

# Environment of Clinical Trial for Traditional Chinese Medicine and Regulations in Taiwan



## Introduction

Chinese medicine has been used for thousands of years in Chinese societies; however, in modern society, which demands evidence-based medicine, it is quite important to conduct a scientific assessment of clinical therapeutic effects and promote them with confirmed effects, since it's important to facilitate the internationalization of traditional Chinese medicine and pharmaceuticals. Currently, the Chinese traditional herbal manufacturers under the governmental guidance are to be developed as one of 10 major new industries, since it is also a main goal of key political commitments. Moreover, the Executive Yuan has instituted a 5-Year Plan of Chinese Herbal Industries Technological Development with the labor division pursuant to respective departments and committees. Accordingly, the Committee on Chinese Medicine and Pharmaceuticals (CCMP), Department of Health, Executive Yuan has been granted the duty of establishing an effective complete traditional Chinese medicine herbal clinical trial system and mechanism. Through scientific clinical verification, the new Chinese herbal products developed by Taiwan may be competitive enough to enter the international markets;

furthermore, in the face of rapid growth and developmental potential of Chinese herbs in global markets, Taiwan is expected to become an international Chinese clinical trial base by striving for foreign clinical trial executions in Taiwan.

To build a high-quality and reliable clinical trial environment for traditional Chinese medicine, CCMP has been commissioning and subsidizing numerous plans of clinical trial for traditional Chinese medicine (including commissioned and subsidized plans) in 2001, including clinical therapeutic studies, therapeutic effectiveness assessment, laws for new drugs, clinical trial education, adverse drug reaction reporting system and the establishment of a clinical trial center for Chinese medicine, for more than 8 years. The key executive achievements consist of: (1) Chinese medicine clinical trial centers built in 15 medical institutions through subsidization (Chi Mei Medical Center, Show Chwan Memorial Hospital, National Taiwan University Hospital, Chang Gung Memorial Hospital, Taichung Veterans General Hospital, Tri-Service General Hospital, Tao Yuan General Hospital, China Medical University Hospital, National Cheng Kung University Hospital, Taipei Veterans General Hospital, Chung Shan Medical University Hospital, Kaohsiung Medical University Hospital, Changhua Christian Hospital, Taipei City Hospital, and Buddhist Tzu Chi General Hospital) with more than 100 projects executed every year, and the rich fruits include a new Chinese medicine drug certified by IND/NDA (similar to FDA procedures) in 2005, for the first time; (2) annual checks of trial centers ensure that the clinical trial centers conform to GCP aided with the Joint Institutional Review Board (JIRB) for Traditional Chinese Medicine to accelerate IRB examination of clinical trials in each center, and the supervision and statistic mechanisms of adverse drug reaction (ADR) reporting system for traditional Chinese medicine helps the research and investigation of ADR; (3) execution of Chinese medicine fundamental studies, promotion of constructing quality safety background data and enhancement of pre-clinical trial procedures; (4) research and institution of relevant laws and policies, promotion of practical operation and prospective plans and facilitation of Chinese medicine clinical trials and

industrial development; and (5) promotion of clinical trial training and Chinese medicine related courses and enhancement of professional level of medical staff and competent operators in Chinese medicine and pharmaceuticals.

To promote the Chinese medicine clinical trial research and to disseminate the previous achievements of CCMP projects, the Department of Pharmaceutical Services of Traditional Chinese Medicine, Chang Gung Memorial Hospital Taoyuan Branch was commissioned to hold the Symposium on Achievements Presentation of Clinical Trials (ADR, JIRB, GCP) for Chinese Medicine 2001-2008 on Nov. 1, 2008. The participants totaled more than 200 members, including traditional Chinese medicine associations, pharmacist associations, public traditional Chinese medicine associations, school representatives, biotech corporations, pharmaceutical manufacturers and law-related persons. In addition, Chang Gung Memorial Hospital Taoyuan Branch was commissioned to execute the data collection and collective edition of Achievements Collection of Chinese Medicine Clinical Trial Plan, National ADR Clinical Guideline for Chinese Medicine, and Chinese Medicine GCP and JIRB Clinical Guideline and has obtained the predicted achievements under the schedule. Therefore, the efforts of the units in charge of performing the project and the colleagues undertaking the affairs over the years are appreciated full heartedly. Moreover, the gratitude is for the previous project directors, the staff in the clinical trial centers and experts and scholars who have given aid and who have dedicated their endeavors to the accomplished 162 projects collaboratively, all these years. Hopefully, the previous achievements overview and lectures in the symposiums on achievements presentation are summarized in this book so as to review the clinical studies for traditional Chinese medicine in the past few years, offer an opportunity for pertinent operators and those dedicated to joint learning, and move toward an objective of sound examination laws and clinical trial environment for traditional Chinese medicine.