

Advanced Topics in Pharmacoepidemiology

進階藥物流行病學研究

課程內容

- 醫療產品上市後安全信息偵測及快速評估 (safety signal detection and refinement)之相關研究方法與資料。
- 效果與安全性比較研究(comparative safety and effectiveness research) 討論進行效果與安全性比較研時可能面臨的挑戰，與可能的解決方式。
- 效益及風險評估 (benefit-risk assessment)：綜觀效益及風險評估之緣起與目的。並藉由案例分享討論其方法學及未來展望。
- 不可測的干擾因素(unmeasured confounders)：介紹傾向評分修正法(propensity score calibration)與其應用在藥物流行病學研究中控制不可測的干擾因素。

教育目的

- 提供醫療產品上市後安全信息偵測之概念與評估方法。
- 了解進行非隨機的效果與安全性比較研究所面臨的問題與可能解決方法。
- 了解醫藥品的風險評估現況，以及決策過程需考量因素及挑戰。
- 描述如何利用外部資訊與傾向評分修正法調整研究關係中不可測的干擾因素。

教育對象

- 具備基礎藥物流行病方法學能力並熟悉目前藥物法規環境之學員。
- 對於進階的安全信息偵測、效果與安全性比較研究、效益及風險評估及修正不可測干擾因素之研究方法有興趣的學員。

課程師資、單位、課程主題

■ 陳建煒

國立臺灣大學醫學院教授

醫療產品的上市後安全信息偵測及快速評估

■ 賴嘉鎮

杜克大學臨床研究所與國立成功大學臨床藥學與藥物科技研究所

效果與安全性比較研究-挑戰與解決方法

■ 張家嫻

武田藥品工業株式會社

醫藥品的效益風險分析之簡介-以健康加值資料庫為例

■ 洪楨苓

北卡羅來納大學教堂山分校公共衛生學院流行病所

使用外部資訊修正不可測的干擾因素

Advanced Topics in Pharmacoepidemiology

Content

The educational session covers four advanced topics in pharmacoepidemiology for post-marketing evaluation of medical products, including:

- Safety signal detection and refinement: relevant methods and data sources.
- Comparative safety and effectiveness research: trade-offs between different studies designs and advanced methods for reducing the biases that can distort estimates of non-randomized research.
- Benefit-risk assessment: relevant tools and characterization of uncertainties, case study from recent regulatory history, and the challenge and future development of benefit risk assessment.
- Unmeasured confounders: application of propensity score calibration in pharmacoepidemiologic studies.

Educational Objectives

- To provide an overview of post-marketing safety signal detection and refinement for medical products.
- To understand challenges and proposed methodological solutions in non-randomized research.
- To give a conceptual work with several examples and the way forwarding to benefit-risk assessment of medical products.
- To describe how to use external information to control for unmeasured confounders in the main study with propensity score calibration.

Target Audience

- Those who have basic exposure to modern epidemiology concepts and familiar with current regulatory environment for medical products.
- Those conduct comparative effectiveness research and assumes knowledge of introductory pharmacoepidemiologic methods.
- Those interested in the methods to evaluate benefits and risks.
- Those interested in methods dealing with the problem of unmeasured confounders.

Course Faculty, Affiliation and Topics

■ **K. Arnold Chan**

National Taiwan University College of Medicine

Post-Marketing Safety Signal Detection and Refinement for Medical Products

■ **Edward Chia-Cheng Lai**

Duke Clinical Research Institute and National Cheng-Kung University College of Medicine

Comparative Safety and Effectiveness Research- Challenges and Proposed Solutions

■ **Chia-Hsien Chang**

Takeda Pharmaceutical Company Limited

Benefit and Risk Assessment of Medical Product- what can we learn from healthcare databases?

■ **Jin-Liern Hong**

Gillings School of Global Public Health, University of North Carolina at Chapel Hill

Adjustments for Unmeasured Confounders with External Information using Propensity Score Calibration