U.S. FOOD & DRUG ADMINISTRATION

FDA Regulation of Digital Health

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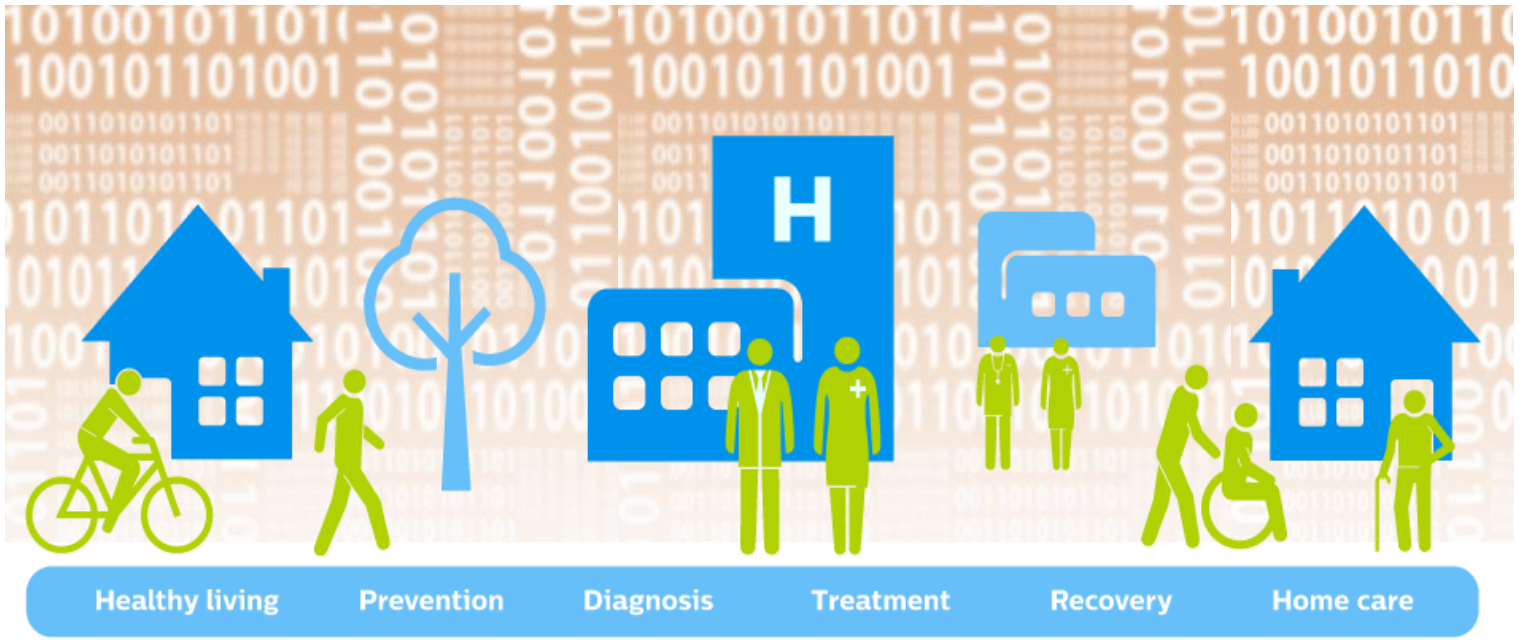
Office of the Chief Counsel



- **Used as a medical product**
- **Incorporated into a medical product (include a pharmacologic product)**
- **Used to develop a medical product**
- **Used to study a medical product**
- **Used as a companion or adjunct to a medical product, including diagnostics and therapeutics**

Outline

- Device Definition
  - Software “carve out”
- New FD&C Act Provisions
  - Section 515C (PCCPs)
  - Section 524B (cybersecurity)
- Digital Health Resources
  - CDRH
  - CDER

Definition of “device”

“… an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
2) **intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or**
3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. **The term ‘device’ does not include software functions excluded pursuant to section 520(o).”**

Section 201(h)(1) of the FDCA

Section 520(o): Regulation of Medical and Certain Decision Support Software

Definition of "device" excludes certain "software functions" intended...

