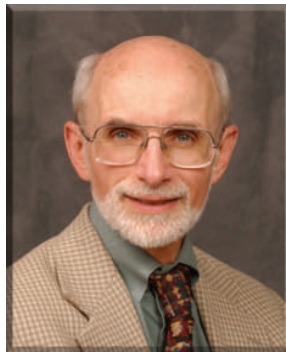


Newsletter



Volume 3

June 2006



Message from the President

This issue of the newsletter focuses on the affiliation that the Clinical Research Institute (CRI) has with the University of Kansas School of Medicine – Wichita (KUSOM-W) and its various departments. CRI is administratively separate from KUSOM-W but its collaborative relationship with the school and its faculty works to the benefit of both parties as well as to the CRI's study sponsors.

From CRI's perspective, this affiliation gives CRI access to principal investigators and their patients in many different therapeutic areas ranging from pediatrics to general adult medicine to geriatrics. From the school's perspective, this affiliation enhances faculty's ability to conduct clinical trials research. From the sponsor's perspective, this affiliation affords the efficiency and quality of CRI with the ability to work with multiple medical experts in a diverse range of specialties. As a result, CRI and its sponsors have access to a wide range of patient populations in virtually every therapeutic area being targeted by drug discovery efforts.

KUSOM-W has the following departments: Anesthesiology, Family and Community Medicine, Internal Medicine, Obstetrics-Gynecology, Pediatrics, Preventive Medicine, Psychiatry and Surgery. Neurology faculty are in the departments of Internal Medicine and Psychiatry.

The immediate past issue of this newsletter focused on KUSOM-W faculty within the department of psychiatry who have served or who are currently serving as principal investigators on CRI studies. In this issue, Dr. Dismuke, Dean of KUSOM-W, discusses the role of the school in the delivery of health care services to central Kansas with its population of over 1 million people. Drs. Schrage and Witley discuss their departments of internal medicine and pediatrics, respectively. Future issues will focus on specific investigators who either are currently involved or who are interested in working with CRI on clinical trials in their areas of expertise.

As explained on page 3, CRI draws on a population of over 4.5 million people from its research catchment area, particularly for phase I studies in normal volunteers and bridging studies in various special populations.

We at CRI welcome the opportunity to speak with you about the potential that this affiliation has for you in terms of your drug development efforts.

A handwritten signature in black ink, appearing to read 'Julide H. W.' followed by a flourish.

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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KUSOM-W Campus and Wichita/Surrounding Area



Ed. Dismuke, MD

The University of Kansas School of Medicine-Wichita (KUSOM-W) is positioned to expand its involvement in clinical trial and translational research through its collaboration with the Clinical Research Institute (CRI). Enhancing research is one of the medical school's four specific goals. Clinical trials research is an area of opportunity and expertise for KUSOM-W. This is in part, due to KUSOM-W's large patient population. The Wichita metropolitan statistical area has a population of 600,000 with two of Wichita's hospitals being the largest in the state and having over 1400 beds between them. Wichita is the primary referral area for all of south central and western Kansas, as well as northern Oklahoma, making the total referral population well over 1 million. KUSOM-W is made up of 10 academic departments: Anesthesiology, Family and Community Medicine, Internal Medicine, OB/Gyn, Pathology, Pediatrics, Preventive Medicine, Psychiatry, Radiology, and Surgery. KUSOM-W has 120 paid faculty members with an additional 925 providers on staff as volunteer faculty. Approximately 80%

of Wichita's 973 active physicians serve as KUSOM faculty, with the majority of these physicians having active practices with diverse patient populations available for clinical trial and translational research.

A specific example of Wichita's participation in clinical trials is our National Cancer Institute (NCI) Community Clinical Oncology Program (CCOP). The Wichita CCOP enrolls 800-1000 patients in NCI cancer research protocols each year, making it one of the most successful in the country.

The Wichita CCOP enrolls patients in studies associated with six different NCI research organizations, including the Southwest Oncology Group (SWOG), the North Central Cancer Treatment Group (NCCTG), which is led by the Mayo Clinic, the M.D. Anderson Cancer Center (MDACC), the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Children's Oncology Group (COG), and the University of Rochester Cancer Center (URCC), Rochester, NY. Not surprising, the Wichita CCOP is one of the most productive participants in SWOG, NCCTG, MDACC, and URCC. As a result, Wichita is an integral part of a plan to establish an NCI-designated cancer center.

CRI has an established track record in the area of clinical research particularly in psychiatry and early drug development research and is now extending that expertise in additional therapeutic areas. It is the intention of KUSOM-W to provide academic research opportunities for its faculty through our collaboration with CRI.

