

# Insurance

## *Navigating the International Insurance Market*

Frank F. Goudsmit

### ABSTRACT

*Biotechnology is a global business, with more United States (U.S.)-based biotechnology companies conducting clinical trials and establishing facilities overseas. This article identifies some of the risks facing biotechs that conduct business or research in foreign countries. It also provides information that can help biotech firms navigate the intricate web of international insurance issues.*

### INTRODUCTION

**B**iotechnology is a global business. Some U.S.-based biotechnology companies open facilities overseas, but even a firm that never owns a square foot of property outside the U.S. can face an array of international exposures. This is especially relevant to the growing number of U.S. biotechnology companies conducting clinical trials in foreign countries. Many factors influence the decision about where to conduct a trial, but too often biotechs overlook an important consideration in the early planning stages: the insurance they need to protect them in the event that research subjects are injured as a result of the product or treatment being tested.

Insurance requirements vary from one country to another, and the demands of a specific country can have a significant impact on a biotech's

clinical research and its bottom line. Biotechnology firms have unique exposures that require highly tailored policies that respond to different issues at various stages of development. The complexity of international insurance for life science companies can create snafus that may delay clinical trials and conceal gaps in coverage that can leave a company dangerously unprotected.

The issue of insurance coverage for biotechs takes on new urgency in today's market. A few years ago, insurers were engaged in fierce competition for new business, courting even high-risk life science businesses with relatively low premiums. Since the terrorist attacks of September 11, 2001, insurance prices have increased, and underwriters without long-term commitments to the biotech industry have walked away from the challenges the market presents. As a result,

biotech firms that don't demonstrate their ability to assess and manage their risks effectively, both domestically and overseas, may find it harder to get adequate insurance coverage to meet their specialized needs. Nowhere is this a more crucial issue than in human clinical trials.

### CLINICAL TRIALS GO GLOBAL

Clinical research and development has become a global undertaking. It's unclear exactly how many human clinical trials for new drugs take place overseas, but the trend is undeniable: dependence on overseas trials has grown sharply. In 1980, the FDA tracked the work of just 41 foreign clinical investigators conducting drug research under an Investigational New Drug application. By 1990, the figure grew to 271 and by 1999 to 4,458.<sup>1</sup> One pharmaceutical giant conducts about 35% of its clinical trials overseas, a percentage that it expects to rise steadily.<sup>2</sup>

Biotechnology and pharmaceutical companies conduct trials overseas for many reasons. The treatment may target an ailment or condition that is more prevalent in a particular country or region, or it may be necessary to find a pool of people who are not receiving other forms of treatment for a disease, such as HIV. In the past, drug companies were compelled to conduct trials overseas because regulatory authorities in many countries would not accept clinical data generated elsewhere. That changed markedly with the establishment of the International Conference on Harmonization of Technological Requirements for Registration of Pharmaceuticals for Human Use



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(ICH) in 1990. ICH has streamlined the drug development process by producing a single set of technical requirements for the registration of new products in the European Union, Japan and the U.S.. In addition to reducing the duplication of time and resources that a biotech firm was forced to commit to the development process, the ICH's operating practices have enhanced patient safety in the clinical trials process.<sup>3</sup> While the three regions account for the largest share of drug development and sales, the impact of ICH extends further as pharmaceutical and biotechnology companies begin to apply the standards throughout their global operations and as organizations like the World Health Organization and other countries look to its standards as a model.

Most biotech firms, pharmaceutical companies and universities that conduct clinical trials overseas have legitimate reasons for doing so and apply the highest ethical standards. But some researchers may have questionable motives. Companies may conduct clinical trials overseas in what may be perceived as environments with favorable regulation and less litigation. In some cases, foreign countries may court them with attractive funding programs.

One of the great ethical issues concerning overseas trials involves standards of care for people who live in poverty and lack access to basic health services. With the prospect of treatment with a promising drug held out before them, people who are desperately poor or ill may overlook the risks, even if they understand them. Some researchers have gone to developing countries to conduct human experiments that would not bear up to scrutiny in the U.S.. Dr. Henry J. Heimlich, inventor of the Heimlich maneuver, has been criticized for experiments in the 1990s in which he injected HIV patients in China with malaria in an effort to kill the AIDS virus, a practice that the U.S. Centers for Disease Control and medical

ethicists have said could not be justified.<sup>4</sup> Last year, a federal investigation concluded that asthma research carried out in rural China by a professor at the Harvard School of Public Health was not properly monitored to ensure the safety of participants. The U.S. Office for Human Research Protections said some of the research lacked the necessary review by an ethics committee and that the researchers subjected the families to risks even though they were unlikely to benefit from the research. Consent forms were too difficult to understand, were changed without review and did not list the risks and discomfort associated with some tests.<sup>5</sup>

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## UNDERWRITING ISSUES FOR CLINICAL TRIALS

Before issuing coverage for an overseas clinical trial, insurance underwriters will want to determine the company's motive for conducting the trial in a foreign country and ensure that its procedures reflect best practices for patient protection. While the potential for loss cannot be eliminated entirely, biotech companies that manage their risks effectively improve their ability to minimize the impact and prevent a crisis from escalating.

