

CRN SOLUTIONS IN ORTHOPEDIC AND VASCULAR AREAS

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GOAL & APPROACH

- Our idealistic goal is to provide near-real time 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 investments in registries and other 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'*

CRN IS OUR SOLUTION

HAVING FEW NATIONAL REGISTRIES, AND NONE COLLECTING DETAILED DEVICE INFORMATION WE NEED TO INTEGRATE RELEVANT 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**
- **Implement device identification**

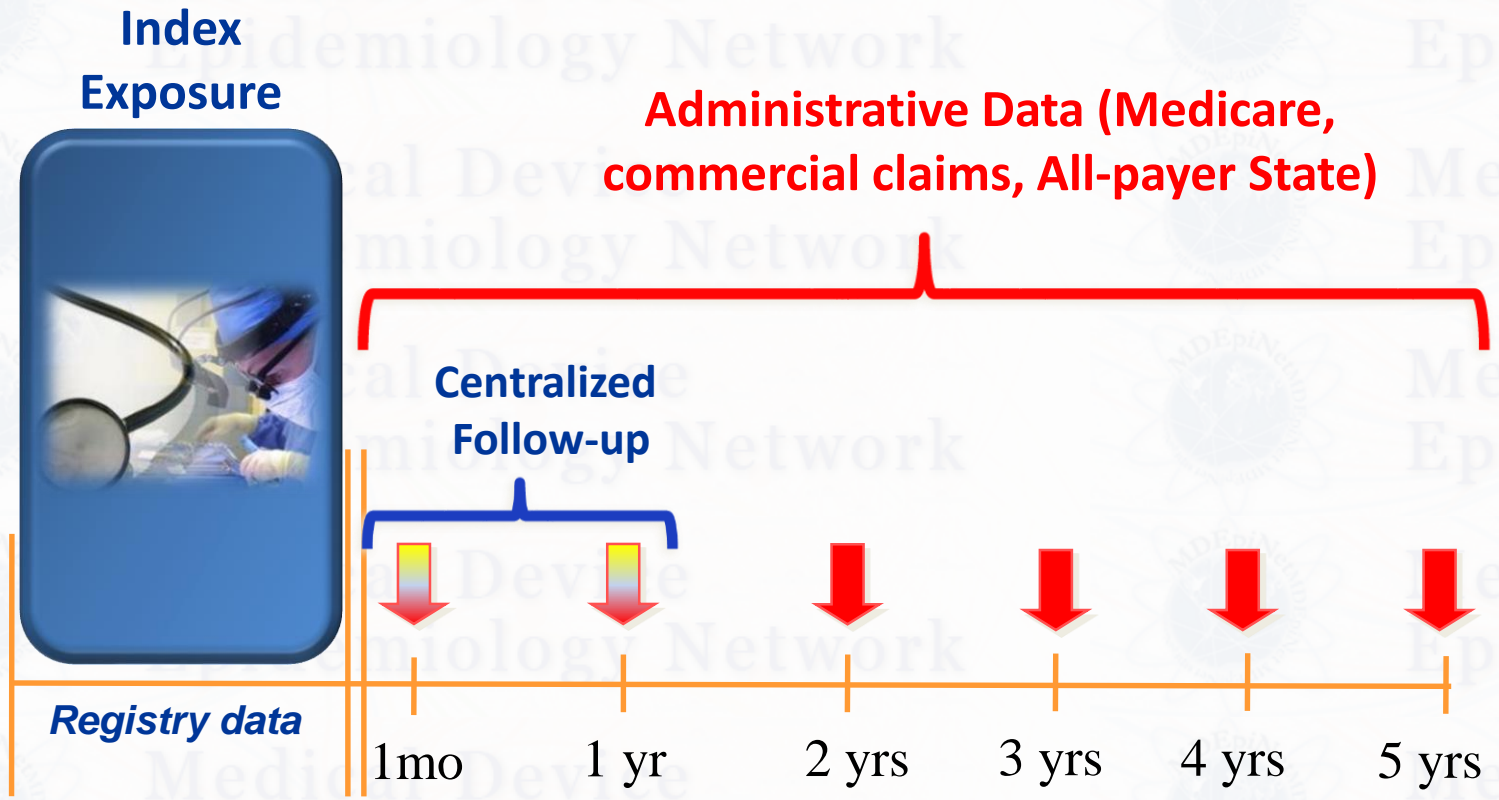
HOSPITALIZATIONS FOR PRIORITY PROCEDURE/GROUP OF PROCEDURES

