REPORT

State of Clinical Inventory and Sample Management for Clinical Trials

Research Report 2023

PRESENTED BY

SLOPE

PUBLISHED BY

FIERCE Biotech

Executive Summary

Slope's inaugural *State of Clinical Inventory and Sample Management* survey gathered insights from 146 biopharma professionals on the impacts of inefficient, manual processes for managing clinical supply — lab kits, devices, ancillary supplies, and investigational product (IP) — and samples on budgets, timelines, data integrity, and patients.

The survey findings highlight the pain felt by study teams as the complexity of the supply chain is not supported by standardized processes and technology. There is an acknowledgment of the problem, and yet most have not transformed the way they are operationalizing their clinical trials to address it.

The existing processes currently in place are incapable of ensuring the availability of crucial clinical inventory, including lab kits, drugs, devices, and other essential supplies. Moreover, there is a significant lack of transparency regarding the biospecimen chain of custody. This lack of visibility leads to various negative consequences, such as delays in studies, reduced trial outcomes, exceeded budget limits, and most importantly, a direct impact to the performance of research sites and the well-being of their patients.

To learn more about this report, the data behind it, and Slope's Clinical Trial Execution Platform, email info@slopeclinical.com

Key Findings

95%

of biopharma professionals report having experienced an **increase in clinical trial budgets, timeline delays, or data quality concerns** as a direct result of clinical inventory or bio-sampling issues. In addition, almost one half confirmed the **absence of real-time chain of custody** and/or sample visibility.

89%

of biopharma professionals report that **reducing clinical supply waste is very important or moderately important** to their companies.

74%

of biopharma professionals say their **research sites do not have the necessary clinical supply** they need to enroll and retain patients.

71%

of biopharma professionals report that a **fully traceable supply chain of custody is very important in demonstrating a clinical trial's data integrity**, with only 3% indicating non-importance.

Continue reading for deeper insight into these key findings →

> This survey underscores that the process for clinical inventory and sample management needs to change — and that inefficiencies and visibility gaps are leading to increased costs, timelines, and risk. As an industry, we need to do a better job addressing these systemic issues.

Hope Meely
Chief Clinical Officer, Slope

Survey Demographics

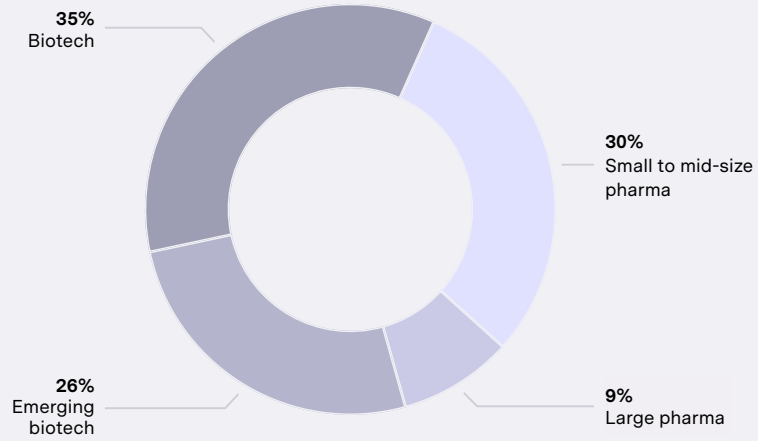
BY THERAPEUTIC AREA

54% Oncology / hematology	**38%** Cardiovascular
44% Immunology	**32%** Central nervous system
41% Rare disease	**27%** Infectious disease

