Digital Health

Center for Devices and Radiological Health

Bakul Patel

FDA

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Overview

CDRH's vision and approach	• a patient and innovation focused approach
Mobile apps	• a narrowly tailored and focused approach
Health IT strategy and framework	• a non-regulatory strategy that promotes "safe innovation
Software as a medical device	• a path towards international regulatory convergence

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Vision

- **Patients** in the U.S. have **access** to high-quality, safe, and effective medical devices of public health importance first in the world.
- The U.S. is the world's leader in regulatory science, medical device **innovation** and manufacturing, and radiation-emitting product safety.
- U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and **facilitates** device approval or clearance.
- Devices are legally marketed in the U.S. and remain **safe, effective, and of high-quality.**
- Consumers, patients, their caregivers, and providers have **access to understandable science-based information** about medical devices and use this information to make health care decisions.

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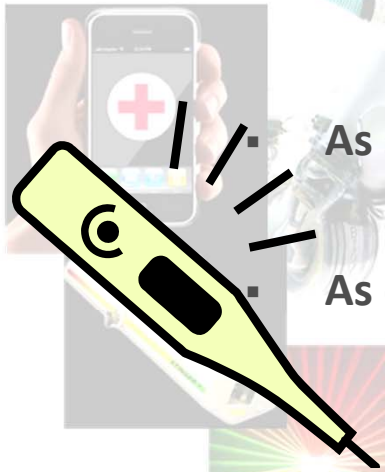
Medical device

The Section 201(h) of the Food, Drugs and Cosmetics Act defines a medical device as any product with medical purpose that does not achieve its principal intended purposes by chemical action or by being metabolized.



- **As simple as a tongue depressor or a thermometer**
- **As complex as robotic surgery devices**

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A risk based approach for medical devices since 1976

Increasing Risk

Classification determines extent of regulatory control (Risk Based)

Class I
- General Controls

Class II
- General controls
- Special controls

Class III
- General controls
- Premarket approval (PMA)

General Controls
- Electronic Establishment Registration
- Electronic Device Listing
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)
- Premarket Notification [510(k)] (unless exempt)

Special Controls (addressing Risk)
- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Recommendations or Other Actions
- Special Labeling (e.g., 882.5970, Cranial Orthosis)

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Smart Regulation

Platform independent

Promote innovation

Promote patient engagement

Protect patient safety

Functionality focused

Narrowly tailored

Risk based

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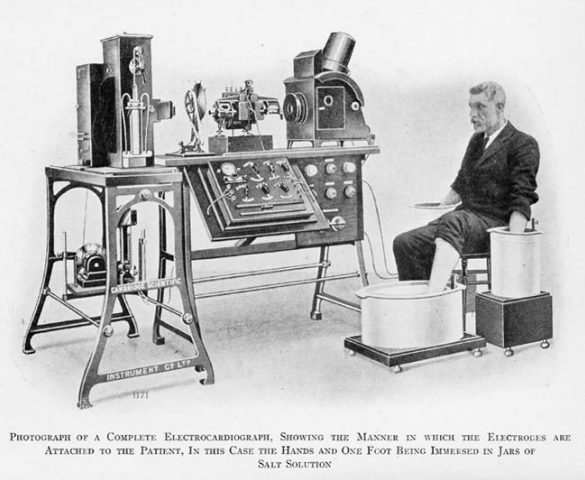
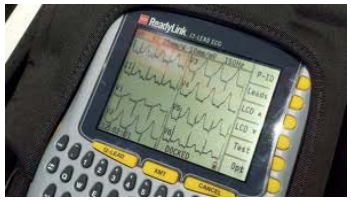
Functionality focused (EKG machine)



PHOTOGRAPH OF A COMPLETE ELECTROCARDIOGRAPH, SHOWING THE MANNER IN WHICH THE ELECTRODES ARE ATTACHED TO THE PATIENT, IN THIS CASE THE HANDS AND ONE FOOT BEING IMMERSED IN JARS OF SALT SOLUTION



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Mobile apps

- a narrowly tailored and focused approach

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500 million

Smartphone users will be using health apps by 2015[1]

1 Research2Guidance 2010

"By the end of 2017, the total mHealth market revenue will have grown by 61% (CAGR) to reach US$26 billion." [2]

[2] research2guidance report 2013-2017

Health related mobile apps –landscape

- *Apple App Store – 43,000 apps (health related categories)*
  - *Healthcare & Fitness (23,728) + Medical (19,484)* (according to http://148apps.biz/ as reported on September 09, 2013)

