

# AN OVERVIEW OF BIO FARMA

## Capability and Capacity in mRNA-based Vaccine Development

WHO/MPP mRNA Technology Transfer  
*April 2023*

# OVERVIEW PHARMACEUTICAL SOEs HOLDING

Officially formed by the Minister of SOEs on **January 31<sup>th</sup> 2020**, the Pharmaceutical SOE holding currently consists of three SOEs member group: **PT Bio Farma (Persero)** as the holding company and **PT Kimia Farma Tbk.** And **PT Indofarma Tbk.** As a subsidiary.



- Vaccines
- Anti sera
- Other life Science products



- OTC & Ethical
- Medical Services
- Retail



- Herbal
- Medical Devices



Distribution



Production



R&D



Export Distributions > 150 countries (polio vaccine: 2/3 global supply)

13 of Pharmaceutical manufacture (vaccines, drugs, herbal products, dan medical devices)

Largest distribution channel

Retail pharmacy network (1,262), clinic (600), dan diagnostic laboratory (62)

# Bio Farma in Brief



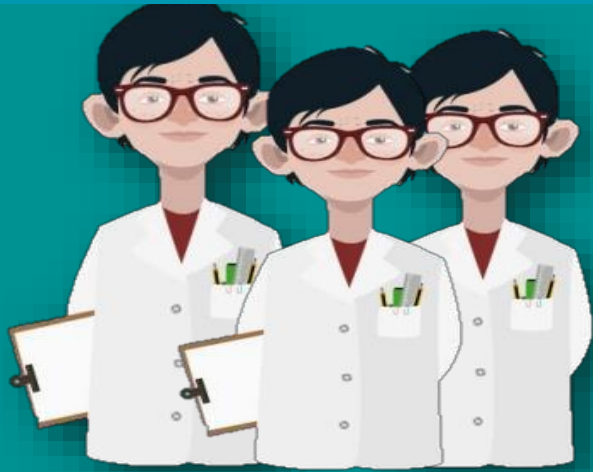
Established  
in Aug 6,  
1890



Moved to Bandung  
in 1923



State-owned Enterprise (100 %)  
Vaccines & Antisera manufacturer



1500 Employees



Implement Integrated System  
GMP, GLP, GCP, ISO9001, ISO14001,  
OHSAS18001, ISO 17025, ISO 27001 ERM, CSR  
Based ISO 26000



WHO pre-qualified Vac ( DTP,  
DT, TT, DTP-HB, m/b/tOPV,  
Measles and TT, HB in Uniject,  
Td, Pentabio~ 17 products)

# BIO FARMA CAPABILITIES

## PQ WHO Milestones of Vaccine Products

YEAR	VACCINE
1997	OPV, measles 10 ds
2001	DTP, DT, TT (vial)
2003	TT (Uniject)
2004	Hep B (Uniject)
2006	DTP-HepB, measles 20 ds
2009	mOPV1
2010	bOPV 20 ds
2011	Td
2014	DTP/Hb/Hib (Pentabio) 5ds, 10ds
2015	bOPV 10 ds
2019	mOPV2
2020	Novel OPV2 (WHO EUL)

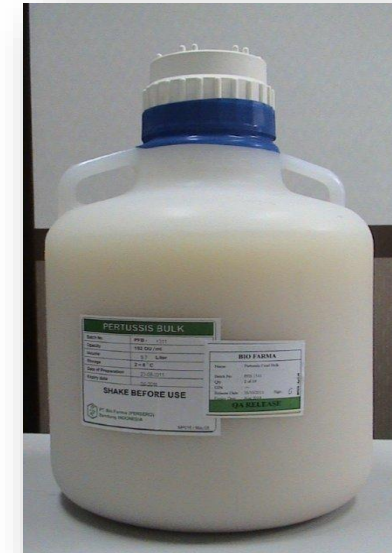
Others :

- SEASONAL FLU Vaccine (Flubio), BCG, sIPV,
- Antisera : Tetanus, Diphtheria, Snake Venom