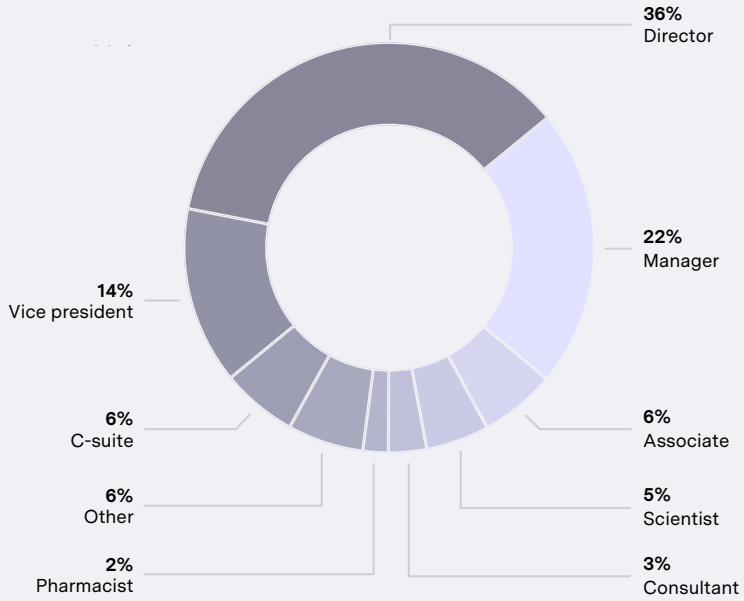
BY TRIAL TYPE

50% Preclinical	**68%** Phase I	**67%** Phase II
	56% Phase III	**32%** Phase IV

BY COMPANY TYPE



BY TITLE / ROLE



PRESENTED BY SLOPE
PUBLISHED BY FIERCE Biotech

Survey Demographics

- Preferred clinical supply vendors (~70) were mentioned in the survey.
- Most are mentioned by just one or two participants.
- Those mentioned by three or more participants are listed below.

- Three out of ten participants (61%) live in the United States. The remaining participants live in nineteen other countries.
- India, UK, Canada, Belgium, and Israel each account for more than 1% of participants.
- All other counties each have 1% of participants.

14 ThermoFisher	**8** Catalent	**6** Almac	**5** World Courier
5 LabCorp	**3** IQVIA	**3** PPD	**3** Icon
3 Sigma-Aldrich	**3** VWR	**3** Parexel	**3** Lonza

Survey Demographics

BASE SIZES

The total number of participants in the study is 146, but not every participant answered every question.

Most findings are based on the total of 146 participants.

EXCEPTIONS

143 Finding #4	**145** Finding #8	**145** Finding #11	**142** Finding #12
142 Finding #15	**144** Company type	**132** Job title	**132** Preferred providers

RESULTS & INSIGHTS

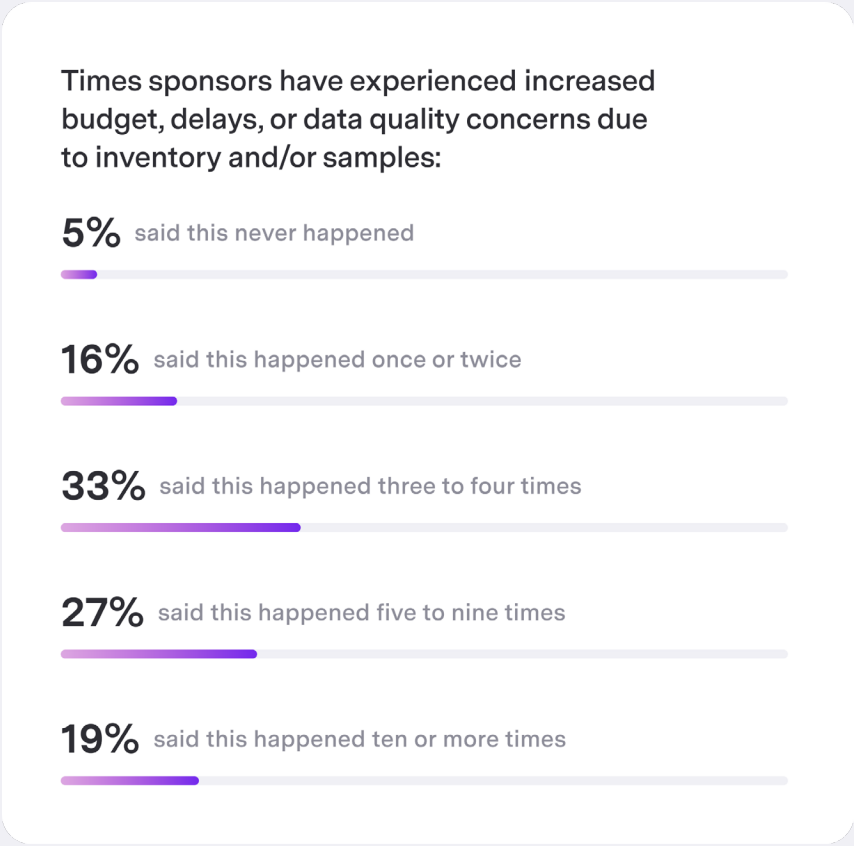
Inventory or sample issues increase clinical trial budgets, timeline delays, and data quality concerns

In 2023, sponsors are aware that issues with clinical inventory and sample management have a direct impact on the success of the clinical trial.

According to the survey, 95% of biopharma professionals have experienced an increased clinical trial budget, timeline delay, or data quality concern as a direct result of lab kit supply, drug supply, or sample issues.

Respondents indicated the number of times they have experienced issues within the same clinical trial, data ranging from one to two times (16%) to ten or more times (19%), with the median being four times (49%).

