

All stakeholders should work together to strengthen the clinical trial ecosystem in our country

That the COVID-19 pandemic has changed our world is clearly an understatement.

The initial days of the pandemic-induced lockdown led to difficulties in managing clinical trials. The patients could not visit hospitals and the logistics supply chain was also impacted. During this time, maintaining patient safety was of paramount importance and so was maintaining the quality and integrity of clinical trial data.

Many innovative risk mitigation strategies were deployed, for example:

- ▶ Direct to patient shipment of

investigational medicinal products (IMP) so that the patient receives IMP at their home,

- ▶ Home nursing care visits for administration of IMP or for collecting biological samples which were required for evaluating patients' safety and IMP efficacy,

- ▶ Video/tele-consulting of trial participants by doctors, etc.

The clinical trial protocols were amended to accommodate the flexibility that was required

to mitigate the pandemic induced risks. The Regulators and the Ethics Committees accorded priority review for such amendments.

While the pandemic



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accelerated the adoption of these changes that have made a positive impact, it is imperative that these should be continued in 2021 and beyond. Moreover, there will be a wide scale adoption of digital technologies in clinical trials, e.g., digital biomarkers, digital informed consent, e-health record directly feeding data to the e-CRF, etc. We will see more decentralised trials being conducted wherein the patient will be able to participate in the clinical trials from the comfort of his/her home and will need to visit the hospital site only for specific purposes.

The COVID-19 pandemic has caused wide-scale awareness amongst the general public about the importance of clinical trials to prove the safety and efficacy of drugs and vaccines. This should continue since it will aid greatly in the development of innovative treatment options for the patients.

It will be important for all the stakeholders to work together in the future for strengthening the clinical trial ecosystem in our country. This will help in our endeavour of finding safe and efficacious treatment options for the unmet medical needs of our patients.