



Thriving in Clinical Research - Overcoming Common Challenges as a Site

**A Three-Part Series - Webinar 2:
Study Start-up**

Introductions



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Today's Agenda



1 WCG 2023 Site Survey Overview and Current Market Trends

2 Start-Up Processes / Issues and Bottlenecks

3 Solutions

4 Conclusion and Audience Questions

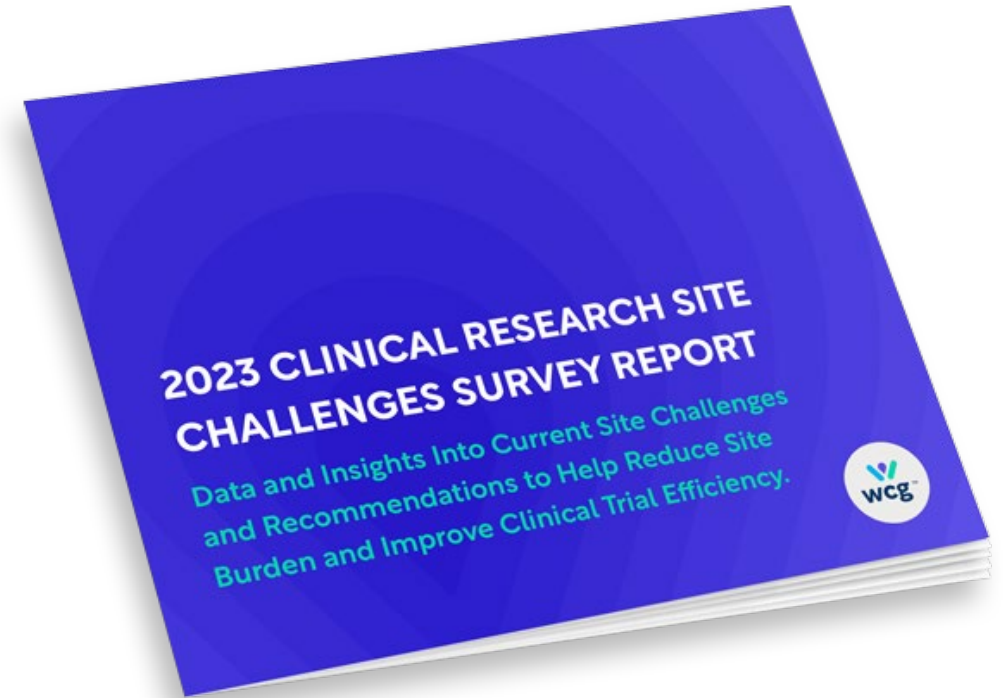
Polling Question 1

What type of organization do you represent?

2023 Site Challenges Survey Report Overview



- WCG polled over 500 clinical research sites in March of 2023 to gain insights surrounding the leading challenges they are facing in today's research landscape.
- In addition to the survey results, the report also includes recommendations for sites, sponsors, and CROs to reduce site burden and improve trial efficiency.
- This presentation is aimed at bridging the connection between the day-to-day operations of a site and the objectives of Sponsors and CROs.

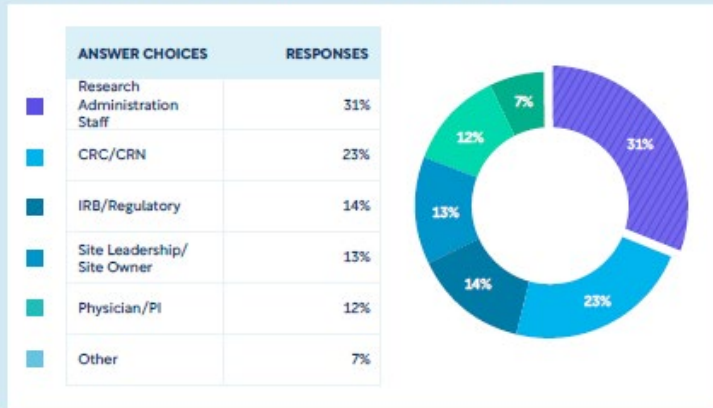


Full report can be downloaded for free at:
www.wcgclinical.com/2023-site-challenges-report

2023 Site Challenges Survey Report - Background

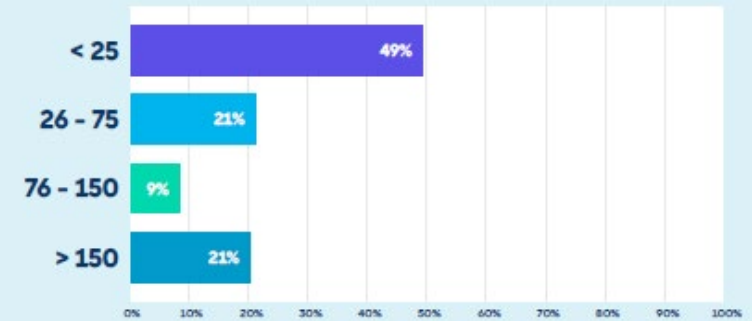


What is your role at your research site?



