OIR Perspective

MDIC Workshop

"Advancing EUA IVD Products Toward Full Marketing Status"

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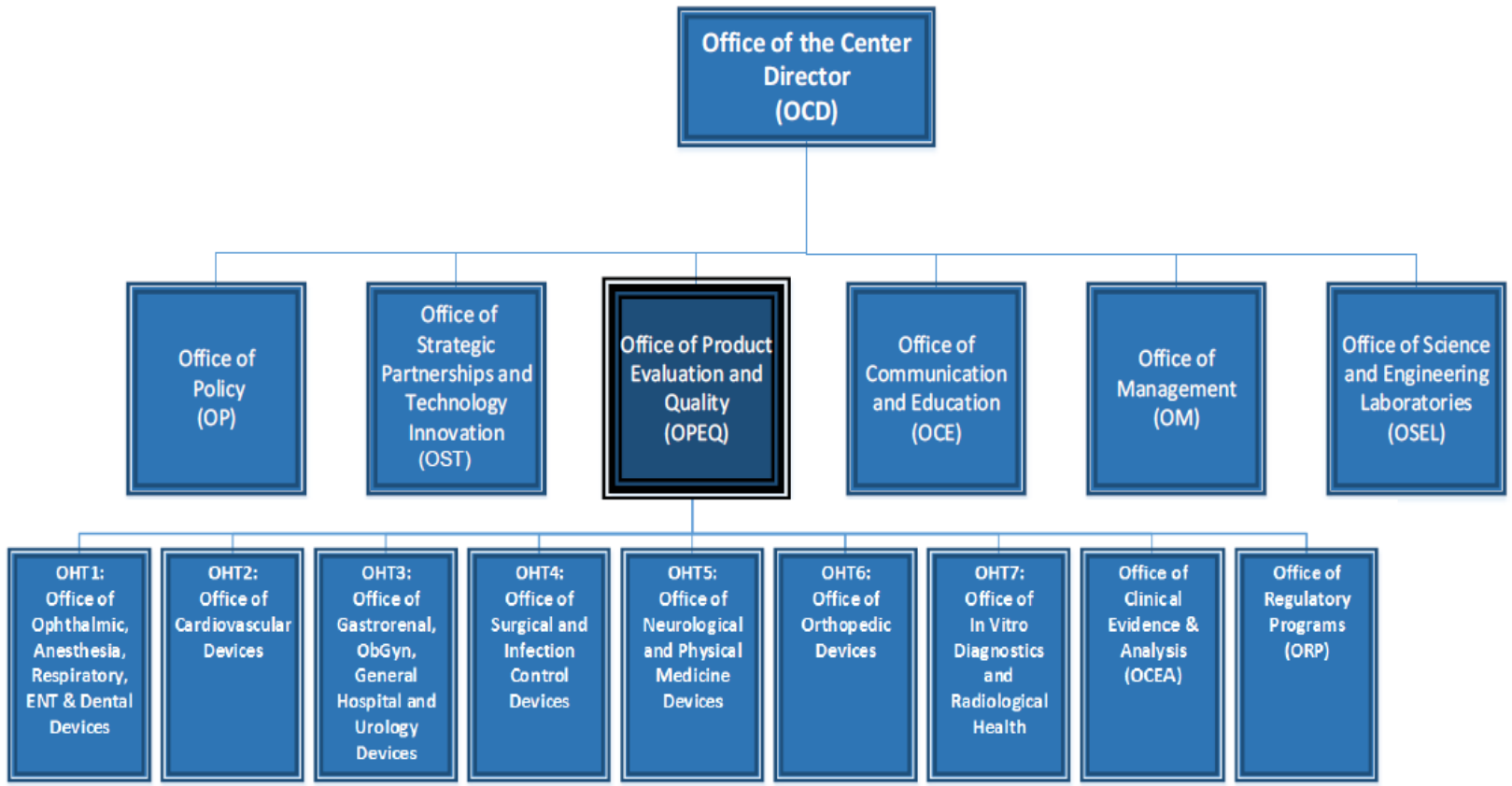
CDRH (After Reorganization)



CDRH Vision

- Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.
- The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.
- U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.
- Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.
- Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

What Is a Medical Device?

