
Clinsoft Clinical Research
Simplifying Clinical Research

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Presentation Overview

Clinsoft Overview

Clinical Trial Management

Clinical Data Management Services

Medical Writing & Pharmacovigilance Services

Overview

ClinsoftCR

- Started in 2008 with a small group of 7 team members.
- Expanded to a big team of expert professional and is transcending geographical boundaries
- Being a pioneer is what defines the company best, doing everything with utmost precision.
- Impeccable track record in confidentiality & intellectual property since inception.
- Clinsoft clinical research ranks amongst the Top Clinical management services in North India.

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Established Service Platform

Pre- Clinical & Clinical development

IND pharm-tax

Phase-1 , BA/BE studies

Clinical Trial Management (Phase 1-4)

Bioanalytical & immunogenicity

Central Lab services

Stats & Data management services

Medical writing

Regulatory , Pharmacovigilance services

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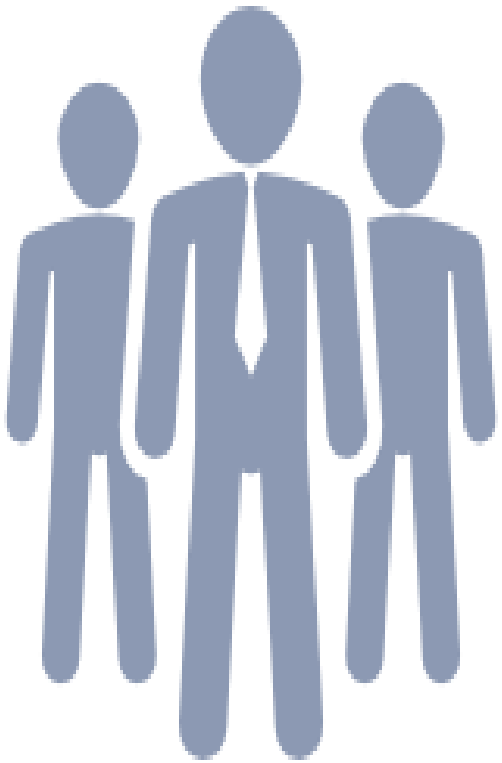
Team Experience



ClinSoft Clinical Research has highly skilled workforce of employees with 80% having advanced degrees

This team has diversified experience in various therapeutic areas and comes from a strong back ground of clinical research.

Our team consists of Project Managers, Associate PM's, Site Management Personnel, Clinical Data Managers, Associate Medical Writers, Biostatisticians, Statistical Programmers, Pharmacologist, Doctors and their associates

