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Optimizing Real-World Evidence Framework for Oncology: Challenges, Opportunities, and Way Forward for India

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ABSTRACT

Given the increasing prevalence of rare and metastatic cancers, the utilization of real-world evidence (RWE) has become imperative. RWE plays a crucial role in generating oncology data that aids healthcare providers in their routine clinical practice and, more importantly, informs policymaking decisions. Pfizer and IQVIA joined forces to convene a ground breaking round table discussion involving stakeholders from both private and public organizations. The primary objective of this collaborative initiative was to explore the current state of the real-world evidence (RWE) framework in India, particularly within the realm of oncology. By assessing recent changes in the healthcare landscape, the discussion aimed to identify opportunities for government initiatives, acknowledge associated challenges, and chart a path forward for optimizing oncology clinical decision-making.

Several key outcomes emerged from this pioneering endeavour. Firstly, there was a strong emphasis on the significance of public-private partnerships in generating real-world data (RWD) within the Indian context. Specifically, the integration of electronic health records (EHRs) and cancer registries was highlighted as crucial for enhancing the quality and accessibility of RWD. Secondly, the discussion underscored the importance of harnessing real-world claims data obtained from both private and government insurance schemes to advance health outcome research. This data source holds immense potential for informing evidence-based decision-making in the field of oncology. Additionally, the round table meeting facilitated the generation of longitudinal RWD through government-led initiatives, opening avenues for comprehensive and long-term data analysis. Lastly, the exploration of utilizing RWE in reimbursement decisions and potential expansion of indications emerged as a significant area of focus.

The insights and conclusions derived from this round table meeting serve as a foundation for continued discussions. The diverse and extensive collection of RWD pertaining to oncology therapeutics holds immense potential to guide decision-making not only within India but also across other Asia-Pacific countries

Keywords: Real-world evidence, policymaking, oncology

INTRODUCTION

Real-world evidence (RWE) holds great significance in the realm of oncology research. Unlike data derived from controlled clinical trials, RWE provides insights into the effectiveness, safety, and utilization of treatments and interventions in real-world clinical practice. By analyzing data collected from routine patient care, RWE offers a comprehensive understanding of how treatments perform outside the controlled settings of clinical trials.1 RWE has the potential to fill gaps in knowledge and complement the findings of clinical trials, as it captures long-term outcomes, patient experiences, and real-world treatment

patterns. It enables researchers and healthcare providers to evaluate treatment effectiveness in diverse patient populations, identify subgroups that may benefit the most, and uncover potential risks or benefits associated with specific treatments. RWE also plays a vital role in health economics, helping assess the value and cost-effectiveness of interventions, inform reimbursement decisions, and guide resource allocation.2 Additionally, RWE facilitates post-marketing surveillance of oncology treatments, enabling the detection of rare adverse events or long-term safety issues that may not have been captured during clinical trials.

Overall, the significance of real-world evidence in oncology research lies in its ability to bridge the gap between controlled clinical trials and real-world patient care. It enhances our understanding of treatment effectiveness, safety, and value, guiding evidence-based clinical decisions, shaping healthcare policies, and ultimately improving patient outcomes in the field of oncology. The generation of real-world evidence (RWE) in oncology has witnessed remarkable progress, particularly in the United States and Western Europe. In these regions, significant investments by biopharmaceutical companies in infrastructure and the utilization of patient-level data have contributed to the prolific growth of RWE. Furthermore, the presence of robust local regulatory guidance has played a crucial role in fostering the development and implementation of RWE in clinical decision-making.4

This round table opinion aims to provide a clear understanding of the strategies that can support the use of evidence in the Indian context. The panelists provided solutions that support the transfer of knowledge from scientific research, and public health surveillance into policies and innovative programme.

METHODS

In recognition of the value of RWE in driving the generation of new insights, a roundtable was conducted by Pfizer partnered with IQVIA Consulting and Information Services India Pvt. Ltd. IQVIA on September 25, 2021. Pfizer partnered with IQVIA to bring together regulators, pharma experts, oncologists, research institutes and patient groups from various governing bodies from India. Ethics clearance is not applicable here as no datasets were developed or analyzed during the conduct of the study.

