CASE STUDY

Emerging Biotech Saved Over $300,000 on Phase I Oncology Trial with Slope

Operational efficiencies, data integrity, and savings enabled advancement of clinical program during economic uncertainty

Slope is a global provider of biospecimen lifecycle software, data, and services for clinical trials.

With a focus on tech-enabling the full biospecimen lifecycle, Slope offers expertise that empowers sponsors to make informed decisions using high-quality, real-time sample data. Slope has supported thousands of the most complex, sample-intensive trials worldwide and has been adopted by nearly 80% of NCI-designated cancer centers.

To learn more, visit SlopeClinical.com

Emerging Biotech Saved Over $300,000 on Phase I Oncology Trial with Slope's Biospecimen360™ Software

Operational efficiencies, data integrity, and savings enabled advancement of clinical program during economic uncertainty

$81,452
savings with full oversight of sample journey

100%
traceable chain of custody for samples

ZERO
study delays due to sample loss

87%
site supply utilization

40%
reduction in supply waste

$308,507
consolidated cost savings

CUSTOMER PROFILE

A US-based, emerging biotech organization with highly complex, sample-intensive Phase I Oncology programs

The Challenge

The emerging biotech was facing operational difficulties within its Phase I Oncology programs because of its complicated designs and sample requirements. Each study had an intricate network of clinical sites, a detailed clinical sample schema, multiple external sample destinations, and required shipping conditions. This was compounded by economic pressures and supply chain inefficiencies during the COVID pandemic.

Relying on manual processes for clinical inventory, resupply, and sample management strained the supply chain and impacted the company's ability to control costs. Without the ability to track clinical inventory usage at the site, the biotech sent all the required kits for the entire length of the trial at study start, contributing to supply waste due to expiration or having too many of the wrong kits. On the flip side, not enough of the right kits for the patient visit hindered patient enrollment and retention.

The biotech also lacked visibility and control over the entire sample journey, from laboratory kit use through receipt of all individual samples at the lab. Samples provide crucial data for safety and efficacy, and are necessary for advancing clinical programs. Without monitoring the full sample journey, the biotech was at risk of regulatory issues, protocol challenges, and lost data integrity.

The Solution — Why Slope?

The emerging biotech needed a way to simplify and automate current processes for managing and mitigating risk surrounding clinical inventory (laboratory kits, medical devices, ancillary supplies) and biological samples.

Slope's Biospecimen360™ software transforms chaotic biospecimen operations into protocol-specific workflows for sponsors, CROs, clinical research sites, and labs. All key stakeholders have real-time access to the sample journey, eliminating the black box between the time of sample draw at the site to receiving a report from the lab. Operational workflows are aligned with the protocol, empowering the sites to use the right inventory for each visit and for each patient. In contrast, other systems tend to have data visibility lags. With Slope, trials are delivered on time, on budget, and with data integrity.

The company partnered with Slope to understand the real-time status of clinical trial activities, uncover risks, and reduce supply waste and operational expenses.

> **"We needed a way to manage samples that didn't involve piecing together data from disparate sources, only to find out that there were still gaps. For all of our studies, Biospecimen360™ helps us mitigate risk by giving full insight into the status of samples at every stage of their lifecycle — from site collection to arriving at their destination. I would recommend B360™ to any Phase I program with sample management needs!"**
>
> — Sr. Director, Translational Medicine

Key Financial and Operational Results

To quantify the ROI of Biospecimen360™, a comparison was made between two oncology studies of similar design, led by the same clinical operations team at the emerging biotech — one study using manual processes, the other leveraging B360™.

