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Asia's emergence in cancer immunotherapy: challenges and opportunities

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ABSTRACT

Asia's role in cancer immunotherapy research is rapidly expanding, driven by cutting-edge facilities, innovative technologies, and collaborative efforts. This commentary examines the region's growing impact, highlighting key clinical trials, emerging research hubs, and unique challenges that we face. It discusses the need for standardization in cell and gene therapies, and more broadly all immunotherapies, addressing cost and accessibility issues. We examine the implications of genetic diversity in Asian populations as well as cultural and linguistic factors that affect clinical trials and patient care. The analysis extends to emerging opportunities in technological innovation and international collaboration, while addressing critical challenges in regulatory oversight, data transparency, and intellectual property protection. The success of the recent SITC-World Immunotherapy Council-Asia conference is showcased as a catalyst for future collaborations. By tackling these challenges and using innovations, Asian countries can significantly contribute to global advancements in cancer immunotherapy, potentially improving outcomes for patients worldwide.

INTRODUCTION

Cancer immunotherapy has revolutionized oncology treatment globally, offering new hope for patients with previously untreatable cancers. In recent years, Asia has emerged as a significant contributor to this field, marked by a surge in high-quality research output and clinical trials. This commentary examines Asia's growing influence in cancer immunotherapy, highlighting both the challenges and opportunities unique to the region. The recent success of the SITC/World Immunotherapy Council (WIC)-Asia conference underscores the region's commitment to advancing cancer immunotherapy. This gathering of leading researchers and clinicians from across Asia and beyond has fostered collaborations and knowledge exchange, setting the stage for future breakthroughs. Asia's diverse patient populations and rising cancer incidence rates provide crucial insights that can enhance the global understanding and effectiveness of immunotherapies. Additionally, the region's investment in state-of-the-art research facilities and innovative technologies is accelerating the development of novel treatments. By exploring Asia's substantial contributions, unique challenges, and considerable potential in cancer immunotherapy, we aim to highlight the importance of international collaboration and the need for tailored approaches that consider the unique genetic, cultural, and economic factors of the region. This commentary illuminates recent breakthroughs while building on a foundation of longstanding efforts to harmonize Asian and Western cancer research paradigms and clinical trials. Notable milestones in this journey include the seminal 2019 CSI-WIC-SITC symposium in Hefei, where SITC made significant contributions including the sponsorship of Lisa Butterfield's participation. This event built on the visionary cross-cultural collaborations spearheaded by Michael Lotze some two decades prior. Through meticulous examination of progress across diverse Asian nations, we present a nuanced and comprehensive panorama of the region's burgeoning influence in cancer immunotherapy. As shown in figure 1a,b, the distribution of major immunotherapy research centers and clinical trial sites across Asia is extensive, with circle sizes reflecting relative research output based on JITC publications (2020–2024), while individual colors represent various types of research facilities. At the same time, we also identify patterns in cancer profiles that are prioritized in Asian immunotherapy efforts and compared with those in Western regions clarified in figure 1c,d. This holistic perspective underscores rapid advancements, contextualizing them within the broader tapestry of global oncological research. It highlights the increasing interconnectedness and mutual enrichment of Eastern and Western scientific approaches, offering insight into the evolving landscape of international collaboration in the fight against cancer.

