U.S. FOOD & DRUG ADMINISTRATION

Regulatory Considerations Digital Health Measures in Psychiatry

ISCTM
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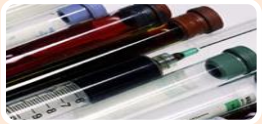
No Financial Disclosures to Report

U.S. FOOD & DRUG ADMINISTRATION

FDA

-  Center for Food Safety & Applied Nutrition
-  Center for Drug Evaluation & Research
-  Center for Biologics Evaluation & Research
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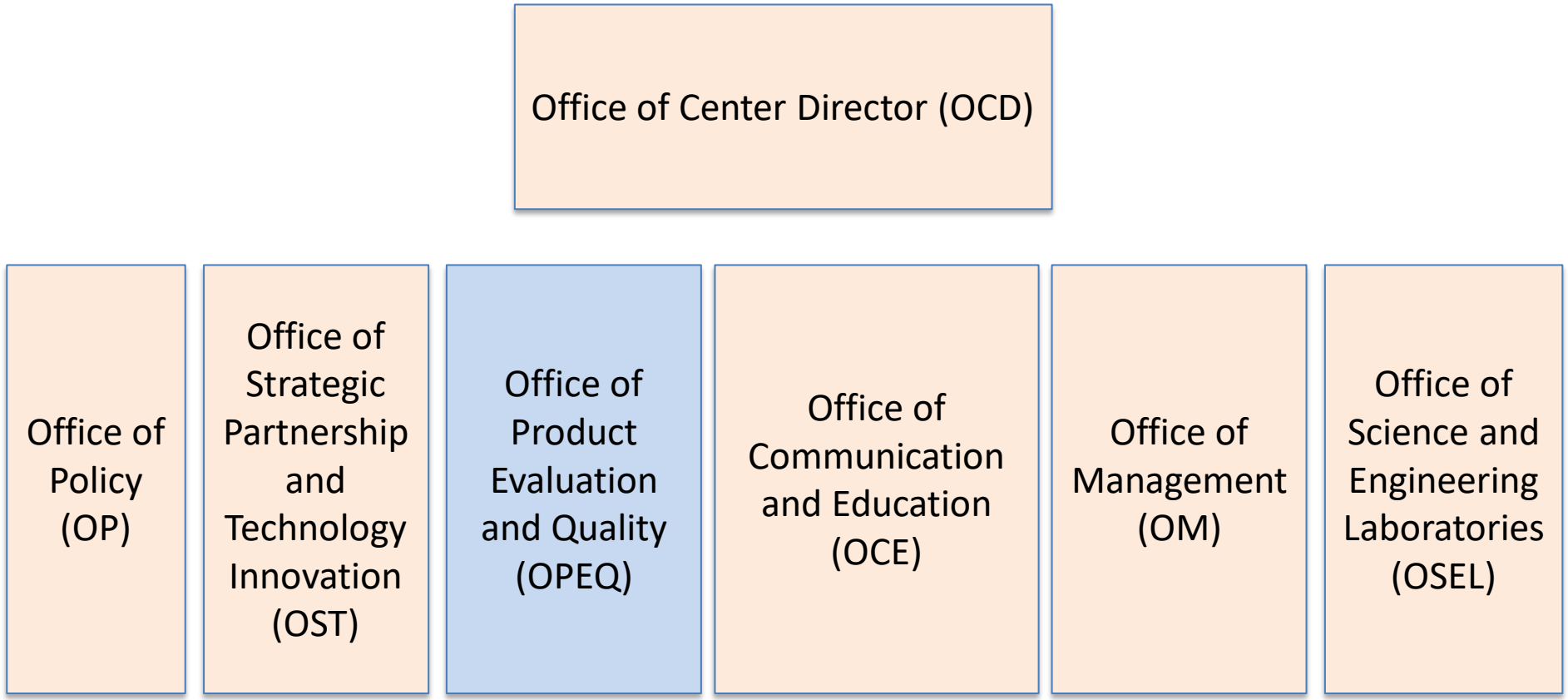
Center for Tobacco Products
-  Center for Devices & Radiological Health
-  Center for Veterinary Medicine
-  National Center for Toxicological Research

