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# Navigating the Intricacies of Insuring International Clinical Trials

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As life science firms grow and expand around the globe, Chubb has the solutions, services, and expertise they need every step of the way.

The life sciences industry is one of innovation. Those in the business of risk management have long known that life sciences companies can move at incredible speeds, propelling scientific breakthroughs and introducing new solutions to the public on a consistent basis.

Over the past several years, many life sciences companies have been working across international borders to develop life-changing medications and therapies even more quickly than before. While an open exchange of information can lead to faster breakthroughs, when that work takes place across countries, it can also make certain aspects of development more complicated.

One such area is clinical trials, which are subject to a variety of laws and regulations that may differ around the world. For companies operating across multiple countries, this adds layers of complexity to their management of risk. But there are ways to prepare for that complexity. This Global Risk Spotlight highlights five key points for risk managers to consider as they go about arranging insurance for clinical trials on a global basis.

## Prepare to Pivot

As clinical trials roll out internationally, insurance must be put in place where and when it is needed, sometimes on an extremely tight timeframe. Insurance programs must also adapt as a trial evolves, for example, as protocols are amended, sites shift, and participants change. If coverage is inadequate or delayed, trials can be delayed. Given the exorbitant costs of trials, any setbacks or derailments can be incredibly expensive, so risk managers must be agile and decisive as challenges develop.

## Properly Address Local Regulations

Regulations unique to specific countries and territories make insuring clinical trials particularly complicated. When insuring clinical trials outside the United States, locally admitted insurance policies specific to clinical trials are often required, and these policies can have vastly different requirements. For example, in Germany, insurance must cover a test subject's travel to and from a trial. Some countries allow one policy for all trials, while Italy requires separate policies for each trial. Changes in legal, regulatory, and political environments can also shift the landscape for clinical trials. The boards of local ethics committees that review trials to ensure they are ethical and as safe as possible may also weigh in on insurance requirements. Failure to obtain proper insurance coverage in a particular jurisdiction may result in significant underinsured product liability exposures – bringing claims that can stretch across years and result in millions in defense costs alone. Insufficient limits or improper policy language can also lead to trial delays or shutdowns, triggering financial repercussions and potential reputational damage.

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## Anticipate Ongoing Evolution

Life sciences firms may be drawn to new territories where patient population, clinical investigators, or trial costs are more favorable. They may also be involved in mergers or acquisitions or new partnerships with manufacturers and even competitors. As firms grow and the landscape changes, additional amounts of insurance coverage and more sophisticated program structures and services may be needed to optimize a program's efficiency and effectiveness. For example, as life sciences firms expand their operations, one option may be to utilize a multinational master program that combines the consistency, security, and expertise of one global insurer with the requisite locally admitted policies where trials are conducted. Firms should consider any prospective insurer's ability to adjust their insurance programs as their global footprint expands and becomes more complex.

## Assess and Mitigate Supply Chain Risk

Supply chain exposures have recently been greatly exacerbated by many factors and show little signs of abating. Actively identifying supply chain vulnerabilities and assessing risk management and contingency plans to mitigate these risks is essential.

Some questions to ask before committing to a supplier include:

- Do all supplier contracts include appropriate indemnifications?
- Is business interruption coverage adequate to address losses if disruptions in just-in-time or back-up supplies upend a trial?
- How should contingency plans be updated to ensure continuity in today's environment?

## Instill Certainty and Consistency in Claims Handling

When insurers handle multinational claims, strong relationships with local legal counsel and knowledge of the local regulations are essential to mitigate exposure. Claims may be filed in multiple countries, and consistency in claims handling strategies, as well as careful coordination of claims – locally and globally – is critical.

## Conclusion

Working with a global insurer with extensive life sciences experience and expertise can help ensure that the intricate and dynamic process behind insuring clinical trials is handled thoughtfully, effectively, and efficiently. A true partnership between insurer and insured can help life sciences companies evolve and push new scientific breakthroughs to market.

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