Thriving in Clinical Research – Overcoming Common Challenges as a Site

A Three-Part Series - Webinar 1:
Participant Recruitment & Retention

Introductions

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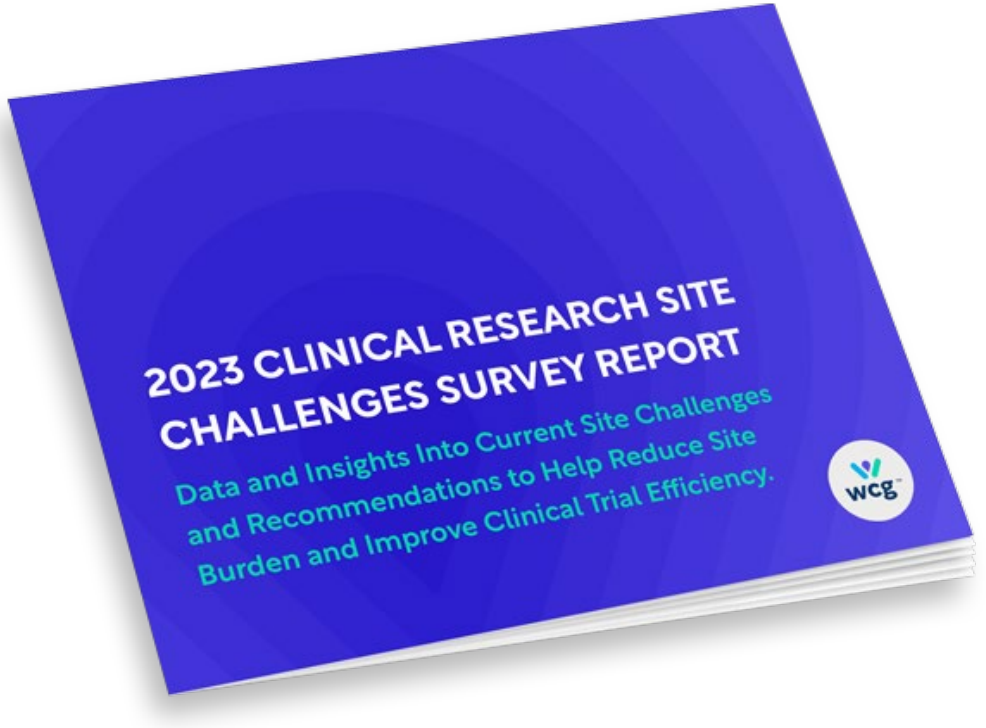
Today's Agenda

1. WCG 2023 Site Survey Overview and Current Market/Site Support Trends
2. Recruitment and Retention: The Participant Pathway
3. A Closer Tactical Look: Identification
4. Conclusion and Audience Questions

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.

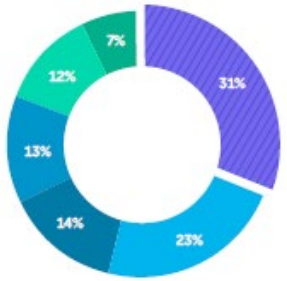


Full report can be downloaded for free at:
www.wcgclinical.com/2023-site-challenges-report

2023 Site Challenges Survey Report - Background

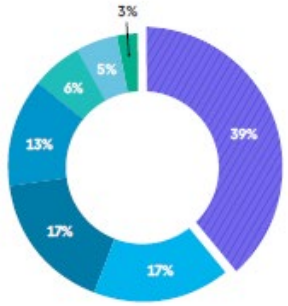
What is your role at your research site?

ANSWER CHOICES	RESPONSES
Research Administration Staff	31%
CRC/CRN	23%
IRB/Regulatory	14%
Site Leadership/ Site Owner	13%
Physician/PI	12%
Other	7%



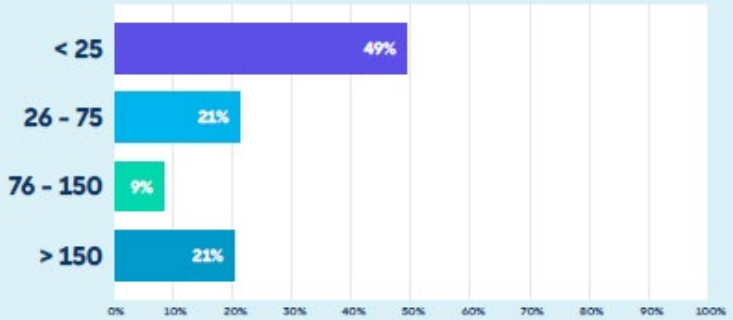
What type of research site do you represent?

ANSWER CHOICES	RESPONSES
Academic Medical Center	39%
Physician Practice	17%
Independent Research Site	17%
Community Hospital	13%
Integrated Health Care Delivery System	6%
Site Network	5%
Other	3%



- **31% of respondents are research admin staff**
- **23% are CRCs/CRNs**
- **39% of respondents are from AMCs**
- **17% are from physician practices**

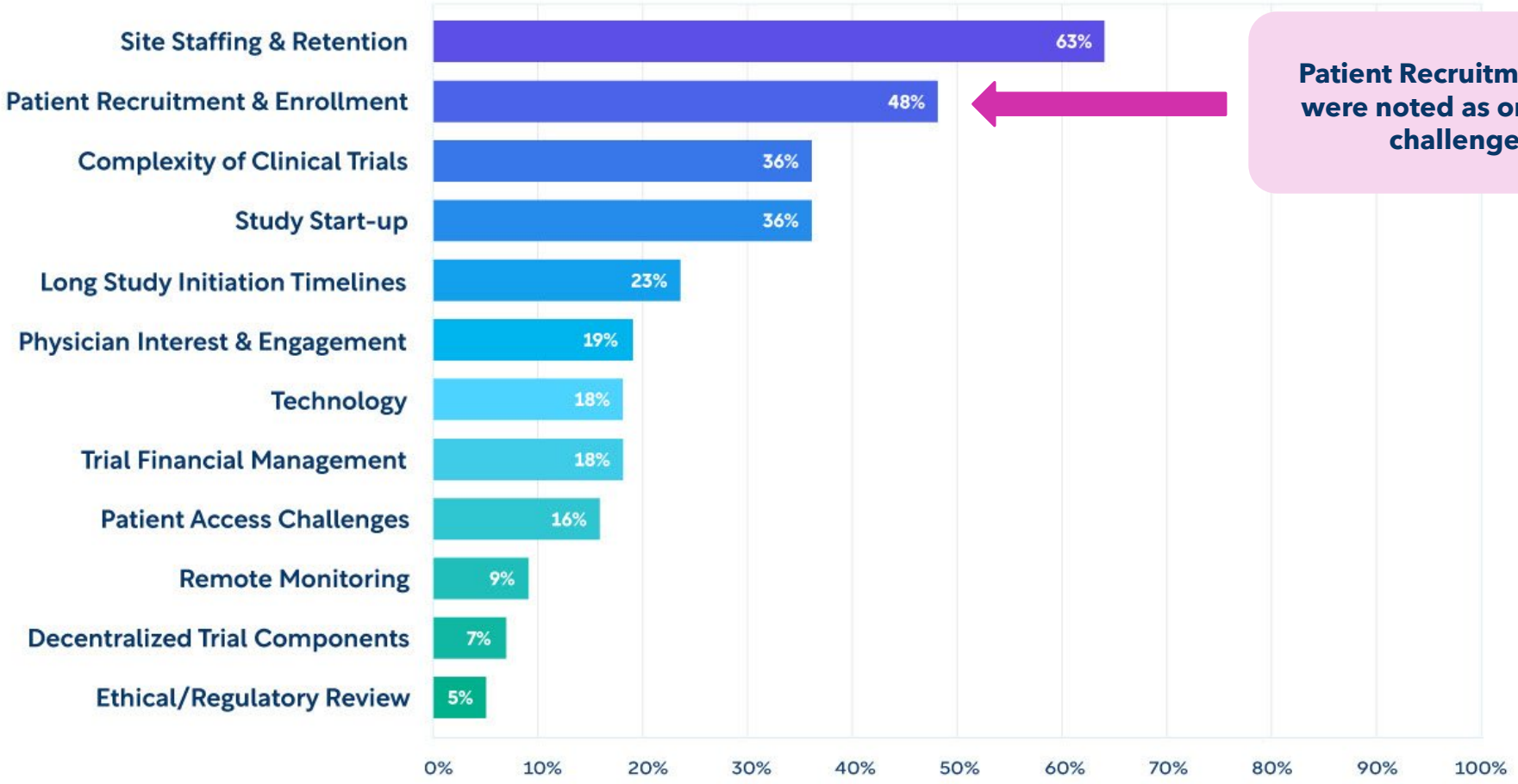
Please select the current number of open and enrolling trials at your site:



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

Survey Results - Top Issues Impacting Research Sites

What are the top issues impacting your site today?



