WHITE PAPER

The Value of Turning a Static Lab Manual into Software-Guided Workflows

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SLOPE

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Executive Summary

If we think of clinical trial execution as a sport, then the lab manual is the playbook that translates the design of a study into actionable sample management processes. For clinical research sites, who are on the front lines of patient care, this descriptive document outlines every step of specimen management in their purview — from pulling clinical supplies to preparing a shipment. Study coordinators, nurses, and lab technicians rely on these detailed procedures to guide them through a patient visit. At face value, the lab manual is a crucial resource; but in the modern landscape of clinical research, the utility of this static document has been bogged down by complex and ever-changing study designs. This white paper sheds light on the lab manual's current role in sample management, the inherent risks and challenges with traditional approaches, and the ways in which research sites can leverage technological innovations to completely revamp their operations across all of their studies.

The Current State of Sample Management from the Site Perspective

Complicated specimen management schemes have proliferated in response to innovations in precision medicine. Personalized approaches to patient care require specialty assays, a greater body of diverse data, and specific conditions that dictate when and how a patient can be enrolled, tested, and treated. These tailored approaches to clinical research are as exciting as they are necessary for scientific advancement, but their implications for study execution should be considered — especially when it comes to site operations.

For clinical research sites, these nuances in study design yield complex lab kits with more visits and containers, complicated requisition forms, and intricate instructions for when to pull certain kits or when to collect certain patient samples. Once all of the biospecimens for a patient visit are collected, site staff face the daunting task of methodically processing specimens, transferring them to the appropriate return containers, storing and packaging them at the right temperature, and ensuring that they are sent to the right labs at the right times.

When a study requires sites to manage several kits, supplies, stipulations, and shipping destinations, the lab manual becomes incredibly dense. Even if sampling instructions are clearly defined, the interpretation of these details is tedious and subject to error. Clinicians may be prone to overlooking important information pertaining to sample collection, processing, shipping, and storage. This is compounded by the fact that research sites are oftentimes juggling responsibilities across multiple studies, sponsors, labs, and patients simultaneously. What's more, site staff often receive limited

training on the interpretation and execution of lab manual instructions, so their confidence in their understanding of study-specific processes is hindered.

In addition to executing on the instructions in the lab manual, clinicians must also juggle the documentation of several data points. Using the requisition form, internal paperwork, and spreadsheets, clinicians are expected to meticulously document administrative details, collection dates and times, chain-of-custody checks, and other records that make up the sample audit trail. These manual processes are not only prone to oversight and error — they also make it difficult to sift through disjointed, paper-based records when addressing queries and sample-related investigations.

Study amendments further complicate the utilization of the lab manual. When a trial sponsor updates a protocol or any study plans, these changes are subsequently implemented in an updated version of the lab manual. Site staff are tasked with keeping track of these modifications, which may impact the kits on hand, biospecimen collections, shipping destinations, and shipping frequencies.

Study Risks That Stem from Using Static Lab Manuals

Using paper- and PDF-based lab manuals comes with inherent risks, and those risks are amplified by an intricate study design. With more variables at play that directly impact sample management, site processes that were once sufficient are now buckling under the pressure of the demanding trial paradigms that dominate the modern clinical research landscape.

Risks are inevitable in any operation, but it's important to highlight the preventable vulnerabilities that emerge as a direct consequence of working with static lab manuals.

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Lapses in protocol & lab manual compliance

Let's face it — humans make mistakes, especially when they are juggling multiple tasks and priorities at once. When clinicians read through a lab manual — especially when they are in a hurry — they are at risk of committing an accidental oversight that can result in a protocol deviation and sample mishandling. The downstream effects for the patient and the study's overall integrity can be detrimental, with consequences spanning from a lack of data integrity, to difficulties with patient attrition.

Broken audit trails

Sample and data reconciliation is a normal part of clinical trial execution. But when the specimen audit trail is scattered across disjointed paperwork and spreadsheets, the process of piecing together the sample journey becomes a major and often impossible undertaking. A static lab manual provides site staff with a comprehensive overview of specimen management procedures, but it's not an interactive document that can prompt the reader to record data points or perform chain-of-custody checks, nor can it house any of this data in one centralized location. As a result, the reconciliation process often involves more time, effort, and back-and-forth with study stakeholders during the trial lifecycle.

