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ORIGINAL RESEARCH

Exploration of Real-World Data Sources in Latin America, Middle East and North Africa, and Asia Pacific, to Support Oncology Evidence Generation: A Targeted Literature Review and Regional Recommendations

Shouki Bazarbashi · Alexander Chiu · Nancy Dreyer · Chirag Ghai · Alexandra Guarin · Soo Chin Lee · Fernando Petracci · Gustavo Werutsky · Cameron Wong · Manmohan Singh

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ABSTRACT

Introduction: In recent years, the role and utility of real-world evidence in complementing randomized controlled trials in oncology has become increasingly evident, accompanied by ongoing progress in real-world data (RWD) capabilities. Beyond Western regions such as North America and Europe, RWD in the broader international landscape has similarly matured, but is comparatively not as well characterized.

Methods: Recognizing a need to better understand contemporary availability and characteristics of oncology RWD sources outside North America and Europe, a targeted literature review was conducted, focused on English language articles published from January 1, 2020 to May 1, 2025. The review encompassed select representative countries from Latin America (LATAM), Middle East and North Africa (MENA), and Asia Pacific (APAC).

Results: Of the 466 publications ultimately included in review, data extraction yielded

Shouki Bazarbashi, Alexander Chiu, Nancy Dreyer, Chirag Ghai, Alexandra Guarin, Soo Chin Lee, Fernando Petracci, Gustavo Werutsky, Cameron Wong Order is alphabetical, given equal author contribution to this work.

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S. Bazarbashi
King Faisal Specialist Hospital & Research Center, Riyadh, Saudi Arabia
e-mail: bazarbashi@gmail.com

A. Chiu
AXA Hong Kong and Macau, Hong Kong, China
e-mail: subclavian@netvigator.com

N. Dreyer
University of North Carolina, Chapel Hill, NC, USA
e-mail: NDreyer@dreyerstrategies.com

N. Dreyer
Dreyer Strategies LLC, Newton, MA, USA

C. Ghai · C. Wong
Medical Affairs & Real-World Evidence, Blue Matter Consulting, New York, NY, USA
e-mail: cghai@bluematterconsulting.com

C. Wong
e-mail: cwong@bluematterconsulting.com

A. Guarin
Pfizer Inc., Bogota, Colombia
e-mail: alexandraguarin78@yahoo.com

S. C. Lee
National University Cancer Institute, Singapore, Singapore
e-mail: csilsc@nus.edu.sg

F. Petracci
Instituto Alexander Fleming, Buenos Aires, Argentina
e-mail: fpetracci@yahoo.com

G. Werutsky

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103 unique oncology RWD sources (61 in LATAM, 9 in MENA, 33 in APAC). Across the regions, similarities and differences were observed. While some countries like Brazil and Taiwan demonstrate potential impact of government-led initiatives across the entire health system, other countries like Argentina and Mexico rely more on site-level or network/consortium approaches for data collection and analysis. Overall, a common trend was seen in emerging examples of progress towards advanced RWD capabilities such as biobanks or clinicogenomic datasets.
***Conclusion*:** Looking ahead, continued investment and coordinated, multi-stakeholder effort will be critical to fully realize potential of oncology RWD in these regions.

Keywords: Asia Pacific; Latin America; Middle East; Oncology; Real-world data; Real-world evidence

Key Summary Points

Why carry out this study?

Real-world data (RWD) availability, capabilities, and use in generation of real-world evidence (RWE) continue to grow in Western regions such as North America and Europe, with demonstrated value in therapeutic areas like oncology.

Relative to North America and Europe, the landscape of oncology RWD in non-Western countries is less characterized; as a result, a targeted literature review (TLR) was conducted to explore and highlight current availability and characteristics of oncology RWD sources in Latin America, Middle East and North Africa, and Asia Pacific.

What was learned from the study?

TLR findings demonstrate that oncology RWD capabilities in non-Western countries are heterogeneous within and across regions; while predominantly registry-based, emerging examples of innovation such as claims and clinicogenomic databases are indicative of ongoing evolution and progress.

To support further RWE generation and acceptance withing these regions, continued investment, regulatory alignment, and cross-sector collaboration will be critical, and ultimately benefit oncology patients by more equitable and informed decision-making.

