RISK NOTE

Risk Management in Clinical Trials

Although the information found in the original "Insurance in Clinical Trials" risk note published in 2006 is still valid, this new risk note is to provide an update on the risk management of emerging practices in the clinical trial and research areas. To facilitate this updated information, we've incorporated an FAQ style.

1. What are the risks in clinical trials?

Clinical trials and research are essential for the development of new treatments and methodologies to improve health outcomes and provide value to the healthcare system.[1] Although there are many potential benefits, the risks are high if not managed properly. Losses can arise from various factors such as:

- negligence in conducting the trials leading to participant harm or injury;
- defective drugs from poor design, manufacturing or labelling leading to participant injury and/or side-effects;
- misleading marketing practices that falsely promote drugs
- ethical concerns around protecting participants' rights and safety through transparency and consent;
- confidential and patient data breach;
- breach of Intellectual property rights due to misuse of confidential information, patents or data outcomes

Certain classes of clinical trial risk pose even higher exposures:

- Clinical trials involving children, for example, are viewed as being high risk. Children are a vulnerable group for research. Research which poses moderate or

[1] https://innovativemedicines.ca/wp-content/uploads/2024/05/6588_IMC_2024ResearchNote_ClinicalTrialsCanada_v2-1.pdf

substantial risks to participants with no potential for direct benefit, should be performed very cautiously on children.

- Clinical trials involving healthy participants, as opposed to those whose health is compromised, are also high risk. The potential for damages (in pain and suffering, medical expenses and loss of future income) are greater when the plaintiff can allege that they were in good health before they participated in the trial.

Although carrying out of the research or clinical trial protocol usually rests with the health care agency or the principal investigator, the Sponsors carry high exposures related to the drug or product itself that are being tested on participants.

2. How to manage risks associated with the Sponsor in clinical trials?

To manage potential liability exposures associated with participating in clinical trials and the drugs or products being tested, health care agencies should at a minimum, ensure they are fully indemnified by the Sponsor for their participation. Adequate insurance of the Sponsor is essential to financially back the indemnity that is obtained.

To fully appreciate the significance of the Sponsor having proper insurance, it is important to understand the common law rule of joint and several liability, sometimes called the "deep pocket rule" or the "1% rule". This rule makes each and every defendant in a tort lawsuit liable for the entire amount of the plaintiff's damages regardless of the defendants' relative degree of fault or responsibility. A co-defendant's inability to pay could find the defendant with the "deep pockets" paying 100% of the damages when they are as little as 1% responsible for them. A Sponsor should be able to indemnify the health care agency and be independently and financially capable of meeting the responsibilities arising from its own negligence. A Sponsor's failure to meet those responsibilities could prove very costly for the health care agency.

If a Sponsor is unable to obtain insurance or high enough limits, it may indicate that the Sponsor does not have sufficient experience or expertise in a particular area. Generally, an insurance company's underwriting process will involve obtaining details on the number of years that a company has been in business. A sponsor that is not well-established may have difficulty obtaining insurance.

3. What Insurance is required from the Sponsor to manage clinical trial risks?

The recommended insurance limits (or self-insurance) for the Sponsor to financially back the indemnity they grant and thereby limit the risks of the principal investigators, the health care agency and associated parties (i.e. directors, officers, employees, agents etc.) are as follows:

> "The Sponsor shall procure and maintain, at its sole expense, policies of general liability insurance in the amounts of not less than $10,000,000 per occurrence, and minimum $10,000,000 aggregate naming the "Indemnitees" as additional insureds. Such insurance shall include clinical trial liability, broad form contractual liability and shall also provide product liability coverage. The obligation to maintain the insurance shall survive the completion or early termination of the Agreement. If any such insurance is on a claims-made basis and that insurance is cancelled or non-renewed, it must contain at least a 24-month extended reporting period."

Evidence of appropriate insurance should be obtained from the Sponsor in the form of an insurance certificate. The insurance certificate must be read carefully to ensure that the required insurance extensions listed above are specifically stated and included. If they are not, then they may not be part of the coverage, in which case you may need to inquire further.

While the above language recommends an insurance limit of $10,000,000, in some cases limits of $5,000,000 per occurrence and $5,000,000 aggregate are the most that is available or reasonably affordable. This is often driven by the insurance market that may be unwilling to provide higher limits to smaller pharmaceutical companies.

