IMDRF International Medical Device Regulators Forum

U.S. FDA Center for Devices and Radiological Health Update

Jeff Shuren

Director

Center for Devices and Radiological Health

CDRH Strategic Priorities Update

The Center for Devices and Radiological Health (CDRH) issued its 2014 – 2015 Strategic Priorities in February 2014:

- Strengthen the Clinical Trials Enterprise;
- Strike the Right Balance between Premarket and Postmarket Data Collection; and
- Provide Excellent Customer Service.

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/ucm384132.htm

Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversible Debilitating Diseases or Conditions – Final Guidance

- *Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions – Final Guidance* issued April 13, 2015.
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf.
- A pathway for expedited patient access to devices that are of a potential significant public health benefit because they are intended to treat or diagnose patients with life-threatening or irreversibly debilitating conditions whose medical needs are unmet by current technology – what some have called "breakthrough devices."
- Some data collection for devices marketed under this pathway might be moved from pre- to postmarket, provided there is still a reasonable assurance of safety and effectiveness concerning the device.

Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval Final Guidance

- The FDA also issued a final guidance document on achieving the right balance between pre-market and post-market data collection – a critical step in providing timely patient access to safe and effective breakthrough devices. Guidance issued April 13, 2015.
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393994.pdf
- Federal law requires us to consider whether reliance on postmarket controls can reduce the extent of data otherwise required to demonstrate effectiveness during premarket review.
- Provides greater clarity and transparency for determining when data can be collected postmarket and actions available to FDA when approval conditions are not met.

Retrospective Review of PMA Device Types

- The FDA is proposing changes to reduce premarket data collections through reclassification, postmarket controls, or shift to postmarket data collection for certain Class III (high-risk) devices for which there is a good understanding of postmarket performance based on several years of experience with these devices.

- The FR notice issued April 28, 2015 solicits comments on the product codes that have been identified as candidates for reclassification, reliance on postmarket controls to reduce premarket data collection or a shift in premarket data collection to the postmarket setting based on our current understanding of the technology.

  - https://www.federalregister.gov/articles/2015/04/29/2015-09884/retrospective-review-of-premarket-approval-application-devices-striking-the-balance-between.

- As of December 31, 2015, CDRH reviewed 69% of procodes; exceeding its 50% target.

Device Initiative on the Science of Patient Input

- *Patient Preference Information – Submission, Review in PMAs, HDE Applications, and De Novo Requests in Device Labeling Draft Guidance* issued May 18, 2015.
  - Submission is voluntary
  - Does not change standard for approval
  - Outlines agency thinking on how patient perspectives on benefits and risks can be incorporated to inform FDA's benefit-risk determination
  - Patient preference information may be helpful in identifying a subpopulation that clearly consider benefits to outweigh risks

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM446680.pdf

Device Initiative on the Science of Patient Input

- Medical Device Innovation Consortium (MDIC) Collaboration
  - Patient Centered Benefit-Risk Project
    - Developed a framework for incorporating patient preferences into the device development and assessment process. Framework available on MDIC website: http://mdic.org/wp-content/uploads/2015/05/MDIC_Summary_Report_SinglePage_5.7.151.pdf
    - Compiling a catalog of methods or collecting patient preference information that can be used to design, develop, and market devices that meet the needs of patients.

Establishing a National Evaluation System

- **Planning Board Report** – In February 2015, the multi-stakeholder Planning Board issued a report with recommendations for how to establish the surveillance system.
  - Provides a pathway to realizing a national system that harnesses novel data sources, modern analytical techniques and the participation of all stakeholders to optimize patient care.
- **Medical Device Registry Task Force Report**
  - Identify existing registries that may contribute and leverage on-going registry efforts (e.g., quality assurance, reimbursement)
  - Identify priority medical devices in need of registries
  - Define governance and data quality practices to meet multi-stakeholder needs
  - Develop strategies for the use of registries to support premarket approval and clearance
  - Report – is being rolled out August 2015

21ST CENTURY CURES

- 21st Century Cures Act passed the U.S. House of Representatives on July 10, 2015.
- Principal Device Provisions:
  - Priority Review for Breakthrough Devices
  - Third Party quality system assessment
  - Valid scientific evidence
  - Least burdensome concept training and oversight
  - Recognition of standards
  - Easing regulatory burden with respect to certain class I and class II devices
  - Advisory Committee Process
  - Humanitarian device exemption application
  - Health software
  - CLIA waiver study design guidance for in vitro diagnostics
- Senate is working on their version of 21st Century Cures.

THANK YOU