敬請張貼

淡 江 大 學 統 計 學 系

學 術 演 講

講　題：What will ICH E17 impact on MRCT?

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地　點：B302A（淡水校園商管大樓）

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摘 要

Recently, global drug development has attracted much attention from pharmaceutical companies. Unlike traditional clinical trials, the design of multiregional clinical trial (MRCT) recruiting subjects from many countries around the world under the same protocol has led to a new strategy for drug development. This kind of design has been widely adopted by global pharmaceutical companies, which seek simultaneous drug development, submission, and regulatory approval throughout key world markets to hasten the market availability of the drug, as well as improved patient access to new and innovative treatments. However, a key issue for conducting MRCTs is how to demonstrate the efficacy of a drug in all participating regions while also evaluating the possibility of applying the overall trial results to each region. The idea of an MRCT was first raised in the 11th Q&A of ICH E5. To establish a framework for how to demonstrate the efficacy of a drug in all participating regions while also evaluating the possibility of applying the overall trial results to each region by conducting an MRCT, the ICH released the E17 guideline “General principle on planning/designing Multi-Regional Clinical Trials” in 2017 to describe general principles for the planning and the design of MRCTs.

In this presentation, we will discuss some practical issues raised by ICH E17 and how Taiwan implement ICH E17 for drug evaluation.

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