



南京国际新医药与生命健康产业
创新投资峰会

NANJING INTERNATIONAL SUMMIT ON INNOVATION AND INVESTMENT
IN NEW MEDICINE AND LIFE SCIENCES & HEALTH CARE INDUSTRY



南京江宁高新区
Nanjing Jiangning Hi-Tech Development Zone

DIA



SF

Quantitative
Science
Forum 2020

药物研发定量科学论坛

9月28-29日 | 南京江宁会展中心
September 28-29 | Jiangning Convention and Exhibition Center, Nanjing



DIA中国微信订阅号

2020

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Director and Head of Statistics and Statistical Com-
putation, Eli Lilly and Company (China)

中国作为生物医药发展大国，近几年来在生物技术和医药创新上有了长足的发展，也迅速推动了医药领域生物统计研究设计与数据分析的人才需求。结合生物统计和数据科学最新的研究进展，DIA中国统计社区精心打造的定量科学论坛将继续为包括监管机构、学术界以及国内外医药企业的定量科学人员提供一个讨论数据科学创新的平台，也为药物研发中其它关键参与者，包括临床、注册、运营等相关人员提供了深入了解数据科学方法进展以及在药物研发中的应用。届时，来自监管机构、企业、中国临床试验生物统计学组(CCTS)以及中国临床试验数据管理学组(CDMC)的专家将与参会者共同对当前热点问题，包括新冠疫情对临床试验的影响以及国内外新冠疫苗研发的案例分享，适应性设计在验证性临床试验中的应用，使用真实世界数据和人工智能加速新药研发进程等等，进行探讨。

主要内容

- COVID-19疫情下的临床试验 | Hot
- 新冠药物/疫苗研发中的统计学考虑 | Hot
- 监管机构指导原则的相关讨论 | Hot
- NMPA临床试验数据递交指导原则探讨
- 真实世界数据支持监管决策
- 适应性设计—从理论到实践
- 早期临床研究中的统计学试验设计
- Estimand在肿瘤试验设计实施和分析评估中的应用
- 数据科学在药物研发中的应用
- 临床试验中的中心化统计监察

目标听众

- 统计师和其他数据科学家
- 数据管理专家
- 监管科学家
- 学术界中的定量科学专家
- 监管机构中的定量科学专家
- 临床医生

会议联系人

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本次会议提供桌面展示机会。有关更多详细信息敬请联系

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In recent years, biotechnology and pharmaceutical innovation have achieved remarkable development in China. The rapid development of innovative drugs has promoted the innovation of experimental design and the demand for data management and analysis talents. 2020 QSF provides a platform for quantitative scientists from regulators, academia, domestic and multi-national pharmaceutical companies to discuss data science innovation. It also provides insights into the progress of data science methods and their application in drug development for other key players in drug development, including clinical, registration and operational personnel. In QSF, to the regulatory agencies, pharmas, the experts from China Clinical Trial Statistics (CCTS) Working Group and Chinese Clinical Data Management Committee (CDMC) will work with participants to discuss the current hot topics, including Clinical Trials Conducted during COVID-19 Pandemic, Statistical Considerations in the Development of COVID-19 Drugs and Vaccines, Real World Evidence in Supporting Regulatory Decision Making, etc.

Main content

- [Clinical Trials Conducted during COVID-19 Pandemic | Hot](#)
- [Statistical Considerations in the Development of COVID-19 Drugs and Vaccines | Hot](#)
- [Discussion on Regulatory Guidelines | Hot](#)
- NMPA clinical trial submission Guideline in-depth discussion
- Real World Evidence in Supporting Regulatory Decision Making
- Adaptive Design – Theory To Practice
- Application of estimand in oncology drug development, conduct and analysis
- Statistical Design for Dose Finding in Early Drug Development
- Data science implementation in drug development
- Centralized Statistical Monitoring in Clinical Trials

TARGET AUDIENCE

- Statisticians and Other Data Scientists
- Clinicians
- Data Management Expert
- Regulatory Scientists
- Quantitative Science Experts in Academia
- Quantitative Science Specialists in Regulatory Agencies

9月28日

08:30-09:00	签到 二层	
09:00-10:10	主会议 二层 百家湖厅	
10:10-10:30	茶歇及交流 二层, 休息区	
10:30-12:00	分会场 102 二层 百家湖厅 新冠药物/疫苗研发中的统计学考虑	分会场 202 二层 汤山厅 “江宁药谷”高质量发展战略研讨会-闭门会 仅限邀请
12:00-13:30	午餐 负一层 翠屏山厅	
13:30-15:00	分会场 103 二层 百家湖A厅 适应性设计-从理论到实践	分会场 203 二层 汤山厅 真实世界数据支持监管决策
15:00-15:30	茶歇及交流 二层, 休息区	
15:30-17:00	分会场 104 二层 百家湖A厅 临床试验中的中心化统计监察	分会场 204 二层 汤山厅 数据科学在药物研发中的应用
18:00-20:00	VIP&讲者晚餐 仅限邀请 二层 百家湖厅	