Not having the supplies needed for each patient visit, and mishandled or lost samples are two of the main reasons for these staggering statistics.



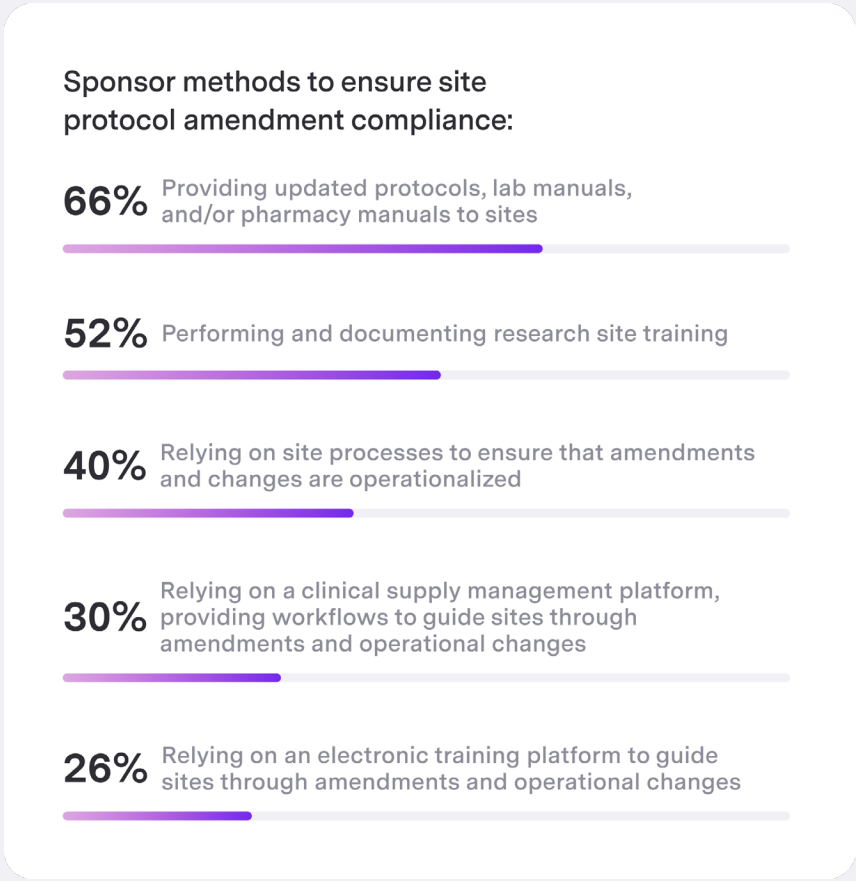
RESULTS & INSIGHTS

Protocol compliance resulting from amendments is still reliant on updated manuals and training

Making sure sites are informed of and trained on new amendments ensures regulatory compliance. However, the process for ensuring sites transition to new protocol and lab manuals resulting from amendments or operational changes still relies on updating documents and site training.

According to the survey, two thirds of sponsors reported providing sites with updated protocol amendments, laboratory manuals, and/or pharmacy manuals as the method of ensuring compliance with new changes.

CONTINUED ON FOLLOWING PAGE



Protocol compliance resulting from amendments is still reliant on updated manuals and training (cont.)

Due to the reliance on self-training and implementation with this approach, it is not ideal for ensuring compliance and standardization. This method involves a highly manual process that puts the burden on the site to implement changes enforced by the sponsor.

Only 32% of respondents leverage technology and training platforms for initial sample collection training, and to share protocol and operational changes.

More than half of biopharma professionals report that research sites are guided through the sample collection, storage, and shipping processes for clinical trials by:

72% Providing protocols, amendments, and laboratory manuals to research sites

57% Performing research site training, either by site visit or virtual meeting

Other ways of providing this guidance to research sites rely on electronic solutions:

32% Relying on site processes to ensure that amendments and changes are operationalized

