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## MDEpiNet Annual Meeting

*Travelling through the NETs of the NEST: Toward Collective, Collaborative Intelligence via Continuum of Evidence Generation*

**Day one**

**White Oak Campus, Silver Spring, MD**

**THURSDAY, OCTOBER 19**

<b>7:30-8:00</b>	<b>Registration</b>	<b>Presenter/Affiliations</b>
<b>8:00-8:10</b>	<b>Welcome and the Key Objectives</b>	Danica Marinac-Dabic, <i>FDA</i>
<b>8:10-8:30</b>	<b>Opening Remarks</b>	Harlan Krumholz, <i>Yale</i>
<b>8:30-10:00</b>	<b>Session 1: MDEpiNet Portfolio: It takes a village</b>	

**Objectives:**

- (1) present a brief overview of MDEpiNet portfolio, accomplishments and
- (2) discuss the impact and value proposition for patients, payers, health care professionals, industry and health systems

MDEpiNet: Portfolio Overview - Jesse Berlin, *J&J*

MDEpiNet: Accomplishments - Danica Marinac-Dabic, *FDA*

**Moderator:** Art Sedrakyan, *WCM*

**Panel Responses and Discussion:**

- Tamara Syrek Jensen, *CMS*
- Kathy Blake, *AMA*
- Rick Kuntz, *Medtronic*
- Scott Smith, *ASPE*
- Terrie Cowley, *TMJA*
- Rachael Fleurence, *NESTcc*
- Seth Bilazarian, *Abiomed*
- Jeff Dunkel, *Titan Spine*

**10:00-10:15 Break**

**10:15-11:45 Session 2: Unleashing the Power of Flexible TPLC Evaluation**

**Objectives:**

- (1) Present the need for “rules of engagement” in the NEST system
- (2) Examine potential for TPLC decision-making using a variety of approaches

NEST needs (governance and rules of engagement)

Rachael Fleurence,  
*NESTcc*

Learning Hub for Surveillance Development Efforts  
Nesting Premarket Clinical Trials in Registries  
The Promise of RWE: We are doing it!

Fred Resnic, *Lahey*  
Mitch Krucoff, *Duke*  
Gregory Pappas, *FDA*

**Moderator:** Sharon-Lise Normand, *Harvard*

**Discussants:** Joseph Ross, *Yale*  
Owen Faris, *FDA*

**11:45-12:45 Lunch Session 3: with CDRH Director**

**11:45 Grab Lunch**

**12:00-12:10 Advancing Evidence Generation for Medical Devices**

**Jeff Shuren, *FDA***

**12:10-12:45 Discussion and Networking**

**12:50-1:50 Concurrent A and B, rooms TBA**

**A. *Citizens of the World: Global Opportunities for Health Technology Evaluation***

**Objective:**

- (1) Discuss what needs to happen next to strategically bridge the infrastructure and methodological gaps in international space as regulators, professional societies, registries, and other stakeholders increasingly open the door to the wealth of international data in of support the decision making.

Update from IMDRF

Melissa Torres, *FDA*

International Registry Consortia in Vascular space

Jack Cronenwett,  
*Dartmouth*

New international consortia and efforts to establish  
ISODORA & Journal for Surgery & Devices

Art Sedrakyan, *Cornell*

Can we better leverage HTAi?

Sean Tunis, *HTAi*

**Moderator:** Danica Marinac-Dabic, *FDA*

**Discussant:** Kathleen Lyons, *BMJ*  
Hiroshi Ohtsu, *Japan*

**B. *Capitalizing on International Partnerships: Expanding Infrastructure Opportunities***

**Objective:**

- (1) Discuss specific examples of data solutions in international space

How to build on international convergence efforts: The  
processes and beyond

Peter G. Goldschmidt,  
*Worldddg*

Lessons Learned from Harmonization by Doing (HBD) and  
international collaboration

Kazuhiro Sase, *Japan*

Big Data Application for Devices in Australia

Louisa Jorm, *UNSW,*  
*Australia*

Healthcare Data Exchange Framework: scalable economy of secure information and services

