Empowering Sites for Clinical Trial Success Webinar Series – Part 2

Decoding the Top Site Challenges of 2024: Recruitment & Retention

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Speaker Introductions

Amy Thue

Associate Director, Project Management at WCG

Kelly Wren

Sr. Scientist, Clinical Operations at Merck

Aaron Cooper

Site Director at Elixia

Miranda Olson

Manager, Site Services at WCG

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Today's Agenda

1. 2024 Site Challenges Report Overview
2. Data & Insights on Recruitment & Retention
3. A Site Perspective on Recruitment & Retention
4. How Merck is Helping Their Sites
5. Addressing Compounding Challenges & Identifying Strategic Solutions
6. Panel Discussion & Audience Questions
7. Conclusion

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Polling Question #1:

What type of organization do you represent?

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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

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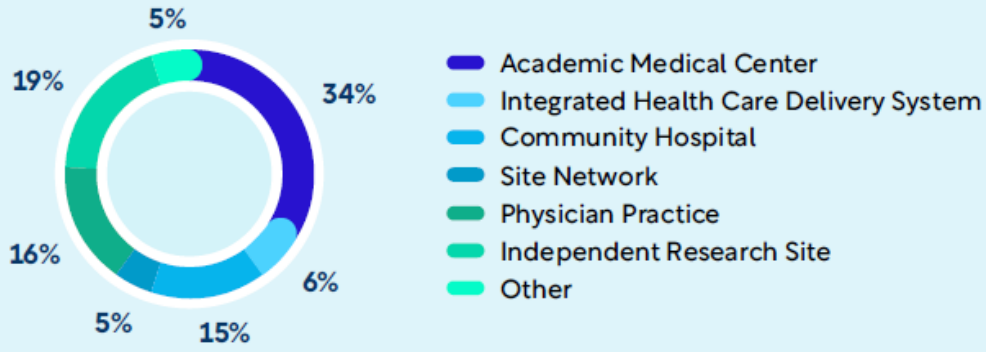
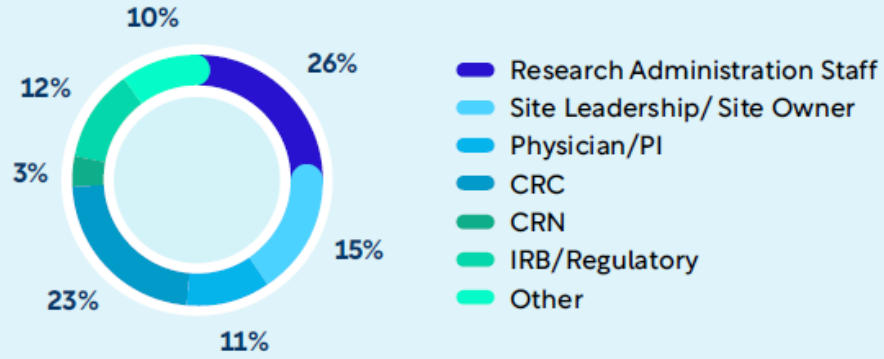
2024 Clinical Research Site Challenges Report - Background

Site Types, Job Titles, and Site Region

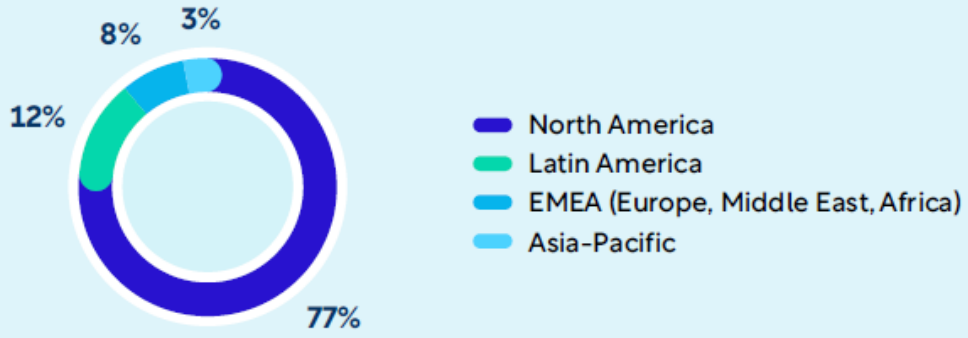
What type of research site do you represent?



What is your role at your research site?



What region is your site based in?



