White Paper

China Embraces Decentralized Clinical Trial Solutions

Surveys show patients, sponsors and CROs in China see the benefits of virtual and hybrid trials. Concerns remain around regulatory gaps, digital data collection and study logistics.

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Introduction

The biopharmaceutical industry in China, like the rest of the world, was forced to swiftly adopt decentralized clinical trial (DCT) approaches to maintain progress during to the COVID-19 pandemic. And, like the rest of the world, its patients, investigators and sponsors were hopeful about the benefits of using these tools.

Two new surveys conducted by IQVIA in China found patients are overwhelmingly open to participating in fully decentralized as well as hybrid virtual trials, and to using wearables, electronic data collection and other digital tools as part of that experience.

Our surveys showed that sponsors, CROs and investigators were also ready to engage. They see DCTs as a way to help them recruit and retain patients in this increasingly competitive marketplace. However, they still have some concerns about logistics, the reliability of digital data collection, and the still evolving regulatory landscape.

The results of these surveys offer exciting insights into the perception of virtual trial adoption in China as well as cultural perceptions that could help shape DCT approaches there. Further, the results suggest that these models will continue to be an important part of the clinical research landscape long after COVID-19 is under control.

Patients in China welcome decentralized trials

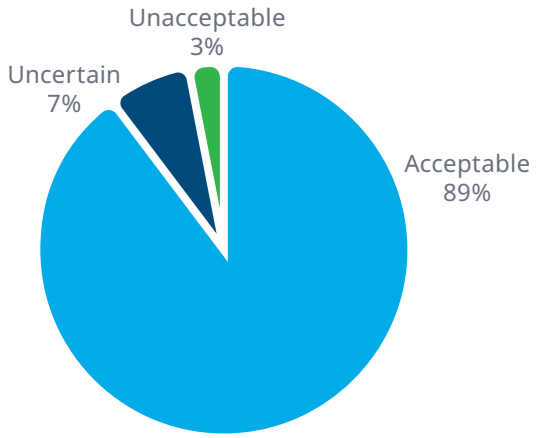
China is one of the most important markets for clinical research in the world. Its 1.4 billion citizens, vast pools of treatment-naive patients, and growing demand for new therapies make it a desirable location for sponsors. It is also proving to be an excellent locale for DCTs.

Decentralized trials create a more patient-centric research experience, easing the burden of participation and reducing the disruption it causes to patients' daily lives. It also makes it possible for sites to recruit and treat more patients from further away, which aids in recruiting and retention.

Decentralized trials create a more patient-centric research experience

These benefits have been clear since the first DCTs were deployed, and the pandemic only reinforced that value proposition. With trial sites shut down, and patients unwilling or unable to travel, DCTs offered a way to keep research moving forward.

Acceptance of overall decentralized clinical trials concept



Survey of 685 respondents from West China Hospital, Sichuan University, Oct 2020.

