AFT SDC at Mayo Notice - New COVID-19 Form AFT trials

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

Over the next few weeks, the AFT SDC at Mayo will be rolling out a new form in Rave for each of your studies called COVID-19 Pandemic Related Documentation and Testing. This form will be added at the Subject Level and will collect information on COVID-19 testing and symptoms and any COVID-19 pandemic related treatment discontinuations, study discontinuations, and deaths.

Please note that 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 COVID-19 pandemic.

In addition to the new form, there will also be a checkbox added to the Deviation form that should be used to indicate which deviations are due to any COVID-19 pandemic-related reason. Once checkbox becomes available on the deviation form, sites will need to retroactively check this box for any deviations that have already been entered and were due to the COVID-19 pandemic.

If you have any questions about the new form or checkbox, please contact your study Data Manager.

Thank you,

Daniel

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