Registry Based Trials

DCRI Clinical Operations

Britt Barham

Duke Clinical Research Institute

Project Leader

Duke Clinical Research Institute
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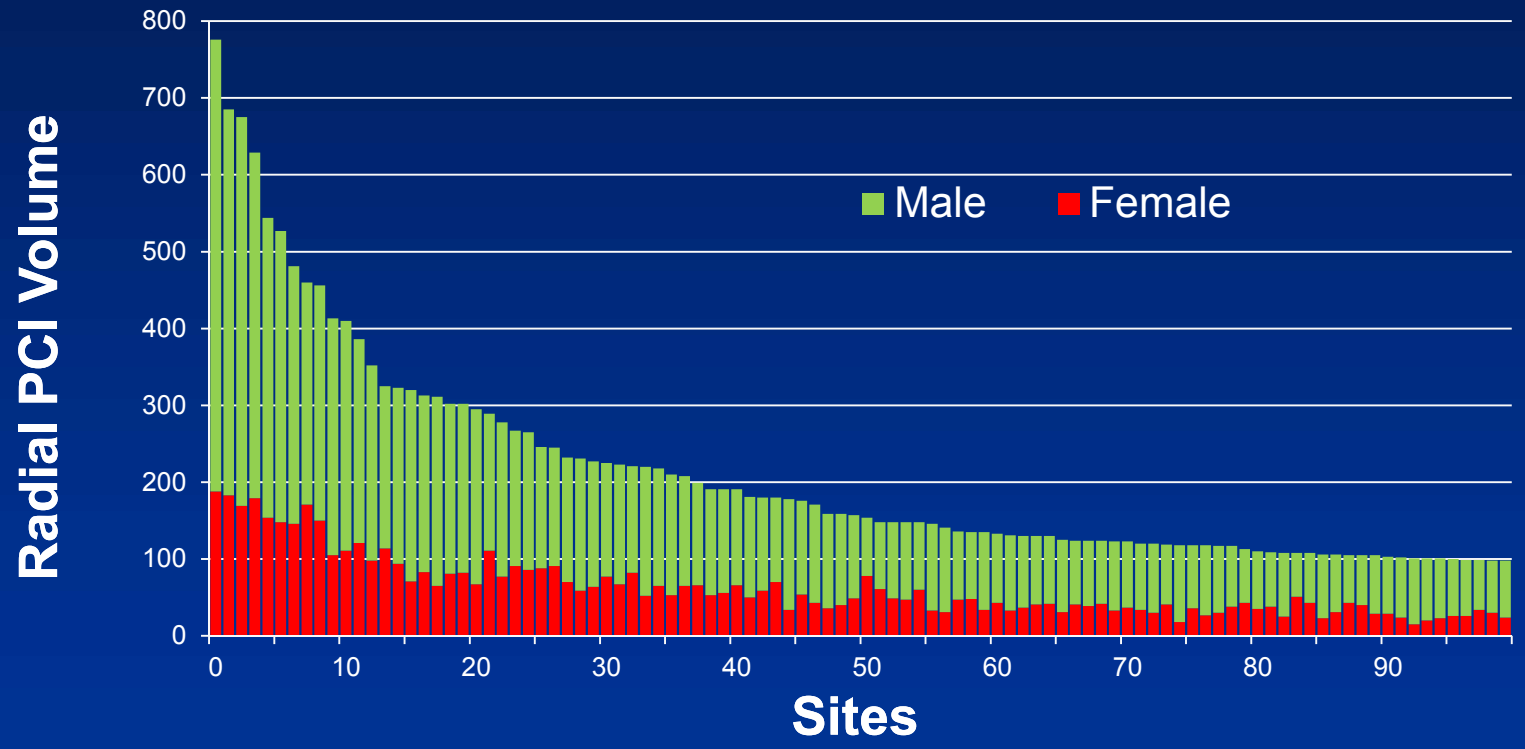
SAFE-PCI for Women Trial Structure

