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Considerations for Technology Adoption and Regulations for NCDs and Mental Health:

Regulatory Experience from Indonesia

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Ministry of Health, Republic of Indonesia

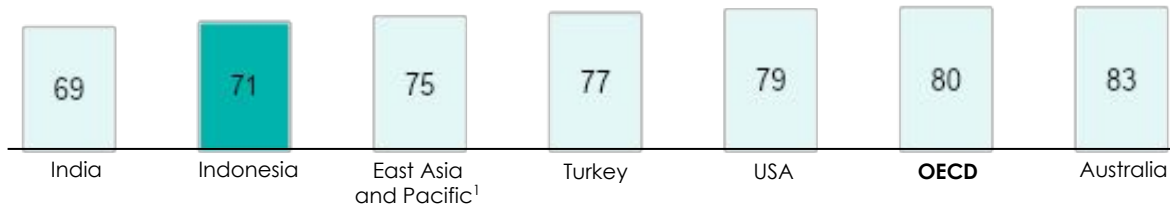
19th June 2024



- 1. Background**
2. Role of Regulators on Health Technology Adoptions
3. Initial result
4. Conclusion

We have persistent health challenges

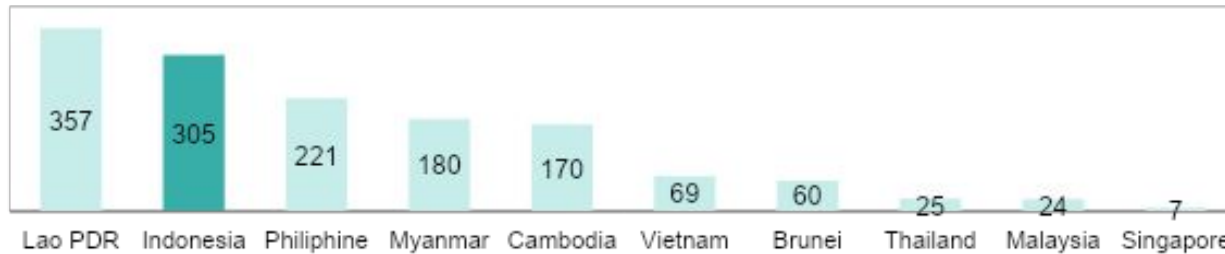
Life expectancy at birth (2018), year



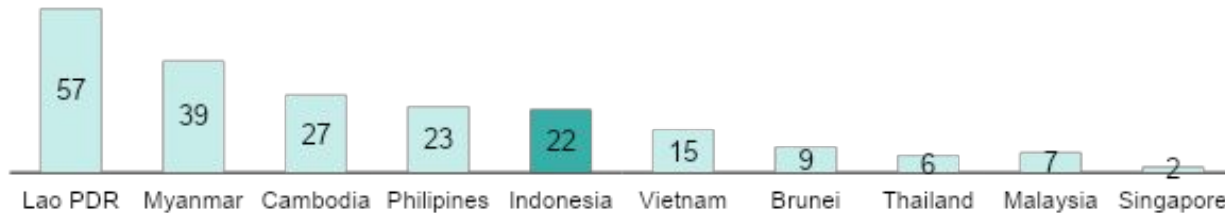
1. Including China, Malaysia, Myanmar, Philippines, Thailand, Vietnam, Papua new Guinea, East Timor, Pacific islands

