Overcoming Obstacles – Addressing Key Site Challenges Now & Into the Future:

The Complexity of Clinical Trials

Introductions

Trevor Cole, MBA-HCM, CCRC, PMP, RN

Program Director, WCG

Michelle Mack, PhD

Associate Director of Research Operations, Duke University School of Medicine

Suzanne Rose, MS, PhD, CCRC, FACRP

Executive Director of Research, Stamford Hospital

Susan Night, JD

Sr. Vice President, Strategy and Growth, TD2 Oncology

© WCG Clinical 2025. All rights reserved.

Agenda

1. Overview of WCG's 2025 Clinical Research Site Challenges Report
2. Defining and Reviewing Survey Results Around Complexity
3. Examining the Increasing Complexity of Clinical Trials
4. Panel Discussion
5. Audience Questions and Closing

© WCG Clinical 2025. All rights reserved.

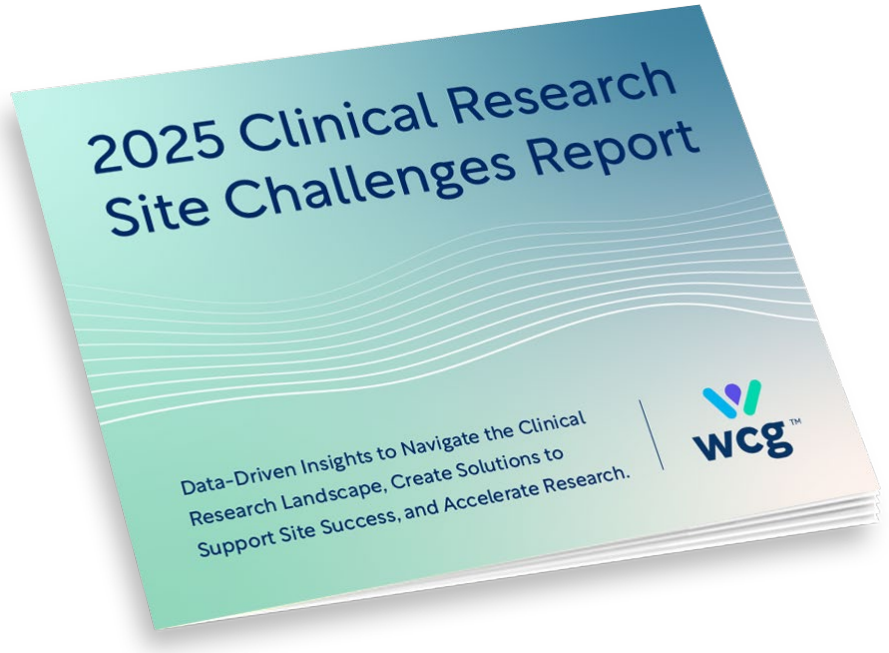
Polling Question 1 –

What type of organization do you represent?

© WCG Clinical 2025. All rights reserved.

2025 Clinical Research Site Challenges Report Overview

- WCG surveyed over 600 clinical research sites around the globe between July and September of 2025 to gain insights surrounding the top challenges they are facing, solutions they are implementing, and more.
- Utilizing the survey results, industry data, and insights from WCG experts, we published our 2025 Clinical Research Site Challenges Report in October.
- In addition to the survey results, this report also features actionable recommendations for sites, sponsors, and CROs to overcome barriers and enhance clinical trial efficiency.

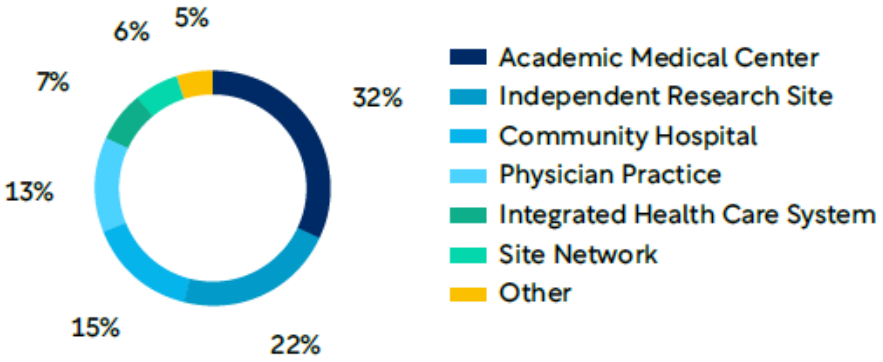


The full report can be downloaded for free at:
https://www.wcgclinical.com/insights/2025-clinical-research-site-challenges-report/

