Contact

chitranjan.r@yahoo.com

www.linkedin.com/in/chitranjan-r-a-clinipreneur-03647b77 (LinkedIn)

Top Skills

Software Product Management
Python (Programming Language)
Data Analytics

Languages

English (Full Professional)
Bhojpuri (Native or Bilingual)
Kannada
Hindi (Native or Bilingual)

Certifications

Project Management Foundations: Procurement
Scrum: The Basics
Introduction of Clinical Research
Enhancing Resilience
Learning Excel 2019

Honors-Awards

First Prize (University Level Hindi Essay Writing)
Second Prize (Inter-Class Firelss Cooking)
Second Prize (Inter Class Quiz Competition)
Great Leadership Award (Appreciation Award)
Participated in Junior Sprinter-Cyclothon

Chitranjan R, A CLINIPRENEUR

IIT Patna MBA (GenAI & Data Analytics||Rare Star Award Winner 2025 India (Volunteer)||Clinical & Safety Tech Solution Strategist|| API Learner||CSV Expert||Mentor & People Leader||Quality-Focused||Founder–Dil Ki Suno|
New Delhi, Delhi, India

Summary

About Me
As a Clinical Systems & Technology Expert with 10+ years of cross-functional experience, I specialize in bridging the gap between life sciences operations and digital platforms. With a foundation in Biotechnology and a proven track record across CROs, pharma, and MedTech, I bring a deep understanding of clinical research combined with strong product, validation, and system implementation expertise.

Techno-Functional Strategist – Aligning clinical workflows with scalable digital solutions
CSV Specialist – Delivering audit-ready systems that meet stringent regulatory expectations
Mentor & Capability Builder – Training teams and mentoring 1000+ students across India since 2015
Social Contributor – Awarded Rare Star Award – 2025 for rare disease community leadership

My Domain Expertise
Product Management & Platform Ownership: Hands-on experience in implementing and managing enterprise-level clinical platforms including Veeva Vault (eTMF, CTMS, RIM), ArisG (LifeSphere Safety), Legacy CTMS, and eSource Platforms (ClinSpark).
Computer System Validation (CSV): Extensive knowledge of GxP, 21 CFR Part 11, Annex 11, with validation lifecycle leadership (IQ/OQ/PQ), defect management, traceability, and compliance documentation.
Customer-Facing SME: I serve as a subject matter expert for connected medical device platforms, conducting platform

onboarding, client training bootcamps, SSO support, access provisioning, configuration of devices, study templates, and triage of escalations via JIRA & Service Desk tools.
Clinical Trial Efficiency: Skilled in trial process optimization, stakeholder collaboration, and improving eTMF health through compliant document management and audit-readiness.

Value I Deliver
I bring a solution-driven mindset backed by regulatory know-how and technology implementation experience to ensure that clinical systems not only comply but perform, scale, and enable smarter trials. My approach focuses on aligning business goals with platform capabilities to enhance operational agility, data integrity, and trial success.

Beyond Work
An active mentor since 2015, I've supported 1000+ students across India to become industry-ready through resume optimization, LinkedIn training, and career mentorship. I've also led rare disease awareness programs, winning the Rare Star Award (2025) for my contributions.

Let's connect to collaborate on transforming clinical operations through intelligent systems and purposeful innovation.

Email me to connect: chitranjan.healthtech@gmail.com

Thanks for checking out my profile.

Experience

IQVIA
Subject Matter Expert/Managed Services Lead (Manager): IT Design & Dev Solutions (eSource Platform)
May 2024 - Present (1 year 8 months)
New Delhi

Clinical IT Systems – Subject Matter Expert (SME)

As Clinical IT SME, oversee ops support, API integrations, and config in ClinSpark eSource for early-phase trials—bridging clinical/tech, optimizing workflows, compliance, usability, and user experience in global studies.

