

### **Executive summary**

Vinay Mahajan has worked for Novartis Pharmaceutical Private Limited from July 2001 as a statistical programmer to a Director, Data Operations Development Units in a series of different roles. Over the years, the responsibilities have increased from an individual contributor under supervision, a trial programmer responsible to deliver at a study level, a lead programmer for a group of molecules and a Senior Group Head managing large teams across sites.

His 16+ years of experience included functional and operational management of global teams and programming units within disease area comprising of multiple molecules; providing strategic inputs in the development of the function and site.

As a Senior Group head for local India team has supported the development of the road map for the programming team, define the job roles and career path, create competency development methodology, create training plan for the team and make team productive, developed clinical pharmacology programming team, early phase drug development, lead program programmers, submission coordinators and safety coordinators for submission, participation in vendor assessment.

As a global head of Data Review Programming team, has the experience of developing programmers for setting up patient profile programs, data check programs to check data consistency and cross comparison of data across panels and various study specific requests for data cleaning. Has experience working and collaborating in cross functional team providing technical and functional inputs.

As a global head of Data Processing team, has the experience of setting up a completely new global team, to process the data from Oracle Clinical tables into SAS datasets, performs data transformation algorithms for statistical programming team. In this role has defined job roles and career path for the development of the team.

In the role of a project manager for computer systems, which are built in-house for TFL macros, efficacy end point calculations, CTC grading, other reference data which are based on WHO coding system, has the experience of defining a problem, converting it into a functional specification, coding the system, qualifying it and releasing it into production.

As a Programming team lead has worked on clinical trials, summary of clinical safety and efficacy, summary of clinical pharmacology for submissions across health agencies world over, (Data Monitoring Committee) DMCs and (Data Safety Monitoring Board) DSMBs, Interim Analyses (IAs), preparation of various submission documents Development Safety Update Review (DSUR), Periodic Safety Update Review (PSUR)/Periodic Benefit Risk Evaluation Report(PBRER), Risk Management Plan (RMP), Bioresearch Monitoring Office (BIMO), Office of Scientific Investigation (OSI listings), Briefing Book (BB), Investigator Brochures (IBs), health authority questions and publications in various therapeutic areas; ensuring audit readiness.

### **Key Skills**

**Effective leadership:** 12+ years of effectively leading programming teams across sites for statistical reporting from Clinical pharmacology, early development to Full development, data review reporting and data processing team

**Programming regulatory experience:** Hands on experience of regulatory submissions, planning and preparation of integrated databases and analyses including interpretation of Health Authority Questions and proposing responses. Experience in preparation for Advisory Committee meetings by providing programming support. Ensuring audit readiness by effective implementation of organizational SOPs.

**Collaboration, Team Building and Communication:** Interaction with diverse functional groups during the deployment of standardized outputs for Validation and Monitoring outputs, active participation in the Clinical Trial Team in capacity of a lead programming proposing identifying issues and proposing solutions, development of generic and customized training plan for statistical programmers to cater to function/ project needs.

### **Educational background**

Executive MBA Welingkar Institute Mumbai, 2006 – 2008

MSc (Statistics) Mumbai University, 1999 – 2001

BSc (Statistics) Mumbai University, 1996 – 1999

#### **Certifications:**

Data science, Johns Hopkins University, by Jeff Leek, Roger D. Peng, Brian Caffo – 2016, 2017

Health Informatics on FHIR, Georgia Institute of Technology, by Mark L. Braunstein, MD - 2016

eHealth: More than just an electronic record, The University of Sydney, many instructors - 2016

European Computer System validation certification – 2015

SAS certifications – base and advanced 2004, 2005

#### **Work experience: Novartis Pharmaceuticals Private Limited (2001 – present)**

**Director , Data Operations Development Units** Jan 2018 - present

**Sr. Group Head** Dec 2015 – Dec 2017

**Group Head** 2010 – 2015

**Expert statistical programmer** 2008 – 2010

**Lead statistical programmer** 2006 – 2008

**Statistical programmer** at various levels 2001 – 2006

**International assignment** at North America head quarter for 9 months

**People management roles:**

1. Mid-year and end year reviews of the associates based on the pre-defined objectives, promotion proposals, career development discussions, competency assessment based on the Learning agility and Sustained Performance criteria
2. Site development support; hiring and on-boarding new teams and fresh university graduates, defining job description, career road map for the oncology programming team as well as data review and data processing team
3. Global head role for the data review team (12 people globally – manager of 1 manager) – patient profile programming, data check programming, study specific data checks for efficacy and safety data
4. Global head role for the data processing team (15 people globally – manager of 1 manager) – conversion of data from Oracle clinical tables into the SAS datasets for the statistical programming team
5. Group head role for the SAS programming team in various phase of clinical trials (20 people – manager of 2 managers) – clinical pharmacology, early phase clinical studies, full development phase
6. Development of matrix reports, slides for business review meetings across different Line Functions, coordinate managers' meeting once a week
7. Contributions to the selection of CRO partners by auditing and interviewing them