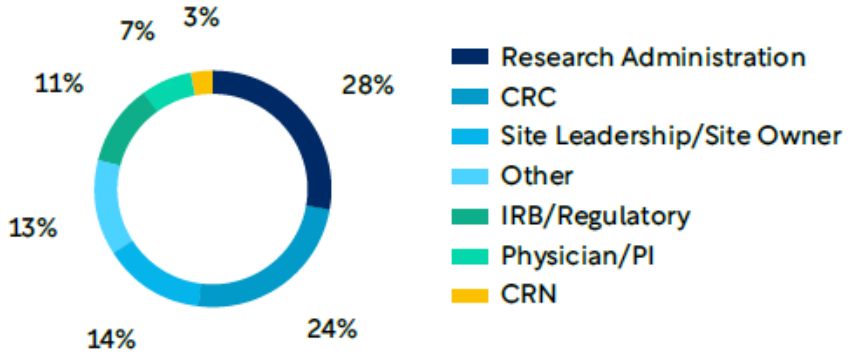
© WCG Clinical 2025. All rights reserved.

2025 Clinical Research Site Challenges Report - Background

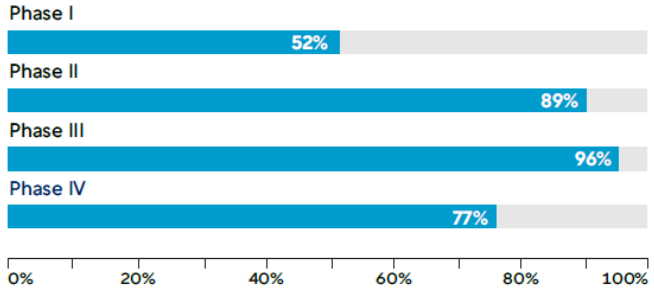
What type of research site do you represent?



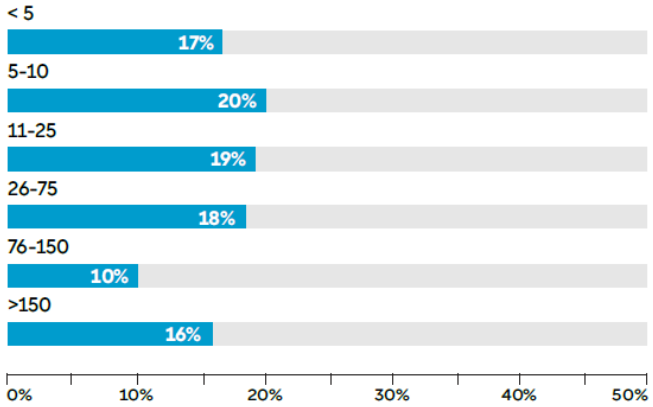
What is your role at your research site?



What study phases does your site support? (Please check all that apply)

