Regulatory Guidance on NASH Data Specifications in Clinical Trials

Draft Agenda

Meeting Open		
Moderator: *Veronica Miller, Forum for Collaborative Research*		
10:00am ET	Welcoming Remarks	*Veronica Miller, Forum for Collaborative Research*
10:05am ET	Addressing Data Challenges in Noncirrhotic Nonalcoholic Steatohepatitis (NASH) and Drug-Induced Liver Injury (DILI): Developing Technical Specifications for Submitting Clinical Trial Data Sets for Treatment of NASH	*Paul "Skip" Hayashi, Food and Drug Administration* *Ruby Mehta, Food and Drug Administration* *Y. Veronica Pei, Food and Drug Administration* *Vaishali Popat, Food and Drug Administration*
10:55am ET	Conclusions*/* Next Steps	*Veronica Miller, Forum for Collaborative Research*
Adjourn Webinar		