CTI CLINICAL TRIAL & CONSULTING

# December Newsletter

*Where Life-changing Therapies Turn First™*

Volume 11, Issue 12

Check out the new and improved CTI website!

www.ctifacts.com

**Upcoming Meetings CTI will be Attending …**

**Biotech Showcase 2014**
San Francisco, CA
January 13-15

**JP Morgan's 32nd Annual Healthcare Conference**
San Francisco, CA
January 13-16

**ASTS Winter Symposium**
Miami, FL
January 23-26

**Phacilitate Cell & Gene Therapy Forum 2014**
Washington DC
January 27-29

**Outsourcing in Clinical Trials West Coast**
San Francisco, CA
January 28-29

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

## Health Outcomes Research and Alternative Data Collection Methods

Randomized controlled trials (RCT) are considered the gold-standard for determining the efficacy of a therapeutic intervention. They have innate limitations as they operate in an idealized patient setting and only measure efficacy in restrictive populations. As such, they cannot provide a true indication of effectiveness within a diversified target population. Administrative claims databases are available that can be used to overcome this limitation. However, researchers are limited to the data elements collected in the database while the issue of data integrity can be problematic. **Prospective observational studies provide researchers the flexibility to define and collect data in real-time to meet study objectives but at a financial cost that can be comparable to a RCT.**

The electronic medical record (EMR) has become one of the most important new technologies in healthcare. The widespread implementation of electronic records in clinical sites across the United States, coupled with innovative statistical methodologies, presents enormous opportunities for clinical researchers. Data retrieved from EMRs allow for the examination of health care utilization patterns and associated outcomes in a real-world setting. Evidence that is collected from EMRs promises to broaden knowledge beyond what can be learned in a carefully structured study. But the use of EMRs is not without its challenges. First and foremost EMRs are designed to support clinical work flow and not necessarily research.

**CTI has developed a cost-effective methodology enabling researchers to analyze treatment protocols and health outcomes across multiple centers within a relatively short timeframe.** The methodology includes a three-step process:

**Congratulations to these recently promoted CTI employees:**

Jim Westerkamp – Executive Director, Consulting Management

**Welcome the newest CTI employees:**

Patty Conrad - Accountant

Irina Kruch – Clinical Trial Associate, Germany

Matthias Wüpping – Regulatory Specialist II

Joe Womeldorff – Visualization Analyst

**Quick Links…**

Website

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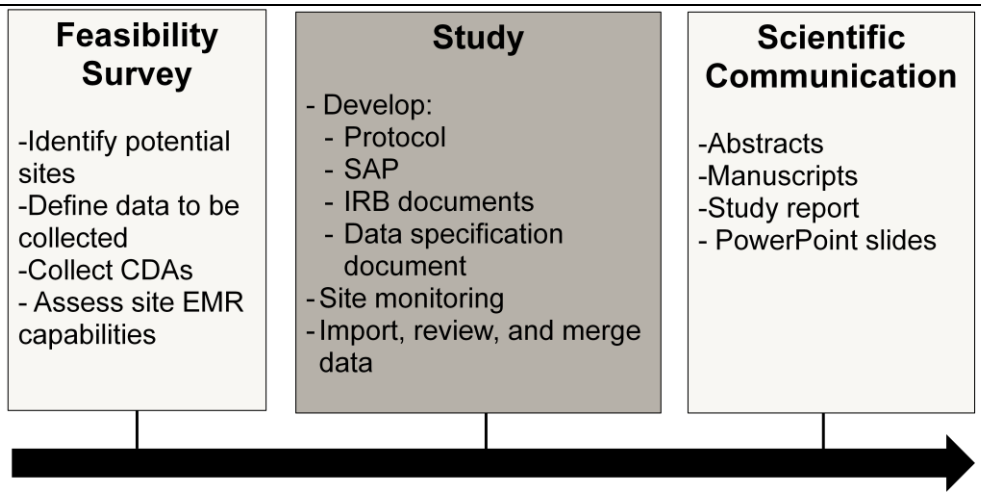


These steps are designed to minimize any potential barriers to implementation, analysis and interpretation of study results. The process begins with an electronic feasibility survey to identify potential centers. The survey assesses the availability of key patient-level data, necessary IT infrastructure, and human resource availability. Once the centers are identified, regulatory, IT, and clinical logistics are coordinated to optimize electronic data collection and transfer with minimal burden to the sites. All sites need to have negotiated CDAs in advance of survey and protocol distribution. The results are tracked and the responding sites are assessed.

A well-conducted observational study using EMRs may prove highly useful in certain situations provided that potential biases have been adequately addressed. The quantity of data available to researchers will continue to grow in line with the increase in utilization of EMRs. This data collection approach will enable the research community to gain new insights on contemporary real world management practices and patient outcomes in an efficient manner.

If you'd like to discuss CTI's approach to health outcomes research and alternate data collection methods, please contact:

William Irish, MSc, PhD
Vice President Biostatistics & Health Outcomes Research
birish@ctifacts.com

## About CTI

CTI Clinical Trial and Consulting Services is an innovative, international drug and device development organization that delivers a full spectrum of clinical trial and consulting services from bench to commercialization with a focus on immunology and a passion for helping life-changing therapies succeed in chronically and critically ill patient populations. CTI's focused therapeutic approach provides pharmaceutical, biotechnology and startup

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| | firms with clinical and disease area expertise from a unique mix of academic, medical and industry specialists; rich intellectual capital in transplantation, immunology, infectious diseases, hematology, cardiology, nephrology, hepatology, regenerative medicine and rare diseases; flexible study designs that accelerate development programs and deliver high approval ratings that are among the best in the industry; and exceptional global project management and gold standard safety and data management systems that strengthen their program's success potential. Established in 1999 and headquartered in Cincinnati, OH; CTI has offices in North America, Europe and South America. |