An overview of medical devices

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USAID FROM THE AMERICAN PEOPLE

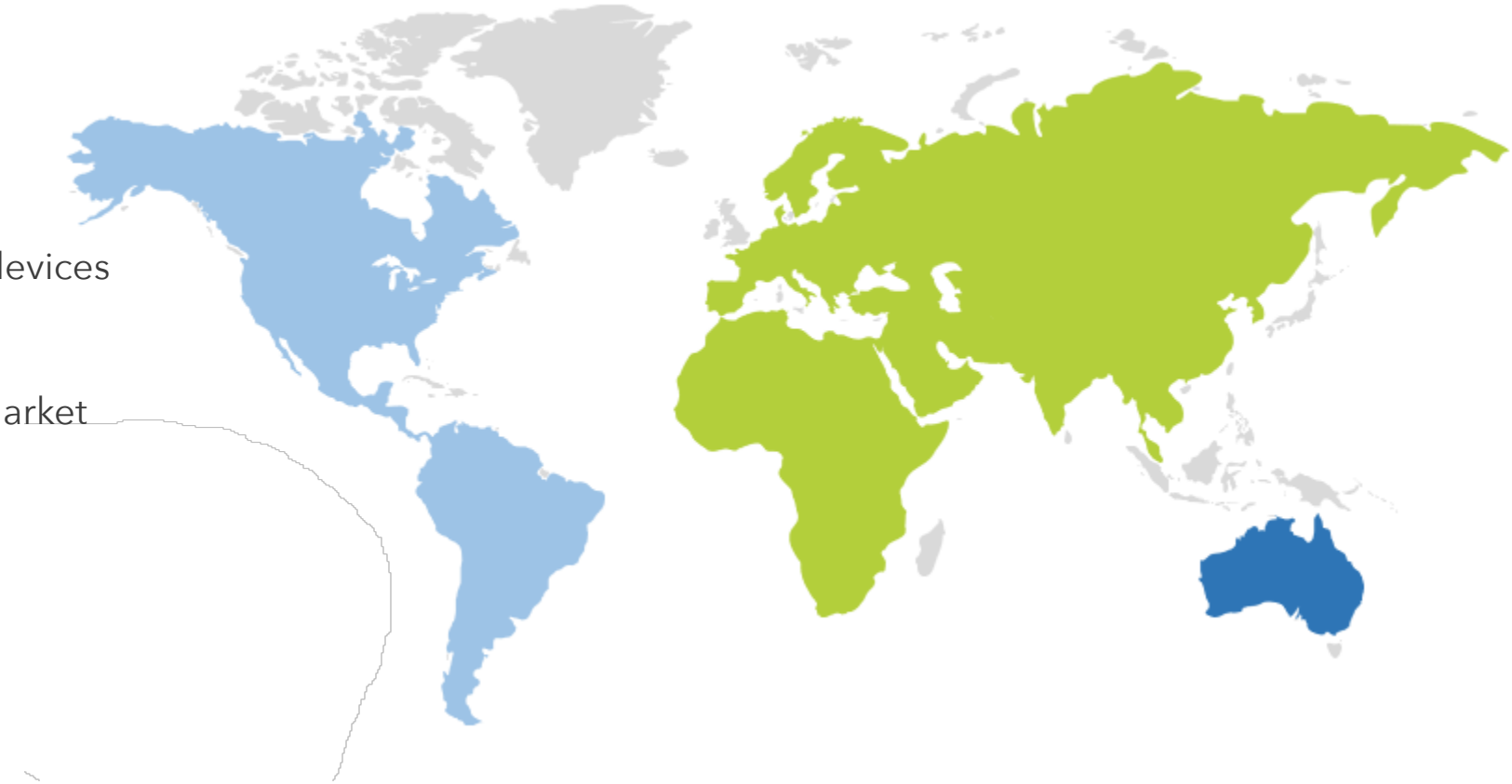
ANSI American National Standards Institute

Standards Alliance

SAHPRA South African Health Products Regulatory Authority

Agenda

1. Differences between medical devices and pharmaceuticals
2. Definitions of medical devices
3. IMDRF classification of medical devices
4. Steps to bring a new device to market
5. Call for convergence



Though both are vital to healthcare, the medical device and pharmaceutical industries are distinctly different

