Study of Access For Enhancement of STEMI for Seniors:

The SAFE STEMI for Seniors Protocol

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What is SAFE STEMI for Seniors?

- ***Public health clinical trial: >65 y.o STEMI <6 hrs***
  - **Radial access PCI in seniors**
  - **Multivessel PCI in seniors**

- ***IDE(s) clinical trial:***
  - **DES labelling for STEMI (Medtronic)**
  - **iFR guided multivessel PCI (Volcano-Philips)**

- ***Registry-based CRN randomized trial:***
  - **Index procedure (NCDR Cath-PCI)**
  - **Long term follow up (Claims data)**

- ***Lesson in partnered problem solving***

SAFE STEMI for Seniors: Study Design

IDE

STEMI Patients Eligible for Radial Access
N=1100

DES Eligible?

No → BMS Registry
N=100

Yes

Unequivocal 1-Vessel disease by angio?

Yes → Single Vessel CAD
DES to IRA
N=400

No → Multi-Vessel CAD
iFR examination
N=600

Randomize 1:1

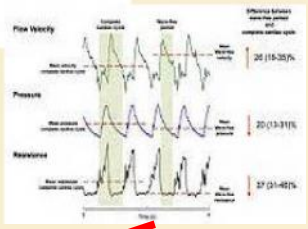
IRA-only revascularization
N=300

Complete revascularization
N=300

U.S. TRI in Seniors
- RIVAL
- RIFLE STEACS
- MATRIX

Patient Flows

IDE



MV PCI in STEMI
- PRAMI
- CvLPRIT

STEMI Patients Eligible for Radial Access
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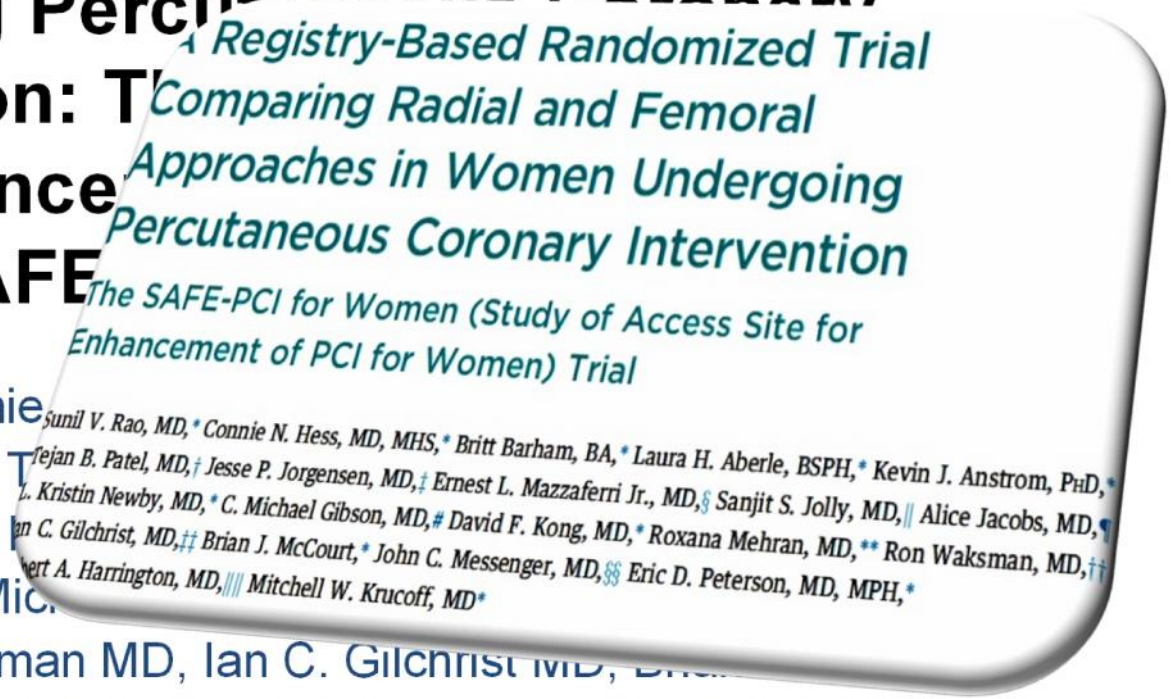
TCT 2013 Featured LBCT

