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Science & Tech Innovation Research Report

Strategic Collaborations between Hong Kong and Shenzhen in Biotechnology–Capitalising on Opportunities in the Loop for Policy Innovations

Contents

Executive Summary

Since the promulgation of the Outline Development Plan for the Guangdong-Hong Kong-Macao Greater Bay Area in February 2019, much attention has been drawn to collaboration on innovation and technology (I&T) between Hong Kong and Shenzhen, the two major cities of the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) overlooking the same narrow riverbed. Indeed, the synergy between the two cities has been impressive in terms of co-development. According to the Global Innovation Index 2019 published by the World Intellectual Property Organization, Shenzhen-Hong Kong ranked second globally as a science and technology cluster, ahead of innovation hubs such as Beijing (4), San Jose-San Francisco, CA (5), Boston-Cambridge, MA (7), New York City, NY (8), and Shanghai (11). This demonstrates the enormous potential the two cities can unleash in I&T collaboration, which tops not just national but also international standards.

As an industry showing promising potential all over the world, biotechnology serves as an excellent point of departure for bolstering I&T collaboration between HK and SZ. Both cities can draw on their respective strengths, and call on their respective governments for support to facilitate development. Hong Kong enjoys a competitive edge in basic research and boasts the world's second-largest biotech financing centre in the Hong Kong Stock Exchange. Meanwhile, Shenzhen has been leveraging on substantial government support to develop mature I&T enterprises and supply chains. That is why in the past, the Hong Kong-Shenzhen (HK-SZ) mode of collaboration was often seen as "basic research in Hong Kong, large-scale production in Shenzhen, and finally financing in Hong Kong through public listing." Yet, such a way of division along research and commercialisation lines is oversimplistic: it fails to account for the differences between high-tech and conventional manufacturing and capture the different advantages the two cities enjoy in various niches of biotechnology. In order to unleash complementary advantages and realise win-win cooperation, Hong Kong and Shenzhen should develop a comprehensive, multifactored and refined division of labour along different niches.

Whilst the nation is attaching increasing importance to biotech development amid a continuous stream of new innovations, the two cities have notably failed to leverage on their synergy to pursue co-development. The main challenges for this are: a lack of long-term planning and action plan to coordinate development

and lack of focus on industrial, academic and research collaboration; poor systemic and regime linkage between Hong Kong and the Mainland; unsmooth passage of bio-materials and medical devices across the border; as well as underdevelopment of a biotech industrial cluster marked by an absence of world-renowned biotech enterprises. With the inclusion of the Hetao Shenzhen-Hong Kong Science and Technology Innovation Cooperation Zone (the Loop) into a national strategic platform,[1] it is more important than ever to coordinate and plan the collaborative development of "one zone, two parks" of the "one river, two banks" at the Loop, resolve existing issues that hamper HK-SZ collaboration, and support the development of an international I&T hub in the GBA. The report thus approaches collaboration in biotech as an entry point and centres the study on the development of the Loop.

Situated right at the Hong Kong-Shenzhen border, the Loop encompasses the Hong Kong park (i.e., Hong Kong-Shenzhen Innovation and Technology Park in the Lok Ma Chau Loop) south of the Shenzhen River and the Shenzhen park (i.e., the Hong Kong-Shenzhen Innovation and Technology Park, covering the Futian Free Trade Zone and the Huanggang Checkpoint area) north of the River. In addition to bridging HK-SZ collaboration in I&T, the Loop should serve as the pivot that drives the development of the HK-SZ biotechnology cluster. When it comes to the overall development direction, the "two parks" should be treated as "one zone" rather than two individual areas: where the two cities differ in systems and standards, the more flexible system and the more internationalised standards should be adhered to; where they differ in incentive policies and measures, greater incentives and more supportive measures should be adopted. This way, the Loop can pursue collaborative development as a whole and serve as a pivot that drives the long-term development of the two cities.

We believe the development of biotech in the Loop has significant implications, not just in optimising the entire biotech supply chain including drug discovery, preclinical research, clinical trials, and production and product launch, but also in helping achieve breakthroughs in common key and core technologies. Three developmental goals are identified for the Loop: 1) as a pilot and demonstration area for collaboration between Hong Kong and Shenzhen in biotech, with a view to explore the most effective mode of cross-border collaboration and the most advanced biotech policies; 2) as a pilot area for international biotech regulatory standards setting, with the objective of introducing the most advanced and robust regulatory regime to the Mainland; 3) as a biotech transformation cluster in the GBA that expedites the transfer of advanced scientific findings into production.

[1] In his speech on 14 October 2020 to mark the 40th anniversary of the establishment of the Shenzhen Special Economic Zone (SEZ), President Xi Jinping stressed the importance of "well-planning for and developing the Hetao Shenzhen-Hong Kong Science and Technology Innovation Cooperation Zone." The 14th Five-Year Plan adopted in March this year also designated the Loop as one of the four major collaborative platforms in the GBA.

Biotech is a broad-scoped discipline. As biomedicine has the highest significance and the biggest potential for collaboration, it forms the focus of the present study. Having taken into account the respective strengths and development directions of the two cities, four major areas of collaboration centred on the Loop are put forward **(Table 1)**:

Table 1 | Four major areas of collaboration between Hong Kong and Shenzhen

Area of collaboration	Overview of mode of collaboration
Drugs and vaccines	Coordinated in the Loop to achieve all-stage and multifactored collaboration that encompasses drug development, production and product launch
Genetic testing and therapies	With collaborative development in the Loop, teams in Hong Kong and Shenzhen will focus on different markets; market access restrictions will be eased to allow eligible enterprises in the Loop to enter the Mainland market
Advanced medical devices	Corporates establish themselves in the Loop to leverage Hong Kong's strengths in medical research and clinical trials and Shenzhen's expertise in AI and mechanical manufacturing
Application of AI to biotechnology	

In order to foster the above-mentioned ecosystem, it is incumbent for the two cities to devise a comprehensive, concrete and long-term plan. We make four recommendations **(Recommendations 1–4)** for the reference of the two governments to address existing barriers that hamper collaboration. Moreover, the development of biotech in Hong Kong and Shenzhen is closely related to national planning and policies. The Central Government's support is essential for addressing issues of a more marco or cross-border nature. We thus put forward three recommendations **(Recommendations 5–7)** for the reference of Central Ministries and Departments.

Recommendation 1 | Establishing anchor institutions in the region to expedite development of a biotech industrial cluster

Hong Kong and Shenzhen have yet to establish a world-renowned biotechnology industrial cluster. Meanwhile, Shanghai and Boston have adopted an "anchor institution" approach: major enterprises or research institutes were introduced to create an environment conducive to the development of local start-ups and industries. This in turn facilitates the formation of a world-class biotech industrial cluster.

Drawing on the above-mentioned approach, we recommend that a multipronged strategy be adopted to expedite the development of the HK-SZ biotech industrial cluster in the Loop. In the short-term, government departments and relevant organisations in the two cities should proactively approach leading biotech enterprises. Incentives like tax concessions, rental discounts and government-guaranteed low-interest loans can be provided to attract

enterprises to set up regional headquarters or research centres in the Loop; moreover, the National Development and Reform Commission can launch a Shenzhen-Hong Kong Biotechnology Collaborative Development Fund that pools together funds from the governments of the Guangdong Province, the Hong Kong SAR and the Shenzhen Municipality. Along with the Hong Kong Growth Portfolio previously established by the Government of the Hong Kong Special Administrative Region (the Hong Kong SAR Government; or the Hong Kong government), part of the proposed Fund shall be invested in promising biotech enterprises in the Loop to facilitate their development into unicorns in the medium term.

We further recommend the joint establishment of a cross-border biotech mega research institute in the Loop by the University of Hong Kong, the Hong Kong University of Science and Technology and the Chinese University of Hong Kong, together with Shenzhen institutions like the Shenzhen Institute of Advanced Technology, the Chinese Academy of Sciences and the Southern University of Science and Technology, with the cooperation of existing platforms and facilities in the GBA. The sharing of substantial funding and advanced facilities will foster interdisciplinary and cross-institutional collaboration. In the long-term, not only will this attract international talent, but also provide a comprehensive career path for the local workforce, as well as further attract foreign enterprises by providing advanced research support to biotech enterprises. The institute will observe three principles: leverage cutting-edge research opportunities to better appeal to world-class talent; resolve regional problems and increase the uniqueness of scientific research; and operate independently from universities to expedite the progress of advanced research.

Recommendation 2 | Establishing all-stage ancillary facilities to optimise biotech research and development supply chain

Collaborative planning by the two governments is indispensable to the development of biotech in the Loop. While Shenzhen has established a Science and Technology Innovation Commission to coordinate planning and manage funding matters, the Hong Kong government has yet to put in place a designated body to advise on long-term scientific development and to promulgate a blueprint for biotech development, which makes it difficult to discuss the planning of the Loop with Shenzhen. Drawing reference from economies like the US and Singapore, we recommend that the Hong Kong government set up a Science and Development Office to provide forward-looking scientific advice on biotechnology, formulate a blueprint for the development of the biotech industry, optimise the government's funding mechanism for research and development (R&D) activities, formulate a funding allocation strategy that aligns with the blueprint, and establish a peer review mechanism.

The Loop also provides an opportune moment for optimising ancillary facilities in support of the R&D process. For the preclinical research stage, the two governments should establish Good Laboratory Practice (GLP) laboratories, in particular large-scale animal laboratories. For phase 1 clinical trials, we suggest that the approval process be expedited in Hong Kong to fully realise the city's edge in clinical trials. Phases 2 and 3 trials are to be conducted with a multicentre approach. We recommend that HK-SZ cross-border multicentre clinical trials be coordinated in the Loop. Hong Kong's internationalised clinical trial management and

its branding advantage will be leveraged to introduce Hong Kong-style management into the Mainland to meet international standards. For the production stage, we recommend that production lines for cutting-edge products and pilot batches be set up in the Loop. For the product launch stage, as new drug approval standards in the Mainland are increasingly in line with international standards, particularly with marked improvement in the quality of clinical trial data, Hong Kong's Department of Health should consider adding mainland China into its designated list, so that new drugs that are launched in any two places on the list will be recognised in Hong Kong; in the long run, Hong Kong can attract and train talent in drug approval and explore the development of an independent new drug approval mechanism. Likewise, the Shenzhen government should seek approval from the Health Commission of Guangdong Province to relax relevant requirements and allow the use of efficacy data of drugs and medical devices, which have already been approved in Hong Kong, on Shenzhen patients for further registration in the Mainland. This will expedite the overall approval process.

Recommendation 3 | Establishing a one-stop service platform in the Loop to provide professional support services

To better leverage the Loop to help Mainland enterprises expand into international markets and Hong Kong enterprises access the Mainland market, we recommend the joint establishment of a one-stop service platform in the Loop by the Hong Kong-Shenzhen Innovation and Technology Park Limited and the Futian district government to provide biotechnology transfer services. First, such a platform can liaise with the competent regulators of the two cities, including the GBA sub-centres for drug and medical device evaluation and inspection established by the National Medical Products Administration in the Shenzhen park, and the subsidiaries of the National Intellectual Property Administration and the Human Genetic Resources Administration of China, Ministry of Science and Technology that we propose to be set up in the Loop. Second, the platform can interface with research project funds set up by the two governments, venture capital funds, research institutes and collaboration opportunities, as well as professional services such as intellectual property services. Finally, the platform can attract Contract Research Organisations (CRO) and Contract Development and Manufacturing Organisations (CDMO) to share some of their R&D procedures with biomedical companies, thereby enhancing the clinical trial capabilities and quality control standards of healthcare organisations.

Recommendation 4 | Encouraging knowledge transfer in tertiary institutions and nurturing multi-skilled talent well-versed in biotech and business

While the Regulation of Shenzhen Special Economic Zone on Scientific and Technological Innovation contains a number of measures aimed at encouraging knowledge transfer, Hong Kong has a lot to catch up on. To prevent researchers and enterprises from flowing one way and congregating into a particular park in the Loop, and to more efficiently transfer world-class research outcomes into the industry, we propose the following recommendations:
1) the University Grants Committee of Hong Kong should establish an assessment framework for knowledge transfer in tertiary institutions

and link certain government fundings with universities' performance under the framework, thereby incentivising university researchers to engage in knowledge transfer activities; 2) universities in Hong Kong should revise regulations on researchers engaging in outside work to increase hours available for knowledge transfer activities so as to facilitate their engagement in cross-border activities; and 3) universities should also provide courses geared towards the training of multi-skilled talent with backgrounds in biotech and business, with a view to closing the talent gap on business operations and investment in the biotech industry.

Recommendation 5 | Strengthening coordination and seeking comprehensive authorisation

Despite the high-level framework provided by the Office of the Leading Group for the Development of the GBA, policy oversight and coordination between the two cities are still insufficient, marked by the absence of a coordinated development plan for "one zone, two parks". We therefore recommend the establishment of a relevant body, designated channel or platform under the Leading Group framework to provide oversight and coordination of the Loop's development under the "one zone, two parks" arrangement, and expedite the formulation of a HK-SZ "Joint Policy Package" that encompasses a range of issues like attraction of top-notch talent, movement of researchers, management of organisations, capital flow and opening up of the network, etc.

In order to create a pilot and demonstration area for HK-SZ collaboration in biotech, more autonomy should be conferred to the Loop to instigate reforms. We recommend that the Shenzhen Municipal Government first seek the approval of the Central Government on implementing comprehensive authorisation in the Loop, and that the Hong Kong and Shenzhen governments also jointly seek the authorisation of various Ministries and Departments to implement pilot policies in biotech reform. Meanwhile, appropriate fault tolerance mechanisms and effective incentivising measures should be put in place in the Loop to ensure the successful implementation of comprehensive authorisation. A biotech expert advisory committee consisting of top-notch professionals within China and from overseas should be established in the Loop to put forward specific recommendations on the development of the biotech industry, as well as exploring issues like ethics review procedures, mutual recognition of results in clinical trials, drug application review and approval procedures, etc.

Recommendation 6 | Bridging the two cities' systems and regimes

The competent Central authorities should work on smoothing out differences in the two cities' systems and regimes. In terms of market access, Hong Kong does not place any restrictions on Mainland enterprises, but the Mainland subjects Hong Kong enterprises to restrictions by means of a negative list. We therefore recommend that the National Development and Reform Commission and the Ministry of Commerce ease restrictions on the negative list in relation to foreign capital accessing the stem cell, genetic diagnostics, and therapy markets, and allow direct entry to the Mainland market by Hong Kong biotech enterprises that are registered in the Loop and have Hong Kong permanent residents of Chinese nationality serving as a legal person or major shareholder, and treat said enterprises as if they were domestically-owned enterprises.

With regard to the intellectual property (IP) regime, we recommend that the National Intellectual Property Administration set up a subsidiary in the Loop, with a view to expedite approval of patent applications by enterprises registered in the Loop. We also recommend the Administration to make reference to Hong Kong's patent re-registration system and recognise standard patents granted by Hong Kong's Intellectual Property Department's original grant patent (OGP) system, with a trial scheme to be run in the GBA first.

In relation to the registration and launch of new drugs, the National Medical Products Administration can consider delegating certain powers in new drug approval, so that the GBA sub-centres established in the Shenzhen park of the Loop can be tasked with new drug approval procedures for relevant organisations and enterprises in the Loop and all-stage intervention for the approval procedures.

Recommendation 7 | Facilitating passage of bio-materials and medical devices between Hong Kong and Shenzhen

Finally, although cross-border flow of goods in specific areas into the Loop has seen improvement, the Mainland's export regime in relation to biological materials and samples still needs to be optimised. We recommend the establishment of a subsidiary of the Human Genetic Resources Administration in the Loop, optimisation of the Mainland's export regime in relation to biological samples, and improvement of entry-exit inspection and quarantine procedures for human genetic resources by Mainland and Hong Kong Customs, so that eligible Hong Kong institutions, research institutes and enterprises to utilise said resources in the Loop, provided that appropriate risk management protocols are in place.

Moreover, to speed up approval of the import of bio-materials and medical devices, we recommend that the competent Central authorities allow Shenzhen customs and market regulators to further improve the inspection and quarantine procedures for importing bio-materials, expedite testing and allow enterprises on the "White List" to import bio-materials. The relevant Central authorities can also authorise the use of unregistered imported medical devices for R&D and testing purposes by Loop-based biomedical enterprises and specific healthcare organisations in Shenzhen.

With development of the Loop as its focus, the present study approaches collaboration in biotech as an entry point to draw up seven major recommendations to the Central Government and the governments of Hong Kong and Shenzhen with regard to the collaborative development of "one river, two banks" and "one zone, two parks". Under these, 19 proposals are put forward (see Figure 1). We believe that these recommendations can help overcome barriers hampering HK-SZ collaboration and foster the complementary cooperation of the two cities, so that we can seize the golden opportunities under the national plan to create a biomedical powerhouse in the GBA that promotes biotechnological innovations at the cutting edge of the global scientific community.

Figure 1 | Summary of the Seven Recommendations

HK-SZ policies

1 Establishing anchor institutions in the region to expedite development of a biotech industrial cluster

- 1.1: Attracting leading enterprises to establish a presence in the Loop
- 1.2: Providing ample funding for start-ups to nurture them into unicorns
- 1.3: Establishing a cross-border biotech mega research institute

2 Establishing all-stage ancillary facilities to optimise biotech research and development supply chain

- 2.1: Establishing a Hong Kong Science and Development Office to formulate a blueprint for biotech development
- 2.2: Establishing ancillary facilities for preclinical research
- 2.3: Expediting the approval of Phase 1 clinical trials in Hong Kong
- 2.4: Coordinating multicentre clinical trials with "Hong Kong-style" management
- 2.5: Establishing production lines in the Loop and improving the product launch regime for new drugs in the two cities

3 Establishing a one-stop service platform in the Loop to provide professional support services

4 Encouraging knowledge transfer in tertiary institutions and nurturing multi-skilled talent well-versed in biotech and business

- 4.1: Establishing an assessment framework for knowledge transfer to foster a culture conducive to knowledge transfer on campus
- 4.2: Relaxing regulations on professors engaging in outside work to foster knowledge transfer
- 4.3: Nurturing multi-skilled talent with backgrounds in biotech and business

Central Government policies

5 Strengthening coordination and seeking comprehensive authorisation

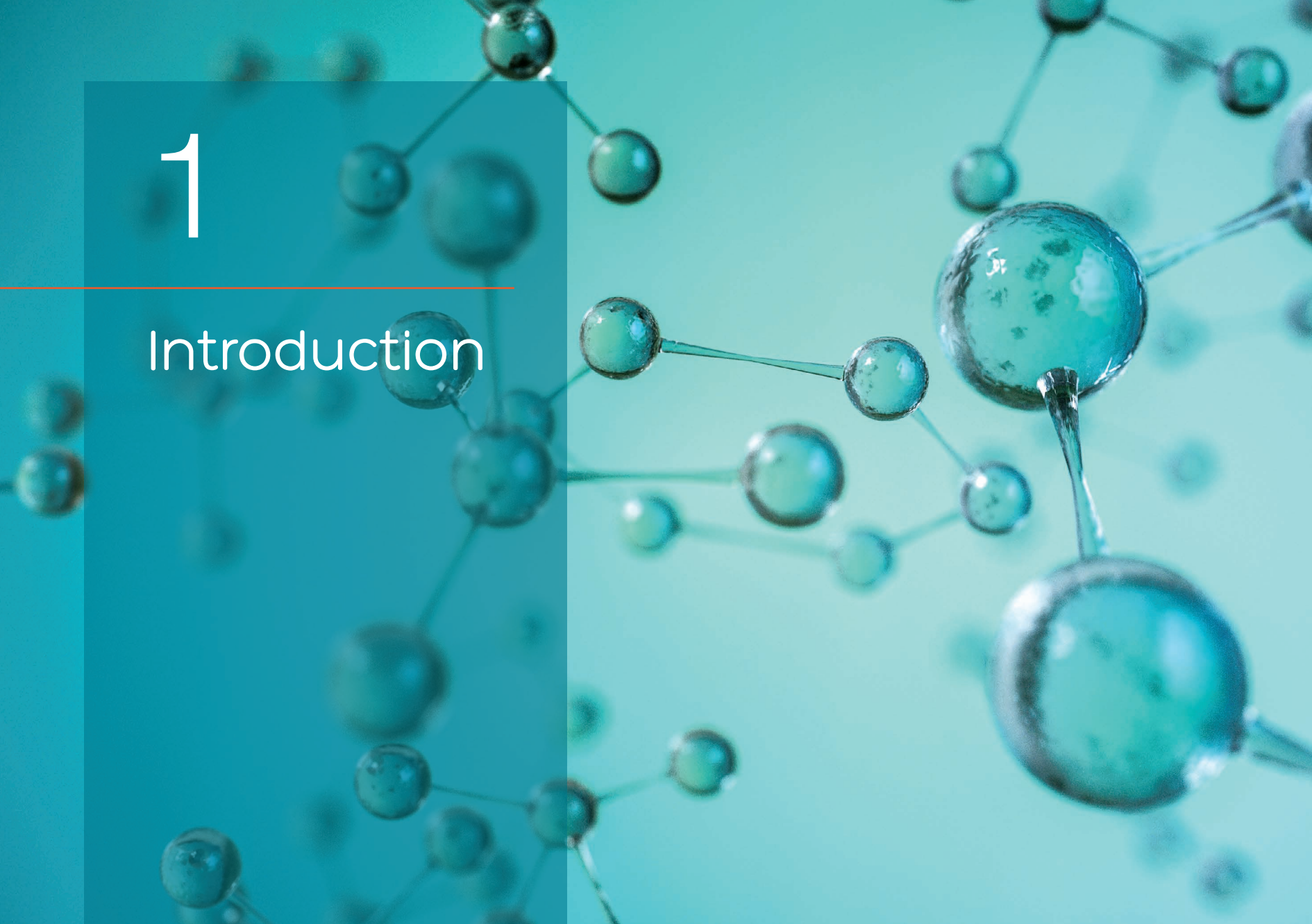
- 5.1: Establishing a designated body under the Leading Group for the Development of the GBA to coordinate the collaborative development of "one zone, two parks"
- 5.2: Seeking comprehensive authorisation from the Central Government to implement pilot policies in biotech reform

6 Bridging the two cities' systems and regimes

- 6.1: Relaxing regulations set by the Negative List to allow designated enterprises to enter the Mainland market
- 6.2: Coordinating the intellectual property regimes in Hong Kong and the Mainland
- 6.3: Expediting evaluation and approval of new drugs in the Loop

7 Facilitating passage of bio-materials and medical devices between Hong Kong and Shenzhen

- 7.1: Optimising the mechanism by which Mainland bio-materials are transported across the border into the Hong Kong park
- 7.2: Easing restrictions on the import of bio-materials and medical devices



1

Introduction

As the two core cities of the Guangdong-Hong Kong-Macao Greater Bay Area (GBA, see **Figure 1**), Hong Kong and Shenzhen accounted for approximately 45% of the economic output of the entire GBA in 2020. As the birthplace of leading tech giants such as Tencent, Huawei and DJI, Shenzhen's achievements in innovation and technology (I&T) are formidable. For the long-term development of the two cities and the region at large, it is of crucial importance to foster I&T collaboration between Hong Kong and Shenzhen by leveraging their respective strengths and realising complementary co-operation. This is not only beneficial to the sustained development of the two cities, but also conducive to building an international innovation hub in the GBA.

Figure 1 The Guangdong-Hong Kong-Macao Greater Bay Area

As one of the most globally competitive industries and with the greatest development potential among various I&T sectors, biotechnology (biotech) has been identified as one of the nine new industries of strategic importance under the "Outline of the Fourteenth Five-Year Plan for the National Economic and Social Development and the Long-Range Objectives Through the Year 2035" (the 14th Five-Year Plan)[2] and one of the four pillar industries driving the development of the GBA forward.[3] Biotech also provides excellent opportunities for fostering Hong Kong-Shenzhen (HK-SZ) collaboration. While biotech generally encompasses areas including fisheries, animal husbandry, forestry, the environment and even minerals, the present study centres on biomedicine owing to its unmatched influence and potential for collaboration within biotech. Firstly, both Hong Kong and Shenzhen demonstrate an edge in biotech. While Hong Kong's tertiary institutions produce advanced research that is internationally recognised, Shenzhen boasts an assembly of mature enterprises and a complete supply chain. Secondly, the development of biotech is a shared priority for both governments. Having identified biotech as one of its four areas with a competitive edge, the Hong Kong SAR Government has over the years made significant investments into the sector, including allocating HKD 5 billions to the Health@InnoHK research cluster focused on healthcare technology. Meanwhile, with national and provincial policy backing,[4] the Shenzhen Municipal Government has, in designating biomedicine as one of its seven new industries with strategic importance,[5] strived to establish a "one-core, multicentre" cluster that has the Pingshan National Biological Industry Base at its heart. HK-SZ collaborative development in biotech can help foster new engines of future economic growth, thereby further enhancing the technological and industrial competitiveness of the GBA.

