**Overview of the FDA guidance for conducting clinical research during COVID-19 pandemic.**

*By: Perez, T., Perez, R. L., & Roman, J. (2020). Conducting clinical research in the era of Covid-19. The American Journal of the Medical Sciences, 360(3), 213-215.*

**Oversight**

* Investigators should determine if it is in the best interest of the subject to continue in a trial and/or continue the use of a trial drug.
* In accordance with research informed consent requirements, the subject should be informed of any protocol changes that could affect their participation, as this is new relevant information.
* Industry sponsors should be in contact with each investigative site to provide guidance on safety procedures to be continued such as labs or other vital status measurements.
* IRBs/ECs may need to change their review processes if they are accustomed to meeting in person or submissions are still on paper. Some central IRBs/ECs already have electronic submissions in place and committee members meet via a secure teleconference format.

**Study visits**

* Alternative means of obtaining data may need to be incorporated after approval from the FDA or IRB/EC. For example, telehealth visits (telephone calls and video conferencing) can be substituted for in-person visits.

**Study drug, supplies and equipment**

* A process for the safe shipment of the investigational product or trial drug directly to the subject that meets sponsor approval as well as local, state, and federal laws can be developed.
* Similarly, contingency measures to maintain the manufacture and supply of study drug to research sites during a pandemic or other emergency should be implemented.

**Procedures**

* Some protocol-specified assessments for efficacy will most likely be delayed or missed and could affect the integrity of the study. However, protocol specified procedures that put the subject or research staff at risk for contracting the virus should be postponed to a later date. These include situations that require close respiratory/facial contact and/or aerosol generating procedures (e.g., pulmonary function testing, nebulization, bronchoscopy, collection of sputum samples, intubation).
* Sponsors should seek guidance from the FDA when such protocol changes are considered to affect proposed study endpoints and/or statistical analysis.

**Communication**

* In accordance with research informed consent requirements, investigators should maintain contact with trial subjects and keep them informed of protocol changes that could affect their participation (new information).
* Sponsors should be in contact with each investigative site to provide guidance on safety procedures to be continued such as labs or other vital status measurements.

**Data integrity**

* Sponsors and investigators are required to document and maintain a log of all missing data and protocol deviations in the study regulatory files.
* Any deviations and changes to the protocol should be reported to the local or centralized IRB/EC as soon as possible. As it relates to COVID-19, the documentation should include a description of the deviation/missing data, its relationship to COVID-19, subject ID (if applicable), and any mitigation instituted.
* IRB/ECs should acknowledge and render a decision as to whether it is safe for subjects to continue in a clinical trial.
* Sponsors should provide additional information in the final clinical study report to the FDA. The report should include contingency measures that were put in place to manage study conduct during the COVID-19 crisis, a log of all trial participants affected by COVID-19 (to include subject ID, clinical site, and the deviation), the justification for the changes implemented, and the impact of the changes on the data results and safety.