



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

# Study Start-up

# Introductions



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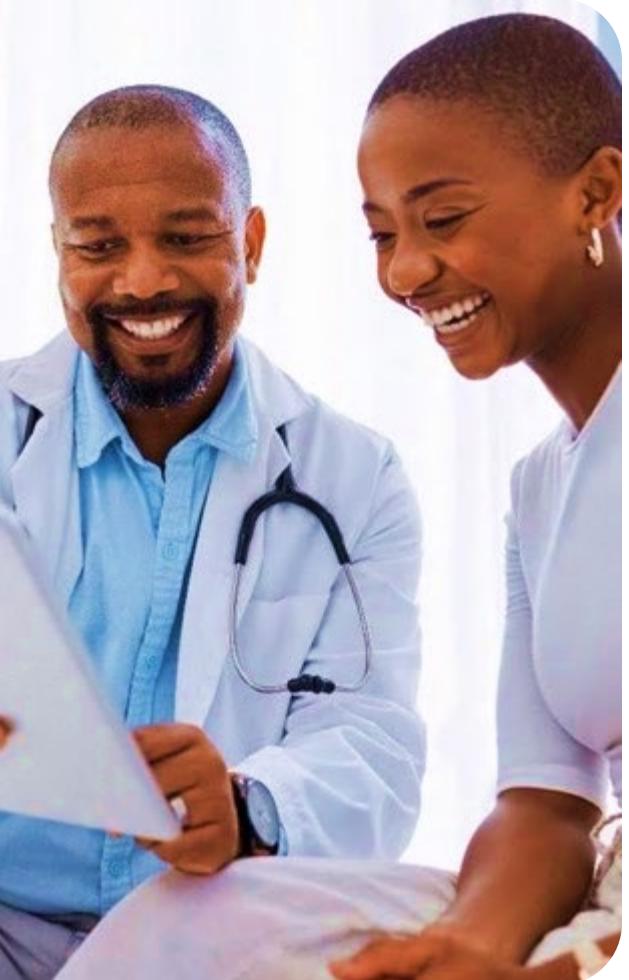


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# Agenda



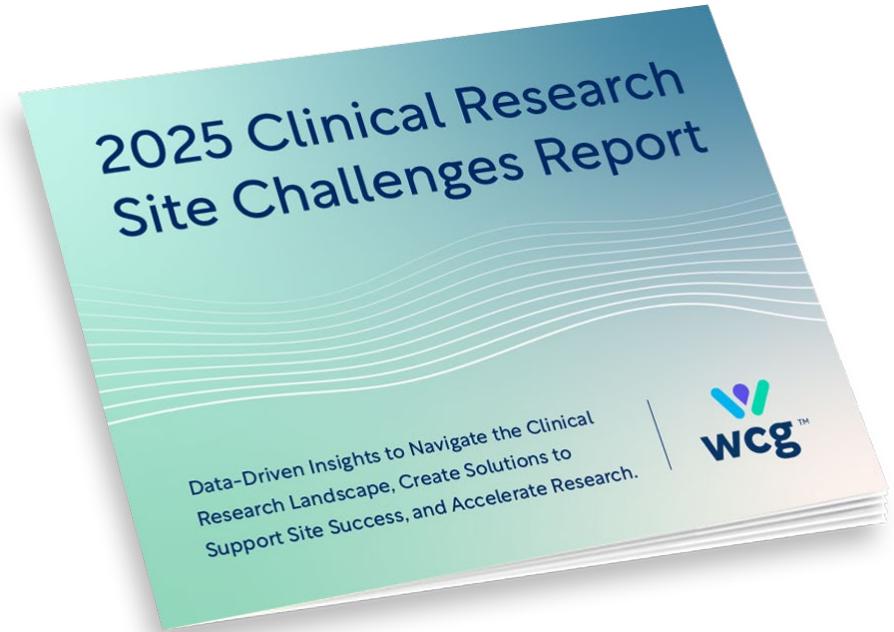
- 1 Overview of WCG's 2025 Clinical Research Site Challenges Report
- 2 Study Start-up Survey Results
- 3 Examining the Study Start-up Process
- 4 Panel Discussion
- 5 Audience Questions and Closing

