2nd DIA China Cardiac Safety Workshop

June 19-20 | Beijing Vision Hotel

The Workshop will gather the top Cardiac experts to in-depth discuss the latest issues in Cardiac Safety from government agency, academia and industry perspectives.

Learning Objectives:

Keynote Lecture 1:
CV Safety in Basic and Clinical Research: From Ion Channels to Cell Based Assessments

Keynote Lecture 2:
Translational and Experimental Medicine Priority Areas
Session 1: Regulatory Sciences – CV Safety Coming of Age
Session 2: Early Phase Cardiac Safety Assessment
Session 3: Exposure-Response Modelling for IQT Study
Session 4: Non-Clinical CV Safety Assessments
Session 5: Translational and Experimental Medicine Approaches to Cardiac Safety
Session 6: Cardiac Safety Biomarker Development and Evaluation
Session 7: ECG Monitoring Beyond the QT Interval
Session 8: Cardio-Oncology and Beyond

Target Audience
• Drug development and clinical research managers and associates
• Pharmacovigilance, drug safety and drug surveillance personnel
• Pharmaceutical physicians and medical directors
• Safety pharmacology and non-clinical scientists
• Clinical pharmacology scientists
• Regulatory affairs officers
• Outsourcing and marketing managers
• Decision makers in cardiac drug safety, including toxicology, pharmacology and compliance

Program Co-Chairs
Haiyan LI, MD
Professor of Cardiology
Director, Drug Clinical Trial Center,
Peking University Third Hospital

Boaz MENDZELEVSKI, MD
Independent Consultant, Cardiac Safety Consultants Ltd.

http://en16961.eventdove.com/
Contact: Erning NING
Email: erning.ning@DIAglobal.org
Tel: +86. 10. 57042655
AGENDA | DAY 1 | Sunday, June 19

8:30 – 8:40 Chairman Welcome and Opening Comments
Haiyan LI, MD
Professor of Cardiology
Director, Drug Clinical Trial Center,
Peking University Third Hospital

8:40 – 9:20 Keynote Lecture: CV Safety in Basic and Clinical Research: From Ion Channels to Cell Based Assessments
Ganxin YAN, MD, PhD
Board-Certified Clinical Cardiologist and Electrophysiologist in USA, Professor of Medicine at Thomas Jefferson University, Professor at Lankenau Institute for Medical Research and Xi'an Jiaotong University

Session 1: Regulatory Sciences – CV Safety Coming of Age
Chair:
Boaz MENDZELEVSKI, MD
Independent Consultant, Cardiac Safety Consultants Ltd.

9:20 – 9:40 PMDA: Consolidating CV Safety in Japan
Kaori SHINAGAWA, MD, PhD
Senior Scientist for Clinical Medicine, Office of New Drug II, Pharmaceuticals and Medical Devices Agency

9:40 – 10:00 US FDA: The CiPA Initiative Update
David STRAUSS, MD, PhD
Senior Advisor, Translational and Experimental Medicine, Office of Clinical Pharmacology, CDER, FDA

10:00 – 10:20 EMA: The European Perspective of CV Safety
Krishna PRASAD, MD, FRCP
Group Manager, Consultant Cardiologist, Licensing Division, MHRA

10:20 – 10:40 H-Canada: Managing Shifting CV Safety Paradigms
Colette STRNADOVA, PhD
Senior Scientific Advisor, Therapeutic Products Directorate, Health Canada

10:40 – 10:50 Tea Break

Session 2: Early Phase Cardiac Safety Assessment

10:50 – 11:10 The TQT Waiver Application: Regulatory Position - Video
Jiang LIU, PhD
Scientific Lead of Interdisciplinary Review Team (IRT) for QT Division of Pharmacometrics, Office of Clinical Pharmacology Center for Drug Evaluation and Research, FDA

11:10 – 11:30 The E14 Analysis Versus the ER Modelling Approach
Jiang LIU, PhD
Scientific Lead of Interdisciplinary Review Team (IRT) for QT Division of Pharmacometrics, Office of Clinical Pharmacology Center for Drug Evaluation and Research, FDA

11:30 – 11:50 Panel Discussion
Moderator:
Yaning WANG, PhD

Invited Panelists:
Xinghe WANG, PhD
Beijing Shijitan Hospital

Jennifer HOU, MD, PhD
Medical Director, Beijing Estart Medical Technology Ltd.