INTRODUCTION

Background

Oncology continues to be one of the fastest-evolving therapeutic areas, with an expanding pipeline of targeted agents, immunotherapies, and combination regimens. While randomized controlled trials (RCTs) remain the gold standard for establishing efficacy and safety, their generalizability to broader patient populations is often limited due to restrictive eligibility criteria,

Latin American Cooperative Oncology Group (LACOG), Porto Alegre, Brazil
e-mail: gustavo.werutsky@lacogcancerresearch.org

M. Singh (✉)
Medical Affairs, Pfizer Hong Kong Ltd, 21/F, Kerry Centre, 683 King's Road, Quarry Bay, Hong Kong, China
e-mail: manmohan.singh@pfizer.com

controlled settings, and relatively short follow-up periods [1]. Consequently, complementary approaches are needed to capture the complexity of cancer care in routine clinical practice.

Real-world data (RWD), defined as health-related information derived from sources such as electronic health records (EHRs), cancer registries, administrative claims databases, and patient-reported outcomes, has become increasingly important in oncology evidence generation [2]. After observational analyses of the RWD, resulting real-world evidence (RWE) provides insights into treatment patterns, adherence, long-term safety, healthcare resource utilization, and outcomes among diverse and underrepresented patient populations who may not be adequately reflected in RCTs [3–6]. Furthermore, RWE can inform questions of sequencing, comparative effectiveness, and health system performance, all areas of high relevance to clinicians, regulators, and payers alike.

Current oncology RWD generation in Non-Western countries

The landscape for oncology RWD development in non-Western countries has expanded considerably in recent years. Beyond North America and Europe, there is substantial investment in the establishment of cancer registries, digitization of healthcare systems, and data linkage initiatives to support oncology research. Regulatory agencies in countries such as China and Japan have begun to issue definitions and methodological guidance for the use of RWD and RWE in clinical development and post-marketing evaluation, signaling greater alignment with global standards [7–9].

Objective of Review

The objective of this review is to explore and highlight the current availability and characteristics of international oncology RWD sources outside North America and Europe through a targeted literature review (TLR). By systematically mapping the breadth and depth of these data assets, the review seeks to provide insights into how oncology RWD is being collected, curated, and utilized in these countries. Importantly, the review aims to support further generation and acceptance of RWD among local stakeholders – including physicians, payers, and regulators – informing potential applications of available RWD for clinical practice, health technology assessment, and regulatory decision-making. This work aspires to strengthen the role of RWD in oncology across non-Western countries and to promote its integration into the global evidence ecosystem.

METHODS

High-Level Approach

A TLR via keyword-based search of PubMed (Supplementary Material – Search Strings) was conducted in May 2025, to identify relevant publications that referred to oncology RWD sources in non-Western countries. Specifically, countries in regions beyond North America and Europe, namely, Latin America (LATAM), Middle East and North Africa (MENA), and Asia Pacific (APAC). A set of major countries were also selected to be representative of each region (Supplementary Material – Country Scope). During this selection process, certain countries (e.g., China, Japan, and South Korea in APAC) were excluded, given (1) the likelihood of significantly more advanced/mature RWD capabilities and established sources relative to others in-region, and/or (2) the anticipated high volume of non-English language literature. After identification of sources via TLR, the search was supplemented with additional desk research (e.g., source-specific websites outlining founding year, purpose, etc.) as needed, and consultation with local, treating oncologists involved in RWE research. This article is based on literature review of previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

Screening and Selection

While not systematic in nature, the TLR was conducted in accordance with guidelines established by Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) [10]. Literature was identified via pre-defined search strategy, with key criteria including full-text access and publication in English, from January 1, 2020 to May 1, 2025 (for recency). Records were then removed prior to screening based on title, per discretion of a human reviewer (i.e., no software or artificial intelligence tool used). During full-text screening, records were considered eligible for data extraction if they referred to a specific oncology RWD source in one or more in-scope countries. "Oncology" was defined as inclusive of data on patients with cancer, either exclusively or alongside other therapeutic areas. "RWD source" was defined per the Framework for the US Food and Drug Administration (FDA) RWE Program's examples, such as: EHR; administrative, medical claims, or billing database; product or disease registry; and other datasets informing on health status (e.g., biobank/genomic database, patient-generated via mobile device) [11]. However, single-site institutions (e.g., research universities) and one-off research studies were not included in this definition.

