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HKSTP

Developing Hong Kong into Asia's Leading Clinical Innovation Hub

November 2023

Contents

Executive Summary

Purpose

This report identifies clinical research as a strategic pillar of Hong Kong's Innovation and Technology (I&T) development. Clinical trials are crucial to the biotechnology value chain, with significant socioeconomic implications for Hong Kong, driving not only academic success, but also economic growth and healthcare development. As the experience from the UK National Institute for Health and Care Research (NIHR) shows, a GBP 1 investment in clinical trials can yield up to GBP 7.6 in economic benefit, highlighting its economic potential.

As the world flocks to biotechnology development, studies predict a global expansion on clinical trials with an annualised growth of 6% over the next decade, with Asia set to outperform. However, despite having renowned academics, world-class healthcare infrastructure, and internationally recognised trial quality, the number of clinical trials conducted in Hong Kong has declined by 22% between 2015 to 2021, behind the 48% average increase in major economies and the 285% exponential growth in mainland China.

Through a combination of expert surveys and interviews covering approximately 250 stakeholders, this study unveils the gaps that explain Hong Kong's lagging competitive position and makes policy recommendations that develop Hong Kong into the go-to place for clinical research and commercialisation, attract top-tier biotechnology firms, foster talent development, and strengthen Hong Kong's position as the bridge between China and the West. The study contemplates important policy proposals such as the establishment of a Clinical Research Institute for policy facilitation, as well as building Hong Kong's drug primary review authority.

Challenges

The challenges are found to be three-fold. Firstly, there is a capacity constraint for both clinical investigators and research support staff. 70% of survey respondents considered the number of investigators insufficient. Hospital clinicians are overburdened, with little incentive to participate in clinical research as they are overburdened by complicated administrative procedures, with their overtime efforts not being recognised; this is not to mention the fact that they have to manage administrative procedures themselves.

Secondly, Hong Kong has an unnecessarily long and duplicative trial approval and contract agreement timeframe relative to neighbouring economies. Especially for phase 1 first-in-human studies, 90% of respondents reported a Clinical Trial Certificate approval process that takes more than three months. Together with slow patient recruitment due to an underutilised patient base, trial start-up time can often take more than a year, driving pharmaceutical companies away due to commercial concerns.

Finally, the broader value chain is found to be incomplete, both in terms of ancillary facilities for clinical research and market access at a later stage. Hong Kong doesn't have sufficient central laboratories and manufacturing facilities, nor an effective agreement in place to conduct multi-centre trials in the Greater Bay Area (GBA). In addition, companies have limited incentives to place clinical trials in Hong Kong if there is no regulatory capability to review trial results for drug registration, as drugs first need to be registered overseas before going through a secondary review in Hong Kong based on foreign approvals.

Recommendations

This report recommends a multi-pronged strategy for Hong Kong to become Asia's leading clinical innovation hub, encompassing government facilitation, talent development, clinical operation, as well as the broader value chain.

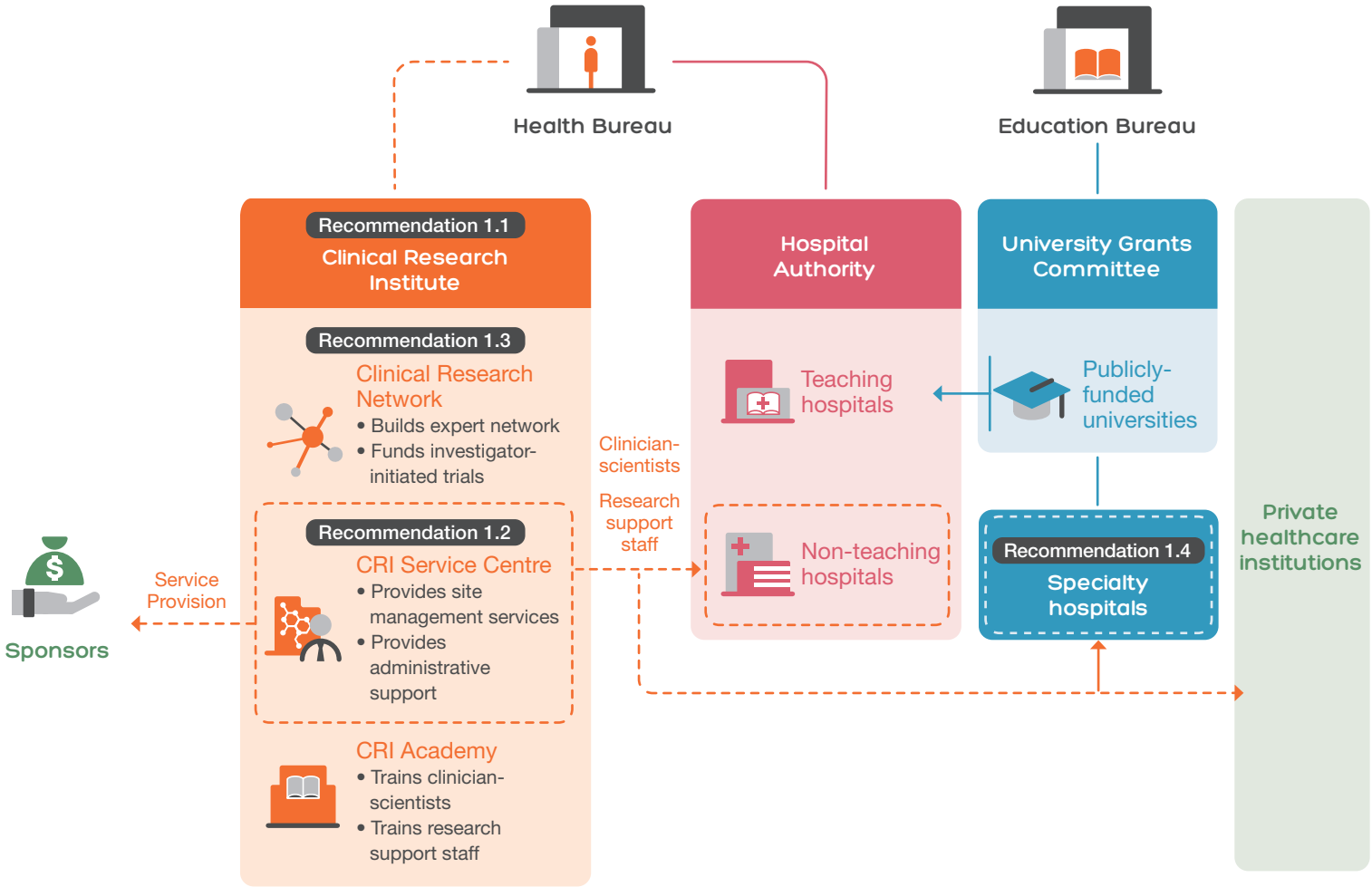
Strategic facilitation through a Clinical Research Institute

The Hong Kong SAR Government (hereafter "the Government") should strengthen its role in facilitating clinical research. Referencing NIHR's practices in the UK, a Clinical Research Institute (CRI) should be set up directly under the Health Bureau to foster concerted efforts between universities, the Hospital Authority (HA), and the private sector, expanding the scope of the current Research Office. Rather than only funding research schemes like the Health and Medical Research Fund (HMRF), the proposed CRI should perform three key functions:

- **CRI Service Centre** to act as a one-stop service centre for pharmaceutical companies, hospitals, and other agencies by providing centralised research support services, referencing the successful experience of Clinical Research Malaysia (CRM). With independent budgeting, it would be empowered to provide feasibility studies, patient referral, site management, administrative support, and radiology and laboratory services especially for non-teaching hospitals currently without a dedicated research centre;
- **Clinical Research Network** to bring together an international network of investigators, hence promote research collaboration and exchange. These networks can act as funding intermediaries and mentorship platforms for younger specialists;
- **CRI Academy** to groom clinical research talents by offering professional and certified training, particularly for clinical research coordinators.

  The CRI should also advise on the establishment of university-run research centres and speciality hospitals in specific disease areas.

Figure i. Relationship between the Clinical Research Institute and other stakeholders



Building career paths for research personnel

A comprehensive talent development strategy is needed to build career paths not just for investigators but also research coordinators, research nurses, and other support staff. This involves grooming young talents and unleashing the full potential of existing personnel. Clinical research activities should be better incentivised in the HA while being cognizant of the current manpower challenges by:

- incentivising clinical research participation. Promotions should factor in clinical research activities, clinicians' overtime efforts should be remunerated, and flexible arrangements should be in place for unused sponsor fees to be utilised for research development;
- developing innovative models that allow clinicians' work to be split between clinical duties and research, such as clinician-scientist posts and clinical research fellowships;
- providing more professional training opportunities to systematically cultivate clinical research specialists. Tertiary education and specialist training should include more research components.

Establishing a primary review authority for drug registration

This report calls for the Government to set up a primary review authority for new drug registration, similar to the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and China's National Medical Products Administration (NMPA). It will catalyse systemic change by providing a clear regulatory pathway towards drug commercialisation from bench to bedside; personnel employed will complete the talent ecosystem and migrate between academia, industry, and regulators. More importantly, it reinforces Hong Kong's position to connect the world in drug access: harnessing Hong Kong's international reputation for research and medical excellence, Chinese pharmaceutical companies could have drugs listed in Hong Kong to go international based on multilateral agreements, while foreign drugs can enter the Chinese market through an enhanced Medicine Link arrangement for use in the GBA. Specific actions to be taken include:

- capacity building through a regulatory pipeline for innovative drugs. Global drug regulatory experts could be invited both as advisors and full-time staff;
- becoming a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and be part of multilateral agreements on drug approval;

- collaborating with the NMPA through mutual abridged review for drug registration and recognition of trial approvals; and
- other cross-border initiatives such as cross-border research funding and easing the flow of biological samples and biochemical materials.

Although achieving the intended vision can take up to 8 years, it is envisaged that the abridged review can be achieved by 2026.

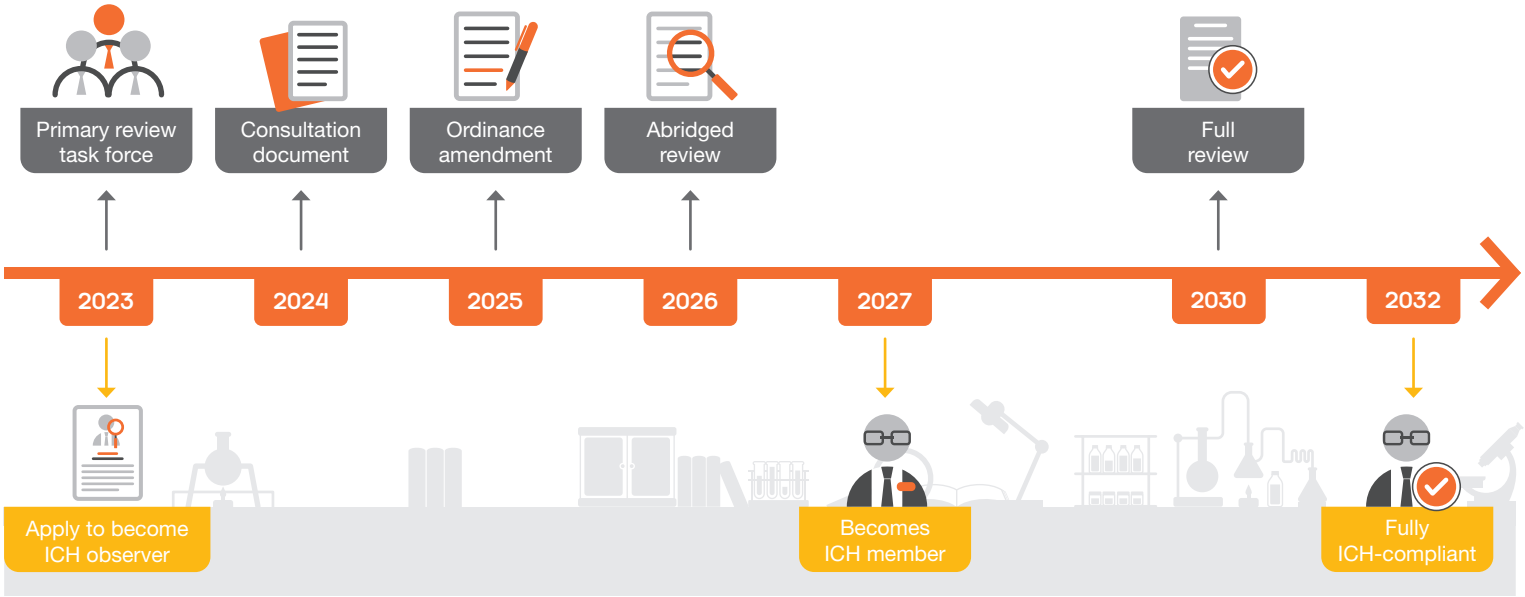
Attracting businesses through more efficient regulatory processes and preferential policies

Hong Kong's business appeal would improve if duplicative regulatory processes are removed and preferential policies are in place to make clinical research and development more efficient and profitable. For example:

- ethics committees can develop a mechanism to recognise each other's approvals, and government agency can allow low-risk studies to be approved in principle if there are no regulatory objections upon ethics committee approval, referencing practices from Australia, Singapore, and Taiwan;
- the HA's patient database should be optimised to adhere to international standards, and facilitate data access for patient referral, site monitoring and data auditing, similar to Korea National Enterprise for Clinical Trials (KoNECT); and
- attraction and provision of central laboratories and small-scale manufacturing facilities, facilitated by preferential tax and land arrangements, would supplement the ecosystem by providing critical infrastructure and expertise.

Clinical research is one of the growth engines for Hong Kong's future. That said, this report has uncovered multiple policy gaps from government, talent, and business perspectives. As regional counterparts rush to capture future opportunities in biotechnology, Hong Kong cannot be complacent in past achievements. Instead, the Government should facilitate concerted efforts to build Hong Kong's clinical research capacity, attractiveness, and global connectivity, hence, to become Asia' leading clinical innovation hub.

Figure ii. Proposed roadmap for Hong Kong to introduce a primary review mechanism



Notes: (1) Referencing the legislative timeline for the Pharmacy and Poisons (Amendment) Ordinance 2020 for Advanced Therapy Products, it would take four years for the introduction of abridged review and another four years for full review at best.

(2) ICH observership is granted in a biannual ICH Assembly meeting, while that for membership (fulfilling Tier 1 guidelines) and full compliance (fulfilling Tier 2 guidelines) take two and five years respectively (ICH, 2020). An extra year is reserved for industry preparation before full compliance.

(3) Harmonisation with the NMPA and collaboration with leading drug regulatory bodies would achieve upon Hong Kong's introduction of full primary review mechanism.

Summary of Policy Recommendations

Recommendation

1 Institutionalising strategic facilitation by the Health Bureau

1.1 Establishing a Clinical Research Institute (CRI) to provide strategic facilitation

1.2 Setting up a Service Centre to provide centralised support services

1.3 Setting up a Clinical Research Network with funding support to enhance investigator collaboration

1.4 Developing research centres and specialty hospitals while pioneering the development of university-run hospitals

Recommendation

2 Building a talent development strategy for clinical research professionals

2.1 Recognising clinical research in the HA through incentives such as promotion factors

2.2 Creating clinician-scientist positions and expanding clinical research fellowships

2.3 Offering professional training for research support staff

2.4 Enhancing tertiary education and specialist training to nurture research-minded clinicians

Recommendation

3 Positioning Hong Kong as the "super-connector" of drug development

3.1 Establishing Hong Kong's drug primary review authority

3.2 Expediting drug registration and clinical trial approval with the NMPA

3.3 Optimising joint funding schemes to enable cross-border clinical research

3.4 Facilitating cross-border flow of human genetic materials, chemical and biological entities

Recommendation

4 Accelerating clinical trials through start-up and capability improvement

4.1 Promoting mutual recognition of Ethics Committee (EC) approvals

4.2 Introducing a Clinical Trial Notification scheme

4.3 Standardising and facilitating Clinical Trial Agreement settlement

4.4 Building a comprehensive trial registry and allowing targeted access to the HA's patient database

4.5 Supporting the private clinical trials sector through quality assurance of ECs and capability building

Recommendation

5 Addressing infrastructure and skill gaps to foster clinical trial activities

5.1 Offering tax and land incentives to attract clinical trials and related R&D activities

5.2 Gearing up research infrastructure and expertise through laboratories and manufacturing facilities

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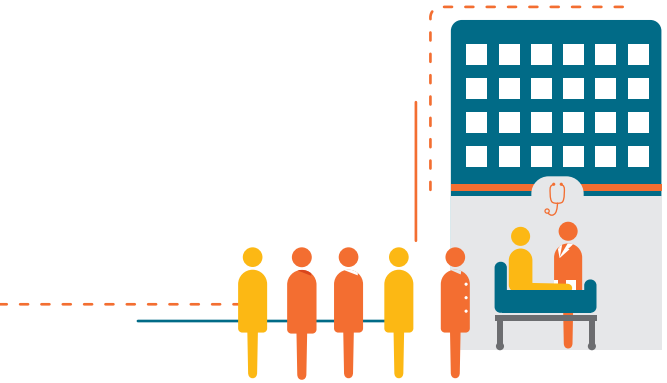
Developing Hong Kong into Asia's Leading Clinical Innovation Hub



Hong Kong's future will be driven by innovative technologies. Amongst different sectors within the I&T space, Hong Kong has a clear edge in biotechnology (biotech). Two of its universities are ranked top 50 globally in medicine and top 100 in pharmacy and pharmacology (Quacquarelli Symonds Limited, 2023).[1] The city has one unified public healthcare service provider while 17 of its private hospitals have been accredited by international bodies for their healthcare service delivery;[2] and its close adherence to quality and standards in various fields such as testing, certification, and manufacturing makes the city a prospective global biotech hub (ACHS, 2023; JCI, 2023).[3]

[1] The University of Hong Kong (HKU) is ranked 31st and 79th respectively in medicine, and pharmacology and pharmacy, while the Chinese University of Hong Kong (CUHK) is ranked 32nd and 71st.

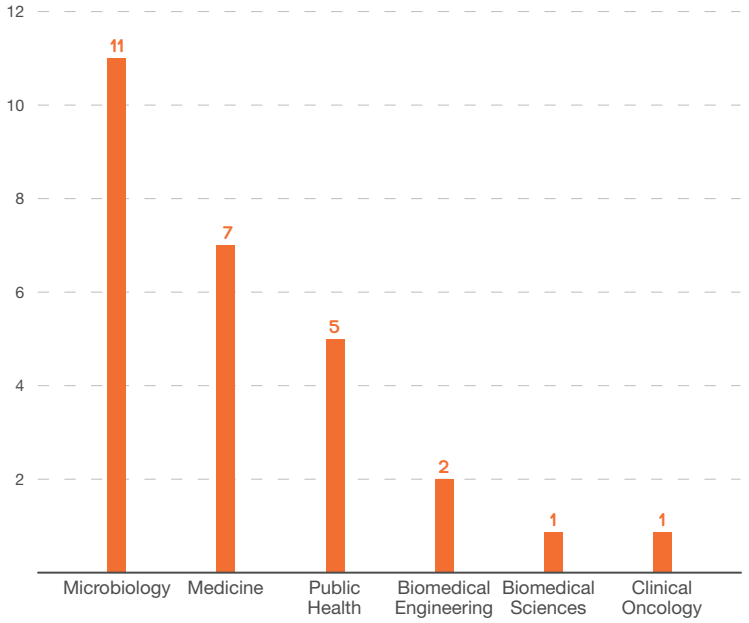
[2] Hong Kong currently has 15 private hospitals accredited by the Australian Council on Healthcare Standards (ACHS) and 2 private hospitals by the Joint Commission International (JCI). In 2009, the Hong Kong Government launched a pilot hospital accreditation scheme with the ACHS, and all the public hospitals participating in the scheme were accredited for four years (Legislative Council Secretariat of the HKSAR Government, 2011).

[3] For instance, the Hong Kong Accreditation Service is a signatory of various Mutual Recognition Arrangements (MRA) and is recognised by more than 100 economies (Innovation and Technology Commission of the HKSAR Government, 2023b). Hong Kong's Pharmacy and Poisons Board was also admitted to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) in 2016 in recognition of its compliance with the scheme's Good Manufacturing Practice (GMP) standards (PIC/S, 2023).

The Government has therefore designated life and health sciences as a key development area in the *Hong Kong Innovation and Technology Development Blueprint* published last year; in fact, biotech had has also been designated as an evolving industry of strategic importance in China's *14th Five-Year Plan* (Innovation, Technology and Industry Bureau of the HKSAR Government, 2022; Central People's Government of the PRC, 2021). Thus, the sector's development in Hong Kong could become a strategic step in deepening socioeconomic ties with the mainland.

The quality of Hong Kong's clinical trials is a perfect showcase of Hong Kong's strengths in biotech. Many of Hong Kong's top biotech scholars come from the departments of medicine **(Figure 1)** (Clarivate, 2023). The city's advanced hospital infrastructure generates high quality clinical trial data that is recognised by major drug regulatory bodies including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and China's National Medical Products Administration (NMPA).[4]

Figure 1. Number of Hong Kong's Highly Cited Researchers in different biotech disciplines



Note: As many biotech researchers are highly cited in the "cross-field" category, the above categorisation is based on the department to which the researcher has primary affiliation.
Source: Clarivate (2023)

[4] Specifically, specialties in four hospitals were designated as accredited sites for NMPA clinical trials. They include Queen Mary Hospital, Prince of Wales Hospital, Hong Kong Eye Hospital, and Hong Kong Sanatorium & Hospital (NMPA, 2019).

Clinical trials play a critical role in innovation-based economies for several reasons:

Advancing innovation: Clinical trials aim to evaluate the safety and efficacy of innovative interventions in human subjects. It is pivotal in the translational journey before commercialisation **(Figure 2)**.

Unsurprisingly, prominent ones are often led by academics. The ground-breaking Phase III IRESSA Pan-Asia Study (IPASS) led by Professor Tony Mok from The Chinese University of Hong Kong (CUHK), for example, revolutionised the standard of care for Asian patients with non-small cell lung cancer (Department of Clinical Oncology, CUHK, 2023). Likewise, the Phase II and III studies on treatments for chronic hepatitis B conducted by Professor Lai Ching Lung from the University of Hong Kong (HKU) have redefined the treatment endpoints for the disease, which is particularly prevalent in Asia (Department of Medicine, School of Clinical Medicine, HKU, 2020).

The far-reaching impact of such trials reflects the ability of local investigators and bolsters the international standing of Hong Kong as a biotech hub.

Figure 2. Typical translational journey of pharmaceutical products

Stages	Basic research	Target validation	Compound screening	Lead optimisation	Pre-clinical test	Phase 1 trials	Phase 2 trials	Phase 3 trials	Drug registration
Number of drug candidates			>10,000	~250	10–20	~6	~4	~2	
Probability of success						~66.4%	~48.6%	~59%	
Cycle time (year)		~1.5	~1.5	~1.5	~1	~1.5	~2.5	~2.5	~1.5

Source: Sun, et. al. (2022)

Enhancing patient care: Clinical trials provide patients with access to investigational drugs, which can be critical to those in need of late-line treatment and those with rare diseases as the drug development process for such diseases are exceptionally long.[5] Besides, the promotion of research in hospitals fosters evidence-based medicine, where clinicians make medical decisions based on the best available scientific evidence. This improves general patient care, hospital culture, and Hong Kong's international reputation, thereby retaining mid-career clinicians to stay in the public healthcare sector while also attracting foreign clinicians and talent.[6]

Saving healthcare costs: As trial drugs are sponsored by pharmaceutical companies instead of healthcare providers, studies in Austria show that healthcare cost savings can be up to USD 110 million per year (Walter et. al., 2020).[7] Besides, better treatments for patients imply reduction of hospitalisation and easing of financial burden.

Driving economic growth: Clinical trials, particularly those funded by pharmaceutical companies, can also generate significant economic returns. Studies quantifying the spillover effects of clinical trial investments estimated a leverage rate of up to 760% (National Institute for Health and Care Research, 2019).[8]

Prof Tony Mok, Chairman of the Department of Clinical Oncology at CUHK, was named a "Giant of Cancer Care" for his contribution and leadership in research and clinical for lung cancer (OncLive, 2020). Prof Mok believes that clinical research is the foundation for advancing medical innovation and improving patient care quality, without which, new therapeutic devices, drugs, and methods cannot be developed.

[5] Teenage and young adult patients with acute lymphoblastic leukaemia participating in trials have a higher survival rate (Hough, et. al., 2017). For gastric cancer, clinical trials are used as post-second line treatment and may prolong survival (Smyth & Moehler, 2019).

[6] Research and innovation are indicators adopted by international rankings for hospitals such as World's Best Hospitals. The global top three hospitals, namely Mayo Clinic–Rochester, Cleveland Clinic, and Massachusetts General Hospital, have all established research institutes (Newsweek, 2023).

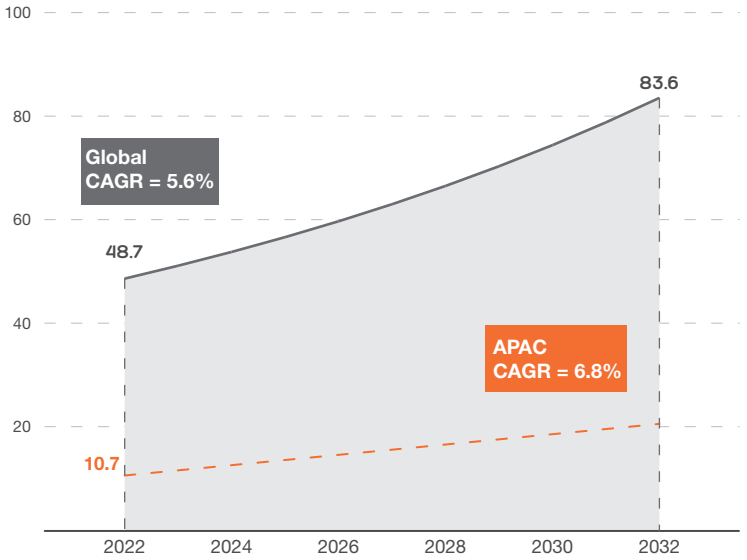
[7] In the UK, the total estimated medical cost saving was GBP 28.6 million (USD 36 million) in 2018/19 (National Institute for Health and Care Research, 2019). In Austria, saving was up to EUR 100 million (USD 110 million) in 2018.

[8] In the UK, sponsored clinical trials contributed GBP 355 million to the National Health Services (NHS) and GBP 2.7 billion to the economy in 2018/19, suggesting a leverage rate of 760%. In Austria, such trials contributed EUR 74 million to healthcare institutions and EUR 144 million to the economy in 2018, suggesting a leverage rate of 195% (Walter, et. al.,2020).

Asia Pacific accounts for around 20% of clinical trial's global market share in 2022 **(Figure 3)** (Precedence Research, 2022). In the next ten years, the expected growth of clinical trials in APAC (6.8%) is expected to outpace the global market (5.6%). Notably, mainland China is the main growth engine for Asia's clinical trial market, with the number of trials increasing by a staggering 285% between 2015 and 2021, driven mainly by Chinese sponsors (Castaneda & Hillman, 2022).[9]

While nearly all leading regional economies have shown double-digit growth, the number of trials in Hong Kong has actually declined by 22% during the same period **(Figure 4, P.15)**. Hong Kong has so far missed the opportunity to elevate its international status and trial capabilities by tapping into resources in the mainland, including talent, research infrastructure, capital, and patient pool.

Figure 3. Predicted clinical trials market size (USD billion)



Source: Precedence Research (2022)

[9] Only one in four commercial clinical trials in China are sponsored by an overseas company.

Figure 4. Number of clinical trials in Asia Pacific and global economies

	Number of trials		Percentage change
	2015	2021	
Asia Pacific			
Mainland China	**2,989**	**11,498**	**+285%**
Malaysia	168	271	+61%
South Korea	1,354	2,013	+49%
Australia	1,656	2,308	+39%
Singapore	268	322	+20%
New Zealand	452	517	+14%
Japan	3,473	3,692	+6%
Hong Kong SAR	**426**	**334**	**-22%**
Global			
US	7,695	9,932	+29%
UK	2,394	2,439	+2%

Note: The above only includes interventional trials. The validity for clinical trial certificates in Hong Kong has changed from two years to five years in 2015.
Source: World Health Organization (2023), Pharmacy and Poisons Board of Hong Kong (2023)

The Government needs to step up policy efforts to enhance the clinical research ecosystem so that Hong Kong can become the clinical trial destination of choice in Asia. Furthermore, the Government should leverage on the advantage of "one country, two systems" to ride on the explosive growth in the mainland.

This study aims to conduct a systematic review of the current clinical research ecosystem in Hong Kong and provide policy recommendations to:

1. **Build Hong Kong into Asia's leading clinical innovation hub and create a new engine for economic growth;**
2. **Create new job opportunities in clinical research for our younger generation;**
3. **Bridge international and mainland Chinese markets and improve patients' drug access by leveraging on "one country, two systems".**

A concerted effort is required by medical schools and healthcare service providers to build Hong Kong's capacity and attractiveness; the city's drug regulatory system needs to be enhanced in order to better connect with mainland China and international counterparts.

2 Research Methodology and Gaps Identified

2.1 Research methodology

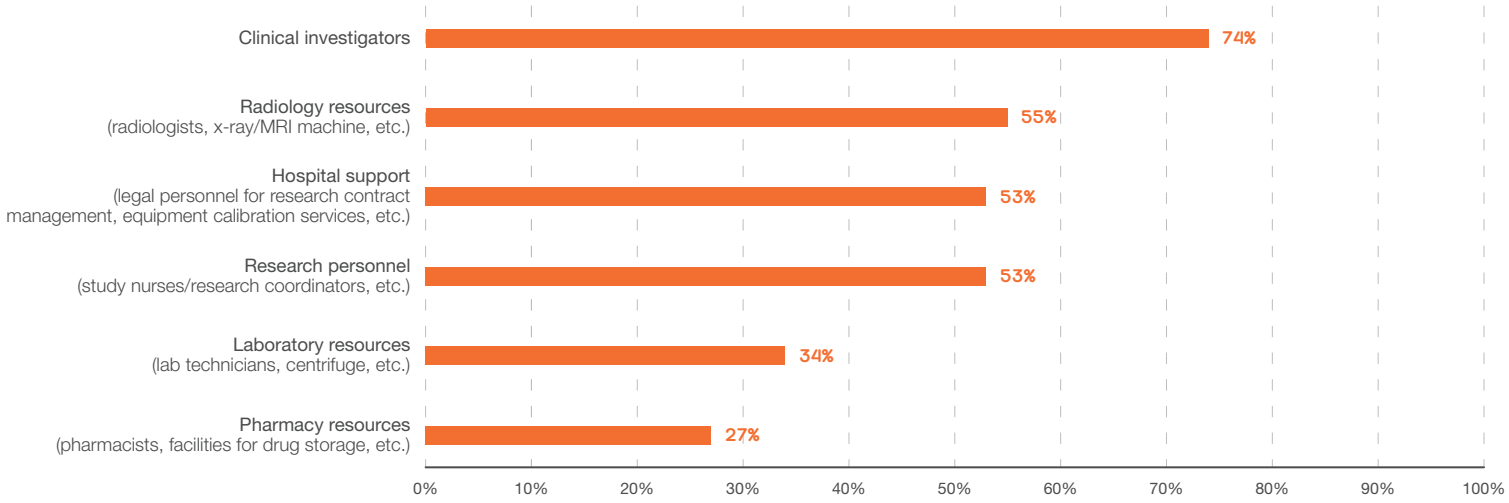
The research was carried out based on surveys and stakeholder interviews. An online survey was conducted in October 2022 with 81 respondents comprising of clinical operation teams of multinational pharmaceutical companies, biomedical startups, Contract Research Organisations (CROs), as well as investigators from medical schools and the public and private healthcare sectors **(Appendix 1)**. Survey responses captured front-line views on the advantages and disadvantages of Hong Kong as a clinical innovation hub, including hospital capacity and investigator availability, clinical trial approval processes, subject recruitment and trial management, GBA opportunities, as well as comparisons with regional counterparts.

The research team then conducted in-depth interviews and focus groups between December 2022 and June 2023 to get a holistic view of the concerns and pain points. The 166 interviewees cover the above groups and their senior management, as well as other professionals including pharmacologists and pharmacists, biostatisticians, research nurses, research coordinators, charity funds, and regulators **(Appendix 2)**. The list of consented interviewees is provided at the end of the report.

2.2 Gaps identified

The above process has uncovered key issues that handicap Hong Kong's capacity to take on world-class clinical trials, create inefficiencies which diminish its attractiveness for pharmaceutical companies, and undermine its potential to become a hub for global drug access.

