Original Study

Perspectives on Anti-BCMA Bispecific Antibodies use in Multiple Myeloma–Experience from Asian Countries

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Abstract

B-cell maturation antigen targeted bispecific antibodies have transformed the treatment landscape for heavily pre-treated relapsed/refractory myeloma in Asia, showing impressive efficacy despite limited access and adoption challenges; regional expert discussions highlight the need for ongoing research into response durability, toxicity and infection management, and patient selection to inform future clinical guidelines and optimize patient outcomes.

Background: The management of relapsed / refractory myeloma particularly those who are heavily pretreated and penta-refractory has experienced a paradigm change with the advent of bispecific antibodies targeting B-cell maturation antigen (BCMA), offering new hope for these patients. The diverse experiences in the use of bispecific antibodies across Asian countries/regions underscore the complexities of integrating these therapies into clinical practice. With limited availability and varying access through clinical trials, compassionate access programmes and early commercial use, these agents are demonstrating impressive efficacy, yet present unique challenges in widespread adoption of these agents. **Methods:** A roundtable discussion among myeloma experts from Asia has highlighted consistent efficacy but also raised concerns about the durability of response and the management of associated toxicities and infections. **Results:** These discussions emphasize the need for ongoing research to better understand the nuances of treatment sequencing and patient selection. **Conclusions:** The insights gained will contribute to developing strategic frameworks and consensus guidelines that can effectively guide clinicians in optimizing outcomes for myeloma patients in diverse healthcare settings.

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Introduction

The management of relapsed / refractory multiple myeloma has undergone a remarkable transformation with the advent of bispecific antibodies targeting B-cell maturation antigen (BCMA), providing new hope for patients, especially those who are heavily pretreated and penta-refractory. However, while these developments are promising, much of the clinical trial data has been derived from populations in the United States and Europe. This raises queries about the applicability of these treatments in Asia, where drugs such as thalidomide and bortezomib have shown differing safety profiles compared to Western populations,[1-4] highlighting the need for more region-specific research and tailored treatment strategies.

A roundtable discussion involving myeloma and Infectious disease experts with experience in the use of bispecific antibod-

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Table 1 BCMA Bispecific Therapy Availability and Reimbursement in Asia

Countries / Region	BCMA BsAb Commercial Availability	BCMA BsAb Reimbursement / Coverage by National Insurance
China	Teclistamab	No
	Elranatamab	
Japan	Teclistamab	Yes
	Elranatamab	
South Korea	Teclistamab	No
	Elranatamab	
Thailand	Teclistamab	No
India	Teclistamab	No
Malaysia	No	No
Taiwan	Teclistamab	Yes (either 1 only and cap at 39 vials)
	Elranatamab	
Hong Kong	Teclistamab	No (expected early 2026)
	Elranatamab	
Singapore	Teclistamab	No
	Elranatamab	

ies from Asia was convened during the Asian Myeloma Network Summit in Seoul, Korea in October 2024, to discuss the current landscape of refractory multiple myeloma treatment in their respective regions, focusing on the availability and efficacy of treatments, toxicity management, infection control, vaccination practices, and future directions.

This paper aims to provide a perspective on these discussions, highlighting key regional differences and common challenges faced by clinicians in managing myeloma across Asia.

Availability and Experience with Treatments

The availability of BCMA-bispecific antibodies varies significantly across Asia, reflecting differences in healthcare infrastructure and regulatory processes. Typically, these therapies are used as single agents, but there is some emerging experience with combining them with anti-CD38 treatments. Each country in the region faces unique challenges in terms of access. Understanding and navigating these availability landscapes is crucial for optimizing patient outcomes in myeloma care across Asia. The current status of BCMA bispecific therapy availability and reimbursement in Asia is outlined in Table 1.

Efficacy of Treatments

In multiple myeloma, standard therapy typically combines immunomodulatory agents, proteasome inhibitors, and anti-CD38 antibodies, yet patients who progress after these regimens face limited options and poor outcomes. B-cell maturation antigen (BCMA) has emerged as a compelling therapeutic target and anti-BCMA bispecific antibodies have been developed to deliver potent, off-the-shelf T-cell–redirecting activity.

