

BIOANALYSIS AT THE FINISH LINE:

Supporting Clinical Studies

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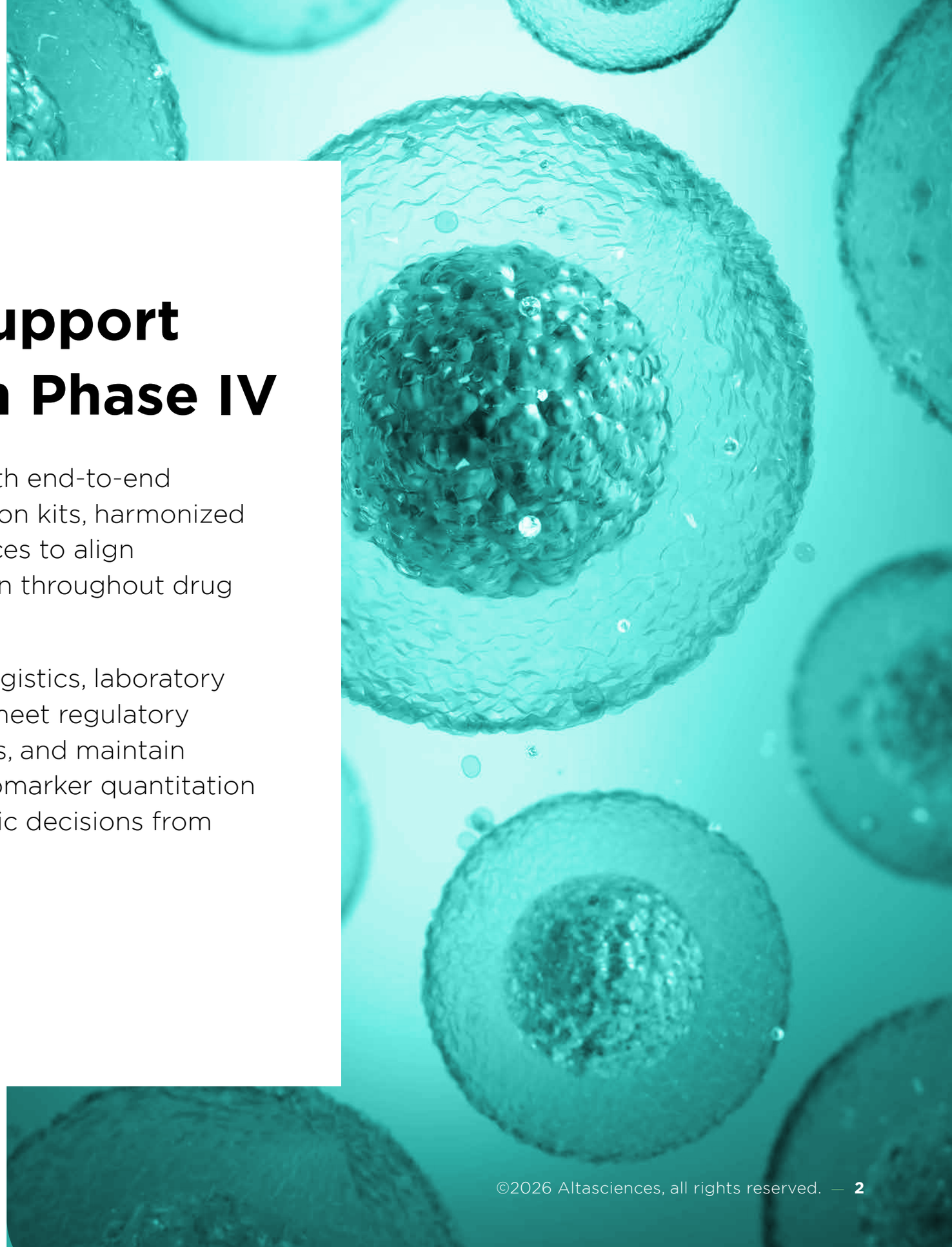
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Clinical Bioanalysis Support From Phase I Through Phase IV

We combine reliable bioanalytical capabilities with end-to-end sample management, specialized sample collection kits, harmonized laboratory operations, and integrated CRO services to align scientific requirements with operational execution throughout drug development.