Data Extraction and Analysis

Relevant data from publications was extracted and populated by a reviewer into a pre-specified Microsoft Excel spreadsheet (Supplementary Material – Extraction Framework). Subsequently, a second independent reviewer verified the data extraction, with any disagreements resolved by consensus or a third independent reviewer. Extracted data were then narratively synthesized overall, including collective synthesis within country clusters to provide region-specific findings.

RESULTS

Overall

The PubMed search identified an initial set of 22,892 records, of which 10,897 underwent full-text screening per pre-specified review process. Ultimately, 466 publications were considered eligible and included in review (Fig. 1). Because the spreadsheet was designed with each row as a unique RWD source (i.e., not publication, to account for duplicate mentions), data extraction yielded a total of 103 oncology RWD sources (61 in LATAM, 9 in MENA, 33 in APAC) (Fig. 2).

LATAM

Among the five selected LATAM countries (Argentina, Brazil, Chile, Colombia, Mexico; Supplementary Material – Country Scope), most oncology RWD was documented in Brazil and Colombia, with 31 and 20 data sources, respectively. In contrast, there was minimal presence of established oncology RWD sources in Argentina (2) and Chile (1). Across all countries, data were primarily collected via registries or population-level databases, which accounted for 33 and 18, respectively, of the region's 61 total sources identified. All registries captured only oncology data, of which ~ 25% were focused on a specific tumor (e.g., breast, leukemia, cutaneous lymphoma). Population-level databases were mostly national, established by the Ministry of Health within their respective countries. Data variables collected by these sources typically included epidemiology, demographics, and treatment patterns and effectiveness, with limited or no collection of quality of life (QoL) or healthcare resource utilization (HCRU).

MENA

In MENA, each of the five selected countries (Algeria, Lebanon, Qatar, Saudi Arabia, United Arab Emirates; Supplementary Material – Country Scope) had one to three established oncology RWD sources, with the most in the United Arab Emirates (3). Of the nine total sources, seven were registries, primarily serving as national (e.g., Saudi Arabia, Qatar, Lebanon) or regional (e.g., Abu Dhabi) cancer surveillance. As a result, most data captured were oncology-specific, covering epidemiology, demographics, and, in some instances, treatment patterns and effectiveness.