# **Polling Question 1 -**

## **What type of organization do you represent?**

# 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.

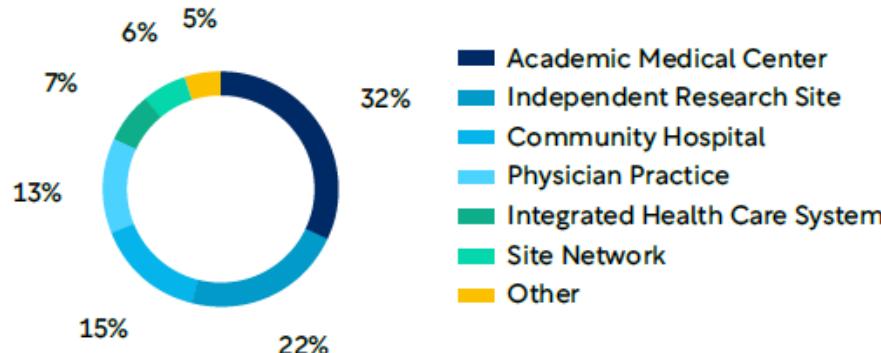


**The full report can be downloaded for free at:**  
<https://www.wcgclinical.com/insights/2025-clinical-research-site-challenges-report/>

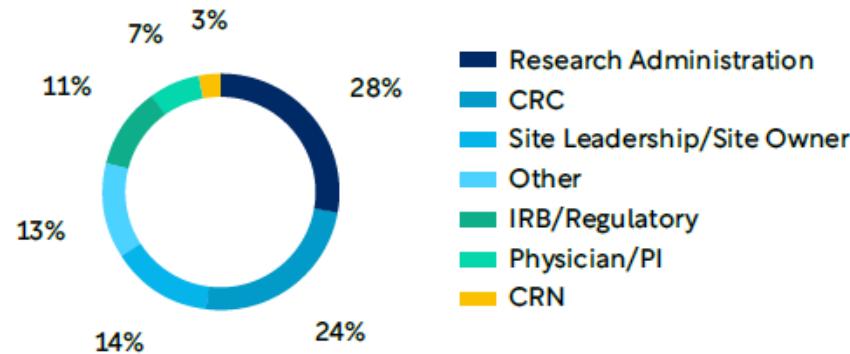


# 2025 Clinical Research Site Challenges Report - Background

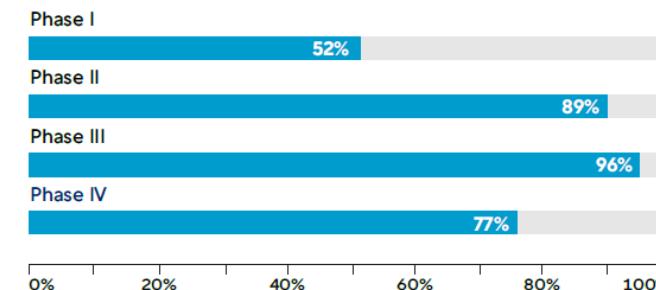
## What type of research site do you represent?



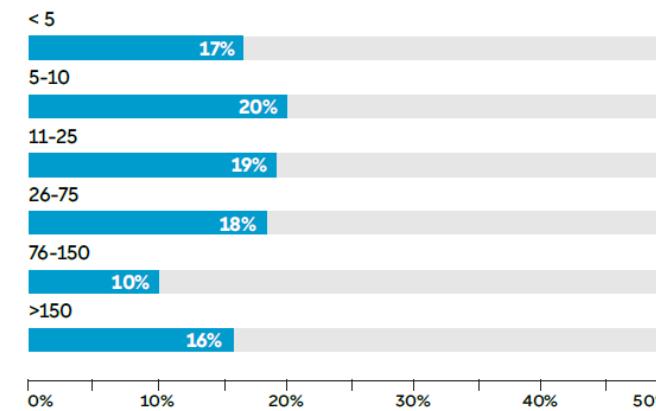
## What is your role at your research site?



