Moving the Needle: Value and Use of **Real-World Evidence in Oncology Clinical** Pathways Decision-Making

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Introduction

- Oncology presents unique challenges with limited time frames to demonstrate therapeutic value.
- This research investigates the role of RWE in complementing traditional RCTs to inform clinical decision support and payer strategies, ultimately driving more patient-centric care and valuebased decision-making.

Methods

• An advisory board of eight US oncology clinical-decision makers was conducted to understand RWE utilization in oncology pathways (Table 1).

Table 1. Advisory Board Participants*

ADVISOR	ROLE
1	Director of Pharmacy at an Academic Cancer Institute
2	Chief Pharmacy Officer at an Academic Medical Center
3	Director of Pharmacy Cancer Care Services at a Large Private Integrated Health Medical Ce
4	Director, System Pharmacy Formulary Management & Clinical Services at an Integrated He
5	Former Medical Director at an Oncology Medical Center
6	Medical Director at a large Integrated Delivery Network (IDN)
7	Medical Director at an Academic Medical Center
8	Former Pathway Adopter at a Cancer Institute

*Pharmacy directors (n=4); Medical directors (n=3); Consultant (n=1)

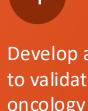
• A formal gap analysis assessing actionable data needs, stakeholder confidence in RWE, and dissemination strategies to inform pathways and clinical decision support was presented to participants. Emphasis was placed on RWE role in validating clinical trial findings, addressing critical patient-centric outcomes, and optimizing pathways (Figure 1). Figure 1. Study Objectives

Study Objectives:

- To understand and validate the use and value of oncology RWE in clinical pathways decision-making
- Identify areas for improvement and industry leadership for the sponsor of this global qualitative research project



Identify areas for improvement and industry leadership in the realm of oncology RWE and communication to PBDMs



Conclusions

- This research underscores a call to action for oncology stakeholders.
- Leveraging RWE in a collaborative environment is an opportunity and an imperative to optimize treatment pathways, strengthen clinical decision maker alignment, deliver superior patient outcomes, and enhance patient care in the evolving oncology landscape.

Abbreviations

HEOR, health economics and outcomes research; PBDM, population-based decision makers; QoL, quality of life; RCTs, randomized controlled trials; RWE, real-world evidence.

Advisors agreed RWE has significant potential to reshape oncology decision-making when it directly informs actionable outcomes, validates treatment effectiveness beyond clinical trials, and considers patient experiences and financial impacts (Figure 2). • Challenges persist, including inconsistent interpretations of RWE potential, non-standardized research prioritization, and a lack of practical application frameworks (Figure 3). Figure 2. Summary of Key Findings Resource use and patient preference play a significant role in pathway decision-making **Transparency and Value:** Total cost of care is important RWE is not the primary driver Total cost needs to be connected to value of a product but contributes to the total Cost of hospitalizations (length of stay), ED visits, managing side effects, etc. evidence used for decision-PMPM is considered an important metric making **Complete transparency of cost components is critical** Health Delivery System Ĭ Ĭ Ĭ **Characteristics of Valuable RWE** RWE needs to be reliable, credible, relevant, and reputable to be considered in clinical pathway Integrity and Validate: decisions Effective data representation beyond clinical trials is crucial for the meaningful integration of RWE Data needs to be reliable, into decision-making processes reputable, credible, and Health equity is a challenge across trial population, as well as RWE generation High value associated with integration of marginalized populations relevant **Population-Based Pathways** \iff • Efficacy and safety endpoints hold the highest significance in clinical pathway decisions • Pathways focus on population-based approaches, seeking specific data confirmation relevant to Value Proposition of Data: different populations RWE outcomes should go Adherence/Persistence beyond clinical trial data The frequency of treatment administration and infusion durations influence decision-making, especially during the COVID-19 era Abandonment and persistence rates impact decisions, considering a breaking point for reimbursement Discuss evidence generation priorities to meet the needs of PBDMs Humanistic **Patient Experience Data:** QoL is valuable, but not a driver over other efficacy endpoints • QoL associated with key toxicities is needed QoL is an important, but • QoL between trials is challenging due to different scales and measures – QoL is a composite score, it comparisons are limited by is challenging to pinpoint specific aspects differing measurement tools Develop actionable key themes from discussion to validate and enhance HEOR/RWE plans for Work-Flow Challenges / Committee Visibility oncology portfolio to support PBDM There is sequential consideration of efficacy, safety, and cost in pathway review **Different Perspectives:** • Decision-makers often lack visibility into pathways upfront, posing challenges in workflow alignment Customizing information and data needs to the institutional review committees Definition and components needed for clinical pathway **Tailor Engagement** submission varies • Engagement strategies may vary based on the size and nature of the pathway committee, infrastructure for decision-making and institution Meeting with medical prescribers, physicians, and pharmacists on clinical pathway teams is an effective avenue for communicating RWE Navigating program preferences and customizing approaches for industry publications and material handling is crucial Discussion • There is a critical need for more nuanced, collaborative approaches to integrating RWE into oncology clinical decision-making. support.