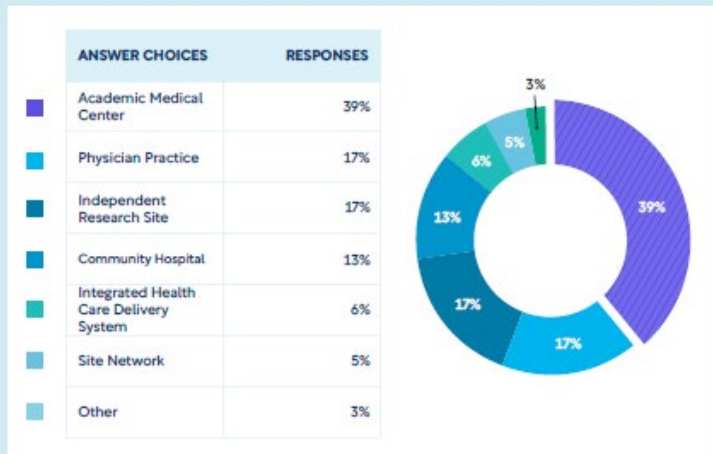
- **31% of respondents are research admin staff**
- **23% are CRCs/CRNs**

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



Over half of all respondents are operating more than 26 trials at any one time.

What type of research site do you represent?

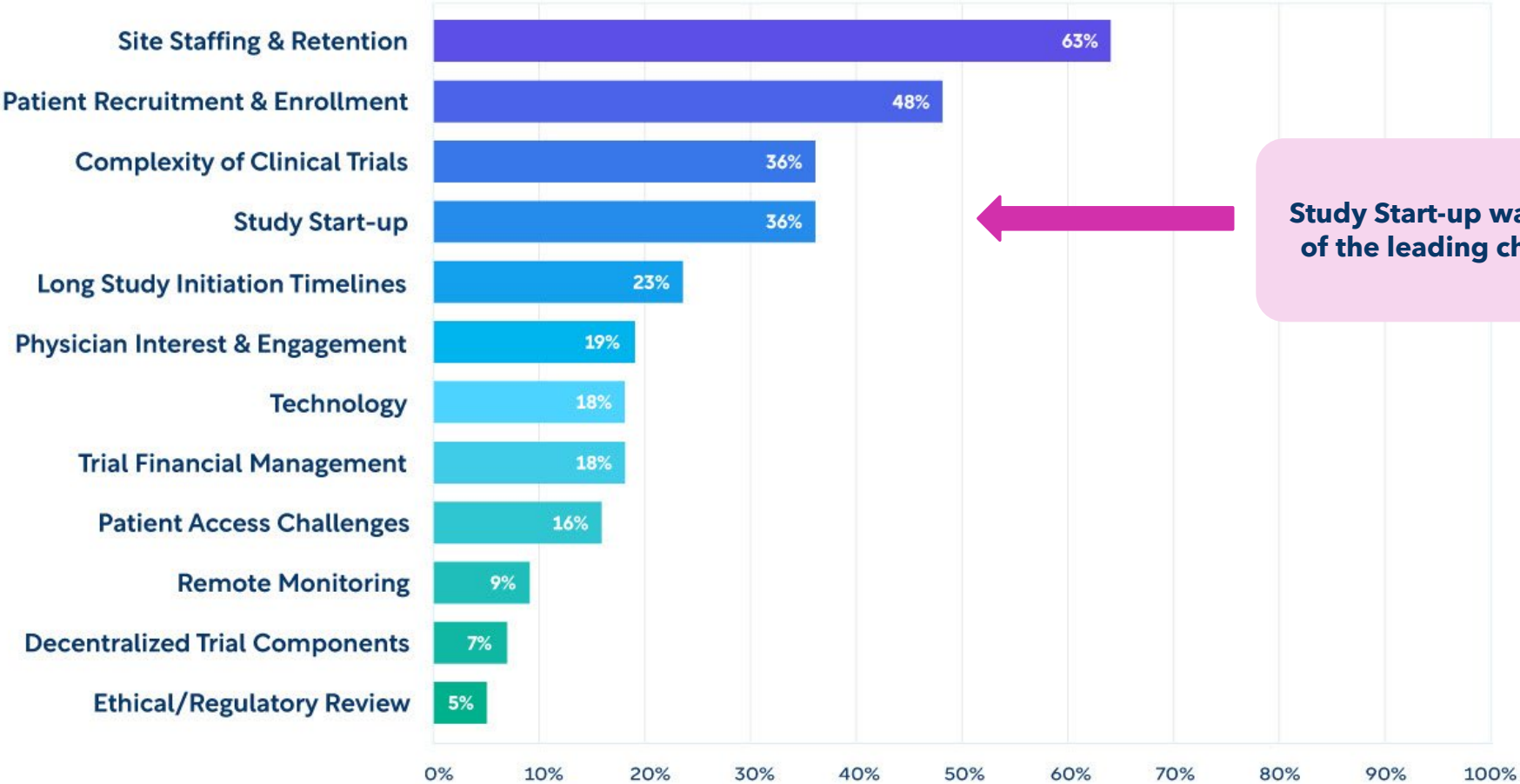


- **39% of respondents are from AMCs**
- **17% are from physician practices**

Survey Results - Top Issues Impacting Research Sites



What are the top issues impacting your site today?



