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Eight Technological "Must Haves" to Support Your Decentralized Clinical Trial

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Over the past decade, there has been a gradual uptick in the popularity of decentralized clinical trials (DCTs)—a trend that has accelerated dramatically due to Covid-19. Now, there will be no going back, largely due to the convenience and flexibility for patients. "Patient-centricity" is more than an industry buzzword; it is a form of enlightened self-interest for sponsors and researchers. By minimizing the burden of participating in a clinical trial, sponsors simplify recruitment and increase retention and compliance. Study effectiveness is amplified—and drugs get to market faster, saving patient lives and sponsor money.

These trials—largely conducted remotely—make use of technology and other novel solutions to minimize the patients' need to travel. Site visits may be replaced by visits from a home nurse, or to the patient's own primary care physician, while wearables, apps, and home-monitoring devices collect data on an ongoing basis.

All this creates an avalanche of disaggregated data from multiple sources that must be carefully tracked, analyzed, and managed. So, it's not surprising that while patients prefer this alternative to site-anchored studies, DCTs are not always simple for sponsors and contract research organizations (CROs).

Consequently, sponsors can be as wary of DCTs as patients are appreciative of them. Sponsors often feel that DCTs increase operational complexity, business risk and regulatory hurdles. Fortunately, with the right technology those fears are unfounded—leaving as the only question how to choose that "right technology." Here are eight key features that help simplify DCT management and ensure its success; look for them as you consider clinical operations platforms:

1. **Collects all your data in any form.** Seek a platform that is able to aggregate, analyze, and visualize all the data collected across your trial, including data from wearables, apps, and more traditional forms of data collection.
2. **Harmonizes that data.** Collecting the data isn't enough; find a system that can integrate data across source systems, to optimize analysis.
3. **Supports detailed examination.** You need the same attention to detail that clinical research associates traditionally supply onsite—but you need it remotely. Look for a system with dynamic drill-down capabilities for further interrogation of issues with source data.
4. **Able to process calculated metrics.** Comprehensive risk management requires in-depth analysis. You want the flexibility to set user-defined metrics for more relevant analyses and greater actionability.
5. **Has a built-in audit trail.** Regulatory bodies require demonstrated proof of monitoring and risk-based data management; some systems provide that automatically.
6. **Offers machine learning capabilities.** Machine learning enables systems to quickly analyze data and provide near-real-time insights, facilitating many aspects of risk-based monitoring.
7. **Supports independent system set-up and use.** The ideal platform enables you to be self-sufficient—receiving support from the vendor when you want it, but not requiring perpetual services in order to operate effectively.
8. **Is 21 CFR compliant.** This should almost go without saying; it is important for your technology to comply with the Code of Federal Regulations for the Food and Drug Administration.

Armed with these eight features in a data-management platform, sponsors and CROs can be secure that data management will be streamlined, that risk-based monitoring and risk-based quality management will be readily accomplished, and that all regulatory requirements will be met automatically.

In fact, they may find that technology-enabled DCTs are simpler to manage than traditional trials.

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