



The Department of Biostatistics Establishes Third Data Coordinating Center

The Mailman School's Department of Biostatistics has launched the Biostatistics Center for Clinical Trials Management (BCCTM), the Department's third major data coordinating center dedicated to innovative statistical design and the analysis and management of data for clinical trials taking place around the Columbia University Medical Center and at sites around the University, country, and world.

According to Center Director Emilia Bagiella, PhD, associate professor of clinical Biostatistics, "The Department created this center in response to the overwhelming demand for specialized statisticians to help investigators create data management programs and to run the analysis and management side of trials. We officially opened for business in November 2007 and already we are managing five federally-funded, multi-center clinical trials in the areas of neurology, pulmonary medicine, and diabetes."

Says Bruce Levin, PhD, professor and chair of the Department of Biostatistics, "Over the years, the statistical methodology for designing, conducting, and analyzing clinical trials has become more and more sophisticated, and the requirements for conducting clinical trials have become more and more rigorous. Increasingly, funding and regulatory agencies are demanding that an independent statistical and data management core be in charge of storing, monitoring, and analyzing data from clinical trials. Each of our centers offers the type of expertise investigators are seeking to carry out the data management side of their studies."

In addition to increased regulation, there has been a marked rise in the number of large multi-center, multi-national trials taking place. The Department's data coordinating centers have kept pace with parallel development of internet-based procedures and more sophisticated web-based data management applications, allowing for fast and secure data transfer and reporting.

"The mission of the new center," says Dr. Bagiella, is "to respond to these changes and to fulfill the new, more rigorous requirements for the conduct of clinical trials." Working with Dr. Bagiella to fulfill BCCTM's mandate are two very experienced software engineers, Sudhir Marathe, PhD, an associate research scientist, and Veena Singh, PhD, a senior programmer and analyst, who work tirelessly to develop state of the art, secure, user-friendly web-based applications tailored to the specific requisites of each clinical trial they manage.

The Department's two other centers include the Data Coordinating Center (DCC), which is jointly housed in the New York Psychiatric Institute and is the oldest of the three, and the Statistical Analysis Center (SAC), which was founded in 2000 by Dr. Levin.

Headed by Howard Andrews, PhD, associate clinical professor of Biostatistics and Neuroscience (in Psychiatry), DCC provides data management and project management support for clinical trials and longitudinal epidemiological studies in psychiatry, geriatrics, child environmental health, and other health sciences. DCC's staff of 15 also has extensive experience in the processing and analysis of secondary data sources, including vital statistics and other large public data sets.

SAC, under the direction of John L.P. (Seamus) Thompson, PhD, clinical professor of Biostatistics and Neurology, has a track record of successful trial innovation. It is committed to improving the scientific quality and efficiency of randomized clinical trials through close collaboration with eminent clinical investigators; the application of innovative statistical designs; and the development of state-of-the-art, customized data management systems that are responsive to the needs of clinical and statistical investigators.

Dr. Thompson designed the highly successful double-blinding algorithm and International Normalized Ratio (INR) management system for warfarin in the National Institutes of Health (NIH)-funded Warfarin-Aspirin Recurrent Stroke Study (WARSS) trial for prevention of recurrent stroke. He has also pioneered an approach to trial funding in which clinical and statistical principal investigators receive separate grants ensuring that each maintains scientific and budgetary independence within their spheres of expertise, while collaborating closely. The NIH and other industry sponsors have recognized the advantages of this approach.

Dr. Thompson is currently statistical principal investigator for three National Institute of Neurological Disorders and Stroke-sponsored trials, all of which also have industry support. These include the large Warfarin vs. Aspirin in Reduced Cardiac Ejection Fraction (WARCEF) trial for heart failure, which currently operates in over 200 sites in nine countries.

SAC has a staff of ten with a wealth of experience in clinical trials. The team is experienced in statistical design and analysis, the development of advanced web-based electronic data capture systems, protocol design and implementation, and high quality data management.

“Conducting clinical trials is perhaps the most essential scientific way we can obtain credible evidence that will improve the way doctors treat patients,” said Dr. Levin. “Nothing excites a biostatistician more than to see a well-designed and well-executed clinical trial reach an important conclusion, on time and on target. To see more of those kinds of results, we need the science and skillset of modern clinical trials management groups, and I congratulate Dr. Bagiella on opening the Biostatistics Center for Clinical Trials Management. She joins an expert group of field leaders housed in our department, and we look forward to many years of productive trial results.”