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AI-based Medical Devices Integration to Support the Health Technology Transformation

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Health System and Data Challenges

Petabytes of Health Data produced everyday

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270 Million Indonesian people with both digital and paper based medical data

More than 60,000 health facilities produce health data both digital and paper based

400+ health app/system owned by center government and local government

Health data from **medical devices and IoT devices** are **not integrated and scattered**

1. Huge amount of health data produced everyday/ everytime
2. **Unstandardized** and **scattered** health data
3. **Overlapping** and **redundant** data production / collection across system/app
4. **Lack of integration and interoperability** of health data on National scale
5. **Data driven** health policies isn't fully implemented yet

Ministry of Health is committed to Health System Transformation

6 pillars of transformation to support Indonesia's health

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Vision
In line with the President's vision to create a healthy, productive, independent and equitable Indonesian health society

Outcome RPJMN* in health sector

- Improving maternal, child, family planning and reproductive health
- Accelerate the improvement of community nutrition
- Improve Disease control
- Healthy Living Community Movement (GERMAS)
- Strengthening health system & drug and food control

6 main category

1 Primary services transformation

- a Health Education
- b Primary Prevention
- c Secondary Prevention
- d Primary services's capacity and capability improvement

2 Secondary services transformation

- Secondary & tertiary access and quality improvement

3 Health security system transformation

- a Improving Pharmaceutical & medical equipment sector resilience
- b Strengthening of lab-based surveillance and resilience of emergency response

4 Health financing system transformation

5 Health Human Capital Transformation

6 Health-tech transformation

- a Health Tech
- b Biotech

*National Mid Term Development Plan

Digital Transform Towards Future Health Services

We Aim for 'from-Birth-to-Death' Seamless Integrated Health Services

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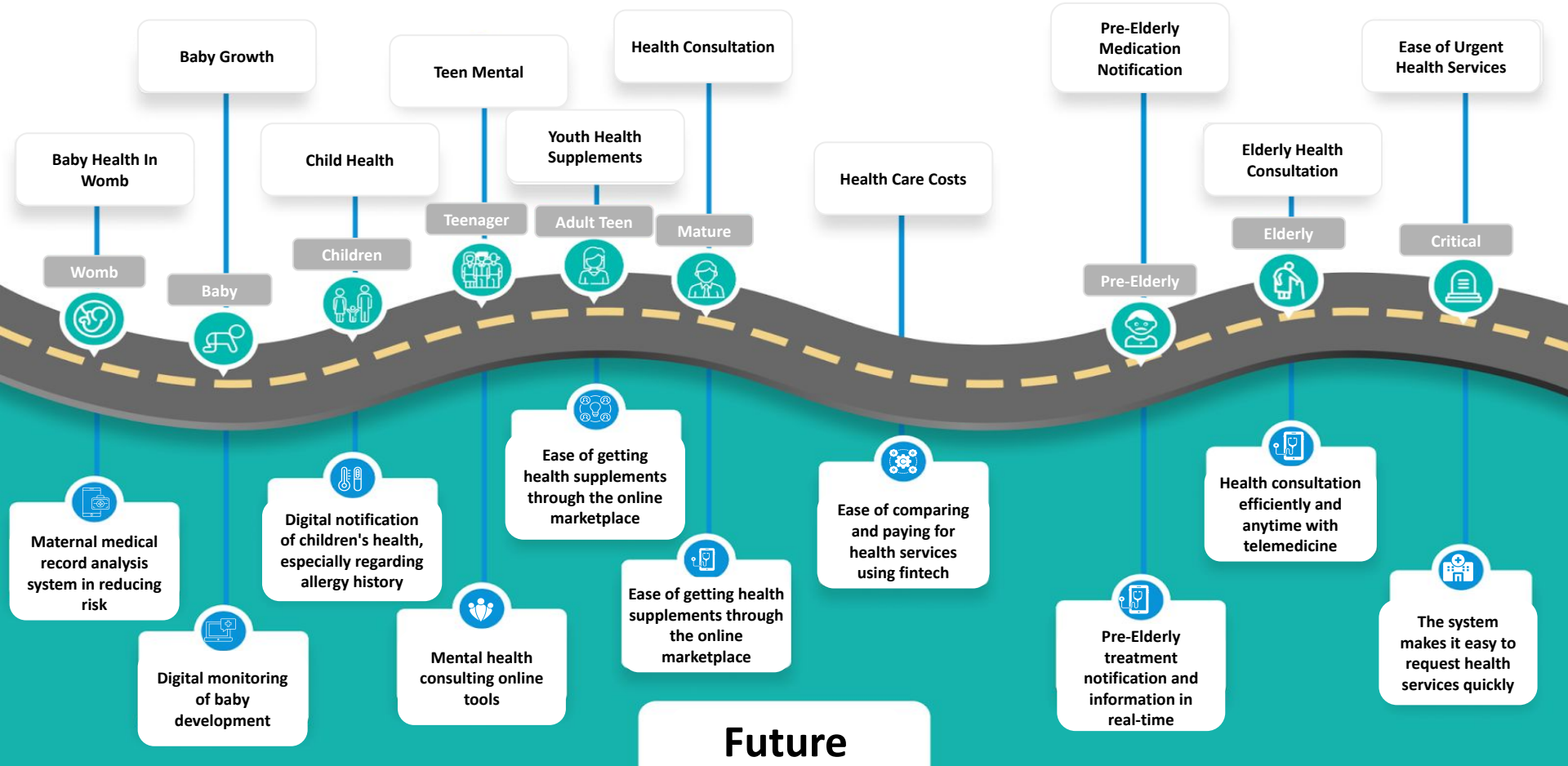

