



LAXMI R. MEDA


B Pharmacy, RTMNU, Nagpur, PG Diploma FSQM IGNOU Nagpur.

About Me

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 28 August 1996

 Nagpur, Maharashtra

SUMMARY

Certified Clinical Research Coordinator with over 5 years of hands-on experience in the medical and clinical research industry. Proven expertise in therapeutic areas including cardiovascular, pulmonology, and urology. Adept at handling diverse study systems such as ICON, iSite, Medidata, Calyx, and Covance. Demonstrates strong capabilities in site leadership, training, and management. Effective in collaborating with multiple CROs and sponsors globally and overseeing site initiation, team staffing, financial operations, and vendor and sponsor communication. Attendee and participant in various national and international clinical research conferences.

Education

PG Diploma of FSQM

IGNOU LIT, Nagpur.
Maharashtra

PG, June 2020

Bachelor of Pharmacy

Agnihotri College of Pharmacy, Wardha.
Nagpur, University,
Maharashtra

Graduated, June 2019
CGPA - 7.84
Division First Class

Higher Secondary School Leaving Certificate

Sushil Himmatsighka high School, Wardha.
Nagpur Board
Maharashtra

Passed, March 2015
Marks-52.46%

Secondary School Leaving Certificate

ZP, Majri, Chandrapur
Nagpur Board,
Maharashtra

Passed, March 2013
Marks 75.82%

Professional Qualifications and Affiliations

- Online Nida GCP 2021
- ICH/GCP Certificate 2021 (AIIMS,Nagpur)
- ICH/GCP Certificate 2023 (GMC Nagpur) and ICH GCP E6 R3 Certificate 2025 (Nagpur)

Study Co-ordinator, Clinical Research :

At Government Medical College and Super Speciality Hospital, Nagpur
Dec 2020.

At NKPSIMS Lata Mangeshkar Hospital, Hingna, Nagpur- Apr 2025 to Nov 2025.

- Site lead for training and supervising site team
- Hands-on experience with study systems including : (iMedidata, calyx, CLIN phone, icon, I site ICON , lifespere, oracle , AG Mednet Judi ,perceptive ,Medable, HOT TSS temperature handling data, Cenduit IWRS \ IRT system , Xcellerates , Kayentis clinform , etc)
- Managing sponsor and CRO communication
- Handling patient recruitment, informed consent (including AV consent), and EDC platforms
- Attended multiple investigator and monitoring meetings
- Successfully cleared Quality Assurance and Sponsor audits
- SAE Reporting and SUGAM portal handling
- Participated in national and international clinical trials across various therapeutic areas:
Cardiovascular, Pulmonary, oncology, Urology, Gastroenterology , etc.

Experience:

Joining December 2020

Previous and Present participation in clinical trials:

Indication of Trial	Clinical Phase of Trial (I-IV)	Role in Trial	Year
Cardiovascular (Heart Failure)	Phase II	Study Coordinator	2020
Cardiovascular: Observational study	Phase III	Study Coordinator	2021
Multiple indication: rare disease	Biospecimen collection	Study Coordinator	2021
Pulmonologist : Covid study (Nasal Spray)	Phase IV	Study Coordinator	2021
Cardiovascular: Increase Lipoprotein with CAD	Phase II	Study Coordinator	2021
Urology <i>Benign prostatic hyperplasia (BPH)</i>	Phase IV	Study Coordinator	2021
Urology Prostate Cancer <i>Benign prostatic hyperplasia (BPH)</i>	Phase III	Study Coordinator	2021

Cardiovascular ,PAD	Phase III	Study Coordinator	2022
Cardiovascular disease and Chronic kidney disease.	Phase III	Study Coordinator	2022
Cardiovascular: STEMI and NON STEMI	Phase IV	Study Coordinator	2022
Cardiovascular: Acute Coronary Syndrome	Phase IV	Study Coordinator	2023
Cardiovascular: Recent Myocardial Infraction	Phase IV	Study Coordinator	2023
Cardiovascular: Hypertension	Phase III	Study Coordinator	2023
Oncology	Phase IV	Study Coordinator	2023
Gastroenterology :Ulcer colitis	Phase IV	Study Coordinator	2024
Cardiovascular: Myocardial infraction with BMI	Phase III	Study Coordinator	2025

Skills

- Ability to work independently, good communication skills, has experience in working on complex and medium to large projects
- Database management
- Site Start-Up & Staff Training
- Project Management & Vendor Coordination
- Knowledge of Food and Drug Administration (FDA) regulations.
- Knowledge of NDCT Rule 2019
- Knowledge of ICH/GCP Guidelines
- Problem solving, Time management and Alcoa Principles.
- SAE Reporting/SUGAM PORTAL Handling
- Face to Face Sponsor Audit done
- Compassion/Confident
- Financial Oversight and Business Development
- Good communication & interpersonal skills with strong analytical , team building, problem solving and organizational abilities and Computer handling

Roles & Responsibilities:

- Accompanied the clinical research manager while interacting with patients directly
- Patient Recruitments.
- Informed consent process, Audio video Consent.
- Different types of electronic data capture systems handles.
- Training with different Connect portals.
- Reviewed clinical data and assisted the clinical research manager in providing reports and presentations.
- ALCOA Principles and Time Management
- Strong Communication and Leadership Skills
- Investigators meetings attend.
- Successfully phased Quality assurance audit.

- Successfully phased Sponsors audit.

CONFERENCES & EVENTS ATTENDED

- Multiple national and international conferences related to clinical research and pharmaceutical development
- Represented institution in sponsor meetings, regulatory forums, and industry workshops



Personal Details

Father's Name : Mr. Rajan Meda
Birthday : 28 August 1996
Gender : Female

Marital Status : Married
Nationality : Indian

Declaration

I, **LAXMI RAJAN MEDA**, hereby declare that the information contained herein is true and correct to the best of my knowledge and belief.

Place : Nagpur

Laxmi Rajam Meda