# Kwan Hwang

Statistical Programmer at INC Research

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## Summary

1, With ten years experience in clinical research field;
2, Good soft skilll in Team building and Project management ;
3, Have good communication skills, coordination and cooperation relations with clients;
4, With 10 years in clinical research, bio-statistics, software programming experience
5, Excellent skills in SAS, Experienced in a SAS macro for SDTM ADAM and TFL programing
6, Proficiency in all kinds of clinical data exchange standards,such as HL7, MedDRA, CDISC, CDASH and STDM etc
7, Open and flexible thinking, powerful problem-solving ability

## Experience

**Statistical Programmer at INC Research**

September 2013 - Present (2 years 10 months)

- Uses SAS software (BASE, STAT, GRAPH, MACRO) for the production of datasets, tables, listings, and figures, and outputs requested (e.g., patient profiles) per programming specifications, Statistical Analysis Plan, and other study related documentation.
- Performs Quality Control to ensure that outputs meet quality standards and project requirements. Works with Programmer, Biostatistician, and other project team members to resolve discrepancies or any findings.
- Develops specifications for outputs and mock-up displays for tables, listings, and figures according to statistical and Sponsor requirement. Anticipates and addresses potential programming issues, establishes the basis for efficient programming, accurately defines all variables to be accepted by peer review and sponsor/ requestor with little rework
- May act as the Lead Statistical Programmer, directs the programming activities of other programming personnel and monitors progress on programming deliverables.
- Negotiates and establishes accurate time estimates for completion of study programming activities with internal team members and Statistical Programming management and completes project programming activities within timeframe allotted.
- Manages scheduling and time constraints across multiple projects, sets goals based on priorities from management, and adapts to timeline or priority changes by reorganizing daily workload. Keeps project team members informed of programming progress and issues requiring their attention.
- Maintains well organized, complete, and up-to-date project documentation, testing, and verification/quality control documents and programs in compliance with Company and sponsor standards.

• Regularly attends and prepares in advance for internal and external team meetings, contributes ideas and demonstrates respect for opinions of others.
• Displays willingness to work with others and assist with projects and initiatives as necessary to meet the needs of the business.

**Statitstical and Database Programer at Covance**

April 2012 - September 2013 (1 year 6 months)

• Statistical analysis plan (SAP) review.
• SAS programming to generate analysis dataset, following CDISC standard.
• SAS programming to generate tables, listings and graph for phase I study according to SAP.
• Data issues feedback to clinical data management before database lock.
• Carry out all activities according to appropriate Covance SOPs, working within the framework of Quality Management System and to GCP.
• Perform edit checks per specifications through SAS programming and complete data transfer specifications.
• Perform other duties as required.

**Data Management Associate at VitalStrategic Research Institute**

June 2010 - April 2012 (1 year 11 months)

1.Verifying that all research staff, facilities and investigational products have adequate qualifications and resources and these remain adequate throughout
2.Verifying that the investigator follows the approved protocol and all GCP procedures
3.Adverse events, concomitant medications, and inter current illnesses are reported in accordance with the protocol on the CRFs
4.Communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator
developing and writing trial protocols (outlining the purpose and methodology of a trial);
5.coordinating with the ethics committee, which safeguards the rights, safety and wellbeing of all trial subjects;
6.managing regulatory authority applications and approvals that oversee the research and marketing of new and existing drugs;
7.locating and assessing the suitability of facilities at a study centre;
8.liaising with doctors/consultants (or investigators) on conducting the trial;
9.setting up the study centres, which includes ensuring each centre has the trial materials and training site staff to trial-specific industry standards;
10.training site staff to industry standards;
11.monitoring the trial throughout its duration, which involves visiting the study centres on a regular basis;
12.verifying that data entered on to the CRFs is consistent with patient clinical notes, known as source data/ document verification (SDV);
13.collecting completed CRFs from hospitals and general practices;

14.writing visit reports;
15.filing and collating trial documentation and reports;
16.ensuring all unused trial supplies are accounted for;
17.closing down study centres on completion of the trial;
18.discussing results with a medical statistician, who usually writes technical trial reports;
19.archiving study documentation and correspondence;
preparing final reports and occasionally manuscripts for publication.