Health Digital Transformation Roadmap

Focusing on improving the data quality and encouraging the digital health ecosystem

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Priority Activities	2021	2022	2023	2024
Integration and Development Health Data	Health data **architecture design**	Development of a **single-health identity**-based big data system	**Implementation of an AI-based** health analysis system	Expanded coverage of **single-health identity**
Integration and Development Application System	Health system **interoperability** architecture design	**Integrated** health facilities information system development	**Implementation of integrated** health facilities information system	**Expanding the scope of the integrated** health facilities information system
Ecosystem Development Health Technology	Health information system **infrastructure and security assessment**	**Expansion of telemedicine** supporting infrastructure	AI, Blockchain & IOT-based **Regulatory Sandbox Implementation**	Health technology innovation **licensing expansion**

The focus in 2022 is **system development from architectural design** already made in 2021

SatuSehat Platform (Indonesia Health Services)

National Health Big Data Platform : Enhancing Services Through **Integrate** & **Standardize**

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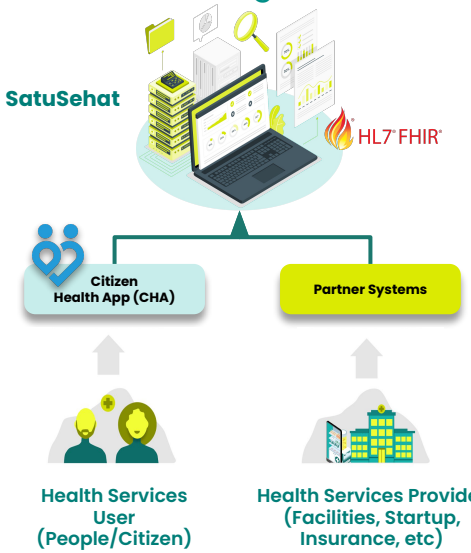

SatuSehat ensure **data interoperability of the entire ecosystem of healthcare industry** so it can be used more widely for the better outcome

Provide standardized specifications and mechanisms for business processes, data, technical and security

10,260
Puskesmas*

11,347
Clinics

2,985
Hospitals

5,862
GP & Dentist Clinics

1,400
Laboratoriums

30,199
Pharmacies

Sumber : MoH RI

Home > National

Health Ministry Launches Integrated Health Data Platform SATUSEHAT

Translator: Dewi Elvia Muthiariny
Editor: Petir Garda Bhwana

27 July 2022 09:36 WIB

41
Hospitals
Alpha Testing

31
Health Companies
Beta Testing

*Micro Level Citizen Health Center

Integration and Benefits Architecture of SatuSehat

Collaboration : SatuSehat connect everyone to benefit everyone

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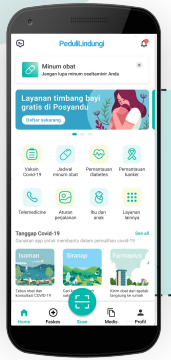


Patient/User

- Personal Health Record
- Health Promotion
- Personalized Education
- Wearable Devices Integration
- etc

