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CURE4CANCER

Advancing Global Health Equity:

Expanding the U.S.-Australia Cancer Alliance Toward an Asia-Pacific Collaborative Effort to Save Millions of Lives

REPORT >>

ADVANCING GLOBAL HEALTH EQUITY:

EXPANDING THE U.S.-AUSTRALIA CANCER ALLIANCE TOWARD AN ASIA-PACIFIC COLLABORATIVE EFFORT TO SAVE MILLIONS OF LIVES

A REPORT FROM THE ASIA SOCIETY POLICY INSTITUTE AND CURE4CANCER

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Cure4Cancer (C4C) is an international movement that brings together patients, clinicians, scientists, policymakers, regulators, industry leaders, philanthropists, the media, and other closely related stakeholders in the global fight against cancer. The international movement is sustained through multi-stakeholder collaboration and cross-pollination among its global partners; thus, it cannot be limited to any single institution or country. Our mission is to accelerate the development of cancer cures and prevention through increased public awareness, cooperation, and regulatory harmonization on patient-centric international clinical trials. Through research, analysis, and collaboration, Cure4Cancer and its partners seek to accelerate the eradication of cancer as a major cause of death in a lifetime. The Asia Society Policy Institute serves as the movement's policy research and operational arm. For more information and a list of our partners and supporters, visit https://cure4cancerglobal.org/about-us/.

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PREFACE

Cancer remains one of the most pressing global health challenges, claiming 10 million lives each year with devastating effects on family members and loved ones, and placing immense strain on healthcare systems across the world. As Nelson Mandela once said, "It always seems impossible until it's done." This report, Advancing Global Health Equity: Expanding the U.S.-Australia Cancer Alliance Toward an Asia-Pacific Collaborative to Save Millions of Lives, embodies that spirit of perseverance and global cooperation, offering a roadmap toward equitable cancer care through international collaboration.

This report is the second in our series on Advancing Global Health Equity for the Cure4Cancer. It builds on the framework of international collaboration and regulatory harmonization on clinical trials as described in our first report, and uses new Australian initiatives as a case study. The U.S.-Australia partnership, grounded in an innovative concept of the hub-and-spoke network model of clinical trials and access to precision oncology, demonstrates how collaboration may transcend borders to overcome disparities in cancer care and prevention to help patients in diverse communities. This report emphasizes the power of sharing knowledge, regulatory harmonization, and inclusion of diverse populations to ensure that scientific advances reach all those in need, regardless of geographic, racial-ethnic, or economic barriers.

Drawing from the strength of this partnership, this report calls for the simultaneous expansion of multilateral collaboration across the Asia-Pacific, a region that represents the world's largest and fastest growing economy, and where cancer care disparities are vast. It is this spirit of collective action and mutual learning that will drive the future through advancing global health equity. We invite policymakers, healthcare leaders, and researchers across public and private sectors globally to join this vital mission to ensure access to innovative life-saving treatments and prevention are expanded to all communities, which would in turn stimulate economic development and accelerate the cure for cancer—eliminating it as a cause of death—for all of humanity.

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INTRODUCTION

Cancer continues to pose a significant global burden, severely impacting individuals, families, healthcare systems, and economies. Despite substantial advancements in cancer prevention, screening, and treatment, incidence and mortality rates remain unacceptably high. In 2022 alone, nearly 20 million new cancer cases were diagnosed, with roughly 10 million people succumbing to the disease.[1] This escalating incidence is driven by various factors, including aging populations, lifestyle changes, and increased exposure to risk factors such as tobacco use, unhealthy diets, physical inactivity, and environmental carcinogens. The economic repercussions are equally profound, with the total annual economic cost of cancer estimated at approximately US$1.16 trillion.[2]

Despite impressive advancements in cancer therapy, significant disparities persist in access to cancer care and treatment outcomes. These inequities are precipitated by socioeconomic status, geographic location, healthcare infrastructure, and the availability of medical professionals. One of the most glaring inequities in cancer care is access to clinical trials. Clinical trials are essential for developing new treatments and improving existing therapies,[3] yet less than 5% of cancer patients globally are enrolled in them.[4] This low participation rate is influenced by numerous barriers, including a lack of awareness, geographical barriers, excessively stringent eligibility criteria, and limited availability of trials in diverse global communities and regions.[5]

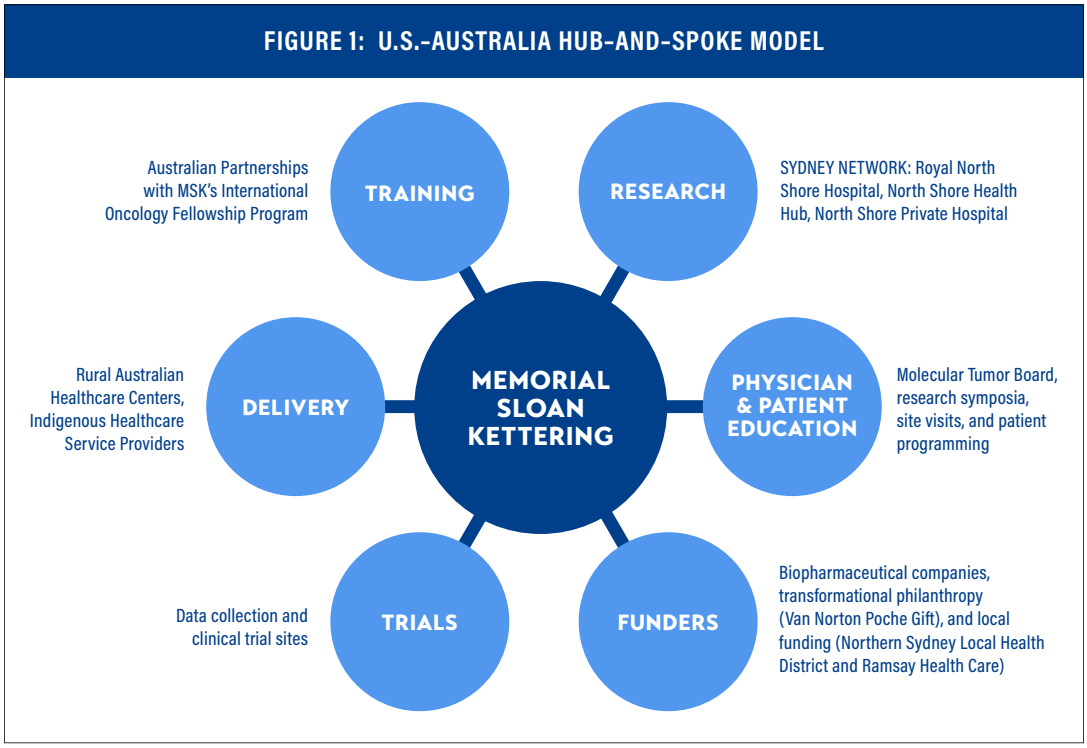
The severe global cancer burden and existing inequities in cancer treatment underscore the urgent need for innovative approaches to clinical trials. International clinical trials offer significant advantages by enrolling diverse patient populations, thereby enhancing the applicability of findings across different genetic and environmental contexts.[6] Collaborative efforts also promote data and knowledge exchange, fostering innovation and reducing redundant efforts. The Cure4Cancer initiative, led by the Asia Society in partnership with Bloomberg New Economy International Cancer Coalition and Memorial Sloan Kettering Cancer Center (MSK), aims to accelerate cancer treatment development through global collaboration. It focuses on patient-centric clinical trials with a hub-and-spoke network model, regulatory harmonization,[7] and data sharing to enhance innovation and access to advanced therapies.

The hub-and-spoke model offers a promising solution that enables international collaboration, diverse patient enrollment, and efficient resource utilization. By leveraging the resources and infrastructure of the hub, spokes can conduct high-quality trials without the need for extensive local infrastructure, making it feasible to host sites in resource-constrained settings. The collaboration between MSK in New York and Sydney's leading cancer research institutions exemplifies the initial success of the hub-and-spoke model. Enhanced operational efficiency, high-quality data collection, and significant advancements in cancer treatment have set a precedent for future international trials, including those organized at the state-to-state level.[8]

The hub-and-spoke model as well as larger U.S.-Australia cancer research cooperation efforts may offer salience beyond a bilateral partnership and into the greater Asia-Pacific (APAC) region. Assured data sharing, regulatory harmonization, and scientific coordination between Washington and Canberra hold wisdom for how an APAC cancer clinical trial scheme may unfold and benefit the larger region.

This report draws on familiar international and multilateral organizational meetings to synthesize lessons on how to integrate partners in the APAC region into a clinical trial network. For regional stakeholders, inclusivity and openness are key values in any prospective network. This report is not an exhaustive overview of the U.S.-Australia Cancer Alliance, but provides a set of concrete policy recommendations for a hypothetical APAC cancer clinical trial collaborative platform, by building upon the novel initiatives of U.S.-Australia clinical trial collaboration and the hub-and-spoke model.

FIGURE 1: U.S.-AUSTRALIA HUB-AND-SPOKE MODEL



PART I: U.S.–AUSTRALIA COLLABORATION

I. CANCER BURDEN AND TREATMENT DISPARITIES IN AUSTRALIA

Overview of Cancer Burden in Australia

Cancer remains a significant public health challenge in Australia and affects communities across the country. Australia has one of the highest incidence and mortality rates due to cancer in the world: about 165,000 new cases were diagnosed in 2023, with approximately 51,300 deaths.[9]

The most prevalent cancers include breast cancer in women, prostate cancer in men, colorectal cancer, melanoma, and lung cancer. The various factors for these high incidence rates include an aging population, lifestyle choices, and better means of diagnostic capabilities.

