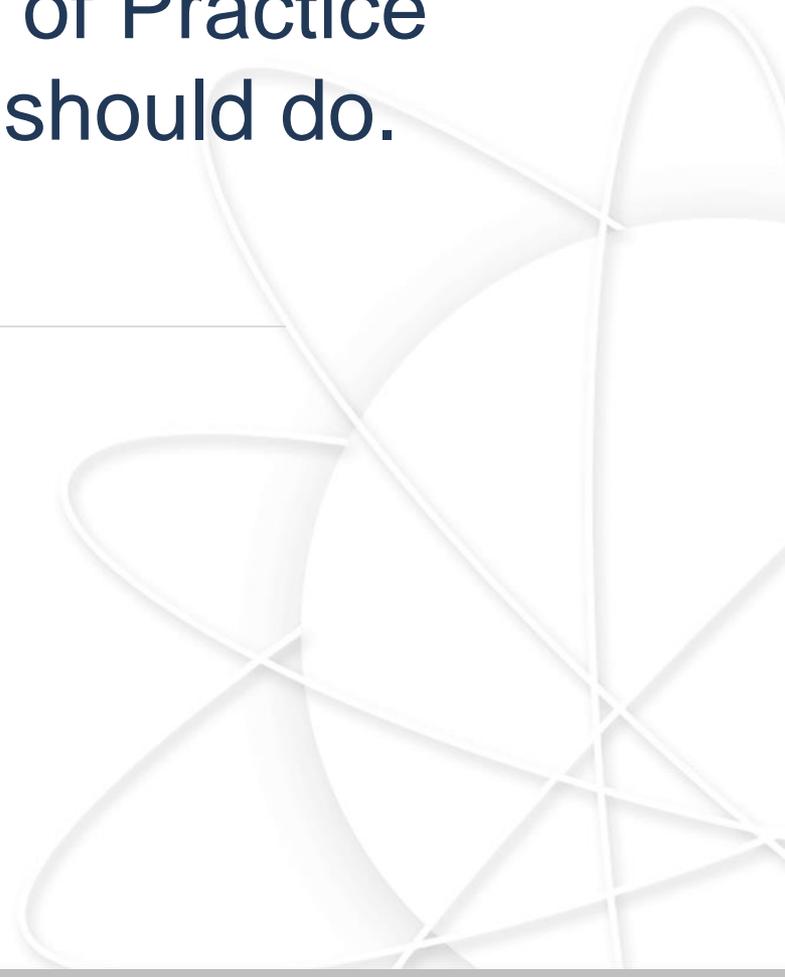




# Why do we need a Community of Practice and what it should do.

May 1, 2018  
Art Sedrakyan



# Why CRN are important: Helping build NEST

- In the past 2 years over 40 examples of use of RWE to support device evaluation but most are in CV area.
- CRN has been documented as a “better, faster, cheaper” way to generate evidence
- CRN can be used for a variety of categories of devices, types of companies, and for the range of regulatory decisions
- The Coordinated Registry Network (CRN) COP is the “low hanging fruit” for NEST, that may help NEST reach the goals in the short term.