Health Facilities

Integrated EMR.
Precise and coherent patients' medical treatment record across any facilities can be used to support more comprehensive clinical decision

Efficient data input due to integrated system allow medical personnel to put more focus on services than data input and administrative stuff

HL7® FHIR®

SatuSehat

- FHIR API
- Terminology Server
- Master Data
- Developer Hub

Government

Integrated dashboard for evidence based policy and data driven decision-making

Precise and Up-to-date information for detecting, predicting, prescription any health problem and support health resilience system

Health Industry

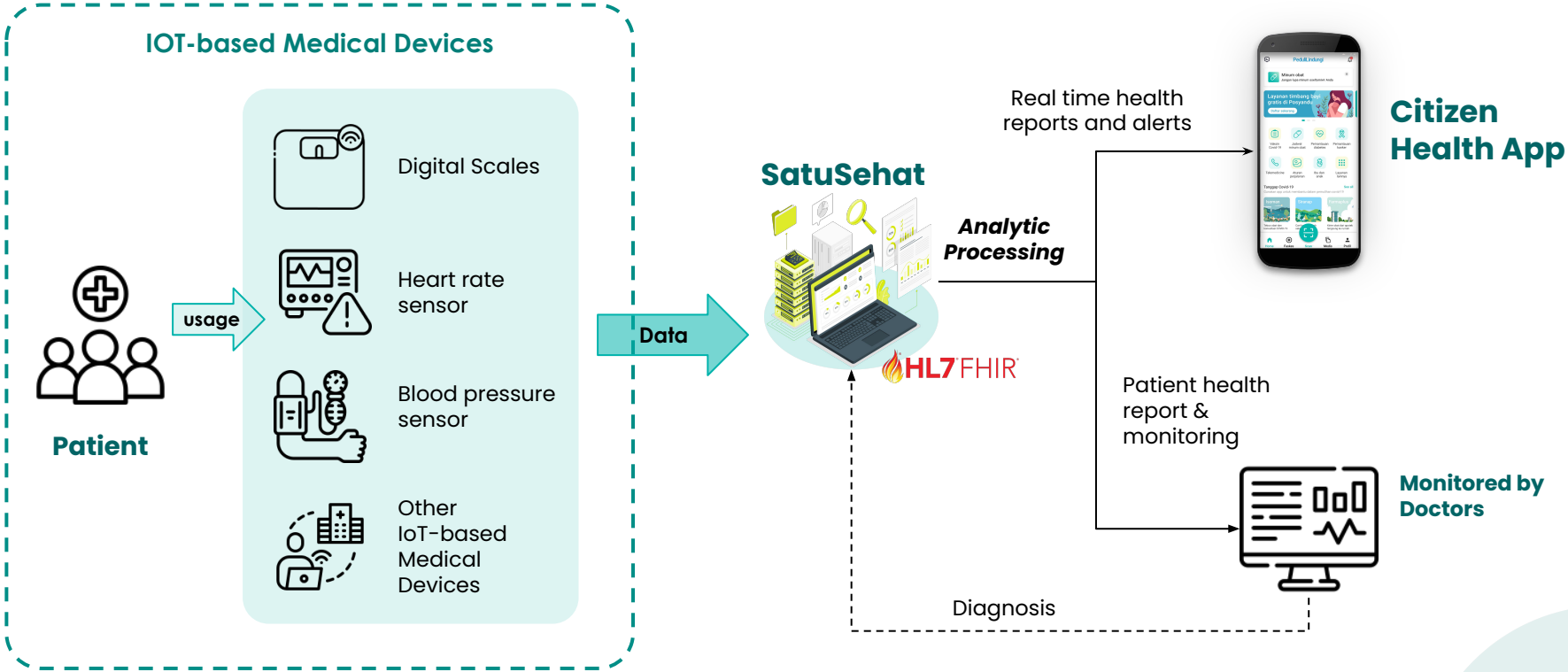
Insight sharing and utilization to strengthening collaboration

- Insurance Company
- *Health-Tech*
- Pharmacy
- Laboratorium
- Biotech Lab
- *etc.*

Health industry player can share their data with government through IHS to enrich each other's insight

SatuSehat and Medical Devices for Personalized Care

Various medical devices have the potential to be integrated with SatuSehat



Various wearable devices and IoT Health *tools can be* ***integrated*** *into SatuSehat and* ***analyzed into personalized patient health profiles*** *according to the patient's condition*

