Traditionally, clinical research has been conducted in large academic teaching hospitals, but there is a significant trend, encouraged by the National Institutes of Health (NIH), for exceptional community hospitals to conduct clinical research. Here, as we discuss our experience as we made the transition from a community hospital with a reputation for excellent patient care to a hospital engaging in this relatively new form of medical academic research, we offer insights that may benefit clinicians and patients.

Our Experience
The Neurosciences Institute at Hoag Memorial Hospital Presbyterian, a 498-bed non-profit hospital in Newport Beach, California, recently joined with 50 hospitals in the United States and Canada in a federally-sponsored clinical trial under the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health.

The Interventional Management of Stroke III trial (IMS III) was designed to test the clinical outcomes and safety of intravenous (IV) tissue plasminogen activator (tPA) compared to the combination of IV and intra-arterial (IA) tPA and/or thrombectomy.

Our institute had participated in a long list of trials sponsored by pharmaceutical and medical device companies, but the NINDS trial represented Hoag's first federally-funded trial. Trials funded by the federal government come with equal technical requirements but much greater accounting and record-keeping requirements than privately-funded trials. Because Hoag needed to establish specialized record keeping to properly conduct NIH-funded trials, we viewed our participation in it as a significant milestone in the development of our neurology clinical trial programs. Hoag research physicians have been approached to conduct further federally funded studies, both in neurosciences and other areas. Each potential trial is reviewed carefully by each Center of Excellence and evaluated for scientific merit, patient benefit, and staff funding support.

Many community hospitals do not participate in clinical trials because they lack the infrastructure and space required for clinical research. The role...
of a dedicated Clinical Research Coordinator with expertise in FDA regulations is paramount in any research program’s success.

Participation in trials brings unique benefits to patients, physicians, nursing staff and the community. Because it is relatively uncommon for community hospitals to participate in clinical trials, it is important to highlight the benefits it brings to our patients, physicians, nursing staff and the community at large. We also discuss the requirements of participating in clinical trials and considerations to address when starting a neurology-based clinical trial program.

**Patient Benefits.** For our patients, clinical trial participation brings a wide range of benefits. Patients have the option to participate in cutting-edge studies normally reserved for high level academic programs in large cities, but are allowed to stay in their community, close to family and the physicians they already know and trust. For acute stroke studies, transfer to a remote institution for study participation would not be possible.

In this day of rising health care costs, perhaps the most immediate benefit a patient sees is that he or she does not incur personal costs for any medical care received as part of a clinical trial protocol. The patient also gains access to care beyond the traditional standard, often including a battery of tests to help understand the effects an experimental treatment or medicine may have, and these tests and procedures would not necessarily be available to the patient.

Even patients that do not qualify for an ongoing clinical trial can rest assured that a hospital that participates in clinical trials is likely at the forefront of new technologies and treatments.

**Physician Benefits.** Community hospital-affiliated physicians who participate in clinical trial protocols gain the best of both worlds, so to speak. They enjoy the satisfaction that comes with practicing at the highest level while still living in the community setting of their choosing without the pressure associated with academic hospitals and tenure requirements. Many of the physicians who have chosen to relocate to Hoag bring with them years of experience in academic medicine and clinical trials, and the option of continuing this type of work and raising the standard of subspecialty care in the community is very attractive.

Involvement with clinical trials also attracts a high quality of nursing staff dedicated to the benefit and safety of their patients, as well as to the advancement of medical science. Hoag hospital is a Magnet Hospital that is active in Nursing Research and committed to nursing excellence. Clinical trial participation allows staff to catch a glimpse of how treatments may change in the future. This exposure can help maintain the staff’s flexibility and readiness to adapt to new technologies and procedures. It also shows how experimental science can eventually lead to changes in patient care and can illuminate the reasons why procedures change over time.

**Hospital/Community Benefits.** Hoag Neurosciences Institute’s interest in advancing clinical care helps the hospital build the programs that significantly benefit its communities. The institute has earned numerous awards over the years, and the hospital is one of the certified Orange County Comprehensive Stroke Neurology Receiving Centers. These achievements reflect the hospital’s commitment to its patients and help attract the most qualified, talented physicians. Clinical trial participation is a piece of an overall puzzle that helps us build a great hospital for our community.

**Investment Requirements**
Participating in clinical research is not something that any hospital can simply do without planning and investment in the right resources. Extra human resources, well-trained physicians and infrastructure are all essential.