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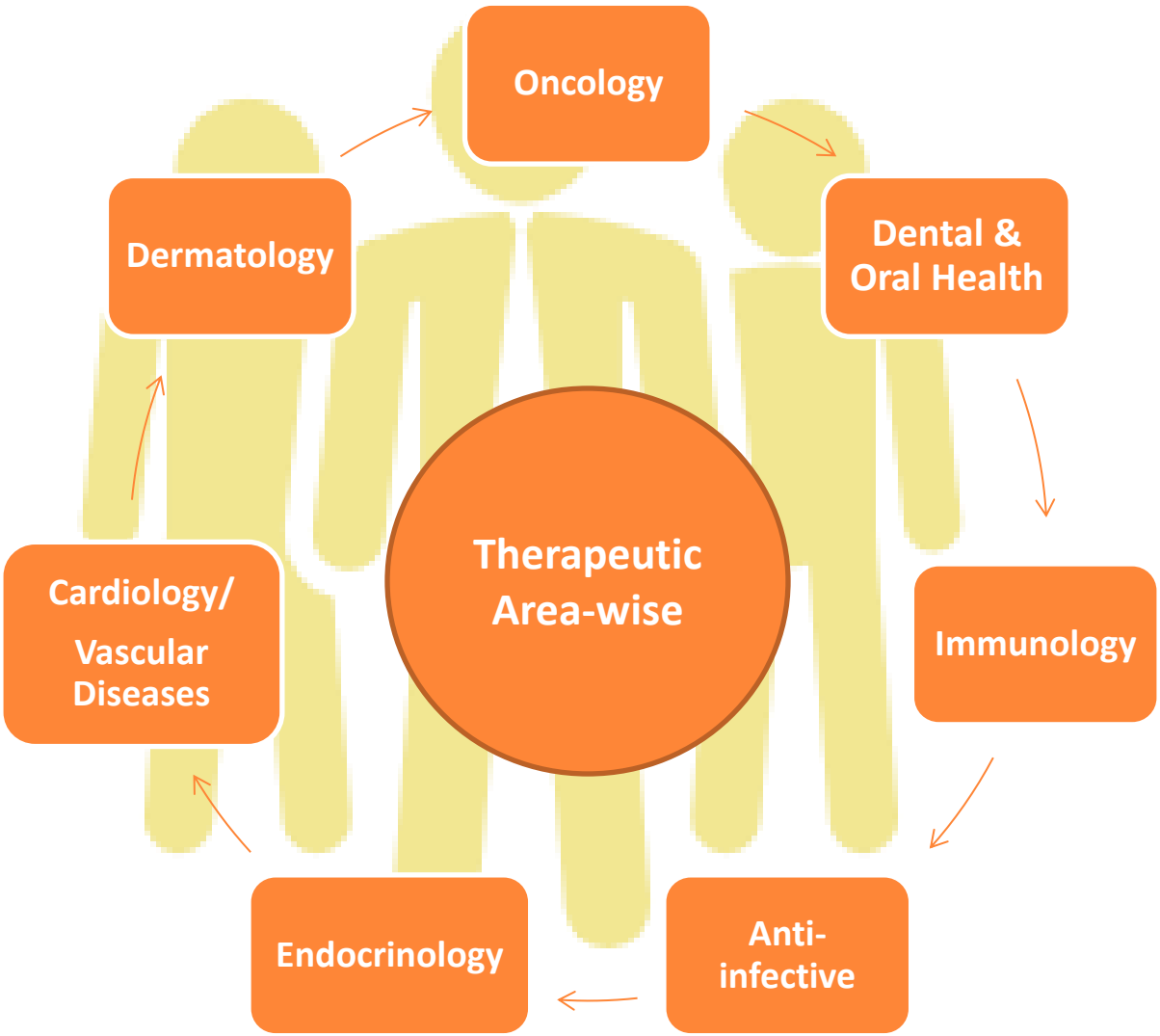
Clinical Research Experience