Two different worlds in one health setting

	Innovation	Technology Lifecycle	Nature	Product Diversity	Compliance	Outcome	Adverse Event
MEDTECH (more than 2,000,000 different products- 6700 Categories)	Physicians Engineering IT	Rapid and iterative	Mostly Mechanical w/ inert effect on body	Diverse product sets	Higher compliance based on professional use	Depends on surgeons' skills & training and patient's response	Adverse events most often local in nature
PHARMA (20,000 Prescription Drugs)	Pharmacology Chemistry Biotechnology Genetics	13 years for patent protection	Chemical Interacts actively w/ body	Limited products and therapeutic areas	Compliance dependent on patient use	Dependent on patient response to therapy	Patient system toxicity

Drugs yesterday, today and tomorrow

As simple as a tongue depressor or a thermometer

As complex as robotic surgery devices

Intended use

as defined by the manufacturer is a significant factor in determining whether a product is regulated as a medical device

Unregulated

Intended for fitness and general wellness

Regulated

Intended for diagnosing medical conditions

Heart rate measurement device

IMDRF definition of "Medical Device"

Medical Device means 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) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensa-tion for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing info by means of in vitro examination of specimens derived from human body

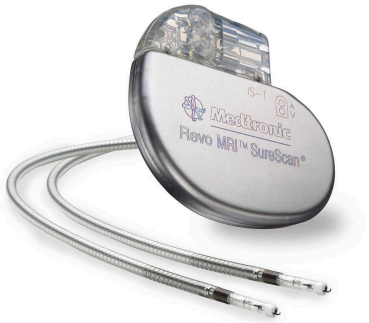
and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but may be assisted in its intended function by such means

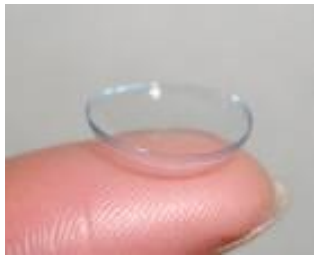
https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf

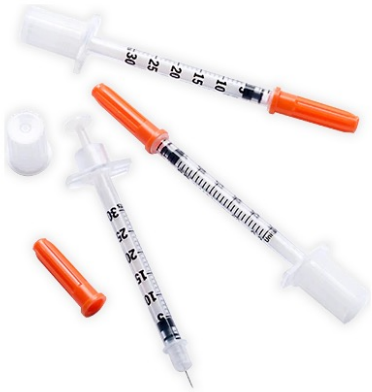
Variability Across Jurisdictions:

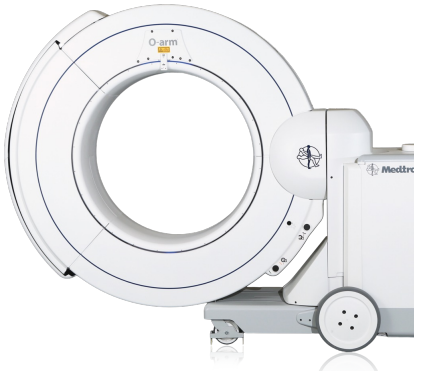
- disinfection substances
- aids for persons with disabilities
- devices incorporating animal and/or human tissues
- devices for in-vitro fertilization or assisted reproduction technologies

