

## **CASE STUDY**

Rapid enrollment and compliant data collection for a seasonal influenza vaccine trial



(8) Retention

96% retention rate

**Diversity** 

42% diversity achieved across the sites

Compliance

**95%** compliance with the 7-day reactogenicity reporting requirements





## **Phase III** trial of an investigational influenza vaccine



### **13 Headlands Research** sites involved

## Vaccine trials require large sample sizes, timely recruitment, and an at-risk, unvaccinated population

A large pharma company starting a phase III trial of the efficacy of an investigational influenza vaccine (compared with a licensed flu vaccine) needed to find numerous high-quality sites who could recruit participants quickly during periods of potential pathogen exposure within their area. To test efficacy, vaccine trials rely on the presence of the target pathogen and the ability to reach individuals before they receive a vaccine from their doctor, pharmacy, or other health center for that season.

The study spans two seasons, with the first six-month period beginning in September 2024. The sponsor partnered with a CRO to initiate 189 sites nationwide, and for the first period, the aim was to recruit 30,000+ men and women aged  $\geq$ 50 years, with sufficient numbers of older adults (>65 years old) who are at greater risk of serious complications from the flu.

Because Headlands Research had previously worked with both the sponsor and CRO, our ability to collaborate as a network was known to both organizations. As a result of this relationship, the sponsor approached us to identify appropriate sites within our network that had the right population demographics as well as proven performance in vaccine trials.

# We implemented a proactive, strategic approach

Thirteen sites were selected to support the trial. As soon as the locations were chosen, the sites proactively began communicating with their communities and databases, as well as on social media channels, about the upcoming study and their choice to receive their flu vaccine during the trial or from their doctor or pharmacy. As a result, our sites were recruiting for weeks before the study began.

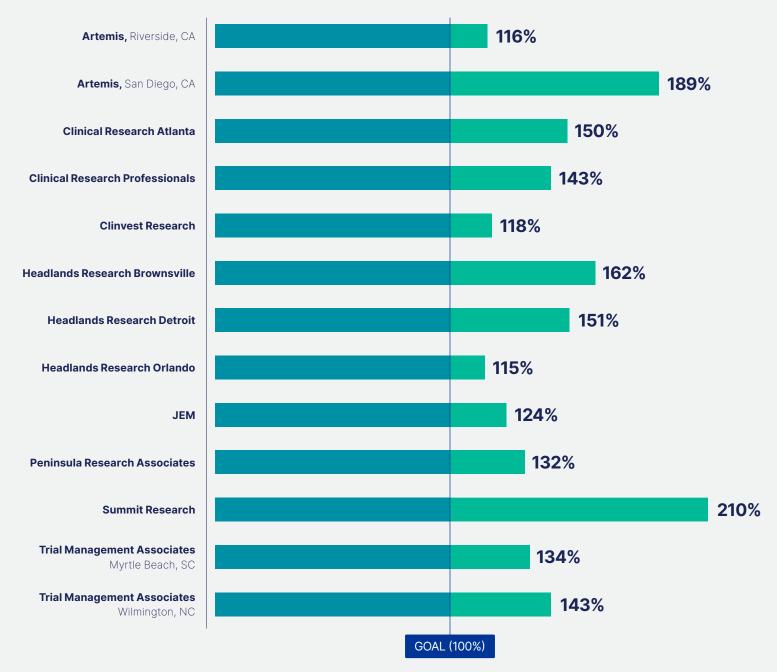
Interested participants were informed of the study timeline, including when it would start, and were placed on a hold list. As soon as the study started, they were quickly contacted, scheduled into the study, and underwent screening.

# Headlands Research approach met our pillars of retention, diversity, compliance, and quality

#### **Enrollment and retention**

The early outreach and word-of-mouth marketing resulted in rapid enrollment of eligible participants, and three sites ranked in the top 20 and four sites in the top 25 for enrollment. Of the 2,924 participants screened by Headlands Research sites, 2,668 were enrolled. To date, the sites have a **96% retention rate.** In addition, the Headlands Research sites overall reached a **percentage to goal for enrollment of 145%**.

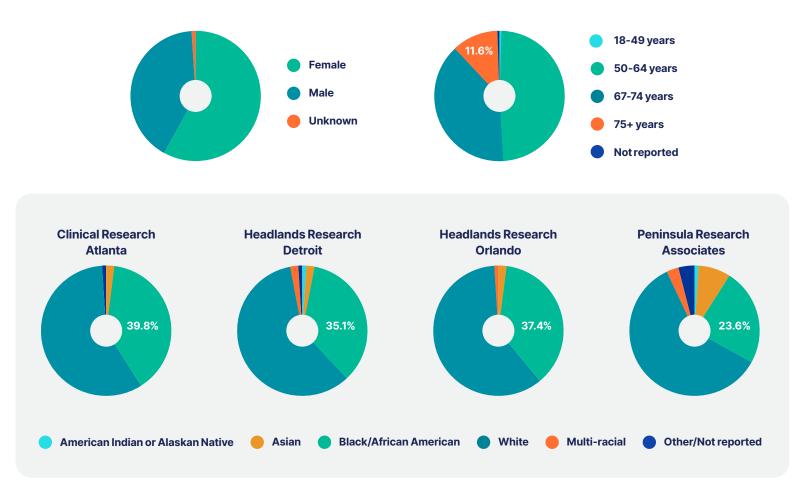
#### Every Headlands Research site exceeded its enrollment goal:



#### **Diversity**

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The participants were balanced well in terms of sex, and we successfully reached older adults, enabling efficacy assessments for the highest-risk age groups. The strategic geographic distribution of our sites also enabled inclusion of typically under-represented racial and ethnic populations.





#### Compliance

In addition, the sites achieved **95% compliance**, on average, with the 7-day reactogenicity reporting requirements according to the protocol.

### Quality

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Our quality team completed a quality review of the first 10 to 15 charts for risk mitigation and found minimal queries.





# **Our ongoing commitment**

As a result of our proven performance on vaccine trials, Headlands Research continues to partner with sponsors and CROs on multiple vaccine studies.

In every study, Headlands Research adheres to our pillars of commitment, including quality, retention, diversity, and compliance.

Contact us to discuss how Headlands Research sites can support your next vaccine trial.

CONTACT US



headlandsresearch.com

