



1st BOAO INTERNATIONAL CONFERENCE ON
REAL WORLD STUDIES
OF MEDICAL PRODUCTS

第一届博鳌国际药械真实世界研究大会

会议手册

CONFERENCE MANUAL

2022年12月8日 Dec.8, 2022

中国·博鳌 | Boao · China



海南自由贸易港 博鳌乐城国际医疗旅游先行区简介

海南自由贸易港博鳌乐城国际医疗旅游先行区（以下简称“乐城先行区”）是全国唯一的“医疗特区”，位于海南省琼海市，临近博鳌亚洲论坛核心区。2013年2月28日，国务院批复同意设立乐城先行区，并赋予九项独一无二的支持政策，可概括为“四个特许”：特许医疗、特许研究、特许经营和特许国际交流。经国务院批准同意，国家发展改革委、卫生健康委、商务部、中医药管理局、药品监督管理局等多部门，又先后赋予了乐城先行区一系列的特殊优惠政策。

2018年4月11日，习近平总书记莅临乐城先行区考察并作出重要指示：实现“两个一百年”奋斗目标，要坚持以人民为中心的发展思想，经济要发展，健康要上去，人民的获得感、幸福感、安全感都离不开健康，要大力发展健康事业，要做身体健康的民族。乐城先行区始终牢记习近平总书记殷切嘱托，坚持“以人民为中心”发展理念，围绕“一本三基四梁八柱”战略框架，践行让中国人尽快用上全世界最先进的药械、推动中国健康产业发展、助推中国医疗卫生事业改革“三大使命”，聚焦医院、医生、患者、先进药械和监管“五要素”，以制度集成创新推动政策红利加快释放、营商环境不断优化，吸引医疗机构、药械企业、医学院校、CRO组织、保险公司等优质产业资源纷纷聚集，乐城先行区的金字招牌效应不断彰显，已从政策高地成为健康产业创新发展高地。

乐城先行区坚持以制度创新为核心驱动，持续释放高质量发展的活力动力。从政策突破、产业建设到创新引领，乐城先行区创造了全国或全省多个“第一”或“唯一”：国内第一个率先成立医疗药品监督管理局，试点“医疗+药品”二合一监管改革；创建国内第一个未上市特许药械全流程追溯平台，实现对进口特许药械全流程的实时跟踪监管；创立国内唯一的特许药械保税仓，大幅提高特许药械进口效率；建设全国唯一一个汇集全球创新药械的长期展示馆——“永不落幕”国际创新药械展，吸引了来自16个国家的80家全球国际创新药械厂商参展；打造国内唯一的“全球特药险”，推动“医、保、药”产业生态体系构建；发布海南自贸港第一个园区制度集成创新改革方案；出台第一部海南自贸港单行条例《海南自由贸易港博鳌乐城国际医疗旅游先行区条例》，以立法促进乐城先行区高水平改革开放。

乐城先行区目前已有24家医疗机构开业运营，25家医疗机构在建或筹建。乐城先行区国际影响力持续提升，吸引了各大跨国药企、国际知名医疗机构、医疗园区和国际人才的目光，加快成为全球创新创业的热土。2020年12月，国务院办公厅公布第三批大众创业万众创新示范基地名单，乐城先行区作为海南唯一单位成功入选（全球化创业方向）。

乐城先行区已和世界排名前30强的药械企业建立直接合作，引进使用的未在国内上市的国外创新药械超270种，基本实现医疗技术、装备、药品与国际先进水平“三同步”，成为国际创新药械产品率先进入中国市场的最主要通道，为建设医疗领域开放新高地和国内国际双循环重要窗口打下坚实基础，加快满足人民群众日益增长的医疗健康需求。

真实世界研究是国家药品监管科学行动计划的重要组成部分，也是海南自贸港的重大制度创新之一。乐城先行区在全国率先开展临床真实世界数据应用试点工作，为国际创新药械加速进入中国市场提供“绿色通道”，对药械注册监管改革具有深远意义。成立海南省真实世界数据研究院，承担国家药监局药品医疗器械监管科学研究基地相关工作。建立我国首个真实世界研究重点实验室——国家药监局海南真实世界数据研究与评价重点实验室。结合乐城先行区实际打造了中国首个区域性真实世界数据收集、治理和应用平台，具有机制创新、技术创新、监管创新、服务创新四大特点，是我国建立真实世界研究新标准、新方法、新工具的一次重要实践和探索。作为新兴的跨学科领域，真实世界研究涉及临床医疗、生物统计、信息数据等交叉学科，为加强人才培养，乐城先行区与海南大学合作开设了全国首个以“真实世界数据应用”为培养目标的多学科、跨领域的硕博研究生培养点，打造我国真实世界研究领域高端人才培养基地。

乐城先行区临床真实世界数据应用试点工作自开展以来，已有6款医疗器械和3款药品产品，通过使用乐城真实世界数据辅助临床评价获得国家药监局注册批准，加快其在中国上市速度。乐城临床真实世界数据应用试点工作为国家药监局将真实世界数据用于药品医疗器械临床评价的监管决策以及制定相关指导原则等法规和标准奠定坚实的实践基础，为中国药品医疗器械审评审批制度改革、加快国外创新医疗产品在中国注册审批、让更多中国病患受益贡献了乐城智慧和海南力量。

海南自由贸易港建设中的乐城先行区，改革不停歇，创新不止步。到2025年，乐城先行区将在建设特色技术先进临床医学中心、尖端医学技术研发转化基地等方面取得突破性进展，实现医疗技术、装备、药品与国际先进水平“三同步”。到2030年，医疗服务及科研达到国内领先、国际先进水平，充分形成产业集聚和品牌效应，建设成为世界一流的国际医疗旅游目的地和医疗科技创新平台。

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欢迎辞

真实世界研究（RWS）在药械研发及监管决策方面的作用越来越被认可，正日益受到全球监管机构和药械企业的关注，也为中国药械审评审批制度改革提供新的途径和方法。目前，我国在真实世界研究领域的探索稳步快速前进。为顺应发展的需求，充分发挥海南自由贸易港博鳌乐城国际医疗旅游先行区临床急需进口药械政策、国家药监局药品医疗器械监管科学研究基地（海南省真实世界数据研究院）和海南真实世界数据研究与评价重点实验室等资源优势，在国家药监局的大力支持下，海南省人民政府以海南博鳌作为永久会址，举办年度“博鳌国际药械真实世界研究大会”。

第一届博鳌国际药械真实世界研究大会将于12月8日在博鳌亚洲论坛国际会议中心举行。本次会议由海南省人民政府主办，国家药品监督管理局支持，海南博鳌乐城国际医疗旅游先行区管理局、海南省药品监督管理局、海南省卫生健康委员会、中国食品药品国际交流中心承办。

本届大会主题为“真实世界数据研究与药械监管创新发展”。大会设主论坛及八个平行论坛，汇集国内外药械监管机构、科研院所、医疗机构、学会协会、药械企业等资源，共同搭建真实世界研究交流平台。希望通过“博鳌国际药械真实世界研究大会”，展现国内外阶段性研究成果，促进政府部门、学术界、产业界的沟通与对话，形成合力共同推动将真实世界数据/证据用于药物研发与监管决策。“博鳌国际药械真实世界研究大会”愿发出声音、凝聚共识、形成方案，促进监管机构、科研院所、医疗机构、药械企业等多方共同思考、共同谋划、共同行动，推动真实世界研究成为我国医药产业发展的新引擎！

海南自由贸易港博鳌乐城国际医疗旅游先行区欢迎您的到来！

Welcoming Speech

As its role in medical product R&D and regulatory decision-making is increasingly recognized, real-world studies (RWS) draws more and more attention from regulatory agencies and medical product companies all over the world, and it will become a new path towards the reform of the medical product review and approval system in China. At present, China is making steady and fast headway with RWS. In alignment with the development trend, the People's Government of Hainan Province will host the Boao International Conference on Real-world Studies of Medical Products annually at the permanent venue of Boao, in a bid to bring into full play Lecheng Pilot Zone's policies for imported drugs addressing urgent clinical needs, and its status as the National Medical Products Administration (NMPA) base for scientific research in drugs and medical devices regulation (Hainan Institute of Real World Data) and as NMPA Key Laboratory for Real World Data Research and Evaluation in Hainan.

The 1st Boao International Conference on Real-world Studies of Medical Products will be held in Boao Forum for Asia (BFA) International Convention Center on Dec.8th,2022. The conference is hosted by the People's Government of Hainan Province, supported by the National Medical Products Administration (NMPA), and organized by the Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration (Lecheng Pilot Zone), Hainan Medical Products Administration, Hainan Health Commission, and China Center for Food and Drug International Exchange.

The theme of this conference is "real-world data studies and innovation and development of medical product regulation". The conference consists of one main forum and eight sub-forums.It brings together domestic and foreign pharmaceutical and medical device regulatory agencies, colleges and universities, scientific research institutes, medical institutions, societies and associations and pharmaceutical companies and serves a platform for exchanges on real-world studies. It is hoped that through the Boao International Conference on Real-world Studies of Medical Products, we can showcase domestic and overseas research outcomes that have been achieved so far, promote communication and dialogue between government departments, academia and industry, and jointly promote the use of clinical real-world data for drug and medical device product registration and regulatory decision-making. The Boao International Conference on Real-world Studies of Medical Products is a great opportunity for us to make ourselves heard, build consensus and develop plans, and also promote regulatory agencies, scientific research institutes, universities, medical institutions and medical device companies, and stakeholders to think, explore and act together, for the purpose of steering RWS to become a new engine for the development of China's pharmaceutical industry!

Welcome to Boao Lecheng International Medical Tourism Pilot Zone of Hainan Free Trade Port!



大会组织机构

主办单位

海南省人民政府

支持单位

国家药品监督管理局

承办单位

海南博鳌乐城国际医疗旅游先行区管理局

海南省药品监督管理局

海南省卫生健康委员会

中国食品药品国际交流中心

协办单位

国家药监局药品审评中心

国家药监局医疗器械技术审评中心

中国健康传媒集团

国家药监局南方医药经济研究所

中国药品监督管理研究会

中国医学科学院

中华医学会

世界中医药学会联合会真实世界研究专委会

北京大学医学部

北京中医药大学

上海交通大学医学院附属瑞金医院

四川大学华西医院

温州医科大学附属眼视光医院

国家药监局海南真实世界数据研究与评价重点实验室

中国工程科技发展战略海南研究所

中共海南省委外事工作委员会办公室

海南大学

海南省真实世界数据研究院

海口国家高新技术产业开发区

Organization

Host

The People's Government of Hainan Province

Supporter

National Medical Products Administration (NMPA)

Organizers

Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration

Hainan Medical Products Administration

Hainan Provincial Health Commission

China Center for Food and Drug International Exchange

Co-organizers

Center for Drug Evaluation, NMPA

Center for Medical Device Evaluation, NMPA

China Health Media Group

National Medical Products Administration Institute of Medical Economics

China Society for Drug Regulation

Chinese Academy of Medical Sciences

Chinese Medical Association

Specialty Committee of Real-World Study, World Federation of Chinese Medicine Societies

Peking University Health Science Center

Beijing University of Chinese Medicine

Ruijin Hospital, Shanghai Jiao Tong University School of Medicine

West China Hospital, Sichuan University

Eye Hospital, Wenzhou Medical University

NMPA Key Laboratory for Real World Data Research and Evaluation in Hainan

Hainan Research Institute of Chinese Engineering Science and Technology strategy for Development

Foreign Affairs Office of Hainan Province, The People's Republic of China

Hainan University

Hainan Institute of Real-World Data

Haikou National Hi-Tech Industrial Development Zone



大会导览

报到处

时 间: 12月7日 10:00-18:00
12月8日 08:30-12:00

地 点: 博鳌亚洲论坛会议中心大酒店 二层 大堂

用餐区导航

日期	时间	类型	地点
12月8日	12:00-13:30	自助午餐	博鳌亚洲论坛会议中心大酒店一层怡景西餐厅

会议直播

本次会议采用主论坛线上线下相结合（海南博鳌会场）+ 分论坛线上直播的形式召开
会议视频回放截止观看时间：12月23日

观看方式

大会官网：www.lechengrws.com



可凭注册的手机号 / 邮箱观看大会精彩直播

联系人

会议秘书处: 崔娟 18201072113
住宿联系人: 苏婷婷 13718500120
嘉宾服务联系人: 范瑶 18310091583

Conference Navigation

Registration

Time: 10:00-20:00, Dec 7
08:30-12:00, Dec 8

Venue: 2nd floor lobby, Boao Forum for Asia (BFA) International Convention Center

Dining

Date	Time	Type	Venue
Dec 8	12:00-13:30	Lunch buffet	Yijing Restaurant on the 1st Floor, BFA International Convention Center

How to watch

The conference will be held in the form of hybrid online and offline main forum (BFA venue in Hainan) + online live broadcast of the Sub-Forums.
The deadline for viewing the video replay of the conference is December 23.

How to watch:
Official website of the conference: www.lechengrws.com



You can watch the conference live with your registered mobile phone number/email address.

Contacts

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Accommodation: Su Tingting : +86-13718500120
Guests: Fan Yao : +86-18310091583

东屿岛

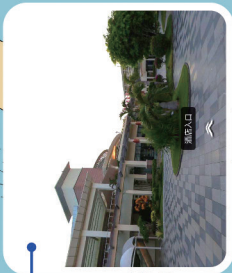
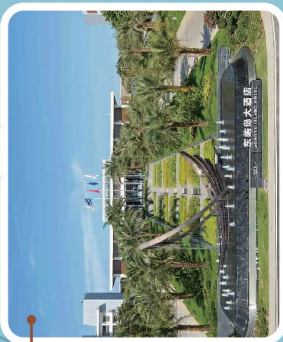
DONGYU ISLAND 东屿岛

博鳌亚洲论坛永久会址



图例

- 机场跑道
- 机动车 (步行) 路段
- 海底隧道



会议日程一览表

12月7日 全天报到		
12月8日		
08:30-11:45	主论坛 真实世界数据研究与药械监管创新发展 海南博鳌会场：博鳌亚洲论坛国际会议中心东屿宴会厅 A	线下会场 + 线上直播
14:00-16:40	专科专病真实世界数据研究实践	线上直播
14:00-16:30	真实世界数据研究与生物统计	
14:00-16:30	真实世界数据研究与信息技术	
14:00-16:30	真实世界数据研究与医疗卫生经济学	
14:00-17:00	真实世界数据与药品研究	
14:00-17:00	真实世界数据与器械研究	
14:00-16:30	真实世界数据与中医药研究	
14:00-16:30	真实世界数据研究与药械上市后安全性评价	



主论坛日程

真实世界数据研究与药械监管创新发展

时 间: 12月8日 08:30-11:45

时 间	演讲题目	演讲嘉宾
主持人 王斌 海南省委常委、宣传部长，省人民政府副省长		
08:30-08:40	王斌常委主持开场	
08:40-08:55	大会致辞	海南省委副书记，省人民政府省长冯飞
08:55-09:05	开幕致辞	国家药品监督管理局徐景和副局长
09:05-09:15	院士致辞	中国工程院王辰院士
09:15-09:25	世卫组织致辞	世界卫生组织驻华代表 Gauden GALEA
09:25-09:35	国外监管机构致辞	美国食品药品监督管理局 (FDA) 驻华办公室 Vanessa Shaw-Dore (肖慧薇) 主任
主持人 陈平雁 教授 海南省真实世界数据研究院执行院长		
09:35-09:55	真实世界证据助力药品监管决策， 促进监管科学发展	国家药品监督管理局药品审评中心 孔繁圃 主任
09:55-10:15	真实世界数据助力医疗器械创新发展	国家药品监督管理局医疗器械技术审评中心 孙磊 主任
10:15-10:35	基于乐城真实世界研究的 药械临床评价方法学探索	海南大学 校长 海南省真实世界数据研究院 名誉院长 骆清铭 院士
10:35-10:55	真实世界数据研究 在乐城先行区的实践、思考和展望	上海交通大学医学院附属瑞金医院 宁光 院士
10:55-11:15	欧盟数据分析和真实世界询问网络 (DARWIN) 的新进展	欧洲药品管理局 (EMA) Andrej Segec 科学管理员
11:15-11:35	日本监管机构为在监管决策中 使用真实世界数据所做的努力	日本药品医疗器械综合机构 (PMDA) Hanako MORIKAWA 主评审官
11:35-11:45	大会倡议	海南省真实世界数据研究院执行院长 陈平雁 教授

平行论坛日程

专科专病真实世界数据研究实践

时 间: 12月8日 14:00-16:40

时 间	演讲题目	演讲嘉宾
主持人	北京中医药大学东直门医院 商洪才常务副院长 海南博鳌乐城国际医疗旅游先行区管理局 吕小蕾常务副局长	
14:00-14:10	致辞	海南省药品监督管理局 李亚丽 副局长
14:10-14:35	儿科疾病真实世界数据	重庆医科大学附属儿童医院 李秋 院长
14:35-15:00	代谢疾病真实世界数据	中国科学技术大学生命科学与医学部 翁建平 副部长
15:00-15:25	心血管疾病真实世界数据 - 转化医学探索	首都医科大学 心血管重塑相关疾病教育部重点实验室 杜杰 主任
15:25-15:50	眼部疾病真实世界数据	温州医科大学附属眼视光医院 周翔天 教授
15:50-16:15	皮肤疾病靶向药物真实世界研究	中国医学科学院皮肤病研究所 陆前进 执行所长
16:15-16:40	血液肿瘤队列研究经验分享	中国医学科学院北京协和医学院 血液病医院血液学研究所 王建祥 副所长



平行论坛日程

真实世界数据研究与生物统计

时 间: 12月8日 14:00-16:30

平行论坛

真实世界数据研究与生物统计

时 间	演讲题目	演讲嘉宾
主持人	海南省真实世界数据研究院执行院长 陈平雁教授	
14:00-14:30	药物真实世界研究的统计学考虑	国家药品监督管理局药品审评中心 王骏 部长
14:30-15:00	强化稳健因果推断: 比较新疗法和基于真实世界数据外部对照	乔治城大学医学中心生物统计学系 谭铭 主任
15:00-15:30	估计目标: 在真实世界研究中选择合适估计目标的路线图	瓴路药业(上海) 圣方医药研发 陈杰 博士
15:30-16:00	增加透明性, 建立对真实世界二次应用数据研究的信任	罗氏全球监管科学 RWD 分会负责人、政策负责人 Gracy Crane 博士
16:00-16:30	RCT 是否回答了正确的研究问题? 制药行业对于 RCT 和 RWE 应用的一些观点	阿斯利康医疗与 支付方证据统计高级总监 Mario Ouwens 博士

平行论坛日程

真实世界数据研究与信息技术

时 间: 12月8日 14:00-16:30

时 间	演讲题目	演讲嘉宾
主持人	北京大学第一医院医学统计室主任、海南省真实世界数据研究院副院长 姚晨教授	
14:00-14:30	健康医疗大数据时代的认知计算	中国科学院自动化研究所 张文生 副总工程师
14:30-15:00	基于真实世界数据的观察性研究的 信息学新方法	美国德州大学 徐华 教授
15:00-15:30	真实世界数据采集、治理与管理的 一体化解决方案	北京大学第一医院医学统计室主任 海南省真实世界数据研究院副院长 姚晨 教授
15:30-16:00	整合多种来源的真实世界患者数据	安斯泰来真实世界数据战略与联盟 Sandeep SANGA 高级总监
16:00-16:30	医疗器械流行病学网络: 构建用于器械监管决策 的真实世界数据和证据框架	波科亚太区首席医务官 及医学事务和卫生经济副总裁 张明东 博士

平行论坛

真实世界数据研究与信息技术



平行论坛日程

真实世界数据研究与医疗卫生经济学

时 间: 12月8日 14:00-16:30

平行论坛

真实世界数据研究与医疗卫生经济学

时 间	演讲题目	演讲嘉宾
主持人	北京大学药学院 史录文教授 天津大学药物科学与技术学院 吴晶教授	
14:00-14:30	基于 RWD 的药品价值判断	清华大学 万科公共卫生与健康学院 赵琨 教授
14:30-15:00	真实世界研究 (RWS) 在卫生技术评估中的应用	中山大学药学院 宣建伟 教授
15:00-15:30	使用回顾性索赔数据进行成本效果分析 (CEA): 说明性案例研究	辉瑞公司生物统计学执行总监 Joseph C. Cappelleri 博士
15:30-16:00	确定医药产品的整体价值: 随机对照临床试验以外的卫生经济学和结果研究证据	艾伯维美国总部公司真实世界 证据与分析高级总监 竟永华 博士
16:00-16:30	真实世界数据在国际上医保应用及案例	百济神州医学部 卫生经济学和结果研究 (HEOR) 主管、执行总监 唐伯雄 博士

时 间: 12月8日 14:00-17:00

时 间	演讲题目	演讲嘉宾
主持人	国家药品监督管理局药品审评中心 王骏部长	
14:00-14:30	英国药品与健康产品管理局: 监管方使用真实世界数据方式的演变	英国药品与健康产品管理局(MHRA) Daniel O'Connor 医学评估员
14:30-15:00	FDA 的真实世界证据项目	美国食品药品监督管理局(FDA)药品审评 与研究中心医药政策办公室 John Concato 副主任
15:00-15:30	何时能信任真实世界证据, 原因何在	艾昆纬真实世界解决方法 荣誉首席科学官 Nancy A.Dreyer 教授
15:30-16:00	基于临床真实世界数据的药物疗效和安全性 研究: 目前的进展、面临的挑战和未来的发展	加拿大药物与卫生技术局 袁洪波 博士
16:00-16:30	药物研发中的数据科学和数字健康: 催化理论产生影响	杨森制药首席数据科学官 和战略与运营全球总监 Najat Khan 博士
16:30-17:00	利用真实世界证据为药物研发创造价值: 整合证据策略的框架	诺华制药全球医学事业部 证据和卓越上市负责人 Amy Rudolph 博士



平行论坛日程

真实世界数据与器械研究

时 间: 12月8日 14:00-17:00

平行论坛

真实世界数据与器械研究

时 间	演讲题目	演讲嘉宾
主持人	温州医科大学眼视光医学部主任、海南省真实世界数据研究院执行院长 瞿佳教授 四川大学华西医院中国循证医学中心主任、海南省真实世界数据研究院副院长 孙鑫教授	
14:00-14:30	FDA 的医疗器械真实世界数据使用情况: 近期、当下和未来	FDA 驻华办公室医疗器械国际项目和政策分析官员 斯考特·冈萨雷斯
14:30-15:00	真实世界数据用于医疗器械临床评价的实践与展望	国家药品监督管理局 医疗器械技术审评中心 刘英慧 部长
15:00-15:30	博鳌眼科器械真实世界研究的实践与思考	温州医科大学眼视光医学部主任 海南省真实世界数据研究院执行院长 瞿佳 教授
15:30-16:00	真实世界数据支持器械监测与评价	四川大学华西医院中国循证医学中心主任 海南省真实世界数据研究院副院长 孙鑫 教授
16:00-16:30	真实世界数据监管科学和医疗器械评价的发展	美敦力公司高级副总裁 Laura Mauri 博士
16:30-17:00	美国国家卫生技术评估系统的适应症扩展测试案例经验分享	强生医疗器械部流行病学和真实世界数据科学副总裁 Paul Coplan 博士

平行论坛日程

真实世界数据与中医药研究

时 间: 12月8日 14:00-16:30

时 间	演讲题目	演讲嘉宾
主持人	北京中医药大学生命科学院 韩东燃特聘教授	
14:00-14:30	中医药临床疗效评价的方法创新与应用 - 思考与探索	四川大学华西医院中国循证医学中心主任 海南省真实世界数据研究院副院长 孙鑫 教授
14:30-15:00	中医药技术评估与真实世界临床研究	北京中医药大学 国际循证中医研究院执行院长 刘建平 教授
15:00-15:30	黎医黎药的传承与创新	海南医学院 谢毅强 教授
15:30-16:00	中医主观表型组学: 真实世界疗效证据系统的根基	北京中医药大学生命科学院 韩东燃 特聘教授
16:00-16:30	真实世界研究在创新药研发和商业化的布局	思路迪医药首席战略官、首席医学官 肖申 博士



平行论坛日程

真实世界数据研究与药械上市后安全性评价

时 间: 12月8日 14:00-16:30

平行论坛

真实世界数据研究与药械上市后安全性评价

时 间	演讲题目	演讲嘉宾
主持人	清华大学药学院 杨悦研究员 北京大学公共卫生学院 詹思延教授	
14:00-14:30	《药物警戒质量管理规范》解读	国家药品监督管理局药品评价中心 沈传勇 主任
14:30-15:00	真实世界证据相关政策进展与思考	清华大学药学院 杨悦 研究员
15:00-15:30	中国 RWD 与上市后安全性评价实践	北京大学公共卫生学院 詹思延教授
15:30-16:00	药物开发生命周期中的真实世界证据	勃林格殷格翰公司全球流行病学及真实世界证据卓越中心 Laura Wallace 负责人
16:00-16:30	真实世界数据在医疗器械有效性评估中的应用	雅培全球数据科学与分析部 Nirav Dalal 副总裁

Overview of Schedule

December 7 Registration		
December 8		
08:30-11:45	<p>Planery session: Real-world data studies and innovation and development of medical product regulation</p> <p>Boao venue: Dongyu Banquet Hall A, Boao Forum for Asia (BFA) International Convention Center</p>	Combination of online and offline
14:00-16:40	Practice of Real-World Data Research on Specialty Diseases	online
14:00-16:30	Real-World Data Study and Biostatistics	
14:00-16:30	Real-World Data Study and Information Technology	
14:00-16:30	Real-World Data Study and Health Economics	
14:00-17:00	Real-World Data and Study on Drugs	
14:00-17:00	Real-World Data and Study on Medical Devices	
14:00-16:30	Real-World Data and Study on Traditional Chinese Medicine	
14:00-16:30	Real-World Data Study and Post-Marketing Safety Evaluation of Drugs and Medical Devices	



Real-world data studies and innovation and development
of medical product regulation

Agenda of Main Forum

08:30-11:45, Dec.8

Time	Item	Speaker
Moderator	Wang Bin Member of the Standing Committee of the Hainan Provincial Party Committee, Director of the Publicity Department of the CPC Hainan Provincial Committee and Vice Governor of the Provincial Government of Hainan	
08:30-08:40	The opening session chaired by Wang Bin	
08:40-08:55	Welcome Remarks	Feng Fei Deputy Secretary of the Hainan Provincial Party Committee, Governor of the Provincial Government of Hainan
08:55-09:05	Opening Remarks	Xu Jinghe Deputy Commissioner of National Medical Products Administration (NMPA)
09:05-09:15	Academician's Remarks	Wang Chen Academician of the Chinese Academy of Engineering
09:15-09:25	WHO's Remarks	Dr. Gauden GALEA WHO Representative in China
09:25-09:35	Foreign Regulator's Remarks	Vanessa Shaw-Dore Director of the China Office in the FDA's Office of Global Policy and Strategy
Moderator	Professor Chen Pingyan Executive president of Hainan Institute of Real World Data	
09:35-09:55	RWE Informing Drug Regulatory Decision making and Promoting Scientific Development of Regulation	Kong Fanpu Center for Drug Evaluation of NMPA
09:55-10:15	RWD Facilitates Innovative Development of Medical Devices	Sun Lei Center for Medical Device Evaluation of NMPA
10:15-10:35	Explorations of Drug and Medical Device Clinical Evaluation Methods Based on Lecheng RWS	Luo Qingming Hainan University Hainan Institute of Real World Data
10:35-10:55	Insights on Application and Prospect of RWS in the Lecheng Pilot Zone	Ning Guang Ruijin Hospital affiliated to Shanghai Jiao Tong University School of Medicine
10:55-11:15	Update on DARWIN EU®--Data Analysis and Real World Interrogation Network	Andrej Segec Data Analytics and Methods Task Force, European Medicines Agency (EMA)
11:15-11:35	Japanese Regulatory Efforts To Accept Real World Data for Regulatory Decision Making	Hanako MORIKAWA Pharmaceutical and Medical Devices Agency, Japan
11:35-11:45	Proposing of the conference initiative and outcomes	Professor Chen Pingyan Executive president of Hainan Institute of Real World Data

Practice of Real-World Data Research on Specialty Diseases *Agenda of Sub-Forums*

14:00-16:40, Dec.8

Time	Topic	Speaker
Moderator	Shang Hongcai Executive vice president of Dongzhimen Hospital, Beijing University of Chinese Medicine Lyu Xiaolei Executive Deputy Director of Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration	
14:00-14:10	Welcome speech	Li Yali Deputy Director of Hainan Medical Products Administration
14:10-14:35	Real-World Data on Pediatric Diseases	Professor Li Qiu President of Children's Hospital of Chongqing Medical University
14:35-15:00	Real-World Data on Metabolic Diseases	Professor Weng Jianping Deputy Director of Life Sciences and Medicine Department, University of Science and Technology of China
15:00-15:25	RWD on Cardiovascular Diseases – Explorations in Translational Medicine	Professor Du Jie Director of Key Laboratory of Cardiovascular Remodeling-related Diseases, Ministry of Education, Capital Medical University
15:25-15:50	Real-World Data on Eye Diseases	Professor Zhou Xiangtian Vice Director of Eye Hospital, WMU
15:50-16:15	Real-World Data on Targeted Drugs for Dermatologic Disease	Professor Lu Qianjin Executive President of Hospital for Skin Diseases, the Chinese Academy of Medical Sciences
16:15-16:40	Experience of Hematologic Oncology Cohort Studies	Profesor Wang Jianxiang Deputy Director of Blood Disease Hospital, Chinese Academy of Medical Sciences



Real-World Data Study and Biostatistics

Agenda of Sub-Forums

14:00-16:30, Dec.8

Agenda of Sub-Forums
Real-World Data Study and Biostatistics

Time	Topic	Speaker
Moderator	Professor Chen Pingyan Executive president of Hainan Institute of Real World Data	
14:00-14:30	Statistical Considerations for Drug RWS	Wang Jun Director of the Department of Statistics and Clinical Pharmacology, Center for Drug Evaluation, NMPA
14:30-15:00	Assessing efficacy of a new treatment with an external control based on real-world data using enhanced doubly robust causal estimate	Professor Tan Ming Department of Biostatistics, Bioinformatics & Biomathematics, Georgetown University Medical Center
15:00-15:30	Estimands: A Roadmap in Choosing Appropriate Estimands in Real-World Studies	Chen Jie Elixir Clinical Research (ECR Global) Overland Pharmaceuticals(Shanghai)
15:30-16:00	Improving Transparency to Build Trust in Real-World Data Studies	Gracy Crane RWD policy lead and Chapter Lead within the Global Regulatory Policy team at Roche
16:00-16:30	Are RCTs answering the right research question? Some perspectives from the pharmaceutical industry on the use of RCT and RWE	Mario Ouwens Senior Director, Medical and Payment Evidence Statistics, AstraZeneca

Real-World Data Study and Information Technology

Agenda of Sub-Forums

14:00-16:30, Dec.8

Time	Topic	Speaker
Moderator	Professor Yao Chen Director of the Medical Statistics Department of Peking University First Hospital, Deputy President of Hainan Institute of Real World Data	
14:00-14:30	Cognitive computing in the era of big data in health care	Zhang Wensheng Vice Chief Engineer of Institute of Automation, Chinese Academy of Sciences
14:30-15:00	Novel Informatics Approaches to Observational Studies using Real World Data	Professor Xu Hua The University of Texas, USA
15:00-15:30	Integrated Solutions for Real-world Data Collection, Governance and Management	Professor Yao Chen Director of the Medical Statistics Department of Peking University First Hospital, Deputy President of Hainan Institute of Real World Data
15:30-16:00	Integrating Real World Patient Data Across Sources	Sandeep Sanga Head of Real World Data Strategy & Alliances at Astellas Pharma
16:00-16:30	MDEpiNet: Establishing a Collaborative Framework of RWD and RWE for Regulatory Decision-Making	Dr. Zhang Mingdong Chief Medical Officer & Vice President of Strategic Medical Affairs, Boston Scientific Asia Pacific



Real-World Data Study and Health Economics

Agenda of Sub-Forums

14:00-16:30, Dec.8

Time	Topic	Speaker
Moderator	Professor Shi Luwen School of Pharmacy, Peking University Professor Wu Jing Deputy Dean of School of Pharmaceutical Science and Technology, Tianjin University	
14:00-14:30	RWD-based Drug Value Judgement	Professor Zhao Kun Vanke School of Public Health, Tsinghua University
14:30-15:00	Application of RWS in HTA	Professor Xuan Jianwei School of Pharmaceutical Sciences, Sun Yat-Sen University
15:00-15:30	Use of Retrospective Claims Data for Cost-Effectiveness Analysis (CEA): Illustrative Case Studies	Dr. Joseph C. Cappelleri Executive Director of Biostatistics, Pfizer
15:30-16:00	Defining the Holistic Value of Pharmaceutical Products: Health Economics and Outcomes Research Evidence Beyond Randomized, Controlled Trials	Dr. Yonghua Jing Senior Director of Real World Evidence & Analytics, AbbVie
16:00-16:30	Applications and Case Studies of Real-world Evidence (RWE) in Drug Development and Reimbursement Around the World	Tang Boxiong Director and Executive Director of Health Economics and Outcomes Research (HEOR) at Department of Medicine, BeiGene USA Inc.