[2] The new industries of strategic importance under the 14th Five-Year Plan are next-generation information technology, biotechnology, new energy, new materials, advanced equipment, new energy vehicles, environmental protection, aerospace and marine equipment.

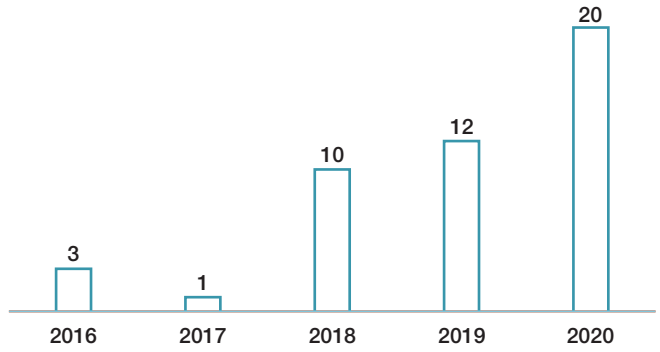
[3] The four pillar industries under the Outline Development Plan for the GBA are next-generation information technology, biotechnology, advanced equipment manufacturing and new materials.

[4] On the national level, support for Shenzhen in initiating international collaborations on biotechnology, establishing a biotech industrial cluster and developing innovations in cross-border flow of biotech resources are documented in "Guidelines of the CPC Central Committee and the State Council on Supporting Shenzhen in Building a Pilot Demonstration Area of Socialism with Chinese Characteristics, "Implementation Plan of Pilot Reforms to Build a Pilot Demonstration Area of Socialism with Chinese Characteristics in Shenzhen (2020-2025)", "Work Plan for Supervision, Innovation and Development of Drugs and Medical Devices in Guangdong-Hong Kong-Macao Greater Bay Area" and "Action Plans for Technological Innovations in the Pilot Demonstration Area of Socialism with Chinese Characteristics". On the provincial level, the Guangdong Government's "Guidelines on the Cultivation and Development of Strategic Pillar Industrial Clusters and Strategic Emergent Industrial Clusters" rendered support for Shenzhen in building up biotech and healthcare industrial clusters, fostering industries with a competitive edge in biologics, advanced medical devices, biomedical materials, in vitro diagnostics etc., and achieving breakthroughs in key and core technologies in areas like precision medicine and stem cells, new drug discovery, biosafety and biomanufacturing.

[5] The industries include next-generation information technology digital economy, advanced equipment manufacturing, biomedicine, new materials, green low-carbon industries and marine economy.

Through talented individuals as well as supportive policy and funding mechanisms, the development of China's biomedical industry is in full swing in recent years. In 2018, the nation established itself as a second-tier research powerhouse by increasing its rate of contribution to global pharmaceutical research and development (R&D) to 4–8%; China received global acclaim by bringing the COVID-19 outbreak under control, with the World Health Organization's validation of the Sinopharm and Sinovac vaccines for emergency use, Chinese vaccines make up two of the eight vaccines authorised by the WHO.[6] Meanwhile, an increasing number of new drugs developed by local pharmaceutical companies have received market approval[7] (see **Figure 2**). However, cities like Beijing, Shanghai and Suzhou are currently more competitive within the Chinese market. Of the 55 biotech enterprises listed on the Science and Technology Innovation Board (STAR market) of the Shanghai Stock Exchange (SSE), 11 are from Shanghai (making up 20% of the total), eight from Beijing (14.5%), five from Suzhou (9.1%), but only three from Shenzhen. Also, as the Hong Kong Stock Exchange (HKEX)'s 2018 amendments to its Listing Rules allowed for the listing of pre-revenue biotech companies, 26 listed companies have their headquarters established in the above-mentioned three cities, compared to only two from Hong Kong (see **Figure 3**).

Figure 2 Number of new drugs developed by Chinese pharmaceutical companies receiving marketing approval by the National Medical Products Administration

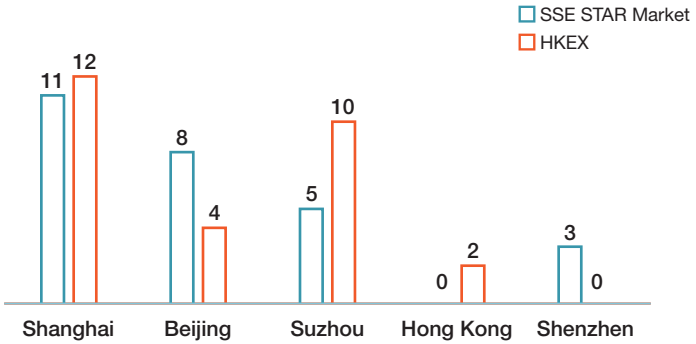


Source: Boston Consulting Group

[6] As at 2 June 2021.

[7] For example, in November 2019, Brukinsa developed by BeiGene, Ltd. was approved by the US Food and Drug Administration (FDA), making it the first new cancer drug developed in China to be approved for use in the US.

Figure 3 Biotech companies listed on the STAR market of the SSE and on the HKEX under Chapter 18A by location of headquarters



Note: SSE STAR market data as at March 2021. HKEX data as at June 2021, inclusive of pre-revenue biotech companies listed after April 2018.
Sources: Shanghai Stock Exchange, Hong Kong Stock Exchange

Compared to Beijing and Shanghai, Shenzhen has weaker basic research capabilities due to an absence of tertiary institutions with expertise in biotech. While Shenzhen stands to benefit from Hong Kong's advanced research capabilities and world-class management experience, Hong Kong can also leverage on Shenzhen's industries and enterprises to retain an edge amid keen competition. Together, the two cities can develop their biotech industry to a nationally and internationally renowned one. **Chapter 2** will elaborate in detail the complementary advantages of the two cities and the significance of collaborative development.

The Hetao Shenzhen-Hong Kong Science and Technology Innovation Cooperation Zone (the Loop) will play a crucial role in the collaboration of HK-SZ biotech industries. Encompassing the Hong Kong park (i.e., Hong Kong-Shenzhen Innovation and Technology Park in the Lok Ma Chau Loop) and the Shenzhen park (i.e., the Futian Free Trade Zone and the Huanggang Checkpoint area) that straddle the Hong Kong-Shenzhen border, the Loop is a national strategic platform centred on I&T development. As one of the four major collaborative platforms of the GBA under the 14th Five-Year Plan,[8] the Loop is a priority for the Central authorities and the governments of the two cities.

[8] The four major collaborative platforms of the GBA under the 14th Five-Year Plan include the Loop, Qianhai in Shenzhen, Nansha in Guangzhou, and Hengqin in Zhuhai.

Entrusted with important functions in the exploration of industrial development, cross-border co-operation, policy innovations, etc., the Loop is highly significant as an example of cross-border collaboration in the GBA. We will dedicate **Chapter 3** and **Chapter 4** to discuss the significance of the Loop to HK-SZ co-operation and regional development, as well as how the Loop can serve as the pivot that drives forward HK-SZ collaboration in the four major areas of drugs and vaccines, genetic testing and therapies, advanced medical devices and application of Artificial Intelligence (AI) to biotechnology.

In **Chapter 5** and **Chapter 6**, the report will put forward a total of seven major recommendations encompassing 19 proposals for the consideration of the governments of Hong Kong and Shenzhen and the Central Government. We believe that these recommendations can help overcome barriers hampering HK-SZ collaboration and foster the complementary co-operation of the two cities. With competitive edges in advanced research and industrial development, such co-operation can create engines of growth for the biotech industry in the GBA, and in turn promote biotechnological innovations at the cutting edge of the global scientific community.

2

The Competitive Edge of HK-SZ Biotech Development and the Significance of Co-operation

Hong Kong: Track record in scientific research with attractive business environment

Dubbed Asia's world city, Hong Kong is the place where East meets West. Thanks to a congregation of world-class research institutes and experts, Hong Kong's tertiary institutions enjoy clear advantages in scientific research, and their output is internationally recognised. Boasting an internationalised business environment, a low tax regime and comprehensive safeguards underpinned by a robust judicial and intellectual property (IP) system, Hong Kong is often seen as an ideal springboard for foreign enterprises keen on entering the Chinese market, and for Mainland enterprises looking to expand abroad. In a highly regulated industry like biotech, Hong Kong's role is particularly important. The leading international financial centre also has a vibrant and globally-orientated capital market that is highly sought after by biotech enterprises looking to raise capital.

Research excellence in tertiary institutions

Hong Kong's tertiary institutions are highly competitive internationally. According to the QS World University Rankings 2022, Hong Kong is second only to London in terms of its concentration of world-class universities,[9] with the University of Hong Kong (HKU), the Hong Kong University of Science and Technology (HKUST), and the Chinese University of Hong Kong (CUHK) making it to the global top 50. Hong Kong has a clear competitive edge in biotech basic research, with HKU and CUHK among the global top 100 in the natural science and medical fields, according to the QS ranking of 2021. In particular, with regard to medicine, pharmacy and pharmacology, and life sciences, HKU ranks 39, 95 and 75, with CUHK at 40, 56 and 98, respectively.

Based on their competitive edge in basic research, universities in Hong Kong have produced new findings in biotech that have garnered international recognition. For instance, HKU's research team with Professor Yuen Kwok-yung has developed the world's first

[9] London, the United Kingdom has four universities at QS's global top 50 in 2022.

COVID-19 intranasal vaccine that has comparatively fewer side effects than conventional COVID-19 vaccines; Professor Guan Yi of HKU and Professor Joseph Sriyal Malik Peiris, Founding Member of Hong Kong Academy of Sciences, were awarded the John Dirks Canada Gairdner Global Health Award in 2021 in recognition of their contribution to infectious disease research in Asia; CUHK's Professor Dennis Lo Yuk-ming invented a non-invasive prenatal test that safely and accurately screens for Down Syndrome during early pregnancy, and was awarded the 2021 Breakthrough Prize—Life Sciences, a distinction dubbed the "Oscars of Medical Sciences"; Professor Nancy Ip Yuk-yu of HKUST developed a drug to treat Alzheimer's, and for that she was awarded the L'OREAL-UNESCO for Women in Science Award, also known as "Women's Nobel Prize".

Hong Kong's reputation in scientific research is well-regarded, with 22 university laboratories designated as State Key Laboratories or Hong Kong Branches of Chinese National Engineering Research Centres by the National Ministry of Science and Technology of which 13 are related to biotech (see **Table 1**).

Table 1 Biotech-related State Key Laboratories or Hong Kong Branches of Chinese National Engineering Research Centres

Universities	State Key Laboratories or Hong Kong Branches of Chinese National Engineering Research Centres
University of Hong Kong	State Key Laboratory of Emerging Infectious Diseases, State Key Laboratory of Brain and Cognitive Sciences, State Key Laboratory of Liver Research, State Key Laboratory of Pharmaceutical Biotechnology
Hong Kong University of Science and Technology	State Key Laboratory of Molecular Neuroscience, Hong Kong Branch of National Engineering Research Center for Tissue Restoration & Reconstruction
Chinese University of Hong Kong	State Key Laboratory of Translational Oncology, State Key Laboratory of Agrobiotechnology, State Key Laboratory of Research on Bioactivities and Clinical Applications of Medicinal Plants, State Key Laboratory of Digestive Disease
City University of Hong Kong	State Key Laboratory of Marine Pollution
Hong Kong Polytechnic University	State Key Laboratory of Chemical Biology and Drug Discovery
Hong Kong Baptist University	State Key Laboratory of Environmental and Biological Analysis

Source: Innovation and Technology Commission

Robust capital market

As a leading international financial centre, Hong Kong has had the world's biggest IPO market in the HKEX for several years. Owing to the city's robust and vibrant capital market, a sizeable number of biotech venture capital funds and private equity funds from the Mainland and abroad have set up headquarters or offices here (see **Table 2**) to take advantage of the excellent financing opportunities and to foster the development of biotech enterprises. In addition, with the HKEX's 2018 introduction of Chapter 18A to its Listing Rules, pre-revenue biotech companies may apply for listing upon completion of Phase I clinical trials of a core product and fulfilment of some other requirements.[10] Since then, a number of biotech enterprises have flocked to the Hong Kong market to raise capital. As of June 2021, a total of 33 pre-revenue biotech companies have been listed under the new regulations. Currently, the HKEX ranks just behind NASDAQ as the world's second-largest biotech financing centre.

[10] This includes having an initial market capitalisation at the time of listing of at least HKD 1.5 billion, having been in operation in the current line of business for at least two financial years prior to listing under substantially the same management, ensuring sufficient working capital, etc.

Table 2 Selected biotech venture capital funds and private equity funds in Hong Kong (in no particular order)

Headquartered in Hong Kong	Established offices in Hong Kong	
	Headquartered in mainland China	Headquartered overseas
Advantech Capital	Hillhouse Capital	OrbiMed
Ally Bridge Group	Sequoia China	Lilly Asian Ventures
Boyu Capital	6 Dimensions Capital	Eight Roads Ventures
Blue Pool Capital	Qiming Venture Partners	
Nan Fung Life Sciences	CBC Group	
Taikang Asset Management	Legend Capital	
LC Capital	Hony Capital	
	CDH Investments	
	YF Capital	
	Greater Bay Area Homeland Development Fund	
	Country Garden Venture Capital	

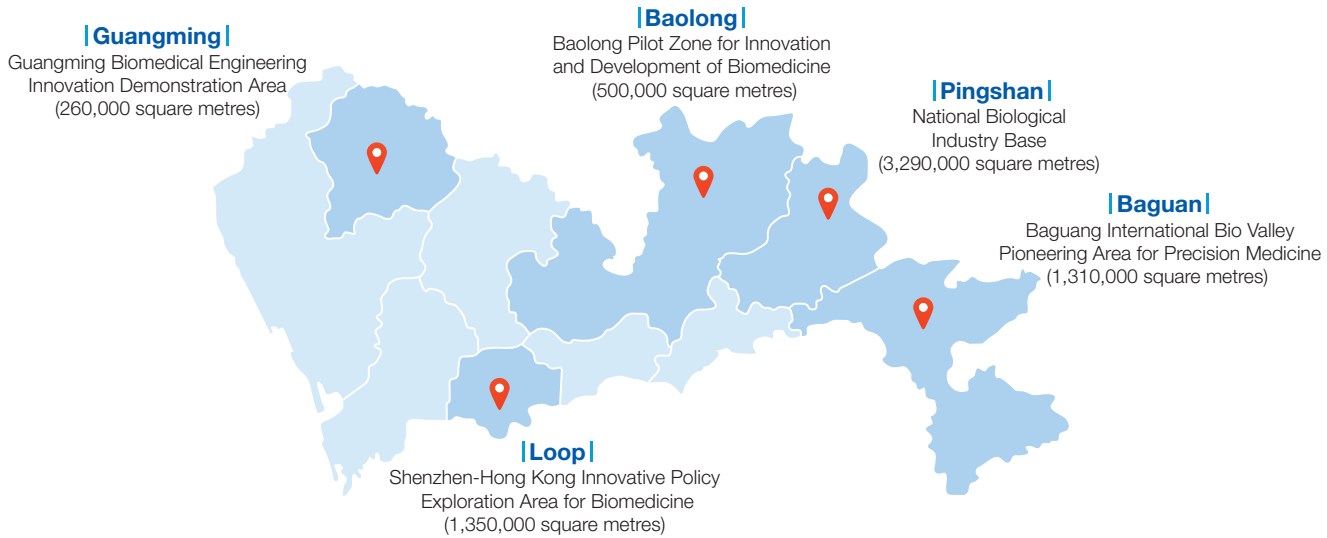
Shenzhen: Government support with mature supply chain

As the nation's first city of innovation, and the first municipality to be designated a national self-dependent innovation demonstration area, Shenzhen has a strong foundation to foster biotech development. In addition, I&T development is a priority for the municipality, with its total R&D investment ranking third nationally at 132.8 billions RMB in 2019, or second nationally in terms of percentage of GDP spent (4.9%).

Biotech development a government priority

To foster biotech development and establish a world-class biomedical industrial cluster, the Shenzhen Municipal Government in early 2020 published a set of "1+3" documents,[11] with the clear goal of establishing a "one-core, multicentre" cluster comprised of the five specialised parks of the Pingshan National Biological Industry Base, Shenzhen-Hong Kong Innovative Policy Exploration Area for Biomedicine, Guangming Biomedical Engineering

Figure 4 | Signature parks of the biomedical industry in the Shenzhen Municipality



[11] "Guiding Opinions on Fostering Development of the Biomedical Industrial Cluster in the Shenzhen Municipality" (《深圳市促進生物醫藥產業集聚發展的指導意見》) and three associated documents including "Implementation Plan of the Development of the Biomedical Industrial Cluster in the Shenzhen Municipality (2020–2025)" (《深圳市生物醫藥產業集聚發展實施方案(2020–2025年)》), "Action Plan for the Development of the Biomedical Industry in the Shenzhen Municipality (2020-2025)" (《深圳市生物醫藥產業發展行動計劃(2020–2025年)》) and "Measures to Foster Development of the Biomedical Industrial Cluster in the Shenzhen Municipality" (《深圳市促進生物醫藥產業集聚發展的若干措施》).

Innovation Demonstration Area, Baolong Pilot Zone for Innovation and Development of Biomedicine, and Baguang International Bio Valley Pioneering Area for Precision Medicine[12] (see **Figure 4**). As of 2020, Shenzhen is home to 24 National Biotech Innovation Platforms, including seven State Key Laboratories, two National & Local Joint Engineering Research Centres, and two National Engineering Research Centres[13] (see **Table 3**).

Table 3 Biotech-related State Key Laboratories and Engineering Research Centres in Shenzhen

State Key Laboratories	State Key Laboratory of Chemical Oncogenomics Jointly Built by Province and Ministry
	Key Laboratory for Monitoring and Evaluation of Cosmetics
	Key Laboratory for Bioequivalence Research of Generic Drug Evaluation
	Key Genomics Laboratory of the Ministry of Agriculture
	State Key Laboratory for Agricultural Genomics
	State Key Laboratory for of Chinese Medicine and Molecular Pharmacology (Incubation), Shenzhen
	Key Laboratory for Health Informatics, Chinese Academy of Science
National & Local Joint Engineering Research Centres	National-local Joint Engineering Research Center for Key Technologies of Chinese Medicine Oral Formulation
	National-local Joint Engineering Research Center for Orthopaedic Biomechanics Materials
National Engineering Research Centres	National Engineering Technology R&D Center for Medical Diagnostic Instrument
	National Engineering Research Center for Biotechnology (Shenzhen Branch)

[12] "One-core" refers to the Pingshan National Biological Industry Base, while "multi-centre" refers to the remaining four parks.

[13] Shenzhen also has eight National-local Joint Engineering Laboratories, four National Enterprise Technology Centres and one national public service platform.

Rapid growth of the Industry

Shenzhen's biomedical industry has experienced rapid growth in recent years. In 2020, the industry's contribution to the city's GDP grew by a phenomenal 24.4%, the fastest pace among its seven new industries of strategic importance. By 2025, the total economic output of the industry is expected to exceed 200 billions RMB. The city has established a biomedical supply chain that integrates drug manufacturing, medical devices and pharmaceutical distribution. Shenzhen is also leading the country in medical equipment specialisations such as gene sequencing and medical imaging, and has developed biomedical specialisations like stem cells and vaccines. Among its nationally leading enterprises are Salubris, Sanofi, China Resources Sanjiu, Joincare, Hepalink, Sinopharm Zhijun, Mindray Medical, BGI Group, Beike Biotech and Neptunus Bioengineering, in addition to start-ups like Chipscreen and Ausa Pharmed. As of March 2021, Shenzhen is home to 21 publicly listed biotech enterprises.[14] Meanwhile, many leading AI enterprises are expanding into biotech, utilising AI and medical technology to improve screening and diagnosis. Examples include Tencent Healthcare and Ping An Technology's Smart Healthcare platform.

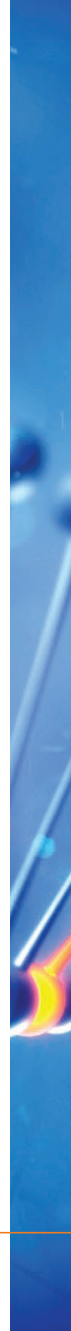
The significance of HK-SZ collaboration

The development of the GBA and the Pilot Demonstration Area of Socialism with Chinese Characteristics (i.e., the "Two Areas") presents Hong Kong and Shenzhen with enormous opportunities. By exploring policy innovations and the bridging of different systems, HK-SZ collaborations on biotech in the Loop can help steer a new course in cross-border collaboration under "One Country, Two Systems", three customs territories, and three legal systems.

With its formidable scientific research capabilities, robust market economic system and world-class business environment, Hong Kong provides biotech enterprises with plentiful and efficient financing opportunities. Meanwhile, Shenzhen has a solid foundation in a multitude of manufacturing industries as well as information and communications technologies. This, coupled with proactive government support, is conducive to the speedy transformation of biotech research outcomes into actual productive capabilities. On the one hand, HK-SZ collaboration can help Shenzhen achieve a system and mechanism for high-quality development; foster a stable, fair, transparent and world-renowned business environment

[14] Of these, ten are on the Main Board, eight on the Growth Enterprise Market and three on the Shanghai Stock Exchange's Sci-Tech Innovation Board.

underpinned by the rule of law in Shenzhen; as well as develop an open economic system. On the other hand, Hong Kong can fully leverage on its unique advantages to proactively participate in the nation's development. This would be conducive to expediting the development of the New Territories North bordering Shenzhen. And by optimising Hong Kong's industrial, spatial and employment structures, HK-SZ collaboration can effectively address such conundrums as insufficient space for industrial development, limited innovative drive and real economy, and a dearth of high-end employment opportunities.



3

Hetao SZ/HK I&T Co-operation Zone as a Pivot: Driving HK-SZ Collaboration Forward

Overview of HK-SZ cooperation

Overlooking the same narrow riverbed, Hong Kong and Shenzhen's biotech industries, academics, and research institutes collaborate frequently. Six Hong Kong universities[15] have established research institutes at the Shenzhen Virtual University Park to pursue advanced research in support of the national plan and for Shenzhen's technological development. These institutes also provide a crucial platform for the implementation of research projects and the cultivation of R&D talent in the Mainland. Hong Kong's universities have also participated in research infrastructure of all kinds. Examples include the Shenzhen-Hong Kong Institute of Brain Science, jointly established by the HKUST with Shenzhen Institutes of Advanced Technology of the Chinese Academy of Sciences (SIAT); the HKU-managed University of Hong Kong-Shenzhen Hospital with full financial support from the Shenzhen Municipal People's Government; as well as the Clinical and Translational Medical Centre being organised by the Hospital. Besides, BGI Group in Shenzhen has been in collaboration with CUHK and HKUST on genomic research and jointly established research centres and laboratories in Hong Kong.

Despite frequent exchanges between the two cities, collaborations in general have been rather fragmented and disorganised. Without a targeted industrial policy to guide the synergistic development of industrial academic and research collaboration, there will continue to be poor coordination between the tertiary education sector, research institutes and enterprises. This leads to the failure to leverage the cities' complementary strengths and maximise their advantages.

Overview of the development of the Hetao Shenzhen/Hong Kong Innovation and Technology Co-operation Zone

Going forward, the Hetao Shenzhen/Hong Kong Innovation and Technology Co-operation Zone at the Loop (Co-operation Zone)

[15] Including the University of Hong Kong, Chinese University of Hong Kong, the University of Science and Technology, City University of Hong Kong, and Baptist University of Hong Kong.

