

Miscellaneous Healthcare Spotlight

Clinical Trials and Tribulations – Getting the Coverage Right

by Evan Smith

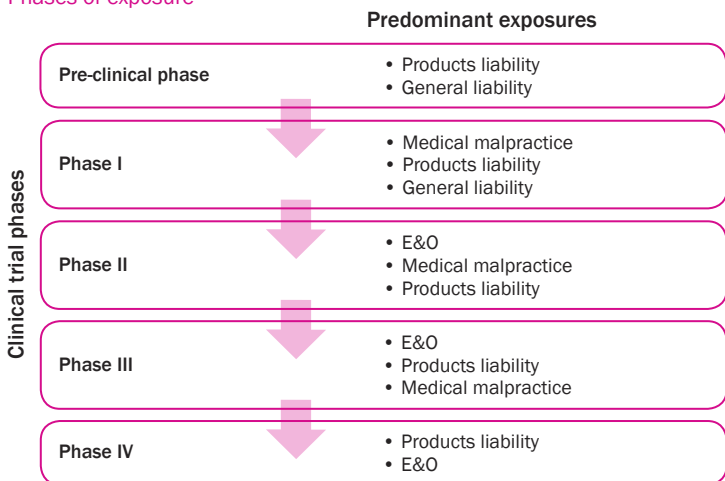


The risk and coverage issues posed by clinical trials are many and varied. No one form of coverage fits all. Job one in structuring coverage for any party conducting clinical trials is understanding exactly the services performed and for whom. From there, you can mold the right coverages into a single policy.

Clinical trials are conducted by a wide range of organizations and people on behalf of trial sponsors or initiators (the party that will ultimately commercialize the concept being tested, often a pharmaceutical company, federal agency or medical institution). Potential conductors of clinical trials run the gamut from hospitals and medical clinics, to Contract Research Organizations (CROs) and governments. Medical providers may include a nurse drawing blood at a lab, an academic researcher handling a government’s potential bubonic plague vaccine, a practitioner recording participant-reported blood pressure measures, or a physician implanting a first-ever device. Different types and levels of risk will clearly attach to these various activities.

Generally, the exposures associated with clinical trials fall into four major categories: errors and omissions, medical professional liability, product liability, and general liability. Some medical expense coverage may also be needed. The specific exposures of any individual insured can vary substantially depending on the particulars of the trial and its protocol. Moreover, clinical trials are conducted in phases; certain types of exposures are more pronounced during certain phases.

Phases of exposure



The pre-clinical phase focuses on proving that a drug or device can feasibly work and on removing hazards so that it can be tested on people. Because the drug or treatment is not yet tested on humans, there is no medical malpractice exposure. Damages during this phase tend to fall into the realm of products liability, because the tester is typically creating, using or testing someone else's product – which can be very costly and difficult to replicate if something goes wrong in the testing or creation process.

In the next phase, Phase I, the experimental drug or treatment is tested for the first time among a small group of people. The purpose is to evaluate its safety, determine a dosage range, and identify side effects. Because this phase marks the first time the safety of the drug is tested on healthy humans, bodily injury exposure is extremely high. Products liability and medical malpractice exposure is evident.

In Phase II trials, the experimental drug or treatment is given to a larger group – a few hundred – to evaluate effectiveness and safety. Products liability and medical malpractice exposure remains high, as clinical work remains central. Bodily injury exposure is a major consideration. E&O concerns ramp up as execution of the trial becomes increasingly large and complex. If, for example, the tester errs in randomization, record keeping, or FDA compliance, a study could be partially or completely void. Replicating this phase of the trial can be extremely expensive when you consider the costs of recruiting new patients and staff, remaking the drug, etc. This is why E&O coverage, which covers financial injury, is needed.

When a trial moves to Phase III, a drug or treatment has been tested as safe, dosage is more set, and a wider net is cast, as the drug or treatment is given to a much larger group – thousands of people – to confirm its effectiveness, monitor side effects, compare it to other treatments, and collect information that will allow it to be safely marketed. E&O exposure increases as the number of people involved and the scope of the trial rise dramatically. Products liability remains an exposure. The severity of medical malpractice exposure is slightly less, since substantial testing has already been done, but the frequency of claims map jump. Immediate medical malpractice claims might arise from things like the alleged mismonitoring of patients undergoing EKGs, blood work, or x-rays. The long term effects of the drug on humans remains in question.

