Conduct of Clinical Trials During the COVID-19 Pandemic: Recommendations from FDA

As the COVID-19 pandemic unfolds, our drug, biologic, and medical device clients conducting or planning to conduct clinical trials may be faced with challenges related to quarantines, travel limitations, site closures or access restrictions, infection transmission concerns of site research personnel and study subjects, and supply chain interruptions. Nonetheless, it remains critical during the COVID-19 pandemic to continue to assure the safety of trial participants, comply with good clinical practice (GCP) requirements, and minimize risks to trial integrity. In this client alert which follows our earlier article on product development considerations for COVID-19 and article on FDA scrutiny of COVID-19 medical product marketing, we briefly discuss the impact the COVID-19 pandemic may have on our life sciences clients, and we provide an overview of FDA's "Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic" issued on March 18, 2020.

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