Building Resilient Vaccine Ecosystem: From Regulatory Perspective

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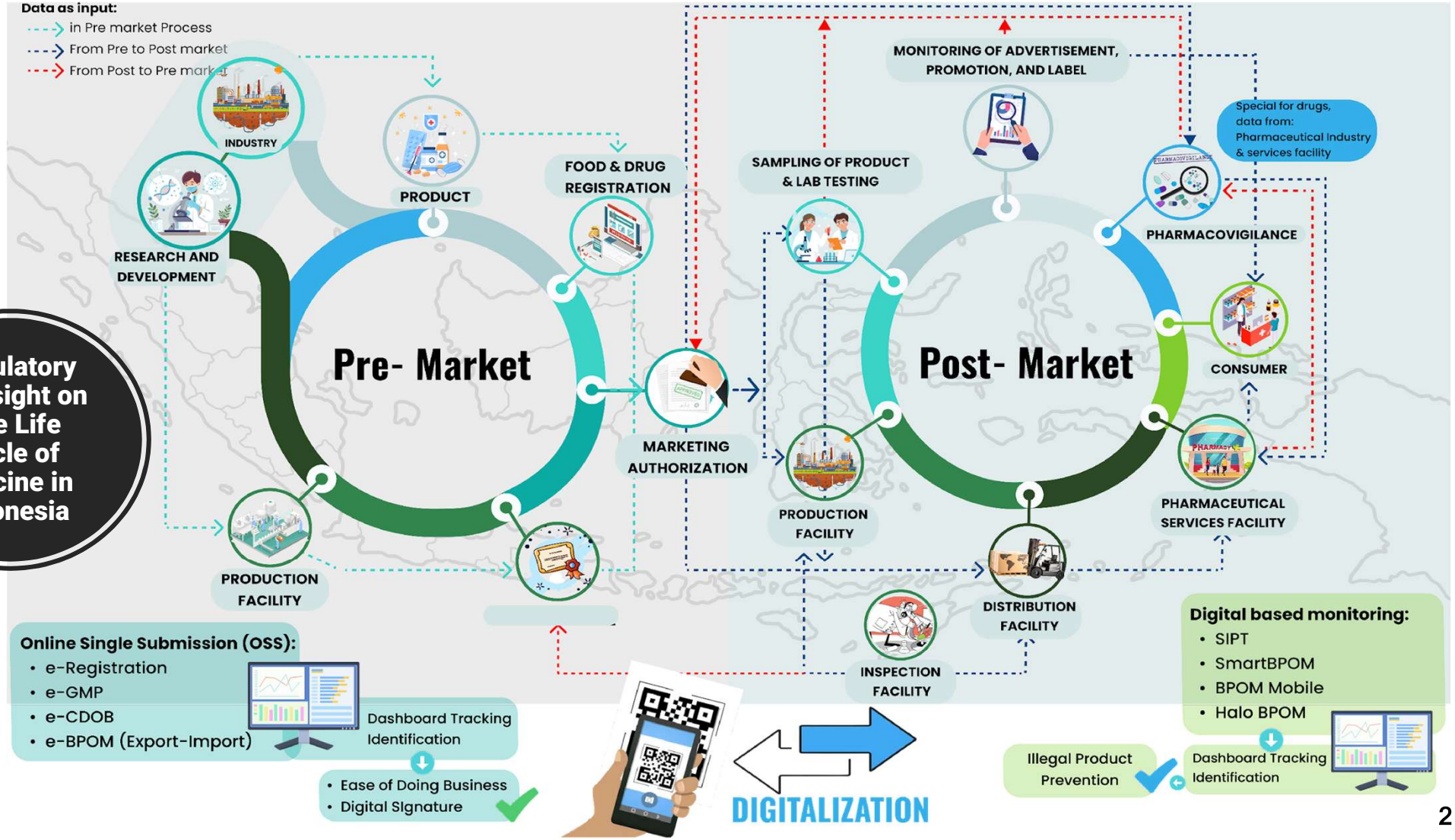
Regulatory Oversight on One Life Cycle of Vaccine in Indonesia



Harmonization of Regulatory Frameworks

- **Adopt international standards**
  (e.g., WHO, ICH, EMA, FDA, ASEAN)
- **Participate in reliance models,**
  with Europe, USA, UK, Australia, Canada, Japan, and Swiss as reference countries
- **Streamline regulatory reviews**
  via regional alliances **as BPOM's experiences in the joint assessment with WHO, EMA, and ASEAN countries**

Agility Regulation

BPOM is always establishing on agile and adaptive regulation in view of technological changes and global trends