Greater challenges in mitigating the impacts of staff turnover

Manual processes become problematic when site staff leave the organization, or are out on vacation or sick leave. When a clinician is expected to perform a patient visit for a study they've never supported before, or when a study coordinator is contacted about a lab query for a trial that is assigned to one of their colleagues, clinicians must haphazardly follow procedures in a lab manual that they aren't familiar with, or attempt to piece together data from disparate, paper-based sources. This creates an added challenge for site staff, many of whom are straining under the stress of high workload and turnover.

Operating cash

Inefficient site operations translate into higher overhead costs. Working with a static lab manual inevitably increases the amount of time and effort that clinicians are spending on reading directions and executing the various steps that are required during sample collection, processing, storage, and shipping. Error-prone methods also contribute to downstream inefficiencies due to the added amount of work required for reconciliation and data entry.

Deconstructing the Current Gaps in Sample Management Processes

In order to better understand the role that the lab manual plays in specimen management, it's important to examine the various steps involved in conducting a patient visit. By scrutinizing each stage of the sample journey — from its nascent state as an empty collection container in a lab kit, to its final state as a biospecimen that is ready for shipment and analysis — we can more accurately identify the gaps in conventional site practices as they relate to the utilization of the lab manual.

1

Pulling lab kits & inventory for a patient visit

When a patient arrives for a visit, clinicians refer to the lab manual to determine the lab kit(s) and bulk supplies that are required for biospecimen collection, preparation, and shipment. Once all supplies have been identified, site staff search for the inventory in their facility. In many cases, study coordinators have to reference spreadsheets and sort through a mountain of lab kits from other studies, kitting vendors, and trial sponsors in order to locate the needed supplies for the visit. This step can be both time-consuming and risky without a proper inventory management system in place. Disorganized supplies and a lack of a centralized, digital system to keep track of on-hand inventory can result in lab kits and bulk supplies being lost, expired, or out of stock.

2

Sample collection

Once the inventory has been pulled from storage, site staff sort through all of the collection supplies in the lab kits. A nurse or study coordinator painstakingly flips through the lab manual to determine which biospecimens should be collected in accordance with the protocol. Even though there may be several collection containers in the kit, this does not mean that all of them are used. Many protocols contain predefined conditions that dictate when a patient sample should be collected. For example, a specific biomarker may only be collected at a patient's Cycle 1 Day 1 visit if the patient meets certain criteria. Perhaps the

patient must be part of a certain demographic in order to merit the collection, or maybe the patient is required to have a certain test result at Screening in order to qualify for testing. These stipulations can be easily overlooked and misinterpreted in a static lab manual, resulting in erroneous collections or critical collections being completely missed.

Once all of the mandatory biospecimens have been identified, clinicians must carefully follow the collection instructions that are prescribed in the lab manual. The procedures for each collection container require meticulous attention to detail; just one misread or overlooked step could threaten sample integrity. Downstream, these errors can harm the patient, who may be forced to repeat a visit or even drop out of a study.

As various biospecimens are collected from a patient, site staff across multiple departments must document several sample-related data points on the requisition form and in internal paperwork. Patient demographics — along with collection dates and times — must be accurately recorded in order to ensure seamless processing of biospecimens at the receiving lab. Under traditional site operations, the recording of these data points is often paper-based, manual, and fragmented.

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3

Sample processing & storage

Once biospecimens are collected, they often must be processed immediately. As was the case for specimen collection, site staff must promptly follow the elaborate processing instructions in the lab manual for each biological sample, ensuring that they are centrifuged or fixed (if needed), transferred to the appropriate return containers, and stored at the correct temperatures. Additional data points are also recorded at this stage.

This step is particularly critical because it can have a major impact on sample integrity. One mistake could be costly, resulting in a biospecimen being nonviable for analysis. For instance, if a specimen that should be frozen is placed in a refrigerator, or if a sample is transferred to the incorrect return container, then the lab may deem the patient sample unusable.

4

Sample shipping

Once processing is complete, site staff refer to the lab manual to determine shipping logistics — including sample destinations, courier details, shipping temperatures, which shippers to use for packaging biospecimens, blackout days, and shipping frequencies. On complex trials, this step can be complicated.

