Clinical Trial … and Error

Clinical Score leads the industry as a "voice of the sites" by gathering front-line opinions and observations from Study Coordinators and other Clinical Professionals.

Scenario #2

The Event

During a routine audit of Sunnyside Hospital by Federal Regulatory Agency X1, a major violation for non-compliance was cited for "failure to return Sponsor-supplied study agent." During the Investigational Drug Pharmacy review, auditors discovered that a Sponsored-supplied oral investigational drug, U-571, was still in stock at the Sunnyside Pharmacy. The reviewed study was both closed to new accrual and without patients actively being treated with investigational drug for greater than 90 days. Per the Federal Regulatory Agency X1 guidelines governing clinical research, U-571 should have either been returned to the Sponsor or locally destroyed with the Sponsor's authorization.

Corrective and Preventative Action Plan

The failure to return or destroy Sponsor supplied study agent within the stated time frame of the Federal Regulatory Agency X[1] is an all too common finding at audits. The most troubling aspect of this event is that it can easily be prevented with the development of an effective internal communication plan. Investigational drug pharmacies, especially in community hospital settings, are often located in a space not conducive to regular interaction between pharmacy and clinical research staff. In addition pharmacy staffs at these facilities often have multiple responsibilities which limit their availability to participate in routine research related activities and meetings. This combination can often lead to poor communication practices between the two essential groups. This discovery of noncompliance often comes as a surprise to both pharmacy and research staff alike. A viable corrective and preventative action plan should include a strong communication strategy between these two essential groups.

If a routine meeting between research staff and pharmacy is not a feasible option at the institution, then a repeatable two-way communication strategy should be employed. It is recommended that this strategy include a directed email to the entire research and pharmacy teams and is generated by the primary Sponsor contact at the institution. This person should be a project manager, regulatory director, lead research nurse or primary contact for all Sponsor communications. This notice should be sent out at least monthly and include a list of all studies that are no longer actively accruing patients. In addition this email should generate a response from designated pharmacy key personnel to respond with an account of all active patients being treated on trial. It should be noted that the 90 day requirement of the Sponsor does not start until either date of the study closure to new accrual or the date of the last patient treatment; whichever is the later date. This strategy should foster a good communication plan between the two groups and prevent future occurrences of non-compliance.

An additional mechanism to strengthen this preventative action plan would be the installation of a routine quality assurance monitoring plan. The monitoring plan should include a strong review of all investigational Sponsored drug inventory at the pharmacy and take place at least on a quarterly basis.

Footnote[1]: Federal Regulatory Agency X is this scenario refers to the National Cancer Institute (NCI) Audit Branch. All audit guidelines referenced are taken directly from the Clinical Trials Monitoring Branch (CTMB) guidelines for auditing clinical trials for the NCI National Clinical Trials Network (NCTN) Program, version date of March 1, 2014.

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