Tigermed

Tigermed DCT Solutions | Decentralized Clinical Trials

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Navigating Decentralized Trials on a Global Stage

Push the Boundaries of Clinical Research with Tigermed

At Tigermed, we're here to help clinical trial sponsors who are looking to take their trials international, who want to maximize their budget and streamline trial execution, who care deeply about the people actively participating in their trials.

A decentralized trial is often the best fit for sponsors with these goals in mind. This trial design benefits everyone involved—it's cost-effective, lowers the participation burden, and, with the right partner, can take trial efficiency to a new level. We've executed over 200 clinical trials that incorporate decentralized elements; our clients enjoy an average 30% cost reduction with 40% improved efficiency.

As clinical trial designs become increasingly advanced and more complex, trial sponsors benefit most from working with an experienced thought partner to optimize their multi-national trial. Navigating decentralized trial logistics within a worldwide regulatory landscape poses an incredible challenge. Sponsors will need perspective into the intricacies of each region's rules for decentralized trials.

Recently, Tigermed published the "Global Regulatory Handbook of Decentralized Clinical Trials," which provides an in-depth overview of the regulations and guidelines across 19 regions. Dive into the highlights of our report below:

Global Regulatory Handbook of Decentralized Clinical Trials

Download the DCT Report >

The Tigermed Approach to Decentralized Clinical Trials

Decentralized trials leverage many different digital tools and remote methods to streamline data collection without the need for on-site visits. Study designs can take on many shapes and sizes to best suit a sponsor's needs, whether a hybrid or full decentralized design.

A full decentralized design offers a completely remote experience that can streamline data collection virtually and minimize the participation burden. Alternatively, a hybrid design strikes a balance by utilizing some decentralized elements where appropriate, while still having other activities performed on-site.

Most of our sponsors opt for a hybrid trial, incorporating some decentralized elements to reduce the total number of visits, but not eliminate them. This design can catalyze significant benefits for saving time, money, and burden for participants.

Remote data collection and monitoring optimizes time and budget. Reducing in-office visits keeps costs down and maximizes time investment, while decentralized tools streamline data management in real time.

The convenience of decentralized trials reduces potential barriers to participation and increases retention. This benefit overcomes the recurring enrollment and retention issues commonly seen in traditional trials. Better participation enables the successful completion of study timelines, preventing unnecessary delays and costs.

Taking your decentralized trial globally enhances geographic diversity. Participation from a broader geographic range promotes diversity and makes results potentially more applicable to the general public.

Tigermed tailor-fits the incorporation of decentralized elements to each trial's need. This strategy can include tools like:

eConsent Electronic Informed Consent

Providing information to study participants and obtaining their consent through smart devices using digital media.

eCOA Electronic Clinical Outcome Assessment

A broad term that encompasses several electronic methods for collecting clinical outcome assessment data, including ePRO (see below).

ePRO Electronic Patient-Reported Outcome

Collecting patient-reported outcomes electronically, often through a computer or mobile device.

eDiary Electronic Patient Diary

A type of ePRO that captures participant experiences in real time by asking a series of questions or prompts.

DTP Drug to Patient

Delivering an investigational drug directly to a participant's home or a designated location instead of requiring travel to a trial site.

Telemedicine

Using videoconferencing or other technologies to provide remote medical care and consultations.

HCP Local Health Care Provider

Healthcare providers or facilities that are local to the trial participant and provide medical care or support during the clinical trial.

Wearable Devices

Digital tools worn on the body that can collect real-time health and behavioral data.

Risk-Based Monitoring

Centralized monitoring software that encompasses all risk functions and detection features, like quantifying key risk indicators and data visualization.

Remote Monitoring

Technology and tools that facilitate the overseeing and managing of clinical trials without requiring on-site visits.

We successfully incorporate these elements and maintain regulatory compliance by having a deep understanding of global decentralized clinical trial policies. Tigermed closely and actively collaborates on initiatives led by regulatory authorities to keep our pulse on present and developing guidelines.

Global Regulatory Guidance to Decentralized Trials

Many countries have regulations that allow decentralized elements, while others are still working to develop specific guidance.
Check out our breakdown of regulatory policies for three major regions across the globe:

America

USA

Since 2018, the United States has released several regulatory guidances regarding incorporating decentralized elements into clinical trials. The May 2023 guidance "Decentralized Clinical Trials for Drugs, Biological Products, and Devices (Draft)" is essential to successfully implementing decentralized trials in the U.S. Adherence to the guidelines makes all the aforementioned decentralized elements permissible.

America

Argentina

Argentina does not currently have specific guidelines for decentralized trials. However, many major decentralized elements are covered by other guidances from COVID-19 and for telemedicine. Other trials have successfully incorporated DTP and wearable devices despite a lack of specific regulatory guidelines by following the National Administration of Drugs, Food, and Medical Technology (ANMAT). As such, most decentralized elements are permissible here, per detailed protocol guidance from ANMAT.

America

Brazil

Specific regulatory guidances for decentralized trials, eCOA, DTP, and wearable devices are not currently available. Nevertheless, Brazil does have other guidances for biobanks, telehealth, and from the pandemic that are useful. These come with additional justifications and regulatory reporting requirements for different decentralized elements.

Other trials have also successfully incorporated local HCPs with detailed procedures and protocols reporting to regulatory authorities. Working with local regulatory authorities is recommended due to the distinct absence of specific guidelines for some decentralized elements.

Asia Pacific

Asia Pacific has the most complicated regulatory landscape, with great variance in the permissibility of decentralized elements and available guidance. We strongly recommend that sponsors work with a partner who has local expertise.

