



### Background

Drug Induced Liver Injury (DILI) presents a critical challenge to the pharmaceutical industry and patient care. In June 2016, IQ launched a new initiative to define best practices for the detection, monitoring, management and prevention of DILI in clinical trials and post-marketing pharmacovigilance programs.

### Working Groups Making Excellent Progress

IQ-DILI currently has 6 working groups:

1. Monitoring and assessment of potential DILI in patients with abnormal hepatic biochemical tests at baseline;
2. Causality assessment in all patterns of DILI (hepatocellular, cholestatic, hepatic steatosis, vascular) and best practices for drug rechallenge;
3. Immune-related liver injury due to immunotherapy, such as checkpoint inhibitors;
4. Development of strategies to investigate potential emerging biomarkers for the assessment of DILI;
5. Adjustments in monitoring and assessment of DILI during clinical trials based on nonclinical toxicology findings;
6. Post-marketing pharmacovigilance programs and Risk Evaluation and Mitigation Strategies (REMS) for DILI.



### DILI Steering Committee

Abnormal  
Baseline WG

Immunotherapy  
WG

Biomarkers  
WG

Causality  
Assessment  
WG

Nonclinical  
WG

Post-marketing  
Pharmacovigilance  
WG

The working groups are conducting an extensive review of literature and presentations at past conferences, and will summarize knowledge gathered in those published resources in a series of white papers. Detailed outlines for white papers are expected to be ready by the end of this year. In the meantime, working groups are also designing surveys to collect information from member companies on current practices.

### Collaborations with Related IQ Leadership Groups Established

Dr. Will Treem, interim Co-Chair of the DILI initiative, met with leaders of several related IQ Leadership Groups (LGs) including the Clinical

### Highlights

- Working groups making excellent progress towards white paper production and survey development 
- Collaborations established with IQ Clinical Pharmacology, Drug Metabolism and DruSafe Leadership Groups
- IQ-DILI progress acknowledged by the IQ Board of Directors
- The Steering Committee will meet on November 10 and establish collaborations with key opinion leaders from academics and regulatory agencies
- Number of member companies has reached 12
- Help us receive broader input to our surveys!
- Please join us! 

### Events

Face-to-face Meetings:

- IQ-DILI Steering Committee face-to-face meeting, Boston MA, November 10
- IQ-DILI meeting with stakeholders, Boston MA, November 10

Pharmacology LG, Drug Metabolism LG, and DruSafe LG. Each LG will appoint a liaison to the DILI Steering Committee and the liaisons will be invited to participate in all Steering Committee activities.

## IQ-DILI Progress Acknowledged by IQ Board of Directors

Dr. Arie Regev, interim Co-Chair of the DILI initiative, presented a progress update at the IQ Board of Directors meeting in early October. The presentation was well-received and the Board commended the group for the significant progress it made in just 3 months.

## Upcoming Face-to-Face Meeting and Meeting with Academics and Regulators in Boston

The Steering Committee will hold its second face-to-face meeting on November 10 to review progress and plan its activities for 2017. Most notably, a group of distinguished DILI scientists from academia and FDA will join part of the meeting to discuss ways to collaborate with the IQ-DILI initiative. IQ-DILI deems it essential to leverage the expertise and perspectives of these academic and regulatory experts in such critical areas as nonclinical testing, new biomarkers, in-silico and in-vitro models, causality assessment and phenotypes of DILI in clinical practice.

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## New members

IQ-DILI welcomes two new members: Bayer and Boehringer Ingelheim, who bring the number of member companies to 12. They are: AZ, Bayer, BMS, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, Otsuka, Pfizer, Sanofi, Takeda, and Theravance.

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## Requests for IQ Members

Help with IQ-DILI surveys: IQ-DILI would like to solicit input to its surveys from all IQ companies. At the October IQ Board of Directors meeting, the IQ Board kindly agreed to help distribute DILI surveys to companies that have not yet joined the DILI initiative. While IQ-DILI will first pilot the surveys within the current 12 companies to make sure that surveys are clear and effective, we request that Board members from other IQ companies identify a colleague or colleagues to be the point of contact to facilitate survey responses. We will soon send you the current draft of survey questionnaires and additional background information.

Consider bringing your company into the DILI initiative: we will greatly benefit from broader participation, expertise, perspectives and resources from ALL IQ companies. Please forward this newsletter to your colleagues and ask them to consider joining our group! We also plan to hold a webinar in the near future for your interested colleagues. We are always available to answer any questions you and your colleagues may have.

## Teleconferences

### Steering Committee

- November 21
- December 19

### Abnormal Baselines WG

- November 9
- November 23
- December 7
- December 21

### Immunotherapy WG

- November 10
- December 8
- December 22

### Causality Assessment WG

- November 9
- November 23
- December 7
- December 21

### Biomarkers WG

- November 22
- December 6
- December 20

### Nonclinical Translation WG

- November 14
- December 12

### Post-marketing Pharmacovigilance and REMS WG

- November 4

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