WEBINAR

Implementing ICH E8 R1 Recommendations Increases Site and Participant Relationship Scoring Measures

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Today's Presenters

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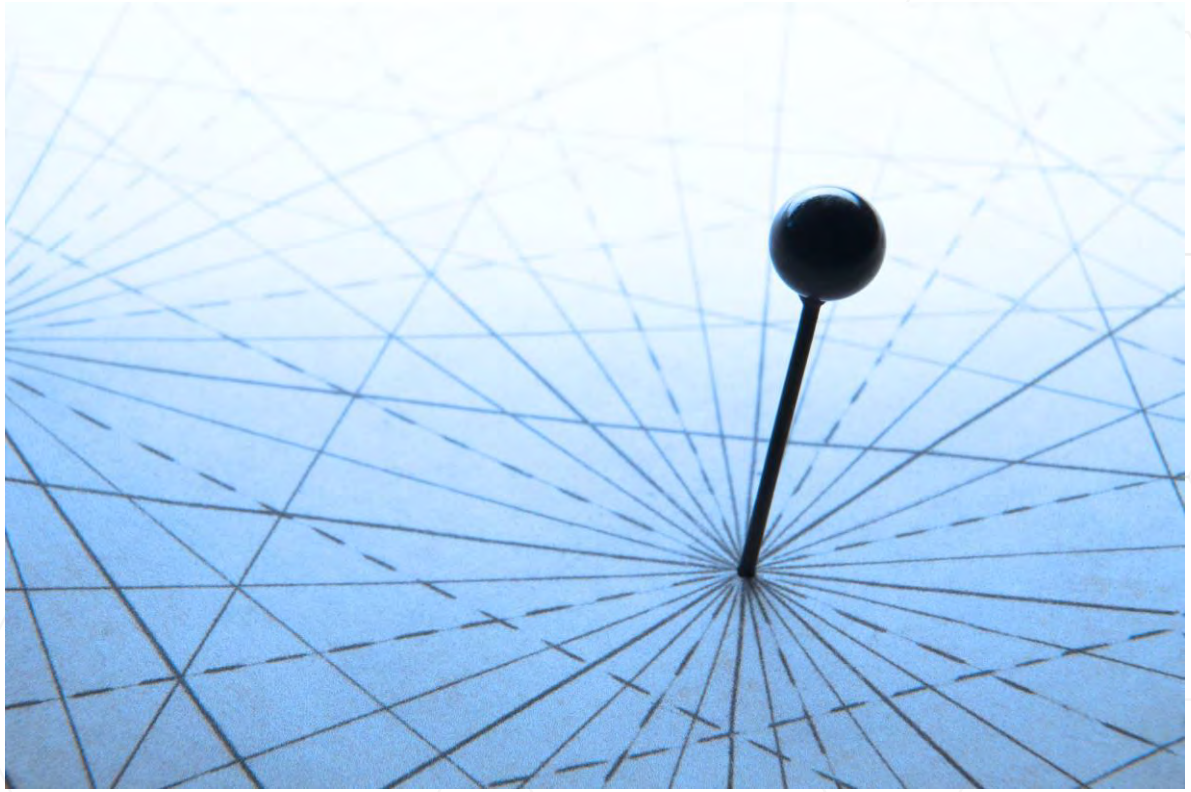
WCG

What is ICH E8 (R1)?

What is ICH E8, anyway?

A high-level guidance that serves as a general roadmap to other ICH Guidelines concerning clinical trials.



Key Themes in ICH E8 R1

- Quality by Design
- Critical to Quality factors
- Focusing on Activities Essential to the Study
- Engaging Stakeholders in Study Design
- Establishing a Culture that Supports Open Dialogue
- Using Multiple Sources of Data
- Checking Operational Feasibility

General Principles Key Differences

1

Protection

- Clinical Trial Subjects to Clinical Study Participants
- Adds that confidentiality of participants should be protected
- Speaks of ensuring that all assessments are necessary and undue burden is avoided for study participants

2

Scientific Approach

- Expansion of clinical trials designed, conducted and analyzed to include planned and reported according to sound scientific principles
- Quality by Design explicitly called out
- Focus on multi-regional development and partnering with regulatory authorities early

3

Patient Input

- Brand new section
- Encourages selecting endpoints that are meaningful to patients and developing drugs that are better tailored to patients' needs

WCG Industry Research

WCG Avoca 360 Assessment of the Clinical Research Industry

SITUATION

Industry and regulatory focus on **patient centricity is imperative** to ensure the survival of the clinical trial industry. Most Sponsor and Provider organizations base their study designs on feedback from investigators and patients who are familiar with the clinical trial industry. In order to expand the patient pool for clinical research, Sponsors must develop protocols that meet the needs of research naïve patients and investigators.

