

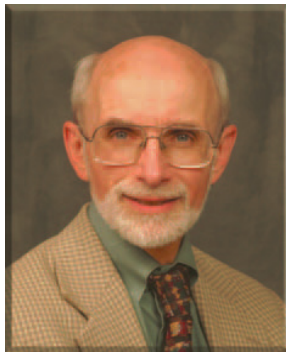
# Newsletter



Volume 4

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## Message from the President



This issue highlights: (a) the Clinical Research Institute's (CRI) capabilities in terms of metabolic disorders on page 2, (b) the experience of CRI in terms of both conduct and consultation on various types of clinical trials on page 3, and (c) a study recently completed by CRI in 19 days involving genetically defined volunteers on page 4. Taken together, these examples illustrate the breadth of CRI and its commitment to providing sponsors with quality data in a timely and cost effective manner.

CRI, through its affiliation with the KU School of Medicine, Wichita, has the opportunity to work with a skilled team of physician investigators with considerable clinical knowledge and clinical trials experience in obesity, diabetes, and related metabolic disorders and also sizable patient populations from which to recruit study participants. This team is comprised of Drs. Dismuke, Early, and Schrage. Together this team has 99 years of clinical experience and has conducted 47 clinical trials.

These investigators have access to CRI's resources and infrastructure including a team of certified clinical research coordinators (CCRC) with over 75 years experience and a regulatory affairs department, which is led by Bryan Baker, VP of CRI clinical operations; two 16-bed clinical research units for studies requiring subject confinement during critical periods of a study; and the grants and contracts department led by Mark Taylor, VP of CRI business operations. Together, these investigators and the resources of CRI translate into high quality, timely and successful study completion.

The story on page 4 illustrates this point. This study began with the sponsors requesting CRI input into study design and logistics. The study involved one of CRI's special population databases. In this case, the study population was CYP2D6 extensive (EM) and poor metabolizers (PM). The study was completed within 3 months of first contact. The time from first participant in, to last participant completed was 19 days without the need for any recruitment campaign.

You can find out more about the capabilities of CRI in metabolic disorders on page 3 and more about all of the capabilities of CRI by visiting our website, [www.cri-research.net](http://www.cri-research.net). Please, also feel free to contact Bryan Baker, Mark Taylor, or me. We would be happy to explore how CRI can meet your needs in the areas of obesity and metabolic disorders or any of CRI's other therapeutic areas (see above).

Sheldon Preskorn, MD  
Chief Executive Officer  
Clinical Research Institute

CRI has an affiliation with the University of Kansas School of Medicine (KUSOM) to further the scholarly and research activities of KUSOM faculty through their involvement as investigators on CRI clinical trials. As a result, sponsors have access to highly trained and experienced investigators in a wide range of therapeutic areas.

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J. Schrage



J. Early

## Metabolic Syndrome

- Central Obesity
- Insulin Resistance
- Hypertension
- Low HDL Cholesterol
- High Triglycerides

CRI, through its affiliation with the University of Kansas School of Medicine – Wichita (KUSOM-W), has access to a team of highly skilled and experienced principal investigators who conduct trials in the various disease processes which compose the metabolic syndrome. Specifically, they conduct studies in the areas listed above.

This team is comprised of Edwards Dismuke, MD, James Early, MD, and Jon Schrage, MD. Together, these investigators have 99 years of clinical experience and have conducted 47 clinical trials in obesity, diabetes, and related metabolic disorders. These investigators also have extensive experience in proven behavioral management approaches to life style modification and health promotion relative to the treatment of these disorders and can employ these approaches in a clinical trial if specified by the study protocol.

Through their clinical work and research, these investigators have access to large populations of patients with the above conditions. For example, the KUSOM-W internal medicine clinics care for large numbers of patients with chronic medical conditions including the various components of the metabolic syndrome. These clinics have an electronic patient medical record system that can facilitate recruitment for clinical trials. These patient populations, through collaboration with CRI, may be further supplemented by the clinical trial participant databases maintained by CRI.

S. Edwards Dismuke, MD, MSPH is the dean of KUSOM-W, and has appointments in both the Departments of Preventive Medicine and Public Health and Internal Medicine. He is board certified in internal medicine. Dr. Dismuke maintains a clinical practice specializing in dyslipidemia. He studied cardiovascular epidemiology as a Robert Woods Johnson Clinical Scholar and Fellow in Medicine at the University of North Carolina. He is active in research regarding cardiovascular risk prevention, especially in the areas of dyslipidemia and hypertension. Dr. Dismuke has been a Co-Principle Investigator on National Heart, Lung, and Blood Institute grants including HMG CoA reductase inhibitors in the elderly and Systolic Hypertension in the Elderly Program (SHEP). He has received over 2.5 million dollars of funding from the W.K. Kellogg Foundation in the area of developing model educational programs in health promotion and disease prevention. He is a past president of the Association for Prevention Teaching and Research (APTR).

