OPEN ACCESS Freely available online

Journal of Clinical Trials

Editorial

Clinical Trials during Covid-19

Abigail MK*

Department of Biotechnology, Andhra University, Visakhapatnam, India

EDITORIAL NOTE

The current novel coronavirus disease 2019 (COVID-19) pandemic has led to substantial changes in health risks, access to health care, and daily interactions. Through these and other challenges, the pandemic is affecting ongoing clinical trials that are evaluating interventions aimed at preventing or treating diseases other than COVID-19. Meaningful alterations to the implementation of protocol-specified procedures for adherence and retention of study participants, without careful consideration of the consequences to statistical analysis, can compromise the generalizability of clinical trial results about efficacy and safety of studied interventions in the postpandemic setting [1].

With ClinicalTrials.gov listing over a third of a million studies active in all 50 American states and 210 countries [2], participants in clinical trials are arguably at increased risks [3], such as financial difficulties, emotional trauma and adverse health outcomes. As with any clinical trial and especially during this pandemic, it is key to maintain deep trust and open communications between the investigator and participant.

In this setting, in conjunction with collaborative investigators, institutions, ethics review boards and Sponsors, investigators should disclose beyond the traditional elements of the risks, benefits, and alternatives to a clinical intervention [4], such as possible delays in investigational treatments or suspension of clinical trial activities due to COVID-19. This disclosure preserves transparency and underscores how informed consent is not a binding contract that requires participants to commit to a single treatment option. The voluntary process is dynamic and ongoing, which aims to constantly inform the patient about any changes from the start to the end of the clinical trial [5]. Ultimately, it should always be the participant's decision as to whether they would like to continue partaking in the study, provided that they have been presented all their options and undergone the decision-making process.

Hence, the analyses should aim to make inferences relevant to the postpandemic period. If the COVID-19 pandemic has meaningfully compromised trial conduct, confirmatory trials to achieve targeted levels of reliability may be needed.

REFERENCES

1. Guan WJ, Liang WH, Zhao Y. Comorbidity and its impact on 1590 patients with COVID-19 in China: A nationwide analysis. EurRespir J. 2020;55(5):547.
2. United States National Institutes of Health (NIH). Trends, Charts, and Maps. 2020.
3. Singh AG, Chaturvedi P. Clinical trials during COVID-19.
4. Bal BS, Choma TJ. What to disclose? Revisiting informed consent. Clin Orthop Relat Res. 2012;470(5):1346-1356.
5. Appelbaum PS, Lidz CW, Klitzman R. Voluntariness of consent to research: A conceptual model. Hastings Cent Rep. 2009;39(1): 30-39.

Correspondence to: Abigail MK, Department of Biotechnology, Andhra University, Visakhapatnam, India, E-mail: abigail987@gmail.com

Received date: June 05, 2020; **Accepted date:** June 19, 2020; **Published date:** June 26, 2020

Citation: Abigail MK (2020) Clinical Trials during COVID-19. J Clin Trials. 10:e415. doi: 10.35248/2167-0870.20.10.e415