



The future <sup>+</sup> of clinical trials has arrived.

## About Hawthorne Effect

Hawthorne Effect collaborates with sites participating in clinical research to function as an extension of their research team. We do this by leveraging our Accelerated Clinical Trials (ACT™) Platform and network of clinicians to bring first-class standard of care, quality, and data collection to a patient's preferred location, typically to the patient's home.

The Hawthorne Hero Network is a global community of medical professionals with varying specialties and broad scopes of practice. Our Heroes are vetted, qualified, and trained through the ACT Platform, enabling them to successfully conduct visits at a place and time that is convenient for the patient.

For sites and institutions that choose to provide this option to patients, the Hawthorne Effect solution takes care of the following:

- + **Visit coordination and management** to ensure the successful end-to-end completion of the visit in the window according to the protocol
- + **Data collection and QC** matching Sponsor quality expectations and requirements
- + Collection, storage, and transfer of **source documents and data** for entry into the EDC
- + **Full training and certification** of Hawthorne Heroes to meet protocol and industry standards
- + Available supporting documentation for **submission of Heroes on the DoA**
- + **Support on audits** and communications with site team members and sponsors



## Our Hawthorne Hero Network

Hawthorne Heroes are medical professionals representing a broad spectrum of clinical credentials, such as Physicians, Nurses, Advanced Practice Nurses (NPs, CNSs), Physician Assistants, Sonographers, Phlebotomists, and Certified Cognitive Specialists, and more.

Heroes are professionals who become an extension to your study teams, easing the burden of participating in clinical research for patients. They are passionate about delivering high-quality care and supporting clinical trials to drive innovative healthcare through connecting with patients at in-home visits.

All Heroes complete a multi-part screening process that includes application completion, reference reviews, background checks, credential confirmation, and interviews. Once Heroes are onboarded, the HE team can match them to specific studies based on the study-specific needs (patient distribution, assessment requirements, etc.) and Hero profile (language, location, availability).

Scan to learn more



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## Comprehensive Hero Training

Together with the study sponsor or clinical investigator, HE develops a protocol-specific training plan that is built into the full-featured Learning Management System (LMS) on the ACT platform, which provides training and professional development opportunities for Heroes.

HE requires all Heroes to complete fundamentals training related to Good Clinical Trial Conduct, conduct of study visits, visit etiquette, reporting of adverse events, and more.

The Hawthorne Effect LMS also supports customized role-based protocol training for each study. The LMS tracks user progress, provides completion certificates and manages expirations.

Hawthorne Effect ensures that Heroes are prepared for the specified visit they are conducting. Audit trails and training records are available to the site investigator and sponsor as needed to support the delegation of authority.

## Equipment Selection & Maintenance

Hero visits are strategically designed to utilize standardized equipment and materials, as outlined with the sponsor in the study visit plan, to ensure quality and consistency of assessments. The Hawthorne Effect study team coordinates logistics, distribution of study materials, and tracking to ensure Heroes are prepared for each visit, as well as to ensure a positive patient experience.

Hero study bags are reviewed with the sponsor team and customized based on the protocol assessments and associated instruments. This includes everything from hand sanitizer to blood draw kits, centrifuges, and echo machines!

## Technology-Enabled Data Collection

Ensuring high quality data collection of even the most-complex assessments is a Hawthorne Effect core value. The ACT platform is HIPAA, GCP, and CFR Part 11 Compliant for high-quality data capture and is interoperable with clinical trial management systems and electronic medical records.

Through a unique combination of training, equipment, visit orchestration, and electronic data capture tools, the ACT platform enables Hawthorne Heroes to conduct and collect data for a large range of complex assessments such as: Echocardiograms, vascular ultrasound, 12-Lead ECGs, Lab Collections, 6-Minute Walk Tests, and more. We ensure that the quality of a Hero visit meets the expected quality standard.

## Quality & Regulatory Oversight

Regulatory requirements have been assessed to strictly adhere to Good Clinical Trial Conduct. Our Heroes function as an extension of the study/investigator team. The ACT Platform provides a streamlined mechanism for inclusion on the Delegation of Authority as the role performing patient study visits and providing data and source documents, allowing true collaboration between the site and HE.

Hawthorne Effect undergoes quality audits by the Sponsor to vet and ensure that our quality systems for identifying, credentialing, background checking, and training of Heroes are performed in accordance to GCP and ICH guidance and to verify that we have the appropriate levels of liability, indemnification, and privacy protection coverage for the responsibilities HE will deliver in any study.