OBJECTIVE

This research looks across clinical research stakeholders -- Sponsors, Providers, Site Staff and Patients -- *regardless of their clinical trial experience* to **identify opportunities for improvement of the experience for Patients and Sites**.

Small population of physicians and patients contribute to what we know about motivations and impediments toward clinical trial participation

3%

of physicians participate in clinical research

<5%

of cancer patients participate in clinical research

CenterWatch Assessment of Global Site Relationship Benchmarks

SITUATION

Strong **sponsor and site relationships are essential for the success of clinical trials**. By working together, sponsors and sites can improve enrollment rates, reduce delays, and save money. They can also improve the patient experience, which is ultimately the goal of all clinical trials.

OBJECTIVE

Respondents identified the sponsors they worked with the most in the previous two years and rated their performance on the **47 attributes** included in the 2023 survey.

Poor communication and collaboration between sites and sponsors can lead to increased timelines and cost of clinical trials.

80%

of clinical trials fail to meet their enrollment goals

60%

of clinical trials experience delays

Clinical trials are unchartered territory

PATIENTS

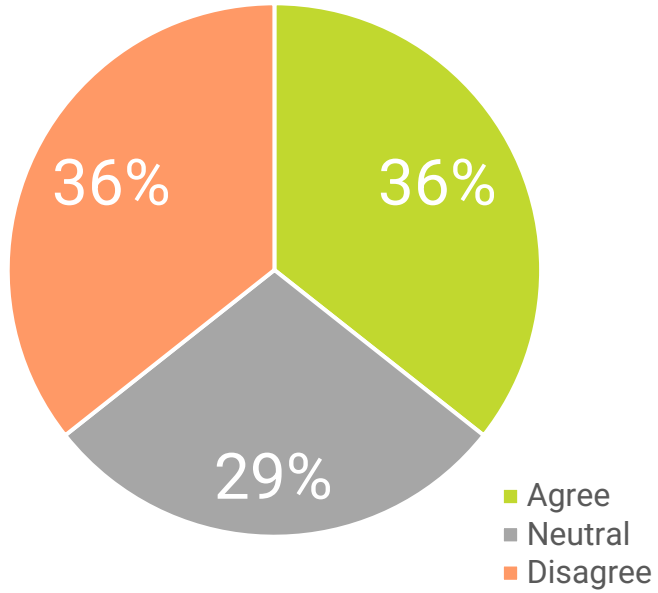
75%

*of national respondents have no personal experience with clinical trials**

> *Not open to trying things that haven't been proven to work.*
>
> *It would depend upon the trial and what was involved.*

> *They **seem very scary** and I feel usually they just look for the side effects and don't really care how bad a person can potentially get.*

I believe clinical trials only benefit the pharmaceutical companies that run them.



*No experience themselves and no friends/family who have participated
Base: N=200 National Respondents

In addition to ‘fear of the unknown,’ there are also “tangible” concerns

PATIENTS

86% *have concerns about **getting sick or feeling unwell***

> *What happens to our bodies by participating in these experiments is my biggest concern.*
>
> *Having significant side effects from the trial making my situation worse than it was before I got involved in the clinical trial.*

What am I committing to?

