How To Build a Hybrid Visit Strategy That Delivers High-Quality Results

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After almost 20 years, Home Trial Support (HTS) for clinical trials continues to drive the patient-centric, hybrid trial design movement. HTS enables in-home or remote clinical visits for trial patients and can be leveraged in both hybrid and decentralized clinical trials (DCTs), depending on the requirements of a protocol. The convenience of in-home clinical visits for patients is unparalleled; they can avoid frequent travel to clinical sites that may be far away, minimize the need to set up childcare for in-person visits, and receive treatment from the comfort of their own homes – making trials more convenient to any participant.

Thanks to the benefits they create for patients, in-home clinical visits also positively impact drug developers, allowing sponsors to increase patient enrollment, engagement, and retention. By creating more accessible trials, sponsors can also shorten their timeline to market. However, despite the notable advantages of implementing HTS, there is still some hesitation across the industry to adapt trials to include more hybrid options. There are several factors contributing to this hesitancy, including sponsors not willing to adopt a new approach and site concerns of losing money and access to patients. While these concerns are a natural response to change, proper protocol design and collaboration with an experienced hybrid trial operational team can help your trial reap major benefits.

Familiarize Yourself with a Relatively New Landscape

As the clinical trial community strives to create more accessible options for patient participation, hybrid trials and DCTs have become intriguing strategies. While your team explores the solutions that might work best, consider first the definitions of a hybrid and decentralized trial, both of which differ from the traditional clinical trial model:

- **Hybrid model (specifically, HTS):** this model keeps the site centric to research operations and communications, allowing a mix of traditional site activity paired with local, trained, selected, and often specialized healthcare professionals to conduct a research visit in a patient's home or own community. Mobile clinicians operate under direct delegation of a clinical trial PI and abide by the regulations of said site's country, supported by an in-country team. This model works to incorporate all options, digital or face-to-face, for complete, high-quality data collection while maintaining the patient-care team relationship. In-home data collection for an HTS hybrid trial is done using technology integrated into the site's EDC system that supports the functionality of a DCT model.
- **Decentralized model:** this model is focused on completing clinical trial activities without using clinical research sites via the use of digital tools and technologies, such as mobile devices. Although this activity can be paired with in-home visits by clinicians when necessary, DCTs aim to be fully remote with little to no clinician-patient interaction and minimal site involvement. This creates more convenient trial participation, allowing participants to join from anywhere in the world with a mobile device.

While both offer appealing benefits, conducting a site-based trial with HTS is a strong hybrid option that offers patients flexibility. Due to the complexity of clinical trials and patient care, the cost of HTS is often the chief concern for drug sponsors. Though the up-front cost of working with a remote trial vendor may initially seem challenging on a tight budget, it can help you ensure patient retention and trial efficiency in the long run as opposed to realizing too late that it's a worthwhile option and losing money due to delays and inefficiencies.

It's also critical to gather input from those involved in the trial, including the principal investigator, clinical site staff, and a clinical research organization (CRO) team, if involved. If a sponsor is willing to leverage remote visits throughout the trial but none of their functional teams are, this can be a significant roadblock.

Optimize Your Approach

If you're hoping to optimize in-home visits for your trial, start considering where to implement them from the beginning. Ideally, this means baking remote visits into your trial protocol. This works best when vendor teams are included in protocol design and investigator meetings as early as possible to ensure remote visits are strategically and effectively implemented from

an operational perspective. By allowing your vendor access to your protocol in the draft stage, they can make recommendations and provide input to minimize cost along the way.

To establish maximum efficacy, secure buy-in from your sites. In-country engagement is a crucial component of achieving this, as establishing an in-country team that speaks the local language ensures productive dialogue and engagement with sites. In many instances, site teams face anxiety that implementing remote visits will cause them to lose money and patients; however, creating more accessibility through solutions like HTS generates more patients and more money for an investigative team. Sites must also reckon with the element of building trust with this integrated care team, i.e., *who is going to be working with my patients if it isn't me and my team?* Early engagement and communication with a vendor can help build trust between remote and on-site teams.

