Clinical Trials and Tribulations
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My hunch is that every P&T committee member can easily recall an instance in which a previously congenial relationship between an investigator and his or her pharmaceutical company trial sponsor soured for reasons that, over time, became murky. For myriad reasons, clinical trials do not always meet their milestones in terms of recruitment of patients, reporting of data, adequate handling of unanticipated adverse drug events, or related goals. When milestones are not met, tongues wag and fingers are pointed at others.

Earlier this year, the Association of American Medical Colleges (AAMC) released a report, entitled Clinical Trial Contracts: A Discussion of Four Selected Provisions,1 that summarized the deliberations of a blue ribbon advisory panel of national experts. Regrettably, Pharmaceutical Research and Manufacturers of America (PhRMA), an original participant in the discussions about the report, did not endorse the final wording, but I find that the report itself offers some sound advice to all parties involved in clinical trial contracting. I will briefly comment on each of the report’s four selected provisions in turn.

The first of the four selected provisions concerns intellectual property rights emanating from clinical trials. I cannot detail every aspect of the advisory board findings; however, the experts recommend clinical trial contracting that explicitly addresses “the scope of the definition of inventions and the disclosure of said inventions or improvements.”1 The report calls for an explicit discussion of the ownership of a serendipitous discovery made in the course of following clinical trial protocols. Various stakeholders may find the sample contract language provided in the body of the report to be extremely helpful.

The second provision comments on policies for the publication of the results from clinical trials. In general terms, the advisory board reiterates that academic institutions cannot accept contract language that restricts publication in any way:

Publication is necessary for the academic institution to fulfill its academic mission and disseminate the fruits of research. Research integrity is the cornerstone of the academic endeavor, and academic institutions must demonstrate that research is being conducted in an unbiased manner irrespective of the funding source.1

It is interesting that the advisory board endorses all of the uniform standards for manuscripts submitted to biomedical journals developed by the International Committee of Medical Journal Editors. These so-called uniform standards go a long way toward protecting all parties involved in the design, construction, and publication process for clinical trials. PhRMA, in contrast, noted the following:

“As owners of the study database, sponsors have discretion to determine who will have access to the database.”

The advisory board wants all contract language to reflect the fact that researchers should have free access to the data and should be able to analyze the data independently and to prepare manuscripts and publish them without fear of restriction.

The third provision regarding indemnification is similarly unambiguous. The advisory board recommends that contract language explicitly identify whom the sponsor indemnifies and holds harmless and says that exceptions to this indemnification should be enumerated. I consider the sample contract language offered in section 3 to be of value.

In the final provision, “Medical Care of an Adverse Consequence,” the advisory board strongly suggests the following:

- The contract should contain a prohibition against billing a patient’s insurer.
- Financial responsibility for payment to trial participants for treatment resulting from an injury or illness suffered in the course of the trial should rest solely with the sponsor.
- Sponsors should not place dollar caps on medical treatment amounts.

This explicit assignment of responsibility is laudable and, again, sample contract language provided in the report is helpful.

I am not naive enough to believe that a blue ribbon panel from the AAMC will be able to solve all of the challenges inherent in the conduct of complex clinical trials, but I do believe that this document goes a long way toward providing good solid common sense with accompanying legal language for all of the concerned stakeholders. I urge P&T committee members who are directly involved in clinical trials or who supervise their content to carefully review the AAMC report. We should all strive for clinical trials without tribulation.

As usual, I am interested in your views. You can reach me at my e-mail address, david.nash@jefferson.edu.

REFERENCE

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