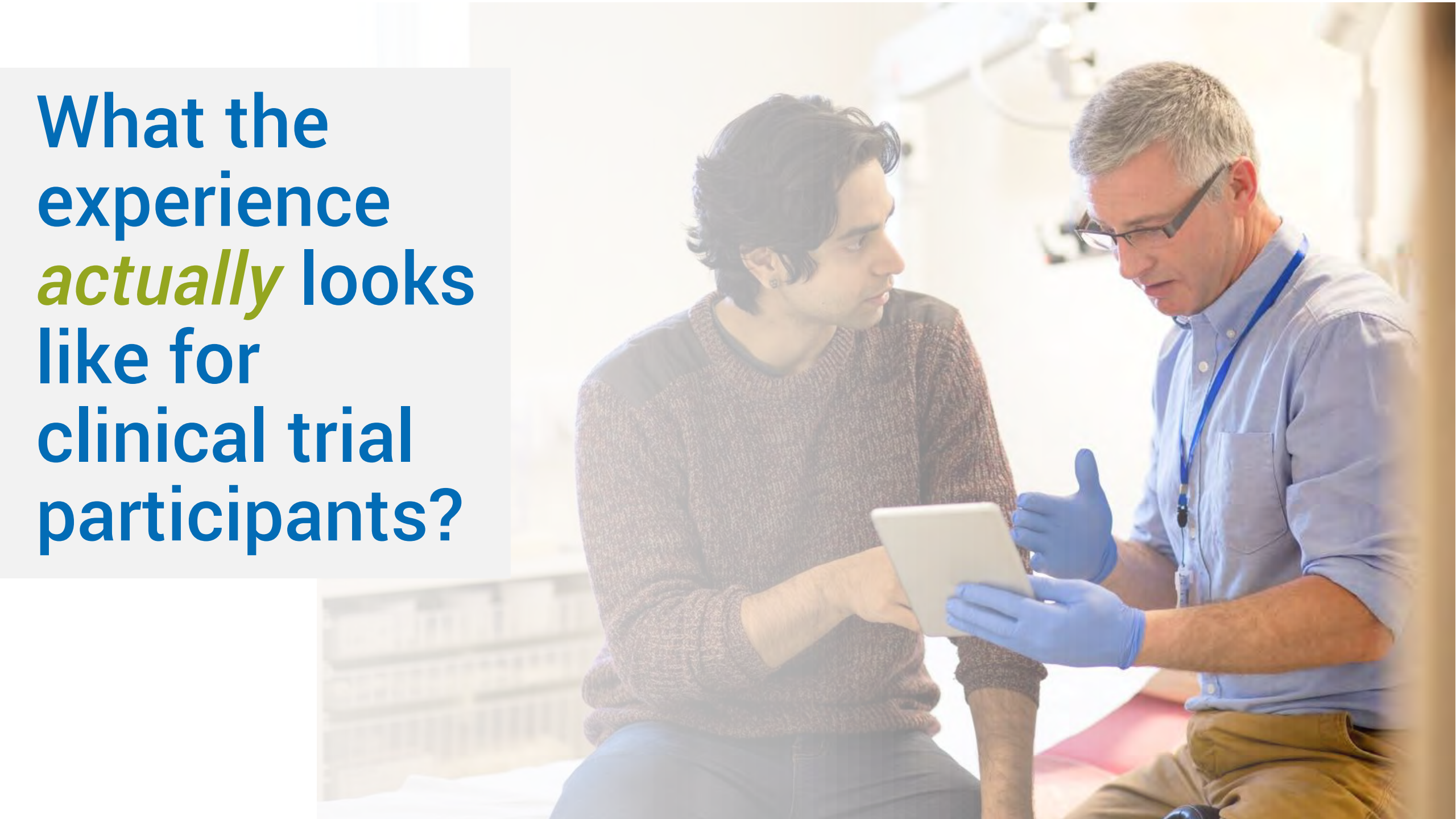
72% *have concerns about **time commitment***

80% *have concerns about **number of procedures** required*

83% *have concerns about **types of procedures** required*

Base: N=200 National Respondents

What the experience *actually* looks like for clinical trial participants?



Experiences are generally reported as being positive

PATIENTS

61% *said they had **no issues with feeling sick or unwell***

> *It was a good experience. My medical condition improved, and I was able to contribute to science. The medication is now approved and is helping people.*

What was the experience like?

72% *said their expectations on **time commitment** were met*

72% *said **tests and procedures** met expectations*

80% ***liked the healthcare professionals** they worked with*

Base: N=46 Clinical Trial Participants

Overall, they felt it was worthwhile and would participate again

PATIENTS

85%

agree that *'the time I spent participating in this clinical trial was worthwhile'*

90%

said they would *'definitely'* or *'probably participate in a clinical trial again in the future'*

"It was easy, the product being tested improved my skin, and I was paid - easy money.

