Early Feasibility Studies in the United States to Increase Patient Access

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Professional Background

• With CDRH since 2007
• Research scientist and review consultant in Office of Science & Engineering Labs
  – One of the first EFS Program representatives
• Transitioned to Office of Device Evaluation in 2018 – Clinical Trials Program
• TPLC reorganization to OPEQ
  – Now in Office of Clinical Evidence & Analysis
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
Early Feasibility Study Program

- Appropriate for devices in an **early stage** of development to be evaluated in a **small human clinical study in the US**
- Flexible approaches to address risk while protecting human subjects
- Tools for communicating device evaluation strategy
- CDRH invested in significant training for EFS and built an informal program for promoting its use
Key Policies for EFS Program

• Device evaluation strategy based approach
  - Pairs available non-clinical testing with key device attributes and clinical mitigations
  - Right testing at the right time

• Possible to leverage data from earlier versions of the device

• Unknowns and risk can be addressed by...
  - Using clinical mitigations to provide patients with extra protection
  - The use of more frequent/detailed reporting

• Allows for timely device and clinical protocol changes
  - Possibility for more changes to be made through 5-day notification rather than prior FDA approval

• Provides tools for communicating available data to CDRH

EFS is a way to collect early human data that cannot be obtained by pre-clinical methods.
Device Development to Clinical Studies

Feasibility
Pivotal
(much more known about device, procedure, indication)

FIH
EFS
EFS Program Benefits

Multiple stakeholders benefit!
• Collaborative relationship between FDA & sponsors/innovators
• Early access for clinicians and patients to potentially beneficial devices
EFS Program at a Glance

Significant FDA interaction from first Pre-Submission to EFS IDE review
Over 200 EFS approved to treat >2500 patients

- Neurological & Physical Medicine Devices
- Cardiovascular Devices
- Ophthalmology, ENT, Respiratory & Anesthesia Devices
- Gastro, Renal, Urological Devices
- Surgical Devices and Infection Control
- Orthopedic Devices
- In Vitro Diagnostics & Radiological Health
- Neurological & Physical Medicine Devices
- Cardiovascular Devices

Number IDEs

- Submitted
- Approvals

What Comes After an EFS IDE Approval?

- FDA approval of IDE: Typically 1-2 review cycles
- IRB approval of IDE: ~ 2-3 months (MDIC baseline metrics)
- Contracting & budgeting: >120 days (MDIC baseline metrics)
- 1st patient enrolled: >180 days (MDIC baseline metrics)

MDIC has undertaken numerous efforts to address these challenges
Clinical Studies Beyond the EFS

• Sponsor interest in learning from the EFS to
  – Improve the device
  – Design and conduct efficient larger studies (e.g., pivotal)

• Approaches to facilitate transition to pivotal
  – Start discussion early while the EFS is ongoing
    • E.g., request expansion after EFS patients have been treated but while pivotal study design being developed
  – Address necessary non-clinical testing to support a pivotal study in parallel with EFS progress
Summary

• EFS Program designed to facilitate early clinical study of devices in the US while protecting human subjects

• Device evaluation strategy based approach key to successful submission

• EFS Program supports
  – Learning from the study to improve the device design and efficient pivotal studies
  – Utilization by a diverse set of clinical specialties