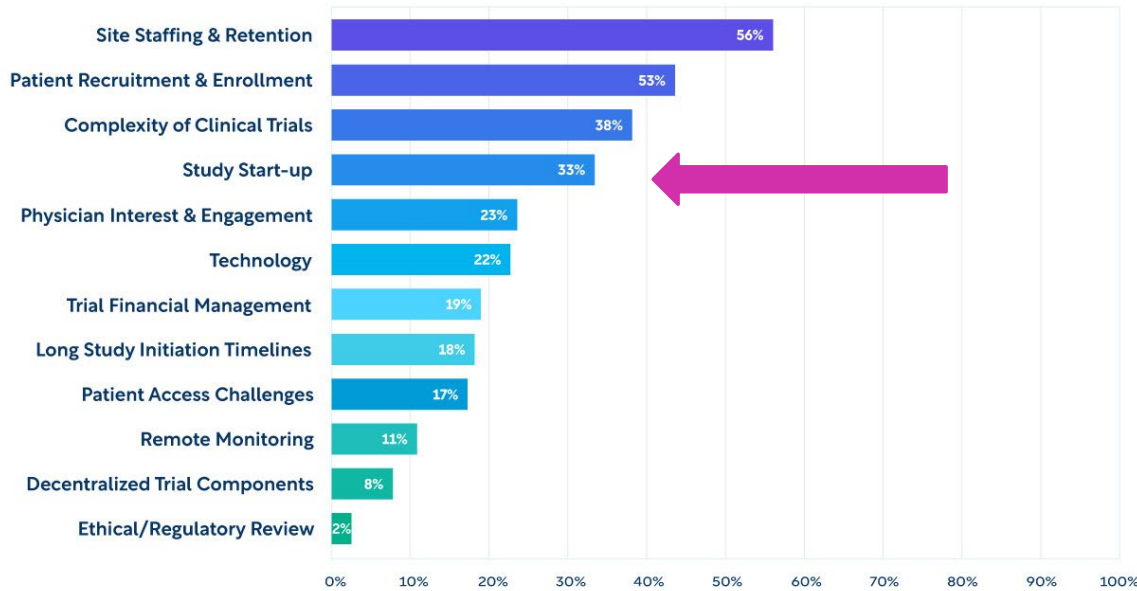
Study Start-up was identified as one of the leading challenges for sites.

Top Issues Impacting Research Sites - AMCs vs Non-AMCs



AMCs

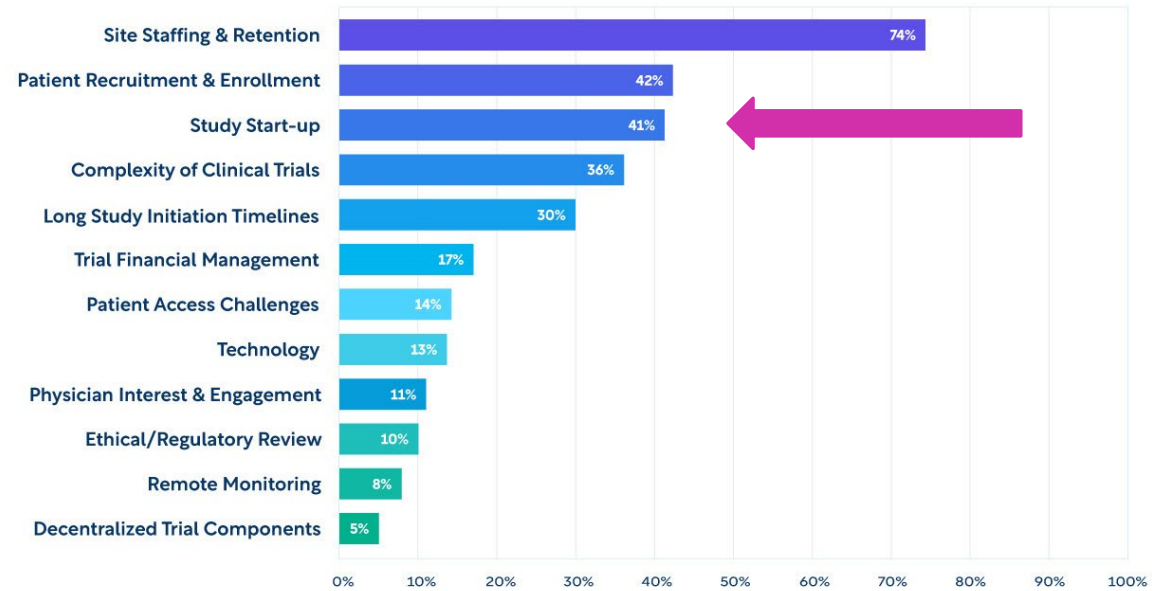
What are the top issues impacting your site today?



WCG's 2023 State of Sites & Site Capacity Survey

Non-AMCs




What are the top issues impacting your site today?



WCG's 2023 State of Sites & Site Capacity Survey

Have Sites Reached Capacity?

Are these challenges impacting your site's ability to agree to participate in new studies?

