

Governance Processes & Statistical Considerations

Processes & Publications: Academic View

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Background / Importance

- This meeting is testimony to the importance of AF and major questions regarding therapy
- We need data to evaluate current and future techniques for AF ablation
- The results of the registry must be made available in a peer-reviewed fashion

What Works Well Today?

- Ablation can provide a major clinical benefit
- CABANA will address mortality in a clinical trial
- The STS database shows us what can be done, with acute and 30-day follow-up
- NCDR ICD provides a model for short-term:
 - Compliance has been excellent
 - HIPAA issues have been addressed
 - Data are already being analyzed and published

What's Missing, Broken or Does Not Work Well Today?

- AF ablation is variable
 - Techniques
 - End points
 - Success rate
- The STS and NCDR-ICD do not provide long-term follow-up
- Individual parties have agendas regarding data
 - FDA
 - Industry
 - Academics

Short-Term Priorities (1-3 Years)

- Establish standardized data elements
- Develop a HIPAA-compliant NCDR-AF Registry with universal buy-in
 - Academics
 - Industry
 - FDA
- Two levels of registry data
 - Broad data base with minimal f/u
 - More focused sub-groups
- Industry and FDA should have representation on leadership committees that are led by academic representatives
- Create a sustainable funding mechanism

Long-Term Priorities (3-5 Years)

- AF ablation will continue to develop, in part related to the result of the AF registry
- Medical therapies will also advance: should these be followed similarly?
- Data must be disseminated in an unconflicted, academic fashion
- Ongoing surveillance will be necessary
 - Focus of original registry
 - Mechanism for standardized evaluation of new therapies