News Release

Lotus Clinical Research to present Assay Sensitivity Case Study at ACCP

PASADENA, CA, September 10, 2010

Lotus Clinical Research will be presenting a poster entitled "Assay Sensitivity Can Be Higher in Single-Site than Multiple-Site Acute Pain Studies: A Case Study" at the upcoming American College of Clinical Pharmacology (ACCP) Conference September 12-14, 2010 in Baltimore, MD. The poster summarizes one of Lotus Clinical Research's case studies regarding Assay Sensitivity and how it can be higher in Single-Site studies than in Multiple-Site studies. The authors define Assay Sensitivity as the ability of a trial to distinguish an effective treatment from a less effective or ineffective intervention.

Past studies have shown that clinical trials on new analgesics often fail to statistically differentiate active drug from placebo, despite, in many cases, known efficacy of the study compound. These reasons are typically multi-factorial including trial design, placebo response rates and site to site variability. This case study focuses on the site to site variability and the results show that increasing the number of sites increases the risk of study failure.

For this case study, Lotus performed a post hoc analysis on a large multicenter acute pain study in which 1 research group (Lotus) accumulated a substantial proportion of the overall study sample giving us an opportunity to compare the assay sensitivity of a study conducted within 1 research group with the assay sensitivity conducted under similar conditions at a large number of sites. This trial failed to meet its primary endpoint as it was not statistically significant when compared to placebo. However, the key results of the analysis indicate that this result was most likely a "false negative" resulting from dispersing large numbers of subjects over multiple sites and the trial could have been positive had a single site with standardized methodologies been utilized (thereby increasing Assay Sensitivity).

This post-hoc analysis was performed by calculating the standardized effect size for the subgroups of interest; all patients studied at Lotus Clinical Research (n=126) vs. all patients studies at other research sites in the aggregate (n=277). The standardized effect size is an important measure of assay sensitivity because it is the factor that drives the statistical power of the study and in fact has an inverse square relationship with the study "n". The standardized effect size of the Lotus group was 64% higher than the other group. If that standardized effect size was applied to the whole study and the sponsor had used only the Lotus group, they would have seen a positive result. Again, because the sample size needed varies inversely with the square of the standardized effect size, even small changes in the standardized effect size have a significant impact on the sample size. The results indicate that the sample size requirements almost tripled in the multicenter environment. In addition, the time needed to achieve 80% power was greatly reduced with the Lotus group.

From the results of the analysis, the authors concluded that improving the quality and efficiency of clinical research may be better achieved by increasing enrollment at a single research center rather than dispersing large numbers of subjects across multiple sites.

Click here to view poster: http://www.lotuscr.com/abstracts/LotusAssaySensitivityACCP2010Poster.pdf

About Lotus Clinical Research

Lotus Clinical Research, Inc. strives to efficiently and accurately evaluate novel drugs and medical devices on behalf of our clients while ensuring the highest possible degree of patient safety and comfort. In 2001, Lotus began conducting hospital based Phase II-IV studies in the inpatient setting. In early 2008, Lotus acquired a 50 bed research unit within Huntington Memorial Hospital in which it conducts early phase and proof of concept studies that require specialty procedures and/or difficult to recruit populations. Being positioned inside a major medical center gives Lotus unprecedented access to technological resources and patients with specific disease states. Additionally, standard hospital stay duration can be manipulated by bringing patients into their research unit when they are ready for discharge from the hospital so that the treatment period of the clinical investigation can be completed.

For more information, visit http://www.lotuscr.com.

Lotus Clinical Research, Inc.
Kimberly Britt
619-303-3383