Source: World Bank, WHO Global Health Observatory

Maternal mortality² (2015), per 100,000 live-births

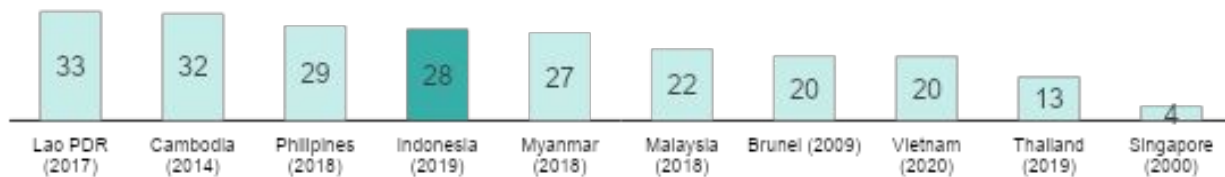


Infant mortality rate (2015)², per 1,000 live-births



2. ASEAN Statistical Report on Millennium Development Goals 2017 Jakarta, ASEAN Secretariat, August 2017

Stunting prevalence³, %



3. ASEAN Food and Nutrition Report 2021

In addition,

2nd

Highest **Tuberculosis** burden in the world

73%

of deaths are **contributed by NCDs**, higher than SEA average of 60%

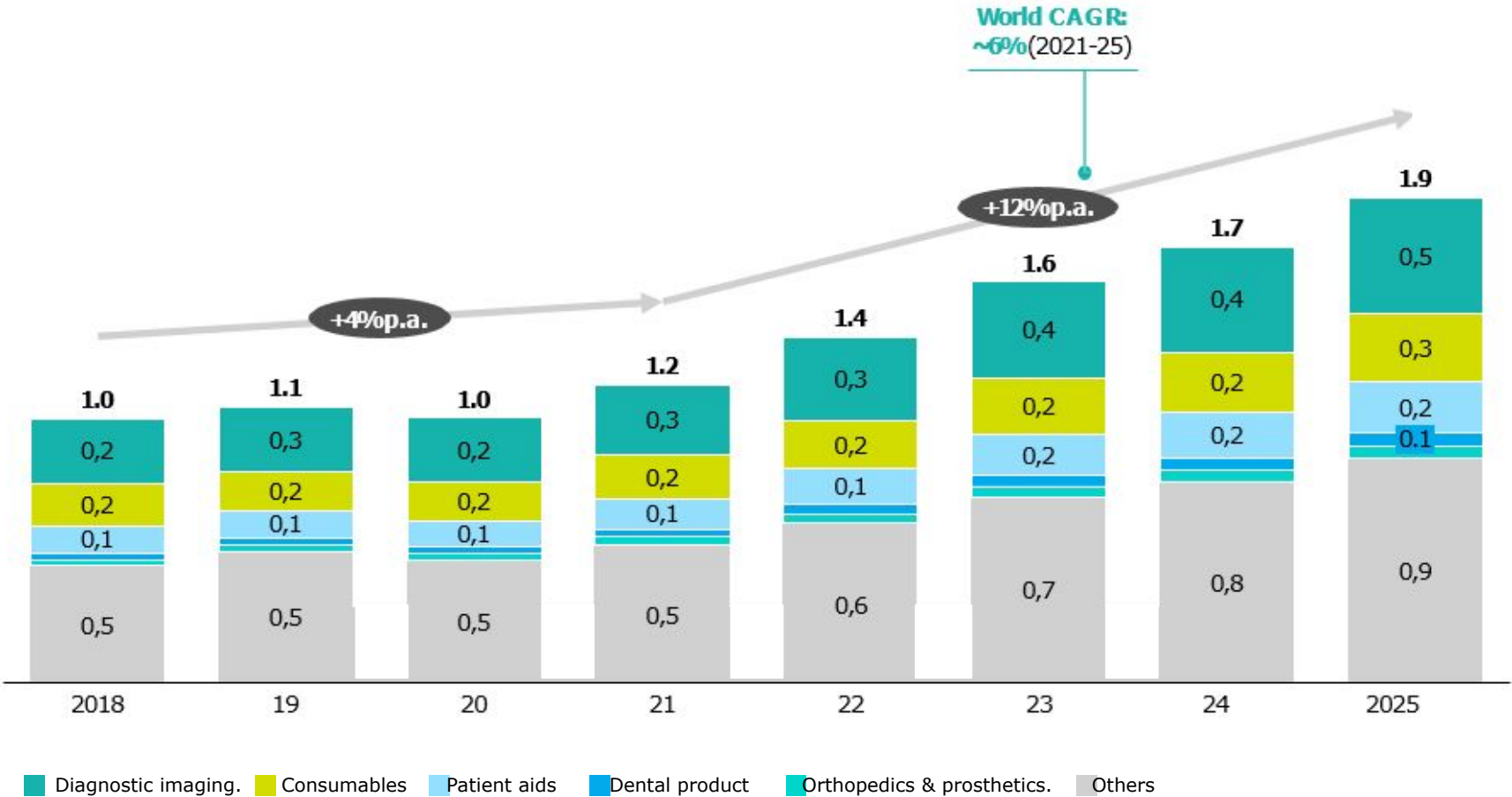
39%

of population **aged 15+ years are smoking** – highest prevalence of smoking amongst ASEAN

Indonesia medical devices opportunity is high, as our market growth is likely ~2x that of our peers

Indonesia's medical device market size, growth by segment 2015-25

USD bn



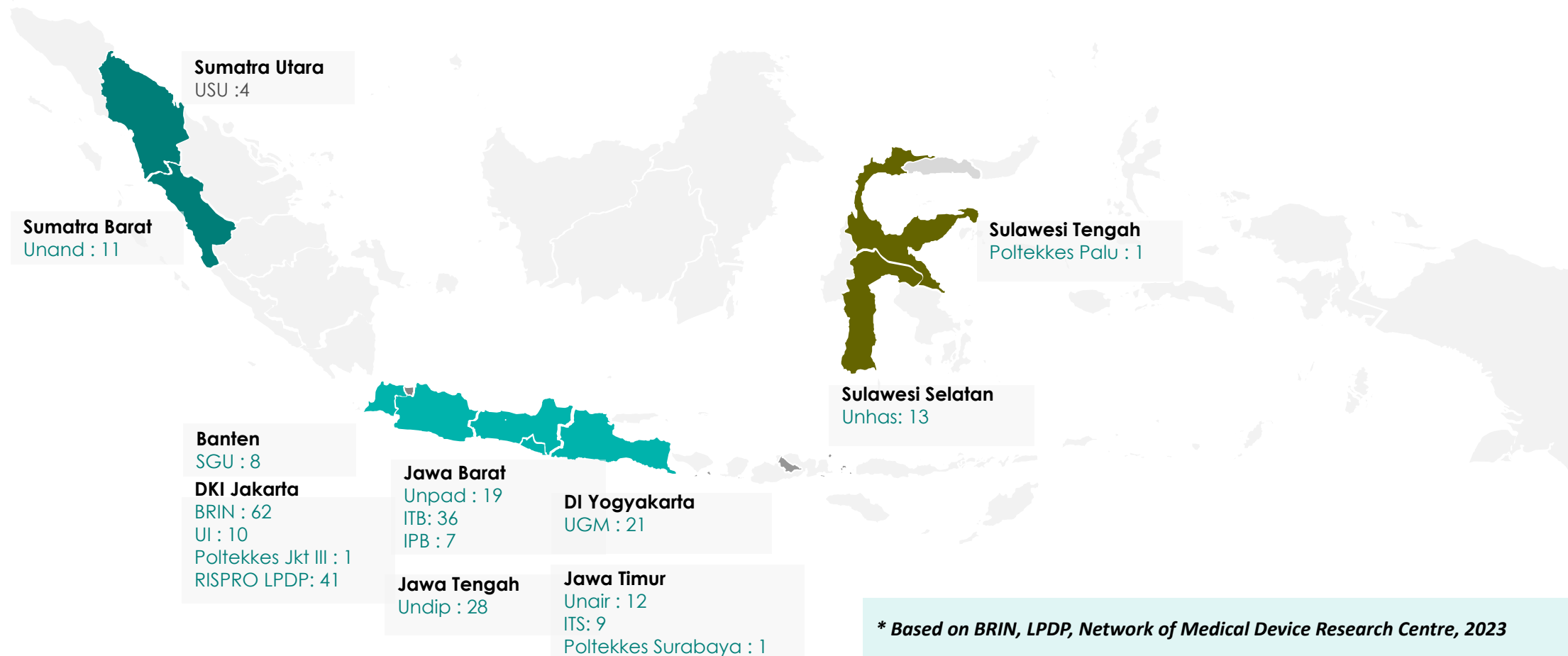
Key growth driver

- 1 Increasing # of insured population**
 ~87% population covered by national health insurance (~98% goal by 2024)
- 2 Expanding private providers**
 More private hospitals opening, though most in urban areas
- 3 Rising prevalence of chronic diseases**
 Stroke, heart, diabetes, and TB are main causes of death that requires continuous care