Real-World Data and Study on Drugs

Agenda of Sub-Forums

14:00-17:00, Dec.8

Time	Topic	Speaker
Moderator	Wang Jun Director of the Department of Statistics and Clinical Pharmacology, Center for Drug Evaluation, NMPA	
14:00-14:30	UK MHRA: Evolving regulatory approaches to Real-World Data	Daniel O'Connor Expert Medical Assessor the Medicines and Healthcare Products Regulatory Agency, the UK(MHRA)
14:30-15:00	FDA's Real-World Evidence Program	John Concato Office of Pharmaceutical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)
15:00-15:30	When to trust Real World Evidence on Drugs, and Why	Nancy A. Dreyer Chief Scientific Officer Emerita IQVIA Real World Solutions
15:30-16:00	Pharmacoepidemiologic Observational Study: a Brief Review of Current Progress, Challenges and Future Direction of Development	Yuan Hongbo Scientific Consultant to Canadian Agency for Drugs and Technologies in Health
16:00-16:30	Data Science and Digital Health in Pharmaceutical R&D: Catalyzing theory to impact	Najat Khan Chief Data Science Officer and the Global Head of Strategy &Operations for Janssen Research & Development
16:30-17:00	Creating value from real-world evidence for drug research: A framework for an integrated evidence generation strategy	Amy Rudolph Novartis



Real-World Data and Study on Medical Devices

Agenda of Sub-Forums

14:00-17:00, Dec.8

Time	Topic	Speaker
Moderator	<p>Professor Qu Jia Optometry Director of the School of Ophthalmology and Optometry, Wenzhou Medical University, Executive President of Hainan Institute of Real World Data</p> <p>Professor Sun Xin Director of China Evidence-based Medicine Center, West China Hospital, Sichuan University and Deputy President of Hainan Institute of Real World Data</p>	
14:00-14:30	FDA's Recent, Ongoing, and Future Use of Medical Device RWD	<p>Scott Gonzalez FDA International Program and Policy Analyst - Medical Devices, China Office</p>
14:30-15:00	RWD for Medical Device Clinical Evaluation: Application and Prospect	<p>Liu Yinghui Director of the First Department of Clinical and Biostatistics of Center for Medical Device Evaluation (CMDE) of NMPA</p>
15:00-15:30	Practices of and Reflection on Real-world Studies of Ophthalmic Devices in Boao	<p>Professor Qu Jia Optometry Director of the School of Ophthalmology and Optometry, Wenzhou Medical University, Executive President of Hainan Institute of Real World Data</p>
15:30-16:00	RWD Supporting Monitoring and Evaluation of Medical Devices	<p>Professor Sun Xin Director of China Evidence-based Medicine Center, West China Hospital, Sichuan University and Deputy President of Hainan Institute of Real World Data</p>
16:00-16:30	Development of Real-World Data Regulatory Science and Medical Device Evaluation	<p>Laura Mauri Senior Vice President, Medtronic</p>
16:30-17:00	Experience with National Evaluation for Health Technology Test Cases for Label Extensions	<p>Paul Coplan Vice President of Epidemiology and Real-World Data Sciences for Medical Devices at Johnson and Johnson</p>

Agenda of Sub-Forums

Real-World Data and Study on Medical Devices

Real-World Data and Study on Traditional Chinese Medicine *Agenda of Sub-Forums*

14:00-16:30, Dec.8

Time	Topic	Speaker
Moderator	Han Dongran Distinguished Professor, School of Life Sciences, Beijing University of Chinese Medicine	
14:00-14:30	Innovative Methods of TCM Clinical Efficacy Evaluation and Their Applications: Thoughts and Explorations	Professor Sun Xin Director of China Evidence-based Medicine Center, West China Hospital, Sichuan University and Deputy President of Hainan Institute of Real World Data
14:30-15:00	On the Assessment of Health Technologies in TCM and Real-world Clinical Practice	Liu Jianping Director of Centre for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine
15:00-15:30	Li Medicine: Preservation and Innovation	Xie Yiqiang Professor of School of Traditional Chinese Medicine, Hainan Medical University
15:30-16:00	Subjective Phenomics of TCM: The Foundation for Efficacy RWE System	Han Dongran Distinguished Professor, School of Life Sciences, Beijing University of Chinese Medicine
16:00-16:30	RWS in R&D and Commercialization of Innovative Drugs	Xiao Shen Chief Strategy Officer and Chief Medical Officer of 3D Medicines



Real-World Data Study and Post-Marketing Safety Evaluation of Drugs and Medical Devices

Agenda of Sub-Forums

14:00-16:30, Dec.8

Time	Topic	Speaker
Moderator	Yang Yue Researcher of the School of Pharmaceutical Sciences, Tsinghua University Professor Zhan Siyan Dean of School of Public Health, Peking University	
14:00-14:30	Interpretation of Pharmacovigilance Management Regulations	Shen Chuanyong Director of Center for Drug Reevaluation, National Medical Products Administration
14:30-15:00	Progress and Thoughts on RWE-related Policies	Yang Yue Researcher of the School of Pharmaceutical Sciences, Tsinghua University
15:00-15:30	RWD and Post-marketing Safety Evaluation Practices in China	Professor Zhan Siyan Dean of School of Public Health, Peking University
15:30-16:00	Real World Evidence Throughout the Drug Development Lifecycle	Laura Wallace Head of Global Epidemiology and Real World Evidence at Boehringer Ingelheim
16:00-16:30	Use of Real-World Evidence in Assessing Effectiveness of Medical Devices	Nirav Dalal Vice President, Global Data Science & Analytics, Abbott

Agenda of Sub-Forums

Real-World Data Study and Post-Marketing
Safety Evaluation of Drugs and Medical Devices

主论坛

出席领导和参会嘉宾



冯 飞

海南省人民政府

海南省委副书记，省人民政府省长。



王 斌

海南省人民政府

海南省委常委、宣传部长，省人民政府副省长。



徐景和

国家药品监督管理局

国家药品监督管理局副局长。



孔繁圃

国家药品监督管理局药品审评中心

国家药品监督管理局药品审评中心主任，仿制药质量与疗效一致性评价办公室主任，曾任原国家食品药品监督管理局药品安全监管司药品监管专员，原国家食品药品监督管理局医疗器械技术审评中心主任、党委书记，原国家食品药品监督管理局医疗器械监管司司长。自2018年11月全面负责药品审评中心工作以来，持续深化药品审评审批制度改革，积极推动审评体系和审评能力现代化，全力促进医药产业高质量发展。



孙 磊

国家药品监督管理局医疗器械技术审评中心

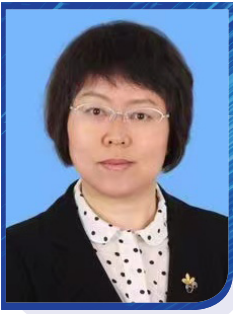
国家药品监督管理局医疗器械技术审评中心主任、党委副书记，副研究员。曾任中国药品生物制品检定所药检处处处长（主持工作），国家食品药品监督管理局稽查二处处长，负责药品、医疗器械重大案件的查处；医疗器械监管司副司长，分管医疗器械生产、经营的监督工作、主持全面工作。



沈传勇

国家药品监督管理局药品评价中心

理学博士，副教授，现任国家药品监督管理局药品评价中心（国家药品不良反应监测中心）主任，国家药品监督管理局药物警戒研究与评价重点实验室主任，《中国药物警戒》期刊主编，兼任第十二届国家药典委员会委员、中国药学会第二十五届常务理事、药物警戒专委会负责人。曾任四川省成都市卫生局副局长、国家食品药品监督管理局药品认证中心副主任、国家食品药品监督管理局管理总局机关服务中心主任。北京市第十五届人大代表。



董江萍

国家药品监督管理局中国食品药品国际交流中心

国家药品监督管理局中国食品药品国际交流中心副主任（主持工作），主任药师。曾任国家局药品审评中心化学药品药学专业审评员、审评管理与协调部副部长、信息部部长；国家局药品注册管理司化学药品注册处处长、综合处处长；国家局食品药品审核查验中心副主任，分管药品检查核查和国际合作项目。2022年8月至今主持国际交流中心工作。



贾 宁

海南博鳌乐城国际医疗旅游先行区管理局

海南博鳌乐城国际医疗旅游先行区管理局局长，
海南省医疗保障局局长。



朱 宁

海南省药品监督管理局

海南省市场监督管理局副局长，
海南省药品监督管理局局长。



陈少仕

海南省卫生健康委员会

海南省卫生健康委员会副主任。



主论坛 院士/专家嘉宾



王 辰

中国工程院副院长，中国医学科学院北京协和医学院院校长

呼吸病学与危重症医学专家。中国工程院院士，美国国家医学科学院、欧洲科学院外籍院士，欧洲科学与艺术学院院士，中国医学科学院学部委员。国家呼吸医学中心主任。担任世界卫生组织（WHO）多项重要专业职务。Chinese Medical Journal 总编辑，《柳叶刀》新冠委员会成员。长期从事呼吸与危重症医学临床、教学与研究工作。主要研究领域包括呼吸病学、群医学及公共卫生。在慢性气道疾病、肺栓塞、呼吸衰竭、新发呼吸道传染病、控制吸烟等领域作出多项重要创新，改善医疗卫生实践。在 New Engl J Med、Lancet 等国际权威期刊发表论文 290 余篇。获得国家科技进步特等奖、一等奖、二等奖。具有中国工程院、中国医学科学院、北京协和医学院、中日医院、卫生部科教司、北京医院、朝阳医院和北京呼吸疾病研究所的领导和管理工作经验，在学科建设和行政管理上取得显著业绩。推动创立我国住院医师、专科医师规范化培训和“4+4”医学教育制度。



骆清铭

海南大学校长，海南省真实世界数据研究院名誉院长

中国科学院院士、中国医学科学院学部委员。现任海南省科协主席、教育部高等学校生物医学工程专业教学指导委员会主任。曾获国家自然科学二等奖（2010 年）、国家技术发明二等奖（2014 年）和黄家驷生物医学工程奖（技术发明类）一等奖（2021），入选中国科学十大进展（2011 年）。



宁 光

上海交通大学医学院附属瑞金医院院长

中国工程院院士，上海交通大学医学院附属瑞金医院终身教授。现任上海交通大学医学院附属瑞金医院院长，国家代谢性疾病临床医学研究中心主任。同时任中国医师协会内分泌代谢科医师名誉会长，中华医学会内分泌学分会前任主任委员，《中华内分泌代谢杂志》总编辑，Journal of Diabetes 主编，是教育部长江学者特聘教授、973 项目首席科学家。宁光教授长期致力于内分泌代谢病临床与科研工作，尤其在内分泌肿瘤与糖尿病诊治及研究领域取得创新性成果。在 Science、JAMA 等 SCI 杂志发表论文 500 余篇，获国家科技进步二等奖 4 项及上海市科技进步一等奖 3 项。宁光教授获评 2017 年度树兰医学奖，2014 年度中国医师奖、吴阶平医药创新奖、第二届“白求恩式好医生”奖。同时获得“以色列糖尿病联盟终身成就奖”、“美国内分泌医师协会国际内分泌医师奖”和“Yutaka Seino 杰出领导奖”。



陈平雁

海南省真实世界数据研究院执行院长

教授，博士生导师，博士后合作导师，南方医科大学生物统计学系前主任。2004 年创建国内第一个生物统计学系，国内率先开设生物统计本科专业。中华预防医学会生物统计分会主任委员，国际生物统计学会中国分会副理事长，广东省生物统计学会会长；广州市重大行政决策论证专家。发表论文 280 余篇，其中 SCI 收录论文 80 余篇，发表在 SMMR、SIM、NEJM、JAMA、JCO、JAMA-IN、ERJ、JASN、Radiology 等期刊，累积影响因子超过 500。主编《SPSS 统计软件应用教程》系列研究生规划教材影响广泛。

主论坛

国际组织及国外监管机构嘉宾



高力

世界卫生组织驻华代表

公共卫生医生，1998年加入世卫组织工作，曾在苏瓦、马尼拉和日内瓦担任非传染性疾病及健康促进相关领域的技术官员、区域顾问和协调员。2018年4月起任世界卫生组织驻华代表，负责协调世界卫生组织与中国之间在卫生健康相关领域的合作，主要包括 COVID-19 疫情应对、医改十年评估、控烟控酒宣传、中国数字卫生现状研究等，作为西太平洋区域世卫组织的代表，协调以西太“面向未来”愿景为目标的促进公共卫生领域创新工作。



肖慧薇

美国食品药品监督管理局（FDA）驻华办公室主任

2020年4月加入FDA，任FDA驻华办公室主任。在国际工作领域，肖慧薇有15年以上的国际公众健康项目的实施和管理经验，统筹高层部门间协作项目。曾任美国疾病预防控制中心（CDC）全球健康保障处（DGHP）副主任，负责CDC的全球卫生安全议程（GHSA）在越南的工作；曾任CDC驻刚果民主共和国办公室全球健康保障处GHSA项目副主任、美国卫生资源与服务局的HIV/AIDS局主管。她负责4.9亿美元联邦政府经费所支持的雷恩怀特项目B部分和艾滋病药物辅助项目，该项目在华盛顿特区等美国20个州和地区开展。



Andrej Segec

欧洲药品管理局（EMA）科学管理员

英国伦敦卫生与热带医学院流行病学硕士，培训药剂师（斯洛伐克布拉迪斯拉发夸美纽斯大学）。2008年入职欧洲药品管理局（EMA）。在监测及流行病学领域，担任药物警戒风险评估委员会（PRAC）运营经理、抗感染治疗和疫苗风险管理专家，重点负责在于监管决策中真实世界证据的产生和使用，以及欧盟数据分析和真实世界查询网络（DARWIN EU）的建立。



Hanako MORIKAWA

日本药品医疗器械综合机构（PMDA）主评审官

日本药品医疗器械综合机构医疗器械二处主评审官。



平行论坛

政府部门及学术界主持/演讲嘉宾

[按首字母排序, 排名不分先后]



Daniel O'Connor

英国药品与健康产品管理局 (MHRA) 医学评估员

伦敦帝国理工学院肿瘤抑制基因博士, 于 2006 年加入英国药品与健康产品管理局 (MHRA), 担任医学评估员。此前曾在路德维格癌症研究所伦敦大学学院分所和大学学院医院担任临床讲师。他在 MHRA 许可批准部门工作期间, 主要参与罕见病、早期获取药物计划以及患者报告结局方面的工作, 是第一版牛津药物学专家手册的编辑作者, 以及《孤儿药物和罕见疾病专家意见》和《孤儿药物杂志》的编委成员。



杜杰

首都医科大学心血管重塑相关疾病教育部重点实验室主任

北京市心肺血管疾病研究所副所长。国家重点研发计划首席科学家、北京学者。致力于解决心血管病的早期诊断、风险评估、精准诊治的问题及其产业化, 开展了系列临床转化研究。推动自主研发的临床诊断产品的产业化。



