

RWD centralized teams:

Talent makes the difference in the success of an RWD Center of Excellence



Over the last decade, real-world data from electronic health records (EHR), insurance claims and sources like wearables and digital apps have become prolific. Most life sciences organizations have used real-world data (RWD) to answer questions across the product lifecycle. They've also recognized that RWD brings insight to both medical and commercial teams. For many pharma companies, EHR and claims data have become a foundation for clinical development, medical affairs, post-market safety surveillance, access strategy and go-to-market insights. When EHR and claims data are linked together, this integrated data yields even more powerful insight.

To maximize the value of this data, many biopharma companies have centralized the RWD function. The role of a centralized RWD team often includes:

- Maximizing the value and efficiency of data across the organization
- Creating a single platform of data, analytics and tools
- Building expertise and sharing best practices across the business

The success of these centralized RWD teams depends on their ability to:

- Understand the business questions across the product life cycle and the role each business function plays in answering them
- Understand each therapeutic area and the data elements that define diseases, treatment options and measures of patient response
- Interface with internal customers to evaluate the utility of data and tools to answer the business questions across teams and diseases

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The evidentiary plan forms the value story

Centralized RWD teams are sometimes referred to as “integrated evidence teams” because they support the end-to-end evidentiary plan that underpins the brand value narrative. The measure of this team’s success is the ability to deliver on the brand’s evidentiary plan throughout its life cycle. These plans are designed to support several themes.



A need for new interventions

There is an unmet medical need that causes patient suffering and cost burden to payors.



Clinical effectiveness

This product demonstrates clinical effectiveness over available options.



Safety

Short- and long-term safety analyses support a positive risk benefit profile.



Patient adherence and satisfaction

Patients will adhere to the regimen and experience an improvement in overall health.

Each of these themes encompasses a host of questions that may take multiple studies or analyses to demonstrate. Delivering on this end-to-end evidentiary plan is challenging intellectually and interpersonally. As such, the factors most critical to this team’s performance are the traits of the person who leads RWD.

The profile of the RWD team leader

An RWD team leader needs to have strong commercial business strategy experience. The best commercial leaders have an innate curiosity about the practice of medicine, clinical research and the economics of diseases and treatments. They need to appreciate the analysis required for go-to-market planning, access contracting, marketing and sales execution. They should understand the relationship between clinical trials and FDA regulatory decision-making.

More importantly, RWD leaders need to see the big picture relationship between the clinical research supporting drug labeling, promotional claims and the provider, payer, patient value story. In many pharmaceutical companies, commercial leaders sit at the intersection of clinical research and commercial go-to-market functions. Their position affords them a more complete view of the needs of medical/research teams as well as those of the access and commercial teams.

To succeed, the RWD team leader should have knowledge across a spectrum of business domains. First, they need to understand the parlance of medicine, research, regulatory affairs, compliance and technology. They must appreciate the spectrum of research approaches and data for evidence generation. Strong commercial leaders also cultivate an acuity for the nuances of regulated commercial speech, FDA evidentiary expectations, compliance requirements for research data, patient privacy, data use rights and data governance.

Realistically, a centralized RWD team requires the convergence of a half dozen knowledge domains that no single leader could master. Therefore, it’s important that RWD team leaders demonstrate openness and acceptance of guidance from internal leaders



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in clinical research and regulatory affairs to ensure compliance with the additional requirements imposed upon interventional study data. They may lean on a technical leader with experience in cloud platforms, data architecture and machine learning. They need to interact effectively with the data governance and compliance functions, and support new policy development needed for an RWD platform.

The RWD leader works across business functions and therapeutic areas to create a matrix of questions across products at each phase of their life cycle. A cross-functional working group should prioritize those questions and identify commonality among them. To accomplish this, the RWD team lead will need to tap into clinical and research experts who may be direct or dotted line reports. These experts will help ensure the unique dynamics of each disease are considered and ensure that the RWD under consideration represents the population with this condition. They will also evaluate the quality of analytics and tools to be used with the data. The right research talent should include experts who can understand the entire span of research functions from translational discovery and clinical development to HEOR and safety. This background is key to identifying the value that each dataset may contribute to each research function to maximize synergies and make conscious trade-offs. The RWD team is seeking to maximize data value for the organization and trying to avoid a case-by-case approach to procuring data. Without their oversight, the voice of one vocal researcher can result in narrow data license that supports a single study. Sometimes, this study does not meet the needs of the broader medical, research and safety functions. Further, the findings from such studies may not fit into the commercial strategy.

