Jaya Kumawat
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CURRICULUM VITAE

OBJECTIVE:

Working in ~~Clinical Research~~Patient –Analytics leveraging technology (big data platform and data science) is ~~is~~ my passion. I wish to continue contributing and grow in the space of life science big data analytics ~~,and~~ clinical trials & real ~~-data~~world data management in a leadership position, wherein my employer can leverage from my experiences and knowledge within the IT, pharmaceuticals ~~& CRO~~& CRO space.

EDUCATION:

- Strategic Management (Indian Institute of Management, Calcutta)
- Certification in Business Analytics using R (Indian Statistical Institute , Bangalore)
- B.Tech (Computer Science & Engineering), June 1995
  Alma mater: Manipal Institute of Technology

TOTAL WORKING EXPERIENCE: Appx 18~~19~~ years

SKILLS & EXPERIENCE:

~~BIG~~ PATIENT DATA ANALYTICS (Big Data Analytics & Data Science)

~~*BIG DATA PLATFORM –FRAMEWORK TO IMPLEMENT TRIAL MANAGEMENT ANALYTICS.* Sponsor's partner with SIs to reign in data silos. Silos represent challenges for data ingestion, analysis, and presentation. The challenge of preparing and isolating clean data to drive decision-making in trial management is similar across sponsors. Sponsors can adopt a Trial Management Analytics (TMA) framework including initiative planning, source data integration, data organization, analysis of data, and presentation of data to improve the expenditure, quality, success, and safety of clinical studies. Clinical data Pipeline (Operations and Patient data pipeline on data warehouse platform)~~

a. *PHARMA PATIENT DATA ASSESSMENT/GAP ANALYSIS*: Perform a gap analysis of the patient data ecosystem for pharma and recommend a solution strategy and roadmap for their scientific data analytic needs.

b. *PATIENT IDENTIFICATION (FOR RWE(HEOR), CLINICAL R&D, MEDICAL & PHARMA COMMERCIAL)*: ***Enabled by Big Data Analytics Leveraging Real World Data (EMR)*:**
~~*a.* *TRIAL PLANNING AND CLINICAL TRIAL RECRUITMENT STRATEGY* ***Enabled by Big Data Analytics Leveraging Real World Data (EMR)*:~~ Cohort Generation solution that identifies patient population based on IE criteria. Integrates real world information form EHRs in a trials analytic structure. Optimizes the trial planning and patient recruitment strategy by assessing IE criteria against global real world ~~data.~~.

c. *SAFETY/PHARMACOVIGILANCE:*
~~*b.*~~
FDA Sentinel Project using TreeScan:

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Building next generation of Safety Signal Identification & Evaluation tool for a top pharma company. This tool would provide an early assessment of potential safety signals identified by regulatory agencies such as FDA's Sentinel Signal Detection System. The system would utilize capabilities of the FDA TreeScan software. Output from the system will be based on the FDA Sentinel statistical approach using real-world data of administrative claims and EMR.

Signal Detection: Process of Signal Detection, current regulations, data science methodologies (text mining – NLP) from social media & publications.
Safety Data Analytics – Case Triaging and Processing, Signal Detection, Safety Data Optimization and Safety Insights (Integrating data from public databases e.g.: WHO-UMC, FAERS, EMRs, IMS PEM etc.) and building insights and data mining on top of these.

d. *FRAMEWORK TO IMPLEMENT TRIAL MANAGEMENT ANALYTICS*. Sponsor's partner with SIs to reign in data silos. Silos represent challenges for data ingestion, analysis, and presentation. The challenge of preparing and isolating clean data to drive decision-making in trial management is similar across sponsors. Sponsors can adopt a Trial Management Analytics (TMA) framework including initiative planning, source data integration, data organization, analysis of data, and presentation of data to improve the expenditure, quality, success, and safety of clinical studies. Clinical data Pipeline (Operations and Patient data pipeline on data warehouse platform)

~~c.~~e. *NEXT GENERATION RBM* - Big Data Patient Data pipelines with outlier and fraud detection. Building RBM metrics as per Transcelerate and MCC.

