

RAPID Working Group
Phase II-III
Implementation and Application "101"

Mitchell W. Krucoff, MD, FACC

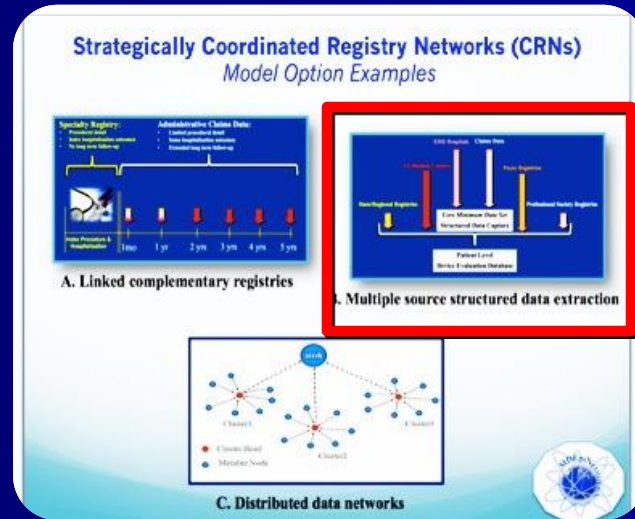
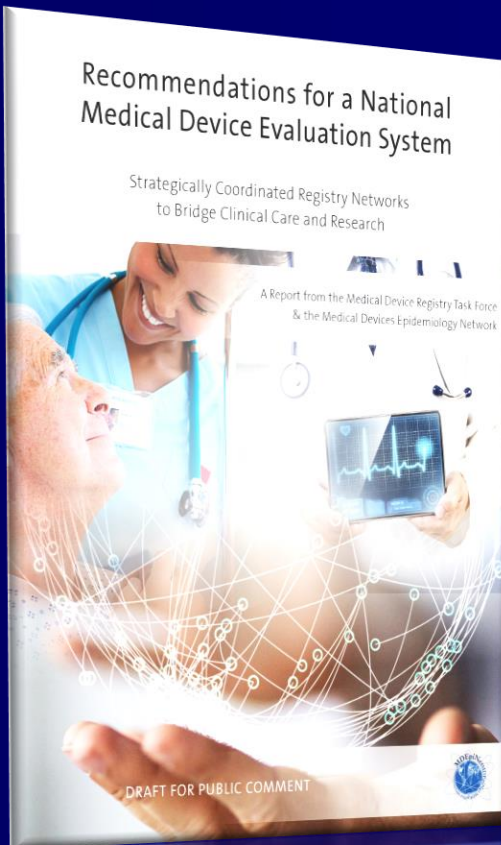
Professor, Medicine/Cardiology
Duke University Medical Center
Director, MDEpiNet Coordinating Center
Director, CV Devices Unit
Duke Clinical Research Institute



Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER



Piloting NEST Principles



- **CRN structure for clinical trials:**
 - Leveraging RWE
 - Site-based research: from double the work to dual purpose
- **Core minimum data set**
- **Use/re-use**
- **Today's focus:**
 - Peripheral artery revasc devices (RAPID)
 - First CRN-based clinical trial (SPEED)

De-Constructing The 21st Century (NEST) Clinical Trial Model: *From doubling to dual-purposing site-based work*

Site based work flow:

- Clinical descriptors
- Device identification
- Procedural information
- Outcomes of interest

RAPID Phase I

Structured Core Data:

- BUILD (Sentinel)
- UDI/GUDID/SUDI
- RAPID core min data set

Structured RWE

Clinical Trial Database:

- Clinical descriptors
- Device identification
- Procedural information
- Outcomes of interest

Phase III

Implementation:

- VQI
- NCDR
- EPIC
- VAMC
- SIR

Phase II



21st Century (NEST) Trial Clinical Operations Model: *Prospective RCT*

Clinical report work flow:

- Clinical descriptors
- Device identification
- Procedural information
- Outcomes of interest

All Pts

Electronic record systems:

- VQI
- NCDR
- EPIC
- VAMC
- SIR

Part 11 compliant

Clinical Trial Database:

- Clinical descriptors
- Device identification
- Procedural information
- Outcomes of interest

Auto
Study
CRFs

Study
Pts

Structured Core PAD Data
Elements

Novel Ancillary Study Data
(Core Laboratory, QOL)

Study Site Coordinator



Today's RAPID Objectives

- Phase II: Implementing Structured Core Data Elements
- Phase III: RAPID Clinical Trials
- Today's Goals:
 - Identify expert-based working groups:
Implementation from registry/EHRs to clinical trial database
First pilot clinical trial: SPEED
 - Map next step deliverables & timelines
 - Identify resource needs
In kind resources
Fiscal resources (Phase I: \$9,800)



The NEST CRN Vision:

*With a continuous river of structured data you can float a lot of RCT boats
If you don't have to re-build the river every single time*



**“Traditional”
Perspective**



**21st Century
Perspective**



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