

## Background

Clinical trial biospecimen management has historically operated outside standard-of-care workflows, relying on manual schedule tracking and specimen databases. In 2022, NYU Langone Health PCC Clinical Trial Office integrated Epic EMR with LabVantage, an enterprise LIMS, to streamline research biospecimen collection workflows and align them with standard clinical lab draws. This integration leveraged Epic schedulable order workflows to create automated research patient visit calendars in LabVantage, replacing older manual processes and improving specimen collection coordination. However, downstream documentation remained inefficient. A FileMaker Pro database was still used to track specimen collection, processing, storage, and distribution through manual entry.

**Operational time studies identified manual database entries as the primary bottleneck:**

- mean entry time of 11 minutes per specimen
- average delay from collection to entry of 60 days
- median delay of 14 days.

These delays contributed to inaccurate freezer inventories, difficulty locating specimens, prolonged quality checks, delayed sponsor query resolution, and delayed biospecimen activity reporting.

### KEY PROBLEM

Legacy specimen documentation depended on manual FileMaker entry after collection, creating major delays between collection and database availability. This limited real-time visibility into specimen status, freezer location, and operational metrics.

**11 MINUTES**

Mean entry time per specimen

**60 DAYS**

Avg delay to create entry

**14 DAYS**

Median delay to create entry

## Goals

Replace the FileMaker Pro specimen database with a customized clinical trial specimen management platform in LabVantage to:

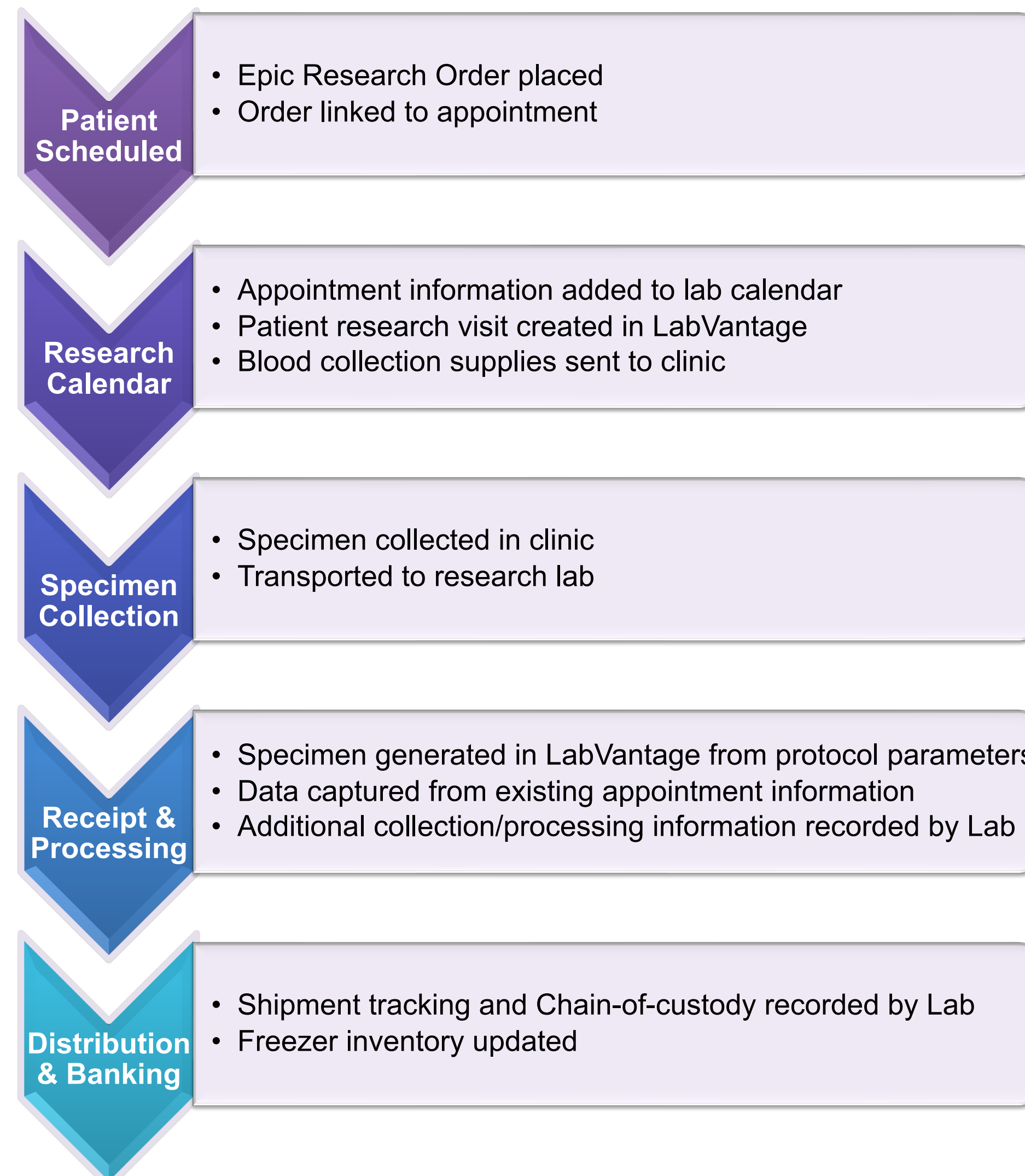
- Reduce manual data entry time
- Enable real-time recording of research visits and specimen collection
- Eliminate delays in maintaining up-to-date specimen records
- Improve freezer inventory accuracy
- Improve biospecimen activity reporting