With significant advances in cancer treatment and early detection, the overall survival rates are higher. The five-year relative overall survival rates for breast cancer, prostate cancer, colorectal cancer, and melanoma are approximately 91%, 95%, 70%, and 90%, respectively.[10] In 2024, cancer is expected to be the cause of an estimated three in every ten deaths in Australia, up from a gradual increase from 17% in 1971 but within the 28%–30% range recorded since the turn of the century.[11]

Several national screening programs have been implemented with the aim of improving early detection and treatment outcomes.[12] Examples include BreastScreen Australia, the National Bowel Cancer Screening Program, and the National Cervical Screening Program. These programs target specific age groups and promote regular screening to detect cancer early, when it is most treatable. Despite these efforts, participation rates vary, and socioeconomic and geographic disparities persist.[13]

Investment in cancer research and clinical trials has been one of the major factors contributing to progress in cancer treatment and improvement in outcomes. Australia is one of the leaders when it comes to cancer research, with many studies and trials adding to global knowledge and innovation, accounting for 5% of global industry-sponsored clinical trials activity through a modest population of 25 million people. However, further engagement of the CALD population and rural populace in clinical trials is still required to ensure that new treatments are effective across various groups.

While there has been significant improvement, socioeconomic status and geography continue to be barriers. As this disparity makes clear, targeted interventions are urgently required to increase health service access, reduce inequities in early detection and screening programs, and assure equal options for treatment for all Australians. Continued investment in research and international collaboration is essential to further reducing the cancer burden and improving outcomes for all individuals, regardless of background or location.

Cancer Treatment Disparities in Australia

The Australian health care system is universal but still has inequities between different socioeconomic and cultural groups. While theoretically the system is to guarantee equal access for all Australian citizens and residents to all treatments in regard to cancer for every group, there is still the pragmatic barrier of geographic accessibility, health literacy, and cultural factors that prevent this from occurring in reality. Delivering equity in health care access and outcomes remains an important priority for improving health outcomes for all Australians which would in turn accelerate global innovation through cancer clinical trials.[14]

Socioeconomic Disparities

Socioeconomic status becomes a major factor in cancer treatment outcomes. Generally, the lower the socioeconomic status, the higher the relative excess risks of death and poor outcomes, due to low health literacy, financial barriers, and lack of access to preventive services. Disparities between the public and private healthcare systems exacerbate these challenges. Patients with private health insurance usually enjoy better access to timely and advanced treatments than those using the public health system.[15]

Geographic Disparities

Geographic location indeed represents a significant determinant of access and the quality of cancer care. Individuals who reside in rural and remote areas face considerable challenges in accessing specialized care compared to those in urban centers, including limited access to healthcare services, fewer specialist facilities, and longer travel times to receive treatment. Pronounced delays in diagnosis and treatment adversely affected patient survival outcomes in rural areas.[16] According to Cancer Council Australia, rural Australians are 1.4 times more likely to die from the disease.[17]

Cultural and Linguistic Diversity

The CALD communities have special barriers to cancer care in Australia and present with significant disparities in the treatment outcomes. Language barriers, cultural differences, and generally lower levels of health literacy result in delays to diagnosis and suboptimal treatment. As of June 2023, 8.2 million Australians were born overseas, 30.7% of the population, with substantial immigration from the APAC.[18] While this diverse cultural heritage enriches Australia's economic prosperity, it has also exacerbated inequalities and challenges in the healthcare space.

Indigenous Australians experience higher cancer incidence and mortality rates compared to other Australians. The Australian Institute of Health and Welfare (AIHW) reported that Indigenous Australians are less likely to participate in cancer screening programs and more likely to be diagnosed at a later stage.[19] CALD patients are less likely to participate in clinical trials, exacerbating already suboptimal outcomes.[20] Meanwhile, as 23% of Australians speak a language other than English at home, options for communicating health conditions can be lacking to ensure patient understanding.[21] Cultural differences and the lack of culturally appropriate healthcare services further hinder effective treatment for indigenous populations and CALD populations alike.

Healthcare System

Australia's universal insurance system provides wide access to essential healthcare services, however, treatment disparities arise as a consequence of the widely dispersed nature of the health resources across Australia. Urban centers generally have better access to oncology specialists and advanced treatment technologies. Differences in healthcare funding and resource allocation between states and territories also play a role. Efforts at better resource distribution are necessary to address these disparities effectively.

Current disparities especially hinge on high out-of-pocket health costs for patients receiving more advanced care, undermining the universal insurance system's intended affordability.[22] Up to 15% of healthcare expenditures come from out-of-pocket patient payments, and one in three Australian households spends over 10% of their income on healthcare.[23] Fewer than half of Australian adults possess insurance coverage for private hospitals, making the patient care selection complex when considering financial factors.[24]

The amalgamation of these challenges has led to an uptick in private health insurance for Australians seeking stronger health coverage. But, conversely, patients with rare diseases like cancer have been forced to bear the brunt of health expenditures often falling out of the universal insurance system's remit—a 2024 Medical Journal of Australia study identified that cancer patients were more likely to report out-of-pocket healthcare expenses than other categories of study participants, regardless of socioeconomic factors.[25] Inequalities within Australia's healthcare system thus not only diminish patients' insured treatment options but also strain cancer patients' financial wellbeing, often leading to lesser-quality care.

Promoting Participation in Clinical Trials

Expanding cancer screening programs and increasing participation among disadvantaged and CALD populations can lead to earlier diagnosis and better treatment outcomes. Public health campaigns and community engagement should be appropriately tailored to improve screening uptake.[26] Increasing the inclusion of CALD and patients with lower socioeconomic status in clinical trials ensures that new treatments are effective across diverse populations. Addressing language barriers, providing adequate support, and dispensing culturally sensitive care can enhance trial participation.[27]

International collaboration has been one of the most promising approaches toward addressing these disparities in clinical trial participation. Collaboration will allow combining of resources, standardization of treatment protocols, and augmentation of research capabilities. More importantly, a diverse population included in research studies will ensure that the research results are applicable to a wide range of patients and also aid in developing appropriate interventions. International collaborations should be funded and supported through government policies, and public-private partnerships must leverage funding and support.

Cancer treatment disparities in Australia are a multifaceted issue requiring a comprehensive approach. By addressing geographic, socioeconomic, and ethnic disparities, stakeholders may make significant strides toward equitable cancer care. Leveraging international collaboration in clinical trials and

enhanced screening programs would ensure that all Australians have access to timely, high-quality cancer treatment, which is essential for improving public health equities.

II. URGENCY OF INTERNATIONAL COLLABORATION ON CLINICAL TRIALS

International collaboration and the implementation of clinical trials in Australia will be crucial in addressing disparities in cancer treatment and improving patient outcomes. Under such trials, the inclusion of diverse patient populations will be accelerated, ensuring that new treatments are effective across different genetic and environmental contexts. Involvement in international trials ensures early access to innovative therapies for Australian patients—a factor particularly critical for patients with rare or advanced cancer. Such therapies offer potentially life-saving options years before they become available through local healthcare systems.[28]

International collaboration in clinical trials fosters the exchange of knowledge, expertise, and resources between Australian researchers and their global counterparts. Such partnerships improve quality and breadth of research by making the findings stronger and generalizable to a larger population. In return, Australian researchers have the opportunity to be exposed to global best practices and the latest methodologies, raising the standard of cancer research in Australia.[29]

The economic benefits of conducting international clinical trials in Australia are extensive. These trials attract substantial investment from global pharmaceutical companies, which can be used to develop and maintain state-of-the-art research infrastructure. This investment not only boosts the local economy but also creates jobs for healthcare professionals, allowing further development of the medical research sector in Australia.[30]

Australian regulatory framework should be in harmony with international standards to help facilitate international clinical trials. The Therapeutic Goods Administration (TGA) should streamline its processes to align with those of major regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Such harmonization can reduce delays and simplify the approval process for international trials, making Australia a more attractive destination for global research efforts.[31]

Robust ethical oversight is crucial for protecting trial participants and ensuring research integrity. The National Health and Medical Research Council (NHMRC) should work toward standardizing ethical review processes across Human Research Ethics Committees (HRECs) to expedite trial activation while maintaining high ethical standards. Clear guidelines and efficient communication channels between HRECs and researchers can facilitate timely and ethical approvals.[32]

Investing in training programs for researchers and clinical trial staff is similarly essential for building a skilled workforce capable of conducting high-quality trials. Initiatives like the Australian Teletrial Program (ATP), which aims to bring trials to regional and remote areas, should be expanded to enhance trial accessibility and participation. These programs comprehensively train researchers in trial design, data management, and patient recruitment to make sure studies are well competent.

Obstacles to Clinical Trial Conduction

Regulatory Challenges

Despite efforts to streamline processes, navigating the regulatory landscape in Australia can still be complex and time-consuming. Significant discrepancies in the regulatory requirements between Australia and other countries pose serious barriers to seamless conduct of international trials. Harmonizing regulations and reducing bureaucratic barriers are essential for making Australia an attractive destination for global clinical trials.

One such example is clinical trials' local sponsorship requirements. The TGA requires that all clinical trials conducted in Australia must have an Australian entity serve as trial sponsor, including trials conducted by international and multinational pharmaceutical companies. While this practice ensures compliance with local laws and strict localization, it has presented hurdles for expedited clinical trials led by foreign entities.[33]

The country's stringent biosecurity regime has also compounded related regulatory processes. As a part of the 2015 Biosecurity Act, Australia has added supplemental customs screenings and detailed requirements for goods imported from countries with a higher risk of disease.[34] These strictures, while important to protecting Australia's distinct biodiversity, add layers of regulatory approvals for APAC partners attempting to import materials deemed critical for clinical trials, including biological materials like tissues and cell lining.[35] Thus, Australia's strict customs classifications and standards related to clinical trial initiatives have necessitated special resources and attention from trial sponsors.

Ethical and Cultural Barriers

Ethical considerations and cultural differences are relevant in patient recruitment and participation, especially when dealing with Indigenous Australians and culturally diverse populations. Such barriers are best overcome by culturally sensitive approaches and involvement of community leaders and/or advocates. An environment of trust needs to be developed by working with the communities and ensuring trials are designed and conducted in such a manner to protect cultural values and practices.

Geographic and Demographic Challenges

Australia's geography and dispersed population can make it difficult to conduct trials uniformly across the country. For instance, in 2019, the states of Victoria, Queensland, and New South Wales together hosted nearly 80% of the country's clinical trials, compared to a much lower 15% or less in the states of Western Australia and South Australia.[36] These geographic disparities have naturally lent themselves to severe demographic disparities. Between 2006 and 2020, only 0.8% of Australian clinical trials focused on the health of First Nations Peoples.[37]

Ensuring that patients in remote and rural areas have access to clinical trials requires innovative solutions like telehealth, and mobile trial units and patient centric clinical trial design. These approaches can help overcome logistical challenges and ensure that all patients can participate in clinical research. Australia has made marked progress in this arena during recent years. As a part of Australia's A$22 billion Medical Research Future Fund, a long-term fund established by the national government in

2015, early priority has been placed on developing infrastructure and monitoring capabilities with respect to the country's faraway regions.

