U.S. FDA Update

COVID-19 Overview

2988
EUAs Received

505
Medical Devices Authorized

23
GUIDANCE DOCUMENTS

37
WEBINARS

>335,000
EMAILS and CALLS To CDRH Help Desks, 1-800 Line, Email Boxes

>35,000
WEBINAR PARTICIPANTS

*Data as of September 11, 2020

COVID-19 Overview

- Information on Emergency Use Authorizations (EUAs) for Medical Devices: **https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices**

- Draft Guidance on the *Transition Plan for Medical Devices Distributed Under Enforcement Policies or EUA During the COVID-19 Public Health Emergency* will be issued in the coming weeks.
  - Outlines a transparent, phased approach for coming back into compliance with regulatory requirements over the course of one year.

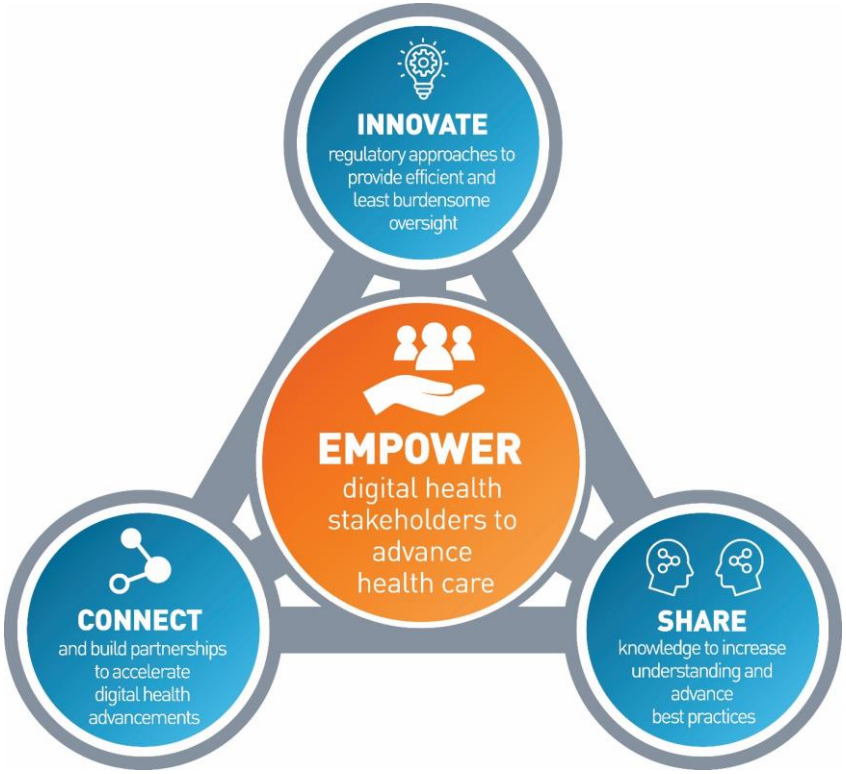
FDA's Digital Health Center of Excellence

Fostering Responsible Innovation

Goal: Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation.

The Digital Health Center of Excellence aims to:

- **Connect and build partnerships** to accelerate digital health advancements.
- **Share knowledge** to increase awareness and understanding, drive synergy, and advance best practices.
- **Innovate regulatory approaches** to provide efficient and least burdensome oversight.



Center of Excellence Anticipated Outcomes

- Strategically advance science and evidence for digital health technologies that meets the needs of stakeholders.
- Efficient access to a highly specialized expertise, knowledge, and tools to accelerate access to digital health technology.
- Aligned regulatory approach to harmonized international regulatory expectations and standards.
- Increased awareness and understanding of digital health trends.
- Consistent application of digital health technology policy and oversight approaches.
- Reimagined medical device regulatory paradigm tailored for digital health technologies.

Roadmap for Center of Excellence

Following is our roadmap for bringing the benefits of digital health to all Americans, efficiently and collaboratively:

Raise Awareness and Engage Stakeholders

Phase I: Communication

Fall 2020

- Stakeholder Listening Sessions
- Update and develop resources for FDA staff
- Begin operationalizing the DHCoE and outcome measurement
- Amplify work being done at FDA in digital health

Build Partnerships

Phase II: Coordinate

Fall and Winter 2020

- Build strategic partnerships for policy, regulatory science, and fellowships
- Develop resources for external stakeholders
- Create a digital health community of practice
- Assemble FDA and CDRH advisory groups