By coordinating method requirements, sample logistics, laboratory workflows, and delivery schedules, we help you meet regulatory expectations, manage increasing sample volumes, and maintain critical timelines—delivering reliable drug and biomarker quantitation to inform pharmacokinetic and pharmacodynamic decisions from discovery through Phase IV.

Explore our Bioanalytical Capabilities



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At a Glance: Bioanalysis You Can Depend On

285+

clinical trials supported annually

400+

bioanalytical specialists supporting integrated development programs

Complex Modalities

- mAbs
- Multispecific mAbs
- Antibody-drug conjugates (ADCs)
- Peptides
- Oligonucleotides
- Gene therapies
- Vaccines

Capacity for up to

60,000

samples per month for PK, biomarker, and anti-drug antibody (ADA) analysis

685+

off-the-shelf assay solutions across diverse biological matrices

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Key Performance Drivers

	Driver	Operational Importance	Sponsor Benefit
Analytical Platforms	**LC-MS/MS and LBA platforms**	Supports complex analytical requirements across small and large molecule programs, including selected high-throughput and automated workflows.	✓ Helps keep studies on schedule while delivering sensitive, reproducible bioanalytical data.
	Diverse technologies across LBA and LC-MS/MS	Multiple options to quantify complex biological compounds and attain desired sensitivity based on the context of use.	✓ Helps ensure mitigation strategies are available to derisk program continuity.
	Method validation and transfer processes	Maintains assay comparability across sites, instruments, and study phases.	✓ Reduces variability and promotes continuity throughout development.
Method Consistency	**Long-term method performance trending**	Monitors assay consistency over multi-year studies.	✓ Strengthens regulatory confidence and defensible submission data.
	Cross-validation and harmonized workflows	Standardizes assay execution and data review practices across laboratories.	✓ Ensures reproducible data across regions and study sites.
	Clinical sample handling, LIMS-based tracking, and specialized sample management kits	Customized collection kits, laboratory manuals and forms, shipment tracking, standardized manifests, receipt/QC, unique IDs, storage oversight, and discrepancy management.	✓ Protects sample integrity and maintain visibility from collection through analysis, reporting, and data transfer.
Sample Management	**Sample and reagent lifecycle management**	Allows stability monitoring, reagent bridging, long-term storage strategies, and inventory oversight.	✓ Helps maintain assay continuity and audit readiness throughout long-duration studies.
	Quality assurance	Maintains traceability, documentation consistency, and inspection readiness.	✓ Reduces regulatory risk and supports submission readiness.
Quality & Oversight	**Scientific and operational study oversight**	Coordinates assigned bioanalytical scientific leads, project/client management, QC reviewers, QA, data management, and laboratory teams.	✓ Supports informed decision-making, clear communication, and reliable delivery through study execution.
	Special populations	Supports studies involving complex or variable patient cohorts.	✓ Enables reliable data generation across multiple therapeutic areas.

