Bad Data In, Bad Data Out?: FDA Issues a Warning Letter Against a Clinical Trial Investigator

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In June 2013, the Food and Drug Administration (FDA) issued a Warning Letter to a clinical trial investigator for not complying with applicable requirements governing clinical investigations and the protection of human subjects. The Warning Letter is a reminder of FDA's enforcement authority and a wake-up call to pharmaceutical and medical device company sponsors that rely on investigators to conduct and oversee those studies where data generated may be used to support marketing applications.[1]

The clinical investigator was involved in a Phase III multicenter study for a new potential use of a well-known commercially-available drug. While the clinical site received an FDA-483 and responded, FDA implied that, while the site implemented new procedures which might prevent recurrences, the issues should not have occurred in the first place. The specific deficiencies identified by FDA related, among other things, to: (1) failure to conduct the study according to the investigational plan; (2) failure to maintain adequate and accurate case histories that record all observations and data concerning the investigation of each individual; and (3) failure to obtain appropriate informed consent.

While the particular observations are important, the general language used by the agency is, perhaps, more noteworthy. FDA noted in the Warning Letter that the non-compliance "raises concerns about the validity, reliability, and integrity of data reported" at the clinical site, as well as concerns about protecting the study subjects. Such language indicates that the agency will carefully review whether non-compliance with good clinical practices may effect the validity of the data generated at the site. Should the data be found invalid, not only will this negate substantial time and money, but the sponsor will also be unable to use the data to support the marketing application due to the deficiencies.

Sponsors and clinical sites must remain vigilant to follow FDA's requirements concerning clinical investigations. Sponsors' monitoring programs of clinical sites must work effectively, and the sites should be mindful that FDA can show up at any time. Failure to act proactively can lead to study disruptions and, potentially, the inability to use valuable data for FDA approval. The loss in time, money and reputation with FDA will be immeasurable.

1 Warning Letter (June 12, 2013) available at: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm360128.htm.

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