- **Clinical and Data Coordinating Center – DCRI**
- **Study Chair – Mitchell W. Krucoff, MD**
- **Principal Investigator – Sunil V. Rao, MD**
- **DCRI Project Leader – Britt Barham**
- **Funding Sources**
  - Terumo Medical, Abbott Vascular, The Medicines Company, Eli Lilly, Medtronic, ACIST Medical Systems, FDA Office of Women's Health*, Guerbet*
- **Partners**
  - National Cardiovascular Research Infrastructure (NCRI), American College of Cardiology (ACC), FDA Office of Women's Health, Cardiac Safety Research Consortium (CSRC)
- **DSMB**
  - Spencer King (chair), Olivier Bertrand, Alexandra Lansky, Timothy Morgan

Site Identification: Male vs. Female Radial PCI

NCDR PCI records from 2009Q3 through Jan 2011



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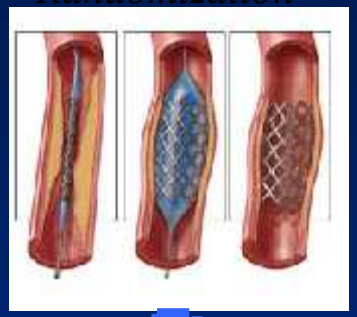
SAFE-PCI for Women Workflow

Randomization



Demographics

Medical Hx

Procedural data

Index Hosp MACE

NCDR® National Cardiovascular Data Registry CathPCI Registry®

Autopopulate

Part 11 Compliant

60% site coordinator workload reduction

Analytic Database

Unique pages for trial

ORACLE®

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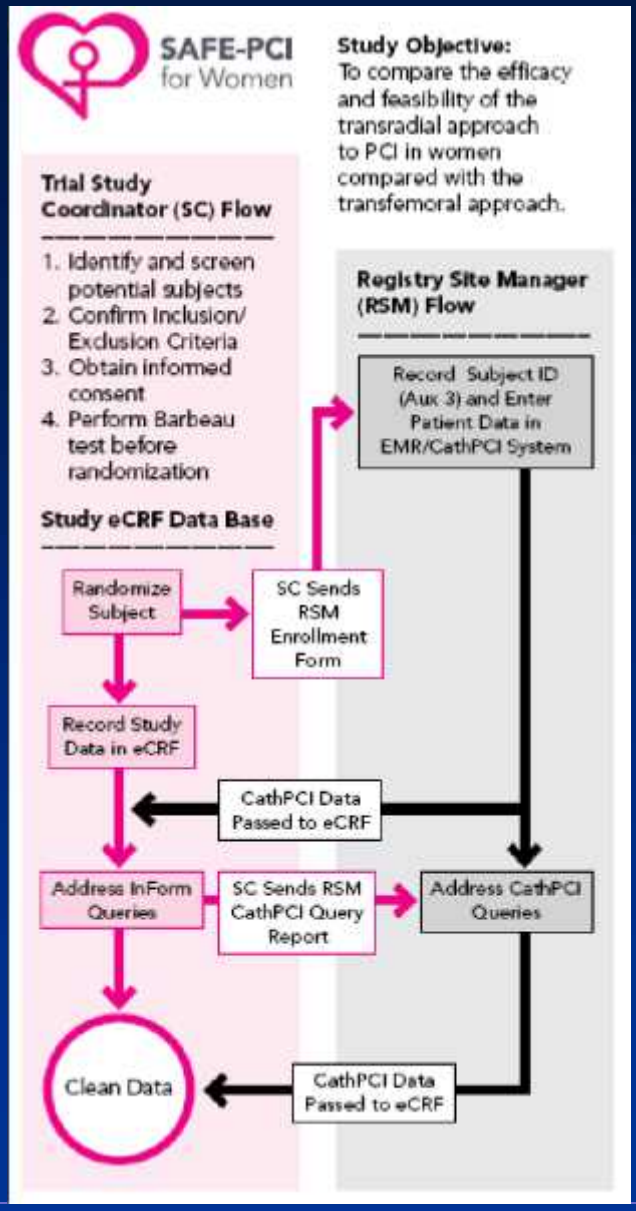
Site Workflow

Entry and harvest of registry data within 14 days post discharge for study patients