Figure 5 | Hetao Shenzhen/Hong Kong Innovation and Technology Co-operation Zone

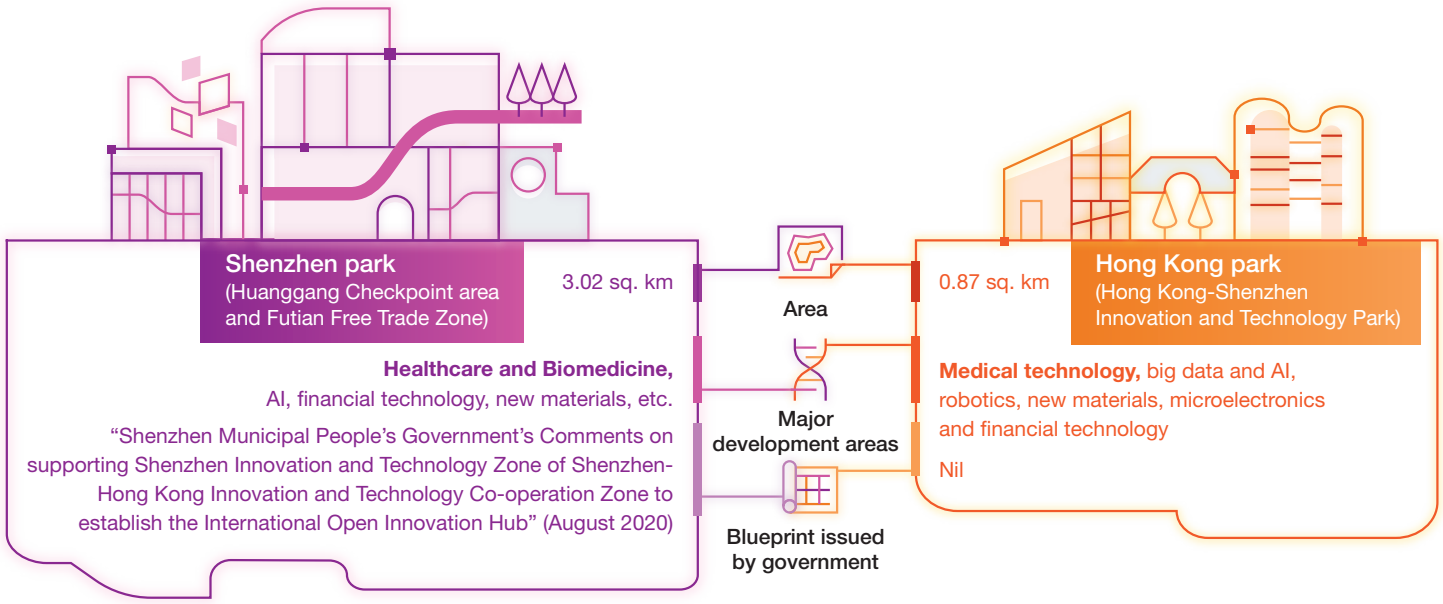
(See **Figure 5**), situated right at the Hong Kong-Shenzhen border, will play a pivotal role in HK-SZ collaboration. The Co-operation Zone is divided into two sections: to the south of Shenzhen River is the Hong Kong park (i.e., the Hong Kong-Shenzhen Innovation and Technology Park[16]), covering an area of 0.87 sq. km at the Lok Ma Chau Loop; to the north of the River is the Shenzhen park (i.e., the Shenzhen Innovation and Technology Zone), taking up 3.02 sq. km of land adjacent to the Lok Ma Chau Loop, including the Futian Free Trade Zone and Huanggang Checkpoint area.

In 2017, the governments of Hong Kong and Shenzhen signed the "Memorandum of Understanding on Jointly Developing the Lok Ma Chau Loop by Hong Kong and Shenzhen" to mark the start of their joint development of the Loop. As both a major strategic platform for building the "Two Areas" and the only platform focused on technological innovation in the GBA, the Loop will have important implications for both HK-SZ co-operation and the development of the GBA.

[16] That is the Area A of the Loop in the Co-operation Agreement on Joint Comprehensive Study of the Lok Ma Chau Loop signed by the governments of Hong Kong and Shenzhen in 2008.

In recognition of "one zone, two parks" at "one river, two banks" as the Loop's mode of collaborative development, the governments of Hong Kong and Shenzhen reached a consensus on the overall planning and operation, as well as the cross-border infrastructure of the Loop. Nonetheless, the progress the two areas have made in industry planning and establishment varies (see **Figure 6**). Even though the operator for the Hong Kong park, i.e., Hong Kong-Shenzhen Innovation and Technology Park Limited (HSITPL),[17] has commissioned two consultancy studies and identified six major development areas, these developments have been halted due to

Figure 6 Progress of the development of Hetao Shenzhen/Hong Kong Innovation and Technology Co-operation Zone



Sources: Hong Kong Legislative Council, Shenzhen Municipal Government, and media reports

[17] Hong Kong-Shenzhen Innovation and Technology Park Limited is a subsidiary wholly owned by Hong Kong Science and Technology Parks Corporation. Of the ten directors in the Board of Directors, four are nominated by the Hong Kong side (including the Chairperson), three by the Shenzhen side, with the other three jointly nominated by both sides.

paperwork, and a concrete or long-term blueprint has yet to be materialised. Meanwhile, the governments of Shenzhen and Futian[18] have already confirmed the planning for the Shenzhen park[19] and committed to aligning itself with the most conducive tech innovation mechanisms from Hong Kong and overseas, and holistically considered how to create a favourable policy environment. Shenzhen park is on track to realise its medium and long-term plans for 2035;[20] and has rolled out a "Policy Package" that supports technological research, and innovation and entrepreneurship in the Shenzhen park.[21] The policies facilitate the input of resources from Hong Kong, Macao and overseas, as well as enable research institutes in the Mainland to go international, thereby opening up the possibility for "the mode of the Loop" in international innovation collaborations.

Figure 7 Current state of the Hetao Shenzhen/ Hong Kong Innovation and Technology Co-operation Zone (aerial view)

Aerial photo taken on 1 June 2021. The island to the south of the Shenzhen River (i.e., the horizontal river in the middle of the photo) where land formation works are in progress is the Hong Kong park. The built-up area to the north of the River is the Shenzhen park (Huanggang Checkpoint area).

In relation to the Zone's construction progress (see **Figure 7**), the first batch of development of the Hong Kong park is expected to begin by the end of 2022 and one-tenth of the total surface area of the park, amounting to around 120,000 sq. m of land covered by buildings, is expected to be completed by phases during the period of late-2024 to 2027.[22] Meanwhile, the Futian Free Trade Zone located at the Shenzhen park completed the construction of a research space of 370,000 sq. m in 2020 and is now in use by four innovation platforms.[23] Demolition works at the Huanggang Checkpoint area were completed in 2020 to free up a total of

[18] The Shenzhen Municipal Government set up the Steering Group on the Development of the Hong Kong-Shenzhen Innovation and Technology Park in the Loop, with its office managed and operated by the Futian District Government.

[19] In August 2020, the Shenzhen Municipal Government issued "Shenzhen Municipal People's Government's Comments on supporting Shenzhen Innovation and Technology Zone of Shenzhen-Hong Kong Innovation and Technology Co-operation Zone to establish the International Opened-up Innovation Hub" (《深圳市人民政府關於支持深港科技創新合作區深圳園區建設國際開放創新中心的若干意見》), which suggested setting up an experimental zone for state-of-the-art biomedical technology in the Loop to achieve policy breakthrough in the adoption of new drugs and new medical devices in use internationally, and to encourage the development of advanced clinical technological research projects on stem cells and immune cells.

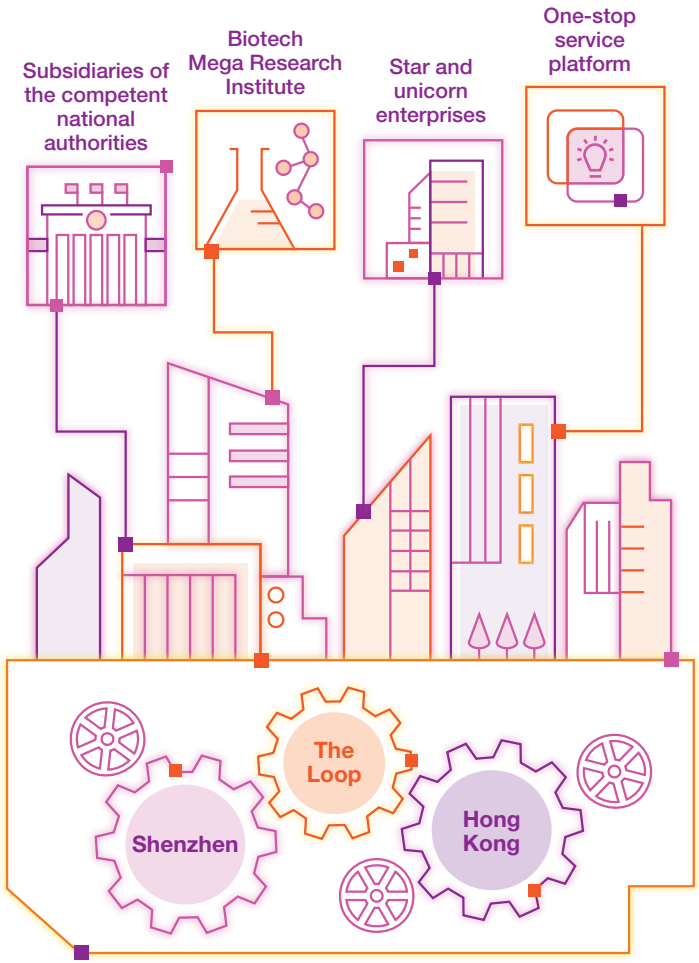
[20] In September 2020, the Shenzhen Municipal government organised a hearing on "Technological innovation planning for Shenzhen Innovation and Technology Zone of Shenzhen-Hong Kong Innovation and Technology Co-operation Zone (2020-2035) (Draft for Consultation)" (《深港科技創新合作區深圳園區科技創新規劃(2020-2035年)(徵求意見稿)》.)

500,000 sq. m of land, with the layout plan confirmed in August of the same year. As of February 2021, 138 research projects, the majority of which are focused on biotech, have been implemented and completed in the Shenzhen park. Many of these projects are collaborations with Hong Kong institutes, including the Clinical and Translational Medical Research Centre of the University of Hong Kong-Shenzhen Hospital, the Institute of Virology of HKU and the Wet Lab for Brain Science of HKUST.

Driving HK-SZ sustained development with the Co-operation Zone

Hong Kong and Shenzhen can leverage their complementary advantages to achieve win-win co-operation. As engines of growth in I&T development within the GBA, the sum of the two are greater than their parts. In order to address the lack of coordination

Figure 8 Ways by which the Co-operation Zone fosters HK-SZ sustained development



[21] In August 2020, the Futian District Government issued "Supporting Measures for technological research, innovation and entrepreneurship in Shenzhen Innovation and Technology Zone of Shenzhen-Hong Kong Innovation and Technology Co-operation Zone" (《深港科技創新合作區深圳園區科研及創新創業若干支持措施》) Subsequently, in January 2021, the "Supporting Measures for technological research, innovation and entrepreneurship in Shenzhen Innovation and Technology Zone of Shenzhen-Hong Kong Innovation and Technology Co-operation Zone at the Loop (《河套深港科技創新合作區深圳園區科研及創新創業若干支持措施》)" was revised and published.

[22] Hong Kong park is developed in two phases, which are each divided broadly into three batches. Three buildings are set to complete in stages in 2024–25 during the first batch of the first phase; another five buildings will be completed in 2025–27. Four buildings of the entire batch are mainly designated as wet labs.

[23] The four innovation platforms include the Hong Kong-Shenzhen Innovation and Technology Park, International Biomedical Industrial Park, International Quantum Research Institute and Shenzhen-Hong Kong Synergistic Innovation Centre.

between the two cities, a "pivot" is required to conduct technology transfer that brings basic research outcomes from Hong Kong into Shenzhen for mass production. A pivot can also improve governmental, industrial, academic and research linkage between the two cities by facilitating the sharing of resources and facilities like research funding, enterprises, parks and national large-scale scientific facilities between Shenzhen and Hong Kong organisations. As the Loop is at the forefront of HK-SZ co-operation, enjoying a more flexible regime structure and significant policy support, it is well-positioned to synthesise the research and industrial advantages of the two cities and play the role of the pivot in driving forward collaborative development between Hong Kong and Shenzhen (see **Figure 8**).

The Loop should establish itself as a comprehensive and multifaceted industrial system that is attractive to sophisticated, leading biomedical enterprises and star enterprises specialised in various biotech subsectors, and commit itself to nurturing promising local start-ups into unicorns. [24] It should also leverage Hong Kong's vital role in connecting mainland China with other countries and create an international innovation powerhouse in biotech by congregating the best enterprises from Hong Kong, Shenzhen and abroad. To realise this vision, we believe the Loop should encompass four main categories of enterprises or platforms: a cross-border biotech mega research institute, subsidiaries of competent national regulators, a one-stop service platform dedicated to biotech transfer, as well as star and unicorn enterprises.

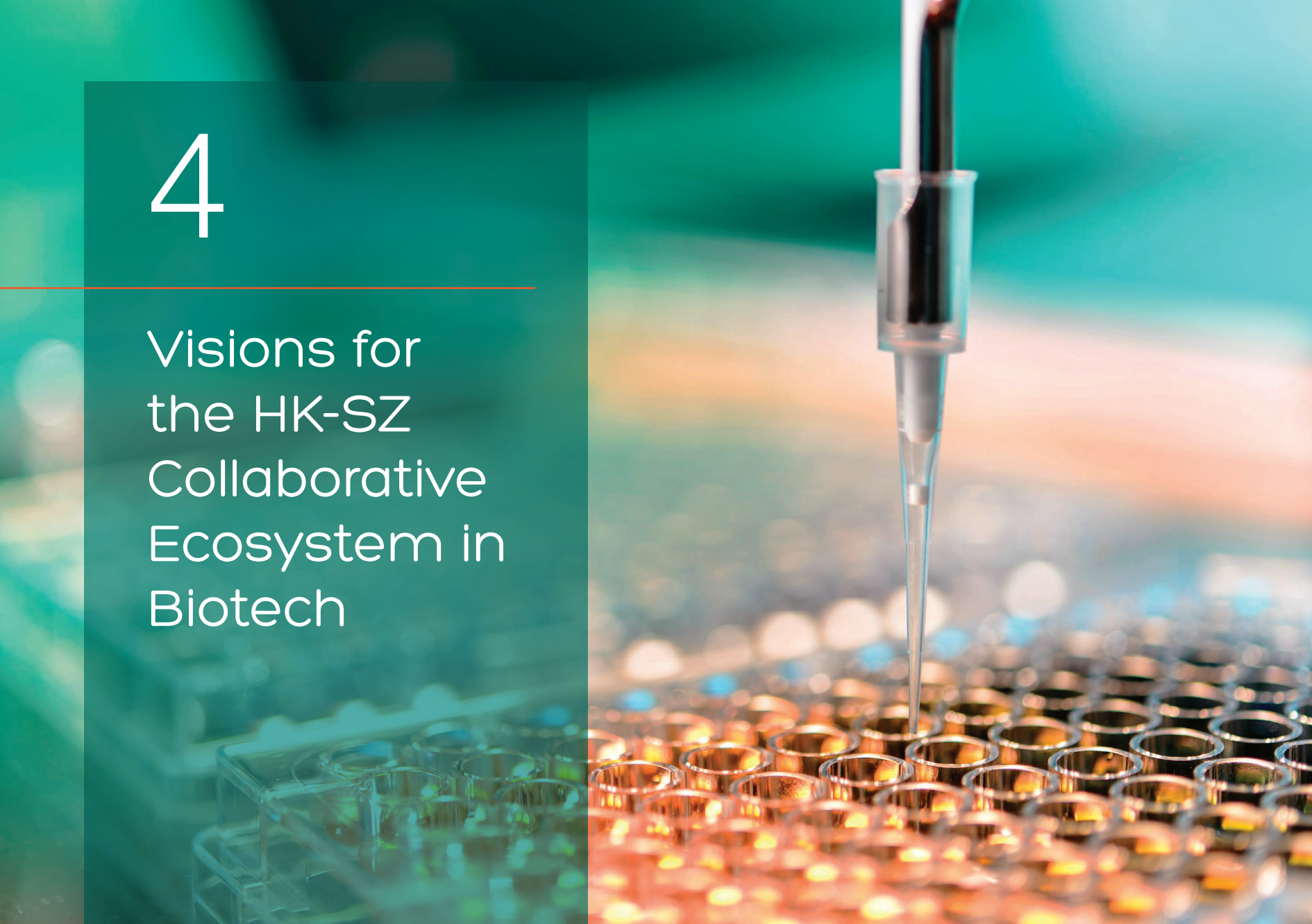
Apart from housing these facilities and organisations, the Loop can play a pivotal role in exploring the best and most innovative biotech policies in relation to cross-border collaboration. When it comes to the overall development direction, the "two parks" should be treated as "one zone" rather than individually: where the two cities differ in systems and standards, the more flexible system and the more internationalised standards should be adhered to in order to support the speedy development of advanced industries; and where they differ in incentive policies and measures, greater incentives and more supportive measures should be adopted. Harmonising such differences can help prevent researchers and enterprises from flowing one way and congregating into a particular park. Such measures will then enable the Loop to pursue holistic, collaborative development as a whole, and serve as a pivot that drives the long-term development of the two cities. We shall elaborate on this further in our policy recommendations in **Chapter 5** and **Chapter 6**.

[24] Usually refers to privately held start-ups founded within the last ten years with a valuation of over USD 1 billion.

As the pivot interlocking the two cities, the Loop can better connect HK-SZ advantages to strengthen collaboration and optimise the biotech ecosystem, thereby fostering an international innovation hub in the GBA. Our goals for the Loop are as follows: 1) to be a pilot and demonstration area for collaboration between Hong Kong and Shenzhen in biotech with a view to explore the most effective modes of cross-border collaboration and the most sophisticated biotech policies; 2) to be a pilot area for international biotech regulatory standard-setting and whose best practices can be used to build the most advanced and robust regulatory regime in the Mainland; and 3) to be a biotech transformation cluster in the GBA that expedites the deployment of advanced scientific findings into production.

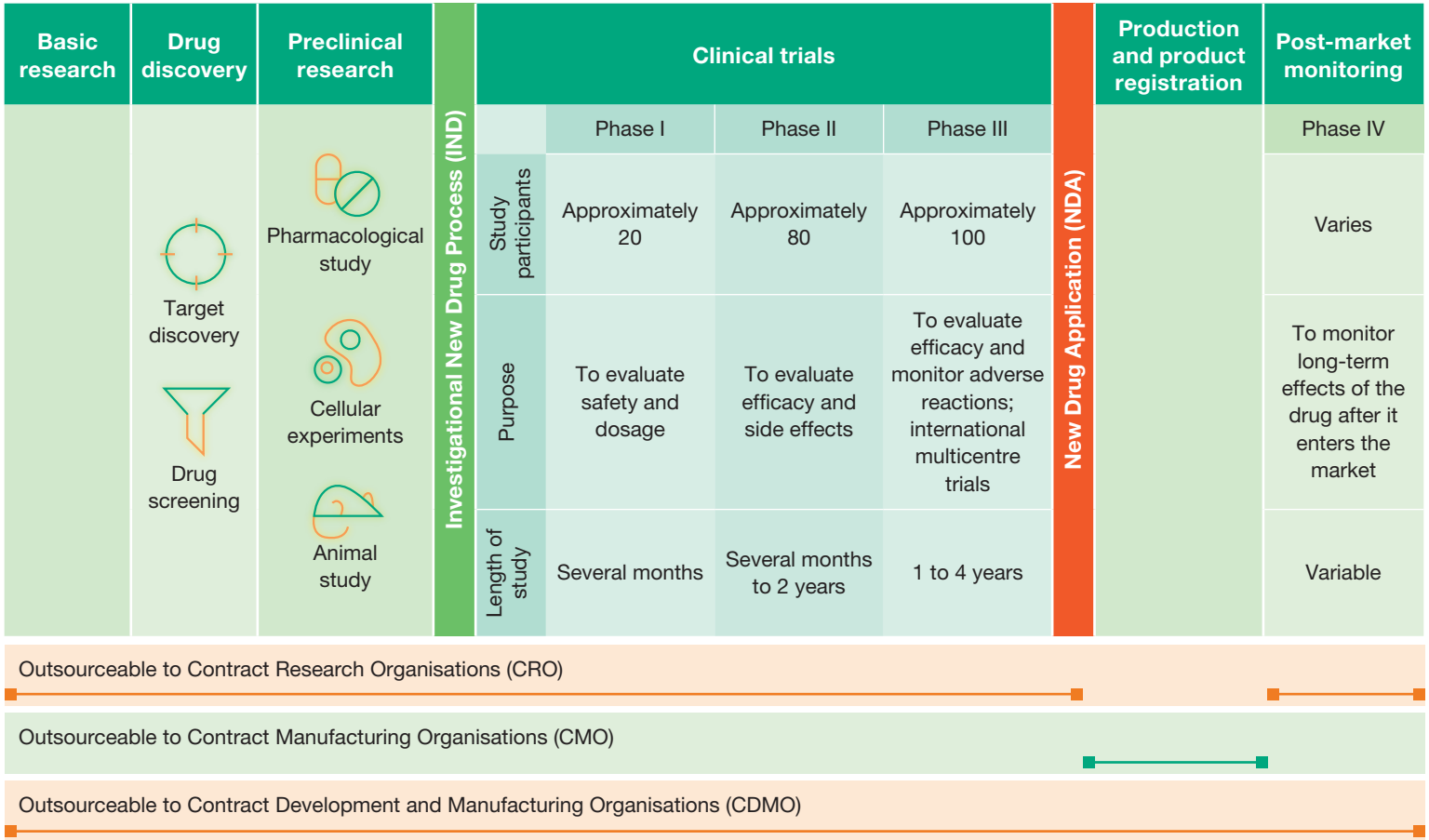
4

Visions for the HK-SZ Collaborative Ecosystem in Biotech



In the past, the mode of I&T collaboration between Hong Kong and Shenzhen was often described as basic research by tertiary institutions and research institutes in Hong Kong, followed by the deployment of research outcomes by Shenzhen, which utilises its comprehensive supply chain to carry out large-scale production of the research outcomes for the huge Mainland market. However, industrial collaboration between the two cities is no longer confined to a division of labour along research and production lines, nor is it a simple sum of production elements and procedures of the two cities. Rather, it is better represented as an integration of innovative resources from Hong Kong and overseas with Shenzhen's supply chain to form an industrial cluster with complementary advantages. There is therefore not just one mode of HK-SZ collaboration. The two cities need to collaborate closely across every stage in the R&D process and may play different roles in the supply chain of various biotech niches. This chapter will focus on four areas: drugs and vaccines, genetic testing and therapies, advanced medical devices and application of AI to biotechnology, all of which are important branches of biotech that lend themselves well to existing advantages of the two cities. HK-SZ collaboration in these four areas can be highly valuable.

Figure 9 | R&D process for conventional drugs



Note: Describes the R&D process for conventional drugs (biological and chemical drugs). Vaccine development requires different numbers of study participants: 20-80 in Phase I; several hundred in Phase II; 300–3,000 in Phase III. The required numbers for gene therapy and cell therapy are smaller.

Biomedical development process

In the biomedical industry, [25] the R&D process for drugs and vaccines is the most complex, and conceptually touches on processes in other areas like genetic testing and therapies and advanced medical devices. We therefore give a simple overview of the conventional R&D process for drugs and vaccines in **Figure 9**, which broadly divides itself into drug discovery, preclinical research, clinical trials and production and product registration.

The drug discovery stage begins with target discovery, where the pathogen or genetic mutation of the relevant illness and the signal transduction pathway are identified. The next step is called drug screening, which is the search for biomolecules or chemicals that can act on the target to treat the disease, and the identification and optimisation of the candidate compounds.

Preclinical research, meanwhile, entails pharmacological study, cellular experiments and animal study. Pharmacological study is concerned with pharmacodynamics, pharmacokinetics and toxicology study,[26] and can be conducted in vitro (in test tubes or cell culture) or in vivo (in the body of animals). Animal tests can be conducted in laboratories designed for small animals (e.g., mice) or large animals (e.g., dogs, pigs and monkeys). While laboratory standards differ according to experiments, they have to be conducted in laboratories conforming to Good Laboratory Practice (GLP) guidelines set forth by the competent drug regulator. [27]

Following the preclinical stage is the clinical trial stage, where tests are conducted in the human body. Drug developers are required to submit an Investigational New Drug Process (IND) application to the competent authorities (see **Figure 10**). The clinical stage is divided into four phases, with study participants, purpose and length of study varying at each stage. Generally speaking, as the study progresses in phases, the length of study and number of participants increase, while technical complexity decreases. Therefore, Phase I trials need to be conducted in a region with established clinical strengths and a shorter length of study, while later phases are mainly conducted simultaneously around the world with a multicentre approach. Clinical trial procedures need to conform to Good Clinical Practice (GCP) guidelines.[28] The above processes from drug discovery to clinical trials may be conducted by pharmaceutical companies themselves or outsourced to universities or Contract Research Organisations (CRO).