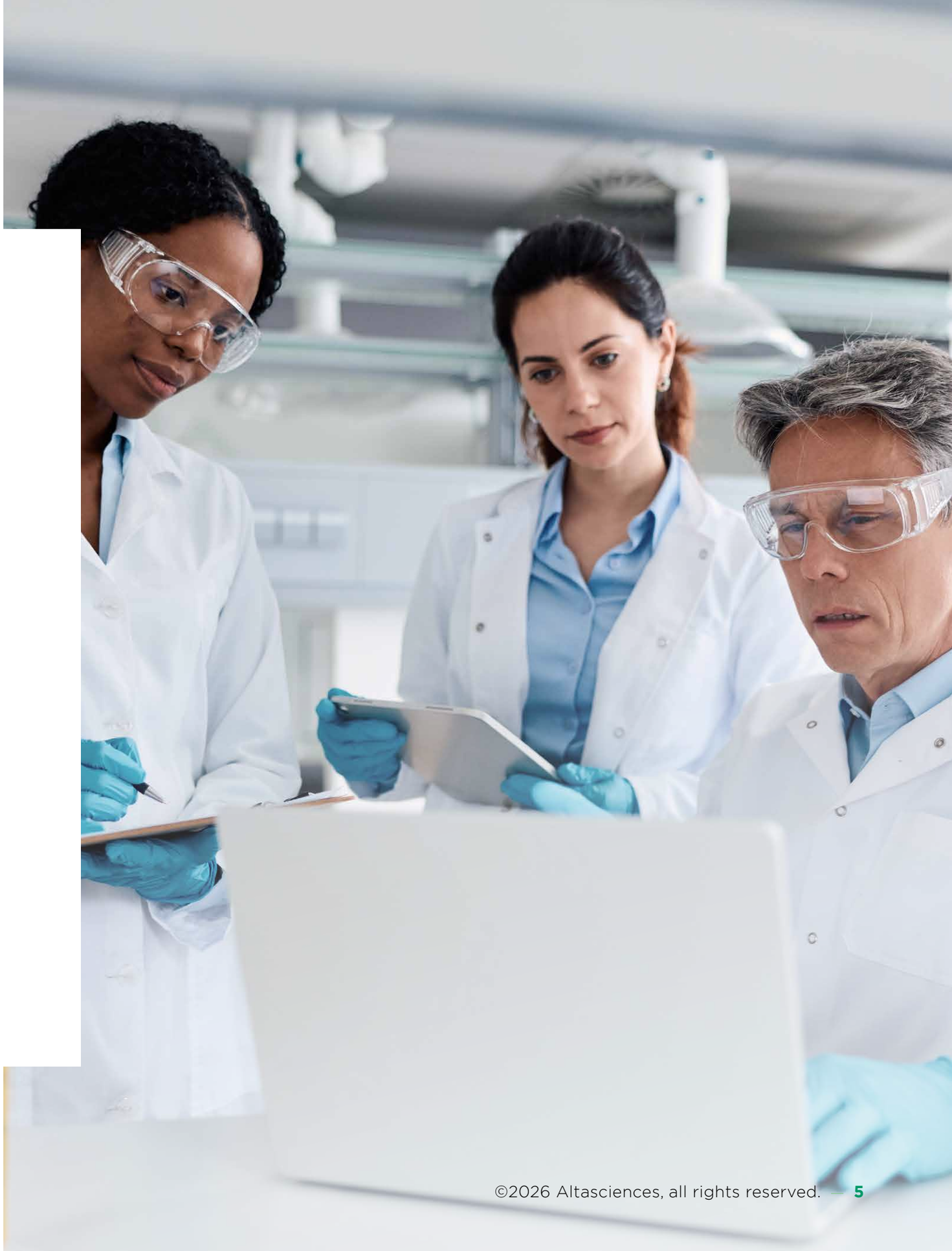
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Reporting and Data Delivery Support

Bioanalytical support depends not only on sample analysis, but also on timely, usable data. Our bioanalytical, data management, and CRO services are coordinated at every stage to enable sponsor-specific reporting requirements, interim data transfers, query resolution, and database lock milestones.

This helps you receive decision-ready outputs in formats and timelines needed for study teams, downstream reporting, and regulatory review.