Experts representing various domains of the healthcare system shared their perspectives during the roundtable discussion, focusing on the following overarching themes:

1. The global impact of real-world evidence (RWE) on healthcare: Experts examined how RWE is influencing healthcare practices and decision-making on a global scale. They delved into the transformative potential of RWE in improving patient outcomes and shaping healthcare policies.
2. The existing RWE framework in India: The discussion centered around the current state of the RWE framework in India. Experts explored the initiatives and infrastructure already in place, analyzing their strengths and limitations. They sought to understand how India can leverage and enhance its existing RWE framework to meet the unique healthcare challenges of the country.
3. Solutions and the way forward: Participants of the roundtable engaged in identifying potential solutions and strategies to optimize the utilization of RWE in India. They brainstormed innovative approaches, discussed best practices, and proposed actionable steps to foster the growth of RWE in the Indian healthcare system. The focus was on developing a roadmap for the future, ensuring that RWE plays a central role in evidence-based decision-making and healthcare improvement.

By addressing these key themes, the experts aimed to gain a comprehensive understanding of the global impact of RWE, assess the current RWE framework in India, and propose feasible solutions for further

development and integration of RWE into the Indian healthcare landscape.

OBSERVATION

1. The global impact of real-world evidence (RWE) on healthcare

The 21st Century Cures Act directive has recognized the immense potential of real-world evidence (RWE) in supporting supplementary indications and post-approval study requirements for drugs, as mandated by the U.S. Food and Drug Administration (FDA). The FDA employs RWD (real-world data) and RWE for monitoring post-marketing safety and adverse events, as well as for making regulatory decisions. The growing interest in leveraging RWE to inform healthcare decision-making, particularly in the field of oncology, has gained significant traction. 5,6 Various stakeholders, including the Central Drugs Standard Control Organization (CDSCO), National Health Authority (NHA), Indian Council of Medical Research (ICMR), Tata Memorial Hospital (TMH), patient advocacy groups, and medical experts from Taiwan and the USA, have engaged in discussions to explore the utilization of RWD in healthcare decision-making. Integration of longitudinal RWD has been proposed to enhance regulatory decision-making in India and other Asia-Pacific markets.

RWE holds numerous applications throughout the clinical development process, with evidence from the global scenario indicating its value. Firstly, RWE can accelerate the discovery and approval of anticancer drugs by expediting the impact of new therapies on patient outcomes. Notably, the FDA has granted approvals based on RWE for various indications. Table 1 provides the details of FDA approved studies based on RWE data.

Table 1: FDA approvals based on real-world evidence data

Drug	Type of RWE	Regulatory action supported	Total no. of patients enrolled	Date of approval
Pembrolizumab	Expanded access study data to support clinical efficacy	Supplementary indication approval for microsatellite instability—high or mismatch repair deficient cancers (Original marketing application approval was for unresectable or metastatic melanoma)	149	May 23, 2017
Lutetium Lu dotatate	Expanded access study data to support clinical efficacy and safety	Original marketing application approval for SSTR-positive GEPNETs	229	Jan 26, 2018
Palbociclib	EHR data, claims data, and post marketing safety reports to support clinical efficacy and safety in new patient population	Supplemental indication approval for male breast cancer (Original marketing application approval was for postmenopausal women with hormone receptorpositive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer)	59	Apr 04, 2019
Avelumab	EHR data as historical control for efficacy	Original marketing application approval for MCC	88	March 23, 2017
Blinatumomab	Retrospective data from clinical sites as historical control for efficacy	Supplementary indication approval for MRD-positive ALL (Original marketing application approval was for Philadelphia chromosome-negative relapsed or refractory B cell precursor ALL)	116	March 29, 2018

ALL- Acute lymphoblastic leukemia; HER- Electronic health record; GEP-NET Gastroenteropancreatic neuroendocrine tumor; MCC-Merkel cell carcinoma; MRD- Minimal residual disease; SSTR- Somatostatin receptor

RWE also contributes to the development of treatment guidelines and aids safety monitoring by the FDA. Furthermore, RWD derived from electronic health records (EHRs) enables trial design optimization and feasibility assessment, informing protocol design and site selection. RWE can facilitate indication expansion by leveraging natural experiments that occur through off-label use of therapies. 7,8,9,10,11An example of this is the FDA approval of expanded indications for Ibrance® (palbociclib) based on real-

world use in male patients with advanced or metastatic breast cancer.12

Additionally, RWE plays a crucial role in market access and drug reimbursement, as payers increasingly consider RWE to guide coverage decisions. In the oncology landscape, where multiple high-cost agents compete for market share, RWE informs clinical value assessments requested by payers. The abundance of data generated daily through patient interactions with the healthcare system, including billing claims, EHRs, patient registries, and personal health devices, can be transformed into valuable evidence using rigorous methods and analytics.

