CASE STUDY TEAL HEALTH

Teal Health's Partnership with Slope Contributes to FDA Breakthrough Designation for Groundbreaking At-Home Cervical Cancer Screening Device

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CUSTOMER PROFILE

Teal Health is on a mission to redesign women's healthcare — starting with cervical cancer screening. The company is seeking FDA approval for an at-home cervical cancer screening device called the Teal Wand™, which in May 2024 joined a shortlist of devices that have received Breakthrough Device Designation within the category of microbiology — a distinction awarded to only 4% of all breakthroughs.

Teal Health's SELF-CERV Pivotal Trial at a Glance

609 participants

16 clinical research sites

1208 samples of 2 sample types

Samples processed on **3** different IVD tests at **6** labs

Initial end of enrollment target **6 months**

The Challenge

Teal Health has embarked on a mission to roll out the first-ever at-home screening device for cervical cancer. The Teal Wand™ — designed for self-collection of vaginal cells for primary HPV testing — strives to make cervical cancer screening more comfortable, convenient, and modern by replacing the traditional Pap smear.

Trena Depel, Teal's VP of Regulatory, Clinical, and Quality, was tasked with overseeing the company's first trials. Before testing the feasibility and efficacy of the Teal Wand™ on a larger participant population, Teal Health started by conducting a pilot study. Significant operational challenges surfaced during this first trial, particularly in the areas of inventory management and sample handling.

Manual Tracking of Inventory and Samples

In the initial pilot study, the Teal team encountered considerable difficulties due to the manual nature of their inventory and sample tracking processes. Trena and her colleagues were responsible for maintaining inventory records, which included the Teal Wand™ and other necessary materials. This manual tracking system was not only labor-intensive, but also prone to errors and inconsistencies. The reliance on site-specific labeling and tracking often led to inefficiencies, as mismanaged inventory resulted in either shortages or surplus supplies at different locations.

In order to minimize product waste, Trena's team would move supplies around across various sites, which was both a time and money expenditure. Trena estimates that this manual management cost Teal Health about $40,000 a year for labor and shipment. These activities were not only time-consuming and distracting, but they were also a burden on sites when they were required.

These inefficiencies also extended to managing samples. In total, Trena estimates that she and one of her colleagues spent 15% of their time on inventory and sample management. This critical diversion of resources is particularly consequential for a small startup that operates with few resources, meaning they were not able to focus as many of their efforts on other critical activities like site initiation and study management.

Handwritten Air Waybills, Manifests, and Logistics Management

Another major challenge faced by Teal Health had to do with the creation and management of air waybills and manifests. Sites were required to produce handwritten manifests for shipping samples and Teal had to generate waybills for every shipment — a process that was not only time-consuming, but also susceptible to human error.

The accuracy and legibility of these handwritten documents were critical, yet inconsistencies were common — leading to shipping and testing delays, as well as a lack of sponsor visibility to data that is critical to sample tracking. The manual nature of tracking sample shipments also meant that Teal Health staff had to dedicate substantial time and effort to ensure that each sample was correctly labeled, shipped, and traceable.

Scaling Challenges for the Pivotal Study

Recognizing the limitations and inefficiencies experienced during the pilot study, Teal Health understood that a more robust and scalable solution was imperative for their upcoming pivotal trial. This larger and more complex study would involve a greater number of sites and participants, as well as an expansion from managing samples across 2 labs to 6 labs.

What did Slope's onboarding process look like for Teal Health?

- **Gathered study documents** (protocol, lab manual, etc.) and drafted configuration plan
- **Created a procurement plan** for study supplies and shipped inventory in time for enrollment
- **Conducted a live demo** of fully configured platform with Teal Health team and labs to ensure alignment with expectations
- **Facilitated study kickoff** to review the configuration plan, timelines, and lab vendor plan
- **Constructed the platform** well before first participant enrolled
- **Customized 30-minute training plan** for site platform users and granted appropriate access within days of SIV

The increased scale amplified the need for an efficient and reliable system to manage inventory and samples across multiple locations.

The anticipated complexity of the pivotal study underscored the inadequacies of Teal Health's existing processes. The manual tracking and logistical hurdles that were difficult to manage in a smaller pilot study would be untenable in a larger trial. Unless Teal implemented significant improvements, the risk of logistical bottlenecks, sample mismanagement, and operational inefficiencies threatened to undermine the progress and success of the pivotal study.

The Solution

Trena discovered Slope's Biospecimen360™ software after one of her new colleagues recommended taking a look at their biospecimen lifecycle solution.