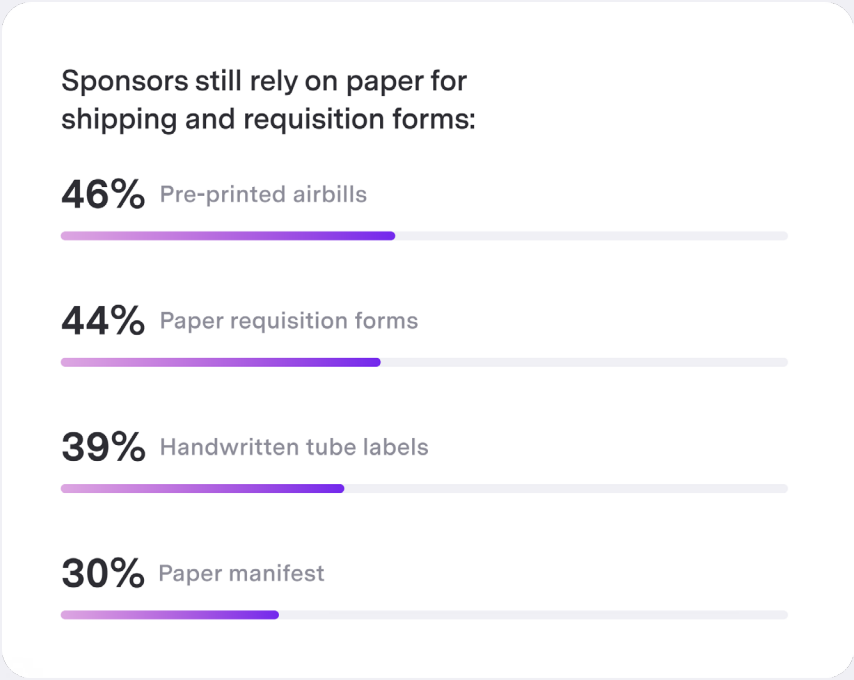
21% Relying on a clinical supply management platform, providing workflows to guide sites through amendments and operational changes

RESULTS & INSIGHTS

Pre-printed airbills and paper requisition forms are standard

Pre-printed airbills and paper requisition forms are used most often. Paper documents are difficult to manage — especially during study changes — and cause versioning chaos at sites and downstream collaborators. In addition, handwritten forms create legibility issues resulting in unnecessary queries that take time and effort to manually resolve by sites, sponsors, and vendors.

The transition to the electronic management of tube labels, requisitions, manifests, or airbills is also a work in progress. Preprinted airbills, (46%), and paper requisition forms, (44%), remain the most common ways of handling delivery information, and only 15% of respondents use electronic systems to create their materials.



RESULTS & INSIGHTS

Research sites lack the necessary clinical supply for patient enrollment and retention

The majority of sponsors acknowledged that current processes for ensuring clinical supply availability are unreliable. The main reason is the lack of visibility into how much inventory a site has, versus what that site actually needs.

Most of the surveyed sponsors said their research sites do not have the necessary lab kits, devices, ancillaries, and other clinical inventory they need to enroll and retain patients to support their studies. These are not isolated issues. Almost one third, of respondents said sites have the necessary supply less than half the time.

Such problems with clinical inventory availability prevent sites from being able to enroll patients, conduct essential assessments, and/or adequately treat and maintain their patients during studies.

RESULTS & INSIGHTS

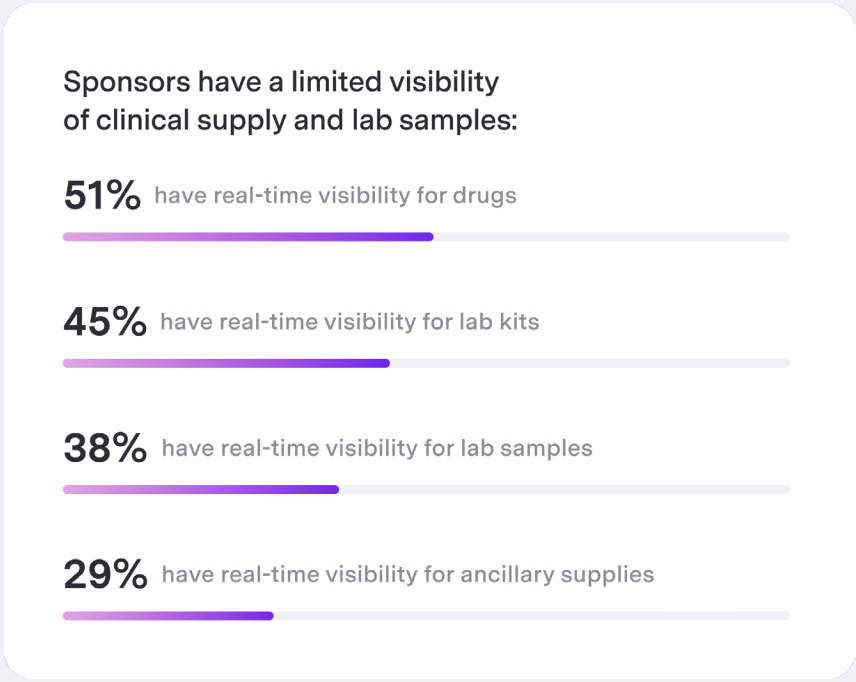
Real-time visibility to clinical supply is limited, opening sponsors up to regulatory risk

One in four sponsors have no real-time chain of custody visibility into any supply, including lab kits, lab samples, ancillary supplies, or drugs.

