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August 2011 Newsletter



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

Upcoming Medical Meetings CTI will be Attending ...

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

European Society for Organ TransplantationGlasgow, UK
September 3 – 7

BioPharm America Boston, MA September 7 – 9

Stem Cells USA
Regenerative Medicine
Congress
Boston, MA
September 13 – 15

The United States Renal Data System for Outcomes Research

Health-related retrospective databases, in particular claims databases, continue to be an important data source for outcomes research. These databases are important as they allow researchers to examine medical care utilization as it occurs in routine clinical care. Retrospective databases often provide large study populations and longer observation periods, allowing for examination of specific subpopulations and rare events. In addition, retrospective databases provide a relatively inexpensive and expedient approach for answering time-sensitive questions posed by decision makers.

The United States Renal Data System (USRDS) is a national data system that collects, analyzes, and distributes information about end-stage renal disease (ESRD) and chronic kidney disease (CKD) in the United States. The USRDS is funded directly by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in conjunction with the Centers for Medicare and Medicaid Services (CMS). Coverage rate is 100% as participation in the USRDS is mandatory since May, 1995; that is, all ESRD patients, regardless of insurance coverage and age, are included in the USRDS database. However, claims such as hospitalizations, costs, and clinical services are restricted to Medicare patients. The USRDS has provided valuable insights that have helped to guide evidence-based medical decisions in CKD transplantation. In addition to producing the Annual Data Report on ESRD and CKD in the United States, the USRDS also provides standard analysis files (SAS datasets) and specialized datasets to researchers.

A major strength of the USRDS claims database is that it allows for an individual to be followed longitudinally over time. With linkage to the kidney transplant registry, the USRDS provides a more complete history of health care utilization in patients with ESRD. 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 additions to CTI:

Michelle Cosgrove -Manager, Business **Development Operations**

Jennifer Valentine -Director, Business Development

Congratulations to the following CTI employee recently promoted:

Sharon Blackaby -**Executive Administrative** Specialist

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The USRDS-linked database also includes data on the donor, allowing for a more comprehensive analysis of the data by donorderived risk strata (e.g., donor type, expanded criteria donors, age > 60 years). However, there are limits to the degree to which claims data can accurately capture an individual's medical history. Claims data are collected for the purpose of payment and not for research. While these data are excellent for understanding "real world" patterns of healthcare utilization and outcomes, they are subject to possible reporting errors. Careful attention to variable definitions is required (e.g., use of ICD-9-CM diagnosis codes); otherwise results can be misleading.

With an accomplished team of experts including database programmers, clinicians, statisticians and epidemiologists, CTI is well positioned to conduct a retrospective database analysis to meet client needs. We are particularly adept at analyzing data utilizing the USRDS database.

To learn more about the USRDS or other drug development or clinical research activity, please contact CTI.

For more information contact:

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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.