



Smarter questions • Smarter answers

# eClinical Technology Adoption and Challenges in Study Startup

**Industry Standard Research**

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# METHODOLOGY



# Data Collection

On behalf of goBalto, Industry Standard Research (ISR) conducted a web-based, quantitative survey.

goBalto contacts and ISR's proprietary Health Panel were used to recruit research participants.

Research was conducted in July 2018.

goBalto was NOT identified as the sponsor of the research.

Respondents were screened to ensure they worked for a CRO, pharma sponsor or med device manufacturer; had applicable primary role such as clinical operations, or if CRO, had primary role such as project manager or senior management; and had responsibility for at least one clinical trial.

**262** respondents completed the ~20 minute survey.

**194** unique companies were surveyed.



# Respondent Profile

**262** respondents completed the survey

**67%** Sponsor

**29%** CRO

**5%** Med device manufacturer

Top primary role for Sponsor & Med device: Clinical operations or study startup (**78%**)

Top primary roles for CRO: Project/study mgr, asset mgr, clinical trial lead (**36%**), Senior mgmt (**24%**)

**47%** of respondents have more than 10 years of experience in current role

**63%** located in North America

**24%** in Western/Eastern Europe

**53%** are responsible for 1 to 20 clinical trials

**47%** are responsible for more than 20 trials

# Segmentation Analysis

	Sponsor	CRO	Total
1-10 trials	76	25	101
11-50 trials	56	23	79
>50 trials	55	27	82
Total	187	75	262



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# EXECUTIVE SUMMARY



# Top Criteria for Site Selection/Identification

- 78% Availability of suitable patient population
- 69% Experience and qualifications of the investigator

Sponsors/CROs weigh criteria higher:

- **CRO's**
  - Track record of start-up cycle times, on similar trials
  - Managing timing of Institutional Review Board meetings
- **Sponsors doing more than 50 trials a year**
  - Academic or "thought leader" credentials





# Top Data Sources Used for Site Selection

- Sponsor/CRO historical data from prior studies
- Study site patient data (e.g., EMR integration)

Sponsors and CROs are overwhelmingly interested in site information based on their own internal data from prior studies



# Top Aspects that Speed Patient Recruitment

- Better site selection (i.e., selecting sites on current data)
- Better site identification (i.e., finding potential sites based on historic data)

Enabling site to reduce repetitive work (i.e., SIP) ranked last across sponsors and CROs regardless of trials size



# Top Aspects Helping Manage Contracting with a Site

- 70% Budget cost estimator and negotiation tool
- 67% Integration of existing contract language and budget template

Other generic functionalities, such as eSignature, analytics, document management, etc. ranked significantly lower



# Aspects that Help with Process Optimization

- Internal: Detailed (document and document component) cycle times
- Internal: High-level (milestone) cycle times

Sponsors and CROs are focused on internal process optimization and less on comparison against their peers



# Top Challenges for the Site Collaboration Processes

- Site contracting and budgeting 73%
- Site identification and selection 58%

**33%** of respondents have **no plans** to implement a technology to address the **biggest challenge** “Site contracting and budgeting”

CROs focus more on **specific functions** (e.g., Site contracting and budgeting, RA and IRB/Ethics Committee submission, etc.)

Sponsors focus more on the **bigger picture** (e.g., Site identification and selection, resource allocation and regulatory compliance.)



# eClinical Software Usage/Satisfaction in Site Collaboration

- Moderately/Highly satisfied

IVRS	88%
EDC	80%
Study Start-up Application	77%
eTMF	75%
Full Solution Provider	73%
CTMS	69%
Internally Developed System	69%
Excel	61%

- Clear business ownership
- Multiple or no business owners

- Full Solution Providers, biggest challenges cited:
  - 51% Reporting across multiple applications
  - 43% Integrating multiple applications

Higher satisfaction correlated with clear business ownership

# Full-Service Provider Deployment

- **Only 22%** are using a Full-Service Provider **whereas 47%** are using multiple industry-leading application providers
- Organizations implementing Full-Service Provider solutions **still plan to integrate** with other solutions
  - IVRS 79%
  - EDC 76%
  - CTMS 73%
  - Study start-up application 69%
  - eTMF 64%

# Top Drivers for Clinical Applications

- Improved study quality
- Faster study execution



Quality is slightly more of a driver than speed





# Percentage of Study Costs Unaccounted For

- 74% of respondents indicate it is < 25%
- Research<sup>1</sup> shows that it is > 50%

1. Sertkaya A, Birkenbach A, Berlind A, et al. Examination of clinical trial costs and barriers for drug development. US Department of Health & Human Services. July 2014. Available at: <https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development>



# 59% of Respondents Identified Barriers for Successful Outsourcing

Top barriers:

- 72% Difficulties in identifying qualified CROs
- 68% Cost of outsourcing is higher than insourcing

“Low-tech and difficult options for real-time operation and quality insight” was ranked second when selected



# 66% of Respondents Identified Challenges in Adopting New Clinical Systems

- Top challenges:
  - 88% Complexity of adopting new systems (e.g., deployment time, training, ease of use, SOP changes, etc.)
  - 84% Lack of integration with existing systems

“Internal resistance to change”, “Lack of executive support for change” and “Unavailability of budget to pursue investment in technology” were highly ranked - Indicating that specific projects suffer from **Lack of executive support or budget** for change.

- Top reasons for internal resistance to change:
  - 83% Having to maintain old systems in addition to new systems
  - 83% Belief that current systems and processes are working adequately



# Elements for Successful Technology Implementation and Deployment

## Top technology elements:

- 75% Facilitate efficient start-up (e.g., parallel vs. sequential work) across departments by utilizing a workflow application
- 67% Functionality dedicated to critical areas (e.g., site identification, site selection, study library, contracting, submissions, IP release, etc.)

## Top steps taken to ensure technology deployments:

- 70% Training and refresher courses as appropriate
- 58% Communicated benefits and have set clear expectations



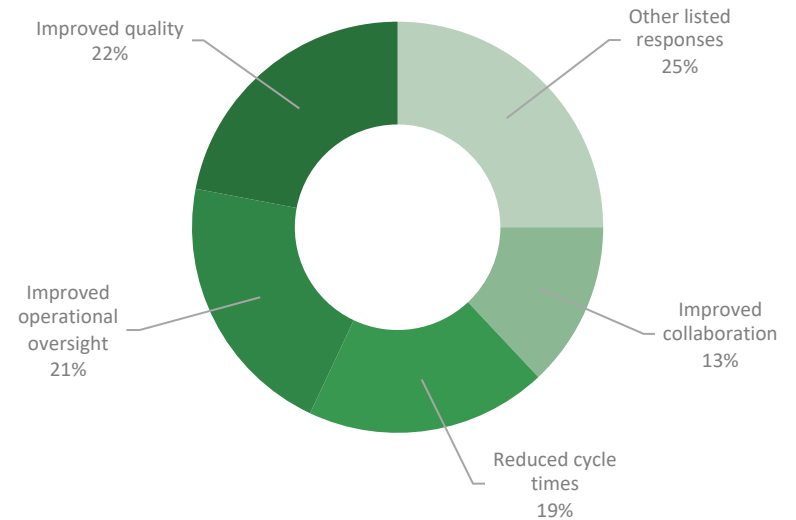
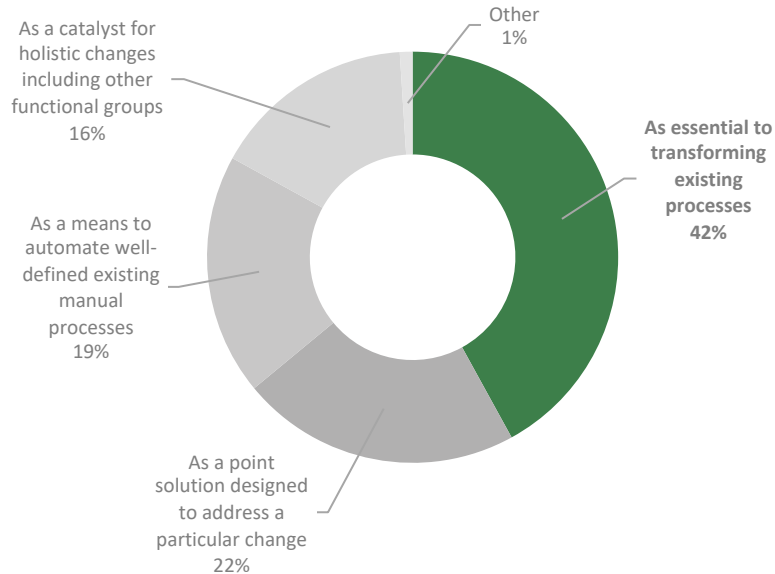
# What is Essential to Transforming Existing Processes

- **42%** see technology as essential
- Top Challenges of Implementing New Clinical System:
  - Not involving end users in the decision-making process
  - System is not a complete replacement for incumbent system
- **Only 54%** have implemented (or plan to implement) process changes
- The top non-technology changes cited:
  - 56% Align processes to maximize the effectiveness of technology adoption
  - 55% Implementation of cross-functional teams

# Technology Perceptions

View of technology use within site collaboration

Biggest improvement as a result of technology adoption





# Measures of Technology Projects

- Top measures of Effectiveness:
  - 69% Key Performance Indicators (KPIs)
  - 54% Meeting established goals (e.g., cycle time reductions)
- Top measures of rate of adoption:
  - 52% System reporting showing utilization
  - 42% Deployments are mandatory
- Top site collaboration improvements from technology adoption:
  - 56% Improved quality
  - 49% Improved collaboration



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# ECLINICAL TECHNOLOGY IN STUDY STARTUP USAGE & FUTURE DEPLOYMENTS

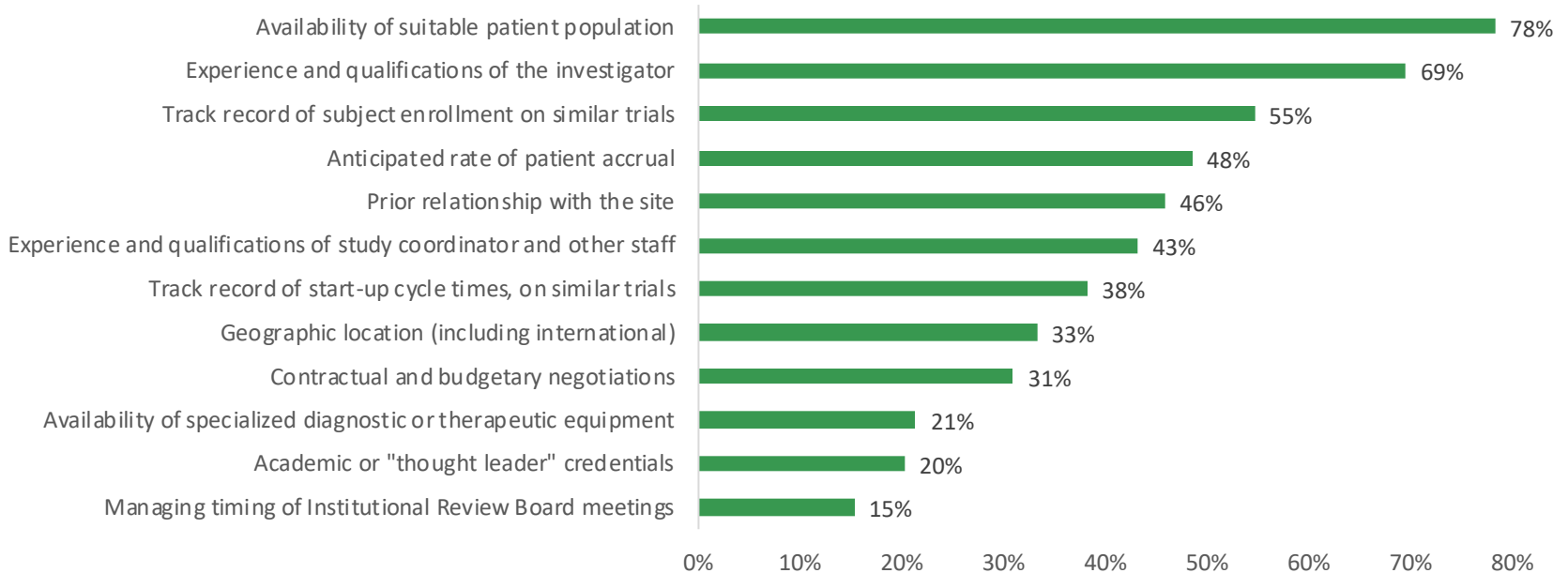
## *SITE SELECTION*





# Criteria for Site Selection/Identification

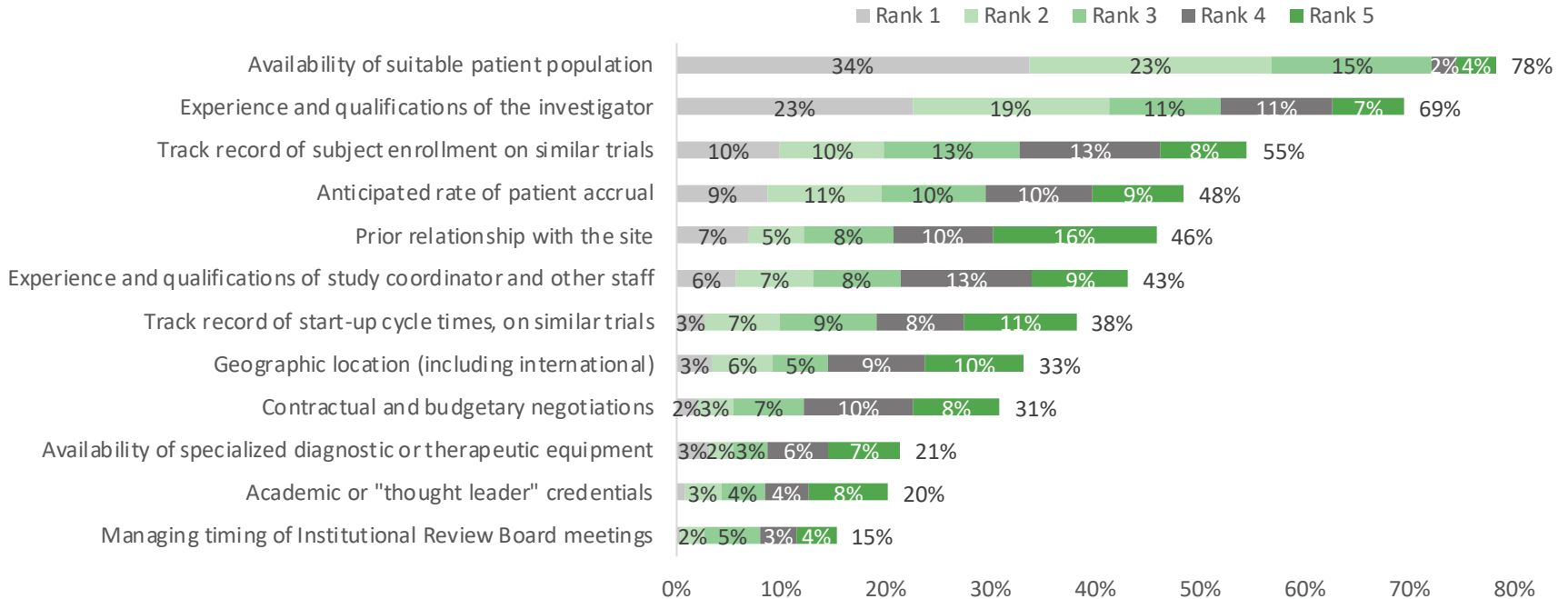
From the list below, what are the five (5) most important criteria for site selection/identification? Select five. (n=262)





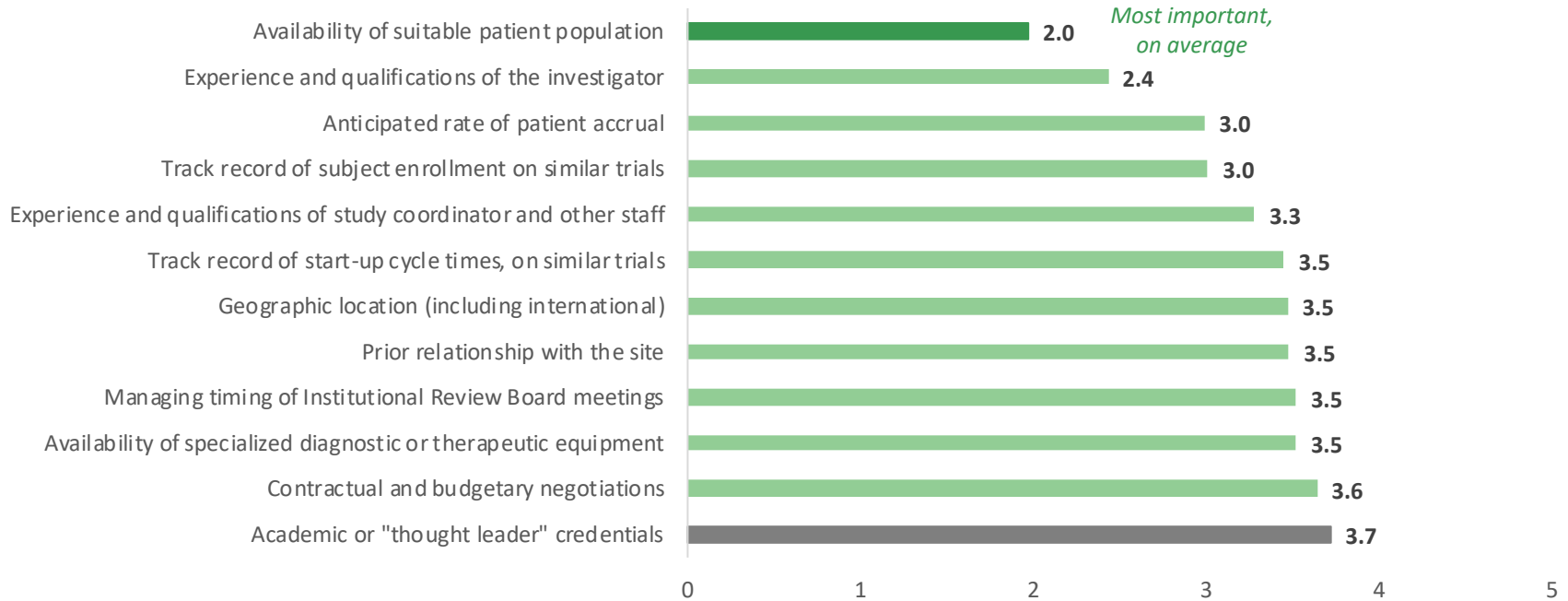
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# Average Ranking: Top 5 Criteria for Site Selection/Identification

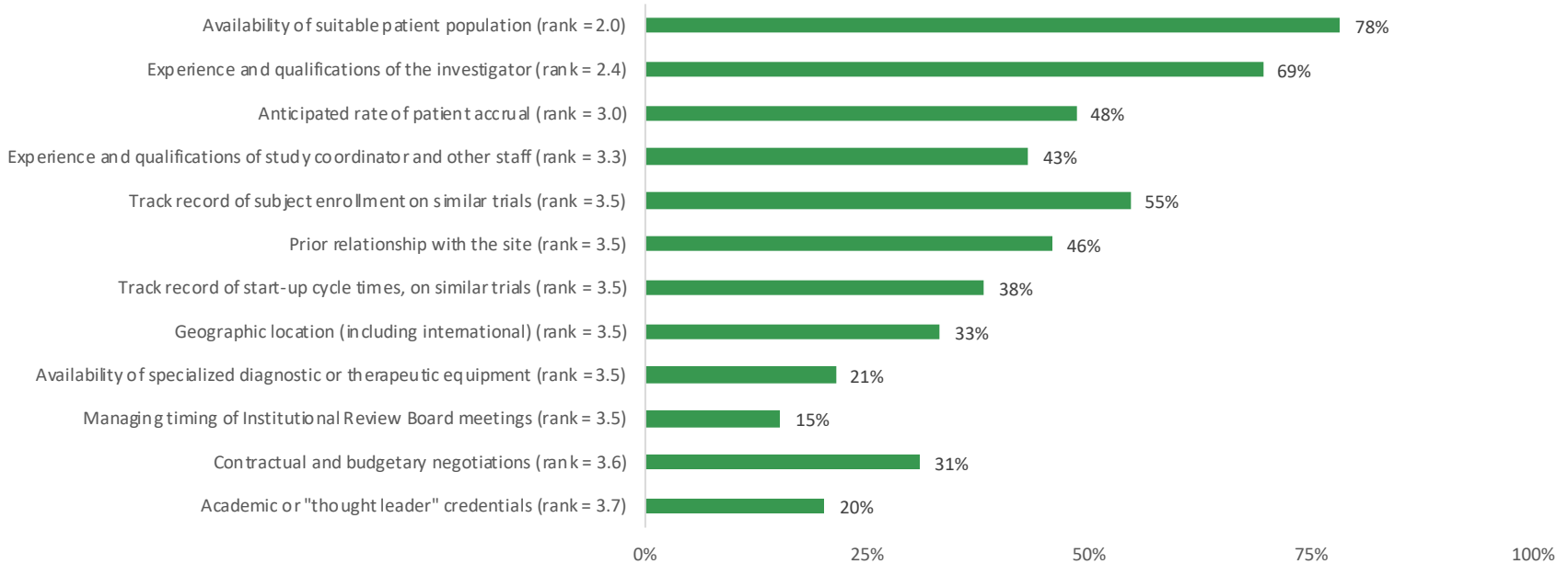




# Criteria for Site Selection/ Identification (prevalence and ranking)

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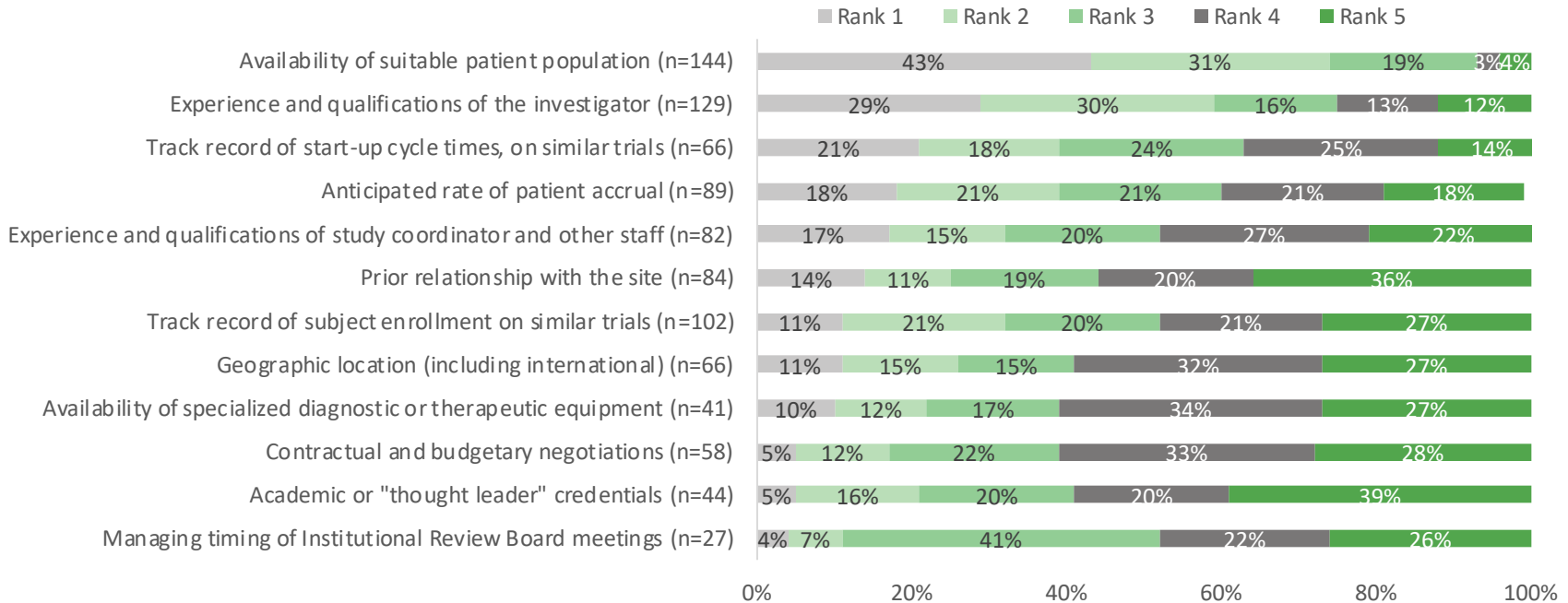
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# Sponsors: Rank Top 5 Criteria for Site Selection/Identification

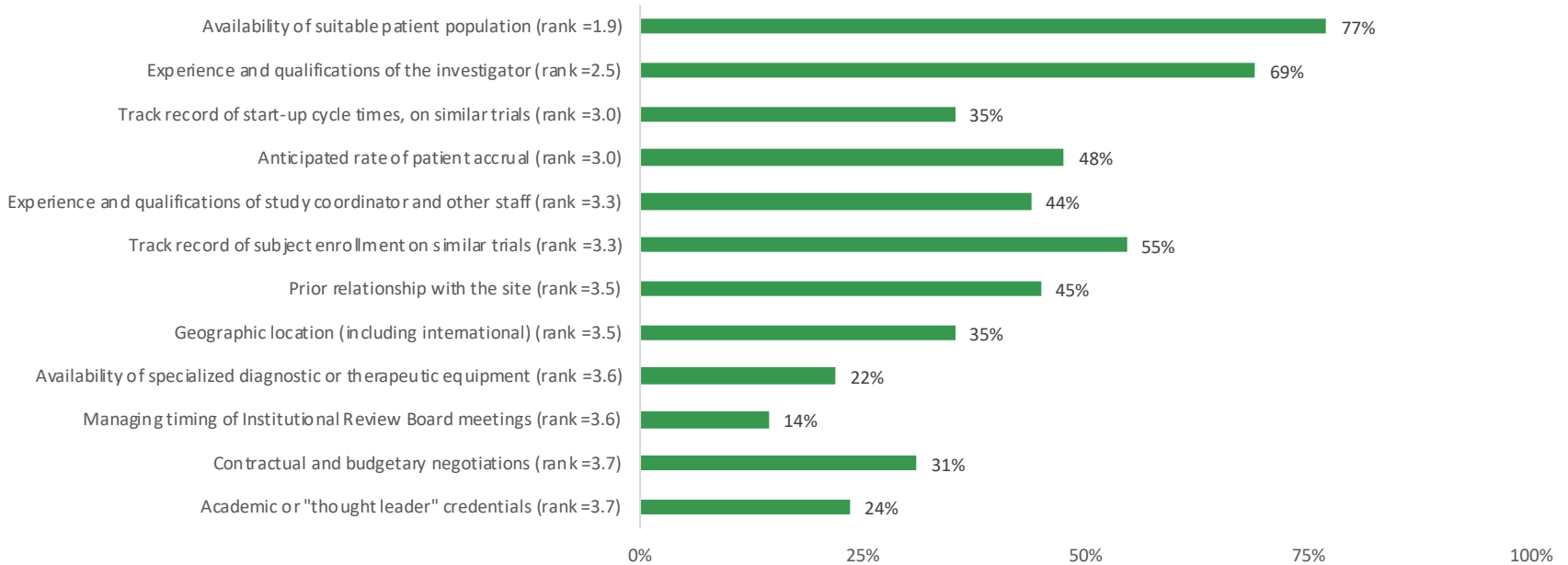
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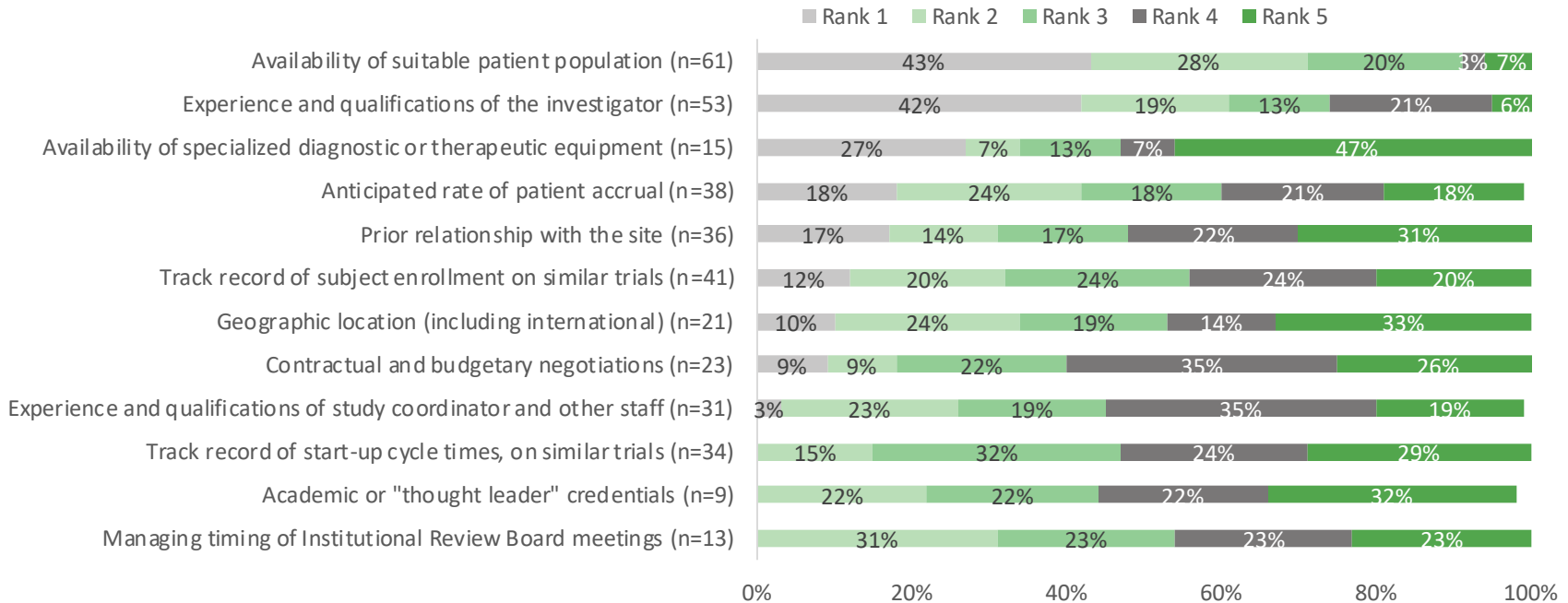
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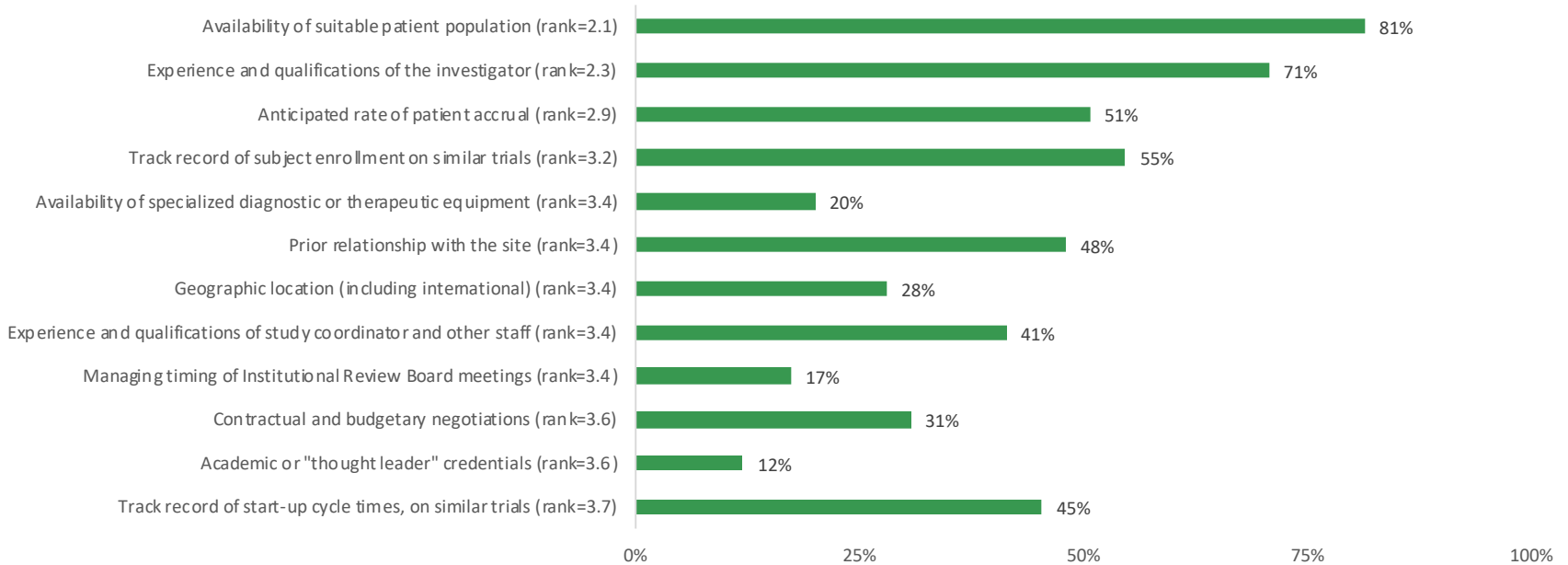
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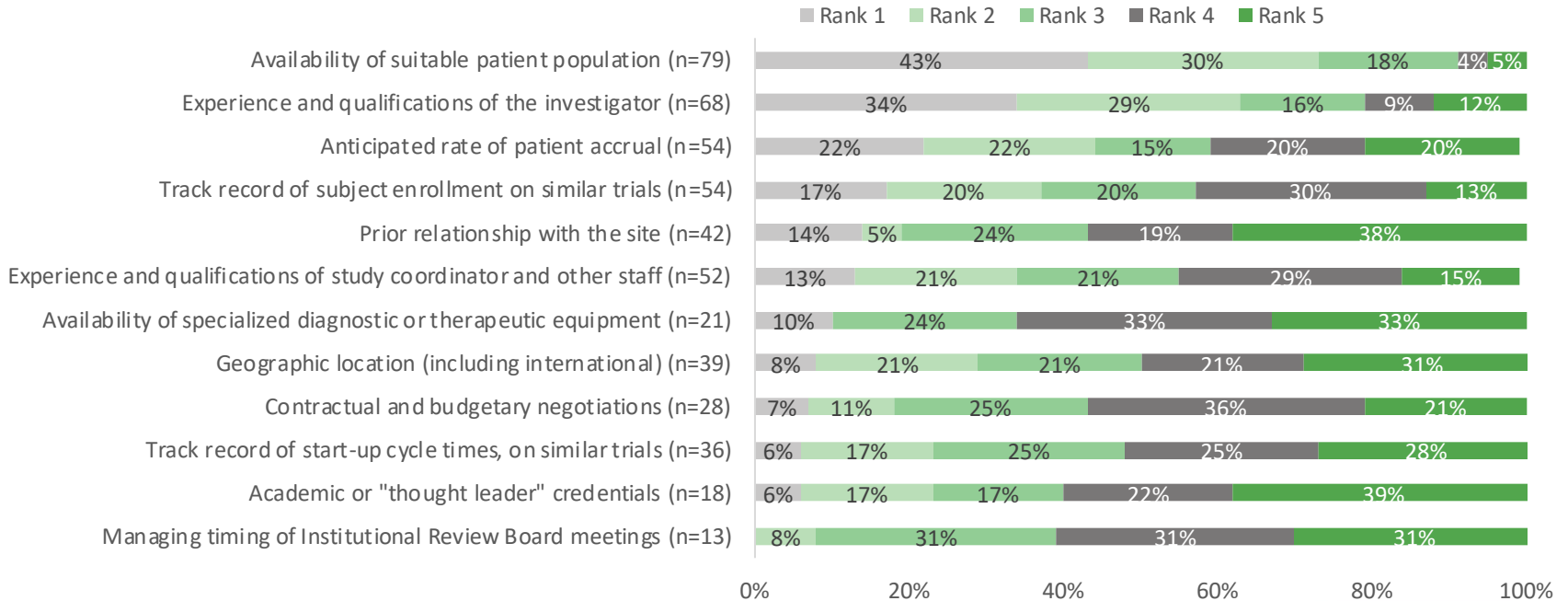






# 1-10 Trials: Rank Top 5 Criteria for Site Selection/Identification

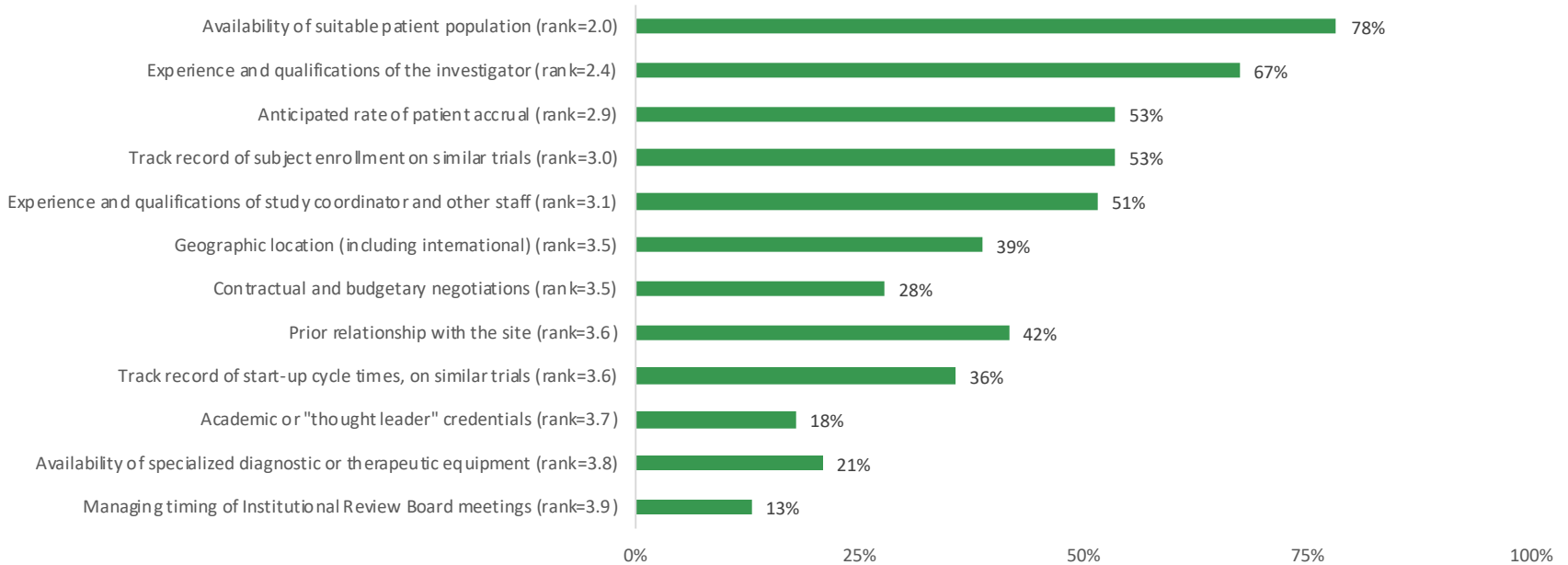
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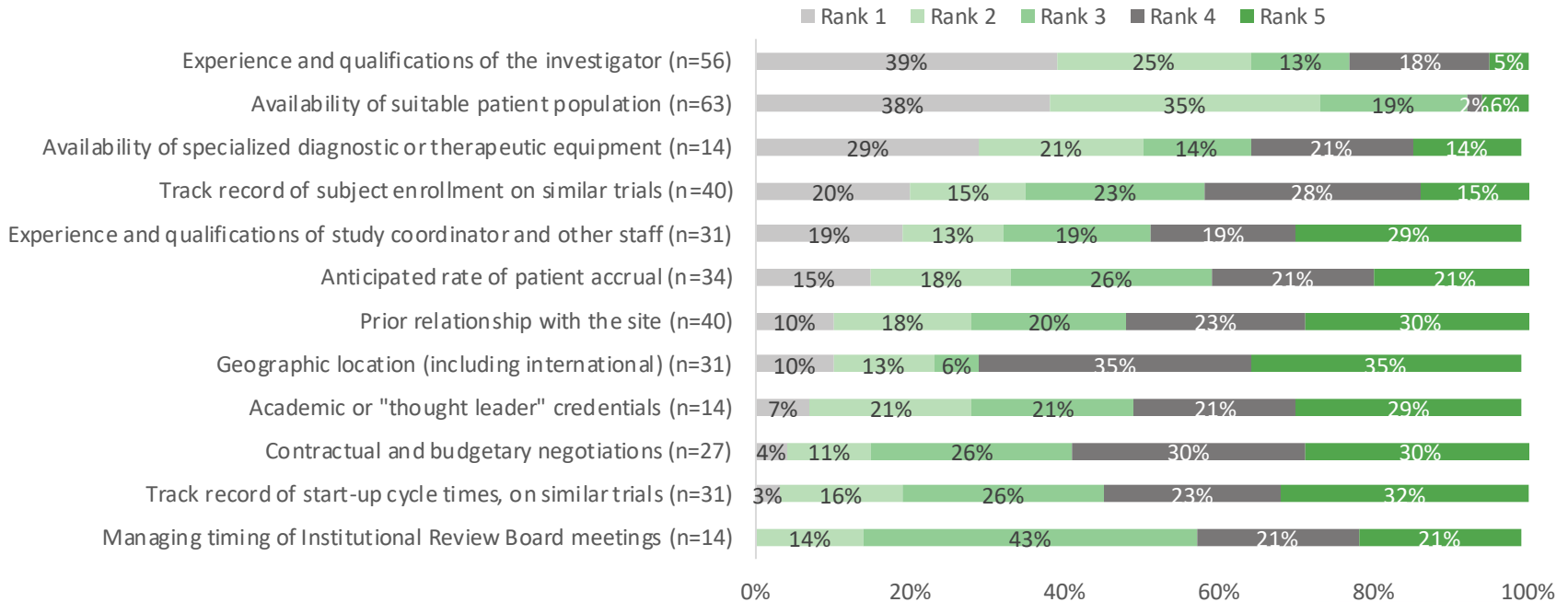
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# 11-50 Trials: Rank Top 5 Criteria for Site Selection/Identification

