Conference Agenda

October 12, Monday / 9:00-11:30
Keywords Session: International and Domestic NDA Submission Regulatory Requirements and Strategy
Session Chair: Carrie Zhang, SCDM Board Advisor; 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!
Keesa Ayukw, M.D., M.P.H., Good Clinical Practice Assessment Branch Chief, Center for Drug Evaluation and Research, Food and Drug-Administration, USA

Topic 2: Data Management in search of a Model vs Models in search of Operations
Demitra N. Zambas, SCDM Board Advisor, VP and Global Head of Data Monitoring and Management, Pfizer

Topic 3: Effective preparation of clinical data submission materials for MRCT trials
Zhenhong Tian, SCDM China Steering Committee Member; Senior Director GDO, Biostatistics & Statistical Programming, Parexel China Co., Ltd.

Session 13, Tuesday / 13:05-14:30
Session 2: Data management and quality expectation in compliance with the new Chinese GCP regulations
Session Chair: Daniel Liu, SCDM China Steering Committee Member; OSD, Beijing Clinical Service Center

Topic 1: Assurance and Control of the Standardization and Authenticity of Clinical Research Data
Sun Ruhua, 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
Mai Chai, CA.Head, Yeowei Medical Data

Topic 3: Discussion on External Data QC for OME 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: Zhenhong 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)
Ruijin 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 Clinical Data Management, MSD Argentina 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: PSMR new requirement for combination products
Holly Lee, 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 Lu, 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: Hoying Sun, General Manager, Meta Clinical Technology

Topic 1: Overcome challenge of COVID-19 and robust DM productivity in Complex Study
Wei Zhang, Manager, eJiffy Company Limited

Topic 2: Facing emergencies such as the epidemic, how to use call center to improve the quality of clinical data
Liu Cui, Associate Manager, Call Center, Meta Clinical Technology

Topic 3: Risk Management: How to Collect and Report of the Impact while staying compliant
Yangyi Wu, Senior Director, Data Management, Parexel

October 17, Saturday / 10:00-12:00
Session 6: Data Management from Visualization
Session Chair: Yanzhong Deng, SCDM China Steering Committee Member; General Manager, Beijing Trust Medical Clinical

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 18, Sunday / 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: HL7 WHO/bug 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, Yuen Rien Life Science Technology Co., Ltd.

Topic 3: Implementation and application of integrated data collection platform in early phase study
Qingguang Yu, Data Manager (Analyst), PPC