Ming-Shiang Wu – Director, Taiwan Clinical Trial Consortium

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Professor Ming-Shiang Wu, director of the

Taiwan Clinical Trial Consortium, elaborates on the activities of the organization and its role to promote Taiwan's clinical trial infrastructure and attract more international trials to the country. He also goes on to explain the key strengths of Taiwan within the Asia Pacific region.

Please begin by introducing the Taiwan Clinical Trial Consortium and its mission within Taiwan's clinical trial ecosystem.

The Taiwan Clinical Trial Consortium (TCTC) was formed in 2011 with the purpose of making Taiwan a centre of excellence for new drug and new medical device clinical trials in Asia Pacific and facilitating the commercialization of biomedical products. The TCTC has three primary missions – reduce the duration of clinical trials based on creating advanced platforms, attract international pharmaceutical companies to conduct trials in Taiwan, and help Taiwanese biotech companies in the commercialization of new drugs and medical devices.

Our government has several initiatives to enhance the infrastructure of our medical centres. The Ministry of Health and Welfare gave large budgets to six medical centres to transform into centres of excellence for clinical trials. For example, the National Taiwan University Hospital is one institute which was involved in the initiative.

Next, the TCTC was established and is funded by the Ministry of Science and Technology to link together all these centres from around Taiwan. 13 disease-specific consortiums, all of which are Asian prevalent, make up the TCTC. For example, liver diseases are a very pressing issue in Taiwan and there are 10 hospitals within this specific consortium dedicated to this therapeutic area

What makes Taiwan a competitive destination to conduct clinical trials?

Taiwan has excellent medical physicians and we are ranked within the top three in the world in terms of quality and service. The same standard of care in the most advanced markets like the US, for example, can be found here in Taiwan at a reasonable cost. We have the capabilities to ensure that all procedures are followed as the should be to try and make the trial as safe for patients as possible. Furthermore, the level of English in Taiwan is very high within the region and in fact, all medical records in the country are in English as well. This creates a very internationally appealing environment.

The amount of well-established hospitals in such a small country speak volumes about our focus on improving infrastructure. There is strong government policy support for the development of a conducive environment for carrying out clinical trials. Currently, there are 134 hospitals in Taiwan that are qualified by the TFDA to conduct clinical trials.

In which therapeutic areas does Taiwan have the most clinical expertise?

In liver disease, Taiwan has a very successful experience in the eradication of Hepatitis B and C, and we are the first country to have a national vaccine program for the disease. Taiwan was the first country to run a clinical trial for a hypopharyngeal carcinoma CAR-T therapy, which was brought to market.

Another area where we have strong expertise is in lung cancer. Taiwan has many outstanding researchers who are running trials for an important new drug, Afatinib, and the principal investigator of this trial even sits on the TCTC board of directors. The TFDA approved this drug sooner than the US FDA because the global clinical trial was conducted here in Asia. Additionally, the TCTC also has a specific consortium for phase I oncology clinical trials which is very successful. Each year Taiwan conducts more than 20 phase I oncology trials.

Despite having a strong clinical infrastructure, there are obvious gaps in Taiwan's population size and diversity compared to other countries in the region. How can Taiwan position itself to overcome this key challenge?

The large majority of Taiwan's population is of the Han ethnic group, which is are the descendants of mainland Chinese. Although Taiwan is a small country, more than twice as small as South Korea or Japan, this is not a concern for us. Instead, we must focus on quality, speed, and operation mode. As part of the TCTC's hospital network, we are able to work with doctors to keep them informed about trials and actively connect patients to enrol in clinical trials.

Taking Helicobacter pylori therapy as an example, this is a bacteria with a high prevalence of drug resistance. There is no clear basis for whether drugs be selected according to drug resistance or according to the patient's medical history for those who have failed twice in eradication. It is estimated we must screen at least 20,000 patients for a trial of 400 cases which is very difficult. Through the multi-centre cooperation of the alliance, not only can speed up the collection and reduce the burden, but also complete the trials that were difficult to carry out.

How does this multi-centre connectivity help to improve the success rate and reduce the burden of large trials?

With the TCTC, we link 22 medical centres and 40 hospitals along with several academic institutions together. Each establishment has its own strengths – NTUH each day has 8,000 outpatients in its outpatient centre. Our established network helps to get to know patients very quickly, allowing Taiwan to be in the niche of shortening clinical trial processes. We can be very efficient in finding the right patients who would fit into the trail, cutting down the time for something which often can be very lengthy. Furthermore, TCTC's platform connects experienced PI's to discuss trials and define standards for trial procedures.

Last year, the TCTC and Novotech, Australia's largest CRO, signed a Memorandum of Understanding on future clinical trials. How was this partnership formed and what is its scope of collaboration?

In addition to our 13 diseases specific consortiums, we have one centralized office to assist manufacturers and contract research organizations in the evaluation of cases and PIs, greatly improving the efficiency of implementing clinical trials and providing relevant clinical trial statistics

and regulatory advice according to the needs of the project. We have all the data that CRO's need to set up a clinical trial including feasibility and even the selection of PIs. In our agreement with Novotech, we will provide resources related to clinical trials in Taiwan, including trial feasibility assessment, trial host selection, and assistance with patient recruitment. On the other hand, Novotech will internationally promote the TCTC's clinical research experience and expertise.

We chose Novotech to be a partner of TCTC not only because it is the biggest CRO in Australia, but because Novotech has conducted many multi-site international clinical trials and we are honoured to be a part of their success. We look forward to continuing the expansion of the scope of this cooperation in the future.

What final message would you like to deliver on behalf of the TCTC and Taiwan's clinical trial environment?

The TCTC is an excellent platform for the development of new drugs and devices because of our high number of experienced PIs and the close links it established among medical centres. Taiwan is well positioned with the region, close to China and Japan, facilitating the exchange of information in areas healthcare and clinical research. Furthermore, Taiwan's IT capabilities are very strong, making it easier to manage data paired with extensive amounts of data which come from our National Health Insurance program. Overall, Taiwan has a very high-quality clinical research infrastructure and a competitive price.

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