The MDEpiNet PASSION Registries for Cardiovascular Devices Think Tank II

The Import and Challenges of Open Science: A Professional Society View

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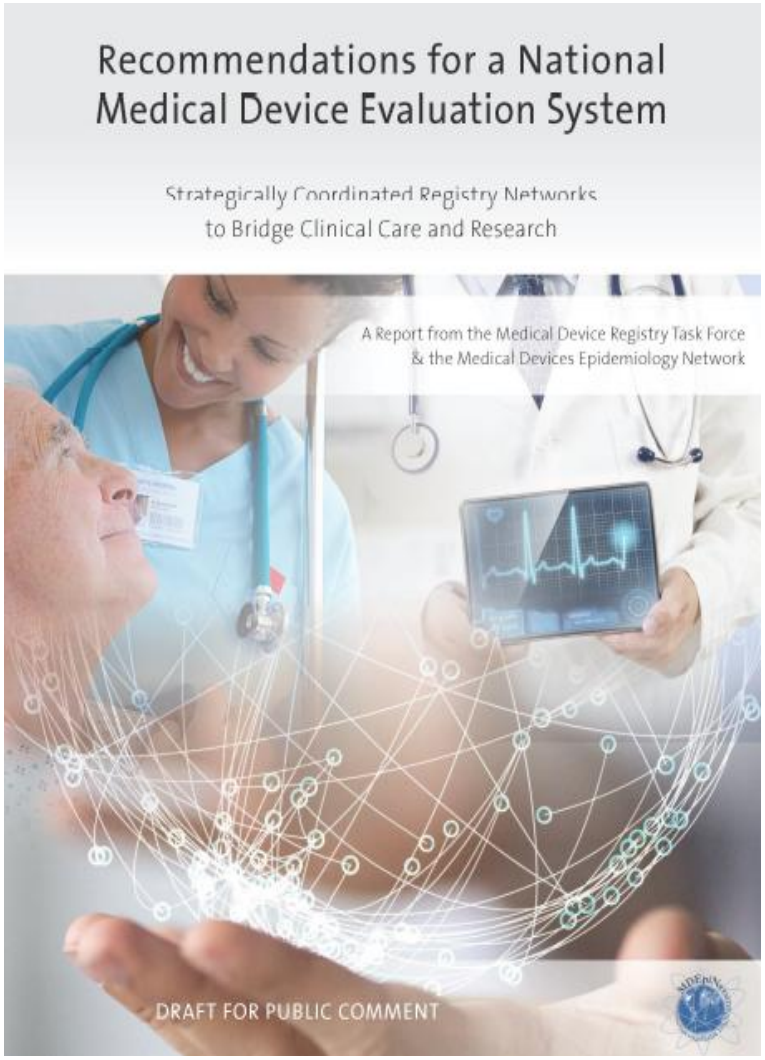
Disclosures

- Senior Medical Officer

ACC- National Cardiovascular Data Registry



Recommendations for a National Medical Device Evaluation System

Coordinated Registry Networks

Medical Registry Task Force
MDEpiNet

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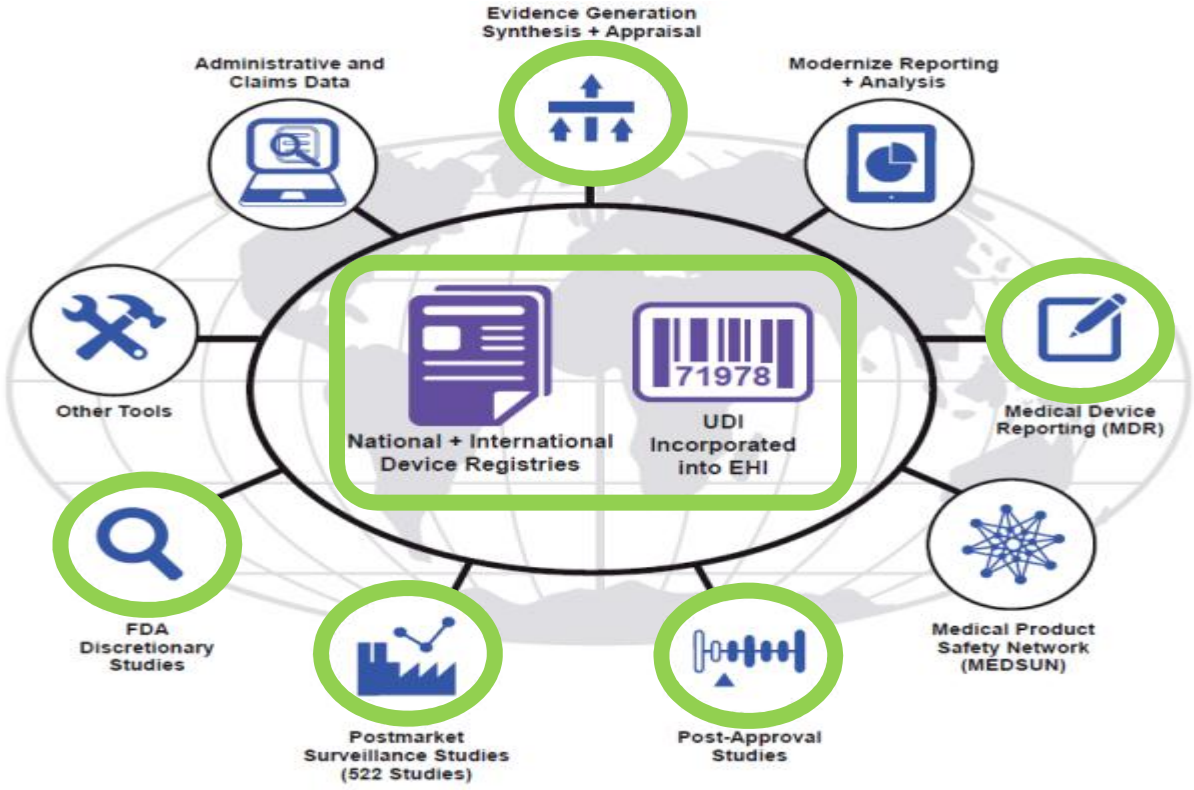
Coordinated Registries Network