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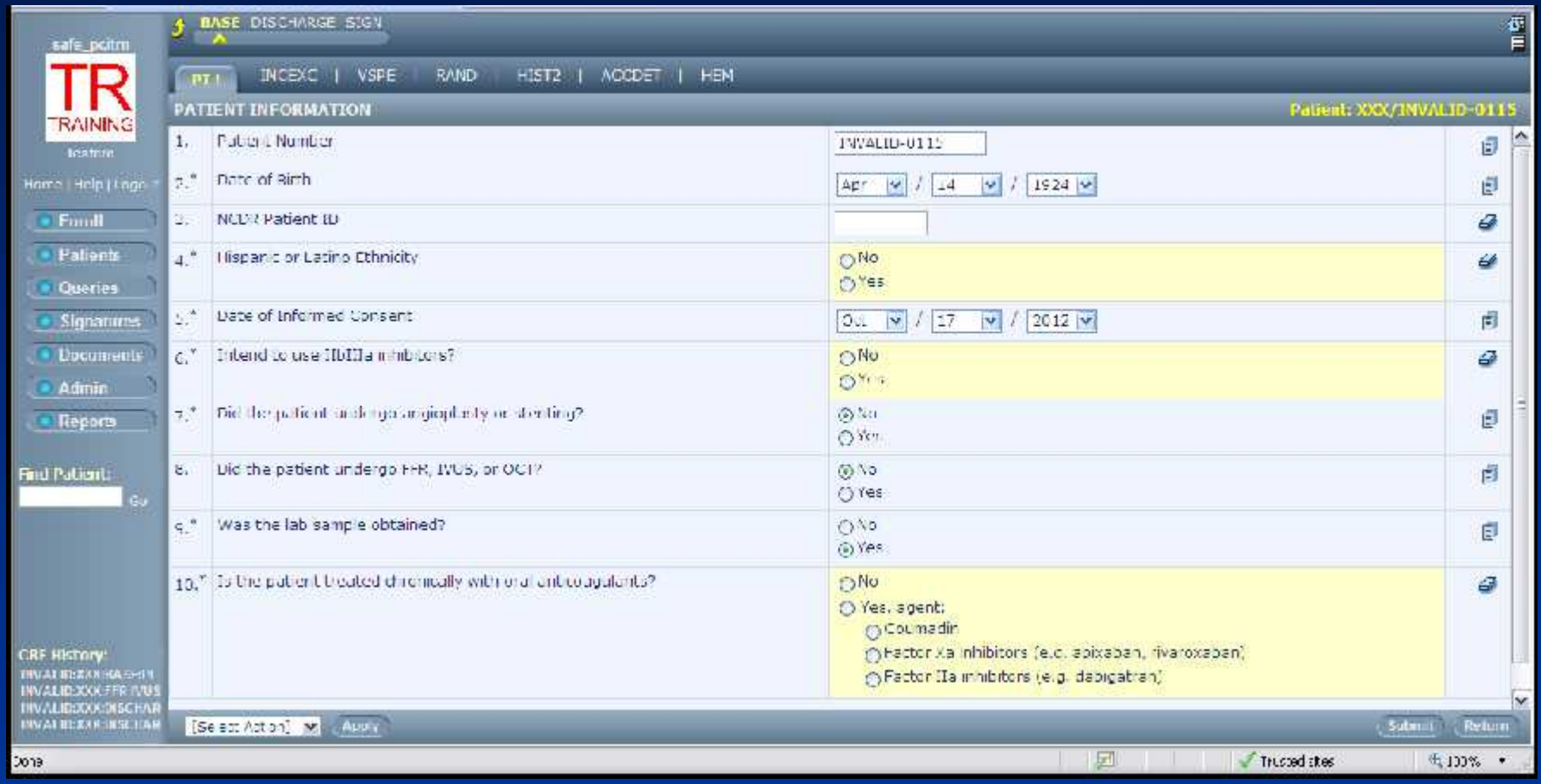
SAFE-PCI for Women eCRF Screenshot