Regulators face challenges as innovative treatments and tailored drug developments emerge. To address this, ICMR regulators have emphasized global collaboration on COVID-19 RWE and observational studies. Regulatory frameworks and guidance documents on RWE usage throughout the product lifecycle are being developed, with situations such as contextualizing safety profiles and conducting studies in rare diseases, pediatrics, and oncology identified as amenable to regulatory acceptance. RWE complements randomized controlled trials (RCTs), acting as a bridge to local data and supporting regulatory decision-making, indication expansions, and reimbursement decisions.

The European Union already incorporates RWD and RWE in pharmaceutical regulation, particularly in safety monitoring and disease epidemiology. However, further investigation is needed to establish the evidentiary value of RWE in effectiveness assessments. 13 The FDA has also introduced an RWE framework based on three pillars: appropriateness of RWD use, research design and evidence adequacy, and compliance with regulatory requirements. 14 In 2021, the FDA released several guidance documents related to RWE, addressing its use and data standards for supporting regulatory decision-making.

Considering regulatory agencies' reliance on RWE, expedited approvals and availability of new medicines to local patients can be facilitated through streamlined processes. By leveraging reference agency assessments and performing focused reviews on the applicability of results to the local population and healthcare system, regulatory agencies can expedite the approval process. Utilizing RWD to assess ethnic differences across regions and optimizing the implementation of multiregional clinical trial guidelines further supports efficient regulatory decision-making.

2. The existing RWE framework in India

The latest drug and clinical trial regulatory act provide provisions concerning accelerated drug approvals and waivers of post-marketing surveillance or phase 4 studies at the time of submission of a new drug under the following conditions:

- A new drug is approved and marketed in countries specified by the Central Licensing Authority (CLA) with no major unexpected serious adverse events reported; or
- Application for new drug import for which the CLA already granted permission to conduct a global trial is ongoing in India and, in the meantime, the drug has been approved for marketing in a country; or
- No probability or evidence, based on existing knowledge, of difference in the Indian population of enzymes/genes involved in new drug metabolism or any factors affecting pharmacokinetics and pharmacodynamics, safety, and efficacy of the new drug; or
- An applicant has given an undertaking in writing to conduct a phase 4 trial to establish the safety and effectiveness of new drug as per the design approved by the CLA; or
- Where the drug is indicated in life-threatening condition or disease of special relevance or an unmet need (such as extensively drug-resistant tuberculosis, hepatitis C, H1N1, dengue, malaria, HIV), or rare/orphan diseases

for which drugs are not available or are available at a high-cost.

These provisions allow for the approval of a drug that demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that occurs earlier but may not be as robust as the standard endpoint used for approval. Once the drug enters the market, its manufacturers must conduct post-marketing clinical trials to verify and describe the drug's benefits. The regulatory body may withdraw the approval if further trials fail to demonstrate the predicted clinical benefit. Since 1992, several drugs that treat life-threatening diseases under an accelerated approval pathway have successfully been brought to market and have significantly impacted the disease course. For example, many antiretroviral drugs used to treat human immunodeficiency virus infection and acquired immune deficiency syndrome entered the market via accelerated approval and subsequently altered the treatment paradigm. Several targeted anticancer drugs have also come to the market through this pathway.15

The experts also highlighted the need to incorporate patient perspectives for charting out an appropriate course of action. The health care community uses these data to support coverage decisions and develop guidelines and decision support tools for use in clinical practice. The health care sector in India is expanding rapidly due to expansion in services, strengthening of exposure, and increasing expenditure by the private and public domains. Health care in India is offered through two key channels: public and private. The government, i.e., the public health care system, comprises partial secondary and tertiary care institutions in major cities and focuses on offering primary health care facilities in rural areas. The private sector provides the majority of secondary, tertiary, and quaternary institutions of care, with a major concentration in metros, tier I and tier II cities. Compared to western countries, India is quite cost-competitive. With growing healthcare expenditure, there is significant scope for enhancing healthcare services.16

Electronic medical records (EMRs) have altered the way medical data is recorded and have the potential to be a reliable data source for drug development and clinical care. One such example is the Tata Memorial Hospitals (TMH), which has gone completely electronic with patient medical records and generates huge volume of data. TMH is responsible for 25% of the population-based cancer registries in the country and runs hospital-based cancer registries. The disease management group in the hospital runs prospective audits, which also contribute to RWE at TMH.