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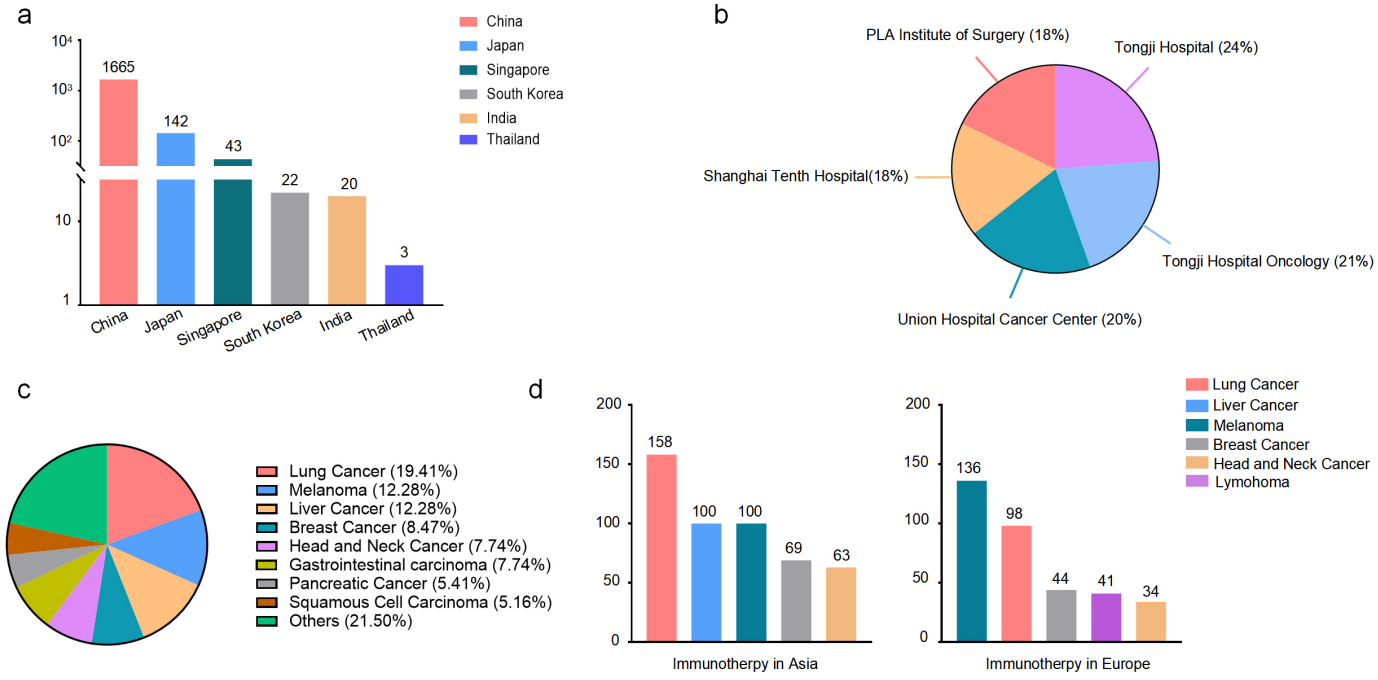

Figure 1 Distribution and research output of major Asian cancer immunotherapy centers (2020–2024). The graph illustrates the geographical distribution and relative research contributions of major cancer immunotherapy centers across Asia based on JITC publication data from 2020 to 2024. The bar chart shows China leads with 1665 publications, followed by Japan (142), Singapore (43), South Korea (22), India (20), Thailand (3) (a). The pie chart highlights the relative contributions of key Chinese institutions, with Tongji Hospital's OBGYN (24%) and oncology (21%) departments, PLA Institute of Surgery (18%), Shanghai Tenth Hospital (18%), and Union Hospital Cancer Center (20%) being major contributors (b). The pie chart highlights the relative contributions of main cancer types in Asian countries based on JITC publication data from 2020 to 2024, with lung cancer (19.41%) and melanoma (12.28%), liver cancer (12.28%), breast cancer (8.47%), and head and neck cancer (7.74%), gastrointestinal cancer (7.74%), pancreatic cancer (5.41%), squamous cell carcinoma (5.16%) and others (21.50%) being main types of contribution (c). The graph illustrates the relative research contributions of major immunotherapy cancer types across Asia and Europe based on JITC publication data from 2020 to 2024. The main types of tumors for immunotherapy in Asia are concentrated in lung cancer (158), liver cancer (100), melanoma (100), breast cancer (69), head and neck cancer (63); in Europe, they are concentrated in melanoma (136), lung cancer (98), breast cancer (44), head and neck cancer (41), and lymphoma (34) (d).

ASIA'S GROWING IMPACT ON CANCER IMMUNOTHERAPY RESEARCH

Asia's contribution to cancer immunotherapy research is increasingly recognized for its potential to advance the field significantly. The region's cutting-edge research facilities, innovative technologies, emerging research hubs, and collaborative efforts with global institutions are accelerating the development of novel treatments and clinical trials.