Key Responsibilities:

- Act as Subject Matter Expert for ClinSpark and medical device integrations, advising stakeholders on implementation best practices, system capabilities, and strategic platform improvements.
- I lead customer platform releases while managing pre-upgrade, live, and post-upgrade support to ensure smooth and error-free deployment.
- Manage Jira Service Desk operations—triaging development tickets, diagnosing and resolving technical issues, and ensuring proper escalation management to maintain system stability.
- Provide support/Lead document improvement initiatives to ensure alignment with ClinSpark's system capabilities, with a dedicated emphasis on optimizing documentation for report modules and related workflows.
- Support efforts to enhance clarity, accuracy, and compliance in all user-facing materials, enabling effective use of ClinSpark's reporting features across clinical operations.
- Administer platform configuration including user provisioning, SSO management, and study workflow setup within the Super Admin environment.
- Serve as API SME—conduct API testing, root cause analysis, and impact assessment while enhancing ClinSpark's reportAPI, recruitAPI, and related interfaces. Provide client support and training to ensure effective API utilization and customer satisfaction.
- Collaborate with cross-functional teams to ensure smooth upgrade activities completion.
- Develop and deliver training and enable materials—SOPs, video walkthroughs, user guides, and role-specific onboarding for geographically distributed study teams.
.- Acts as a use access manager for Indian and European regions where I provide ClinSpark system access based on roles and rights.

ArisGlobal

2 years 7 months

Subject Matter Expert/Solution Lead- Cloud Platform Tech-Safety Systems: LSMV and ArisG

July 2022 - May 2024 (1 year 11 months)

Bengaluru

- Manage platform upgrades and releases, including hotfixes, minor/major releases, & hyper care support, ensuring smooth deployment and stability.

-Lead Operational Qualification (OQ) activities by writing, executing, & documenting test scripts and validation steps in compliance with regulatory standards.
- Configure key modules such as document types, binder structures, envelopes, workflows, milestones, mail inbox, attributes, access control, roles & security, reports, templates, & serverless components.
- Serve as Technical Reviewer (Validation) for Installation Qualifications (IQs), providing QC-compliant review comments and ensuring timely closure of findings.
- Author & review Change Requests (RFCs) and manage validation documentation as needed.
- Handle performance diagnostics using AWS & Jenkins—collecting heap/ thread dumps to resolve issues like high utilization or application slowness.
- Collaborate with Infrastructure, DevOps, Engineering, Product, and Global Support teams to resolve platform, access, & configuration issues.
- Draft & review User Requirement Specifications (URS) & Functional Specification Requirements (FSR).
- Develop & execute test plans, test scripts, and test reports for sandbox, system, & UAT testing environments.
- Manage user access for 20+ clients across sandbox, validation, & production systems, ensuring correct provisioning & security compliance.
- Report product-related issues to the Professional Services team & ensure prompt resolution with minimal downtime.
- Write & review validation change controls, IQ/OQ protocols, and clinical SOPs to maintain compliance with GxP standards.
- Prepare and maintain the Master Validation Plan (MVP) to support inspection readiness & system lifecycle management.
- Perform application restarts when performance degradation is reported & ensure minimal impact to ongoing activities.
- Ensure all system configurations are completed according to client specifications and business needs.

Subject Matter Expert- Clinical Product Implementation (CTMS and eTMF)

November 2021 - July 2022 (9 months)

Bengaluru

As a Solution Lead at ArisGlobal, I led the end-to-end implementation of the LifeSphere Clinical Suite (CTMS, eTMF, SDD, TD), aligning product delivery with client goals in global clinical operations. My role focused on delivering scalable, compliant solutions through strategic collaboration with stakeholders and cross-functional teams.

Key Responsibilities & Achievements:

- Product Implementation & Client Engagement:
Managed full-cycle implementation of LifeSphere platforms, translating client requirements into tailored configurations for seamless go-lives.
- SME & Stakeholder Collaboration:
Acted as a clinical domain SME, addressing functional and technical queries, and advising both clients and internal teams throughout implementation.
- Workflow Analysis & Optimization:
Assessed client workflows to identify process gaps, proposing enhancements that improved clinical oversight and operational efficiency.
- Training & Enablement:
Created and delivered comprehensive training for sponsors, CROs, and site users to ensure effective product adoption and end-user confidence.
- Compliance & Quality Assurance:
Supported validation activities (IQ/OQ), working with QA and compliance teams to ensure platform alignment with 21 CFR Part 11, Annex 11, and GxP requirements.
- Documentation & Best Practices:
Authored SOPs, user manuals, and implementation templates to support consistency, scalability, and knowledge transfer across projects.
- Continuous Improvement:
Drove innovation by identifying and addressing product/process gaps, contributing to the evolution of delivery methodologies and long-term client success.
Impact:
By integrating domain knowledge, product expertise, and a client-centric mindset, I delivered impactful solutions that enhanced platform performance, improved regulatory readiness, and empowered clinical teams globally.

