In the complex landscape of clinical research site management, provider organizations, including academic medical centers, hospitals and stand-alone research centers, should consider opportunities for operational efficiency. Among the drivers for change is a decrease in research funding, a factor that triggers additional cost containment measures. Increased requirements imposed by regulatory authorities and Institutional Review Boards (IRBs), increases in the expertise required to plan and execute clinical studies and increased study site expenses are also significant factors. Changes in the structure of research organizations designed to decrease costs and improve efficiency are valuable mechanisms for coping with these factors.

Enterprise Governance: Centralized vs. Decentralized

In the traditional model, research organizations function within a decentralized (silo) operational and administrative model. Research-specific activities are scattered over several different departments and research centers throughout the academic medical center. In this model, a common problem is the lack of adequate training on research requirements for senior management assigned research responsibilities. Departmental training programs may not be equipped to adequately cope with the complicated clinical research regulatory environment. Decentralized (silo) operational models are often highly inefficient, and may lead to clinical research work products being completed in duplicate or triplicate work streams, completed incorrectly, or noncompliant with regulations. These problems are often addressed by implementing the wrong solution. For example, internal operational and administrative gap analyses lead many academic research institutions to compensate for decentralized model deficiencies with increased staffing or implementation of new technologies or software. In contrast, moving towards a centralized and hybrid model can reduce indirect operating costs, reduce cycle times and increase overall patient satisfaction.

Figure 1 highlights some of the research activities that might benefit when research activities are transferred from solo investigators or solo departments to either a hybrid or centralized model. For example, the creation of a central organization responsible for the clinical trials unit management and scheduling of research nurses study coordinators could be considered. Both the hybrid and centralized models can improve quality and efficiency. The difference is the degree of centralization. In the hybrid model, only a limited number of functions are managed centrally, while in the full, centralized model, most research activities are standardized and controlled by an overarching, core research organization. Understanding the operational models for clinical trials units provides the framework for the potential services and structure for the execution of clinical trials.

Defining the Operational Model for Clinical Trial Units (CTU)

There are three basic types of CTUs:

1. CTUs based in an academic medical center (AMC) may include overnight biomedical research services staffed by trained clinical research nurses and staff. Most AMC CTUs are located on the main AMC campus, function in a decentralized operational model and are able execute all phases (1 through postmarketing) of clinical research studies. Ancillary and food service departments are available on site (in most cases), and emergency medical treatment availability depends on the location of the CTU (in hospital offered).
The Clinical Trials Unit: Defining, Staff Assessment and Scheduling Restructuring for Operational Efficiency

2. The private practice CTU setting is generally established within the clinical investigators private clinic and may function with either a decentralized or centralized operational model. The private practice CTU is also considered a biomedical research facility; however, unlike most AMC CTUs, the hours of service may vary. Not all private practice CTUs have established overnight facilities, and staffing models shift to provide coverage for the patient census and clinical trial requirements. Research patients may be required to travel to ancillary service providers (if ancillary services are not provided on site), food services are generally catered and emergency medical care is available at the nearest hospital.

3. Finally, the research-only CTU is similar to the private practice CTU. The primary difference is the research-only CTU is staffed by dedicated research staff, and patients seen are solely for the purposes of clinical research. Staffing models are generally similar to the private practice model with emergency medical care available at the nearest hospital.

There are pros and cons for each of the CTU models. For example, while AMC CTUs typically coordinate services with multiple departments and systems, many private practices and research-only facilities have fewer departments to coordinate and may have lower indirect costs. However, AMC CTUs may offer patients a “one-stop shop” for all clinical research-related services, leading to higher patient satisfaction.

Once defining the scope of services and CTU model, the next step in transformation is mapping research operational activities managed throughout the organization in order to provide insight into areas targeted for streamlining. Understanding where research operations and administrative activities can be shared will potentially lead to a reduction in duplicate efforts.

Staffing realignment within clinical trial units requires review, possible deconstruction and re-mapping, as the propensity to incur operational inefficiencies and noncompliance activities can acutely impact clinical trial operations, data and patient care.

