Biomedical and Health Informatics Lecture Series

Tuesday, November 9, 2010
12:00-12:50 p.m., Room RR-134

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"Data Management Solutions for CTSA Settings: A Case Study from UNC-CH"

An important initiative of UNC-CH's Translational and Clinical Sciences Institute (TraCS) involves developing data management solutions that are secure, of high quality, and easily accessible and affordable for clinical and translational researchers. At the early planning stages for UNC-CH's CTSA, it was clear that in spite of a proliferation of data systems and services across campus, many clinical and translational investigators had no access to systems beyond a spreadsheet for single-keyed data entry and manual editing of data with no provision for audit trails. Further, little or no coordination existed across the various campus systems in use at that time. The provision of comprehensive data management services was identified as a critical unmet need for translational and clinical research conducted at UNC-CH. To transform the research landscape, leaders of both the Biostatistics and Biomedical Informatics Cores undertook the establishment of such a service with the goal of providing TraCS investigators with access to a data management system for data capture, processing, management, and reporting that is suitable for the size and scope of the research effort.

Two years later, considerable progress has been made on the TraCS Data Management Initiative. An off-the-shelf software solution, REDCap, has been identified for, and is currently in use on, small to moderately sized TraCS studies with low complexity. At the same time, the team has designed and developed a comprehensive, state-of-the-art system for projects for which REDCap is not sufficient, building upon the knowledge and experience of the Collaborative Studies Coordinating Center at UNC-CH. For this seminar, the TraCS DMS will be demonstrated and the features designed to ensure high quality data, such as the granular authorization system, complex conditional logic, compliance with industry standards such as CDISC ODM, and integrated study management features will be described. Guidance currently in use for how and when to engage investigators in determining the most appropriate data management solution will be discussed, and a cost model for use in grant applications will be reviewed.

Lisa LaVange, PhD, is Professor and Director of the Collaborative Studies Coordinating Center (CSCC), Department of Biostatistics, Gillings School of Global Public Health, University of North Carolina at Chapel Hill (UNC-CH). Dr. LaVange is Deputy Director of UNC's CTSA (NC TraCS) and as such, serves on the TraCS Steering Committee. She is associate director of both the Biostatistics and Biomedical Informatics cores and oversees the TraCS Data Management Initiative. As CSCC Director, she manages approximately 90 faculty, staff, and students involved in multi-site clinical trials and epidemiological studies. Dr. LaVange is Principle Investigator (PI) of the Coordinating Center for the NHLBI-sponsored Hispanic Community Health Study/Study of Latinos, an epidemiological study of 16,000 Hispanics/Latinos designed to examine risk factors of cardiovascular and pulmonary disease. She is also PI of the Genomics and Informatics Center for the NHLBI-funded Subpopulations and Intermediate Outcomes in Chronic Obstructive Pulmonary Disease Study (SPIROMICS), a longitudinal follow-up study of 3,200 COPD patients with the objectives of identifying homogeneous patient subgroups and potential surrogate markers for use in future therapeutic clinical trials. Prior to joining UNC, Dr. LaVange was Vice President of Biostatistics and Data Management for Inspire Pharmaceuticals, Inc., where she directed the cystic fibrosis drug development program. She served as Vice President of Statistics for Quintiles, Inc. where she managed over 200 employees in five offices across North America. She is experienced in drug development for respiratory and cardiovascular disease, CNS, and ophthalmology. Dr. LaVange is a Fellow of the American Statistical Association and served as President of the International Biometric Society (ENAR; 2007). Her research areas include methods for the design and analysis of clinical trials and complex sample survey data. She teaches courses in Clinical Trials and Statistical Consulting.