The Phase II pivotal studies of anti BCMA-bispecific antibodies have demonstrated remarkable efficacy in triple class exposed and penta-refractory myeloma.[5,6] Through early real-world application of these therapies in Asia, whether through direct access programs or early commercial use, these agents have demonstrated substantial initial benefits, with efficacy aligning with the trial data. Predictors of response and resistance to BCMA-targeting bispecific antibodies in Asian myeloma populations remain incompletely defined, but emerging signals mirror global experience while raising Asia-specific considerations that warrant prospective validation. Teclistamab demonstrated consistent efficacy and safety profiles in the China cohort of the MajesTEC-1 trial, aligning with results from the pivotal cohort, for the treatment of triple-class exposed relapsed/refractory multiple myeloma.[7] Results from MagnetisMM-3 for elratanamab in Japanese patients showed the overall response rates (ORRs) were consistent with those observed in the broader trial population, and no new safety concerns were identified.[8] While the initial efficacy of these treatments is well-documented, the longevity of response is not yet fully understood. Long-term follow-up studies are required to evaluate the durability of response, particularly in heavily pre-treated cohorts. Determining the optimal duration of therapy and understanding how treatment cessation may impact depth / duration of response and relapse rates are critical areas for ongoing and future research.

Some clinicians have adapted dosing schedules pragmatically, often spacing out doses beyond the third or fourth cycle when many patients have achieved good responses, especially when managing simultaneous infections. This flexibility in dosing has raised questions about the optimal dosing intervals for maintaining efficacy while minimizing toxicity.[9,10] Understanding how these dosing adjustments impact immune recovery particularly on T-cell exhaustion, infection risks, and patient outcomes is vital. Investigating the relationship between dosing intervals, immune system recovery, and treatment efficacy could inform optimal dosing of these biologically active therapies.

In addition, currently, the predictors of response and failure in patients receiving BCMA-targeting therapies are not well-established for Asian myeloma patients although several poor prognostic factors, including presence of extramedullary disease and

pre-existing exhausted T cell phenotype might be predictors of failure.[11] Host determinants may be especially pertinent in Asia, for example, immune repertoire polymorphisms, microbiome composition, smaller body size affecting pharmacokinetics of fixed-dose agents, and infection epidemiology may further influence exposure and T-cell function, as the landmark trials focused mainly on the Western populations. Identifying biomarkers or clinical characteristics that can reliably predict patient outcomes would significantly enhance treatment personalization. Critically, most evidence comes from small regional cohorts; hence harmonized, multi-omic biomarker programs, linked to standardize dosing and longitudinal sampling across Asia, are needed to distinguish true biological predictors from confounders and to enable tailored, durable T-cell–redirecting strategies in Asian patients.

To address the current gaps in understanding and optimize the use of BCMA-targeting bispecific antibodies, several research directions should be pursued. One critical area involves conducting detailed subgroup analyses to better comprehend efficacy variations among different patient profiles. These analyses could provide valuable insights into tailoring treatments for specific subgroups. Additionally, longitudinal studies are essential for tracking the durability of responses over extended periods, offering a clearer picture of the long-term benefits and potential late-onset issues associated with these therapies. Trials exploring various dosing strategies are also necessary to assess their impact on efficacy, toxicity, and immune recovery, with an eye toward adaptive dosing schedules that align with individual patient responses. Moreover, focused research on identifying biomarkers as predictors of response or resistance could greatly enhance personalized treatment approaches. Establishing regional and international registries to compile real-world data on treatment outcomes, adverse effects, and patient characteristics is crucial. Such registries would contribute to a more comprehensive understanding of these therapies across diverse clinical settings, ultimately informing better clinical practice. The IMWG led Immunotherapy database might serve this purpose as many Asian centers are also participating in the endeavor.

