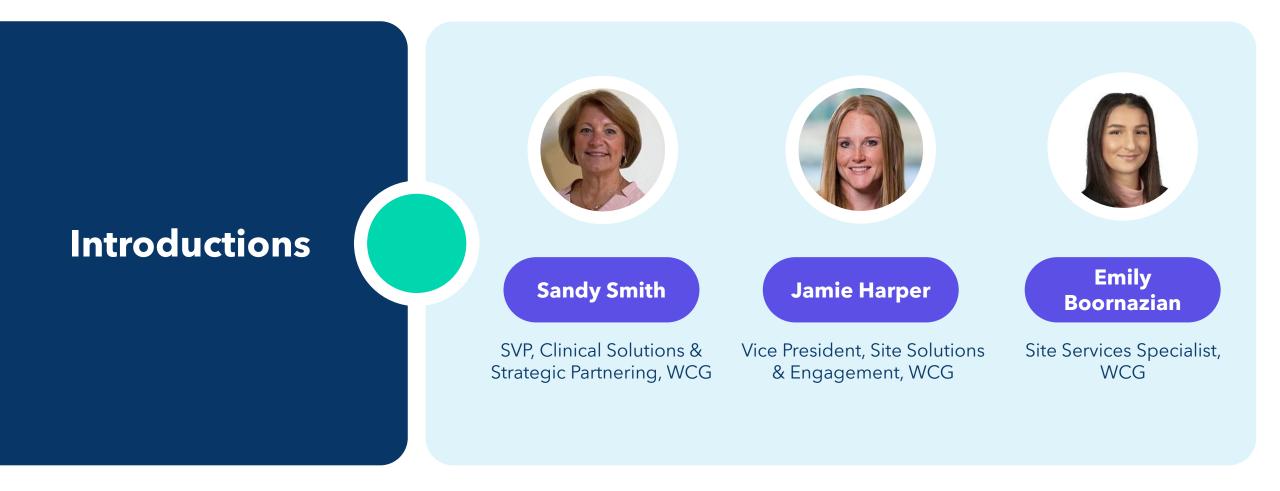


Thriving in Clinical Research -Overcoming Common Challenges as a Site

A Three-Part Series - Webinar 3: Site Capacity

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Today's Agenda





WCG 2023 Site Survey Overview and Current Market Trends

Embracing Anticipated Turnover

Overcoming Site Capacity Challenges

Combining Technology with People

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-today operations of a site and the objectives of Sponsors and CROs.

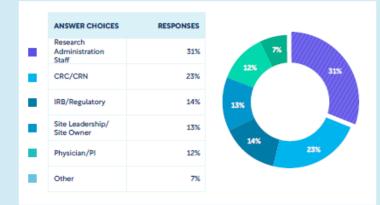


Full report can be downloaded for free at: www.wcgclinical.com/2023-site-challenges-report

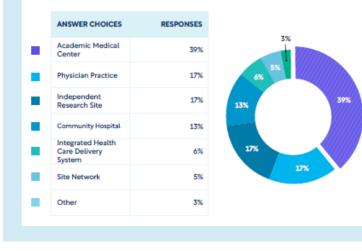
2023 Site Challenges Survey Report - Background



What is your role at your research site?



What type of research site do you represent?

