

PSC Forum 1

Thursday, October 19, 2017
 Marriott Marquis
 Washington, D.C.
 9:00 am - 12:00 pm ET

DRAFT AGENDA

8:00	Welcome Reception and Registration	
9:00	Session I: Overview & PSC Project Updates	
9:00	Welcome & Introductions	<p>Moderators: Veronica Miller, Forum for Collaborative Research Keith Lindor, Arizona State University Rob Myers, Gilead Sciences, Inc</p>
9:20	PSC Project Updates	<p>Presenters: Gideon Hirschfield, University of Birmingham Ricky Safer, PSC Partners Seeking a Cure Martine Walmsley, PSC Support</p>
9:45	Working Group Updates: PSC Patient Databases Inclusion/ Exclusion Criteria for PSC Clinical Trials	<p>Presenters: Rachel Gomel, PSC Partners Seeking a Cure Gideon Hirschfield, University of Birmingham</p>
10:05	Discussion	
10:15	Session II: Regulatory Perspectives	
10:15	FDA: PSC Pathways and Endpoints	<p>Moderator: Veronica Miller, Forum for Collaborative Research</p> <p>Presenter: Suna Seo, U.S. Food and Drug Administration</p>
10:35	EMA: EU Perspective	<p>Presenter: Elmer Schabel, European Medicines Agency</p>
10:55	Discussion	
11:15	Session III: Clinical Trial Management	
11:15	Lessons Learned: Simtuzumab Program	<p>Moderator: Kris Kowdley, Swedish Medical Center</p> <p>Presenter: Rob Myers, Gilead Sciences, Inc</p>
11:35	Discussion	
11:45	Session IV: Wrap-Up	
11:45	Additional Topics for Discussion	<p>Moderator: Veronica Miller, Forum for Collaborative Research</p>
11:55	General Updates & Next Steps	
12:00	Adjourn and Lunch Reception	