



Volume 10, Issue 5

May 2012 Newsletter



CTI Clinical Trial and Consulting Services is a repeat winner of "Best Places to Work" in Greater Cincinnati

Upcoming Medical Meetings CTI will be Attending ...

American Transplant Congress
Boston, MA
June 2 – 6

Bio International
Boston, MA
June 18 – 21

Drug Information Association
Philadelphia, PA
June 24 – 28

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

Longitudinal Data Analysis Methods to Evaluate Change

Many studies lend themselves to the measurement of change. For example, targeted interventions can cause a decline in cholesterol levels or improvement in renal function. The research design need not be experimental but may also be observational. Data can be collected prospectively or retrospectively and time can be measured in a variety of units—months, years, sessions, and so on.

The data collection schedule can be fixed (everyone has the same periodicity) or flexible (each person has a unique schedule). The major focus of longitudinal data analysis is concerned with how individuals change throughout the duration of the study and examining factors that influence inter-individual differences in change i.e., What predicts differences among individuals in their changes? Change in this case does not necessarily imply growth or an increase over time. The statistical models currently available care little about the direction (or even the functional form) of change. They lend themselves equally well to outcomes that decrease over time (e.g., weight loss among dieters) or exhibit complex trajectories (including plateaus and reversals).

With longitudinal data the usual assumptions for standard statistical analysis do not hold. In particular, the repeated observations on the same individual are not independent and the variance of the repeated measurements is not usually constant over the duration of the study. The correlation among repeated measures is a positive feature of longitudinal data because correlated observations provide more precise estimates of the rate of change than would be obtained from an equal number of independent observations of different individuals. The correlation within-subjects cannot be ignored though and needs to be taken into account in the analysis. In this regard two aspects of the data require modeling: 1. Mean response over time; and 2. Covariance

Employee Update

Please welcome the newest additions to CTI:

Betina Dellarossa, M.D. –
Manager, Business
Development Latin
America

Julia Höchst – Clinical
Trial Assistant Europe

Els Roggeman – Clinical
Project Manager Europe

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among repeated measures on the same individual.

CTI is currently involved in several observational longitudinal studies where the analysis of change and predictors of change are of particular interest. By measuring and charting changes over time—both naturalistic and experimentally induced—we can uncover the temporal nature of their development.

To learn more about these methods and how we may be of assistance, please contact us.

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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.