A Registry-Based Randomized Trial Comparing Radial and Femoral Approaches In Women Undergoing Percutaneous Coronary Intervention: The Study of Access Site for Enhancement of PCI for Women (SAFE-PCI for Women)



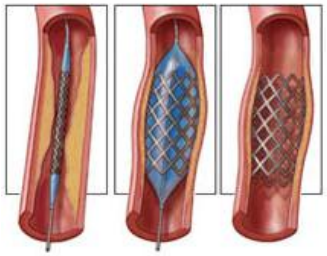
Sunil V. Rao MD, Connie
Kevin Anstrom PhD, T
Ernest L. Mazzaferri
Kristin Newby MD, C. Mic
Mehran MD, Ron Waksman MD, Ian C. Gilchrist MD,
Eric D. Peterson MD MPH, Robert A. Harrington MD, Mitchell W. Krucoff MD *on behalf of the SAFE-PCI for Women Investigators*

DCRI

Rao S et al JACC Cardiovascular Int 7(8)2014

SAFE-PCI for Women workflow

Randomization



Demographics

Medical Hx

Procedural data

Index Hosp MACE

NCDR® National Cardiovascular Data Registry

CathPCI Registry®

Autopopulate

Part 11 Compliant

65% site coordinator workload reduction

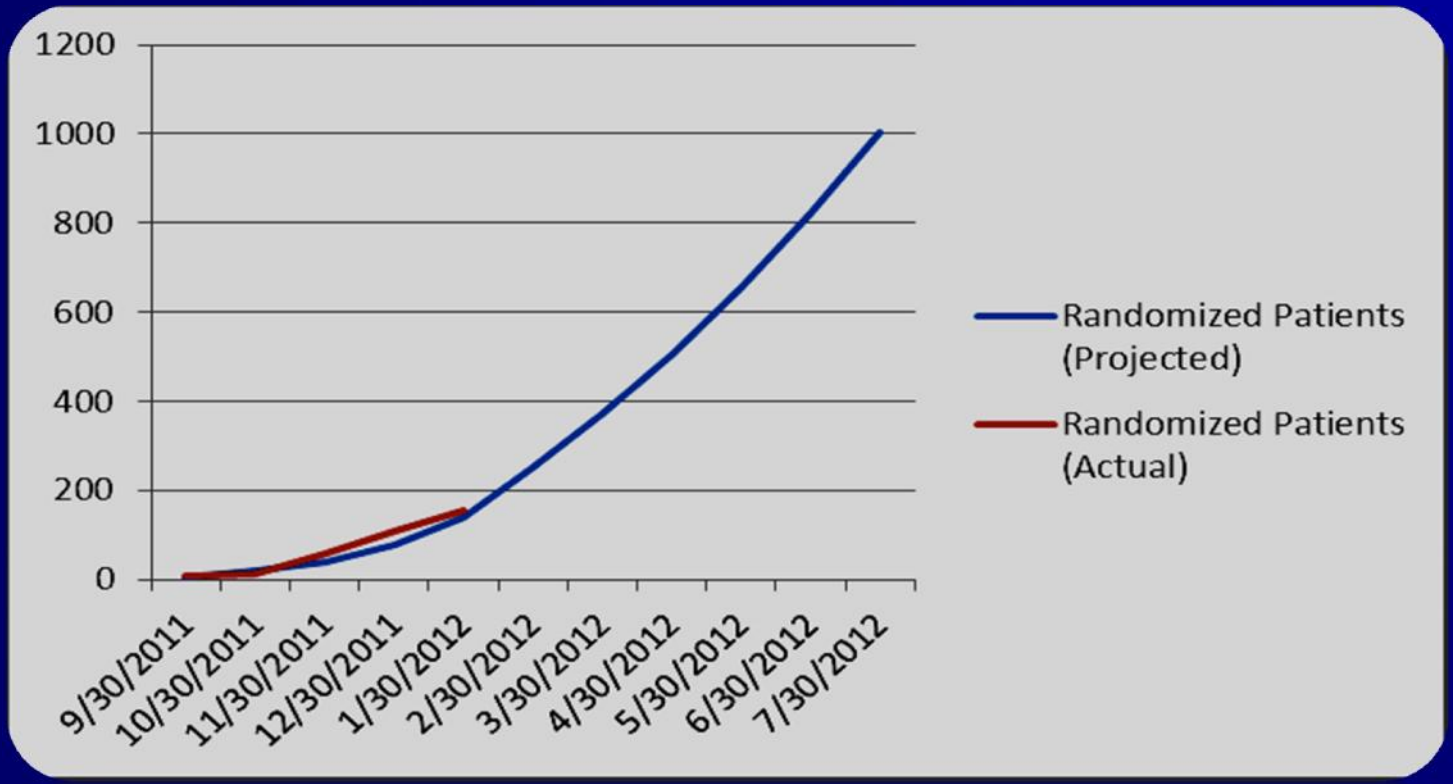
Unique pages for trial

Analytic Database

ORACLE®

DCRI

Efficiency Accelerates Enrollment



The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?

Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.

Embedding a randomized clinical trial into an ongoing registry infrastructure: Unique opportunities for efficiency in design of the Study of Access site For Enhancement of Percutaneous Coronary Intervention for Women (SAFE-PCI for Women)

Connie N. Hess, MD, MHS,[a] Sunil V. Rao, MD,[a] David F. Kong, MD,[a] Laura H. Aberle, BSPH,[a] Kevin J. Anstrom, PhD,
C. Michael Gibson, MD,[b] Ian C. Gilchrist, MD,[c] Alice K. Jacobs, MD,[d] Sanjit S. Jolly, MD,[e] Roxana Mehran, MD,[f]
John C. Messenger, MD,[g] L. Kristin Newby, MD, MHS,[a] Ron Waksman, MD,[h] and Mitchell W. Krucoff, MD[a] *Durham, NC; Boston, MA; Hershey, PA; Ontario, Canada; New York, NY; Denver, CO; and Washington, DC*

Lauer M et al, NEJM 2013

Hess C et al, Am Heart J 2013

Rao S et al JACC Cardiovascular Int 7(8)2014

http://www.forbes.com/sites/larryhusten/2013/09/01/a-disruptive-taste-of-the-future/

