

Berkeley



FORUM
for Collaborative
RESEARCH

The Liver Forum: Pediatric Working Group Meeting

Monday, March 20, 2017

The Mayflower Hotel
1127 Connecticut Avenue NW
Washington, DC

www.hivforum.org



Meeting's Focus

The development of a pediatric transatlantic natural history cohort

- Regulatory agencies express the need for natural history data in pediatric NAFLD/NASH.
- This meeting is intended to be the opening discussion on the viability of cohesive and comparative cross-national natural history cohorts to fill the unmet need.



Meeting's Focus (cont.)

Pediatric issues in NAFLD/NASH clinical trials.

- Challenges and strategies related to the recruitment, enrollment, retention, and engagement of patients in long-term clinical trials for pediatric NAFLD/NASH.
- Specific needs for developing and validating non-invasive biomarkers for the pediatric population.



Draft Agenda

8:30 AM	Welcome Coffee Reception and Check-in	Malene Cobourne, <i>Forum for Collaborative Research</i> Katherine Greene, <i>Forum for Collaborative Research</i>
8:45 AM	Overview and Summary of Identified Gaps	Moderator: Veronica Miller, <i>Forum for Collaborative Research</i>
9:05 AM	Regulatory Approach in Pediatric NAFLD/ NASH	Moderators: Veronica Miller, <i>Forum for Collaborative Research</i> Jeffrey Schwimmer, <i>University of California, San Diego</i> Presenter: Elmer Schabel, <i>European Medicines Agency*</i>
9:35 AM	Existing NAFLD/NASH Pediatric Research Across the Atlantic	Moderators: Veronica Miller, <i>Forum for Collaborative Research</i> Jeffrey Schwimmer, <i>University of California, San Diego</i> Panelists: Ingrid Delaet, <i>Intercept Pharmaceuticals</i> Michael W Fried, <i>University of North Carolina</i> Piotr Socha, <i>The Children's Memorial Health Institute*</i>



Draft Agenda

10:15 AM	Advantages and Disadvantages of Retrospective and Prospective Approaches in Developing a Natural History Cohort	Moderators: Veronica Miller, <i>Forum for Collaborative Research</i> Jeffrey Schwimmer, <i>University of California, San Diego</i> Presenter: Miriam Benedicta Vos, <i>Emory University</i>
10:45 AM	Pediatric NAFLD/NASH Natural History Inclusion Criteria	Moderators: Veronica Miller, <i>Forum for Collaborative Research</i> Jeffrey Schwimmer, <i>University of California, San Diego</i> Presenter: Cynthia Behling, <i>Sharp HealthCare*</i>
11:15 AM	Key Information Needed to Track Disease Progression in Pediatric Studies	Moderators: Veronica Miller, <i>Forum for Collaborative Research</i> Jeffrey Schwimmer, <i>University of California, San Diego</i> Presenter: Joel Lavine, <i>Columbia University</i>



Draft Agenda

11:45 AM	Retention and Engagement in Pediatric NAFLD/NASH Clinical Trials	Moderator: Miriam Benedicta Vos, <i>Emory University</i> Panelists: Dan Peres, <i>Immuron Limited</i> Reshma Shringarpure, <i>Intercept Pharmaceuticals</i> Stavra Xanthakos, <i>Cincinnati Childrens Hospital Medical Center</i>
12:15 PM	Validation of Non-Invasive Biomarkers in Pediatric NAFLD/NASH Clinical Trials	Moderator: Joel Lavine, <i>Columbia University</i> Panelists: Keri Hildick, <i>Perspectum Diagnostics</i> David Kleiner, <i>National Cancer Institute</i> Dan Peres, <i>Immuron Limited</i>
12:45 PM	Next Steps: Open Discussion	Moderator: David Shapiro, <i>Intercept Pharmaceuticals</i>
1:00 PM	Adjourn & Lunch Reception	



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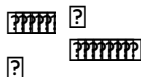


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