Henry Yau – Managing Director, HKU Clinical Trials Centre

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Henry Yau is managing director of the Hong Kong University (HKU) Clinical Trials Centre in Hong Kong and CEO of the Centre's mainland China arm. Yau explains how the clinical trials landscape has evolved in Hong Kong over the past five years, especially in relation to the COVID-19 pandemic. He also covers some hot-button issues in global clinical research and how they pertain to Hong Kong, including cohort diversity, digitalisation, and convergence with medicine regulation and approvals.

We spoke in 2018. Was there any change in Hong Kong's clinical trial environment over the past five years, in particular during the COVID-19 pandemic?

Yes, the clinical trial environment here changed a lot, and I witnessed significantly increased activities during the pandemic, in particular for addressing the special needs for COVID-19-related research.

For instance, by partnering with HKU's strong force in microbiology and infectious diseases and with HKU-CTC's good experience in vaccine trials, we were well-prepared for clinical trials on many COVID-19 vaccines based on various technology platforms, including omicron-based inactivated vaccines developed by the biopharma industry as well as a nasal vaccine and a DNA-based vaccine

created by our university researchers. Our comprehensive expertise and experience allowed us to respond immediately when asked to manage and run those trials.

Notably, the new omicron variant was first isolated in Hong Kong from HKU's laboratory and transferred to a biopharma in Beijing for manufacturing of a new version vaccine, and then we were entrusted to conduct a pivotal clinical trial for that vaccine. The trial involved 1800 volunteers, and HKU-CTC was the sole unit responsible for its management. In addition to functioning as a study centre, we were also delegated by the company to oversee the entire project. This included obtaining necessary approvals from the ethics committee and the Hong Kong Department of Health, setting up study site facilities, assembling the study team, recruiting volunteers, performing vaccinations, taking and processing biospecimens, collecting data, ensuring data quality via monitoring and other measures, and performing statistical analysis and reporting. Throughout the process, we remained committed to meeting all regulatory requirements and maintaining the highest standards of research ethics.

Running trials during the pandemic was very challenging, but on the plus side, this offered us a good opportunity to strengthen our teamwork and test our competence. Our dedication and expertise allowed us to successfully complete those trials and contribute valuable data for the development of the new vaccines. On the other hand, it also drew the attention of governmental bodies and even the public on the value of clinical trials and paved the way for a better clinical trial environment here. People in Hong Kong now are more aware of what phase 1, 2, 3 trials are, why randomization, double-blinding and placebo are applied, and are more willing to participate in clinical trials!

What did you learn from the pandemic that could potentially improve the way clinical trials are undertaken in Hong Kong?

We certainly learned valuable lessons about the increasing complexity and challenges of running clinical trials. Scientific designs became more intricate, timelines were compressed, and demands for high-quality data increased. We reconfirmed the importance of having a comprehensive, multidisciplinary team with expertise in various domains to efficiently manage clinical trials. Over the years, our centre has built a robust team that includes clinical professionals (such as medical doctors, nurses and pharmacists), laboratory professionals (such as laboratory technologists/technicians), data management professionals (such as data managers, data analysts, statistical programmers and biostatisticians), ethics and regulatory affairs experts, medical writers, project managers, study coordinators, monitors and quality management specialists, as well as specialists in laws and regulations, finance, information technology, corporate communications and volunteer relations.

Thanks to our in-house expertise, we were able to kick-start our trials within a short timeframe without compromising on quality. For example, for the large-scale vaccine trial I just mentioned, the process began in February 2022 when the idea was first presented. Within just three months, we finalized the trial protocol, set up the site and study team, and obtained all required approvals, and by May the first volunteer was vaccinated. This showcased our competence and efficiency in execution.

One particularly interesting aspect of this trial was site selection. Since it involved a large number of participants and was during the pandemic, we couldn't conduct it within a hospital or clinic setting. We discussed with the Hong Kong SAR government, and secured their support by allocating a space in a sports centre for the trial. This presented unique challenges as we had to set up the

entire infrastructure and design the whole workflow – including an area for participants registration, consultation rooms, vaccinations rooms, a pharmacy for refrigerated storage of vaccines, a laboratory for blood specimens handling, stations for COVID-19 rapid testing, and even Internet and WiFi connections – all within a very tight timeline. Despite these obstacles, we successfully accomplished the feat, demonstrating our ability to adapt and operate effectively even in non-traditional trial settings.

Given the severity of the pandemic and the fact that no Western-researched vaccines had been approved in China, did you feel pressure to deliver strong data from these clinical trials and make these vaccines available to the public as soon as possible?