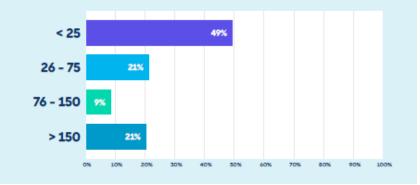


- 31% of respondents are research admin staff
- 23% are CRCs/CRNs

• 39% of respondents are from AMCs

• 17% are from physician practices

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



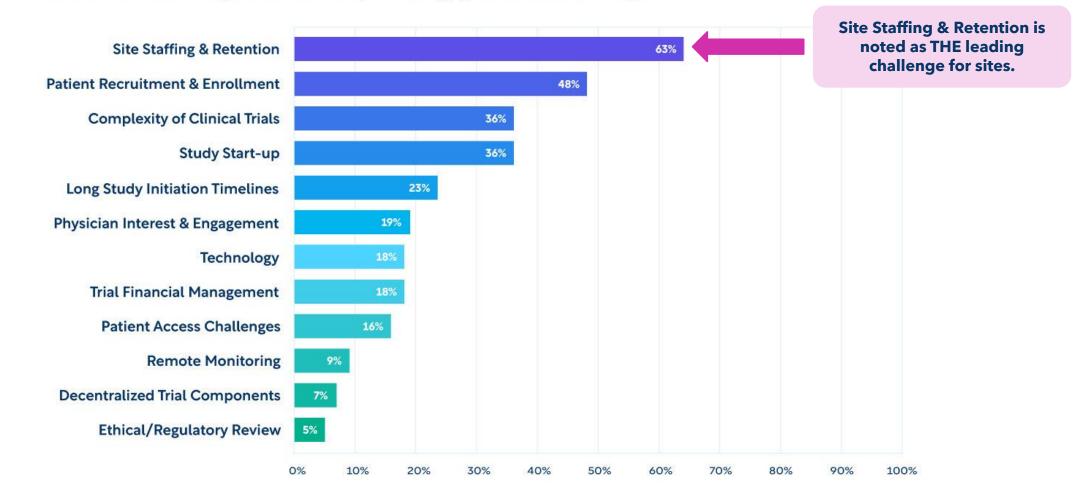
Over half of all respondents are operating more than 26 trials at any one time.

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Survey Results - Top Issues Impacting Research Sites



What are the top issues impacting your site today?



WCG's 2023 State of Sites & Site Capacity Survey

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Source: WCG 2023 Site Challenges Survey Report

Top Issues Impacting Research Sites - AMCs vs Non-AMCs

56%



AMCs

Site Staffing & Retention

Complexity of Clinical Trials

Trial Financial Management

Patient Access Challenges

Ethical/Regulatory Review

Remote Monitoring

Long Study Initiation Timelines

Decentralized Trial Components

Study Start-up

Technology

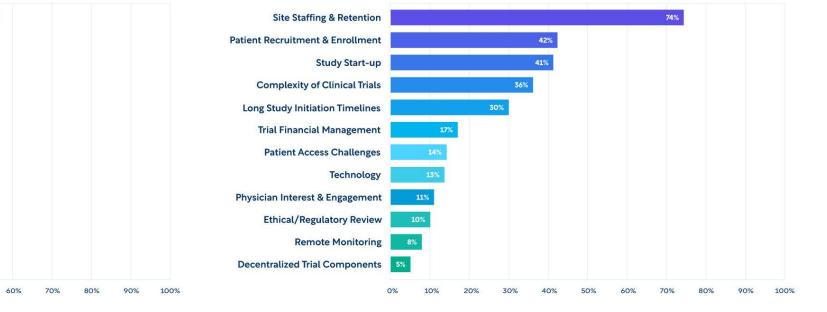
Patient Recruitment & Enrollment

Physician Interest & Engagement

What are the top issues impacting your site today?

Non-AMCs

What are the top issues impacting your site today?



WCG's 2023 State of Sites & Site Capacity Survey

WCG's 2023 State of Sites & Site Capacity Survey

0%

10%

20%

30%

40%

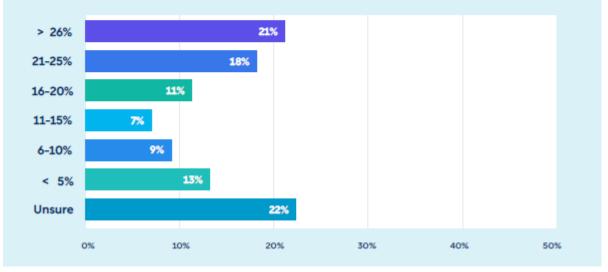
50%

Staff Turnover Trended Higher at AMCs



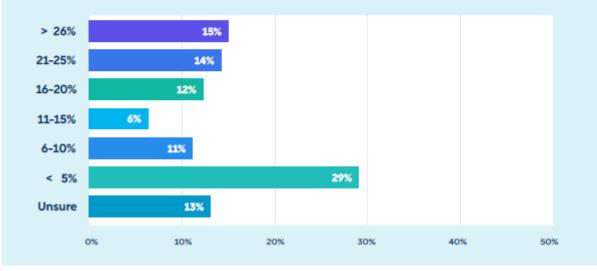
AMCs

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?



