



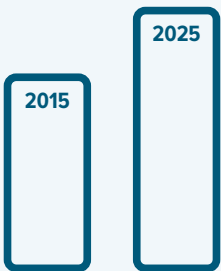
# Overcoming Complexity in Modern Clinical Trials

Clinical trials are more complex than ever, with growing demands straining timelines and budgets. Success requires fresh thinking, close collaboration, and a right-sized partner for integrated, effective strategies.

## The Challenge: Clinical Trial Complexity Is Rising

### Growth in Trial Demands

(Source: Tufts CSDD & Industry Data)



**76%**

of trials now require amendments (up from 57% in 2015)



**40%**

increase in the number of trial procedures over the past decade



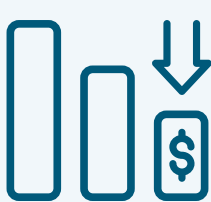
**12+ vendors**

up from 4–5 vendors per trial in 2010



**\$800K**

per day lost revenue from trial delays



**2.7M**

per day lost revenue from trial delays for blockbuster drugs

## Root Causes of Protocol Complexity



Growth of personalized oncology and rare disease studies



Use of advanced modalities (e.g., cell/gene therapy, radiopharmaceuticals)



Increasing endpoints, eligibility criteria, and clinical biomarkers



Logistical challenges (just-in-time manufacturing, global site variability)



Lack of early optimization and cross-functional alignment

## Veristat's Best Practices for Managing Complex Clinical Trials

1	<b>Take a Multidimensional View Early</b> <ul style="list-style-type: none"><li>Involve clinical, operational, regulatory, payer, and patient perspectives</li><li>Challenge assumptions during protocol design</li></ul>
2	<b>Plan with the End in Mind</b> <ul style="list-style-type: none"><li>Align protocols to commercialization or partnership goals</li><li>Build in endpoints/data collection that support long-term success</li></ul>
3	<b>Collaborate Early and Often</b> <ul style="list-style-type: none"><li>Engage cross-functional stakeholders and decision-makers from Day 1</li><li>Use advisory boards, advocate groups, statisticians, and internal teams</li></ul>
4	<b>Work in Lockstep with Sites</b> <ul style="list-style-type: none"><li>Build tailored training and protocols</li><li>Incorporate site feedback into design</li></ul>
5	<b>Build Patient-Centric Flexibility</b> <ul style="list-style-type: none"><li>Reduce patient burden in rare disease and oncology populations</li><li>Offer remote visits, ePROs, concierge services</li></ul>
6	<b>Engage Regulators Early</b> <ul style="list-style-type: none"><li>Avoid costly amendments</li><li>Gain alignment on novel endpoints or adaptive designs</li></ul>
7	<b>Creativity + Flexibility are Essential</b> <ul style="list-style-type: none"><li>Conduct “mock runs” of trials</li><li>Simulate logistics and data flow pre–pre-first-patient-in</li></ul>

## Rethinking the Trial Playbook

Clinical trials today require a multi-dimensional, integrated, and creative approach. Sponsors who engage early, plan holistically, and build flexibility into every stage are best positioned to:



- Minimize amendments
- Reduce time to approval
- Improve patient experience
- Control costs and protect revenue



Creative Thinking



Operational Integration



Trial Success in Today's Complex World

## Learn more about Veristat's Global Clinical Trial capabilities

With over 30 years of clinical trial planning and execution experience, trust Veristat for trial success.



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