Our primary focus are always on ensuring the integrity and accuracy of the data collected from clinical trials, and to safeguard the rights, safety and well-being of trial participants. As a professional clinical trial organization, we have the responsibility to run good clinical trials with all the necessary quality management, assurance and control measures in place to ensure correct and reliable data is obtained so that conclusions about safety and efficacy could be drawn. However, it is essential to clarify that our responsibility does not include guaranteeing the success or effectiveness of any product. We did implement different measures to increase the efficiency of our work, but we never compromised on the integrity of the data or the adherence to regulatory requirements. Our commitment to maintaining the highest standards remained unwavering, even during the pandemic.

How would you characterize your organization's level of collaboration with multinational companies that have the capacity to invest in multicentre global trials? Is there any specific area of research interest or strength?

Yes, multinational pharmaceutical companies are our regular collaborators among other various types of organizations.

To speak on disease areas, oncology is a significant area of focus, and many companies are investing heavily in this field. Similar to western regions, we conduct numerous oncology trials such as on lung cancer, gastrointestinal cancer, and breast cancer. Liver cancer, in particular, is more predominant in Asia, making it a special area of focus for us. In addition to liver cancer, we also conduct a lot of trials in liver diseases such as hepatitis, as hepatology research is another strength of ours. We have renowned investigators in this area, who are considered leading experts in hepatology research. Such expertise allows us to conduct a significant number of phase one and early phase trials in hepatology and oncology.

Overall, we are actively engaged in a wide range of clinical trials, collaborating with multinational companies and focusing on areas that have specific relevance and significance in Hong Kong and Asian countries. Our goal is to contribute to medical advancements and improve patient outcomes through rigorous and high-quality research.

How would you describe the HKU Clinical Trials Centre's growth in terms of number of clinical trials and which phases are you able to cover?

We have experienced overall growth in the number of clinical trials, particularly with a trend shifting towards phase one and early phase trials. On average, we have about 70 to 80 new clinical trials

initiated under our centre every year. A decade back, a majority were phase three trials. But since the opening of our Phase 1 Centre in 2014, we have seen a rise in the number of phase one and phase two trials.

With the establishment of our Phase 1 Centre nine years ago, we now have a dedicated facility with 24 beds, enabling us to efficiently recruit healthy volunteers and patients for phase one and early phase trials. As we continue to expand our capabilities and expertise in conducting these early phase trials, we are attracting more pharmaceutical companies and research institutions seeking to conduct innovative and cutting-edge research in Hong Kong. Our focus on early phase trials allows us to contribute significantly to the translation of medical discoveries and the development of new therapies, positioning HKU-CTC as a key player in the evolving landscape of clinical research.

Ethnic diversity in clinical trials is a hot topic globally, but is this a trend you have witnessed locally and what impact do you expect to experience in Asia?

I have definitely witnessed a demand for ethnic diversity in clinical trials, and this puts Hong Kong in an advantageous position. For instance, many pharmaceutical companies, both big pharmas and start-ups, are choosing Hong Kong as a location for their trials with the intention of eventually entering the Mainland China market. This trend is particularly evident for drugs developed by US or European pharmas, which typically start their trials with Caucasians from North America or Europe. However, in order to cover the global populations, they would also go to other regions including Asia to collect data that demonstrates safety, efficacy, and pharmacokinetics relevant to those populations. Such data is crucial for preparing drug registrations, in particular in Asian countries where local data is highly valued for regulatory purposes. Some companies may specifically approach us in Hong Kong to conduct phase one trials for pharmacokinetics and safety evaluation in the Chinese population, and subsequently proceed to conduct additional trials in Mainland China to meet the marketing registration requirements there. The demand for Chinese data for drug approvals in Mainland China is one of the significant factors attracting clinical trials to Hong Kong.

Overall, this trend is expected to have a positive impact on the clinical trial landscape in Asia, especially in Hong Kong, as it attracts more studies and fosters collaborations between pharmaceutical companies and local research institutions. It opens up opportunities for Asian patients to participate in cutting-edge research, and strengthens the region’s position as an essential player in the global clinical trial arena. As Hong Kong continues to demonstrate its capabilities in conducting high-quality research and producing reliable data, it will remain an attractive location for multinational companies seeking to expand their trials to Asian populations.

One of Hong Kong’s main points of attractiveness is its connectivity to mainland China with its enormous patient population, but are clinical trials conducted in Hong Kong considered in the mainland’s regulatory decisions?

Hong Kong has a long history of involvement in international clinical trials, and research data generated here is well accepted by regulatory authorities worldwide. To qualify for clinical trial data acceptance by the Chinese National Medical Products Administration (NMPA), we have obtained the NMPA’s recognition for our teaching hospital, Queen Mary Hospital (QMH), since 2006. To date we have 13 clinical specialties approved, including oncology, cardiology, GI & hepatology, haematology, and endocrinology, among others. Before a trial targeting for supporting an application to the NMPA for marketing approval of a drug, the sponsoring pharma company should make a declaration to the NMPA, identifying the NMPA-recognized hospitals/clinical specialties that

are going to take part in the trial. If a NMPA-recognized Hong Kong hospital is planning to join the trial with its data accepted as “local data” by the NMPA, the Hong Kong Department of Health should be notified upfront and the Hong Kong regulatory approval will be subject to the NMPA’s approval. Alternatively, the Hong Kong hospital may start the trial under an independent regulatory approval by Hong Kong, and any clinical trial data submitted to the NMPA subsequently will be regarded as “non-local data”.

