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INCREASE YOUR SPEED TO MARKET:

Commercial Strategies for a Successful Product Launch

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With the launch of new blockbuster drugs becoming less frequent, there is increased scrutiny on the importance and success of clinical trials, mandatory to determining the safety and efficacy of a developing product. The road to commercialization is daunting – the process of bringing a product to market is long and the failure rate high, ultimately impacting the price of products that do make it to market.

Pharmaceutical and biotechnology companies assume the risk of these failed investments, and there are numerous market factors determining this failure rate, including: complex trial design and failure to meet endpoints; low patient recruitment, adherence, retention and consistent access; disparate safety data and lack of validation; and regulatory burdens and unexpected changes.

Let's build a better road to commercialization by recognizing there is value in accelerating clinical trial timelines with qualified patients – from earlier regulatory filing and launch to growth stages of commercialization. To succeed in today's market, companies need to mine the value that can be found in the time and insights created between post-clinical and pre-commercialization. **Do this by:**

- Building relationships with patients and gathering behavioral data early, then embrace innovative digital technology to find and engage patients
- Demonstrating value by adding health economics outcomes research earlier in the clinical development process to garner better evidence to support pricing arguments
- Planning for the delivery of integrated patient services that include comprehensive HUB, specialty pharmacy, and distribution strategies much earlier in the development process
- Mitigating risk and ensuring product safety and efficacy with integrated pharmacovigilance that spans the clinical/commercial divide
- Preplanning medical communication strategies to formulate better results from the quality data gathered in order to achieve better product claims and provide ongoing support and assurance to patients and caregivers.

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To advance clinical trial performance, companies need a global partner with an integrated commercialization model designed to expedite the clinical trial process, achieve high economic value, deliver best-in-class patient services, and manage the unexpected.

Expedite the Clinical Trial Process

It's time to transform current clinical trial practices by including commercialization strategies into clinical development plans. Knowing that patient recruitment is a major cause of trial delay, start by putting patients at the center of the process. Build relationships with patients earlier in the trial planning process by tapping into the growing online influence of engaged patients. Understand the forces impacting their journeys by gathering data on their experiences, fears and concerns. Then harness this powerful data to influence trial design at the earliest stages, improve early regulatory review protocols, co-create recruitment and educational content, and share and raise awareness.

Work with a trusted partner who understands how streamlined communication and innovative engagement methods foster faster recruitment in order to design a clinical trial that reduces complexities, avoids oversights, closes the time gap between phases, and lowers cost. Leverage a comprehensive digital patient-finding platform that has the ability to successfully find and convert qualified patients to participate in clinical trials, patient databases, and market research, and can also manage patient prescreening, registration and tracking, helping companies accelerate enrollment. The platform's database should also provide companies the ability to find, educate, and onboard patients faster post-launch, increasing time to revenue creation.

Achieve High Product Economic Value

Health economics and outcomes research (HEOR) and real world evidence (RWE) are essential strategies needed in demonstrating the economic and clinical value of improving patient outcomes. Integrating both earlier into regulatory phases allows companies to identify unmet needs and support the value of healthcare interventions, as well as inform payers on new therapies' total cost of care. HEOR experts, using RWE and technology like artificial intelligence (AI), can improve clinical trial certainty by modeling who will receive the most benefits.

Breaking down the complexity of reimbursement and cost-to-coverage dynamics using the HEOR and clinical data collected early in the trial process, coupled with a pricing strategy that includes comparative and cost effectiveness studies, will help increase payer acceptance. Working with experts who understand the payer landscape and the product launch environment will ultimately help stakeholders in patient care make better decisions. The use of health economics evidence is increasingly being used through post-launch in developing value-based contracts to demonstrate how effective disease-state management lowers cost.

Patient-Centered Program Modeling

As with the halcyon days of blockbuster drugs, the one-size-fits-all patient services solution is no longer a relevant option. Companies need to advance beyond traditional HUB models to achieve greater value and this approach includes customized patient education and support services, like clinical nursing and the use of digital behavioral influence tools, to enhance adherence and health outcomes. An integrated access and affordability solution – HUB, co-pay and patient assistance programs – plays a role in navigating complex onboarding processes, overcoming pricing barriers to manage cost, and increasing market share.

Optimizing a product launch for commercial success includes developing a distribution strategy to address unique patient populations, therapies and channel/network needs. Work with a trusted partner to develop an integrated and customized distribution solution that includes direct-to-patient and global channels to ensure that patients have access to the therapies they need when and where they need them.

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Preemptively Mitigate Risk

As patients demand increased drug safety, companies must address disparate safety data and lack of validation, as well as regulatory burdens and unexpected changes. If the goal is to proactively design clinical trials that provide patients with safe and effective drugs, the approach must include the ability to deliver congruent data aggregated in one place to ease cross database analysis, improve safety and speed decision time.

Delivering high-quality medical information helps mitigate patient and caregiver concerns and decreases the potential financial risk a company could be exposed to. As the front line contact to patients and key stakeholders, ensure you work with a trusted medical communications team that compliantly addresses questions from healthcare professionals and patients. Partnering with experts who know the day-to-day impact of regulatory changes and who have a robust post-market monitoring process increases the probability of market success prior to and post-launch. It's important that the team is compliant with all pertinent regulations governing patient outreach of any kind.

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Conclusion

Time matters in protecting investments and achieving greater market success. Let's advance clinical trial performance by increasing opportunities to demonstrate value in the post-clinical and pre-commercialization timeframe. Build a seamless approach that begins with transforming patient insights into powerful messages and enrolling and retaining qualified patients for clinical trials. Evidence-based understanding, pricing strategies and payer insight are needed to execute a comprehensive market access strategy that enables payers, providers, and patients to make better decisions about treatments. Having a patient services ecosystem – that delivers best-in-class experiences through enhanced patient education and affordability programs, along with an integrated distribution strategy – in place prior to launch – helps companies achieve value across the entire lifecycle of their brands. Earning credibility with patients and providers and maintaining compliance throughout the product lifecycle helps reduce risk and protect the safety and efficacy of therapies.

By choosing the right partner with an integrated commercialization model specifically built to achieve high economic value earlier, manage risks, and immediately provide the ability to scale up for launch – companies are better prepared to increase the speed to market and achieve full market potential.