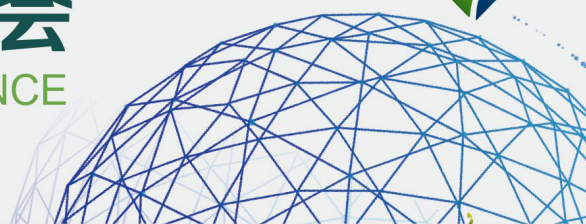


# 临床数据管理2020年度大会

## CLINICAL DATA MANAGEMENT 2020 CONFERENCE

2020年10月12日-18日 | OCTOBER 12-18,2020



### Conference Agenda

October 12, Monday / 9:00-11:30

**Keynote Session: International and Domestic NDA Submission Regulatory Requirements and Strategy**  
Session Chair: Carrie Zhang, SCDM Board Advisory; SCDM China Steering Committee Chair; Head of Clinical Data Center, GCMA, Shanghai Henlius Biotech, Inc.

**Topic 1: GCP Compliance and Enforcement – What you need to know!**

Kassa Ayalew, M.D., M.P.H., Good Clinical Practice Assessment Branch Chief, Center for Drug Evaluation and Research, Food and Drug Administration, USA

**Topic 2 : DM Operations in search of a Model vs Models in search of Operations**

Demetris N. Zambas, SCDM Board Advisory; VP and Global Head of Data Monitoring and Management, Pfizer

**Topic 3 : Effective preparation of clinical data submission materials for MRCT trials**

Zhenglong Tian, SCDM China Steering Committee Member; Senior Director GDO, Biostatistics & Statistical Programming, Parexel China Co., Ltd.

October 13, Tuesday / 13:00-14:30

**Session 2: Data management and quality expectation in compliance with the new Chinese GCP regulations**  
Session Chair: Daniel Liu, SCDM China Steering Committee Member; CSO, Beijing Clinical Service Center

**Topic 1: Assurance and Control of the Standardization and Authenticity of Clinical Research Data**

Sun Ruihua, Deputy director of the Clinical Research Data and Project Management Platform of China-Japan Friendship Hospital, director of the Beijing Clinical Research Quality Promotion Center, China-Japan Friendship Hospital Branch Center and professor of Beijing University of Traditional Chinese Medicine.

**Topic 2: Establishment of Independent Data Management Quality Management System**

Max Chai, QA Head, Yeedo Medical Data

**Topic 3: Discussion on External Data QC for DME clinical trials**

Cloud Li, Principal Clinical Data Manager, China Novartis Institutes for BioMedical Research

October 14, Wednesday / 9:30-11:00

**Session 3: Discussion about data management in Real World Data**

Session Chair: Zhenglong Tian, SCDM China Steering Committee Member; Senior Director GDO, Biostatistics & Statistical Programming, Parexel China Co., Ltd.

**Topic 1 : From Real-World Data to Real-World Evidence**

Professor Pingyan Chen, Department of Biostatistics, Southern Medical University

**Topic 2 : Informatics Assessment of RWD in Practice: Strategy, Standard and Challenge**

Sheng Feng, APAC Head of RWD, Parexel International

**Topic 3 : Data management and data quality case share for Real World Data (RWD)**

Ruolin Zhang, VP of Clinical Data Service, HLT

October 15, Thursday / 9:00-11:00

**Session 4: New requirements driven by FDA**

① LOINC (Logical Observation Identifiers Names and Codes)

② Post-marketing Safety Reporting for Combination Products

Session Chair: Joyce Lai, SCDM China Steering Committee Member; Regional Director, Clinical Data Management, Global Data Management & Standards, MSD R&D (China) Co., Ltd.

**Topic 1 : Implementation of LOINC in Clinical Research**

Cecilia Rubio, Associate Director of Global Data Management & Standards, External Data Acquisition Operations (EDAO) Program Manager, MSD Argentina

**Topic 2 : PMSR new requirement for combination products**

Holly Luo, Manager, Case Processing Team Lead, Worldwide Safety, Pfizer (Wuhan) R&D Co., Ltd

**Topic 3 : Integrated “Complaint-Vigilance” Process and Device Malfunction Assessment & Associated Person Data Collection for Combination Products in Clinical Trial**

Lily Lv, Principle clinical data manager, MSD R&D

October 16, Friday / 13:00-14:30

**Session 5: Exploration and practice of Clinical Data Management under Urgent Situation**

Session Chair: Hualong Sun, General Manager, Meta Clinical Technology

**Topic 1 : Overcome challenge of COVID-19 and robust DM productivity in Complex Study**

Wei Zhang, Manager, dMed Company Limited

**Topic 2 : Facing emergencies such as the epidemic, how to use call center to improve the quality of clinical data**

Lili Cui, Associate Manager, Call Center, Meta Clinical Technology

**Topic 3 : Risk Management: How to Collect and Report of the Impact while staying compliant**

Yafang Wu, Senior Director, Data Management, Parexel

October 17, Saturday / 10:00-12:00

**Session 6: Data Management from Visualization**

Session Chair: Yazhong Deng, SCDM China Steering Committee Member; General Manager, Beijing Trust Medical Consulting Co., Ltd

**Topic 1 : RBQM and Centralized Statistical Monitoring**

Fish Wang, Director Client Services, Professional Services, Medidata Solution

**Topic 2 : Visualized Patient Profile**

Icy Du, Director, Programming, Zai Lab

**Topic 3 : Auto Translate Raw Data to SDTM Base on Metadata**

George Xiang, Manager, Statistical Programming, Beijing Trust Medical Consulting Co., Ltd.

**Topic 4 : How to utilize data to evaluate site performance and maximize the success of a clinical trial**

Yi Wang, Director of Data Management, Kelun Pharmaceutical Research Institute

October 17, Saturday / 14:00-15:30

**Session 7: Data Management in Decentralized Clinical Trials**

Session Chair: Wei Zhang, SCDM China Steering Committee Member; Head of Data Management, GSK Shanghai R&D

**Topic 1 : HLT WHODrug Chinese artificial intelligence automatic coding technology and application cases**

Xiaohui Rong, Data Management Director, HAPPY LIFE TECH

**Topic 2 : Practice and application of the central laboratory in the electronic transmission and reception of test sample data in Phase III clinical trials**

Kevin Yang, General Manager, Xi'an Riehen Life Science Technology Co., Ltd.

**Topic 3 : Implementation and application of integrated data collection platform in early phase study**

Qingyang Yu, Data Manager (Assoc), PPC