# Currently there are 15+3 CRNs

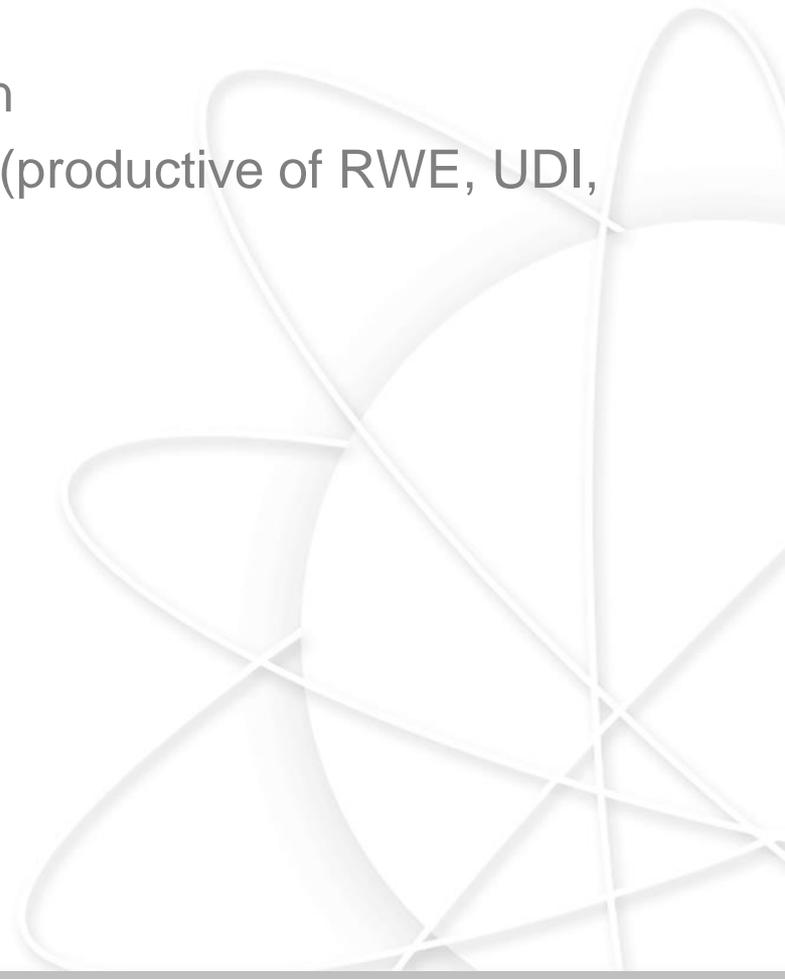
- There are 15 CRNs that have been formally launched
  - Orthopedic CRN
  - VISION Vascular CRN
  - SPARED (prostate ablation)
  - Women's Health CRN
  - NBIR (breast implant) CRN
  - ICVR
  - ICOR
  - American Hernia Society Quality Collaborative CRN
  - Robotic CRN
  - Cardiac CRN
  - DAISI Neuro CRN
  - TMJ CRN
  - GI CRN
  - VANGUARD CRN
- Three nascent CRNs that may be launched in the future:
  - The American College of Radiology has launched an institute which may become a CRN
  - OIR is working with partners to create Systemic Harmonization and Interoperability for Enhancement of Laboratory Data (SHIELD), a CRN for in vitro Diagnostics (IVDs)
  - An NIH funded project promoting creation of software as a medical device may evolve into a CRN

**CRN come from many places and are at different stages of development**



# Goal and Vision for Community of Practice (COP)

- The goal of the COP is to help CRNs develop and mature.
- The vision of a mature CRN
  - Producing RWE for device evaluation
  - Mature across a number of domains (productive of RWE, UDI, informatics, methods, governance)



# COP structure

- Steering Committee – made up of CRN and MDEpiNet leadership
- Operations Committee –
  - Support the Steering Committee and coordinate the Work Groups
- Work Groups
  - In multiple domains
  - Collect best practices and lessons learned for CRN
  - Work with CRN around their specified needs



# **MATURITY MODEL AND CRN SELF ASSESSMENT TOOLS**

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# Purpose of the Maturity Model

- Provide a vision for a mature CRN
- Develop domains the define technical areas related to CRN development
- Guide the CRN Self-Assessment tool that may be useful to CRN to identify needs and prioritize development efforts.

What the Maturity Model is

- NOT; a tool to rank CRN
- NOT; a tool to prioritize efforts
- NOT; a research tool





# IMDRF

International Medical  
Device Regulators Forum

## Medical Device Registry Definition

***“Organized system that continuously and consistently collects relevant data in conjunction with routine clinical care, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g. international, national, regional, and health system)’ with a primary aim to improve the quality of patient care”.***

The IMDRF definition approximates the definition of CRN.



## Key Registry Attributes

- ❑ **DEVICE:** The registry contains sufficient information to uniquely identify the device. Ideally, the unique device identifier would be included, but when the UDI is not available, the registry would include a combination of identifiers (catalog, number, manufacturer, description) that, in combination, will assist in uniquely identifying the device.
- ❑ **QUALITY IMPROVEMENT SYSTEM:** The registry is part of a health care delivery quality improvement system or evolving into one as device technologies are diffused into practice and need continuing evaluation (including outlier identification).
- ❑ **BENEFICIAL CHANGE:** The registry has established mechanisms to bring about beneficial change in health care delivery through stakeholder participation, ownership and integration into the relevant health care systems.
- ❑ **EFFICIENCY:** The registry is embedded in the health care delivery system so that data collection occurs as part of care delivery (i.e., not overly burdensome, not highly complicated, not overly costly, etc.) and integrated with work flow of clinical teams.
- ❑ **ACTIONABLE DATA:** The registry provides actionable information in a relevant and timely manner to decision makers.
- ❑ **TRANPARENCY:** The governance structure, data access, and analytical processes of the registry are transparent
- ❑ **LINKABILITY:** Information in the registry can be linked with other data sources for enhancement including adequate follow up achievement.
- ❑ **TOTAL DEVICE LIFE-CYCLE:** The registry can serve as infrastructure for seamless integration of evidence throughout the device life cycle.