

# SAFE PCI for Women: NCDR View

Fran Fiocchi, MPH  
Director, NCDR Research Studies  
American College of Cardiology



PINNACLE Registry<sup>™</sup>

ACTION Registry<sup>®</sup>-GWTG<sup>™</sup>

CathPCI Registry<sup>®</sup>

IMPACT Registry<sup>™</sup>

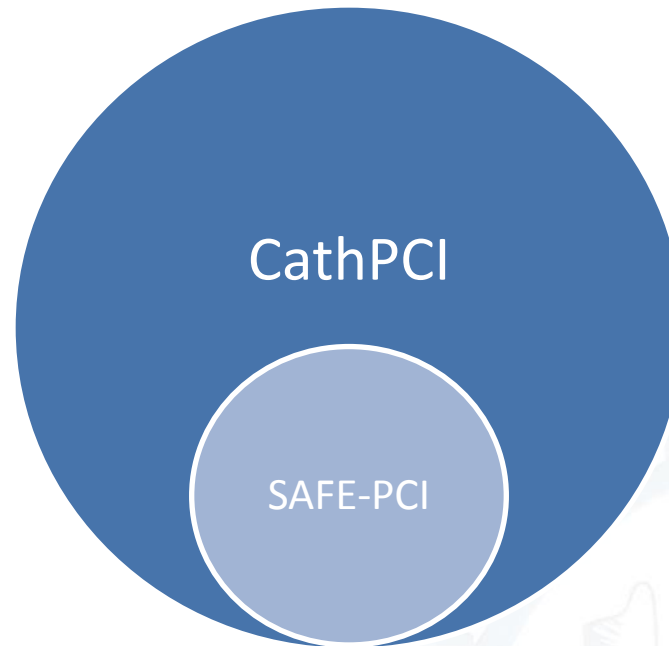
CARE Registry<sup>®</sup>

ICD Registry<sup>™</sup>

STS/ACC TVT Registry<sup>™</sup>



# NCDR's Role in SAFE-PCI



Support for site recruitment

Data Release Consent Forms

Daily transfer of study data to DCRI



*Helping Cardiovascular Professionals  
Learn. Advance. Heal.*

# Lessons Learned

- Successes (and challenges) have shaped the NCDR's infrastructure and processes for research
  - Dedicated research team
  - IRB and compliance SOPs
  - Better communication with Registry Site Managers and study site investigators
- Research-ready sites
- New research study id fields



# Expansion of NCDR Research

- SAFE-PCI was a launching pad for the NCDR's foray into clinical research studies
- Interest in NCDR data to support research
- More opportunities to link with external data sources such as claims data and other clinical data sources
- Our experiences to date have provided us with the opportunity to build a robust clinical research infrastructure necessary to advance cardiovascular science



*Helping Cardiovascular Professionals  
Learn. Advance. Heal.*

# Our Focus Going Forward

- Generating new knowledge and evidence
- Tracking patient safety and real-world outcomes
- Prospective post-market safety surveillance
- Monitoring safety and effectiveness
- Generating evidence for CMS Coverage Determinations
- Improving quality of care for patients



*Helping Cardiovascular Professionals  
Learn. Advance. Heal.*