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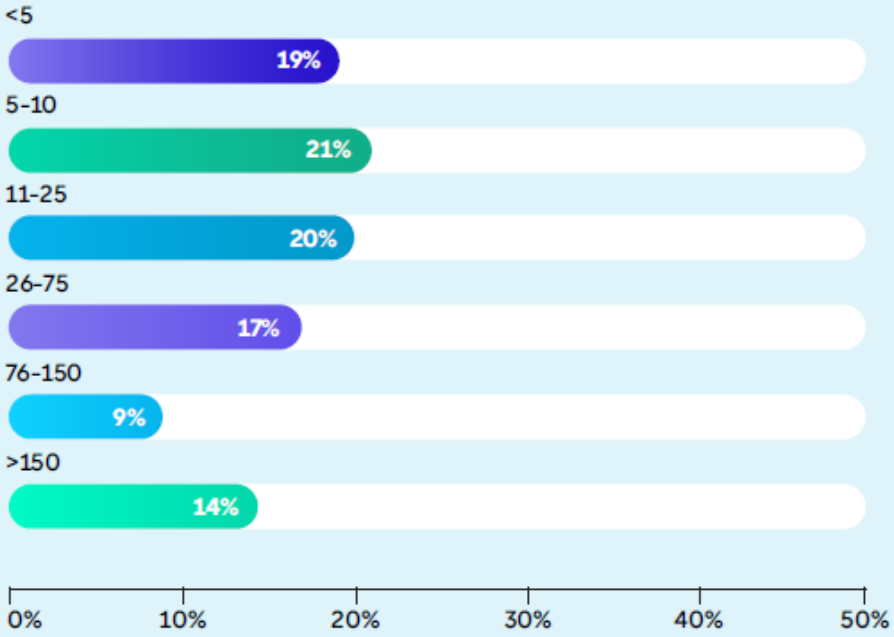
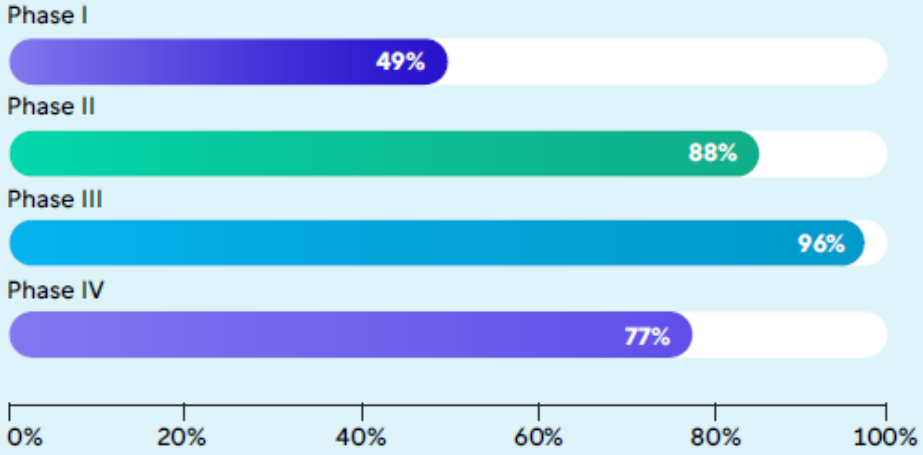
2024 Clinical Research Site Challenges Report - Background

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?



