

# EvGen: National Medical Evidence Generation System

Melissa Robb

April 20, 2016

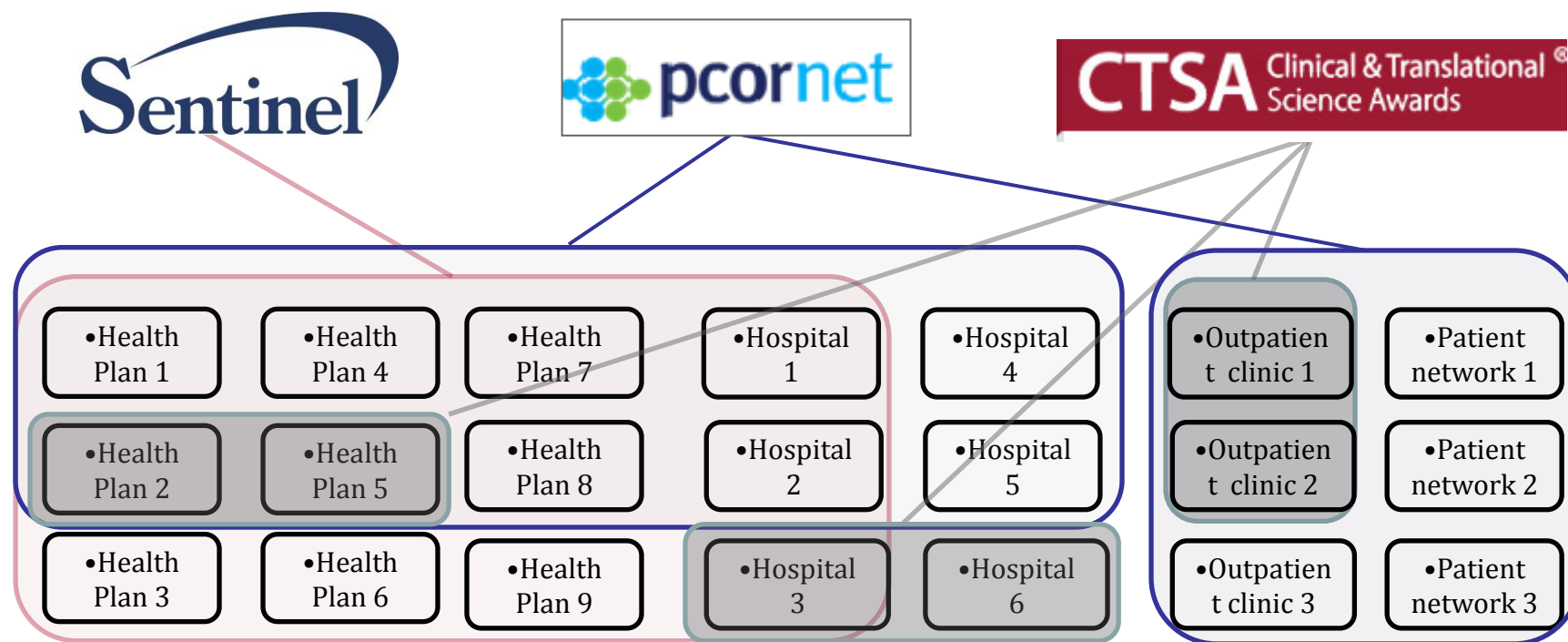
# Vision

A national medical evidence generation system that allows for integration of clinical care and clinical research (for those systems and patients willing to participate), that would allow for the conduct of observational and interventional research and surveillance (learning) by leveraging and linking information collected by multiple entities

## Call to Action

- Decisions about health and healthcare are best made when informed by high quality evidence
  - Medical product regulation
  - Payment
  - Individual consumer/patient/provider decisions
  - Policies
- Our current system of generating evidence has challenges
  - Generalizability
  - Feasibility
  - Efficiency
  - Sustainability

# Partners in a National Infrastructure



- Each organization can participate in multiple networks
- Each network controls its governance and coordination
- Networks share infrastructure, data curation, analytics, lessons, security, software development
- Other potential partners: disease or treatment-specific networks

# Informed by Ongoing Projects, Including:

- FDA
  - Sentinel Initiative
  - National Device Evaluation System
- NIH Health Care Systems Research Collaboratory
- CTSA
- PCORI-PCORnet
- Reagan-Udall Foundation IMEDS Project
- Precision Medicine Initiative
- VA Million Veteran Program
- Coordinating Efforts—ONC, ASPE

## Governance Issues Are Key

- Patient Privacy
- Data Security
- Transparency and Confidentiality
- Access
- Conflict of Interest
- Intellectual Property
- Separate governance structures are likely to have different funding models

## Crucial Steps to Progress

- Organize operational systems to enable clinicians, patients, consumers, industry, government, and healthcare systems to participate
- Establish a framework for confidentiality and security
- Adopt a common approach to configuring digital healthcare data
- Eliminate barriers that promote complexity, while ensuring appropriate safeguards
- Ensure that each linked group of projects has appropriate governance in place