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 Network (MDEpiNet)
Coordinating, Science and Infrastructure Center

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Associate Director, Office of Clinical Evidence and Analysis
Center for Devices and Radiological Health, U.S. Food & Drug
Administration

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Day 1 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	International Collaborations and Partnerships in Regulatory Setting: MHRA Perspective	June Raine, *MHRA*
8:25am-8:40am	MDEpiNet as a NEST Data Partner: Needs and Opportunities	Rachael Fleurence, *NESTcc*
8:40am-8:55am	Building Global Communities and Research Networks in Surgery, Interventions & Technologies	Art Sedrakyan, *WCM*
8:55am-9:10am	*Moderated Q&A* *Moderators*: Danica Marinac-Dabic, *FDA/CDRH* Scott Smith, *HHS/ASPE*	
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 Stakeholders	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 Poulose, *OSU*
9:55am-10:25am	*Moderated Discussion with Presenters and Participants* *Moderators:* Terri Cornelison, *FDA* Art Sedrakyan, *WCM* *Panel:* Diana Zuckerman, *NCRH* Maria Bragg, *Medtronic* Sharon-Lise Normand, *Harvard* George Gibeily, *FDA/CDRH* *All Presenters*	
10:25am-10:30am	**Break**	
10:30am-11:15am	**Session III: CRNs: National Efforts in Vascular Device Research**	
10:30am-10:45am	VISION CRN: Testing a Mature Infrastructure to Assess Long-Term Outcome Studies of EVAR	Phil Goodney, *Dartmouth*

	Devices (*NEST test case and demonstration project*)	
10:45am-11:00am	CRN-based Evaluation for Research and Surveillance Projects: A case of RAPID/SPEED OPC development (*NEST demonstration project*)	Danny Bertges, *UVM*
11:00am-11:15am	*Moderated Discussion with Presenters and Participants* *Moderators:* Jack Cronenwett, *Dartmouth* Pablo Morales, *FDA/CDRH* *Panel:* Misti Malone, *FDA/CDRH* *All Presenters*	
11:15am-11:35am	**Session IV: Fireside Chat with Amy Abernethy**	**Amy Abernethy, *FDA***
11:35am-12:20pm	**Session V: CRNs: International Efforts in Vascular Device Research**	
11:35am-11:50am	ICVR Registry Studies and ruptured AAA: Testing International Collaboration to Support Regulatory Decision-Making	Adam Beck, *UAB*
11:50am-12:05pm	MDEpiNet in Europe: Summary of EVAR and PVI Studies Using Claims Data	Christian Behrendt, *EU MDEpiNet Chapter, Hamburg-UKE*
12:05pm-12:20pm	*Moderated Discussion with Presenters and Participants* *Moderators***:** Jack Cronenwett, *Dartmouth* Pablo Morales, *FDA/CDRH* *Panel:* Aaron Lottes, *Cook* Marc Schermerhorn, *Harvard* *All Presenters*	
12:20pm-1:00pm	**Lunch Break and Networking** Elective topic: Value of Partnerships and Teaming	Angela Brown, *Empowering Actions*
1:00pm-2:00pm	**Session VI: CRN in Orthopedics: Progress and New Opportunities**	
1:00pm-1:15pm	Using the OrthoCRN to Study Device Performance in Joint Replacement Devices (*NEST test case*)	Art Sedrakyan, *WCM* Liz Paxton, *Kaiser*
1:15pm-1:25pm	Emerging Needs in Spine Devices: Evidence Gaps and Performance Evaluation	Vince Devlin, *FDA/CDRH*
1:25pm-1:35pm	Shoulder Devices: Early Successes and Opportunities	Stephen Weber, *FDA/CDRH*
1:35pm-2:00pm	*Moderated Discussion with Presenters and Participants* *Moderator:* Stephen Weber, *FDA/CDRH* *Panel:* Paul Voorhorst, *J&J* Hong Cheng, *FDA/CDRH* W. Benjamin Nowell, *Creaky Joints* *All Presenters*	
2:00pm-3:30pm	**Session VII: Approaches to CRN Maturity: Examples from Multiple CRNs**	
2:00pm-2:15pm	SPARED Prostate: Evaluating Safety and Efficacy of Cancer Ablation Devices	Jim Hu, *WCM*
2:15pm-2:30pm	Devices in Stroke: Advancing Evidence and Decision Making for Neurothrombectomy Devices in DAISI	David Liebeskind, *UCLA*

2:30pm-2:45pm	Breast Implants: NBIR Approach to Registry	Danica Marinac-Dabic, *FDA/CDRH* on behalf of Andrea Pusic, *Harvard*
2:45pm-3:00pm	PCORTF Efforts to Advance CRNs maturity	Danica Marinac-Dabic, *FDA/CDRH* Stephanie Garcia, *ONC*
3:00pm-3:30pm	*Moderated Discussion with Presenters and Participants* *Moderators:* Charles Viviano, *FDA/CDRH* *Panel:*　　Sung Yoon, *FDA/CDRH* 　　　　　JoAnn Kuhne, *Sientra* 　　　　　*All Presenters*	
3:30pm-3:40pm	**Break**	
3:40pm-5:00pm	**Session VIII: CRNs for complex, cross-disciplinary devices**	
3:40pm-3:50pm	Robotic Devices Registry (RASD)	Martin Martino, *LVHN* Jeff Levy, *Case Network*
3:50pm-4:00pm	VANGUARD CRN	Kevin Baskin, *VANGUARD*
4:00pm-4:10pm	ESRD CRN	Murray Sheldon, *FDA/CDRH*
4:10pm-4:20pm	Benefits for Manufacturers in Using Registry Approach	Richard Kuntz, *Medtronic*
4:20pm-5:00pm	*Moderated Discussion with Presenters and Participants* *Moderators:* Dorian Korz, *FDA/CDRH* 　　　　　Art Sedrakyan, *WCM* *Panel:*　　Joe Drozda, *Mercy* 　　　　　Jesse Berlin, *J&J* 　　　　　Kazuhiro Sase, *Juntendo, Japan* 　　　　　Hiroshi Ohtsu, *NCGM, Japan* 　　　　　Jack Cronenwett, *Dartmouth* 　　　　　*All Presenters*	
5:00pm–5:15pm	**Day 1 Concluding Remarks**	**Art Sedrakyan,** *WCM*
6:00pm	**Reception at All Set Restaurant (Silver Spring, MD)** *co-sponsored by MDEpiNet and the Institute for Surgical Excellence*	