Figure 5. Percentage of respondents indicating an inadequacy of resources to support clinical trials in Hong Kong



2.2.1 Insufficient hospital capacity due to talent shortage

74% of respondents agree that there is an inadequate number of clinical investigators **(Figure 5, P.17)**. Within which, most believe that the root causes are preoccupation with clinical services (89%) and the lack of administrative support from hospitals (89%) **(Figure 6)**. Furthermore, 91% of respondents believe that sponsorship and promotion opportunities would enhance the willingness of clinicians to conduct clinical trials **(Figure 7)**.

Several factors limit the ability and willingness of potential clinical investigators, particularly Hospital Authority (HA) clinicians, to engage in clinical research.

Firstly, the HA currently faces an inadequacy of clinicians and a shortfall of clinical service, leaving little room for clinical research.

Figure 6. Percentage of respondents stating the underlying reasons of insufficient clinical investigators

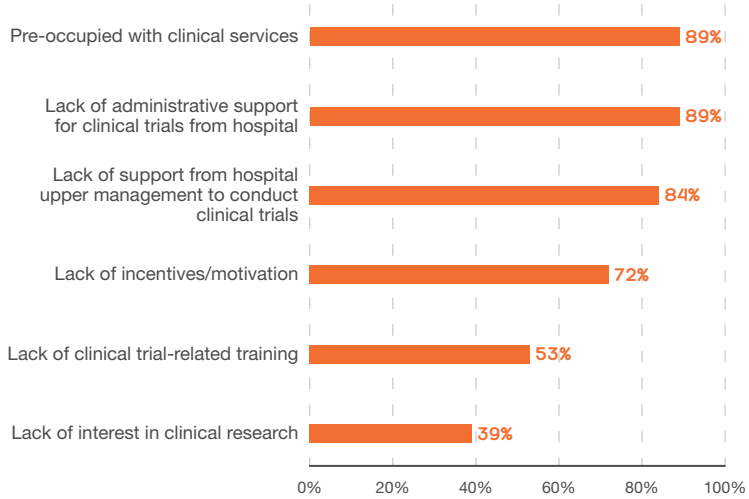
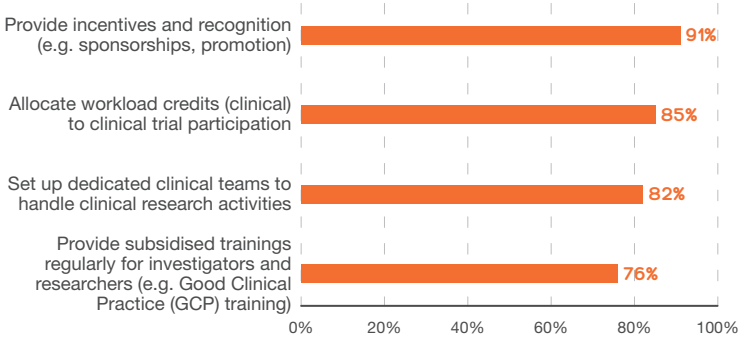


Figure 7. Percentage of respondents agreeing with proposals to raise clinicians' willingness to conduct clinical trials

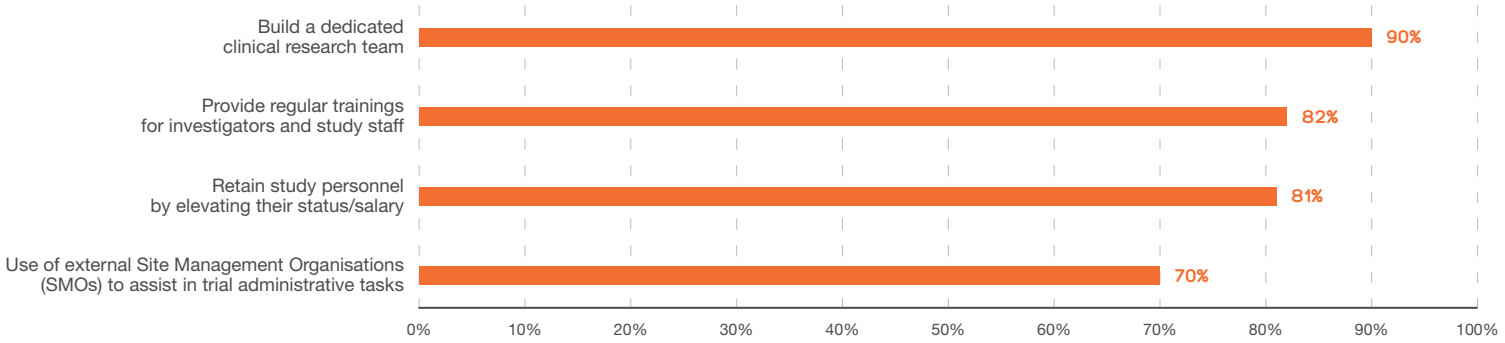


Secondly, such deficiencies lead to insufficient resources for research. Contrary to the two public teaching hospitals, i.e. the Queen Mary Hospital and the Prince of Wales Hospital, non-teaching hospitals are not well-staffed in research support. The relatively unclear career prospects and unattractive wages lead to high staff turnover. Many HA clinicians dedicated to research need to perform support-staff responsibilities themselves. As such, most respondents agree that there should be dedicated research support (90%) coupled with research trainings (82%) and elevated status and salary (81%) **(Figure 8)**.

Thirdly, clinicians receive no monetary nor career incentives even as they managed to secure sponsorships and improve healthcare service. All these factors collectively drive talent away from clinical research.

In the 2023 *Policy Address*, the Government has proposed to establish a new Cluster Clinical Research Office in 2024/25. The Office would need to provide additional resources for research support as well as incentives for medical team's participation in clinical trials, in order to fully unleash the research potential of the medical sector.

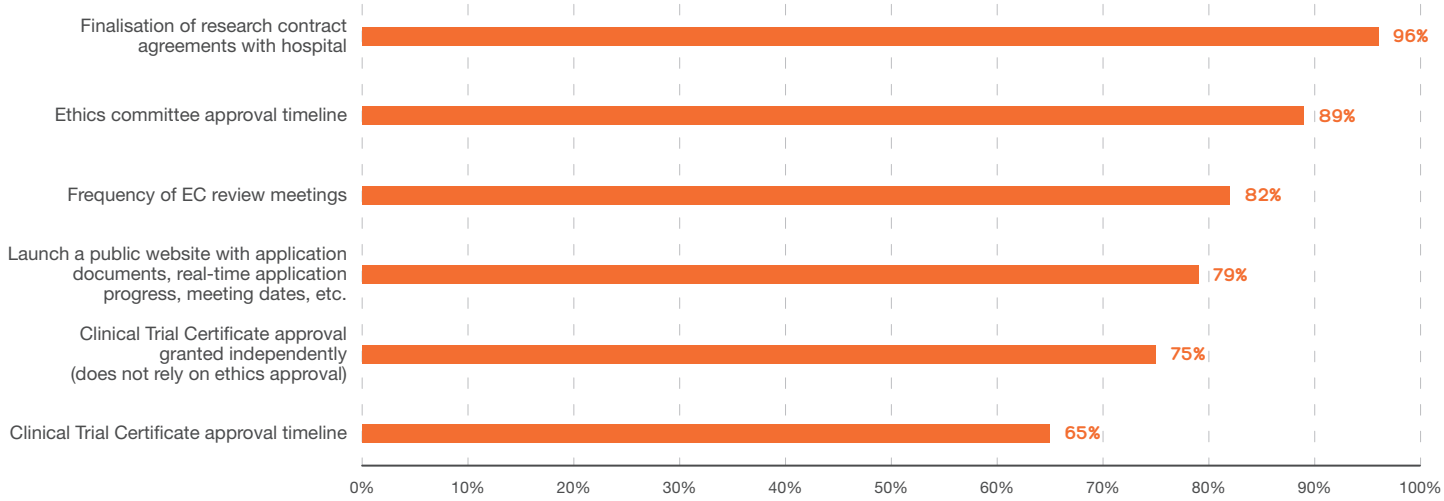
Figure 8. Percentage of respondents indicating processes or strategies required



2.2.2 Long study start-up time and delays in study subject recruitment

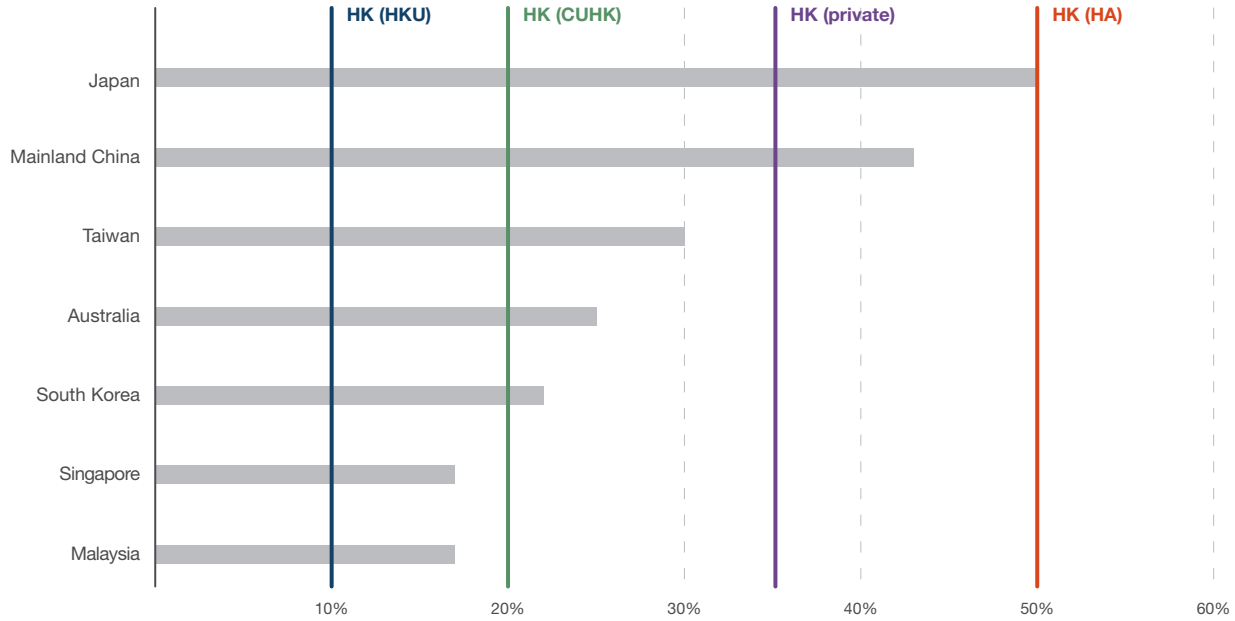
Top areas in which respondents saw a need for enhancement include Clinical Trial Agreement (CTA) (96%) and Ethics Committee (EC) approval (89%) **(Figure 9)**. The negotiation process for CTA with the HA is reported to be very long, with varying contract terms and pricing between hospitals. This results in a delay as sponsors have to secure different HA hospitals' agreement separately.

Figure 9. Percentage of respondents indicating enhancements needed to speed up clinical trials



Besides, CTA negotiation would not commence before sponsors secure EC approval through the principal investigators. Sponsors also need to obtain separate EC approvals from up to three ECs; specifically, the lengthy approval process of the HA's EC delays the entire process, with 50% of respondents reporting that it lasts more than three months **(Figure 10)**. These requirements unnecessarily prolong the study start-up time.

Figure 10. Percentage of respondents taking more than three months to obtain Ethics Committee approval



Note: The time needed for obtaining the approval is calculated from the moment an application is submitted until the approval is received.

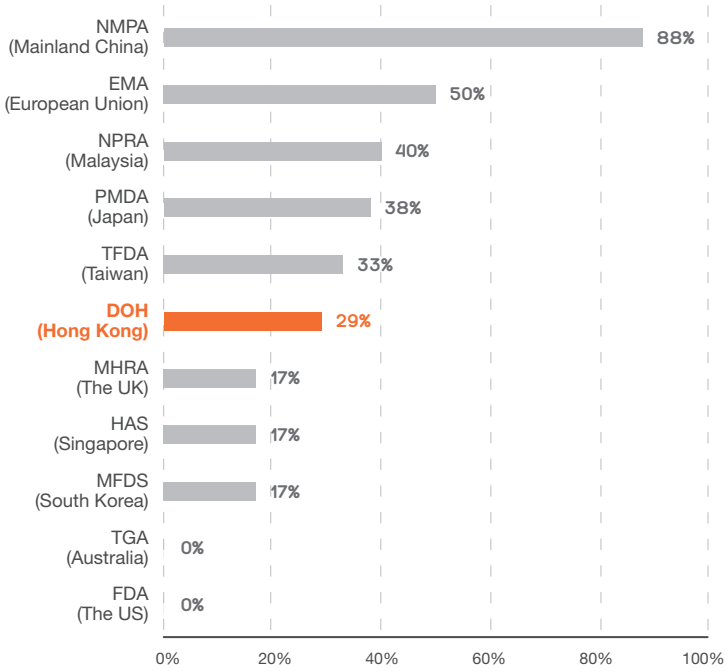
Hong Kong's regulatory approval process is conducted in parallel with the EC. The turnaround time for late phase studies is relatively competitive, with only 29% of respondents taking more than three months to obtain the Certificates for Clinical Trial / Medicinal Test, or Clinical Trial Certificate (CTC) from the Department of Health (DOH) **(Figure 11)**.

However, for Phase 1 First-in-human (FIH) studies, Hong Kong is the least competitive among leading economies with 87% of respondents taking more than three months for CTC approval **(Figure 12, P.23)**. This is primarily due to the requirement for an additional committee review by the Pharmacy and Poisons Board (PPB) which is only held every two to three months.[10]

The time needed to get new drugs to patients is a key priority for pharmaceutical companies. The comparatively long start-up time renders Hong Kong uncompetitive.

Study subject recruitment is the next step upon regulatory approval. Most survey respondents attribute such delays to investigators being preoccupied with clinical services (70%), limited subject population (68%), and a lack of recruitment strategy (65%) **(Figure 13, P.23)**.

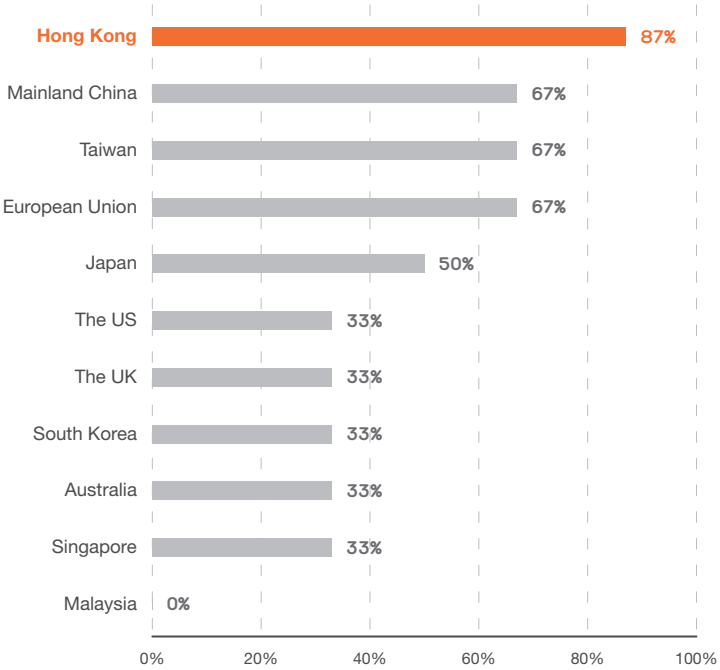
Figure 11. Percentage of respondents taking more than three months to obtain regulatory approvals for late phase in different economies (2018–2022)



Note: The time needed for obtaining the certificates is calculated from the moment an application is submitted until the approval is received.

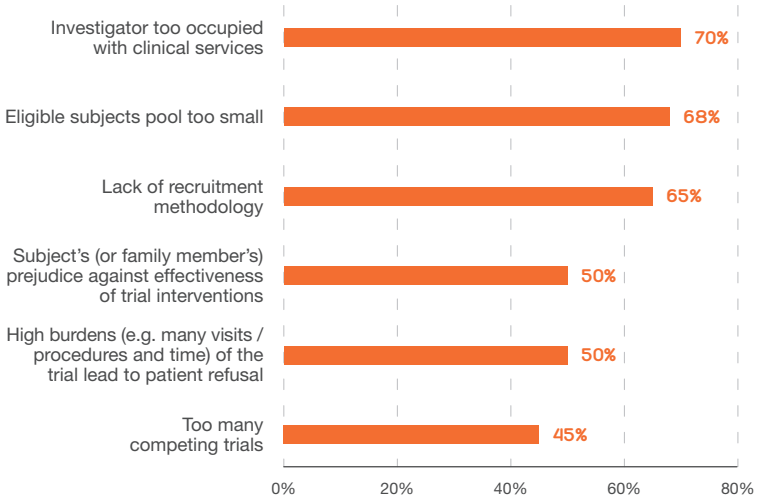
[10] The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee under the Pharmacy and Poisons Board, which holds five meetings in a year, is responsible for reviewing Phase 1 FIH trials (PPB, 2023).

Figure 12. Percentage of respondents taking more than three months to obtain regulatory approvals for Phase 1 FIH trials in different economies (2018–2022)



Note: The time needed for obtaining the certificates is calculated from the moment an application is submitted until the approval is received.

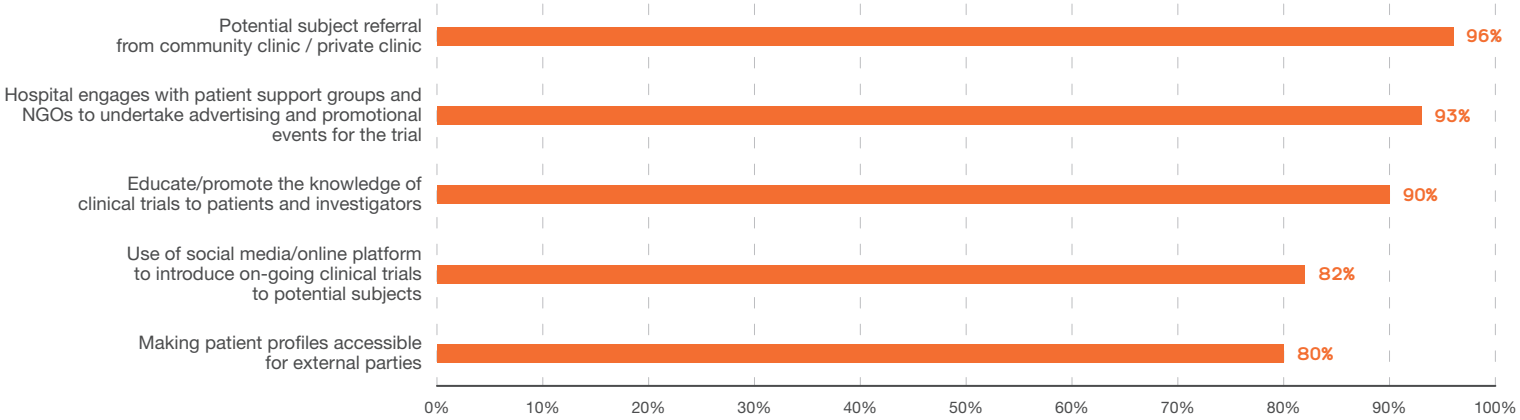
Figure 13. Percentage of respondents stating reasons for delayed or failed subject recruitment



While some structural factors affecting investigators are discussed above, respondents expressed that good recruitment strategies may overcome some of these barriers through means such as having potential subject referral from community clinic / private clinic (96%) and making patient profiles accessible for external parties (80%) **(Figure 14)**.

However, despite the existence of a territory-wide electronic patient database managed by the HA, access rights are highly restricted along with other validation problems.[11] The clinical trial potential of the private healthcare sector, which hosts around one-third of in-patients of Hong Kong and more than half of the out-patients, are also underdeveloped (Census and Statistics Department of the HKSAR Government, 2021).

Figure 14. Strategies that respondents suggested to accelerate the development of Hong Kong's clinical trials industry (respondents by percentage)



[11] The HA manages a Clinical Management System (CMS) for patient identification and patient statistical analysis.

2.2.3 Incomplete value chain: Absence of primary review capabilities and infrequent collaboration with the GBA

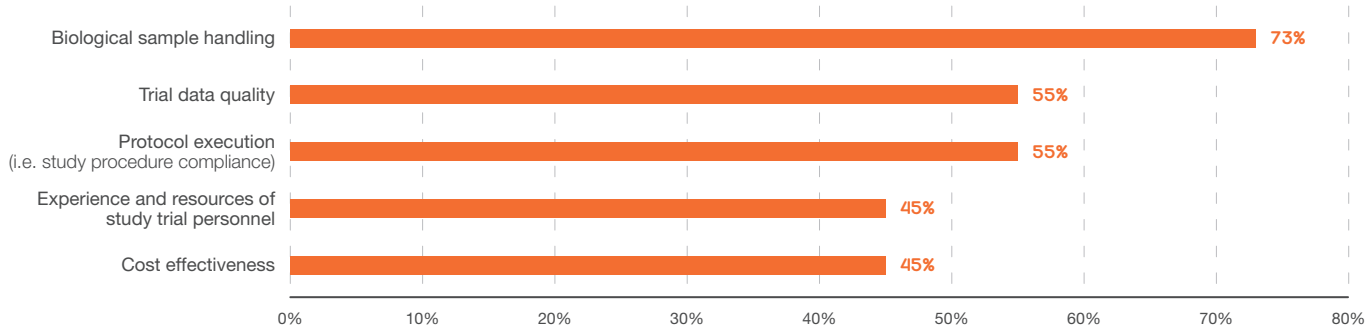
Hong Kong adopts a secondary review system which relies on foreign approvals for drug registration. Without an independent primary review mechanism, there is no local regulatory pathway for local and overseas pharmaceutical companies to attain product registration and commercialisation.

As a result, companies would rather conduct clinical trials and submit results for registration elsewhere before obtaining secondary approval in Hong Kong. For locally-developed drugs where investigators have limited resources overseas, this could imply a dead end for biomedical innovation.

Practically, it is impossible for Hong Kong to complete all phases of clinical trials alone due to the amount of trial data needed for product registration. The 86-million population of the GBA presents enormous opportunities for Hong Kong to expand its clinical trials footprint. However, Hong Kong is not well-aligned with the GBA in terms of drug regulations, investigator collaboration, patient access, and materials flow.

Survey respondents pointed out that biological sample handling (73%), trial data quality (55%), and protocol execution (55%) are key to regional collaboration **(Figure 15)**. As such, the Shenzhen-Hong Kong Loop can serve as a pilot area for material access and trial data analysis, fostering more cross-border collaboration. More platforms are required to strengthen investigator partnerships across the border, to radiate Hong Kong's world-class clinical trials and to grow its own clinical trials industry.

Figure 15. Percentage of respondents suggesting levers for collaboration with the Greater Bay Area

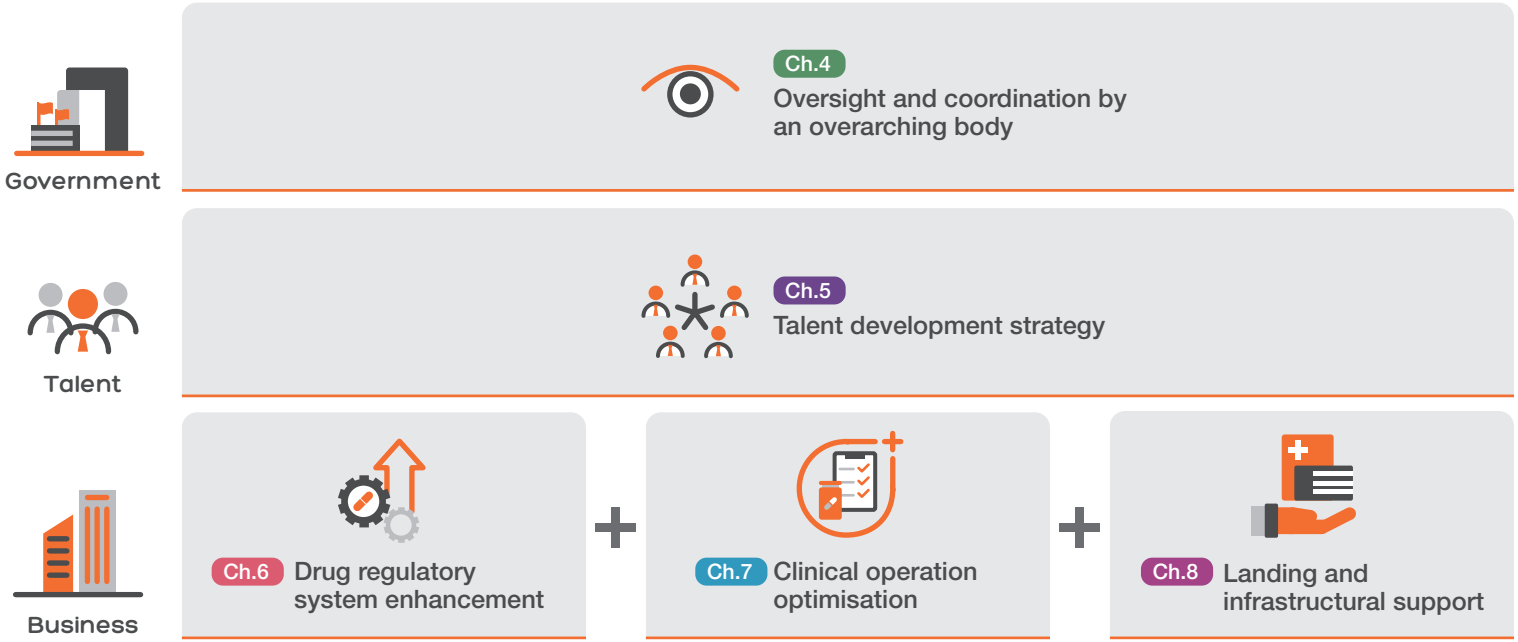


3

Building Blocks of a Leading Clinical Innovation Hub

This report has identified five building blocks for Hong Kong to become a leading clinical innovation hub. For a new drug to reach the commercial market, a pharmaceutical company needs to be provided with landing and infrastructural support, smooth clinical operations and the drug needs to be successfully registered. Government oversight and coordination would play a vital role, and the entire value chain needs to be supported by a comprehensive talent strategy **(Figure 16, P.27)**.

Figure 16. Building blocks of a clinical innovation hub



An overarching governing body (Ch.4) is needed as the coordinator and intermediary to bring about concerted efforts in clinical research and to mobilise potential investigators and patients more effectively. It should steer clinical research activities currently fragmented among teaching hospitals and public and private sectors. It should provide strategic direction (Recommendation 1.1) and facilitate clinical trials collaboration through network building (Recommendation 1.3). It should also fill in critical resource gaps in research support services (Recommendation 1.2) and develop research centres and specialty hospitals in specific disciplines where Hong Kong has a significant edge (Recommendation 1.4).

A talent development strategy (Ch.5) is critical as talent is the most valuable asset in clinical research. Yet, there is no clear career path for investigators and research support staff. The Government should strategise talent development spanning research career development and training in the public healthcare system (Recommendations 2.1 and 2.2), the provision of career-based professional training (Recommendation 2.3), and the enhancement of tertiary education and specialist training (Recommendation 2.4).

An internationally-recognised drug regulatory system (Ch.6) catalyses the development of a leading clinical innovation hub. The ultimate goal of sponsored trials is to have drugs registered and commercialised. Under “one country, two systems”, Hong Kong can unleash its potentials by establishing a drug primary review system which connects with both foreign and mainland counterparts (Recommendations 3.1 and 3.2). Hong Kong can facilitate locally-registered foreign drugs to be used in mainland China and vice versa, benefitting patients’ drug access. Meanwhile, cross-border collaboration is critical for effective completion of trials and registration, leveraging mainland China’s talent and patient pool as well as complete supply chain. Specific measures include joint funding schemes (Recommendation 3.3) and cross-border flow of human genetic materials (Recommendation 3.4).

Efficient clinical operation (Ch.7) can attract pharmaceutical companies and contract research organisations to conduct trials in Hong Kong. As delays in obtaining clinical trials data will increase costs and forgo revenue, it is necessary to review and expedite the trial start-up (Recommendations 4.1, 4.2 and 4.3), subject recruitment processes (Recommendation 4.4) and to build capacity through the private sector (Recommendation 4.5).

Landing and infrastructure support (Ch.8) can help to attract clinical trials and their related R&D activities. Echoing the proactive policies announced in the *Hong Kong Innovation and Technology Development Blueprint*, preferential tax and land incentives should be offered to attract investments in clinical trials and related R&D activities in central laboratories and manufacturing facilities (Recommendation 5.1), while these ancillary facilities should also be readily available (Recommendation 5.2).

4

Recommendation 1.

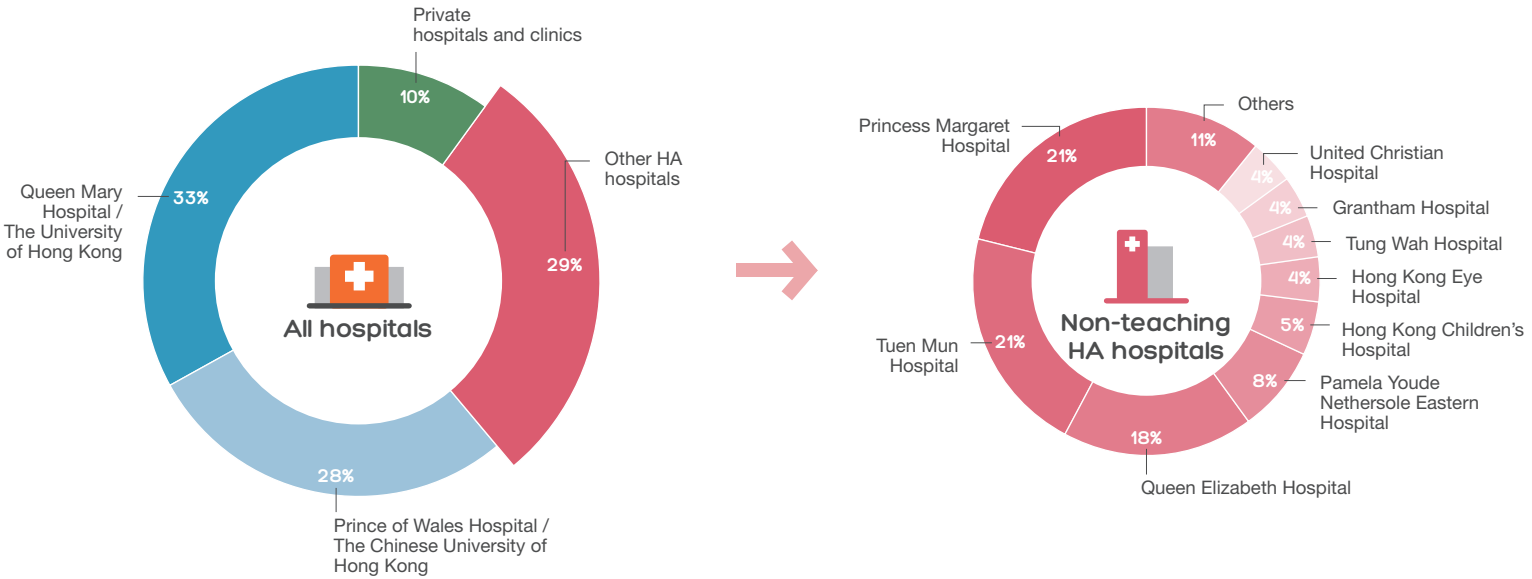
Institutionalising Strategic Facilitation by the Health Bureau

Hong Kong's clinical trials development can be enhanced by coordinating the fragmented institutions in town, providing overburdened investigators with research support, strengthening investigator collaboration networks, and increasing resources dedicated to research through research centres and specialty hospitals.

In Hong Kong, clinical research is concentrated in the two public teaching hospitals, while other public and private hospitals are more geared towards clinical service. As the HA is focused on reducing patients' waiting time, clusters, hospitals, departments, and clinicians are not encouraged to conduct research.[12] In other words, the majority of hospital capacity and subject population is underutilised **(Figure 17, P.31; and Appendix 3)**.

[12] Nearly all of the HA's quality improvement key performance indicators are based on patient waiting time (HA, 2023).

Figure 17. Distribution of clinical / Medicinal Tests trials in 2022



Source: Pharmacy and Poisons Board of Hong Kong (2023a)

The two public teaching hospitals have dedicated university-run Clinical Trial Centres (CTCs) providing administrative and research support, i.e. the HKU Clinical Trials Centre (HKU CTC) and CUHK's Clinical Research Management Office (CRMO). However, clinical research activities in non-teaching hospitals are under-supported and rely primarily on individual principal investigators. Only three public non-teaching hospitals hire a handful of research support staff such as research nurses and study coordinators, which are shared within their respective clusters.[13,14] Investigators are approached by pharmaceutical companies or CROs directly but their capacity is constrained by limited research and administrative support; in some instances, they may have to perform these tasks on their own.