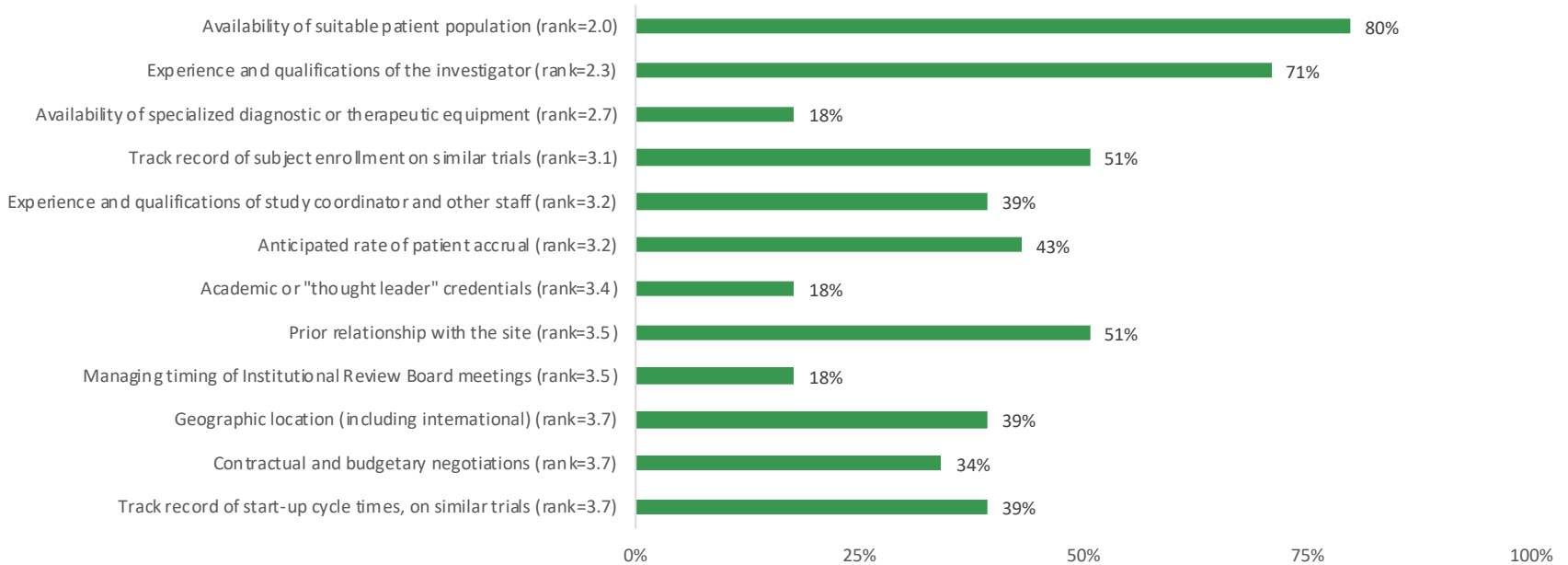
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# 11-50 Trials: Rank Top 5 Criteria for Site Selection/Identification (prevalence and ranking)

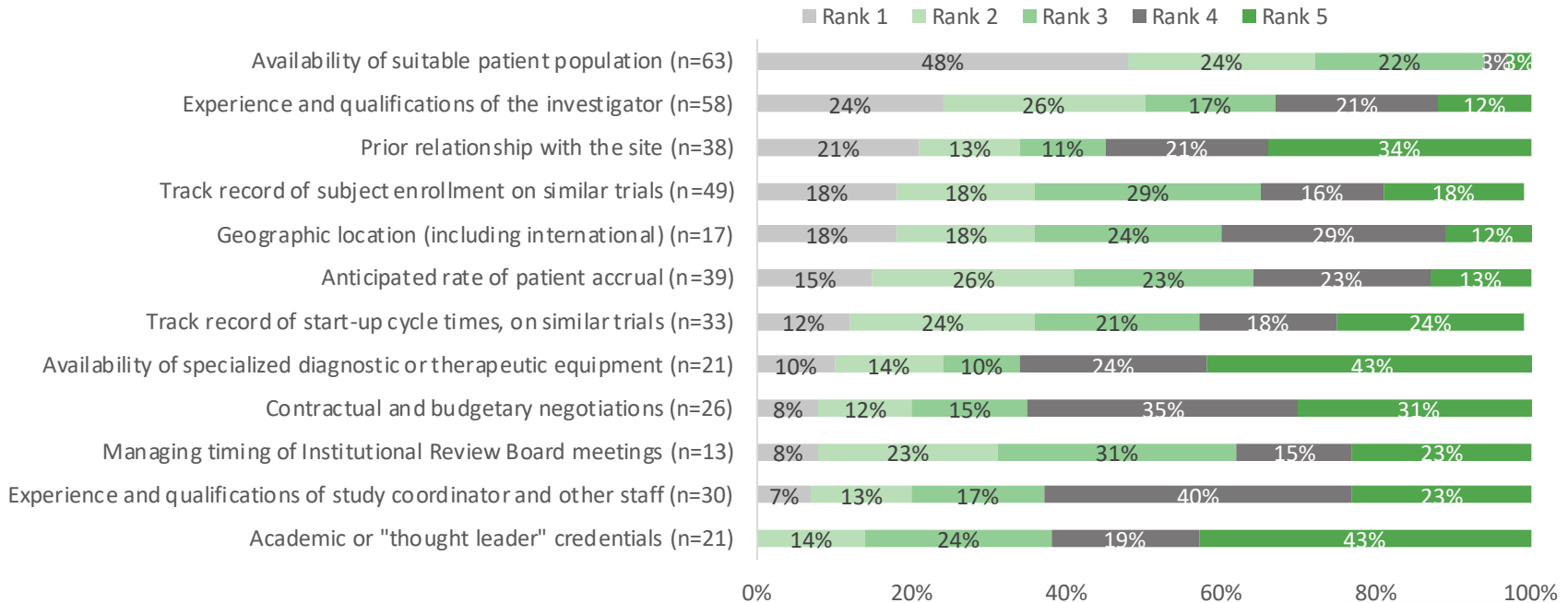
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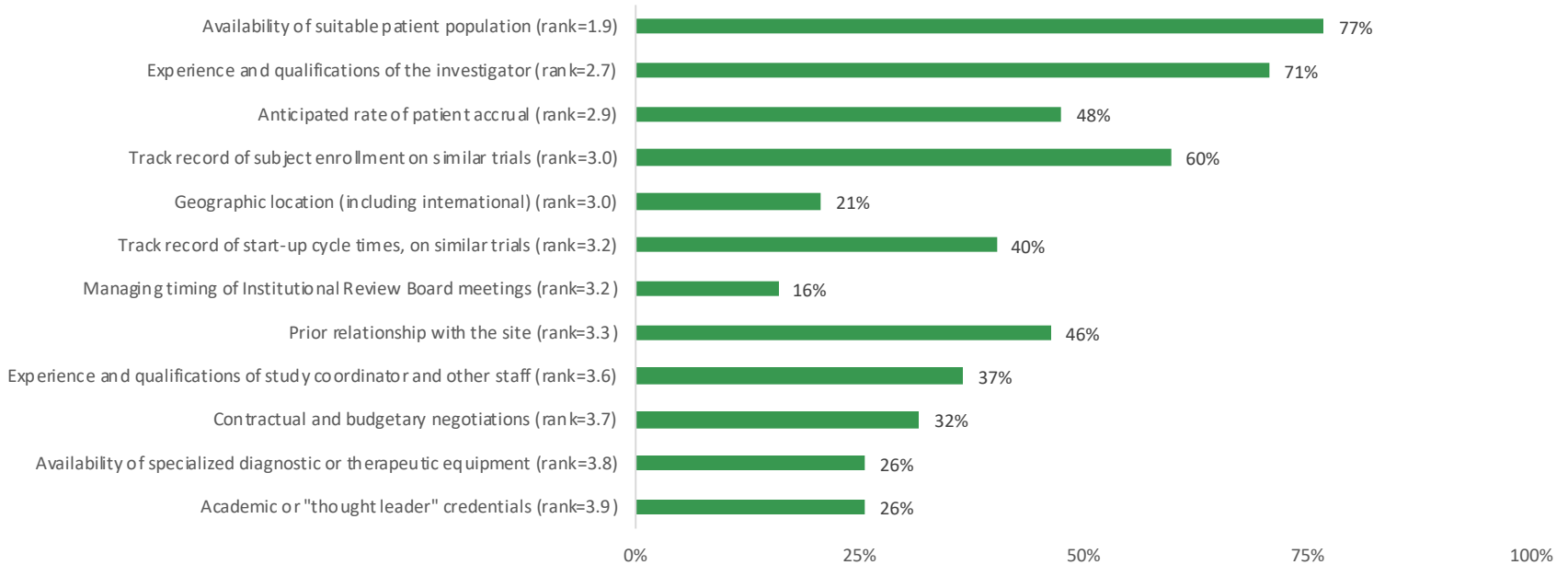
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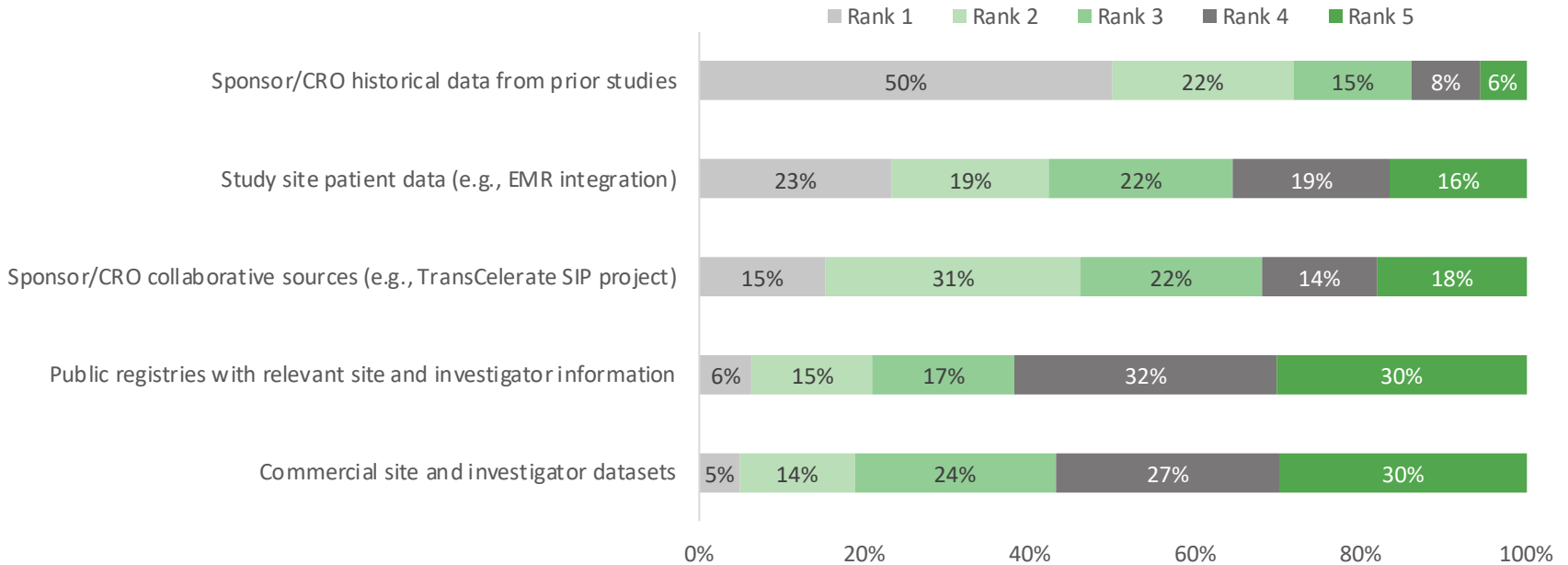
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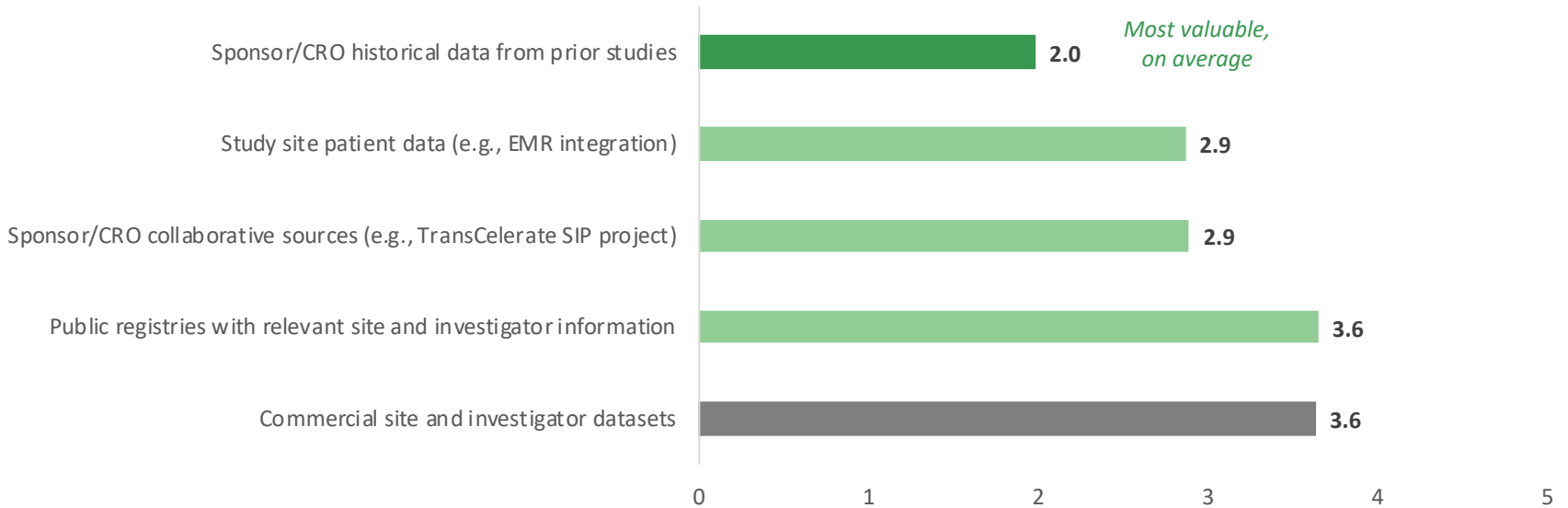
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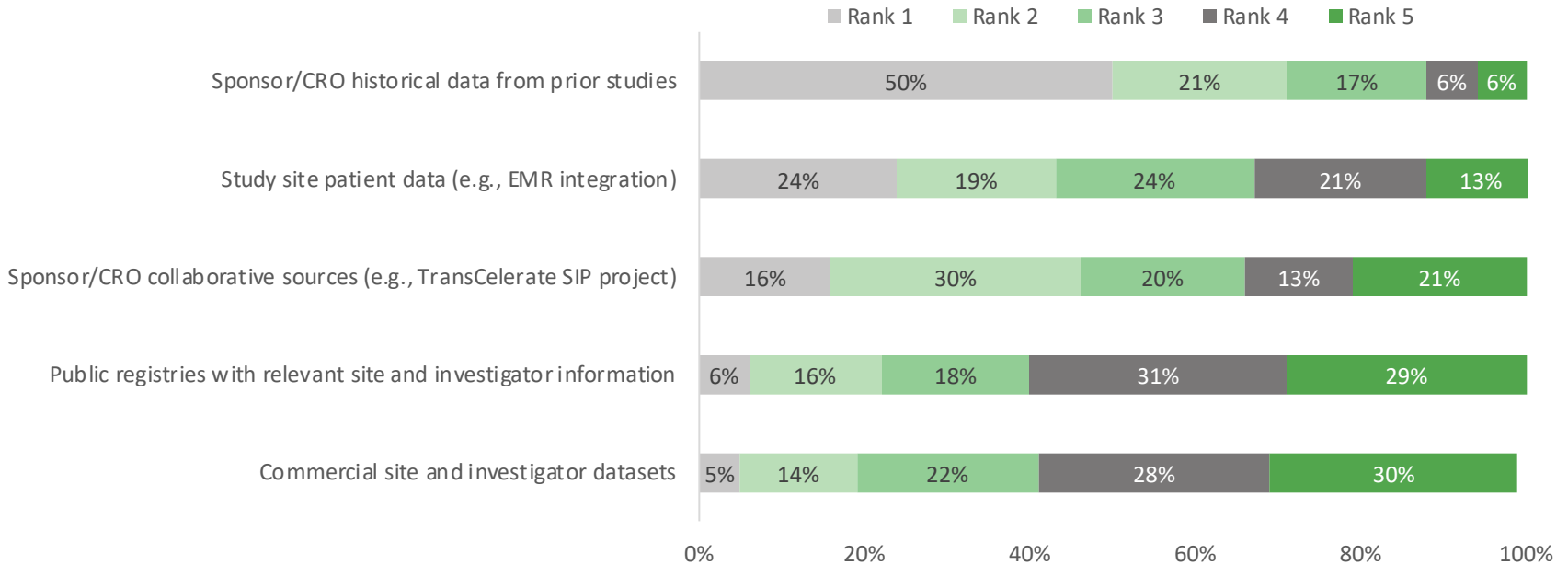






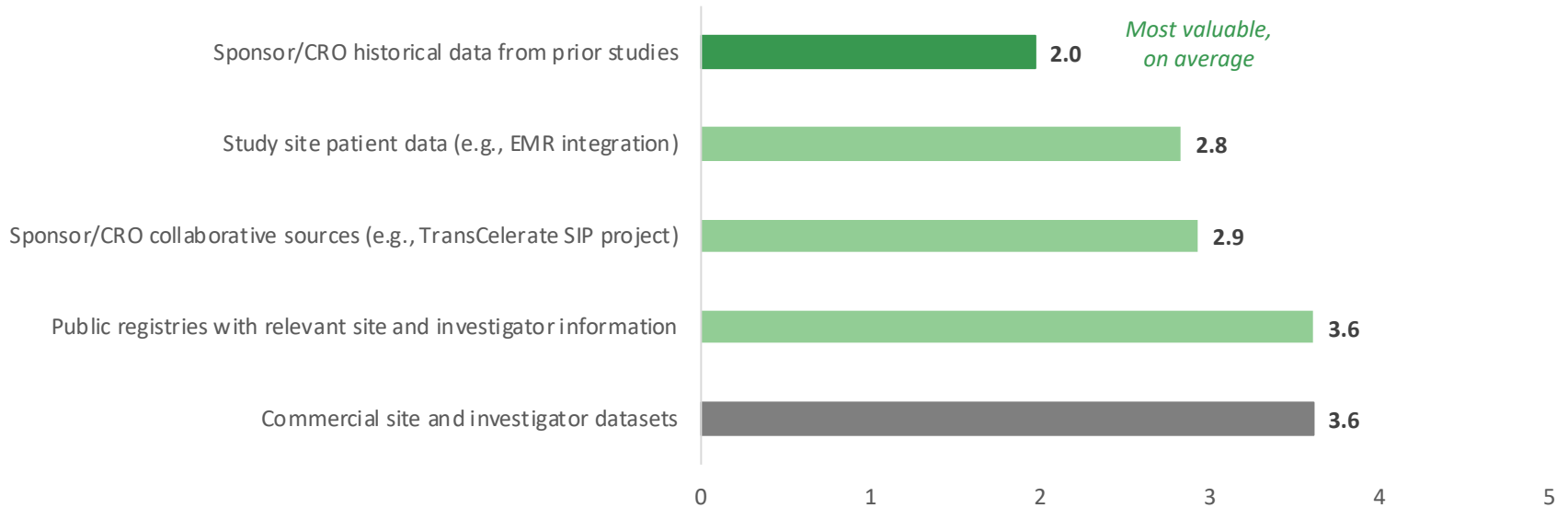
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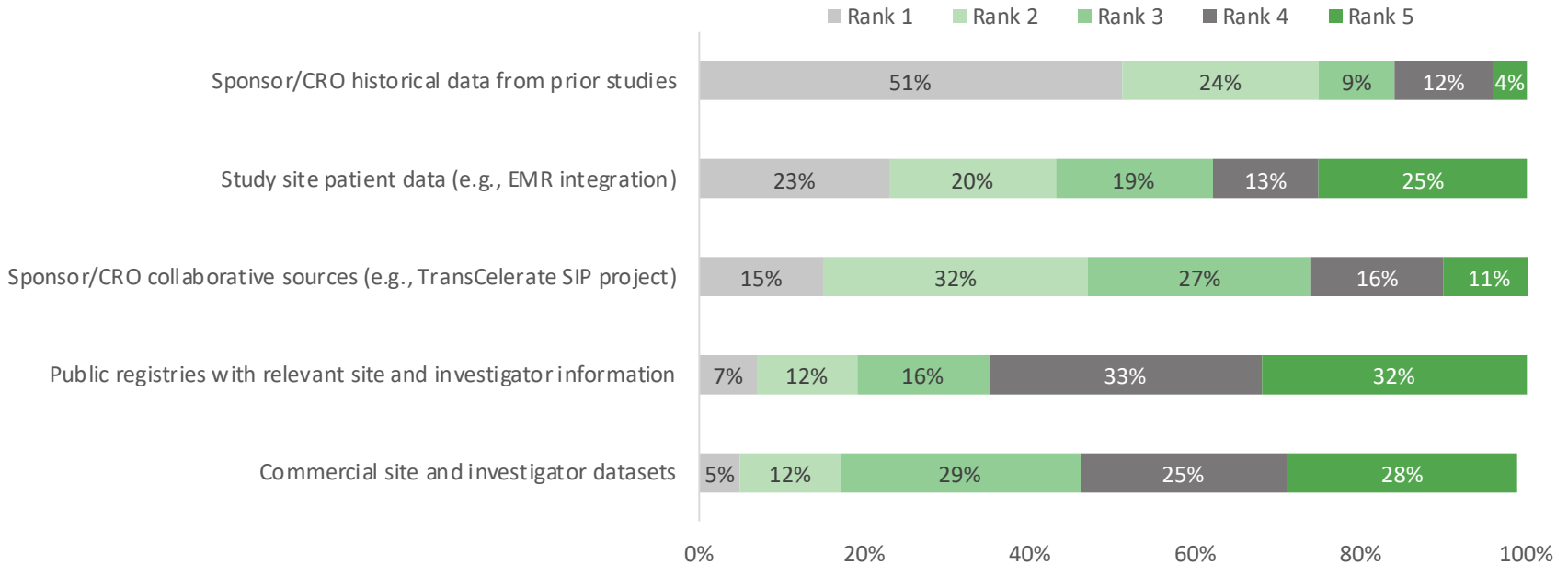
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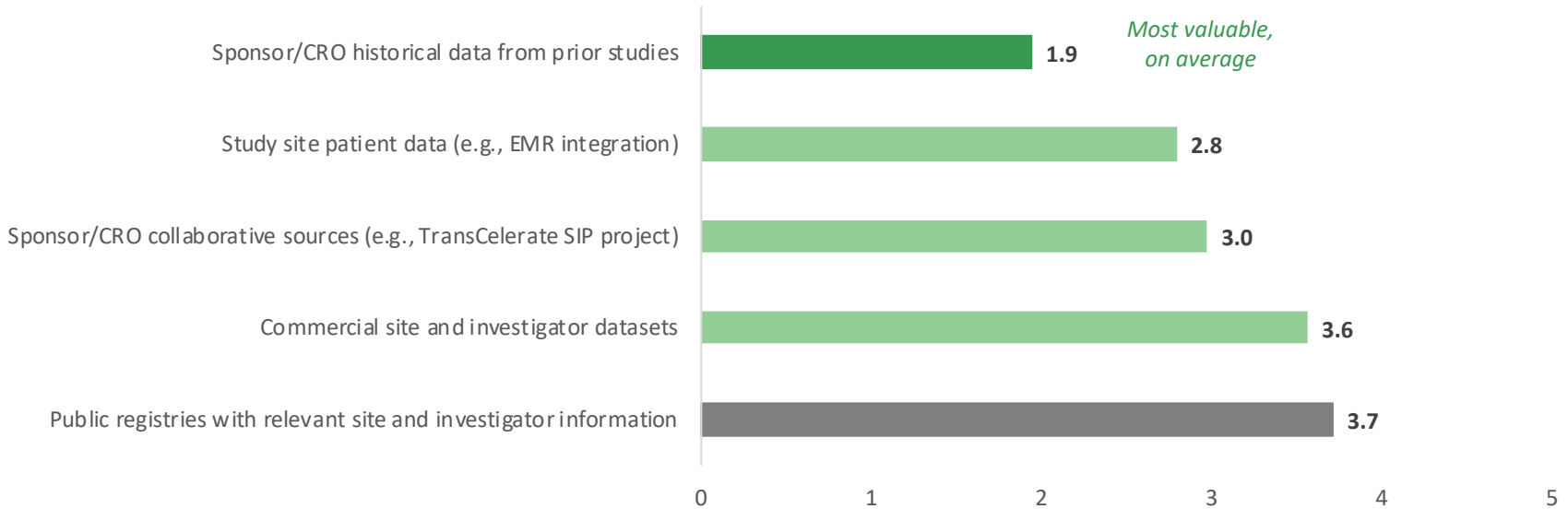
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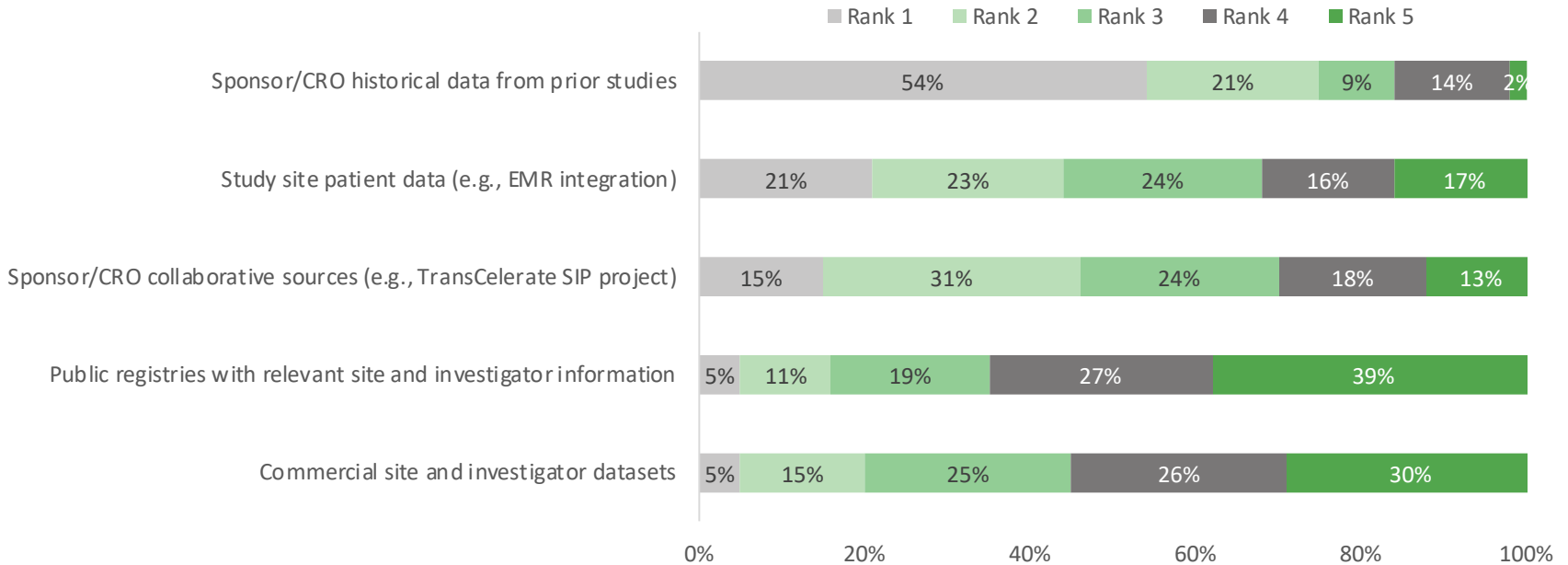
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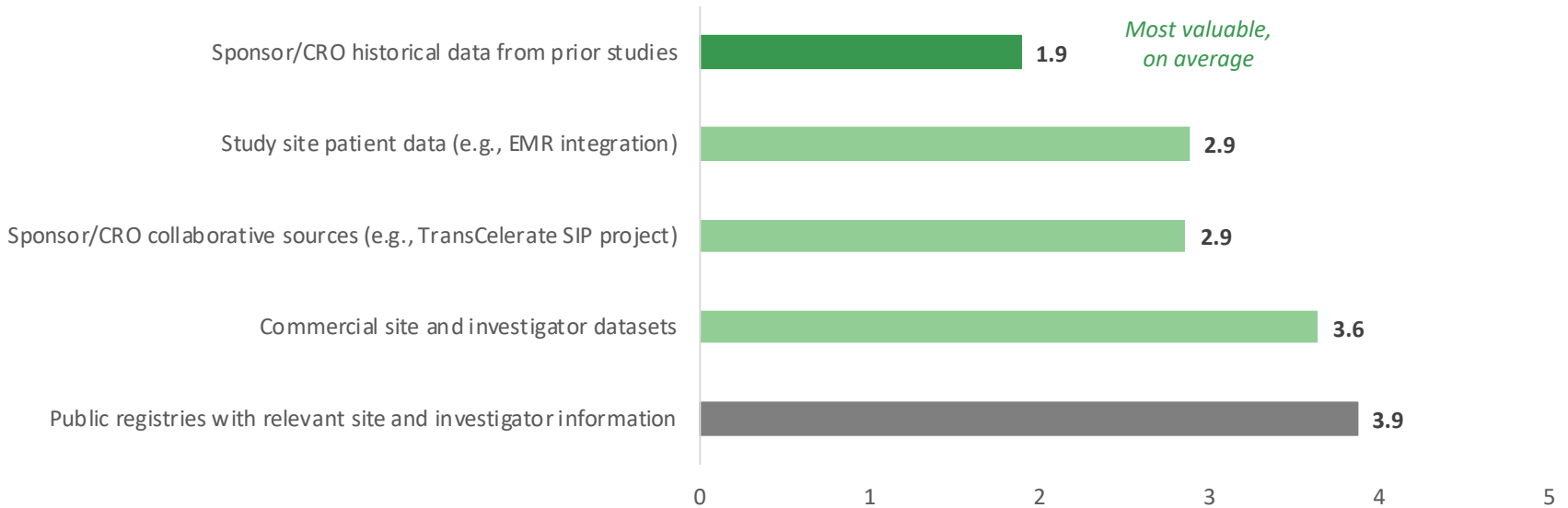
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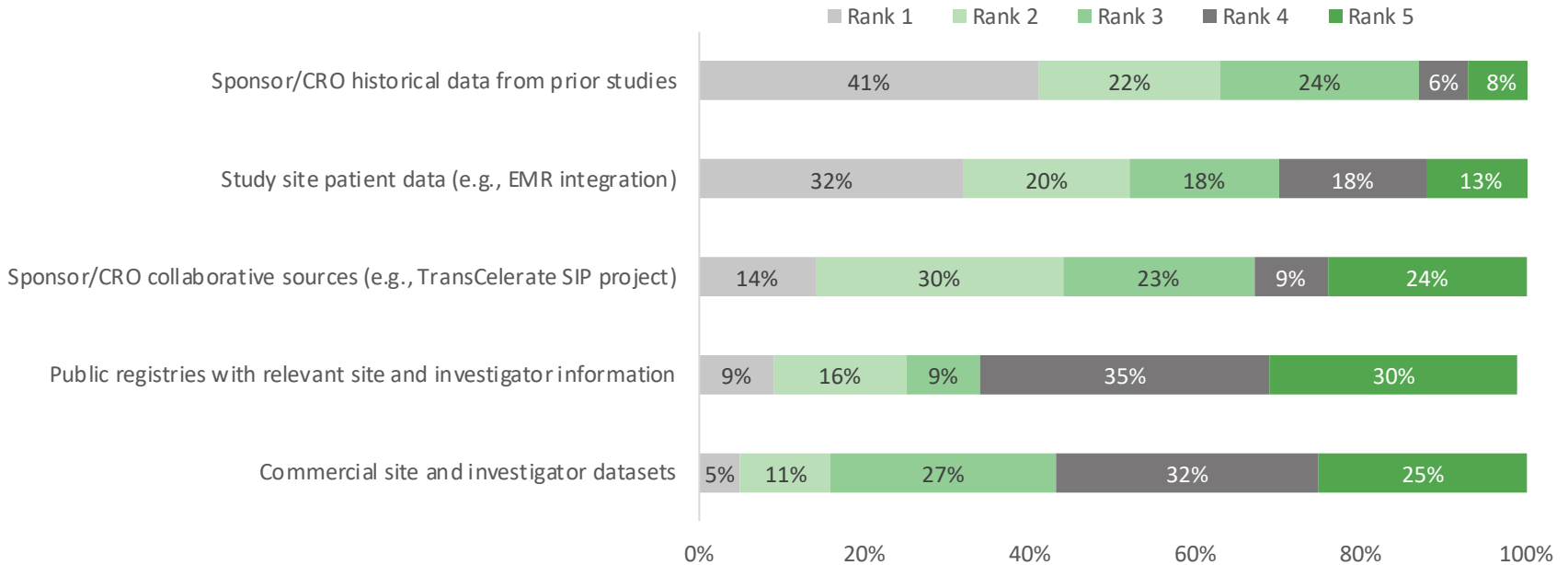
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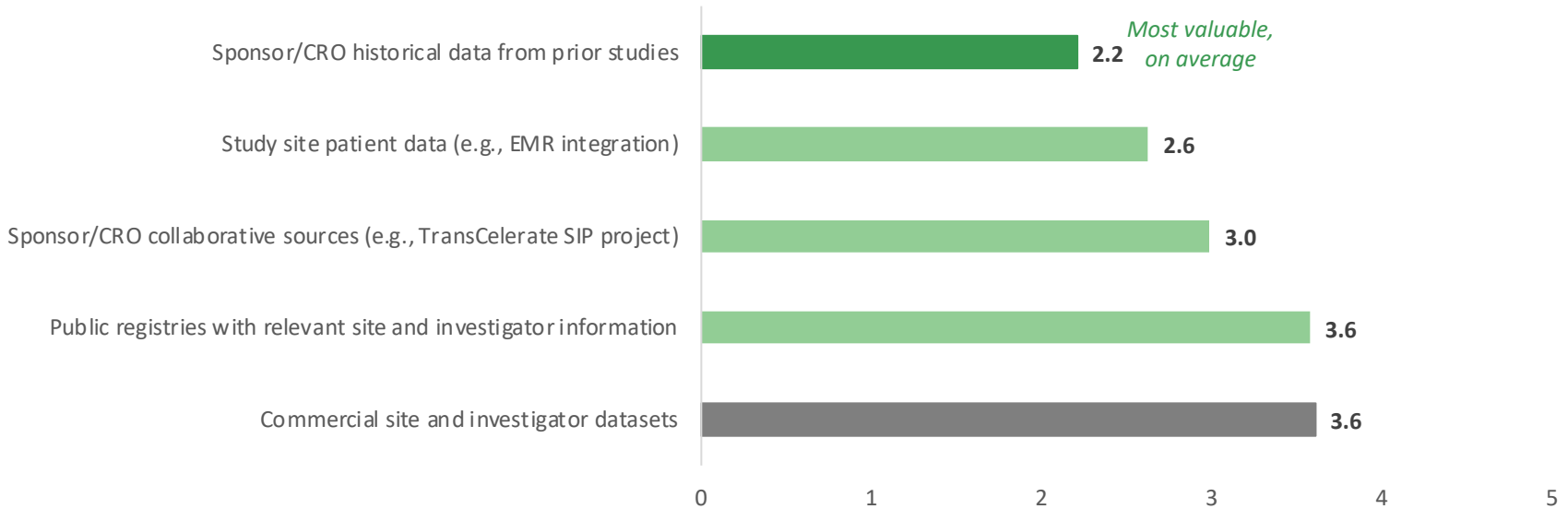
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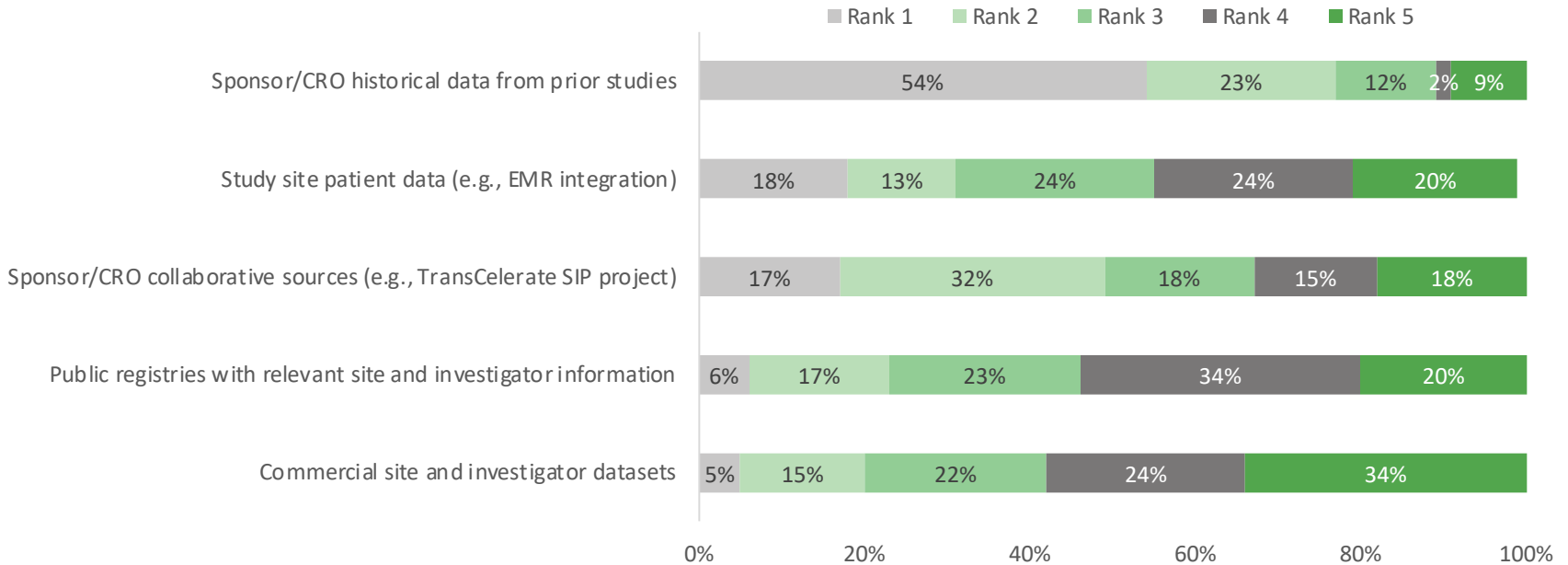






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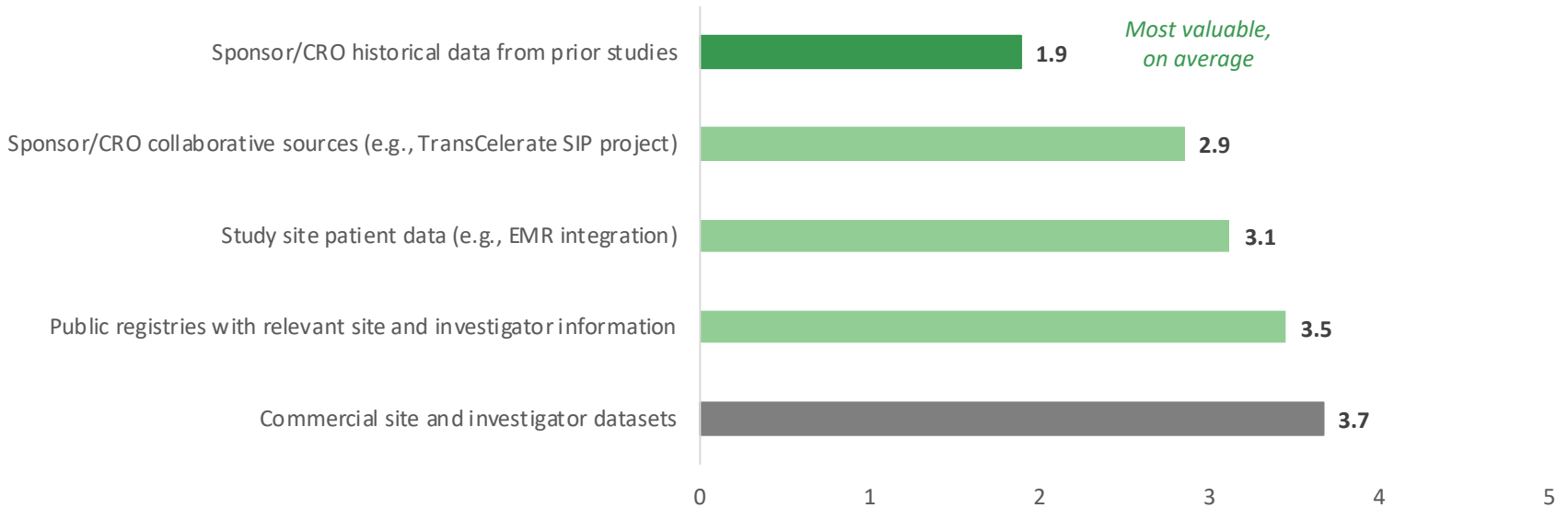
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# Other Data Sources for Site Selection?