Base: N=46/48 Clinical Trial Participants

Opportunity to leverage experience to attract new participants

PATIENTS

45%

*say that a **friend or family member** would be among their **most trusted sources** for information on clinical trials*

Base: N=200 National Respondents

Healthcare professionals represent even greater potential to connect with patients

PATIENTS

45%

*say that a **friend or family member** would be among their **most trusted sources** for information on clinical trials*

79%

*say that their **regular doctor or healthcare professional** would be among their **most trusted sources** for information on clinical trials*

Base: N=200 National Respondents

Understanding the site experience

Site staff generally agree that trials are designed with patients in mind and are likely to recommend participation to a friend

SITES

> *I have seen things **work miracles** for people that would've never even tried it because of cost.*

65%

agree that *'clinical trials are designed with patients/ volunteers in mind'*

82%

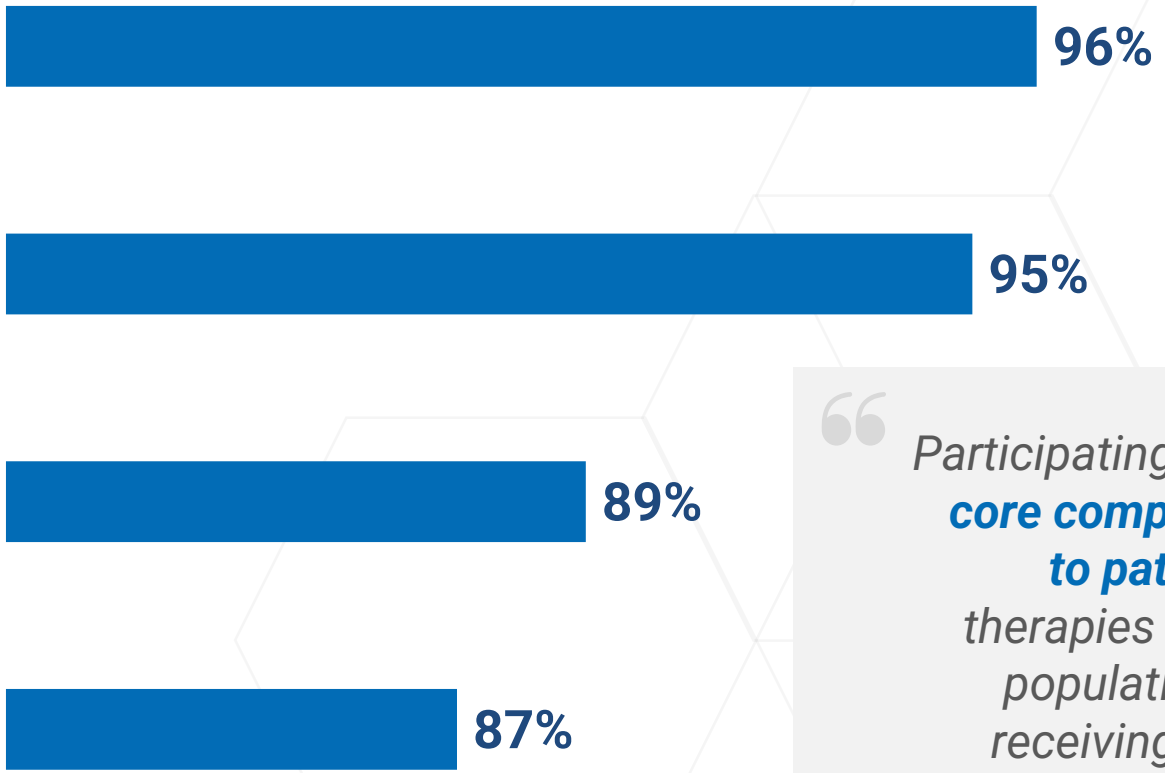
said they would *'definitely'* or *probably recommend participating to a friend or family member'*

Base: N=112/113 Site Sample

Sites have altruistic motivation for participating in trials

SITES

REASONS FOR PARTICIPATION



> *Participating in clinical research is a **core component to our dedication to patients**. Ensuring the best therapies available for our patient population is important to them receiving the best care possible.*

Base: N=112 Site Sample

Because of this, there is strong likelihood to participate again

SITES

84%

agree that *'the time I spent participating in this clinical trial was worthwhile'*

94%

said they would *'definitely'* or *'probably participate in a clinical trial again in the future'*

> ***Scientific innovation is exciting and groundbreaking, and it is fulfilling to be part of it.*** *Especially given the vulnerability of our patient population, it is motivating knowing that our work makes or will potentially make a difference in their lives.*

