

**Orthopedic Strategically Coordinated Registry Network
(ORTHO-CRN) Annual Meeting
November 2, 2020
Virtual Only
Draft Agenda**

OBJECTIVES: To advance strategic and tactical dialogue between the stakeholders regarding the Orthopedic Strategically Coordinated Registry Network (Ortho-CRN). This meeting will serve as a catalyst to foster communication and engagement by all stakeholders in the orthopedic community around this effort to promote innovation for orthopedic medical devices. Through this meeting, we will provide an update on National Evaluation System for health Technology orthopedic test cases, impact of the Ortho-CRN in developing and existing registries and capitalizing on digital solutions and novel methods.		
TIME	TOPIC	PRESENTER/PANELIST
9:00 -9:05	Welcome and Opening Remarks	William Maisel, MD, MPH, FDA
9:05-10:30	Session 1: National Evaluation System for health Technology (NEST)	Moderators: CAPT Raquel Peat, PhD, MPH, FDA Flora Sandra Siami, MPH, NESTcc
9:05-9:15	Overview of NEST and Project Objectives	Dure Kim, PharmD, NESTcc
9:15-9:25	Real World Evidence Analysis for Premarket and Postmarket Approval Studies of Annular Closure Devices	Kevin Haynes, PharmD, MSCE, HealthCore
9:25-9:35	Developing Objective Performance Criteria for Hip and Knee Replacement Devices	Art Sedrakyan, MD, PhD, Weill Cornell Medicine
9:35-9:45	Developing Capacity to Conduct Proactive Post Marketing Safety Surveillance of Intervertebral Body Fusion Devices	Frederic Resnic, MD, MSc, Lahey Hospital
9:45- 9:55	Testing the Feasibility of Registry and Claims Data Linkages for Orthopedics	Nilay Shah, PhD, Mayo Clinic
9:55-10:05	Testing the Feasibility of Registry and Claims Data Linkages for Orthopedics	Kevin Haynes, PharmD, MSCE, HealthCore
10:05-10:10	Menti Survey- Participant Assessment on Gaps in Evidence	Colin O'Neill, MBE, FDA
10:10-10:30	Informing NEST: Ecosystem Panel on Key Gaps in Evidence for Orthopedic Devices	Vincent J. Devlin, MD, FAAOS, FDA Danica Marinac-Dabic, MD, PhD, MMSc, FISPE, FDA Kevin J. Bozic, MD, MBA, FAAOS Joseph Chin, MD, CMS Elise Berliner, PhD, AHRQ Elizabeth Paxton, PhD, MA, Kaiser Patient Representative, TBD
10:30-10:40	Break	
10:40-11:45	Session 2: Impact of Ortho-CRN and Promising Future Areas in Evidence Generation with Real World Data	Moderators: Vincent J. Devlin, MD, FAAOS, FDA Patricia Franklin, MD, MBA, MPH, University of Massachusetts
10:40-10:50	Pediatric Spinal Registries: How to Bridge Existing Gaps	Michael Vitale, MD, MPH, Columbia University Medical Center Peter Newton, MD, Rady Children's Hospital
10:50-11:00	Adult Spine Registries: American Spine Registry: Future Opportunities for Collaboration	Anthony L. Asher, MD, Director, American Spine
11:00-11:10	Implant Reactivity Portfolio	Yelizaveta Torosyan, MD, PhD, FDA

11:10-11:20	International Collaborations	Robert Nelissen, MD, PhD, LUMC
11:20-11:25	Menti Survey- Participant Assessment on Gaps in Evidence	Sahlee Sabala, MPH, FDA
11:25-11:45	Group Discussion	
11:45-11:55	Break	
11:55-12:55	Session 3: Focus on Imaging: Capitalizing on Digital Solutions and Novel Methods	Moderators: Danica Marinac-Dabic, MD, PhD, MMSc, FISPE, FDA Jeff Dunkel, NuHope
11:55-12:05	Imaging Data and Registries	Jens Jorgenson, MD, Society of Vascular Surgery and VQI
12:05-12:15	Value of Artificial Intelligence in Imaging Data	Pierre-Francois D'Haese, PhD, Rockefeller Neuromodulation Institute
12:15-12:25	Blockchain Advancing Imaging Data Use	Yelena Yesha, PhD, University of Miami
12:25-12:35	Integrating Distributed Analytics for Imaging	Vahan Simonyan, MS, PhD, MDEpiNet-HIVE
12:35-12:55	Group Discussion	
12:55-1:00	Closing Remarks: Action Items	CAPT Raquel Peat, PhD, MPH, FDA