Alliance Foundation Trials

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Alliance Foundation Trials – FAQ COVID-19 Pandemic Related Documentation and Testing

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

Alliance Foundation Trials (AFT) has received questions related to **COVID-19 Pandemic Related Documentation and Testing** and is providing response to FAQs below to ensure sites continue to provide this vital health information to AFT for safety monitoring and reporting of enrolled participants.

1. **What is the COVID-19 Form?**

   The COVID-19 form is an eCRF (electronic case report form) in the RAVE EDC (electronic data capture system). This eCRF was added for the collection of information on COVID-19 testing and symptoms and any COVID-19 pandemic related treatment discontinuations, study discontinuations, and deaths.

2. **Is the form required for every AFT participant enrolled?**

   As previously communicated in an AFT notification sent 5 June 2020 (SDC at Mayo Notice: New COVID-19 Form for AFT Trials, available here), "this form needs to be filled out for each patient that is currently on study or was still on study as of December 1, 2019, even if the patient was not impacted by the COVID19 pandemic". This form is required and provides AFT with information necessary for monitoring of participant safety and health.

3. **Does the study Informed Consent Form (ICF) require updates to mention and inform subjects that data related to COVID-19 is being collected?**

   No, ICFs do not require and AFT is not planning to update ICFs for the collection of data related to COVID-19. Participants that sign an AFT consent provide (authorize as per HIPAA) the AFT research team with access to medical records, which include Protected Health Information (PHI). This includes any health information that is collected about the participant. During the study, personal health information from participant's medical records and all data resulting from participating in an AFT study will be collected. PHI that may be collected includes: results of any blood tests, scans, physical examinations, or other procedures; results of testing on blood and tumor samples collected as part of this study, and genetic information.

4. **Does the study protocol require updates related to the collection of COVID-19 relate data?**

   Per AFT's central IRB 10 July 2020 (Advarra, available here), "COVID-19 screening procedures that may be mandated by the healthcare system in which a clinical trial is being conducted do not need to be reported as an amendment to the protocol, even if done during clinical study visits, unless the sponsor is incorporating the data collected as part of a new research objective". AFT is not collecting COVID related data as part of a new research objectives. Data is

being collected as part of the participant's medical record for purposes of safety monitoring and reporting. (FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards, available here)

5. **Why does AFT need to collect COVID-19 related information?**

   As the sponsor and IND holder, "under FDA regulations at 21 CFR 312.32, a sponsor must report to FDA any serious adverse event (SAE) that is both unexpected and for which there is a reasonable possibility that the drug caused the serious adverse event, i.e., there is evidence to suggest a causal relationship between the drug and the adverse event" (FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency, q23, available here). The AFT research team must be able to determine causality of AE/SAE to determine association with COVID-19 or investigational drug. Ensuring the safety of trial participants is paramount.

Please send questions to my attention at compliance@alliancefoundationtrials.org.

Sincerely,

Daniel Jones, MSN RN
Acting Director of Quality Management and Compliance, AFT
Alliance Foundation Trials, LLC

cc:
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