9月29日

8:30-10:00	分会场 105 二层 百家湖A厅 COVID-19疫情下的临床研究	分会场 205 二层 汤山厅 NMPA临床试验数据递交指导原则探讨
10:00-10:30	茶歇及交流 二层, 休息区	
10:30-12:00	分会场 106 二层 百家湖A厅 Estimand在肿瘤试验设计实施和分析评估中的应用	分会场 206 二层 汤山厅 早期临床研究中的统计学试验设计
12:00-13:30	午餐 负一层 翠屏山厅	
13:30-17:00	分会场 二层 百家湖厅 监管机构指导原则讨论 (一) + (二) 含茶歇20分钟	
17:00-17:10	闭幕致辞	

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September 28 | Monday

08:30-09:00	Register 2nd Floor	
09:00-10:10	Main Meeting 2nd Floor, Bai Jia Hu Room	
10:10-10:30	Tea Break and Networking 2nd Floor, Foyer	
10:30-12:00	Session 102 2nd Floor, Bai Jia Hu Room Statistical Considerations in the Development of COVID-19 Drugs and Vaccines	Session 202 2nd Floor, Tang Shan Room “Jiangning Medicine Valley” High-quality development strategy seminar - <i>Invited Only</i>
12:00-13:30	Lunch B1 Floor, Cui Ping Shan Room	
13:30-15:00	Session 103 2nd Floor, Bai Jia Hu Room A Adaptive Design – Theory To Practice	Session 203 2nd Floor, Tang Shan Room Real World Evidence in Supporting Regulatory Decision Making
15:00-15:30	Tea Break and Networking 2nd Floor, Foyer	
15:30-17:00	Session 104 2nd Floor, Bai Jia Hu Room A Centralized Statistical Monitoring in Clinical Trials	Session 204 2nd Floor, Tang Shan Room Data Science Implementation in Drug Development
18:00-20:00	VIP/Speaker Dinner - <i>Invited Only</i> 2nd Floor, Bai Jia Hu Room	

September 29 | Tuesday

8:30-10:00	Session 105 2nd Floor, Bai Jia Hu Room A Clinical Trials Conducted during COVID-19 Pandemic	Session 205 2nd Floor, Tang Shan Room NMPA Clinical Trial Submission Guideline In-Depth Discussion
10:00-10:30	Tea Break and Networking 2nd Floor, Foyer	
10:30-12:00	Session 106 2nd Floor, Bai Jia Hu Room A Application of Estimand in Oncology Drug Development, Conduct and Analysis	Session 206 2nd Floor, Tang Shan Room Statistical Design for Dose Finding in Early Drug Development
12:00-13:30	Lunch B1 Floor, Cui Ping Shan Room	
13:30-17:00 <i>Tea break 20 minutes</i>	Session 2nd Floor, Bai Jia Hu Room Discussion on Regulatory Guidelines Part 1 and 2	
17:00-17:10	Closing Plenary Session	

08:30-09:00 注册签到 | 二层

09:00-10:10 **主会议** | 二层 百家湖厅

10:10-10:30 茶歇及交流 | 二层, 休息区

10:30-12:00 **分会场 102** | 二层 百家湖厅
新冠药物/疫苗研发中的统计学考虑

自2019年底, 新冠疫情突袭并迅速席卷全球。新疾病的出现和疫情的流行迫切需要新的有效治疗药物和预防性疫苗, 国内外制药企业纷纷展开对于新冠药物和疫苗的研发工作。目前, 多家疫苗已开展人体临床试验, 部分一进入III期临床研究; 新冠药物的研发也如火如荼。如何应用统计学设计和方法加快新冠药物和疫苗的研发是他们所关注的问题之一。我们将邀请国内外新冠药物和疫苗临床研究的参与者, 对新冠临床研究中的主要统计学考虑以及创新型设计的应用进行分享与讨论

