Alcon

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA
http://www.ahwp.info

Artificial Intelligence: Global Regulatory Development

Yiting Cai

Regional Regulatory Affairs Manager

Hosted By
SULTANATE OF OMAN

وزارة الصحة
Ministry of Health

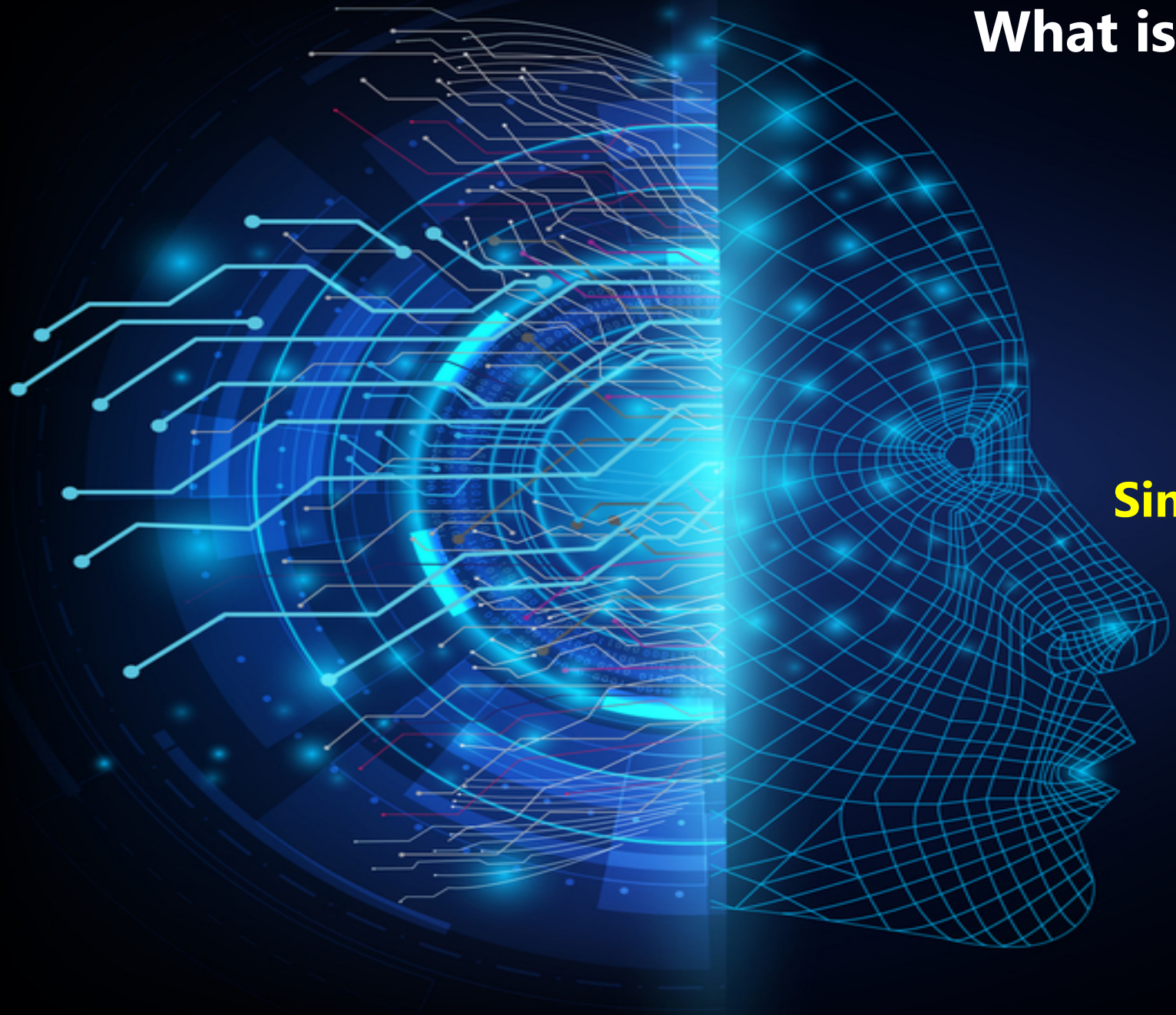
PADC
DG of Pharmaceutical Affairs & Drug Control

Disclaimer

Views expressed in this presentation are solely those of the presenter and not necessarily those of AHWP or Alcon

The presenter makes no warranty, express or implied, that the statements made are correct, and will not require modification as experience and technological advances dictate, or will be suitable for any purpose or workable in any application, or otherwise. The presenter do not assume any liability whatsoever for the accuracy and completeness of the information presented"

What is Artificial Intelligence?



