



The Hidden Healthcare Benefits That Home Trial Support Provides

By Medical Research Network

When it comes to Decentralized Clinical Trials (DCTs), whether they are digital or in-person based, the very first benefit that we shout about is relieving the burdens of cost and logistics from the patient and/or their caregivers. That benefit is almost certainly followed up by explaining that through relieving those burdens patients are more likely to remain enrolled and engaged in the trial, which in turn relieves sites and sponsors of the pressures of trial recruitment.¹

While these are very real, and particularly important benefits that come with services such as Home Trial Support (HTS), there are so many more that don't get discussed, and due to that are sometimes missed or not even considered.

HTS solutions offer a vital mix of benefits for patients, sites, and sponsors – many, like the above mentioned are discussed in greater detail ([you can read about these here](#)), while others have somewhat been forgotten in the conversation, often as they offer “hidden” value as a byproduct of the service. However, it is these hidden benefits that amplify the value of HTS.

Unpacking the Hidden Healthcare Benefits of HTS

Patient safety and well-being is ultimately why we are all here: to ensure that we can treat patients in a way that will give them a better quality of life.

Patient & Caregiver Safety

During treatment in a clinical trial this is more critical than ever – patients are very often more vulnerable or immunocompromised, making them more susceptible to infection and/or accidental harm. Should the patient fall ill, or even just fall over and seriously hurt themselves, sites and sponsors will most likely need to report it as either an Adverse Event (AE) or Serious Adverse Event (SAE) – even if there is no link to the trial and/or Investigational Medicinal Product (IMP).

A visit to a traditional clinical trial site at a hospital or similar medical facility instantly exposes patients to potential infection. In the US it is estimated that 1.7 million patients are affected by Healthcare Associated Infections (HAIs), with 99,000 dying as a result.²

While in England alone (not including Scotland, Wales and Northern Ireland) the National Health Service (NHS) reported that an estimated 65,300 of 13.8 million in-patients were affected by an HAI.²

Further, some HAIs, such as norovirus, are highly contagious and^{3,4} can easily spread from the patient to the caregiver/family. This puts additional strain on the patients' support systems, which can ultimately lead to discontinuation in the trial.

HTS is one of the simplest ways to limit patient and caregiver exposure to HAIs from traditional site settings. MRN HTS Healthcare Professionals (HCPs) follow strict protocols when it comes to ensuring all equipment is sterilized, and they wear the appropriate level of PPE required. Further, while it may seem obvious to some, they will not attend a visit if they are unwell. Instead MRN will organize a replacement HCP if required.

Patient Wellbeing

Limiting exposure to traditional site locations also has the potential to limit or relieve treatment-related symptoms patients may experience.

A study that looked at the effectiveness of a symptom-focused home healthcare program for cancer patients – with patients randomly assigned to either receive home healthcare or traditional site-based care.⁵

The study found that there were notable improvements in the symptoms experienced by those patients receiving home healthcare – showing that the home healthcare program was more effective when it came to helping patients manage any treatment adverse events.⁵

When looking as to why the home healthcare approach was so effective, it was also noted that the nurse-patient relationship, reassurance and empowerment patients said they experienced from receiving treatment at home may have also contributed to the improvement in symptoms experienced.⁵

MRN has seen the relief that patients experience due to having access to HTS during a trial, as presented in multiple HTS [case studies](#).^{6,7,8,9}

It is important to note that while treatments, especially in oncology, may be the cause of severe patient discomfort, just as often it is the disease being treated that is the source of pain. And the pain experienced is not always just physical – it can be emotional and mental as well. This makes the home environment so critical when it comes to supporting patients as it provides them with familiar, comfortable spaces and allows them the feeling and sense of stability and control.