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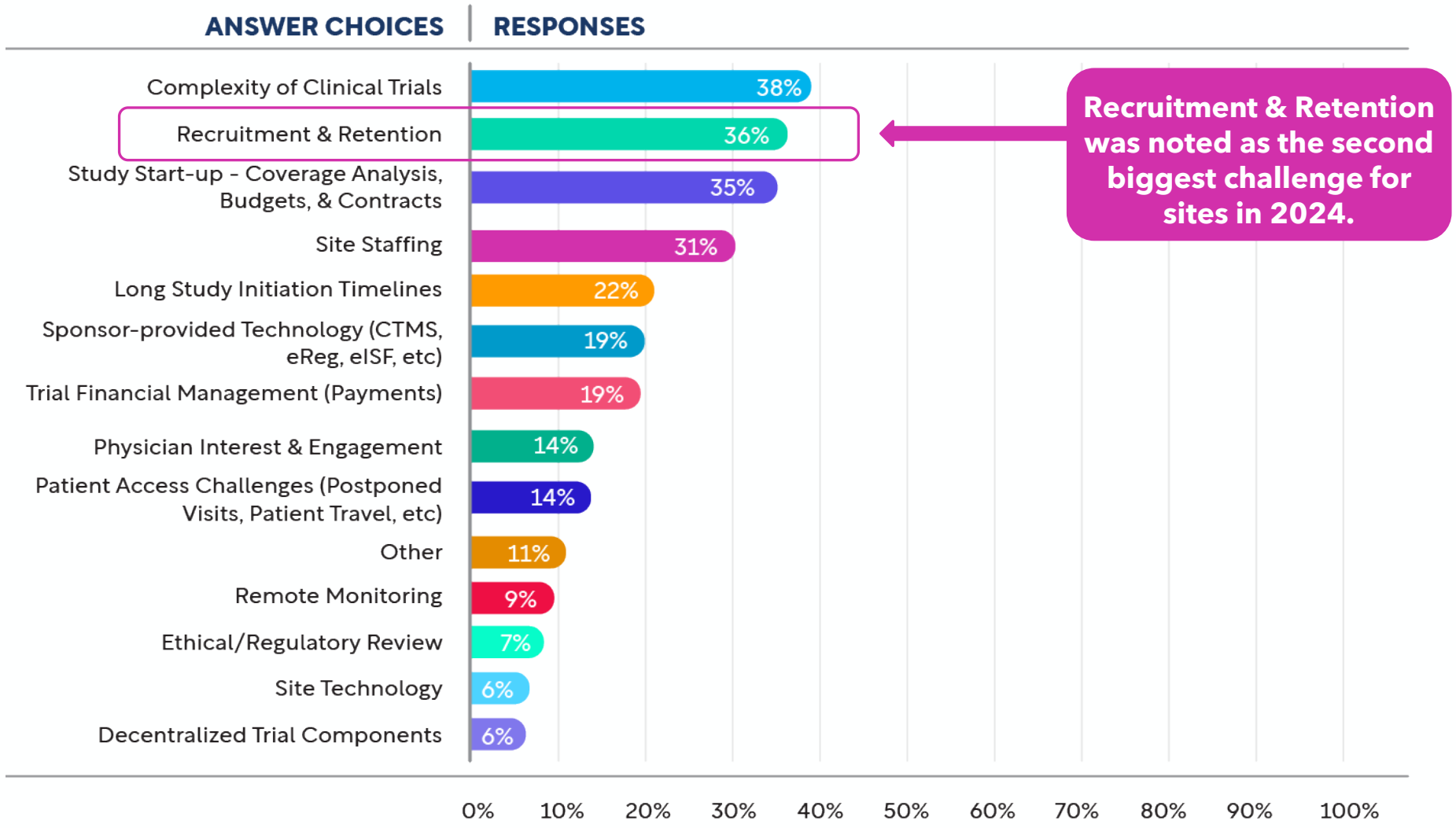
The Top Research Site Challenges in 2024

According to WCG's 2024 Clinical Research Site Challenges Survey



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The Top Research Site Challenges in 2023

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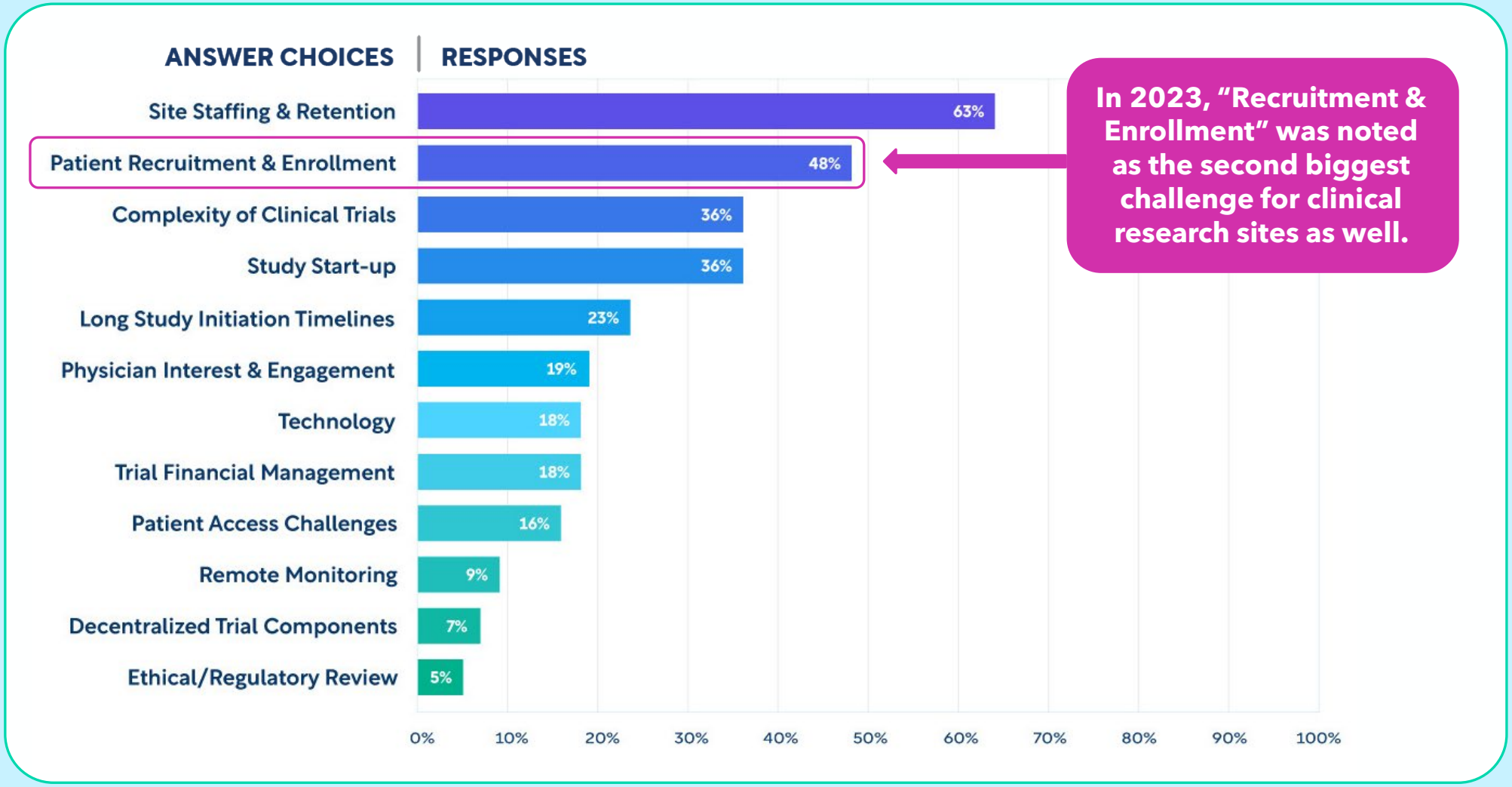

