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Expanding Accessibility in a Phase 3 Influenza Study Through Community-Based Research:
A Collaborative Case Study

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Background

This ongoing Phase 3 study seeks to evaluate the safety, efficacy, and immunogenicity of a new seasonal influenza vaccine compared to a licensed inactivated vaccine in adults aged 50 and older. Given the potential severity of influenza symptoms and influenza-related complications, ensuring broad participation and adherence to study protocols is essential.

Challenge

Despite increased focus on improving equity in clinical research, many trials continue to struggle with two persistent challenges: lack of participant diversity and low retention rates. Both issues can significantly impact data quality, generalizability, and the overall success of a study. A 2021 review of U.S.-based adult flu vaccine studies from 2011 to 2020 found that approximately 80% of participants self-identified as white, while other racial and ethnic groups – including Black, Hispanic, and Native American – were consistently underrepresented. This lack of diversity limits the ability to generate meaningful data on vaccine safety and efficacy in populations that may be disproportionately affected by influenza-related complications.

Historically, many populations have been significantly underrepresented in clinical trials. In the U.S., Black individuals comprise approximately 14% of the population but accounted for only 8% of clinical trial participants in 2020, according to the FDA's 2020 Drug Trials Snapshot Summary Report. Similarly, Hispanic or Latino individuals represent about 18% of the population, yet made up just 11% of participants. These disparities are particularly concerning in vaccine research, where population-wide immunity depends on understanding how vaccines perform across a wide range of demographics and risk profiles. Retention poses an additional barrier, with the industry having an average retention rate of 82%. Even in trials enrolling primarily healthy individuals, travel requirements, work schedules, and family responsibilities can make consistent study participation difficult. For many patients, the burden of frequent site visits can result in missed visits, noncompliance, or early withdrawal. These disruptions can delay study timelines, inflate costs, and weaken the statistical power needed to evaluate study outcomes.

Study Approach

To operationalize this approach in a global Phase 3 Influenza study, EmVenio Clinical Research implemented a combined community-based approach. Community-based research models bring clinical research into local communities through mobile visits and sites, meeting patients where they are. This method supports the entire clinical care process, from outreach and recruitment to participation and followup, ensuring accessible trial services. By overcoming barriers like transportation, scheduling, and health issues, these models enhance trial accessibility and representation. EmVenio deployed highly trained mobile research clinicians to conduct 103 in-window, unscheduled illness visits for patients who were too ill to visit a study site. These visits took place in the U.S., Canada, and Germany and helped maintain protocol adherence while prioritizing patient safety, comfort, and convenience. EmVenio also expanded trial accessibility by establishing community-based research sites within two local U.S. communities. These sites provided a flexible and familiar setting for study participants, significantly enhancing access for underrepresented groups. By reducing logistical challenges, EmVenio's model supported higher enrollment and improved retention while contributing to a more diverse and representative study population.

Therapeutic Area

- Influenza

Indication

- All human Influenza A or B strains

Trial Design

- Randomized Observer-blind Active-controlled Phase 3 Trial

Study Duration (Estimated)

- 21 Months

Study Completion (Estimated)

