

REGISTRY- BASED IDEAS FOR THERAPEUTIC DEVICES: INDUSTRY VIEW

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HOW DID WE GET HERE?

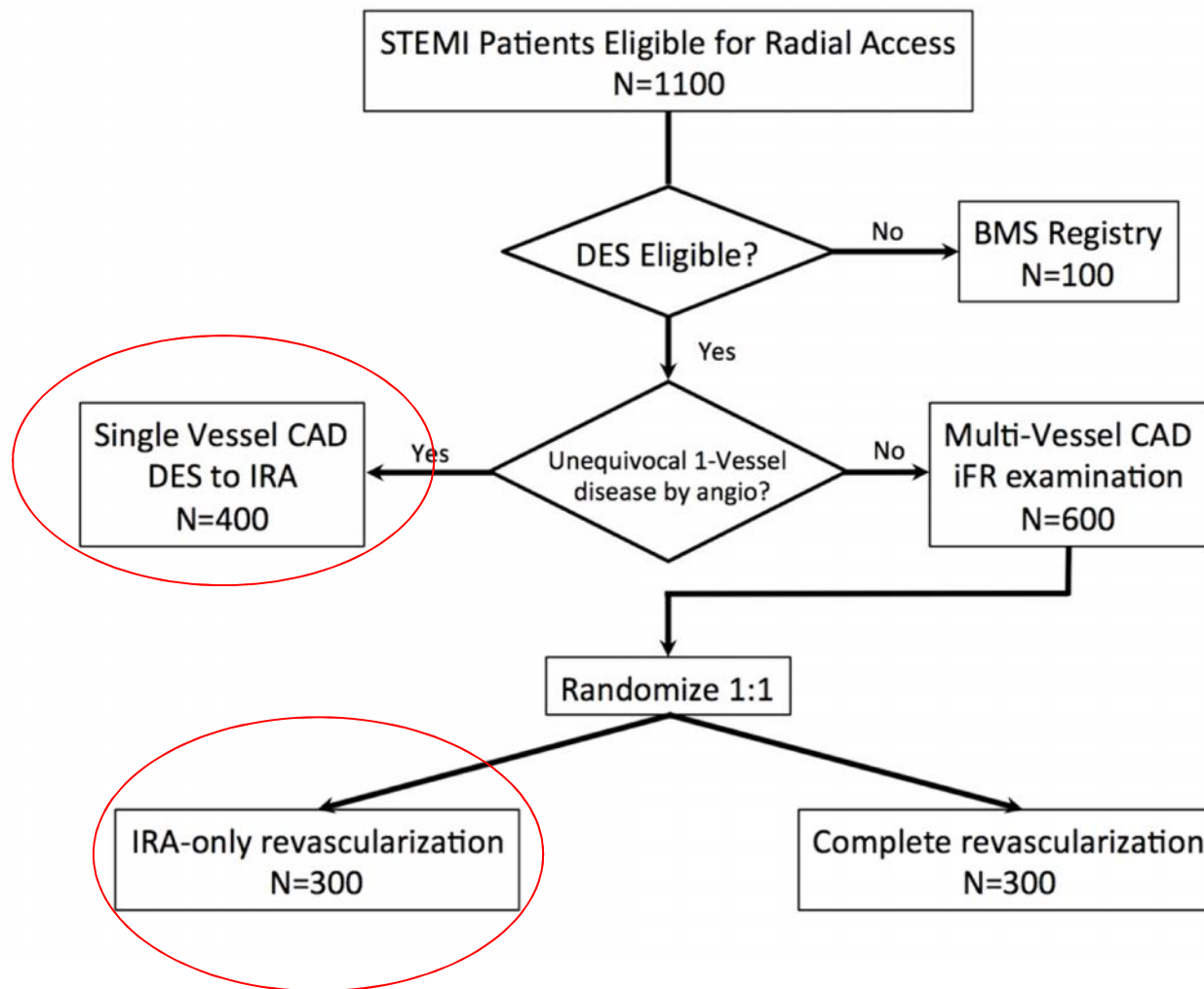
- SAFE-PCI – Proof of concept for a treatment strategy
- IDE trial for post-market label extension for test article(s) with existing PMA
- IDE trial to support initial PMA application