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Recruitment & Retention Challenges Persist

Understanding the Challenges Through Data and Insights

85%

of all clinical trials fail to recruit enough participants

80%

of delays in clinical trial timelines are due to recruitment and retention

37%

of sites selected for clinical trials do not meet enrollment targets

11%

of sites selected for clinical trials fail to enroll a single participant

Sources: Tufts CSDD, Cambridge University Press

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The Financial Impact of Recruitment & Retention Challenges

Examining the Financial Burden Across the Industry

$1.9 billion

is spent on recruitment efforts annually

32%

of overall trial costs come from recruitment, making it the largest cost driver for trials

$800k

average dollar value of lost or delayed prescription drug or biologic sales from one day delay in drug development

9 out of 10

trials ultimately double their original timeline in order to meet enrollment goals

Sources: Tufts CSDD, Cambridge University Press, Deloitte Intelligent Clinical Trials Report

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What Sites are Saying

Ways Sponsors and CROs Can Better Support Sites

Percent of sites and staff rating the impact of various operating approaches on patient participation experience:

Operating Approaches for Patient Participation Experience	Site Rating
Debit cards for patient expense reimbursement	58%
Transportation assistance	55%
Remote and telehealth visits	43%
Home health study visits	32%
Pharmacy-based study visits	26%

Percent of sites rating top areas for sponsors to address to better ensure their operating viability:

Areas for Sponsors to Address to Better Ensure Site Operating Viability	Site Rating
Ensure study budgets reflect true work efforts	67%
Ensure CRAs/study monitors are better qualified	54%
Simplify protocol complexity	47%
Solicit site input on study design and implementation	46%
Increase patient recruitment and retention support services	**41%**

Source: Tufts CSDD

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A Site Perspective on Recruitment & Retention

Aaron Cooper

Clinical Research Site Director, Elixia

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Recruitment & Retention Challenges

A Site Perspective

Unique Challenges Sites Face – Having a Dual Role: A Research Entity and Patient Advocate.

- **Research Entity:**
  - Conducting rigorous research by ensuring protocols are followed and generating high-quality data.
  - Coordinating with sponsors, CROS and other stakeholders to meet recruitment and study goals.
  - Upholding ethical standards in research and protecting participant safety and rights.

- **Patient Advocate:**
  - Creating a supportive and inclusive environment for participants from all backgrounds.
  - Ensuring participants fully understand the commitment and are informed throughout the process.
  - Tailoring outreach efforts to address cultural or socioeconomic factors that may hinder access.
  - Respecting participant autonomy, including their right to withdraw at any time without repercussions.

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Recruitment & Retention Challenges

A Site Perspective

Balancing the Two Roles –

- **Navigating Ethical Complexity:**
  - Balancing the need to meet recruitment targets and generate high-quality data with the ethical obligation to safeguard participant well-being.
- **Building Trust:**
  - Acting transparently and equitably to foster long-term trust with participants and the community.
- **Advocating for Diversity and Inclusion:**
  - Proactively engaging underrepresented groups to ensure equitable access to research benefits.
- **Enhancing Retention:**
  - Maintaining positive participant relationships through ongoing support and regular follow-ups, ensuring participants feel valued throughout the study.

