敬請張貼

# 淡 江 大 學 統 計 學 系

## 學 術 演 講

講　題：Statistical considerations in clinical trials

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地　點：B302A（淡水校園商管大樓）

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### 摘 要

Clinical trials are mainly divided into three phases: Phase I, Phase II and Phase III. Each Phase has its main purpose. For example, the primary objectives of a phase I trial are to provide information on the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of an investigational medicinal product (IMP). The primary objective of a phase II trial is to determine the dose(s) and regimen for Phase III trials. Trials in Phase II are typically conducted in a group of patients who are selected by relatively narrow criteria, leading to a relatively homogeneous population and are closely monitored. Trials in Phase III are designed to confirm the efficacy and safety for the intended indication and recipient population. In this talk, we provide the statistical considerations in Phase I, Phase II and Phase III trials. Finally, some examples are illustrated to understand the trial design in different phases.

**Key words:** Clinical trials, Phase I trials, Phase II trials, Phase III trials