KHUSHBU PATEL

27, Ankit Society, Near Gyanda Girls High school, Ghatlodiya, Ahmedabad,
Gujarat (380061) India
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SUMMARY:

A certified professional offering a year of experience in clinical research coordination. Demonstrated ability to support the management and coordinate the tasks of multiple clinical research studies. Expert in liaising among stake holders. Special talent for creating and maintaining databases and reports.

EXPERIENCE:

- **Executive Clinical Research Co-Ordinator**
  Kaizen Hospital From: - Jun 2017 to till Date

- **Executive Clinical Research Co-Ordinator**
  CIMS Research Private Ltd. From: - Jun 2016 to Jun 2017

- **Quality Assurance Officer**
  ACULIFE Healthcare Pvt. Ltd. From: - Dec 2015 to Jun 2016.

JOB RESPONSIBILITY:

Kaizen Hospital, Ahmedabad
Executive Research Coordinator

- Attending Investigational Meeting
- Helping PI negotiate the study budget direct costs with sponsor to cover all costs
- Maintaining communication and correspondence with subject, Sponsor, Monitor, and other site study personnel
- And other mentioned below.

CIMS Research Private Ltd., Ahmedabad
Executive Research Coordinator

- The role involves using an in-depth knowledge of trial protocols and their application in practice, alongside a working knowledge and compliance with the local, national and international research regulations.
- To assist in filling & filing of Pre-trial essential documents such as Confidentiality Disclosure agreements. Feasibility Questionnaires, Critical Information sheets, Site specific information. Updated C.V.'s of proposed study team members & any such information as required by the document specialist of the sponsor company in a timely manner.
- Correspondence with the Ethics Committee for submission and approval of essential trial specific documents.
- To participate in Pre-trial assessment visits, Site initiation visits, Close-out visits & routine monitoring visits as per their delegated duties.
- To identify patients eligible to enter clinical trials by Pre-screening / Screening the patient as per inclusion / exclusion criteria.
- To facilitate the informed consent process in accordance with GCP.
- To ensure that clinical trial recruitment records are accurately maintained.

- To ensure that trial specific investigations are undertaken as required by the research protocol in order to establish eligibility and safety to enter the trial.
- To register/randomize patients into trials through IVRS & IWR5 processes.
- To maintain tracker of trial specific milestones & facilitate the collection and documentation of accurate data. Through internal monitoring maintain accurate source documentation of patient events in nursing and medical notes.
- To ensure the safe administration of treatments and drugs that are given within the context of a clinical trial & perform Study Drug Accountability.
- Co-ordinate with PI & facilitate protocol specific investigational procedures as required for the study patients.
- Record and report adverse events which occur while patient is in the clinical trial to the relevant personnel and act as required.
- Report and record serious adverse events that occur whilst the patient is being treated on a clinical trial to the PI and relevant sponsor personnel & Ethics Committee within time frames.
- Accurately document data collected into the case report forms (CRF) & eCRF's.
- Attend meetings relevant to the nature of the job such as Investigators Meet, as appropriate and as agreed upon & also complete online webex training as & when required.
- Corresponds with respective CRA's, Auditors & Inspectors during various monitoring visits, audits & regulatory inspections.

ACULIFE Healthcare Pvt. Ltd., Ahmedabad
Quality Assurance Officer

- Analysed manufacturing processes and evaluated individual products for quality.
- Reviewed client contracts and production agreements to confirm all signatures.
- Ensured compliance with all established quality control protocols.
- Identified any defective parts and products.
- Prepared quality assurance reports.

HANDLING OF CLINICAL TRIAL:

Trial Name	Indication	Sponsor/CRO	Phase
Ticagrelor with Aspirin or alone in high risk patient after coronary intervention	Cardiovascular Disease	AstraZeneca	Phase IV
Study to evaluate the effect of dapagliflozin on the incidence of worsening heart failure or cardiovascular death in patient with chronic heart failure with reduced ejection fraction	Chronic Heart Failure	AstraZeneca	Phase III
A multicentre, Randomised, 12 week treatment, Double blind study to assess the efficacy and safety of QMF149(150/80 microgram) compared with MF twisthaler(200 microgram) in adult and adolescent patients with asthma	Mild Asthma	Novartis	Phase III
Comparative Study of Rabeprazole single release 40 mg tablet with Rabeprazole duel release 80 mg capsule	gastroesophageal reflux disease	cliantha	BA/BE
Rabeprazole single period study for acid reflux	gastroesophageal reflux disease	cliantha	BA/BE
pentoprazole dual-release gastro resistant tablets 80 mg	gastroesophageal reflux disease	Sunpharma	Phase III
Sinus node dysfunction registry 1	Atrial Fibrillation	Janssen Scientific Affairs, LLC	Registry Trial

Identifying high risk patient post myocardial infarction with reduced left ventricular function using external loop recorder	Heart Failure	Medtronic	Registry Trial
A prospective, single arm, Multicentre, Observational, Real world, Post marketing surveillance to evaluate safety and performance of the Biomine Morph sirolimus-eluting coronary stent system for very long coronary lesions.	Coronary Artery Disease	AstraZeneca	Registry Trial
International registry to assess medical practice with longitudinal Observation for treatment of heart failure	Acute Heart Failure	Novartis	Registry Trial

AREAS OF EXPERTISE:

- Project Planning
- Clinical Data Collection
- Data Capture Enhancement
- Maintain Case Report
- IRB Communication
- GCP and other Regulatory Guidelines
- Study Feasibility Assessment
- IVRS & IWRS process
- Clinical Study Monitoring
- Reporting & Documentation
- Interpersonal & Communication Skill

ACADEMIC CREDENTIALS:

- Certificate course in **Clinical Research**, from **Imperial Institute of Clinical Research**, Ahmedabad.
- Qualified **Bachelor of Pharmacy** from Gujarat Technology University with 8.54 CGPA in **May 2015.**
- Cleared **HSC** from Gujarat state board with 82.90 % in **2011.**

ACHIEVEMENTS:

- Spot Appreciation Award (2 Times) at CIMS Hospital
- 1st Rank in Oratory Competition held by "Bruhad Gujarat Sanskrit Parishad".
- 2nd Rank in Debate Competition held by Lions Clubs International.

COMPUTER PROFICIENCY:

Windows, MS Office, Internet, SAP.

PERSONAL DETAILS:

Date of Birth:	03 August 1993
Gender:	Female
Language:	English, Hindi, Gujarati
Husband Name:	Dhruval Vinodbhai Patel
Permanent address:	27, Ankit Society, Near Gyanda Girls High school, Ghatlodiya, Ahmedabad, Gujarat (380061) India
Nationality:	Indian
Marital Status:	Married

Declaration:

I hereby declare that all the information provided is correct and to the best of my knowledge and belief.

Date: **Khushbu Patel**