Base: N=112 Site Sample

That said, the site experience is not always “ideal”…

SITES

Start-Up

% strongly agree

31% *‘budget negotiation was timely & efficient’*

31% *‘contracting process was timely & efficient’*

Maintenance

% strongly agree

38% *‘protocol was clear & easy to follow’*

29% *‘study stayed on timeline’*

Closeout

% strongly agree

27% *‘compensated fairly & on time’*

> *“The benefits for people and the improvements in medicine, far outweigh the stress, incompetence, issues, faulty devices or changes that occur during a clinical trial. They are all different, but they all have issues in one way or another.*

Base: N=112 Site Sample

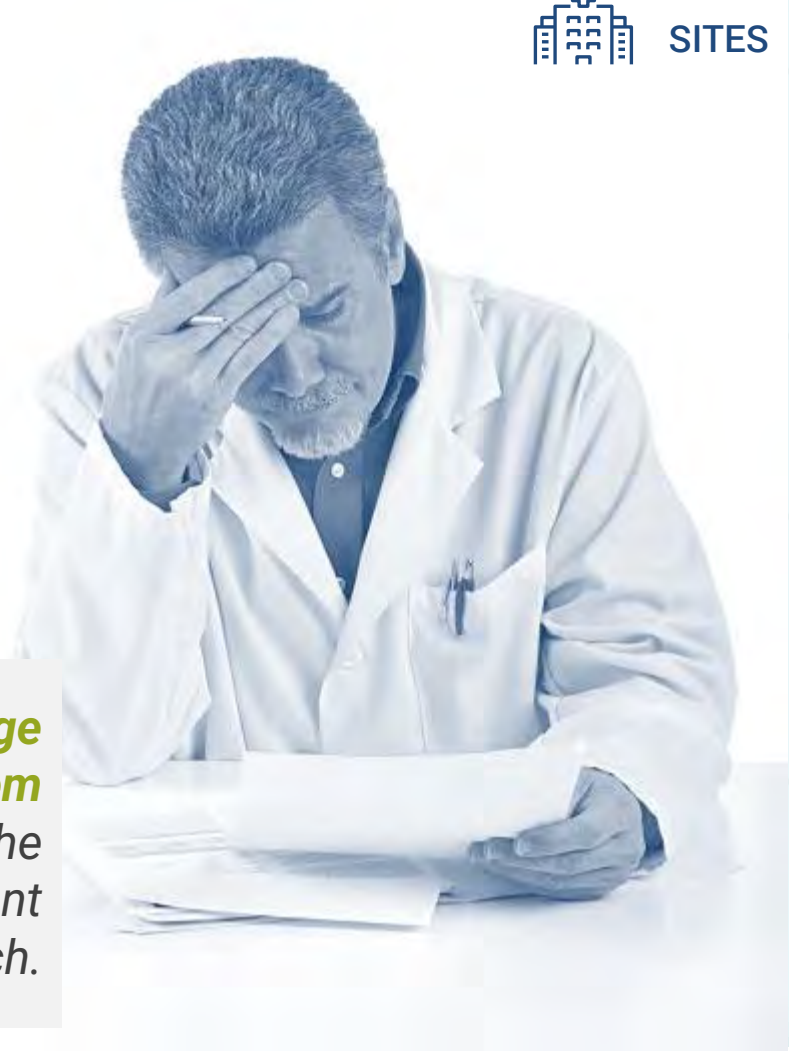
…and, only a minority feel that the site perspective is considered

SITES

15% *'strongly agree' that 'clinical trials are* ***designed with sites/site staff in mind'***

> ***ASK SITES FOR INPUT ON YOUR PROTOCOL***. *You are NOT an expert at boots-on-the-ground enrollment. As someone who is.*

> ***Put clinical trialist physicians, nurses & pharmacists in charge of the research divisions with sufficient authority to run them properly***. *It's clear that the companies are too interested in the financial aspects & care too little about the science or patient care aspects of pharmaceutical research.*



