Safety of Atrial Fibrillation Ablation Registry Initiative (SAFARI)

Marcia S. Yaross, Ph.D.
Vice President, Clinical, Regulatory and Health Policy
Biosense Webster, Inc.
What is SAFARI?

• National (US) Atrial Fibrillation (AF) ablation registry initiative to:
  – Collect “real world” data on AF ablation across broad range of providers and patients
  – Inform guidelines for the use of and techniques for ablation therapy to treat AF
  – Provide standardized language for the collection and reporting of clinical data,
  – Provide benchmarking data to providers and third-party payers
  – Establish patient-level historical control data for use in studies to evaluate new technologies
  – Provide framework for post-approval studies of new AF ablation technologies
  – establish a more generalized safety and effectiveness profile of ablation procedures to communicate to patients
Who is SAFARI?

- Pan-stakeholder Initiative
  - FDA
  - CSRC
  - ACC/NCDR
  - HRS
  - Industry
  - Hospitals
  - Payers

Represented on Exec Ops Committee

Roles TBD
SAFARI Governance Structure

- Stakeholder Community
  - Industry
  - Payers
  - Government
  - Professional Societies
  - Hospitals

- Steering Committee

- Executive Operations Committee

- Registry development team
- Data use & publications Committee
- Budget Committee
- Ad Hoc Meeting Committee
Key Milestones in SAFARI Development

- **1st “Thinktank” Meeting** – April 2009, Silver Spring, MD
  - “white paper” summary to be published in AHJ

- **2nd Stakeholder Meeting** – January 13, 2010, Seaport Hotel, Boston, MA

- **Study Start** – TBD
  - Phased approach
  - Draft data collection instruments near ready for testing
    - Short and long versions

---

**NCDB® Atrial Fibrillation Ablation Study - Long Form**

- **A. Demographics**
  - Last Name, First Name, Middle Name
  - SSN, Patient ID, Other ID
  - Birth Date, Sex, Male, Female
  - Race (check all that apply)
  - Hispanic or Latino Ethnicity

- **B. Adverse or non-supply**
  - Admission Date, Patient Zip Code
  - Admitted for this procedure

- **C. History and Risk Factors**
  - Hypertension, Type 2 diabetes, History of CHF

---

*Biosense Webster®
a johnson & johnson company*
Why SAFARI?

Areas of Consensus – Potential Value of an AF Registry

• Accrual of a large, longitudinal sample of real-world safety data
• Ability for individual physicians and/or institutions to monitor their outcomes and compare to national norms
• Manufacturer access to observational dataset to monitor post-market performance of their products
  – post-approval study commitments
  – detection of potential safety signals
• Drive utilization of the existing practice guidelines
• Develop safety, effectiveness hypotheses
• Improve patient and referring physician awareness of therapy
Why SAFARI?

Areas of Consensus – Methodology & Logistics

• Research questions should be prospectively specified
  – To be discussed in January 2010 pan-stakeholder meeting
• Safety endpoints first priority
• Data must be monitored to assure quality, reliability
• All stakeholders need to be involved in transparent process
• Start with pilot to assess feasibility
Open Issues for SAFARI

Challenges Unsolved to Date

- Assessment of effectiveness in observational AF study
  - Variations in post-procedure monitoring
- Long term outcomes
  - Complexity of AF ablation care pathway for non-acute endpoints
- Trade-offs between data granularity and cost/clinician burden
- Registry duration/Prospective stopping Rules?
- Safe Harbor for Industry Participation (off-label procedures)
- Funding source(s)?
  - Carrots vs. Sticks? – important to not confound coverage decisions
  - Need to balance investment in registry vs. interventional clinical trials
  - Competition for $$, patients, clinician time
Thank you