[25] According to documents published by the Shenzhen Municipal Government, the biomedical industry can be broadly defined to encompass conventional drugs, advanced medical devices, the integration of bioinformatics and information technologies, bioengineering, etc.

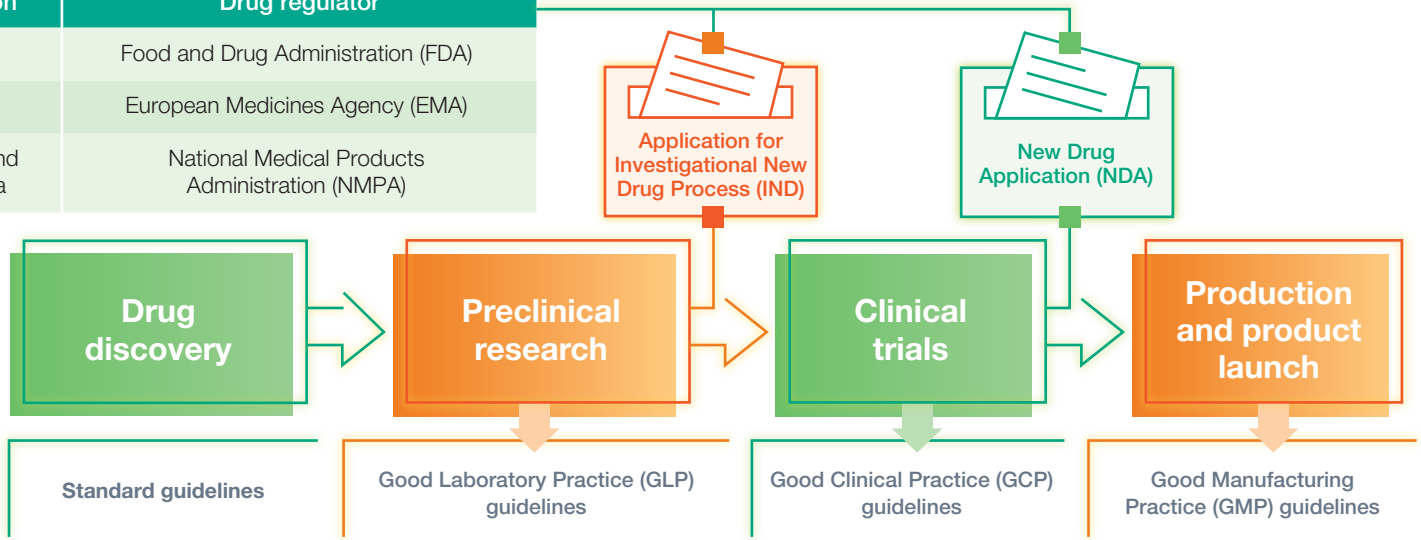
[26] Pharmacodynamics studies the effects of drugs on the body; pharmacokinetics studies how drugs change in the body, including their absorption, distribution, metabolism and excretion; toxicology study seeks to understand drug exposure and toxic reactions.

[27] In 1992, the Organisation for Economic Co-operation and Development (OECD) formulated the most influential set of GLP guidelines which became the basis on which different countries adapted and optimised their own guidelines. China's GLP for Non-Clinical Laboratory Studies guidelines came into effect on 1 September 2017.

[28] In 1996, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) formulated the GCP guidelines, which became the standards on which different countries adapted and optimised their own guidelines. China's newly-revised GCP came into effect on 1 July 2020.

Figure 10 Regulatory standards of the biomedical industry

Region	Drug regulator
US	Food and Drug Administration (FDA)
EU	European Medicines Agency (EMA)
Mainland China	National Medical Products Administration (NMPA)



Note: The Chemistry, Manufacturing, and Controls (CMC) encompasses stages like drug discovery, preclinical research, clinical trials, production and product registration, and have to be in compliance with GMP standards.

After clearing the clinical trial and New Drug Application (NDA) stages and receiving approval from the competent authorities, new drugs and biologics may proceed to the commercial production stage. Provided that production facilities conform to Good Manufacturing Practice (GMP) guidelines,[29] production may be handled by the pharmaceutical companies themselves or outsourced to Contract Manufacturing Organisations. Meanwhile, Contract Development and Manufacturing Organisations (CDMO) can take up commercial production as well as the Chemistry, Manufacturing, and Controls (CMC) of the entire R&D process,

[29] Apart from the standards devised by the World Health Organization (WHO), guidelines formulated by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) are widely adopted around the world. In China, the Good Manufacturing Practices for Pharmaceutical Products (Revised 2010) came into force on 1 March 2011.

such as the use of chemicals during the drug discovery stage and quality control and manufacturing of pilot[30] batches in clinical trials, all of which need to be in compliance with GMP.

The major drug regulatory and management organisations mentioned above usually include the Food and Drug Administration (FDA) of the US, the European Medicines Agency (EMA), and the National Medical Products Administration (NMPA) of China, etc. In Hong Kong, preclinical research, clinical trials, production and approval for product registration are under the purview of the Pharmacy and Poisons Board (PPB) of Hong Kong and the Drug Office of the Department of Health (DH), the Board's executive arm. Yet the scale of the PPB is significantly smaller than the three aforementioned regulators and it also does not have any independent capacity for new drug approval.

Drugs and vaccines

Drug and vaccine innovation is a critical part of the biomedical industry, and also one of its most lucrative sub-sectors. Hong Kong is internationally renowned for its clinical trial prowess, with many specialties in four local hospitals having received NMPA approval[31] to conduct clinical trials of drugs. Additionally, clinical trials conducted in various hospitals of Hong Kong have frequently won the recognition of the FDA and EMA. The HKU Clinical Trials Centre affiliated with Queen Mary Hospital, in particular, is a founding member of the International Clinical Trial Center Network (ICN), which gives it the same stature as the clinical trials centres of Harvard University and Cambridge University. Many leading global pharmaceutical companies like AstraZeneca and Pfizer have conducted clinical trials in Hong Kong. Meanwhile, Shenzhen is home to a number of mature pharmaceutical companies like Hepalink Pharmaceutical, Kangtai Biological Products, Chipscreen, etc. It also attracts large international pharmaceutical companies like Sanofi Pasteur to establish research and production facilities there.

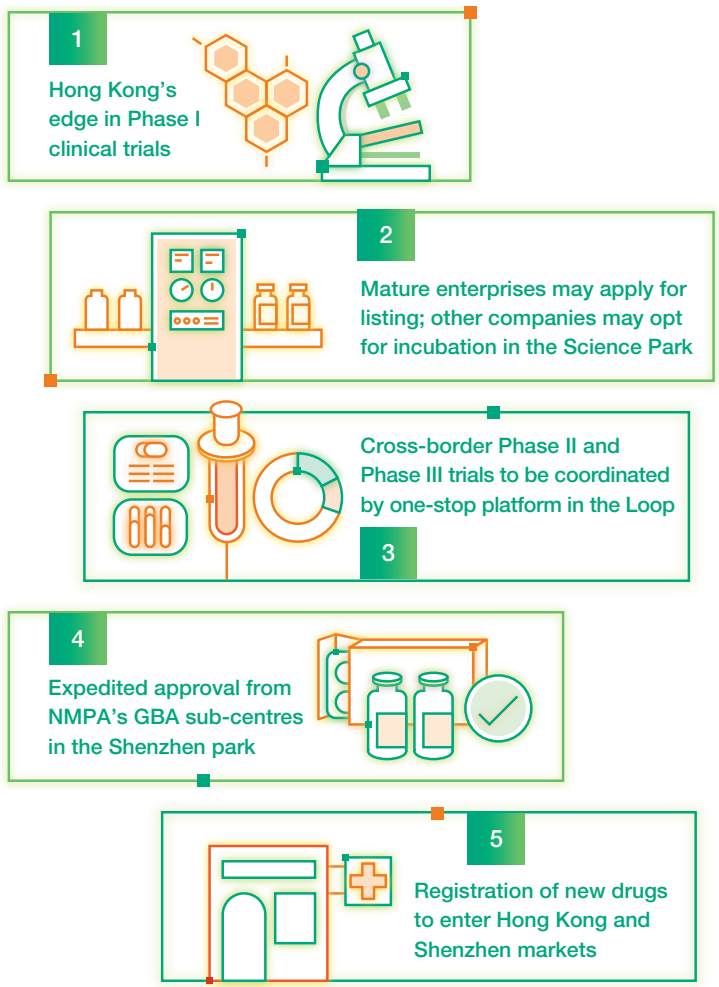
To unleash the competitive edges the two cities enjoy in drug development, the government departments concerned should proactively attract or encourage enterprises that have completed preclinical research to conduct clinical trials in the two cities. Under our recommendations, Phase I trials will be conducted in Hong Kong's clinical trials centres (see **Recommendation 2.3**). Upon their completion, mature companies can apply for listing in Hong Kong after fulfilling the HKEX's listing requirements, while other companies can establish a presence in the Hong Kong Science Park or the Loop to take advantage of supportive incubating measures such as venue and equipment provision, funding from the two cities and business matching, etc. (see **Recommendation 1.2**) Thereafter, as the companies move forward with Phase II and III trials using a multicentre approach, they will engage medical intermediaries or Contract Research Organisations (CRO) in the Loop[32] to coordinate and manage clinical trials involving the joint effort of numerous hospitals in

[30] A pilot batch is produced during the product development stage for quality testing purposes. For biotech products, a pilot batch is primarily produced for use in clinical trials.
[31] Including Queen Mary Hospital, Prince of Wales Hospital, Hong Kong Eye Hospital, and Hong Kong Sanatorium & Hospital.

Hong Kong, Shenzhen[33] and the GBA (see **Recommendations 2.4**). Detailed procedures are illustrated in **Figure 11**.

Upon completion of Phase III trials, enterprises can register their new drugs with drug regulators of various countries and regions using the Loop's one-stop service platform (see **Recommendation 3** for details). For the mainland Chinese market, enterprises can enjoy expedited drug approval by submitting an NDA to the NMPA's GBA sub-centres in the Shenzhen park[34] (see **Recommendation 6.3** for details); upon approval of the new drug, they can proceed with commercial production in Shenzhen, followed by registration in the Mainland. For the Hong Kong market, unlike now, NMPA-approved pharmaceutical products will be recognised by Hong Kong's DH so enterprises will be able to proceed with the production and sale of advanced products in Hong Kong after obtaining NMPA approval (see **Recommendation 2.5** for details). The all-stage, multifactored mode of collaboration will help maximize the two cities' competitive edges, improve the drug and vaccine production chain, and establish a world-class biotech industrial cluster.

Figure 11 Co-operation procedures for HK-SZ biomedical development



[32] For instance, the HKU Clinical Trials Centre has set up a limited company in mainland China in preparation for establishing a presence in Futian, Shenzhen, with a view to introducing Hong Kong's world-class clinical trial management experience into the Mainland and offering its service to enterprises and research institutes.

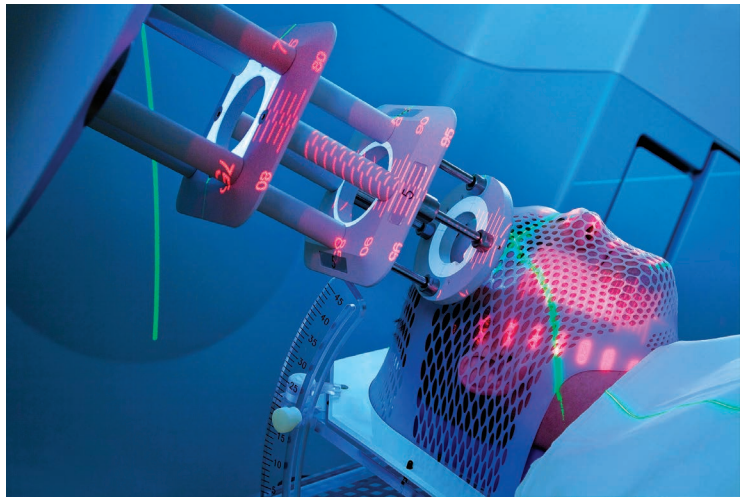
[33] According to the NMPA's website, certain specialties in 19 Shenzhen hospitals have received GCP-accreditation from the NMPA.

[34] On 23 December 2020, the NMPA's GBA sub-centres were established, in charge of the approval and inspection of drugs and medical device technology in the Hetao Shenzhen-Hong Kong Science and Technology Innovation Cooperation Zone.

Genetic testing and therapies

Genetic testing is the evaluation of gene-related diseases, physical fitness and personal traits by employing the tools of chromosome structures and DNA sequences. Armed with genetic technology, scientists have developed more targeted therapies that treat illnesses by correcting or replacing faulty genes. Genetic testing, diagnostics and therapies provide the foundations for sustained development of precision medicine, which, unlike conventional medicine, takes into consideration differences in genes, the environment and living habits to achieve customised and precise treatment. Hong Kong universities have achieved excellent results in basic and applied genomic research, most notably in the research output of Professor Dennis Lo Yuk-ming of CUHK. Meanwhile, Shenzhen enjoys certain advantage in genetic testing and precision therapies. In addition to boasting leading national enterprises like BGI Group, Shenzhen has already developed into the world's largest genomic research centre and the national leader of DNA sequencing application. Shenzhen's China National GeneBank is the world's fourth-largest comprehensive gene bank and contributes to roughly 40% of global DNA sequencing data.[35] Hong Kong and Shenzhen can therefore achieve win-win co-operation in these areas to unleash enormous potential.

Under our recommendations, Hong Kong universities and enterprises will join force with Shenzhen's research institutes and enterprises to pursue collaborative R&D through the large biotech research institute (see **Recommendation 1.3** for details), with the Hong Kong corporate branch focusing on Hong Kong and overseas markets and the Shenzhen branch on the Mainland market. We also recommend relaxing market access restrictions, which we will elaborate on later (see **Recommendation 6** for details).



[35] The world's three largest gene banks are the National Center for Biotechnology Information (NCBI) of the US, the European Bioinformatics Institute (EBI) and the DNA Data Bank of Japan (DDBJ).

Advanced medical devices

Another major priority is advanced medical devices, which utilise AI technology to substantially improve surgical accuracy. HK-SZ collaboration in advanced medical devices can fully integrate and unleash Hong Kong's medical advantages and Shenzhen's expertise in AI. With a strong record in medical research, Hong Kong has an edge in medical device development, and has long provided clinical advice on medical devices like MRI and CT. Hong Kong is therefore well-positioned to design and develop clinical medical devices and take charge of quality management later. Meanwhile, home to top-notch AI companies like Tencent and DJI, Shenzhen has formidable expertise in software development technology and quality management; Shenzhen also boasts enterprises with strong experience in medical devices like Mindray Medical. An enterprise that installs itself in the Loop can therefore leverage the two cities' talent pool and industrial advantages, as well as the comprehensive development and supply chain in advanced medical devices. Also, as illustrated above, given that Hong Kong's clinical trial prowess is highly recognised and that medical device development requires fewer study participants compared to drug development, clinical trials for medical device products can also be conducted in Hong Kong after the design process is completed.

In summary, Hong Kong universities and enterprises can focus on prototype development, with the Hong Kong side taking charge of medical engineering and the Shenzhen side concentrating on computing and programme development. For Class II or III medical devices,[36] enterprises can, upon completion of preclinical research, conduct clinical trials in Hong Kong's specialty departments or clinical trials centres that are recognised by major drug regulators around the world.[37] Similarly, for subsequent quality management, Hong Kong can focus on hardware verification and validation while Shenzhen can conduct software testing. Finally, enterprises can enjoy expedited approval for production and product registration in the Mainland via the NMPA's GBA sub-centre for the Approval and Inspection of Medical Device Technology in the Shenzhen park. Commercial production may commence in either Hong Kong or Shenzhen after approval is granted.

[36] There are generally three classes of medical devices: Class I devices are low-risk devices that are usually unregulated; Class II devices are intermediate-risk devices, and they can be registered to enter the market by means of notification to the NMPA, with only a few requiring the submission of clinical trial data; Class III devices are high-risk devices regulated by the NMPA that requires the submission of clinical trial data.

[37] In the absence of legislation governing the regulation of medical devices in Hong Kong, enterprises can elect to apply for recognition by choice.

AI and biotech

One of the major trends at the forefront of biotech is the application of AI. By utilising AI algorithms, technologies and platforms, such as big data and machine learning, it is possible to substantially increase the efficiency of biotech R&D, image analysis and disease diagnosis. AI can also be applied to drug development and clinical data prediction to optimise the R&D process for biotech research. Notably, AI biotech giant Insilico Medicine has moved its global headquarters from the US to Hong Kong and located its drug development and clinical data prediction platforms in Hong Kong. Such application can drastically reduce the length of study and R&D costs. For instance, Insilico Medicine's trailblazing application of AI led to the discovery of a clinical compound candidate with the potential to treat idiopathic pulmonary fibrosis. The company has proceeded to the preclinical research stage, with the entire R&D process taking a mere 18 months and USD 2.6 millions, which is highly cost-effective compared to the conventional drug development process that on average takes 4.5 years and USD 670 millions.

Moreover, AI technology can boost the effectiveness of image analysis and disease diagnosis. At the height of the COVID-19 outbreak in mainland China, hospitals in Wuhan began to employ the algorithm software, called Axial AI and developed by AI enterprise Skymind, to analyse CT images of patients' lungs in seconds. That greatly reduced the time doctors spent on studying the images and sped up diagnoseis of COVID-19 with an accuracy of over 90%. Public hospitals in Hong Kong have also introduced the technology and have started employing AI to identify patients whose chest images show potential infection with COVID-19 and require medical attention immediately.

Similar to advanced medical devices, given Hong Kong's edge in biotech research and healthcare and Shenzhen's leading AI technologies, HK-SZ collaboration in the niche of "AI + biotech" stands a chance of achieving nationally and even internationally leading standards. By establishing their presence in the Loop, enterprises can leverage the two cities' talent pool and industrial advantages to efficiently promote business growth.

5

Policy recommendations for the governments of Hong Kong and Shenzhen

To foster an ecosystem for HK-SZ collaboration in biotech, the two governments need to devise a long-term, concrete and comprehensive development plan. In this chapter, we shall focus on some of the issues hampering HK-SZ collaboration and propose policy recommendations for the reference of the two governments. To ensure long-term collaborative development under "one zone, two parks" at the Loop, coordination on the policy-making level should be stepped up to prevent talent and enterprises from flowing one way and congregating into a particular park owing to differences in tax and rental incentives.

Establishing anchor institutions in the region to expedite development of a biotech industrial cluster

Anchor institutions usually refer to core institutions or enterprises in a specific area. There are two types of anchor institutions, one of which is top universities or mega research institutes. Through fundamental scientific research and knowledge transfer, these institutions support local enterprises of various scales with basic research and help nurture spin-off enterprises of high potential into unicorns, thereby generating huge profits with research outcomes. The other type of anchor institutions is large enterprises, such as large pharmaceutical corporations, which draw small and medium-sized enterprises (SMEs) to relocate near them so as to take part in the upstream or downstream operations or seek opportunities for acquisition by the giants. Anchor institutions play a crucial role in the development of the local economy and industries as they create numerous employment opportunities and drive the growth of upstream and downstream industries, as well as generating a good source of tax revenues.

Nonetheless, there is a lack of world-class leading biotech corporation or industrial cluster in either Hong Kong or Shenzhen. Despite the rapid growth of industry in Shenzhen, there are relatively fewer leading core enterprises and major multinationals. SMEs make up the majority of biomedical companies in Shenzhen, along with a few medium-sized companies that constitute the backbone of the industry. Thus, there are few companies with the potential to grow into leading enterprises. One of the reasons behind so is the absence of anchor institutions, which exert significant influence on their surrounding areas.

However, there is no lack of successful cases of anchor institutions in other areas. Take Zhangjiang Hi-Tech Park in Shanghai as an example. Right from the start of development, the municipal government and the operator of the Park took the initiative to attract giant multinational pharmaceutical corporations, such as Roche and GSK, to set up regional headquarters or R&D centres in the park. The establishment fostered the formation of a local biomedical supply chain, hence attracting and nurturing local innovative pharmaceutical companies like Green Valley, CITIC Guojian Pharmaceutical Industry Co., MicroPort and Fudan-Zhangjiang. Another good example can be found in Greater Boston in the US, which houses an all-rounded and multifaceted world-class biotech industrial cluster. In the following section, we shall analyse the example of Kendall Square in Greater Boston before proposing a multipronged strategy to build a biotech industrial cluster in the Loop by establishing anchor institutions.

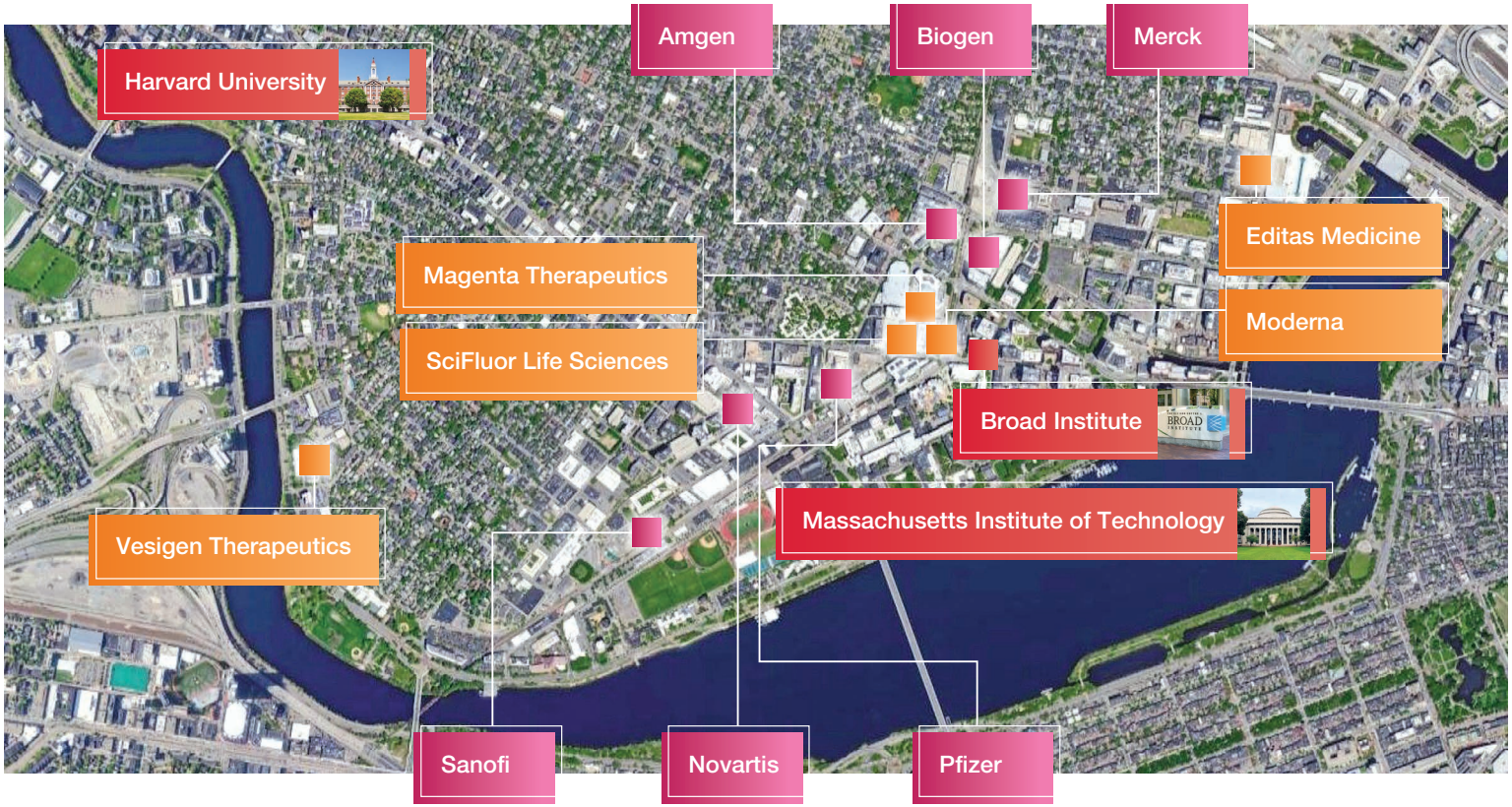
Kendall Square: Greater Boston's Biotech Industrial Cluster

Encompassing Boston and Cambridge, Massachusetts, Greater Boston is a top cluster for health sciences in the US, where 19 out of the 20 largest pharmaceutical companies locate their offices. With Kendall Square as its centre and strategic proximity to the Massachusetts Institute of Technology (MIT) and Harvard University, the area is frequently named "the most innovative square mile on the planet" (see **Figure 12**). Attracted by top universities, a top-notch talent pool and policy incentives, large pharmaceutical corporates (marked in pink in the figure), including Novartis, Pfizer, AstraZeneca, etc., have set up their regional headquarters or R&D centres in the area. Many start-ups with great potentials (marked in orange in the figure) can also be found there. Among them, many are spin-off companies of universities, such as Moderna, a spin-off of Harvard University that developed a COVID-19 vaccine. These start-ups have gradually grown into unicorns. They also stand a good chance of going public or being acquired by conventional large pharmaceutical enterprises.

