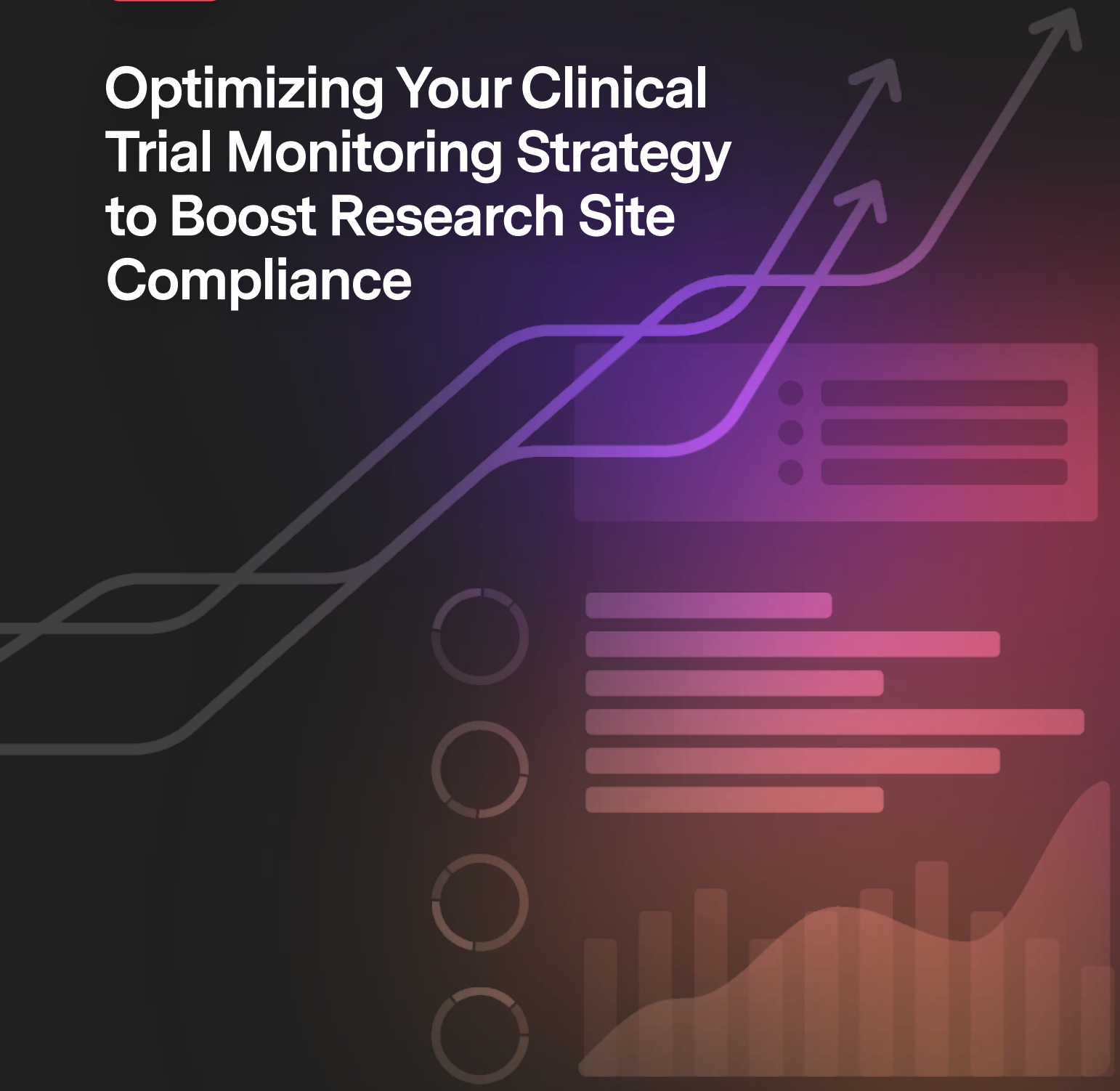
E-BOOK

Optimizing Your Clinical Trial Monitoring Strategy to Boost Research Site Compliance



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INTRODUCTION

Optimizing Your Clinical Trial Monitoring Strategy to Boost Research Site Compliance

Sponsors who are at the helm of clinical trial operations are responsible for crafting a robust monitoring strategy for every clinical trial. Part of their mission is to implement plans and solutions that safeguard patient well-being, ensure the accuracy and completeness of trial data, and facilitate compliance with both currently approved study documents and regulatory requirements.