*Do you use another data source for site selection that you find valuable? Please explain. (n=31)*

- According to the experience of the CRA
- Advocacy group
- Centerwatch, previous collaborations, sites performance in previous similar studies
- CTRI Website
- Discussion with other Pharma
- GlobalData
- Information from our Medical Affairs Colleagues
- Information from peers
- IQVIA
- KOLs feedback
- Local relationships with investigators
- Local research groups members lists, e.g. NOGGO (North and East German Society for gynecologic oncology), lists and rankings from accreditation and certification institutions
- Other colleagues' feedback
- Own database
- Previous studies
- Prior experience with the site / PI; CRA / Country Head feedback
- Publication in specific field by the principal investigator
- Publications on relevant studies
- Publications; investigator peer referrals; site network data
- Published scientific literature to identify potential investigators with experience in conducting relevant studies
- Referral
- Reference from other physicians
- Referrals from other PIs
- Site survey with patient selection criteria questions
- Social media listening
- Third party sources such as WCGIRB and their datasets as regards IRB and previous site performance
- Use of site for other studies with same sponsor
- Using Central IRB database to identify sites
- Vendor conference/ recommendation
- We are now utilizing my expertise and Clinical Trial Educators, professionals who know what is needed for good enrollment
- Word of mouth



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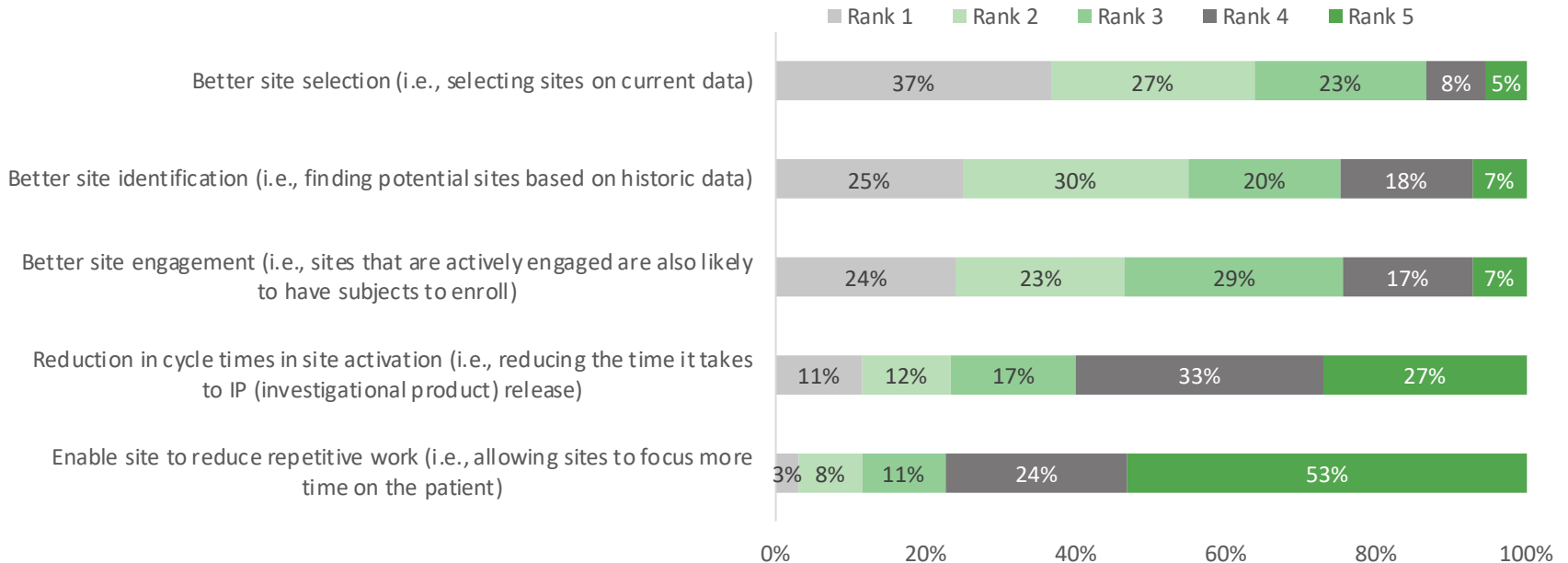
# ECLINICAL TECHNOLOGY IN STUDY STARTUP USAGE & FUTURE DEPLOYMENTS

## *PATIENT RECRUITMENT*



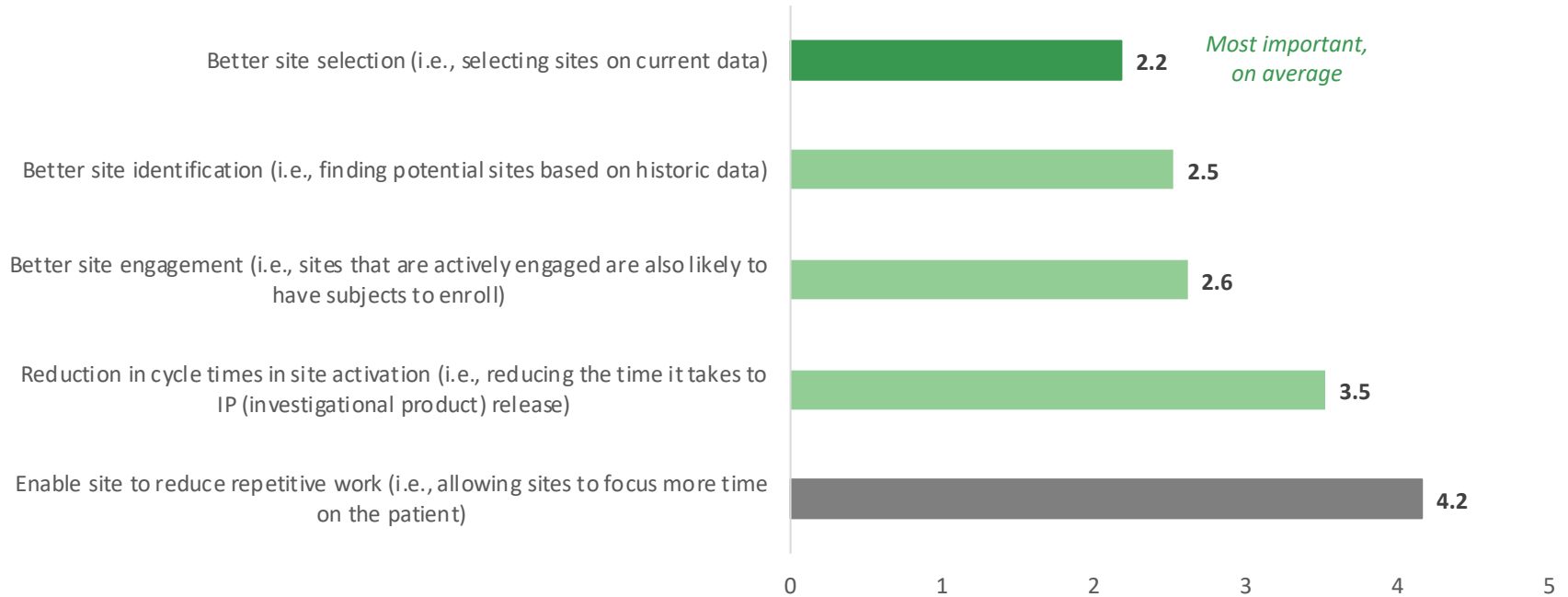
# Ranking of Aspects that Speed Patient Recruitment

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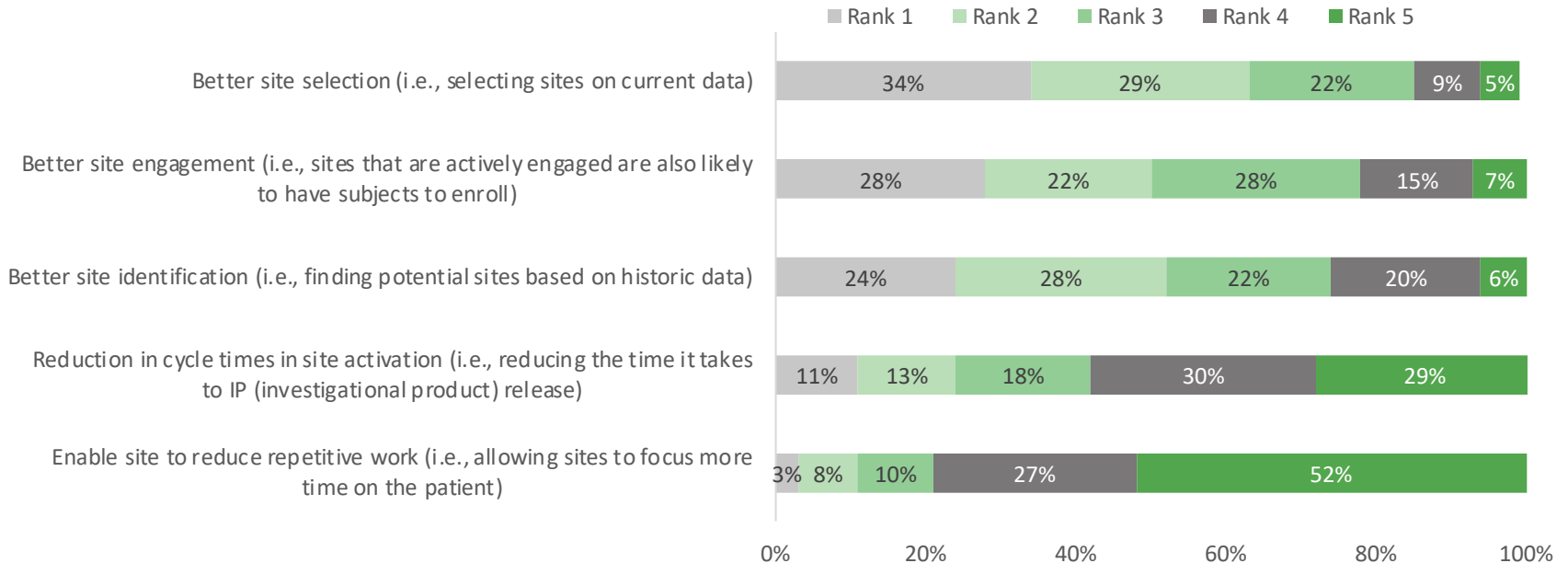
# Average Ranking: Aspects that Speed Patient Recruitment





# Sponsors: Ranking of Aspects that Speed Patient Recruitment

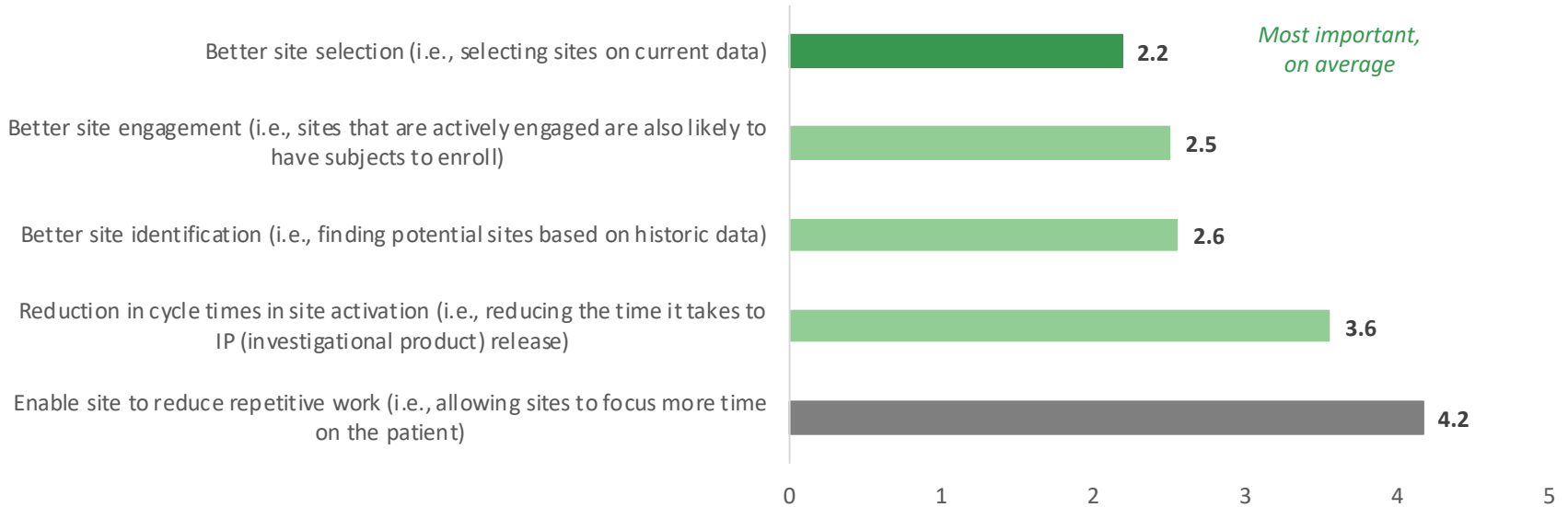
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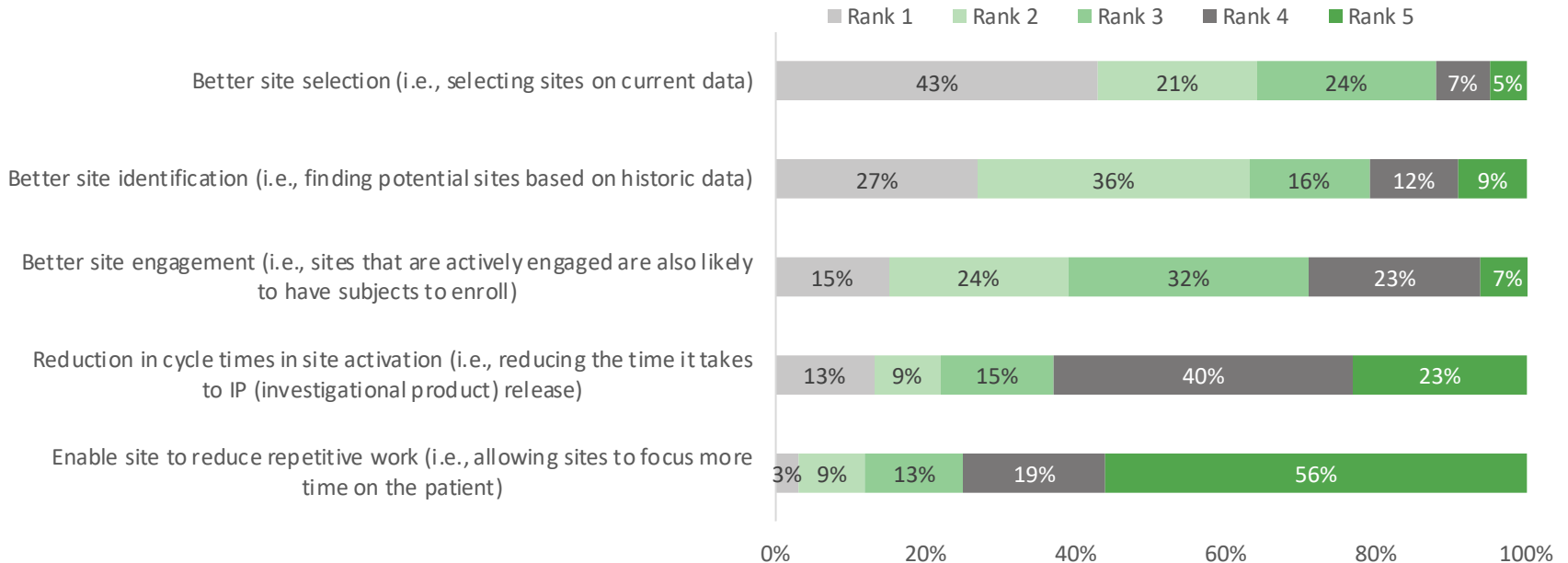






# CROs: Ranking of Aspects that Speed Patient Recruitment

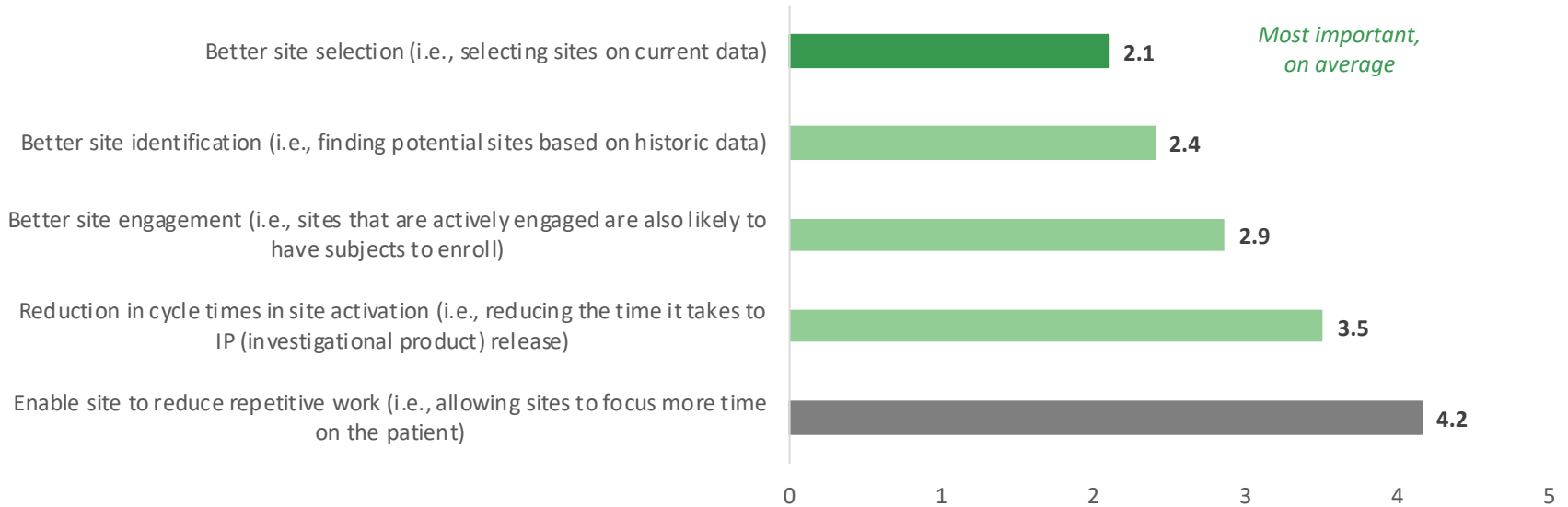
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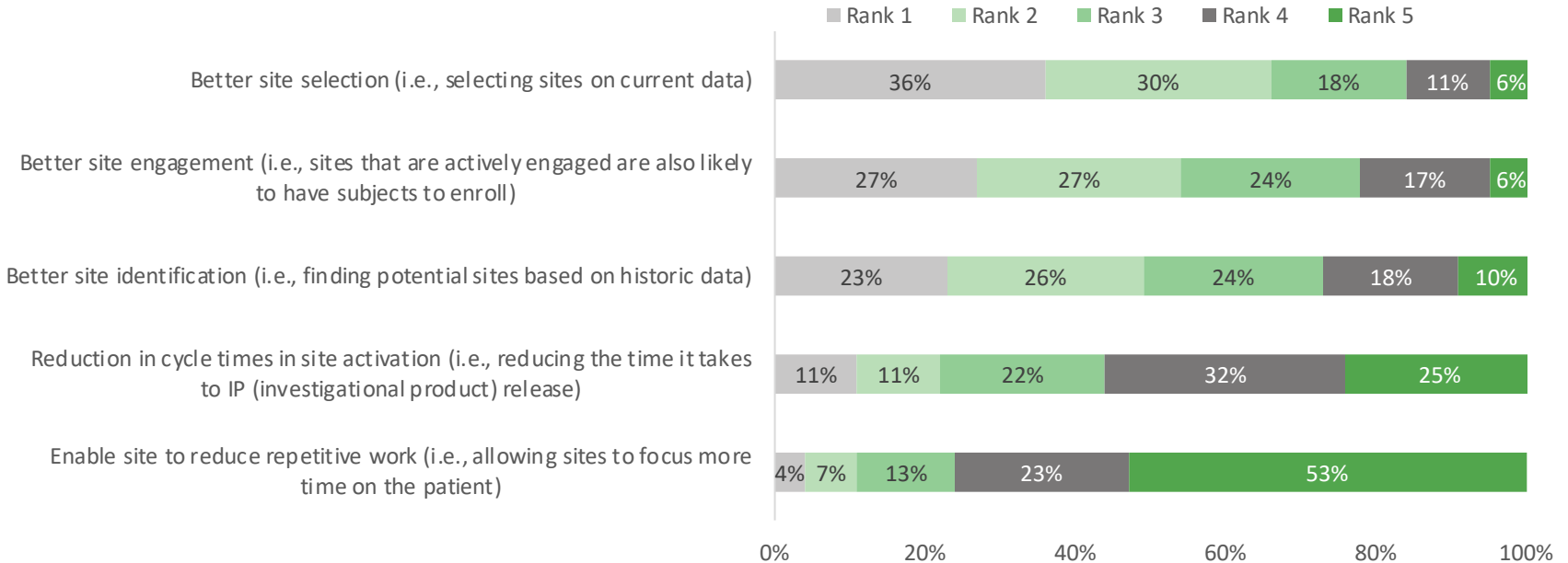
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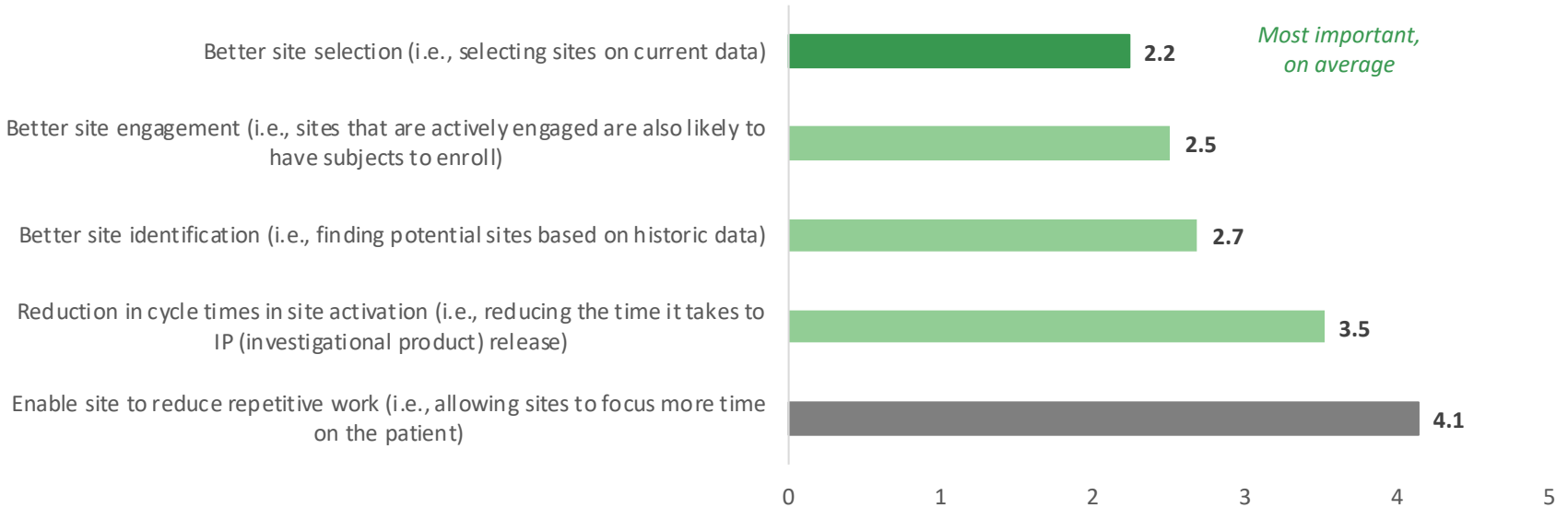
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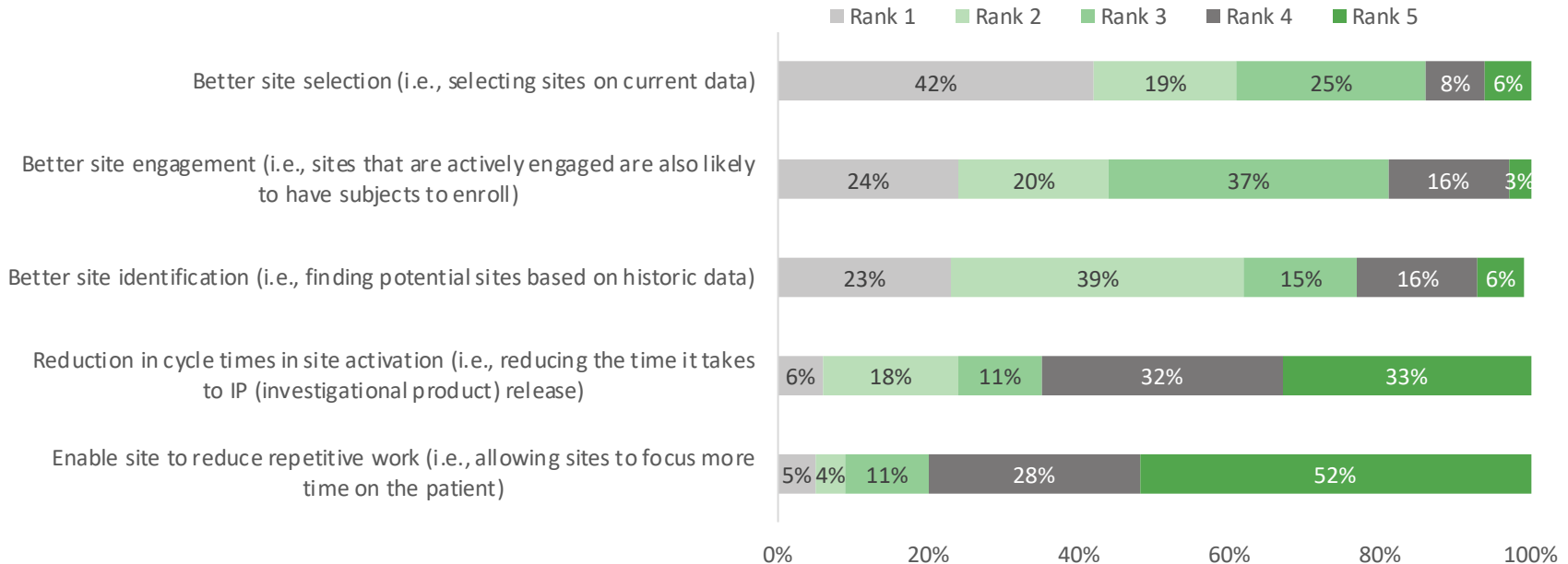
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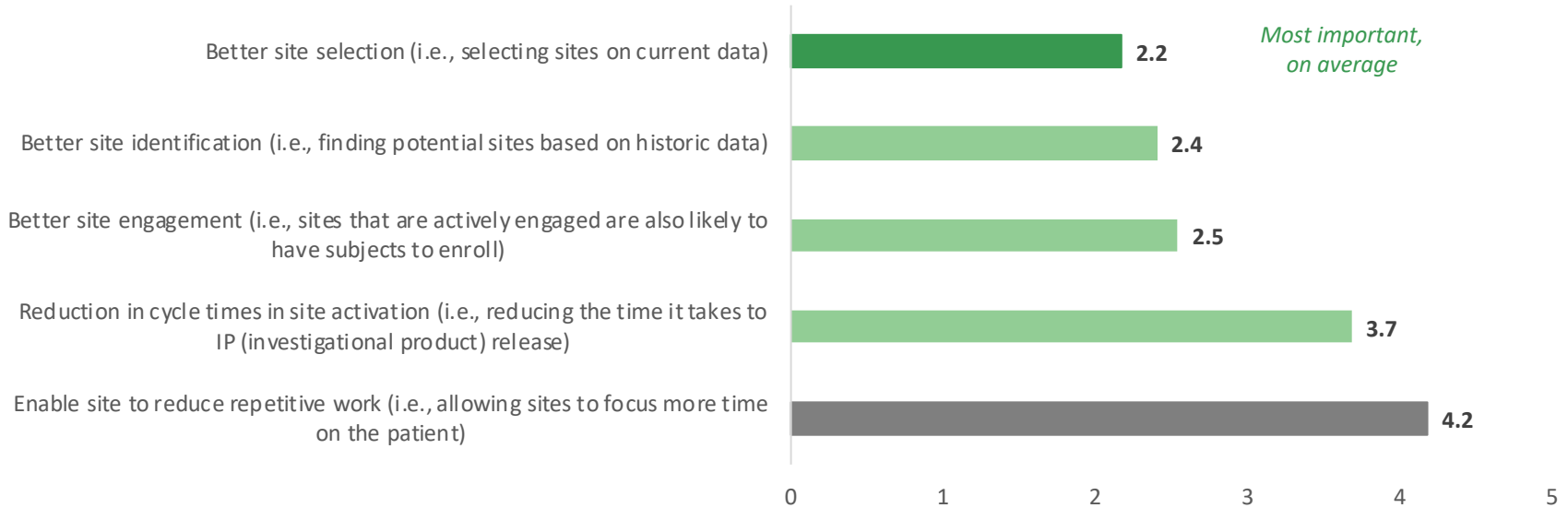
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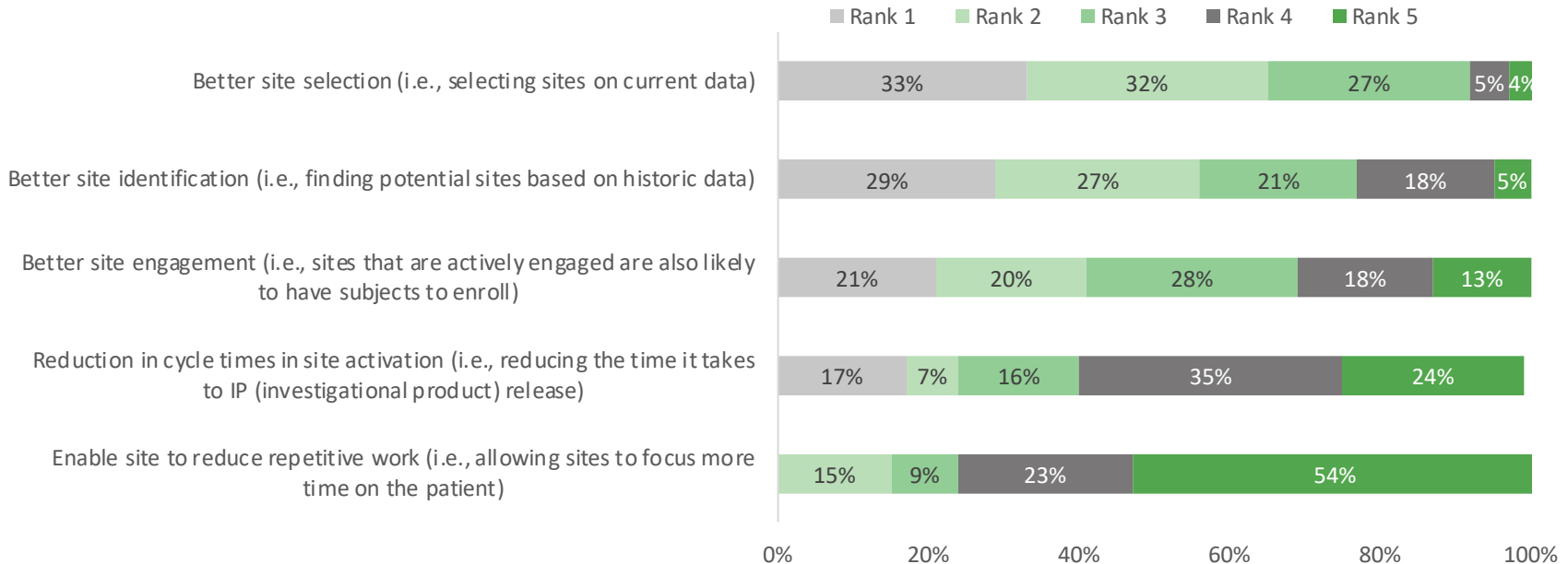
What are the most important aspects that can speed patient recruitment in clinical trials? Rank the following options in order of importance where “1” is most important and “5” is least important. (mid-size companies with 11-50 trials only, n=79)





# >50 Trials: Ranking of Aspects that Speed Patient Recruitment

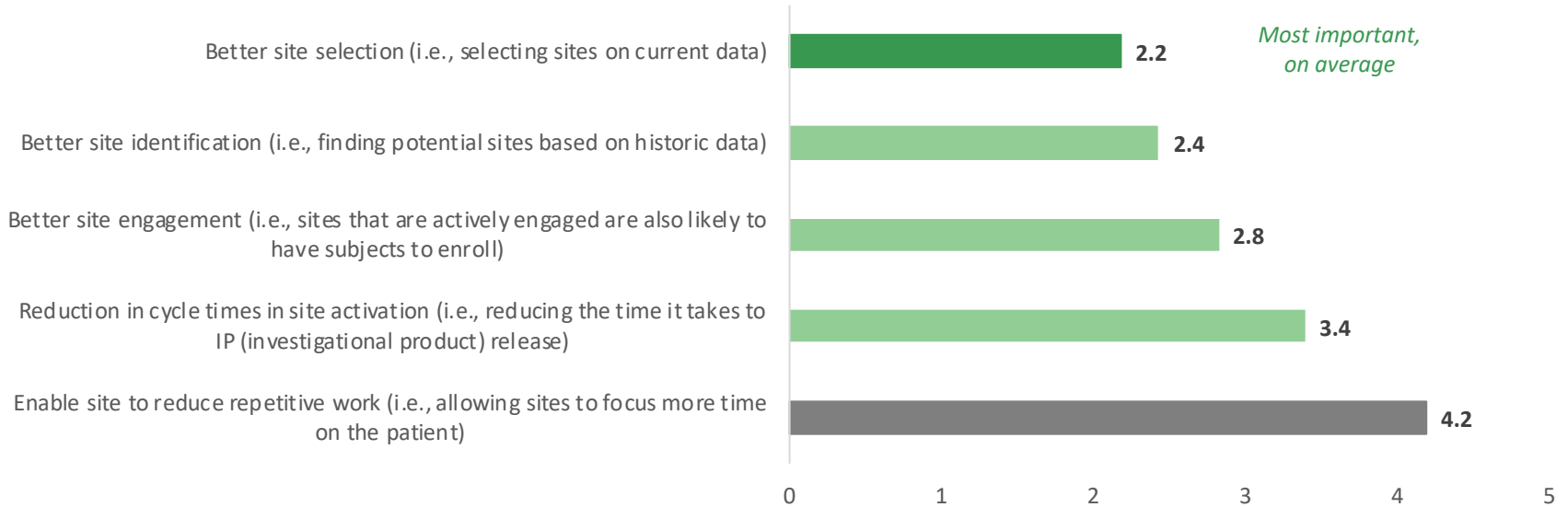
What are the most important aspects that can speed patient recruitment in clinical trials? Rank the following options in order of importance where “1” is most important and “5” is least important. (large companies with >50 trials only, n=82)





# >50 Trials: Ranking of Aspects that Speed Patient Recruitment

What are the most important aspects that can speed patient recruitment in clinical trials? Rank the following options in order of importance where “1” is most important and “5” is least important. (large companies with >50 trials only, n=82)







# Other Aspects that Speed Recruitment?

*Do you know another aspect that can speed patient recruitment in clinical trials? Please explain. (n=37)*

- A good study coordinator
- Advertising
- Appropriate staffing at the site
- Audit results
- Better financial packages offered; providing high quality equipment and resources
- Better project setup incl. identification and mitigation of potential bottlenecks for recruitment
- Better regulatory oversight and timeline
- Better understanding of internal processes and timelines at identified sites
- Competitive enrollment
- Concentrate on sites that do not have concurrent, potentially competitive studies
- Define scope of population and alternate population
- Depends on PI interest in clinical trials
- Engagement from sponsor/CRO during startup period
- Engaging with patient populations who have the condition being studied
- Ensuring clinical trials are offered to all eligible patients, raising awareness of clinical trials in patient advocacy groups or through advertising
- Feedback on protocol prior to finalization to limit challenges in eligibility
- Frequent communication and information sharing with site
- Geographic location of the sites
- Good advertisement (internet), good promotion at patient advocacy groups, good site relationship via Medical Affairs
- Incentive program
- Incentives
- Knowledge of country specific market (if any competing drug already avail)
- Matching site with subjects who have expressed interest in participating in a clinical trial; potential subjects are usually in a CRO/academic database
- Mobile apps, improved I/E criteria that fit the study, community/home based research (i.e. Science 37) that goes where the subject is
- Money
- More patient and site friendly protocols, use of community based practices (closer/more convenient to patients), general (non-study specific) education of the public about clinical trials, simplifying ICFs, reduced work loads at investigative sites
- Offering additional compensation for recruitment milestones met usually motivates sites
- Participation of investigators to previous studies and/or advisory board(s) on the same or similar molecules
- Patient incentives
- Perform regular lunch meetings with sites, use patient advertisements tools (flyers, posters, letters, website)
- Site patient engagement activities (long-term relationships for chronic diseases, not advertising)
- Site patient network
- Social media advertising
- Social media exposure, tech integration for patients
- Specific site experience of project manager
- Use of companies like Leapcure or PEP
- Use of referral system, eventually patient associations/advocacy groups



Smarter questions • Smarter answers

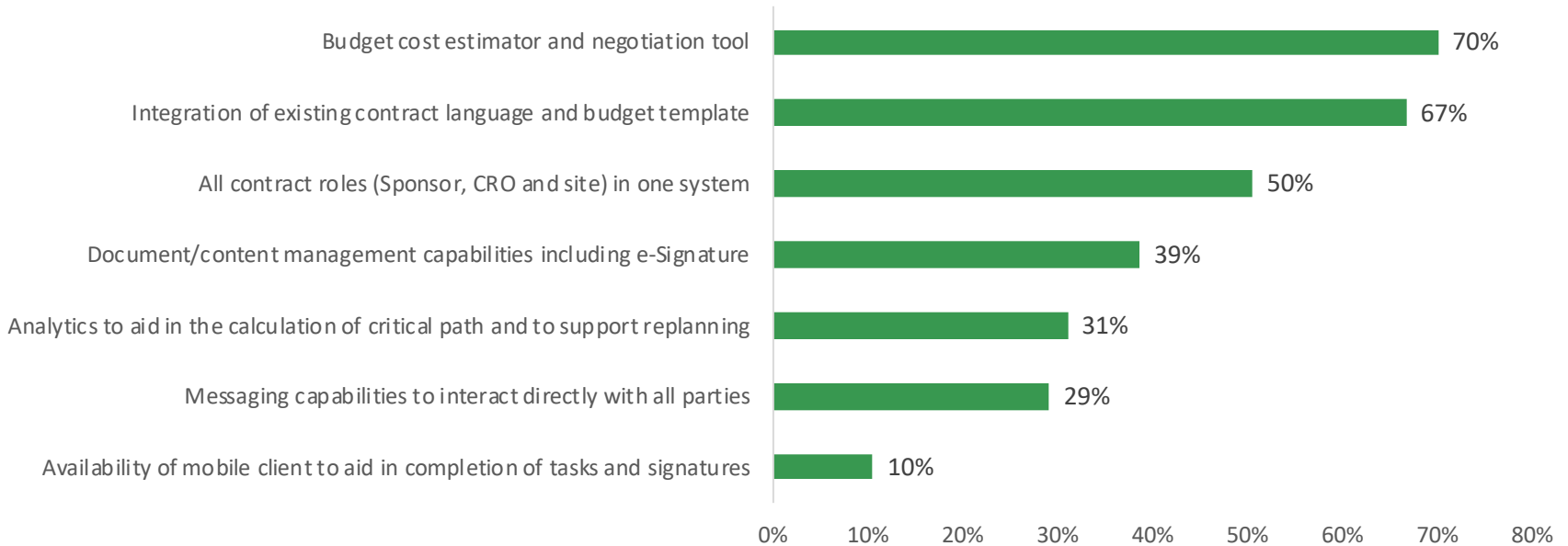
# ECLINICAL TECHNOLOGY IN STUDY STARTUP USAGE & FUTURE DEPLOYMENTS

## *CONTRACTING AND PROCESS OPTIMIZATION*



# Aspects that Help Manage Contracting with a Site

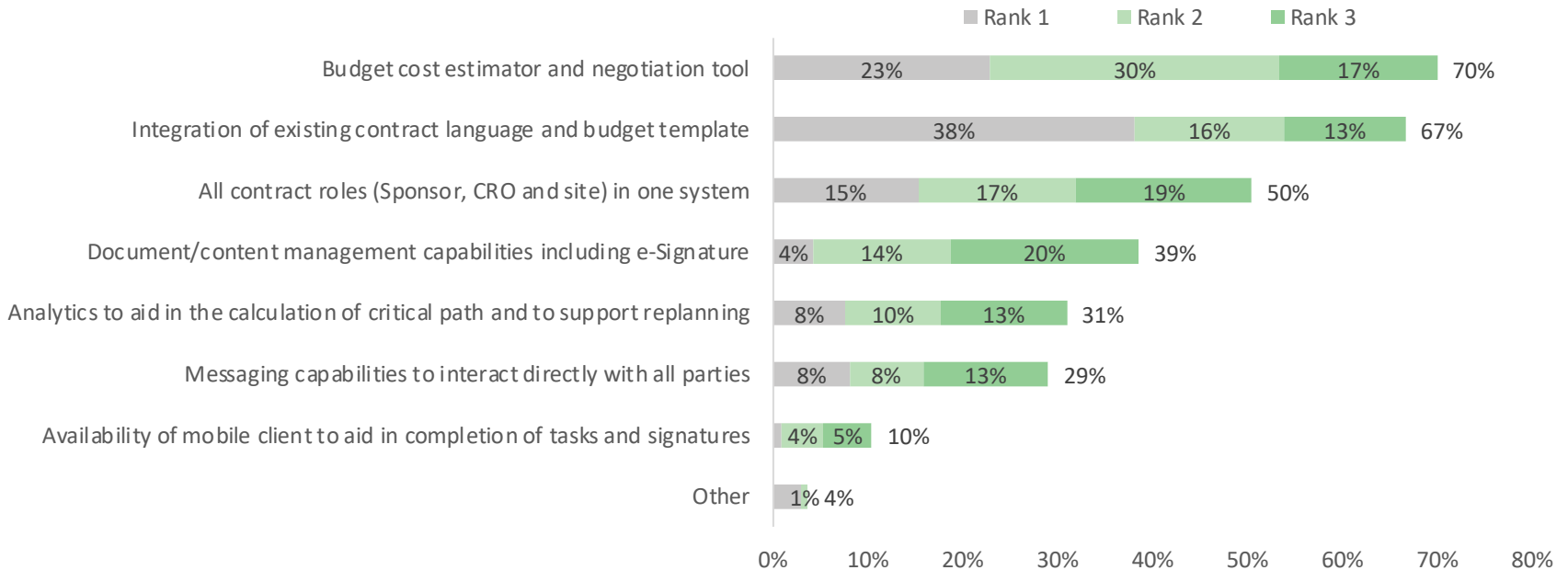
*From the list below, what are the three (3) most important aspects that can help with the successful management of contracting with a site for clinical trials? (only respondents who answered “yes” to recent interactions received this question, n=210)*





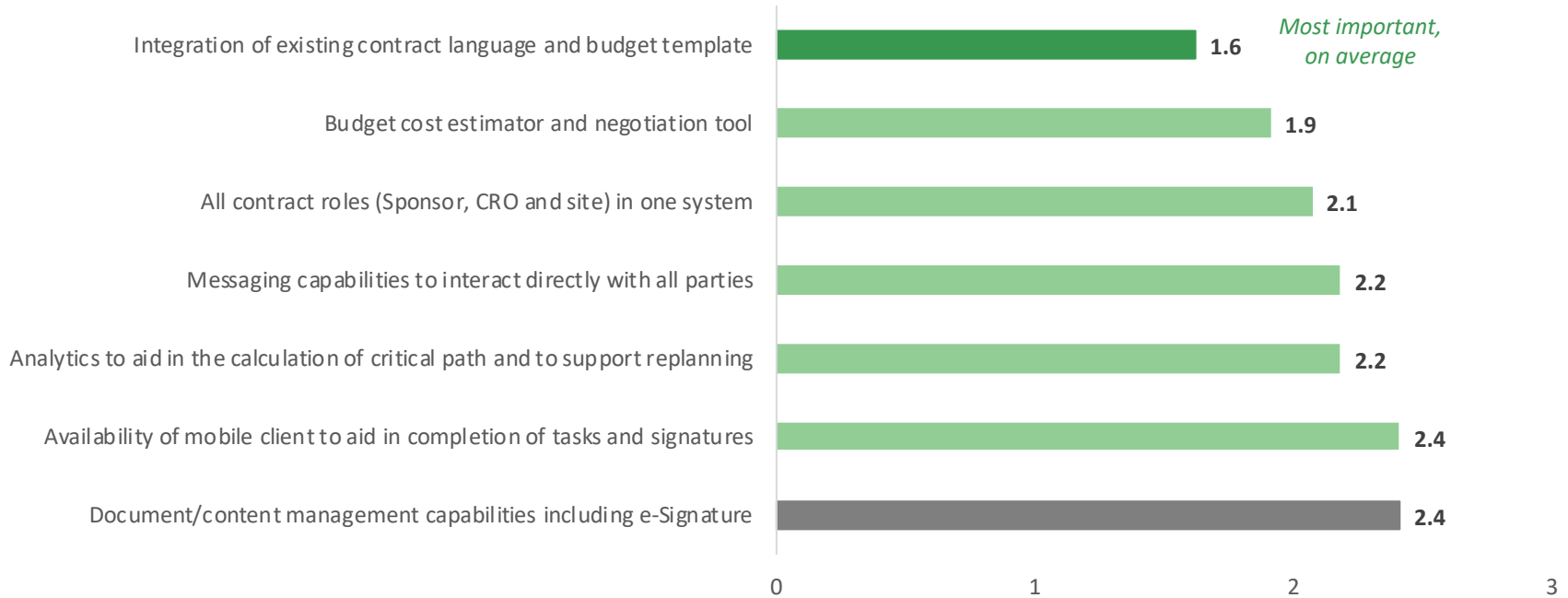
# Rank Top 3 Aspects that Help Manage Contracting