The survey noted visibility differences across clinical inventory types. More respondents (51%) have real-time oversight of their drugs, than lab samples (38%). The difference between the rates of real-time visibility into drugs and lab samples is likely due to strict regulations for both sites and sponsors around investigational products.

Lab samples have limited visibility, as they originate from lab kits with only 45% visibility. The low visibility of lab samples is concerning because they play a crucial role in collecting safety and efficacy data. Moreover, for personalized medicines, lab samples are an essential component of the drug supply chain.

This lack of visibility opens sponsors up to the regulatory risk of not being able to confidently prove appropriate study oversight and patient safety evaluation.



RESULTS & INSIGHTS

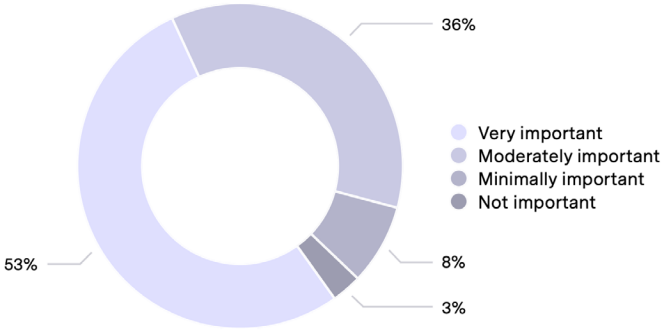
Reducing waste is a top concern, but bulk orders and antiquated processes perpetuate the problem

The increase in sustainability initiatives and mounting financial pressures are drawing more attention to the impact of supply waste. However, waste can be accepted as a consequence of doing business to avoid patients showing up to a visit without the necessary supplies.

Despite 89% of sponsors acknowledging the high importance of waste reduction to their companies, the ongoing dependence on bulk orders is impeding progress in this area: to ensure that research sites have enough viable lab kits on hand, the current process is to send bulk supply orders prior to trial start (44%) and manually reorder supplies (43%) through a form or system.

In other words, even though reducing clinical supply waste is a priority for these sponsors, the existing practice of ordering supplies in large quantities, without visibility to what is actually needed, is preventing them from achieving this objective.

The importance of waste reduction:



42% Bulk supply prior to trial

43% Manual reorder requests by research site, sponsor, or CRO (form or system)

36% Regularly scheduled resupply driven by time, not patient enrollment

32% Electronically triggered, predictive resupply based on patient enrollment and expected visits

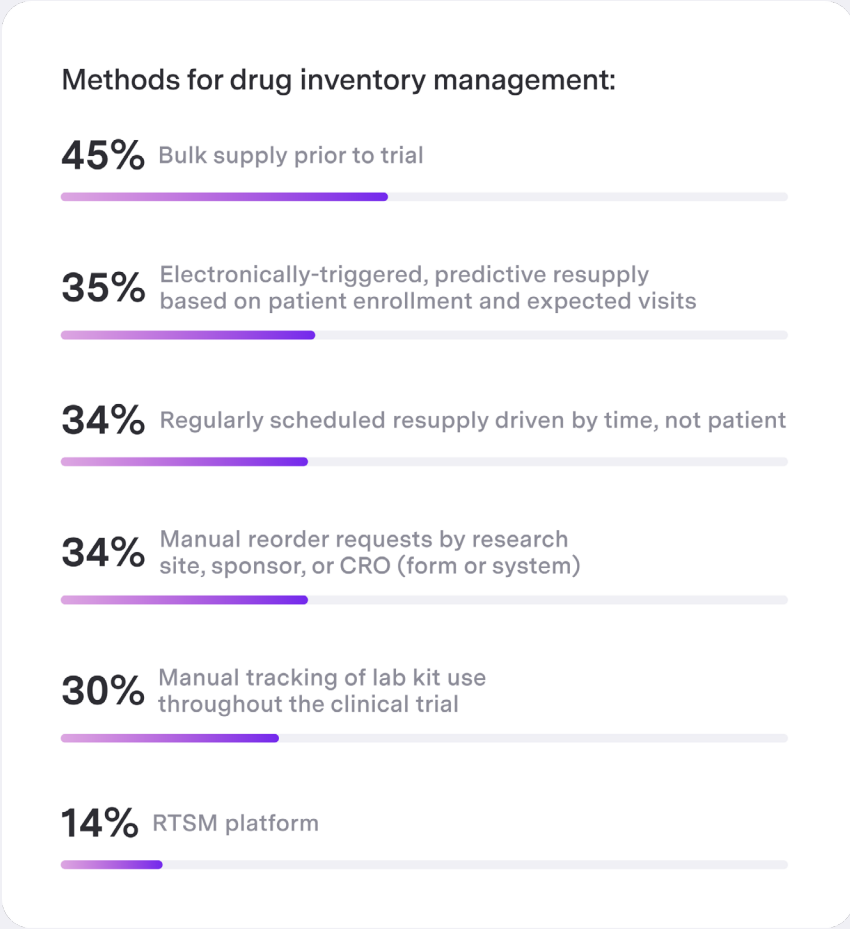
32% Manual tracking of lab kit use throughout the clinical trial