## Solutions and Methods

In 2024, LabVantage was customized to support clinical trial specimen management using the existing Epic-integrated workflow foundation.

**Key build requirements included:**

- Generate trackable specimens based on protocol-defined parameters
- Associate specimens with existing patient-specific Epic appointments and orders
- Leverage demographic and appointment information from Epic research visit calendars
- Customize fields for clinical trial lifecycle tracking
- Capture third-party laboratory identifiers
- Document shipment conditions and tracking
- Record custody transfers and internal chain-of-custody
- Track specimen processing status
- Optimize electronic freezer inventory functionality
- Enhance reporting for dynamic metrics



## Outcomes

In 2025, LabVantage customizations enabled staff to generate trackable specimens directly from existing patient research visits. Patient demographic, appointment, and protocol-specific specimen parameters are pre-filled during specimen receipt and processing in the research laboratory.

**Additional fields were created to capture:**

- Shipment and distribution details
- Central lab requisition identifiers
- Internal chain-of-custody tracking

The Manhattan team is currently piloting the workflow with investigator-initiated trials.

### BEFORE

- Email/excel and manual workflows used for specimen coordination
- FileMaker pro specimen tracking and manual, delayed entry after collection
- Inaccurate freezer inventory
- Delayed/unreliable reporting & metrics

### AFTER

- Integrated Epic + LabVantage workflow
- Specimens generated from research visits with real-time data entry
- Chain-of-custody/shipment tracking
- Improved freezer inventory visibility
- Enhanced reporting & metrics

**36%↓**

Decrease in mean time per entry

**98%↓**

Decrease in collection-to-entry time

**1 DAY**

Maximum delay to create entry

## Lessons Learned & Future Directions

Reliable biospecimen management and lifecycle tracking are feasible and crucial for ensuring high-quality, reproducible research, sample integrity, and operational efficiency. Streamlining high-volume clinical trial specimen management requires a system that integrates:

- Patient demographics
- Appointment information
- Protocol-driven specimen workflows
- Real-time data entry

**Next steps include:**

- Training and implementation across all NYULH cancer centers
- Expansion across all clinical trials
- Patient tracking with automated scheduling notifications
- Bi-directional EMR integration for point-of-care data capture
- Enhanced dashboard reporting for comprehensive biospecimen metrics

