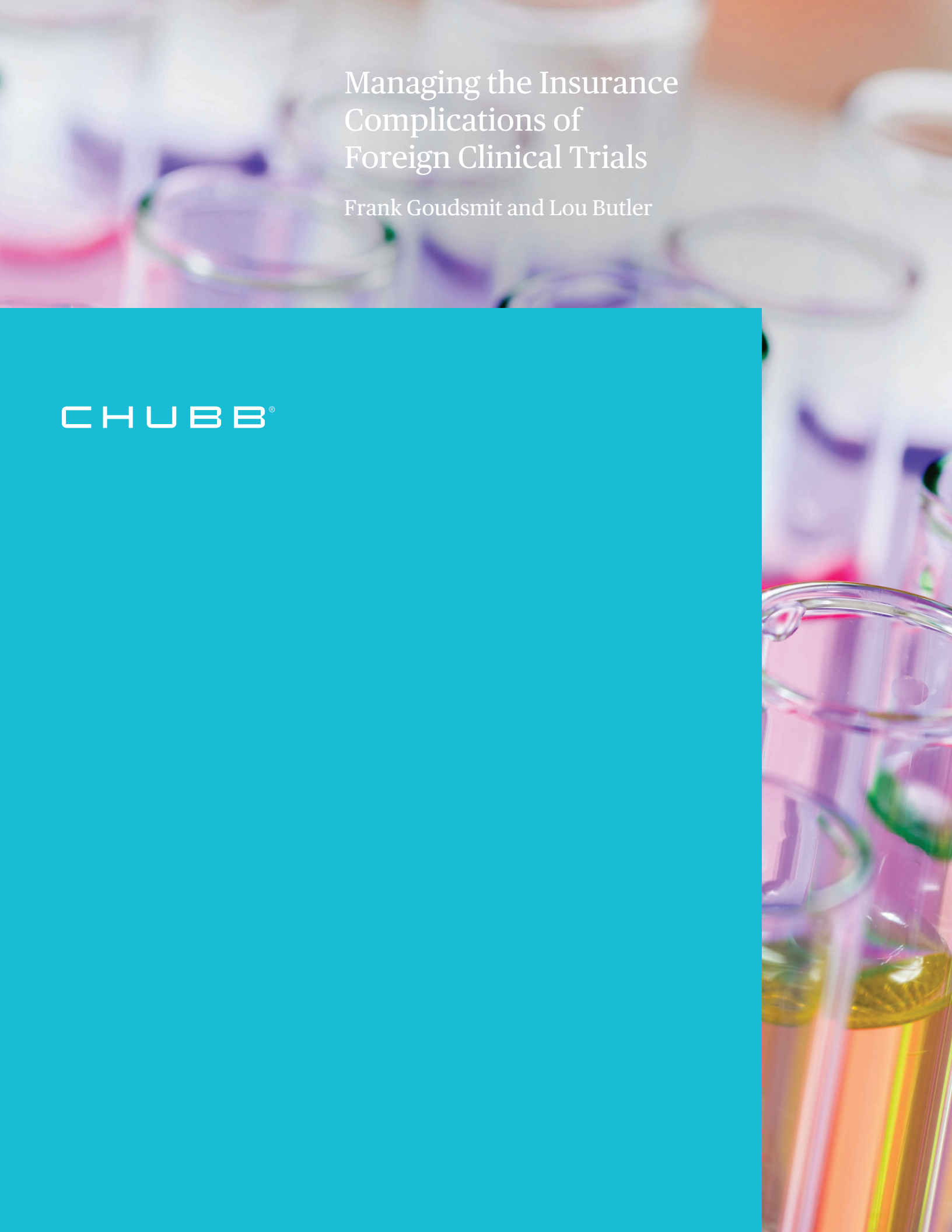

Managing the Insurance Complications of Foreign Clinical Trials

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Problems related to inadequate insurance coverage can lead to delays in clinical trials and costly setbacks in the approval process.

Companies often consider conducting clinical trials outside the United States for patient access, economic, research and regulatory reasons, but when making a decision about a location, it is crucial to factor in the potential insurance implications. Insurance laws vary significantly from country to country as do the insurance requirements for clinical trials.

Even the most diligent trial sponsor can make missteps when it comes to identifying and obtaining the appropriate insurance coverage in a given country. Sponsors may inadvertently violate local insurance laws, expose themselves to excessive liability, or unknowingly purchase insurance limits well beyond the requirements of a particular country. The consequences can be severe. Problems related to inadequate insurance coverage can delay clinical trials, resulting in costly setbacks in the approval process and shortened patent protection periods.

Because of the complexity presented by foreign clinical trials, sponsors should work with an insurer that has experience not only in the United States but also around the world, and that can compliantly provide local insurance and claims expertise in the specific countries where the trial will be conducted.

Risks of Clinical Trials Abroad

A variety of factors contribute to a decision to conduct trials abroad. The disease being studied may predominantly affect people in certain regions, such as sub-Saharan Africa or South Asia. Because of the widespread use of prescription medications in the United States, it may be difficult to find an adequate pool of treatment-naïve trial participants. Some nations require clinical trials to be conducted locally before a drug or device can be approved for sale in the country.

Economic considerations play a considerable role. Regions such as Eastern Europe or India offer high-quality hospital and medical facilities but the overall costs of studies are typically far lower than in the United States. All of these factors have led to a large number of studies being conducted outside the United States. Of the more than 38,000 studies listed as recruiting as of May 2016 by the U.S. National Institutes of Health, 54 percent were non-U.S. only, 40 percent were U.S. only, and 6 percent were both U.S. and non-U.S.[1]

For trial sponsors, a significant liability exposure is presented by the investigational drug or device being studied that could cause bodily injury. When clinical trials are held abroad, however, sponsors also need to consider the legal climate in a given country and the regulations governing the trials themselves as well as the insurance coverage and required limits of liability. For instance, the required limits can reach up to 6 million euros per patient in some EU nations, but are far lower in others.

