bing he

Associate Director at Shanghai Hengrui Pharmaceuticals Co., Ltd.

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Summary

To date, I have about 11 years' experience in data management and statistical analysis of clinical trials. When I attended Southeast University as a graduate student, I had a basic knowledge of clinical trials and also assisted several teachers to conduct data entry and analyze clinical data. After graduation, I have worked for about 2.5 years as a statistician for two Contract Research Organizations (CROs) and nearly 9 years as a clinical programmer for Pfizer. So far, I have finished analysis of clinical data for about 80 projects sponsored by some multinational or local pharmaceutical companies such as Pfizer, Novartis, Roche, TakeDa etc. The projects I conducted cover phase 1-4 and involve in multiple therapeutic fields.

Specialties: SAP writing with mock TLFs;Statistical programming for data analysis and clinical data management.

Experience

Associate Director of Clinical Programming at Shanghai Hengrui Pharmaceuticals Co., Ltd.
February 2016 - Present (5 months)

The resposibility includes people management, development of clinical data reporting system, SOP creation and other supports to clinical trial projects.

Senior Manager of Clinical Programming at Pfizer (China) Research and Development Co,ltd
April 2015 - January 2016 (10 months)

Provides leadership and expertise in Data Analysis Reporting operations.

Ensures internal and external data analysis reporting operations are executed to advance research, development, and commercialization of the Pfizer portfolio

Delivers programming outputs (datasets, tables, listings, figures, compliance and oversight documentation) for submissions, product defense, and commercial support. Provides expertise in clinical programming, partnering with internal and external groups to ensure quality and compliance in data analysis reporting/ clinical programming deliverables.

Manager of Clinical Programming at Pfizer (China) Research and Development Co,ltd
April 2012 - April 2015 (3 years 1 month)

The responsibility includes the management of a project team, training juniors and programming to produce tables/listings/figures for clinical projects.

Senior Technical Supervisor of Clinical Programming at Pfizer (China) Research and Development Co,ltd

September 2010 - March 2012 (1 year 7 months)

The responsibility includes the management of a project team, training juniors and programming to produce tables/listings/figures for clinical projects.

Technical Supervisor of Clinical Programming at Pfizer (China) Research and Development Co,ltd

April 2009 - August 2010 (1 year 5 months)

The responsibility includes the management of a project team, training juniors and programming to produce tables/listings/figures for clinical projects.

Clinical Programmer at Pfizer (China) Research and Development Co,ltd

December 2006 - April 2009 (2 years 5 months)

Clinical Programmers in the Clinical Programming and Writing (CPW) Group of China R&D Center (CRDC) provide clinical programming support for various Pfizer global and regional clinical studies. They work closely with statisticians to implement analyses as specified in statistical analysis plans, table shells, and programming requirement documents. They are responsible for extracting data from databases to produce tables, graphs, analyses, and data listings based on clinical data, either for regulatory submission and reporting purposes for new drug application or for marketing support. They may also provide input and review for the activities of other statistics and clinical programming personnel, e.g. the review of Case Report Forms, protocols, statistical analysis plans, table shells, programming requirement documents, and databases in the future. Clinical programmers work primarily in the SAS programming language, and follow standardized quality control procedures for the development, testing (including peer review), and implementation of their programs. They work closely with colleagues in the Report Publishing Group to coordinate inclusion of components into clinical study reports.

Senior statistician at RUNDO International Pharmaceutical Research & Development Co., Ltd

April 2005 - December 2006 (1 year 9 months)

The company website: http://www.rundo-cro.com/En/

Be responsible for the trial design, assisting in data management, SAP writing, statistical programming, statistical consulting service and statistical quality control.

Statistician at ShangHai Careway Consulting Co.Ltd

July 2004 - March 2005 (9 months)

- Be responsible for all assigned statistical tasks on clinical trials, e.g. analysis plan, reporting activities, statistical analyses to support clinical study report, and statistical consultation.
- Ensure timeliness and quality of deliverables for the assigned tasks on trial/work package deliverables.
- Also participate in clinical trial design, development of case report form, development of clinical database and data management.

Skills & Expertise

Data Management
Clinical Study Design
Clinical Data Management
SAS programming
Medical Devices
Clinical Trials
Clinical Research
Regulatory Submissions
Clinical Development
CRO
Biotechnology
Protocol
GCP
Analysis
Pharmaceutical Industry
Management
Lifesciences
Program Management
Data Analysis
Statistics

Education

Southeast University
MS, Epidemiology and Health Statistics, 2001 - 2004

Southeast University
BS, Preventive Medicine, 1996 - 2001

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