SAFE-STEMI FOR SENIORS

STUDY OF ACCESS SITE FOR ENHANCING PCI IN STEMI FOR SENIORS

- Next stage in proofs-of-concept
- Public health focus: Senior population (both genders, age \geq 65 years)
- NCDR registry prospectively linked with claims data for long term (1-year) follow up
- Randomization of stabilized STEMI patients
 - **Single IRA only vs. IFR guided multivessel intervention**

PATIENT FLOWS



DEVICE SPECIFIC STUDY OBJECTIVES

Simultaneously address potential advances in STEMI care for patients at least 65 years old:

- Revascularization with DES test article
- Radial success with DES test article for primary PCI
- Reduced bleeding and vascular complications with radial arterial access for primary PCI in STEMI

RIGOROUS STUDY DESIGN WITHIN THE CONTEXT OF A REGISTRY DATASET

- **Data Safety Monitoring Board**
- All subjects will sign **Informed Consent** before being enrolled in the study
- **CEC Adjudication** of serious adverse events
- **Angiographic Core Lab**

INDUSTRY VIEW

- High quality data
- Adjudication possible
- CFR Part 11 compliant – IND and IDE applications
- Faster enrollment, Reduced site workload
- Uniform data formats and definitions across pre- and post-market studies
- Potentially reduced costs

INDUSTRY VIEW (CONT..)

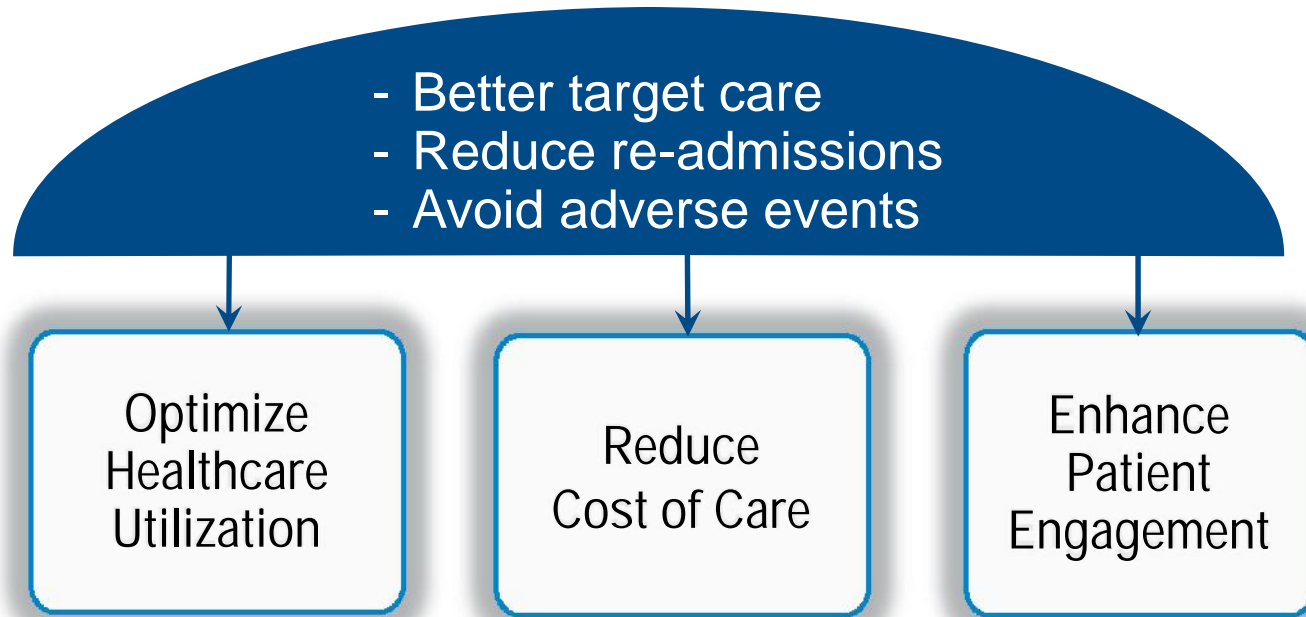
- Promising approach for future clinical investigations
- Excellent avenue for indication expansion for an approved product in the post-market environment
 - Applicability of outcomes in CMS population to broader population