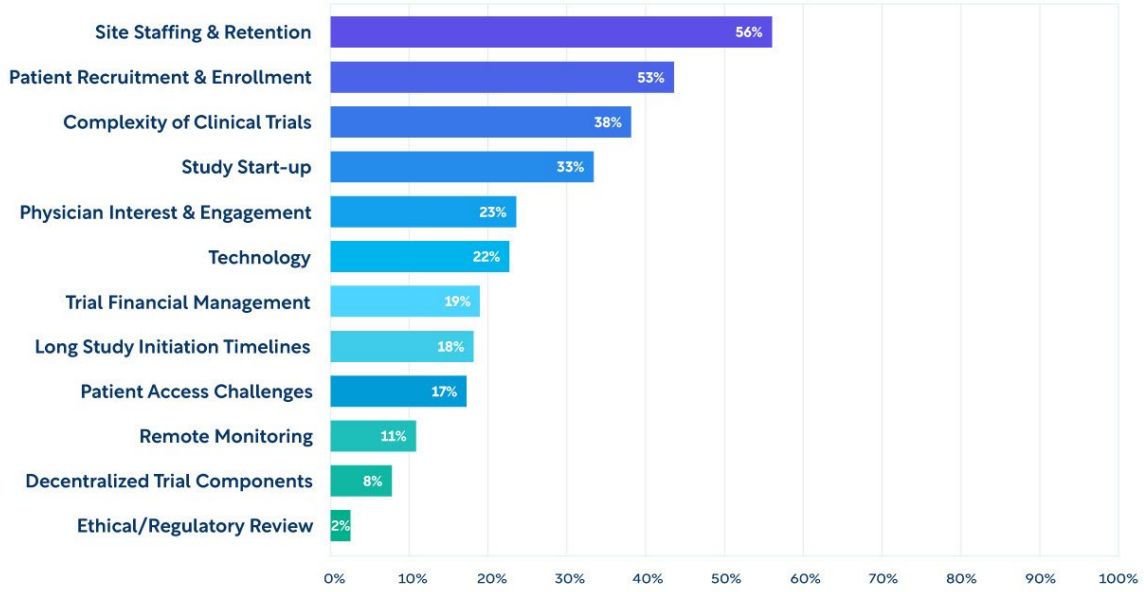
Patient Recruitment & Enrollment were noted as one of the leading challenges for sites.

WCG's 2023 State of Sites & Site Capacity Survey

Top Issues Impacting Research Sites – AMCs vs Non-AMCs

AMCs

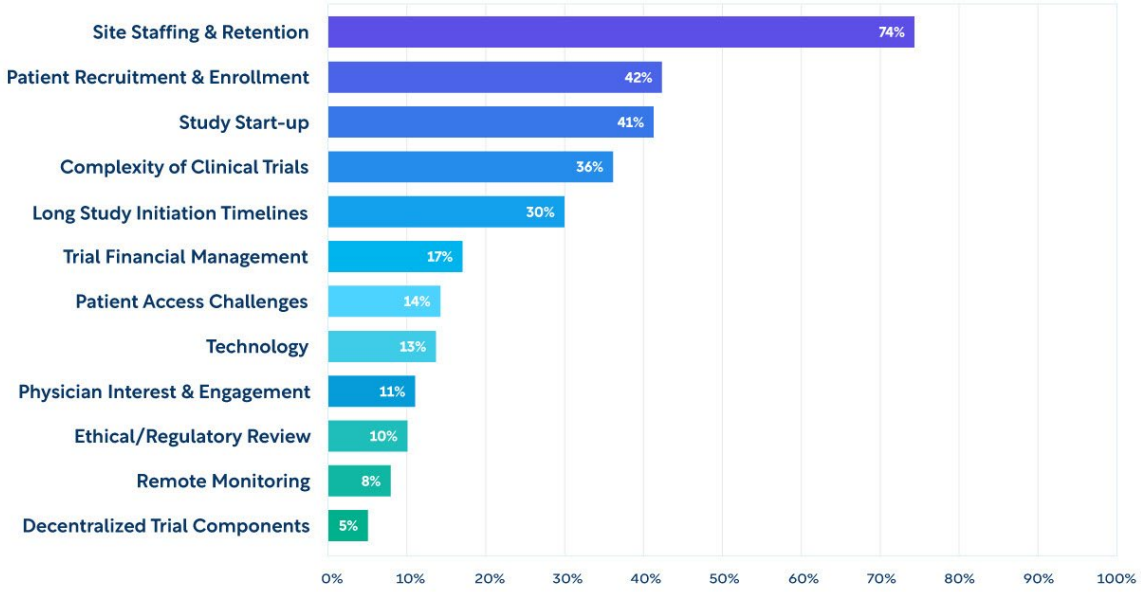
What are the top issues impacting your site today?



WCG's 2023 State of Sites & Site Capacity Survey

Non-AMCs

What are the top issues impacting your site today?

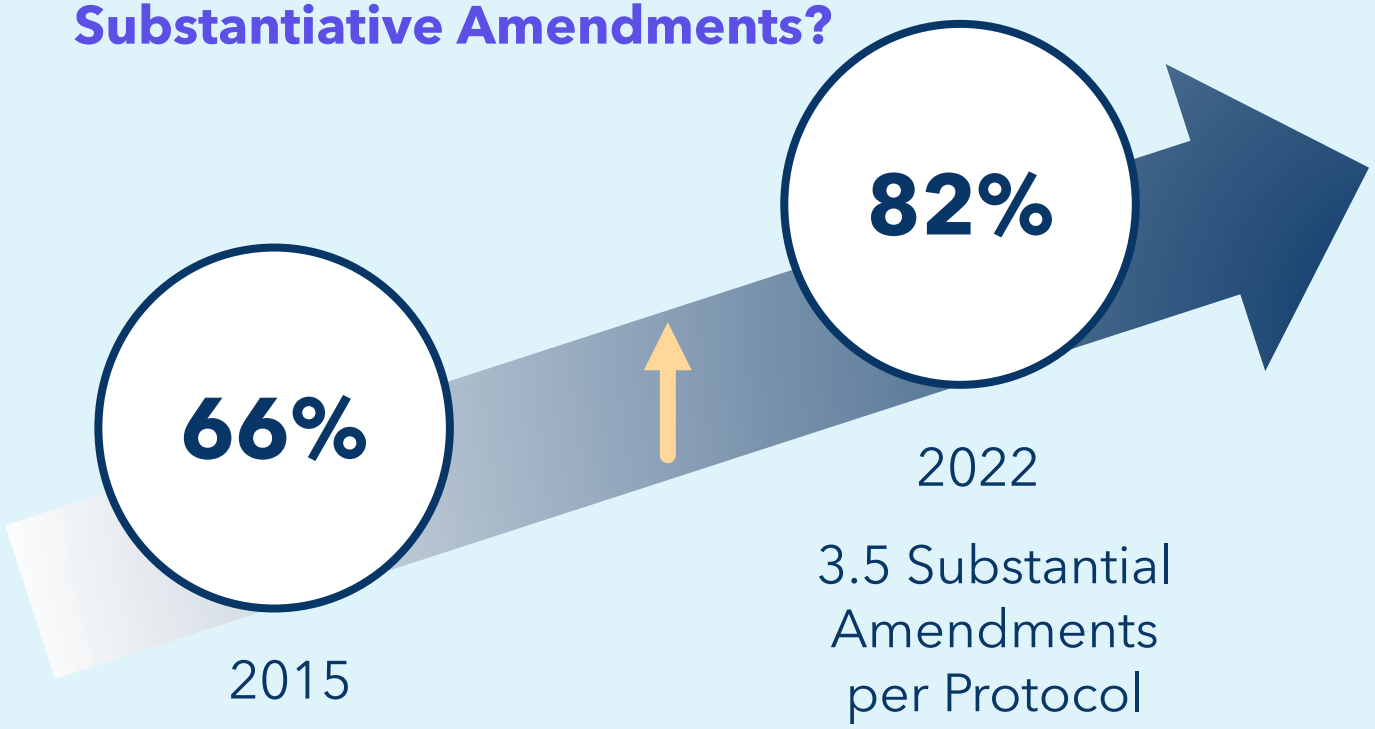


WCG's 2023 State of Sites & Site Capacity Survey

The Impact of Amendments on Clinical Trials

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

What % of Phase 3 Research Have Substantiative Amendments?



