

Liver Forum Meeting #5
Thursday, 10 November 2016
1:30 - 8:30 pm

DRAFT AGENDA

1:30 PM	Welcome Coffee Reception & Check-in	
2:00 PM	Session I: Introduction & Updates	Moderators: Veronica Miller, <i>Forum for Collaborative HIV Research</i> Arun Sanyal, <i>Virginia Commonwealth University Medical Center</i> David Shapiro, <i>Intercept Pharmaceuticals</i>
2:00 PM	Liver Forum Updates	Presenters: Arun Sanyal, <i>Virginia Commonwealth University Medical Center</i> Veronica Miller, <i>Forum for Collaborative HIV Research</i>
2:15 PM	Regulatory Updates	Presenters: Lara Dimick-Santos, <i>U.S. Food and Drug Administration</i> Elmer Schabel, <i>Bundesinstitut für Arzneimittel und Medizinprodukte</i>
2:45 PM	Recognition for Outstanding Service	Presenters: Arun Sanyal, <i>Virginia Commonwealth University Medical Center</i> David Shapiro, <i>Intercept Pharmaceuticals</i> Recipient: Captain Anissa Davis-Williams, <i>U.S. Food and Drug Administration</i>
2:50 PM	Session II: Focus on Biomarkers	Moderators: Veronica Miller, <i>Forum for Collaborative HIV Research</i> Quentin Anstee, <i>Newcastle University Medical School</i>
2:50 PM	FDA Biomarker Qualification in Drug Development Under IND or NDA/BLA	Presenter: Shashi Amur, <i>U.S. Food and Drug Administration</i>
3:10 PM	FNIH: NASH Biomarker Consortium	Presenter: Roberto Calle, <i>on behalf of FNIH</i>
3:20 PM	Liver Forum - FNIH Collaborations	Presenter: Arun Sanyal, <i>co-chair FNIH Biomarker Consortium</i>
3:30 PM	IMI: Accelerated Drug Portal	Presenter: Julia Brosnan, <i>on behalf of IMI</i>
3:35 PM	Session III: Definitions WG Update	Moderators: David Shapiro, <i>Intercept Pharmaceuticals</i> Stephen Harrison, <i>University of Oxford</i>
3:35 PM	Beyond Baseline Definitions: Scientific Agenda Moving Forward	Presenter: Sophie Megnien, <i>Genfit Corp</i> Discussants: Pierre Bedossa, <i>University of Paris Diderot</i> Vlad Ratziu, <i>Hôpital Pitié Salpêtrière et Université Pierre et Marie Curie</i> Brent Tetri, <i>Saint Louis University School of Medicine</i> Saul Karpen, <i>Emory University School of Medicine</i> Jeff Schwimmer, <i>University of California, San Diego School of Medicine</i> Vincent Wong, <i>The Chinese University of Hong Kong</i>
4:15 PM	Coffee Reception	
4:45 PM	Session IV: Pediatric Updates	Moderators: Joel Lavine, <i>Columbia University Medical Center</i> Richard Torstenson, <i>Novo Nordisk</i>
4:45 PM	Regulatory Updates	Presenters: Elmer Schabel, <i>Bundesinstitut für Arzneimittel und Medizinprodukte</i> Ruby Mehta, <i>U.S. Food and Drug Administration</i>
5:00 PM	Status of Pediatric NASH Research	Presenters and Panelists Miriam Vos, <i>Emory University School of Medicine</i> Jeff Schwimmer, <i>University of California, San Diego School of Medicine</i> Ruby Mehta, <i>U.S. Food and Drug Administration</i> Rajarshi Banerjee, <i>Perspectum Diagnostics</i>

5:40 PM	Session V: Mechanism of Action and Surrogate Endpoints	Moderators: David Shapiro, <i>Intercept Pharmaceuticals</i> Arun Sanyal, <i>Virginia Commonwealth University Medical Center</i>
5:40 PM	Linking Mechanism of Action to Endpoint Selection in NASH Trial	Panel: Laurent Fischer, <i>Tobira Therapeutics, Inc.</i> Rob Myers, <i>Gilead Sciences, Inc.</i> Scott Friedman, <i>Icahn School of Medicine at Mount Sinai</i> Anna Mae Diehl, <i>Duke University Medical Center</i> Detlef Schuppan, <i>Mainz University Medical Center</i> Eileen Navarro, <i>U.S. Food and Drug Administration</i>
6:20 PM	Session VI: New WG Prioritization	Moderators: Veronica Miller, <i>Forum for Collaborative HIV Research</i> Arun Sanyal, <i>Virginia Commonwealth University Medical Center</i>
6:20 PM	<u>Possible New Working Groups:</u> 1. Efficiency in Trial Recruitment 2. Framework for Placebo Arm Cohort 3. Adaptive trial design and new analytic approaches 4. Biomarker Surrogate Endpoints 5. DILI/NASH 7. HCC and Other Disease States 6. Other?	Discussants: Claudia Filozof, <i>Covance</i> Donna Cryer, <i>Global Liver Institute</i> Peter Traber, <i>Galectin Therapeutics, Inc.</i> Robert Arch, <i>Takeda Pharmaceuticals International, Inc.</i> Sudha Shankar, <i>FNIH</i> Claude Cohen-Bacrie, <i>SuperSonic Imagine</i> Claude Sirlin, <i>University of California, San Diego</i> Erwin de Buijzer, <i>Humedics GmbH</i> Arie Regev, <i>Eli Lilly and Company</i> Joanne Imperial, <i>FibroGen, Inc.</i>
6:50 PM	Session VII: Wrap Up & Next Steps	Moderator: Veronica Miller, <i>Forum for Collaborative HIV Research</i>
7:00 PM	Adjourn & Networking Reception	