In 2004, MIT and Harvard University jointly established the Broad Institute, a biotech mega research institute with the objective of enhancing in-depth, cross-disciplinary, cross-institutional and multinational research to find solutions for complex, contemporary biomedical conundrums. The Institute's advanced research further fosters industrial, academic and research collaboration; promotes the commercialisation of research outcomes; and nurtures the rapid development of a biotech industrial cluster in Kendall Square.

Kendall Square sets a good example for the development of a biotech industrial cluster in the Loop. By drawing in star and leading enterprises within a short period of time, the Loop can quickly create a favourable environment for local start-ups and industrial development. At the same time, nurturing local potential start-ups into unicorns will advance the overall industrial growth in the area. Building a biotech mega research institute is, in the long run, beneficial to industrial, academic and research collaboration building upon strong basic research and to encourage the industrialisation of advanced technology in the area.

Figure 12 | Biotech industrial cluster in Kendall Square and its vicinity



Note: International large pharmaceutical corporations are marked in pink squares; biotech companies founded by researchers of Harvard University, MIT and/or Broad Institute are marked in orange squares; red square indicates the Harvard University, Massachusetts Institute of Technology, and Broad Institute.
Photo source: Google Maps

Recommendation 1.1 | Attracting leading enterprises to establish a presence in the Loop

In the near future, both governments, including InvestHK,[38] the Economic and Trade Office of the Hong Kong SAR Government[39] and the Hong Kong Science and Technology Parks Corporation (HKSTP) on the Hong Kong side; and the Shenzhen Science and Technology Innovation Commission and Commerce Bureau of Shenzhen Municipality on the Shenzhen side, should reach out to leading enterprises proactively.

They can offer tax relief, rent reduction and government-guaranteed low-interest loans, in the hope of attracting leading biotech corporations in China and overseas to establish their headquarters or R&D centres in the Loop. They will in turn develop into anchor institutions in the area.

In relation to tax mechanisms, though the profit tax rate in Hong Kong is lower than those in Singapore and Australia, the latter two offer more attractive tax concession policies (see **Table 4**). In terms of tax concessions for enterprises, Singapore offers tailormade incentives—a tax exemption for 5 to 15 years—to high tech corporations. For start-ups, the Singaporean government offers tax exemptions of a given percentage on the first SGD 200,000 of chargeable income. As for tax incentives for research and development, the Australian government has a tax rebate based on R&D costs. In contrast to tax deductions provided in Hong Kong and Shenzhen, this tax refund allows tech companies without a profit to receive a direct refund of part of their R&D expenses. Owing to its long R&D cycle and huge amount of capital required, biotech enterprises take more time to make a turnover than their conventional counterparts. Therefore, a tax refund policy is of vital importance to biotech start-ups.

As for Shenzhen, not only is the tax rate higher, but tax concessions of a similar nature are absent. Though eligible enterprises are entitled to a lower tax rate,[40] the Shenzhen park is excluded from the area covered by the enterprise income tax concession pilot programme. However, more open economic reforms have been put in place in other areas of China. Since 2020, the Hainan Free Trade Port, for one, has implemented lower tax rates (15%) for certain industries, including medicine, scientific research, technological service, etc.[41] To avoid inconsistency in tax concession policies in the two parks, the governments of

[38] InvestHK of the Hong Kong SAR Government provides professional advice and services to support overseas and Mainland entrepreneurs, SMEs and multinationals that wish to set up an office or expand their existing business in Hong Kong from the planning stage right through to the launch and expansion of their business.

[39] With their 17 and 13 offices in the Greater China Region and overseas respectively, Hong Kong Economic and Trade Offices (HKETOs) are responsible for enhancing the world's knowledge about the unique advantages of Hong Kong, boosting the economic and trade benefits of Hong Kong, and supporting enterprises on their business expansion in Hong Kong.

[40] Tax concessions in the mainland China are applicable to: corporate income tax rate for high-tech enterprises with support from the State, Small and Thin-profit Enterprises, and selected industrial enterprises in Qianhai, Hengqin and Pingtan in Fujian Province. The tax rates are 15%, 20% and 15% respectively.

[41] For details, please see "Notice Concerning Preferential Corporate Income Tax Policy in the Hainan Free Trade Port" issued by the Ministry of Finance and the State Administration of Taxation in 2020.

Table 4 | Comparison of tax rates and concessions in different places

Policy	Hong Kong	Shenzhen	Singapore	Australia
Profits tax rate	First HKD 2 millions: 8.25%; Above 2 millions: 16.5%	25%	17%	30%
Corporate tax concession	NIL	NIL	Different tax concessions, such as: **Manufacturers or providers of products and service with high technological content:** 5–15 years tax exemption. **Enterprises with headquarters in Singapore:** Tax exemption or preferential tariff rate, depending on their contributions to the local economy.	NIL
R&D tax concession	First HKD 2 millions: 300% tax deduction; Above 2 millions: 200% Tax deduction	**Concessions for R&D from Central Government:** additional deduction of 75%, on top of other tax deductions. **Concessions for eligible technology transfer by high-technological enterprises:** Not more than RMB 5 millions: 100% tax deduction; Balance: 50% tax deduction.	250% tax deduction	Tax refund: 43.5% or 38.5% of R&D costs, depending on the annual revenue of enterprise. 30% tax refund for R&D cost amounting to AUD 0.1 billion. R&D cost must be at least AUD 20,000.

Note: Only profits tax rates applicable to general enterprises are listed. The lower tax rates various governments designated for selected categories of enterprises are not included here.
Source: PricewaterhouseCoopers

Hong Kong and Shenzhen can draw on the policies of the Australian Government as a reference and jointly implement an R&D tax refund policy for corporates in the Loop. For biotech enterprises without headquarters or R&D centres in the Loop, the Shenzhen government can also appeal to them with a corporate income tax rate of 15% in the Shenzhen park.

Comparing the rents of different innovation and technology parks, we find that enterprises have to pay higher rents for offices and laboratories in the Hong Kong park (see **Table 5**). Meanwhile, rents in Singapore are as low as half of those in Hong Kong, while rental costs in Shenzhen are much more competitive, at less than 20% of Hong Kong's rental cost. The current rental cost in the Shenzhen park is similar to the current rental cost in Guangming Science City.[42] Therefore, we suggest that the Hong Kong SAR Government and HKSTP explore the feasibility of rent reduction and offer more competitive rents in the Hong Kong park to attract enterprises.

Table 5 Rent comparison of innovation and technology parks

Innovation and Technology Parks	Rent (sq. ft. per month)
Hong Kong Science Park	HKD 23–32
Biopolis, Singapore	HKD 14–21
Technology Park Bentley, Australia	Approx. HKD 6
Guangming Science City, Shenzhen	Approx. HKD 5

Sources: HKSTP, sbwl.com, JTC Corporation of Singapore, Burgess Rawson of Australia

[42] Under the "Supporting Scheme of Enterprise Offices" of the "Support Measures for Scientific Research, Innovation and Start-ups in the Shenzhen Park of the Shenzhen-Hong Kong Innovation and Technology Co-operation Zone in the Loop", office rental support of $50/sq. m per month is given to tech enterprises, provided that the supporting area does not exceed 1,000 sq. m. The support will last for 36 months at most, starting from the date the first subsidy is issued.

[43] In 2020, the Hong Kong SAR Government launched Enhancements to the Special 100% Loan Guarantee but it is not a long-term policy. Instead, it aims to support businesses affected by the pandemic.

Many governments also provide enterprises with government-guaranteed low-interest loans. Launched in 2011 by the Hong Kong SAR Government, the SME Financing Guarantee Scheme aims to help local SMEs and non-listed enterprises obtain financing from participating lenders to meet their business needs. Eligible enterprises may enjoy subsidised interest rates and guaranteed coverage for 5 to 7 years by the Hong Kong government.[43] Starting from 2020, the Shenzhen government has provided guaranteed loans for start-ups. The loan is offered by a government-guaranteed fund (guaranteed loan ratio not exceeding 90%), which also subsidises the loan interest for enterprises. The loan supports personal start-ups registered within the previous three years and lenders targeting job-creating small-sized enterprises.[44] Since it takes time for biotech enterprises to generate a profit, it is rather difficult for them to acquire loans, and as such, more generous financing is required. We suggest that both governments relax their criteria, such as by expanding the categories of enterprises covered (not just new business starters) and raising the guaranteed loan ratio. By acting as the loan guarantor, the governments can stimulate banks to issue more low-interest loans to biotech enterprises.

The above suggestions regarding taxation and rents are summarised below (see **Table 6**):

Table 6 Summary of proposed policy incentives for the Loop

Policy Incentive	Proposal
Tax concession	R&D tax refund in the Loop Tax exemption for enterprises with headquarters or R&D centres in the Loop
Rent reduction incentives	Setting more competitive rents
Low-interest loans	The government acts as bank loan guarantor to offer generous loans

[44] Refers to the "Implementation methods of Loan Guaranteed for Start-ups in Shenzhen" issued by the Shenzhen government in 2020.

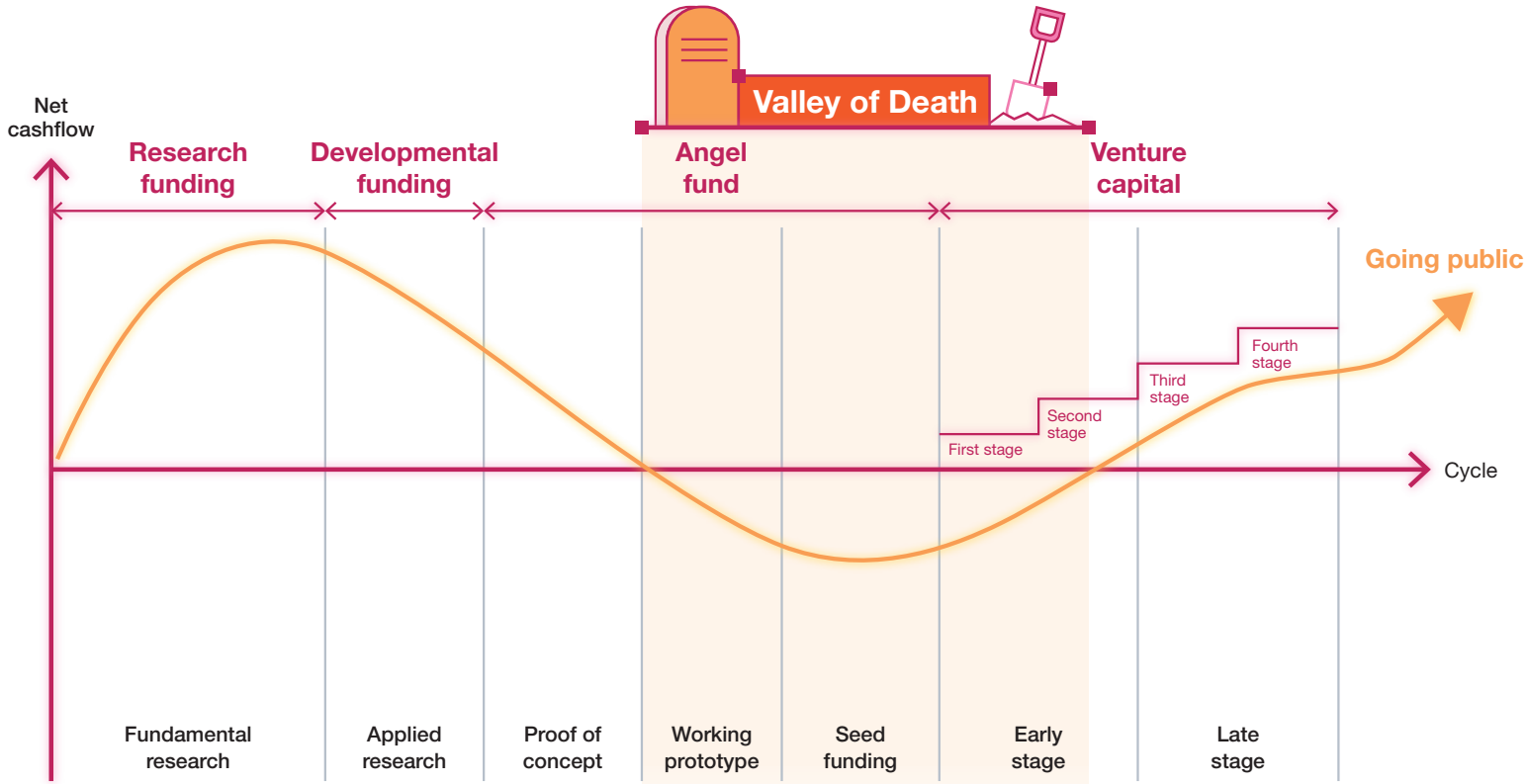
Recommendation 1.2 | Providing ample funding for start-ups to nurture them into unicorns

In addition to drawing in star enterprises, more adequate financing support from the government is necessary for the development of local unicorns. Biotechnology requires a longer investment cycle and large amount of capital. Generally, it takes a biomedical enterprise 10 years and USD 250 millions to launch a product in the market. Even though both governments in Hong Kong and Shenzhen have provided generous research allowances and more mature enterprises can file a listing application under Cap. 18A at the HKEX, biotech enterprises still face the challenge of fund shortage during the stage from prototyping to clinical trials; this is also known as the "valley of death" (see **Figure 13**). Given the limitations of conventional venture capital funds, we suggest that the governments provide potential biotech enterprises with sufficient financial support in a more effective and innovative manner.

As proposed in the Foundation's report "Building the Technology Bridge for Scientific Breakthroughs: Developing an Innovation Hub of the Future", we advise the **Hong Kong SAR Government to make the best use of the Hong Kong Growth Portfolio with a value of HKD 22 billions**[45] to establish a system of limited partnership / general partnership. The government then provides funds as a limited partner and assign an independent professional organisation as the general partner to manage the funds on its behalf. **Part of the funds can be invested in eligible biotech enterprises in the Loop** so as to enable them to develop into unicorns in the long run.

[45] In 2015, the Hong Kong SAR Government set up "Future Fund" with a provision of HKD 220 billions. In 2020, the government announced that HKD 22 billions of the Fund will be spent on the establishment of a new portfolio, named "Hong Kong Growth Portfolio", to make strategic investments in projects with a Hong Kong nexus.

Figure 13 | Net cashflow of enterprises in different cycles, including the "valley of death"



Furthermore, we suggest that **the National Development and Reform Commission**[46] **assume the role of the initiating party, which links together the Guangdong Provincial Government, the Hong Kong SAR Government, and the Shenzhen Municipal Government to establish the Shenzhen-Hong Kong Science and Technology Innovation Cooperation Fund**. This will provide funding to frontier basic research and technology transfer of research findings in biotech jointly conducted by Hong Kong and Shenzhen, support the construction of local testing centres and clinical trial centres, as well as attract scientists. To meet the needs of applicants for their technological research and market demand, the Fund should cover the expenses incurred by quality assurance and the hiring of professional services, on top of expenses on research and equipment, to aid the research and development process.

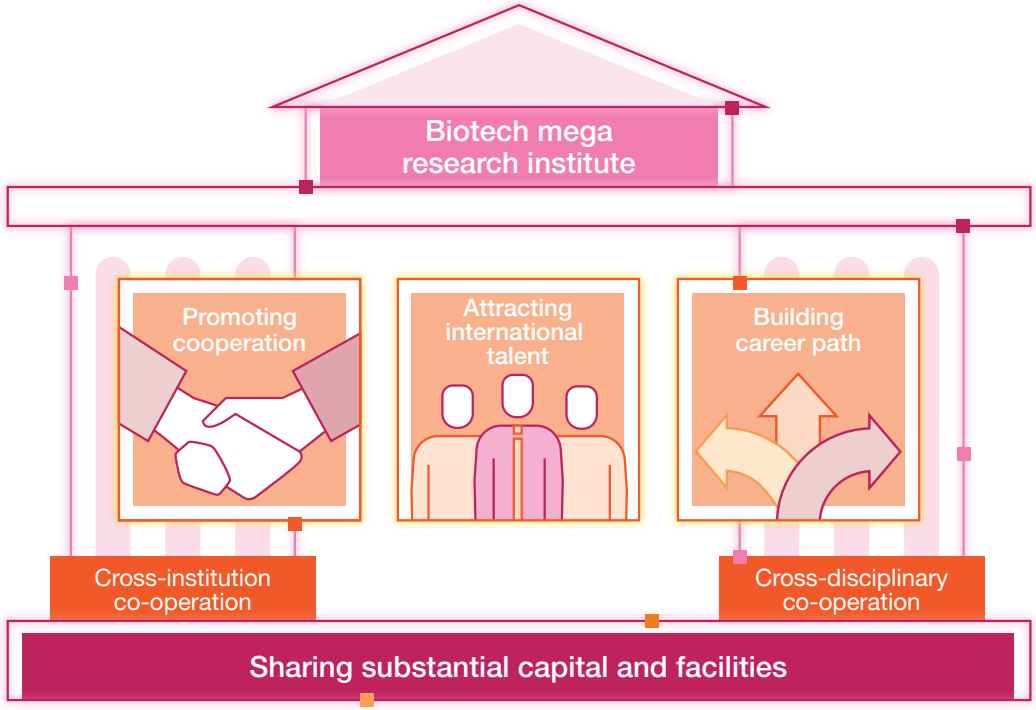
Recommendation 1.3 | Establishing a cross-border biotech mega research institute

A survey on the willingness of Mainland talent to stay in Hong Kong for either a short or prolonged period shows that those from professional, scientific and technical sectors have lower intention than the overall average. The higher their education level (i.e., PhD), the lower their willingness to stay in Hong Kong for a short or longer period.[47] If adequate and quality employment opportunities are secured for them, they will be more inclined to stay in Hong Kong. In the long run, enhancing the level of advanced research and attracting high-calibre individuals are crucial to the sustained development of the biotech industrial cluster. A mega research institute can play a pivotal role in helping achieve these two goals (see **Figure 14**).[48]

First, establishing a biotech mega research institute is conducive to promoting cross-institution and cross-disciplinary co-operation and pursuing interdisciplinary research in biology, medicine, chemistry, engineering, mathematics, statistics, etc., which can in turn help tackle increasingly complex biological challenges. Second, provision of substantial capital and state-of-the-art equipment will be appealing to world-class research talent. A sustained advanced research platform should also be established to assist them in making major scientific breakthrough. In addition to attracting international talent, the mega research institute will serve as an important infrastructure for nurturing talent by providing a comprehensive career path and large and stable advanced research opportunities. Finally, the Broad Institute in Kendall Square offers a useful reference in that it renders support to the advanced technological research of downstream enterprises in similar fields. It demonstrates how a biotech mega research institute connects the academic and industrial sectors; thereby fostering industrial, academic and research collaboration; and encouraging high-tech industrialisation in the area.

The Hong Kong SAR Government has developed the medical technology and innovation platform, Health@InnoHK, with HKD 5 billions to focus on healthcare areas, including drug discovery, molecular diagnostics, R&D of vaccines, medical devices and so on. However, the funding period for research lasts only for 4 to 5 years and the final application of the technology being developed is one of the assessment criteria. Therefore, applicants may be inclined to pursue medium and short-term application-orientated projects that can be completed within 5 years, which is not conducive to building a long-term advanced technological and innovative cluster.

Figure 14 | Establishment of a biotech mega research institute



[46] Under the "Investment management within Central Budget for developing Guangdong-Hong Kong-Macao Greater Bay Area and Yangtze River Delta regional economic integration" released in April 2021 by the National Development and Reform Commission, priority should be given to Shenzhen-Hong Kong Innovation and Technology Co-operation Zone at the Loop. The main initiatives they support include technology and innovation platforms with more participation from Hong Kong and Macao, as well as projects of other signature and significant areas of the Greater Bay Area.

[47] In 2019–2020, HKU, CUHK, and OHKF conducted a survey of 3,000 highly skilled individuals aged 18–59 from mainland China who were residing in Hong Kong. There were five options for each question, ranging from "Very unlikely" (1) to "Very likely" (5). The figure shows that professional, scientific and technical talent's willingness to stay in Hong Kong (short-term: 3.52; long-term: 3.06) was below the overall average (short-term: 3.90; long-term: 3.46). That of talent with the highest education level of doctoral degree (short-term: 3.6; long-term: 3.1) was significantly lower than that of master-degree holders (short-term: 3.8; long-term: 3.4) and that of bachelor-degree holder (short-term: 4.0; long-term: 3.6).

[48] See OHKF's research report *Unleash the Potential in Science and Technology Innovation: Develop Hong Kong into an International R&D Powerhouse.*

In recent years, cross-institutional mega research institutes have been set up all over the world. **Table 7** summarises and compares two renowned biotech mega research institutes: the Broad Institute of the US and the Francis Crick Institute of the UK. The former was jointly founded by MIT, Harvard University and Harvard-affiliated hospitals in 2004, with the aim of promoting cross-disciplinary, cross-institutional and multi-regional research and providing solutions to biomedical challenges. The research projects involve more than six disciplines and almost 100 institutes from more than 40 countries, bridging cultural and institutional divides. While in the UK, the Francis Crick Institute provides comprehensive support to biomedical research at home and abroad. Adopting a unique researcher scheme, the Institute openly recruits international scientists, including top research pioneers and emerging researchers, to broaden the talent pool.

In mainland China, mega research institutes are becoming an important avenue for conducting advanced research and attracting top-notch talent. In mathematics, the Yanqi Lake Beijing Institute of Mathematical Sciences and Applications (BIMSA) was jointly established by institutions including Tsinghua University and the Chinese Academy of Sciences, with planned collaborations with other Beijing institutions including the Renmin University of China and Beijing University of Aeronautics and Astronautics, as well as with enterprises like Alibaba, Tencent, NetEase and Microsoft Research. In biotech, instead of cross-institutional mega research institutes, there are more research institutes and large laboratories co-established by the Chinese Academy of Sciences with provincial and municipal governments. Examples include the National Institute of Biological Sciences in Beijing and the Guangzhou Institutes of Biomedicine and Health, Chinese Academy of Sciences. Therefore, a biotech mega research institute in the Loop would be conducive to building a demonstration area that fully integrates industrial, academic and research activities in biotech, paving the way for a new mode of industrial, academic and research collaboration in China.