Center for Devices and Radiological Health (CDRH)



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

David McMullen, MD, Office Director

John Marler, MD, Deputy Office Director

CAPT Nina Mezu-Nwaba, PharmD, MPH, MSc, Deputy Office Director

Christopher Loftus, MD, Chief Medical Officer

Sergio de del Castillo, Associate Director for Policy

Division 5A: Division of Neurodiagnostics, Neurointerventional, and Neurosurgical Devices

Xiaolin Zheng, PhD, Division Director

Neurodiagnostic Team Jay Gupta, MS, Assistant Director	Neurointerventional Team Naira Muradyan, PhD, Assistant Director	Neurosurgical Team Adam Pierce, PhD, Assistant Director
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

Vivek Pinto, PhD, Division Director

Neurostimulation-Neurology Team CDR Jitendra Virani, MS, Assistant Director	Neuromodulation – Psychiatry Team Pamela Scott, MS, Assistant Director	Physical Medicine – Acute Injury Team Heather Dean, PhD, Assistant Director	Physical Medicine – Neurodegenerative Team Amber Ballard, PhD, Assistant Director
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

Types of Premarket Submissions

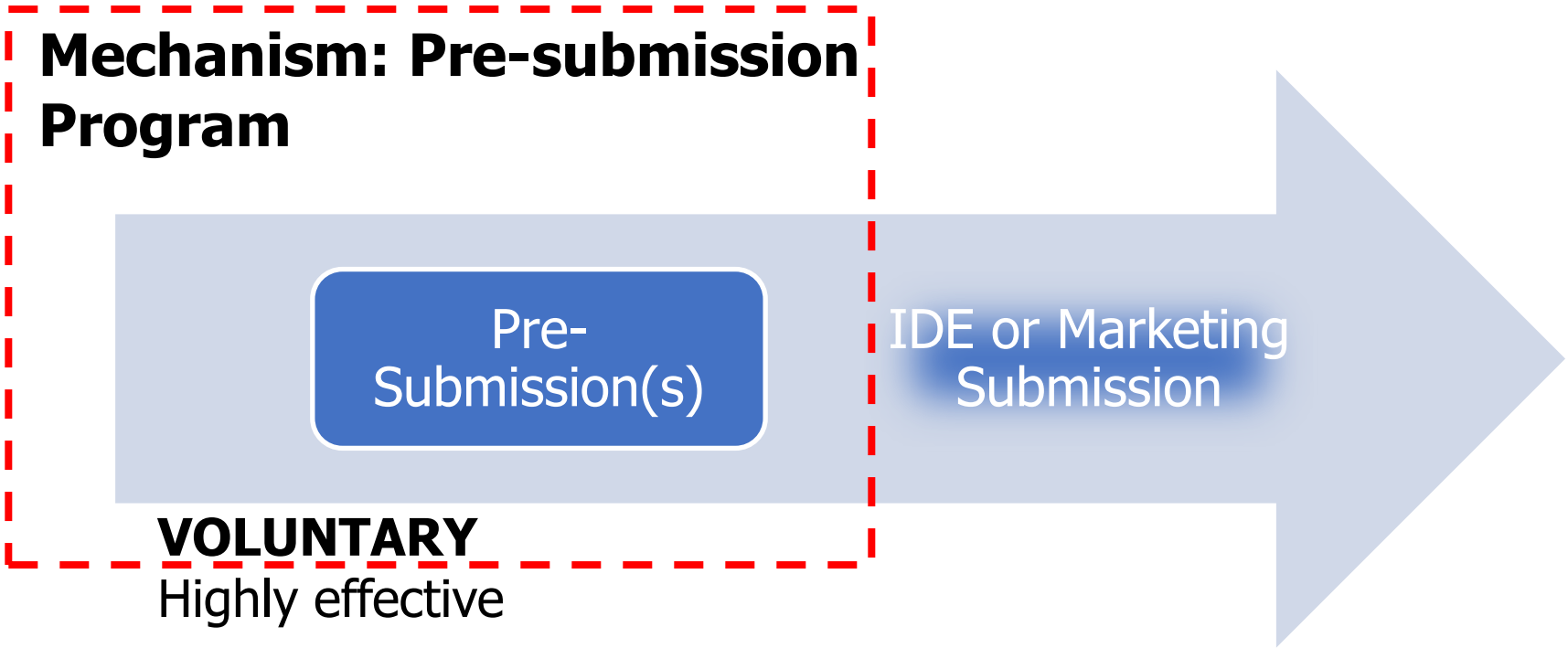
Research and development ongoing

- Q-submissions (Q-sub)
- Investigational Device Exemption - IDE
  - *STRONGLY encourage a Q-sub prior to an IDE submission*
- 513(g) Device Classification Request

