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MDEpiNet Annual Meeting

Travelling through the NETs of the NEST: Toward Collective, Collaborative Intelligence via Continuum of Evidence Generation

October 19-20, 2017

White Oak Campus, Silver Spring, MD

Day One

THURSDAY, OCTOBER 19

7:30-8:00	Registration	Presenter/Affiliations
8:00-8:10	Welcome and the Key Objectives	Danica Marinac-Dabic, FDA
8:10-8:30	Opening Remarks	Harlan Krumholz, Yale
8:30-10:00	MDEpiNet Portfolio: It takes a village!	

Objectives:

- (1) Present a brief overview of MDEpiNet portfolio, accomplishments and capabilities
- (2) Discuss the impact and value proposition for patients, payers, health care professionals, industry and health systems

MDEpiNet: Portfolio Overview - Jesse Berlin, J&J

MDEpiNet: Accomplishments and Capabilities - Danica Marinac-Dabic, FDA

Moderator: Art Sedrakyan, WCM

Value Panel Discussion:

- Jyme Schafer, CMS
- Kathy Blake, AMA
- Theodore Lystig, Medtronic
- Scott Smith, ASPE
- Terrie Cowley, TMJA
- Rachael Fleurence, NESTcc
- Seth Bilazarian, Abiomed
- Jeff Dunkel, Titan Spine

10:00-10:15 Break

10:15-11:45 Unleashing the Power of Flexible TPLC Evaluation

Objectives:

- (1) Present the need for “rules of engagement” in the NEST system
- (2) Examine potential for TPLC decision-making using a variety of approaches

NEST Needs (Governance and the Rules of Engagement)
Learning Hub for Surveillance Development Efforts
Nesting Premarket Clinical Trials in Registries
The Promise of RWE: We are doing it!

Rachael Fleurence, *NESTcc*
Fred Resnic, *Lahey*
Mitch Krucoff, *Duke*
Gregory Pappas, *FDA*

Moderator: Sharon-Lise Normand, *Harvard*

Discussants: Joseph Ross, *Yale*
Owen Faris, *FDA*

11:45-12:00 Grab Lunch

12:00-12:10 Advancing TPLC Evidence Generation for Medical Devices Jeff Shuren, *FDA*

12:10-12:45 Discussion and Networking

12:50-1:50 Concurrent International Sessions : Sections B and C

Citizens of the World: Global Opportunities for Health Technology Evaluation

ROOM - Section B

Objective:

- (1) Discuss bridging the infrastructure and methodological gaps in international space as regulators, professional societies, registries, and other stakeholders increasingly open the door to the wealth of international data in support of the decision making.

Update from IMDRF

Melissa Torres, *FDA*

International Registry Consortia in the Vascular Space

Jack Cronenwett,
Dartmouth

New International Consortia and Efforts to Establish
ISODORA & Journal for Surgery & Devices

Art Sedrakyan, *WCM*

ISPOR International Initiatives on the Assessment of the
Values of Medical Technologies

Lou Garrison, *ISPOR*

Healthcare Data Exchange Framework: Scalable Economy
of Secure Information and Services

Vahan Simonyan, *FDA*

Moderator: Danica Marinac-Dabic, *FDA*

Discussant: Kathleen Lyons, *BMJ*
Hiroshi Ohtsu, *Japan*

Capitalizing on International Partnerships: Expanding Infrastructure Opportunities

Room - Section C

Objective:

- (1) Discuss potentials of data solutions in international space.

How to Build on International Convergence Efforts: The
Processes and Beyond

Peter G. Goldschmidt,
World Development Group

Lessons Learned from Harmonization by Doing (HBD) and
international collaboration

Kazuhiro Sase, *Japan*

Big Data Application for Devices in Australia

Louisa Jorm, *UNSW,*

Can We Better Leverage HTAi?

Australia

Sean Tunis, *HTAi*

Moderator: Ben Eloff, *FDA*

Discussant: Jing Xie, *Medtronic*

2:00-3:00 Nodes in the Network: Can the Learning Health Care System Find More Synergies?

