



# AdvaMed

Advanced Medical Technology Association

## SAFARI and the Future

*Marcia S. Yaross, Ph.D.*

*Vice President, Worldwide Clinical, Regulatory  
and Health Policy*

*Biosense Webster, Inc.*



- “*Keep it Simple*” principle
- Tasks associated with present scope are significant
  - Defining the questions to be answered
  - Identifying funding sources
  - Establishing infrastructure
  - Addressing questions of data monitoring, access to outcomes beyond index ablation encounter
- Premature to talk about future expansion?



- Scope currently defined as catheter ablation of AF
- Newly marketed catheters – already within scope
- Newly marketed ancillary technologies – data management committee could periodically review data collection forms for adequacy
- Therapies beyond catheter ablation – if registry warranted, address separately

- Very important question
  - Do we have good understanding other registries?
  - Are there areas of overlap or complementarity?
- Human clinical research should not be unnecessarily duplicative
  - Resources are limited
  - Even with HIPAA protections, some increased loss of privacy is risked, societal reward should be commensurate
- If complementary, impact on SAFARI “Key Questions”?

- Focus critically important; keep goals clear and attainable
- Where relevant to SAFARI “Key Questions,” collect medication data

- Attractive concept but potentially complex?
  - Confounding of literature if same subjects entered into multiple databases, subsequent publications?
  - Confounding of costs – who pays for what?
  - Confusion of what data entered where?
    - Impact on SAFARI?
    - Impact on future trial?
- Important to define prospectively to minimize compromising quality of each endeavor



**AdvaMed**

Advanced Medical Technology Association

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

Date