

Program

Recent Research Advances in Drug-Induced Liver Injury 2009

A national/international discussion of recent new findings in the field of drug-induced liver injury (DILI), work in progress, and work that needs to be done.

The program is being co-sponsored by the Food and Drug Administration/Center for Drug Evaluation and Research (FDA/CDER), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the American Association for the Study of Liver Disease (AASLD).

National Labor College, Silver Spring MD, 8-9 April 2009
10000 New Hampshire Avenue at Powder Mill Road, Silver Spring MD 20903

Wednesday, 8 April

7:30 *Continental Breakfast*
8:00 Introductions and Brief Opening Statements Janet Woodcock, FDA/CDER
Alan Goldhammer, PhRMA
Neil Kaplowitz, AASLD

8:15 **Session I: Moderator, Roger Ulrich, CalistogaPharma**

Session IA: Genetic susceptibility to DILI or liver disease

8:15 Systems biology approach to ximelagatran injury Karin Cederbrant, AZ
8:45 MHC II haplotype marker for lumiracoxib injury Tim Wright, Novartis
9:15 Powerful HLA marker of flucloxacillin injury susceptibility Ann Daly, U Newcastle
9:45 *Break*

Session IB: Can animals be used to show idiosyncratic responses?

10:15 The mouse as a model for susceptibility to DILI Ivan Rusyn, UNC
10:45 Idiosyncrasy in ordinary laboratory animals John Senior, FDA
11:15 Mouse models of halothane-induced liver injury Cynthia Ju, U CO
11:45 Discussion of material presented in IA and IB All
12:15 *Lunch*

1:15 **Session II: Moderator, Paul Watkins, UNC**

Session IIA: Findings from DILI genetic networks

1:15 Findings from the SAEC international network Matt Nelson, GSK
2:00 The Spanish DILI network Raul Andrade, U Malaga
2:45 General discussion – panel of speakers above, audience Panel; All
3:15 *Break*

Session IIB: What do the gene findings mean for DILI mechanisms?

3:45 Genotype-phenotype relationships Roger Ulrich, Calistoga
4:15 Implications of genetic susceptibility to DILI David Goldstein, Duke U
4:45 Mechanisms of liver injury in susceptible people Neil Kaplowitz, USC
5:15 General discussion –speakers and audience All

6:00 – *Reception: wine and cheese, mingle and relax ---*

7:00 *Dinner on your own*

Thursday, 9 April

7:30 *Continental Breakfast*

8:00 Session III: Moderator, Leonard Seeff, NIH

Session IIIA: Research in Progress A

8:00	Screening populations for transaminase elevations	Heide Stirnadel, GSK-UK
8:20	Metabolic effects in subjects taking acetaminophen	Tom O'Connell, UNC
8:40	Update on acetaminophen hepatotoxicity	Will Lee, UTSW
9:00	Liver injury in patients on anti-tuberculosis therapy	Jussi Saukkonen, Bost U
9:20	General discussion, panelists and audience	All
10:00	<i>Break</i>	

Session IIIB: Research in Progress B

10:30	Cellular imaging of hepatocytes to predict clinical DILI	Michael Aleo, Pfizer
10:50	Blood transcriptomic findings in acute liver injury	Rick Paules, NIEHS
11:10	Human hepatocyte cultures for study of DILI	Sangeeta Bhatia, MIT
11:30	Update on liver transplants for DI-ALF	Arie Regev, Lilly
11:50	General discussion –speakers and audience	All

12:30 *Lunch*

Session IV: Moderator, Lana Pauls, FDA

Session IV: Research that Needs to be Done

1:30	Research opportunities under the new FDA guidance	Mark Avigan, FDA/CDER
1:55	eDISH-like methods to track hepatotoxicity: case studies	Jack Ostroff, Pfizer
2:20	IOM and DILIN suggestions and plans	Paul Watkins, The Hamner
2:40	In silico simulation of DILI using the Entelos platform	Harvey Clewell, The Hamner
3:00	<i>Adjourn</i>	

For details and changes follow information posted at website: <http://www.fda.gov/cder/livertox>

Registration by AASLD: \$400 for industry; \$200 for government or academia

(go to <http://www.aasld.org>, Meetings, Hepatotoxicity Special Interest Group Meeting)

Lodging reservations on your own at NLC (<http://www.nlc.edu> under "For Current Students," click on Reserve a Room, group ID 3568, password 37000175; send copy to lana.pauls @fda.hhs.gov)

or at Silver Spring Hotels