



**Empowering Sites for Clinical Trial
Success Webinar Series - Part 3**

Decoding the Top Site Challenges of 2024: Study Start-Up



Today's Agenda



- 1 2024 Site Challenges Report Overview
- 2 Data & Insights on Study Start-Up
- 3 Accelerating Clinical Trial Activation Timelines
- 4 Panel Discussion & Audience Questions
- 5 Conclusion

Speaker Introductions



**Sandy Smith, RN,
MSN, AOCN**

SVP, Clinical Solutions &
Strategic Partnering at WCG



Tiffany Pearce

Director, Clinical Trials Office
at Henry Ford Health



**Leah Potts, MBA,
CCRP**

Associate Director, Study
Contracts at AstraZeneca



Brad Gruener

Vice President, Site
Services at WCG

Polling Question #1:
What type of organization do you represent?

2024 Clinical Research Site Challenges Report Overview



- WCG surveyed over 850 clinical research sites between April and June of 2024 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 2024 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.



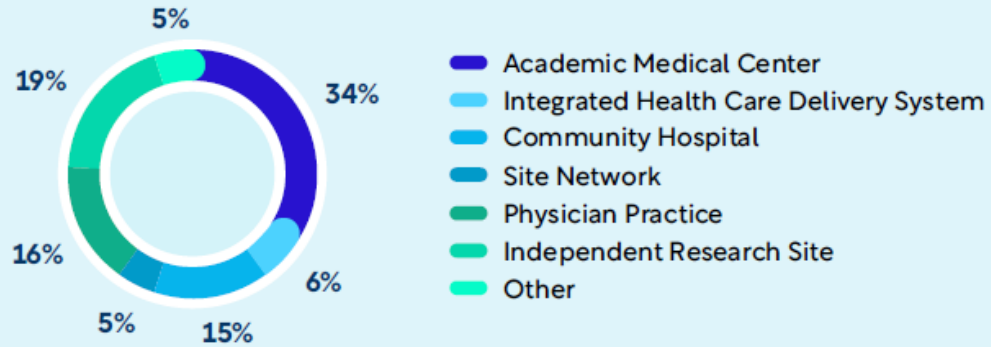
**The full report can be downloaded for free at:
www.wcgclinical.com/challenges**

2024 Clinical Research Site Challenges Report - Background

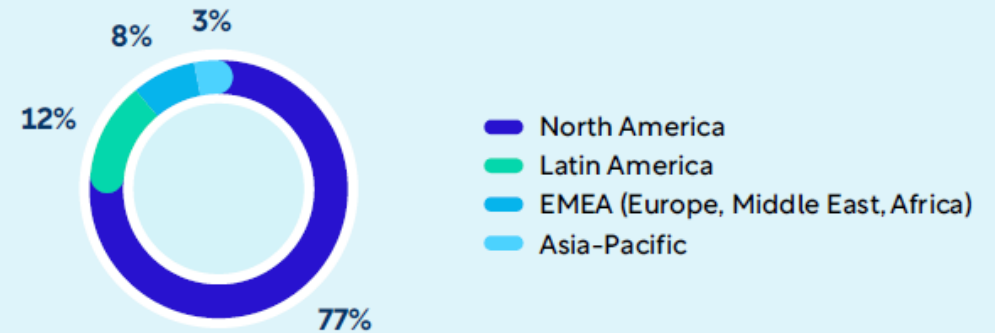


Site Types, Job Titles, and Site Region

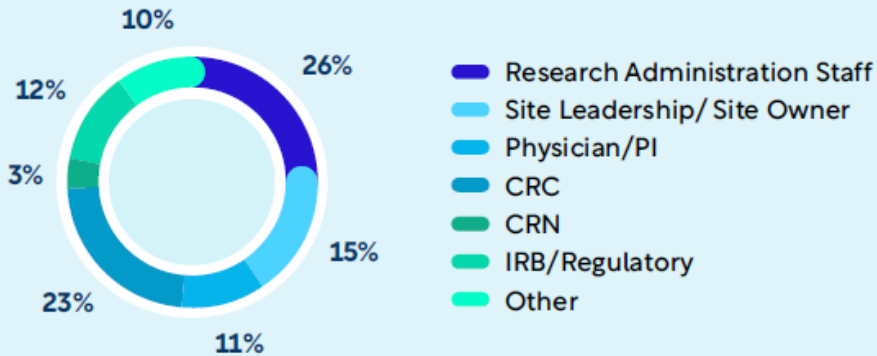
What type of research site do you represent?



