CASE STUDY UNIVERSITY OF ARIZONA CANCER CENTER

University of Arizona Cancer Center Reduced Scheduled Test Deviations by 44% with Slope

Slope's clinical inventory management software slashed the number of missed patient assessments, boosting trial safety and efficacy data across 11 disease teams

SLOPE | THE UNIVERSITY OF ARIZONA Cancer Center

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CUSTOMER PROFILE

The University of Arizona Cancer Center (UACC) is the only NCI-designated comprehensive cancer center in Arizona. UACC is dedicated to clinical trials because cancer patients with access to clinical trials have the potential to live longer and have a better quality of life.

UACC's Clinical Research Operation at a Glance

70 staff supporting clinical research

70 investigators

~90 open and enrolling studies

~250 active studies (open and closed to accrual)

~200 samples processed per week on average

~3,000 kits managed at any given time

Receiving lab kit inventory daily

Shipping samples daily

The Challenge

As UACC's Clinical Research Laboratory Manager, Carolyn Lane believed she had run out of options to get The University of Arizona Cancer Center's inventory management issues under control.

Carolyn had long been grappling with how to best manage lab kits and other clinical supplies, having tried numerous methods to address fundamental issues with the way her site was handling on-hand supplies and resupply orders. Despite her best efforts, UACC's system remained fraught with problems, which had direct implications on the efficiency and effectiveness of their research operation.

For years, UACC relied on a pen-and-paper system to track and reorder lab kits and other critical supplies. This rudimentary approach was inadequate given the scale and complexity of their operations. At any given time, the cancer center managed around 3,000 on-hand lab kits — a volume far too large for manual tracking methods. The inherent limitations of this strategy became increasingly apparent:

Volume and Complexity

The sheer number of lab kits and supplies UACC was receiving from sponsors made it impossible to efficiently track and manage inventory using paper. This method was cumbersome, prone to human error, and could not keep up with the dynamic, complex nature of clinical research logistics.

Timeliness of Reordering

Paper records were ineffective for timely reordering of supplies. Staff members found it challenging to determine when supplies were running low, often realizing the need to reorder only when it was too late.

Decentralized Tracking

With inventory management spread across 11 disease teams and managed by 8 different staff members, centralizing and maintaining accurate inventory records was nearly impossible. This decentralized approach led to fragmented, inconsistent inventory data, making it challenging to maintain a coherent and comprehensive overview of what was in stock.

Collectively, these fundamental issues led to several operational problems:

Locating Kits and Realizing Shortages

Staff frequently had trouble locating specific kits and only realized inventory shortages at critical moments — such as when a patient visit was imminent. The inability to efficiently track the usage and expiration of kits often resulted in delays and disruptions in scheduled clinical activities.

Reporting and Reordering Challenges

The manual system hindered the ability to report kit usage accurately and reorder in a timely manner. This led to frequent shortages and overstock situations, further exacerbating inventory management issues.

Communication with Sponsors

Providing accurate, comprehensive inventory updates to clinical trial sponsors was a constant struggle. The lack of a centralized, tech-enabled process meant that inventory reports were often outdated and unreliable, hindering collaboration with sponsors.

Understanding the Link Between Clinical Inventory and Scheduled Test Deviations

Carolyn noticed that the operational challenges stemming from UACC's inventory management processes were causing protocol deviations — specifically scheduled test deviations, wherein a lab test is missed, delayed, or out of window. Unsurprisingly, samples can't be collected on time — let alone collected at all — without the appropriate supplies.

Scheduled test deviations are the most common protocol deviations at UACC each year, accounting for over 60% of all documented deviations in 2023.

These particular deviations are significant because they present the following risks:

Gaps in Safety and Efficacy Data

Missing lab data stemming from missed collections can have severe consequences. For instance, if an important safety test is not conducted on a Phase I trial due to a missing kit, critical health indicators can be overlooked, potentially leading to patient toxicity and organ damage. Similarly, without necessary efficacy data that makes up many trial's primary and secondary endpoints, sites and sponsors can't determine whether or not a patient is responding to treatment.

Operational Inefficiencies

Deviations also contribute to significant operational inefficiencies for site personnel. At UACC, each deviation must be documented in OnCore — their clinical trial management system (CTMS) — requiring detailed explanations and corrective actions. This process involves multiple stakeholders — including physicians, regulatory teams, and clinical research coordinators — who must review IRB and FDA reporting requirements, as well as EDC data entry. Moreover, lab queries and "expected sample reports" generated from uncollected samples further compound these inefficiencies, disrupting normal research site workflows.

Sponsor Relationships

Maintaining a strong relationship with sponsors is crucial for the success of clinical trials. Poor site performance can tarnish an institution's reputation with sponsors. Sponsors and monitors evaluate compliance with study protocols, and repeated failures can lead to exclusion from future trials. The competitive nature of clinical research means that institutions must perform optimally to secure ongoing and future partnerships with sponsors.

Impact on Patient Experience

Patients enrolled in trials often face the inconvenience of rescheduling and recollecting samples due to inventory-related issues. These disruptions not only affect patient compliance and satisfaction, but also pose logistical challenges for both patients and staff.

