



## Case Study

*Provonix is a specialized contract research organization (CRO) providing exceptional support in all data-related aspects of clinical trials. Our **Biostatistics, Programming, Data Management, Medical Writing and PK** services ensure a consistency in the quality of your data and the optimal reporting for global regulatory submissions.*

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# More Than a Trial: A Multi-Regional Clinical Development Plan

## Challenge

A pharmaceutical company was in the midst of a US Phase I trial on a promising compound. Thinking ahead, and preparing for a Phase II trial, they recognized the advantages of getting near simultaneous approval in Europe and Japan as well as the US. The company asked Provonix to create a clinical development plan to meet their goal of regulatory approval in the US, EU, and Japan.

They turned to Provonix because of our proven record for understanding worldwide regulatory requirements. The client also relied on our reputation for innovation; they knew they needed more than a standard analysis and a global network of clinical sites.

## Action

Prior to 2007 the approval process in Japan started after approval was gained in other regions. Typically, Phase I and bridging studies were performed after Phase I and II trials were completed in the US/EU. The Japanese review process generally took longer as well. This procedure resulted in a drug-approval delay in Japan of over four years.

Provonix substantially revised the company's clinical development plan for this compound. The major revisions were based on updated guidelines for drug approval in Japan. Additional studies and sub-population analyses in already planned studies were added to ensure that the company could meet regulatory approval criteria in all regions.

## Outcome

Provonix made significant changes to the company's clinical development plan. The plan, submitted to PMDA in Japan, was approved. Utilizing the knowledge and experience of the Provonix staff, this pharmaceutical company was able to move forward with development in Japan and receive regulatory approval in three major regions. Provonix's knowledge of worldwide regulatory guidelines and procedures helped this company accelerate approval in a potential high-market area. Without this knowledge, and our originality in applying it, Japanese approval would be significantly delayed.