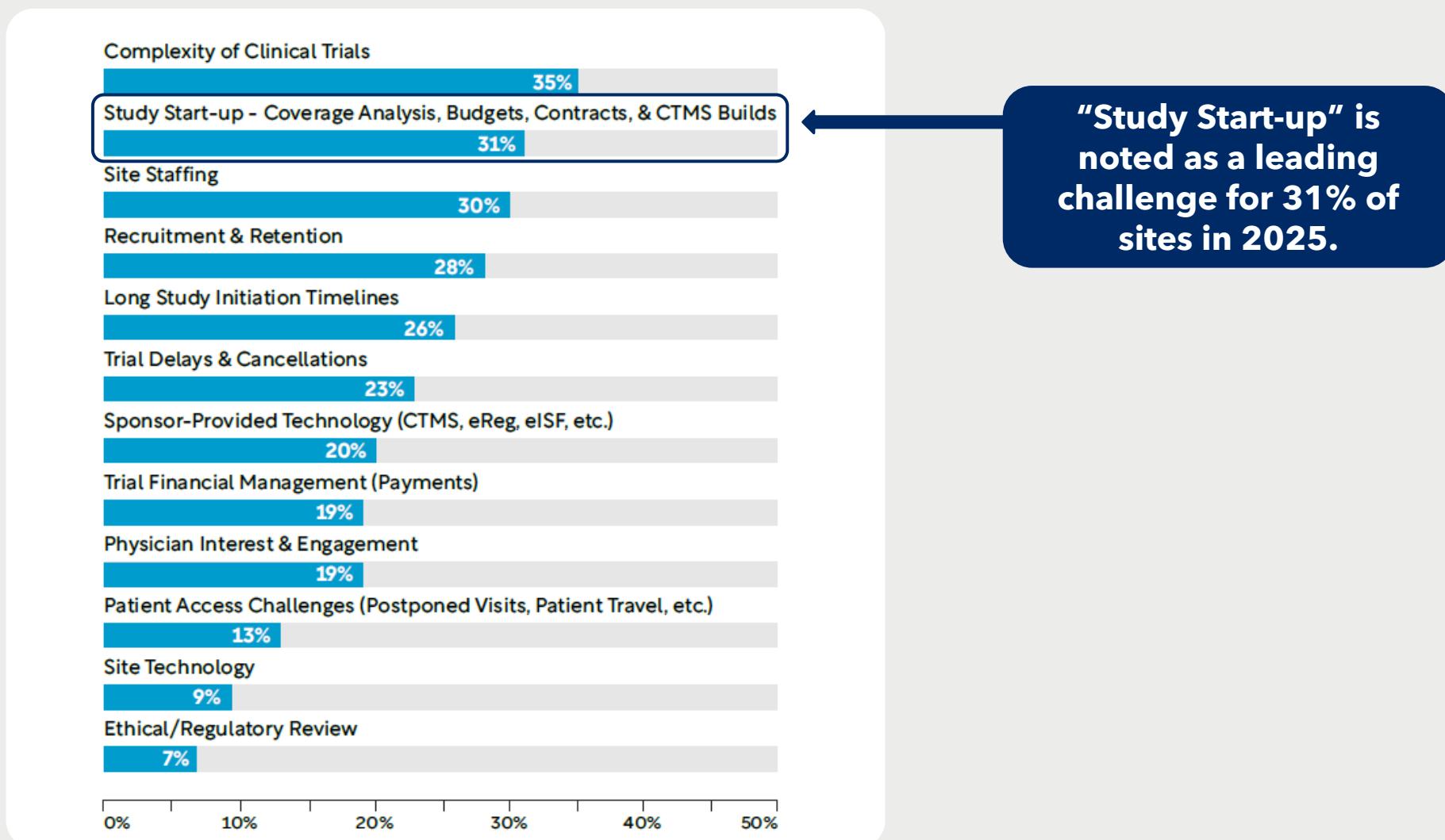
## What study phases does your site support? (Please check all that apply)



