

4 WAYS TO ALIGN REAL-WORLD DATA (RWD) & STAKEHOLDER NEEDS

Outcomes are the single common definition of value to patients, healthcare providers and biopharmaceutical companies. So, why do we have difficulty aligning on the value of treatment if there are data of mutual interest across industry stakeholders?



10-20%
—improvement in—
PATIENT OUTCOMES
have been reported by healthcare providers through use of big data

TOP 10 DRUG LAUNCH FAILURES
due to value gaps
cost industry

~\$12B





21ST CENTURY CURES ACT, PDUFA VI, EMA GUIDANCE 2018
have time commitments on the effective use of RWD

Source: Big Data in the Healthcare & Pharmaceutical Industry: 2017 – 2030 – Opportunities, Challenges, Strategies & Forecasts; *FiercePharma

Aligning Real-World Data & Stakeholder Needs

1

Include outcomes that matter to patients much earlier in development



It is likely not possible to assess a sufferer of Duchenne Muscular Dystrophy using a six-minute walk test. However, assessing a patient on their ability to get dressed in a morning is an outcome that matters and is more informative than the six-minute walk test. Including these types of real-world outcomes much earlier in development better demonstrates the value of the therapy to improve patient lives, leading to greater probability for payer acceptance. It means moving away from clinical or regulatory gold standards and forces the validation of new measures that create meaningful data when appropriate.

2

Better utilization of endpoint data



Outcomes data can be used in study design to identify more sensitive or relevant endpoints. This approach can be used to measure the endpoint in the study conduct, create a rationale and provide a direct and efficient way to gather data that matters in determining product value.

3

Leverage environmental forces and market dynamics to expedite approvals



The 21st Century Cures Act, PDUFA VI, and anticipated guidance from the EMA specifically address the use of RWD and the importance of seeing how the therapy behaves in the real world. There is legislated pressure to address the historical barriers to RWD use. The biopharmaceutical industry needs to be moving the dialogue forward to frame how requirements such as how CFR part 11 are met with RWD, unique patient identifiers, common data models and a use-case based standards framework for RWD.

4

Investments in solutions and capabilities must be made but with delivery flexibility in mind



Advances in technology such as machine learning can significantly improve the ability to leverage RWD and there are many blue chip technology players leading the charge. Don't be overwhelmed by technology advancements. Consider choosing technology vendors with life sciences experience who really understand the complexities of the data and the research environment. The data technology market is highly dynamic today and it is not clear among the many new entrants who will mature. Forming partnerships and deploying staged investments may help to maximize the chance for success as market dynamics play out. Whatever your RWD approach/platform looks like, ensure it can respond to changes in the environment as they occur.

The Here and Now

The use of real-world data has the potential to be transformational and the value we can gain from real-world data is far more transparent than it was only a year ago. By thinking about study design differently, embracing the advances in technology both the access to data, and by bringing in patient outcomes much earlier in development, you can accelerate your drug development journey, better articulate the value story to payers and ultimately get treatments to patients much sooner.

To learn more download the full presentation or contact us to speak to one of our RWD experts.

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