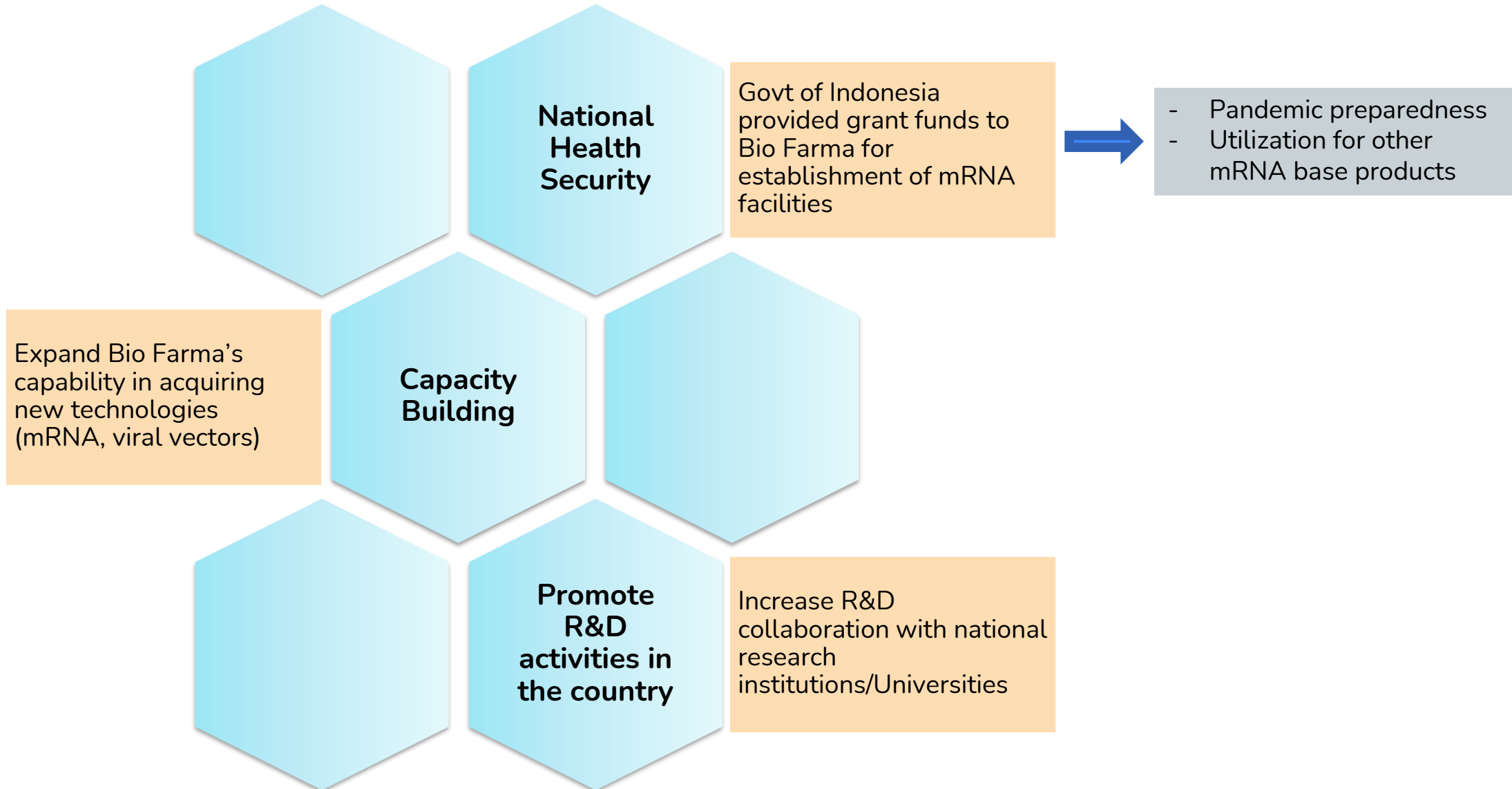


### API

1. Polio bulk
2. Measles bulk
3. Diphtheria bulk
4. Tetanus bulk
5. Pertussis bulk
6. Hib bulk



# National Strategy in mRNA base Vaccine development



# BIO FARMA CAPABILITIES

## Technology and Production Equipments

### List of existing acquired vaccine technology platforms:

1. Live attenuated: BCG, OPV, nOPV, Measles, rubella
2. Inactivated: Pertussis, Covid-19
3. Subunit toxoid: Tetanus, diphtheria
4. Subunit protein: influenza
5. Subunit recombinant protein: hepatitis B, Covid-19
6. Polysaccharide conjugate: Hib conjugate

