

Bipasha Paul

Kopar Khairane • Navi Mumbai, 400710

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OBJECTIVE

Results-oriented Clinical Research Associate with a strong background in clinical research and data management, seeking a challenging role in Clinical Research or Data Management to leverage my expertise in ensuring data accuracy, maintaining regulatory compliance, and contributing to the success of clinical trials.

EDUCATION

- Advanced Post Graduate Diploma in Clinical Research and Clinical Data Management
Cliniminds Delhi | March 2022
- Score: 82% (First Division)

- MSc. Biotechnology
Dr. D.Y. Patil Biotechnology and Bioinformatics Institute, Pune, Maharashtra | 2018-2020
- CGPA/Grade: 9/A (First Division)

- BSc. Biotechnology
St. Edmund's College, Shillong, Meghalaya | 2015-2018
- Score: 65% (First Division)

CERTIFICATIONS

- Basic CRISPR Certificate Course | Biotechnika, Pune, Maharashtra | December 2020
- Python and Bio-python Certificate Course | LifeGen Bio LLP, Pune, Maharashtra | October 2020
- Information Privacy Security (IPS) | CITI PROGRAM

SKILLS

- Microsoft Office: MS Word, MS PowerPoint, MS Excel, Teams, SharePoint
- Python and Bio-python
- Database: RedCap, iMedidata (Rave), Emmes: CRID
- Oncology: Infectious Disease, Thoracic

WORK EXPERIENCE

Clinical Research Associate

Vasta Bioinformatics Pvt. Ltd., Navi Mumbai, Maharashtra | October 2022 – Present

- Data Management: Managed the data for specific clinical studies, ensuring accurate and secure record-keeping throughout the research process.
- Clinical Trial Management: Responsible for the overall management of designated clinical trials, including the preparation of trial-related documentation per protocol and Case Report Forms (CRFs).
- Documentation Review: Reviewed and maintained data management documentation, ensuring that all records were up-to-date and compliant with regulatory standards.
- Clinical Knowledge: Provided valuable clinical insights when documenting study amendments, record management systems, and identifying tracking tools, contributing to effective data management.
- Data Accuracy: Ensured the accuracy and integrity of data collected from clinical trials, making necessary updates to findings as required, and maintaining data quality in accordance with industry standards.
- Patient Registration and Data Update: Managed patient registration and maintained detailed patient records throughout the trials.
- Data Collection and Submission: Ensured the completeness and timely submission of data into various data collection systems, such as electronic CRFs, cancer research databases, and PC-based systems, in strict compliance with protocol requirements and ICH-GCP guidelines.
- Discrepancy Management: Actively worked on resolving discrepancies and queries related to data, maintaining data quality and integrity.
- Quality Assurance: Focused on improving data quality and consistency in electronic data capture systems, contributing to high-quality research outcomes.
- Communication with Sponsors: Communicated observations to the sponsor, including deviations, protocol violations, safety alerts, and quality issues that could affect the trial's quality.

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Clinical Research Co-Ordinator

Vasta Bioinformatics Pvt. Ltd., Navi Mumbai, Maharashtra | December 2021 - October 2022

- Ensured completeness and submission of data into the data collection form, complying with ICH-GCP guidelines.
- Significantly improved quality assurance and consistency in electronic data capturing.
- Collaborated with cross-functional teams to maintain data integrity and meet protocol requirements.
- Participated in global conference calls and meetings to review ongoing clinical trials.
- Verified investigator adherence to approved protocols and GCP procedures.
- Communicated deviations/violations and quality issues to the sponsor.

CLINICAL RESEARCH KNOWLEDGE

- Clinical Research & Phases (Phase I-IV)
- Good Clinical Practices (ICH GCP, Indian GCP, Schedule Y & ICMR)
- Trial Design, Protocol & CRF Design
- IND Application, Clinical Study Report, NDA Submission
- Site Selection, Initiation, and Study Close-Out

PROJECT EXPERIENCE

- Summer Trainee

North Eastern Hill University, Shillong, Meghalaya | June 2017

- Conducted advanced molecular biology techniques at the State Level Biotech Hub.

- Research Intern

St. Edmund's College, Shillong, Meghalaya | July 2017 - Feb 2018

- Investigated changes in phenotype due to SNP in *Solanum lycopersicum*.

- Research Intern

Dr. D.Y. Patil Biotechnology and Bioinformatics Institute, Pune, Maharashtra | June 2019

- Explored the O-GlcNAcylation of Twist1 in Cancer Cells.

MSc Thesis: "Role of Twist O-GlcNAcylation in Chromosomal Aberration" | December 2019 - July 2020

- Focused on Twist1's role in chromosomal aberration and metastasis, emphasizing O-GlcNAcylation.

- Intern

Prophecy Market Insights, Pune, Maharashtra | November 2020 - January 2021

- Worked as a Market Research Intern.

- Research Intern

GRG Health, Pune, Maharashtra | February 2021 - May 2021

- Served as a Market Research Intern.

LEADERSHIP & ACTIVITIES

- St. Edmund's College, Shillong, Meghalaya

- Student Representative: Organized departmental programs and activities.
- Attendee: Participated in a guest lecture on Herpetofauna of India.
- Participant: Attended a seminar on "Minor Research in Biological Science."

- North Eastern Hill University, Shillong, Meghalaya

- Participant: Engaged in a Science Communication Workshop.

- Dr. D.Y. Patil Biotechnology and Bioinformatics Institute, Pune, Maharashtra

- National Science Day: Presented a poster.
- COVID-19 Quiz: Participated in a quiz competition.