For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

AI-Enabled Medical Devices and Africa's Evolving Regulatory Landscape

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Agenda

What is AI

AI in Medical Devices

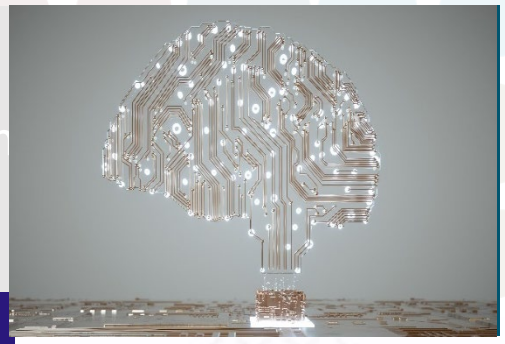
Global AI Regulatory Landscape and Key Considerations

What is AI

Overview of AI

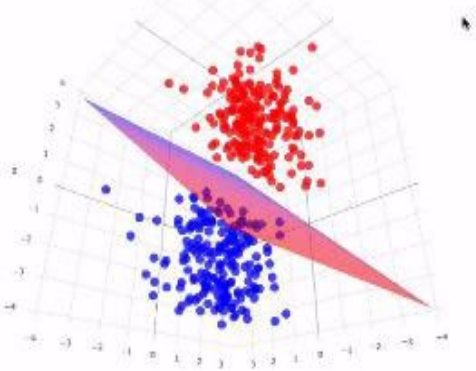
Artificial Intelligence System *

Engineered system that generate outputs such as content, forecasts recommendation or decisions for a given set of human-defined objectives



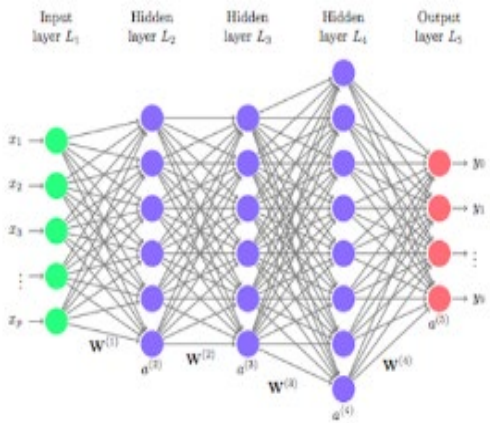
Machine Learning *

Process of optimizing model parameters through computational techniques, such that the model's behavior reflects the data or experience



Deep learning *

AI approach to creating rich hierarchical representations through the training of neural networks with many hidden layers



Generative AI

Subset of ML that is trained on vast amounts of information and able to generate **predictive** responses to inputs in form of text, images, or computer code that simulate human responses

