

Press Release

GBAICTI, HKUMed and GSK signed the Tripartite Memorandum of Understanding (MoU)

The Greater Bay Area International Clinical Trial Institute (GBAICTI), the Department of Pharmacology and Pharmacy of the LKS Faculty of Medicine, The University of Hong Kong (HKUMed), and GSK signed a tripartite Memorandum of Understanding (MoU) today (September 9). The three parties jointly established a strategic framework to advance clinical data and real-world studies (RWS) in the Greater Bay Area (GBA).

This collaboration aims to develop Hong Kong into a leading regional and international hub for real-world research, while actively exploring the use of real-world data to support drug registration in Mainland China. The collaboration will initially focus on conducting high-quality research in Hong Kong, with plans to gradually expand the scope of studies to other cities in the GBA (e.g., Macau and Shenzhen).

Highlights of the tripartite collaboration include:

1. **Clinical Trials and Real-World Studies (RWS):** Explore collaborative directions for clinical trials and RWS, including a study that aims to leverage data from selected healthcare settings in the GBA to advance innovative treatments.
2. **Jointly developing and advancing novel methodologies for RWS:** Apply medical data analysis to enhance data quality, usability, and interoperability, in order to build a comprehensive evidence base for regulatory submissions.
3. **Academic exchange:** Jointly organise local and international academic events
4. **Talent development:** Nurture a new generation of clinical research professionals in areas such as study design, data analysis, and regulatory science

The Real-World Study and Application Centre (RWSAC), which will be established under the GBAICTI by the end of this year, aims to enhance the access to and application of health and medical databases, and to foster collaboration between Hong Kong and the Mainland in relevant areas, particularly in integrating real-world data generated through the special measure of using Hong Kong-registered drugs and medical devices used in Hong Kong public hospitals in the Guangdong-Hong Kong-Macao Greater Bay Area (GBA), to achieve three major objectives: (1) to accelerate the research and development (R&D), approval and market launch of innovative medical products; (2) to promote the application of real-world data in support of evidence-based decision-making, thereby optimising treatment strategies and enhancing healthcare system efficiency; and (3) to develop Hong Kong into a leading region and global hub for real-world studies, with a view to attracting more international collaboration and investment.

Professor Bernard Cheung Man-yung, Chief Executive Officer of GBAICTI, said, "We are pleased to witness the official launch of this tripartite collaboration. GBAICTI serves as the facilitator to provide the necessary resources and a collaborative platform to facilitate effective communication among stakeholders. Through this collaboration, we aim not only to perform clinical research at the highest level, but also to accelerate the transformation of innovative local research into practical medical solutions that would benefit patients in Hong Kong, the Greater Bay Area, and beyond."

This collaboration marks a pivotal step for Hong Kong in building world-class capabilities for clinical trials and RWS. The signing of MoU not only lays the foundation for the tripartite cooperation but also adds new momentum to Hong Kong's biomedical innovation ecosystem. Looking ahead, GBAICTI will use this as a blueprint to actively establish strategic partnerships with more industry partners, clinical trial centers, and

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GBAICTI

contract research organizations (CROs) to jointly promote the development of clinical trials, making a significant contribution to strengthening Hong Kong's position as an international health and medical innovation hub.

Established and wholly owned by the Hong Kong Special Administrative Region Government, the GBAICTI officially commenced operation in November last year. Together with the GBA International Clinical Trials Center in Shenzhen, the establishment of "one institute, one center" marked the first benchmark for co-ordinated development under "one zone, two parks" of the Hetao Shenzhen-Hong Kong Science and Technology Innovation Co-operation Zone. GBAICTI is actively establishing the GBA Clinical Trial Collaboration Platform to provide a full range of support to medical research institutions in the future. It includes introduction of artificial intelligence technologies to assist with matching of clinical trial studies; establishment of a co-ordinated ethics review mechanism between the two places to enhance approval efficiency; promotion of talent exchange and professional training; building of a research talent pool. This will create an efficient and synergistic innovation ecosystem for the tripartite collaboration.

For enquiries, please contact:

Greater Bay Area International Clinical Trial Institute

Ms. Cathy Shen

Email: cathy.shen@gbaicti.hk