Source: Fitch solution, press search, expert interview

Medical device research are spread across Indonesia (2023)

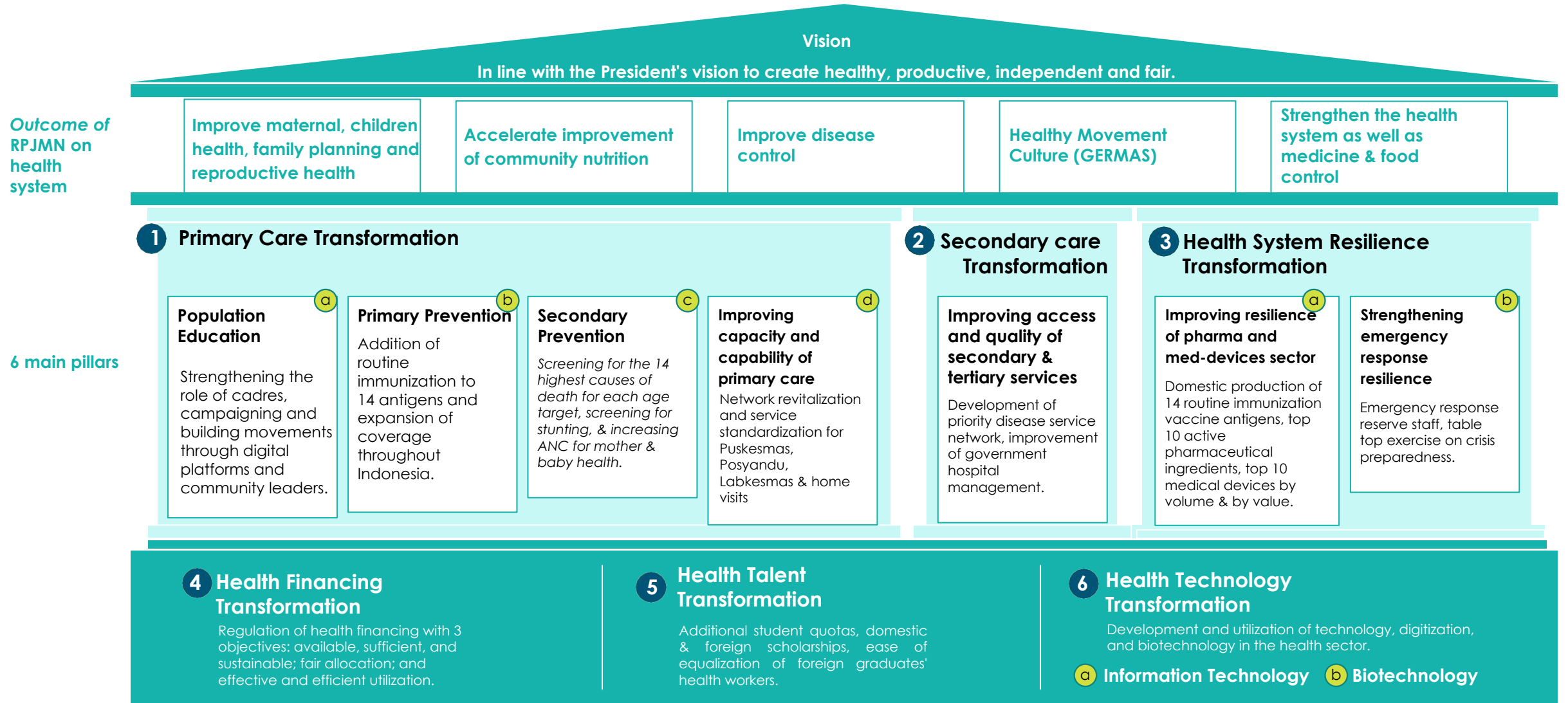
284 research by BRIN, LPDP, 12 education institution/university, and 3 health vocational school



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MoH is committed to implementing a **health system transformation**

The 6 pillars of transformation supporting the Indonesian health system



We strives for the **resilience of pharmaceuticals and medical devices** by end-to-end approach

Research and development



- **Task force** R&D ecosystem development
- **Technology transfer** facilitation
- Facilitate **clinical trial, including for medical devices**
- Facilitate the **change source** of active pharmaceutical ingredient
- Collaboration with stakeholders in **research networks**
- Facilitate the development of **innovative medical devices** and those for national health programs

Production



- **Intervention of incentives and disincentives** for the pharmaceutical
- **Simplification of licensing process**
- **Facilitate testing and calibration** performance and use of medical devices

Market Access



- **Substitution of imported products:** if it is a domestic product that can meet national needs, the imported product will be frozen.
- **Implementation of the Local Content (TKDN)** is the main choice in the procurement of goods and services, for drugs by prioritizing domestically produced raw materials, for medical equipment after the rules for calculating TKDN are determined
- **Implementation of increasing the use of domestic products (P3DN)**, especially in government, regional and private hospitals

Regulator: Provide policy related to **innovation and research** to strengthen health system

- **Health Law (new) established as a fundamental effort to strengthen national health system**, learning from past pandemic experience.
- **Health Law (new) designed as a means to uplift the national health system, closing the gaps with other countries**, through a leapfrogging policy and intervention.
- **Leapfrogging policy**: primary care integration, specialized medical doctors arrangement, pharma and medical device resilience, biotechnology, and digital health.
- **Pharma and medical device resilience**: access to innovative medicines & medical devices, local production, **research and development**, and integrated management of supply chain.



The Draft Health Law was passed at the Legislative Plenary Session on July 11, 2023, and was signed by the President of the Republic of Indonesia on August 8, 2023, as Law No. 17 of 2023 concerning Health.