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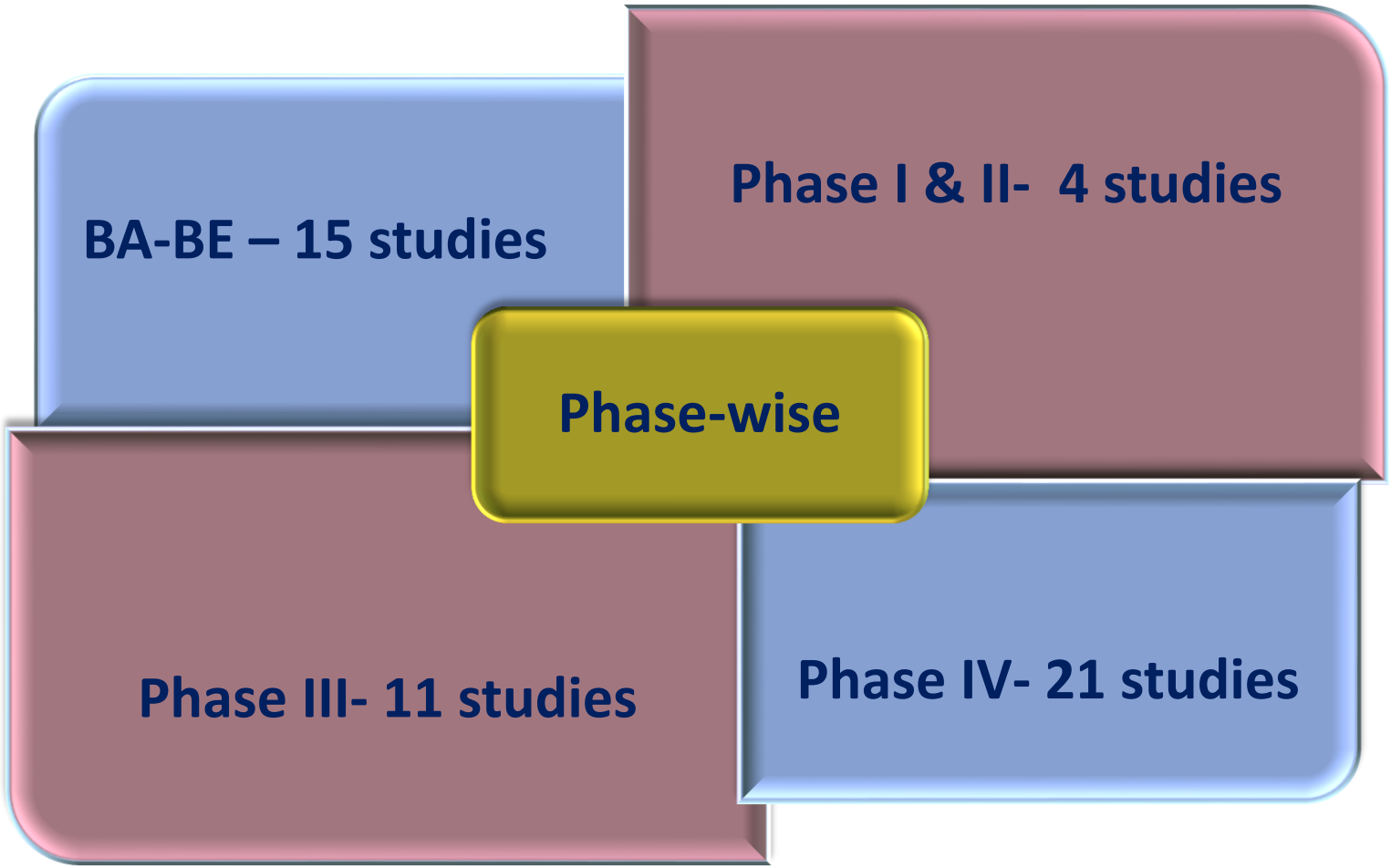
Clinical Research Experience



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Capabilities In Patient Based Studies

- 26-member strong Clinical Operations, medical monitoring & Regulatory Affairs team
- Have a good mix of experienced staff with prior experience in multinational CROs and Big Pharma
- Strong therapeutic experience in Oncology, Diabetes and auto-immune disorders
- Advantages offered:

✓ **India Advantage**: faster patient recruitment, up to 40% cost savings relative to US or Europe

✓ **"One stop shop" solution:** Regulatory support, Trial management, IP management and Data Management

✓ **Strong project management** systems & Long track record of working with several national and international clients

