IMDRF International Medical Device Regulators Forum

U.S. FDA Center for Devices and Radiological Health Update

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21st Century Cures Implementation

- Establish Breakthrough Device Pathway
- Change HDE Limit to 8000 Patients
- Streamline Process for 510(k) Exemptions
- Modifications to Classification Panels
- Allow for Central IRBs
- Update CLIA Waiver Guidance
- Recognition of Standards
- Train and Audit Least Burdensome
- Clarify Medical Software Regulation
- Cleaning and Validation Data

21st Century Cures Accomplishments

Provision	Implementation actions completed	Date completed
Exemptions (Sec. 3054)	Published lists of Class I and Class II devices exempt from requirement to submit a 510(k)	Final Class I list: April 13, 2017 Final Class II list: July 11, 2017
Humanitarian Device Exemptions (Sec. 3052)	Published amendment to regulations changing the HDE population limit from 4,000 to 8,000	June 7, 2017
Central IRB (Sec. 3056)	Published amendment to regulations removing the word "local" where needed to comply with new law	June 7, 2017
Cleaning/Validation (Sec. 3059)	Published FR Notice identifying reusable device types for which 510(k)s are required to include certain validation instructions for use and validation data regarding cleaning, disinfection, and sterilization	June 9, 2017 (statutory deadline was June 11, 2017)
Classification Panels (Sec. 3055)	Published FR Notice soliciting public input for panel membership; finalized "Procedures for Meetings of the Medical Devices Advisory Committee" guidance addressing Cures-related changes	June 23, 2017 (FR notice) September 1, 2017 (guidance)
Antimicrobial Susceptibility Testing (Sec. 3044)	Held public workshop	September 13, 2017