Regardless of location, the trial must be conducted in accordance with applicable requirements set forth by one or more regulatory agencies, whether under national health authorities, the European Medicines Agency, or the U.S. Food and Drug Administration (FDA). FDA regulations, for instance, require hiring an investigator who reports to the agency on a regular basis and an institutional review board at the hospital to oversee the trial. In the European Union, a similar role is played by the ethics committee.

Besides the regulatory requirements for clinical trials, there may be differences in the laws governing the required insurance - and how those laws are interpreted in practice. The wording of the insurance policies may have to follow specific guidelines in a given region, but that

wording may be interpreted differently by regulatory bodies, the ethics committees, contract research organizations or site investigators. For example, whether extending reporting periods are required may depend on the drug or device being studied as well as the interpretation of the guidelines by the appropriate authorities. In such cases, the various parties or regulators may seek extended reporting periods where they are not specifically required by law. Agreeing to such terms could significantly increase the liability exposure for the trial sponsor.

Russia and many other countries also require that insurance policies be issued by a locally licensed or "admitted" insurer. That means that a company's U.S.-based policy may not be able to provide payment in case of a loss. In addition, the company may run the risk of tax violations. India, for instance, has been stringent in seeking to ensure that taxes are paid on claims involving losses in India, even if the claim is paid outside the country with a non-Indian policy.[2] Countries such as Italy require that claims be handled locally.

India also provides an example of how changing regulations can impact clinical trials. In 2013, India's Supreme Court ordered the central government to require that informed consent interviews be videotaped for all trial participants in the country, and the top court has taken an active interest in the government's process for approving trials.[3] India has also issued stricter liability rules for injuries or deaths that occur during a trial.[4]

Managing the Risk in Contracts and Informed Consent

Wherever a trial takes place, a key step in managing liability exposure is through the contractual agreements that the sponsor

reaches with the Contract Research Organization (CRO), with the investigator and the site. Contractual terms generally include a representation and warranty from the CROs that they have the expertise to run the study, the ability to recruit the appropriate test subjects and will be able to provide an institution of the requisite quality to host the trial. The contractual terms also cover the timing for the results and submissions to the FDA or other appropriate regulators.

It is critical that sponsors pay close attention to contractual wording so that they do not take on more liability than they intend, or agree to unnecessary or one-sided indemnification provisions. Sponsors should seek to make sure that the insurance limits being requested by the CROs are appropriate for the country in question and that medical malpractice coverage is provided where appropriate.

A critical part of the contractual arrangement is the informed consent form, which must demonstrate that the test subject has provided clear consent to participate in a trial of an experimental drug or device with full awareness of the inherent risks of participating. The consent form must be drafted in wording that the test subjects understand. The consent form and the risks of the trial should be explained in person to the test subjects; those discussions and signings should be witnessed. These steps are critical in reducing potential liability.

Local Claims and Regulatory Expertise

When it comes to handling claims in other countries, such as Eastern Europe, India or Africa, local expertise is critical. Difficulties can arise from cultural differences as easily as legal issues. In many countries, injuries that occur during a trial may become a liability for the trial sponsor even if the test subject was injured in an accident unrelated to the trial but which occurred at the test site. While there may not be a high number of claims in foreign clinical trials, the ones that do occur can be very expensive. To minimize the claims exposure, it is crucial to know the local legal procedures, to have relationships with local counsel, and to understand the cultural expectations. In countries with less litigious cultures, claims may be more readily settled.

An insurer that is experienced in providing coverage for clinical trials in countries around the world can help sponsors navigate the very complex issues that can arise.

Sponsors also need to understand the regulatory framework of the country where the trial will take place as it applies to both clinical trials and insurance. The failure to obtain the proper insurance can expose a sponsor to potentially significant product liability claims as well as severe liability in cases where there are lapses in the contractual informed consent procedures. Insufficient limits and improper policy language may lead to delays in starting a trial, or to having a trial shut down, which can cause significant delays in obtaining approvals and in bringing the new product to market.

Navigating Complex Risks

The risks associated with clinical trials differ significantly from one country to the next, and the exposures may be far greater in one country than another. An insurer that is experienced in providing coverage for clinical trials in countries around the world can help sponsors navigate the very complex issues that can arise. The carrier should have experience not only globally but also in the country where the trials will take place.

An insurer that has established relationships with local counsel can help mitigate the claims exposure and make sure that claims are handled in the most appropriate way. Because of the potential for significant claims, sponsors should look to work with a carrier that is recognized for its financial strength.

Conducting clinical trials abroad may often be the best option, but sponsors should recognize that obtaining the right insurance coverage is a critical part of a prudent risk management strategy for the development process.

About the Authors

Frank Goudsmit, CPCU, is Senior Vice President and a 28-year veteran underwriter with Chubb Life Sciences, who has several decades of experience in developing global clinical trial liability insurance solutions for Life Sciences companies. Mr. Goudsmit has collaborated on the development of insurance policy wordings, and has helped clinical trial sponsors benchmark themselves against, and implement, best practice risk management controls. He has been a frequent speaker on clinical trial insurance issues such as clinical trial risk mitigation, compensation guidelines and compulsory insurance requirements.

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Endnotes:

1. Trends, charts and maps, Clinical Trials.gov, data as of May, 2016. See: https://clinicaltrials.gov/ct2/resources/trends
2. India to tax Adidas insurance claim, Wall Street Journal, March 23, 2011. See: http://online.wsj.com/news/articles/SB10001424052748704050204576218132454647812?mg=reno64-wsj
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