IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

11:20 – 11:35

United States of America

Melissa Torres

Associate Director, U.S. Food and Drug Administration

European Commission

European Union

US FDA Update

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Overview

- Medical Device User Fee Agreements (MDUFA)
  - International Harmonization
  - Digital Health
  - Total Product Lifecycle Advisory Program (TAP)
- Food and Drug Omnibus Reform Act
  - Cybersecurity
  - Predetermined Change Control Plans
- Digital Health Updates
  - Clinical Decision Support Software Guidance

Medical Device User Fee Amendments Update

Medical Device User Fee Amendments (MDUFA) Overview

- Program where industry pays **user fees** which the agency uses to increase review capacity to meet performance goals on review timelines and implement targeted process improvements.
- Helps **assure patients have access to safe, effective, high-quality devices in a timely fashion** and there is a clear, predictable path to market for new innovations.
- The user fees authorized by MDUFA are crucial to enabling CDRH to **continue to modernize** our regulatory programs.
- The program is reauthorized every five years based on new negotiated agreements and new legislation:
  - MDUFA I: FY 2003-2007
  - MDUFA II: FY 2008-2012
  - MDUFA III: FY 2013-2017
  - MDUFA IV: FY 2018-2022
  - **MDUFA V: FY 2023-2027**

Themes of the MDUFA V Agreement

- **Review Performance |** Introducing a new goal structure with opportunities for "add-on" payments, as well as improving goals for PMA Total Time to Decision, 510(k) Total Time to Decision, Pre-Submissions, and De Novo decisions
- **Hiring & Retention |** Providing resources and associated goals to enhance hiring and retention of world-class technical and scientific staff
- **Performance Accountability |** Supporting a high-quality program through regular audits by a quality management team and independent assessments
- **Financial Transparency |** Adding new accountability mechanisms and enhanced reporting
- **Program Improvements |** Launching a ***TPLC Advisory Program Pilot***, as well as enhancing programs to support patient science and engagement, real-world evidence, consensus standards, ***digital health***, and ***international harmonization***

MDUFA V International Harmonization Commitments

- There are **five broad commitments** related to international harmonization efforts:
  1. Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees
  2. Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners.
  3. Assess the extent of CDRH implementation of IMDRF technical documents and make this information publicly available.
  4. Support the creation of a forum to engage with relevant stakeholders to identify opportunities for regulators to leverage one another's approach to decision making.
  5. Participate in outreach activities to other regulatory authorities that encourage harmonization

- Issue a strategic plan later this year with additional details and timelines associated with achieving these international harmonization objectives.
  - Publish an annual assessment of our international harmonization activities.