Missing lab data can also result in the exclusion of a patient's data from the study altogether, delaying study milestones and negating sacrifices made by the patient.

While deviations are inevitable in clinical research, Carolyn found it important to address avoidable and procedural deviations through process improvements and SOPs. Scheduled test deviations in particular are a key metric for evaluating both the success of clinical trials and the effectiveness of clinical operations.

> "Rescheduling a patient due to inventory issues is a major hassle. Telling them we don't have the lab kit and they'll need to return in 2 days is tough, especially when they're sick and oftentimes traveling from far away. Despite the inconvenience, they need to come back for a critical sample — because this trial may be their only viable treatment option."

Carolyn Lane
Clinical Research Laboratory Manager
University of Arizona Cancer Center

In an attempt to improve their inventory management workflows, UACC transitioned to centralizing inventory management using an Excel spreadsheet that only Carolyn could edit. However, this manual method still relied heavily on individual staff members to report kit usage and expired kits. Predictably, this led to frequent oversights and a persistent lack of accurate inventory data.

The inadequacies of UACC's inventory management system culminated in a particularly heartbreaking incident. Carolyn recounted a distressing story where the center did not have a rare sample tube needed for a patient visit scheduled for the next day. This tube was critical for screening a critically ill oncology patient for a trial that represented his last hope after he had progressed on several prior treatments.

In a desperate bid to source the tube, Carolyn drove all over Tucson and made numerous calls, but her efforts fell short. The screening visit had to be delayed by four days, jeopardizing the patient's chance for timely treatment.

This incident was the tipping point for Carolyn. Realizing that the existing system was untenable, she began searching for a more robust solution. It was during a routine Internet search that she discovered Slope's inventory management solution for clinical trials (Slope IM).

How Did UACC Implement Slope IM?

- The Slope team **uploaded over 3,000 kits** from a spreadsheet into the platform
- **Kits were organized** by the disease team
- **User-friendly interface made staff training easy**
- The full transition to Slope IM took **about 3 months**
- **Slope provided continuous support** during and after the transition

The Solution

Since implementing Slope IM, the University of Arizona Cancer Center has revolutionized its inventory management practices through several drastic improvements.

Centralized and Accessible Inventory Data

A centralized software solution ensures that all relevant inventory information is stored in a single, easily accessible platform. Authorized personnel can access up-to-date inventory data from any location, facilitating smoother operations and better coordination across different teams and facilities.

> "I believe Slope has improved our site's productivity tremendously. Going from a massive Excel inventory spreadsheet to Slope [IM] was one of the best operational changes our team experienced. Slope helped us log inventory quicker, keep track of our collection kits, and quickly ascertain what study kits need to be reordered. My favorite feature from Slope [IM] is the ability to produce reports on inventory, items, or movement. It even provides our site with an audit trail."

Sonja Velickovic
PK Specimen Management Coordinator

Automated Weekly Repors

Reports ensure that inventory levels are consistently monitored and updated without requiring manual intervention. As a result, UACC staff can focus on other critical tasks, knowing that their inventory data is always current.

Easy Access to Current Data Metrics

Data metrics have enhanced transparency and communication both within UACC and with sponsors. Teams can quickly retrieve information about inventory levels, usage patterns, and potential shortages, enabling them to make informed decisions about inventory in real time. This immediate access to data has improved UACC's ability to manage resources effectively and respond swiftly to any inventory-related issues.

Expanded Use to Include IT Inventory

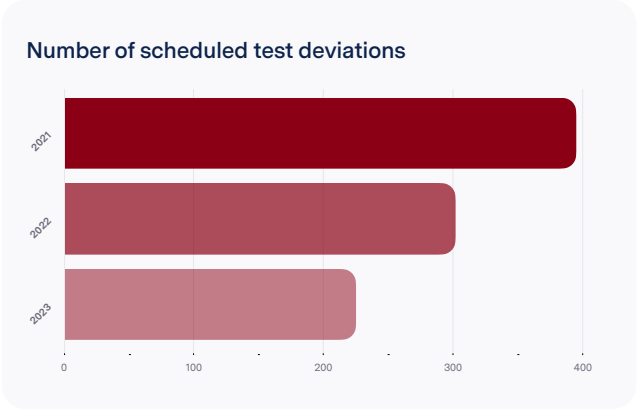
Beyond managing clinical trial supplies, UACC has expanded the use of Slope IM to include IT inventory and devices provided by sponsors. By integrating IT inventory management into the Slope IM platform, the Cancer Center has achieved greater operational cohesion and simplified its inventory oversight processes.

Facilitated Identification of Inventory and Equipment Locations

Slope IM's platform has also enhanced UACC's ability to identify specific inventory and equipment locations across multiple disease teams and facilities. This capability is crucial for an institution that operates on a large scale and across various campuses. The ease of tracking and locating equipment has reduced downtime and improved the utilization of resources. Staff can quickly determine the whereabouts of specific items, facilitating better coordination and faster responses to the needs of various disease teams.

The Impact

Data on scheduled test-related deviations from the year before Slope IM's implementation were compared with those from the implementation year and the subsequent year. This data was recorded in OnCore, UACC's clinical trial management system (CTMS).



