摘　　要

昂貴的藥物研發成本，促使製藥生技產業的委外營運模式，以合約方式提供在藥物研發過程中專業化服務的產業，而近年來由於委外研發服務的高效率，已明顯縮短了新藥開發的時程；同時，在全球醫藥研發服務產業的市場中，約有超過七成的收益來自於臨床試驗服務；由此顯見醫藥研發服務產業中的臨床試驗部分的重要性。

醫藥研發服務是個高度國際性競爭的產業，如何找到發展的核心利基以突破重圍，是許多後進企業或國家所必需面對的嚴峻考驗。因此，本研究主要描述台灣目前的醫藥研發服務產業以及臨床試驗產業發展概況，並探討台灣是否具備發展臨床試驗產業的實力。透過本研究，希望對於台灣發展臨床試驗產業，或是推動台灣成為亞太臨床試驗中心，都能提供作為規劃與執行時的參考資訊。

本研究重要結論與建議如下：

1. 以新藥研發價值鏈而言，台灣目前在每一個階段的工作均已佈局，其中又以臨床試驗階段最有潛力加入國際的競爭市場；長期而言，為追求醫藥產業最大的經濟效益，應強化國內的基礎研發工作，進而刺激與培養國內醫藥研發服務產業的能量。
2. 產業政策的落實不能只談邏輯架構或觀念，應該設定明確的推動方案、目標與達成時間表，要推動產業必須貫徹以管理的觀念；同時也應加速業者與官方之間的溝通協調，其中包括藥政主管單位對於產業發展應由被動轉為積極主動的角色，另外，政府部門跨部會的整合也是相當重要的。
3. 國內的全民健保制度涵蓋了所有醫療資源的運用，而健保制度的設計缺乏鼓勵預防與醫藥研發的投入的機制。因此建議應深入分析與探討健保對於產業的影響，進而能以更積極正面的態度促進製藥生技或醫藥研發服務產業的發展。
4. 建議國內可以由政府與製藥產業界共同出資，成立具有公信力且目標明確的教育訓練組織，提供以實務為導向且有系統的在職教育，用以規劃與培植國家未來所需要的專業臨床試驗人才。
5. 建議國內應就醫療院所執行臨床試驗相關作業訂定管理原則，包括臨床試驗贊助款的管理與運用規範、相關執行人員的權利義務等，藉由透明化的標準與明確的獎勵制度，提高醫師與醫院參與臨床試驗的動機；同時也應鼓勵醫院設立專責的臨床試驗辦公室，執行各項協調、整合與管理的工作，並促進與產業界間的互動。

關鍵詞：醫藥研發服務產業、臨床試驗、委外

ABSTRACT

The cost of drug research and development has soared during the past years. And this compels pharmaceutical and biotechnology companies to look for new, smarter ways of running their businesses. One of their strategies is trying to accelerate drug development by outsourcing. The size of the outsourcing market for Contract Research Organizations (CROs) is rising. Clinical-trial operations hold over 70% of the revenue in the CRO industry.

Competition in the CRO industry is extremely international in scope. The key issues for the catching-up company or country is to find their own niche. This study goes on to identify and profile the development of clinical trials and the CRO industry in Taiwan. It also seeks to identify ways of showcasing Taiwan as an Asia-Pacific Clinical Trail Service Center.

There are several conclusions from this study:

1. In the value chain of new drug discovery and development, the current status in Taiwan has the potential to join the international market by conducting the clinical trials. In the long term, we should consolidate our basic medical research to pursue the maximum benefit of biotechnology and pharmaceutical industry, and then to enhance the capability of CRO in Taiwan.
2. The policy for improving industry must be set up after the explicit acting plans, goals and time schedule. It should go through with management, not just a structure or concept. We have to hasten the communication between industry and government. The medical legal authorities need to be more active. Ultimate integration of the functions of the related government departments is exceedingly important.
3. The National Health Insurance (NHI) system covers all of the medical resources in Taiwan, but it lack for the incentive to encourage the medical research. It is recommended that NHI Program should probe into the impact of the biotechnology and pharmaceutical industry, and then try to revise it with more positive thinking.
4. It is very important for Taiwan to improve the professional in clinical trials. Setting up a training center funded by both government and industries is strongly recommended. The organization will have the definite goals and accountability, and provide practical training and systematic continuing education.

5. We need more regulating operations of clinical trials of hospitals in Taiwan. These operations should include the usage of the fees from sponsors, and the rights and responsibilities of all staff. We should set up a transparent standard and obviously encourage a mechanism to enhance the motivation of physicians and hospitals to participate in clinical trials. Hospitals should be encouraged to establish an independent office for clinical trials to perform all the details. This office will promote the interaction within the industries.

Keywords: CRO (Contract Research Organization)、Clinical Trial、Outsourcing.