The Meteoric Rise of RWE and HEOR: Operating with Efficiency and Fostering Innovation between the Two Groups

OP10

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Introduction

Definitions	
Real World Evidence (RWE) is evidence about the usage and potential benefits or risks derived from analysis of data relating to patient health status and/or delivery of healthcare.[1] Several functions within the pharmaceutical industry generate and utilize RWE.	Health Economics and Outcomes Research (HEOR), analyses that identify, measure, or describe economic consequences based on represented health outcomes of the use of a medical product.[2]

- RWE and HEOR
  - Are increasingly being used in the industry to get the right medicines to the right patients at the right time.
  - Have grown in importance, and the needs for each in demonstrating treatment patterns, burden of disease, incidence/prevalence, adherence/persistence, comparative effectiveness, and real-world outcomes, have expanded globally in recent years.[3,4]
- RWE teams generate insights and evidence that inform development, regulatory discussions, and post-marketing strategy.
- HEOR teams generate evidence to inform decision makers regarding healthcare resource allocation as well as the value add on patient outcomes. They also utilize observational research to fulfill this mission.

Objectives

- RWE and HEOR teams are both responsible for RWE generation through observational research, yet confusion emerges on scientific accountability for research projects and what Decision-Making Committee is responsible for its endorsement.
  - Contributing factors include the specific objective of the study, and the market/region and the end customer (Regulators, Company Internal, Health Care Providers, Payers, HTA bodies, Policymakers, etc.)
- This poster identifies suggested best practices for operating efficiently and with impact in a cross-functional organization to inform health care decisions.
- We also identify areas for business efficiency when addressing the needs of external stakeholders.

Methods

2024 HEOR Benchmarking Exercise by AESARA

Figure 1. Overview of benchmarking exercise of HEOR organizations in pharmaceutical companies

- AESARA conducted a benchmarking exercise of **HEOR organizations in pharmaceutical companies** (see figure 1).
- AESARA conducted a **thematic analysis of the primary and secondary research** to develop the HEOR benchmarking report.

7 Companies **:10** HEOR organizations

- **3** Large companies (> US$30B annual revenue)
- **3** Medium companies (>US$10B- $30B annual revenue)
- **1** Small company (US$0B- $10B annual revenue)

- **7** Global only or Global + US HEOR organizations
- **3** US-only HEOR organizations

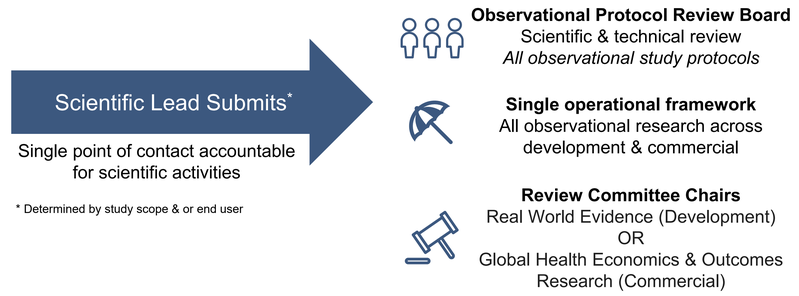
Primary research with HEOR leaders and team members through semi-structured interviews on topics
- Organizational structure and positioning
- Team characteristics
- Capabilities and infrastructure
- Ways of working

Secondary research on annual reports and company websites to characterize company size and assets by therapeutic area

RWE Governance Structure at Gilead Sciences

- A real-time example of fostering innovation includes an initiative at Gilead Sciences to streamline ways of working, procedures, and governance of observational research.
- A new Review Committee, the Observational Protocol Review Board (oPRB) was made effective as the sole committee for endorsement of all observational company-sponsored and collaborative studies.

Figure 2. Streamlining Observational Research at Gilead Sciences



Results

2024 HEOR Benchmarking Exercise by AESARA

Figure 3. Key takeaways from benchmarking exercise of HEOR organizations in pharmaceutical companies

2 companies have HEOR organizations **exclusively own RWE responsibility;** the remainder share RWE capabilities with other functions (e.g., Epidemiology, Medical Affairs, Clinical and Data Analytics)

"RWE experts are going to exist in various other functions because various external stakeholders are asking for RWE. It's going to be counter-productive to try to centralize execution of RWE…the strategic aspects should be centralized with HEOR."

- HEOR Leader

Key Challenges Reported
- Duplication of efforts results in business inefficiency
- Lack of governance of RWE protocols, methods and analyses results in potentially conflicting outputs
- Stratification of RWE roles and responsibilities, particularly by end-user, potentially limits the external utilization of RWE

Potential Solutions
- Delineate scope by evidence application, end-user or type of study
- Establish **governance structures**
- Strengthen Evidence Generation Plans (EGP) to coordinate RWE
- Centralize data warehousing

RWE Governance in Practice at Gilead Sciences

The Gilead Sciences governance structure was informed through the experiences of these case studies:

COVID-19 example
- In 2020-2022, the COVID-19 pandemic was rapidly evolving and demand for new evidence from payers and scientific bodies (e.g. guidelines groups) was extremely high.
- HEOR, RWE and Medical Affairs groups had weekly governance meetings to discuss data sets, methodology, and results, resulting in rapid publication of studies using the latest data available and using robust methodologies
- This collaboration led to **successful reimbursement in multiple countries**, including supporting the Joint Procurement Agreement in Europe.

HIV-1 example
- HEOR and the RWE group were utilizing IQVIA Longitudinal Access and Adjudication Data (LAAD) to answer similar questions but for different stakeholders. This duplication was identified in cross-functional discussions prior to protocol development.
- The groups then joined forces as co-scientific leads to develop a protocol and conduct the research, resulting in a publication which **can be used for payer discussions as well as with HCPs.**
- If the above structure had been in place, some of the inefficiencies could have been avoided.

Conclusions

- **Lack of clarity on conduct of RWE generation** in pharmaceutical companies can **lead to business inefficiencies**.
- Outputs of AESARA's HEOR benchmarking project demonstrate a critical need to **better define the breadth of RWE** to operationalize the best ways of working.
- Solutions presented in AESARA's HEOR benchmarking included **centralization of RWE (observational research) strategy, governance and data warehousing** to enable streamline execution of RWE.
- **Real world implementation of a cross-functional governance** structure at Gilead Sciences demonstrate the **success of centralizing RWE (observational research) review** to **improve cross-functional collaboration** and **enable meaningful generation of high- quality evidence.**

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