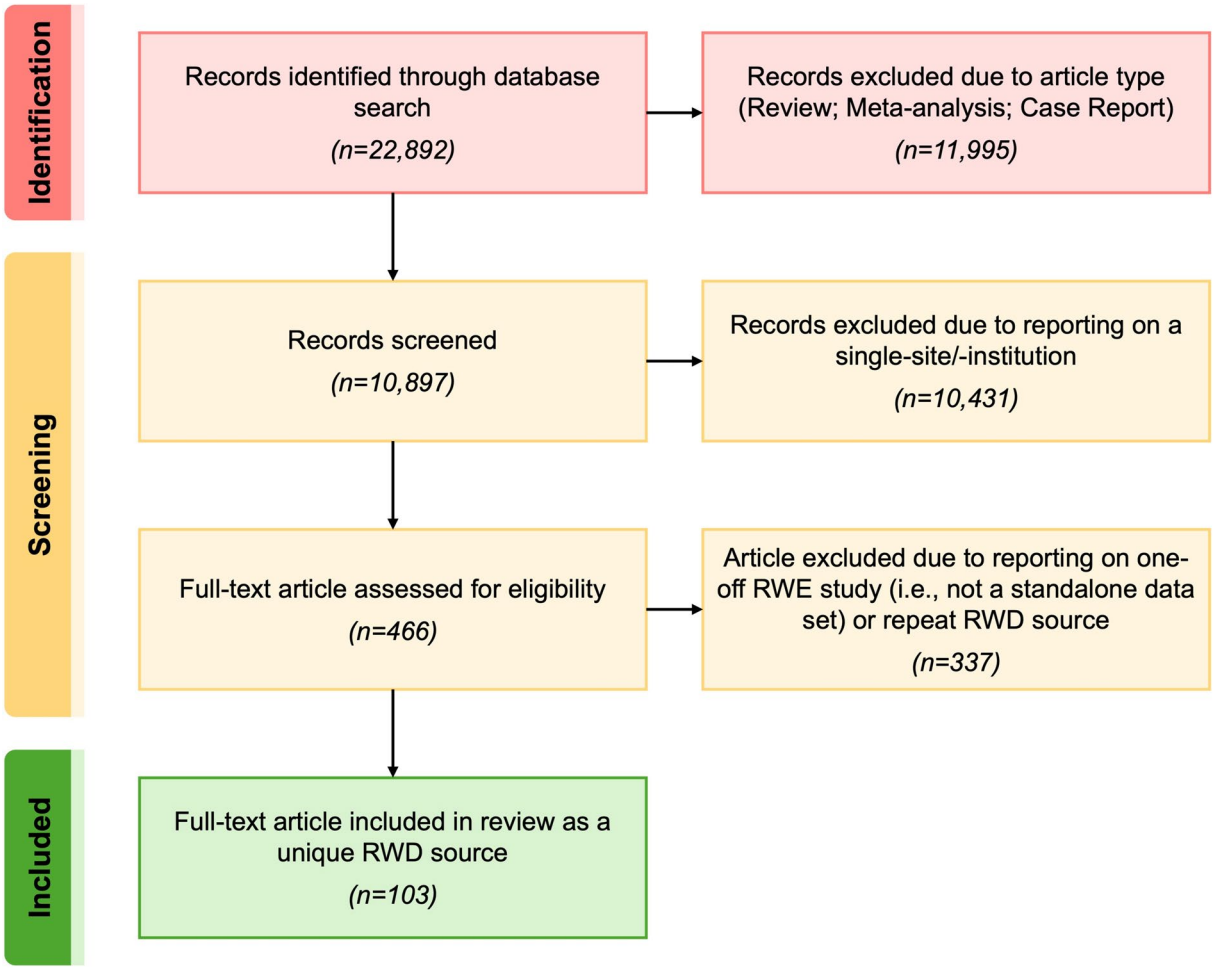

Fig. 1 PRISMA flow diagram. *RWD* real-world data, *RWE* real-world evidence

Beyond registries, MENA also had the Dubai Real-World Claims Database, providing cost and HCRU data related to cancer and other diseases, and the Qatar Genome Program, a national initiative aimed at enabling personalized medicine approaches [12, 13].

APAC

Across APAC's six selected countries (Hong Kong, India, Indonesia, Singapore, Taiwan, Thailand; Supplementary Material – Country Scope), greatest oncology RWD presence was observed in Taiwan with 13 sources and India with 10 sources. In comparison, only one, two, and three sources were identified in Southeast Asian countries of Indonesia, Singapore, and Thailand, respectively. Regardless of the quantity of in-country RWD sources, the majority of sources comprised registries, such as several regional population-based registries in India, representing Maharashtra, Delhi, Varanasi, Tripura, and other locales [14]. Of the 13 sources in Taiwan, 2 were biobanks: Taiwan Biobank, established in 2012, and National Biobank Consortium of Taiwan, established in 2024 [15, 16].

