

Newsletter

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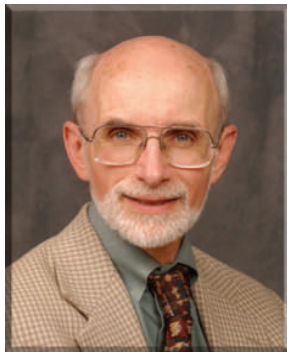
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Message from the President

For many of our sponsors, Clinical Research Institute (CRI) is synonymous with excellence in drug development research in psychiatry and phase I studies. Many do not realize that CRI's expertise and abilities extend beyond these two areas to the 12 areas specified in the box to the left. For that reason, CRI investigators in these various therapeutic areas will be profiled in this and subsequent issues of the CRI newsletter.

This issue focuses on the CRI investigator team in geropsychiatry and neuropsychology. That team includes Drs. Connie Marsh, Lyle Baade, and Susan Carr. This team has distinguished themselves in efficacy trials of elderly individuals with various dementias or major depression. The team has also assessed the cognitive effects of neurological and psychiatric medications as well as drugs in other therapeutic classes but which nevertheless have the potential to affect cognitive performance. More details concerning the work of this team are found on pages 2 and 3 of this issue and can also be found on the CRI website, www.cri-research.net.

Each CRI investigative team is supported by CRI in terms of its clinical and business operation arms headed by its management team. That includes the trained and highly experienced CRI coordinators under the management of Bryan Baker, CRI VP, Clinical Operations and the grants and contracts personnel under Mark Taylor, CRI VP, Business Operations.

Sponsors thus benefit from the quality and attention to detail that sponsors know they can expect from a study conducted by CRI. That quality begins with the efficient turnaround of study budgets and contracts

through the submission and approval of protocols and onto the execution of the study plan. CRI has experience and expertise in the recruitment of study participants including highly specialized populations such as healthy elderly with mild cognitive impairment. Another story in this issue illustrates that fact with recruitment data from just such a study (page 2).

In addition, CRI can provide synergy by bringing together the expertise in different therapeutic and research areas to answer questions which cross traditional therapeutic classes. For example, CRI has put together investigators in different therapeutic areas to answer questions about the relative effects of drugs in specific therapeutic classes on specific cytochrome P450 enzyme function.

To support its continued growth, CRI is pleased to announce its expansion, and to offer research services in all of the therapeutic areas as noted above. We welcome you to call CRI for your future research endeavors.

A handwritten signature in black ink, appearing to read 'Sullivan' followed by a stylized flourish.

Recruiting success in a bridging study: Physically healthy, elderly individuals with mild cognitive impairment

The Clinical Research Institute (CRI) is known for its ability to conduct phase I and bridging studies in its clinical research unit (CRU). The populations for the bridging studies have included, by way of example but not limited to: physically healthy, elderly individuals with mild cognitive impairment to test the effects of investigational neurotropic agents, individuals with residual symptom schizophrenia to test for a variety of endpoint effects of novel antipsychotics, and individuals who test sero-positive for human immunodeficiency virus (HIV).

Often, the recruitment of appropriate subjects is the most daunting aspect of these studies. Sponsors specifically seek out CRI to do these studies because they know that CRI will conduct the study in a high quality, timely and cost efficient manner.

The following outlines CRI's recent experience with just such a bridging study that required participants who were physically healthy, elderly individuals with mild cognitive impairment. The study had aggressive time-lines and CRI was able to conduct the study as a single site and meet the deadline while providing the high quality data that sponsors expect from a CRI conducted study.