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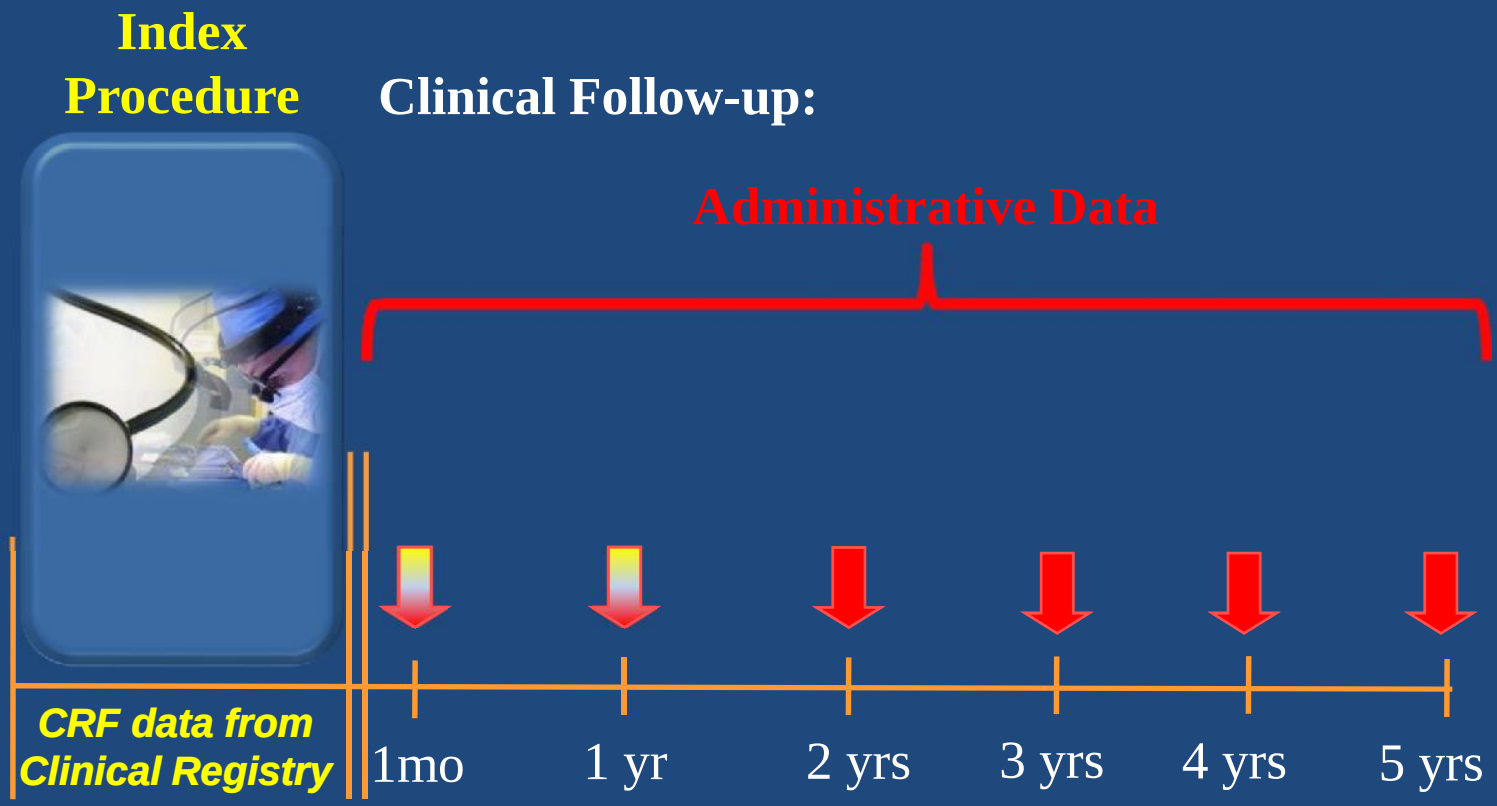