10th MDEpiNet Annual Meeting

Day 2 Agenda

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**	
8:10am-8:20am	An Update on NEST: From Real-World Data to Real-World Evidence	Robbert Zusterzeel, *NESTcc*
8:20am-8:30am	NEST-Funded MDEpiNet Test-Cases	Art Sedrakyan, *WCM*
8:30am-8:40am	Assessing Dataset Fitness with the NEST Data Quality Framework	Keith Marsolo, *Duke*
8:40am-8:50am	Use of Healthcare Databases for Medical Device Assessment: J&J's Experience with Databases and NEST Test-Cases	Jesse Berlin, *J&J*
8:50am-9:00am	Using Real-World Data to Study Medical Devices: An Abbott Perspective	Julie Prillinger, *Abbott*
9:00am-9:40am	***Panel Discussion and Q&A*** ***Moderator:*** Owen Faris, *FDA/CDRH*	
9:40am-9:50am	**Break**	
9:50am-11:30am	**Session II: Tailoring Methods to Data Infrastructure**	
9:50am-10:05am	CRNs in Australia: 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	Bakul Patel, *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-11:30am	***Moderated Discussion with Presenters and Participants*** ***Moderator:*** Christina Mack, *IQVIA* Kristi Mitchell, *Avalere* ***Panel***: Vahan Simonyan, *WHISE/Emblema* Julia Skapik, *Cognitive Science* Jesse Berlin, *J&J* Jimmy Tcheng, *Duke* *All Presenters*	

11:30am-12:10pm	Lunch Break	
12:10pm-1:45pm	**Session III: Patient Science and Engagement Efforts**	
12:10pm-12:25pm	Rapid-Cycle and Real-time Data to Inform Patients Choices	Fadia Shaya, *ICTR, University of Maryland*
12:25pm-12:40pm	TMJ Patient-Led Roundtable	Terrie Cowley, *TMJA*
12:40pm-12:55pm	Centered on the Patient: Lessons on Direct Patient Outreach	Christina Mack, *IQVIA*
12:55pm-1:10pm	HUGO effort (*NEST test case and demonstration project*)	Joseph Ross, *Yale*
1:10pm-1:25pm	HEROs national infrastructure	Jodi Akin, *Hawthorne*

1:25pm-1:45pm	*Moderated Discussion with Presenters and Participants*
	Moderator: C. Daniel Mullins, *University of Maryland*
	Panel: Elise Berliner, *AHRQ*
	              Debi Willis, *MyLinks*
	              All Presenters	

1:45pm-1:55pm	**Break**	
1:55pm-4:20pm	**Session IV - Expanding and Advancing Our Methods and Infrastructure**	
1:55pm-2:05pm	Accelerating Clinical Innovation	Benjamin Eloff, *HHS*
2:05pm-2:15pm	Bridging the Sentinel infrastructure	Sarah Dutcher, *FDA/CDER*
2:15pm-2:25pm	Building Linkages Capabilities with PCORNet	Thomas Carton, *LPHI*
2:25pm-2:35pm	Artificial Intelligence: VA Perspective	Gil Alterovitz, *VA*

2:35pm-3:00pm	*Moderated Discussion with Presenters and Participants*
	Moderators: Danica Marinac-Dabic, *FDA/CDRH*
	                 Helen Burstin, *CMSS*
	Panel: Joe Drozda, *Mercy*
	                 Ralph Brindis, *ACC*
	                 All Presenters	

3:00pm-3:05pm	**Break**	
3:05pm-3:15pm	More on Value of CRN	Greg Pappas, *FDA/CBER*
3:15pm-3:25pm	What can MedSun Bring to the Table	Julie Morabito, *FDA/CDRH*
3:25pm-3:35pm	Advancing Diagnostic Interoperability to Enable Clinical Decision Support: SHIELD Initiative	Michael Waters, *FDA/CDRH*
3:35pm-3:45pm	Cyber Bermuda Triangle: Privacy – Trust Security	Michaela Iorga, *NIST*
3:45pm-3:55pm	Registry Approach to Enhance Safety: Collaboration with MDEpiNet	Mark Slack, *CMR Surgical*

3:55pm-4:20pm	*Moderated Discussion with Presenters and Participants*
	Moderators: Art Sedrakyan, *WCM*
	                 Helen Burstin, *CMSS*
	Panel: Yelena Yesha, *University of Maryland*
	                 Mary Beth Ritchey, *RTI Health Solutions*
	                 Oki Mek, *HHS*
	                 All Presenters	

4:20pm-4:25pm	**Day 2 Concluding Remarks and Next Steps**	