

10th MDEpiNet Annual Meeting

Addressing Challenges in National and Global Health Technology Research and Surveillance

October 22-23, 2019

FDA Headquarters, Silver Spring, MD

Building 31, Great Room

MEETING CHAIRS



Art Sedrakyan, MD, PhD

Professor at Weill Cornell Medical College
Director - Medical Device Epidemiology (MDEpiNet) Coordinating,
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Danica Marinac-Dabic, MD, PhD, MMSc, FISPE

Associate Director, Office of Clinical Evidence and Analysis
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Administration

Meeting Agenda

TIME	TOPIC	PRESENTER
7:30am-7:55am	Registration	
7:55am-8:10am	MDEpiNet: A Pioneering Decade in Review	Danica Marinac-Dabic (FDA/CDRH)
8:10am-9:10am	Session I: Real World Evidence (RWE) and Evidence-Based Decision Making	
8:10am-8:25am	Total Product Life-Cycle Approach: Regulatory Grade Evidence for Decision Making	TBD
8:25am-8:40am	MDEpiNet as a NEST Data Partner: Needs and Opportunities	Rachael Fleurence (NEST)
8:40am-8:55am	Building Global Communities and Research Networks in Surgery, Interventions & Technologies	Art Sedrakyan (WCM)
	Moderators: Danica Marinac-Dabic (FDA) and Scott Smith (ASPE)	
8:55am-9:10am	Q&A	
9:10am-10:25am	Session II: CRNs: Advancing the Research and Surveillance: Lessons learned from Women's Health and Abdominal Core CRNs	
9:10am-9:25am	CRN Data Model and Engaging patients using apps (<i>NEST test case</i>)	Charles Rardin (Brown)
9:25am-9:40am	Summary of CRN-claims Domain and Plans for Future Research	Bilal Chughtai (WCM)
9:40am-9:55am	Hernia Repairs: Making Progress with CRN	Benjamin Poulouse (OSU)
9:55am-10:25am	Moderated Discussion with Presenters and Participants	Moderator: Ben Fisher (FDA/CDRH) and Art Sedrakyan (WCM)
		Panel: Patient (TBD), Industry (TBD), Sharon-Lise Normand (Harvard), George

Gibeily (FDA/CDRH),
Presenters

10:25am-10:35am	Coffee Break	
10:35am-12:05pm	Session III: CRNs: Role in Vascular Device Research	
10:35am-10:50am	VISION CRN: Testing a Mature Infrastructure to Assess Long-Term Outcome Studies of EVAR devices (<i>NEST test case and demonstration project</i>)	Phil Goodney (Dartmouth)
10:50am-11:05am	ICVR Registry Studies and ruptured AAA: Testing International Collaboration to Support Regulatory Decision-Making	Adam Beck (UAB)
11:05am-11:20am	CRN- based Evaluation for Research and Surveillance Projects: A case of RAPID/SPEED OPC development (<i>NEST demonstration project</i>)	Danny Bertges (UVM)
11:20am-11:35am	MDEpiNet in Europe: Summary of EVAR and PVI Studies Using Claims Data	Christian Behrendt (EU MDEpiNet Chapter, Hamburg-UKE)
11:35am-12:05pm	Moderated Discussion with Presenters and Participants	Moderator: Jack Cronenwett (Dartmouth) and Pablo Morales (FDA/CDRH)
		Panel: Misti Malone (FDA/CDRH), Aaron Lottes (Cook), Marc Shermerhorn (Harvard), Presenters
12:05pm-12:40pm	Lunch Break and Networking Elective topic: Value of Partnerships and Teaming; Angela Brown (Empowering Actions) and Greg Pappas (CBER)	
12:40pm-1:50pm	Session IV: CRN in Orthopedics: Progress and New Opportunities	
12:40pm-1:00pm	Using the OrthoCRN to Study Device Performance in Joint Replacement Devices (<i>NEST test case</i>)	Art Sedrakyan (WCM) and Liz Paxton (Kaiser)
1:00pm-1:10pm	Emerging Needs in Spine Devices: Evidence Gaps and Performance Evaluation	Vince Devlin (FDA/CDRH)

1:10pm-1:20pm	Shoulder Devices: Early Successes and Opportunities	Stephen Weber(FDA/CDRH)
1:20pm-1:50pm	Moderated Panel Discussion	Moderator: Raquel Peat (FDA/CDRH) Panel: Paul Voorhorst (J&J), Hong Cheng (FDA/CDRH), Ben Nowell (Creaky Joints), Presenters
1:50pm-3:20pm	Session V: Approaches to CRN Maturity: Examples from Multiple CRNs	
1:50pm-2:05pm	PCORTF Efforts to Advance CRNs maturity	Danica Marinac-Dabic (FDA/CDRH) and Stephanie Garcia (ONC)
2:05pm-2:20pm	Devices in Stroke: Advancing Evidence and Decision Making for Neurothrombectomy Devices in DAISI	David Liebeskind (UCLA), and Adnan Siddiqui (Buffalo)
2:20pm-2:35pm	SPARED Prostate: Evaluating Safety and Efficacy of Cancer Ablation Devices	Jim Hu (WCM)
2:35pm-2:50pm	Breast Implants: NBIR Approach to Registry	Andrea Pusic (Harvard)
2:50pm-3:20pm	Moderated Discussion with Presenters and Participants	Moderator: Carlos Pena (FDA/CDRH) Panel: Sung Yoon (FDA/CDRH), JoAnn Kuhne (Sientra), Industry (TBD), Presenters
3:20pm-3:30pm	Coffee Break	
3:30pm-4:45pm	Session VI: CRNs for complex, cross-disciplinary devices	
3:30pm-3:45pm	Benefits for Manufacturers in Using Registry Approach	Mark Slack (CMR Surgical)
3:45pm-4:00pm	Robotic devices registry (RASD)	Martin Martino (LVHN) Jeff Levy (Case Network)
4:00pm-4:15pm	VANGUARD and ESRD CRNs	Kevin Baskin (VANGUARD) Murray Sheldon (FDA/CDRH)