	ANSWER CHOICES	RESPONSES
	Yes	52%
	No	37%
	Unknown	11%

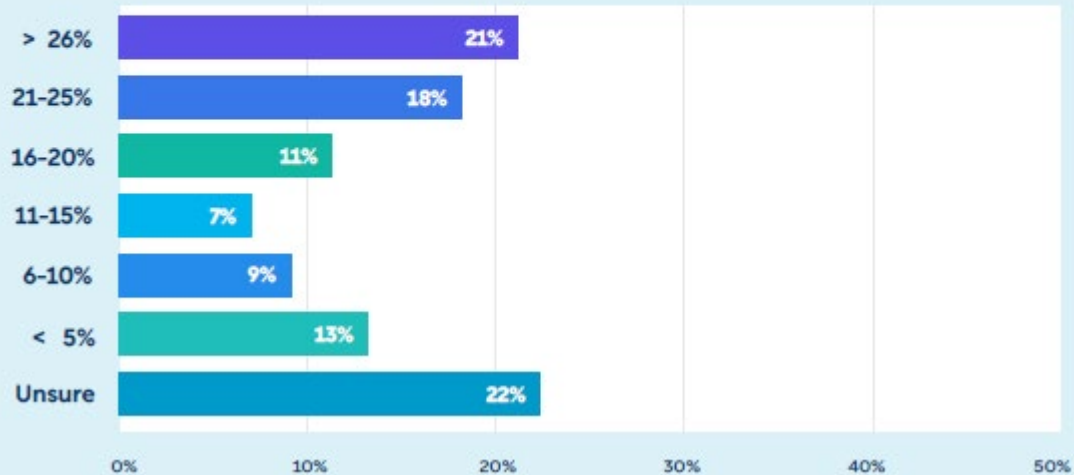


Impact of Site Staff Turnover



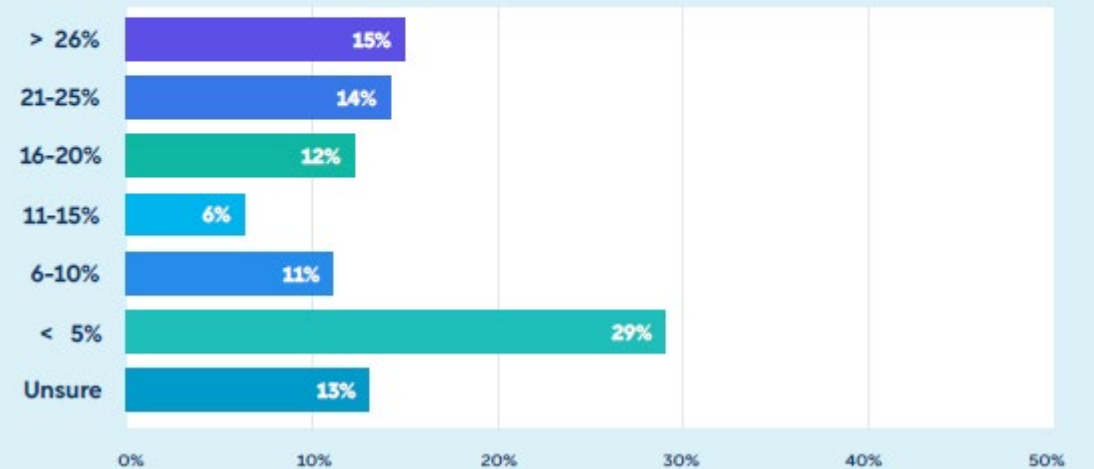
AMCs

Approximately what was the percentage of staff turnover at your organization in the last year?