Recent regulation highlights

BPOM Regulation No.8/2020 → replacement → BPOM Regulation No.14/2024

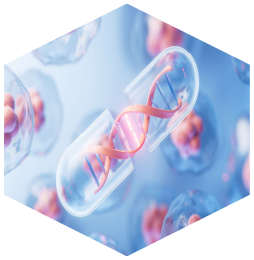
Control of Drugs and Food Distributed Online

BPOM Regulation No.7/2024 → revision → BPOM Regulation No.7/2025

Standards for Good Manufacturing Practice of Medicines

Head of BPOM Regulation No.24/2017 → 5 times revision → BPOM Regulation No.15/2019, No.27/2020, No.13/2021, No.15/2023, No.23/2025 → replacement in progress → 2025

Criteria and Procedures for Drug Registration



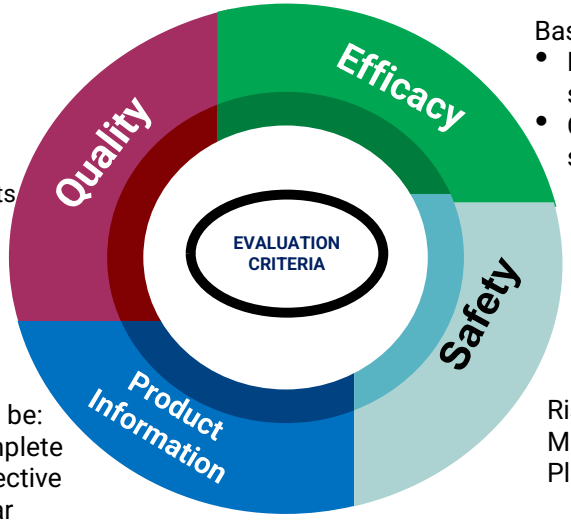
BPOM Regulation No.8/2025

Guideline for Assessment of Advanced Therapy Medicinal Products (ATMPs)

Marketing Authorization Vaccine Oversight

Medicines & Biologicals, including vaccine's Evaluation Criteria (Risk-Based Assessment)

Based on Quality data:
- Active ingredients
- Finished product
- Comply GMP



Based on:
- Nonclinical studies
- Clinical studies

Should be:
- complete
- Objective
- Clear

To ensure rational medicine

Risk Management Plan (RMP)

Public protection towards unexpected risk medicines by providing assurance on the quality, safety, and efficacy of medicinal product marketed in Indonesia.

Accelerated Pathway for Drug Registration

BPOM **support** the investment on providing **innovative drugs** in Indonesia, in order to promote the availability of innovative medicine in Indonesia

BPOM provides an Accelerated review process of new drugs through **100 Working Days** for:

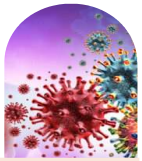
- Lifesaving Drug
- Orphan Drug in Indonesia
- **Drug intended for national health programs** equipped with supporting doc for program or result of PQ WHO
- IND developed with at least one clinical trial conducted in Indonesia
- First Registration of New Drugs by Pharmaceutical Companies investment in Indonesia

BPOM provides accelerate review process of new drug through **90 working days** for reliance to 7 reference countries

50 working days for **IND** by Pharmaceutical Companies Investment in Indonesia

Regulatory Support for Expediting Vaccine Access

Expedited Pathways for Emergency Use



Create **Emergency Use Authorization (EUA)** frameworks **(20 working days)**

Utilize **rolling submissions**

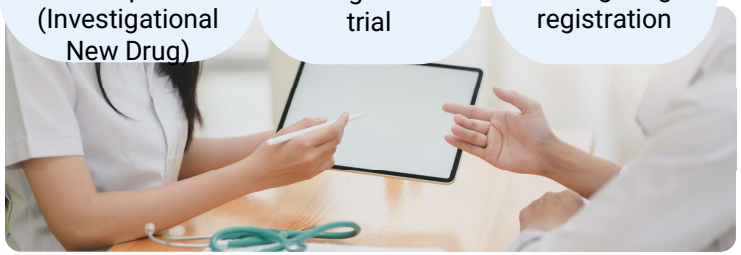
Support **adaptive clinical trial designs**

Regulatory Assistance for Drug Development

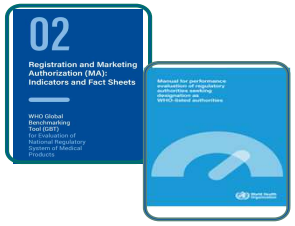
During drug development (Investigational New Drug)

During clinical trial

During drug registration



Toward WHO-Listed Authority



BPOM is now in progress to achieve **WHO-listed Authority (WLA)** status for vaccine from WHO

Benefits of BPOM as one of WHO-listed authority for vaccine industry:

