Large pharmaceutical companies and biotechnology firms are required to conduct human clinical trials before they can apply for a New Drug Application (NDA) with the US Federal Food and Drug Administration (FDA). These human clinical trials are often conducted in the hospital setting.

**Commercially sponsored clinical trials**

Before a trial begins, the hospital will enter into a Clinical Trial Agreement “CTA” (or a Master Agreement covering multiple trials) that details the roles and responsibilities of the hospital and the drug sponsor. The drug sponsor should assume liability for any injury caused directly by the product or drug being tested. The hospital and/or its physician serving as Principal Investigator (PI) will assume liability for mistakes in administering the drug or use of the product being tested.

All aspects of how the trial is to be conducted are clearly spelled out in the trial protocol which is filed with the FDA. It is imperative that these procedures are carefully followed because often the indemnity by the drug sponsor will be denied if the protocol is not properly followed.

A hospital’s professional liability insurance should cover commercial clinical trials conducted at its facilities. Clinical trial participants, as patients being treated by the hospital and its physicians, are covered by traditional hospital professional liability (HPL) coverage. We will undertake a thorough review of your HPL coverage to confirm that there are no restrictions on coverage relating to conducting commercial clinical trials at the hospital.

**Investigator initiated clinical trials**

A hospital’s physician may approach a commercial drug company to initiate a clinical trial. Usually, these trials are to test an existing drug for a disease for a novel use. The physician becomes the Principal Investigator (PI) in partnership with the drug company. In this circumstance, the PI may write the protocol and submit it to the FDA. In these trials, the hospital and PI have become the “sponsor” of the trial and often indemnify any outside clinical sites for liability arising from the trial. The PI and hospital should 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 the potential broader commercial application for its drug as a result of the PI initiated trial.

Again, the hospital’s HPL coverage will typically respond to allegations of medical malpractice brought by a clinical trial participant. But, what coverage is provided to the sponsoring hospital/PI for claims arising from the activities at the outside clinics? Very careful review of coverage is strongly recommended, as well as consideration of contractual indemnity to the hospital/PI from the outside clinics for their own professional acts in treating patients who are clinical trial participants.
Hospital research initiated clinical trials

A hospital researcher may discover or develop a novel drug and want to take it into clinical trials. In this scenario, the hospital or PI becomes the sponsor and 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 trial subjects both inside and outside of the sponsoring hospital’s facilities. Under these circumstances, it is unlikely that traditional hospital professional liability coverage anticipates all of the exposures created by the hospital/spONSOR activities. Hospitals may find it necessary to purchase a separate Products/Clinical Trials policy to cover this exposure.

The hospital/spONSOR will also be required to enter into agreements or contracts with contract manufacturers, 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.

In some cases, the hospital/spONSOR may conduct trials in foreign countries. This opens up an entire new category of risk and compliance requirements. Every foreign country has different regulations around human clinical trials. The hospital/spONSOR’s CRO and insurance broker can help sort through the compliance issues surrounding foreign clinical trials.

At some point in the clinical trial process, if the drug shows clinical promise, a hospital will transfer the rights to further development and commercialization to a commercial drug company through a Technology Transfer Agreement. These agreements will often require the drug company to make upfront or milestone payments to the hospital. Some agreements also require royalty payments if and when the drug begins to generate revenue from commercial sales. 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 should be 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 hospital facility. For example, the drug company may ask for advice in preparing the protocol or to perform the lab services needed during the trial. These activities create a new exposure, professional errors and omissions that are not typically anticipated by traditional HPL coverage. HPL coverage is usually triggered by alleged injury or damage to a patient. Providing other professional services to a third party can result in a financial loss to the outside party who may look to the hospital for reimbursement. For example, the hospital provides lab services related to the trial and does not follow the proper data reporting procedures, resulting in the need to repeat the trial at great cost to the third party drug sponsor. The drug company seeks monetary reimbursement for the cost of repeating the trials. Insurance coverage for this type of loss is not usually part of a HPL program. A hospital providing these types of professional services needs to analyze its risk exposure and determine the optimal risk financing strategy for this potential claim.

Why Willis Towers Watson

A proper enterprise-wide risk management program requires taking a careful look at the human clinical trials activity in the hospital setting. The Willis Towers Watson Life Sciences Practice has teamed up with the Willis Towers Watson Health Care Practice to develop tools to help assess the human clinical trials risk in the hospital setting.

Your CTAs or Master Agreements will contain insurance and indemnification clauses that should be carefully reviewed by your Risk Management and Legal departments and broker with expertise in both healthcare and life sciences.

In the case of Investigator Initiated trials, your HPL language will likely need to be endorsed to accept this risk. 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? Willis Towers Watson will guide you through the appropriate answers to these and other questions.
Everywhere you plan to be

Clinical trials expertise

- Core clinical trials service commitments
- Efficient, reliable and time-sensitive service
- Carrier partnerships to ensure broad and compliant coverage
- Access to global regulatory and compliance information. Online database of life science expertise throughout our global network. This information is provided by country and includes:
  - Non-admitted status
  - In-country regulations
  - Insurance limits
  - Medical professional liability requirements
  - Certificate protocols
  - Specific information requirements for each country

Life science expertise

- 350 industry colleagues in more than 100 countries including 200 in USA
- More than 500 clients in North America and 700 Globally
- The most advanced loss modeling in the industry
- A globally integrated practice that operates as a key part of your team, providing industry specialist insight and complete insurance solutions

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