**Clinical Reseach Associate at VitalStrategic Research Institute**

June 2010 - June 2011 (1 year 1 month)

1.Overall project management, in both the technical and the administrative aspects, of clinical projects in a timely and effective manner and in accordance with GCP.
2.Study Preparation, External Supplier Management, Customer Maintenance
3.Site monitoring and management
4.Primarily responsible for liaising with sponsors and leading company project teams of cross-functional members, which generally include project CRAs, study coordinators, statisticians, data management, regulatory affairs and medical writing personnel.
5.Information release
6.Project assessments and initiation, resource procurement and planning, project implementation, leading and motivating a cross-functional team, milestone planning and tracking, ensuring that projects are progressing according to quality standards, SOPs, ICH and/or other guidelines

**Chief Technology Officer at Magnsoft**

January 2009 - June 2010 (1 year 6 months)

Strategy & Planning

In partnership with the company's founders, identify opportunities and risks for delivering the company's services as a web-based business, including identification of competitive services, opportunities for innovation, and assessment of marketplace obstacles and technical hurdles to the business success.
Identify technology trends and evolving social behavior that may support or impede the success of the business.
Evaluate and identify appropriate technology platforms (including web application frameworks and the deployment stack) for delivering the company's services.
Select and set up a software revision control sytem and repository (in the absence of a system administrator).
Establish a specification conformance and testing regimen based on user stories and the User Experience design.
Select and manage company staff or outsourced vendors who will implement the application.
Establish and supervise the software development process, setting short-term objectives and assessing progress as defined by the selected software development methodology.

Review and approve proposed development releases and manage the release process.
Establish an application deployment process and supervise deployment to staging and production servers.

Operational Management

Define and communicate company values and standards for acquiring or developing systems, equipment, or software within the company.
Ensure that technology standards and best practices are maintained across the organization.
Ensure company technical problems are resolved in a timely and cost-effective manner.
Develop, track, and control the development and deployment annual operating and capital budgets for purchasing, staffing, and operations.
Promote achievement of the company's business goals within a context of community collaboration by developing policies for sharing software code, technological innovation, business processes, and other intellectual property.

**Clinial Data Management Expert;Biostatistic Expert at The National Clinical Trial Center for Chinese Herb (Chengdu) CDUTCM**

January 2000 - December 2008 (9 years)

Clinial Data Manager

contributing to the design of protocols, which define what and when data are to be collected;
designing and approving forms on which data are collected;
designing databases and ensuring they meet requirements for the entry and reporting of clinical data;
training clinical research associates to help improve the quality of the data being collected;
producing summaries and listings of safety and efficacy data;
testing new processes and systems for the management of clinical trials.

Biostatistic Expert

Leads the planning and implementation of statistical analysis for clinical study reports and regulatory dossiers.
collaborate with researchers as they design studies, helping them find the best approach to data gathering given the question the researchers are trying to answer. provide advice on such topics as sample size (how many subjects need to be included in a particular study for the results to be meaningful) and data collection (what methods will be used to gather the data).
Represents company at internal and sponsor technical meetings.
use statistical software to turn the data into useful information. They use standard statistical procedures and terms to help researchers pinpoint which results were significant and which were inconclusive,

warranting further study. Biostatisticians sometimes find themselves cleaning up an imperfect data set to help researchers glean conclusions from it.

Utilizes advanced statistical methods (interim analysis stopping rules, analysis of pharmacokinetic parameters, logistic regression etc.

Writes statistical sections for protocols, protocol analysis plans, mock tables shells and finalizes clinical/ statistical integrated reports.

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## Skills & Expertise

**Clinical Data Management**
**GCP**
**Clinical Research**
**Biostatistics**
**Data Management**
**SAS**
**Analysis**
**Healthcare**
**CDISC**
**Strategic Planning**
**Health Economics**
**Databases**
**Data Analysis**
**Outcomes Research**
**Microsoft Office**
**SPSS**
**Research**
**Negotiation**
**Quality Assurance**
**Data Mining**
**Stata**
**R**
**Bioinformatics**
**Administration**
**Linux**
**Matlab**
**PowerPoint**
**SQL**
**Programming**
**C#**
**Database Administration**
**Photoshop**
**Budgeting**
**Health**
**Hardware**

**MySQL**
**Newsletters**
**PHP**
**Planning**
**SQL Server**
**Ubuntu**
**XML**
**Mac OS X**
**Health Outcomes**
**Problem Solving**
**Clinical**
**Python**
**CRO**

## Education

**Chengdu University of Traditional Chinese Medicine**
Master, ophthalmology, 1999 - 2004

**Sichuan University**
Bachelor, biology, 1997 - 1999

## Interests

Clinical data Management ,Biostatistic ,Tennis

## Languages

**English**
**Chinese (Simplified)**

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## **1** person has recommended Kwan

"Innovative people"

— **zheng jianxing**, worked directly with Kwan at VitalStrategic Research Institute

Contact Kwan on LinkedIn