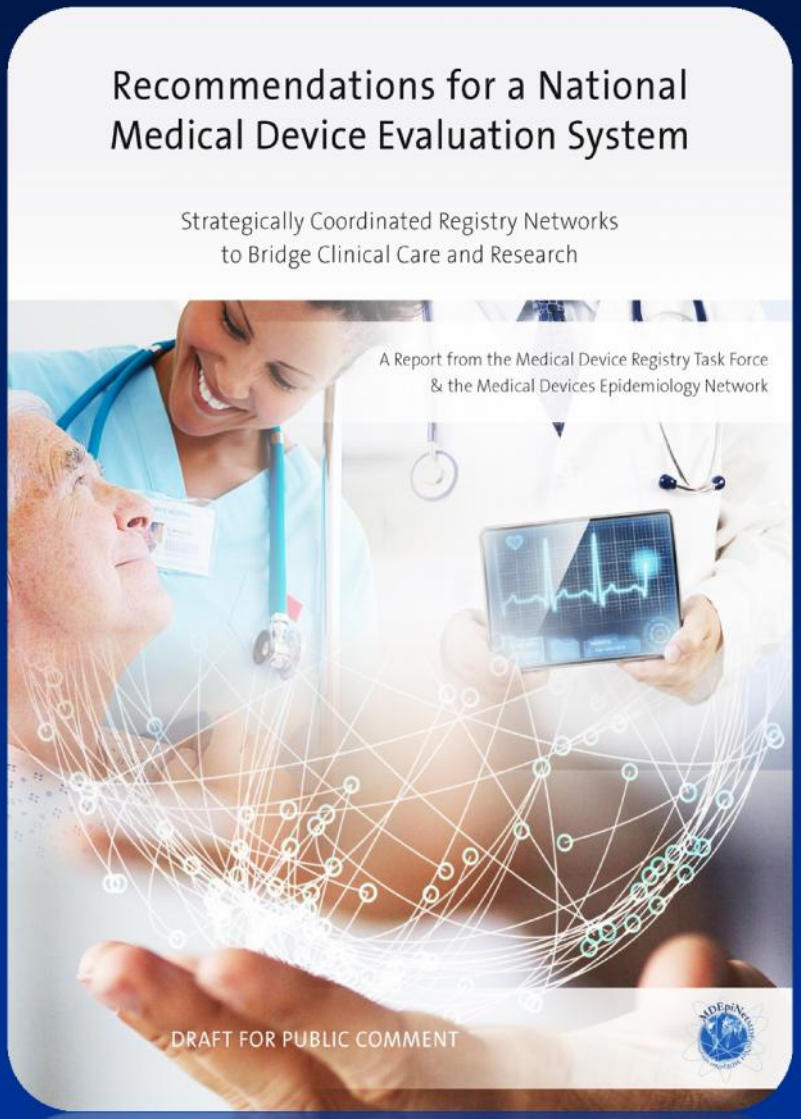
SAFE STEMI for Seniors: Linked NCDR-Claims Data "CRN" Structure