主持人

蒋志伟 博士

北京康特瑞科统计科技有限责任公司 总经理

李乔 博士

加科思新药研发生物统计与数据科学负责人

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新冠疫苗临床研发中的统计学策略分享

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为COVID-19实验量身定制统计假设

詹萍

神州细胞生物统计高级总监

新冠药物临床试验设计中的经验分享

张薇

百济神州生物统计总监

有效的新冠疫苗, 路在脚下

王永吉 博士

强生统计与决策科学部资深统计师

12:00-13:30 午餐 | 负一层 翠屏山厅

08:30-09:00 REGISTER | 2nd Floor

09:00-10:10 **Main Meeting** | 2nd Floor, Bai Jia Hu Room

10:10-10:30 Tea Break and Networking | 2nd Floor, Foyer

10:30-12:00 **Session 102** | 2nd Floor, Bai Jia Hu Room

Statistical Considerations in the Development of COVID-19 Drugs and Vaccines

From the end of 2019, coronavirus attacked and becomes global epidemic quickly. The emerging of new disease and the pandemic call for new effective drugs and preventive vaccines urgently. Pharmaceutical industries from all over the world start R&D of COVID-19 drugs and vaccines. To date, multiple vaccines stepped to the stage of human clinical trials, some of which have started Phase III trials. R&D of COVID-19 drugs is popular as well. The parties of COVID-19 drug and/or vaccine trials will be invited to this session, and share with us the statistical considerations and applications of innovative statistical designs in COVID-19 trials.

CHAIR

Zhiwei JIANG, PhD

CEO, Beijing KeyTech Statistical Consulting Co., Ltd

Qiao LI, PhD

Head of Biostatistics and Data Science, Jacobio

Experience Sharing of two RCTs in COVID-19 Pandemic

Prof. Chen YAO

Deputy Head, Peking University Clinical Research Institute

Statistical Strategy Sharing in the Clinical Developemnt of COVID-19 Vaccine

Zhiwei JIANG, PhD

CEO, Beijing KeyTech Statistical Consulting Co., Ltd

Tailoring COVID-19 Study Hypothesis to its Characteristics

Ping ZHAN

senior director, Biostatistics, SinoCellTech

Experience sharing in designing COVID-19 clinical trials

Wei ZHANG

Director, Biostatistics, Beigene

The Road to a COVID-19 Vaccine

Yongji WANG, PhD

Principal statistician, Statistics & Decision Sciences, J&J

12:00-13:30 Lunch | B1 Floor, Cui Ping Shan Room

13:30-15:00

分会场 103 | 二层 百家湖A厅
适应性设计-从理论到实践

更加高效、更加灵活的药物研发需求和统计学技术的日益完善使得适应性设计的落地成为可能。近年来，FDA和NMPA相继更新和出台了适应性设计的监管指南，在规范适应性设计应用的前提下，也促进了研发型药企更多地开始涉足这一领域，旨在提升药物的研发效率。但是，适应性设计的实践仍然需要清醒的认识并给予足够的谨慎。数据完整性的保持和实际操作过程中的困难是采纳适应性设计的首要考量。

主持人**刘恋**

先声药业统计与数据管理负责人

汪涛 博士

恒瑞医药生物统计与编程部负责人

揭盲的样本量再估计

丛秀玉

云顶新耀高级总监，数据管理与生物统计负责人

无缝设计在确证性临床试验中的应用

王显红 博士

恒瑞医药生物统计与编程部临床统计总监

许根宁 博士

药明康德生物统计及临床统计编程部资深高级统计师

谭韬

再鼎医药生物统计副总监

嘉宾讨论：适应性设计的应用策略与实践考量

以上讲者及

李伟东 博士

和铂医药副总裁兼生物统计负责人

张翔 博士

再鼎医药副总裁

生物统计/编程及数据管理部门

CDE讲者已邀请

分会场 203 | 二层 汤山厅
真实世界数据支持监管决策

尽管随机对照试验证据仍然是评价治疗有效性的金标准，但通过仔细分析和解释将真实世界数据（RWD）转换为真实世界证据（RWE）的兴趣和潜力越来越大，因为RWE可用于为医疗保健决策提供信息，并有可能支持监管决策。历史上RWE主要用于医疗产品上市后安全性监测，现在申办方开始使用RWE来支持临床试验设计、适应症扩展，甚至新的适应症申请。然而，RWE的应用也提出了对其可信性的担忧，例如由于缺乏随机化、数据质量和由于数据挖掘导致虚假结果的可能性导致的偏倚。

