Verana Health

Verana Research Network Combines Innovative Technology With Face-to-Face Encounters to Help Improve Operational Efficiencies at Research Sites

A big part of the heart and soul of any clinical trial is the research site, where patients are evaluated and potentially treated for a myriad of conditions. Drug innovation would not be possible without a strong site infrastructure. However, sites face many challenges when executing trials, such as staffing constraints and difficulty finding patients for trials.

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A 2023 Clinical Research Site Challenges Survey Report outlined some of the challenges that research sites face:

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To better understand these challenges, Verana Health conducted 10 site visits across California, Florida, New York and Tennessee, between March and August 2023. Our goals were to:

- Identify the pain points of the clinical research coordinators and clinical research managers.
- Learn about systems and processes the sites utilize on a day-to-day basis (e.g., CTMS, patient identification, IWRS, recruitment, patient visit scheduling).
- Build a rapport with the clinical research coordinators and clinical research managers.

This white paper describes how Verana Health is combining its data-driven technology, with research from its onsite visits, to help improve efficiencies at clinical trial sites.

[1]https://www.wcgclinical.com/insights/the-great-resignation-its-impact-on-clinical-research-where-we-go-from-here-part-1/

Onsite observations

The sites that our Clinical Trials team visited echoed the same recruitment challenges that were presented in recent site surveys. Those challenges include:

- Cumbersome patient recruitment processes - The majority of sites found the patient recruitment process to be complicated and time consuming.
- High turnover rates among staff - Sites note high turnover rates are leading to a need for consistent staff training and knowledge transfer.
- Complexity of clinical trial protocols - Sites are facing difficulties adhering to trial protocols, possibly due to their complexity.
- Multiple technology platforms - Managing and maintaining information across multiple technology platforms (e.g., CTMS, EDC, etc.) posed a challenge, especially for large-volume practices.
- Desire for User-Friendly systems:
    - Sites are looking for user-friendly systems that require minimal training to provide patient lists of potentially eligible candidates.
    - One site conveyed that it had been dealing with the complexities of certain clinical trials and finding the right patients in electronic health records (EHRs). The site also shared that staff turnovers and challenging protocols are major concerns.
    - Another site, which has been conducting multiple competing trials, noted challenges with various tools and technology for patient identification for each protocol. The site also expressed a desire for a simplified tool which is less time-consuming and cumbersome.

Overcoming challenges with Verana Health solutions

Verana Health is utilizing the following tools to help research sites address many of the above aforementioned challenges. These tools aim to address patient identification and trial and technology complexity:

- Verana Trial Connect (VTC) - Provides clinicians and research staff participating in clinical trials with a curated list of their own practice patients that have a high potential for study recruitment. Using VTC, the research staff cross-references patient records to specific inclusion and exclusion criteria for trials that are offered in the application.
- VeraSite - A site selection tool that may help clinical trial sponsors identify practices that have specific patient populations that fit their clinical trials and provide insights into impact of certain inclusion and exclusion criteria on the eligible trial population.

Examples of Verana Research Network and VTC

A New England research site was experiencing difficulty finding and recruiting patients for a Phase 3 trial on advanced neovascular age-related macular degeneration (wet AMD), due to competing trials and capacity issues. Since this site is part of the Verana Research Network (VRN) – an expanding clinical trials network of

active trial locations affiliated with therapeutic-specific medical societies – Verana Health was able to seamlessly provide the site with a Verana Remote Coordinator (VRC) who was able to utilize the VTC database and EHR system to locate potentially eligible patients. The VRC was also able to identify additional notes on upcoming appointments, which was crucial for the site. The end result was an increased amount of screenings at the site. **The VRN site found the integration of VRC to be instrumental in overcoming recruitment challenges and expressed interest in utilizing this service for future trials.**

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Case Study: Enhancing Clinical Trial Recruitment Efficiency with VRC

Another large site from Tennessee that was conducting a Phase 2 trial on diabetic retinopathy, was facing enrollment challenges for a crucial trial that was reaching the end of enrollment. As a potential VRN site, it was quite simple to onboard the site to utilize the VTC platform within a couple of days. The site was very proactive and reviewed more than 500 charts across three weeks, and enrolled additional patients in the trial through utilization of VTC. After receiving such successful results, the site formally joined the VRN, positioning itself to benefit from future Verana Health offerings. The dedicated research team expressed its satisfaction and relayed that it was able to fine-tune the process, specifically for its practice needs. In addition, the site noted that had it been able to collaborate with the VTC platform and team earlier, the number of enrollments would have been even higher, underscoring the potential for future growth and success within our network.

VeraSite as a future solution

During our face-to-face encounters, many sites expressed frustration over not having the correct, or right amount of trial opportunities. Verana Health's new VeraSite tool is poised to help alleviate such frustration. Prior to the official launch of VeraSite in 2024, Verana Health has already successfully matched many principal investigators and sponsors, utilizing the data that powers VeraSite. The following two examples help demonstrate the potential of VeraSite:

A small site in a suburban area had some experience but a difficult time being selected for trials, perhaps due to being positioned in a densely populated geographic area. Using de-identified, curated real-world data from the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight), Verana Health was able to showcase the site for a number of trial opportunities. The site was selected for a Fuchs' dystrophy trial, largely due to the ability of VeraSite to demonstrate the site had an attractive patient population that fit the study protocol.

In another case, a small site in a very competitive geographic trial environment, wanted to stand out from other sites. Though it had experienced research staff and a robust patient population, the site was located in proximity to busier research centers. Using IRIS Registry data, Verana Health discovered the site would be a strong fit for a wet AMD trial and presented the site and its capabilities to the sponsor. The site was awarded the trial.

Conclusion

The success of VRN and VTC in helping sites better attract clinical trials holds great promise for the future of trials. Verana Health's onsite visits have allowed us to better understand the challenges that sites face, when executing trials. This valuable feedback will continue to be essential as we improve our existing tools and launch new ones, such as VeraSite. Verana Health is dedicated to combining its innovative technology and high-quality real-world data, with site engagement, to help address challenges across the clinical trials landscape.