Examples of medical devices

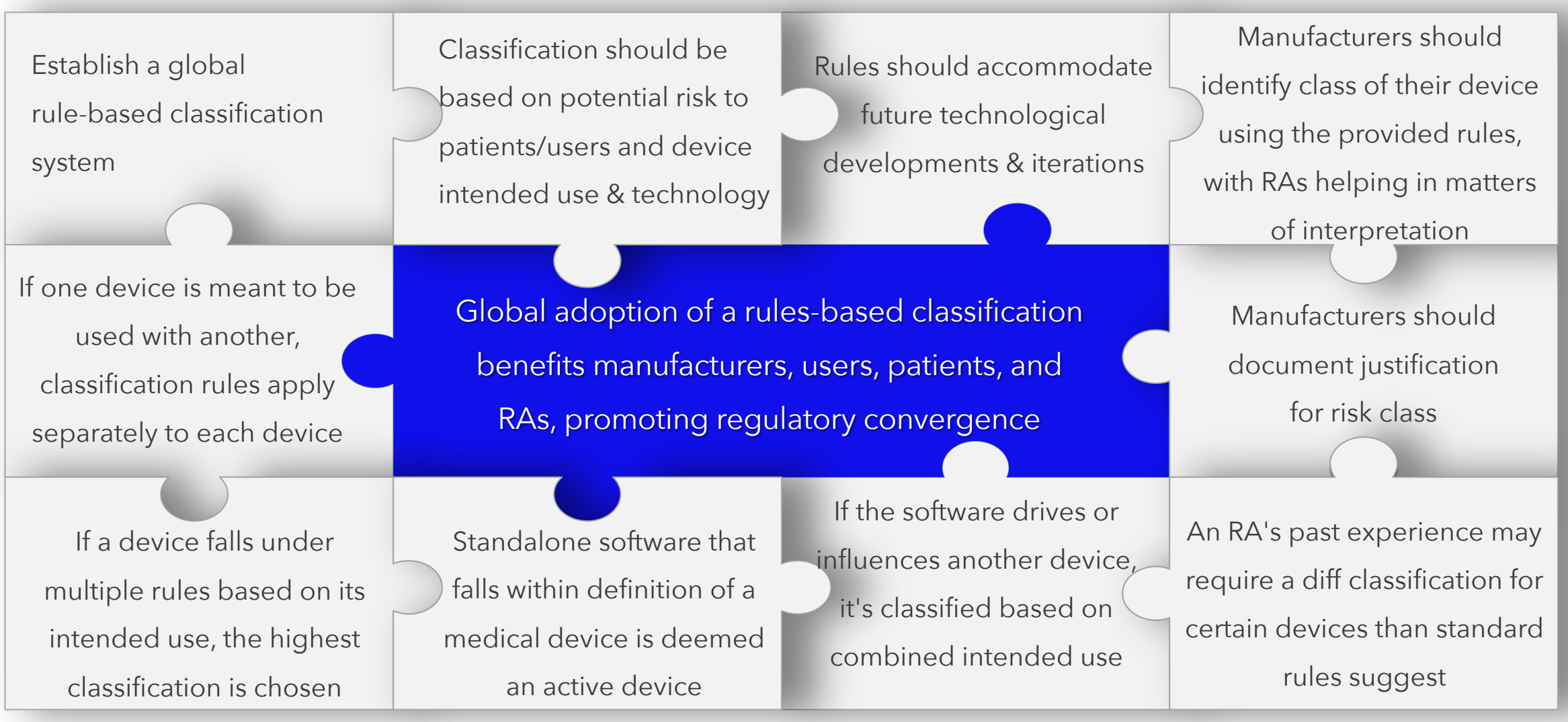








IMDRF classification recommendation for medical devices

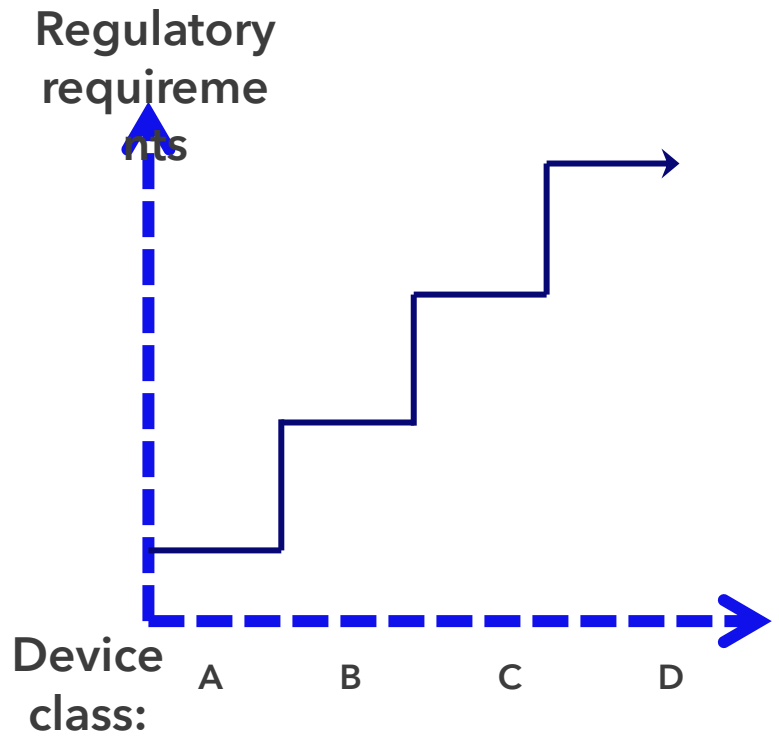


https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

IMDRF proposed classification system for medical devices

WHO also recommends the IMDRF classification

Class	Level	Device examples
D	High risk	Heart valves, implantable defibrillator
C	Moderate-high Risk	Lung ventilator, bone fixation plate
B	Low-moderate risk	Hypodermic Needles, suction equipment
A	Low risk	Surgical retractors, tongue depressors



