FDA and TeleHealth: An Evolving Landscape

Marisa L. Cruz, MD
Senior Medical Advisor
Center for Devices and Radiological Health, FDA

www.fda.gov

CDRH Objectives

- Enable "**patient-centered**" public health.

- Foster **trust in innovative technologies** as an enabler of a new health care paradigm.

- **Partner with customers** to be "digital-future ready".

2014
2015
2016
2017

RF Wireless Guidance

Mobile Medical App (MMA) Guidance

FDASIA Health IT Report

Premarket Cybersecurity Guidance

Medical Device Data Systems Guidance

MMA Guidance Update

General Wellness Guidance

Medical Device Accessories Guidance

Post-market Cybersecurity Guidance

Interoperability Guidance

FDA Approach to TeleHealth Products: The Upshot

- Tailored, risk-informed regulatory approach

- General wellness apps and MDDS products under enforcement discretion

- Focus on digital health/telehealth products whose functionality could pose a risk to patient safety if the product does not function as intended

Legislation and TeleHealth: Recent Developments

- 21st Century Cures Act codifies FDA approach by excluding MDDS and general wellness apps from definition of a medical device.

- MDUFA IV underscores importance of Digital Health by requiring the establishment of a Digital Health Unit, and requiring that the agency explore new premarket pathways and use of RWE in evaluating DH products.

Digital Health Innovation Action Plan

FDA

An Integrated Approach

Refine policies & provide guidance

> Issue guidance conforming to software provisions of the 21st Century Cures legislation

> Revise regulations for products that are not devices post 21st Century Cures

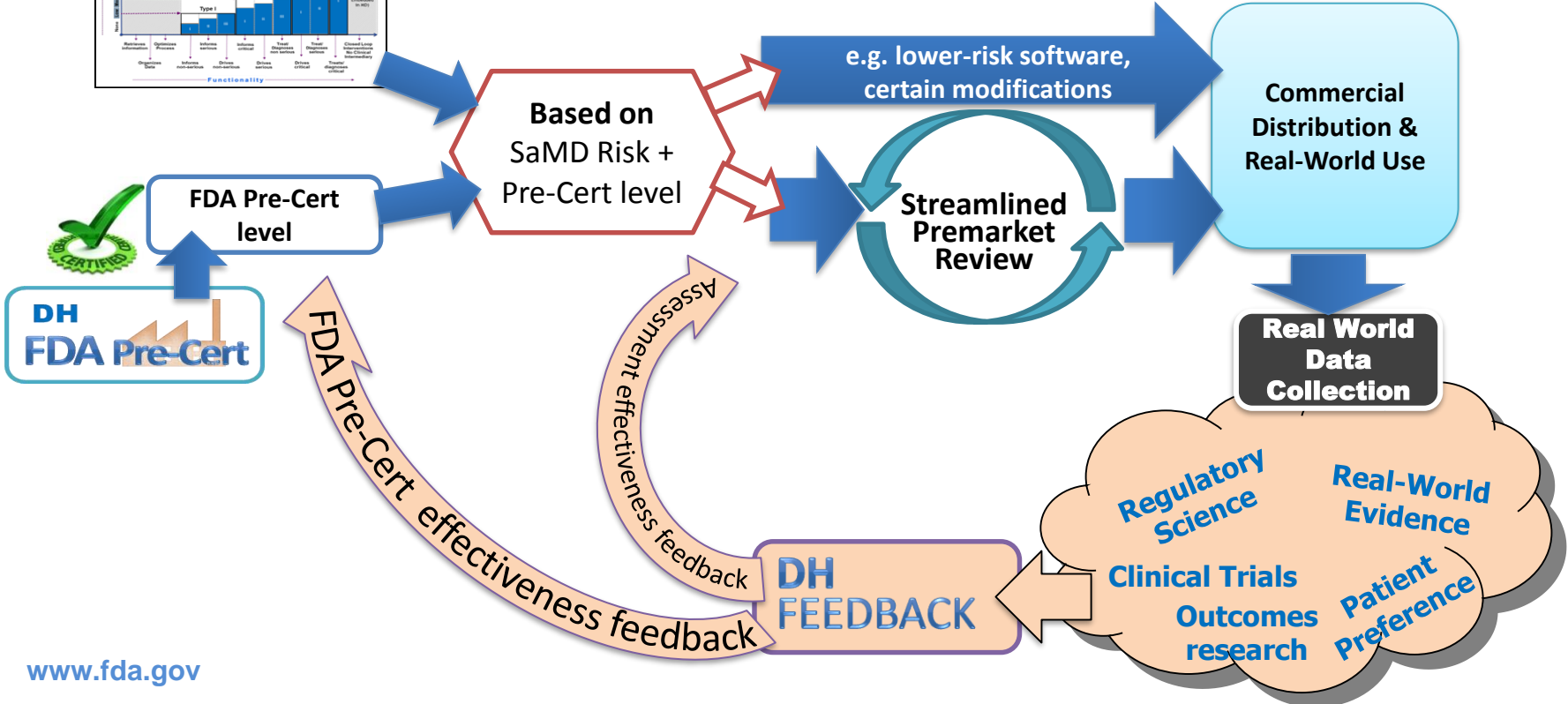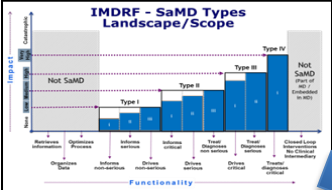**Explore new streamlined pathway for software**