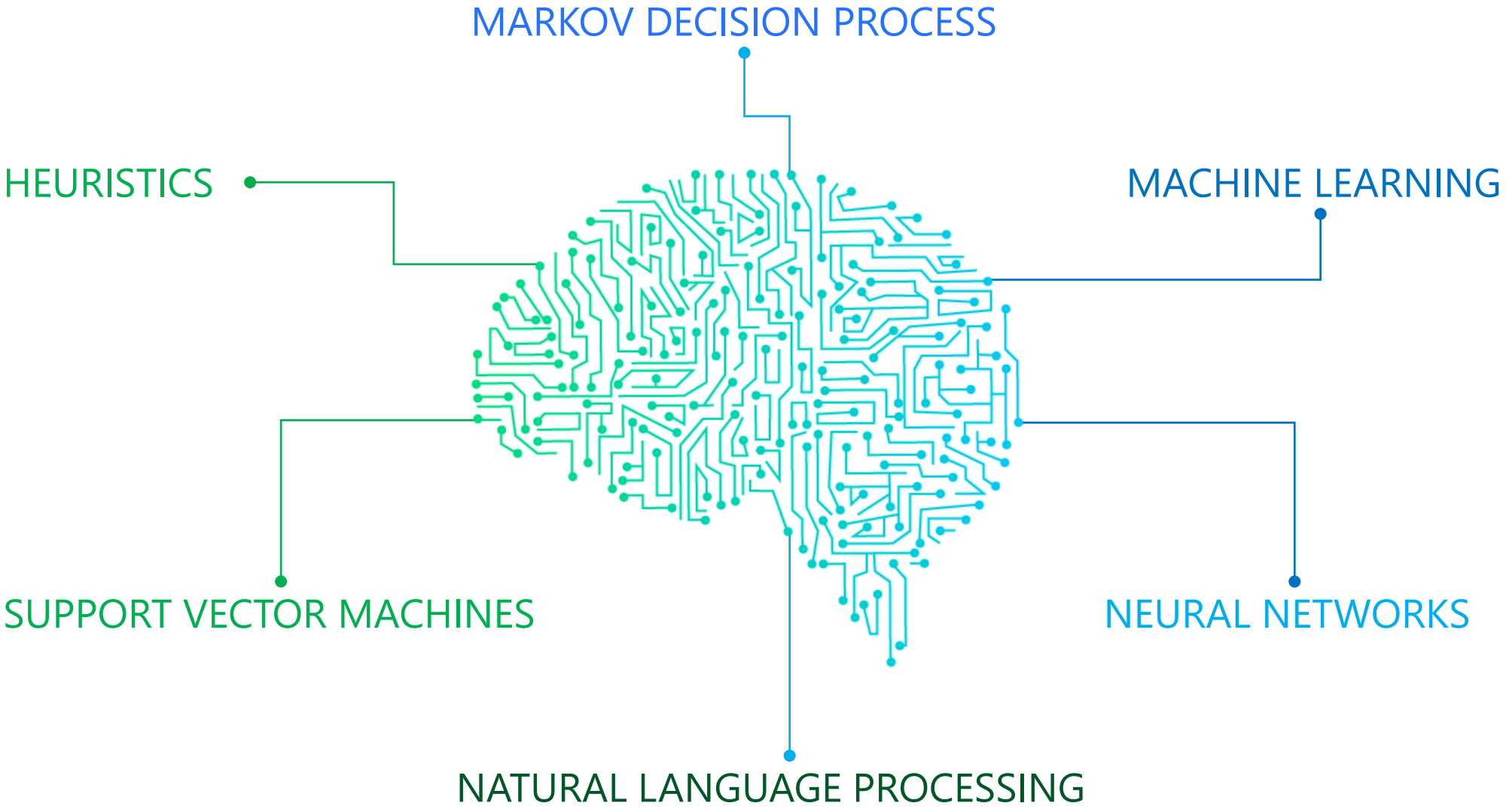
Computer Systems

Simulate Human Intelligence

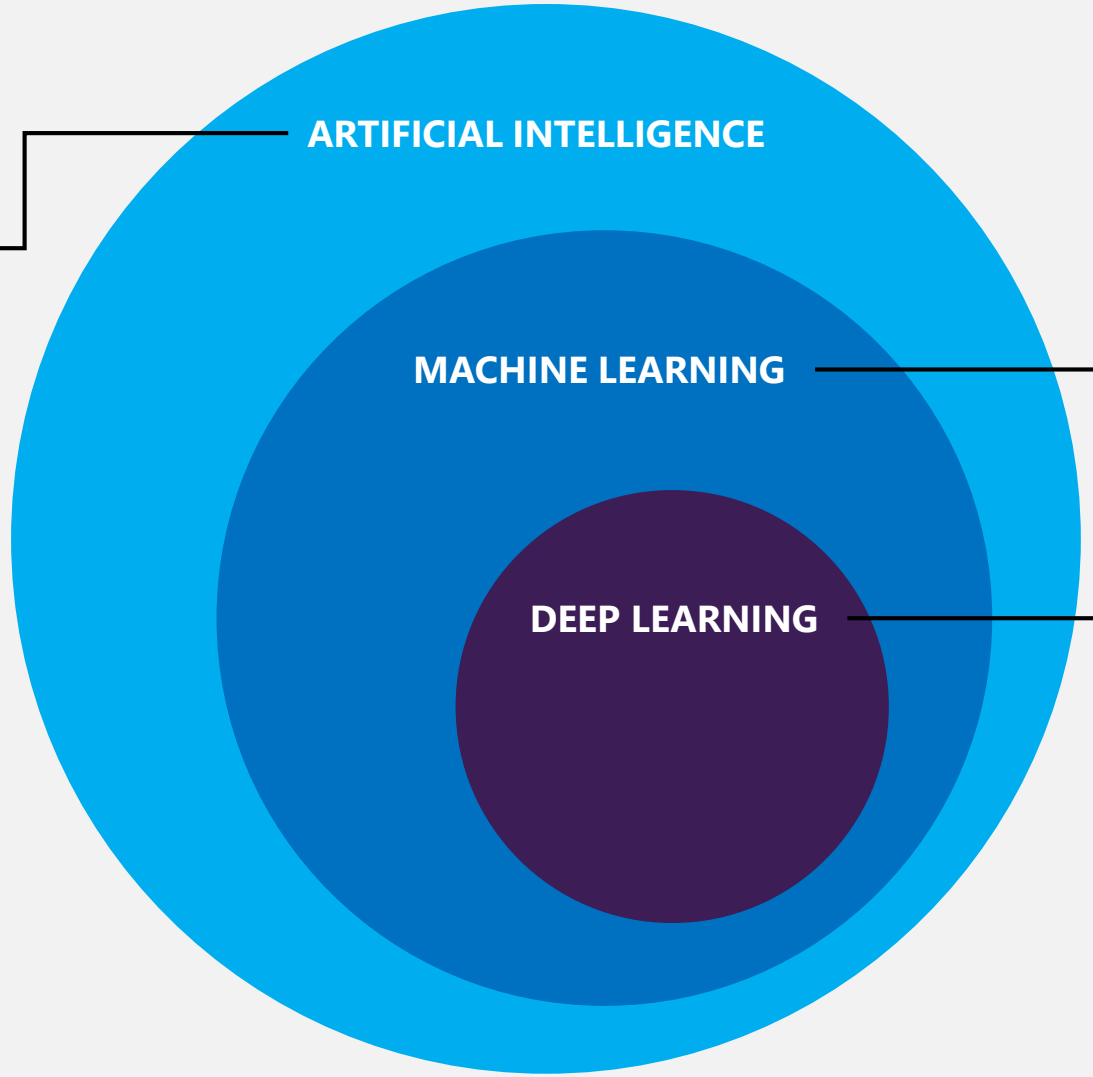
Learning
Problem Solving
Decision Making