There is also an absence of structured network that brings together investigators from different institutions. As most clinical trials fall into the two public teaching hospitals, academics would leverage their personal networks for collaborations; yet, clinicians in other institutions may not have similar access to academics. Besides, there is a need to aggregate clinicians, patients, and resources for diseases that require tertiary healthcare, along with a strong academic and research presence.

Currently, the development of clinical research in Hong Kong is overseen by the Health Bureau's Research Office and other administrative personnel.[15] To build Hong Kong's clinical research capability and to more effectively engage the HA while minimising the burden to the already-stretched manpower and resources, the Health Bureau needs to actively strategise and expand these efforts. The HA needs to fully utilise the proposed Cluster Clinical Research Office in order to better support staff participation in clinical research in non-teaching hospitals.

HKU Clinical Trials Centre Managing Director Henry Yau is also the immediate past Chairman of the International Clinical Trial Center Network. He believes that if there is an integrated platform coordinating all hospitals, resources and policies and supporting clinical investigators, research institutions, and the biomedical industry, Hong Kong is set to become an ideal hub for clinical research and translational medicine.

[13] They are the Queen Elizabeth Hospital, Pamela Youde Nethersole Eastern Hospital, and Tuen Mun Hospital.

[14] Individual university departments may also have research support units specifically for their members, such as the Comprehensive Clinical Trial Unit within CUHK's Department of Clinical Oncology.

[15] The closest body or personnel undertaking such tasks is a team led by a Deputy Secretary for Health of the Health Bureau, of which the Principal Assistant Secretary for Health is responsible for "health and medical research policies" among many other bestowed responsibilities, and the Head of Research Office oversees the Health and Medical Research Fund (HMRF) and commissions research in health and health services, etc. (Health Bureau of the HKSAR Government, 2023).

Recommendation 1.1. Establishing a Clinical Research Institute (CRI) to provide strategic facilitation

A Clinical Research Institute (CRI) should be established under the Health Bureau to drive Hong Kong's clinical research strategy and foster collaboration within the Greater Bay Area. It should formulate an overarching strategy to position Hong Kong as the preferred destination for clinical research, with an independent budget to distribute additional resources. As a general principle to incentivise clinical research, resource distribution should be performance-based.[16]

The CRI could take over the existing Research Office under the Bureau, including its bestowed tasks such as management of the Health and Medical Research Fund (HMRF), and oversee functions including:

- **A one-stop service centre for sponsors and investigators (Recommendation 1.2);**
- **A clinical research network to facilitate collaboration (Recommendation 1.3); and**
- **An academy for talent development (Recommendations 2.2 and 2.3, Ch.5).**

Finally, the CRI could promote social awareness of clinical trials through public campaigns and international conferences.

Phase 1 trials have the highest growth potential among all phases in Hong Kong.[17,18] In the long run, the CRI could explore the possibility of establishing a third Phase 1 clinical trials centre upon evaluating the expansion needs.[19]

To realise the CRI's vision, support by other institutions including universities, the HA, and the private sector is critical **(Figure 19, P.35)**. Among them:

- **Universities** should lead clinical research activities and radiate their research excellence by grooming more clinical researchers, managing research centres and specialty hospitals, and engaging clinicians from other sectors;
- **The HA** should support universities' clinical research, synergise with the private sector, and encourage research activities by rewarding clinicians' research excellence, facilitating placements of CRI talent and personnel, streamlining trial start-up process, and collaborating with other sectors;
- **The private sector** needs to amplify universities and the HA's clinical research capabilities and capture market opportunities with the support of CRI's services.

[16] For instance, the Government offered additional funding of HKD 100 million starting from 2019 for initiating a total of 200 clinical trials on novel therapeutic drugs at each Phase I center (HKSAR Government, 2021).

[17] The revenues for phase 1, 2 and 3 clinical trials are USD 4 million, USD 13 million, and USD 20 million respectively; The decreasing marginal return and per capita return in turn suggests decreasing profitability (Sertkaya, et. al., 2014).

[18] Among all clinical trials / medicinal tests held in Hong Kong in 2022, 4% were phase 1 trials. 24% were phase 2 trials, and 43% were phase 3 trials (PPB, 2023).

[19] There are currently 24 beds in the two centres respectively (HKU CTC, 2023; CUHK Phase 1 CTC, 2023). It is estimated that at least 36 beds are needed to fulfill current trial demand.

The CRI can take reference from the UK's NIHR, a government-funded healthcare research agency parallel to universities and the National Health Service (NHS). The NIHR reports directly to the UK Government's Department of Health and Social Care (DHSC) and is led by the Department's Chief Scientific Adviser. It has an independent budget to distribute resources to university academics and NHS clinicians, and coordinates them through: funding academic and NHS research; investing and supporting research infrastructure in both university- and NHS-hospitals; managing Clinical Research Networks and Specialties; and providing clinical research training **(Appendix 4)** (NIHR, 2023). The NIHR enabled sponsored trials which generated a total income of GBP 355 million for the NHS over the financial period of 2016/17 to 2018/19; in 2018/19 alone, these trials contributed GBP 2.7 billion to the economy and created 47,500 jobs (NIHR, 2019).

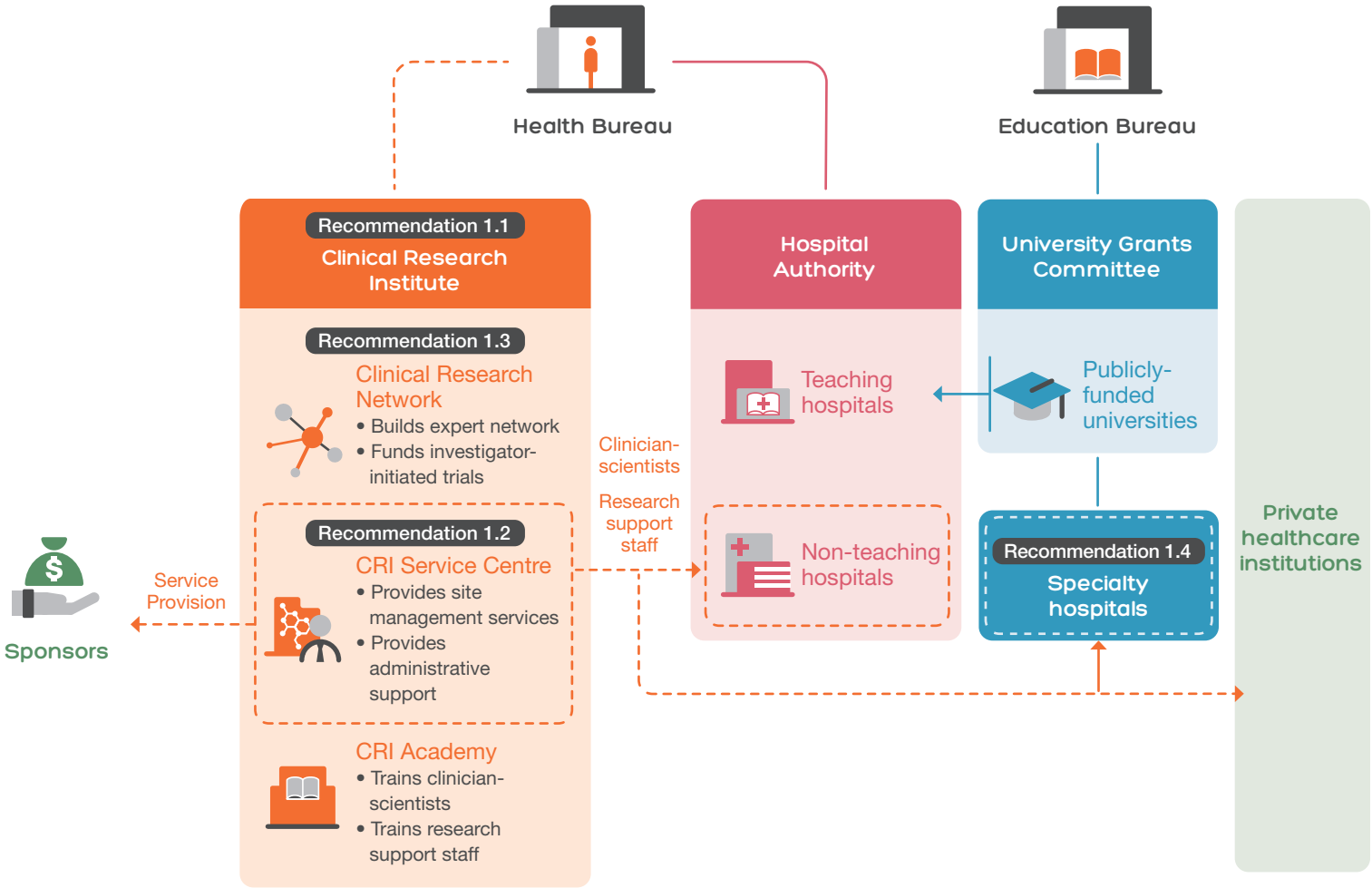
Based on the experiences from Singapore Clinical Research Institute (SCRI) and Clinical Research Malaysia (CRM) **(Figure 18)**, assuming that around 15% of clinical trials in Hong Kong would subscribe to CRI's services, the CRI would require a staff number of around 50.

Figure 18. Staff composition and trial processed by Singapore Clinical Research Institute (SCRI) and Clinical Research Malaysia (CRM)

Organisation	Staff allocation	Number of trials processed
Singapore Clinical Research Institute (SCRI)	56, including: • Study design and Biostatistics support: 6 • Protocol development: 5 • Study planning, management, legal: 10 • Research Informatics: 5 • Site management: 7 • Data validation and Electronic Health Record: 6 • Pharmacovigilance: 2	41 out of 263 (15.6%) in 2017
Clinical Research Malaysia (CRM)	168 Study coordinators, plus staff from Finance, Purchasing, IT, Business Development and more	135 out of 223 (60.5%) in 2022*

Note: There were 135 industry-sponsored clinical trials conducted within Ministry of Health facilities processed by CRM in 2022
Source: Singapore Clinical Research Institute (2018), Clinical Research Malaysia (2022)

Figure 19. Relationship between the Clinical Research Institute and other stakeholders



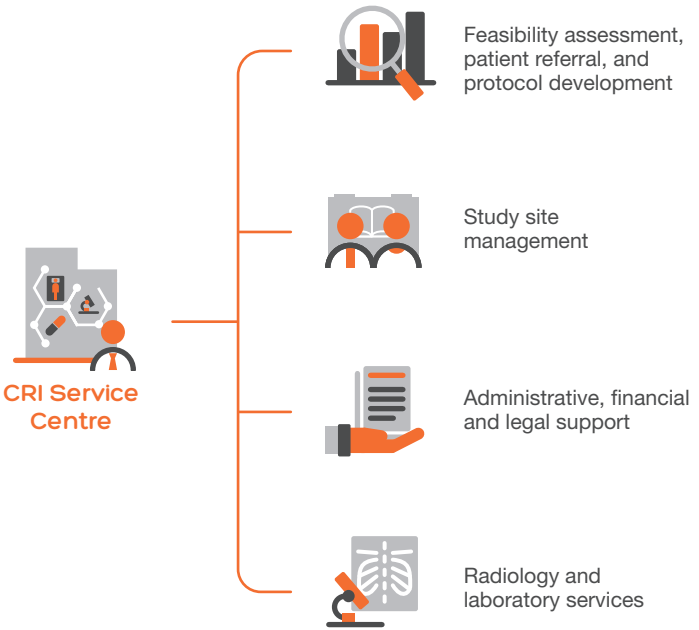
Recommendation 1.2.
Setting up a Service Centre to provide centralised support services

The CRI should encompass a Service Centre to provide centralised services. Positioned as a one-stop shop for study sponsors and investigators, its service delivery will fill the gaps of non-teaching hospitals and the private sector. Its functions should include the following **(Figure 20)**:

Feasibility assessment, patient referral, and protocol development: The Centre would become the first point of contact for sponsors to conduct study feasibility assessment and identify potential investigators; It should also conduct patient referral upon commencement of a study **(Recommendation 4.4, Ch.7)**. It should help parties, especially clinicians and startups, to develop research protocols.

Study site management: It should hire, train, and deploy research support staff, especially research nurses and coordinators; it could also consider hiring research pharmacists.[20,21] In addition, the centre should work closely with the HA's central coordinating office and cluster research offices for placement of personnel.[22] The deployment of these staff should best be cluster-based, depending on the studies available, to maintain their relationships with the respective investigators. Due to the nature of their duties, some personnel such as biostatisticians and lab technicians could be stationed at the CRI.

Figure 20. Functions of the Clinical Research Institute's Service Centre



[20] As the administration of trial drugs are currently partly borne by general pharmacists, the Centre should assess the need for research pharmacists to cope with increasing number of trials. They should be deployed to hospitals, or alternatively, the option of establishing a research pharmacy at the CRI could be explored.

[21] With their scientific medication training background, it is suggested that the role of research pharmacists could be expanded. Potential duties include: medication research, protocol preparation, general study services (from compounding and dispensing to patient counselling and adverse reaction monitoring), data analysis, and transition-of-care services (Swiatek & Daly, 2016).

[22] The HA's central coordinating office has various responsibilities including serving as a one-stop application or communication platform for principal investigators; meanwhile, the cluster research offices in all HA clusters have responsibilities including providing administrative support to the principal investigators (HA, 2023).

Administrative, financial, and legal support: The Centre should feature a dedicated administrative support team not only to oversee the terms of Clinical Trial Agreements (CTAs) but also to manage the negotiation processes, such as scope of services and pricing **(Recommendation 4.3, Ch.7)**.

Radiology and laboratory services: Radiology services are currently being outsourced to the private sector; sponsors face difficulties in identifying suitable vendors. The Centre should provide these services along with laboratory services to reduce hospitals' burden.

The Centre can take reference from Clinical Research Malaysia (CRM), a government-owned company under the purview of Malaysia's Ministry of Health. It is financially independent and generates income by charging sponsors service fees.[23] CRM offers complimentary feasibility studies and investigator matching, manages and reviews CTAs, deploys research coordinators, and trains both investigators and research support staff (CRM, 2023). This alleviates the investigators' workload, improving trial efficiency and quality.

With substantial support from the CRM, Malaysia achieved a significant increase in the number of sponsored trials and research talent from 2017–2021[24] **(Figure 21)**. The CRI's Service Centre could similarly catalyse Hong Kong's clinical trial development by unleashing the potential of the underexplored segments in the research ecosystem.

Figure 21. Clinical research development in Malaysia

	2017	2022	Difference
Number of sponsored trials	171	223	+30%
Number of skilled jobs in clinical research	1,880	2,688	+43%
Number of study coordinators	113	168	+49%
Gross National Income	RM 250+ million	RM 1,025+ million	+310%

Source: Clinical Research Malaysia (2022)

[23] The CRM charges a fee of 20% on the value of the trial budget (CRM, 2023).

[24] There was a nine-time growth of sponsors utilising CRM's service between 2014 to 2022 and 296% increase in feasibility studies through CRM between 2013 and 2021 (CRM, 2023).

Recommendation 1.3.
Setting up a Clinical Research Network with funding support to enhance investigator collaboration

A Clinical Research Network should be established to enhance investigators' collaboration in Hong Kong and the Greater Bay Area. It would promote research collaboration, serve as an exchange platform to influence local, regional and global standards of care, and elevate investigators' research recognition.

The Network could feature specialty-focused streams to bring together investigators of the same specialist areas, thereby formalising platforms such as committees between different hospitals' chief-of-staff within the HA and professional specialty societies. It is envisaged that the Network can be extended beyond the city as cross-border platforms are lacking. The Network could facilitate mentoring of junior investigators with dedicated funding in place.

The Network would not only attract pharmaceutical companies to reach out for sponsored trials, but also facilitate local and regional multi-centre investigator-initiated trials with funding from the CRI and the GBA.

Amongst various clinical research grants in Hong Kong, the HMRF's grant for investigator-initiated projects is the only research grant available to HA clinicians, while clinicians can apply along with academics[25] **(Figure 22, P.39)**. On one hand, the funding cap could be increased to enable more multi-centre trials in Hong Kong. On the other hand, a dedicated channel could be set up for HA clinicians as they face difficulties competing with academics for grants. Potentially, these grants could cover not just the project costs but also the hourly wages of healthcare professionals who are not in a full-time research job.[26]

For cross-border collaboration, similar to the three joint funding schemes under the Research Grants Council and the Innovation and Technology Commission, the Health Bureau could collaborate with provincial health commissions in the mainland and introduce similar joint funding schemes under the HMRF **(Recommendation 3.3, Ch.6)**.

Such networks are widely adopted in leading economies and are often government-funded. For instance, the Singapore Clinical Research Institute (SCRI) has established networks to target diseases specific to Asian population; its Asian Thoracic Oncology Research Group (ATORG) features top investigators including Professor Tony Mok from the CUHK serving on its executive committee and scientific steering committee (SCRI, 2023a). More examples can be found in **Appendix 5**.

[25] The HMRF funds investigator-initiated research projects and health promotion projects. The normal grant ceiling for a proposal is HKD 1.5 million and the usual duration is 3 years; There is also a seed grant with a grant ceiling of HKD 500,000 per project for larger-scale pilot studies and small-scale research (Health Bureau Research Fund Secretariat, 2023).

[26] The funds in Figure 22 do not cover emoluments of investigators and other full-time staff, thus serving as additional funding support to their research projects. However, contrary to university academics, there are healthcare professionals such as HA clinicians who are not in full-time research jobs and have to spend uncompensated time on research projects.

Figure 22. Funds available for clinical research in Hong Kong

Scheme / Source	Research requirement	Eligible applicants	Maximum funding per project
Research Grants Council (RGC)	Research with high academic vigour and pertinent to Hong Kong's needs	Full-time university academics	HKD 10–75 million
Innovation and Technology Fund (ITF)	Projects contributing to the upgrading and development of Hong Kong's manufacturing and services industries	Universities, R&D centres, companies, and others[27]	HKD 1–15 million
Hong Kong Science and Technology Parks Corporation (HKSTP)'s Clinical Translational Catalyst (CTC)	Investigational New Drug (IND) enabling studies and clinical trials	HKSTP biomedical companies	HKD 8 million
Health and Medical Research Fund (HMRF)	Health and medical research and health promotion	Healthcare or healthcare-related professionals researching not for commercial use	HKD 0.5–1.5 million

Source: University Grants Committee (2023), Legislative Council Secretariat of the HKSAR Government (2022), Hong Kong Science and Technology Parks Corporation (2023), Health Bureau Research Fund Secretariat of the HKSAR Government (2023).

[27] Including self-financing degree-awarding institutions, the Hong Kong Productivity Council, the Vocational Training Council, the Clothing Industry Training Authority and the Hong Kong Institute of Biotechnology (Innovation and Technology Commission of the HKSAR Government, 2023).

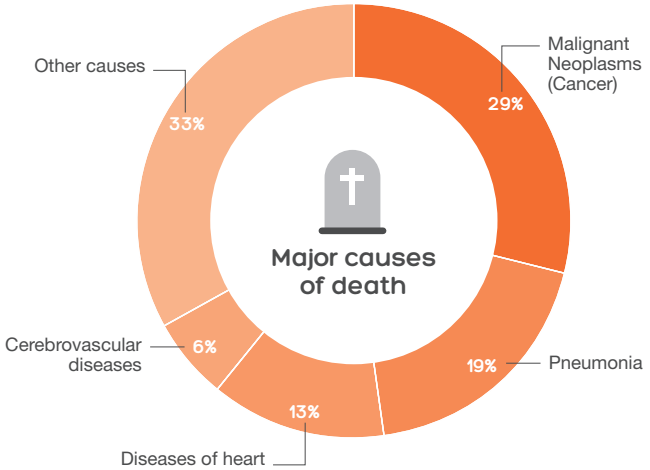
Recommendation 1.4. Developing research centres and specialty hospitals while pioneering the development of university-run hospitals

Apart from engaging more HA clinicians in clinical research, the Government should also steer innovative and emerging models to strengthen and expand patient outreach by academics, in addition to the potential expansion of teaching hospitals.[28]

There should be more university-run research centres attached to HA hospitals. Currently, there are several renowned examples including CUHK's Sir Yue-Kong Pao Centre for Cancer at Prince of Wales Hospital, and the future HKU Jockey Club Centre for Clinical Innovation and Discovery and the HKU Jockey Club Institute of Cancer Care at Grantham Hospital, both of which delivering not only cancer-specific services but also research and education (Prince of Wales Hospital, n.d.; HKU Jockey Club Institute of Cancer Care, 2017). The centres rightly ride on universities' research excellence and hospitals' existing or future profile in clinical oncology.

The proximity of research facilities to hospital wards is known to enable research activities by bringing biological resources sampled from hospital main blocks to laboratories close by. There should be more research centres for specific areas of interest, not only in oncology but also hepatitis and infectious diseases,[29] taking into consideration Hong Kong's major causes of death and key research focus **(Figure 23; Figure 24, P.41)**.

Figure 23. Major causes of deaths in Hong Kong in 2021

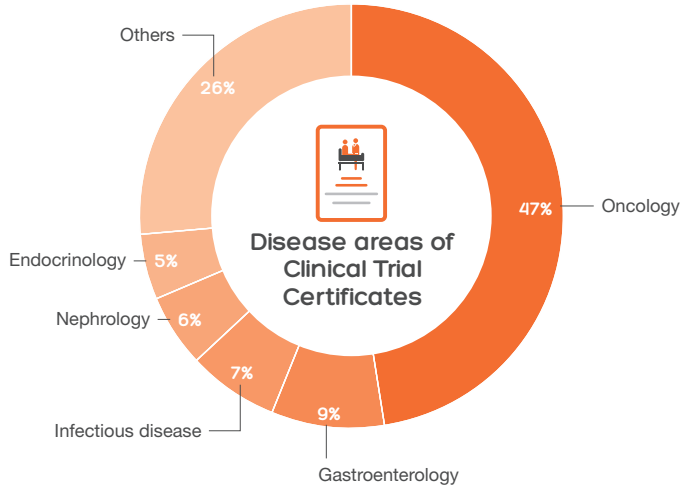


Source: Centre for Health Protection, Department of Health of the HKSAR Government (2023)

[28] In the HA's two 10-Year Hospital Development Plans, apart from providing 1,650 additional beds, the Queen Mary Hospital and the Prince of Wales Hospital will both be renovated to better promote integrated research, teaching and education (Food and Health Bureau of the HKSAR Government & HA, 2019). It was also reported that Kwu Tung Hospital and Northern District Hospital to be constructed and expanded in the Northern Metropolis as stated in the Second 10-year Hospital Development Plan will also be developed as teaching hospitals.

[29] The HA has established an Infectious Disease Centre at the Princess Margaret Hospital which started operation in 2007; However, despite it aims to act as a training and research centre and collaborates with universities' research units, the Centre is mainly for management of infectious disease patients (Hong Kong Hospital Authority Infectious Disease Centre, 2007).

Figure 24. Disease area breakdown of Clinical Trial Certificates issued in 2022



Source: Pharmacy and Poisons Board of Hong Kong (2023)

Specialty hospitals should be developed by the HA, in collaboration with universities, to achieve better aggregation of academics, state-of-art facilities, and patients in designated therapeutic areas. The Hong Kong Children's Hospital serves as the tertiary referral centre for complex and uncommon paediatric cases (Hong Kong Children's Hospital, 2023). The Hong Kong Eye Hospital serves as a secondary and tertiary eye referral centre and hosts the CUHK's Department of Ophthalmology and Visual Sciences (Hong Kong Eye Hospital, 2023) **(Figure 25, P.42)**.

Moving forward, the Government could explore having more specialty hospitals run by universities, which will allow more flexibility for research.

University-run specialty hospitals are prominent in leading economies **(Figure 26, P.43)**. Such models are also available in Hong Kong in dentistry and Chinese medicine: The Prince Philip Dental Hospital (PPDH) is operated by the HKU and houses research facilities of the university's Faculty of Dentistry; The Chinese Medicine Hospital will be operated by the Hong Kong Baptist University (HKBU) and will encompass a Clinical Trial and Research Centre (Prince Philip Dental Hospital, 2023; Research Office of the HKBU, 2021).[30,31] Meanwhile, the HKU-Shenzhen Hospital is a prominent university-run general hospital offering services to mainland patients with Hong Kong Management experience. It houses research centres, laboratories, and a clinical trials centre (The University of Hong Kong–Shenzhen Hospital, 2023).

The Government could reference foreign models to develop university-run specialty hospitals to strengthen tertiary healthcare and clinical research, especially for key disease areas in which Hong Kong has a significant advantage.

[30] The PPDH is run by HKU primarily for the training of dentists. It does not provide public dental services and cases will be initially screened by a member of the hospital or faculty.

[31] HKBU was selected by the Government as the contractor for the service deed of Hong Kong's first Chinese Medicine Hospital, which will be in Tseung Kwan O and will start operation in 2025.

Figure 25. Existing models to foster clinical research in Hong Kong

University-run research centres

HKU Jockey Club Centre for Clinical Innovation and Discovery, and the HKU Jockey Club Institute of Cancer Care, Grantham Hospital

CUHK Sir Yue-kong Pao Centre for Cancer, Prince of Wales Hospital

Academic-attached specialty hospitals

Hong Kong Children's Hospital (HKU and CUHK)

Hong Kong Eye Hospital (CUHK)

University-run specialty hospitals

Prince Philip Dental Hospital (HKU)

Chinese Medicine Hospital (HKBU)

Photo courtesy of the Planning Office for The Chinese Medicine Hospital, Hong Kong Baptist University

Figure 26. Examples of prominent university-run cancer hospitals

Hospital	Description
National University Cancer Institute (Singapore)	• A public hospital for paediatric and adult cancers • Houses a Haematology-Oncology Research Group, a Developmental Therapeutics Unit, and works closely with the Cancer Science Institute of the National University of Singapore (NUS) • Reports to the National University Health System, an individual corporate under the Ministry of Health represented by the NUS among others
Beijing Cancer Hospital (Mainland China)	• A public hospital specializing in cancer treatment, research, prevention, and medical education • Houses academics supported by national research funding • A specialised national-level oncology database, multiple oncology-specialty laboratories, research wards, and an online trial referral portal • Reports to PKU Healthcare, a listed company with representation from the Peking University among others • Administered by the Peking University and the Beijing Hospitals Authority
University of Texas MD Anderson Cancer Centre (The US)	• A public tertiary care and research facility devoted to cancer patient care, research, education, and prevention • Five research institutes and 20 research centres established for different fields of cancer research, supported by research grants • Reports to the University of Texas System

Source: National University Cancer Institute Singapore (2023), Beijing Cancer Hospital (2023), University of Texas MD Anderson Cancer Centre (2023)

5

Recommendation 2.

Building a Talent Development Strategy for Clinical Research Professionals

Hong Kong needs to formulate strategies with the aim to cultivate local investigators and research support staff. Currently, the lack of recognition for HA clinicians conducting research, unclear career prospects outside academia, a lack of early career and professional trainings, and minimal research components in tertiary education and specialist trainings have driven the city's talent away from clinical research.

There are dedicated clinicians from the HA who conduct clinical research in their own time despite demanding work hours, passionately contributing to drug development and benefiting patients. Some have even become regional leaders in their own right, having led numerous sponsored trials. Not only have they achieved academic excellence, but their dedication has also improved patient care and hospital reputation, while securing pharmaceutical companies' sponsorships and saving healthcare costs.

Dr Owen Tsang, Consultant of the Department of Medicine and Geriatrics at the Princess Margaret Hospital, is ranked the top 1% of highly cited researchers globally this year (Clarivate, 2023). Dr Tsang considers clinical research crucial in discovering innovative clinical strategies. Through consistent practice of research skills, clinicians can produce meaningful results, contributing to the advancement of medical science and people's well-being.

However, the HA's lack of recognition and training opportunities frustrates them and deters other clinicians from fully unleashing their talents in clinical research. Besides, contrary to the relatively clear career path for academics, there are no dedicated clinician-scientist positions within the HA for clinicians who prefer to conduct downstream research that emphasise on clinical applications; Furthermore, some clinician-scientists such as clinical pharmacologists, who conduct scientific studies of drugs for human use, could better support various specialities when completely immersed in clinical settings **(Figure 27)**.

Research trainings for early-career clinicians are also inadequate. The Research Grants Council (RGC) introduced the Clinical Research Fellowship Scheme in 2001 to provide training for young clinicians, but no HA clinician benefitted from the scheme in the past ten years (UGC, 2023).[32] HA clinicians have limited incentive to join as they have to pause their clinical careers for up to three years' while competing with academics for research funding.

[32] The scheme aims to encourage young academics and HA clinicians who completed or nearly completed their specialist training to devote themselves full-time for up-to-three-years at HKU or CUHK for clinical research under the General Research Fund. The RGC and the respective university will share the cost of each fellowship which supports the maintenance costs of the fellow or the salary costs of his or her replacement. There is one quota per year for the scheme.

Figure 27. Multiple barriers deter HA clinicians from conducting research

Meanwhile, back to the formative years, not only do clinicians lack research training at their tertiary and specialist training stages, there is an acute shortage of support staff due to a lack of structured professional training.

Recommendation 2.1. Recognising clinical research in the HA through incentives such as promotion factors

Instead of taking clinicians off from existing duties and diverting hospitals' resources for clinical service, the HA should instead promote measures to recognise research efforts and achievements.

Promotion factor: As these clinicians have improved patient care quality, they should be considered for promotion and salary increments.

Overtime remuneration: As sponsors and possibly research grants would have covered the investigators' hourly wages, clinicians should receive overtime remuneration, similar to the arrangement currently administered by the HA for clinicians working overtime.[33,34]

Profit reinvestment: Profits from sponsor fees should be used for investigators to conduct investigator-initiated trials and hire research support staff. Currently, such profits are distributed to respective departments after subtracting costs from the hospital account. The investigator could only use the profits for clinical research following cumbersome procedures which require an approval from the chief of service or the hospital chief executive. Referencing university practices, such profits could be partly kept in investigators' research accounts managed by the CRI **(Figure 28, P.47)**.

Training opportunities: There could be more research training opportunities for highly competent clinicians. The HMRF has introduced a Research Fellow Scheme which supports early to mid-career healthcare professionals to attend overseas training programmes and conduct a small-scale research project (Health Bureau Research Fund Secretariat of the HKSAR Government, 2023).

Meanwhile, the scheme is only limited to junior academics and professionals posted to the two public teaching hospitals, and does not cover the hiring of relieving staff, thus the fellow's institution has to absorb the staff cost.

As such, the scheme should have dedicated quota for all HA clinicians to participate. It should also cover the full cost of hiring relieving staff.

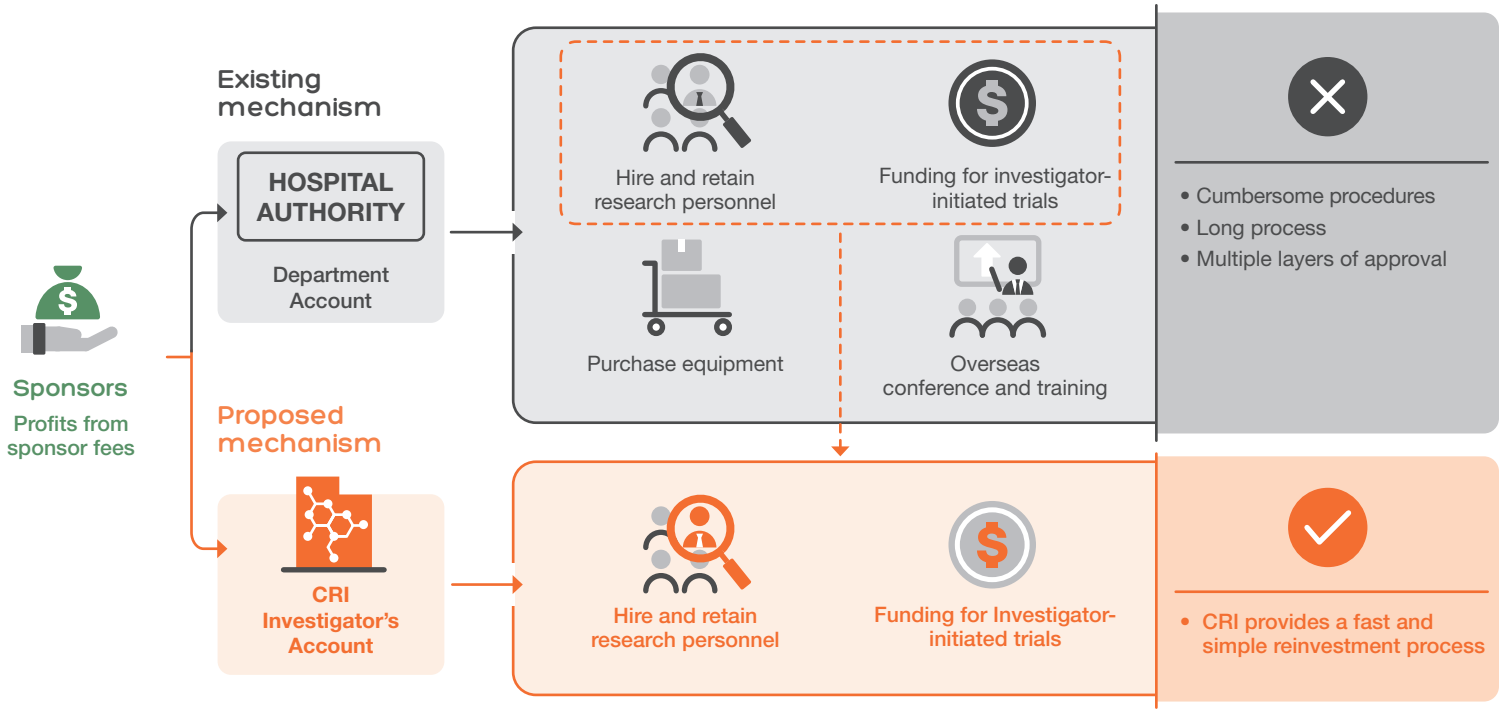
In mainland China, there is a stronger research atmosphere and community in public hospitals. The Central Government has stated clearly that clinicians should be familiar with clinical development of their specialties and be continuously exposed to new technologies (PRC Ministry of Human Resources and Social Security of the People's Republic of China, PRC National Health Commission and

[33] The HA currently offers compensation for clinicians working overtime. A Fixed Rate Honorarium is granted on a monthly basis to clinicians who work consistently long hours by nature of their duties, while the Special Honorarium Scheme rewards clinicians who work extra service sessions on a voluntary basis during peak seasons (Food and Health Bureau of the HKSAR Government & HA, 2019).

