Effective Data Validation Process Using Advanced Technology in Clinical Trials: Current Challenges and Lessons Learned

Date: March 25-26, 2015
Location: Xiamen, China

Co-organizer: China Data Management Committee, Professional Committee of Statistical Theory and Method, The Chinese Health Information Society

Program Chair
Hualong SUN, MD, PhD
General Manager
Meta Clinical Technology

Program Committee
Daniel LIU, PhD
Chief Scientific Officer
Beijing Clinical Service Center

Tracy CHEN
Clinical Data Manager
PAREXEL International

Dorothy DAI
Clinical Data Manager
PAREXEL International

Success of clinical studies depends on quality and integrity of its final database. However, no matter how much care is taken in collecting and monitoring data, data discrepancies and errors will invariably find their way into a clinical database. The vast majority of these data inconsistencies and errors could be alleviated with careful efforts of clinical data validation. Thus, validation of clinical data collected in clinical studies is crucial risk-focused quality process for ensuring quality and integrity. This training program is designed to discuss principles, types, process and skills of clinical data validation, including data standard, data management system or data capture tool, validation tool testing, specification, operation and query handling/resolution, as well as analysis of common validation risks. The interactions with attendees during the program may enhance the real world know-how skills and understanding of clinical data validation.

Learning Objectives

• Regulatory requirements on clinical data quality
• Definitions of metrics of data quality and data management
• Data validation specification development
• Establishment of data validation tool
• Documentation in data validation
• QA/QC requirements in data validation
• Application of risk-based monitoring approach in data validation process
• Challenges and essential elements in the management of data validation

Targeted Audiences

• Clinical project management
• Clinical data management
• Clinical monitor
• Clinical research professionals
• Clinical research assistant
• QA/QC professionals
• Clinical investigator and coordinator
• CRF/data standardization professionals

Registration:

Contact: Erning NING
Tel.: +86 10. 57042655
Email: Erning.ning@diachina.org
8:30 – 9:15  Regulatory Requirements of Data Quality in Clinical Trials

Daniel LIU, PhD
Chief Scientific Officer
Beijing Clinical Service Center

• Data quality in ICH-GCP
• Data quality in FDA 21 CFR Part 11
• ALCOA+ principle
• Data integrity

9:15 – 10:15  Good Data Standard Practice Related to Data Quality

Hualong SUN, MD, PhD
General Manager
Meta Clinical Technology

• Regulatory requirement regarding CDISC
• Data standard and data quality
• Database design considerations

10:15 – 10:30  Tea Break

10:30 – 12:00  Rationale of Data Validation

Hualong SUN, MD, PhD
General Manager
Meta Clinical Technology

• Sources of data error
• Data validation and management strategies
• Documents required before DVS creation
• Understanding protocol specific validations
• Practice

12:00 – 13:00  Lunch

13:00 – 14:30  Data Validation Specification Development (Case Study, Practice)

Tracy CHEN
Clinical Data Manager
PAREXEL International

• To get input from project members
• Completeness, correctness and consistency of data
• Different type of checks
• Defining data validation: system checks, automated checks, manual checks
• Case study
• Practice

14:30 – 15:15  Challenges and Lesson Learnt on Offline Data Validation

Tracy CHEN
Clinical Data Manager
PAREXEL International

• Defining offline listing data validation
• Patient profiles
• UAT for offline listing
• Challenges and lesson learnt in SAS offline listing review

15:15 – 15:30  Tea Break

15:30 – 17:00  Data Validation Tool Set Up and Testing (Case Study, Practice)

Dorothy DAI
Clinical Data Manager
PAREXEL International

• Test data creation
• Procedure of UAT
• Test script creation
• Case study
• Practice
9:00 – 10:30  Query Handling and Resolution (Group Discussion)

Dorothy DAI
Clinical Data Manager
PAREXEL International

- Formula of “L S A” in query writing
- General rule on query writing
- Query text for different type of checks
- Query resolution
- Group discussion

10:30 – 10:45  Tea Break

10:45 – 11:30  Challenges of Data Validation in Paper Studies

Dorothy DAI
Clinical Data Manager
PAREXEL International

- Handling of data clarification form (DCF) and site generated clarifications (SGC)
- Self evidence correction
- Challenges of data validation in paper studies

11:30 – 12:15  Safety Data Validation

Dorothy DAI
Clinical Data Manager
PAREXEL International

- Lab data review
- Physical examination/vital sign data review
- Handling of adverse events
- Practice

12:30 – 13:30  Lunch

13:30 – 14:15  Challenges and Points to be Considered in Data Validation

Hualong SUN, MD, PhD
General Manager
Meta Clinical Technology

- Metrics of data quality in different study stage
- Challenges and points to be considered
- Group discussion

14:15 – 15:00  How to Apply Risk-Based Monitoring Approach to Data Validation Process

Daniel LUI, PhD
Chief Scientific Officer
Beijing Clinical Service Center

- Regulatory requirement on risk-based monitoring critical data and non-critical data
- Centralized data monitoring in data validation process

15:00 – 15:15  Tea Break

15:15 – 16:00  Handling of Protocol Deviation

Tracy CHEN
Clinical Data Manager
PAREXEL International

- Defining protocol deviation
- Protocol deviation reporting and management
- Practice

16:00 – 17:00  External Data and SAE Reconciliation (Case Study, Practice)

Tracy CHEN
Clinical Data Manager
PAREXEL International

- External data reconciliation
- SAE reconciliation
- Case study
- Practice

17:00 –  Wrap Up