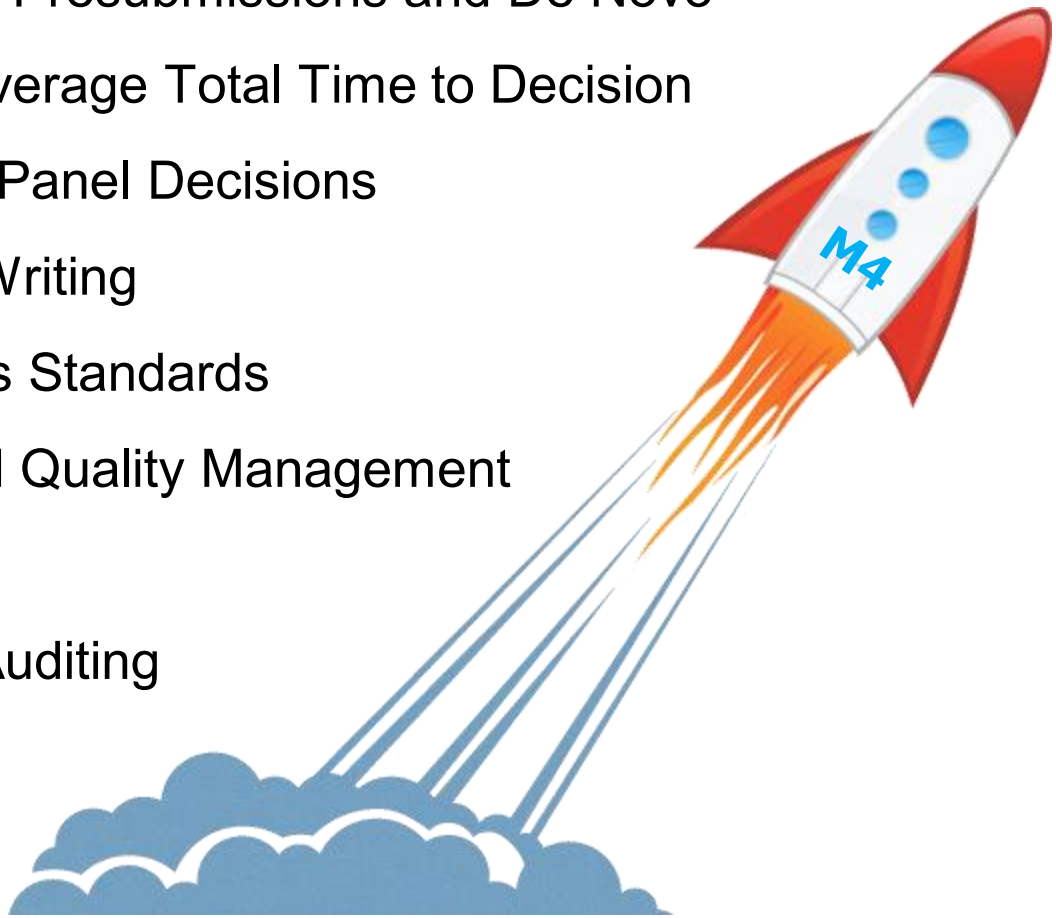
FDARA Implementation

USER FEES
FDA Reauthorization Act of 2017

- MDUFA 4
- Inspections
- Accessories
- Third Party Servicers
- Pediatric Devices
- Postmarket Surveillance Pilots
- Hearing Aids
- Contract Imaging Agents
- FDA Employee Salaries
- User Fee Reporting

MDUFA 4 Implementation

- Add Performance Goals for Presubmissions and De Novo
- Reduce 510(k) and PMA Average Total Time to Decision
- PMA Approvable and Post-Panel Decisions
- Improve Deficiency Letter Writing
- Enhance Use of Consensus Standards
- Establish Digital Health and Quality Management Programs
- Independent Assessment/Auditing
- Patient Engagement
- Real World Evidence



Launch Date: October 1, 2017

Digital Health Innovation Action Plan

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-Certification for SaMD

A voluntary program that allows manufacturers of Software as a Medical Device ("SaMD") to demonstrate their embedded Culture of Quality and Organizational Excellence (CQOE) to ultimately participate in a streamlined and predictable FDA regulatory pathway.

Purpose/Goal

Allows manufacturers of SaMD with **FDA Pre-Cert** status (demonstrated culture of quality and organization excellence):

- To have the ability to get SaMD to market faster;
- To iterate based on real world experience;
- To have an excellent regulatory experience; and
- To have regulatory predictability.

Public health/innovation outcomes

1. Companies strive for excellence rather than compliance;
2. Promotes high quality and effective innovation;
3. Transparent **FDA Pre-Cert** status increases user confidence beyond regulatory oversight; and
4. Allows FDA to focus resources on higher risk digital health products.

Example of CQOE scorecard elements of interest where a company shows commitment towards …

- Providing safe patient experience
- Being clinically responsible
- Delivering highest product quality
- Being cybersecurity responsible
- Being proactive v/s reactive

Scope of the Pre-Certification SaMD Pilot

- Manufacturers developing or planning to develop software as a medical device (SaMD) as defined by IMDRF.

> ***IMDRF SaMD Definition***
> *Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device*

- Limited to maximum of 9 pilot participants.
- Software function not excluded from medical device definition by 21st Century Cures Act.

MDDT Program

Qualification of Medical Device Development Tools (MDDT) Final Guidance issued August 10, 2017

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM374432.pdf

- Voluntary program.
- Reduces regulatory burden in evaluating medical devices.
- Facilitates development and timely evaluation of medical devices.
- Supports regulatory submissions and decision-making (e.g., study population enrichment, reduce or minimize the use of animals using simulations).
- Tool submitters may be a person, group, consortium, or organization (including the federal government).

MDDT and Qualification

- An MDDT is a method, material, or measurement to assess effectiveness, safety, or performance of a medical device.
- Qualification is a conclusion, based on FDA review, that within the context of use (COU), a MDDT can be relied upon to have a specific interpretation and application in medical device development and regulatory review.

Categories of MDDTs:

COAs: Instruments that measure how a patient feels or functions (i.e. patient-reported outcome (PRO) for pain severity).

BTs: Test or instrument used to detect or measure a biomarker (i.e. instrument or method for measuring blood pressure).

NAMs: Non-clinical test model or method measures or predicts device function or *in vivo* device performance (e.g., *in vitro* models to replace animal testing).

Benefits of Qualification:

- Innovation
- Collaboration
- Reduce individual resource expenditure
- Bridge gaps between research and development
- Qualified MDDT applied in multiple device submissions
- Efficiency in CDRH review resources
- Minimizes uncertainty in review process

Real-World Evidence

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices Final Guidance issued August 31, 2017

https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm513027.pdf

- The guidance defines Real World Data (RWD) and Real World Evidence (RWE) and describes examples of RWD/RWE use for medical devices.
- The guidance clarifies how real world data is evaluated for relevance and reliability to determine whether it is sufficient for generating the types of real-world evidence that can be used in FDA regulatory decision-making for medical devices.
- When sufficiently robust, RWE can potentially be used to support practically any medical device regulatory decision.

THANK YOU