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



# The Top Site Challenges in 2025



Source: WCG 2025 Clinical Research Site Challenges Report

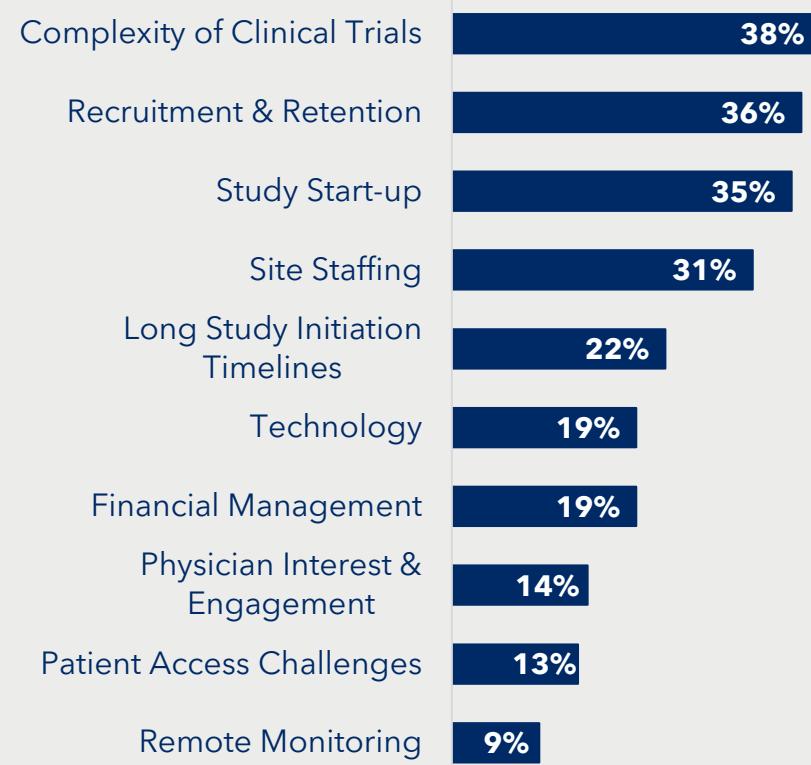
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# Study Start-up as a Top Site Challenges from 2023 - 2025

## The Top Site Challenges of 2023



## The Top Site Challenges of 2024



## The Top Site Challenges of 2025



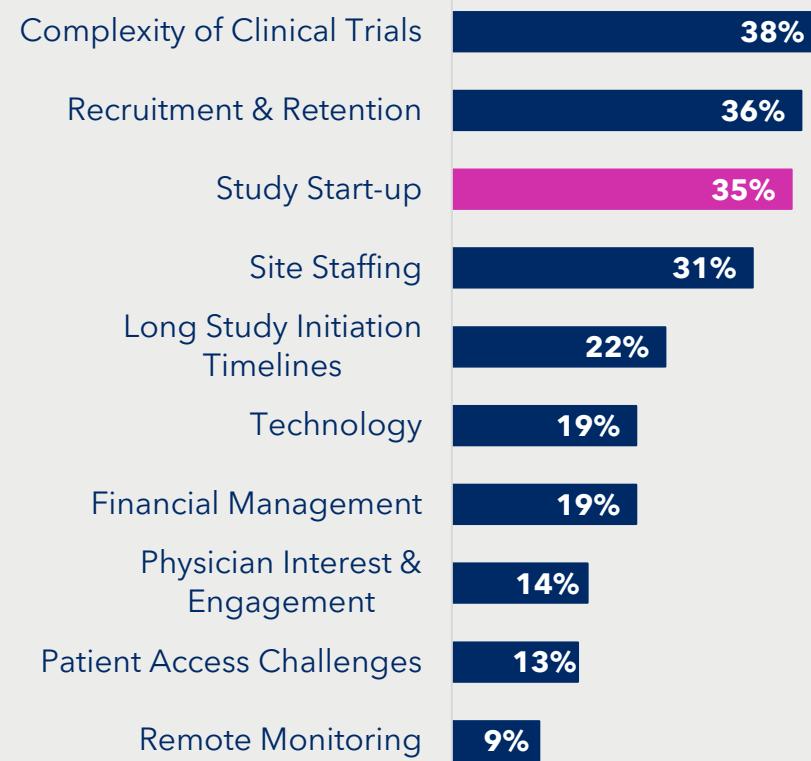
Source: WCG Clinical Research Site Challenges Report, 2023-2025.

