FDA Psychiatric Device Pipeline and Regulations: A Staff Perspective

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FDA-CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)
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Disclosures None

Today's Goals

- Introduction to FDA Review of Psychiatric Devices
- Device Classifications and Regulatory Implications
- Submission Pathways
- Investigational Device Exemption (IDE) Process
- Pre-submission Process
- Answer Questions

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.

Medical Device Definition

- 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…" or

  - "…intended to affect the structure or any function of the body …and which does not achieve any of its primary intended purposes through chemical action….and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

A Risk Based Approach for Regulating Medical Devices since 1976

Increasing Risk

Classification determines extent of regulatory control (Risk Based)

Class I
- General Controls

Class II
- General controls
- Special controls

Class III
- General controls
- Premarket approval (PMA)

General Controls
- Electronic Establishment Registration
- Electronic Device Listing
- Quality Systems/Good Manufacturing Practices
- Labeling
- Medical Device Reporting (MDR)
- Premarket Notification [510(k)] (unless exempt)

Special Controls (addressing Risk)
- Guidance documents
- Mandatory Performance Standard
- Performance testing, such as biocompatibility, engineering, animal, etc.
- Special Labeling
- Post-market surveillance

Premarket Approval (PMA)

Class III devices, standard for approval is a "reasonable assurance of safety and effectiveness"

De Novo

Process for classifying devices that don't have a suitable predicate device. Standard for granting is a "reasonable assurance of safety and effectiveness"

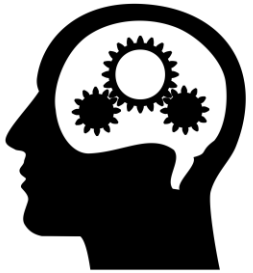
Premarket Notification [510(k)] Program

Class II, standard for clearance is "substantial equivalence"

Humanitarian Device Exemption (HDE)

Standard for approval is a "reasonable assurance of safety and probable benefit." For small populations with disease or condition with US incidence < 8,000/year

When is Clinical Data Needed?



- PMA: typically needed
- De novo: typically needed, but not always
- 510(k): typically not needed, but sometimes

You can request feedback on any protocols through a Pre-submission, preferably before starting the study

When is an IDE Needed?

Investigational Device Exemption

- When a device is a significant risk device.
- 21 CFR 812.3(m) defines “Significant Risk” as an investigational device that:

(1) Is **intended as an implant** and presents a potential for serious risk to the health, safety, or welfare of a subject;

(2) Is **purported or represented to be for a use in supporting or sustaining human life** and presents a potential for serious risk to the health, safety, or welfare of a subject;

(3) Is **for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health** and presents a potential for serious risk to the health, safety, or welfare of a subject; or

(4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Review of Marketing Submissions

- Evaluation of the results from all clinical and non-clinical testing, including, but not limited to:
  - Mechanical, electrical performance testing, sterilization information, human factors studies, non-clinical animal or biocompatibility studies, clinical performance data