Research and development complete

- Premarketing Application (PMA)
- DeNovo (DEN)
- Humanitarian Device Exemption (HDE)
  - must demonstrate safety and probable benefit
- Premarket Notification (510(K))

Early Interaction Progression



Review points to consider

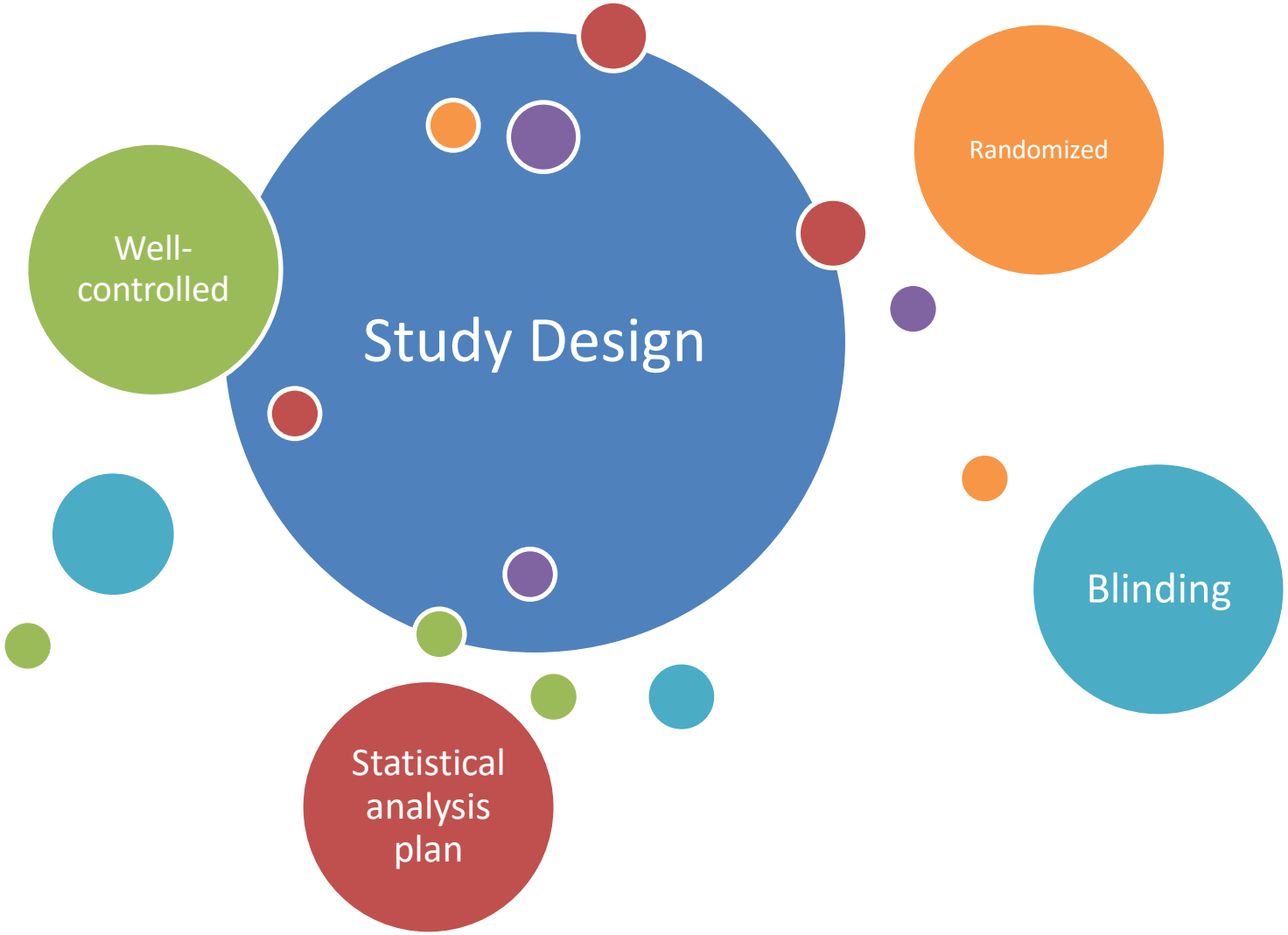
Disclaimer

- The following slides are NOT intended to be guidance