Now, please rank the following options in order of importance for aspects that can help with the successful management of contracting with a site for clinical trials where “1” is most important and “3” is least important. (only respondents who answered “yes” to recent interactions received this question, n=210)





# Average Ranking: Top 3 Aspects that Help Manage Contracting

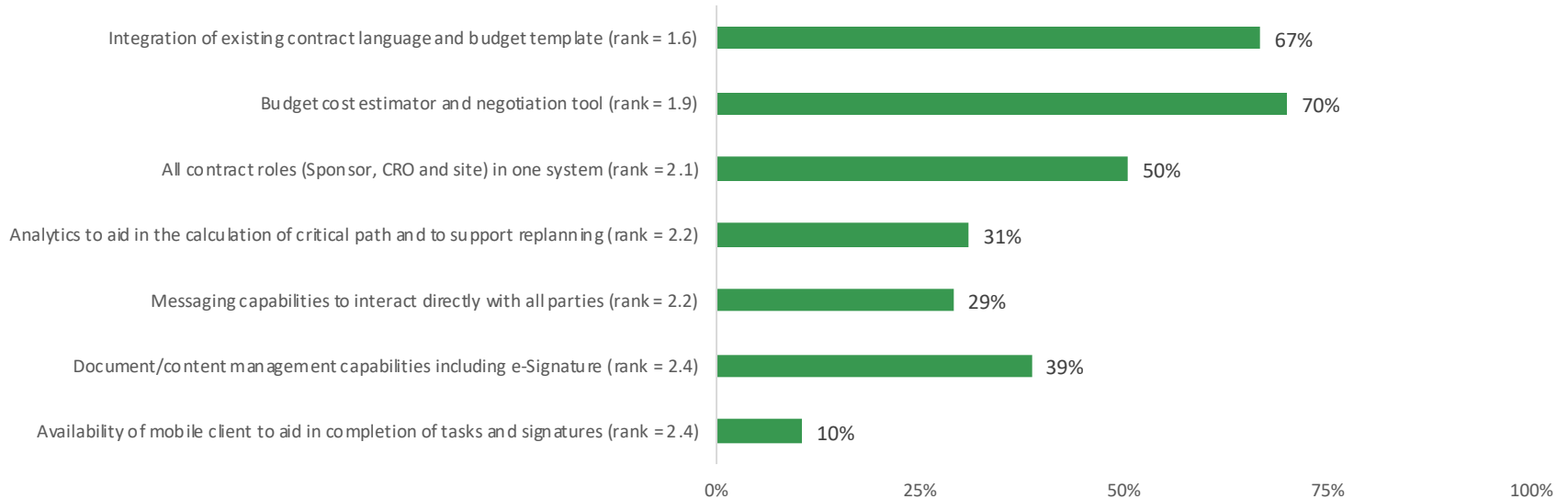




# Aspects that Help Manage Contracting with a Site (prevalence and ranking)

From the list below, what are the three (3) most important aspects that can help with the successful management of contracting with a site for clinical trials? (only respondents who answered “yes” to recent interactions received this question, n=210)

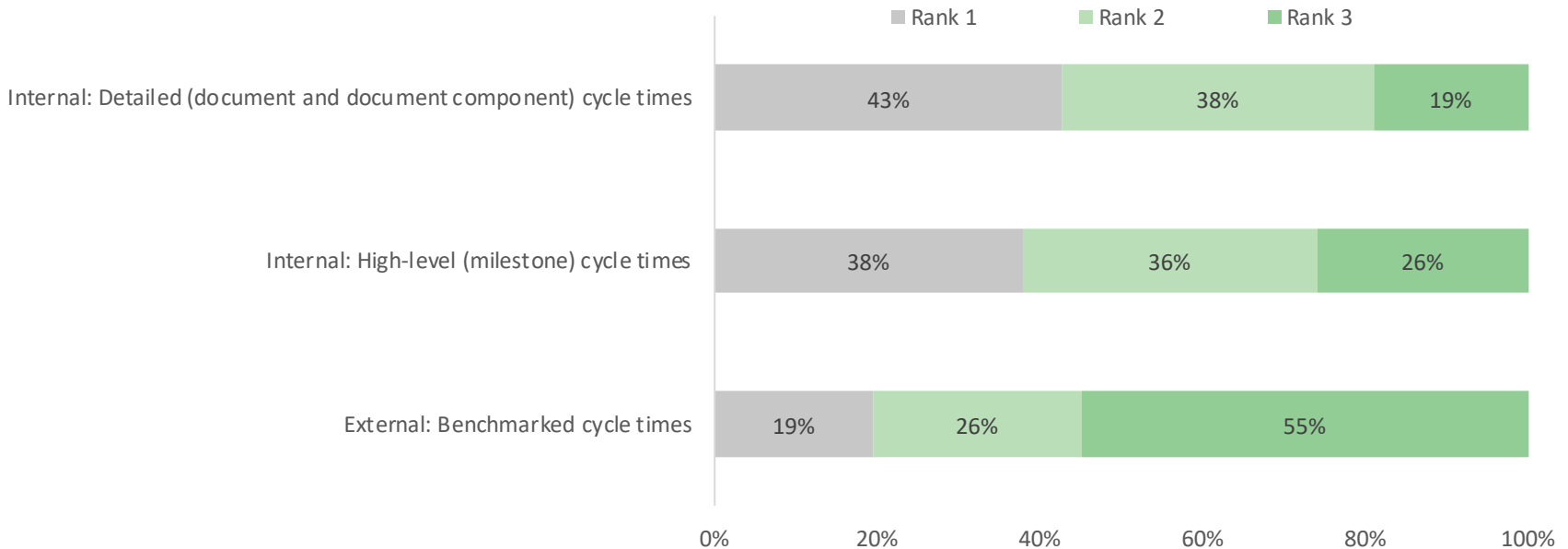
Now, please rank the following options in order of importance for aspects that can help with the successful management of contracting with a site for clinical trials where “1” is most important and “3” is least important. (only respondents who answered “yes” to recent interactions received this question, n=210)





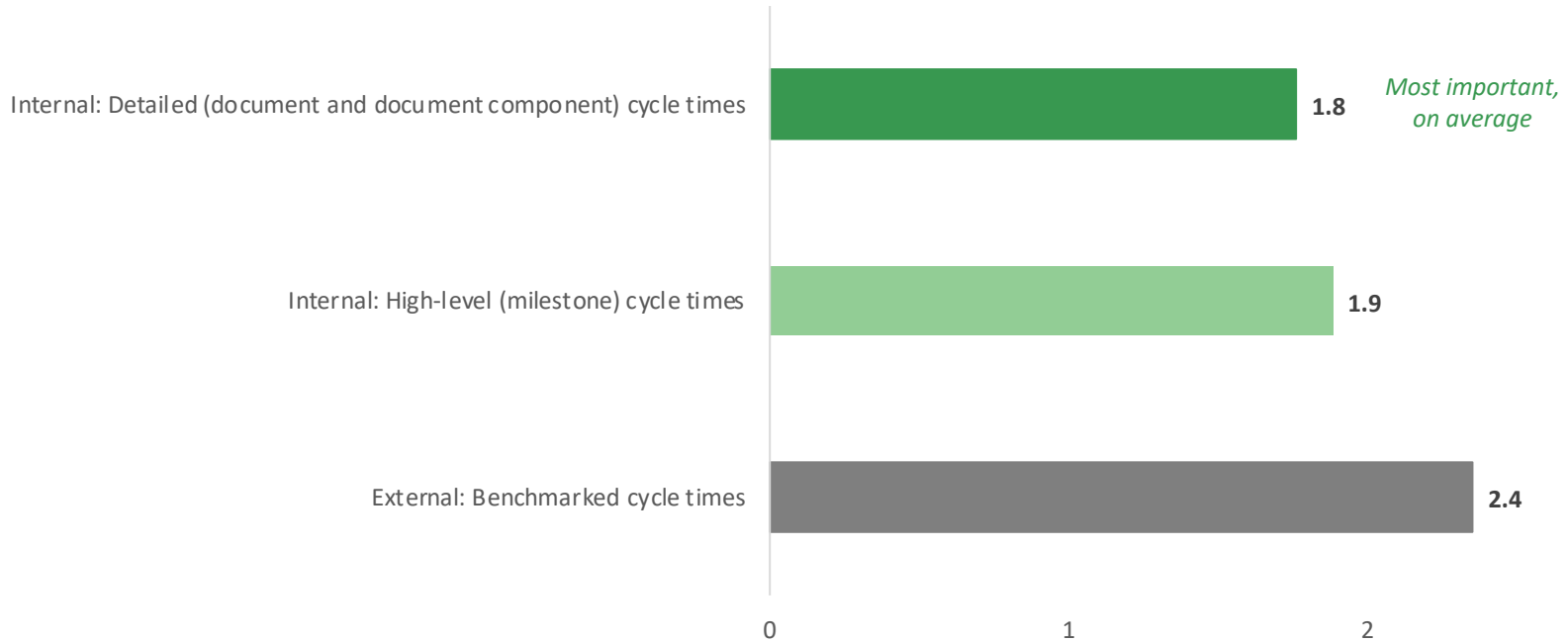
# Ranking of Aspects that Help with Process Optimization

What are the most important aspects of analytics that can help your organization with process optimization/efficiencies? Rank the following options in order of importance where “1” is most important and “3” is least important. (n=262)





# Average Ranking: Aspects that Help with Process Optimization







# Other Aspects that Help with Optimization?

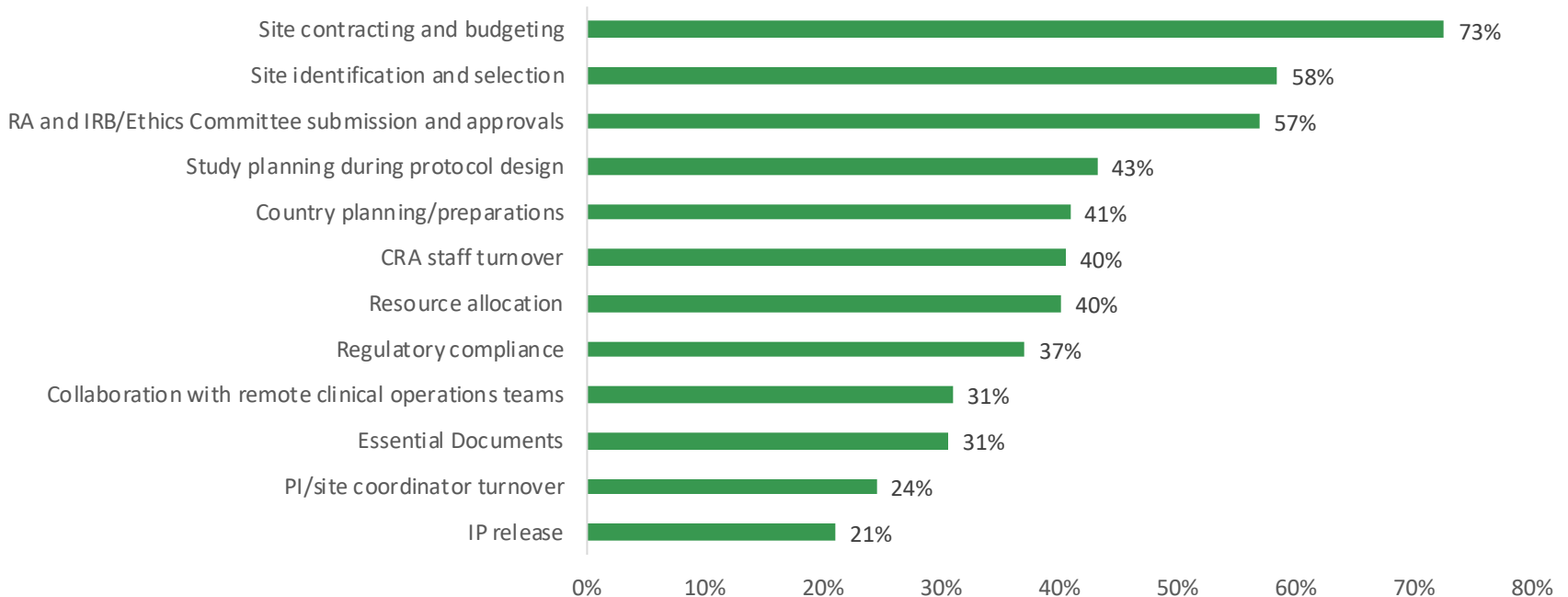
*Do you know another aspect of analytics that can help your organization with process optimization/efficiencies? Please explain. (n=10)*

- Analysis of historical data/contracts/performance
- Consultant performance assessment
- Contractual outsourcing
- Integration of internal systems in one place (eTMF, eCRF, iTrack)
- Internal: efficiency measures / error rates
- Knowledge of historical contract and budget negotiations
- Patient engagement programs with risk mitigation plan
- Rate card utilization
- Site coordinator that can facilitate the process on the ground
- Ways to normalize data between different studies (size, location, TA); hard to compare apples to oranges



# Challenging Site Collaboration Processes

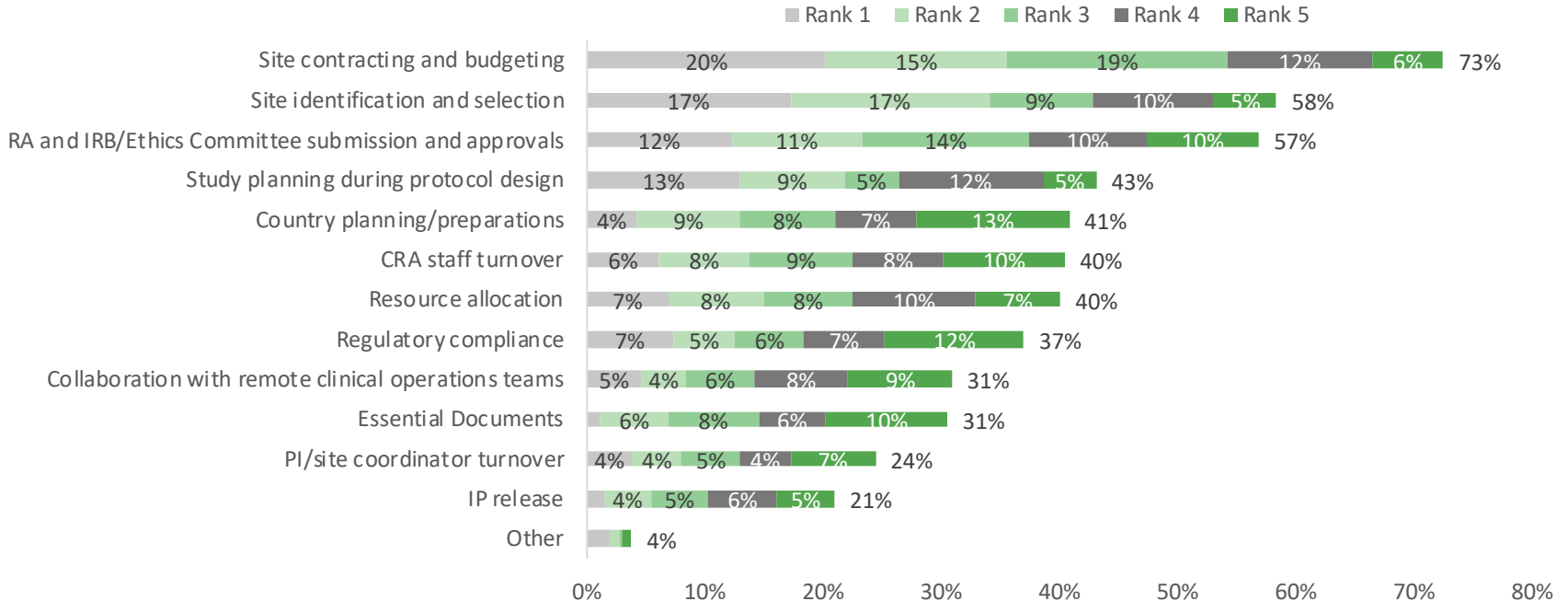
From the list below, please select the five (5) most challenging site collaboration processes for your organization. Select five. (n=262)





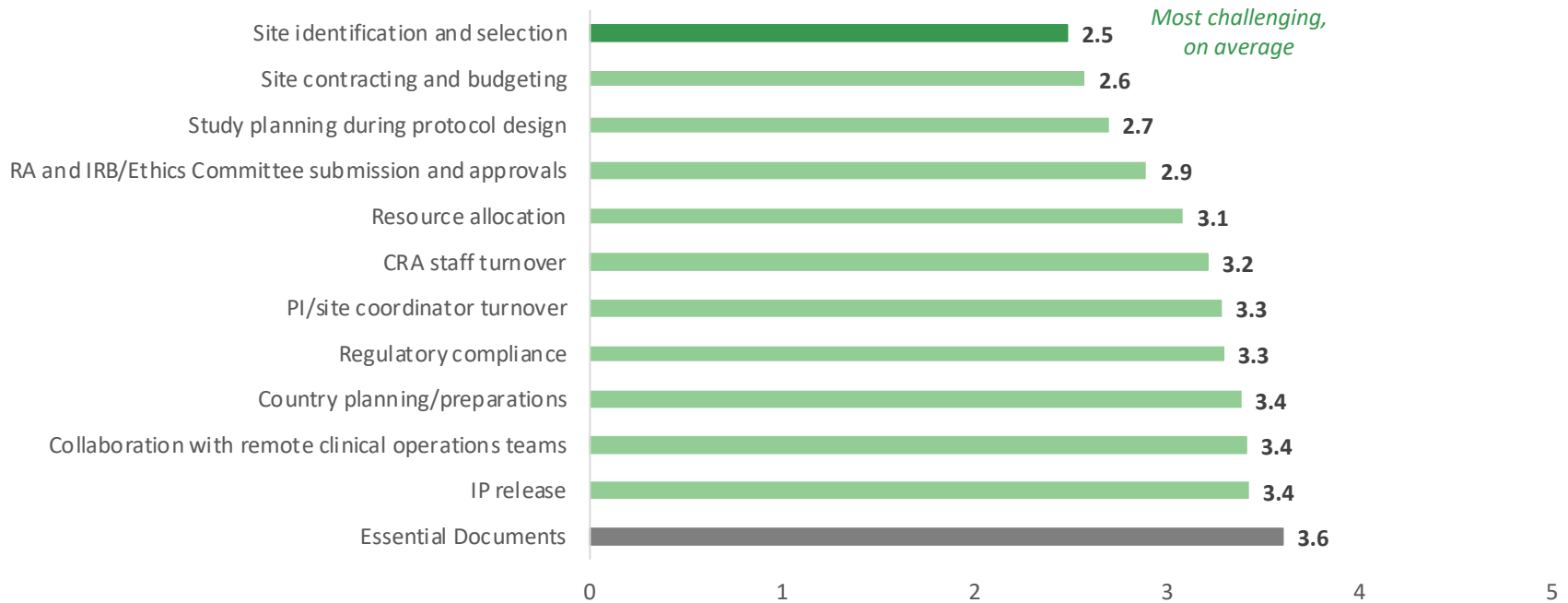
# Rank Top 5 Site Collaboration Processes

Now, please rank the following options in order of the most challenging site collaboration processes for your organization where “1” is most challenging and “5” is least challenging. (n=262)





# Average Ranking: Top 5 Site Collaboration Processes

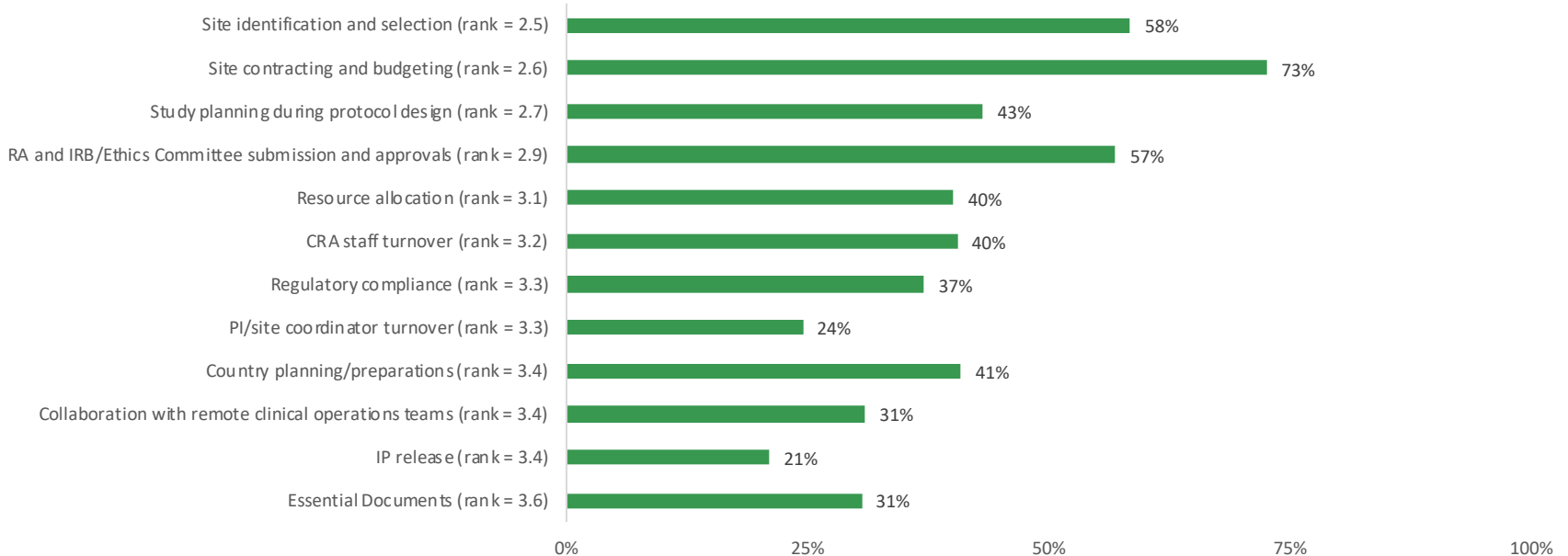




# Challenging Site Collaboration Processes (prevalence and ranking)

From the list below, please select the five (5) most challenging site collaboration processes for your organization. Select five. (n=262)

Now, please rank the following options in order of the most challenging site collaboration processes for your organization where "1" is most challenging and "5" is least challenging. (n=262)

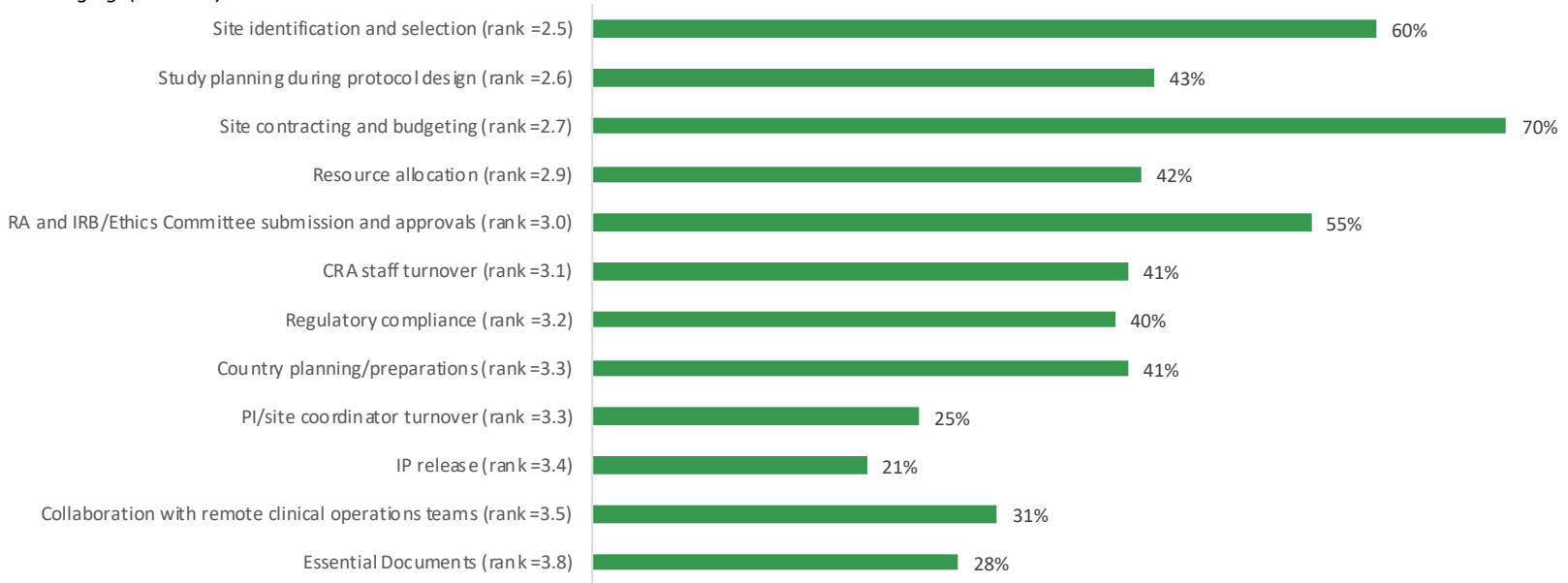




# Subset Comparison: Challenging Site Collaboration Processes (sponsors)

From the list below, please select the five (5) most challenging site collaboration processes for your organization. Select five. (n=187 sponsor respondents)

Now, please rank the following options in order of the most challenging site collaboration processes for your organization where "1" is most challenging and "5" is least challenging. (n=varies)

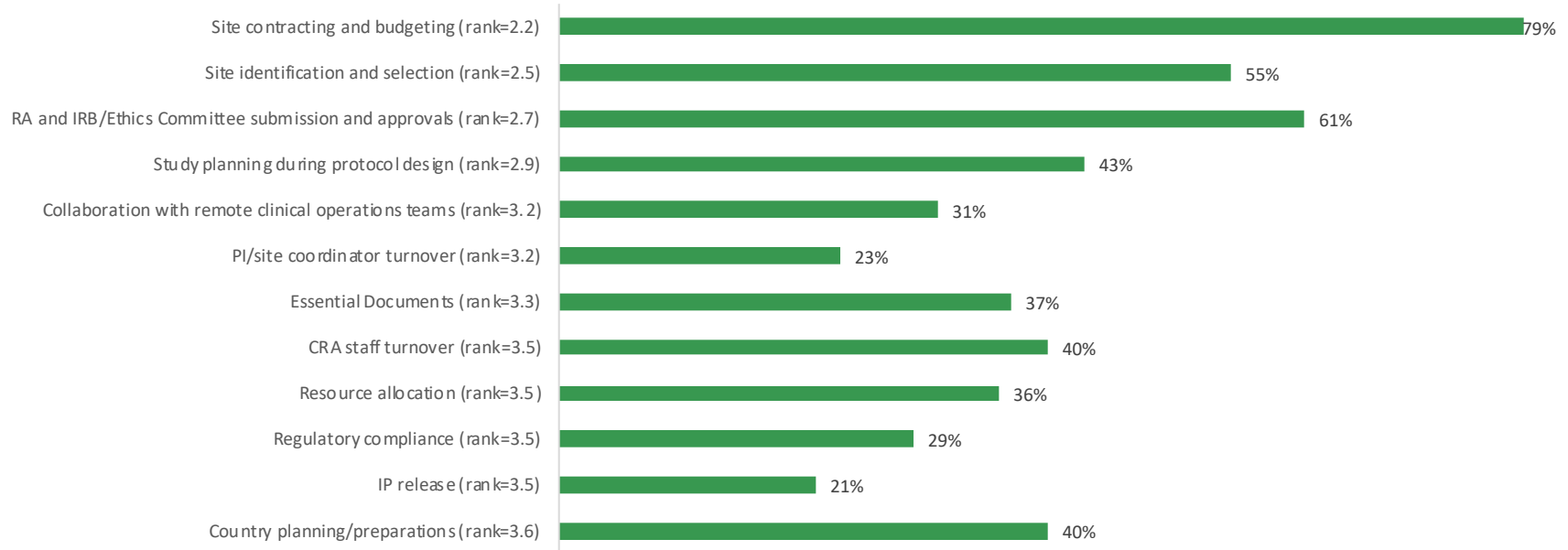




# Subset Comparison: Challenging Site Collaboration Processes (CROs)

From the list below, please select the five (5) most challenging site collaboration processes for your organization. Select five. (n=75 CRO respondents)

Now, please rank the following options in order of the most challenging site collaboration processes for your organization where "1" is most challenging and "5" is least challenging. (n=varies)

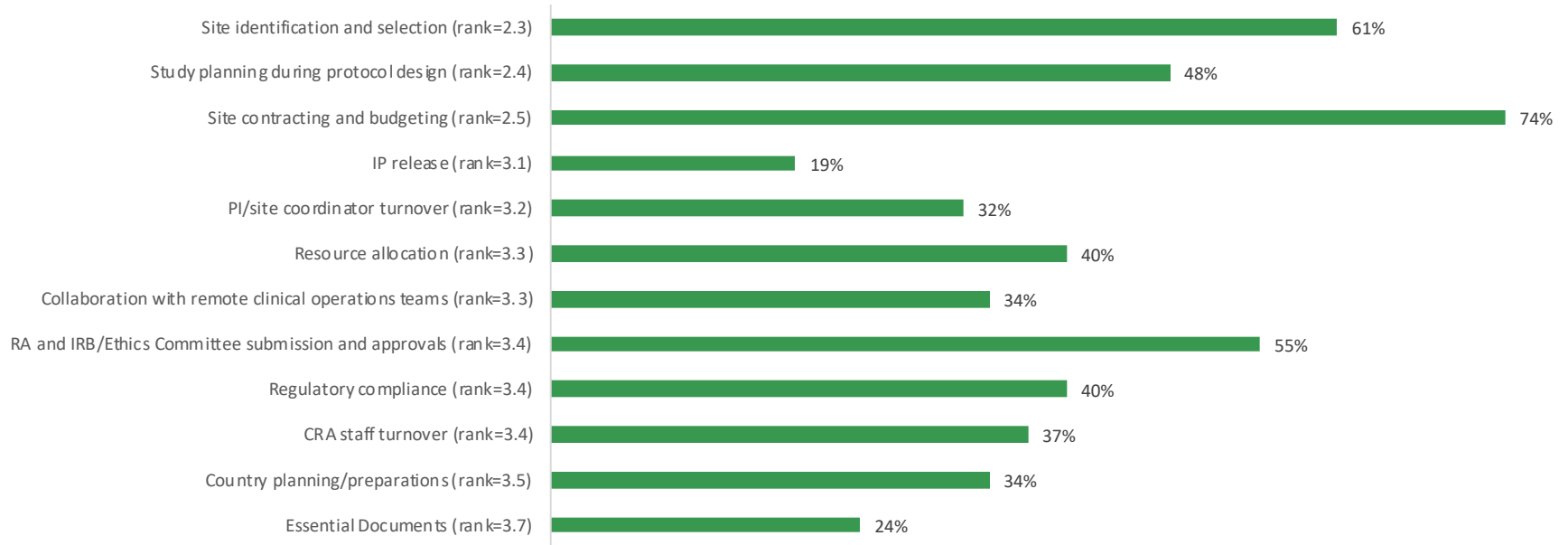




# Subset Comparison: Challenging Site Collaboration Processes (1-10 trials)

From the list below, please select the five (5) most challenging site collaboration processes for your organization. Select five. (n=101 respondents conducting 1-10 trials)

Now, please rank the following options in order of the most challenging site collaboration processes for your organization where "1" is most challenging and "5" is least challenging. (n=varies)



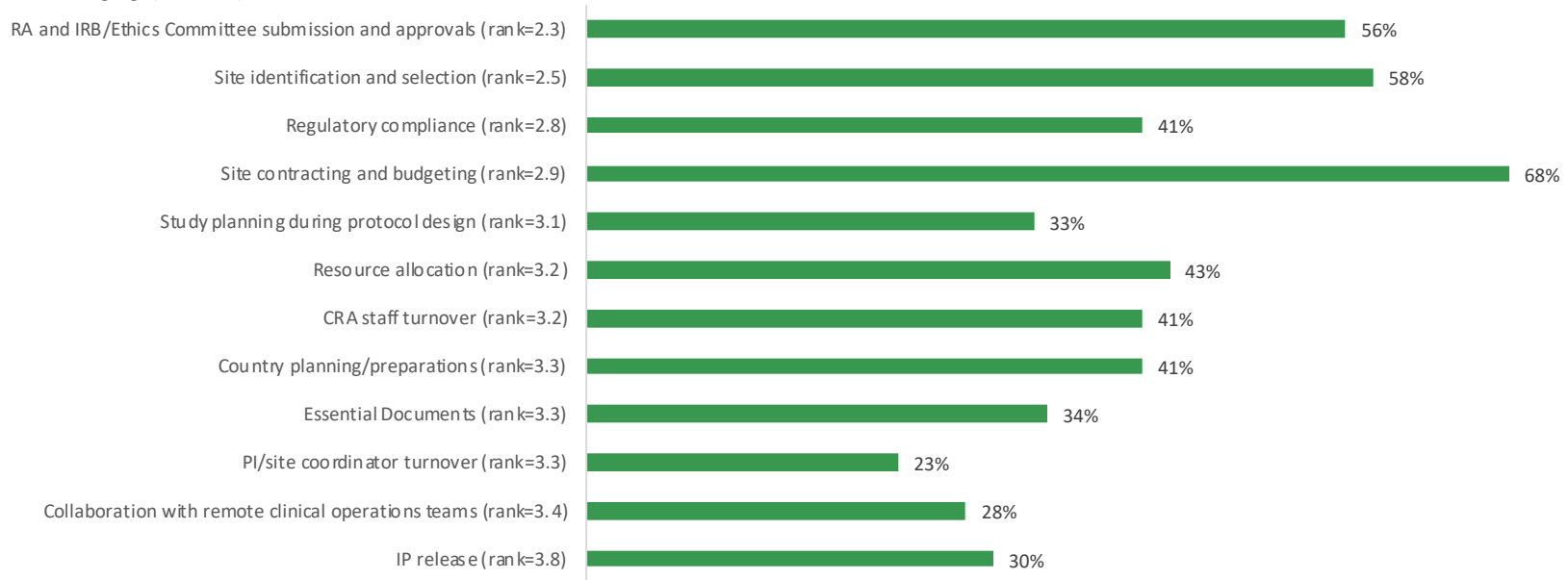




# Subset Comparison: Challenging Site Collaboration Processes (11-50 trials)

From the list below, please select the five (5) most challenging site collaboration processes for your organization. Select five. (n=79 respondents conducting 11-50 trials)

Now, please rank the following options in order of the most challenging site collaboration processes for your organization where "1" is most challenging and "5" is least challenging. (n=varies)

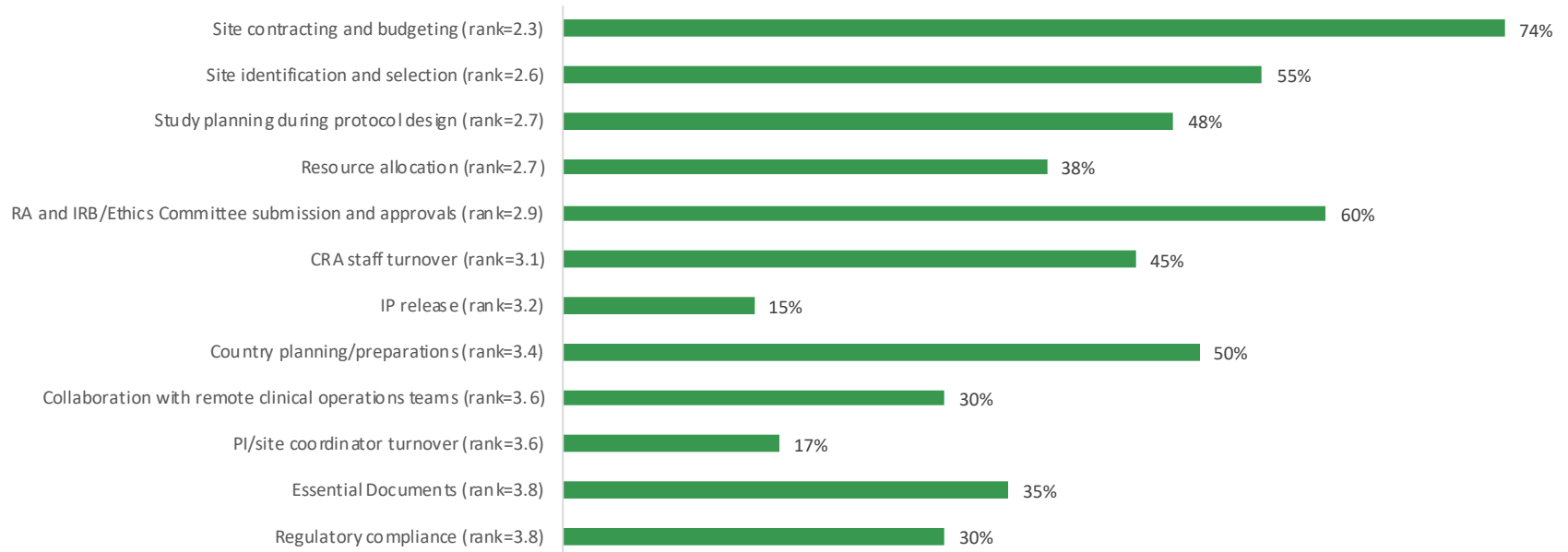




# Subset Comparison: Challenging Site Collaboration Processes (>50 trials)

From the list below, please select the five (5) most challenging site collaboration processes for your organization. Select five. (n=82 respondents conducting >50 trials)

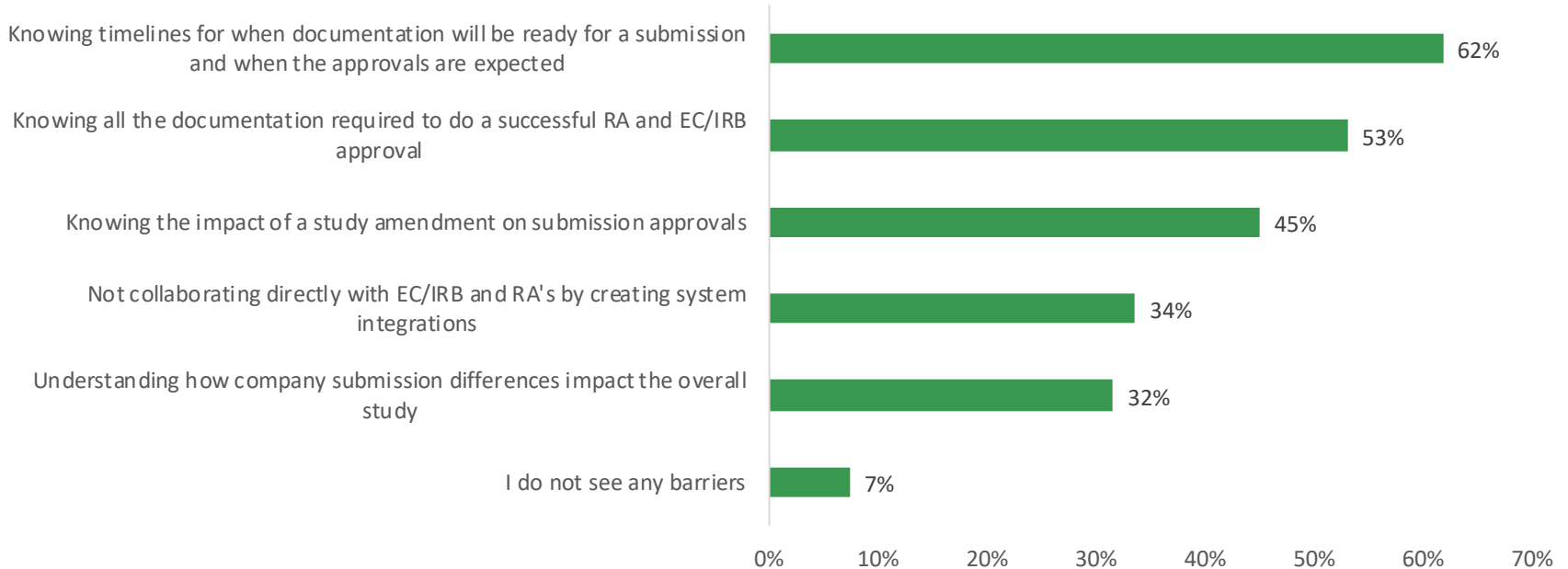
Now, please rank the following options in order of the most challenging site collaboration processes for your organization where “1” is most challenging and “5” is least challenging. (n=varies)





# Barriers for Managing Submissions

*Which of the following do you see as a barrier(s) for successfully managing submissions? Select all that apply. (only those who selected “RA and IRB/Ethics Committee submission and approvals” received this question, n=149)*