Integration Use Case : Robotic Telesurgery

Establishment of Robotic Telesurgery Center In Indonesia

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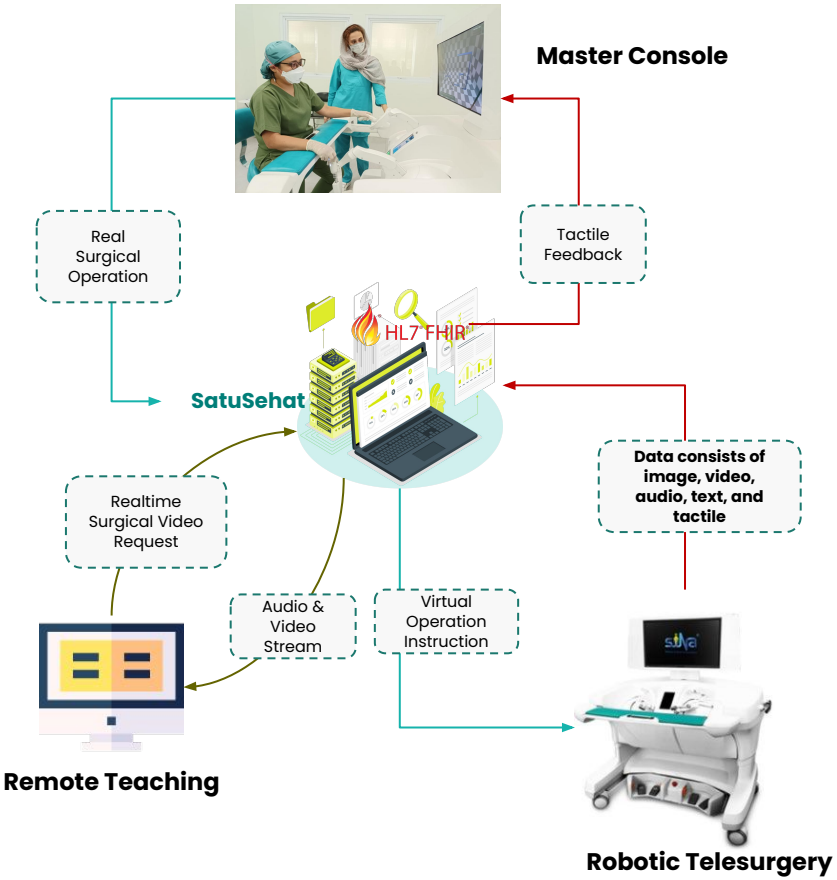

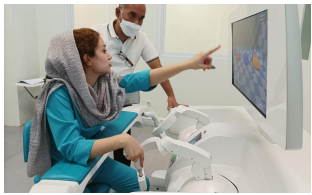

1. Pilot Project on **Establishment of Indonesia-Iran Robotic Telesurgery Center** improve access to surgical services for communities in remote areas through distance surgery/telesurgery
2. Encourage **joint research** in the field of medical and surgical intervention, pilot in 2 hospitals, **Sardjito Hospital and Hasan Sadikin Hospital**
3. **Data Interoperability** through SatuSehat Platform

SatuSehat Data Standardization and Management

Master Data Management to build reliable data ecosystem for further use

Patient Data (Master Patient Index)

- Product data specially designed as a standard for patient data to be validated by DUKCAPIL for data related to demographics
- Can be used as the main standard for patient data by all Health Service Facilities in Indonesia via IHS

Health Facilities Data

- Master data specially designed as a standard for Health Service Facility data which consists of 35 types of healthcare facilities.
- This data is compiled based on various sources such as SISDMK, RS Online, SIMADA, and others

Health Human Resources Data

- Specially designed data product as a standard data index for health workers combined from various data sources for health personnel (Name, STR, SIP, etc.)

Data on Medical Devices and Medicines (KFA Dictionary)

- Data product designed as Master data for Pharmacy, Drugs, and Medical Devices collected from various data sources such as BPOM, LKPP as reference standards for drug data (active substance content, size, volume, etc.) and medical devices

Financing Data

- The data product is designed as a Financing Master data that can be used by all Health Facilities and can be used as a standard for the preparation of cost formats for services, actions, and others.

Service Data

- Data products that are designed as Service Master data that can be used by all Health Facilities and can be used as service coding standards.