Robert KLEIMAN, MD
Chief Medical Officer and Vice President, Global Cardiology, ERT

Boaz MENDZELEVSKI, MD
Independent Consultant, Cardiac Safety Consultants Ltd.

11:50 – 12:10 The Intensive QT (IQT) Study as a Substitute to the TQT Study
Jay MASON, MD
Chief Medical Officer, Spaulding Clinical Research, Professor of Medicine, University of Utah, USA

12:10 – 12:20 Q&A

12:20 – 13:30 Luncheon

2016 Quantitative Science Forum
August 14-15 | Beijing Xinjiang Plaza

http://en16957.eventdove.com/

Contact: Runshan Chen
Tel: +86. 10. 57042653
Email: runshan.chen@DIAglobal.org
Session 3: Exposure-Response Modelling for IQT Study

13:30 – 14:30 Panel Discussion: ER Modelling: What Is It and How Can It Support the IQT Approach and Does ER Modelling Obviate the Need for Assay Sensitivity?

Moderator:
Yaning WANG, PhD

Invited Panelists:
Luana Pesco KOPLOWITZ, MD, PhD
President and Chief Medical & Scientific Officer, DUCK FLATS, LLC, USA

Gailing LI, PhD
Director, Clinical Pharmacology & Experimental Medicine, Janssen Pharmaceutical R&D

Haiyan LI, MD
Professor of Cardiology
Director, Drug Clinical Trial Center, Peking University Third Hospital

14:30 – 14:50 Tea Break

Session 4: Non-Clinical CV Safety Assessments

14:50 – 15:10 CiPA: Overview and Objectives
Jufeng WANG, PhD
Director, National Center for Safety Evaluation of Drugs, National Institutes for Food and Drug Control

15:10 – 15:30 Stem Cell Proarrhythmia Assessment
Jufeng WANG, PhD
Director, National Center for Safety Evaluation of Drugs, National Institutes for Food and Drug Control

15:30 – 15:50 Ion Channel Proarrhythmia Assessment
Yanfang XU, PhD
Professor, Hebei Medical University

15:50 – 16:10 Preclinical Evaluation Methods for the Potential Effects of Drug Induced QT Prolongation
Xijie WANG, PhD
Senior Director, National Shanghai Center for New Drug Safety Evaluation and Research

16:10 – 16:30 Panel Discussion: The CiPA Paradigm for Predicting CV Risk in Humans
Moderator:
Jufeng WANG, PhD
Director, National Center for Safety Evaluation of Drugs, National Institutes for Food and Drug Control

Invited Panelists:
Kaori SHINAGAWA, MD, PhD
Senior Scientist for Clinical Medicine, Office of New Drug II, Pharmaceuticals and Medical Devices Agency

Krishna PRASAD, MD, FRCP
Group Manager, Consultant Cardiologist, Licensing Division, MHRA

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<tr>
<td>9:00 - 9:30</td>
<td>Keynote Lecture: Translational and Experimental Medicine Priority Areas - via Video</td>
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<td>David STRAUSS, MD, PhD</td>
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<td>Senior Advisor, Translational and Experimental Medicine, Office of Clinical Pharmacology, CDER, FDA</td>
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<td>9:30 - 9:50</td>
<td>Translating Non-Clinical CV Safety Assessments into Clinical Risk Management</td>
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<td>Haiyan LI, MD</td>
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<td>Director, Drug Clinical Trial Center, Peking University Third Hospital</td>
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<td>9:50 - 10:10</td>
<td>Coffee Break</td>
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<td>10:10 - 10:40</td>
<td>Development of Novel Biomarkers of Cardiac Safety – Scope and Outlook</td>
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<td>Jay W. MASON, MD</td>
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<td>Chief Medical Officer, Spaulding Clinical Research, Professor of Medicine, University of Utah, USA</td>
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<td>10:40 - 11:00</td>
<td>ECG Biomarkers for Proarrhythmia Assessment – Application to TQT or IQT Clinical Studies</td>
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<td>Robert KLEIMAN, MD</td>
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<td>Chief Medical Officer and Vice President, Global Cardiology, ERT</td>
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<td>11:00 - 11:20</td>
<td>Non ECG CV Safety Biomarkers</td>
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<td>11:20 - 12:00</td>
<td>Pane Discussion: Why are Non-QT CV Safety Biomarkers Still not Used in Clinical Development?</td>
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<td>Boaz MENDZELEVSKI, MD</td>
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<td>Independent Consultant, Cardiac Safety Consultants Ltd.</td>
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<td>12:00 - 13:00</td>
<td>Lunch Break</td>
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<td>13:00 - 13:20</td>
<td>Design of Alternative Early Phase QT Studies for Cytotoxic Compounds</td>
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<td>Weixian XU, MD, PhD</td>
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<td>Associate Professor of Cardiology</td>
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<td>14:30 - 14:50</td>
<td>Vascular Complications of Vascular Endothelial Growth Factor Receptors (VEGFR) Inhibitors</td>
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<td>Xinheng FENG, MD, PhD</td>
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<td>15:30 - 15:50</td>
<td>Late Onset Cardiotoxicity: Incidence, Risk and Prediction</td>
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<td>Director, Drug Clinical Trial Center, Peking University Third Hospital</td>
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<td>16:10 - 16:20</td>
<td>Chairman Summary and Closing Comments</td>
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Li Haiyan is a cardiovascular physician. She is the director of Clinical Trial Institution in Peking University Third Hospital. She also serves as the vice director in Peking University Biomedical Ethics Committee.