Early funding priorities have included improving rural, regional, and remote (RRR) clinical trial–enabling infrastructure, where the A$75 million ATP in 2017 set the objective of an "interconnected clinical trial system" across all states.[38] In 2021, a stand-alone RRR clinical trial program was established with 35 state and national partners aimed at the improvement of medical workforce training and clinical trial delivery in underserved communities.[39] Although these programs are still considered emerging by public health experts, they represent a good-faith, grassroots effort from Canberra to improve health equity.

Funding Limitations

Securing adequate funding for clinical trials, especially those initiated by academic researchers, can be challenging. More investment by the government and private sectors in these trials is necessary to ensure that promising research can go forward without budgetary limitations. Funding agencies should prioritize research that addresses health disparities and supports the development of treatments for underrepresented populations.

Despite standing out as an oncology clinical trial hub, funding for relevant projects in Australia remains behind peer countries when it comes to patient expenditure and direct government clinical sponsorship for international trials. Australia's average clinical trial spending per capita at €7.93 ranks well below its developed peers, with the original 15 EU member states at €8.20, the United States at €17.98, and the United Kingdom at €18.15.[40]

This metric does not mean that Australia lags in its attention and resources devoted to clinical trials. But Australia's comparatively limited patient expenditure has contributed to physicians and stakeholders' perceptions that clinical trials with Australia are difficult to scale internationally. In a 2022 survey of Australian oncologists, 54% of respondents indicated that there were insufficient in-country funding opportunities dedicated to international trials.[41] Such a gap must be addressed through considered patient-centric programming and infrastructure buildup from Canberra.

Data Sharing

Australia's international clinical trial funding gap holds particular salience when it comes to how the pharmaceutical industry approaches regional collaboration. Between 2015 and 2019, industry-sponsored clinical trials represented nearly a third of all clinical trials in Australia, while between 2006 and 2020, nearly half were supported by some degree of industry involvement.[42]

Although serious multinational investment in clinical trials is a positive development, industry and government must work hand in hand to improve patient access, limit treatment disparities, and, most of all, set an example for robust data sharing among a variety of stakeholders. As of 2023, only one in five clinical trials surveyed by the University of Sydney planned to share their data with outside stakeholders.[43] Unlike the U.S. National Institutes of Health (NIH), the Australian NHMRC does not mandate data sharing for its funded or involved projects, and refusing a data sharing request is permitted in "transparent and justifiable" cases.[44]

In the future, the NHMRC may consider altering their data sharing mandate with companies, while local governments may also consider more tight-knit collaboration on data transmission. When data is cordoned off from researchers, policy stakeholders, and patients themselves, effective solutions that may have otherwise been reached faster fall behind on drug discovery timelines. As discussed in the next section, effective examples of data sharing not only help maximize clinical trials but can present a good-faith model for multinational and regional frameworks.

STRATEGIES FOR EFFECTIVE IMPLEMENTATION

Regulatory Harmonization

To facilitate international clinical trials, Australia's regulatory framework must align with international standards. The TGA should continue to streamline its processes to be compatible with those of major regulatory bodies like the FDA and the EMA. Harmonizing regulatory requirements can reduce delays and simplify the approval process for international trials.

Strengthening Ethical Reviews and Efficiency

Robust ethical oversight is essential to protect trial participants and ensure the integrity of the research. The NHMRC should work toward standardizing ethical review processes across Human Research Ethics Committees (HRECs) or Institutional Review Boards (IRBs) to expedite trial activation while maintaining high ethical standards. Clear guidelines and efficient communication channels between HRECs and researchers via central or network-wide reviews can facilitate timely ethical approvals.

Building Research Capacity

Investing in training programs for researchers and clinical trial staff is crucial for building a skilled workforce capable of conducting high-quality trials. Initiatives like the ATP, which aims to bring trials to regional and remote areas, should be expanded to enhance trial accessibility and participation. These programs can provide training in trial design, data management, and patient recruitment, ensuring that researchers are well-equipped to conduct rigorous studies.

Enhancing Patient Recruitment

Effective patient recruitment strategies are essential for the success of clinical trials. Raising public awareness about the benefits of clinical trial participation and working with patient advocacy groups can help reach underrepresented populations. Utilizing digital platforms for patient engagement and recruitment can also increase participation rates. Strategies such as targeted advertising, social media campaigns, and partnerships with community organizations can be effective in reaching diverse populations.

Infrastructure Development

Developing and maintaining state-of-the-art research infrastructure, including specialized cancer treatment centers and data management systems, is critical for supporting large-scale international clinical trials. Government and private-sector investments should focus on building these capacities. Infrastructure improvements should also include the development of centralized databases and biobanks, which can facilitate data sharing and collaboration among researchers.

III. OPPORTUNITIES AND FUTURE DIRECTIONS

With the harmonization of regulatory frameworks, robust ethical oversight, plus capacity for research, Australia will be enabled to play a leading role internationally in cancer research that will advance health outcomes in cancer patients from around the world. This effort requires the collaboration of the government, healthcare providers, and the community for the support and participation of Australians in international clinical trials.

As of 2024, the status of clinical trial implementation in Australia is robust and evolving. The Australian Clinical Trials Alliance (ACTA) recently highlighted the country's significant advancements, including the implementation of the ATP, making them more accessible and cost-effective. Additionally, an A$1.89 billion investment has been announced to enhance health and medical research, supporting initiatives like a "National One Stop Shop" for streamlined trial processes.[45]

Opportunities

Leveraging Technology

Advancements in technology, such as liquid biopsy, telemedicine, electronic health records, and data analytics offer significant opportunities for improving the efficiency and reach of clinical trials. These technologies can facilitate remote monitoring, enhance data collection, and improve patient engagement. For example, telehealth can enable patients in remote areas to participate in trials without the need for frequent travel, making participation more convenient and feasible.

Liquid Biopsy

The application of liquid biopsy in patient-centric clinical trials is transforming the landscape of cancer research and treatment, offering a less invasive, more flexible, and patient-friendly alternative to traditional tissue biopsies. Liquid biopsies allow the detection and monitoring of circulating tumor DNA (ctDNA), circulating tumor cells, and other tumor-related biomarkers from a simple blood sample, minimizing the physical and emotional burden on patients. This approach is especially valuable in clinical trials focused on patient centricity, as it reduces the need for invasive surgical biopsies, which are often associated with discomfort, risks, and longer recovery times.

Liquid biopsies allow trial designs to be made more for the patient by offering more ease in testing, which is non-invasive and thus much easier. All in all, this enhances the participant experience since participants will be required to visit a hospital less often, and procedures are reduced or can even be done in a decentralized or remote setting.

In addition to patient convenience, using liquid biopsy in clinical trials provides researchers with real-time insights into disease progression and treatment response, allowing for faster and more accurate adjustments to personalized treatment regimens. The ability to track molecular changes in tumors over time through serial blood draws can lead to more dynamic and tailored therapeutic interventions, improving patient outcomes. This real-time monitoring is critical in adaptive clinical trial designs, where treatments are adjusted based on individual responses. As a result, liquid biopsy plays a key role in creating a more personalized, patient-centered approach to cancer treatment, improving the quality and efficiency of data collection in clinical trials.

Remote Monitoring

Remote monitoring is a transformative tool in patient-centric clinical trials, enhancing accessibility and convenience for participants while maintaining high-quality data collection. By using digital health technologies, such as wearable devices, mobile apps, and telemedicine platforms, researchers can track patients' health metrics in real time without requiring frequent visits to clinical sites. This approach reduces the physical and logistical burden on participants, enabling them to engage in trials from the comfort of their homes, which is especially beneficial for individuals who face challenges like travel distance, mobility issues, or time constraints. With continuous data collection on vital signs, physical activity, medication adherence, and even specific biomarkers, clinicians can monitor patients' responses to treatments more closely and make timely adjustments.

The patient-centric nature of remote monitoring supports a more flexible and personalized trial experience, giving patients greater autonomy while ensuring their safety and wellbeing. The real-time data generated allows for earlier detection of side effects or treatment inefficacy, enabling quicker interventions that improve outcomes. Moreover, remote monitoring facilitates decentralized and hybrid trial designs, which expand access to more diverse and geographically dispersed patient populations and ensure broader representation in clinical research.

For researchers, remote monitoring enhances data accuracy and consistency by reducing reliance on self-reported information. The wealth of continuous data collected over time provides more comprehensive insights into treatment effects, allowing for more informed decision-making. Overall, remote monitoring plays a crucial role in modernizing clinical trials, making them more patient-friendly, efficient, and adaptable to individual needs.

Increasing Global Collaboration

Strengthening global collaborations can enhance the capacity to conduct large-scale, multicenter trials that yield more generalizable results. Initiatives like the Global Alliance for Genomics and Health provide frameworks for international data sharing and collaboration. By working together, researchers can pool resources and expertise to tackle complex research questions and accelerate the development of new treatments.

Policy Support and Advocacy

Continued advocacy for policy changes that support clinical trial research is essential. This includes lobbying for increased funding, streamlined regulatory processes, and policies that incentivize participation in clinical trials. Policymakers should recognize the value of clinical trials in improving public health and invest in creating a supportive environment for research.

Expanding Teletrial Programs

Expanding programs, like the ATP, and RRR infrastructure to cover more regions and therapeutic areas can significantly enhance trial accessibility. These programs can serve as models for other countries facing similar geographic and demographic challenges. By leveraging telehealth technologies and mobile units, researchers can bring trials to patients in underserved areas, reducing barriers to participation and improving health equity.