Smarter questions • Smarter answers

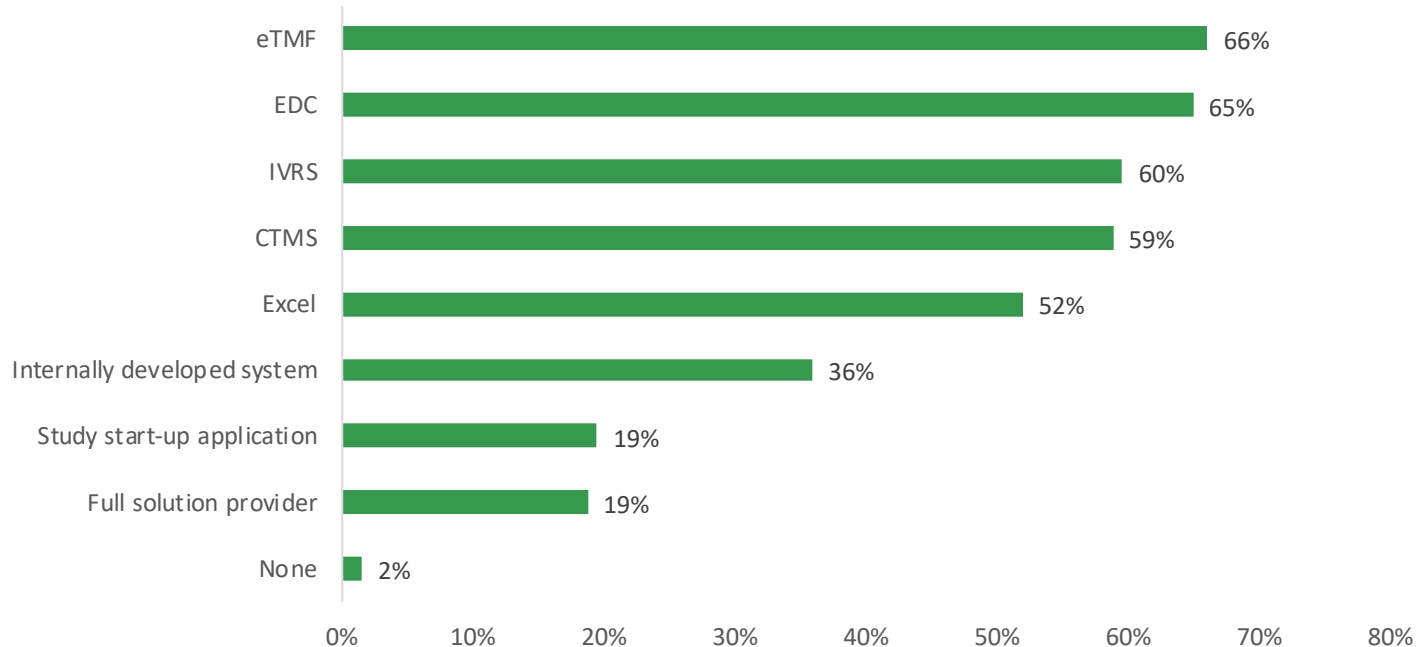
# ECLINICAL TECHNOLOGY IN STUDY STARTUP USAGE & FUTURE DEPLOYMENTS

*APPLICATION IMPLEMENTATION  
AND INTEGRATION*



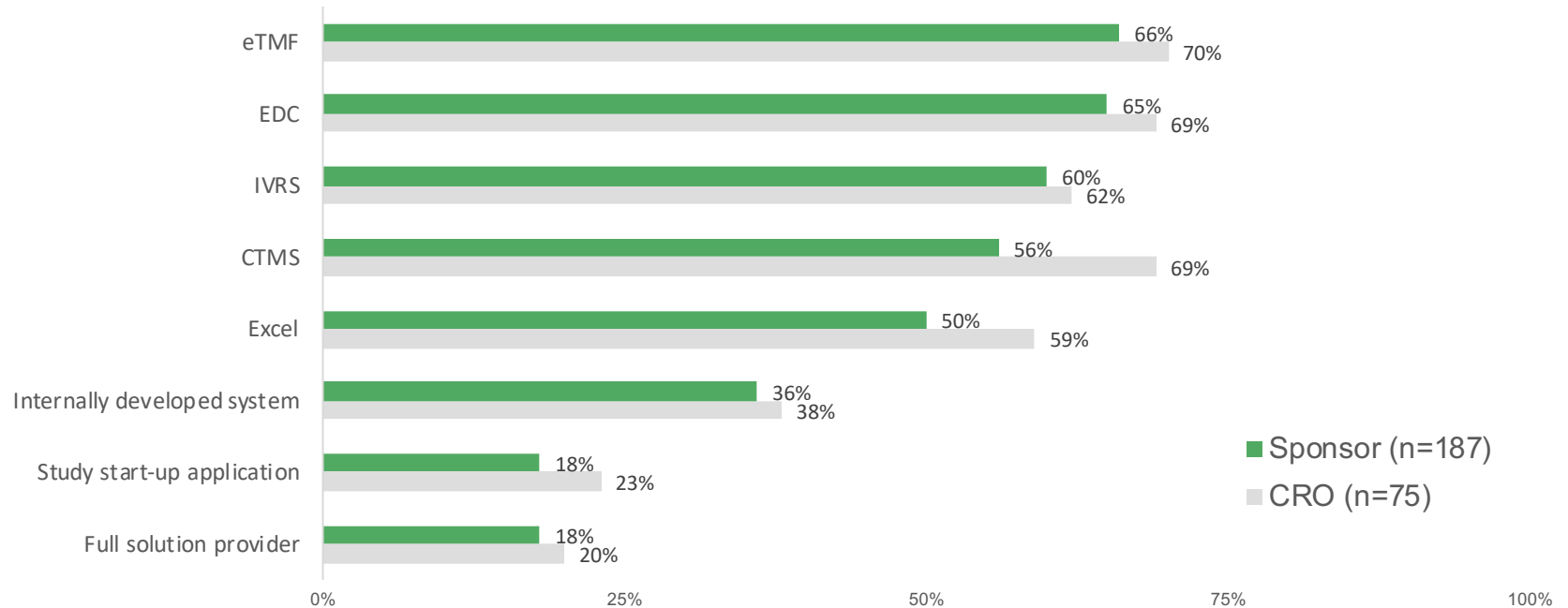
# Applications to Manage Site Collaboration Process

What applications does your organization currently utilize to manage the site collaboration process? (n=262)



# Subset Comparison: Applications to Manage Site Collaboration Process (sponsors and CROs)

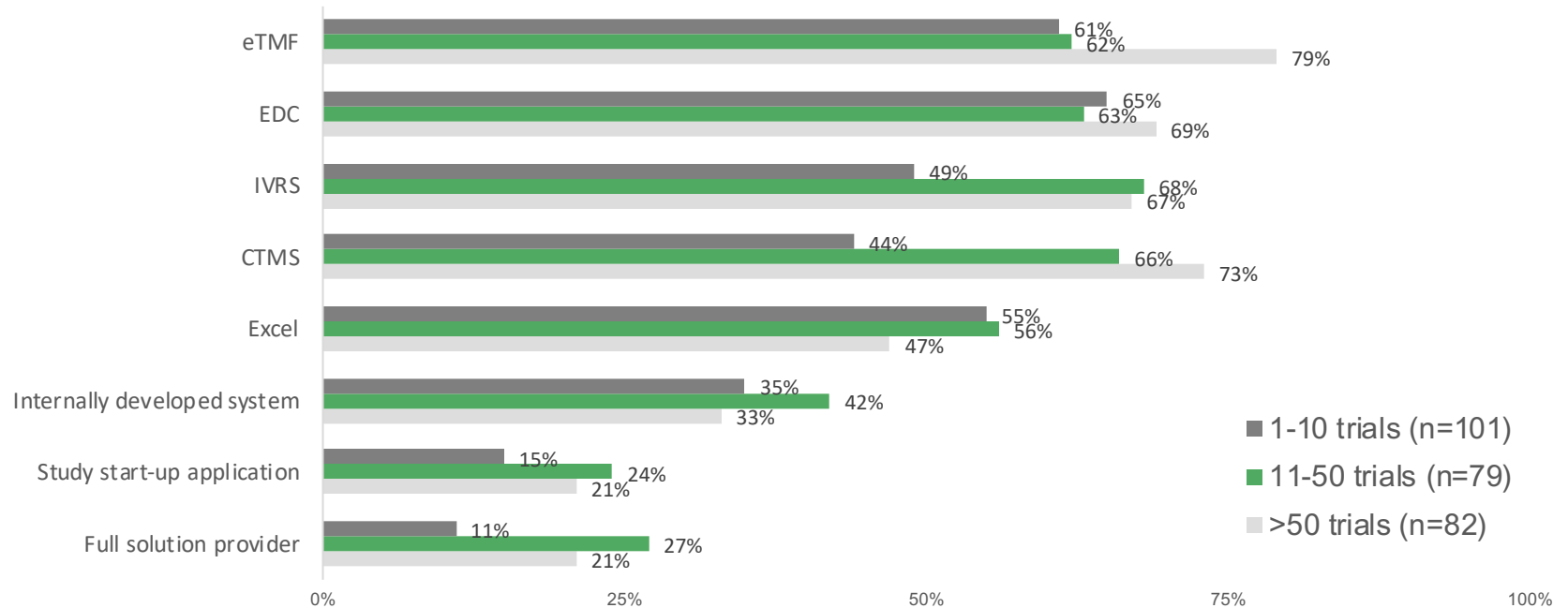
What applications does your organization currently utilize to manage the site collaboration process? (n=187 sponsor and 75 CRO respondents)





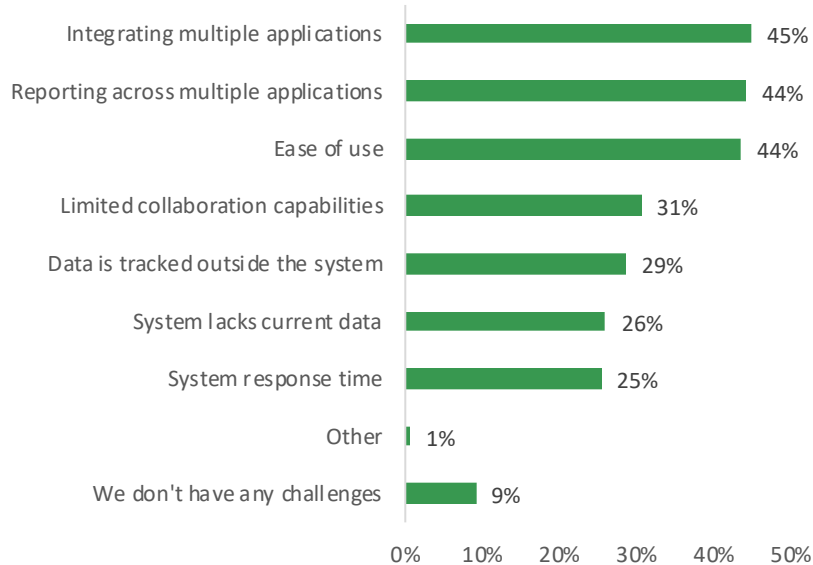
# Subset Comparison: Applications to Manage Site Collaboration Process (by trial volume)

What applications does your organization currently utilize to manage the site collaboration process? (n=varies by size)

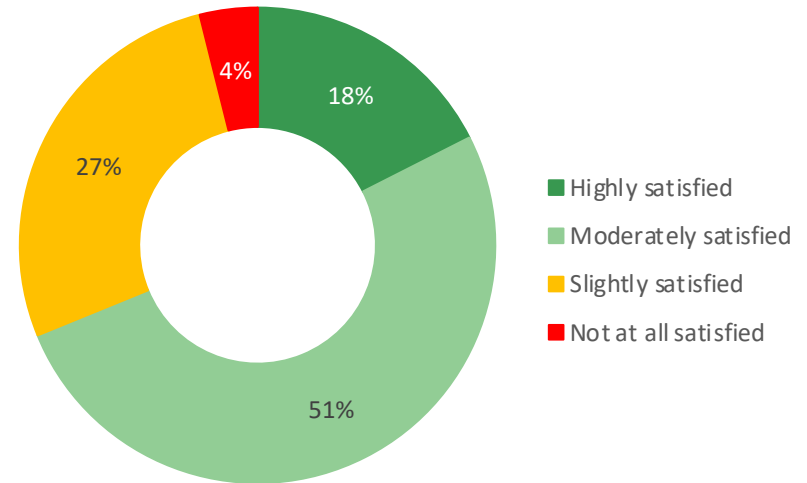


# Challenges/Satisfaction: CTMS

What are the biggest challenges, if any, your organization faces in utilizing a CTMS to manage the site collaboration process? Select all that apply. (only those who selected "CTMS" received this question, n=154)



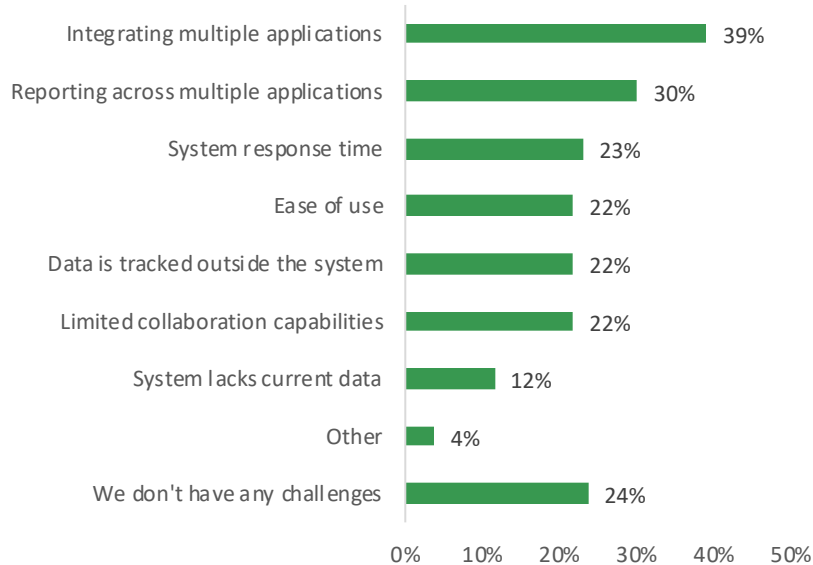
How satisfied are you with your current CTMS application? (only those who selected "CTMS" received this question, n=154)



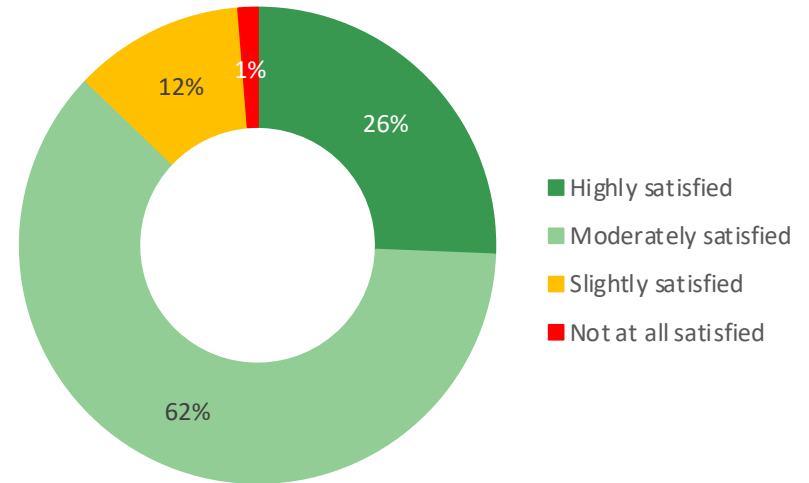


# Challenges/Satisfaction: IVRS

*What are the biggest challenges, if any, your organization faces in utilizing an IVRS to manage the site collaboration process? Select all that apply. (only those who selected "IVRS" received this question, n=156)*

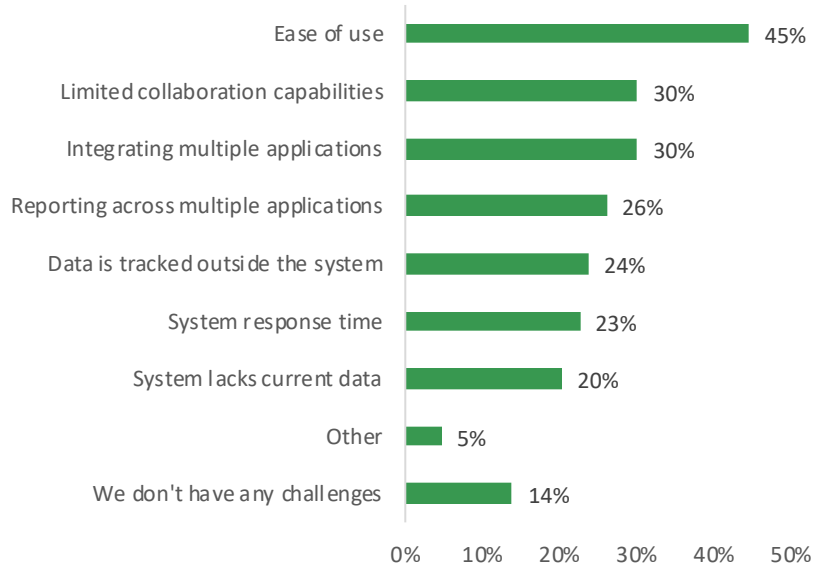


*How satisfied are you with your current IVRS application? (only those who selected "IVRS" received this question, n=156)*

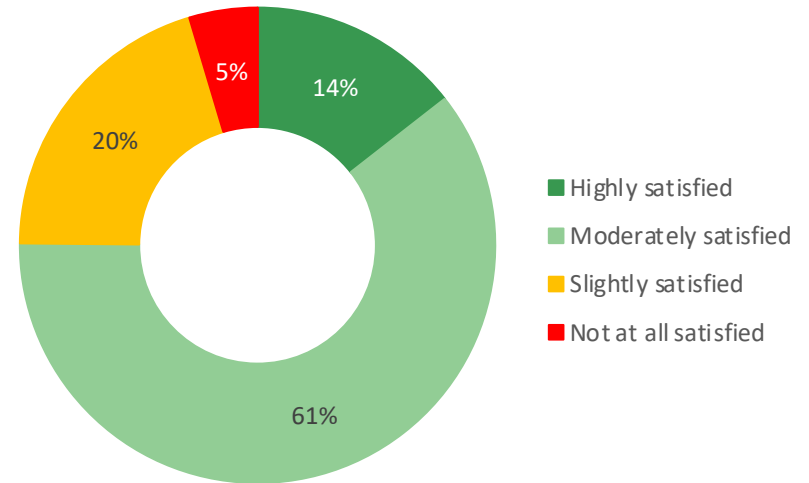


# Challenges/Satisfaction: eTMF

*What are the biggest challenges, if any, your organization faces in utilizing eTMF to manage the site collaboration process? Select all that apply. (only those who selected "eTMF" received this question, n=173)*

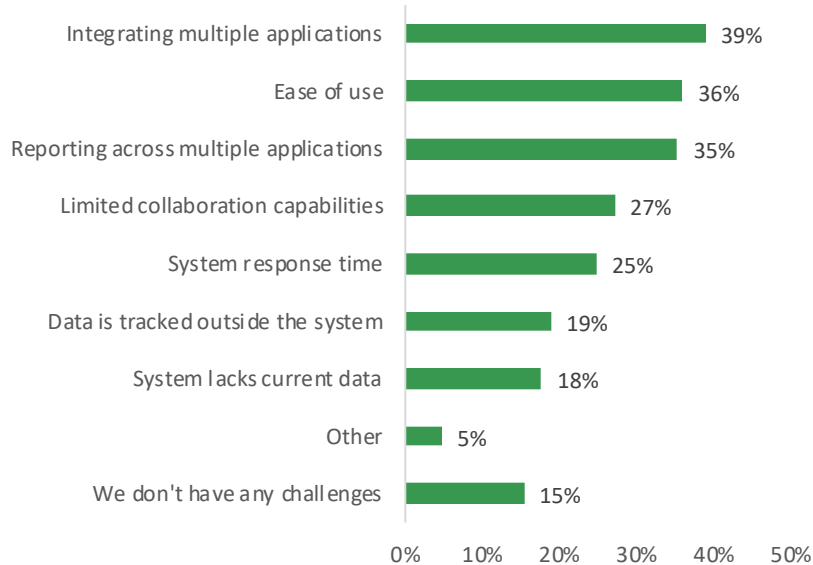


*How satisfied are you with your current eTMF application? (only those who selected "eTMF" received this question, n=173)*

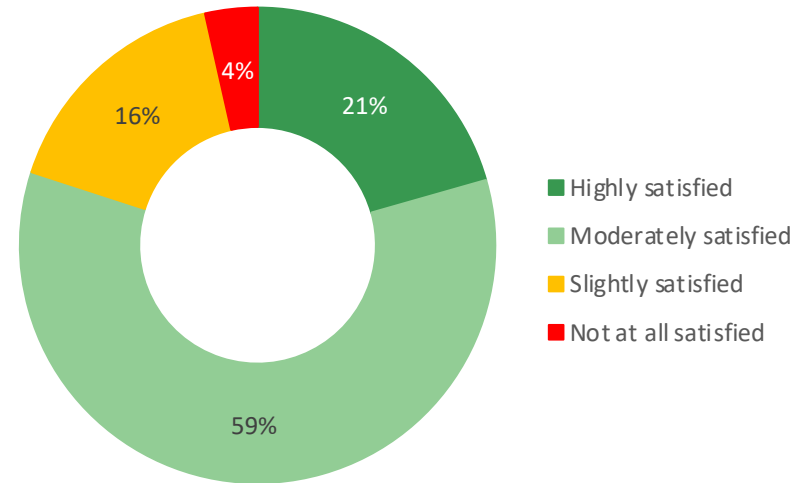


# Challenges/Satisfaction: EDC

What are the biggest challenges, if any, your organization faces in utilizing an EDC system to manage the site collaboration process? Select all that apply. (only those who selected “EDC” received this question, n=170)

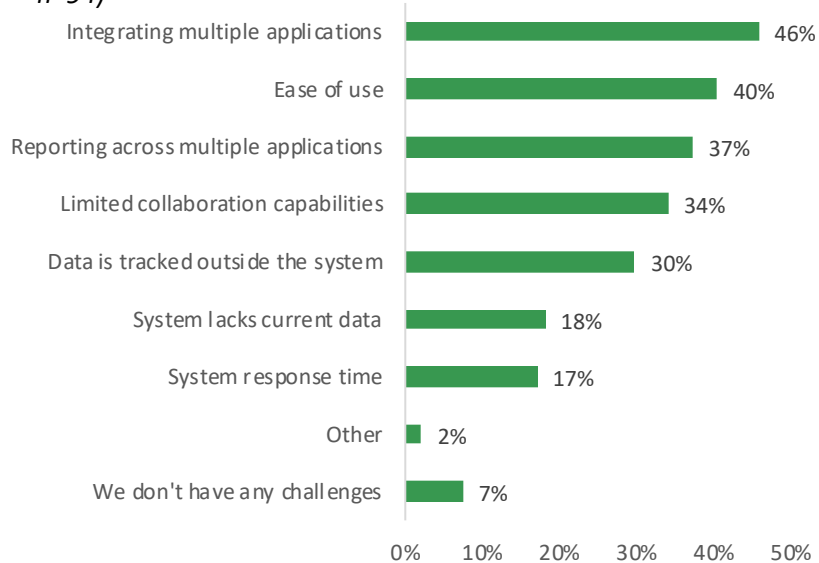


How satisfied are you with your current EDC application? (only those who selected “EDC” received this question, n=170)

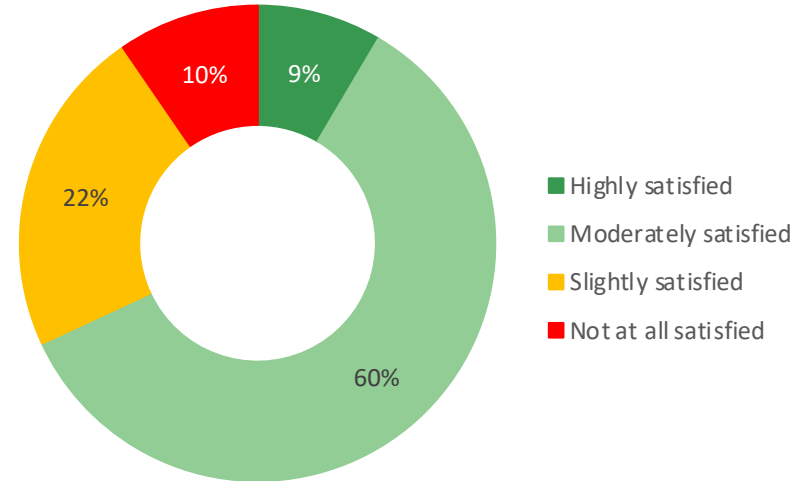


# Challenges/Satisfaction: Internally Developed System

*What are the biggest challenges, if any, your organization faces in utilizing an internally developed system to manage the site collaboration process? Select all that apply. (only those who selected "internally developed system" received this question, n=94)*

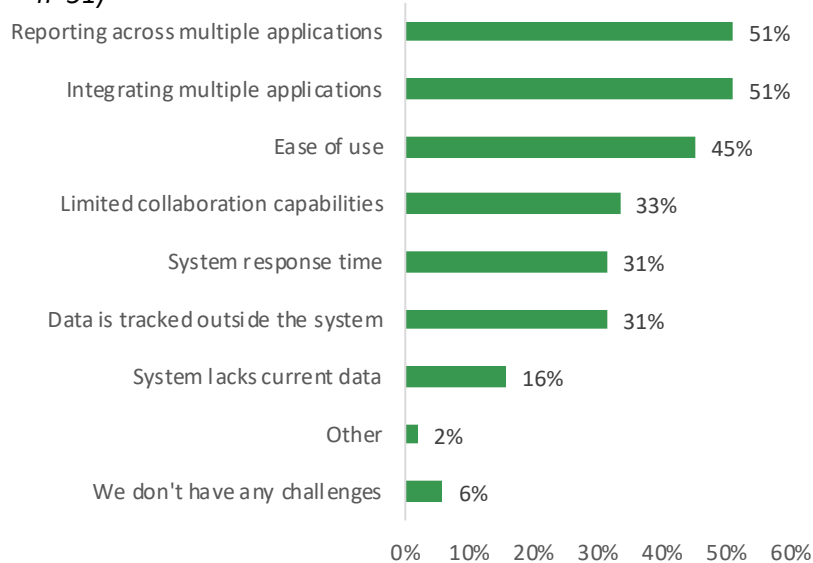


*How satisfied are you with your current internally developed system application? (only those who selected "internally developed system" received this question, n=94)*

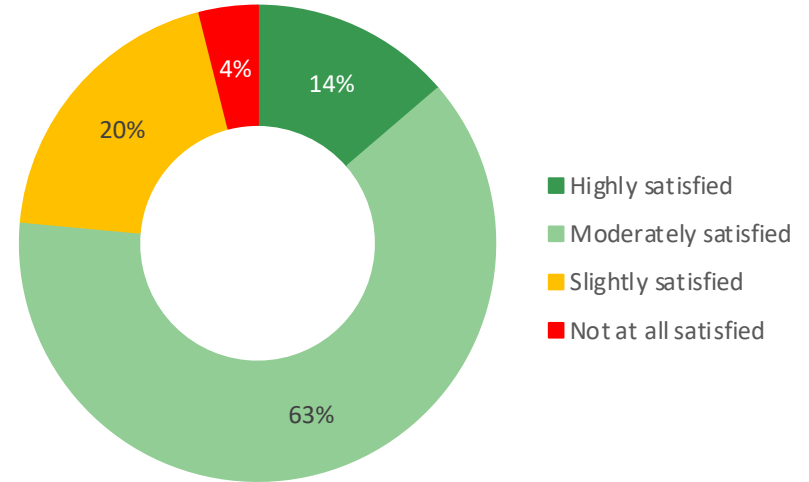


# Challenges/Satisfaction: Study Startup Application

What are the biggest challenges, if any, your organization faces in utilizing a study start-up application to manage the site collaboration process? Select all that apply. (only those who selected "study start-up application" received this question, n=51)

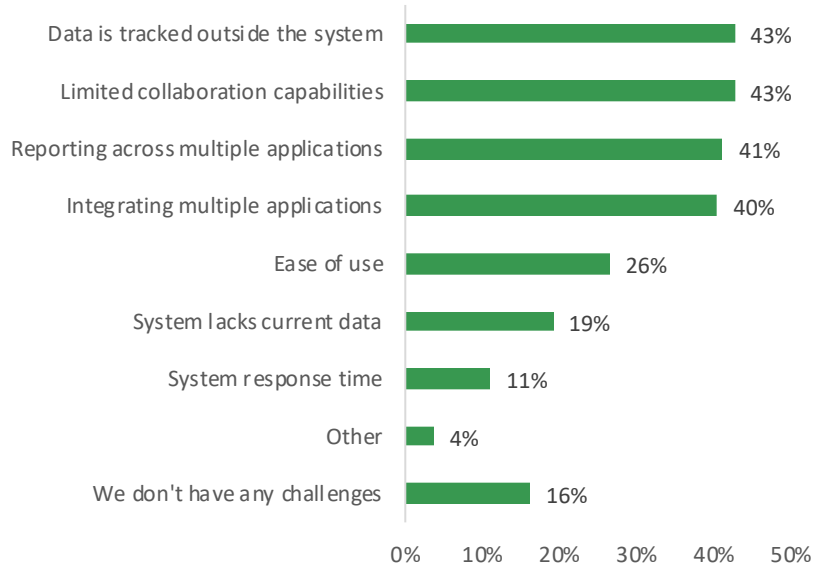


How satisfied are you with your current internally developed system application? (only those who selected "internally developed system" received this question, n=94)

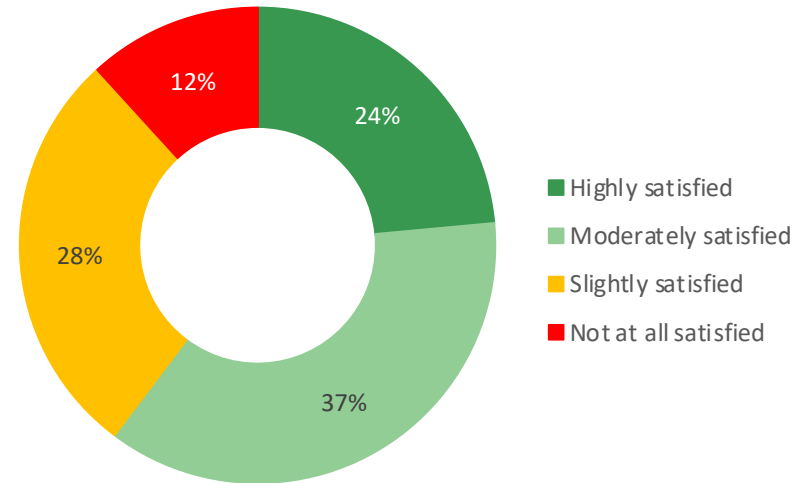


# Challenges/Satisfaction: Excel

*What are the biggest challenges, if any, your organization faces in utilizing Excel to manage the site collaboration process? Select all that apply. (only those who selected "Excel" received this question, n=136)*



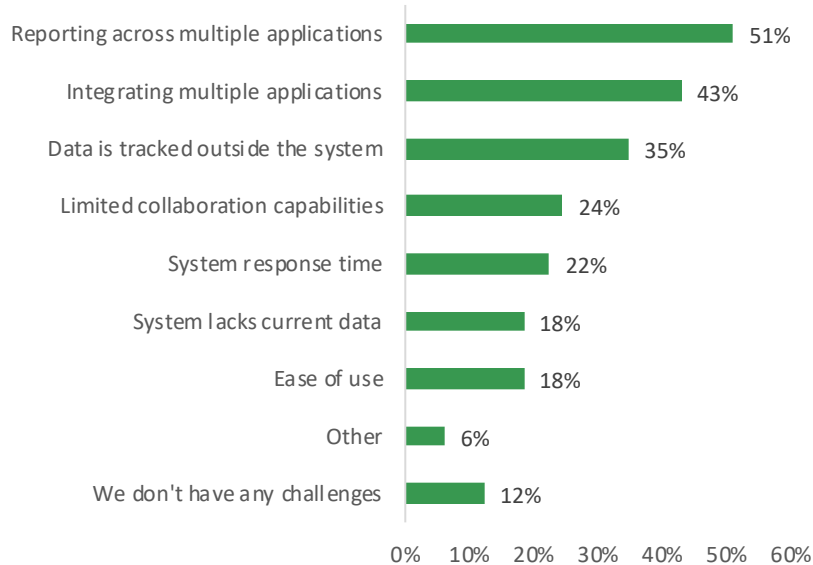
*How satisfied are you with your current Excel application? (only those who selected "Excel" received this question, n=136)*



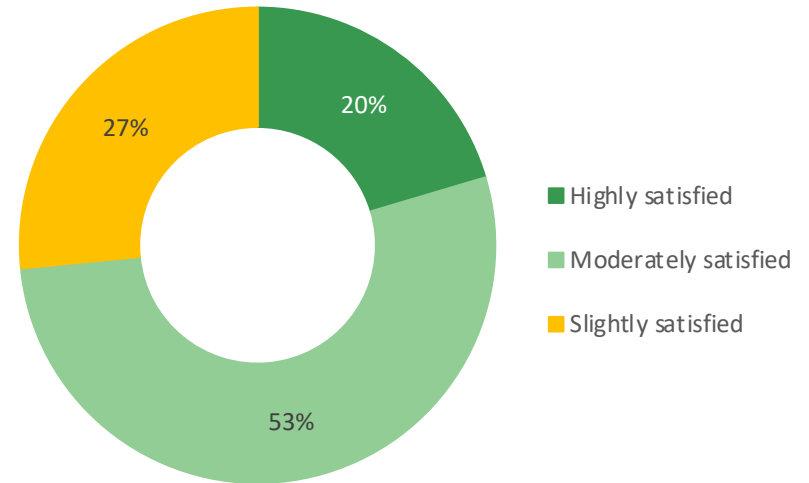


# Challenges/Satisfaction: Full Solution Provider

What are the biggest challenges, if any, your organization faces in utilizing a full solution provider to manage the site collaboration process? Select all that apply. (only those who selected "full solution provider" received this question, n=49)

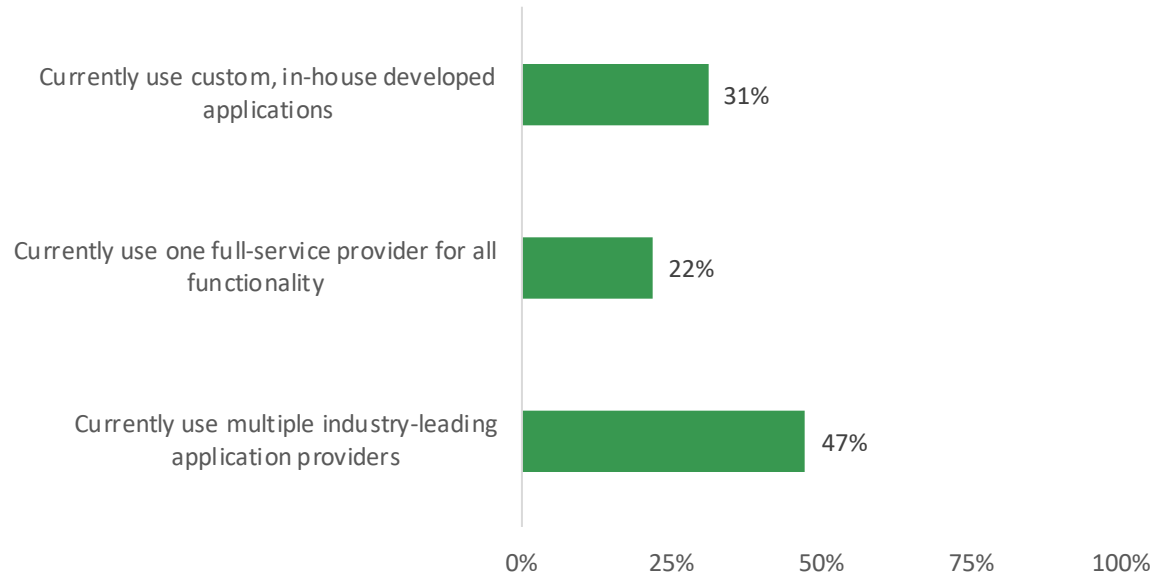


How satisfied are you with your current full solution provider? (only those who selected "full solution provider" received this question, n=49)



# Application Provider Use

*When thinking about specific applications such as “site selection”, “site activation”, “quality management system”, and “study execution software”, what does your organization currently use? (n=262)*

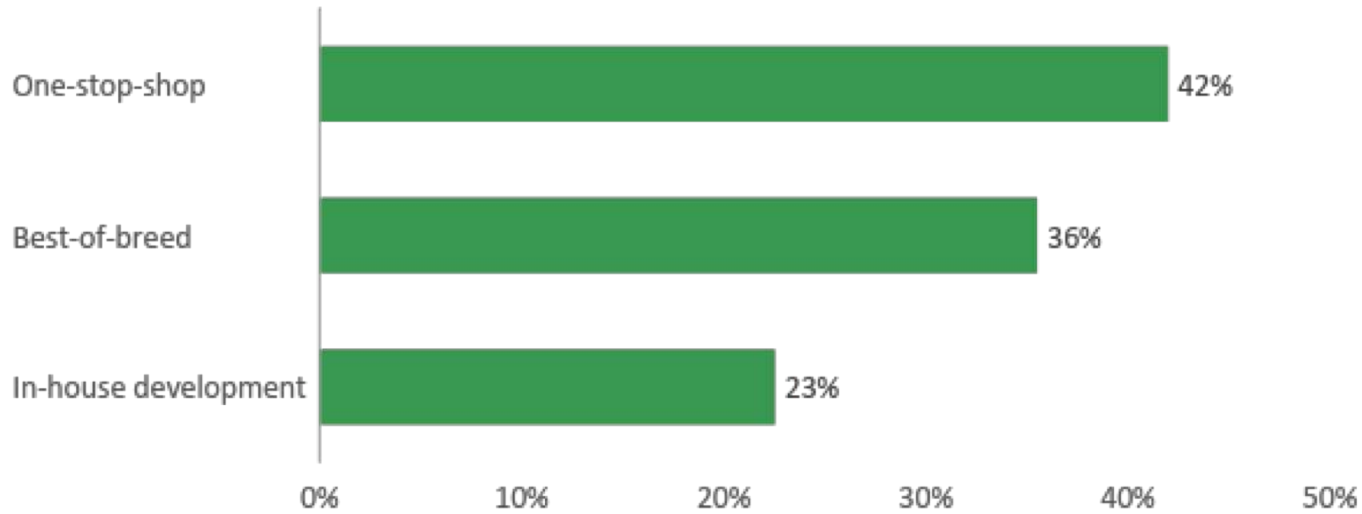






# Software/Application Solutions Philosophy

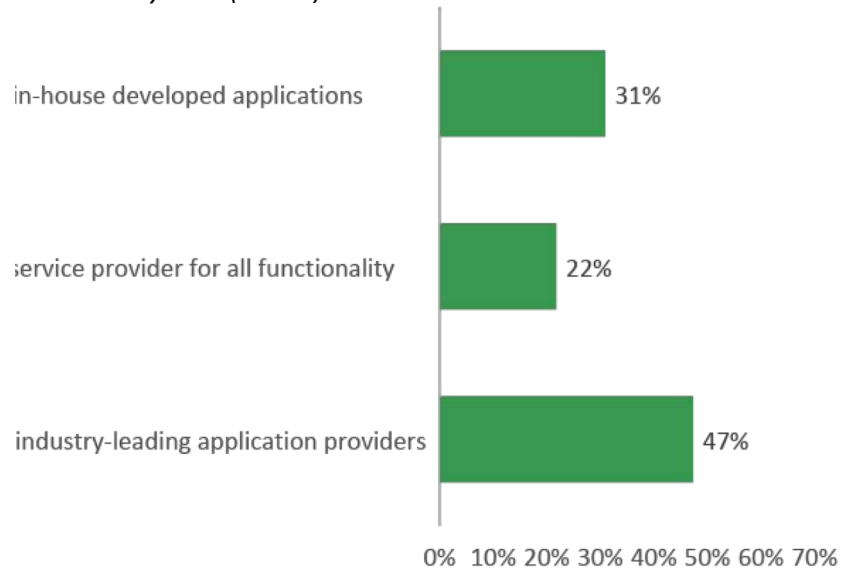
*Organizations have different philosophies for how they implement software/application solutions. Some organizations follow the “best-of-breed” philosophy where they look for the best applications regardless of how many they maintain and integrate. Other organizations follow the “one-stop-shop” philosophy where they look for one solution that might not be industry leading, but it is easier to maintain and integrate. Still another approach is to build software applications “in-house.” Which philosophy best fits with your organization? (n=262)*



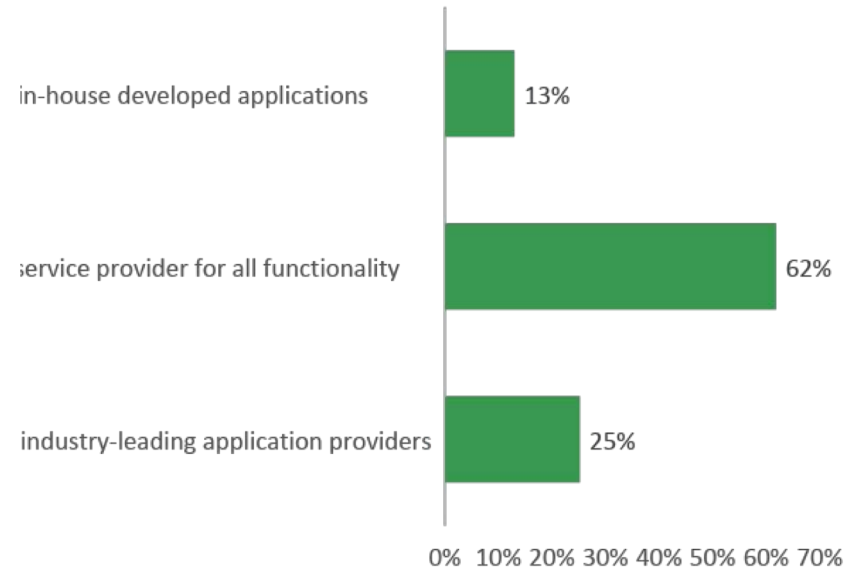


# Application Provider Use vs. Preference

When thinking about specific applications such as “site selection”, “site activation”, “quality management system”, and “study execution software”, what does your organization currently use? (n=262)

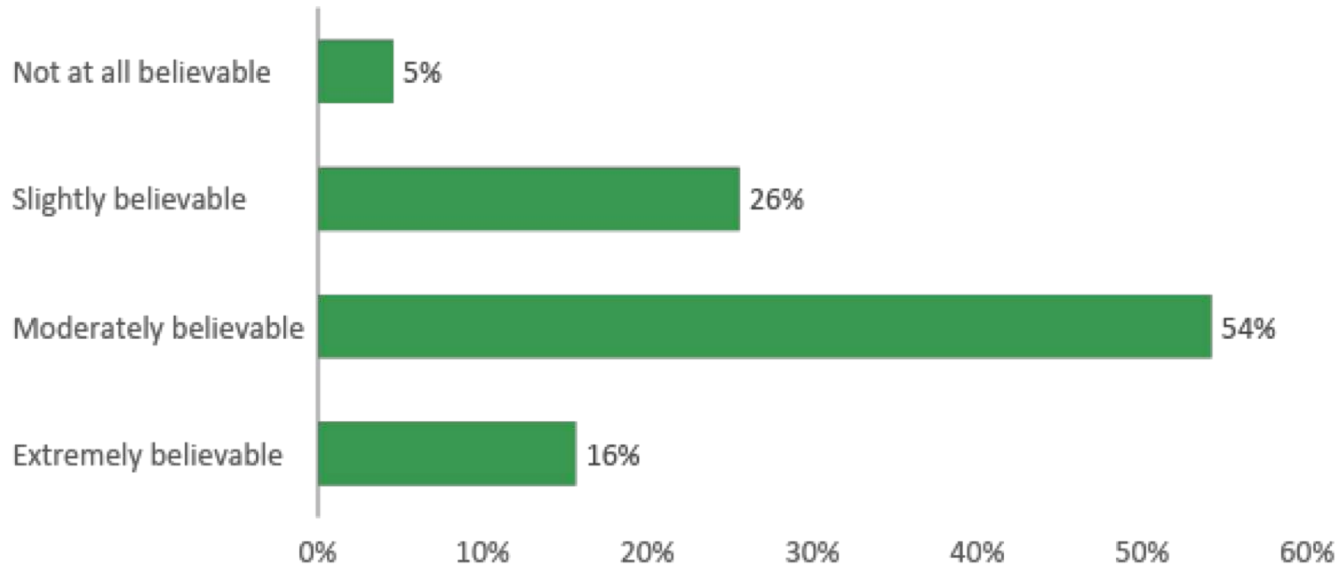


If the choice were completely up to you, what would you prefer to use for “site selection”, “site activation”, “quality management system”, and “study execution software”? (n=262)