韩东燃

北京中医药大学生命科学学院特聘教授

北京中医药大学生命科学学院特聘教授, 教育与信息中心副主任, 中西医结合基础专业中医药大数据方向学术带头人。聚焦中医药大数据生态体系的顶层设计和标准化建设, 牵头校内大数据和信息化方向的多项原创性工作, 负责多项国家重点研发项目, 谷歌学术累计引用超过 3400 次。美国发明专利 2 项, 国内发明专利 8 项, 均为首要发明人。



John Concato

美国食品药品监督管理局 (FDA) 药品审评与研究中心医药政策办公室副主任

纽约大学医学博士、耶鲁大学公共卫生博士, 内科医生和流行病学家。FDA 药品评估研究中心 (CDER) 医疗政策办公室 (OMP) 负责真实世界证据分析副主任。致力于加强与药物开发和监管审评相关的政策, 重点关注真实世界证据 (RWE), 同时还参与制定 FDA 内部流程及评估, 与外部利益相关者就 RWE 进行互动, 支持 RWE 示范项目和指南的制定。曾担任耶鲁大学医学院和美国退伍军人事务部 (VA) 的医学教授; VA Million Veteran Program 基因组大型生物库的两位创始首席研究员之一。



李秋

重庆医科大学附属儿童医院院长

教授、博士生导师，国家儿童临床医学研究中心主任，国家卫生计生委中青年突出贡献专家，国务院政府特殊津贴专家。重庆市英才·名师专家；首批重庆市医学领军人才，重庆市首席专家工作室-首席专家，民盟中央常委、全国人大代表。中华医学会儿科分会常委、秘书长，中国医院协会儿童医院管理分会副主任委员，教育部高校教指委儿科学专业指导委员会副主委，中华医学会儿科分会肾脏学组副组长。主持国家级项目十多项，曾荣获重庆市科技进步一等奖，教育部科技进步二等奖，重庆市教学成果一等奖，宋庆龄儿科医学奖等多项奖项，担任人卫社教材主编及副主编。



李亚丽

海南省药品监督管理局

海南省药品监督管理局副局长。



刘建平

北京中医药大学国际循证中医研究院执行院长、循证医学中心主任

医学博士，教育部长江学者特聘教授，博士生导师。享受国务院政府特殊津贴。国际补充整合医学研究会 (ISCMR 2017-2019) 主席，世界卫生组织传统医学顾问，国务院学位委员会第七届中西医结合学科评议组成员；中国中西医结合学会循证医学专业委员会名誉主任委员。主持国际合作及国家级课题 10 余项；研究领域涉及中医药循证医学标准规范、临床混合研究方法、证据综合等。主编《中医临床真实世界研究方法》等教材及专著 10 部；国内外发表学术论文 660 余篇，被 SCI 收录 257 篇。



刘英慧

国家药品监督管理局医疗器械技术审评中心

国家药品监督管理局医疗器械技术审评中心临床及生物统计一部部长。医学博士，国际医疗器械监管机构论坛 (IMDRF) 医疗器械临床评价工作组主席，全国医疗器械临床评价标准化技术归口单位副组长。



1 第一届博鳌国际药械真实世界研究大会

BOAO INTERNATIONAL CONFERENCE ON
REAL WORLD STUDIES
OF MEDICAL PRODUCTS



陆前进

中国医学科学院皮肤病研究所执行所长

主任医师，教授，博士生导师。享受国务院特殊津贴专家。同时还担任中国医学科学院皮肤病医院执行院长，中国医学科学院免疫性皮肤病基础与转化研究重点实验室主任，北京协和医学院长聘教授，中华医学会皮肤性病学会主任委员，亚洲皮肤科学会理事，世界华人医师协会皮肤科分会副会长，中国医师协会皮肤科分会副会长，中国免疫学会常务理事，中华医学会皮肤性病学会分会红斑狼疮研究中心首席科学家，Clinical Immunology 杂志副主编。



瞿佳

温州医科大学眼视光医学部主任，海南省真实世界数据研究院执行院长

教授、主任医师、博士生导师；温州医科大学眼视光医院集团总院长；兼任眼视光学和视觉科学国家重点实验室主任、国家眼视光工程技术研究中心主任、国务院学位委员会临床医学学科评议组成员、教育部高等学校眼视光医学教育指导委员会主任委员、中国老年医学学会副会长、眼科分会主任委员、中华医学会眼科学分会副主任委员等。先后承担 973 项目首席科学家、国家自然科学基金重大项目等百余项研究工作。获国家科技进步二等奖 2 项，国家教学成果奖 3 项、获中华医学科技奖一等奖等省部级奖项 10 余项。



商洪才

北京中医药大学东直门医院常务副院长

博士，研究员，博士生导师。教育部中医内科学（北京中医药大学）重点实验室主任，北京中医药大学心血管病研究所副所长。研究方向为中医临床证据评价、效应特点及其机制。目前主持国家重点研发计划、国家自然科学基金杰出青年科学基金、重点项目等国家级项目多项。国家杰出青年科学基金获得者。获国家科技进步二等奖 3 项，省部级一等奖 6 项。发表论文 200 余篇，发表 SCI 收录论文 70 余篇，IF 总计 247；SCI 他引 600 余次、中文他引 1121 次，被 Nature reviews cardiology 等国际知名刊物引用；授权发明专利 6 项，软件著作权 2 项。



史录文

北京大学药学院教授

博士生导师，北京大学医药管理国际研究中心主任，中国药促会药物政策专业委员会副主委，中国研究型医院学会药物经济学专委会主委，北京药学会药物经济学专委会主任委员，北京医学会罕见病学会副主任委员，中国中药协会药物临床评价研究专委会副主委，现代医院管理能力建设专委会药事管理分会副主委，仿制药质量和疗效一致性评价专家委员会委员，国家卫健委第二届罕见病诊疗与保障专委会委员，国家医保局医药价格和招标采购指导中心专家组成员，《中国药学》（英文版）等杂志副主编。



斯科特·冈萨雷斯

美国食品药品监督管理局 (FDA) 驻华办公室医疗器械国际项目和政策分析官员

曾在 FDA 医疗器械和辐射健康中心 (CDRH) 工作 9 年多，在体外诊断和辐射健康办公室 (OIR) 和战略伙伴和技术创新办公室 (OST) 工作，在 FDA 任职期间，曾担任上市前 / 上市后首席审评员、诊断 X 射线系统处代理主任及体外诊断和辐射健康处 (OIR) 高级技术顾问。冈萨雷斯少校是放射性电子产品监管方面的专家，曾参与诊断 X 射线系统及主要配件的检测、基本安全和关键性能方面的多项国际标准的制定。



孙鑫

四川大学华西医院中国循证医学中心主任，海南省真实世界数据研究院副院长

研究员，博士生导师，国家杰青。现任国家药监局海南真实世界数据研究与评价重点实验室主任、四川省真实世界数据技术创新中心主任、海南省真实世界数据研究院副院长、中国循证医学杂志和 Journal of Evidence-Based Medicine (SCI 收录) 执行主编。主要研究方向为真实世界数据研究体系理论创新与应用；以疗效为导向的现代中药研发、评价与应用。先后主持国家自然科学基金、国家重点研发、国家药监局等纵向课题 20 余项，在 JAMA、BMJ、International Journal of Epidemiology、Critical Care Medicine 等以第一 / 通讯发表 SCI 论文 110 余篇，H 指数 36。主编《循证医学》研究生规划教材、《循证中医药学》专著。获四川省科技进步一等奖、教育部科技进步二等奖、BMJ 杰出研究成就奖。



谭铭

乔治城大学医学中心生物统计学系主任

统计学博士，乔治城大学医学部和乔治城隆巴迪国家综合癌症中心生物统计生物信息和生物数学系终身教授。担任多个 NIH 及药企新药临床试验数据安全监管委员会委员及主任委员，美国 FDA 专家委员会委员和多个美国国立卫生研究院项目评审委员会委员及多家药企研发及投资公司的专家顾问，《Molecular Carcinogenesis》执行主编。长期研究新药研发的试验设计及统计方法，在国际著名期刊发表学术论文 200 多篇。



王建祥

中国医学科学院北京协和医学院血液病医院血液学研究所副所长

教授，博士生导师，主任医师。中国医学科学院血液病医院白血病诊疗中心主任、国家血液病临床医学研究中心主任、中国医师协会内科医师分会副会长、中国医师协会血液科医师分会副会长，J Hematol & Oncol 副主编、Blood 编委。曾任中华医学会血液学分会主任委员、中华血液学杂志主编 (2012-2016)、中国抗癌协会血液肿瘤专委会主任委员 (2012-015)。“杰青”、“新世纪百千万人才工程”国家级人选、卫生部突出贡献专家、国务院津贴专家。CD19、CD33 CAR-T 主要研发者、白血病治疗领军人，预后分层、强化诱导、全程管理，显著改善了急性白血病的疗效。牵头制定了《急性髓系白血病》《急性淋巴细胞白血病》《慢性髓性白血病》多部诊治指南。NIH 博士后杰出研究奖，第十届“吴阶平医学研究奖 - 保罗·杨森药学研究奖”一等奖，天津市科学技术进步奖一等奖 (第一完成人)。



王 骏

国家药品监督管理局药品审评中心

博士，研究员，国家药品监督管理局药品审评中心统计与临床药理学部部长。毕业于中国疾病预防控制中心，2005年开始在中国疾控中心信息中心工作，2011年加入药品审评中心，主要从事新药统计学审评、临床药理审评和一致性评价工作，主持或参与多项临床试验统计学相关指导原则制修订工作，是《真实世界证据支持药物研发与审评的指导原则》《用于产生真实世界证据的真实世界数据指导原则》等指导原则的主要执笔人，ICH E9(R1)、M14专家工作组成员，负责ICH E17等指南在中国的转化实施工作。



翁建平

中国科学技术大学生命科学与医学部副部长

医学博士，教育部特聘教授，同时还担任中国科学技术大学临床医学院执行院长、附属第一医院（安徽省立医院）副院长、蚌埠医学院院长。重点开展的研究领域包括2型糖尿病及其并发症的早期防治、特殊类型糖尿病的分子遗传机理研究、人工胰腺的开发与应用、新的糖尿病易感基因致病机制研究以及慢性非传染性疾病队列建立与应用。两次承担教育部“创新团队发展计划”，先后牵头国家重点研发计划、十二五重大科技专项等多个大型项目。



吴 晶

天津大学药物科学与技术学院副院长

教授，2007年获沈阳药科大学与北京大学联合培养药物经济学博士学位，2013-2014年美国南加州大学 Schaeffer 卫生政策与经济研究中心访问学者。主要社会兼职包括中国药学会药物经济学专业委员会副主任委员、中国研究型医院学会药物经济学专业委员会副主任委员、天津市医疗保险研究会副会长、天津市药学会药物经济学专业委员会主任委员等。主要研究方向为卫生经济学与药物经济学。近五年发表英文论文（SSCI&SCI）40余篇，中文论文60余篇，主持国家自然科学基金3项，合著有《药物经济学》《中国药物经济学评价指南导读2022》《中国药物经济学评价指南与导读2015》《基本药物制度：理论与实践》等著作。《中国药物经济学评价指南2020》主要执笔者之一。



谢毅强

海南医学院教授

博士生导师，教育部高等学校中西医结合类专业教指委、海南省重点学科中医学学科带头人、首批海南省“双百”人才团队带头人、海南省领军人才、海南省南海名家、海南省优专家、海南省515人才工程第一层次人选。国家自然科学基金会审专家、中华中医药学会养生康复分会副主任、中华中医药学会中医药防治重大疾病基础研究平台专家委员会青年副主任、世中联内分泌分会副会长、中华中医药学会糖尿病分会常委，海南省中医药学会副会长。《TMR Modern Herbal Medicine》《International Journal of Chinese Medicine》等期刊编委。主持国家自然科学基金4项，海南省课题3项，在研经费500余万元。近年来发表论文150余篇，主（参）编著作13部。获得海南省科技进步奖2项、海南省教学成果奖1项，发明专利14项。



徐 华

美国德州大学教授

美国医学信息学院院士，哥伦比亚大学生物医学信息学博士。德克萨斯大学休斯顿健康科学中心计算生物医学中心教授兼主任，生物医学信息学学院创新副院长。UTHealth 计算生物医学中心主任。研究方向包括生物医学自然语言处理 (NLP) 和数据挖掘，以及临床和转化研究中将其应用于电子健康档案数据二次使用，研究得到美国国立医学图书馆、美国国家癌症研究所等多个机构的资助，实验室开发的方法 / 工具广泛应用于支持各种生物医学研究。



宣建伟

中山大学药学院教授

中山大学药学院医药经济研究所所长。国家药物政策与医药产业经济研究中心研究员，上海市千人计划专家。在临床研究、卫生经济学、医疗大数据、政策研究等领域发表了 300 余篇学术文章。多次与中国国家发展改革委、卫生健康委、医疗保障局合作进行政策研究，曾在多个跨国企业领导全球临床研究，研究成果已应用于许多国家医疗决策的制定。



杨 悦

清华大学药学院研究员

清华大学药学院研究员，博士生导师。中国第一位药事管理方向药学博士学位获得者。主要从事药事法规政策与监管科学研究。国家药品监督管理局《药品管理法》《疫苗管理法》《医疗器械监督管理条例》宣讲团成员。代表性著作有《美国药品监管科学研究》《药品上市许可持有人制度导读》《21 世纪治愈法案》等。



姚 晨

北京大学第一医院医学统计室主任，海南省真实世界数据研究院副院长

博士生导师，教授。北京大学第一医院医学统计室主任、海南省真实世界数据研究院副院长兼任北京大学临床研究所副所长。中国医师协会循证医学专业委员会主任委员、中国卫生统计学会统计理论与方法专业委员会副主任委员，世界中医药学会联合会真实世界研究专业委员会副会长、吴阶平医学基金会肿瘤医学部副主任委员，国家食品药品监督管理局药品 / 器械审评专家库专家。参与博鳌乐城飞秒激光眼科治疗系统真实世界研究项目等多项研究，相关成果已经发表在《中国食品药品监管》等杂志。



袁洪波

加拿大药物与卫生技术局科学顾问

国际药物流行病学学会 (ISPE) 董事会成员, 主导政府监管事务, 曾担任比较疗效研究小组主席。2002 年获得加拿大麦吉尔大学流行病学与生物统计学系博士学位。2010 年至今参与 200 多项各类上市新药临床疗效和安全性药物保险 (HTA) 评审。



詹思延

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教授, 博士生导师。兼任北京大学第三医院临床流行病学研究中心主任。中国药学会常务理事, 药物流行病学专委会主任委员, 中华预防医学会流行病学分会主任委员。《药物流行病学杂志》主编、《中华流行病学杂志》副主编、Science Bulletin 医学版副主编, 《流行病学》统编教材第 7、8 版主编、长学制《临床流行病学》第 2 版主编。主要研究方向药物流行病学、临床流行病学与循证医学, 近年来承担科技部、国家自然科学基金等多项课题, 以第一或责任作者发表论文 200 余篇。2016 年获第 17 届吴阶平 - 保罗杨森医学药学奖、2017 年获北京市优秀教师称号、2020 年北京市抗击新冠肺炎疫情先进个人、享受国务院政府特殊津贴。



张文生

中国科学院自动化研究所副总工程师

研究员、博士生导师, 中国科学院大学人工智能首席教授, 中科麦迪健康医疗人工智能研究院院长, 科技创新 2030—“新一代人工智能”重大项目首席科学家。国家“云计算和大数据”、“物联网与智慧城市”重点研发专项总体组专家, 中国仪器仪表学会物联网工作委员会副理事长、中国人工智能学会智能服务专委会副主任。曾任科技处长、重点项目处长、所务委员 / 所长助理。主要研究: 人工智能、机器学习、大数据模式挖掘、跨模态数据标注、医疗数据分析推理。发表论文 200 余篇, 国内外发明专利 50 余项, 国家二等奖 1 项, 省部级二等奖 5 项。



