



**MDEpiNet: Registry Assessment of Peripheral Interventional Devices (RAPID)
Phase II / III Spring 2018 Working Group Meeting**

LOCATION: FDA HEADQUARTERS, WHITE OAK CAMPUS BUILDING 31, GREAT ROOM 10903 NEW HAMPSHIRE AVENUE SILVER SPRING, MD 20993		MEETING DATE/TIME: WEDNESDAY, MAY 2, 2018 07:00am-4:00pm EST
TIME	AGENDA ITEM	SPEAKER(S)
7:00am- 7:30am	Registration and Refreshments	
INTRODUCTORY SESSION		
7:30am-7:40am	Welcome and Introductions:	<i>Mitchell Krucoff, Duke University / MDEpiNet</i>
7:40am-7:50am	RAPID SPEED: An Overview	<i>Jack Cronenwett, Dartmouth-Hitchcock / Society for Vascular Surgery</i>
7:50am-8:00am	Objectives of the Day	<i>Pablo Morales, US Food and Drug Administration</i>
SPEED UPDATES		
<i>Moderators: Jack Cronenwett, Dartmouth-Hitchcock / Society for Vascular Surgery and Pablo Morales, US Food and Drug Administration</i>		
8:00am-8:10am	Executing SPEED: Key Logistics	<i>Jens Jorgensen, Society for Vascular Surgery Patient Safety Organization</i>
8:10am-8:20am	Clinical Variables Selected for Analysis	<i>Misti Malone, US Food and Drug Administration</i>
8:20am-8:30am	Statistical Analysis Plan	<i>Roseann White, Duke Clinical Research Institute Sharon-Lise Normand, Harvard</i>
8:30am-8:50am	The SPEED OPC Results: First Public Look	<i>Daniel Bertges, University of Vermont medical Center/Society for Vascular Surgery</i>
8:50am-9:30am	Open Discussion	<i>Schuyler Jones, Duke Clinical Research Institute Aaron Lottes, Cook Medical</i>
9:30am-9:45am	Break	
THE RAPID SPEED Program: Value to Industry		
<i>Moderators: Josh Smale, C.R. Bard and Jennifer Jones-McMeans, Abbott Vascular</i>		
9:45am-9:55am	RAPID SPEED Cost and Value to Industry: Key Features	<i>Robert Thatcher, 4C Medical Technologies</i>
9:55am-10:05am	Industry Leadership and Involvement: A Key to RAPID Success	<i>Melanie Raska, Boston Scientific</i>
10:05am-10:15am	Intellectual Involvement and Buy-in: From UDI to Biostats	<i>Ted Heise, Med Institute</i>
10:15am-10:45am	Open Discussion	<i>Justin Recknor, W.L. Gore Kenneth Cavanaugh, US Food and Drug Administration</i>



RAPID INFORMATICS		
10:45am-11:00am	Improving Access GUDID Data	<i>Terrie Reed, US Food and Drug Administration</i>
11:00am-11:15am	Supplemental UDI data for RAPID	<i>Joseph Drozda, Mercy Health System</i>
11:15am-11:30am	Generic core data elements for RAPID	<i>James Tcheng, Duke University</i>
11:30am-11:45	Open Discussion	
WORKING LUNCH: BREAKOUT GROUPS		
11:45-12:00pm	Get Lunch and sit with work group	
12:00pm-1:00pm	Protocol and Stats	<i>Daniel Bertges, University of Vermont Medical Center / Society for Vascular Surgery</i> <i>Jack Cronenwett, Dartmouth-Hitchcock / Society for Vascular Surgery</i> <i>Roseann White, Duke Clinical Research Institute</i>
	GUDID and Informatics	<i>Joseph Drozda, Mercy Health System</i> <i>Ted Heise, Med Institute</i> <i>Terrie Reed, US Food and Drug Administration</i> <i>James Tcheng, Duke University</i>
	Governance and Outreach/Visibility	<i>Ralph Brindis, American College of Cardiology</i> <i>Brian Fortier, Aorta Medical</i> <i>Jens Jorgensen, Society for Vascular Surgery Patient Safety Organization</i>
1:10pm-1:10pm	BREAK	
REPORTS FROM BREAKOUT GROUPS		
1:10pm-1:30pm	Reports from Breakout Groups	<i>Working Group Leads</i>
DEFINING RAPID Partnerships		
<i>Moderators: Joeseeph Drozda, Mercy Health System and Danica Marinac-Dabic, US Food and Drug Administration</i>		
1:30pm-1:40pm	NEST Coordinating Center Demonstration Project Status for RAPID: What does it mean?	<i>Rachael Fleurence, National Medical Device Evaluation System Coordinating Center</i>
1:40pm-1:50pm	Relevance to RAPID	<i>Julia Skapik, Cognitive Medical Systems, Inc</i>
1:50pm-2:00pm	ROI-Value Proposition for Registry Partners	<i>Gregory Pappas, US Food and Drug Administration</i>
2:00pm-2:15pm	Open Discussion	
2:15pm-2:30pm	BREAK	



RAPID Beyond SPEED: NEXT STEPS

Moderators: Mitchell Krucoff, Duke University and Kenneth Cavanaugh, US Food and Drug Administration

2:30pm-2:40pm	Adding Data Sources	<i>Schuyler Jones, Duke Clinical Research Institute</i>
2:40pm-2:50pm	Alignment with (VISION) Vascular Implants and Surveillance Outcomes Network Initiative: Linking to CMS Claims	<i>Art Sedrakyan, Weill-Cornell University</i>
2:50pm-3:00pm	OPCs Beyond SPEED: New patient, anatomic indications	<i>Pablo Morales, US Food and Drug Administration</i>
3:00pm-3:45pm	Brainstorming: Selection of next RAPID project	<i>Jack Cronenwett, Dartmouth-Hitchcock / Society for Vascular Surgery</i> <i>Pablo Morales, US Food and Drug Administration</i> <i>Robert Thatcher, 4C Medical Technologies</i>
3:45pm-4:00pm	Closing Remarks	

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