Acta Scientific Otolaryngology

Volume 3 Issue 5 May 2021

Short Communication

Critical Issues and Challenges in Conducting Clinical Trial during the Covid-19 Pandemic

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Received: March 25, 2021

Published: April 03, 2021

The COVID-19 pandemic has an ongoing impact on the conduct of clinical trials across the world and India is no exception. The disease has the potential to impact the scientific integrity and patient safety of ongoing trials. It has also affected the trial patient recruitment and retention. This may be due to several reasons like self-isolation/quarantine by patients and study site personnel, travel restriction across various districts of a state or interstate travel and also blocked access to Clinical trial sites in hospitals which may have been converted to Covid Care centres.

Irrespective of any crisis or Pandemic situation the priority in all Clinical Trials should be the safety of the trial participants. All the stakeholders of a Clinical trial, Sponsor, Investigator, Ethics Committee and regulatory agency should work towards this common goal.

Sponsors need to make decisions regarding continuation of trial recruitment, continuation of use of Investigational drug/device for ongoing trial participants, management of collection and processing of Biological samples and also reporting of all Serious Adverse Events (SAE). The Project managers and clinical research associates should be in continuous contact with the various sites Investigators, Clinical research coordinators, other site personnel and sometimes even with the site Ethics Committee if site is shut down due to wide spread staff positivity.

The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India is the National Regulatory Authority (NRA) of India for the conduct of Medical research.

The CDSCO released a notice on 30th March 2020 regarding the conduct of Clinical Trials during the Covid-19 outbreak. It mentions that the protection of rights, safety and wellbeing of patients is of paramount importance and decisions must be taken in interest of the trial subjects. It also specified that any communication between sponsor/ethics committee/investigator regarding the implementation of protocol amendments/deviations/modifications due to the current scenario may be sent via Email/ any other electronic mode to Indian higher authorities.

The Indian Council of Medical Research (ICMR) released on May 6th 2020, National Guidelines for Ethics Committees reviewing Biomedical and Health Research to support the ethical conduct of Research in India during the Covid 19 pandemic. These guidelines include statement of general principles, general ethical issues, ethical review procedures, informed consent and vulnerability.

These documents released by the Regulatory authorities in India were extremely important as they helped all the stakeholders of clinical trials in conducting the clinical studies and continue to do as the Pandemic still rages on.