**Team set-up and development:**

1. Contributions to the road-map for the site specific development of the programming and statistics team
2. Development of the job profiles and career ladder along with other senior managers in the organization
3. Development of fresh college graduates or post graduates from various domains into fully productive independent resources
4. Development of the customized training material for new joiner SAS programmers

**Project management roles for new drug application submissions:**

1. Manage submission activities for FDA, EMA, PMDA(Japanese) submissions for a few molecules, define the pooling strategy based on the analysis plan
2. Author some sections of the analysis plans for Briefing book for US FDA, Summary of Clinical Safety, Summary of Clinical efficacy, Summary of Clinical Pharmacology, Risk Management Plan, 120 safety updates, etc.
3. Development of clinical data review specifications along with Data management, database development and clinicians

4. Work with the different Line functions like Statistics, data management, clinicians to come up with the analysis plans and timelines
5. Identification of appropriate resources for programming and deliver as per timelines and quality
6. Work on Health Authority Questions, ad-hoc analysis, publication requests, yearly Investigator Brochure updates for molecules in development
7. Contributions as a technical expert to development of Standard macros to produce standard outputs, Efficacy endpoints related to RECIST guideline, CTC grading for lab values
8. Contributing to the roles of Independent programmer and essaying the role.
9. Supporting external Data Monitoring Committee (DMC) and Data Safety Monitoring Board (DSMB) analysis
10. Supported audit readiness for trials

**Clinical trial analysis at study and pooled level:**

1. Started contributions on studies as a support programmer and then gradually increased contributions to a Trial programmer, Lead programmer, co-lead submission activities
2. Review and provide comments on the analysis plan
3. Prepare the programming specifications
4. Worked on a mega trial with more than 25,000 patients
5. Pooled analysis of more than 50 studies in one molecule (one of the many examples)
6. Preparation of the Case Report Tabulation (CRT) for US FDA submission for many studies using an internal tool
7. Various SAS macros – decimal alignment, mixed table, graphs (patient profile style: lab, dosing, death, completion information)

**Computer system validation:** Lead Computer System Validation activities by authoring, co-authoring and reviewing the following documents:

1. The functional specifications and design specifications
2. Oversee the coding of the system based on the documents defined in point #1
3. Validation of the system by means of the Installation Qualification document, Operational and Performance Qualification documents
4. Define the test scripts and have testers perform the testing activities
5. Document the validation report based on the testing – detail the deviations and ascertain fitment of the system for release

**Technical contributions:**

1. Create simple tools based on UNIX commands – “follow one-liner programming techniques for completing routine tasks”, compare Tables vs. Listings using AWK scripting concept
2. Develop of a SAS based tool to create programming specifications based on a SAS based program
3. Development of a SAS based tool to create empty programs containing header and standard macro calls based on the QC and tracking sheet

4. Development of a SAS and UNIX based tool to compare the status of programming time vs. the planning for SAS programming
5. Development of SAS based tool to create a question paper of SAS questions for interviews
6. SME role on various internal systems
7. Contributions as a programming lead to the Standard Output team
8. Contributions to the BIMO dataset initiative, OSI listings

**People development:**

1. Teaching of basic SAS skills
2. Comparison of a Table vs. Listing vs. Graphs
3. Linking of FDA label to a CSR to individual TLFs in individual studies, in pooled analysis
4. Knowledge sharing sessions for junior as well as senior programmers
5. Interpretation of First Interpretable Results
6. Review of many scientific and technical papers for continuous learning
7. Played a major role in helping a few associates move from one Line function to other to pursue career dreams
8. Development of training material and deliver to a global audience

**Contributions to the external clinical trials researchers:**

1. Work with Ayurvedic doctors for conducting clinical trials – assist them in clinical trials methodology as defined in GCP, ICH guidelines
2. Act as a visiting faculty for various clinical trials related aspects – operational, technical and scientific
3. Contributions to the development of “CONSORT for Ayurveda” – ongoing work
4. Own work on identifying similarities and dissimilarities between Ayurveda and western medicine, Ayurveda and ICH, Ayurveda and GCP
5. Own work on “narrative review” – on 139 studies in 2010, 140 studies in 2014
6. Presentations and lectures in various colleges and national level conferences

**Technology and guidelines:**

SAS, Microsoft office, R (used for additional review of the outputs), IBM Clearcase

ICH and GxP guidelines required for the Clinical trials