Li Haiyan's clinical major is vascular disease, especially coronary interventional diagnosis and treatment. She has rich clinical experience in hypertension, hyperlipidemia, heart failure and cardiovascular emergency rescue.

Li visited Intravascular Ultrasound Central Lab and Cardiac Catheterization Lab in University of California at Los Angeles (USLA) as a visiting scholar. During that time, she issued four SCI articles, two of which were published in international cardiovascular journal. As a principal researcher, Li participated in more than 30 clinical trials involving thrombolytic drugs, anti-hypertensive drugs, lipid lowering drugs, anti-heart failure drugs, coronary heart disease drugs, etc. She participated in several clinical trials based on international multi-center and completed drug trials from Phase I to Phase IV. She has abundant experience in organizing, managing, and carrying out clinical drug trials. She published more than 30 professional articles. In 2008, she got support from GCP platform of “Significant New Drug” of National Science and Technology Project.
Boaz MENDZELEVSKI 博士 / MD
美国BioClinica公司心脏病学部副总裁
Vice President of Cardiology, BioClinica Inc., USA

Boaz Mendzelevski, MD is a consultant cardiologists and Vice President of Cardiology for BioClinica.

Dr Mendzelevski received his degree in Medicine and Board Certification in Internal Medicine from the Ben-Gurion University Medical School and Soroka Medical Center in Beer-Sheva, Israel. He then obtained his Board Certification in Cardiology from the Shaare-Zedek Medical Centre in Jerusalem, Israel. He completed his subspecialty training in Interventional Cardiology and Electrophysiology at the Royal Brompton National Heart and Lung Hospital and the University of London, both in London, UK.

Dr Mendzelevski was a co-founder of Cardiac Alert Ltd, the first European core ECG lab in London UK, which was later acquired by a Quintiles Transnational and became Quintiles Cardiac Safety Services (QCSS or QECG).

Dr Mendzelevski served as Chief Medical Officer and Vice President of Cardiology for Quintiles and later joined Covance to launch its European Cardiac Safety Services. In 2008 he joined Medifacts International which, following merger activities, became CoreLab Partners and more recently BioClinica.

Dr Mendzelevski is a consultant to the pharmaceutical and biotechnology industry and provides expert input regarding cardiovascular safety in drug development. He has published in several journals and authored over 250 cardiology expert reports, most of which supported NDA regulatory submissions. He has been a member of multiple DSMBs and DMCs and provides input on safety issue to the industry and regulatory agencies.

Dr. Mendzelevski’s research interests involve CV Safety of new drugs in development, including drug induced QT prolongation and arrhythmia and cancer therapy cardiotoxicity. He supported the development of the ICH-E14 cardiac safety guidance and the implementation of ICH-E14 in US, Europe and Japan. He chaired or co-chaired the European DIA Cardiac Safety Conferences since 2006 and the US DIA/FDA CV Safety conference in Type 2 Diabetes compounds, has co-chaired sessions at the ICOS and CSRC annual meetings and the DIA/ICOS Cardio-Oncology Conference and is chairing and co-chairing the Annual DIA-Japan Cardiac Safety Workshops since 2010. He is a regular speaker and chairperson at other scientific and industry meetings.
Dr. Gan-Xin Yan is a board-certified clinical cardiologist and electrophysiologist in USA, Professor of Medicine at Thomas Jefferson University, Professor at Lankenau Institute for Medical Research and Xi’an Jiaotong University. Dr. Yan is also an adjunct professor of Temple University, Shanghai Jiaotong University, Huazhong University of Science and Technology, Ximen University and Zhengzhou University.

