

Translational Central Lab Services

Conquering the complexity of biomarker-driven trials

PRECISION
for medicine®



Precision medicine clinical trials—driven by biomarker data—pose unique challenges.

The kit development, logistics, sample management, and data collection are inherently complex. They require an approach to central lab services that is systematic and robust—and that can simplify clinical trial management. They require a translational central lab services solution.

Precision's harmonized approach is rooted in a deep understanding of the needs of both early phase trials and those with complex biomarker designs.

Clinical Trial Supply

- Kitting
- Logistics
- Courier and supply chain

Biospecimen Management

- Inbound/outbound
- Sample processing
- Storage
- Shipment/tracking

Biospecimen Data Services

- Database setup
- 21 CFR Part 11
- Discrepancy reporting

Precision Lab e-Portal

- Centralized reporting
- Inventory reports
- Kit reorder*
- eSRF creation*

*Coming soon

Expertise in complex kit development and global logistics drives accurate and timely sample collection



Custom Kit
Production



Clinical Site
Training



Global Shipping
and Logistics



Supply Chain
Management



Online Management,
Tracking, and Reporting

The most critical step in sample analysis starts with obtaining the right specimens. Precision excels in all steps required to ensure the right samples are collected, processed, and transported to exactly where they need to be.

Logistical Management

- Export/import permits
- 24-hour staff to receive deliveries and resolve shipment issues
- Knowledge in planning best path for shipment
- Experience with all major couriers—eg, QuickSTAT, World Courier, FedEx, Marken

Clinical Kitting Specifications

- Kitting facility designed specifically for custom kit development
- Trial and visit specific kits
- Multiple sample type kitting
- Detailed kit status reporting
- Completed kits shipped from the United States and Europe

Clinical Site Training

- Collection-specific QA plans
- Development of training documentation
- Competency and monitoring programs

Global processing and logistical expertise ensure sample integrity



Precision's complete solution to biospecimen management begins with a global network of sample processing labs. Our primary biorepository—specifically designed to facilitate rapid sample accessioning, sample pulls, and shipments to testing sites—ensures the integrity of your clinical samples and your clinical study.

- Sample processing in North America, Europe, Africa, Asia, and Oceania
- 100,000 ft² primary biorepository and 6 additional storage facilities with storage under controlled conditions and all temperatures
- Inbound/outbound sample management
- >30M biospecimens managed
- Same-day PBMC isolations

PBMC DATA

Viability

≥90.6%

Recovery

1.67x10⁶

Cells/mL blood processed

PBMC and clinical samples processed across 5 continents



20+

Years of global trials

55+

Countries with active sample logistics

30^M

Biospecimens managed

A dedicated team and purpose-built systems safeguard all aspects of sample data accuracy and data quality



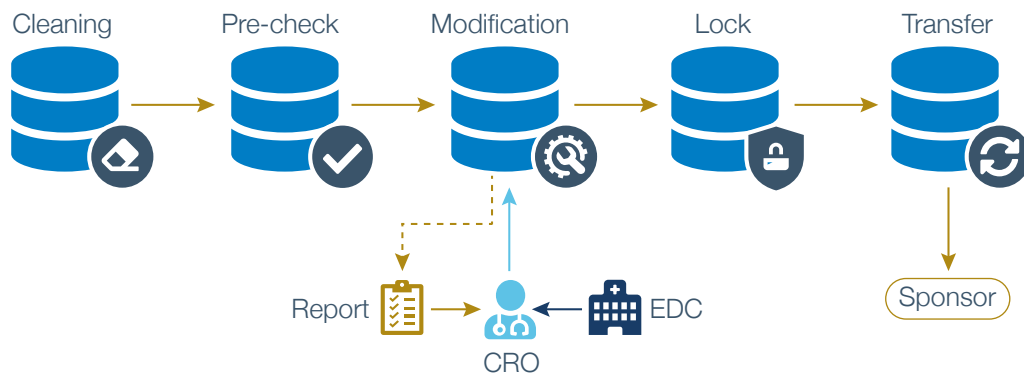
Every study and every sponsor need is unique. Precision's Data Services team answers those needs, establishing specific database parameters and data handling requirements for total data integrity, no matter the study complexity.

Precision technologies optimize data management

- QuartzBio
- PrecisionLIMS
- Precision's Lab e-Portal



Database lock and reconciliation workflow



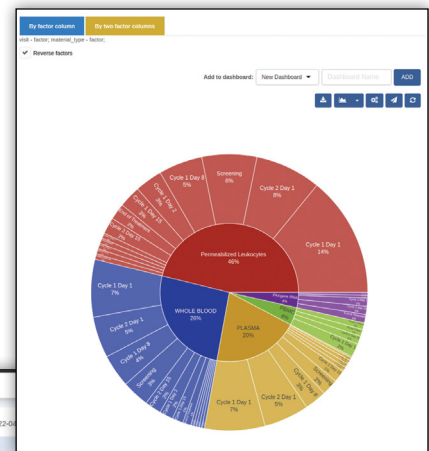
Real-time visibility into project, sample, kit, and shipment status provides 24/7 access to critical study data and activities