Side Effects

Cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) are significant considerations when administering bispecific antibodies, yet experiences with these adverse effects vary regionally. Generally, the incidence of CRS appears consistent with published clinical trial data, with proactive management strategies such as the use of tocilizumab and steroids being employed at early stages of CRS to mitigate severity. This approach has contributed to effectively managing CRS, thereby shortening the duration of symptoms. ICANS, on the other hand, is relatively infrequent. Despite higher rates of CRS (96.2%) and neurotoxicity (34.6%) in the Teclistamab MajeTEC-1 China cohort compared to the pivotal RP2D cohort, these differences were likely due to the smaller sample size and close inpatient monitoring rather than ethnic differences, with all CRS events being grade 1 or 2 and primarily driven by grade 1 pyrexia, neurotoxicity events including headaches and a single unresolved grade 1 insomnia, none of which resulted in treatment reduction or discontinuation.[12] Of the Japanese cohort in the Elranatamab MagnetisMM-3 trial (n = 12), CRS occurred in 58.3% of patients, primarily after the first step-up dose and no ICANS was reported.[8] A unique issue observed in some patients includes tumor flare reactions, where rapid onset of symptoms can occur, requiring immediate management.[13] These experiences highlight the importance of individualized treatment strategies and comprehensive monitoring protocols to manage side effects effectively, ensuring patient safety and optimizing treatment outcomes.

Infections

Across Asia, it is also well recognized that infectious complications are common in patients undergoing treatment with bispecific antibodies,[14-17] and even higher risk observed in patients receiving combination of bispecific antibodies with agents like daratumumab or pomalidomide.[17,18] In addition, infectious complications of bispecific antibodies in the region may have distinct patterns as influenced by local epidemiological factors, but data in this regard is lacking. This highlights the need for cautious evaluation of patients, balancing efficacy of bispecific antibodies with the potential for heightened infection risk.

Most centers advocate infectious diseases screening before initiating bispecific antibodies as recommended by international guidelines.[19,20] Pneumocystis prophylaxis with trimethoprim-sulfamethoxazole and herpes prevention is oral acyclovir are considered essential. The use of fluoroquinolone for bacterial prophylaxis is variable with some physicians using them in a time-limited manner during the early phase of therapy when risk is higher. Specifically in Asia, there are 3 unique concerns, namely, the reactivation of Hepatitis B, tuberculosis (TB), and the risk of infections with multi-drug-resistant organisms. Firstly, the high prevalence of Hepatitis B necessitates testing before initiating bispecific antibodies, as untreated hepatitis can complicate treatment outcomes. Several centers have adopted standard protocols for hepatitis screening and prophylaxis with antivirals in hepatitis B carriers.

Secondly, in many countries in Asia, TB is endemic, and the prevalence is high in some countries like India,[21] therefore excluding active infection and evaluating for latent TB before commencing bispecific antibodies is important. When evaluating active symptomatic TB, many centers start with initial tests like sputum Acid- Fast Bacilli (AFB) smear, mycobacterial culture, TB polymerase chain reaction (PCR), and chest X-ray. If these results are negative but clinical suspicion remains high, further evaluations, such as chest computed tomography (CT) and bronchoscopy with bronchoalveolar lavage (BAL), are considered. Positron Emission Tomography-Computed Tomography (PET-CT) performed for evaluation of multiple myeloma may sometimes reveal incidental radiological findings which may allude to the diagnosis of TB and prompt diagnostic evaluation as appropriate. In addition, drug resistance testing is emphasized in countries like India where baseline resistance rates are high.[22] It is also observed that there is a range of practices and opinions on the evaluation and screening of latent TB. In general, routine screening is not practiced for hematologic patients receiving bispecific antibodies. Concerns about false negatives in immunocompromised patients,[23] lack of reimbursement, and potential challenges with indeterminate results[24] complicating treatment decisions were discussed. However, screening may

be considered for high-risk cases, such as those with known TB contacts. If the interferon-gamma release assay (IGRA) result is positive, active TB should be excluded through further testing. In India, given the high background prevalence of TB, when clinical suspicion is high, patients are empirically initiated on Anti-Tubercular Therapy (ATT) despite negative microbiological results, rather than being treated for latent TB. Inherently, variation in practices exist across different institutions due to differing prevalence, resources, and institutional protocols.

Thirdly, the burden of antimicrobial resistance in Asia is high.[25] Drug resistant bacterial infections complicating bispecific antibodies may result in severe complications with limited treatment options and contribute to poor outcomes. Screening for the carriage of multi-drug-resistant organisms (MDROs) to guide infection prevention measures and inform choice of empiric antibiotics may be useful but may be difficult to implement in some centers due to resource limitations.

