What is MDEpiNet?

MDEpiNet is a global public private partnership that brings together leadership, expertise, and resources from health care professionals, industry, patient groups, payers, academia, and government to advance a national patient-centered medical device evaluation and surveillance. The MDEpiNet Coordinating Center at Weill Cornell Medicine supports MDEpiNet operations under a grant from the US Food and Drug Administration (FDA)/ Center for Devices and Radiological Health (CDRH).

What does MDEpiNet do?

Our mission is to develop and test novel methods, infrastructure, and partnerships for the creation of re-useable real-world data resources and support device evaluation by multiple stakeholders. Our vision for MDEpiNet is to be a global leader in the development of innovative approaches for robust, relevant, and reliable evidence generation throughout the medical device lifecycle.
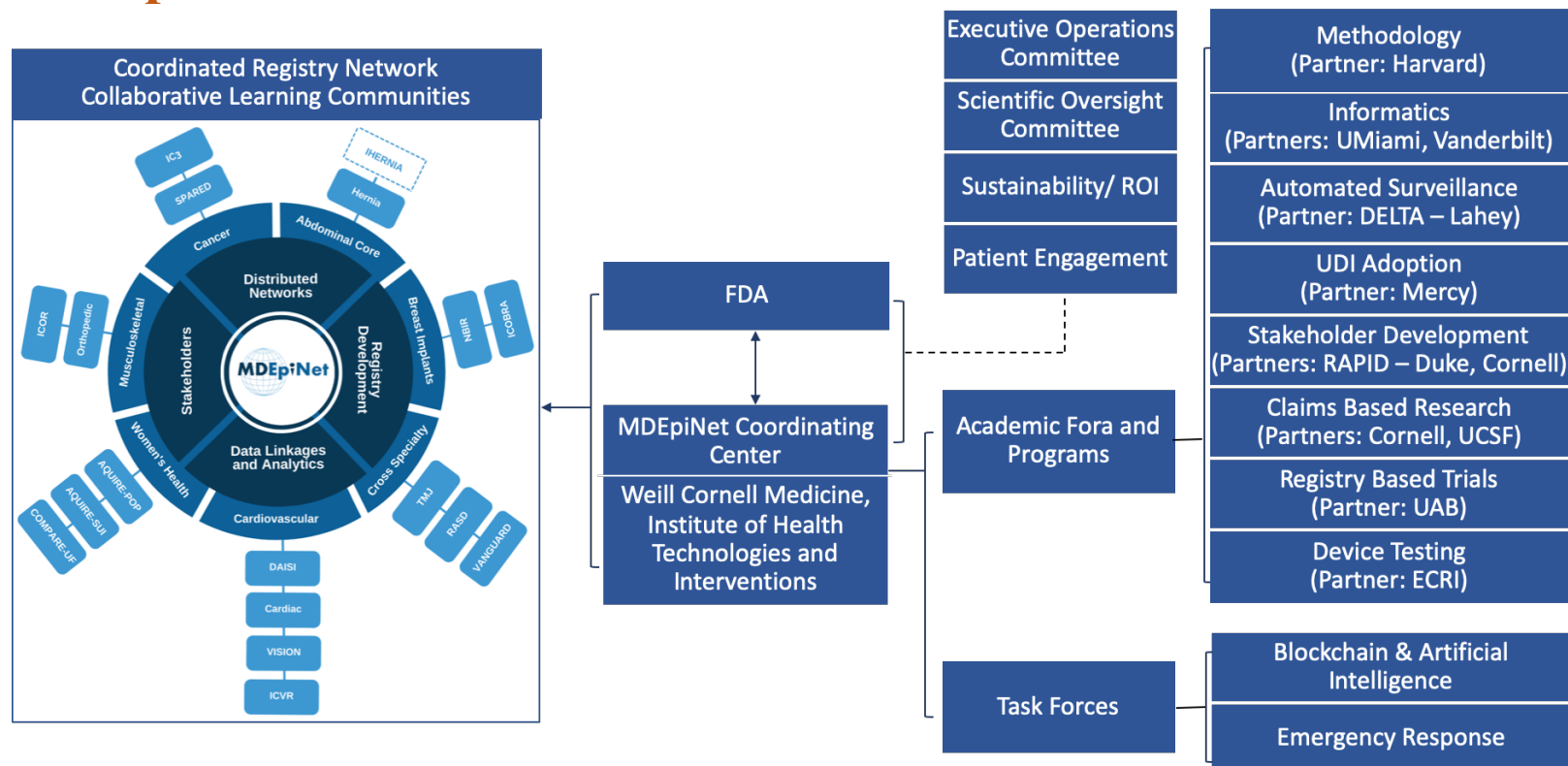
Partners