What region is your site based in?



What is your role at your research site?

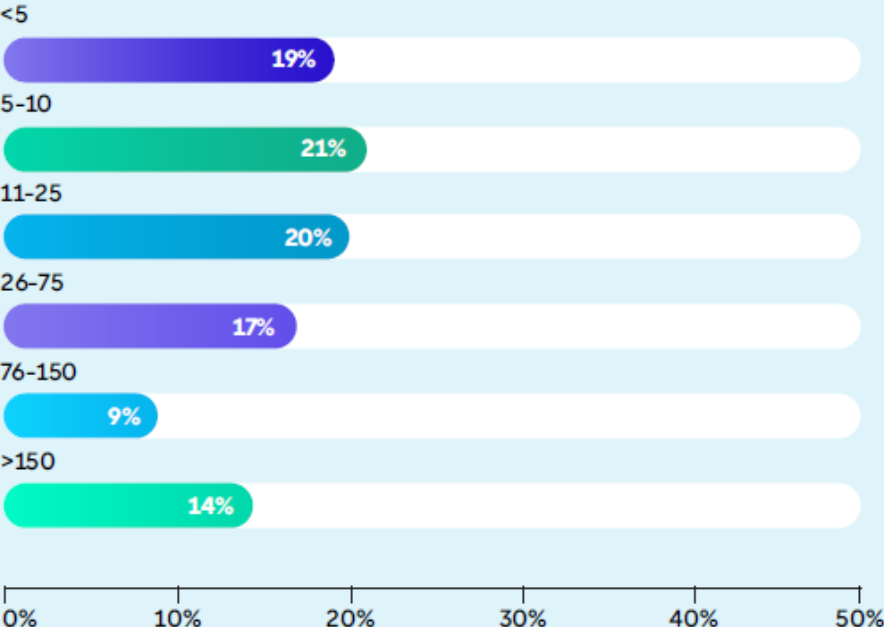


2024 Clinical Research Site Challenges Report - Background

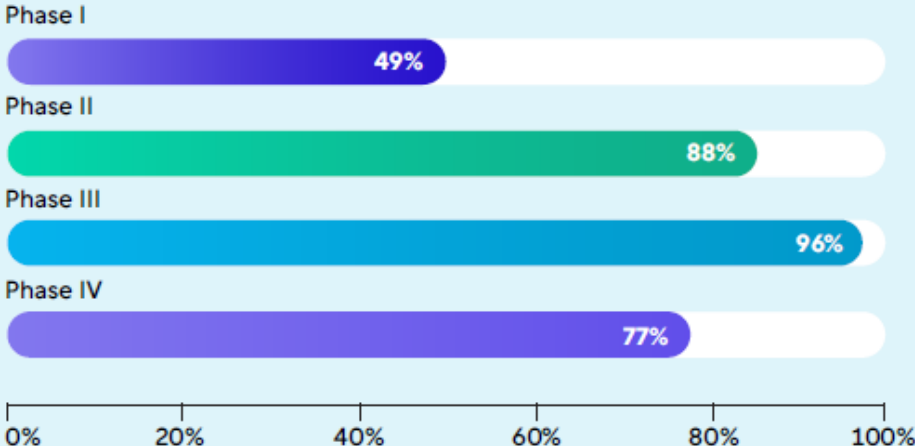