From a patient perspective, remote visits sell themselves. Trial participants can have their weekly blood draws from the comfort of their own home, avoid traveling to sites weekly, and gain access to treatment they may not have otherwise been able to receive. Even if only 60% to 80% of visits can be conducted at home, this is still a major benefit to the patients. As a result of this convenience, patients are more likely to stay on for the length of a study, a huge win for clinical trial teams.

Ultimately, clinical trials are fragile projects that must remain flexible. To ensure that all components run smoothly, investigators, sites, vendors, and CROs must maintain open communication, collaboration, and transparency.

Consider a Partner at the Forefront

MRN is an organization that provides HTS, integrated trial services, site and patient support, and data collection technologies to drug sponsors. From its conception, MRN has focused on the idea that making trials more accessible for patients will increase recruitment and retention, allowing investigators to get the data they need faster and bring a drug to market more rapidly. Overall, MRN's mission is to get important drugs into the hands of patients as soon as possible.

As the market leader of global in-home visit trial delivery, MRN partners with a drug sponsor's team over the lifespan of a trial to manage every element of their remote delivery. After gaining an understanding of the protocol, providing any necessary feedback, gathering information from a clinical trial team, and assessing and mitigating potential risks, MRN proceeds to handle all aspects of remote trial delivery, even managing and monitoring the nurses' schedules, ensuring the delegation log is signed, and addressing all minor issues that may come up. MRN's HTS nursing teams capture patient data via electronic data capture, which is instantly available to the trial site upon visit completion.

MRN also has a clinical services team that will assess a protocol from a clinical perspective to advise on what trial activities are safe to do at home. From there, the sponsor, site, and MRN team can collaborate to determine the visit schedule and settings that work best for the protocol. Engaging in these early conversations and negotiations can help build trust between teams and, ultimately, yield better results for the trial.

Beyond the HTS program, MRN also offers on-site professional support, i.e., resources to help increase screening throughput and data entry on-site. There is also an exciting new offer that when paired with HTS creates an even more efficient ecosystem: an MRN site network, featuring new sites across multiple countries that will provide trial access to new communities. The goal of the site network is to open access beyond major research centers and into rural centers with populations that have not historically had access to clinical trials. By working with MRN's HTS and site network in conjunction, you can onboard clinical sites that will have all the support, training, and tools needed to run trials on-site or with a hybrid model.

From a cost perspective, working with a vendor that has a preexisting relationship with a site can help improve your success rate and alleviate the need to open new sites that may not successfully recruit patients. Trust, understanding, and ease of onboarding will all help to ensure that the trial runs smoothly and successfully for patients.

Choose the Path Best Suited For Your Trial

Whether you are ready to implement remote visit options in your clinical trial or just opening up to the idea, planning ahead is crucial. Start by determining where remote visits fit into your protocol. If you're not sure what that looks like, work with a knowledgeable, experienced vendor that can advise on how to design remote visit options that improve patient enrollment, retention, and overall patient experience.

About MRN

MRN is an innovative market-leader of patient-centric and site-centric solutions for efficient clinical trial delivery. Through our integrated in-home visit delivery, our global site network of trained, research ready sites in new communities, and digital trial solutions, we allow the medical research community to create more flexible, efficient, and accessible clinical trials. We customize our solutions to optimize each individual trial protocol and deliver accelerated timelines. By engaging patients and empowering research sites, we increase trial recruitment and enrollment rates, improve site participation and engagement, and improve patient retention around the world.

About the Author

Helen Marks has over 10 years' experience at MRN, developing and refining operational processes and leading both HTS and site support projects. She holds a PhD in cancer biochemistry and, as a cancer survivor, has a particular interest in improving accessibility and patient centricity in oncology, as well as in the rare diseases that MRN supports.

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