What else?

- Can registry based IDEs for therapeutic devices drive value in healthcare?

Add Value to Health Care Delivery

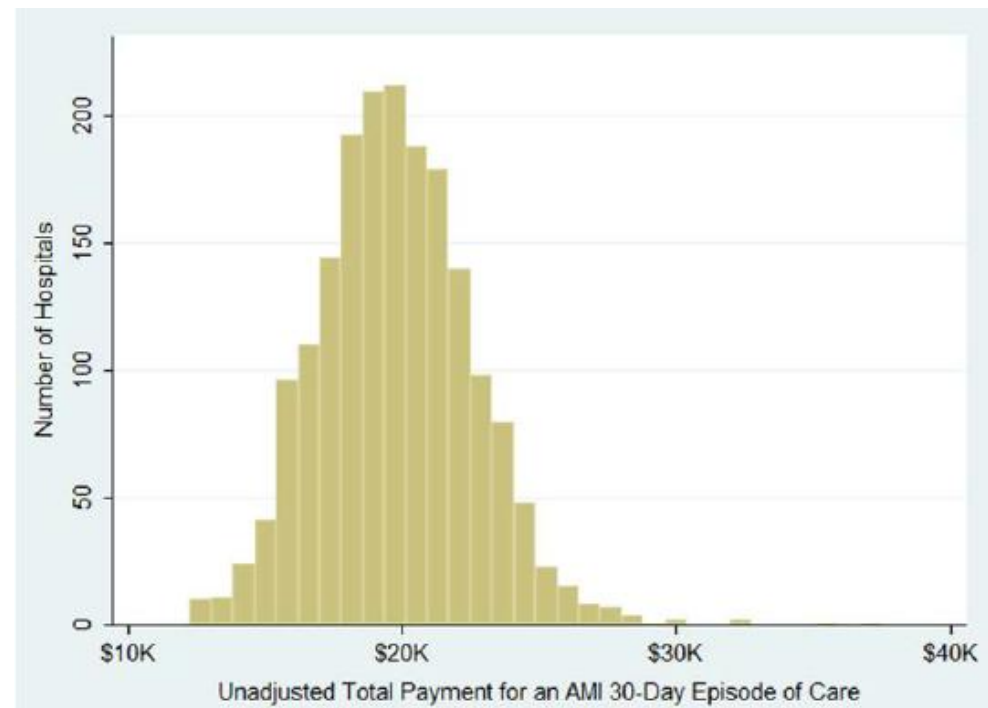
Improvement in care and patient engagement while reducing costs for variety of chronic diseases



CMS FOCUS ON AMI CARE

- AMI is a common condition in the elderly with a substantial range in payments due to different practice patterns
- 30-day all-cause mortality and readmission measures for AMI are publically reported
- AMI serves as a model condition for examining the association of payments for an episode of care with the quality of a hospital's care