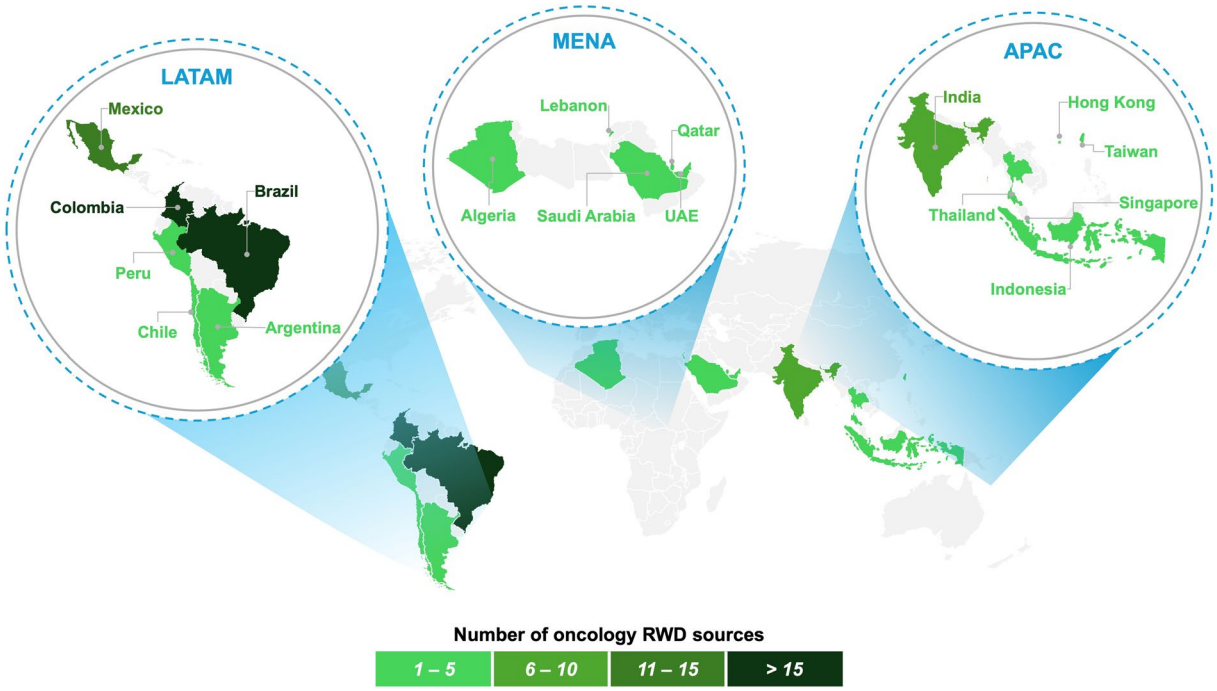

Fig. 2 Volume and spread of oncology RWD sources across selected in-scope countries. *APAC* Asia Pacific, *LATAM* Latin America, *MENA* Middle East and North Africa, *RWD* real-world data, *UAE* United Arab Emirates

DISCUSSION

Evolution of Oncology RWD in Non-Western Countries

By viewing each region's oncology RWD landscape in its entirety, a clearer picture emerges of both the current state and opportunities for future progress (Fig. 3). While countries were deliberately selected with expectation that their RWD capabilities would be less advanced than North America or parts or Europe or East Asia, TLR findings confirmed that oncology RWD is nevertheless available, with RWE being continuously produced and used to support cancer research. Additionally, although RWD presence was dominated by registries in all regions, each had emerging examples of innovation (e.g., clinicogenomic datasets) that are indicative of how RWD may evolve over time.

Overall, the total number of RWD sources in each LATAM country varied greatly. The large difference between countries like Brazil and Colombia versus Chile or Argentina can likely be attributed to the former countries' more established data infrastructure at the national level. For example, Brazil's Unified Health System Information and Informatics Department (DATASUS) was founded more than 30 years ago in 1991 by the Ministry of Health's Digital Health and Information Secretariat, with the intention of promoting accessibility, integration, and security of health information [17]. By implementing a unified health record that allows for interoperability across systems within the country's public healthcare system, DATASUS is proof of Brazil's modern advances in digitization. As a result, the data source has been reliably utilized to for many RWE studies, leading to 44 publications found in the TLR.

In other LATAM countries like Argentina, several similar barriers to robust RWD collection may exist. Besides absence of a single national EHR, there may be continued lack of digitization (i.e., paper medical records) in both public and private health systems, few to no health technology vendors focused on

