

# Phasing of Registry Implementation

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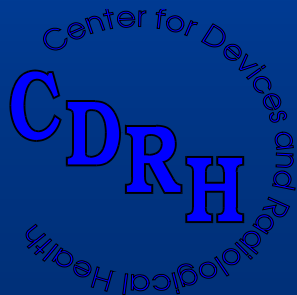
Office of Surveillance and Biometrics

Center for Devices and Radiological Health

Food and Drug Administration

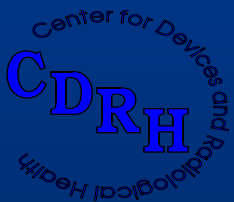
SAFARI Thinktank II

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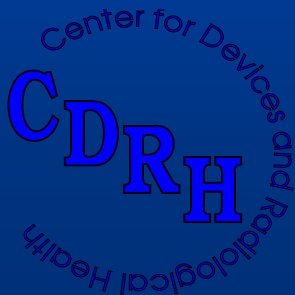
# Plan for Initial Pilot

- Beta testing completed
- Pilot data collection at 4-6 sites
  - Should include follow-up
  - Evaluation of methods to obtain follow-up at pilot sites
- Add additional sites
- Modifications to address specific questions related to safety and effectiveness



# Follow-up Phase of the Registry

- Follow-up should be included when the registry is initiated
  - First stages of infrastructure building
  - Follow-up information valuable information collected by this registry
  - Demonstrated difficulty in adding follow-up in later phase in other registries
  - Pilot testing of follow-up needed



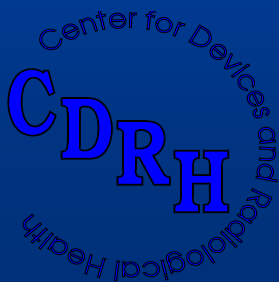
# How should follow-up data be collected?

- Centralized vs localized collection?
- Type of follow-up contact?
  - Clinical visits
  - Telephone contact
  - Mailed questionnaires
  - Combination
- Length of Follow-up?



# How should follow-up data be collected?

- Follow-up collected by linking to administrative data
  - Cost
  - Successfully done in the past
  - Can be tested in pilot phase
  - Limitations - percent of patients “matched”



# Follow-up Phase of the Registry

What type of follow-up information is needed

- Current picture
  - Safety (Stroke, AE)
  - Long term effectiveness
- Future directed questions
  - Detailed info for specific questions



# Stopping Rules for SAFARI

- No pre-set stop date for SAFARI
- Start-up cost of establish new registries in the future
- Designed as a flexible registry that can accommodate evolving technology and safety/effectiveness questions
  - Drugs
  - Surgical
- Annual reviews by independent committee on phasing in/out components of SAFARI