However, for clinical trials other than pivotal registration trials, the NMPA may exercise flexibility and accept taking reference to clinical trial data collected from Hong Kong hospitals for certain purposes without official approvals by the NMPA. Pharma companies are however recommended to consult with the NMPA first. While this is not a standard regulatory process, it served the purposes of many trials and helped accelerate many companies’ clinical development process in the mainland.

Do you see opportunities for your organization to collaborate with the burgeoning Chinese biotech ecosystem, as these companies look to expand their clinical trial footprint internationally?

We see significant opportunities within the growing Chinese biotech ecosystem. Hong Kong’s unique position as a bridge between the West and China makes it an attractive destination for both global and China-based biotech companies. Global companies come to Hong Kong with the goal of penetrating the Chinese market, while China-based companies are increasingly looking to Hong Kong to expand their clinical trials globally.

Over the past five years, we have witnessed a notable increase in China-based biopharma companies choosing Hong Kong as a strategic location. They value Hong Kong’s international reputation and recognize it as the most cosmopolitan city within China. With our deep understanding of US FDA and EMA requirements, as well as our extensive collaborative experience with international companies, we are well-equipped to support China-based companies in their global endeavours. Our strong focus on international standards and the practice of producing materials in English further enhances our appeal to Chinese clients. As the Chinese biotech ecosystem continues to expand and companies seek to expand their clinical trials globally, we see ourselves playing a crucial role in facilitating and supporting these endeavours in Hong Kong.

What impact might Hong Kong creating its regulatory system for primary review and approval of drugs have on the city’s attractiveness as a clinical trials destination?

Taking reference to countries with similar population size but have been performing primary review and approval of drugs, we see the potential for Hong Kong to do the same.

In the past, establishing a primary review system may not be a focus of the Hong Kong government, but the perspective is shifting now. In order to position Hong Kong as a technological hub, especially in the field of biomedical development, we must strengthen our regulatory system. Having the competence to review and approve drug marketing applications is vital to attracting more research and investment in the long run. It will enhance our appeal to global companies and researchers looking for a reliable and efficient regulatory environment, and Hong Kong will be able to boost its capabilities further and contribute significantly to the growth of the biomedical research landscape in the region.

The HKU Clinical Trails Centre has recently established a spin off company. Can you tell us about the strategy behind this decision and what your vision for the centre is?

The establishment of the spin-off company was a strategic decision to expand our reach and capabilities into the mainland, particularly the Greater Bay Area (GBA). Over the past 25 years, HKU-CTC has grown significantly, and we have developed the required competences and capacities to conduct early-phase as well as large-scale pivotal clinical trials efficiently and with high quality. However, we realized that in order to serve a larger geographical area such as the GBA, we needed to have a base there.

The spin-off serves as a platform for us to manage clinical trials not only in Hong Kong but also in the GBA. Our vision is to build a strong network of hospitals within the area, including institutions from Hong Kong, Shenzhen, Macao and others. By harmonizing quality standards, contractual requirements and workflows across this network, we aim to attract more sponsors and CROs to allocate their clinical trials to this region.

To support this initiative, we are in the process of developing an electronic platform called eSMO+ (i.e. electronic site management organization system). This cloud-based platform will facilitate the management of clinical trial organizations throughout the region by supporting harmonization and streamlined operations across multiple sites, significantly improving the efficiency and quality of clinical trials management.

We are already connected with some hospitals in the region. This exciting development will position the GBA as a leading region and enhance the overall ability and capacity to contribute to the advancement of clinical research and healthcare innovation.

What message would you like to deliver to a global audience regarding how Hong Kong can serve as a hub for clinical research?

Hong Kong has unique advantages that we can build upon, and holds tremendous potential to be a leading hub for clinical research in the global landscape. Hong Kong has world-class universities and healthcare systems, globally renowned researchers and clinician scientists in biomedical sciences, solid track records in clinical research, and an international culture strategically located between the East and the West. While the real potential of Hong Kong was not fully realized in the past, we are now at a turning point. The Hong Kong government is substantially increasing its inputs – in terms of both policy and financial investment – into the innovation and technology sector, including biomedicine, and is actively working to encourage involvement in research by service-based public and private hospitals. I believe there will soon be major policy supports and incentives to foster a more research-friendly environment. This presents a golden opportunity for Hong Kong to upgrade itself into a hub for clinical research and biomedical R&D, not only for the country but also for the entire Asian region and even on a global scale.

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