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Site Participant Recruitment Challenges

A Site Perspective

- **Limited Participant Awareness and Understanding:**
  - Lack of knowledge about clinical trials in the general population.
  - Misinformation or distrust, especially in minority groups.
  - Site or recruitment staff educating the participant of clinical research trials.
- **Eligibility Criteria:**
  - Stringent inclusion/exclusion criteria reduce the pool of potential participants.

- **Competing Priorities:**
  - Competing with other research sites or trials for the same pool of participants.
  - Limited site resources to dedicate exclusively to recruitment efforts.
- **Operational Constraints:**
  - Insufficient staffing or time to focus on recruitment strategies.
  - Lack of tools to efficiently identify and reach eligible participants.

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Site Patient Retention Challenges

A Site Perspective

- **Patient Engagement and Communication:**
  - Participants feeling undervalued or disconnected from the research process.
  - Participants are people, a site has the ability to have a personal relationship with the participants to enhance the experience.
- **Participant Experience:**
  - Inconvenience or discomfort during visits (e.g., lengthy procedures, invasive tests).
  - Site internal operation logistics.
    - Put yourself in their shoes, how would you rate your experience?
- **Logistical Issues:**
  - Scheduling conflicts with work or family commitments.
  - Transportation difficulties or frequent site visits.

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Overcoming Recruitment & Retention Challenges

A Site Perspective

Limited Patient Awareness and Understanding

- **Community Engagement**: Conduct outreach programs such as health fairs, workshops, or seminars to raise awareness about clinical research.
- **Patient-Centric Education:** Use simple, culturally appropriate language to explain trial benefits and processes.
- **Build Trust:** Address misinformation by highlighting participant safety measures, oversight by regulatory bodies, and the informed consent process.

Eligibility Criteria

- **Early Feasibility Assessments:** Collaborate with sponsors to ensure inclusion/exclusion criteria are realistic and aligned with the patient population's characteristics.
- **Pre-Screening Tools:** Use pre-screening questionnaires and technology like EMR (Electronic Medical Records) searches to efficiently match participants with studies.

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Overcoming Recruitment & Retention Challenges

A Site Perspective

Competing Priorities

- **Site Differentiation:** Highlight the site's unique strengths, such as staff expertise, patient engagement programs, or efficient processes, to attract participants over competing sites.
- **Enhanced Recruitment Resources:** Allocate dedicated recruitment staff or freelance professionals to ensure focused efforts.
    - Use creative marketing strategies like targeted ads on social media to reach potential participants.

Operational Constraints

- **Leverage Technology:** Use CTMS (Clinical Trial Management Systems) or recruitment platforms to streamline the identification, tracking, and communication with potential participants.
- **Cross-Train Staff:** Train existing staff in recruitment best practices to optimize workforce efficiency.
- **Optimize Workflows**: Implement tools like checklists, workflows, and calendars to ensure recruitment tasks are prioritized and tracked efficiently.

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Sponsor Recruitment Challenges

A Site Perspective

Misalignment with Site Processes

- **Generic Strategies:** Sponsor-provided services often use standardized approaches that may not align with the site's specific patient population, local demographics, or established recruitment processes.
- **Lack of Flexibility:** Sites may find it difficult to integrate sponsor-driven recruitment campaigns into their day-to-day workflows.

Overpromising and Underdelivering

- **Unrealistic Expectations:** Sponsors may overestimate the effectiveness of their recruitment campaigns, leading to pressure on sites to meet unachievable enrollment targets
- **Insufficient Leads:** Recruitment services sometimes generate fewer leads than promised, leaving sites scrambling to fill gaps.
- **Increased Workload:** Sponsor-led efforts can generate a large volume of leads that require pre-screening, follow-up, and documentation, often without providing additional resources to handle the workload.

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Sponsor Recruitment Challenges

A Site Perspective

Limited Communication and Collaboration

- **Lack of Transparency**: Sites are often not included in the planning stages of sponsor recruitment efforts, resulting in misaligned goals and expectations.
- **Delayed Feedback Loops:** Sponsors may take too long to provide updates on campaign performance or fail to act on feedback from sites.

Poor Quality of Referrals

- **Ineligible Patients**: Referrals from sponsor campaigns often fail to meet the study's inclusion/exclusion criteria, leading to high screen failure rates and wasted resources.
- **Uninformed Participants:** Patients referred through sponsor efforts may have limited understanding of the trial, requiring additional time and effort from site staff to educate them.

Lack of Local Knowledge

- **One-Size-Fits-All Approach:** Recruitment efforts may not account for site-specific barriers, such as competition with nearby trials or regional healthcare dynamics.