Vahan Simonyan,  
*FDA*

**Moderator:** Ben Eloff, *FDA*

**Discussant:** Jing Xie, *Medtronic*

**2:00-3:00 Session 4: Nodes in the network: can the learning health care system find more synergies?**

**2:00-2:30** The Power of the Ecosystem – Rob Califf (Duke/Varilly)

**Objective:**

- (1) To bring together major programs using and promoting the real- world evidence in healthcare to discuss current and future synergies between the programs

2:30-3:00 Panel  
Sentinel

Richard Platt,  
*Harvard Pilgrim*

NIH Collaboratory

Cathy Meyers, *NIH*

NEST

Rachael Fleurence, *NESTcc*

PCORnet

TBD

MDEpiNet

Art Sedrakyan, *WCM*

**Moderator:** Kathy Blake, *AMA*

**3:00-3:15 Break**

**3:15-4:45 Session 5: Concurrent A and B, rooms TBA**

**A. Demonstration of innovative approaches for using real world evidence for device evaluation**

**Objective:**

- (1) Present innovative efforts to build CRN-like platforms for use of real-world evidence and approaches to architecture to support them. Specific focus will be on non-implantable categories of medical devices (laboratory tests, monitors, radiology) that exist in highly digitalized spaces than may be brought together into a platform which functions like a CRN

Pre-Vent: a network of NICUs bringing together RWE including monitor wave forms

Randall Moorman,  
*UVA*

A new institute at the American College of Radiology

Keith Dreyer, *ACR*

Three models for use of Real Work Evidence in the In Vitro Diagnostic Space

Mike Waters, *FDA*

CASAE: A Breakthrough Technology for Distributed Data System - providing a demo MITRE

Jay Schnitzer / Robyn Wade, *MITRE*

**Moderator:** Gregory Pappas, *FDA*

**Discussants:** Konstantinos Makrodimitris, *FDA*  
Debbie Bucci, *ONC*

## **B. Learning Together and Learning from Each Other: Collaborative Efforts to Advance Evidence Generation**

### ***Objective:***

(1) Present novel collaborative efforts to advance collective learning from variety of available data sources

Biocompute object

Dennis Dean, *Seven Bridges Genomics*

Raja Mazumder, *GW*

Medtronic/Mercy Collaborative

Darrell Johnson,  
*Medtronic*

Harnessing the Intersection of Epidemiologic and Genetic Evidence

Lisa Torosyan, *FDA*

Beyond traditional data sources for devices

Christina Mack, *Quintiles*

WebShield and eP3 network

Jonathan Hare/Jack Lewin  
*WebShield*

***Moderator:*** Ram Tiwari, *FDA*

***Discussants:*** Vahan Simonyan, *FDA*,  
Julia Skapik, *Cognitive Medicine*

**5:00-5:15 Day one Wrap up:**

**Sharon-Lise Normand,  
*Harvard***



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## MDEpiNet Annual Meeting

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**Day Two**

**White Oak Campus, Silver Spring, MD**

**FRIDAY, OCTOBER 20**

8:00-8:30	Registration and Poster Walk	Presenter/Affiliations
8:30-11:45	Strategically Coordinated Registry Networks (CRNs) for Health Technologies: Tactical Look at the National Landscape	
8:30-10:00	CRNs - Part I	

**Objectives:**

- (1) to present current CRNs; maturity models and
- (2) to engage the program leads to identify success stories, themes, and lessons learned.

Ortho CRN	Rebecca Love, <i>Kaiser</i>
VISION Vascular	Phil Goodney, <i>VQI</i>
SPARED (prostate ablation)	Jim Hu, <i>Cornell</i>
	Ben Fisher, <i>FDA</i>
Robotic	Jeff Levy, <i>CaseNetwork</i>
	Binita Ashar, <i>FDA</i>
Women's Health	Danica Marinac-Dabic, <i>FDA</i>
	Julia Skapik, <i>Cognitive Medicine</i>
American Hernia Society Quality Collaborative	Benjamin Poulouse, <i>Vanderbilt</i>

