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## MESSAGE FROM THE PRESIDENT



The core of Clinical Research Institute (CRI) is its ability to provide quality clinical trials research services. Nevertheless, CRI is regularly asked to provide more services. On page 2 and 3, we review CRI's "360-degree" view of study design, protocol development, operational deployment and medical writing.

We continue with a story on Peggy Hayes, one of CRI's talented and important resources. Peggy and CRI have teamed up on many projects including protocol synopses, complete protocols and final study reports. The depth of her experience, which includes drug development positions with numerous pharmaceutical enterprises as well as regulatory filings, means Peggy is uniquely qualified to fulfill the rigors of clinical trials and demands of regulatory agencies.

Another resource that continues to expand is CRI's wide-ranging capabilities in CNS surrogate markers. On page 3, a recent study required running multiple EEGs on specifically identified study participants. We were able to deploy several EEG techs for high throughput screenings involving 400 EEGs on 200 subjects. We were able to do this with scheduling flexibility relative to ebb-and-flow of recruitment activity and still complete the entire process in 4 months.

In keeping with past issues in which we highlight individual staff members, you'll find a story on Craig Plank, one of the more recent personnel additions to CRI.

Finally, I would like to call your attention to an important upcoming change with respect to the production and distribution of this newsletter. It is fitting to describe the change to an "e-letter" as an attempt to move away from the somewhat antiquated print version. We certainly hope that you express your desire to continue to receive our dispatches. While the frequency will increase to monthly, the content will decrease to shorter but we trust nonetheless engaging information on CRI's "comings and goings", personnel, insights and industry perspective from CRI.

**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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## PROTOCOL & MEDICAL WRITING...A 360° VIEW

As many of you know, the staff of CRI and Dr. Preskorn have been together and conducting clinical drug trials for more than 20 years. Having done so means we've seen our share of protocols and operationalized hundreds of studies. It is for this experience that sponsors turn to CRI for "front end" comments on or development of protocol synopses and complete protocols. More specifically, CRI can:

- Draft concepts for unique and challenging studies to answer vital questions.
- Draft protocols that provide the opportunity to "step back" and thoroughly review the strategic objectives of the study from an independent perspective.
- Complete synopsis and protocol preparation incorporating FDA requirements.
- Develop Investigator Brochures (IB).
- Review the IB to minimize potential obstacles in study design or protocol execution.
- Prepare post-study summaries and reports.
- Prepare study write-up for publication.

CRI provides the expert advice of study physicians and coordinators who understand the logistical, timing, costs and

recruitment issues related to study execution based on a cumulative 165 years of experience and more than 250 clinical trials.

These services are brought to you via a team approach that includes Dr. Preskorn, Bryan Baker and Peggy Hayes and our study coordinators. It is through this team that you get the 360-degree viewpoint from all critical areas.

Dr. Preskorn provides over 30 years of experience ranging from preclinical to clinical pharmacology, neuroscience and clinical medicine and the perspective of a seasoned principal investigator. Bryan Baker has over 20 years experience in operationalizing studies. Often what looks good on paper or from the perspective of "good science" can be problematic (or even impossible) to execute. Bryan's experience in study logistics, operational issues, quality control and general feasibility are augmented by CRI's own study coordinators from a "boots on the ground" perspective.

Last, but certainly not least, is the third party expertise of Peggy Hayes, a professional medical writer with over 30 years of experience in regulatory and industry-related expertise.

### PEGGY E. HAYES



An important member of the CRI team is Peggy Hayes, a medical writer with whom we've worked for over 4 years. Peggy brings a wealth of experience to the table with 30+ years in all types of professional writing including science, academic, clinical practice, grants and contracts and regulatory. Add to that CRI's experience and sponsors have at their disposal a team of professionals that can navigate the science, regulatory and clinical trials processes to assure actionable outcomes with no in-process problems or back-end surprises.

Upon receiving a Doctorate of Pharmacy from the University of Tennessee, Peggy served as an Assistant Professor at the UT College of Pharmacy; Assistant and Associate Professor of Pharmacy, Psychopharmacology Consultant in the Department of Psychiatry at the Medical College of the University of Virginia/Virginal Commonwealth University and as a pharmacy consultant to the Health Care Financing Administration.

Peggy spent 11 years in drug development. As Associate Director and later as Senior Associate Director at Novartis Pharmaceuticals, Peggy served as Project Leader for Phase III studies and was directly responsible for IND applications, investigators' brochures, protocol development, regulatory safety updates, clinical investigator and CRO selections, final study reports and other NDA-related activities.

