



Helping Hands

Having nurses regularly visit patients at home is improving the standard of patient care, and hospitals offering this service are seeing a rise in trial recruitment and retention rates

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To be able to discuss how site nursing support benefits the clinical trial industry and home care in particular, the ongoing obstacles need to be understood. Clinical trial sites face many challenges, such as engaging minority groups efficiently and quickly identifying patients, while coping with increased work load due to the small pool of available research locations.

Equal Representation

One barrier that continues to impact clinical trials is the enrolment of ethnic minority groups. These classes remain underrepresented in treatment experiments that could save their lives. However, some diseases are more prevalent in different racial and ethnic groups – African Americans are approximately 70% more likely to be diagnosed with diabetes, for example (1). Therefore, to produce a drug that will best treat these patients they must be included in clinical trials.

This remains an obstacle for several reasons: a lack of minority principal investigators (PI), a lack of awareness of clinical trials among these groups or patients living too far from an enrolling location. Given the importance of a patient's inclusion in studies, sponsors must find effective ways to involve sites that minority groups have access to and can therefore be recruited for these trials.

Registration

Enrolment timelines are also dependent on region and therapeutic area, as the 2013 Tufts Center for the Study of Drug Development (TCSDD) impact report highlights the disparity by location. The mature North American clinical trial market has faster average enrolment times than those run in Asia Pacific or Europe. Another study from TCSDD also found that, on average, clinical phases are 40% longer for central nervous system (CNS) drugs compared to non-CNS drugs (2).

Selecting Productive Sites

Sponsors have the added challenge of finding high-performing sites. Approximately 48% of locations have reported missed enrolment targets, with over 80% of studies delayed as a result (3). With the recent push by the FDA to ensure that clinical trials are fairly representing the patients that will use a medical product, experiments must be set up in places that have the ability to recruit the appropriate patients in a timely manner.

Industry statistics	
11%	Sites fail to enrol a single patient
37%	Sites under-enrol
48%	Trial sites miss enrolment targets
80%	Trials are delayed, mainly due to enrolment

Source: Tufts Center for the Study of Drug Development

Table 1: Registration rates

Finding a Solution

Site nursing support is a service that has undergone a transformation due to the tremendous growth in the clinical trials sector. This flexible service is tailored to, and built upon, the specific needs of each individual study protocol and can alleviate many of these industry challenges.

Knowledgeable Nurses

Training staff to screen for appropriate patients within a wider pool can be especially helpful for both trial-naïve and resource-constrained sites. When a trial has complex inclusion and exclusion criteria, it can be a struggle to identify eligible patients and get even one subject enrolled.

Having a targeted team of nurses that are able to go into the site and perform study tasks is valuable to both the location and sponsor. Not only can this take pressure off the places trying to recruit patients and conduct all trial visit activities, but it also gives the sponsor the additional support of team members completely dedicated to their study.

Going back to the same tried and tested locations is tempting for sponsors, as they know the staff are trial-trained and trustworthy. However, this repetition can cause its own challenges as sites become saturated and are no longer able to dedicate time to both patient screening and other study activities. This limits the resources available to focus on finding the right subjects for the trial, which ultimately impacts recruitment rates.

A large number of sites might like to be involved, but may be lacking the required skills or staff numbers. This can make it time-consuming and expensive to set up these locations, deterring many sponsors from using trial-naïve sites. To work around time and financial constraints, placing experienced nurses at these locations as part of the study team can make an incredible difference.



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“ “ When a study-assigned nurse is placed at a location, they are dedicated to clinical trial patients from the moment they walk into the hospital ” ”

Trial-naïve sites using nurse support services enrol more subjects than those that do not. They also experience acceleration in recruitment for longer compared to places that do not due to the availability of resources dedicated to finding patients. This service also opens up a whole new population to the sponsors because these locations may have never been used before.

The site service can place a nurse across several locations in one country or offer the ability to cover multiple countries, giving consistency across the study and reducing training costs. Additionally, it allows for best practice sharing.

When a study has very specific expertise requirements of those running the trial, appropriate staff may not be available at all sites. A dedicated team with these qualifications who are able to work across multiple locations allows for consistency for the sites and subjects.

Preferred by Patients

Nurse support is also incredibly important for the patient, particularly for large-scale studies for common diseases as hundreds of them will be seen. In this scenario, identifying subjects for clinical trials, on top of the day-to-day work of the department, is extremely challenging without extra resources. In addition to the large-scale recruitment efforts for one project, a site can be working on numerous studies, compounding the problem and adding complications to their training and staffing requirements.

When a study-assigned nurse is placed at a location, they are dedicated to clinical trial patients from the moment they walk into the hospital. The day-to-day work that may be pulling the nurse away from them is no longer an issue. The use of dedicated site nurses for database searches, specifically when inclusion and exclusion criteria is complex, can result in the recruitment rate doubling. Not only is this beneficial for the sponsor, but the patient's experience is more positive and consistent when they have a dedicated, expert team looking after them.

Two-Pronged Approach

In addition to the implementation of this service, a number of studies have adopted a combination of site nurse support and home trial support services. This double approach creates added value for the team as it improves the relationship of the site with the homecare group and increases the understanding of different roles between team members. Recruitment rates rise when the nurse support service is able to perform targeted patient identification, and retention rates increase when those subjects take up home trial support, reducing the burden by allowing them to participate from home.

As well as these services providing advantages for the site and sponsor – as they work in tandem to increase recruitment

and retention – they also benefit the patient when the same nurse undertakes their location activity and home visit, supplying continuity of care between the hospital and the home.

The combined support methods have proven to increase the chance of enrolling adult and paediatric patients into a trial because they embrace a patient-centric approach. A subject being visited at home enables them to participate in the trial while maintaining their work and family schedules despite being sick, in pain or living far from the site.

Successfully Integrating

Assimilating a nurse into the study team has its challenges, but collaborating with the sites has proven to be successful. The PI is often engaged in the job description creation and the interview and selection process, allowing them to have more control over who will be placed in their department.

Remaining respectful of sites and their staff is important as they are running their own businesses. This is key for a smooth integration and working relationships between staff and home or support nurses. The latter have successfully assisted trial teams at various levels, including conducting study visits, overseeing screening, running clinics, seeing patients and managing an entire department.

The increase in site nurse support and home trial support in clinical trials demonstrates a substantial shift in the importance of patient-centricity within the industry. By ensuring access to new therapies to all populations and providing easier treatment procedures through the provision of home care, the patient evidently has become and will continue to be integral to the industry.

References

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2. Tufts Center for the Study of Drug Development Report, *Parexel Biopharmaceutical R&D Statistical Sourcebook: 2015/2016*
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About the author



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