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Posted by Rachel Silver-Kessler on Tue, Oct 29, 2019

WHAT'S DRIVING DEMAND FOR REMOTE RESEARCH COORDINATORS?

close up of businessman hand showing texture the world with digital social media network diagram concept Elements of this image furnished by NASA

Traditionally, a clinical research coordinator works on site during a clinical trial, gathering and synthesizing information, organizing data and managing processes. However, the need for research coordinators may be outpacing availability at many research sites. There is a growing need for research that includes global populations and studies that explore devices after they're released, in addition to the research required before devices receive approval.

As a result, more sponsors are turning to remote research coordinators and site support services to manage data and supplement on-site teams.

Here are a few reasons why this innovative approach works so well.

- Technological Advances
- Increased Data Needs
- Streamlined Processes Generate Cleaner Data, Faster
- Global Outlook

Read on for more details!

Why Demand For Remote Research Coordinators Is Growing

Technological Advances

The prevalence of technology and collaborative platforms has allowed many industries to benefit from a distributed workforce. Remote research coordinators can manage study sites, gather and enter data for subjects enrolled in the trial, oversee teams and perform all their other necessary tasks from your office or their own home offices or co-working space. Telemedicine capabilities and digitized medical records also increase the availability of remote research data. When a remote research coordinator is working at a home office or co-working space, they can use VPNs or other encryption to ensure they are meeting federal standards for the protection and privacy of health data. Study sponsors may also consider providing dedicated computers to help control access and security.

Additionally, study participants can gather their own data remotely using wearable devices or the remote capture capabilities built into the medical device being tested. When data is generated remotely instead of at a study site, there is no need to send a research coordinator there.

Although there are considerations needed, including access to appropriate technology, adjusting typical site contracting practices, and buy-in needed from research sites, there will be significant savings and efficiencies compared with on-site work.

Increased Data Needs

Another trend in clinical research is the need for more robust clinical evidence for approval, and ongoing studies of devices after they are approved. These post-market clinical trials are used to assess continued safety and efficacy, or look for longitudinal data to guide long-term use, product improvements, and additional indications.

While this is a significant improvement in patient safety, it's also now the law for medical device manufacturers doing business in the European Union. The new EU medical device regulation, going into force in May 2020 for devices and May 2021 for IVDs, requires all existing devices to be reapproved with safety and efficacy evidence, and stipulates additional post-market surveillance requirements for them.

The need for additional data often contributes to the demand for clinical research coordinators. And it may be challenging to connect with qualified candidates in all the geographic areas included in the study. This may be especially true in studies covering large rural areas where locations may be distributed far apart, making it time- and cost-prohibitive to hire one coordinator for each site or require the coordinator to travel between sites.

Remote research coordinators help fill this void, allowing medical device manufacturers to conduct research in a scalable way. This helps trials be completed on time and on budget and can support more effective project management. Lowering costs of initial trials and after-market research helps keep costs in line, protecting device manufacturer investments and access for patients.

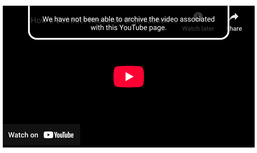
Streamlined Processes Generate Cleaner Data, Faster

When a remote research coordinator offloads certain tasks from on-site clinical providers, such as data collection, data entry, and even IRB/EC submissions, the on-site clinical providers can focus on their patients and research subjects. This allows the on-site care providers to attend to patients – screening and selecting appropriate candidates, guiding informed consent discussions, potentially accelerating enrollment, and attending to procedures and follow-up care. As soon as data is available in an electronic medical health record or mobile device data repository, the remote research coordinator can extract relevant research information for entry in case report forms. Remote research coordinators should be qualified to examine such medical information, bringing clinical expertise and human judgement to processes that artificial intelligence has yet to fully prove possible in this arena.

And, pairing remote research coordination with remote monitoring makes clean data available for analysis even faster than traditional approaches. When a remote monitor is also able to review medical records securely and verify with reported research data, the regulatory and good clinical practice requirements are fulfilled. This can be accomplished nearly in real time, instead of delayed by weeks or months between on-site visits for traditional source data verification.

For even more efficiency in ensuring robust data and study compliance, the same strategy is true for remote trial master file (TMF) reviews. These can often be performed at half the cost of an in-person audit, and keep study quality high and costs lowered.

See how remote services can reduce costs and improve efficiency.



Global Outlook

A global market often requires device studies to be conducted around the world to generate accurate data that supports the ethical principles of justice, beneficence, and respect for persons, as well as regulatory submission requirements. Medical device manufacturers can improve the efficiency of global clinical trials by conducting them simultaneously with remote research coordinators. The study will benefit from having one coordinator or a consolidated team handling the data and processes the same way, rather than a large number of on-site coordinators who may use different methods or report data in disparate ways that make data analysis more challenging.

By running a clinical trial using a global population, the study will benefit from a varied population, ensuring that the device is tested in the appropriate target populations and able to be marketed to a broader audience.

And, of course, using remote research coordinators for a global study can significantly reduce costs, by offloading certain tasks like data collection and entry to a central team from on-site clinical staff, allowing them to focus their attention on patients.

How to Use a Remote Research Coordinator

There are several ways to use remote research coordinators for clinical trials. As long as an internet connection is available and access to confidential information is controlled and secured, the choice in approach depends on study, sponsor, and site considerations.

One option is to house your remote team at your own office, where they coordinate their efforts and connect with sites. Remote coordinators may also be distributed, using their own office space to work.

A team of remote research coordinators may also be part of a contract research organization's site support team. This allows site staff to focus on their own clinical and research competencies while a highly competent remote research team handles the support tasks, like data collection and entry and IRB/EC communications.

Hiring remote research coordinators can help you more effectively manage data entry and keep your trial on track. And IMARC's site support services can help. Learn more about how we can help develop a remote research coordination plan for your study.

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