

Five Ways to Risk Manage Clinical Trials

by Anji Henderson and Kevin M. Quinley

Remembering the police officer's helmeted head and dark glasses on an impassive face, hand poised on his holster while peering through the rear-view mirror may help a motorist drive more carefully to avoid another moving violation. "Fear factors" may inspire short term driving improvement but leave bad motoring habits untouched once the anxiety recedes.

Similarly, in the arena of life science product liability, companies may avoid a "483", warning letter or other FDA sanctions but still face product liability lawsuits. Behind the legal landscape of clinical trials are policies rooted in regulatory history. These policies protect the safety of test subjects and ensure ethical behavior of those to whom the subjects have entrusted themselves for treating, diagnosing or preventing disease.

Question: Who protects the company conducting clinical trials from product liability and lawsuits?

Answer: The company's management team. To help make this happen, here are five tips to improve the clinical trial risk management process.

1. Pursue regulatory compliance, but don't mistake it as the end-all and be-all of risk management. Many life science firms enjoy a history of FDA compliance but regulatory spotlessness does not keep them from being named in product liability lawsuits. FDA regulations establish minimum standards for compliance. Clinical trial stage companies – like all life science firms – should zealously outperform the regulatory standard and embrace thorough risk management principles which include but also transcend FDA compliance.

Just as big trees grow from little acorns, many large life science firms started as clinical stage companies. Many Medmarc policyholders are at the clinical trial stage or have products at this phase of the development life cycle. Further, Medmarc actively pursues business with life science firms at the clinical trial phase. This stage does not signal immunity from product liability, however. Accordingly, in this issue of Rx for Risk, we look at risk management considerations in the clinical trial process and offer five specific tips on bulletproofing the clinical trial process from expensive liability claims.

"The best car safety device is a rear-view mirror with a cop in it." – Dudley Moore

2. Avoid financial conflicts of interest in clinical trials. Some companies pay clinical investigators based on the number of subjects they enroll. Such financial incentives can lead to recruitment of subjects not ideally suited for a clinical trial. There should be no financial conflicts of interest between the subject and the investigator or any member of the IRB (Institutional Review Board) without thoroughly disclosing the conflict to the subject. For example, the flagship Cleveland Clinic recently tightened its disclosure policies after revelations that the facility and its doctors had financial ties to medical device firms whose products they were testing at the facility.¹

The appearance of bias in this relationship could jeopardize clinical trial data integrity and therefore, the findings of the clinical trial. While it is best that neither the investigator nor any member of the IRB have a financial interest in a trial's outcome, such arrangements are not uncommon. Thus, the clinical investigator and the member of the IRB with such compensation arrangements

should disclose them, do so in writing and have the patient sign the disclosures.

3. Recruit seasoned investigators trained in clinical research. Use investigators who have formal training in clinical research rather than relying on investigators with backgrounds limited to medical school or private practice experience.

Clinical researchers need to have in their resumes some stretch of formalized training that is offered at most research institutions. This training better equips investigators to discuss observations and analysis with IRB members, who may be from diverse disciplines.

Investing this time in due diligence regarding investigators' credentials, background and experience is time well spent. It also blunts any argument by a plaintiff attorney that the clinical trial company failed to do its homework or simply outsourced its responsibility to clinical trial subjects.

4. Insist that clinical investigators carry their own third-party liability insurance coverage. Product liability insurance typically excludes coverage for a medical professional's negligence. Have you verified first-hand that the clinical investigator has his or her own professional liability insurance coverage for clinical trial participation? Check on the amount of the policy limits and compare them to the amount of coverage you carry on your own product liability policy. Are the limits at least equal?

Product liability versus professional liability coverage can be an area of tension between the sponsor and the investigator. A sponsor may wish to use the services of the investigator for future clinical trials. An investigator may leverage that knowledge and refuse to provide those services unless the sponsor agrees to include him as an insured with professional medical coverage. One solution is for each party to procure its own coverage by utilizing the expertise of seasoned insurance underwriters.

5. View informed consent as an ongoing process, not just a perfunctory form. Informed consent represents an area that presents clinical trial sponsors with an opportunity to appoint an independent "patient advocate" to explain risks and benefits to the subject. Clinical trial sponsors should strive to thoroughly communicate all known risks and potential (though not guaranteed) benefits of any trial. The process of informing subjects of the risks should occur in an atmosphere free of coercion, pressure or superficiality. The consensual nature of informed consents is a red bulls-eye for the plaintiff's bar.

Forms shoved at a patient with the comment, "Here's the stuff that the lawyers require you to sign" is not informed consent and makes the process vulnerable to later attack by enterprising personal injury attorneys. Make the process bulletproof by taking time to explain, answering questions, being thorough, documenting everything and appointing patient advocates.

Closing Comments

While this is not an exhaustive list of considerations for risk managing the clinical trial process, these tips will help life science firms identify key areas that continue to attract product liability litigation. Nothing substitutes for zealous patient concern and good ethics.

The Management Team of companies conducting clinical trials does not need cops, the FDA or personal injury attorneys to coerce them into embracing best practices. In the realm of lawsuit prevention, there are no absolutes or guarantees. Nevertheless, life science firms should read and heed these tips to avoid liability claims arising from clinical trials!

Anji Henderson, J.D. is a Loss Prevention Specialist with Medmarc Insurance Group. Kevin Quinley CPCU is Senior Vice President of Medmarc Insurance Group.

¹ "Cleveland Clinic to Tighten its Disclosure Policies," *Wall Street Journal*, 2/9/06, p. A3.

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Inquiries regarding Medmarc should be directed to:

Eastern & Midwestern States

Bill Igoe
(800)-356-6886 ext. 330
bigoe@medmarc.com

Western & Pacific States

Cindy Melocik
(800)-356-6886 ext. 337
cmelocik@medmarc.com

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