Study Phases and Number of Enrolling Trials

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



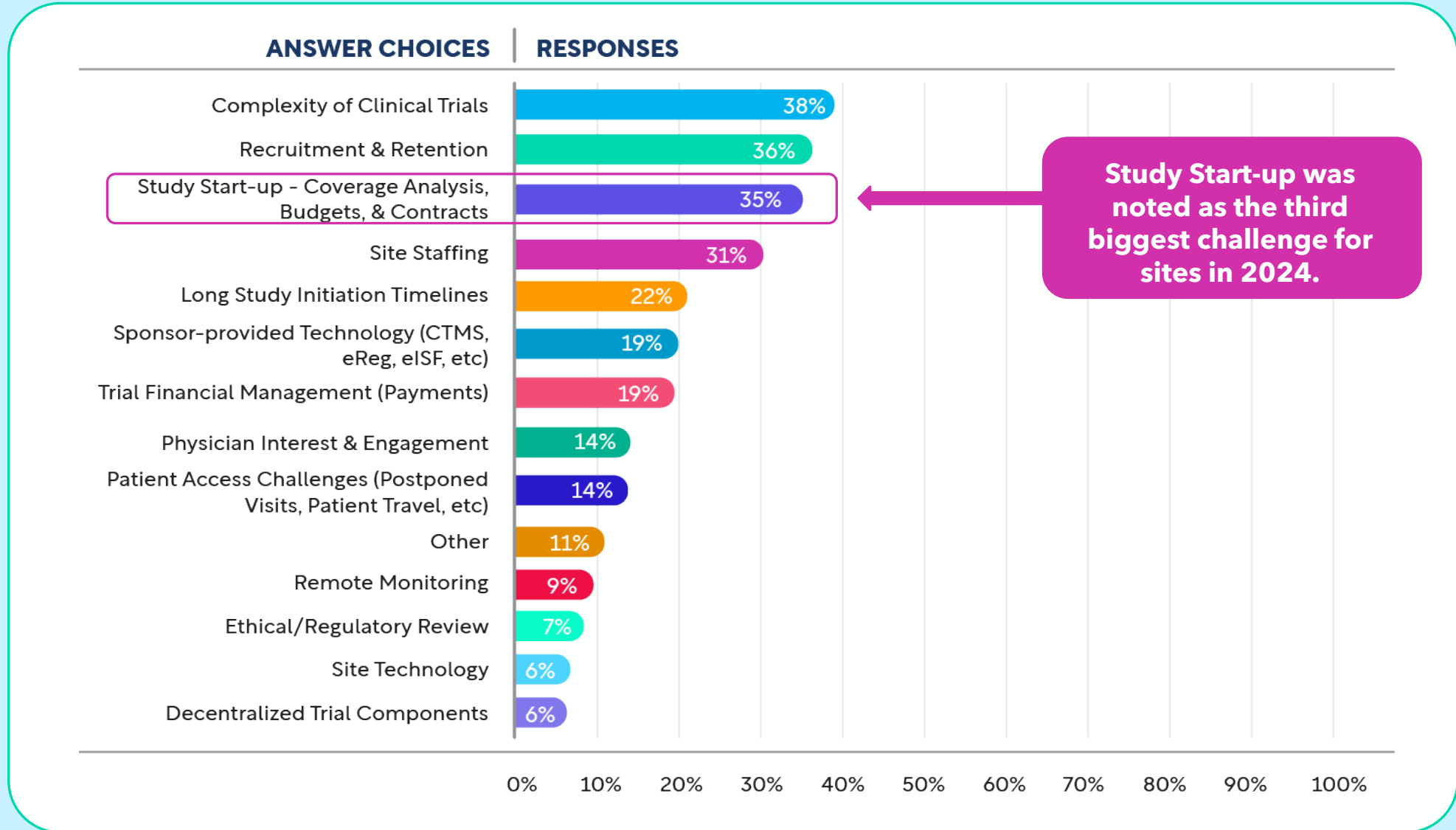
What study phases does your site support?