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%**

Source: Tufts CSDD

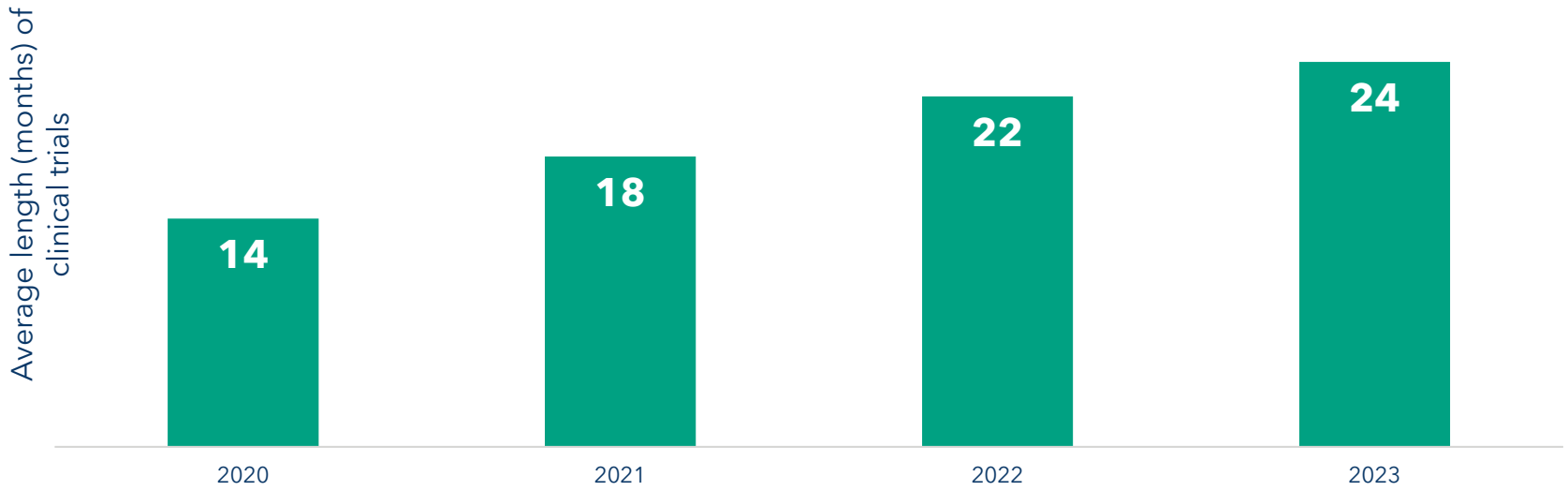
Substantial Protocol Amendment Definition: Changes made to a protocol, in all countries where it is executed, requiring obtaining internal sponsor company approval followed by approval by an ethical review board (ERB)/ institutional review board (IRB)/regulatory authority and re-consenting study volunteers.

Current Market Landscape

Clinical trials continue to face numerous headwinds ranging from research **staff shortages** and **capacity demands**, to increasingly **complex protocol designs** and the **inability to meet trial enrollment** targets and timelines:

Phase II & III protocols average **263 procedures** per patient, supporting approximately **20** endpoints

These challenges have contributed to the increasing trend in overall trial duration:



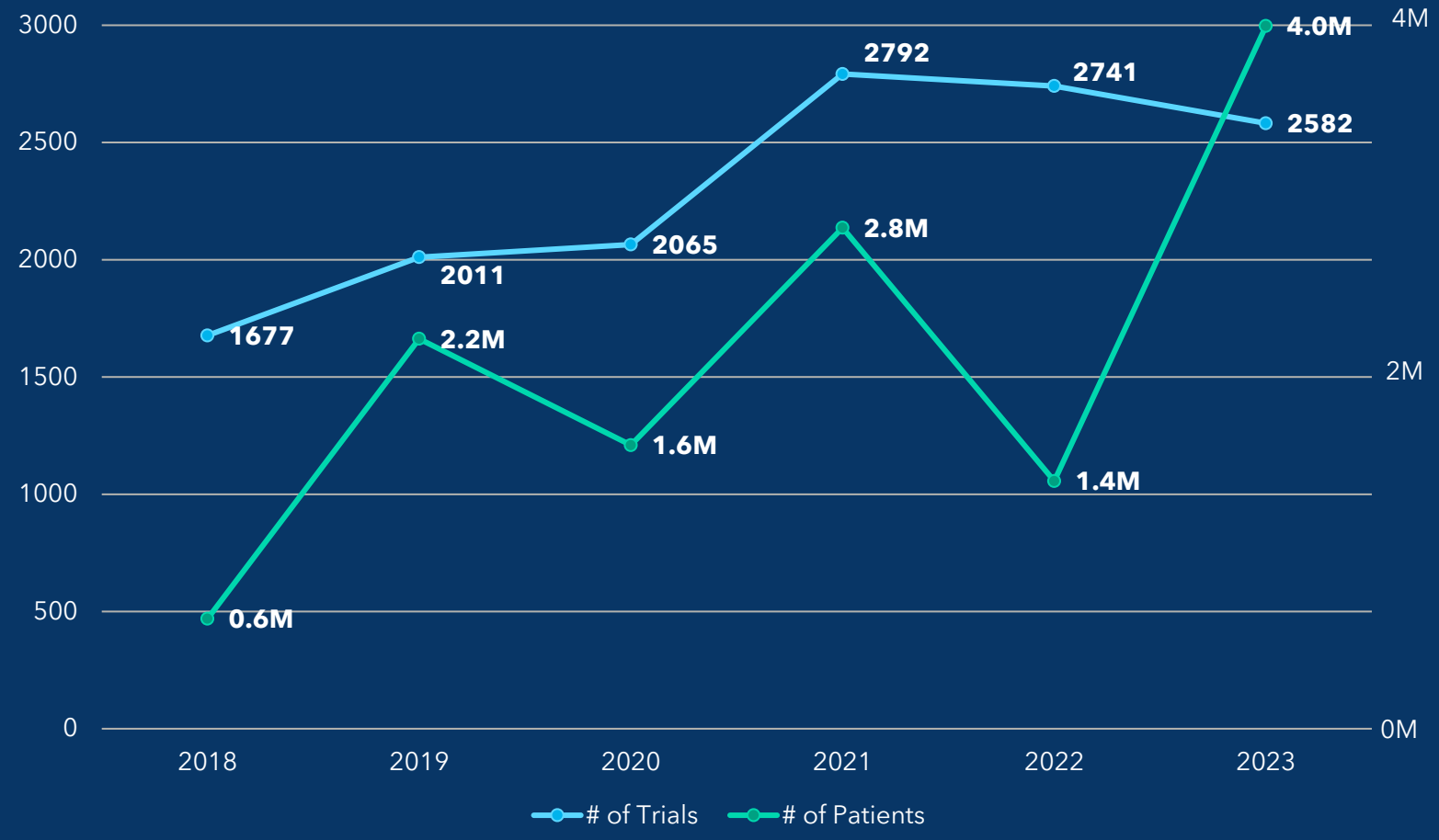
WCG Data Intelligence Platform & Tufts 2022 CSDD

10

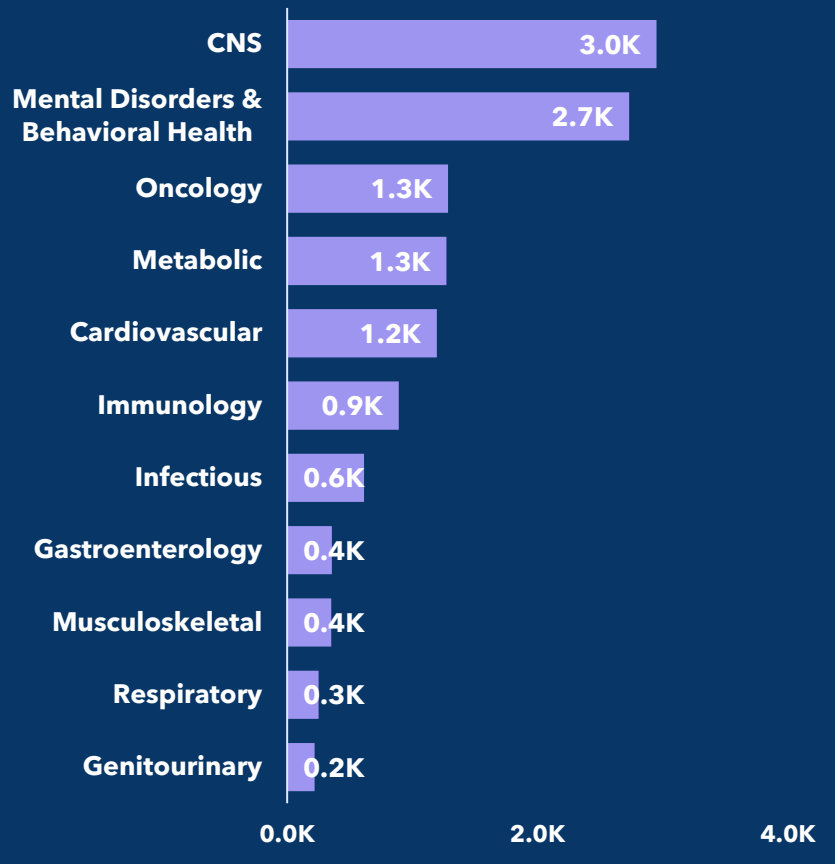
Months longer on average to complete a clinical trial in 2018 compared to 2023

