



## Vascular Implant Surveillance and Interventional Outcomes Network (VISION)

### 2020 VISION: What we've done, and what lies ahead

Wednesday, September 2, 2020

9:30am - 2:30pm ET

Zoom Meeting:

<https://weillcornell.zoom.us/j/98932134679>

#### Chairs:

Philip Goodney, *Dartmouth-Hitchcock* & Art Sedrakyan, *Weill Cornell Medical Center*

Time	Topic	Presenter
9:00-9:15	<b>Sign-On</b>	
9:30-11:30	<b>AM Session: VISION Impact, Value and Sustainability</b>	
9:30 – 10:15	<b>VISION Impact from the Past Year</b>	<b>Moderator</b>
	<i>Introduction and Goals (5 minutes)</i>	Philip Goodney, MD, MS <i>Dartmouth-Hitchcock (VQI)</i>
	<i>Gender Differences (8 minutes)</i>	<b>Speakers</b>
	<i>Commentary: Danica Marinac-Dabic, MD, PhD, MMSc, FISPE, FDA (4 minutes)</i>	Niveditta Ramkumar, PhD, MPH <i>Dartmouth-Hitchcock</i>
	<i>Long-Term Surveillance After EVAR (8 minutes)</i>	Jesse Columbo, MD, MS <i>Dartmouth-Hitchcock</i>
	<i>Commentary: Scott Williams, MS, RAC, Cook (4 minutes)</i>	
	<i>VQI Center Specific Survival Reintervention and Surveillance (SRS) Reports (8 minutes)</i>	Philip Goodney, MD, MS <i>Dartmouth-Hitchcock (VQI)</i>
	<i>Commentary: Jens Eldrup-Jorgensen, MD, FACS, Maine Health (4 minutes)</i>	
10:15-10:45	<b>VISION Project Summaries from Investigators with Ongoing Projects</b>	<b>Moderator</b>
	<i>Outcomes of Paciltaxel coated devices vs. non-drug coated devices (7 minutes)</i>	Philip Goodney, MD, MS <i>Dartmouth-Hitchcock (VQI)</i>
	<i>Commentary: Misti Malone, PhD, MS, FDA</i>	<b>Speakers</b>
	<i>EVAR conversion events (7 minutes)</i>	Daniel Bertges, MD <i>University of Vermont Medical Center</i>
	<i>Commentary: Brian Pullin, MS, FDA; Carmen Gacchina Johnson, PhD, FDA (3 minutes)</i>	Salvatore Scali, MD, FACS, DFSVS, RPVI <i>University of Florida, Gainesville</i>

Comparison of event calculation with and without claims-based follow-up (7 minutes)  
*Commentary:* Jacqueline Major, PhD, MS, FDA (3 minutes)

Livia de Guerre, MD  
*Beth Israel Deaconess*

10:45-11:30

**VISION Value-Driven Sustainability**  
*MDEpiNet Capabilities and Offerings (5 minute introduction by moderator)*

**Moderator**  
Art Sedrakyan, MD, PhD  
*Weill-Cornell Medicine*

- Disparities in diffusion of endovascular devices: Goodney/Arya (3 minute *Quickshot presentation*)
- Use of post-acute care and frailty: Arya/Goodney (3 minute *Quickshot presentation*)
- Outcomes of dialysis access procedures: Woo (3 minute *Quickshot presentation*)
- Using registry-claims linkages for randomized trial long-term follow up, including in VA populations: Farber (3 minute *Quickshot presentation*)
- NOSI-120, COVID-19 Testing: Scali (3 minute *Quickshot presentation*)

**Speakers**  
Philip Goodney, MD, MS  
*Dartmouth-Hitchcock (VQI)*

Shipra Arya, MD, SM, FACS  
*Stanford*

Karen Woo, MD  
*UCLA*

Alik Farber, MD  
*Boston Medical Center*

Salvatore Scali, MD, FACS, DFSVS, RPVI  
*University of Florida, Gainesville*

VISION and VQI: Potential Future Opportunities (5 minutes)  
*Commentary:* Gregory Pappas, MD, PhD, FDA