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https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-wng64.pdf

Understanding global patient access from international manufacturer perspective

Initial markets

- ✓ Transparent and Predictable Regulatory Environment
- ✓ Leverage of International Best Practices and Standards

International Market Expansion Strategy

Following markets

- ➢ Local Testing & Standards
- ➢ Local Inspections
- ➢ Local Labeling Requirements
- ➢ Local Classification
- ➢ Country of Origin Requirements (COO)

Steps to bring a new device to initial markets

Identify classification & regulatory pathway

Classification can inform regulatory pathway and level of evidence needed

Develop valid scientific evidence [1]

Clinical data, bench testing and/or animal studies appropriate to the potential risk of the product

Prepare premarket submission

Each type has own process, law and regulation, review times and evidence requirements

Establish product

Identify intended use, indications for use, duration of use & target patient population

Verify that product is a medical device

1 https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf

https://www.who.int/publications/m/item/who-global-model-regulatory-framework-for-medical-devices-including-in-vitro-diagnostic-medical-devices--annex-3

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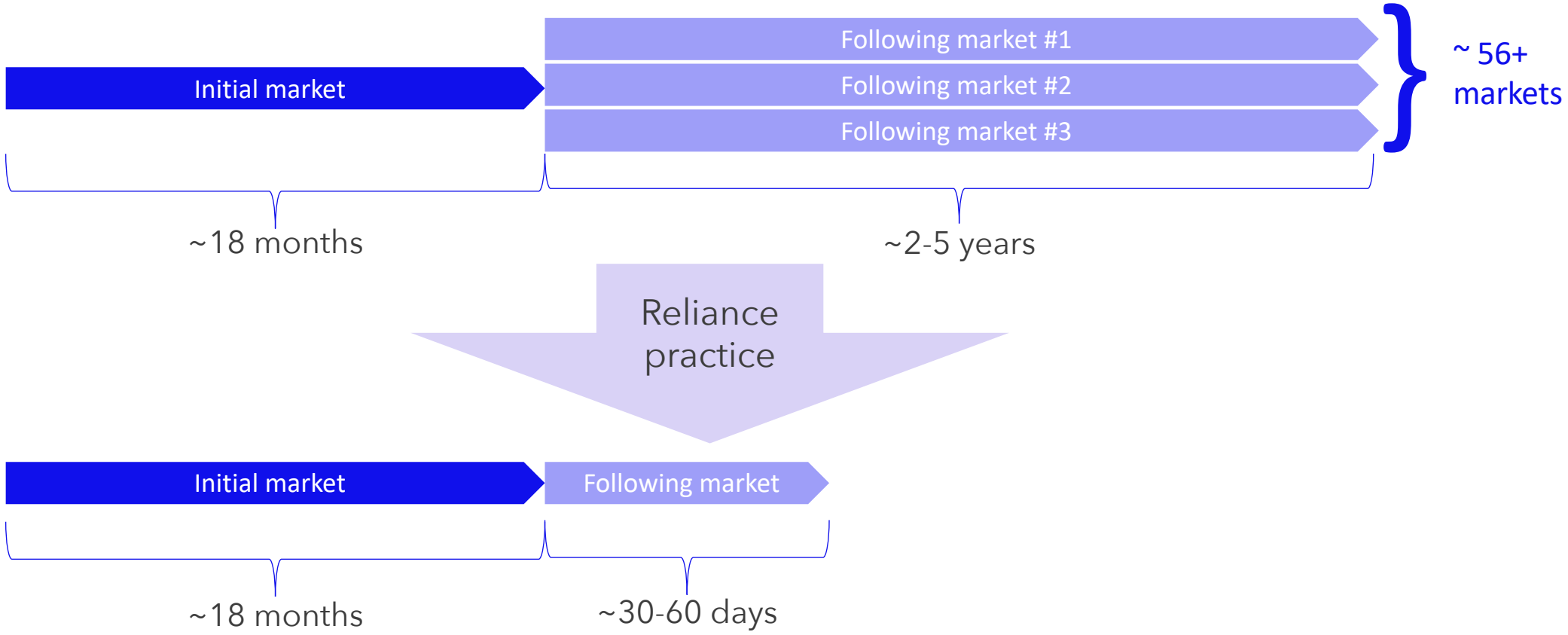
Post-market surveillance