- Please reach out via the pre-sub process for specific questions about your regulatory approach

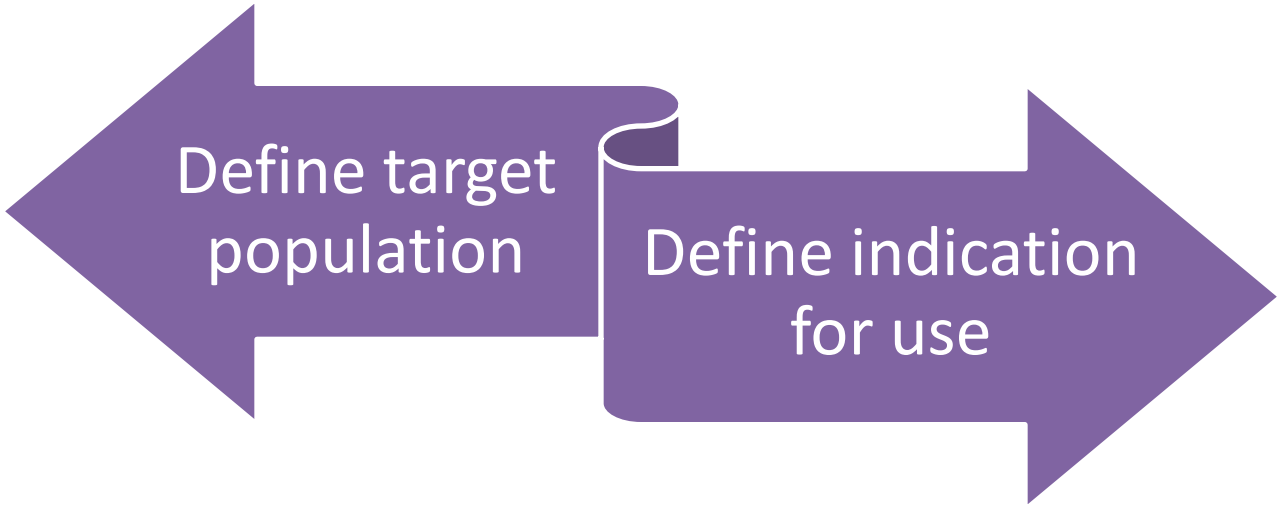
Key Elements for Digital Marketing Submissions

- Indications for Use (IFU) Statement
- Description of Technology
- Labeling
- Biocompatibility
- Software and Cybersecurity
- EMC, Electrical Safety, Wireless Testing, MR Compatibility
- Performance testing
- Benefit-Risk Analysis