Build and Sustain Capacity

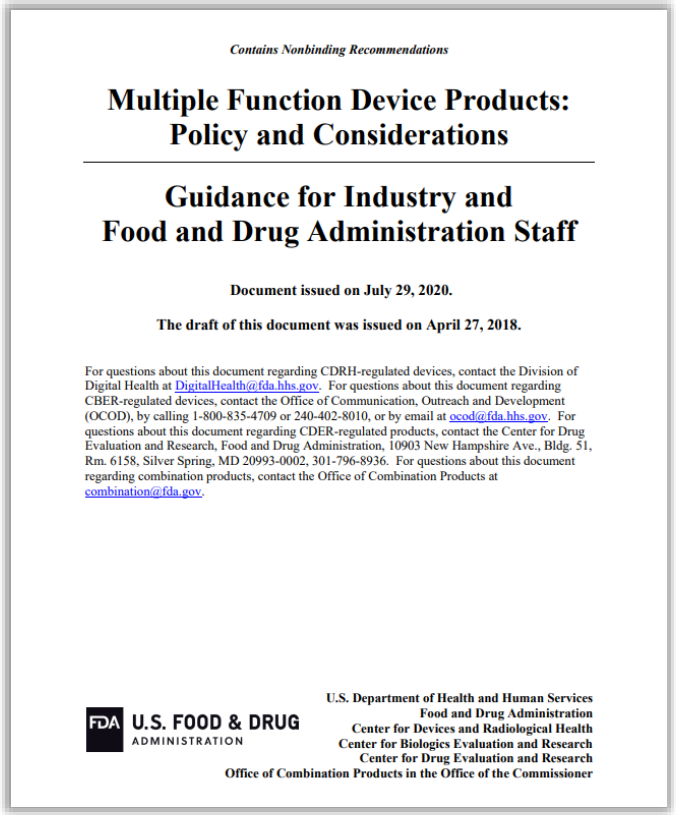
Phase III: Amplify

Winter 2021 onwards

- Continued strategic partnership building and communication
- Update and implement regulatory framework for digital health
- Harmonization with other regulators

Multiple Function Final Guidance

- ✓ Published on July 29, 2020.
- ✓ Clarifies the FDA's policy for digital technologies that include multiple functions, or contain at least one device function and one "other function."
- ✓ Incorporates feedback from public comments to clarify and provide examples of FDA's policy on products with multiple functions. Examples include both software and hardware products.
- ✓ Provides clarity for manufacturers, FDA staff, and other stakeholders on certain medical software provisions of the 21st Century Cures Act.



Contains Nonbinding Recommendations

Multiple Function Device Products: Policy and Considerations

Guidance for Industry and Food and Drug Administration Staff

Document issued on July 29, 2020.

The draft of this document was issued on April 27, 2018.

For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health at DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 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 the 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.

FDA U.S. FOOD & DRUG ADMINISTRATION

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

MDIC, NEST, AND NESTcc

National Evaluation System for health Technology (NEST) is a national evaluation system developed to efficiently generate better evidence for medical device evaluation and regulatory decision-making.

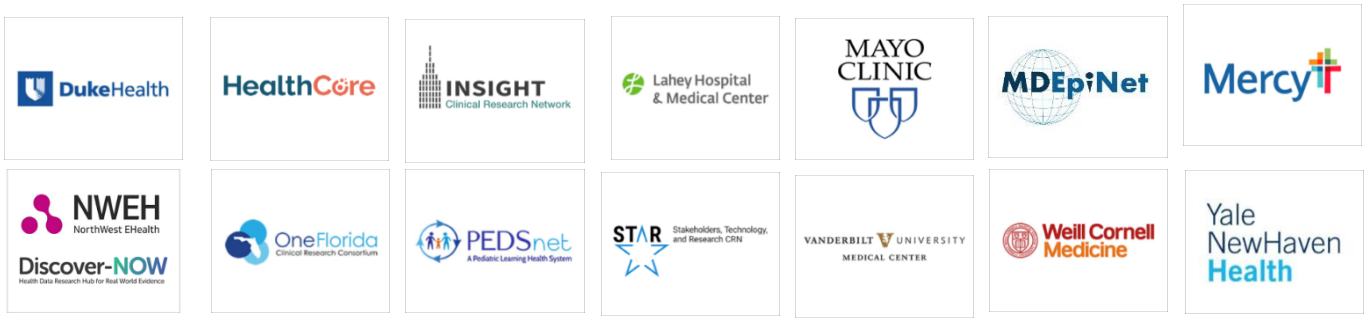
NEST is operated by the Medical Device Innovation Consortium (MDIC), a public-private partnership.

In 2016, MDIC was awarded a grant from the FDA to establish the "NEST Coordinating Center (NESTcc)" as an operational business unit within MDIC that provides:

- Governance for the NEST ecosystem.
- Development & maintenance of the research infrastructure.
- Standards for methodology and data quality.
- Assessment of the strengths and limitations of RWD data sources.

