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Injectable medical device trial

US-based human factor research study



The challenge

Osteoporosis is a disease that affects approximately 10 million Americans resulting in a decrease in bone mineral density and mass. While osteoporosis is more commonly found in women, it can also affect men, and 12.6% of people over the age of 50 live with osteoporosis. Osteoporosis is often referred to as a "silent disease" that goes unnoticed until a bone fracture occurs.

Our client approached us for research aimed at assessing the usability of a new, injectable device containing an FDA-approved osteoporosis medication. The study's objective was to evaluate the design of this device to prove non-inferiority against the existing injection method.

Since the device was specific to this medication, we needed to recruit users who were already prescribed the drug and represented a small subset of the osteoporosis population. Additional challenges included limited site availability and diagnosis confusion. However, because this trial was not testing a new medication and offered compensation, motivation to take part was high amongst eligible patients.

Our solution

Though the patient recruitment for this trial had several challenges, Antidote was confident in our ability to reach the right audience and successfully find participants for this study. To directly address the challenges associated with the nature of this trial and highlight the benefits of participating, we used the following tactics.

To address the challenges associated with solely recruiting users of a specific medication, we:

- Used ad copy that clearly highlighted the medication name
- Targeted demographics that had a higher likelihood of using this medication
- Expanded recruitment efforts to multiple digital and partner channels to increase our reach

To counter the limited site availability, we:

- Worked closely with the sponsor and site team to align outreach around specific areas at specific times
- Maximized our ad distribution at times when we knew sites were accepting patients

To curtail issues surrounding diagnosis confusion, we:

Trained our patient care advocates on the specifics of the study to ensure patients had the correct diagnosis and were users of the medication before being referred to a site

Our efforts resulted in:

59 randomizations



9 months of recruiting

215,736 visitors 9 months of outreach efforts 11,969 prescreener completions 270 eligible 130 phone validated **59** consented **59** Randomized

To speak directly to patient motivation, we highlighted:

- The altruistic benefits of participating in research
- The compensation provided to participants
- The study's ease of participating, as it only involved a single, one-hour visit

Results

Our recruitment efforts resulted in 130 patients passing phone validation and 59 randomizations due to Antidote's outreach. The original agreement was for a two-month campaign, but due to the number of potential participants that remained in the pipeline at the end of our initial contract, the client extended the project to total 9 months of recruitment.

At Antidote, our mission is to enable faster medical innovation by connecting sponsors and patients, both for clinical trials testing potential medications and new medical devices. From full-service recruitment to tailored service options, get in touch today to learn how Antidote can enable your research to progress more quickly: hello@antidote.me.

^{1.} https://health.gov/healthypeople/about/workgroups/osteoporosis-workgroup