IMDRF International Medical Device Regulators Forum

US FDA Update

IMDRF Open Stakeholder Session

September 2021

COVID-19 Response Snapshot

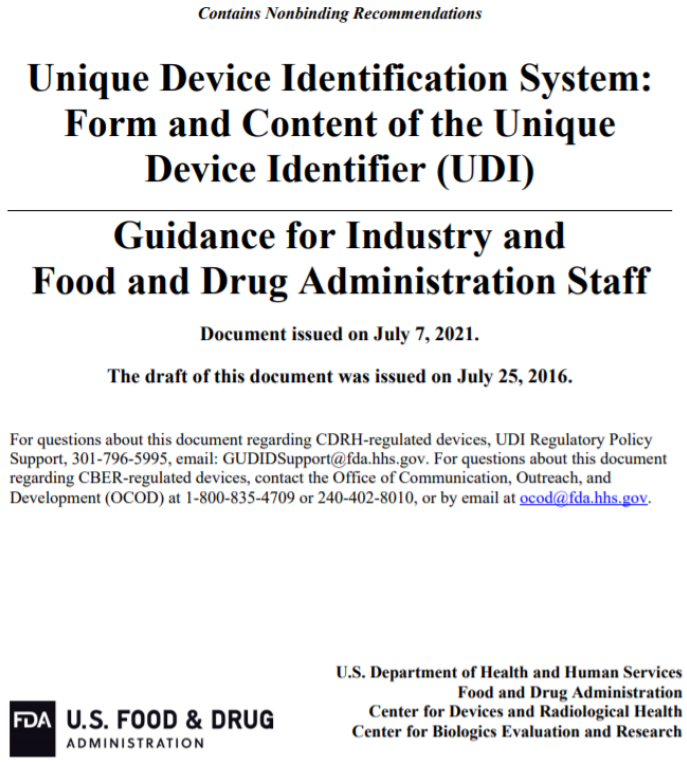
Unprecedented COVID-19 response in addition to normal operating conditions:

- 38% overall increase in premarket submissions in 2020 alone
- >1600 new medical devices for COVID-19
- Outreach to >1,000 manufacturing sites across 12 countries
- Development of >300 FAQs
- Outreach including >90 webinars and Town Halls
- Development of 13 EUA templates (diagnostic tests, antibody tests, PPE, etc.), 28 guidances
- Over 400,000 public inquiries
- Shortage mitigation and realignment of staff to COVID activities
- And much more

FDA Final Guidance
Form and Content of the UDI

Incorporates references to internationally used terms from IMDRF UDI WG/N48: FINAL 2019 Unique Device Identification system (UDI system) Application Guide.

- The term “data delimiter,” corresponds to the term “qualifier” as used in ISO/IEC 15459-3 and IMDRF UDI N48
- Issuing agencies or other entities may refer to the easily readable plain-text form of the UDI as the human readable interpretation (HRI)



Contains Nonbinding Recommendations

Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)

Guidance for Industry and Food and Drug Administration Staff

Document issued on July 7, 2021.

The draft of this document was issued on July 25, 2016.

For questions about this document regarding CDRH-regulated devices, UDI Regulatory Policy Support, 301-796-5995, email: GUDIDSupport@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.

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

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-system-form-and-content-unique-device-identifier-udi

FDA Draft Guidance Document: Remanufacturing of Medical Devices

- Provides clarity between “servicing” and “remanufacturing” of a medical device.
- Outlines guiding principles:
  1. Assess whether there is a change to the intended use
  2. Determine whether the activities, individually and cumulatively, significantly change the safety or performance specifications of a finished device
  3. Evaluate whether any changes to a device require a new marketing submission
  4. Assess component/part/material dimensional and performance specifications
  5. Employ a risk-based approach
  6. Adequately document decision-making
- Provides illustrative examples

Contains Nonbinding Recommendations

Draft – Not for Implementation

Remanufacturing of Medical Devices

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 June 24, 2021.

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 the Regulation, Policy, and Guidance Staff at RPG@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.

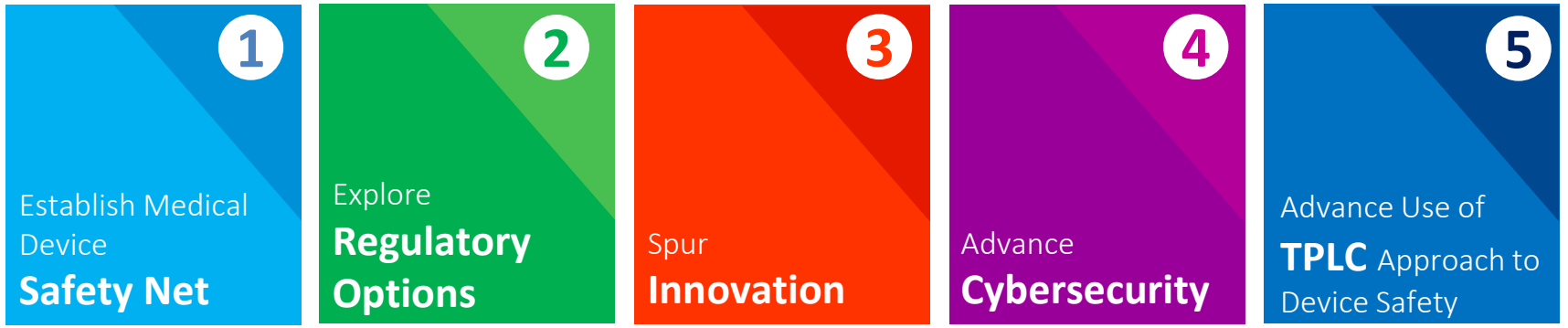
FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

