

# Setting the Stage: Regulatory Contributions to Deep Brain Stimulation Devices

National Academies: Forum on Neuroscience and Nervous System Disorders  
Exploring the Adoption of Implantable Brain Stimulation into Standard of Care for  
Central Nervous System Disorders – A Workshop  
October 31, 2023

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OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

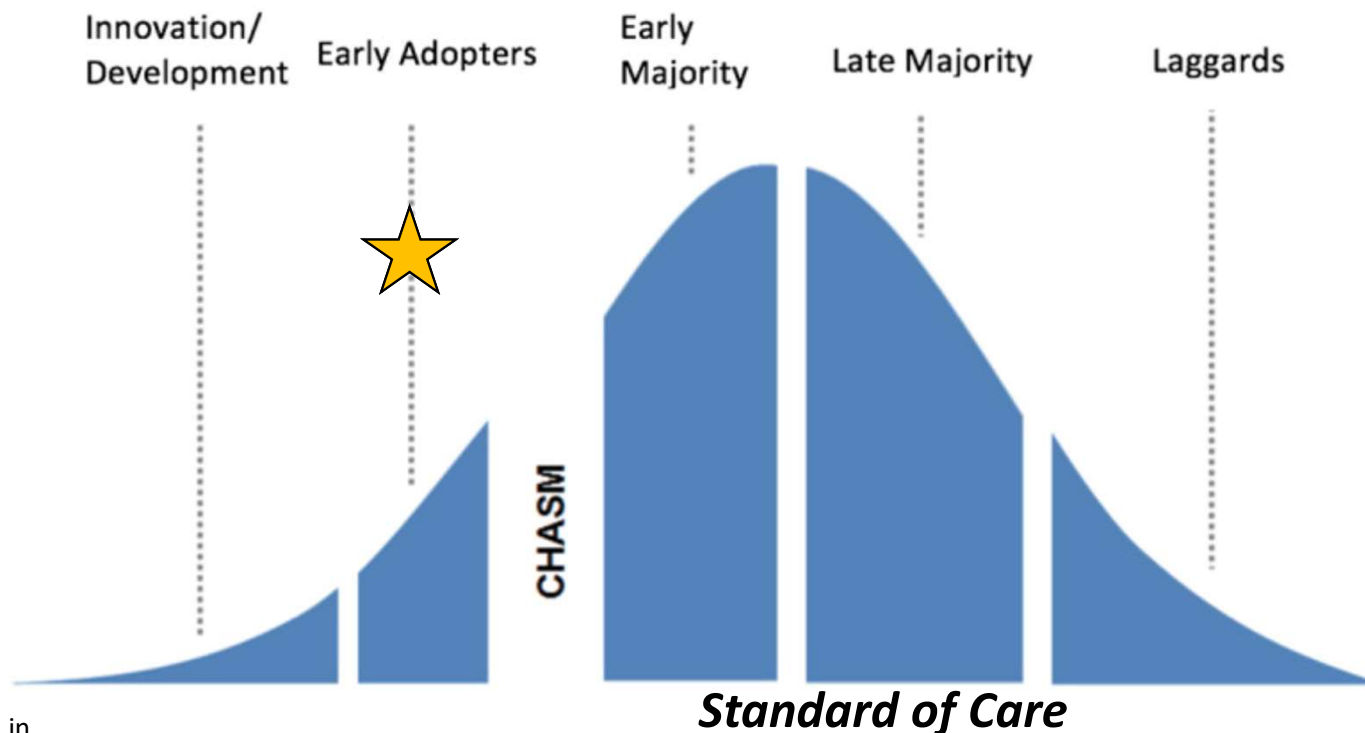
Center for Devices and Radiological Health

Food and Drug Administration

**No Financial Disclosures to Report**

# DBS Devices

- FDA has PMA/HDE approved DBS devices for the treatment of Parkinson's disease, essential tremor, epilepsy, dystonia, and obsessive-compulsive disorder
- There is considerable ongoing research into its use for other conditions. What can we do to help better ensure this technology will be available long term





## 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.



## The Office of Health Technology 5: Office of Neurological and Physical Medicine Devices

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EEG + Non EEG  
devices  
Neurocognitive  
Devices  
Mobile Medical  
Applications for  
Neurodiagnostic  
uses

Embolization Coils  
Flow Diverters  
Guidewires &  
Catheters  
Neurothrombectomy  
devices  
CSF Shunts and  
Drainage Catheters

Cranial  
Materials  
Other  
Neurosealant  
Materials  
Neuro-  
Ablative  
Devices  
Surgical  
Instruments  
Stereotactic  
Systems

### Division 5B: Division of Neuromodulation and Physical Medicine Devices

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Deep Brain  
Stimulation and  
non-invasive  
devices for  
Alzheimer's Disease  
Epilepsy  
Headache  
Movement  
Disorders

Deep Brain  
Stimulation  
Vagal Nerve  
Stimulation  
Computerized  
Behavioral Therapy  
Digital Therapeutics  
for  
Major Depression  
PTSD  
Anxiety  
Insomnia

Assistive Devices  
Brain Computer  
Interfaces  
Medical  
Exoskeletons  
Prosthetic Devices  
Orthoses  
Wheelchairs  
Walkers

Pain Therapy  
Devices  
Spinal Cord  
Stimulation  
Diathermy Devices  
Transcutaneous  
electrical  
stimulation  
Powered muscle  
stimulation  
Traction devices

# New Programs

- DBS has the potential to alleviate symptoms and improve quality of life for patients with debilitating conditions.
  - Different risk-benefit profile for specific populations and sub-populations
  - Clinically meaningful assessment tools and outcomes
  - Patient perspectives (customer insights)
- [Collaborative Communities](#)
- [Breakthrough Program](#)
- [Total Product Life Cycle Advisory Programs \(TAP\)](#)

# Resources



- **Q- Submission Program:** an opportunity to obtain **FDA feedback** prior to IDE or marketing submission
  - Guidance document:  
<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf>
- **General Submission Questions:** Division of Industry and Consumer Education (DICE)
  - Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
  - Phone: 1(800) 638-2041 or (301) 796-7100  
*Press 1 to speak to the Consumer Team*  
*Press 2 to speak to the Industry Team*
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