Furthering CSRC Initiatives
A Role for the ACC
What We Do...

- **Quality Care**: Leading the way in defining quality care for the cardiovascular community and patients

- **Education**: Providing the very best cardiovascular knowledge for every clinician

- **Advocacy**: Shaping the future of health care nationwide to increase patient value and access to quality care
SAFARI
incubator to birth

SAFE-PCI
incubator to birth and beyond
SAFARI – Part One

Safety of Atrial Fibrillation Ablation Registry Initiative

- Originally convened via CSRC (DCRI, ACC, HRS, STS, NHLBI, FDA, CMS, and AHRQ)
- Safety and effectiveness of AF ablation procedures
- Houston we have a problem.
SAFARI – Part Two

Executive Committee

FDA support
Inclusion criteria, metrics and dataset
Pilot test of data collection (10 sites)

Implementation plan for registry development
Follow-up data collection feasibility study
NCRI Mission

Integrate existing resources to efficiently execute large, simple clinical research projects

– Site recruitment and education
– Randomization, Research Data Collection
– Quality Improvement Registry Data collection
– Data standards submissions
– Research opportunity development
– Reusable
NCRI’s infrastructure opens doors…

| Site Descriptor Database | • Database of research ready sites within the NCDR  
                      | • An approach for targeted recruitment |
|--------------------------|---------------------------------------------|
| Data Transfer System     | • Connects CathPCI with an EDC System  
                      | • Provides mechanism for modified CRFs, additional data collection |
| Randomization            | • Connection with EDC system allows us to track randomized patients within the registry |
| SDTM Output              | • Data Collection tool/ EDC system that can export data in SDTM compliant structure (ready for FDA submission) |
| Data Standards           | • Create CV standards in CDISC and HL7  
                      | • Load all standards in NCI repository for future uses in trials |
| Enhance Site Research Readiness | • Employ educational webinars/ training to NCDR sites to become research ready |
| Future Research          | • Ready for large randomized clinical trials  
                      | • Post approval studies and CER |
Trans-Radial Education And Therapeutics (TREAT) Initiative Thinktank/Incubator II

The SAFE-PCI for Women
SAFE-PCI for Women Study

Study of Access Site For Enhancement of Percutaneous Coronary Intervention for Women

DCRI
- Study Coordinating Center

ACC
- Registry Platform

Pilot study for the National Cardiovascular Research Infrastructure (NCRI) grant
NCRI infrastructure at work for SAFE-PCI…

- Execute Data Release Consent Form (DRCF) with sites allowing transfer of CathPCI data
- Populate SDD with research ready sites
- Timely data transfer of CathPCI data to DCRI
- Clinical support - triage data entry questions
- Program support - triage study questions
SAFE-PCI Milestones

**SDD**
- Site Descriptor Database (SDD) housing ≈ 50 research ready CathPCI Registry® sites

**Enrollment**
- First active and enrolling site September 2011

**Patient randomization**
- First patient randomized September 2011

**CathPCI**
- Successful merge of CathPCI Registry® data with study specific data from DCRI EDC system

**Timing**
- ≈24 month subject enrollment; 3-6 month site enrollment
Clinical registries provide a platform for phase 3 & 4 research studies...

**Pre-Market**

- Phase 1
  - Safety is primary endpoint
  - Small sample size (n < 20)
  - Highly selected population (must meet several selection criteria)
  - Short duration

- Phase 2
  - Safety and efficacy are primary endpoints
  - Limited sample size (n ~ 25-50)
  - Highly selected population
  - Short duration

- Phase 3
  - Safety and efficacy are primary endpoints
  - Larger sample size to test hypotheses (n ~ 150-250)
  - Selected population
  - Pivotal studies (randomized controlled trial, RCT)
  - Longer duration

**Post-Market**

- Post-Approval
  - FDA driven and negotiated
  - Centers defined
  - Generally a Phase 3 continuance
  - Sample size pre-determined
  - Study interval defined

- Post-Market
  - Sponsor driven
  - Generally RCT or Claims based
  - Direct product comparisons
  - Costs collected
  - Sample size pre-determined
  - Study interval defined

- Traditional Registries
  - Product performance and safety data
  - Effectiveness is the primary endpoint
  - Hypothesis generating
  - Large and usually undefined sample size
  - Real world population
  - Continuous duration
  - Treatment not assigned

**Role for New Generation of Clinical Registries**

- Traditional Registries
  - Continuous duration
  - Treatment not assigned

- Phase 4
  - Randomized controlled trial, RCT
  - Direct product comparisons
  - Costs collected
  - Sample size pre-determined
  - Study interval defined

**Clinical registries provide a platform for phase 3 & 4 research studies...**
Thank you