International Conference on Pharmacovigilance and Protection for Research Participants (ECD 2020) & CIOMS Consensus Report on Drug-Induced Liver Injury (DILI)’”

November 20th, 2020 online.

Part 1: Pharmacovigilance, Drug Safety and Protection for Research Participants
Part 2: The CIOMS Consensus Report on Drug-Induced Liver Injury (DILI)

Guest connection details:
https://zoom.com.cn/j/4875564168
Meeting ID: 487 556 4168  Passcode: 135246
Connect by phone - find your local number: https://zoom.com.cn/u/acNEQYXJXH

Organizers:
Council for International Organizations of Medical Sciences (CIOMS) www.cioms.ch
Shanghai Ethics Committee for Clinical Research (SECCR), Shanghai Clinical Research Center (SCRC); www.srcrnet.org

► Programme (see next page)
### Programme

**ECD2020**  
20 November 2020  

#### Part 1: Pharmacovigilance, drug safety and protection for research participants

<table>
<thead>
<tr>
<th>Time</th>
<th>CET</th>
<th>U.S. EST</th>
<th>Session Title</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:30 PM</td>
<td>6:30 AM</td>
<td>0:30 AM</td>
<td><strong>Keynote Speech</strong></td>
<td>Chingli Hu</td>
</tr>
<tr>
<td>1:40 AM</td>
<td>6:40</td>
<td>0:40 AM</td>
<td>Current status of pharmacovigilance in China</td>
<td>Qing Zhang</td>
</tr>
<tr>
<td>2:10 AM</td>
<td>7:10</td>
<td>1:10</td>
<td>The integration of international pharmacovigilance progress and China's ADR monitoring system</td>
<td>Haibo Song</td>
</tr>
<tr>
<td>2:40 AM</td>
<td>7:40</td>
<td>1:40</td>
<td>The Swiss experience of handling ethical review of COVID-19-related applications</td>
<td>Dominique Sprumont</td>
</tr>
<tr>
<td>3:10 AM</td>
<td>8:10</td>
<td>2:10</td>
<td>Panel session: Questions &amp; Answers</td>
<td>Host (Guoying Cao) + Panel (the above speakers)</td>
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<tr>
<td>3:30 AM</td>
<td>8:30</td>
<td>2:30</td>
<td>Safety monitoring during clinical trials</td>
<td>Panos Tsintis</td>
</tr>
<tr>
<td>4:00 AM</td>
<td>9:00</td>
<td>3:00</td>
<td>Drug safety issues in multicenter clinical research in the U.S.</td>
<td>Delia Yi-Dan Christiani</td>
</tr>
<tr>
<td>4:30 AM</td>
<td>9:30</td>
<td>3:30</td>
<td>Drug safety and protection of participants’ rights</td>
<td>Yimin Mao</td>
</tr>
<tr>
<td>5:00 AM</td>
<td>10:00</td>
<td>4:00</td>
<td>Practice of Pharmacovigilance and Specific Practice of Drug-Induced Liver Injury</td>
<td>Fangli Shu</td>
</tr>
<tr>
<td>5:30 AM</td>
<td>10:30</td>
<td>4:30</td>
<td>Panel session: Questions &amp; Answers</td>
<td>Host (Wei Zhu) + Panel (the above speakers)</td>
</tr>
</tbody>
</table>

#### Part 2: Webinar session on CIOMS consensus report on Drug-Induced Liver Injury (DILI)

<table>
<thead>
<tr>
<th>Time</th>
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<th>Session Title</th>
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</tr>
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<tbody>
<tr>
<td>8:00 PM</td>
<td>13:00</td>
<td>7:00 AM</td>
<td>Welcome and introduction</td>
<td>Arie Regev</td>
</tr>
<tr>
<td>8:05 PM</td>
<td>13:05</td>
<td>7:05</td>
<td>What CIOMS Is And What It Does : The DILI Initiative</td>
<td>Lembit Rägo</td>
</tr>
<tr>
<td>8:15 PM</td>
<td>13:15</td>
<td>7:15</td>
<td>Principles in Detection, Characterization and Risk Assessment of DILI in Clinical Trials</td>
<td>Arie Regev</td>
</tr>
<tr>
<td>8:30 PM</td>
<td>13:30</td>
<td>7:30</td>
<td>Liver Safety Biomarkers and Herbal and Dietary Supplement Hepatotoxicity</td>
<td>Robert Fontana (via pre-recording)</td>
</tr>
<tr>
<td>8:45 PM</td>
<td>13:45</td>
<td>7:45</td>
<td>Best practices in post-market DILI risk assessment, risk minimization and communication</td>
<td>Walter Straus</td>
</tr>
<tr>
<td>9:00 PM</td>
<td>14:00</td>
<td>8:00</td>
<td>Panel session: Questions &amp; Answers</td>
<td>Arie Regev (Host) Lembit Rägo, Walter Straus (panel)</td>
</tr>
<tr>
<td>9:20 PM</td>
<td>14:20</td>
<td>8:20</td>
<td>Summary and key takeaways Closing remarks</td>
<td>Arie Regev &amp; Lembit Rägo</td>
</tr>
</tbody>
</table>

**End of event: 09:30 PM (China) | 14:30 h (CET) | 08:30 AM (U.S. EST)**

▶ Speaker details (see next page)
Fangli Shu
Director of Pharmacovigilance Safety Operation, IQVIA

Lembit Rägo
Secretary General, Council for International Organizations of Medical Sciences (CIOMS)

Arie Regev
Associate Professor of Medicine, Division of Gastroenterology and Hepatology, Indiana University School of Medicine
Previously: Associate Professor of Medicine, University of Miami School of Medicine

Robert Fontana
Professor of Medicine and Medical Director of Liver Transplantation of the University of Rochester
PI of five NIDDK- and NIAID-funded liver injury trials
Chair of the DILIN steering committee
Chair of the AASLD Hepatotoxicity Special Interest Group

Walter Straus
Associate Vice President of Clinical Safety and Risk Management at Merck (MSD)

束芳丽
艾昆纬医药科技(上海)有限公司
中国药物警戒安全运营总监

Lembit Rägo
国际医学科学组织理事会秘书长

Arie Regev
印第安纳大学医学院胃肠病学
肝病学部药学教授

Robert Fontana
密歇根大学医学教授和肝移植医学主任

Walter Straus
默克公司临床安全和风险管理副总裁

密歇根大学医学教授和肝移植医学主任

DILIN首席研究员
DILIN指导委员会联合主席
AASLD肝毒性特别小组前任主席