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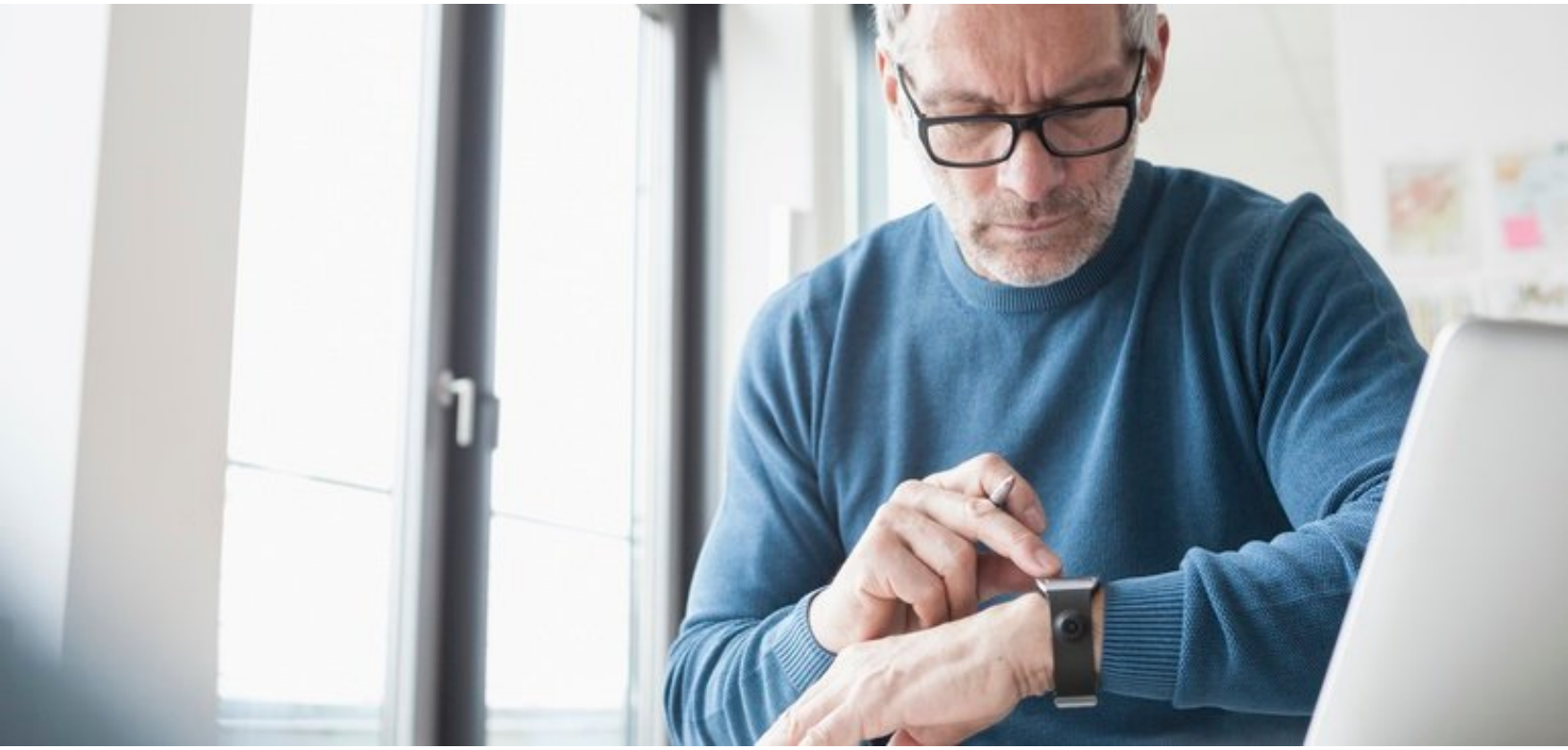
How RWE can help Biotechs optimize the value of their asset



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Traditionally, real-world data (RWD) and real-world evidence (RWE) have not been viewed as critical components to be incorporated into the drug development journey to demonstrate value for market access and product launch/commercialization. With the majority of small and emerging biotech companies choosing to seek out partnership or licensing deals to support pivotal trials and ultimately commercialization of their asset, there was little exposure to the numerous benefits RWD and RWE can provide to these companies early in their development planning and execution.