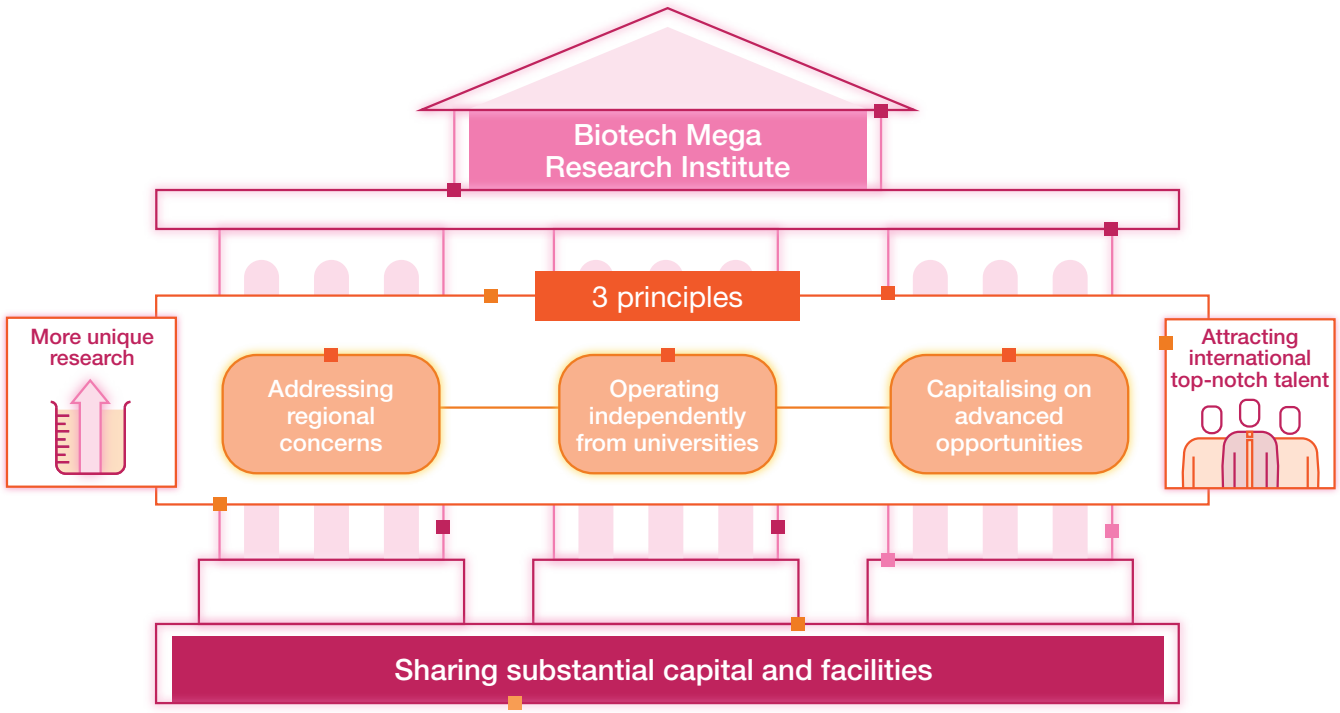
Table 7 | Broad Institute and Francis Crick Institute

Feature	Broad Institute	Francis Crick Institute
Member institutions	MIT, Harvard University, Harvard-affiliated hospitals	Medical Research Council, Cancer Research UK, Wellcome Trust, University College London, Imperial College London, King's College London
Category of institution	Registered non-profitable organisation	Registered non-profitable organisation
Source of funding	Federal Government (33%), charitable donation (28%), the industry (17%), investment income (5%), other incomes (17%)	Member institutes (82%), government projects (15%), charitable donation (2%), incomes from investments and others (1%)
Composition of Board of Directors	Among 17 members of the Board, 5 come from member institutes, 9 from other universities and the industry, 3 are the founders and administrative officers of the Institute	Among 12 members of the Board, half belong to member institutes, and the other half from other universities and the industry
Disciplines covered	Medicine, Biology, Chemistry, Computational Science, Engineering, Mathematics and Statistics	Biomedicine, Physics, Chemistry, Engineering, Computational Science
Huge recurrent expenditures and state-of-the-art facilities	About USD 500 millions per annum Recent infrastructure projects include the COVID-19 Biobank jointly built with Biogen and Partners HealthCare	More than GBP 150 millions per annum Recent infrastructure projects include research facilities for COVID-19 jointly set up with UK Research and Innovation

Sources: Broad Institute, Francis Crick Institute

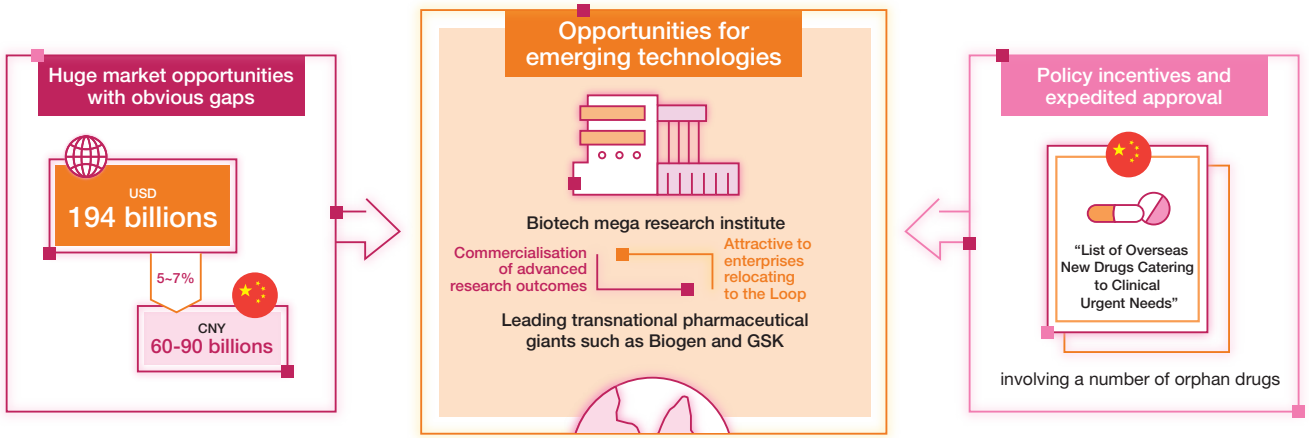
Given Hong Kong universities' significant advantages in advanced research in biotech, we recommend **the joint establishment of a cross-disciplinary and cross-institutional biotech mega research institute** (see **Figure 15**) **spearheaded by HKU, HKUST and CUHK, in collaboration with Shenzhen institutes like the Shenzhen Institutes of Advanced Technology, the Southern University of Science and Technology and Shenzhen University, as well as existing platforms and facilities in the GBA.**[49] **The institute shall observe three principles: capitalising on advanced opportunities, addressing regional concerns and operating independently from universities.**

Figure 15 | The proposed biotech mega research institute



[49] Including National Centre for Technological Innovations in the GBA in Guangzhou, State Key Laboratories and Sub-centres of National Engineering Research Centres in Hong Kong and Shenzhen, Health@InnoHK research cluster and joint laboratories co-organised by universities and enterprises, etc.

Figure 16 | How the biotech mega research institute can facilitate the development of an industrial cluster—rare diseases as a case in point



Source: Boston Consulting Group

Capitalising on advanced opportunities: the institute should focus its attention on advanced scientific enquiries and resolving major challenges in medicine, such as emerging infectious diseases like novel coronavirus diseases, common age-related diseases like Alzheimer's, rare diseases like albinism, and new fields of study like epigenetics,[50] as well as disruptive technologies such as next generation testing technologies, next generation genetic manipulation technologies and synthetic biology technologies.

Taking rare diseases as an example (see **Figure 16**), studies have identified enormous market opportunities, with the global market estimated to reach roughly USD 194 billions, and the Chinese market at CNY 60–90 billions, by 2030.[51] Meanwhile, effective treatments exist for fewer than 5% of rare diseases only, suggesting huge unfulfilled demand. Consequently, many governments have introduced policy incentives, including research grants, expedited

[50] Epigenetics is the study of the relationships between phenotypes, diseases and genes, which can help predict the impact genetic defects may have for the invention of more targeted prevention and treatments.

[51] Statistics by the Boston Consulting Group show that the cumulative transactions made by the top 20 pharmaceutical companies of the world in the field of rare diseases amount to USD 218 billions in 2020. Established pharmaceutical giants have been proactive in acquiring companies specialised in rare diseases: in 2018, Takeda Pharmaceuticals acquired rare disease giant Shire, Sanofi acquired Bioverative to gain a foothold in haemophilia, and Novartis acquired biotech company AveXis with expertise in gene therapies; in 2019, Roche acquired gene therapy pioneer Spark Therapeutics; in December 2020, AstraZeneca acquired rare disease giant Alexion Pharmaceuticals.

approval[52] and tax breaks, to facilitate research and development of orphan drugs. By designating rare diseases as a key research area, the institute should be able to attract transnational biomedical enterprises which are leaders in rare disease research to set up a presence in the Loop, thereby fostering commercialisation of the institute's advanced research outcomes and expediting the formation of a biotech industrial cluster. Such an operating model may achieve similar results in other advanced fields of study or disciplines.

In addition to providing competitive remuneration and benefits packages, opportunities for pursuing advanced research and achieving scientific breakthroughs are highly attractive to world-class researchers and enterprises. Moreover, the institute can also introduce stringent regulatory mechanism in advanced fields of technology on the cutting edge of science, such as stem cells and gene therapies, with a view to developing the Loop into a national regulatory node, establishing a pilot area for international biotech regulatory standards setting, and speeding up the reform of the Mainland's clinical trial and healthcare regimes.

Addressing regional concerns: the institute should consider addressing medical challenges of a regional nature. For instance, primary liver cancer is a common form of malignant tumour in China, which accounts for more than half of the new cases of the world; 80% of the world's nasopharynx cancer patients live in China and Southeast Asia, and each year, between 35,000 to 40,000 people from Southern China and Southeast Asia die from this disease. Research on such diseases with obvious regional association is not only advantageous to the institute, but also highly significant. On one hand, the higher number of patients in the region can facilitate research, and on the other, the regional characteristic substantially increases uniqueness of research. As such, the institute stands a chance of developing into a reputable organisation with world leadership in these areas of research.

Independent operation from universities: the institute should operate independently from its member institutions. Doing so can ensure the institute's autonomy in terms of financial management, daily operation and research directions. Being free from administrative or financial restrictions placed by member institutions, the institute can expedite project progress of advanced research. In this area, much can be learnt from the mode of management of the Broad Institute and the Francis Crick Institute (see **Table 7** above).

The biotech mega research institute can facilitate the development of an industrial cluster and a robust biotech ecosystem. In the long run, it may provide advanced research support to leading transnational biomedical enterprises and build up a talent pool for enterprises of different sizes. Therefore, building on the basis of **Recommendations 1.1 and 1.2**, the Loop may make greater effort to attract high quality enterprises to establish a presence. Driven by the mega research institute, the industrial cluster may develop a "talent-research-enterprise" virtuous circle that lays a solid foundation for the development of the HK-SZ biotech industry.

[52] According to the "Work Procedures for Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs", the Center for Drug Evaluation of NMPA has established special channels for a list of overseas new drugs catering to urgent clinical needs, in which technical review will be completed in three months after acceptance for orphan drugs, and six months for other overseas new drugs.

Figure 17 | How the biotech mega research institute facilitates the development of the industrial cluster

Establishing all-stage ancillary facilities to optimise biotech research and development supply chain

Optimising R&D procedures and ancillary facilities can help foster HK-SZ collaboration and development in biotech. Beginning with R&D procedures in biotech, we shall elaborate on key issues surrounding five important areas and propose targeted recommendations to address them. These areas are: (1) government coordination; (2) preclinical research; (3) Phase I clinical trials; (4) Phase II and III clinical trials; and (5) drug manufacturing and product launch.

Recommendation 2.1 | Establishing a Hong Kong Science and Development Office to formulate a blueprint for biotech development

To coordinate I&T development, the Shenzhen Municipal Government has established the Shenzhen Science and Technology Innovation Commission to manage national and provincial tech projects and funding; formulate, organise and implement tech planning and policies; as well as nurture and provide service to high-tech enterprises. In Hong Kong, a number of government bodies are involved in biotech research, including the Innovation and Technology Bureau, which manages the Innovation and Technology Fund; the Food and Health Bureau, which manages the Health and Medical Research Fund; the Education Bureau, which funds the universities; and the Hospital Authority (HA), which oversees the public hospital system. Although the Chief Executive-led Steering Committee on Innovation and Technology[53] and the Financial Secretary-led Committee on Innovation, Technology

[53] Chaired by the Chief Executive, the Steering Committee on Innovation and Technology is responsible for steering collaboration between various bureaux and departments and their participation. It is made up of the Chief Secretary and the Financial Secretary, ten Bureau Secretaries and six Permanent Secretaries and Heads of Departments.

and Re-industrialisation[54] have been established to coordinate the various government bodies, the governance structure suffers from a lack of a body designated for advising on long-term scientific development and from the absence of visionary scientists on the committees. As such, despite having identified biotech as one of its four areas with a competitive edge,[55] the government has not issued any blueprint for development.

Looking abroad, both the US and Singapore have set up designated scientific advisory bodies. The US Office of Science and Technology Policy provides the President and senior officials with analysis and assessment on the impact of science and technology on major policies and initiatives. In 2012, the White House unveiled the National Bioeconomy Blueprint, with the goal of building a foundation for the US bioeconomy of the future. Similarly, Singapore has established a Science Advisory Board with the mandate of identifying important areas of research and international trends on basic research. Every five years, the National Research Foundation of Singapore formulates national strategies for the country's scientific and technological research.

Hong Kong can follow in the footsteps of the US and Singapore and **establish a Hong Kong Science and Development Office to advise the government on matters related to biotech** (see **Figure 18**). The primary objective of the Office is **to formulate a blueprint for the development of the biotech industry**, and provide forward-looking scientific advice on areas such as clinical research. Second to that is **the optimisation of the government's research funding mechanism** and the consolidation of research funding that is scattered across various government bodies. It should on one hand **devise a funding allocation strategy that aligns with the blueprint for industrial development**, and on the other revise the allocation of universities' research funding, **allowing institutions to collect overhead charges on a specified portion of the total funding for research projects.**[56] Thereby, encouraging universities to relax restrictions on researchers engaging in technology transfer and outside work and facilitating the effective commercialisation of advanced research outcomes. Furthermore, as the peer review mechanism carries significant weighting in the evaluation of research projects, the Office should encourage **a more widespread adoption of the peer review mechanism** in the government's research projects.

Recommendation 2.2 | Establishing ancillary facilities for preclinical research

In the biomedical R&D process, preclinical research is the stage that follows drug discovery. Broadly speaking, three types of laboratories are required for preclinical research: in-vitro (test tube or cell culture), small animal, and large animal laboratories. In

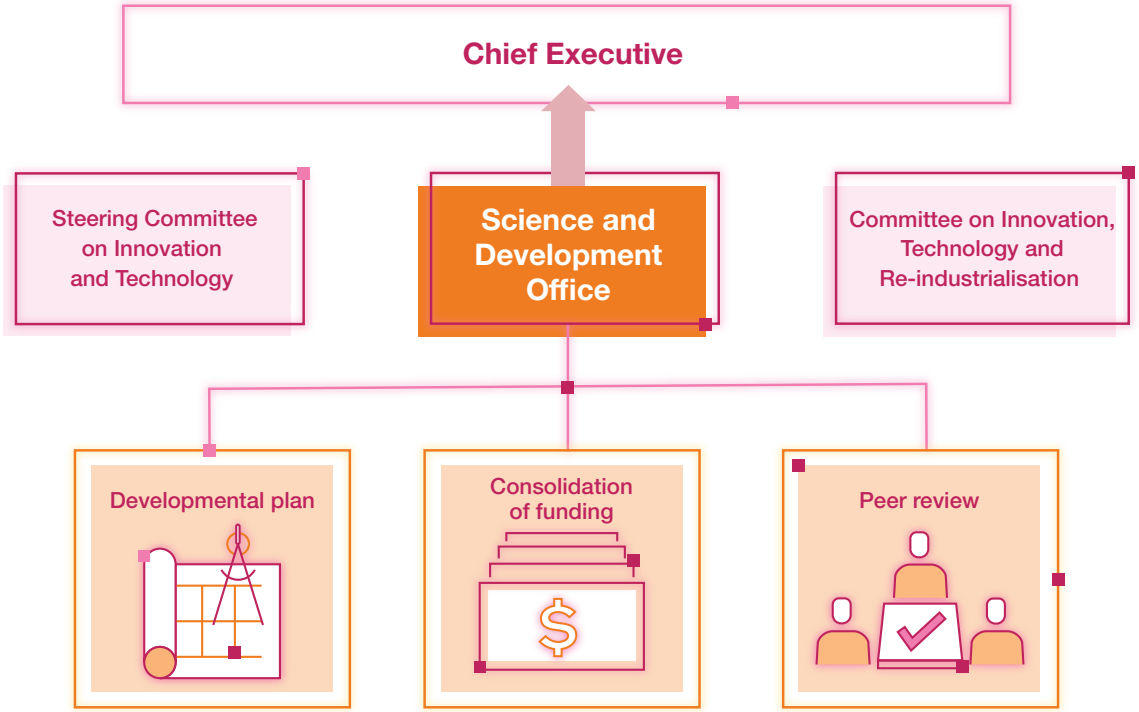
[54] Chaired by the Financial Secretary, the Committee on Innovation, Technology and Re-industrialisation is tasked with advising the government on fostering innovation in Hong Kong and steering the direction of technological development.

[55] Including biotech, AI, smart city and fintech.

[56] Overhead charges for Hong Kong universities are generally low (about 15–30%). HKUST even levies no overhead charges on collaborative projects with NGOs. Globally, as other top universities have generally higher overhead charges, universities are more willing to encourage researchers to engage in knowledge transfer. For example, although Harvard University has an overhead charge of only 26% for research projects outside of campus, the charge for in-campus projects amounts to 69%, with Stanford University having a charge as high as 72% for in-campus projects.

preclinical trials, regulators will only accept data from laboratories that conform to the their standard guidelines (i.e., GLP, Good Laboratory Practice). Currently, Hong Kong and Shenzhen have no GLP-accredited laboratories recognised by major drug regulators of the world. While there are 12 and 11 NMPA GLP-accredited laboratories in Shanghai and Beijing respectively,[57] Hong Kong and Shenzhen currently have none that has received accreditation, and each city has only one meeting the relevant standards (but

Figure 18 | Establish a Hong Kong Science and Development Office



[57] According to data derived from the NMPA's Notices of Announcement for GLP Accreditation, as at April 2020.

has not yet been accredited): in particular, the Animal Laboratory of the Centre for Biopharmaceutical Safety Evaluation newly established by the Shenzhen Institute for Drug Control came into operation in April 2021 in the Nanshan Science and Technology Park; the GLP Drug Safety Testing Center of the Hong Kong Science and Technology Parks is expected to come into operation in early 2022. Meanwhile, GLP laboratories that can conduct large animal tests are few and far between. There are eight NMPA-accredited laboratories authorised to conduct experiments on non-rodents[58] in both Shanghai and Beijing, compared to none in Hong Kong and Shenzhen. To build up comprehensive ancillary facilities for preclinical research in the area, we recommend that **the two governments establish GLP laboratories, particularly those that can conduct large animal experiments, in the Loop.**

Recommendation 2.3 | Expediting the approval of Phase I clinical trials in Hong Kong

The next stage, clinical trials, can be completed either in Hong Kong or Shenzhen. Given that Hong Kong's internationalised clinical trial management system has better international recognition, and that fewer number of study participants are involved in the first phase, Phase I trials may be completed entirely in Hong Kong. Yet, clinical trials in Hong Kong is subject to all kinds of limitations, and the HA has not attached enough importance to it. Of particular note, the HA's vision and mission speak of "providing high-quality [healthcare] services" to maintain "the health of our community", "thus helping its members to avoid the need to spend time in our hospitals whenever possible", but it does not seek to achieve this goal with advanced research or clinical trials. Therefore, even though many hospitals in Hong Kong have taken part in clinical trials, only three[59] have set up clinical trial centres to systematically manage and develop clinical trials. Compared with other regions, these centres are under-funded, leading to sluggish development (see **Table 8**). Unlike HA hospitals, Grade III Level A hospitals in mainland China (i.e., its top-ranked hospitals) are strong advocates of scientific research, with equal emphasis on research, healthcare and education, and hospitals are evaluated based on their research input and output.[60]

In Hong Kong, applications for Phase I trials are subject to a processing time as long as half a year;[61] in Shenzhen, the governmental approval part of the applications are handled by NMPA with a maximum processing time of 60 days.[62] In Australia, a hotspot for Phase I trials, applications can be approved in about 30 days. In Hong Kong, Phase I applications must go through two steps: step one is to apply for approval with the hospital's Ethics Review Committee (ERC),[63] which can take about three months; step two is to apply for the Certificate for Clinical Trial/Medicinal Test[64] with the Department of Health (DH)'s Drug Office, which can take two to three months. Both applications can be submitted simultaneously, but on one hand, the relevant review committee of the Pharmacy and Poisons Board (PPB) have merely nine members holding only five meetings a year, and on the other, the content reviewed by the two organisations overlap.

[58] The reproductive systems of non-rodents are more similar to that of human, and therefore experiments with non-rodents are more valuable for reference. Non-rodent species include animals other than the orders of Rodentia and Lagomorpha.

[59] The three hospitals are Queen Mary Hospital, Prince of Wales Hospital and the Hong Kong Sanatorium & Hospital.

Table 8 Comparison of various governments' policy incentives in support of the establishment of clinical trial centres

Region	Policy incentives in support of clinical trial centres
Hong Kong	In 2011, the Hong Kong government provided funding to the Faculties of Medicine of HKU and CUHK to establish Phase I clinical trial centres. Each university was given a funding of HKD 40 millions to support the centres' first five years of operation. It was not until 2019 that the two centres received an additional HKD 100 millions to conduct a total of 200 clinical trials of new drugs.
Shenzhen	According to a 2021 plan of the Shenzhen Municipal Government, one municipal clinical centre shall be established for each category of disease, and each health and medical institution shall establish no more than two municipal clinical centres, with each centre receiving no more than a maximum of RMB 30 millions in funding.
Taiwan	The Taiwanese government has since 2005 designated six hospitals to establish "Centers of Excellence for Clinical Trial and Research". Each centre is provided with operating funding for three years at a time, at a total of approximately USD 3 millions. Hospitals take turns to receive funding.
South Korea	The South Korean government has since 2007 designated 15 hospitals all over the country to establish regional clinical trial centres, each of which received matching funds worth USD 5 millions to support the operation for the first five years. A designated body was subsequently established to provide support for the clinical research industry, including a total funding of USD 10 millions over five years to support the operation of selected clinical trial centres.

Sources: Legislative Council of Hong Kong, Shenzhen Science and Technology Innovation Commission, Chee et al. (2016) and Government Research Bulletin, Ministry of Science and Technology, Taiwan

[60] An example is the "Evaluation and Analysis of the Research Competitiveness of Grade III Level A Hospitals of Shanghai" jointly issued by the Department of Science and Education, Shanghai Health Committee and the Shanghai Health Development Research Center.

[61] In Hong Kong, processing time for Phase I clinical trials is not only longer compared with Phase II and III trials, but also to other regions.

[62] In 2015, the NMPA promulgated the "Announcement on Amendment of Review and Approval Procedures for Clinical Trials of Drugs", which specifies that in relation to application for clinical trials of drugs in China, an applicant may commence with the trial in accordance with the submitted proposal should s/he not receive a rejection or query from the Drug Review Center of the NMPA within 60 days from the date the application is acknowledged.

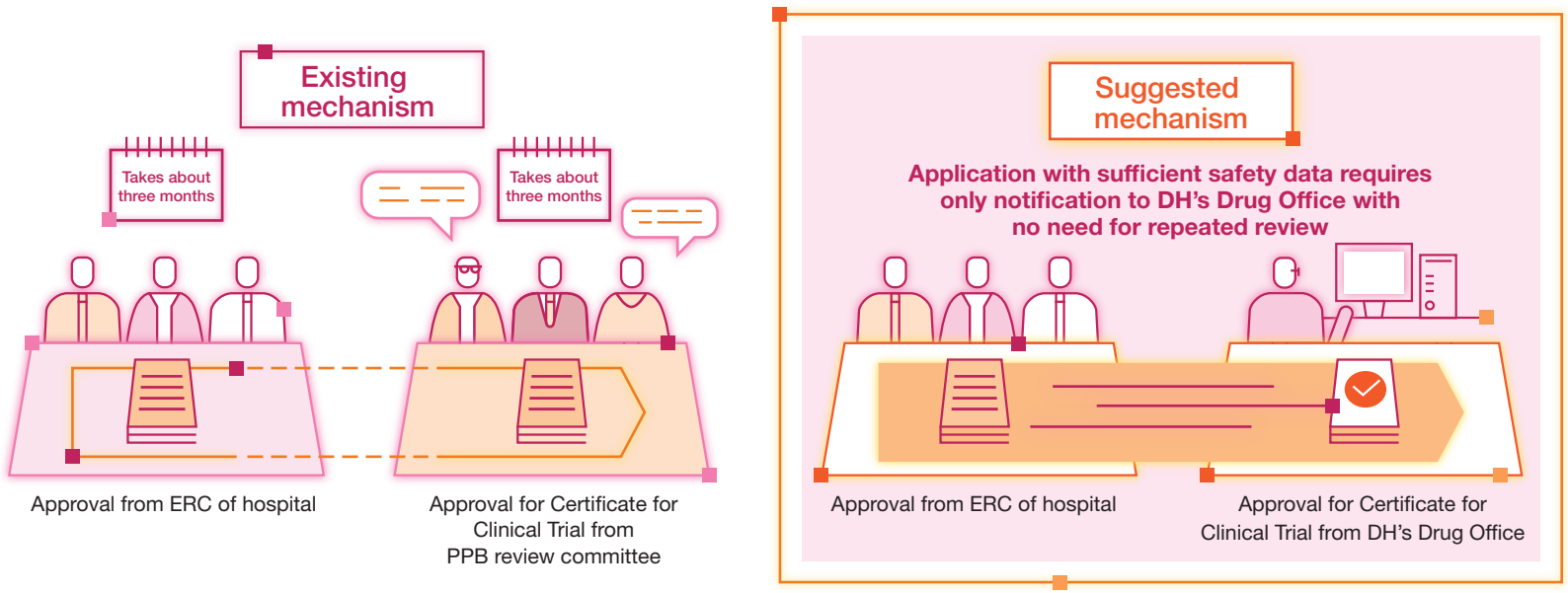
[63] The objectives of the ERC are to safeguard the rights, safety and well-being of clinical research participants and to subject the research to preliminary review and continuous monitoring on the ethical and scientific level.