Notably contributing clinical trials in Asia

We cannot help but mention Asian's contribution in clinical trials specifically in lung cancer, nasopharyngeal carcinoma, esophageal cancer and breast cancer. A notable example of Dr Caicun Zhou from Shanghai East Hospital has been leading studies of a phase 3 trial of camrelizumab, a PD-1 inhibitor, combined with chemotherapy demonstrated significant improvements in progression-free and overall survival for patients with advanced squamous NSCLC. Ma Jun and his team from the Sun Yat-sen University Cancer Center have achieved a series of groundbreaking clinical trial results, realizing a shift from the "American plan" to the "Chinese plan" in diagnosis and treatment of nasopharyngeal carcinoma. The team of Song Erwei from Sun Yat-sen Memorial Hospital's found that SHR-A1811 exhibited acceptable tolerability, promising antitumor activity, and favorable pharmacokinetic characteristics in advanced solid tumors in phase 1 clinical trials. Professor Jianhua Fu of the Sun Yat-sen University Cancer Center was the first to apply the combination of chemoradiotherapy and immunotherapy in the neoadjuvant treatment of esophageal squamous cell carcinoma and completed the world's first phase 2 clinical trial. These results are all highlighting Asia's capability to conduct large-scale, high-impact immunotherapy studies,[1] highlighting the need for robust quality control measures and standardized data collection protocols across diverse healthcare systems.

Immunotherapy promotion in China's largest hospital

At First Affiliated Hospital of Zhengzhou University, Dr Yi Zhang's work in promoting immunotherapy represents a continuation of progress that began decades ago. Since 1997, when discussions about dendritic cells were just beginning, Dr Yi Zhang has been at the forefront of immunotherapy research and implementation. While his

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team has made significant advances in understanding dendritic cell biology and its clinical applications, they also faced challenges in standardizing production protocols and optimizing therapeutic efficacy. Today, under Dr Zhang's leadership, First Affiliated Hospital of Zhengzhou University demonstrates both the promise and challenges of advancing cancer treatment in China, particularly in translating cellular therapy research into clinical practice.

ASIAN ADVANCEMENTS IN CELL AND GENE THERAPIES

The cell and gene therapy landscape in Asia has shown remarkable growth, with CAR-T clinical trials increasing from 82 to 428 between 2019 and 2024 (39.2% annual growth rate). China has pioneered dual-target CAR-T cells addressing tumor antigen escape and optimized manufacturing protocols reducing production time to 7–10 days. Japan's regulatory framework through ASRM and PMDA enables conditional early approval after demonstrated safety, accelerating the development of treatments like Kymriah. Singapore leverages its biomedical infrastructure through ACTRIS to advance natural killer (NK) cell therapeutics specifically designed for prevalent Asian cancer types. South Korea has established competitive cell therapy capabilities through policy initiatives supporting domestic innovation, with companies like TiCARos pioneering manufacturing approaches that potentially reduce production costs by 30–40%.

Innovative AI developments

The integration of artificial intelligence (AI) and machine learning in cancer research and treatment is a rapidly growing field in Asia. Scientists including the lead author (JY) and others are pioneering AI applications in pathology and radiology, enhancing cancer diagnosis accuracy and treatment planning. Cheng Sun's team developed the TIMES scoring system for cancer prognosis prediction, which has been implemented as an online diagnostic tool with 82.2% testing accuracy.[2] These advancements support personalized treatment plans and improve patient outcomes. Chinese multicenter study showcased AI helped predict lung cancer treatment outcomes effectively.[3] The integration of AI with telemedicine platforms facilitates remote diagnosis and monitoring, particularly benefiting rural and underserved areas.[4 5]

Emerging importance of investigator-initiated trials in China

China's pharmaceutical landscape is witnessing a significant shift with the rising importance of investigator-initiated trials (IITs) in industry-based research. While this trend reflects a more collaborative approach between academic institutions and the pharmaceutical industry, it also presents unique challenges. Key concerns include maintaining data transparency, ensuring appropriate ethical oversight, and standardizing informed consent processes across diverse cultural contexts. The growth of IITs in China is accelerating the development of tailored immunotherapies, but success depends on establishing robust quality control mechanisms and harmonized regulatory frameworks. Another noteworthy contributor to China's cancer immunotherapy landscape is Professor Bo Huang from the Chinese Academy of Medical Sciences. With extensive international experience and a focus on tumor immunology, Professor Huang has made significant contributions to understanding T-cell metabolism, the tumor microenvironment, and CAR-T cell therapy. While the growth of IITs in China demonstrates the region's research maturity, it also highlights critical challenges in trial implementation. Data quality assurance, standardization of protocols, and ethical oversight require careful consideration. Recent experiences from multicenter trials, such as the zuberitamab study,[6] provide valuable insights into maintaining high standards while leveraging Asia's rapid recruitment capabilities. However, the scalability of such success depends on addressing key issues including informed consent processes in diverse cultural contexts and the standardization of data collection across different healthcare systems.