RESULTS & INSIGHTS

Resupply based on patient enrollment is available, however the industry has yet to make the transition

Resupply should be based on patient enrollment, rather than through bulk orders or reactive, manual ordering. Similar to the approach for lab kits, the most common way of ensuring that research sites have enough viable IP on hand to conduct patient visits is to send bulk supply prior to clinical trial start — with over 45% of biopharma professionals leveraging this approach.

Modern, data-driven technologies that automate the replenishment process by accurately tracking the needs of each site are available, but the industry is still making the transition. The survey found electronically triggered, predictive resupply based on patient enrollment and expected visits is used for lab kits by 32% of people, and for drugs by 35% of the executives.



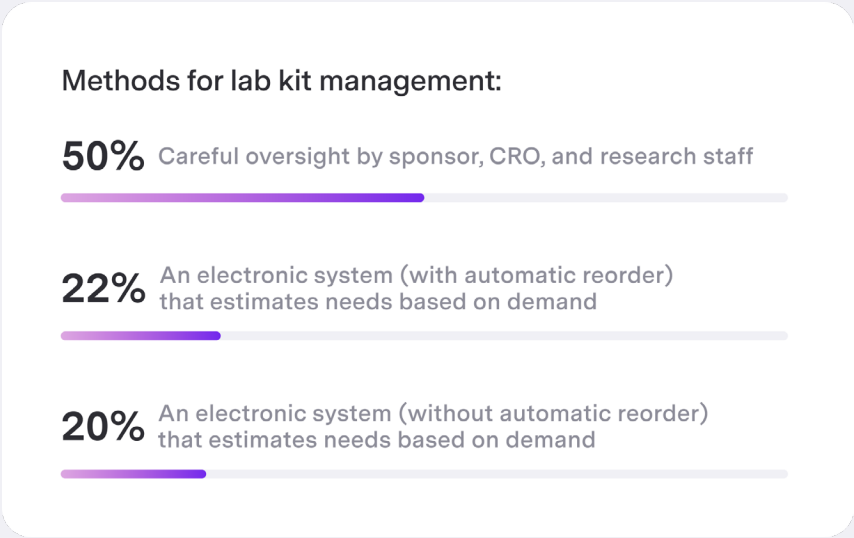
RESULTS & INSIGHTS

Lab kit supply management is resource-intensive

Half of biopharma executives report that estimating the number of lab kits needed at certain times across trials is done by careful oversight by the sponsor, CRO, and research site staff.

This oversight, due to the lack of visibility into current lab kit status, requires intensive manual resources — from managing spreadsheets, to emails and phone calls across all stakeholders.

Again, most executives have yet to start using electronic systems that estimate needs based on demand, and automatically reorder lab kits. Such systems are only used by 20% of the surveyed sponsors. Seven percent of respondents bypass the need to estimate by providing lab kits in bulk at regular intervals.



RESULTS & INSIGHTS

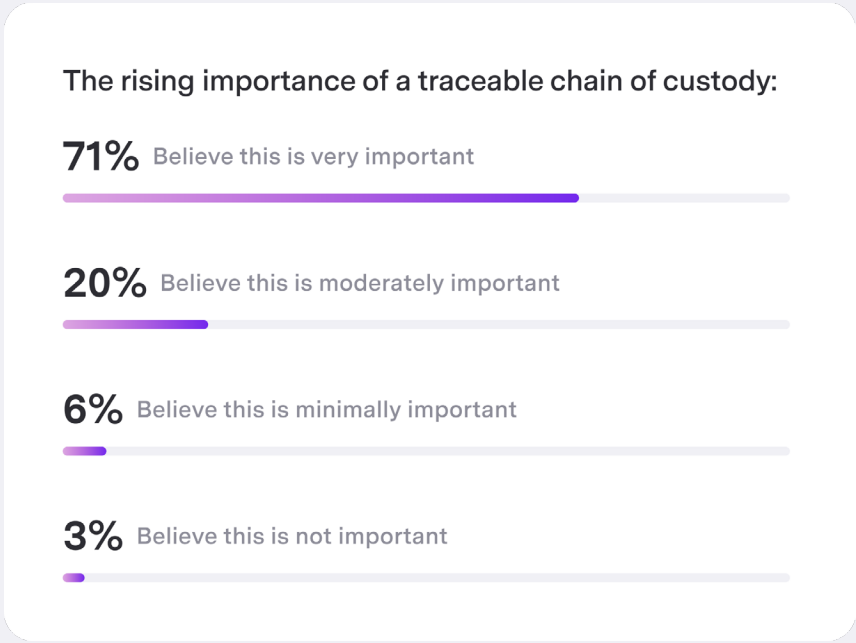
Traceable chain of custody demonstrates data integrity

