

Building Coordinated Registry Networks : A Core Strategy to Build the National System

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Epidemiology Network

**Medical Device
Epidemiology Network**

Epidemio

**Medical E
Epidemio**

GOAL & APPROACH

- Our focus of Coordinated Registry Network (CRN) is to provide timely information on performance of specific medical devices for decision making by patients, physicians, regulators and all other stakeholders
- Approach is to facilitate and/or leverage national and *international* investments in registries and other stakeholders' relevant data systems (dual purposing) to create '*National Medical Device Evaluation System on a fairly immediate basis, greatly minimizing the cost or development resources needed*'

Example International CRN: Uncemented hip device use

Legend:

- Cemented (Green)
- Cementless (Blue)
- Hybrid (Red)

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 Cemented  Cementless  Hybrid

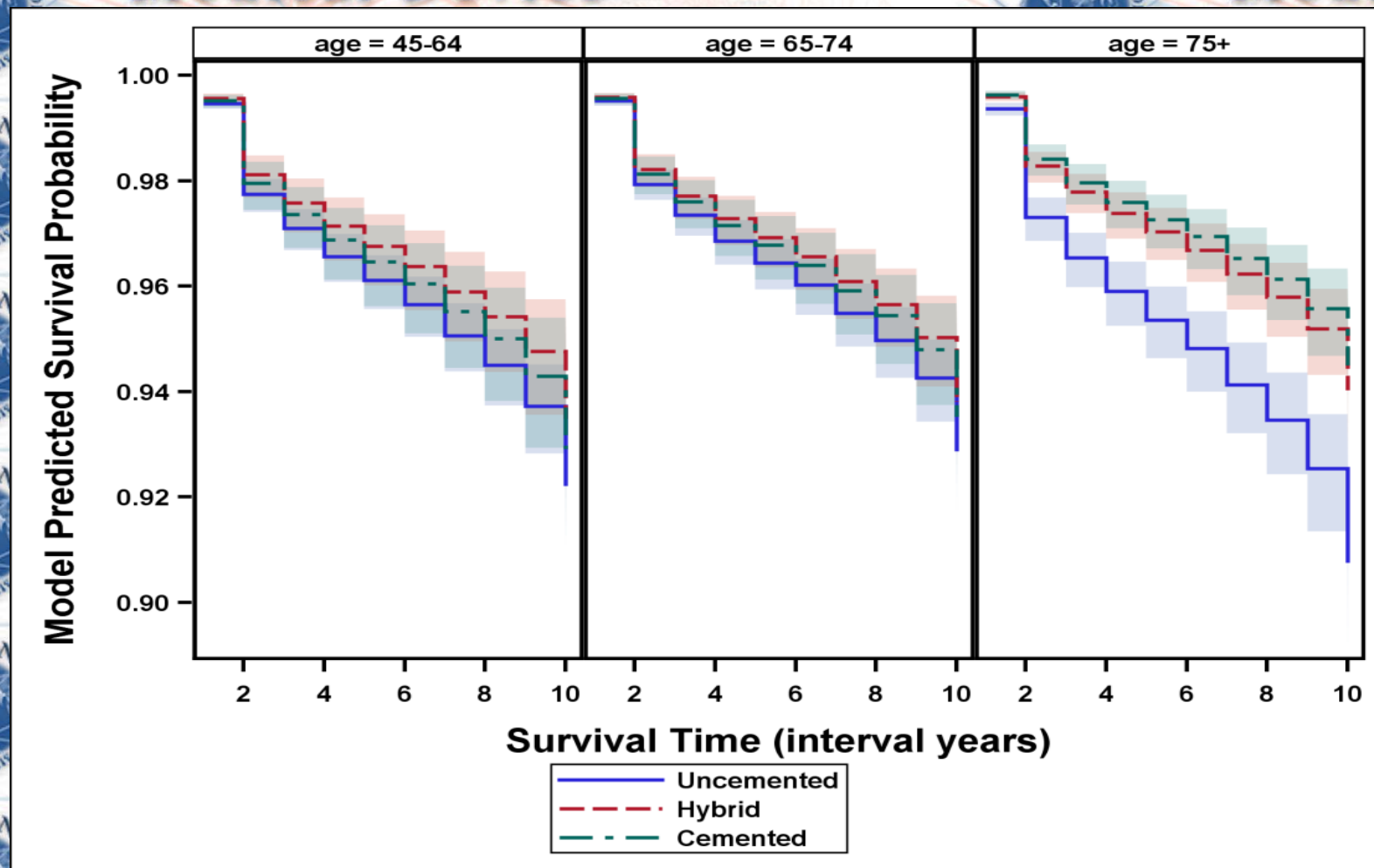
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Fixation Study Results

