



**Project Facilitate & EA Navigator –
 FDA Oncology Center of Excellence (OCE) and
 Reagan-Udall Foundation for the FDA
 Working Together to Enable Patient Access to Investigational Oncology Drugs**

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**May 16, 2019
 1:00 pm - 3:30 pm
 FDA White Oak Campus, Great Room A**

AGENDA		
Time	Topic	Speaker
1:00 – 1:05 PM	Introduction	Rea Blakey Associate Director External Outreach and Engagement, OCE
1:05 – 1:10 PM	Opening Remarks	Ned Sharpless Acting Commissioner, FDA
1:10 – 1:15 PM	Welcome	Richard Pazdur Director, OCE
1:15 – 1:20 PM	Welcome	Ellen Sigal Board Chair Reagan-Udall Foundation for the FDA
1:20 – 1:30 PM	Reagan-Udall EA Navigator (Overview of Updates & Live Demo)	Amar Bhat Interim Executive Director Reagan-Udall Foundation for the FDA
1:30 – 1:40 PM	FDA’s Current Oncology Single Patient IND Process and Plan for Project: Facilitate Pilot	Jessica Boehmer Regulatory Scientist, Office of Hematology and Oncology Products (OHOP)
1:40 – 1:55 PM	Question & Answer	



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AGENDA		
Time	Topic	Speaker
1:55 – 3:20 PM	Panel Discussion & Audience Participation <u><i>For Discussion:</i></u> <ul style="list-style-type: none"> • Identify gaps in patient and healthcare provider knowledge of the current system for SPI requests • Identify challenges with the current system for SPI requests • Suggestions for improving the current system • Audience participation Questions 	<u>Moderator:</u> Rea Blakey Associate Director, External Outreach and Engagement, OCE <u><i>Panelists:</i></u> <ul style="list-style-type: none"> • Monica Epstein Oncology Nurse, NIH/NCI • Elena Gerasimov Director of Programs, Compassionate Use Navigator, Kids v Cancer • Monica Hughes Chief, Project Management Staff, Division of Oncology Products 2, OHOP • Chul Kim Oncologist, MedStar Georgetown University Hospital • Michael Menefee Oncologist, OHOP, FDA • Michele Russell-Einhorn Director of Regulatory Affairs, Advarra
3:20 – 3:30 PM	Concluding Remarks	Gideon Blumenthal Deputy Director, OCE