A Whitepaper from DDi

USA, UK, EU & China - Decentralized Clinical Regulations Differences

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It's important to note that regulations surrounding DCTs are constantly evolving, and sponsors should consult with regulatory agencies in each country to ensure compliance with current regulations.

Decentralized clinical trials (DCTs) are becoming increasingly popular in the pharmaceutical industry, as they offer many benefits such as reducing costs, increasing patient participation, and providing real-time data. However, the regulations surrounding DCTs vary by country. Here is a brief overview of DCT regulations in the USA, UK, EU, and China:

The FDA guidance on DCTs includes the following recommendations:

The USFDA has recognized the potential benefits of decentralized clinical trials (DCTs) and has issued several guidance documents to facilitate their use. In September 2020, the FDA released a guidance document entitled "Enabling Remote Informed Consent for Remote Clinical Trials During COVID-19" to help clinical trial sponsors navigate the challenges of obtaining informed consent in DCTs. Additionally, the FDA has published guidance documents related to decentralized approaches for clinical trial monitoring, data collection, and patient safety monitoring. Overall, the FDA encourages the use of DCTs as a way to increase patient access to clinical trials while maintaining high regulatory standards for safety and data integrity.

The MHRA guidance on DCTs includes the following recommendations:

In the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA) has also provided guidance on decentralized clinical trials (DCTs). The MHRA has stated that DCTs can offer benefits such as improved patient access, reduced burden on trial participants, and increased flexibility in trial design. However, they emphasize that DCTs must still adhere to the same regulatory standards as traditional clinical trials. The Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK has issued guidance on conducting remote clinical trials during the COVID-19 pandemic, which includes recommendations for DCTs. The MHRA encourages sponsors to discuss their plans for DCTs with them in advance and to consider the potential risks and benefits of this approach. The guidance emphasizes the need for DCTs to be conducted in accordance with the principles of Good Clinical Practice (GCP), This includes the need for appropriate study design, conduct, monitoring, and reporting, as well as the need for ethical considerations and the protection of study participants. And provides recommendations for ensuring the safety and integrity of data collected remotely. The MHRA's guidance also addresses issues related to data privacy and informed consent, trial design, and data management.

The EMA guidance on DCTs includes the following recommendations:

The EU CTR, which has come into effect in 2022, includes provisions for DCTs and allows for the use of electronic methods for obtaining informed consent, collecting and storing data, and monitoring patients. The CTR also requires sponsors to have a risk-based approach to study design and to ensure that data protection and privacy are maintained throughout the trial. The EU member states may have additional requirements for DCTs that are not addressed by the CTR. The EMA also emphasizes the importance of ensuring that DCTs are conducted in accordance with the principles of Good Clinical Practice (GCP). Overall, the EMA encourages the use of DCTs as a way to increase patient access to clinical trials while maintaining high regulatory standards for safety and data integrity.

The NMPA guidance on DCTs includes the following recommendations:

In China, the regulatory authority responsible for overseeing clinical trials is the National Medical Products Administration (NMPA). The NMPA has also provided guidance on decentralized clinical trials (DCTs). The NMPA

recognizes the potential benefits of DCTs, such as increased patient access, reduced trial costs, and improved data quality. However, they emphasize that DCTs must still adhere to the same regulatory standards as traditional clinical trials to ensure patient safety and data integrity. Overall, the NMPA encourages the use of DCTs as a way to increase patient access to clinical trials while maintaining high regulatory standards for safety and data integrity.

Overall, while there are some differences in the regulations across countries, the common thread is the importance of ensuring patient safety and data quality in DCTs. As DCTs continue to grow in popularity, it is likely that these regulations will continue to evolve and adapt to the changing landscape of clinical trials.

Regulatory Authorization	Parameter	Description
USA		
FDA	Electronic Informed Consent	The use of electronic informed consent (eConsent) can facilitate enrollment and improve the informed consent process by providing interactive tools to help patients understand the study information and the informed consent document.
	Remote Monitoring	Sponsors should develop strategies to remotely monitor patient safety and data quality, including the use of electronic patient-reported outcomes (ePRO), remote imaging, and wearable devices.
	Site Oversight	Sponsors should develop plans for site oversight and management, including training and support for site staff, remote monitoring of site performance, and regular communication with sites.
	Data Integrity and Security	Sponsors should ensure the security and integrity of trial data by implementing appropriate data management and security measures.
	Regulatory Compliance	DCTs must still comply with all applicable FDA regulations, including those related to the protection of human subjects, data integrity, and trial conduct.
UK		
MHRA	Risk Management	Sponsors should identify and manage potential risks associated with DCTs, including risks related to patient safety, data protection, and study conduct.
	Technology	Sponsors should ensure that the technology used in DCTs is fit for purpose and meets regulatory requirements, including those related to data protection, security, and confidentiality.

MHRA	Patient Consent	The use of electronic informed consent (eConsent) is acceptable for DCTs, but sponsors should ensure that patients are fully informed about the trial and their rights as study participants.
	Remote Monitoring	Sponsors should develop strategies to remotely monitor patient safety and data quality, including the use of electronic patient-reported outcomes (ePRO), remote imaging, and wearable devices.
	Site Oversight	Sponsors should ensure that study sites are appropriately trained and supported, and that site performance is regularly monitored.
	Data Integrity and Security	Sponsors should ensure the security and integrity of trial data by implementing appropriate data management and security measures.
	Regulatory Compliance	DCTs must still comply with all applicable regulations, including those related to the protection of human subjects, data integrity, and trial conduct.
EU		
EMA	Risk Management	Sponsors should identify and manage potential risks associated with DCTs, including risks related to patient safety, data protection, and study conduct.
	Technology	Sponsors should ensure that the technology used in DCTs is fit for purpose and meets regulatory requirements, including those related to data protection, security, and confidentiality.
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CHINA		
NMPA	Risk Management	Sponsors should identify and manage potential risks associated with DCTs, including risks related to patient safety, data protection, and study conduct.
	Technology	Sponsors should ensure that the technology used in DCTs is fit for purpose and meets regulatory requirements, including those related to data protection, security, and confidentiality.
	Patient Consent	The use of electronic informed consent (eConsent) is acceptable for DCTs, but sponsors should ensure that patients are fully informed about the trial and their rights as study participants.
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