BIOSTATISTICS & CLINICAL DATA MANAGEMENT:

a. *EDC, CTMS & CLINICAL APPLICATIONS EVALUATION:*
Vendor & system evaluation and building capability maturity models. Systems considered: Oracle Clinical, PhaseForward-Inform, Medidata- Rave, SAS- PheedIT, and Oracle–RDC. CTMS Applications like Perceptive Impact, StudyManager, and Siebel CTMS.

b. *CLINICAL DATA MANAGEMENT:*
- End to end Clinical data management process, viz Protocol Review, Database Design in Oracle Clinical: Study Design, Definition, DCI, DCMs and Question sets (CDISC compliance), CRF design, Data Validations, Report Generation, Data Extraction.
- Conduct as per industry standards and compliances such as ICH, GCP, SCDM-GCDMP, CDISC, SEND, SDTM, GAMP

c. *STATISTICAL ANALYSIS*
- ~~Strategized and then guided the SAS programmers to program the Manual and more complicated checks into the SAS software.~~
- Insight in Statistical Analysis Plan & generation of Table, listings and Figures for CSR.

COMPUTER SYSTEM VALIDATION

End to end Computer System Validation (for 21 CFR Part 11 compliance of software systems used in pharmaceuticals).

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TECHNICAL SKILLS

- Big Data Analytics, Data Science (Artificial Intelligence, Machine learning applications to RWD, patient data/clinical research)
- Data Warehouse, ETL (Informatica) , Relational Databases (Oracle 9i)
- Working knowledge of Oracle databases, PL/SQL and data management concepts.
- JAVA, ColdFusion, JavaScript, VB, Pascal, Systems Programming
- Back-end: Oracle RDBMS (PL/SQL)
- Markup Languages: XML, XSL, HTML.

BUSINESS DEVELOPMENT

Responsible for costing/budgeting, solution, proposal design and development. Developing, designing and implementation of business development strategies based on market research.

PROFESSIONAL EXPERIENCE:

SAAMA TECHNOLOGIES: *March '2017 – till date*

DESIGNATION: Associate Program Director – Clinical Operations

ROLE: Program Manager**,** Requirements building, building end to end Big Data Solutions, RFP , business strategist.

JOB RESPONSIBILITIES:

- Member of the LSCOE (Life Science – Center of Excellence).
- Client Presentations & Demos.
- Design and Development of **Operations and Patient Data Repository for Big Data platform (FAE – Fluid Analytics Engine,** Saama's Modern Analytics Platform**).**
- Pharmacovigilance SME to enable with development of PVG /signal detection using ML/AI, data/text mining methodologies (~~ege.g.~~ NLP).
- Proposals and RFP responses
- Business solutions (e.g.: Clinical Financial Forecasting, Clinical Data Review using ML/AI, Clinical Trial Optimization etc.).
- Strategic Partnerships within the pharma/CRO industry.
- Developed Computer system validation capability/templates for the company.

PROJECTS:

- **AMGEN (Campbell, USA):** ***Visited Saama Campbell office for customer demo.*** Implement a SaaS, cloud based, 21 CFR Part 11 compliant data platform that supports the near real-time acquisition of patient and operational, clinical trial data from various source systems that will be used for exploratory analysis.

- **BMS, Celgene, Kiowa Kiri ~~etc~~etc. (East Coas~~te~~, USA) :** ***Visited Saama Bridgewater office for customer demos*** **of Patient Data Analytics .**

- **Trial Management Analytics:**

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Was it only One visit to USA, while in Saama ?

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Design and Development of **Operations and Patient Data Repository for big data platform (FAE – Fluid Analytics Engine).**

- Operations & Patient KPIs
- Patient Data Flow across the end to end pipeline (through ODM , biostats adapters)
- Meta data Driven design.

- **Clinical Financial Spend Forecasting**
  Reduce the overall Clinical Trials budgetary variance from the current 11-17% to 5-7% across the entire portfolio of studies through predictive modeling.

PERSISTENT SYSTEMS LTD: ***October' 2013 – Dec' 2017***

DESIGNATION:

- **Senior Industry Expert – Life Science and Healthcare**
- **Associate Principal Analyst**

ROLE: SME, Anchoring Pharmaceuticals, Clinical Research and Regulatory.