Image: Analytics Insight

What Makes a Machine Intelligent?



Machine Learning and Deep Learning

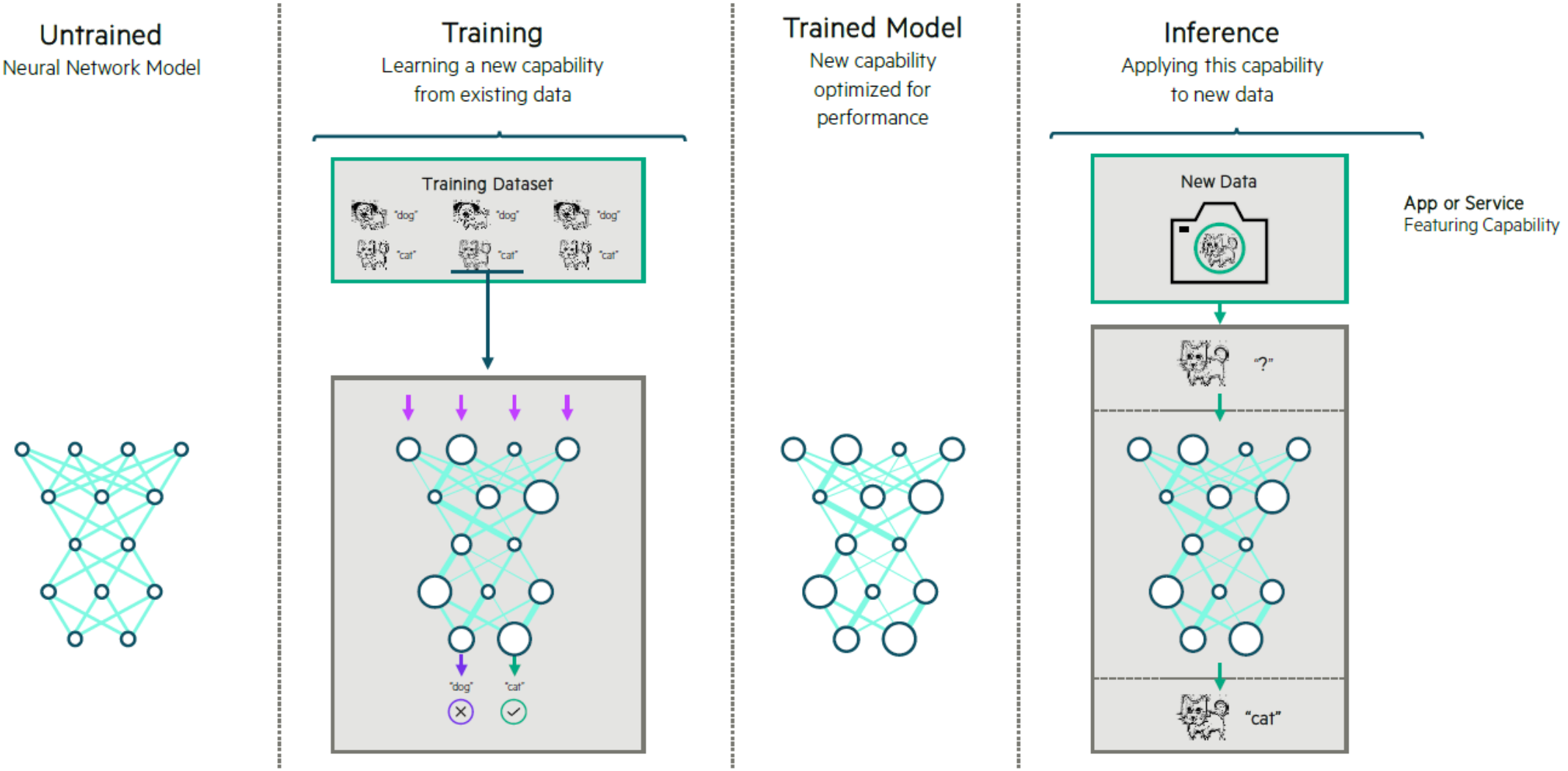


simulation of human intelligence processes by computer systems, particularly in areas of learning, problem solving and decision making

ability of machines to automatically learn and improve from experience without being explicitly programmed

a type of unsupervised machine learning that gain certain types of knowledge through artificial neural networks (algorithms)

Learning via Artificial Neural Network



Alcon

Image from Paul Haverfield, Hewlett Packard Enterprise, "AI: The Ethics"

Dogs or Muffin / Bagel / Mop

Muffin?

Bagel?

Mop?