# Study Start-up as a Top Site Challenges from 2023 - 2025

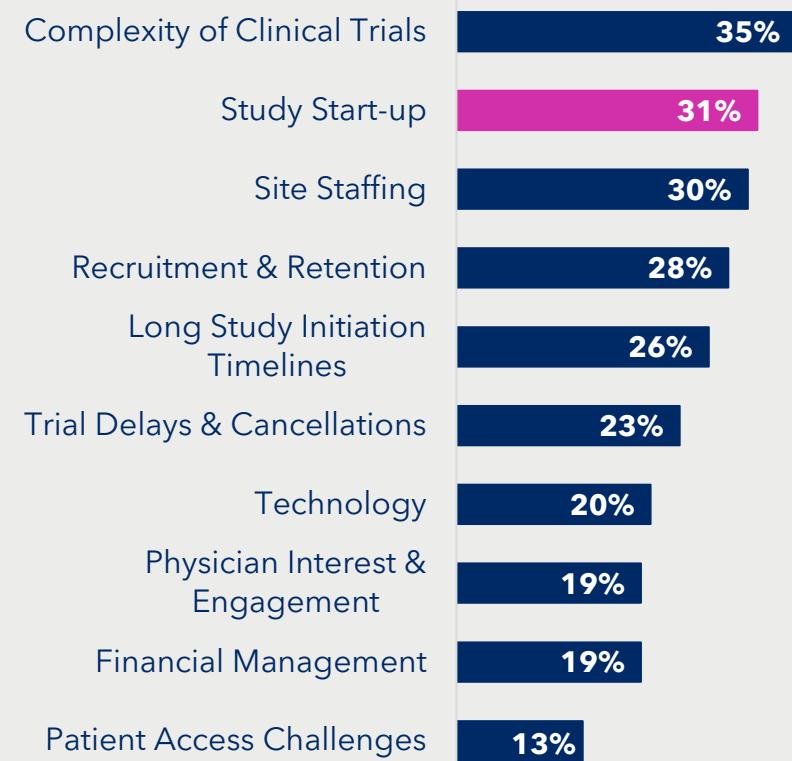
## The Top Site Challenges of 2023



## The Top Site Challenges of 2024



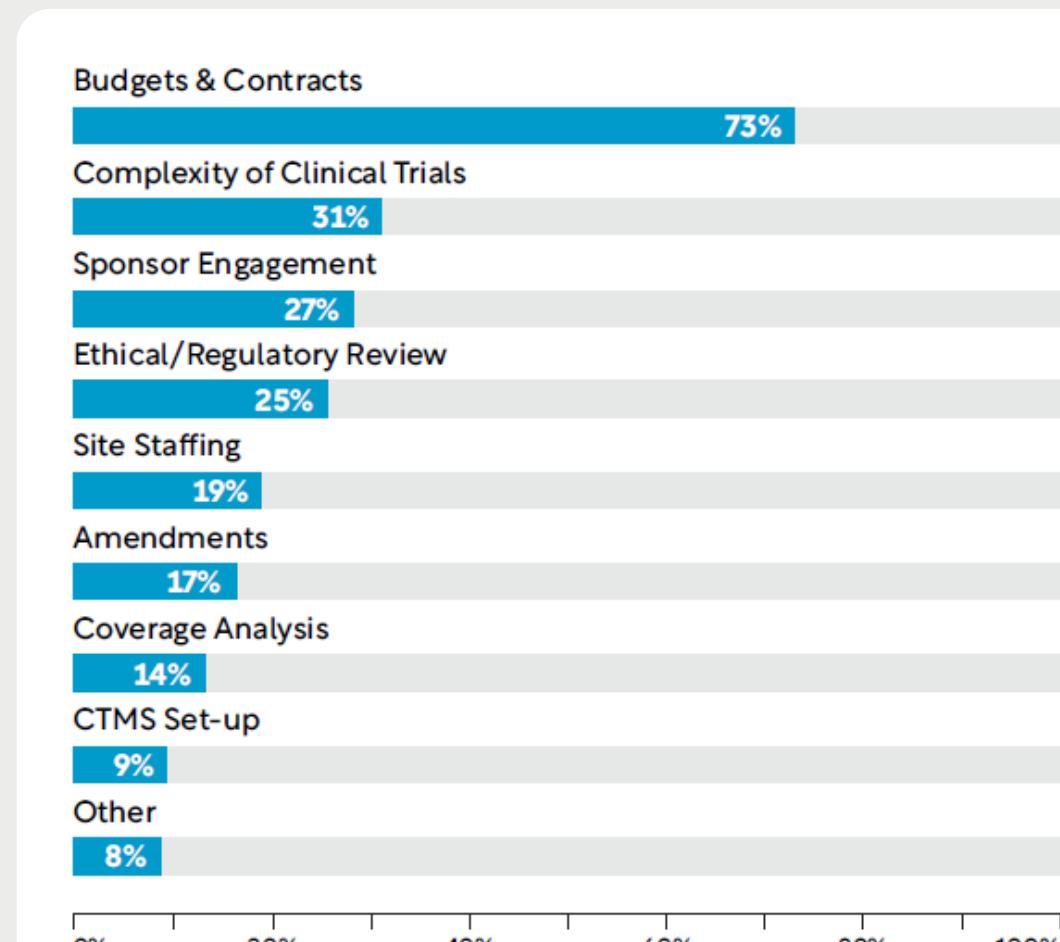
## The Top Site Challenges of 2025



Source: WCG Clinical Research Site Challenges Report, 2023-2025.

**Polling Question 2 -**  
**What is the largest contributor to your  
study start-up timelines?**

# The Largest Contributors to Site Start-up Timelines in 2025



Source: WCG 2025 Clinical Research Site Challenges Report

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## Current Industry Activation Timelines

Across all therapeutic areas, there is a disparity in median time for trial activation, defined as time from site selection to completion of contract.

For the past 3 years for Phase I-III trials, the median timeframe for trial activation is **9.4 months for AMCs and hospitals vs. 4.8 months at independent sites/physician practices**. Additionally, **budget negotiation timelines trended 5 days longer in 2024**.

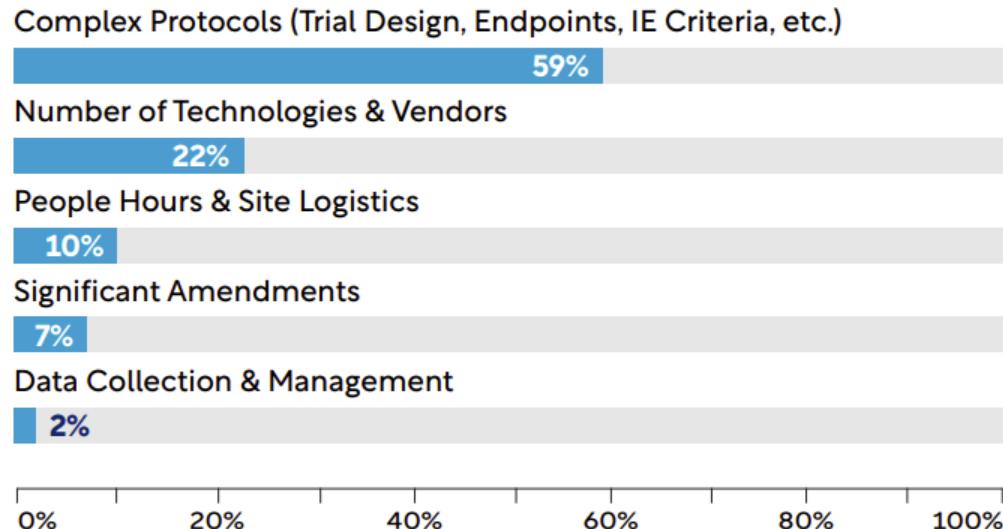


# Panel Discussion: Sponsors and Study Start-up

What are some practical suggestions for sponsors to ease the start-up process and accelerate site activation? What about sponsors utilizing CROs?

# Complexity Continues to Drive Endpoints

Which of the following factors contributes the most to complexity in your clinical trials?



42%  
increase

in procedures required in phase III trials since 2015.

37%  
increase

in number of endpoints in phase III trials since 2015.

47%  
of sites

site “simplifying protocol complexity” as a top area for sponsors to address when it comes to their site’s operating viability.

46%  
of sites

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

Source: Tufts Center for the Study of Drug Development <sup>1,2</sup>

# Panel Discussion: How do you Eliminate or Limit "White Space" in your Start-up Process?

A majority of start-up delays are caused by the "white space".



# Panel Discussion: Pre-Start-Up Efficiencies

What are some suggestions you'd give to sites to set them up for success earlier in the process, such as during site evaluation or feasibility?

