Hawthorne Health

Case Study:

Hawthorne Health's Support for BTK Clinical Trials

Background and Challenges

Hawthorne Health (HH) partnered with sponsors conducting clinical trials for cardiovascular disease (CVD), specifically targeting BTK (below-the-knee) conditions, like Chronic Limb Ischemia. A significant challenge in these clinical trials is that many patients are often excluded from research due to various barriers, including geographic location, mobility limitations, and accessibility to clinical trial sites. Other challenges included limited resources and staff bandwidth at participating site locations, as well as the ability for data capture of study visits for complex assessments such as Duplex Ultrasounds (DUS), Wound Assessments, ABI/TBI, and PK blood draws.

Desired Outcome and Key Success Criteria

The goal was to enhance participant inclusion, ensure in-window protocol visits and high quality DUS image and data capture, as well as improve access to clinical trials, particularly for those living in underserved or remote areas. Success criteria included:

- High data and DUS image quality and protocol compliance with in-window visits.
- Increased enrollment by enabling easier access to trial sites for a larger, more diverse patient population.
- Faster scheduling of study visits and a broader reach through community-based locations.
- Greater oversight and real-time tracking for study activities, ensuring data availability for key stakeholders.

The Solution and Methodology

HH addressed these challenges by deploying several key solutions:

1. Community-Based Study Visits

- HH employed GCP- and protocol-trained Heroes, including Vascular Sonographers and Nurses, to conduct in-community visits. This ensured more localized and accessible study participation opportunities, reducing travel burdens for participants.
- By utilizing a vast network of Hero's, visits were scheduled within 7 days, providing faster response times and greater flexibility.

2. Hawthorne Health's Visit Delivery Platform (VDP):

- This technology allowed for real-time tracking updates, site oversight for study activities, and seamless data access for key stakeholders involved in the study.
- The platform facilitated Hero readiness and onboarding within 2 weeks, enabling quick execution of study visits, managing logistics, and ensuring all procedures were followed.

3. Extensive Hero Network:

- With over 4,000 GCP-trained Hero's, HH ensured that study visits could be conducted by skilled and diverse healthcare professionals.
- Hero's available to conduct visits across all 50 U.S. states, ensuring geographical coverage and diversity in patient inclusion.

4. Widespread Study Location Network:

- To further enhance accessibility, HH provided a range of study location options including more than 1,000 patient service centers and community pharmacies, and the option for in-home visits. This extensive network meant that over 90% of the U.S. population lived within 10 miles of a potential study visit location.

Conclusion, Results, and Lessons Learned

HH's solution significantly increased access to BTK clinical trials, allowing previously excluded patient populations to participate. The combination of technology, community-based Hero visits, and extensive site network enabled efficient, in-window protocol adherence and timely data capture. Key results included:

- Enhanced Patient Inclusion: Patients who were typically excluded from trials due to location or lack of access were now able to participate.
- High Patient Satisfaction: Of 2,000 patients surveyed, 99% reported very satisfied with their experience.
- Faster Study Visit Scheduling: Visits were scheduled within a 7-day window, expediting trial participation.
- High Protocol Compliance: With GCP-trained Hero's conducting visits, the data captured met the high standards required for clinical trial integrity with 96% of study visits being conducted within window.

Lessons learned from this initiative highlighted the importance of utilizing a broad Hero network, community-based study locations, and an advanced platform for data capture and study oversight. Additionally, procedures were developed and utilized to execute in-window diagnostic imaging for the Duplex Ultrasounds. These elements collectively ensured that clinical trials could reach a more diverse and inclusive patient population while maintaining high-quality standards in data collection and protocol compliance.

Hawthorne Health