Similar to observations in Europe and United States, it has been observed that infections commonly occur early in the treatment course. Bacterial and viral infections (especially respiratory viral infections) are common, largely due to aggressive disease progression leading to immunodeficiency and neutropenia.[15,26] In addition, corticosteroid use for CRS/ICANS early in the treatment course also contributed to increased infection risk.[15] Interestingly, some practitioners have noted fewer bacterial infections with linvoseltamab[27] compared to other agents like teclistamab and elranatamab, although this observation requires further investigation to ascertain whether it represents a true difference in infection risk or simply anecdotal variance.

The T-cell activation, T-cell exhaustion, and hypogammaglobulinemia with bispecific antibodies are well-described.[19,26] In light of this, protracted viral infections[28] and reactivation of latent infections such as cytomegalovirus (CMV) may be expected.[29] Notably, it is well established that the prevalence of CMV-positive populations is significantly higher in Asian countries compared to Western countries,[30] which should be taken into consideration. Though the pivotal trials indicated perhaps lower incidence of CMV reactivation (DNAemia), a recent single center real world experience from US indicated that it could be much higher (49%) when CMV monitoring is practiced.[31] As a group, there is a signal suggesting that CMV reactivation in patients on bispecific antibodies might be important to study. However, its evaluation remains a complex issue, necessitating a deeper understanding of which patients are most at risk. For risk evaluation, current evaluation of CMV immunity using serological assays is inadequate as it does not evaluate T-cell function. There are immunoassays evaluating CMV-specific T-cell mediated immunity,[32] its use has been evaluated mainly in solid organ transplantation and the cutoffs in hematological malignancies are not well defined. In addition, such immunoassays are not readily available in the region. Some international experts recommend checking CMV PCR at the start of treatment with bispecific antibodies and continuing to monitor if it is detectable.[19] However, there is no consensus on the frequency of surveillance and thresholds for pre-emptive treatment to-date, or if we should wait to treat only when CMV disease occurs. In the setting of CMV reactivation, practical yet difficult decision regarding the frequency of dosing and the continuation of treatment with bispecific antibodies invariably arises. Dose attenuation is known to be effective in helping viral DNA reduction and treatment recommendations are often personalized.

Although uncommon, fungal infections may also present a notable challenge in our region. In some centers, the occurrence of fungal infections was potentially exacerbated by concurrent conditions, such as post-COVID-19 complications in patients receiving high-dose steroids. This underlines the importance of context-specific considerations when evaluating infection risks associated with bispecific antibodies.

Profound hypogammaglobulinemia seems to be universal with BCMA-targeted bispecific antibodies. However, the frequency of evaluation and prophylactic measures, including intravenous immunoglobulin (IVIG) support, are variably implemented based on regional healthcare resources and patient affordability. In many cases, IVIG is crucial for preventing severe infections[33] or mitigating repeated infections[15], although its use is often limited by cost. IVIG has been shown to produce a 10-fold reduction in the incidence of severe infection in patients treated with Teclistamab.[26] In addition, granulocyte colony-stimulating factor (G-CSF)[34] as primary and on-demand prophylaxis for neutropenia might reduce severe infections.

Understanding the timing, context and pattern of infections is essential for effective management. We have observed that infections often follow a phased pattern: initial bacterial infections correlate with severe immunodeficiency early in treatment; mid-phase infections emerge as immunoglobulin levels decline; and late-phase infections, such as recurrent respiratory infection, sinusitis, and bacterial infections, occur in patients with significantly reduced immunoglobulin levels despite IVIG supplementation.