MDUFA V Digital Health Commitments

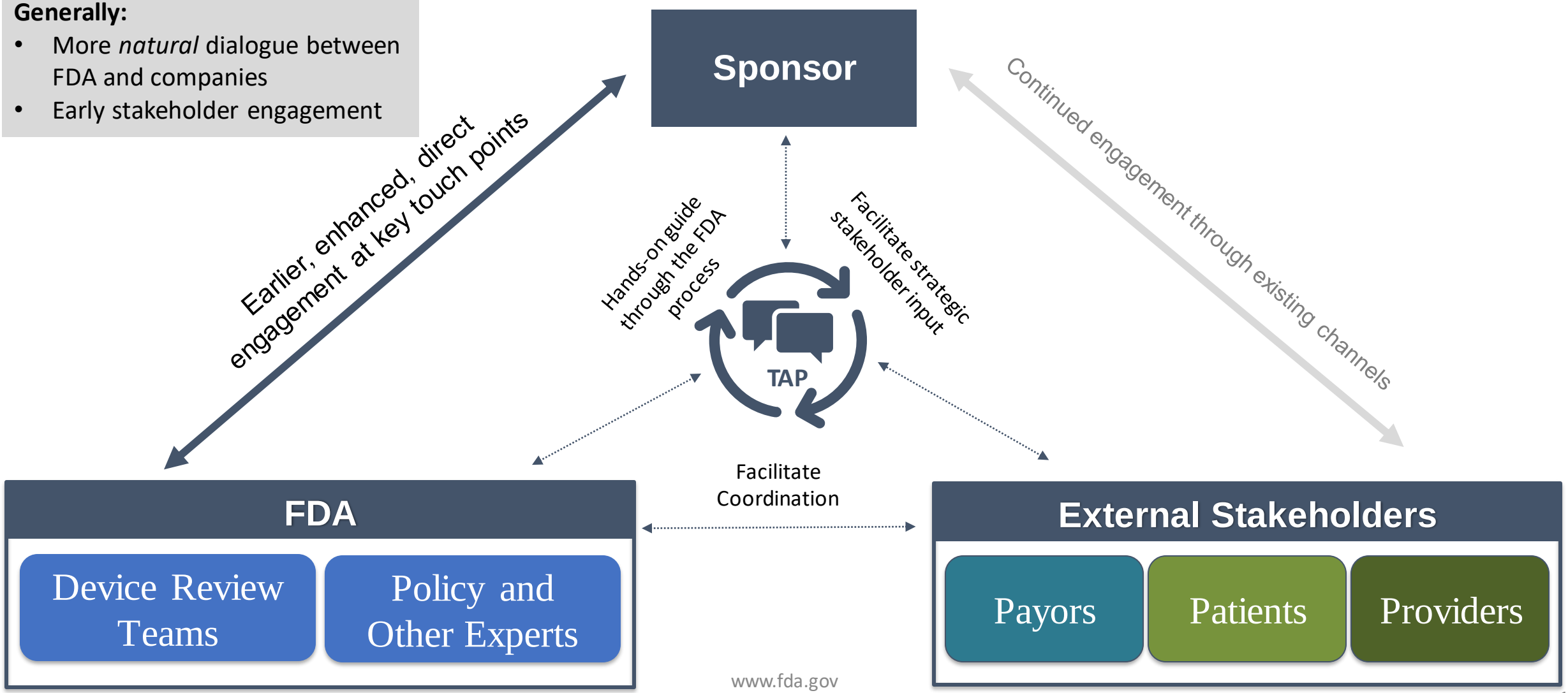
The FDA will continue to build its digital health expertise and continue working to streamline and align FDA review processes with software lifecycles for digital health products.

1. **Continue to develop software and digital health technical expertise** to provide assistance for premarket submissions that include digital health.
2. **Strengthen efforts to expand staff understanding** of digital health topics and enhance consistent evaluation in submissions
3. **Continue to participate in international harmonization efforts** related to digital health.
4. **Finalize the draft guidance**, "Content of Premarket Submissions for Device Software Functions," by 18 months from close of the comment period.
5. **Publish draft guidance** describing a process to evaluate a predetermined change control plan for digital health devices.
6. **Engage with stakeholders**, including patients, users, and industry, through roundtables, informal meetings, and teleconferences to explore regulatory approaches to digital health technologies.

Total Product Lifecycle Advisory Program (TAP)

Generally:

- More *natural* dialogue between FDA and companies
- Early stakeholder engagement



Enrollment Criteria

- Devices with a granted Breakthrough designation**
- No Pre-Submissions submitted after granted Breakthrough designation**
- Devices will be early in their device development process (e.g., have not yet initiated a pivotal study) at time of enrollment
- Each participant will have a maximum of one device enrolled in the pilot per fiscal year
- Devices regulated by our Center for Biologics Evaluation and Research (CBER) and combination products are outside the scope of the Pilot at this time

***In FY26-FY27, may also include devices with a granted request for inclusion in STeP*

Food and Drug Omnibus Reform Act

Background

- The Consolidated Appropriations Act for 2023 was signed into law December 29, 2022 and includes the Food and Drug Omnibus Reform Act (FDORA)
- FDORA authorized a number of new amendments to the Food, Drug, and Cosmetic Act
- Covers a broad range of areas, including cybersecurity, premarket review and product jurisdiction, pandemic preparedness, inspections, clinical trials, etc.
  - Section 3305 – Ensuring cybersecurity of medical devices
  - Sec. 3308 – Predetermined change protocol plans for devices