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Use Case : Medical Devices and Medicines Data Dictionary (KFA)

Standardization of Medical Device Nomenclature in SatuSehat

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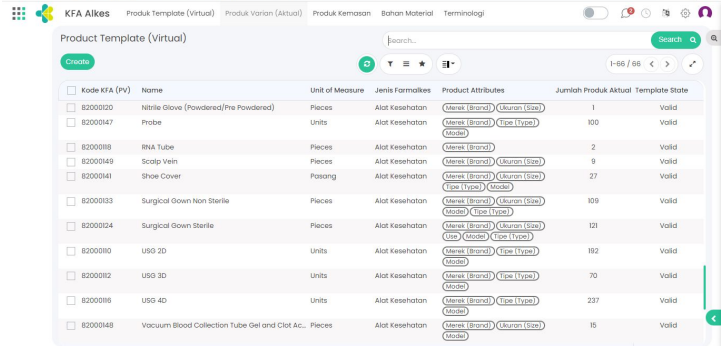
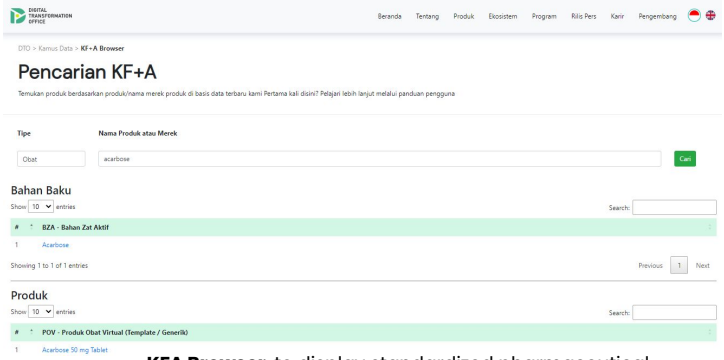
Industry	as a KFA user to **standardize the code on the product.** If the data is collected correctly, the pharmaceutical and medical devices industry can accurately calculate production needs.
Health Facilities	can **calculate accurately the need** for medicines and medical devices
Doctors	make prescriptions using the KFA code for **standardization of prescribed products.**
Pharmacist	as a user who uses the KFA code to standardize products used to **make prescription compounding for patients.**
Distributor	play a role in the **use of the appropriate KFA code in distributing pharmaceuticals** in accordance with the logistics unit.
Public	can **search for product information** with various references.



KFA management tools, used to manage data content from the Pharmacy and Medical Devices Dictionary.



KFA Browser, to display standardized pharmaceutical and medical device data.

Healthcare Precision and Accuracy powered by AI

Artificial intelligence requires large and quality data intake

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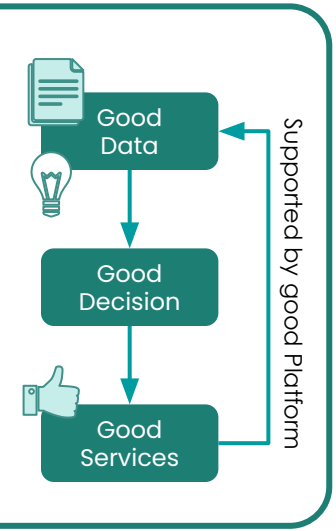

Health Big Data Ecosystem (Predictive Analytics using AI)

- Patients
- Health Workers
- Pharmaceutical Industry
- Researcher
- Government

AI-based Analytics

- Personalized Health Advice
- Clinical Decision
- Precision Medicine
- Health Advance Analytics
- Data-driven Healthcare

***Artificial Intelligence-based health data analysis** will **increase speed, precision, and accuracy** in decision-making related to health services*