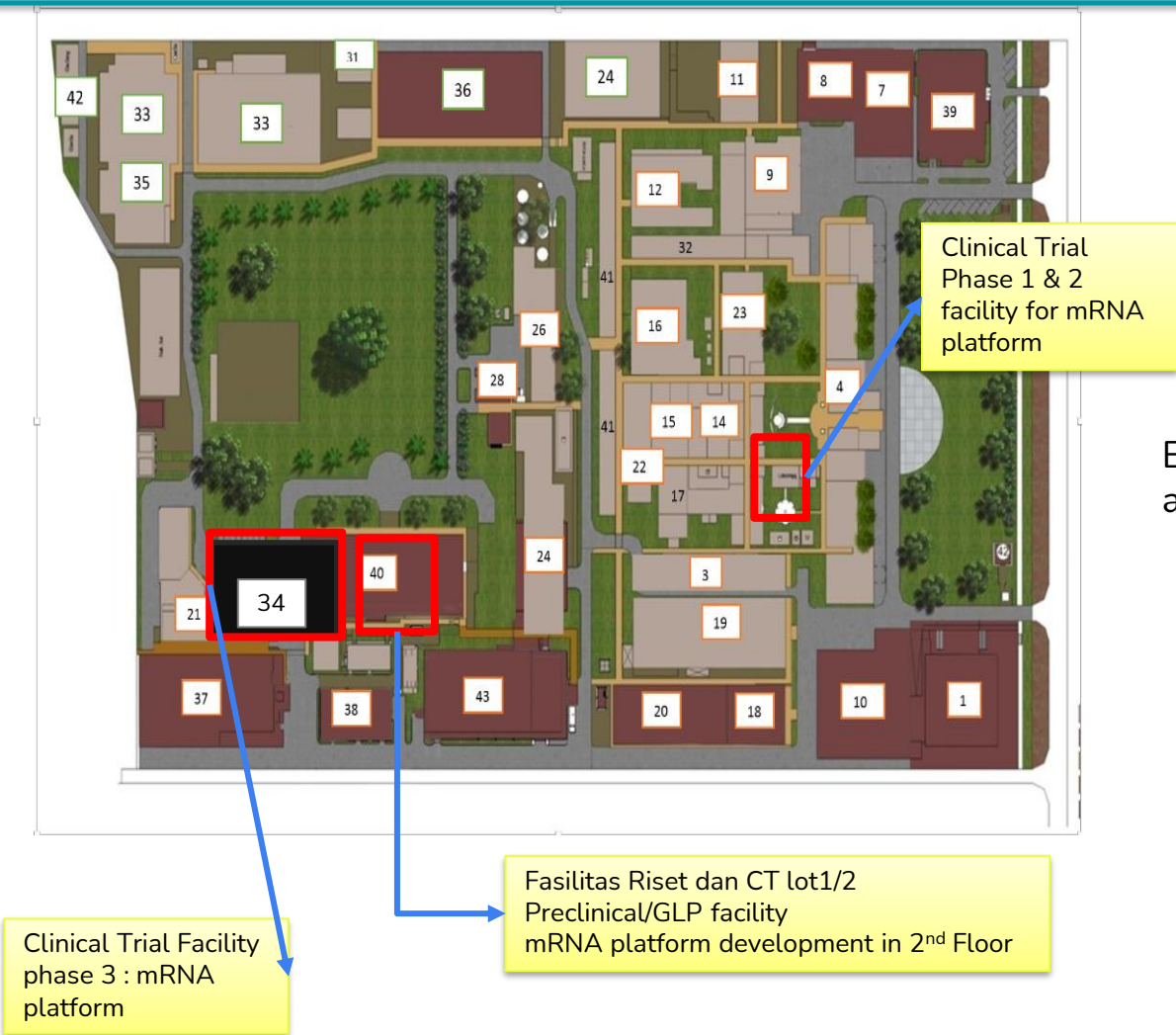
### List of vaccine technology platforms to be acquired:

1. mRNA
2. Viral vector  
(i.e adenovirus-based vaccine)



# BIO FARMA mRNA VACCINE PROGRAMME

## Construction of Facilities to Accommodate New Technology Platforms



**Government funding: Building No. 40 (mRNA research lab);  
Building No. 14 and 34 (pilot scale production facility)**



Building No.14: estimated completion by Q1 2024:  
adenovirus dan mRNA pilot Scale for Phase 1/2 IMP



Building No. 34: estimated completion by Q4 2024:  
6 floor with 5 Platform technologies for Pilot scale production of  
phase 3 IMP

# BIO FARMA mRNA VACCINE PROGRAMME

## Request for Access to Technology Transfer, Capacity Building & Raw Materials

Aspects	Requests
Access to technology	Access to know-how from mRNA vaccine developers/ vaccine Hub comprising of <ol style="list-style-type: none"><li>1. Vaccine seed</li><li>2. Production process</li><li>3. QC methodology</li><li>4. Formulation technology</li></ol>
Capacity Building	<ol style="list-style-type: none"><li>1. Training to acquire expertise in mRNA-based vaccine development</li><li>2. Regulatory oversight on mRNA vaccine</li></ol>
Raw Materials	Facilitate procurement of critical raw materials by transfer technology donor/ vaccine Hub*