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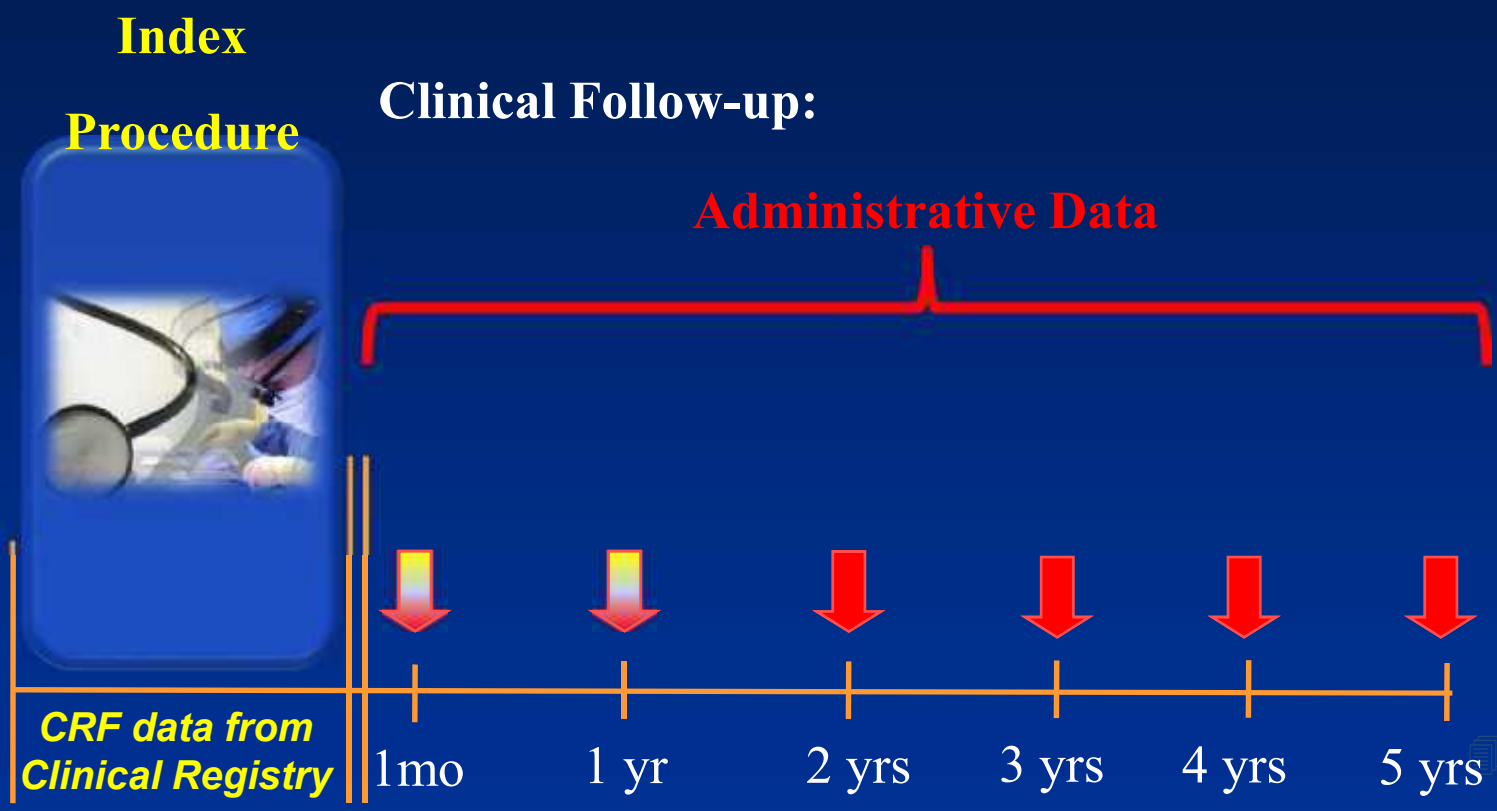
SAFE-PCI in STEMI for Seniors

- **Clinical and Data Coordinating Center – DCRI**
- **Study Chair – Mitchell W. Krucoff, MD**
- **Principal Investigator – David F. Kong, MD**
- **DCRI Project Leader – Lisa Hatch**
- **Funding Sources**
  - Medtronic, Philips Healthcare/Volcano, Terumo Medical
- **Partners**
  - National Cardiovascular Research Infrastructure (NCRI), American College of Cardiology (ACC)

What is SAFE-PCI in STEMI for Seniors?