ABOUT THE STUDIES

Phase I, US-only

Indication: Oncology

Design: 3×3 dose escalation

Number of escalation sites: 8–10

Estimated enrollment time: 36 months

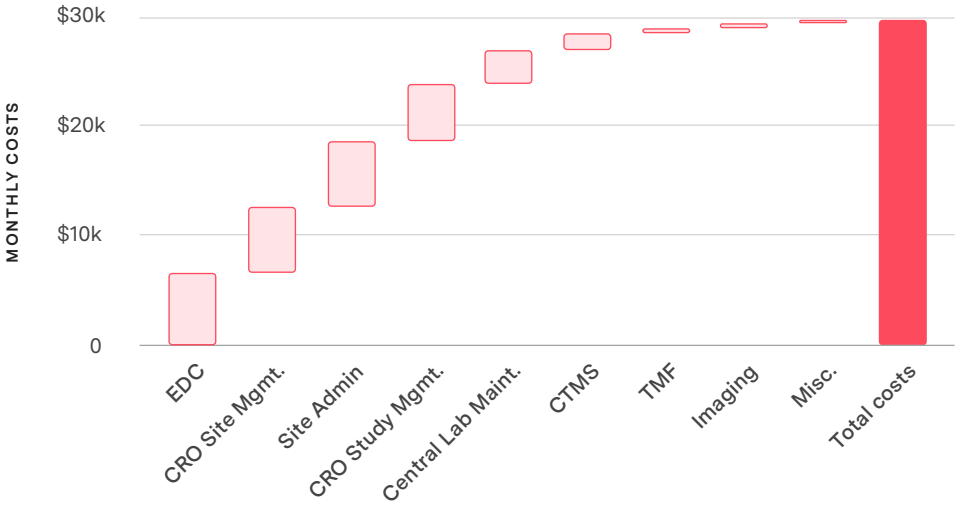
Protocol amendments: multiple

Laboratory: multiple analytical labs

Biosampling: genomics, pharmacokinetics, pharmacodynamics, biomarker, tissue

Clinical inventory: lab kits and shipping supplies provided

Monthly Costs of Study Delay with Manual Processes



$88,800

Cost of 3-month delay

Preventing Study Delays

Both studies had multiple protocol amendments. The study that leveraged manual processes had three separate month-long delays that were attributed to clinical supply and biospecimen issues. The monthly cost of the delay was $29,600, or a total of $88,800 over the 3 months. The study that leveraged Biospecimen360™ did not incur any costs for supply- or sample-related delays. Additional time of sponsor staff and associated salaries and benefits were not quantified in this analysis, and would add to the overall cost.

Preventing Patient Replacement

Finding and enrolling patients in the beginning of a study is more expensive than monitoring them throughout the study. If patients have to be replaced, it will increase costs and the study will likely be delayed. The study that leveraged manual processes had to replace three patients due to clinical supply or biospecimen issues or late-identified non-evaluability with one of these replacements. That resulted in a month-long escalation delay and additional subject visits for the non-evaluable patient remaining in the study. The study that leveraged B360™ did not have to incur any costs for patient replacements.

Patient Replacement Costs

Prior to enrollment

$9,400

Estimated screening costs of two patients prior to enrollment in clinical trial

Post-enrollment with 1-month delay

$48,300

Estimated cost of one patient after four visits, replacement screening, and 1-month delay[1]

Sample Chain-of-Custody Cost Savings by Using Biospecimen360™

Manual tasks performed by sponsors, CROs, sites, and lab staff to oversee and demonstrate sample chain of custody and reconciliation were reviewed. These efforts were quantified using the automation factor that Biospecimen360™ provides, which resulted in direct cost savings.