Efficient Supply Distribution and Control

With Biospecimen360™, Teal was able to distribute devices to sites as needed, allowing for supply efficiency and assurance that supplies were used on a first-in, first-out basis. Inventory preparedness, coupled with a reduction in inventory waste, had the potential to set up Teal for success.

Ability to Track Samples across 6 Labs

Teal loved that Biospecimen360™ could help them track samples from study sites to the initial study lab. Traditionally, this effort would have required a manual review of tracking numbers and reports across several stakeholders, demanding hours of time every week and hindering Teal's ability to exercise real-time oversight.

Augmented Support with Inventory and Sample Management

With 16 high-enrolling sites shipping samples to 6 different labs simultaneously, inventory and sample management were going to demand full-time support from Teal Health's team. Teal knew they could benefit from the efficiencies gained from tech-enabling their inventory management and sample management processes, coupled with the support of Slope's in-house operations experts — who managed configuration, training, and study oversight.

Electronic Manifest Generation

Biospecimen360™'s interface could automatically capture sample metadata that was needed for downstream processing at the lab — including device lot numbers, sample barcodes, collection dates and times, and resuspension dates. By adopting a solution that enabled sites to generate electronic manifests, Teal and their labs could have quicker access to more accurate sample metadata needed to process biospecimens.

Real-Time Visibility to Enrolled Subjects

Teal's pivotal study was going to be enrolling hundreds of participants in a relatively short amount of time, so they needed a way to monitor study progression in real time. Since Teal was able to manage all of their inventory and samples directly in the Biospecimen360™ software, they were also able to leverage this data to keep track of enrollment — something that would have been more challenging to do in the EDC due to data lag.

Full Access to Chain-of-Custody Data Needed for Regulatory Compliance

Teal Health knew they would benefit from having access to the chain-of-custody data for every patient sample for regulatory purposes. Biospecimen360™ gives study stakeholders access to the entire sample journey — including the physical journey of the sample, who performed what actions, when they were performed, and more.

Ease of Training and Onboarding for Sites

If Teal was going to completely overhaul the way they were managing their inventory, samples, and sample metadata, they needed their sites to adopt a solution that not only improved their compliance with study procedures, but also improved their efficiency. Slope's operations team was able to train and onboard site users a few days after SIV and grant them access to Biospecimen360™. Video training proved to be particularly useful for helping sites learn how to use the platform, but Biospecimen360™'s user-friendly interface made the entire rollout process incredibly seamless. Easy site user access to Slope's operations team also ensured that sites never had to wait for answers to their questions.

Actionable Insights

The data in Biospecimen360™ enabled Trena's team to take important actions and make important decisions throughout the SELF-CERV trial.

For example, real-time enrollment data in the platform helped Teal manage their inventory, and enhanced their site relationships so they could recognize site contributions in real time. Chain-of-custody data enabled Teal to move samples from site to lab and lab to lab. Sample reports in Biospecimen360™ proved especially invaluable, as Teal used sample reports regularly to match data from lab to sample ID/subject ID, and move samples across labs for multiple tests. The data also came in handy during study monitoring and inventory reconciliation.

The Impact

Teal Health's adoption of Biospecimen360™ for its SELF-CERV pivotal trial had a measurable impact on the overall success of its clinical and biospecimen operations. These improvements ultimately accelerated the pace of the trial and improved the overall quality of their study data.

Accelerated Enrollment Timelines

Teal Health set an already lofty goal of hitting their enrollment target in a 6 month timeframe — but with Slope's support, Teal Health was able to complete enrollment in just 4.6 months. By improving inventory preparedness and optimizing sample tracking processes, Teal Health was able to ensure that they could enroll every possible participant and guarantee that every single one of their samples could be promptly tested.

No Deviations Due to Sample- or Inventory-Related Issues

Teal Health did not miss a single patient visit due to inventory issues, and every sample arrived at their respective labs as expected. Given the reality that most trials deal with deviations stemming from missed or out-of-window/delayed collections, this was a major accomplishment that only bolstered the integrity of Teal Health's data.