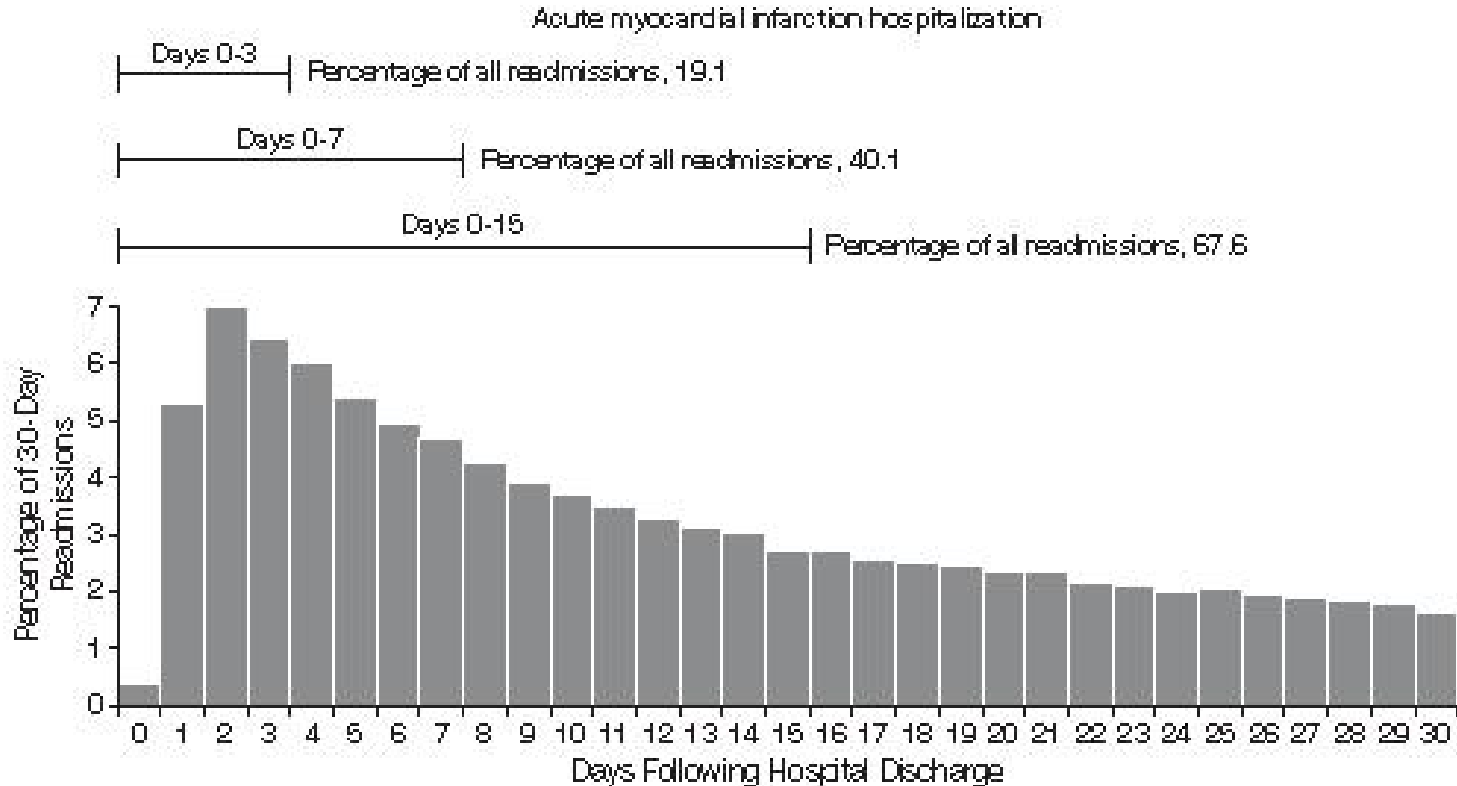
Distribution of Payments for an AMI 30-Day Episode of Care



Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for AMI (Version 1.0).