Regulation on **Medical Device** in Indonesia

Indonesia Medical Device Regulation Based on Regional and Global Practices:



ASEAN Medical Device Committee (AMDC)
AMDC TC chair 2015-2021

RISK CLASSIFICATION



AMDD

In Minister of Health Regulation Number 62, 2017

Law No. 17 of 2023 on Health

1

Government Regulation No. 5/2021

Implementation of Risk-Based Business Licensing

2

Regulation MoH No. 14/2021

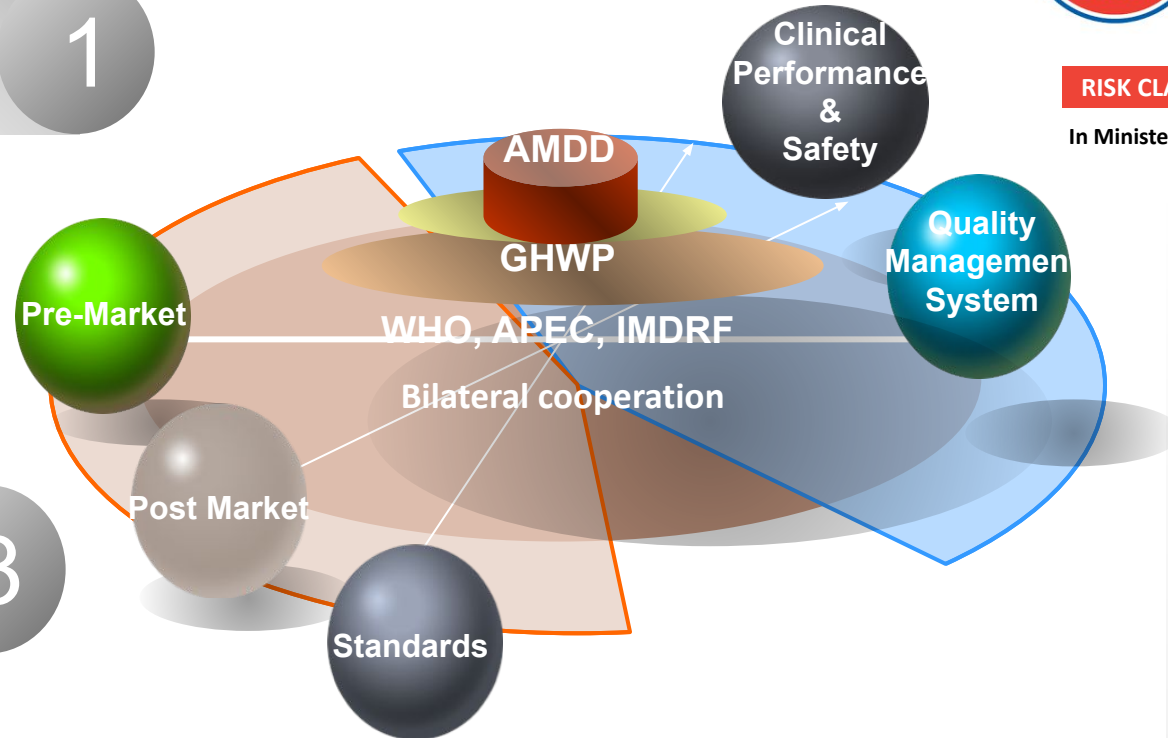
Standards for Business Activities and Products in the Implementation of Risk-Based Business Licensing in the Health Sector

3

Regulation MoH No. 62/2017

Product License of Medical Devices, In Vitro Diagnostic Medical Devices and Household Health Products