*Source: ISO/IEC 22989

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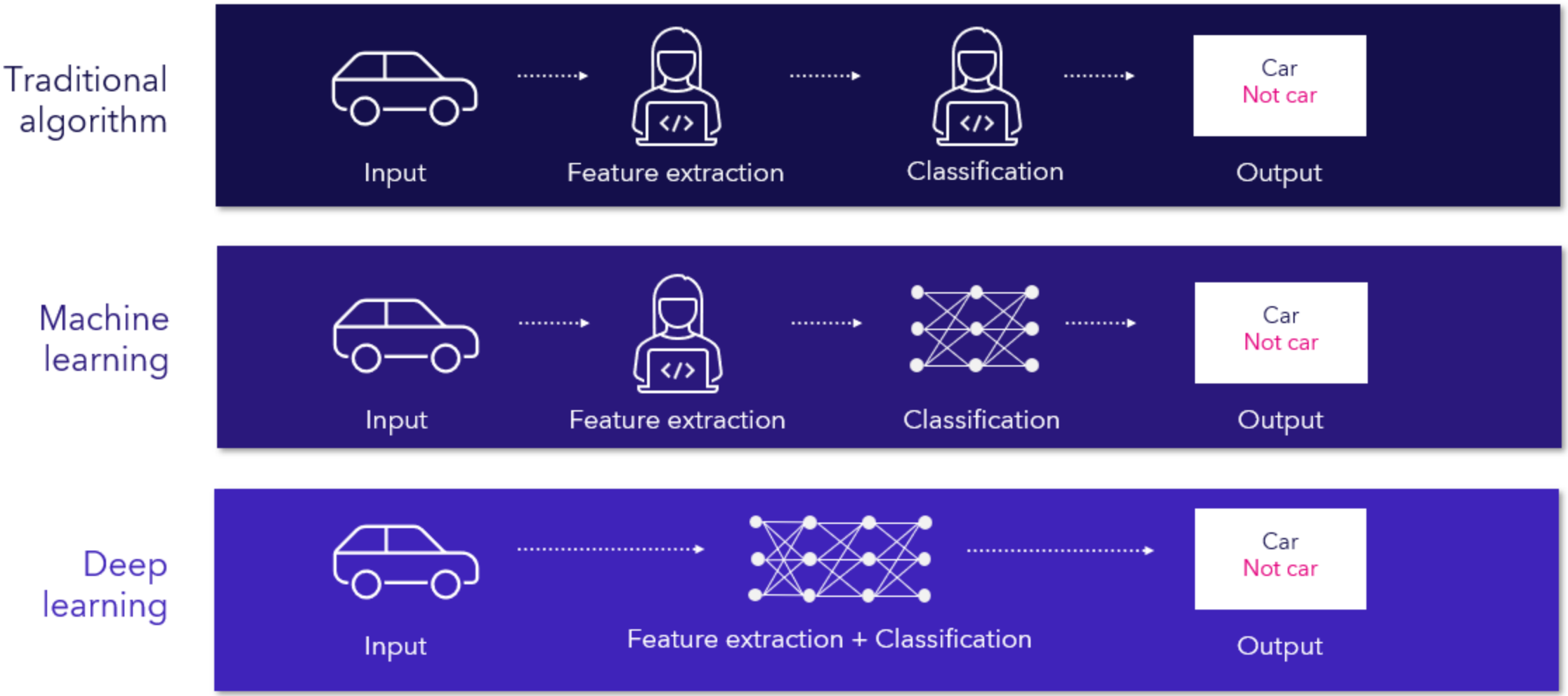
Examples of different types of AI



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AI in Medical Devices

AI in medical devices

AI and ML in Medicine

Offering potentially revolutionary capabilities

The use of AI-enabled medical devices has the potential to address some of the most critical challenges in healthcare

With the dramatic increase in connected devices and electronic health record data, there is both increased opportunity to understand and treat patients, as well as increased burden on physicians

AI techniques, if leveraged responsibly, offer the opportunity to provide meaningful insight driven care

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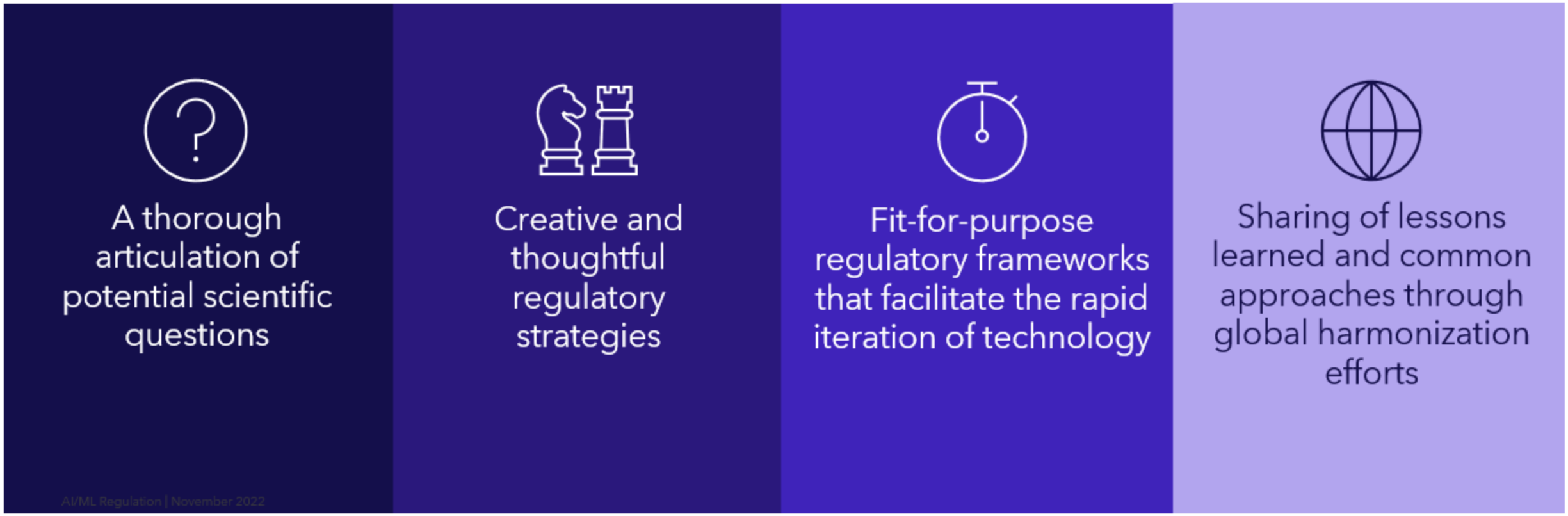
Innovative technology requires thoughtful regulation