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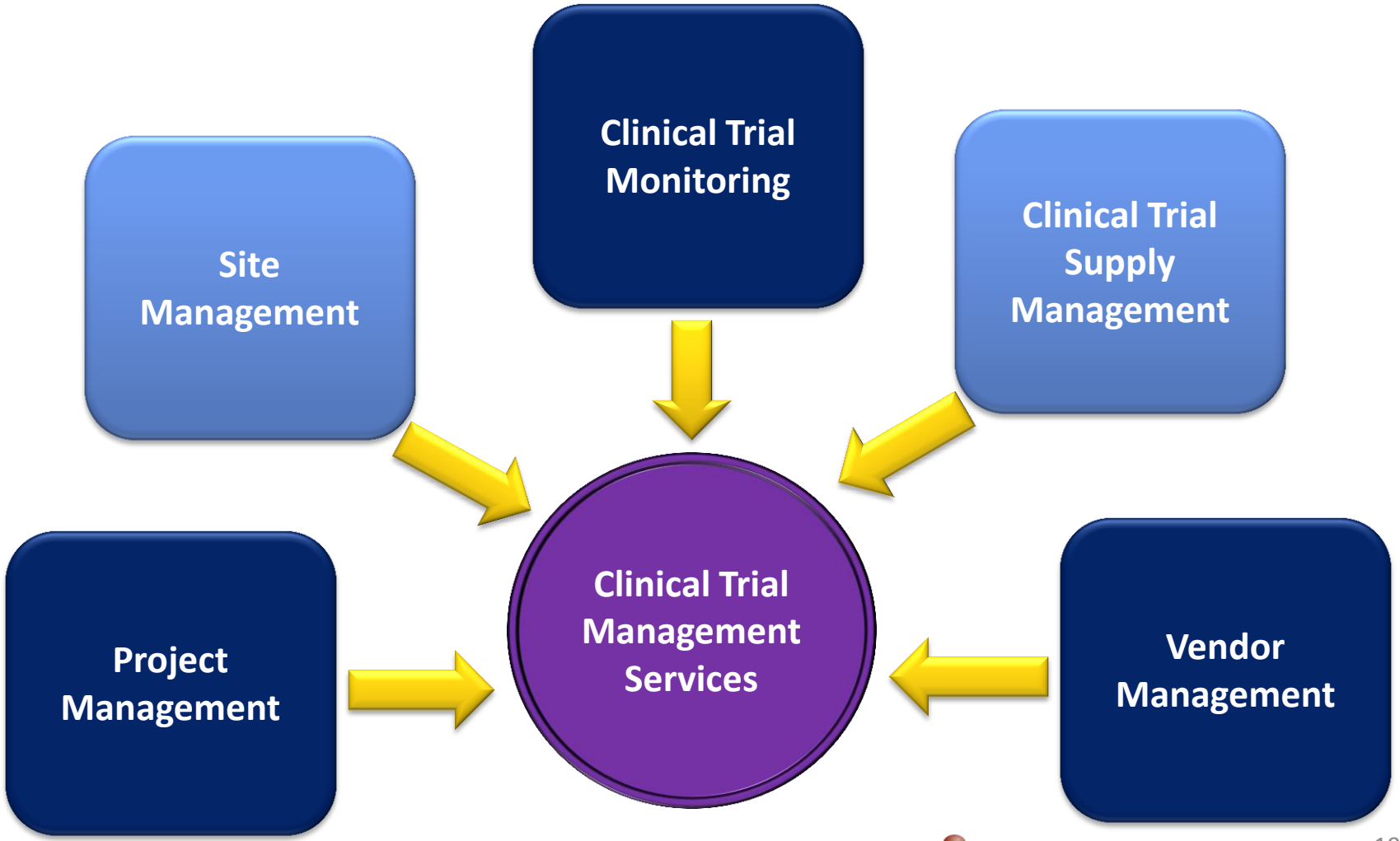
Clinical Trial Management Services



Simplifying Clinical Research

Clinical Operations- Project Management

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Study Set-up

- Synopsis receipt & review by internal departments
- Discuss & finalized synopsis with Sponsor
- Exchange of responsibility matrix
- Feasibility assessment
- Finalization of Budget & milestone payment
- Signing of the MSA or LoI
- Handover meeting
- Site selection
- Study team set-up & training
- Regulatory and EC submissions
- Investigator meeting
- Receipt of study supplies at ClinsoftCR

Study Conduct

- Site initiations
- Patient recruitment
- Site monitoring (clinical, safety, drug a/c, DM queries)
- Co-ordinate & track Investigator payments
- Regular meetings on study progress & MoMs
- Use RACI to identify issue escalation path & teams
- Sponsor /customer feedback mechanism

Study Closure

- Data queries and resolution process
- Data base lock
- Site close-out activities
- Discussions and approval of Statistical analysis report
- CSR writing
- Study supplies return and/or destruction
- Archiving study documents (Post Study)