The reality is that the modern landscape of clinical research makes monitoring a daunting task. Outdated paper-based processes and a lack of standardization put research sites at greater risk for missed biospecimen collections, sample mishandling, and incomplete or erroneous data entry.

What's more, data lag and a sprawling network of clinical systems and vendors hinder real-time oversight by sponsors and CRAs. Sponsors are often left to manually piece together the biospecimen lifecycle or rely on clinical systems that are limited in their capabilities, making the timely identification of study trends, issues, and risks nearly impossible.

This guide considers the most common research site compliance challenges, prevalent pitfalls in traditional clinical trial monitoring strategies, and the ways in which sponsors can optimize their monitoring plans to improve biospecimen compliance, data integrity, drug development timelines, and patient outcomes.

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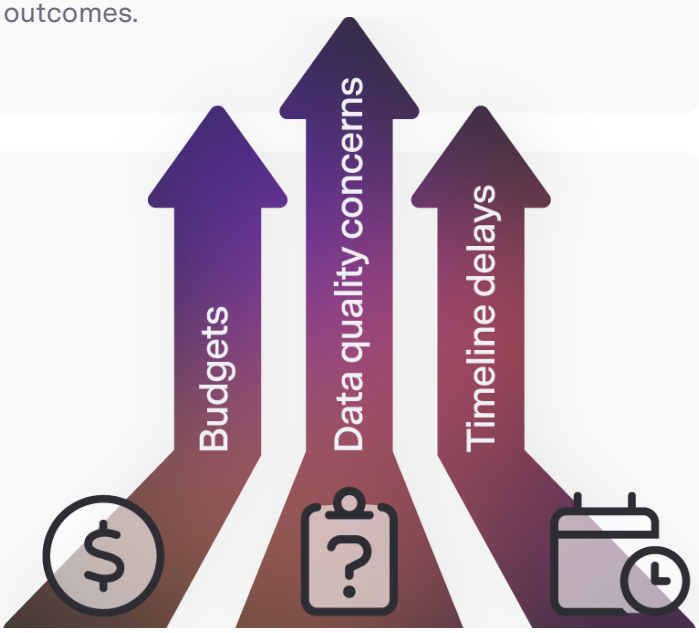


Exploring Critical Research Site Compliance Issues That Necessitate Monitoring

Protocol deviations and missing or inconsistent data are significant contributors to data integrity issues on a clinical trial. When research sites deviate from approved study documents or standard processes, vulnerabilities emerge, posing risks to trial integrity and impeding crucial study milestones — from screening and enrollment, to dose escalation decisions and database locks. This in turn can stifle drug development, wreak havoc on study budgets, and most notably, harm patients.

So **where does research site compliance typically falter?** An estimated 95% of biopharma professionals have experienced an increase in clinical trial budgets, timeline delays, or data quality concerns as a direct result of clinical inventory or bio-sampling issues at their research sites.[1]

Lab kit management

Traditionally, the majority of research sites rely heavily on paper-based processes and spreadsheets to manage their lab kits. Not only do most research sites lack a standardized process for managing clinical inventory amongst each other, but even within research site organizations it's common for study coordinators to have their own distinct processes for managing on-hand inventory and ordering.

Oftentimes reliant on paper-based processes and spreadsheets, research sites grapple with the challenge of maintaining a standardized approach to clinical inventory management. Within organizations, it's common for study coordinators to champion their own distinct processes for managing their on-hand inventory and resupply requests for lab kits. Because this is often a decentralized and highly manual process, site personnel may have trouble locating on-hand supplies, tracking lab kit expiration dates, or ordering more lab kits when needed.

Today's complex studies also demand sophisticated kitting schemes. Imagine having to manage several lab kit types for every study — including visit-specific lab kits for various cohorts and study arms; unscheduled visits; and more. These conditions put site personnel at a heightened risk of pulling the incorrect lab kit for a visit, or being short-handed on lab kits that are needed for imminent patient visits — especially when these lab kits are often subject to manual oversight.

Misinterpreting study documents puts patient samples at risk.