4



Asia-Pacific Economic Cooperation

Priority Working Area: Medical Devices



World Health Organization

Working Group 5: Medical Device and IVD



SOUTH-EAST ASIA REGULATORY NETWORK



GHWP

Working Group 5: Clinical evidence for performance and safety



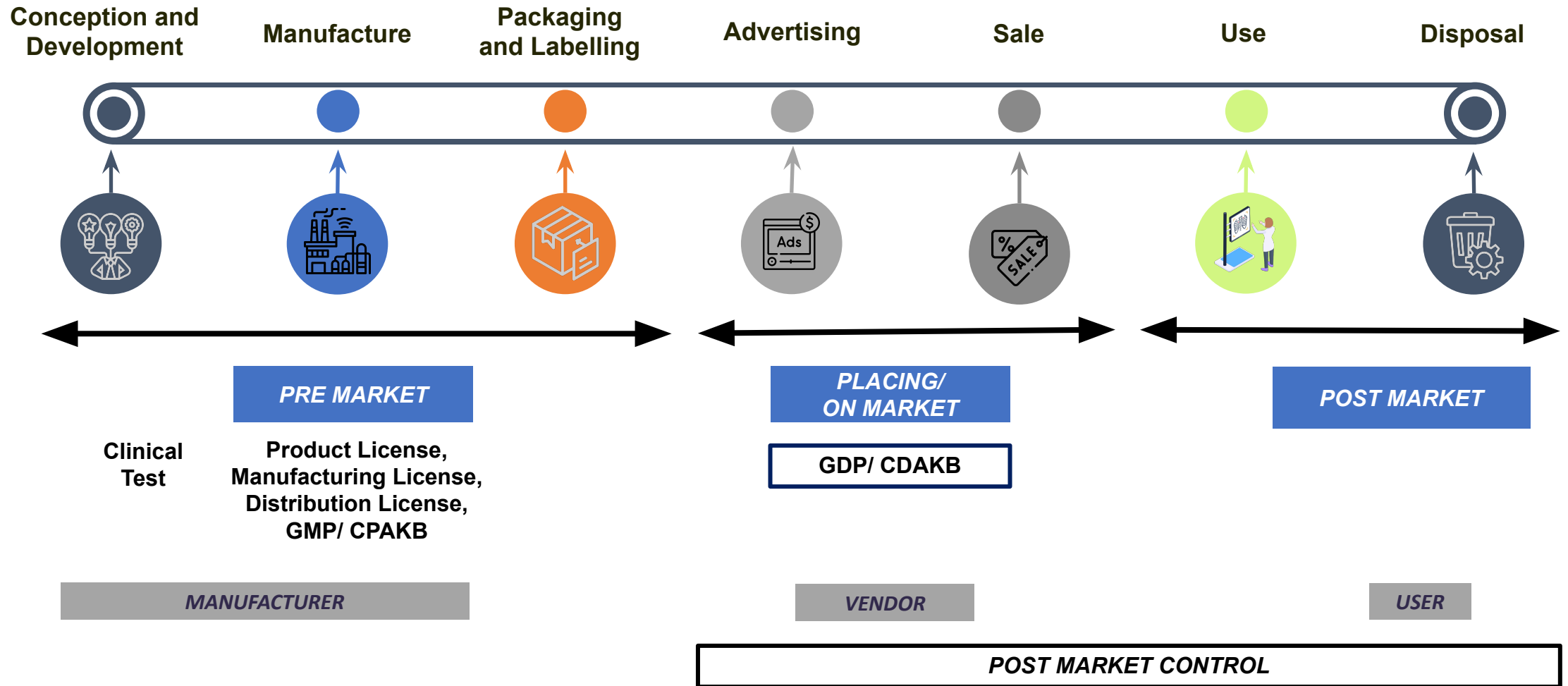
ASEAN MEDICAL DEVICE DIRECTIVE



Indonesia has ratified ASEAN MEDICAL DEVICE DIRECTIVE (AMDD) in 2018, 10 ASEAN Member states has harmonized their MD regulation

Medical Device Life-cycle

Technology developers should consider **an integrative approach** to develop the products



Quality Management System

Another consideration for technology developers



Medical Devices Industry

- Mandatory to implement Good Manufacturing Practice MD Guidance, which develop by MOH adopted from ISO 13485:2016
- A technical responsible person who already has GMP-MD training certificate
- MoH Regulation No. 20 Year 2017 regarding GMP-MD Guidance
- MoH Regulation No. 14 Year 2021

Medical Devices Distributor

- Mandatory to implement Good Distribution Practice MD Guidance
- A technical responsible person who already has GDP-MD training certificate
- MoH Regulation No. 4 Year 2014 regarding GDP-MD Guidance
- MoH Regulation No. 14 Year 2021



The certification process (including audit) is conducted by MoH

<https://sertifikasialkes.kemkes.go.id>

Directorate for Medical Device Control

MoH is also in charge of **product registration**

<https://regalkes.kemkes.go.id/>

Directorate for Medical Device Production & Distribution

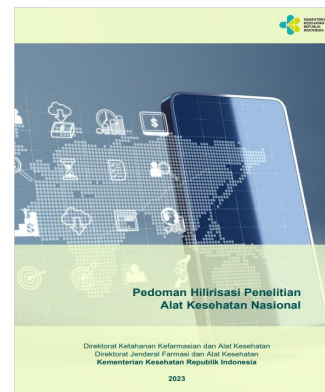
Regulator: **Support** MD research

1. MD resulted from research-support

- a. Continuous ventilator
- b. *Open System* PCR for TB Diagnostic Kit
- c. *Open System* PCR for HPV Diagnostic Kit
- d. Heart and Vascular Non-invasive Screening Device Skrinig
- e. Nanocrystalline HA Bone Graft
- f. Physical Diagnostic Device of Electromyography

2. National Guidance: Downstreaming MD Research

A guidance for medical device (MD) researcher/inventors on developing their projects, to optimize the capacity of research and to minimize the risk on falling to valley of death.



Capacity building on MD Clinical Trials
Jakarta, Juli 2023



Exhibition of MD Research from Universities
Solo, Juli 2023



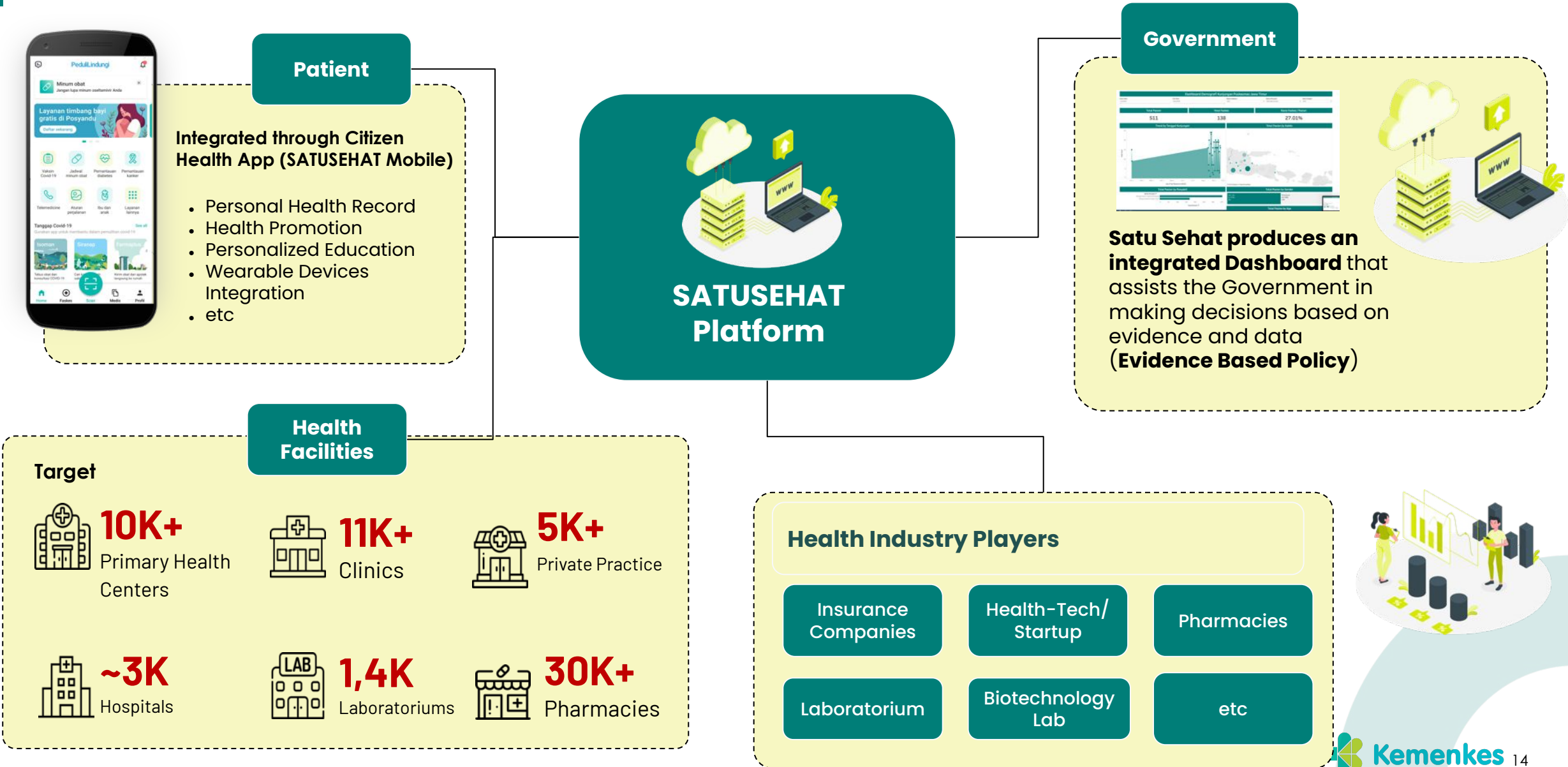
Match-making
Researchers and Industry
1.Semarang, Agustus 2023
2.Surabaya, September 2023



