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Questions to be Addressed by SAFARI

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BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

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Scope of the Registry

The key to a successful registry is to clearly identify the objective and critical questions FIRST; what is the overall goal? What is the purpose for the development of evidence?

Data collection tools MUST be simple, logistically feasible, & relevant to registry objectives

- Primarily representative of "real word" safety for AF catheter ablation
- Not a replacement for randomized, well-designed clinical trials
- Very clearly defined inclusion criteria; all-comers?
- Consensus related to on-label/off-label use; no IDE clinical pt inclusion
- Drive hypothesis generation for future clinical trials; impact decision making
- Registry should be complimentary to:
  - Drive utilization of Guidelines and consensus
  - Support evolution of AF Ablation therapy
  - Allow for variety of catheter technologies
- Partnership to support mutual goals of:
  - Patient access to safe and effective therapy
  - Advancing the science

Safety Questions

• Consist of valid questions that can be answered by a registry; rigor of reporting required by randomized, controlled IDE trials not applicable

- Is safety profile different when performed outside of trials ,i.e. community hospitals with less experienced operators?
- More focus on evaluation of safety in women and elderly patients
- Understand all-cause mortality rates
- What is “real-world” stroke risk?
- Explore major complications with ensuing sub-population review
- Focus on gross safety outcomes with emphasis on acute, procedural events
- Capture information regarding ablationist and experience

Challenges in Evaluating Effectiveness

Should not be the primary focus of the registry, obstacles in capturing this information and interpreting it are significant

- No crisply defined endpoint
- Would require a common definition of “success” to assess durability of results; definitions of recurrence
- Agreement on blanking period and application of results
- Repeat ablation procedures and interpretation of efficacy long-term
- Rigor of rhythm monitoring, i.e. Holter and how long, 24h,72h, etc)
- Is effectiveness measured with or without drug? What level of drug is acceptable to claim success?
- Patient follow-up may occur at referral sites, not site of procedure
- Without stringent definitions/methods, establishing performance goals or historical controls from registry data could be “skewed” and not representative as a bar for future study design

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How does registry effort fit with CABANA?

Public information on CABANA is limited to posting on clintrial.gov & presentation in public forum

- Active comparator is PVI; registry will allow much broader collection of techniques and assessment of such
- Will CABANA allow other energy sources as commercial availability broadens?
- Will there be competition for patients? Will overlap be allowed?
- CABANA will likely gather more adverse event data
- Likely differences in monitoring of data between CABANA and registry will can lead to questions of over/under reporting
- Propose registry and CABANA be “de-coupled” and each is a stand-alone evaluation