How can we mimic the Serengeti?

Strengthening National System for Medical Device Postmarket Surveillance



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The Challenge

- We have many and varied “stand alone” electronic data repositories
- Opportunity to leverage these “stand alone” registries to better assess benefit/risk and safety surveillance analytics
- Requires ideally some form of import of data sharing and open science to accomplish this goal

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What is a Coordinated Registry Network?

- **AHRQ-** "organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes."
- **FDA-** "system that collects and maintains structured records on a specific disease, condition, procedure, or medical product for a specific time period and population."

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Successful CRN

- Identify priority medical device types for which the establishment of a longitudinal registry network is of significant public health importance.
- Define registry network governance and data quality practices that promote rigorous design, conduct, analysis, and transparency to meet all stakeholder needs.

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Characteristics of a Coordinated Registry Network

- Ensure ability to identify medical devices - UDI
- Use standardized clinical vocabularies, common data elements, and outcome definitions as required
- Linkage across disparate data sources
- Create robust governance

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CRN Goals

- Promote development of integrated/interoperable domain-specific data sets
- Promote durable linkage of patient and medical device throughout product life cycle
- Improve reliability and generalizability of data collection through optimization of structured reporting across silos
- Reduce overhead of critical data collection; lower impact on workflow

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CRN Goals

- Demonstrate feasibility of meaningful linkage of UDI and unique patient identification across time and healthcare venues
- Provide innovative mechanisms to promote patient-centered care, improve accounting for cost saving strategies, enable point-of-care study of device safety and effectiveness in the context of use- and provider-specific parameters, and promote more effective anticipatory patient and device selection based on critical historical patient-specific data integrated with evidence-based best practices.

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National Cardiovascular Research Infrastructure (NCRI)

- **Initiated in 2009 by DCRI and ACCF**
- **Four goals to improve cardiovascular research**

Replace the repetitive assembly and disassembly of short-lived clinical investigator networks with a stable and enduring operational infrastructure for clinical research;	Standardize and harmonize cardiovascular data to achieve complete syntactic and semantic interoperability throughout the network;	Coordinated and facilitate the transfer of selected, standardized cardiovascular data into existing and future national registries; and	Develop an enduring library of content for education and training of clinical investigators and site personnel.

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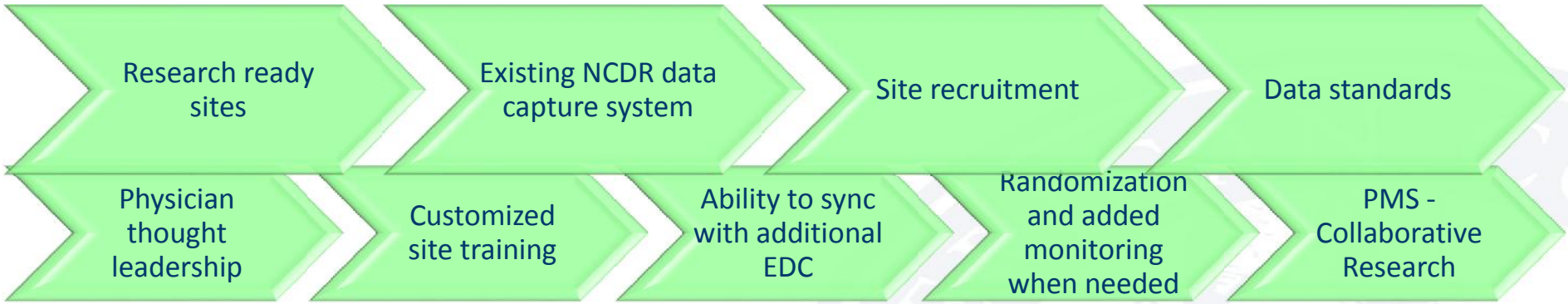
Registry Platform
Clinical Research Studies using NCDR



