

FULL-TIME EQUIVALENT (FTE) CAPABILITIES

FOR RESEARCH SUPPORT SERVICES

Altasciences is a forward-thinking, mid-size contract research organization offering pharmaceutical and biotechnology companies a proven, flexible approach from lead candidate selection to clinical proof of concept.

One of the ways that we facilitate and expedite delivery of our comprehensive suite of research support services is through a Full-Time Equivalent agreement (FTE) option that offers maximum flexibility, and ensures you have consistent access to our experts through the different phases of your drug development program.

Altasciences' FTE Advantages

- · Increased resource flexibility and enhanced ability to manage workload fluctuations
- · Quick and easy access to specific skills/expertise through our world-class team
- Readily accessible training resources
- A flexible approach adapted to your specific needs

25+ years of expertise

FULLY INTEGRATED Service Offering

OUR FTE OFFERING PROVIDES FLEXIBLE, ACCESSIBLE SUPPORT IN THE FOLLOWING AREAS:

Organizational

- Due diligence assessment
- Post-acquisition integration
- Vendor/subcontractor qualification and management

Quality and Compliance

- GxP Training
- Performance of independent GCP. GLP or GCLP system and/or study-specific audits
- Pre-approval inspection (PAI) readiness assessments
- PART 11 compliance assessments
- Data integrity assessments

Scientific

- Clinical protocol development
- Clinical program design and strategy
- Regulatory science and strategic quidance

Trial Services

- Project/program management
- Biostatics
- CDISC/SEND
- Data management
- Clinical monitoring
- Site feasibility and qualification

Compliance Remediation

- Review of responses and support for remediation in response to FDA 483 and warning letters
- Post-submission regulatory deficiency remediation
- Independent third-party review of:
 - Deviation investigations

- Validation reports

- Laboratory investigations
 - Method validation reports



to see how Altasciences supports your drug development programs from lead candidate selection to clinical proof of concept, and beyond.

Altasciences offers integrated, full-service solutions, all customizable to specific sponsor requirements. Seamless integration is achieved through proactive internal and external communication, ensuring that you will not need to repeat the same information twice - Tell Us Once™, and we'll take care of the rest.

altasciences.com