



# STREAMLINING CLINICAL TRIAL AGREEMENT NEGOTIATIONS

by Norman M. Goldfarb

When a pharmaceutical enters clinical (human) testing, the pharmaceutical company (the “sponsor”) contracts with physicians (“investigators”) at hospitals, clinics, and offices (“sites”) to conduct the research (“clinical trials”), using a contract called a “clinical trial agreement.” Clinical trial agreements cover numerous topics such as the duties of each party, payment amounts and terms, confidentiality, ownership of any inventions, publication rights, and financial responsibility if a subject in the trial is injured. Like any contract, the devil is in the details, with potentially huge financial gains and, especially, losses turning on the choice of a few words.

In most other industries, the supplier provides a draft contract to the customer, but in clinical research, the customer almost always provides it to the supplier. Although these draft contracts generally cover most of the same topics, the specific terms and wording vary substantially, placing the burden

on sites to understand and negotiate often-critical fine points. Major universities employ attorneys and contract professionals to read and negotiate these contracts, but over two-thirds of the research now is done outside academia, mostly at sites without the necessary skilled negotiators.

As a result, it takes, on average, 35 days for community-based investigative sites to negotiate clinical trial agreements, and 96 days for academic medical centers.<sup>1</sup> More investigative sites attribute study delays to contract and budget negotiations than to subject enrollment.<sup>2</sup> Over 50% of investigators say that the terms and structure of clinical trial agreements are not fair

or equitable. Almost half associate the feeling of fear or suspicion with budget negotiations.<sup>3</sup> These are remarkable statistics, given that contract negotiations cost pharmaceutical companies an average of more than \$1 million per day in lost revenue.

In 2004, the Association of the British Pharmaceutical Industry addressed this problem by negotiating a very successful model clinical trial agreement with the National Health Service (NHS) Trusts, the umbrella organization for most investigative sites in the United Kingdom.<sup>4</sup> This success was not the result of creative new approaches to difficult terms, just some reasonable compromises. Most of the model

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agreement required no compromises at all, just agreement on how to draft the many noncontroversial sections.

One example of a compromise is as follows:

The NHS Trust agrees that all reasonable comments made by the Sponsor in relation to a proposed publication by the NHS Trust will be incorporated by the NHS Trust into the publication.

Many academic institutions in the United States would object to this language because it may impinge on academic freedom and the institution's public mission and tax-exempt status. Notice, however, that the arbiter of what is a "reasonable" comment is left undefined. In practice, it is the author of a paper who decides, leaving the sponsor with the option of requesting a restraining order from a court (and finding other investigators for future studies).

In the United States, over 250 sites, sponsors, and contract research organizations (CROs) have joined together in

the Model Agreement Group Initiative (MAGI). MAGI is close to finishing the first edition of a flexible "multiple-choice" model clinical trial agreement to streamline negotiations both in the United States and internationally. Currently, there are representatives from over two-thirds of the *U.S. News & World Report's* Top-50 Research Medical Schools and Honor Roll hospitals, the four largest pharmaceutical companies, and the nine largest CROs. Membership in MAGI is free and there is no obligation to use the resulting model agreement.

MAGI members help draft one or more of 100+ sections of the model agreement. All members may then review and comment on the drafts. Each new member also may suggest improvements, so the model agreement will evolve over time. The multiple-choice architecture makes it easy to incorporate new alternatives, including state- and country-specific versions. An accompanying commentary explains their pros and cons. Even if a sponsor does not adopt MAGI language for its contract template, the language and

commentary are available for counter-proposals from sites, as well as education of all parties.

MAGI also publishes an eNewsletter, co-manages a biannual educational conference, and offers professional Clinical Research Contract Professional (CRCP) certification.<sup>5</sup>

MAGI members are optimistic that this initiative will succeed where prior efforts have failed because of its "big tent" and "multiple choice" strategies. Given the huge challenges faced by the pharmaceutical industry, it no longer can afford the luxury of wasting so much time and so many resources on negotiating clinical trial agreements. Most investigators, however, have an alternative—over the past three years, the number of active investigators in the United States has declined by 11%. ▲

<sup>1</sup> Adam Chasse, *Overcoming Contracting Challenges in Clinical Research*, Address at the Drug Information Association Annual Meeting (2003).

<sup>2</sup> *U.S. Site Survey*, THE CENTERWATCH MONTHLY, May 2002.

<sup>3</sup> RapidTrials Industry Survey, 2003, available at [www.rapidtrials.com/news.jsp](http://www.rapidtrials.com/news.jsp) (last visited May 22, 2005).

<sup>4</sup> Available at [www.abpi.org.uk/publications/pdfs/guid-ancemodelcta\\_final\\_.pdf](http://www.abpi.org.uk/publications/pdfs/guid-ancemodelcta_final_.pdf) (last visited May 22, 2005).

<sup>5</sup> More information available at [www.firstclinical.com/magi](http://www.firstclinical.com/magi) (last visited May 22, 2005).

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