The RWD team needs a technical lead to work with the IT organization on the approach for the storage, access and use of the data and a strategy for homegrown or licensed analytics. The technical team should lead development and implementation of an enterprise-wide strategy for the data platform, analytics and tools. They need to consider access controls, de-identification, linking and any security and auditing features required to maintain privacy and compliance with applicable federal and state regulations related to collection.

Funding for the RWD organization, data, platform and tools comes from across the organization. Each team contributes to the integrated evidentiary plan. Therefore, when the RWD team serves the needs of all research and commercial functions, it is more likely to be seen as deserving of funding. Sometimes, RWD teams born out of an HEOR function fail to address the needs of other research and commercial functions. This approach can deprive the rest of the business from the benefits of shared data, methods and insights, and ultimately, prevents the full product value story from being realized.

One of the areas where RWD teams seem to suffer most is failing to bring best practices and cultivate standardized approaches to common types of analyses. For example, every product merits a patient journey that traces early symptoms, initial clinical presentation, testing, diagnosis, initiation of therapy, switches, discontinuation of therapy and long-term outcomes. This journey helps every product leader and their associated medical counterparts understand the barriers to diagnosis and treatment, identify gaps in care, quantify high-cost events and measure adherence to clinical guidelines. A standard methodology across products for this important exercise accelerates insight and galvanizes the organization around a unified strategy to advance the product. Therapeutic area commercial leaders will embrace a group that can create a best practice for this foundational analysis.

PITFALLS TO AVOID WHEN BUILDING A CENTRALIZED RWD TEAM

There are a few common pitfalls that have caused some companies to abandon the initiative to establish a centralized RWD team, such as:

- Failing to align the RWD team's plan directly to each brand's evidentiary plan
- Not maximizing data synergies and establishing the team's economic value
- Neglecting to serve the spectrum of business stakeholders across the organization
- Failing to cross-pollinate methods and data across business functions and therapeutic areas
- Not funding an effort of this magnitude sufficiently

How can RWD teams avoid these pitfalls? First, all service organizations (those not running a P&L) are judged by their value and service levels. With regard to value, RWD teams should tie their success metrics to delivery of the end-to-end evidentiary plan. They should measure the extent to which they advance best practices in data and methods. They must gain organizational alignment on the operational and financial metrics against which they will be measured.

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Collaboration drives organizational alignment

Once the journey has been mapped and the key gaps and product opportunities identified, alignment on its implications is critical. Cross-functionally, the entire team should align on the areas where evidence can establish the unmet need and unique product value that will help secure regulatory approval, payer and market access, provider adoption, guidelines placement and patient adoption. Managing this effort in a way that maximizes team participation and commitment requires cross-domain knowledge and an inclusive leadership approach. Only with a collaborative style can the RWD leader create a winning approach and enthusiastic support for the plan.

The most critical factor in the success of centralized RWD teams is the matrix of talent to drive stakeholder engagement and strategic alignment. The right collaborative leader helps guide the organization to a map of shared questions and a common set of data, tools, IT infrastructure and a governance framework. To deliver this outcome, the RWD leader should have strategic understanding of the full commercial opportunity, and how drug discovery, development, safety, market access and commercial functions contribute to the product's overall success.

At times, an HEOR or research leader is chosen for this role. But they are often siloed from exposure to the broader commercial picture and insulated from market research that informs commercial strategy. Therefore, the RWD team is best served by someone with a strong commercial background who can thoughtfully engage medical and commercial stakeholders, capture their needs, and leverage clinical and technical experts to identify data that best answers the greatest number of questions. Lastly, the RWD team lead needs to be empowered by the organization to lead these functions and remove roadblocks that can arise from a shift in power away from groups that have traditionally held the keys to the organization's data. While this shift can take effort and requires strong executive support, it has the potential to yield benefits to the organization, and ultimately, to the patients who will benefit when the full product evidentiary narrative unfolds for the market.



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