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Overcoming Sponsor Recruitment Challenges

A Site Perspective

Suggestions to Address Challenges -

- **Early Involvement of Sites:** Sponsors should engage sites during the planning phase to align recruitment strategies with local needs.
- **Competing Site Geographical Locations:** Determine geographic locations of competing sites and compare to target of advertisements to identify referral challenges. Are you in the same zip code as another site that will be receiving referrals?
- **Customized Campaigns:** Could materials and approaches be tailored to the site's patient population and community.
- **Regular Communication:** Ongoing dialogue between sponsors and sites is essential to adjust strategies and improve outcomes.
- **Resource Support:** Sponsors should provide sites with additional resources, such as recruitment coordinators, funding, or technology tools.

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Partnering with Healthcare Providers

A Site Perspective

How Can a Site Partner With Healthcare Providers?

- **Build Trust and Relationships with Healthcare Providers**
- **Establish Mutual Goals:**
  - Emphasize the shared objective of improving patient care through clinical research.
  - Showcase how the trial outcomes can align with the provider's goals, such as access to innovative therapies.
- **Regular Engagement:**
  - Organize meetings, webinars, or workshops to educate providers about your clinical trials.
  - Maintain consistent communication to keep them informed about new and ongoing studies.
- **Educate Providers on Clinical Trials**
  - Simplify trial details and offer training.

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Partnering with Healthcare Providers

A Site Perspective

Create Referral Pathways -

- **Streamlined Referral Process:**
  - Design a simple process for providers to refer patients, minimizing their administrative burden.
  - Use tools like referral forms, electronic medical record (EMR) integration, or dedicated points of contact at your site.
- **Provide Value to Healthcare Providers:**
  - **Access to New Treatments:** Highlight how their patients can benefit from cutting-edge therapies not yet available in the general market.
- **Collaborate on Community Outreach:**
  - **Joint Awareness Campaigns**
  - **Culturally Tailored Outreach:** Work with providers to develop outreach materials tailored to cultural and linguistic needs of their population.

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Partnering with Healthcare Providers

A Site Perspective

Recognize and Address Provider Concerns -

- **Clarify the Workload Impact:** Reassure providers that referring patients will not interfere with their clinical practice or create extra administrative burden.
- **Patient Retention and Care Coordination:** Ensure providers that referred patients will continue to receive quality care and that their involvement in trials will not compromise ongoing treatments.
- **Feedback:** Set up systems for providers to share feedback and receive updates about referred patients' progress.
- **Measure and Adapt Collaboration Efforts:** Monitor referral rates, enrollment numbers, and feedback from providers to evaluate the partnership's effectiveness.

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MERCK

How We Help Our Sites

By Kelly Wren, Senior GTOS (DRS) at Merck

Challenges Sites Are Facing

- Staff shortages
- Increasingly complex trials
- Overburdened with multiple systems which change from trial to trial
- Recruitment and retention challenges
- Keeping up with administrative tasks
- Following up with patients and possible patients
- Study start-up complexities

What Are We Doing to Support Our Sites?

- Well Planned Investigator Meetings
- Enrollment Support Materials
- Site Augmentation
- Patient Reimbursement
- Patient Enrollment Management Platform
- Clinical Trials Website Platforms
- Recruitment & Retention Support
- Recruitment Refresher Training

Investigator Meetings

- Gallery walks featuring our supporting vendors, websites and enrollment support materials.
  - This allows our vendors to showcase their capabilities directly to the sites.
- Detailed presentations which go through the protocol and the patient's journey in its entirety.
- Sessions to give a detailed explanation of the type of recruitment and retention support is planned in support of our sites.
- Discussions with other sites so sites can learn from each other's successes and failures.

Enrollment Support Materials

Personalized enrollment support materials are created for each individual trial in which Merck is running and translated for use for each country that is a part of that trial's country footprint.

- **The materials are developed in order to:**
  - To aid in the conversations the site is having with potential patients and caregivers about the trial and what will be required of them.
  - Aid patients in keeping up with appointments, drug regiment routine and much more.
  - Marketing materials are developed (posters, flyers, etc.), in which sites can use in their own recruitment efforts.
  - Presentations and letters are developed to aid the sites in conversations in which they are having with area physicians about the trial.

Site Augmentation Support

- Providing sites with support staff to conduct the studies when needed.
- This support allows sites to continue their work in support of our trials while they are finding/training a full-time employee replacement.
- We have created a fully automated solution in which our CRMs/CRDs can submit a request for site augmentation support which is first reviewed by our TIS team and then by our GTO team for approval.
    - All approvals are communicated automatically via email to not only our internal teams but also our vendors.
    - Our internal team is also able to automatically able to keep track of the status of all the requests so the site can be updated accordingly.