It is not uncommon for the shipping logistics of a singular patient visit to look something like this: Five biospecimens are shipping to lab A — two are shipping ambient on the day of collection, two are shipping frozen on the day of collection, and one is shipping frozen one week after collection. This same patient visit also has two biospecimens going to lab B frozen on the day of collection, and one biospecimen going to lab C

refrigerated on the day of collection.

Considering all of the variables at play in this scenario, it's easy to see how site staff could ship a sample to the wrong location, forget to ship a sample one week after collection, or ship a sample in the wrong kind of shipper. A static lab manual usually provides research sites with the correct guidance, but important instructions can be easily overlooked.

Using Technology to Bring Lab Manuals to Life

Many clinical research sites are underutilizing technology in their specimen management operations. Digital tools already exist that can turn a static manual into an interactive workflow that streamlines clinical trial execution at the site level.

Use a centralized clinical trial platform to manage inventory

Successful biological sample management cannot occur without successful inventory management — after all, biospecimens can't be collected, processed, and shipped without the appropriate supplies on hand. Study coordinators often rely on paperwork and spreadsheets to keep track of inventory, but these outdated approaches to record-keeping make it more difficult to maintain continuity among site staff, locate supplies, track lab kit expirations, and identify trends that inform resupply orders.

A clinical trial execution platform for managing inventory can significantly enhance a site's ability to monitor their supply use. Not only does this consolidate inventory data so that it's easily accessible and searchable, but it can eliminate the need for manually monitoring low inventory or supply expirations with automatic alerts.

Turn lab manual instructions into software-guided workflows

No need to decipher complex sampling instructions or reinvent the wheel during every patient visit — research sites can leverage technology to walk their personnel through every step of collection, processing, storage, and shipping. Site staff can use the lab manual to perform a one-time kit configuration setup using a digital specimen management platform; after that, sites never have to worry about sifting through a text-heavy lab manual again. All clinicians have to do is follow the predefined guardrails that were established during configuration as a clinical trial software guides users through every step of sample management.

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Reduce and eliminate paperwork, spreadsheets, and duplicate data entry by integrating data capture into digital workflows:

Specimen management encompasses more than just the physical collection and processing of a biospecimen — it also demands the meticulous collection of sample data, including collection dates and times, administrative questions, and sample chain-of-custody records.

Clinical research sites can reduce manual effort — as well as the amount of time and effort spent on query resolution and data reconciliation — by leveraging a clinical trial execution platform

that automatically captures pertinent sample data in tandem with key specimen management steps. This capability not only ensures that all administrative data is collected in real time, but this data can be fed into other data sources, like an electronic data capture (EDC) system. The centralization and digitization of this information also equips sites to efficiently respond to queries and reduces the need for duplicate data entry.

Use technology to maintain visibility to patient samples after they leave the facility

Traditional tools offer site staff limited visibility to biospecimens after they have shipped. Clinicians can usually refer to a courier's tracking number to determine whether a biospecimen has reached its initial destination, but these details usually must be manually recorded and researched during sample-related investigations.

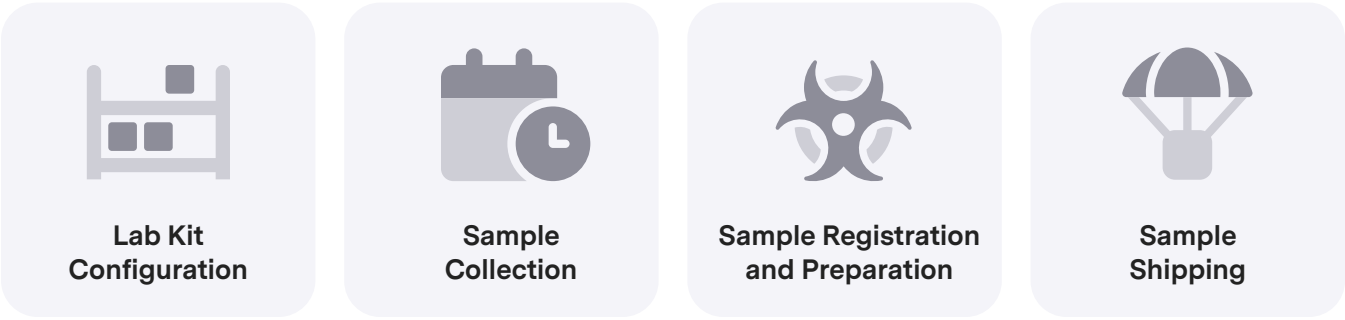
Even then, the post-shipment specimen audit trail is limited — especially if patient samples are arriving at one facility (like a central lab) before being shipped to another.

