



## Clinical Financial Services

### ACADEMIC MEDICAL CENTER IMPROVES FINANCIAL MANAGEMENT OF CLINICAL TRIALS

The Wayne State University School of Medicine is the nation's largest single-campus medical school. Located in the Detroit Medical Center among specialty hospitals and research centers, the School of Medicine offers an ideal venue for both learning and research.

In addition to the School's own research endeavors, each year it conducts more than 300 clinical trials for 140 pharmaceutical and biotechnology companies. These trials span 17 departments—reflecting the School's wide range of medical specialties and treatment areas.

While such trials bring significant benefits to patients, clinicians and research sponsors, until recently, they were causing some administrative frustration for School of Medicine leaders. Administrators recognized that clinical trials can and should be an important source of much-needed funding for the institution. But without specialized financial management, they could not maximize the opportunities inherent in the clinical trial enterprise.

Fortunately, the School's leaders were proactive in analyzing the situation—and then identifying and implementing a successful solution.

#### UNDERSTANDING THE CHALLENGES

Historically, Wayne State's School of Medicine placed little institutional focus on the business of clinical trials. It was largely left to individual faculty members to identify and finalize contracts, and their respective departments to manage and track them. In 2004, the Dean of the School of Medicine initiated a taskforce to research the clinical trial enterprise. The team's marching orders: to identify barriers preventing optimal execution of clinical trials.

Over its 90-day investigation, the taskforce identified issues around personnel practice (including a lack of specialized job descriptions related to clinical trials) and contract execution (including the need for a faster, more streamlined process that would meet institutional and sponsor requirements). The other key area that was creating barriers: program accounting.

“The taskforce found that while we were good at accounting for our own in-house research programs, our cash-based systems and processes weren't optimal for sponsored clinical trials,” explains James Barbret, Associate Vice President for Research, Wayne State University. “With clinical trials, expenses and revenue streams are often disjointed. So, in many cases, our teams were earning revenue, but we weren't recognizing those earnings until the funds were actually

#### CHALLENGES

Lack of time and expertise to properly manage finances associated with clinical trials:

- Internal policies and procedures weren't designed to accommodate the idiosyncrasies of the clinical trial enterprise
- There was a disconnect between clinical-trial expenses (which are activity-based) and revenue streams (which are milestone-based)
- The School uses a cash basis for accounting, but clinical trials require accounting on an accrual basis

#### SOLUTION

- Updating institutional policies and procedures and outsourcing Contract Administration to Clinical Financial Services, the industry's only company focused exclusively on financial management of clinical trials

#### RESULTS

- Operational efficiency enhancements for all stakeholders in clinical trials
- More time to focus on medical, not business, aspects of clinical trials
- Significantly improved planning and reporting capabilities
- Recouping hundreds of thousands of dollars in lost revenues

received—which was sometimes months later or not at all.”

In short, as Barbret notes, “Using our accounting system for clinical trials was like trying to fit a square peg into a round hole: it just wouldn’t work.”

Thus, the taskforce recommended that the School address the following:

- Institutional policies and procedures, including the School’s policy against charging expenses without funds or a budget, the Sponsored Program Office’s policy of not budgeting clinical trials until funds were received, and the overall policy of recognizing revenue only when funds were received—often months after funds were earned and/or an invoice was issued
- Patient records, including the lack of updates reflecting patients’ inclusion in trials and the inability to break out trial costs versus patient accounts
- Infrastructure, including the need for a single, centralized approach and system for managing clinical trials

## DEPLOYING A SOLUTION

In implementing a standardized approach to clinical trials, the School of Medicine updated operational policies to reflect the idiosyncrasies of these projects. The School also identified the need for a single technology solution that could capture and track activities throughout the clinical-trial lifecycle. And with limited time and resources, the School decided to buy—not build.

“After carefully considering the options and potential solutions, we decided to outsource this very important function to Clinical Financial Services, LLC,” Barbret explains. “CFS is the only company that focuses exclusively on providing financial administrative services for clinical trials.”

CFS’s Contract Administration services cover all aspects of financial management throughout the clinical-trial lifecycle. “When a study is submitted, CFS assumes responsibility for entering it into a central database,” Barbret says. “That saves our study coordinators valuable time and, just as important, helps to accelerate pharmacy reviews and approvals.”

As a study progresses, stakeholders can enter and/or view information via CFS’s secure online portal: “Having a common data set means our financial managers can quickly and easily pull reports on earnings accrued, invoiced and received,” notes Barbret. “It also provides study coordinators with convenient updates on a study’s progress, including how many participants have been recruited.”

CFS handles all tracking, invoicing and collections—so Barbret and other leaders at the School of Medicine can rest assured that they aren’t missing any funds.

## REAPING THE REWARDS

The School launched a pilot program to test CFS’s Contract Administration service in 2005. Covering 39 internal medicine studies and 28 pediatric studies, the study revealed:

- Almost \$140K in non-refundable fees that should have been (but were not) invoiced
- Over \$35K in non-refundable fees that the School invoiced but had not been paid (sponsors had no record of the invoices and CFS re-submitted them)
- More than \$148K in patient visits that needed to be invoiced in order to be paid
- Nearly \$58K in advances that had been invoiced and had not been paid

Based on the success of that program, within two months the program was rolled out to the remainder of the School of Medicine departments. Today, clinical trials throughout the school are managed through CFS—and all stakeholders continue to enjoy many benefits.

“Without doubt, the most significant advantages of working with CFS are financial,” Barbret notes. “By partnering with CFS, we now have accurate accruals, improved collections and better financial controls. Perhaps best of all, our reporting and business intelligence capabilities are outstanding. We can quickly see where we are and where we need to be, and we can address at-risk studies before they become problems.”

Barbret says the CFS solution has also liberated physicians and other clinicians from the “business” side of clinical trials, and allowed study coordinators to avoid time-consuming and error-prone manual tasks.

Last but not least, the institution now has a stronger position when working with sponsors: “This is an excellent way to answer sponsors’ questions about technology and how you’re using it to further these studies,” Barbret says, adding that collecting data is one thing, but getting it together in a format that you can give back to the sponsor is something else altogether.

“CFS delivers a very clean, consistent format, and we can tell pharma companies, ‘When you do business with Wayne State, here’s how you’re going to receive information,’” he notes.

## SOLVING YOUR CHALLENGES

Barbet encourages other institutions to consider the speed, efficiency and effectiveness of CFS’s solutions.

“Financial management of clinical trials requires highly specialized capabilities,” he concludes. “CFS brings those to the table, and can help institutions to dramatically improve management of the clinical trial enterprise.”

