



January 25, 2021

**Alliance Foundation Trials Statement Regarding Use of COVID-19 Vaccine and Emergency Use Authorization (EUA) Issued by FDA for Participating Sites in the United States**

Dear AFT Investigators, Site staff, Monitors, Partners, and Colleagues,

Alliance Foundation Trials, LLC (AFT) is not prohibiting the use of an EUA COVID-19 vaccine in any of its trials. AFT will defer to the treating physician and site policies as to whether or not a patient should be allowed to join or continue in an AFT study based upon the patient's COVID-19 vaccine status.

If a patient has received the vaccine, we ask that the site capture this information on the **Concomitant Medication form**. Sites continue to be responsible for documenting and submitting any Serious Adverse Events according to the study-specific safety and protocol guidelines.

AFT leadership will be seeking regulatory guidance from our central IRB and will work with our Study Chairs and pharmaceutical partners to issue additional study-specific guidance, as information becomes available.

Sites based outside of the United States should follow guidance from their appropriate local regulatory authorities.

If you have any questions regarding this statement, please contact the Director of Quality Management and Compliance:

**Majagamy Ramos-Bordonaro, MSRA, CCRP**  
email: [quality@alliancefoundationtrials.org](mailto:quality@alliancefoundationtrials.org)  
phone #: 617-525-6673

This information will be continuously updated on the following AFT webpage:  
<https://alliancefoundationtrials.org/covid-19-resources>

Sincerely,

**Daniel Jones, MSN RN**  
*Associate Director, Quality Management and Compliance*  
*Associate Medical Monitor*  
Alliance Foundation Trials, LLC

