The International Clinical Trials Roadmap: Steering Clear of Legal and Practical Roadblocks

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ABSTRACT: The conduct of clinical trials abroad by U.S. academic institutions and the pharmaceutical and medical device industries has become increasingly commonplace. Despite the frequency of such clinical trials, their conduct is hardly a routine matter. Academic institutions and industry continue to encounter numerous legal and practical challenges in implementing clinical trials abroad successfully. This article responds to the ongoing need for a resource focused on identifying, explaining, and addressing the complex challenges inherent in the conduct of clinical trials abroad. It provides an overview of the key legal and practical issues that U.S. academic institutions and industry may face when conducting clinical trials abroad, highlights the significant controversies or concerns raised by those legal and practical issues, suggests approaches to tackling those issues, and identifies relevant resources for further information and guidance.


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This article was prepared with the assistance of Hannah H. Freeman, an associate with Ropes & Gray LLP.
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