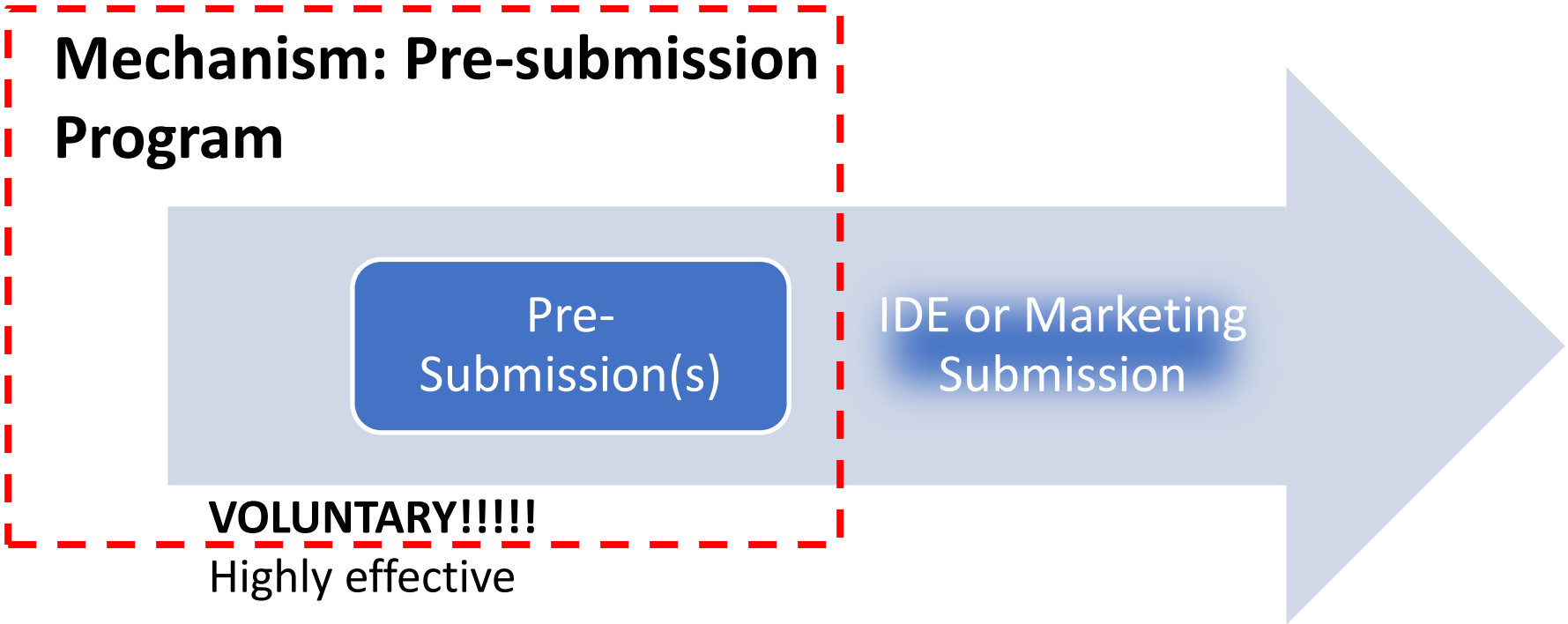
Review Points to Consider

- Device studies are designed to support a "reasonable assurance of safety and effectiveness"
- Medical device trials differ from drug studies – 1 study rather than 2 RCTs
- Endpoints of interest can be highly diverse between studies
  - ➢ Dependent on indication for use being sought
- Typically, a single pivotal trial follows feasibility stage(s)
  - Early feasibility Study
  - Feasibility Study
  - Pivotal Study

Review Points to Consider

- Recommend evaluating the safety and effectiveness of the device in the population for which it is to be indicated
- Time frames for evaluating the primary endpoint should be defined
  - E.g., Acute vs. chronic insomnia
- Endpoints should be prespecified
  - 1 or more “safety” endpoints
  - 1 or more “effectiveness” endpoints

Sample Early Interaction Progression



Pre-submissions

What is it:	**An opportunity to ask questions about a clinical trial design, non-clinical animal study, regulatory pathway, or other questions related to a planned IDE or marketing application prior to submission**
What you get:	**Written feedback in 70 days or 5 days in advance of meeting (whichever sooner)** **Meeting (optional) within 75 days after submission receipt**
What it is not:	**Pre-submissions are NOT intended for "pre-review" of data** **The purpose of any discussion during the meeting is to clarify our feedback, not to respond in real-time to new information or proposals.**

Why Engage As Early As You Can?

- Pre-submission interactions allow potential issues to be identified earlier, and we can work through them with you as appropriate
  - This is particularly useful if there are concerns related to novel technology or testing
- If needed, you can submit a supplement to get additional feedback

Recently Granted De Novo: NightWare:

- Indications for Use
- Risk/AEs


THE DOOR
THE HOUSE
THE TREE
SHIRT
PANTS
THE CAT
THE DOG
10-12
"Now! ... That should clear up a few things around here!"

Useful Links on FDA Internet

- How to Study and Market Your Device:
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm
- Premarket Submissions:
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/default.htm
- FDA/CDRH Overview of Device Regulation:
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
- IDE Program:
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm

It’s About the Patients