- 239,442 patients from across 6 registries
- 59% female
- Patients classified in three age classes
 - 45-64
 - 65-74
 - ≥ 75

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Survival of Uncemented, Hybrid, and Cemented Hip Replacements by Age Group



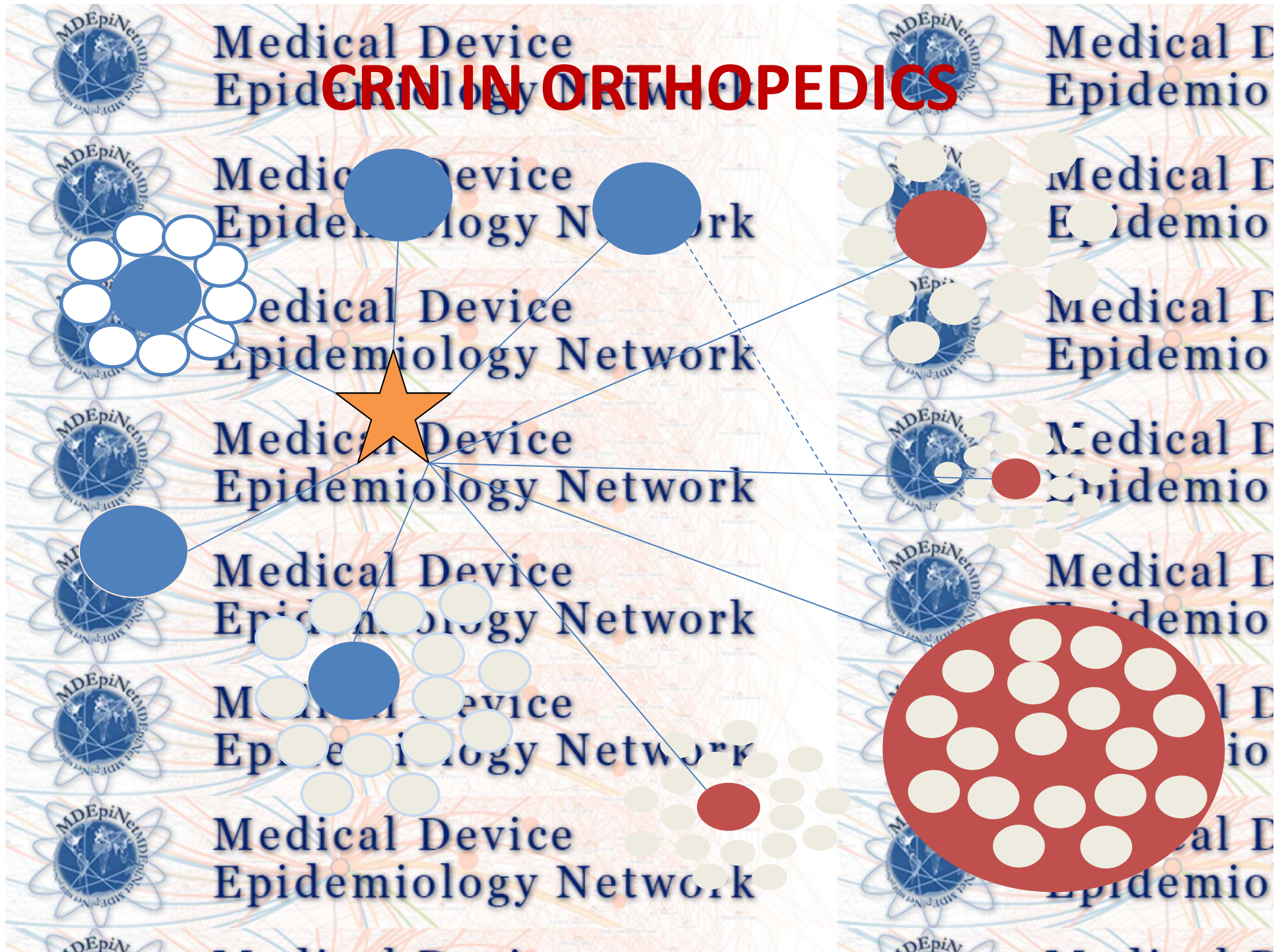
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CRN IS A REALISTIC APPROACH