赵琨

清华大学万科公共卫生与健康学院

清华大学万科公共卫生与健康学院卓越访问教授, 国家卫计委药物与卫生技术综合评估中心副主任。兼任国家卫健委罕见病诊治与保障专委会副主委, 中国卫生经济学会卫生技术评估专委会副主委、秘书长, 在中华预防医学会、中国医药创新促进会、医药政策专委会等学会协会担任重要职务。曾任 ISPOR 亚太区主席 (2018-2020), 亚洲卫生技术评估联盟主席 (2021-2022)。主持开展国家卫健委分级诊疗体系建设第三方评估、国家临床医学重点专科建设项目等重要项目的评估, 推进国家药品临床综合评价工作, 组织编制《国家药品临床综合评价管理指南》《抗肿瘤药物临床综合评价指南》《卫生技术评估》《卫生技术评估与政策评价 --- 理论与方法篇》等重要著作。作为第一作者及通讯作者在核心杂志发表文章 80 余篇。



周翔天

温州医科大学附属眼视光医院教授

温州医科大学附属眼视光医院教授，主要从事近视发病机制和临床防控等研究，提出近视形成的巩膜缺氧学说。入选国家杰出青年科学基金、国家自然科学基金优秀青年科学基金，中组部青年拔尖人才（国家“万人计划”），浙江省卫生领军人才等，现任中华医学会眼科分会青年委员会副主任委员、中华眼科学会视觉生理学组副组长、中华眼科学会专家会员，亚太眼科学院 fellow、ARVO Global Committee Members, 《Experimental Eye Research》《BJO》《Eye & Contact Lens》《中华眼科杂志》《中华眼视光学和视觉科学杂志》等杂志编委。已在眼科和视觉科学主流学术期刊上发表 SCI 文章 100 多篇，如 PNAS, IOVS 等杂志，如在领域主流杂志《Investigative Ophthalmology & Visual Science》上 20 余篇；已授权发明专利 9 项，包括 2 项国际专利；获得 2007 年度和 2009 年度国家科技进步二等奖（排名第三、第四）。



吕小蕾

海南博鳌乐城国际医疗旅游先行区管理局

海南博鳌乐城国际医疗旅游先行区管理局常务副局长。



平行论坛 企业界演讲嘉宾

【按首字母排序，排名不分先后】



Amy Rudolph

诺华制药全球医学事业部证据和卓越上市负责人

博士，诺华制药全球医学事业部证据和卓越上市负责人。Amy 于 1999 年开始从事制药行业，专注于以创新研究设计、实施科学和整合证据为重点的变革。曾任美国 HE&OR(卫生经济学和健康结果研究)以及医疗准入部门的负责人，曾在美国 HE&OR、数字医学、前期产品开发、CER(比较效果研究)和沟通部门担任领导职务。Amy 的工作聚焦于高血压(诺华制药公司)、动脉粥样硬化和卒中(辉瑞制药公司)等领域。拥有 13 项专利并发表了多篇文章，涵盖临床前研究、药物开发和健康结果研究等领域。



陈杰

瓴路药业(上海)高级副总裁，圣方医药研发首席科学官

统计学博士，同时担任瓴路药业(上海)责任有限公司生物统计和数据科学部负责人。美国斯坦福大学创新设计研究中心访问学者。陈博士具有超过 27 年的生物制药研发经验，是《Contemporary Clinical Trials》和《Journal of Biopharmaceutical Statistics》的编委，也是美国统计学会真实世界证据科学工作组共同主席。陈杰博士著有《医学产品安全性评价：生物学模型和统计方法》一书，并发表学术论文 50 余篇。



Gracy Crane

罗氏全球监管科学 RWD 分会负责人、政策负责人

GracyCrane 是一名癌症生物学家，生物医学硕士和癌症生物学博士学位，并在牛津大学(英国)和麻省理工学院(美国)完成了博士后培训。在制药行业拥有超过 12 年的经验，担任过不同的角色，包括医疗和科学事务、临床开发、健康结果研究和真实世界数据。在过去的 5 年中，供职于罗氏个性化医疗部门的全球数据科学团队，领导罕见癌症领域药物研发的真实世界证据策略。她在真实世界数据方面发表多篇文献，并在多个相关国际会议上担任讲者。



肖申

思路迪医药首席战略官、首席医学官

西弗吉尼亚大学博士，在约翰霍普金斯大学和北卡罗来纳大学完成博士后研究工作。思路迪医药 CSO&CMO。曾在 FDA 工作近 20 年，负责过数百个新药开发阶段的审评工作，同时作为临床评审员和 / 或综合评审小组负责人 (multi-discipline review team leader) 负责了十余款新药的上市审批。同时还负责药物评价与研究中心 (CDER) 新药审批中肾毒性相关咨询工作。此外，他还为 FDA 的医疗器械和辐射健康产品中心 (CDRH)、生物制品评价与研究中心 (CBER) 以及美国司法部提供肾病相关的咨询工作。负责和参与了多个 FDA 新药开发指南的起草和制定；与欧洲和加拿大药物监管机构 (EMA, Health Canada) 等讨论特定药物的药监标准、讨论 ICH 指南等。曾任职于南京军区南京总医院及全军肾病研究中心。获国家科技进步三等奖、全军科技进步二等奖等殊荣。



Joseph C. Cappelleri

辉瑞公司生物统计学执行总监

纽约市立大学（巴鲁克学院）的统计学、哈佛大学流行病学公共卫生学硕士学位，康奈尔大学心理测量学博士学位。美国统计协会研究员。合著约 1200 份外部演讲和 600 份关于临床和方法论主题的出版物，包括回归不连续性设计、荟萃分析和健康测量量表。2021 年获得 ISPOR Avedis Donabedian Outcomes Research 终身成就奖。



Laura Mauri

美敦力公司高级副总裁

哈佛医学院医学博士、哈佛大学文学学士、理学硕士，兼美敦力首席科学、医学及法规事务官，美敦力执行委员会成员。Mauri 博士于 2018 年担任美敦力全球临床研究和分析副总裁。2020 年开始，涉及法规事务，成为美敦力全球执行委员会一员。曾在 Brigham and women's Hospital 担任心脏介入专家长达 15 年之久。在 Brigham and women's Hospital 完成了专科培训。Mauri 博士还是美国临床研究学会、大学心脏病学家协会等学会协会的委员。她发表了近 200 篇论文，曾担任《循环》杂志的高级编辑，并于 2017 年获得美国心脏协会颁发的 Josepha.Vita 临床研究奖。



Laura Wallace

勃林格殷格翰全球流行病学及真实世界证据卓越中心负责人

Laura 女士 2016 年加入勃林格殷格翰公司，2020 年起担任勃林格殷格翰公司全球流行病学及真实世界证据卓越中心负责人。曾在美国布朗大学、南康涅狄格州立大学以及阿拉斯加大学费尔班克斯分校接受流行病学、心理学以及公共卫生方面的教育，目前从事流行病学工作。她于 2002 年进入制药行业，曾在包括流行病学、真实世界证据、药物安全及风险管理、药物开发以及医学事务等多个部门工作。



Mario Ouwens

阿斯利康医疗与支付方证据统计高级总监

Ouwens 博士在阿斯利康领导一个由 11 位统计学家组成的医疗与支付方证据统计小组，在过去的两年中，高度参与了 COVID-19 相关研究。他曾主导促使巴西国家卫生监督门 (ANVISA) 开始采用真实世界证据 (RWE) 的两个研讨会之一。2022 年，Ouwens 博士在 PPMA 上介绍了 RCT 结合 RWS 的综合证据及专家意见，并发表了包括“实用临床试验设计和统计分析的最佳实践建议：改进的德尔福方法”等在内的 6 篇文章。在阿斯利康公司内部，Ouwens 博士开发了实效性临床试验指南和 SIDE-L 框架，用于在 Statistical Interpretation Design External and Labeling 标准下评估观察性研究的质量。在过去 5 年中，Ouwens 博士经常在欧洲 ISPOR 会议上发表口头发言和在研讨会上演讲，并每年在 PPMA（欧洲最大的市场准入、定价和证据大会）进行介绍。他的工作在 NICE (UK) 的技术支持文件中被引用。



Najat Khan, Ph.D.

杨森制药首席数据科学官和战略与运营全球总监

宾夕法尼亚大学有机化学博士，柯盖德大学化学学士、经济学学士，同时担任强生数据科学委员会（Johnson & Johnson Data Science Council）的联合主席，是杨森管道决策机构（包括发展委员会和投资委员会）的核心成员，负责监督杨森研发战略、管道和投资组合优化，并在整个制药管道中全面结合数据科学和数字健康，推动患者的转型创新。其团队利用人工智能（AI）、机器学习、数字健康和真实世界证据（RWE）为患者带来变革性的价值。Najat 曾是波士顿咨询集团（BCG）的合伙人。2022 年，Najat 被《端点新闻》（Endpoints News）评为生物制药和生物技术领域 40 岁以下的前 20 名领导者。



Nancy A. Dreyer

艾昆纬真实世界解决方法荣誉首席科学官

北卡罗来纳大学教堂山分校的流行病学兼职教授，Dreyer Strategies LLC 总裁，国际药物流行病学学会和药物信息协会的成员，布兰迪斯大学信托人。她帮助推动了真实世界证据用于支持监管决策，美国、欧盟和中国机构最近发布的关于使用真实世界证据支持监管决策的指导文件中引用了她的工作成果。



Nirav Dalal

雅培全球数据科学与分析部副总裁

Nirav 先生深耕于医疗器械行业二十余载，致力于借助“大数据”和机器学习等途径提升医疗健康水平并创造医学价值。加州州立理工大学电气工程理学硕士学位；佩珀代因大学 MBA。已累计发表 50 多篇同行评审期刊论文、会议摘要及美国专利相关文件。曾多次在 FDA、先进医疗技术协会（AdvaMed）、医疗健康大数据中心、美国商会、美国医疗器械设计和制造展、全球心血管临床试验专家论坛上发表重要讲话，内容涉及医疗器械、真实世界证据、数字健康、卫生经济学和数据科学领域。



Paul Coplan

强生医疗器械部流行病学和真实世界数据科学副总裁

Paul 领导一个由流行病学家、数据专家和生物统计学家组成的团队。他是运用流行病学和真实世界证据开发新疫苗、药物和医疗技术并评估其上市后安全性和有效性的先驱者，参与了多种器械的上市后监测，以及强生公司的新冠肺炎等 8 种疫苗和 9 种药物的开发，撰写了 90 多篇科学文章和 500 多篇国际医学会议演讲，保持与美国食品药品监督管理局、欧洲药品管理局以及其他国家监管机构的合作。保罗在国家卫生技术评价体系数据质量框架工作组担任行业联合主席（FDA 担任监管方联合主席），同时也是医疗器械创新联盟患者输入科学工作组指导委员会成员。他领导了业界、监管机构和学术界之间的竞争前合作计划，为医疗产品评估、HIV 药物评估、疫苗和阿片类镇痛药的安全性评估建立风险收益评估框架。



Sandeep SANGA

安斯泰来公司（中国）投资有限公司高级总监

Sandeep 负责真实世界数据战略与联盟，生物医学数据领域专家。加州大学旧金山分校心血管研究所的博士后，接受过医学基因组学和应用数据科学的培训，重点方向是哮喘和结节病。Sandeep 是健康与生命科学行业的资深人士，曾担任多种科学、产品和商业有关的角色。Sandeep 和他的团队已经建立并将多个行业特定的 SaaS 产品推向市场，帮助客户快速从纵向和横向的临床、表型、基因组学和成像数据中获得最大价值。



唐伯雄

百济神州医学部卫生经济学和结果研究（HEOR）主管、执行总监

唐伯雄博士建立了百济国际卫生经济学和结果研究团队，负责 HEOR 职能并实施全球卫生经济学及成果研究战略。兼任国际药物经济学健康成果研究协会（ISPOR）亚洲分会工业委员会会长。在加入百济神州之前，他供职梯瓦（Teva）、辉瑞制药、强生公司和葛兰素史克公司，曾兼任复旦大学客座教授、浙江大学医学院客座研究员。唐伯雄博士在医药，卫生经济学和结果研究学领域有超过 20 多年的经验，发表了 30 多篇的学术论文，100 多篇科学文稿，文摘以及在各类重大国际科学大会上的演讲。



竟永华

艾伯维美国总部公司真实世界证据与分析高级总监

中国药科大学的药学学士学位，美国俄亥俄州医学院的药理学硕士学位、美国辛辛那提大学博士学位。过去 15 年，曾就职艾伯维等大型医药公司，并带领团队支持了多种畅销药物（阿立哌唑、艾乐妥、波立维和修美乐）的真实世界证据。他在真实世界证据研究设计和执行方面具有丰富的专业知识。自 2014 年以来，竟永华带领团体开发了艾伯维的真实数据平台，增强了公司真实世界证据研究能力，代表艾伯维参加了 PhRMA 真实世界证据工作组。竟永华博士是国际药物经济学和结果研究学会（ISPOR）亚洲联盟的长期成员，与亚洲和世界各地的真实世界证据专家有着良好的联系。



张明东

波士顿科学公司亚太区首席医务官及医学事务和卫生经济副总裁

美国国立卫生研究院国立癌症研究所博士后，助理研究员。美国贝乐医学院分子病毒学博士。曾任职香港中文大学医学院教授，美国食品药品监督管理局医务官和流行病学家。先后在国际上具有影响力的学术杂志上发表逾四十篇研究论文。在食品药品监督管理局任职期间，多次参加各种医疗器械及分子诊断试剂 PMA 及 510k 的评审、主持上市后研究设计、负责医疗器械的风险评估等。



Main Forum Leaders and Attendees



Feng Fei

Hainan Provincial People's Government

Deputy Secretary of the Hainan Provincial Party Committee, Governor of the Provincial Government of Hainan.



Wang Bin

Hainan Provincial People's Government

Member of the Standing Committee of the Hainan Provincial Party Committee, Director of the Publicity Department of the CPC Hainan Provincial Committee and Vice Governor of the Provincial Government of Hainan.



Xu Jinghe

National Medical Products Administration (NMPA)

Deputy Commissioner of National Medical Products Administration (NMPA).



Kong Fanpu

Center for Drug Evaluation (CDE), NMPA

Director of CDE, NMPA; Director of the Office of Generic Drug Quality and Efficacy Consistency Evaluation; former staffer of Drug Regulation of the Department of Drug Safety Regulation of the former China Food and Drug Administration (CFDA), former Director-general and Party Secretary of the Medical Device Technical Review Center of the former CFDA; former Director-general of the Department of Medical Device Regulation of the former CFDA. Since taking full charge of CDE in November 2018, he has continued to deepen the reform of the drug review and approval system, actively promoted the modernization of the review system and review capability, making every effort to promote the high-quality development of the pharmaceutical industry



Sun Lei

Center for Medical Device Evaluation (CMDE), NMPA

Director General of Center for Medical Device Evaluation (CMDE) of NMPA, Associate Researcher. He was once the Deputy Director (presiding) of Drug Testing Division of National Institution for the Control of Parametrical and Biological Products, Director of Division of Investigation and Enforcement II, responsible for the investigation and enforcement of severe cases for drugs and medical devices; then the Deputy Director General of Department of Medical Device Supervision, in charge of the supervision of manufacturing and distribution of medical devices, preside the overall work.



Shen Chuanyong

Center for Drug Reevaluation, NMPA

Doctor of Science, Associate Professor; currently the Director of Center for Drug Reevaluation (National Center for ADR Monitoring), NMPA; Director of the Key Laboratory of Pharmacovigilance Research and Evaluation, NMPA; Editor-in-chief of Chinese Journal of Pharmacovigilance. He is also a member of the 12th National Pharmacopoeia Committee, the executive director of 25th council of the Chinese Pharmaceutical Association, and the head of the Pharmacovigilance Special Committee under the association. He was the deputy director of the Chengdu Health Bureau of Sichuan Province, deputy director of the Drug Certification Center of the former China Food and Drug Administration, and director of the Institutional Service Center thereof. He is a delegate of the 15th Beijing Municipal People's Congress.