本分会场通过介绍首个国内监管机构基于前瞻性开展的RWE研究批准的医疗产品的案例，向听众展现了RWE应用中的挑战和机遇。

主持人**王勇 博士**

药明康德生物统计副总裁

博鳌乐城真实世界数据研究

任燕 博士

四川大学华西医院

中国循证医学中心中国循证医学助理研究员

真实世界试验设计统计学考量要点

张晓薇 博士

百济神州（上海）生物科技有限公司统计部统计师

基于数据驱动的全局患者画像描绘

唐凡 博士

勃林格殷格翰亚太区健康信息科学部负责人

15:00-15:30

茶歇及交流 | 二层, 休息区

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<p>13:30-15:00</p>	<p>Session 103 2nd Floor, Bai Jia Hu Room A Adaptive Design – Theory To Practice</p>	<p>Session 203 2nd Floor, Tang Shan Room Real World Evidence in Supporting Regulatory Decision Making</p>
	<p>More efficient and flexible drug development needs and the recent improvement of statistical methodologies have made it possible to implement adaptive design. Both FDA and NMPA have recently updated and issued regulatory guidelines for adaptive design, which promoted pharmaceutical companies to explore more in this area, aiming to improve the efficiency of drug development. However, the practice of adaptive design still requires a clear understanding and sufficient caution. Maintaining data integrity and feasibility challenges remain the primary considerations for adopting adaptive design.</p> <p>CHAIR Lian LIU Head of Statistics and Data Management in Simcere</p> <p>Tao WANG, PhD Head of Biostatistics and Programming in Hengrui</p> <p>Application of Promising Zone Design in Unblinded Sample Size Re-estimation Julie Cong Senior Director, Head of Biometrics, Everest Medicines</p> <p>Application of Seamless Design in Confirmatory Clinical Trials Alice WANG, PhD Director, Clinical Statistics, Biostatistics & Programming, Hengrui Medicine Ken-Ning HSU, PhD Principal statistician, Biostatistics and Statistical Programming, WuXi Clinical Tao TAN Senior Director, Head of Biometrics, Zailaboratory</p> <p>Panel discussion: Strategic and Operational Considerations in Applications of Adaptive Design Clinical Trials speakers above and Michael LEE, PhD Vice President, Head of Biometrics, Harbour BioMed Charlie ZHANG, PhD VP, Biostatistics/Programming, Zailaboratory</p> <p>CDE Panelist invited</p>	<p>While randomized controlled trial evidence remains the gold standard for evaluation of treatment efficacy, there is increasing interest and potential for converting real world data (RWD) into real-world evidence (RWE) that, through careful analysis and interpretation, can be used to inform healthcare decision making and potentially support regulatory decision making. Historically used for post-market safety monitoring, sponsors are now beginning to use RWE to support clinical trial design, indication expansion, and even new indication applications. However it also presents concerns that continue to cast shadows on its credibility, such as biases due to lack of randomization, data quality, and the potential for spurious results due to data mining.</p> <p>By presenting the case of first China regulatory approval of medical product based on a prospectively conducted RWE study, this session presents the audience with the challenges and opportunities in RWE applications.</p> <p>CHAIR Yong WANG, PhD VP, Biostatistics and statistical programming WuXi Clinical</p> <p>Real World Data Research – case from Boao Yuecheng study Yan REN, PhD Assistant researcher, Chinese Evidence-based Medicine Center, West China Hospital, Sichuan University</p> <p>Statistical considerations for study design with Real World Data Xiao-wei ZHANG, PhD Principle Statistician, Stats-Postapp, BeiGene</p> <p>Re-envisioned Patient Journey Mapping - A Holistic and Data-driven Approach Fan TANG, PhD Head, Regional Health Informatics & Analytics Lead - Asia, Boehringer Ingelheim</p>
<p>15:00-15:30</p>	<p>Tea Break and Networking 2nd Floor, Foyer</p>	

15:30-17:00

分会场 104 | 二层 百家湖A厅
临床试验中的中心化统计监察

由TransCelerate提出的RBM中的中心化监察在美国和欧洲已经实施了许多年。虽然全球累计了很多的洞察，在中国的临床试验里中心化监察的经验仍然有限。中心化统计监察 (CSM) 将统计监察和中心化监察结合在一起。CSM以中心化的方式使用统计方法发现潜在的错误数据或研究中心的不当行为。统计方法包括使用最新的技术，使得我们可以找到非随机的问题，以尽早地发现到个体受试者的数据问题，而这些问题可能潜在地影响到试验的成功和监管递交风险。

主持人
杨雪 博士

杨森(中国)研发中心，统计决策部副总监

远程拨入——临床试验中的中心化统计监察
Kris Lauwers
 强生经理

神经类药物研究中发现风险的实例分享
覃龙 博士

Signant Health高级总监

Quality Tolerance Limits and Thresholds for RBM
 - A statistician's perspective

叶斌琪
 勃林格殷格翰(中国)投资有限公司
 医学部高级生物统计师

分会场 204 | 二层 汤山厅
数据科学在药物研发中的应用

21世纪数据就是新的石油。数据所提供价值是无穷尽的，数据在现代科技发展中扮演越来越重要的角色。药物研发周期长，科学性强，大量数据分析，投资大，风险高，如何高效利用数据以促进药物研发进程突显其重要性。通过搜集，存储和分析大量医疗信息，可以帮助研发人员更好地理解人类疾病及其治疗方法，从而确定新药研发方向，从而减少药物研发成本，并为发现新的治疗手段提供线索。本次会议部分，我们会讨论数字化时代药物研发中数据科学角色定位，及如何利用公司整合数据及医疗大数据推进以数据为驱动的药物研发应用实例，用以指导发展以病人为核心的数据分析结果。