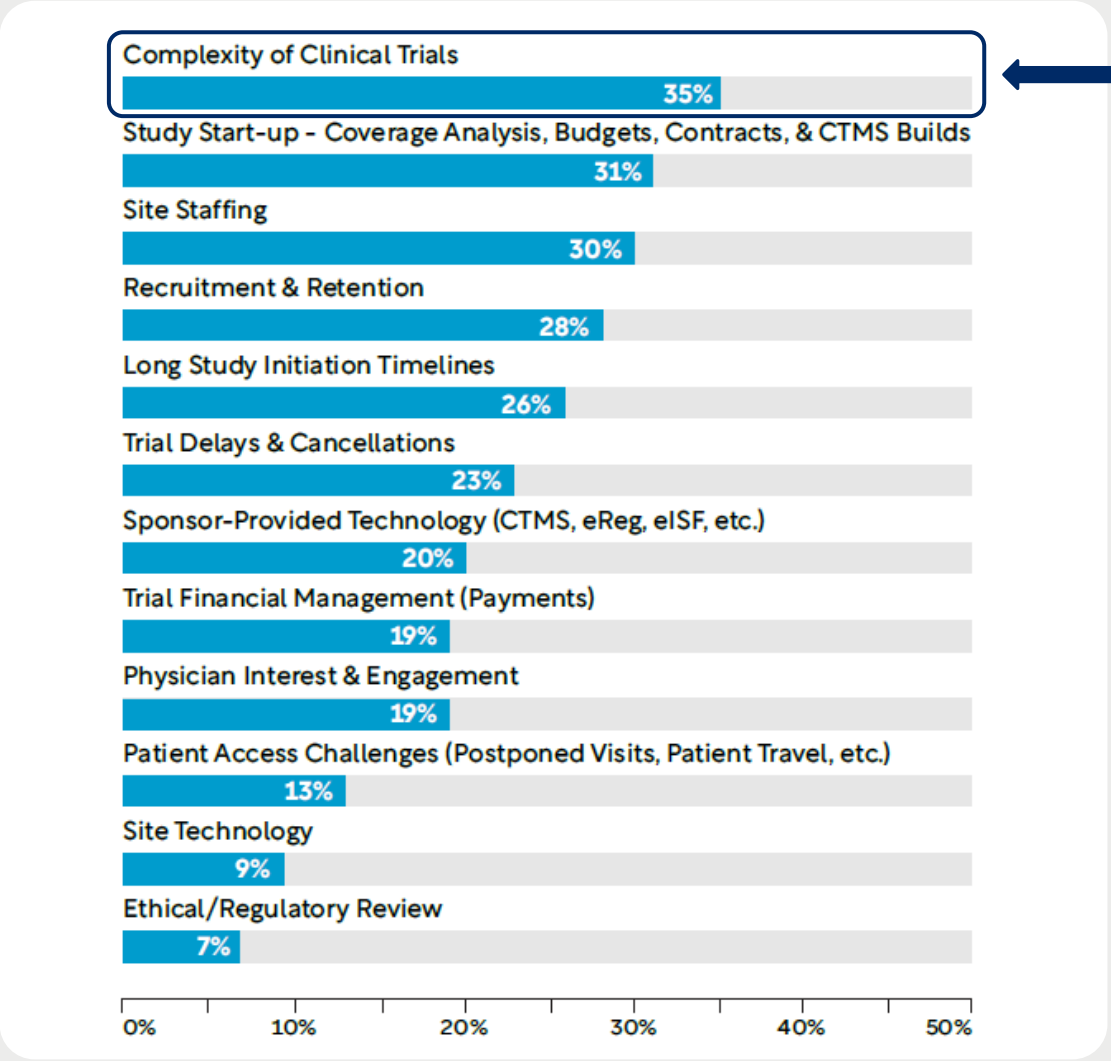


Please select the current number of open and enrolling trials at your site:



© WCG Clinical 2025. All rights reserved.

The Top Site Challenges in 2025



"Complexity of Clinical Trials" is noted as the leading challenge for 35% of sites in 2025.

Source: WCG 2025 Clinical Research Site Challenges Report

© WCG Clinical 2025. All rights reserved.

Defining Complexity…

- Complexity can be a summation of many study challenges, such as protocol design (master protocol, adaptive, etc.), multiple protocol amendments, and the number of systems/tech, which may be why it is cited as a continual challenge.
- Some complexity is necessary and expected as science and knowledge progress - minimizing unnecessary or overly burdensome complexity is where efforts should be directed.
- **Complexity has a direct impact on capacity. Complexity commonly impacts burden.**
  - Since complexity increases scope, necessary resources, and risk it requires a balance of quality, budget, and timeline to achieve success.

© WCG Clinical 2025. All rights reserved.