Relieving Pressures On Sites = Greater Healthcare Access

Even before COVID-19, global healthcare resources were being stretched to the limit. Post COVID-19, they have cracked under the pressure. The UK faces an endemic of “corridor-care” - where patients are treated in corridors, even if they require overnight monitoring - and “bed-blocking” – where patients are not discharged as there is no adequate homecare or suitable housing for the patient, so they have nowhere to go.¹⁰

In the US, there are just not enough doctors - the physician shortage is estimated to reach 86,000 doctors by 2036 – and there are no signs of it slowing down.¹¹

McKinsey ran a physician survey with 35% of respondents indicating they are likely to leave their current roles in the next 5-years. 60% of those respondents said they planned on leaving clinical practice altogether.¹¹ The impact this has had on the industry is evident in wait times patients experience to receive non-emergent care.¹²

These issues are indicative of the global issues the healthcare industry is facing as a whole – including those in clinical research.^{13, 14} And increasing complex clinical trial protocols¹⁵ are adding further burdens to our already-stretched healthcare structure.

HTS can immediately help alleviate the pressure on trial sites. HTS HCPs can take on most trial visits where portable equipment can be used and where a study physician is not required – allowing sites to redeploy their resources as needed.

MRN’s HTS HCPs can perform a range of medical procedures in the home, from simple check-ups to more complex procedures.

Further, they can administer IMPs – even those that require specialized handling, as we work with Cencora – a world leader in pharmaceutical logistics and supply chain.

By alleviating pressures on sites, two things happen:

1. They can effectively enroll more patients onto the trial, which ultimately brings more healthcare solutions to more patients.
2. They are able to stay on top of or even accelerate trial timelines as the HTS HCPs share the burdens of running a clinical trial.

Protocol & IMP Adherence

Ensuring that protocols are followed, and IMPs are stored and administered correctly are critical to ensuring patient safety and to limit the possibility of AEs/ SAEs – it is also key to ensuring accurate data is collected and that the trial is an overall success. And, given the strain traditional sites are under, it is no surprise that protocol deviations remain the number one cause of enforcement action letters sent to sites by the FDA.¹⁶

When it comes to HTS, the HCPs are effectively responsible for bringing the clinical trial or treatment plan into the home. MRN’s HCPs ensure that all protocols are followed. Further, they receive additional training for any protocol amendments.

While the HCP performs the visit, the site will continue to maintain oversight as each home visit is recorded and submitted via electronic visit form directly to the site’s portal. This ensures accurate and timely reporting and data collection.

Given that MRN’s HCPs spend more time with the patients in their home environment, they are better placed to identify any needs that patient may have that can be supported by their physician, as well as any lifestyle changes that could have a positive/negative impact on their participation in the study. All these observations are included in the visit report that is submitted to the site or, where urgency is needed, they will contact the site directly.

MRN’s HCPs are also capable of not just overseeing things like IMP administration, but can train patients/caregivers on how to administer the IMP if required.

They are also able to observe the patients more keenly when the IMP is administered, as the patient will be the sole focus of their attention, unlike a traditional site where they may have to split their time between patients.

An example of this comes from past MRN Nurse, Helena Baker (RGN), who said “When I’m administering chemotherapy or IMP in patients’ homes, I am sitting directly in front of them. I am immediately able to see whether the patient is having a reaction or not, something that could get missed in the chemotherapy day unit until the reaction is much further advanced. HTS gives us much greater control over the drug administration.”

Conclusion

The benefits for home healthcare interventions in clinical trials can be truly boundless – benefiting patients, sites and sponsors.

The key to optimizing the solution to gain the most value from it is to build it into the trial protocol from the start. This will immediately alleviate site burdens and make trial participation for patients far more accessible and ultimately safer.

Learn more about [MRN’s Home Trial Support Solutions here](#).

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About MRN

MRN accelerates patient recruitment and improves patient engagement and retention through site-centric and patient-centric solutions.

As an innovative market-leader, MRN provides customized solutions to optimize each individual protocol and create more flexible, efficient and accessible clinical trials that deliver accelerated timelines.

Through integrated in-home visit delivery and a vast global network of trained, research ready sites, all empowered by MRN's digital solutions, MRN engages with and empowers diverse communities around the world to participate in and advance medical research.

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