[64] When a clinical trial is conducted on human beings for the first time, it needs the approval of the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee to ascertain the safety of research.

Meanwhile, Australia's Therapeutic Goods Administration (TGA) offers two different schemes for applicants. Namely, the Clinical Trial Application Scheme is for application of clinical research or new drugs of higher risks; the Clinical Trial Notification Scheme is for applications with sufficient preclinical safety data and/or those with clinical trials completed elsewhere already. An overwhelming majority of clinical trials are conducted under the Clinical Trial Notification Scheme, where clinical trials may commence as soon as the applicant has notified the TGA upon approval from the ERC. As the TGA need not engage in repetitive reviews, the entire process takes about 30 days only.

We therefore recommend that **the review process of Phase I clinical trials in Hong Kong be expedited** (see **Figure 19**). **On one hand, we recommend increasing the number of members of the review committee and frequency of meetings to expedite the review process; on the other, Hong Kong may draw on Australia's model and permit clinical trials to commence provided that there is sufficient safety data and that the applicant has notified the DH's Drug Office upon approval of the ERC. This way, the review committee can focus its review work on applications without sufficient safety data.** Besides, at present, the DH has not yet set out clear and

Figure 19 | Expediting approval for Phase I clinical trials in Hong Kong



specific requirements for applications of clinical trials.[65] As such, the DH should make reference to the world's major drug regulators and publicise the relevant guidelines, while making sure that ERCs of the hospitals are well aware of, and take full consideration of, the guidelines while reviewing the applications.

Recommendation 2.4 | Coordinating multicentre clinical trials with "Hong Kong-style" management

As Phase II and III clinical trials require more study participants, they are often conducted in a global multicentre setting. It is unfeasible for these trials to be completed solely in Hong Kong due to insufficient number of cases. Therefore, in addition to improving staffing at the DH's Drug Office to shorten processing time for local Phase II and III trials, Hong Kong should also encourage collaboration between local clinical trial centres and hospitals in Shenzhen.

The National Development and Reform Commission is currently implementing a "1+N+X" mode of collaborative innovation network for clinical research in Shenzhen,[66] in which "N" refers to building up a collaborative network in clinical research consisting of health and medical institutions within Shenzhen and beyond, including top-notch institutions from Hong Kong, with a view to provide a grand collaborative platform in clinical research for biomedical enterprises. Shenzhen, for its part, has released a plan[67] to encourage its healthcare institutions to apply to become clinical trial organisations and enhance the standards of clinical research.

As the nation continues to roll out these measures, Hong Kong should seize the opportunities to collaborate with Shenzhen and **coordinate cross-border multicentre clinical trials in the Loop. By making full use of the reputational advantage of Hong Kong's internationalised clinical trial management system, the city can introduce the "Hong Kong-style" management model into the Mainland via the Loop to enhance its alignment with international standards.** A good case in point is the University of Hong Kong-Shenzhen Hospital, whose establishment helps introduce Hong Kong's advanced and international management system to the Mainland.[68] For clinical trials, Hong Kong can rely on relevant platforms or organisations in the Loop, such as the Clinical and Translational Medicine Research Centre to be built by the University of Hong Kong-Shenzhen Hospital in the Shenzhen park, or the University of Hong Kong Clinical Trials Centre (China) Limited to be established by the HKU Clinical Trials Centre, to introduce relevant experience into Shenzhen, or even the entire GBA. Such organisations can also coordinate clinical trial centres in Hong Kong and Shenzhen hospitals or other Phase II and III trial centres of hospitals located in the GBA so as to develop the Loop into a

[65] Although DH's application guide for the Certificate for Clinical Trial/Medicinal Test does list documents to be submitted, the relevant requirements, such as those to be fulfilled in the preclinical research stage, are not specified.

[66] "1" refers to the establishment of an internationally competitive translational medicine research centre by the Shenzhen Academy of Medical Sciences; "N" refers to building up a collaborative network in clinical research consisting of health and medical institutions within Shenzhen and beyond to provide a grand collaborative platform in clinical research for biomedical enterprises; "X" refers to seizing the opportunities the Central Government has conferred to Shenzhen as a pilot reform area with comprehensive authorisations, so as to foster the transfer and application of advanced technology and basic medical research outcomes in Shenzhen.

[67] "Implementation Plan on Reform to Optimise the Steady Supply of Generic Drugs and Usage Policy in Shenzhen" by the Shenzhen Municipal Government.

[68] Wholly invested by the Shenzhen Municipal Government, the University of Hong Kong-Shenzhen Hospital came into operation in October 2012 to introduce HKU's modern management system into the Mainland, including medical appointments, division of primary and specialist care, fixed fees and rates etc.

clinical trial demonstration area. Such a mode of co-operation may be piloted in the three national clinical research centres in the GBA,[69] with the possibility of gradually extending to other Grade III Level A hospitals. Relevant hospitals and clinical trials centres can engage in advanced research projects such as clinical research involving stem cells.

Moreover, to effectively popularise the "Hong Kong-style management" and experience in Shenzhen, **Shenzhen should expedite unilateral recognition of qualifications and professional titles of Hong Kong healthcare professionals and biotech researchers, so that doctors and researchers from Hong Kong can more easily participate in and even manage biomedical research and clinical trial projects conducted in Shenzhen.**

Recommendation 2.5 | Establishing production lines in the Loop and improving the product launch regime for new drugs in the two cities

For the production stage, we recommend **the establishment of GMP[70]-compliant production lines in the Loop to manufacture advanced biotech products and pilot batches, so as to ultimately establish a pilot batch transformation cluster for biotech in the GBA.** Compared with conventional biotech products, advanced products may be produced in smaller factories. For instance, unlike conventional inactivated vaccines, it is easier to manufacture and mass-produce mRNA vaccines in a smaller production space;[71] it is also feasible to produce advanced medical devices such as surgical robots in small factories as the scale of production is smaller. Likewise, pilot batches required in clinical trials do not take up much space to produce.

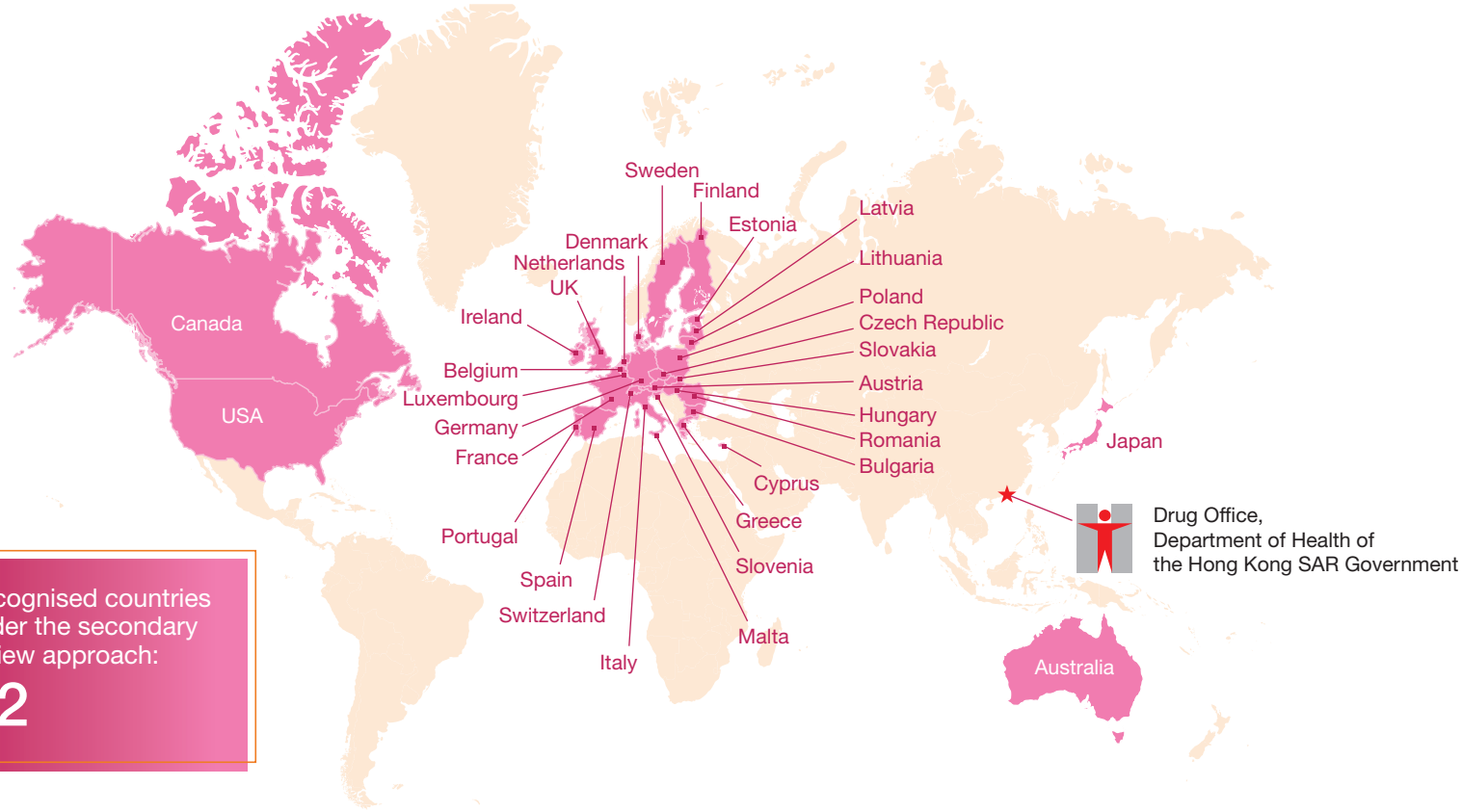
For the drug registration and product launch stage, whereas pharmaceutical companies in Shenzhen may submit an NDA to the NMPA, a body with authority to approve new drugs is absent in Hong Kong. Hence, new drug applications are currently reviewed and approved under the secondary review approach, in which new drugs must receive approval from at least two drug regulatory authorities in 32 recognised countries and regions (see **Figure 20**),

[69] Including Shenzhen No. 3 People's Hospital, the First Affiliated Hospital of Guangdong Medical College and Nanfang Hospital of Southern Medical University.

[70] The PPB joined the Pharmaceutical Inspection Co-operation Scheme (PIC/S) in 2016, which shows that Hong Kong's manufacturing quality management has reached international standards. Production lines accredited as GMP-compliant in Hong Kong are also recognised by PIC/S members, including many major drug regulators of the world.

[71] The production cycle of Pfizer's mRNA vaccine lasts 9–13 days, whereas that of Sinovac's inactivated vaccine lasts more than 40 days. Given the difference in production cycle, the batch size and factory area also differ.

Figure 20 | Recognised countries under the secondary review approach



Recognised countries under the secondary review approach:

32

Source: Drug Office, Department of Health of Hong Kong

which do not include mainland China. It is worth noting that the NMPA's 2015 reform to improve validity of clinical trial data[72] has substantially increased clinical data quality in the Mainland. Also, with the NMPA joining the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017, the Mainland's review standards for drugs and medical devices have become better aligned with international standards. Yet, Hong Kong has not updated its list of recognised countries and regions since 2012.

We therefore recommend that **the DH review the list and consider the inclusion of Mainland China and the recognition of NMPA-approved drugs**. Such measure will also send out a positive message that encourages pharmaceutical companies in the Mainland to engage in research and register for new drugs in Hong Kong. Drawing on the experience of the Advisory Panel on COVID-19 Vaccines established by the government during the COVID-19 epidemic, Hong Kong can explore establishing an independent drug review mechanism in the long run. By bringing in and training drug review professionals, particularly multilingual talent well-versed in registration of new drugs and medical devices in the US FDA and EU EMA frameworks, the city can explore building up independent drug review capabilities.

Meanwhile, with the implementation of the "Hong Kong drug-connect" policy,[73] designated healthcare organisations in the GBA can now utilise drugs and medical devices already approved for use in Hong Kong and Macao. The NMPA has also delegated the authority for approval to the Guangdong Provincial Government. However, our survey found that, in contravention of the policy intent to expedite the registration of clinically urgent drugs and medical devices, regulators still required applicable

[72] The NMPA promulgated the Announcement on Inspection of Clinical Trial Data (2015/117) on 22 July 2015 to subject unapproved drugs that have been reported for production or import to self-inspection of clinical data. Under the document, 1,622 clinical trial projects are subject to self-inspection, with particular emphasis on stringent standards and monitoring, strict accountability as well as severe punishment.

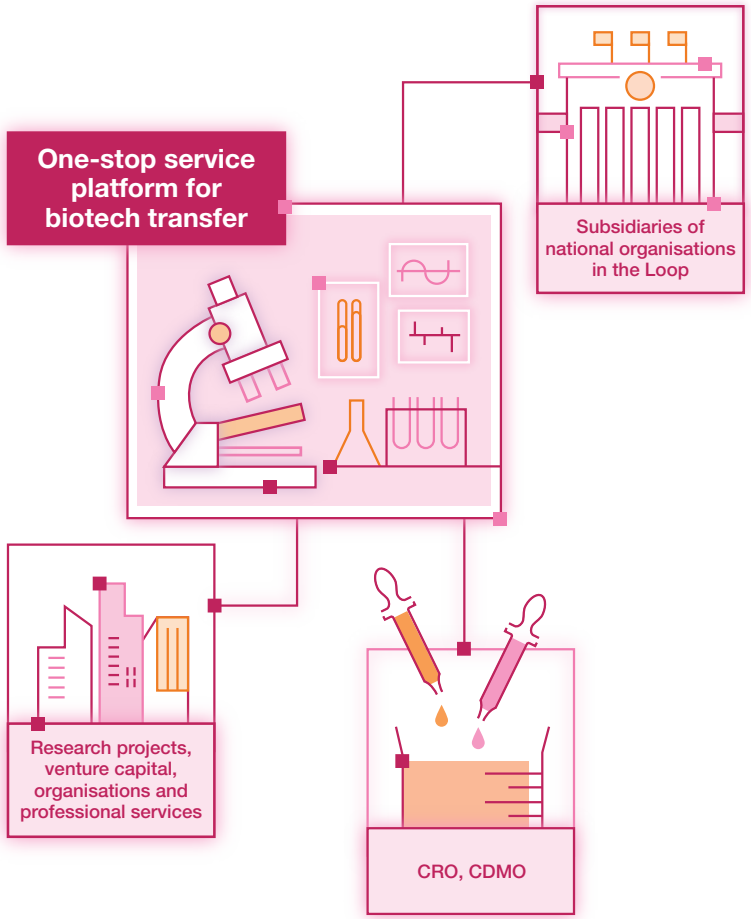
[73] In November 2020, eight departments including the NMPA issued the "Work Plan on Innovations on Drug and Medical Device Regulation in the GBA", authorising designated healthcare organisations in the nine GBA cities in the Mainland to use clinically urgent drugs that have been authorised for use in Hong Kong and Macao. With NMPA agreement, the new arrangement is for the State Council to authorise the People's Government of the Guangdong Province to approve the drug use (i.e., Hong Kong drug-connect), with the University of Hong Kong-Shenzhen Hospital being the first pilot hospital.

drugs and medical devices to go through the conventional procedures and produce proof of clinical data in compliance with NMPA standards before registration. As such, **the Shenzhen Municipal Government should seek the approval of the Health Commission of Guangdong Province to relax relevant requirements and allow the use of efficacy data of drugs and medical devices, which have already been approved in Hong Kong, on Shenzhen patients for further registration in the Mainland.** The NMPA's GBA sub-centre should take charge of the review work (see **Recommendation 6.3**) to expedite the review and approval procedures for drugs and medical devices in the Mainland.

Establishing a one-stop service platform for biotech transfer

Biotech companies in Hong Kong and the Mainland need to seek larger markets to scale up. In the process of commercialisation, enterprises must proactively open up new markets abroad to ensure long-term survival and achieve rapid development. While Hong Kong enjoys easier access to conventional markets in the West and emerging markets in the Association of Southeast Asian Nations (ASEAN) region, Shenzhen can aid international enterprises in entering the Mainland market. Owing to differences between the mainland Chinese and international systems in taxation and legal environment, foreign enterprises seeking to enter the Mainland market may need to deploy additional resources to understand and comply with the Mainland regime. Enterprises also find that

Figure 21 Establishing a one-stop service platform for biotech transfer in the Loop



the Mainland market lacks transparency and predictability.[74] It is up to the authority to provide adequate support to overcome these barriers.

Recommendation 3 | Establishing a one-stop service platform in the Loop to provide professional support services

We therefore recommend **the establishment of a one-stop service platform in the Loop to provide biotech transfer service for Hong Kong and Shenzhen**. The platforms may be jointly established by the administrators of the two parks (i.e., the Hong Kong-Shenzhen Innovation and Technology Park Limited and the Futian District Government) through consultations and adopt market-orientated operation with the authorisation of government institutions. The platform can foster the sharing of technology industrial policies and developmental dynamics between the two cities, and also the sharing of public data in commercial, taxation, customs and judicial arenas. It should also address the needs of biotech enterprises through various stages, such as investment, registration and production by leveraging on resources from Shenzhen, Hong Kong and around the globe. Specifically, we recommend that the platform should have the following three major functions (see **Figure 21**):

Bridging regulators of the two cities: A single channel should be set up at the Loop's one-stop service platform so that a single application can be submitted simultaneously to government departments of the two cities, making it easier for researchers and enterprises of the two cities to register research applications to departments of both governments. Apart from the NMPA's GBA Sub-centre for the Approval and Inspection of Medical Device Technology that have already been established in the Shenzhen park, other national regulators, in particular the National Intellectual Property Administration and the Human Genetic Resources Administration of China, can also establish offices in the Loop (see **Chapter 6** for details of the recommendation). The single channel can interface with national organisations and corresponding bodies in Hong Kong such as the DH's Drug Office and the Intellectual Property Department, making it easier for applicants to submit applications to relevant departments of the two governments. Regarding overseas drugs entering the Mainland market and Mainland drugs accessing the overseas market, enterprises can apply to overseas regulators for patent, clinical trials and registration for product launch through other private professional services providers in the Loop.

[74] Hong Kong Trade Development Council Research conducted an online survey from June to July 2020 with 259 start-ups that are headquartered in Hong Kong having been in operation for less than eight years. 43% of respondents feel that the Mainland and Hong Kong systems are different. 39% are worried about uncertainty in the market environment. 34% feel the GBA market has insufficient transparency.

Moreover, the Central Government can proactively explore how to best coordinate the regulatory regimes of the two cities and harmonise their regulations, particularly in the area of intellectual property recognition. To foster a globally competitive business environment, other national organisations can consider expediting approval procedures by establishing "green channels" to facilitate enterprises registered in the Loop to enter the Mainland market. We shall continue to elaborate on these proposals in **Chapter 6**.

Bridging capital, research organisations and professional services of the two cities: In addition to integrating the above-mentioned Shenzhen-Hong Kong Biotechnology Collaborative Development Fund, the one-stop service platform should also link enterprises with research projects at different levels of governments in the Mainland, venture capital funds, relevant institutions and research organisations as well as professional services. On the one hand, the platform can help researchers apply for funding provided by the Central authority and various levels of local governments and collaborate with research institutions and organisations on research; and on the other, HK-SZ enterprises can access venture capitals of the two cities via the Loop. This makes the Loop the best platform to link enterprises with both research and capital from both the Mainland and Hong Kong. Meanwhile, enterprises can obtain legal and accounting services required in the research process via the platform. In the area of intellectual property in particular, enterprises can obtain support on mediation and arbitration via the Intellectual Property Arbitration Centre of China (Shenzhen) established in the Shenzhen park and staffed with barristers and lawyers from Hong Kong and Macao (see **Recommendation 6.2** for details); enterprises can also hire eligible barristers and lawyers trained in Hong Kong and Macao to deal with litigations in the Mainland.[75]

Attracting CROs and CDMOs: It is common for conventional pharmaceutical enterprises in the biotech industry to outsource certain procedures of the R&D process to third parties to achieve cost reduction. Whereas Contract Research Organizations (CROs) can take charge of preclinical and clinical research, Contract Development and Manufacturing Organizations (CDMOs) can take up the Chemistry, Manufacturing and Controls (CMC) of the entire commercial production and R&D process, which includes quality control and production. CROs from the Mainland can establish themselves in the Loop to assist Hong Kong enterprises in conducting research in the Mainland. Similarly, CROs from Hong Kong can also establish themselves in the Loop to introduce services aligned with international standards into Shenzhen, including research and production services that meet regulatory standards of major drug regulators of the world, as well as quality assurance services that meet international standards. Hong Kong CROs can also help with application submission to major drug regulators of the world, fostering collaboration between healthcare organisations and enterprises from the Mainland and biotech service organisations from overseas, thereby enhancing the clinical trial capabilities and quality assurance standards of Mainland healthcare organisations.

[75] The General Office of the State Council issued a document in October 2020 to implement a pilot measure that permits eligible legal practitioners in Hong Kong and practising lawyers in Macao to practise in certain areas in nine cities of the Guangdong Province.

Encouraging knowledge transfer in tertiary institutions and nurturing multi-skilled talent well-versed in biotech and business

Tertiary institutions are cradles for ground-breaking technological innovations of the world. However, it is only after successful technology transfer that consumers may benefit from such research outcomes. One of the objectives of the Regulation of Shenzhen Special Economic Zone on Scientific and Technological Innovation implemented in 2020 is to encourage knowledge transfer in tertiary institutions.[76] Despite this, the Hong Kong government has not yet put forth policy incentives of a similar scale to foster knowledge transfer in tertiary institutions. To leverage the world-class biotech research output of tertiary institutions in Hong Kong, we should promote entrepreneurship among researchers, or encourage them to engage in transfer of advanced technology. Yet, there is a dearth of such talent in the biotech industry. On one hand, universities have not cultivated a culture of knowledge transfer, with researchers discouraged or even limited from engaging in knowledge transfer, resulting in low number of patent application, licenses granted and spin-off companies founded; on the other hand, there is a mismatch between what the industry requires and what graduates of biotech programmes can offer, with few equipped with research management and entrepreneurship skills.

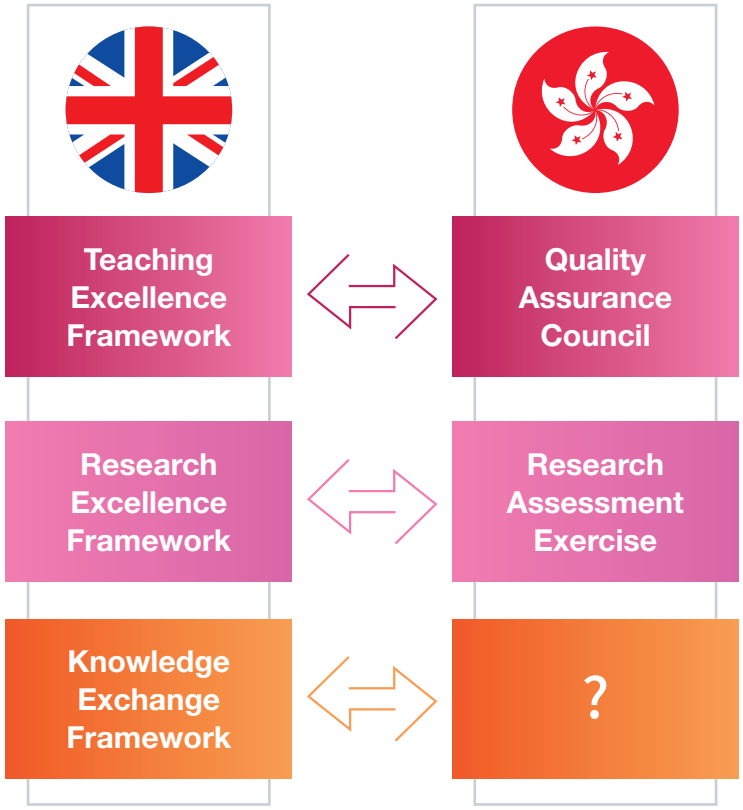
Recommendation 4.1 | Establishing an assessment framework for knowledge transfer to foster a culture conducive to knowledge transfer on campus

To foster a culture conducive to knowledge transfer on campus, we recommend that an assessment framework for knowledge transfer be established in Hong Kong that is linked to university funding from the government. Even though knowledge transfer along with teaching and research are seen as the three main functions of universities, knowledge transfer has little impact on the amount of funding universities receive and the career progression of researchers. Hong Kong has established a teaching assessment framework in the form of the Quality Assurance Council and a research assessment framework through the Research Assessment Exercise, in reference to the UK education system. Yet, while the UK has started to put equal emphasis on knowledge transfer by implementing the Knowledge Exchange Framework since the second half of 2020, Hong Kong still lacks such a framework (see **Figure 22**).