Dong Jiangping

China Center for Food and Drug International Exchange, NMPA

Deputy Director (presiding over work) of China Center for Food and Drug International Exchange, NMPA. Chief Pharmacist. She has served as a professional reviewer of chemical drugs, head of the review management and coordination office and head of the information office in Center for Drug Evaluation, NMPA; head of the Division of Chemical Drugs and of the Division of General Affairs, the Department of Drug Registration, NMPA; Deputy Director of Center for Food and Drug Inspection of NMPA, in charge of drug inspection and validation and international cooperation programs. She has been presiding over the work of China Center for Food and Drug International Change, NMPA since August, 2022.



Jia Ning

Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration

Commissioner of Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration, Commissioner of Hainan Healthcare Security Administration.



Zhu Ning

Hainan Medical Products Administration

Deputy Commissioner of Hainan Administration for Market Regulation,
Commissioner of Hainan Medical Products Administration.



Chen Shaoshi

Hainan Provincial Health Commission

Deputy Director of Hainan Provincial Health Commission.

Main Forum

Academicians/Experts



Wang Chen

Vice President of the Chinese Academy of Engineering, President of the Chinese Academy of Medical Sciences and Peking Union Medical College

An expert in respiratory medicine and critical care medicine. He is Academician of the Chinese Academy of Engineering, foreign member of the National Academy of Medicine of the US and the Academy of Europe, fellow of European Academy of Sciences and Arts, and divisional committee member of the Chinese Academy of Medical Sciences, and Director of National Respiratory Clinical Research Center. He holds multiple important professional posts in the WHO. He is the editor-in-chief of Chinese Medical Journal and member of the Lancet COVID-19 Commission. He has long been engaged in clinical, teaching and research work in respiratory and critical care medicine. His main research areas include respiratory pathology, population medicine and public health. He has made several important innovations and improved healthcare practices in the areas of chronic airway diseases, pulmonary embolism, respiratory failure, emerging respiratory infectious diseases, and smoking control. He has published more than 290 papers in prestigious international journals such as New Engl J Med and Lancet. He has received the Special Prize, First Prize and Second Prize of the National Science and Technology Progress Award. He has taken leadership and managerial roles in the Chinese Academy of Engineering, Chinese Academy of Medical Sciences, Peking Union Medical College, China-Japan Friendship Hospital, Department of Science and Education of the Ministry of Health, Beijing Hospital, Chaoyang Hospital and Beijing Institute of Respiratory Diseases, and has achieved remarkable performance in discipline building and administration. He has facilitated the creation of the standardized training and "4+4" medical education system for resident and specialist physicians in China.



Luo Qingming

President of Hainan University, Honorary President of Hainan Institute of Real World Data

Academician of the Chinese Academy of Sciences; Fellow of the Chinese Academy of Medical Sciences; Chairman of Hainan Association for Science and Technology; and Director of the Steering Committee of Biomedical Engineering Teaching in Institutions of Higher Education, Ministry of Education. He has won the second prizes of the National Natural Science Award (2010) and the National Technology Invention Award (2014), and the first prize of Huang Jiasi Biomedical Engineering Award (2021), and was selected for China Top Ten Science and Technology Progresses (2011).



Ning Guang

President of Ruijin Hospital Affiliated to Shanghai Jiao Tong University School of Medicine

Academician of the Chinese Academy of Engineering, tenured professor of Ruijin Hospital Affiliated to Shanghai Jiao Tong University School of Medicine; President of Ruijin Hospital Affiliated to Shanghai Jiaotong University School of Medicine; Director of National Clinical Medicine Research Center for Metabolic Diseases; Honorary Director of the Branch of Physicians in Endocrinology and Metabolism, Chinese Medical Doctor Association; former director of the Branch of Endocrinology, Chinese Medical Association; Editor-in-chief of Chinese Journal of Endocrinology and Metabolism; Editor of Journal of Diabetes. He is also the Changjiang distinguished professor of the Ministry of Education and chief scientist of the 973 program (National Basic Research Program). He has long been engaged in the clinical treatment of endocrine and metabolic diseases, and secured innovative outcomes in the diagnosis, treatment and research of endocrine tumors and diabetes. He has published 500 papers in SCI-indexed journals such as Science and JAMA. He has won 4 second prizes of the National Science and Technology Progress Award, 3 first prizes of the Shanghai Science and Technology Progress Award, the 2017 Shulan Medical Award, the 2014 Chinese Physician Award, Wu Jieping Medical Innovation Award, the second Bethune Doctor Award; he also claimed the Israel Diabetes Alliance Lifetime Achievement Award and International Endocrinology Award from the American Association of Clinical Endocrinology and the Yutaka Seino Distinguished Leadership Award.



Chen Pingyan

Executive President of Hainan Institute of Real World Data

Doctoral Supervisor, Cooperative Postdoctoral Supervisor, and Former Director of the Department of Biostatistics, Southern Medical University (1997-2019). He is the first in China to establish the department of biostatistics (2004), and the undergraduate major in biostatistics (2005). Chen is Executive President of Hainan Institute of Real World Data; Director of the Biostatistics Branch of Chinese Preventive Medicine Association; Vice Chairman of the International Biometric Society-Chinese Region; Chairman of Guangdong Biostatistics Association; and an expert in argumentation of administrative policies in Guangzhou. Chen published more than 280 papers on SMMR, SIM, NEJM, JAMA, JCO, JAMA-IN, ERJ, JASN and Radiology, among which 80 papers are published on SCI journals with a cumulative impact factor over 500. He is Editor-in-chief of the postgraduate textbook SPSS Statistical Software Application.

Main Forum

Guests from International Organizations and Foreign Regulatory Institutions



Gauden GALEA

WHO Representative in China

Public health physician, currently working as the WHO Representative in China, based in Beijing since April 2018. He has been coordinating the collaboration between WHO and China across all health concerns, with a primary focus on: the COVID-19 response, the review of a decade of health sector reform, advocacy for tobacco and alcohol control, and exploring the digital health landscape of China. On behalf of the Western Pacific Region of WHO, he has been coordinating an effort promoting innovation in public health within the "For the Future" vision of the Region. Dr Galea has worked for WHO since 1998. Before assuming his current post, he worked in WHO/Europe. He previously held posts in Suva, Manila, and Geneva as technical officer, regional adviser, and coordinator respectively in areas related to NCDs and Health Promotion.



Vanessa Shaw-Dore

Director of the China Office in the FDA's Office of Global Policy and Strategy (OGPS)

Vanessa Shaw-Dore joined FDA in April 2020 as Director of the China Office. Ms. Shaw-Dore previously served as Deputy Program Director of the Center for Disease Control's (CDC) Division of Global Health Protection (DGHP) overseeing CDC's Global Health Security Agenda (GHS) work in Vietnam. Prior to her time in Vietnam, Ms. Shaw-Dore served in the same office as Deputy Program Director for CDC's Democratic Republic of the Congo country office, and Branch Chief in the Health Resources and Services Administration HIV/ AIDS Bureau, Division of State HIV/AIDS Programs. In that role, Ms. Shaw-Dore oversaw \$490 million in federal funds in support of Ryan White Part B and AIDS Drug Assistance Program grants for 20 states and U.S. territories, including Washington D.C. Ms. Shaw-Dore has 15+ plus years of operations and management experience with international public health programs. She has also led the coordination of high-level interagency programs.



Andrej Segec

Scientific administrator of Data Analytics and Methods Task Force, European Medicines Agency

Pharmacist by training (Comenius University, Bratislava, Slovakia) with an MSc in Epidemiology (London School of Hygiene and Tropical Medicine, London, UK). He has worked for the European Medicines Agency (EMA) since 2008, holding a number of roles in pharmacovigilance, from signal detection and signal management, monitoring of the performance of the EMA pharmacovigilance system, in surveillance and epidemiology, as committee manager for the operations of the Pharmacovigilance Risk Assessment Committee (PRAC) and as a risk management specialist for anti-infective therapies and vaccines. In the current role, Andrej's focus is on the generation and use of real world evidence in regulatory decision making and the establishment of the Data Analysis and Real World Interrogation Network (DARWIN EU).



Hanako MORIKAWA

Pharmaceuticals and Medical Devices Agency (PMDA)

Principal Reviewer of Office of Medical Devices II, Pharmaceuticals and Medical Devices Agency (PMDA).

Sub-Forums

Hosts/Speakers from Government Departments and Academia



Daniel O'Connor

Expert medical Assessor of the Medicines and Healthcare products Regulatory Agency, the UK (MHRA)

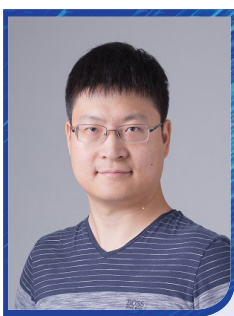
His PhD in the field of tumour suppressor genes was awarded from Imperial College London. He joined the Medicines and Healthcare products Regulatory Agency (MHRA) as a Medical Assessor in 2006 from a clinical lecturer post at UCL/UCL/Ludwig Institute for Cancer Research. He works in the licensing division of the MHRA with special interests in rare diseases, early access and patient reported outcomes and engagement. He is editor author of the first edition Oxford Specialist Handbook of Pharmaceutical Medicine and on the editorial board of the journals Expert Opinion on Orphan Drugs and Rare Disease and Orphan Drugs Journal.



Du Jie

Director of Key Laboratory of Cardiovascular Remodeling-related Diseases, Ministry of Education, Capital Medical University

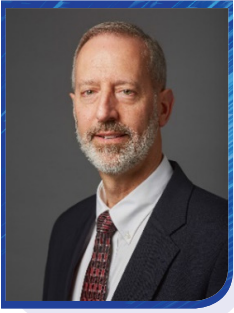
Deputy Director of Beijing Institute of Heart, Lung and Blood Vessel Diseases. Chief Scientist of National Key Research and Development Program, Beijing Scholar. He is committed to the early diagnosis, risk assessment and precise diagnosis and treatment of cardiovascular diseases as well as the related commercialization issue. He has conducted a series of clinical translational research and advanced commercialization of self-developed clinical diagnostic products.



Han Dongran

Distinguished Professor, School of Life Sciences, Beijing University of Chinese Medicine

Distinguished Professor of School of Life Sciences, Beijing University of Chinese Medicine, Deputy Director of Education and Information Center, Academic Leader of Big Data of Traditional Chinese Medicine in the Basic Professional of Integrated Traditional Chinese and Western Medicine. Focusing on the top-level design and standardization construction of the big data ecosystem of traditional Chinese medicine, he led a number of original work in the direction of big data and informatization in the university, and was responsible for a number of national key R&D projects, which were cited more than 3,400 times by Google Scholar. 2 invention patents in the United States and 8 domestic invention patents, all of which are the primary inventors.



John Concato

Associate Director for Real-World Evidence Analytics in the Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)

As an internist and epidemiologist, Dr. Concato seeks to enhance policies related to drug development and regulatory review. His responsibilities include a focus on real-world evidence (RWE) and involve work developing internal Agency processes for evaluating RWE, interacting with external stakeholders regarding RWE, supporting RWE demonstration projects and guidance development, and serving as the Chair of the RWE Subcommittee. Prior to joining FDA, his career focused on generating research as an independent investigator, research center director, and Professor of Medicine at Yale University School of Medicine and the U.S. Department of Veterans Affairs (VA); he also was one of two founding principal investigators of the VA Million Veteran Program genomic mega-biobank. He received M.D. and M.S. degrees from New York University and an M.P.H. degree from Yale University.



Li Qiu

President of Children's Hospital of Chongqing Medical University

Professor, doctoral supervisor, director of the National Children's Clinical Medical Research Center, Young and Middle-aged Experts with Outstanding Contributions of the National Health and Family Planning Commission of China, and experts eligible for special government allowances from the State Council. The first batch of leading medical talents in Chongqing, chief expert of Chongqing Chief Expert Studio, member of the Standing Committee of the Central Committee of the Democratic League and deputy to the National People's Congress. Member of the Standing Committee and Secretary General of the Pediatrics Branch of the Chinese Medical Association, Vice Chairman of the Children's Hospital Management Branch of the Chinese Hospital Association, Vice Chairman of the Pediatrics Professional Instructor Committee of the Higher Education Guidance Committee of the Ministry of Education, and Deputy Head of the Nephrology Group of the Pediatrics Branch of the Chinese Medical Association. He has presided over more than 10 national projects, won the first prize of Chongqing Science and Technology Progress Award, the second prize of Science and Technology Progress Award of the Ministry of Education, the first prize of Chongqing Teaching Achievement Award, the Song Qingling Pediatric Medicine Award and many other awards, and served as the chief editor and deputy editor of the textbook of People's medical publishing house.



Li Yali

Hainan Medical Products Administration

Deputy Director of Hainan Medical Products Administration.



Liu Jianping

Executive Dean of International Evidence-based Chinese Medicine Research Institute, Director of Evidence-based Medicine Center, Beijing University of Chinese Medicine

Doctor of Medicine, Distinguished Professor of the Chang Jiang Scholars Program, the Ministry of Education, and Doctoral Supervisor. He is granted the special government allowance of the State Council. He ever studied abroad and worked at the University of Liverpool in the UK. He holds the following academic positions: President of International Society of Complementary and Integrative Medicine Research (ISCMR) (ISCMR 2017-2019); Advisor on Traditional Medicine of World Health Organization; Member of the 7th Integrated Chinese and Western Medicines Discipline Evaluation Group of the Academic Degrees Committee of the State Council; and Honorary Director of the Evidence-based Medicine Professional Committee of Chinese Association of Integrative Medicine. He is Editor-in-chief of 10 textbooks and monographs, and publishes more than 650 academic papers at home and abroad, 229 of which are included in SCI.



Liu Yinghui

Director of the First Department of Clinical and Biostatistics of Center for Medical Device Evaluation (CMDE) of NMPA

Doctor of Medicine, Chairman of the medical device clinical evaluation working group of the International Medical Device Regulators Forum (IMDRF), the deputy leader of the national medical device clinical evaluation standardization technology NFP (national focal point).



Lu Qianjin

Executive President of Hospital for Skin Diseases, the Chinese Academy of Medical Sciences

Chief Physician, Professor, and Doctoral Supervisor, granted with special government allowances of the State Council. He is Executive President of Hospital for Skin Diseases and Executive Director of Institute of Dermatology, the Chinese Academy of Medical Sciences; Director of the Key Laboratory of Basic and Translational Research in Immunodermatology, the Chinese Academy of Medical Sciences; Director of the Dermatology Branch, Chinese Medical Association; member of Asian Dermatological Association; Deputy Director of the Dermatology Branch, World Association Of Chinese Doctors; Deputy Director of the Dermatology Branch, Chinese Medical Doctor Association; Executive Director of Chinese Society for Immunology, and Chief Scientist of the Lupus Erythematosus Research Center of the Dermatology Branch, Chinese Medical Association. Associate Editor of Clinical Immunology.



Qu Jia

Optometry Director of the School of Ophthalmology and Optometry, Wenzhou Medical University, Executive President of Hainan Institute of Real World Data

Professor, chief physician and doctoral supervisor. President of Wenzhou Medical University Eye Hospital Group. Qu is Director of National Key Laboratory in Ophthalmology, Optometry and Visual Science, Director of National Ophthalmology & Optometry Engineering Technology Research Center; member of the Clinical Medicine Discipline Evaluation Group of the Academic Degrees Committee of the State Council; Director of the Steering Committee of Ophthalmology and Optometry Medical Education of Institutions of Higher Learning, Ministry of Education; Vice Chairman, and Director of the Ophthalmological Branch, Chinese Geriatrics Society; and Deputy Director of Chinese Ophthalmological Branch, Chinese Medical Association. He ever served as Chief Scientist of the “973” Programme and undertook more than 100 research projects. He has won 2 second prizes of National Science and Technology Progress Award, 3 National Teaching Achievement Awards, and more than 10 provincial and ministerial level awards including the first prize of Chinese Medical Science and Technology Award.



