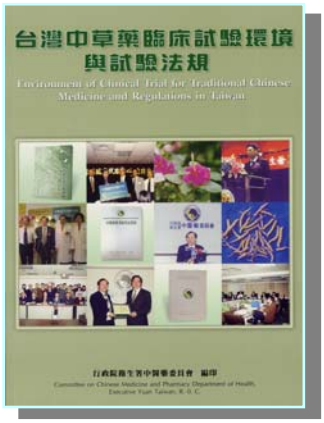
臺灣中草藥臨床試驗環境與試驗法

簡 介



中藥在華人世界已有千年以上的使用歷史，然在講究實證醫學的今日，如何將中藥臨床療效進行科學之評估，並將確認療效者加以推廣，則是中醫藥能否邁向國際之最重要的工作之一。政府已將輔導製藥業並使其發展成為為重要施政目標，行政院並訂定「中草藥產業技術發展五年計畫」，依部會分工，本署(會)之任務為建立完整之中草藥臨床試驗體系與機制並經由有效地運作，透過臨床科學性驗證，使台灣所發展之新的中草藥產品得以有良好之競爭力，以進軍國際市場。並期配合中草藥在全球市場之快速成長及發展潛力，積極爭取國外臨床試驗於台灣執行，期將台灣打造成國際級的中藥臨床試驗基地。

為建立高品質及可信之中藥臨床試驗環境，本會自九十年度起開始輔導國內優良教學醫院成立中藥臨床試驗中心，由申請醫院提出相對配合款，本會協助推動設立中藥臨床試驗中心及相關實驗室。各中心每年均辦理臨床試驗訓練課程，以長期規劃為目標，持續培育臨床試驗所需人才；此外，並積極參與國際組織及相關研討會，達成學術交流並吸取先進國家新藥研發之經驗，彰顯政府推展中藥臨床試驗中心的決心，並促成跨國的合作發展聯盟。

在其他的配套措施方面，本會亦規劃成立中草藥不良反應通報系統及中醫藥聯合人體試驗醫學倫理委員會，並研擬修訂 IND 及 NDA 相關法規，以及重要疾病之中藥臨床試驗基準，使中草藥產品在研發與臨床試驗階段有指引可供依循。

為使各界瞭解國內中藥臨床試驗環境建置情形，並廣為利用，本年度除已建置中藥臨床試驗中心聯合網頁外，並出版「台灣中草藥臨床試驗環境與審查法規」一書，以供參考。

Foreword

The existence of Chinese medicine in Chinese society has been over thousand years already. However, situated in today's strong evidence-based medicine, how to carry out scientific assessment of therapeutic effect for clinical trial of Chinese medicine and how to promote the identified effect are one of the important tasks to determine whether Chinese medicine can move forward to international market. The Government has listed these two items as an important policy goal: assist with pharmceutical industry and let it develop as one of ten newly risen industries. Executive Yuan has also enacted "5-year plan: Technological Development of TCM pharmaceutical Industry". According to the plan, the assignment of CCMP is to build up an optimized infrastructure and mechanism for TCM clinical trial, create a strong competitive advantage for TCM new product through effective operation and clinical scientific accreditation, so as to beat in the international market. Follow with fast-growing tempo and development potential of Chinese medicine in the global market, our committee works for the execution of foreign clinical trial in Taiwan progressively. Let Taiwan be the international base of the clinical trial for Chinese medicine.

In behalf of constituting a high-qualitative and reliable environment for clinical trial of Chinese medicine, our committee has assisted with domestic teaching hospitals to institute clinical trial center for traditional Chinese medicine since 2001. Applied hospital can request for respective subsidization. Our committee helps for the institution of clinical trial center for traditional Chinese medicine and related laboratories. As long-term goal, each center would hold yearly training courses of clinical trial and educate continuously necessary personnel for this field. Apart from this, each center would achieve academic exchange and absorb the experience on R & D of new medicine from other advanced countries through active participation of international organized or related symposia. It shows decisive attitude of the government towards the promotion of clinical center for traditional Chinese medicine and helps realize the achievement of international cooperation and alliance development.

Regarding other respective facilities, our committee also plans to implement the ADR Reporting system for Chinese medicine and the Joint Institutional Review Board for Traditional Chinese Medicine. For the sake of providing guidance in the phase of R & D and clinical trial of Chinese medical products, we also plan to revise related regulations and the norm of clinical trial for important diseases.

To generalize the building status of domestic environment of clinical trial for Chinese medicine and its application, except the constructed joint website of clinical trial centers, our committee does publish the book "Environment of

Clinical Trial for Traditional Chinese Medicine and Regulations in Taiwan ” to serve as reference.