- Definition of a medical device is specified in section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321) *
- Section 201(h) states in part:
  - The term “device”…means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…”
  - “…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man…” or
  - “…intended to affect the structure or any function of the body of man and which does not achieve any of its primary intended purposes through chemical action.…”

What are In Vitro Diagnostic Products (IVDs)?

"...**reagents, instruments, and systems** **intended for use in the** **diagnosis of disease** **or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae … intended** **for use in the collection, preparation, and examination of** **specimens taken from the human body.**"

[21 CFR 809.3]

A Risk Based Approach for Medical Devices since 1976

Class I
low risk
- Generally exempt from premarket review
- In some cases require 510(k) / De Novo

Class II
Moderate/Controlled Risk
- Requires 510(k) to demonstrate substantial equivalence / De Novo if no classification exists

Class III
High Risk
- Requires PMA (Premarket approval)

General Controls [Electronic Establishment, Registration, Electronic Device Listing, Quality Systems, Labeling, Medical Device Reporting (MDR)]

Performance standards
Special Controls [Controls to address safety and effectiveness]

Clinical performance data (to support a reasonable assurance of safety and effectiveness)

De Novo

- Pathway for novel, low/moderate risk devices
  - No predicate device
- MDUFA IV: 150 FDA days for review
- Does submitted information demonstrate :
  1. Probable benefits outweigh probable risks AND
  2. General and special controls are adequate to provide assurance of Safety and Effectiveness
- If marketing is granted:
  - Create a new regulation in Class I or II
  - Device serves as predicate for future devices
  - Summary posted online

De novo Classification Process

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080197.pdf

Emergency Use Authorization (EUA)

- With an EUA, FDA can authorize:

  - Use of unapproved medical countermeasure
  - Unapproved use of approved medical countermeasure

  to **diagnose**, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents when certain criteria and pre-requisites are met

- **An EUA is not a substitute or shortcut to full approval or clearance**

[FD&C Act § 564]

EUAs for IVDs

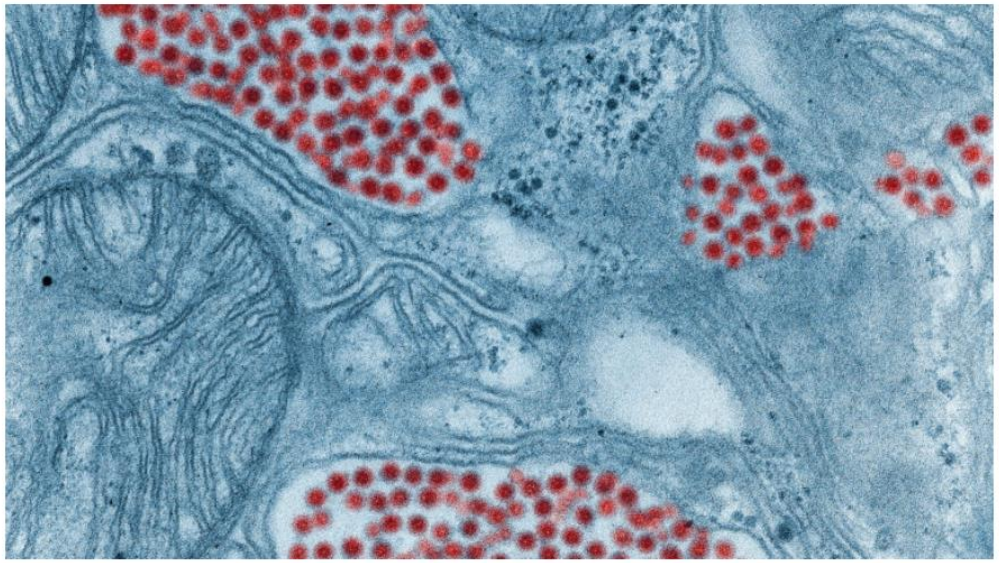
- 57 EUAs
- 4 have progressed to De Novo/510k

- Are there steps we can take to help advance more EUA IVD products toward full marketing status?