Base: N=112 Site Sample

Attributes with Lowest Sponsor Performance Ratings: 2023, 2021, 2019

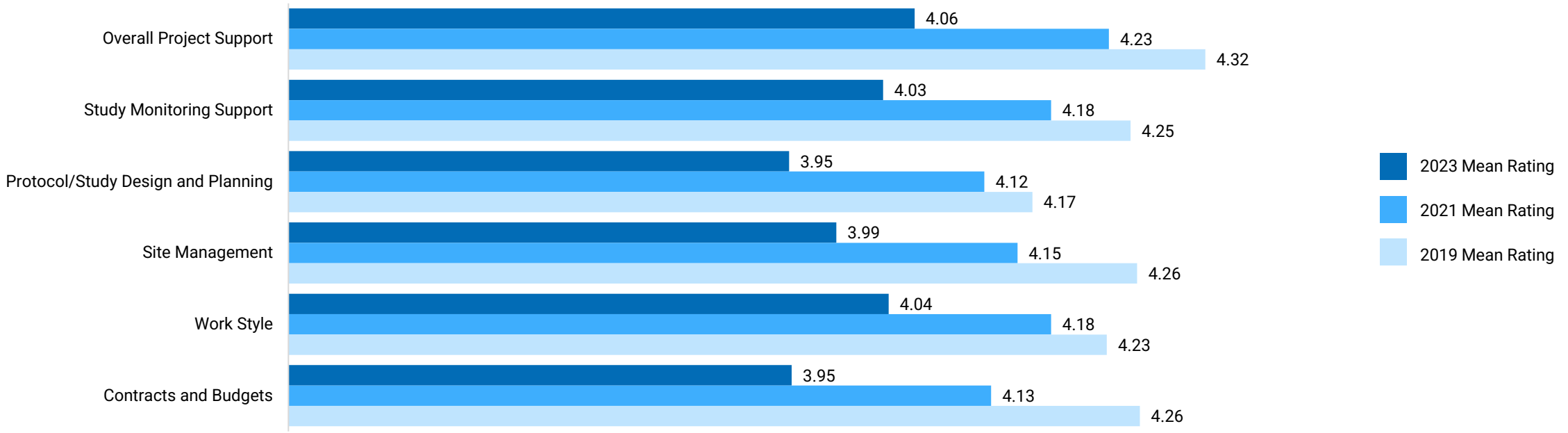
Sponsors' Lowest-Rated Attributes	2023 Mean Rating	2021 Mean Rating	2019 Mean Rating
Protocol patient-friendliness	3.91	4.19	4.31
Appropriate number of protocol amendments required	3.88	4.05	4.147
Ongoing solicitation of feedback from sites and acting upon it*	3.87	—	—
Solicitation and inclusion of feedback from sites in protocol design	3.83	4.04	4.07
Flexibility to modify protocols	3.81	4.06	4.17

*New attribute

2023 Sample Size = 3,623 | 2021 Sample Size = 3,719 | 2019 Sample Size = 4,182

Mean rating = average of all performance ratings provided on a scale from 1 to 5. Excellent is equivalent to 5 points. Very good is equivalent to 4 points. Good is equivalent to 3 points. Fair is equivalent to 2 points. Poor is equivalent to 1 point. Question as asked in 2023: *"Please evaluate the sponsor on the attributes below using a 1-to-5 scale, with "Poor" scoring 1 and "Excellent" scoring 5. Please rate only the attributes on which you worked directly with the sponsor. If an attribute does not apply or you don't know, select "N/A - Don't know."*

Sponsor Performance by Attribute Category: 2023, 2021, 2019



2023 Sample Size = 3,623 | 2021 Sample Size = 3,719 | 2019 Sample Size = 4,182

Note: Sites were asked to evaluate sponsors on 47 attributes.

Mean performance rating = average of all performance ratings provided on a scale from 1 to 5. Excellent is equivalent to 5 points. Very good is equivalent to 4 points. Good is equivalent to 3 points. Fair is equivalent to 2 points. Poor is equivalent to 1 point. Question as asked in 2023: *"Please evaluate the sponsor on the attributes below using a 1-to-5 scale, with "Poor" scoring 1 and "Excellent" scoring 5. Please rate only the attributes on which you worked directly with the sponsor. If an attribute does not apply or you don't know, select "N/A - Don't know."* These were grouped into six general categories.

