Memo Re: COVID-19 FDA Guidance

Date: March 24, 2019

Purpose

This memo updates you on the March 18, 2020 FDA Guidance on conducting trials during the COVID-19 pandemic, and Cancer Insight's plan to follow this Guidance.

Background

Recognizing the COVID-19 pandemic may impact the conduct of clinical trials due to quarantines, site closures, travel limitations, supply chain interruptions, site personnel or trial participant infection with the virus, and similar challenges, FDA has issued a guidance for industry, investigators, and IRBs conducting clinical trials during the COVID-19 pandemic.

FDA Guidance Details

FDA has outlined the following points to guide sponsors in ensuring patient safety and minimizing risk to trial integrity:

- Safety of trial participants is the foremost consideration. FDA has instructed Sponsors to consider all circumstances and focus on the safety of trial participants when making determinations regarding study conduct modifications. FDA recognizes that an important part of the consideration is the nature of the disease under study in the trial.
- Trial participants must be kept informed of any changes to study and monitoring plans that could impact them.
- Protocol deviations to minimize or eliminate immediate hazards or to protect the life and well-being of research participants may be implemented without prior IRB approval, but must be reported afterwards.
- Implementations of alternative processes (e.g., data collection, visit procedures, monitoring, etc.) should be documented and specifically detailed, including reasons, duration, and which trial participants were impacted.
- Missing data: If changes in study visit schedules, missed visits, or patient discontinuations lead to missing information, specific and detailed information must be recorded in the case report form, including the relationship to COVID-19 (e.g., missed study visits or discontinuations due to COVID-19). This information will be summarized in the final clinical study report.
- If any efficacy endpoints are not collected, specific reasons for failing to collect the assessment must be documented.

- Prior to locking the database, it may be necessary to address in the statistical analysis plan how protocol deviations related to COVID-19 will be handled for the prespecified analyses.
- Sponsors may use central or remote monitoring in place of on-site monitoring visits.

Cancer Insight's Approach

Cancer Insight will follow all FDA and IRB guidance. The key to Cancer Insight's approach is to ensure that specific and detailed documentation is obtained regarding any protocol disruptions, changes, or deviations. This information will be included in future final Case Study Reports and IND submissions. We fully appreciate that all such matters must be documented and appropriately attributed to COVID-19.

References:

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic – Guidance for Industry, Investigators, and Institutional Review Boards (March 2020)

WIRB Expert Panel Webinars: "Clinical Trials in the Era of COVID-19 – The Changes You Need to Make Now"