

# Furthering CSRC Initiatives A Role for the ACC



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# 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



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**SAFARI**  
incubator to birth

**SAFE-PCI**  
incubator to birth and beyond



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# 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..





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# 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



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# 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



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# 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





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# Trans-Radial Education And Therapeutics (TREAT) Initiative Thinktank/Incubator II

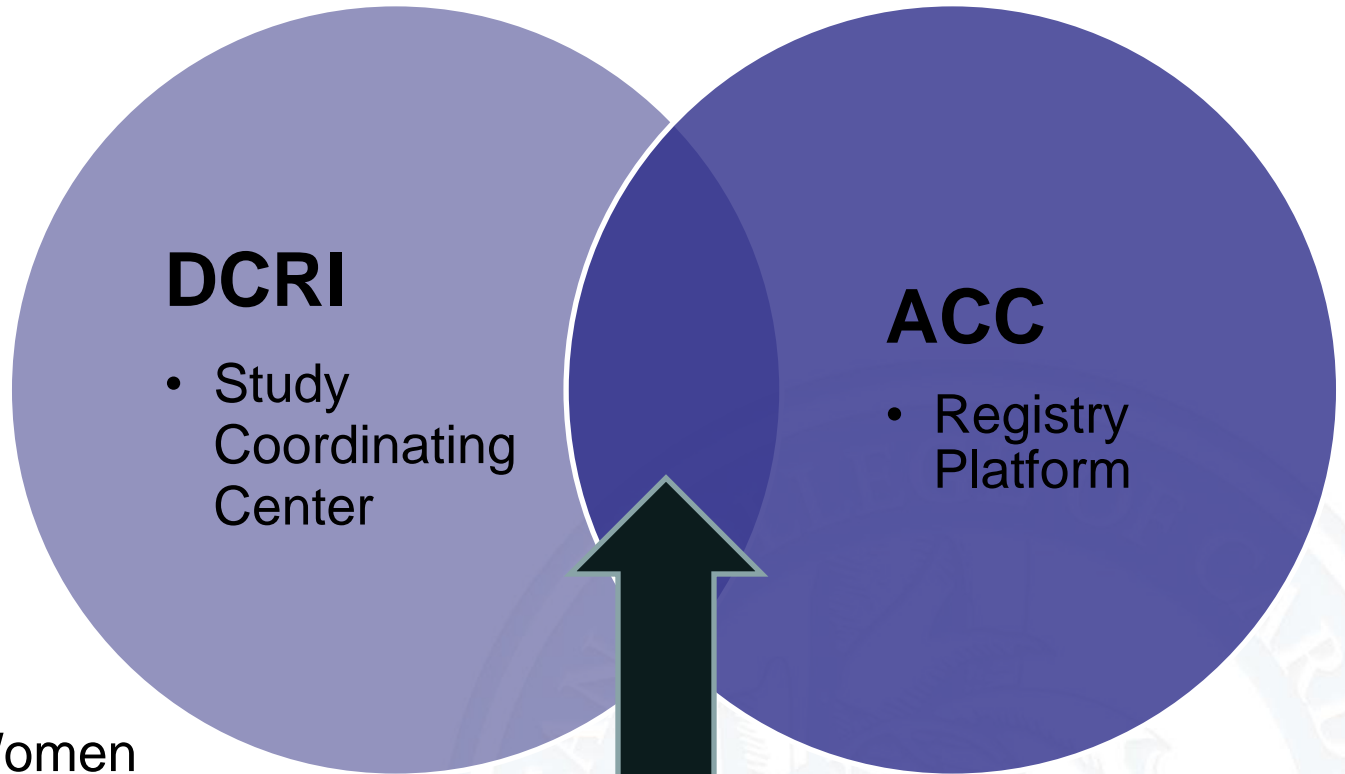
## The **SAFE-PCI** for Women



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# SAFE-PCI for Women Study

**S**tudy of  
**A**ccess Site  
**F**or  
**E**nhancement of  
**P**ercutaneous  
**C**oronary  
**I**ntervention for Women



**Pilot study for the National  
Cardiovascular Research  
Infrastructure (NCRI) grant**



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# 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 -trriage data entry questions
- Program support-trriage study questions



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# 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**

**Post-Market**

**Role for New Generation  
of Clinical Registries**

**Phase 4**

**Phase 1**

**Phase 2**

**Phase 3**

**Post-Approval**

**Post-Market**

**Traditional Registries**

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

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

- 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

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

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

- 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

# Thank you



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