

Challenges of managing multiple stakeholders at research site in the current pandemic**Priyadarshini Arambam**

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The Corona virus disease 2019 (covid-19) outbreak caused by severe acute respiratory syndrome corona virus-2 (SARS-CoV-2) was sudden and unexpected. Its emergence created significant disruption in various healthcare systems that cut across disciplines including clinical research. Various challenges emanated from multiple stakeholders at research centers due to fear of getting COVID-19, travel limitations, quarantine, isolation, site closures, and interruption of supply chain for the investigational products have impacted both new and ongoing clinical trials for both covid-19 and non-covid-19 studies. The data is collected from the academics and clinical research department of Batra Hospital and medical research center which is a covid centre. The department employed numerous strategies including home delivery of investigational product by study staff to the participants, modifying the doses of drugs if necessary in the interim to prevent cessation of the study agents, provided alternative means of medical care by investigators and adoption of e-portal for ethics committee functioning to manage and support individual stakeholders. All the ongoing studies (33) continued to run well with feedback to the individual sponsors. The new recruitment was however a challenge. The strategies applied minimized the risks of protocol deviations without compromising the safety of trial participants, good clinical practice (GCP) and trial integrity. Challenges emanated from multiple stakeholders during pandemic can be overcome by modifying strategies in compliance with the applicable regulatory requirements that can significantly prevent disrupting the functions of stakeholders at the trial site.

Biography

Priyadarshini Arambam a PhD scholar in Public Health from Amity University. She is the General Manager Academics & Clinical Research at Batra Hospital & Medical Research Centre, a multi speciality hospital. She has published more than 15 papers in reputed journals and has been invited in national and international conferences.

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