VINAY MAHAJAN

SMR Vinay Prangan, Flat No. 403, Madhapur main road, behind Ratnadeep supermarket, Madhapur,
Hyderabad, Andhra Pradesh, India
Mobile : +91 9966999523
mahajvi@yahoo.co.in

Summary of Qualifications

Dynamic and driven SAS professional (Statistical Analyst) with nearly 10 years of experience and extensive knowledge in clinical trials, including SAS programming and data analysis. Strong foundation in fundamental statistics.

Education

University of Bombay (Mumbai) – Wellingkar management Institute	**Mumbai, India**
➢ Post Graduate Program in Management studies (PGPMS/ E-MBA)	October 2008
University of Bombay (Mumbai)	**Mumbai, India**
➢ Master of Science, Major: Statistics, 78%	May 2001
University of Bombay (Mumbai)	**Mumbai, India**
➢ Bachelor of Science, Major: Statistics, 80%	August 1999

Professional Certifications, Training and Memberships

➢ SAS Institute, Inc:
  ➢ Advanced SAS certification- November 2005
  ➢ Base SAS certification- December 2004
➢ Student member of Actuarial Society of India since 2001
➢ GCP and SAS trainings

Professional Experience

Novartis HealthCare Pvt Ltd (NHPL),

Group Head - Hyderabad, India	**Apr 2010 to present**
Expert Statistical Analyst– Hyderabad, India	**Jul 2008 to Mar 2010**
Lead Statistical Analyst– Hyderabad, India	**Sep 2007 to Jun 2008**
Lead Statistical Analyst– Mumbai, India	**Jan 2007 to Sep 2007**
Senior Statistical Analyst – Mumbai, India	**Mar 2005 to Jan 2007**
Statistical Programmer – Mumbai, India	**Jan 2004 to Sep 2004**
Statistical Programmer – East Hanover, NJ, USA*	**Mar 2003 to Dec 2003**
*International Assignment at Novartis US Headquarters	
Statistical Programmer – Mumbai, India	**Jul 2001 to Feb 2003**

Management activities

➢ Contribute to the development of long-term goals and operating policies for the Oncology Biometrics organization through leadership role on the management team.

➢ Manage timelines, quality and preparation of statistical reporting deliverables and ensure that they comply with Oncology Biometrics, project and regulatory guidelines globally.

➢ Manage resources within the assigned group and share resources, as required, with other programming groups to ensure optimal Biometrics support across projects.

➢ Ensure that relevant SOPs/NIPs/Working practices are in place and followed.

➢ Recruit talent, coach and develop reports on site.

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Clinical Trial Activities

➢ Planned and managed statistical analysis projects in global clinical trials with current focus on **Oncology trials** using **SAS software package.**

➢ Ensured clinical trial data integrity per the Standard Operating Practices based on FDA guidelines.

➢ Reported safety and efficacy reports data to support publications and registration of the drugs including case report tabulation (CRT) and other required analyses including Novartis Global Clinical Trials mainly for phase II and III, in compliance with Statistical Principles for Clinical Trials (ICH E9) and Good Clinical Practices (GCP).

➢ Design and execute the statistical analysis plan,

➢ Participate in clinical trial process by reviewing protocol, CRF, data management and statistical plan.

➢ Generate statistical analysis datasets, tables and listings for individual studies, NDA, Health Authority submissions, Investigator brochure, Integrated Summary of Safety and Efficacy as well as adhoc requests from clinicians.

➢ Ensure the design of CRF will meet the statistical criteria of Protocol and give inputs to the validation and analysis plan of the Data.

➢ Coordinate the acceptance test for CRO programming activity.

➢ Created SAS utility programs and macros to enhance efficiency of internal operations and quality improvement.

➢ Integrate the Pharmacokinetic data with the clinical data for analyzing the PK profile of the drug.

Non Clinical Trial Activities

➢ Conducted Quality assurance tests as a super user for the internal SAS based reporting tool for clinical data.

➢ Acted as a primary liaison between IT and Clinical trial functional teams.

➢ Effectively mentored new hires on UNIX programming and internal information systems.

➢ Trained offshore associates on the internal SAS macro based tool.

➢ Strengthened relations between India and USA sites.

➢ Interviewed and facilitated the recruitment of new associates in the team.

Corporate Awards

➢ Vision Award (2010), PQS Awards (2008, 2009)

➢ Above and Beyond Recognition awards for different clinical projects (2003 – 2009)

➢ "Best Pal" of the Year at Novartis (B&SR INDIA) – (2005)

➢ Global support for standardization of Standard Safety Reporting Tool in Novartis – (2003)

Achedemic Achivements

➢ University of Bombay (Mumbai) – for the first rank in the class of 2001 - Master of statistics:

    o Prof. G.S.Pirolkar Memorial Prize.

    o The Late Dr. (Kum.) Vijaya Salpekar Prize.

    o Principal V.K. Jog Memorial Prize.

➢ University of Bombay (Mumbai) – Bachelor of statistics:

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- o Awarded the National Scholarship for 1999-2000 for securing 80%.
- o Recognition award for exemplary proficiency achieved in Statistics for 1998-1999.

Other Computer Skills

➤ MS Office Suite, HTML, SQL Reporting Services, MS Project, Splus.

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Signature

19-Apr-2012
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Date