

The conduct of clinical research trials is an essential part of the discovery, learning, and testing process for new medical research and treatments as well as drugs. Thus, improving clinical research trial delivery in dedicated performance sites is a gateway to better scientific knowledge, medical discoveries and effective new treatments for many diseases. While clinical research can be conducted in various settings, academic, medical, and industrial institutions have chosen to construct clinical research performance sites to provide a shared infrastructure on which to perform clinical research trials. We call this shared human and physical resource infrastructure a Clinical Research Unit (CRU), although they go by other names such as Performance Sites. Operationally, the CRU has intuitive economies of scale and scope. On the other hand, clinical trials have a complex operational structure that makes it difficult to plan and schedule them at a shared CRU site. Our research creates a systems analysis method that optimizes complex operational planning and coordination needs of sites that perform clinical research trials. The time sensitive and resource specific treatment sequences of the many trial protocols make it very difficult to capture the dynamics of this unusually complex system. The inadequacy of existing approaches for site planning and participant scheduling are exhibited in high and variable Time to First Available Visit (TFAV) metrics and high staff overtime costs.

Mark Van Oyen is a Professor of Industrial and Operations Engr. (IOE) at the University of Michigan, which he joined in 2005. His interests include the analysis, design, control, and management of operational systems, with emphasis on performance and flexibility, frequently contributing to the control and performance analysis of queueing network models. Most of his current research focuses on healthcare operations research and systems engineering with some work in medical decision making. He has served as Associate Editor for Operations Research, Naval Research Logistics, and IIE Transactions and Senior Editor for Flexible Services & Manufacturing. He was a faculty member of the Northwestern Univ. Sch. of Engineering (1993-2005) and Loyola Univ. of Chicago's Sch. of Bus. Admin. (1999-2005) and has worked in industry for GE Corporate R&D and Lear Siegler's Instrument & Avionic Sys. Div.

Blake Roessler, M.D., is a Professor in the University of Michigan (U-M) School of Medicine's Department of Internal Medicine (Division of Rheumatology). He is Program Leader for MICHR's Clinical Research Support Group and Medical Director of the Michigan Clinical Research Unit (MCRU). Dr. Roessler is board-certified in internal medicine and rheumatology. He is an expert in early stage clinical development of novel human therapeutics and regulatory matters. Dr. Roessler also has a long-standing interest in development of model systems and clinical applications for diagnosis of bone and joint disease, and is currently studying Raman spectroscopy as a diagnostic platform technology.

Jivan Deglise-Hawkinson is a Ph.D. candidate in the Industrial and Operations Engineering (IOE) department at the University of Michigan and he plans to graduate by the year 2015. His research focuses on developing new methodologies based on operations research and systems models to provide improved access and resource coordination in longitudinal health care settings. The emphasis is on settings in which patients need to follow a series of treatments/diagnostics that can be time-sensitive and resource specific. Such settings occur in clinical research (trials/studies), in destination hospitals (e.g. Mayo clinic) as well as the treatment of many chronic dis-

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