DIA QSF

Quantitative Science Forum 2020

药物研发定量科学论坛

9月28–29日 | 南京丽湖雅致会展中心

September 28-29 | Nanjing Lakehome Hotel

DIA中国微信订阅号

2020

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礼来中国生物统计与统计计算部负责人
Director and Head of Statistics and Statistical
Computation, 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	
09:00-10:20	**开幕式**	
10:20-10:30	茶歇及交流	
10:30-12:00	分会场 102&202 **新冠药物/疫苗研发中的统计学考虑**	
12:00-13:30	午餐	
13:30-15:00	分会场 103 **适应性设计–从理论到实践**	分会场 203 **真实世界数据支持监管决策**
15:00-15:30	茶歇及交流	
15:30-17:00	分会场 104 **临床试验中的中心化统计监察**	分会场 204 **数据科学在药物研发中的应用**
18:00-20:00	VIP&讲者晚餐	

9月29日

8:30-10:00	分会场 105 **COVID–19疫情下的临床研究**	分会场 205 **NMPA临床试验数据递交指导原则探讨**
10:00-10:30	茶歇及交流	
10:30-12:00	分会场 106 **Estimand在肿瘤试验设计实施和分析评估中的应用**	分会场 206 **早期临床研究中的统计学试验设计**
12:00-13:30	午餐	
13:30-16:30 *含茶歇20分钟*	**监管机构指导原则讨论（一）+（二）**	
16:30-17:30	**闭幕式 | 致辞+讨论**	

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Program at a Glance

DIA QSF Quantitative Science Forum 2020 药物研发定量科学论坛

September 28 | Monday

08:30-09:00	Register	
09:00-10:20	**Opening Plenary**	
10:20-10:30	Tea Break and Networking	
10:30-12:00	Session **Statistical Considerations in the Development of COVID-19 Drugs and Vaccines**	
12:00-13:30	Lunch	
13:30-15:00	Session 103 **Adaptive Design – Theory To Practice**	Session 203 **Real World Evidence in Supporting Regulatory Decision Making**
15:00-15:30	Tea Break and Networking	
15:30-17:00	Session 104 **Centralized Statistical Monitoring in Clinical Trials**	Session 204 Data Science Implementation in Drug Development
18:00-20:00	VIP/Speaker Dinner	

September 29 | Tuesday

8:30-10:00	Session 105 **COVID-19疫情下的临床研究**	Session 205 **NMPA Clinical Trial Submission Guideline In-Depth Discussion**
10:00-10:30	Tea Break and Networking	
10:30-12:00	Session 106 **Application of Estimand in Oncology Drug Development, Conduct and Analysis**	Session 206 **Statistical Design for Dose Finding in Early Drug Development**
12:00-13:30	Lunch	
13:30-16:30 *含茶歇20分钟*	Session **Discussion on Regulatory Guidelines Part 1 and 2**	
16:30-17:30	**Closing Plenary Session**	

08:30-09:00	签到
09:00-10:20	**开幕式**
10:20-10:30	茶歇及交流
10:30-12:00	分会场 102&202 **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 题目待定 **蒋志伟 博士** 北京康特瑞科统计科技有限责任公司 总经理 题目待定 **詹萍** 神州细胞生物统计高级总监
12:00-13:30	午餐

08:30-09:00	Register
09:00-10:20	**Opening Plenary**
10:20-10:30	Tea Break and Networking
10:30-12:00	Session **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

Topic TBD
Zhiwei JIANG, PhD
CEO, Beijing KeyTech Statistical Consulting Co., Ltd

Topic TBD
Ping ZHAN
senior director, Biostatistics, SinoCellTech

12:00-13:30	Lunch

13:30-15:00	分会场 103 **适应性设计–从理论到实践**	分会场 203 **真实世界数据支持监管决策**
	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 **彭猛业** 苏州泽璟生物制药有限公司 适应性2/3期无缝设计—实例分享 **王显红** 恒瑞 **谭韬** 再鼎 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	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 题目待定 **任燕 博士** 四川大学华西医药中国循证医学中心
15:00-15:30	茶歇及交流	

13:30-15:00	Session 103 **Adaptive Design – Theory To Practice**	Session 203 **Real World Evidence in Supporting Regulatory Decision Making**
	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. CHAIR **Lian LIU** Head of Statistics and Data Management in Simcere **Tao WANG, PhD** Head of Biostatistics and Programming in Hengrui Application of Promising Zone Design in Unblinded Sample Size Re-estimation **Julie Cong** Everest Medicines **Jack Peng** Zelgen Biopharmaceuticals Adaptive Phase 2/3 Seamless Design – Case Sharing **Alice WANG** **Genning XU** **Tan TAO** 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	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. 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. CHAIR **Yong WANG, PhD** VP, Biostatistics and statistical programming WuXi Clinical Topic TBD **Yan REN, PhD** The Chinese Cochrane Center, West China Hospital, Sichuan University
15:00-15:30	Tea Break and Networking	

15:30-17:00

分会场 104
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—题目待定
Kris LAUWERS
强生

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
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的角色定位，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
勃林格殷格翰

如何推动数据驱动的药物研发组织
罗氏的一些探索
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的角色定位
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

15:30-17:00

Session 104
Centralized Statistical Monitoring in Clinical Trials

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.