- *"The **healthcare apps market is dominated by exercise apps** …. Sleep and meditation, and weight loss apps are expected to grow at the highest CAGR during the forecast period."* – September 2013 Researchandmarket report -- http://www.researchandmarkets.com/research/6hlqd6/mhealth_apps_and

- *Breakdown of available health-related apps – M. Shaw., Health digest news*
  - ***96 %*** *-- Calorie counting, Cardiovascular fitness, Strength training, Sleep improvement – consumer focused*
  - *remaining 4 % -- more specialized apps, for e.g. remote patient monitoring."*

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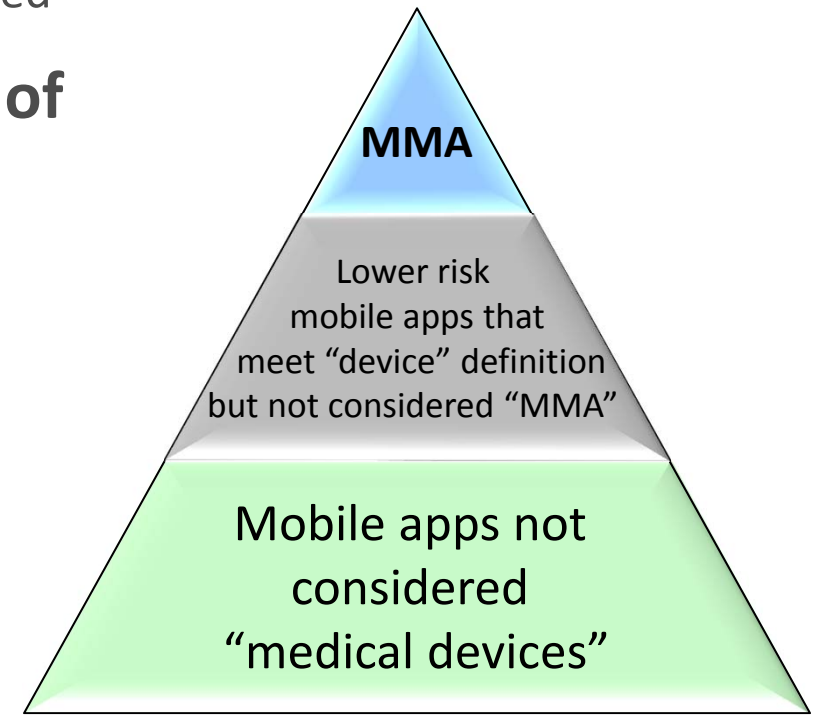
Focused oversight

- **Focuses only on traditionally regulated functionality**
  - Cleared, approved or otherwise regulated
- **Provides users with same level of assurance of patient safety**
- **Identifies types app that FDA does not intend to enforce requirements**
- **Clarifies what is not a device – (Outside of FDA's Jurisdiction)**



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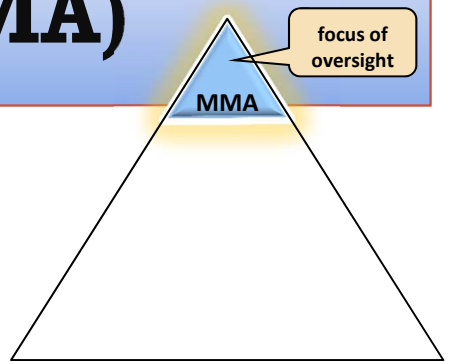
Mobile medical apps (MMA)



"mobile medical app" is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ; and either is intended:

- to be used as an accessory to a regulated medical device; **or**
- to transform a mobile platform into a regulated medical device

Examples in Section V-A + Appendix C

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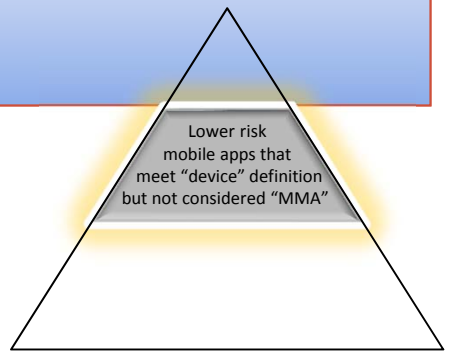
Mobile apps – under enforcement Discretion