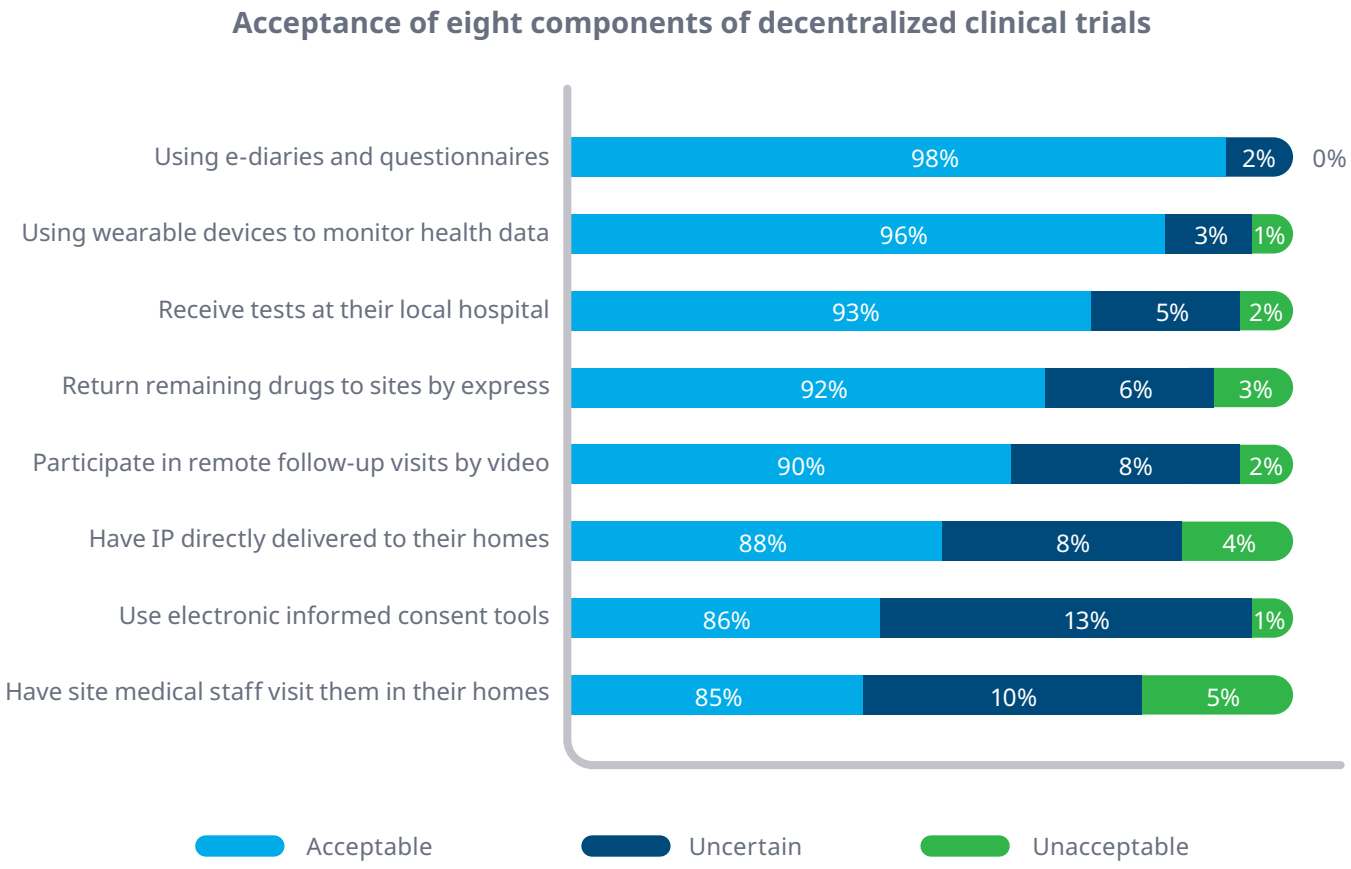
While the industry was hesitant to adopt DCTs before the pandemic necessitated an abrupt evolution to the traditional site-based trial model, our research shows that patients had no problem making the transition.

In a survey of 685 patients from West China Hospital at Sichuan University, 89 percent said virtual trials are an acceptable option for clinical research.[1] The survey also found that nearly all of them approved of the use of electronic diaries (e-diaries) and questionnaires (98%), wearable devices (96%), and video health visits (90%) as part of the research process.

This suggests that patients in China are eager to take advantage of the ease and flexibility of virtual trial participation and are not concerned about adopting a more technology-enabled experience.

The survey results are not surprising, given the tech-savviness of even elderly Chinese citizens. More than 90 million Chinese people over 60 years old now regularly use the Internet, and 85 percent of elderly mobile users have more than 20 apps on their phones, including 63 million who use WeChat. Chinese citizens have also become accustomed to "internet hospitals," where patients receive telehealth services from healthcare institutions. These virtual health services have become increasing common in China's healthcare sector and were projected to surpass 60 million users in 2020, which is a prediction that was made prior to the pandemic.

High acceptance of DCTs and related components



Survey of 685 respondents from West China Hospital, Sichuan University, Oct 2020.
Authors: Zuo Zejin, Chen Lei, Huang Peng from West China Hospital and Hu Min from IQVIA and China Pharmaceutical University

While certain populations will still need some training and assurances about using technology for clinical research participation, the survey results indicate a strong willingness among China's patients to embrace DCTs.

Competitive advantage

For CROs and sponsors conducting trials in China, these results offer support for using virtual trial elements in their projects. These patients are tech-savvy, and they may see telehealth, wearables and other DCT elements as an added benefit of participation.

Sponsors, CROs and other healthcare professionals also see the benefits of using DCTs to support their research goals and to keep patients engaged. In IQVIA's 2020 survey of industry stakeholders in China, respondents ranked "recruiting subjects," as the leading challenge that virtual trials could help them solve.[2] They also see DCTs as a way to improve subject retention and to simplify the research process for staff and patients, which is important in this increasingly competitive marketplace.

These results show that using DCT elements may offer a competitive advantage, allowing them to recruit more patients faster, and easing the burden of participation as a way to increase retention.