Digital solutions exist that can provide site staff with full visibility to the sample journey. Having this information at their fingertips, study coordinators can improve their communication with sponsor stakeholders and vendor labs during sample reconciliation, while maintaining peace-of-mind that their patients' samples are being handled properly. If important patient results are delayed or canceled, having visibility into the sample journey can provide more context.

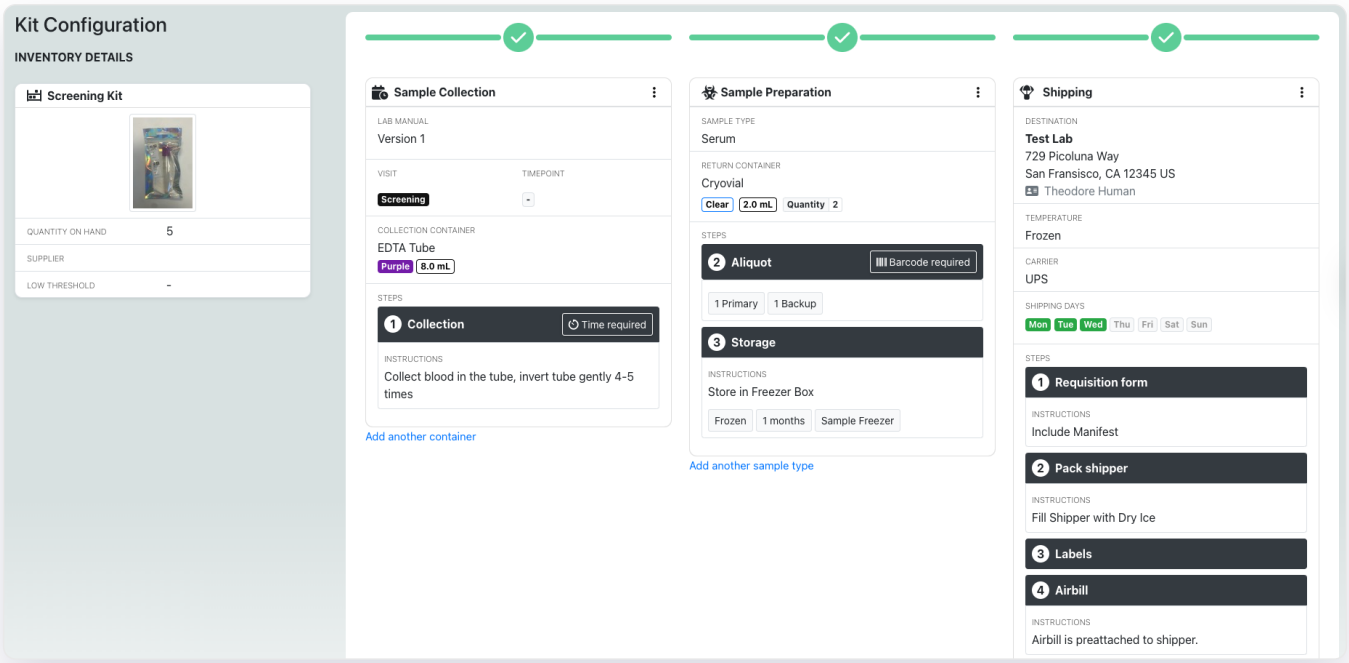
The Future of Sample Management: Putting Clinical Research Sites at the Center

Slope's clinical trial execution platform empowers research sites to maximize efficiency and compliance across all of their studies. 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, sites are empowered to know the history of every specimen, better address queries, and stay up-to-date with study-specific changes, so they can spend less time sifting through binders and more time treating their patients.