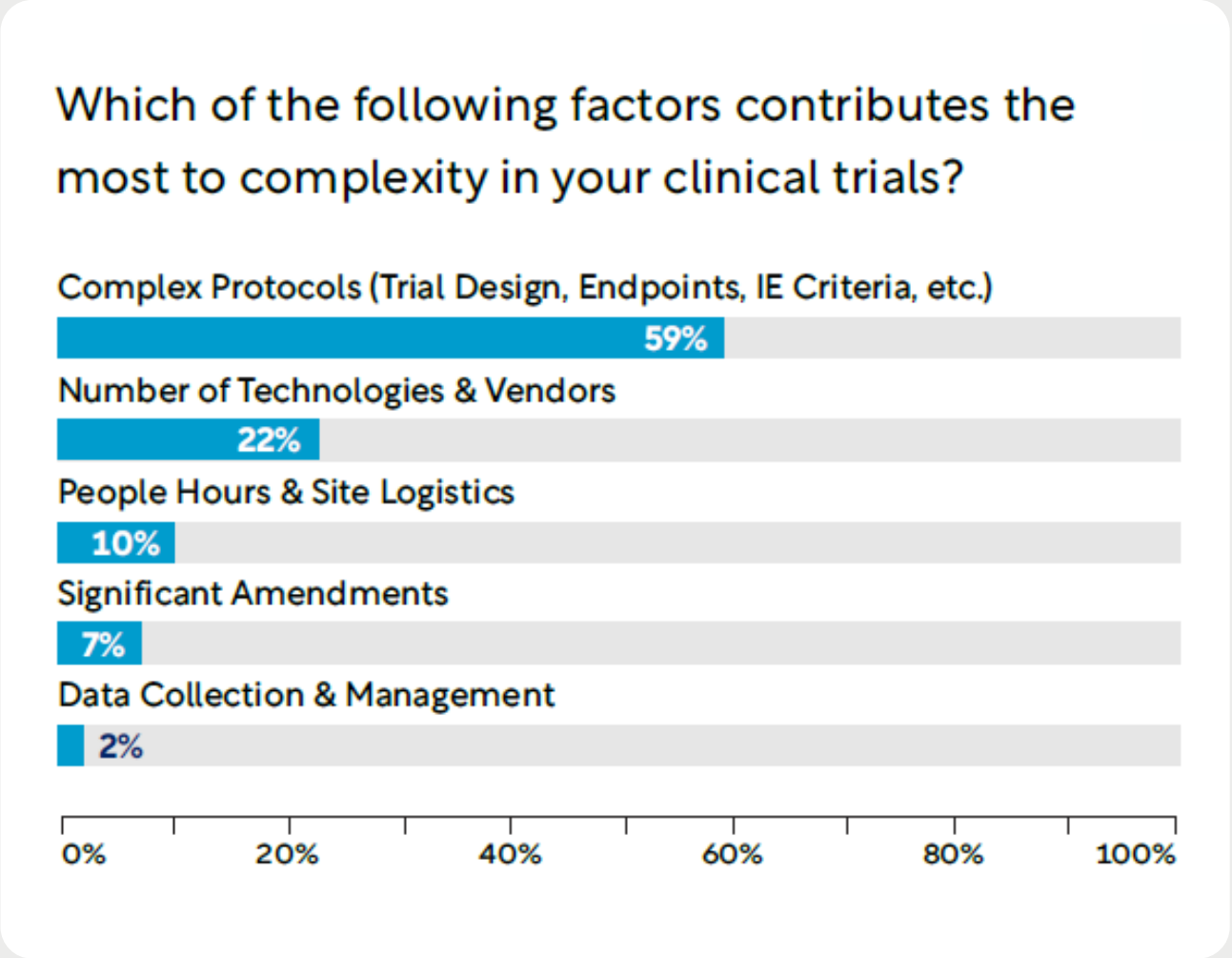
Polling Question 2 –

What is the top factor you believe is contributing the most to clinical trial complexity?

© WCG Clinical 2025. All rights reserved.

What Sites Feel is Driving the Most Complexity

According to WCG's 2025 Clinical Research Site Challenges Report



Source: WCG 2025 Clinical Research Site Challenges Report

© WCG Clinical 2025. All rights reserved.

Examining the Increasing Complexity of Clinical Trials

Clinical Trial Durations by Phase

Phase I Trials

Time Period	Mean Trial Duration in Months
2008-2013	13.8
2014-2018	14.8
2018-2021	20.3

Phase II Trials

Time Period	Mean Trial Duration in Months
2008-2013	27.1
2014-2018	30.2
2018-2021	40.6

Phase III Trials

Time Period	Mean Trial Duration in Months
2008-2013	26.8
2014-2018	28.5
2018-2021	39.4

Source: Tufts CSDD

© WCG Clinical 2025. All rights reserved.

Panel Discussion - Complex Protocols

From your experience, which aspects of protocol complexity most significantly affect site performance or engagement, and why?

© WCG Clinical 2025. All rights reserved.

Panel Discussion - Complex Protocols

What practical steps can sites and sponsors take to reduce protocol complexity, and when complexity is unavoidable, what strategies have you found most effective in supporting operational feasibility and minimizing site burden?