Clinical Review Points to Consider



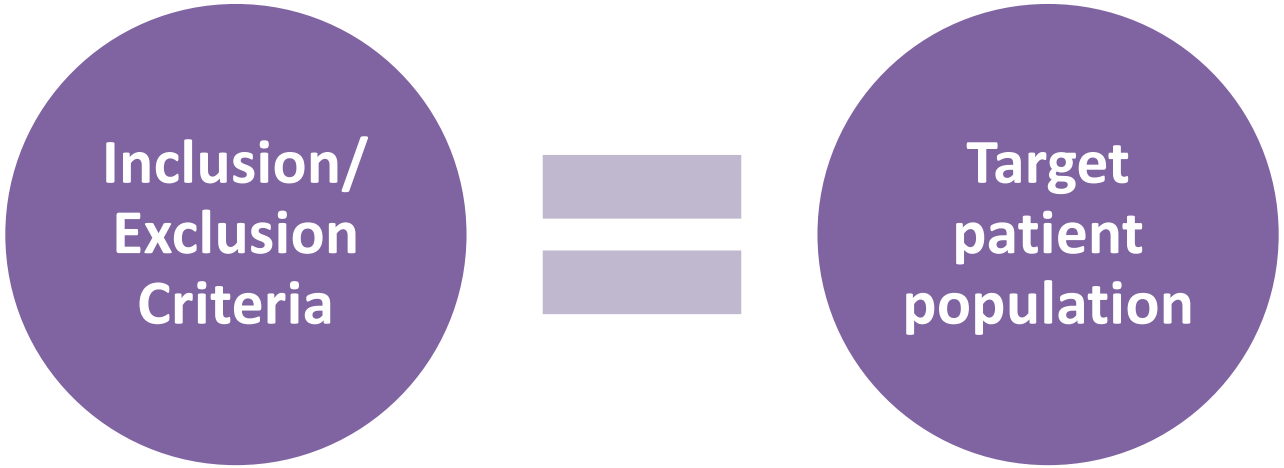
Clinical Review Points to Consider



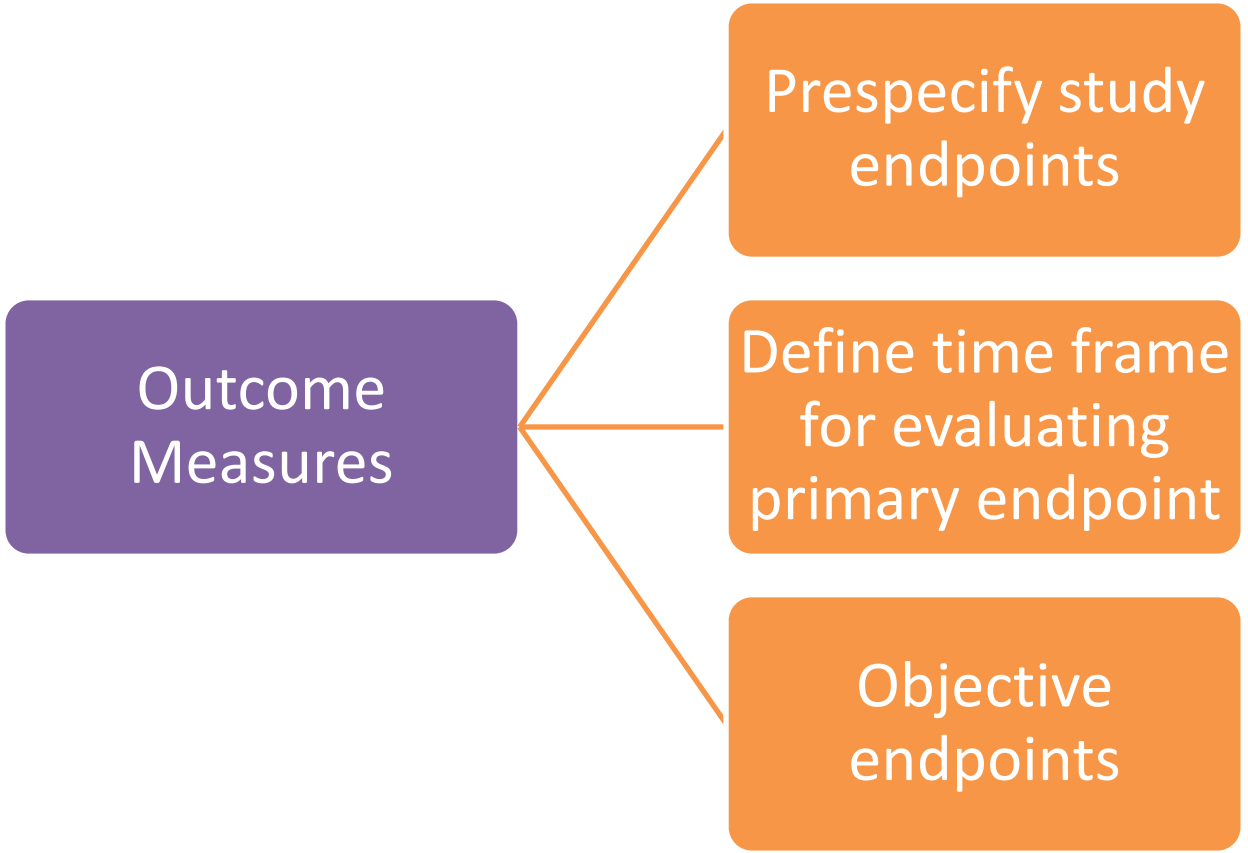
E.g., Adjunctive use vs. Standalone therapy