World-class research environments

Asia boasts several world-class research environments that are driving innovation in cancer immunotherapy. The A*STAR Biopolis in Singapore exemplifies this progress. This integrated research complex, hosting 17 institutes across biomedical sciences, physical sciences, and engineering, creates a synergistic environment for cutting-edge biomedical research. Notable contributions from A*STAR researchers, such as John Connolly at the Parker Institute for Cancer Immunology, have advanced our understanding of cancer immunology and immunotherapy, solidifying Singapore's position as a hub for innovative cancer research in Asia. With the growing interest in non-T cell-based immunotherapies, such as NK cell therapies, researchers across Asia are making valuable contributions. For instance, Cheng Sun at the University of Science and Technology of China is conducting promising research in this area. His laboratory of immunotherapy explores potential new targets against cancer using NK cell-related approaches. This work may contribute to our understanding of how to manage immunosuppressive cells in tumors and could potentially lead to improvements in immunotherapy outcomes for patients with cancer. Across Asia, governments are investing heavily in research infrastructure. Japan's Tsukuba Science City and South Korea's Daejeon Research Complex rival the best facilities globally. Asian populations demonstrate distinctive genetic characteristics impacting immunotherapy efficacy. HLA-A02:01, predominant in Western populations, occurs at substantially lower frequencies in East Asians (10–15% vs 40–50% in Caucasians), while HLA-A11:01 and HLA-A24:02 show higher prevalence. These differences necessitate Asia-specific cell therapy targeting strategies. EGFR mutation prevalence in NSCLC varies dramatically between Asian (30–50%) and Caucasian (10–15%) populations,

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correlating with differential responses to immune checkpoint inhibitors. Cultural and linguistic factors significantly impact patient perspectives on novel treatments, informed consent processes, and treatment adherence patterns, necessitating culturally calibrated communication protocols. Recent work on $CD93^+$ monocytes,[7] $SPI1^+CD68^+$ macrophages in gastric cancer,[8] and FcγRIIB deletion in glioblastoma treatment[8] demonstrates how individual institutions contribute unique perspectives to our understanding of cancer immunology. However, this diversity also highlights the need for standardized protocols and quality metrics across quite varied research environments. In Japan, autologous active lymphocyte NK cell therapy and dendritic cell immunotherapy have achieved significant results. The South Korean biotech company TiCARos has been granted approval by the Ministry of Food and Drug Safety (MFDS) for a new drug clinical trial (IND) of its independently developed CAR-T product, which was used in the treatment of refractory hematologic malignancies and advanced solid tumors. In summary, Asian countries and regions such as Singapore, Japan and the Republic of Korea have made remarkable progress in the field of immunotherapy. These studies and advancements brought new hope to patients with cancer, making significant contributions to the development of immunotherapy worldwide.

Evolving global research landscape: challenges and opportunities

The landscape of cancer immunotherapy research faces unprecedented opportunities and challenges. While geopolitical tensions, particularly between China and the USA, have led to policy changes affecting international collaboration, these challenges have paradoxically strengthened regional cooperation within Asia. The current environment has catalyzed increased domestic investment in research capabilities throughout Asia, evident in the emergence of new research hubs and the development of innovative approaches to cancer immunotherapy. The ripple effects of these policies extend beyond research collaboration to impact drug development and commercialization. Market access barriers, tariffs, and complex regulatory approval processes vary significantly across Asian countries. This variation affects everything from clinical trial implementation to drug availability and pricing, creating a complex landscape for both academic researchers and industry partners. This is evident in the emergence of new research hubs and the development of innovative approaches to cancer immunotherapy, exemplified by recent advances in biomarker development[9] and novel therapeutic strategies.[7 10] Less developed regions in Asia have weak medical infrastructure, making it difficult to carry out corresponding treatments; in addition, with resource allocation unbalanced, rural patients may lose the opportunity for immunotherapy. Other barriers, including genetic heterogeneity, population diversity, cultural specificity, and even language barriers can impact patient treatment choices and immunotherapy outcomes. While adapting to evolving geopolitical realities, the fundamental principle of global scientific exchange in cancer research must prevail. Comparison with other regions provides valuable insights. While Europe's centralized EMA framework offers efficiency in multicountry trials, Asia's diverse regulatory landscape presents unique challenges in harmonization. Similarly, experiences from Central/South America in managing cost and access issues could inform Asia's strategies for broader immunotherapy implementation.

