# WHO MINDS THE MACHINES? DEVELOPING A GOVERNANCE FRAMEWORK FOR PRE-MARKET AUTHORISATION OF RESPONSIBLE ARTIFICIAL INTELLIGENCE APPLICATIONS IN HEALTHCARE IN SOUTH AFRICA


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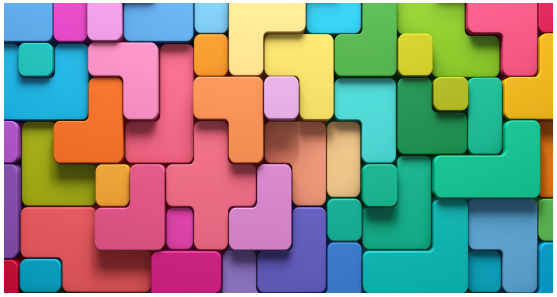
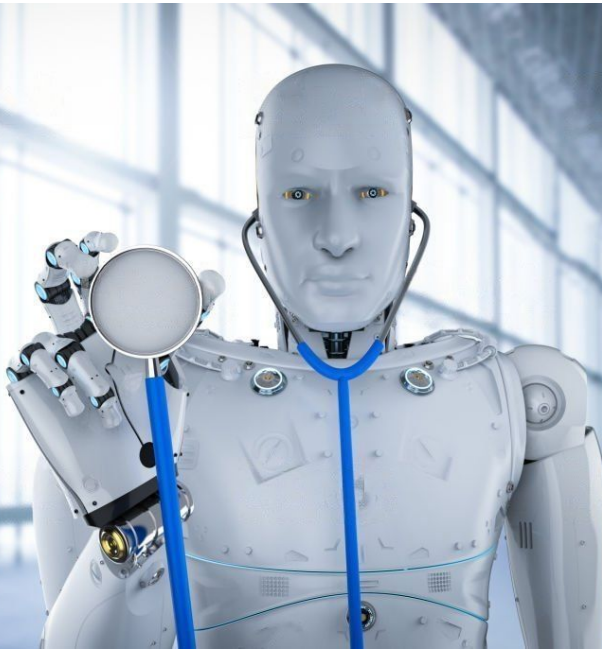


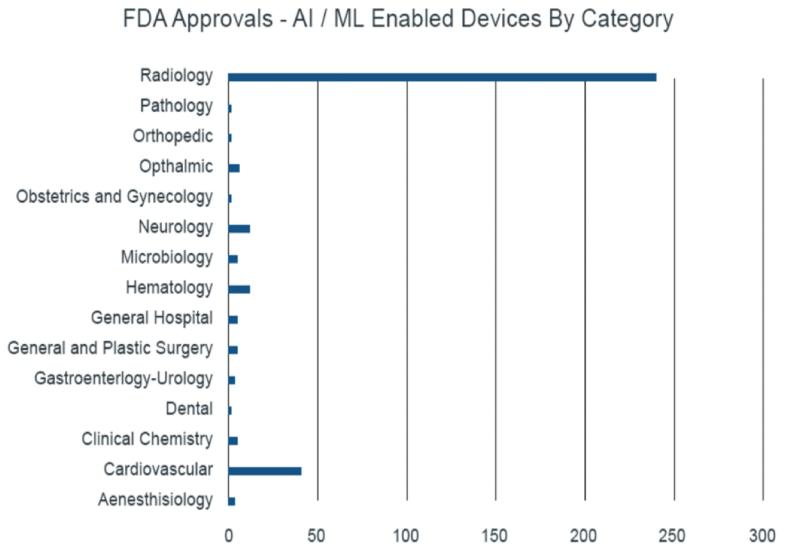
DS-I Africa
Data Science for Health Discovery and Innovation in Africa

LAW Group

# AI use in healthcare



- Diagnostic
- Pathology
- Prognosis
- Drug discovery
- Clinical trials
- Administrative




