

Liver Forum 7

Thursday, October 19, 2017

Washington Marriott Marquis Hotel

901 Massachusetts Ave NW, Washington, DC 20001

2:15 - 7:15pm ET

DRAFT AGENDA

12:30 PM Welcome Reception and Registration

2:15 PM Session I: Project Overview

2:15 PM Welcome and Introduction Katherine Greene, *Forum for Collaborative Research*

Moderator: Veronica Miller, *Forum for Collaborative Research*

2:25 PM Regulatory Perspective Updates and Remarks
Lara Dimick-Santos, *CDER, U.S. Food and Drug Administration*
Elmer Schabel, *European Medicines Agency*
Irene Tebbs, *CDRH, U.S. Food and Drug Administration*
Daniel Krainak, *CDRH, U.S. Food and Drug Administration*

3:10 PM Session II: Defining Endpoints for Advanced Disease

Moderator: David Shapiro, *Intercept Pharmaceuticals*

3:10 PM Compensated Cirrhosis & Clinically Meaningful Benefit Naga Chalasani, *Indiana University School of Medicine*

3:25 PM Cirrhosis Endpoints: ACLF and MELD Rajiv Jalan, *University College London*

3:40 PM Decompensated Cirrhosis: Endpoints and Experience in U.S. Phase 2B/3 Trials Arun Sanyal, *Virginia Commonwealth University*

3:55 PM Group Discussion

4:35 PM Break

5:00 PM Session III: U.S. Payer and Care Delivery Perspectives

Moderator: Veronica Miller, *Forum for Collaborative Research*

5:00 PM Lessons Learned in HIV and HCV Carl Schmid, *The AIDS Institute*

5:15 PM Medicare Coverage: A Review Louis Jacques, *ADVI*

5:40 PM Panel Discussion: Multiple Perspectives
Louis Jacques, *ADVI*
Heather Patton, *Southern California Permanente Medical Group*
Hal Yee, *Los Angeles County Department of Health Services*

6:20 PM Session IV: Working Groups

Moderator: Katherine Greene, *Forum for Collaborative Research*

6:20 PM Case Definitions Working Group
Sophie Megnien, *Genfit*
Brent Tetri, *Saint Louis University*

6:30 PM Pediatric Issues Working Group Miriam Vos, *Emory University*

6:40 PM Placebo Arm Data Working Group Eric Lefebvre, *Allergan*

6:50 PM Standard of Care Working Group
Manal Abdelmalek, *Duke University*
Sven Francque, *Antwerp University Hospital*

7:00 PM Session V: Wrap-Up

7:00 PM Open Discussion / Meeting Close
Veronica Miller, *Forum for Collaborative Research*
Arun Sanyal, *Virginia Commonwealth University*
David Shapiro, *Intercept Pharmaceuticals*

7:15 PM Evening Reception

8:30 PM Adjourn

**This is not an official function/event of the American Association for the Study of Liver Disease (AASLD)™*