The Number of Clinical Trials With Decentralized Components (DCTs) Continue to Rise

Total Number of Patients Needed for Trials With DCT Components



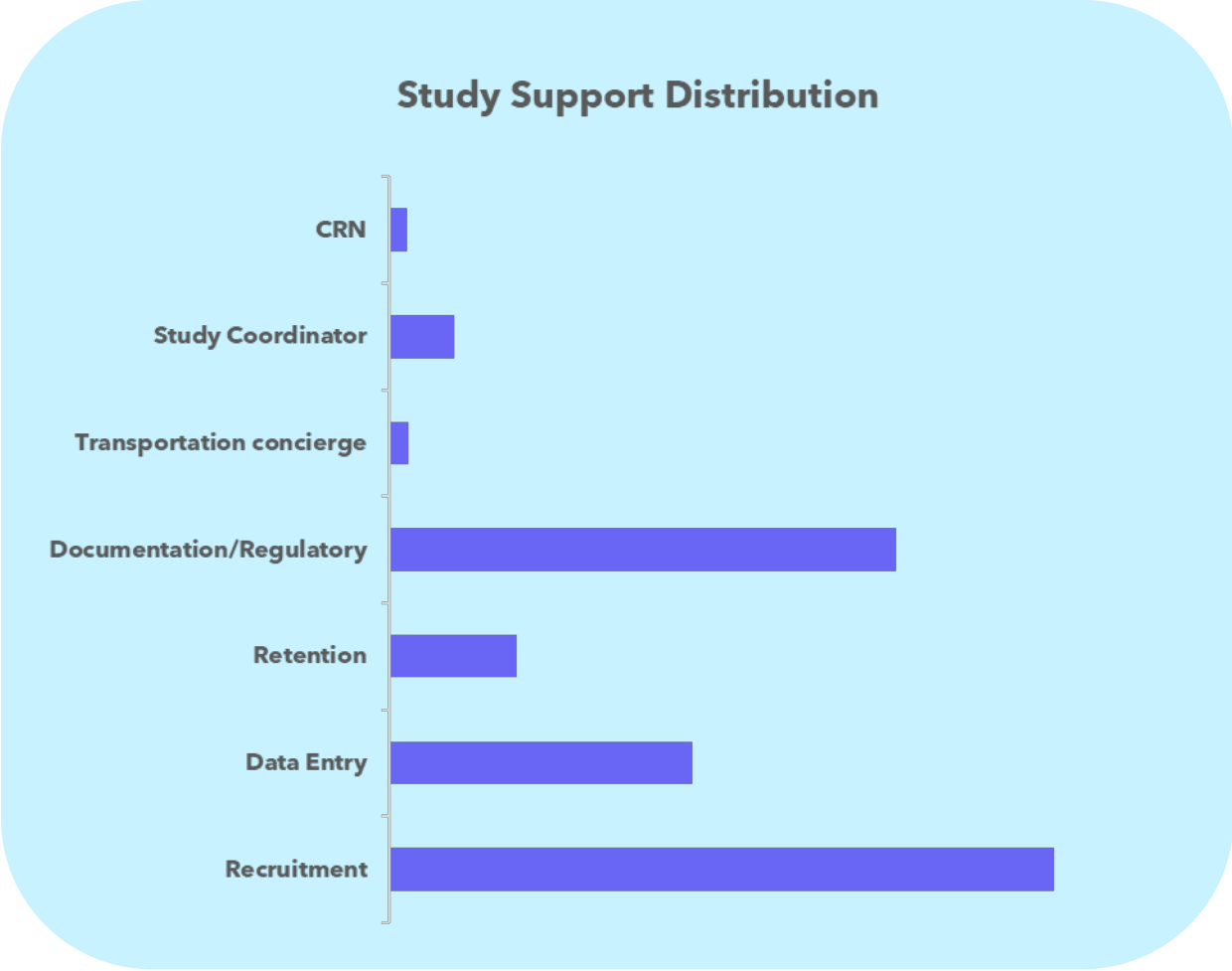
Therapeutic Areas Utilizing DCT Components Most Frequently



Our Experience Matches The Survey Results

The study support distribution covers our experience across:

- ***2500+ Sites***
- ***800+ Protocols***
- ***90+ Sponsors***
- ***40+ Countries***



Recruitment is a Process

At the core –

Recruitment and Retention is the Participant's Pathway

Recruitment can be broken down to Identification & Enrollment.

- **Identification** is the process of locating potentially qualified participants through referral sources internal or external to the site.
- **Enrollment** is the process of contacting those identified, informing of the study, and assessing their qualifications.

Retention can be broken down to Participant Retention and Participant Data Entry.

- **Participant Retention** is the process of having each Participant complete the study per the protocol
- **Documentation** is the process of entering all the data and resolving any queries as required for the ultimate goal which is submission by the sponsor.

Why is Recruitment a Challenge?

We are talking about People.

- People who are interested in learning about participating in a trial for something concerning their health.
- Each person has a story and their own motivation to participate (or not to participate). *They also may have circumstances impacting their ability to participate.*
- People introduce complexity and infinite variables to an otherwise straightforward process.

Properly interacting with people who demonstrate interest in participating in a trial takes time, energy, and dedication. **And it should!**

Keeping Focus

Trials are not Transactional

- The Investigators and Trial Sites are directly interacting with participants in either a care capacity or a trial capacity.

  These could be patients the clinic has seen for years, or they could be new to the clinic because of the trial.

- The participant's lives are impacted by the indication being studied. They are volunteering with the hope of advancement.

- The Investigator and Study Team are accountable for each person raising their hand and enrolling in that study.

These interactions between the study site and the participant are not transactional. **They are transformational.**

Keeping Focus on What is Important

1st QUESTION!

QUESTION:

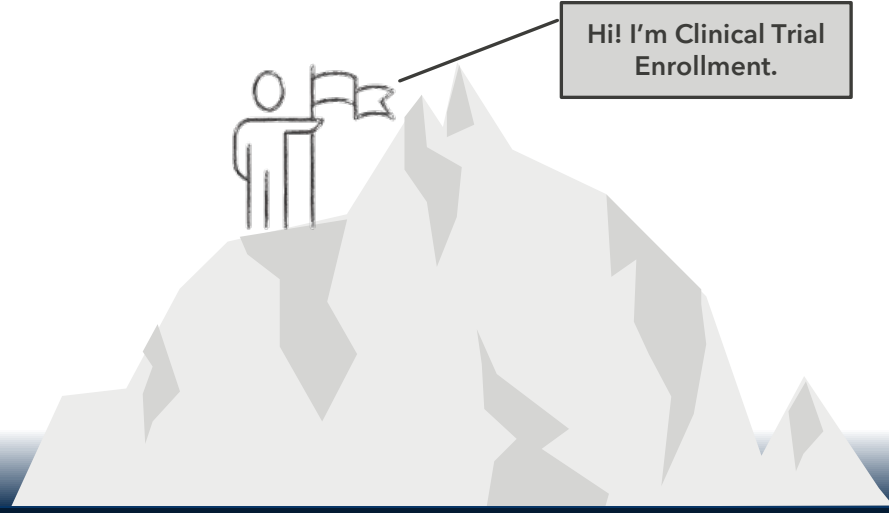
How can Sponsors build an open communication line with sites regarding recruitment challenges?