# How are Sites Responding to the Increasing Workload Overall?

What solutions has your site implemented to address these challenges? (Please select all that apply)

Hiring Additional Staff

34%

Staff/PI Training

33%

Implementing Technology Solutions

26%

Participating in More Industry-Sponsored Trials

23%

Partnering with Clinical Services Companies

19%

Limiting Study Participation to Specific Therapeutic Areas

16%

Participating in Fewer Studies

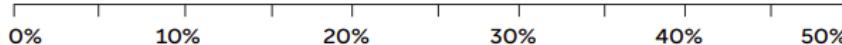
16%

Selecting Trials with Less Complex Designs

15%

Other

10%



We continue to see sites become more strategic about how they are engaging with sponsors and selecting studies for participation.

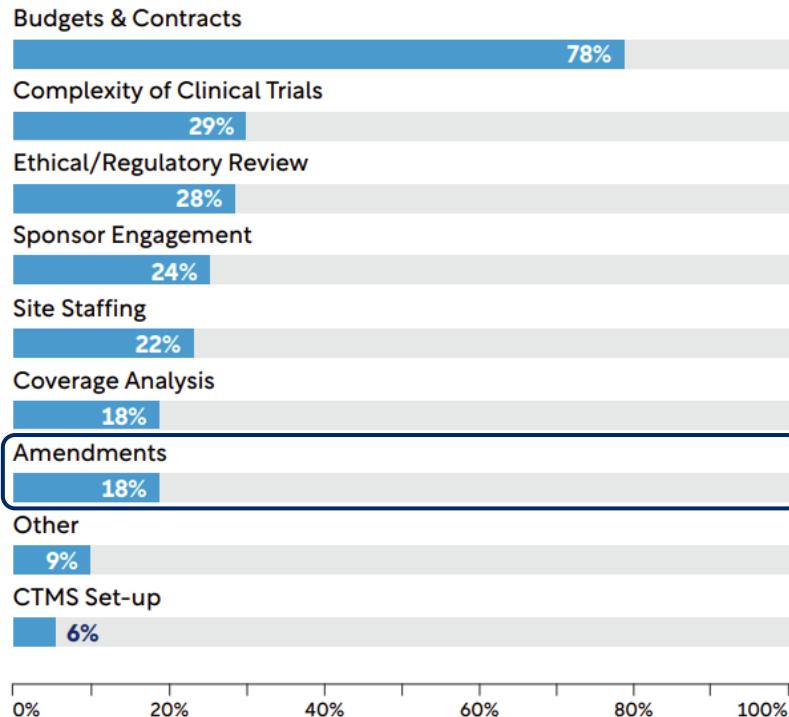
# Panel Discussion: Protocol Amendments

Sites continue to struggle with the burden that amendments create, especially when introduced during study start-up. What strategies or policies have you found to be helpful when navigating amendments?

# How are Sites Responding to the Increasing Workload Overall?

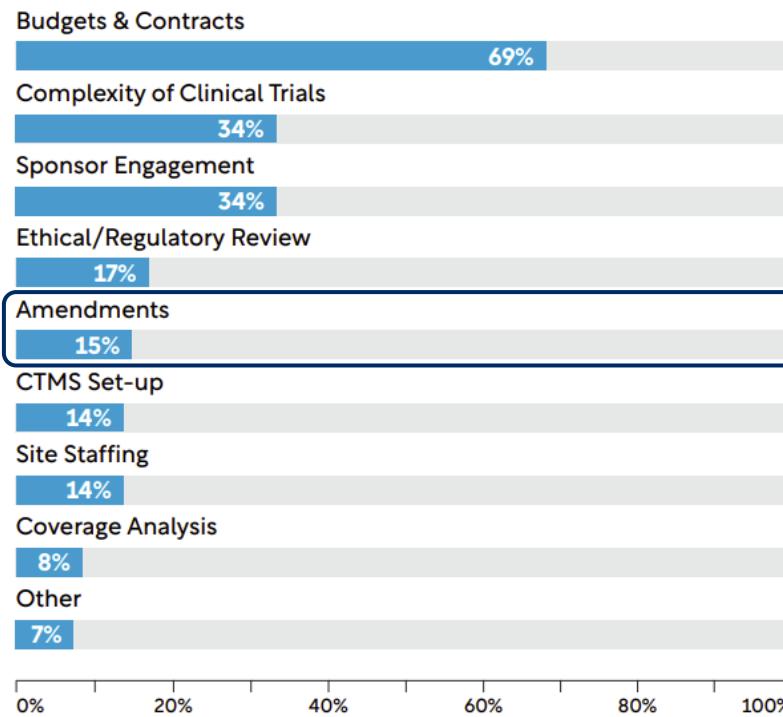
## ACADEMIC MEDICAL CENTER, HEALTH SYSTEM, COMMUNITY HOSPITAL & SITE NETWORK DATA