Clinical Review Points to Consider

Evaluate safety and effectiveness in target population



Clinical Review Points to Consider



U.S. FOOD & DRUG ADMINISTRATION

Special Programs

FDA Patient Engagement

- We are committed to understanding the views of patients during medical device development and regulatory decision-making
- We are evaluating ways to engage with patients to capture view points
- You can review the websites below to see the ongoing initiatives and new initiatives

https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-patient-engagement

https://www.fda.gov/patients/learn-about-fda-patient-engagement

Breakthrough Devices Program

- Intended to help patients have more timely access to certain medical devices and device-led combination products that **provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions** by expediting their development and prioritizing their review
  - Voluntary program
  - Access to Breakthrough Interactions (Sprints, etc…)
  - Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

Medical Device Development Tools (MDDTs) Program

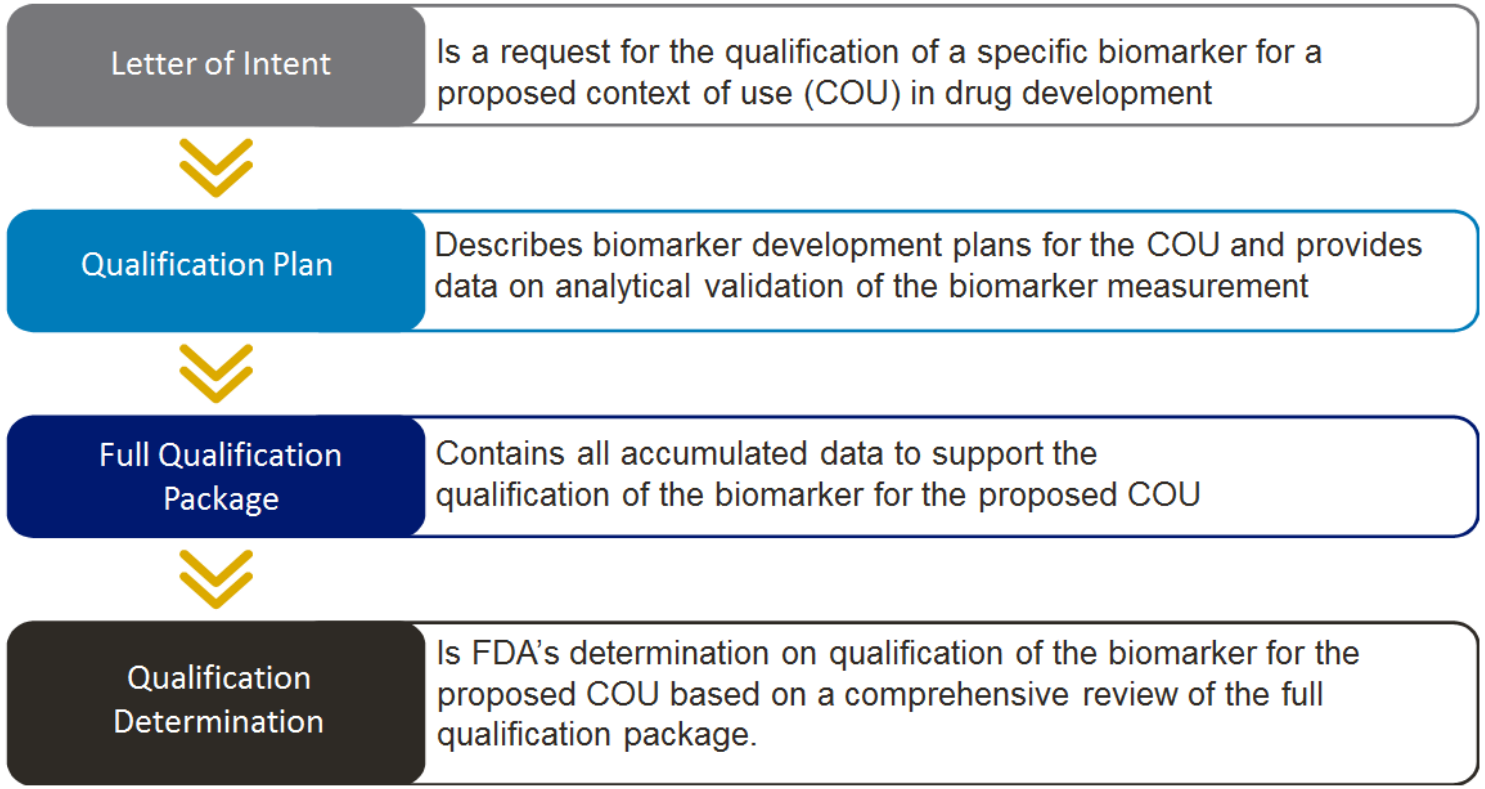
- The FDA's Medical Device Development Tools (MDDT) program is a way for the FDA to qualify tools that medical device sponsors can use in the development and evaluation of medical devices.