- **Examples.. (See Section V-B + Appendix B)**
  - Apps that coach patients with conditions such as cardiovascular disease, hypertension, diabetes, obesity or other disease or conditions
  - Apps that provide calculator tools such as Mean arterial pressure, Glascow Coma Scale score, APGAR score, NIH Stroke Scale
  - Apps that provide a clinician with best practice treatment guidelines for common illnesses or conditions
  - Apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications between patients, healthcare providers, and caregivers

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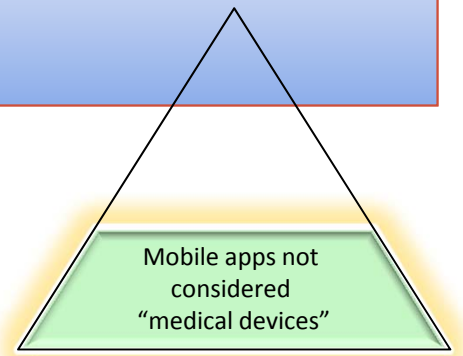
Mobile apps – not medical devices



- **Appendix A**
- Library of clinical descriptions for diseases and conditions;
- Medical flash cards with medical images, pictures, graphs, etc.;
- Medical board certification or recertification preparation apps;
- Games that simulate various cardiac arrest scenarios to train health professionals in advanced CPR skills.
- Allow users to input pill shape, color or imprint and displays pictures and names of pills that match this description;
- Find the closest medical facilities and doctors to the user's location;
- Help guide patients to ask appropriate questions to their physician
- Help patients track, review and pay medical claims and bills online;
- Manage or schedule hospital rooms or bed spaces

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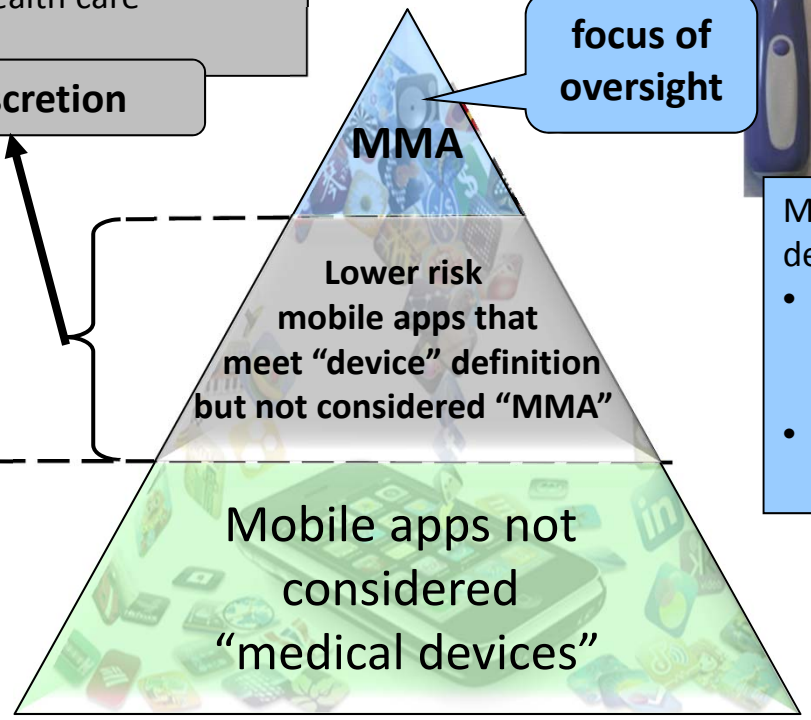
Mobile medical apps (MMA)

- Patient self-management apps
- Tools to organize and track their health information (not for treating or adjusting medications)
- Tools to access to health information document and communicate with health care providers
- Tools that automate simple health care providers tasks

Enforcement Discretion

No regulatory requirements



focus of oversight

Mobile apps that meet "device" definition that are either intended

- To be used as an accessory to already regulated medical device,

or

- To transform a mobile platform into a regulated medical device.

Addressing evolving landscape

- **Web page for mobile medical app**
  - http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm

- **FDA, on this website intends to have a list of**
  - exemplary types that we intend to exercise enforcement discretion, regulate or have considered not devices.