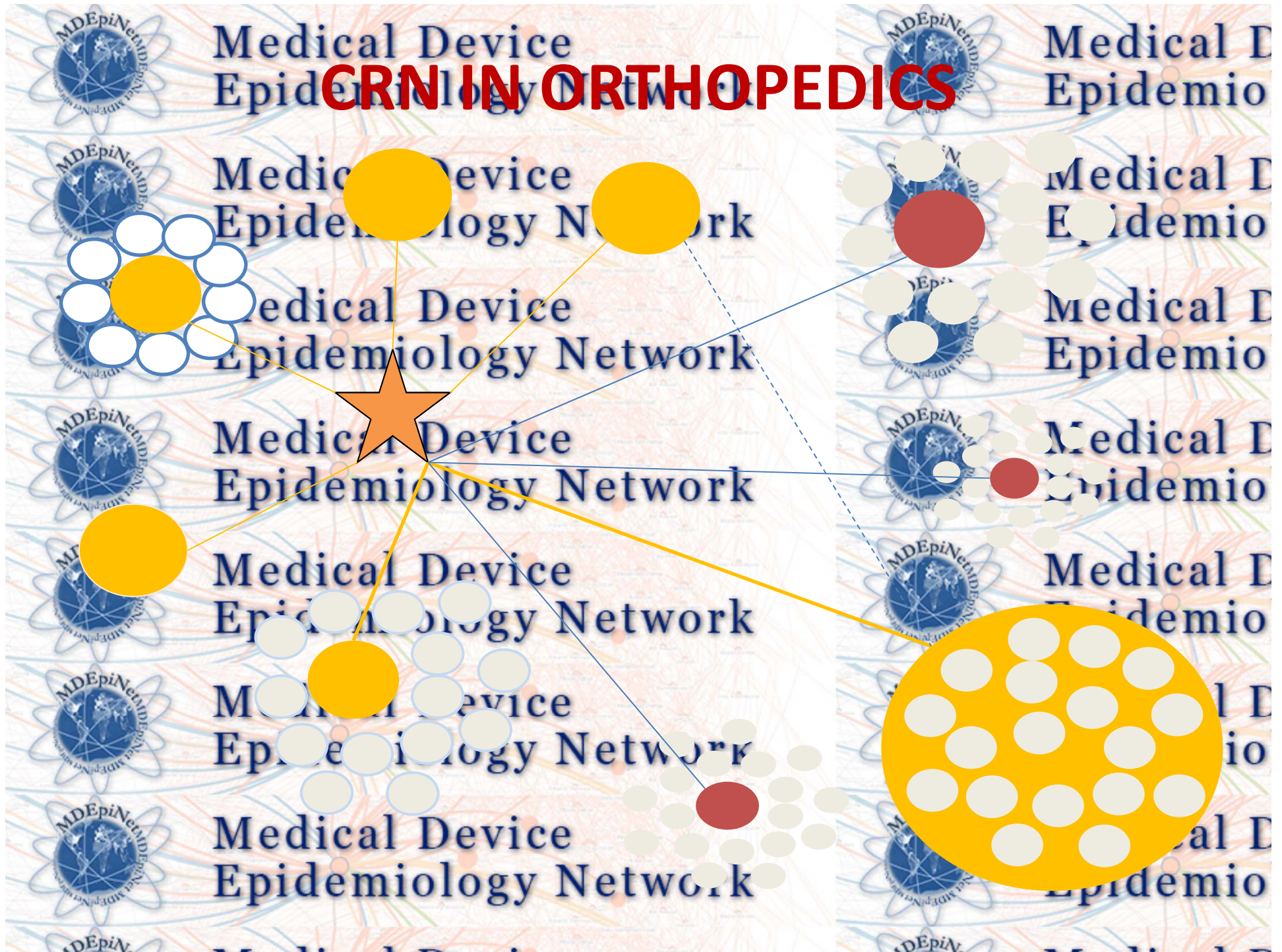
**HAVING HANDFUL OF NATIONAL REGISTRIES, AND
FEW COLLECTING DETAILED DEVICE INFORMATION WE
NEED TO INTEGRATE DATA**

- Major 'Quality and safety' registries initiated by professional societies, states, healthcare systems, NIH/AHRQ, other
- CMS claims including Part A,B,C,D
- Commercial claims
- PCORI CDRNs
- All payer State databases
- Comprehensive EHRs

