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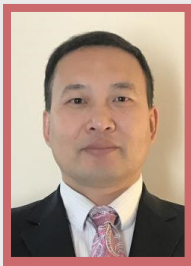

David Yu

BioPharma Services, Canada

Navigating the Clinical Research through COVID Pandemic: The Perspective from A Global Early Phase CRO

The ongoing COVID-19 pandemic has a potential impact on the design and management of clinical trials. Biopharma Services Inc. (BPSI) has developed guidelines for the design and conduct of clinical trials by adapting the concepts from regulatory guidances and understanding the current science. To ensure sufficient statistical power of the study is achieved, the sample size is appropriately increased in the initial period of the study for BA/BE trials. A group dosing option is utilized for larger sample size studies to maintain social distancing at the clinic facility and statistical procedures to accommodate the groups effects in BA/BE trial is considered. Vaccinations during clinical trials are closed considered based on the duration of the clinical trial, potential interaction and best interst of the volunteers. Electronic documents are adopted for certain study documentation where appropriate to reduce any unnecessary exposure. BPSI has implemented a number of COVID-19 related standard operating procedures to ensure the rights, safety and wellbeing of participants and medical staff, for example strict procedures are implemented to guide the clinic activities including staggered times for subjects' dosing, samplings, and assessments to reduce contacts and to maintain the study design integrity. The above critical steps has been successfully utilized in our company and there have been no failed studies due to the impact of COVID-19. In addition, the safety concerns, especially the concerns of not being infected during the clinical trial was achieved.

Biography

He is currently working in BioPharma Services, Canada