ALTASCIENCES

BIOLOGICS/BIOSIMILARS CLINICAL TRIALS

Altasciences has provided services to the global biopharmaceutical industry for 30+ years, with a particular expertise in developing programs and conducting **preclinical assessments** and full-service **clinical pharmacology** studies for novel biologic or biosimilar products. We have the scientific, medical and **bioanalytical expertise** to design studies to meet your objectives, your recruitment timelines, manage the associated risks and develop the methods required to analyze the product and any anti-drug antibodies produced.

Full-Service Clinical Experience

We have been conducting studies for 10+ years on various types of biologics.

Studies/Year

- **20** Clinical
- **70** Bioanalytical
- **10** Data Services

Biologics

- Recombinant Proteins
- Monoclonal Antibodies
- Vaccines
- Small Inhibitory RNA
- Antisense RNA

Conducted numerous clinical pharmacology studies for biosimilar submissions, recruiting up to **250 subjects per study.**

- **14** Pharmacokinetic Comparison of Test versus Reference studies
- **6** Immunogenicity studies
- **8** Pharmacodynamic studies

Tailored Integrated Services

We provide comprehensive early stage clinical drug development services, including the necessary clinical support solutions in this critical stage of drug development.

- Recruitment
- Clinical Conduct
- Pharmacy
- Clinical Monitoring
- Protocol Development
- Data Management
- Biostatistics
- Medical Writing
- PK and PD Analysis
- Quantitative Bioanalysis
- Method Development and Validation
- Project Management

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Bioanalytical Expertise

Renowned for our vast experience in LC-MS/MS and Ligand Binding bioanalytical platforms, we provide support for all stages of drug development (from preclinical to Phase IV) for both small and large molecules programs, including immunogenicity testing. We offer:

- Bioanalytical capabilities supported by over 200 highly-trained specialists, working with the latest equipment in state-of-the-art, purpose-built laboratories
- Dedicated Method Development teams and space
- Analysis performed (as needed)
- Capacity for upwards of 60,000 study samples a month
- Designated containment Level 2 (CL2) areas for work with Risk Group 2 (RG2) Pathogens – known infectious material and monkey serum/plasma/tissues
- The latest equipment to ensure compliant, on-time regulatory submissions

LC-MS/MS

- PK assessment of recombinant proteins and monoclonal antibodies
- Product characterization including glycosylation patterns

Ligand Binding

- PK assessment of recombinant proteins and monoclonal antibodies
- Immunogenicity assessment by measuring anti-drug antibodies (ADA)
- Neutralizing antibody detection through competitive binding

Study Design

We design, conduct, analyze and report all our studies in-house.

- Complete programs designed in collaboration with our regulatory consultants
- Individual study designs
- Distinctive recruitment and retention strategies
- Specialized pharmacies
- Experts in clinical conduct on biologics
- Bioanalytical support — PK, PD and ADA
- In-house biostatisticians, data managers and medical writers with expertise in biologics

How we Facilitate Outsourcing of your Biologic and Biosimilar Programs

- We understand that speed, quality and meeting recruitment milestones are vital
- We routinely dose high-risk compounds
- Our studies are designed to meet regulatory requirements in multiple regions
- We design, conduct and report on innovator biologics
- We design complex studies with multiple endpoints (BE, ADA, POC)
- Our pharmacies and pharmacists have the required equipment and experience
- We have a successful record in recruiting and retaining healthy participants for biosimilar studies

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