CRN IN ORTHOPEDICS



CRN IN ORTHOPEDICS



ORTHOPEDIC DISTRIBUTED CRN

Coordinating Center

- Create Learning network
- Device data harmonization
 - Support all linkages
 - Aggregate findings

Analytic queries

Frequencies, Crosstabs,
Cox regression results,
survival probabilities



IDS data

Registry 1



CLAIMS

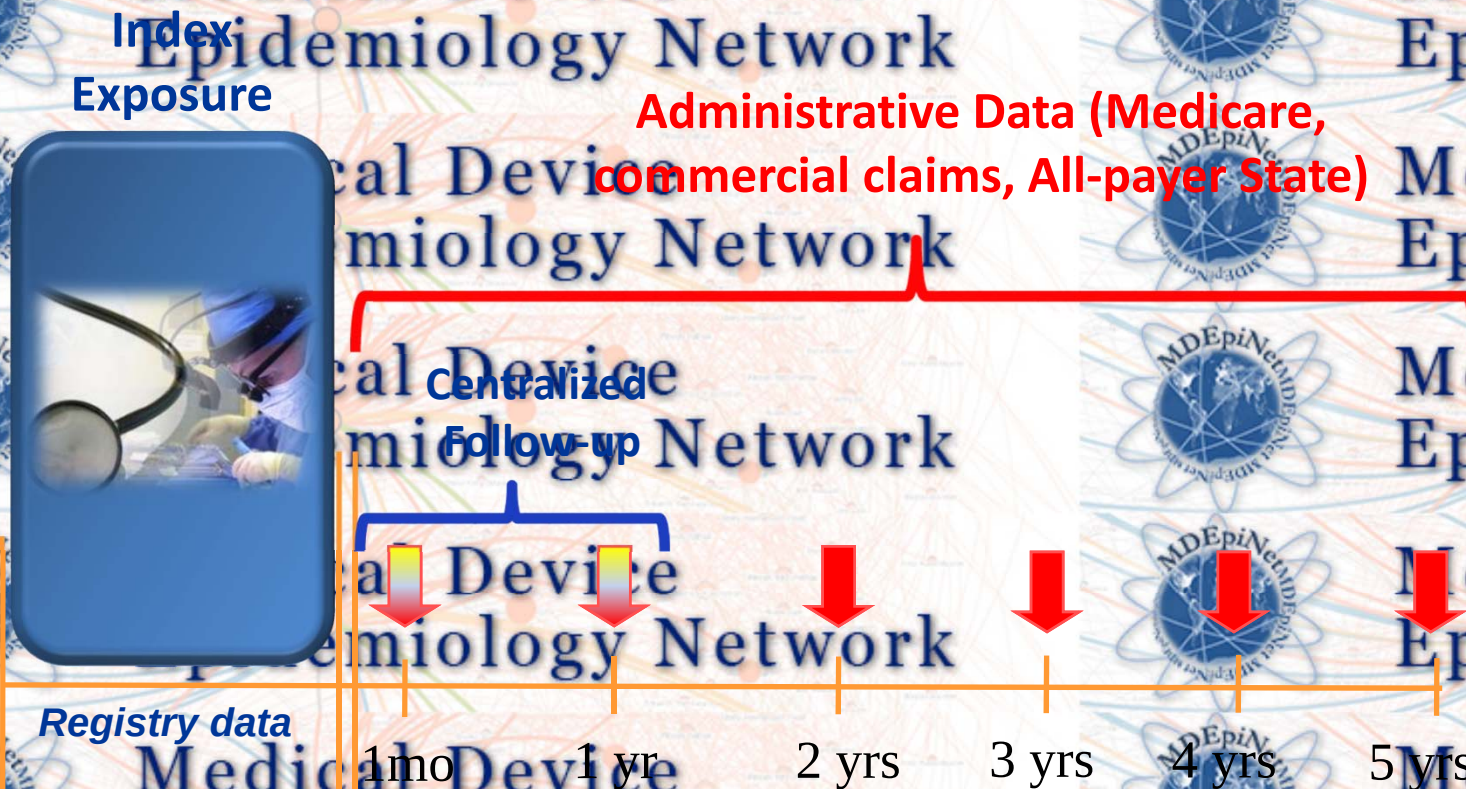
Registry 2



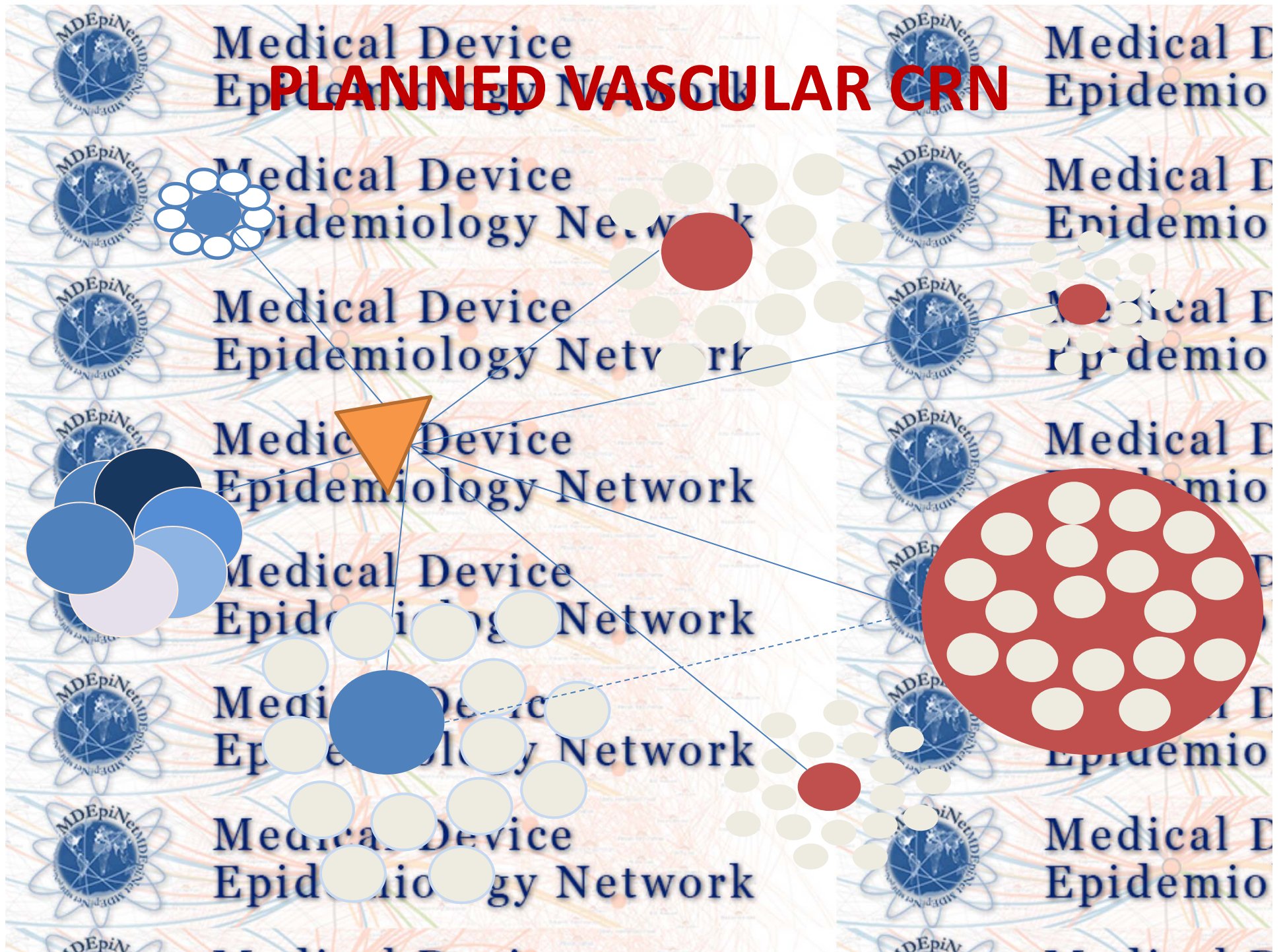
CLAIMS

Registry 3

SIMPLE VASCULAR CRN



PLANNED VASCULAR CRN



KEY POINTS FOR DISCUSSION

- Even with optimistic expectations about registry and related data maturity our efforts should be scaled up to be powerful and timely enough to address particular device-related questions (e.g. outlier performance)
- For effective CRN **timely and seamless** access to key national data sources must be achieved and stakeholder alignment and support is critical
 - The process has to be efficient/not burdensome to justify data sacrifices made compared to direct data collection
- Sufficient device and clinical outcome data will always be a challenge and we have to be able to make decisions based on imperfect CRN data