Non-AMCs

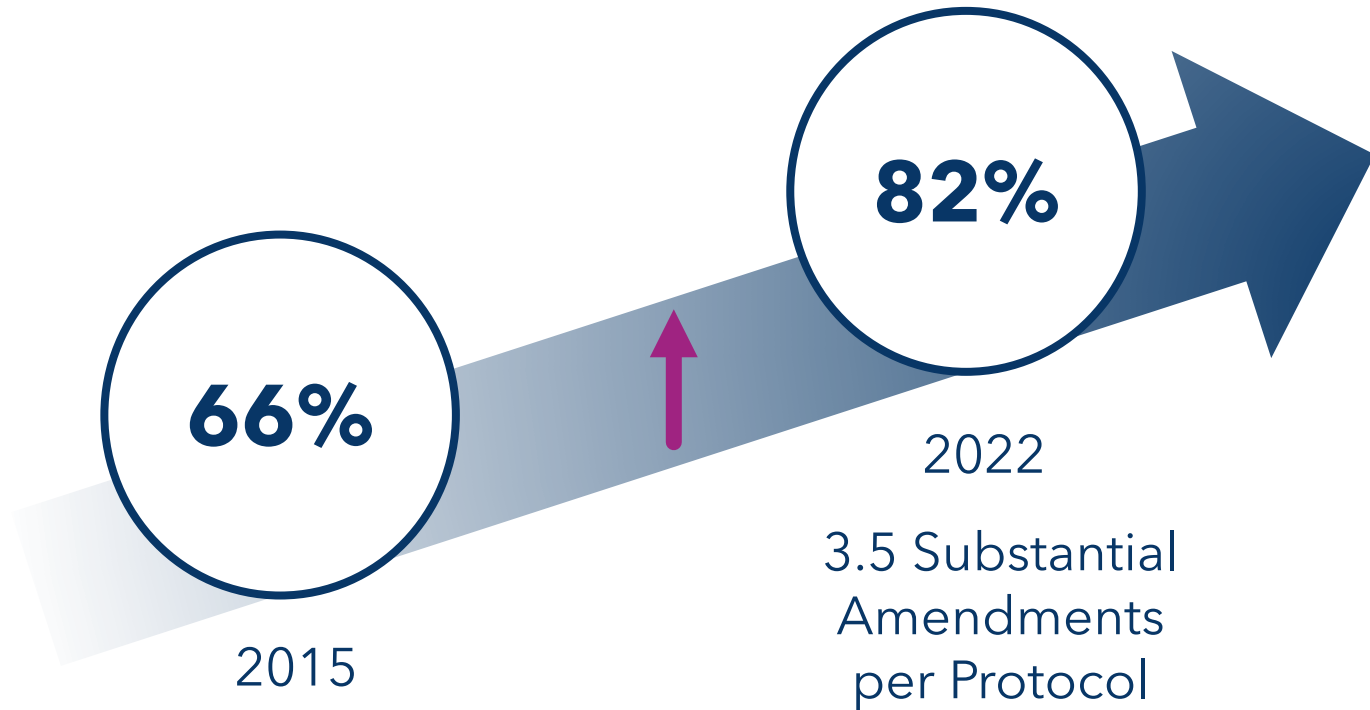
Approximately what was the percentage of staff turnover at your organization in the last year?



The Impact of Amendments on Clinical Trials

What % of Phase 3 Research Have Substantiative Amendments?

More than 75% of clinical trial protocols require at least one substantial Amendment



Phase I & III Protocols saw the greatest increase in number of substantial Amendments since 2015

Phase I
Increased by
15%

Phase III
Increased by
16%

Substantial Protocol Amendment Definition: Changes made to a protocol, in all countries where it is executed, requiring obtaining internal sponsor company approval followed by approval by an ethical review board (ERB)/ institutional review board (IRB)/regulatory authority and re-consenting study volunteers.

Polling Question 2

What is your current actual average timeframe for completing clinical trial budget negotiations?

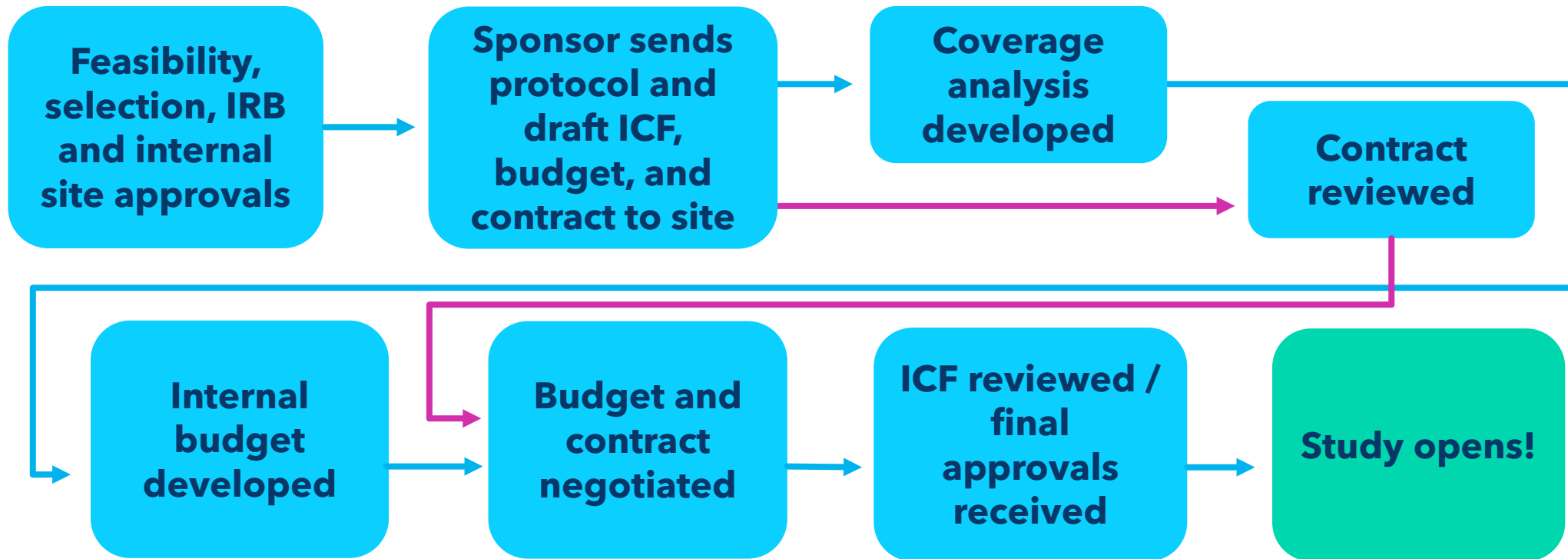
Polling Question 3

What is your current actual average timeframe for completing clinical trial contract negotiations?