National Cancer Registry Program (NCRP), Indian Council of Medical Research (ICMR) launched the NCRP with a network of cancer registries across the country, with the following
objectives:

- To generate RWD on the prevalence and distribution of various cancers
- Conduct epidemiologic research
- To create a database for the development of strategic aids in National Programme for prevention & Control of Cancer, Diabetes, Cardiovascular Diseases & stroke (NPCDCS)
- To train people in cancer registration and epidemiology

Public–private partnerships are a way to improve the Indian health care system in terms of infrastructure, community facilities, and other related services.17 Various government-initiated schemes have been implemented at both the state and central levels (e.g., Pradhan Mantri Swasthya Suraksha Yojana).18 The vision of the Health and Family Welfare Division is to provide policy inputs aligned to the National Health Policy 2017 and make India's health sector robust, economically viable, and accessible. Swasth Digital Health is one of the examples of health initiatives. These initiatives provide advice and policy guidance to key stakeholders involved in public health development and management.

They engage with the Ministry of Health and Family Welfare (MoHFW), AYUSH, the department of pharmaceuticals, the NHA, state and local governments. They also collaborate with reputed international and national academic institutions, research organizations (ICMR), development partners, and eminent experts to advance the discussion on making a long-term impact on policy approaches.

Solutions and the way forward:

Large-scale schemes such as Ayushman Bharat, Pradhan Mantri Jan Arogya Yojana (PM-JAY) and Digital Health Mission have the potential to generate substantial longitudinal RWD, which can be analyzed to draw meaningful conclusions in clinical decision-making.

During the roundtable discussion, numerous initiatives and recommendations were proposed to steer health care policy decision-making in oncology, considering the numerous benefits of Real-World Evidence (RWE). The panel agreed that India has vast RWE capabilities; however, this potential remains unexplored in regulatory and health care decision-making.

Improving health care infrastructure

With the introduction of the National Health Research Policy, health research organizations and the Indian government are taking initial steps toward approaching RWE; however, evolving RWE still requires multiple hands and efforts to strengthen its broader implementation. Awareness, training on RWE study design to all healthcare stakeholders and development of appropriate tools to capture RWD are the need of the hour for establishing a robust Health Technology Assistant (HTA) system in India. One of the key initiatives by the Indian government is the introduction of a uniform electronic health record system for the creation and maintenance of EHRs by health care providers.19

Effective public–private partnerships

Learnings from the COVID-19 pandemic have paved the way for effective public–private partnerships (PPPs). A few examples encapsulating the successful PPP experiences in India include the pan-nation telemedicine network (moving forward, it will be leveraging information technology ([IT)] to manage patients' EHRs, capacity-building, and training of HCPs as well as health workers for pandemic management, contact tracing, containment). The vision is also to deploy IT for governance and information dissemination. The government has also launched an integrated health information platform to aid National Digital Health Mission (NDHM). The Hospital Information System, National Medical College Network, My Hospital Network, Drug and Vaccine Distribution Management System, COVID Dashboard, Health and, Wellness Center, Laqshya National Program for the elderly, Mental Health, EMR, and MoHFW budget are examples of noteworthy PPPs.

When industry experts and clinicians collaborate, there is an expectation from the clinical side that real-world evidence (RWE) studies will generate clinical insights that are directly applicable to their patient care practices. The industry expects RWE studies to provide evidence to support treatment approaches. To a clinician, an industry RWE study often has the "look and feel" of a post-marketing support study. Hence, there is a need to harmonize the clinician's and industry's expectations to conduct RWE studies. Furthermore, the industry could also help physicians and institutes by providing infrastructure, and training forming ethical committees, and initiating the global trials. 19, 20

Health Care Initiatives

The government of India invited public opinion and the involvement of different stakeholders to set up a multistakeholder committee that aimed to formulate a new health research policy. Universal health coverage (UHC) is a system that ensures

access to various health services people need without facing financial hardship. A few countries have successfully implemented UHC reforms; however, the experts envisaged the need to expand it worldwide. Implementation of UHC would enable more individuals to seek health care, ultimately generating a lot of claims data that could be utilized for research purposes. Key research partners who actively support the UHC movement are the World Bank, the German Agency for International Cooperation (GIZ), World Health Organization (WHO), the National Institute of Public Finance and Policy, and the Public Health Foundation of India. Recent government policies such as Ayushman Bharat PM-JAY and NDHM are major steps toward UHC. More comprehensive implementation of these policies will generate vast RWD. These data can be utilized for future health care/regulatory decision-making and guiding clinical practice.

National Digital Health Mission (NDHM) is a potent RWD tool for real-time analytics and real-time health care decision-making. It is integrated with health, doctor, and hospital ID systems, along with various health facilities, data, and health records of individuals, which would upgrade the digital health infrastructure of the country. It creates an integrated health care system, linking practitioners with patients digitally by giving them real-time access to health records. NDHM is necessary to support the integrated digital health infrastructure of the country. Through digital highways, it will bridge existing gaps among different stakeholders in the health care ecosystem. NDHM is a seamless online platform that provides a wide range of data, information, and infrastructure services, duly leveraging open, interoperable, standards-based digital systems while ensuring the security, confidentiality, and privacy of health-related personal information. Ayushman Bharat PM-JAY is the world's largest insurance scheme funded by the government of India, with over 10.7 crore 107 million families benefiting from the scheme and close to 500 crore million people set to be enrolled. The NHA was planned to converge with the Employees' State Insurance Corporation (ESIC) scheme and bring their IT platform into ESIC, so that data remain valuable and transparently accessible.

