

# Translational Central Lab Services

Conquering the complexity of biomarker-driven trials

PRECISION  
for medicine®



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

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



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

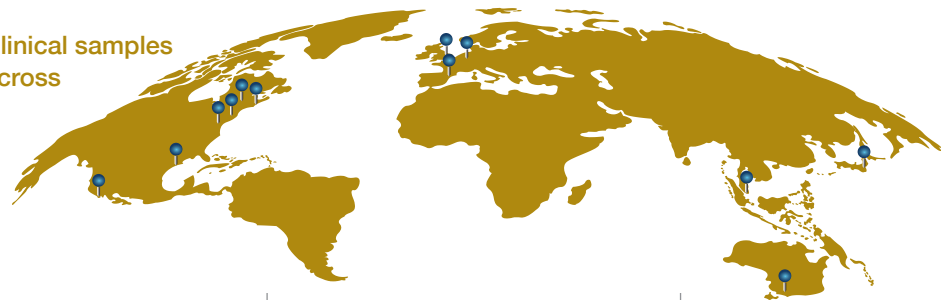


Precision's complete solution to biospecimen management begins with a global network of sample processing labs. Our primary biorepository—specifically designed to facilitate rapid sample accessioning, sample pulls, and shipments to testing sites—ensures the integrity of your clinical samples and your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

- Sample processing in North America, Europe, Africa, Asia, and Oceania
- 100,000 ft<sup>2</sup> 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  
**1.67x10<sup>6</sup>**  
Cells/mL blood processed

PBMC and clinical samples processed across 5 continents



**20+**

Years of global trials

**55+**

Countries with active sample logistics

**30<sup>M</sup>**

Biospecimens managed

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



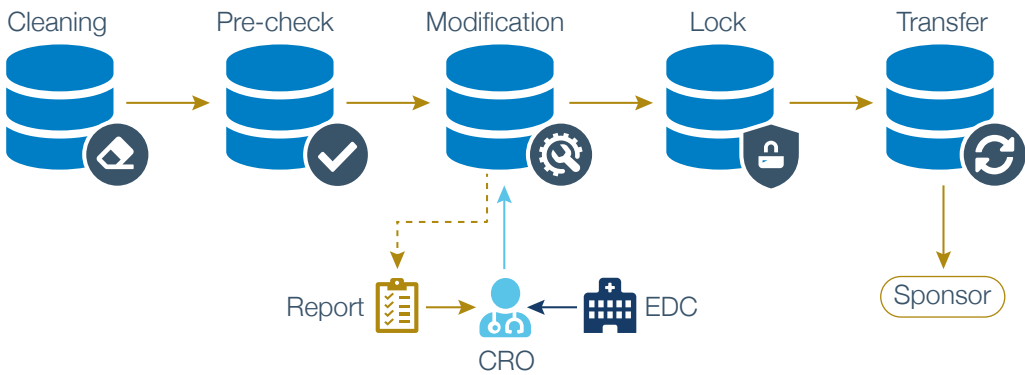
Every study and every sponsor need is unique. Precision's Data Services team answers those needs, establishing specific database parameters and data handling requirements for total data integrity, no matter the study complexity.

**Precision technologies optimize data management**

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



Database lock and reconciliation workflow

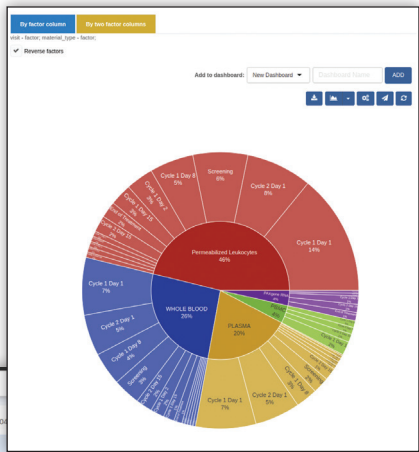


Real-time visibility into project, sample, kit, and shipment status provides 24/7 access to critical study data and activities

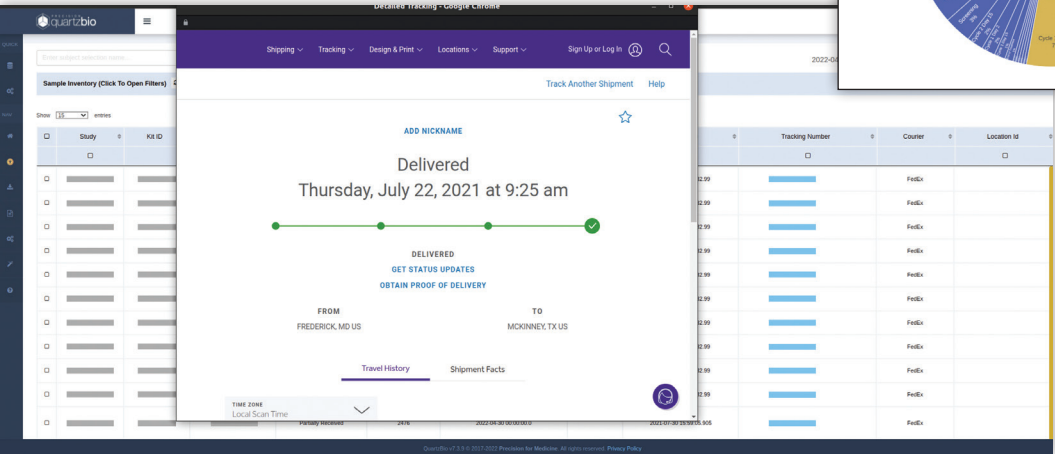


Precision's Lab e-Portal gives sponsors immediate access to study data, sample inventory data, shipment status, and clinical sample collection kit inventories. Track shipment status to know expected arrival times at clinical sites.

- The e-Portal provides:**
- Centralized data reporting and analytics available anytime
  - Continuously updated data
  - Sample inventory reports
  - Kit inventory reports



Inventory query and summary



Kit inventory view and link to shipping tracker

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

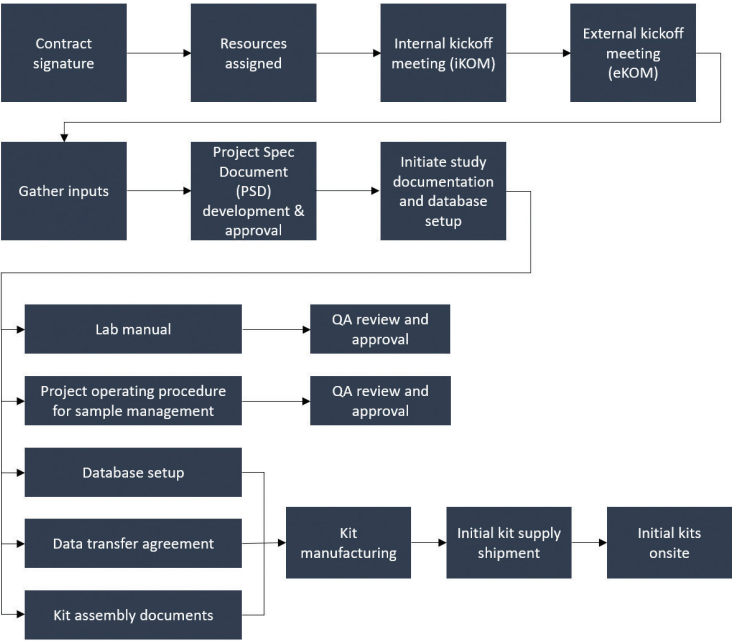


Precision's foundation of strong program management integrates all aspects of a central lab service project and provides:

- 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 development**



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