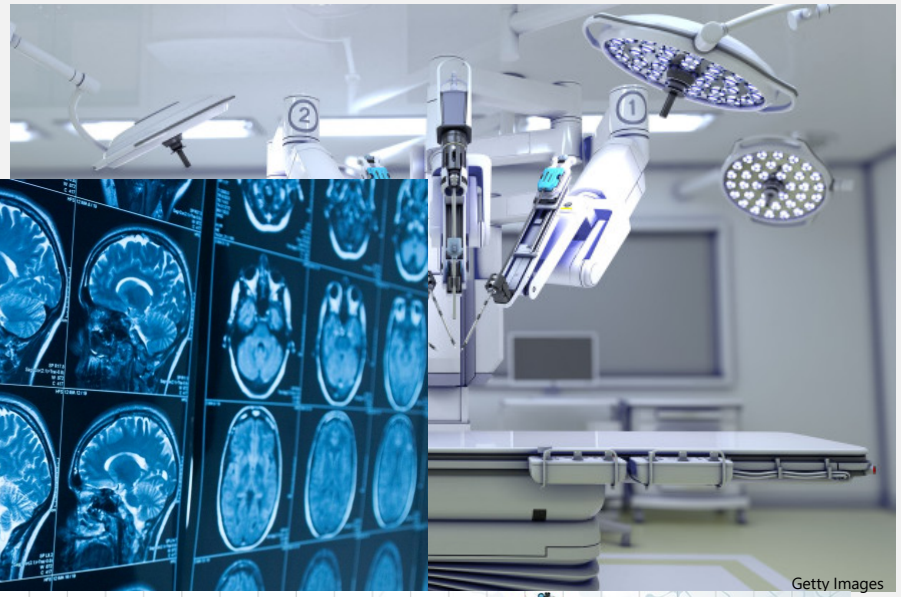
Applications of AI in Medical Technology

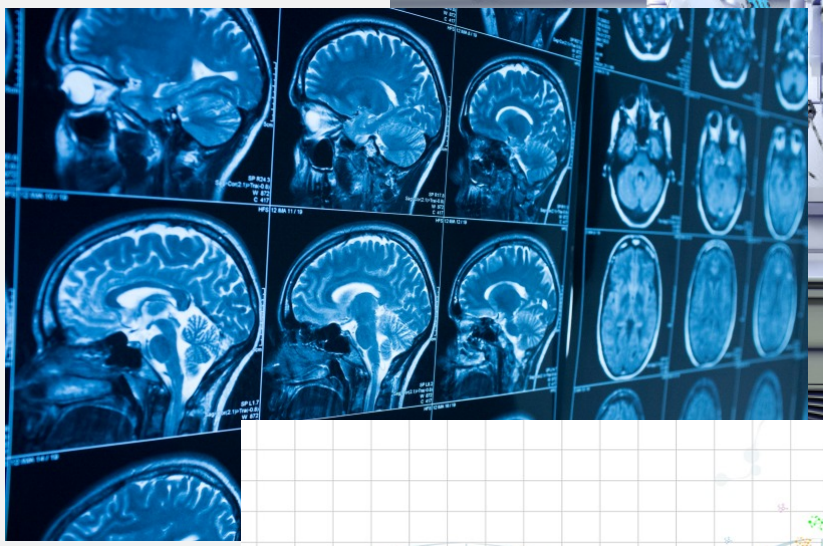
A.I.–assisted robotic surgery

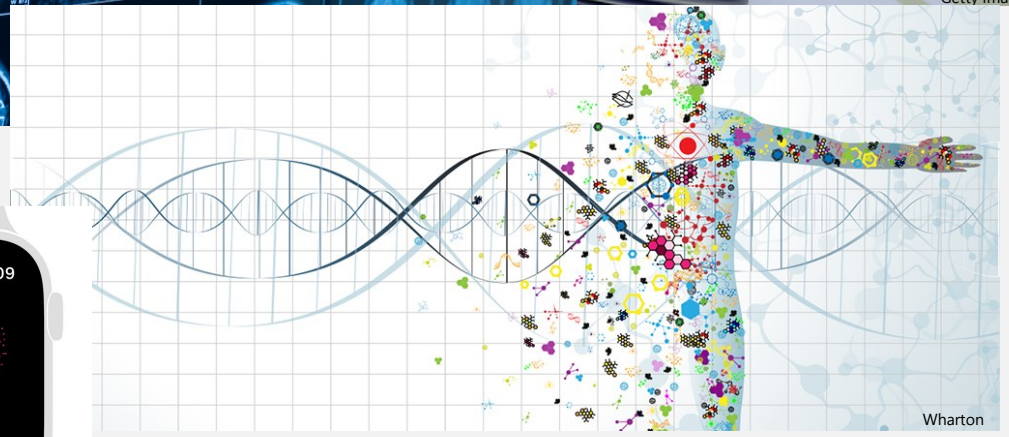
Clinical diagnosis

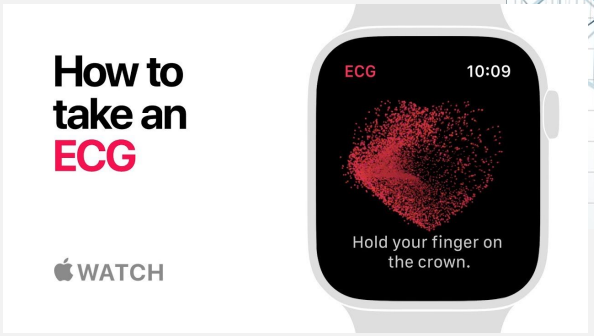
Precision medicine

General “well-being”