As most global clinical trials are facilitated by contract research organizations (CROs), this presents a significant opportunity for transformation and leadership by CROs. The implementation of the Tele-trial model will require costs and time from all stakeholders, including the pharmaceutical sponsors. Implementation will require training at remote and rural sites, enhanced coordination, an increased number of visits across multiple locations, and additional costs for delivery of IMP and any ancillary supplies to the sites. CROs routinely manage these activities. The additional costs are offset by offering access to an expanded trial population. CROs may produce real-world data and advocate with sponsors to incorporate tele-trial methodologies in their study protocols as recruiting mechanisms.

A CRO can provide resources and expertise to support the implementation of (tele)-trials at remote and rural sites. Resources are required to set up the necessary infrastructure, including remote monitoring capabilities, telecommunication systems, and remote data collection tools. Additionally, CROs provide training and support to site staff and investigators to ensure that they are proficient in conducting trials, including using tele-trial methodologies. CROs can support implementation of data management in tele-trials, including remote data collection, storage, and analysis. By implementing rigorous quality control measures, CROs help to ensure the integrity and reliability of the data collected in tele-trials. Finally, CROs can play a significant role in addressing the geographical disparities in clinical trial participation and ensure that a diverse range of patients is included in the research process by collaborating with local healthcare providers and community organizations to identify suitable trial sites and establish partnerships that facilitate access to healthcare services and trial participation for patients in remote areas.

Focus on Personalized Medicine

Personalized medicine, based on genetic, environmental, and lifestyle factors of the individual in therapies, is the future of cancer treatment. Clinical trials focused on personalized medicine can help identify the most effective treatments for specific patient subgroups, reducing disparities in treatment outcomes. By incorporating genetic and biomarker data into trial designs, researchers can develop targeted therapies that provide the best possible outcomes for each patient.

Clinical trials are indispensable in the fight against cancer, particularly in addressing treatment disparities in Australia. By implementing international clinical trials, harmonizing regulatory frameworks, building research capacity, and leveraging technology, Australia can ensure that all cancer patients have access to the best possible treatments. Overcoming such barriers requires immense effort from the government, healthcare providers, and the community in terms of regulatory, cultural, and financial difficulties.

PART II: MULTILATERAL ASIA-PACIFIC COLLABORATIVE PLATFORMS

I. THE IMPORTANCE OF U.S.-AUSTRALIA COLLABORATION

Cancer is one of the most significant health challenges worldwide, necessitating a concerted effort that transcends national boundaries. The international collaboration between the United States and Australia on cancer treatment exemplifies the profound impact that strategic partnerships can have on global health outcomes. By working together, the United States and Australia leverage their unique strengths and resources, accelerating the development of innovative cancer therapies and improving patient care. This example of openness, transparency, and inclusivity in clinical trial harmonization seeks to serve as a compelling model and call to action for other countries in the APAC region to both learn from and directly participate in.

One of the key benefits of this collaboration is the pooling of diverse expertise and resources. The United States, with its extensive network of research institutions and advanced technological infrastructure, complements Australia's robust clinical trial framework and strong emphasis on healthcare quality. This synergy facilitates the rapid progression from research to clinical application, ensuring that groundbreaking treatments reach patients more quickly and efficiently. For instance, joint initiatives like Cancer Moonshot, which aims to reduce cancer mortality and improve patient outcomes through cutting-edge research, exemplify how collaborative efforts can lead to significant advancements in cancer treatment.

The representation of diverse populations in the clinical trials in both countries makes it possible for such results to be more generalized easily. This diversity is essential in developing treatments effective across a range of genetic backgrounds and varied environmental contexts—a basic requirement for addressing disparities in the treatment outcome. Such integration of rural and remote populations in Australia would add value to the trials in that it would ensure that the performance of treatments could be performed in varying settings and that the benefit of new therapies can apply broadly.

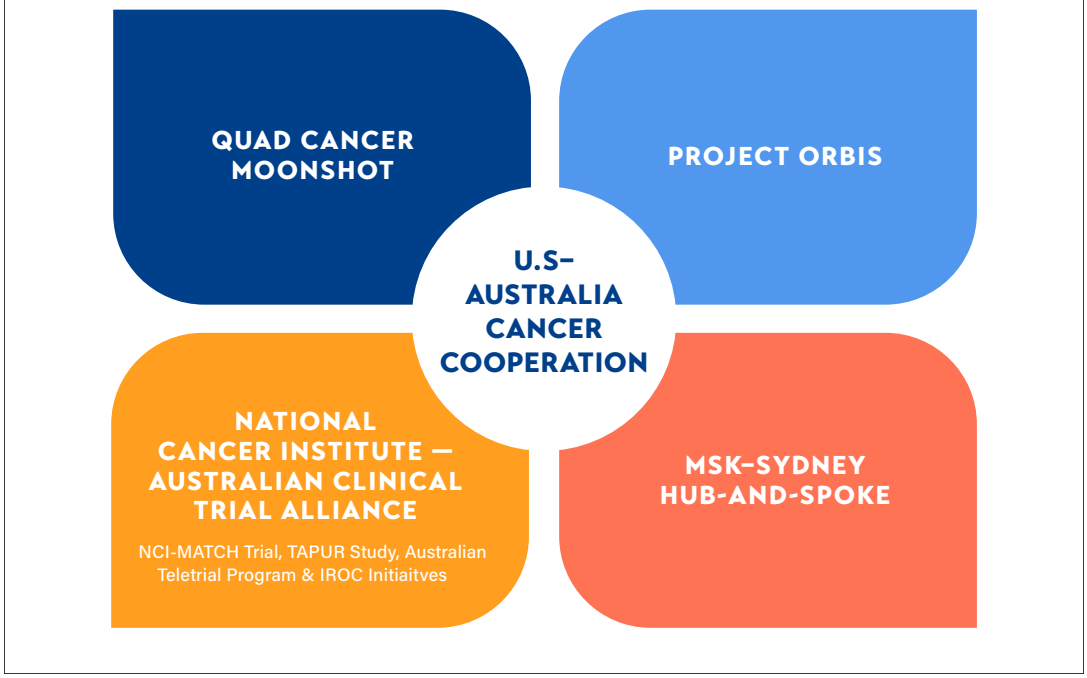
It also underlines the importance of this collaboration in terms of economic benefits. Mechanisms for joint funding and shared investments in research infrastructure promote innovation and economic growth in both countries. Such investments contribute to building top-notch research facilities, creating jobs, and providing training for healthcare professionals. The spillover effect of such benefits outside the healthcare sector contributes to general prosperity in both countries.

Policy harmonization and streamlined regulatory processes further enhance the efficiency of collaborative efforts. By aligning regulatory frameworks, the United States and Australia can reduce bureaucratic delays and facilitate the smooth implementation of international clinical trials. This regulatory alignment ensures that research findings can be quickly translated into new treatments, benefiting patients worldwide.

II. U.S.–AUSTRALIA COLLABORATION ON CANCER MOONSHOT

The Cancer Moonshot initiative, spearheaded by the United States, seeks to expedite cancer research; synergize resources, expertise, and data; and improve treatment modalities. The bilateral collaboration between the United States and Australia, initiated in 2016, underscores the critical importance of international cooperation in addressing cancer treatment challenges.

FIGURE 2: U.S.-AUSTRALIA CANCER COOPERATION MAP



Joint Research and Clinical Trials

A cornerstone of this collaboration involves joint research initiatives and coordinated clinical trials. By amalgamating their resources and expertise, researchers from both nations can undertake more comprehensive and robust studies. This collaboration enables the inclusion of diverse patient populations, crucial for developing treatments that are efficacious across varied genetic backgrounds and environmental contexts. For instance, clinical trials conducted under this partnership can yield insights into differential responses to novel therapies among diverse populations, thereby fostering the development of more personalized and effective cancer treatments.[46] NIH and NHMRC data sharing may also inspire alterations to domestic policies that better position each country for larger, regional clinical trial frameworks.

Enhanced Research Infrastructure and Training

The U.S.-Australia partnership significantly bolsters research infrastructure and training opportunities. Both countries benefit from shared databases, biobanks, and cutting-edge research facilities, sup-

porting high-quality research and the rapid translation of scientific discoveries into clinical practice. Additionally, training programs for researchers and clinicians are integral to this collaboration, cultivating a skilled workforce adept at conducting advanced cancer research.

Economic and Policy Benefits

Economic benefits are another pivotal aspect of the U.S.-Australia Cancer Moonshot collaboration. The initiative attracts substantial investment from both governmental bodies and the private sector, thus enhancing local economies and supporting the establishment of state-of-the-art research facilities. These investments not only generate employment but also offer professional development opportunities, further fortifying the cancer research ecosystem in both nations.

The collaboration places significant emphasis on policy and regulatory alignment to streamline the approval and implementation of joint research projects. Harmonizing regulatory frameworks between the two countries mitigates bureaucratic delays and facilitates the smooth conduct of international clinical trials. This regulatory alignment is crucial for ensuring that research findings can be swiftly translated into new treatments, thus benefiting patients globally.

The U.S.-Australia collaboration on the Cancer Moonshot initiative represents a paradigm shift in international health cooperation. This partnership not only accelerates innovation but also promotes equity in healthcare outcomes, serving as a powerful testament to the transformative potential of international collaboration in addressing global health challenges.

III. U.S. NATIONAL CANCER INSTITUTE AND THE AUSTRALIAN CLINICAL TRIALS ALLIANCE

The collaboration between the Australian Clinical Trials Alliance (ACTA) and the U.S. National Cancer Institute (NCI) embodies a significant effort to address cancer treatment inequities through high-profile and impactful clinical trials. This partnership leverages the strengths and resources of both nations to advance global cancer research and treatment.