The Study Start-Up Process



What *MIGHT* the process look like?



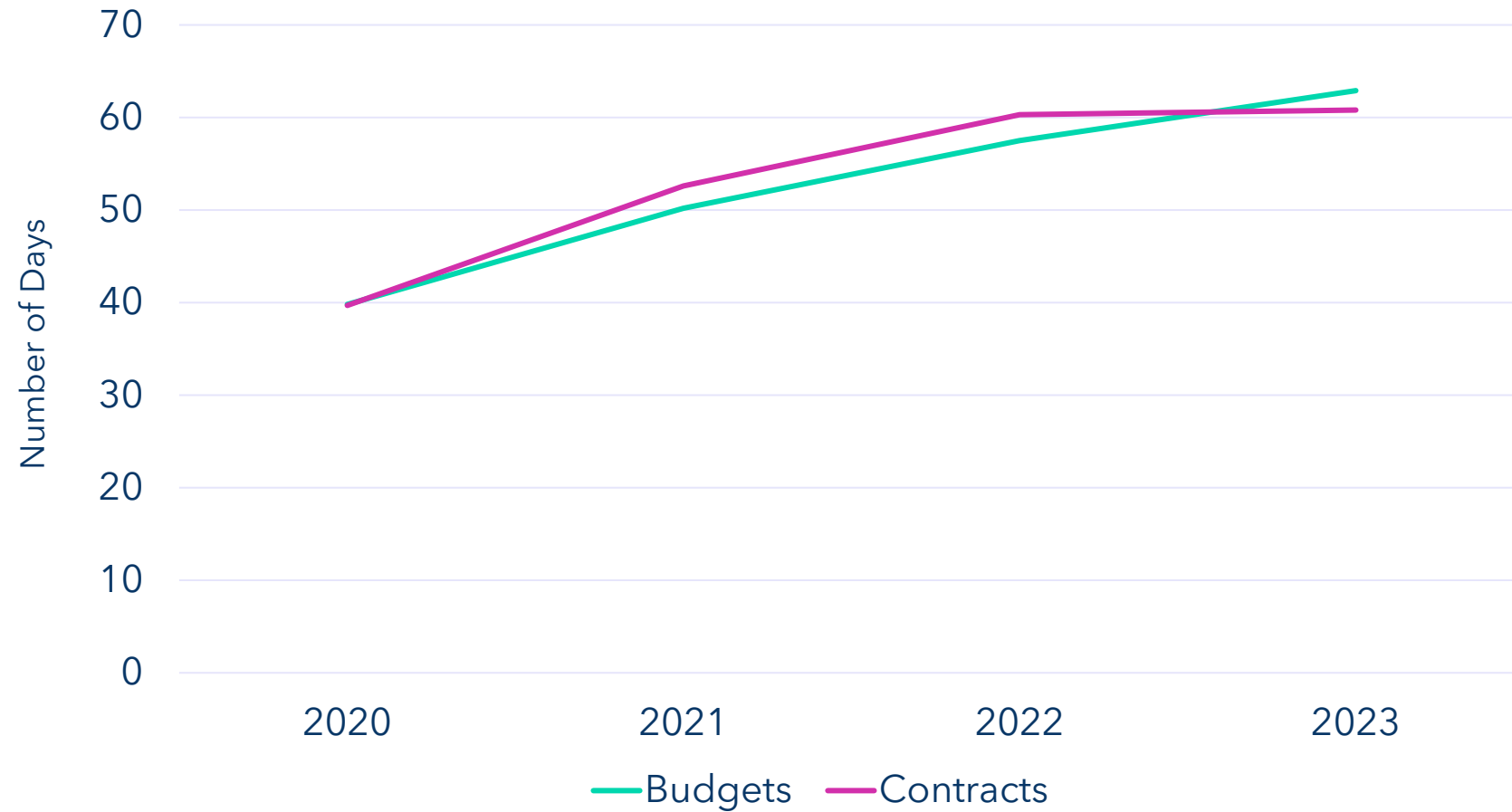
Get Ahead of Process-Related Issues

- **Define what the process looks like to YOUR site**
 - Get detailed!
- **Develop the coverage analysis before the internal budget**
- **Develop a “playbook” for contract and budget requirements**
 - Get stakeholder feedback prior to implementation!
- **Contract and budget should be finalized prior to finalizing the ICF**

