Case Study: Vascular Ehlers-Danlos Syndrome (vEDS)

Phase 3 | Rare Disease, Cardiology

Challenge

The sponsor faced significant obstacles enrolling patients with a rare, high-risk vascular disorder dispersed across a wide geographic area. The protocol required close monitoring of participants over a lengthy 40-month period, including an open-label extension. Relying solely on traditional site visits would have created substantial burden for patients, threatening both recruitment and long-term retention.

FDA Guidance

Based on the FDA's recommendation to pursue a remote trial design, the sponsor engaged Science 37, leveraging our ability to deliver nationwide in-home visits at scale.

Solution

Science 37 deployed its Direct-to-Patient Site in alignment to reduce patient burden and expand participation access. This complex, multi-year trial required frequent monitoring and coordination across dispersed patients. Study medications were shipped to participants and administered by research-grade nurses with investigator oversight. Daily electronic diaries enabled real-time data collection, while local imaging facilities supported protocol requirements. Targeted outreach through patient advocacy networks and ongoing virtual engagement strategies helped ensure safety monitoring and maintain high retention throughout the trial.

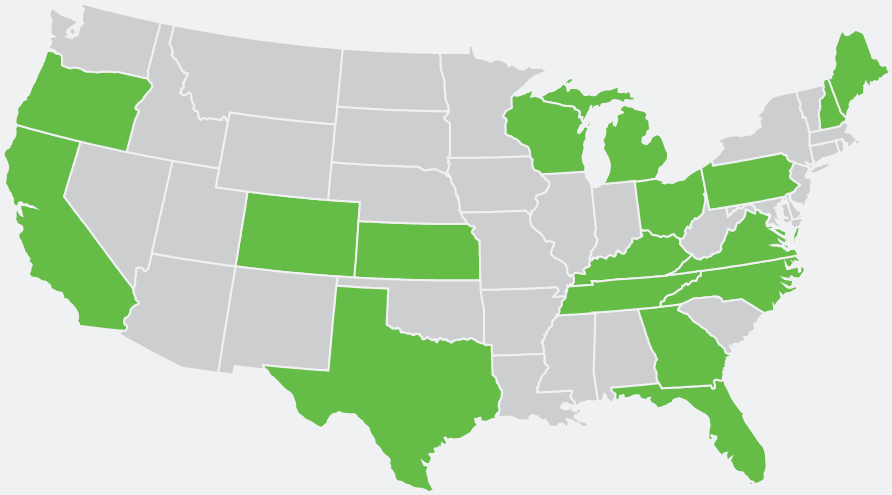
Science 37 Results

Enrolled

100%

of Total Study Participants

Enrolled 40 participants despite rarity and geographic dispersion



Expanded Access

Enrolled across 19 states as a single site

Green states indicate where Science 37 enrolled participants

Scan to Learn More about Our Direct-to-Patient Site.

www.science37.com

FDA INSPECTED

The First & Only FDA-Inspected Direct-to-Patient Site