**Moderator:** Art Sedrakyan, *Cornell*

**Discussant:** Seth Blumenthal, *PCPI*

10:00-10:15	Break	
10:15-11:45	CRNs – Part II	
	CDCRN	Pablo Morales, <i>FDA</i>
	DAISI/Neuro	Carlos Pena, <i>FDA</i>
		Murray Sheldon, <i>FDA</i>
	NBIR – CRN	Andrea Pusic, <i>MSKCC</i>
		Ben Eloff, <i>FDA</i>

CATNIP

TMJ

VANGUARD

RAPID/EP PASSION

Cynthia Long, *FDA*

Terrie Cowley, *TMJA*

Lisa Torosyan, *FDA*

Kevin Baskin, *VANGUARD/SIR*

Greg Pappas, *FDA*

Pablo Morales, *FDA*

Daniel Canos, *CMS*

**Moderator:** Art Sedrakyan, *Cornell*

**Discussant:** Kristi Mitchell, *Avalere*

<b>11:45-12:00</b>	<b>Call for action: Launching the CRN Task Force</b>	<b>Rachael Fleurence, <i>NESTcc</i></b>
<b>12:00-1:00</b>	<b>Lunch and CRN Teams Networking</b>	
<b>1:00-1:10</b>	<b>Let's get to Work! Instruction to the CRN Breakouts</b>	<b>Danica Marinac-Dabic, <i>FDA</i></b>
<b>1:15-3:30</b>	<b>Breakout Sessions (Rooms TBA)</b>	

Breakout sessions will be held concurrently. Each group will address different aspects of CRN development. The objectives of the sessions will be to develop perspectives for the formation of the Taskforce. Each session will have a moderator to facilitate the work of the group and a scribe to report. The breakouts will be facilitated by a panel and the moderator

**A. Data definition data, capture, quality assurance and adherence to informatics standards in CRN**

**Moderator:** Jimmy Tchong, *Duke*

**Panel:**

- Lisa Lang, *NLM*
- Mera Choi, *ONC*
- Kathleen Hewitt, *NCDR*
- Stan Huff, *Intermountain*
- Seth Blumenthal, *PCPI*
- Peter G. Goldschmidt, *Worldddg*
- Julia Skapik, *Cognitive Medicine*

**B. Implementation of UDI into CRNs**

**Moderator:** Behnaz Minaei, *FDA*

**Panel:**

- Joseph Drozda, *Mercy*
- Kevin Baskin, *VANGUARD/SIR*
- Rebecca Love, *Kaiser*
- Industry
- Indira Konduri, *FDA*
- Phil Goodney, *VQI*

**C. Patient engagement, protection, PROs, data privacy and transparency in CRNs**

*Moderator:* Karen Ulisney, *FDA*

*Panel:*

- Annie Saha, *FDA*
- Jodi Akin, *Hawthorne Effect*
- Anna McCollister-Slipp, *Galileo*
- Joel Gagnier, *U Michigan*
- Industry (large and small)

**D. Governance of CRN and relationship to NESTcc governance**

*Moderator:* Rachael Fleurence, *NESTcc*

*Panel:*

- Art Sedrakyan, *Cornell*
- Kathy Blake, *AMA*
- Pablo Morales, *FDA*
- Danica Marinac-Dabic, *FDA*
- Industry (large and small)

**E. Methodologies (design, linkage, integration of imaging, analytics) for CRN**

*Moderator:* Sharon-Lise Normand, *Harvard*

*Panel:*

- Matt Brennan, *Duke*
- Guy Cafri, *Kaiser*
- Daniel Canos, *CMS*
- Asiyah Yu, *FDA*
- Caryn Etkin, *AJRR*
- Lilly Yue, *FDA*
- David Liebeskind, *UCLA*
- Hiroshi Ohtsu, *Japan*

**F. CRN partnership building and sustainability**

*Moderator:* Jesse Berlin, *J&J*

*Panel:*

- Marissa Miller, *NIH*
- Anne Trontell, *PCORI*
- Elise Berliner, *AHRQ*
- Jeff Dunkel, *Titan Spine*
- Ben Eloff, *FDA*
- Murray Sheldon, *FDA*

**3:30-4:00** Reports from Breakout Scribes

**4:00** Summary and Next steps

**Art Sedrakyan, WCM**