Patient Reimbursement

- We have worked with our country colleagues in order to collect information around what is allowed and what is not allowed within their country around patient reimbursement.
- Using this information, our sites can use our patient reimbursement vendor without it hitting their study budget.
- The solution is easy for the sites and patients to use, while allowing patients to get reimbursed for everything from milestones, travel, meals, hotel stays, etc.
- In order to take the stress off the patient and the site the vendor will:
  - Book flights and hotels for the patients/caregivers as needed.
  - Book car services for the patient/caregivers as needed.

Patient Enrollment Management Platform

Our Patient Enrollment Management Platform allows sites to:

- Prepare for effective pre-screening.
- Improve clarity and specificity within our protocol's schedule of activities to prevent lost time due to follow-ups.
- Make it easier for sites to receive and process patient referrals, saving the site's time and effort.
- Providing sites with a digital patient database for cross-trial use. Allowing them to more quickly identify candidates.
- It includes online learning capabilities to reduce the burden of onboarding.
- It identifies why patients are voluntarily dropping out of the enrollment funnel which in turn removes barriers to site enrollment goals.
- Improves clarity within any protocol amendment to prevent lost time due to follow-ups.
- Makes it easier for sites to submit and review slot requests to reduce enrollment delays.
- Predicts enrollment risks which allow us to support sites sooner.

Clinical Trials Website Platforms

- Our website platform was released in 2023 and currently supports 18 countries with 6 more planned within Q4 2024 and Q1 2025.
- This platform features all the trials in which Merck is currently supporting and pulls all of its content from ClinicalTrials.gov.
- Our website automatically pulls all of its information from ClinicalTrials.gov. So once a trial begins to actively recruit or a new site comes live – it is pulled to our website.
- Our team also has the ability to create customized websites for their program or trials and tie them to recruitment campaigns with multiple vendors.
- For countries that are not currently a part of our platform's country footprint we can simply stand up a standalone website in order to support that country.

Recruitment & Retention Support

- We deal with many recruitment and retention support vendors to support our sites.
- Sites have the ability to opt in to the support or opt out.
- All of our recruitment campaigns are tied back to our clinical trials website platform. So, there is no need to create a new website each time we have a recruitment campaign tied to it.
- If there is a pre-screener tied to a particular trial or program that pre-screener is placed on our website and the pre-screener process is done by our vendors.
- We have integrated all of our vendors systems into our platform so that patients can see all of studies in one place.

MERCK

Thank you!

Addressing Compounding Challenges in Recruitment & Retention

By Miranda Olson

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Compounding Challenges Require Connection

41% of sites noted increasing patient recruitment and retention support services as a top area for sponsors to address to better ensure their operating viability.*

Complexity =
Need for a Fit for Purpose Solution

A Fit for Purpose Solution is:

- Qualitative *and* Quantitative
- Tailored
- Flexible
- Integrated

*Source: Tufts CSDD

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Communication in Action – Study Example

What Do We Know?

- **Study enrollment is at 400/500 patients (80%).**
- **Study has been open for 1 year.**
- **2 months remaining.**
- **Average screenings per site has declined in the last few months.**
- **Each site on the study would need to enroll 2 patients on average in 2 months to meet the enrollment target on time.**
- **Sponsor is implementing a media campaign to identify patients for a last push to bring additional potential participants to sites.**

Site A

Enrollment Goal: 8
Screenings: 7
Enrollments: 5

Opted out of media campaign

Site B

Enrollment Goal: 6
Screenings: 1
Enrollments: 1

Opted into media campaign

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Communication in Action 📞

Context is Key to Deliver a Solution That Will Work!

Site A

Enrollment Goal: 8
Screenings: 7
Enrollments: 5

Site reviewed their database but 4 months ago 1 of their 2 study coordinators moved to a new role. Site recently hired a new coordinator to fill this role who will not start and be fully trained in for 3 months.

Site has moved focus to training new hire, maintaining enrolled participants, and patient care. Once study coordinator is fully trained in, site will refocus efforts on enrolling on trials.

Site B

Enrollment Goal: 6
Screenings: 1
Enrollments: 1

Site recruitment team flags patients coming into the clinic who may qualify for the study to discuss when patient is onsite. PI sees 10 patients on average per week with who may qualify.

Site is participating in the media campaign to boost the number of potential participants to enroll and has capacity to enroll more patients.

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Site B

Compounding Challenges & Strategic Solutions

Balancing other time sensitive study priorities

Balance of recruitment and retention activities

Potential participant education, availability and interest

Large database for retrospective chart review

Establishing connection with media referrals

Prospective chart review

Dedicated WCG CRC support that is:

Tailored to the specific current challenges of both the study and site.

Integrated into the site's systems and processes.

Flexible as needs are met and priorities change.