Planning: CTU Staffing Reorganization Considerations

Staffing realignment is a complex process and requires the review of policies, organizational structure, scheduling and financial forecasting. Mapping current CTU staffing activities and job responsibilities, defining departmental and vendor/ancillary services touch points and stakeholders, and defining the type of CTU are the first steps in determining staffing realignment. Defining roles and associated tasks provides clarity for the required CTU operating model. While some tasks are performed by a single role (position), others may be performed by many people. For example, a clinical trials unit may have eight research nurses, although they each manage different research protocols, they may also be able to perform other administrative tasks related to study management. Further, the various tasks performed for the execution of clinical research may be completed by the research nurse or other members of the study team, such as the research coordinator.

Diagraming research positions and the clinical trial activities in a roles and responsibilities matrix clarifies duplicate efforts. Figure 2 highlights overlapping tasks across positions.


Clearly outlining job responsibilities, scheduling and related work instructions enables staffing analysis. Multiple staffing models should be considered when designing an efficient CTU. Alternative staffing models might include flexible alternative work arrangements and oncall nurses to optimize the increase or decrease in patient visits. Work arrangements should provide patients the required standard of care nursing care, as well as provide nurses/staff with appropriate meal sanction coverage, optimize shift change procedures and minimize the impact to direct/indirect costs. Clearly defined job responsibilities, better scheduling tools and related work instructions will enable analyses of current and future staffing needs. For example, collecting information on current work schedules can provide valuable information useful for decision-making.

While developing alternative work models, it is important to work with the appropriate departments and stakeholders to provide novel design solutions to increase operational efficiency and support patient satisfaction. Further, examination and outline applicable federal, state and local union, employment and wage laws governing the staff within the CTU, leveraging expertise found in human resource and legal departments. For example, in certain states, two nurses are required during each shift as a safety mechanism. Once the legal parameters are defined, alternative staffing models should be considered in light of impact on hours of operation, flexible staffing arrangements, and staff reorganizations hiring or downsizing. Large changes in the scope of clinical activities (e.g., adding overnight coverage) will require significant changes to staffing requirements.

Whether an AMC, private practice or research-only CTU, several different staffing models should be considered to optimize patient satisfaction, decrease indirect costs, increase operational efficiency and contain costs. For example, exploring
options for CTU coverage to include on-call hours may provide information valuable for cost containment initiatives.

### Implementing the New Staffing Model

Implementation of an alternative work schedule will continue to support the effective, efficient and reliable evaluation of clinical research studies to include, new pharmaceuticals and medical devices in collaboration with clinical investigators, as well as, industry sponsors. CTU restructuring includes a focus on growing and transforming the CTU into an operationally efficient, customer oriented service unit with an emphasis on quality and compliance. Implementing an alternative work schedule is one approach step in improving optimization. Below are several benefits of the alternative work schedule:

- Optimization of customer service including patients and clinical investigators
- Staffing efficiency and utilization
- Increase in research nursing training and education
- Personal investment in the success and vision of the CTU
- Streamlining Nursing and Staff Scheduling procedures
- Assisting in the CTU public relations campaign

Developing an alternative work schedule (AWS) for research nurses requires consideration of organizational policies, labor laws and call options. After defining the AWS, clearly outlining the components for managing the model is required. For example, developing a call calendar for managing the call schedule enables clear tracking for the new model. Documenting the call shifts and verifying the research nurse acceptance improves implementation of the AWS.

While the goal of CTU realignment may appear consistent for each stakeholder, the motivators may differ across management and CTU research personnel. Management pursues increased efficiency, elimination of duplicate processes and to drive continuous improvement. Research nurses seek the ability to improve the health of research patients, adhere to protocol requirements and monitor adverse patient events. Consistent monitoring of the new staffing model allows opportunity to make adjustments to the staffing design as needed in order to optimize the staffing model and mitigate risk.

### Conclusion

Assessing the operating model of a clinical trials unit is a complex process. Determining the volume of investigators and the number of studies in the CTU is a driver for number of staff. However, the required skills and activities are driven by the type of study and operating model. Specifically, does an opportunity for sharing a research nurse exist based on the study protocol? Further, could some of the administrative responsibilities be centralized into a core function?

Defining a centralized or hybrid model to provide integration and streamlining of processes supports operational efficiency in the management of clinical research studies.

