

CONTACT

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Ahmedabad, Gujarat, India

KEY ACHIEVEMENT

- Green Belt Certification from TCS
Project: Automation of Clean Patient Tracker
- 3 times 'Opel' award for the best performer in Cognizant
- 2 times 'Best team' award in Lambda Therapeutic Research Ltd

SKILLS

Project Management, People Management, Negotiation skills, Decision Making, Ability to Work under Pressure, Adaptability, Self-motivation, Teamwork, Coordinate multiple projects simultaneously

Domain knowledge:

Setup to Closeout, CRF Designing using MS-Word, eCRF specs, DMP creation, eCRF completion guideline, Edit check specs, External vendor data reconciliation, SAE reconciliation, Data Transfer agreement, Discrepancy management, Post Production change management, UAT, RCA CAPA, QC

Tools:

ClinTrial 4.5, OC/OC-RDC 4.5.3, DataFax, InForm 4.5, RAVE 5.6.4, IReview/JReview, Toad, Eclipse, Oracle Discoverer, iDART

Therapeutic Area: Immunology, Cardiovascular, Neuroscience, Oncology

Kalpesh Patel

Clinical Data Manager

PERSONAL STATEMENT

I am having a strong Clinical Data Management experience of 10+ years. I have worked with top CROs in industry. I have worked extensively in all the phases of Clinical trial with a wide range of therapeutic areas. I am an expert in EDC technology and worked with all the top used tools in Industry.

WORK EXPERIENCE

Assistant Manager

Aug-2016 - date

(Role: Lead Data Manager/Team Lead)

Tata Consultancy Services Pvt Ltd, Mumbai, India

- People Management (Team Leader): managing team of 8-10 members, responsible for recruitment, onboarding, access management, mentoring, feedback, appraisal, retention
- Project Management (Lead Data Manager): Responsible to manage multiple projects as a Lead
 - Define resource requirements and work with supervisor to prioritize resource assignments across projects
 - Plan, communicate, drive and track CDM study activities to meet client timelines, milestones
 - Participate in the implementation of new processes and technology.
 - QC of task before its delivery to client to ensure the expected quality

Clinical Data Analyst III

Dec-2011 - Aug-2018

PAREXEL International, Hyderabad, India

- Responsible to manage study as a SPOC
- Responsible for eCRF specs, Edit check, UAT, Discrepancy management, Reconciliation,
- eCRF completion Guidelines, Data review guidelines as per the company/sponsor requirements and standards.
- Working on change requests as per changes in guidelines or protocol amendments.
- Identifying the Data trends during the Data review and providing relevant feedback for training needs of sites to clients.
- Effectively communicating with all the stakeholders of projects including internal and external clients, vendors.

Data Analyst

May-2010 - Dec-2011

Cognizant Technology Solution, Mumbai, India

- Ensure that the DMP documents are prepared and updated as per requirement.
- Track metrics specified in the data management plan (DMP).
- Perform data management activities as defined on the assigned project in a timely and efficient manner.
- Provide ad-hoc data listings to the study team as per requirement.
- Provide inputs, if any, proactively to improve the process and or quality.
- Perform database audit as a part of Quality Control.
- Perform Device data reconciliation

OTHER COURSES AND TRAINING

- Trained on CDISC Implementation in CDM by Phase-Forward, Germany (Jan 2008)
- Attended first annual conference of ISCR, Mumbai (Jan 2008)
- Attended training workshop on Advanced Good Clinical Practice conducted by Lambda Therapeutic Research Limited, Ahmedabad Lambda Therapeutic Research Ltd

WORK EXPERIENCE (continued)

Sr. Data Coordinator

Jun-2007 – May-2010

Lambda Therapeutic Research Lrd

- Database designing using Clintrial 4.5, Database testing.
- Designing and review of study specific CRF's.
- Preparation/Review of Data Management Plan.
- Acquisition and management of external data like Lab Data and ECG data
- Validation and review of clinical data using 'ClinTrial' Data Management System.
- Graphical report generation using I-Review.
- Data retrieval for statistical analysis.
- Handling of CRF's at Data Management Center.

Sr. Executive

Sep-2006 – May-2007

Mphasis India Pvt Ltd

- As a Customer Care Executive, handling of calls of Customer. Listen the query carefully and answer the same.
- Resolve the query of customer according to their Request/Complaint. Maintain the standard quality record as per client need.

EDUCATION

B.Sc (Biochemistry) Gujarat University	<i>2003-2006</i>
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HOBBIES & INTERESTS

- Walking
- Cycling
- Yoga
- Cricket

Personal Details

- Date of Birth: 15/04/1986
- Marital Status: Married
- Nationality: Indian

Declaration:

I hereby declare the above details are true and correct to the best of my knowledge. It would be pleasure to work with your firm.

Date:

(Kalpesh Patel)