CURRENT AMI DATA

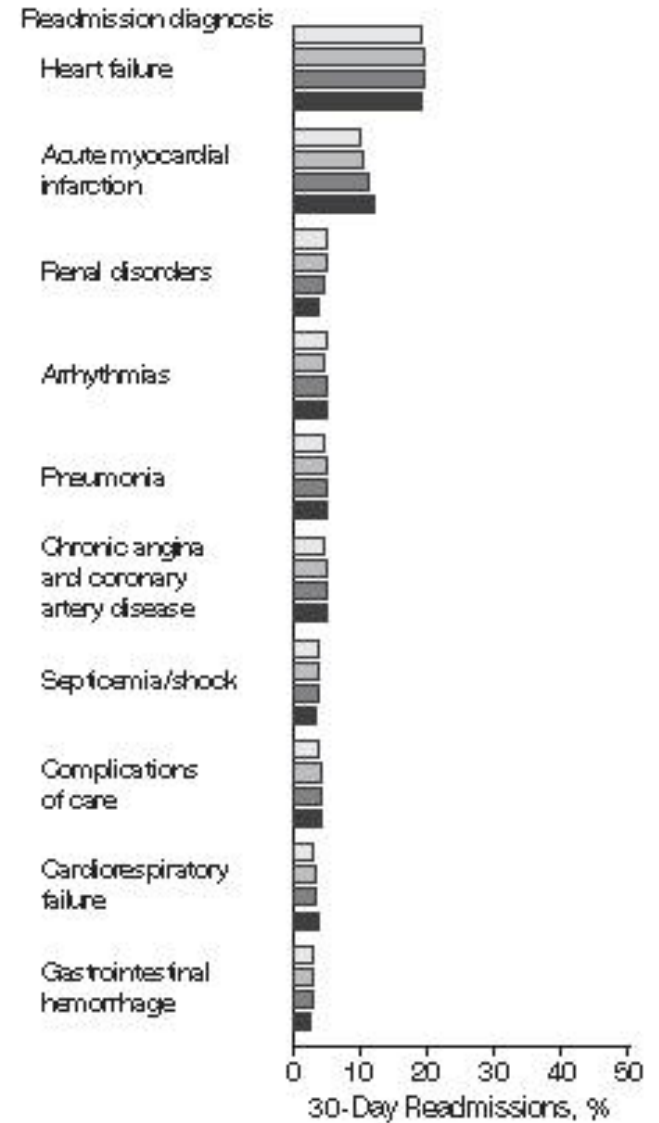
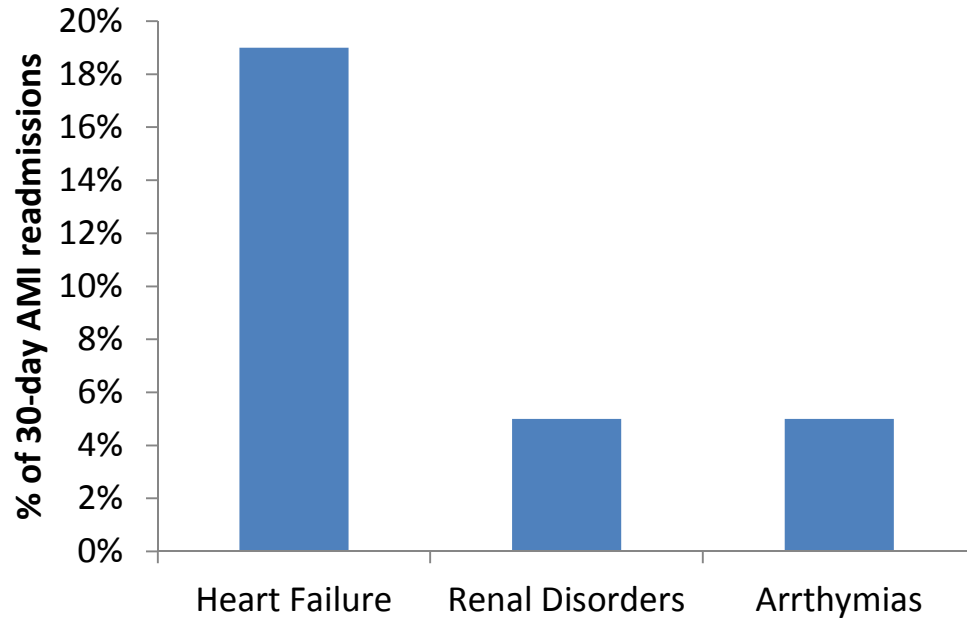
MAJORITY OF AMI READMISSIONS OCCUR WITHIN 15 DAYS