CHAIR
Xue (Loya) YANG, PhD
Associate Director, Statistics & Decision Sciences
Janssen Research and Development, LLC.

Topic TBD
Kris LAUWERS
BE, Janssen R&D

In-Study Analytics to Detect the Risks – Case Studies in Neurology Trials
Michael QIN, PhD
Senior Director, Signant Health

Quality Tolerance Limits and Thresholds for RBM - A statistician's perspective
Binqi YE
Senior Biostatistician, Boehringer Ingelheim

Session 204
Data Science Implementation in Drug Development

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.

CHAIR
Connie DAI, PhD
VP, Scientific Strategy & Innovation, Hlifetech

Zhenglong TIAN
Head of Biostat & Statistical Programming, Asia, Parexel

Using Data Mining on EHR and Claims Databases to Identify and Visualize Disease Trajectories in SSc/SSc-ILD
Yahui TIAN
Boehringer-Ingelheim

How to Drive a Data-driven Drug Development Organization – Some Explorations from Roche
Meng CHEN, PhD
Director, Biometrics China site head, Roche

Roles Data Science to Play in Pharmaceutical R&D of Digital Era
Bruce XUE, PhD
VP, Data Science, Everest Medicines

18:00-20:00 VIP/Speaker Dinner

8:30-10:00	分会场 105 **COVID–19疫情下的临床研究**	分会场 205 **NMPA临床试验数据递交指导原则探讨**
	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** 罗氏（中国）投资有限公司 高级统计科学家 COVID–19疫情下开展的注册临床研究中统计学方面的监管考量 讲者已邀请	药物临床试验数据是在监管审评中至关重要。规范，高质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 统计编程副总监 **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 openchecks, 支持中文的CDISC一致性检查开源框架介绍 **李聃** 赛诺菲 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
10:00-10:30	茶歇及交流	

8:30-10:00	Session 105 **Clinical Trials Conducted during COVID-19 Pandemic**	Session 205 **NMPA Clinical Trial Submission Guideline In-Depth Discussion**
	COVID-19 pandemic has impacted health case 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. Heath 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. ORGANIZER **Anny-Yue YIN, PhD** Associate VP, Biometrics and Medical Writing CStone Pharmaceutical CHAIR **Kezhen LIU, PhD** Associate Director, Biostatistics Statistical challenges due to COVID-19: Intercurrent events, estimands and missing data **Jiawei WEI, PhD** Associate Director, Analytics, Novartis COVID-19 Related Treatment Discontinuations in Oncology Trials – Statistical Evaluations and Solutions **Bingying XIE** Senior Statistical Scientist, Roche (China) Holding Ltd.	Clinical trial data play a critical role in 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. CHAIR **Xiaoli Shi** Associate Director, Statistical Programming, hrglobe **Zhenglong Tian** Head of Biostat & Statistical Programming, Asia, parexel Translation and Generation of High Quality Define.xml with Chinese Support **John Wang** dMed Biopharmaceutical Openchecks – Open Source Framework for CDISC Conformance Checking – Chinese Support **Dan Li** Sanofi Develop the Submission of Clinical Trial Data Efficiently **Yankui Ou** Trustcro
10:00-10:30	Tea Break and Networking	

10:30-12:00

分会场 106

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

诺华制药生物统计总监

王秋珍

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

韦加为 博士

诺华中国分析部副总监

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

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

分会场 206

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

百济神州

联药爬坡试验设计中的统计学考量

蒋书屏

恒瑞医药

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

勃林格殷格翰（中国）投资有限公司生物统计师

12:00-13:30 午餐

10:30-12:00

Session 106
Application of Estimand in Oncology Drug Development, Conduct and Analysis

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.

CHAIR
Susan WANG
Head of Biostatistics & Data Sciences
Asia, Boehinger-ingelheim

Xiaoni LIU,PhD
China Biostatistics Head, Novartis

Patient Journey and Estimand in Oncology: A Case Study of Car-T
Jiawei WEI, PhD
Associate Director, Analytics, Novartis

Impact of Covid-19 on Oncology Study Objective and analysis under estimand framework
Leslie Meng
Associate Director, Boehringer-Ingelheim

Cases sharing: on definitions and analysis strategies for oncology endpoints in the estimand framework
Fan Xia, PhD
Head of Biostatistics, Director, Zailaboratory

Panel Discussion
speakers above

Session 206
Statistical Design for Dose Finding in Early Drug Development

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.

CHAIR
Jie LI, PhD
Head of Biostatistics, dMed Biopharmaceutical

Yazhong DENG
GM, TrustCRO

Dose Escalation Methods Considering Toxicities of different Onset Timeframes
Hongjie ZHU
Beigene

Statistical Considerations in the Design of Dose Escalation of Drug Combination
Shuping JIANG
hrglobe

Challenges and Considerations in Oncology Dual-Agent Dose Finding
Meiruo LIU
Boehringer-ingelheim

12:00-13:30 Lunch

13:30-16:30 *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副总监

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：邀请中
拟邀请 CDE统计专家，CDE临床专家，CSCO临床专家，学术界统计专家，工业界统计专家

16:30-17:30 **闭幕式 | 致辞+讨论**

13:30-16:30 *Tea break* *20 minutes*	Session **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

Discussants
CDE statistical expert, CDE clinical expert, CSCO clinical expert, academia statistical expert, industry statistical expert

16:30-17:30	**Closing Plenary Session**