Abbott

Operational Excellence Specialist (Medical Office- Strategy & Operational Excellence)

January 2021 - November 2021 (11 months)
Mumbai, Maharashtra, India

My role in Abbott Healthcare:

Core Expertise & Responsibilities:

Training & Learning Development:
- Designed and delivered comprehensive training programs, enhancing team proficiency in clinical and regulatory processes.
- Led knowledge-sharing initiatives to foster continuous learning and skill development.

Quality Management & Compliance:
- Ensured adherence to Quality Management Systems (QMS), regulatory standards, and industry best practices.
- Maintained 100% compliance with GxP, CSV, and clinical trial regulations, ensuring audit readiness.

Process Improvement & Operational Excellence:
- Identified and implemented process enhancements, optimizing efficiency and reducing operational risks.
- Applied Lean & Six Sigma principles to drive continuous improvement in workflows.

Medical Communications & Triaging:
- Managed and streamlined medical communication triaging, ensuring timely response and resolution of critical queries.
- Collaborated with cross-functional teams to enhance communication efficiency in clinical and regulatory environments.

GSK
NCE eTMF Regulatory Affair Consultant
June 2020 - January 2021 (8 months)
Mumbai, Maharashtra, India

Professional Summary:
Regulatory Affairs and eTMF professional with expertise in Clinical Trial Applications (CTA), Regulatory Submissions, and Trial Master File (TMF) documentation.

Key Responsibilities & Achievements:

Regulatory Compliance & Documentation:
▪#Maintained comprehensive knowledge of CTA and TMF regulatory landscapes, ensuring 100% compliance with internal SOPs, GxP, and external guidelines (EMA/FDA).

▪#Monitored and ensured document completeness, audit readiness, and alignment with regulatory timelines.

Stakeholder Engagement & Communication:
▪#Led independent communication with global cross-functional teams including regulatory leads, country teams, and external stakeholders.
▪#Collaborated effectively to manage regulatory expectations and resolve submission-related challenges.

Clinical Trial Application (CTA) Management:
▪#Coordinated timely CTA submissions in compliance with EU Clinical Trial Directive and country-specific requirements.
▪#Managed clinical trial submissions and reviews for non-EU countries, ensuring regulatory accuracy and completeness.

Tracking, Documentation & Reporting:
▪#Maintained and updated internal regulatory tracking systems to ensure alignment with protocol-specific milestones and submission timelines.
▪#Provided consistent documentation updates to ensure audit readiness and submission traceability.

Project Execution & Ownership:
▪#Delivered multiple regulatory tasks independently while adhering to strict timelines and quality standards.
▪#Aligned deliverables with CTA Team Leads, Global Regulatory Leads, and Regional Representatives.

Process Optimization & Continuous Improvement:
▪#Identified opportunities to improve regulatory workflows and document handling processes.
▪#Actively contributed to knowledge sharing, team capability enhancement, and self-directed learning.

Tata Consultancy Services
Site Monitoring Consultant- Subject Matter Expert (Clinical Tech)
May 2018 - May 2020 (2 years 1 month)
Mumbai, Maharashtra, India

Professional Summary:
Experienced Clinical Systems Specialist with over a decade of expertise in Clinical Operations, specializing in CTMS implementation, optimization, and

migration. Proven track record as a Solutions Strategist and Subject Matter Expert (SME) in platforms like Veeva Vault CTMS, Veeva Vault eTMF, and Legacy CTMS systems. Adept at bridging business needs with platform functionality, ensuring system usability, regulatory compliance, and operational efficiency in global clinical trial environments.

Key Responsibilities & Achievements:

▪#Acted as Solutions Strategist and SME for clinical systems, providing strategic input on CTMS workflows, configurations, and process enhancements for global clinical operations.

▪#Led CTMS migration initiatives from legacy systems to Veeva Vault CTMS, ensuring accurate data mapping, configuration, validation coordination, and post-deployment support.

▪#Supported CTMS integrations with eTMF platforms and regulatory systems to ensure seamless data flow and centralized trial management.

▪#Delivered process optimization consulting, collaborating with clinical teams to streamline workflows for Start-up, Conduct, and Close-out phases.