QUESTION:

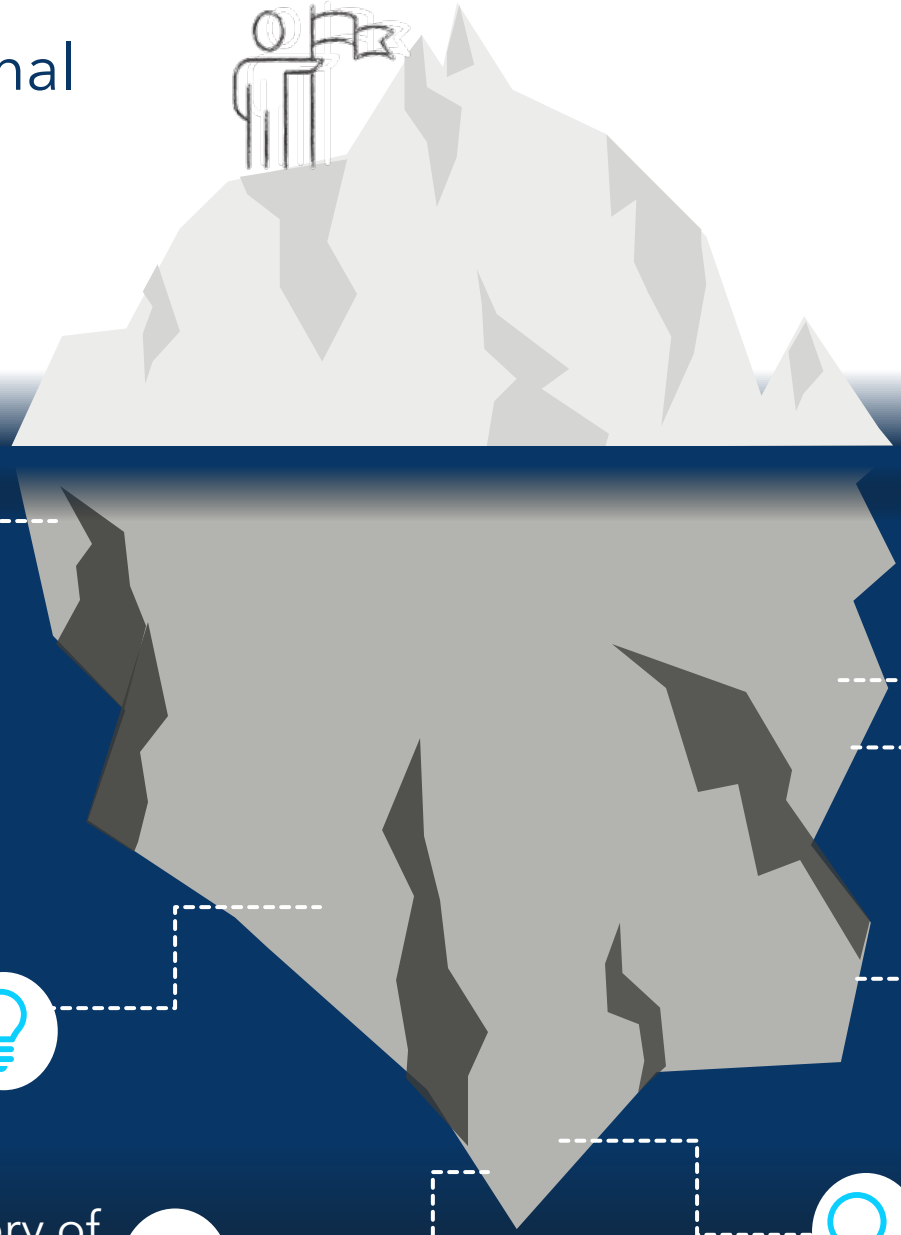
What are some key strategics I can enlist to allow my site to shift vision from a reactive to proactive state?

- Trial success comes first
- Trials are not transactional
- Understand the reality of referral sources contribution potential and work collaboratively to achieve realistic targets.
- Accept that change in clinical trials is a reality

Understanding trials are not transactional helps not underestimate the work required.



example:
Enrollment from an Internal Referral



Review of ICF with Patient

Update the EDC

Schedule & Reschedule Patient Appointments

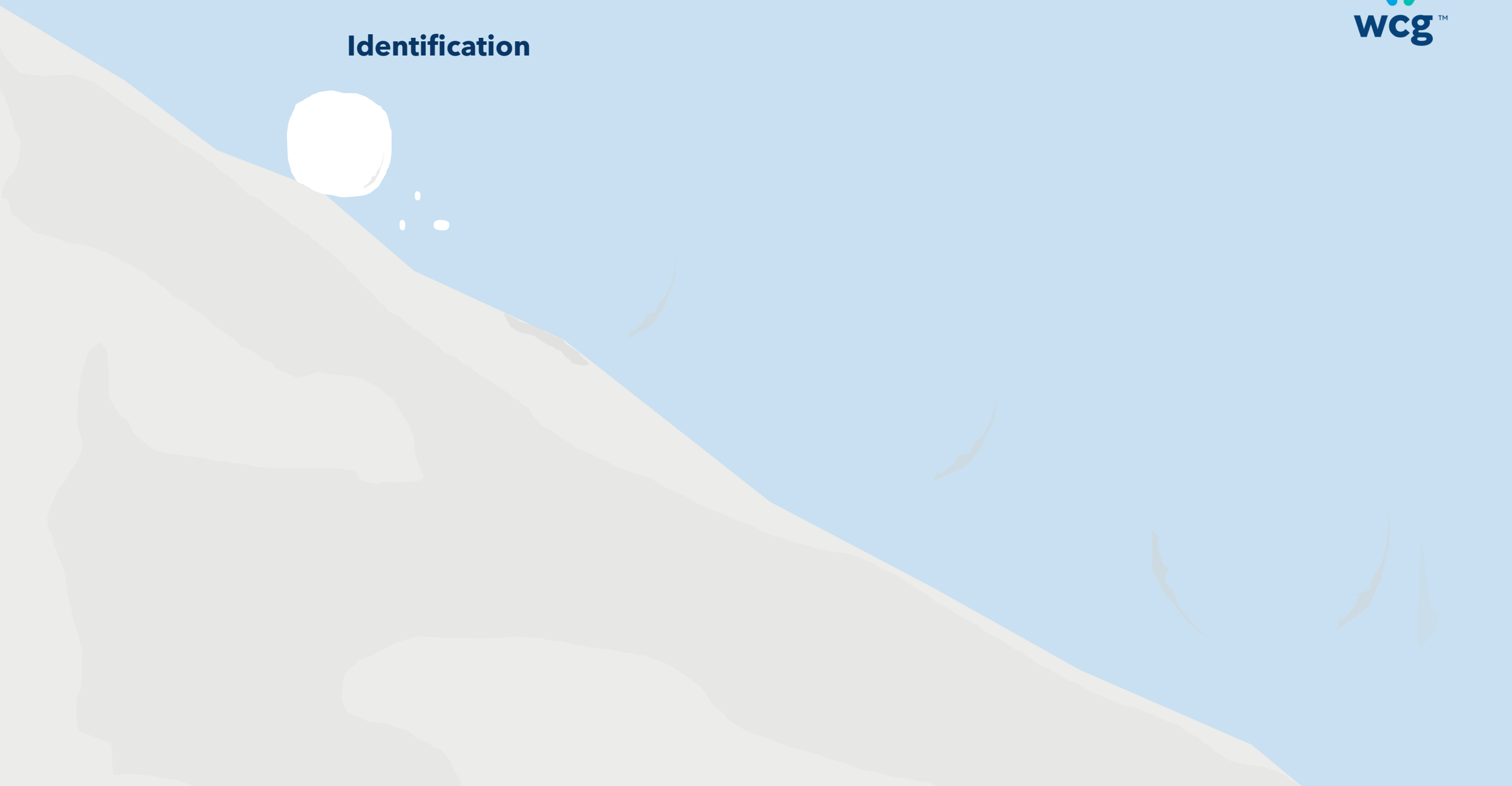
Inform Patient on Basics of Clinical Trials