Sample management

Research sites often lean on static or templatized lab manuals for the nuanced tasks of collecting, processing, storing, and shipping patient samples. Unfortunately, lab manuals tend to be dense in nature, increasing the likelihood that site personnel may accidentally overlook

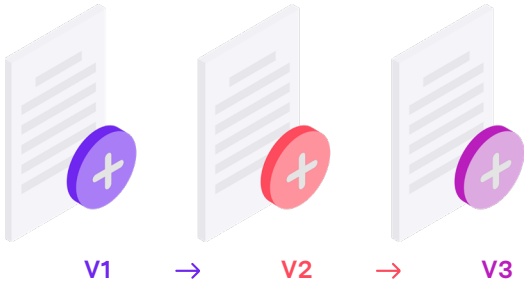
a critical sample collection or misinterpret a sample handling instruction. Under these traditional workflows, there is no way to enforce guardrails that would otherwise minimize the risk of protocol deviations before they occur.[2]

> **Early-phase studies that are more sample-intensive in nature often require several biospecimen collections for each patient visit. Multiply that across several patient visits in one day across several trials and sponsors, and it's easy to see how research sites are prone to making mistakes.**

Complex clinical trial plans and designs that are necessary in today's clinical research landscape also have downstream effects on sample collection schemes, putting research site personnel at a greater risk of committing accidental oversights. Conditional and reflex testing, which hinges on samples being collected or testing being performed when certain conditions are met, also complicates the sample journey.

Let's also consider the common characteristics of studies at various phases, and how these attributes may impact research site operations. Early-phase studies that are more sample-intensive in nature often require several biospecimen collections for each patient visit. Multiply that across several patient visits in one day across several trials and sponsors, and it's easy to see how research sites are prone to making mistakes.

High-enrolling late-phase studies may be less complex in nature from a bio-sampling perspective, but they are also susceptible to error due to the high volume of patients that may be enrolled on the same trial. Some sponsors may be familiar with cases where multiple patients were seen on the same trial on the same day, and their samples get swapped. Patient ID errors can be detrimental, as they invalidate lab testing.



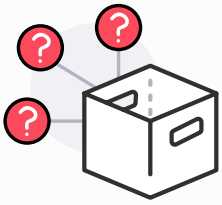
Protocol amendments and other study changes

Enforcing compliance with lab kit management and sample management also necessitates a comprehensive strategy for enforcing compliance with protocol amendments and other study modifications. Study changes that may impact research site operations include, but are not limited to: addition or removal of a lab kit; modification of a lab kit (in the form of collection supplies being added or removed, or requisition form changes); and procedural changes (i.e. changes to shipping frequency, shipping destination, processing instructions, etc.).

These modifications, which can be either significant or subtle in nature, increase the likelihood of site compliance errors. If sites continue to use outdated lab kits or older versions of the lab manual that are no longer aligned with current protocol versions, they run the risk of missing critical sample collections, mishandling samples, or otherwise collecting a sample to which the patient didn't consent.

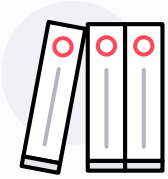
Traditional Approaches to Monitoring Clinical Inventory and Biospecimens Aren't Effective

What common inadequacies of monitoring strategies for clinical inventory and patient samples should sponsors be concerned about?



Lab kit data isn't accurate

Sponsors and CRAs are expected to ensure that lab kit supply is sufficient throughout the trial. Unfortunately, sponsors and monitors often have limited visibility to accurate, real-time lab kit data due to a lack of standardization among sites and limitations in centralized monitoring solutions for kits.



Sample management procedures are difficult to enforce

Sponsors and CRAs are accountable for ensuring that the collection and management of patient samples is in compliance with study documents, including the protocol and lab manual. The reality is that most sites aren't properly equipped with the tools and resources they need to proactively prevent non-compliance with sample management procedures.

Sample tracking requires a lot of manual work

Sponsors need to quickly identify sample compliance issues and performance trends so that they can implement corrective actions to prevent future deviations. For most, sample tracking is an incredibly cumbersome process that relies heavily on emails, phone calls, and searches in disconnected clinical systems to piece together the sample journey.

Protocol amendments & other study mods exacerbate compliance issues

While many sponsors provide site training on study changes that impact lab kits and lab manuals, these methods fall short of guaranteeing that site personnel will follow through with collecting, processing, storing, and shipping biospecimens based on currently approved study documents.

