pharmaceutical COMPLIANCE MONITOR

Trusted Collaboration

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Outsourcing different aspects of the clinical study process is a growing trend; 64 percent of trials are currently outsourced. Of those that don't currently, 54 percent plan to outsource in the future. Sponsors outsource to clinical research organizations (CROs) to control operational and infrastructure costs and allow them to concentrate on what they do best – drug development.

Although there are obvious benefits to outsourcing, it creates new challenges around quality, oversight, collaboration, and governance. With outsourcing, processes and systems are often duplicated or disparate. Sponsors, CROs, and sites use their own SOPs and processes, resulting in a duplicated effort and data entry.

Furthermore, there are challenges around CRO and site benchmarking and governance. Sponsors can't benchmark CRO and site performance across studies and it is difficult to identify bottlenecks and monitor CROs and site performance. Separate systems can also pose potential compliance risks.
What's needed are systems and environments of "trusted collaboration" that facilitate centralized communication and collaboration in order to keep all parties aligned on shared goals and processes.

Eliminate redundancies

Redundant processes increase the time required to complete tasks — these delays result in increased costs. These redundancies occur most often when sponsor and CRO SOPs require that they perform the same task; without visibility into each other's processes and they unwittingly perform the same work. Collaborating organizations should document, share, and compare their internal processes to identify the redundancies. Documenting processes in a project management tool or, even better, using a workflow-driven process automation tool helps teams visualize and analyze processes. Efficient, repetitive processes, supported by intuitive data systems and specialized teams concentrates resources and the right talent where it's most effective.

Increase visibility

When sharing systems, the system owner can own the data and metrics generated through process tracking. This data can be leveraged for performance predictions across a portfolio or therapeutic area, can derive performance indicators for service providers to induce sponsors to engage with them and can help proactively identify bottlenecks or issues with information exchange or collaboration. For example, a clinical unit director runs 10 studies on an indication using three CROs. Without a central system of data collection and collaborative processes, she will have great difficulty determining which processes were most efficient because the data used to access benchmarks were maintained in different systems and collected using different criteria.

By sharing systems and processes, she can enforce best practices for all engaged CROs, she can benchmark the performance of CROs working on similar projects, improve predictability, and eliminate bottlenecks. Shared data also improves compliance because teams are using the same systems and processes resulting in the same desired outcome.

Standardize data

Defining the "gold standard" or a data dictionary that defines how study performance data is used and interpreted is critical to achieving data integrity. This data should also be shared to prevent duplications and inconsistencies between sponsor and CRO. Quality performance data enables all parties to analyze the metrics and make solid data-driven decisions, often in real-time. Systems today can be integrated using APIs to enable partners to connect their systems to facilitate sharing, thereby decreasing the potential for errors resulting from inconsistent data handling or analysis.

Having a centralized, single sign-on system or portal, can reduce the friction experienced by users who are required to learn and use multiple systems and manage multiple passwords; it also encourages system utilization. Using a single system can reduce the need to train users on different systems and allows them to interact with and grow expertise using one system. This not only saves costs, but enables users to become more productive as their experience with the single system deepens.

Facilitate re-use

Organizations that have clear processes and expectations can more effectively train staff and realize repeatable, consistent results. For example, a protocol approval for the German regulatory authority does not change frequently. If an organization doesn't have this process well documented, each person that manages a protocol in Germany must research and interpret the authority's regulations and those of their own organization and possibly a sponsor organization; this could lead to lack of compliance with the submission to the regulatory authority, lost time, and costly mistakes.

During the site identification process, sponsors and CROs often request information already provided by sites during previous trials. Maintaining a consistent, supervised database of site performance metrics, such as site startup cycle times, site ethics requirements, facilities, capabilities, and staff documents and details can enable easy access to site information and set sponsors and CROs up for a more efficient data-driven targeted site selection process.

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As outsourcing continues to increase, sponsors and CROs must work on ways to collaborate by building on the strengths of each organization and utilizing information and resources in a more uniform, consistent manner. Systems that centralize work, provide data on process flows and support compliance and collaboration across organizations should be considered as a means to support the organization's goals and objectives.