[34] Overtime remuneration of HA clinicians securing research grants for investigator-initiated projects could be reimbursed directly by the CRI or alternatively through their hospitals.

PRC National Administration of Traditional Chinese Medicine, 2021). In some municipalities, clinicians' promotions are linked with research quality, contribution, and evidence-based impact (Beijing Municipal Human Resources and Social Security Bureau and Beijing Municipal Health Commission, 2023).[35] Clinicians with outstanding research achievements will enjoy a faster promotion track. Hong Kong should take a similar approach to keep up with the broader competitive landscape.

Figure 28. Existing and proposed profit reinvestment mechanism from sponsored trials



[35] In Beijing, clinicians have to submit relevant evidence, including first authorships and editorships of journal articles, involvement in industry standards proposals, authorship of clinical trial reports, and number of clinicians and researchers mentored for promotion.

Recommendation 2.2. Creating clinician-scientist positions and expanding clinical research fellowships

Clinician-scientists: These positions should be created and attached to HA hospitals, with their duties covering both clinical service and research. They can be employed by the CRI with a clear career ladder comparable to normal clinicians; their administrative duties can include senior positions in the CRI and other platforms such as ethics committees. Trainee clinician-scientists should be able to be qualified to become specialists **(Recommendation 2.4, Ch.5)** and non locally-trained doctors hired as clinician-scientists should also be recognised to eventually attain full registration.

Compared with academic positions, clinician-scientists' research would be more focused on real-world application, and they would have no teaching duties; they would be based in different HA hospitals rather than mainly teaching hospitals. Therefore, clinician-scientists would become key figures to build a research culture in HA hospitals and to foster Hong Kong's clinical research development. For clinician-scientists in teaching hospitals, they can also serve academic appointments. The CRI should select or even import clinicians with vast research experience for these positions. The creation of these positions would in turn allow research-minded medical graduates and mid-career HA clinicians to join and continue serving in the public healthcare sector. It would also attract foreign clinicians to settle in Hong Kong by providing room for research.

Clinician-scientist positions are prominent in foreign regions. Singapore Health Services Group (SingHealth) has created such positions to allow room for translational and clinical research in designated therapeutic areas alongside clinical services (SingHealth, 2021b). The National Health Services (NHS) also employs clinical pharmacologists where they would specialist in toxicology or cardiovascular risk management for patients and also conduct research including clinical trials (NHS, n.d.).

Pharmacist-scientists: A similar track for pharmacists can be created. Not only could the role of research pharmacists can potentially be expanded **(Recommendation 1.2, Ch.4)**, clinical pharmacists can also serve as clinical trial investigators as they have expertise in both the science and practice of rational drug therapy.

In the US, there has been a long history of clinical pharmacists approved by the FDA to serve as principal investigators, with the National Institute of Health (NIH)'s strong support (Bayat, et. al., 2000; Burton et. al., 2010).[36] Recently, Singapore has taken the move to allow registered pharmacists to be sole principal investigators in clinical trials with lower risk (Chief Pharmacist's Office, Ministry of Health of Singapore, 2021).[37] Although such practice is not restricted in Hong Kong, it is relatively uncommon. While it is common to have academic-pharmacists lead and participate in clinical trials, pharmacists in the HA can be better encouraged to engage in research as an investigator. Such atmosphere can be fostered by creating pharmacist-scientist

[36] In the US, most of the clinical trials involving clinical pharmacists in 2009 were sponsored trials.

[37] In 2021, Singapore allowed registered pharmacists to be principal investigators for lower risk clinical trials involving locally registered products. The pharmacist must have appropriate postgraduate qualification, holds a primary appointment in a local institution, and have a demonstrated track record of research. A clinician should act as a co-investigator interventional clinical trials to provide direct medical supervision and monitoring of the trial subjects.

positions; together with clinician-scientist positions, they would act as research role models in HA hospitals.

Clinical research fellowships: More part-time fellowships should be funded to attract young clinicians to clinical research. Building on the experiences of HKU School of Clinical Medicine and the D.H. Chen Foundation **(Figure 29)**,[38] these fellowships offer protected time for clinicians to acquire skills and experience in the research community (Li Ka Shing Faculty of Medicine, HKU, 2021a; The D.H. Chen Foundation, 2023). Going forward, with the creation of clinician-scientist positions, fellows could conduct research in non-teaching hospitals under the guidance of clinician-scientists.

Figure 29. Clinical Fellowships of HKU School of Clinical Medicine and The D.H. Chen Foundation

HKU School of Clinical Medicine Clinical Research Fellowship Scheme		The D. H. Chen Foundation Clinical Research Fellowship Program at the Hong Kong Children's Hospital
Encourage research culture within the clinical setting		Enhance pediatric research expertise and capability
For early career HA clinicians		For early to mid-career HA clinicians
Part time research work for six months to one year		Part-time research work for two consecutive years
Basic science or clinical research project under an attachment programme at the School of Clinical Medicine		Research work conducted under the supervision of medical faculty of CUHK or HKU
Offer protected time and resources: HKUMed will reimburse HA for the actual staff costs		Offer protected time and resources: Relieving staff will be hired to provide medical service

Source: Li Ka Shing Faculty of Medicine, The University of Hong Kong (2021a), D.H. Chen Foundation (2023)

[38] One fellowship has been granted for a HA clinician since the introduction of the HKU School of Clinical Medicine's scheme in 2020. Six fellowships have been granted for HA clinicians since the introduction of the D.H. Chen Foundation's scheme in 2019.

Recommendation 2.3. Offering professional training for research support staff

To provide clinical research training opportunities, an Academy should be established under the CRI. Apart from trainings for investigators, structured training should be provided for research support staff, especially clinical research coordinators (CRC). CRCs are key personnel who assist investigators to manage the study and ensure compliance with protocols and regulations. The courses could be credit-bearing for potential progression to tertiary training.

Both the Singapore Clinical Research Institute (SCRI) and Clinical Research Malaysia (CRM) have developed national training programmes for CRCs in collaboration with local and overseas partners, which correspond to their systematic career paths along with clearly defined prerequisites **(Figure 30 and Appendix 6)**.

In Malaysia, senior study coordinators are even given the opportunity to receive training in renowned institutions like Singapore's NUS Hospital, Canada's Princess Margaret Cancer Centre, and Japan's National Cancer Centre (CRM, 2022).

Figure 30. Singapore Clinical Research Institute's Clinical Research Coordinator training programmes

Career ladder	Course Level	Course features
Senior CRCs and above plus five years of relevant experience	**Level 3**	• Four-day training course • Skills in planning departmental activities and managing clinical research teams
Senior CRCs and above plus two years of relevant experience	**Level 2**	• Six-day training course • Project management skills • Ability to coordinate investigator-initiated clinical research with proficiency across different study designs
CRCs with less than one year of relevant experience	**Level 1**	• Seven-day programme • From on-site operations, protocol feasibility to study start-up, ethics and regulation, recruitment, and study closure

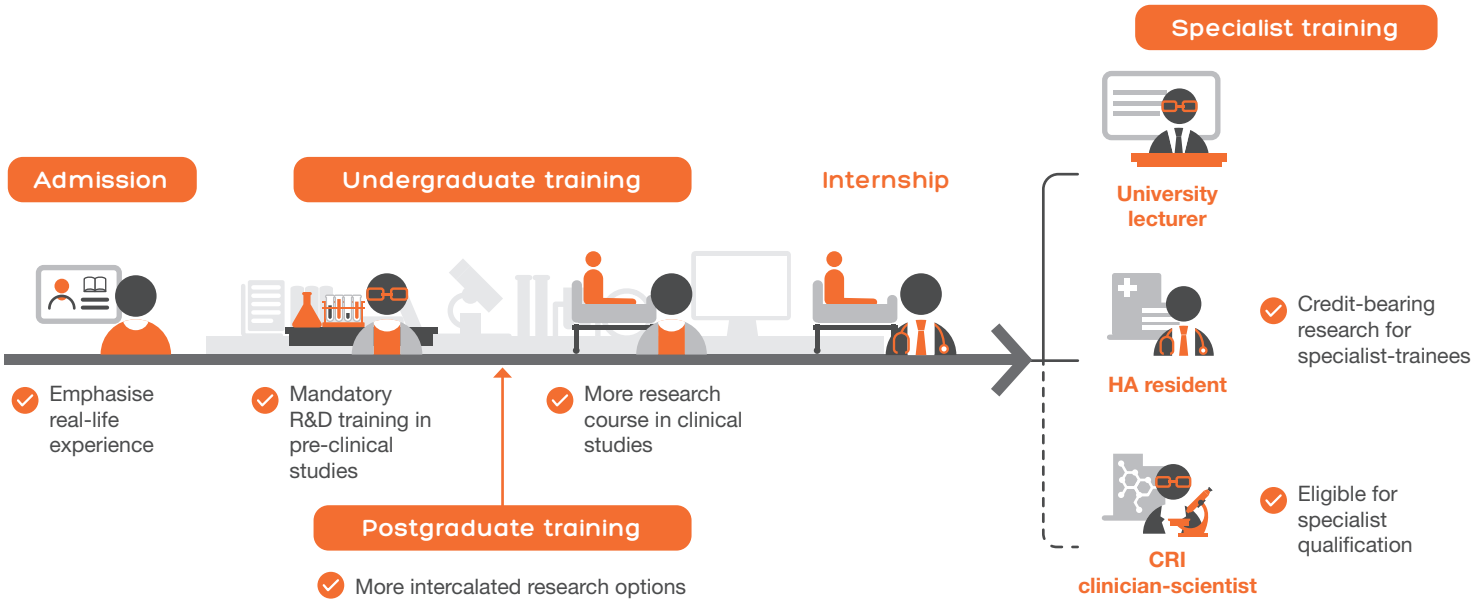
Source: Singapore Clinical Research Institute (2023c)

Recommendation 2.4. Enhancing tertiary education and specialist training to nurture research-minded clinicians

To foster the development of clinicians with a research-oriented mindset, it is essential to enhance tertiary education and specialist training throughout their early career stages **(Figure 31)**.

Admission: Medical schools in Hong Kong select students primarily based on academic achievements. This is different from other leading medical schools which have a stronger emphasis on candidates' medical related work and research experience. For example, Harvard Medical School (HMS) offers Doctor of Medicine (MD) programmes at the graduate level to students who demonstrate interest through clinical research, medical-related work, relevant community engagement experiences (Harvard Medical School, 2023). Hong Kong medical schools should consider creating graduate entry routes into their medical programmes to cultivate more clinician-scientists proficient in diverse biomedical fields and skilled in both clinical practice and independent biomedical research. They can bring unique perspectives and address a growing demand for healthcare

Figure 31. Proposed research components in tertiary education and specialist training



professionals with research expertise. By strengthening research capacities, these trained professionals play a crucial role in advancing medical knowledge, improving patient care, driving innovation, and establishing Hong Kong as a hub for clinical trials.

Undergraduate training: Continuous research exposure should be ensured starting from undergraduate training, encompassing pre-clinical studies and clinical studies.

During the pre-clinical phase, local curricula should offer mandatory and structured research components. Currently, students from HKU's Bachelor of Medicine and Bachelor of Surgery (MBBS) Programme can select research as an option during their "Enrichment Year". Only the few students from Bachelor of Medicine and Bachelor of Surgery (MBChB) Programme selected to the "Global Physician leadership Stream" (GPS) at CUHK will enjoy enhanced training in research. Such arrangements limit research exposure for other medical students.

To remedy this, local medical curricula should include knowledge in therapeutics, device development, and practical research skills for all students. Authorities can also take reference from Oxford University's research-dedicated third year of preclinical studies. All students must undertake a self-initiated experimental research project within university research laboratories or beyond (University of Oxford Medical Sciences Division, n.d.).

During the clinical phase there is still a lack of opportunities to explore research within laboratories and clinical settings. HKU only provides a four-week elective for students to conduct laboratory or clinical research after their examinations in the sixth year. Similarly, CUHK only offers a clinical elective where students could engage in a laboratory-based attachment in their fifth year (Li Ka Shing Faculty of Medicine, HKU, n.d.; Faculty of Medicine, CUHK, 2023a). Nonetheless, the research attachments available to local medical students are not well structured. At HKU, there is no supervisor assigned for the post-examination elective at HKU. For CUHK, students opting for a clinical elective in their fifth year are only guided by a Faculty-based Coordinator of Clinical Elective instead of dedicated clinicians from their respective fields (Li Ka Shing Faculty of Medicine, HKU, 2020b; Faculty of Medicine, CUHK, 2023b).

On the contrary, medical students at Cambridge University get up to three six-week placements in clinical or translational research in their fourth and fifth year, and a seven-week research placement between their fifth and sixth year (School of Clinical Medicine, University of Cambridge, 2023). This well-structured clinical research elective is complemented by the guidance of leading clinician-scientists at designated teaching hospitals (Nuffield Department of Primary Care Health Sciences, University of Oxford, 2023; School of Clinical Medicine, University of Cambridge, 2023).

Postgraduate training: Research postgraduate training augments physicians' and pharmacists' undergraduate training to provide advanced knowledge on the design and implementation of rigorous clinical trials. HKU currently offers two programmes to prepare medical students for a research career, namely the Master of Research in Medicine (MRes[Med]) for MBBS students of higher caliber to pursue during their enrichment year, and the joint MBBS/Doctor of Philosophy (PhD) Programme for a PhD undertaken between pre-clinical and clinical training of the MBBS curriculum (Li Ka Shing Faculty of Medicine, HKU, 2020a). However, both

programmes only accept medical students and limit clinical research exposure for students from other disciplines.

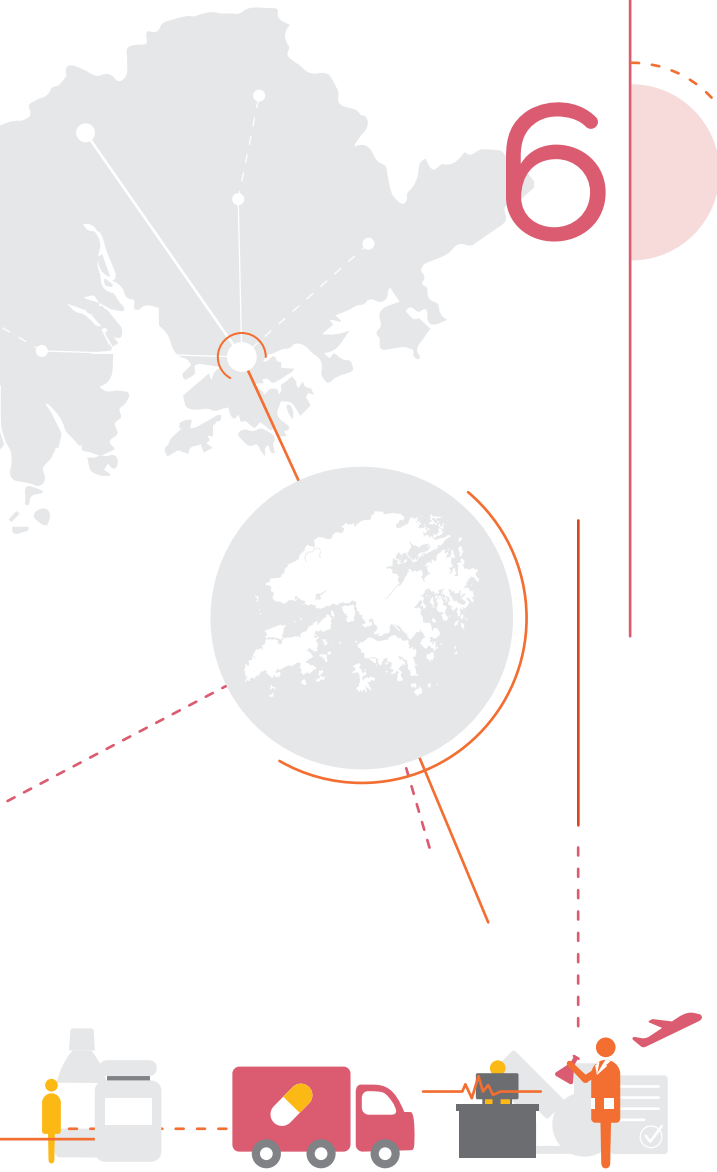
Hong Kong should adopt a graduate entry route into medical programmes to encourage the integration of research and clinical practices by including research-oriented students from basic science and other fields.

For example, HKU offers students from biomedical science (BBiomedSc) and biomedical engineering (BME) programmes new articulation pathways to the MBBS programme upon satisfactory completion of their own course requirements and fulfillment of MBBS' admission criteria. Students are exempt from certain biomedical science components and MBBS' enrichment year since they are already fulfilled. Hence, students can obtain both BBiomedSc/BME and MBBS degrees within eight years. These graduate-entry programmes can further include tailored modules to prepare for careers within Hong Kong's upcoming counterpart to the FDA authority.

A world-renowned example is Harvard's graduate-entry Health Sciences and Technology (HST) Programme jointly offered by HMS and the Massachusetts Institute of Technology (MIT). Hong Kong should encourage similar interdisciplinary collaboration by broadening the articulation pathways to other disciplines, such as physical sciences and engineering (HST, MIT, 2023). Their prior knowledge enriches the clinical research environment and fosters a multidisciplinary approach to evidence-based medicine.

Specialist training: Most medical graduates eventually gain specialist qualifications while serving in public hospitals. Although most colleges under The Hong Kong Academy of Medicine (Academy) feature designated research projects as a graduation requirement, there could be more incentives for specialist trainees to undertake optional research work. For instance, working with universities to ensure that optional research projects conducted for specialist accreditation can contribute towards a postgraduate degree. Credit-bearing arrangements could be made for research components in Continuing Medical Education (CME) and Continuous Professional Development (CPD) of clinicians.

Potential establishment of a new medical school: Given the shortage of clinician-scientists, a third medical school dedicated to research-intensive clinical training would address the current gaps in Hong Kong's clinical research landscape, as well as meeting the high demand for skilled labour to support clinical services. This is evident according to our survey responses, as experts in the field agreed that there is a shortage of clinical investigators **(Figure 5, P.17)**. Additionally, the lack of dedicated clinical research teams in hospitals and insufficient training for researchers **(Figure 7, P.18)** highlight the importance for a dedicated medical school which can effectively tackle these issues. As opposed to teaching hospitals geared towards a distinct clinical focus, the new medical school, ideally affiliated with a public hospital designated by the HA, would allow faculty and graduates to design and conduct translational clinical research, closing the gap between bench and bedside. In the long run, the proposed medical school could also form a partnership with NMPA to obtain GCP accreditation for new diagnostics, therapeutics, and healthcare products to receive market approval in mainland China.



6

Recommendation 3.

Positioning Hong Kong as the "Super-connector" of Drug Development

Despite being China's most international city, Hong Kong so far has not fully leveraged the opportunity to bridge the drug development supply chains in mainland Chinese and foreign markets. Regulatory hurdles must be overcome to develop the city into a global drug registration, talent, and bio-samples hub.

Global drug registration hub: Upon the completion of clinical trials, novel drugs need to be registered with regulatory authorities before they can be commercialised. In fact, drug registration is not a stand-alone process as pharmaceutical companies would engage authorities once their drugs reach clinical stage. Companies would often have their trials conducted in the respective jurisdictions to ensure that the data produced is fit for registration, especially for those having local clinical data requirements.[39] Typically, companies would have their trials conducted and drugs registered in major markets such as the FDA, EMA, Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and

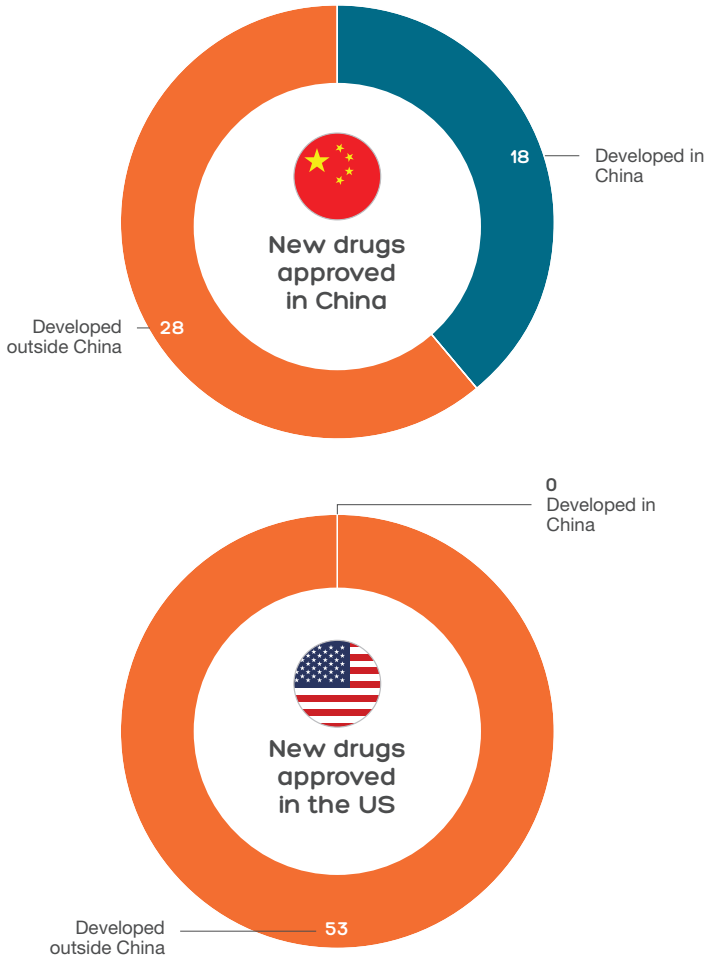
[39] The FDA states that due to resource constraints for foreign clinical site inspections, additional efforts are needed to fulfill regulatory requirements (FDA, 2012). The EMA and NMPA offer guidelines on the need of bridging studies for extrapolation of data to overcome ethnic differences (EMA, 2006; NMPA, 2018).

increasingly the NMPA; they would then file applications with the available clinical data to other authorities and fulfill further requirements if needed to expand into more markets.

Hong Kong currently adopts a secondary review system where novel drugs need to be approved by two foreign authorities before they can be registered (PPB, 2023b).[40] Under such regulatory arrangement, there is no incentive for companies to conduct trials in Hong Kong. Ironically, despite an increasing number of drugs being developed in Hong Kong, they can only be commercialised by obtaining drug approvals overseas; as a result, companies prefer to have trials conducted elsewhere.

Although Hong Kong has a mere seven million population, it could become one of the go-to-places for drug registration by leveraging on its "one country, two systems" advantage. To achieve so, Hong Kong must establish its primary review system and collaborate with the NMPA and other major drug regulatory authorities (such as the FDA, EMA and PMDA). So long as there is close collaboration to streamline drug review processes and enhance patients' novel drug access, pharmaceutical companies would be able to benefit from Hong Kong's global market connectivity. With the current difficulties faced by novel foreign drugs to enter mainland China and those in mainland China to internationalise, especially for the latter **(Figure 32)**, Hong Kong should seek to become the drug development bridge between mainland Chinese and international markets **(Figure 33, P.56)**.

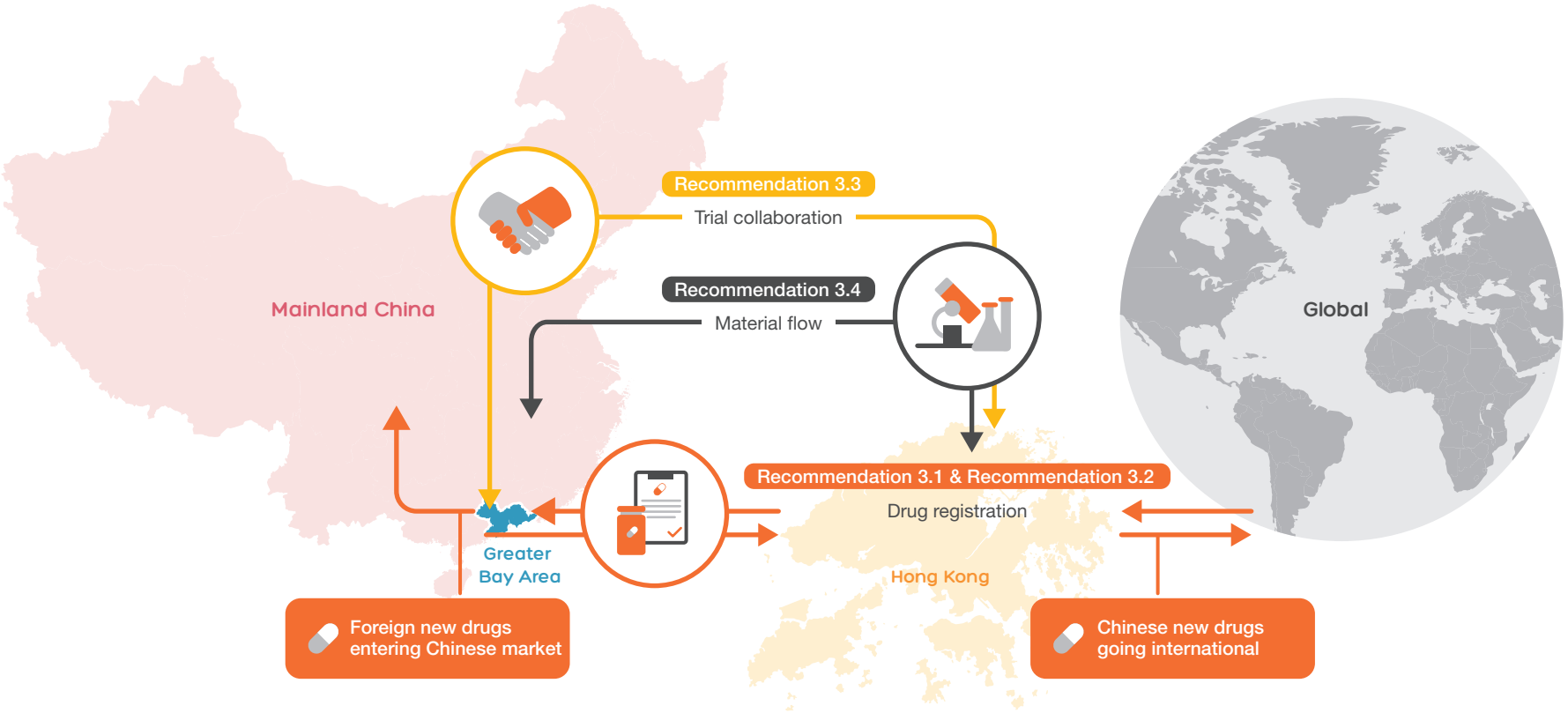
Figure 32. Breakdown of new drugs approved in mainland China and the US in 2020



Source: Wang & Wang (2021), U.S. Food and Drug Administration (2021)

[40] The Hong Kong Drug Office's reference list consists of 36 countries, including the 4 additions proposed in 2022. Registration of pharmaceutical products containing a new chemical or biological entity in Hong Kong should have obtained registration approval in any two countries on the list.

Figure 33. Positioning Hong Kong as the bridge between mainland Chinese and international markets



Global talent hub: Hong Kong could become the bridge between mainland Chinese and foreign talent. While it should continue to coordinate multi-centre clinical trials in Asia and beyond, the rapidly developing industry in mainland China, particularly the GBA presents a golden opportunity for Hong Kong to pursue trial collaborations **(Figure 34, P.58)**. The number of clinical trials in Guangdong Province has grown from 471 in 2015 to 884 in 2018, resulting in an 88% increase (Guangdong Pharmaceutical Association, 2019); Guangzhou has been the forerunner in the region and has even given birth to world-renowned academics.

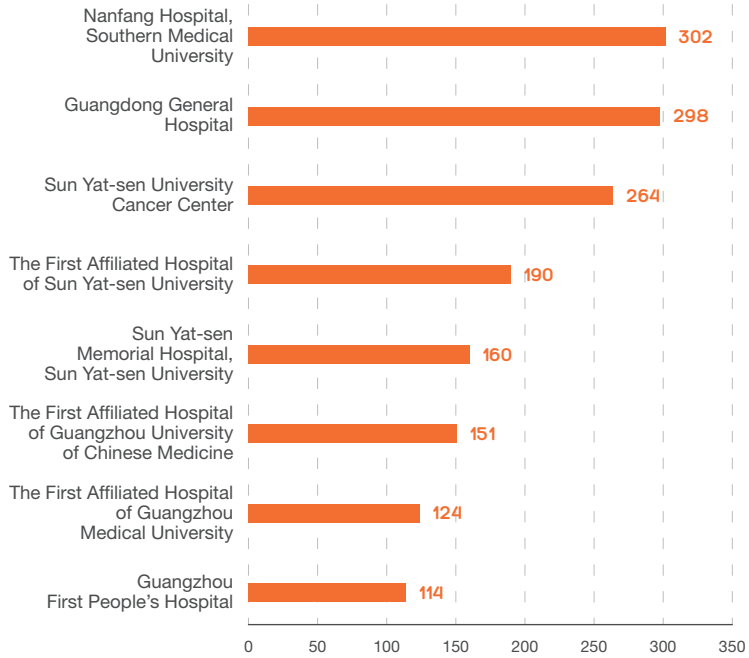
Hong Kong would eventually increase its trial capabilities by serving as a bridge for multi-regional partnerships. Below are several initiatives for Hong Kong to set foot in other GBA cities and foster closer collaboration:

- The University of Hong Kong–Shenzhen Hospital (HKU–SZH), an HKU-run public general hospital in Shenzhen, allows academics from the HKU to solicit co-appointments at the hospital with the same contract terms. This has attracted academics to serve the hospital including as senior management, thereby importing Hong Kong's management experience into the mainland.
- HKU Clinical Trials Centre (HKU CTC) has introduced a digital cloud platform called "eSMO+" for both Hong Kong and the GBA, which facilitates centralised trial management including project registration, progress tracking, trial drug management, biospecimen management, quality management and standard operating procedures (SOPs) training.
- Hong Kong Science and Technology Parks Corporation (HKSTP) and HKU CTC are also planning to build a training centre in the Shenzhen Loop to train clinical investigators, research coordinators and other professionals. These would facilitate the import of Hong Kong's international clinical trial management experience into the GBA.

Prof Yilong Wu (front row, first right), a world-renowned thoracic oncologist from the Guangdong Provincial People's Hospital, has collaborated with Prof Tony Mok on studying epidermal growth factor receptor mutated lung cancer since 1999. Both of them were jointly awarded the National Science Progress Award in 2018. Prof Wu expresses that Hong Kong's international environment is irreplaceable, in that it allows mainland investigators to build international research partnerships, while assisting Chinese drugs to enter international markets.

Photo Courtesy of Prof Tony Mok

Figure 34. Number of clinical trials conducted by hospitals in the Greater Bay Area (2014–2018)



Source: Health Commission of Guangdong Province (2019)

HKU-SZH allows Hong Kong academics to not only become principal investigators in Shenzhen and tap into the vast resources in the GBA but also to share their experience with mainland Chinese academics for future collaborations. Meanwhile, HKU CTC drives regional research collaboration through facilitating standardisation and talent cultivation through its platform and training centre. More such initiatives should be promoted.