4:15pm-4:45pm

Moderated Discussion with Presenters and Participants

Moderators: Dorian Korz (FDA/CDRH) and Art Sedrakyan (WCM)

Panel: Joe Drozda (Mercy), Jesse Berlin (J&J), Kazuhiro Sase (Juntendo, Japan)/ Hiroshi Otsu (NCGM, Japan), Jack Cronenwett (Dartmouth), Presenters

4:45pm-5:00pm

Day 1 Concluding Remarks

Art Sedrakyan (WCM)

6:00 – Reception /Silver Spring

DAY 2

October 23

TIME	TOPIC	PRESENTER
7:30am-8:00am	Registration	
8:00am-8:10am	Welcome and Goals for the Day	
8:10am-9:40am	Session I: Partnership Spotlight: NEST and MDEpiNet in 2020 and Beyond	
	Rachael Rath/Robbert Zusterzeel (MDIC/NESTcc)	
9:10am-9:40am	Panel: Discussion - Q&A Moderator: Owen Faris	
9:40am-9:50am	Coffee Break	
9:50am-11:25am	Session II: Tailoring Methods to Data Infrastructure	
9:50am-10:05am	Artificial Intelligence: Big Data Approaches to Medical Device Research	Louisa Jorm (UNSW) AUS MDEpiNet Chapter

10:05am-10:20am	Leveraging EHRs for Health System Based Research and Surveillance: VA experience	Michael Matheny (Vanderbilt)
10:20am-10:35am	Digital Health Needs and Opportunities for Methods Development	Marisa Cruz (FDA/CDRH)
10:35am-10:50am	Automated Surveillance: Successes and Vision for the Future	Fred Resnic (Lahey)
10:50am-11:05am	Methodology/Infrastructure alignment	Ted Lystig (Medtronic)
11:05am-11:25am	<p>Discussion</p> <p>Moderator: Christina Mack (IQVIA) and Kristi Mitchell (Avalere)</p> <p>Panel: Vahan Simonyan, Julia Skapik (Cognitive Science), Industry (TBD), Jimmy Tcheng (Duke)</p>	
11:25am-12:00pm	Lunch Break	
12:00pm-1:50pm	Session III: Patient Science and Engagement Efforts	
12:00pm-12:15pm	CDRH Successes with Patient Reported Outcomes	TBD (FDA/CDRH)
12:15pm-12:30pm	TMJ Patient-Led Roundtable	Terrie Cowley (TMJA)
12:30pm-12:45pm	Centered on the Patient: Lessons on Direct Patient Outreach	Christina Mack (IQVIA)
12:45pm-1:00pm	My Studies App	TBD (FDA/CDER)
1:00pm-1:15pm	HUGO effort (NEST test case and demonstration project)	Joe Ross (Yale) or Sanket Dhruva (UCSF)
1:15pm-1:30pm	HEROs national infrastructure	Jody Akin (Hawthorne Effect Inc.)
1:30pm-1:50pm	<p>Discussion</p> <p>Moderator: C. Daniel Mullins, University of Maryland</p> <p>Panel: Elise Berliner (AHRQ), Debi Willis (MyLinks), Presenters</p>	
1:50pm-2:00pm	Coffee Break	
2:00pm-3:45pm	Session IV - Expanding and Advancing Our Methods and Infrastructure	

2:00pm-2:15pm	National All Payers Data Base	Scott Smith (ASPE)
2:15pm-2:30pm	Bridging the Sentinel infrastructure	TBD (FDA/CDER)
2:30pm-2:45pm	What can MedSun Bring to the Table?	TBD (FDA/CDRH)
2:45pm-3:00pm	Cloud Computing: Lessons Learned and Points to Consider	Michaela Iorga (NIST)
3:00pm-3:15pm	Global UDI Implementation	Terrie Reed (FDA/CDRH)
3:15pm-3:45pm	<p>Discussion Moderator: Art Sedrakyan(WCM) and Helen Burstin (CMMS) Panel: Joe Drozda (Mercy), Ralph Brindis (ACC), Yelena Yesha (University of Maryland), Industry (TBD)</p>	

3:45pm–4:00pm Day 2 Concluding Remarks and Next Steps

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