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Source: WCG 2023 Site Challenges Survey Report

U.S. Investigators Participating in Clinical Trials



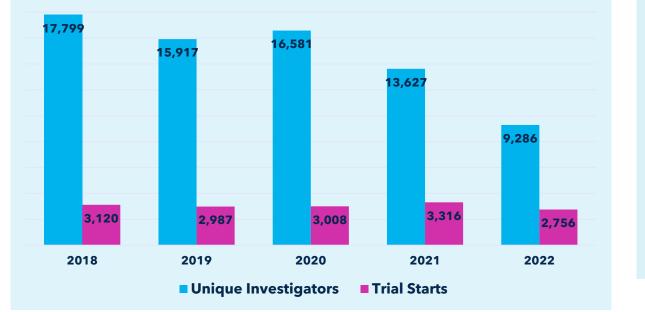
44%

40%

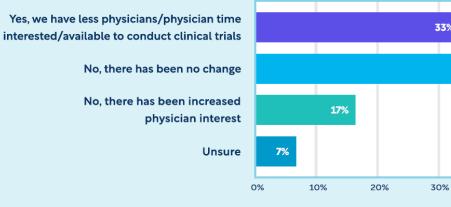
50%

33%

U.S. Investigators



Has your site experienced a change in physician interest/availability to conduct clinical trials?



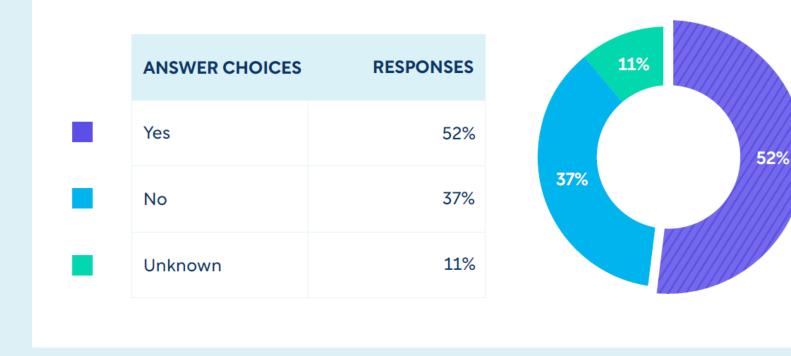
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Source: WCG 2023 Site Challenges Survey Report and WCG Data Intelligence Platform

Have Sites Reached Capacity?



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

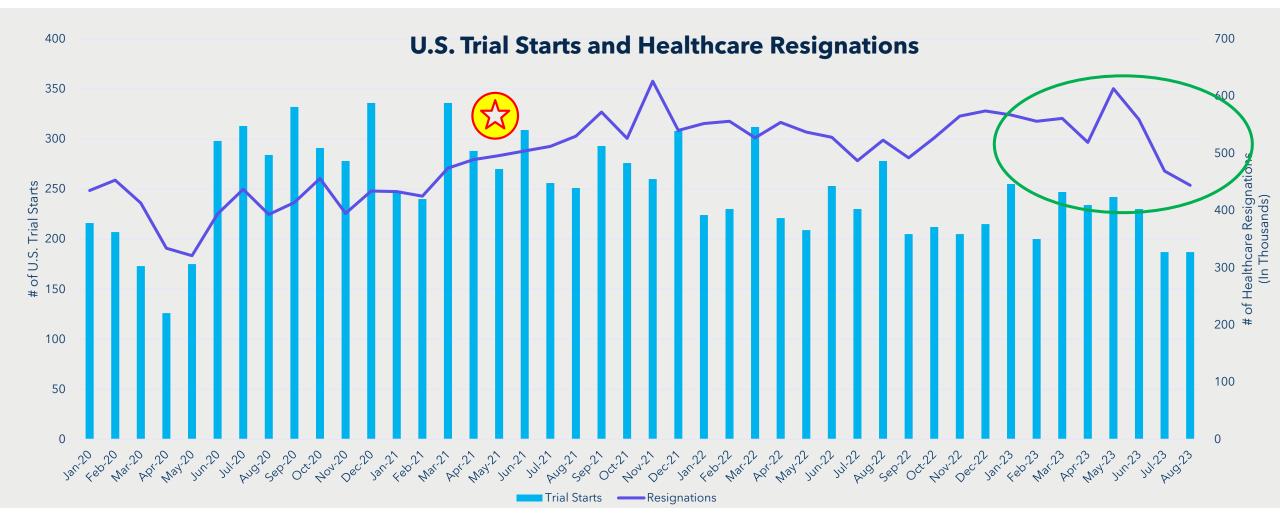


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Healthcare Resignations Show Signs of Slowing





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Source: WCG Data Intelligence Platform and the U.S. Bureau of Labor Statistics



Site Capacity can hold a different definition for every Healthcare Organization (HCO), Principal Investigator (PI), and study team member.

