

Crisis In Foreign Clinical Trials



William Gallagher Associates
Phone: 888.261.8884
www.WGAins.com

Market conditions for Products Liability Insurance for Clinical Trials started to deteriorate in 2002, later than the market tightening for most other lines of insurance coverage. This change was initially caused by worsening claims results and increases in the cost of reinsurance in this sector. However, the market has always been small. There are only a few insurers capable of providing the appropriate coverage on a global basis. This means that small changes in the insurance market can have a big impact on insurance buyers. The “perfect storm” of claims and reinsurance problems was joined when one of the market leaders, CNA Insurance, changed its entire underwriting team and philosophy in 2002. This constricted the supply of insurance and further added to higher pricing. In 2003, prices are increasing even more rapidly and underwriting standards are growing more stringent. In Europe, several insurers in this sector are experiencing financial problems thereby further reducing the supply of insurance and leading to long delays in obtaining quotes. This whitepaper attempts to provide a detailed summary of these matters.

William Gallagher Associates (WGA) is a leading independent commercial broker, specializing in providing risk management, employee and executive benefits services to companies with difficult and complex risks. These include a focus on Life Sciences, Technology, Energy, Healthcare, Financial Risks, Environmental and other industry groups. WGA has offices throughout North America and Europe, including Boston, MA; Princeton, NJ; Columbia, MD; Atlanta, GA; and Paris, France.

Underwriting Considerations

The leading US insurers for Clinical Trials Insurance include CNA, Chubb, Medmarc, and ACE. As claims activity has increased and pressure from reinsurers has emerged, these and other insurers have made the underwriting process more onerous for buyers of this insurance. Applications have gone from three-page forms to forms of ten pages or more. Supplemental forms are now required in Germany and many other countries. Completion of these applications for the most favorable underwriting results requires a close coordination between the clinical staff, the finance team and WGA. Insurers now also want to have a hand in reviewing the language for Informed Consent Agreements. They are particularly concerned about “readability” standards and are making requirements that European consent forms meet US legal standards, since lawsuits can be brought in the US as well as in the country of the trial for claims arising out of a foreign clinical trial.

Pricing Considerations

Premiums are increasing and this is evident in many ways. First, minimum premiums are on the rise such that even the smallest trials may now generate premiums in excess of \$25,000 per trial. Second, the cost of excess or higher limits of insurance is going up. This is because insurers buy reinsurance in order to offer high limits of coverage and the price of reinsurance has been driven up in all lines of coverage in the post-9/11 world. But perhaps the greatest reason for rate increases is the higher number of larger claims settlements both in the US and overseas, which has reduced profitability of this line of business for insurers. In the case of large trials, involving 500 or more subjects, the cost of insurance and the variation in cost between different countries might have a material impact on the decision of where to conduct a trial. Rates have increased most in countries such as France, Germany and Italy.

Insurer Financial Ratings

The global insurance market is still attempting to recover from 9/11 claims and a decade of inadequate pricing during the 1990s. After two or three years of rate increases (depending upon the line of coverage), it is easy to become somewhat cynical about the need for more rate increases from insurers. It does seem that there has been a bit of piling on, at least by the most financially stable insurers. But, it is impossible to deny that the financial ratings of various commercial insurers

have dropped throughout the world in the past three years. The recent collapse of Kemper Insurance in the US is the most glaring evidence that there are still a number of insurers with financial and claims problems that need to be fixed.

In the area of Foreign Clinical Trials insurance, this has become most evident. Some ailing insurers like AXA in France have dropped out of the market. In Germany, Hannover and Gerling are struggling, and they have lost some key staff, as well. All of these and other European insurers have had their financial ratings cut and/or put on negative watch. This means that the supply of insurance has dropped while demand is stable and growing. Insurance markets are no different than other markets in this situation. Lower supply with growing demand will equal higher prices and poorer service. WGA is seeing both of these symptoms in the European market. Delays of six weeks or more in obtaining complete premium quotations are becoming common.

Many hospitals which host clinical trials in foreign countries will not accept a US insurance policy and demand that local coverage is purchased. Indeed, in certain jurisdictions like France and Germany, it is the law to require local insurance. US insurers like Chubb, CNA, Medmarc, and Ace can directly or indirectly provide some coverage on a primary basis in certain European countries. But, their delivery systems are often slow, cumbersome and expensive. Also, US insurers will often limit their capacity to US based companies and then cap their policies at one or two per drug in each country due to concerns about aggregation of risk in one country or with one drug.

Conclusion

WGA maintains a complete database of information about insurance requirements and market conditions for locally required insurance throughout Europe and around the world. We have successfully handled insurance requests from Central America to Russia to Singapore for our clients. For more information about Clinical Trials Insurance, contact your Account Executive at WGA or email us at info@WGAins.com.