

Leveraging Site Companies for Clinical Trial Execution

A Phase I/II, randomized, modified double-blind study to investigate the safety and immunogenicity of different doses of Influenza vaccine in adult participants 50 years of age and older.

Study Background

Site companies have emerged in the last several years as strategic partners for Sponsors and CROs in advancing clinical research. For this trial, the sponsor authorized AMR Clinical to dynamically manage participant allocation within AMR Clinical sites. This included transferring lab supplies between AMR Clinical sites and responsively re-allocating internal resources to ensure timelines were met. This flexibility empowered AMR Clinical to maximize the effectiveness of our recruitment investment and meet participants where they are.

For this critical vaccine trial, the Sponsor embraced an innovative approach to clinical trial execution by using two multispecialty site research companies to deliver the main cohort of participants. AMR Clinical's performance on this trial validates the thesis of decreasing cost, minimizing timelines and prioritizing quality. AMR Clinical estimates ~25% cost savings for the Sponsor on this study based on streamlined operations and improved timelines.

Indication: Influenza healthy adults aged 50 and over

- 22 US Sites - 11 AMR Clinical Sites
- 850 US participants - 425 participants allocated to AMR Clinical
- Client prioritized Spanish ICF to accelerate diverse enrollment
- Complex pharmacy prep capped enrollment at 5 participants per site per day
- Lab availability and shipments limited enrollment to only Monday, Tuesday and Wednesday

50%
OF TOTAL US STUDY
ENROLLMENT

98%
RETENTION
RATE

1 MONTH
ACCELERATED
ENROLLMENT
COMPLETION

AMR Clinical Highlights

- Sites were able to retain subject interest even with a 3-month delay for study start
- All AMR Clinical sites enrolled first participant within 24 hours of receiving greenlight
- 98% retention rate
- Enrollment completed 4 weeks ahead of schedule
- AMR Clinical internally monitored subject diary tracking daily to ensure compliance
- Single point of contact using AMR Clinical Project Delivery for unified reporting across 11 sites vs. each site individually
- Managed enrollment vs. competitive enrollment resulted in material alignment to diversity targets based on the US Census (2020)
- 17% Screen Fail Rate

Managed Enrollment Enhanced Alignment with Diversity Targets (2020 Census)

