



CDER Small Business and Industry Assistance Webinars 2025



BsUFA III Regulatory Science Pilot Program: Progress Update

January 22, 2025, 1:00 – 3:00 pm EDT

1:00 – 1:05 pm	<p><u>Welcome and Overview</u> Kori Adair, PharmD <i>Pharmacist</i> Small Business and Industry Assistance (SBIA) Division of Drug Information (DDI) Office of Communications (OCOMM) Center for Drug Evaluation and Research (CDER)</p>
1:05 – 1:15 pm	<p><u>BsUFA Program Introduction & Recap from Last Engagement</u> Darlese Solorzano</p>
1:15 – 1:25 pm	<p><u>Updates on the BsUFA Program Research Portfolio</u> Kimberly Maxfield</p>
1:25 – 1:55 pm	<p><u>Awardee Presentation for Internal Research</u> Jeffry Florian, PhD <i>Associate Director</i> Division of Applied Regulatory Science (DARS) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS) CDER FDA</p> <p>Kristina Howard, DVM, PhD <i>Research Veterinary Medical Officer</i> DARS OCP OTS CDER FDA</p>
1:55 – 2:10 pm	<p><u>Programs Next Steps</u></p> <ul style="list-style-type: none">• <u>Interim Report Out with Poll Questions</u>• <u>Reagan-Udall Foundation Introduction</u> <p>Kimberly Maxfield Darlese Solorzano</p>
2:10 – 2:25 pm	<p><u>Reagan-Udall Foundation</u> Susan Winckler, RPh, Esq <i>Chief Executive Officer</i> Reagan-Udall Foundation for the FDA</p>
2:25 – 2:55 pm	<p><u>Question and Answer Session</u> <i>Moderator:</i> Darlese Solorzano</p> <p>Kimberly Maxfield Emanuela Lacana Sarah Yim Jeffry Florian Kristina Howard Susan Winckler</p>
2:55 – 3:00 pm	<p><u>Closing Remarks</u> Darlese Solorzano</p>