Source: Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices | FDA

diagnostic accuracy

alleviation of staff shortages in low-resource settings

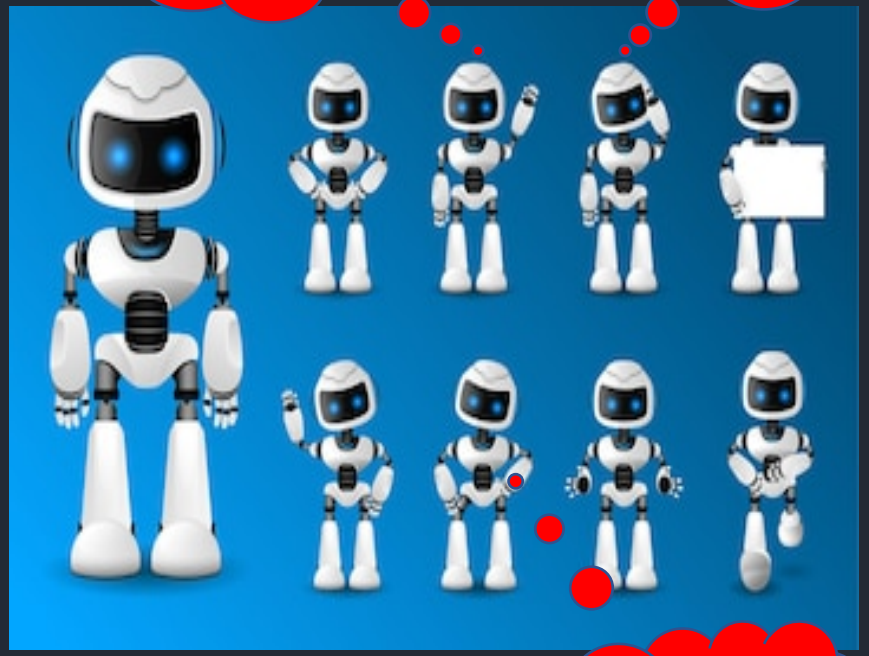
reduced health-related costs

workflow efficiency

## Benefits of AI SaMD

Derogation of Human rights

Infringement of Ethical norms



Legal compliance challenges

## Risk of AI SaMD

**Ethical Concerns**

# Who minds the machines- when they can operate with some degree of **Autonomy**

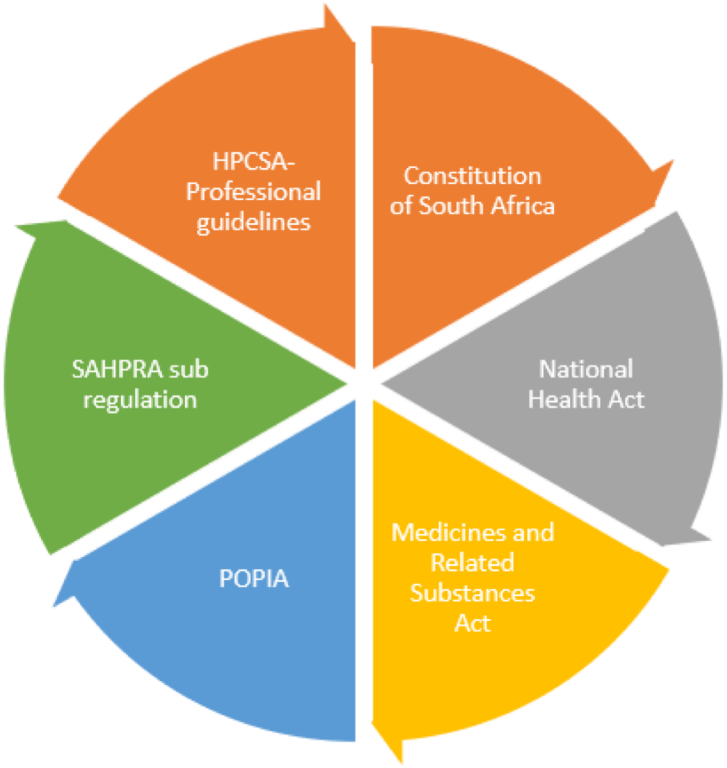
Unsupervised

Semi-Supervised

Supervised

Does this mean AI is like the terminator?

