30 YEARS
SMARTER EQUIPMENT SOLUTIONS

Opening the door to decentralized clinical trials

Introduction

When you think of a clinical trial, you probably imagine the traditional centralized model where the volunteer cohort attends a specified research center to receive experimental treatments and be monitored. But times are changing, not least because of the COVID-19 pandemic, which has forced investigators to think outside of the box and conduct clinical trials away from their normal venues.

In any clinical trial, the biggest challenge is always how to recruit and retain volunteers, and the key to this is to make a patient-centric process as easy and convenient as possible. This is especially important amid a global pandemic; existing and potential participants may be reluctant to enter an unknown environment where they could come into contact with strangers. Overcoming this challenge has brought decentralized trials to the fore, and they look set to continue long after the pandemic is over. This white paper takes a look at what you need to successfully decentralize your clinical trial and how choosing a sourcing partner with the necessary expert knowledge and experience can help ensure that you have all the technology and support you require, when and where you want it.

Doing the groundwork

It is an ill wind that blows no good, and that's certainly the case in relation to the COVID pandemic and decentralized trials. The pharma industry has long been seeking answers to the crucial questions 'How can the clinical trial timeline be reduced?', 'How do you reach out to potential volunteers who are unwilling or unable to visit the trial site?', 'How do you retain participants and encourage them to be more compliant?', and 'How can we make trials more cost effective and patient friendly?'.

In that respect, the move towards decentralized trials had already begun and has been accelerated by the pandemic as the industry seeks new ways to continue its investigations. But how do you go about that? How do you standardize procedures and equipment to avoid introducing any bias into your results? Ideally, you need a supplier that not only has the technical know-how to guide you through the process, but also established relationships with companies specializing in home healthcare. This is certainly the case at Woodley, where our long-term contacts with companies in this sector enable us to deliver a complete package tailored to your specific decentralized trial needs.

Taking the trial to the patient

Over the last couple of years, there has been much discussion around making studies more patient-centric and accessible by removing the need for participants to visit a dedicated trial site at a specified time and date, in an effort to minimize the likelihood of non-compliance. Missed visits may lead to the investigators having to recruit additional volunteers, lengthening the start-up period and, ultimately, the trial itself. Taking the trial to the patient, rather than bringing the patient to the trial, has great potential to speed up timelines and, because it is convenient, is likely to increase retention of participants.

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With the right equipment, almost everything that would usually be monitored at an investigative site can be easily and conveniently replicated in a patient's home. But what do you need? Will you be taking bloods? Monitoring blood pressure and other vital signs? Completing questionnaires? When a trial relies on nurses going from home to home, it is crucial that the equipment used is not only easy to transport, but also robust and durable. And that's where Woodley comes in. With our extensive experience in home healthcare, we can advise on the most appropriate choice for your trial environment, from infusion equipment, centrifuges and ECG monitors, to small lockable refrigerators with remote temperature monitoring to enable samples and medication to be stored at a patient's home. It could even be clinically-validated wearables that capture and feed back data in between visits.

Dealing with the logistics

The logistics of delivering everything to the right place at the right time is a challenge with the traditional clinical trial model, but the situation becomes even more complex when studies are decentralized. How do you ensure that devices are delivered to multiple, geographically widespread locations? And what about validation? Each device must be fully validated in accordance with the regulations that apply in the country where it is being used, and compliance must be maintained throughout the study. At the same time, you also need to ensure that all users have the appropriate training. The more sites that are involved, the greater the challenge. Woodley is perfectly positioned to help guide you through the process, using its internal infrastructure and external partnerships to take the pressure off and ensure that you have everything you need, exactly when and where you need it.

Working together to drive innovation

As decentralized trials and technology continue to advance, so too does the demand for new innovations to allow more detailed investigations to be performed either in the patient's home or through remote feedback. Technology is revolutionizing the way we receive and process data, and customers are increasingly coming forward to seek advice about what is and isn't possible.

Woodley Trial Solutions have built solid supplier and client relationships which helps us provide new and innovative methods of vital data capture. This significantly increases clinical trial efficiency. Whatever you need, from novel technologies to regulatory compliant software that allows safe and secure patient device connectivity, we can help.

Summary

Running a successful clinical trial is a complex process at any time, and even more so once the process is decentralized and there are multiple sites spread across a large geographical area to service. We're proud of Woodley's 30-year track record of managing the entire equipment supply chain, along with all the technical support necessary to support a successful trial. We know that customers rely on our extensive knowledge, global experience, and responsiveness to help avoid the pitfalls that can make or break a trial, and enjoy working with them to achieve their goals.

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