **gained growing recognition and support**. This visibility has **strengthened credibility and attracted development partners** to engage in dialogue and explore opportunities to contribute to the implementation of AVSSR.



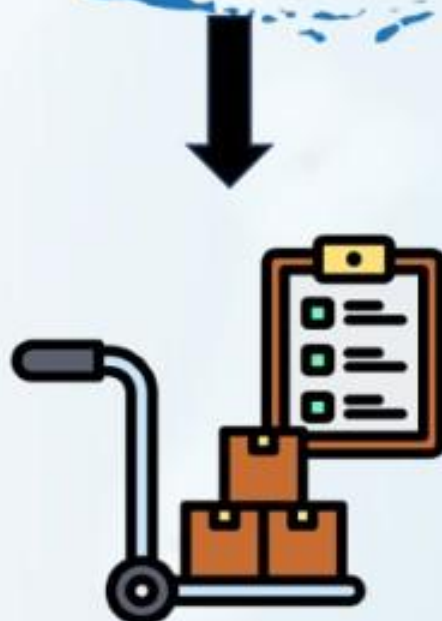
....we continue to **welcome** more partners to join us on this path

ASEAN Vaccine Security and Self-Reliance (AVSSR)

PROGRESS (2021-PRESENT)



2. Regional pooled procurement & stockpiling mechanisms (In Process..)



Pooled Procurement

- ❖ **Increases purchasing power** by distributing costs across a larger volume
- ❖ **Enhances efficiency** by sharing workload, expertise, and human resources.
- ❖ However, there are **challenges**:
 - Common local needs
 - Strong political commitment
 - Harmonization of regulatory authorities
 - Different financial mechanisms
 - Different National Immunization Programs

ASEAN Vaccine Security and Self-Reliance (AVSSR)

PROGRESS (2021-PRESENT)



3. Vaccine Information Sharing

AVSSR Consultative Meetings (2021-2025)

ASEAN-ROK, Virtual



ASEAN Meeting on the AVSSR: the ASEAN Vaccine Dashboard, Virtual



ASEAN Consultative Meeting on the AVSSR



Purpose of the Meetings

- Review the progress of the AVSSR Strategic and Action Plan 2021–2025
- Discuss the strategic direction beyond 2025
- Provide platforms for ASEAN Member States to update on national vaccine-related developments
- Strengthen collaboration with international organizations and development partners

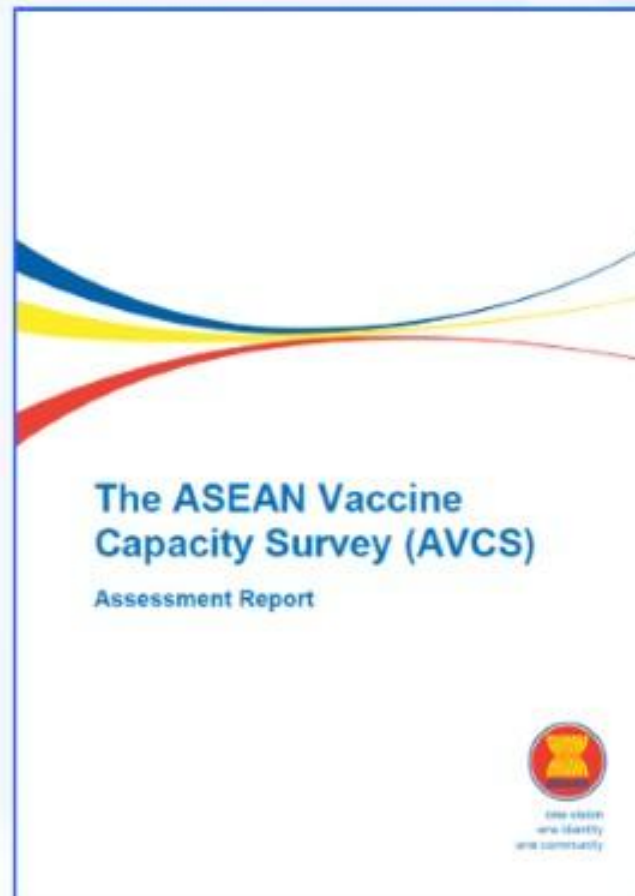
ASEAN Vaccine Security and Self-Reliance (AVSSR)

PROGRESS (2021-PRESENT)



3. Vaccine Information Sharing

ASEAN Vaccine Capacity **Survey** (AVCS)



ASEAN Vaccine Capacity Survey*,
collected in 2023 and published in 2025

Objectives

The **AVCS** was conducted to understand the current status, capabilities, and gaps in vaccine infrastructure across ASEAN Member States following the COVID-19 pandemic.

Key Challenges

1. Limited vaccine R&D capacity and infrastructure
2. Insufficient courses in local institutions on vaccine research, development, and manufacturing disciplines
3. Limited workforce availability
4. Insufficient local production facilities

*7 countries participated in AVCS: Brunei Darussalam, Indonesia, Lao PDR, Malaysia, The Philippines, Singapore, Thailand

ASEAN Vaccine Security and Self-Reliance (AVSSR)

PROGRESS (2021-PRESENT)



3. Vaccine Information Sharing



ASEAN Vaccine **Dashboard**

- Currently under development as part of AVSSR implementation
- Aims to serve as a long-term regional platform for vaccine information sharing
- Designed to enable regular updates and data visualization across the vaccine value chain
- Supports collaboration among ASEAN Member States
- Helps inform evidence-based decision-making

ASEAN Vaccine Security and Self-Reliance (AVSSR)

PROGRESS (2021-PRESENT)



4. Capacity Building

Onsite Training



- **Topic:**
 - (1) Technology transfers in Vaccines
 - (2) Regulatory Aspects
 - (3) Risk Communications
- **Date:** 26 – 27 September 2024, Bangkok
- **Participants:** approx. 80



- **Topic:** Pandemic preparedness, covering both global and regional movements
- **Date:** 20 August 2025, Bangkok
- **Participants:** approx. 90

Online Training



- **Topic:** Intellectual Property (IP) for Advancing ASEAN's Vaccine Ecosystem
- **Date:** 3 Episodes, June-September 2025

ASEAN Vaccine Security and Self-Reliance (AVSSR)

PROGRESS (2021-PRESENT)



5. Monitoring & evaluation mechanism



Strategy 5

Monitoring & evaluation mechanism



AVSSR Steering Committee

- **Strategic Direction** – Guides implementation of the AVSSR plan
- **Coordination** – Connects Member States, working groups, and partners
- **Monitoring** – Tracks progress, identifies challenges

Strategy 2

Establishing regional pooled procurement & stockpiling mechanisms

Strategy 3

Establishing vaccine information sharing platform

Strategy 4

Capacity Building

ASEAN Vaccine Security and Self-Reliance (AVSSR)

Lessons Learned: over 5 years of AVSSR Implementation

Strengths

- **Strong political commitment & regional framework**
- **Shared experiences among ASEAN Member States**
- **Active engagement of development partners**

Challenges

- **Limited budget and human resource**
- **Diverse National Prioritization**
- **Regulatory systems with varying maturity levels across Member States**



Opportunity

AVSSR's international recognition attracts strong interest from partners and stakeholders





Thank You



acknowledging the crucial role of vaccines as a fundamental medical intervention



SCAN ME
NVI
INTRO
DUCTION



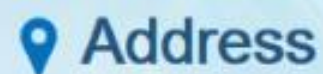
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