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Are You Considering Hiring a Clinical Research Consultant?
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Modernizing Site Monitoring

for the New Era of Clinical Development

By now it is well-documented that the clinical development process has undergone and continues to experience structural change, influenced by several concurrent trends at play. The number of clinical trials continues to grow globally by 10%-12% per year, taking place in more sites and countries, and are rising in cost as well as duration. At the same time, increasing digitalization enables sponsors to reach more participants at more sites around the world, facilitating the development of better therapies through increased diversity in participant populations and improved data quality.

These forces, acting in parallel to one another, present new opportunities and challenges for clinical trial design and conduct. Innovations in technology and creative applications throughout the development process offer researchers new ways to solve the challenges presented by these trends. Take virtual site monitoring for example – the pioneering, wearable, live video streaming device paired with a multifunctional telemedicine application affords the ability to minimize and even eliminate some of the most common issues associated with clinical research site monitoring.

Not to be confused with remote site monitoring, this virtual site monitoring technology offers sponsors and clinical research associates (CRAs) the ability to virtually tour sites

and complete tasks that previously could only be done on site. Using a proprietary camera affixed to 3D-printed eyewear, site staff can offer their CRAs a first-person view of their facilities, equipment, and supplies that would otherwise be inspected in person. This technology is more appropriate for site monitoring than a mobile phone or handheld camera because it provides a more stable, higher-quality video stream and does not require any video capture expertise. Employing this method and technology, sponsors can address several of the most complicated challenges that have arisen because of larger trends.

Increasing quantity, complexity, and globalization

With more clinical trials taking place in more countries, sponsors must rely on technology to conduct necessary clinical research site monitoring tasks. The demands of the clinical research associate role have increased in parallel to the increase in the quantity of trials and research sites involved in each. From pre-study qualification visits (PSQVs) to interim monitoring visits (IMVs), each carries a hefty list of tasks which traditionally required CRAs to travel extensively around the world to carry out in-person.

A major issue among sites and CRAs is the burnout that results from excessive travel. Burnout can lead many tenured CRAs to leave the industry altogether. This churn means there's a continuous demand for hiring and training. Another consequence of globalization is that sponsors must also consider additional legal and regulatory challenges related to conducting clinical trials in more countries.

These globalization-fueled challenges can be addressed with virtual site monitoring. Since it enables a CRA to conduct site visits remotely, they can complete two to three times more site visits per week without the burden and stress of travel. Offering a remote alternative to travel helps sponsors and CROs keep talented CRAs on the team, improving retention and costs associated with high churn. To address legal and regulatory monitoring challenges, virtual site monitoring complies with 21 CFR part 11, HIPAA, HITRUST, and SOC-2.

High startup costs and time

Even before the pandemic, a major industry initiative was to contain the increasing time and cost of clinical trials. One way to do so is to consider the costs for site initiation and monitoring activities, for which sponsors might allocate 25%

or more of an entire study budget. In addition, the process of qualifying and initiating sites often requires six months or more, a significant variable in the study startup schedule.

Using the virtual site monitoring approach, a CRA can see exactly what a study coordinator sees in real-time, high-resolution video at any site in the world. They can perform PSQVs and other site visits virtually in a fraction of the time, eliminating the need for constant travel while still providing visual access to facilities, people, and documents required for proper site monitoring.

Designing protocols for the new era

Decentralized, globalized clinical trials, facilitated by digital technologies like virtual site monitoring, benefit sponsors, sites, and participants alike. By enabling access to diverse participant populations, improving data accuracy, and minimizing burdens, decentralized trials improve the clinical development process. The quality, safety, and efficacy of the resulting products also benefit. Yet they can also introduce new challenges, as in the case of clinical site monitoring – expanding trials to more countries and sites presents obvious logistical challenges. Virtual site monitoring is a good example of an innovative solution spurred by a problem, but like many others in this new era of clinical development modernity, it should be planned for in advance.

In this way, a broader challenge for protocol designers is to front-load decentralized trials with methods and solutions in anticipation of the known challenges as well as the unexpected, rather than backing into solutions mid-study. The past eighteen months have proven that agile designs and technology enablement are key components of the new era of clinical development. Virtual site monitoring is just one microcosmic example – technology can transform site management and address longstanding challenges to this one aspect of clinical development. It is incumbent upon the clinical development community to collaborate as we continue redefine the drug discovery landscape.

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