If the risks of the trial are considered low (i.e. early non-clinical research or later phase, non-invasive, not on children, not on healthy subjects) then a $5,000,000 limit may be sufficient. On the other hand, if the risks of the trial are higher and $5,000,000 is the highest limit of insurance available, the health care agency should carefully assess the risks in relation to the opportunities of participating in that particular trial. The health care agency should document the reasons for accepting less than $10,000,000 limits.

These limits of insurance were reviewed in 2025 and based on market analysis, these limits are the recommended levels and attainable for Sponsors. Many Sponsors are large enough that they can attain these limits or higher either via private insurers or through

self-insurance policies. For smaller Sponsors, based on market feedback, limits of minimum $5,000,000 are readily available if they approach insurance markets that specialize in clinical trial coverage.

We do not recommend accepting limits of less than $5,000,000 under any circumstances if the trial involves testing on human subjects. Some bio-tech companies carry as little as $1,000,000 or $2,000,000 in liability insurance. The business of pharmaceutical research is extremely risky and from a risk management perspective, limits such as these are insufficient for the exposures.

4. What is an occurrence and aggregate limit?

Occurrence-based insurance covers events that take place while the policy is or was in effect, regardless of when the claim is reported. The aggregate limit is the most an insurer will pay within the policy period, irrespective of how many claims are made against it during that period. The result is that the limit of insurance could be eroded by previous losses. This is a concern when a pharmaceutical company has one policy which covers their participation in multiple trials with multiple products and involving many participants. When faced with a class action lawsuit involving hundreds of plaintiffs, just how much protection will such insurance really provide?

5. What is a 24-month extended reporting period and when is it required?

Clinical Trial Liability, professional liability and products liability, which provide coverage for the part of the trial involving product/drug and testing on human subjects, are usually written on a "claims made basis" rather than an occurrence basis. This means that claims must be discovered and reported within the policy period to be covered. The problem with this is sometimes it may take years before the damage that a drug has caused is discovered. As a result, these liabilities may not be insured because the period of the policy has lapsed before such damage has manifested itself. As a safeguard from this situation, adding a 24-month extended reporting period clause will help by lengthening the 'time to report' on claims made liability policies.

6. How can health care agencies manage risk in clinical trials?

To manage potential liability exposures associated with participating in clinical trials a health care agency's best defense is to:

- materially adhere to the Sponsor's protocol;
- administer medical care in accordance with generally accepted standards;
- comply with all appropriate laws and regulations governing research including ethical guidelines and informed consent;
- ensure it is fully indemnified by the Sponsor;
- Ensure all parties in the clinical trial have appropriate insurance

7. What are Clinical/Contract Research Organizations (CRO)s and Academic Research Organizations (ARO)s?

Many Sponsors are choosing to use Clinical/Contract Research Organizations (CRO)s and/or Academic Research Organizations (ARO)s who manage and oversee all aspects of the clinical trial from beginning to end on behalf of the Sponsor and in some cases have decision making authorities:

- CROs are commercial, for-profit entities that primarily partner with pharmaceutical, biotechnology, and medical device companies, offering standardised processes and comprehensive services for large-scale, multi-centre trials. They excel in regulatory compliance and meeting strict sponsor timelines, providing end-to-end services from site selection to data management.[2]
- AROs are typically affiliated with universities, medical schools, or teaching hospitals, operating on a non-profit basis and focusing on investigator-initiated trials and academic research. Their strong connections to academic medical centres and specialist networks make them particularly suited for complex or novel trial designs requiring deep academic expertise.[3]

In these cases, the Sponsor still holds the ultimate responsibility for the study's design, conduct, and outcome including the necessary financial resources. Although CROs/AROs do carry significant roles, they may be reluctant to provide the health care agency with an indemnity. If that's the case, the Sponsor should also indemnify the health care agency for

[2] https://www.thepbcgroup.com/post/academic-research-organisations-aros

[3] https://www.thepbcgroup.com/post/academic-research-organisations-aros

the actions of the CRO/ARO in the clinical trial. The CRO and ARO should each have liability insurance requirements similar to that of the Sponsor.

In summary, all of these factors combine to make risk management in clinical trials a complex issue. Health care agencies want to participate in research and protect themselves and their assets from loss at the same time. Reconciling the risks with the opportunities is a challenge. Insurance and indemnification are at the core of adequate protection from liability risk in clinical trials.

If you have any questions about indemnity and insurance provisions related to clinical trials, please contact HCPP at hcpp@gov.bc.ca

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