Global bio-samples hub: Cross-border multi-centre clinical trials require the flow of trial drugs and also biological samples, as samples collected from trials have to be shipped to pharmaceutical companies and CROs' central laboratories for data analysis.

Meanwhile, the export of human genetic materials, including biological samples, from the mainland is still strictly regulated despite current preferential policies.[41] As such, dedicated central laboratories have to be established in mainland China to cater for its samples, creating additional costs and unpreferred segregation with samples from other parts of the world.

Hong Kong could become a global bio-samples hub and the go-to place for central laboratories if cross-border material flow could be facilitated with a streamlined customs clearance process, making it possible to aggregate samples from both mainland China and foreign regions. This would not only attract high value-added R&D activities including data analysis, but also boost the clinical trials industry by having these ancillary facilities in place.

[41] Although the Central Government allowed mainland branches of Hong Kong's universities to export human genetic resources to Hong Kong in 2019 under the "16 Policy Measures", it is reported that few, if not none, has successfully achieved so (HKSAR Government, 2019).

Recommendation 3.1. Establishing Hong Kong's drug primary review authority

The Government should establish an independent drug primary review authority, building upon the existing Drug Office and Pharmacy and Poisons Board. It is essential to ensure that the proposed authority has review capabilities on par with international standards. The Government has proposed to set up a preparatory office for the Hong Kong Centre for Medical Products Regulation (CMPR) in the 2023 *Policy Address*. As such, this preparatory office should:

- define a clear roadmap and develop the necessary expertise to build a regulatory framework for primary review;
- coordinate with the NMPA to harmonise and expedite drug registration and clinical trial approval processes **(Recommendation 3.2)**;
- seek to become a regulatory member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) [42] **(Appendix 7)**;
- build collaborations with leading drug regulatory bodies through initiatives such as ACCESS Consortium **(Appendix 7)**.

Establishing a new regulatory authority is a major undertaking. There should be a clear roadmap for a new drug regulatory framework implemented through a phased approach, while retaining the current secondary review mechanism **(Figure 35, P.60)**.

Two review pathways should be introduced **(Figure 36, P.61)**:

- **Abridged review** which involves performing limited independent assessment with one foreign reference approval. The "1+" mechanism was announced in the 2023 *Policy Address* to be effective from 1 November 2023. It could gradually be expanded to include a broader range of new drugs in addition to life-threatening or severely-debilitating disease;
- **Full review** which performs assessment of all quality, non-clinical, and clinical data, at best with an investigational new drug (IND) mechanism through which sponsors are engaged once they enter clinical stage.

The above pathways' turnaround time should not be longer than the existing secondary review pathway (including the time needed to obtain two foreign approvals). The existing approval timeline should also be expedited to enhance patients' drug access. This could be achieved through building dedicated panels and teams of experts for drug registration in the authority.[43]

The introduction of the above pathways should involve risk and benefit assessments. The authority should develop review capabilities starting with applications of the lowest risk: from drug reformulations, then new indications and eventually novel drugs.

While a universal requirement for local clinical data may not be necessary, a fast track could be provided for applications with local clinical data to encourage conducting clinical trials in town.

[42] The Government has joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as an observer in 2023.

[43] The approval time for drug registration in Hong Kong is reported to be around 9 to 12 months, with some cases up to 14 months and beyond; this is mainly due to repeated dossier screening, review by an overburdened committee with infrequent meeting under the Pharmacy and Poisons Board (Recommendation 4.2, Ch.7), and other additional queries.

Figure 35. Building Hong Kong's regulatory capability through a multi-faceted approach

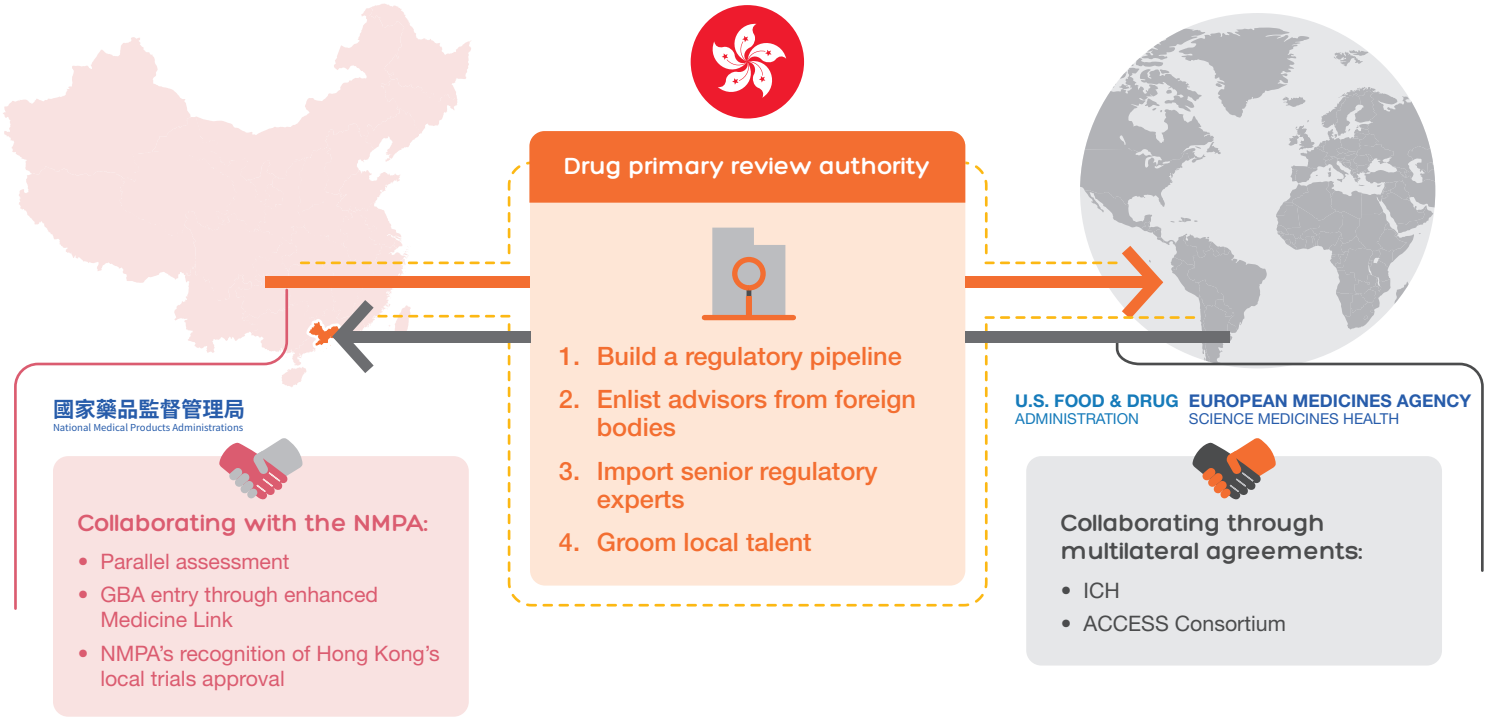


Figure 36. Proposed regulatory framework for drug review in Hong Kong

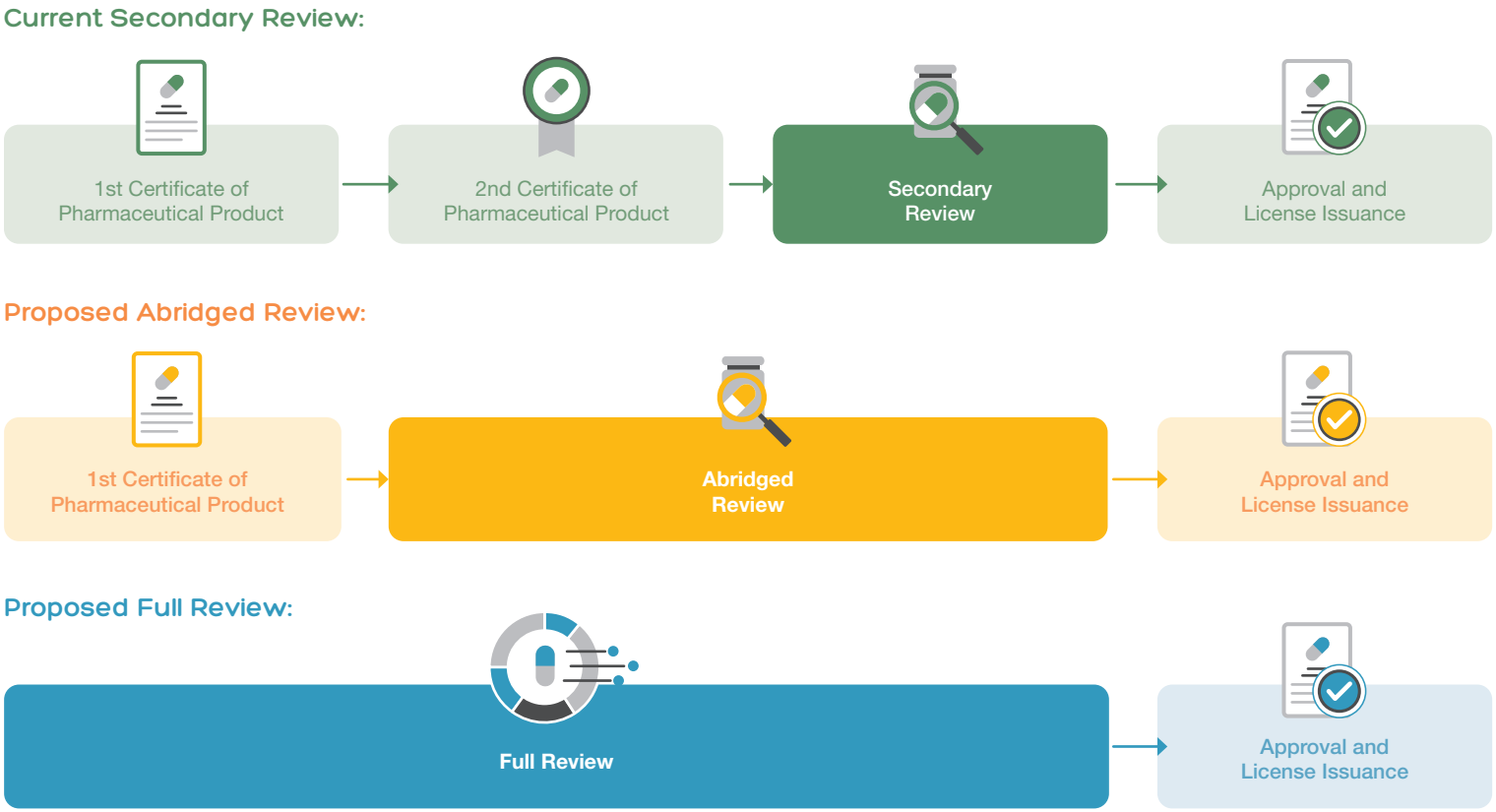
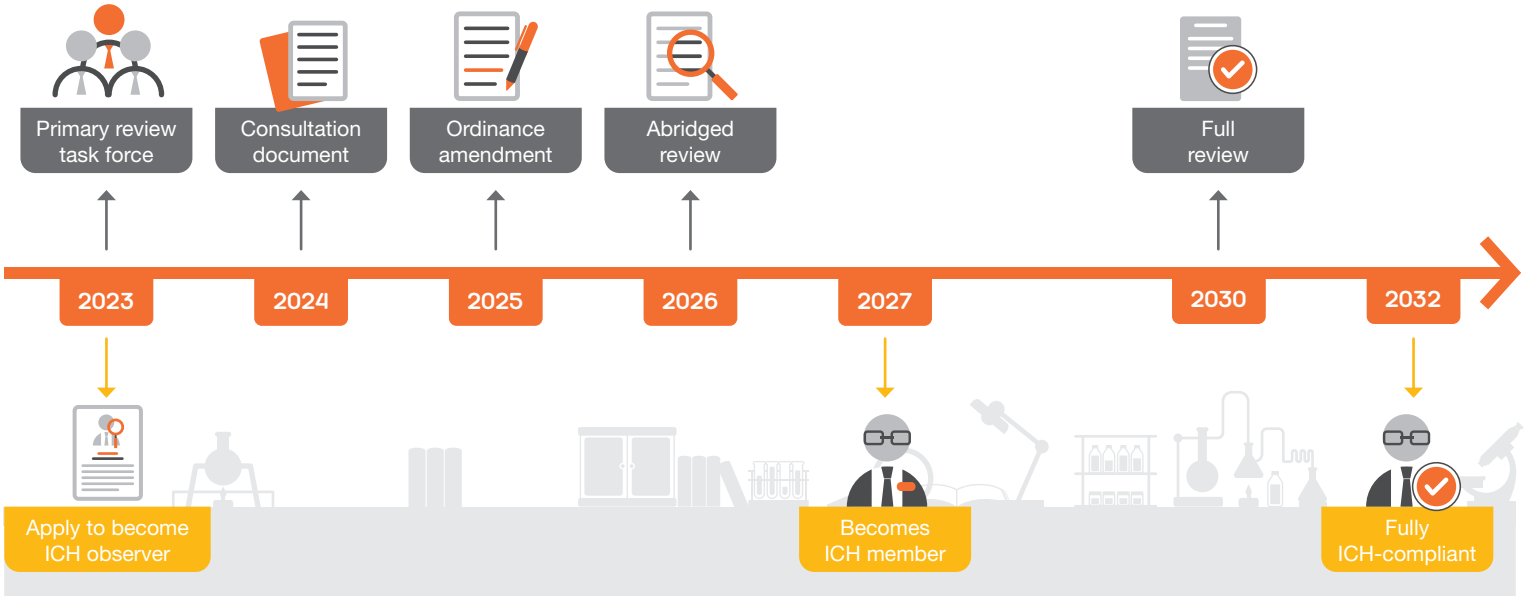


Figure 37. Proposed roadmap for Hong Kong to introduce a primary review mechanism



A proposed timeline is presented above **(Figure 37)**.

To implement the new framework, the authority needs to build its regulatory capability, including to:

- enlist advisors from leading drug regulatory authorities such as the FDA, EMA, and NMPA:
- hire senior regulatory staff with international experience;
- groom a pool of local talent in regulatory science;
- establish collaborations with major regulatory authorities through communication, training, information sharing and staff attachments.

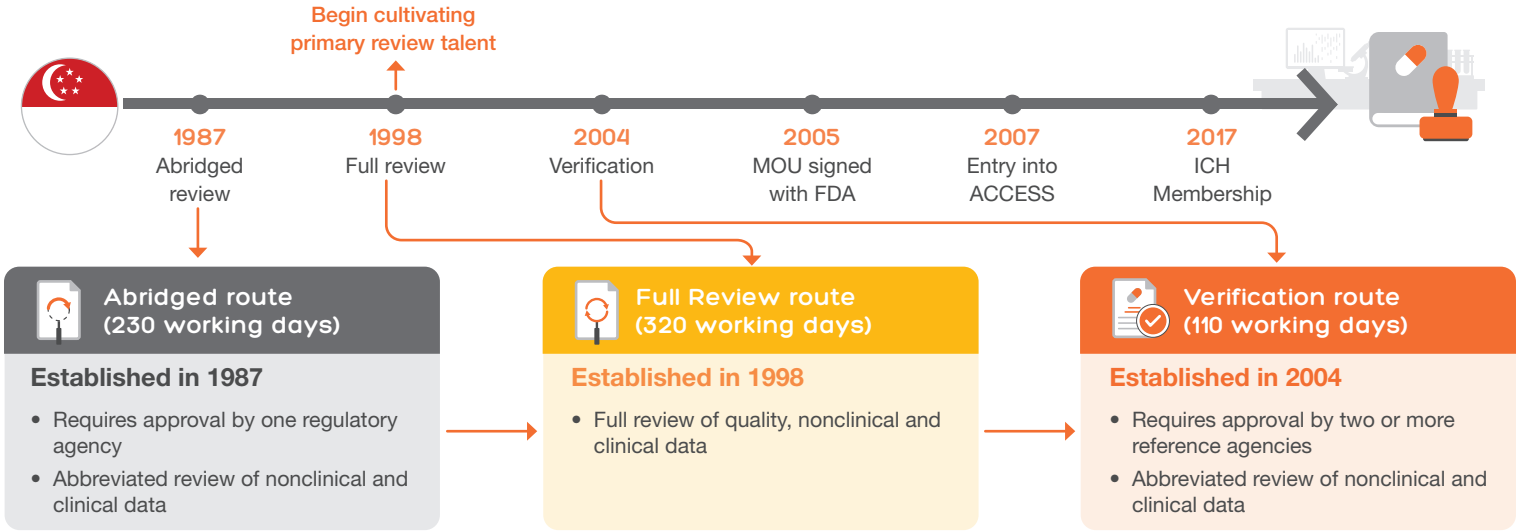
Notes: (1) Referencing the legislative timeline for the Pharmacy and Poisons (Amendment) Ordinance 2020 for Advanced Therapy Products, it would take four years for the introduction of abridged review and another four years for full review at best.
(2) ICH observership is granted in a biannual ICH Assembly meeting, while that for membership (fulfilling Tier 1 guidelines) and full compliance (fulfilling Tier 2 guidelines) take another two and five years respectively (ICH, 2020). An extra year is reserved for industry preparation before full compliance.
(3) Harmonisation with the NMPA and collaboration with leading drug regulatory bodies would achieve upon Hong Kong's introduction of full primary review mechanism.

Both Singapore (5.5 million) and Switzerland (8.7 million) feature comparable population sizes to Hong Kong. Their respective regulatory authorities, the Health Sciences Authority (HSA) and Swissmedic, showcase how small economies can develop primary review capabilities for drug registration. Both of them are admitted to the ICH and multilateral drug review alliances including ACCESS Consortium.

Singapore is a particularly relevant example as it offers a verification route similar to Hong Kong's secondary review mechanism, and also an abridged route and a full review route **(Figure 38)**. While its verification route relies on two or more designated foreign approvals for novel drugs, the abridged route requires only one designated foreign approval and the full route calls for an independent review by the HSA (HSA, 2022).[44]

To support the primary review process, the HSA has a Medicines Advisory Committee comprised of 30 professional evaluators (Chan, 2017).

Figure 38. Requirements for different drug registration routes in Singapore



Note: The above turnaround time covers both screening and evaluation.
Source: Chan (2017); Singapore Health Sciences Authority (2019)

[44] The foreign approvals accepted by the HSA include: FDA, EMA, Health Canada, Australia's Therapeutic Goods Administration (TGA), and the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

With varying requirements in dossier and foreign references **(Figure 39, P.65)**, the three routes' turnaround time last from 110 to 320 working days (HSA, 2022).[45] The HSA also introduced a priority review route within the abridged review route for certain life-threatening or emergency conditions.[46]

Between 2013–16, most drug registration applications in Singapore went through the abridged review route (92%), compared with verification (4.25%) and full review (3.75%) (Chan, 2017). This is because most applicants have already obtained two or more foreign approvals beforehand, rendering the full review route unnecessary. Despite so, they prefer the abridged review route rather than verification due to the flexibility it confers to industry to seek approval for clinical indications or quality specifications that may not be the same as those approved by reference agencies (Chan, 2017).[47,48]

Referencing the success of our regional counterparts, Hong Kong's proposed drug primary review authority would be an important catalyst to:

1. attract and retain sponsors for clinical trials by offering a clear regulatory pathway towards commercialisation;
2. train pharmaceutical talent for the ecosystem including academia, pharmaceutical companies, and the drug regulatory authority;
3. serve as a bridge for mainland Chinese pharmaceutical companies to go abroad and foreign pharmaceutical companies to enter the mainland market.

[45] That said, for abridged review and verification routes, the HSA focuses on reviewing late phase clinical data and relies on foreign approval for objective elements such as pre-clinical data, early-phase clinical data, and quality specifications (Chan, 2017).

[46] They include: the absence of a treatment option, lack of safe and effective treatments, and diseases conditions of local public health concern (HSA, 2022).

[47] Approximately 80% of applicants gone through the abridged review route have already two or more foreign approvals (Chan, 2017).

[48] As the verification route relies on assessment reports from the reference agencies, and the clinical indications and quality specifications must be the same as those approved, industry considers these requirements to be restrictive as companies may plan different strategies for different markets (Chan, 2017).

Figure 39. Dossier required by the Singapore's Health Sciences Authority review routes for drug registration

Documents	Full review	Abridged review	Verification
Administrative documents	✓	✓	✓
Technical document overview and summaries	✓	✓	✓
Quality documents	✓	✓	✓
Non-clinical documents	✓	✗	✗
Clinical documents	✓	✓	✓

Note: ✓ indicates requirement for complete documents, while ✗ indicates no such requirement in ICH Common Technical Document (CTD), and ✓ indicates that requirement for study reports of pivotal studies and synopses of all studies.
Source: Singapore Health Sciences Authority (2019)

Recommendation 3.2. Expediting drug registration and clinical trial approval with the NMPA

Close regulatory collaboration and harmonisation with the NMPA is critical for the proposed primary review authority to achieve its stated purpose.

Parallel assessment: The proposed authority should work towards parallel assessment of drug registration applications with the NMPA, referencing international practices such as Project Orbis. In other words, once a novel drug has been approved or is being reviewed by either authority, the approval process should be expedited by the other authority through sharing of application information.

Enhanced Medicine Link: Currently, the Medicine Link allows drugs registered in Hong Kong to be used in designated healthcare institutions in the GBA upon review by the Medical Products Administration of the Guangdong Province on clinical urgency (Medical Device Division, Department of Health of the HKSAR Government, 2020).[49] The Government could facilitate drugs approved through its full review pathway to directly pass through the Medicine Link without additional review by the Guangdong authority and regardless of clinical urgency **(Figure 40, P.67)**.

Recognising Hong Kong's clinical trial approval results: Currently, sponsors have to engage with the NMPA and seek their approval for IND before conducting trials in Hong Kong if the data produced would be used to support drug registration in mainland China.[50] Hong Kong could aim for local clinical trials approval to be recognised by the NMPA directly for progressing into late phase trials without prior engagement and IND approval.

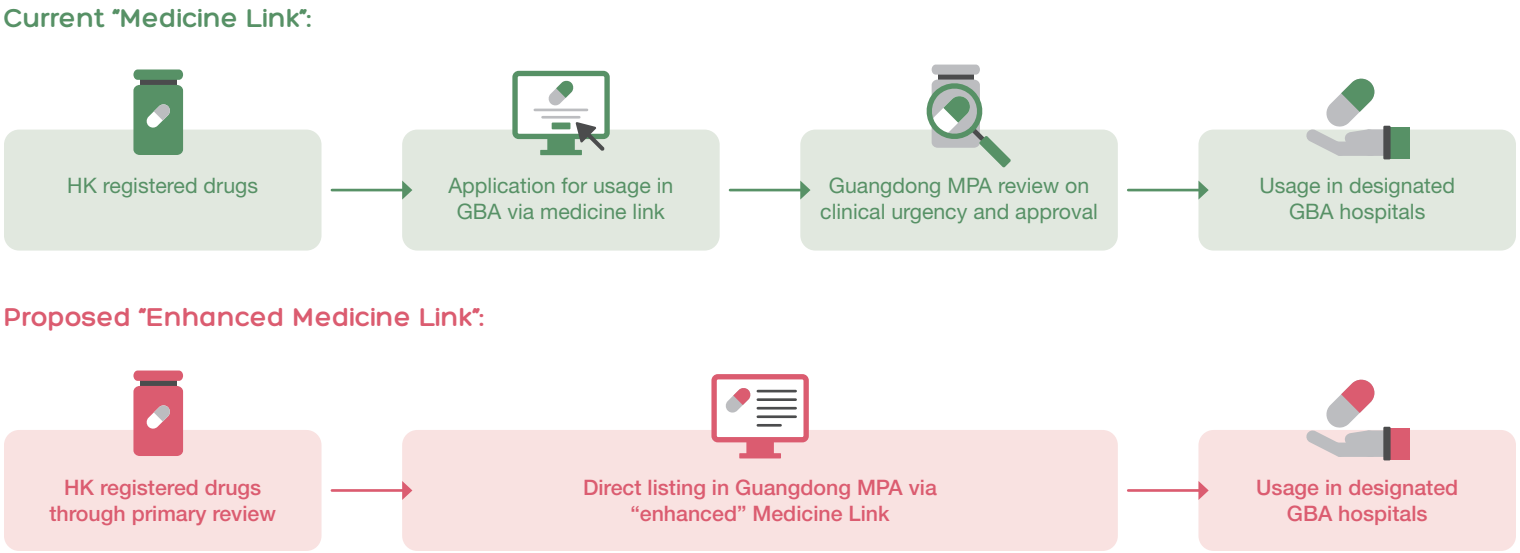
Simplifying access to the NMPA: The NMPA has established a GBA branch in the Shenzhen Loop to process clinical trial and drug applications in the GBA. Riding on such development, a separate green channel could be offered for pharmaceutical companies with an R&D base in Hong Kong.[51] Furthermore, an NMPA office could be established in Hong Kong for easier access to the NMPA through the GBA Branch.

[49] Since the introduction of the Medicine Link in 2021, as of end August 2023, 26 drugs and 17 medical devices have been allowed to be used in the 19 designed healthcare institutions in the GBA.

[50] The NMPA instructs applicants to engage with the Drug Review Centre to determine the completeness of application materials and trial feasibility before applying for the first clinical trial of a novel drug (NMPA, 2020b).

[51] The NMPA has established two branches in the Shenzhen Loop and Shanghai Zhangjiang respectively to "assist pre-evaluation and mid-evaluation communication and guidance and related inspection work", "promote more new technologies, new drugs and new devices in the Greater Bay Area", and "become a platform for collaboration in deepening the drug and medical device evaluation and approval system" (NMPA, 2020a).

Figure 40. Existing Medicine Link and proposed enhancements for drugs registered in Hong Kong through primary review



Recommendation 3.3.
Optimising joint funding schemes to enable cross-border clinical research

To facilitate cross-border collaboration, a Clinical Research Network involving investigators from both Hong Kong and the GBA should be established by the proposed CRI **(Recommendation 1.3, Ch.4)**. The Network should work with mainland authorities to roll out joint funding schemes.

There are currently three joint funding schemes administered by Hong Kong's Research Grants Council (RGC) and Innovation and Technology Commission (ITC), along with respective mainland authorities **(Appendix 8)**. However, these schemes only benefit university academics but not HA clinicians for clinical trials, as no joint funding arrangement has been introduced for the Health and Medical Research Fund (HMRF) — the only grant available to HA clinicians.

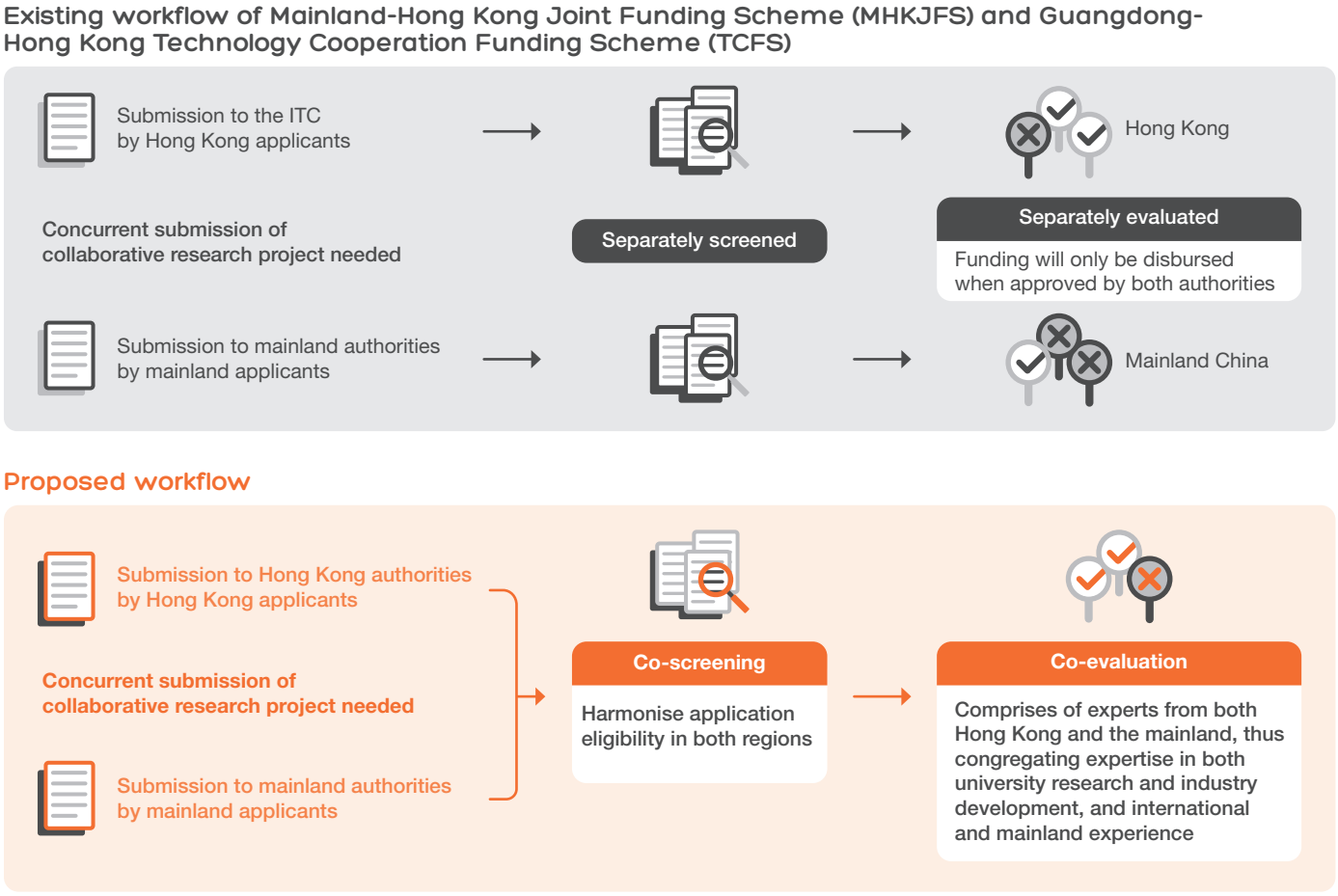
The Health Commission of Guangdong Province administers a Medical Research Fund to specifically support applied research conducted by mid-level healthcare professionals aiming to solve medical and healthcare problems (Health Commission of Guangdong Province, 2023). A joint funding scheme could potentially be introduced between the HMRF and this fund.

Meanwhile, funding mechanisms of the existing joint-funding schemes could be further reviewed. Currently, applications submitted by Hong Kong and mainland applicants are being separately screened and evaluated **(Figure 41, P.69)**. As such, not only do different authorities have different application criteria, but there are also instances where applications are only approved by one side of the border.[52]

These barriers could be overcome by treating applications in Hong Kong and the mainland as "one pair" by aligning application criteria and allowing co-evaluation by assessors in both regions. The synchronisation of approval processes would enable more cross-border clinical research.

[52] The varying application criteria include applicant eligibility, project duration, ownership of intellectual property rights, application limit of project number, method of subsidy, etc.

Figure 41. Existing and proposed workflows of cross-border joint-funding schemes



Note: The National Natural Science Foundation of China (NSFC)/RGC Joint Research Scheme has a largely similar workflow to that of MHKJFS and TCFS.
Source: Innovation and Technology Commission (2023); Shenzhen Science and Technology Innovation Commission (2020); Department of Science and Technology of Guangdong Province (2021); Ministry of Science and Technology of the PRC Government (2021)

Recommendation 3.4. Facilitating cross-border flow of human genetic materials, chemical and biological entities

Cross-border flow of human genetic materials has to be cautiously dealt with due to national security concerns. That said, Hong Kong's Lok Ma Chau Loop can be an opportunity for policy breakthrough **(Figure 42, P.71)**.

The Administration of Human Genetic Resources of China can consider setting up an office in the Hong Kong Loop to expedite application processes, arrange on-site inspections where necessary, and eventually regulate the flow of biological samples to the area.[53] Pharmaceutical companies and CROs can set up central laboratories there for sample handling and data analysis with legal restrictions to prohibit the transport of such materials out of the region.

