Public Meeting on
Independent Third-Party Assessment of IND FDA-Sponsor Communication Practices in PDUFA VI

August 11, 2020

9:30 – 9:35 am	**Welcome and Introduction** **Emily Ewing,** Center for Drug Evaluation and Research, FDA *Meeting Facilitator, Program Evaluation and Implementation Staff*
9:35 – 10:20 am	**Presentation of the Assessment** **Valerie Overton,** Eastern Research Group *Vice President*
10:20 – 10:35 am	**FDA Perspective** **Rachel Kichline,** Center for Drug Evaluation and Research, FDA *Director, Business Process & Analysis Staff*
10:35 – 11:15 am	**Industry Perspectives** **Eric Larson**, AbbVie *Senior Manager, Regulatory Affairs (Global Regulatory Strategy, US/Canada)* **Todd Paporello**, Bayer Pharmaceuticals *Vice President and Head of Regulatory Affairs Americas* **Cartier Esham**, Biotechnology Innovation Organization (BIO) *Executive Vice President of Emerging Companies*
11:15 – 11:30 am	**Break**
11:30 – 12:25 pm	**Q&A and Open Public Comment**
12:25 – 12:30 pm	**Closing**