

**Liver Forum 14**  
**Friday, March 31 – Saturday, April 1, 2023**  
 Bethesda Marriott  
 5151 Pooks Hill Road, Bethesda, MD 20814

**DAY 1 AGENDA**

08:30 AM	<b>Registration and Light Breakfast</b>	
9:00 AM	Welcome and Housekeeping	<i>Paula Blay, Prism Event Management</i>
<b>Session I: Introductory Remarks and Program Overview</b>		
<b>Moderator: Veronica Miller, Forum for Collaborative Research</b>		
9:05 AM	Introductions and Welcome	<i>Judith Ertle, Boehringer Ingelheim and Arun Sanyal, Virginia Commonwealth University</i>
9:10 AM	Forum Updates	<i>Brenda Rodriguez, Forum for Collaborative Research</i>
9:15 AM	Program Overview and Acknowledgments	<i>Sehyr Khan, Forum for Collaborative Research</i>
9:20 AM	FDA-CDER-DHN Organizational Updates	<i>Charmaine Stewart, U.S. Food and Drug Administration</i>
<b>Session II: Treatment Response</b>		
<b>Moderators: Judith Ertle, Boehringer Ingelheim and M. Shadab Siddiqui, Virginia Commonwealth University</b>		
9:25 AM	Recap on NITs for Diagnosis and Prognosis	<i>Arun Sanyal, Virginia Commonwealth University</i>
9:40 AM	Patient Monitoring using the ELF™ Test: The evidence so far...	<i>Matthew Gee, Siemens Healthineers</i>
10:00 AM	NIT's and Treatment Response: MRE, MRI-PDFF and cT1	<i>Michael Middleton, University of California, San Diego</i>
10:20 AM	Monitoring of Treatment Response with FibroScan-based Biomarkers	<i>Céline Fournier, Echosens</i>
10:40 AM	Panel Discussion	<i>Roberto Calle, Regeneron Pharmaceuticals, Inc. Henry Chang, Fatty Liver Foundation Charmaine Stewart, U.S. Food and Drug Administration José Willemse, Dutch Liver Patients Association</i>
11:10 AM	<b>Break</b>	
<b>Session III: Learning Lessons from Current Programs: OCA</b>		
<b>Moderators: Naga Chalasani, Indiana University School of Medicine and Indiana University Health and Julia Wattacheril, Columbia University</b>		
11:40 AM	OCA Program Learnings	<i>Michelle Berrey, Intercept Pharmaceuticals</i>
11:50 AM	Resmetirom: A Thyroid hormone Receptor-β Agonist for the Treatment of NASH PHASE 3 Results	<i>Becky Taub, Madrigal Pharmaceuticals</i>
12:00 PM	Panel Discussion	<i>Jennifer Berg, Patient Representative Michelle Berrey, Intercept Pharmaceuticals Charmaine Stewart, U.S. Food and Drug Administration</i>
12:15 PM	<b>Lunch</b>	

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**DAY 1 AGENDA – continued**

<b>Session IV: Cirrhosis Working Group Updates</b>		
<b>Moderator: Veronica Miller, Forum for Collaborative Research</b>		
1:15 PM	Overview: Trials in Patients with Cirrhosis	<i>Arun Sanyal, Virginia Commonwealth University</i>
1:25 PM	Compensated Cirrhosis Risk Stratification	<i>Mazen Nouredin, Houston Research Institute</i>
1:35 PM	Application to Clinical Trials	<i>Naga Chalasani, Indiana University School of Medicine and Indiana University Health</i>
1:45 PM	Open Discussion	<i>All attendees</i>
<b>Session V: Placebo Arm Database and Digital AI/ML Histology Working Group Updates</b>		
<b>Moderator: Veronica Miller, Forum for Collaborative Research</b>		
2:05 PM	Placebo Arm Database Working Group Update	<i>Manal Abdelmalek, Mayo Clinic Rochester and Michael Cooreman, Inventiva Pharma</i>
2:20 PM	Panel Discussion	<i>Panelists as above</i>
2:50 PM	Digital AI/ML Histology Working Group Update	<i>David Kleiner, National Institutes of Health</i>
3:05 PM	Panel Discussion	<i>Elaine Chng, HistoIndex David Kleiner, National Institutes of Health Mathieu Petitjean, PharmaNest</i>
3:35 PM	<b>Break</b>	
<b>Session VI: Dialogue on AASLD Guidance for NASH, Employing NIT-based Referral Pathways for Clinical Trials</b>		
<b>Moderators: Jörn Schattenberg, University Medical Center, Mainz and Donna Cryer, Global Liver Institute</b>		
4:05 PM	Understanding NIT to Optimize Enrollment in NASH Clinical Trials	<i>M. Shadab Siddiqui, Virginia Commonwealth University</i>
4:20 PM	Panel Discussion	<i>Marge Connelly, LabCorp Jeff McIntyre, Global Liver Institute Ruby Mehta, U.S. Food and Drug Administration José Willemse, Dutch Liver Patients Association</i>
<b>Session VII: Additional Working Group Updates and Day 1 Recap</b>		
<b>Moderator: Veronica Miller, Forum for Collaborative Research</b>		
4:35 PM	Histology Working Group	<i>Melissa Palmer, Liver Consulting LLC</i>
4:45 PM	Pooling of Endpoints and Combination Therapy Working Groups	<i>Michelle Long, Novo Nordisk</i>
4:55 PM	Recap of Day 1	
5:00 PM	<b>Networking Reception</b>	

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**DAY 2 AGENDA**

08:30 AM	<b>Registration and Light Breakfast</b>	
<b>Session VIII: Stretch Exercise: New Look at Statistics</b>		
<i>Moderators: Veronica Miller, Forum for Collaborative Research and Arun Sanyal, Virginia Commonwealth University</i>		
9:00 AM	Desirability of Outcome Ranking (DOOR) Analysis	<i>Scott Evans, George Washington University</i>
9:30 AM	Open Discussion	<i>All attendees</i>
10:00 AM	Hybrid Randomized/Real-World Data Designs: A Case Study of Semaglutide and Cardiovascular Outcomes	<i>Lauren Dang, University of California, Berkeley</i>
10:30 AM	Open Discussion	<i>All attendees</i>
11:00 AM	<b>Break</b>	
<b>Session IX: NASH Drug Development in the Era of Approved Drugs</b>		
<i>Moderator: Manal Abdelmalek, Mayo Clinic Rochester and Pamela Danagher, Terns Pharmaceuticals</i>		
11:30 AM	Panel Discussion	<i>Kathy-Ann Cadogan, GlaxoSmithKline Henry Chang, Fatty Liver Foundation Mark Hartman, Eli Lilly and Company Matt Melaragno, Merck &amp; Co., Inc Steven Schoenfeld, Galectin Therapeutics, Inc. Rosemarie Sellati, Regeneron Pharmaceuticals, Inc. Charmaine Stewart, U.S. Food and Drug Administration Brent Tetri, Saint Louis University</i>
<b>Session X: Wrap-Up: Where do we go from here?</b>		
<i>Moderator: Veronica Miller, Forum for Collaborative Research</i>		
12:30 PM	Closing Panel	<i>Judith Ertle, Boehringer Ingelheim and Arun Sanyal, Virginia Commonwealth University</i>
12:45 PM	Open Discussion	<i>All attendees</i>
1:15 PM	<b>Adjourn</b>	