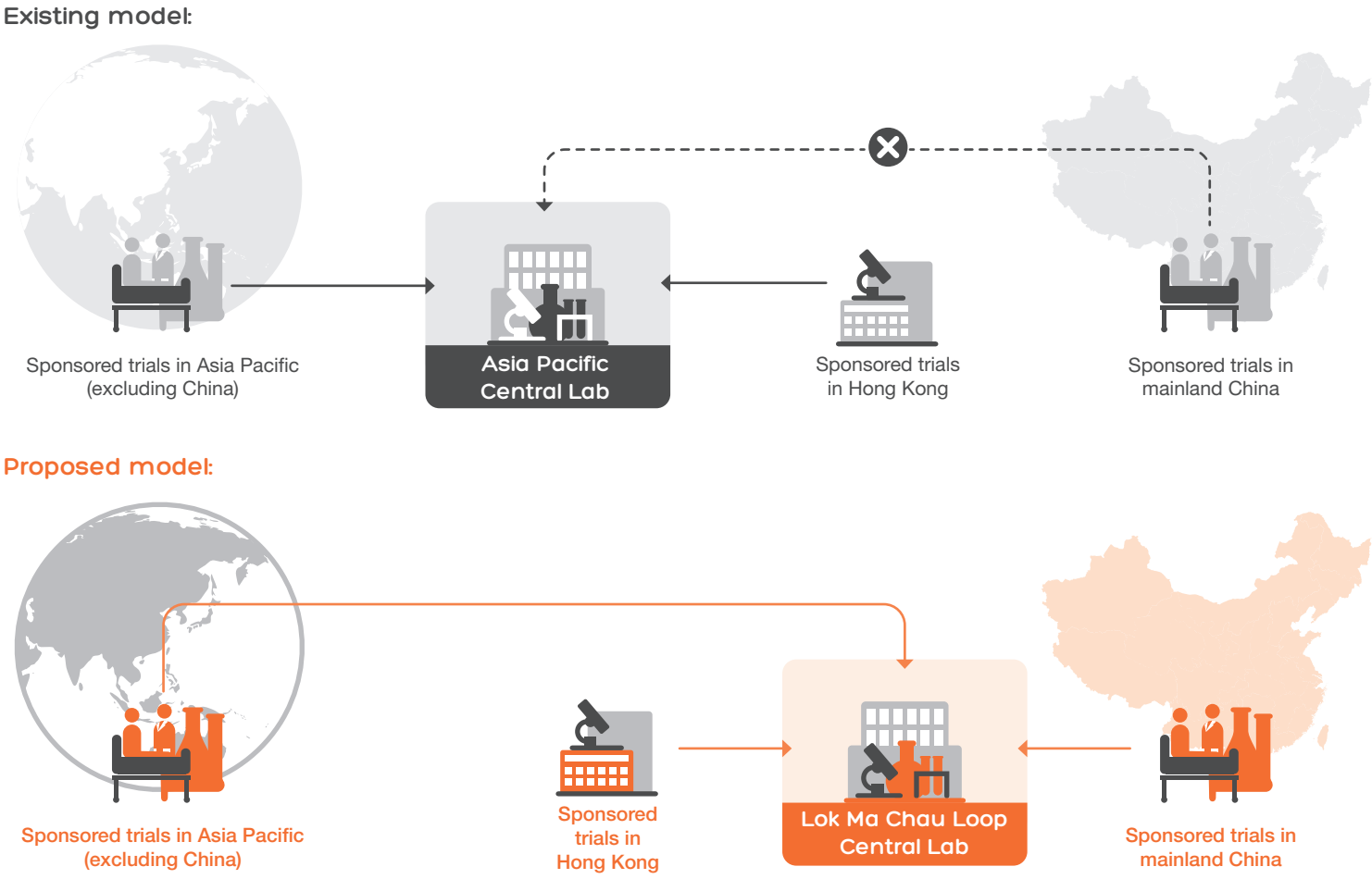
Furthermore, the cross-border flow of chemical and biological entities, including trial drugs, is subject to stringent and complicated customs controls in the form of inspection and quarantine procedures; it also involves examination by various departments.[54] Referencing the one-stop customs clearance service platforms for biological materials set up by the General Administration of Customs of China,[55] a similar platform can be established within the Shenzhen-Hong Kong Loop to speed up the approval timeline.

[53] The Administration of Human Genetic Resources of China is responsible for reviewing applications and filing for the collection, storage, export, and scientific research, clinical trials, and disclosure with/to foreign entities involving human genetic materials (Ministry of Science and Technology of the PRC Government, 2019 & 2021).

[54] Such as the Customs, health quarantine authorities, the Science and Technology Innovation Commission, and the State Administration for Market Regulation.

[55] For instance, the South China Biomaterials Import-export Service Platform offer "one application, one examination, and one approval" for biomaterials, thereby shortening the import-export permission approval time from 20 days to 7 days, and customs clearance time from 3–7 days to 1 day (KingMed Diagnostics 2022).

Figure 42. Existing and proposed models of cross-border flow of human genetic materials, chemical and biological entities



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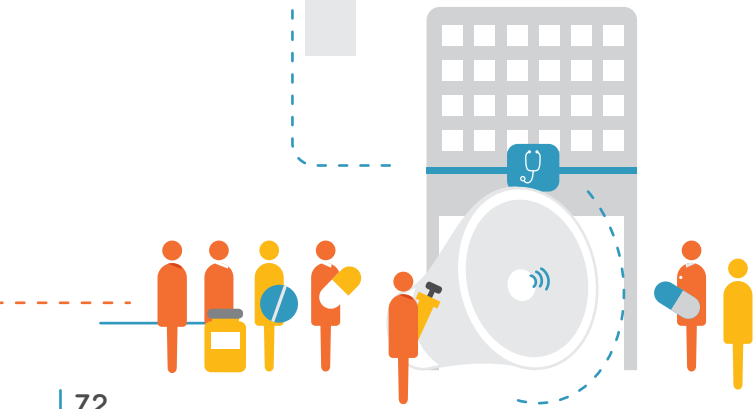
Recommendation 4.

Accelerating Clinical Trials through Start-Up and Capability Improvement

To boost Hong Kong's appeal for clinical trials, start-up processes must be streamlined to keep up with our competitors. Patient recruitment also needs to become more efficient by making better use of the trial registry and patient database as well as fostering the development of the private sector.

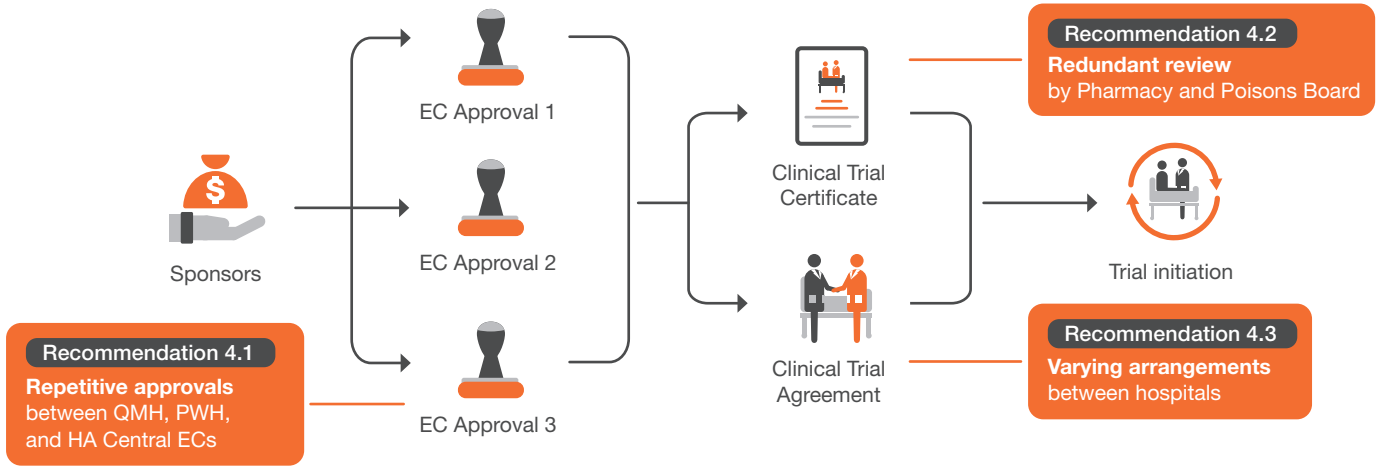


Hong Kong's clinical trial start-up time is longer than regional counterparts primarily due to the fragmented process. Sponsors must obtain:

- Ethics committee (EC) approval from committees governing the healthcare institutions where the trial takes place;
- Certificates for Clinical Trial/Medicinal Test, also known as the Clinical Trial Certificates (CTCs), from the Pharmacy and Poisons Board of Hong Kong (PPB) through the Department of Health's Drug Office; and
- Clinical Trial Agreements (CTAs) with the respective healthcare institutions **(Figure 43)**.

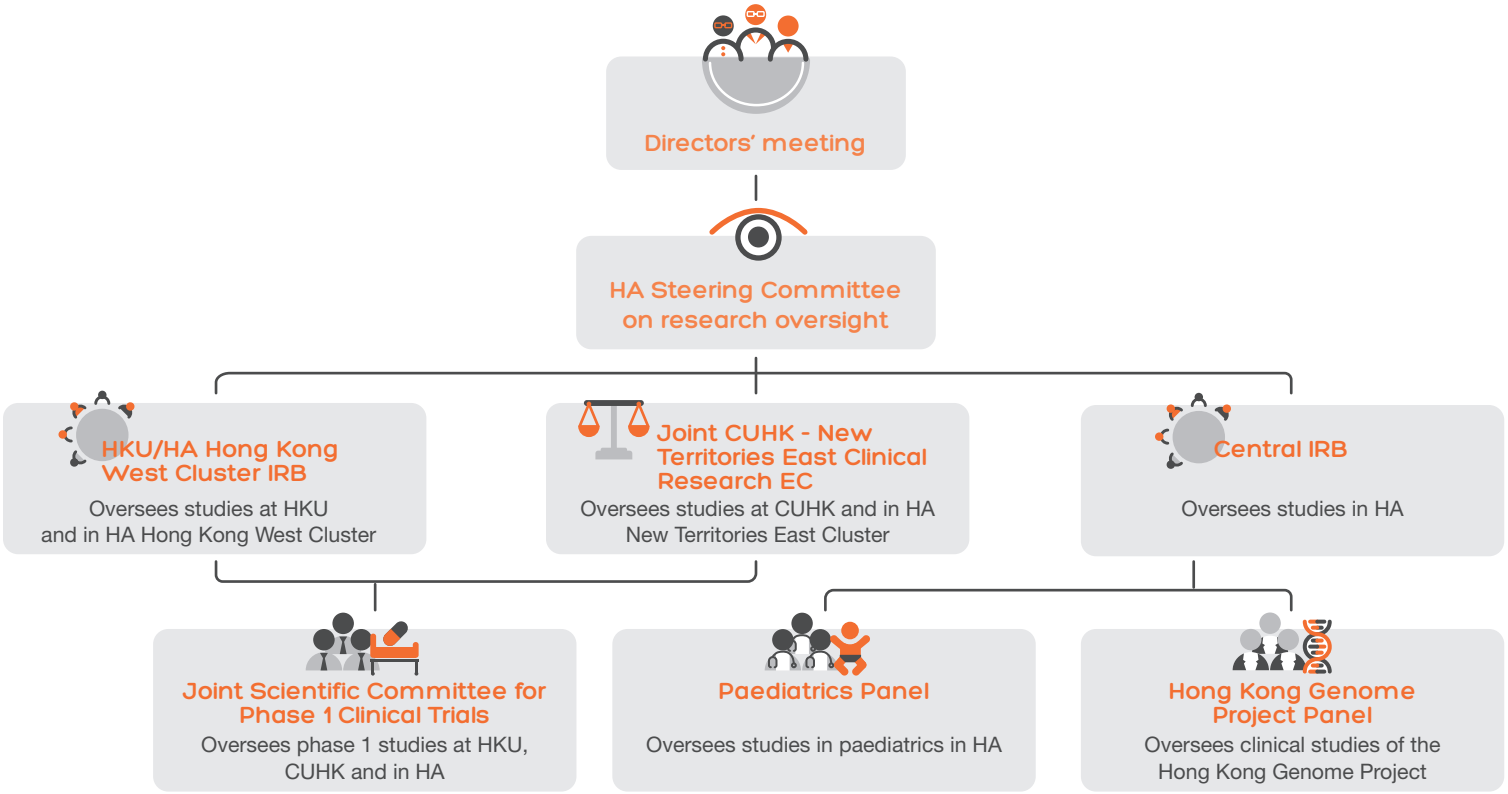
Applications for EC approval and CTC can be made concurrently, yet the CTC will be issued only after EC approval is obtained. CTA negotiation will kick start upon EC approval.

Figure 43. Clinical trial approval process in Hong Kong



There are three ECs overseeing the ethical and scientific aspects of clinical trial applications within HA hospitals. Two of them oversee the two teaching hospitals' clusters while a Central EC was created in 2021 by combining four cluster-based ECs and it oversees the other five clusters; Additionally, three sub-committees or panels are designated for specific research phases or disease areas **(Figure 44)** (HA, 2022).

Figure 44. Structure chart of Ethics Committees overseeing Hospital Authority hospitals



Source: Hong Kong Hospital Authority (2022)

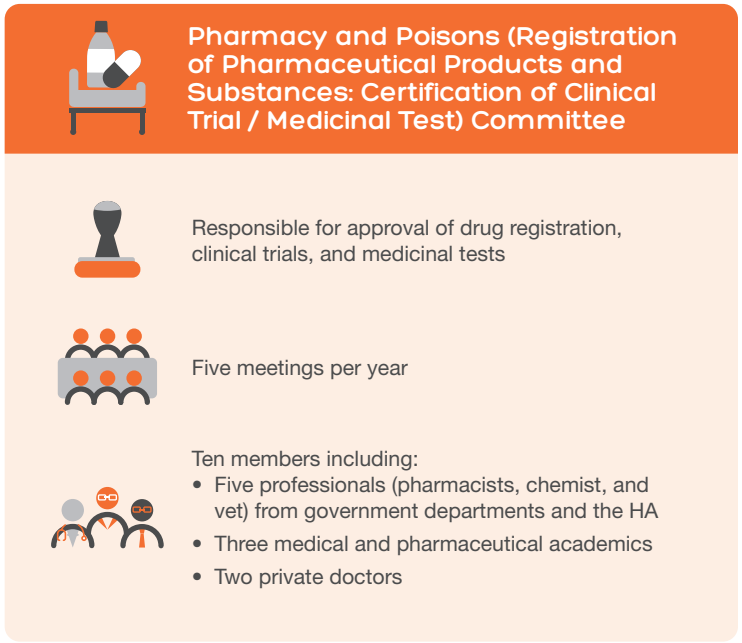
Applicants will have to obtain up to three EC approvals if their study sites span all three jurisdictions. Phase 1 trials have to be approved by a dedicated sub-committee upon referral from the ECs (HA, 2022).

For CTC approval, a committee under the PPB reviews applications for phase 1 first-in-human trials. However, decisions heavily rely on EC approvals as it is overburdened with responsibilities, suffers from a lack of manpower, holds infrequent meetings, and reviews materials already reviewed by the ECs **(Figure 45)**. A comparison of the dossier processed by ECs and PPB is presented in **Appendix 9**. For late phase trials, they are reviewed by an understaffed Drug Office.[56]

The next step is CTA negotiation. In non-teaching hospitals, master agreements are negotiated based on templates by the HA's legal department.[57] However, legal terms cannot be revised further and different hospitals provide varying schedule terms and pricings. Besides, hospitals' administrative departments do not have enough personnel to deal with sponsors on contract negotiation. In many occasions, investigators and research support staff have to deal with sponsors directly.

All these factors collectively lead to Hong Kong's lengthy start-up timeline **(Figure 46, P.76–77)**. The detailed start up processes for late phase trials in non-teaching hospitals and phase 1 first-in-human trials in teaching hospitals are presented in **Appendix 10**.

Figure 45. The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial / Medicinal Test) Committee



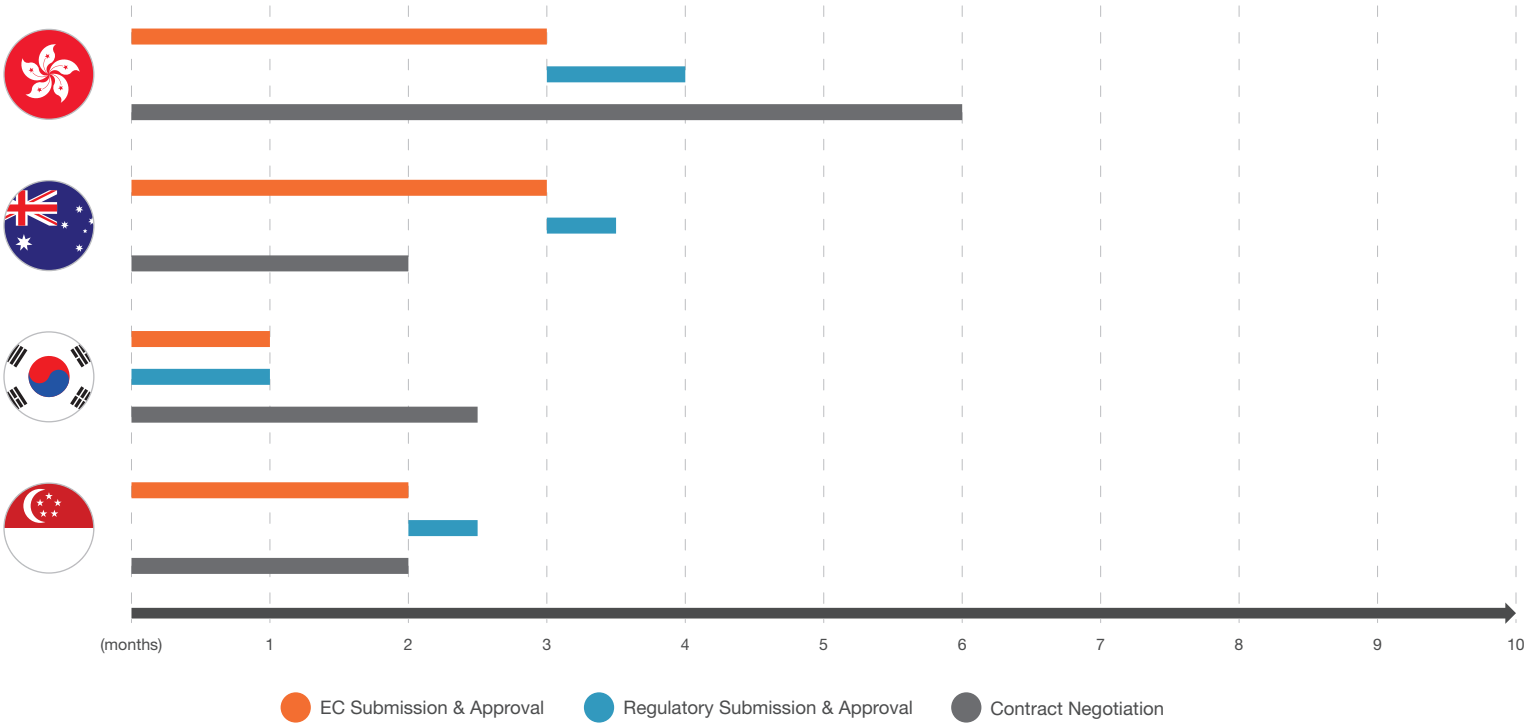
Source: Pharmacy and Poisons Board (2023c)

[56] There are currently around 13 pharmacists and scientific officers responsible for reviewing drug registration in the Drug Office. It is estimated that three to six more pharmacists are needed to handle current demand.

[57] The two universities through their clinical trials centres, rather than the HA, are the contracting parties for trials taking place in the two teaching hospitals. Therefore, the two centres serve as the single windows for trials at the two hospitals; Their templates for master agreements are also open to further revisions.

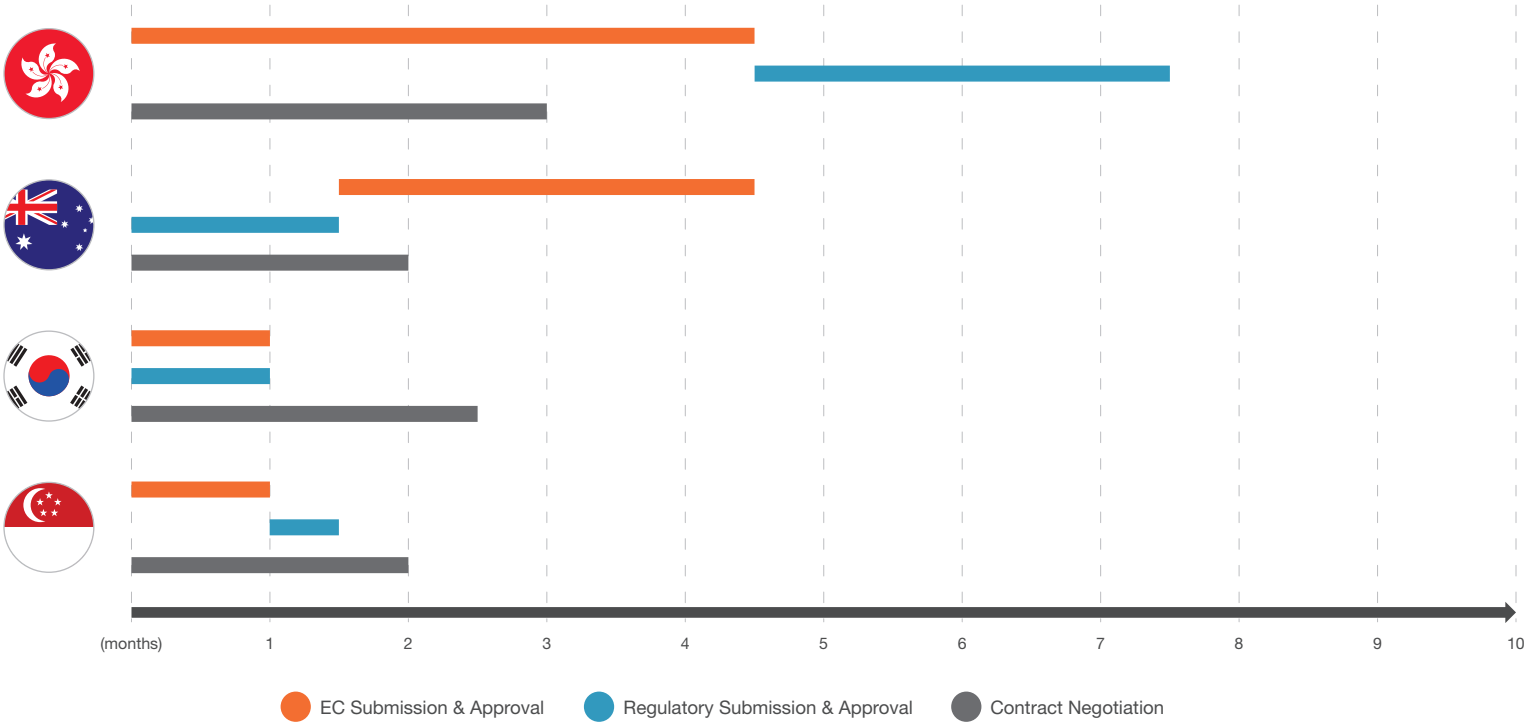
Figure 46. Late phase and phase 1 study start-up timelines of selected Asia Pacific economies

Late phase study start-up timelines



Note: The time needed for obtaining the certificates or settling the agreement is calculated from the moment an application is submitted or negotiation commences until the receival of approval or settlement of agreement.

Phase 1 first-in-human study start-up timelines



Note: The time needed for obtaining the certificates or settling the agreement is calculated from the moment an application is submitted or negotiation commences until the receival of approval or settlement of agreement.

Hong Kong's trial capability is also limited by a lack of digitalisation, underscored by the absence of a comprehensive trial registry and difficulties to access and utilise the HA's patient database.

Clinical trial registries in Hong Kong are scattered across institutions. The PPB has recently introduced a registry based on the Clinical Trials Certificates issued but containing limited information; Meanwhile, the HKU and the CUHK have clinical trial registries with relatively comprehensive data, but trials are registered voluntarily, meaning that not all trials are captured.

Meanwhile, trial registries are effectively utilised only if there are dedicated personnel to monitor and conduct patient recruitment, and this calls for access to patient databases. The HA's unified patient database, the Clinical Management System (CMS), provides patient statistics and details across public healthcare institutions. Besides, the Health Bureau's Electronic Health Record Sharing System (eHealth), an electronic sharing platform of health records between the public and private sectors, also offers a vast amount of patient data. That said, understandably, the access rights to these data are highly restrictive.

Furthermore, when a suitable patient is identified as a study subject, his or her future trial data along with past medical records recorded in the CMS should be monitored by sponsors' clinical research associates and audited by regulators. However, the HA's CMS has not been validated in accordance with major drug regulatory bodies' regulations, and no access rights have been granted to external parties.[58] As an unconventional remedy, investigators in Hong Kong have to print out all relevant records and sign on them to confirm their authenticity before passing on to other parties involved. With stricter regulations put forth by major drug regulatory authorities, Hong Kong's role in clinical trials is at risk.[59]

[58] Drug regulatory authorities have stated the need for direct access by sponsor representatives, including monitor and auditors, and regulatory inspectors to all relevant data for all trial participants (FDA, 2007; EMA, 2023).

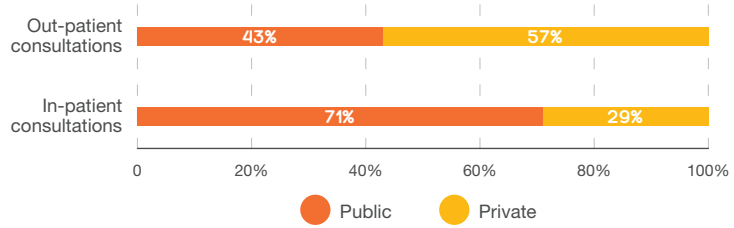
[59] Recently, there has been significant development in the regulation of computerised systems adopted in clinical trials. The ICH has included a new section on data governance in its latest proposed harmonised guideline on GCP, which calls for system validation for conformity to the established requirements (ICH, 2023). The EMA has also issued a guideline on the said topic and specifically stated that sponsors should consider whether to commence a trial at the study site if its system has not been validated (EMA, 2023).

Although Hong Kong's private healthcare sector serves 29% of in-patient consultations and 57% of out-patient consultations, it only hosts 10% of all clinical trials in 2022 **(Figure 47)** (Census and Statics Department, 2021; Pharmacy and Poisons Board of Hong Kong, 2023).

In fact, private clinics rather than hospitals take up most trials in the private sector **(Figure 48)**. With government initiatives for primary healthcare and strategic purchasing from the private sector, private out-patient healthcare could become a key growth engine for Hong Kong's clinical trial development especially in chronic diseases.

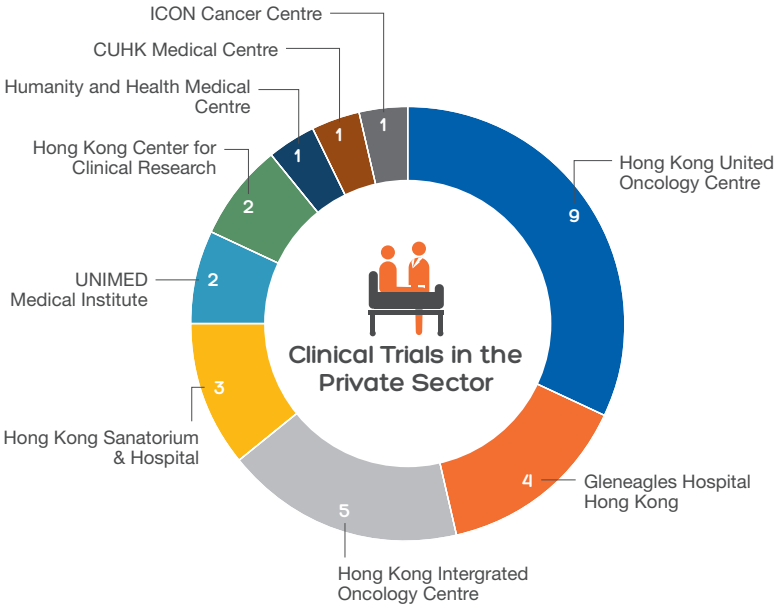
That said, as private clinics are relatively scattered, better quality control, research support, as well as assistance in patient recruitment are needed.

Figure 47. Public-Private split for in-patient and out-patient consultations



Source: Census and Statistics Department of the HKSAR Government (2021)

Figure 48. Distribution of clinical trials in the private sector in 2022 (number of study sites)



Source: Pharmacy and Poisons Board of Hong Kong (2023a)

Dr Jacky Li, a private clinical oncologist who founded the Hong Kong United Oncology Centre, has been a principal investigator in many global multi-centre clinical trials on lung cancer. Dr Li calls for the Government to lead campaigns to raise public awareness of clinical research while establishing a clinical trial database in Chinese for public access, and to introduce the private sector in cancer care within the umbrella of Hospital Authority.

Recommendation 4.1.
Promoting mutual recognition of Ethics Committee (EC) approvals

Given the similarity of HA study sites, the CRI should promote mutual recognition of EC approvals overseeing HA hospitals. Upon approval by any of the three ECs, subsequent applications to the other two should be automatically approved. Applications should be submitted to the dedicated sub-committee for phase 1 trials without the need of passing through ECs.

Within individual ECs, review processes could be accelerated by offering an expedited review pathway for applicants who have already obtained clinical trial approvals from foreign authorities.[60] Insignificant protocol alternations should be processed without requiring a resubmission. Meeting frequencies could also be increased with the help of clinician-scientists **(Recommendation 2.2, Ch.5)**.

Given the emphasis on timeliness, most regional counterparts have introduced measures to centralise EC approvals to one per study **(Figure 49, P.81)**. For instance, Malaysia has established a centralised EC for the public healthcare sector. For regions with more than one ECs, two main trends are observed: First, Australia and Singapore promoted mutual recognition between ECs, with the former having an additional certification scheme in place; Second, New Zealand, mainland China, and Taiwan promoted co-evaluation amongst ECs with clear division of labour.

Given Hong Kong's local context, mutual recognition would be the best way forward without creating unnecessary burden to regulators and applicants. In the long run, with an accreditation scheme for private ECs in place **(Recommendation 4.5)**, mutual recognition could expand to private ECs as well.

[60] The three ECs currently offer expedited review pathways for trials with protocols incurring lower risks, but by no means reliant on foreign approvals (Li Ka Shing Faculty of Medicine, HKU, 2021b; Joint CUHKNTEC CREC, 2023).

Figure 49. Common practices for centralising EC approvals

Region	Practice
Mutual recognition	
Australia	• ECs distributed among public and private healthcare institutions, with Australian Capital Territory and Northern Territory having established territory-wide committees • The National Health and Medical Research Council under the Department of Health and Aged Care introduced a National Mutual Acceptance scheme for ECs certified under the Council's National Certification Scheme
Singapore	• Two centralised ECs established within three public healthcare clusters • Six specialty boards created under each EC, one to two meetings per board per month • Mutual recognition between ECs achieved
Co-evaluation	
New Zealand	• Four district-based ECs established by the Health Research Council under the Ministry of Health • One meeting per EC per month • Joint assessment for multi-centre clinical trials
Mainland China	• ECs distributed among public and private healthcare institutions • The Central Government has formulated policies on "collaborative assessment", where the leading site's EC will first comment on the ethical and scientific aspects of the application followed by other sites' comments on site feasibility through a simplified process • The Central Government latest document in 2017 suggests that collaborating sites' EC should directly recognise the leading site's EC approval
Taiwan	• The Centre for Drug Evaluation under the Ministry of Health and Welfare introduced a process, called Collaborative IRB Review (c-IRB), where one of the seven designated ECs is assigned to conduct full-board review followed by expedited review by 36 sub-ECs in respective hospitals
One centralised EC	
Malaysia	• The National Institutes of Health under the Ministry of Health's EC oversees all government hospitals • Two meetings per month • There are exceptions with university hospitals and certain localities

Source: National Health and Medical Research Council of the Australian Government (2021b); SingHealth Group (2021a); National Healthcare Group of Singapore (2010); Health and Disability Ethics Committees of the New Zealand Government (2023); National Health and Family Planning Commission of the PRC Government (2016); PRC State Council (2017); Center for Drug Evaluation, Taiwan (2019a); Medical Research and Ethics Committee of Malaysia (2021)

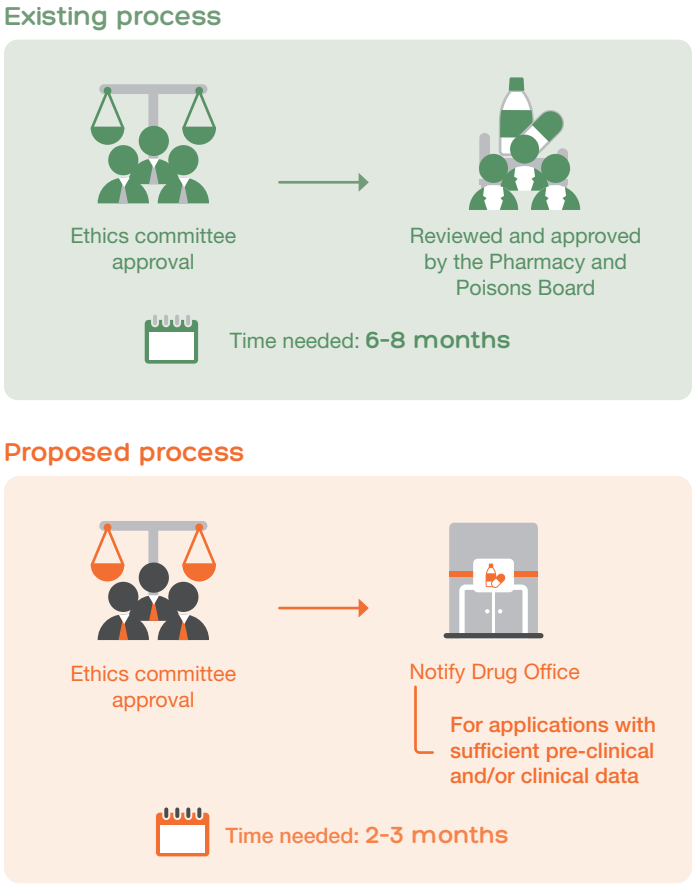
Recommendation 4.2.
Introducing a Clinical Trial Notification scheme

Progressing to CTC approval, for low-risk clinical trial applications with sufficient preclinical or clinical data, a Clinical Trial Notification (CTN) scheme should be introduced, where the Drug Office would only need to be notified upon EC approval instead of requiring the PPB to conduct an independent review **(Figure 50)**. The scheme should start with ECs overseeing HA hospitals and eventually cover private ECs upon the introduction of an accreditation scheme **(Recommendation 4.5)**.