Capacity Building on
Clinical Evaluation Report (CER)
Jakarta, Desember 2023

SATUSEHAT Platform creates an **integrated health service**

Health data integration in all health facilities in Indonesia



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Local production of MD is developed

Through research and technology adoption

Collaboration on **innovative research** had resulted:

1. Electromedic medical device

- a. **Universitas Gadjah Mada**
 - Ventilator ICU (V-01)
- b. **Institut Teknologi Bandung**
 - Ventilator CPAP and HFNC
- c. **Universitas Diponegoro-GAKESLAB**
 - EKG

2. IVD

- a. **Universitas Padjadjaran**
 - Rapid test antigen (Deteksi CePAD)
 - TB detection kit (INDIGEN)
- b. **Universitas Indonesia**
 - IVD Dengue
 - Swab stick
- c. **Institut Teknologi Sepuluh November - GAKESLAB**
 - Non-invasive blood glucose measurement (IGLUCCO)
 - Non-invasive cholesterol measurement (ICHOL)

Collaboration on **research funding** had resulted:



Dengue Rapid Test
UGM - PT Konimex



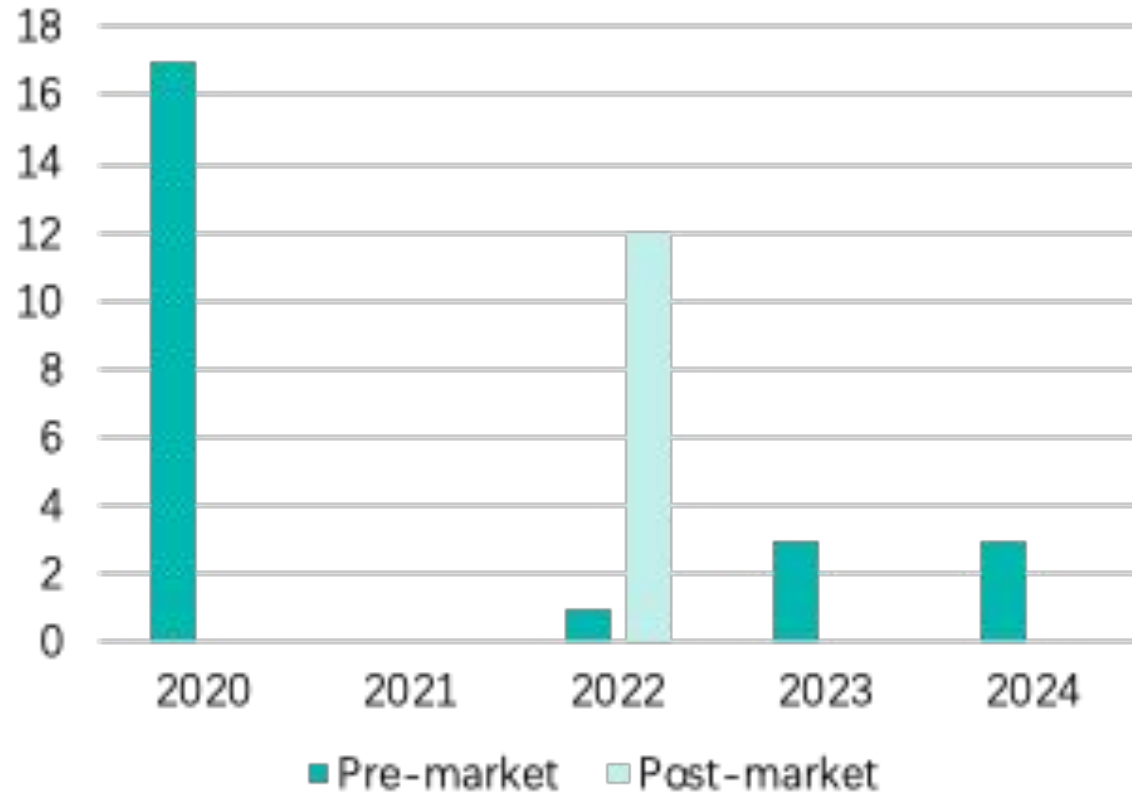
Rapid Test Autoimmune Thyroid Disease
Universitas Brawijaya – PT Biofarma