The Top Research Site Challenges in 2024



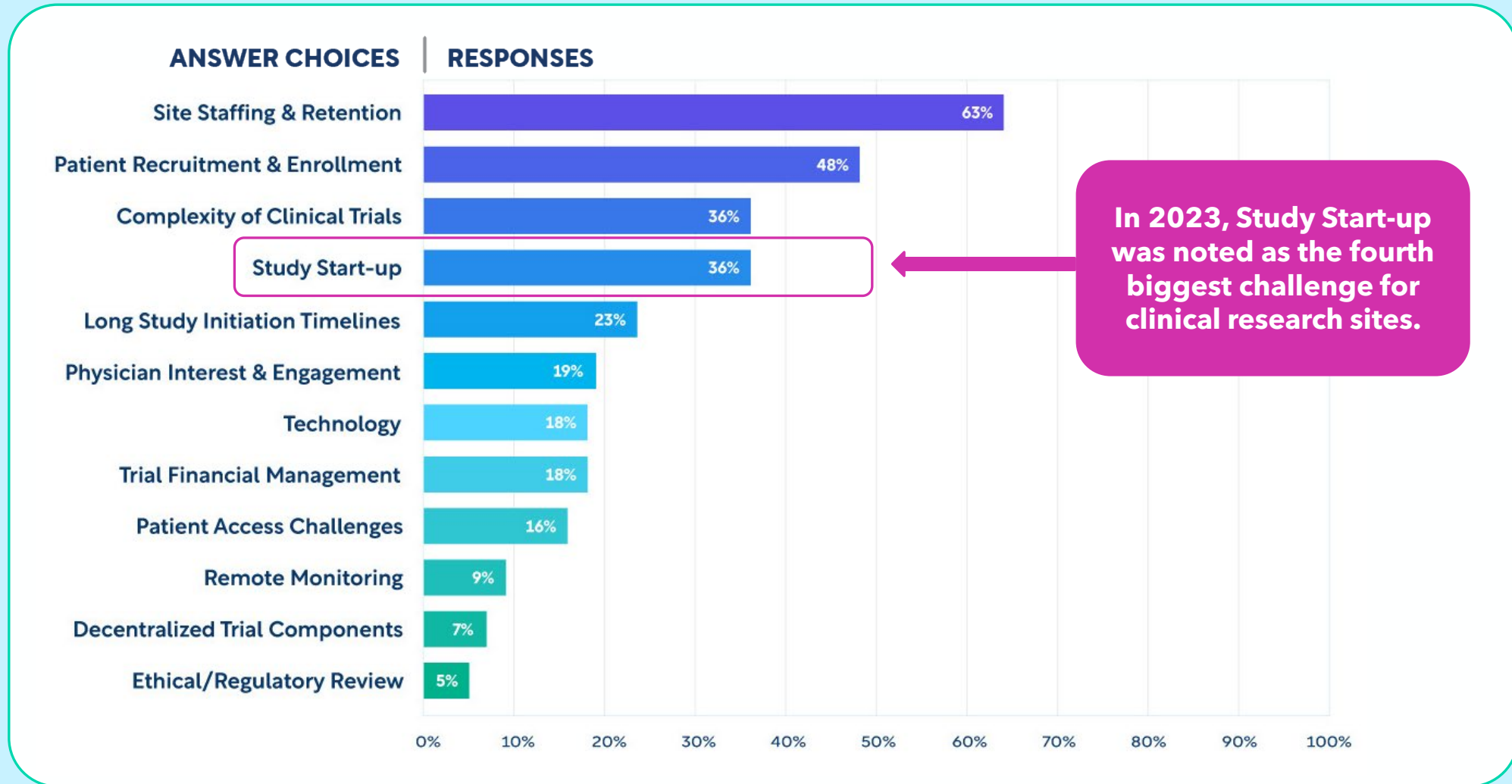
According to WCG's 2024 Clinical Research Site Challenges Survey