Given that researchers' performance in knowledge transfer has little impact on the amount of government funding that institutions receive, assessment and promotion of academics are still largely dependent on the amount of research funding they secure and the number of journal articles published. Stakeholders of this study

[76] Includes encouraging and commending researchers engaged in knowledge transfer (Article 95), and researchers working part-time in enterprises (Article 85), etc.

Figure 22 | Hong Kong lacks an assessment framework for knowledge transfer



Sources: *Times Higher Education,* Research England, and University Grants Committee

reflected that the number of patents filed carries very low weight in terms of researchers' key performance indicators. Likewise, the current assessment and promotion frameworks have largely ignored actions that represent actual transfer of patents into commercial application, such as the granting of licences and formation of spin-off companies.

Therefore, to foster a more vibrant culture of knowledge transfer among institutions, and to encourage commercialisation of research outcomes by researchers, we recommend **that the UGC establish an assessment framework for knowledge transfer in tertiary institutions**[77] **and link certain government funding with universities' performance under the framework**, thereby encouraging healthy competitions among universities, strengthening their commitment to knowledge transfer and entrepreneurship and removing barriers for researchers.

Recommendation 4.2 | Relaxing regulations on professors engaging in outside work to foster knowledge transfer

Not only do professors and academics in Hong Kong lack incentives to engage in knowledge transfer, they are also given little flexibility to take part in such activities, with limitations on the number of hours permitted for outside work, clinical service and consultancy work. As we have pointed out in our research report "Building the Technology Bridge for Scientific Breakthroughs: Developing an Innovation Hub of the Future", the UGC requires

[77] See Our Hong Kong Foundation's report *Building the Technology Bridge for Scientific Breakthroughs: Developing an Innovation Hub of the Future*, which also recommends that the government substantially increase recurrent funding on knowledge transfer so as to encourage professors to engage in knowledge transfer.

that all institutions limit faculty and staff members to spending less than the equivalent of one day per week in a year on outside work, inclusive of weekends, public holidays, and annual leaves. Such a policy undoubtedly hampers talent from engaging in knowledge transfer and innovative work. Overseas academic institutions are, in contrast, more proactive in encouraging researchers to commercialise their research outcomes. For instance, the MIT put in place a policy in 2015 to give professors complete autonomy over time dedicated to outside professional activities, provided that they have fully satisfied their teaching and research duties, and that declaration of the nature of professional activities is made to avoid conflict of interest. The intention of the policy is to encourage collaboration and exchange between academics and industry, businesses, government bodies and other organisations, as well as to incentivise applied research and commercialisation of research outcomes.

Permitting researchers in Hong Kong and Shenzhen to spend more time on research and exchange is key to biotech collaboration in the two cities. Given that it takes considerably more time for Hong Kong researchers to travel to other GBA cities compared to engaging in local activities, it is far from enough to allow only one day per week for outside work. We therefore recommend **that universities in Hong Kong revise regulations on researchers engaging in outside work and ease relevant restrictions, including increasing hours available for knowledge transfer activities.** For example, to encourage more researchers to engage in knowledge transfer and research commercialisation, universities should at least permit researchers to engage in knowledge transfer-related activities during weekends, public holidays and annual leaves.

Recommendation 4.3 | Nurturing multi-skilled talent with backgrounds in biotech and business

It takes multi-skilled talent with expertise in research and professional knowledge to excel in biotech entrepreneurship and investment. Those in management of biotech enterprises, for instance, have to be well-versed in business management and scientific knowledge; likewise, a good understanding of biotech is essential to venture capitalists and relevant legal practitioners. Unfortunately, there is a dearth of such multi-skilled talent in Hong Kong. For example, management positions of universities'

spin-off companies are often filled by professors or doctoral researchers they supervise, who may not understand how businesses work despite their advanced scientific knowledge. Recognising market demand, many world-class universities are providing interdisciplinary degrees in biotech and business (see **Table 9**), most of which work with the industry to offer classes taught by industry practitioners and provide internships. Notably, over 90% of tuition of MIT's programme is borne by its industry partners, including large pharmaceutical enterprises like Amgen, AstraZeneca, Johnson & Johnson and Sanofi, etc.

Despite having nurtured a great number of talent in the respective fields of biotech and business, universities in Hong Kong have not produced enough multi-skilled talent with interdisciplinary expertise. The only relevant programme is the Bachelor of Science (BSc) in Biotechnology and Business established by HKUST in 2016. To the universities' credit, preparation is underway to launch HKU's Master's degree in biotech investment, and students in CUHK's BSc in Biomedical Sciences may elect to concentrate on Strategic Management and Entrepreneurship. We propose **that universities in Hong Kong should, in response to market demand, establish more relevant programmes to develop talent with backgrounds in biotech and business or professional services.**

Of course, talent with business acumen do not only come from tertiary institutions; they can also switch from business or finance into the biotech industry and subsequently develop into managerial professionals with biotech knowledge. In order to nurture business talent in the biotech industry, tertiary institutions from Hong Kong, the Mainland and abroad can offer professional training programmes in the area, particularly courses catered to professionals from business or finance. This is not unlike the "integrated advanced training platform"[78] that the two governments have earlier agreed to establish at the Loop. By leveraging reasonable share allotment, biotech enterprises can further integrate the business acumen of professional managers and the innovative prowess of researchers, with a view to foster transfer of research outcomes.

Table 9 Select universities that provide interdisciplinary degrees in biotech and business

University	Degree
Massachusetts Institute of Technology	Leaders for Global Operations (LGO) Dual Degree Program in Biological Engineering and Business
Harvard University	MS/MBA Biotechnology: Life Sciences
Cambridge University	MPhil in Bioscience Enterprise
University of California, Berkeley	Robinson Life Sciences Business and Entrepreneurship Program

Sources: The universities' websites

[78] See the *Memorandum of Understanding on Jointly Developing the Lok Ma Chau Loop by Hong Kong and Shenzhen* that the Hong Kong and Shenzhen governments signed in 2017.

6

Policy recommendations for Central Ministries and Departments

Biotechnology is an emerging industry of strategic importance to the nation. The 14th Five Year Plan seeks to "pursue the integration and innovation of biotechnology and information technology, expedite the growth of industries including biomedicine, biotechnology breeding, biomaterials, bio-energies, and foster diversity and robust growth in the bio-economy". HK-SZ biotech development is thus intertwined with the planning and policies of the nation. The two cities are however facing issues of a more macro nature that may be beyond the prerogatives of their respective governments. Against the backdrop of "One Country, Two Systems", support from the Central Government is as well needed to tackle specific problems. In Chapter 6, we will present our recommendations to the Central Government regarding these issues.

Strengthening coordination and seeking comprehensive authorisation

Recommendation 5.1 | Establishing a designated body under the Greater Bay Area Leading Group for the Development of the GBA to coordinate the coordinated development of "one zone, two parks"

In 2018, the Leading Group for the Development of the Guangdong-Hong Kong-Macao Greater Bay Area (the Leading Group)[79] was formed by the State Council to steer the development of the GBA. To pursue coordinated development of the Loop, the governments of Hong Kong and Shenzhen established a Joint Task Force led by the Vice Mayor of Shenzhen Municipality and the Secretary for Innovation and Technology of the Hong Kong SAR Government back in 2017 and has convened biannual meetings. To coordinate daily operations, construction headquarters were set up by Shenzhen Government and three task forces were formed by Hong Kong's

[79] Chairman: Han Zheng (Member of the Standing Committee of the Central Political Bureau of the Communist Party of China, Vice Premier of the State Council); Vice-Chairmen: Li Xi (Member of the Central Political Bureau of the Communist Party of China, Communist Party Secretary of Guangdong), He Lifeng (Vice-Chairman of the National Committee of the Chinese People's Political Consultative Conference, Chairman of National Development and Reform Commission); Members: Zhang Xiaoming (Deputy Director of the Hong Kong and Macau Affairs Office of the State Council), Carrie Lam Cheng Yuet-ngor (Chief Executive of Hong Kong SAR), Ho Iat Seng (Chief Executive of Macao SAR), Luo Huining (Deputy Director of the Hong Kong and Macao Affairs Office of the State Council, Director of the Liaison Office of the Central People's Government in Hong Kong), Fu Ziying (Deputy Director of the Hong Kong and Macao Affairs Office of the State Council, Director of the Liaison Office of the Central People's Government in Macao).

the Innovation and Technology Commission, which are responsible for formulating the Joint Policy Package, property management and talent attraction issues respectively. Meanwhile, the Hong Kong-Shenzhen Innovation and Technology Park (HKSITP) directly reports to the Joint Task Force on the development of the Hong Kong park on a regular basis. Nonetheless, as mentioned in **Chapter 3**, coordination between the two governments remains inadequate. Not only do the two parks differ greatly in work progress, there is also a lack of planning for coordinated development.

We therefore recommend **the establishment of a relevant body, designated channel or platform under the Leading Group, which would strengthen the oversight and coordination of the Loop's development under the "one zone, two parks" arrangement, and expedite the formulation of a HK-SZ "Joint Policy Package".** The designated body will assist in implementing bottom-up and top-down planning to further enhance Leading Group's orchestration of both parks' planning, construction progress and major projects; which will in turn ensure the two parks' coordinated development. Furthermore, the operations of both parks will be further harmonized, while regular reporting and communication mechanism with the Leading Group should be established to ensure smooth and effective communication.

Table 10 lists some of the directions for this designated body to coordinate the HK-SZ "Joint Policy Package", covering five areas including talent attraction, talent flow, management of organisation, capital flow and opening up of network:

Table 10 | Coordination by designated body under the Leading Group

Area	Specific proposals
Talent attraction	Coordinate the systems devised by both governments to attract talent and devise a tailor-made proposal to attract international top biotech talent and research teams. Also to allocate research funding based on research direction, arrange for environment and devices, accommodation, education for children, social security, concessionary tax rates and/or tax refund policy, etc.
Talent flow	Coordinate to optimise the two regions' work and residence permits for overseas tech talent by targeting those who frequently travel between both cities and providing them with special visa after verification. Also to streamline the arrangements for talent crossing the border between Hong Kong and Shenzhen parks.
Management of Organisation	Appropriately relax the administrative regulations on public institutions[80] and tertiary institute management for HK-SZ partner research institutes. Also to explore the implementation of management approaches that can bridge the training system with that of the Hong Kong tertiary education sector.
Capital Flow	Explore the feasibility of allowing definite amount of tech funds to be freely convertible and opening up the the capital account for investment institutions.
Opening up of Network	Seek delegation of authorities from the Bureau of Cyber Security of Cyberspace Administration of China, where upon approval from the Shenzhen Municipality, HK-SZ partner research institutes and R&D centres of biomedical enterprises at the Loop can access the international cyberspace.

Recommendation 5.2 | Seeking comprehensive authorisation from the Central Government to implement pilot policies in biotech reform

In order to develop the Loop into a HK-SZ biotech collaboration pilot and demonstration area, more autonomy should be conferred to the Loop to instigate reforms and biotech development in a flexible manner. In 2020, the Central Government announced the *Plan on implementing pilot reforms in Shenzhen to build the city into a demonstration area of socialism with Chinese characteristics (2020-2025)* and issued the first batch of authorisations as attachment, offering Shenzhen Municipality with greater autonomy to instigate reform. Provided there is prior notification to the Central Government, the Shenzhen Municipal Government can review items on the list by itself. Unlike the previous authorisation practice of "discussion on an issue basis, review by every level,

[80] Including public service providers with government functions and non-public service departments etc., specialising in education, technology, culture and health activities, such as schools, hospitals and scientific research institutes, etc.

and item by item", it is not necessary to declare every item for review, except specified ones requiring approval, so as to facilitate the reform of key areas.

To create a biomedical powerhouse in the Loop for the GBA and even the entire nation, we recommend **that the Shenzhen Municipal Government seek the approval of the Central Government on implementing comprehensive authorisation in the Loop, followed by the Hong Kong and Shenzhen governments jointly seeking the authorisation of various ministries and departments to implement pilot policies in biotech reform.** Examples include improving drug approval procedures, facilitating the sharing of human genetic resources, streamlining the cross-border flow of research materials and devices, and supporting the testing and certification of drugs and medical devices which have yet to complete clinical research procedures at eligible institutes at the Loop, etc. To ensure the smooth implementation of comprehensive authorisation, and to launch pilot measures of biotech system and regime reform, appropriate fault tolerance mechanisms and effective incentivising measures should be put in place in the Loop.

A biotech expert advisory committee consisting of government representatives and top-notch professionals within China and from overseas should be established in the Loop to put forward specific recommendations on the development of the biotech industry, as well as exploring issues like ethics review procedures and mutual recognition of clinical trial results and standards, and drug application review and approval procedures, etc. To improve the ethics review of clinical trials in Hong Kong and Shenzhen, the advisory committee can foster cooperation between the ethic committees of both cities and explore the application of Hong Kong regulations and standards at the Loop. Furthermore, cooperation between ethics committees in the two cities and foreign countries and regions, such as the US and the EU, should be promoted to bridge their ethics review rules and standards.

Bridging the two cities' systems and regimes

Recommendation 6.1 | Relaxing regulations set by the Negative List to allow designated enterprises to enter the Mainland market

The two cities have yet to harmonise their regulations on market access. In Hong Kong, enterprises from the two cities are on an equal footing as Mainland enterprises are not subject to any restrictions. However, under the Mainland's restrictions on market access, besides existing restrictions that forbid persons of foreign nationalities to act as the legal representative of public institutions and private non-enterprise units, the Negative List of foreign investment in China (2020) promulgated by the National Development and Reform Commission and the Ministry of Commerce bars foreign investors from investing in the development and application of human stem cells, genetic diagnostics and therapy technology. As Hong Kong is designated as a "foreign" region, it is difficult for Hong Kong enterprises specialised in genetic diagnostics and therapies to enter the Mainland market.

As such, we recommend **that the National Development and Reform Commission and the Ministry of Commerce ease restrictions set by the Negative List in relation to foreign capital, and allow direct entry into the Mainland market by Hong Kong biotech enterprises that are registered in the Loop and have Hong Kong permanent residents of Chinese nationality serving as their legal person or major shareholder.** Said enterprises should be subjected to conditions applicable to domestically-owned enterprises, including but not limited to scope of business, market access conditions, investment restrictions and shareholding ratio. Such measures may first be piloted in the GBA, with the objective of their gradual expansion to the entire country so that foreign and domestic capital can eventually be managed by the same principles.

Recommendation 6.2 | Coordinating the intellectual property regimes in Hong Kong and the Mainland

With regard to intellectual property (IP) regime, Hong Kong's existing standard patent (R) system recognises by allowing the "re-registration" of patents granted in three regions, including the National Intellectual Property Administration (NIPA) in China (see **Table 11**). However, the NIPA has neither provided Hong Kong applicants with an expedited channel for application, nor established a mechanism to expedite the recognition of patents to those already approved by the Intellectual Property Department (IPD) of Hong Kong. Meanwhile, in Hong Kong, an original grant patent system for standard patents (i.e., standard patent (O)) was introduced in 2019, under which applicants may file a standard patent directly in Hong Kong, without the need to have previously filed it with a designated patent office outside of Hong Kong. Given that the NIPA provided ample assistance and technical support as the IPD established the original grant patent system,[81] and reference was made to the experience of the NIPA while the examination guidelines were drawn up,[82] Hong Kong has the need and ability to better coordinate with the Mainland's patent system.

Table 11 | The two standard patent systems in Hong Kong

Standard patent (R) system	Standard patent (O) system (since 2019)
Applicants may apply for "re-registration" in Hong Kong on the basis of a patent already granted in one of the three designated patent offices (namely the China National Intellectual Property Administration, the United Kingdom Intellectual Property Office and the European Patent Office). The IPD will not carry out substantive examination. More than half of standard patent (R) applications received by the IPD were based on patents already granted by the Chinese authorities.[83]	The IPD will conduct formal and substantive examination of the application. The latter includes examining the patentability of the underlying invention, i.e., whether the invention is new, involves an inventive step and is industrially applicable.

Source: Intellectual Property Department of Hong Kong

[81] As early as 2011, the Advisory Committee on review of the patent system in Hong Kong already proposed that substantive examination may be taken over by the NIPA, a suggestion subsequently endorsed by the LegCo and IPD.

[82] In formulating its Patents Examination Guidelines, the IPD made reference to examination guidelines then in use by the World Intellectual Property Organization and other jurisdictions, including Australia, mainland China, New Zealand, Singapore and the United Kingdom.

[83] Of the patent applications the IPD received in 2016, 58.8% had received prior approval by the NIPA, 38% by the European Patent Office, and 1.8% by the United Kingdom Intellectual Property Office.

Since an integrated IP regime applicable to both the Mainland and Hong Kong has yet to be established, the NIPA may explore the coordination of the two regulatory regimes to better harmonise the IP regimes, with a view to addressing differences in the regimes in the longer term. In 2017, the NIPA implemented a prioritised patent granting mechanism to expedite granting of patent associated with the nation's prioritised industries such as biotech.[84] We recommend **that NIPA set up a subsidiary or an office in the Loop, with a view to expediting the approval of patent applications by enterprises registered in the Loop by making reference to the above-mentioned prioritised granting mechanism. We also recommend that the NIPA consider making reference to Hong Kong's patent (R) system and recognise standard patents granted under the Hong Kong IPD's patent (O) system, with a trial scheme to be run in the GBA first.** The NIPA can also share its patent database with Hong Kong and coordinate the original grant patent systems in Hong Kong and the Mainland by providing technical assistance and patent expertise. In the event of IP disputes, enterprises may obtain support on mediation and arbitration via the Intellectual Property Arbitration Centre of China (Shenzhen) mentioned in **Recommendation 3**. They can also hire eligible barristers and lawyers trained in Hong Kong and Macao to deal with litigations in the Mainland.

Recommendation 6.3 | Expediting evaluation and approval of new drugs in the Loop

In relation to the registration and launch of new drugs, in addition to our recommendations for the governments of Hong Kong and Shenzhen (see **Recommendation 2.5** for details), **the NMPA may consider delegating certain powers in new drug approval and exploring the administrative feasibility of such delegation, so that the two GBA sub-centres for drug and medical device evaluation and inspection established in the Loop may be tasked with new drug approval procedures**, instead of merely functioning as a communication channel between the NMPA and enterprises. The biotech expert advisory committee mentioned in **Recommendation 5.2** can render comprehensive and professional support to the GBA sub-centres in conducting all-stage intervention for the approval procedures of drugs and medical devices. One such intervention includes the sub-centres providing step-by-step communication with applicants for drug registration, from clinical research to registration and product launch. Such communication can help applicants complete the evaluation and approval procedures at the sub-centres more efficiently.

[84] In 2017, the NIPA promulgated the Measures for the Administration of the Prioritised Examination of Patents, which permits prioritised examination of specific applications. The NIPA undertakes to issue an Opinion on the First Examination within 45 days after the submission of the application and to close the file within 12 months. Re-examination files would be closed within 7 months. This shortens the normal examination time of 33 months by 21 months.

Facilitating the passage of bio-materials and medical devices between Hong Kong and Shenzhen

Recommendation 7.1 | Optimising the mechanism by which Mainland bio-materials are transported across the border into the Hong Kong park

Although the cross-border flow of goods into the Loop has seen improvement in some areas, the Mainland's export regime in relation to biological materials and samples still needs to be optimised.

Under the *Regulation of the People's Republic of China on the Administration of Human Genetic Resources* issued in 2019 by the State Council, export or joint research with foreign institutions of genetic resources and information are subject to approval by the Human Genetic Resources Administration of China (HGRAC). Furthermore, these articles are subject to customs control, meaning the import-export inspection and quarantine procedures are complicated and stringent, and involves approval and examination by various departments including the Customs, health quarantine authorities, the Science and Technology Innovation Commission, and the State Administration for Market Regulation. Although the General Administration of Customs of China has set up three import-export service platforms for biological materials to offer a swift one-stop customs clearance service, thereby shortening the approval time for exporting special items and importing biological materials from 20 days to three working days, such platform is not available at the HK-SZ border. Moreover, the Single E-lock Scheme[85] launched by customs of both cities does not cover biological materials.

To optimise the import-export regime for biological materials, the Central Government announced 16 policies regarding the construction of the GBA in November 2019. They include "easing restrictions on export of human genetic resources to Hong Kong and Macao". In July 2020, the HGRAC approved three subsidiaries, hospitals, and research institutes of Hong Kong tertiary education institutions in the Mainland to be pilot organisations of human genetic resource management, which means these institutions can apply for human genetic resources in the Mainland for research purposes in Hong Kong. Building on this development, we recommend **the establishment of a HGRAC subsidiary in the Loop to optimise the Mainland's export regime in relation to biological samples. It can also improve the import-export inspection and quarantine procedures for human genetic resources by Mainland and Hong Kong Customs, so that eligible Hong Kong institutions, research institutes and enterprises may utilise said resources in the Loop, provided that appropriate risk management protocols are in place.**

[85] Launching the Single E-lock Scheme in 2016, the Customs and Excise Department of the HKSAR Government and the Mainland Customs make use of one single e-lock and the technology of GPS on the principle of "Across the Boundary with One Single E-lock under Separate Monitoring" to reduce duplicate inspection on the same shipment by both customs authorities at the boundary, thereby streamlining the clearance process and expediting the flow of transhipment cargoes. Since biological materials are goods controlled by licence or permit, it is not covered by the Scheme.

Recommendation 7.2 | Easing restrictions on the import of bio-materials and medical devices

On the other hand, the import flow for bio-materials such as biologicals, biological samples and specimen is complicated and inefficient; it also takes considerable time to review and approve the importation of medical devices.[86] Therefore, we recommend that the competent Central authorities allow Shenzhen Customs and market regulators to further improve the inspection and quarantine procedures for importing bio-materials, expedite inspection and allow enterprises on the "White List" to import bio-materials. The "White List" should comprise biomedical enterprises in the Loop which conduct sound safety and risk management of biologicals, with no precedence of high-risk incidents. The Central authorities concerned can also authorise the use of unregistered imported medical devices for R&D and testing purposes by Loop-based biomedical enterprises and specific healthcare organisations in Shenzhen.

[86] For example, the best period for testing of Specific Pathogen-free (SPF) mice is 4 to 6 weeks after they are born. Under the prevalent mechanism, SPF mice are to be quarantined for 30 days upon arrival; Foreign commercial genome sequencing usually requires results within 10–15 days but under the prevalent mechanism, the customs clearance of imported DNA/RNA of animal and plant for genetic test usually takes around two weeks.

7

Conclusion

As the twin engines of the GBA, high expectations have been placed on research collaborations between Hong Kong and Shenzhen, with the Hetao Shenzhen-Hong Kong Science and Technology Innovation Cooperation Zone named as one of the key Guangdong-Hong Kong-Macao cooperation platforms in the 14th Five-Year Plan. With development of the Loop and the collaborative development of “one river, two banks” and “one zone, two parks” as its focus, this study approaches collaboration in biotech as an entry point by drawing up seven major recommendations, encompassing 19 proposals, to the Central Government and the governments of Hong Kong and Shenzhen.

In addition to driving the sustained economic growth of both cities, the significance of HK-SZ cooperation lies in setting a model for the development of the GBA. While fully realising the city’s edge and proactively integrating itself into the nation’s development, Hong Kong can also contribute to the further opening of national systems and the establishment of an open economy. We believe these recommendations will help overcome the hurdles hampering HK-SZ collaboration and foster the complementary cooperation of the two cities, so that they can seize the golden opportunities under the national plan to create a biomedical powerhouse in the GBA and take biotechnology innovation to new international heights.

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