**Clinical Research Coordinator.** A fundamental human resource need is an experienced clinical research coordinator. Trials have specific protocols, and physicians and nursing staff should not be expected to be responsible for immediately knowing and adhering to protocols because their first responsibility is to the patient. When a physician first sees a patient who may qualify for a clinical trial, he or she then involves the trial coordinator
who comes in to help discuss the clinical trial with the patient and/or the family. If the patient agrees to participate via informed consent, the coordinator lays out the specific order of treatment steps that are required of the trial, and the physician then implements treatment.

Because the clinical research coordinator is so important to the trial process, it is best to find someone with the appropriate experience. FDA regulations do not specify qualifications for coordinators, but Hoag requires each coordinator to have a strong clinical and research background.

The coordinator at Hoag plays a significant role in evaluating potential studies and assessing whether the hospital’s resources meet trial requirements. Does the hospital have the required equipment, laboratory space and physician experience to participate in the trial?

A coordinator without a deep clinical research background may be less able to accurately assess trial requirements and match them to hospital resources, and without that understanding, more physician time and energy may be necessary to judge a hospital’s ability to successfully carry out a trial.

Physicians. The physicians affiliated with a hospital play a very important role in a trial, for they act as the principle investigators for the trial, making decisions about which patients are appropriate, ensuring patient safety during study participation, and interacting with the trial sponsors to ensure that the study protocols are followed accurately. It therefore goes without saying that the physician needs to be well-trained, intimately familiar with the trial’s area of medical focus and keenly aware of the ins and outs of clinical research.

Adequate Infrastructure. On the infrastructure side, because experimental medicines, technologies, and procedures are on the cutting edge of medicine, very often the latest testing equipment may be required to gather data. Adequate laboratory facilities and pathologists are also necessary for the extra tests required of clinical trials, and tests must be done in a timely manner—especially for acute stroke research. These could include new biomarker assays, genetic sequencing instruments, digital scanners and robotic systems.

Occasionally, private companies sponsoring trials may supply equipment to a hospital specifically for a trial, but most often, it is essential to have all of the equipment and facilities required by the trial protocol.

Accounting Resources. An experienced clinical research coordinator, well-trained physicians, and adequate infrastructure all combine to qualify a hospital to participate in privately-sponsored clinical trials, but federally-funded trials require significantly more accounting rigor than private trials. A patient will not know the difference between a pharmaceutical company-sponsored trial as opposed to an NIH-funded trial, but the hospital must accurately account for all of the time associated with a clinical trial. Because so much more rigor is required by the United States government, a hospital wishing to engage in federally funded trials must invest in more record keeping and accounting resources than with other types of trials.

At Hoag Neurosciences Institute, administrators are supportive of the clinical trial programs, and they are involved in some of the decision making around clinical trials. For example, Hoag’s Neurosciences Institute has a research committee that meets every month, and the Medical Director of the Neurosciences Institute (also a physician) participates in these meetings.

This body works collaboratively, weighing a clinical study’s scientific merit, its benefits to patients and to the community and also analyzing whether the financial support offered by a clinical trial sponsor is adequate. While the Neurosciences Institute does not rely on clinical trials as a profit center, it is essential for the hospital and the Institute to break even.

Patient Concerns
Some patients and their families may harbor concerns about the clinical trial process. At Hoag, physicians and clinical trial coordinators make every effort to ensure patients that all clinical tri-
als adhere to strict good clinical practice guidelines as regulated by the FDA. Community hospitals such as Hoag, academic institutions, and contracted clinical research organizations are required to work with independent institutional review boards (IRBs), which focus on protecting the rights and welfare of the people who agree to participate in clinical trials. These IRBs oversee the research studies to ensure that the studies adhere to scientific, ethical, and regulatory guidelines.

Informed consent is an essential component for any patient who participates in a clinical trial. As part of the trial process, a candidate or, if the candidate is incapacitated, people authorized to act on his or her behalf must sign documentation noting that there is a clear understanding of what will happen to the candidate during the trial. The patient must have plenty of time to ask questions about the trial and the protocol must be explained in language the patient understands.

An Expanding Opportunity
Hoag Neurosciences Institute has been involved with clinical trials for four years. Our strong clinical trial program has provided our patients with a resource that they may be unable to get at a different hospital, and it attracts talented physicians and nurses. As noted, clinical trial participation brings many benefits to a hospital’s patients, physicians, staff and community, but it comes with investment requirements and considerations. With the proper resources, planning and execution, many community hospitals can take advantage of the benefits, and our hope is that we inspire other hospitals.

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The website for Hoag Neurosciences Institute is: www.hoaghospital.org/neuroscience/