Decentralized, Hybrid or Traditional: Choosing the Best Option for Your Clinical Trial

While elements of decentralized and hybrid trials existed prior to the coronavirus pandemic, the ongoing crisis accelerated the demand for an alternative to the traditional, on-site model as the pharmaceutical industry was focused on managing patient safety and ensuring data integrity for COVID-19 vaccines and ongoing studies. Yet, despite this need, many sponsors are still facing challenges in applying new strategies to existing clinical operations.

To better understand how to create a future clinical trial, sponsors will first need to take into consideration patient centricity at every step. Here, we define the various trial models and offer insights to help sponsors decide when it is most optimal to use a specific approach.

Defining Decentralized and Hybrid Trials

Decentralized trials are those executed through telemedicine and mobile or local healthcare providers using procedures that vary from the traditional clinical trial model, according to the FDA. Fully decentralized models are entirely run with remote visits conducted via telemedicine and/or other electronic communications with no physical on-site patient visits. In contrast, traditional models are where all patient visits are on-site. While there are many benefits to fully decentralized models, due to a variety of factors from patient preference to operational logistics, most sponsors are taking a hybrid approach.

So what does a hybrid model look like? This approach might use a traditional site-based model to ground the study and then apply certain decentralized elements that go directly to the patient to better engage and retain them in a study.

Choosing the Right Model

Whether to deploy a less site-based versus a traditional on-site model depends on five factors: endpoints, study design, investigational product, patient population, and regulatory.

Deciding endpoints — Sponsors will need to consider how endpoints will be measured, collected and confirmed. Will they be collected digitally (wearable, ePRO, etc.)? Can they be recorded or observed via telemedicine (rash, fever, etc.)? Can they be collected via home health visits (blood pressure, blood draw, etc.)? Finally, how will that data be accepted by regulatory authorities?

Choosing study design — The study design should inform how many decentralized elements can be incorporated. For example, an interventional study that has a high touchpoint for patients, such as a neurological study, may have some visits virtual, but may be less adept at moving into a fully decentralized model. Whereas a non- or low-interventional study may be better suited for a fully decentralized program.

Safety profile of IP — If a study drug has a well-characterized safety profile, then it could lend itself to a decentralized approach. On the other hand, if there is some concern about the uptake of the drug, a hybrid approach may be a better strategy. In this case, a sponsor may choose to have the first dosing in the clinic, allowing the patient to get accustomed to the drug and the physician to observe any adverse effects. Follow-up dosing appointments may be completed at home with a nurse or healthcare professional. Other considerations include whether the study drug is easy to administer and whether there are special storage requirements.

Determining specific patient population needs — Sponsors will want to consider the particular patient population enrolled in the study. For example, in a rare disease trial, the patient population may include pediatric and/or elderly populations who may require family, guardians and other homecare providers to help them travel to sites. So, what can you do to make it easier for the patient to participate and stay engaged? One solution is to provide transportation, including Uber and taxi services, for patients with hindered mobility or patients in geographically remote locations. In addition, incorporating digital health solutions, such as apps, can further alleviate burden.

Understanding regulatory considerations — When deploying a decentralized or a hybrid approach, sponsors will need to consider the fact that certain solutions may work in some, but not all, countries involved in a particular study. Therefore, sponsors will need an understanding of the local and regional regulations, and where deploying specific solutions, such as eConsent, make the most sense, as well as how quickly they can be engaged in different countries.

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Conclusion

As the industry moves toward more hybrid and decentralized models, it is important for sponsors to assess the feasibility of conducting patient-centric virtual study visits. While a hybrid model can be implemented in almost all types of clinical trials, in evaluating the best approach — whether traditional, decentralized or hybrid — sponsors should follow the five considerations outlined above to increase the probability of study success.

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