Early Feasibility IDE Study: Accessing FDA's Innovative Regulatory Pathway to Accelerate Your Time to Market

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- I, Semih Oktay DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

I consult to the Cardiovascular Device Industry and have consulting service agreements with a majority of these device manufacturers

Early Feasibility Clinical Studies: Regulatory Realities & Challenges

- What qualifies a device for EFS IDE submission?
- What does “less nonclinical information” actually mean?
- Factors for successful regulatory interaction with EFS IDEs

Early Feasibility Clinical Studies: *What qualifies for EFS IDEs?*

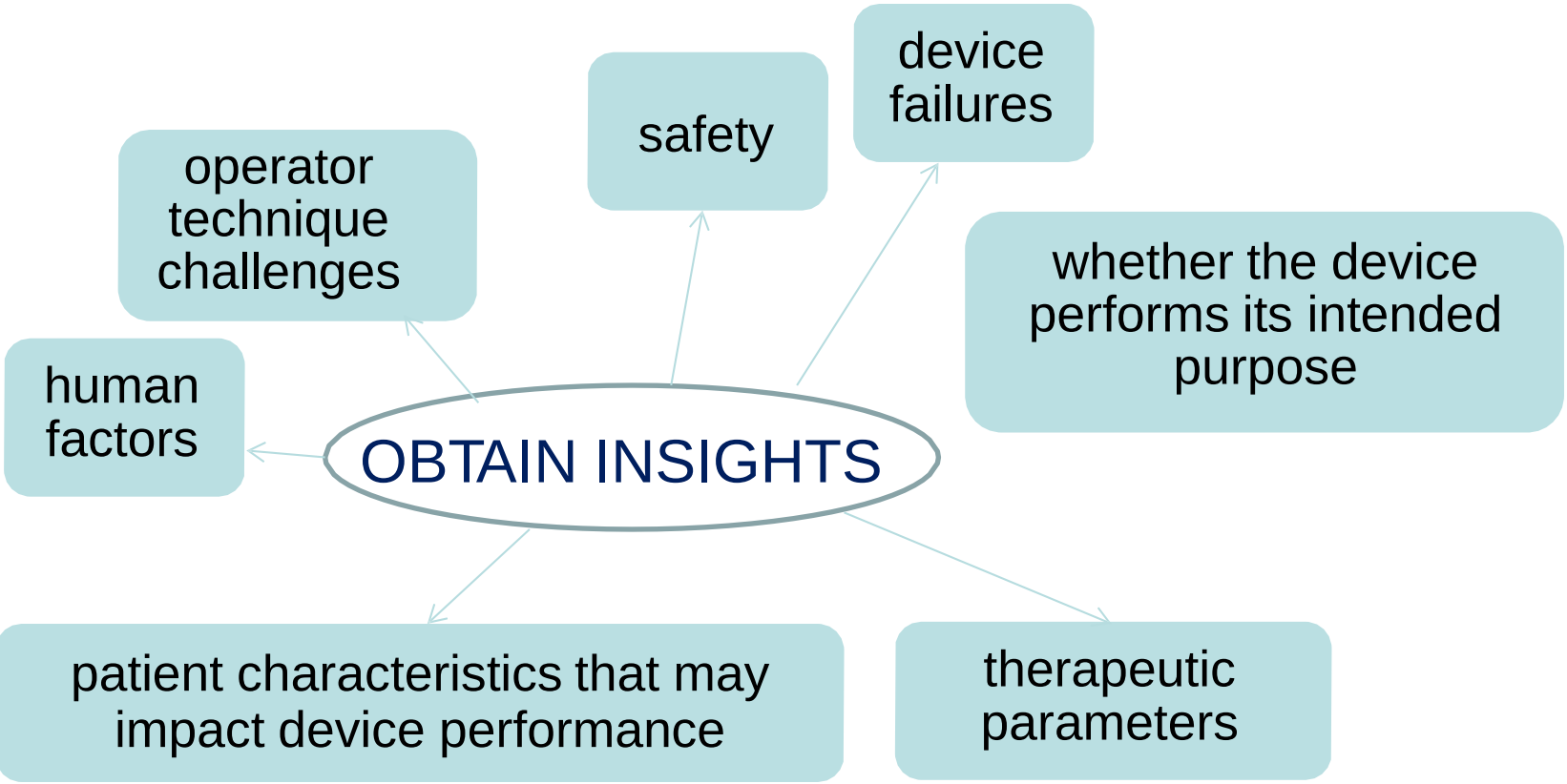
- Novel devices/products
- EF clinical study is appropriate when clinical study is needed to provide information that **cannot be practically obtained through additional nonclinical testing**
  - Justification may not be easy
  - "me too" devices may not be good candidates

Definition: Early Feasibility Study

From the FDA IDE EFS Guidance:

- Small number of subjects
- Device may be early in development, typically before the device design has been finalized
- May involve a new intended use for a device that has already been in clinical use
- May be done after, concurrently or in conjunction with non-US studies

Early Feasibility Study Purposes



Source: Dr. Andrew Farb and Dorothy Abel of FDA

FIH vs. EFS

- Not every first-in-human use of a device requires an early feasibility study
  - The nonclinical evaluation for a particular device may be well-established such that a larger feasibility or even a pivotal study may be the appropriate initial study
- A US EFS does not necessarily involve the first clinical use of a device
  - The device may have been used clinically, but the early stage of device development still fits EFS criteria for clinical use in the US
  - The device may be marketed for a different indication, but the new indication introduces uncertainties best addressed with an EFS

Early Feasibility Clinical Studies: *What does less nonclinical data mean?*

- Must provide clear benefit-risk determination to support rationale for less data
  - Use FDA Guidance Documents

    http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279103.pdf

    http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM296379.pdf
  - Reality check: FDA's comfort level may not be consistent (reviewer-dependent)
- Animal studies could incorporate acute and short term implant endpoints

EFS Guidance

Device Evaluation Strategy (DES) Table

- Provides a systematic, tabular approach to identify the information needed to support study initiation
- Supports doing the right testing at the right time
  - Emphasizes the need to consider the rationale for the testing strategy (i.e., what the testing is intended to address) before determining whether the results are supportive
- Promotes consideration of the clinical context for the EFS and all available information (e.g., device design, leveraged information, and new non-clinical testing)

Early Feasibility Clinical Studies: *Additional Challenges*

- Combination products
  - Differences in regulations and regulatory philosophy between CDRH and CDER
- FDA resources available to handle EFS IDEs
  - Internal training to educate reviewers on EFS initiative
  - Experienced versus new reviewers, as well as cross-office and cross-center review teams and comfort level with level of less nonclinical data

Early Feasibility Clinical Studies: *Successful Process*

- Effective use of early interaction with FDA is highly important – well planned and executed pre-submission process is a key factor for success
- Perform a thorough risk analysis
- Provide thorough justifications for performing less nonclinical testing

Who to Contact to Get Started?

- Contact an FDA EFS Representative
  - Andrew Farb, MD: Andrew.Farb@fda.hhs.gov
  - Dorothy Abel, BSBME: Dorothy.Abel@fda.hhs.gov
- Provide summary information
  - Device design concept
  - Clinical context
  - Rationale for conducting an EFS
  - Device Evaluation Strategy (DES) sample rows
- FDA will work with you to prepare an initial Pre-Submission for the subject matter experts to review
- Collaboratively work with the review teams to develop an IDE

THANK YOU