Science 37

CASE STUDY

Science 37 Decentralized Trial Model Delivers In MDD Through Centralized Enrollment™.

Science 37 outperforms traditional recruitment methods more than 20:1—potentially saving up to four months on study timeline

Faster Recruitment

Broad Geographic Access

Real-Time Data Integration

THE CHALLENGE

Globally, more than 80% of clinical trials fail to enroll on time resulting in an extension of studies, or the addition of new study sites. More than 40% of trials must amend the protocol, delaying the trials by four months.[1]

A global leader in pharmaceuticals was looking to pilot an interventional study in major depressive disorder (MDD) using a decentralized clinical trial (DCT) model, in parallel to their Phase IIb trial. The sponsor was looking to evaluate operational feasibility, data quality, enrollment speed, and retention in decentralized trials. Both the trial conducted with 13 traditional brick and mortar sites and the Science 37 pilot, were to take place over 18 months. The study is currently ongoing.

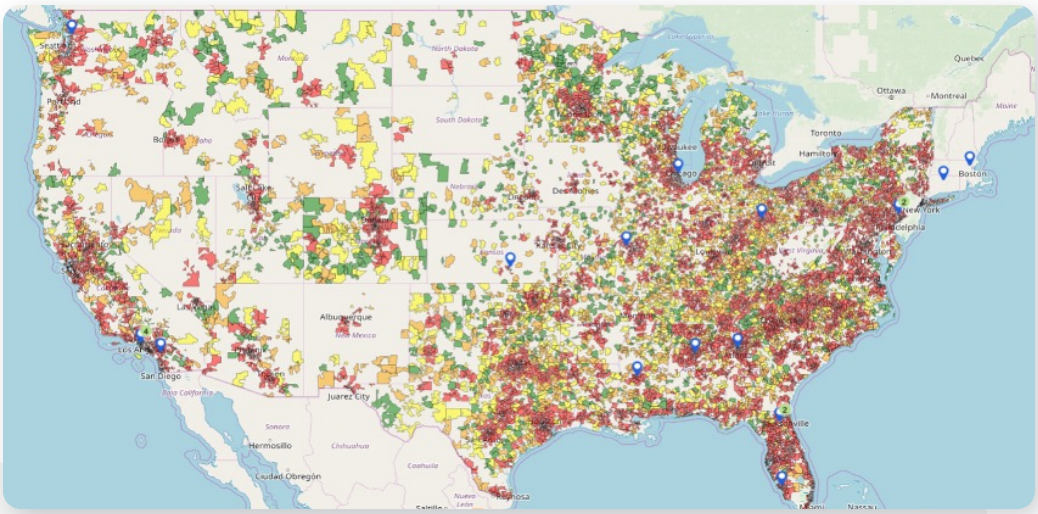
THE SOLUTION

Science 37 expands reach beyond the confines of traditional sites, reaching patients who may otherwise be unable to access the trial. Leveraging Centralized Enrollment™, Science 37 prescreened more than 13,000 geographically-dispersed patients from across the United States – helping to broaden recruitment efforts to enable more patients to qualify and enroll in a shorter time frame than brick and mortar sites.

In this study, the participant completes activities remotely, leveraging Telemedicine visits with investigators and raters. Mobile nurses support patients in the comfort of their own homes. Participants are able to use their own devices by downloading the Science 37 app, or via provisioned devices. Through this model, Science 37 delivers broad geographic coverage.

Map shows total signups for the trial of approximately 70,000 which resulted in 13,000 qualified patients for screening.*

- High Urban / Metropolitan zip codes
- Micropolitan zip codes
- Small town zip codes
- Rural zip codes
- B&M site location



THE RESULTS

Science 37 has observed a 98% retention rate for participants in the DCT model, which is remarkable for a study in this pre-qualified patient population. By comparison, a traditional trial experiences dropout estimates of 17.5% for psychotherapy conditions.[2] Beyond retention, this model proved itself safe and efficient, enabling real-time responses to participants with suicidal ideation and timely collection of adverse events.

* As of February 2022

[1] Perspect Clin Res. Recruitment and retention of participants in clinical studies: Critical issues and challenges, 2020 Apr-Jun 11(2): 51-53

[2] Dropout from individual psychotherapy for major depression: A meta-analysis of randomized clinical trials https://pubmed.ncbi.nlm.nih.gov/26067572/#:~:text=We%20conducted%20a%20random%2Deffects,17.5%25%20for%20psychotherapy%20conditions%20specifically

KEY RESULTS

Science 37 Outperforms Traditional Recruitment Methods More than 20:1—Potentially Saving Up to Four Months on Study Timeline.

- 21x faster recruitment in the DCT pilot study, than the brick and mortar sites
- Access to both high urban/metro zip codes as well as rural
- Initial sponsor concerns regarding the potential for suboptimal adverse event reporting in a DCT model were not justified
- Real-time data integration into the sponsor's external EDC system

Science 37 Accelerates Enrollment, Delivering Results

This study demonstrates the magnitude of our ability to efficiently find patients and effectively enroll them into studies, unlocking large swaths of underrepresented patient populations from across the country, not just patients who happen to live close to a research site. The Centralized Enrollment network of the Science 37 Operating System, leverages standardized processes and unifying technology platforms to not only accelerate enrollment but also to create greater compliance to the protocol and the highest-quality data for clinical trial execution.

Unbound by geography, Science 37's Metasite™ leverages Centralized Enrollment™ to broaden access for under-represented patients, accelerate screening and speed patient enrollment.

To learn more, visit **www.science37.com/metasite**.

Science 37®

About Science 37

Science 37 accelerates clinical research by enabling universal access to patients and providers, anywhere. The Science 37 Operating System™ — underpinned by an end-to-end technology platform and supported by specialized networks to enable trial orchestration — enables up to 15x faster trial enrollment, 28% greater patient retention and 3x more diversity. Science 37 and its Operating System can be configured to conduct the full clinical trial, act as a virtual site (known as Metasite™) or deploy its technology in combination with any of its specialized networks to enable flexibility across nearly any study design. Founded in 2014 as a pioneer in decentralized clinical trials, Science 37 has conducted more fully decentralized, interventional clinical trials than any other provider and has the most complete Operating System.