JOB RESPONSIBILITIES:

- SME for Clinical Research, Pharma and regulatory.
- Developed Computer system validation capability for the company.
- Drive all sales presentations & demos for Clinical Research, Pharma and Regulatory compliances opportunities.
- Developed offerings for Clinical data Management, Risk Based Monitoring and electronic patient reported outcomes.
- Interact and visit client sites to do gap analysis and provide solutions and seek business opportunities.
- Understand the existing clinical solutions and strategize to grow the existing accounts.

PROJECTS:

IQVIA (Quintiles IMS): SME, Business representative for clinical research (Clinical Trial Optimization Solutions) & Offering new solutions based on industry requirements.

Dana Farber Cancer Institute (Boston, USA): *Visited DFCI for about two months.*
The objective of this visit was to meet with the Dana-Farber Enterprise Informatics team and the clinical trials team to discuss and understand their business requirements and expectations towards the CRF eco-system and workflows within various groups at Dana Farber. There were recommendations based on this visit on what all can Persistent assist with based on the workflow to be developed by Persistent.

Thermo Fisher Scientific (San Francisco, USA)
Business Analyst for software to be developed for a bioassay on nuclear radiation.

Pharmica Consulting: Business development in CTMS and Pharmacovigilance systems.

John Hopkins University: Gap Analysis of existing systems and offering state of art solutions e.g.: Collaborative Clinical Trial Portal, CDM through tablet-Health Education etc.

ASPEN Pharma & Dr.Reddy's Lab: Computer System Validation Consultancy.

PPCE (Phoenix Progressive Certifications Enterprise): August' 2011 – October' 2013

DESIGNATION: Head Biometrics
JOB RESPONSIBILITIES:

- Setup Clinical Data Management & Biostatistics functions for the company.(Using Oracle Clinical & EDC software Clinfoware) through:
  - Procurement of clinical systems.
  - SOP development.
  - Build strategic partnerships.
  - Build teams.
- Business development
- Designing strategies to build and grow the organization as a Clinical Research Allied Services Provider globally.
- Develop Systems and Processes, Documentation, Templates for the organization.

LUPIN LIMITED (RESEARCH PARK): February' 2010 – Jan2011

DESIGNATION: Head Biometrics & Consultant
JOB RESPONSIBILITIES:
Independently organize and manage all Biometrics activities on clinical projects, provide work direction to Project team members as appropriate viz Data managers, Biostatistician, Data Entry Operators, CDCs etc.

~~Responsible for managing (responsibilities included but not limited to):~~

- ~~Clinical Data Management & Related Activities.~~
- ~~SAS Activities as related to Clinical Data Management (CDM).~~
- ~~Software Systems as related to CDM.~~
- ~~System and process development and training.~~
- ~~General Managerial Activities.~~

CLINIRX RESEARCH PRIVATE LTD. - September' 2007 – July' 2008

JOB RESPONSIBILITIES:

- **Manager for all EDC endeavors at CliniRx**
- **Data Management –** Have a sound understanding of the OC as a CDM application.
  - Expertise includes writing DMPs, CRF annotation, database design, database testing and validation, definition and validation of edit checks, and electronic and manual edit check review.
  - TMS Coding: Medical dictionary coding (WHODRUG & MedDRA)
- **OLS Validation:**
  - Project Manager for Oracle Clinical validation project.
  - Responsible for complete OC, TMS, AERS and RDC Validation Project (with Oracle Implementation Partner – DBMS Consulting).

NAGARRO SOFTWARE PVT. LTD, Gurgaon: (May' 2004 – March' 2006)

Senior Software Engineer
Project: CTDG (Common Technical Document Generator)
End Client: Bristol Myers Squibb Company (BMS- A Global Pharmaceutical Co).

VGL SOFTECH LTD and COMPUCOM Software Ltd, Jaipur SSE & SE

Over 5+ years of experience of working in software development in Java related technologies with oracle as back end.

Guest Faculty: At Pune University & other Clinical Research institutes.
About 2 years of experience as a faculty at Aptech and BIIT.

Seminars Presented:

- Speaker at various National and International conferences related to Clinical Research (**ISCR, Stata, World Pharma Trials etc.)**.
- Presented seminars on E-Commerce to a team of IAS officers in Jaipur.

Extra- Curricular Activities:

- Worked as a comparer and **News Reader with All India Radio – Jaipur**
- Dance, Music & Painting.
- X-tempo speeches and debates.

Jaya Kumawat