Key Capabilities

- Established the Collaborative Learning Communities (CLC) of national and international Coordinated Registry Networks (CRNs) to address the limitations of traditional registries and data repositories by building linked data systems from multiple sources
- Major programs that focus on patient-led roundtable, Unique Device Identification (UDI) adoption, data interoperability, novel methodology development and application, international registry consortia collaborative studies
- Over 160 partnering public and private sector organizations from the health technology ecosystem globally (academic partners like University of California San Francisco (UCSF) and University of Alabama (UAB), professional associations, registries, industry, patient organizations, health systems and more)
- Over 120 national/regional registries from 45 countries
- 12 National CRNs and 4 International Registry Consortia
- Over 780 clinical experts across clinical areas
- Over 250 methodologists (statisticians, epidemiologists, data scientists, informaticians, health care researchers)
- Access to hundreds of millions of patients (Registries, National and State claims data, National and International EHRs and Integrated Health Care Delivery Systems)
- MDEpiNet HIVE (High Performance Integrated Virtual Environment), with blockchain solutions with analytical tools for cloud computing
- International chapters in Europe, Asia and Australia
- Over 250 core publications in peer review journals featuring methods, infrastructure and partnerships in RWE space (over the past 6 years)
- Recognized as the National Evlauation System for health Technology Coordinating Center (NESTcc) data network collaborator
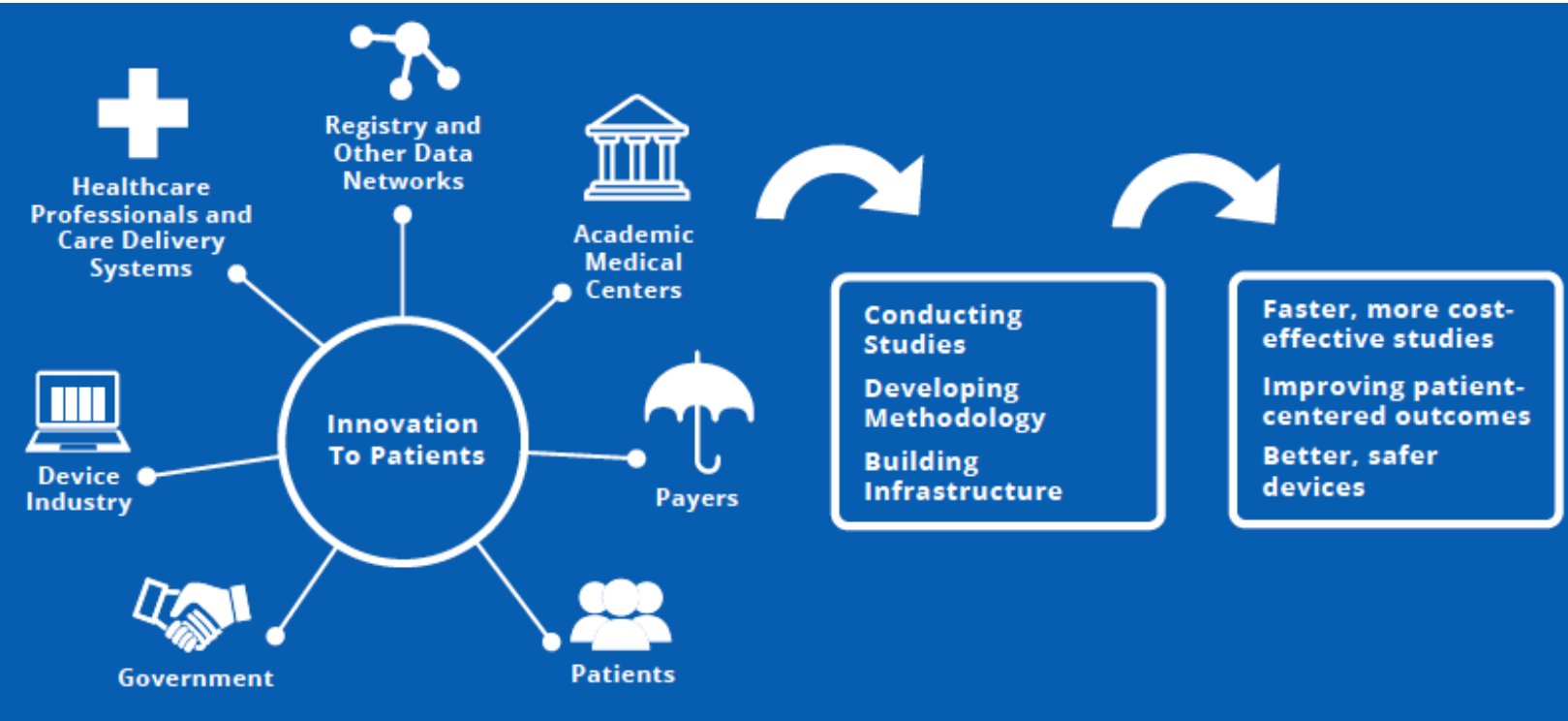
MDEpiNet Structure