In addition, Peggy served as Senior Strategic Consultant and Senior Director at Quintiles' CNS therapeutics unit in San Diego where she was the Senior Medical Writer for protocols, regulatory documents and final study reports for Phase I through IV studies in Alzheimer's disease, insomnia, depression, stroke, multiple sclerosis and bipolar disorder.

Peggy has been the PI or co-investigator on 11 different research grants and contracts, has authored or co-authored over 30 different articles, monographs and book chapters and co-authored two books. Additionally, she has prepared numerous protocols and study reports.

Since 2002, Peggy has focused on medical writing and regulatory consultation in CNS which is a perfect fit with CRI. This relationship is especially beneficial to sponsors in need of clear and concise protocols and timely reports that meet the rigorous demands of the clinical and regulatory environments.

The bottom line is that CRI provides a turn-key, concept-to-execution approach...from conceptual study design or sketches to complete protocol development and full-fledged operational plans; case report forms for accurate and high quality data capture, data analysis and final study reports.

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## **SURROGATE MARKERS IN CNS STUDIES**

Clinical Research Institute has long been known for studies utilizing surrogate markers for the effect of drugs on brain function. These studies have ranged from normal volunteers to the various special populations CRI has available including, but not limited to, participants with mild probable Alzheimer's, chronic schizophrenia, chronic depression and generalized anxiety disorder. Two recent studies illustrate CRI's capabilities.

The first study was an inpatient study looking at the procognitive effect of a novel agent in individuals with cognitive impairment associated with schizophrenia. The surrogate markers included the MATRICS (Measurement and Treatment Research to Improve Cognition in Schizophrenia), CogState testing and 64 channel electroencephalogram (EEG) to measure P50, N100, Mismatched Negativity Test (MMN) and P300 evoked responses.

The second study, an outpatient study, involved repeated 22-channel digital EEG studies on 200 individuals on a specific drug to identify the incidence and stability of specific waveforms in that population. Selected individuals were then randomly assigned to two different drug conditions in a random-assignment, balanced, crossover design to assess the prevalence of those waveforms on one treatment versus the other.

In addition to EEG studies, CRI has extensive experience correlating drug pharmacokinetics versus 24-hour holter monitoring, QTc changes, blood pressure changes and computerized cognitive test batteries, to name a few. CRI also has the capabilities and a trained staff of Registered EEG Technologists and Registered Nerve Conduction Study Technologists available to conduct digital EEG testing, ambulatory EEG testing (24 - 72 hours), Nerve Conduction/EMG testing on both inpatient and outpatient studies. Data is interpreted by board certified physicians and promptly reported assuring high-quality, reliable and actionable data.

## **FROM PRINT TO ELECTRONIC**

This is the final *print* issue of the CRI newsletter. We are laying the groundwork to move from print to electronic, e-mail specifically. In doing so, it is our desire to communicate monthly on topics related to clinical trials, news or related activities at CRI and insights or commentary from Dr. Preskorn.

The first step in this process is to make sure you're given the opportunity to "opt in" or "opt out" of this communication. If you have been receiving the print version and would like to receive the electronic version, please send an e-mail to Craig Plank, [cplank@cri-research.net](mailto:cplank@cri-research.net). In the subject line, please indicate "Subscribe" or "Unsubscribe." For those of you for whom we have current e-mail addresses, we will send a similar note to which you can reply.

E-mail addresses will be used for the purpose of disseminating this information only and please rest assured that the information is securely stored and it's use limited to this specific communication.

Our intent is to provide engaging, useful or interesting information in a somewhat shorter, less time-consuming, easily accessible format. We look forward to having you as a subscriber. We anticipate our first issue will be e-mailed in March.



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## MEET CRAIG PLANK



Perhaps you've not seen or heard much from our newest member of the CRI team but Craig joined us a year ago February. Craig has several broad areas of responsibility including developing and implementing participant recruitment programs. In that regard, Craig was instrumental in working with dBase developers to design and execute a custom data base for study participants.

This new dBase includes a robust search mechanism to help readily identify potential subjects for a particular study based on multiple variables arising from the inclusion/exclusion criteria. Additionally, as business development director, Craig serves a more traditional role in "recruiting" studies and physician investigators and researchers for CRI. In that regard, Craig has been actively engaged with Dr. Preskorn, Bryan Baker and Mark Taylor in strategic marketing program development and implementation.

Craig has 25 years experience in business strategy, strategic marketing, communications and advertising. He brings wide-ranging expertise in both business-to-business and business-to-consumer marketing and communications. His past includes entrepreneurial experience having been instrumental in two different start-up enterprises.

Craig is a 1980 graduate of Wichita State University with a Bachelor's degree in general studies. Prior to joining CRI, he provided marketing and communications consulting and creative services to a variety of business and consumer-related enterprises.

## HOW TO REACH US

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