HCO may define site capacity as **number of studies conducted and available**

PI may define site capacity as number of studies conducted and available and number of patients enrolled

Study team may define site capacity as number of studies conducted and available, number of patients enrolled, number of visits to be scheduled, amount of data to be entered, etc.



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How Do We Fill Our Day?



How Do We Fill Our Day?

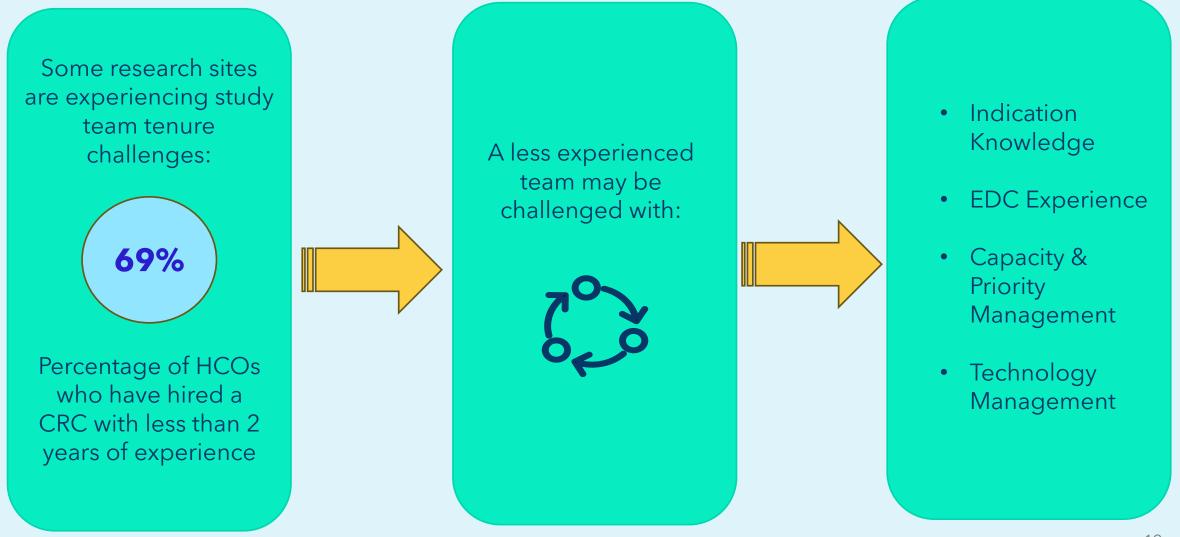






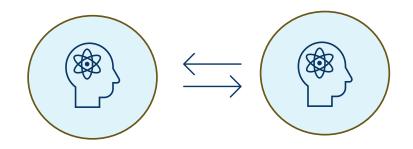
Embracing Anticipated Turnover





Who are the Subject Matter Experts?





Access to proficient indication knowledge is essential to a site coordinator's day to day responsibilities:

- Reviewing Patient Charts for Eligibility
- Investigating Potential Deviations or Queries
- Entering Medical History and Medication Data

Experience Resources:

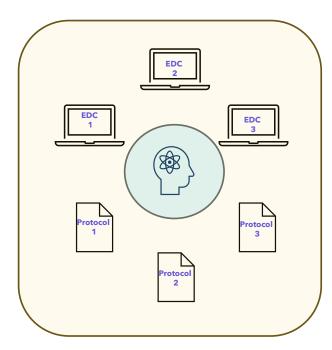
- Senior Coordinators
- Principal and Co-Investigators
- SOC or Research Nursing Staff
 - Regular Education Session
 - Webinars
 - External Resources

Who is Trained on the Study?