Discover Our CRO Services



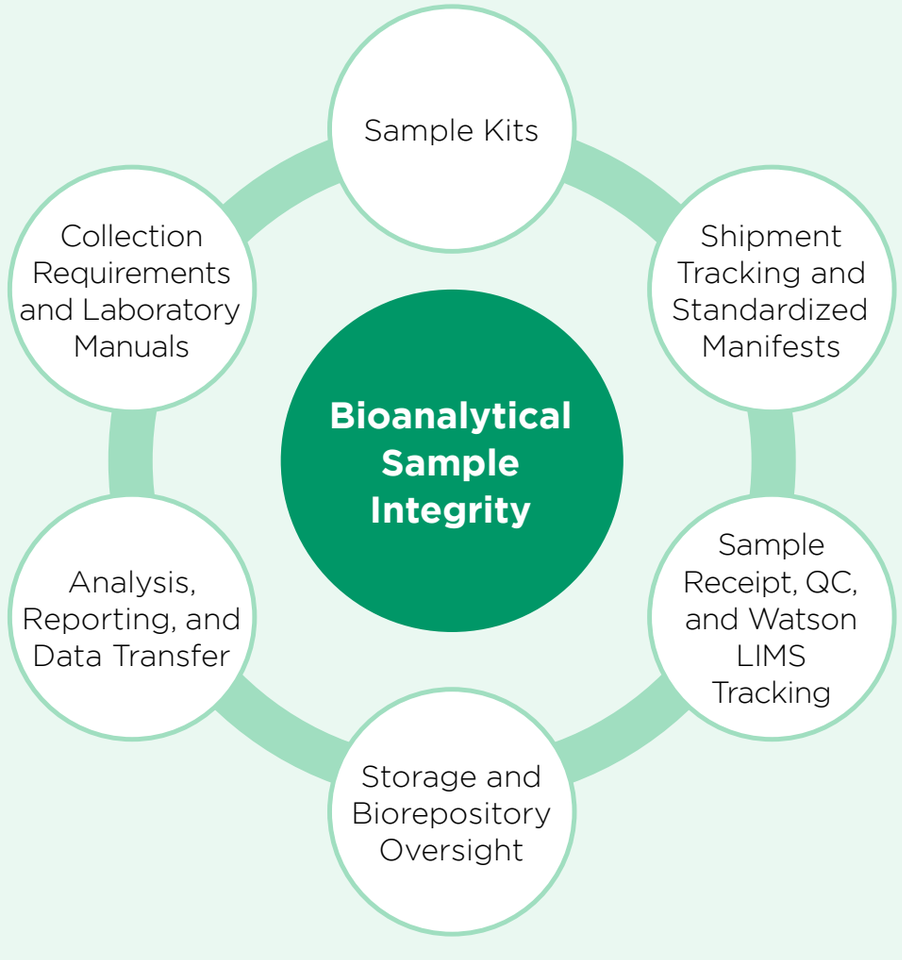
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Proactive Study Management

For clinical-stage programs, bioanalytical execution requires proactive coordination from study start-up through data delivery. Early in the drug development journey, we work with you to align study scope, intended use of data, collection requirements, shipment expectations, batch strategy, and operational timelines. This connects method requirements with the logistics needed to protect sample integrity at every touchpoint: collection, transport, receipt, storage, quality control review, reporting, and data transfer.

As studies progress, teams monitor sample receipt, tracking, and discrepancies that could affect timelines. Through quick, factual communication, we help keep you informed and expectations aligned to maintain sample integrity, project momentum, and reliable data delivery.



Clinical Sample Logistics at a Glance

- Clinical samples received daily from sites around the world
- Shipments coordinated from 70+ sites
- 300+ shipments and 50,000 samples received monthly, on average
- Experience with FedEx, MNX, and World Courier

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Operational Design for Clinical Bioanalysis

Clinical bioanalysis requires consistency, confirmation, and operational discipline from study start-up through data delivery. Science, operations, digital systems, and quality oversight programs are supported at all stages of the process.

Through clinical studies, we help mitigate operational risk across four critical pressure points.

1. Multi-Site Complexity vs. Unified Control

For clinical studies, a dedicated bioanalytical Principal Investigator provides strategic oversight of bioanalytical activities, helping maintain cross-functional alignment and timely delivery of high-quality data. Each program is assigned a dedicated client manager who serves as a consistent point of contact for contract management, issue resolution, and stakeholder coordination.

2. Sample Volume vs. Compressed Timelines

Managing increasing sample volumes requires coordinated logistical planning, staffing, and instrument capacity. Our bioanalytical teams help deliver accurate, reproducible data while maintaining compliance, scientific quality, turnaround expectations, and study milestone alignment.

3. Assay Drift vs. Multi-Year Lifecycle Consistency

We use LIMS-based traceability to electronically track samples, reagents, and reference standards, including freeze/thaw cycles and storage conditions, while long-term performance trending helps maintain assay and critical reagent consistency throughout the method lifecycle. Together, these practices promote comparability across studies, sites, instruments, and program stages.

4. Documentation Complexity vs. Inspection-Ready Data

Our workflows allow for documented data review and quality oversight across protocols, validation plans, bioanalytical plans, laboratory methods/SOPs, and reporting expectations. From sample receipt through disposition, this helps maintain chain-of-custody, audit readiness, and quality data for downstream reporting and regulatory review.