(A) *for administrative support;*

(B) *for maintaining or encouraging a healthy lifestyle;*

(C) *to serve as electronic patient records;*

(D) *for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results and certain other related information;*

(E) *to provide recommendations to health care professionals for clinical decisions, where the user can independently review the basis of the recommendation.*

See section 520(o) of the FDCA for full text

New FD&C Act Authorities: Section 515C

- **New section 515C added by Consolidated Appropriations Act**
  - enacted on December 29, 2022
  - added section 515C “Predetermined Change Control Plans for Devices” to the FD&C Act
  - Section 515C provides FDA with express authority to approve or clear PCCPs for devices requiring PMAs or 510(k)s
- **Predetermined Change Control Plan (PCCP)**
  - included in a marketing submission
  - Manufacturers pre-specify and seek premarket clearance for intended modifications in a marketing submission

New FD&C Act Authorities: Section 515C

- **Draft Guidance: Marketing Submission Recommendations for a PCCP for AI/ML-Enabled Device Software Functions**
  - issued April 3, 2023
  - modifications made to an ML-DSF in accordance with an authorized PCCP can be implemented without triggering the need for a new marketing submission

Contains Nonbinding Recommendations

Draft – Not for Implementation

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

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 April 3, 2023.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact digitalhealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact druginfo@fda.hhs.gov. 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

New FD&C Act Authorities: Section 524B

- **Section 524B "Ensuring Cybersecurity of Devices"**
  - Premarket submissions for "cyber devices" must include certain information related to cybersecurity

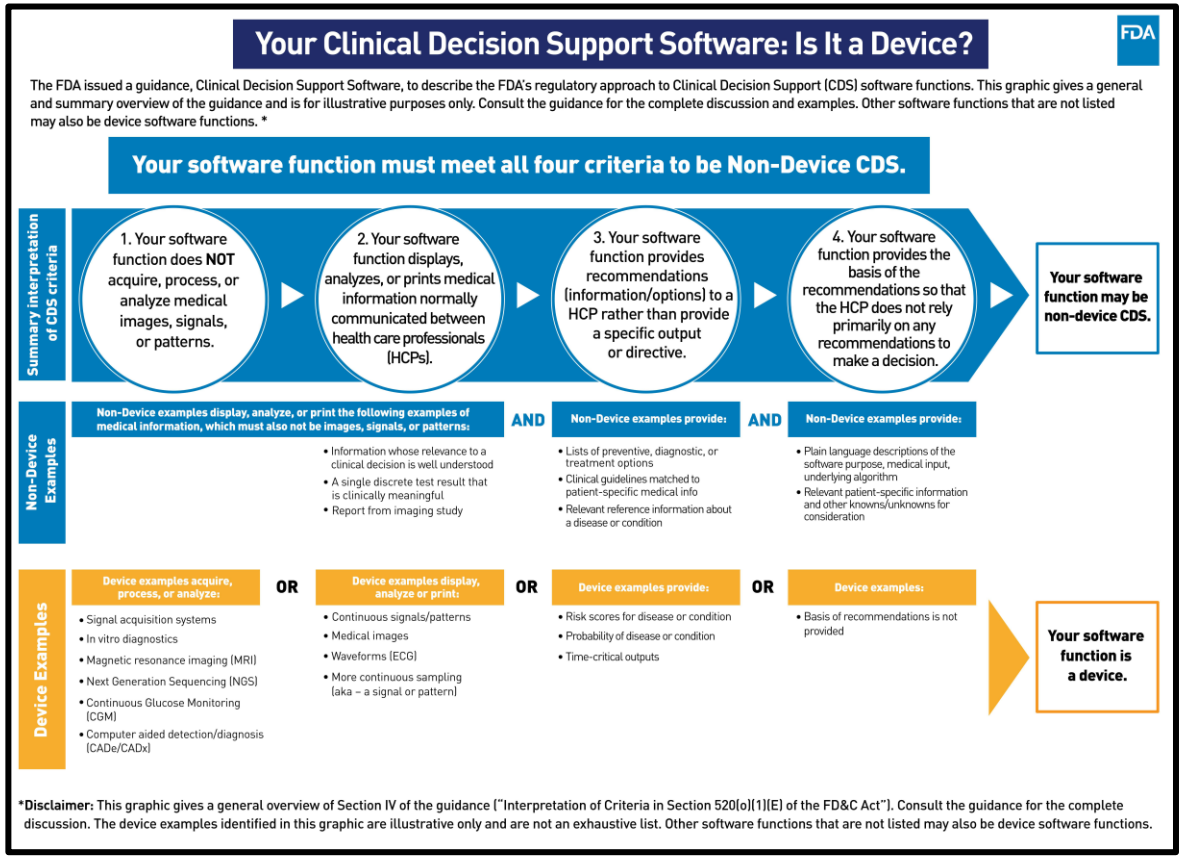
New FD&C Act Authorities: Section 524B

- **Final Guidance: Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act**
  - issued March 30, 2023
  - "…before October 1, 2023, FDA generally intends not to issue RTA decisions based solely on information required by section 524B of the FD&C Act."

