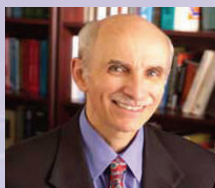


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MESSAGE FROM THE PRESIDENT



The Clinical Research Institute (CRI) is affiliated with the Kansas University School of Medicine in Wichita KS (KUSOM-W). As a result of this affiliation, faculty researchers at the KUSOM-W have access to research opportunities to further their research interests and expand their ability to provide quality health care to the population in Wichita and the surrounding region. In turn, CRI and its clients have access to experienced investigators from many different clinical departments. This issue of the CRI newsletter highlights the collaborative relationship between CRI and researchers in Obstetrics and Gynecology (Ob-Gyn), several of whom have faculty appointments at the KUSOM-W.

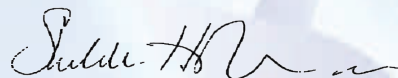
For CRI clients, this means that their study is done by nationally recognized Ob-Gyn physician-investigators supported by CRI research staff. CRI's expertise includes regulatory affairs, participant recruitment and study conduct.

Page 2 provides a recent example of a study conducted through this collaboration in the area of hypoactive sexual desire disorder. CRI was the largest enroller in this study as a result of our recruitment strategies, database, and the extensive clinical services provided by these physician researchers in Ob-Gyn.

The clinical services, expertise and the volume of patient care provided by the Ob-Gyn physicians is outlined on the top of page 3. The principal investigator on the study outlined on page 2 was David Grainger, M.D., who is highlighted on the bottom of page 3. On this same page, you'll find a list of the various areas of Women's Health in which these researchers in Ob-Gyn and/or CRI have expertise relevant to the conduct of research studies.

On the back of page 4, we present Alyson Voth, R.N. who exemplifies the high caliber of study coordinators at CRI. Of note, Alyson was the study coordinator for the hypoactive sexual desire disorder discussed on pages 2 and 3.

CRI welcomes the opportunity to visit with you about how our affiliation with the KUSOM-W can assist you with your drug development plans in the area of Women's Health.



Sheldon Preskorn, M.D.
President & CEO

CRI THERAPEUTIC AREAS

- *Psychiatry*
- *Geriatrics/Dementia*
- *Neurology*
- *HIV*
- *Infectious Disease*
- *Obesity & Nutritional Disorders*
- *Pediatrics*
- *Women's Health*
- *Internal Medicine*
- *Renal Impairment*

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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.

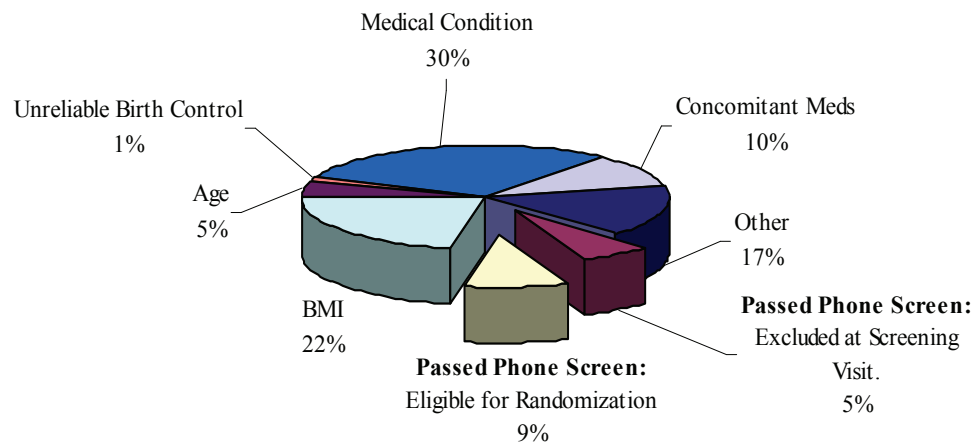
Recruitment of Pre-menopausal Females with Hypoactive Sexual Desire Disorder (HSDD)

CRI recently completed a study in pre-menopausal females with Hypoactive Sexual Desire Disorder (HSDD) in which speed of enrollment was critical to the sponsor. Therefore, CRI implemented an extensive recruitment campaign targeting females 18 - 45 years of age.

Over a 3-month period, the CRI team conducted in-depth phone screenings on 272 individuals who called in response to the recruitment campaign. As Figure 1 illustrates below, over 85% of callers having HSDD were excluded by phone screening primarily due to medical conditions (30%), Body Mass Index (BMI) (22%), and concomitant medications (10%).

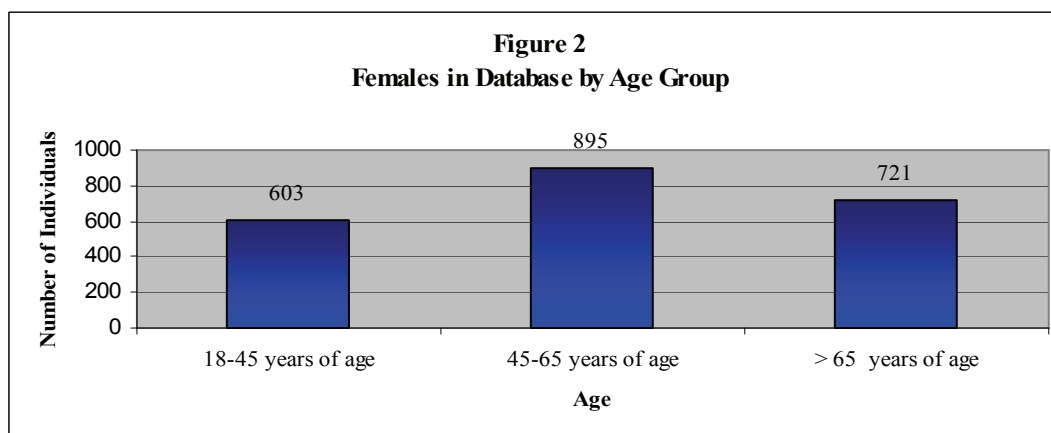
14% (38 out of the 272 callers) passed the phone screening and thus had face-to-face screening. 28 out of those 38 (i.e., 9% of the 272 callers) met all inclusion and exclusion criteria for enrollment into the study (Figure 1).