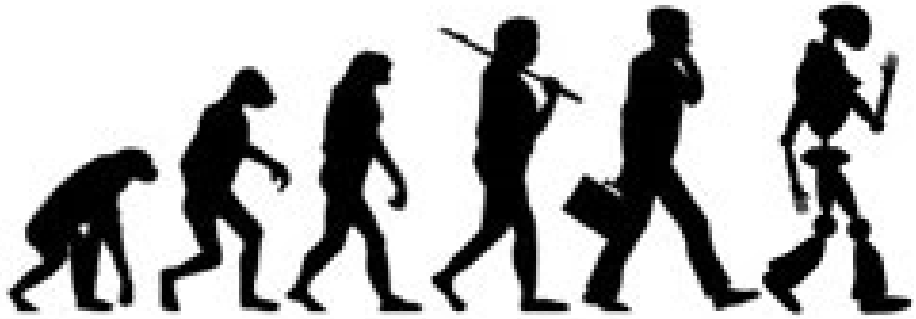






Characteristics of AI in Medical Technology

- **Software based**
- **Capability to learn and adapt**
- **Capability to evolve**



Current Regulatory Approaches (General)

- Existing conformity assessment procedure elements to demonstrate that devices meet **essential principles of safety and performance**
  - Quality Management System
  - Postmarket Surveillance System
  - Technical Documentation
  - Declaration of Conformity

- Existing device change approval pathway(s) to manage software changes

Current Regulatory Approaches (SaMD specific)

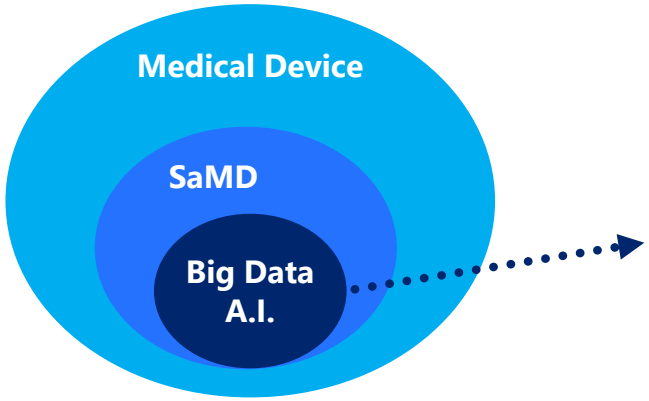
- IMDRF risk categorization for software as a medical device (SaMD)

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	**IV**	**III**	**II**
Serious	**III**	**II**	**I**
Non-serious	**II**	**I**	**I**

- IMDRF approach to clinical evaluation for SaMD

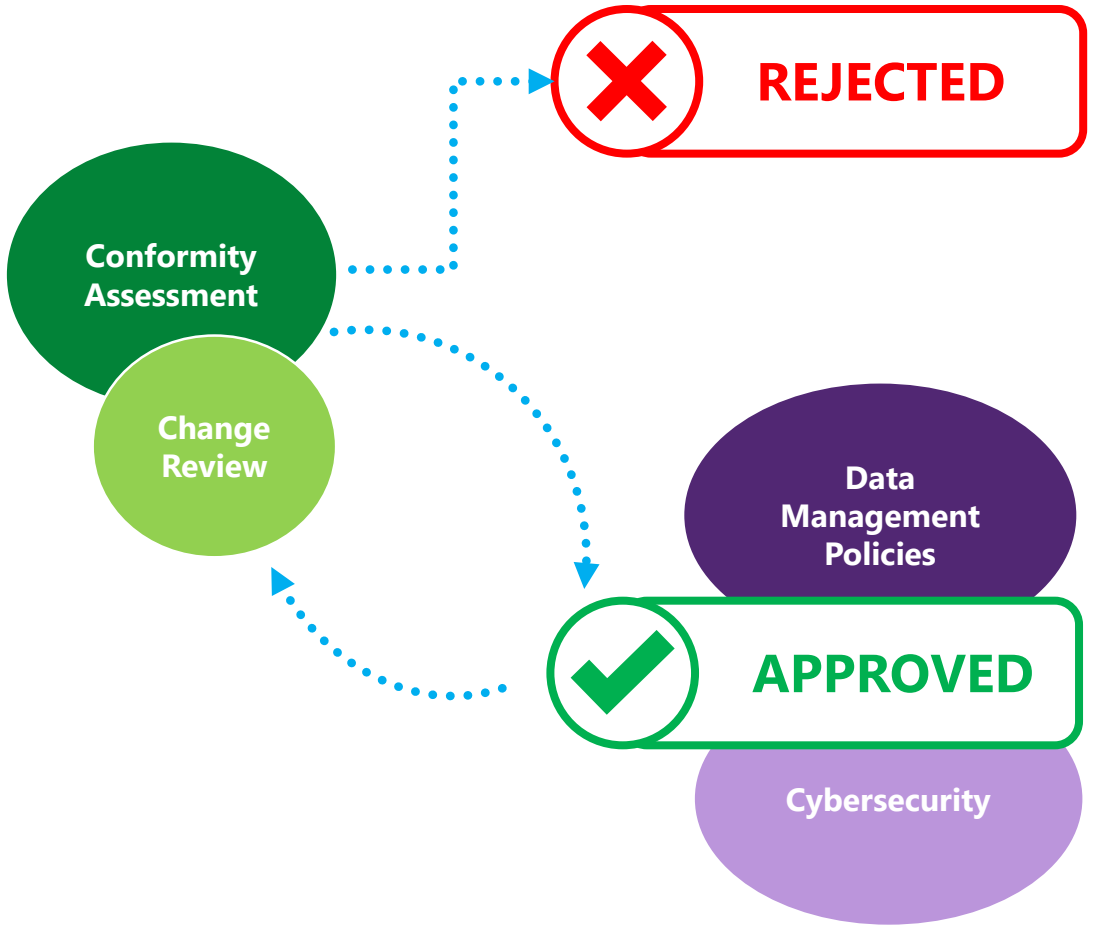
Clinical Evaluation		
Valid Clinical Association	**Analytical Validation**	**Clinical Validation**
Is there a valid clinical association between your SaMD output and your SaMD's targeted clinical condition?	Does your SaMD correctly process input data to generate accurate, reliable, and precise output data?	Does use of your SaMD's accurate, reliable, and precise output data achieve your intended purpose in your target population in the context of clinical care?