- **Questions – MobileMedicalApps@FDA.HHS.gov**

- **Provide internal coordination to maintain consistent policy decisions related to mobile medical apps**

Health IT strategy and framework

- a non-regulatory strategy that promotes “safe innovation

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FDASIA Health IT Report
Categories of Health IT Functionality

Administrative Functionality*	Health Management Functionality*	Medical Device Functionality*
• Admissions; • Billing and claims processing; • Practice and inventory management; • Scheduling; • General purpose communications; • Analysis of historical claims data; • Determination of health benefit eligibility; • Reporting communicable diseases; • Reporting on quality.	• Health information and data management; • Data capture and encounter documentation; • Electronic access to clinical results; • Most clinical decision support; • Medication management; • Electronic communication (e.g. provider-patient, provider-provider, etc.); • Provider order entry; • Knowledge management; • Patient ID and matching.	• Computer aided detection software; • Remote display or notification of real-time alarms from bedside monitors; • Radiation treatment therapy planning software; • Arrhythmia detection. * Examples provided. Not intended to be an exhaustive list of functionalities.
No Additional Regulatory Oversight	Primary Focus of Proposed Health IT Framework	Primarily FDA Oversight

FDASIA Health IT Report
Strategy and Recommendations for Health Management Health IT Framework

- Promote the Use of Quality Management Principles
- Identify, Develop, and Adopt Standards and Best Practices
- Leverage Conformity Assessment Tools
- Create an Environment of Learning and Continual Improvement

Health IT Safety Center

FDASIA Health IT Report
Clinical Decision Support

Encompasses tools intended to enhance, inform, and influence health care decisions.

Health Management Functionality[1]

- Clinician order sets;
- Drug-drug interactions and drug-allergy contraindication alerts;
- Drug dosing calculations;
- Drug formulary guidelines;
- Reminders for preventative care;
- Access to treatment guidelines;
- Calculation of prediction rules.

Medical Device Functionality[2]

- Computer aided detection/diagnostic software;
- Remote display or notification of real-time alarms from bedside monitors;
- Radiation treatment planning;
- Robotic surgical planning and control;
- Electrocardiography analytical software.

[1] If a product with health management functionality meets the statutory definition of a medical device, FDA does not intend to focus its oversight on it.

[2] CDS that have medical device functionality and present higher risks warrant FDA's continued focus and oversight.

The Agencies will engage in a public process that includes a public meeting and public comment period, and FDA's issuance of draft guidance for public comment to clarify the types of medical device clinical decision support that should be the focus of FDA's oversight.

Software as a medical device

- a path towards international regulatory convergence

Goals

- International convergence and common understanding of Software as a Medical Device (SaMD):
  - Generic types of SaMD
  - Generic risks of SaMD that affect public health
  - Expectations of controls required to minimize generic risk

- Establish a framework for regulators to incorporate converged controls into their regulatory paths or classifications.

Framework Overview

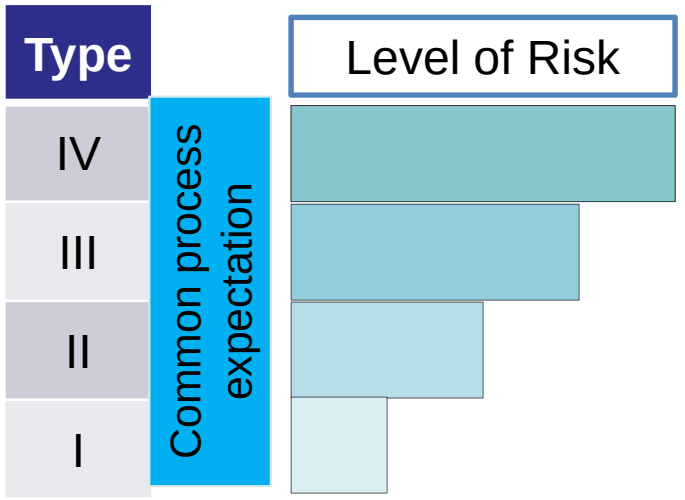
SaMD definition statement:
- Significance of recommendation
- Context of use

Risk Categorization

9 criteria based on definition statement

4 Categories based on similarity of impact

General and Special Controls Considerations



Criticality of context

- Critical situation or condition
  - where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health.
- Serious situation or condition
  - where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions
- Non-Serious situation or condition
  - where an inaccurate diagnosis and treatment is important but not critical for interventions

Significance of information

- To treat or to diagnose
  - To provide therapy to a human body;
  - To diagnose/screen/detect a disease or condition
- To drive clinical management
  - To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
  - To aid in making a definitive diagnosis.
  - To triage or identify early signs of a disease or conditions.
- To Inform clinical management
  - To inform of options
  - To provide clinical information by aggregating relevant information

