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RESEARCH AND DEVELOPMENT IN THE HOSPITAL SETTING

COMMERCIALLY SPONSORED CLINICAL TRIALS

Large pharmaceutical companies and biotechnology firms must conduct human clinical trials before they can apply for approval of a new drug with the U.S. Federal Food and Drug Administration (FDA). These trials are often conducted in hospitals, especially hospitals known for expertise in treating certain disease classes (e.g., cancer, central nervous system disorders, immune disorders). So, too, a hospital physician may be chosen as a principle investigator (PI) for a trial involving his or her specialty. Before a trial begins, the hospital enters into a clinical trial agreement (CTA) detailing the roles and responsibilities of the hospital and the drug sponsor. This is one of many points at which risk management issues should be raised.

- CTAs usually contain insurance and indemnification clauses that should be carefully reviewed by the hospital's risk management and legal departments as well as by an experienced insurance broker.

- The drug sponsor (the company that is conducting the trial) accepts the liability for any injury directly caused by the product or drug being tested, while the hospital and/or its physician (PI) will accept the medical professional exposure for mistakes in administering the drug or in the use of the product being tested.

- One current trend is for a research hospital to negotiate a master agreement with large drug firms that may be conducting several trials at its facility. In so doing, the hospital avoids having to review every individual agreement, saving time and money. Again, the hospital risk manager should review these master service agreements (MSA) to ensure that the contract requirements are consistent with the hospital's risk-handling philosophy and risk financing program structure.

- All aspects of the clinical trial are clearly spelled out in the trial protocol filed with and approved by the FDA. This protocol must be followed to the letter; if it is not, the indemnity by the drug sponsor may be denied.

- Generally, the hospital's Professional Liability insurance will provide coverage for untoward events arising from commercial clinical trials conducted at its facilities. Trial participants, as patients being treated by the hospital and its physicians, are covered by traditional Hospital Professional Liability (HPL) policies. We suggest a careful review of your HPL insurance policy to confirm that there are no coverage restrictions relating to commercial clinical trials. If the hospital utilizes a captive or some other form of risk self funding, it should be clear that this exposure is a covered activity.

- By agreeing to conduct a commercial clinical trial, the hospital has a responsibility to manage the trial according to the clinical trial agreement and trial protocol. If the hospital fails to comply with the agreement or makes and

error in conducting the trial that requires the sponsor to repeat the trial, the hospital may receive a demand from the sponsor for reimbursement of the costs. This loss is a "financial damages" claim and would not be covered by an HPL policy. Errors and Omissions Professional liability coverage would be needed to cover this risk exposure. Many hospitals do not purchase E&O coverage, so this risk must be measured and a decision made to retain or insure this risk. The cost to repeat a trial can be in the millions of dollars.

INVESTIGATOR-INITIATED COMMERCIAL CLINICAL TRIALS

A hospital physician may approach a commercial drug company to initiate a clinical trial. Usually, these trials are to test an existing drug in treatment of a disease for which it was not originally developed. The requesting physician becomes the principle investigator (PI) in partnership with the drug company and may also write the protocol and submit it to the FDA. Often the PI recruits outside clinical facilities to participate in these trials. In such cases, the hospital and PI are the trial sponsor and often indemnify the outside clinical sites for liability arising from the trial. The PI and hospital should be sure to seek indemnification from the drug company for claims arising from the product. However, some drug companies are reluctant to provide indemnification if they don't see a potentially broad commercial application for its drug as a result of the PI-initiated trial.

Again, the hospital's HPL coverage will probably respond to allegations of medical malpractice brought by a clinical trial participant. Less certain is what coverage is provided to the sponsoring hospital/PI for claims arising from the activities at the outside clinics. Careful scrutiny of coverage is strongly recommended. Traditional HPL language will usually need to be endorsed to accept this risk. Other issues arise as well: If the hospital uses an alternative risk financing program (captive, trust, RRG), does it want to accept this risk into the program? What retention is appropriate for this exposure?

HOSPITAL-INITIATED CLINICAL TRIALS

A hospital researcher may discover a novel drug and want to take it into clinical trials. The hospital or PI becomes the sponsor and, in this scenario, there is no commercial drug company to provide an indemnity backstop. As the sponsor, the hospital/PI files the protocol with the FDA and is responsible for all aspects of the trial. Frequently, these trials recruit subjects from both inside and outside of the sponsoring hospital's facilities. Under these circumstances, it is unlikely that traditional hospital Professional Liability coverage would anticipate all of the exposures created by the sponsoring activities. Hospitals may find it necessary to purchase a separate Products/Clinical Trials policy.

The hospital/sponsor may also need to enter into agreements or contracts with contract manufacturers (CMO), contract research organizations (CRO) and outside clinical sites. These agreements should be reviewed carefully with an eye toward contractual risk transfer between all of the involved parties and compliance with insurance requirements.

The hospital/sponsor may conduct trials in foreign countries, which opens up entirely

new categories of risk and compliance requirements. Most countries have their own regulations governing human clinical trials. The hospital/sponsor's CRO and insurance broker can help sort through the compliance issues that arise in foreign jurisdictions.

Hospitals rarely take a novel drug completely through clinical trials to commercialization. At some point in the process, if the drug shows promise, the hospital will transfer the rights to further development to a commercial drug company through a Technology Transfer Agreement. These agreements often require that the drug company makes upfront or milestone payments to the hospital. Some agreements also require royalty payments if and when the drug generates revenue. If not negotiated properly, technology transfer agreements may contain clauses that obligate the hospital/sponsor to continue some form of Product Liability coverage or indemnify the drug company for certain types of product claims. These agreements should be reviewed by the hospital risk management and legal departments, and insurance language written to anticipate the risk exposure created by technology transfer activities.

OTHER PROFESSIONAL SERVICES

In some cases, the hospital may be asked by a commercial drug company to perform other professional services associated with a clinical trial being conducted at its facility. The drug company, for example, may ask for advice in preparing the protocol or performing the lab services needed during the trial. These activities create an exposure to professional errors and omissions that is not typically anticipated by traditional HPL coverage. HPL coverage is triggered by alleged bodily injury or property damage. An error in providing professional services to a third party, however, can result in a financial loss to the outside party, who may then look to the hospital for reimbursement. If, for example, the hospital provides lab services related to the trial and does not follow the proper data reporting procedures, the trial may need to be repeated at great cost to the third-party drug sponsor. Since insurance coverage for this type of loss is not usually part of an HPL program, a hospital providing these types of professional services will need to analyze its risk exposure and determine a strategy for handling this risk.

A proper risk management program requires a full assessment of the human clinical trial activity in your facility. The Willis Life Sciences Practice has teamed up with the Willis Health Care Practice to develop special expertise and tools to assist you in this endeavor.

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POTENTIAL SOLUTIONS

Before determining the appropriate risk transfer response, we suggest a thorough risk review process be undertaken to measure the total exposure to risk presented by your research activity. Willis has developed a risk review tool that will generate a custom report that will outline the risks, propose solutions and describe the value if the solutions are implemented.

After the risk review is conducted, we can work together to decide the best course of action. Potential solutions include:

- Purchasing an insurance program that addresses the identified exposures
- Redrafting contracts to assure that risk acceptance by you and risk transfer to outside parties is maximized
- Accepting the risk exposure into your captive or other risk financing program, with or without reinsurance

CONTACTS

For further information about conducting a risk review or if you have any questions, please contact

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