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CTI Clinical Trial and Consulting Services

CTI Clinical Trial and Consulting Services named "Best Places to Work" in Greater Cincinnati for Second Consecutive Year

The "Non-Inferiority" Concept in Clinical Trials

There are generally two distinct approaches for establishing the efficacy of a drug in clinical research. One approach is to demonstrate that the test drug is superior to a control group (placebo, active, lower dose) by showing that the test drug improves the outcome. Alternatively one could demonstrate that the test drug is "similar" (non-inferior) to a known effective therapy (active control). The non-inferiority trial is designed to show that the test drug is no worse than the control by *a priori* defined amount, the non-inferiority margin. By setting the non-inferiority margin, the study essentially attributes the efficacy of the active control drug to the test drug, thereby demonstrating the drug's effect.

An important property of clinical trials and critical to non-inferiority studies is assay sensitivity. Assay sensitivity is a property of a clinical trial defined as the ability of a trial to distinguish an effective treatment from a less effective or ineffective intervention. Without assay sensitivity, a trial is not internally valid and is not capable of comparing the efficacy of two interventions. There is no direct evidence of assay sensitivity in a non-inferiority study. When a test drug is shown to be non-inferior to an active control, but the study lacks assay sensitivity, both drugs could be efficacious or both drugs could be inefficacious.

Assay sensitivity for a non-inferiority trial depends upon the chosen margin of inferiority ruled-out by the trial, and the design of the planned non-inferiority study. The chosen margin of inferiority in a non-inferiority trial cannot be larger than the largest effect size which the control intervention reliably and reproducibly demonstrates compared to placebo or no treatment in past superiority trials. The non-inferiority margin can be difficult to quantify (and be clinically relevant), especially in transplantation as was demonstrated at the recent FDA advisory board regarding the approval of Belatacept.

CTI has extensive experience in the design and analysis of non-inferiority trials. CTI is also well versed in the methods used to determine non-inferiority margins as described in the FDA draft guidelines for non-inferiority trials. CTI fully understands the issues and complexities of designing a successful non-inferiority study. Please call us if you need help in designing your non-inferiority or any other study.

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Upcoming Medical Meetings CTI will be Attending …

CTI will have a significant presence at upcoming medical meetings over the next few months.

The International Society for Heart & Lung Transplantation – Chicago, IL
April 21-24, 2010

International Liver Transplant Society – Hong Kong
June 16-19, 2010

CTI will be exhibiting:

American Transplant Congress – San Diego, CA
May 1-5, 2010
www.atcmeeting.org/2010

BIO International – Chicago, IL
May 3-6, 2010
http://convention.bio.org/

If you are interested in scheduling a meeting with CTI at one of these events, please contact Nick Schatzman at 513-598-9290 or via email at nschatzman@ctifacts.com

Employee Update

Please welcome the newest addition to CTI:

Dr. Günter Stetter - Director Clinical Operations, Europe

Renate Hochdorfer - Clinical Trial Assistant, Europe

Laura Piker – Research Associate

CTI Clinical Trial and Consulting Services (CTI) is a unique drug and market development company offering a full range of services which encompass the entire lifecycle of drug development. These services include regulatory pathway design, clinical trial management, data analysis, medical writing, CME and training program development, market analysis and development and other consulting services. CTI focuses on the specific disease areas of solid organ transplant, hepatitis, infectious disease, end-stage organ disease and hematology/bone marrow transplant. With its combined expertise of clinical knowledge and market experience, CTI is uniquely positioned to incorporate both clinical and market driven endpoints and interpretations to provide extraordinary results.