Manufacturers take a comprehensive product lifecycle approach, including ongoing monitoring, vigilance reporting, risk assessment, and continuous improvement

The future of medical products is in convergence, harmonization, trust, and reliance[1]



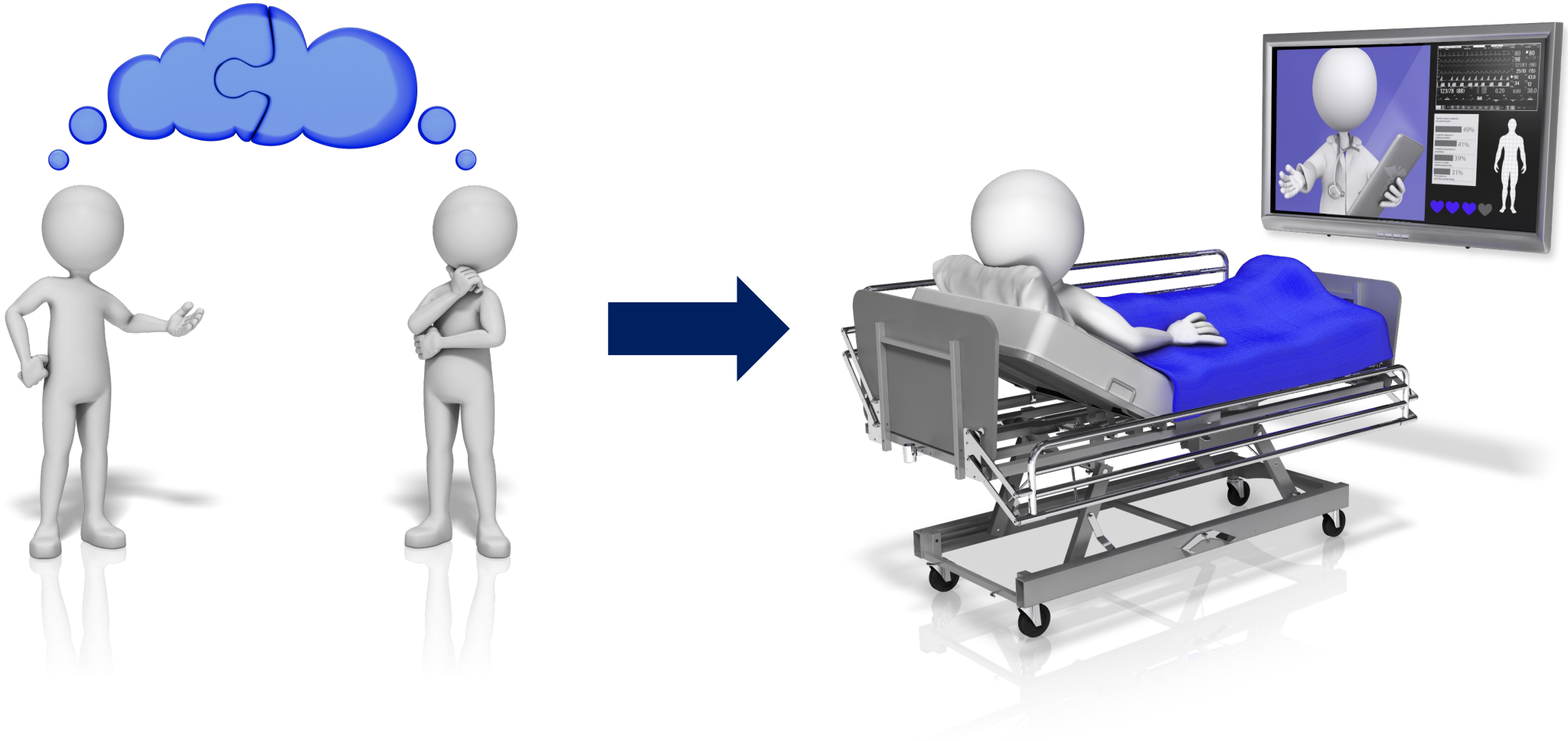
1 "The future of medical products regulation is in convergence/ harmonization, collaboration, and networking based on reliance and trust." Azatyan, S., MD, PhD (2020, November 3). WHO Activities: focus on reliance [Conference Presentation], 10th Asia Regulatory Conference. https://arc.ifpma.org/wp-content/uploads/2016/05/ARC_2020_S.Azatyan-WHO-01-11-2020.pdf, page 16.