## Health governance framework




## Shortcomings when applied to autonomous AI SaMD

- Outdated legislation
- Ambiguous terms
- Unclear regulatory pathways
- Single certification stage
- Insufficient post-deployment surveillance mechanisms
- Inadequate liability cover

# Ethical guidelines on AI

Soft law guidelines-

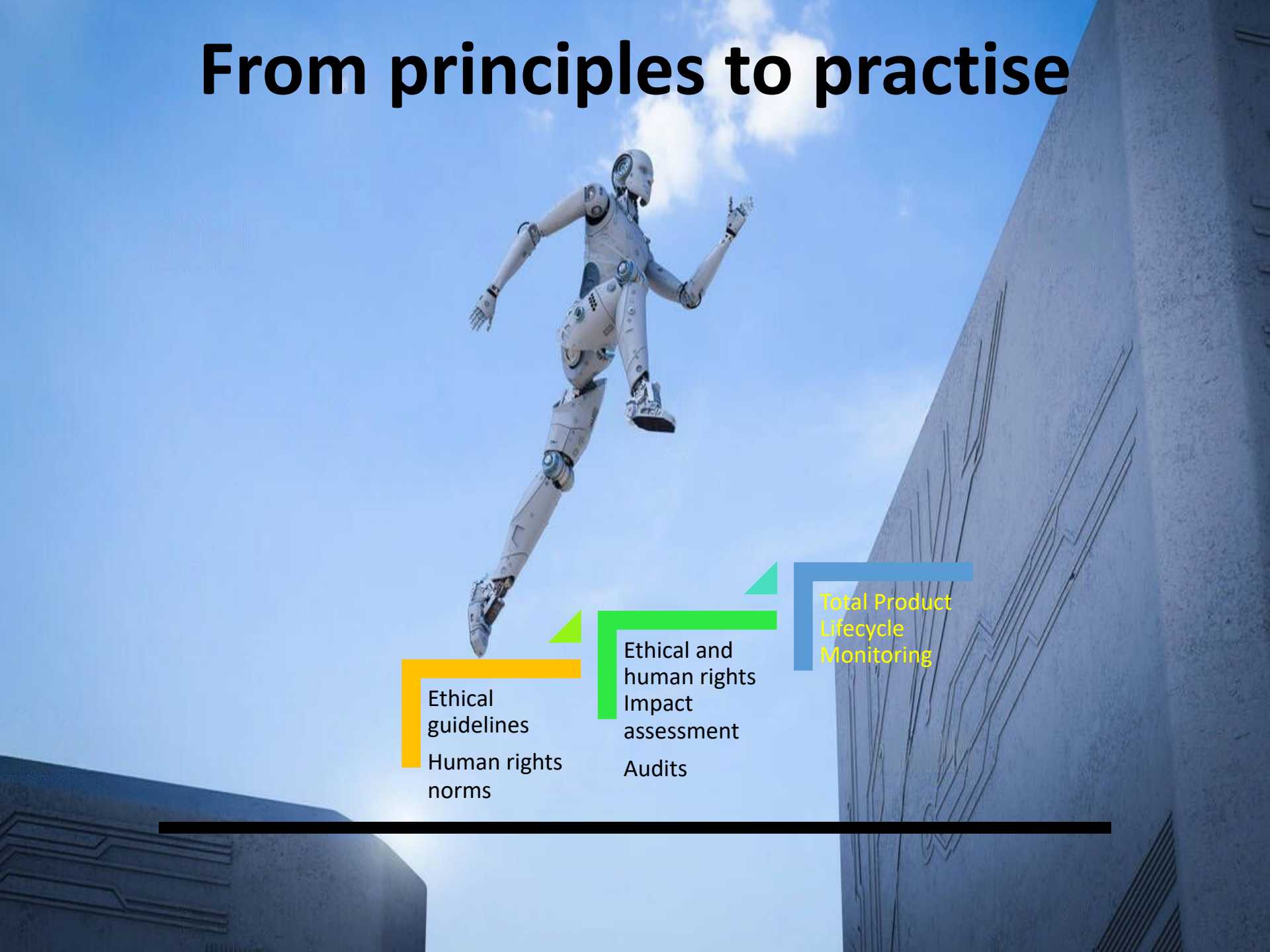
not legally enforceable

Open to various

interpretations- results in "ethics washing"

**Absence of ethical guidelines from LMIC-global south**

# From principles to practise



# IMPACT ASSESSMENTS

**DEFINITION**

- Emerging approach for holding organisations that design and deploy AI systems accountable to those affected by the AI softwares
- A way to pre-emptively detect potential impacts arising from the design, development and deployment of AI SaMD

**DEVELOPED BY**

- Consultation with key stakeholders in Healthcare
- Regulatory Agency-SAHPRA. Government Officials. RECs. Patients of different cultural groups. Health practitioners. Academia. Civil Society.

