Furthering CSRC Initiatives
A Role for the ACC

Helping Cardiovascular Professionals
Learn. Advance. Heal.

NCDR®
National Cardiovascular Data Registry

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

Cardiac Safety Research Consortium
www.cardiac-safety.org

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CARDIOLOGY
FOUNDATION

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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

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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

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

The SAFE-PCI for Women

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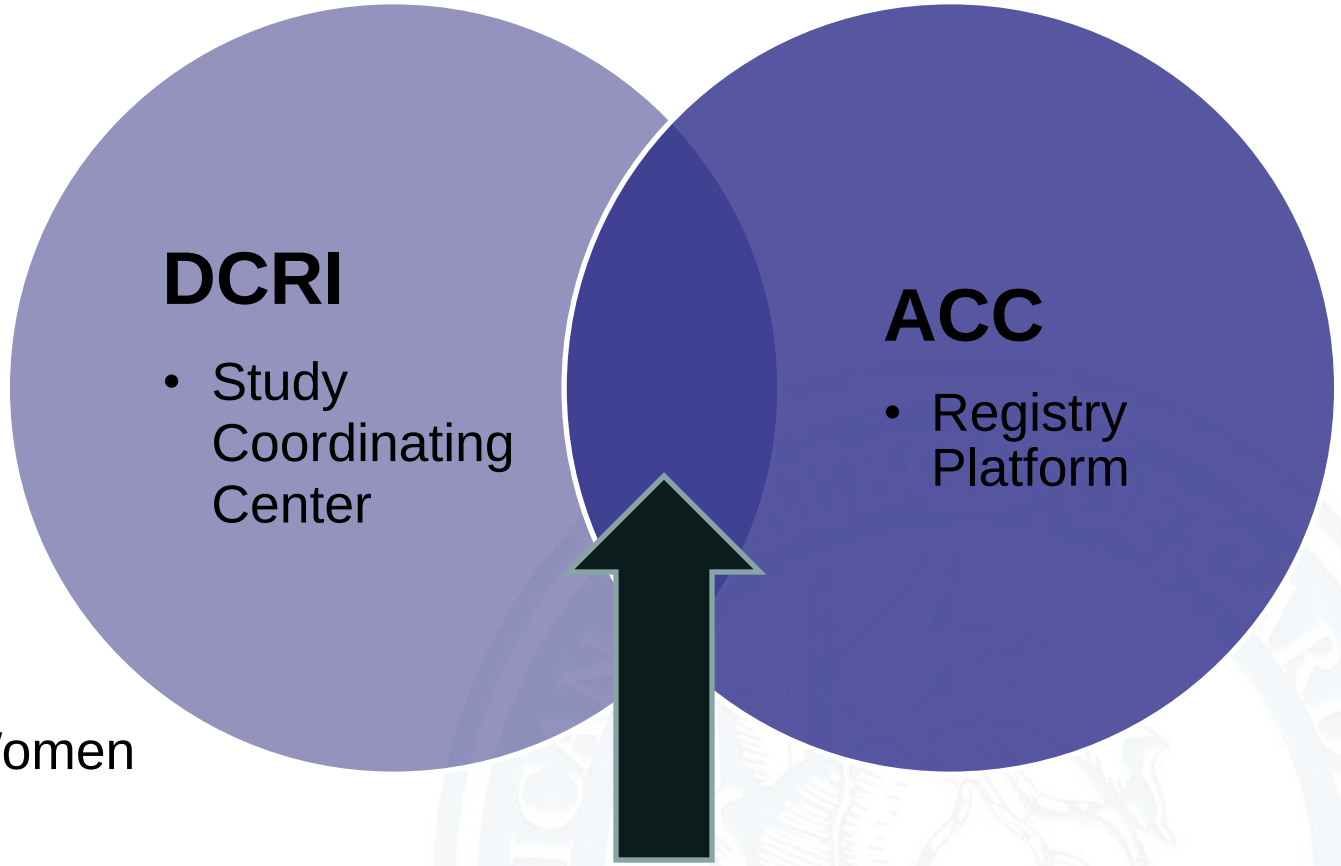
SAFE-PCI for Women Study