Section 3305 Overview
General

- Requires “cyber device” premarket submissions to:
  - Have policies and procedures for addressing vulnerabilities and exploits, including coordinated vulnerability disclosure;
  - Design, develop, and maintain processes and procedures to provide **reasonable assurance that device and related systems are cybersecure**;
  - Ensure device can be updated and patched;
  - Provide a Software Bill of Materials (SBOM).
- Includes provision for FDA to draft regulations to add additional requirements we determine are needed to “demonstrate reasonable assurance that the device and related systems are cybersecure”
- Enables FDA to exempt certain devices or device types from meeting cybersecurity requirements
- Provides tailored prohibited act authority

Section 3305 Overview
Website Updates

- Update public information including FDA website to include:
  - Information on identifying and addressing cyber vulnerabilities for
    - Healthcare Providers
  - Health Systems
  - Device Manufacturers
  - Information on how to access support from HHS, CISA, etc to improve cybersecurity of devices
- First update no later than 180 days from enactment of FDORA
- Annually thereafter

Section 3308 Overview
Predetermined Change Control Plans for Devices

2022 Omnibus Appropriations Bill

Amends section 515 of the FD&C Act so that changes to a device consistent with an approved predetermined change control plan do not require a supplemental application. It may also require that change control plans include labeling required for safe and effective use of the device.

Scope

This provision applies to all devices—it is not specific to software or devices with special controls. It applies to both premarket approvals and 510(k) applications. This is consistent with what FDA has been proposing for several years in both our AI/ML Action Plan and Discussion Paper.

Predetermined Change Control Plans

Predetermined change control plans describe planned changes that may be made to the device (and that would otherwise require a supplemental application under section 515) if the device remains safe and effective without any change.

Digital Health Updates

Clinical Decision Support Software Background


One Hundred Fourteenth Congress
of the
United States of America
AT THE SECOND SESSION
Begun and held at the City of Washington on Monday, the fourth day of January, two thousand and sixteen

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

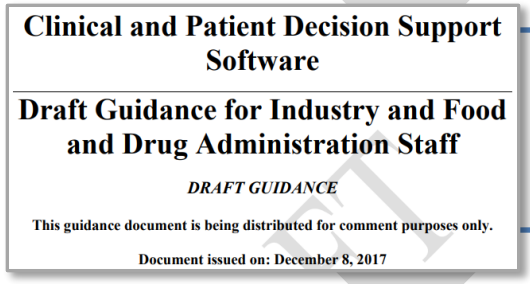
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Dec 2016: 21st Century Cures Act:
Amended device definition


Clinical and Patient Decision Support Software

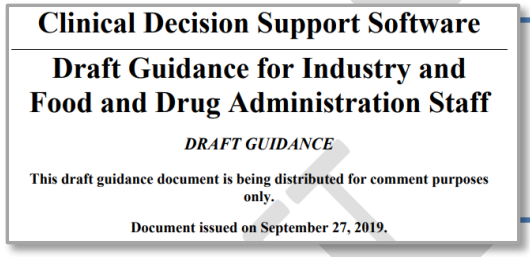
Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on: December 8, 2017

Dec 2017: First Draft Guidance:
"Clinical and Patient Decision Support Software"


Clinical Decision Support Software

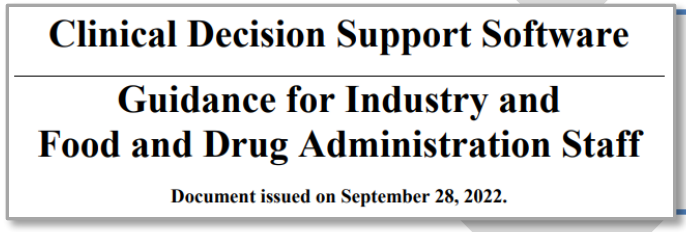
Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 27, 2019.

Sept 2019: Revised Draft Guidance:
"Clinical Decision Support Software"


Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 28, 2022.

Sept 2022: Final Guidance:
"Clinical Decision Support Software"

What is Clinical Decision Support (CDS)?

