

Insurance Times: Biotech insurers confront rising clinical trial exposure

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"Inadequate informed consent forms, improper recruitment of test subjects and potential conflicts of interest between clinical investigators and business partners leave many U.S. and Canadian biotechnology companies exposed to clinical trials litigation," warns a life sciences specialist with the Chubb Group of Insurance Companies.

"Clinical trials litigation has become a thorny issue, which I fear will grow at an alarming rate as more trials get under way over the next few years," said Frank Goudsmit, a life sciences underwriting manager at Chubb & Son, who will chair a panel discussion on the issue at the upcoming BIO 2002 conference in Toronto. "High-profile deaths, including an 18-year-old who died during a gene-therapy experiment at the University of Pennsylvania and a healthy 24-year-old who died during an asthma study at Johns Hopkins University, have garnered a great deal of media coverage. Many other cases are not publicized and are settled privately. If the biotechnology industry is going to thrive, clinical investigators must take greater steps to reduce the potential for litigation."

A survey conducted earlier this year by CenterWatch, a patient information group that monitors clinical research, revealed that 30 percent of volunteers did not understand their study could carry additional risks and discomforts, and 70 percent didn't know what questions to ask at the outset of the informed consent process. "The burden is on the clinical investigator to be sure that the participant fully understands the informed consent form. This can be done by 'testing' a volunteer's understanding of the form to uncover any weaknesses in the process," said Goudsmit.

Recruiting volunteers for trials can pose potential risks to the clinical investigator who is anxious to begin the study, Goudsmit added. Clinical investigators should be cautious in their use of financial incentives that attract volunteers who may "hide" critical health history that could negatively impact the outcome of a clinical trial. Use of patient databases to recruit subjects may lead some patient/volunteers to believe their physician is "prescribing" a clinical trial as part of their treatment.

Conflicts of interest between a clinical investigator and business partners can also lead to litigation. In some cases, the trial sponsor and the clinical investigator may even be part of the same company.

"There is tremendous pressure on the clinical investigator to run a successful clinical trial and bring a new drug to market as quickly as possible," said Goudsmit. "In their zeal to meet these pressures, clinical investigators may inadvertently overlook safety procedures or critical data. Select types of work may be subcontracted out, such as the recruitment of volunteers, and the clinical investigator may lose some control over the process." Clinical investigators can help avoid some of these pressures by hiring staff with specialty and patient group experience. Workload demand assessments also should be performed regularly. Other ways in which clinical investigators can reduce the potential for litigation include:

- All informed consent documents should meet readability testing standards for a sixth grade reading level.
- Financial disclosures, indicating a potential conflict of interest, should be revealed in the informed consent documents.
- Clinical investigators should carefully review all changes to the informed consent form made by the institutional review board to ensure that critical information has not been inadvertently omitted.

"Even as clinical investigators cope with the mounting pressures of finding the next blockbuster drug, ensuring patient safety has become a top priority for the biotechnology industry," said Goudsmit.

"Adopting a strong risk management philosophy and implementing these and other specific measures can greatly help reduce exposure to clinical trials litigation."