



Liver Forum #2

Tuesday, 21 April 2015
Grand Hotel Wien, Quadrille Ballroom
Kärntner Ring 9, 1010 Wien, Austria
13:30 - 20:30

AGENDA

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| 13:30 | Welcome Reception and Check-in | |
| 14:00 | Session 1: Project Overview & Updates | Moderators: Gary Burgess, <i>Vectura Limited</i> Veronica Miller, <i>HIV Forum</i> Arun Sanyal, <i>Virginia Commonwealth University</i> |
| | Welcome & Introductions Operating Principles Liver Forum Goals & Objectives Updates since Liver Forum 1 Objectives for Liver Forum 2 | |
| 14:30 | Session 2: Regulatory Perspectives & Updates | Moderators: Gary Burgess, <i>Vectura Limited</i> Arun Sanyal, <i>Virginia Commonwealth University</i> Elmer Schabel, <i>EMA/BfArM</i> Lara Dimick-Santos, <i>FDA/CDER/DGIEP</i> Ruby Mehta, <i>FDA/CDER/DGIEP</i> |
| | EMA Perspectives & Updates FDA Perspectives & Updates; Experience with Recent Applications | |
| | Discussion | All |
| 15:00 | Session 3: Towards Data-driven Collaboration | Moderators: Veronica Miller, <i>HIV Forum</i> David Shapiro, <i>Intercept Pharmaceuticals</i> Veronica Miller, <i>HIV Forum</i> Bettina Hansen, <i>Erasmus MC Rotterdam</i> |
| | Updates from Working Group: Baseline Data Standardization Experiences and Lessons from PBC | |
| | Discussion | Panelists: Borje Darpö, <i>Cardiac Research Safety Consortium</i> Scott Friedman, <i>Icahn School of Medicine (P)</i> Joanne Imperial, <i>FibroGen (P)</i> Rohit Loomba, <i>UC San Diego</i> Rob Myers, <i>Gilead Sciences</i> |
| 16:00 | Break | |

16:30 **Session 4: Speaking a Common Language: Definitions**

Working Group Updates

Discussion

Current State of Science
How Far Will Current State of Science Get Us?
Opportunities for Collaboration to Advance the Science

Moderators:

Markus Peck, *EASL*
Arun Sanyal, *Virginia Commonwealth University*
Stephen Harrison, *Brooke Army Med Center* (P)
Sophie Megnien, *Genfit*

Panelists:

Laurent Castera, *EASL*
Jude Oben, *University College London*
Rebecca Taub, *Madrigal Pharmaceuticals*

17:30 **Session 5: Pediatrics & Adolescents**

Regulatory Perspective for Pediatric Studies
Working Group Updates
Addressing Gaps in Knowledge: Natural Progression, Long-term Issues
Biomarkers and Diagnostics for Pediatrics & Adolescents

Discussion: Opportunities for Collaboration

Moderators:

Carol Brosgart, *UC San Francisco*
Gary Burgess, *Vectura Limited*

Ruby Mehta, *FDA/CDER/DGIEP*
Joel Lavine, *Columbia University*
Miriam Vos, *Emory University*
Krishna Polu, *Raptor Pharmaceuticals*

Panelists:

Dennis Grasela, *Bristol-Myers Squibb*
Stefan Neubauer, *Perspectum Diagnostics*

18:30 **Session 6: Summing Up & Next Steps**

Working Group Mandates
Reports & Publications
Diagnostics Roundtable
Liver Forum 3: November, San Francisco (AASLD)

Gary Burgess, *Vectura Limited*
Veronica Miller, *HIV Forum*
Arun Sanyal, *Virginia Commonwealth University*

19:00 **Adjourn & Networking Reception**

(P) Joining by phone