Robust policy frameworks

The experts emphasized the need to develop guidelines on RWE for post-marketing studies, Health Technology Assessment (HTA) and to generate more data for real-world settings or specific subgroups and guide decisions around indication expansion and reimbursement in Asian countries.

Opportunity for early engagement and pilots between health care providers such as sponsors and regulatory bodies

Given the varying degrees of acceptance of RWE among regulatory authorities and across therapeutic areas, early engagement between sponsors and regulatory authorities is critical to ensure early alignment to promote transparency and agree upon objectives. Health care professionals (HCPs), via mechanisms such as the US FDA RWE Subcommittee and the European Medicines Agency (EMA), Innovation Task Force (ITF) in Europe, are provided an opportunity to build partnerships and promote convergence in regional RWE regulatory strategies. It is important to document the rationale behind using an RWE approach rather than a traditional clinical trial approach for transparency with regulatory agencies. Additionally, the establishment of RWE frameworks globally is creating new opportunities for regulators, industry, and key stakeholders to partner, share experiences and generate mutual trust. The Indian health care sector is growing at a fast pace, and the government of India is earnestly creating an enabling environment for this sector, as the link between RWE and health care decision-making is now more than ever becoming clear to public policy leaders.

Overcoming Health Care RWD Challenges

Going into granularity on data issues in India, the experts emphasized the need to generate high quality evidence and proposed ways to make it painless for HCP working at the ground level. Several initiatives, including the Gates Foundation Initiative, have enabled data availability in the public domain.21 The MoHFW is now setting up an extension of the Integrated Health Information Platform to allow the availability of health care data in the public domain for research purposes.

The experts discussed ways to deal with data transparency issues in India and put forth the example of methods by which the ICMR and National Cooperative Development Corporation anonymize the data before making them publicly available. After anonymizing them, the National Family Health Survey also shares data with the MoHFW and other agencies for policy and program purposes. With the program's growing popularity, requests for more funds were made, and attempts are being made to involve more centers in the future. A few ICMR initiatives, along with National Digital Health, standardized EHRs, and the National Health System Cost Database (NHSCD), aim to develop a large and common database to record and manage health care data. Given that there is a worldwide policy framework in place for the new drug approval and post authorization clinical trial requirements, it is possible to adapt and define it in the Indian health care system. Effective collaboration across institutions might also assist in leveraging the value of data provided, as it will provide a reliable data source, and analysis of these data will produce robust evidence. While the government's comprehensive healthcare scheme serves as a data source, it requires a policy framework to effectively utilize this data for research and decision-making purposes.

DISCUSSION & CONCLUSION

The FDA relies on Real-World Data (RWD) and Real-World Evidence (RWE) to monitor post-marketing safety and adverse events, which play a crucial role in making regulatory decisions. Within the healthcare community, these data are utilized to support coverage decisions and develop guidelines and decision support tools for clinical practice. Medical product developers also leverage RWD and RWE to aid in clinical trial designs and observational studies, leading to the development of innovative treatment approaches.

India has immense potential to influence healthcare decision-making by developing and analyzing RWE data. Recent government initiatives like Ayushman Bharat, PM JAY, and the NDHM represent significant strides towards achieving Universal Health Coverage. Further comprehensive implementation of these policies will generate extensive RWD, providing valuable insights for informed decision-making in the Indian healthcare system

The available data presents an opportunity for future healthcare and regulatory decision-making, as well as guiding clinical practice. However, to build a strong healthcare framework in India, it is crucial to raise awareness and develop key competencies. Longitudinal oncology data needs to be generated using reliable methodologies. Establishing partnerships with industry, academia, and research organizations is vital to create a conflict-free platform that serves as a standard, robust, and reliable data source. Efficiently utilizing existing data from platforms like PM-JAY or NDHM, along with hospital-based registries, will be essential to generate further evidence. Additionally, defining Real-World Evidence (RWE) frameworks and their applicability in indication expansion and reimbursement decisions is imperative.

Declaration by Authors

Ethical Approval: This response is not applicable as it originates from a round table discussion and may not be relevant in this context. This article is based on 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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