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Site B

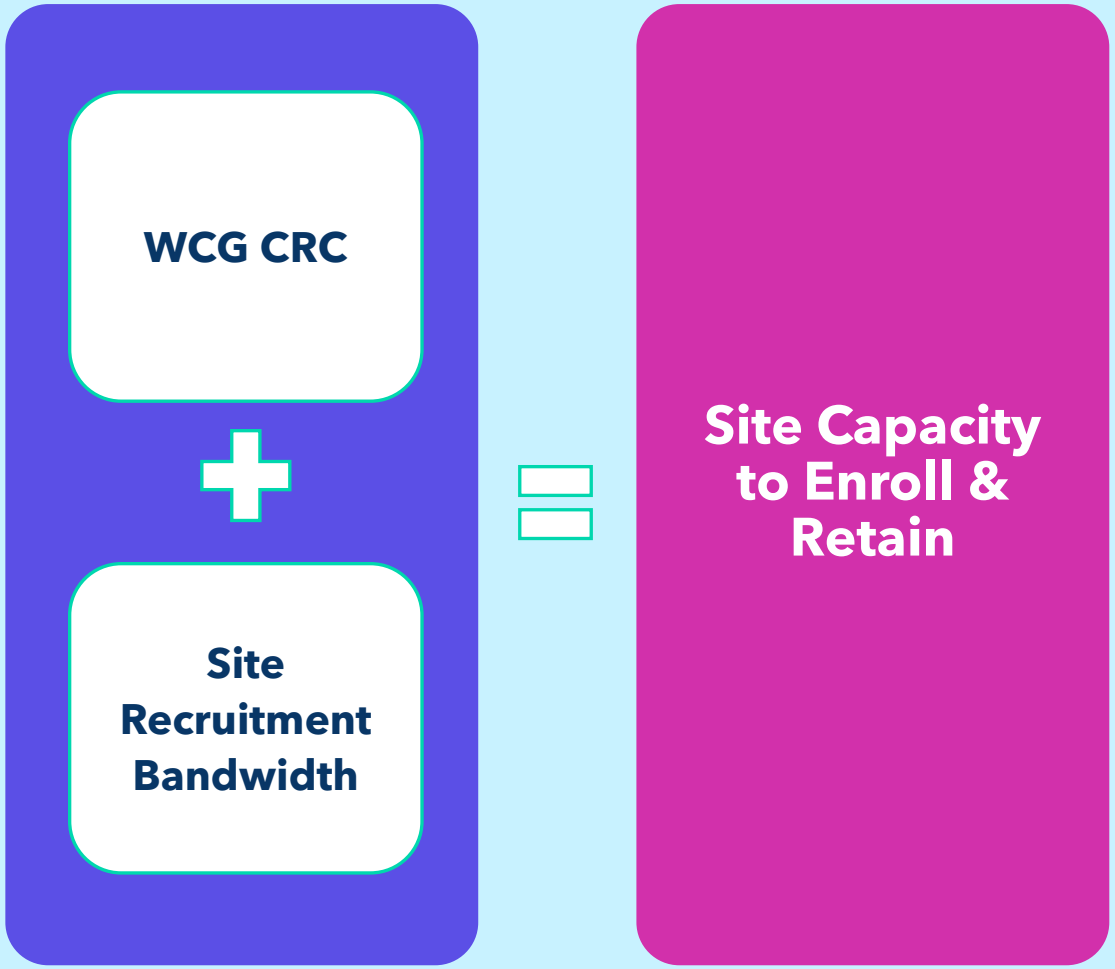
Deploying Strategic Solutions

Tailored Solutions:

Identify
- Full retrospective database review.

Enroll
- Contacting the identified individuals, informing them of the study, assessing their qualifications and gauging interest.
- Media Referral Processing.

Looking Ahead
- Ability to pivot support as needed.
- To support Study Coordinator in retention duties as patients enroll into the trial and site reaches their enrollment capacity.



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Overcoming Recruitment Challenges

Recruitment Challenges are Complicated, but the Solutions Don't Have To Be.

- **Establishing open** communication channels between teams to best support study.
- **Tailoring integrated** support plans designed to accelerate study activities and address specific challenges of the study *and* site.
- **Maintain clear and consistent** communication channels throughout the duration of the study between sponsor/CRO and site.

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Panel Discussion & Audience Questions

Don’t Forget to Register for Part 3 of our 2024 Site Challenges Webinar Series!

Part 3: Study Start-up – December 12th

wcgclinical.com/events

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

www.wcgclinical.com/challenges

wcg™

Polling Question #2:

Are you interested in learning more about WCG's Site Enablement solutions for sites or Recruitment & Retention solutions for sponsors/CROs?

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Thank you!

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