Dr. Yan is the pioneer who created the cardiac wedge preparation that has been used in universities, research institutes and pharmaceutical industries over the world. He has received research or drug service grants from many international pharmaceutical companies including Johnson & Johnson, GlaxoSmithKline Novartis, Gilead, Pfizer, Astellas, Roche, AstraZeneca etc. He has published more than 100 peer-reviewed scientific papers in basic and clinical cardiology and electrophysiology that have been widely cited (Google citations>11000). In 1996, he, with Dr. Antzelevitch, names the Brugada syndrome. He is also the first person who named J wave syndromes in 2004. He is currently on the Editorial Boards of Heart Rhythm, Cardiology and Journal of Cardiovascular Electrophysiology. He is the Editors of the textbooks of “Management of Cardiac Arrhythmias” (2012) and “J Wave syndromes (2016, in press).”

Dr. Kaori Shinagawa majored in internal medicine, with an emphasis on cardiology. After graduating from National Saga Medical School in 1992, she conducted medical examinations and patients treatments including clinical electrophysiological studies as a cardiologist. She received her doctoral degree of Medical Science in 2000. Her main research field was to investigate the electrophysiological mechanisms and pharmacological treatment of atrial fibrillation, and she was a postdoctoral fellow of Dr. Stanley Nattel’s laboratory at Montreal Heart Institute from 1999 to 2002. She worked as a cardiologist at Eiju general hospital from 2002 to 2005.

Since March 2005, she has been working at the Pharmaceuticals and Medical Devices Agency (PMDA). She is currently Senior Scientist for Clinical Medicine, PMDA. She has been involved mainly in the review and consultation of new cardiovascular drugs, and creating new guidelines for Japanese drug application. She has also been involved in International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) activities since 2005 including E14 topic. She has authored over six papers for a variety of cardiovascular journals. Dr. Shinagawa’s findings have been featured in Circulation, J Am Coll Cardiol, PACE, and Cardiovascular Res.

She also received Kimura Memorial Award from the Japanese Heart Rhythm Society in 2000.
David STRAUSS MD, PhD
Senior Advisor, Translational and Experimental Medicine,
Office of Clinical Pharmacology, CDER, FDA

Dr. Strauss received both a B.A. in chemistry and M.D. from Duke University, and a Ph.D. in clinical physiology from Lund University, Sweden. He has published 90 peer-reviewed journal articles and book chapters and has led regulatory science research since joining FDA in 2010. He currently serves as the Senior Advisor for Translational and Experimental Medicine in the Office of Clinical Pharmacology, where he provides strategic, scientific, and operational leadership in several priority areas including early pharmacology studies, biomarker development and evaluation, disease and pharmacologic modeling, induced pluripotent stem cell research and silico modeling. Additionally, Dr. Strauss oversees and coordinates FDA’s research activities supporting the Comprehensive In Vitro Proarrhythmia Assay (CiPA) Initiative and has led two FDA-sponsored clinical trials to study novel ECG biomarkers that can be applied in phase 1 clinical trials using exposure-response modeling.

Colette STRNADOVA PhD
Senior Scientific Advisor, Therapeutic Products Directorate, Health Canada

Dr. Colette Strnadova is a senior scientific advisor with the Therapeutic Products Directorate of Health Canada. Her professional responsibilities include cardiac safety consultations for drug submissions. Dr. Strnadova served as the Health Canada representative on two International Conference on Harmonisation (ICH) guideline projects: the ICH S7B guideline, which deals with the assessment of the potential for delayed ventricular repolarization in safety pharmacology studies, and the ICH E14 guideline, which deals with the assessment of QTc interval prolongation liability in clinical trials. She has also developed Health Canada guidance documents on the analysis and review of QTc data and Product Monograph content for drugs with QTc prolongation liability. Dr. Strnadova currently serves as the Health Canada representative on the Cardiac Safety Research Consortium (CSRC) Executive Committee, the ICH E14/S7B Working Group, and the ILSI Health and Environmental Sciences Institute Cardiac Safety Committee.
Krishna PRASAD 医学博士 / MB, BS, MD, FRCP