Start-Up Initiation



Negotiation Timelines

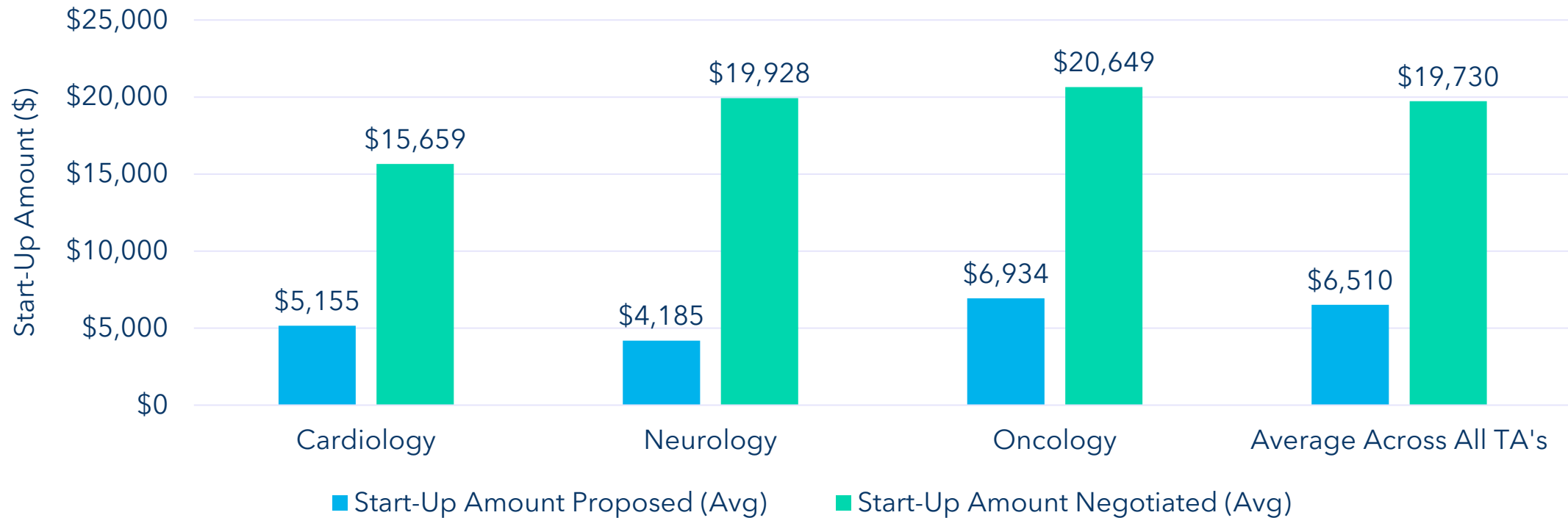


Longer Negotiations - Why?



Budget Negotiation Trends - 2023

Comparison of Start-Up Cost Negotiations

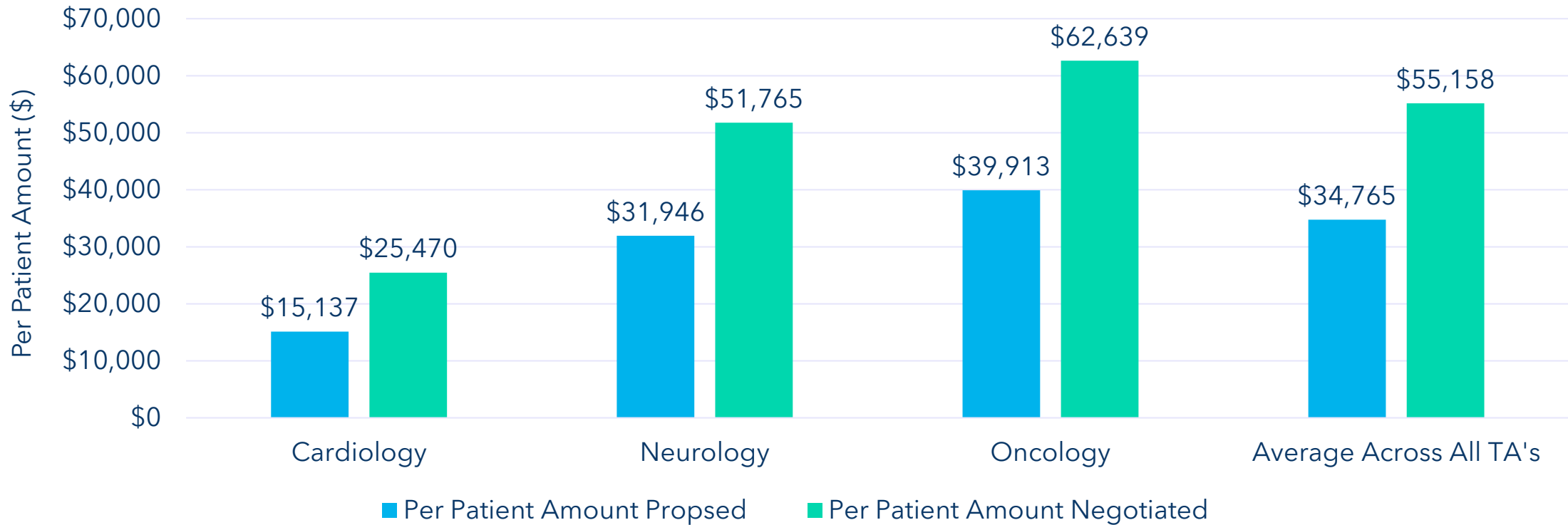


Longer Negotiations - Why?