▪#Designed and delivered training programs (Web-Based and instructor-led) for global teams on Veeva Vault CTMS/eTMF and legacy CTMS usage.

▪#Reviewed and maintained Regulatory Dossier documentation, ensuring compliance with GCP, 21 CFR Part 11, and company SOPs.

▪#Administered CTMS platforms, managing role-based access, system audits, change requests, and compliance checks.

▪#Collaborated cross-functionally with QA, IT, scientific teams, and stakeholders to define system requirements, support validation (CSV), and lead UAT efforts.

▪#Created and maintained SOPs, workflow diagrams, and process maps to support documentation, audits, and system training.

Accenture in India

Medical Services Analyst, Subject Matter Expert, eTMF/Clinical Documents Specialist

July 2017 - February 2018 (8 months)

Bengaluru Area, India

• End-to-End activities for site managements including (Full protocol package preparation, EC dossier, preparation of site related documents, different regulatory submissions, tracking on-going studies, clinical study report writing (CSR activities), query management.

• End to end eTMF management and clinical document reconciliation as per the compliance.

• Worked closely with project managers, global trials clinical team and site management leads on assigned project related activities.

• Working on trackers management and vendor management.

• Liaise with CRA to prompt collection of documents, review of data points, findings from EDC and file reviews, etc.

• Preparation of minutes of meeting.

• Responsible to ensure relevant clinical trial systems are updated in timely manner.

• Train and mentor new joiners and provide process related trainings.

• Updating frequently asked question-answers.

IQVIA

1 year 11 months

Clinical Process Associate-02, eTMF Lead-Record and Information Management

February 2017 - July 2017 (6 months)

Bengaluru, Karnataka, India

My Roles and Responsibility are as below-

• I substitute the role of global RIM (QPM)/QRPM-RM and Portfolio Management LEADS for ongoing global projects.

• Direct POC for Global CL/CPM for end to end processing and e-TMF delivery to the clients at global level.

• Hosting the Kickoff Meetings for client study setup, ELVIS training's, e-TMF management and quality delivery for Clinical leads, CTAs, CRAs, PMAs

• Closely working with Close-out activities globally with more than 75 projects and adhere the timelines of Customers to deliver the export of Trail Master Files (TMF)

• TMF Process Management and QC.

• Responsible for performing daily support activities ensuring that the Trial Master File (TMF) is compliant and inspection ready.

• Functions include TMF set-up, managing TMF file structures and archiving of Trial Master Files; eTMF query resolution, eTMF user support and training, and assisting with the oversight of the eTMF vendor; performing quality control review of study documents to ensure they adhere to SOPs and meet regulatory requirements and ICH guidelines.
• Working collaboratively across functional areas and contribute to positive team relationships, both locally and globally. The Associate, TMF Process Management and QC, will lead initiatives and will serve as a subject matter expert in TMF Process Management.
• Updating weekly trackers and adhered on 100% compliance as per the QuintilesIMS.
• Attending weekly call with study to team to manage the discrepancy and set out study agendas for next level.
• Updating Record Management tools as per requirements.
• End to end activities related to Project Matrix tool and updates as per sponsor requirement.
• Support drafting of communications for stakeholders
• Support drafting of briefing materials for senior management
• Continuously working with Central-Indexing Team, Physical Storage Team, Regulatory Team, e-TMF workflow Team, ENF Team.

Clinical Process Associate 2-TMF Lead,Clinical-Global Del Network-Record and Information Management

May 2016 - February 2017 (10 months)

Bengaluru Area, India

End to end activities on Trails Master Files or Central controllers Files.
Closely working with Close-out activities globally with more than 75 projects and adhere the timelines of Customers to deliver the export of Trail Master Files (TMF).
TMF Process Management and QC.
Responsible for performing daily support activities ensuring that the Trial Master File (TMF) is compliant and Inspection Ready.
Functions include TMF set-up, managing TMF file structures and archiving of Trial Master Files; eTMF query resolution, eTMF user support and training, and assisting with the oversight of the eTMF vendor; performing quality control review of study documents to ensure they adhere to SOPs and meet regulatory requirements and ICH guidelines.
Working collaboratively across functional areas and contribute to positive team relationships, both locally and globally. The Associate, TMF Process Management and QC, will lead initiatives and will serve as a subject matter expert in TMF Process Management.

