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-Would Data to Real-Would 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