How Does Research Site Compliance Impact Patients and Biospecimen Data?

Missed collections or mishandled samples hinder data integrity and incite patient burden

Sample management errors at a research site can come in many forms. If a site doesn't miss a mandatory sample collection altogether, perhaps they collect a sample but forget it in storage. Perhaps they don't process it correctly, don't label it correctly, or don't ship it to the right place on the right day. These kinds of oversights have downstream implications for data integrity. A missed collection or mishandled sample can amount to a critical data point that's not being captured for a specific patient at a specific visit and/or timepoint.

The implications cannot be overstated. A missing data point could equate to a primary or secondary endpoint for a trial, offering invaluable insight into the safety and efficacy of a treatment. Samples are the backbone of clinical trial data. If a biospecimen can't be tested for any reason, there will be major data gaps.

It's also important to consider the implications for the patient. For instance, if samples that impact patient treatment decisions (such as study inclusion or exclusion) are mishandled, the patient may be denied a potentially lifesaving or life-changing treatment.

Alternatively, a site may be able to bring a patient back in to redraw missed or mishandled samples. But this requires the patient to come back to a facility, sometimes traveling hours or having to take time off work.

Patient samples are precious. They require a lot from vulnerable populations — from children to advanced-stage cancer patients.

Even if bio-sampling gaps can be filled through patient rescheduling, this doesn't negate the reality that the patient had to extend themselves beyond the burden they consented to at the beginning of the trial through no fault of their own. The experience inherently asks a lot of patients — as they navigate a debilitating disease, they are also having to go to regular research visits and endure invasive biospecimen collections for treatments whose safety and efficacy have yet to be proven.

> We should be monitoring patient samples with precision and real-time data access so that we are able to quickly identify compliance issues before it's too late, and prevent compliance issues from happening in the first place.

Patient samples are precious. They're vital to the execution of the trial, but they require a lot from vulnerable populations — from children to advanced-stage cancer patients. That alone should mean that we should be monitoring patient samples with precision and real-time data access so that we are able to quickly identify compliance issues before it's too late, and prevent compliance issues from happening in the first place.

More lab and EDC queries means more data reconciliation

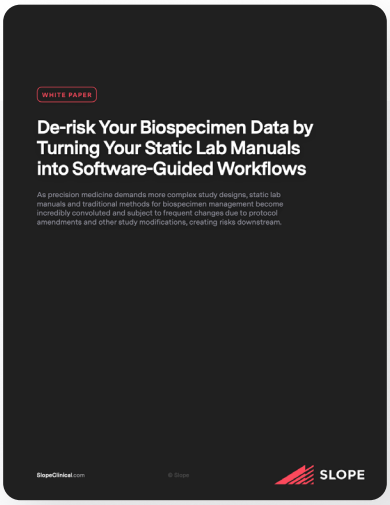
Lab queries stem directly from missing information or discrepancies on requisition forms or biospecimen container labels. These queries can pose serious issues, because they must be resolved before lab results can be reported, samples can be shipped from central labs to third-party specialty labs, and before database locks can occur. Not only can this hold up critical patient treatment decisions, but it may also hinder downstream sample testing, interim and final analysis timelines, and more.

Research site compliance with entering and reconciling data in the EDC also impacts overall data integrity and study milestones. EDC queries may result from missing sample metadata — like collection dates and times and administrative information — or discrepancies between the EDC and other clinical systems (e.g. LIMS).

> **Ultimately, sponsors should explore monitoring solutions that prevent queries from happening in the first place.**

Sponsors look to the EDC as a source of truth about biospecimen data, but data inconsistencies can introduce a lack of visibility to the biospecimen lifecycle. In addition, a higher EDC query rate translates to more time and resources needed for data reconciliation across several study stakeholders — including sponsor team members, site study coordinators, labs, and CROs. This not only has the potential to put unnecessary strain on study stakeholders who are already busy, but it also jeopardizes study milestones.

Ultimately, sponsors should explore monitoring solutions that prevent queries from happening in the first place. When they do occur, sponsors can streamline their access to the information they need in order to resolve the query, enabling critical study decisions, and accelerating preparation for sample analysis milestones and regulatory submissions.