- Economical
- Reduces data entry burden
- Real world population
- Consecutive patients
- Larger patient volumes
- Can use central randomization mechanism
- Ongoing data capture

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SAFE-PCI for Women

In a nutshell…	Programmatic outcomes…

• NCRI proof of concept
• First multicenter randomized trial comparing radial with femoral access in U.S.
• First randomized trial comparing interventional strategies in women
• Sponsored by DCRI
• Used NCDR CathPCI Registry platform
• Estimated 65% per patient workload reduction
	• $750 per patient reimbursement
	• ~ $5 million budget
	• Study start up time cut in half
	• Included research naive sites
	• Wider enrollment spread
	  • 90% sites enrolled at least 1 patient
	  • > 70% sites enrolled at least 10 patients

SAFE PCI → SAFE STEMI for Seniors

FDA Commissioner Rob Califf

Am J Cardiol 1998;82:639-658.

FIGURE 3. RMC (top row, second from right) with the University of California-San Francisco houseofficer basketball team.

REGISTRY

FDA Commissioner Rob Califf

"There are times that industry are more transparent as to their data than are academic institutions"

Braunwald Lecture
ACC Annual 16, Chicago

H.M. Krumholz et al., "A Historic Moment for Open Science: The Yale University Open Data Access Project and Medtronic," Annals of Internal Medicine 2013

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CRN Challenges
Professional Society Obligations

- Can we share data between individual Registries and:
  - Maintain HIPAA compliance
  - Maintain integrity of consistent/accurate data interpretation in an open system
    - Presently- NCDR Open Access and Use Policy using our contracted analytical centers
  - Maintain as appropriate the proprietary interests of Industry
  - De-identified data sharing as opposed to data pooling

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Defining CRN Collaboration Success

Academic/Professional Society Goals:

- The Registry should maintain the traditional goals of the professional societies:
  1) Patient Care 2) Education, 3) Research, 4) Members' interests.
- Are the professional societies governing boards still supportive of the CRN
- Are other professional societies being included or do they feel excluded?

Governance Goals:

- Does the present/proposed structure work? Stakeholder trust?

Cost/Benefit Goal: The CRN must provide benefits by meeting all goals at a reasonable cost with ideally an overall cost reduction.

Scientific Integrity Goals:

- Objective, bias-free, and scientifically based reports?
- Is the CRN in compliance of COI policies?

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Key Alignment of CMS, Pre-Market and Post-Market FDA and the CRN

- Will be a continuous work in evolution
- Constant alignment of stakeholder's aims and goals
- Sensitivity and maintaining focus to hospital/clinician burden of data collection and costs
- Acknowledgement and sensitivity to Industry needs
  - Issues of availability to patient level vs. aggregate data, timeliness, industry independent analytical capabilities, and their own regulatory needs
  - Requirements for PMS, PAS and IDE studies
- Patient's needs and rights – informed consent and IRB issues for both IDE and PAS studies

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CRN Formula for Success:
Working Collaboratively with FDA and CMS

- Realizing that we are all in the "Same Boat"
- Avoidance of "Turf Wars" - Professional societies, academia, industry and governmental agencies …. "holding hands"
- Promotion of true transparency and "blame free" environment – working towards solutions
- Communication, communication and communication
  - Extemporaneous leadership calls
- Documentation

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Highest Priority

- EMR integration
- 100% data availability
- Global Reach – Global Registry harmonization
- Patient Consent
- Governance
- PAS studies and IDE labeling extensions – helps strike right balance between pre and post market evaluations

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Highest Priority

- National Consortium- **PASSION (Predictable and Sustainable Implementation of National Registries for CV Diseases)**
  - **Develop the "Poster Child" - RAPID CRN** arm focused on PAD
  - Advisory body for registry derived RCTs with all potential stakeholders - NHLBI, FDA, CMS, PCORI, AHRQ, patient groups, Industry, academia, etc.
- Real-time analysis of data captured
- Stable funding and sustainable registry and registry derived RCT model
- Eliminate systematic redundancy
- Clinical registries become the standard infrastructure for conducting pre and post market research.

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