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Expertise Across Various Therapeutic Areas

Our clinical bioanalytical expertise spans a broad range of therapeutic areas, patient populations, and modalities. Our expertise spans LC-MS/MS, ligand binding assays (LBA), flow cytometry, immunogenicity testing, biomarker analysis, cell-based assays, ELISpot, microsampling, pharmacokinetic/pharmacodynamic (PK/PD), and more.

Rather than limiting support to a specific therapeutic area, our teams adapt bioanalytical strategies to each study's needs. Selected examples below highlight areas where clinical bioanalysis may require complex sample logistics, specialized matrices, large-cohort sample management, biomarker strategy, or immune profiling.

Metabolic Disorders

- 50+ early-stage trials completed involving anti-diabetic and hypoglycemic agents, including insulin, GLP-1, SGLT-2, and DPP-4 therapies
- In one single-center trial, Altasciences enrolled 75 Type I and Type II diabetic patients over four weeks
- Metabolic bioanalytical assay experience includes exenatide, glucagon, insulin glargine, insulin aspart, and metformin
- PK and PD bioanalysis for large-cohort metabolic programs with repeat sampling demands
- Laboratories are located within a few minutes' drive of our clinical pharmacology unit enabling PK and PD bioanalysis

CNS Programs

- 200+ CNS studies completed
- Altasciences' CNS Center of Excellence brings together experienced Principal Investigators, clinicians, and neuroscientists to aid complex early-phase CNS studies.
- Centralized database of 400,000+ participants
- PK and PD bioanalysis for complex CNS studies

Immuno-oncology and Immunomodulation

- Our expertise includes:
  - immunogenicity testing
  - cytokine and biomarker analysis
  - immunophenotyping by flow cytometry
  - oligonucleotides, cell and gene therapy
  - targeted and combination therapies
  - antibody-drug conjugates (ADCs)

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Why Sponsors Choose Altasciences for Late-Phase Bioanalysis

We help ensure sample handling, method application, data review, documentation, and communication remain aligned—for reliable, inspection-ready data for downstream decision-making and regulatory review.

Backed by over 30 years of bioanalytical experience, our scientific and operational depth spans diverse therapeutic areas and complex modalities, from small molecules and biologics to peptides, oligonucleotides, gene and cell therapies, bispecific and multispecific antibodies, and ADCs. Our teams tailor bioanalytical strategies to each study, helping you receive the right level of scientific, operational, and regulatory support as programs evolve to support confident program progression and keep key milestones on track.



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Additional Resources

Publications

- Bioanalytical Developments for the Analysis of Antisense Oligonucleotides
- *The Altascientist:*
  - Microsampling
  - The Evolution and Advancement of Liquid Chromatography-Mass Spectrometry in Drug Development
  - Quantitative PCR (qPCR) and Droplet Digital (ddPCR)—Leading-Edge Analysis for Your Gene Therapy Programs
  - Biomarker Strategies to Enhance Early-Phase Drug Development

eBook

- Key Biomarkers of Immunomodulation: Complement Factors and Cytokines
- Altasciences' Facilities: Moving in Unison
- Key Considerations for Nonclinical AAV Gene Therapy Development

Fact Sheets

- Bioanalytical Services
- Bioanalytical Expertise for Immunomodulatory Drugs
- Translational Biomarker Assays

Webinars and Videos

- Overcoming Bioanalytical Challenges for PK/PD Assessment in Phase I Biologics Studies
- Transitioning Novel Scientific Workflows to Routine Bioanalysis
- The True Meaning of Moving in Unison
- Moving in Unison: Overcoming Challenges Through Clinic-Lab Collaboration

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About Altasciences

Altasciences is a drug development organization dedicated to safely accelerating early-phase development for biotech, biopharmaceutical, and pharmaceutical companies. By combining the scale and expertise of a leading CRO/CDMO with the flexibility and personalized approach of a mid-size partner, Altasciences delivers unified solutions across nonclinical, clinical, bioanalytical, formulation, and manufacturing services. Through intentional integration and true collaboration, the company removes barriers from lead candidate selection to clinical proof-of-concept—helping sponsors save time, reduce complexity, and make confident, data-driven decisions that enable earlier returns on investment. Guided by over 30 years of experience, Altasciences helps clients reach critical milestones faster.

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SPEAK WITH AN EXPERT

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