Interested in learning about how Slope can transform your trials? Be sure to check out our white paper on how our software platform can de-risk your trial by turning your complex lab manuals into software-guided workflows.

Download white paper >

THE BOTTOM LINE

Gaps and Delays in Biospecimen Data Are Harmful to Patients and Study Milestones

Patient outcomes, trial decisions, study timelines, increases and reductions in operation costs, and the overall success and speed of drug development hinges on a single variable — data. Without patient samples and the lab kits to collect those samples, trials are dead on arrival.

Patient Impacts

- Inability to perform patient safety monitoring
- Sample redraws
- Visit rescheduling
- Preventable screen fails and dropouts
- Shorter patient life and/ or reduced quality of life

Study Milestone Impacts

- Database locks
- Interim and final analyses
- Scheduled data reviews
- Study expansion
- Regulatory submissions
- Publication timing

Decision Impacts

- Inclusion/exclusion
- Treatment decisions
- Dose escalation
- Amendment decisions
- Funding decisions

Time Efficiency Impacts

- Hours spent each week reconciling lab queries and EDC queries
- Valuable time lost to manual sample tracking and sample investigations
- More on-site monitoring required
- Longer trials

Monetary Impacts

- At least 50-70% lab kit waste that inflates study budgets by thousands
- Larger study budgets due to delays
- Drug approval delays that decrease revenue by millions of dollars
- More on-site monitoring and site training required
- Larger teams and more vendors required to manage studies
- Unable to hit critical funding milestones or raise additional capital
- Patient replacement that costs tens of thousands of dollars per patient

CHECKLIST

Signs That You May Need to Bolster Your Monitoring Plan

Ideally, your monitoring strategy should minimize protocol deviations and optimize your ability to quickly detect compliance issues that put your study at risk.

Here are some common signs you should look for that may indicate that there are gaps in your monitoring plan:

- [ ] Data reconciliation is diverting precious hours from your team or requiring significant vendor support
- [ ] Lab queries are hindering patient treatment decisions, sample shipments, and taking time away from other important tasks
- [ ] Your team is spending hours performing manual sample tracking or sample investigations
- [ ] Database locks are delayed or otherwise down to the wire
- [ ] There are obvious gaps in your visibility to the journey of every sample (e.g. site sample handling activity or sample shipments from central labs to third party labs)
- [ ] Your research sites are having to enter the same data in multiple places
- [ ] You have to look up your biospecimen data in multiple systems and vendor portals
- [ ] Protocol deviations are happening far too often on your trial
- [ ] You're not able to easily surface study trends and site performance metrics
- [ ] You have to spend a lot of time tracking your study milestones
- [ ] Data lag is hindering your visibility to real-time biospecimen data
- [ ] Your visibility to accurate, real-time lab kit data is limited
- [ ] Your study has tens of thousands of dollars in lab kit waste
- [ ] Your study suffers from high percentages of lab testing cancellations due to missed sample collections or sample mishandling
- [ ] Your team and your leadership is having trouble accessing the data needed to make decisions about study conduct, funding, etc.
- [ ] Patients on your trial have had research visits rescheduled due to issues with lab kit management or sample management
- [ ] Patients on your trial have been forced to screen fail, re-screen, or drop out of your trial altogether due to sample management issues

What Factors Influence Clinical Trial Monitoring?

In order to improve your monitoring strategies, it's important to take into account the broader clinical trial landscape and the overarching factors that influence how monitoring — and clinical trials more generally — are conducted.

Let's take a look at **three different variables** that influence the way that sponsors monitor their clinical trial activity.

1 ICH GCP guidelines for clinical trials

Sponsors often look to ICH GCP guidelines to inform their monitoring strategies.

The guidelines are very clear in defining that the purposes of monitoring are to ensure that:

a. The rights and well-being of human subjects are protected.

b. The reported trial data are accurate, complete, and verifiable from source documents.

c. The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

GCP guidelines dictate that sponsors should document their monitoring strategies for every trial in a formal monitoring plan. This plan should be "tailored to the specific human subject protection and data integrity risks of the trial," and should discuss the monitoring methods to be used.

