

WCG 360 Protocol Assessment™

According to the Tufts Center for the Study of Drug Development, 57% of protocols had at least one substantial amendment, and nearly half (45%) of those amendments were deemed “avoidable”. Similarly, protocols with at least one substantial amendment had fewer actual screened and enrolled patients relative to the original baseline plan than those protocols without an amendment.

WCG’s 360 Protocol Assessment™ is an integrated, turn-key solution that addresses ICH E8 R1 expectations and improves clinical trial predictability by providing sponsors with an operational risk and feasibility assessment of the protocol by representing all industry stakeholders.

This process helps decrease the number of required protocol amendments by highlighting key risks during the planning phase of the trial. The 360 Protocol Assessment provides a holistic view of a sponsor’s protocol to ensure quality by design. WCG’s quality, operations, and diversity, equity and inclusion subject matter experts identify potential areas of risk in conjunction with its vast network of investigators, sites, and patient advocacy groups to ensure all key stakeholder input is received. Finally, through WCG Data Intelligence, we provide deep insights into the competitive landscape of the protocol being reviewed that can be leveraged for site selection.

The assessment incorporates strategies to proactively mitigate or manage the identified risks for faster, less costly clinical trial execution.

As a result, sponsors can:

- **Identify** areas of risk and clarity as well as corresponding mitigations that can be addressed in the planning phase.
- **Reduce** uncertainty in clinical trial execution.
- **Drive** enterprise-level decision-making through a thorough risk assessment to achieve higher quality trials and better outcomes.
- **Take a more proactive approach** to diversity and inclusion planning that begins at the earliest stages of protocol design, long before recruitment planning.
- **Benchmark** their protocol against the current competitive landscape in the market.

