CLINICAL TRIALS MONITORING

Good Clinical Practice requires clinical trial monitoring. In addition, FDA guidelines specifically require IND sponsors to develop and follow a clinical monitoring plan for their trial. Investigators who hold the IND or IDE are responsible for meeting this requirement. Fortunately, the University provides free clinical monitoring for investigator-held IND or IDE studies. Monitors include Kathy Mischke and Valerie O’Brien in the Research Services Organization, and Janet Sauers in the Cancer Center.

“We offer assistance that will support researchers in monitoring and reporting how they perform clinical trials and documenting any concerns,” says O’Brien. Mischke adds, “Investigators who have worked with us see us as part of the study team.”

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DIRECTOR’S UPDATE

by Jasjit S. Ahluwalia, M.D., M.P.H., M.S.
Executive Director

These are exciting times for clinical and translational researchers at the University. Institutional commitment to research has never been stronger, and the desire to tackle urgent global health issues is driving innovative research collaborations beyond the confines of our University.

We are not the only ones to think along these lines. Building on existing partnerships with several University researchers, health sciences leaders in India are interested in working more closely with our institution to improve research and educational opportunities. As a result, Senior Vice President for Health Sciences Frank Cerra convened a team to explore promising collaborations with some of our counterparts in India. I was honored to be part of that team, and having recently returned, am excited to relay what we have learned.

First, we learned that India is a compelling partner for many reasons, including its well-trained physicians, unprecedented economic growth and investment in health care, a spectrum of needs driven by chronic and acute illnesses, a large population base, and a common language. Equally important, we witnessed enthusiasm for strong partnerships to improve research and education in the health sciences.

Second, we announced a clinical research partnership on bone marrow transplantation with Manipal Hospital in Bangalore, which aims to increase scientific collaboration and training opportunities for students and physicians from Minnesota and India and to provide state-of-the-art cancer care for patients in Bangalore.

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In addition, we signed a memorandum of understanding with the Indian Council of Medical Research in Delhi to undertake joint research development. ICMR is India’s equivalent of the NIH. A protocol for obesity and diabetes management using bariatric surgery is being developed. Other opportunities include cardiac stem cell therapies, advanced management of heart failure, and use of left ventricular assist devices.

As these early but promising discussions continue, you will be kept abreast of new developments.

Trish Grover, senior research nurse clinician in pediatric endocrinology, agrees. She works with principal investigator Antoinette Moran, M.D., who holds the IND for two products in a five-year multi-center study on cystic fibrosis-related diabetes. “The process has been very educational,” says Grover. For instance, O’Brien flagged a potential issue with their protocol, which stated subjects would get a blood glucose reading 90 minutes after their main meal. “This seemed reasonable to us,” says Grover, “but Val pointed out that we would have to report any deviation from 90 minutes, even if it was two minutes earlier or later.” O’Brien suggested they re-write a clarification to include a window of time for the blood draw, which is the standard of care. “The best part is that we’re attuned to some of these issues now, and we can advise colleagues,” Grover adds.

“Clinical trial monitoring” is sometimes confused with “data and safety monitoring.” DSM is independent of the investigators and study team, involving independent review of the progress of a clinical trial, review of the safety data, and review of the critical endpoints. Clinical trial monitoring, on the other hand, provides assurance that the record and report of data for use by a data and safety monitoring committee are complete and accurate.

There are plans to expand the University’s free clinical trials monitoring service to include investigator-initiated studies that do not involve investigator-held INDs or IDEs. In the meantime, a range of resources (including protocol templates and tracking tools) are available by contacting the RSO at 612-625-8904 or mishc016@umn.edu.
Study Recruitment: Tips from IPF Trials

Idiopathic pulmonary fibrosis (IPF) is a rare but devastating form of lung disease, affecting approximately 15 in 100,000 people. The mean survival rate is three to five years—worse than many cancers. Currently there is no FDA-approved therapy for IPF. The poor prognosis of patients with IPF and the lack of therapeutic options drive the search for new approaches to the treatment of this serious disease. Toward this aim, Timothy Whelan, M.D., is leading the University’s participation in a multi-site randomized, double-blind, placebo-controlled Phase III clinical trial of pirfenidone in patients with IPF.

