U.S. FOOD & DRUG ADMINISTRATION

Leveraging the VISION CRN Infrastructure for Advanced Device Research and Surveillance

EDUCATE project:

Regulatory Perspective

Jose Pablo Morales, MD
FDA Division of Cardiovascular Devices
RAPID working group meeting
March 20, 2019

Center for Devices and Radiological Health
CDRH

Disclosure Statement

I, Jose Pablo Morales, 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

EDUCATE and MDEpiNet

MDEpiNet PASSION
Project Submission Form
Updated 2/6/2018

1. Title of Project Concept	Evaluating **D**evices **U**sing **C**laims **a**nd Registry Data
2. Submission Date	7/18/2017
3. Submitter name, title, email address, and phone number	Philip Goodney, Co-Principal Investigator, Society for Vascular Surgery Patient Safety Organization, Philip.P.Goodney@hitchcock.org Jose Pablo Morales, Co-Principal Investigator, Food and Drug Administration, jose.morales@fda.hhs.gov Matthew Mell, Co-Principal Investigator, Stanford Medical Center, mwmell@stanford.edu Art Sedrakyan, Co-Investigator, Weill Cornell Medical Center (Coordinating Center), ars2013@med.cornell.edu Jack Cronenwett, Co-Investigator, Society for Vascular Surgery Patient Safety Organization, Jack.L.Cronenwett@dartmouth.edu

Contains Nonbinding Recommendations

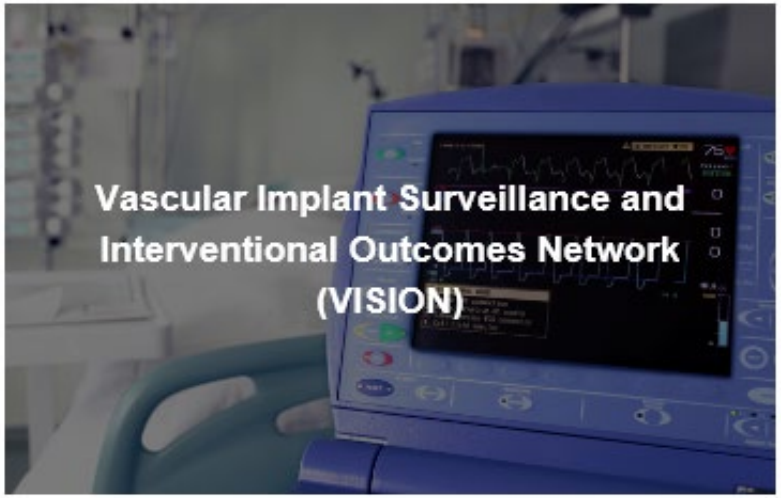
Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 31, 2017.

The draft of this document was issued on July 27, 2016

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf



https://nestcc.org/demonstration-projects/

EDUCATE Goals

- Evaluate the accuracy of claims data for assessing the effectiveness of endovascular grafts via a 3-way linkage (industry pre-market device trials, Medicare claims, and the Vascular Quality Initiative registry).
  - Long term monitoring is central to total life cycle surveillance.

EDUCATE Goals

- Serve as a potential data source to optimize the interval and modality of surveillance imaging for follow-up of patients with implanted EVAR devices, or in some instances for specific patient characteristics (personalized medicine).
  - CT with contrast has inherent risks of contrast induced nephropathy and excessive radiation, plus a significant cost burden to our health system
    - Potential Favorable Benefit/Risk to move in this direction

Potential Regulatory Benefits

- If this innovative data set proves capable of mirroring the findings derived from the current standard data collected in industry sponsored IDE studies, the FDA may be willing to consider alternative data sources to lessen the burden on manufacturers.
  - For example, FDA could use registry data linked with claims as a measure to assess the long-term effectiveness of the devices
    - Take care of issues related to incomplete follow-up, poor patient compliance and procedures performed at other centers
  - This process could result in greater efficiency, coverage, accuracy and economy of device monitoring.

Current Limitations

- Current CT imaging requirements on FDA regulated studies assess loss of patency, endoleak, migration, aneurysm expansion.
  - Not all these device events result in intervention.
- Do we need new legislation?
- Do data sharing regulation and policies allow for this model to be adopted?
- Are FDA and manufacturers willing to test this approach with a real application?

Contact Information

Jose Pablo Morales, MD

Medical Officer

FDA Division of Cardiovascular Devices

(301) 776-8936

Jose.Morales@fda.hhs.gov

Thank You