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Under Contract

In the US, there is no common approach to intellectual property provisions in clinical trial agreements – meaning contract negotiations between sponsors and sites can be frustrating, hurried and costly to resolve. This look at four issues can help sponsors get more clued up

Blaine Templeman, Kristen Riemenschneider and Amy Ryan at Arnold & Porter LLP

While standardisation of clinical trial agreements (CTAs) is common in some jurisdictions – take, for instance, the widespread use in the UK of forms developed by the Association of the British Pharmaceutical Industry – such uniformity is only an aspiration in the US.

Most non-US sponsors that wish to conduct trials in America will carefully build a template for their study, or accept a form from the clinical trial organisation or their law firm, only to send the chosen form out to several sites and discover two things. Firstly, there are several issues that sites in the US address in a mostly uniform fashion – financial disclosure obligations, representations and warranties, consent documentation provisions, indemnification and insurance. Secondly, there exists no common approach to intellectual property (IP) provisions in CTAs, such as retained rights in data, definition of inventions, and matters relating to the disclosure and prosecution of inventions.

The variety of comments with regard to these provisions can be perplexing for the sponsor, and the process for resolving them costly. Often, this process begins with frustration, followed by a rush to the finish in the hope of getting all sites up and running so the trial can move forward. What starts as a thoughtful endeavour can soon become a hurried attempt to get the best deal that can be completed quickly – all the while with each side comforting itself with the thought that these contracts are not commonly subject to litigation.

To demystify some of the comments that sponsors may encounter when negotiating CTAs with US trial sites, the following IP issues and possible solutions can be considered.

Issue 1: Data Ownership

In the vast majority of cases, a clinical site will agree to permit the sponsor to own the clinical data. Note that this

point does not apply to studies performed by units of the US Government, such as the Department of Veterans Affairs or the National Institutes of Health. Contracts with the US Government present their own unique set of issues, which are not addressed here.

The disposition and ownership of study data should generally be straightforward. Recently, however, there has been a trend in clinical sites proposing language whereby the site retains the right to use data for "patient care". There is generally no explanation of what the clause might mean.

Three possible interpretations come to mind. A clinical research site may:

a) Want to use the data collected on a specific study subject during a trial for the ongoing treatment of that patient
b) Be concerned that an investigator may utilise the knowledge he or she has learned as part of the study, and the site may want to be sure it has the right to continue to use that knowledge
c) Ask to use the aggregated unanalysed data from its site in order to make overall treatment decisions for its patients

When discussing this issue with several clinical sites, there seemed to be uncertainty as to the purpose of the request. Nevertheless, even though there appeared to be a lack of clarity of purpose, the request continued to be made.

Proposed Resolution
With respect to option 'a' above, the proposed use is permissible, but wholly outside the control of the sponsor – so it does not really need to be addressed in the CTA. The health records of the subject will include information from procedures and tests performed on the patient, so the attending physician will have access to that information.

Option 'b' is not really something a sponsor can address. A doctor in the US has wide latitude to exercise his or her medical judgement, which will necessarily include certain information based on knowledge acquired during a trial. A sponsor is not in a position to change that reality.

The final option, 'c', remains a concern. Study data from a single site should not be used for making overall treatment decisions. Language should be used which clarifies that, even if the site retains the right to use data for "patient care", the sponsor is not responsible for the site's use of study data for that purpose.

Issue 2: Inventions Contemplated by the Protocol

Sponsor CTA templates commonly propose that the sponsor owns all IP arising from the clinical study or relating to the drug being tested. Clinical sites have become increasingly concerned about the breadth of this sort of language. Often, the site will express legitimate concerns about how to parse IP generated by an investigator who might have multiple practices: research, private practice, instructor and investigator for multiple trials.

In addition, over the past few years, a comment has been raised by some clinical sites that have become particularly attentive to the potential value of new uses of a study article that might be discovered during a trial as a result of clinical observation. This issue often confounds site contracting officers when it is raised, as it seems unrelated to the subject at hand – carrying out a very specific clinical trial – and most compounds have multiple uses. However, no sponsor intends to give away new, unanticipated uses of its compound in exchange for the conduct of a trial.

Several sites have proposed language to address this as follows: "Let the sponsor own inventions contemplated by the protocol." Another version of the language requires joint ownership by the clinical site and the sponsor of inventions not contemplated by the protocol.