2:00-2:30 The Power of the Ecosystem

Robert Califf,
Duke/Verily Life Sciences

Objective:

- (1) To bring together major programs using and promoting the real- world evidence in healthcare to discuss current and future synergies between the programs

2:30-3:00 Synergies Panel Discussion

Sentinel

Richard Platt,
Harvard Pilgrim

NIH Collaboratory

Cathy Meyers, *NIH*

NEST

Rachael Fleurence, *NESTcc*

PCORnet / OHDSI,

Michael Matheny,
Vanderbilt and VA

MDEpiNet

Art Sedrakyan, *WCM*

Moderator: Kathy Blake, *AMA*

3:00-3:15 Break

3:15-4:45 Concurrent Sessions – Sections B and C

Demonstration of Innovative Approaches for Using Real - World Evidence for Device Evaluation

ROOM - Section B

Objective:

- (1) Present innovative efforts to build CRN-like platforms for use of real-world evidence and approaches to architecture to support them. Specific focus will be on non-implantable categories of medical devices (laboratory tests, monitors, radiology) that exist in highly digitalized spaces than may be brought together into a platform which functions like a CRN

Pre-Vent: a Network of NICUs Bringing Together RWE Including Monitor Wave Forms

Randall Moorman,
UVA

A New Institute at the American College of Radiology

Keith Dreyer, *ACR*

Three Models for Use of RWE in the In Vitro Diagnostic Space

Mike Waters, *FDA*

CASAE: A Breakthrough Technology for Distributed Data System - providing a demo MITRE

Jay Schnitzer / Robyn Wade, *MITRE*

Moderator: Gregory Pappas, *FDA*

Discussants: Konstantinos Makrodimitris, *FDA*
Debbie Bucci, *ONC*,
Jonathan Reich, *FDA*

Learning Together and Learning from Each Other: Collaborative Efforts to Advance Evidence Generation

ROOM – Section C

Objective:

(1) Present novel collaborative efforts to advance collective learning from variety of available data

BioCompute Object

Dennis Dean, *Seven Bridges Genomics*

Raja Mazumder, *GW*

Medtronic/Mercy Collaborative

Joseph Drozda, *Mercy*

Harnessing the Intersection of Epidemiologic and Genetic Evidence

Lisa Torosyan, *FDA*

Beyond Traditional Data Sources for Devices

Christina Mack, *Quintiles*

WebShield and eP3 network

Jonathan Hare/Jack Lewin
WebShield

Moderator: Ram Tiwari, *FDA*

Discussants: Vahan Simonyan, *FDA*,
Julia Skapik, *Cognitive Medicine*

5:00-5:15 Day One Wrap Up:

Sharon-Lise Normand,
Harvard



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Day Two

FRIDAY, OCTOBER 20

8:00-8:30	Registration and Poster Walk	Presenter/Affiliations
8:30-11:45	Strategically Coordinated Registry Networks (CRNs) for Health Technologies: Tactical Look at the National Landscape	
8:30-10:00	CRNs - Part I	

Objectives:

- (1) To present current CRNs maturity models and
- (2) To engage the program leads to identify success stories, common themes, and lessons learned.

Ortho CRN – ICOR USA	Rebecca Love, <i>Kaiser</i>
VISION - Vascular CRN	Phil Goodney, <i>VQI</i>
SPARED (prostate ablation) CRN	Jim Hu, <i>Cornell</i> Ben Fisher, <i>FDA</i>
Robotic CRN	Jeff Levy, <i>CaseNetwork</i> Binita Ashar, <i>FDA</i>
Women’s Health	Danica Marinac-Dabic, <i>FDA</i> Julia Skapik, <i>Cognitive Medicine</i>
American Hernia Society Quality Collaborative	Benjamin Poulouse, <i>Vanderbilt</i>

Moderator: Art Sedrakyan, *WCM*

Discussant: Seth Blumenthal, *PCPI*

10:00-10:15	Break	
10:15-11:45	CRNs – Part II	
	CDCRN	Pablo Morales, <i>FDA</i>
	DAISI – Neuro CRN	Carlos Pena, <i>FDA</i> Murray Sheldon, <i>FDA</i>
	NBIR – Breast Implants CRN	Andrea Pusic, <i>MSKCC</i> JoAnn Kuhne, <i>Sientra</i>