Budget Negotiation Trends - 2023

Comparison of Per Patient Cost Negotiations

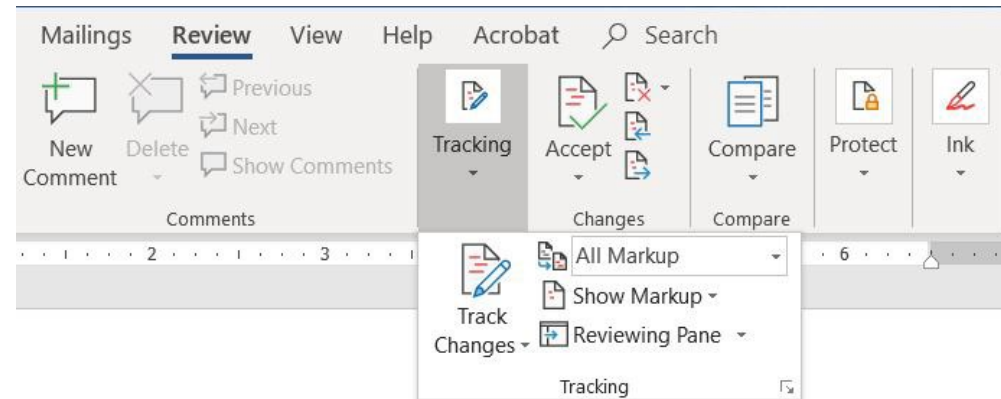


Longer Negotiations - Why?

Contract Negotiation Trends - 2023

Failure to Track Changes

- Poisons the well
- Slows down negotiations
- Reputational damage

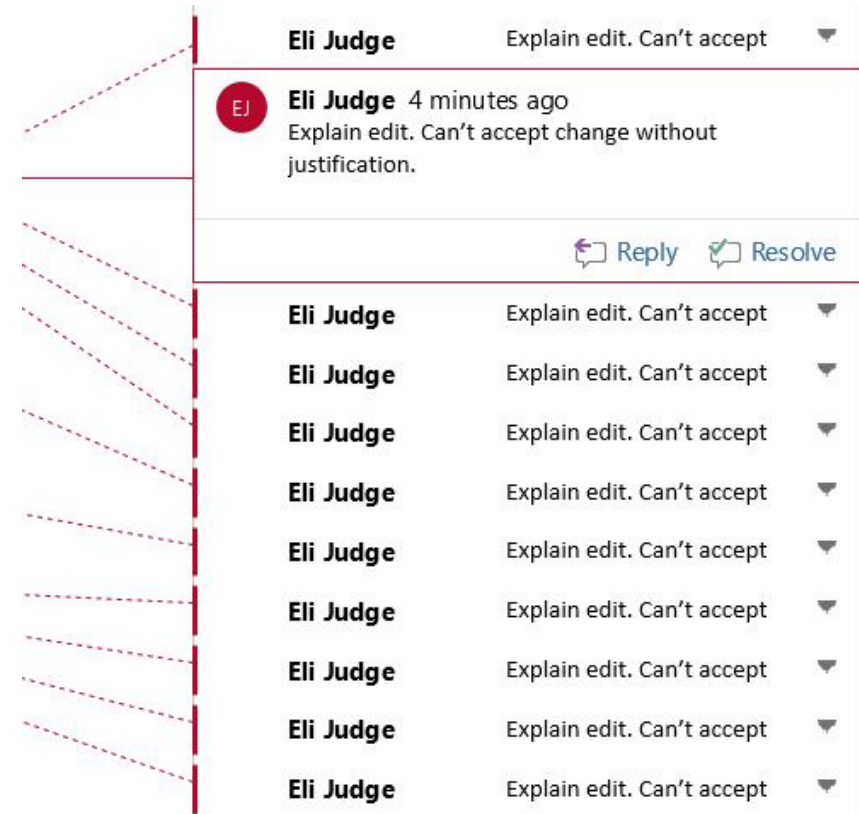


Longer Negotiations - Why?

Contract Negotiation Trends - 2023

Being Required to Justify ALL Changes

- We encourage providing meaningful rationale for changes and when rejecting edits
- HOWEVER...some sponsors/CROs lately require clarification on EVERY CHANGE
- Each side needs to bring knowledge and judgment to the table during negotiations



Longer Negotiations - Why?



Contract Negotiation Trends - 2023

Bad Habits

- Deleting language in chunks, just to replace with similar language in your “preferred” phrasing
 - Weave in the language you want; use as much of the template language as you can
- Rationale that simply says “[*Sponsor/Institution*] prefers this language” ≠ meaningful
 - We can infer that it’s preferred language if it’s being edited; WHY is it preferred / required?
 - Are there operational reasons why you can’t accept certain language? EXPLAIN!!

Solutions

- ***Get ahead of issues (identify your process hurdles)***
- ***Don't be part of the problem (negotiation delays).***

EQUIP your negotiators with information/knowledge.

BE CLEAR in your negotiation requests.

ASK QUESTIONS during negotiations.

BE PREPARED to negotiate!



Audience Questions

Polling Question 4

Would you like to learn more about WCG's coverage analysis, budget, and contract solutions for sites?

Don't forget to join us for part 3 of our series on Site Capacity on December 5th!

Thank you!



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