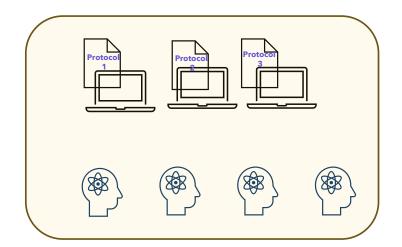
Each Protocol comes with its own **Nuances** that differ in:

- EDCs
- Schedule of Events
- Sponsor Specific Processes



Cross-Training strengthens study teams' knowledge base and ease transitions/coverage:

- Increase skill sets
- Uncover hidden talents



Study Team Responsibilities



Job Description 2023

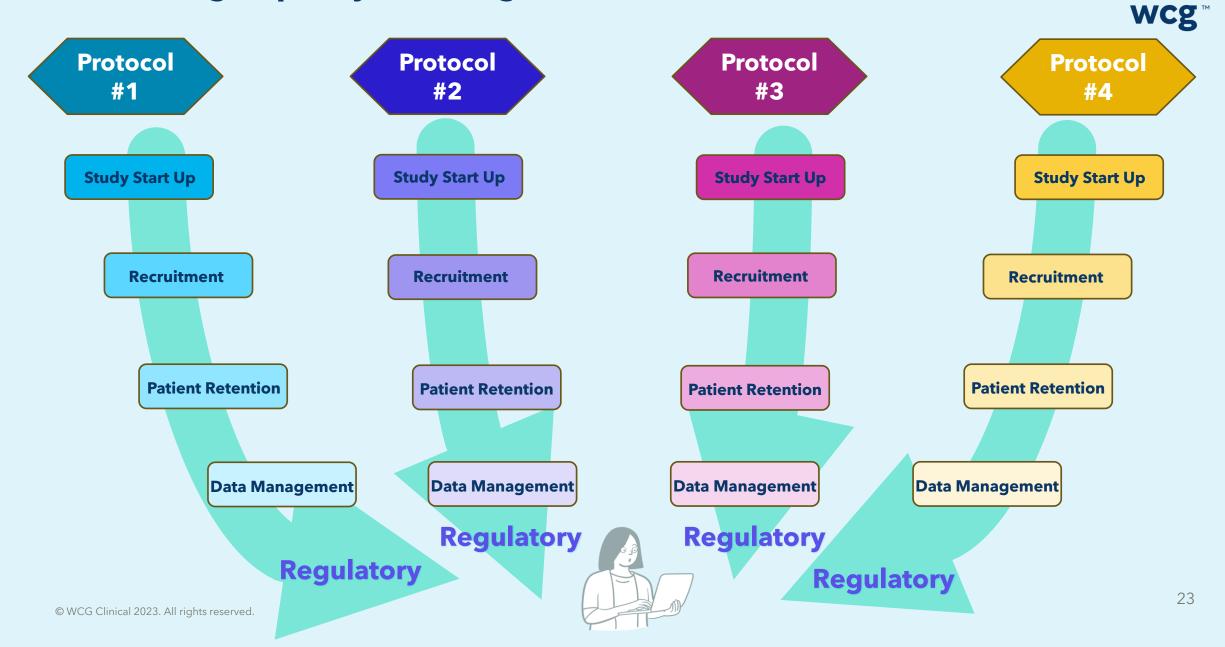
- **Overseeing** the trouble-free running of clinical trials
- **Collecting data** obtained from research, coding and analyzing it
- Managing budgets set aside for research
- **Communicating** with participants regarding study objectives
- Administering questionnaires and monitoring participants to ensure they adhere to the study's rules
- Liaising with laboratories regarding research findings
- Monitoring the study to ensure that it complies with protocols, is ethically-conducted and follows regulatory standards
- **Maintaining research records** of study activity, including case report forms, drug dispensation records or other regulatory forms as per FDA guidelines
- **Directing** the collection, labeling, storage and transport of all specimens
- Making sure that all **equipment and supplies** needed for the study are in-stock and in good working order