Internal Medicine



Jon Schrage, MD

The Department of Internal Medicine at KUSOM-W has the largest group of hospitalists in Wichita. Along with an average inpatient census of greater than 80, the department's two active ambulatory sites also provide care to more than 100 patient visits/day. The Internal Medicine's full-time faculty consists primarily of general internists/hospitalists. The department also has several sub-specialty faculty, including neurologists as volunteer and full-time faculty.

Departmental faculty are actively involved in research endeavors including National Institute of Health (NIH) trials and clinical research trials. Past and current research endeavors include clinical trials in: HIV (including Phase 1), obesity, diabetes, oncology, seizure disorders, movement disorders, as well as other related educational research projects. With a large patient base, current plans include expansion of research in the areas of metabolic syndrome (obesity, hypertension, dyslipidemia, and prediabetes/diabetes), increasing the number of cancer and HIV clinical trials along with increasing evidence-based medicine/quality improvement activities. In addition to the full-time and volunteer faculty's projects, several resident physicians are actively involved in both cardiology and gastrointestinal research studies as they prepare to enter these competitive fellowship arenas.

The department of Internal Medicine has created a research infrastructure to meet the research mission. James Kallail, Ph.D, who has written several funded grants, serves as our Associate Chair for Research and Amanda Golbeck, Ph.D, an exceptional biostatistician, provide excellent internal resources for research activities.

As a result, the internal medicine department has seen an increasing number of faculty actively participating in research activities, including serving as investigators on various clinical trials. Currently, the department is well positioned to support the efforts of its investigators as well as provide for collaboration with faculty from other departments.

Pediatrics



Robert Wittler, MD

The Department of Pediatrics at the KUSOM-W has as its primary mission the provision of an exceptional pediatric education for medical students, residents and faculty by modeling quality patient care and integrating evidence-based medicine. The department recognizes that the foundation for quality patient care and evidence-based medicine is clinical trial and translational research. For this reason, a goal for the department is to enhance research and scholarly activity.

The pediatrics department has full and part time faculty with expertise in neonatal medicine, cardiology, child abuse and neglect, developmental and behavioral pediatrics, pediatric critical care medicine, pediatric infectious diseases, metabolic disorders, hemoglobinopathies, and pediatric nephrology to include pediatric hypertension. Most of the pediatrics faculty have a special interest in pediatric obesity. The pediatrics faculty is also involved in providing medical services for the Sedgwick county juvenile detention system. KUSOM-W pediatric faculty consists of active pediatric clinicians in Wichita with an integral role in fulfilling the mission of the pediatrics department.

During fiscal year 2005, there were 23,484 patient visits to the KUSOM-W pediatric resident and faculty clinics. The neonatology and pediatric intensive care units are the busiest in the state of Kansas.

An example of the department's research efforts is the work done by Barry Bloom, M.D., part time faculty and neonatologist. Dr. Bloom has been involved in numerous multi-center collaborative projects resulting in multiple publications of his work in peer reviewed journals. Dr. Bloom has also been instrumental in the Pediatrix Clinical Data Warehouse, a dataset for monitoring performance in neonatology at multiple sites.

CRI's Recruitment Area for Phase I and Bridging Studies: 4.5 Million People

CRI regularly recruits study participants from Wichita, KS, Oklahoma City, OK, Tulsa, OK, Kansas City, MO and Springfield, MO. Combined these cities have a total population of over 4.5 million individuals. Below are some of the demographics for these 5 urban areas.



Metropolitan Statistical Area

Parameter	Wichita, Kansas	Oklahoma City, Oklahoma	Tulsa, Oklahoma	Kansas City, Missouri	Springfield, Missouri
Population	540,000	1,100,000	808,000	1,810,800	322,000
% White	77%	72%	73%	77%	95%
% Black	9%	11%	10%	13%	2%
% Hispanic	9%	8%	5%	6%	.5%
% Asian	3%	3%	2%	2%	1%
% High School graduate or higher *	88%	87%	87%	85%	86%

*For those over 25 years of age.

Source: www.census.gov, 6-1-06



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CRI Conducts Clinical Trials in the Following Therapeutic Areas

- ▶ **Obesity & Nutritional Disorders**
- ▶ **Infectious Disease**
- ▶ **HIV**
- ▶ **Pediatrics**
- ▶ **Neurology**
- ▶ **Geriatrics/Dementia**
- ▶ **Women's Health**
- ▶ **General Psychiatry**
- ▶ **Addiction Medicine**

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