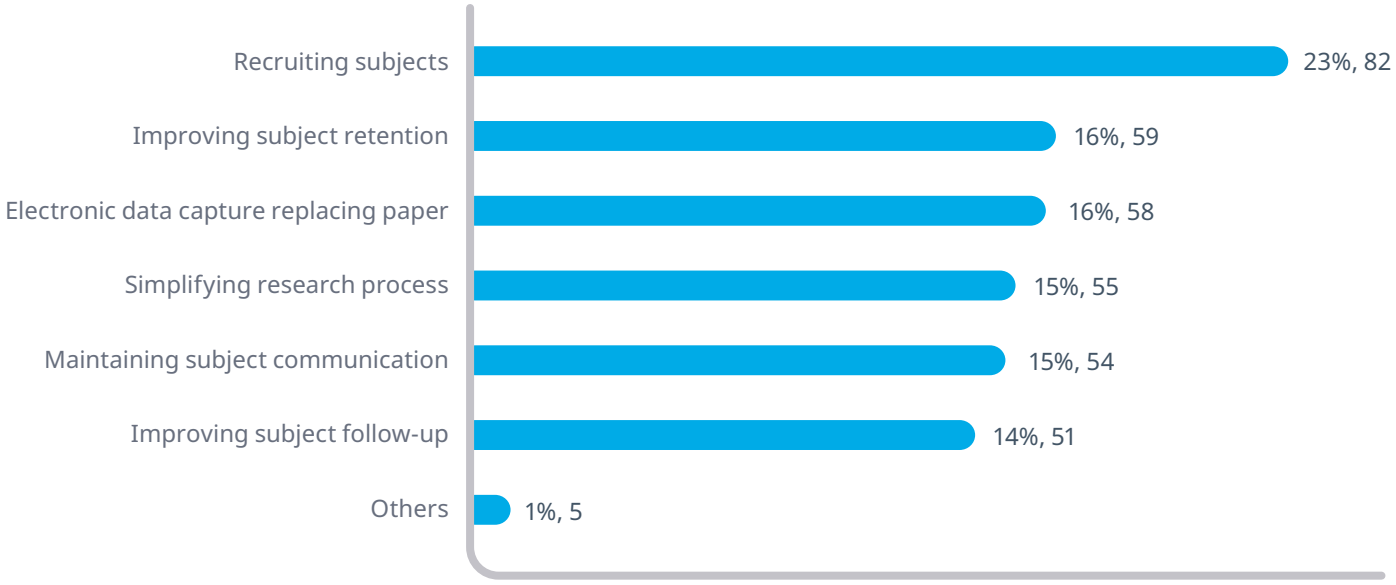
However, sponsors, CROs and other stakeholders also noted several challenges to making DCTs a mainstream part of the clinical research process in China.

Shifting regulations

The biggest challenge CROs and sponsors see to adopting fully decentralized and hybrid virtual trials in China is the lack of existing policies and regulations, according to our survey results. Because DCTs are still a new research model, regulations continue to evolve.

In July 2020, China Center for Drug Evaluation (CDE) published its "Guidelines for the Management of Drug Clinical Trials During the (Coronavirus Pandemic)." This document provides guidance for using electronic informed consent, remote monitoring, and direct-to-patient shipments of investigational therapies. IQVIA

Problems that can be addressed by decentralized clinical trials



IQVIA survey of 161 leaders from pharmaceutical and medical device companies, contract research organizations and other industry stakeholders, conducted October 30, 2020, at the 2020 DIA China conference.

believes regulations related to DCTs will continue to take shape in China, offering sponsors and CROs clearer guidance on how, when and where DCT elements will be accepted.

The survey also found that they are concerned about the adequacy of electronic informed-consent tools, which may be driven by the lack of clarity from regulators. Consent forms are among the most important documents captured in any trial, so sites need to be confident that e-consent forms are acceptable, reliable, and provide easy access.

In reality, e-consent tools can be more reliable than paper-based documents, because patients are able to sign all consent forms through an automated system, creating a single source of consent data that can be accessed by all relevant site staff, sponsors, and auditors as needed. These platforms can be set to alert staff and patients when a consent form needs to be updated, and send notifications if a patient fails to update their forms so they don't fall out of compliance with the trial.

Digital divide

The survey also found an overall hesitation among industry stakeholders to accept digital technologies for clinical research. They cite "accuracy of data collection," and "security of data storage" among their chief concerns. They also worry that sites will reject these models, and that immature technology and network environments may limit their adoption.

