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RISK MANAGEMENT CONSIDERATIONS FOR HUMAN CLINICAL TRIALS



Products Liability Insurance does not normally include the liability of an unproven, unregulated product in its testing stages. Usually, this isn't a problem for manufacturers, since products aren't distributed until the company and regulators feel the products are safe under normal use circumstances.

In the case of pharmaceuticals, medical devices or diagnostics, this isn't correct. Testing is normally conducted in phases that can span years. Especially in the later phases of testing, when clinical trials testing is being conducted, there may be significant, uninsured liabilities incurred by the manufacturer. These potential liabilities have created the need for clinical trials liability insurance.

From a risk management perspective, a sponsor company must take its clinical trials loss avoidance very seriously. While your company may be covered for general liability, it probably is not covered for clinical trials liability. A company needs to purchase additional liability insurance specifically designed to cover clinical trials.

This is a specialty area in the insurance industry and all clinical trials policies are different. It is important to make certain that your policy is specifically written to cover all of the exposures for anticipated trials.

View from a Risk Management Perspective – not just insurance:

In addition to insurance, a crucial component of prudent risk management is contractual design. No policy covers everything and the first line of defense is favorable language in the Clinical Trial Agreement, the Protocol and the Informed Consent.

This results in three important risk management issues:

1. Favorable indemnification language serves to insulate and pass your liability on to others involved in the trial.
2. It clarifies who is responsible for what in case of a claim.
3. It actually makes your company a better risk to potential underwriters which results in broader coverage and lower pricing. Underwriters hate gray areas and therefore charge extra when confronted with it.

You should not only work with a law firm to construct and negotiate such language, but also your insurance professional. A qualified and specialized insurance broker knows the insurance market and, specifically, what potential gaps in coverage need to be filled.

Insurance Policy Considerations:

Properly constructed clinical trials insurance not only protects the company from liability, but also provides an increased level of comfort for investors by demonstrating prudent financial and risk management.

As brokers, we strive to create seamless programs. If the company's current liability insurance company offers clinical trials insurance, it is worth analyzing and considering the specifics of its policy. While there are occasional reasons to use separate insurers, it is preferable to have both products liability and clinical trials coverage with the same carrier. This avoids coverage disputes over claims and reduces the possibility of gaps in coverage.

Clinical Trials insurance is specific and personal to the trial or trials. Underwriters limit coverage to the specified trials of listed products and for no other tests or products. As such, the application process is very important. Clarity and specificity are the key. An experienced broker is vital for consultation when filling out the application.

Limits:

An additional key consideration is the common question: "How much should we buy?" There is no set rule for establishing coverage limits or minimums, but the consensus in the insurance community is that a clinical trials liability policy should carry a minimum limit of \$1 million and can have upper limits of \$10 million through \$20 million or more. Key factors include the type of drug/device/test being tested, the location of the test, the number of participants, the condition, situation and age of the participants and which phase the test represents.

Long Term Protection:

As most of these policies are written on a "claims-made" basis, claims are covered only if the claim is made within the policy period which usually tracks with the time when the trial is actually in process.

However, it is not uncommon for claims to be filed several years later. This is addressed by the Extended Reporting Period (ERP). This common provision covers claims that were incurred during the policy period (the trial), but are reported later after the trial and therefore the trial has expired. The length and pricing of the ERP can and should be negotiated up front. Naturally the length of the ERP is determined based upon the circumstances surrounding a particular trial. For instance, trials on children usually require a longer reporting period, while terminally ill patients are shorter.

Loss Sharing:

Another key component of a Clinical Trial Policy is the deductible or Self-Insured Limit (SIR). Generally, deductibles act differently than SIRs. For example, with a deductible, the carrier usually retains all the rights to defend and settle cases regardless of the amount involved (within the limit). So, if a claim can be settled within the deductible, the carrier has little to lose and will more likely pay the claimant and settle the case, then ask that you reimburse that deductible.

With an SIR, the amount for which the insured is responsible is many times higher than a standard deductible, but the insured retains the control of the defense and has a say as to whether a case should be settled and, if so, the settlement amount.

The decision to take one route versus another depends in part on the financial status of the insured, any sensitive issues surrounding the drug or device and in which phase a drug is being tested. Any decision should be done with careful consultation with your broker.

Who Controls the Defense?

Finally, there is the issue of defense inside or outside the limits of liability. A policy that places defense cost outside the limit pays all defense costs and that amount does not decrease the limit available to settle a loss. With defense within the limits, every dollar spent of defense reduces the limit or the amount available to settle.

Naturally, there is a premium price difference with "within limits" being substantially less expensive than "outside of limits." Again, a decision on which option to take should only be done in close consultation with an experienced broker.

Conclusion:

The inherent activity of a clinical trial understandably brings with it the risk of litigation and loss. However, with a holistic risk management approach that includes both contractual protection and then tailored insurance to back up and fill the gaps, firms can move with confidence into this exciting and necessary arena.

For information about foreign or domestic Clinical Trials Insurance (or any issue involving the risk needs of a Life Science company) please contact Harry Wallace at 240.482.1716 or hwallace@rcmd.com



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