Bernard Cheung – CEO, Greater Bay Area International Clinical Trial Institute (GBAICTI)

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Hong Kong is quietly re-engineering how clinical research is organised and delivered across one of the world's most dynamic life-sciences regions. Through the Greater Bay Area International Clinical Trial Institute (GBAICTI), Hong Kong's long-established academic and regulatory strengths are being connected with the scale, infrastructure, and talent of the wider GBA to create a more coordinated, internationally large-scale credible trial ecosystem. GBAICTI CEO Bernard Cheung explores how this model is taking shape, why collaboration matters more than competition, and what it could mean for patients and innovators alike.

What drew you to the role of Chief Executive Officer at the GBAICTI, and how does your professional background inform the way you approach this mandate?

My career has been anchored in medicine and clinical research. I spent more than 25 years at The University of Hong Kong as a clinical academic in clinical pharmacology and internal medicine, alongside my work as an Honorary Consultant Physician at Queen Mary Hospital. During that time, I was closely involved in the development and governance of the University's Clinical Trials Centre and later served as Medical Director of its Phase I Clinical Trials Centre, supporting early-phase and first-in-human studies. Acting as Principal Investigator on multiple clinical programmes gave me a practical view of how trials are designed, regulated, and delivered in real settings.

After stepping away from full-time academic duties, I joined the Hong Kong SAR Government as Biotechnology Director at the Innovation and Technology Commission. That role broadened my perspective from execution to policy and funding. I gained first-hand insight into how public investment decisions are made, how innovation is balanced with accountability, and why Hong Kong has chosen to invest so heavily in innovation and technology. A substantial share of that investment is linked to health, biotechnology, and ageing, even across fields such as engineering, robotics, and artificial intelligence, where medical applications are increasingly central.

The contrast between academia and government was instructive. Academic research values intellectual freedom and unconventional thinking, while government innovation progresses through careful planning, peer review, and incremental change. Bringing these two perspectives together has been formative. I understand the expectations of funding bodies, but I also understand what it means to be a responsible steward of public resources. Standards have risen significantly over the past two to three decades. Today, the expectation is not simply to conduct research, but to operate at the cutting edge and to meet the highest international benchmarks.

Hong Kong is well positioned to do this. It combines globally ranked universities, a highly international research community, and a regulatory environment that supports rigorous clinical research while preserving academic freedom. Researchers work comfortably in English, collaborate widely, and operate within established processes for clinical trial certification and Institutional Review Board (IRB) approval. This combination of academic depth, policy experience, and international connectivity ultimately led me to accept the opportunity to lead GBAICTI.

What gap was the GBAICTI created to address, and why does this model matter for Hong Kong and the wider region?

Hong Kong has developed a strong and credible clinical research base over several decades. While the overall scale has been relatively modest, the quality of execution has been consistently high. When conducted to international Good Clinical Practice standards, trials based in Hong Kong have contributed to the development of many medicines in use today, with data accepted by regulators in the United States, Europe, and Chinese Mainland. That ability to support regulatory submissions across three major markets from a single jurisdiction is an important differentiator.

The establishment of GBAICTI was not a response to gaps in capability, but to fragmentation. Clinical research in Hong Kong has traditionally been distributed across universities, public hospitals, and individual investigators, with limited coordination at a system level. The Institute was

therefore conceived as a non-operational, one-stop platform that aligns stakeholders, streamlines processes, and removes avoidable friction, without duplicating the work of existing clinical trial centres or contract research organisations.

The GBA adds a further strategic dimension. By linking Hong Kong and Macao with major mainland cities such as Guangzhou and Shenzhen, it creates a compact and well-connected region with a population of around 87 million. This area combines new hospital infrastructure, advanced technology, and a strong concentration of clinical and scientific talent drawn from across China. Efficient transport and short travel distances mean that patients and investigators remain close to study sites, which is unusual for a region of this scale.

The Institute’s role is to connect these complementary strengths. Hong Kong contributes established research standards, regulatory credibility, and an international orientation, while the wider GBA brings scale, infrastructure, and patient access. Rather than positioning itself in competition with established centres such as Beijing or Shanghai, the objective is to build a coordinated regional network that can operate at an internationally competitive level. Individually, institutions already perform well. Working together, the region has the potential to achieve a level of impact that none could reach alone.

How does the GBA network enhance trial quality and scale, and what role does the Institute play within this landscape?

