AF Ablation Update & Challenges:

FDA View

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How Did We Get Here?

- FDA has been involved in clinical trials since the mid to late 1990's
- Advisory Panel meetings in 1998, 2000 and 2007
- Until recently, no devices approved for AF
- Recently, the 1st device was approved for paroxysmal AF

Pre-market IDE studies

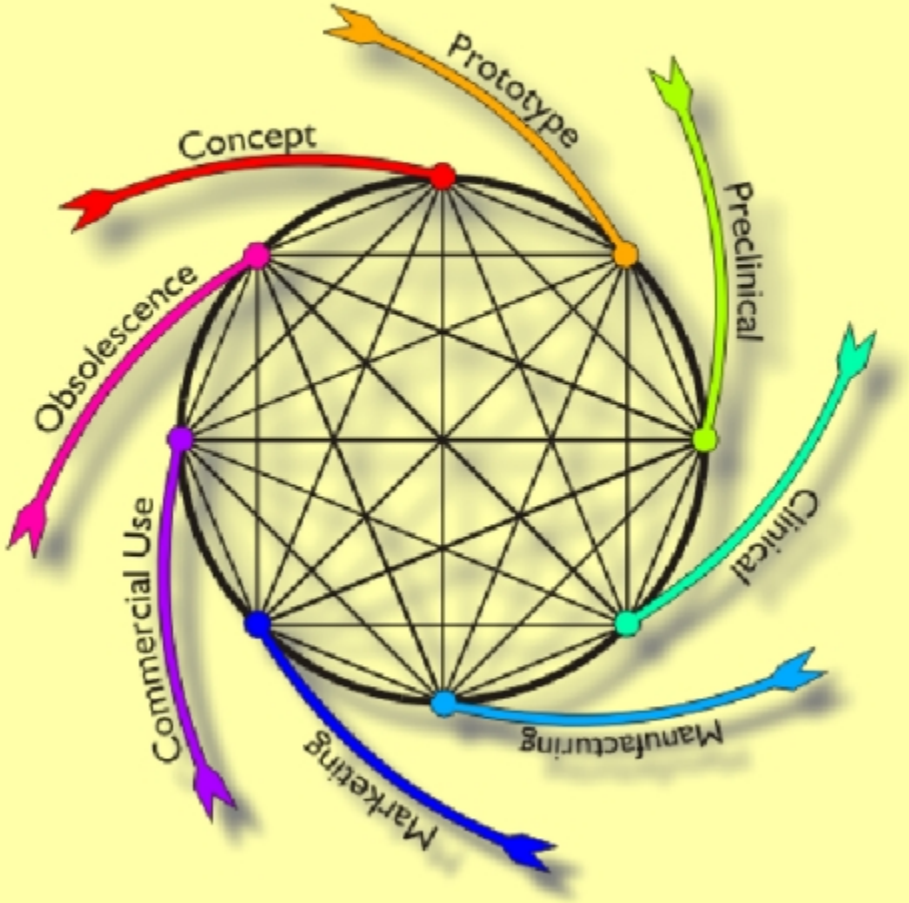
- Relatively modest numbers of patients
- Conducted at a limited number of sites
- High volume
- “Centers of excellence”
- Relatively brief follow-up

- How “generalizable” is this information?

FDA's Perspective

- Our mission is to promote & protect the public health
- AF is clearly a major public health issue
- Given the high prevalence of AF & increasing AF ablation procedures,
- FDA needs valid scientific evidence to support advancement in device-based therapy
- BUT – premarket studies are only the beginning of that process

CDRH Vision - Total Product Life Cycle



How Does the Registry Help FDA?

- Pre-market studies have limitations
- Alternate studies can be helpful to characterize
  - Long-term safety
  - Long-term effectiveness
  - Larger sample
  - Outcomes based on a broader clinician experience

Challenges for the Registry

- Procedures & follow-up
  - Attempts to “standardize” may have advantages and disadvantages
- Data elements
  - What do we need vs. what would we like
- Data collection
  - Patient follow-up is critical
  - How can we leverage technology to help

FDA's Goals

- Short term safety in a broad range of operator experience
- Long-term effectiveness outcomes
- Long-term safety
- Outcomes according to operator experience & ablation technique
- Outcomes in a much larger population