Artificial Intelligence in Healthcare

IMDRF/AIMD WG/N67 Machine Learning-enabled Medical Devices

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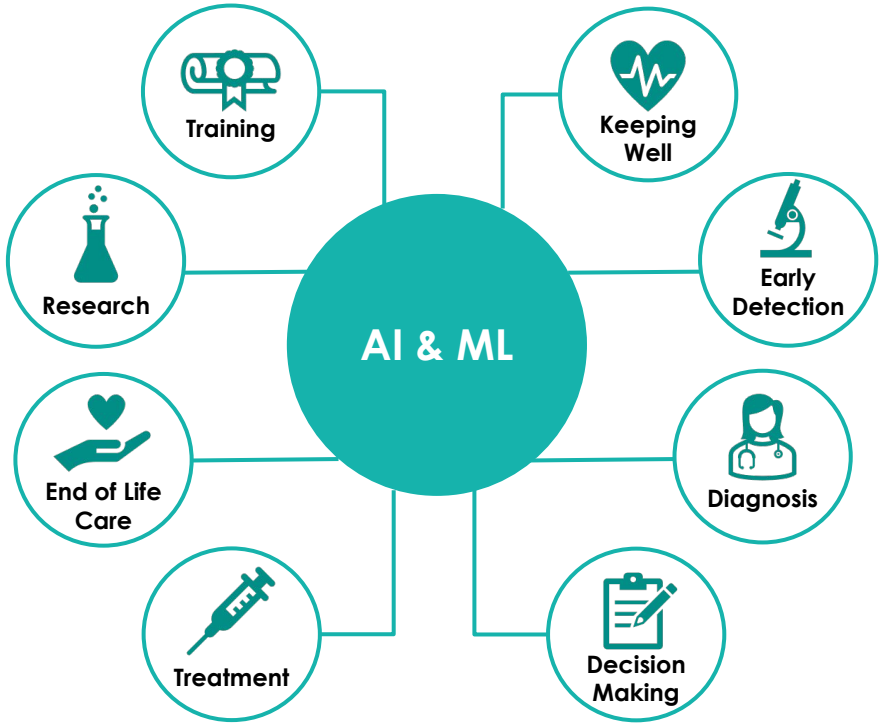
- Artificial intelligence is **ability of computers to emulate human-thought and perform tasks or behaviour** such as making decisions or predictions in real-world environments.
- **Machine learning** is the technology or algorithms enable to analyse the data, identify patterns, make decisions and improve themselves over time.



- There has been accelerated adoption and use of ML-enabled approaches in medical devices. We refer to these medical devices as **Machine Learning-enabled Medical Devices, or MLMD.**
- MLMD has potential to transform health care by **deriving new and important insights from the vast amount of data generated** during all phases of the healthcare process.

General Concept of Artificial Intelligence & Machine Learning

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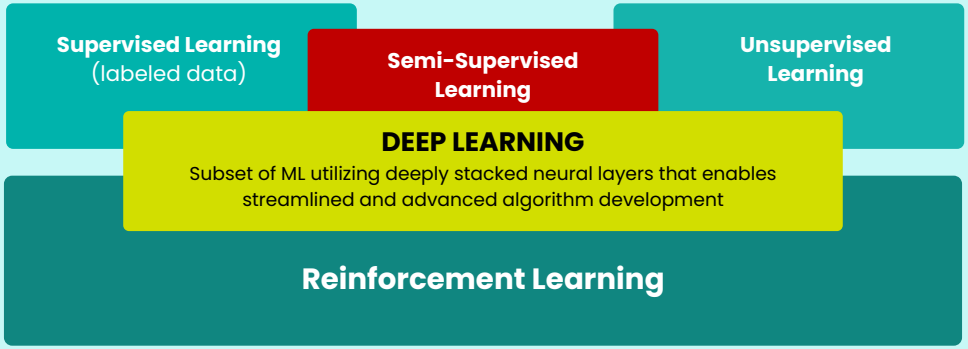
ARTIFICIAL INTELLIGENCE (AI)

Programming computers to perform tasks to mimic human capabilities- such as understanding language, recognizing objects and sounds, learning, and problem solving - by using logic, decision trees, machine learning, or deep learning.

MACHINE LEARNING (ML)

Subset of AI that gives "Computers the ability to learn without being explicitly programmed" – based on work by Arthur Samuel



Source : https://www.imdrf.org

References

- **IMDRF/SaMD WG/N10 FINAL : 2013**

  Software as a Medical Device (SaMD): Key Definitions

- **IMDRF/GRRP WG/N47 : 2018**

  Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices(3.0 Definitions)

- **ISO/IEC DIS 22989**

  Information technology — Artificial intelligence — Artificial Intelligence Concepts and Terminology

- **ISO/IEC TR 24027**

  Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making

Key Definitions

Machine Learning-enabled Medical Device (MLMD)

> A medical device that uses machine learning, in part or in whole, to achieve its intended medical purpose.