The Top Research Site Challenges in 2023



According to WCG's 2023 Clinical Research Site Challenges Survey

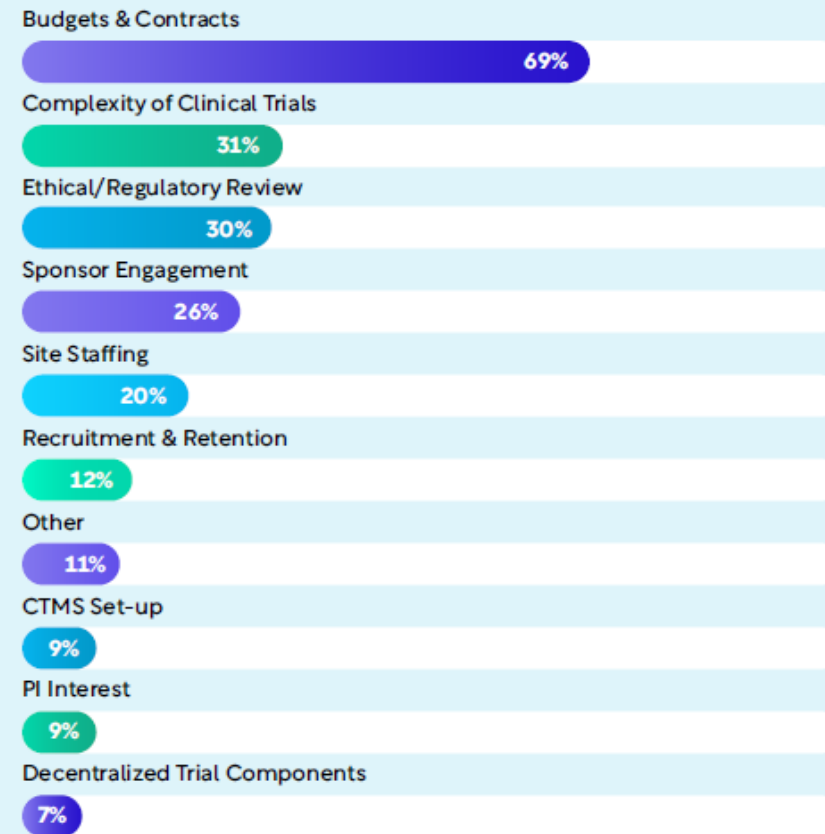


The Top Site Challenges - Study Start-Up



Largest Contributors to Study Start-Up Timelines

What were the largest contributors to your study start-up timelines last year?



Polling Question #2:

For research institutions and sites - What is your average study start-up time?

Data from Across the Industry

Study Start-Up



**31.4
Weeks**

total duration from site identification to study start-up, one month longer than the average duration observed 10 years ago.

**30-
40%**

of sponsors and CROs report they are somewhat or completely unsatisfied with their site initiation processes.

Current Activation Timelines

Industry Averages

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

For the past 3 years for Phase I-III trials, the median timeframe for trial activation is at **8.12 months for AMCs and hospitals vs. 4.37 months at independent sites/physician practices.**



Clinical Trial Activation & Study Start-Up Timelines

An Ideal Scenario



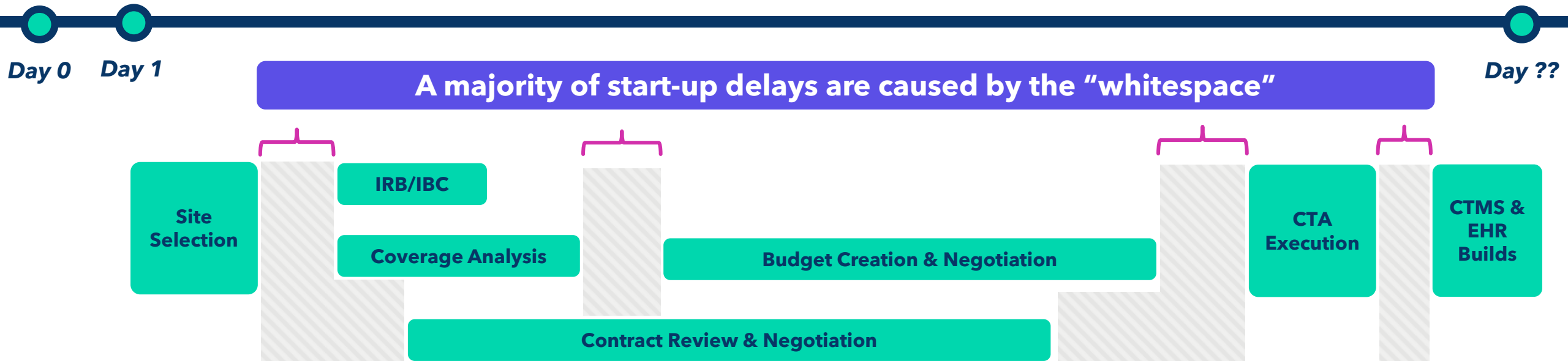
Clinical Trial Activation & Study Start-Up Timelines