What was the largest contributor to your study start-up timelines last year?  
(Please select your top three)



## INDEPENDENT SITE & PHYSICIAN PRACTICE DATA

What was the largest contributor to your study start-up timelines last year?  
(Please select your top three)



# But the Amendment Challenge is Beginning to Shift Outside of Just Oncology...

Phase II protocols have twice as many substantial protocol amendments compared to non-oncology protocols.<sup>1</sup>

Phase III trials face a nearly 40% increase in substantial amendments compared to non-oncology protocols.<sup>1</sup>

In a recent WCG survey of over 600 site representatives, 87% reported significant delays to start-up as a result of amendments.<sup>2</sup>



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

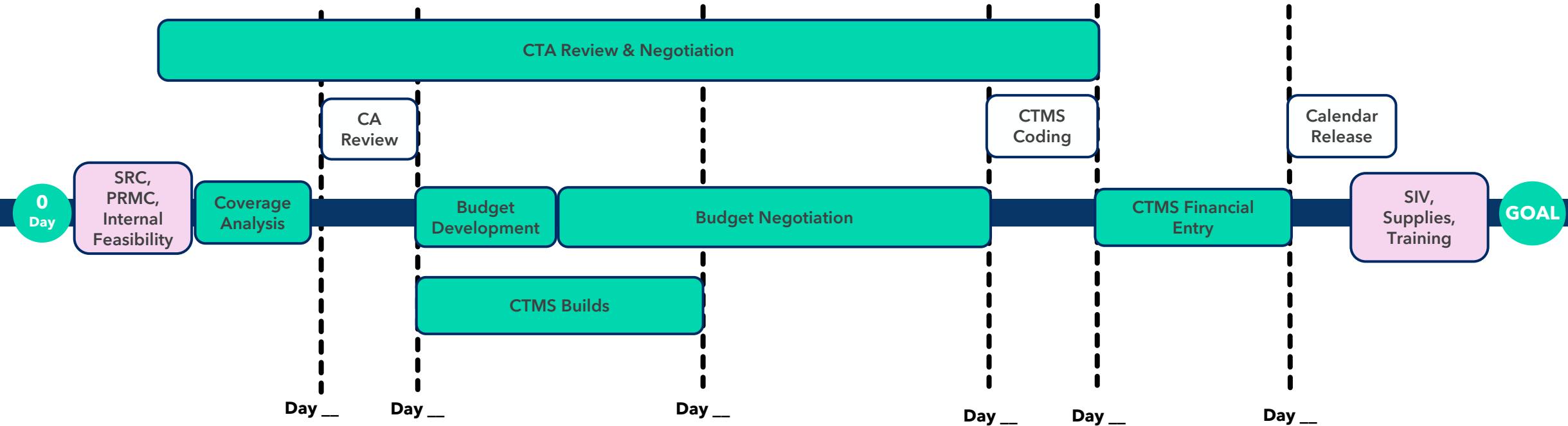
**Navigating Protocol Amendments:  
Identifying Challenges and Exploring  
Strategies to Drive Efficiencies**

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

# Panel Discussion: Start-up Timelines

As many know, sites and sponsors do not define the start-up timeline the same way. How do sites vs. sponsors define their start-up "start" and "stop"? What would you recommend to sites developing these policies for the first time?

# Study Start-up Process Assessment



## Process Assessment:

1. Establish which services are completed by which teams.
2. Confirm current process and timelines.
3. Establish target timeline for each service and overall process.
4. Implement improvements to each service and remove white space.

### **Polling Question 3 -**

**How would your organization use a  
sponsor/CRO-prepared coverage analysis as  
part of the study start-up document package?**



# Audience Questions



**Polling Question 4 -**  
**Would you like to learn more about**  
**WCG's Study Start-up Solutions?**

Don't Miss Out on Part 3 of the Webinar  
Series on December 10 -

## Overcoming Obstacles : Addressing Key Site Challenges Now & Into the Future - Site Staffing

***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/](https://events.wcgclinical.com/navigating-protocol-amendments/)

# Thank you!



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