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Five Steps To Enhance The Clinical Trial Patient Experience

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As competition within the drug development landscape intensifies and further scientific advances are made, clinical trial protocols become more complex. In response, the industry is shifting to refocus on the needs and experience of clinical research patients. Integrating home health support, or remote visit services, to improve the patient-centricity of clinical trials has been used in its most basic form for some time. Best practices to fully harness patient-centricity and ensure trial success include:

1. Early Assessment And Implementation Results In Rapid Deployment

Review your protocol(s) and study concept document(s) to assess areas for integration of remote visits in your clinical trial. Expediting documentation and proactively including transparent language with the option for remote visits in your protocol prevents IRB/EC delays and ensures integration of the service beginning with the first patient enrolled.

2. Enhance Transparency Through Integrated Technology And Communication

Start your study off right by determining required reporting, and provide regular status updates and communication to study investigators and sponsor staff. Applying technology to increase communication and regular updates to the principal investigator will allay concerns and confirm patient oversight and support.

3. Establish Quality-Based Key Performance Indicators (KPIs)

Quality certification should drive the collection, review and improvement of your service-related KPIs. Relevant KPIs may include: percent of visits conducted within protocol window, percent of ordered visits completed, time elapsed between in-home visit and receipt of source documents by site and percent of patient drop-out across trials and sites. KPIs such as these maintain quality and foster transparency and trust at the site, sponsor and provider levels.

4. Understand The Impact Of Country Regulations And Service Nuances

It's important to understand any specific country laws/regulations (especially around patient data) as well as cultural norms that may impact the benefit of home patient care. Establishing this information up front will guide your use and benefit of home health care.

5. Find The Right Providers That Are A Best Fit For Your Unique Trial Needs

Ensure success by identifying and training the right providers. Providers should be qualified per local requirements and hold valid certifications (e.g., insurance). Routine and practical training should be protocol-specific, tested and verified prior to the provision of services. All providers should have knowledge of and compliance with local and regional privacy laws and regulations.

As the industry continues to invest in patient-centric systems and processes, trials become more efficient and enrollment, retention and timelines are improved. Ultimately, the clear winner is the patient, who will benefit from having faster access to treatments.



Mr. Keens has extensive industry experience, including roles in clinical operations, project management, consulting and business development leadership across both large global and growing CROs. He leverages his experience to help biotech and pharmaceutical sponsors identify needs and examine how Firma may deploy expertise and resources to support these needs to achieve their drug development goals. Mr. Keens earned his undergraduate degree in Biology/Psychology from James Madison University, and his Master's degree in Public Health from The University of Virginia.



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