



**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.scrnet.org

► Programme (see next page)

ECD2020
20 November 2020
Programme

China	CET	U.S. EST		
1:30 PM	6:30 AM	0:30 AM	Keynote Speech	Chingli Hu
China	CET	U.S. EST	Part 1: Pharmacovigilance, drug safety and protection for research participants	
1:40	6:40	0:40 AM	Current status of pharmacovigilance in China	Qing Zhang
2:10	7:10	1:10	The integration of international pharmacovigilance progress and China's ADR monitoring system	Haibo Song
2:40	7:40	1:40	The Swiss experience of handling ethical review of COVID-19-related applications	Dominique Sprumont
3:10	8:10	2:10	Panel session: Questions & Answers	Host (Guoying Cao) + Panel (the above speakers)
3:30	8:30	2:30	Safety monitoring during clinical trials	Panos Tsintis
4:00	9:00	3:00	Drug safety issues in multicenter clinical research in the U.S.	Delia Yi-Dan Christiani
4:30	9:30	3:30	Drug safety and protection of participants' rights	Yimin Mao
5:00	10:00	4:00	Practice of Pharmacovigilance and Specific Practice of Drug-Induced Liver Injury	Fangli Shu
5:30	10:30	4:30	Panel session: Questions & Answers	Host (Wei Zhu) + Panel (the above speakers)
China	CET	U.S. EST	Part 2: Webinar session on CIOMS consensus report on Drug-Induced Liver Injury (DILI)	
8:00 PM	13:00	7:00 AM	Welcome and introduction	Arie Regev
8:05	13:05	7:05	What CIOMS Is And What It Does : The DILI Initiative	Lembit Rägo
8:15	13:15	7:15	Principles in Detection, Characterization and Risk Assessment of DILI in Clinical Trials	Arie Regev
8:30	13:30	7:30	Liver Safety Biomarkers and Herbal and Dietary Supplement Hepatotoxicity	Robert Fontana (via pre-recording)
8:45	13:45	7:45	Best practices in post-market DILI risk assessment, risk minimization and communication	Walter Straus
9:00	14:00	8:00	Panel session: Questions & Answers	Arie Regev (Host) Lembit Rägo, Walter Straus (panel)
9:20	14:20	8:20	Summary and key takeaways Closing remarks	Arie Regev & Lembit Rägo

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

► Speaker details (see next page)



胡庆澧 Chingli Hu

- 上海市临床研究伦理委员会主任委员
- 上海交通大学医学院附属瑞金医院终身教授
- 原世界卫生组织副总干事
- Chairman of Shanghai Ethics Committee for Clinical Research
- Emeritus Professor, Ruijin Hospital
- Former Deputy Director-General of WHO



曹国英 Guoying Cao

- 复旦大学附属华山医院机构办主任
- 复旦大学附属华山医院伦理委员会委员
- 上海市临床研究伦理委员会委员
- Director of CCP Office, Huashan Hospital of Shanghai Fudan University
- Member of Ethics Committee, Huashan Hospital, Shanghai Fudan University
- Member of Shanghai Ethics Committee for Clinical Research



张清 Qing Zhang

- 上海市药品监督管理局副局长
- Deputy director of Shanghai Drug Administration



宋海波 Haibo Song

- 国家药品监督管理局药品评价中心
- Chief Pharmacist of Chinese Medicine, Center for Drug Re-evaluation, NMPA



Dominique Sprumont

- 瑞士纳沙泰尔大学法学院教授
- 卫生法研究院创立人
- Professor of Law/ Co-founder, Institute of Health Law, University of Neuchatel, Switzerland



朱伟 Wei Zhu

- 复旦大学教授
- 上海市临床研究伦理委员会副主任委员
- Professor of Fudan University
- Vice Chairperson of Shanghai Ethics Committee for Clinical Research



Panos Tsintis

- 皇家内科医师学会会员 (FRCP)
- 英国药物医学院院士 (FPPM)
- Fellow of the Royal College of Physicians (FRCP)
- Fellow of the Faculty of Pharmaceutical Medicine (FPPM)



Delia Yi-Dan Christiani

- 哈佛大学公共卫生学院
- 医学博士、法学博士
- M.D., J.D., MSCI, Harvard School of Public Health



茅益民 Yimin Mao

- 上海仁济医院消化内科主任医师
- 上海市脂肪性肝病诊治研究中心常务副主任
- 中华医学会肝病分会药物性肝病学组组长
- Chief Physician of Gastroenterology, Renji Hospital
- Standing Vice Minister of Shanghai Treatment and Research Center for Fatty Liver Disease
- Group Leader of Drug-Induced Liver Disease, China Medical Association



束芳丽

Fangli Shu

艾昆特医药科技(上海)有限公司
中国药物警戒安全运营总监

• Director of Pharmacovigilance Safety
Operation, IQVIA



Lembit Rāgo

国际医学科学组织理事会秘书长

• Secretary-General, Council for
International Organizations of Medical
Sciences (CIOMS)



Arie Regev

印第安纳大学医学院胃肠病学
肝病学部药理学教授
(原) 迈阿密大学医学院医学教授

• 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

密歇根大学医学教授和肝移植医学主任
多中心药物诱导肝损伤组织(DILIN)首席研究员
DILIN指导委员会联合主席
AASLD肝毒性特解小组前任主席

• Professor of Medicine and Medical Director of
Liver Transplantation at the University of
Michigan
• PI of the multi-center Drug Induced Liver Injury
Network(DILIN)
• Co-chair of the DILIN Steering committee
• Past Chair of the AASLD Hepatotoxicity Special
Interest Group



Walter Straus

默克公司临床安全和风险管理副总裁

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