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Results

Acknowledgments

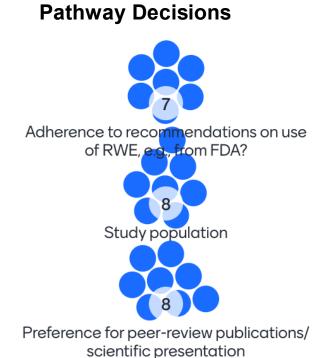
This study was funded by GSK (Philadelphia, PA, USA).

Leveraging RWE in a collaborative environment is an opportunity and an imperative to optimize treatment pathways, improve payer alignment, deliver superior patient outcomes, and enhance patient care in the evolving oncology landscape.

Figure 3. Advisor Ratings on Perceived Value of Key RWE Study Design Elements (N=8)

A. Impactfulness of Published RWE Study Type for **Clinical Pathway Decisions to Better Highlight** Safety & Efficacy of Study

Not impactful	PROs/QoL
	HCRU/Total cost of care
	Qualitative data
	Patient preferences
	Other



THEMES

Partnerships

Data Analytics Support

Value for Pathway Analysis

Nference Collaboration

Internal Data Analysis

Publication Collaboration

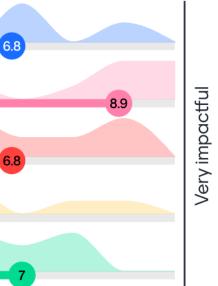
Data Transferability

healthcare decision-making.

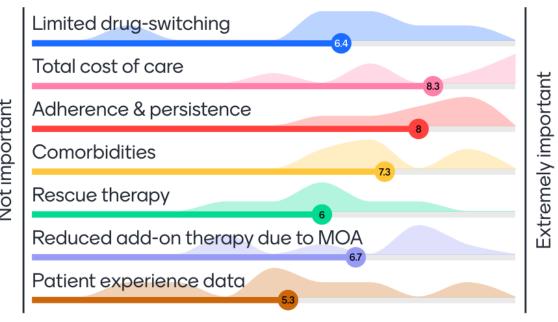
• By prioritizing actionable, patient-centered outcomes, fostering strategic partnerships, and addressing implementation challenges, RWE can significantly enhance the quality of clinical decision

Disclosures

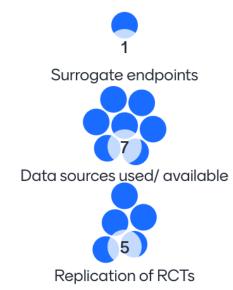
Phoenix Riley and Susan Hogue are employees of AESARA, which received consulting fees from GSK to conduct this study. Caitlyn Solem and Sumati Rao are employees of and may hold stock in GSK.

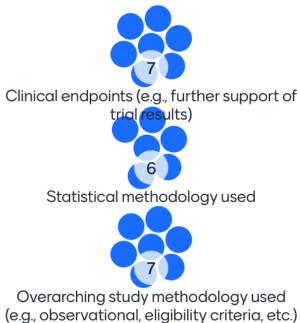


B. Importance of Factors to Distinguish Between Options when Clinical Differentiation is Limited



C. Importance of Design Elements to Ensure Confidence in Oncology RWE Being Generated to Support Clinical







Use of AI and/or digital aspects

Others

FSK

To overcome these challenges in RWE acceptability, advisors identified promising opportunities through collaboration (Table 2).

 While all agreed these collaborations can strengthen evidence generation, enhance quality measure understanding, and create more robust data collection, most agreed these measures were not currently implemented.

Table 2. Opportunities and Areas of Improvement for Decision Makers and Pharma Collaboration TAKEAWAYS

- One decision-maker has established 5 collaborative partnerships with pharma
- companies, and they are continuing to grow and are described as ongoing
- Partnerships involve entities that perform data analytics based on specific needs from pharma companies
- Collaborations extend beyond general data analytics and are valuable for pathway analysis
- This highlights the multifaceted utility of RWE in various aspects
- Specific mention of collaboration with Nference, a company that works with pharma partners, with Mayo Clinic as the expert
- Organization engages in internal data analysis based and data submitted, emphasizing a commitment to reduce bias and increasing reliability of analysis
- Collaborative efforts extend to publications, with pharma participants serving as co authors on papers produced by one organization
- Emphasis on importance of data being transferrable, indicating focus on interoperability and use of products that can effectively read and integrate various types of data, including scans

• This integrated approach suggests RWE faces implementation hurdles; coordinated efforts among stakeholders could substantially enhance its practical utility in