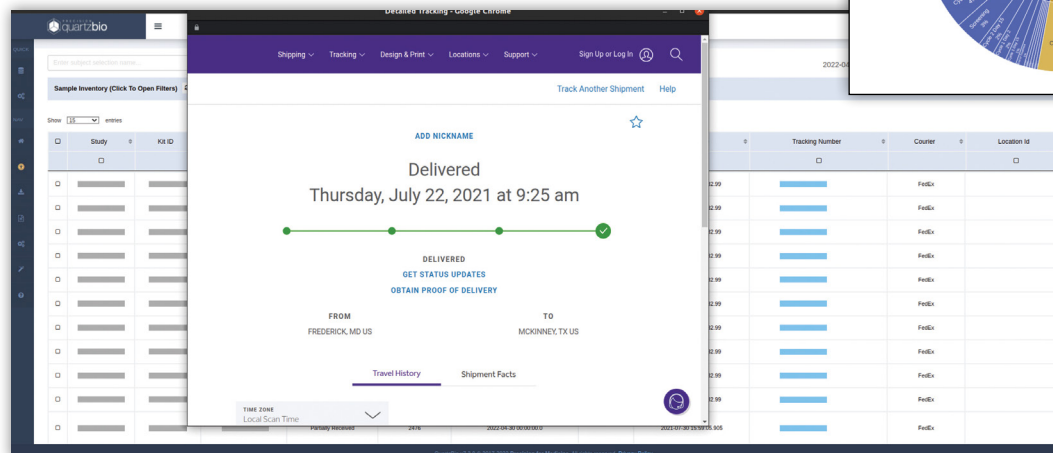
Precision's Lab e-Portal gives sponsors immediate access to study data, sample inventory data, shipment status, and clinical sample collection kit inventories. Reorder kits as needed, then track shipment status to know expected arrival times at clinical sites.

The e-Portal provides:

- Centralized data reporting and analytics available anytime
- Continuously updated data
- Sample inventory reports
- Kit inventory reports
- Online kit reorder*
- eSRF creation*



Inventory query and summary



Kit inventory view and link to shipping tracker

*Coming soon

Robust processes and program structure enable quick startup and promote study success

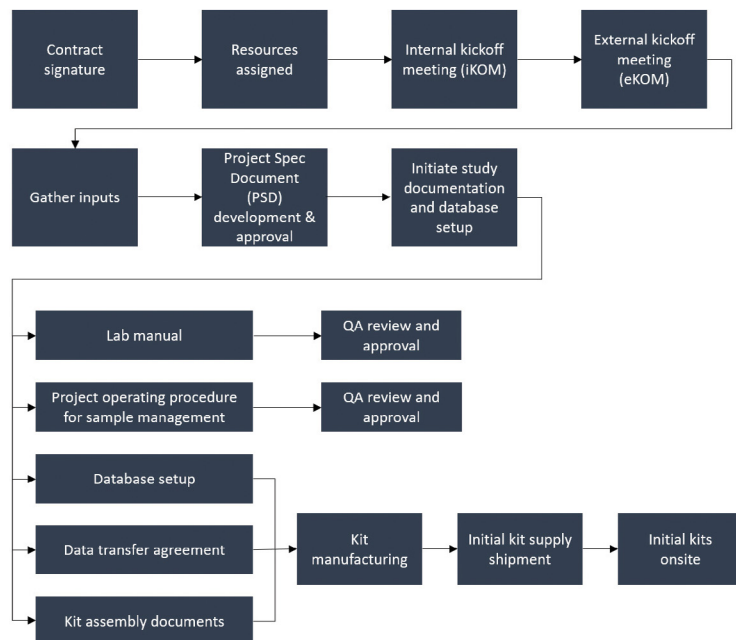


Precision's foundation of strong program management integrates all aspects of a central lab service project and provides:

- Project manager as a primary point of contact
- Dedicated study startup structure for rapid project initiation
- Document creation
- QA-approved lab manual creation
- Site training documentation

The Program Management team at Precision has developed detailed workflows to ensure consistent processes and rapid startup. Projects involving kitting can be started in as little as 8 weeks, and projects without kitting can begin in only 6 weeks.

Project initiation workflow



Solving the most complex challenges in biomarker-driven and precision therapeutic and diagnostic development



7

LABS ACROSS NORTH AMERICA AND EUROPE

12

SAMPLE PROCESSING LOCATIONS

600

CLINICAL TRIALS CONDUCTED

11^M

AVAILABLE BIOSPECIMENS

350⁺

IVD AND CDx SUBMISSIONS AND GLOBAL REGISTRATIONS

Providing End-to-End Solutions for Therapeutic and Diagnostic Development

Biospecimens



Specialty Labs



Companion Diagnostics



Clinical Trials



Central Lab Services



Data Sciences



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