主持人
戴鲁燕 博士

开心生活科技战略与创新副总裁

田正隆
 精鼎医药研究开发(上海)有限公司
 亚太区统计与编程部资深总监

使用数据挖掘辨别并可视化电子病历和保险数据库中的SSc/SSc-ILD疾病发展

田亚慧 博士
 勃林格殷格翰(中国)投资有限公司
 医学部健康信息与分析科学资深生物统计师

如何推动数据驱动的药物研发组织
陈梦 博士
 罗氏产品开发中心生物统计与数据管理中国区总监

数字化时代的医药研发中数据科学角色定位
薛富波 博士
 云顶新耀副总裁，数据科学

18:00-20:00 VIP & 讲者晚餐 *仅限邀请* 二层 百家湖厅

15:30-17:00	<p>Session 104 2nd Floor, Bai Jia Hu Room A Centralized Statistical Monitoring in Clinical Trials</p>	<p>Session 204 2nd Floor, Tang Shan Room Data Science Implementation in Drug Development</p>
	<p>The Central Monitoring in RBM, as proposed by TransCelerate, has been implemented for several years in US and EU. Although a great deal of insight has been gained globally, there is still limited experience in clinical trials conducted in China. Centralized Statistical Monitoring (CSM) combines centralized monitoring with statistical monitoring. CSM allows for the potential detection of erroneous data and site misconduct across sites in a centralized manner. The statistical methods including the use of latest technologies, allow us to pick up non-random errors or patterns, and drill down into individual patient data to discover issues early on that could affect the study and risk the success of the regulatory submission.</p> <p>CHAIR Xue (Loya) YANG, PhD Associate Director, Statistics & Decision Sciences Janssen Research and Development, LLC.</p> <p>Topic TBD Kris LAUWERS BE, Janssen R&D</p> <p>In-Study Analytics to Detect the Risks - Case Studies in Neurology Trials Michael QIN, PhD Senior Director, Signant Health</p> <p>Quality Tolerance Limits and Thresholds for RBM - A statistician's perspective Binqi YE Senior Biostatistician, Boehringer Ingelheim</p>	<p>In 21st century, data is the new oil. The value provided by data could be enormous, and data play an increasingly important role in the development of modern technology. Drug research and development cycle requires long-term investment, deep scientific insight, extensive data analyses, huge finance investment, but it also high risk. How to efficiently use data to promote the drug research and development become more and more important. By collecting, storing, and analyzing large amounts of medical information, we can help researchers better understand human diseases and the treatment approach, thereby determining the direction of new drug development, thereby reducing the cost of drug development, helping provide clues to explore new treatments. In this section, we will discuss the role of data science in drug research and development in the digital era, and how to leverage corporate level integrated database and medical big data (e.g. EHR, etc) to support data-driven drug development, so as to develop patient-focused data analytics.</p> <p>CHAIR Connie DAI, PhD VP, Scientific Strategy & Innovation, Hlifetech</p> <p>Zhenglong TIAN Head of Biostat & Statistical Programming, Asia, Parexel</p> <p>Using Data Mining on EHR and Claims Databases to Identify and Visualize Disease Trajectories in SSC/SSc-ILD Yahui TIAN, PhD Senior Biostatistician-Health Informatiics and Analytics, Boehringer Ingelheim</p> <p>Powering Data to Accelerate Discoveries - an effort to Organize Internal Data Meng CHEN, PhD Director, Biometrics China site head, Roche</p> <p>Roles Data Science to Play in Pharmaceutical R&D of Digital Era Bruce XUE, PhD VP, Data Science, Everest Medicines</p>
18:00-20:00	<p>VIP/Speaker Dinner - <i>Invited Only</i> 2nd Floor, Bai Jia Hu Room</p>	

8:30-10:00

分会场 105 | 二层 百家湖A厅
COVID-19疫情下的临床研究

COVID-19疫情给全球若干城市和地区的医疗卫生系统带来无法承受的压力。由于医疗资源占用、隔离措施、出行限制、公共服务的减少，疫情在多个层面上影响着在研药物临床试验和受试者。如治疗延迟和治疗终止、访视超窗或取消、疗效评估和安全性评估缺失等。这些变化不可避免地影响受试者的利益和风险，并影响试验的整体结果。全球多个卫生监管机构发布了关于在疫情期间进行的临床试验的指导原则。如美国FDA，EMA和中国国家药品监督管理局均发布疫情期间进行的临床试验指南，强调保护患者安全和临床试验的完整性。FDA还发布了专门针对统计考虑的指南。本分会场将从多个方面讨论对在COVID-19疫情下开展的临床试验的统计考量。