Over the past five to ten years, we have seen an upward trend in the number of smaller companies commercializing on their own, and an increase in their need to leverage RWE to drive market access and successful product launches. In addition, for the companies that have alternate exit strategies, they are also finding that RWD and RWE can play a vital role in helping them improve outcomes and optimize the value of their asset.

Using Real-World Data to drive a "patient- rst" approach

RWD is data that is collected outside a traditional clinical trial, usually via standard healthcare practice. It can be acquired from a variety of real-world settings, including electronic health records (EHR), medical claims, product and disease registries, laboratory tests, and potentially sensors, and health and fitness apps. The benefits of RWD are numerous – starting with the impact on patient outcomes - and incorporating RWD in clinical development can provide a more holistic view of the patient population, which can then help determine meaningful endpoints.

Matthew Gordon, Vice President of Real-World Evidence Strategy, Parexel, uses a recent example with a rare disease program. "We can review information through various real-world data sources to not only gain a better understanding of the overall natural history of patients, but also what are some of the potential challenges they are facing that can inform the conduct for an upcoming trial? This not only allows for a more efficient approach to the trial, but ultimately allows us to ensure we incorporate a patient-first approach, targeting endpoints and approaches that matter most."

In addition, the use of RWD can drive efficiencies by helping identify appropriate sites for clinical trial enrollment based on patient data mapping. Other uses can continue further down the development pathway as part of proof-of-concept, registration and approval.

Gordon added, "We're helping build support for whichever path they are on."

How Biotechs can leverage RWE to the fullest

Demonstrating Asset Value

Real-world evidence (RWE) is the translation of RWD into actual evidence that has traditionally been used to support objectives like regulatory submissions, go/no-go decisions, marketing and sales decisions, safety analysis and more. However, for biotech companies, it is important to note that it can also be a valuable tool to help articulate and demonstrate the value of their asset in discussions with investors, licensing partners and mergers-and-acquisition activity.

With the growing acceptance of RWE by a more diverse group of stakeholders, there is now a greater range of use for biotech organizations that can be tailored to the strategic goals of the organization, development stage of the product, and ultimate exit strategies.

Gordon notes that RWE has often been used to "engage with different stakeholders like physicians and patients for information that might be used for payers in the commercialization space. But what we're seeing now is a breakthrough in the adoption of RWE to support a number of objectives, including making things more efficient during the actual drug approval process. And it's being used much earlier to characterize the overall therapeutic setting."

Generating Approval Data

Some biotech companies leverage RWE to help generate an approval for their product. One approach is to collect comparison data from external control arms. External control arms model comparators using real-world data that would otherwise have been collected from the control or standard-of-care arms of trials. In addition to saving both time and money, external control arms resolve the concerns some participants have of receiving the placebo instead of the experimental therapy. For example, during COVID-19 vaccine trials, participants often wanted to know if they received the vaccine, and that concern grew even more as other vaccines were authorized and became available.

When to plan and deploy real-world evidence

The decision to use RWE is dependent upon the plans for its use. In addition to informing clinical trial decisions and potential use in regulatory submissions, RWE has significant uses in commercialization plans—which are of interest to potential investors, partners or acquirers.

Many biotechs are focused (appropriately) on the regulatory approval pathway and understand the importance of RWE - even as early as the initiation of Phase II clinical trials - but, due to resource constraints or other factors, they do not incorporate RWE into the clinical planning. However, the earlier in the product life cycle, or even company life cycle, RWE is incorporated, the more options biotechs will have and more flexibility in how it is used.

"Ultimately," said Gordon, "it comes down to the resources that are available to an organization. Either way, incorporating RWE supports the organizational goals regardless of whether or not product commercialization is part of the future planning."

The incorporation of RWE also demonstrates to investors and potential partners that the biotech is prepared to support its exit strategy and has given some thought to their overall planning.

Jimmy Brown, Vice President, Parexel Biotech says, "If you're looking for an exit strategy in terms of co-development or selling an asset or trying to be acquired, you want to have at least thought of what a customer would look at. And what I've seen is companies building their targeted product profile. They're looking to leverage that RWE around health care utilization and costs and around what the market landscape looks like from a reimbursement perspective."

Ultimately, RWE is a tremendously versatile tool biotech companies at all stages can leverage to help achieve their ultimate goals, whether that involves taking their product to market themselves, partnering with a larger pharma company, or attracting investors or buyers.