

UROLOGY

Ostomates and Patients with Stomas



90%+ Referral Randomization
Achieved to Complete Enrollment
Ahead of Schedule in Two
Complex Urology Trials

Succes at a Glance

- **Over 90%** of pre-qualified patient referrals provided by Trialbee were **randomized** into a complex urology study with restrictive I/E
- Live medical secondary screening disqualified **60% of referrals** before they were sent to sites - reducing site burden while improving patient education and reducing I/E criteria ambiguity
- White glove project management improved screening scripts and funnel conversion rates
- Enrollment completed **ahead of schedule**

Challenge

There are many reasons why a clinical trial sponsor can find patient recruitment difficult. Sometimes, trials can be too cumbersome for most patients. In other cases, study designs that require highly specific eligibility criteria will inevitably narrow a candidate pool significantly.

A leading global medical device company, specializing in finding new solutions for patients with intimate health conditions, faced both of these challenge for two complex urology studies.

Driving much of the recruitment burden was the nature of medical device trials - patients were required to be using specific models and sizes of catheters or colostomy bags to qualify.

This requirement, and several other stringent criteria like it, resulted in many potential candidates falling short of eligibility. Additionally, there were areas for improvement in how patients were screened, with ambiguous screening materials leading to confusion and, potentially, some eligible candidates being dropped from the process.

Because the sponsor's team is incredibly close to the community of patients they serve, they took these challenges head-on and committed to improving access, and the experience, for everyone.

Solution

The company knew it needed a solution that delivered better insights into patient journeys throughout the recruitment process - insights that they could then build into both study designs and their patient outreach strategies.

Understanding patient concerns, such as leakage and infection risks, could help improve patient access into their studies, create more compelling messaging, and provide better patient experiences. In Trialbee, they found a partner that shared their commitment to this more patient-centric approach.

The company worked with Trialbee to employ its hyper-targeted Precision Recruitment approach. This included live medical secondary screening, where patients spoke with a nurse (equipped with approved scripting) who was able the patient find key information about their medical devices to determine likely eligibility. This process helped in two key ways:

- Potential confusion with study design and ambiguities were clarified and confirmed
- Areas where I/E criteria were unnecessarily restrictive were identified and resolved

Trialbee's team worked closely with the medical device company to harness these real-time patient insights, pinpointing where potential participants were being excluded or dropped out to further refine scripting.

The Honey Platform™ was implemented to streamline management of the recruitment funnel and more efficiently produce higher-quality referrals.

The device company also leveraged Trialbee's global expertise to develop a solution that could be mobilized to bring in patients from all over the world. The experienced Trialbee team, along with the flexibility of Honey allowed them to connect with patients wherever they live, in the appropriate languages, and in compliance with varying global standards and regulations.

Results and Benefits

By collaborating with Trialbee, the medical device maker was able to make data-driven iterations to its outreach materials, web forms, and screening scripts, enhancing both the number and quality of referrals.

Trialbee's medical secondary screening was able to streamline the screening process. By quickly removing ineligible patients, they were able to dramatically reduce the burden on site managers, enabling a focus on more qualified participants.

With the Honey Platform, the sponsor's team was able to manage site partners more effectively and easily monitor patient activity from the beginning of the recruitment process all the way to randomization. Highlights from the company's collaboration with Trialbee include...

- **Over 90%** of Trialbee referrals **randomized** into the trial
- Approximately **500 patients** from all over the world responded and completed the web pre-screener
- Trialbee's screening strategy quickly identified ineligible patients, **disqualifying 60% of candidates**, allowing sites to focus only on qualified individuals
- This focused approach allowed the first trial to **achieve enrollment targets early** – even before all Trialbee's referrals were processed
- The sponsor has been delighted with Trialbee's flexibility, rapid deployment, and Honey Platform – noting that **Principal Investigators log in daily**, a testament to the platform's value and ease of use

Participant Spotlight: The Human Side of Clinical Research

Live medical secondary screening can do much more than pre-qualify patients. In this trial, one screening identified an individual who worked as a full-time ride app driver **until his car was stolen**. The nurse also uncovered that as a veteran of the United States military, he did not have enough insurance to cover more than four new colostomy bags each month. Combined with his loss of income due to the car theft, he was **washing and re-using a limited supply of bags**.

Trialbee knew the compassionate sponsor would want to hear about the situation immediately. The teams collaborated and as a result, **he was the first patient enrolled**. Further, they structured study follow-up in a way that allowed him to continue receiving ongoing bags for a significant amount of time post-trial while his insurance benefits and working situation were positively resolved.



In Their Own Words...

"Honey is amazing. And even better, it's the entire support system from Trialbee that makes my job very easy. We really feel listened to, and it's a true partnership with both teams on a mission to put patients first."
- **Senior Clinical Trial Recruitment Manager**

"I believe Trialbee Honey has the potential to dominate the industry for patient recruitment. We sites are so grateful for your team, and for your hard work in creating the platform we need! Thank you, Trialbee!"
- **Alycia Ketter, MS, SAS-AP**
Wright State Physicians

