

DERMATOLOGY / RARE DISEASE

Chronic Spontaneous Urticaria (CSU)



Rescued Ultra Rare Study by
Accelerating Recruitment from
28% of Goal to Successfully
Close Enrollment **3 Weeks Early**

Succes at a Glance

- Ultra rare CSU dermatology study
- 28% of goal at seven months into trial before Trialbee helped rescue the study
- In only three months, Trialbee generated **168 pre-qualified referrals** and **31 consents**
- Enrollment quickly caught up and was successfully closed 3 weeks early
- Sites were thrilled with medical secondary screening for pre-qualified referrals

Challenge

Rare diseases are often very difficult to treat because it is inherently challenging to find enough patients to participate in clinical research. It's also expensive to run a trial, with the average cost to recruit a single patient ranging from \$50,000 to more than \$100,000 USD for some indications. Yet this research is vital, as it offers patients hope and reassures them that, despite the rarity of their disease, they are not forgotten.

An emerging biotech organization experienced just this kind of difficulty finding patients to test a new biologic study drug for the ultra-rare Chronic Spontaneous Urticaria (CSU) commonly known as Hives. CSU affects only 0.5%-1% of the general population[1], so the potential patient pool was incredibly small. In addition, this particular trial required moderate-to-severe CSU patients with diagnosis, which are even more difficult to identify.

Despite all of their internal efforts, recruitment was only at **28% of goal** seven months into the trial. As they were activating additional sites, the sponsor wanted to support them with expert outreach through digital outreach and manage all activity in a Patient Recruitment Platform (PRP). This strategy would help find patients while also facilitating communication around the specific needs of these studies and encourage engagement throughout the enrollment process, leading to better results.

Within three months, the Trialbee team rescued the study and helped complete enrollment early.

Solution

The biotech, which had limited experience with central recruitment advertising campaigns, reached out to multiple providers to understand different approaches that would work best for their target patient population, sites, and study team.

After a thorough evaluation process, they selected Trialbee to support the CSU trial as well as a concurrent atopic dermatitis study. Key decision factors were Trialbee's...

- Proven results connecting with ideal patients in hard-to-recruit studies across therapeutic areas
- Pre-qualification process for all potential participants
- The project management team's experience and success with global rare disease recruitment (15-20% of all indications supported)

As the CSU had fallen far behind recruitment goals, Trialbee responded with a sense of urgency to launch a **Rescue Kit™** solution:

- **Precision Recruitment** for hyper-targeted digital outreach to patients and care team members, a critical component of rare disease success
- **Medical secondary screening** of all interested patients before they are sent to sites – easing site burden and improving referral quality
- **Access to the Honey Platform™** to create a single funnel with standardized data formats and real-time performance reporting
- **Unprecedented transparency** and actionable insights including detailed ROI for every outreach channel and tactic to inform budget decisions
- **Actionable insights** to track patient journeys, site performance, and follow-up where required
- **White glove project management** delivered by an expert and experienced global team committed to proactive consulting and ongoing improvement of campaign results
- **Expedited implementation** leveraging best practices for templated creative material design and proactive IRB submission

Results and Benefits

Precision Recruitment with the Trialbee Rescue Kit had an immediate impact on the CSU trial's outlook and randomization outcomes. Despite it being an ultra rare indication, Trialbee was able to...

- Rapidly accelerate enrollment from 28% of goal before Trialbee, to meeting 100% of objectives and closing enrollment for the study **3 weeks ahead of schedule**
- Connect with and refer first medically pre-qualified patient within a week of launch, with **168 total pre-qualified** referrals sent to 50 sites in only **3 months**
- Directly contribute **14 randomizations** (with **many more** qualified referrals in the pipeline when enrollment was closed) while significantly expanding awareness to support site recruitment efforts
- Expedite implementation timelines, achieving kickoff to go live with both studies concurrently in just **6 weeks** – and campaign launch **3 days** after approval
- Concentrate on regions with high conversion rates, prioritizing those with more site capacity, to continuously optimize ad budgets and assist sites with depleted patient databases

In addition to the number of patients randomized, the biotech team realized critical benefits of the Honey Platform, including:

- **Highly satisfied and engaged sites** who were pleased by the quality of referrals, access to helpful patient information, and ease of use of the Honey Platform to reduce administrative burden
- **Real-time reporting** on the recruitment funnel status, enrollment progress, site performance, and participant journeys for both trials
- **Total control over** the entire recruitment campaign, including overall trends down to detailed patient information including qualifying screening responses, medical history, and contact preferences

The team also recognized Trialbee as a valuable asset in project delivery and management. Trialbee's approach to reporting and commitment to transparency boosted confidence in the partnership, while the expert project managers brought extensive experience from working with sponsors, CROs, and clinical sites, providing a holistic understanding of all stakeholder needs.

Following these successes, the biotech company expanded its partnership for a third dermatology study, demonstrating trust and confidence in Trialbee's recruitment strategy and proven results.

[1] Hsieh J, Lee JK. Chronic spontaneous urticaria. CMAJ. 2017 Jan 16;189(2):E77. doi: 10.1503/cmaj.150951. Epub 2016 Jul 11. PMID: 27402076; PMCID: PMC5235931.

In Their Own Words...

"Some companies refer anyone and everyone, but that's not the case with Trialbee. When I talk to our Principal Investigators and study coordinators, the feedback is always really consistent – the referrals coming out of the Honey Platform are solid. We've seen other campaigns that turn into wild goose chases, but with Honey, the referred patients are much more likely to qualify. Sites are very happy as a result, and so are we."

- **Vice President of Medical Affairs**