Slope's sample management tools streamline site processes into four simple steps:



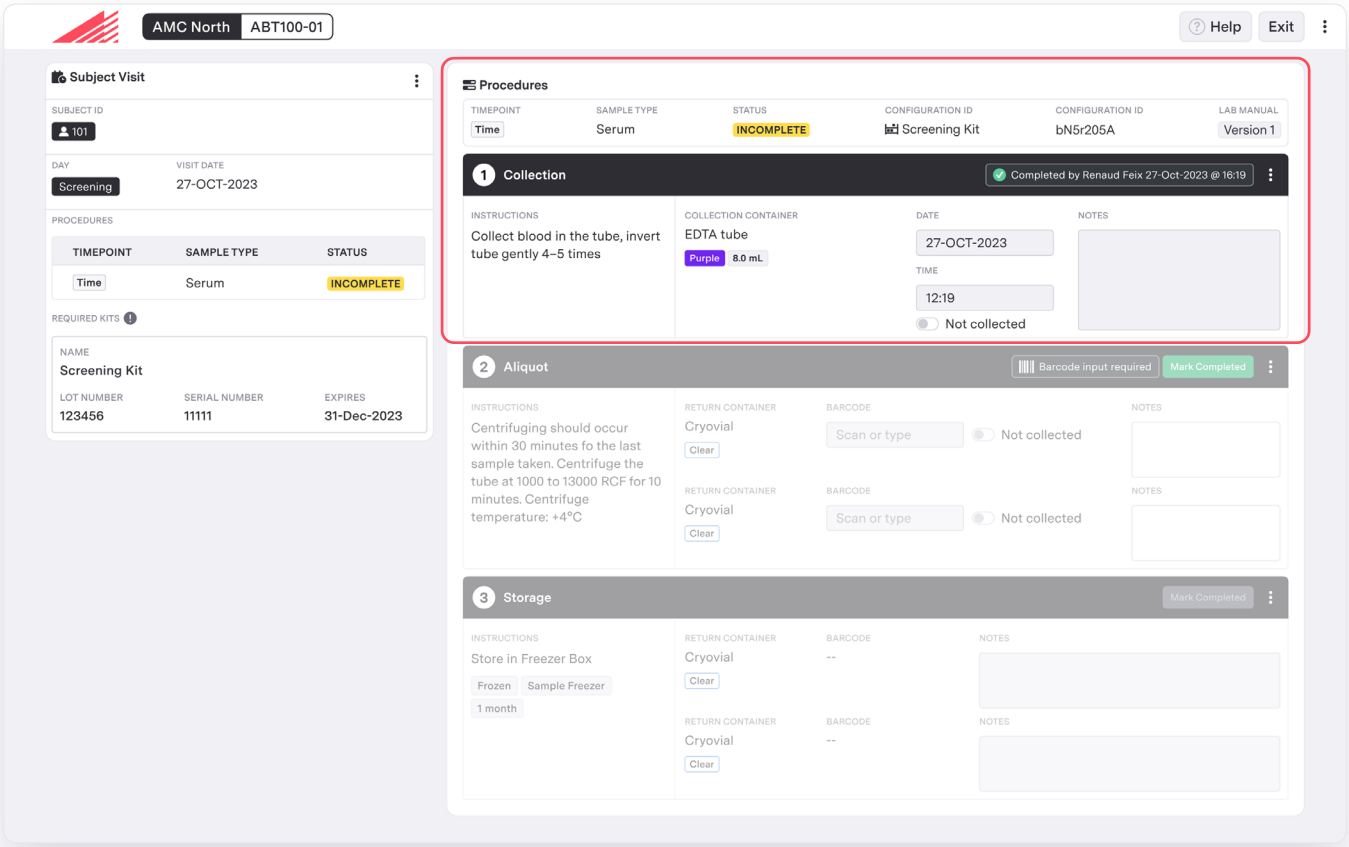
1 Lab Kit Configuration



Lab kit configuration establishes guardrails for all visit types by turning the lab manual into protocol-guided workflows.

- Define visits, timepoints, collection containers, and procedures directly in the software
- One-time setup ensures consistency and streamlines processes across all patient visits
- Operationalize the components of any lab kit
- Seamlessly transition to new amendments