# Believability of Single Vendor

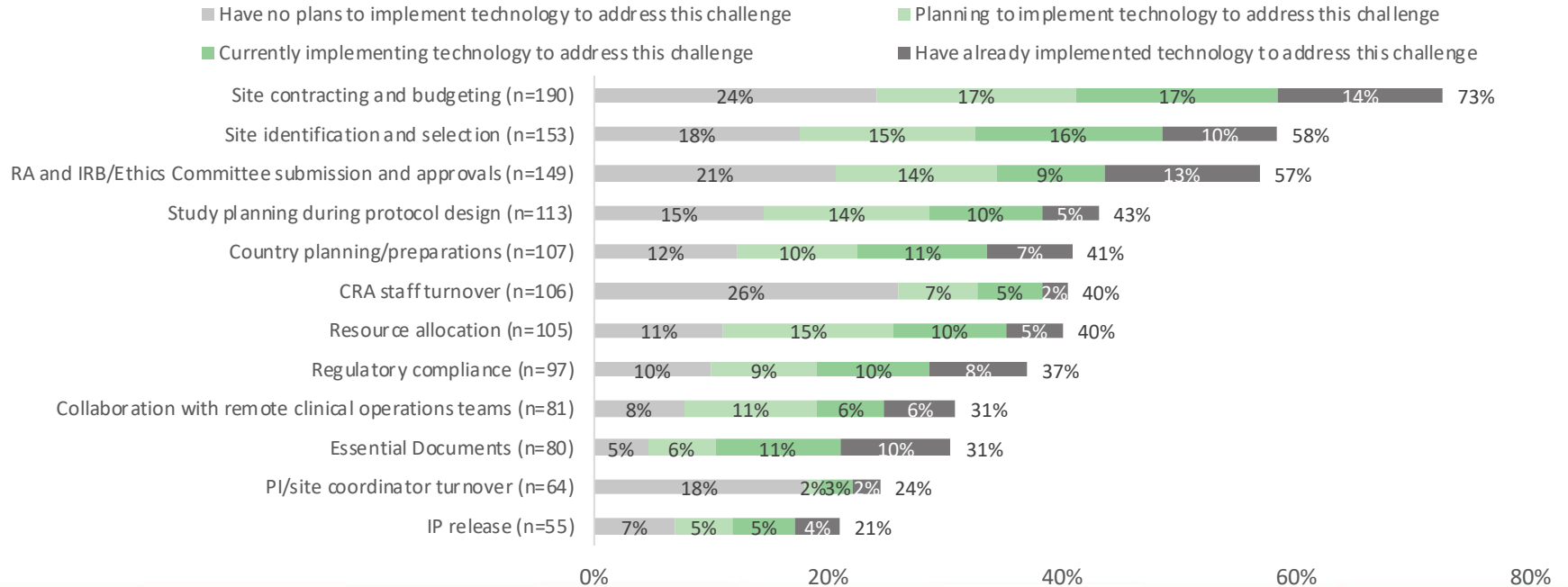
*How believable is it that one vendor could provide industry-leading applications across “site selection”, “site activation”, “quality management system”, and “study execution software”? (n=262)*





# Technology Implementation Plans to Meet Challenges

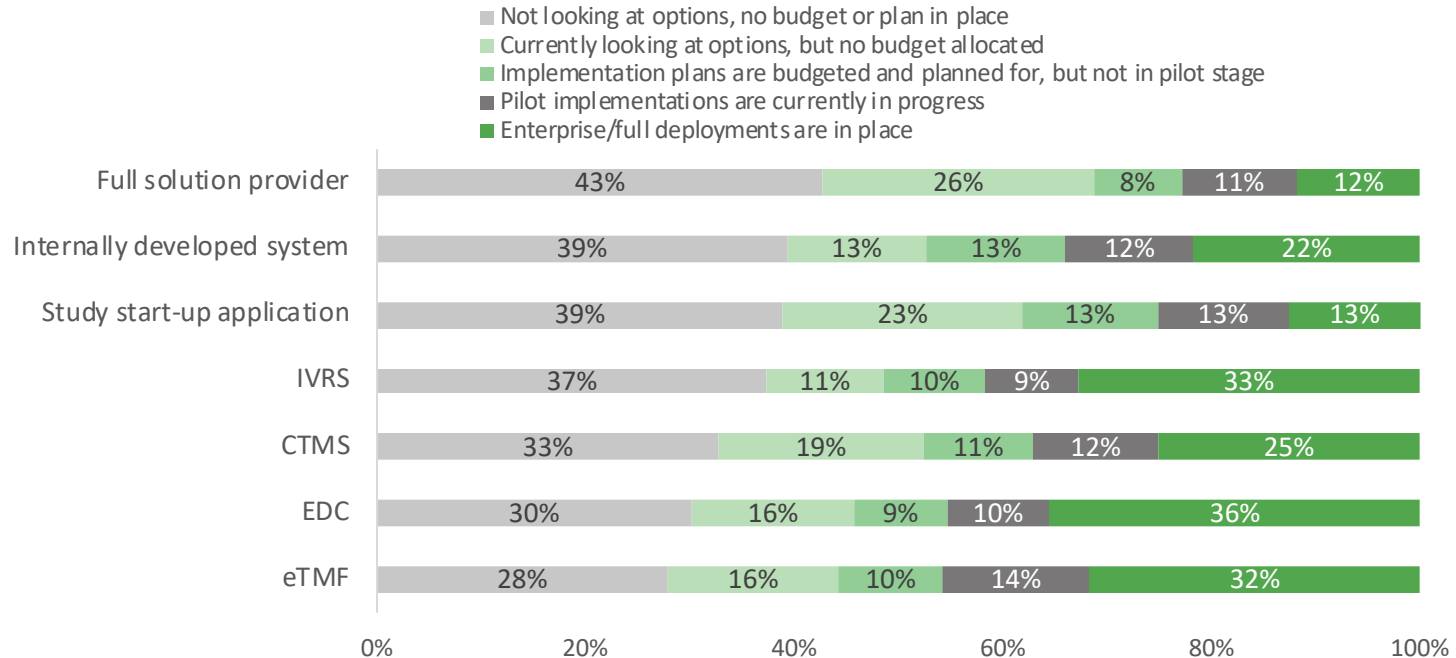
Below are the five challenges you previously selected regarding the site collaboration processes. For each (row), please select your company's technology implementation plans to meet those challenges, if any. (analysis based on challenge n/262)





# Technology Implementation Plans by Application

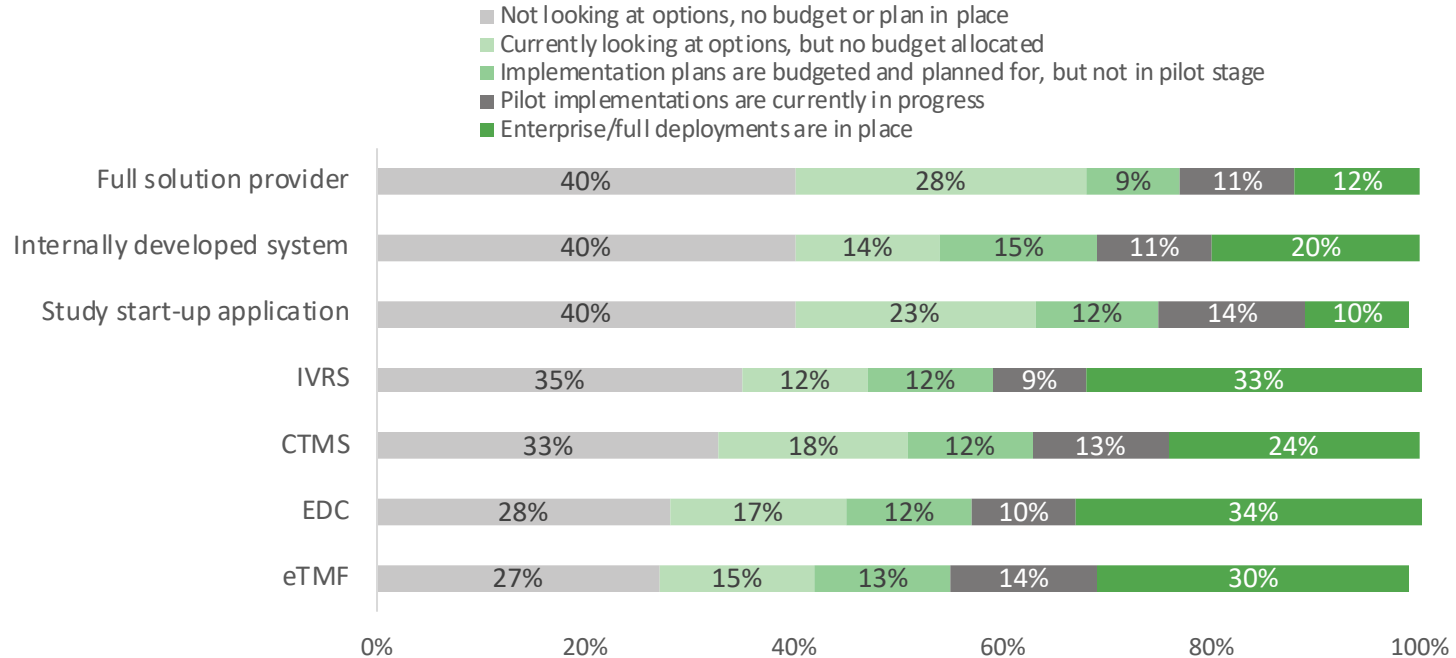
Below are some of the applications we have been referencing in this study to manage the site collaboration process. For each (row), please select your company's technology implementation plans. (n=262)





# Sponsors: Technology Implementation Plans by Application

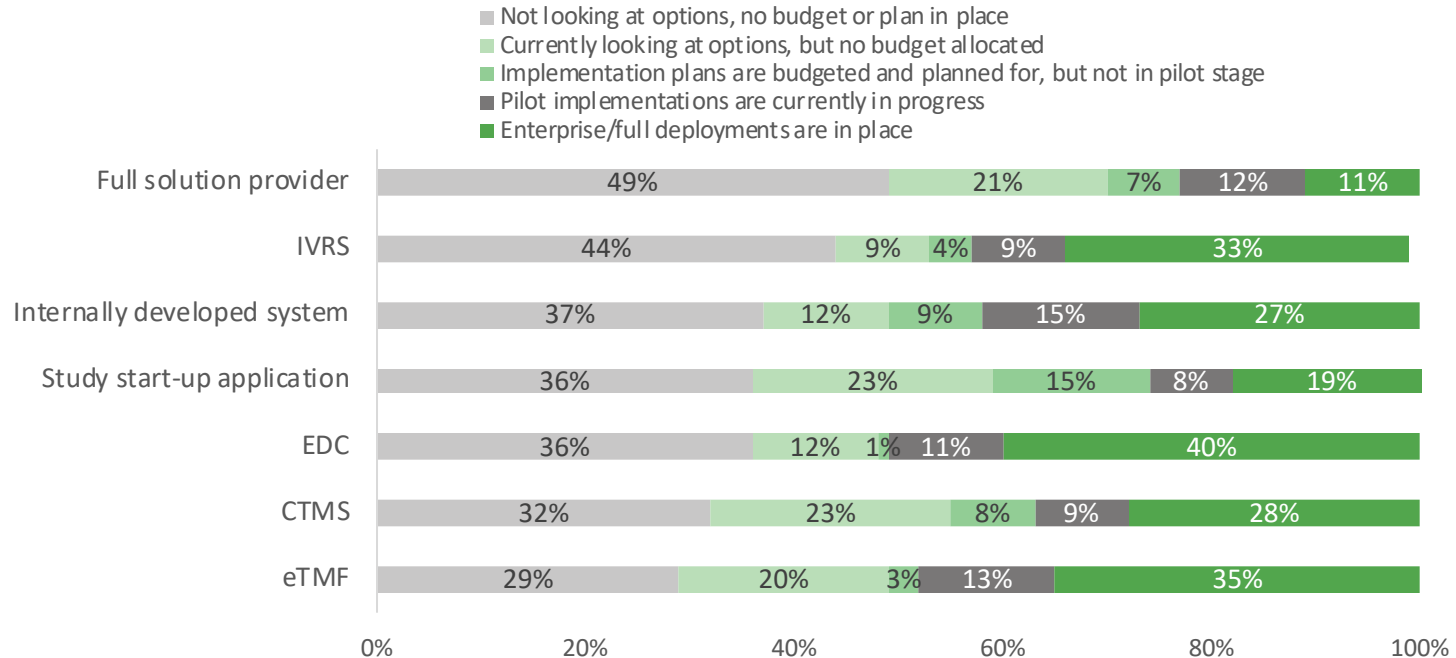
Below are some of the applications we have been referencing in this study to manage the site collaboration process. For each (row), please select your company's technology implementation plans. (sponsors only, n=187)





# CROs: Technology Implementation Plans by Application

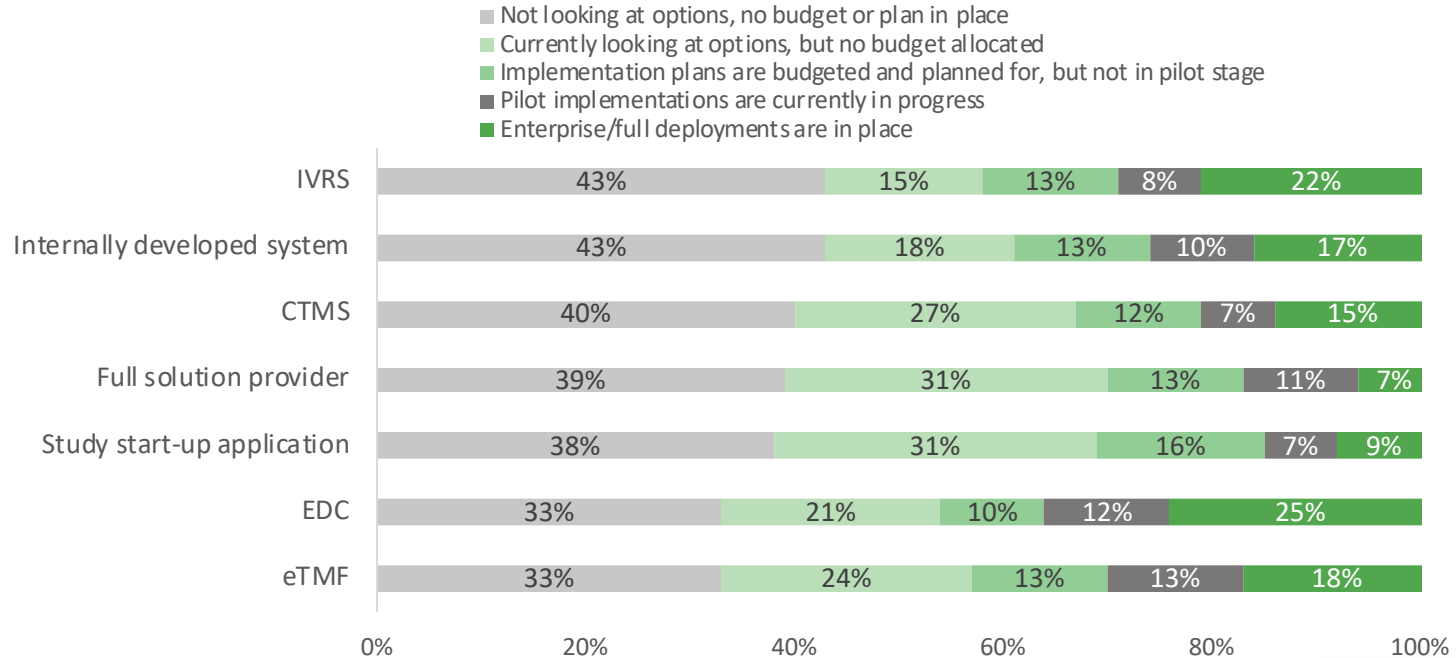
Below are some of the applications we have been referencing in this study to manage the site collaboration process. For each (row), please select your company's technology implementation plans. (CROs only, n=75)





# 1-10 Trials: Technology Implementation Plans by Application

Below are some of the applications we have been referencing in this study to manage the site collaboration process. For each (row), please select your company's technology implementation plans. (smaller companies with 1-10 trials only, n=101)

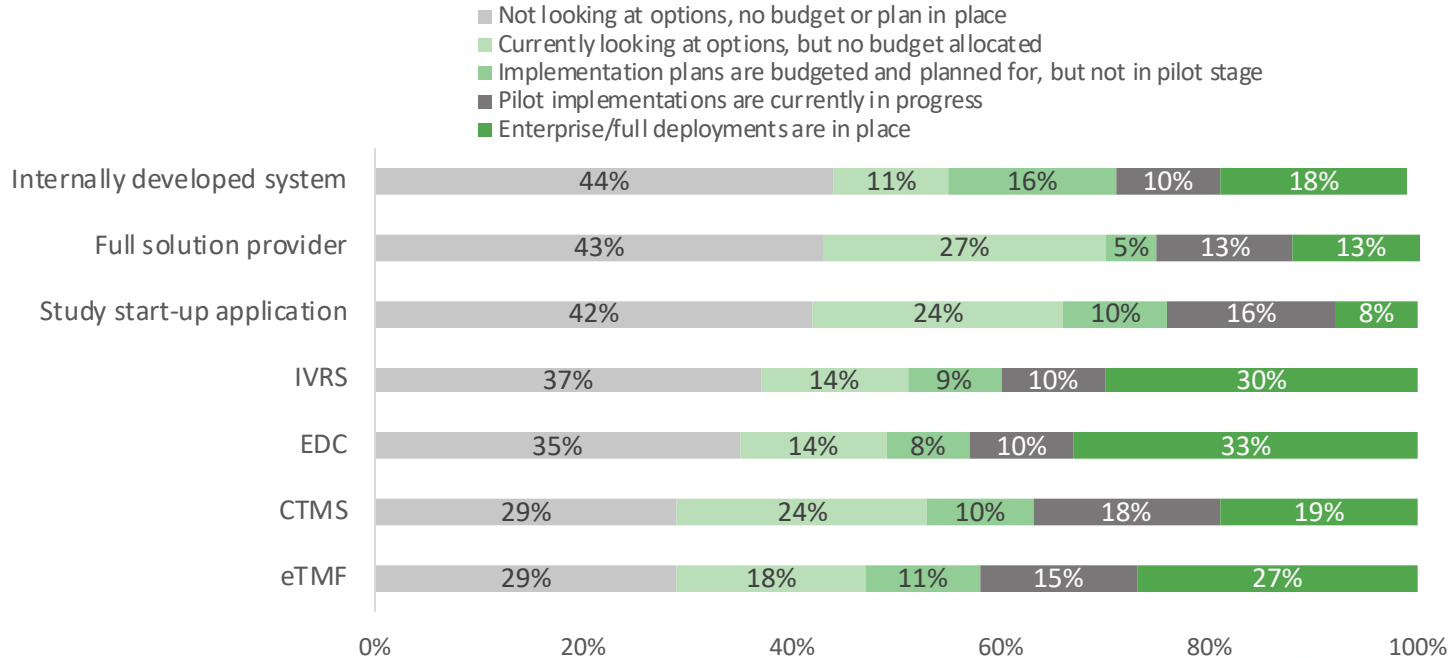






# 11-50 Trials: Technology Implementation Plans by Application

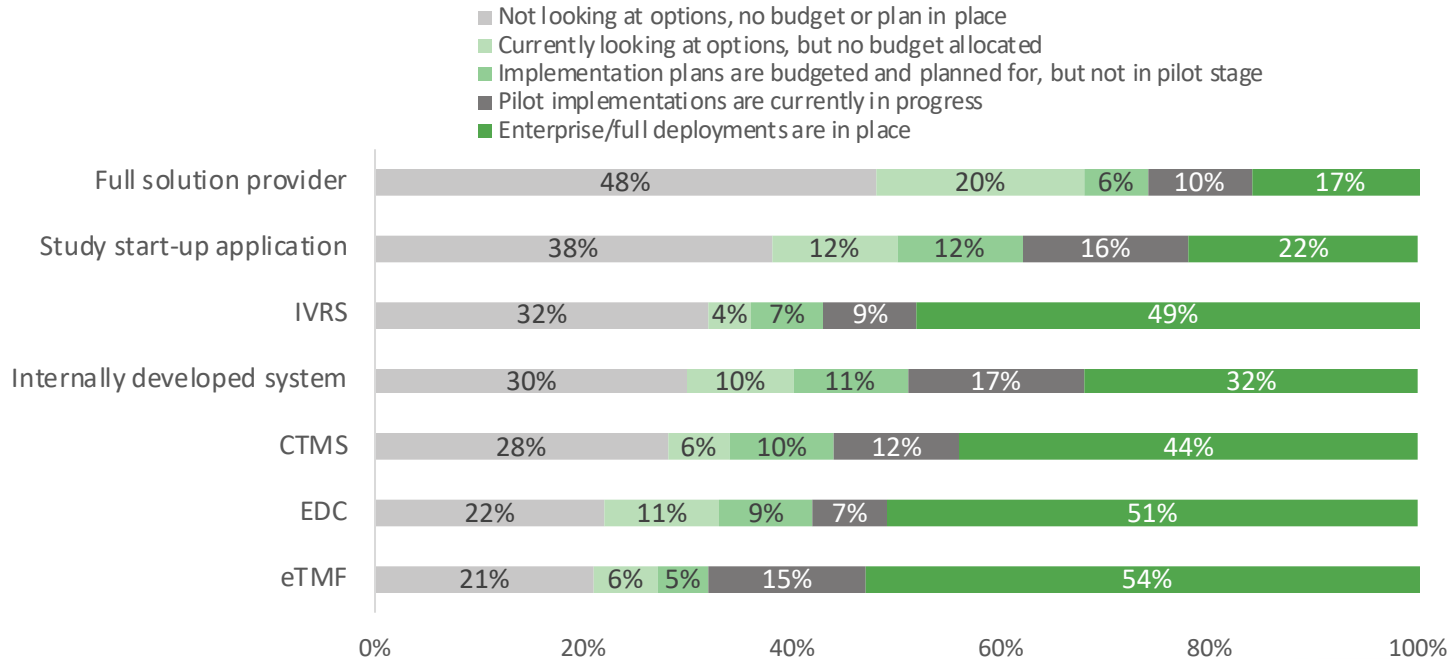
Below are some of the applications we have been referencing in this study to manage the site collaboration process. For each (row), please select your company's technology implementation plans. (mid-size companies with 11-50 trials only, n=79)





# >50 Trials: Technology Implementation Plans by Application

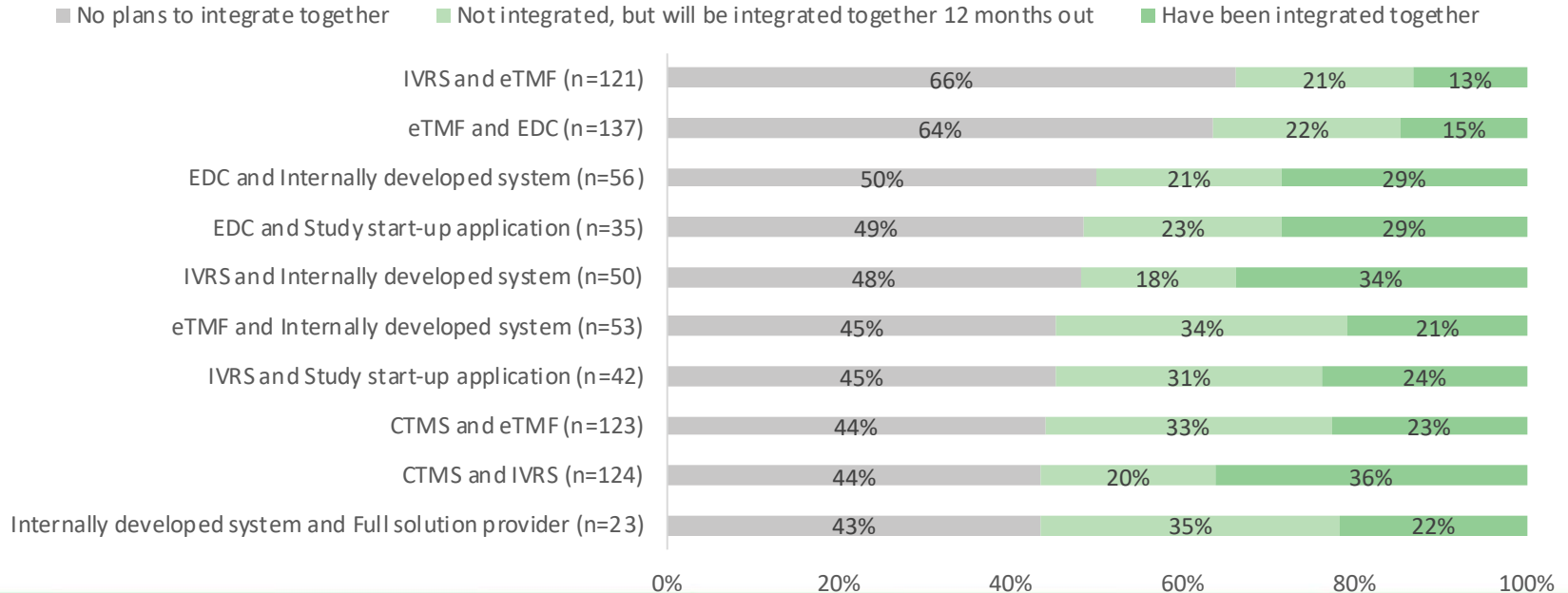
Below are some of the applications we have been referencing in this study to manage the site collaboration process. For each (row), please select your company's technology implementation plans. (large companies with >50 trials only, n=82)





# Integration of Current Applications: Respondent Selected (1)

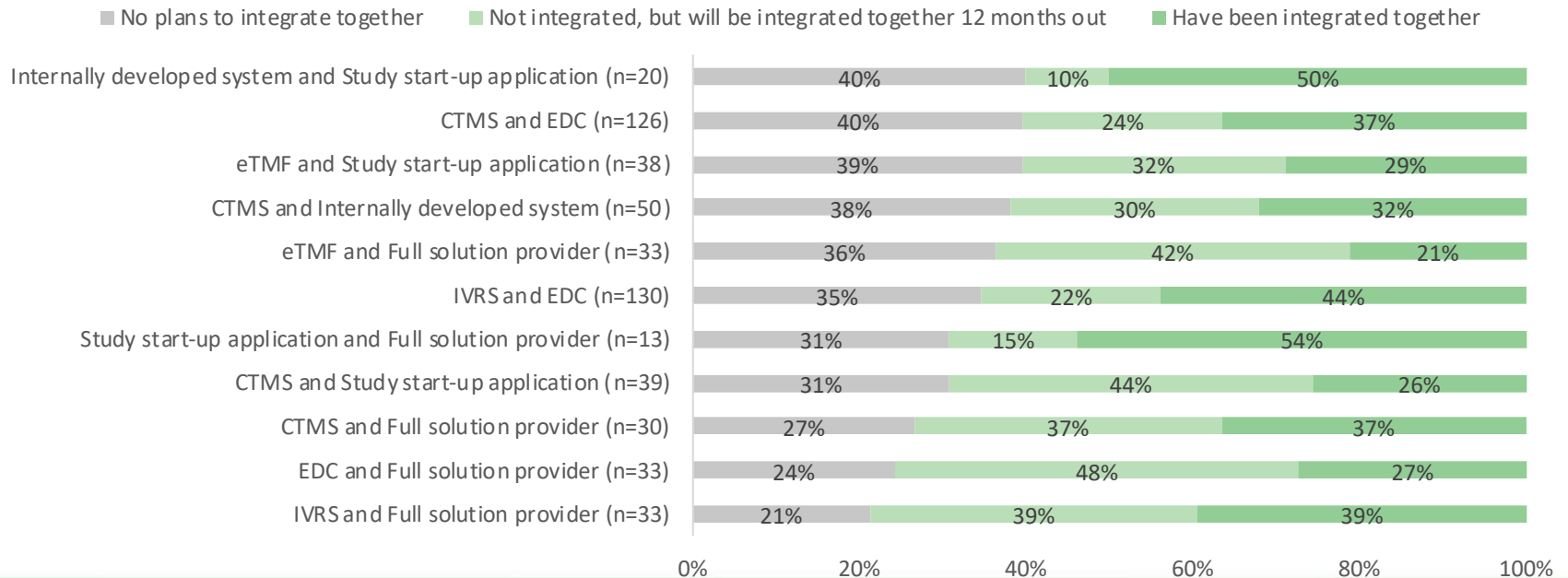
Given your responses from a previous question, we understand your organization uses the specified applications below to manage the site collaboration process. For each row, indicate whether the applications have been integrated together, will be integrated 12 months out, or there are no plans to integrate. (analysis based on respondent-selected pairings; application and other specify pairs (n=24) are not shown – for majority, there are no plans to integrate)





# Integration of Current Applications: Respondent Selected (2)

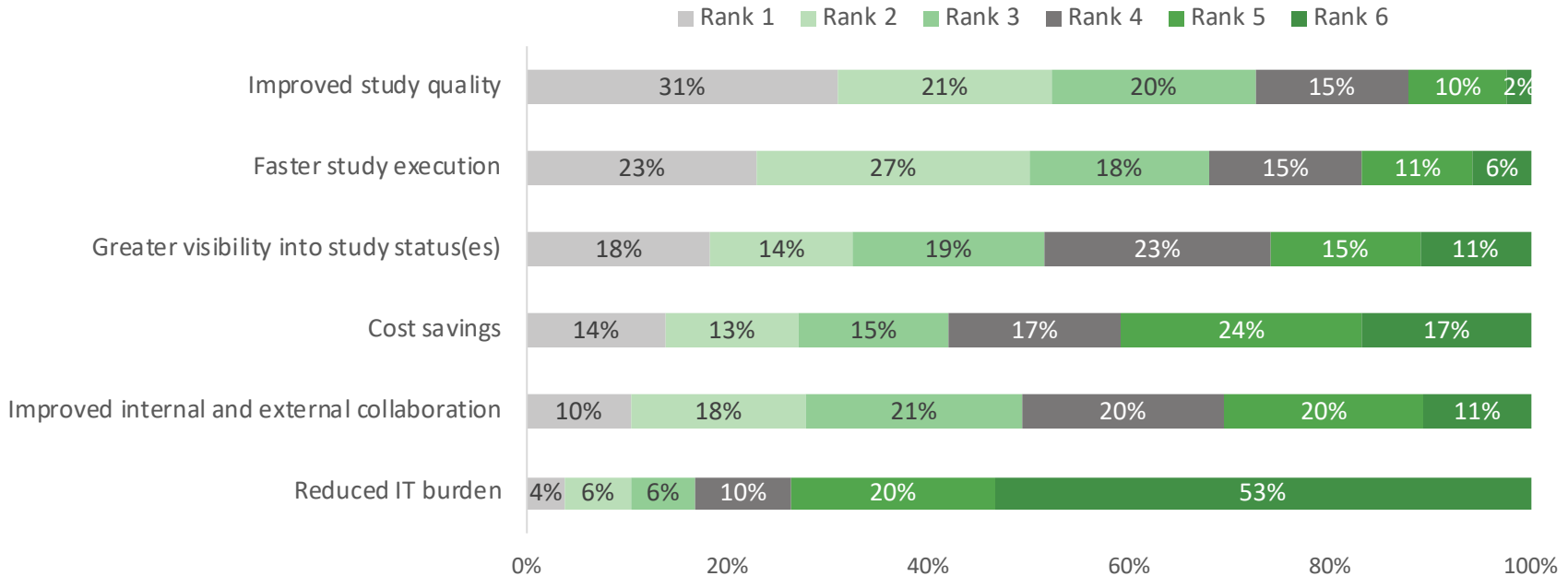
Given your responses from a previous question, we understand your organization uses the specified applications below to manage the site collaboration process. For each row, indicate whether the applications have been integrated together, will be integrated 12 months out, or there are no plans to integrate. (analysis based on respondent-selected pairings; application and other specify pairs (n=24) are not shown – for majority, there are no plans to integrate)





# Ranking of Drivers for Clinical Application Integration

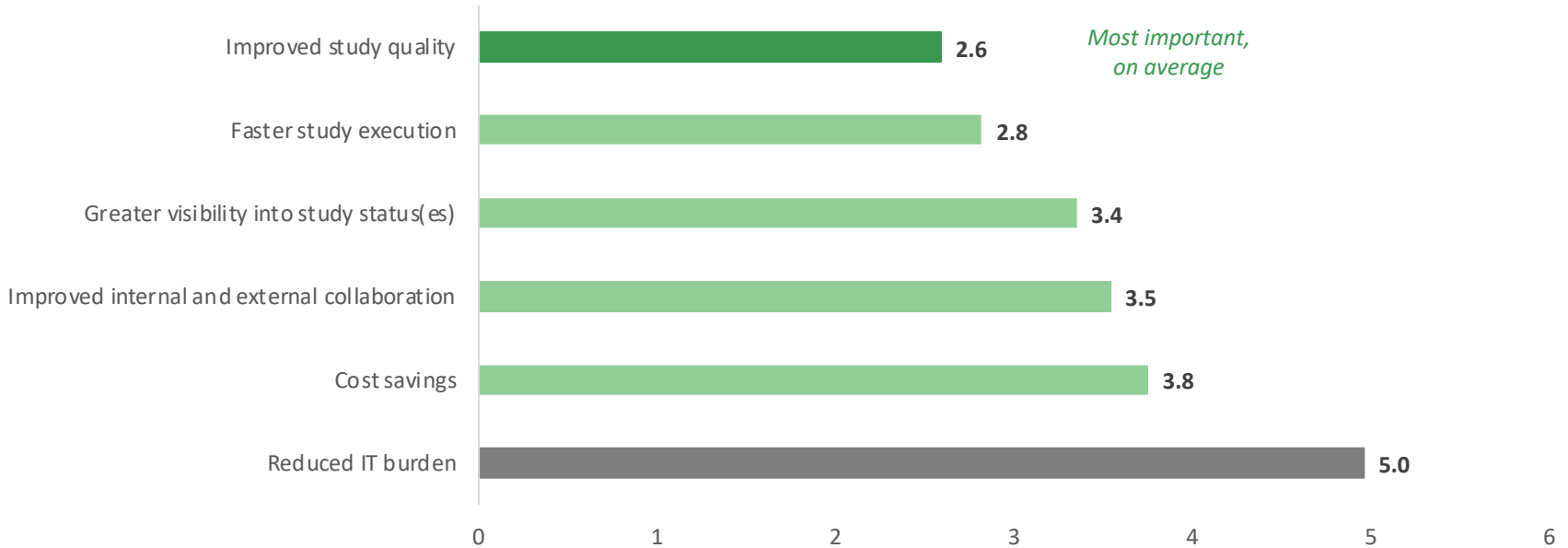
What are the most important drivers for clinical applications (e.g., CTMS, EDC, eTMF, etc.) integration? Please rank the following integration drivers in order of importance where “1” is most important and “6” is least important. (n=262)





# Average Ranking: Drivers for Clinical Application Integration

What are the most important drivers for clinical applications (e.g., CTMS, EDC, eTMF, etc.) integration? Please rank the following integration drivers in order of importance where "1" is most important and "6" is least important. (n=262)





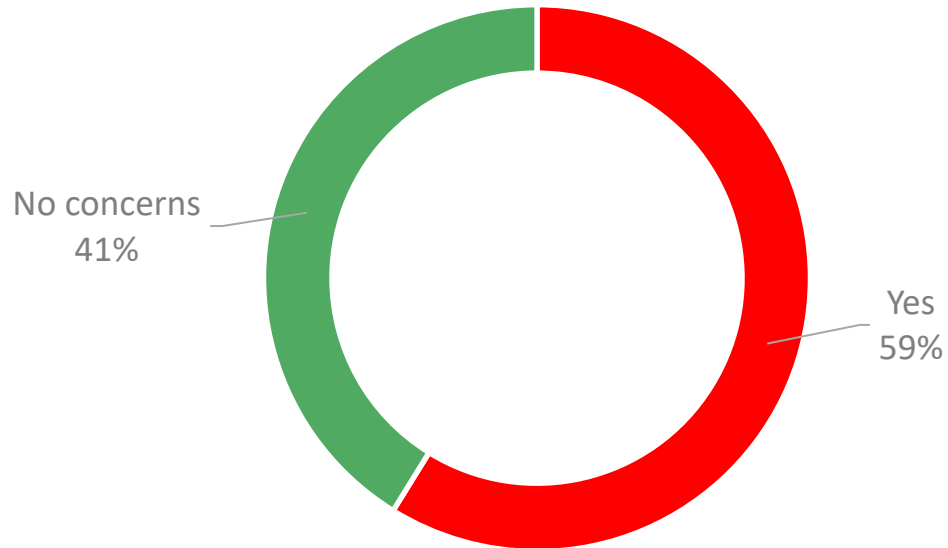
Smarter questions • Smarter answers

# ECLINICAL TECHNOLOGY IN STUDY STARTUP USAGE & FUTURE DEPLOYMENTS

## *OUTSOURCING*

# Are There Barriers for Successful Outsourcing?

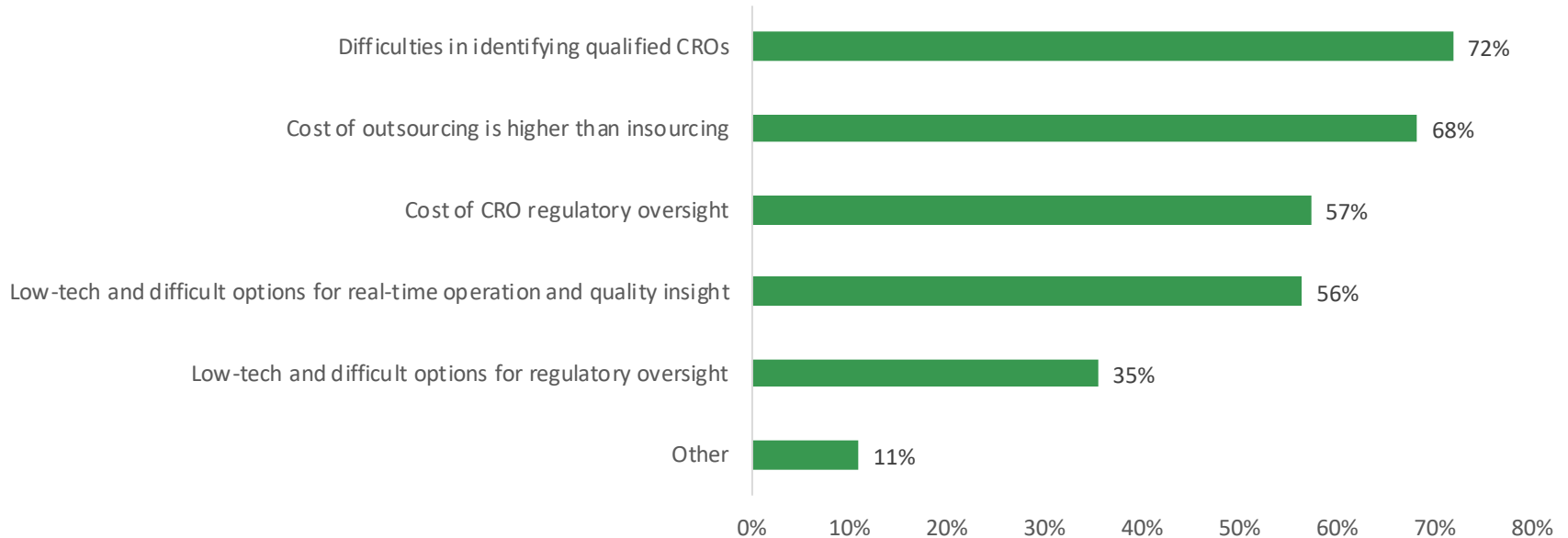
*Do you think there are barriers for successful outsourcing? (only Med device and Sponsor companies received this question, n=187)*





# Barriers for Successful Outsourcing

*What do you see as the three (3) biggest barriers for successful outsourcing? Select three. (only Med device and Sponsor companies who said “yes” to there being barriers for successful outsourcing received this question, n=110)*



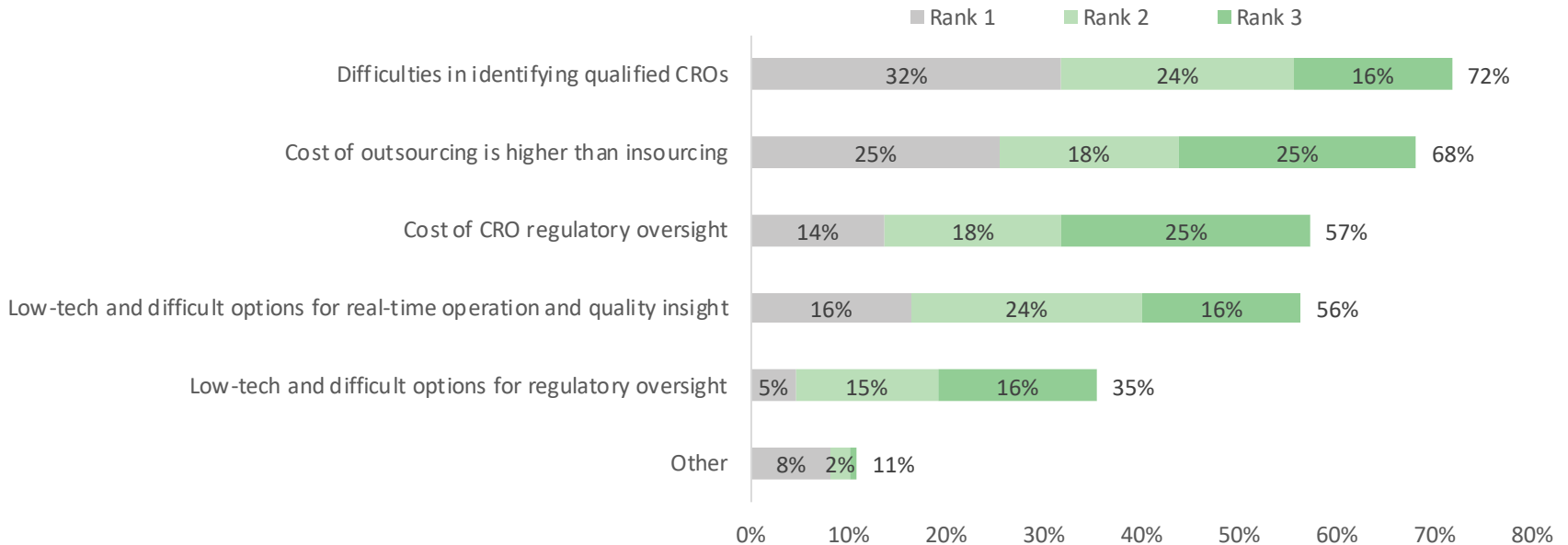
# 'Other Specify' Barriers

- "A" team for CRO presentation and bid defense, "B" team for study execution
- Communication in study planning phase between the FSP and the sponsor
- CRO engagement
- CRO profit incentive to slow the study
- CRO quality
- Finding a CRO who understands Medical Device trials
- For global/local studies, decisions are taken globally, not at local level. At local level only for local trials it is possible to select EDC systems, medical writing, CSR, but there are budget issues.
- Lack of sponsor control of project team
- People go with the easiest common denominator; not researching or knowing good new options
- Quality of CRO execution
- Quality of services provided by CRO



