Taiwan as a Clinical Trial Center of Excellence in the Asia Pacific

Located in the center of the Asia Pacific region, Taiwan is very active in medical research, having published about 22,585 papers in clinical medicine between 1996 and 2006. Taiwan ranks third in “Country Rankings in Clinical Medicine” in the Asia Pacific, just after Japan and Australia. Taiwan also has good patient resources: with a population of 23 million, it is one of the most densely populated countries in the world. Thus, researchers in Taiwan are always able to finish patient recruitment in their international clinical trials according to tight schedules and timelines.

In addition, Taiwan has good clinical investigator resources. A large number of well-qualified clinical investigators and research nurses are experienced in many investigational new drug (IND) international clinical trials covering a wide range of diseases. All clinical investigators in Taiwan receive Good Clinical Practice (GCP) training, and many also receive international clinical investigator accreditations. They are familiar with the International Conference on Harmonization (ICH) GCP guidelines as well as international multi-institutional clinical trial procedures. Taiwan is especially strong in cancer, cardiovascular disease, as well as viral hepatitis and the associated liver disease research. Many of Taiwan’s investigators are members of international medical trial advisory boards and safety data management boards, and/or are principal investigators in international clinical trials.

Major Pharmaceutical Companies
In some international clinical trials sponsored by major pharmaceutical companies, the quality of clinical trials performed in Taiwan is ranked among the best by worldwide institutions. Taiwan has demonstrated clinical research excellence in its national vaccination program against the hepatitis B virus (HBV) as well as in the prevention of HBV liver disease and hepatocellular carcinoma. Ribavirin combined with interferon treatment — for which its use in successfully treating chronic hepatitis C was first reported by the National Taiwan University Hospital in 1996 — has been one of the biggest breakthroughs in the treatment of patients with chronic hepatitis C virus infection in the last 15 years. Taiwan is also active in clinical genomic research; for instance, an article on the discovery of a five-gene signature that predicts the prognosis and treatment outcome of lung cancer patients, also by the National Taiwan University Hospital,
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was recently published in the New England Journal of Medicine.

Clinical Trials in the Hospitals
Taiwan has national health insurance that covers the whole population. It also boasts excellent infrastructure for clinical trials and research, with National Centers of Excellence for Clinical Trial and Clinical Research set up in several major university teaching hospitals. Premium hospitals in Taiwan such as the National Taiwan University Hospital, the Veterans General Hospitals, and the Chang-Gung Memorial Hospitals rank among the top hospitals in clinical medicine in the Asia Pacific. For example, more than 800 clinical research projects were initiated at the National Taiwan University Hospital in 2006. Several hospitals in Taiwan have several thousand beds, making them one of the largest hospitals in the region. There are 22 medical centers, 61 teaching hospitals, and 556 hospitals with 34,000 physicians and 146,382 hospital beds in Taiwan.

High-standard clinical-related researches are also carried out and actively supported by local premium research institutions such as Academia Sinica and the National Health Research Institutes. Moreover, well established and successful national multi-institutional clinical trial organizations, such as the Taiwan Cooperative Oncology Group, are capable of larger-scale multi-institutional clinical trials for various kinds of cancers. Clinical trial facilities for herbal medicine have also been established in Taiwan.

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<th>2005</th>
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<tr>
<td>Phase I</td>
<td>14</td>
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<td>Phase II</td>
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<td>Phase III</td>
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<td>Phase IV</td>
<td>4</td>
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<td>Total</td>
<td>120</td>
<td>133</td>
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The Department of Health

The local regulatory authority, the Department of Health (DOH), has in place comprehensive regulations and GCP guidelines for clinical trial protocols, informed consent, biospecimen collections, institutional review boards (IRBs), regulation updates, clinical trial inspections, and training and support for local hospitals in Taiwan. The IRBs in Taiwan are of high international standard, and many hospital IRBs have already passed international accreditation. These IRBs are generally efficient and the clinical approval time can be as short as four weeks. The national efficiency of IRBs in Taiwan is further enhanced by the presence of the Joint IRB in Taiwan that can handle multi-institutional clinical trials in one application and approval by the DOH.

There are a number of sizable contract research organizations (CROs) in Taiwan that can manage high-quality clinical trials efficiently in Taiwan and in the rest of the Asia Pacific at very competitive costs, and that have an excellent track record.

Taiwan's Ministry of Economic Affairs (MOEA) offers substantial financial incentives so as to encourage companies to carry out their preclinical or clinical R&D activities in Taiwan. The MOEA has also set up single-window services for the promotion of these activities in Taiwan. The Scientific and Technology Advisory Group of Taiwan’s Executive Yuan, a very high-level office of the central government that is responsible for the national policies and funding of national clinical research, is also very active in the funding and establishment of clinical trial infrastructure in Taiwan.

Because of the high quality, speed, and relatively low costs of clinical trial operations in Taiwan, almost all major international pharmaceutical companies have established their clinical trial offices in Taiwan, performing their international IND or new drug approval (NDA) clinical trials with excellent results. All of these companies appear to be expanding their clinical trial operations in Taiwan. In 2006, the number of international clinical trials approved in Taiwan was about 133.

Chang-Gung Memorial Hospital

Taipei Veteran's General Hospital

National Taiwan University Hospital
Summary
In summary, Taiwan can be regarded as a center of excellence for clinical trials in the Asia Pacific region. However, further increases in efficiency and reductions in cost of the clinical trials performed locally, as well as more government clinical trial incentives for the big international pharmaceutical companies to perform clinical trials in Taiwan, may further its clinical trial competitiveness in the Asia Pacific.

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