**` Tahseen**

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**Career Summary**

Clinical research professionalwith more than 4 years of proven skill-sets in driving various projects for Quest Diagnostics (6 Months), Bharti Research Institute of Diabetes and Endocrinology (1 year) and Excel Life Sciences (since November 2012).

**Currently working as senior analyst in ELI research India Pvt Ltd**

**EDUCATION**

Oct 2009-Sept 2010: **Post Graduate Certificate in Clinical Research**Cranfield University.

**GroupThesis**- Designing the Business Model for Contract Research Organization and the research on countries for expansion of business of CRO

**Client**- ICRI Global Research UK

**Individual Thesis**- Insulin Patches –Are they Effective **Client** – Cranfield Health

* **Skill gained during my Degree**
* Deep knowledge of clinical trial process.
* Detailed knowledge of GCP and ICH guidelines including basic understanding regulatory requirements.

2004-2007 MJP Rohilkhand University U.P India

**Bachelor of Science- Life Sciences**

**EMPLOYMENT HISTORY**

**Employer** : **ELI Research India Pvt Ltd**

**Job Title** : **Senior Analyst**

**Period** : **2Nov 2016 – Till date**

**Responsibilities include:**

* Identify and apply appropriate codes from specific dictionaries to Case Report Form (CRF) terms that require manual coding (e.g. adverse events, medications/procedures, and medical conditions/history).
* Accurately and consistently apply coding conventions to Case Report Form terms in accordance with all applicable procedures.
* Review all coded terms within the clinical database for accuracy and consistency and appropriately address coding discrepancies or inconsistencies.
* Accurately generate data queries where applicable to resolve coding discrepancies.
* Maintain coding documentation within project files as appropriate.
* Assist with the development, review and update of Data Management Coding Study Specific Procedures when applicable.
* Generate and review status reports and metrics as appropriate.
* Perform other duties reasonably related to the position as directed by manager/designee
* Analyse patient charts carefully to know the diagnosis and represent every item with specific codes
* Collect health information as documented by medical specialists and code them appropriately
* Consult medical specialists for further clarification and understanding of items on patient charts to avoid any misinterpretations
* Ensure that codes tally with doctors’ diagnosis
* Advocate for patients where their medical history is needed as evidence
* Evaluate and re-file appeals of patient claims that were denied
* Be updated about new coding rules as codes change from time to time
* Develop good client relationship in the course of duty
* Collect and distribute coding related information and billing issues
* Provide accurate answers to queries on coding

**Employer** : **Excel Life Sciences India Pvt Ltd**

**Job Title** : **Clinical Research Coordinator**

**Appointed at**: **All India Institute Of Medical Sciences (AIIMS) New Delhi**

**Period** : **15Nov 2012 – 15 Oct 2016**

* **Two year experience of site supervisory visit**.
* Experienced in following clinical research project work.
  + **Global Study**
    - Ophthalmology - Uveitis (Three)
    - Ophthalmology - Conjunctivitis (One)
    - Ophthalmology – Corneal Edema (One)
    - Breast Cancer – startup activities (One)
    - Ophthalmology – Cystoid Macular Edema - startup activities (One)
    - Pulmonary Fibrosis - startup activities is ongoing (One)
    - Ophthalmology – Kertokonus study (Only feasibility done)

**Responsibilities include:**

* Assist in Pre Study Selection visits
* Coordinate collection of essential documents for regulatory & EC submission
* Track study & site start-up till SIV (Site Initiation Visit)
* Creation & management of PMF (Project Master File) & site ISF (Investigator’s
* Site File) at the head office till SIV.Maintain feasibility documents at Head Office
* Review feasibility database for completion and coordinate with team for timelyupdate of data in the database
* Identify potential sites for clinical trials
* Conduct of general and/or trial feasibility by direct discussion with the investigators and study teams.
* Execute recruitment strategies for the designated sites
* Mapping & Meeting with referral physician/centers in designated cities
* Maintaining database for all activities, this includes pre-screening database
* Updating medical histories in the database with pertinent data gathered at the site (where ever available)
* Performing on-site visit to engage Investigators, referral physician & potential studyparticipants
* Participate in recruitment outreach programs, LnL/CME/ Conferences etc.,
* Provide regular updates on the referral and recruitment activity to LM on a monthly basis
* Follow up with referred patients till they are screened/ randomizedOther activities as required & in pursuit of patient recruitment and referral function.

