



# 9<sup>th</sup> MDEpiNet Annual Meeting

## *Building Collaboratives without Borders*

October 23-24, 2018  
FDA Headquarters, Silver Spring, MD  
Building 31, Great Room

### Meeting Agenda

#### *Day 1*

## CRN Community of Practice - Learning Healthcare System for Devices

TIME	TOPIC	PRESENTER
7:30am-8:00am	Registration	
8:00am-8:05am	Welcome and Goals of the Day	Art Sedrakyan, <i>WCM</i>
8:05am-8:40am	Session I - MDEpiNet Accomplishments	
8:05am-8:20am	MDEpiNet / Championing International Collaboratives	Danica Marinac-Dabic, <i>FDA</i>
8:20am-8:40am	MDEpiNet / Spotlight on the CRN Community of Practice	Art Sedrakyan, <i>WCM</i>
8:40am-12:10am	Session II - CRN Showcase	
8:40am 9:20am	<u>Vascular – VISION CRN</u> <i>Moderator:</i> Jens Jorgensen, <i>VQI</i> <i>Discussants:</i> Ted Heise, <i>Cook</i> Pablo Morales, <i>FDA</i>	Phil Goodney, <i>VQI</i>
9:20am-10:00am	<u>Orthopedic – ORTHO CRN</u> <i>Moderator:</i> Stephen Weber, <i>FDA</i> <i>Discussants:</i> Paul Voorhorst, <i>J&amp;J</i> Nathan Glusenkamp, <i>AAOS</i>	Liz Paxton, <i>Kaiser</i>
10:00am-10:10am	Coffee Break	
10:10am-10:50am	<u>Prostate Ablation – SPARED CRN</u> <i>Moderator:</i> Benjamin Fisher, <i>FDA</i> <i>Discussants:</i> Charles Viviano, <i>FDA</i> Fernando Bianco, <i>URN</i>	Michael Gorin, <i>Johns Hopkins</i>

10:50am-11:30am **Breast Implants – NBIR CRN** Andrea Pusic, *Harvard*

**Moderator:** Sung Yoon, *FDA*  
**Discussants:** Jesse Berlin, *J&J*  
Ingrid Hopper, *ICOBRA*

11:30am-12:10pm **Women’s Health – WHT CRN** Danica Marinac-Dabic, *FDA*

**Moderator:** Benjamin Eloff, *HHS*  
**Panel:** Colleen Skau, *AUGS*  
Elisabeth Erikson, *Dartmouth*  
Beth Hodshon, *Yale*  
Terrie Reed, *FDA*  
Kim Rodriguez, *Acessa*

12:10pm-1:25pm **Session III - Working Lunch – MIPS/MACRA** Sophia Sugumar, *CMS*

1:25PM-2:40PM **Session IV & V - Breakout Sessions**

**A. Quality Improvement and Beneficial Change**

**Moderator:** Kristi Mitchell, *Avalere*  
**Panel:** Colleen Skau, *AUGS*  
Nathan Glusenkamp, *AAOS*  
Jack Cronenwett, *M2S/Medstreaming*  
Phil Goodney, *VQI*  
Ralph Brindis, *ACC*  
Kathy Blake, *AMA*

Panel Discussion with stakeholders on the following topics:

- a. Value of Routine Feedback
- b. Outlier Assessment of Devices and Providers
- c. Advantages and Limitations in QCDR Participation

**ROOM: SECTION A**

**B. Data Quality and Longitudinal Outcomes**

**Moderator:** Nilsa Loyo-Berrios, *FDA*  
EMR Data  
Data Linkages  
Automated Surveillance  
Data Quality  
Return on Investment

Christina Mack, *IQVIA*  
Jialin Mao, *WCM*  
Fred Resnic, *Lahey*  
Theodore Lystig, *Medtronic*  
Gregory Pappas, *FDA*