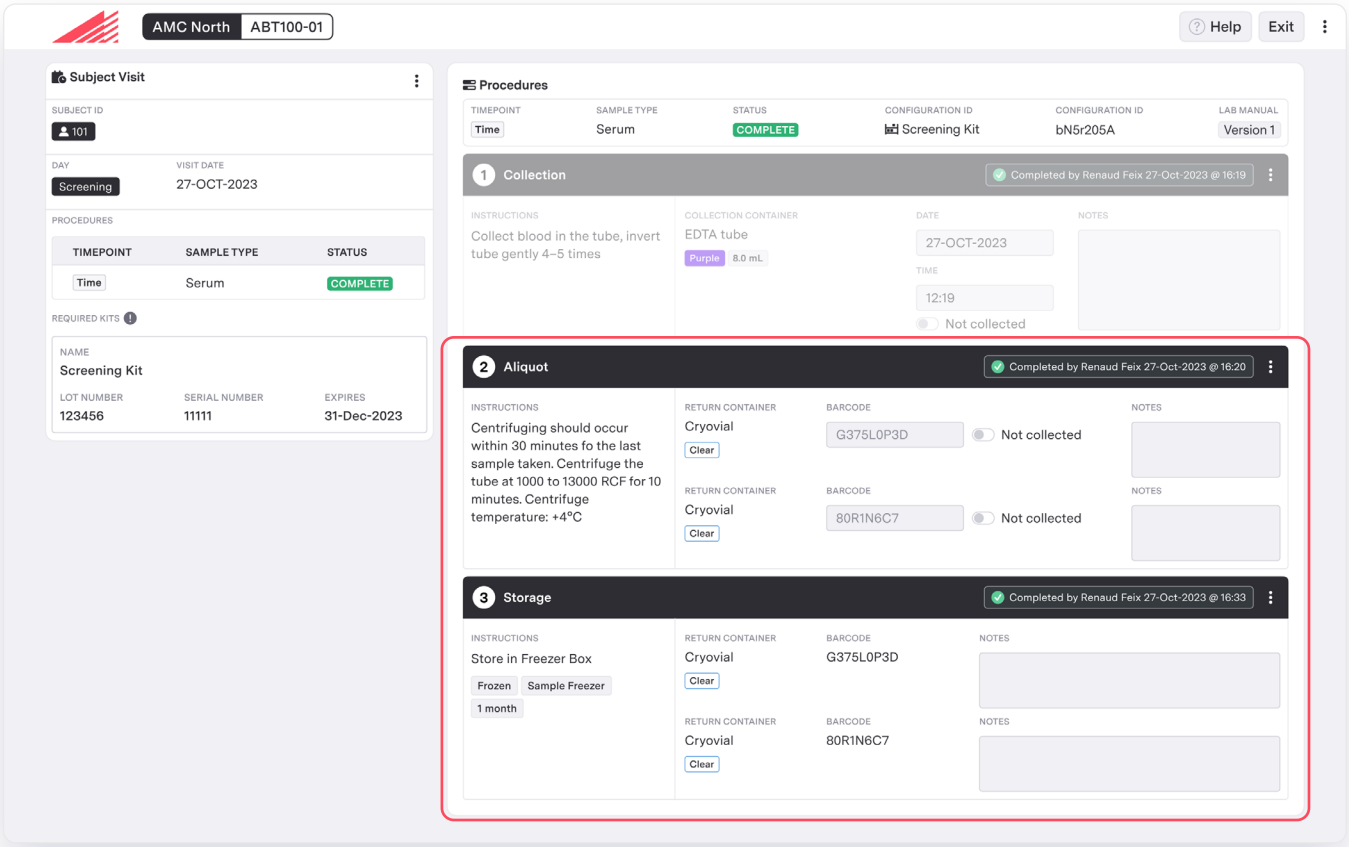
2 Sample Collection



Sample collection facilitates accuracy and compliance by ensuring patient samples are collected in accordance with the lab manual.

- Maximize efficiency and compliance
- Interface enforces consistent capture of pertinent sample collection data
- Never miss a PK timepoint