Medical Devices

> Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s)

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- Diagnosis, prevention, monitoring, treatment or alleviation of diseases
- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury
- Investigation, replacement, modification, or support of the anatomy, or of a physiological process
- Supporting or sustaining life
- Control of conception
- Cleaning, disinfection or sterilization of medical devices
- Providing information by means of in vitro examination of specimens derived from the human body

Technical Standards Definitions

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Bias

Human cognitive, data and engineering bias

Continuous learning

Training on each exposure to data on ongoing basis during the operation phase of MLMD

Reliability

Consistent behaviour and results

Supervised learning

ML uses labelled data during training

Unsupervised learning

ML uses only unlabelled data during training, output is unknown, ability to find patterns

Semi-supervised learning

ML leverages both combination of supervised and unsupervised learning

Training dataset

A set of data used to train the ML model

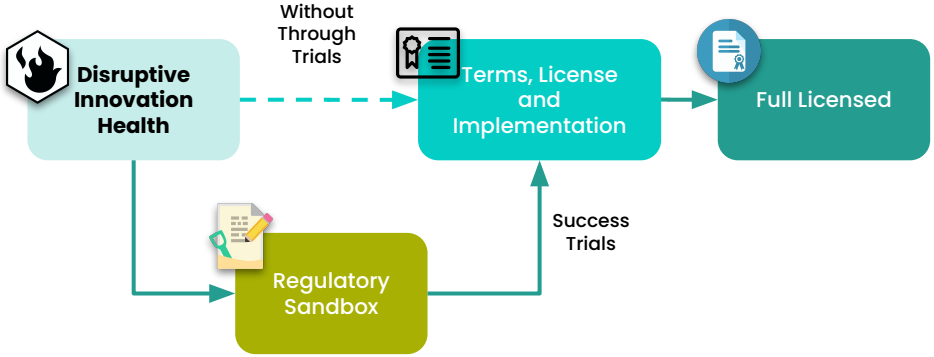
Test dataset

A test data never been used in the ML training to estimate the performance of ML models

Training

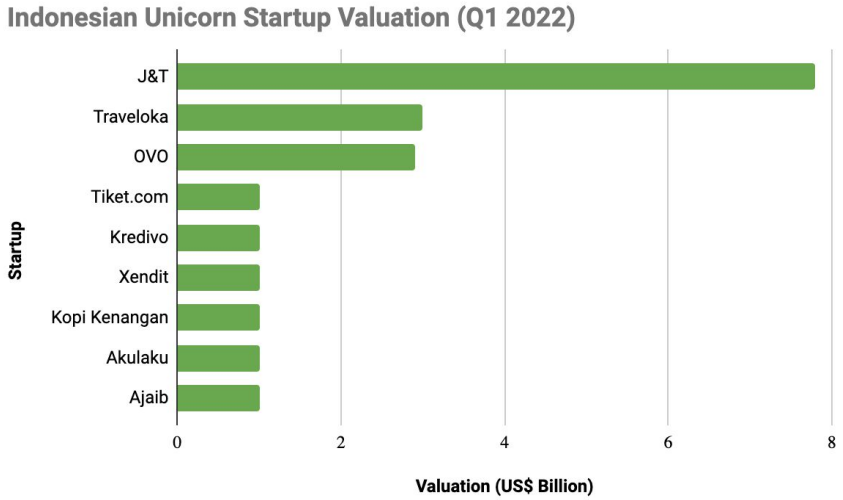
Process to improve ML model based on algorithms by using training data

We also encourage the medical devices ecosystem through Regulatory Sandbox to support the transformation



Health Innovation Regulatory Sandbox can be a space where **innovations in the biotech sector** can pilot innovations or new business models in an environment that safe and monitored by regulators.

The implementation of the Regulatory Sandbox will also **encourage user growth** to increase the value of each innovation.



Recently, **5 fintech startups** now have unicorn status, regulated and supervised by OJK (Otoritas Jasa Keuangan) through **the Regulatory Sandbox program**.