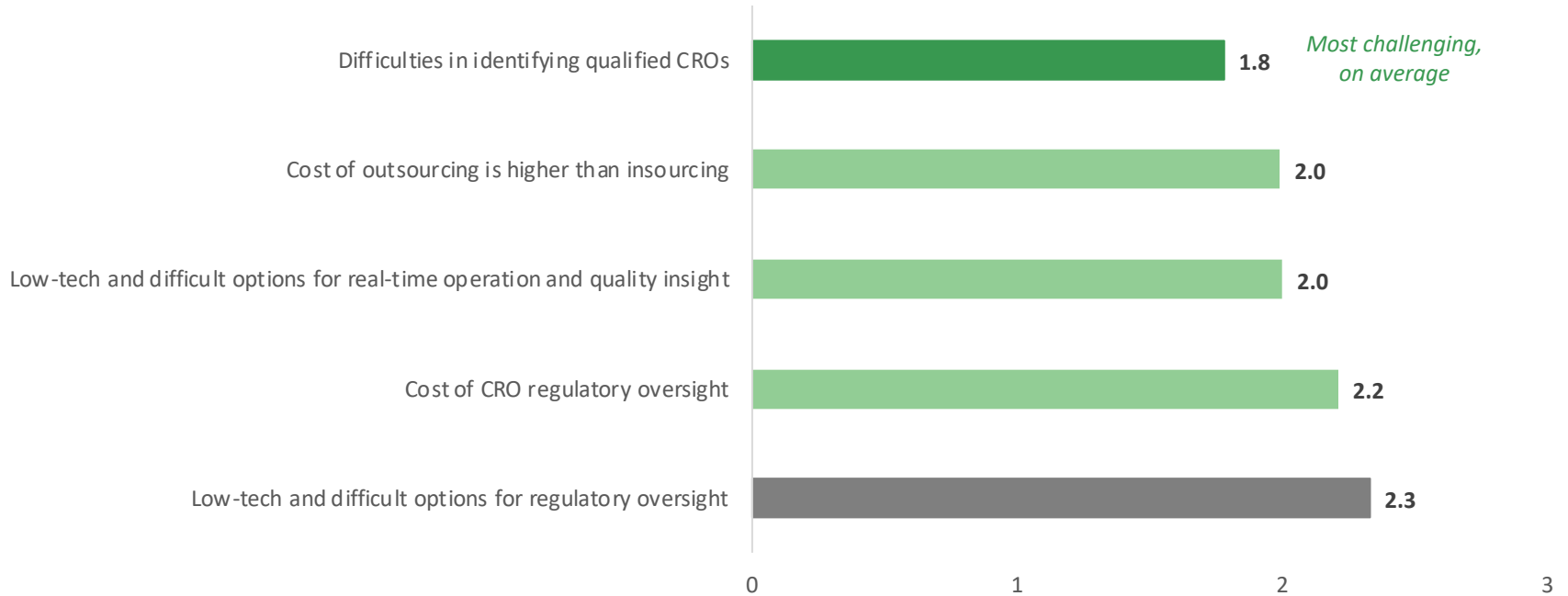
# Rank Top 3 Barriers for Successful Outsourcing

Now, please rank the following options in order where “1” is the most challenging barrier and “3” is the least challenging barrier in terms of how much they impact successful outsourcing. (Only Med device and Sponsor companies who said “yes” to there being barriers for successful outsourcing received this question, n=110)





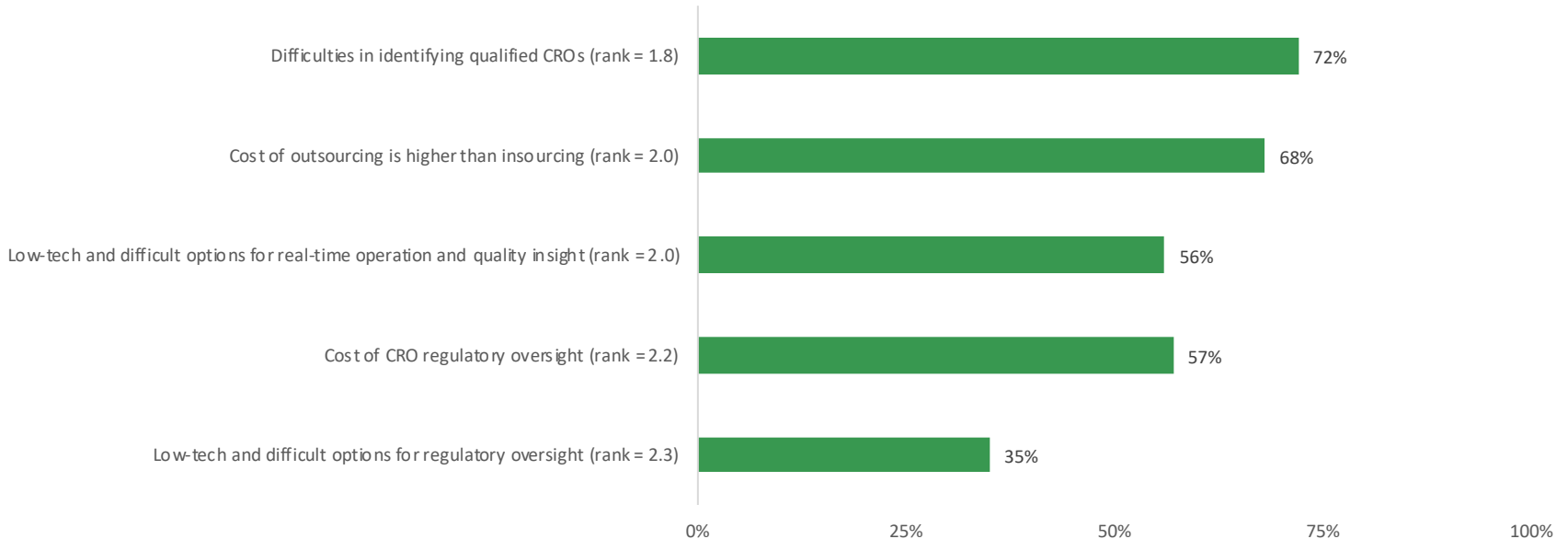
# Average Ranking: Top 3 Barriers for Successful Outsourcing





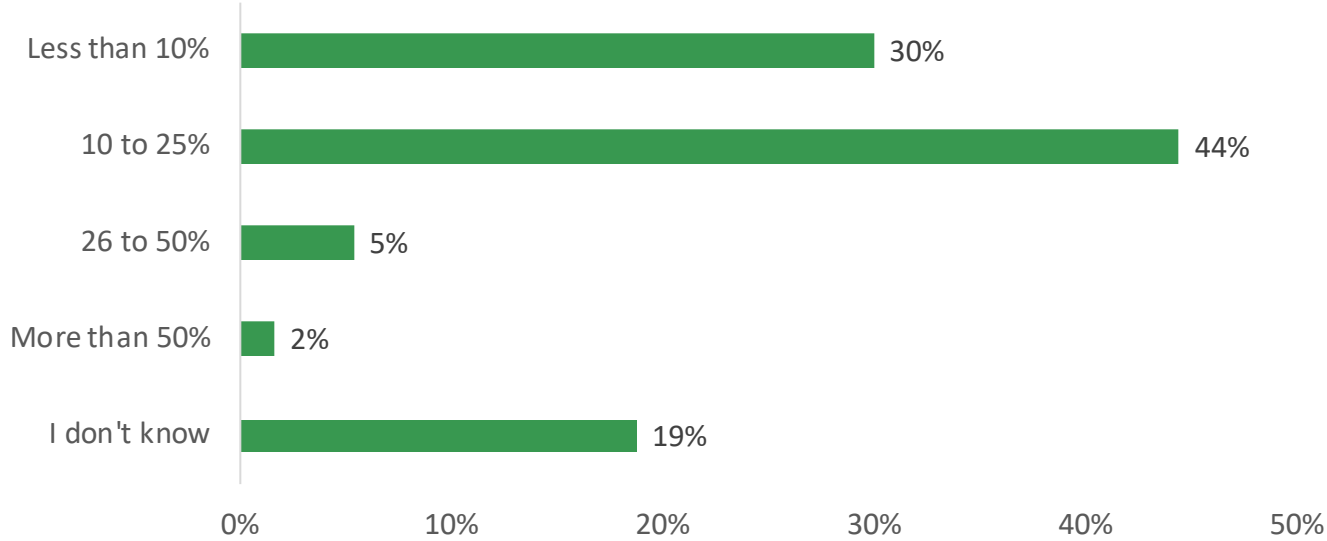
# Top 3 Barriers for Successful Outsourcing (prevalence and ranking)

Now, please rank the following options in order where “1” is the most challenging barrier and “3” is the least challenging barrier in terms of how much they impact successful outsourcing. (only Med device and Sponsor companies who said “yes” to there being barriers for successful outsourcing received this question, n=110)



# Percentage of Study Costs Unaccounted For

*For a typical clinical study at your organization, approximately what percentage of the final study costs are unaccounted for (i.e., cannot be attributed to a specific business activity, for example, protocol writing, site identification, supplies, manufacturing/drug product costs, data management, monitoring, safety, etc.)? Your best estimate is fine. (only Med device and Sponsor companies received this question, n=187)*





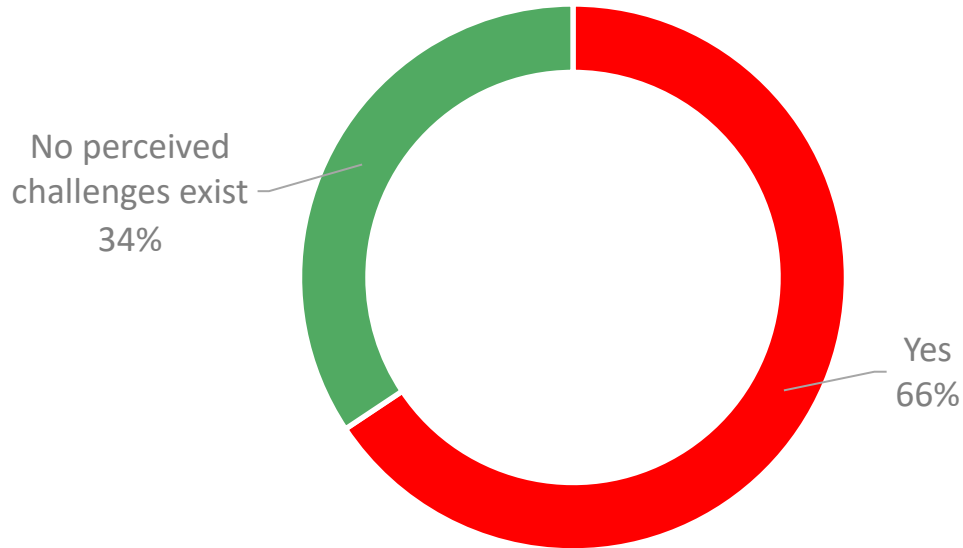
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# BARRIERS TO ADOPTING ECLINICAL SOLUTIONS IN STUDY STARTUP



# Are There Challenges in Adopting New Clinical Systems?

*Do you think there are challenges in adopting new clinical systems? (n=262)*

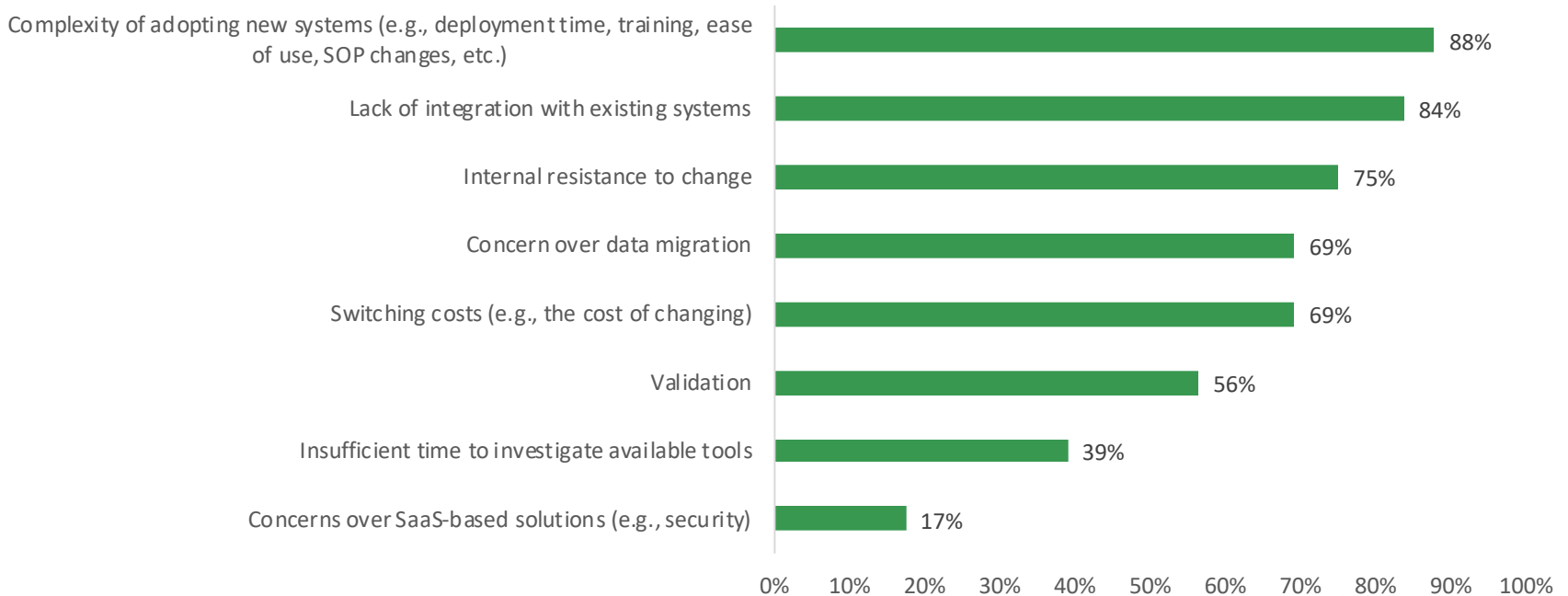






# Challenges in Adopting New Clinical Systems

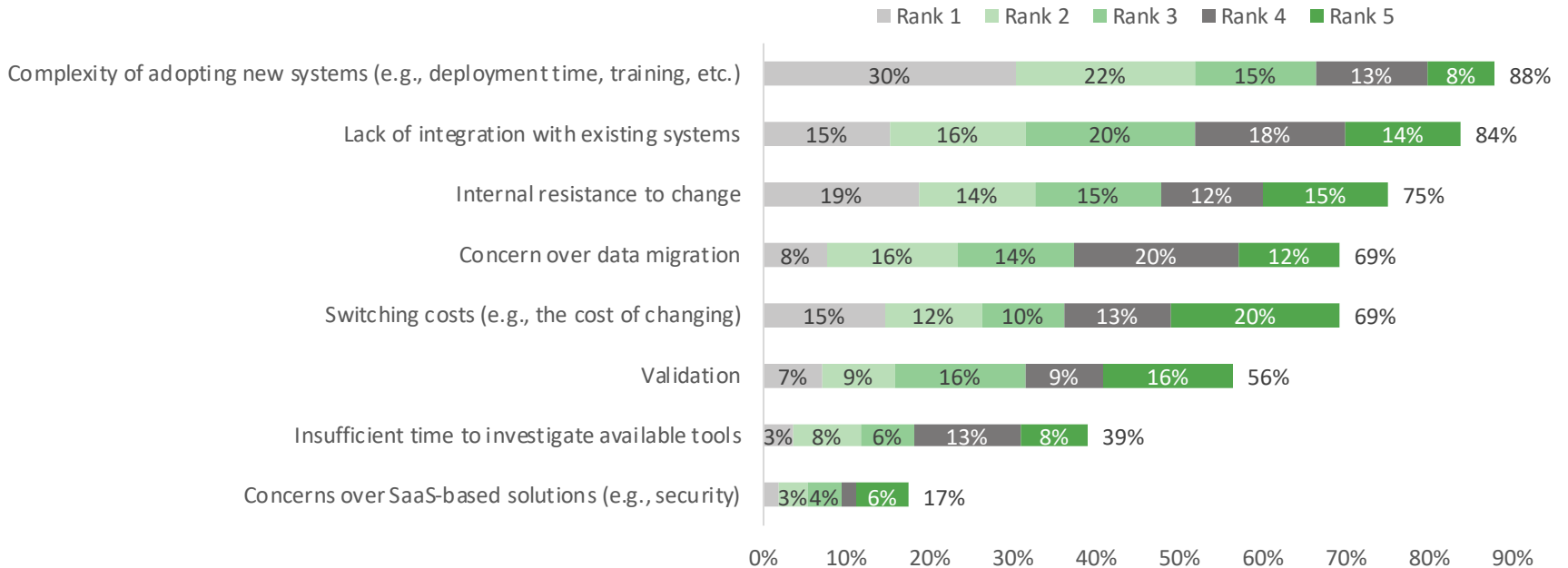
What are the five (5) biggest perceived challenges in adopting new clinical systems? Select five. (only respondents who said “yes” to there being challenges in adopting new clinical systems received this question, n=172)





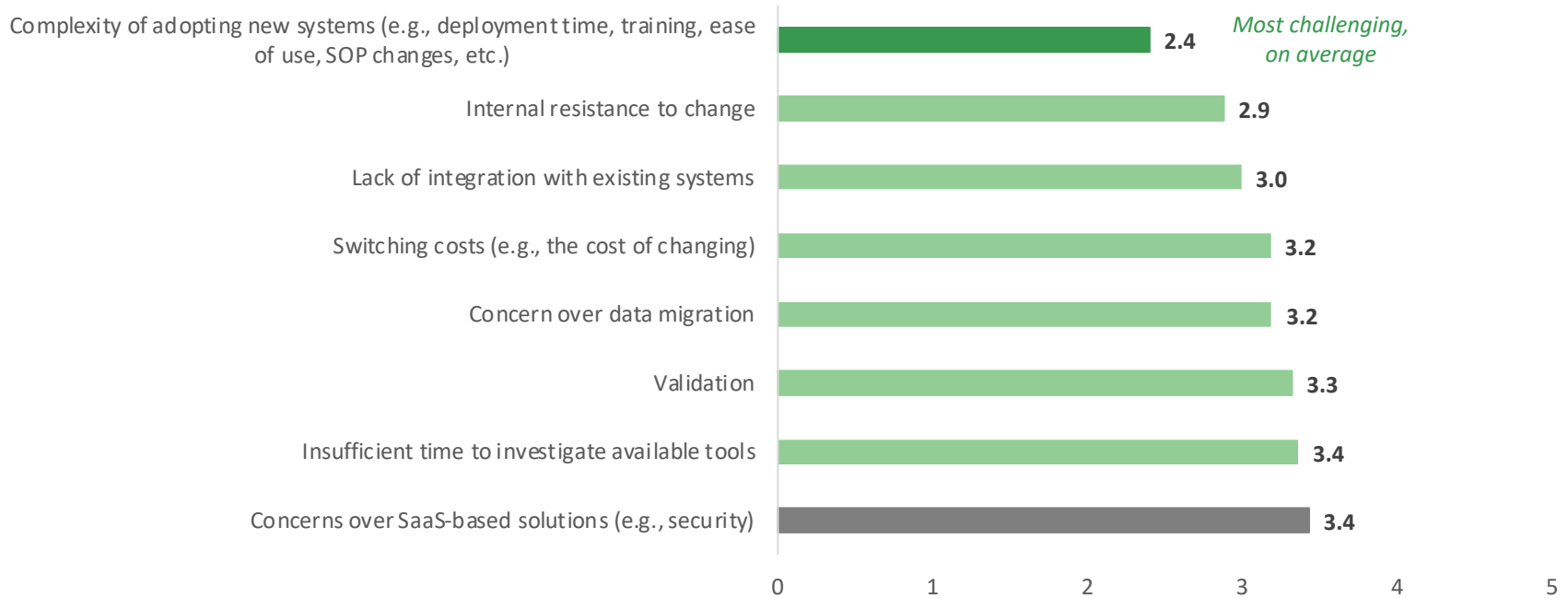
# Rank Top 5 Challenges in Adoption

Now, please rank the following options in order of the biggest perceived challenges in adopting new clinical systems where “1” is most challenging and “5” is least challenging. (only respondents who said “yes” to there being challenges in adopting new clinical systems received this question, n=172)





# Average Ranking: Top 5 Challenges in Adoption

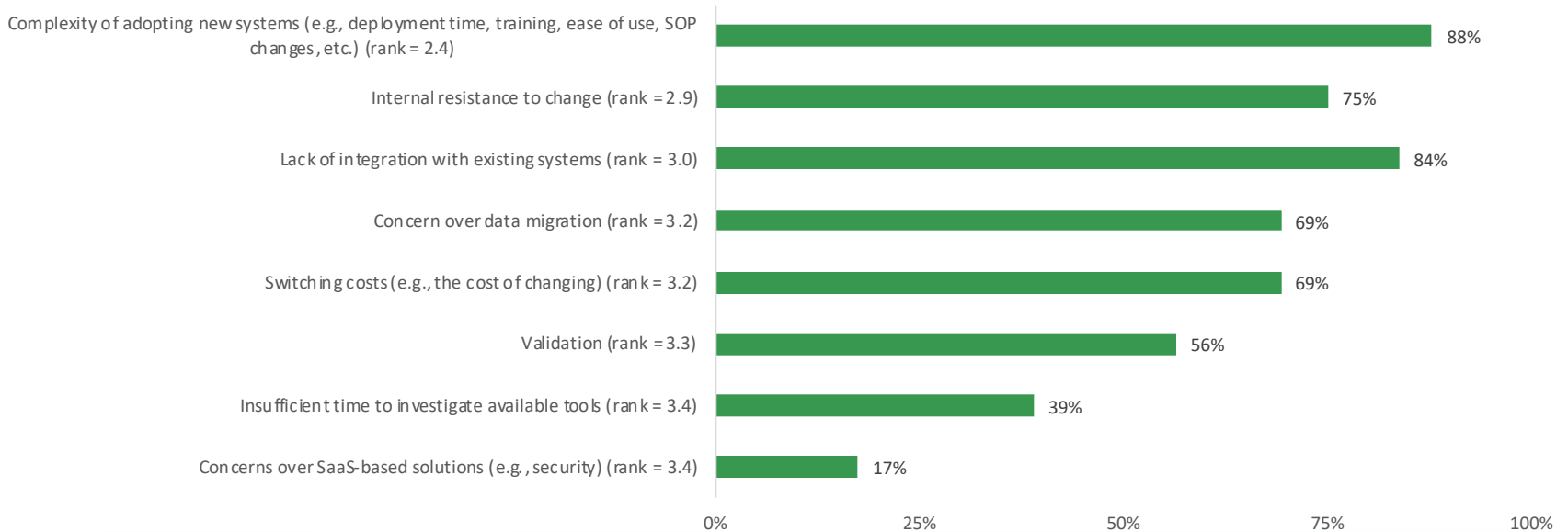




# Challenges in Adopting New Clinical Systems (prevalence and ranking)

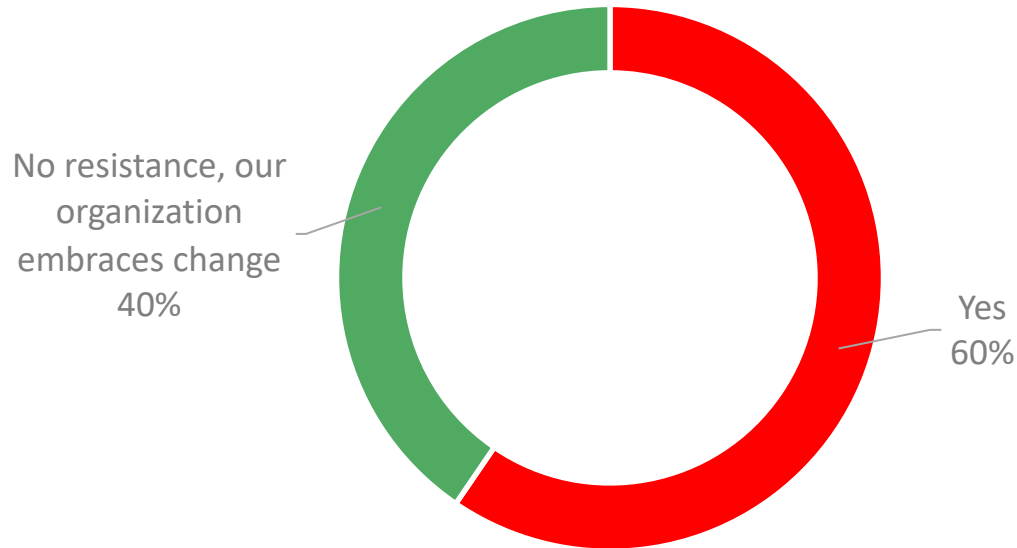
What are the five (5) biggest perceived challenges in adopting new clinical systems? Select five. (only respondents who said “yes” to there being challenges in adopting new clinical systems received this question, n=172)

Now, please rank the following options in order of the biggest perceived challenges in adopting new clinical systems where “1” is most challenging and “5” is least challenging. (only respondents who said “yes” to there being challenges in adopting new clinical systems received this question, n=172)



# Is There Resistance to Adopting New Technologies?

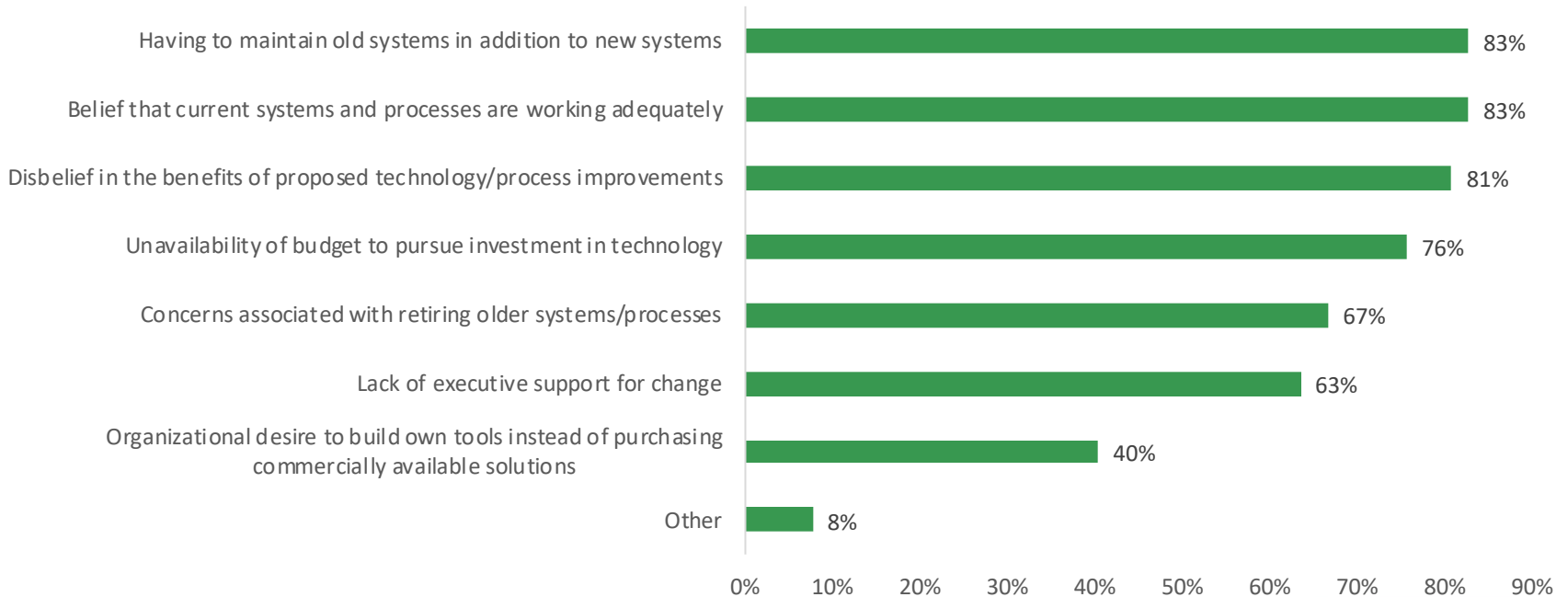
*Do you think there is resistance to adopting new technologies? (n=262)*





# Reasons for Resistance to Adopting New Technologies

*What are the five (5) biggest reasons for resistance to adopting new technologies? Select five. (only respondents who said “yes” to there being resistance to adopting new technologies received this question, n=156)*



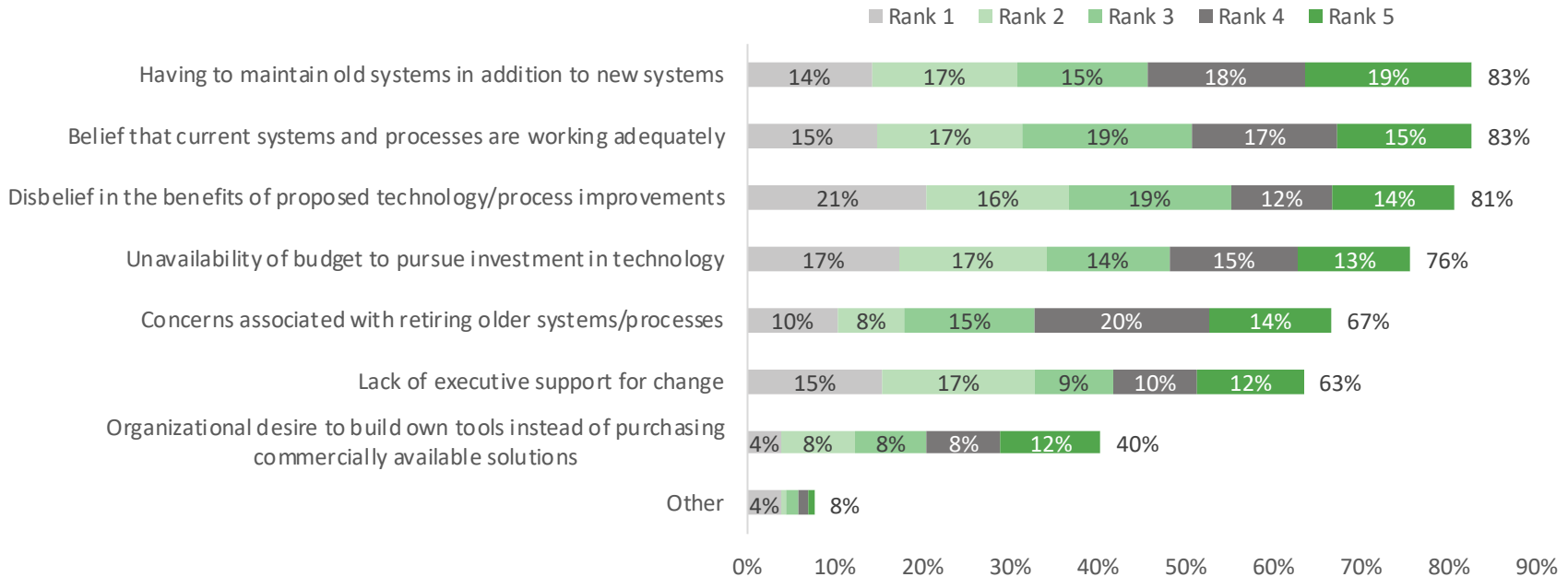
# 'Other Specify' Reasons

- Complexity of learning the system
- Concern over new regs negating imagined utility and limiting ROI
- Cost of new technologies
- Current systems do the job effectively
- Differing opinions on needs
- Fear
- Inertia to change
- Lack of proper implementation/change management to reach users at all points of the spectrum of "readiness"
- Learning process is too long
- Luddites
- Unintended consequences when capabilities of new systems are not properly anticipated, vetted or tested



# Rank Top 5 Reasons for Resistance

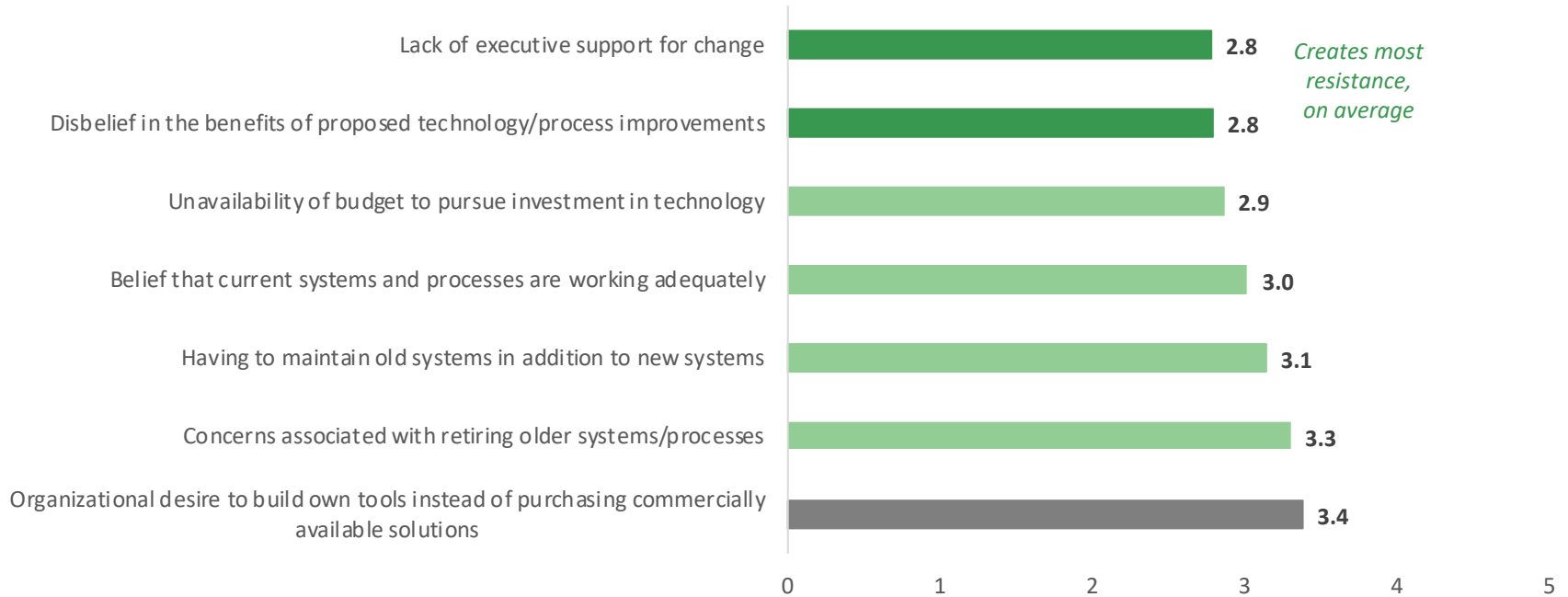
Now, please rank the following options in order of the biggest reason for resistance to adopting new technologies where “1” is creates the most resistance and “5” is creates the least resistance. (only respondents who said “yes” to there being resistance to adopting new technologies received this question, n=156)







# Average Rank Top 5 Reasons for Resistance

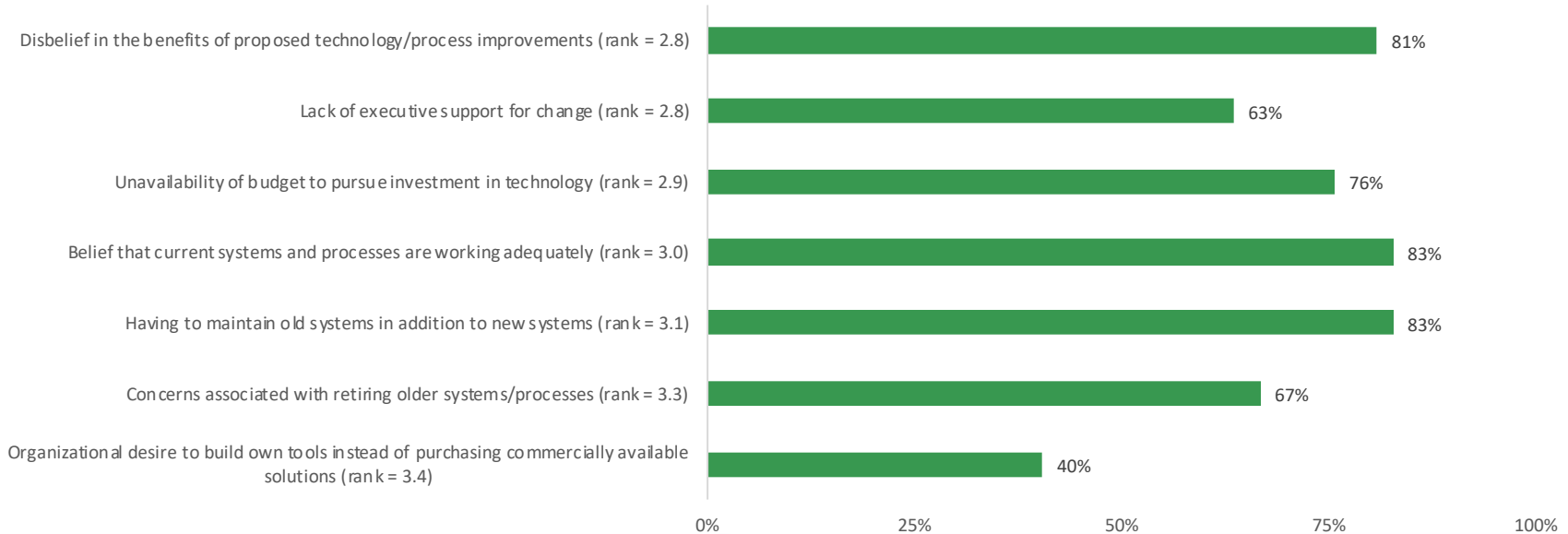




# Reasons for Resistance to Adopting New Technologies (prevalence and ranking)

What are the five (5) biggest reasons for resistance to adopting new technologies? Select five. (only respondents who said “yes” to there being resistance to adopting new technologies received this question, n=156)

Now, please rank the following options in order of the biggest reason for resistance to adopting new technologies where “1” is creates the most resistance and “5” is creates the least resistance. (only respondents who said “yes” to there being resistance to adopting new technologies received this question, n=156)





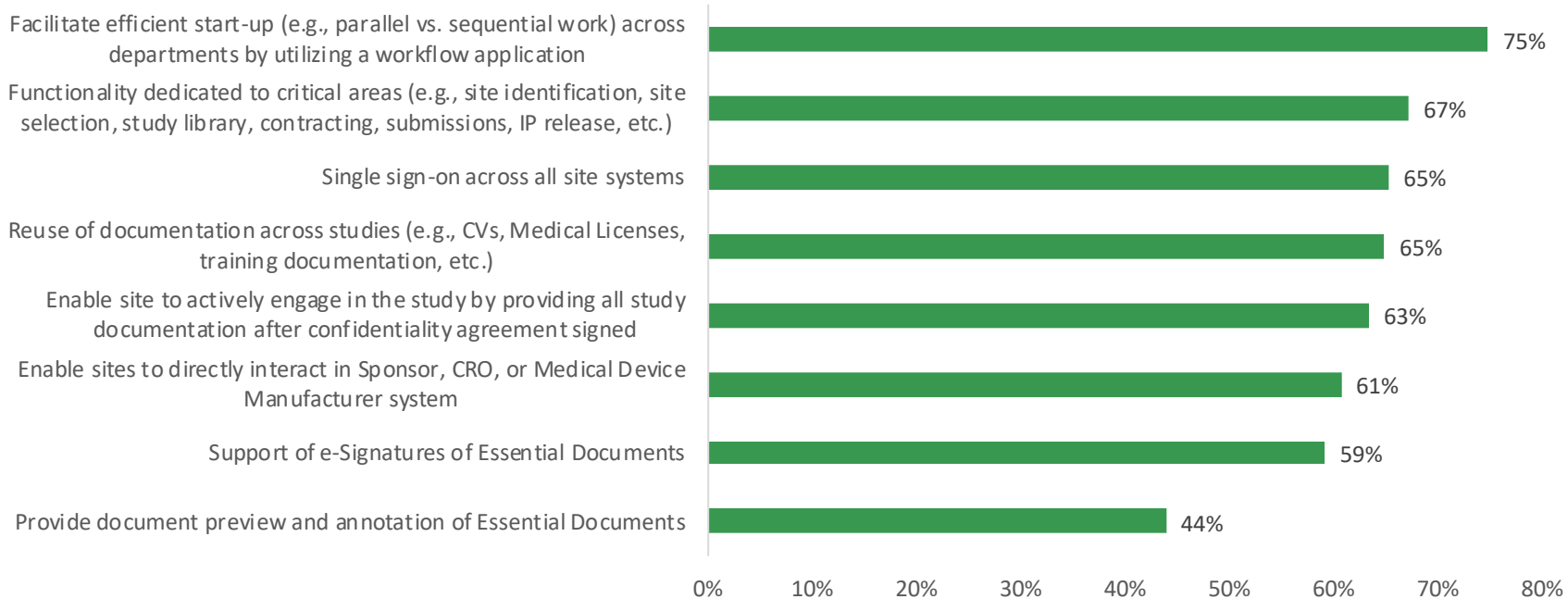
Smarter questions • Smarter answers

# CHANGE MANAGEMENT IN STUDY STARTUP TECHNOLOGY PROJECTS



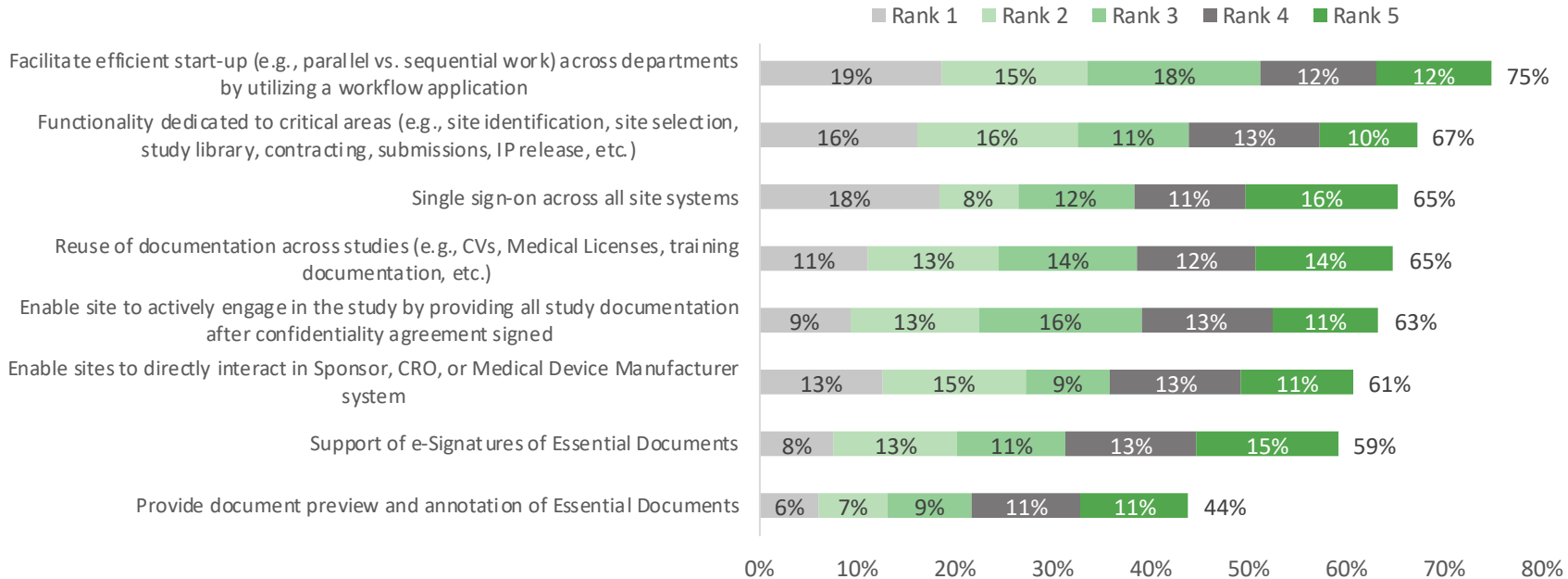
# Elements for Successful Technology Implementation