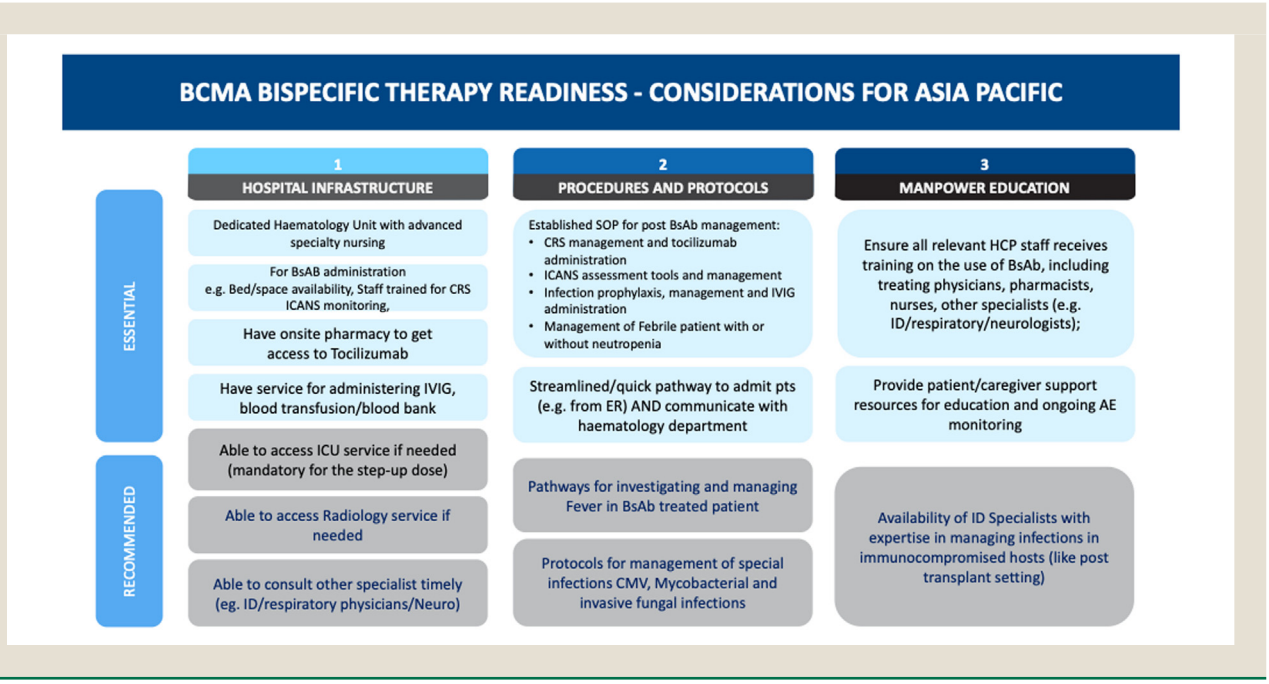
Collectively, these insights underline the importance of regional collaboration and the establishment of detailed registries to document infection patterns and outcomes. Such efforts would facilitate the development of tailored infection prevention and management strategies, ultimately enhancing patient care and treatment success across Asia.

Vaccination Practices

Vaccination practices for immunocompromised myeloma patients undergoing bispecific antibody therapy also vary significantly across regions, reflecting a need for tailored approaches and further research into optimizing vaccine efficacy and timing. Countries like South Korea and Singapore have implemented a regimen of vaccinations prior to the initiation of bispecific treatments, encompassing vaccines for influenza, pneumococcal disease, COVID-19, and herpes zoster. However, the schedule and need for more than 1 booster doses makes pre-BsAb vaccination not a practical solution. There remains a substantial knowledge gap regarding the most effective timing for these vaccinations and their overall efficacy in this vulnerable patient population.

Myeloma patients inherently face challenges due to their immunodeficient state, raising questions about the effectiveness of vaccines.[20] Current evidence suggests that patients on BCMA therapies may exhibit a poor antibody response to COVID-19 vaccinations[35] however the effect on T cell immune responses remain

Figure 1 BCMA bispecific therapy readiness – considerations for Asia Pacific.



unknown and perhaps plausible, highlighting the importance of exploring optimal windows for vaccine administration—potentially before commencing treatment. Despite this, an interesting observation has emerged: those who received the COVID-19 vaccine prior to treatment rarely succumbed to the disease, suggesting some degree of protective benefit.[36]

The discussion extends to newer vaccines, such as the shingles, RSV vaccine, where there is insufficient data to establish comprehensive guidelines. This uncertainty suggests continued reliance on antiviral prophylaxis, like acyclovir or valacyclovir, even post-vaccination, to prevent shingles outbreaks.

More broadly, current guidance is largely extrapolated: there are no randomized trials, and few adequately powered prospective studies—especially in Asian cohorts—evaluating immunogenicity, optimal timing, or clinical effectiveness of these vaccines. As such, recommendations on pre-treatment priming, holding or spacing doses around vaccination, and the use of additional boosters should be considered provisional until validated by prospective studies with standardized endpoints.