China

Chinese Mainland

In 2021, regulatory guidelines for clinical trials introduced the incorporation of decentralized elements. China's Center for Drug Evaluation released three guidance documents specifically for DCTs, referred to as Patient-Centric Clinical Trials, in 2023. The regulatory body has also sought input from local industry experts.
Chinese regulators value the thoughtful and thorough design of decentralized trials, prioritizing the experience and safety of trial participants. The major decentralized elements are permissible here with a detailed explanation of protocols and fair treatment of participants.

China

Hong Kong

Hong Kong does not currently have specific guidance on decentralized trials. Present clinical trial guidelines do allow for activities like RBM. However, remote monitoring is not explicitly permitted, and no detailed regulations exist for the use of telehealth in clinical trials. It is recommended that sponsors consult with the Department of Health and Institutional Review Boards.

China

Taiwan

Taiwan released relevant COVID-19 guidances for decentralized trials, including the adoption of DTP, telemedicine, and centralized and remote monitoring. In 2023, the Taiwan Food and Drug Administration released a "Guideline for Implementing Decentralized Clinical Trials." Incorporating a risk management plan regarding data privacy with electronic systems for decentralized trials is recommended.

Asia Pacific

Australia

Specific guidance for decentralized trials is not currently available. However, relevant guidelines come from pandemic guidance that encourages the use of remote monitoring, e-signatures, and telehealth. Other clinical trial guidances permit eConsent, and past trials have successfully incorporated other decentralized elements such as eCOA, ePRO, and eDiary. This requires a detailed protocol for incorporating decentralized elements to obtain regulatory approval.

Asia Pacific

Japan

Japan does not have specific guidance on decentralized trials, though plans are underway to draft this guidance. Guidelines from the pandemic introduce the use of DTP, local HCPs, remote monitoring, and RBM. Additional guidance has been provided for eConsent, e-signatures, eCOA, and ePRO, but there has yet to be any guidance for telemedicine and wearable devices. It is recommended to consult the Pharmaceuticals and Medical Devices Agency until the official release of a decentralized trial guidance in Japan.

Asia Pacific

South Korea

Past guidance has detailed the requirements for eConsent, wearable devices, and DTP, but no specific decentralized trial guidance is currently available. Previous studies have also successfully incorporated eCOA, ePRO, and eDiary when providing detailed protocols.

Telemedicine is very limited in South Korea, and there are no clear guidelines for clinical trials on telehealth or local HCPs. Electronic prescriptions also lack clear guidance. Sponsors targeting this area should consult the Ministry of Food and Drug Safety.

Asia Pacific

Singapore

Singapore does not have specific guidance for decentralized trials, eCOA, ePRO, or wearable devices. Previous studies have successfully used eCOA, ePRO, and eDiary by providing approved protocol details to the Health Sciences Authority. Pandemic guidance also includes eConsent, DTP, telemedicine, local HCPs, and remote monitoring, and additional guidance covers eConsent and e-signatures.

Asia Pacific

Southeast Asia

This region includes the Philippines, Malaysia, Indonesia, Vietnam, and Thailand. With the exception of Malaysia, the guidelines for decentralized trials in this area are unclear.

Malaysia released a decentralized trial guidance document in 2023 that comprehensively covers eConsent, e-signatures, DTP, local HCPs, other at-home trial procedures, remote data collection (eCOA, ePRO, and wearable devices), monitoring, and telemedicine. Most major decentralized elements are permissible in Malaysia, though we recommend consulting relevant regulatory authorities.

EMEA

Europe (Spain, Italy, Poland)

In 2022, the "Recommendation Paper on Decentralized Elements in Clinical Trials" provided a comprehensive overview encompassing all facets of decentralized trials. However, this document does not dive into every scenario for implementing decentralized elements. Trial sponsors are encouraged to consult the European Medicines Agency scientific advice working party or national competent authorities.

Most decentralized elements are permissible here, though careful consideration must be given to feasibility, patient safety, patient and investigator inclusion, and a risk-benefit evaluation of the decentralized design.

EMEA

United Kingdom

The United Kingdom separated from the European Union in 2020, but the guiding regulatory document on European decentralized trials remains a valuable resource for this region. Additional guidelines for the U.K. also come from several COVID-19 guidances regarding decentralized trials.

Again, most decentralized elements are permissible, but the Medicines and Healthcare products Regulatory Agency manages final protocol approval.

EMEA

South Africa

All trials in South Africa, including decentralized trials, must comply with the International Council for Harmonisation guidelines. Additional regulatory guidance from the pandemic provides broad guidelines for ethical standards regarding participant recruitment, informed consent, and more. Most decentralized elements may be incorporated into clinical trials with the proper submission of detailed procedures surrounding each element and the approval of the South African Health Products Regulatory Authority.

Summary

The variability and intricacies of global regulatory policy for decentralized trials can present logistical challenges. Most sponsors greatly benefit from working with an experienced partner in decentralized trials, especially if they are looking to take their trial international.

Our Tigermed teams have deep knowledge of regulations and working relationships with regulatory authorities globally. We also have local expertise in the Asia Pacific market, one of the most complex regulatory landscapes and the second most popular destination for clinical trials (China). As a leader in global decentralized clinical trials, Tigermed will continue to update guidance documents and collaborate with regulators, industry professionals, and patients to move toward the future of clinical trials, together.

Ready to take the next step for your decentralized trial? Click HERE to schedule a meeting with us today. You can also find out where to meet our clinical and regulatory experts at in-person events worldwide HERE.