- **FY 2023 A-List**
  - Final Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Digital Health Resources (CDRH)

- **Digital Health Center of Excellence**
  - Guidances with Digital Health Content
  - Digital Health Policy Navigator
  - Infographics



Digital Health Resources (CDER)

- Digital health technologies in clinical investigations
- AI/ML used in drug and biological product development

Digital Health Technologies in Clinical Investigations

Enable Remote Data Collection in Decentralized Clinical Investigation

- More frequent or continuous monitoring compared to traditional methods
- Longitudinal view of participant's health status
- Improved recruitment and retention of participants leading to less missing data

Improve Access to Clinical Investigations

- Meet a participant where they are at for a clinical investigation
- Fewer visits to a study site places less burden on participants
- Reach a more diverse population, advancing health equity

Facilitate Innovative Clinical Investigation Endpoints

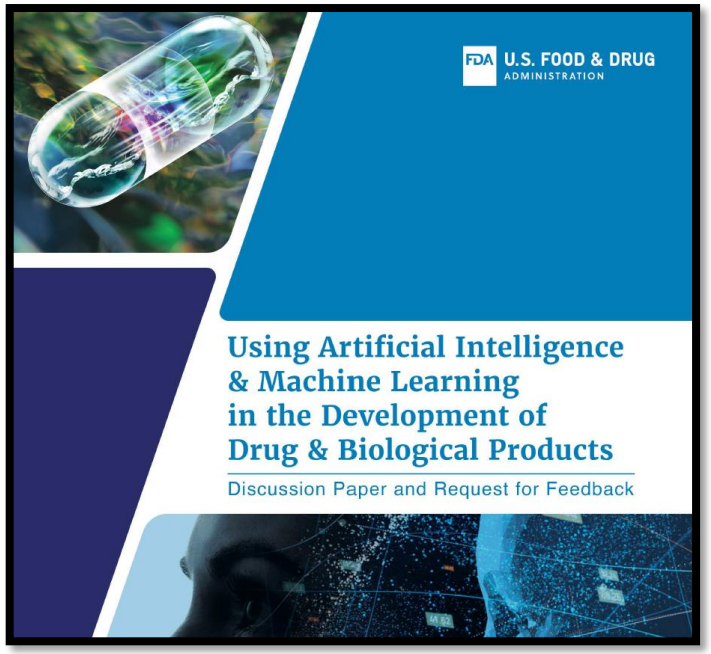
- New types of data to inform novel endpoints
- Complementary to other forms of data used to support a regulatory submission

Capture Real-World Data (RWD) and Patient-Generated Health Data (PGHD)

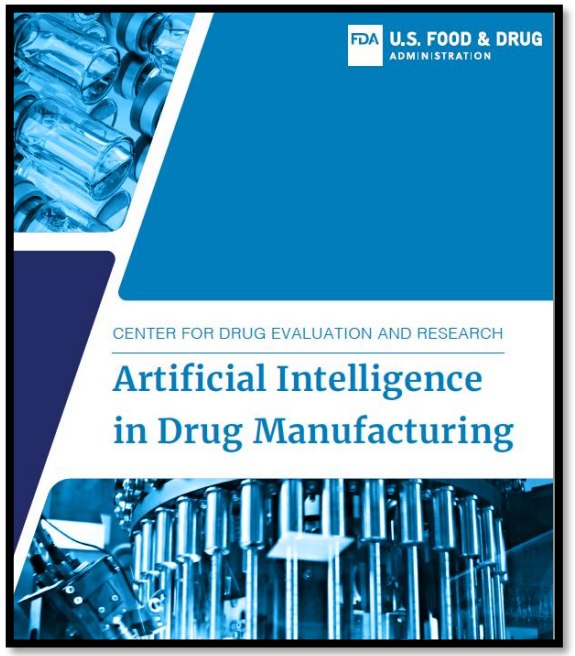
- Data reflects a participant's daily life
- Remote and longitudinal follow-up with participants beyond the clinical investigation
- More detailed picture of the impact of a medical product on a participant

Adapted from presentation by Anindita Saha, Assistant Director, Digital Health Center of Excellence
FDLI 2023 Annual Conference

Drug and Biological Product Development



- CDER, CBER, CDRH
- AI/ML in drug development
  - including the development of devices intended to be used with drugs



- CDER
- part of CDER's Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative
- focuses on NDAs, ANDA, and BLAs that could be all or in-part developed using AI/ML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