NCI-MATCH (MOLECULAR ANALYSIS FOR THERAPY CHOICE)

Description	The NCI-MATCH trial stratifies patients based on the genetic mutations in their tumors rather than their cancer type, thus evaluating the efficacy of targeted therapies across a spectrum of malignancies.
Collaborative Effort	Australian sites, including major research hospitals and academic institutions, actively participate in this trial, contributing critical insights into the genetic landscape of cancer and optimizing targeted treatment strategies.
Impact	The trial's findings are instrumental in advancing precision medicine, facilitating the development of therapies tailored to specific genetic profiles. As of 2023, over 6,000 patients have been enrolled globally, with significant contributions from Australian cohorts.[47]

TAPUR (TARGETED AGENT AND PROFILING UTILIZATION REGISTRY)

Description	The TAPUR study, initiated by the American Society of Clinical Oncology (ASCO), evaluates the efficacy of FDA-approved targeted therapies for advanced cancer patients based on their specific genetic profiles. This real-world evidence study seeks to identify effective treatments beyond standard indications.
Collaborative Effort	Australian researchers, through ACTA, contribute substantial data and clinical insights, validating the use of targeted therapies in diverse genetic contexts. This collaboration includes over 120 clinical sites, with significant participation from Australian institutions.
Impact	TAPUR has provided crucial data on the effectiveness of targeted cancer therapies, influencing treatment guidelines and supporting personalized treatment plans. The study has enrolled over 2,000 patients, with findings that have already led to significant changes in clinical practice.[48]

AUSTRALIAN TELETRIAL PROGRAM

Description	The innovative ATP program extends clinical trials to regional and remote areas in Australia, thus improving accessibility and addressing geographical disparities in cancer treatment. The program leverages telehealth technologies to conduct trials remotely.
Collaborative Effort	Supported by the ACTA and modeled on successful U.S. teletrial frameworks, the ATP has enabled the inclusion of patients from over 50 remote sites across Australia, significantly increasing trial participation.
Impact	By enhancing trial accessibility, the ATP ensures that diverse patient populations contribute to and benefit from advanced cancer research. The program has enrolled over 1,000 participants since its inception, demonstrating its effectiveness in bridging the urban-rural divide in healthcare access.[49]

IMAGING AND RADIATION ONCOLOGY CORE GROUP INITIATIVES

Description	The Imaging and Radiation Oncology Core (IROC) Group, part of the NCI's National Clinical Trials Network, focuses on quality assurance for trials involving advanced imaging modalities and radiation therapy. This initiative supports trials aimed at developing and validating innovative imaging and radiation techniques.
Collaborative Effort	Australian institutions, including leading cancer research centers, participate in these trials, contributing to the refinement of imaging and radiation protocols.
Impact	Ensuring high-quality standards in imaging and radiation enhances the reliability and efficacy of these treatments in clinical practice. The IROC initiatives have supported over 150 clinical trials, with substantial contributions from Australian research sites.[50]

The collaborative trials not only advance scientific knowledge but also bolster the global fight against cancer by ensuring that research findings are applicable to a diverse range of patient populations. The joint efforts of the ACTA and the NCI highlight the critical role of international collaboration in developing and implementing effective cancer treatments. This partnership exemplifies how leveraging collective expertise and resources can accelerate innovation and promote global health equity.

IV. THE HUB-AND-SPOKE MODEL IN CLINICAL TRIALS: MSK-SYDNEY COLLABORATION

In the quest for advancing global health equity, the hub-and-spoke model of conducting clinical trials stands out as a strategic and innovative approach.[51] This model, epitomized by the collaboration between MSK and Sydney's leading cancer institutions, exemplifies how international partnerships can streamline clinical research, broaden patient access, and ensure high-quality data collection. Safety and quality of this model are strengthened by several decentralized clinical trial approaches including the Australasian Teletrial Model.[52]

Importance of the Hub-and-Spoke Model

The hub-and-spoke-model in clinical trials refers to a cancer network where an academic medical center (the hub) coordinates and manages the core activities of clinical trials, while community clinics (the spokes) serve as equal partners to implement these trials across diverse and geographically dispersed locations.

- **Centralized Expertise and Resources**: By centralizing specialized resources, regulatory approvals, and data management at the hub, the model ensures high standards of research integrity and compliance. This centralization also facilitates the sharing of expertise and best practices.
- **Broadened Access**: The spokes, often situated in remote or underserved areas, extend the reach of clinical trials to diverse populations. This inclusivity is vital for the generalizability of research findings and for addressing health disparities.
- **Efficiency and Scalability**: The hub-and-spoke model enhances operational efficiency by leveraging the infrastructure and capabilities of both the central hub and peripheral spokes. It allows for the scalable and flexible deployment of clinical trials, accommodating various patient demographics and geographic locations.

Key Elements and Advantages of the MSK-Sydney Hub-and-Spoke Model

The collaboration between MSK and Sydney embodies the hub-and-spoke model's strengths, offering significant advantages in conducting clinical trials.

1. **Centralized Coordination (Hub):**
    - **Regulatory Oversight:** MSK in New York City oversees regulatory approvals, ethical reviews, and protocol development, ensuring that all trials adhere to international standards.

- **Resource Consolidation:** The hub consolidates advanced medical equipment, experienced personnel, and robust data management systems, providing a solid foundation for high-quality research, as well as global education and training for clinical trials.

2. **Decentralized Implementation (Spokes):**
   - **Local Execution:** The Sydney network, including Royal North Shore Hospital, North Shore Private Hospital, and North Shore Health Hub, conducts the trials locally. This setup allows for the recruitment of a diverse patient population, addressing geographical and demographic disparities. The same approach to cancer networks applies to rural and underserved regions across New York tri-state area and the rest of the United States.
   - **Increased Accessibility:** By extending trials to rural and Indigenous Australian communities, the spokes ensure broader access to cutting-edge treatments.
3. **Data Integration and Quality:**
   - **Advanced Data Systems:** Centralized data management at the MSK hub integrates and analyzes data from all spokes, ensuring consistency and high-quality data collection.
   - **Technology Utilization:** The use of telehealth and digital technologies facilitates seamless communication and data transfer, enhancing operational efficiency.

Strategic Priorities

The MSK-Sydney collaboration focuses on four strategic priorities to drive international clinical trials and promote global health equity:

1. **International Clinical Trial R&D and Data Infrastructure**
   - **Objective:** To establish a comprehensive and resilient infrastructure that supports international clinical trials and fosters seamless data sharing.
   - **Location:** Sydney's North Shore Health Hub is designated a future hub (NORTH STAR Van Norton Poche) for initiating new international trials in partnership with MSK. This location provides the necessary logistical and infrastructural support for high-caliber research activities.
   - **Data Integration:** The initiative aims to develop an advanced data sharing infrastructure utilizing privacy-protected, AI-assisted cloud computing systems. This infrastructure will significantly enhance the capabilities for biomarker and drug discovery, building upon the principles of MSK's Cancer Data Science Initiative.
   - **Operational Framework:** The creation of a standardized platform for the storage and analysis of clinical trial and real-world data is imperative. This platform will enable researchers to aggregate and compare patient characteristics, biomarker results, and clinical outcomes across institutions, fostering a unified approach to data-driven medicine.
   - **Impact:** The establishment of this collaborative infrastructure is anticipated to attract substantial funding from the pharmaceutical industry and academic grants, thus ensuring the sustainability of the initiative. By accelerating the development of novel treatments, this infrastructure will play a crucial role in advancing significant medical breakthroughs.

2. **International Investigator-Initiated Trials and Biomarker Development**
    - **Objective:** To support investigator-initiated trials and expedite the development of global biomarkers.
    - **Harmonized Workflow:** Implementing a standardized process for the acquisition and analysis of biospecimens is critical. This ensures uniformity and reliability across various disease areas and biomarkers, enhancing the integrity of research findings.
    - **Focus on Biomarkers:** The initiative prioritizes the conduction of biomarker clinical trials to advance the precision oncology ecosystem. Liquid biopsy biomarkers will be pivotal, offering non-invasive, comprehensive molecular profiling that supports precision medicine. Notably, within the MSK-Sydney collaboration, a prospective international study leveraging plasma ctDNA detection has already shown improved overall survival rates for lung cancer patients.[53]
    - **Collaboration and Funding:** This framework will attract collaboration and funding from the pharmaceutical and biotechnology industries, enabling the most transformative trials.

3. **Clinical Trials Training**
    - **Objective**: To provide specialized training and mentorship for clinical trial personnel.
    - **Training Programs:** Fund international clinical trial fellowships for Australian and American trainees to gain specialized training at MSK and in Sydney. This bidirectional training will include medical, surgical, and radiation oncology, as well as pathology and radiology.
    - **Curriculum Development:** Collaborate with MSK's Office of Graduate Medical Education and International Oncology Fellowship Program and Sydney's Advanced Training Programs to develop comprehensive training modules.
    - **Impact:** This training initiative will equip clinicians with the requisite skills to innovate within an evidence-based framework, thereby enhancing the quality and efficiency of international clinical trials.

4. **Bilateral Educational Exchange**
    - **Objective**: To foster educational exchanges that enhance global oncology research and clinical practice.
    - **Educational Events**: The initiative will host a series of conferences, research symposia, webinars, and site visits in New York City and Sydney. These events are designed to facilitate knowledge sharing and collaborative efforts among global oncology leaders.
    - **Molecular Tumor Board**: Implement video conferencing for international study participants, providing tailored treatment recommendations and fostering the practice of precision oncology.
    - **Impact**: This exchange will shape the next generation of global oncology leaders, promoting collaborative research and improving cancer care worldwide.

Funding and Economic Impact

Transformational Philanthropy: The initiative is supported by a US$20 million and A$20 million gift from Gregory John Poche and Kay Van Norton Poche, which will establish NORTH STAR Van Norton Poche cancer trials initiative in Sydney in collaboration with MSK. Additional funding from MSK, the Northern Sydney Local Health District, Ramsay Health Care, and other stakeholders will support the initiative's strategic priorities.

Economic Benefits: The collaborative infrastructure and increased trial accessibility are expected to generate significant economic benefits, attracting industry investment and creating professional development opportunities. Clinical trials also provide financial sustainability for healthcare delivery, reducing overall healthcare costs by improving clinical outcomes and patient experiences.

The hub-and-spoke model exemplified by the MSK-Sydney collaboration represents a transformative approach to conducting clinical trials. By leveraging centralized expertise and decentralized implementation, this model broadens access, ensures high-quality data collection, and promotes global health equity.

V. ADVANCING GLOBAL HEALTH EQUITY THROUGH THE HUB-AND-SPOKE MODEL IN CLINICAL TRIALS

The collaboration between MSK and Sydney's leading cancer centers serves as a paradigm of how the hub-and-spoke model can be effectively implemented to achieve comprehensive and inclusive clinical research. Central to this model are the concepts of centralizing essential resources, regulatory oversight, and data management at a primary hub while decentralizing trial execution and patient access across multiple peripheral sites. This groundbreaking model is poised to revolutionize the landscape of cancer treatment and research, addressing critical disparities in healthcare access and outcomes.