The GBA brings together complementary strengths that go beyond patient numbers alone. Cities such as Guangzhou have a long-standing tradition in medicine and clinical research, while Shenzhen, although comparatively young, has invested heavily in modern hospitals, advanced equipment, and facilities that meet international standards. Across the region, there is a strong concentration of clinical and scientific talent, with many senior clinicians and researchers trained at leading medical schools elsewhere in Chinese Mainland before moving into the GBA. In that sense, the region functions as a magnet for expertise, much as Hong Kong does for international researchers.

Within this setting, GBAICTI occupies a deliberately defined position. We do not execute clinical trials, and we do not seek to replace established operators. Trial conduct remains with experienced centres such as The University of Hong Kong and The Chinese University of Hong Kong, which already have mature operational capabilities. Our mandate is to act as a network builder, or what we often describe as a super connector, linking researchers, hospitals, patients, industry partners,

and regulators across Hong Kong, the GBA, and internationally.

By strengthening coordination across this network, we focus on removing avoidable friction that can slow trials down, particularly around start-up timelines, clinical trial certification, and IRB approval. We support the ecosystem through facilitation and targeted funding rather than direct execution, helping investigators access broader collaborator networks and patient pools while giving sponsors greater confidence in delivery and timelines. The objective is to make the system work more smoothly, while responsibility for trial conduct and data integrity remains firmly with the institutions best placed to deliver it.

Since the Institute's establishment, where have you focused your initial efforts, and which priorities will shape its development over the next two years?

Given how recently the Institute was established, our early focus has been deliberately pragmatic. We started by addressing the points in the clinical research pathway where delays most often arise, particularly during trial start-up. Working closely with government counterparts and the Hospital Authority, we concentrated on contracting as a key bottleneck. This included supporting the move towards standardised site contract templates across public hospitals and facilitating a Clinical Site Agreement initiative that allows sponsors to work from a common framework. We are not the contract owner. Our role has been to bring parties together and help them reach alignment more efficiently, rather than allowing progress to stall over non-essential detail.

In parallel, we have focused on the regulatory and ethics approval environment. Ethics review in Hong Kong is now more centralised than in the past, and while this is not solely our achievement, part of our mandate is to support further simplification and better usability, including through digital platforms. An important practical advantage is that clinical trial documentation in Hong Kong is largely conducted in English, apart from patient-facing materials, which means that protocols and documents developed in Europe or the United States can usually be adopted with minimal modification. Under the "One Country, Two Systems" framework, approval processes in the mainland remain distinct, but our emphasis is on aligning requirements rather than removing differences, in a way that is comparable to how European systems operate across jurisdictions.

Another early priority has been clarifying how Hong Kong and Shenzhen work together under the "one institute, one centre" model. The Institute operates from Hong Kong, while our Shenzhen counterpart, Bay Trial, functions under the Shenzhen Medical Academy of Research and Translation. Although they operate within different regulatory and healthcare systems, the two are

aligned in mission and designed to be complementary. Hong Kong builds on its mature academic trial infrastructure, while Shenzhen can provide more direct operational support where needed, particularly for smaller developers. The intention is clear coordination rather than duplication.

Looking ahead, workforce capability is a central theme. Some performance indicators inevitably depend on external factors such as sponsor activity, but what we can directly influence is readiness, speed, and quality. Over the next one to two years, we are focused on professionalising clinical research as a recognised career pathway. This includes plans for an International Clinical Trial Academy, targeted for launch in 2027, to provide structured and continuous training for clinical research coordinators, research nurses, investigators, and data specialists across Hong Kong and the GBA. As international standards evolve, particularly with updates to ICH GCP guidelines and the shift towards more digital trial operations, ongoing training becomes essential. Alongside initiatives such as the Hong Kong Clinical Trials Portal, which will be launched later this year, these efforts are intended to strengthen capability and consistency across the ecosystem, without replicating the operational roles of established trial centres.

How has industry responded to the Institute’s work so far, and where do you see the strongest opportunities in terms of sponsors and therapeutic focus?

Industry feedback has been constructive and broadly positive, with a clear understanding that this is a long-term effort rather than an immediate transformation. Engagement with sponsors has been collaborative, based on working through challenges together rather than taking an adversarial stance. Sponsors value having a credible platform where their perspectives are heard and where dialogue with both the Institute and the wider public sector feels meaningful. That sense of mutual trust is an important foundation for progress.