Phase I Oncology - 30 Subjects - Sample Chain-of-Custody Cost Savings by Using B360™ - Research Site

Research site workflows	Hours	Platform automation factor[2]	Savings (hours)	Average hourly	Total cost savings
Collection, registration and processing of samples	1.5	50%	0.75	$28.21	**$16,994**
Ship sample from site to lab	0.5	50%	0.25		
Documentation of sample collection and completion of required shipment manifests	0.75	85%	0.64		
Monitoring of outbound shipments	0.25	50%	0.12		
Schedule patient visit and maintain inventory	1	75%	0.75		
Total research site hours saved per patient visit			**2.51**	**×30 patients ×8 visits**	

Phase I Oncology - 30 Subjects - Sample Chain-of-Custody Cost Savings by Using B360™ - Sponsor/CRO

Sponsor/CRO workflows	Hours	Platform automation factor	Savings (hours)	Average hourly[3]	Total cost savings
Triage sample collection workflows	0.5	50%	0.25	$62.00	**$81,542**
Ensure representatives ship samples to the correct destination within required time frame	1.0	80%	0.8		
Compile sample reports	1.0	75%	0.75		
Process/review protocol requisitions	0.75	90%	0.68		
Monitor onsite clinical supplies and samples	1	75%	0.75		
Schedule and track inbound shipments	1	75%	0.75		
Schedule and track outbound shipments	1	75%	0.75		
Reconcile sample issues	1	75%	0.75		
Total sponsor/CRO hours saved per patient visit			**5.48**	**×30 patients ×8 visits**	

Phase I Oncology - 30 Subjects - Sample Chain-of-Custody Cost Savings by Using B360™ - Lab Kitter

Kitting services workflows	Hours	Platform automation factor	Savings (hours)	Average hourly[4]	Total cost savings
Acknowledge research site orders and create new lab kit	0.45	100%	0.45	$25.64	**$10,461**
Process representative orders and ship kits, maintain stock levels and confirm order completion	1	100%	1		
Monitoring of outbound shipments	0.25	100%	0.25		
Total kitting services hours saved per patient visit			**1.7**	**×30 patients ×8 visits**	

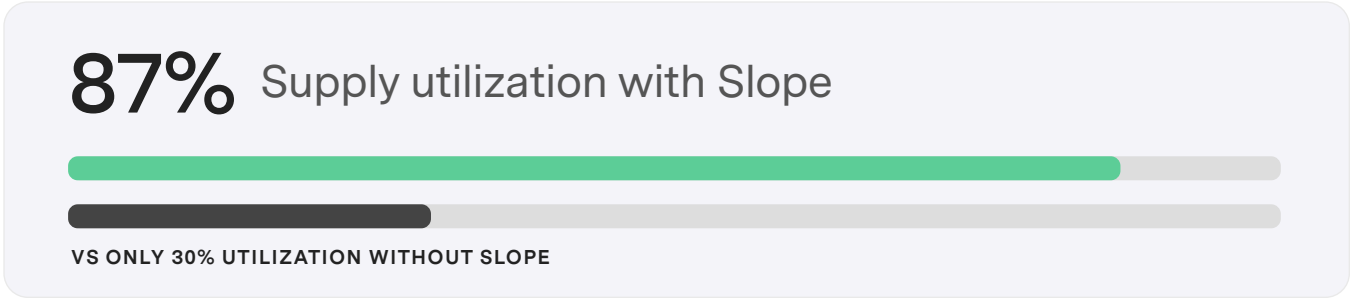
Clinical Inventory and Data-driven Resupply

Biospecimen360™ tracks clinical inventory needed for a clinical trial, including those at the sponsor, supplier, research sites, or in transit. It makes sure that the right amount of lab kits are available when needed, avoiding waste and preventing research sites from running out of supplies. This real-time analysis helps predict future supply needs and prevent overloading research sites at the start of a study.

The data-driven inventory and resupply capabilities have several cost benefits.

1. **Less waste** - Using Biospecimen360™, the biotech company was able to use 87% of the supplies given to research sites, compared to only 30% when they used manual methods. This means they were able to avoid wasting a lot of money on unused supplies.
2. **Fewer upfront costs** - Clinical supplies can be procured on an as-needed basis rather than purchasing and shipping bulk supplies at the start of a program. This approach can save money by avoiding unnecessary purchases and the cost of storing excess supplies.
3. **Rushed shipping** - Biospecimen360's data-driven replenishment of clinical supplies cuts down on the number of costly rush shipments. Last-minute lab kit or ancillary supply orders may occur if sites have difficulty in inventory management or expiring lab kits, both of which are mitigated by the leveraging patient demand to inform resupply.