Efficient and **effective** global regulatory processes for evolving technology call for:



Importantly, AI-enabled medical devices are medical devices and should be regulated through **existing regulatory frameworks,** with regulation **based on intended use and the risk of product**

Global AI Regulatory Landscape and Key Considerations

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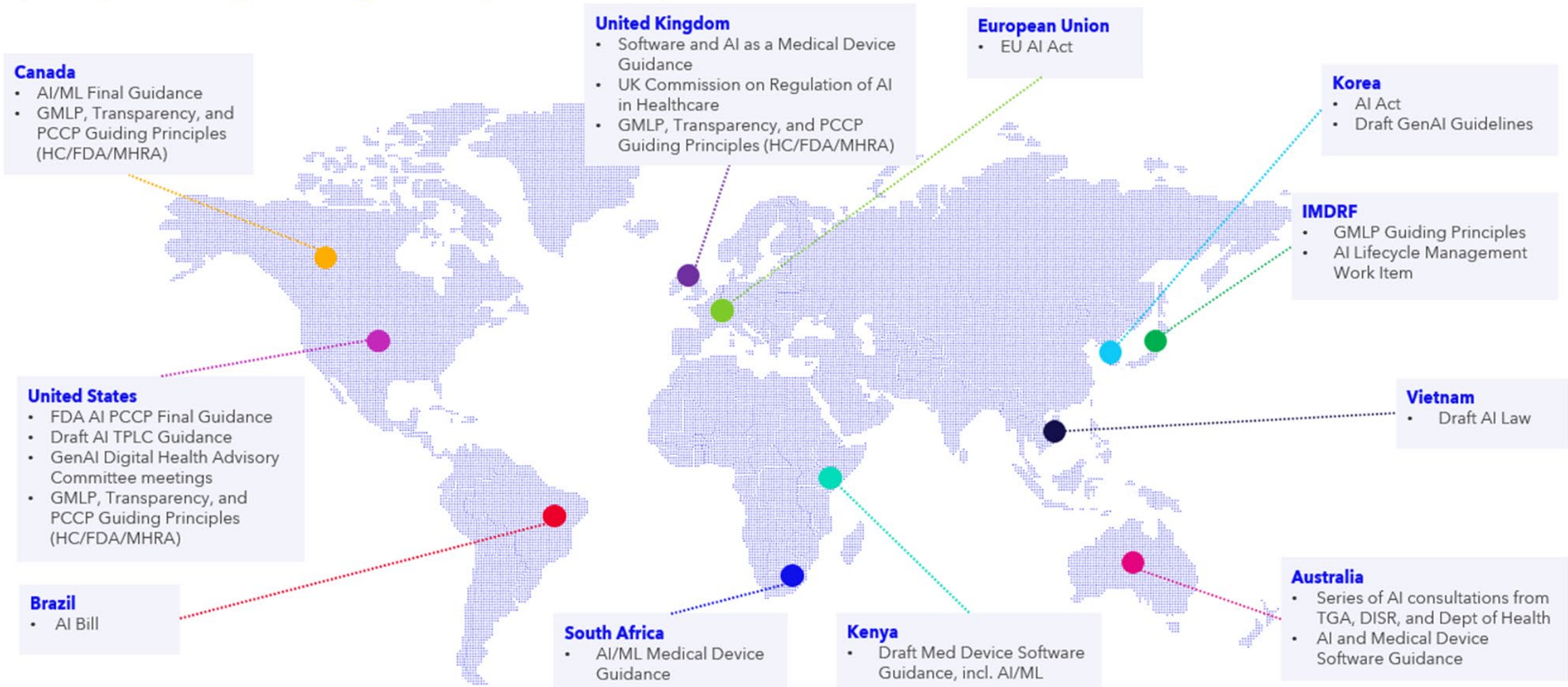
Expanding AI Regulatory Landscape



Canada
- AI/ML Final Guidance
- GMLP, Transparency, and PCCP Guiding Principles (HC/FDA/MHRA)