Discuss Study Expectations with Patient

Query of EMR

Review of Flagged Records

Compounding Effort Required with Success



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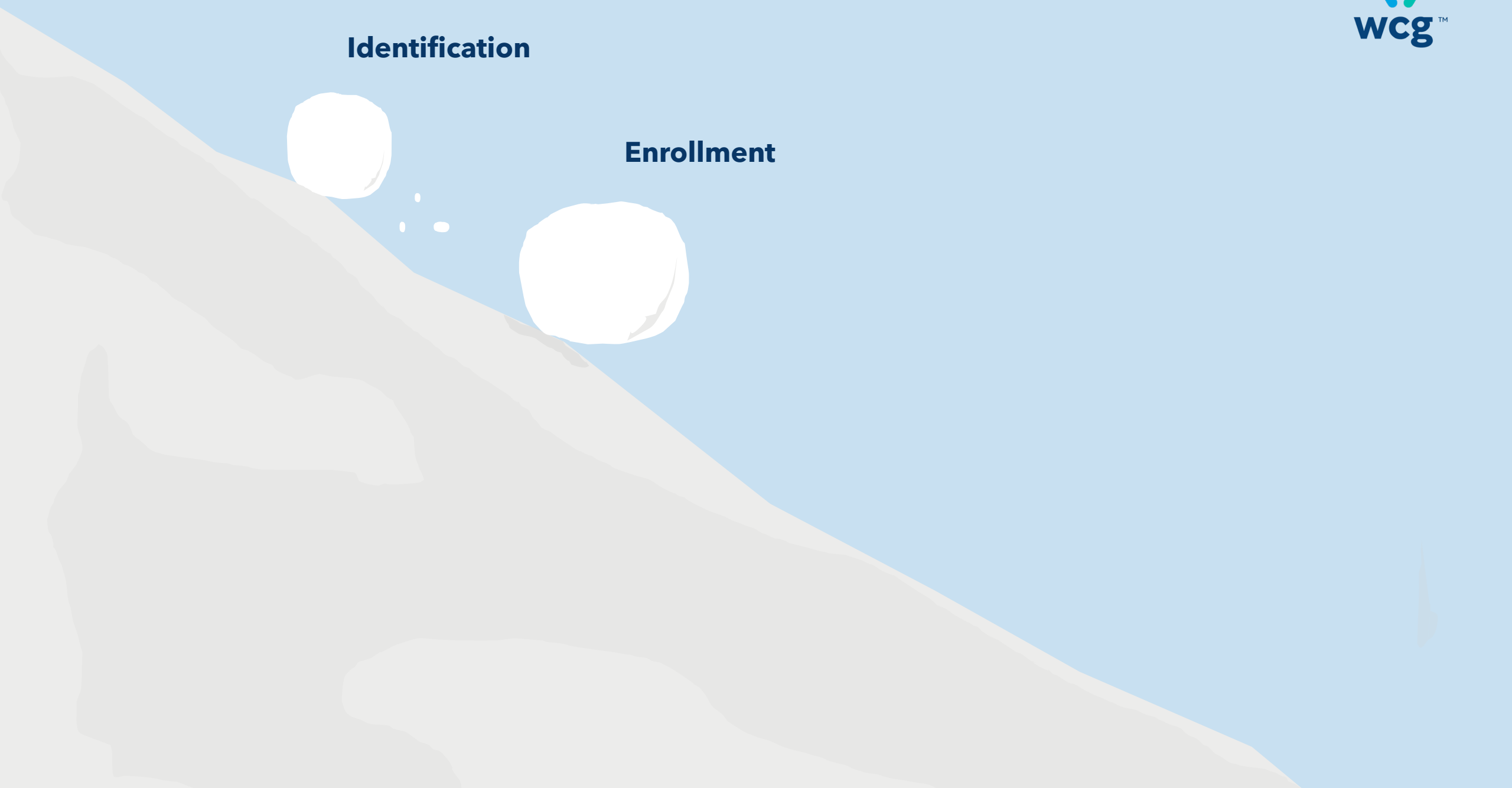

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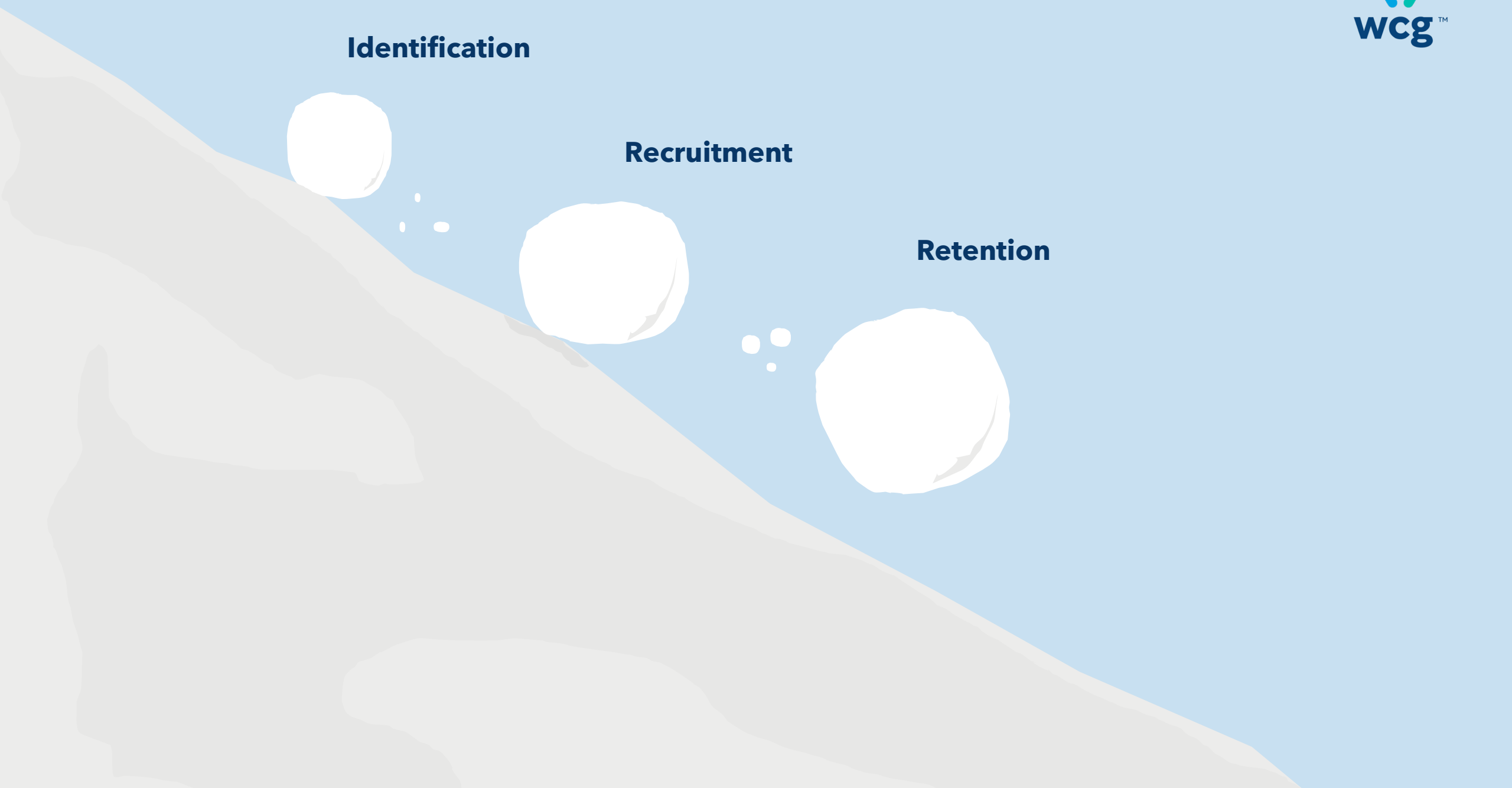