These proposals are troubling on a few levels. Firstly, it seems obvious that the protocol should not be thought of as a tool that contemplates inventions. The protocol is a clinical document that sets out how the study is to be conducted; one of its primary functions is to ensure the safety of participants, not to be a means to assess invention ownership. Secondly, it seems unlikely that an invention could be novel or non-obvious if the invention is contemplated in a clinical study protocol.

So, the basis for acknowledging inventions in a protocol seems to be undermined by the proposed language itself. In addition, agreeing in advance to joint ownership of new inventions can present issues down the road if one or both parties want to commercialise the new IP or enforce it against a third party.

Proposed Resolution
US sponsors and clinical sites might take a cue from the UK, which gives sponsors ownership of "all intellectual property rights and know-how arising from and relating to the clinical

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trial, the investigational medicinal product (including but not limited to its formulation and use alone or in combination with other drugs)".

Things should be kept simple. A sponsor should reasonably expect to own inventions arising from a trial related to the study or the study product and its uses (whether alone or in combination). However, this may sometimes prove a difficult point to win. Consider two other formulations, in which the sponsor could own all:

- Inventions arising from the performance of the trial in accordance with the protocol
- Inventions arising from the study that relate, or are specific, to the drug and its uses (whether alone or in combination, or if a component of another product)

Issue 3: Invention Disclosure in Options

Sometimes, a clinical site will only agree to offer a sponsor an option to some or all inventions. There can be many reasons for this approach – a site may have a policy of not granting rights to inventions that have not yet been developed; or may have received funding from a public bond issuance, and the terms of the bonds may not permit grants of invention ownership at less than current market value at the time of discovery. While this might not be the sort of provision a sponsor is comfortable with, it may agree to an option for some inventions if necessary, in order to ensure the site's participation in a trial.

If an option is contemplated, the mechanism for invention disclosure becomes very important. Some clinical sites will include provisions on invention disclosure that tie the inventions available for license to those deemed patentable as part of the site's disclosure process. The sponsor must carefully consider the implications. Determination of patentability is not the only measure of value for an invention; the sponsor should seek a broader disclosure of potential inventions that might fall under the option.

Proposed Resolution

Sponsors and clinical sites should agree to work together to decide whether an invention has arisen during a trial, and should include language in the CTA which contemplates that process. In most cases, the sponsor understands its proprietary technology better than anyone and will be in the best position to determine whether there is an invention, so should not be left out of the process. The sponsor may want to include language in the CTA requiring the site to report developments on a regular basis, regardless of whether those developments meet the site's definition of an "invention".

Issue 4: Prosecution of New IP

This commonly arises with regard to the patenting of new inventions. Firstly, neither party should assume that pursuing a patent is the best and only path to protect an invention. In many cases, it is preferable for a party to hold a new development as a trade secret, such as the optimisation of a manufacturing process. However, if a CTA includes an option, then some form CTAs will include boilerplate language requiring the sponsor to seek patent protection for new inventions, or forfeit the rights to them. This may be undesirable for a sponsor that wishes, for valid business reasons, to hold the invention as a trade secret.

Proposed Resolution

If trade secret protection is important to the sponsor, it should include language in options that permit it to seek a license, even if it does not secure patent protection for the invention. One mechanism for doing so in the US is to draft and file a provisional patent application – giving the invention a definitive date, time and scope – but then refrain from filing a non-provisional patent application. A carve-out can be added to the CTA stating that the site would not obtain title or second prosecution rights if the sponsor provides a reasonable basis for its decision not to continue prosecution.

About the authors

Blaine Templeman is a Partner in Arnold & Porter LLP's New York office, and a member of the firm's Corporate & Securities and Intellectual Property groups, as well as its Life Sciences team. His practice focuses on counselling US and international clients in the protection, development and commercialisation of their products and IP portfolios through domestic and cross-border collaborations, licensing, asset purchases, mergers and acquisitions, contract manufacturing and distribution, clinical trials, services agreements, sponsored research and outsourcing.

Email: blaine.templeman@aporter.com

Kristen Riemenschneider is Counsel in Arnold & Porter LLP's Intellectual Property and Government Contracts practice groups. Based in the firm's Washington, DC office, she covers a broad range of legal issues facing technology, biotech and pharma companies, including federal government contractors. Kristen is a registered patent attorney.

Email: kristen.riemenschneider@aporter.com

Amy Ryan is Counsel in Arnold & Porter LLP's Washington, DC office. A member of the firm's Intellectual Property practice group, she specialises in technology-related transactions. Amy regularly assists clients with drafting and negotiating a broad range of contracts for the commercialisation and protection of IP and technology.

Email: amy.ryan@aporter.com