Job Requirements 2023

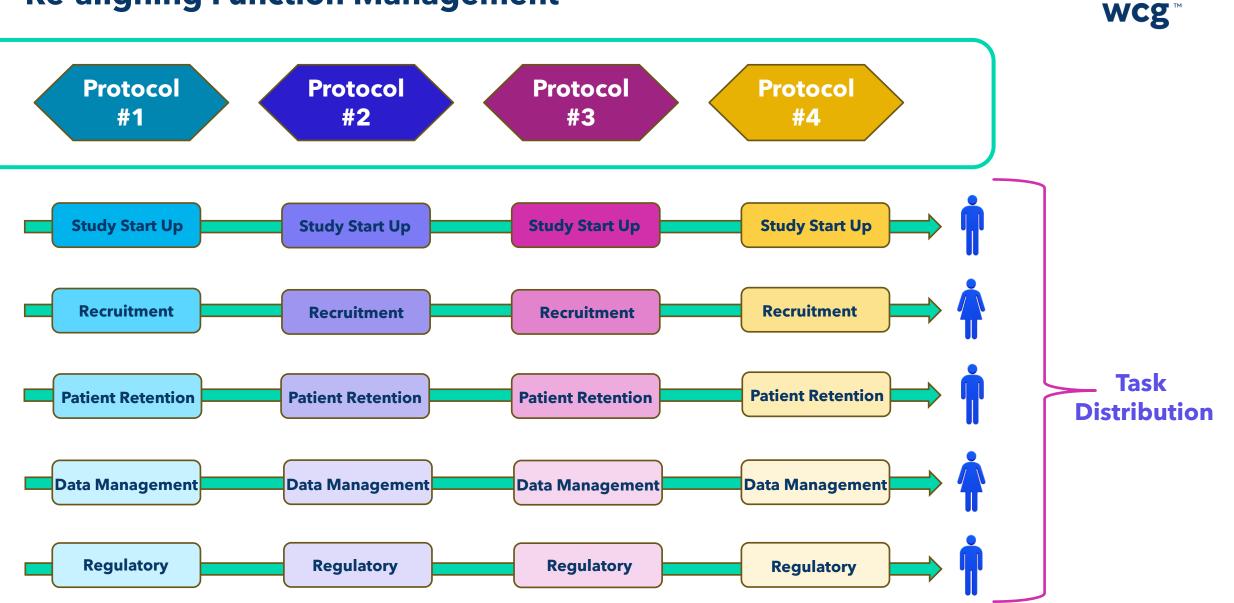
- Associates or Bachelor's Degree
- 1-3 years of relevant experience
- Familiar with GCP, ICF I/E criteria and adhering to protocols, or healthcare knowledge