- June 2026

Scope

- United States
- Canada
- Germany

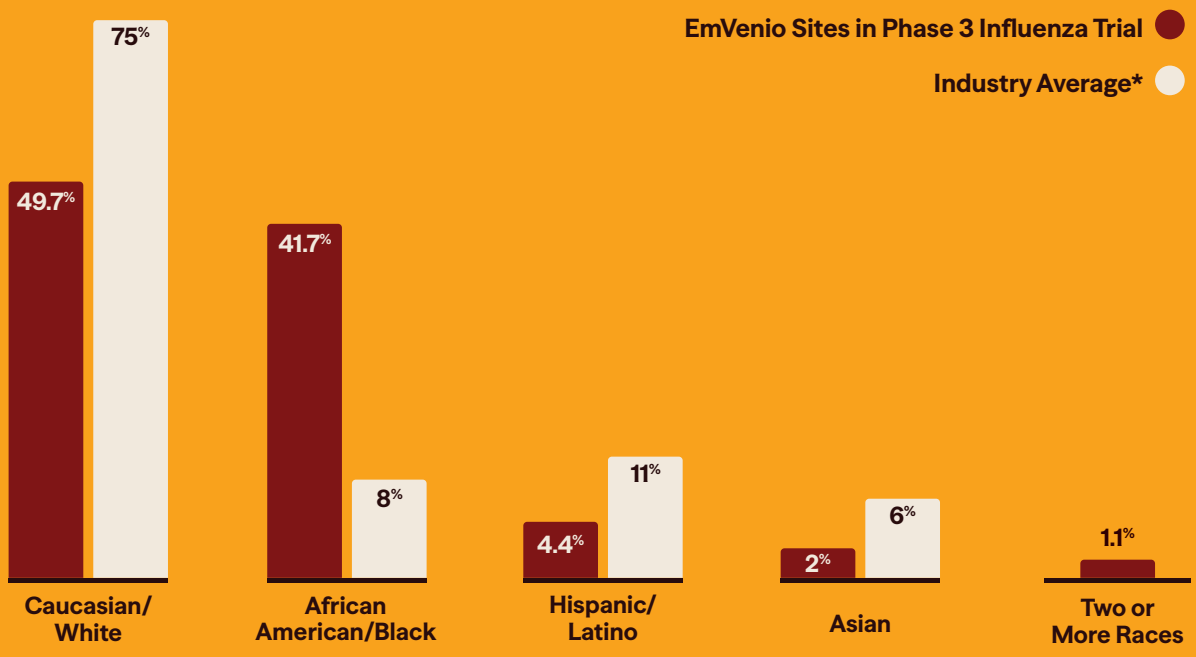
Total Study Enrollment (Estimated)

- 56,000

Enrollment and Retention

The community-based design of this study has enabled enrollment of a more representative patient population compared to traditional site-based models. Among the 104 patients randomized at EmVenio's two sites, the racial and ethnic distribution reflects greater inclusion of historically underrepresented groups.

Patient Distribution by Race (%)

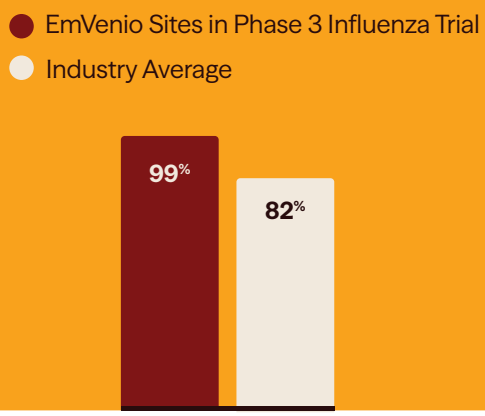


* Percent Participation in Clinical Trials by Subpopulation for New Molecular Entities and Therapeutic Biologics Approved in 2020

The data clearly demonstrates increased participation among African American/Black participants (41.7%) - more than triple the industry average of 8%, based on the FDA's 2020 Drug Trials Snapshot Summary Report. This highlights the potential of community-based research models to meaningfully engage diverse populations by reducing barriers to access and fostering trust within local communities.

Retention outcomes also reinforce the strength of this approach. Of 104 patients randomized and 594 total study visits conducted at EmVenio's sites to date, only one patient has withdrawn from the study, representing a retention rate of approximately 99% and a dropout rate of less than 1%. This is significantly better than the industry average of approximately 82% retention and 18% dropout, suggesting that community-based research models not only improve research access but also foster sustained engagement throughout the trial experience.

Patient Retention Rate



Conclusion

This Phase 3 Influenza vaccine trial illustrates the power of community based research to expand study reach, engage more inclusive patient populations, and significantly improve patient retention. By collaborating with experienced partners to integrate mobile visits and establish sites within local communities, the study successfully reduced logistical barriers while maintaining protocol adherence and enabling broad, high-quality data collection

This case study underscores the value of decentralized and hybrid research models in making clinical trials more accessible and representative. As the industry continues to prioritize equity and patient-centricity, this approach offers a compelling blueprint for future studies and a path toward better outcomes for all.

Note: This case study has been anonymized to maintain confidentiality as per the ongoing nature of the study and sponsor agreements.