© WCG Clinical 2025. All rights reserved.

Examining the Increasing Complexity of Clinical Trials

Trends in Substantial Protocol Amendments

	2013 - 2015		2018 - 2021	
	Proportion with at Least 1 Substantial Amendment	Mean Number of Substantial Amendments	Proportion with at Least 1 Substantial Amendment	Mean Number of Substantial Amendments
Phase I	52%	1.8	67%	3.1
Phase II	77%	2.2	89%	3.3
Phase III	66%	2.3	82%	3.5

Source: Tufts CSDD

© WCG Clinical 2025. All rights reserved.

Panel Discussion - Significant Amendments

How do substantial protocol amendments typically impact site operations and staff workload? What downstream effects have you observed, and what strategies or best practices can help reduce the burden, rework, and complexity caused by these amendments?

© WCG Clinical 2025. All rights reserved.

Protocol Complexity & Clinical Trial Data Collection

In a recent study by the Tufts Center for the Study of Drug Development of 105 trials from 15 different biopharma companies, nearly one-third of the information collected included non-core procedures that didn't support primary or secondary endpoints.

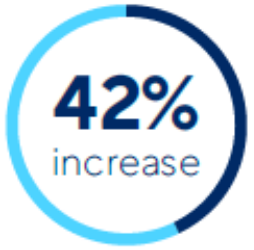
These non-core procedures accounted for up to 32.5% of Phase III data collected per participant.

Source: Tufts CSDD

© WCG Clinical 2025. All rights reserved.

Examining the Increasing Complexity of Clinical Trials

Endpoints, Procedures, and What Sites are Saying Could Help



in procedures required for Phase III trials since 2015.

in number of endpoints in Phase III trials since 2015.

cite "simplifying protocol complexity" as a top area for sponsors to address when it comes to their site's operating viability.

say “soliciting site input on study design and implementation” is a top area for sponsors to address.

Source: Tufts CSDD

© WCG Clinical 2025. All rights reserved.

Panel Discussion - Data Collection and Management

With the growing volume of data points and study endpoints, how can sites and sponsors work together to streamline data management and strengthen governance structures? What approaches have proven most effective in balancing efficiency with data integrity?

© WCG Clinical 2025. All rights reserved.

Panel Discussion - People Hours & Site Logistics

How do you plan and manage staffing hours at sites to ensure adequate resources and appropriate budgeting for required skills and workload? What proven logistical practices or tips can help maintain quality while balancing protocol complexity?

© WCG Clinical 2025. All rights reserved.

What Sites Want & Need for Technology-Enabled Trials

of sites want stronger and more robust budgets.

of sites want more effective site technical support.

of sites want more integrated and consistent technology.

Source: SCRS 2024 Landscape Survey

© WCG Clinical 2025. All rights reserved.

Panel Discussion - Number of Technologies & Vendors

As technology and vendor solutions continue to expand and influence study operations, how have you approached maintaining operational feasibility while evaluating or accepting new sponsor trials? What practices have helped you strike a balance between innovation and site capacity?

© WCG Clinical 2025. All rights reserved.

Panel Discussion - Key Takeaways Regarding Complexity

In today's environment of increasing trial complexity, what key lessons or strategies would you share for selecting the right trials, adapting to diverse trial designs, and effectively collaborating with a broad range of stakeholders?

© WCG Clinical 2025. All rights reserved.

Polling Question 3 –

What other factors do you believe are contributing to clinical trial complexity?

© WCG Clinical 2025. All rights reserved.

Audience Questions

© WCG Clinical 2025. All rights reserved.

Polling Question 4 –

Would you like to learn more about WCG's Site & Study Enablement Solutions?

© WCG Clinical 2025. All rights reserved.

Don’t Miss Out on Parts 2 and 3 of the Webinar Series on Nov 19 and Dec 10 –

Overcoming Obstacles – Addressing Key Site Challenges Now & Into the Future

Register today!

Join us for a Collaborative Workshop on
December 5 at 11 a.m. - 12:30 p.m. EST –

Navigating Protocol Amendments: Identifying Challenges and Exploring Strategies to Drive Efficiencies

Register today by scanning the QR code or visiting our website at:
events.wcgclinical.com/navigating-protocol-amendments/

© WCG Clinical 2025. All rights reserved.

Thank you!

wcgclinical.com

© WCG Clinical 2025. All rights reserved.