How to Design Better Clinical Trial Protocols: Addressing Complexity at the Start

According to WCG's 2026 Clinical Research Site Challenges Report, 41% of sites have reported trial complexity as the top issue they are combating, up six points from 2025. As a result, trial teams have faced delays, amendments, higher costs, and increased site and participant burden.

30-35% of procedures conducted per protocol were non-core or deemed non-essential.[1]

43% of sites said optimized protocol design would have the greatest impact on improving site performance.[2]

10 years of increasing timelines for Phase II and Phase III clinical trials.[1]

Designing feasible protocols that reduce burden while maintaining scientific rigor is becoming a non-negotiable for successful study activation. Teams who get protocol design right early on can avoid certain challenges that would otherwise impact study timelines and complicate study start-up.

A Checklist for Effective Protocol Design

When writing your next protocol, ask these questions:

- ☑ Are endpoints necessary and clearly defined?
- ☑ Is the level of complexity justified?
- ☑ Are eligibility criteria aligned with real-world patient populations?
- ☑ Has the protocol been tested in a real world setting?
- ☑ Have sites and participants provided input?
- ☑ Can data and AI tools help benchmark the protocol against similar trials?

Every aspect of a protocol directly impacts how a trial performs. By assessing feasibility early in protocol design, sponsors, CROs, and sites can have confidence that their study is ready for first-patient-in.

See how Trial IntelX™, powered by ClinSphere®, uses predictive foresight to help your team improve trial design and avoid unnecessary burden from the start.

LEARN HOW

1. Tufts Center for the Study of Drug Development. (2025, November/December). Impact report (Vol. 27, No. 6)
2. WCG's 2026 Clinical Research Site Challenges Report