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Endpoint-Based Protocol Development: AN OUTCOMES-BASED APPROACH TO CLINICAL TRIAL TESTING

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A shift toward more targeted therapeutics, combined with the need to meet specific endpoints in clinical trials, has placed a significant emphasis on esoteric laboratory tests within the test menus employed in clinical trials. Biopharmaceutical companies and clinical research organizations have long relied on central laboratories for maintaining a full continuum of testing capabilities where routine safety testing can be performed in conjunction with esoteric and indication-specific testing. However, when it comes to selecting the right test to produce desired data outcomes, central labs often aren't consulted until after the protocol has been finalized.

As sponsors continue to be challenged by increasingly complex protocols and data collection requirements, they are starting to consider an alternative testing approach that involves consulting with a central lab in matching clinical diagnostic endpoints to outcomes. The goal of this outcomes-based protocol development approach is to optimize the utility of the diagnostic testing undertaken in meeting the ultimate desired outcomes of the clinical trial by ensuring that appropriate testing is accounted for early in protocol development. Involving a central lab partner during this critical phase ideally positions sponsors for success by dissecting the multitude of tests available and applying them to achieve their desired outcomes.

A Winning Formula for Smarter Testing

Outcomes-based protocol development employs six key principles to optimize test selection in clinical trials.

1. **Involve laboratory experts early.** While the standard is often for sponsors to engage with their labs after the protocol is finalized, obtaining an expert review during protocol development ensures that the most appropriate tests are chosen for the desired outcome and that the data collected will be interpreted properly and supports the regulatory submission.
2. **Begin with the end in mind. Sponsors that** involve their central labs early in the protocol development process can work with these scientific experts to identify outcomes first, and then select lab tests that support the endpoints required to support those outcomes. By keeping the study outcomes in mind from the beginning, sponsors increase their chances for success in selecting the tests that provide the right endpoint data.
3. **Consider schedules, timing and logistics.** Asking the right questions, such as when is the data needed and how will it be delivered, can help determine the appropriate timeline for meeting goals. The sooner outcomes and endpoints are defined, the sooner logistics will fall into place, making it easier to establish a timeline toward the end goal.
4. **Understand state of the art.** With the wide array of testing options now available, sponsors often feel overwhelmed by choice when it comes to knowing which tests will ultimately achieve the desired data endpoints without increasing risk. Just because a test is new or state-of-the-art doesn't mean that it's the right test to produce the correct endpoint for the desired outcome. Newer or more complex tests may provide positive results, but they can just as often produce redundant or potentially contradictory results. Conversely, tests that provided meaningful data a few years ago may no longer support the desired endpoints. The increasing complexity of test options suggests an expert consultation is critical during protocol development.
5. **Balance technical possibilities with study demands.** Understanding that the tests chosen can significantly influence outcomes, clinical logistics, and costs, sponsors should work with central labs to understand the local regulations and allocate extra time to address any potential roadblocks.
6. **Assess the impact on patients.** Enrolling patients is a common challenge for most trials. Choosing an appropriate set of screening diagnostics can help streamline the process of enrolling the most appropriate patients as quickly as possible. Sponsors can also significantly improve patient safety by focusing testing only on what is necessary to prove the safety and efficacy of the drug.

With the shift toward more targeted therapies and the increased pressure clinical trial sponsors face to collect more data, sponsors are starting to think differently about the role central labs play in optimizing clinical trials. In addition to considering the central lab as a place where diagnostic tests are performed, sponsors have begun to view to them as partners that can add value and help accelerate the path from molecule to clinic. Planning for clinical diagnostic testing with a central lab partner early in protocol development using the principles discussed above can help optimize clinical trials, drive efficiencies, avoid potential protocol amendments, and minimize costly study delays. PV

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