RWD58

# Real-World Evidence (RWE) Opportunities to Enhance Local Decision-Making in Oncology for Emerging Markets: A Multi-Regional Oncologist & Payer Committee Perspective

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## Background

- Unlike the U.S. FDA and EU EMA, most health authorities of countries in Emerging Market regions have yet to issue their own formal guidance or regulatory frameworks for the generation and use of RWE[1]
- However, there is demand amongst healthcare stakeholders in these countries to nevertheless grow regional real-world data (RWD) and RWE capabilities, to support clinical, payer, and regulatory decision-making, especially in oncology[2]
- In the clinical setting, oncologists in Emerging Markets may use RWE to guide and optimize their decision-making, such as by better understanding treatment patterns, adverse event management, or dosing[2]
- Similarly, in payer and regulatory settings, RWE can complement data generated in randomized controlled trials (RCTs) by providing insight into product usage, benefits, and pharmacoeconomics[2]
- Given minimal RWE and RWD infrastructure in oncology, there is opportunity for RWE innovation in Emerging Markets, that accounts for and incorporates specific needs and interests of healthcare stakeholders in these regions

## Objectives

- Perform a situation assessment of the current state of RWE in oncology in Emerging Market regions
- Identify future RWE initiatives that can support real-world research excellence in oncology in Emerging Markets
- Determine highest priority RWE initiatives that would be most impactful for oncology patients in Emerging Markets
- Capture most critical considerations for implementing the highest priority RWE initiative

## Methods

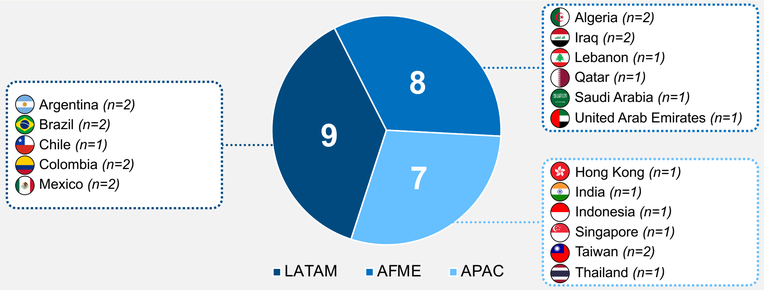


**Figure 1. Membership by region**

### RWE Insights Committee in Oncology for Emerging Markets (RICO)

- RICO was conceptualized to capture direct feedback on high-impact RWE initiatives from Emerging Market oncologist and payer advisors, across three regional committees: Latin America (LATAM), Middle East, Russia, and Africa (MERA), and Asia Pacific (APAC)
- Across the three committees, membership included 15 medical oncologist key opinion leaders (KOLs), specializing in a variety of tumor types, and 9 payer experts, with representation from both insurance companies and formulary committees; all members also had strong familiarity with and expertise in generating and interpreting RWE
- After membership was finalized, two types of RICO meetings for each region were convened between December 2021 and April 2022, using a primary market research-based, panel-style workshop format
- As part of the first set of meetings, live polling through Mentimeter captured RWE experiences, including RWD sources and RWE study designs commonly used, and discussion focused on current state of RWE in the region, including challenges and barriers, and identification of future RWE initiatives
- In the second set of meetings, members voted through Google Forms to prioritize which RWE initiatives they perceived as being most impactful for patients; subsequently, they were presented with stimuli of draft RWE initiatives and study designs which they then adapted and improved upon, to ideate on for future RWE innovation

## Results

### Summarization of current real-world research landscape in oncology in Emerging Markets, informed by KOLs in the region

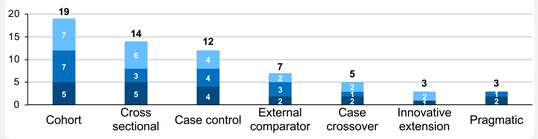


**Figure 2. Polling on commonly used RWE study designs**

- Across regions, members were most familiar with traditional research; in particular, cohort and cross-sectional studies
- In contrast, few knew about innovative RWE study designs such as innovative extensions and pragmatic trials

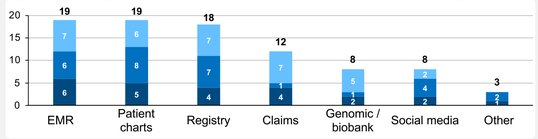


**Figure 3. Polling on RWD sources considered for studies**

- Across regions, members most frequently use EMR, patient charts, and registries as RWD sources
- Notably, multiple members also cited social media as an emerging, patient-centric source of information

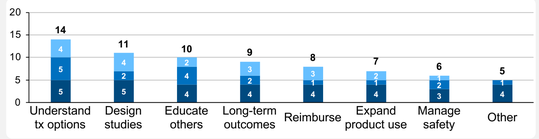


**Figure 4. Polling on how RWE is used by oncologists & payers**

- Most members use RWE to understand treatment options, but others also cited using it to design studies and educate others
- Those that mentioned using RWE for reimbursement also discussed its value when designing value-based agreements