Underwriters look for evidence

that a biotech has established good management practices, policies and procedures. A clinical trial must have proper protocols and controls in place to ensure that researchers follow it. Long-term follow-up of patients is a formidable challenge in overseas trials, but prudent biotechs should establish a monitoring system to identify potential chronic effects of the product after the trial ends.

Adequate informed consent forms are crucial in any clinical trial, but they raise special issues in trials performed in foreign countries. Informed consent forms must be written in a way that will be thoroughly understood, taking into account language, culture and literacy. An underwriter might ask what procedures researchers are using to ensure that subjects understand that their participation is voluntary as well as the potential risks and alternative treatments. The Centers for Disease Control Institutional Review Board has approved a generic short informed consent form for use with research subjects who do not read English.<sup>6</sup> The National Cancer Institute also provides a list of resources that provide information about protecting human research subjects.<sup>7</sup> These are good starting points for biotechs developing consent forms for overseas trials.

## CLINICAL TRIALS & INSURANCE ISSUES

Even as countries move toward harmonizing standards and practices for clinical trials, liability insurance remains a tangled web of requirements and obstacles. Only a few insurers are able to provide product liability insurance for clinical trials, and fewer still have the ability to issue coverage in multiple foreign jurisdictions.

Insurance should be part of the planning process for an overseas trial, as varying requirements could influence where a trial is conducted. Some

countries require dedicated limits of insurance for research subjects in their country. A large trial in a country that requires very high limits could exhaust most or all of the coverage that an insurer is willing or able to provide for any single drug or medical device.

Here are some of the insurance issues that biotechs conducting overseas trials may encounter.

#### **Admitted versus Non-Admitted.**

Some countries require “admitted” insurance, while others do not. An admitted policy is written and issued in the country by an insurer licensed to do business under local insurance laws. Coverage written on a “non-admitted” basis does not require the insurer to be licensed in that country, and the insurer is not subject to the same statutory requirements. The ability to use non-admitted coverage affords a trial sponsor greater flexibility. In these cases, clinical trials could be covered under a company’s global corporate casualty program. Insurance written on a “non-admitted” basis also allows the insurer more flexibility in the design of the policy and the coverage. The U.S., the United Kingdom, Australia, Brazil, Canada and Denmark are among the countries that do not mandate admitted insurance. Nevertheless, most countries where trials are conducted do require admitted coverage, and more and more countries are adopting that stance.

When a country requires admitted coverage, the biotech’s master global insurance policy would exist as excess coverage above the insurance policy underwritten in the specific location. Most master global policies also cover differences in conditions between the corporate policy and the local/admitted policy in effect in a specific country.

**Coverage Limits and Reporting Periods.** The minimum amount of coverage and other required policy provisions vary from country to country, and sponsors must take this into consideration when they decide where

to conduct a trial.

France, for example, requires sponsors to buy admitted coverage of 760,000 euros (U.S.\$816,687) per patient with an aggregate of 4.6 million euros (U.S.\$4.94 million) per protocol. Most insurers write product liability for drugs on a “claims made” basis, which means a claim is covered under the policy that is in effect at the time that the claim is submitted. Policies written on an “occurrence” basis, in contrast, allow claims to be covered under the policy in effect at the time of the injury. Most insurers do not write occurrence policies for drugs or other liability exposures that may not emerge for many years. France, however, requires that clinical trials policies provide for an extended 30-year reporting period. This means that a trial participant has 30 years to submit a claim based on an injury that occurred during the policy period. A standard U.S. policy might allow for reporting 60 days after the policy expires. Where it’s available, coverage for extended reporting periods can be costly. In the U.S., for example, insurers might charge up to 200% of the initial policy premium.