Strategically Coordinated Registry Networks



BRIDGING UNMET CLINICAL CARE AND CLINICAL RESEARCH NEEDS WITH STRATEGICALLY COORDINATED REGISTRY NETWORKS

Report from the National Medical Device Registry Task Force & The Medical Devices Epidemiology Network

Mitchell W. Krucoff, Sharon Lise Normand, Fred Edwards, Theodore Lystig, Eve Ross, Elise Berliner, Kristi Mitchell, James Tcheng, David Blaser, Ralph Brindis, Jack Cronenwett, Pamela Gavin, Linda Harrington, Amy Helwig, Kevin Larsen, William Maloney, Matthew McMahon, Bray Patrick-Lake, John Rumsfeld, Julia Skapik, Art Sedrakyan, Danica Marinac-Dabic

VIEWPOINT

Bridging Unmet Medical Device Ecosystem Needs With Strategically Coordinated Registries Networks

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Harvard T. H. Chan School of Public Health, Boston, Massachusetts; and MDEpiNet Methodology Center, Harvard Medical School, Boston, Massachusetts.

In June 2014, the Medical Device Epidemiology Network (MDEpiNet) Public Private Partnership,[1] on behalf of the US Food and Drug Administration Center for Devices and Radiologic Health (CDRH), convened the Medical Device Registries Task Force (MDRTF) (see eAppendix in the Supplement). The task force was launched to address the CDRH's commitments[2,3] to strengthen the medical device postmarket surveillance system using existing resources and under current authorities and to develop an integrated system that efficiently and effectively achieves its basic functions, from timely identification of postmarket signals to facilitating premarket device clearance and approval.