Specimen Challenges

Why the huge surge in EEE cases? Federal rules requiring quick sample disposal mean we may never know

By HELEN BRANSWELL @HelenBranswell / NOVEMBER 27, 2019



A mosquito salivary gland infected by EEE.

https://www.statnews.com/2019/11/27/surge-eee-cases-federal-rules-requiring-quick-sample-disposal/

Definitions

What are RWD and where do they come from?

Real-world ***data*** are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD can come from a number of sources, for example:

- Electronic health records (EHRs)
- Claims and billing activities
- Product and disease registries
- Patient-generated data including in home-use settings
- Data gathered from other sources that can inform on health status, such as mobile devices

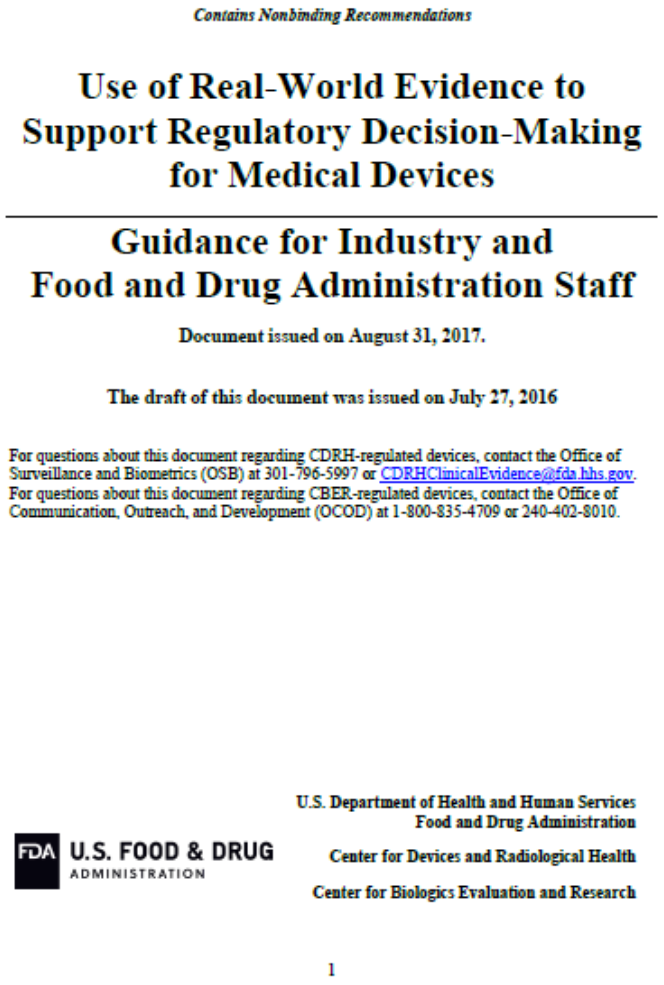
What is RWE?

Real-world ***evidence*** is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective).

FDA Guidance for Industry

Important Considerations

- Relevance
- Reliability



Contains Nonbinding Recommendations

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 31, 2017.

The draft of this document was issued on July 27, 2016

For questions about this document regarding CDRH-regulated devices, contact the Office of Surveillance and Biometrics (OSB) at 301-796-5997 or CDRHClinicalEvidence@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.

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

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Summary

- CDRH has a risk based approach to regulation of medical devices, including IVDs
- De Novo is a pathway for novel, low/moderate risk devices
- An EUA is not a substitute or shortcut to full approval or clearance
- CDRH/OIR is committed to working with all stakeholders to advance EUA products to full marketing status as efficiently and effectively as possible

Thank you!