¹Diagnoses and Timing of 30-Day Readmissions after Hospitalization for Heart Failure, Acute Myocardial Infarction, or Pneumonia. Dharmarajan K, Hsieh AF, Lin Z, et al. JAMA. Jan 23/30, 2013-Vol. 309, No.4, pages 355-363

CURRENT AMI DATA

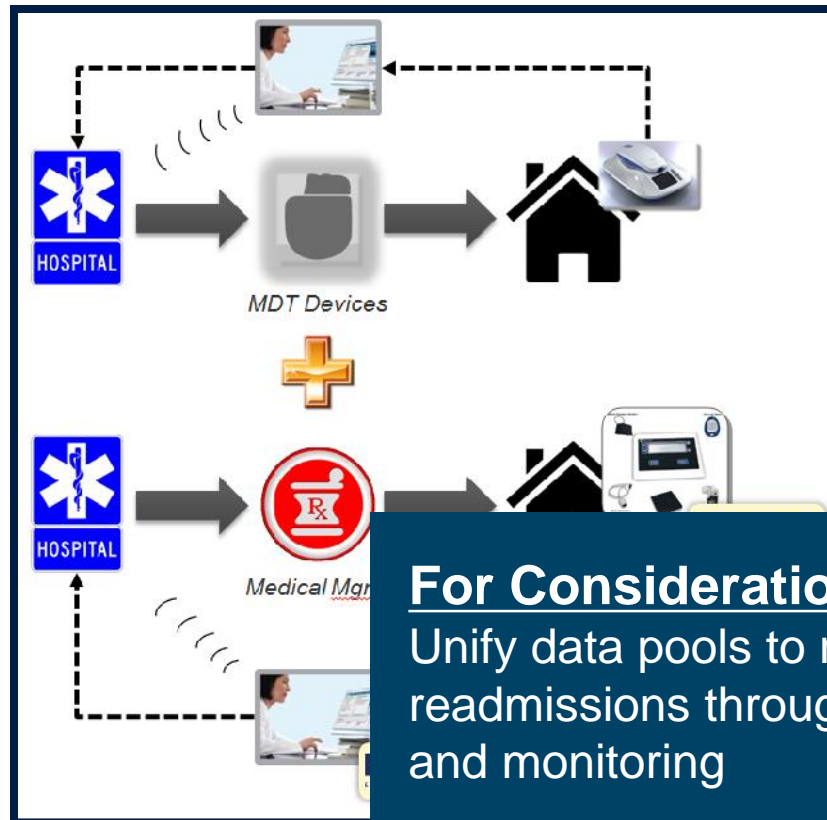
REASONS FOR READMISSION



¹Diagnoses and Timing of 30-Day Readmissions after Hospitalization for Heart Failure, Acute Myocardial Infarction, or Pneumonia. Dharmarajan K, Hsieh AF, Lin Z, et al. JAMA. Jan 23/30, 2013-Vol. 309, No.4, pages 355-363