The MDRTF included broad stakeholder representation and was mandated to examine the objectives and logistics of leveraging existing electronic registries and information repositories in support of a national system. This work was done in parallel with efforts at the Engelberg Center at the Brookings Institution, which in 2015 reported recommendations from their planning board for a "national medical device surveillance system." These recommendations depicted a system that "supports optimal patient care by leveraging the experiences of pa-

The MDRTF recognized that most existing registries, electronic health records (EHRs), and data sources do not contain all the elements necessary for device evaluations, including device and procedural details, patient descriptors, or long-term outcomes. However, the MDRTF recognized that such limitations could be mitigated through interoperability solutions that strategically link complementary registries and data sources to produce networks for which the data composite could support robust device evaluation. The MDRTF termed this structure the strategically *coordinated registries network*, or CRN—with the recognition that many key elements in such networks (such as EHRs, administrative claims data, or mobile device outputs) are not registries per se. The MDRTF recommends strategic CRNs as the foundational architectural construct for the national system that will augment national registry development and unique device identifier implementation rather than replace them.

The proposed CRN structure could provide novel, important attributes to the national system. Creation of CRNs could encourage efficient "dual-purpose" leveraging of existing registries, EHRs, administrative-data resources, and lessons learned from existing linked-registry models such

www.mdepinet.org

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Krucoff MW, Normand SL et al, JAMA 2015