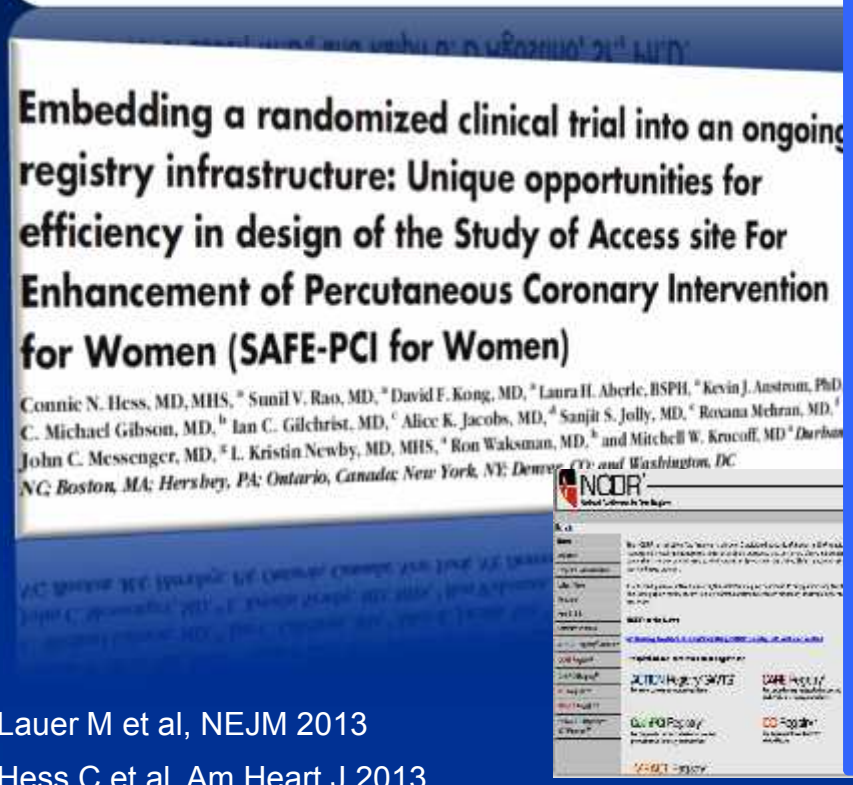
- *Public health clinical trial: >65 y.o STEMI <6 hrs*
  - Radial access PCI in seniors
  - Multivessel PCI in seniors
- *IDE(s) clinical trial:*
  - DES labelling for STEMI (Medtronic)
  - iFR guided multivessel PCI (Philips Healthcare/Volcano)
- *Registry-based CRN randomized trial:*
  - Index procedure (NCDR Cath-PCI)
  - Long term follow up (Claims data)
- *Lesson in partnered problem solving*

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



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,[a] 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]

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Larry Husten, Contributor

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A new study from Scandanavia may influence the treatment of heart attacks. But it also may end up having a much bigger impact on the entire field of medicine by pointing the way to an entirely new way of performing randomized clinical trials rapidly and inexpensively. One expert said the trial design may represent "a

17

79

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

Lauer M et al, NEJM 2013

Hess C et al, Am Heart J 2013

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

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MDEpiNet

Registry Based Trial Challenges

- **Technological**
  - *Hemodynamic/auto-populating system (EMR → CathPCI software)*
  - *Staging database at site level*
- **3rd Party**
  - *Utilization of outside vendor for registry data entry*
- **Site Personnel (Registry Site Managers)**
  - *Understanding and buy-in*
  - *Chart abstraction, coding, scanning*

Registry Based Trial Start-up Challenges

- **Budget Negotiation**
- **Study Site Agreements:**
  - Multi-party agreements (heavy revision process, lengthened signature timeline)
  - Insurance for investigator initiated trial: required professional and general liability coverage amounts higher than “industry standard”
  - Indemnification language required by investigator initiated trial

Registry Based Trial Advantages

- Mechanism for identifying participating sites and evaluating site metrics (such as extent and proportion of transradial procedures)
- Reduction of redundant data entry (~60% data needed for SAFE PCI patients from CathPCI registry)
- Reduced trial costs, specifically per patient reimbursement
- Enrollment proceeding as projected