

HEXAWARE

Minimizing Protocol Deviations in Clinical Trials for an American Biopharma Service Provider

Hexaware's innovative solution enhanced operational efficiency, reduced manual errors, and improved performance in protocol deviation management.

Case study



Client

| Client

- Challenge
- Solution
- Benefits
- Summary

The client is an American biopharmaceutical service provider that specializes in conducting clinical trials for pharmaceutical clients, expediting the drug approval process. They sought efficient protocol deviation management to address challenges related to data accuracy and procedural adherence.



Challenge

Client

| **Challenge**

Solution

Benefits

Summary

Deviations from the approved trial protocol are common in clinical trials. The client, a leader in clinical operations, found managing these deviations particularly challenging, as they work with an average of 15 systems and 10 to 12 standard operating procedures (SOPs), along with numerous forms, templates, checklists, and manuals for 3 to 4 trials simultaneously.

These deviations can significantly impact ongoing trials in several ways. Based on research from the Tufts Center for the Study of Drug Development, the average number of protocol deviations reported is approximately 75 for Phase II trials and 119 for Phase III trials. This data highlights the ongoing challenges faced in managing protocol deviations during clinical trials, emphasizing the need for effective strategies to mitigate their impact on trial integrity and efficiency.

A protocol deviation occurs when study activities diverge from the Institutional Review Board-approved protocol without significant consequences. Given the prevalence of such deviations in clinical research, addressing them is essential for maintaining the integrity and efficiency of trials.



Solution

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Hexaware delivered a comprehensive solution for managing and reporting protocol deviations in clinical trials, complemented by a centralized hub for clinical trial monitoring. Key features of this solution include a unified study view that consolidates information, prebuilt workflows aligned with study protocols, and built-in reminders and approval processes. Additionally, the solution offers a dashboard with meaningful metrics, allowing users to drill down into detailed information from multiple systems for any given project. This holistic approach enhances efficiency, improves data quality, and ensures compliance, ultimately leading to better patient outcomes.



Benefits

Client

Challenge

Solution

Benefits

Summary

The protocol deviation management solution significantly optimized clinical trials, reduced effort, and improved performance, delivering the following benefits:

- A cohesive solution that facilitates more efficient operations across multiple levels of the organization.
- A substantial reduction in the effort required to manage protocol deviations.
- Minimized manual errors, enhancing data accuracy.
- Improved employee performance and overall operational efficiency.



Summary

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| **Summary**

Hexaware's comprehensive solution streamlined the management and reporting of protocol deviations in clinical trials. By providing a centralized clinical trial monitoring hub, it enhanced operational efficiency across various enterprise levels, significantly reduced effort in managing deviations, minimized manual errors, and improved employee performance. The clinical trial optimization ultimately led to more effective clinical trials and better outcomes for the pharmaceutical industry.



About Hexaware

Hexaware is a global technology and business process services company. Every day, Hexawarians wake up with a singular purpose: to create smiles through great people and technology. With this purpose gaining momentum, we are well on our way to realizing our vision of being the most loved digital transformation partner in the world. We also seek to protect the planet and build a better tomorrow for our customers, employees, partners, investors, and the communities in which we operate. With offices across the world, we empower enterprises to realize digital transformation at scale and speed by partnering with them to build, transform, run, and optimize their technology and business processes.

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