Strategic Areas of Focus

Coordinated Registry Network (CRN) is a key MDEpiNet strategy to bring together real-world data from a variety of sources to address the needs of device evaluation for multiple stakeholders. Since 2017, MDEpiNet has been developing Collaborative Learning Communities (CLC) for CRNs to speed the development and maturity of the networks. CLC's main goal is to promote CRN development as a robust source of evidence for device evaluation in multiple areas. The center of the diagram above depicts functions of the coordinating center. The coordinating center collaborates with various MDEpiNet programs that serve as laboratories for methods development and often leverages the methods and tools developed by them for advancing and maturing CRNs. The MDEpiNet has other projects that are not currently CRNs, but are research and surveillance demonstration initiatives that have a potential to become CRNs

National CRN

- Cardiac Devices
- Devices used for Acute Ischemic Stroke Intervention (DAISI)
- Abdominal Core Health
- National Breast Implants Registry (NBIR)
- Orthopedic Devices
- Robotics Assistend Surgery Devices (RASD)
- Studies for Prostate Ablation Related Energy Devices (SPARED)
- Temporomandibular Joint (TMJ)
- Venous Access: National Guideline and Registry Development (VANGUARD)
- Vascular Implants Surveillance and Interventional Outcomes Network (VISION)
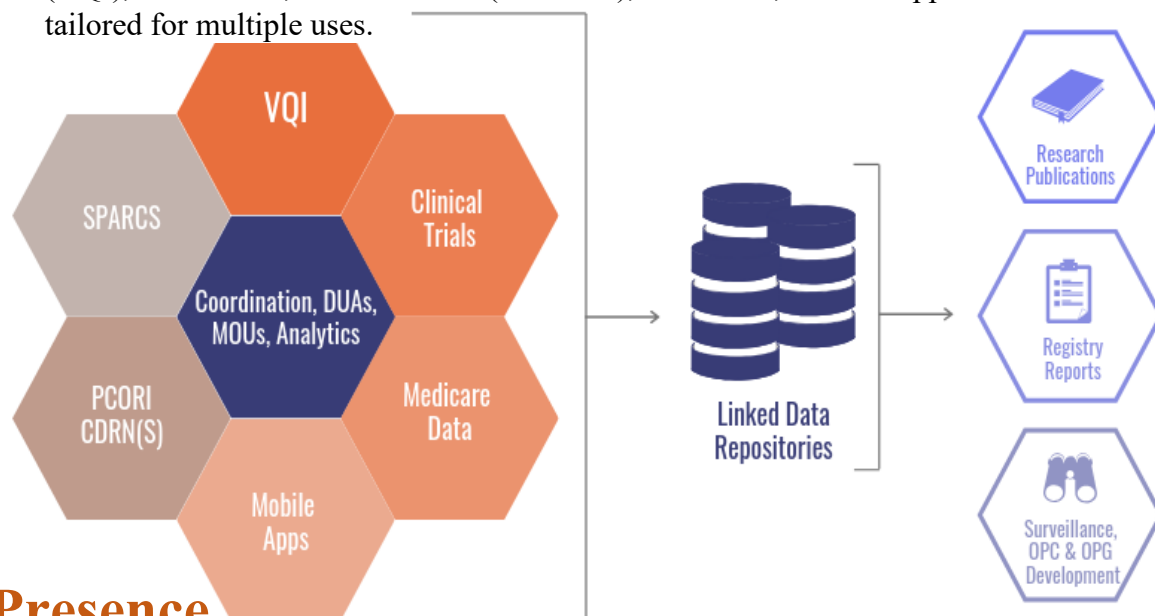- Women's Health Technologies (WHT)

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International CRN

- International Consortium of Vascular Registry (ICVR)
- International Consortium of Orthopedics Registry (ICOR)
- International Consortium of Colorectal Cancer (IC3)

Example CRN

MDEpiNet Vascular CRN – VISION which encompasses data sets from national registry (VQI), claims data, NY State data (SPARCS), PCORNet, Mobile Apps and clinical trial data tailored for multiple uses.

International Presence