

**9th MDEpiNet Annual Meeting:
Building Collaboratives without Borders
October 22-24, 2018
Draft Agenda**

Pre-conference Workshops: Monday, October 22

Overall theme: Focus on methodologies and tools relevant to CRNs capacity building

Objectives: To provide state of the art educational opportunity in analytical approaches applied to medical devices

TIME	TOPIC	PRESENTER
	Breakout Sessions	
12:00pm-2:00pm	Missing Data	Joseph Hogan (Brown)
12:00pm-2:00pm (Session 1) 2:30pm-4:30pm (Session 2)	DELTA Tutorial	Fred Resnic (Lahey)

DAY 1: Tuesday, October 23 = CRN Community of Practice – More than a Set of Building Blocks

Overall Theme: Building a CRN Community of Practice to assist CRN development as a robust source of evidence for device evaluation and serve as a foundational component of NEST

Objectives:

- I. To bring together CRN Community of Practice (COP) and present update on CRN maturity models
- II. To discuss the stakeholders interest and impact of CRNs on NEST evidence generation
- III. To discuss the CRN needs and opportunities to learn from each other
- IV. To present new tools to augment CRN capacity
- V. To promote international collaborations between CRNs via international registry consortia

TIME	TOPIC	PRESENTER
7:30am-8:00am	Registration	
8:00am-8:05am	Welcome and Goals of the Day	Art Sedrakyan (WCMC)
8:05am-8:20am	MDEpiNet: Building	Danica Marinac-Dabic (FDA)
8:20am-8:40am	Spotlight on the CRN Community of Practice	Art Sedrakyan (WCMC)
8:40am-9:20am	<ul style="list-style-type: none"> • CRN 1 – Vision • Responses • Discussion 	Moderator: TBD Phil Goodney (VQI) Responders: Ted Heise (Cook) Pablo Morales (FDA)
9:20am-10:00am	<ul style="list-style-type: none"> • CRN 2 – Orthopedic 	Moderator: Stephen Weber (FDA) Liz Paxton (Kaiser)

	<ul style="list-style-type: none"> • Responses • Discussion 	Responders: Paul Voorhorst (J&J) Nate Glusenkamp (AAOS)
10:00am-10:10am	Coffee Break	
10:10am-10:50m	<ul style="list-style-type: none"> • CRN 3 – SPARED • Responses • Discussion 	Moderator: Ben Fisher (FDA) Michael Gorin (Johns Hopkins) Responders: Charles Viviano (FDA) Fernando Bianco
10:50am-11:30am	<ul style="list-style-type: none"> • CRN 4 – NBIR • Responses • Discussion 	Moderator: Sung Yoon (FDA) Andrea Pusic (Harvard) Responders: Jesse Berlin (J&J) Ingrid Hopper (ICOBRA)
11:30am-12:10pm	<ul style="list-style-type: none"> • CRN 5 – Women’s Health • Responses • Discussion 	Moderator: TBD Danica Marinac-Dabic (FDA) Panel: Colleen Skau (AUGS) Beth Hodshon Terrie Reed (FDA) Kim Rodriguez (Acessa)
12:10pm-1:25pm	Lunch Break – Speaker from CMS to discuss MIPS/MACRA	Sophia Sugumar
1:25pm-2:40pm (Parallel Session 1)	Breakout Sessions on data quality & reporting: context is CMS MIPS, QCDR and responsiveness to other stakeholders: Session 1) Quality Improvement/Beneficial Change <ol style="list-style-type: none"> a. Value of routine feedback b. Outlier assessment of devices and providers 	Moderator: Kristi Mitchell (Avalere) Panel: Kathy Blake (AMA) Jack Cronenwett (VQI) Phil Goodney (VQI) Ralph Brindis (ACC) Nate Glusenkamp (AAOS)

1:25pm-2:40pm (Parallel Session 2)	Session 2) Data Quality and Longitudinal Outcomes <ul style="list-style-type: none"> a. Representativeness, consecutive enrollment, and completeness of data. b. Data linkages c. Automated surveillance d. Data quality and advancing data linkages 	Moderator: Nilsa Loyo-Berrios (FDA) Presenters: <ul style="list-style-type: none"> a. Jialin Mao (WCMC) b. Fred Resnic (Lahey) c. Ted Lystig (Medtronic) d. Christina Mack (IQVIA)
2:40pm-2:50pm	Coffee Break/Change Rooms	
2:50pm-3:30pm	Augmenting Capacities and Collaborations across CRNs <ul style="list-style-type: none"> • Patient Generated Data: • UDI and Supplemental UDI • Data Automation 	Moderators: Danica Marinac-Dabic (FDA) Debi Willis (Patient Link) Terrie Reed (FDA) and Liz Paxton (Kaiser) James Tcheng (Duke) and Jack Cronenwett (M2S/Medstreaming)
3:30pm-4:30pm	Panel Discussions for CRNs Making Progress: <ul style="list-style-type: none"> • Robotic CRN • DAISI Neuro CRN • GI CRN • VANGUARD CRN • Cardiac CRN 	Moderators: Owen Faris (FDA) and Danica Marinac-Dabic Jeff Levy (Robotic) David Liebeskind, Sameer Ansari, Adnan Siddiqui (DAISI) Cynthia Long (FDA- GI) Kevin Baskin (VANGUARD) John Laschinger, Ralph Brindis (Cardiac)
4:30pm-5:15pm	International Opportunities to Leverage CRNs: <ul style="list-style-type: none"> • ICVR • Health Canada • Update from IMDRF 	Moderator: Art Sedrakyan (WCMC) Jack Cronenwett (ICVR) Harindra Wijeyesundera (Health Canada) Danica Marinac-Dabic (FDA)
5:15pm-5:30	Day 1 Concluding Remarks	Art Sedrakyan (WCMC)

DAY 2: Wednesday, October 24,**Overall Theme: National Evaluation System for health Technologies (NEST) Coordinating Center Programs Leadership Exchange Forum****Objectives:**

- I. To bring together the leadership community engaged with NESTcc Programs
- II. To promote familiarity with the directions, resources and challenges facing NEST
- III. To provide dialogue and opportunity to promote collaborative and strategic efficiencies through lessons learned or more direct interactions between and across NESTcc Programs on behalf of NEST as a transformational public health initiative
- IV. To summarize specific areas in which MDEpiNet could best support NESTcc

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

11:45am-12:45pm	Working Lunch: Roundtable with the NESTcc Data Quality and Methods Subcommittee Chairs	Presenters: 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: <ol style="list-style-type: none"> 1. HealthCore 2. OneFlorida 3. MDEpiNet 	Charles Bailey (PEDSnet) Kevin Haynes (HealthCore) Art Sedrakyan (MDEpiNet) Betsy Shenkman (OneFlorida)
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 Discussion with test-case stakeholders: <ol style="list-style-type: none"> 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 	Kristina Finney (AJRR) Paul Coplan (J&J) Lesley Curtis (Duke) Joe Drozda (Mercy)
3:15pm-4:15	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	Summary Visions, Next Steps and Adjournment Objectives: <ol style="list-style-type: none"> a. <i>Highlight key messages from the day</i> b. <i>Consider value of future cross-talk and collaboration opportunities across Demonstration Project, Network Collaborators, Test-Cases and Methods and Data Quality Subcommittees</i> c. <i>Envision focused areas of growth, expansion of the NESTcc community of operations</i> 	Closing Comments: Owen Faris (FDA) Rachael Fleurence (MDIC/NESTcc)