Note: \*Bio Farma shall make efforts in securing supply through contractual agreement with relevant vendors

# BIO FARMA mRNA VACCINE PROGRAMME

## Partner Exploration in mRNA Vaccine Platform



Manchester University, UK

### Product pipeline :

- COVID-19 Vaccine
- mRNA Vaccine

### Collaboration Scheme:

Research collaboration for mRNA seed preparation

### Progress :

- MTA & Agreement already final
- On-going mRNA seed preparation for COVID-19



Afrigen, South Africa

### Product pipeline :

- COVID-19 Vaccine
- mRNA Vaccine

### Collaboration Scheme:

Bio Farma as Technology Transfer recipients from Afrigen as one of WHO spoke for mRNA in ASIA

### Progress :

- 6 BF researchers trained in Afrigen on April 2022 for basic research
- Agreement between MPP and BF for ToT in R n D Scale has been signed



BioNTech, Germany

### Product pipeline :

- COVID-19 Vaccine
- mRNA Oncology for solid tumors : BNT-151/152 (IL-2, IL-7), BNT142(CD3+CLDN6)

### Collaboration Scheme:

Technology Transfer of mRNA Vaccine focusing in mRNA for Oncology therapeutic and vaccine

### Progress :

- Awaiting business model partnership for new TB vaccine

# Intended applications for mRNA technology: Academy, business and government collaboration



## Government of Indonesia (Ministry of Health):

- **Indonesian Transformation on Health care System:** increasing resilience on drug, vaccine, and medical device sector
- Strategy for resilience in vaccine: **mastering technology of viral vector and nucleic acid-based**
- Vaccine: **14 antigens including in national immunization program**, where Government is ready to absorb local production as priority
- Government **funding for mRNA and adenovirus platform facility, and in purchasing vaccines (more than USD 2 bio per year)** for routine immunization and pandemic preparedness
- **Research funding scheme** in collaboration with Universities and research agency
- **Strengthening regional resilience** in partners with other ASEAN countries and IOs



## University of Indonesia:

- mRNA platform as part of the University R n D portfolio (sequence structure, formulation and adjuvant)
- Develop new technologies for delivery of mRNA
- Developmental Program: HIV, HPV, Malaria vaccines, immunomodulatory drugs



## Bio Farma

- Non–Clinical Development of mRNA candidate Vaccine
- Clinical Development of mRNA vaccine
- CMC, Licensure, Registration, and Commercialization

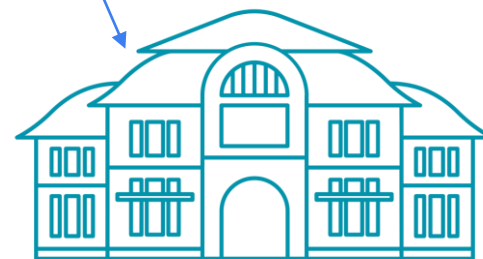
**mRNA vaccine for Dengue, Malaria, TB**

# BIO FARMA mRNA VACCINE PROGRAMME

## mRNA Technology Acquirements Progress

Aspect	Program	Partner
Technology for mRNA seed construction	Construction of Modified mRNA based on Delta SARS-CoV-2 (as model)	University of Manchester
Facility building for mRNA	Bio Farma currently: <ul style="list-style-type: none"> <li>a. Research Laboratory</li> <li>b. Pilot scale for phase I/II IMP</li> <li>c. Pilot scale for phase III IMP and limited commercial production</li> </ul>	Government of Indonesia
Technology production and QC	Technology training from WHO Technology Transfer Hub	Afrigen; Introduction packages; essentials for mRNA tech. establishment
Development of mRNA based vaccine	<u>Pandemic preparedness:</u> <ul style="list-style-type: none"> <li>- Development of new generation of mRNA vaccine (low COGS, thermostable)</li> </ul> Other product: <ul style="list-style-type: none"> <li>- Oncology</li> </ul>	<ul style="list-style-type: none"> <li>- Afrigen, WHO/MPP</li> <li>- University of Indonesia</li> <li>- IOs: CEPI</li> </ul>
Participation on CEPI global network in pandemic preparedness	Production facility establishment and capacity building for pandemic/outbreak	CEPI

# Thank You



Bio Farma