GCP guidelines make notable mentions of leveraging a "centralized monitoring" approach to supplement on-site monitoring with "a remote evaluation of accumulating data, performed in a timely manner." According to the guidelines, centralized monitoring processes can be used to identify missing or inconsistent data, protocol deviations, analyze performance metrics, and more.

The guidelines also discuss incorporating risk reduction activities into monitoring plans, ensuring that "the approach used to reduce risk to an acceptable level should be proportionate to the significance of the risk."

GCP standards offer a comprehensive blueprint for how we can incorporate clinical inventory

and samples into our monitoring strategies. By applying centralized and risk-based strategies to our monitoring of these two factors, we're able to drive efficiencies on our trials and further safeguard the integrity of our clinical trial data.

2 Clinical trial complexity

A robust monitoring strategy should also address the nuances of study complexity, as these nuances put research sites at a heightened risk of compliance issues.

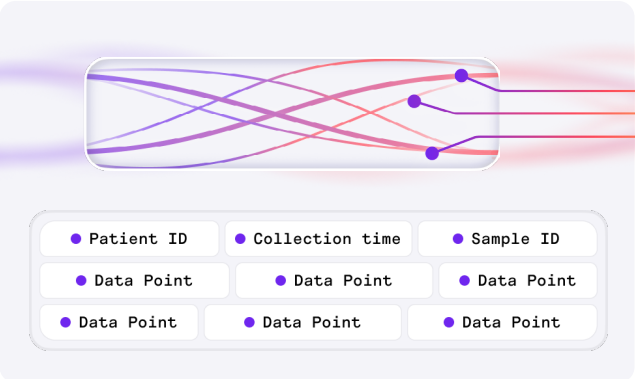
Modern clinical trial designs often call for multiple cohorts, phases, sub-studies, and adaptive trial design elements. These technicalities often require several different lab kit configurations to accommodate complex assessment schedules in the protocol and bio-sampling schemes in the lab manual. For instance, a trial that has four cohorts may require unique lab kits for each cohort's C1D1 visit (i.e. C1D1 Cohort A, C1D1 Cohort B, etc.). Assessment schedules may also include several unscheduled visits that are performed if certain conditions are met. All told, research sites may have dozens of kit types to keep track of for a single study.

Modern clinical trials also require more biospecimen data — the data points that are traditionally collected on lab kit requisition forms, including collection dates and times for different samples and timepoints, and administrative information. These details are directly tied to specific samples for the sake of sample processing, reflex testing, collection dates and times for determining sample stability, and more.

When it comes to biospecimens, bio-sampling schemes may be complex because sponsors are in the stage of drug development where they are trying to prove the safety and efficacy of a drug based on extensive biomarker, safety, and PK data. This inevitably creates a scenario where several samples may need to be collected at a singular patient visit — each with their own unique collection, processing, storage, and shipping procedures.

Modern clinical trials also require more biospecimen data — the data points that are traditionally collected on lab kit requisition forms, including collection dates and times for different samples and timepoints, and administrative information. These details are directly tied to specific samples for the sake of sample processing, reflex testing, collection dates and times for determining sample stability, and more.

Sample metadata is critical to study execution. But because these trials are complex, they require more data points. And because they require more data points, a robust strategy for monitoring this sample metadata is critical to maximizing the completeness and accuracy of this information.



Consider solutions that will give your study teams real-time access to sample metadata

3 Clinical trial vendors

Under the traditional CRO model, the monitoring function plays a significant role in vendor selection. It's not uncommon for sponsors to hire third-party site monitors to support the monitoring plan for their trials. Each site will be assigned to a CRA, who will support all of the monitoring activities, including on-site monitoring, centralized monitoring, etc.

Per GCP guidelines, monitors are responsible for the following tasks, which are of note for the inventory management and sample management conversation:

a. making sure that supplies are sufficient throughout the trial.

b. verifying that research sites are following the approved protocol and all approved amendments.

c. verifying that source documentation is accurate, complete, up to date and maintained.

d. communicating deviations from the protocol, and taking corrective action to prevent recurrence of the detected deviations.

So what are the downsides to traditional vendor monitoring solutions? Not only are they expensive, but there is high turnover with site monitors. Monitors have to do a lot of manual work to verify source documents, and they may not have the resources to quickly and easily identify site performance metrics and real-time sampling compliance issues. Monitors also introduce an additional barrier between the sponsors and the sites — which, while not inherently a negative, may cloud sponsor visibility to the real-time research site data that sponsors need in order to make critical decisions about their trial. Having that additional degree of separation can introduce inefficiencies.