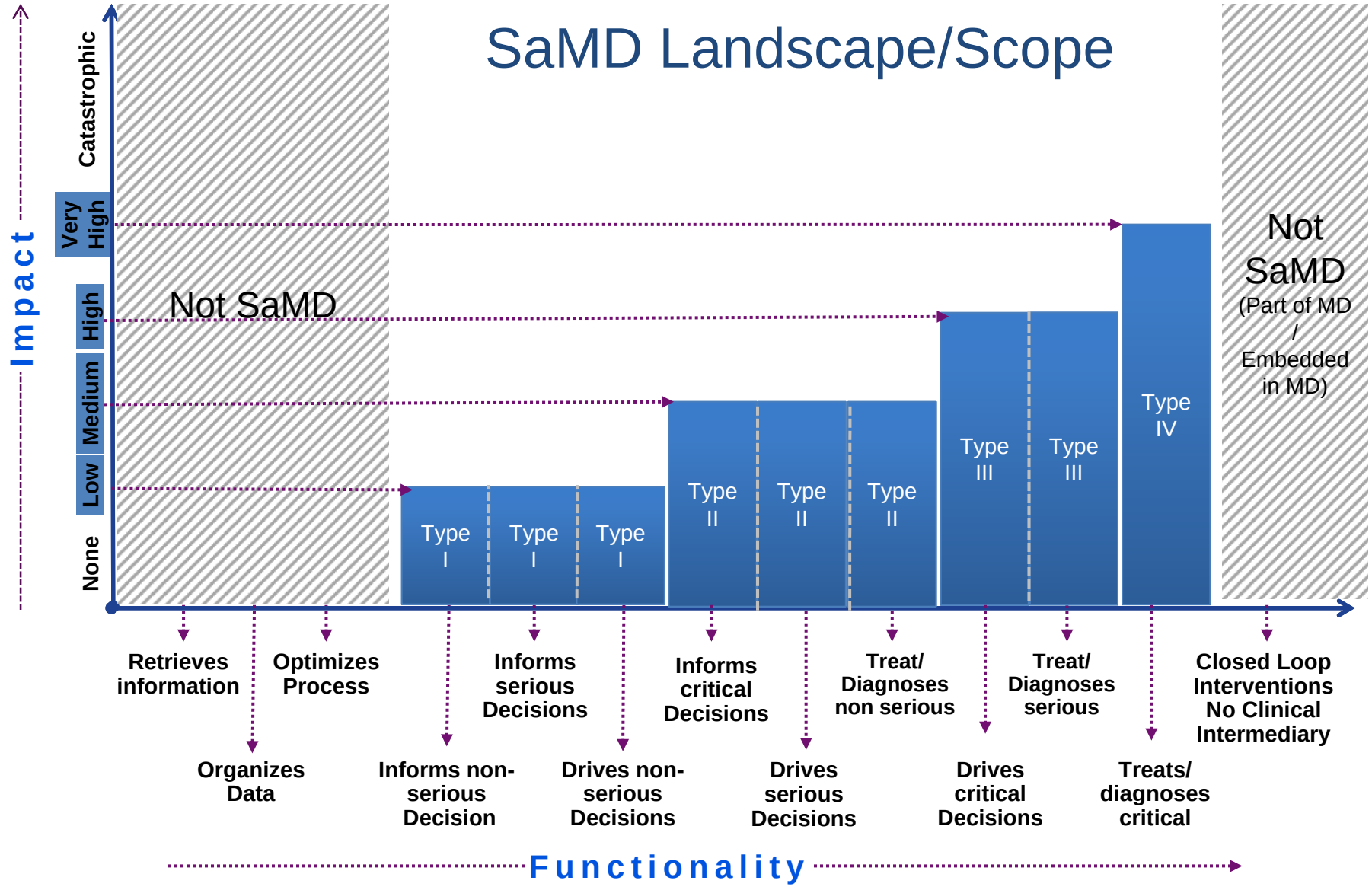
SaMD Categorization

Increasing significance

Increasing criticality

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 International Medical Device Regulators Forum



In Summary

Digital Health

- Beneficial to drive better health outcomes
- Enables patients empowerment
- Enables efficient health care – processes and decisions

FDA's Policies Drive Towards…

- Promoting patient engagement technologies
- Providing regulatory clarity by using focused regulatory oversight
- Understanding and addressing stakeholder needs and expectations

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