- https://www.fda.gov/medicaldevices/scienceandresearch/medicaldevicedevelopmenttoolsmddt for more information and link to Guidance Document

- Email MDDT@fda.hhs.gov with questions

CDER Biomarker Qualification Program

Biomarker Qualification Process



General Considerations for DHT Regulation

- Diagnostic considerations – clinical flow, output, interpretation
- Treatment considerations – outcome measure choice
- Non-clinical and related issues

Contact Information

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Division of Neuromodulation and Physical Medicine Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

It's About the Patients

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

Thanks!

Additional References

Types of Premarket Submissions

Premarket Notification [510(k)] (Class I and II):

- Required for most Class II devices
- You must demonstrate device to be marketed is **substantially equivalent** to a legally marketed device (same intended use and technological characteristics that do not raise different questions of safety and effectiveness)
- FDA "clears" 510(k)s

De Novo Petition (Class I and II):

- For new device type with low/moderate risk:
  - No identifiable predicate device;
  - New intended use; or
  - Different technology that raises different types of questions of safety or effectiveness

Premarket approval (PMA) (Class III):

- Approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).

Humanitarian Device Exemption (HDE):

- Annual US incidence less than 8000 individuals
- Approval standards:
  - Safety: information showing no unreasonable/significant risks
  - Effectiveness: Probable benefit

FDA Guidance Documents

- Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation – Non-clinical Testing and Clinical Considerations
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/implanted-brain-computer-interface-bci-devices-patients-paralysis-or-amputation-non-clinical-testing
- Benefit Risk Guidance for PMA and De Novo Submissions
  https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm517504.pdf
- Benefit Risk Guidance for IDE Submissions
  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm451440.pdf
- Patient Preference Information in Premarket Submissions Guidance
  https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm446680.pdf
- Leveraging Real World Evidence in Premarket Submissions Guidance
  https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm513027.pdf
- Breakthrough Devices Program
  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf

FDA Guidance Documents

- Software
  https://www.fda.gov/downloads/MedicalDevices/.../ucm089593.pdf
- Biocompatibility
  https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf
- Wireless Technology
  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM077272.pdf
- Cybersecurity
  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf
- Electromagnetic Compatibility
  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM470201.pdf

FDA Guidance Documents

- Significant Risk/Non-Significant Risk Guidance Document
  - http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf
- 513(g) Guidance Document – when to assess the appropriate device classification
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm209851.pdf
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
  - http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf
- De Novo Classification Process (Evaluation of Automatic Class III Designation)
  - https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080197.pdf

Point of Contact for General Submission Questions

Division of Industry and Consumer Education

DICE

EMAIL : 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

When is an IDE Needed?

When a device is a significant risk device. 21 CFR 812.3(m) defines "Significant Risk" as and investigational device that:

- ✓ Is **intended as an implant** and presents a potential for serious risk to the health, safety, or welfare of a subject;
- ✓ 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;
- ✓ 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
- ✓ Otherwise presents a potential for **serious risk to the health, safety, or welfare of a subject**.