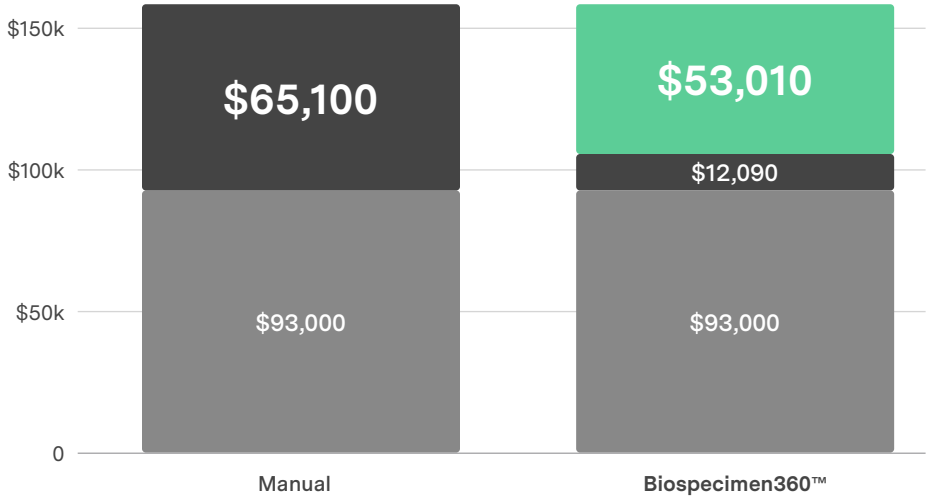
For purposes of this analysis, waste was defined as non-enrollment, expiration, excess supply, and/or loss.



See below how clinical supply waste drives clinical trial cost.