Good health is not possible without access to medical products

"Recognizing that effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products."[1]

1 Sixty-seventh World Health Assembly, May 2014: https://apps.who.int/gb/ebwha/pdf_files/WHA67-REC1/A67_2014_REC1-en.pdf

Regulators and manufacturers are committed to timely patient access to safe, effective, and quality medical devices



Ensuring Safety & Efficacy of Medical devices

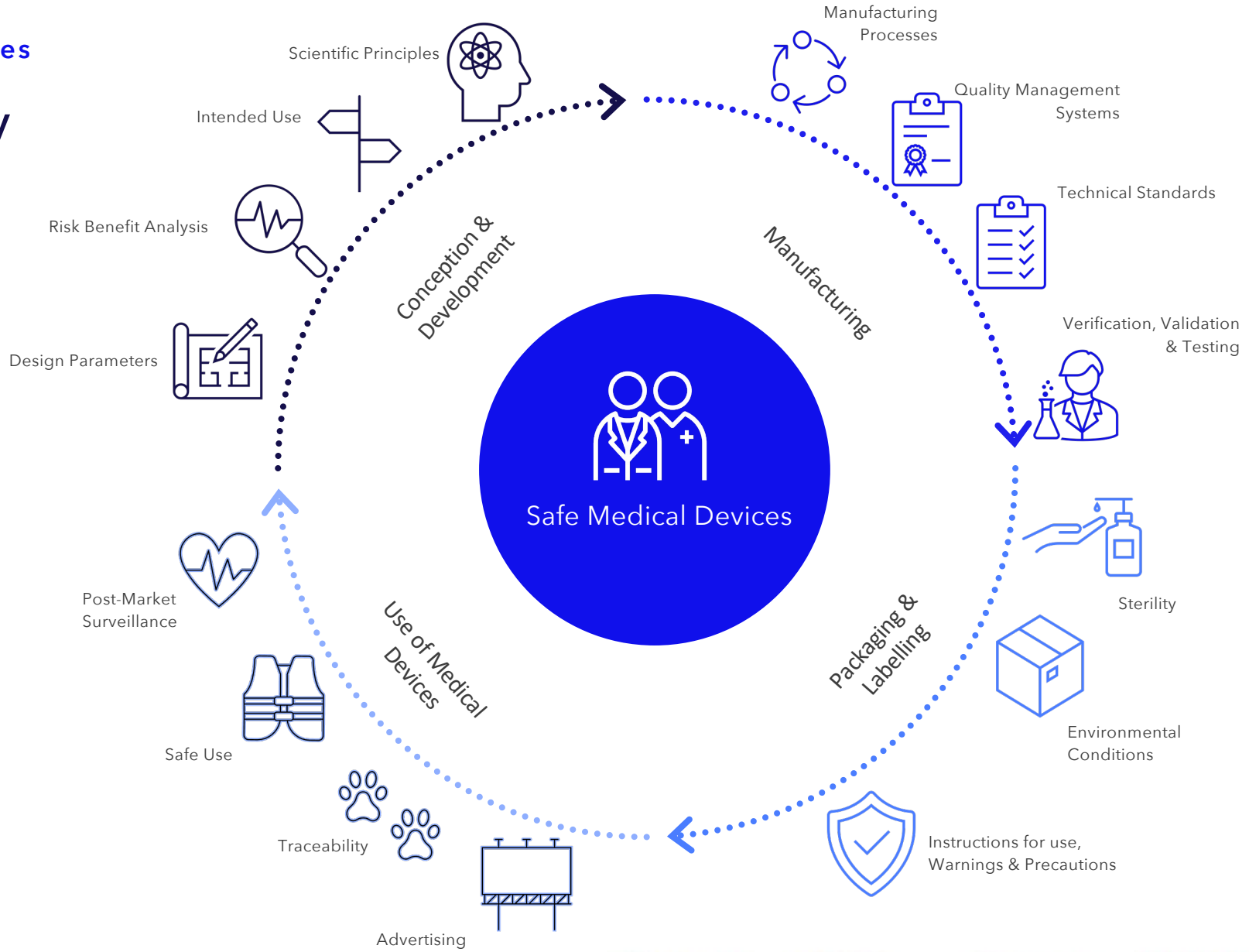
Shared Responsibility

Governments:

- Establish policies and regulations to ensure timely access to medical devices that are both safe and effective, with periodic revisions to accommodate technological advancements
- Foster harmonized regulatory efficiencies
- Drive healthy cooperation and transparency with stakeholders to ensure regulations are streamlined and practical

Manufacturers:

- Ensure products manufactured and maintained to meet or exceed required standards for safety and performance



The call for regulatory convergence and reliance for all regulators

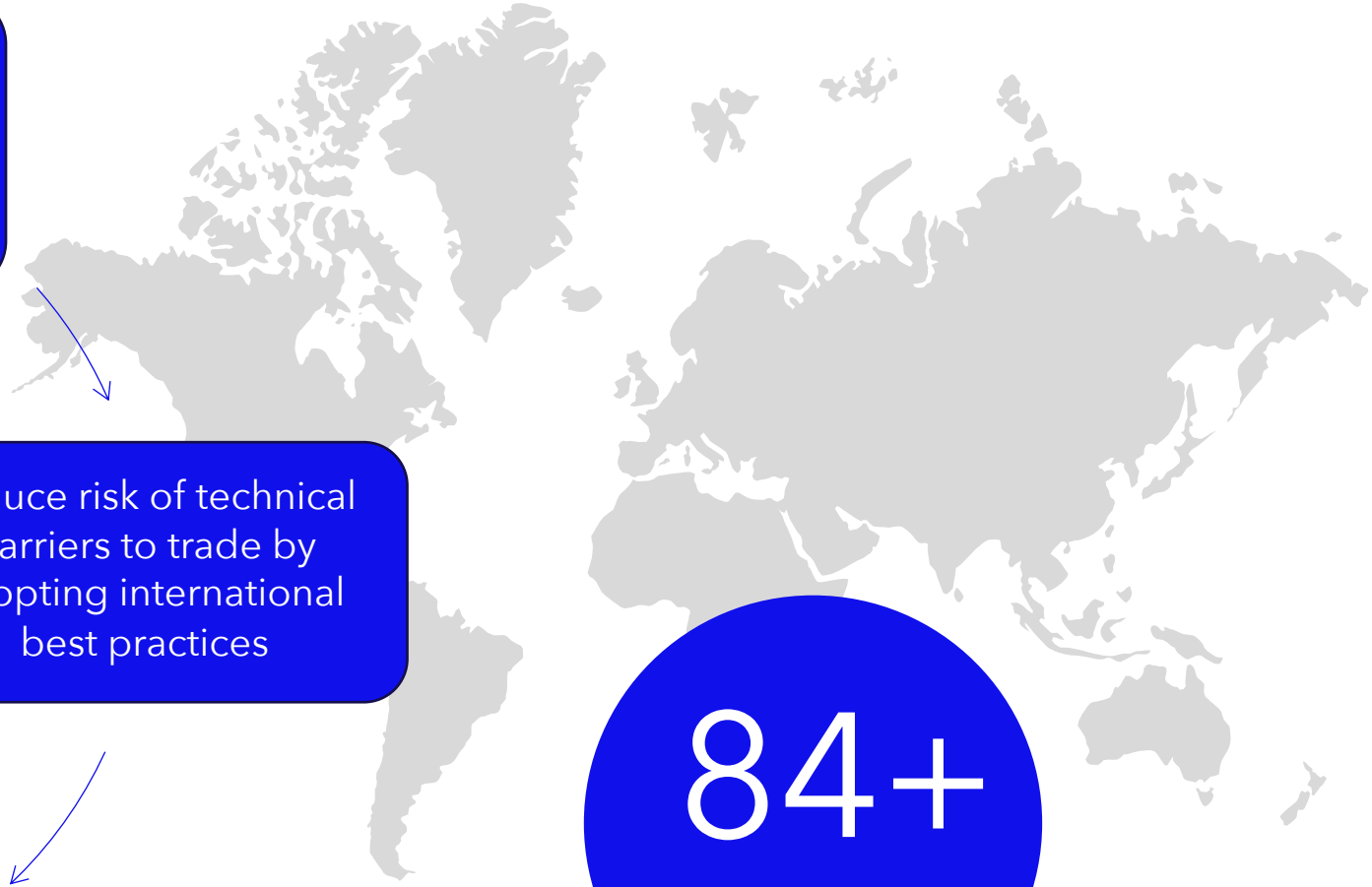
Around the globe

Enhance gov efficiency through collaborative regulation: share audits, exchange info & leverage experiences

Reduce risk of technical barriers to trade by adopting international best practices

