

IP Considerations for Naming Clinical Trials

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With hundreds of thousands of clinical trials being conducted worldwide on an annual basis, creating a unique name for a new trial can prove almost impossible. When even a brief internet search can return multiple trials sharing the same name, it can be tempting to follow suit and settle on a name regardless of overlap. But there might be confusion when clinical trials share similar names — in the worst-case scenario, it places the sponsor at risk for trademark infringement and/or violations of unfair competition laws.

Therefore, it's essential to conduct a comprehensive legal evaluation prior to naming any clinical trial. Below is a recommended step-by-step guide on how to evaluate a proposed clinical trial name to reduce potential liability exposure and avoid inadvertent legal violations.

1. Search Internet Databases

A search in any of the major internet search engines is the fastest, most cost-effective way to begin assessing a trial name's viability. In order to gain an understanding of what already exists in this space, the search should begin broadly, and gradually narrow in scope. At a minimum, it should be run with a combination of keywords consisting of the proposed trial name with 1) the relevant field of science and, separately, 2) the term "clinical trial."

2. Cross-Reference Clinical Trial Databases

Even if search engines do not produce relevant results, it doesn't mean you are out of the woods. Regardless of whether the preliminary internet search has been cleared, it's important to also conduct a worldwide search of applicable clinical trial databases. Several such resources to consider include:

- <https://clinicaltrials.gov/>
- <https://ichgcp.net/clinical-trials-registry/>
- <https://www.ncbi.nlm.nih.gov/guide/>

During this search, a sponsor's legal counsel should check for acronyms and similarly named trials (think plural versions of words, or spelling and phonetic variants). This procedure is identical to one that would be adopted for standard trademark clearance searching.

To the extent that any similar names are found, either in the internet or database search, the sponsor's legal counsel should conduct a risk assessment of the potential trademark/unfair competition violations, as further described in Step 3 below.

3. Conduct a Trademark Clearance Search

If both internet and clinical trial searches return minimal or acceptable levels of risk, the sponsor should then proceed with a trademark clearance search for the proposed clinical trial name, in addition to running a search for any associated acronym. Legal counsel should conduct this search on a global basis, and the search should not be limited to the country where the trial is being conducted. In all cases, it is essential to consider results from the World Intellectual Property Organization's registration system, the Madrid Protocol.

To the extent that there are any hits for similarly named registered trademarks, the similarities with the proposed clinical trial name should be assessed by the sponsor's legal counsel pursuant to the applicable country's trademark laws, and should be inclusive of the risk assessment below.

4. Conduct a Risk Assessment of Likelihood of Confusion

At each of the outlined steps above, it is essential to keep risk assessment in mind. A risk evaluation can help determine if there are sufficient differences — generally considering overall name, medical indication, location, and scope — between the two clinical trials to avoid the possibility of confusion. If the proposed clinical trial name creates confusion with another existing clinical trial and/or is widely recognized, there could be claims for trademark infringement or unfair competition violations. In cases where there are high risks of conflict, it is prudent to choose an alternative name for the study to avoid trademark infringement.

Therefore, any relevant search result can be assessed by legal counsel for risk level, taking into account trademark law and other risk mitigation principles, including the following:

- *Compare Clinical Trial Details.* Any similarly named, existing clinical trials should be evaluated for their indications or purpose, location, and size. For example, if the existing trial only had 50 patients in another country, and was related to heart disease, it may be less likely to create confusion with the proposed clinical trial, if the proposed trial is on a larger scale in the U.S., and is related to brain cancer.
- *Identify Goods and Services Category.* For registered trademarks in the U.S., this would include an assessment of whether the proposed clinical trial is in the same goods or services category as the similarly named registered trademark. For example, for searches run through the U.S. Patent and Trademark Office (USPTO), there could be likelihood of confusion between the two names if the similarly named registered trademark is in one of the following classes of goods and services: 005 Pharmaceuticals; 010 Medical Devices; 035 Clinical Trial Management 042 Medical and Scientific Research, namely Clinical Trials; and 044 Clinical Trial Analysis.
- *Identify the Sponsor.* For any similarly named, existing clinical trial, it is crucial to identify the sponsor of the clinical study. Depending on the results of the internet search and comparison of the clinical trial details, it may

be prudent to seek consent from the applicable sponsor to use the name. This would proactively avoid potential issues down the road.

When choosing a clinical trial name, potential infringement of intellectual property is generally not one of the first hurdles that come to mind. The associated dangers are very real though, and a sponsor should be mindful of taking proactive steps to minimize these risks before a clinical trial begins in earnest.

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