WORLD IMMUNOTHERAPY COUNCIL-ASIA: A CATALYST FOR COLLABORATION AND PROGRESS

The evolution of cancer immunotherapy in Asia demonstrates the power of strategic regional collaboration. Recent gatherings like the SITC-WIC-Asia have revealed several insights into the region's immunotherapy landscape. These insights extend beyond scientific achievements to address fundamental challenges in research implementation and clinical translation. Key areas of progress include the development of standardized approaches to clinical trial management, enhanced data sharing mechanisms, and improved regulatory harmonization efforts. The successful implementation of multicenter trials, such as the recent study of zuberitamab,[6] provides a model for maintaining high research standards while leveraging Asia's diverse patient populations. Particularly noteworthy is the emerging framework for quality control in multicenter trials, addressing issues of data consistency, biospecimen handling, and regulatory compliance across different healthcare systems. These advances are crucial as the region works to establish itself as a leading force in global immunotherapy research.

FUTURE DIRECTIONS AND COLLABORATIONS

Asian countries' advancement in immunotherapy faces both opportunities and regulatory challenges. While Japan's stringent regulatory framework through the Pharmaceuticals and Medical Devices Agency and Sakigake designation provides a model for innovation oversight, other countries are still developing their regulatory infrastructure. Several critical factors will shape the future of immunotherapy research in Asia. The need to balance efficient trial implementation with robust oversight through regulatory harmonization represents a primary challenge, while establishing consistent data quality standards across diverse healthcare systems remains crucial. As a general principle, individuals with access to high-quality clinical trials in general have better outcomes and better care, contributing to equipoise in the clinical efforts. Equally important is addressing disparities in healthcare delivery and treatment availability to ensure broader access to immunotherapy. The development of specialized expertize through workforce training in immunotherapy research must continue, alongside

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efforts to maintain scientific exchange and international collaboration despite ongoing geopolitical challenges. The potential inclusion of Australia in the WIC Austral Asia group offers opportunities to strengthen regulatory harmonization and ethical oversight frameworks while maintaining the advantages of Asia's efficient trial recruitment capabilities.

COMPARATIVE ANALYSIS OF IMMUNOTHERAPY REGULATORY FRAMEWORKS

Asian regulatory approaches vary significantly across the region. Japan's PMDA established the Sakigake designation system, accelerating approval for innovative therapies through priority consultations and expedited reviews. China's NMPA has implemented reformed review pathways incorporating real-world evidence evaluation and distinguishing between minimally and substantially manipulated cell products. Singapore's HSA employs a risk-stratified framework through CTGTP regulation, categorizing products based on manipulation degree and intended application. South Korea's MFDS pioneered conditional approval pathways for cell therapies demonstrating promising early outcomes, enabling earlier commercialization of several domestically developed therapies.

CONCLUSION

Asia's role in cancer immunotherapy continues to evolve, shaped by both scientific advancement and practical realities. The region's unique advantages in patient populations, technological capabilities, and research infrastructure position it to make lasting contributions to global cancer care. Success will require sustained commitment to quality, transparency, and international collaboration, even as the research landscape grows more complex. The success of initiatives such as the SITC-WIC-Asia conference, building on earlier efforts such as the 2019 Hefei meeting, demonstrates the power of collaboration in overcoming obstacles and accelerating progress. The path forward demands careful navigation of regulatory challenges, market access barriers, and data quality concerns while maintaining the momentum of scientific innovation. By addressing these challenges while leveraging its unique strengths, Asia can help drive the next wave of breakthroughs in cancer immunotherapy, ultimately benefiting patients worldwide. The upcoming WIC-Asia meeting in Singapore (21st - 22nd July 2025) will provide an important platform to showcase emerging talent and foster new collaborations, furthering the region's contribution to global cancer care advancement.

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