



Association of Academic Health Centers

*Leading institutions that serve society*

## **Investing in Clinical Trial Compliance**

The number of clinical trials is rapidly increasing both in the U.S. and throughout the world given the need for new treatments and cures for disease and disability. Simultaneous expansion of regulations governing such trials is placing tremendous strain on the administration and management of clinical trials and their associated compliance functions within academic health centers. Academic health centers must allocate increasing amounts of funds in the areas of infrastructure, personnel, and IT systems, as well as in strategic planning and other operations, to ensure a safe and effective clinical trial process.

### **What are clinical trials?**

Clinical trials, the backbone of the nation's efforts to bring new drugs and technologies to market, are essential to the research mission of academic health centers nationwide. Clinical trials advance scientific knowledge and promote discoveries to treat and cure illness and disease. They serve to increase the quality of life and longevity of countless people in this nation and around the world. During a trial, researchers gain important information and understanding about an experimental treatment, including its risks, benefits, and efficacy.

After researchers test new therapies or procedures in the laboratory and in animal studies, those experimental treatments with the most promising results are moved into clinical trials under strict scientific guidelines. The trials are carefully designed and carried out with human volunteers under the highest ethical standards, including the informed consent of participating human subjects and the approval of the institutional review board. Every clinical trial is closely supervised by the appropriate authorities within an institution and follows all strict state and/or federal regulatory standards. Participants in a clinical trial follow a specific protocol while being seen regularly by the physician and research staff to monitor their health and safety.

### **Who sponsors clinical trials?**

Clinical trials are sponsored or funded by a variety of organizations or individuals in addition to federal agencies such as the National Institutes of Health (NIH), the Department of Defense (DOD), and the Department of Veterans Affairs (VA). Other sponsors might include medical institutions, foundations, voluntary groups, and pharmaceutical companies. Trials can take place in a variety of locations, including academic health centers, hospitals, doctors' offices, and community clinics.

### **Why should academic health centers perform clinical trials?**

Academic health centers, the leading institutions that serve society through research and education, must conduct clinical trials as part of their core mission to improve the nation's health and well-being. Researchers in academic health centers generate the ideas that eventually need to be tested in clinical trials. New approaches to treatment must be evaluated on large numbers of carefully selected patients in trials conducted by



investigators who can interpret sophisticated data and determine whether a treatment should be released to market. These competencies and skills, as well as the necessary research infrastructure to conduct such trials, are found largely within academic health centers.

### **The high cost of compliance**

Federal oversight of the academic health center research enterprise has expanded in recent years, in part, as a response to some well-publicized incidents in research involving human subjects. Regulations cover an increasingly broad spectrum of research operations and touch all research processes from human subjects to budgeting, billing, and reimbursement. There are no signs that the intensity of the regulatory environment is abating. Rather, governmental rules and regulations are multiplying with their impact spreading across the institution.

Establishing an effective and efficient process for clinical trials billing can be particularly costly given the large number of individuals, the number of sites involved, and the IT integration that is necessary. The IT industry has not kept pace with clinical trial operations and the demand for services, often forcing academic health centers to turn to homegrown IT solutions or to purchase IT software from multiple vendors, thus increasing expenditures. In addition, hospitals affiliated with academic health centers may not invest sufficiently in clinical trial billing operations in part because the benefits of having clinical trials within their institutions may not be fully recognized. As a result, academic health centers may find it difficult to partner on clinical trial IT investments.

Thus, academic health centers are faced with a growing number of requirements that must be met with limited and strained resources. The costs of compliance are skyrocketing; for a one-year period, some institutions reported increases as high as 70%, according to a 2005 report by the Association of Academic Health Centers. Expenditures are required to create and staff the systems needed to increase efficiency and effectiveness. Of note, the personnel with the required skills and competencies to manage the complex and technical aspects of clinical trial processes are hard to find and in high demand throughout the country. Compliance is now considered to be the most commonly expanded academic health center function today.

### **Academic health centers transform compliance**

The heightened concern over accountability, along with the regulatory environment, has changed the way academic health centers approach compliance, with the result that the organization, management, and funding of compliance has become a top priority for academic health center leaders. Academic health center leaders view compliance as an ongoing and evolving function, with a continuing need to improve processes and structures to respond to changing priorities or focus areas. As a result, the oversight and management of compliance within academic health centers, particularly with regard to clinical trials, is being transformed. Compliance programs for clinical trials comprise



multiple elements that include budgeting and billing, training, auditing, and monitoring. One of the most critical areas of concern in clinical trials compliance is the billing of services for subjects in clinical trials, which is complex and involves multiple stakeholders from principal investigators to hospital and physician office billing clerks. In response, academic health centers have created new infrastructure, changed policies and procedures, and implemented new systems that include educational programs and auditing and monitoring activities.

A significant move toward consolidation of compliance functions is underway in academic health centers across the nation as existing decentralized organizational structures may not be able to accommodate new legal and regulatory environments. Research administrators are acquiring additional responsibilities and new administrative offices are being established for oversight. Changes in organizational structure are occurring, resulting in enlarged compliance structures at the institutional, school, and/or departmental level, adding to institutional expenditures on needed infrastructure.

#### **Compliance expenditures ensure reputation and public trust**

Clinical trials can garner tremendous prestige for academic health centers and can heighten awareness, credibility, and trust with the public. However, the current and future reputation of an institution is at peril should there be a failure to comply with any one of an array of regulations. Such a failure puts the institution at risk for potential investigations and financial repercussions by federal agencies, as major academic health center settlements of upwards of \$20 million in recent years have revealed. An institution's credibility and relationship with the public can be permanently damaged.

Therefore, an academic health center must place clinical trials compliance among its highest priorities despite the regulatory burden, the rapid utilization of resources needed, and the complexity of managing this process. This is a national problem confronting all of the nation's academic health centers. Ultimately, the public's trust in the institution must be the guiding force in all aspects of clinical trials compliance and the issue against which all expenditures of effort and finances should be judged.

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