Phase I Oncology - Clinical Supply Savings - 24 Months

Consolidated Savings from B360™ Implementation

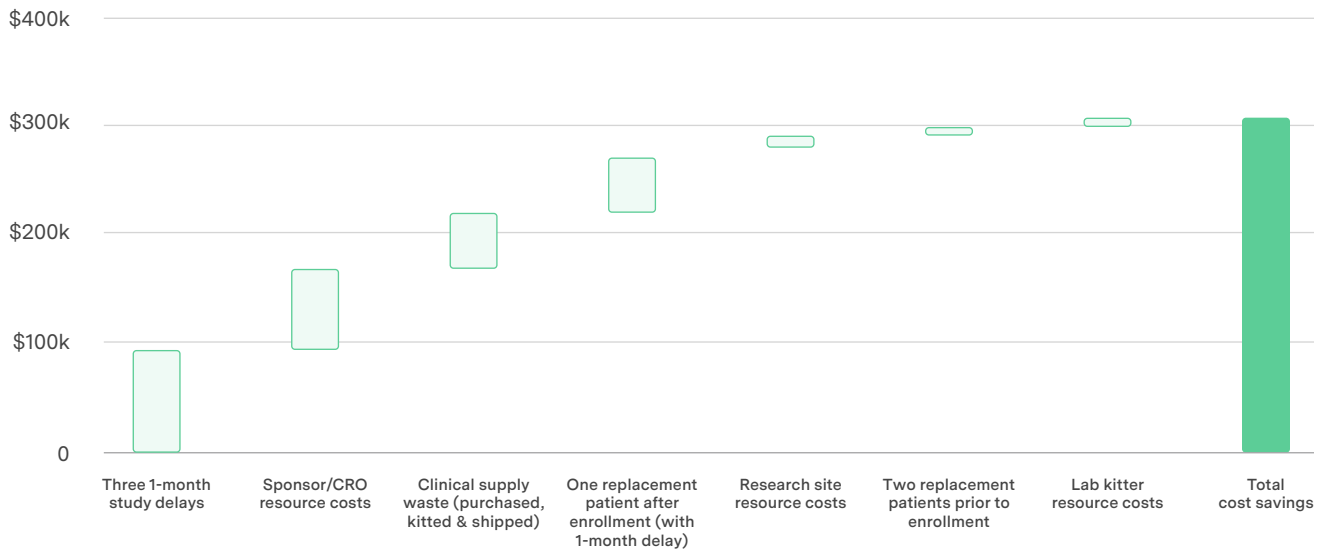


40%

Waste reduction with B360™

Savings
Waste
Clinical inventory

The chart shows how much money was saved by using Biospecimen360™ during a Phase I Oncology clinical trial, compared to the cost of a similar trial using manual processes.



$308,507 Consolidated study cost savings

Additional Benefits of Biospecimen360™

The complexity of clinical trials and economic challenges have created stress for sponsor companies. These include regulatory requirements, data collection & integrity, lack of resources, and staff morale. A proactive approach using the Biospecimen360™ can address these risks and contribute to successful biospecimen lifecycle management — not only in terms of cost savings, but also in terms of risk mitigation for all stakeholders.

Risk Mitigation

Biospecimen360™ will directly mitigate risk in at least four ways:

- Fosters collaboration
- Provides real-time visibility
- Demonstrates traceable chain of custody
- Ensures trial compliance

Collaboration

One of the biggest risks in complex clinical trials is poor coordination among collaborators, which can lead to issues with data quality and availability. The traditional methods of communication and oversight, such as manual project management, spreadsheets, phone calls, and site visits, are inadequate and lead to confusion and dissatisfaction among collaborators.

Biospecimen360™ is designed to improve collaboration and coordination among all clinical trial stakeholders including sponsors, CROs, research sites, labs, and suppliers. By providing real-time data on clinical trial activities, it allows for transparency and improves performance and satisfaction among all stakeholders. This can lead to better resource planning and productivity, and ease the risk associated with clinical supply coordination.

Real-Time Visibility

Regulatory requirements dictate that sponsors must have full visibility and provide documentation of clinical trial progress, including the status of clinical supplies and lab samples. The traditional method for compiling this documentation is for clinical professionals to manually track and manage data, which is difficult and time-consuming, especially with limited resources and more requirements.

Biospecimen360™ offers a systematic, real-time solution for complete visibility of clinical supply progress. It eliminates the need for data consolidation by providing one central location for all data, and allows the full journey of clinical supplies to be tracked from receipt to conclusion of the program. It also provides systematic, repeatable, and documentable workflows for all collaborators to follow throughout the clinical trial.

Traceable Chain of Custody

Sponsors must document the whereabouts of all biological samples to prove chain of custody. Gaps in knowledge about a sample's lifecycle can lead to it being considered unusable during an audit, wasting time and resources. Manual processes, such as spreadsheets and handwritten notes — for handling, storage, and coordination of samples — can lead to errors and threaten the integrity of the trial's data.

Biospecimen360™ provides data that trace biological samples throughout their lifecycle and maintains a record of each step. Through this data, a sponsor can prove that a biological sample is valid and has not been tainted.

Protocol Adherence

Sponsors must ensure data integrity and clinical trial protocol adherence, but the complexity and frequency of amendments make this difficult. The onus is placed on the sponsor to ensure all collaborators — including research sites and suppliers — are performing as the protocol requires. Sponsors will create operational manuals to accompany the protocol, and will use staffing resources such as comparing varying data sources or physical monitoring, all to counteract potential non-compliance. Manual processes and relying on staffing resources can lead to errors and wasted time.

Biospecimen360™ is designed for a specific protocol, and ensures protocol adherence through any trial changes and amendments. Sites are empowered with software-guided workflows to always choose the right kit, for the right patient, at the right time.

