



VIRTUAL SERIES

Starting:
November 16, 2020

11TH ANNUAL MEETING SERIES

**Session IV: Digital Health Solutions for MDEpiNet
Coordinated Registry Networks (CRNs).**

Monday, January 25, 2020

US Eastern Time	TOPIC	PRESENTER
2:00PM-5:00PM	Session: Digital Health Solutions for MDEpiNet CRNs Co-chairs: Danica Marinac-Dabic, <i>FDA/CDRH</i> Anindita Saha, <i>FDA/CDRH</i>	
2:00 - 2:05	Opening Remarks/Goals of the Day	Art Sedrakyan, <i>WCM</i>
2:05 – 2:35	Regulatory Context and PCOR Opportunities (10 minutes each) Digital Health: Regulatory Vision Regulatory Framework for Artificial Intelligence / Machine Learning based SaMD PCOR/CRN Context: Focus on Novel AI/ML Tools to advance CRN Maturity	Bakul Patel, <i>FDA/CDRH</i> Matthew Diamond, <i>FDA/CDRH</i> Danica Marinac-Dabic, <i>FDA/CDRH</i>
2:35 – 3:05	Advancing the CRNs with Digital Tools: Blockchain/Artificial Intelligence (BAIT) Taskforce and TMJ CRN Use Case (10 minutes each) Overview of BAIT: Overarching CRN Gaps and Digital Solutions Standing Up Patient Driven CRN Leveraging Blockchain/HIVE Integration: Focus on TMJ CRN Implementing the TMJ Core Minimum Data Set on Blockchain/HIVE Ledger	Vahan Simonyan, <i>MDEpiNet HIVE</i> Yelena Yesha, <i>U Miami</i> Martha Velezis, <i>FDA Contractor</i>
3:05- 3:30	Moderated Discussion with Panel: Lessons Learned and Integration with Other Data Sources Annie Saha, <i>FDA</i> Carolyn Rose, <i>Carnegie Mellon</i> Elise Berliner, <i>AHRQ</i> Fadia Shaya, <i>UMaryland</i> Gil Alterovitz, <i>VA</i> Terrie Cowley, <i>TMJA</i>	

3:30- 3:40	Short Break (10 minutes)	
3:40 – 4:30	Moving the Field Forward: BAIT Pilot Portfolio to Advance CRNs (10 minutes each) Pilot 1. Securing Medical Devices Pilot 2. Metadata Catalog Pilot 3. Use of AI to identify Device Safety Signals Pilot 4. Identifying Causal/Explanatory variables Pilot 5. Federated Analytics	Yelena Yesha, <i>UMiami</i> Michaela Iorga, <i>NIST</i> Charles Kaminski, <i>LexisNexis Risk Solutions</i> Pierre D’Haese, <i>Neurotargeting and Rockefeller Neurosciences Institute</i> Patrick Lilley, <i>Liquid Biosciences</i> Vasant Honavar, <i>PSU</i>
4:30- 5:00	Moderated Discussion with Panel: Pilots and Beyond Andrew Auerbach, <i>UCSF</i> Art Sedrakyan, <i>WCM</i> Eliot Seigel, <i>VA, U Maryland</i> James Tcheng, <i>Duke</i> Mark Dredze, <i>Johns Hopkins</i>	
5:15PM-6:15PM	Happy Hour: Hosted by MDEpiNet BAIT Task Force Guest Speaker: Jose Arrieta, <i>Johns Hopkins</i>	

**MDEpiNet Annual Meeting Objectives: To present frameworks and achievements of MDEpiNet’s partnerships and engage stakeholders in determining the value, needs, and future areas of focus for MDEpiNet to advance the discipline of medical device research and surveillance.*