Title: Navigating the Regulatory Pathway for Medical Devices: A Conversation with the FDA, Clinicians, Researchers, and Industry Experts
Date: February 26
Time: 10:00 AM – 3:00 PM EST
Format: Web Conference

Time	**Topic**		**Speaker**
10:00	Welcome, Overview of the Day, and Introduction to Indiana CTSI		Aaron Lottes, George Wodicka (Purdue University) Sharon Moe, Sara Wiehe (Indiana CTSI)
10:15	Keynote Q&A		Jeff Shuren (FDA)
11:15	Break		
11:25	Translational Pathway	From Academic Discovery to Regulatory Review	Neal Fearnot (MED Institute, Cook Group)
11:40		Early Feasibility Studies – A First Step Into Clinical Studies	Andy Farb (FDA)
11:55		Future of Medical Device Development Across Indiana and the Midwest Region – Importance of Academic Partnerships	Rob Lyles (Cook Regentec)
12:10		Panel Discussion	Speakers from Translational Pathways Session + Douglas Kelly (FDA)
12:30	**Lunch Break**		
1:00	**Parallel Workshops**		**Co-Chairs**
	Pediatric Medical Devices		Craig Goergen (Purdue University) Nicole Ibrahim (FDA) Amra Racic (Medtronic) David Reuter (Seattle Children's)
	Diagnostics and Disease Detection		Jackie Linnes (Purdue University) Tim Stenzel (FDA) Kay Taylor (BD) Alan Wright (Roche)
	Digital Health and Wearable Devices		Chi Hwan Lee (Purdue University) Bakul Patel (FDA) Subbu Venkatraman (Eko Devices) *TBD: Clinician*
	Invasive and Implantable Devices		Hugh Lee (Purdue University) Misti Malone (FDA) Ram Iyer (Cook Medical) Nabil Dib (International Society for Cardiovascular Translational Research)
2:30	Workshop Report-outs and Wrap-up		Workshop co-chairs Aaron Lottes, George Wodicka
3:00	Adjourn		