Vendors include more than just CROs — they also include the various systems involved in monitoring a trial. Sponsors need to be able to quickly monitor data in order to quickly identify notable trends and potential research site compliance issues. In order to surface that data, sponsors rely on various systems, including the EDC to access biospecimen data from the research sites. The downfall to this approach is that there is data lag with the EDC, where it can take sites several days — if not weeks — for sites to enter data into the EDC.

Sponsors will also use LIMS data to access biospecimen data, including central lab portals, specialty lab portals, and more. Lab systems also have inherent limitations that inhibit access to useful data to sponsors. Ultimately, labs aren't in the business of building systems — they're in the business of testing samples and transferring the raw data to sponsors. From a systems perspective, LIMS data is not incredibly reliable as a source for monitoring research site activity. To make matters worse, sponsors are working with several lab vendors on a single trial — meaning that sample management and ClinOps teams are having to manually piece together biospecimen data across several LIMS to obtain data for their samples.

58% **of biopharma professionals report that their research sites miss required sampling timepoints or have misplaced patient samples at least three times per month**[3]

How Can a Clinical Trial Execution Platform Augment My Monitoring Plan?

Sponsors can improve data integrity and accelerate their trials with the help of a clinical trial execution platform that streamlines and guides inventory and sample management workflows across all of their sites.

Prevent deviations before they happen, while also monitoring real-time biospecimen data — enabling better, quicker decision-making, expedited study and drug development timelines, lower operating expenses, and the best possible patient experience.

Standardize site processes across your entire trial or program

A clinical trial execution platform relies first and foremost on formalizing a singular process for managing clinical inventory, patient samples, and sample metadata across all sites who are performing the work for a trial or program.

Use technology to supplement research site training

Educating sites on sample management procedures can only go so far in setting up sites for success. They also need access to tools that facilitate and streamline their operations.

Focus your monitoring efforts on lab kits and samples

Samples are the linchpins of clinical trial data. Ensuring that they are properly managed — and that sites have the supplies they need to collect the samples — will only make your trial more efficient and successful.

Implement a strategy that sites will willingly adopt

These days, sponsors are often weary of imposing technology on sites — especially with all of the tech that already exists in this space. Consider a clinical trial execution platform that not only benefits you as a sponsor, but actually helps sites do their jobs better. They will thank you.

Ditch data lag and duplicate work by connecting various clinical systems

So many monitoring activities rely on reconciling and sifting through various systems, like EDC, IRT, and LIMS. Consider a solution that brings data from these disconnected systems together so that you have a singular source of truth for data.

Centralize and accelerate your monitoring of critical activity and trends

Digitally accessing data in real time can reduce the need for on-site monitoring, drive efficiencies, and surface insightful data about site performance.

INTRODUCING SLOPE

The solution that enables real-time access to high-quality biospecimen data

Slope's clinical trial execution platform enables sponsors to help their research sites be **more efficient and compliant** on their trials.

The platform's sample management solution dramatically improves day-to-day site operations by transforming static lab manuals into software-guided workflows that make it easier to collect, process, and ship biospecimens the right way during patient visits, while automatically capturing critical patient sample data. With Slope, sponsors are empowered to know the history of every specimen, spend less time reconciling data, and keep their research sites up to date with study-specific changes, so that they have improved access to the data they need in order to make critical study decisions.

Slope's clinical operations team uses the lab manual to configure guided workflows for all sites who are participating on the trial so that sponsors can empower their sites to be set up to perform study activities in Slope from Day 1. The software can also automatically roll out study amendments to sites as soon as they receive approval to perform study activities under the latest version of the protocol.

- Our **centralized inventory management system** integrates with third-party kitters and enables sponsors to standardize site processes for tracking lab kits and other supplies, reducing waste by up to 40% and granting sponsors additional oversight
- **Guided sample workflows** replace static lab manuals with software-based workspaces that facilitate sample collection, processing, storage, and shipment
- **API integrations** facilitate automatic, real-time data transmission between EDC, LIMS, IRT/RTSM, couriers and other clinical systems, so that the entire biospecimen lifecycle lives in one place
- Our **sponsor dashboards and enhanced search capabilities** enable users to access reports or drill down into specific data by protocol, inventory type, site, subject, visit, samples, shipments, alerts, and more
- The **sample journey view** brings the sample audit trail and chain-of-custody data together so that sponsors can track samples in real-time

Sites love Slope.