Korea MFDS – Current Approach



Def: Standalone software that diagnose or predict diseases by analyzing big data

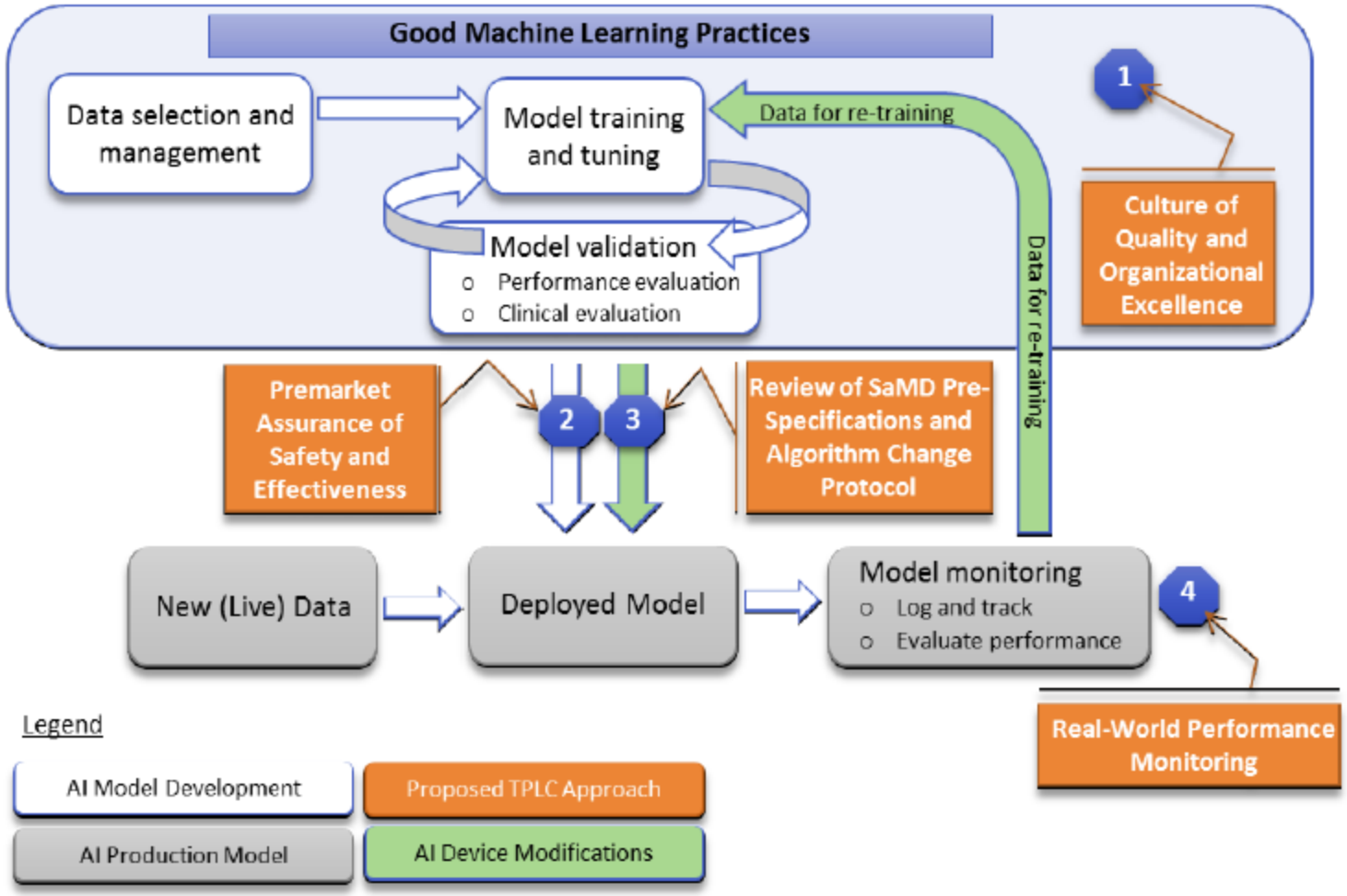
Existing Category
Medical Imaging
Organ Function Test
Blood Test
New (Draft) Category
Vital Signs
Human-derived sample



