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Statistical Issues on the Conduct of Clinical Trials During the COVID-19 Pandemic

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Abstract

The COVID-19 outbreak is impacting clinical trials in many ways, such as patient recruitment, data collection and data analysis. To proceed in this difficult time, the adoption of new technologies and new approaches for conducting clinical trials needs to be accelerated. Simultaneously, regulatory agencies such as the US FDA and EMA have issued guidance to help the pharmaceutical industry conduct clinical trials of medical products during the COVID-19 pandemic. In this talk, we will address some statistical issues in the conduction of clinical trials during the COVID-19 pandemic. Specifically, statistical issues related to protocol modifications caused by COVID-19 will be raised.

Keyword: COVID-19, protocol modifications, heterogeneity