**Achievements during Project:**

* Successfully coordinate with all sites for all global study in India.
* Successfully manage AIIMS site with two projects.
* Gain experience of MA filing of NDA to DCGI.
* Experience of IRB/IEC dossier preparation and there followup with regulatory bodies.
* Successfully maintaining IHF documentation for the sponsor perspectives
* Nominated for the star the quarter award

**Employer** : **Bharti Research Institute of Diabetes and Endocrinology**

**Job Title** : **Clinical Research Coordinator** (CRC)

**Period** : October 2011- to- Nov-2012

**Responsibilities include:**

* On-Site Coordination of the overall conduct of the study to ensure compliance with study management, protocol GCP & other requirements at all assigned sites
* Coordinating Ethics Committee submission, approval and queries
* Worked with Monitors in completing of training of team at site regarding GCP, Protocol, Safety Reporting, maintenance of essential documents & regulatory documents such as Ethics Committee submission and other regulatory requirements
* Assist in the process of administering the informed consent to potential patients and discussing in detail the patient information sheet
* Schedule subject visits as per the protocol to ensure maximal subject compliance & retention
* Follow up with site team for timely completion of the Source Documentation and ensuring that all the relevant information required in the Case Record Form are present in the source document
* Complete the Case Record Forms within the timelines and with minimal errors
* Coordinate all lab related activities – shipment of samples through the designated courier and ensure timely receipt/ review/ filing of the lab reports
* Compile and update the Trial Master File
* Maintain study related logs – screening, enrolment, drug administration, temperature and other communication logs
* Responsible for the management of study materials and supplies - distribution, ordering, tracking, storage, reconciliation and destruction

**Trainings, Conferences and Presentations**

|  |  |  |
| --- | --- | --- |
| **S.No.** | **Date** | **Event** |
| **1** | **29-Feb2012 - 02 March 2012** | **Practical Diabetology CoursefromSteno Diabetes Centre Copenhagen** |
| **2** | **22-April-2012** | **Attend workshop on “Treating diabetes in**  **Adolescents is different from treating in Adult”** |
| **3** | **6-Feb-2012** | **Training on Infectious Substances, Biological**  **Substances and Related Hazards Training"** |
| **4** | **18-Nov-2012** | **ICH-GCP Training** |
| **5** | **24-Jun-2013** | **Attend CME Conference on Intraocular Inflammations** |
| **6** | **1-Feb-2013** | **Northern India Regional Investigator’s Meeting**  **The Park, New Delhi India** |
| **7** | **6-Jul-2013** | **Clinical Research Conference**  **“Practical Solutions to Challenges in Clinical Research”** |
| **8** | **10 – 11 May 2014** | **Investigators meet**  **Hotel Vivanta by Taj Goa** |

**PRESENTATIONS: -** Epileptic drugs, Ethics in clinical research,Designing the Business Model for Contract ResearchOrganization and the research on the countries forexpansion of business of CRO

**LANGUAGES**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Read** | **Write** | **Speak** |
| **English** | √ | √ | √ |
| **Hindi** | √ | √ | √ |
| **Urdu** | √ | √ | √ |
| **Arabic** | √ | √ | **NA** |

**SKILLS**

**Communication**:

Team spirit; good ability to adapt to multicultural, good communication skills gained through my experience of writing reports and oral presentation,

Good Organizational skill.

**Computer Skill:** Operating System Windows Vista/XP, Microsoft Word, Power point, Project, and Excel, ClinTrial Inform**,** Oracle Clinical**, i**Medidata RAVE

**Hobbies:** Play Cricket, Science Fiction and Indian Cinema

**Willingness to travel** : As per business requirements

**Willing to relocate**: Yes

**References:** Can be provide immediately on request