Opportunities for restructuring are likely greater in the academic medical center with several distinct clinical departments. As the number of separate clinical practices increases, so does the potential for silos and duplication of efforts in the execution of clinical research. In private practices, the likelihood of separate processes tends to decline, as research nurse support may cover activities related to clinical care and clinical research. In research-only CTUs, the opportunity for reorganization may exist; however, the primary business purpose is managing clinical research studies, therefore limiting the probability of decentralization.

In order to fully understand the inefficiencies in current process, a review of personnel, services and operating structure is required. Examining the job roles and associated tasks to identify duplication of efforts and opportunities for cross coverage is essential. Ascertaining associated skills and mapping to positions provides insight for streamlining functions in the unit.

Determining the state employment laws and examining organizational policies offer guidance for developing AWS. Working with human resources and aligning with institutional stakeholders to develop new working shifts enables ease during implementation.

Defining the new model to include position restructuring, AWS and integration necessitates policy revision.

As the race to bring novel medical therapies to the global marketplace tightens, right-sizing CTUs provide opportunities for realignment and increased efficiency. It is essential for leadership to design and implement revised staffing models. Leveraging existing infrastructure and change management methodologies, as well as aligning clinical trials operations (including the CTU) with staff realignment, will impact performance and expedite clinical research into bedside practice.
The Clinical Trials Unit: Defining, Staff Assessment and Scheduling Restructuring for Operational Efficiency

Authors

Erika Stevens, MA
Senior Managing Director
FTI Consulting, Inc

Erika Stevens is a Senior Managing Director at FTI Consulting, Inc leading the Research Technology practice as part of the Research and Compliance practice. Within her 20 years’ experience in leading clinical research operations, administration and compliance activities at various institutions, she often works with clients to grow the research enterprise, improve system/process integration and streamline organizational research operations. Ms. Stevens is the president of the New York Metropolitan Chapter of the Association of Clinical Research Professionals (ACRP) and an ACRP Associate Board of Trustees member and serves on the Brightpoint Health Board of Directors. Ms. Stevens holds her B.A. from the University of Vermont, her M.A. from Case Western Reserve University and her M.A. from Temple University. She also holds a Graduate Certificate in Gerontology from Case Western University.

Susan Autry, MBA
Executive Director,
American Heart Association (AHA)

Institute for Precision Cardiovascular Medicine Susan Autry, MBA, joined the American Heart Association in July 2015 and serves as the Executive Director for the new Institute for Precision Cardiovascular Medicine. The Institute will house the AHA Data Discoverability Portal, the Cardiovascular Genome Phenome Study (CVGPS), Research Funding Program, and manages the precision medicine partnerships, projects and initiatives. She previously was Executive Director for the University of Southern California’s Clinical and Translational Science Institute (CTSI) and prior to that in the same role at the University of California San Francisco’s (UCSF) CTSI. Her career includes management of numerous partnerships among diverse entities, including national labs, industry and foundations, along with state, federal and private funding agencies and government. She specializes in bridging science, medicine, engineering, education and other diverse disciplines. She holds a bachelor’s degree in Physics from the University of Texas, Arlington and a Master of Business Administration, with Specialization in Science and Technology Management, from the University of California, Davis.

Christina Eberhart
Senior Manager in the Advisory Services
Life Sciences practice of Ernst & Young LLP

Christina Eberhart is a Senior Manager in the Advisory Services, Life Sciences practice of Ernst & Young LLP. She has over 12 years of clinical research experience, contributing in such roles as Director of Clinical Operations, Director of Quality Assurance, Clinical Research Associate, Manager of Quality Assurance, and the Principle of an Investigator Trial Network. Prior to joining Ernst and Young, Christina founded PhaseCare, LLC. PhaseCare’s primary focus provided clients the tools to build Quality Management Systems (QMS) as well as access to a Trial Site Network for Phase II to Phase IV inpatient and outpatient protocols. Additionally, Christina has conducted quality control monitoring for Sponsors and CROs as well conducted quality assurance auditing for the biotechnology industry. She has contributed to the development of onboarding and training systems for Clinical Research Departments at Academic Medical Centers and the Division of Acquired Immunodeficiency Syndrome (DAIDS) within the National Institute of Health (NIH).

Notes

3. Rubin, Elaine; Lazar, Danielle; Gaich, Nick; Haray, David, “The Clinical Trials Landscape: Limitations, Strengths and Promise”, Association of Academic Health Centers