Sponsor & Provider Point of View

SPONSORS & PROVIDERS

Site Burden: *Strain on time and staffing resources*

> ***Available resources to conduct a clinical trial.*** *Dedication of the investigator. Trained/skilled staff to conduct a specific trial.*

> ***Don't have the staffing****, don't understand the amount of staffing required,* ***don't have the time****, don't have the patient population.*

Base: N=112 Site Sample

…and, acknowledge their *own* role in creating potential obstacles

SPONSORS & PROVIDERS

> ***Overzealous protocols*** *and unclear information.*
>
> ***Bureaucratic start-up process*** *and tight budgets with lack of support from the Sponsor.*
>
> ***Overly complicated and constantly amended protocols.***
>
> *Start-up timelines, limited access to patient population,* ***potential benefit of trial vs. burden on patients/burden on staff.***

Complexity

> *Not being able to find the right patients to meet criteria. Not having enough time to conduct complex trials. And* ***even if the PI has a great interest in participating, some of those who coordinate may prefer a less complex trial to enroll subjects in because of the burden placed on them****.*

Key Take-Aways

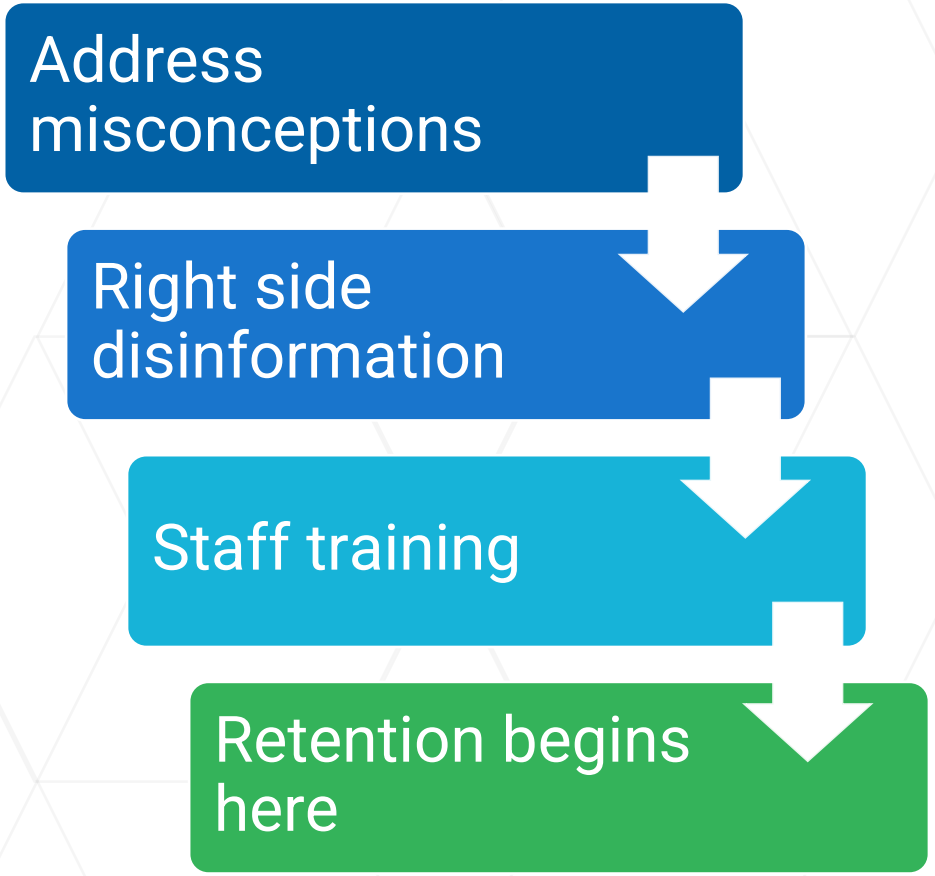
	FINDINGS	IMPLICATIONS
PATIENTS 	• Clinical trials are an “enigma” for most people • Though actual trial participants generally report a favorable experience, there is a lack of understanding and awareness among the broader population	→ Suggests a need to **raise awareness and educate** to inform and reduce barriers to participation
SITES 	• Site personnel are motivated to participate in trials, wanting the best for patients and insight into the latest science in their TAs • They truly believe in the good that clinical trials can offer, but the experience is not always ideal	→ **Site perspective needs to be elevated in importance** when designing trials
SPONSORS & PROVIDERS 	• Sponsors & Providers generally understand that Sites are motivated by altruistic reasons • That said, they realize that they are highly burdened by the strain on resources and complexity that trials bring	→ Indicates potential **need to revisit how trials are designed, staffed and compensated**

Industry Next Steps

Increase Education and Raise Awareness

Most Important Information Needed to Make a Decision
Potential risks and benefits
Purpose of the clinical research study
Information about the study drug being researched
Types of medical procedures required
How confidentiality will be protected
Results and information for earlier phase studies on the study drug
If summary of study results will be received
Potential costs and reimbursements
Length of participation in the clinical research study
Physical location of the study site

Participants who feel involved and informed during their clinical trial experience are more likely to enroll and be compliant.



