



In this Issue

- ▶ [International Clinical Trials: Look Before You Leap](#)
- ▶ [As Venture Capital Increases – So Do Insurance Risks](#)

Quick Facts

The National Venture Capital Association just celebrated their 40th anniversary

Lifesaving medical innovations brought to market by venture capital include the pacemaker, MRI, ultrasound, angioplasty and stent grafts

Source; Seattle PI

International Clinical Trials: Look Before You Leap

By Frederic Nouaille
Audit & RiskSolutions

Logistical problems and financial pressures prompt many medical technology and life sciences companies to sponsor human clinical trials outside the borders of the United States. As important as the decisions made regarding in what countries to conduct clinical trials, which Clinical Research Organization (CRO) to use and the development of protocols, is the need to learn the local requirements and comply with them. Often one such requirement is the need to provide evidence of acceptable clinical trial insurance protection.

For example, The European Union Clinical Trials Regulation No 536/2014 published on the 27th of May 2014 set out to simplify and harmonize the administration of clinical trials throughout the European Union. However, it has not resulted in a streamlined and simple clinical trials insurance structure. Insurance requirements continue to vary among countries and failing to incorporate insurance requirements into the clinical trial planning process can cause delays and cancellation of trials.

One Size Does Not Fit All

In addition, once a policy is in place for a clinical trial taking place in a country with specific insurance requirements, the United States for example; it is likely that the policy cannot be amended or extended to include other countries or other trials. In many situations, one policy will not satisfy local or ethics committee requirements. Also, coverage requirements are not uniform among countries. Further, ethics committees are known to have different interpretations of what constitutes compliance with local regulatory requirements. The following illustrates this last point.

Several years ago, a company successfully completed Phase I and II trials of a combination device for people suffering from severe allergies due to spring season pollen. When the company was ready to launch the Phase III study in four European countries, two of the four ethical commissions would not allow the trial to start, because the insurance certificates failed to meet their requirements. Since there is only one spring pollen period per year, the Phase III trial in these two countries was delayed by one year.

Another issue related to clinical trials conducted outside the United States is coverage jurisdiction. Insurance protection that meets the requirements of a specific country and local ethics committee may only cover claims brought in the country where the clinical trials were administered and fail to provide coverage for claims made in other countries.

When Time Is Not On Your Side

TechAssure is an international association of privately held, entrepreneurial insurance and risk consultants specializing in mitigating the risks faced by emerging growth companies and the venture capital firms that back them. **TechAssure** member agencies service more than 3,000 technology and life sciences companies worldwide.

TechAssure Locations:
Boston, Chicago,
Columbus, Dallas, Denver,
Indianapolis, Minneapolis,
New York, Philadelphia,
Salt Lake City, San Diego,
San Francisco, Seattle, St.
Louis, Washington DC,
Toronto, Montreal, Paris,
London, Amsterdam,
Sydney, Melbourne, India

In companies conducting clinical trials often there is a lack of timely communications between Regulatory Affairs/Quality Assurance and Finance on matters pertaining to clinical trials insurance. Typically, Finance learns of the need for evidence of acceptable insurance within a few days or week, prior to submitting protocols to ethical commissions. When this happens, procuring the necessary insurance coverage can be a race against time.

Coordinating national and international insurance placements is not a task for general insurance brokers. Placing coverage using multiple insurance policies for individual trials conducted in several countries parallels the complexity of complying with the regulatory requirements in those countries. To this end, it is important to work with specialists who focus on the unique business and insurance/risk management needs of medical technology and life sciences companies conducting world-wide clinical trials.

Practical Tips for Evaluating a Clinical Trial Insurance Specialist

Start Early

- Understand what you will need to do
- Recognize the lead time to establish a relationship with a specialist

Check References

- Firm's reputation
- Team leaders and other personnel
- Watch for high turnover

Be Clear About What You Need

- Access to resources
- Regularly scheduled calls
- Meetings

As Venture Capital Increases – So Do Insurance Risks

By Aurelien Le Bail
Audit & RiskSolutions

Venture Capital firms need to manage their risks. We advise our VC clients to implement an insurance program combining Directors and Officers coverage and Professional Liability. These insurance programs include management, professional and outside directorship liability coverage components.

Insurers assess the litigation risks and establish their pricing based on the following risk factors;

- Range of asset classes (types of funds, infrastructure, growth expansion, recovery, private debt etc.)
- Industry specialization of portfolio companies
- Investments size
- Limited partner base (institutional shareholders, individuals etc.)
- Board representation
- Financial statements of portfolio companies

When financial markets tighten, we face significant increases in claims involving VC firms and management. The source of claims vary but many involve limited partners and portfolio companies and their legal representative in case of bankruptcy.

Facing these challenges, the choice of a specialized broker is a key success factor, as they will provide an understanding of the VC risks and experience in the market.

Insurers have adapted to the new challenges and propose new insurance coverage such as;

- Defense cost (incurred by individuals) in case of investigation
- Defense cost and indemnities in case of Employment Practices claims
- Cash reserve related to the nomination of a mandatory/conciliator in case of financial difficulties



of a portfolio company

Specialist brokers such as TechAssure members will help you to assess your potential exposure and issue the best insurance policy to manage these risks.