Henry Yau – Managing Director, HKU Clinical Trials Centre

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06.06.2024

Tags: Hong Kong, HKU Clinical Trials Centre, Clinical Trials, APAC

Last Autumn, the Hong Kong government announced a plan to create a one-stop-shop clinical trial institute across the Greater Bay Area (GBACTI) as part of its plan to promote biomedical research, development and drug registration. Henry Yau, managing director of the Hong Kong University (HKU) Clinical Trials Centre in Hong Kong and CEO of the Centre's mainland China arm, outlines the potential impact of this plan, including as an economic driver and diversification tool for the territory. He also explains how Hong Kong has simplified its drug registration process by implementing the "1+ Mechanism," which requires only one approval from a recognized country, plus some local evidence or data, for pharmaceutical products indicated for life-threatening or severely debilitating diseases.

What significant developments have occurred in Hong Kong's clinical research landscape since our last conversation over a year ago?

I'm excited to say there have been significant developments in Hong Kong's clinical research landscape. In particular, after October last year, the Chief Executive of Hong Kong announced a plan to establish a clinical trial institute known as the Greater Bay Area International Clinical Trial Institute (GBAICTI) or CTI for short. This institute, established by the Hong Kong government, aims to enhance clinical research in Hong Kong by providing a dedicated platform for conducting trials

and advancing biomedical research and development.

The establishment CTI is part of a broader initiative by the Hong Kong government to promote biomedical research, development, and drug registration. One notable change is the implementation of the “1+ (One Plus) mechanism” in the drug registration process. Previously, Hong Kong required two approvals from recognized countries for new drug registration. However, now – for pharmaceutical products indicated for life-threatening or severely debilitating diseases and granted priority review or similar designations – they only require one approval from a recognized country, along with some local evidence or data, to streamline the approval process. This approach aims to accelerate the approval process while maintaining regulatory standards.

While the 1+ mechanism represents progress, the Hong Kong government aims to establish its own drug review mechanism akin to the FDA. This long-term goal involves building local capacities to independently approve drugs rather than relying solely on approvals from other jurisdictions. Although establishing a primary review mechanism will take time, the transition to the 1+ mechanism marks a step towards achieving this objective.

What prompted, in your view, the government’s shift in stance towards a unified Clinical Trials entity, streamlining processes into a one-stop shop?

I believe this mandate stems from the changing economic landscape in Hong Kong. Traditionally, Hong Kong’s economy relied heavily on finance, real estate, tourism, and import-export industries. However, in recent years we have seen a significant paradigm shift in economic structure, prompting the government to seek new economic drivers.

Recognizing the potential of technology and research as key economic drivers, the government has intensified efforts to promote technology development in various fields, including IT, AI, big data, and biomedical research. This shift in focus aims to leverage Hong Kong’s strong foundation in research and innovation for commercialization and economic growth.

In light of this strategic direction, the government identified the need to streamline the entire ecosystem for biotechnology and biomedical development. This includes promoting clinical research to facilitate the translation of research findings into practical applications. To attract companies to conduct clinical trials in Hong Kong, it’s essential to streamline the registration and marketing authorization processes.

Moreover, Hong Kong's small market size necessitates connecting its biomedical ecosystem with the larger market in Mainland China, particularly the Greater Bay Area (GBA). By tapping into the GBA market, which is significantly larger than Hong Kong's market alone, the government aims to create more opportunities for growth and innovation.

Overall, this decision is a continuation of the government's ongoing strategy to transform Hong Kong into a hub for technology and biomedical research.

We have recently learnt Hong Kong is pursuing observer status with the ICH for the next five years. How do you envision the challenge of training personnel for primary reviews, and what steps are being taken to address potential gaps in expertise?

Yes, indeed. This does presents a significant challenge that we must address strategically. Historically, Hong Kong hasn't cultivated personnel for primary reviews, as this wasn't a focus area in the past. However, recognizing the importance of this capability, the government is now committed to moving in this direction. They understand the necessity of acquiring professional expertise to conduct primary reviews effectively.

To bridge the gap in expertise, the government is likely considering a two-pronged approach. Firstly, they may invest in training existing personnel by sending them to countries renowned for their expertise in this domain, such as China, the US, or the UK. Collaborative efforts with these countries could facilitate knowledge exchange and skill development, which are essential for building a competent workforce.

Secondly, the government may opt to recruit talents from both within and outside Hong Kong. Given the vast pool of experienced professionals, especially in China, tapping into this resource could expedite the process of assembling a skilled team. However, it's crucial to maintain a balance and not solely rely on one source for talent acquisition.

While individuals from China bring valuable experience, it's equally important to consider candidates from overseas to ensure diversity of expertise and perspectives. This multi-dimensional approach would enrich the talent pool and enhance the breadth of Hong Kong's primary review capabilities.

Given Hong Kong's plan to establish itself as a clinical trials hub for the Greater Bay Area, there's a discussion on the existing clinical trial centers. Rather than creating new infrastructure, how do you propose leveraging the two existing centers to maximize efficiency?