Overcoming Capacity Challenges



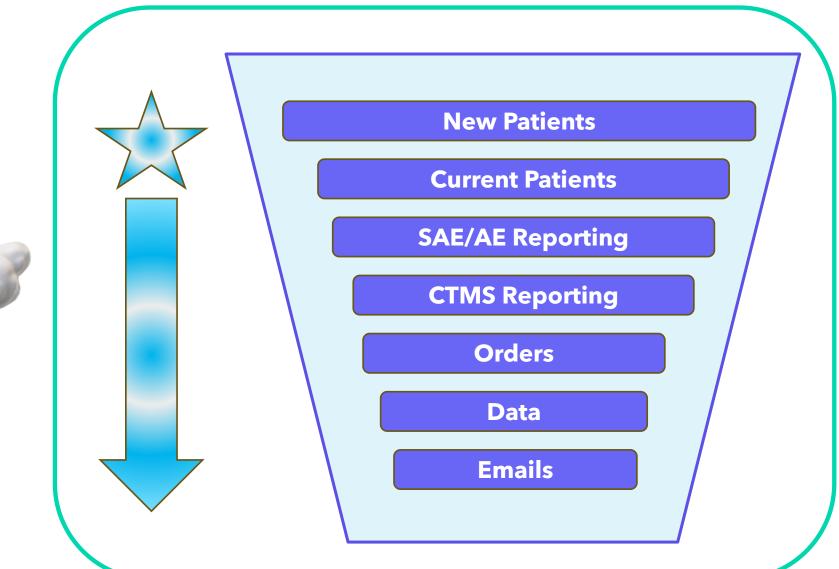
Re-aligning Function Management



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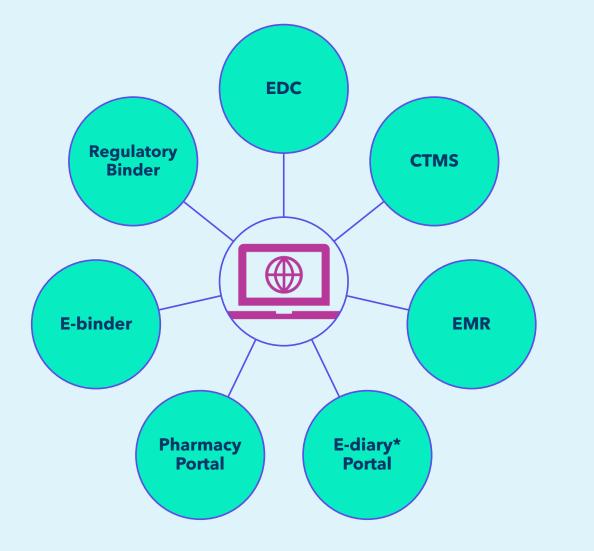
Priority Funnel





Technology Management





Maintaining each technology portal associated with a protocol is an increasing challenge for study teams and patients





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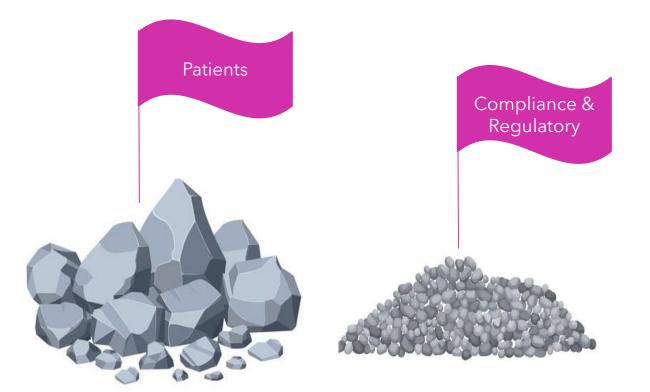
How Could We Fill Our Day?





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How Could We Fill Our Day?

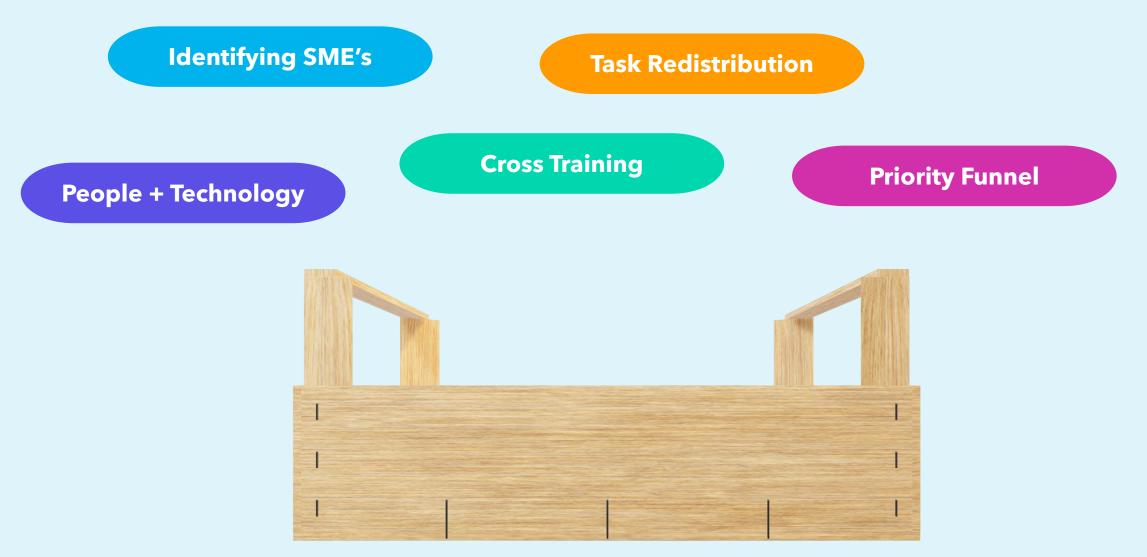






Creative Solutions







Audience Questions

WCG Educational Opportunities



CRC | CRA | PI Free CenterWatch WCG Patient Forum **Training Modules & Weekly Subscription** Guides www.wcgclinical.com/insights/wcgwww.centerwatch.com/newsletters patient-forum www.centerwatch.com MAGI **AVOCA Quality** Consortium **New Orleans: April 14-17, 2024 The Clinical Research** www.theavocagroup.com Conference

Webinars | Podcasts | Blogs | White Papers www.wcgclinical.com/insights

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Thank you!



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