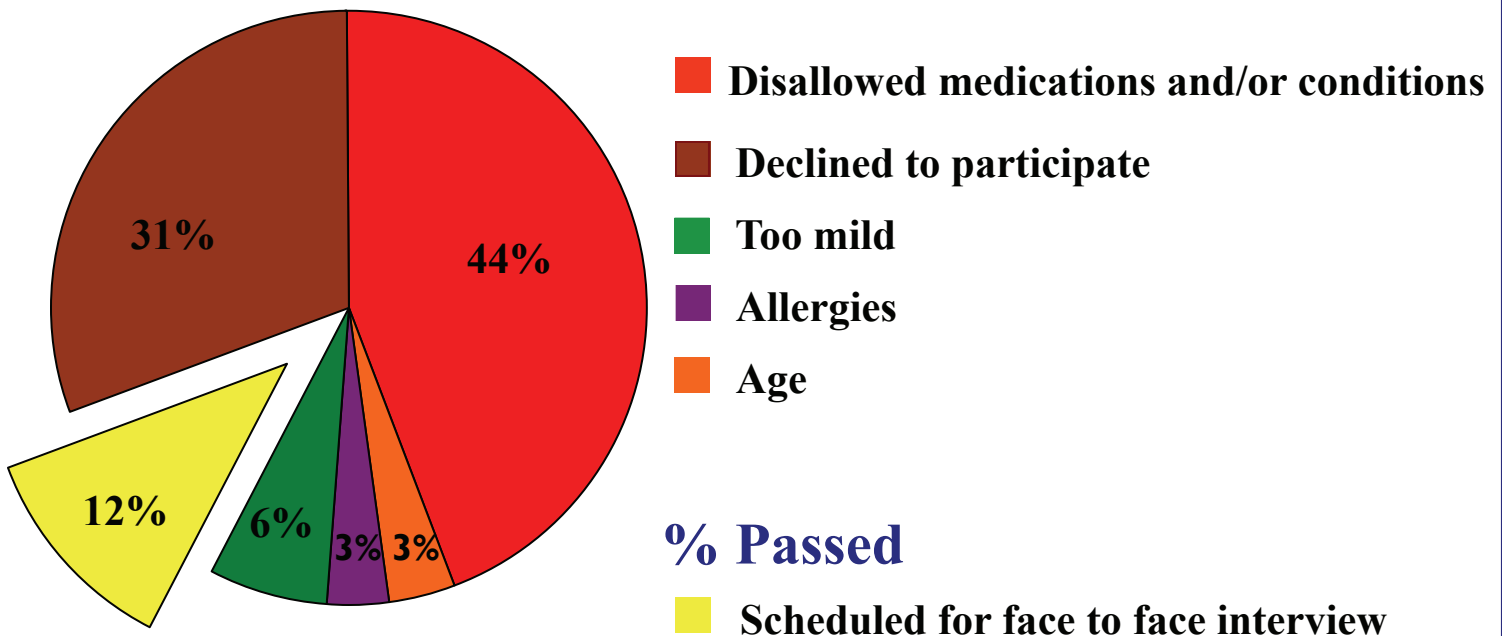
Based on an analysis of demographic factors, CRI targeted a newspaper and TV advertising campaign to cover the catchment areas of Wichita KS, Tulsa OK, and Oklahoma City OK. Together these three cities have a combined population of 1,217,000 over the age of 50 which was an inclusion/exclusion criteria for this specific study. The advertising campaign was designed to reach between 85 to 95% of the target population in these three larger Midwestern cities.

The first metric by which CRI measures the success of the campaign is the number of calls generated. In this regard, the campaign generated 2,150 calls. The next step is to screen out ineligible callers and then to identify and enroll the eligible callers. CRI does this screening process in the most time- and cost-efficient manner possible consistent with completing the study on time.

Of the 2,150 calls, 94% were screened out during the first telephone call and then the face-to-face screen for a variety of reasons as spelled out in Figure 1 below. Thus, only 136 (or 6% of the total 2,150 individuals who called in response to the advertising campaign) met all of the inclusion and exclusion criteria for the study. Of these 136 individuals, CRI enrolled 81 individuals and tested the cognitive effects of the investigational neurotropic agent, as well as its safety, tolerability, and pharmacokinetics in a population that much more closely matched the patient population that will be studied in the efficacy trials. In addition, the study yielded additional data on the dose and plasma concentrations needed to affect cognitive performance in this special population. This information was vital to selecting the dose(s) that would be tested in the phase II studies. Of these 81 participants, only one did not complete the entire protocol but instead was withdrawn from the study based on the judgment of the principal investigator in consultation with the sponsor.

This study is but one of many examples of the expertise that CRI brings to the conduct of its studies.

Results of Phone Screening: % Failed & Why



Geropsychiatry



Connie M. Marsh, M.D. (left), is Clinical Associate Professor for the Department of Psychiatry and Behavioral Sciences at the University of Kansas School of Medicine-Wichita (KUSM-W), Director of Geriatric Psychiatry and Director of Consultation-Liaison Psychiatry Training. She is certified with the American Board of Psychiatry & Neurology, with added qualifications in geriatric psychiatry and in psychosomatic medicine. She has also been a board examiner for the American Board of Psychiatry and Neurology.

A member of the American Association for Geriatric Psychiatry, and the International Psychogeriatric Association, Dr. Marsh is currently serving on the Board of Directors for the Great Plains Chapter of the Alzheimer's Association. Her research experience includes studies in geriatric depression, dementia and Alzheimer's Disease.