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



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

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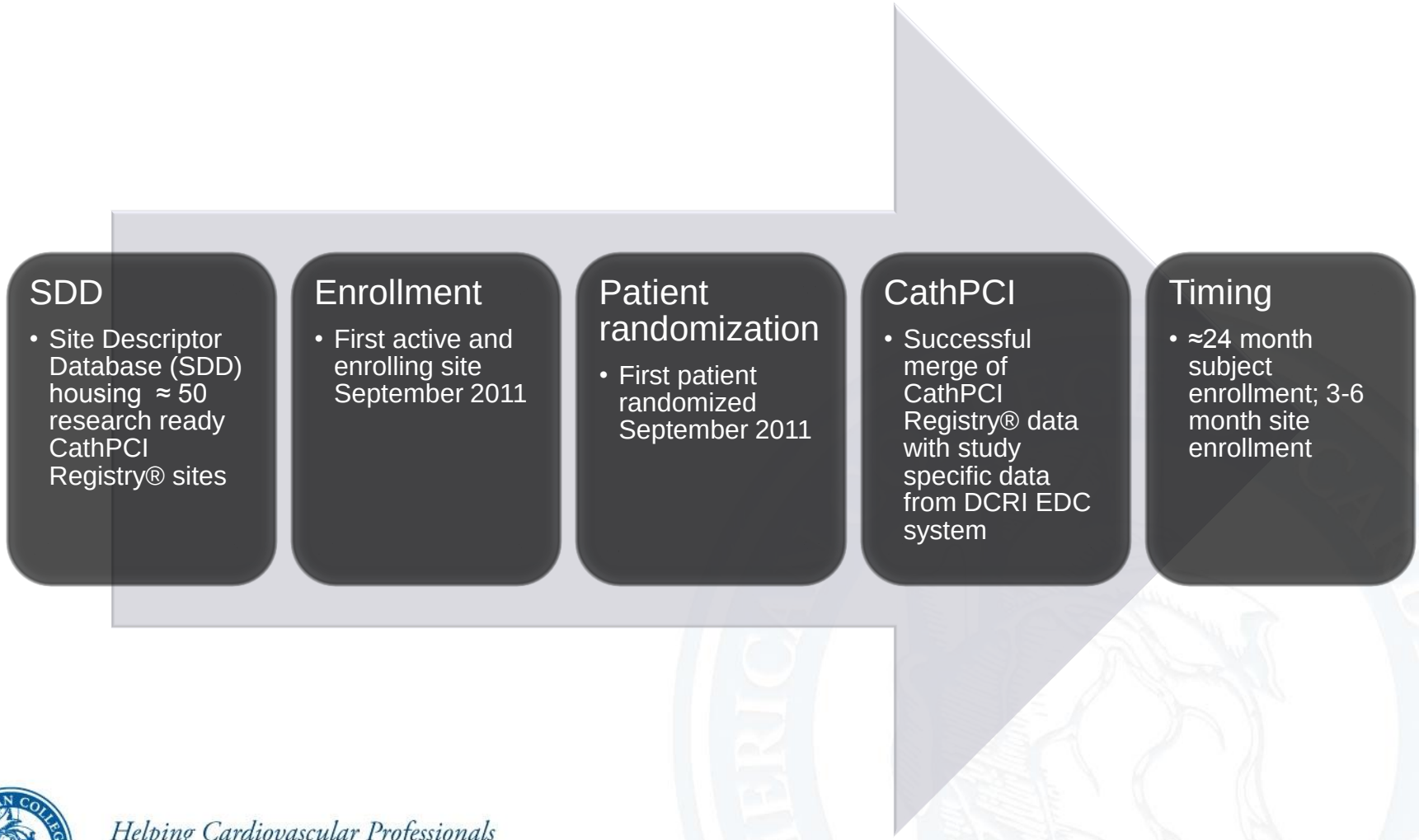
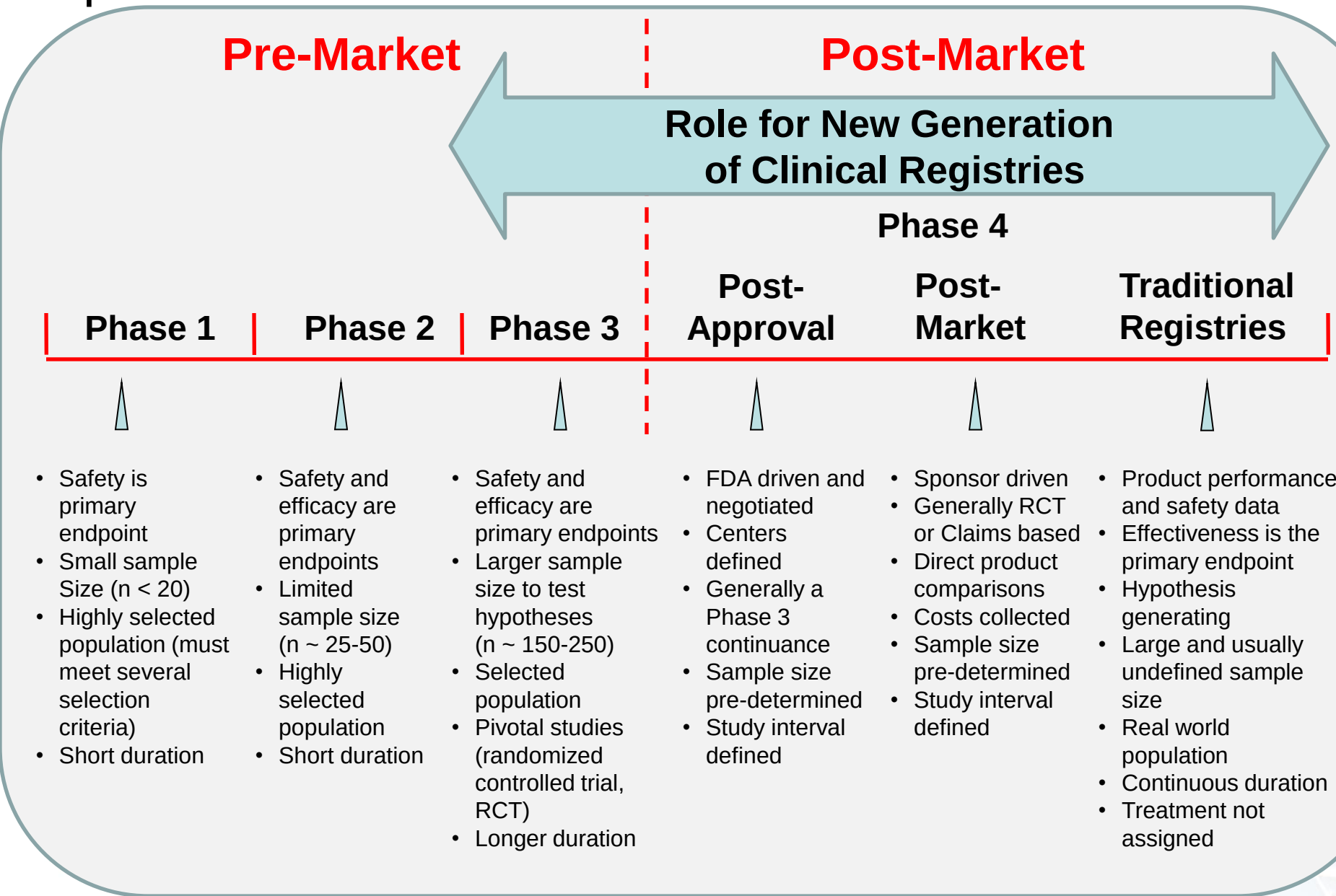
NCRI infrastructure at work for SAFE-PCI…

- 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 -triage data entry questions
- Program support-triage study questions

SAFE-PCI Milestones



Clinical registries provide a platform for phase 3 & 4 research studies…



Thank you

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