**Figure 1. Hypoactive Sexual Desire Disorder Study in Females:
Reasons Why Callers Were Excluded By Phone Screening**



In addition to above recruitment campaign, CRI also utilized its database which contains 2200 females (Figure 2). 603 of these were within the age range specified by the study and were evaluated for the study.

**Figure 2
Females in Database by Age Group**



Between these two efforts, CRI exceeded its recruitment target enrolling over 25% of all participants despite being one of 10 sites in the study.

The University of Kansas School of Medicine – Wichita

Obstetrics & Gynecology

The Department of Obstetrics and Gynecology at the Kansas University School of Medicine – Wichita (KUSOM-W) is nationally known for the quality of its faculty and residency program.

The department has 36 faculty and 20 resident physicians from every region of the country. Many faculty members are active clinical research investigators such as David Grainger, M.D., who is highlighted below.

The department has several nationally recognized areas of clinical expertise, patient care and research including maternal-fetal medicine, reproductive endocrinology, gynecologic oncology, obstetrics-gynecology infectious disease, dermatology and gynecology, and urogynecology.

The division of maternal-fetal medicine is staffed by two perinatologists who are involved in the care and delivery of high risk obstetrical patients. This division has an established obstetric ultrasound laboratory with expertise in invasive perinatal procedures including percutaneous umbilical blood sampling, chorionic villus sampling, amniocentesis, and color Doppler vascular studies.

The division of reproductive endocrinology has 4 M.D. faculty with sub-specialty training in this area including Dr. Grainger.

The chair of the department, Douglas Horbelt, M.D., and another faculty member, Jed Delmore, M.D. are board certified gynecologic oncologists trained at the M.D. Anderson Cancer Center in Houston TX.

The department is regionally known for its extensive patient care services. Last year, the department cared for 9,427 outpatients, performed 2,039 major and 218 minor surgical procedures, and had 5,886 deliveries.

Areas of Clinical Trial Capabilities include but are not limited to:

- | | | |
|-------------------------|-------------------------------|-------------------------|
| ✓ Healthy Women Studies | ✓ Hypertension in Women | ✓ Premenstrual Syndrome |
| ✓ Hot Flashes | ✓ Diabetes | ✓ Reproductive Health |
| ✓ Menopause | ✓ Hormone Replacement Therapy | ✓ Urinary Incontinence |
| ✓ Sexual Dysfunction | ✓ Infertility | ✓ Gynecologic Oncology |

David Grainger, MD, MPH, FACOG



David Grainger, MD, MPH, FACOG, from the University of Kansas School of Medicine-Wichita (KUSOM-W) Department of Obstetrics and Gynecology (Ob-Gyn), reflects the research skills highlighted in this newsletter.

Dr. Grainger exemplifies the high quality researchers available to CRI through its affiliation with KUSOM- W. He holds the following faculty appointments at KUSOM- W: Professor and Director, Division of Reproductive Endocrinology and Infertility; Department of Ob-Gyn, Professor, Department of Preventive Medicine; and Associate Dean for Research. Dr. Grainger has also been the Director for The Center for Reproductive Medicine since 1993 and is board certified in obstetrics and gynecology as well as in the sub-specialty of reproductive endocrinology and infertility. He is the immediate past president of the Society for Assisted Reproductive Technology.

Dr. Grainger completed his residency in Ob-Gyn at KUSOM-W. He then completed a fellowship in reproductive endocrinology at Yale University. Dr. Grainger earned a master's degree in Public Health from the University of Kansas in 2000.

Dr. Grainger has been active in clinical trial research since 1990 and has conducted over 35 studies of both medications and devices. Dr. Grainger has authored or co-authored over 90 articles, books and chapters in the areas of device development and hormone therapy.



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Wichita, Kansas 67211

CRI Coordinators Ensure High Protocol Compliance

Alyson Voth, RN, is a CRI coordinator with an admirable track record for coordinating and conducting studies, which exceed expectations for protocol compliance. That was illustrated most recently by the study highlighted on page 2.

This 28-day outpatient study required observed daily dosing over the course of the study, as well as four complete PK profile days.

Alyson was able to quickly and effectively enroll and randomize 21 participants, more than twice the number CRI was contracted to enroll, in less than 2 months. Of the 21 participants randomized into the study, 20 completed all required study procedures for all study visits.

Alyson's organizational skills and her ability to efficiently conduct all of the required outpatient visits while accommodating the participants' busy schedules were reflected in the number of participants remaining compliant with their visit schedules. Her dedication to ensuring high quality, day-to-day study activities resulted in CRI achieving an overall compliance rate of 98.2% (1321/1344) for the timed PK blood draws and 99.4% (501/504) for the outpatient visits.

Prior to joining CRI, Alyson's background included 4 years as an Emergency Room RN at a Level I (II) trauma center here in Wichita.



Alyson Voth, RN
Clinical Research Coordinator
2 years experience

How to Reach Us

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quarterly by the

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