**WHEN TO CONDUCT**

- Design phase-AI developer [discretionary]
- Certification phase- regulatory agency [mandatory]

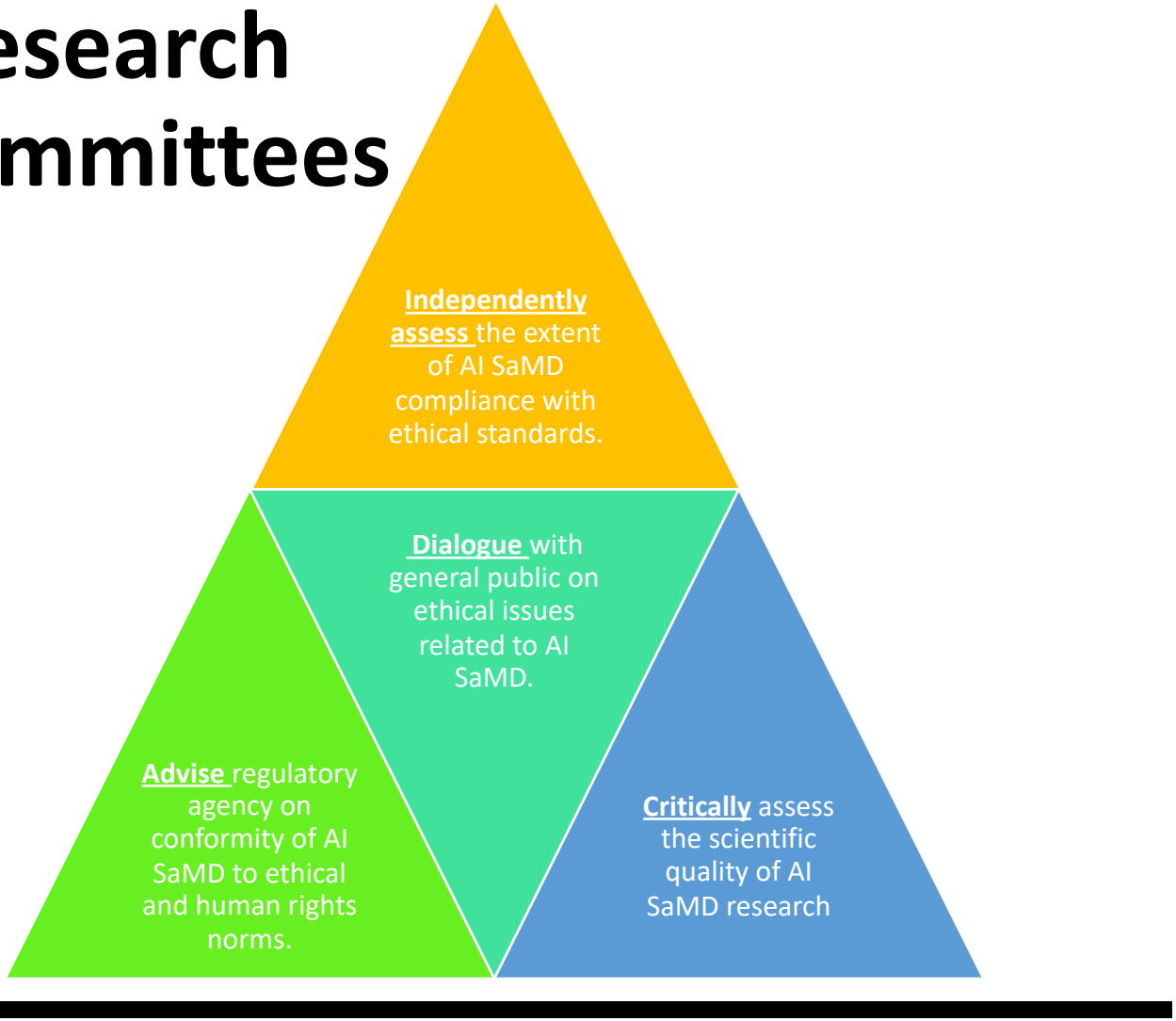
# Aims of Impact assessment

| Set | Define | Provide | Determine | Identify | Assess | Assess | Propose | Determine |
|---|---|---|---|---|---|---|---|---|
| standards of practise | the type of AI SaMD to be assessed and regulated- clinical decision support systems, smart wearables, chatbots, | risk stratification system- high/med/low risk categories | the human rights/ethical norms at risk of infringements | ways to mitigate the risks | the adequacy of mitigation process | the potential impact on patients and various ethical groups | further activities to be carried to minimise harm to acceptable levels | the beneficence of AI SaMD in line with local needs |