Working actively on Record Management Plan preparation, QCs, Reviewing and finalization with the help of CPM/PL.
Constant support to study team for their queries related to Trails Master Files.
Updating weekly trackers and adhered on 100%complaince as per the QuintilesIMS.
Attending weekly call with study to team to manage the discrepancy and set out study agendas for next level.
Updating Record Management tools as per requirements.
End to end activities related to Project Matrix tool and updates as per sponsor requirement.
Support drafting of communications for stakeholders
Support drafting of briefing materials for senior management
Continuously working with Central-Indexing Team, Physical Storage Team, Regulatory Team, e-TMF workflow Team, ENF Team.

Clinical Process Associate 1, Centralized Clinical Operation, Risk Based Remote Monitoring-CRD
September 2015 - May 2016 (9 months)
Bengaluru Area, India

Centralized Clinical Operations as a Clinical Process Associate.

1. Vendor Management
2. Working on InForm and RAVE
3. IAL Cascading
4. Payment for global team.
5. Q&A updates.
6. Query Management for CRA/PL/CPM and Others projects team.
7. Data cleaning and weekly updates and sent to Leads and projects team.
8. Involved in weekly call with site personals (PL,PM,CPM,PMA,CRAs).
9. Performing on AUL and creating AUL for Sites, And sites personals.
10. Actively works on CTMS (Clinical Trials Management System) for Pulling report for manage the sites queries.
11. Working on QLAB and QNET (Vendor Management) and maintain the Trackers for the same.

Hairline International Diagnostics & Health Care Pvt Ltd
Clinical Research Coordinator (Adhoc)
July 2015 - August 2015 (2 months)
Bengaluru, Karnataka, India

Handling international Projects regarding Hair loss therapy,Hair transplantation etc.

it was observational study.

I involved in Making Protocol and Paper CRFs as per sponsors demands.
I was actively participated in the EC coordination and arrange the Ethics Committee meeting. QC and QA of Documents of clinical trials. Managed the Site Master Files (SMF) and Trials Master Files (TMF), Checklist preparation, Subjects coordination, Follow up.

ICBio Clinical Research: CRO
CLINICAL RESEARCH CO-ORDINATOR
September 2014 - February 2015 (6 months)
Bengaluru, Karnataka, India

Therapeutic areas: Hep-B and Osteoarthritis.

Roles and responsibilities:
1. Coordinates with PI, central administration and other stakeholders to ensure that clinical research and related activities are performed in accordance with federal regulations and sponsors policies and procedures.
2. Assists PI to assure that all key personnel or persons ‘engaged’ in the research project have met training requirements in accordance with federal regulations and ICH GCP.
3. Collaborates with PI & IEC to respond to any audit findings and implement approved recommendations.
4. Assists the PI in development of materials and tools necessary to appropriately train individuals involved in the conduct of the study around issues related to protocol requirements, schedule of visits, execution of research plan.
5. Maintain Site master files and Trials master files.
6. Prepares other study materials as requested by the PI. These study materials include, but are not limited to, the informed consent document, case report forms (CRFs), enrollment logs, and drug/device accountability logs.
7. Reviews and develops a familiarity with the protocol, e.g., study proceedings and timelines, inclusion and exclusion criteria, confidentiality, privacy protections.
8. Collects documents needed to initiate the study and submit to the sponsor (e.g., FDA Forms 1572, CVs, etc.).

9. Screens subjects for eligibility using protocol specific inclusion and exclusion criteria, documenting each potential participant’s eligibility or exclusion.
10. Collects data as required by the protocol. Assures timely completion of Case Report Forms
11. Retains all study records in accordance with sponsor requirements and policies and procedures.
12. Maintains effective and ongoing communication with sponsor, research participants and PI during the course of the study.
13. Communicate with EC member to conduct successful meeting and also responsible for writing meeting minutes and file the same at appropriate place.

Ramaiah College Of Arts Science and Commerce
Placement Co-Ordinator
September 2011 - May 2014 (2 years 9 months)
Bengaluru, Karnataka, India

Education

Indian Institute of Technology, Patna
Master of Business Administration - MBA, Data Analytics and Generative AI · (December 2025)

Ms Ramaiah College Of Arts Science and Commerce
B.Sc., Biotechnology, microbiology,chemistry · (2011 - 2014)

Alison
Diploma in Operations Management (Ops), Business Operations