Improved Visibility to Sample Metadata, Site Activity, and Sample Movement

Traditionally, data entry into EDC can take days, weeks, or even months. Because of the ways in which Biospecimen360™ can integrate seamlessly into site sample management workflows, 86% of samples collected for the SELF-CERV trial were entered into

100%
of samples arrived on time

Zero
patients missed due to inventory issues

Hit enrollment target in
4.6 months
rather than anticipated 6 months

Sites reported up to
2 hours
of time savings per week on 1 trial

0%
lab kit waste

0.2 days
average lag time from sample collection to data entry

Biospecimen360™ the same day they were collected; this gave Teal Health the ability to access their sample metadata about 0.2 days after sample collection on average. Having quicker access to this data enabled Teal to keep tabs on their samples in near real time, while giving Teal improved visibility to the entire biospecimen lifecycle — including site activity and lab-to-lab shipments.

Zero Inventory Waste

By integrating their inventory into Biospecimen360™, Teal was able to optimize their resupply orders — ensuring that sites were always prepared for upcoming patient visits, while only supplying sites with what they truly needed. As a result, they saw 0% inventory waste — an impressive achievement that likely saved Teal Health thousands of dollars in operating expenses.

Time Savings and Site Satisfaction

When sponsors adopt technology that requires site adoption, it's crucial that sites see a tangible benefit. Sites who supported Teal's trial reported up to 2 hours of time savings per week — just on their trial alone. In an industry that is plagued by turnover, limited bandwidth, and tech fatigue, the implications of a wider spread adoption of Biospecimen360™ could be significant for sites who support many trials.

Notably, 8 out of 10 site respondents also reported that a Biospecimen360™ integration with the EDC would have helped their sites decrease reconciliation and data entry. Biospecimen360™ is able to integrate with any EDC, thereby reducing data discrepancies and eliminating the need for duplicative data entry.

What do sites have to say about Biospecimen360™?

100% of respondents found Biospecimen360™ easy to adopt and utilize.

"[Biospecimen360™] was easy to use. I think any site struggling with inventory maintenance or enrollment should utilize a database like B360™."

"The training video was super helpful, especially as we were starting off."

"Auto-generation of manifests / waybills is very convenient."

"Our office really enjoyed using Biospecimen360™."

Unified Women's Clinical Research Raleigh

Conclusion

Ultimately, Teal Health's partnership with Slope paid off. The company hit its enrollment target 23% faster than anticipated, gained sample metadata access within 4.8 hours of sample collection on average, and eliminated inventory and sample-related deviations.

In May of 2024, Teal Health announced that it had received Breakthrough Device Designation from the FDA, granting Teal priority review in communications with the FDA, as well as upon final data submission for FDA approval.

The Breakthrough program is significant because it enables patients to have more timely access to devices that could offer a more effective diagnosis and treatment of life-threatening diseases, and it has the potential to benefit populations impacted by healthcare disparities.

Such a milestone is a reminder of the importance of leveraging innovative technology for optimal efficiency and data quality. When we invest in solutions that enable our trials to operate more compliantly and quickly, we are also accelerating the pace of clinical research and improving patient access to life-saving and life-changing healthcare.

KEY TAKEAWAYS

- **Consider EDC integrations to further decrease site burden and queries**
- **Consider lab integrations and e-requisitions to streamline accessioning and reduce lab queries**

CASE STUDY CONTRIBUTOR

Trena Depel, Vice President of Regulatory, Clinical, and Quality at Teal Health, is a seasoned expert with over 25 years of experience commercializing medical devices globally. With expertise spanning regulatory affairs, clinical research, and quality systems, Trena has led groundbreaking initiatives, securing approvals for various devices — ranging from Class II surgical instruments to interventional cardiology/radiology catheters, and active implantable medical devices such as cochlear and middle ear implants. Trena's achievements include securing two Breakthrough Device designations and pioneering advancements in oncology, cardiology, and other therapeutic areas.

teal health

Teal Health is on a mission to design a better healthcare experience for women - starting with cervical cancer screenings. By creating the option for a woman to collect her own screening sample from the comfort of her home or health clinic and providing telehealth follow-up, Teal can increase access to this critical screening. Teal Health is a member of the Cervical Cancer Roundtable, a joint collaboration between the American Cancer Society and the Biden Cancer Moonshot, a coalition of industry leaders with the goal of eliminating cervical cancer as a public health concern in the US.

To learn more, visit www.getteal.com or follow Teal on Twitter at @tealhealth.

Request a demo of

Biospecimen360™

SlopeClinical.com/request-demo

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. 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.

DATA SOURCES

Slope and Teal Health collectively reviewed anecdotal evidence and data captured in Slope's Biospecimen360™ software to determine the reported metrics. Site feedback was collected via a survey that Teal Health distributed to B360™ users in their bi-weekly newsletter.