



**Global Clinical Trials for Alzheimer's Disease:
Chapter 18. Strengthening/Building Alzheimer's
Disease Global Clinical Trial Site Capabilities and
Capacity ... Emerging Markets. Lessons Learned
from Japan**

Yoko Fujimoto, Takeshi Iwatsubo

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Considering the difficulty of clinical development for Alzheimer's Disease (AD), understanding each country's specific situation is an important first step in reducing the operational burden on clinical trials while maintaining the quality of the study. In this chapter, the long history of clinical development for AD in Japan is introduced. There has been a lot of experience in Japan of AD clinical development from the time of developing donepezil to the current global development of AD disease-modifying drugs. However, this experience has not always been a success story and has often been the cause of much frustration, such as the failure of Phase III studies, high regulatory requirements, development and implementation of neuropsychological tests, influence of ethnic factors, etc. However, all of these points provide us with a good source from which we can learn about the challenges of the clinical trials and discuss how to strengthen the quality and efficiency. It's important to take advantage of this experience for future success in the clinical development of AD, especially in emerging markets.

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