Clinical trial capabilities in Patients: Site network

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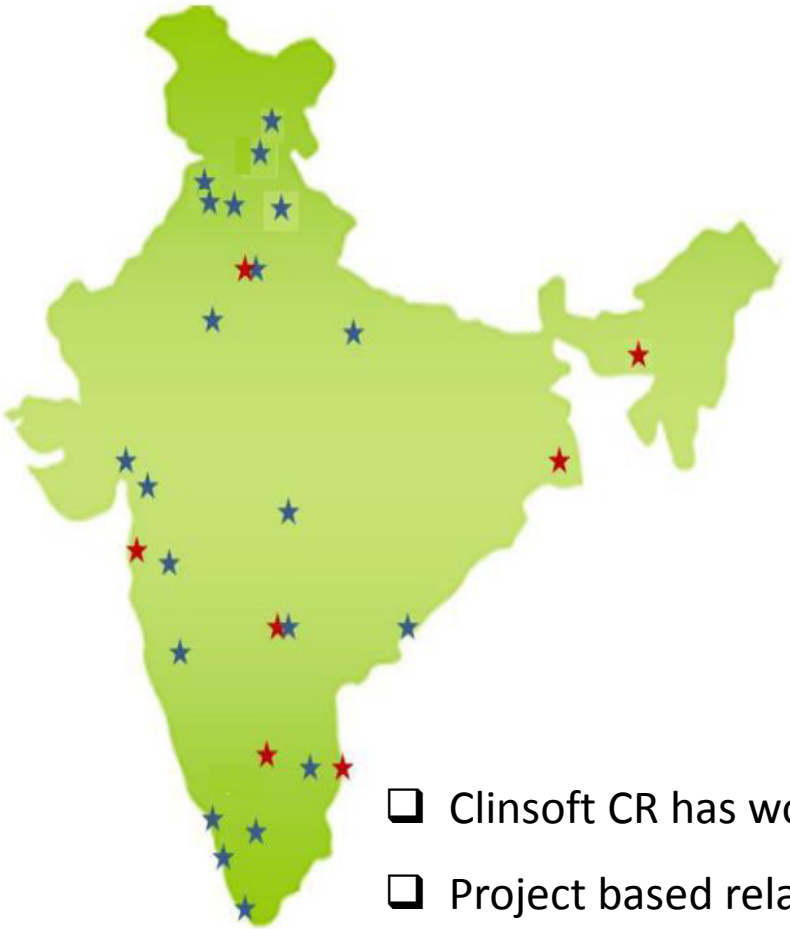

City	No. of Sites
Mohali	2
Amritsar	2
Shimla	1
Kangra	1
Jalandhar	1
Chandigarh	2
Ludhiana	9
Delhi	11
Mumbai	18
Pune	1
Lucknow	1

City	No. of Sites
Bengaluru	25
Ahmedabad	3
Chennai	5
Guragaon	2
Hyderabad	15
Jaipur	2
Karnal	1
Kochi	3
Kolkata	5
Vellore	1
Imphal	1
Nagpur	3

- Clinsoft CR has worked with more than 90 Investigators
- Project based relationship with Investigators, SMOs, Hospitals & Institutes

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Clinical Data Management- Overview

- Expert CRF and database design promotes accurate data collection for clean, reliable data
- Advanced data management technology means your database can be in production in as few as 2–12 weeks depending on complexity of trial
- Our project management methodology fosters efficiencies, allows for early problem solving and reduces oversight time
- Data acquisition

➢ Remote data capture

- Web based through in house eCRF–SAS® PheedIt

- Third party / Sponsor database – Oracle InForm™, MedidataRave®, agCaptureTM, Data labs®

➢ Paper CRF based data capture –SAS® PheedIt database

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Clinical Data Management Services

- Data Management Plan
- Case Report Form (CRF) Design
- Study Setup
- Workflow Management
- Data Capture
- Double data Entry
- Electronic data capture
- Query Management
- Discrepancy Management
- Data Entry & Validation guidelines
- CRF Tracking