For studies of higher risk or novel treatments, while separate reviews by ECs and the PPB should be maintained, the process should be optimised. On one hand, the PPB's scope of assessment should be limited and approval should not be reliant on EC's decision.[61] On the other hand, the PPB's committee should have more members and higher meeting frequency **(Appendix 10)**, while the proposed drug primary review authority would take on the committee's responsibility on drug registrations **(Recommendation 3.1, Ch.6)**.

Australia and Taiwan are forerunners of regulatory optimisation, having introduced the CTN.[62] While Australia relies on the sufficiency of data and the decision made by ECs, Taiwan's CTN is more reliant on foreign regulatory approval and the choice of study sites[63] **(Figure 51, P.83)**.

Figure 50. Existing and proposed approval processes for Clinical Trial Certificates for phase 1 first-in-human trials in Hong Kong

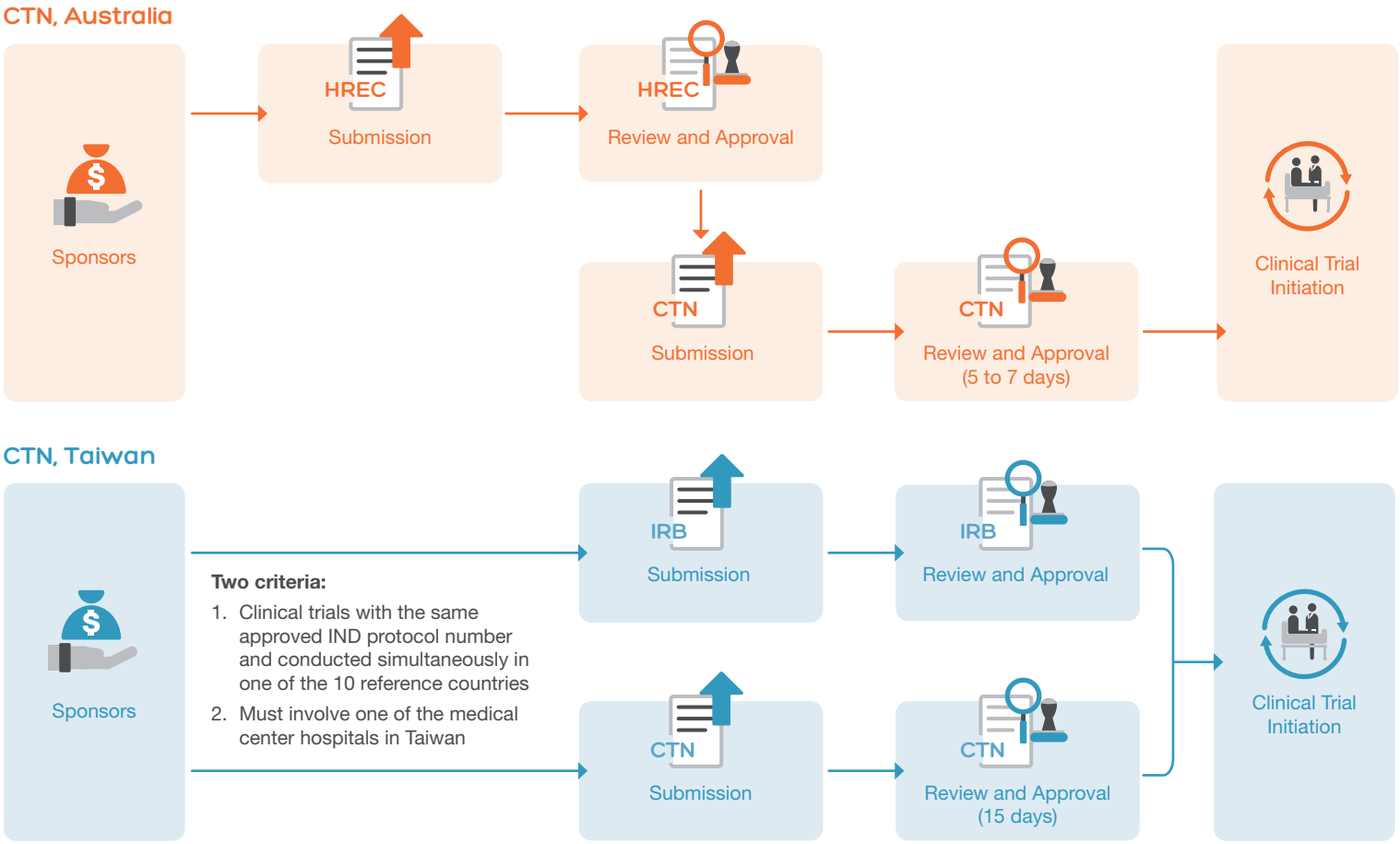


[61] The FDA states that ECs are responsible for reviewing research protocol and related materials, such as informed consent documents and investigator brochures; while the FDA's IND would cover non-clinical reports, clinical studies and Chemistry, Manufacturing, and Controls (CMC) (Davis, 2020; FDA, 2019).

[62] Singapore also has a CTN but is limited to trials of locally registered therapeutic products (HSA, 2023). The UK has introduced CTN for trials involving medicinal products authorised by a country on its approved list, but is pushing for legislative changes which may alter the eligibility for the scheme (MHRA, 2022; MHRA, 2023).

[63] In Australia, while the majority of clinical trials go through CTN, the Clinical Trial Approval (CTA) scheme is generally for high risk or novel treatments, such as gene therapy, where there is no or limited knowledge of safety. In Taiwan, around half of the clinical trials go through CTN (Centre for Drug Evaluation, Taiwan, n.d.).

Figure 51. Clinical Trial Notification schemes in Australia and Taiwan



Note: Human Research Ethics Committees (HREC)
Source: Australia Therapeutic Goods Administration (2022); Center for Drug Evaluation, Taiwan (2019b)

Recommendation 4.3. Standardising and facilitating Clinical Trial Agreement settlement

The CRI Service Centre should conduct a global review of common practices by leading pharmaceutical companies and CROs to assist the HA in optimising legal terms for the master templates. The master agreements should also be open for future revisions.

The Centre should also offer standardised schedule terms and pricing tools. Global practices should be referenced, for instance, sponsors should be entitled to purchase comparator drugs from the HA for clinical trial purpose, especially when they fulfill patients' standard-of-care. The CRI should coordinate with the HA in advance for pre-approved use of the templates.

Most importantly, the CRI Service Centre should facilitate the CTA negotiation process between sponsors and the HA by serving as the intermediary between sponsors, the HA's legal department, and different hospitals' administrative departments. The process should begin simultaneously with EC review.

Leading economies have not only standardised legal terms for CTAs but also schedule terms and pricing tools **(Figure 52, P.85)**, Taking Clinical Research Malaysia (CRM) as an example, it has launched a digital CTA application system followed by briefing sponsors and CROs' staff on its usage. As a result, its CTA review timeline has significantly shortened from 58 days in 2012 to 13 days in 2017 (CRM, 2020).

With the above improvements in place, it is expected that the EC, regulatory and CTA review processes will be streamlined. Details of the proposed start up processes are presented in **Appendix 10**.

Figure 52. Standardisation of contract terms and pricing tools in leading economies

Region	Institution	Process of template standardisation
 Singapore	Singapore Clinical Research Institute (SCRI)	• Developed upon discussions among public healthcare clusters and the Singapore Association of Pharmaceutical Industries (SAPI) • Pre-approved for use in public healthcare institutions
 Malaysia	Clinical Research Malaysia (CRM)	• Developed in conjunction with Ministry of Health officials and IQVIA • Pre-approved for use in all healthcare institutions
 Australia	The Southern and Eastern Border States Panel, and Medicines Australia	• Co-developed agreements • Accepts requests for and reviews changes in templates, and issues approval letters for sponsors to circulate to study sites, easing up on sponsors by providing only one negotiator • Pre-approved for use in public healthcare institutions
 New Zealand	New Zealand Association of Clinical Research (NZACRes)	• Agreements consulted with the New Zealand clinical research industry • Pre-approved for use in public healthcare institutions
 UK	Integrated Research Application System (IRAS)	• Developed by the Department of Health and Social Care (DHSC) and the Association of the British Pharmaceutical Industry (ABPI) • Updated with representatives from the NIHR, NHS, Medical Research Council, DHSC, ABPI since inception • Pre-approved for use in public healthcare institutions

Source: Singapore Clinical Research Institute (2023b); Clinical Research Malaysia (2020); Medicines Australia (2023); New Zealand Association of Clinical Research (NZACRes) (2023); Integrated Research Application System (IRAS) (2023)

Recommendation 4.4.
Building a comprehensive trial registry and allowing targeted access to the HA's patient database

Clinical trial registry: The CRI should build a clinical trial database capturing all trials conducted in Hong Kong, including information such as disease area, inclusion/exclusion criteria and participating sites' contact information. The registry should be bilingual and has a user-friendly design to allow patients to access and leave their details.

Patient database: The HA's patient database offers valuable resources for patient referral. The following steps should be taken **(Figure 53, P.87)**:

1. Validate the CMS in line with major regulatory authorities;
2. Build a platform for external parties, including sponsors and regulatory bodies, to access trial data and medical records of trial subjects;
3. Allow CRI to access CMS and eHealth's patient details.

Firstly, the HA should conduct a thorough validation of the CMS for data compliance as leading drug regulatory authorities including the FDA and the EMA have issued guidance on computerised systems adopted in clinical trials.[64]

Secondly, access to trial subject's information should be granted to external parties including sponsor representatives and regulatory inspectors. As it is not feasible to open up the entire CMS due to privacy concerns, a dedicated platform should be built either through a new research module within the CMS or other existing platforms such as the eHealth.

The eHealth currently contains some patient information from HA's CMS upon patients' opt-in, and allows access by authorised healthcare professionals. A research-specific interface can be developed to sync trial subjects' information on an anonymous basis, allowing access by designated external parties.

Lastly, as the CRI Service Centre would be responsible for both study feasibility assessment and patient recruitment, it should be allowed to access HA's CMS and e-Health. Upon requests by sponsors and investigators, the Centre could assess the disease prevalence and patient distribution, and contact suitable patients respectively. Similar to Clinical Research Malaysia, while complementary feasibility assessment services could be provided, patient referral services should be provided for a charge.

The Korea National Enterprise for Clinical Trials (KoNECT) is a successful example in leveraging patient databases. KoNECT, a non-profit organisation funded by the Ministry of Health and Welfare, provides sponsors with information on study feasibility including (i) disease epidemiology data based on literature review, (ii) national health insurance claims data derived from the National Health Insurance Review and Assessment database, and (iii) integrated information of electronic medical records by healthcare partners **(Figure 54, P.87)** (KoNECT, n.d.).

[64] The FDA's instructions cover areas such as source documentation and retention, internal and external security safeguards, etc.; The EMA's instructions cover areas such as computerised systems, electronic data, user management, security, etc (FDA, 2007; EMA, 2023).

Figure 53. Proposed digitalisation measures for Hong Kong's clinical trial development

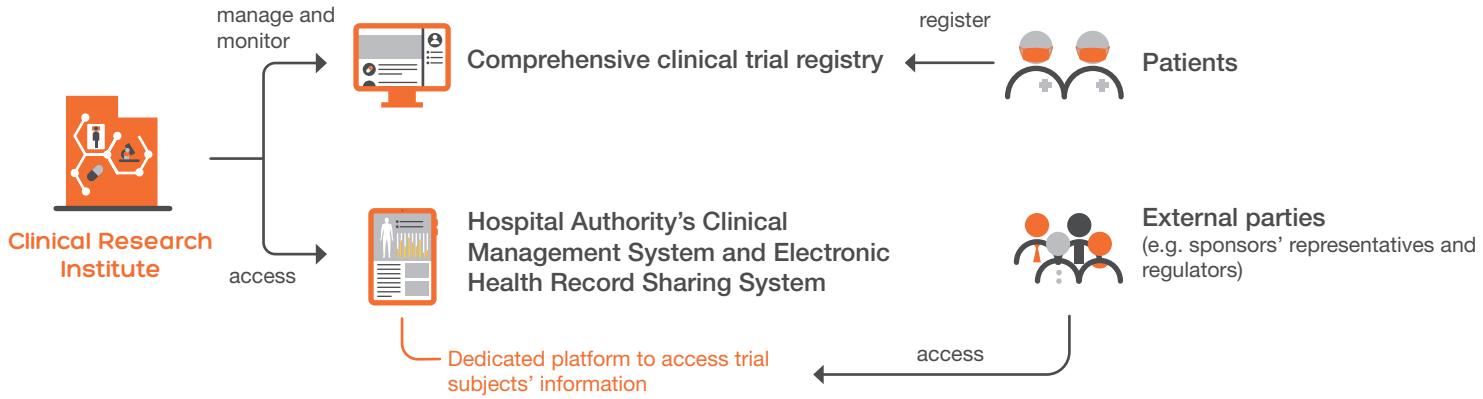
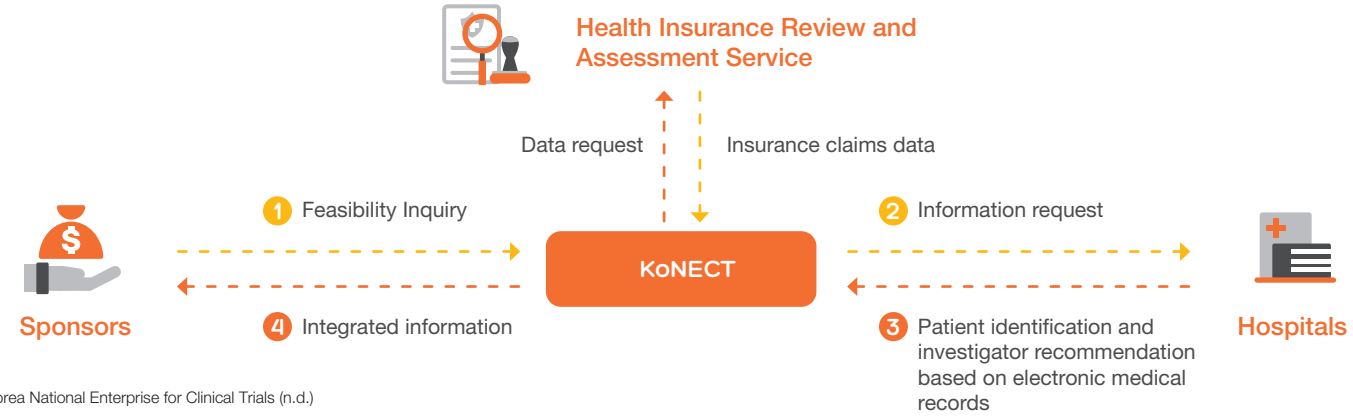


Figure 54. KoNECT's feasibility assessment services based on electronic medical records



Source: Korea National Enterprise for Clinical Trials (n.d.)

Recommendation 4.5.
Supporting the private clinical trials sector through quality assurance of ECs and capability building

To strengthen Hong Kong's private clinical trials sector, measures should be taken to ensure and enhance its trial quality and capability **(Figure 55, P.89)**.

Accreditation scheme for private ECs: An accreditation scheme should be introduced for quality assurance of private ECs, paving way for mutual recognition of ECs in Hong Kong **(Recommendation 4.1)** and their inclusion into the CTN scheme **(Recommendation 4.2)**.

To facilitate EC mutual recognition and the CTN scheme, Australia has on one hand introduced a National Certification Scheme for ECs' mutual recognition, and on the other hand, only ECs registered with the government could refer trials to the CTN scheme (TGA, 2022; TGA, 2021). For Singapore and Taiwan which have EC mutual recognition and CTN respectively, the ECs involved have been designated.[65]

EC certification is in fact a global practice. The SIDCER-FERCAP Foundation, a non-governmental organisation founded by the World Health Organization to promote and harmonise research ethics review, has also introduced a SIDCER Recognition Program to assess and recognise the quality of ECs (SIDCER-FERCAP Foundation, n.d.).

Obviously, only well-developed private ECs should be accredited. Australia's Bellberry Limited is a renowned private EC accredited by the National Certification Scheme: It is a national, private non-profit organisation providing scientific and ethical review of human research projects across Australia, with 12 committees of over 100 members running up to three meetings per week (Bellberry Limited, n.d.). Most importantly, it sustains through charging applicants study review fees and committee members are remunerated. It has reviewed more than 1,000 studies since establishment by offering a short turnaround time of around 20 days (Bellberry Limited, n.d.). Meanwhile, as Hong Kong's private ECs are scattered and not commercially-run, there exists a need to better institutionalise and optimise their operations.

CRI site management services for the private sector: The proposed CRI Service Centre should provide charged site management services to the private sector, building its capability with well-trained research support staff.

Clinical Research Malaysia (CRM), for example, offers site management services not only for Ministry of Health hospitals, but also private healthcare institutions such as Gleneagles Hospital Malaysia, International Specialist Eye Centre, and Island Hospital Penang. This enabled around 20% of Malaysia's clinical trials to take place in private sites (CRM, 2022).

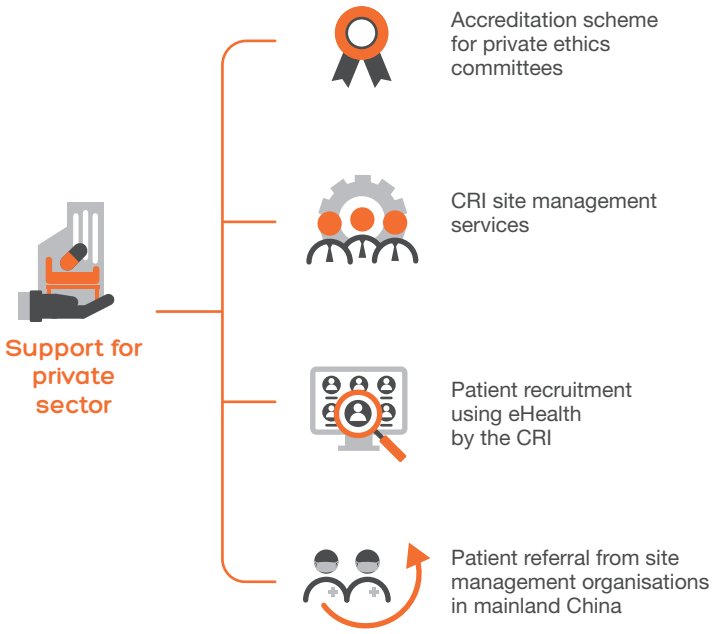
[65] Singapore's mutual recognition between ECs is only limited to the two centralised ECs under the three public healthcare clusters. Taiwan's CTN must involve ECs of the 26 medical centre hospitals (Centre for Drug Evaluation, Taiwan, n.d.).

Patient recruitment using eHealth: The Service Centre should also facilitate patient referral between public and private sectors. As the Centre's staff would have access to both the HA's CMS and eHealth **(Recommendation 4.4)**, they could look for suitable patients for studies in private sites and vice versa.

Connecting with Site Management Organisations (SMOs) in the mainland for patient referral: A stable supply of trial subjects is crucial for the development of the private clinical trials sector. The CRI should connect with SMOs in mainland China for patient recruitment when there are not enough suitable patients.[66]

Hong Kong's development into a clinical innovation hub can be accelerated with faster trial start-up and patient recruitment processes. Despite the straightforwardness of these operational solutions, a strong political will is needed to bring together different parties and enforce these changes.

Figure 55. Proposed measures to strengthen Hong Kong's private clinical trials sector



[66] Renowned SMOs in the mainland include Wuxi Yaomingjinshi Pharmaceutical Technology Co., SMO ClinPlus Co., Pharmaron LinkStart SMO, and Tigermed Hangzhou Simo, all covering more than 150 cities in China and managing around 1000 hospitals.

8

Recommendation 5.

Addressing Infrastructure and Skill Gaps to Foster Clinical Trial Activities

Clinical trials attract a variety of value-added R&D activities. Conversely, the availability and proximity of these activities accelerate the development of clinical trials. However, there are important gaps yet to be filled.

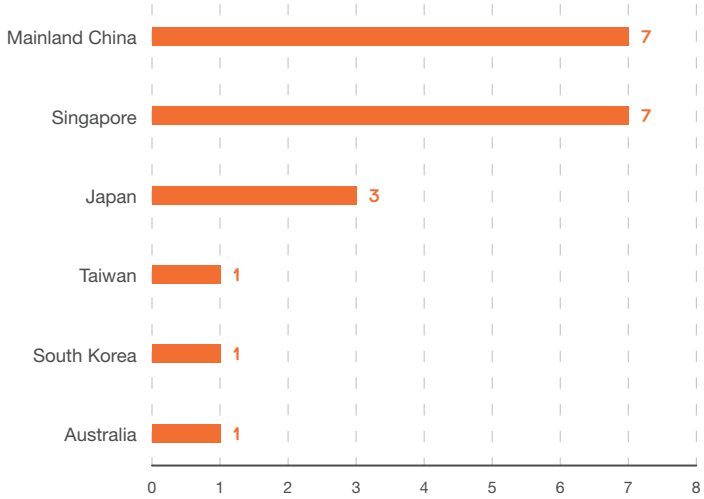
Firstly, Hong Kong does not have any commercial central laboratories for sample handing and data analysis after clinical trials conclude.[67] Despite the rapid expansion of central laboratories in Asia Pacific,[68] Hong Kong has failed to grasp the business opportunities as compared with mainland China and Singapore **(Figure 56, P.91)**.

[67] Besides non-accredited research laboratories in universities for investigator-initiated trials, and clinical laboratories in hospitals, there are laboratories only for pharmacokinetics in the two clinical trials centres in Hong Kong. All of them are however far from large scale central laboratories.

[68] The CAGR of Asia Pacific's central laboratory market size in 2023–2030 is 7.8%, surpassing the global rate of 6.5% (Grandview Research, 2018).

With advanced biotech ecosystems, both mainland China and Singapore have successfully attracted CROs to set up central laboratories in town. While both have introduced favourable industrial policies including tax and land incentives, the development in mainland China is partly attributed to export restrictions on biological samples. Mainland China has also achieved considerable success in nurturing home-grown companies **(Figure 57)**.

Figure 56. Number of central laboratory service providers registered with the ICH's Good Clinical Practice Network



Source: ICH Good Clinical Practice Network (n.d.)

Figure 57. Companies providing central laboratory services in mainland China and Singapore

Region	Companies in common	Region-specific
Mainland China	Eurofins Central Laboratory, ICON Central Laboratories, LabCorp Central Laboratory Services, PPD Laboratories Central Lab, Q2 Solutions	Cerba Research, Frontage Laboratories
Singapore		ACM Global Laboratories, Medpace

Source: ICH Good Clinical Practice Network (n.d.), etc.

Secondly, Hong Kong lacks manufacturing facilities which conform with Good Manufacturing Practice (GMP) with trained personnel to produce pilot batches of trial drugs.[69] These facilities are usually set up by pharmaceutical companies and Contract Development and Manufacturing Organisations (CDMOs). Hong Kong has not been able to ride on the rapid expansion of the CDMO market in Asia Pacific,[70] and is far behind mainland China and Singapore.[71]

Hong Kong also needs to catch up with the advancement of new fields of medicine, such as cell and gene therapy, by catering to their specific manufacturing processes. To date, HKSTP has established collaborations with HKU and CUHK to build the first two PIC/S GMP pilot facilities, and to provide manufacturing service for advanced therapy medicinal products. These facilities also provide theoretical and practical training to develop "key personnels" as required by the Hong Kong Drug Office.[72]

Fueled by the development of its biotech ecosystem and cross-border flow of bio-samples to the Lok Ma Chau Loop **(Recommendation 3.4, Ch.6)**, Hong Kong should introduce competitive tax and land measures to attract investments in the above infrastructure and establish laboratories and manufacturing facilities to fulfill demands. As regional counterparts race to attract biotech investments **(Appendix 11)**, there is no way for Hong Kong to be complacent.

[69] There are 23 biotech and pharmaceutical manufacturing facilities in the three INNOPARKs in Hong Kong, accounting for 14.5% of all industries. When limited to biomedical manufacturing facilities (subtracting supplements, traditional Chinese medicine, and biotech not for medical purposes), there are only 8 manufacturing facilities accounting for 5% of the total. Besides, they mainly produce generic products rather than novel drugs.

[70] The CAGR of Asia Pacific's active pharmaceutical ingredients CDMO market size in 2021–2028 is 8.9%, surpassing the global rate of 6.7% (Grandview Research, 2018).

[71] A survey with relevant respondents from 33 countries shows that mainland China, India, and Singapore are the top regions in Asia they would outsource their pharmaceutical production (Garguilo, 2020).

[72] The Hong Kong Drug Office issued a guidance on the requirement of "key personnel" for pharmaceutical manufacturers, including various authorised persons and heads of production and heads of quality control (Drug Office, Department of Health of the HKSAR Government, 2019).

Recommendation 5.1. Offering tax and land incentives to attract clinical trials and related R&D activities

While Hong Kong's newly established Office for Attracting Strategic Enterprises (OASES) should actively engage with leading pharmaceutical companies, CROs and CDMOs, the Government should offer attractive tax and land incentives to attract investments in clinical trials, central laboratories and pilot manufacturing plants.

Despite having introduced the Enhanced Tax Deduction for R&D Expenditures scheme in 2017,[73] regional counterparts have been far more aggressive **(Appendix 12)**. For example, Australia has provided tax credits for R&D expenditure by rebating the corporate tax rate plus a premium (Australian Taxation Office, 2022). The tax credit is refundable for smaller companies, meaning that they can claim more than their tax burden, giving financial incentives to startups which have not yet turned a profit (Australian Taxation Office, 2022). Similarly, the UK's R&D tax relief also provides large companies with a tax credit; yet their tax credit for small and medium-size companies only applies to loss-making applicants (HM Revenue and Customs of the UK Government, 2023).

To attract R&D investments, regional counterparts have been providing tax-free schemes and lower tax rates for technology companies. Singapore is renowned for its accommodating tax incentives: companies establishing international headquarters in Singapore can apply for tax exemption or reduced tax rates on qualifying income, depending on their level of economic commitment; companies undergoing high quality R&D activities can also enjoy tax exemption for 5 to 15 years for each qualifying project or activity **(Figure 58, P.94)** (PricewaterhouseCoopers, 2023).

In mainland China, reduced tax rates are offered for technology sectors (State Taxation Administration of the PRC Government, 2004). Israel also offers reduced tax rates for technology companies depending on their venture financing ability, revenue growth, and company expansion plans (PricewaterhouseCoopers, 2023).

[73] Companies can enjoy a 300% tax deduction for the first HKD 2 million paid to designated local research institutions for qualifying R&D activities and qualifying expenditures incurred, and 200% for the remaining amount (ITC, 2022).

Figure 58. Tax-free schemes and reduced tax rates for R&D investments in selected economies

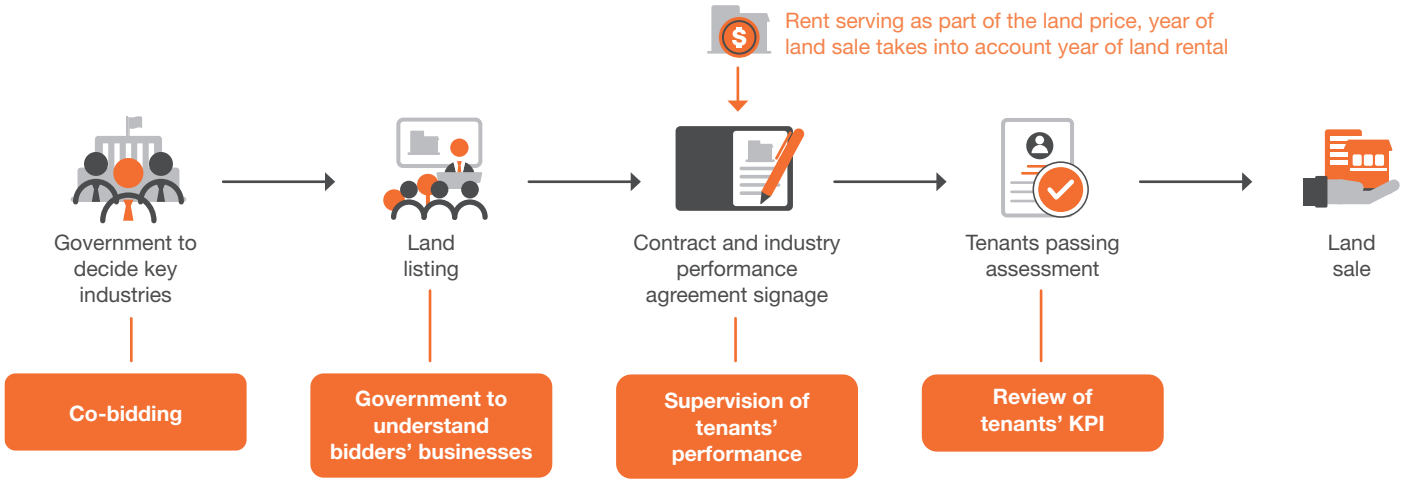
Region	Profits tax rate	Tax-free schemes and reduced tax rates
 **Hong Kong**	**8.25%–16.5%**	• Not available
 **Singapore**	**17%**	• Tax exemption or reduced tax rates on qualifying income for companies establishing headquarters in Singapore, depending on their level of economic commitments • Tax exemption for 5 to 15 years for each qualifying project or activity for companies undergoing activities with high technological content under the pioneer tax incentive • Reduced tax rate of not less than 5% for companies developing or expanding their business
 **Mainland China**	**20%–25%**	• Reduced tax rate of 15% for all highly innovative technology companies • Reduced tax rates for specific technology industries, e.g. 12.5% for software and integrated circuit companies
 **Israel**	**23%**	• Reduced tax rates of 7.5–16% for qualified technology companies with additional criteria, such as securing venture capital financing of at least ILS 8 million, revenue growth of 25%, company expansion of 25% • Reduced tax rates of 7.5–16% for specific technology industries, such as biotechnology, nano-technology, semiconductors, software, and manufacturing

Source: PricewaterhouseCoopers (2023); State Taxation Administration of the PRC Government (2021), etc.

Besides offering R&D units and multi-storey industrial space, flexible land policies are also needed to attract R&D activities as they require huge amounts of space. Upon the *Northern Metropolis Development Strategy* rolled out in 2021, the San Tin Technopole, including the Lok Ma Chau Loop, will be a focal point for these activities. To fulfil companies' land demand and to accelerate land development while ensuring occupiers' business performance, innovative land policies should be offered, including land rental, land sale, and even a combination of both rental and sale.

In Shenzhen's Longgang District, the government would rent out industrial land to companies of key industries and supervise their business performance. The land would become available for sale if they pass assessment. In a similar vein, the Hong Kong Government should allocate land for central laboratories and pilot-batch manufacturing with tailor-made terms and supervision in place **(Figure 59)**.

Figure 59. Land rent-and-sale model adopted in Shenzhen's Longgang District



Source: Longgang District People's Government of Shenzhen (2023)

Recommendation 5.2.
Gearing up research infrastructure and expertise through laboratories and manufacturing facilities

Besides attracting investments, it is critical for the Government to provide solutions and trainings for the development of new modalities such as advanced therapy products, vaccines, and biologics. Laboratories and manufacturing facilities should be set up to provide infrastructure, talent, and industry solutions. The UK, Singapore, and Canada offer relevant references for Hong Kong **(Figure 60, P.97)**.

The UK's Cell and Gene Therapy Catapult is a financially independent laboratory founded by the national funding agency UK Research and Innovation. It offers charged solutions for collaborators on the advancement of cell and gene therapies across the entire product development chain (Cell and Gene Therapy Catapult, 2023). Similarly, Singapore's Bioprocessing Technology Institute (BTI), under the Agency for Science, Technology and Research (A*STAR) of the Ministry of Trade and Industry, offers partnerships and a range of bioprocessing technology advancement services (A*STAR, 2022).