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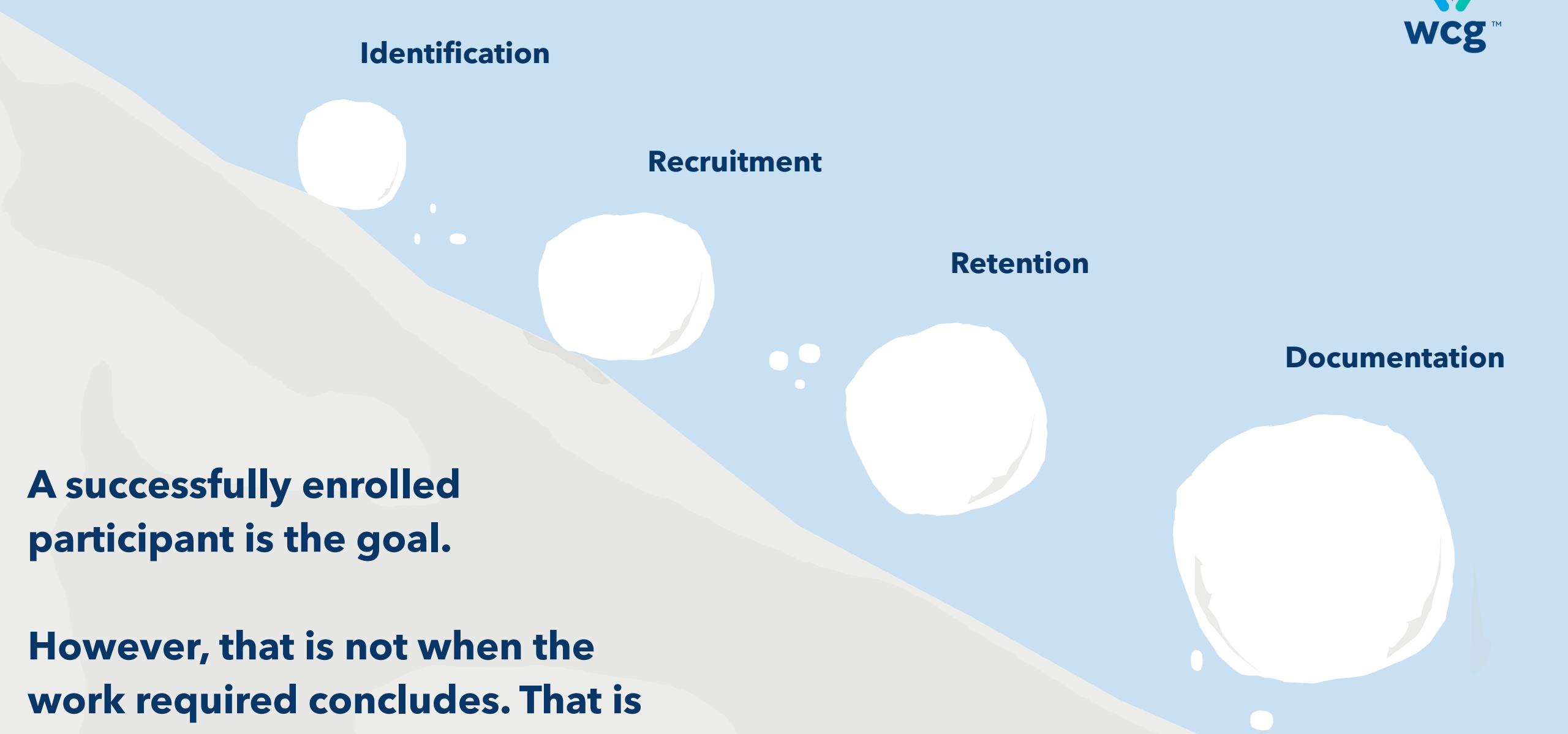
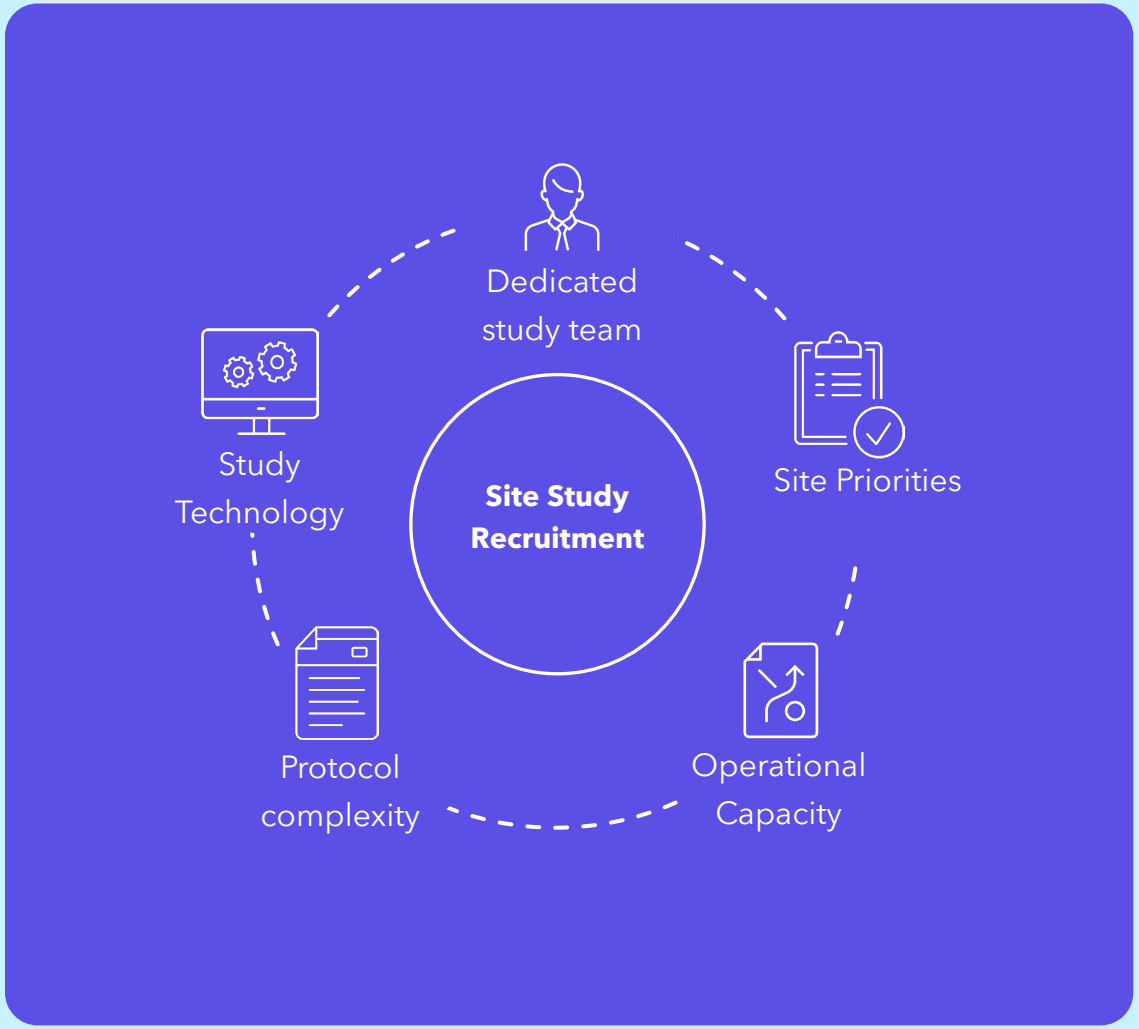


A successfully enrolled participant is the goal.

However, that is not when the work required concludes. That is when the workload increases.

Recruitment & Retention Barriers are Interconnected

Recruitment and retention challenges are often not the cause of one specific barrier but rather an interconnection of multiple factors.



Study Team Capacity

Effective recruitment, screening, and retention requires focus, consistency, and a range of skills across study site team members.

Site Priorities

Study sites are often balancing a portfolio of different studies and patient care takes precedence, thus directing the day-to-day priorities.

Protocol complexity

Protocols continue to grow in complexity, requiring additional resources to identify and retain the right candidates.

Study Technology

A surplus of tools used across sites, sponsors, and CROs creates a lack of interconnectedness and requires additional dedication to ensure systems are updated accurately.

Operational Structure

Sites, that are otherwise qualified for a study, may have specific equipment, staff, or diagnostic needs potentially requiring augmenting.

Recruitment & Retention Barriers are Interconnected

Recruitment and retention challenges are often not the cause of one specific barrier but rather an interconnection of multiple factors.

QUESTION:
Can you share thoughts around training, staffing and retention of clinical research personnel?

ANSWER:
Training is a key first step to ensuring studies run smoothly. It is also a key step to avoiding frustration and burnout. A properly trained team is better able to set priorities and manage complex protocols. The second step is understanding expectations. It's imperative that sites advocate for their teams by way of keeping an open line of communication with your sponsor/CRA, ensuring you understand what is expected of participation on the study and communicating any resource needs proactively.

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Participant Identification

Dedicated efforts towards pre-identifying potential internal candidates and actively fostering any external participant identification strategies.

Participant Screening

Identification processes flow into prescreening which requires a thorough review of the study, confirming participant responses to expanded criteria, and addressing any participant questions.

Study Retention Requirements

Once a patient is enrolled, this initiates the beginning of study retention activities (e.g. scheduling and completing study visits, contacting patients for protocol requirements measures [eDiary compliance], etc).

Data Entry & Data Validation

Enrollments create the data need thereby requiring to ensure participant data is entered accurately and within the timelines stipulated by the study protocol. Further, dedicated effort to data validation for accurate data reporting and query resolution. This workload influences the ability to enroll more participants.

Documentation and Regulatory Upkeep

Dedicated effort towards ensuring source documentation is complete and stored appropriately.

Tasks (Processes) Required On a Typical Study

Recruitment

Participant Identification

Internal Participant identification
- Prescreening existing Participant charts
- Prescreening future appointments

External Participant identification
- Physician Referral Networking
- Community Outreach
- Study Material Development
- Media Outreach
- Media Referral Processing

Participant Enrollment

Participant Enrollment
- FOV Scheduling
- Pre – Screening
- Consent

Participant Concierge Support
- On-going Scheduling Support
- Participant Travel Support
- Participant Visit support

Retention

Participant Retention

Participant Information
- Relay study updates, timeline changes, and protocol amendments
- Provide study education
- Long-term Participant follow-up support

Participant Resources
- Providing transportation assistance
- Appointment follow-up scheduling and reminder calls
- ePRO follow-up
- After-hours point of contact support

Participant Appreciation
- Preparing participant appreciation items (thank you cards, sponsor branded study materials etc.)
- Courtesy participant follow-up

Participant Concierge Support
- On-going Scheduling Support
- Participant Travel Support
- Participant Visit support

Data Verification

Reviewing
- Assessing lab values compared to protocol
- Studying test results for potential adverse event reporting

Collecting
- Finding and extracting data from paper or electronic charts
- Collecting missing signatures and consulting the PI on visit notes
- Gathering source documents

Entering
- Transcribing lab values and test results
- Entering endpoints from source into EDC

Verifying
- Performing other tasks as needed to ensure data is audit ready
- Consulting the study team members on adverse event reporting

Tasks (Processes) Required On a Typical Study

Recruitment

Retention

QUESTION: Do you have any advice for helping participants/patients navigate barriers associated with poverty?