Source : Katadata, 2022

Health Innovation Regulatory Sandbox Stage Flow

The Regulatory Sandbox functions as a monitor and supervisor for every Health Innovation

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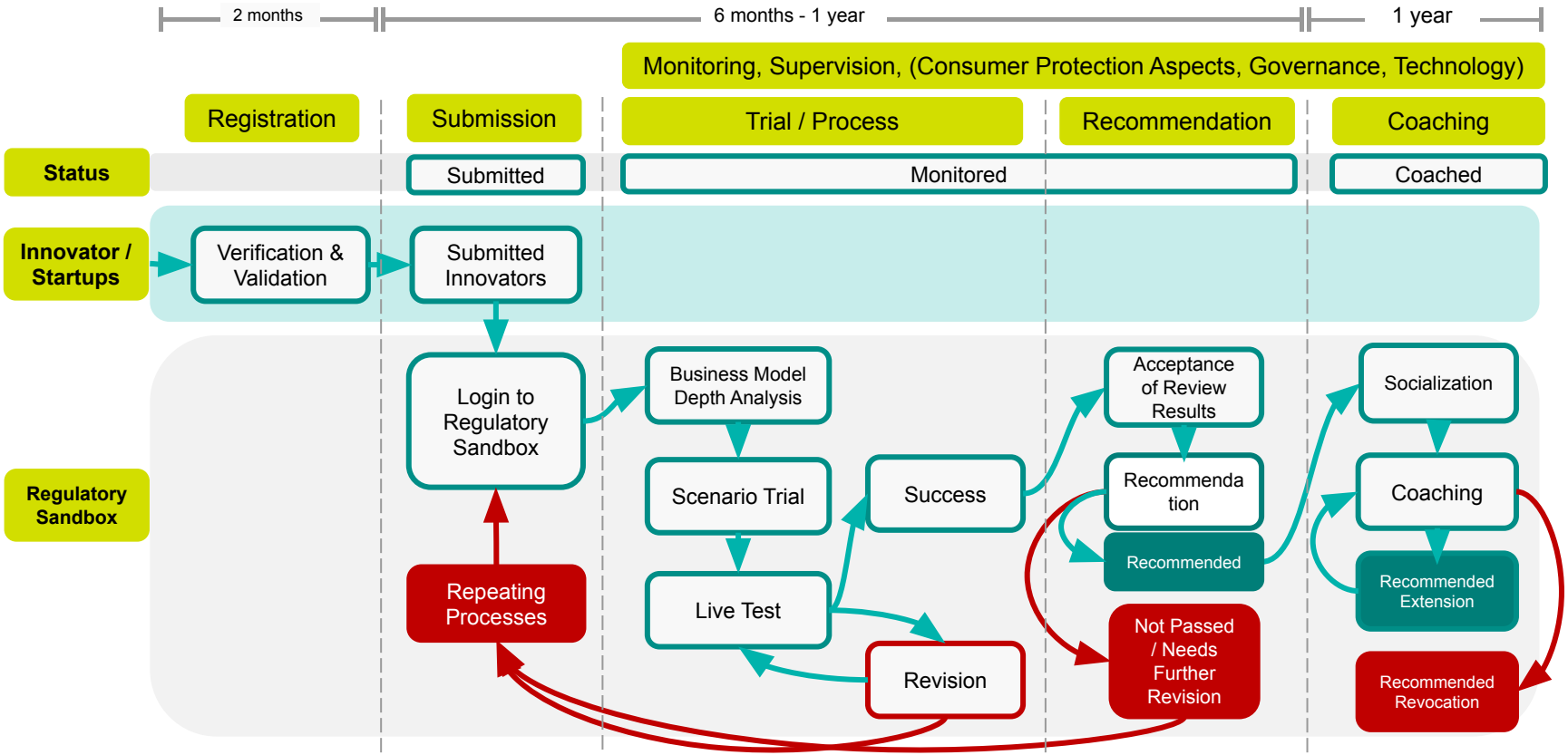

Recommendations

For Development and Implementation of Machine Learning-based medical devices

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Data & System Interoperability

The use of medical devices is ensured that it is in line with the health technology transformation agenda, as well as being part of the grand architecture of health information technology.

Health and Technology Ethics

The use of technology-based tools/methods must still pay attention to ethics towards patients as individuals who have full rights to health services, and use technology proportionally

Governance, Policy, and Regulation

It is ensured that every technological implementation and innovation is in accordance with the principles of good governance, complies with the law, and is equipped with regulations that protect all related parties.

Risk Management

It is necessary to map, calculate, and ensure the control of various risks that will expose both health personnel, patients, and institutions in the use of ML-based Medical Devices

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> MoH is strongly open for any collaboration for long or short term goals. We have tremendous work, to do a health tech transformation, so we invite you all to be the implementation partner.


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