- Strengthening global trust in Indonesian vaccine
- Increase the number of reference countries in reliance program
- Facilitating vaccine exports to global market
- Improving vaccine production and quality standards
- Strengthening industrial competitiveness and innovation
- Increasing investment and international cooperation in vaccine industry

Regulatory Support for Manufacturing

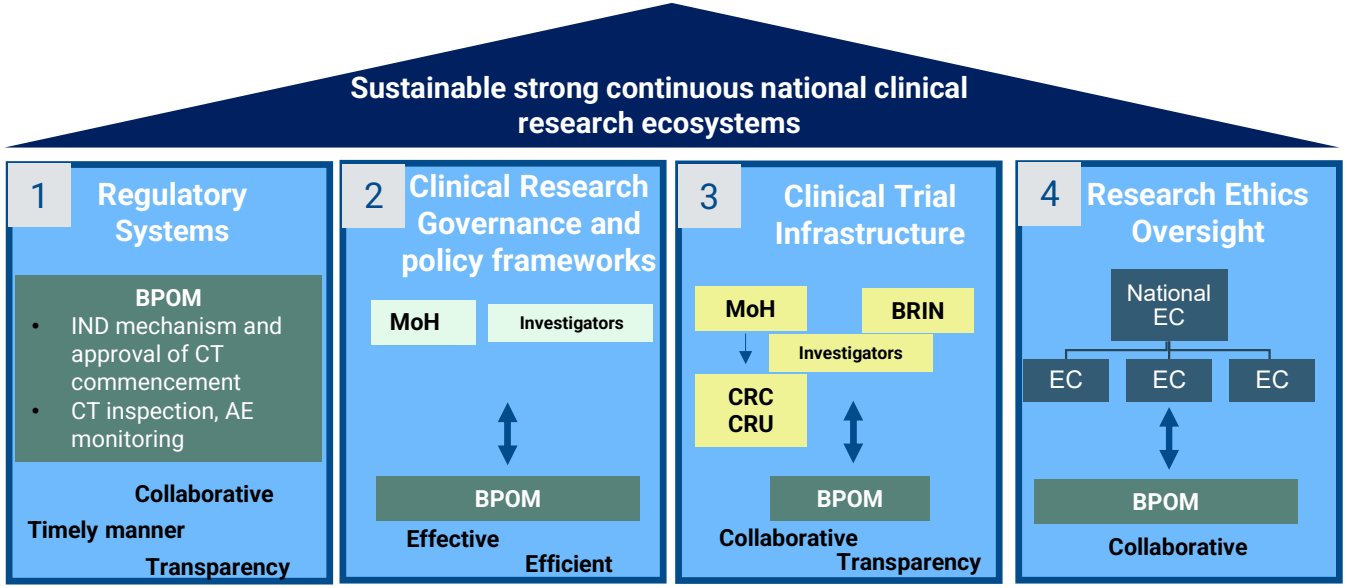
Expedite **site approvals** and **technology transfer reviews**

Fast-track GMP certifications for new manufacturing facilities

100 working days

Collaborative Governance and Oversight for Clinical Trial in Indonesia

1. BPOM performs digital business process
2. BPOM involves advisory committee
3. BPOM & MoH facilitate appropriate data sharing for transparency
4. BPOM uses WHO Global Benchmarking Tools (GBT) to improve CT function



Coordination with Ethics Committee

BPOM improves efficiency in regulatory authorities and ethics committees for oversight of clinical trials, to streamline procedures wherever possible and appropriate

Continuous strengthening through monitoring, evaluation and learning

BPOM conducts effective and efficient governance to maintain the scientific and ethical integrity of a trial and to ensure a risk-based proportionate approach

IND mechanism & approval of CT commencement, CT Inspection, AE Monitoring, Reliance mechanism

Collaboration with stakeholders to Enhance of Clinical Trial Infrastructure including Personnel

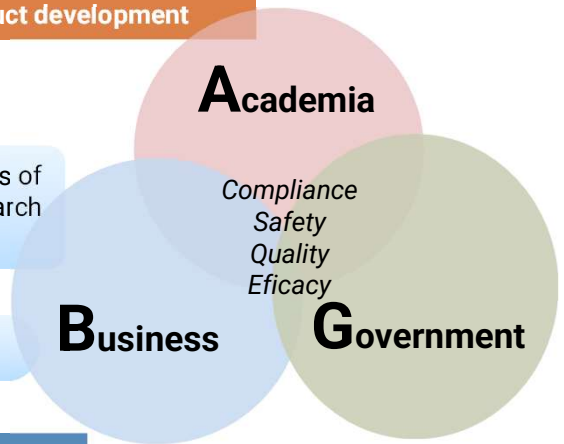
Agreement Between BPOM, the Ministry of Health, and National Research Agency to strengthen clinical trial infrastructure.