NESTcc Milestones

- Recognized as one of the first Collaborative Communities with participation by FDA/CDRH in September 2019.
- Data Quality & Methodology Frameworks published in February 2020.
- NEST Version 1.0 was launched in June 2020
- NESTcc Active Surveillance Task Force selected test cases for signal identification September 2020.
- Established Master Research Agreements with 14 institutions as data owners.



141 million+ Total Population

3,075 Outpatient Practices/Clinics

291 Specialty Clinics

162 Hospitals/Medical Centers

RWD and RWE to Evaluate COVID-19 Diagnostic Testing

Diagnostics Evidence Accelerator

- FDA/CDRH is participating in the COVID-19 Diagnostics Evidence Accelerator, a multi-stakeholder collaborative project to advance the development of diagnostics.
- The Diagnostics Evidence Accelerator will provide important complementary information about real world patterns of use, test performance, and immunity.
- RWD sources are of progressively higher quality, and new methods have improved reliability of results.
- RWD could rapidly generate useful evidence to inform clinical, public health, and policy decisions.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-action-harness-real-world-data-inform-covid-19

UNIQUE DEVICE IDENTIFICATION

IMMEDIATELY IN EFFECT GUIDANCE ISSUED ON 7/1/2020

"Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking"

https://www.fda.gov/media/110564/download

- Outlines enforcement of UDI requirements and the direct mark compliance policy for certain devices
  - FDA does not intend to enforce Standard Date Format, Direct Mark, UDI labeling, and GUDID Data Submission requirements for class I and unclassified devices, that are not implantable, life sustaining or life supporting devices, before September 24, 2022.
  - FDA does not intend to enforce UDI direct mark requirements for class III, life-sustaining/life-supporting, and class II devices that are non-sterile, that are manufactured and labeled prior to their applicable direct mark compliance date, and that remain in inventory.

Accreditation Scheme for Conformity Assessment (ASCA)

- FDA guidance document will create a new voluntary pilot program to enhance confidence in medical device testing included in premarket submissions.
- Under the ASCA Pilot:
  - ASCA-recognized accreditation bodies accredit testing laboratories.
  - ASCA-accredited testing laboratories provide test results to device manufacturers.
  - Device manufacturers include Declarations of Conformity and supplemental documentation in their premarket submissions to FDA.
  - FDA generally accepts test results from ASCA-accredited testing laboratories.
- Standards in the ASCA Pilot:
  - 64 basic safety and essential performance standards, including standards specific to particular device types and normative references.
  - Selected methods from 8 cross-cutting biological evaluation standards.

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

- Benefits:
  - Promotes consistency and predictability in premarket review process.
  - Encourages effective use of FDA resources.
  - Enhances regulatory efficiency by decreasing need for FDA to request additional information regarding testing methodologies.
  - Supports international harmonization
    - ASCA Pilot uses elements from international conformity assessment standards in the ISO/IEC 17000 series (this series is used worldwide by accreditation bodies, testing laboratories, and device manufacturers).
    - Most of the FDA-recognized consensus standards and test methods in the ASCA Pilot are international consensus standards.
    - Signatory status to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) is one qualification for accreditation bodies.

Summary of CDRH PRO Draft Guidance

Draft Issued on 8/28/2020

- **Measure What is Important to Patients**
- **Ensure Patients Understand**
- **Clarify Use of COA in Clinical Study Plan**
- **Leverage Existing Instruments and Information**
- **Consider Alternative Platforms and Parallel Development**
- **Pre-Competitive Collaboration**

"*Principles for selecting, developing, modifying, and adapting patient-reported outcome instruments for use in medical device evaluations*" https://www.fda.gov/media/141565/download

PUBLIC MEETINGS

- **September 29 — Using Patient Preference Information in Medical Device Regulatory Decisions: Benefit-Risk and Beyond**
  - https://www.ispor.org/conferences-education/conferences/upcoming-conferences/ispor-fda-summit-2020/about/registration-information

- **September 30 — Patient-Reported Outcomes (PROs) and Medical Device Investigations: From Conception to Implementation**
  - https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-meeting-patient-reported-outcomes-pros-and-medical-device-investigations-conception

PUBLIC MEETINGS

- **October 22 — Patient Engagement Advisory Committee Meeting on Artificial Intelligence & Machine Learning in Medical Devices**
  - https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee
- **October 27 — Medical Device User Fee Agreements**
  - https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-10272020
- **November 17 — Communicating with the Public about Medical Device Safety**

THANK YOU