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Part 3: Protecting your future Intellectual Property

In part 2 of our series, we introduced a growing and ongoing concern arising from transatlantic clinical trial administration and utilization of data under the General Data Protection Regulation (GDPR), which governs the processing of personal data, including that of clinical trial data subjects and the personnel involved. You can find that article here. In this next part of our series, we explore another complexity of clinical trial contracting: intellectual property provisions.

Who Owns What, When?

Pharmaceutical companies ("Sponsors") and clinical trial sites have an interest in claiming ownership of certain intellectual property, and rights thereto, which may arise from the conduct of a clinical trial. In general, intellectual property provisions in a clinical trial agreement ("CTA") for a Sponsor-initiated study will (i) identify the scope of a discovery, development or invention that the Sponsor wishes to claim intellectual property rights to, and (ii) include assignment language to ensure that all intellectual property rights and interest to that development or invention immediately vest on the Sponsor. The latter is the focus of this article.

As intellectual property laws in the United States dictate that ownership rights initially vest on the original creator or inventor, a third-party can only acquire intellectual property rights if, absent special circumstances or exceptions, the original creator contractually assigns all rights and interest in the development or invention to that third-party (assuming said rights have not been previously assigned elsewhere).

An assignment can include intellectual property rights to developments or inventions that have already been created or that may be created in the future. That said, for an assignment to be effective at the time that it is made (that is, for the rights to existing or future inventions to immediately vest), very specific words (i.e., "*hereby assign* … all right, title and interest …") of assignment must be used. If the words used merely affirm someone's agreement to assign, such as "hereby *agrees to* assign…," then the assignment is not effective and no intellectual property rights vest at that time. Instead, all we'll have is a promise to assign certain rights sometime in the future.

In the context of clinical trials, Sponsors will require all intellectual property rights to any new developments arising from the study to vest at the time the CTA is signed. However, many clinical trial sites – indeed often entire university systems – will argue against the use of the magic words "hereby assign" and will only offer a promise to assign.

Why Do Sponsors and Clinical Trial Sites Care?

Sponsors seek a return on their investment and will naturally want to secure the rights to any new development that is related to a drug or a protocol Sponsor spent time, money, and effort to develop. A present assignment of intellectual property rights, that is made by the correct individual or entity, will secure just that. Conversely, a promise to assign in the future does not guarantee any rights and opens the door to potential ownership disputes with third parties. Case law that is well-known in the pharmaceutical industry supports this concern. A clinical trial site or an investigator can certainly assign intellectual property rights to someone else after the signing of the CTA with the Sponsor and before the promise to assign, included in that CTA, is made effective. If that were to happen, the Sponsor may have an action for breach of contract –yes; however, the intellectual property rights are lost. Still, some clinical trial sites will insist that present assignment of intellectual property rights to an invention that may be developed in the future is disallowed.

Clinical trial sites often offer various reasons for their stance against present assignment. Cited reasons include: (1) present assignment risks tax exempt status; (2) a different office within the institution is the only one with authority to assign intellectual property; (3) site cannot assess the value of impacted rights; or (4) it is against policy. When faced with this situation, as a Sponsor or CRO it will be critical to analyze the issues on a site-by-site basis, be prepared to ask the right questions, and assess the potential risks taking into account the specific protocol, study drug, and the potential for new developments. While there are also other important factors to consider, such as the relationship between the investigator or other study personnel with the clinical trial site; who is signing the CTA as a party; how the party assigning intellectual property rights acquired those rights in the first place, etc., spotting the difference between "hereby assigns" and "agrees to assign" language and navigating negotiations with clinical trial sites may be critical to securing intellectual property rights to future novel discoveries.

If as a Sponsor, CRO, or industry professional, you run into the issues raised in this article and want to talk about our experience navigating intellectual property provisions, let us know. This article scratches the surface in terms of the risk-balancing and arguments for and against the present assignment of intellectual property rights in future developments or inventions. ICE Global Consulting's team of attorneys and experienced global negotiators work with Sponsors, CROs, and sites to resolve these issues unique to clinical trial agreements every day. If you want to discuss these issues or learn how we can help you navigate negotiations, we encourage you to contact us at info@iceglobalconsulting.com and visit our website at www.iceglobalconsulting.com.