Shang Hongcai

Executive vice president of Dongzhimen Hospital, Beijing University of Chinese Medicine

Researcher and Doctoral Supervisor. He is winner of the National Science Fund for Distinguished Young Scholars. He is Director of the Key Laboratory of Chinese Internal Medicine of Ministry of Education (Beijing University of Chinese Medicine); Deputy President of Dongzhimen Hospital of Beijing University of Chinese Medicine; and Deputy Director of Institute of Cardiovascular Diseases of Beijing University of Chinese Medicine. His research interests are the evaluation of clinical evidence of traditional Chinese medicine, the characteristics of the effect and its mechanism. He is leading a number of national projects such as those under the National Key Research and Development Program, and the National Science Fund for Distinguished Young Scholars of the National Natural Science Foundation. He has won 3 second prizes of National Science and Technology Progress Award and 6 first prizes of provincial and ministerial-level awards. He has published more than 200 papers, among which 70 are SCI papers, with the total impact factor at 247. His papers have been cited more than 600 times by SCI papers and 1,121 times by Chinese papers, and cited by internationally renowned journals such as Nature Reviews Cardiology. He has been granted 6 invention patents and 2 software copyrights.



Shi Luwen

Professor of School of Pharmacy, Peking University

Doctoral Supervisor. Director of International Research Center for Medicinal Administration, Peking University. Deputy Director of the Pharmaceutical Policy Professional Committee, China Pharmaceutical Innovation and Research Development Association. Director of the Pharmacoeconomics Professional Committee, Chinese Research Hospital Association. Director of the Pharmacoeconomics Professional Committee, Beijing Pharmaceutical Association. Deputy Director of the Rare Diseases Branch, Beijing Medical Association. Deputy Director of the Drug Clinical Evaluation Research Professional Committee, China Association of Traditional Chinese Medicine. Deputy Director of the Pharmaceutical Management Branch, Committee of Experts on Modern Hospital Management Capacity Building. Member of Committee of Experts on Consistency Evaluation of Generic Drug Quality and Efficacy. Member of the 2nd Committee of Experts on Rare Disease Diagnosis, Treatment and Medical Security, National Health Commission. Member of the Expert Team, Drug Price, Bidding and Procurement Guidance Center, National Healthcare Security Administration. Associate Editor-in-chief of Chinese Pharmaceutical Journal (English edition).



Scott Gonzalez

International Program and Policy Analyst (IPPA) - Medical Devices at the United States Food and Drug Administration (FDA) China Office

Before being named the Acting International Program and Policy Analyst, Mr. Gonzalez spent 9 years in the FDA's Center for Devices and Radiological Health (CDRH) including the Office of In Vitro Diagnostics and Radiological Health (OIR) and the Office of Strategic Partnerships and Technology Innovation (OST). During his tenure at the FDA he has also served as a pre-market/post-market Lead Reviewer and Acting Chief of the Diagnostic X-Ray Systems Branch as well as a Senior Technical Advisor to the Office of In Vitro Diagnostics and Radiological Health. Mr. Gonzalez is a subject matter expert regarding the regulation of electronic product radiation emitting devices and is a contributor to many international consensus standards relating to the testing as well as the basic safety and essential performance of diagnostic x-ray systems and their major components.



Sun Xin

Director of China Evidence-based Medicine Center, West China Hospital, Sichuan University and Deputy President of Hainan Institute of Real World Data

Researcher and doctoral supervisor. Director of NMPA Key Laboratory for Real World Data Research and Evaluation in Hainan. Director of Sichuan Real World Data Technology Innovation Center. Director of Cochrane China Center. Director of MAGIC China Center. Executive Editor-in-Chief of the Chinese Journal of Evidence-based Medicine and Journal of Evidence-based Medicine. Director of the Real World Research Professional Committee, China Association of Traditional Chinese Medicine. His research interests are theoretical innovation and applications of the RWD research system and the R&D, evaluation and application of the modern efficacy-oriented TCM. He has presided over more than 20 vertical projects of National Natural Science Foundation of China and National Key R&D Program of China, and published 119 SCI papers in JAMA, BMJ, International Journal of Epidemiology, Critical Care Medicine, etc., with an H index of 36. He is Chief Editor of postgraduate program textbooks of "Evidence-Based Medicine" and the monograph of "Evidence-Based Traditional Chinese Medicine". He won the first prize of Sichuan Science and Technology Progress Award, the second prize of Science and Technology Progress Award of the Ministry of Education, and the BMJ Outstanding Research Achievement Award.



Tan Ming

Head of Department of Biostatistics, Georgetown University Medical Center

Doctoral degree in statistics. Tenured professor of Biomathematics at School of Medicine, Georgetown University and Georgetown Lombardi National Comprehensive Cancer Center. He is a Committee Member or Chairman of Data and Safety Monitoring Committees for Clinical Trials of New Drug at NIH and pharmaceutical companies, Member of FDA Expert Committee and many National Institutes of Health Project Review Committees, and Expert Consultant of many pharmaceutical R&D and investment companies. He is the Executive Editor of Molecular Carcinogenesis. He has long studied experimental design and statistical methods for new drug development, and has published more than 200 academic papers in prestigious international journals.



Wang Jianxiang

Vice Director of Institute of Hematology & Blood Diseases Hospital, Chinese Academy of Medical Sciences

Professor, PhD Supervisor, Chief Physician. He is Director of Leukemia Treatment Center of Blood Diseases Hospital, Chinese Academy of Medical Sciences, Director of Institute of Hematology, the Vice President of Internal Medicine Branch of Chinese Medical Doctor Association, the Vice President of Hematology Branch of Chinese Medical Doctor Association, the Associate Chief Editor of J Hematol & Oncol, and a member of the Editorial Board of Blood. He once served as Director of Hematology Branch of Chinese Medical Association, Chief Editor of Chinese Journal of Hematology (2012-2016), and Director of China Anti-Cancer Association Hematology Oncology Special Committee (2012-2015). He was selected as "Distinguished Young Scholars" and the National Talent of "New Century Hundred-Thousand-Ten Thousand Talent Project". He is a special expert of the Ministry of Health and is specially funded by the State Council. He is the main developer of CD19 and CD33 CAR-T, a leader in leukemia treatment, with prognostic stratification, intensive induction, and full management significantly improving the outcome of treating acute leukemia. He has led the development of several guidelines for the treatment of acute myeloid leukemia, acute lymphoblastic leukemia, and chronic myeloid.



Wang Jun

Director of the Department of Statistics and Clinical Pharmacology, Center for Drug Evaluation, NMPA

Doctor, Researcher, Director of the Department of Statistics and Clinical Pharmacology of Center for Drug Evaluation, National Medical Products Administration. Wang graduated from the Chinese Center for Disease Control and Prevention (CDC) and started working at the CDC Information Center in 2005. He joined the Center for Drug Evaluation in 2011, mainly engaging in new drug statistical evaluation, clinical pharmacology evaluation and consistency evaluation. Besides, he presided over or participated in the revision of many guidelines related to clinical trial statistics, and was the main author of guidelines such as Guidelines for Real World Evidence to Support Drug Research, Development and Evaluation and Guidelines for Real World Data Used to Generate Real World Evidence. He is also a member of the ICH E9(R1) and M14 Expert Working Group and is responsible for the translation and implementation of ICH E17 and other guidelines in China.



Weng Jianping

Deputy Director of Life Sciences and Medicine Department, University of Science and Technology of China

Doctor of Medicine, Distinguished Professor of Ministry of Education of the People's Republic of China, Executive Dean of School of Clinical Medicine, University of Science and Technology of China; Deputy Dean of the First Affiliated Hospital of USTC (Anhui Provincial Hospital), Dean of Bengbu Medical College. His research areas include the early prevention and treatment of type 2 diabetes and its complications, molecular genetic mechanism of special types of diabetes, the development and application of artificial pancreas, new pathogenesis of diabetes susceptibility genes, and chronic non-communicable disease cohorts and its application. He has undertaken two Projects for Innovative Research Team in University of Ministry of Education of the PRC, and led large-scale projects such as National Key R&D Program, the 12th Five-Year Major Science and Technology Project.



Wu Jing

Deputy Dean of School of Pharmaceutical Science and Technology, Tianjin University

Professor. She received a Ph.D. degree in pharmacoeconomics jointly issued by Shenyang Pharmaceutical University and Peking University in 2007. From 2013 to 2014, She was a visiting scholar at the Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California. Dr. Wu holds the following part-time positions: Deputy Director of the Pharmaceutical Economics Professional Committee of Chinese Pharmaceutical Association; Deputy Director of the Pharmaceutical Economics Professional Committee of Chinese Research Hospital Association; Vice Chairman of Tianjin Medical Insurance Research Association; and Executive Director of Tianjin Health Economics Association. Her research interests are in health economics and pharmacoeconomics. In the past five years, Dr. Wu has published more than 40 papers in English (SSCI&SCI) and more than 60 papers in Chinese. She presided over three programs sponsored by the National Natural Science Foundation of China. She co-authored Pharmacoeconomics (China Medical Science and Technology Press), Pharmacoeconomics (Higher Education Press), and China Guidelines on Pharmacoeconomic Evaluation and Manual 2015, and National Essential Medicine System: Theories and Experiences. She is one of the lead authors of 2020 China Guidelines on Pharmacoeconomic Evaluation and Manual.



Xie Yiqiang

Professor of School of Traditional Chinese Medicine, Hainan Medical University

Doctoral Supervisor, School of Traditional Chinese Medicine, Hainan Medical University. Professor Xie is on the Steering Committee of Integrated Traditional Chinese and Western Medicines Education in Institutions of Higher Education, Ministry of Education. He is head of the team in the first batch of Hainan Province "Double Hundred" talent teams, on the lists of Leading Talents, Nanhai Masters, and Outstanding Experts in Hainan province, and a candidate for first-level talents in 515 Talent Project in Hainan province. He is Final Review Expert of the National Natural Science Foundation of China; Deputy Director of the health maintenance and Rehabilitation Branch, China Association of Chinese Medicine; Deputy Youth Director of the Committee of Experts on the Basic Research Platform for Prevention and Treatment of Major Diseases with Traditional Chinese Medicine, China Association of Chinese Medicine; Deputy Chairman of the Endocrinology Branch, World Federation of Chinese Medicine Societies; Standing Member of the Diabetes Branch, China Association of Chinese Medicine; Vice President of Hainan Provincial Association of Chinese Medicine. He is on the editorial board of TMR Modern Herbal Medicine, International Journal of Chinese Medicine. He has undertaken 3 projects of National Natural Science Foundation of China, and 3 projects of Hainan Province, with a total research fund of more than 5 million yuan. He has published more than 150 papers. He authored or participated in the writing of 13 books. He has won 2 prizes of Hainan Provincial Science and Technology Progress Award, 1 Hainan Provincial Research Achievement Award for Institution of Higher Education, and been granted 14 invention patents.



Xu Hua

Professor of the University of Texas, USA

Professor and Director, Center for Computational Biomedicine. Associate Dean for Innovation. School of Biomedical Informatics. The University of Texas Health Science Center at Houston. Dr. Hua Xu is a Professor and Associate Dean for Innovation at the School of Biomedical Informatics in The University of Texas Health Science Center at Houston (UTHealth), as well as an elected fellow of the American College of Medical Informatics. He directs the Center for Computational Biomedicine at UTHealth. Dr. Xu received his Ph.D. in Biomedical Informatics from Columbia University. His primary research interests include biomedical natural language processing (NLP) and data mining, as well as their applications in secondary use of electronic health records data for clinical and translational research. His research is funded by multiple agencies (i.e., NLM, NCI, NIGMS, AHA, and CPRIT), and methods/tools developed in his lab have been top ranked in a number of biomedical NLP shared tasks and widely used to support diverse biomedical researches.



Xuan Jianwei

Professor of School of Pharmaceutical Sciences, Sun Yat-Sen University

Director of the Institute of Pharmaceutical Economics, School of Pharmaceutical Sciences, Sun Yat-Sen University. Researcher of the Research Center of National Drug Policy & Ecosystem (NDPE), expert of Shanghai Thousand Talents Program. He has published more than 300 academic articles in the fields of clinical research, health economics, medical big data, and policy research. He has cooperated with China's National Development and Reform Commission, China's National Health Commission, and the National Healthcare Security Administration for many times to conduct policy research, and has led global clinical research in many multinational companies. His research results have been applied in many countries for medical decision-making.



Yang Yue

Researcher of the School of Pharmaceutical Sciences, Tsinghua University

Researcher and Doctoral Supervisor at the School of Pharmaceutical Sciences, Tsinghua University. As the first one in China to obtain a PhD degree in pharmaceutical management, she focuses on pharmaceutical regulations, policies and regulation. She is a member of NMPA's communication team for Drug Administration Law, Vaccine Administration Law and Regulations for the Supervision and Administration of Medical Devices. Her representative works include Scientific Research on Drug Regulation in the United States, Introduction to the Drug Marketing Authorization Holder System, and 21st Century Cures Act.



Yao Chen

Director of the Medical Statistics Department of Peking University First Hospital, Deputy President of Hainan Institute of Real World Data

Doctoral Supervisor and professor; Director of the Medical Statistics Department of Peking University First Hospital, Deputy President of Hainan Institute of Real World Data, Deputy Director of Peking University Clinical Research Institute. He holds the following academic positions: Director of the Evidence-based Medicine Professional Committee of Chinese Medical Doctor Association; Deputy Director of the Statistical Theory and Methods Professional Committee of Chinese Health Statistics Association; Deputy Director of the Real World Research Professional Committee of World Federation of Chinese Medicine Societies; Deputy Director of the Department of Oncology of Wu Jieping Medical Foundation; and Expert of Drug and Device Review, National Food and Drug Administration. Professor Yao participated in Johnson & Johnson's real-world research project on Catalys precision laser cataract surgery in Lecheng, Boao, and applied the real-world data in the research in the automated collection process. The paper on this methodological research has been published in China Food and Drug Administration Magazine.



Yuan Hongbo

Scientific Advisor of Canadian Agency for Drugs and Technologies in Health (CADTH)

Board of Director, and past Chair of the Comparative Efficacy Research Group of the International Society of Pharmacoepidemiology (ISPE). He obtained his doctoral degree in the Department of Epidemiology and Biostatistics, McGill University in 2002. Since 2010, Dr. Yuan has provided scientific support to the evaluation of efficacy and safety (HTA) for over 200 various new drug applications.



Zhan Siyan

Dean of School of Public Health, Peking University, Director of the Department of Epidemiology and Biostatistics of School of Public Health, Peking University

Professor, Doctoral Supervisor; Director of Clinical Epidemiology Research Center, Peking University Third Hospital. She is also Executive Director, and Director of the Pharmacoepidemiology Professional Committee, Association of Chinese Pharmaceutical Association; and Director of the Epidemiology Branch of Chinese Preventive Medicine Association. Professor Zhan is Editor-in-chief of Chinese Journal of Pharmacoepidemiology, Associate Editor-in-chief of Chinese Journal of Epidemiology and the medical edition of Science Bulletin, Editor-in-chief of the 7th and 8th editions of the textbook Epidemiology, and Editor-in-chief of the 2nd edition of the textbook Clinical Epidemiology. Her research interests are in pharmacoepidemiology, clinical epidemiology and evidence-based medicine. Professor Zhan has undertaken a number of projects funded by the Ministry of Science and Technology and National Natural Science Fund, published more than 200 papers as the first or responsible author. She won the 17th Wu Jieping-Paul Janssen Medical & Pharmaceutical Award in 2016, and was awarded the title of Beijing Excellent Teacher in 2017, and the title of Outstanding Individual in Beijing's Fight against COVID-19 in 2020. She is granted special government allowance of the State Council.



Zhang Wensheng

Deputy Chief Engineer, Institute of Automation, Chinese Academy of Sciences

Researcher, doctoral supervisor, chair professor of artificial intelligence at the University of Chinese Academy of Sciences, dean of Cmdt Artificial Intelligence Research Institute (Suzhou) Co., Ltd., chief scientist of the major project of Strategy for Science, Technology and Innovation Development until 2030-"new generation artificial intelligence"; member of the group of experts in "Cloud Computing and Big Data sector" and "Internet of Things and Smart Cities" of the National Science and Technology Major Project, vice chairman of the Internet of Things Working Committee of China Instrument and Control Society, deputy director of the Intelligence Services Committee of the Chinese Association for Artificial Intelligence. He previously took on such posts as head of the science and technology section, head of major projects, member of the institute affairs committee, and assistant to the institute head. Recent fields of research include: big data and data mining, Artificial Intelligence, Machine Learning, pattern recognition, 3D physical simulation, embedded video image processing. He has published more than 200 papers, secured more than 50 foreign and domestic inventions and patents, 1 national second prize, and 5 provincial and ministerial second prizes.