Clinical Decision Support (CDS) is a tool that provides health care professionals and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.[1]

CDS includes:[2]

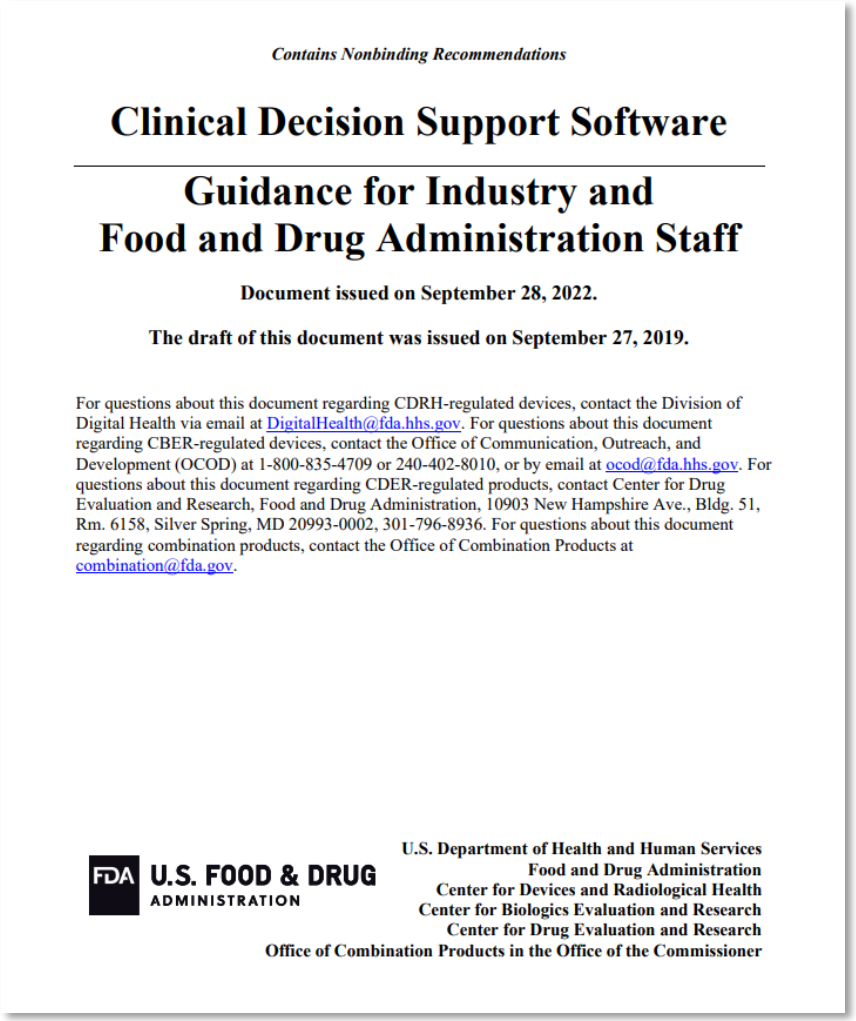
- computerized alerts and reminders for providers and patients;
- clinical guidelines;
- condition-specific order sets;
- focused patient data reports and summaries;
- documentation templates;
- diagnostic support;
- contextually relevant reference information.

[1] *See Office of the National Coordinator for Health Information Technology, "What is Clinical Decision Support (CDS)?" at* www.healthit.gov/topic/safety/clinical-decision-support

[2] FDASIA Health IT Report, April 2014, available at www.fda.gov/about-fda/cdrh-reports/fdasia-health-it-report

Clinical Decision Support Software Guidance Summary

- Focuses on the statutory criteria describing Non-Device clinical decision support software functions
  - Clarifies scope of FDA oversight of clinical decision support software intended for health care professionals as devices
- Provides examples of how FDA intends to consider different kinds of software functions, including non-device clinical decision support functions and device functions
- If unsure of how to apply the guidance/Non-Device CDS criteria:
  - Reach out to DigitalHealth@fda.hhs.gov
  - Consider submitting 513(g) for device determination or Q-Sub for discussion



Contains Nonbinding Recommendations

Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 28, 2022.

The draft of this document was issued on September 27, 2019.

For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health via email at DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6158, Silver Spring, MD 20993-0002, 301-796-8936. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner


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