CT: Clinical Trial
AE: Adverse Event
EC: Ethics Committee
CRC: Clinical Research Center
CRU: Clinical Research Unit
MoH: Ministry of Health

ABG Collaboration and Successful Models of Collaboration in Indonesia

Triple Helix Collaboration in the Innovation Ecosystem

Innovation ecosystem: new product development



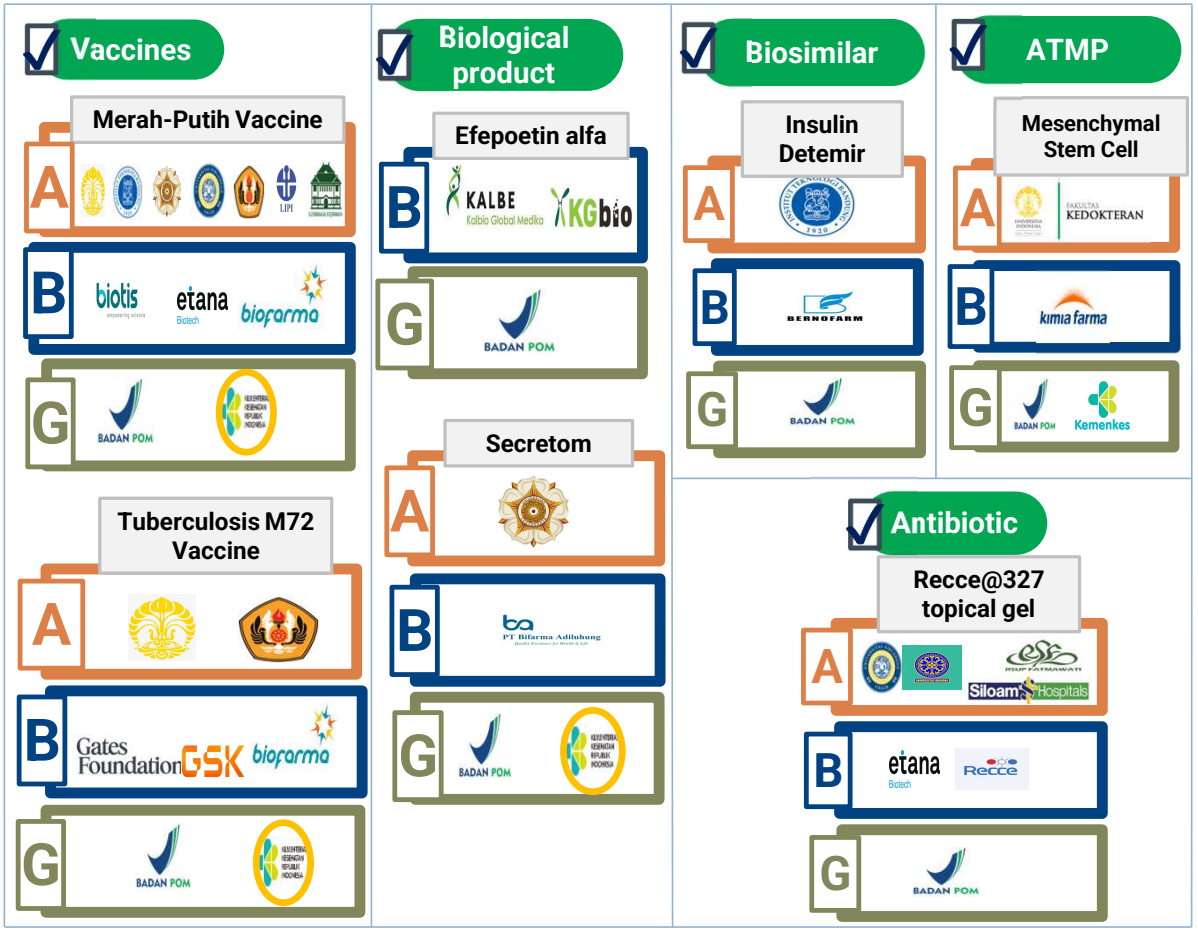
Downstream process of innovation and research results

Technology transfer

Support for upstream to downstream facilities and resources

Regulatory assistance from research to marketing authorization

Collaborate with Academia, Business Sector, and Other Government to support local production of Drug Development



Way Forward

- WLA achievement
- Strengthen Regulatory Reliance and Global Collaboration
- Enhance Regulatory Agility and Innovation Pathways
- Support Local Industry and Self-Reliance and Strengthen the ABG Collaboration
- Build Sustainable Capacity and Regulatory Excellence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