Reduce cost and time to market

Increase patient access to innovative medical devices and improve patient outcome



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Medical Devices regulatory Agency around the world

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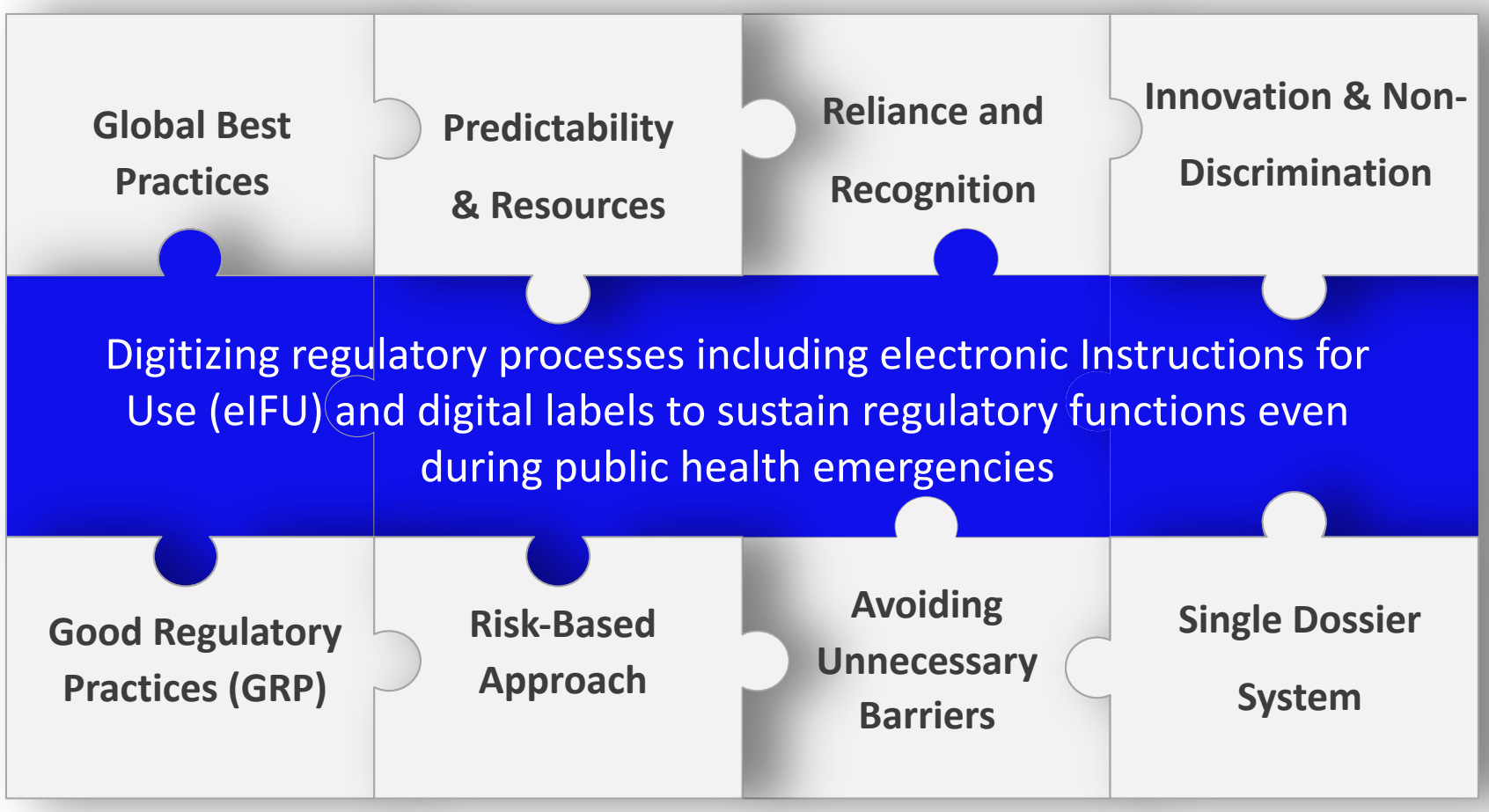
GMTA advocates for Global Convergence in medical device regulation

Foundational principles

- ✓ Adoption of international best practices and standards
- ✓ Regulatory convergence as a cooperative process aligning countries over time
- ✓ Reliance on trusted international documentation and practices to streamline processes

Core tenets



"Coming together is the beginning.
Keeping together is progress.
Working together is success."

Henry Ford

Up next …
IVD overview