组织者**殷悦 博士**

基石药业生物计量负责人，副总裁

主持人**刘柯桢 博士**

基石药业生物统计副总监

COVID-19下的统计挑战：伴发事件，估计目标以及缺失数据

韦加为 博士

诺华中国分析部副总监

肿瘤试验中COVID-19导致的治疗终止

—统计学评估与解决方案

谢冰莹 博士

罗氏（中国）投资有限公司 高级统计科学家

COVID-19疫情期间数据监测和清理的统计学考量

王昕 博士

百济神州统计总监

分会场 205 | 二层 汤山厅
NMPA临床试验数据递交指导原则探讨

药物临床试验数据是在监管审评中至关重要。规范，高质量的临床试验数据不仅可以提高审评效率，而且有利于临床数据的深度再利用。2020年7月国家药品监督管理局（NMPA）发布的《药物临床试验数据递交指导原则》明晰了对递交数据的结构体系，相关数据说明文件，程序等的细则要求，是中国临床试验数据规范化的重要里程碑。本次会议部分会对指导原则进行深入解读，在国际多中心临床试验（MRCT）情况及中文环境下如何落地实施。同时对未来验证规则，未来发展方向，及开源化的验证平台的进展进行探讨。

主持人**史晓丽**

恒瑞医药生物统计及编程部副总监

田正隆

精鼎医药研究开发（上海）有限公司

亚太区统计与编程部资深总监

高质量中文数据说明文件的制作翻译

王军

缔脉生物医药科技（上海）有限公司 统计编程总监

openchecks, 支持中文的CDISC一致性检查开源框架介绍

李聘

赛诺菲统计编程部门高级统计程序员

如何高效完成临床试验数据的递交

区彦逵

北京信立达医药科技有限公司统计部总监

10:00-10:30

茶歇及交流 | 二层, 休息区

8:30-10:00	<p>Session 105 2nd Floor, Bai Jia Hu Room A Clinical Trials Conducted during COVID-19 Pandemic</p>	<p>Session 205 2nd Floor, Tang Shan Room NMPA Clinical Trial Submission Guideline In-Depth Discussion</p>
	<p>COVID-19 pandemic has impacted health care systems around the globe. Due to the combined effect of health care systems on reduced capacity, travel restrictions, reduced public services, the pandemic affects clinical trials and trial patients in multiple ways. Increased treatment delays or discontinuations were seen; so are increased rates of other study procedure deviations, for example, visits been delayed or cancelled causing missing efficacy and safety assessments. These impacts inevitably affect trial patients' benefit and risk and affect trials' overall results. Health authorities around the globe have issued guidelines on clinical trials conducted during the pandemic. For example, FDA, EMA, China NMPA, and other national regulatory agencies have issued guidelines on clinical trials conducted during the pandemic, which emphasized the protection of patient safety and the integrity of the clinical trial. FDA also issued a guidance specifically on statistical considerations. This session will discuss statistical considerations on clinical trials conducted during the COVID-19 pandemic.</p> <p>ORGANIZER Anny-Yue YIN, PhD Associate VP, Biometrics and Medical Writing CStone Pharmaceutical</p> <p>CHAIR Kezhen LIU, PhD Associate Director, Biostatistics, CStone Pharmaceutical</p> <p>Statistical challenges due to COVID-19: Intercurrent events, estimands and missing data Jiawei WEI, PhD Associate Director, Analytics, Novartis</p> <p>COVID-19 Related Treatment Discontinuations in Oncology Trials – Statistical Evaluations and Solutions Bingying XIE, PhD Senior Statistical Scientist, Roche (China) Holding Ltd.</p> <p>Statistical Considerations in Data Monitoring and Cleaning During COVID-19 Pandemic Xin WANG, PhD Director, Statistics, BeiGene</p>	<p>Clinical trial data play a critical role in regulatory review. Standardized, high-quality clinical trial data not only improve the efficiency of the regulatory review, but also facilitate the deep re-utilization of the data in the long run. The Guideline for the Submission of Clinical Trial Data issued by National Medical Products Administration (NMPA) in July 2020 specify the database structure, format requirement, associated documents, code programs, etc. which is an important milestone in the standardization of clinical trial data in China. Here, in this conference section, we will provide an in-depth interpretation of the submission guide, how to implement in Multi-Regional Clinical Trials (MRCT) and in domestic only clinical trials. At the same time, the potential validation/rejection rules implemented in the future, the development direction of submission standard, and the current progress of open-source validation platform are also discussed.</p> <p>CHAIR Xiaoli SHI Associate Director, Statistical Programming, hrglobe</p> <p>Zhenglong TIAN Head of Biostat & Statistical Programming, Asia, parexel</p> <p>Translation and Generation of High Quality Define.xml with Chinese Support John WANG Director of Biostatistics and Programming, dMed Biopharmaceutical</p> <p>Openchecks – Open Source Framework for CDISC Conformance Checking – Chinese Support Dan LI Senior Statistical Programmer, Bio-statistic and Programming Department, Sanofi</p> <p>Develop the Submission of Clinical Trial Data Efficiently Yankui OU Director, Statistical, TrustCRO</p>
10:00-10:30	Tea Break and Networking	