Slope supports unparalleled site adoption across all therapeutic areas, including 75%+ of NCI-designated cancer centers.

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THE UNIVERSITY OF ARIZONA Cancer Center
Penn Medicine ABRAMSON CANCER CENTER
City of Hope
Baylor College of Medicine
DF/HCC DANA-FARBER / HARVARD CANCER CENTER
Dartmouth GEISEL SCHOOL OF MEDICINE
Dartmouth Health
INDIANA UNIVERSITY SCHOOL OF MEDICINE
UNIVERSITY OF UTAH HUNTSMAN CANCER INSTITUTE
NYU Langone Health
Duke Cancer Institute
UNIVERSITY OF IOWA HOLDEN COMPREHENSIVE CANCER CENTER
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O'NEAL COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MINNESOTA Driven to Discover
VANDERBILT-INGRAM CANCER CENTER
Yale SCHOOL OF MEDICINE

> **Slope is a game changer for our site.** It allows us to track patient samples from collection to central lab delivery with ease. We can easily lookup by study, date, and study tubes that were sent and the location."

— Carrie Smith, RN

Chief Operations Officer,
Gabrail Cancer and Research Center

> Our site receives and utilizes thousands of kits from our clinical trial sponsors. **Slope allows us to organize our inventory by disease team, view our inventory anytime, any place, and quickly reorder low inventory.** Supplying our sponsors with reports of current inventory is effortless with Slope."

— Carolyn Lane

Chief Research Laboratory Manager,
Arizona Cancer Center

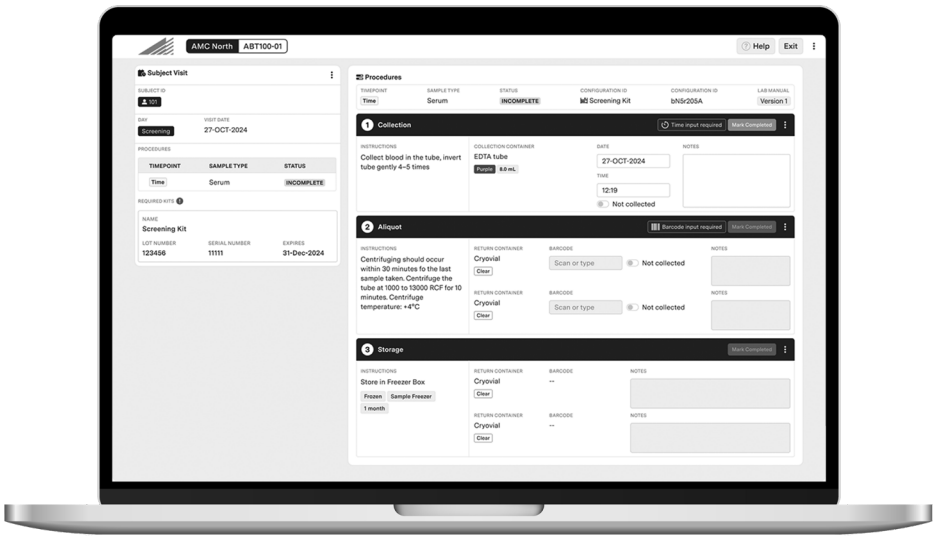
> **Slope has been a great tool to help manage our clinical trial supplies. It's easy to use and helps the teams stay organized!"**

— Jamie Voyten

Senior Clinical Research Manager - Lab,
UPMC Hillman Cancer Center Clinical Research Services

See Slope in Action.

Connect with one of our experts to explore how Slope can help you revamp your monitoring strategy and improve site performance.



Request a demo of Slope's Clinical Trial Execution Platform

SlopeClinical.com/request-demo

FOOTNOTES

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[1] State of Clinical Inventory and Sample Management for Clinical Trials, 2023

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[2, 3] White Paper: De-risk Your Biospecimen Data by Turning Your Static Lab Manuals into Software-Guided Workflows, 2023