國 立 中 央 大 學

統 計 研 究 所

學 術 演 講

主 講 人：許根寧 博士 PAREXEL International (百瑞精鼎)

講　　題：The Role of a Biostatistician in Clinical Research Organization

時　　間：106 年 09 月 19 日（星期二）上午 11：00 ～ 12：00

地　　點：中央大學鴻經館429室

茶　　會：上午 10：30 ～ 11：00　　地　點：鴻經館 510 室

ABSTRACT

A clinical research organization (CRO) is an independent organization which provides services to a pharmaceutical company to organize and conduct clinical trials once the company has identified a promising new molecule. A biostatistician plays a crucial role in clinical trials, who involves in every step of a clinical trial, including trial design, sample size calculation, protocol development, data management, data monitoring, statistical analysis plan (SAP) writing, and clinical trial result reporting. A biostatistician works closely with a data manager, a team of statistical programmers and a medical writer in a trial. At trial start-up, a biostatistician has to propose the trial design, and calculate the associated sample size. After protocol was finalized, a biostatistician assists a data manager in developing clinical report form (CRF) and the specification of dataset. A biostatistician is responsible to all study data tabulation model deliveries and all results of statistical analyses produced by statistical programmers. At the end of clinical trial, a biostatistician often works with a medical writer on writing the clinical study report. In this talk, I will briefly introduce PAREXEL, a global CRO, and all aforementioned jobs of a biostatistician. In addition, I will show the application of statistics in two clinical trial designs.

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