Drug-induced liver injury (DILI) is a major problem for drug development and clinical care. Several unresolved issues require new understanding and consensus. Especially difficult is the much greater cost of adequate safety studies over proof of efficacy studies. This international academic-industry-government conference will discuss current findings and thinking on DILI and drug safety by experts in hepatology and toxicology and special presentations. We encourage you to register, come, participate, and debate the issues for development of new agreements and guidance.

Tuesday, 6 June 2017

7:30 Continental breakfast outside the conference room; Registration

8:00 OPENING REMARKS Sweet and Sour DILI Keynotes John Senior

SESSION I Best Practices in Clinical Drug Development

Moderators: Arie Regev and Naga Chalasani

8:05 Special recognition to N. Kaplowitz
8:10 Alcoholic hepatitis as a drug-induced disorder Gyongyi Szabo
8:30 Detection and management of DILI in NASH/NAFLD subjects in drug development Naga Chalasani
9:50 Reactivation of hepatitis B in clinical trials with immune suppressive drugs Rajender Reddy
9:10 General discussion of issues ALL PRESENT

9:40 mid-morning coffee break

10:00 Chronic liver disease after acute hepatocellular DILI Bob Fontana
10:20 Is chronic liver disease after acute hepatocellular DILI over-estimated? Einar Bjornsson
10:40 Detection and evaluation of DILI in Patients with active or advanced liver diseases Jim Lewis
11:00 General discussion of issues ALL PRESENT
11:30 Lunch break

12:30 SESSION II Evaluating DILI Signals in Clinical Trials to Inform Benefits, Risks

Moderators: Michael Aleo and Mark Avigan

12:30 How the clinical signature of DILI impacts benefits and risks Mark Avigan
12:50 Do pharmacokinetic and hepatocellular steps inform risk assessment? Raj Madabushi
1:10 Drug-induced inhibition of cellular function Yvonne Dragan
1:30 Do histologic features inform DILI mechanisms? Dave Kleiner
1:50 Agents that alter immune tolerance; what can we predict? Amy Rosenberg
2:10 General discussion of issues ALL PRESENT
2:40 Refreshment break

3:10 Quantitative benefit-risk assessment of DILI Rebecca Noel
3:30 Agents that inhibit the BSEP and mitochondrial function – what do we know? Michael Aleo
3:50 Improved survival—what tradeoffs make sense? Dan Suzman
4:10 Need for consideration of issues for guidance revision Bob Temple
4:30 General discussion of Issues ALL PRESENT

5:00 Reception: wine and hors d’oeuvres; mingle, chat, and relax --- dinner on your own
Wednesday, 7 June 2017

7:30 "Continental breakfast outside the conference room"

8:00 SESSION III  New Tools for Detection and Assessment of DILI
Moderators: John-Michael Sauer and Neil Kaplowitz

8:00  Serum microRNAs as predictors in clinical trials  Herb Bonkovsky
8:20  New Methods to Predict DILI Risk  Jack Uetrecht
8:40  Rule-of-2 + RM as predictors — can they help predict DILI?  Minjun Chen
8:55  Predicting DILI: An Inside the “Box” Analysis  Tom Jones
9:10  General Discussion of Issues  ALL PRESENT
9:40  Coffee break

10:10  DILIsym initiative  Paul Watkins
10:30  European Quantitative Toxicology (EQT) – liver, kidney, heart-lung  Jim Stevens
10:50  MIP-DILI (mechanism-based integrated prediction of DILI)  Chris Goldring
11:10  eDISH2  Ted Guo
11:30  General discussion of issues  ALL PRESENT
12:00  Lunch break

1:00 SESSION IV  Consortia for Best Practices to Reduce DILI
Moderators: Paul Watkins and Gyongyi Szabo

1:00  The IQ DILI Initiative  Arie Regev
1:20  The IQ DILI working group on post marketing risk assessment  Frank Czerwiec
1:40  SAFE-T Consortium  Gerd Kullak-Ublick
2:00  LiverTox update and prospects  Jay Hoofnagle
2:20  Expert judgment for causality assessment  Don Rockey
2:40  Chinese DILIN experience  Yimin Mao
2:55  General Discussion of Issues  ALL PRESENT
3:25  Refreshment break
3:40  Is there a general mechanism for DILI? Do we need to know it?  Neil Kaplowitz
4:00  Who speaks for the prescribing physicians?  John Senior
4:20  General discussion of issues  ALL PRESENT
5:00  Adjourn

Registration for the June 2017 Conference
Contact: Critical Path Institute, Tucson, AZ

Register Now

Registration: $700 pharmaceutical industry employees; $350 academic and regulatory participants

Please make lodging reservations on your own at The College Park Marriott Hotel and Conference Center

Special rate for attendees at this link

{Copies of slides shown and transcripts of speakers’ comments and discussions will be posted four weeks after the conference at: www.aasld.org → Events and Professional Development, Drug-Induced Liver Injury Conferences. Previous conference agendas, slides, and comments may be seen at the same site.}