Deepak Saini
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SUMMARY:

Experienced "Clinical SAS Programmer" with a demonstrated history of working in the pharmaceuticals industry. Skilled in **Base SAS**, **Advanced SAS**, **R, SQL**, Statistical Data Analysis, Data Visualization, and **end-to-end SDTM** and **ADaM** standards. A Strong engineering professional Graduated in Computer Science & Engineering.

· **SAS**, **R** and **SQL**	· Clinical Research Analysis
· **Unix commands**	· **TLF** (Table, Listing & Figures)
· Database Management System	· **SDTM, ADaM** & **Define.xml**
· R Shiny	· **Oncology Endpoints**

TOOLS AND TECHNOLOGIES:

- Statistical Tools: SAS v 9.4 for Linux | Windows SAS | R Studio
- SAS Tools: SAS/Base | SAS/Macro | SAS/Graph | SAS/SQL | SAS/ODS
- Database Tool: SQL Developer
- Operating systems: UNIX | WINDOWS
- Version Control: GitHub
- Microsoft Office: Microsoft Suite (Word, Excel, PowerPoint, Access and Outlook)

SUMMARY OF SKILLS:

- I have **6 plus Years** of experience in C**linical Domain** as a **Statistical Programmer**.
- Experience in Analysis and Reporting of clinical trial data of both early and late phase studies in both client specific and CDISC standards –
- Worked on development/validation of SDTM and development/validation of ADaM and TLF
- Familiar with Clinical Trial Phases, Drug Development, Study design, Safety & Efficacy data.
- Experience in creating **SDTM, ADaM, Tables, Listings and Figures**.
- Worked in **R Programming** in Clinical Trial for ADaMs.
- Experience in creating **ADRG, SDRG**, define.xml, Pinnacle report, aCRF for CDISC studies.
- Proficient understanding on SAS Tools which further categorized as SAS Basic, SAS advance – Macro & SQL.
- Good **domain knowledge** on CDISC ADaM, SDTM Mapping and in-depth knowledge of clinical data and CDISC SDTM/ADaM implementation guides.

PROFESSIONAL EXPERIENCE:

- ❖ **GSK,** Bengaluru. Working as a **Senior Programmer** from Dec 2018 to till date.

  Job Responsibilities
  - Working in **Oncology** Therapeutic Area (**Immunotherapy**) as a Study Lead and responsible to understand, program and review various ADaMs Oncology Efficacy Endpoints e.g. **PFS, DOR, TTR, OS, DCR and BOR**.
  - As a study lead working on **SDTM review** and highlighting issues back to Conversion lead in DM meetings.
  - Performing regular **QC using R programming** language
  - Generated key CDISC safety and efficacy ADaM datasets like **ADSL, ADRS, ADTR, ADTTE, ADDATES, ADAE, ADLB, ADEX, ADPC, ADPP etc**.
  - Regularly working in creating and validating of analysis datasets (ADaM), and TLFs/reports.
  - As part of **Oncology Focus Group** involved in developing **standard SAS macros** and **ADaM specifications**.
  - Involved in **mentoring New Joiners** (Fresher's and mid-experienced).
  - Involved in constant regular communication with Study Statistician(s) for understanding study requirements, study design, study endpoints and derivations involved in documents like SAP, Protocol etc.
  - Ability to effectively perform complex programming and related tasks.
  - Experience of working on studies like **ISS** (Integrated Summary of Safety), **DSUR**, **DRB** etc.

- ❖ **TCS Noida, Delhi NCR**. Worked as a SAS Programmer from Dec 2017 to Dec 2018.

  Job Responsibilities
  - Worked in Therapeutic Areas like Rheumatoid Arthritis and Oncology and worked on **end-to-end SDTM mapping**.
  - Worked on building SDTM domains like Demographic Data (DM), Adverse Events (AE), Lab (LB), Vital Signs (VS), and Medical history (MH) etc.
  - Involved in regular study meetings with various stakeholders.
  - Worked on data validation by writing and comparing independent QC programs to verify the output dataset.
  - Involved in Validating, Mapping and conversion of **raw to CDISC SDTM** Dataset as per SDTM IG 3.2.
  - Involved in creating study specific macros and Testing and debugging of existing MACROS for creation of SDTM datasets.
  - Involved in writing complex SQL queries.
  - Worked on tools like MDR.

❖ **Accenture**, Bengaluru. Worked as a **SAS Programmer** from Aug 2015 to Dec 2017.

Job Responsibilities
- Worked as a SDTM Programmer in various TA like Oncology, Vaccines etc.
- Worked on **blockbuster drug - Keytruda (Pembrolizumab).**
- Involved in Mapping Spec creation, CRF Annotation, Pval validation, programming and validation through PL/SQL programming.
- Worked with separate QC Team of three members to validate SDTMs using SAS.
- Worked on **ETL** tools like CONTIVO.
- Worked on major SDTM domains as per SDTM IG.
- Worked on complex **PL/SQL queries** on SQL Developer.

EDUCATIONAL QUALIFICATIONS:

- **Bachelor of Technology** Graduate in **Computer Science & Engineering – Honours Degree** from Rajasthan Technical University (2011-2015).

- **HSC (12th Board)** from C.B.S.E. with **72%** marks (2010-2011).

- **SSC (10th Board)** from R.B.S.E. with **82%** marks (2008-2009).

PERSONAL DETAILS:

Date of Birth: 08 Feb, 1994
Marital Status: Married
Permanent Address: 9-Narsingh Nagar, Nangal, Jhotwara, Jaipur, Rajasthan, India - 302040

DECLARATION

I hereby declare that the details mentioned above are true to the best of my knowledge and I am solely responsible for any consequences.

Place: Bangalore   **Deepak Saini**

Date: