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Asiaâ??s growing importance in clinical research is now unmistakable

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Nearly two years on from our last conversation with Henry Yau, Hong Kongâ??s clinical trials narrative has shifted from institutional intent to operational execution. The managing director of the HKU Clinical Trials Centre reflects on how regulatory reform, ecosystem coordination, and on-the-ground capability are now aligning, repositioning clinical research as a core strategic asset for Hong Kong and the Greater Bay Area. The conversation captures continuity of vision, but also a clear step-change in maturity, confidence, and international relevance.

How has Hong Kongâ??s clinical trials environment evolved over the past two years, and what changes have mattered most in practice rather than in policy alone?

Over the past two years, Hong Kongâ??s clinical research environment has moved from policy signalling to concrete system building. The most important development is the Governmentâ??s published roadmap for establishing the Hong Kong Centre for Medical Products Regulation (CMPR), with a phased introduction of a primary evaluation mechanism for drug registration. According to the Department of Health, the centre is targeted for establishment by the end of 2026, with primary evaluation starting in stages during 2026 and full implementation planned by 2030. This marks a shift from aspiration to a defined sequence with timelines.

Hong Kongâ??s acceptance as an observer to the International Council for Harmonisation (ICH) in October 2023 reinforces that direction. Observer status does not confer regulatory authority or voting

rights, but it places Hong Kong within the ICH framework and reflects a clear long-term goal of applying for full regulatory membership, once the necessary regulatory capacity, legislative foundations, and operational experience are in place. Achieving regulatory membership would require years of sustained alignment and consistent implementation of ICH standards across manufacturing and clinical development. On manufacturing quality, Hong Kong already meets international benchmarks through its membership in the Pharmaceutical Inspection Co-operation Scheme (PIC/S), which it joined in 2016. Local manufacturers and imported products are already required to comply with PIC/S-aligned GMP standards. What is now changing is that regulatory reform is being explicitly linked to clinical development capability.

Drug registration sits at the end of the pipeline, but it depends on the credibility of pre-clinical and clinical data. Questions around what data will be required, whether Hong Kong patient data will be expected, and how regional data may be considered are now part of a broader effort to strengthen the clinical trials ecosystem. As a result, clinical research is no longer treated as a supporting activity. It has become a central pillar of Hong Kongâ??s long-term regulatory strategy.

What does the move toward legally enforced Good Clinical Practice mean for how trials are governed and overseen in Hong Kong going forward?

Clinical trials in Hong Kong have never been unregulated. Any drug trial must obtain a Certificate for Clinical Trial or Medicinal Test from the Drug Office under the Department of Health, and conducting a study without that certificate is a statutory offence. Trial design and conduct have long been expected to comply with ICH Good Clinical Practice (GCP) principles. The shift now is not about introducing new standards, but about how those standards are enforced.

Historically, GCP compliance in Hong Kong has relied on professional norms, sponsor audits, and inspections by overseas regulators. When we participate in industry-sponsored trials, sponsors are responsible for auditing quality. Regulators such as the US FDA or Chinaâ??s NMPA have also inspected Hong Kong sites when needed. What has been missing is a formal local inspection regime, largely because GCP was not embedded in law in a way that supported systematic enforcement.

That is now changing. GCP is being more explicitly codified, with defined inspection powers and legal consequences for non-compliance. This does not mean that every study will be inspected. Even mature regulators operate on a risk-based model rather than inspecting every trial. It does mean that inspections become part of the regulatory mandate, guided by clear criteria, and backed by enforcement mechanisms that did not previously exist. From an operational perspective, this represents continuity rather than disruption. We have always worked to ICH standards. The difference is that expectations will now be formalised, inspections may be conducted by local authorities, and accountability will be clearer. This evolution is essential if Hong Kong is to build a credible primary review capability and, in time, apply for full ICH regulatory membership.

How do you define the respective roles of the GBA International Clinical Trial Institute and HKU Clinical Trials Centre within the emerging clinical research ecosystem?

The Greater Bay Area International Clinical Trial Institute (GBAICTI) fills a facilitation and coordination role rather than an execution role. It is a government-established platform focused on promoting Hong Kong and the Greater Bay Area for clinical research, attracting sponsors, and helping them navigate the clinical trial landscape. It does not run or manage trials directly. HKU

Clinical Trials Centre (HKU-CTC) remains an operator. We function as a site management organization, supporting investigators in running their clinical studies by offering site management services such as feasibility assessment, research ethics affairs, budgeting and payment management, contract management, investigational drug and biospecimen management, site logistical support, and study document archiving. We design and manage investigator-initiated and industry-sponsored studies, providing integrated services similar to a CRO, including regulatory support, project management, monitoring, data management, biostatistics, and final clinical study report development, for non-interventional and interventional trials across phase one to phase three. That distinction is deliberate. The institute serves as a specialised entry point and coordination hub, while execution remains with centres and hospitals that have operational depth, experienced teams, and established infrastructure.

In the past, sponsor attraction was handled mainly by broader government bodies such as InvestHK, the Office for Attracting Strategic Enterprises (OASES), or the Hong Kong Science and Technology Parks Corporation (HKSTP), whose mandates extend well beyond clinical research. The institute differs in that it has a narrow and dedicated focus on clinical trials and works alongside those organisations rather than replacing them. Overseas companies identified through international networks may be referred to the institute when clinical development is central to their strategy, and the institute then connects them with operators such as HKU-CTC to initiate trials on the ground. For us, the role does not change. What changes is the structure of the ecosystem around us. Sponsor attraction, coordination, and execution are now more clearly separated and linked. That shift reduces fragmentation and creates a more coherent operating environment. It is an important step if Hong Kong is to move from individual project success to a consistent, internationally credible clinical research platform.

How has demand for HKU Clinical Trials Centre evolved since early 2024, and what does this reveal about Hong Kongâ??s role in early clinical development?

Following a challenging period marked by lower activity after COVID-19, our operations have begun to stabilise and the market is now entering a phase of consolidation. This is not a rapid rebound, but there are clear signs that conditions are improving. One of the most notable developments is renewed interest from overseas sponsors, which suggests that recent government initiatives are starting to translate into practical engagement rather than remaining at the level of policy ambition.

We are seeing more international companies reassess Hong Kong as a base for early clinical development, particularly for focused proof-of-concept work. A recent example involved a Swiss biotech with an experienced senior management team that explored Hong Kong for early-stage studies. While the companyâ??s overall ambition is global development, its approach was pragmatic. Rather than launching a global trial immediately, it planned a registry study followed by a phase 2a proof-of-concept trial in Hong Kong, alongside a phase 1 study initiated in the United States. This type of strategy is increasingly common. Early phase studies benefit from being tightly designed and operationally efficient, and Hong Kong offers strong investigators, relevant patient populations, and a system that allows sponsors to move quickly once decisions are made. In this case, extensive discussions took place well in advance of the on-site visit, so when the team arrived, most issues had already been resolved and the process moved smoothly.

At the same time, we are seeing a shift in the profile of mainland Chinese companies engaging with us. In earlier years, most China-related activity involved smaller start-ups seeking data to support overseas expansion. That pattern is changing. More large mainland pharmaceutical companies are now paying attention to Hong Kong, and some are beginning to establish a physical presence here.

Contract volumes remain modest and are still at an early stage, but the change in behaviour is meaningful. Establishing offices in Hong Kong involves cost and commitment, and companies would not take that step without a clear strategic rationale. Taken together, these developments suggest that Hong Kong is increasingly viewed not simply as a commercial market, but as a credible and efficient platform for early clinical development within a broader global strategy, which aligns closely with how we see our role at HKU-CTC.

How are trial modalities and therapeutic priorities evolving at HKU Clinical Trials Centre, and where are you seeing the most meaningful shifts?

Oncology continues to sit at the core of our clinical trial portfolio, as it does globally, and it remains the main entry point for many multinational sponsors. What has become more pronounced in recent years is the parallel growth of highly specialised modalities, particularly gene therapy, which is now a clear area of focus rather than a peripheral activity. We are seeing increasing interest in gene therapy trials, especially in hepatology. Hong Kong has deep clinical expertise in liver disease, including hepatitis B, supported by experienced investigators and an established patient base. That combination has attracted a growing number of international developers. Unlike small molecule drugs, where large pharmaceutical companies still dominate, gene therapy programmes are more often driven by smaller overseas biotechs, reflecting where innovation in this field is currently concentrated.

These studies differ fundamentally from more conventional trials. Patient cohorts are small, many programmes are first-in-human or early proof-of-concept, and there is limited precedent to draw on. Our dedicated Phase 1 Unit plays a central role here, enabling us to manage early and first-in-human studies with the level of control and oversight they require. Safety planning, close monitoring, and experienced study teams are essential, as uncertainty is inherent at this stage of development. We are also closely involved in patient recruitment. Clinicians have been engaged, and patients have shown a willingness to participate, often reaching out proactively. While gene therapy trials carry higher perceived risk, careful design and disciplined execution matter more than scale. In practice, unexpected events have been managed appropriately, and patient confidence has been maintained.

Strategically, this reflects a deliberate choice. Hong Kongâ??s compact healthcare system allows expertise and patients to be mobilised efficiently, which suits complex early phase work. Not every centre can run these studies, and sponsors are highly selective when placing first-in-human programmes. The fact that more companies are choosing to work with us in this area speaks to trust in our capabilities and to Hong Kongâ??s role as a credible platform for high value, early clinical development.

What priorities are guiding HKU Clinical Trials Centre as it approaches its next milestone, and how ready is Hong Kong to absorb a higher volume of clinical research?

As we approach the next milestone year, our priorities naturally sit across three interconnected layers: Hong Kong, the Greater Bay Area, and our international engagement. At the local level, the ecosystem is becoming more structured. With the GBAICTI now in place, and with the Hong Kong CMPR progressing toward implementation, Hong Kong is better positioned than before to attract clinical trials from both overseas sponsors and the Chinese Mainland. The limiting factor is no longer intent, but readiness on the ground.

Hong Kong has a strong public healthcare system, with 43 public hospitals under the Hospital Authority, but it has historically been optimised for service delivery rather than for scaling research activity. As policy momentum builds, that imbalance becomes more visible. This is why the Hospital Authorityâ??s establishment of a Central Clinical Research and Innovation Office, supported by cluster-level research support offices, is an important structural step. The objective is to coordinate research more effectively across hospitals, strengthen collaboration with universities, and lower the operational barrier for clinicians who want to engage in research. From our perspective at HKU-CTC, the priority is to work closely with both the GBAICTI and the Hospital Authority, sharing operational experience and infrastructure so that growth in clinical research is matched by consistent quality, governance, and execution.

How does Hong Kongâ??s move toward a primary review system translate into practical capability, and where does HKU-CTC fit into that transition?

A credible move toward primary review inevitably requires deeper capability across the system. That includes regulatory expertise, clearer review processes, and an environment that can support high-quality clinical development from early phase through to submission. Our role is not to shape policy, but to contribute pragmatically by sharing what we have already built through years of operating to international standards.

One tangible example is our digital infrastructure. Over the past six years, we have developed eCPort, our Electronic Cloud Portal for Clinical Trial Institution Management, entirely in house. The platform is now fully operational and supports the early lifecycle of a clinical trial, from project intake and ethics coordination to budgeting, contract workflows, and operational planning. It provides a central interface linking investigators and our site management team, helping to standardise processes and reduce friction at both institution and study levels. eCPort also embeds governance into day-to-day operations. Standard operating procedures are managed digitally, with structured approval workflows and integrated training records, ensuring that updates are communicated, acknowledged, and documented without reliance on paper-based systems. Core trial functions, including investigational product accountability, biospecimen management and participant management, are also integrated. This is not about digitisation for its own sake, but about creating a disciplined, transparent operating environment that can support more complex regulatory expectations as the system evolves.

How does this infrastructure connect to the wider ecosystem across Hong Kong and the Greater Bay Area, and what does it change for sponsors and partners?

eCPort is an internal operational management platform rather than a public-facing trial registry. Its primary purpose is to support consistent and efficient quality management and trial execution. Public access to information on available trials should sit with the GBAICTIâ??s planned Hong Kong clinical trials portal, which is intended to provide a transparent entry point for clinicians and patients. That said, the platform is not confined to HKU-CTC. We are progressively extending access to partner institutions via HKU-CTCâ??s ClinCluster collaborative network, including collaborators in Macau and Hong Kong, so that trial operations across sites can be coordinated on a shared backbone. It is already in use at Macau University of Science and Technology (MUST) and Gleneagles Hospital Hong Kong (GHK), where their dedicated Clinical Trials Centres were launched with HKU-CTCâ??s support in September 2023 and September 2024, respectively. ClinCluster and eCPort have demonstrated initial success by the start of the first ever industry-sponsored novel drug trial in

Macau at MUST in August 2025. Establishment of Gleneagles CTC also reflects a shift in how the Hong Kong private sector approaches clinical research, moving away from ad hoc participation toward more structured and credible trial operations.

We are also extending the systemâ??s relevance for sponsors and, potentially, regulators. A read-only audit and inspection module is being prepared that would allow parts of audits to be conducted off-site, reducing on-site burden and shortening timelines while maintaining oversight. We have discussed this with regulatory agencies and several sponsors operating in China including the Greater Bay Area, who have responded positively. These are practical, execution-focused changes that make Hong Kong and the Greater Bay Area easier to work with, not through ambition alone, but through systems that are already in use.

As Asia becomes more central to global drug development, how does HKU Clinical Trials Centre remain competitive, and what role can Hong Kong realistically play?

Asiaâ??s growing importance in clinical research is now unmistakable. Larger patient populations, deeper understanding of regional disease patterns, and steadily improving clinical and regulatory capabilities have shifted the centre of gravity in global development. That shift creates opportunity, but it also sharpens competition. For us, and for Hong Kong more broadly, the response has never been to compete on cost, which is neither realistic nor sustainable, but to compete on value and competency. Hong Kong will always be a high-cost environment, and we accept that reality. What we can do is build around it by focusing on trials that demand experience, governance, and operational discipline. Our emphasis is therefore on complex, high-value work, including early-phase and first-in-human studies, as well as advanced modalities such as gene therapies. These programmes require experienced investigators, robust quality and safety systems, full professional service support, and an ecosystem sponsors can trust, and they are not easily transferred to low-cost settings.

Competitiveness today also depends on collaboration rather than isolation. Our GBA strategy reflects this. We work closely with partners in Macau and are preparing to deepen cooperation with centres in the Chinese Mainland, allowing sponsors to distribute different components of a programme across sites with varying cost profiles. In this model, Hong Kong retains responsibility for scientific and quality oversight and the most complex elements, while more cost-competitive locations can support scale where appropriate. Sponsors increasingly see value in this balance.

At the same time, Hong Kongâ??s international role remains essential. We continue to position ourselves as a connector between the Chinese Mainland and the global research community by staying closely engaged with international clinical research networks. Our long-standing involvement in the ICN (International Clinical Trial Center Network), as well as our work with CIOMS (the Council for International Organizations of Medical Sciences) and the WHO, reflects this commitment. Through CIOMS, we contributed to the development of Good Governance Practice for Research Institutions, which places institutional responsibility and governance at the centre of research quality. More recently, our participation in the WHOâ??s Global Clinical Trials Forum (GCTF) â?? as one of the only 26 non-state actors worldwide â?? allows us to contribute to a global effort to strengthen collaboration and preparedness across trial systems, drawing directly on lessons from the pandemic.

Operationally, this expansion brings constraints as well as opportunities. We now have a team of more than 100 people and an increasing workload across Hong Kong, the Greater Bay Area, and international initiatives. Cost discipline therefore matters. We do not operate with a profit mandate, but sustainability is essential, and growth has to be selective and deliberate. In the end, our competitiveness rests on clarity of focus. We concentrate on difficult, high-impact work, collaborate

intelligently across the region, and remain anchored in international standards and networks. That is how we believe Hong Kong can continue to play a credible and relevant role as Asiaâ??s presence in global clinical development continues to grow.

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