[1]2021 CISCRP P&I Study

Transparency in Communications

Top 4 Reasons Participants Drop from Clinical Trials[1]
Poor communication with study site
Location of study site
Side effects of the study drug
Procedures during study visits were too cumbersome

Clear, frequent communication before, during, and after study participation will help foster willingness to participate in additional studies.

[1]2021 CISCRP P&I Study

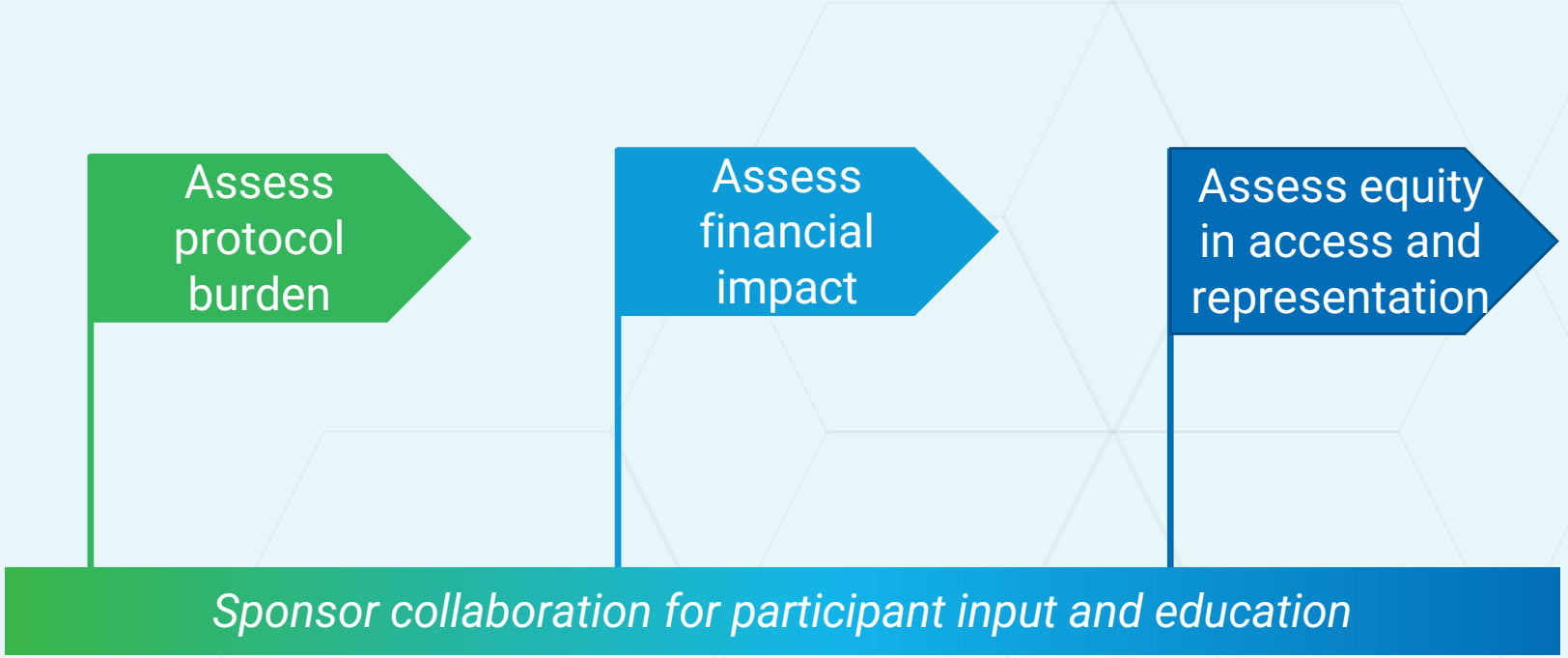
Participant Inclusion

8%

Amount of protocols that utilize a Patient Advisory Board (PAB)[1]

PAB input resulted in simpler protocols and more targeted designs

"The goal of clinical trials is to determine if a new test or treatment works and is safe." (NIH)



[1]Tufts Center for the Study of Drug Development

Available Now!

2023 WCG CenterWatch Global Site Relationship Benchmark Survey Report

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Thank you

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