DRAFT

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices

Medical Device Safety Action Plan



1

Gaining access to data from novel sources of surveillance

Pursuit of active surveillance capabilities within National Evaluation System for health Technology (NEST)

3

Launched Safer Technologies Program (STeP) for device technologies that are safer than current alternatives

Launched the Safety and Performance Pathway

5

Ensuring feedback of device performance information into premarket evaluation

Incorporation and utilization of Unique Device Identifier (UDI) within Total Product Lifecycle (TPLC) workstreams

Spur Innovation Towards Safer Medical Devices

3

Spur
Innovation

Safer Technologies Program ("STeP") to encourage innovation and marketing of device technologies that are safer than current alternatives

- ✓ March 8, 2021: Implementation of STeP began
- ✓ 21 submissions received as of 8/20/21

Establish a voluntary, more modern 510(k) pathway for demonstrating safety and effectiveness for certain moderate risk devices, such as through objective performance criteria

- ✓ Established the Safety and Performance (S&P) Based Pathway (Final Guidance issued in 2019)
- ✓ Issued 5 final and 1 draft device-specific S&P guidances; more device-specific S&P guidances in pipeline

Regulatory Science Tools

Accelerating patient access to innovate, safe, and effective medical devices

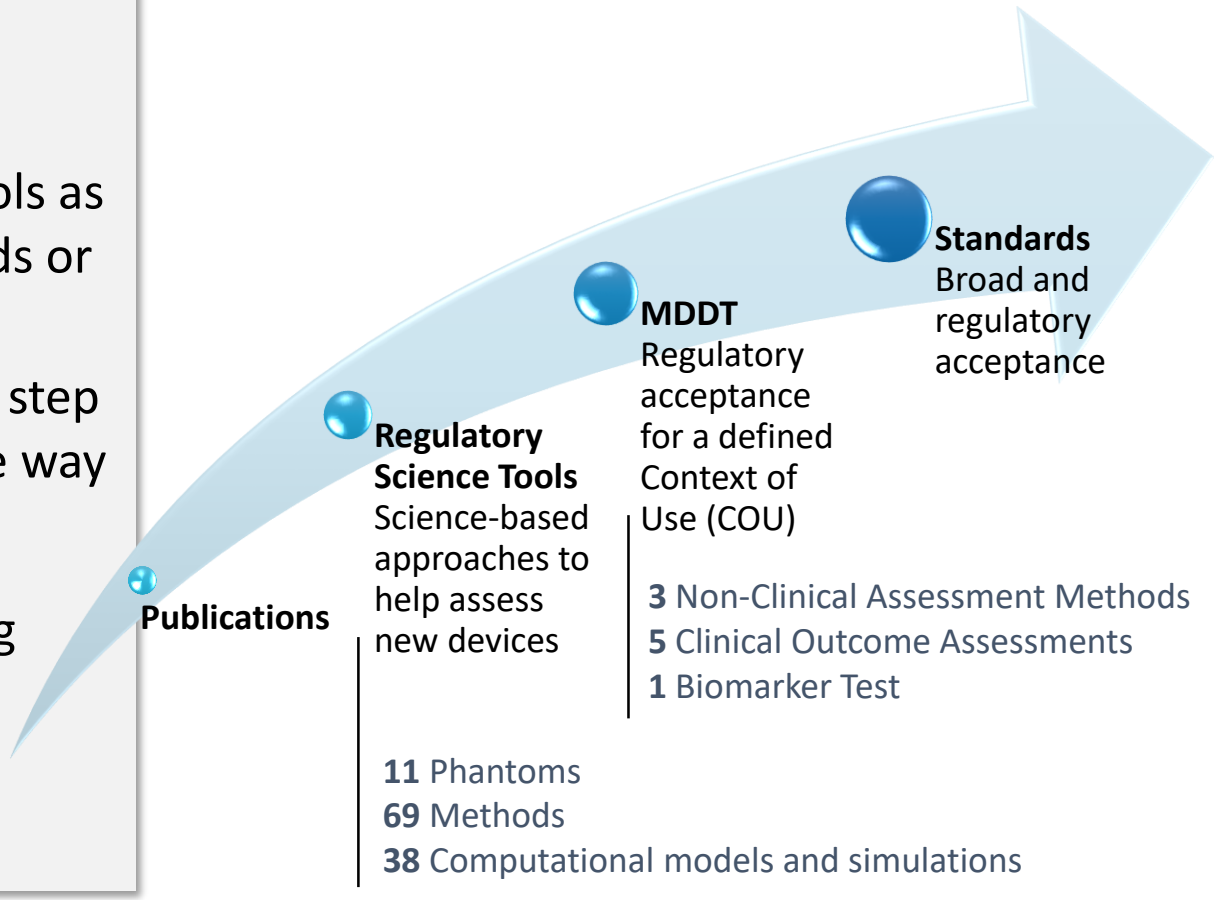
https://www.fda.gov/medical-devices/science-and-research-medical-devices/catalog-regulatory-science-tools-help-assess-new-medical-devices

Recent Accomplishments

- Growth of the Medical Device Development Tools (MDDT) program to qualify tools for developers
- Development of a Catalog of Regulatory Science Tools as a resource for manufacturers to use where standards or MDDTs do not exist
- Publication of adaptive algorithms, a science-based step in ensuring AI/ML field move forward in responsible way

Future Work

- Continue to collate previous work in product catalog
- Collaborate with NIH/NCI to develop specific tools
- Create a broader network of innovation and tools
- Consider third party review



Medical Device User Fee Amendments (MDUFA)

- 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)
- The authorization for the current program (MDUFA IV) expires in September 2022 and will need to be reauthorized (MDUFA V).
  - MDUFA V: FY 2023-2027
- Meetings are being held routinely with industry representatives to develop recommendations for MDUFA V.

Thank you