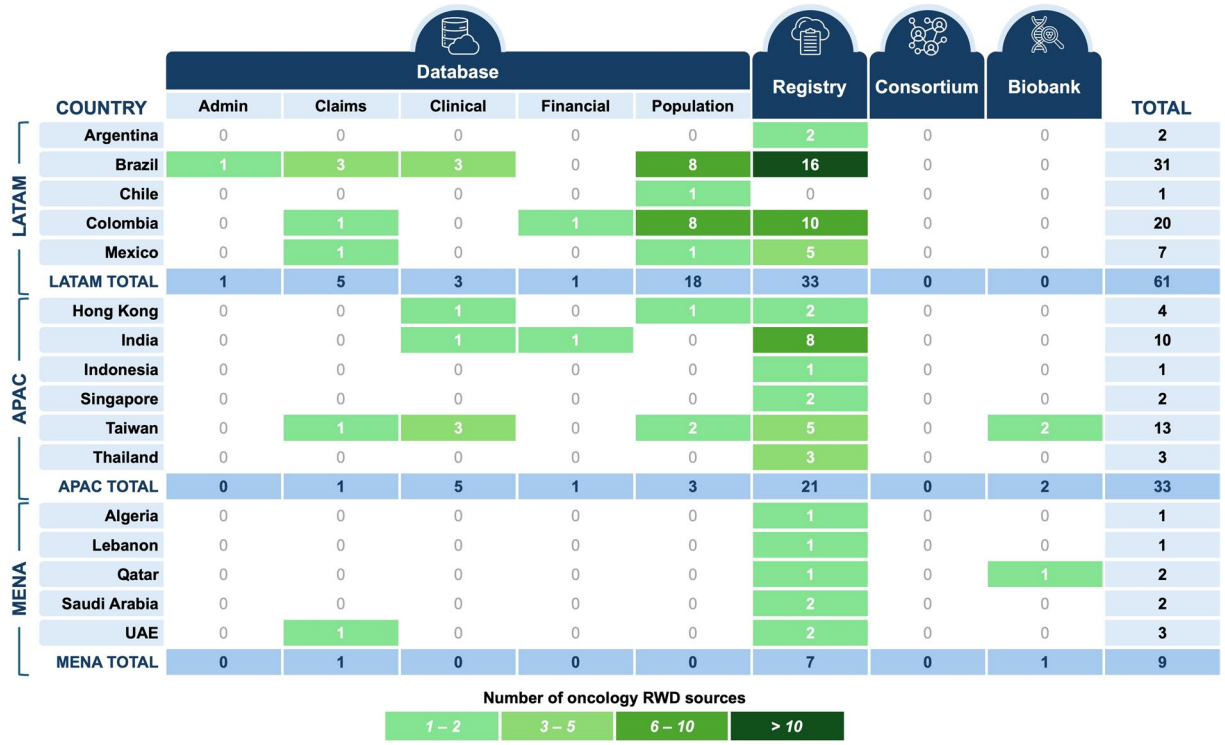

Fig. 3 Oncology RWD sources by type and country. *Admin* administrative, *APAC* Asia Pacific, *LATAM* Latin America, *MENA* Middle East and North Africa, *RWD* real-world data, *UAE* United Arab Emirates

unifying data collection for analysis, or negligible use of value- or outcomes-based payment models that necessitate RWD collection by institutions and third-party payers. As a result, the relatively low number of oncology RWD sources unsurprisingly limits the kinds of evidence that can be generated on local populations. Suboptimal clinical granularity in cancer registries exacerbates this challenge, such as insufficient detail on treatments administered, tumor markers, and death due to disease.

However, in countries like Chile and Argentina that lack many standalone clinical databases or EHR aggregators, there was anecdotal observation of greater focus on investigator-driven efforts at the site- or network-level, led by institutions or research groups such as the Latin American Cooperative Oncology Group (LACOG) [18]. While LACOG-generated RWE was outside of the TLR parameters – given its primarily site-driven research methods – the group engages in not only clinical trials but also real-world, epidemiological studies across tumors [19]. Separately, lack of diverse RWD source types such as biobanks has enabled entry of non-traditional data sourcing organizations such as Biomakers. Chiefly a "precision medicine innovation company," Biomakers provides access to genetic testing in Argentina, Mexico, and Brazil, with analysis of biological samples as a primary goal [20]. Although oncology RWD collection and insights generation may be a byproduct/secondary objective of these testing practices, they have nevertheless enabled development of a multi-country clinicogenomic dataset. Privately-led RWD initiatives in LATAM such as LACOG and Biomakers are driving availability of clinically-rich oncology in the absence of national-level datasets.

Relative to LATAM, the footprint of oncology RWD was much smaller in MENA. Considering selected countries that are part of the Gulf Cooperation Council (GCC) – i.e., Qatar, Saudi Arabia, United Arab Emirates – the Ministry of Health in each country holds authority over most healthcare transactions and, by association,

patient health data [21]. While few in number, the resulting cancer registries at national and regional levels may benefit in some respects. Given comprehensive patient capture across the respective geography, each registry ensures thorough representativeness of the local population. In addition, a registry approach allows for standardized data collection, supporting subsequent RWE generation. Advancements in cancer registry capabilities across the region include the establishment of the Gulf Cancer Registry, which standardizes data collection and cross-border sharing among GCC countries [22]. In Saudi Arabia, the Saudi Cancer Registry's robust infrastructure, mandated by royal decree, ensures comprehensive, nationwide, data capture through regional offices and certified software, with strong quality control measures [23]. Major institutions like the King Faisal Specialist Hospital bolster these efforts through detailed tumor registries, purposefully designed to support research.