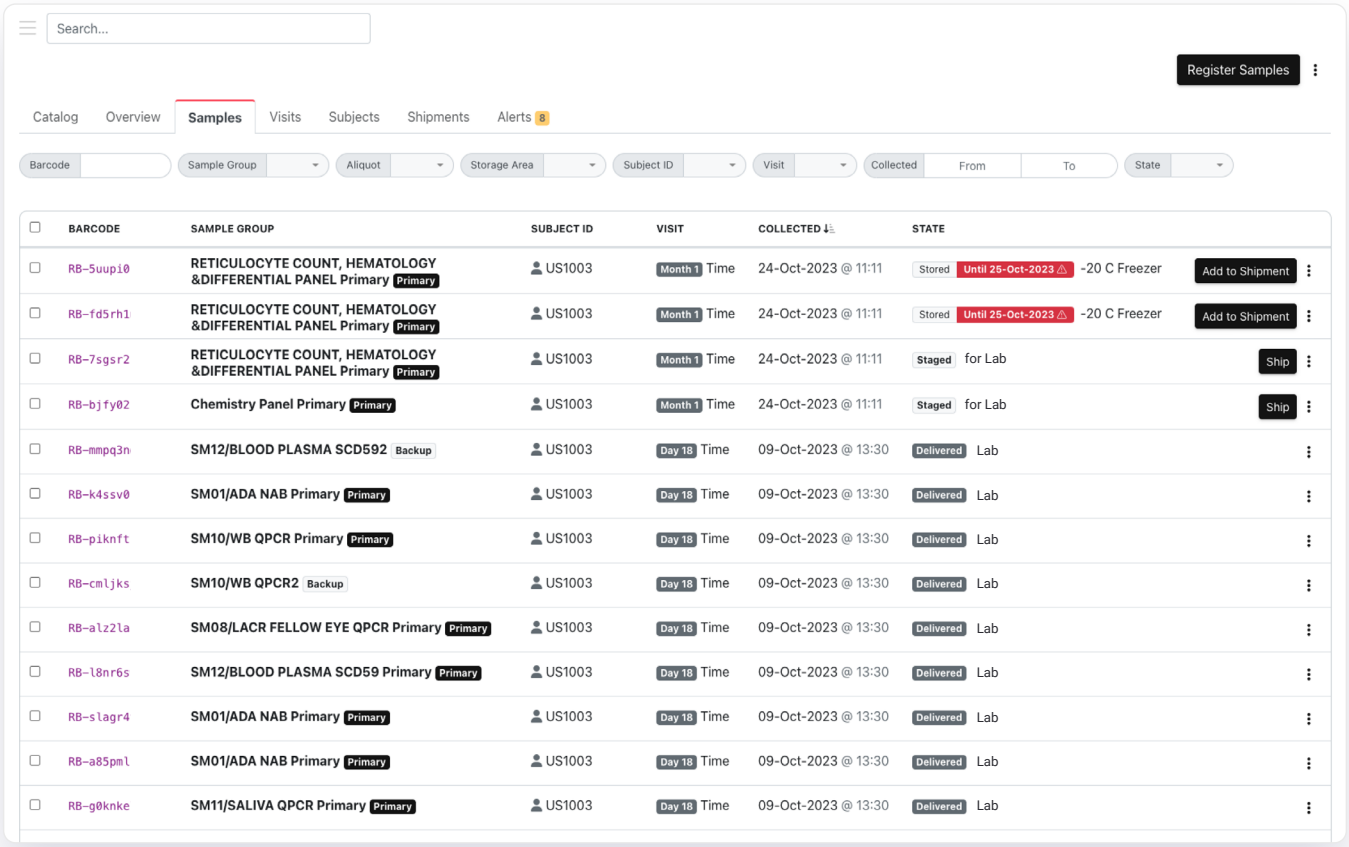
3 Sample Registration & Preparation



Sample registration and preparation walks site staff through the process of readying a specimen for analysis.

- Properly transfer biospecimens to appropriate return containers
- Intuitive, error-preventing aliquoting process
- Interface ensures samples are stored as prescribed in the lab manual

4 Sample Shipping



Sample shipping enables staff to build GCP-compliant shipments to destination labs.

- Get samples to the right places, at the right times
- Never ship on blackout days
- Actionable alerts ensure that batch shipments never fall through the cracks
- Integrations with couriers and carriers allow users to generate tracking numbers and print shipping labels directly from the platform

Request a demo of Slope's **Clinical Trial Execution Platform**

SlopeClinical.com/request-demo

SLOPE

Slope's clinical trial execution platform transforms site operations by digitizing lab manuals and creating guided, study-specific workflows for inventory — ranging from lab kits to devices and IP — and sample management. The entire sample journey from kitting to its final destination at a biorepository is visible to sponsors in real-time, enabling them to have oversight into all clinical trial activities. By integrating with the right partners and data systems, including EDC, RTSM, LIMS, labs, kitters, and shippers, Slope ensures seamless data flow and trial execution for all stakeholders, alleviating the burden from sponsors to connect the dots during reconciliation or track down samples. Slope brings order and efficiency to clinical trials while providing real-time access to all study details so sponsors can unlock actionable data insights, and make critical study decisions..

Learn more at SlopeClinical.com