INDIANA CTSI WINTER RETREAT

Agenda

FEBRUARY 26, 2021

NAVIGATING THE REGULATORY PATHWAY FOR MEDICAL DEVICES: A CONVERSATION WITH THE FDA, CLINICIANS, RESEARCHERS, AND INDUSTRY EXPERTS

WELCOME, OVERVIEW AND INTRODUCTION
10:00 AM - 10:15 AM
Aaron Lattes and George Wodicka (Purdue University); Sharon Moe and Sarah Wiehe (Indiana CTSI)

KEYNOTE Q&A
10:15 AM - 11:15 AM
Jeffrey E. Shuren, MD, JD – Director of the Center for Devices and Radiological Health at the FDA

BREAK
11:15 AM - 11:25 AM

TRANSLATIONAL PATHWAY SESSIONS
11:25 AM: From Academic Discovery to Regulatory Review
Neal Fearnot (MED Institute, Cook Group)

11:40 AM: Early Feasibility Studies – A First Step Into Clinical Studies
Andy Farb (FDA)

11:55 AM: Future of Medical Device Development Across Indiana and the Midwest Region – Importance of Academic Partnerships
Rob Lyles (Cook Regentec)

12:10 PM: Panel Discussion
Speakers from Translational Pathway Sessions plus Douglas Kelly (FDA)

LUNCH BREAK
12:30 PM - 1:00 PM

PARALLEL WORKSHOPS
1:00 - 2:30 PM

Pediatric Medical Devices: Craig Goergen (Purdue University), Nicole Ibrahim (FDA), Susan Alpert (Consultant), David Reuter (Seattle Children’s), Vincent Devlin (FDA)

Diagnostics and Disease Detection: Jackie Linnes (Purdue University), Tim Stenzel (FDA), Kay Taylor (BD), Alan Wright (Roche), Laurence Coyne (FDA)

Digital Health and Wearable Devices: Chi Hwan Lee (Purdue University), Bakul Patel (FDA), Subbu Venkatraman (Eko Devices), Raquel Peat (FDA), Yvonne Chan (Otsuka)

Invasive and Implantable Devices: Hugh Lee (Purdue University), Misti Malone (FDA), Ram Iyer (Cook Medical), Spencer King (Emory University), Ken Cavanaugh (FDA), William Jung (FDA), Ronald Jean (FDA)

WORKSHOP REPORT-OUTS AND WRAP-UP
2:30-3:00 PM
Workshop co-chairs; Aaron Lattes and George Wodicka (Purdue University)

ADJOURN
3:00 PM