ALTASCIENCES

CLINICAL MONITORING

At **Altasciences**, we understand that your clinical trial requirements are unique and require careful management. Your partnership with us gives you access to highly experienced and knowledgeable clinical research associates (CRAs), who will provide you with unbiased and objective representation. You can count on our CRAs for top-quality monitoring, as well as agile, flexible processes, and transparent communication. Their individualized attention ensures compliance with your protocol and Good Clinical Practice (GCP) regulations, while securing participant safety and data integrity.

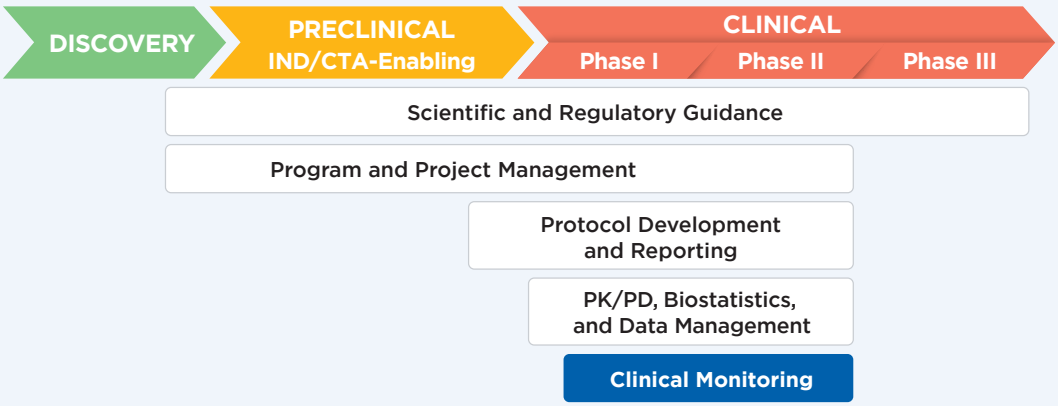
Altasciences' CRAs are dedicated to monitoring all aspects of your study, from site qualification to closure, including:

- Qualifying clinical sites according to established criteria and participant population
- Training sites on the study protocol and plan
- Performing source document verification and review to ensure GCP compliance, participant safety, and data integrity
- Reviewing on-site regulatory documents
- Preparing timely, comprehensive correspondence, and site visit reports
- Closing out the study, resolving outstanding queries, and returning investigational product (IP)

Choose from a variety of monitoring approaches, according to your needs:

- Standard on-site monitoring
- Remote monitoring
- Risk-based monitoring
- A customized combination of approaches

Our **clinical monitoring** services extend from Phase Ib to Phase IIa clinical trials.



Our CRAs are located across North America, with many near our clinics, and bring extensive clinical trial experience across a wide range of therapeutic indications.

contact@altasciences.com
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CRO SERVICES

Program Management

- Dedicated program manager to oversee all aspects of program conduct and deliverables
- Close collaboration with key internal and external stakeholders to ensure seamless and timely communication for successful program completion

Project Management

- Project management team to coordinate all aspects of each study
- Expertise in a wide range of study types and therapeutic areas

Protocol Development and Medical Writing

- Clinical trial protocol development, review, and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Scientific Publication Writing

- Strategic guidance and quality writing for manuscripts, posters, and abstracts
- Expert review and editing of your publication drafts

Regulatory Support

- Extensive experience in preparing study design to meet regulatory requirements
- Preparation and submission of regulatory documents
  - IND/CTA
  - NDA
  - IRB
- Post-submission regulatory deficiency remediation

PK/PD Data Analysis and Interpretation

- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Data Management

- CDISC standards fully integrated in workflow
- Database lock available typically within 2 to 4 weeks of last subject's final visit

Biostatistics

- All programming done using SAS®
- Statistical analysis plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Creation of CDISC-compliant, FDA submission-ready package

Clinical Trial Site Identification, Selection, and Management

- Access to a global network of over 100 active clinical trial sites
- Hybrid approach involving collaboration with clinical and partner sites for specialty
- Quick recruitment through access to histories and data
- Close collaboration during feasibility assessment
- Early identification of participants before site selection
- Dedicated project manager for efficient trial management

Support Services for Nonclinical Studies

- Analytical chemistry
- Analytical biology
- Immunohistochemistry
- Specialized necropsies
- Anatomic pathology and clinical pathology
- Toxicokinetics
- SEND – Standard for Exchange of Nonclinical Data
- Archiving
- Histology

Clinical Monitoring

- Highly experienced and knowledgeable clinical research associates (CRAs), providing unbiased and objective representation
- High-quality monitoring ensures compliance with study protocols and good clinical practice (GCP), securing participant safety and data integrity

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