The time has come to harness the transformative potential of the hub-and-spoke model in clinical trials to address the profound disparities in cancer treatment and care globally. The collaboration between MSK and Sydney's leading cancer research institutions demonstrates the model's efficacy and sets a precedent for international cooperation in clinical research. We call upon policymakers, industry leaders, healthcare professionals, and stakeholders worldwide to support and invest in this innovative model to advance global health equity.

Centralized Coordination and Decentralized Implementation

The hub-and-spoke model's core strength lies in its ability to combine centralized expertise and resources with decentralized patient access and trial execution. This ensures that all clinical trials meet the highest standards of research integrity, facilitating a robust and seamless trial process.

Concurrently, the spokes extend the reach of clinical trials to diverse and underserved populations. This decentralized approach not only enhances the inclusivity and representation of the participant pool but also ensures that cutting-edge treatments are accessible to remote and underserved areas, addressing significant healthcare disparities. Another benefit is the capacity-building of rural and

regional sites that have limited capacity to host trials by themselves for many reasons. In Australia, Canada and New Zealand, the Australasian Teletrial Model is used to foster partnership between primary and satellite sites and enable the delivery of some or all aspects of trials at satellite sites.[54] The Australian Government has developed principles for national teletrials to provide governance for safety and quality of such decentralization through national policy and has allocated 100M to role out the model nationally.[55]

High-Quality Data Collection and Integration

Advanced technologies, such as AI-assisted cloud computing, play a crucial role in the hub-and-spoke model by facilitating the aggregation, standardization, and comparative analysis of clinical trial data from multiple sites. By centralizing data management, the model enhances the reliability and robustness of research findings, ultimately leading to more effective and personalized cancer treatments.

Economic and Professional Development Benefits

The economic viability and professional enrichment potential of the hub-and-spoke model are exemplified by the MSK Sydney NORTH STAR Van Norton Poche Collaboration. Supported by the transformative US$20 million gift, the Sydney hub is expected to attract substantial industry funding and academic grants. This financial support ensures the sustainability of the initiative and creates numerous professional development opportunities, enhancing the skills and expertise of clinical trial personnel across both regions.

Strategic Priorities for Global Health Equity

The four strategic priorities are as follows: 1) establishing a robust R&D and data infrastructure, 2) supporting international investigator-initiated trials and biomarker development, 3) arranging highly organized collaborations to provide comprehensive clinical trials training, and 4) fostering bilateral educational exchange. These priorities are designed to drive international clinical trials and promote global health equity, setting a framework for future collaborations.

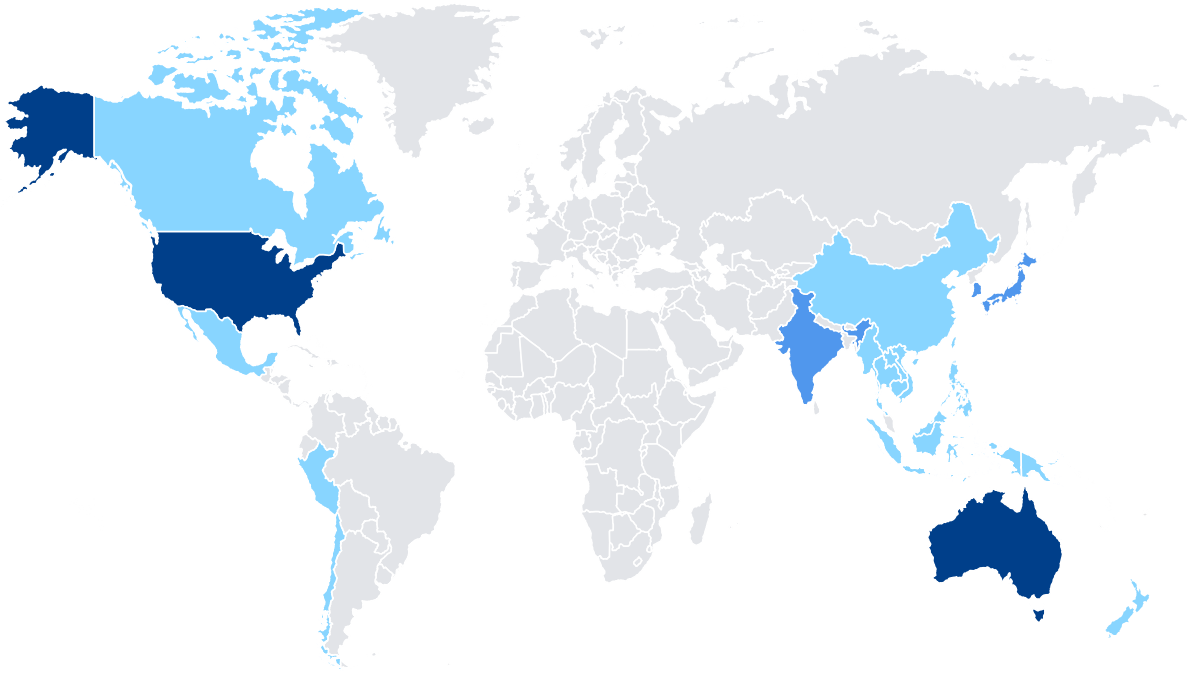
VI. ESTABLISHING A MULTILATERAL, U.S.-AUSTRALIA-APAC CANCER TREATMENT MODEL

Significance

Multilateral and regional cancer clinical trial platforms harbor immense potential in expediting data sharing, scaling trial operations and reach, and pushing different treatment schemes forward in a next step toward finding cures for various forms of cancer. As addressed in last year's Cure4Cancer inaugural report, global regulatory harmonization of clinical trials and therapy approvals could reduce global cancer deaths by a factor of 10%–20%.[56]

Beyond clinical trial operational challenges experienced daily by practitioners, global clinical trials face serious obstacles of idiosyncratic regulatory systems, decentralized implementation, central-local coordination, and the challenges of partner relationship management and cultural differences. These challenges manifest on the small- and large-scale levels for pharmaceutical companies, scientists, governments, and patients across the world.[57]

FIGURE 3: ASIA-PACIFIC PARTNERSHIPS VISUALIZATION MAP



GROUP I: APAC CLINICAL TRIAL LEADERS

Australia
USA

PHASE II EXISTING APAC CANCER PARTNERSHIPS

India
Japan
South Korea

PHASE III: PROSPECTIVE APAC COLLABORATIVE

Australia (APEC)
Brunei (APEC, EAS)
Burma (EAS)
Cambodia (EAS)
Canada (APEC)
Chile (APEC)
China (APEC)
Hong Kong (APEC)
Indonesia (APEC, EAS)
Japan (APEC)
Laos (EAS)
Malaysia (APEC, EAS)
Mexico (APEC)
New Zealand (APEC)
Papua New Guinea (APEC)
Peru (APEC)
Philippines (APEC)
Singapore (APEC, EAS)
South Korea (APEC)
Taiwan (APEC)
Thailand (APEC, EAS)
USA (APEC)
Vietnam (APEC, EAS)

Clinical trial integration, coordination, and harmonization remain global challenges, but research has shown that medium-scale, regional frameworks and platforms provide a potential model to increase global clinical connectivity, ultimately leading to faster cures. Despite incredibly complex diversities in language, culture, geography, and economic status among its various nations, the APAC region presents a particularly poignant case study in how regional clinical trial coalitions may lead to global solutions.

While the Cure4Cancer inaugural report focused on a case study of potential regulatory harmonization between the United States and China under the FDA's Project Orbis initiative, this section of the report seeks to provide policy recommendations on how a U.S.-Australia-APAC clinical trial network could encourage greater regulatory coherence and harmonization among the APAC region. Drawing on other international organizational compacts and frameworks, this section explores the potential opportunities and challenges associated with a multilateral APAC regional cancer clinical trial scheme. Although

U.S.-Australia cooperation serves as an initial example for clinical trial harmonization, the inclusion, participation, and leadership of other APAC countries is critical to advancing this objective.

U.S.-Australia Collaboration as an International Model

As discussed earlier, joint U.S.-Australia collaboration has provided platforms for research breakthroughs, workforce upskilling, economic growth, data integration, and even transformative philanthropy and goodwill from those involved in the U.S.-Australia relationship.

With partnerships dating back to the Obama administration, Washington and Canberra have drawn on a reservoir of bilateral momentum to include additional partners in their joint cancer treatment efforts.[58] For example, in 2019, under Project Orbis, the FDA, Health Canada, and the TGA collaborated on the review of Lenvima (lenvatinib) and Keytruda (pembrolizumab)—representing Project Orbis's first successful review writ large.[59] The approval of Lenvima and Keytruda has since improved the lives of thousands of patients suffering from uterine cancer, of which there are over 400,000 annually with a 20% stage IV relative five-year survival rate.[60] Each treatment was quickly approved thereafter in Japan, New Zealand, and the European Union.[61]

The simultaneous review and approval of Lenvima and Keytruda is an excellent example of the significance of U.S.-Australia cancer cooperation bringing in new partners and setting a mold for an additional mosaic of partnerships among like-minded countries. The original success of Project Orbis—which can in part be attributed to U.S.-Australia bilateral momentum—serves as a model for how other clinical trials in APAC may be delivered by alternate means.

Quad Cancer Moonshot

The United States and Australia have worked with other key partners in cancer research. At the fourth Quad Leaders' Summit in September 2024, the United States, Australia, India, and Japan announced the formation of the historic Quad Cancer Moonshot, leapfrogging existing clinical trial harmonization efforts in the region.[62] Complementing the U.S.-Australia Cancer Moonshot partnership updated in February the same year, the Quad Cancer Moonshot seeks to leverage public and private resources across the APAC to address cervical cancer through improved healthcare infrastructure, expanded research collaboration, and new data systems.[63]

What makes the Quad Cancer Moonshot particularly transformative is its objective to partner with other, more formal international organizations. As part of the initiative's announcement, Washington committed to a US$1.58 billion HPV vaccine pledge for APAC nations through Gavi, the Vaccine Alliance. Other Quad members expressed dedication to working with the United Nations, the World Bank, and the International Atomic Energy Agency to engage in bulk-purchasing efforts of HPV diagnostics for cervical cancer screening (including US$400 million in HPV-related investment from the World Bank over the next three years).[64] Overall, the Quad Cancer Moonshot partnership will kick off a litany of scientific exchanges, joint surveillance projects, and technical visits that will comprehensively strengthen cancer clinical trials across the region.

