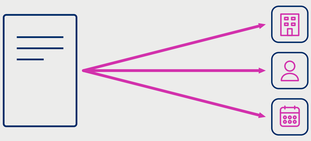
Reducing Site Burden Starts with Better Protocol Design

When protocols are created without considering the feasibility of implementation, sites are left to carry the burden.

WCG's 2026 Clinical Research Site Challenges Report found that clinical research sites are facing increasing challenges without an increase in resources to address them.

Trial Complexity Continues to Rise, Driven By

- Increasingly complex protocols.
- A growing number of non-interoperable technology platforms.
- Costly, time-consuming protocol amendments.
- Greater operational complexity across study execution.



~50%

of start-up time goes to protocol amendments alone, having a downstream impact on sites, participants, and study timelines.

These challenges increase site burden, delay trial timelines, and slow the delivery of potentially life-saving therapies to patients.

What Sites Are Saying

66% of sites rated protocol complexity as the factor contributing most to overall trial complexity.

55% of sites spend at least one-fifth (20%) of start-up time managing amendments.

43% of sites say optimized protocol design would have one of the greatest impacts on performance.

38% of sites said protocol complexity is a deciding factor in whether they accept a study.

Complex protocols and costly amendments strain site budgets, lengthen start-up timelines, and have a downstream impact on participant retention.

How Sponsors/CROs Can See Downstream Impact Before Studies Begin

By connecting protocol burden to real-world operational performance and amendment data, you can design studies that:

- **Quantify burden before the study begins.** Measure how design decisions affect site and participant burden.
- **Separate scientific rigor from unnecessary complexity.** Score individual protocol elements to see what's essential and what's adding to burden.
- **Flag amendment risk before protocol lock.** Identify the design choices most likely to lead to costly amendments.
- **Benchmark against similar trials.** Compare your protocol's burden with comparable studies and see which eligibility criteria have historically driven screen failure.
- **Model the enrollment impact of design changes.** Test the effect of changes on feasibility and enrollment before they reach sites.
- **Build site reality into design.** Ground protocol decisions in real-world site performance data rather than assumptions.



Turn Site Experiences Into Better Protocol Decisions

Hear directly from sites in the 2026 Clinical Research Site Challenges Report and see how real-world data and predictive insights from Trial IntelX™, powered by the ClinSphere®, can help reduce protocol burden before study activation.