Group Manager, Consultant Cardiologist, Licensing Division, MHRA

Currently, I have dual role at the MHRA, the UK regulatory Agency as an Interim Group Manager for several therapeutic areas and an Expert Assessor. I am a practising cardiologist with a special interest in cardiovascular genetics and personalised medicine. I represent the MHRA on the Cardiovascular Working party of the CHMP/EMEA as well as serving as the regulatory chair and the Co-rapp for the E-14 Implementation expert group. I have been involved in E-14 implementation and the Discussion groups. Currently I chair the pharmacogenomics working party of CHMP having been a member since its formal inception. More recently, I have been nominated as the Regulatory chair for the ICH E-18 genomics expert group.

Prior to joining the MHRA, I worked as a BHF supported Research Fellow and Lecturer in Cardiology. My Special areas of interest are heart failure, arrhythmias and sudden death where I was involved in research as an academic, with a number of publications. Areas of interest outside of cardiology are Pharmacogenetics/pharmacogenomics, stratified medicine and drug innovation. I am an author of abstracts, publications including peer review papers, book chapters and editorials. I have an interest in development of regulatory guidance and in enhancing the interaction between academia, regulators and the other stakeholders.

刘江 博士 / Jiang LIU, PhD

Scientific Lead of Interdisciplinary Review Team (IRT) for QT
Division of Pharmacometrics, Office of Clinical Pharmacology,
Center for Drug Evaluation and Research, FDA

Dr. Jiang Liu is a scientific lead of the interdisciplinary review team for QT, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). He received his Ph.D. in Pharmaceutical Science and M.S. in Statistics from the University of Florida, U.S. He had also earned a M.S. in Bioinformatics and a M.S. in Microbiology and Immunology. His work in the FDA focuses on drug cardiac safety assessment and other drug development issues involving pharmacometrics in multiple therapeutic areas which include antiviral products, anti-infective products, transplant and ophthalmology products, cardiovascular and renal products, bone, reproductive and urologic products, hematology and oncology products, and dermatology and dental products. He is also the primary contact of drug development for medical counter measures (MCM) within the division of Pharmacometrics. He has developed strong expertise in drug development and clinical trial designs in the above areas. Dr. Liu has deeply involved in the development of FDA Guidance for Industry in multiple areas. His works on hepatitis C has made significant influence on the current HCV drug development design and regulatory decisions. He has received multiple academic honors including AAPS Regulatory Science Award and FDA Outstanding Service Award. He has published various peer-reviewed papers and book chapters, edited/reviewed for many academic journals, trained several postgraduate fellows, and served as an evaluation expert for organizations such as European Commission (FP7).
Jay W. MASON MD
医学博士 / MD
美国犹他大学斯波尔丁临床研究首席医学官，内科教授
Chief Medical Officer, Spaulding Clinical Research,
Professor of Medicine, University of Utah, USA

Dr. Mason is Professor of Medicine (Cardiology) at the University of Utah, Chief Medical Officer at Spaulding Clinical Research, and an independent consultant in cardiac safety. He obtained his undergraduate degree at Princeton University and his MD degree at the University of Pennsylvania. Dr. Mason trained in Medicine and Cardiovascular Diseases at Stanford University where he was a member of the Faculty from 1975 to 1983 and served as Director of the Cardiac Arrhythmia Service and Co-director of the Cardiac Catheterization Laboratories. He became Chief of Cardiology at the University of Utah in 1983. In 1999 he was appointed Chairman of the Department of Medicine at the University of Kentucky. From 2003 to 2007 he served as Medical Director and Director of R&D at Covance Cardiac Safety Services. His clinical, teaching and research emphasis is in cardiac arrhythmias, electrocardiography and electrophysiology. Dr. Mason chaired the American College of Cardiology’s electrocardiography educational committees for over 20 years and currently chairs or serves on several nationally sponsored safety monitoring boards and scientific initiatives. He has been awarded more than $29M in NIH support during his research career and is author of over 450 research publications.