Registry based IDEs

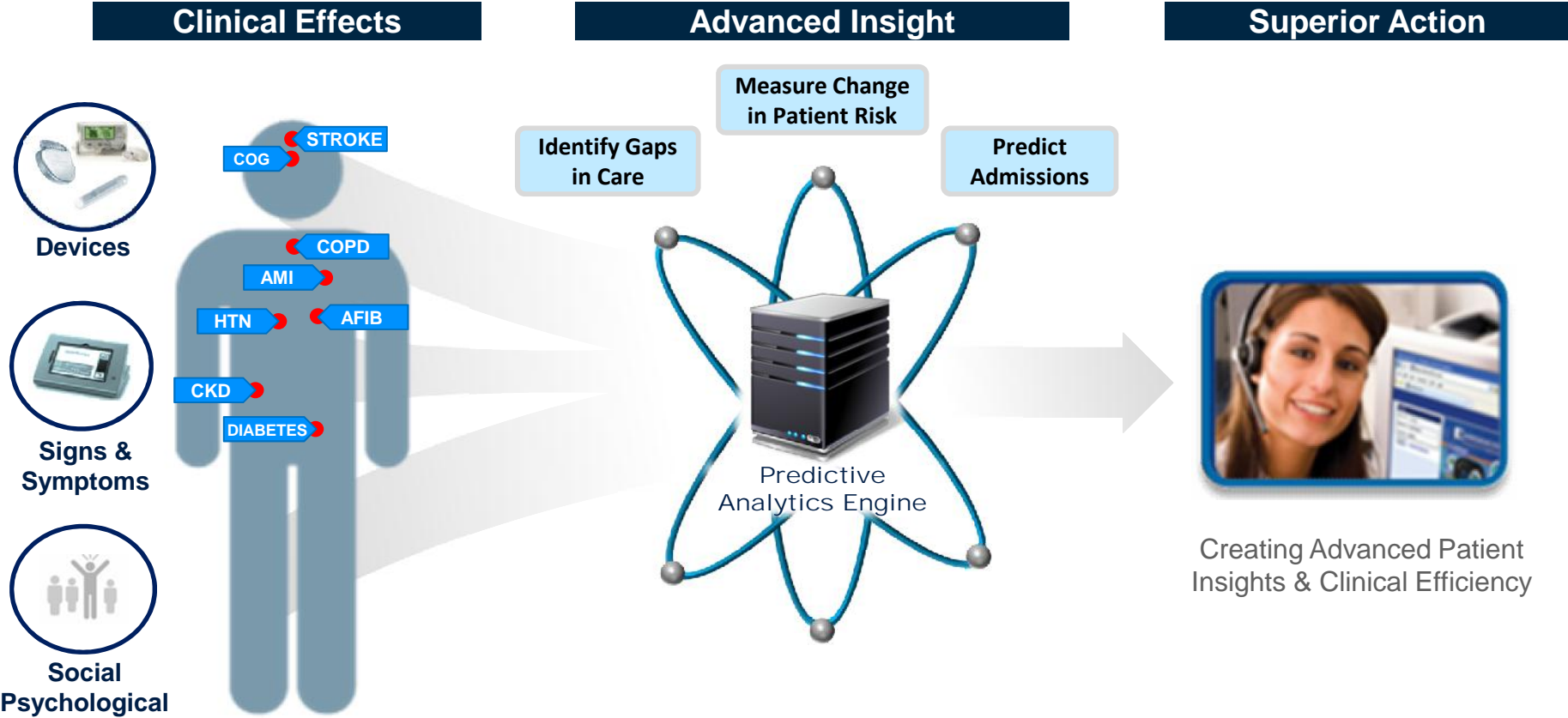
Can they meet the needs of data collection for multiple modalities?



For Consideration:

Unify data pools to reduce patient readmissions through predictive analytics and monitoring

Potential for studies: Capturing vast data array of outcomes for comprehensive patient care



Successful data integration will enable broad disease management and the full, “unrealized” value

FOR PATIENTS

- **Improved Outcomes**
 - Short-term: reduced readmissions at 30 Days (penalty focus) and/or 90 Days
 - Long-term: ability to impact other co-morbidities?
- **Improvement in Quality of Care**
 - Patient Satisfaction Scores
 - Regular Communication with Patients
- **Possibility for Reduced Length-of-Stays**

Thank you