10:30-12:00

分会场 106 | 二层 百家湖A厅
Estimand在肿瘤试验设计实施和分析评估中的应用

ICH E9 R (1) 附录引入了估计目标 (Estimand) 概念, 该附录于2020年1月30日通过, 并于2020年7月30日生效。本附录提供了一个结构化框架, 旨在加强临床试验目标制定、设计、实施、分析和解释之间的联系, 以及申办方和监管方之间关于临床试验应解决的治疗效应的一致认可。该框架使适当的试验计划能够清楚地区分估计目标 (试验目标)、估计方法 (估计值)、估计值的数值结果和敏感性分析。在本附录中, 估计目标被定义为对治疗效应的精确描述, 反映了试验目标提出的临床问题。虽然已经提供了全面的培训材料来帮助理解和应用估计目标, 但估计目标的实际应用仍然具有很大的挑战性, 特别是在肿瘤疾病领域, 通常会采用复杂的临床试验设计。在这一场会议上, 我们将有来自行业和监管部门的统计学家和临床医生来介绍他们在肿瘤试验中应用估计目标的经验和见解。通过专题介绍和小组讨论, 不仅能更好地理解这个概念, 更重要的是启发未来研究估计目标在肿瘤学中的应用

主持人**刘晓妮 博士**

诺华中国生物统计部负责人

王秋珍 博士勃林格殷格翰 (中国) 投资有限公司
生物统计与数据科学亚洲负责人

肿瘤领域的患者历程和估计目标: Car-T的实例分析

廖询

诺华中国统计资深首席统计师

刘蕾

诺华中国临床开发部治疗领域负责人-血液疾病

在Estimand框架下Covid-19对肿瘤研究的研究目的和分析的影响

孟宪花 博士

勃林格殷格翰 (中国) 投资有限公司医学部统计副总监

案例分享:

估计目标框架下肿瘤试验终点的定义与分析策略

夏凡 博士

再鼎医药生物统计负责人

嘉宾讨论

以上讲者及 CDE专家已邀请

分会场 206 | 二层 汤山厅
早期临床研究中的统计学试验设计

早期临床研究中寻找推荐II期剂量 (RP2D) 非常关键, 传统的爬坡方法往往难以应对一些复杂的情况, 比如不良事件的时间效应, 多个合并治疗药物联合爬坡等。本专题通过统计学理论和具体实例应用对以上一些问题做了讨论, 希望通过这些讨论可以对近些年来早期药物开发中的一些热点和难点的解决有所助益。