Despite having two existing clinical trial centers in Hong Kong, there are still gaps that need to be addressed. The center I oversee has been active for 25 years and has made significant contributions to academic research. However, being part of a university's academic research center, there are limitations to what we can achieve. This is where the CTI comes into play. The CTI represents the government and has the authority to engage with various stakeholders, such as the Hospital Authority, more effectively.

In the past, the Hospital Authority (HA) wasn't particularly supportive of research initiatives as its primary focus was on providing clinical services. However, with the government's directive to prioritize research, there's been a noticeable shift in attitude. Even before the CTI is fully operational, we're seeing increased interest and engagement from the Hospital Authority in supporting clinical research efforts.

Moving forward, the key is collaboration while avoiding duplication. We recognize the value of the existing infrastructure and services provided by both the new CTI and the existing HKU-CTC. By working together, we can ensure that resources are utilized efficiently and that the overall ecosystem for clinical research in Hong Kong is strengthened.

Stakeholders have emphasized the need to enhance the motivation, capacity, and knowledge of clinicians to conduct more clinical trials in Hong Kong. What strategies do you suggest for engaging clinicians more deeply in this field?

I agree – enhancing clinician engagement in clinical trials is pivotal, considering it's been identified as a significant challenge in Hong Kong's clinical research landscape. One key strategy involves alleviating clinicians' administrative burden so they can focus more on research. With the CTI and the Hospital Authority stepping in to manage paperwork, contracts, and finances, clinicians can redirect their limited time and energy towards research endeavors. This centralized support system will streamline administrative tasks, freeing up clinicians to dedicate more hours to research activities.

Moreover, to further empower clinicians, the Hospital Authority is implementing a two-tiered support structure. Firstly, at the head office level, a dedicated team will drive policies on facilitating and supporting research. At the hospital cluster level, cluster coordination offices are being established to provide administrative assistance. These cluster coordination offices will handle logistical and administrative aspects, ensuring smoother project management across different hospital clusters. On-site clinical research coordinators (CRCs) will also be provided to assist clinicians directly with research-related tasks during patient consultations. This division of responsibilities allows clinicians to focus on patient care in research while CRCs support protocol adherence, logistics, documentation, and follow-up, maximizing efficiency and productivity.

Furthermore, to address the challenge of patient recruitment, efforts are underway to broaden the participation of hospitals in clinical trials beyond the traditional teaching hospitals. Historically, limitations in patient numbers at select hospitals hindered trial recruitment efforts. However, with the CTI's collaboration with the Hospital Authority, the government aims to encourage participation from a wider array of hospitals across different clusters. By tapping into the resources of various hospitals, we anticipate a significant increase in patient recruitment capacity, thus attracting more pharmaceutical companies to conduct trials in Hong Kong.

Could you provide insights into the HKU-CTC's performance over the past year? How did 2023 fare in terms of the number of trials conducted compared to previous years?

The pandemic was marked by exceptional busyness at HKU-CTC, primarily due to our involvement in various COVID-related projects. However, transitioning into the post-COVID period presented its own set of challenges, including a noticeable stagnation in progress. This was largely influenced by the subdued global investment environment, particularly in Asia, which had a ripple effect on CROs worldwide. Many industry players, including HKU-CTC, experienced slackening activity, compounded by instances of project cancellations driven primarily by financial constraints rather than the failure of the drug itself. Notably, smaller biotech companies were disproportionately affected by these cancellations.

As we move into 2024, there are promising signs of improvement compared to the previous year. We've observed a resurgence in project activities, with major pharmaceutical companies displaying increased levels of engagement. However, the recovery for smaller biotech companies may take longer as they navigate through the aftermath of the pandemic.

It’s important to recognize that the challenges we face are not isolated incidents but reflect broader trends within the market. Many innovative products originating are facing constraints due to limited investments, resulting in delays or cutbacks in clinical trial projects. These companies are compelled to prioritize their resources, focusing on a select few compounds rather than spreading their efforts thin across multiple projects. This strategic shift reflects the need to optimize resources in the face of financial constraints.

Is there a final message you’d like to convey on behalf of HKU-CTC regarding the future of biomedical research in Hong Kong?

While the global landscape may present challenges, biomedical research remains a pivotal domain for advancement. Hong Kong, with its conducive environment and supportive government initiatives, stands as an ideal hub for research and development in this field. Whether it’s established pharmaceutical multinationals or emerging biotech startups, Hong Kong offers a seamless entry point for companies seeking to engage in biomedical endeavors. With the establishment of the CTI and the ongoing efforts of HKU-CTC, accessing support and resources for conducting clinical trials in Hong Kong has never been easier. Our commitment to facilitating biomedical research transcends the barriers we face, with dedicated teams available around the clock to assist companies in navigating the complexities of research and development. As we look forward, we are confident in our mission to solidify Hong Kong’s position as a premier destination for the research and development of biomedical innovation.

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