**ROOM -1404**

2:40pm-2:50pm **Coffee Break/Change Rooms**

<b>2:50pm-3:30pm</b>	<b>Session VI - Augmenting Capacities and Collaborations across CRNs</b>	
	<i>Moderator:</i> Sharon-Lise Normand, <i>Harvard</i>	
	RWE Directly from Patients	Debi Willis, <i>Patient Link</i>
	UDI and Supplemental UDI	Terrie Reed, <i>FDA</i> Liz Paxton, <i>Kaiser</i>
	Data Automation	James Tcheng, <i>Duke</i> Jack Cronenwett, <i>M2S/Medstreaming</i>
<b>3:30pm-4:30pm</b>	<b>Session VII - Panel Discussions for CRNs Making Progress:</b>	
	<i>Moderator:</i> Danica Marinac-Dabic, <i>FDA</i>	
	<u><b>Robotic CRN</b></u>	Jeffrey Levy, <i>Case Network</i>
	<u><b>DAISI Neuro CRN</b></u>	David Liebeskind, <i>UCLA</i> Adnan Siddiqui, <i>UNY</i>
	<u><b>VANGUARD CRN</b></u>	Kevin Baskin, <i>University of Pittsburgh</i>
	<u><b>Cardiac CRN</b></u>	John Laschinger, <i>FDA</i> Ralph Brindis, <i>ACC</i> Daniel A. Canos, <i>CMS</i>
	<u><b>Colorectal IC3 CRN</b></u>	Jeffrey Milsom, <i>WCM</i>
<b>4:30pm-5:15pm</b>	<b>Session VIII - International Opportunities to Leverage CRNs:</b>	
	<i>Moderator:</i> Art Sedrakyan, <i>WCM</i>	
	ICVR Projects	Jack Cronenwett, <i>M2S/Medstreaming</i>
	Canadian Agency for Drugs and Technology in Health	Harindra Wijeyesundera, <i>CADTH</i>
	IMDRF Registry Efforts	Danica Marinac-Dabic, <i>FDA</i>
<b>5:15pm-5:30</b>	<b>Day 1 Concluding Remarks</b>	
	<b>Art Sedrakyan, <i>WCM</i></b>	



Website: [www.mdepinet.org](http://www.mdepinet.org) . Twitter: @mdepinet\_ppp



## *Day 2*

# National Evaluation System for health Technologies (NESTcc) Programs Leadership Exchange Forum

TIME	TOPIC	PRESENTER
7:30am-8:00am	<b>Registration</b>	
8:00 am – 8:10am	<b>Welcome and Goals for the Day</b>	Rachael Fleurence, <i>MDIC/NESTcc</i>
8:10 am-9:45am	<b>Session I: NEST Plenary Presentations</b>	
	<i>Moderator:</i> Rachael Fleurence, <i>MDIC/NESTcc</i>	
	CDRH Perspective	Jeffrey Shuren, <i>FDA</i>
	MDIC Perspective	Pamela Goldberg, <i>MDIC</i>
	Industry Perspective	Jesse Berlin, <i>J&amp;J</i>
	Payer Perspective	Kevin Haynes, <i>HealthCore</i>
	Response to Plenary Presentations, from the perspective of Day 1	Art Sedrakyan, <i>WCM</i>
9:15am—9:45am	Discussion - Q&A	
9:45am-10:00am	<b>Coffee Break</b>	
10:00am-11:30am	<b>Session II: NESTcc Demonstration Projects Roundtable</b>	
	<i>Moderator:</i> Danica Marinac-Dabic, <i>FDA</i>	
	mHealth Data Source in PMS	Sanket Dhruva, <i>UCSF</i>
	Sustainable RWE Infrastructure for IVDs Through SHIELD	Mike Waters, <i>FDA</i>
	ICD Registry DELTA Active Surveillance Pilot	Fred Resnic, <i>Lahey</i>
	RAPID and SAFE STEMI for Seniors	Mitch Krucoff, <i>Duke</i>
	Discussion: Challenges and Collaborative Efficiencies & Opportunities	Danica Marinac-Dabic, <i>FDA</i>

**11:30am-11:45am Lunch Break**

11:45am-12:45pm Working Lunch: Roundtable with the NESTcc Data Quality and Methods Subcommittee Chairs Lesley Curtis, *Duke*  
Sharon-Lise Normand, *Harvard*

**12:45pm-2:00pm Session III: NESTcc Network Collaborators**

**Moderator:** Rachael Fleurence, *MDIC/NESTcc*

Panel Discussion with the following partners:

*PEDSnet*

HealthCore

OneFlorida

MDEpiNet

Charles Bailey, *PEDSnet*

Kevin Haynes, *HealthCore*

Betsy Shenkman, *UFL*

Art Sedrakyan, *WCM*

**2:00pm-2:15pm Coffee Break**

**2:15pm-3:15pm Session IV: Challenges and Opportunities with NESTcc Real World Evidence Test-Cases**

**Moderator:** Owen Faris, *FDA*

**Panel:** Kristina Finney, *AJRR*

Paul Coplan, *J&J*

Lesley Curtis, *Duke*

Joe Drozda, *Mercy*

Panel Discussion with test-case stakeholders:

- a. Identifying the intended use-cases
- b. Considering the value proposition for participating
- c. Discussing technical opportunities and challenges
- d. Identifying challenges and collaborative efficiencies and opportunities

**3:15pm-4:15 Session V - Engagement Opportunities**

**Moderator:** Rachael Fleurence, *MDIC/NESTcc*

A discussion of practical engagement opportunities between NESTcc, MDEpiNet, and society registries

Helen Burstin, *CMSS*

Danica Marinac-Dabic, *FDA*

**4:15pm-4:30pm Closing Comments:  
Summary Visions, Next Steps and Adjournment**

Owen Faris, *FDA*  
Rachael Fleurence,  
*MDIC/NESTcc*