Susan L. Carr, M.D. (right), is Clinical Assistant Professor for the Department of Psychiatry and Behavioral Sciences, at KUSM-W. She is currently completing courses towards a Masters in Public Health. She is a member of the American Psychiatric Association and the American Association for Geriatric Psychiatry. Dr. Carr is certified by the American board of Psychiatry and Neurology and has a subspecialty certification in Geriatric Psychiatry. She completed a fellowship in Geriatric Psychiatry and a separate fellowship in clinical psychopharmacology. Her research experience includes studies in depression, anxiety, and psychotic disorders.

The Geropsychiatry service has inpatient, outpatient, consultation, and nursing home components. Dr. Marsh is associate Medical director of the senior behavioral unit at Via Christi Regional Medical Center. That unit has 28 beds and 623 admissions per year. The Geropsychiatry Outpatient Clinic, directed by Dr. Carr, has approximately 500 patient visits per year.

Neuropsychology



Lyle E. Baade Ph.D., is Associate Professor for the Department of Psychiatry and Behavioral Sciences, at KUSM-W. He is a member of the International Neuropsychological Society, the American Academy of Clinical Neuropsychology, the National Academy of Neuropsychology, the American Psychological Association, and the International Society for CNS Clinical Trials and Methodology. Dr. Baade's research has included studies in neuroscience, primarily in the areas of Alzheimer's, psychotic disorders, epilepsy, and diabetes and the effect of a wide range of drugs on cognitive functioning. He was principal investigator on the MATRICS study (see below).

WHAT DO UCLA, HARVARD, DUKE, & UNIVERSITY OF MARYLAND HAVE IN COMMON WITH CRI? MATRICS!

Lyle Baade, PhD, ABPP, Cn, was the primary investigator for CRI's participation in an NIMH initiative known as MATRICS (Measurement and Treatment Development Activities on Cognition in Schizophrenia).

Cognitive deficits -- including impairments in memory, attention, and executive function are a major determinant and predictor of long-term disability in schizophrenia. These cognitive deficits are generally not helped by antipsychotic medications. The MATRICS program was aimed at supporting the development of pharmacological agents for treating cognition in schizophrenia. Several obstacles to this development have been identified, the first of which is a lack of a consensus on how to measure cognition in patients with schizophrenia. Michael F. Green, Ph.D. from UCLA was the primary investigator for the overall project directed at removing this obstacle. A Wichita team headed by Dr. Baade, joined teams at UCLA, Duke, Harvard and the University of Maryland to field test a neuropsychological battery for assessing the impact of pharmacological treatments of cognitive deficits in schizophrenia. Using a national panel of experts, a list of neuropsychological tests covering all major domains of cognitive functioning was selected. The work at Wichita involved field-testing these instruments by administering them to participants with schizophrenia. After paring the initial group of tests administered to the participants, the Wichita group participated in developing test norms based upon administration of the final battery to normal controls. The Neuropsychology Laboratory at KUSM-W conducted the neuropsychological testing of the schizophrenic participants and the normal controls. Additional information on the project and the consensus battery are available at <http://www.matrics.ucla.edu/index.shtml>. The neuropsychology laboratory has participated in other research including the NIMH sponsored Clinical Antipsychotic Trials in Intervention Effectiveness (CATIE) project, the NIH sponsored study of Neurodevelopmental Effects of Antiepileptic Drugs, testing of a computerized neuropsychological (memory) battery for assessing the effects of novel drugs on cognition in Alzheimer's disease and an evaluation of donepezil hydrochloride as adjunctive therapy in the treatment of cognitive impairment in schizophrenia.



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New Address for Correspondence: 201 S. Hillside, Wichita, KS 62711

CRI Expansion

CRI's administrative offices and outpatient research clinic have relocated to 201 S. Hillside, Wichita KS 67211. CRI's administrative and management staff, along with CRI's clinical coordinators and study physicians took over occupancy of the 7,600 square feet medical building January 9th.

CRI's original 16-bed Clinical Research Unit (CRU) continues its operations at 8911 E. Orme, Suite B, Wichita KS 67207. With the opening of its second 16-bed CRU in late March, CRI will double its available beds to 32.

Administrative Office Space	3,800 sq. ft.
Outpatient Research Clinic	3,800 sq. ft.
Clinical Research Unit	12,500 sq. ft.
Unit #1 (16 beds)	5,500 sq. ft.
Unit #2 (16 beds)	6,000 sq. ft.
Office Space	1,000 sq. ft.

How to Reach Us

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