> Launch an innovative pilot Precertification (Pre-Cert) program to build a new approach to digital health technology, working with our customers and leveraging internationally harmonized principles for software regulation

Building bench strength and expertise

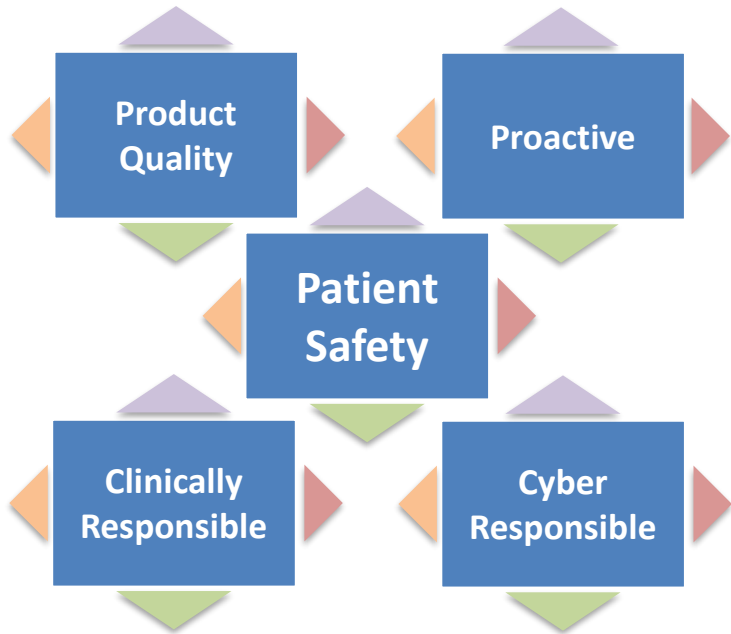> Build Digital Health unit with right technical expertise

> Launch digital health Entrepreneurs-in-Residence program for building the new paradigm

FDA Pre-Cert Pilot Program

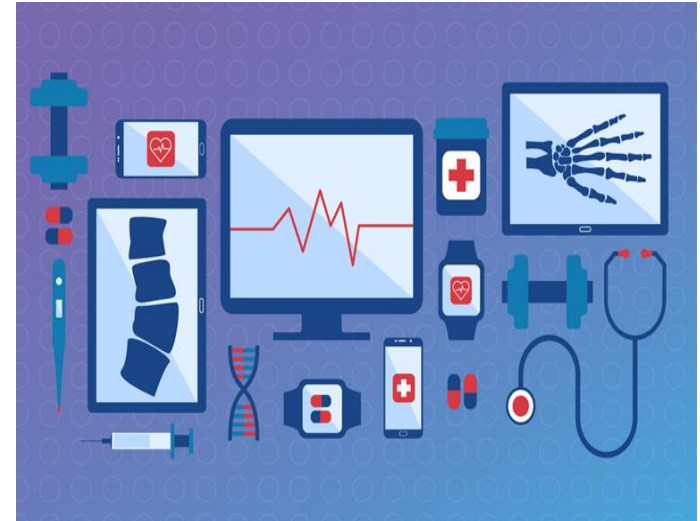# Scorecard Framework

FDA

Excellence Principles

- Product Quality
- Proactive
- Patient Safety
- Clinically Responsible
- Cyber Responsible

Common Validating Perspectives

Internal Processes — Objectives, Measures, Initiatives

Organization/Resource — Objectives, Measures, Initiatives

Customer Processes — Objectives, Measures, Initiatives

Learning and Growth — Objectives, Measures, Initiatives

How will we change and improve continuously toward the excellence principle?

Library of Key performance indicators and measures that demonstrate excellence

TeleHealth and Rural Communities

- FDA recognizes telehealth as an important tool for healthcare delivery in rural communities

- We aim to advance innovation and development in digital health while ensuring patient safety and effectiveness of telehealth devices

Be Part of the Discussion!

- Questions or comments about FDA regulation of telehealth and digital health products? Email digitalhealth@fda.hhs.gov

- Questions or comments about mobile medical apps? Email mobilemedicalapps@fda.hhs.gov

- Feedback on the Pre-Cert Pilot program? Stay tuned for webinar announcements and FAQs at our website: https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/default.htm