# Research Ethics Committee

| | Before research starts | | After research has started | |
|---|---|---|---|---|
| **Research phase** | Planning, preparation of the project | Review | Conduct | End of the research |
| **Roles** | Providing information to researchers, as needed | Ethics review of the research proposal | Follow up of the research project, advocate publication of results. | Review reports from the researchers |

# Role of research Ethics Committees



# Audits

**Definition**

- Systematic independent review of AI SaMD activities and documentation in clinical practise
- To allow for reconstruction of the course of events during AI SaMD clinical use
- To retrospectively verify traceability of AI SaMD output in clinical practise

**Aims**

- To measure reliability and safety
- To measure the quality of AI SaMD output compared to best clinical practise
- To assess security of AI SaMD to external interference

**Outcome**

- To be communicated to regulatory agency, AI developer and clinicians

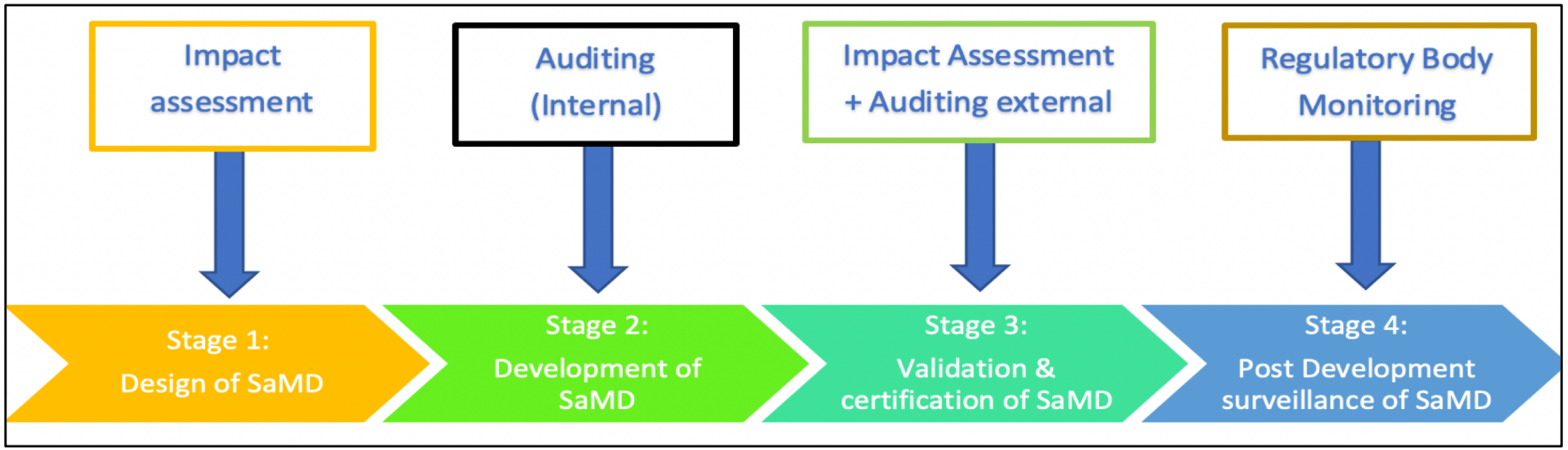
**Certification**

- To provide for transparency
- Improve trust in AI SaMD from patients, clinicians and public

## Regulatory Sandboxes/Airlock system

system where the AI SaMD is not deployed to the general population but undergoes evaluation at specialized hospitals under the supervision of the regulator

# Total product lifecycle assessment



# Incorporating EIA into regulation

- Impact assessment and audits into regulation.
- Use of regulatory sandboxes
- Conclusion of REC will advise competent regulatory authority who will decide if AI SaMD can be used locally
- Provide human centric and responsible AI SaMD

**A BILL**

To direct the Federal Trade Commission to require impact assessments of automated decision systems and augmented critical decision processes, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Algorithmic Accountability Act of 2022".