More than seven out of ten biopharma professionals (71%) believe that a fully traceable supply chain of custody is very important in demonstrating a clinical trial's data integrity.

This is especially important as the industry has seen an 86% increase in endpoints, 88% more assessments, and a whopping 70% surge in procedures that involve biospecimens. This surge amplifies the operational and logistical intricacies, further compounded by the critical need for efficient biospecimen collection and overall sample management.

While most acknowledge its importance, most sponsors do not know the status of their samples in real-time. There are gaps in visibility from the point of collection to analysis at the lab, and challenges in tracing back samples to the originating patient, and locating samples when issues arise.

Demonstrating a traceable chain of custody enables sponsors to fulfill their regulatory obligations, and enables them to have oversight into clinical trial activities.



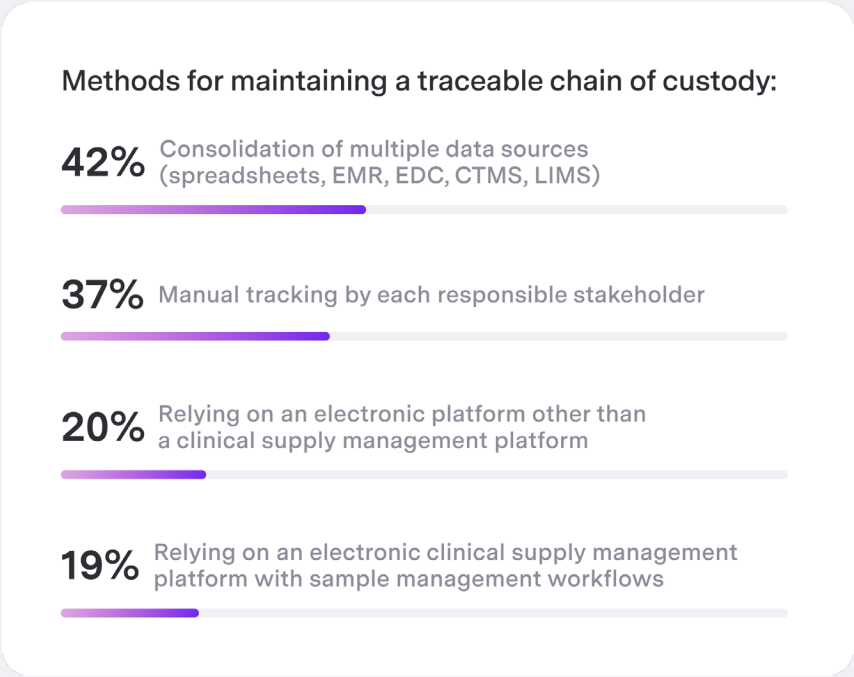
RESULTS & INSIGHTS

Traceable chain of custody is maintained by consolidating disparate data sources

71% of respondents maintain a chain of custody for all samples by "careful oversight and management by the sponsor, CRO, research site staff, and lab."

Oversight can include consolidating multiple data sources (spreadsheets, EMR, EDC, CTMS, LIMS), manual tracking by siloed stakeholders, and/or relying on systems.

Currently, to obtain a traceable chain of custody, sponsors must track down data from multiple stakeholders and data systems, sometimes having to make assumptions where data does not exist.