Financial Summary and Key Takeaways

Through the implementation of Biospecimen360™, the emerging biotech was provided with ROI through risk mitigation, with a fully traceable chain of custody for samples and decreased planned and unplanned costs. **The biotech netted an estimated savings of $308,507 in the study leveraging B360™.**

ROI from implementation of Biospecimen360™

PREVENTING DELAYS AND UNFORECASTED PATIENT COSTS

Preventing clinical research study delays

$88,800

for three months of delay

Preventing patient replacements

$57,700

in average unforecasted costs

DECREASING STUDY RECONCILIATION TIME AND RESOURCES

$16,994

per research site

$81,542

per sponsor

$10,461

per kitting services

AVOIDING SUPPLY WASTE

Decreasing waste by approximately

40%

while providing more efficient procurement

saving an estimated

$53,010

in total clinical supply costs

Implementing a platform mitigates risk through fostering collaboration between stakeholders, providing real-time visibility into clinical supplies, demonstrating a fully traceable chain of custody, and encouraging compliance.

Key Takeaways

- Implementing Biospecimen360™ creates cost-savings
- Implementing Biospecimen360™ mitigates risk
- The combination of cost-savings and risk mitigation delivers ROI

> Biospecimen360™ is a vital tool for sample management. I've been a part of multiple Phase I clinical development programs/studies using B360™. Each study had a complex network of clinical sites, along with a complex clinical sample schema which included multiple external sample destinations and required shipping conditions. As those working in clinical development know, this can be a recipe for disaster getting precious clinical samples safely, within stability, to their final destination.
>
> Biospecimen360™ mitigates those risks by giving full insight into the status of the samples at every stage of their lifecycle — from site collection to arriving at their destination.
>
> I would recommend B360™ to any Phase I program with sample management needs!

— Sr. Director, Translational Medicine

> **Traceable chain of custody**
>
> Biospecimen360™ gave us confidence that all patient samples were collected as mandated by the protocol and allowed us to see where they were at any given time, whether at the site, in transit, or at the receiving lab. This gave me the assurance that sample-related study objectives and endpoints could be addressed.

— Director, Clinical Operations

> **Reconciliation efforts**
>
> Biospecimen360™ was invaluable when preparing for dose escalation meetings. Through filterable reports and real-time alerts, the software allowed us to pinpoint exactly what was missing and where we needed to go to find it so we could support dose escalation with a complete data set. Prior to B360™, this would have been a completely manual process for the team.

— Director, Clinical Operations

Request a demo of Biospecimen360™

SlopeClinical.com/request-demo

FOOTNOTES

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[1] Assumes the best case that the initial patient is in the DLT period with weekly dosing and simple assessments at treatment visit. In addition, a new patient can be identified within 1 month.

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[2] The automation factor is calculated through the average amount of manual time spent on a task that is replaced by platform efficiencies. In order to have the most realistic hourly rates, the average Salary/Hourly is based on data from Salary.com, Glassdoor.com, Zip-Recruiter.com on the lowest positions that could perform the task. The hourly salary costs are not burdened. If burdened costs are used, cost savings could be 33% higher or more depending on location and other factors. In addition, in order to provide a conservative automation number the median number of visits (8 per patient) was used to account for patient attrition.

[3] In order to have the most realistic hourly rates, the average was known for this resource; however, the lowest salary of the person performing the role was used as a conservative estimate. The hourly salary costs are not burdened. If burdened costs are used, cost savings could be 33% higher or more depending on location and other factors.

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[4] In order to have the most realistic hourly rates, the average Salary/Hourly is based on data from Salary.com, Glassdoor.com, Zip-Recruiter.com on the lowest positions that could perform the task. The hourly salary costs are not burdened. If burdened costs are used, cost savings could be 33% higher or more depending on location and other factors. In addition, the number of visits was averaged to account for patient attrition.