Wang Yaning PhD
王亚宁 博士 / Yaning WANG, PhD
美国FDA药品审评与研究中心临床药理学部执行副主任
Acting Director and Deputy Director, Division of Pharmacometrics, the Office of Clinical Pharmacology, FDA

Dr. Yaning Wang is currently the Acting Director and Deputy Director in the Division of Pharmacometrics in the Office of Clinical Pharmacology at FDA. Before joining FDA, Dr. Wang received his Ph.D. in Pharmaceutics and master’s degree in Statistics from the University of Florida from 1999 to 2003. He also obtained a master’s degree in Biochemistry (1999) from National Doping Control Center and a bachelor’s degree in Pharmacy (1996) from Peking University in China. At his current position, Dr. Wang oversees the scientific aspects of reviews, research projects, and policy development within the Division of Pharmacometrics for all disease areas. During his thirteen years of service at FDA, Dr. Wang received numerous awards, including Award of Merit (the most prestigious honor awarded at FDA) and FDA Outstanding Service Award. Dr. Wang is an Adjunct Professor in the Department of Pharmaceutics at the University of Florida, the School of Pharmacy at Health Science Center in Peking University, Peking University Clinical Research Institute and an invited lecturer in the College of Engineering and College of Pharmacy at the University of Michigan. Dr. Wang is the chair of the FDA working group to draft a new guidance for the industry to optimize dose selection during the clinical development stage. Dr. Wang has been on the FDA Regulatory Science and Review Enhancement (RSR) Review Committee for five years. Dr. Wang has been the lead on multiple consults from other FDA offices/centers such as Office of Generic Drug (OGD) and Center for Devices and Radiological Health (CDRH). Dr. Wang serves as the expert reviewer for grant applications to National Institutes of Health (NIH), U.S. Department of Health and Human Services. Dr. Wang served as a committee member for multiple Ph.D. candidates from various universities. He mentored more than thirty former research fellows (visiting scholars, post-doctoral scholars, and Ph.D. candidates) at FDA. Dr. Wang is an invited manuscript reviewer for seventeen scientific journals in the medical, pharmaceutical and statistical areas. He has published 53 papers and given 117 presentations at various national and international meetings. He is a member of the Advisory Committee for Chinese Pharmacometrics Society and a member of the Editorial Advisory Board for the Journal of Pharmacokinetics and Pharmacodynamics. He is also on Board of Directors for International Society of Pharmacometrics (ISoP).
汪巨峰 博士 / Jufeng WANG, PhD
中国食品药品检定研究院国家药物安全评价监测中心主任，研究员
Director, National Center for Safety Evaluation of Drugs,
National Institutes for Food and Drug Control

汪巨峰，药理学博士，中国食品药品检定研究院国家药物安全评价监测中心主任，研究员，中国毒理学会药物毒理与安全性评价专业委员会常务委员，副秘书长。中国毒理学会理事，北京经济技术开发区生物医药产业顾问，美国毒理学会会员。

在美国从事博士后研究及新药研发和安全评价工作近20年。获美国大学心脏协会2001年度“优秀青年科技工作者”奖及17届世界心脏研究大会优秀奖章。2004年进入美国制药企业主要从事新药开发的药效学和安全评价工作，为新药开发研究提供药理学、安全药理学和毒理学的评价规则。在国内外期刊杂志上发表学术论文50多篇，并参与二部专著的编写。

许彦芳 教授 / Yanfang XU
河北医科大学药理教研室副主任


汪溪洁 博士 / Xijie WANG, PhD
国家上海新药安全评价研究中心SD兼科研部部长
Senior Director, National Shanghai Center for New Drug Safety Evaluation and Research

汪溪洁，副研究员，硕士生导师，国家上海新药安全评价研究中心科研管理部部长兼一般毒理部专题负责人。2002年毕业于南京医科大学预防医学专业，获学士学位，2005年和2008年先后获南京医科大学卫生毒理学专业硕士和博士学位。主要从事新药非临床安全性评价工作，负责完成了化药、中药或生物药的非临床安全性评价研究100余项。擅长药物心脏毒性研究和评价，尤其在体外心脏毒性评价方面积累了比较丰富的经验。
Robert KLEIMAN 博士 / MD
ERT全球心血管病学首席科学官及副总裁
Chief Medical Officer and Vice President, Global Cardiology, ERT

Dr. Robert Kleiman is a board certified cardiologist and cardiac electrophysiologist who has performed research in both basic cellular electrophysiology as well as clinical electrophysiology. Dr. Kleiman completed his training at the University of Pennsylvania and was a member of a cardiology practice for 12 years before joining ERT in 2003. Dr. Kleiman is currently ERT’s Chief Medical Officer and Vice President, Global Cardiology. His responsibilities include oversight of ERT’s cardiology services, consulting with external clients and managing overall satisfaction of ERT’s global customers, including all aspects of ERT’s solutions.

