MEDICAL RESEARCH NETWORK

World Courier
AmerisourceBergen

Overcoming the Trials of Trials

How Direct-to-Patient Practices Improve Clinical Trials for Researchers and Manufacturers

AmerisourceBergen

In the world of clinical trials, one of the greatest challenges to overcome, one that should be felt long before the actual study begins, is the recruitment and eventual retention of qualified patients. Finding patients who are not only willing to participate, but who can work their schedule, both personal and professional, around the study's requirements — including trips to the hospital, doctor/nurse availability, regular and predictable availability of study medications, etc. — has grown increasingly difficult. Challenges to overcome include not only the length of time required to source and keep such patients, especially when the trials are of a global nature, but unpredictable delays to the study itself. When time is critical, these are major concerns that can have a decided impact on a manufacturer's bottom line. By moving the trials from a hospital setting into patients' homes, it becomes easier to recruit trial patients and allows for faster completion of important studies.

The Benefits of a Direct-to-Patient Model

Researchers are increasingly seeing the benefit of a patient centric approach using the "direct-to-patient" model in order to overcome these challenges and move studies ahead more effectively. This approach not only puts the patients at the center of the trial experience, but is also designed to make life easier for them and their families as the trial goes on. Using this model, patients no longer have to interrupt their lives with trips to the hospital, which, in some cases, can be many miles away, for procedures that can take several hours to complete. They are not subject to the office hours of doctors and nurses, and are more in charge of their schedule in relation to the trial. In all ways, the patient is at the center of everything, a fact that makes patients easier to recruit — the trial does not have a negative impact on their day-to-day lives — and more likely to complete the study, negating the need to find new participants after the study is well underway. This model increases the operational efficiency of the study, allowing for faster completion times with more reliable results. As well, many countries are actively seeking ways to move more care into the local communities, so the direct-to-patient model is a perfect fit for those initiatives.

As is the case in in-home nursing, the direct-to-patient clinical trial model provides a fully qualified nurse to visit the patient in his or her home and perform all the medically necessary trial protocols, such as infusion, collecting blood samples, etc. The trial coordinator typically works with a reliable specialty logistics company to get needed medications from the pharmacy or study site to the patient's home on time and in perfect condition. In addition to reliable delivery, this specialty logistics company must also be able to provide a full chain of custody to satisfy regulatory requirements, deliver within certain predetermined time windows, be fully cold-chain guaranteed, etc., as well as be prepared to take away blood or other samples after the visit in an approved and appropriate manner in compliant temperature controlled packaging.

Bringing Solutions to the Patient

In some cases, especially when a particular medication is needed on a daily basis, it becomes more advantageous to store the drugs in the patient's home, eliminating the need for a daily delivery and ensuring the medication is available when the doctor or nurse arrives to administer it. One solution is a small, personal RFID-controlled refrigerator, like MyCubixx. This type of device can store medication securely and at an optimal temperature, track its usage and provide reports to researchers, offer Web portal access to stakeholders to monitor real-time events and more.

There are some very real considerations when setting up a home trial in spite of the advances that have been made in direct-to-patient care. Perhaps the most critical is getting a home trial company involved in the process as early as possible in order to maximize the amount of services that can be provided in the home. Looking at trials from the patient's point of view, as opposed to the scientific, commercial or regulatory point of view, allows greater efficiency and better results for the overall patient experience.

Although each country has its own regulatory bodies approving studies as they arise, mentioning within the protocol submission that a certain number of home visits are part of the study parameters is typically enough to gain approval for utilizing a direct-to-patient model. In general, regulators tend to be very supportive of home-care trials, as they see such efforts as delivering better care to patients. However, different countries have different regulations regarding what procedures can be performed in the home, how and when drugs can be administered to patients under a certain age, etc. Home trial partners need to understand these varying regulations and know how to work with them.

Home Trial Protocol Considerations

When patients sign up for a home trial, they must be informed of, and give consent to, home visits as well as the release of their data to third-party organizations. Although patients are only referred to by unique identifiers and not by name, protecting both their confidentiality and the integrity of the study is paramount. This rigid protocol does not only extend to the nurses and researchers involved in the study, but even to the specialty logistics company and the driver who will be attending the patient's home. They are typically restricted from asking patients how they are feeling or anything else that could be considered as giving healthcare advice or information. Again, partnering with the right home trial agency, one that understands both the macro and micro requirements of such a study, is critical.

Partnering with the right home trial agency, one that understands both the macro and micro requirements of such a study, is critical.

These considerations notwithstanding, it is becoming more and more apparent that the direct-to-patient model of home visitation for clinical trials is quickly becoming the way of the future. The current practice of recruiting patients via social media, for example, is only a small step forward, and provides little actual benefit for the patient. Placing patients at the center of everything and adding more of a human element to the process, however, provides better access to patients and makes it more likely that they will follow through with the study by putting their needs at the forefront of the clinical trial. The benefit, in an increasingly competitive market, is that studies are completed more quickly and more efficiently, and this efficiency can help improve overall time to market, improving product access to a broader patient population.

themrn.co.uk
marketing@themrn.co.uk
linkedin.com/company/medical-research-network
@MedResNet

worldcourier.com
marketing@worldcourier.com
linkedin.com/company/world-courier
twitter.com/worldcourier
instagram.com/worldcourier

AmerisourceBergen®

World Courier is a global specialty logistics company that designs world-class logistics and supply chain programs in complete alignment with our customers' business goals. Pharmaceutical companies rely on us because they value the peace of mind that comes with our unsurpassed knowledge, global reach and flawless supply chain execution. Each trusted partnership we form with a customer is deeply rooted in our shared vision of improving global health. With 2,000+ associates in more than 140 offices across the globe, we offer solutions that instill confidence in the on-time, on-temperature delivery of critical products. When trust is absolutely essential, there's only one choice: World Courier.