Jack Cronenwett, MD  
*Dartmouth Hitchcock (VQI)*

12:30-1:45

**PM Session: Afternoon Concurrent Breakout Sessions**

**Breakout 1:** Developing Technologic Solution and Future Directions for VISION

**Moderator**  
Danica Marinac-Dabic, MD, PhD, MMSc, FISPE  
*FDA*

*Commentary:*

- Integration with PROs: Tarver (10 minutes)
- Linkages to under-65 data: Columbo (10 minutes)
- NESTcc Partnerships: Siami (10 minutes)
- Potential for expansion to other medical products (e.g. biologics): Cronenwett (10 minutes)

**Commentary**  
Michelle Tarver, MD, PhD  
*FDA*

Jesse Columbo, MD, MS  
*Dartmouth-Hitchcock*

Sandi Siami, MPH  
*NESTcc*

Jack Cronenwett, MD  
*Dartmouth-Hitchcock (VQI)*

**Breakout 2: Operationalizing your Research Plan****Moderator**

Andrew Hoel, MD  
*Northwestern Medicine*

**Presentations**

- How do I work with VISION analytic team from start to finish: Moore/Mao (20 minutes)
- Prioritization of the research projects: Who goes first? Hoel (10 minutes)
- Prioritization of research projects: What is FDA's perspective on this? Gacchina Johnson (10 minutes)

**Speakers**

Kayla Moore, MPH  
*Dartmouth-Hitchcock*

Jialin Mao, MD, MS  
*Weill Cornell Medicine*

Andrew Hoel, MD  
*Northwestern*

Carmen Gacchina Johnson, PhD  
*FDA*

**Commentary and Q&A (20 minutes)****Breakout 3: Regulatory Science, Stakeholders, and Policy****Moderators**

Misti Malone, PhD, MS  
*FDA*

**Commentary:**

- How to Leverage VISION for Maximum Impact: Implications for Industry: Malas (10 minutes)
- What can Real World Evidence (RWE) be used for? Industry Perspective: Williams, Bloss, Scamperle, Simoes (10 minutes)
- Expansion of RAPID analyses using VISION data (device evaluation): Bertges (10 minutes)
- EDUCATE Summary: Goodney (10 minutes)

**Commentary**

Mahmoud Malas, MD, MS  
*UCSD*

Scott Williams, MS, RAC, *Cook*  
Roberta Bloss, *Gore*  
Tiessa Simoes, *Medtronic*  
Keely Scamperle, *Gore*

Daniel Bertges, MD  
*University of Vermont Medical Center*

Philip Goodney, MD, MS  
*Dartmouth-Hitchcock (VQI)*

**Discussion (20 minutes)****Breakout 4: VISION Next Steps for Priority Areas in Disparities and Expansion of Indications****Moderator**

Shipra Arya, MD, SM, FACS  
*Stanford*

**Commentary:**

- The role of gender in device use: Arya (10 minutes)
- Venous linkages and development: Osborne (10 minutes)

**Commentary**

Shipra Arya, MD, SM, FACS  
*Stanford*

Nicholas Osborne, MD, MS  
*University of Michigan*

- Veterans Affairs: opportunities for collaborations: Spangler, Mureebe (10 minutes)

Emily Spangler, MD  
*University of Alabama, Birmingham VA Medical Center*

Leila Mureebe, MD, MPH  
*Duke, Durham VA Medical Center*

- COVID collaboration: Wohlauer (10 minutes)

Max Wohlauer, MD,  
*University of Colorado*

*Discussion (20 minutes)*

2:00-2:30

**Report Back**

**Moderator**

Art Sedrakyan, MD, PhD  
*Weill-Cornell Medicine*

**Speakers**

- Breakout 1: Marinac-Dabic (5 minutes)

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE  
*FDA*

- Breakout 2: Hoel (5 minutes)

Andrew Hoel, MD  
*Northwestern Medicine*

- Breakout 3: Malone (5 minutes)

Misti Malone, PhD, MS  
*FDA*

- Breakout 4: Arya (5 minutes)

Shipra Arya, MD, SM, FACS  
*Stanford*

Summary and next steps: Goodney/Sedrakyan  
(10 minutes)

**Please Note: All of the above times are in Eastern Daylight Time (EDT)**