

UNDERSTANDING DATA-DRIVEN MONITORING

Data-driven monitoring represents a major departure from traditional monitoring in which clinical research associates (CRA) typically visit sites on a fixed schedule. With regulatory guidance in place and powerful tools emerging, it is possible for sponsors to implement data-driven monitoring strategies to improve quality and reduce monitoring costs.

While the data-driven monitoring lexicon remains unfixed – the basic premise is clear.

THE FOUR KEY PILLARS OF DATA-DRIVEN MONITORING

1



TARGETED MONITORING

Enables the replacement of traditional periodic-based visit schedules with data triggered visits based on whether or not the workload is sufficient to justify a visit. This approach helps to leverage resources more appropriately by focusing on sites that have higher workload and/or monitoring need.

2



RISK-BASED MONITORING

Measures and analyzes risk to determine when action is beneficial and/or required with a site. This approach, in conjunction with targeted monitoring, is particularly beneficial in focusing resources in a timely manner on sites that require higher support.

3



CENTRALIZED (REMOTE) MONITORING

Leverages off-site resources to perform monitoring activities, thereby alleviating the need to perform all activities during a monitoring visit. This approach has the potential to reduce travel costs, labor cost, and more proactively address risks than with traditional monitoring.

4



RISK-BASED SOURCE DATA VERIFICATION (SDV)

Leverages a variety of methodologies to reduce the number of data points that are source data verified on site by CRAs. With the right SDV design strategy, the benefits include a reduction in workload for CRAs when onsite. Risk-based SDV when combined with targeted-and risk-based monitoring can extend the time between visits for high-quality sites.

Data-driven monitoring establishes real-time data surveillance and adaptive monitoring as key governing principles for site and study monitoring. Powered by Perceptive MyTrials®, our Data-Driven Monitoring solution uses eClinical technology to rapidly collect remote study data that allows users to swiftly analyze that data using risk-based and workload assessment techniques, and allocate monitoring resources more effectively and efficiently.

WHEN YOUR DATA IS CLEAR, SO ARE YOUR DECISIONS.