



**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**

Twitter: [#ProjectFacilitate](https://twitter.com/ProjectFacilitate)

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

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



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