

**Orthopedic Strategically Coordinated Registry Network
(ORTHO-CRN) Annual Meeting
November 9, 2018
The Great Room, White Oak Campus, Silver Spring, MD
Draft Agenda**

OBJECTIVES: To advance strategic and tactical dialogue between the stakeholders regarding the Orthopedic Coordinated Registry Network (Ortho-CRN). This meeting will serve as a major planning step to advance our proposal of capitalizing on a partnership within the FDA and the Coordinated Registry Network for orthopedic medical devices. Through this meeting, we will provide an update on potential benefits, international registries, impact and interactions of key stakeholders and future initiatives.		
TIME	TOPIC	PRESENTER/PANELIST
7:30-8:00	Registration	
8:00-8:10	Welcome and Introductions	Danica Marinac-Dabic, MD, PhD, FDA CAPT Raquel Peat, PhD, MPH, FDA
8:10-9:25	Session 1: Defining the Relevance to Unleash the Power of CRNs	Moderators: Danica Marinac-Dabic, MD, PhD, FDA CAPT Raquel Peat, PhD, MPH, FDA
8:10-8:25	CRN Community of Practice and its capacity to help in a broader orthopedic space	Art Sedrakyan, MD, PhD, WCM
8:25-8:40	Ortho CRN infrastructure: collective and individual capabilities	Liz Paxton, MA, Kaiser
8:40-8:55	Building the patient engagement capacity for Ortho CRN	Patricia Franklin, MD, MBA, UMass
8:55-9:10	ROI Lessons learned from other registries	Gregory Pappas, MD, PhD, FDA
9:10-9:25	Q/A Discussions	
9:25-10:15	Session 2: Selected International Efforts in Orthopedics	Moderators: Stephen Weber, MD, FDA Art Sedrakyan, MD, PhD, WCM
9:25-9:35	From Conceptual Framework to Reality: International Registry Consortia and IMDRF patient registry efforts	Danica Marinac-Dabic, MD, PhD, FDA
9:35-9:45	AOANJRR	Stephen Graves, MD, D.Phil, Australian Joint Replacement Registry
9:45-9:55	Global UDI	Terrie Reed, MSc., FDA
9:55-10:05	International Consortium of Orthopedic Registries (ICOR)	Liz Paxton, MA, Kaiser
10:05-10:15	International efforts in other orthopedic areas	Ronald Navarro, MD, Kaiser
10:15-10:25	Coffee/Tea Break	
10:25-11:45	Session 3: TPLC opportunities for Ortho – CRN (early and long-term initiatives)	Moderators: Jeff Dunkel, Titan Spine Mark Melkerson, MS, FDA
10:25-10:40	Regulatory opportunities	CAPT Raquel Peat, PhD, MPH, FDA
10:40-11:00	NESTcc projects AJRR Linkage projects	Art Sedrakyan, MD, PhD, WCM Jialin Mao, MD, WCM
11:00-11:15	AAOS Registry Transformation	Kristina Finney, AAOS
11:15-11:30	Industry efforts	Paul Voorhorst, MS, MBA, J&J
11:30-11:45	Q/A Discussions	

11:45- 1:20	Grab Lunch and Return to Working Lunch Session 4: Designing next Phase Together	Moderator: Stephen Weber, MD, FDA Tara Federici, AdvaMed
12:00-12:30	Efficient device evaluation in a real world vascular registries and leveraging experiences from other CRNs Vascular Device OPC from RWE	Jack Cronenwett, MD, VQI/M2S
12:30-1:20	Session 5: Dynamic OPG/OPC for TPLC evaluation of Orthopedic Devices 1- MARCQI Priorities for Implant Analyses Richard Hughes, PhD, MARCQI 2- ISAR Global Classification Library for Hips and Knees/International Benchmarking Recommendations Stephen Graves, MD, D.Phil, Australian Joint Replacement Registry 3- Application of International Benchmarking Recommendations: Kaiser Permanente Liz Paxton, MA, Kaiser	Richard Hughes, PhD, MARCQI Stephen Graves, MD, D.Phil, Australian Joint Replacement Registry Liz Paxton, MA, Kaiser Responders: Art Sedrakyan, MD, PhD, WCM Paul Voorhorst, MS, MBA, J&J
1:20-4:00 (coffee break 2:40-3:00)	Session 6: Roundtable Perspectives and Discussion: Data Collection and Registry Efforts Spine, Shoulder, Elbow, Foot and Ankle <u>Topic: Pediatric Spinal Disorders 1:20-2:10</u> 1- An Overview of Pediatric Spine Deformity Consortium concept. Bryan Snyder, MD, PhD, Harvard 2- Harms Study Group Registry Michelle Marks, PT, MA and Peter Newton, MD, Harms Registry 3- Pediatric Hospital Perspectives- Children’s Hospital of Philadelphia. Experience from a sponsor-investigator IDE. Patrick Cahill, MD, CHOP Discussion <u>Topic: Adult Spinal Disorders 2:10-2:40</u> 4- Adult Registry Data from The Johns Hopkins Spine Outcomes Research Center Richard Skolasky, Sc.D., Johns Hopkins Spine Outcomes Research Center 5- Kaiser Spine Registries Liz Paxton, MA, Kaiser	Moderator: Vincent Devlin, MD, FDA Peter Newton, MD, Rady Children’s Hospital, San Diego Speakers: Bryan Snyder, MD, PhD, Harvard Michelle Marks, PT, MA & Peter Newton, MD, Harms registry Patrick Cahill, MD, CHOP Richard Skolasky, Sc.D., Johns Hopkins Spine Outcomes Research Center Liz Paxton, MA, Kaiser Ron Navarro, MD, Kaiser Stephen Weber, MD, PhD, FDA CAPT Jonathan Forsberg, MD, PhD, DoD Daniel Guss, MD, AOFAS

	<p>Discussion</p> <p>Coffee Break 2:40-3:00</p> <p><u>Topic: Shoulder and Elbow Surgery 3:00-3:20</u></p> <p>6- The American Shoulder and Elbow Registry Ron Navarro, MD, Kaiser and Stephen Weber, MD, FDA</p> <p>Discussion</p> <p><u>Topic: Osseointegrated Protheses for Amputees 3:20-3:40</u></p> <p>7- Walter Reed National Military Medical Center Registry Data Regarding Care of Amputees CAPT Jonathan Forsberg, MD, PhD, DoD</p> <p>Discussion</p> <p><u>Topic: Foot and Ankle Surgery 3:40-4:00</u></p> <p>8- Update regarding the American Foot and Ankle Society Registry Daniel Guss, MD, AOFAS</p> <p>Discussion</p>	
4:00 – 4:30	Closing Remarks: Action Items	Art Sedrakyan, MD, PhD, WCM Vincent Devlin, MD, FDA Danica Marinac-Dabic, MD, PhD, FDA