Tigermed

Tigermed DCT Solutions | Decentralized Clinical Trials

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Embracing Decentralized Tools for a More Cost-Effective Trial

Push the Boundaries of Clinical Research with Tigermed

Bringing decentralized elements into your clinical trial makes the entire process more streamlined, faster, and cost-effective than conventional trial designs.

Tigermed team has saved sponsors over 30% on costs and increased efficiency by 40% on average by incorporating decentralized elements. Here's why:

1. Using electronic recruitment and minimizing in-office visits lowers the access barrier for eligible participants while lessening any burden. That means better participant recruitment and retention to meet your study endpoints quickly.
2. We implement tools that help you work smarter to get more out of your bottom line and time investment. Real-time remote trial monitoring, data management, and risk analysis easily optimize trial completion.
3. Clinical trial errors are costly both in time and budget. We have a team of experts with extensive knowledge in executing decentralized trials to help you navigate every step of the way.

As study protocols grow evermore complex, finding the right combination of electronic tools and knowing how to implement them can be challenging. That's why many sponsors have partnered with a global clinical research organization like Tigermed to facilitate decentralized trial planning and execution.

> **"We possess the necessary infrastructure and technologies to seamlessly implement remote monitoring, data collection, and patient engagement strategies, these are essential components for decentralized trial success."**
>
> --- Jiaojiao Yu, Vice President and Head of DCT Business, Tigermed

Finding the Right Tools: Our Approach to Optimizing Decentralized Trials

We leverage in-house expertise and cutting-edge technology to guide sponsors through the planning, operation, and delivery of decentralized trials. Sponsor needs are our priority; we tailor our recommendation to the specific needs of each study and budget.

Tigermed teams will find the right tools to meet the specifications of each trial, including giving sponsors the flexibility to use our platforms and any vendor of choice while partnering with us. "We offer valuable insights into protocol design optimization for decentralized settings, enhancing study efficiency and patient-centricity while mitigating risks," said Jiaojiao Yu.

Faster Recruitment. Easier Monitoring. Better Cost-Efficiency.

To create a fit-for-purpose trial, sponsors need access to a toolkit of flexible and comprehensive solutions tailored for empowering digital and decentralized clinical development. At Tigermed, we have created a one-stop toolkit that does just that—putting all the necessary resources at your fingertips.

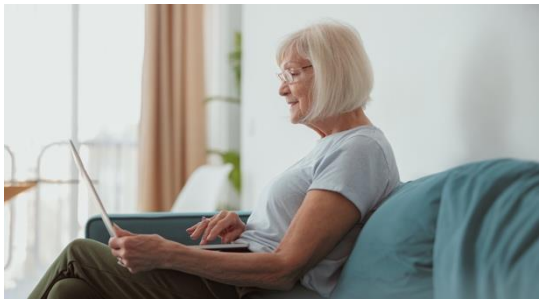
Cost efficiency comes from streamlining the recruitment process and trial monitoring, with saving enrollment time significantly. In a COVID-19 neutralizing antibody trial, we recruited 3,500 eligible subjects within 10 days using electronic recruitment and consent software. That's a 90% faster recruitment time on average seen across Tigermed decentralized trials.

Our recent partnership with one of the world's largest pharmaceutical companies shows how far remote monitoring can go in optimizing clinical trials. Using our decentralized trial integrated solutions, we executed pivotal Phase III trials and pharmacokinetic studies of their migraine treatment. Across 1,400 subjects in China and South Korea, we oversaw a combined hybrid approach to trial monitoring that took advantage of our remote clinical trial management system.

Clinical trial management software is essential—the right package will enhance study quality across many sites and provide crucial cost savings. Our system allows for real-time surveillance of data intake, regulatory documents, and more. It also enables an electronic audit trail for easier drug lifecycle tracking and regulatory compliance. All while meeting regulatory standards and best practices for electronic record keeping (21 CFR Part 11) and system validation (GAMP5).

The hybrid monitoring approach netted a 40% reduction in site monitoring costs and a 36% improvement in visit compliance. That's working smarter to maximize your time and your budget.

Protect Data Integrity. Streamline Risk Management.



Tigermed has executed over 200 hybrid trials across disease areas and 700 oncology trials, including a Phase 3 breast cancer trial for a U.S. biotechnology sponsor. Spanning 700 subjects across 11 countries, we employed several decentralized elements to streamline trial execution without taking on unnecessary risk or sacrificing data quality.

eCOA

Online questionnaire

eDiary

Electronic drug records

The hybrid trial leveraged an online questionnaire (eCOA) and electronic drug records (eDiary), alongside mailing the investigational therapy directly to participants. For sample collection, participants visited a local clinical laboratory to complete blood draws and testing (in-house visits also possible). This design protected the integrity of sample collection protocols while increasing efficiency and minimizing cost.

If a trial uses wearable devices, this can present additional challenges with data fragmentation and monitoring. That's why Tigermed leverages a robust digital integration platform that synchronizes electronically captured data. Our decentralized solutions can handle multiple data sources and generate a cohesive real-time dataset that sponsors can easily leverage for study analysis.

Further, with decentralized tools, risk assessment no longer has to be a time-consuming and labor-intensive task. Our risk-based quality management system is a digital data analysis platform that includes organizational- and trial-level risk management and centralized adaptive monitoring. It encompasses all risk functions and detection features, like quantifying key risk indicators, data visualization, and more.

Sponsors can quickly analyze clinical and operational data to identify outliers, risk trends, and data anomalies. We also provide support every step of the way—including a centralized monitoring team for data surveillance, quality assurance, and risk analysis.

Implementing decentralized elements doesn't have to place trial integrity at risk. Thoughtful hybrid trial design with remote data and risk management tools can bring you the cost savings of a decentralized trial and ensure accurate protocol execution.

A Local Regulatory Guide with Global Expertise

Many sponsors are looking to execute their early-stage trials in China. Doing so, especially while incorporating wearable devices and remote tools, introduces regulatory considerations requiring local expertise.

We faced this challenge head-on in a Chinese Phase 1b/Phase 2 obesity trial. Several tools were incorporated to reduce patient burden, including wearable devices like continuous glucose and temperature monitors, eCOA for self-reporting and records, and ePay for subject reimbursement.

Tigermed closely and actively collaborates on initiatives led by China's regulatory authority, including a 2023 industry report on decentralized trials. Our team of experts with extensive knowledge of decentralized trials and local regulations helped the sponsor navigate the red tape and prevented unnecessary delays in the timeline.

"We bring a wealth of expertise in navigating the complex regulatory landscape governing decentralized trials, ensuring compliance with evolving guidelines and standards," said Jiaojiao Yu.

The design strategy of the obesity trial optimized execution every step of the way, lessening the burden on both participants and the sponsor to meet study endpoints. That's the benefit of incorporating decentralized elements into your clinical trial—making the process streamlined, faster, and more cost-effective for everyone involved.

Next Steps

Tigermed experts can guide you through determining what decentralized elements will best suit your trial and specific needs. Whether you're worried about study quality or have tight budgetary constraints to work around, we can help.

Ready to explore how Tigermed can maximize your clinical trial design? Click **HERE** to schedule a meeting with us today, or join us at an in-person event **HERE**.