This doesn't mean virtual trial technology is not reliable or secure. Using electronic data collection tools can provide greater control and transparency for sites, sponsors and CROs, because they eliminate the added time, and risk of errors and lost data related to paper-based documentation.

The concerns noted in the survey more likely reflect a lack of experience among industry leaders with these technologies, and the risk-averse nature of introducing new methods into the clinical trial workflow. Additional education, sharing of best practices and case studies, and formal steps to verify the reliability of these tools may alleviate some of these fears, and encourage greater adoption of DCTs as a normal part of the trial environment.

The human side of decentralized trials

Along with concerns about the technology itself, sponsors, CROs and site staff in China worry that the "human touch" might be lost in a virtual environment. They fear that communication between doctors and patients may not be thorough enough via telehealth, and that patients may not have the skills or confidence to use the technology in this context.

On the staff side, they are concerned that DCTs and the use of telehealth may place an excessive burden on site staff to respond to patients' IT challenges, leading them to spend more of their time answering technology questions than talking with patients about the treatment and their quality of life.

Many of these issues can be addressed by introducing training for site staff and patients as part of the trial ramp-up process; and by providing support services via tech vendors or a trial concierge to provide support and troubleshooting as participants learn to use these tools.

Sites, sponsors and CROs in China clearly recognize the benefits of adopting the DCT model.

Addressing patients' in-person care needs, though, may be more complicated. Many DCT models leverage direct-to-patient drug shipments, home healthcare visits, and tests conducted at nearby healthcare centers to reduce the number of site visits while still ensuring patients receive the necessary care. But some stakeholders worry that the lack of certified and trained resources in the community make these models difficult to deploy.

With regard to drug shipments, the top issue noted was the safety of drugs and supplies, followed by patient privacy and emergency plans for drugs falling out of controlled parameters. To mitigate these risks, sponsors and CROs will need to establish sound quality management systems that monitor investigational drugs and supplies from their primary source through delivery to the patient; and they will need to employ trained and certified delivery vendors who meet all regulatory requirements. Such services aren't abundantly available across China, and will require upfront planning and collaboration with local vendors to ensure deliveries can be made before the trial begins.

They have similar concerns about access to trained home health nurse services. Most hospitals and trial sites do not expect nurses to conduct medical activities outside of the healthcare environment. As a result, they are not trained or qualified to perform these activities, and site staff may not feel comfortable supervising off-premise care.

CROs and sponsors interested in using home healthcare as part of their DCT approach will need to carefully vet their trial sites' willingness and ability to oversee these healthcare workers, or allow the CRO or other certified vendors to take over that responsibility as part of the trial operations. Nurses' qualifications will have to be reviewed, and the site will need to provide sufficient training on Good Clinical Practice, protocol and standard operating procedures. Once staff is deployed, the site will be responsible for providing them with the necessary tools and guidance, and then overseeing their activities.

Conclusion

There is no question that decentralized clinical trials are becoming an important part of the clinical research landscape in China, and COVID-19 has only accelerated this trend. Despite the concerns mentioned above, it's clear that sites, sponsors and CROs recognize the benefits of adopting this model in order to save time, cut costs and improve the ability to attract and retain patients for future research.

Sponsors can mitigate many of their concerns about using DCTs in China by choosing a clinical trial partner with country-specific and global experience deploying DCTs, as well as a suite of tested technology platforms that meet rigorous data security standards and data localization requirements, to ensure they can confidently move forward with this new research model.

References

1. IQVIA survey of 685 patients from West China Hospital at Sichuan University, conducted Aug 2020. Authors: Zuo Zejin, Chen Lei, Huang Peng from West China Hospital and Hu Min from IQVIA and China Pharmaceutical University.

2. IQVIA survey of 161 leaders from pharmaceutical and medical device companies, contract research organizations and other industry stakeholders, conducted October 30, 2020, at the 2020 DIA China conference.

About the author

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Maggie has 15 years' experience in the clinical research and pharmaceutical industry. Maggie joined IQVIA in 2012, and since 2019 she has served as a leader in clinical trials delivery for IQVIA's customers in China. Before joining IQVIA, Maggie worked at other multinational companies, including Pfizer and Paraxel. She has extensive experience in clinical trials operations and project management and is a member of the Member of Shanghai Pharmaceutical Association Clinical Research Specialist committee. She participated in the publication of "Intelligent clinical research expert consensus" in 2020. Maggie holds a Master's degree in Public Administration from the University of Macau, China, and Bachelor's degree in Biochemistry Engineering from the North-west University of China.

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