Three Ways in which Mobile Research Nursing is Transforming the Clinical Trial Experience

Following the emergence of the novel coronavirus, more than 1000 clinical trials for non-COVID-19 indications were delayed, put on hold, or even postponed outright.[1] In a Medidata survey conducted in April 2020, nearly 70% of investigative site personnel indicated that COVID-19 affected their ability to conduct ongoing studies and 78% believed that the pandemic impacted their ability to initiate new trials.[2]

And yet, according to a report released by Greenphire in October 2020, patient enrolment for global clinical trials has returned to pre-COVID-19 levels.[3] The remarkable recovery in clinical trial participation has been attributed, in part, to the use of technologies and other resources that promote flexibility in how study visits are conducted.

In this shift toward decentralised or hybrid trials, mobile research nurses have been instrumental in keeping studies moving forward and minimising patient dropout.

Mobile Research Nursing Goes Beyond Simply Bringing the Trial to the Patient

As with so many aspects of our lives, COVID-19 has surfaced – and solidified – change in the conduct of clinical research. Within the clinical trial arena, the "new normal" is one which leverages technology to empower patients and offers them greater flexibility and a wider range of options when participating in clinical trials. While technology offers significant advantages, critical study activities remain that require human interaction. It's not surprising then that, in this new normal, mobile research nursing has emerged as an effective, patient-focused solution for encouraging study engagement and enhancing the participant experience.

Here are three ways that mobile nursing is transforming clinical research:

1. Enabling research to continue, even in the most challenging circumstances.

At the start of the COVID-19 pandemic, everything stopped. Site closures and travel restrictions made it virtually impossible for patients to participate in clinical trials, even if they were willing to do so. Caught without a contingency plan in place, many clinical trials simply ground to a halt.

As sponsors frantically searched for solutions, they found mobile research nursing to be an invaluable resource that could rescue studies. Specialist start-up teams were leveraged to enable mobile research nursing to be incorporated into ongoing studies. This could be incredibly complex, resulting in protocol amendments, gaining site consent if they were new to the service and quickly moving resource to be able to meet the visit requirements of patients.

In turn, mobile research nursing providers had to quickly adjust to the need for heightened precautions and the influx of sponsors seeking assistance. That meant adapting existing processes and procedures – or creating new ones – to ensure the safety of both nurses and patients. For example, placing additional telephone calls to perform pre- and post-visit assessments. This was solely designed to keep everyone safe with the additional calls giving patients and research nurses the opportunity to voice any COVID-based concerns before or after a visit.

Having learned these lessons amid the pandemic, both sponsors and mobile research nursing providers are now better prepared for future waves or other unforeseen circumstances that result in site closures. Moreover, sponsors are now more aware of the need to proactively plan for unexpected events by building contingencies into study protocols from the outset.

2. Encouraging patient engagement to increase enrolment and retention.

Patients are more likely to enrol and remain in studies in which they feel valued and are offered solutions that fit with their lifestyle. Clinical trial participation can be a burden, even for the most motivated patients. Frequent travel and absence from work or school can put immense strain on study participants and their families. Replacing on-site visits with off-site visits performed by a mobile research nurse can help to relieve that strain.

A growing number of sponsors were already relying on mobile research nurses to ease the burden of clinical trial participation pre-COVID-19. As this year has unfolded, we have seen significant increases in the adoption of mobile research nursing and expect that this resource will become a staple of clinical trials even after we move beyond the pandemic.

A Quick Case Study

Problem: A paediatric rare disease study required weekly on-site visits spanning a period of several years and was experiencing a high rate of dropouts. If the dropout rate were to continue on the downward curve, the sponsor had identified that patient numbers would have been too low for the study to be sustainable.

Solution: The sponsor amended the protocol, which allowed them to offer the option of mobile research nursing. In this case the mobile research nurses would administer the investigational drug at the child's home or school and perform data collection.

The win-win result: Mobile research nursing visits replaced 75% of the required on-site visits. This meant a reduction in visits from weekly to monthly. Over a two-year treatment period, no further dropouts occurred, and time lost from school and work was minimised. In addition, the children and their caregivers reported increased satisfaction due to the rapport established with their mobile research nurse.

3. Embracing technology while maintaining a human connection.

The pandemic has highlighted a range of new applications for technology in clinical research and healthcare delivery at large. Technology has its limitations, however – from varying levels of tech confidence or literacy to preferences among patients to share sensitive health information with a real person rather than a computer.

More recently, the pandemic has also brought to the forefront the issue of "emotional compensation" for patients who are enrolled in largely video-focused research. Often, patients choose to enrol in a clinical trial for expanded access to treatment as well as personalised attention from the study team. There is some concern that patients may find it more difficult to form bonds or establish trust with their clinicians if all study interactions are virtual.

Mobile research nursing bridges this gap by maintaining, and even strengthening, the human connection in clinical trials. This is especially true as patients are visited regularly by the same nurse (wherever possible) throughout the course of a study. When it is not safe or convenient for a patient to go to a site, a GCP-trained mobile research nurse can perform the study visit at home, or anywhere the patient is comfortable, completing all of the necessary procedures and reporting data back to the site.

As advances in technology have broadened the spectrum of procedures that can be performed off-site or in the home, the number of clinical trials that can be conducted with a mobile research nursing option will continue to increase. Offering participants the flexibility of off-site visits with a mobile research nurse also expands the pool of patients available for recruitment by making studies accessible to those with limited mobility and those who live far away from a clinical research site. Moreover, mobile research nursing visits make it possible for site staff to check in and assess the safety of study participants at more frequent, predictable intervals, even if unforeseen circumstances arise.

Progress on the Path to Truly Patient-centric Clinical Trials

The adaptations required to keep studies moving forward during the pandemic have set the stage for a future in which clinical trials can be truly patient-centric, with a hybrid of site visits, telehealth, and mobile research nursing. For all those engaged in clinical research, the opportunity lies in perfecting this new normal, where patients are put front and centre in the design and conduct of clinical trials.

REFERENCES

1. Clinical Trials. "U.S. Clinical Trial Sites are Most Affected Due to the Covid-19 Pandemic." Available at https://www.clinicaltrialsarena.com/comment/us-clinical-trials-covid-19/.
2. Medidata. "COVID-19 and Clinical Trials: The Medidata Perspective Release 4.0," May 4, 2020.
3. Fierce Biotech. "Patient Enrollment for Trials Back to Pre-COVID-19 Levels: Report," October 28, 2020.

Juliet Hulse

Juliet is an experienced Research Nurse with specialist knowledge in Cardiology, Neurology & Emergency Medical, with more than fifteen years' experience of delivering effective care. Juliet was Director of Research Nursing at Illingworth for over 4 years before deciding to move into her current advocacy focused role. She now concentrates raising awareness of patient centric services and assisting sponsors in protocol design to improve the overall patient experience, a role which her unique background allows her to understand from the perspective of both the sponsor and the patient.