华烨 医学博士 / Ye HUA, MD
和记黄埔药业临床开发和药政事务部高级副总裁兼负责人
Senior Vice President, Head Clinical Development & Regulatory Affairs, Hutchison MediPharma

Ye Hua, MD, MPH is Senior VP, Head of Clinical Development and Regulatory Affairs at Hutchison MediPharm, a novel drug R&D company focusing on drug discovery and development for innovative therapies in oncology and autoimmune diseases. Managing the clinical and regulatory organization, Dr. Hua is responsible for advancing clinical development pipeline and registering new drugs in China and ex-China. Under his leadership, the clinical development programs have grown from 5 small molecules in 7 Phase I oncology clinical trials to 8 small molecules in 31 Phase 1-3 clinical trials in oncology and immunology in China, Australia, and USA.

Native from Shanghai, Dr. Hua graduated from Fudan University Shanghai Medical College in 1992. He worked as a cancer epidemiologist at Shanghai Cancer Institute between 1992 and 1996, and then went to McGill University in Montreal Canada to pursue a Master Degree in cancer epidemiology.

Dr. Hua is a senior clinical research physician who has over seventeen years’ global clinical development and new drug registration experience in the pharmaceutical industry. He started his career in the pharmaceutical industry as a biostatistician at Pharmacia & Upjohn in 1999, and worked through the rank in biostatistics. His most significant achievement being the statistical team leader for the pivotal Phase 3 RA registration trial of Humira that won regulatory approval in the US and EU.

Often contributed to clinical programs beyond his role in statistics, Dr. Hua was well recognized and greatly appreciated by cross-functional development teams. In 2004, one year after joining Novartis, Dr. Hua successfully switched career track back to clinical. Being a medical monitor, he led a number of global Phase II/III registration trials in osteoarthritis, osteoporosis, infectious diseases, oncology and hematology disease areas. As clinical project leader, Dr. Hua contributed to the regulatory approval and life-cycle management for Reclast/Aclasta, Prexige, Zometa, Femara, Proleukin and Cardioxane in the US and EU. His last job in the US was Senior Director, Global Clinical Development, Celgene Corporation where he led several global clinical teams for Revlimid and Pomalyst NDA/sNDA in multiple myeloma indication, and eventually obtained regulatory approval in the US and EU. In addition, he led clinical subteam executed registration trials for Revlimid and Pomalyst in China, and successfully obtained Revlimid regulatory approval in multiple myeloma indication.
徐伟仙  医学博士，副主任医师 / Weixian XU, MD, PhD
北京大学第三医院副主任医师，副教授
Associate Professor of Cardiology, Peking University Third Hospital

长期从事心内科临床诊疗工作，专业方向为超声心动图，主攻工作压力、焦虑及抑郁等慢性心理应激对心血管疾病的影响及干预。在高血压、高血脂、冠心病、心力衰竭、心律失常等疾病的诊疗治疗上积累了比较丰富的临床经验。曾经在美国杜克大学临床研究所及国家药监局药审中心学习工作，特别关注抗肿瘤药物的心血管毒性。

冯新恒  医学博士 / Xinheng FENG, MD, PhD
北京大学第三医院心血管内科主任医师
Professor of Cardiology, Peking University Third Hospital

硕士研究生，主任医师，硕士研究生导师。近年来主要从事心内科临床、教学及科研工作，对心内科疾病及心内科疾病合并心身疾病的诊治有一定经验，在超声心动图评价心血管疾病方面积累了丰富的经验。
王兴河 医学博士 / Xinghe WANG, MD, PhD
主任医师,教授,首都医科大学附属北京世纪坛医院药物I期临床试验研究室主任
Professor, Director, Phase I, Drug Clinical Trial Center, Beijing Shijitan Hospital


The director of the center, Professor Xinghe Wang, M.D. has over 30 years of experience in clinical drug development and Phase I-IV clinical trial design, particularly in anticancer IND Phase 0 and Phase I clinical trials as well as drug-induced QT interval prolongation clinical study. He has been with Beijing Shijitan Hospital Capital Medical University/Capital Medical University School of Oncology/ Ninth Clinical Medical College of Beijing University since 2012. He has over 12 years of experience working in United State since 2000, including 7 years of industry experience with NDT Company as Chief Scientist, 2 years as a Senior Scientist, and 2 years of postdoctoral work at the University of Utah and Indiana University School of Medicine.

