



December, 2013

[Visit our website](#)

## Multicenter Clinical Trials

By Sadik Khuder, PhD, Professor and Senior Biostatistician, Jacobson Center for Clinical & Translational Research

A randomized controlled trial is the most reliable method of determining the effects of treatment or intervention. To be scientifically sound, a trial must be internally valid (the extent to which the results of a study are true and free of bias). On the other hand, to be clinically useful, the result of a trial must be relevant to clinical practice and more likely to be replicated when applied to a defined group of patients in a particular clinical setting. The extent to which clinical trial results can be applied in this way has been variously termed as external validity, applicability or generalizability.

Compared to trials at a single center, multicenter randomized clinical trials provide a better basis for the subsequent generalization of the study findings since the treatment benefits are not dependent on one specific center and, therefore, should be reproducible at other centers. Any bias that might be related to the practice methods of a single center, where methods may be tailored to address local issues, will be reduced. Using many investigators to simultaneously evaluate a treatment gives more sources of feedback, allows more clinicians to gain experience and confidence with the new intervention, and highlights any problems at an earlier time point. Getting feedback from many investigating clinicians is particularly useful in the early stage of intervention development. Other benefits of multicenter trials include a larger number of participants, different geographic locations, the possibility of inclusion of a wider range of population groups, and the ability to compare results among centers, all of which increase the generalizability of the study. In many cases, efficacy will vary significantly between population groups with different demographics and baseline characteristics. Only geographically dispersed trials can properly evaluate the intervention in the context of these differences.

Currently there are 31 investigators at the University of Toledo Health Science Campus participating in more than 60 multicenter clinical trials. The number of patients enrolled from our site for a given trial ranges between 5 and 20. These trials are for treatment of a wide variety of diseases, including gout, chronic obstructive pulmonary disease, AIDS, orthostatic hypotension, osteoarthritis, irritable bowel syndrome, multiple sclerosis, Parkinson's disease, systemic sclerosis, lupus erythematosus, type 2 diabetes, cardiovascular diseases, traumatic brain injury, ovarian and endometrial cancer, cervical cancer, breast cancer, and multiple myeloma.

These trials are both scientifically sound and clinically useful. Moreover, they provide opportunities for the participating investigators to be involved in the advancement of evidence based medicine that may lead to improvements in the standard of care for all.

---

## Mentoring Medical Students in Emergency Medicine Research

By Catherine A. Marco, MD, FACEP and Kristopher Brickman, MD, FACEP

The Medical Student Summer Research program provides a unique opportunity for medical students to work with researchers in an educational setting, and to learn principles of medical research and evidence based medicine. We have hosted numerous medical students through this program and have enjoyed the rewards

and challenges of mentoring summer research students in the Emergency Department. We have mentored students in study design, IRB application, data collection, data analysis, abstract presentation, and manuscript publication on a variety of clinical topics in Emergency Medicine, such as:

- Colonization with Methicillin-resistant *Staphylococcus Aureus*
- Communication with Trauma Patients with Spinal Immobilization
- Pain Scores among ED Patients
- Hypothermia Protocol for Cardiac Arrest Patients

We have found that simple research projects that can be completed within the MSSR summer time frame have the highest likelihood of successful completion and manuscript publication. We have also provided core educational presentations for the students on research topics, including study design, data collection, data entry, and writing a scientific abstract.

Weekly meetings are helpful to communicate about data collection progress, questions and concerns. Goals and objectives set at these meetings have been helpful to students and researchers to maintain progress and ensure ethical and scientifically valid research conduct.

---

## **Centers for Medicare and Medicaid Services initiating mandatory reporting of 8-digit clinical trial number on claims starting January, 2014.**

Clinicaltrials.gov assigns an 8-digit identifier always preceded by 'NCT' to each registered clinical trial. Inclusion of this designator on claim forms submitted to CMS has been requested, but voluntary, since January 18, 2008. CMS uses this number "to identify all items and services provided to beneficiaries during their participation in a clinical trial, clinical study, or registry." It also helps to ensure that information resulting from the research is used to inform coverage decisions for the Medicare population. Effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the "Medicare National Coverage Determination (NCD) Manual."

---

## **UT Research Education Day - save the date: January 14th, 2014**

What is actually required in the drug and device regulations that impact day-to-day tasks of clinical research?

IMARC Research Inc, will be on site to direct the day's discussion on this issue. The program will begin at 8:30AM and adjourn at 4:15PM. Registration and CME costs will be covered by the JCCTR.

---

## **Newly enrolling clinical trials**

A Randomized, Multicenter Study to Evaluate Cardiovascular Outcomes with ITCA 650 in Patients Treated with Standard of Care for Type 2 Diabetes  
Dr. Bourey – Endocrinology

---

## **Research pharmacy services for drug study initiation**

By Gregory Siegel, Clinical Research Pharmacist

The research pharmacy is required to fulfill several roles in support of newly approved drug studies. These include:

### Site Qualification

- Maintain storage location security, provide temperature logs appropriate to required storage conditions.
- Maintain required SOPs
- Maintain BSL 2 lab for dosage formulation

- Assist the study PI with blinding plans and randomization

#### Site Initiation

- Provide in-service training for pharmacists and technicians to properly initiate the study and cover when the research pharmacist is off campus
- Maintain Investigational Medicinal Product logs and notify study PI in case of emergencies
- Participate in sponsor/CRO required training

#### In-life Study Responsibilities

- Calculate dosages, properly prepare sterile products and deliver drug
- Insure drug accountability through record keeping
- Unblind study records in preparation for site monitoring or IRB requirements
- Respond to queries

#### Support close-out visits

The cost for these study related services are part of the study budget and billed to the sponsor. Additionally, the Research Pharmacist fulfills regulatory responsibilities for the institution through appointment to the Biomedical IRB for protocol and adverse event review.

---

## Contact Us

Health Science Campus • Center for Creative Education Bldg.

2920 Transverse Drive, Floor 3 • Toledo, OH 43614

Phone: 419.383.6919 • [ClinicalResearch@utoledo.edu](mailto:ClinicalResearch@utoledo.edu)