US FDA – Current Approach

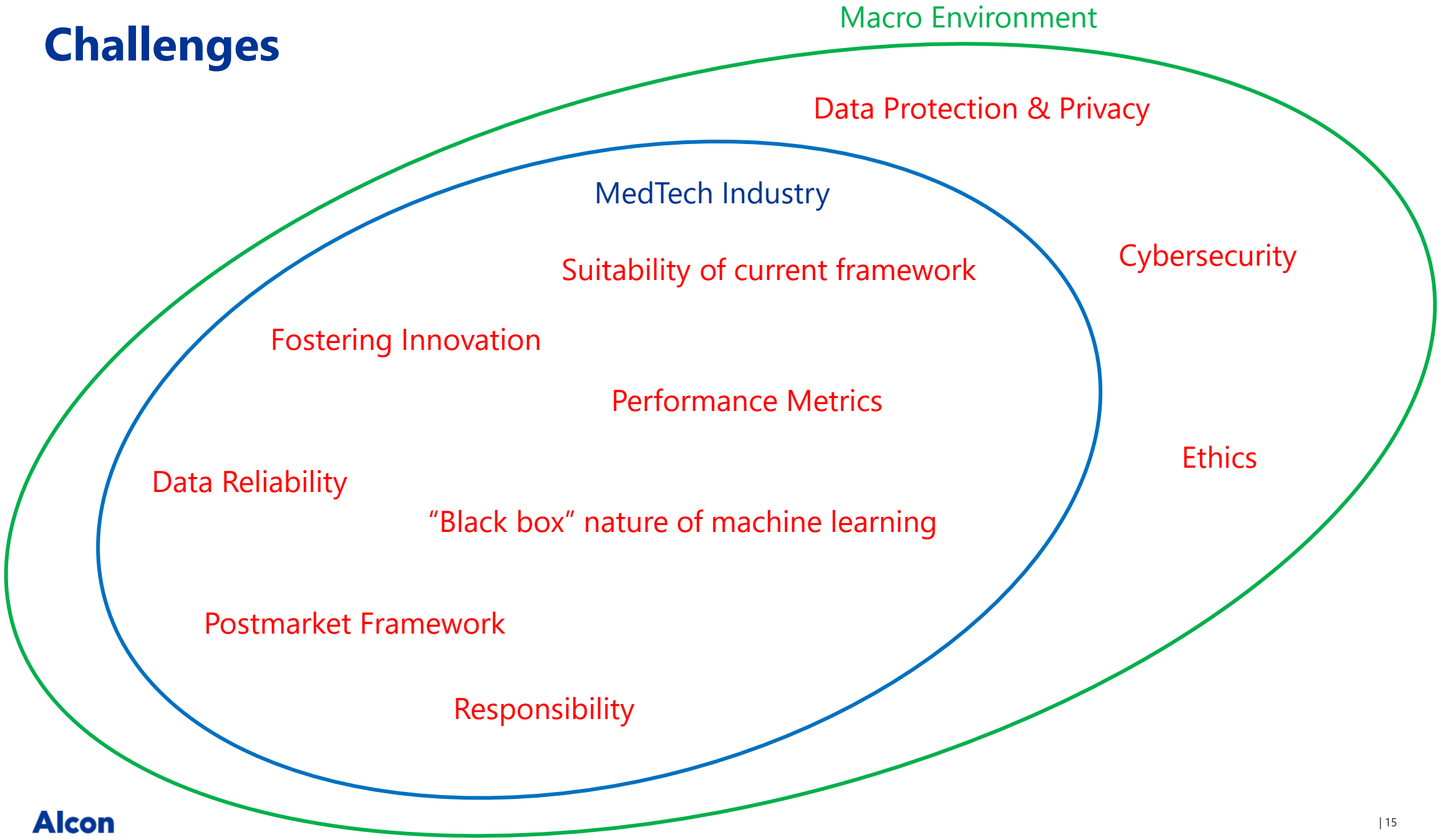
- Artificial Intelligence MD is a subset of SaMD
- Device must submit marketing application to FDA prior to initial distribution of their MD, based on the risk of the SaMD (510k, De Novo or PMA)
- For software cleared under 510k, premarket submissions is required if it falls within specific category of change defined by software modification guidance
- For PMA-approved SaMD, a supplemental application would be required for changes that affect safety or effectiveness, such as new indications for use, new clinical effects, or significant technology modifications that affect performance characteristics

US FDA – Total Product Lifecycle (Proposal)