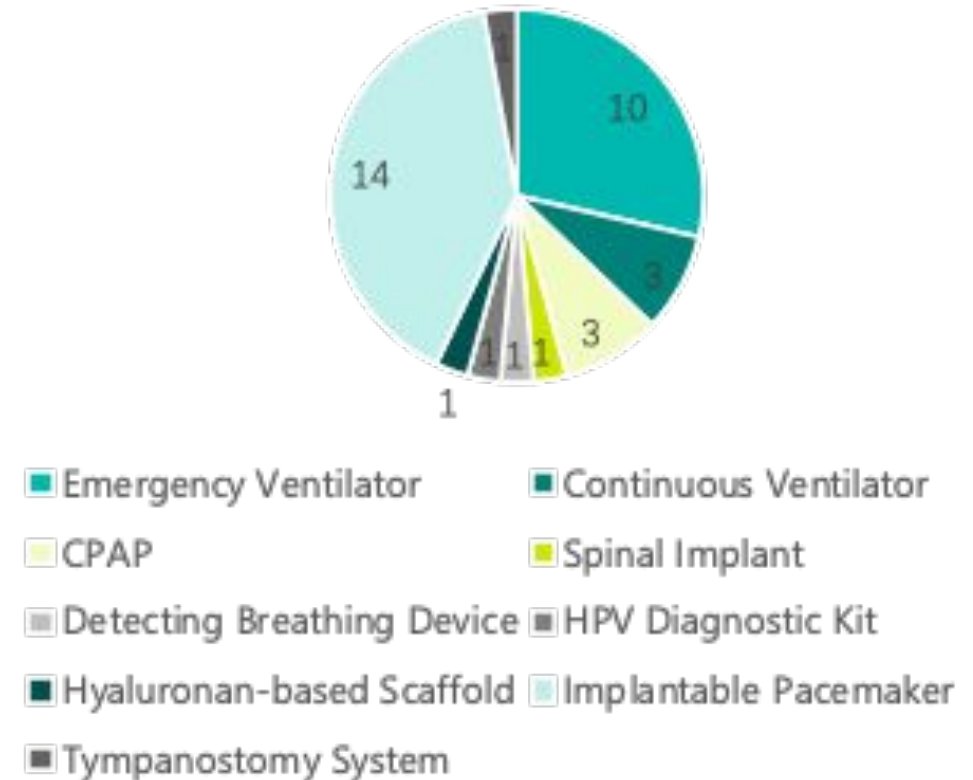
THEIA L450
ITB - PT Eida Sarana Informatika

Since the last 3 years, **clinical trials of medical devices** have been increased in Indonesia