From the beginning, the approach has been deliberately balanced. Establishing credibility with established international biopharmaceutical companies has been a priority, which is why early partnerships and memoranda of understanding have been pursued. A prominent example is the tripartite agreement with GSK, HKUMed, and GBAICTI, which provides a framework for advancing clinical data science and real-world studies in the GBA. At the same time, growing Chinese biopharmaceutical companies are an equally important focus. Many now have strong domestic research and development capabilities and are progressing assets from early discovery through to late-stage clinical development, increasingly with international ambition.

This evolution is reflected in how clinical development is changing. Over the past decade, the emphasis in China has shifted from predominantly early-phase work towards larger, later-stage trials designed to establish clinical efficacy. Clinical trials sit at the centre of that transition. Hong Kong's position as both a financial centre and a credible clinical research environment makes it a natural bridge for companies seeking international capital and global development pathways, particularly as development costs remain comparatively lower in Asia.

In terms of therapeutic focus, rare diseases stand out as a clear opportunity. The scale of the GBA population makes identifying and recruiting patients more feasible, while Hong Kong's highly centralised electronic health records allow this to be done legally and efficiently. Beyond rare diseases, activity remains strong across oncology, cardiometabolic disease, and immunology. What is striking among many well-funded Chinese companies is the breadth of their pipelines, where high-risk, potentially first-in-class programmes are balanced by biosimilars or lower-risk assets. From our perspective, this diversity reinforces the value of a coordinated clinical trial network that can support both breakthrough innovation and more incremental development.

How is the Institute building capabilities around real-world evidence, and how can these data assets support clinical development and regulatory decision-making across the GBA?

Hong Kong brings a distinctive strength to real-world evidence because its public healthcare system has operated a territory-wide electronic medical record for decades. This has enabled longitudinal, population-level analyses that follow patients across care settings and over long-term horizons, supporting both local and multinational research. Such evidence has already contributed to influential work in areas such as osteoporosis and fragility fractures, helping to shape international policy discussions and to highlight unmet needs in ageing-related diseases. Importantly, real-world data generated in Hong Kong have also been used alongside global clinical trial evidence in regulatory submissions, including reviews by authorities in Chinese Mainland, demonstrating how these datasets can meaningfully complement conventional development programmes.

This depth of data explains the growing interest from industry. While China represents the world's largest healthcare market, structured real-world data development there is comparatively recent. By contrast, Hong Kong's system covers all 43 public hospitals and 124 outpatient clinics, with high population coverage and long follow-up, creating a clinically rich and coherent dataset that is

difficult to replicate.

Our role is to help sponsors access and use these assets responsibly and at scale. Engagement already spans several therapeutic areas, with oncology prominent because of its development intensity, and rare diseases emerging as a strategic priority. While Hong Kong's population is small, combining its high-quality data with the scale of the GBA creates new possibilities. Initial cooperation with Shenzhen authorities is under way, including pilot mechanisms that allow secure cross-border exchange of patient records and imaging. These steps lay the groundwork for harmonised datasets and collaborative real-world studies across Hong Kong and Shenzhen, aligned with broader policy efforts to enable cross-border research while maintaining appropriate governance and safeguards.

How does the Institute position itself amid collaboration, harmonisation, and competition across the Asia-Pacific clinical research landscape?

Our perspective starts with Hong Kong's role within China. Clinical trials conducted here generate data that are directly relevant to Chinese patients, which matters less in market terms than in the potential impact for very large patient populations who may benefit from new therapies. Alongside established centres in Beijing and Shanghai, there is a clear and complementary role for a strong clinical research hub in southern China. The GBA brings together scale, modern infrastructure, and a dense concentration of clinical and scientific expertise, creating a credible platform for high-quality development.

Beyond that, we do not view the regional landscape through a competitive lens. Clinical research is inherently collaborative, particularly in multicentre and multinational trials where broader patient access and diversity strengthen the evidence base. Different jurisdictions contribute different strengths. Singapore, for example, shares many structural similarities with Hong Kong and offers clear opportunities for cooperation rather than rivalry. The same applies across the wider Asia-Pacific region, the United States, and Canada. Our role is to ensure that Hong Kong and the GBA are positioned as reliable, well-connected partners within this ecosystem, aligned with international standards and focused on collaboration that ultimately advances science and benefits patients.

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