Beyond this predominance of registries, MENA also has instances of oncology RWD sources that offer more than just foundational epidemiological and clinical data. Innovative initiatives such as the MENA COVID-19 and Cancer Registry, Dubai Real-World Claims Database, and Qatar Genome Program curate a broader set of data variables to enable more expansive RWE applications in the MENA region [12, 13, 24]. In addition, adoption of international coding standards (e.g., ICD-O-3, SEER Summary Stage 2000) and ongoing infrastructure enhancements have greatly improved data quality, interoperability, and research capabilities. As demonstrated during regional collaboration, such as the ICRIM workshop involving 19 MENAT countries, needs such as further standardization, data linkage, and capacity building have been explicitly identified and prioritized for future action [25].

The oncology RWD footprint for APAC was similar to LATAM, with wide-ranging volume of sources – between East Asian and South Asian countries versus those in Southeast Asia – largely driven by national digitization efforts. Similar to DATASUS in Brazil, Taiwan's National Health Insurance Research Database (NHIRD) was constructed in, and maintained since, 2002, collecting data from the compulsory National Health Insurance healthcare system. Designed for research purposes, the NHIRD's claims data may also be linked via unique personal identification number to other hospital and registry data, to jointly support clinical and/or economic RWE studies [26], as observed by the 54 publications found in the TLR. Independent of such national, widespread initiatives, registries accounted for the most – if not only – standalone oncology datasets in other APAC countries (e.g., India, Thailand, Singapore, Indonesia). Countries like Singapore with smaller populations are actively utilizing the full potential of these registry-based approaches, such as multi-country efforts like the Singapore–Malaysia Breast Cancer Registry [27].

Across the three regions, similarities and differences reveal key influences on the extent of and approach to establishment of oncology RWD in non-Western countries, and the overall direction that they are trending towards. Certain countries like Brazil and Taiwan demonstrate how government-led initiatives across the entire health system, as part of digitization efforts, can foster development of impactful, nationally representative databases. Similarly, albeit with some variants, governments in GCC countries also drive collection of population-level clinical data, but via national registries (an approach similarly seen in other regions like the Nordics, with NORDCAN [28]). In other countries, like Argentina and Mexico, where data access and/or ownership remains more at the site level, the creation of network/consortium approaches is observed instead. Furthermore, in LATAM, MENA, and APAC, a common trend was seen of examples emerging of progress towards more mature RWD capabilities, such as biobanks or clinicogenomic datasets, consistent with a macro-trend towards precision medicine [29].

Key Considerations

When considering RWD sources for oncology RWE generation, there are several regional nuances with associated potential challenges to account for. Such datasets enable better understanding of outcomes in local patient

populations, especially those that may be not as well represented in global RCTs [5]. However, lack of variety in types of sources – and data variables available in them – may limit the extent or impact of RWE. For example, predominance of registries will unsurprisingly support primarily clinically-related findings; however, as a result, health economic evidence would be noticeably absent in comparison, besides research leveraging the claims datasets. Additionally, healthcare stakeholders may accept transposability of evidence from another country within their region, but there may be limited representativeness (and therefore generalizability) if the patient sample is heavily sourced from only a select few countries.

Future-Forward Call-to-Action

The landscape of oncology RWD in non-Western countries is at a pivotal stage. The heterogeneity, fragmentation, and uneven maturity of existing RWD sources limit the full potential of RWE generation. To fully realize the potential of these data, a coordinated, multi-stakeholder effort is required.

Regulators, Ministries of Health, and local governments should continue to issue and refine frameworks for the digitization, collection, curation, and use of RWD in oncology, ensuring alignment with international standards while tailoring guidance to local health system realities. Such frameworks should emphasize methodological rigor, transparency, data integration and interoperability, and ethical considerations, including data privacy and patient consent. Perhaps most importantly, incentivizing data capture may critically drive adoption in public and private sectors.