The manufacturing of vaccines and biologics is often safeguarded by government-funded plants to ensure access during times of emergencies and to advance innovation. Canada's Biologics Manufacturing Centre (BMC) is a not-for-profit end-to-end biomanufacturing facility jointly founded by the National Research Council and the Centre for Commercialization of Regenerative Medicine in 2022, tasked to manufacture vaccines and other biologics (Government of Canada, 2023b).

The development of laboratories and manufacturing facilities in the said niche areas would fill the technical gaps and meet local needs. While providing funding support through the New Industrialisation Acceleration Scheme as announced in the 2023 *Policy Address*, the Government can consider targeting CDMOs in order to bring in product innovation expertise and facilitate talent development.

Figure 60. Initiatives for the development of new modalities

Region	Initiatives	Services	Impact
 UK	**Cell and Gene Therapy Catapult**	• Provides solutions for advanced therapy medicinal products process, early-stage development, manufacturing innovation, NHS readiness, health economics and market access, and regulatory affairs and non-clinical studies • Offers apprenticeships and training for talent in advanced therapies	• 132 projects • 23 companies supported to conduct clinical trials • 5,000 talent trained • GBP 1.3 billion in financing raised by UK collaborators
 Singapore	**Bioprocessing Technology Institute**	• Provides solutions for product innovation, cell line development, media development, downstream processing, process development and scale-up, and analytical science and technologies • Offers training and post-graduate programmes by A*STAR Graduate Academy	• Entered into agreement with WuXi Advanced Therapies to advance cell and gene therapy production in Asia-Pacific • Co-produced the first made-in-Singapore drug targeting cancer cells (EBD-129) that cleared the FDA for clinical development
 Canada	**Biologics Manufacturing Centre**	• Possesses pilot-scale and clinical-scale manufacturing capabilities, analytical and process development labs, and quality control systems	N/A

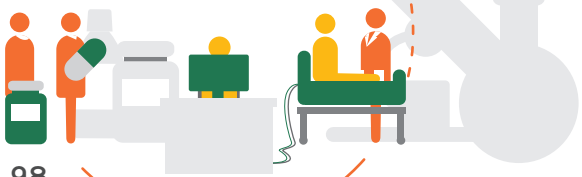
Source: Cell and Gene Therapy Catapult (2023); Agency for Science, Technology and Research (2022); Government of Canada (2023b)

9

Conclusion

Hong Kong has clear potential to become Asia's leading clinical innovation hub. This report has put together five policy recommendations to overcome challenges such as insufficient hospital capacity, lack of regulatory pathway, long clinical trial start-up time, and insufficient landing support. By institutionalising strategic facilitation by the Health Bureau and building a talent development strategy for clinical research personnel, it is hoped that clinical research activities can be supported at each and every stage of the value chain; by establishing a primary review authority, accelerating start-up time and improving trial attractiveness, Hong Kong would be better positioned to attract clinical research activities and become a leader in the biotech industry.

With concerted efforts for policy changes, Hong Kong can achieve its goal of becoming a global biotech hub; the industry would contribute to economic development for years to come.



Government

Ch.4 Oversight and coordination by an overarching body

Talent

Ch.5 Talent development strategy

Business

Ch.6 Drug regulatory system enhancement

+

Ch.7 Clinical operation optimisation

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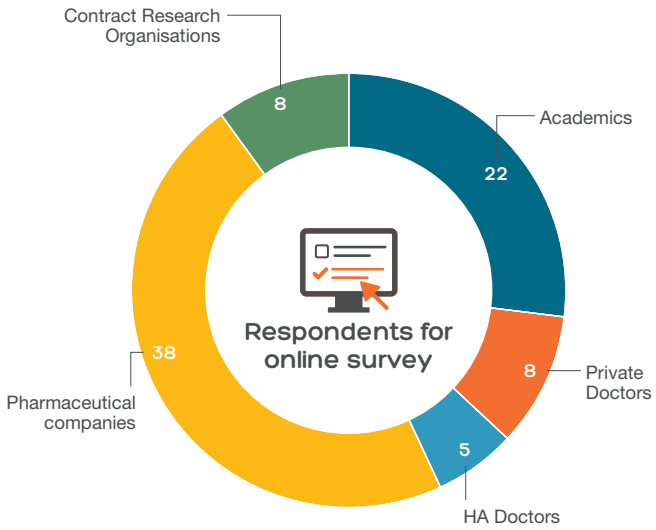
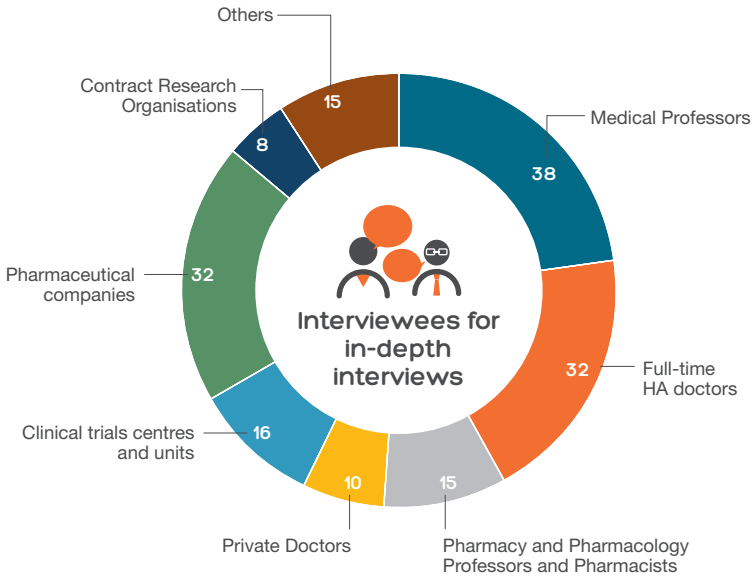
Ch.8 Landing and infrastructural support

Appendices

Appendix 1. Breakdown of respondents for online survey (n=81)

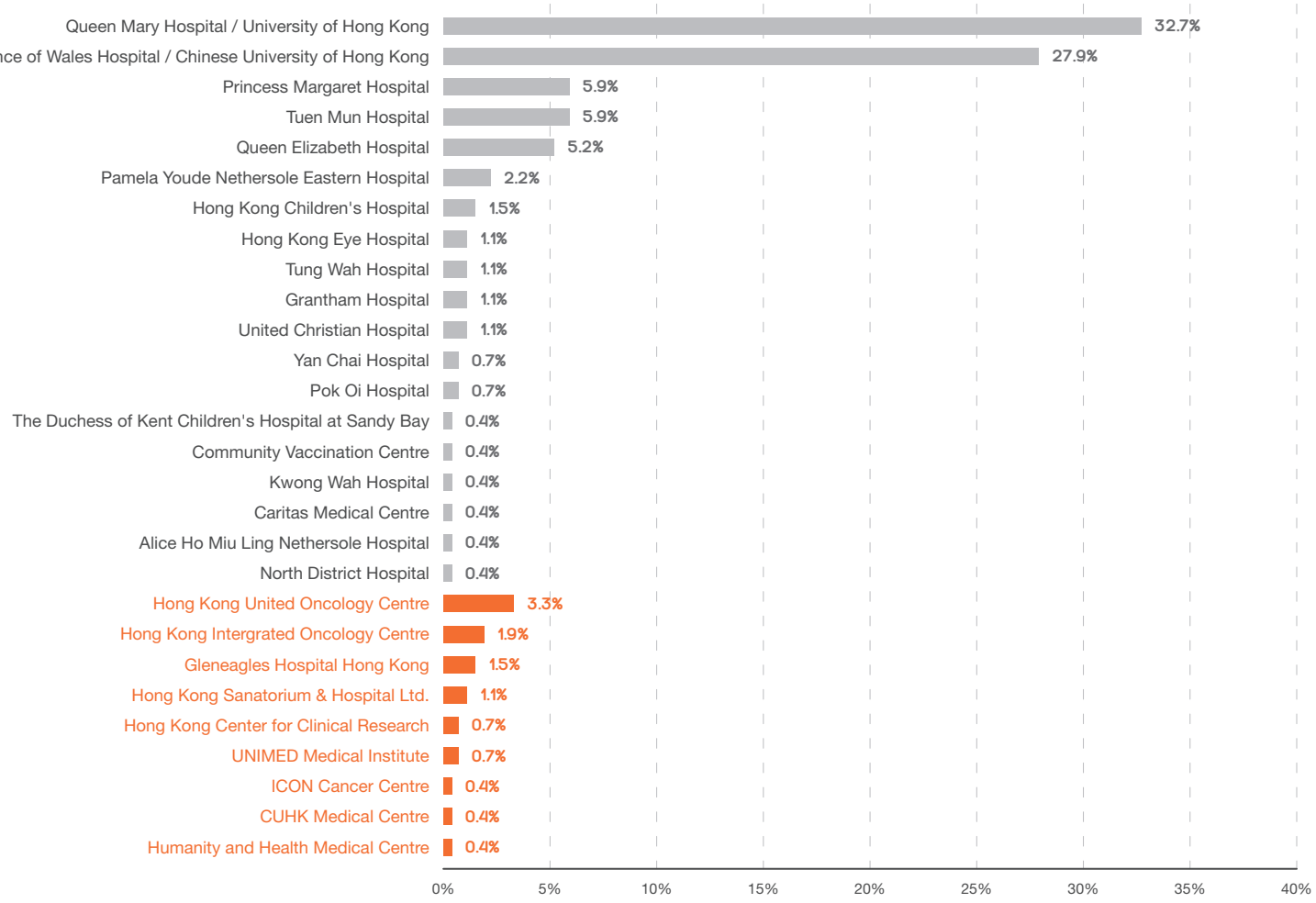


Appendix 2. Breakdown of interviewees for in-depth interviews (n=166)



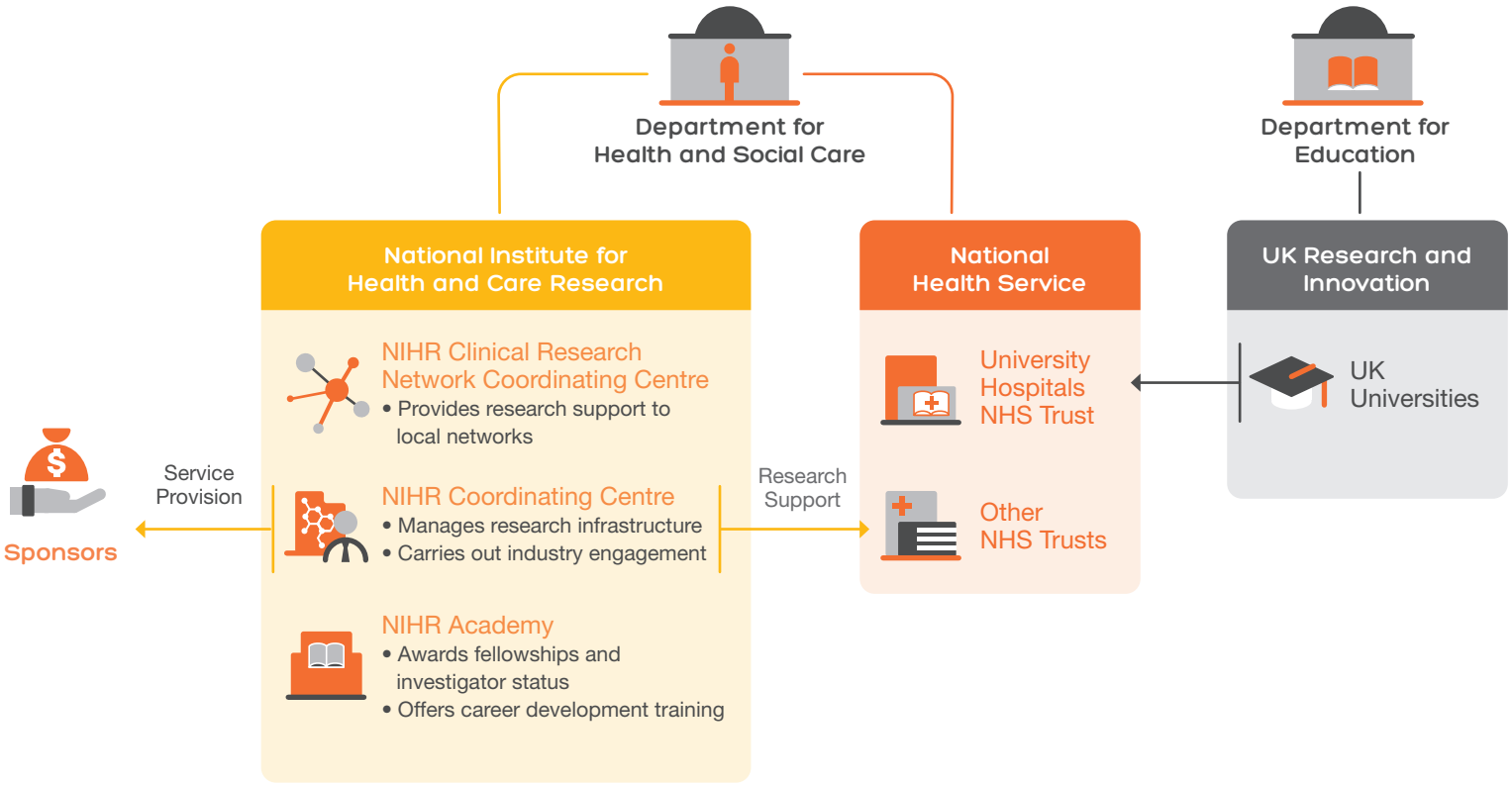
Note: When a stakeholder represents more than one sector, his/her primary affiliation forms the basis for categorisation as above.

Appendix 3. Study site breakdown (n=269) of Clinical Trials / Medicinal Tests in 2022



Source: Pharmacy and Poisons Board of Hong Kong (2023a)

Appendix 4. Relationship of the UK's National Institute for Health and Care Research and other parties



Source: National Institute for Health and Care Research (2023)

Appendix 5. Examples of Clinical Research Networks

Platform	Networks and Features
Singapore Clinical Research Institute (SCRI)	SCRI has established several networks specialised in selected areas of research such as oncology, tuberculosis and infectious disease, and developmental pathways and lymphoma studies: • SCRI collates renowned investigators under research networks, then offers research funding for investigator-initiated studies driven within each network • Networks collaborate with pharmaceutical companies for sponsored trials • Governed by a joint management committee consisting of member institutions not only from Singapore but also other regions
US National Institutes of Health (NIH)	Different institutes have established networks for specific research areas: • The NIH Rare Diseases Clinical Research Network enhances investigator-driven clinical research for more than 280 rare diseases by aggregating interdisciplinary clinician-scientists, research support staff, data providers, and funding • The National Heart, Lung, and Blood Institute's Clinical Research Networks and Multicentre Clinical Studies feature a "clinical research skills development core" to facilitate new investigators' mentoring from senior investigators, with up to USD100,000 per year to cover training costs • The National Institute of Neurological Disorders and Stroke features several Clinical Networks, and all of them have a "clinical coordinating centre" to provide protocol development, a "data coordinating centre" to handle data management, and specialised clinical centres as sites for research, all occupied by academic units or hospitals

Source: Singapore Clinical Research Institute (2023a), U.S. Rare Diseases Clinical Research Network (n.d.), U.S. National Heart, Lung, and Blood Institute (2010), U.S. National Institute of Neurological Disorders and Stroke (n.d.)

Appendix 6. Clinical Research Malaysia's Clinical Research Coordinator training and certification programmes

Career ladder	Courses required	Course features
Senior Clinical Operation Manager	• Foreign exchanges • ESMO Asia Congress • ASCO conferences	• Exposure to advanced international trial protocols
Clinical Operation Manager and Associate Regional Manager	• Protocol compliance • Preparation for regulatory inspection • GCP refresher	• Project management skills and the ability to coordinate more complex industry-sponsored trials
Senior Study Coordinator and Study Coordinator Level 1–Level 2	• Protocol compliance • Patient recruitment and retention • Preparation for regulatory inspection • GCP refresher	• On-site operations of clinical trials from protocol feasibility to study start-up, regulatory adherence, recruitment, and interpreting protocols

Source: Clinical Research Malaysia (2022)

Appendix 7. Multilateral agreements on drug regulatory harmonisation

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	• Initiated in 1990 as an international non-profit association in Switzerland • Aims to achieve greater harmonisation worldwide to ensure that safe, effective, and high-quality medicines are registered in the most resource-efficient manner through the development of ICH Guidelines • Regulatory Members include: 1. European Commission, 2. U.S. Food and Drug Administration (FDA), 3. Japan's Pharmaceuticals and Medical Devices Agency (PMDA), 4. Health Canada (HC), 5. Switzerland Swissmedic, 6. Brazil's National Health Surveillance Agency (ANVISA), 7. Mexico Health Authority (COFEPRIS), 8. Singapore Health Sciences Authority (HSA), 9. South Korea's Ministry of Food and Drug Safety (MFDS), 10. United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA), 11. China's National Medical Products Administration (NMPA), 12. Saudi Food and Drug Authority (SFDA), 13. Taiwan Food and Drug Administration (TFDA), 14. Turkish Medicines and Medical Devices Agency (TMMDA)
The Project ORBIS	• Initiated by the FDA Oncology Center of Excellence (OCE) in May 2019 • Aims to provide a framework for concurrent submission and review of oncology products among international partners • Partners include: 1. Australian Therapeutics Goods Administration (TGA), 2. Brazil's National Health Surveillance Agency (ANVISA), 3. Health Canada (HC), 4. Israel Ministry of Health (IMoH) Pharmaceutical Administration, 5. Singapore Health Sciences Authority (HSA), 6. Switzerland Swissmedic, 7. United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) • As of 17 March 2023, Project Orbis partners have conducted 73 approvals
The ACCESS Consortium	• Initiated in 2007 as a coalition of medium-sized regulatory authorities • Aims to promote greater regulatory collaboration and alignment of regulatory requirements • Partners include: 1. Australian Therapeutics Goods Administration (TGA), 2. Health Canada (HC), 3. Singapore Health Sciences Authority (HSA), 4. Switzerland Swissmedic, 5. United Kingdom Medicines and Healthcare Products Regulatory Agency (UK MHRA)

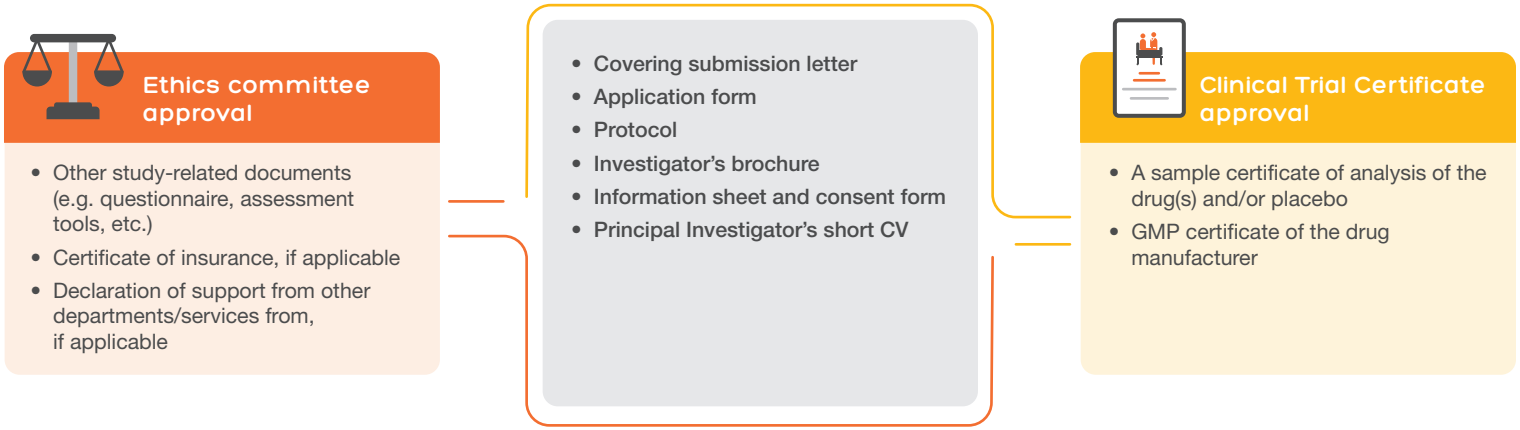
Source: International Council for Harmonisation (2023), Food and Drug Administration (2023), Government of Canada (2023a)

Appendix 8. Existing and proposed joint funding schemes between Hong Kong and the mainland

Scheme	Administering bodies	Eligibility	Purpose
National Natural Science Foundation of China/ Research Grants Council (NSFC/RGC) Joint Research Scheme	RGC and National Natural Science Foundation of China	**HK:** Full-time university academics **Mainland:** Full-time university academics	Supports research proposals jointly submitted by the mainland and Hong Kong academics
Mainland-Hong Kong Joint Funding Scheme (MHKJFS)	ITC and PRC Ministry of Science and Technology	**HK:** Universities, R&D centres, companies, and others **Mainland:** Universities, R&D centres, companies	Supports platform and collaborative R&D projects with an element of Hong Kong and mainland cooperation
Guangdong-Hong Kong Technology Cooperation Funding Scheme (TCFS)	ITC, Department of Science and Technology of Guangdong Province, and Shenzhen Science and Technology Innovation Commission	**HK:** Universities, R&D centres, companies, and others **Guangdong/Shenzhen:** Universities, R&D centres, companies, healthcare institutions	
Health and Medical Research Joint Funding Scheme (Proposed)	CRI and Health Commission of Guangdong Province	**HK:** Healthcare or healthcare-related professionals **Guangdong:** Mid-level healthcare professionals	Supports health and medical research jointly conducted by Hong Kong and Guangdong researchers

Source: Innovation and Technology Commission (2023); Shenzhen Science and Technology Innovation Commission (2020); Department of Science and Technology of Guangdong Province (2021); PRC Ministry of Science and Technology (2021), Health Commission of Guangdong Province (2023)

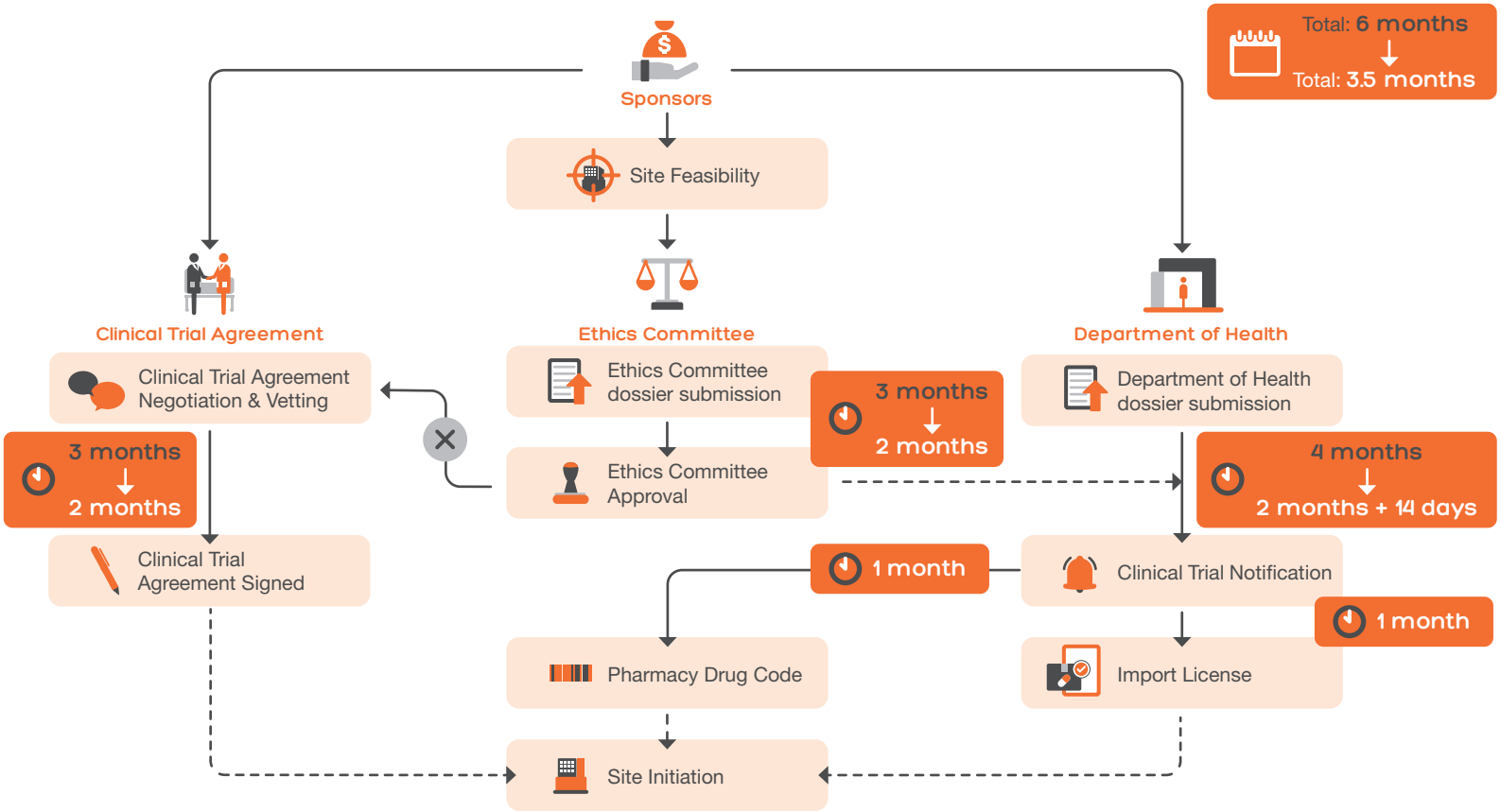
Appendix 9. Dossier requirements for ethics committee approval and Clinical Trial Certificate



Source: Li Ka Shing Faculty of Medicine, HKU (2021), Joint CUHKNTEC CREC (2023), Pharmacy and Poisons Board (2023)

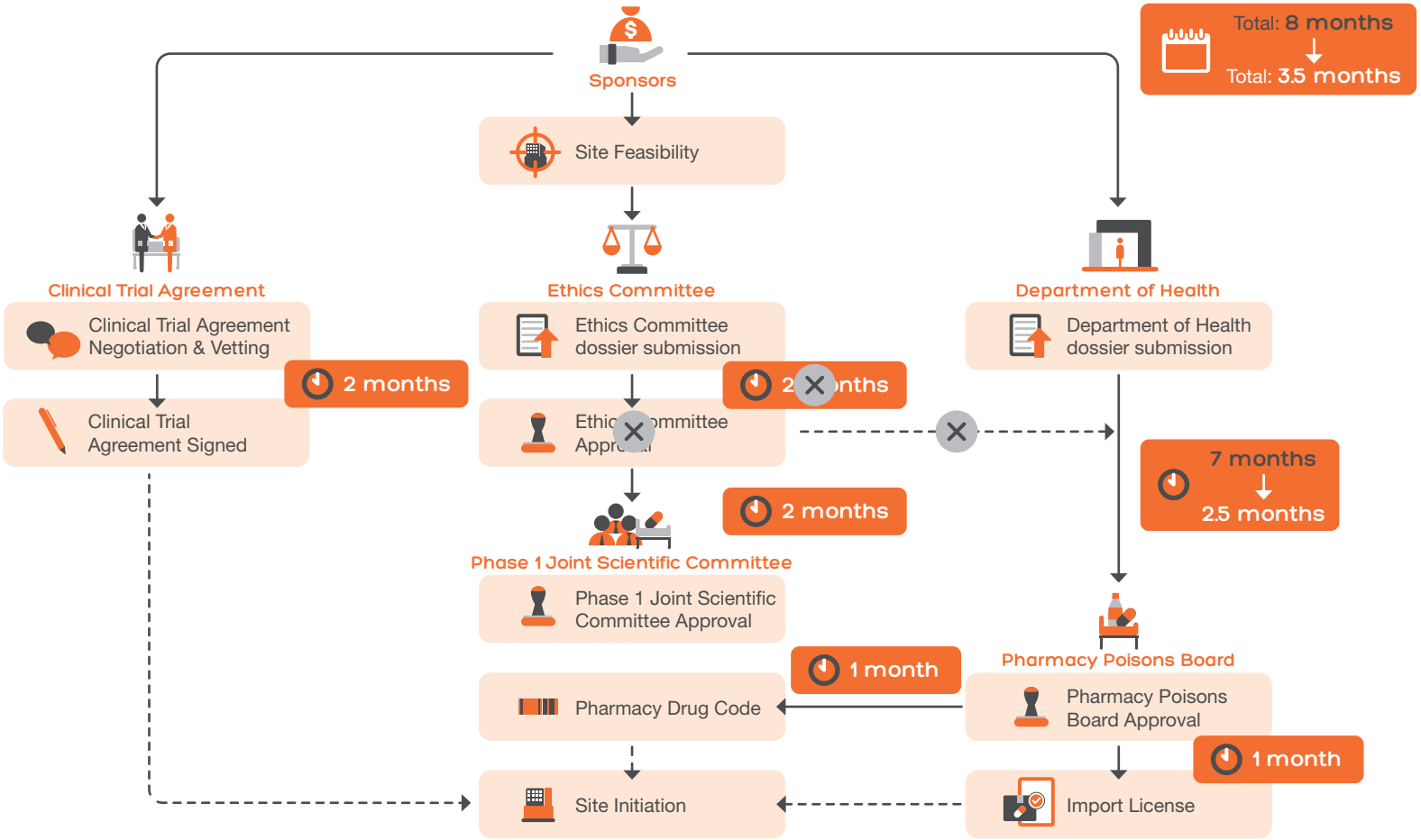
Appendix 10. Existing and proposed start up process for clinical trials

Start up process for late phase clinical trials in non-teaching hospitals



Note: Start-up processes for late phase clinical trials in the two public teaching hospitals have similar flows, but clinical trial agreement negotiation and vetting take place in parallel with Ethics Committee and Department of Health dossier submission and last for only two months, and the Ethics Committee review time also lasts for only two months.

Start up process for phase 1 first-in-human clinical trials without sufficient safety information in teaching hospitals



Note: Phase 1 trials can only take place in the two phase 1 centres attached to the two public teaching hospitals. The existing and proposed start-up processes for phase 1 first-in-human clinical trials assume the applications do not possess sufficient preclinical and/or clinical data.

Appendix 11. Recent investments in central laboratories and manufacturing facilities in mainland China and Singapore

Region	Company	Investment	Description	Jobs created	Gross floor area
Central laboratory investment					
Mainland China (Shanghai)	Eurofins Scientific (2017)	/	Offers biomarker, pharmacokinetics, pharmacodynamics testing services to pharmaceuticals and CROs	50–100	/
Mainland China (Suzhou)	Teddy Clinical Research Laboratory (2016)	/	Offers genomics, pharmacokinetics, pharmacodynamics and toxicology services to pharmaceuticals and CROs	Around 130	10,000 square meters
Manufacturing facilities investment					
Mainland China (Suzhou)	Novartis (2020)	USD 36 million	Manufactures drug substances for early and late phase drugs	190	46,000 square meters
Singapore	Thermo Fisher Scientific (2023)	USD 130 million	Develops and manufactures vaccines and therapeutics	300	
	Sanofi (2021)	USD 638 million	Develops and manufactures vaccines	200	37,240 square meters

Note: Total area of Sanofi is estimated based on Tuas Biomedical Park land rates and Sanofi's investment expenditure.

Source: Blankenship (2020), Eurofins Scientific (2016), Eurofins Scientific (2023), Gehris (2019), Novartis (2023), Teddy Clinical Research Laboratory Limited. (n.d.), Teo (2022), Verdict Media (2022), World Construction Network (2022), Xinhua News Agency (2021)

Appendix 12. Tax incentives for R&D expenditure in selected economies

Region	Profits tax rate	Tax incentives for R&D expenditure
Tax deduction		
 **Hong Kong**	**8.25%–16.5%**	• 200%–300% tax deduction
 **Mainland China**	**20%–25%**	• 200% tax deduction
 **Singapore**	**17%**	• 400% tax deduction
Tax credits		
 **Australia**	**25%–30%**	• Non-refundable tax credit covering corporate tax rate plus 18.5% premium for large companies • Refundable tax credit covering corporate tax rate plus 8.5%–16.5% premium for small companies
 **UK**	**19%–25%**	• Non-refundable tax credit of 20% for large companies • Refundable tax credit of 10% of the loss for non-profitable small and medium enterprises

Source: Innovation and Technology Commission (2022); PricewaterhouseCoopers (2023); PRC State Taxation Administration (2021); Australian Taxation Office (2022); HM Revenue and Customs of the UK Government (2023)

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