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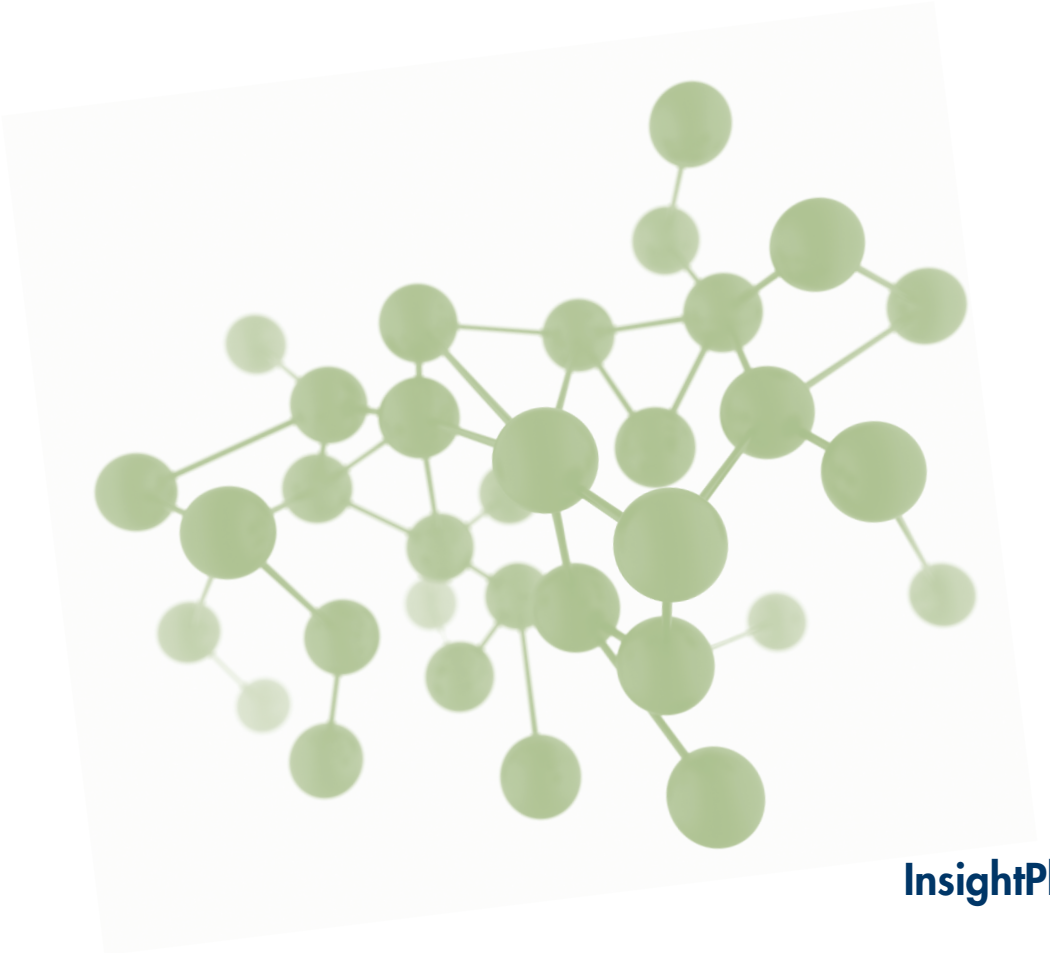
Outsourcing Preclinical Studies to China:

Benefits and Challenges

Eric A. Meyers, MBA



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Benefits and Challenges

by Eric A. Meyers, MBA

About the Author

Eric A. Meyers, MBA, is a consultant to the drug development and medical device industries. His 20 years in the healthcare industry includes senior management positions with Fortune 50 companies and successful startups. Mr. Meyers is a recognized expert in drug development sectors in China and India, leading projects to assist both small and large pharmaceutical companies with their Asia drug development strategies. Mr. Meyers received both an MBA and a B.A. from Harvard University.

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Executive Summary

Within the past several years in China, a number of state-owned labs as well as private and joint venture CRO's have or will soon offer preclinical GLP study services to Western clients. This report, built on discussions, facility visits, and in many cases study monitoring and/or auditing at the most advanced labs, provides a detailed view of the current and evolving preclinical study capabilities in China, their structures and services as well as an analysis of the comparative costs between US and China-based CRO's.

This report reviews the state of preclinical study services in China to identify the current level and near term trends for compliance with Western GLP standards. Competition to supply CRO services is beginning to cause consolidation and attrition within China. A small number of key preclinical service providers, identified and profiled in this report, have emerged as strong CRO providers. A detailed cost comparison between China and US-based CRO's and a detailed case study analysis shows that study savings of between 35–50% are achievable and that these saving are likely to continue through 2012 and beyond. However, as the report details, a series of cultural, language, training and operational issues impact the approach one takes to evaluating and managing preclinical studies when using a China-based CRO. Western companies with and without operations in China have developed successful approaches to conducting preclinical trials in China. The report describes several approaches companies have taken to address such issues.

The cost savings associated with using CRO preclinical services in China are discussed in this report in the context of organizational and operational differences between CRO's based in the West and in China. A number of factors are presented that study sponsors must consider before committing to a Chinese CRO. Small and medium companies can make their preclinical studies budget go further by using China-

based CRO's through appropriate due diligence and upfront project planning. FDA and EU regulators have accepted preclinical data generated by China-based CRO's as described in the report and the FDA has begun to build a resident inspector network in China.

This report describes the impact of language skills and the shortages of key disciplines have on what studies and how best to structure preclinical studies in China. Also evaluated are the broad issues such as IP protection and CRO ownership as well as laboratory animal rights regulations. CRO's in China have access to large NHP breeding facilities and offer a clear advantage to those companies planning NHP studies. The report also discusses the several Western laboratory mice, rat and beagle dog vendors and well as lab animal feed providers operating in China.

The report presents an analysis of the current and near term state of preclinical services available in China beginning with a short introduction to the evolution of preclinical services as well as a background description of the three laboratory ownership categories. Chapter 2 describes the differences in organizational and operational structures, business practices as well as personnel storages and infrastructure issues that impact the choices available to Western companies. Chapter 3 provides a cost comparison and a case study comparing preclinical study cost between the US and China. Chapter 4 provides a discussion of possible caveats and due diligence factors to be considered when considering placing a preclinical study in China. Chapter 5 provides profiles covering operations, facilities and services of the eleven most advanced CRO's in China.

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