### RWE initiatives identified and prioritized for the future

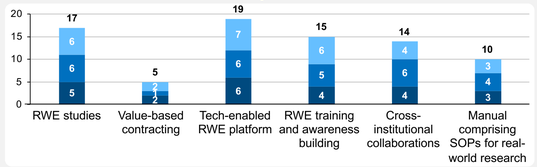


**Figure 5. Prioritized RWE initiatives**

- Several RWE initiatives were identified across six key real-world research themes; the top three RWE priorities for the future include:
  - A tech-enabled RWE platform, either cross-country or in-country (e.g., centralized, national repository) in nature, starting from 2023 with a decade-plus time horizon, was unanimously identified across regions as most impactful
  - RWE studies were also considered a priority; in particular, RICO members emphasized the need for evidence generation in terms of outcomes in local, ethnic, and underrepresented (in RCTs) patient populations, dosing, adverse event and side effect management, and cost effectiveness and pharmacoeconomic modeling
  - RWE training and awareness building was acknowledged as a need, both among other non-KOL oncologists (e.g., through delivery of a structured RWE curriculum) and payers (e.g., outreach guided by targeted discussions around how RWE can complement RCT data)

### What is a tech-enabled RWE platform?

### A multi-country, regional collection of prospective, clinically-rich, patient-level, oncology data made available via technology for on-demand generation of real-world evidence and insights

***What exists today?***

- While oncology RWD collection does take place in Emerging Markets, these initiatives are typically standalone, and none focus on prospective, long-term collection that is collaborative across countries, to support addressing a broad set of research questions on a continuous basis

**Table 1. Select, recent RWD collection initiatives in Emerging Markets**

| Region | Initiative | Description |
|---|---|---|
| LATAM | Latin American Cooperative Oncology Group | Multi-country collaboration to conduct studies in multiple tumors; primarily epidemiological use cases[3] |
| | IRIS study | Multi-country chart review; single product (palbociclib) and retrospective focus[4] |
| MERA | Qatar Genome Program and Biobank | In-country genomic and biobank initiative to support population-based research; single country[5,6] |
| | MOON study | Multi-country chart review in soft tissue sarcoma; small sample (n=200) and retrospective focus[7] |
| APAC | National Health Insurance Research Database | In-country claims data repository designed for use in real-world research; single country[8] |
| | OncoCollect in Breast Cancer | Software pooling patient-level data across three institutions; single therapy area and country[9] |

***What do we need for the future?***

- Development of a tech-enabled RWE platform addresses many traditional barriers to real-world research, such as questionable retrospective data quality, varying data standards and models, and insufficient patient sample sizes at individual data sources
- The platform may also address Emerging Market-specific use cases healthcare stakeholders are most interested in, such as outcomes in local, ethnic populations that may be underrepresented in RCTs

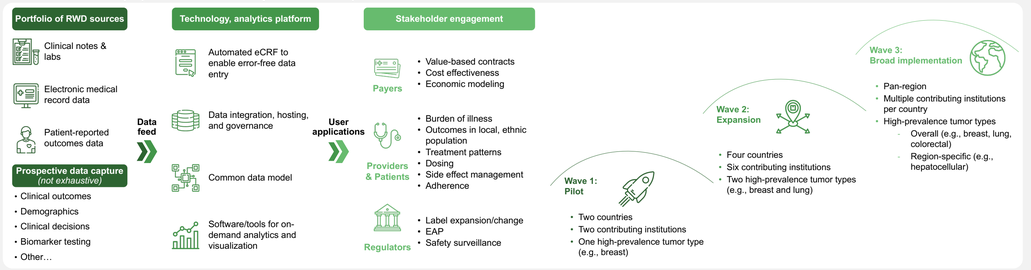


**Figure 6. Tech-enabled RWE platform schematic and implementation process**

## Conclusions

- In Emerging Markets, despite lack of widespread infrastructure, there is deep expertise and awareness around the use of RWE in oncology, within both the healthcare provider and payer communities
- Most challenges pertain to RWD (e.g., quality, mistrust, lack of digitization) and lack of resources; however, there is a strong desire amongst likeminded stakeholders to collaborate on designing and implementing RWE initiatives, as such opportunities would advance regional RWE capabilities and further enable RWE use in local decision-making
- In terms of impact for patients and healthcare stakeholders at large, Emerging Market healthcare stakeholders prioritized three areas: RWE studies in local, ethnic populations that may be underrepresented in RCT data; resources for RWE training and awareness; and, building a tech-enabled RWE platform, which has the potential to establish long-term oncology RWD infrastructure and mechanize ongoing real-world research

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