Additional Desirable Requirements in Managing Patients Starting Bispecific Antibody Therapy

There are fundamental and additional desirable institutional / organizational requirements in managing patients starting bispecific antibody therapy. Figure 1 consolidates the operational requirements for safe BCMA bispecific implementation across 3 domains—hospital infrastructure, procedures/protocols, and manpower/education. It highlights concrete needs such as beds and trained staff for CRS/ICANS monitoring, access to tocilizumab, IVIG, transfusion services, ICU and radiology, streamlined admission pathways, infection workups and timely access to infectious disease and other specialists, alongside structured training and patient/caregiver education. Given the complex care that might be required for optimal management of patients receiving BsAb therapy and the expected widespread use of these agents in Asia we hope the regional health care specialists embrace these requirements for ensuring patients safety and overall better outcomes. Figure 1 can be used as a pragmatic checklist that hospitals can adapt for internal audits of bispecific antibody delivery readiness within their existing quality-improvement workflows.

Future Directions

The future of managing multiple myeloma with bispecific antibodies in Asia relies on addressing key areas identified through clinical experiences and discussions. Central to these efforts is the proposal of establishing a regional myeloma registry, which would capture real-world data and facilitate country-specific analysis, thereby fostering collaborative research. This comprehensive registry would collect detailed patient experiences and outcomes across various settings, providing invaluable information for country-by-country analysis and supporting the sharing of best practices. Such an initiative would be particularly important in understanding real-world variations in treatment responses, including the impact of altering dosing frequencies to promote immune recovery and reduce infection risks, especially in regions facing multi-drug resistance and unique infection patterns. Standardized preemptive management for CRS/ICANS, alongside identification of pragmatic clinical predictors, will be assessed through a multinational registry using harmonized data elements. The infection burden will be quantified, and prophylaxis and vaccination practices will be reviewed and compared across centers within the same registry. Tailored guidance

that considers the diverse healthcare landscapes and epidemiological factors across Asian countries/regions would further enhance therapeutic strategies. Integrating this data into platforms like the IMWG Immune Registry could expand global understanding and optimize care for myeloma patients worldwide.

Conclusion

Anti-BCMA bispecific antibodies show strong efficacy in heavily pre-treated Asian myeloma patients, but real-world integration is complex due to variability in access and infrastructure. A regional registry and tailored, epidemiology-informed guidelines are needed to refine sequencing, strengthen infection management, and translate these advances into consistent outcomes across diverse care settings.

Clinical Practice Points

- Pre-treatment infectious risk assessment and prophylactic antimicrobials should be routine for myeloma patients receiving BCMA-targeted bispecific antibodies.
- Early identification and proactive management of cytokine release syndrome and neurotoxicity are essential to minimize treatment-related complications from bispecific antibodies.
- Flexible dosing schedules and individualized patient management, informed by ongoing research and regional real-world data, can help optimize efficacy and safety of bispecific antibody therapy in diverse Asian populations.

Disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Cinnie Soekojo: Writing – review & editing, Writing – original draft, Project administration, Data curation, Conceptualization. **Shimin Jasmine Chung:** Writing – review & editing, Writing – original draft, Data curation. **Ming-Tao Tsai:** Writing – review & editing, Writing – original draft, Data curation. **Wenming Chen:** Writing – review & editing, Writing – original draft. **Jeffrey Huang:** Writing – review & editing, Writing – original draft. **Jin Seok Kim:** Writing – review & editing, Writing – original draft. **Dong-Gun Lee:** Writing – review & editing, Writing – original draft. **Chang Ki Min:** Writing – review & editing, Writing – original draft. **Kazuhito Suzuki:** Writing – review & editing, Writing – original draft. **Subramanian Swaminathan:** Writing – review & editing, Writing – original draft. **Hiroyuki Takamatsu:** Writing – review & editing, Writing – original draft. **Daryl Tan:** Writing – review & editing, Writing – original draft. **Uday Yanamandra:** Writing – review & editing, Writing – original draft. **Chandramouli Nagarajan:** Writing – review & editing, Writing – original draft. **Wee Joo Chng:** Writing – review & editing, Writing – original draft.

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