主持人**邓亚中**

北京信立达医药科技有限公司总经理

李杰 博士缔脉生物医药科技 (上海) 有限公司
生物统计与编程部执行总监

考虑不同发生时间药物毒性的剂量爬坡方法

朱宏杰 博士

百济神州统计和数据科学部总监

联药爬坡试验设计中的统计学考量

蒋书屏 博士

恒瑞医药生物统计副总监

肿瘤试验中两药物联合剂量爬坡的挑战和考虑要点

刘梅若 博士勃林格殷格翰 (中国) 投资有限公司
生物统计与数据科学部生物统计师

12:00-13:30

午餐 | 负一层 翠屏山厅

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<p>10:30-12:00</p>	<p>Session 106 2nd Floor, Bai Jia Hu Room A Application of Estimand in Oncology Drug Development, Conduct and Analysis</p>	<p>Session 206 2nd Floor, Tang Shan Room Statistical Design for Dose Finding in Early Drug Development</p>
	<p>The estimand concept was introduced in ICH E9 R (1) addendum that was adopted on January 30, 2020 and is coming to effect on July 30, 2020. This addendum presents a structured framework to strengthen the dialogue between disciplines involved in the formulation of clinical trial objectives, design, conduct, analysis and interpretation, as well as between sponsor and regulator regarding the treatment effect(s) of interest that a clinical trial should address. This framework enable proper trial planning that clearly distinguishes between the target of estimation (trial objective, estimand), the method of estimation (estimator), the numeric result of the estimate, and a sensitivity analysis. In this addendum, estimand was defined as a precise description of the treatment effect reflecting the clinical question posed by the trial objective. While comprehensive training materials have been provided to help with the understanding and applications of estimand, the practical application of estimand is still quite challenging, especially in oncology disease area where complex clinical trial designs are usually proposed. In this session we will have statisticians and clinicians from industry and regulatory to present their experience and insights in applications of estimand in oncology trials. Via presentations and a panel discussion, to achieve not only a better understanding of the concept, but more importantly to inspire future research on the application of estimand in oncology.</p> <p>CHAIR Susan WANG, PhD Head of Biostatistics & Data Sciences Asia, Boehringer-Ingelheim</p> <p>Xiaoni LIU, PhD China Biostatistics Head, Novartis</p> <p>Patient Journey and Estimand in Oncology: A Case Study of Car-T Xun LIAO Senior Principal Biostatistician, Biostatistics, Novartis Lei LIU Therapeutic Area Lead, Hematology Clinical Development, Novartis China</p> <p>Impact of Covid-19 on Oncology Study Objective and analysis under estimand framework Leslie MENG, PhD Associate Director, Boehringer-Ingelheim</p> <p>Cases sharing: on definitions and analysis strategies for oncology endpoints in the estimand framework Fan XIA, PhD Head of Biostatistics, Director, Zailaboratory</p> <p>Panel Discussion Speakers above & CDE Panelist invited</p>	<p>Dose finding for recommended phase II dose (RP2D) is critical for early drug development. In recent years, toxicity onset timeframes and combination therapy escalation for dose finding brings challenge to traditional dose finding method and attract attention. This session will touch on dose escalation considering toxicities of different onset timeframes and dose escalation of drug combination. Hope the session will be helpful on these new challenges.</p> <p>CHAIR Jie LI, PhD Head of Biostatistics, dMed Biopharmaceutical</p> <p>Yazhong DENG GM, TrustCRO</p> <p>Dose Escalation Methods Considering Toxicities of different Onset Timeframes Hongjie ZHU, PhD Director, Global Statistics and Data Science, BeiGene</p> <p>Statistical Considerations in the Design of Dose Escalation of Drug Combination Shuping JIANG, PhD Associate Director, Biostatistics, Hengrui</p> <p>Challenges and Considerations in Oncology Dual-Agent Dose Finding Meiruo LIU, PhD Biostatistician, Biostatistics and Data Sciences, Boehringer Ingelheim</p>
<p>12:00-13:30</p>	<p>Lunch B1 Floor, Cui Ping Shan Room</p>	

13:30-17:00 分会场 | 二层 百家湖厅
含茶歇20分钟 **监管机构指导原则讨论 (一) + (二)**

本分会场将邀请来自CDE, 学术界和工业界的专家, 针对处于征求意见阶段的统计及相关临床指导原则进行深入探讨

冀晨 博士

赛诺菲生物统计与编程部总监

朱超 博士

礼来中国生物统计与统计计算部负责人

《抗肿瘤药联合治疗临床试验技术指导原则 (征求意见稿)》介绍
讲者已邀请

《抗肿瘤药物临床试验统计学设计指导原则 (征求意见稿)》介绍
讲者已邀请

药物临床试验适应性设计指导原则介绍
讲者已邀请

讨论嘉宾

以上讲者及

陈峰 教授

南京医科大学研究生院院长

中国卫生信息学会统计理论与方法专业委员会主任委员

中国临床试验生物统计学组 (CCTS) 组长

陈刚 博士

诺思格医药科技股份有限公司高级副总裁

夏结来 教授

空军军医大学卫生统计教研室主任

17:00-17:10 **闭幕致辞**

郭翔 博士

百济神州副总裁, 统计和数据科学部全球负责人

夏结来 教授

空军军医大学卫生统计教研室主任

13:30-17:00
Tea break
20 minutes

Session | 2nd Floor, Bai Jia Hu Room
Discussion on Regulatory Guidelines Part 1 and 2

This session will invite experts from CDE, academia and industry to discuss the newly released statistical and relevant clinical guidelines for public review.

CHAIR

Chao ZHU, PhD

Head of Statistics and Programming, Lilly China

Chen JI, PhD

Director of Biostatistics and Programming, Sanofi

Introduction to Guideline for Clinical Trials of Anti-tumor Combination Therapies
speaker invited

Introduction to Guideline for Statistical Design of Clinical Trials of Anti-tumor Drugs
speaker invited

Introduction to Guideline on Adaptive Designs for Clinical Trials
speaker invited

PANEL DISCUSSION

above speaker and

Feng CHEN, professor

Dean, Graduate School, Nanjing Medical University

Chair of China Association of Biostatistics (CABS)

Chair of China Clinical Trial Statistics (CCTS) Working Group

Gang CHEN, PhD

CSO & SVP, R&G PharmaStudies Co., Ltd.

Jielai XIA , Professor

Director, Department of Medical Statistics, Air Force Military Medical University

17:00-17:10

Closing Plenary Session

Tony GUO, PhD

Global Head of Statistics and Data Science, VP, BeiGene

Jielai XIA , Professor

Director, Department of Medical Statistics, Air Force Military Medical University