United Kingdom
- Software and AI as a Medical Device Guidance
- UK Commission on Regulation of AI in Healthcare
- GMLP, Transparency, and PCCP Guiding Principles (HC/FDA/MHRA)

European Union
- EU AI Act

Korea
- AI Act
- Draft GenAI Guidelines

IMDRF
- GMLP Guiding Principles
- AI Lifecycle Management Work Item

United States
- FDA AI PCCP Final Guidance
- Draft AI TPLC Guidance
- GenAI Digital Health Advisory Committee meetings
- GMLP, Transparency, and PCCP Guiding Principles (HC/FDA/MHRA)

Vietnam
- Draft AI Law

Brazil
- AI Bill

South Africa
- AI/ML Medical Device Guidance

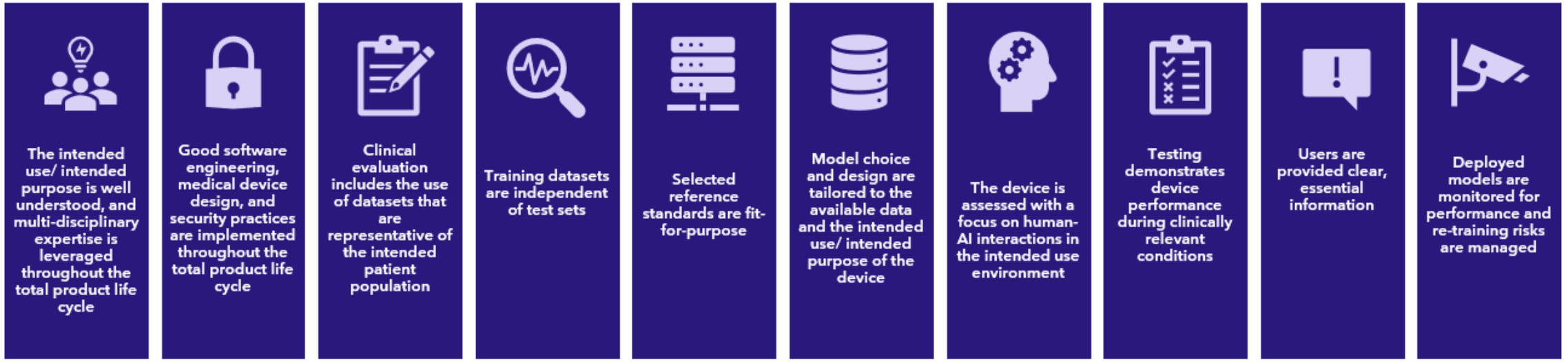
Kenya
- Draft Med Device Software Guidance, incl. AI/ML

Australia
- Series of AI consultations from TGA, DISR, and Dept of Health
- AI and Medical Device Software Guidance

IMDRF Good Machine Learning Practice for Medical Device Development Guiding Principles

- Issued in **January 2025** by the IMDRF Artificial Intelligence/Machine Learning-enabled Working Group
- Proposes **10 guiding principles** to inform further policy and regulatory development
- Serves as a good high-level overview of **evolving regulatory expectations for AI**

Guiding principles:



* IMDRF is comprised of Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea, United Kingdom and USA

Reliance as an enabler for AI-enabled medical devices

Why reliance matters for AI-enabled devices

- Fast-evolving technologies, such as AI-enabled devices, require flexible, forward-looking regulatory pathways
- Reliance enables African regulators to leverage the work of trusted counterparts and international organizations to strengthen regulatory capacity, enhance efficiency, and accelerate patient access

Strategic value

- Practicing reliance for AI-enabled devices:
  - Supports African Medicines Agency goals of harmonization and efficiency
  - Strengthens regulatory confidence through collaboration and knowledge exchange
  - Promotes timely access to cutting-edge technologies

Call to action

- Integrate reliance for AI-enabled devices into regulatory frameworks
- Adopt reliance-based pathways for AI and software devices as part of regulatory modernization
- Continue collaboration with trusted regulators to ensure effective implementation of reliance frameworks

Benefits of eIFU for AI-Enabled Devices

Electronic Instructions for Use (eIFU):

- **Facilitates transparency** for AI-enabled medical devices, including transparency around when AI is incorporated into a medical device
- **Supports innovation and more rapid software improvements** by allowing rapid updates to IFU as the software iterates
- **Benefits patients, healthcare practitioners, and caregivers** by supporting **increased availability, utility, interactivity, and accessibility** of IFU
- **Supports informed decision-making** about patient care and ensures the **safe and effective use** of the device

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