The Reality



Clinical Trial Activation & Study Start-up Timelines

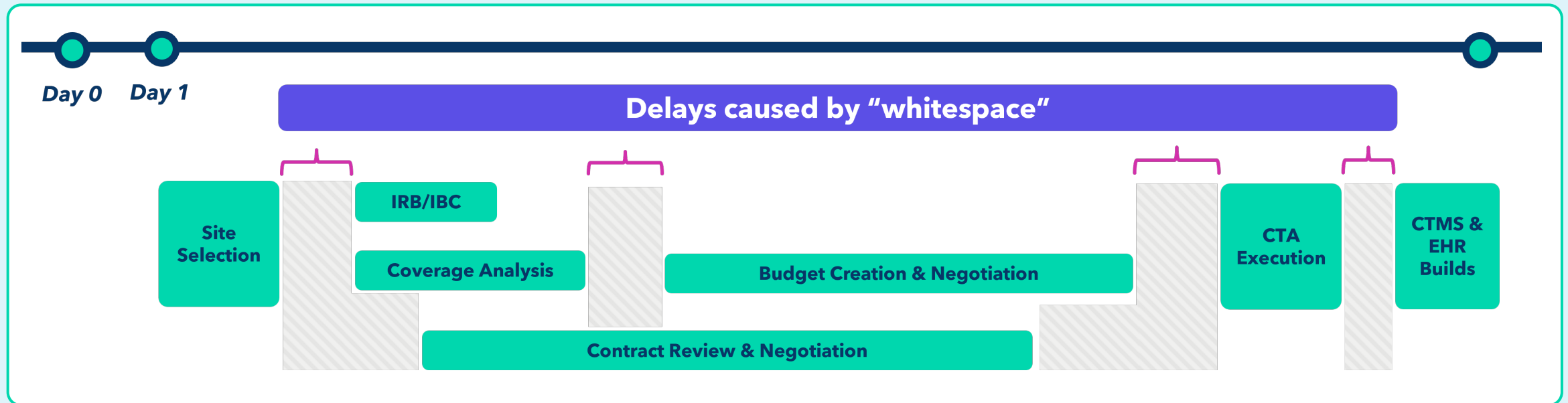
Where Many of the Delays Happen



Accelerating Clinical Trial Activation & Study Start-Up Timelines

What Causes "Whitespace" and Strategies for Eliminating It

- Any handoff is an opportunity for whitespace to creep in.
- This can be internal process transitions or approval steps or communication between different parties (e.g. a round of budget negotiation).
- Some of this is likely unavoidable, so goal is to minimize as much as possible.



Clinical Trial Activation & Study Start-Up Timelines

Diving in Deeper to Other Causes of Study Start-Up Delays



Accelerating Clinical Trial Activation & Study Start-Up Timelines



The Importance of Pre-Start-Up Preparation



Preparation

Pre-study start-up preparation can have a major impact on your overall study start-up timelines.

- What you can do before study start-up begins:
 - Establishing site standards
 - Establishing sponsor/CRO standards using data and precedents from other trials
 - Establish a target, it is easy for something to go unresolved if there isn't a target deadline

Accelerating Clinical Trial Activation & Study Start-Up Timelines

Establishing Workflows and Processes



Preparation Continued

There are opportunities to align processes to limit the opportunity for “white space”:

- Targeted approach for receipt of documents
- Concurrent vs. linear processes
- Approval steps that don't put hold on next step
- Expediting approvals at sponsors

Accelerating Clinical Trial Activation & Study Start-Up Timelines

The Importance of Conducting a Coverage Analysis and Maintaining Billing Compliance



Coverage Analysis

Coverage analysis doesn't need to be a roadblock - it can drive the process forward:

- Standardized approach and template
- Develop playbook and use historical precedent
- Clearly define authority to make final decisions
- Direct connection with budget templates

Accelerating Clinical Trial Activation & Study Start-Up Timelines



Opportunity Cost



Budget & Contract Negotiations

The end stages of a contract or budget negotiation often extend timelines when parties get stuck on last few roadblocks.

- Consider the opportunity cost of these delays
- How to get to decisions faster
- Establishing master agreements and utilizing templates

Accelerating Clinical Trial Activation & Study Start-Up Timelines

Utilizing a CTMS and Equipping CTMS Administrators for Success



CTMS & EHR Builds

CTMS administrators should be well-versed in:

- Study start-up and activation workflows.
- Building calendars and billing grids according to each protocol that are customized to fit within the site-specific study activation workflows.
- Financial data entry for Medicare Coverage Analysis (MCA) and sponsor budgets associated with each protocol.
- Complex amendment changes that may impact the calendar build and financial entry.



Panel Discussion & Audience Questions

Download WCG's 2024 Clinical Research Site Challenges Report Today for Free!



[www.wcgclinical.com/
challenges](http://www.wcgclinical.com/challenges)

Polling Question #3:

Are you interested in learning more about WCG's Study Start-up solutions for sites or Study Planning solutions for sponsors/CROs?

Polling Question #4:

Would you be interested in providing input on your amendments process for WCG's upcoming Amendments Project?

Please select yes if interested and we will follow-up with you!

Thank you!



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