Hip Replacement/Resurfacing
Knee Replacement

Thoracoscopic Esophagectomy
Robotic Cystectomy
Vascular Procedures
Spinal Fusion
Robotic Mitral Valve Plasticity
Robotic Prostatectomy
Endovascular AAA Repair
Catheter Ablation
Laparoscopic Colectomy
Robotic Hysterectomy
Robotic Esophagectomy
Laparoscopic Prostatectomy
Disk Replacement
Laparoscopic/NATS Surgeries
Peripheral Vascular Stenting
Robotic-Assisted Surgeries
Aortic/Mitral Valve Surgery
Laparoscopic Hysterectomy
Thoracoscopic Lobectomy
Robotic Lobectomy
Robotic Prostatectomy
Robotic Nephrectomy
Laparoscopic Cystectomy
ICD/CRT Devices
Robotic Thymectomy
BMP
Carotid Stenting
Laparoscopic Nephrectomy

Spine Surgeries
Coronary Stenting

CRN WITH REGISTRY AND CLAIMS DATA INTEGRATION



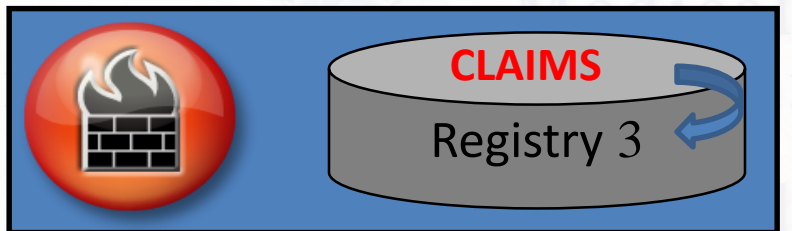
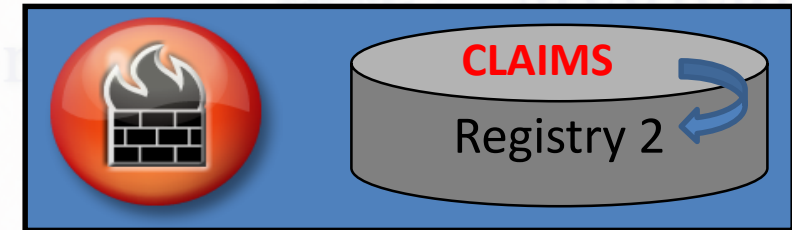
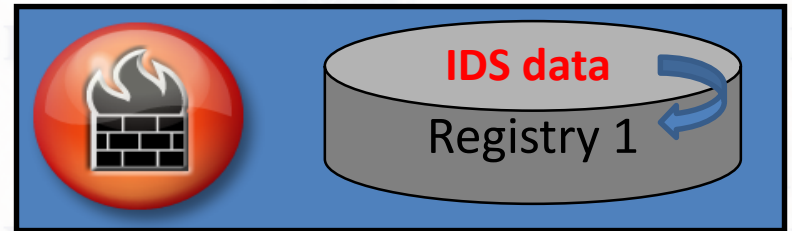
COMPLEX DISTRIBUTED CRN

Coordinating Center

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

Analytic queries

Frequencies, Crosstabs,
Cox regression results,
survival probabilities



KEY SUMMARY POINTS

- Even with the maturity of existing registries, major efforts are needed to create appropriately-targeted CRNs to address particular device-related questions
- For effective CRN both DEVICE and patient identification must be achieved
- Sufficient device and clinical outcome data must be available and has to be inexpensive and not burdensome to justify data quality sacrifices made compared to direct data collection