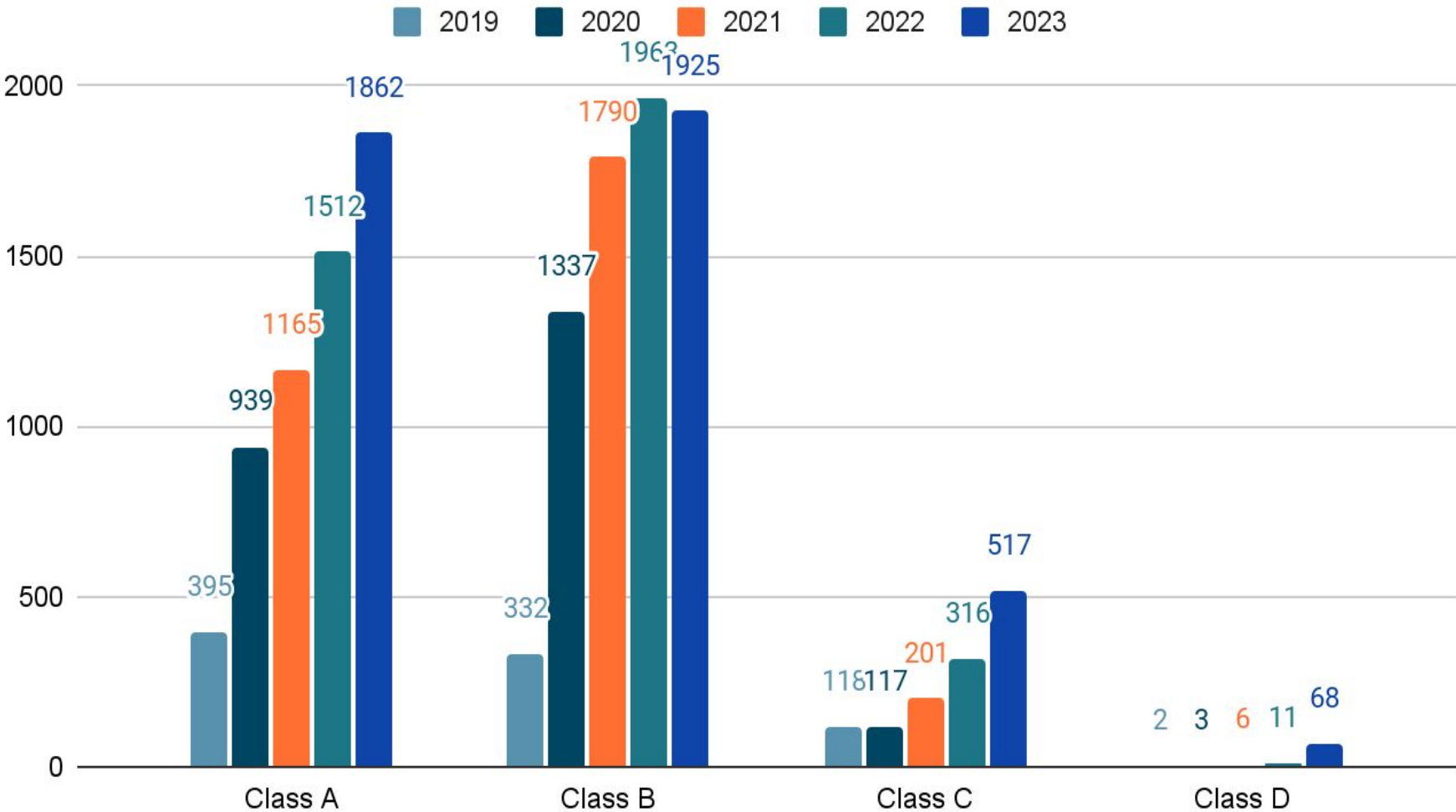
Regulatory Approval



Type of MD



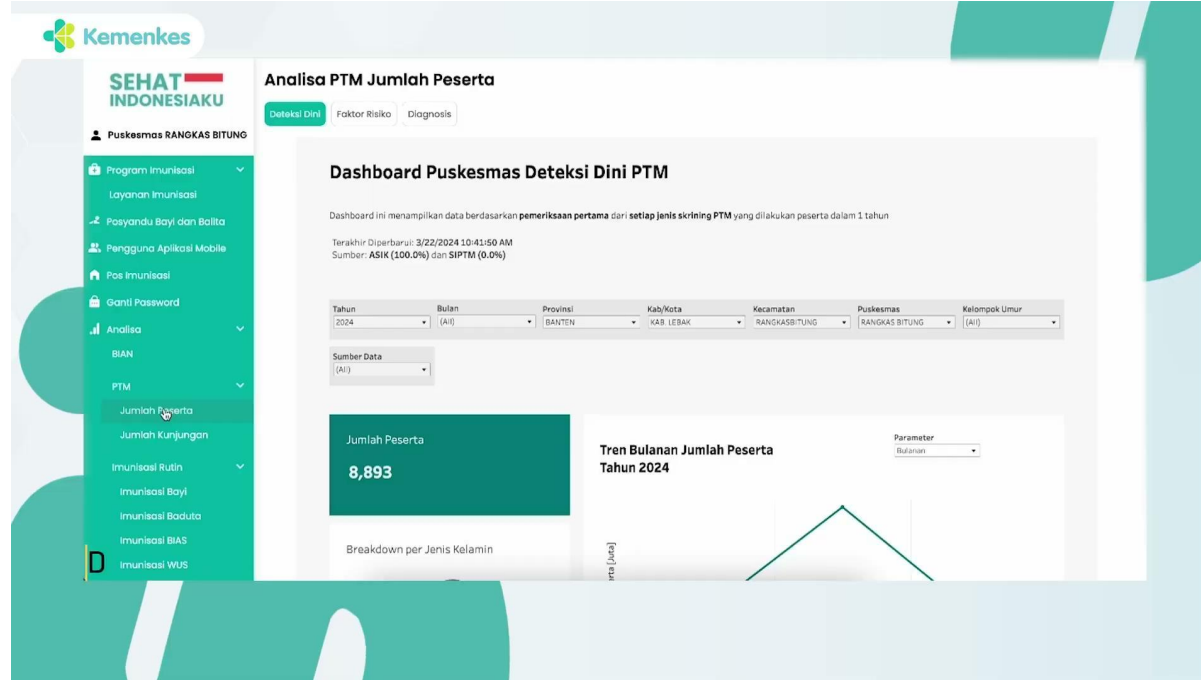
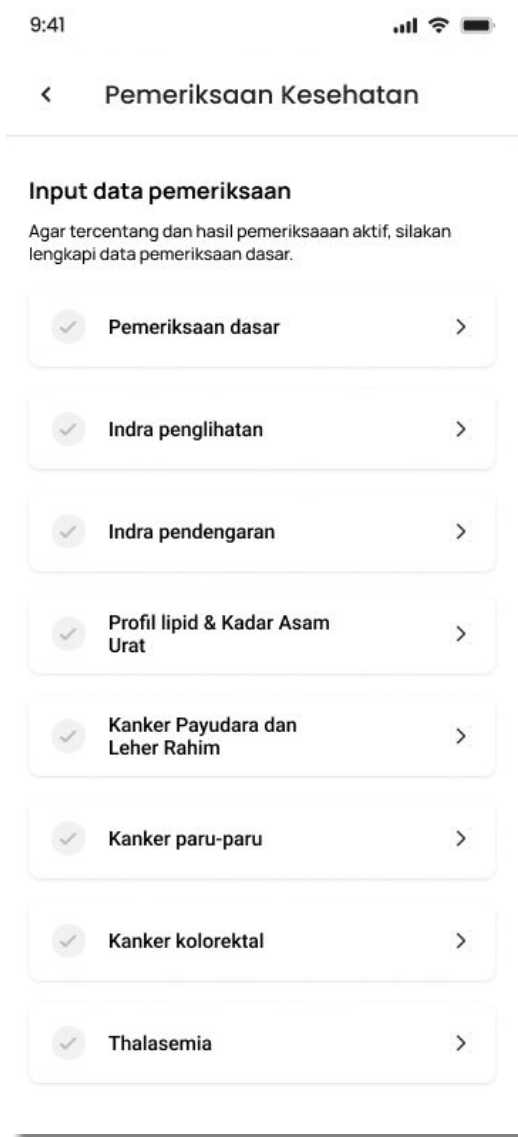
Indonesia capacity in manufacturing medical devices is also increased



Local production capacity for medium-high tech products is increasing rapidly.

Class A: low risk
Class B: low moderate risk
Class C: moderate high risk
Class D: high risk

Digitalization Non-Communicable Disease Screening: SatuSehat Mobile



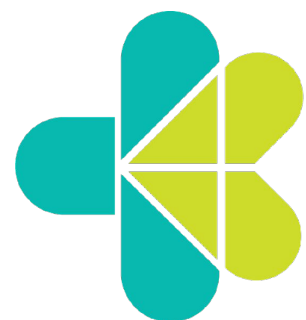
Non-communicable disease screening has been collected using ASIK mobile app. By having sufficient internet connection, digital data reporting can be sent into Satu Sehat and presented in an integrated analytic dashboard. Indonesian citizen now can monitor their NCD status in Satu Sehat Mobile.



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To conclude,

1. Ministry of Health executed its role as a regulator by **transforming national health system**, to achieve one of its mission, health resilience including on medical devices.
2. **A clear role o regulators** - setting the policy, provide support and assistance, strengthen research ecosystem- **on medical device research and innovation, should combine with stakeholders participation**, toward the orientation of fulfilling the safety-quality-performance of medical device.
3. This role should be executed **on adaptive and agile manner**, to narrowing the gap, so the research-resulted products may provide a wide benefit to fulfil the healthcare need and to build health resilience.



Kemenkes

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