ALTASCIENCES

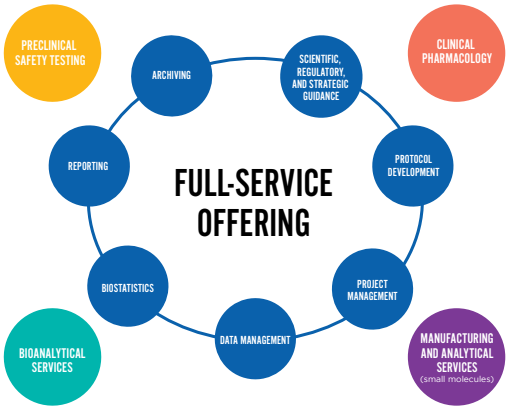
CRO SERVICES

Altasciences has been providing CRO services support to the global biopharmaceutical industry for over **30 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 CRO services team delivers 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.



CLINICAL RESEARCH 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

Clinical Monitoring

- Highly experienced, well-trained CRAs to oversee all relevant aspects of clinical trial conduct
- Oversight to ensure data integrity, patient safety, and compliance with your protocol and GCP

Biostatistics

- SAS programming of all datasets and data presentations
- Statistical analysis planning, including mock TFL shells
- Generation of statistical results and appendices (TFLs) for CSR
- Creation of CDISC-compliant, FDA submission-ready data package

Clinical Trial Site Identification, Selection, and Management

- Access to a global network of over 100 active clinical trial sites
- Close collaboration during feasibility assessment
- Early identification of participants before site selection
- Dedicated project manager for efficient trial management

FULL-SERVICE OFFERING

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

MANUFACTURING AND ANALYTICAL SERVICES

- Turnkey pharmaceutical contract manufacturing solutions, including drug formulation, development, testing, and manufacturing
- 64,000-square-foot cGMP-compliant CDMO facility with analytical labs
  - API formulation development and manufacturing, from discovery through commercialization
  - Clinical supply manufacturing and packaging (Phase I-IV)
  - Creation of small prototype batches to commercial scale
  - In-house R&D and formulation laboratories for analytical testing, including method development and validation, ICH stability testing, and drug product release testing
  - DEA license for Schedule I-V, including pallet positions for Schedule III-V, and vaults for Schedule I-II
  - FDA registered and EU QP inspected
- Experience in manufacturing and testing nearly every available dosage form
- Client-dedicated space and equipment, as required to meet project demands

BIOANALYSIS

- Team of more than 400 dedicated scientists
- Can process over 720,000 study samples/year
- Extensive in-house database of 685+ assays covering 650+ 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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