In a previous multi-site IPF study, the University was one of the largest enrollers of participants—something Whelan hopes to repeat in this study. “Obtaining an adequate number of participants is a crucial element in a clinical trial’s success. However, this is an individual decision for each patient. It is important that the physician (and/or principal investigator) discusses the study’s potential risks and benefits with each patient.”

Whelan has shown that even in rare diseases, it’s possible to have successful clinical trials—and he offers the following advice on study recruitment. “First, it’s important to get the word out to physicians and patients,” he says. Whelan takes time to go on grand rounds at community hospitals and he contacts physicians directly. “I tell them what I’m doing, what clinical trials we’re conducting. I also make sure I call them back when they have any questions.” He reaches patients through education days, where patients, families, and healthcare professionals are invited to the University to hear presentations on the latest in lung disease research and care.

For those studies involving pharmaceutical companies, partnering on resources can be helpful, he says. InterMune, Inc., the company that makes pirfenidone, has sponsored Whelan’s use of patient education days. Other resources that drug companies may provide include templates for referral letters and laboratory backup, he adds. “As a principal investigator, you have to be a business manager, as well as a doctor.”

Last but not least, Whelan stresses that he is part of a team. “I couldn’t do all that I do without my support staff,” including registered nurse Diane Elmajri and study coordinator Lila Schoelkopf. “Their assistance is vital to providing excellent patient care through close follow-up of these chronically ill patients.”

Whelan is currently recruiting participants. For more information, please contact Diane Elmajri at 612 625-1663.

HHMI investigator competition in patient-oriented research: deadline January 18, 2007. The Howard Hughes Medical Institute announces a national competition for the appointment of 15 outstanding physician-scientists as new HHMI investigators. Eligibility is limited to physician-scientists who hold a tenured or tenure-track (or equivalent) faculty position. Applicants must have a current license to practice medicine, have between four and 16 years experience as an independent investigator, and be the principal investigator on an active NIH R01 grant or a project leader on an active NIH P01 grant. Full details are available at www.hhmi.org/investigator_por

NIH accepting multiple PIs in support of team science projects: Beginning with research grant applications submitted in February 2007, the NIH will allow applicants and their institutions to identify more than one Principal Investigator (PI). http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-017.html

The GCRC has expanded its nursing coverage to support more subject visits on evenings and weekends. A 12-hour RN shift was added Mondays through Thursdays (8 a.m. to 8:30 p.m.) and an additional RN shift was added on Saturdays and Sundays.
Cardiovascular disease, the leading cause of death among men and women in the United States, has increasingly become recognized as a cause of early mortality in adult survivors of childhood and young adult cancers.

CAPS scholar and pediatric oncologist Daniel Mulrooney, M.D., hopes to study and increase understanding of the effects of cancer therapy on the vascular system, thus leading to improved preventive measures and early intervention for these patients. “Fortunately, survival rates of childhood cancers are improving,” says Mulrooney, “but complications from treatment can surface later in life, and we need to better understand the long-term effects of our therapies.”

Following a combined residency in internal medicine and pediatrics, Mulrooney completed a fellowship in pediatric hematology/oncology and stem cell transplantation. As part of his fellowship, he also earned a master’s degree in clinical research in 2005. Now an assistant professor of pediatric oncology, Mulrooney plans to study inflammatory biomarkers as predictors of early atherosclerotic disease in adult survivors of childhood and young adult cancer. At the same time, he will examine the role of activated circulating endothelial cells in the reparative process of vascular injury following radiation and/or chemotherapy. This type of multidisciplinary research is innovative in that “few have looked at the late effects of cancer therapies on the vasculature and its endothelial lining to assess long-term cardiovascular health in these patients,” says Mulrooney.

As a CAPS scholar, Mulrooney is allocated 75 percent protected time for research. He works closely with his three research mentors: Joseph Neglia, M.D., M.P.H., professor, Department of Pediatrics, Division of Pediatric Hematology/Oncology/Blood and Marrow Transplantation, Medical School; Robert Hebbel, M.D., Regents Professor, Department of Medicine, Medical School; and James Neaton, Ph.D., professor, Division of Biostatistics, School of Public Health. Mulrooney sees patients at the University of Minnesota Children’s Hospital, Fairview.

For more information on CAPS, go to: www.epi.umn.edu/CAPS