The Quad Cancer Moonshot will not only serve member countries but also transform cancer care for a variety of APAC partners as a part of its inclusive and dynamic vision. The program's Project ECHO will improve cervical cancer vaccine implementation and education networks across ten different "communities of practice" by 2028, including with partners in Vietnam, Indonesia, and Malaysia.[65]

The integration of additional APAC partners will save millions of lives in the APAC region in the coming decades.[66] The Quad Cancer Moonshot project underscores the potential of region-wide clinical trial harmonization.

U.S.-Japan-Korea Clinical Trial Coordination

Although a prominent example, U.S.-Australia collaboration is not the only model that a greater APAC clinical trial network may tap into or emulate. Increased activity between the United States, Japan, and South Korea also fits this same APAC-focused mold.

Separately, Japan and South Korea are some of the largest clinical trial destinations, representing the third largest and largest destinations worldwide, respectively, between 2011 and 2016 (Australia was second).[67] Both countries boast strong patient recruitment bases, advanced medical infrastructure, and, importantly, efficient regulatory processes. The new drug application approval time for Japan's Pharmaceuticals and Medical Devices Agency (PMDA) ranks second across all major regulatory agencies, with an average approval time of around 300 days.[68] Meanwhile, South Korea's average clinical trial startup time is only 152 days, compared to 224-day averages in other top-performing countries.[69]

Both countries have enjoyed a warm relationship with Washington and bilateral medical research programs, but due to geopolitical differences, have struggled to strike commonalities on comprehensive public health cooperation with each other.[70]

However, with new diplomatic momentum in the trilateral U.S.-Japan-South Korea relationship in the last few years, Washington, Tokyo, and Seoul have advanced joint public health efforts, including clinical trial integration. Since 2022, the NCI has welcomed delegates from Japan and South Korea for regular exchanges and supported the countries' commitments to the Cancer Moonshot Initiative (Japan in 2016, and South Korea in 2017).[71] Both Japan and South Korea are also members of the U.S.-led International Cancer Proteogenomic Consortium, which, through the auspices of Cancer Moonshot, has brought together over a dozen countries to study cancer treatment predictive success and share data.[72] After the 2023 Camp David Meetings, the three countries' joint actions have sought to cooperate on cancer at an even more intimate level and in coordinated bilateral settings. The April 2024 U.S.-Japan Leaders' Statement emphasized the work of the FDA and the PMDA to exchange oncology drug product information to ensure earlier access to key pharmaceuticals by cancer patients.[73]

These instances of inclusive and positive cooperation between a variety of APAC partners demonstrate how political challenges may be overcome in a U.S.-Australia-APAC cancer coalition. With the leadership of Japan and South Korea in a potential platform and the growing role of the Quad, even greater quantities of regional players may be heartened to join such an a growing global movement.

China as a Potential Partner

A key component of a possible U.S.-Australia-APAC clinical trial harmonization platform not yet addressed in this report is the inclusion of China. As a 2024 American Association for Cancer Research study has shown, China accounts for 24% of reported global cancer cases and more than 30% of cancer deaths.[74]

China's potential is massive in expediting APAC-clinical trial harmonization due to the scale, reach, and growth of its oncology research system. Chinese clinical trial patient recruitment occurs at a pace two to three times faster than in the United States. Chinese oncology clinical trial activity grew more than 146% between 2017 and 2021—the highest total for any country in the APAC region.[75] Its licensing deals for novel oncology pharmaceuticals increased from 7 such deals in 2019 to 27 in 2023, representing the strength of the country's R&D apparatus.[76]

As described in last year's inaugural Cure4Cancer report, cancer experts and regulatory agency leaders from Washington and Beijing have discussed in-depth the possibility of China joining Project Orbis.[77] Although China is yet to join the initiative, integrating China into a U.S.-Australia-APAC oncology clinical trial harmonization mechanism would be critical to broadening lifesaving impact in the region. China's participation in such a platform may also encourage like-minded, developing APAC countries to join the coalition on a faster timeline. China's inclusion as a valuable partner in a U.S.-led clinical trial harmonization platform is an integral step to bridging wider benefits to new partners and tapping into robust APAC-based oncology resources.

Challenges

The stakes for APAC clinical data sharing and trial harmonization could not be greater than in the present moment, as sentiment behind global data sharing practices remains relatively weak. Since October 2018, the International Committee of Medical Journal Editors and the World Health Organization have required trialists to state whether they plan to share de-identified data at the time of registration. To date, only 23% of trialists have indicated intentions to share data.[78] Australia's own proportion of this statistic also rests at 23% as of August 2023, with only 485 of 2,143 surveyed Australian trialists expressing intent, let alone sharing such data internationally.[79]

Additionally, the APAC region itself brings its own unique challenges to bear on clinical trials. As the region is not united by a shared language or culture, challenges exist in settling on a unified procedure and coordination. In a 2023 ASCO-published APAC clinical trial report, researchers based at National Cancer Centre Singapore (NCCS) encountered serious obstacles in undergoing ethics board reviews and translating materials across 12 countries and regions with 100 contracts and 49 board reviews.[80] These challenges contributed to a "protracted" two-year pre-study preparation timeline, with an average six-month approval time required per clinical site.

The significant delays and setbacks in only one study reflect the nature of diverse regulatory regimes in the APAC region and, moreover, the difficulty of finding overarching frameworks that suit various countries' needs. Ultimately, the NCCS study resulted in a fragmented clinical trial architecture, with only Chinese authorities sharing data with Singapore while Australia and New Zealand reached their own separate agreements.

Although such delays and fragmentation are not uncommon among international clinical trials, the obstacles of the NCCS study underscore the need for an APAC-based coalition to harmonize clinical activity. While the varying technical capabilities, economic capacity, and regulatory regimes of each country should be carefully attuned to, patient lives are needlessly lost during pre-study preparation procedures lasting multiple years.

Such an obstacle may be avoided in the future by drawing inspiration from other APAC-based cooperation mechanisms in which members adhere to common values and protocols. The following section details other APAC-based cooperation platforms in international affairs, economics, climate change, and trade that a U.S.-Australia-APAC clinical trial network may draw lessons from.

East Asia Summit

Since 2005, the East Asia Summit (EAS) has convened leaders from 18 different APAC countries (including the United States and Australia). Configured as a part of the Association for Southeast Asian Nations (ASEAN), the EAS has identified six key areas in which to advance regional peace, stability, and prosperity: 1) environment and energy, 2) education, 3) finance, 4) global health issues and pandemic diseases, 5) natural disaster management, and 6) ASEAN connectivity.

The EAS has played a notable role in unifying regional actors on larger issues in the public health sphere and serving as a platform to express visions for closer coordination in disease prevention and treatment. Examples include a 2021 joint statement on mental health cooperation, a 2014 joint declaration on Ebola prevention, a 2015 joint statement on regional health security, and even a 2020 joint statement on collective capacity to COVID-19 and epidemic response.[81]

The multilateralism expressed at the EAS is no small feat, banding countries like the United States, its Pacific allies, and China together in shared intention. As the member countries wrote in their 2020 COVID-19 joint statement, it is the members' objective to continue "putting people at the center of a whole of government and whole of society response to the pandemic."

A U.S.-Australia-APAC cancer consortium can leverage the EAS's focus on shared values and consensus for its own activities, which will be explored further below. By starting from the ground up on actionable consensus and government response integration, the EAS represents a successful model in stringing together a mosaic of diverse countries on shared issues.

Asia-Pacific Economic Cooperation

The Asia-Pacific Economic Cooperation (APEC) is a multilateral bloc representing 21 member economies based in the APAC region. Established in 1989, the organization seeks to find trade solutions and expand member economies' market opportunities due to the increasing interdependence of APAC countries. APEC ministers and representatives meet regularly throughout the year ahead of an annual summit, which convenes world leaders, trade officials, entrepreneurs, and various business executives.

The intersection of business, trade, and industry concerns leads to influential statements and projects focusing on global health topics. Active since 2003, APEC's Health Working Group has driven global

conversations forward on exploring APAC areas of cooperation in life science, biotechnology, and pharmaceuticals.[82] Previous topics at the Health Working Group include an APAC mental wellness strategic plan, enabling healthcare system resilience, and even a regional "APEC Roadmap" for APAC cervical cancer prevention and treatment.[83] The cervical cancer prevention and sustainable economic advancement program was additionally highlighted at the last APEC High-level Meeting on Health and the Economy in August 2023.[84] Outside of the Health Working Group, the Policy Partnership for Science, Technology and Innovation robustly supports policymakers, entrepreneurs, and practitioners across various STEM fields.[85]

In addition to the summit's economic and policy coordination heft, APEC provides critical opportunities for leaders to meet face to face and raise complex issues. For instance, in 2023, the APEC Summit in San Francisco facilitated a day-long meeting between Joe Biden and Xi Jinping to manage bilateral tensions and for U.S. Treasury Secretary Janet Yellen and Chinese Vice Premier He Lifeng to discuss advancing economic dialogues.[86] These sidebar meetings allowed both sides to express their interest in averting economic decoupling while finding room to jumpstart climate dialogue and other policy working groups.[87]

This year's APEC summit presents significant room for policy conversations and coordination efforts galvanizing APAC clinical trial mechanisms. Led by host country Peru's Minister of Health, Dr. César Vásquez, APEC's Health Working Group in February 2024 highlighted the importance of enhancing public health-adjacent supply chains and HPV vaccination efforts to prevent cancer.[88] In March, the APEC 2024 First Senior Officials' Meeting resulted in a consensus to endorse the Regulatory Harmonization Steering Committee of Medical Products after a two-year pause.[89] The same month, APEC's Digital Economy Steering Group released a comprehensive report on region-wide health data standardization efforts, which specifically addressed clinical trial data sharing and the challenges of using health data across "many fronts."[90] The convergence of various APEC interest groups and stakeholders on the issues of health, data security, and pathways to harmonized clinical trials holds particular significance for introducing region-wide clinical trial mechanisms.

