ALTASCIENCES

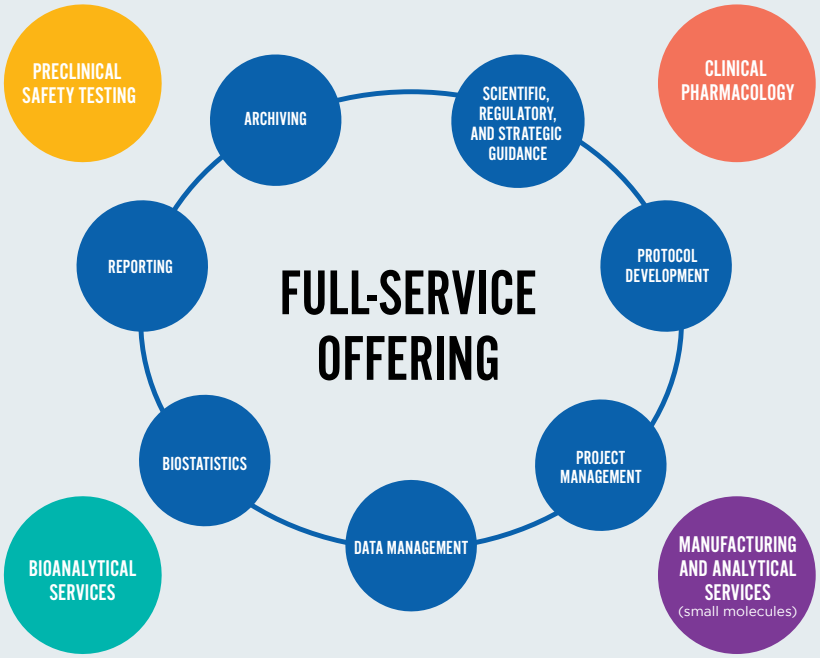
COMPREHENSIVE RESEARCH SUPPORT

Altasciences has been providing research services support to the global biopharmaceutical industry for over **25 years**.

As stand-alone offerings, our expert teams are ready to support, manage, analyze, and report on studies conducted with third-party partners. We are accustomed to managing complex projects with different partners, and have robust communication processes in place to ensure efficient integration.

As part of a complete development program, or single study, with Altasciences, our Research Support Teams deliver the full array of complementary services needed to complete your projects.

We also offer full-time equivalents (FTE) for many of our Research Support Services.



COMPREHENSIVE RESEARCH SUPPORT

Program Management

- Program Manager (Project Leader) oversees the complete program conduct and deliverables.
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion.

Protocol Development and Medical Writing

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

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

Clinical Monitoring

- Highly experienced, well-trained CRAs oversee all relevant aspects of clinicial trial conduct.
- Ensures data integrity, patient safety, and compliance with your protocol and GCP

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

Support Services for Non-Clinical Studies

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

FULL-SERVICE OFFERING

Visit our **YOUTUBE** Channel

MANUFACTURING AND ANALYTICAL SERVICES

- Dedicated to small molecules drug formulation and development
- 30,000-square-foot, GMP-compliant CDMO facility with analytical labs
  - Advanced technology servicing non-sterile development services and non-sterile dosage forms
  - Clinical supply manufacturing and packaging (Phase I-IV)
  - Narcotic storage
  - FDA drug-firm registration
  - DEA licenses
  - EU QP inspected
  - FDA food facility registration
- Manufactured and tested nearly every available dosage form

BIOANALYSIS, SMALL AND LARGE MOLECULE

Small Molecules

- Extensive, in-house database of over 680 assays covering 615 molecules
- Customized, unique solutions in derivatization, chiral separation, drug stabilization, and multiple metabolite quantitation
- State-of-the-art instrumentation to achieve low quantitation with limited sample volume
- Certain small molecules are suitable for our cutting-edge ligand binding platforms

Large Molecules

- We evaluate each request and provide customized workflows to allow accurate platform selection by hybrid LC-MS or ligand binding
- Our experienced and dedicated R&D scientists develop validation-ready assays, customized to your needs, using advanced instrumentation

© 2021 Altasciences. All Rights Reserved. Updated January 2021.