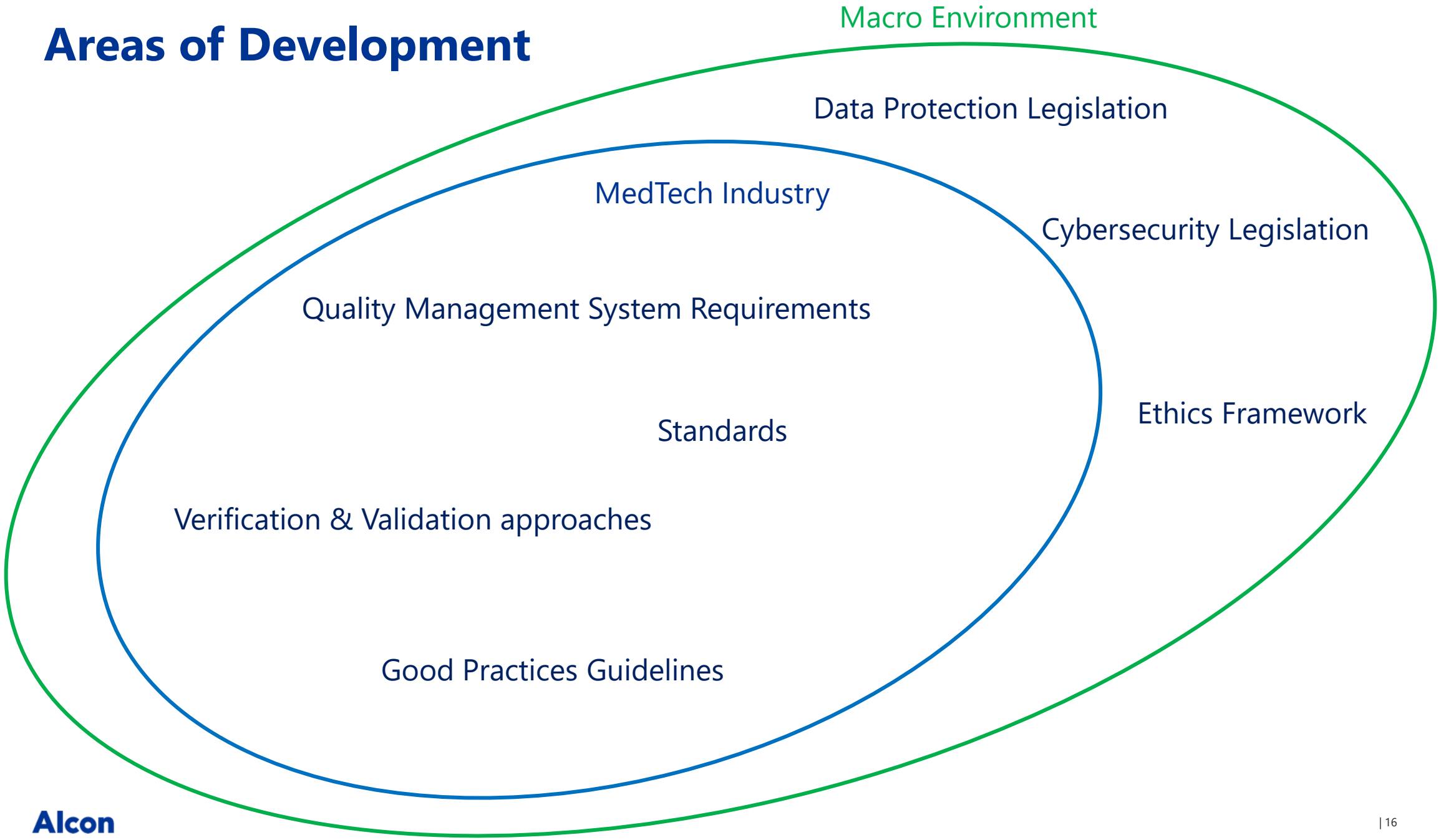


1. QMS and **Good Machine Learning Practices** (GMLP)
2. Pre-market assurance of safety and effectiveness relying on the principle of a predetermined change control plan
   - **SaMD Pre-Specifications** (SPS)
   - **Algorithm Change Protocol** (ACP)
3. Approach for modifications to AI/ML SaMD
4. Transparency and real-world performance monitoring

Challenges

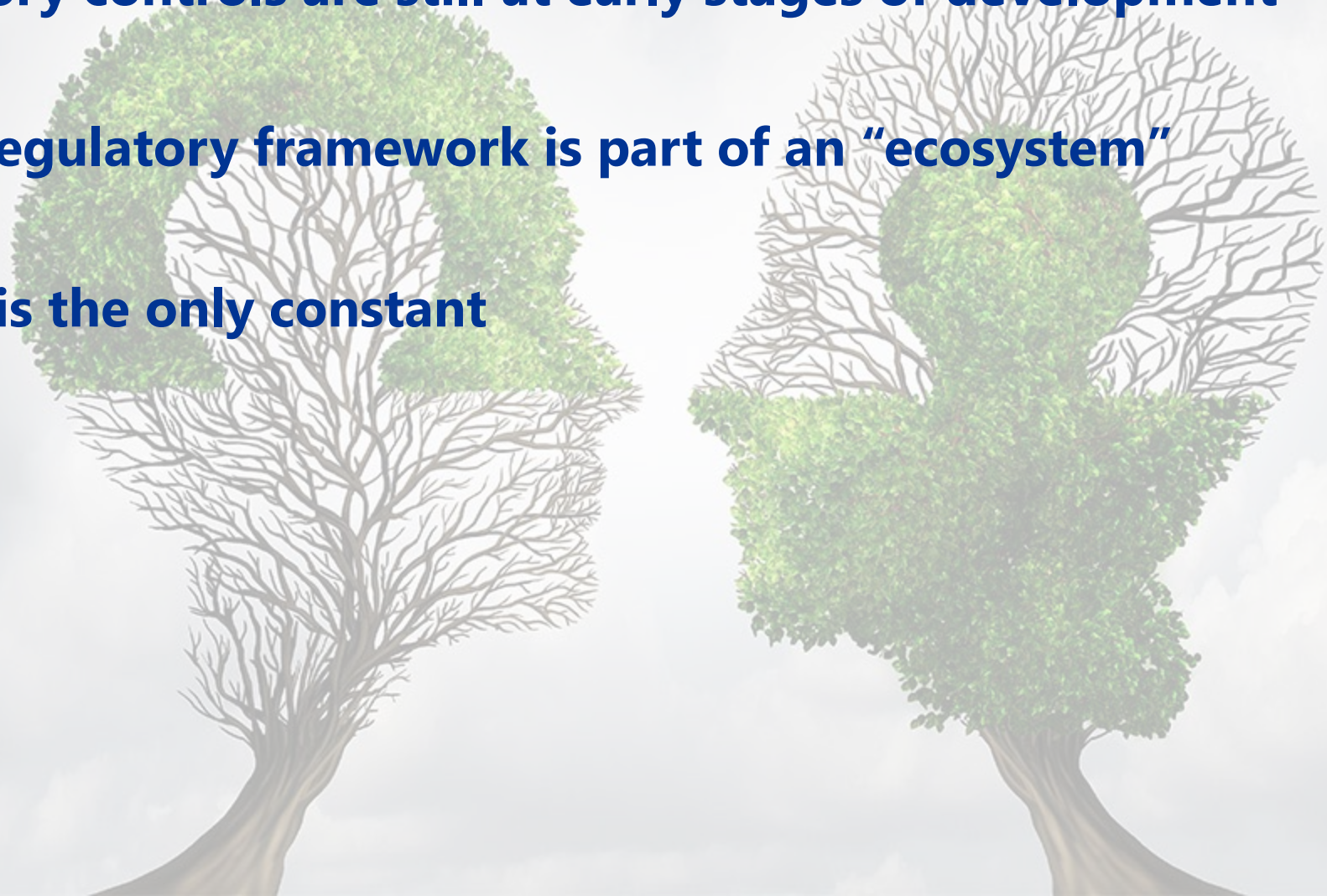

Macro Environment
Data Protection & Privacy
MedTech Industry
Cybersecurity
Suitability of current framework
Fostering Innovation
Performance Metrics
Ethics
Data Reliability
“Black box” nature of machine learning
Postmarket Framework
Responsibility

Areas of Development



Summary

- Regulatory controls are still at early stages of development
- Device regulatory framework is part of an “ecosystem”
- Change is the only constant




Alcon
SEE BRILLIANTLY