Healthcare providers and academic institutions have a central role in strengthening data infrastructure by investing in EHRs, standardizing data capture across institutions, and fostering collaborative networks. Establishing multi-institutional or regional consortia can help overcome fragmentation, particularly in countries where single-site registries dominate.

Industry stakeholders can contribute by partnering with local institutions to enhance data interoperability, co-develop precision oncology databases (e.g., clinicogenomic resources), and fund initiatives that build analytic capacity. Importantly, collaborations should prioritize sustainability and inclusivity, ensuring that benefits extend beyond individual projects to strengthen national data ecosystems.

Patients and advocacy groups should also be engaged in shaping RWD initiatives to ensure that data collection reflects real-world priorities, including QoL, survivorship, and equitable access to care. Embedding patient perspectives into data frameworks will enhance both relevance and acceptance of RWE among local communities.

Looking forward, success will depend on fostering cross-border collaboration, enabling shared learning between countries at different stages of maturity. By pursuing these steps, stakeholders can transform the current oncology RWD landscape into a robust, sustainable foundation for evidence generation, ultimately advancing patient outcomes and health system decision-making across non-Western countries.

Limitations

Our methodology was associated with limitations that should be acknowledged. We aimed for relatively expansive data capture and adherence to PRISMA guidelines despite following a TLR approach. A systematic literature review, in contrast, would have been protocolized and therefore more rigorous and exhaustive, mitigating potential bias in the search strategy (including inclusion/exclusion criteria). As part of the TLR scope, we selected a set of representative countries within each region, but thereby excluded all others, which may have suggested other trends in oncology RWD. We also limited review to English language literature, to avoid introducing potential uncertainties associated with translation software, into extraction; however, additional local sources, described in non-English articles, could have been overlooked as a result. Bias may have been introduced during the screening and selection process due to the high volume of records initially identified, as well as the nature of having a human reviewer

determine inclusion based on titles or full-text. Potential gaps in data extraction were unavoidable, due to wide heterogeneity in robustness, quality, and comprehensiveness of publications. For example, level of specificity – such as around data provenance and collection practices, or potential data variables (including those not analyzed in a specific study) – varied across literature. Further, single-site RWD was omitted, with recognition that some institutions may be quite large.

CONCLUSION

This TLR underscores that, while oncology RWD capabilities in non-Western countries are growing, they remain heterogeneous in scale, maturity, and application. Registries dominate the current landscape, but emerging examples such as claims databases and clinicogenomic platforms highlight promising directions for future development. Regional differences illustrate the importance of tailoring approaches to local infrastructure, governance, and health system needs, while also seeking opportunities for harmonization and cross-country learning. Strengthening the oncology RWD footprint across these regions will require continued investment, regulatory alignment, and cross-sector collaboration. In doing so, non-Western countries can not only enhance the robustness of local oncology RWE but also contribute meaningfully to the overall global evidence ecosystem, ultimately supporting more equitable and informed decision-making for oncology patients worldwide.

Author Contributions. All the authors (Shouki Bazarbashi, Alexander Chiu, Nancy Dreyer, Chirag Ghai, Alexandra Guarin, Soo Chin Lee, Fernando Petracci, Gustavo Werutsky, Cameron Wong, Manmohan Singh) contributed equally to the conception, drafting, critical review, and substantial revision of this article, and have read and approved the final version, and agree to responsibility for the contents.

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Data Availability. Data sharing is not applicable to this article as no datasets were generated and analyzed during the current study.

Declarations

Conflict of Interest. Alexandra Guarin was affiliated with Pfizer (Bogotá, Colombia) at the time this research was conducted, and is now affiliated with Novo Nordisk Inc. (Bogotá, Colombia). Soo Chin Lee has received grant support / research collaborations from Pfizer, Eisai, Taiho, MSD, and Adagene; and advisory board / speaker invitation from Pfizer, Novartis, AstraZeneca, Eli Lilly, MSD, Roche, Gilead, DKSH, Daiichi Sankyo, and Menarini. Manmohan Singh is an employee of Pfizer. Shouki Bazarbashi, Alexander Chiu, Nancy Dreyer, Chirag Ghai, Alexandra Guarin, Fernando Petracci, Gustavo Werutsky, and Cameron Wong have nothing to disclose.

Ethical Approval. This article is based on literature review of previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

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