A U.S.-Australia cancer coalition could tap into APEC's convening power and focus on blending economic, policy, business, and diplomatic stakeholders into a policy incubator setting. APEC's focus on subdividing sectoral issues and institutionalizing working groups is also an effective mechanism to promote end-to-end regulatory coordination and harmonization.

Other Projects

While EAS and APEC represent the two most well-established and robust APAC multilateral platforms, novel programs in the trade and climate realms also present interesting examples that may hold lessons for an APAC-focused regional international clinical trial coalition.

The first platform is the newly introduced Asian Development Bank Institute-Asian Development Bank (ADBI-ADB) Asian Climate Finance Dialogue, which seeks to mobilize private capital, public officials, and central banks in synchronously pursuing international Paris Agreement climate goals.[91] The ADBI-ADB project has spurred climate finance thought leadership, hosted central bank events, and held policy roundtables since its establishment in 2023, aiming to harmonize standard setting and compliance among APAC climate finance regulators.[92]

Although the program is rather new on the international scene, its outsized impact and unique policy approach may hold lessons for other APAC-focused multilateral platforms. As Asia Society Policy Institute researchers have previously argued, excess focus on U.S.-China rivalry and contestation in climate change has minimized the voices of middle powers while spurring domestic competition between Washington and Beijing.[93] Yet programs like the ADBI-ADB dialogue move past a "race to the bottom" competitive ethos to a decentralized "race to the top", inviting a positive, competitive, and collaborative tone to climate finance by including middle APAC powers. Given the U.S.-Australia relationship's productive footing, inviting other APAC countries and stakeholders to take part in a decentralized, multilateral "race to the top" may spur positive change and inject a sense of friendly competition into the U.S.-China climate rivalry.

Another APAC platform that a U.S.-Australia-APAC international clinical trial harmonization scheme may draw upon is the Regional Comprehensive Economic Partnership (RCEP). Conceived in 2011 and signed in 2020, the RCEP represents the largest multilateral trading bloc in the world, accounting for 30% of global GDP, and is expected to eliminate 90% of tariff barriers between its fifteen signatories within twenty years.[94] In bringing an economic and trade fulcrum back to the APAC region, the partnership brings together a diverse constellation of economic systems and values under the umbrella of shared national interests.[95]

Although the United States decided to withdraw from the agreement, Australia is one of the RCEP's principal supporters. In fact, Canberra's support for RCEP originates from statements and negotiations held at previous EAS and APEC summits.[96]

The RCEP represents an example of a "mega-regional" project deepening interoperability, supply chain, and regulatory coordination between established trading partners.[97] This example draws lessons for the same APAC regional actors to coalesce and strengthen relationships in life sciences, pharmaceuticals, and international clinical trials. The RCEP's implementation further enhances the case for APAC-based multilateral clinical trials, as the elimination of tariff barriers, strong public tax incentives, robust patient recruitment networks, and supply chain coordination render clinical trials in the region 30%–40% cheaper than their counterparts in the United States and the European Union.[98]

Finally, sovereign financing initiatives in the public health space led by the Asian Infrastructure Investment Bank (AIIB) also hold lessons for APAC clinical trial schemes. A relative newcomer to the international organization community, the AIIB was founded in 2016 and is the world's second-largest multilateral development institution focused on multilateral development. By the end of 2020, the AIIB had 103 approved members that comprised roughly 79% of the global population and 65% of global GDP.[99]

Headquartered in Beijing, the AIIB has a unique mandate to serve the APAC region through enabling infrastructure connectivity, innovation, and resilience. The AIIB has been particularly active in the public health space, providing sovereign financing for 13 countries between 2020–2022. Each of the projects assisted countries in responding to healthcare capacity challenges during the COVID-19 pandemic, such as by providing emergency supplies, strengthening virus surveillance systems, and increasing social engagement through vaccination awareness campaigns.[100] Many of the AIIB's financing projects in the latter half of the pandemic were cofinanced or supported by the ADB's Asia Pacific

Vaccine Access Facility (APVAX) program, which helped APAC countries with limited resources procure critically needed COVID-19 vaccines.[101] The APVAX project, approved in December 2020, partnered with COVAX on the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator to reach an even greater populational scope.[102]

The AIIB's immunization support campaigns and APVAX partnership are a compelling model for APAC-wide initiatives succeeding in times of serious public health emergencies and instability. The AIIB's rapid response to the COVID-19 pandemic with considerable financial support helped sustain several fragile healthcare systems while providing needed medical resources and services to at-risk regional populations. The example could serve as a basis to help shape how sovereign financing for clinical trials may proceed in the future.

Analysis

From the variety of APAC-based cooperation platforms detailed above, policymakers can draw the following lessons:

Putting Ideology Aside and Prosperity at the Top: One of the most illuminating components of the EAS and APEC is the emphasis on regional political stability, economic prosperity, and public benefit. The value-neutral judgments of political systems and international relationships give member countries ample room to negotiate shared agreements and statements on global public goods and shared challenges like public health, sustainability, and cancer prevention. The U.S.-Australia-APAC program could consider espousing value-neutral judgments on ideology at the gain of casting a wider net with regional partners, leading to more fruitful collaboration and sustained engagement with middle powers in APAC. A shared vision for prosperity and stability may also present opportunities for inclusive leadership from other key partners in the APAC region.

Leave Room for Minilaterals: Not every joint statement, declaration, or regulatory agreement can work for every country involved. Allowing room for pragmatic cooperation between smaller coalitions of countries in the form of minilaterals could help build consensus and provide strong working examples for countries less convinced of certain regulatory models. For example, the RCEP has facilitated greater intra-RCEP trade and smaller agreements on market access, supply chain coordination and transparency, and product standards.[103] The U.S.-Japan-Korea trilateral and Quad Cancer Moonshot have both presented new opportunities for accelerated clinical trial integration. These small-scale projects should not be underestimated as effective regional models and may cross-apply when it comes to regulatory harmonization minilaterals for cancer.

Bring Them All to the Room: All of the above APAC regional platforms succeed because of their emphasis on convening a wide variety of stakeholders at the negotiation and discussion tables. This includes trade ministers, public health officials, entrepreneurs, world leaders, and chief executives. A U.S.-Australia-APAC cancer coalition should prioritize the same openness to different industry leaders and specialists to achieve optimal outcomes and host robust conversations on clinical trial harmonization. Like in the case of last year's APEC meetings, convening powerful leaders can lead to unexpected outcomes on bilateral and multilateral arrangements or even spur new forms of innovation between the public and private sectors.

Institutionalized Regular Mechanisms: Each of the above platforms places an onus on continued and consistent meetings between key members, such as in the case of the APEC Health Working Group and the ADBI-ADB climate finance dialogues. Consistent and regular meetings between the four leaders of the Quad partnership also helped expand Cancer Moonshot and have allowed close coordination on cancer to continue from the top down. By both identifying key thought leaders and sticking to a coherent and regular cadence of their meetings, institutionalized mechanisms can more quickly bring cancer clinical trial harmonization results to the APAC region.

Emphasizing Economic Benefit: Although economic security and prosperity are stated values and objectives of each of the platforms referenced, they emphasize economic aims with varying degrees of specificity. With the involvement of government funding, diverse workforce integration, and investment from industry, clinical trial harmonization presents a strong case for bringing economic vitality to the APAC region. As two resource-rich countries with some of the strongest life science corporations and research ecosystems in the world, the United States and Australia should accentuate the potential economic benefits of harmonized cancer clinical trials to APAC partners across the region.

Humanitarian Service in Times of Crisis: The AIIB's responsiveness to the COVID-19 pandemic through robust financing initiatives helped deliver critically needed vaccines. Its partnership with the ADB through the APVAX project also presented an innovative solution to a regionwide challenge. The Quad Cancer Moonshot was designed with the Quad's credo of being a "global force for good" in mind (the Quad itself was formed to provide disaster assistance in response to the 2004 Indian Ocean tsunami). As improving cancer care teeters on a public health emergency for some APAC countries, the neighborly and punctual spirit of the AIIB's assistance may inspire both urgency and prudent decision-making for a regional clinical trial network. One subtitle that has become clear recently is the "Culture of health equity." Equitable access to care and clinical trials could be viewed as an ethical and moral issue for our societies and systems. Solutions need to be embedded through this "Culture of health equity" that emphasizes the notion that health equity is everyone's business from the top to frontline layers of health systems, trial sponsors, pharmaceutical companies, ethics, funding and regulatory bodies. Otherwise, many solutions could end up being pilot projects without being adopted at scale and speed.[104]

Conclusion

Cancer remains a serious public health and social challenge for APAC countries, but opportunities exist to move forward together as partners in a shared cause. Through the example of the U.S.-Australia relationship, the hub-and-spoke global cancer network model, and a possible APAC-focused clinical trial harmonization scheme, policymakers, industry leaders, healthcare professionals, and researchers are presented with ample roads and choices to deliver stronger cancer outcomes for patients across the region.

Our U.S.-Australia case study builds upon warm bilateral ties and momentum in scientific collaboration. This partnership can inspire stakeholders to reimagine how cancer treatment might be delivered across the APAC region. Our model encourages stakeholders to look beyond political differences, pursuing the greatest benefit for APAC populations by drawing on successful multilateral examples'.

It is both plausible and achievable to revolutionize cancer care and improve global health equity through international clinical trial harmonization. An APAC regional model only represents the tip of the iceberg. If successful, this model could inspire thousands of policymakers and dozens of countries to join the fight against cancer for the improvement of global health itself.

It is imperative that we expand this model locally and globally to enhance cancer research and treatment. We call upon policymakers, industry leaders, healthcare professionals, and researchers worldwide to join this to cure cancer by collaboration in advancing global health equity. The future of oncology is not ivory tower cancer centers, but cancer networks that help all people. Investing in and supporting international clinical trials through the hub-and-spoke network model will not only lead to significant medical advancements but also ensure equitable access to life-saving treatments for all populations. Together, we can make strides toward eradicating cancer as a major global health threat and achieving health equity for all.

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