Spain requires that clinical trial sponsors obtain coverage worth 180,000 euros (U.S.\$194,151) per participant—on the surface far less than France demands. However, Spain does not provide an aggregate limit, so a study with 300 participants in Spain would require 54 million euros in coverage. It’s very unlikely that a combination of losses would approach those limits, but since insurance companies manage their maximum aggregate exposure to an emerging technology, most would be unable to provide that much coverage. Even if an insurance company had the capacity to provide that much coverage, many would have restrictions on how much insurance they are willing to write on any single drug or medical device. If an insurer’s capacity is exhausted in a country requiring high limits, the sponsor may be forced

to find an insurer in another country.

The requirements in France are certainly more typical, but the situation in Spain highlights the importance of thinking through insurance implications while planning a clinical trial. A biotech about to begin a large trial in Spain could experience costly delays because it’s unable to find adequate insurance coverage. If insurance had been considered earlier, the biotech might shift subject counts to other countries for a large trial.

Knowing the statutory insurance requirements is not enough. Even if a country does not have laws requiring a minimum amount of insurance for a clinical trial, ethics committees probably do. Sponsors must submit evidence of insurance to an ethics committee before they will approve a trial. If members of the ethics committee are uncomfortable with the amount of insurance obtained or demand admitted coverage the trial could be delayed.

## **OTHER EXPOSURES**

Human clinical trials represent the most challenging international exposure facing biotechs, but it is not the only exposure.

**Product Liability.** Product liability protects a biotechnology firm from losses associated with bodily injury resulting from use of a product in the marketplace. Unlike human clinical trial liability, product liability insurance is not compulsory. Biotechnology firms, therefore, are not typically obligated to piece together multiple policies to provide coverage in different parts of the world. Nevertheless, product liability insurance is a necessary ingredient in a prudent risk-management plan once regulatory authority to sell the product has been secured.

Many biotechnology and pharmaceutical companies receive regulatory approval to sell products overseas before they receive approval from the U.S. Food and Drug Administration. Most European policies provide

worldwide coverage excluding the U.S. and Canada. However, it is very possible that a U.S.-based company would be sued in the U.S. A U.S.-based firm should have a global master policy with global jurisdiction. This type of policy responds to claims brought in any country.

Many factors determine a company's product liability exposure in foreign countries. It's important to be aware of claim trends, average size of lawsuits, emerging legal issues and average verdicts. Unlike in the U.S., punitive damages are not often imposed in Europe and other foreign countries, so some policies may exclude them. This exclusion can be dangerous, however. As more countries import aspects of the U.S. legal system, punitive damages will become more common in litigation overseas.

**Property.** When it comes to a biotech operation, even a small amount of physical damage can result in a large financial loss. Why? Unlike other businesses that can make repairs and get back to work after a small fire or equipment failure, because of the risk of contamination, a biotech may face expensive delays awaiting recertification of its manufacturing process. This is as true overseas as it is in the U.S.

Indeed in many parts of the world, biotech facilities face greater risks and less adequate protection systems than facilities in the U.S. The water supply may be inadequate for fire suppression in some areas. Safety features taken for granted in facilities in the U.S.—fire detection systems, automatic sprinklers, central station alarms—are not

standard features in many countries. Where they are available, protection systems may not meet National Fire Protection Association standards.

Savvy biotech firms should take advantage of the loss-control and engineering expertise offered by global life science insurers. If biotechs communicate with their insurers about the facilities that they are buying or building, the insurer's loss-control engineers can help them assess protection systems and work with contractors to ensure the facilities meets the biotech's corporate protection standards.

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## ADVICE AND PARTNERSHIP

Biotechs that don't take these prudent risk-management steps expose themselves to devastating losses in the long term. In the short term, they may find it more difficult and more expensive to obtain adequate insurance.

A part of a growing global industry, biotech firms need to establish partnerships with brokers and insurers that know their business and their markets as well as they do. Of course, an insurance company is only as good as its ability to pay claims, so biotechs should ensure that their insurer receives high ratings from agencies like A.M. Best and Standard & Poor's, independent rating companies that assess financial strength and claims paying ability. Just as important is the company's claims philosophy. It's not hard to determine if a company has a reputation for paying claims swiftly and equitably.

It's unreasonable to expect a biotech firm to keep up with the changing insurance requirements of every country in which it wishes to do business or conduct trials. Instead, it should rely upon experts who have the capability to issue contracts globally, preferably through owned offices but also perhaps through affiliate relationships with foreign insurers.

## CONCLUSION

No company engaged in the risky enterprise of creating life-saving and life-enhancing treatments can be immune from potential losses. But with adequate risk-management practices and a specialized international insurance program, a biotech firm can prevent a manageable loss from becoming an entity-threatening disaster, thus allowing it to focus on bringing its product to market. JB&B

### ENDNOTES

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