CATNIP – GI CRN

Cynthia Long, *FDA*

TMJ CRN

Terrie Cowley, *TMJA*

Lisa Torosyan, *FDA*

VANGUARD

Kevin Baskin, *VANGUARD/SIR*

Greg Pappas, *FDA*

RAPID/EP PASSION

Pablo Morales, *FDA*

Daniel Canos, *CMS*

Moderator: Art Sedrakyan, *WCM*

Discussant: Kristi Mitchell, *Avalere*

11:45-12:00	CRNs and NEST	Rachael Fleurence, <i>NESTcc</i>
12:00-1:00	Lunch and CRN Teams Networking/CRN Gallery Walk	
1:00-1:10	Let's Get to Work! Instruction to the CRN Breakouts	Danica Marinac-Dabic, <i>FDA</i>
1:15-3:30	Breakout Working Sessions	

Breakout sessions will be held concurrently. Each group will address different aspects of CRN development. Each session will have a moderator to facilitate the work of the group and a scribe to report.

A. Data Definition, Data Capture, Quality Assurance and Adherence to Informatics Standards (including UDI) in CRN

Moderator: Jimmy Tcheng, *Duke*

Panel:

- Lisa Lang, *NLM*
- Mera Choi, *ONC*
- Kathleen Hewitt, *NCDR*
- Stan Huff, *Intermountain*
- Seth Blumenthal, *PCPI*
- Peter G. Goldschmidt, *World Development Group*
- Julia Skapik, *Cognitive Medicine*
- Joseph Drozda, *Mercy*
- Kevin Baskin, *VANGUARD/SIR*
- Rebecca Love, *Kaiser*
- Indira Konduri, *FDA*
- Behnaz Minaei, *FDA*
- Phil Goodney, *VQI*

ROOM - Section B

B. Patient Engagement, Protection, PROs, Data Privacy and Transparency in CRNs

Moderator: Cara Tenenbaum, *FDA*

Panel:

- Jodi Akin, *Hawthorne Effect*
- Anna McCollister-Slipp, *Galileo*
- Joel Gagnier, *U Michigan*
- Terrie Cowley, *TMJA*
- Industry (Large and Small)
- Katie O' Callaghan, *FDA*

ROOM – 1406

C. Governance of CRN and Relationship to NESTcc Governance

Moderator: Rachael Fleurence, *NESTcc*

Panel:

- Art Sedrakyan, *WCM*
- Kathy Blake, *AMA*
- Pablo Morales, *FDA*
- Gregory Pappas, *FDA*
- Industry (Large and Small)
- Danica Marinac-Dabic, *FDA*

ROOM - 1408

D. Methodologies (Design, Linkage, Integration of Imaging, Analytics) for CRN

Moderator: Sharon-Lise Normand, *Harvard*

Panel:

- Matt Brennan, *Duke*
- Guy Cafri, *Kaiser*
- Daniel Canos, *CMS*
- Asiyah Yu Lin, *FDA*
- Caryn Etkin, *AJRR*
- Lilly Yue, *FDA*
- David Liebeskind, *UCLA*
- Hiroshi Ohtsu, *Japan*
- Vivian Coates, *ECRI*
- Nilsa Loyo-Berrios, *FDA*
- Jialin Mao, *WCM*

ROOM – Section C

E. CRN Partnership Building and Sustainability

Moderator: Jesse Berlin, *J&J*

Panel:

- Elise Berliner, *AHRQ*,
- Jeff Dunkel, *Titan Spine*
- Ben Eloff, *FDA*
- Kathy Blake, *AMA*
- Murray Sheldon, *FDA*
- Phil Goodney, *VQI*
- JoAnn Kuhne, *Sientra*

ROOM - TBD

3:30-4:00 Reports from Breakout Scribes

4:00-4:15 Summary and Next steps

Art Sedrakyan, WCM