From 2021 to 2023, **UACC achieved a 44% reduction in scheduled test deviations**. While not all of this improvement can be directly attributed to lab kit availability, the trend is promising, especially considering no other interventions were introduced at UACC during this period.

> "Having Slope [IM] makes my job three times easier and stress-free. Being able to organize kits by visit, type, and availability is amazing. Receiving emails of kits expiring and/or low volume gives us the ability to order kits ahead of time — especially in the face of weather and shipment delays — keeping our collections on track. Being able to mark kits as used, expired, or discarded during visit planning keeps our inventory up to date in real time. This feature also enables quick responses to sponsors when they request an inventory report, which we can generate in no time."

Shelly Hovelson
PK Specimen Management Coordinator

Conclusion

UACC's adoption of Slope IM across its 11 disease teams has been a major win for its clinical trials office. By reducing scheduled test deviations, the cancer center has not only streamlined its processes, but also enhanced the quality of its clinical trial operation.

UACC patients are happier

First and foremost, fewer protocol deviations have benefited the patient experience. By ensuring that lab kits and other supplies are always available, UACC has been able to minimize the need for patients to return to the clinic or reschedule appointments due to supply shortages. This in turn translates into better patient compliance and satisfaction — both of which are crucial for the success of clinical trials.

UACC studies are running more smoothly

Operational efficiencies have also been markedly improved. The reduction in deviations has led to fewer lab queries and "expected sample" reports, as well as less time spent reporting and managing deviations. Less operational burden has reduced stress for managers and enhanced interoffice relationships across UACC's 11 disease centers. The smooth workflow has not only improved internal dynamics but also strengthened partnerships with clinical collaborators like Banner Health (the largest healthcare system in Arizona).

UACC has maintined its status as a cutting-edge research institution

From a sponsor relationship perspective, the reduction in deviations has enabled UACC to continue being a world leader in clinical research. UACC's ability to maintain high-quality data and avoid significant findings during FDA and sponsor-led audits underscores the reliability and effectiveness of their trial management. This has enabled UACC to continue attracting and managing complex clinical trials, ensuring that they remain a competitive and trusted research site.

> **"What I really like about Slope [IM] is that it is user friendly and easy to get the hang of. It allows me to manage my inventory efficiently. I can see at any time the number of kits I have readily available. I'm also able to see/get notified if I'm running low on kits and if kits are expiring soon. This helps me gauge when to reorder more supplies, which minimizes the risk of using expired kits or not having a kit for a patient."**
>
> **Assumpta Nsengiyunva**
> PK Specimen Management Coordinator

UACC is equipped to handle an increase in trial volume and complexity

Slope IM has proven invaluable in handling increasing trial volumes and complexities. The flexibility and comprehensive organizational capabilities of Slope IM have allowed UACC to manage multiple cohorts within studies and adhere to complex sponsor instructions seamlessly. By centralizing all necessary information within the software, UACC has eliminated the risk of miscommunication and error, further ensuring the integrity of their trials.

Key Takeaways

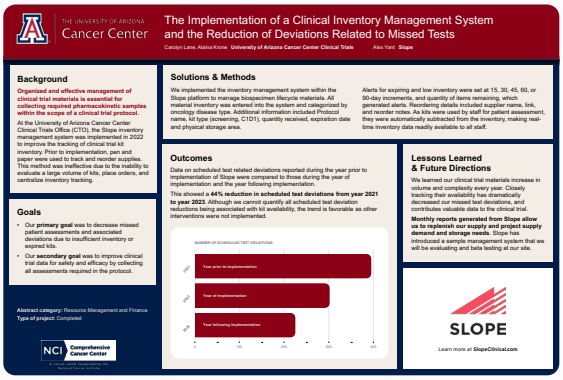
It's important to note that sites' point of entry into Slope IM is different from that of sponsor-led trials. UACC was able to leverage Slope IM to organize and track their inventory; however, for sponsor-led trials where lab kitters are directly involved in the configuration of Slope's Biospecimen360™ software, sponsors have the ability to also reduce waste and control ordering.

Biospecimen360™ can also decrease the number of preventable biospecimen-related deviations through our guided workflows for sample management. These workflows digitize sample collection, processing, storage, and shipping procedures at the site, ensuring that all expected samples are collected and handled in alignment with study requirements.

DATA SOURCE

AACI CRI Poster

The research reported in **this poster** was presented at the 2024 Association of American Cancer Institutes Clinical Research Innovation Meeting in Chicago, IL.



CASE STUDY CONTRIBUTOR

Carolyn Lane is a Clinical Research Laboratory Manager with over 10 years of clinical laboratory and pathology experience. She has a strong interest in advancing cancer treatment through clinical trials. Outside of work, Carolyn enjoys spending time hiking, skiing, and traveling with her family.

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SLOPE

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, while empowering sites with tools to streamline their management of clinical inventory, patient samples, and sample metadata. Slope has supported thousands of the most complex, sample-intensive trials worldwide and has been adopted by nearly 80% of NCI-designated cancer centers.

For more information, visit SlopeClinical.com.