Zhao Kun

Vanke School of Public Health, Tsinghua University

Distinguished Visiting Professor, Vanke School of Public Health, Tsinghua University. Deputy Director of the Center for Comprehensive Drugs and Health Technology Assessment. Deputy Director of the Committee of Experts on Rare Disease Diagnosis, Treatment and Protection, National Health Commission. Deputy Chairman/Secretary-General of the Health Technology Assessment Professional Committee, Chinese Health Economics Association. Deputy Director of the Early Measurement and Evaluation Professional Committee, Chinese Preventive Medicine Association. Deputy Director of the Medical Policy Professional Committee, China Pharmaceutical Innovation and Research Development Association. Director of China Health Insurance Research Association. Director of China Alliance for Rare Disease. Chairman of ISPOR Asia Pacific Conference Program Committee (2018-2020). Chairman of Asian Health Technology Assessment Alliance (2021-2022). Professor Zhao has led the third-party evaluation on the construction of a tiered diagnosis and treatment system, National Health Commission. The evaluation on the project of the national key disciplines in clinical medicine. Professor Zhao is responsible for advancing the comprehensive drug clinical evaluation, and has participated in the writing of the National Guidelines on Managing the Comprehensive Drug Clinical Evaluation, Guidelines on Comprehensive Clinical Evaluation of Anti-tumor Drugs, Guidelines on Comprehensive Clinical Evaluation of Cardiovascular Drugs, Guidelines on Comprehensive Clinical Evaluation on Children's Drugs, and Guidelines on Comprehensive Clinical Evaluation of Rare Disease Drugs. Professor Zhao has published more than 80 papers in core journals as the first author and corresponding author. She is Editor-in-chief of Health Technology Assessment and Policy Evaluation-Theory and Methodology and Health Technology Assessment and Policy Evaluation-Empirical Study.



Zhou Xiangtian

Professor of Eye Hospital, Wenzhou Medical University

Prof. Zhou mainly engaged in research on the pathogenesis and clinical prevention and control of myopia, and proposed the theory of scleral hypoxia in the formation of myopia. He has received National Science Fund for Distinguished Young Scholars, and National Natural Science Fund for Outstanding Young Scholars. Besides, he was selected as Young Top-level Talents of the Organization Department of the Central Committee of the People's Republic of China (Ten Thousand Talents Program) and won honors such as Leading Healthcare Talents of Zhejiang Province. He currently serves as Vice Chairman of the Youth Committee of Chinese Ophthalmological Society, Chinese Medical Association. He is Deputy Group Leader of Visual Physiology Group of Chinese Society of Ophthalmology, Expert Member of Chinese Society of Ophthalmology, Chinese Medical Association, Fellow of Asia-Pacific Academy of Ophthalmology, Member of ARVO Global Committee, and Editor Board Member of prestigious journals such as Experimental Eye Research, BJO, Eye & Contact Lens, Chinese Journal of Ophthalmology, and Chinese Journal of Optometry & Ophthalmology and Visual Science. He has published more than 100 SCI articles in mainstream academic journals in ophthalmology and visual science, such as PNAS, IOVS, etc., and more than 20 articles in mainstream journals in the field, such as Investigative Ophthalmology & Visual Science. He has been granted 9 invention patents, including 2 international patents; he received the second prize of National Science and Technology Progress in 2007 and 2009 (ranking the third and the fourth respectively).



Lyu Xiaolei

Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration

Executive Deputy Director of Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration.



Sub-Forums

Speakers from the Corporate Sector



Amy Rudolph

Global Head of Evidence and Launch Excellence, Global Drug Development at Novartis Pharmaceuticals Corporation

Amy has been in the industry since 1999, dedicated to research design innovation, science implementation and evidence integration. She previously held positions as Head of US HE&OR (Health Economics and Outcomes Research) and Medical Access, as well as leading positions in HE&OR, digital medicine, early products, CER (comparative effect research) and communication. Amy also previously held two other roles in medical affairs with a focus on hypertension with Novartis, and on atherosclerosis and stroke with Pfizer, Inc. Amy has also been granted 13 patents and published numerous articles spanning preclinical research, drug development, and outcomes research.



Chen Jie

Chief Scientific Officer at Elixir Clinical Research (ECR Global) and Senior Vice President at Overland Pharmaceuticals

Doctoral degree in statistics. Dr. Chen Jie is also the head of Biometrics at Overland Pharmaceuticals. He is a visiting scholar at the Center for Design Research at Stanford University. Dr. Chen has over 27 years of biopharmaceutical R&D experience and is on the editorial board of Contemporary Clinical Trials and Journal of Biopharmaceutical Statistics. He is currently co-chair for the project of the American Statistical Association (ASA) BIOP Real-World Evidence Scientific Working Group (SWG). Dr. Chen authored a book on Medical Product Safety Evaluation: Biological Models and Statistical Methods and published over 50 papers in journals.



Gracy Crane

RWD policy lead and Chapter Lead within the Global Regulatory Policy team at Roche

Gracy Crane is a cancer biologist by training with a Master in Biomedical Research and a Ph.D. in Cancer Biology. She has also completed post-doctoral training fellowships at Oxford University (UK) and Massachusetts Institute of Technology (USA). She has over 12 years of experience in the pharmaceutical industry, in varying roles including medical and scientific affairs, clinical development, health outcomes research and real world data. For the past 5 years, she has worked on leading the real world evidence strategy for molecules within the rare cancer space as part of the global Data Science team of the personalized health care department at Roche. Currently, she is the RWD policy lead and Chapter Lead within the Global Regulatory Policy team at Roche. She has authored many publications on this topic and has presented in many international conferences.



Xiao Shen

Chief Strategy Officer and Chief Medical Officer of 3D Medicines

Ph.D., West Virginia University, Dr. Xiao completed postdoctoral research at Johns Hopkins University and the University of North Carolina. He has worked in the FDA for nearly 20 years, responsible for hundreds of New Drug Development and Review Process, and as a clinical reviewer and/or multi-discipline review team leader, responsible for the marketing approval of more than ten new drugs. He is also responsible for the consultation work related to nephrotoxicity in new drug approval at the Center for Drug Evaluation and Research (CDER). In addition, he consulted on kidney disease for the FDA's Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), and the U.S. Department of Justice. Dr. Xiao was responsible for and participated in the drafting and development of multiple FDA new drug development guidelines; discussing drug-specific regulatory standards, ICH guidelines, etc. with European and Canadian drug regulatory agencies (EMA, Health Canada), etc. He worked in Nanjing General Hospital of Nanjing Military Region and the All-Army Nephrology Research Center. He won the third prize of the National Science and Technological Progress Prize and the second prize of the All-Army Science and Technological Progress Prize.



Joseph C. Cappelleri

Executive director of biostatistics at Pfizer Inc.

He earned his MS in statistics from the City University of New York (Baruch College), PhD in psychometrics from Cornell University, and MPH in epidemiology from Harvard University. Dr. Cappelleri is an elected Fellow of the American Statistical Association. He has coauthored approximately 1,200 external presentations and 600 publications on clinical and methodological topics, including on regression-discontinuity designs, meta-analysis, and health measurement scales. He is the 2021 recipient of the ISPOR Avedis Donabedian Outcomes Research Lifetime Achievement Award.



Laura Mauri

Senior Vice President of Medtronic

M.D., Harvard Medical School; B.A., M.S., Harvard University; Senior Vice President and Chief Clinical & Regulatory Officer at Medtronic, Member of the Executive Committee of Medtronic. In 2018, Dr. Mauri became Vice President of Global Clinical Research and Analytics at Medtronic. In 2020, she became Member of Global Executive Committee at Medtronic. Before joining Medtronic, she has been working as an interventional cardiologist at Brigham and Women's Hospital for 15 years. With a Bachelor of Arts and Master of Science from Harvard University, and a PhD of Medicine from Harvard Medical College, she completed her training at Brigham and Women's Hospital. She is Member of reputed associations such as American Association of Clinical Research and American College of Cardiology and Senior Editor of Circulation. She has published about 200 papers and received the Joseph A. Vita Award from American Heart Association in 2017.



Laura Wallace

Head of Global Epidemiology & RWE CoE, Boehringer Ingelheim

An epidemiologist with a background in Epidemiology, Psychology and Public Health who trained at Brown University, Southern Connecticut State, and the University of Alaska, Fairbanks in the United States. She joined the pharmaceutical industry in 2002, working in multiple roles in epidemiology, real world evidence, safety and risk management, drug development, and Medical Affairs. She came to Boehringer Ingelheim in 2016, and since 2020 has worked as the Head of Global Epidemiology & RWE CoE, based in Ingelheim, Germany.



Mario Ouwens

Senior Director of Medical and Payer Evidence Statistics, AstraZeneca

Dr. Ouwens leads a medical and payer evidence statistics group of 11 statisticians at AstraZeneca who have been highly involved in COVID-19-related research over the past two years. His workshop in Brazil was one of the two workshops leading to ANVISA opening for the use of RWE. In 2022, Dr. Ouwens presented the comprehensive evidence and expert opinion of RCTs combined with RWS at the PPMA, and published 6 articles, including "Best Practice Recommendations for Practical Clinical Trial Design and Statistical Analysis: Improved Delphi Methods". Within AstraZeneca, Dr. Ouwens developed the guidelines for pragmatic clinical trials and the SIDE-L framework, being a framework to assess the quality of observational studies related to Statistical Interpretation Design External and Labeling criteria. In the past 5 years, Dr. Ouwens frequently presented at The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Europe in oral presentations and workshops and presented yearly at PPMA, Europe's largest congress in market access, pricing and evidence. His work is referenced in technical support documents of NICE (UK).



Najat Khan, Ph.D.

Chief Data Science Officer and the Global Head of Strategy & Operations for Janssen Research & Development

Doctoral degree in organic chemistry from the University of Pennsylvania, a B.S. in chemistry and a B.A. in economics from Colgate University; she is co-chair of the Johnson & Johnson Data Science Council, and a core member of the Development and Investment Committees, overseeing Janssen's R&D strategy, pipeline and portfolio optimization and investments, and seeking to fully integrate data science and digital health into the overall pipeline to drive transformational innovation for patients. Her team leverages artificial intelligence (AI), machine learning, digital health and real-world evidence (RWE) to bring transformative value to patients. Najat was previously a partner at the Boston Consulting Group (BCG). In 2022, Najat was listed among the Top 20 Leaders under 40 in biopharma and biotech by Endpoints News.



Nancy A. Dreyer

Chief Scientific Officer Emerita IQVIA Real World Solutions

Adjunct Professor of Epidemiology at the University of North Carolina at Chapel Hill, President of Dreyer Strategies LLC, a Fellow of both the International Society of Pharmacoepidemiology and the Drug Information Association, and a Trustee of Brandeis University. She has helped advance the use of real-world evidence for regulatory purposes, influencing the content of recent guidelines by regulators in the US, Europe, and China, each of which cite one or more of her publications.



Nirav Dalal

Vice President of Global Data Science and Analytics Function at Abbott medical devices

He has more than twenty years of experience in medical device industry. Nirav is interested in methods and tools to improve healthcare and create value using “Big Data” and machine learning. He received MS in Electrical Engineering from the California Polytechnic State University, San Luis Obispo and an MBA from the Pepperdine University. He has published more than fifty peer-reviewed journal articles, conference abstracts, and US patents. He is a frequent speaker on medical devices, real-world evidence, digital health, health economics, and data science. His past speaking engagements include talks at the FDA, AdvaMed, Big Data in Healthcare, American Chamber of Commerce, Medical Design & Manufacturing, Global Cardiovascular Clinical Trialists Forum.



Paul Coplan

Vice President of Epidemiology and Real-World Data Sciences for Medical Devices at Johnson and Johnson

Paul leads a team of epidemiologists, data programmers and biostatisticians. Paul has been a pioneer in using epidemiology and real-world evidence to develop new vaccines, medicines and medical technology and to assess their postmarket safety and effectiveness. He has participated in the postmarket surveillance of several devices. He has also helped develop 8 widely used vaccines and 9 medicines. In addition, He has authored over 90 peer-reviewed scientific articles and 500 international medical conference presentations, and has worked with the FDA, EMA and other national regulatory authorities. Paul is a member of the National Evaluation System for Health Technology’s Active Surveillance Workgroup (of which FDA is the regulatory chairman) and the Medical Device Innovation Consortium Science of Patient Input Steering Committee. He has led pre-competitive initiatives for collaboration between companies, regulators and academics in creating benefit-risk frameworks for medical product evaluations, assessing the safety of HIV medications, vaccines, opioid analgesics.



Sandeep SANGA

Head of Real World Data Strategy & Alliances, Astellas Pharma

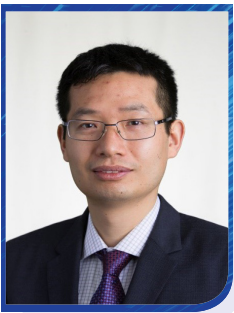
A data-minded biomedical scientist, innovate business leader, product-focused executive and problem-solver. Dr. Sandeep Sanga is Head of Real World Data Strategy & Alliances at Astellas Pharma. He has a deep understanding of health and life science industry with his rich working experience in science, business and product. Sandeep's team has established and brought to the market lots of industry-specific SaaS products, which helps clients quickly obtain useful information from abundant data ranging from vertical and horizontal clinical, phenotypic, genomics, to imaging. He was a postdoctoral fellow at Cardiovascular Institute, University of California where he was trained in medical genomics and applied data science with a focus on asthma and sarcoidosis.



Tang Boxiong

Director and Executive Director of Health Economics and Outcomes Research (HEOR) at Department of Medicine, BeiGene USA Inc.

Dr. Tang established the Global Health Economics and Outcomes Research Team at BeiGene. As Head of HEOR, he is responsible for the implementation of Global Health Economics and Outcomes Research Strategy. Before joining BeiGene, he has worked in Teva, Pfizer, Johnson & Johnson and GlaxoSmithKline. Dr. Tang was Visiting Professor at Fudan University and Visiting Researcher at Zhejiang University School of Medicine and serves as President of Asia Consortium Industry Committee, International Society for Pharmacoeconomics and Outcomes Research (ISPOR). He has been engaged in medicine, health economics and outcome research for over 20 years with publication of over 30 papers, over 100 scientific manuscripts, abstracts and speeches at many large-scale international scientific conferences.



Yonghua Jing

Senior Director of Real World Evidence Analytics, AbbVie

He obtained his Ph.D. degree from University of Cincinnati, Master of Pharmacology from Ohio Medical School and Bachelor of Pharmacy from China Pharmaceutical University. Over the past 15 years, Dr. Jing has worked in AbbVie and led his team in discovering real-world evidence supportive of bestselling drugs (i.e. aripiprazole, Eliquis, Plavix, and Humira). He himself is also an expert on the design and application of real-world evidence. Since 2014, his team has developed a real-world data platform and capabilities to integrate real-world evidence within AbbVie, and he joined PhRMA Real-World Evidence Working Group on behalf of AbbVie. Dr. Jing is a long-time Member of ISPOR Asia Consortium and has a good relationship with experts in real-world evidence worldwide.



Zhang Mingdong

Vice President and Chief Medical Officer, Medical Affairs and Health Economics Asia Pacific (APAC) Boston Scientific Corporation

Research Fellow and Staff Scientist at the US National Institutes of Health. Doctoral degree from the Department of Molecular Virology and Microbiology at Baylor College of Medicine. He previously worked at the Chinese University of Hong Kong as a professor, and at CDRH, FDA as medical officer and epidemiologist. He published 40 papers in high impact journals. During his service in CDRH, FDA, Dr. Zhang provided medical reviews for multiple original PMA and 510k submissions on medical devices including in vitro diagnostic tests; led designs of post-approval studies; and performed risk assessment and health hazard evaluations of medical devices.



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