Come Phase IV, the drug or treatment is in use for specific purposes and post-marketing studies are collecting additional information on risks, benefits, and optimal use. Medical malpractice risk generally does not exist, but product liability exposure remains, as seen with high profile cases of on-market drugs causing heart attacks and other serious effects. There is also substantial E&O exposure associated with critical filings, for taxes, patents, etc., which can make or break the future financial success of the new product.

Insuring the risk

There are a many moving parts to clinical trials risks. The insurer's job, along with the client's broker, is to understand exactly how these parts combine for each particular risk. What is a university, hospital, or other institution running a clinical trial actually doing at each phase of its involvement? With that understanding, we can structure a robust, single-policy solution that encompasses the multi-facets of exposure, including:

- **Errors and omissions insurance** for consequential damages arising from negligent performance or non-performance of any aspect of a trial. *Policies generally can cover the costs of repeating a portion or a whole phase of a clinical trial.*
- **Medical malpractice coverage** for bodily injury claims by subjects arising from medical services or during the course of medical services.
- **Products liability insurance** for liability arising out of the handling, distribution, or manufacturing of drugs/medical devices during the pre-clinical and clinical phases, in Phase IV post-marketing surveillance, and thereafter. *This is vital even when the insured is not the product manufacturer or distributor; it is increasingly sought by those that conducted a trial after the experimental drug or device has been released to market.*
- **Clinical trial medical expense coverage**, sub-limited to respond to out-of-pocket medical expenses required of trial participants. *This coverage can support the insured's timely response to acute medical needs arising from products administered or services rendered during the trial.*
- **General liability** for premises-related bodily injury/personal injury, property damage and advertising liability claims. *Coverage may follow providers or individuals who go into another entity's premises and risk "creating" a general liability hazard elsewhere.*

Guiding the process

Many of these coverages are wholly new to insureds. (Hospitals, for example, typically do not shop for E&O coverage.) They need a carrier that is fully conversant with the risks involved in clinical trials and is able to work with brokers to educate insureds on their particular coverage needs. Key issues might include:

- The true nature of the medical malpractice exposure. Are invasive procedures being done, or are they just drawing participants' blood? Is there a patient-provider relationship? How are adverse findings handled? Is there a procedure in place to always report back such findings to the patient and his/her primary care physician?
- Is coverage required for physicians, assistants, nurse practitioners, and other high level medical providers and in what, if any, medical circumstances is coverage needed for independent contractors?

- What are the right limits? Hint: What are the insured's current assets? What are the contractual requirements? Subcontractors, such as CRO's tend to aggressively require large limits for small providers. The limits carried should balance with the related exposure.
- Contractual indemnification and hold harmless agreements. What types of relationships is the potential insured entering into with product suppliers, trial sponsors, CRO's, etc., and how do these shift exposures and liabilities?
- The extent of the facility-based exposure. How much time are patients spending at the site? Are overnight stays involved? Is sexual abuse and slip & falls a concern?
- Historical exposures. What data is collected? Revenues? Trial enrollees? Subject drug device of trial, adverse outcomes? How is it tracked, by whom?
- Current coverage. Is there coverage in the entity's existing portfolio that applies to its clinical trial exposures?

What does it take to provide robust protection for clinical trials?
First and foremost, asking the right questions.

Who might your risk be?

- Physicians and physician groups; investigators; and scientists
- Hospitals
- Staffing agencies
- Universities
- Research institutes; think tanks; not-for-profit research organizations
- Foundations
- Government agencies (vaccine/ HIV programs)
- Institutional Review Boards (IRB)
- Animal production companies
- Contract Research Organizations (CRO)
- Correctional healthcare
- Pharmaceutical and nutraceutical companies

To learn more about Beazley's solutions for Miscellaneous Healthcare Professional Liability Risks, contact Evan Smith at evan.smith@beazley.com

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