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Life Sciences

Digital Solutions Assessment for a Global Pharmaceutical Company Looking to Optimize Clinical Trials

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Challenge

The biopharmaceutical industry faces significant challenges related to clinical trial design and execution, including rising costs, difficulties with representative patient recruitment and retention as well as cumbersome trial design and management processes. These hurdles become pronounced when factors such as variable disease severity, therapeutic diversity, treatment access, and patient non-compliance are introduced. Confronted with these challenges, a global pharmaceutical company wanted to identify solutions for their neurology pipeline to optimize clinical trial programs and processes.

At the time, the pharmaceutical company did not have a centralized database for patients, investigators, or trial sites. This made finding and engaging patient candidates especially difficult, often leading to postponed trial start dates. In addition, the company lacked real-time remote monitoring capabilities, so research associates needed to make frequent site visits, which increased costs and delayed progress. Clinical site operations were rarely reviewed for performance as a result of the site management being solely focused on verifying collected data.

The company's leadership team aimed to deploy the right blend of data-driven digital solutions to streamline processes and reduce clinical trial costs. A wide range of solutions were available to enhance protocol design, patient recruitment and engagement, trial site management, analysis and reporting, and warehousing. The leadership team needed to evaluate these options against their short-term optimization goals and longer-term vision to become a world-class clinical research organization.

The company understood an objective third-party organization with broad industry and clinical expertise would be best equipped to identify, assess and prioritize the potential digital solutions. They enlisted Guidehouse's Commercial Excellence and Digital Solutions experts to identify optimal solutions.

Solution

From an industry purview, despite the integration of digital solutions into clinical trials over the years, several problems persisted in the market. These encompassed factors such as disparate and disintegrated data sources, processes and systems, redundancies in processes, inhibited decision making because of multiple silo-ed teams and solutions, and lost time due to a lack of familiarity, cohesive workflow, or appropriate tools.

With this in mind, the Guidehouse team focused on solutions that would make it easier for the global company's research and development team to conduct clinical trials and comply with regulatory standards, while being compatible with

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the organization's IT system requirements and synergistic with established business processes and relationships. After gaining cross-functional input, Guidehouse used a multipronged approach to strategically establish criteria and begin evaluating potential solutions. The approach included:

- Inventorying over 300 digital solutions across several aspects of clinical trial design and execution.
- Educating the internal stakeholders on evolving industry trends, and understanding stakeholder objectives, current solutions, processes, and unmet needs.
- Implementing a robust matrix to assess and prioritize the digital solutions for product compatibility and strategic fit to company needs and requirements.
- Designing the pilot program options for the selected digital solutions

In collaboration with company leadership, trial design and management solutions – from protocol design to monitoring and reporting – were identified as focal points for further vetting. This would be the primary consideration, along with company background, experience, and future adaptability of the solution. Based on those criteria, the team employed a series of filters to sequentially narrow down the list of hundreds of inventoried platforms.

Then, 10 prioritized solutions were comparatively assessed for integrability, adaptability, global deployment, ownership and use, and functionality. The team also applied a metric to evaluate each solution against prioritized perimeters, including alignment with the company's development strategy, compatibility with existing IT systems, and whether other synergies existed across the company's portfolio.

Results

The rigorous research and vetting process led to the prioritization of two digital solutions, both of which the pharmaceutical company decided to consider for pilot programs. One solution was a clinical software that provided a single platform for electronic trial design, monitoring, and data collection, management, and reporting. The other was a predictive science- and informatics-based simulator that empowered drug development teams to test proposed clinical trials in a series of "what-if" scenarios during trial design, while minimizing risk and guiding decision-making. To successfully implement these solutions, Guidehouse advised the company on potential pilot program designs to further evaluate each solution's value, potential risks, scalability, and potential desired use across both franchises.

Impact

By investigating the available digital solutions against criteria created objectively from cross-functional input and comprehensive secondary research, the Guidehouse team successfully steered the global pharmaceutical company's leadership team to fit-for-purpose advanced clinical trial digital solutions. Through pilot testing, the company meaningfully enhanced patient recruitment, engagement, and remote monitoring capabilities. This drove operational and cost efficiencies, and enriched the data gathered from the clinical trial. Additionally, the recommended solutions offered compatibility with existing IT systems, allowing for seamless integration with current data management practices. As a result, the global pharmaceutical leadership team confidently greenlit the pilot programs for the two digital solutions in upcoming clinical trials, and was well-equipped with the criteria and framework to assess future opportunities for digital innovation in clinical trials.