ALTASCIENCES

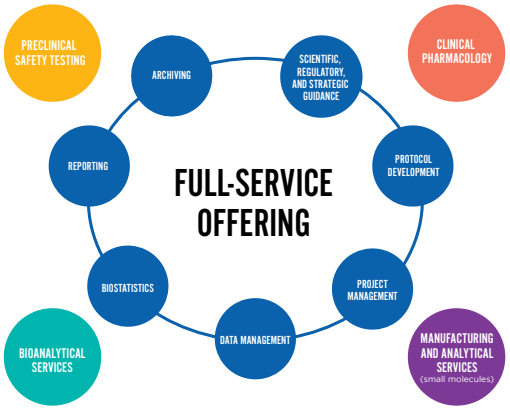
COMPREHENSIVE RESEARCH SUPPORT

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

- 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

Clinical Monitoring

- Highly experienced, well-trained CRAs to oversee all relevant aspects of clinical 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 Nonclinical Studies

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

FULL-SERVICE OFFERING

MANUFACTURING AND ANALYTICAL SERVICES

- Dedicated to small molecules drug formulation and development
- 65,000-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 establishment registration
  - DEA licenses
  - EU QP inspected
  - FDA food facility registration
- Experience in manufacturing and testing nearly every available dosage form

BIOANALYSIS

- Team of more than 260 dedicated scientists
- Can process over 60,000 study samples/month
- Extensive in-house database of over 685 assays covering 620 molecules
- Experience with a wide spectrum of biological matrices in both animal species and humans
- Capabilities:
  - Mass spectrometry (LC-MS/MS)
    - Small molecules, peptides, proteins, and oligonucleotides
    - Labile metabolites and endogenous compounds
    - HRMS equipment
    - Nano/micro flow
  - Ligand binding assays
    - Electrochemiluminescence
    - MSD Imager
    - Immunogenicity assays
    - Quantitative ELISA assays
    - Biomarker panels
    - Cell-based assays
    - Flow cytometry
    - Gene therapy
  - Additional capabilities
    - Transgene expression and RNA analysis
    - Cell lineage and functional immunophenotyping by flow cytometry
    - Droplet digital PCR and quantitative PCR
    - Peptide mapping
    - Western blot
    - Translational biomarkers

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