



Liability Insurance: Protection in the Clinical Trial Setting

Harry Wallace at RCM&D discusses risk management considerations for domestic and foreign clinical trials

Product liability insurance, in its purest form, does not normally include the liability of an unproven, unregulated product in its testing stages. Usually, this is not a problem for manufacturers, since products are not 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 is not the case. Testing is normally conducted in phases that can span years. Especially in the later phases of testing during clinical trials, there may be significant, uninsured liabilities incurred by the drug sponsor. These potential liabilities have created the need for clinical trials liability insurance. While sometimes referred to as 'products liability', their intent is to restrict coverage to the trial itself.

This is a speciality 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 defence is favourable language in the clinical trial agreement, the protocol and, particularly, the informed consent forms. This results in four important risk management advantages:

- ◆ Favourable indemnification language serves to insulate and pass your liability on to others involved in the trial
- ◆ It clarifies who is responsible for what in case of a claim
- ◆ It actually makes your company a better risk to potential underwriters, which results in broader coverage and lower pricing. Underwriters charge more for grey areas or unaddressed issues
- ◆ Tight and properly worded contracts can lead to early dismissals

You should not only work with a law firm to construct and negotiate such language, but also your insurance professional. A qualified and specialised insurance broker will know the insurance market and can identify potential gaps in the coverage that 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. If the organisation's current liability insurance company offers clinical trials insurance, it is worth analysing and considering the specifics of the policy. While there are occasional reasons to use separate insurers, it is preferable to have products' liability, general 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 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 to \$20 million or more. Key factors include the type of drug, device or diagnostic 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.

CLAIMS MADE VERSUS CLAIMS MADE AND REPORTED

Available policies covering clinical trials are generally written on a claims-made basis. As opposed to the more

regular ‘occurrence’ policy, claims made set the trigger of coverage from when the loss is reported to the insured and the carrier.

There is a distinction between claims made and claims made and reported. In the latter instance, a carrier requires that the claim be reported to the carrier in the same policy period in which the claim was made on the insured. This is slightly more limiting than a claims-made policy, which normally requires a report be made to the carrier ‘as soon as practicable’. Naturally, this option usually is set at a higher premium.

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 coincides 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 after the trial has finished and the policy period 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 trials on 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 in all likelihood pay the claimant and settle the case rather than ask that you reimburse that deductible.

About the author



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the Chubb Group of Insurance Companies for 21 years where he held several senior level and management positions. Harry is a graduate of Texas A&M University. He holds a Certified Insurance Counselor designation and is a member of the Professional Liability Underwriting Society. Harry was recently recognised as one of six ‘Power Brokers’ for 2009 by *Risk and Insurance* magazine in the area of pharmaceuticals.

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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 defence and has a say in 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 made after careful consultation with your broker.

WHO CONTROLS THE DEFENCE?

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

CLINICAL TRIALS: BEYOND BORDERS

In some circumstances, sponsors face obstacles when conducting trials in a country outside of where they are domiciled. Being approved by the FDA poses a unique challenge to foreign companies wishing to run trials in the US. Many, if not most, clinical trial policies issued outside the US either restrict or bar coverage entirely for claims brought in the US. This is in part due to the rating differences by carriers. The litigiousness in the US is unique and must be rated separately. In some circumstances, foreign carriers will extend coverage for trials in the US on a limited basis, usually applying a sub limit or a higher deductible, and of course additional premium. Many sponsors choose to purchase a policy solely for trials in the US from an American broker with an American carrier (although US laws do not require it). This is usually a wise choice for obvious reasons. This ‘reverse flow’ method is preferable and usually easier for the sponsor.

US companies wishing to conduct trials overseas are faced with a slightly more complicated issue. Many countries mandate that policies covering trials in their country must meet certain requirements. This can go as far as requiring a policy issued by an admitted carrier in that country, a local broker, premiums in the currency of that country and the policy issued in the language of that country. They also sometimes require minimum limits of liability based on the trial at issue.

This can be further complicated by the fact that some American carriers are admitted to do business in certain countries and some are not. In those situations, it is preferable to work with an American broker who has a relationship with a broker network that can access markets in other countries, as well as the American markets.