# How Decentralized Clinical Trials Deliver on Diversity: A Case Study

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## OVERVIEW

The rapid growth of decentralized clinical trials (DCTs) and agile (hybrid) approaches is enabling greater access to clinical research for all patients, including those often excluded due to gender, race, ethnicity, age, socioeconomic status, location of residency, as well as disability and other non-demographic characteristics.

The three main tenets of DCTs that are driving this more patient-centric methodology are:

1. Participation from anywhere (without geographic restrictions of site locations and travel)
2. Participation at any time (not bound by clinic hours)
3. Participation with ease, empowered by technology and processes (telemedicine, home visits, etc.).

Historically, only patients associated with a clinical trial site or located within approx. a 25-mile radius (or 30-minute commute) from a site have had the opportunity to participate in studies. Agile studies and full DCTs, however, are opening opportunities for any patient anywhere to benefit from participation in clinical research. This can have impacts on measures of diversity beyond geography, including gender and race.

This case study reviews the results from a recruitment campaign for a fully decentralized Phase II study of treatment-resistant depression.

## WHY DIVERSITY MATTERS

Despite making up 39% of the US population[1], estimated rates of clinical trial participation for racial and ethnic minorities alone range from just 2% to 16%[2]. For example, while nearly 14% of Americans are Black, they typically make up less than 5% of trial participants (yet almost 20% of those navigating depression[3]). And while Latinos make up 18% of the U.S. population, they represent just 1% of clinical trial participants.

As a result of the drive towards precision medicine, more targeted drugs and gene therapies are being brought to clinical trials. This lack of diversity among participants can make it particularly challenging to get a complete picture of a drug's safety and efficacy. Ensuring people from diverse backgrounds join clinical trials is also key to advancing health equity.

## METHODOLOGY AND RESULTS

Recruitment was conducted simultaneously in 36 states, using primarily social media strategies supplemented by a registry containing individuals who previously expressed interest in participating in decentralized clinical trials.

The campaign resulted in over 65,000 sign-ups of people who prequalified by completing a brief online questionnaire. Analysis of participant zip codes was cross-referenced with census data allowing classification as rural, suburban, urban, and metropolitan.

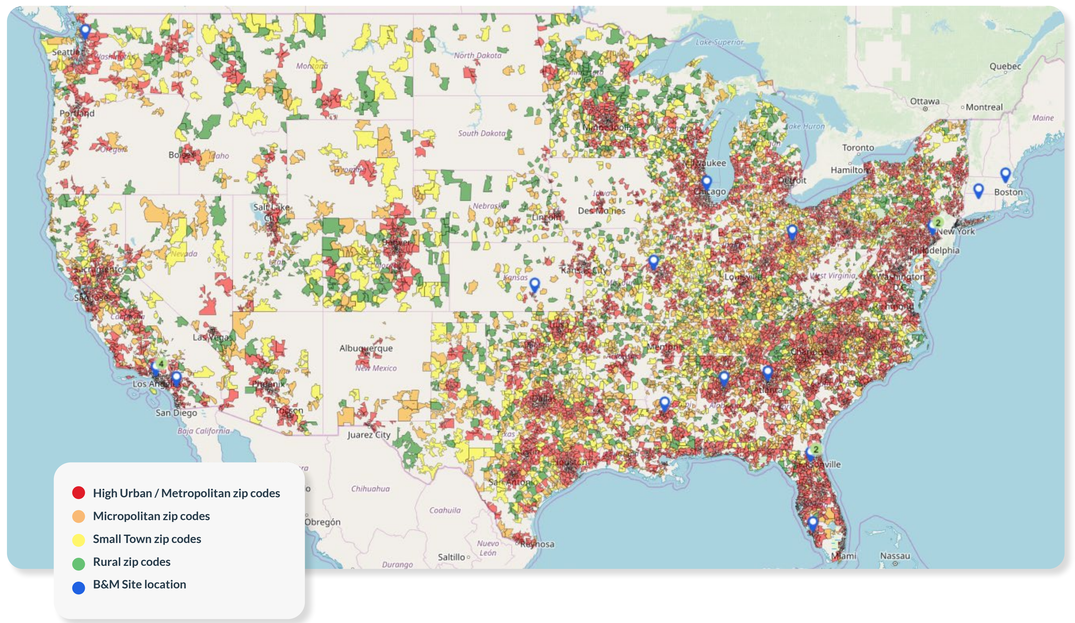
The results, presented graphically as a heat map, show the broad US representation achieved with the recruitment methodology. [see map]

Importantly, the use of a mobile nursing team allowed for any of the "sign-ups" to participate based on eligibility, and, in fact, 13,000 were considered "pre-screen eligible" after completing an interview with the recruitment staff.

From a gender perspective, 82% of signups were female and 16% male (the remainder were either non-binary or declined to report).

The ethnic breakdown was as follows: 79.6% White; 7.6% Black; 6.7% Hispanic; 1.3% Asian; 1.8% Native American; and 0.3% Pacific Islander.

**Total signups of more than 65,000 participants which resulted in 13,000 qualified for screening.**




## CONCLUSION

While there is plenty of work still to be done to increase representation in clinical trials, this case study demonstrates the potential reach of recruitment campaigns in the context of a decentralized approach. When participation is not limited to proximity to a brick-and-mortar site, it opens up access to individuals in suburban and rural areas. Other potential barriers, such as transportation, lack of child care, and stigma, can be overcome by enabling universal participation.

## SOURCES

[1,2] United States Census Bureau

[3] Nursing Research 2013 May-Jun; 62(3): 185–194. https://journals.lww.com/nursingresearchonline/Abstract/2013/05000/African_American_Men_and_Women_s_Attitude_Toward.6.aspx