James Early, MD is a clinical associate professor in the Departments of Internal Medicine and Preventive Medicine and Public Health at KUSOM-W. He is board certified in internal medicine and is a nationally recognized speaker on both metabolic syndrome and obesity. Dr. Early conducts research on lipid disorders, health promotion and disease prevention, and on developing systems needed to promote learning and behavioral change in the components of metabolic syndrome. Dr. Early is the founder of Solutions for Life, a unique partnership between Via Christi Regional Medical Center and Genesis Health Club. This clinical operation provides adult and adolescent medical obesity/weight reduction programs, and has provided pre-operative and post-operative care for over 200 bariatric surgery patients to date. He has developed effective behavioral modification strategies that are employed in his clinic. Dr. Early's clinical trial experience includes a three year study combining these behavioral modification strategies with investigational medication intervention.

Jon Schrage, MD, MPA is professor and chair of the Department of Internal Medicine. He is board certified in internal medicine and endocrinology/metabolism. Dr. Schrage has been involved in research involving intermediate metabolism. While division director of endocrinology, metabolism, and nutrition at Southern Illinois University School of Medicine his division was the subcontractor for the autonomic neuropathy portion of the Diabetes Control and Complication Trial (DCCT). Dr. Schrage has been involved in clinical trials involving pharmacologic agents for diabetic neuropathy, foot ulcer growth factors and meal replacement interventions for obesity. He currently follows nearly 800 difficult to control diabetic patients at the Veterans Affairs Medical Center-Wichita (VAMC-W) and is involved in a multi-disciplinary hypertension clinic.

If you are interested in more information about this team as potential investigators for your study, please contact CRI.

## Experience and Expertise of the Clinical Research Institute Team

CRI's management and clinical teams have over 100 combined years in clinical trials research and a track record for providing pharmaceutical and biotech companies world-wide with quality services; including drug development consultation, recruitment of specialized populations, and the conduction of Phase I-III studies. CRI utilizes its expertise and experience to aid sponsors in making their critical drug development decisions more efficiently, confidently and cost effectively. CRI's expertise and experience is summarized below.

### Research Consultation

- Protocol design & development
- Study feasibility & logistics
- Design of paper and electronic data capture forms

### Recruitment

- Extensive recruitment campaigns throughout the Midwest have built databases of specialized populations to facilitate rapid conduct of studies. CRI databases includes:
  - Individuals with genetically defined drug metabolism status
  - Young healthy adults
  - Healthy elderly
  - Elderly with mild probable Alzheimer's disease
  - Individuals with specific forms of treatment resistant depression
  - Adolescents with specific disorders
  - Individuals with mildly symptomatic schizophrenia

### Range of studies CRI conducts:

- First-in-man: including both single rising dose and multiple rising dose studies
- Drug-drug interaction studies
- Food effect studies
- Pharmacokinetic/Pharmacodynamic studies using various surrogate endpoints including:
  - Tyramine-induced blood pressure elevations
  - QTc and holter monitoring
  - Brain electrical activity mapping
  - Neurocognitive testing
- Proof of Concept studies in target patient populations, including both inpatient and outpatient
- Larger scale phase II-III outpatient studies

### Selected References from Some of the Above Work

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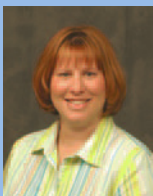
## CRI Completes Cytochrome P450 2D6 Poor Metabolizers Study in 19 Days

From start to finish CRI is known for delivering quality results in a timely manner. In a recently completed study, sponsors described CRI’s work as being “impressive” and “excellent”.

This study involved healthy subjects who were genetically determined to be CYP 2D6 extensive or poor metabolizers. The study was designed to evaluate CYP 2D6 status on the pharmacokinetics of an investigational versus a marketed drug in the same therapeutic area.

The sponsor’s goal was to complete the study in three months from first participant/first visit (screening) to last participant/last visit. Alisa Klick-Davis, the study coordinator, completed the study in one month. She was able to start all participants at once, and the study took 19 days from randomization to completion.

Quality results in a timely manner are why sponsors come back to CRI.



Alisa Klick-Davis, ARNP,CCRC  
12 years experience

## How to Reach Us

The CRI Newsletter is published  
4 times annually by the  
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