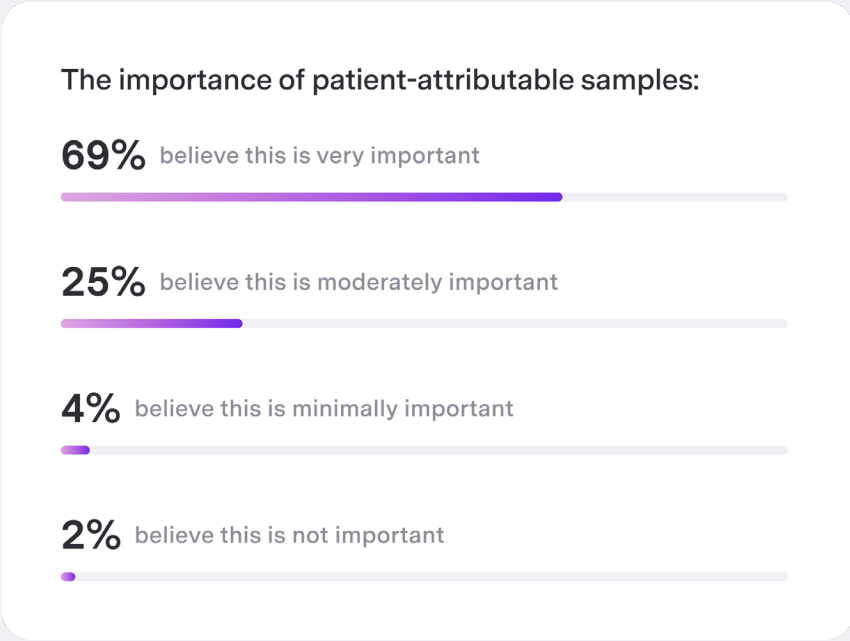
RESULTS & INSIGHTS

Increasing importance of tracing a sample back to its originating draw tube

Seven out of ten of biopharma respondents (69%) noted that it is very important to be able to trace a sample back to an originating draw tube after a sample has been obtained, shipped, and potentially resulted — with an additional quarter of respondents noting it is moderately important.

These results are not surprising given the value attributed to samples for safety and efficacy data that inform dose escalation, and ultimately the ability to advance clinical programs. There are also instances that require sponsors to attribute samples to patients in real-time during the trial, including when a patient withdraws consent. Not to mention, as the industry progresses farther into cell and gene trials, *the sample becomes the therapy*. All sponsors operating in personalized medicine trials should have airtight oversight into samples — all the way back to the subject.

Surprisingly, despite the importance of a given sample's traceability back to its originating draw tube, most survey participants still acknowedged and confirmed a lack of visibility into the status of lab samples mentioned earlier in this report.



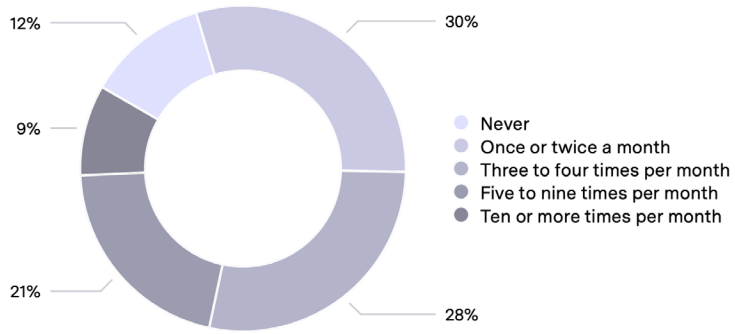
RESULTS & INSIGHTS

Missing required sampling timepoints and misplaced samples are prevalent

Almost 90% of respondents said their research sites sometimes miss required sampling timepoints, or have misplaced patient on-study samples. For most of the survey respondents, the problems are a monthly occurrence, with 58% of respondents suffering such issues three or more times per month, and 9% of people saying they happen at least 10 times per month.

These missed timepoints and misplaced samples can result in lost patient safety data and open the sponsor up to protocol compliance issues.

Frequency of missed sampling timepoints or misplaced samples:



REPORT

Conclusion

The survey data reveals a disconnect between the increasingly complex clinical trials that sponsors are conducting and the manual, paper-based processes that sites and sponsors employ to manage clinical supply and samples. This disconnect has negative repercussions for all stakeholders involved. Sponsors experience costly delays, sites struggle to perform their tasks efficiently, and patients endure extended waits for life-changing therapies.

Leading biopharma companies are recognizing that there is a better way to manage clinical inventory and samples. Modern clinical trial execution platforms empower study teams to conduct streamlined, standardized trials with the necessary rigor to collect high-quality clinical inventory and sample data while safeguarding patients.

Slope is driving this transformation by providing a clinical trial execution platform for sponsors and research sites that are collaborating on complex, sample-intensive clinical trials. The platform reduces operational chaos for sponsors, CROs, research sites, and labs by providing data-driven oversight of clinical trial activities.

Through Slope's clinical inventory, sample management, and data-driven resupply solutions, the platform enables stakeholder collaboration, real-time visibility, traceable chain of custody, and risk mitigation. This results in improved trial outcomes — including boosting patient enrollment and retention, reduction of supply waste, and adherence to study protocols, timelines, and budgets.