- Data Capture/Testing
- Medical Coding
- Adverse Event & Medical History
- Concomitant Medications
- Serious Adverse Event Reconciliation
- Data Validation
- QA/QC (Acceptable limit of 0.05% error rate)
- Database Lock
- Data Transfer (Secured FTP access for Lab data transfer)

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Paper based CRF process

- Develop the CRF
- Write and maintain data management plan
- Specify edit checks (manual and electronic)
- Database creation
  - –Write specifications
  - –Design
  - –Testing
- Programming and validation of edit check programs
- Query management and resolution
- CRF tracking
- Weekly reports
- Missing/expected pages
- Discrepancy counts including time outstanding

- Data entry
- Listing reviews
- Lab data
  - – Receive lab data
  - – Manage lab normal's
  - –Check lab data (specify specific checks)
- Database audit
  - – Frequency
  - – Special milestones
  - – Final audit
- Data transfers
- Coding
  - – AEs
  - –Medications
- SAE reconciliation
- Approve study lock

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Biostatics & Programming

Services

- Statistical inputs for protocol design
- Sample Size Calculation
- Randomization/Blinding
- SAS Coding
- Statistical Analysis
- Statistical Report

Process Elements

- Statistical Analysis Plan
- Report Analysis Plan
  - Tables, Listings and Graphs
- Statistical Analysis Programming
- TLGs programming
- Validation of SAS Code and Statistical Analysis
- Statistical Report
- Data transfer as per SDTM *.xpt, *.dat

Software Tools

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- Oracle Clinical
- Open Clinica
- Nepule
- Medidata Rave
- SAS 9.x
- Argus
- Clinion
- Excel

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Medical Writing- Group

- A 5-member team of skilled medical writers with scientific expertise to support clinical development.
- Have a good mix of experienced staff with prior experience in multinational CROs and Big Pharma.
- Collaborates with our Statisticians and project coordinators in constructing submission-ready clinical documents.

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Medical Writing Services

Regulatory Documents for Phase I to IV Studies

- Investigators brochure
- Clinical study protocols
- Informed consent forms
- Study assessment questionnaires
- Patient dairies
- Clinical study reports DSMB Charters

Services offered as Full service study package or stand alone service

Clinical study reports –Observational studies

- Abstracts and Journal manuscripts
- Poster presentations at medical meetings
- Clinical overview and clinical summary
- Training materials

All of the above listed documents undergo QC and QA review.

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Pharmacovigilance Services

Phase-1/ BE studies **Phase –II and III trials**

Clinical Development

- Centralized Inbound Unit for AEs & SAEs
- Case Triage & Processing
- Medical Review & Causality
- Assessment
- Case Submission
- Safety Signal evaluation
- Periodic Reports (IND AR, NDA PR,ASR)
- Integrated Summary of Safety
- Design Risk Management Strategy

Post-Approval

- Case Processing and submission*
- Literature Search & Review
- Risk Management Plans (RMP,REMS, RiskMAPs)
- Annual & Ad-hoc safety signal evaluations
- Periodic Reports (PSURs, PADERs, Bridging Reports, Ad-hoc Reports)
- Establishing and operating special population registries

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Pharmacovigilance Services

- Personnel well-trained & experienced in the current safety reporting guidelines (ICH E2A & E2C, CIOMS guidelines, US FDA's Good Pharmacovigilance Practices &EMEA's European Directive 2001/20/EC guidelines etc.)
- Customized offerings as per end-user requirements & client specified Service Level Agreements (SLAs)
- Database-independent: Flexibility, knowledge & experience to work on sponsor's proprietary or licensed electronic reporting databases such as Argus Safety, Aris-G, Clintrace, etc.
- Location: In Chandigarh, good internet connectivity, and ample availability of experienced personnel
- IT Support: Good infrastructure manned by in-house IT group
- BCP: Alternate locations for service outages

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Why Clinsoft?

- Operations, CDM and Statistics team
- Entire Project Management
- Basic Facility and Infrastructure
- 3-6 months time frame commitment
- Low cost billing

"Clinsoft Clinical Research Low Risk Pilot Model"

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Contact Details

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