Safety of Atrial Fibrillation Ablation Registry Initiative (SAFARI)

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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

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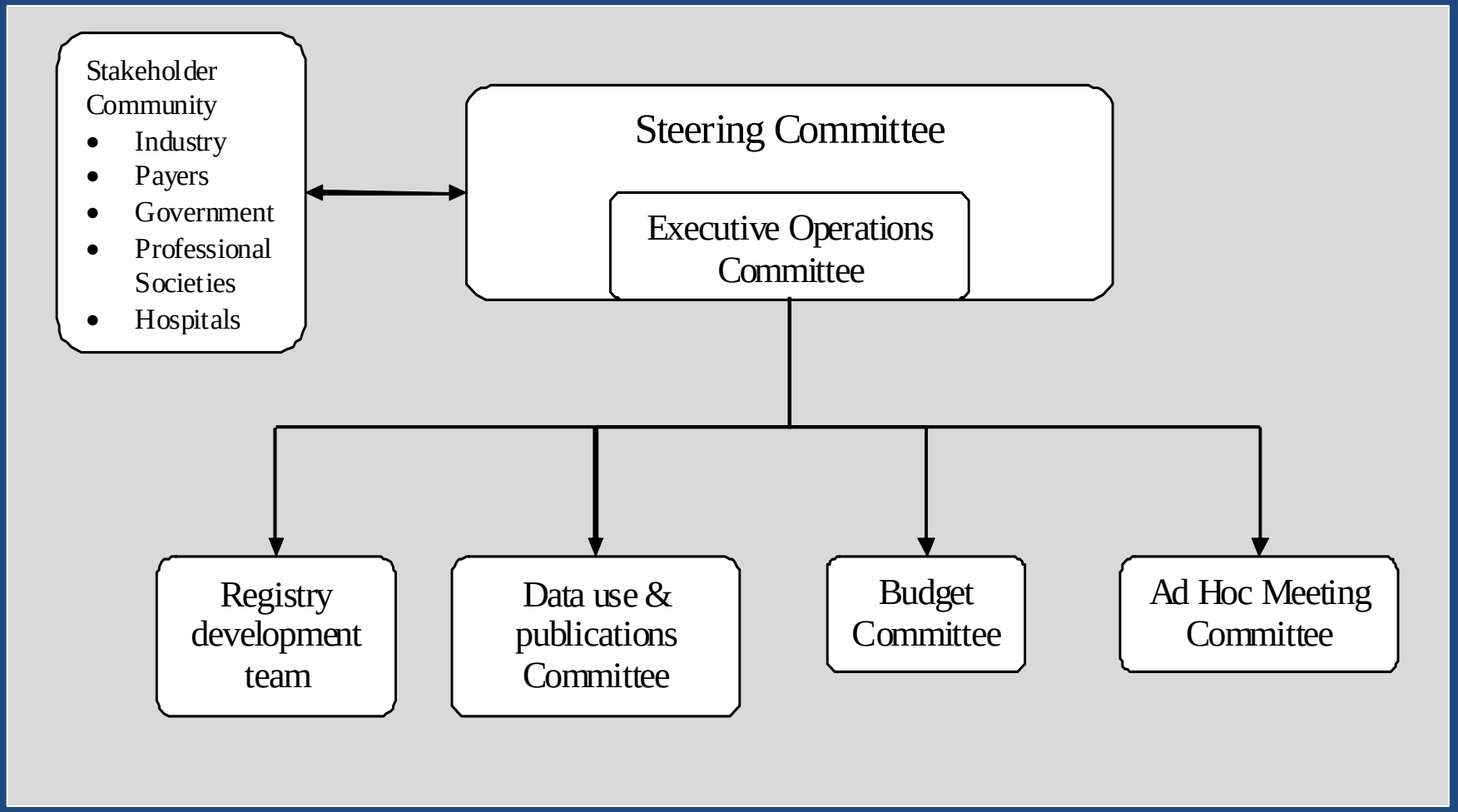
SAFARI Governance Structure



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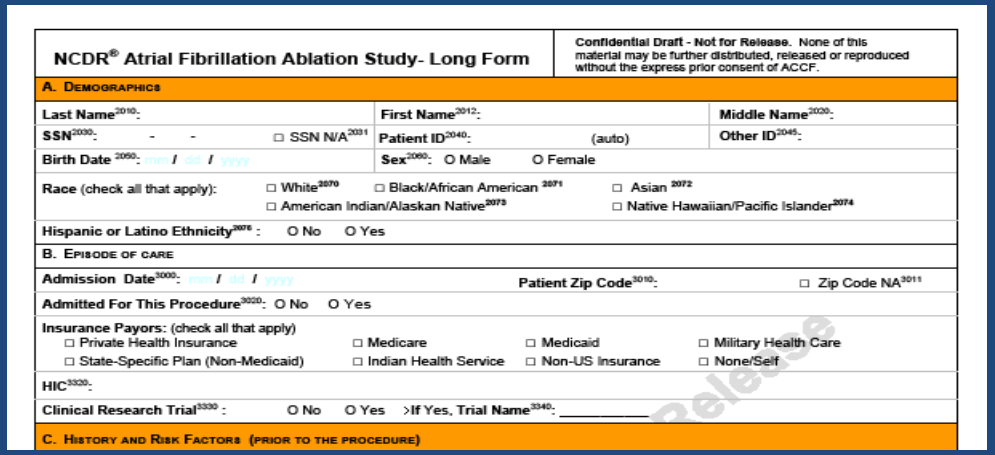
Key Milestones in SAFARI Development

- 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



NCDR® Atrial Fibrillation Ablation Study- Long Form

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A. Demographics

Last Name[2010]:	First Name[2012]:	Middle Name[2020]:
SSN[2030]: - - ☐ SSN N/A[2031]	Patient ID[2040]: (auto)	Other ID[2045]:
Birth Date[2050]: mm / dd / yyyy	Sex[2060]: O Male O Female	

Race (check all that apply): ☐ White[2070] ☐ Black/African American[2071] ☐ Asian[2072] ☐ American Indian/Alaskan Native[2073] ☐ Native Hawaiian/Pacific Islander[2074]

Hispanic or Latino Ethnicity[2075]: O No O Yes

B. Episode of Care

Admission Date[3000]: mm / dd / yyyy Patient Zip Code[3010]: ☐ Zip Code NA[3011]

Admitted For This Procedure[3020]: O No O Yes

Insurance Payors: (check all that apply)
☐ Private Health Insurance ☐ Medicare ☐ Medicaid ☐ Military Health Care
☐ State-Specific Plan (Non-Medicaid) ☐ Indian Health Service ☐ Non-US Insurance ☐ None/Self

HIC[3320]:

Clinical Research Trial[3330]: O No O Yes >If Yes, Trial Name[3340]: _____

C. History and Risk Factors (prior to the procedure)

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

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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

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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

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