AN OVERVIEW OF BIO FARMA
Capability and Capacity in mRNA-based Vaccine Development

WHO/MPP mRNA Technology Transfer
April 2023
Officially formed by the Minister of SOEs on January 31st, 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

**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

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/OPV, Measles and TT, HB in Uniject, Td, Pentabio~ 17 products)

1500 Employees
## BIO FARMA CAPABILITIES
### PQ WHO Milestones of Vaccine Products

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

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

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National Strategy in mRNA base Vaccine development

Govt of Indonesia provided grant funds to Bio Farma for establishment of mRNA facilities

- Pandemic preparedness
- Utilization for other mRNA base products

Expand Bio Farma’s capability in acquiring new technologies (mRNA, viral vectors)

Promote R&D activities in the country

Increase R&D collaboration with national research institutions/Universities
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
6. Polysaccharide conjugate: Hib conjugate

List of vaccine technology platforms to be acquired:
1. mRNA
2. Viral vector (i.e. adenovirus-based vaccine)
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

Clinical Trial Facility phase 3: mRNA platform

Fasilitas Riset dan CT lot1/2 Preclinical/GLP facility mRNA platform development in 2nd Floor
# BIO FARMA mRNA VACCINE PROGRAMME

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

<table>
<thead>
<tr>
<th>Aspects</th>
<th>Requests</th>
</tr>
</thead>
</table>
| Access to technology | Access to know-how from mRNA vaccine developers/ vaccine Hub comprising of  
1. Vaccine seed  
2. Production process  
3. QC methodology  
4. Formulation technology |
| Capacity Building | 1. Training to acquire expertise in mRNA-based vaccine development  
2. Regulatory oversight on mRNA vaccine |
| 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*
<table>
<thead>
<tr>
<th>Product pipeline</th>
<th>Collaboration Scheme</th>
<th>Progress</th>
</tr>
</thead>
</table>
| • COVID-19 Vaccine  
• mRNA Vaccine | Research collaboration for mRNA seed preparation | • MTA & Agreement already final  
• On-going mRNA seed preparation for COVID-19 |

<table>
<thead>
<tr>
<th>Product pipeline</th>
<th>Collaboration Scheme</th>
<th>Progress</th>
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</table>
| • COVID-19 Vaccine  
• mRNA Vaccine | Bio Farma as Technology Transfer recipients from Afrigen as one of WHO spoke for mRNA in ASIA | • 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 |

<table>
<thead>
<tr>
<th>Product pipeline</th>
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<th>Progress</th>
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</thead>
</table>
| • COVID-19 Vaccine  
• mRNA Oncology for solid tumors : BNT-151/152 (IL-2, IL-7), BNT142(CD3+CLDN6) | Technology Transfer of mRNA Vaccine focusing in mRNA for Oncology therapeutic and vaccine | • 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

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Program</th>
<th>Partner</th>
</tr>
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<tbody>
<tr>
<td>Technology for mRNA seed construction</td>
<td>Construction of Modified mRNA based on Delta SARS-CoV-2 (as model)</td>
<td>University of Manchester</td>
</tr>
<tr>
<td>Facility building for mRNA</td>
<td>Bio Farma currently:</td>
<td>Government of Indonesia</td>
</tr>
<tr>
<td></td>
<td>a. Research Laboratory</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Pilot scale for phase I/II IMP</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Pilot scale for phase III IMP and limited commercial production</td>
<td></td>
</tr>
<tr>
<td>Technology production and QC</td>
<td>Technology training from WHO Technology Transfer Hub</td>
<td>Afrigen; Introduction packages; essentials</td>
</tr>
<tr>
<td></td>
<td></td>
<td>for mRNA tech. establishment</td>
</tr>
<tr>
<td>Development of mRNA based vaccine</td>
<td>Pandemic preparedness:</td>
<td>- Afrigen, WHO/MPP</td>
</tr>
<tr>
<td></td>
<td>a. Development of new generation of mRNA vaccine (low COGS, thermostable)</td>
<td>- University of Indonesia</td>
</tr>
<tr>
<td></td>
<td>Other product:</td>
<td>- IOs: CEPI</td>
</tr>
<tr>
<td></td>
<td>a. Oncology</td>
<td></td>
</tr>
<tr>
<td>Participation on CEPI global network in</td>
<td>Production facility establishment and capacity building for pandemic/outbreak</td>
<td>CEPI</td>
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<tr>
<td>pandemic preparedness</td>
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Thank You