SAFARI Thinktank

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Industry Recommendations for SAFARI Registry Development

Phase 0 – Definition & Planning

- Establish working groups or committees to focus on various aspects of the registry.
  - Executive committee to which all other committees will report. (i.e., provide project management)
  - Establish a Steering Committee of representative stakeholders
  - Executive committee to report to the steering committee
  - Operational committees

- Governance and management committee s(senior policy makers- regulatory, reimbursement, clinical research)
  - Define scope & the key question (s) that the registry will address
  - Data collection, management and analysis
  - Regulatory /Legal review

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Industry Recommendations for SAFARI Registry Development

Phase I – Pilot Study

- Define scope and criteria for registry
- Recruit, qualify and train pilot sites to “road test” the registry
- Pilot enrollment period
  - Evaluate usability of data collection instruments
  - Assess compliance with procedural and follow-up data capture
- Pilot evaluation
  - Beta site testing and process changes as needed

Phase 2 – Registry Enrollment

- Site expansion
- Accrue patient data and monitor for data completeness and quality
- Prospective criteria for stopping needs to be determined

Phase 3 – Analysis

- Analyze results per prospective statistical analysis plan
- Communicate results via appropriate peer-reviewed literature

Industry Position

- Professional societies, industry and individuals have indicated substantial support for AF ablation as a therapy option for patients when treated according to published guidelines

- Endorse investment in clinical research (e g Cabana, and others) to advance the evolution of ablation therapy for AF

- Industry supports the development of an appropriately designed and adequately funded registry in centers with adequate infrastructure

- Definition of scope of the objective of the registry is important at this stage, both to insure successful execution of the project as well as to not unduly burden provider's participation

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Recommendations for Scope and Rollout

- Begin with the basics – Generalizability and Safety
  - Focus on the safety with a manageable number of centers
    - Short (max 2-3 page) clinical data form
      - Patient history & risk factors (Age/Gender)
      - Procedure type
      - Acute adverse events
      - Acute procedural result
  - Conduct new pilot in 5-10 centers
    - Representative sample (low & high volume centers)
    - Operator Experience & Facilities
  - Expand to more centers when early phases are successful

- Effectiveness should continue to be addressed via formal, clinical trials with standardized rhythm monitoring procedures.

Thank You