ANSWER: Structure the study and the support for the study to address this from the beginning.

QUESTION: What's the best way to go about retention?

ANSWER: Retention begins at Recruitment – bring your retention strategy into your Recruitment Strategy

Participant Enrollment

Participant Enrollment
- FOV Scheduling
- Pre – Screening
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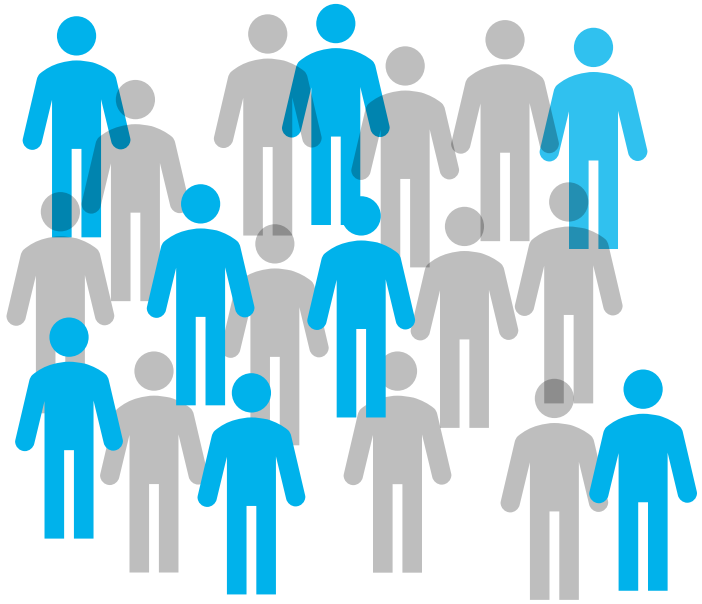
Recruitment Tactics: Identification - A Closer Look

Defining Referral Sources: Internal & External



Internal

Individuals found within the HCO's health record system. The individual is flagged upon meeting the main protocol I/E criteria.

External

Individuals reached by media or networking efforts who raise their hand to learn more about a study that resonates with their personal health status.

Completing the Core Formula

Start with a Clear Understanding of the Protocol

Enrollment Contribution = (Internal participant enrollment) + (External participant enrollment)

QUESTION:
Any information about strategies to recruit patients with low clinical research understanding?

ANSWER:
Treat recruitment as a process and adapt your strategy based on the demographic. Ask the patient questions to gauge their level of understanding and build upon that foundation. The goal is to build trust.

- **Internal Review**
  - Is the targeted participant found in medical records?
  - Is the targeted participant someone that will present throughout the study?
- **External Review**
  - Is the indication and characteristics of the targeted participant such that providers will refer?
  - Is this a condition that the targeted participant will respond to outreach?
  - Is the targeted participant likely to be found in a specific place?

Internal Recruitment as a Process - Sample

The Enrollment Life Cycle

1. Query site database for primary eligibility criteria
2. Review each patient chart to determine eligibility based on extended criteria within the protocol
3. Contact patients who are pre-screen eligible to confirm interest and eligibility via a phone screening
4. Inform and assist the potential participant with any necessary follow-up documentation to confirm eligibility (e.g. obtaining medical records)
5. Assess if feasibility will be fulfilled by site-identified patients. If not, implementation of strategies to identify external candidates via community networking and/or media strategies may be necessary.

EMR System Query – Identification of Potential Participants

This is often the simplest step to complete and thus, it is also often the information used to make feasibility assumptions

- **Utilize primary study eligibility criteria to identify the appropriate ICD 10 codes**
- **Run the codes against site EMR database to pull a query of potential study candidates**

Sites are often provided a snapshot view of a study in order to confirm interest and eligibility, but it may not be enough to properly gauge their enrollment capacity. Thus, feasibility should be considered a moment-in-time best judgment based on the information they have available at that time.

Chart Review

QUESTION:
Are their tools that you would recommend to sites to assist CRCs effort track?

ANSWER:
Centralized systems for tracking are a must. Need to cover all referral sources and track final disposition.

- Review the patient chart against protocol criteria to determine continued eligibility
  - If the site utilizes paper charting, this process will likely require more time for review
  - Academic Medical Centers and Site Networks often have a much larger pool of patient charts for review
- Implement a system of flagging for patients that should be contacted based on preliminary eligibility
  - Connect with primary physicians to provide proactive notice to gauge patient interest, or
  - Proceed to contact the patient by phone to provide study education and gauge interest

Recruitment of External Participants

Bringing in External Participants is not Transactional for a Site

- When a site has exhausted its enrollment potential within its database, the next step is to identify external participants
  - The next step is often to pursue community network opportunities
  - A well executed Community Outreach plan requires extensive focus to identify opportunities, create a tactful plan for outreach, and sufficient time allocated to follow-up.
  - It's important to put yourself in the shoes of the patient
  - Outreach is transactional to a sponsor, as it may be necessary to enroll their study. However, outreach cannot be seen as transactional to a site. The most successful outreach pathways are often the result of long-term relationship-building and mutual collaboration.

External Recruitment

Referral Provider Networking

QUESTION:
Are we able to provide incentives for referrals by non-prescribing medical professionals?

ANSWER:
We recommend compensation for time extended by site staff to identify, review, and refer patients, not enrollment, whenever there could be the appearance of impacting results.

Connecting with local physician and health care networks for the purposes of establishing a referral pathway to the study site

- Identify local clinics that may be treating the demographic of patients
- Formulate your strategy for outreach – gaining attention from clinic teams can be exceptionally challenges as they are also juggling varied patient care priorities
- Consistency is key – your goal is to build trust between your clinics and establish visibility with the referring clinic
- Provide study education to their physician teams and opportunities for them to be involved in active referral of potential participants seeking expanded treatment options
- Foster the connection through continued interaction

External Recruitment

Health & Community Events

Attending/hosting relevant health and community events

- Identify public events in the communities surrounding the sites that are appropriate opportunities to promote and share study education
- Confirm any logistical requirements to attend and/or present at the event (e.g. tickets, funding for a booth, sponsor provisioned study materials prepared for distribution, etc)
- Coordinate the study team strategy in preparation for the event
- Proactively develop a plan for follow up to interested potential participants following event conclusion

External Recruitment

Grassroots Outreach

Providing study education to the community via grassroots outreach

- Identify local areas of interest that may be trafficked frequently by your demographic of patient (e.g. libraries, community centers, colleges, etc)
- Dedicate someone as point to spend frequent time in these communities – distributing study-approved materials, forming connections with the community, and bringing visibility to the study opportunity
- Qualitative tracking of all community networking efforts to target the most effective strategy for outreach

External Recruitment

Media

QUESTION:
What is the best media for advertisement and is Digital advertisement the way to go ?

ANSWER:
Depends on your timing and indication. The biggest benefit for Digital advertisement is that it allows for the best tracking and management.

Is today's AI driven Ad yesterday's Radio Ad?

In past years, a primary tactic for identifying external participant identification was media outreach: Print, Radio, TV, and Digital

Media continues to be a vital primary tactic to identify external participants surrounding research sites.

Remember – A well-run media campaign is designed to increase traffic to the site. When directed to a site without the means to process the referrals, it can negatively impact that site's overall study contribution.

Ultimately, more is more. If you are going to run media, have a plan to minimize the work to the site in order to maximize enrollment contribution.

Participant Prescreening (start of Enrollment)

This is the site's first opportunity to set the stage for the patient's perception of the study

- Provide a thorough overview of the study and why it may be of interest to the patient
- Complete a thorough review of the secondary protocol criteria that were unconfirmed following chart review
- Provide a qualitative explanation for any questions received
- Provide a clear of picture of what the next steps are, both immediately and looking ahead
- Facilitate any remaining steps to determine eligibility (e.g. medical record retrieval)

NOTE:

The time required to prescreen a patient will vary depending on protocol complexity and whether the patient has any additional requests for information.

When phone screens require 20+ minutes to properly complete, it is challenging to appropriately process a high volume of patient screenings.

Conclusion

- Participants are at the center
- We need to recruit to retain as **engaged patients are retained patients**
  - Patient engagement starts at the beginning of recruitment but must be maintained through the study, in some cases this will be years of correspondence.
  - This will require substantial time and resources, especially as protocols grow in complexity.

- **Intersection of Expectations**
  - Begin with a communication of expectations and continue to communicate transparently.
  - Remember we are unified in a common goal - advancing medical breakthroughs around the globe.
  - Understand what is transactional and what is transformational.

Don't forget to join us next week on November 7th for part 2 of our series on study start-up!

Thank you!

wcgclinical.com