He has conducted postdoctoral research at the Institute for Clinical Pharmacological Research of Beijing Medical University, after receiving his Ph.D. degree from Shanghai Medical University and his M.D degree from Norman Bethune Medical University. He is a member of the American Association for Cancer Research, American Association of Pharmaceutical Scientists, American Association for the Advancement of Science and others.
侯杰，医学博士
北京易启医药科技有限公司首席医学官

Dr. Jie Hou has over 20 years experiences on clinical pharmacology research. She started Phase I, Phase II and phase III in Institute of Clinical Pharmacology, Peking University from 1989. She has completed more than 50 studied including Phase I trial, PK, BE study, Phase II/III studies, published more than 30 papers.

She participated in “Guideline for Phase I clinical trial management” drafting and “Guideline for clinical bioanalytical lab management” drafting in 2010-2012, Released in December 2012; “Guidance for First In Human” drafting in 2013 and “Guidance for QTc study in early phase” drafting in 2014 for CFDA.

She focused on cardiovascular clinical pharmacology since 2002 in US and participated in a number of QTc studies.

She was appointed as the director of Phase I Clinical Trial Center in TEDA International Cardiovascular Hospital (TICH) and the early phase director of Fountain Medical Technology Development Ltd. (FMD) since 2008, responsible for establishing TJAB clinical platform of Phase I Center and central lab according to international standard. In less than five years to TICH’s clinical trial unit and phase I center from zero to become the leading ranks. Recently, more than 30 studies including phase I trials of class I INDs and BE studies has been finished. More than 10 trials of the FIH and first TQT study in China have been completed.

So far she is CMO, Beijing Estart Medical Technology Ltd.
Luana R. C. PESCO KOPLOWITZ 医学博士 / MD, PhD, FCP, FFPM
美国DUCK FLATS, LLC总裁兼首席医学及科学官
President and Chief Medical & Scientific Officer, DUCK FLATS, LLC, USA

Luana Pesco Koplowitz received her MD from Rutgers Medical School and her PhD from Rutgers College of Pharmacy and Columbia Pacific University. She completed her training in clinical pharmacology at the University of Miami School of Medicine. She is adjunct Professor of Medicine, Department of Internal Medicine at the University of Delaware Medical School teaching hospital and is also adjunct faculty at the University of Miami Medical School, Department of Internal Medicine, Division of Clinical Pharmacology. She is a fellow of the American College of Clinical Pharmacology and also a member and fellow of the Faculty of Pharmaceutical Medicine of the United Kingdom.

Currently, Dr. Pesco Koplowitz is President and Chief Medical & Scientific Officer of DUCK FLATS Pharma, LLC (Elbridge, NY), a consulting and contract company which specializes in adult and pediatric translational medicine, clinical pharmacokinetics and nonclinical development. Dr. Pesco Koplowitz has received numerous awards in clinical research throughout her career and is a member of numerous medical and clinical pharmacology organizations and committees. She has served on the FDA/PhRMA QT Working Group Committee. Since 2007, she has been a member of the Advisory Committee of the Cardiac Safety Research Consortium (CSRC), which is an FDA/Academia/Pharma committee to help set regulatory policy for drug development research with respect to cardiovascular safety. Since 2015, she is also an invited member of the International Neonatal Consortium of the Critical Path Institute for FDA/EMA.

Dr. Pesco Koplowitz held the position of Global Group Director of Clinical Pharmacology and US Nonclinical Development for the Janssen Research Foundation of Johnson & Johnson. She has worked at Knoll Pharmaceuticals, Fujisawa Pharmaceutical Company (now Astellas Pharmaceuticals), the Squibb Institute for Medical Research (now Bristol-Myers Squibb) and Key Pharmaceuticals (now Merck). She is a frequently-invited speaker and lecturer in overall drug development in adult and pediatric patients, translational medicine, neonatal medicine, clinical pharmacology and cardiovascular safety.

Dr. Pesco Koplowitz has been responsible for numerous successful INDs and NDAs/CTDs in multiple therapeutic areas during her 30-plus year career and holds several use patents in the treatment of various diseases. She is author or co-author on over 30 publications and is a reviewer for the Journal of Clinical Pharmacology.