Partnered Problem Solving

Lesson learned for registry networks

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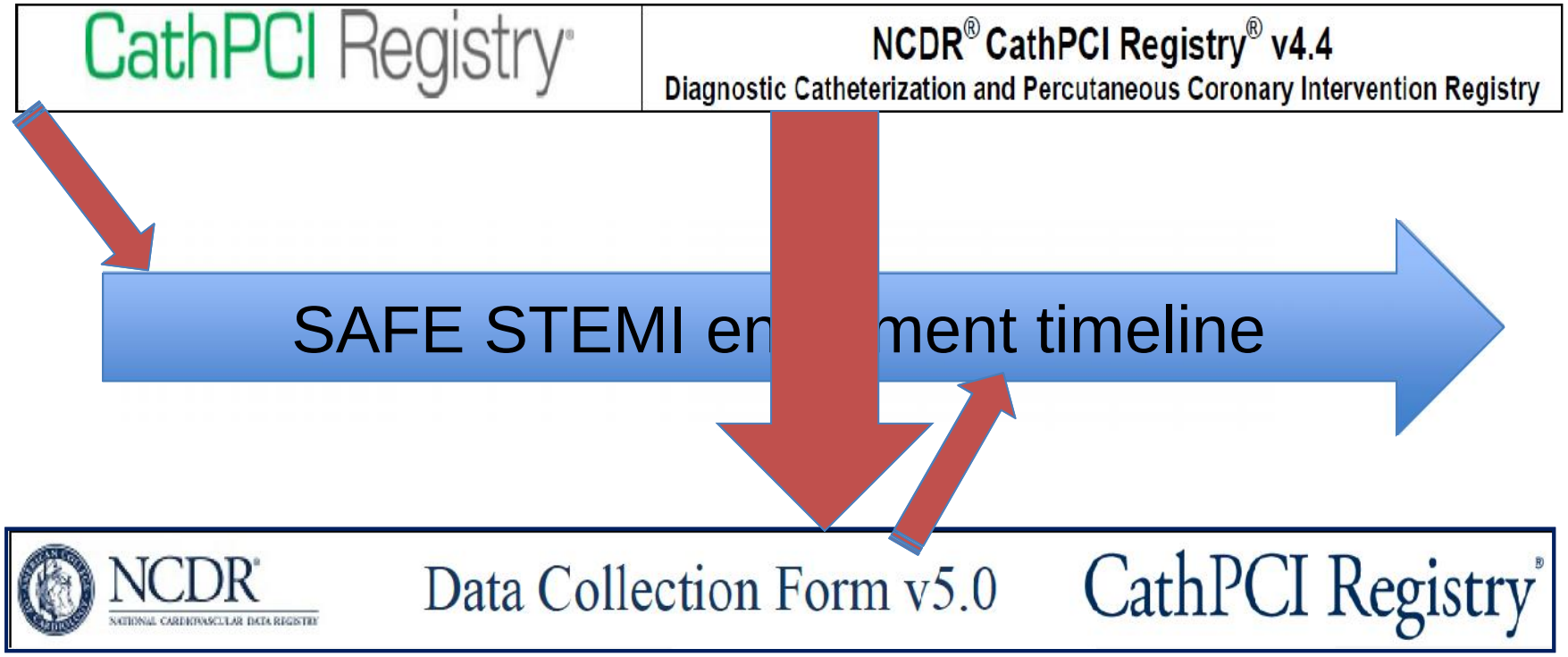
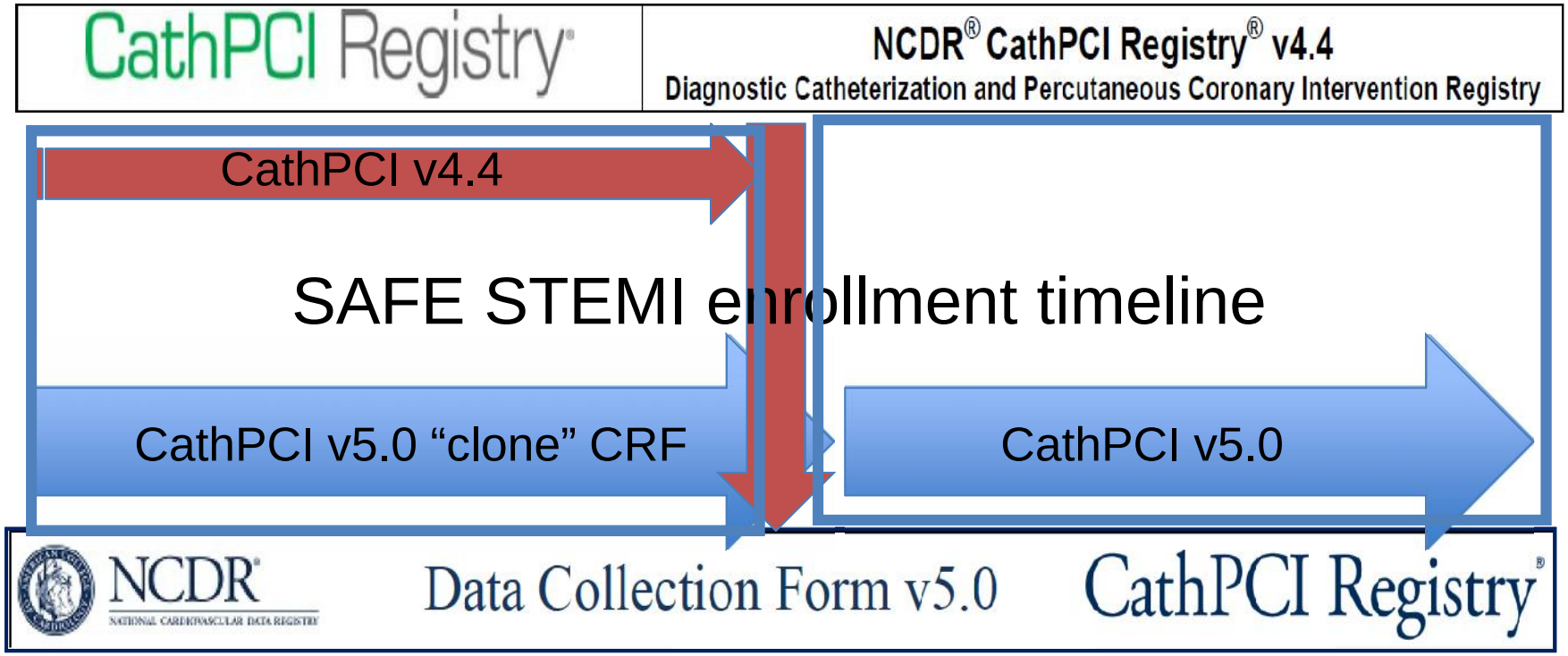
CathPCI Registry



CathPCI Registry



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