*Of the following, which five (5) do you see as the most important elements for successful technology implementation for site collaboration? Select five. (n=262)*

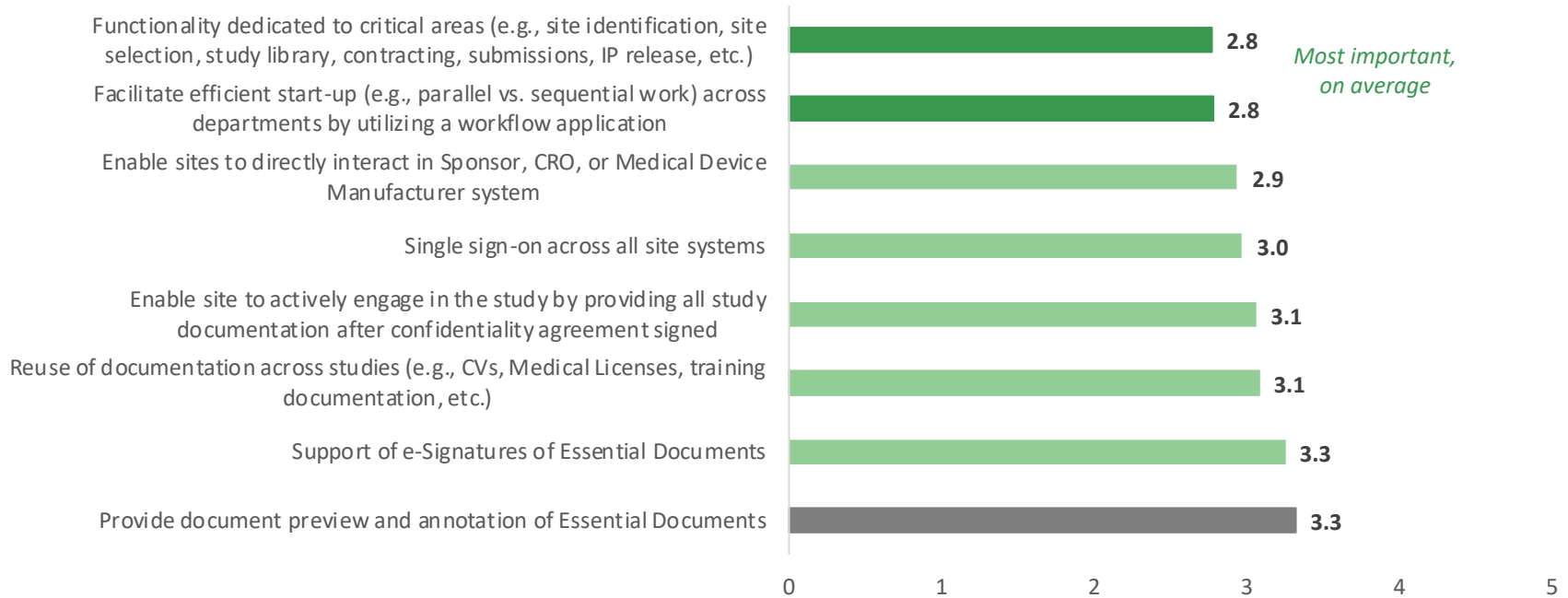


# Rank Top 5 Elements

Now, please rank the following options in order of most important elements for successful technology implementation for site collaboration where “1” is most important and “5” is least important. (n=262)



# Average Ranking: Top 5 Elements

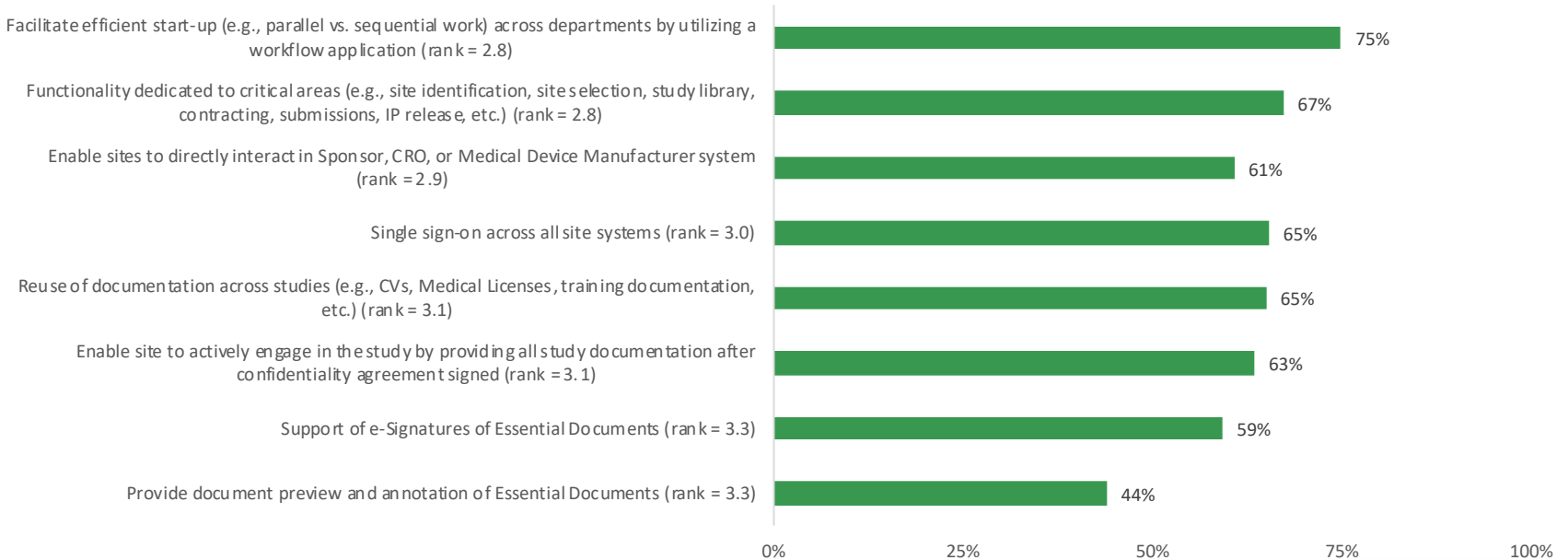




# Elements for Successful Technology Implementation (prevalence and ranking)

Of the following, which five (5) do you see as the most important elements for successful technology implementation for site collaboration? Select five. (n=262)

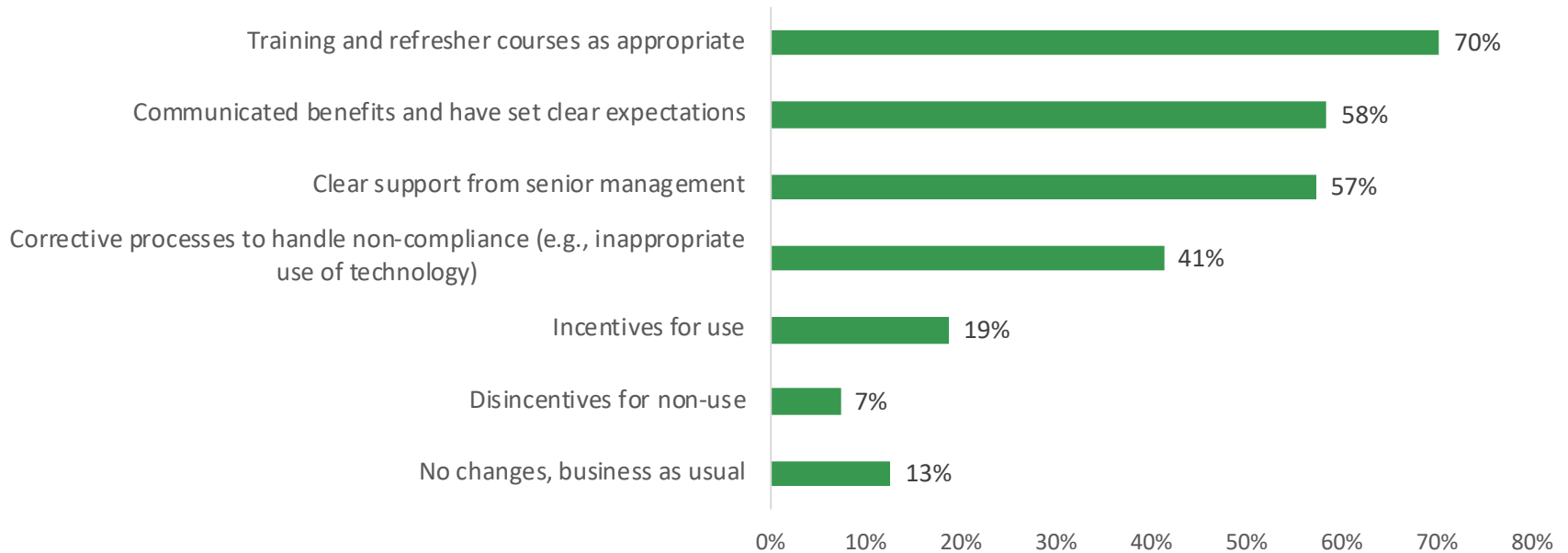
Now, please rank the following options in order of most important elements for successful technology implementation for site collaboration where “1” is most important and “5” is least important. (n=262)





# Steps Taken to Ensure Technology Deployments

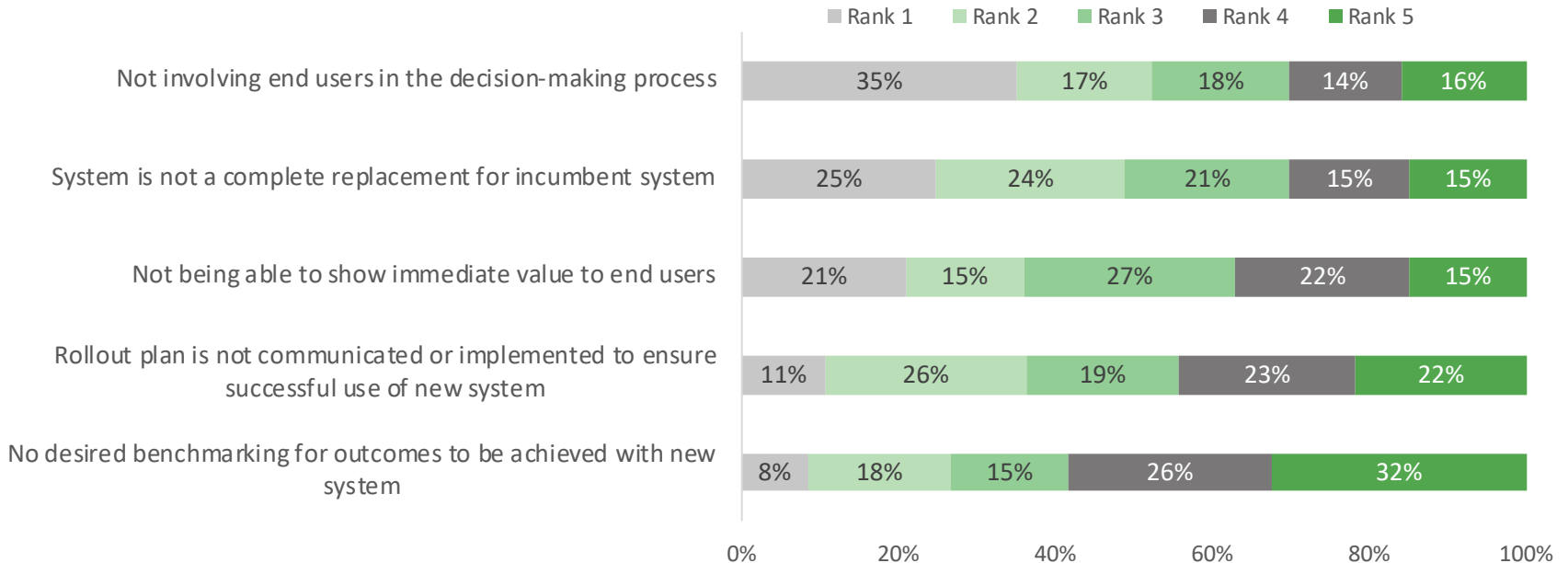
What steps has your organization taken to ensure successful technology deployments? Select all that apply. (n=262)



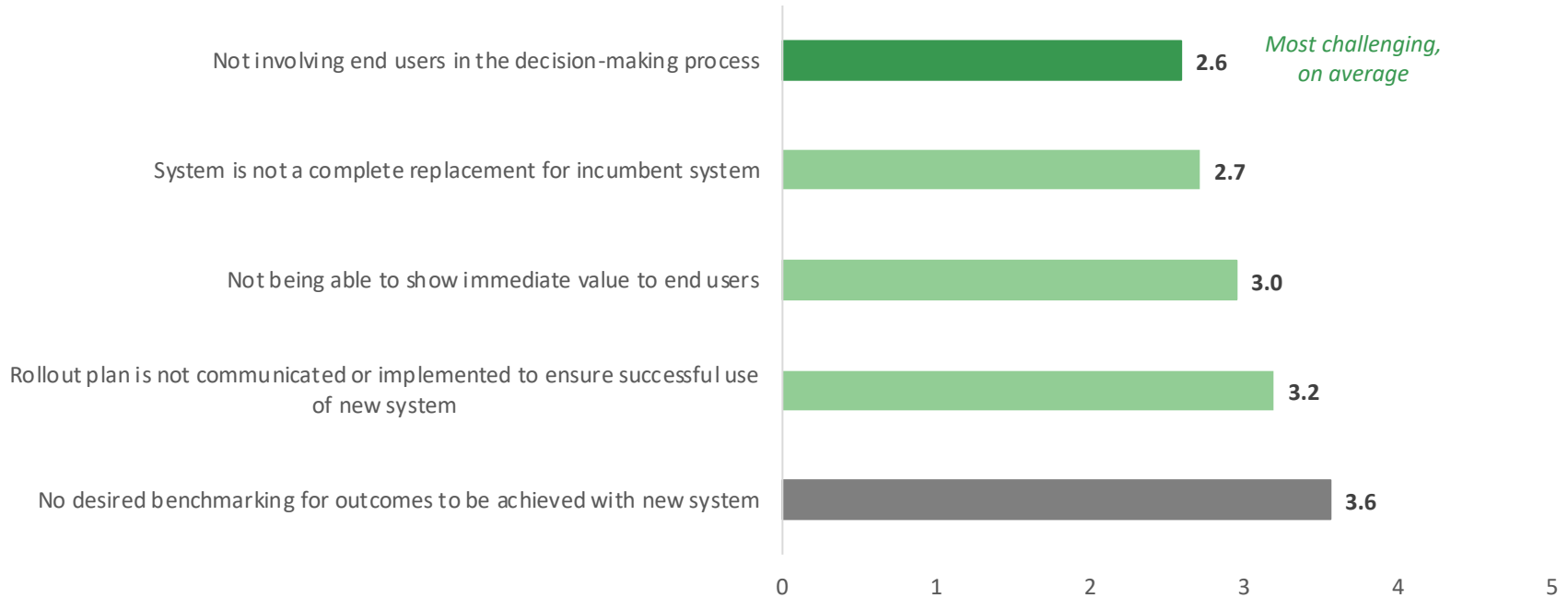


# Ranking of Challenges of Implementing New Clinical System

Please rank each of the following challenges faced when implementing a new clinical system where “1” is most challenging and “5” is least challenging. (n=262)

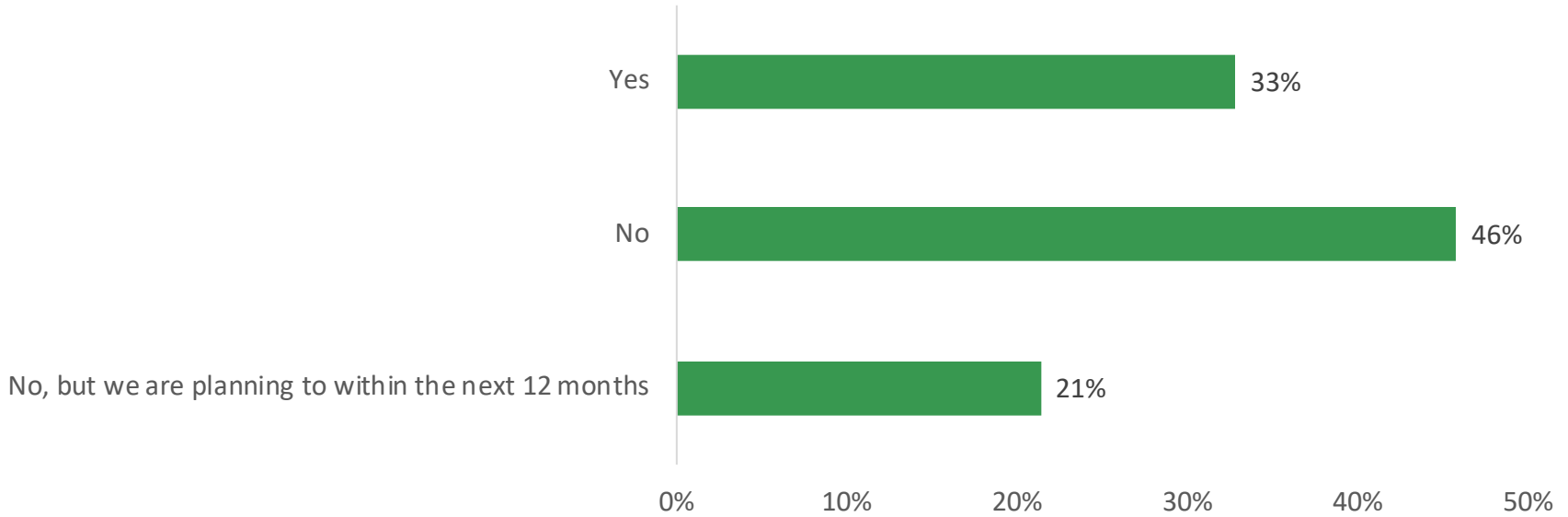


# Average Ranking: Challenges of Implementing New Clinical System



# Implemented Other Changes?

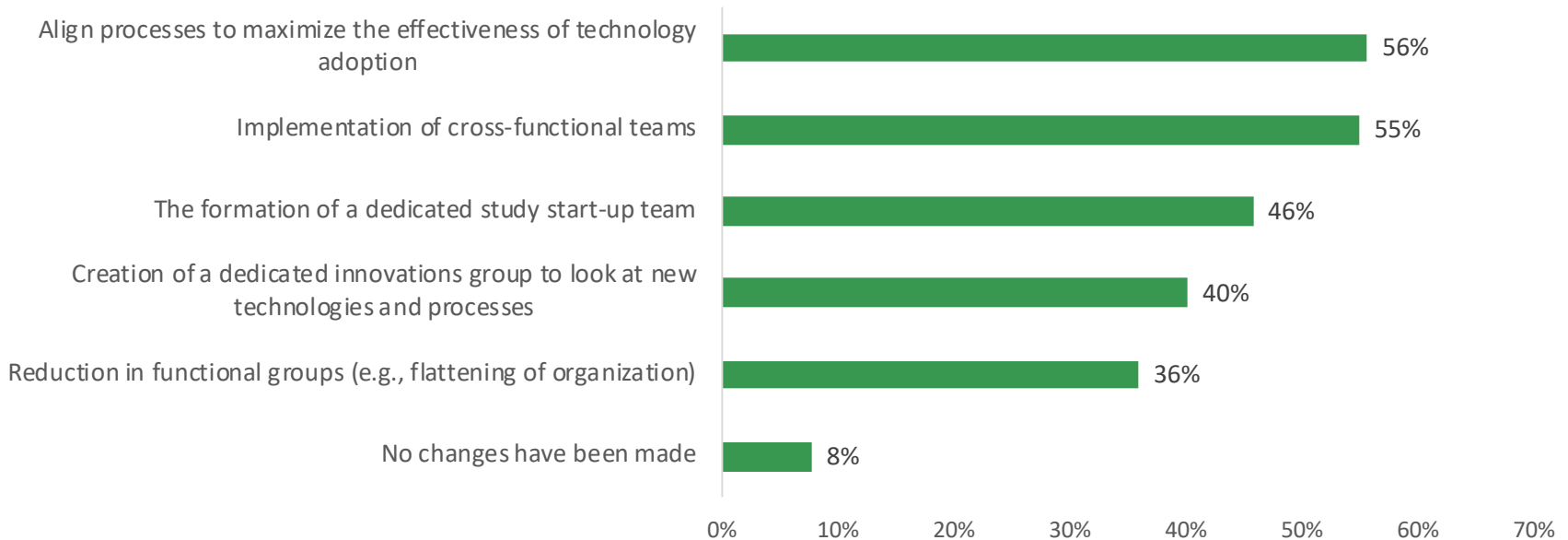
*Apart from the adoption of technology, has your organization implemented other changes (e.g., process changes, organizational structural changes) to address challenges in site collaboration? (n=262)*





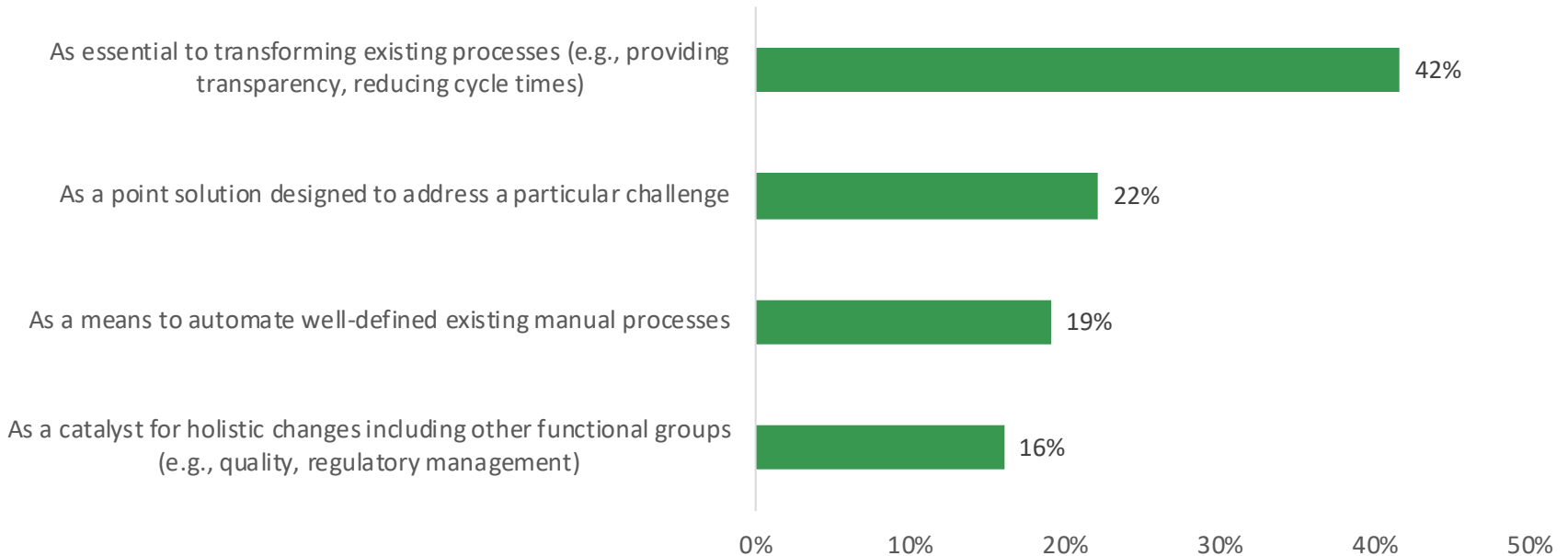
# Address Challenges of Site Collaboration

*Which of the following has/will your organization implement(ed) to address the challenges of site collaboration? Select all that apply. (only respondents who answered “yes” or “no, but we are planning to” regarding implementing other changes received this question, n=142)*



# View Technology Use

*How does your organization view technology use within site collaboration? Select one. (n=262)*





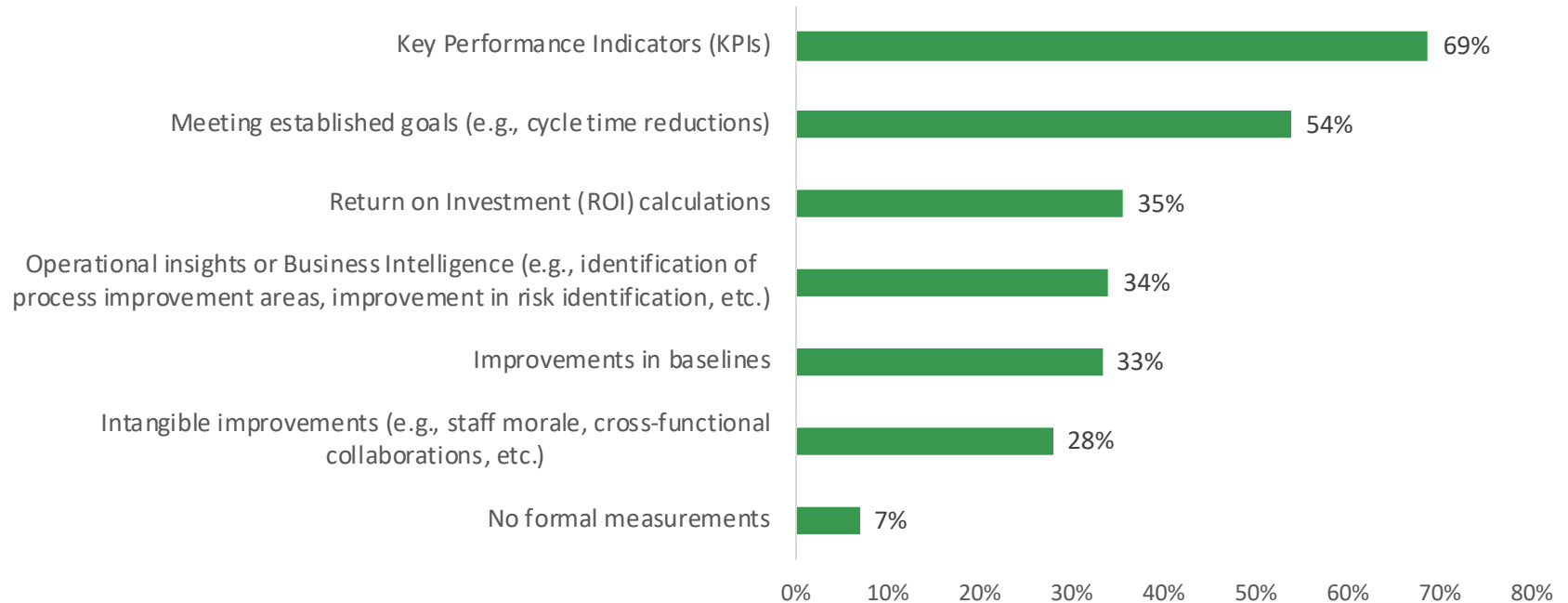
Smarter questions • Smarter answers

# EFFECTIVENESS OF STUDY STARTUP TECHNOLOGY IMPLEMENTATIONS



# Measure Effectiveness of Technology Projects

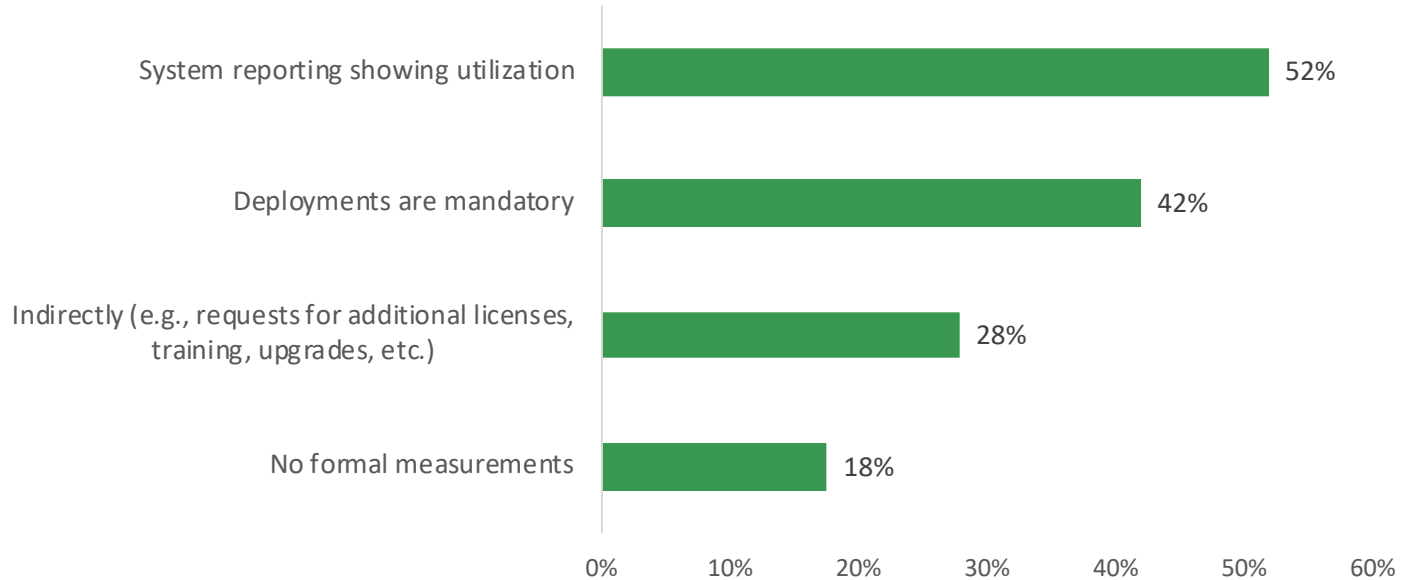
How does your organization measure the effectiveness of its technology projects? Select all that apply. (n=262)





# Measure Rate of Adoption of Technology Projects

*How does your organization measure the rate of adoption of its technology projects? Select all that apply. (n=262)*

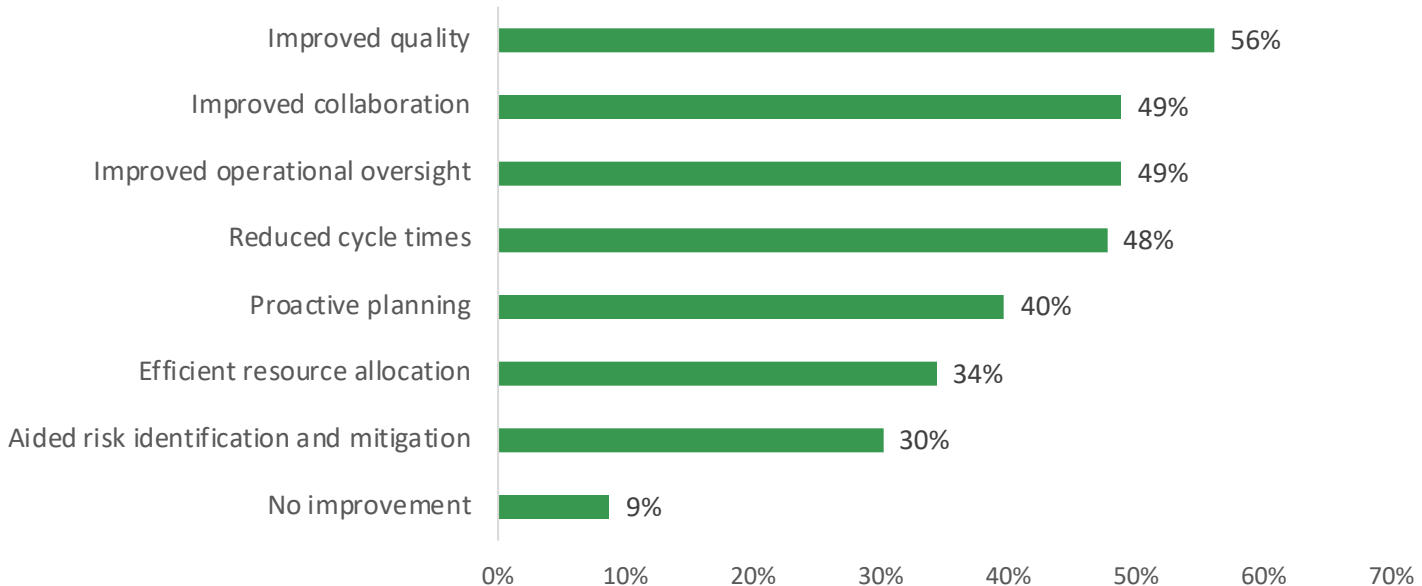






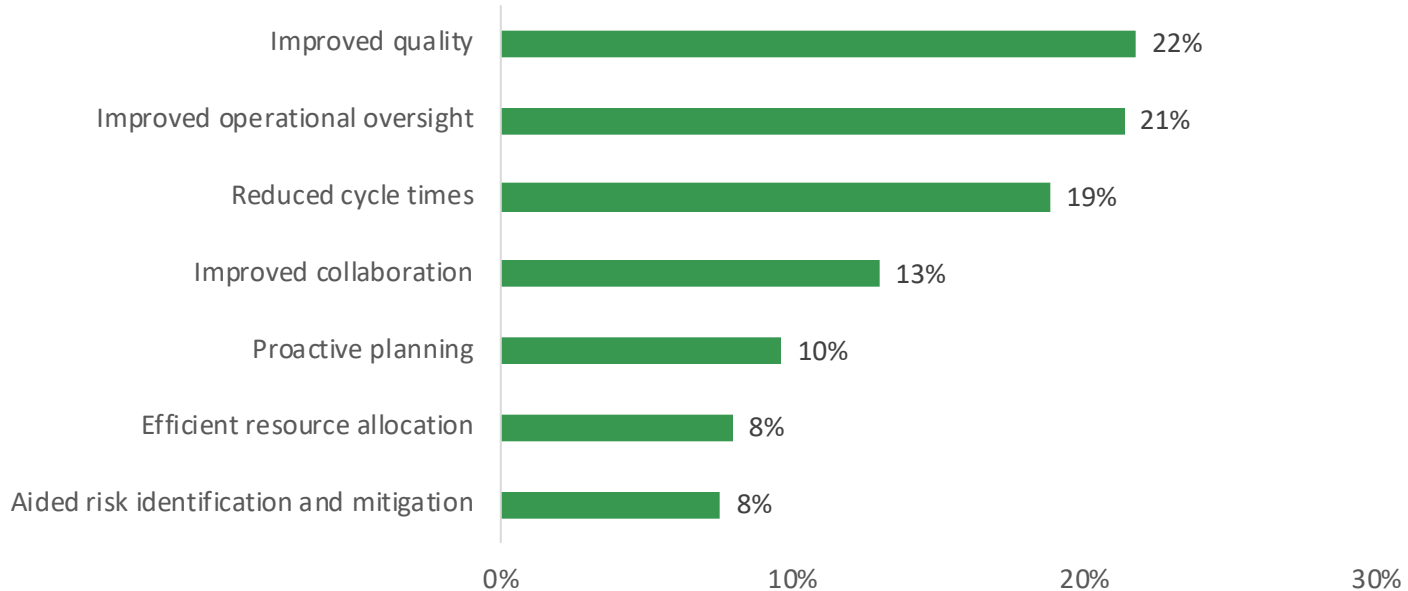
# Improvements as a Result of Technology Adoption

Which of the following have you witnessed as an improvement in site collaboration process as a result of technology adoption/implementation? Select all that apply. (n=262)



# Biggest Improvement

*Which one (1) of the following do you see as the biggest improvement in site collaboration process as a result of technology adoption/implementation? Select one. (only respondents who selected at least one improvement received this question, n=239)*



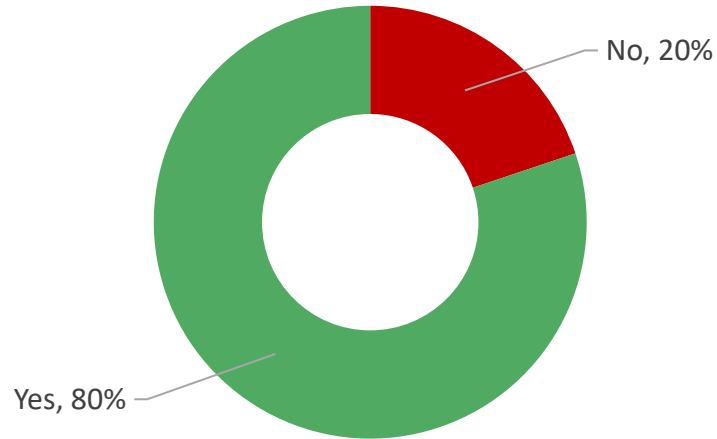


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# RESPONDENT CHARACTERISTICS

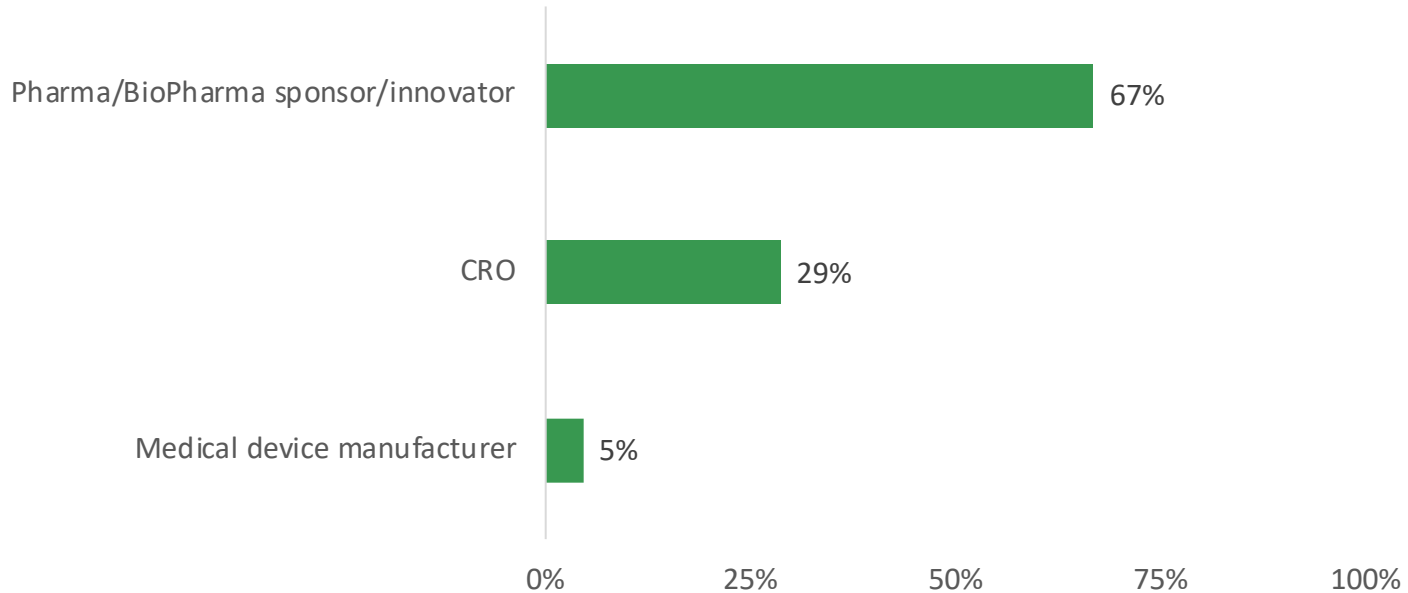
# Interactions with Investigative Sites

*Have you had recent interactions (within the past 18 months) with investigative sites regarding the contracting process or management of site contracts? (n=262)*



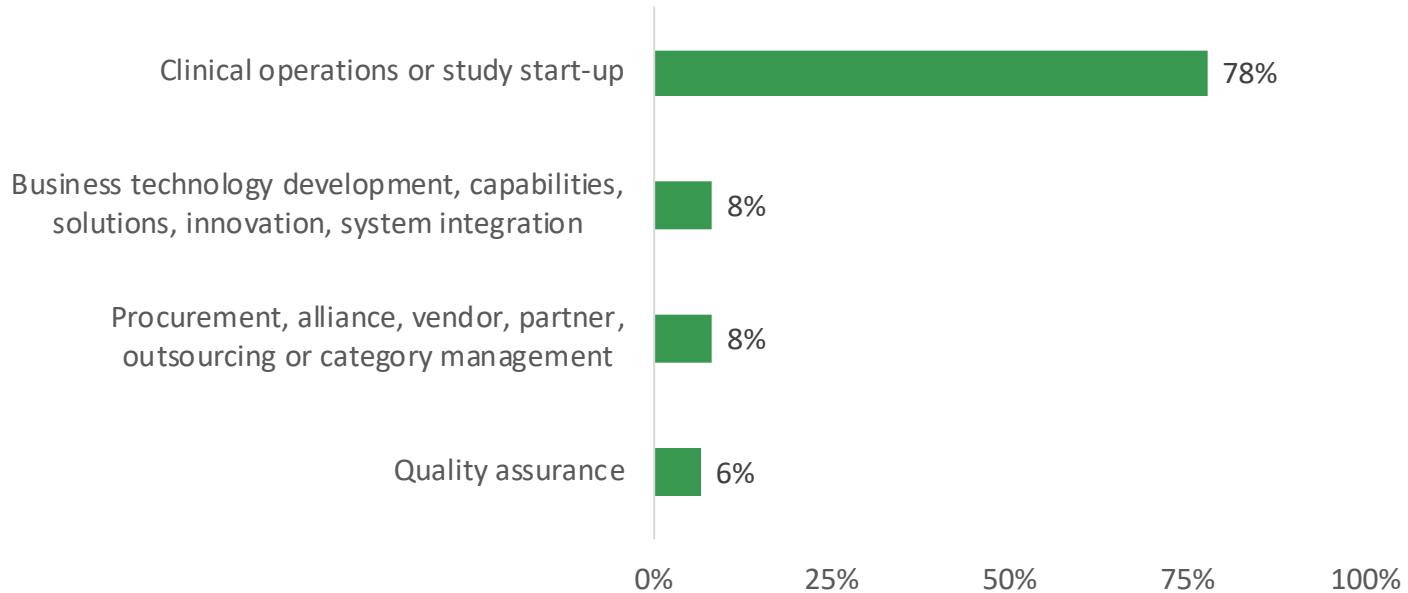
# Type of Organization

What type of organization do you currently work for? (n=262)



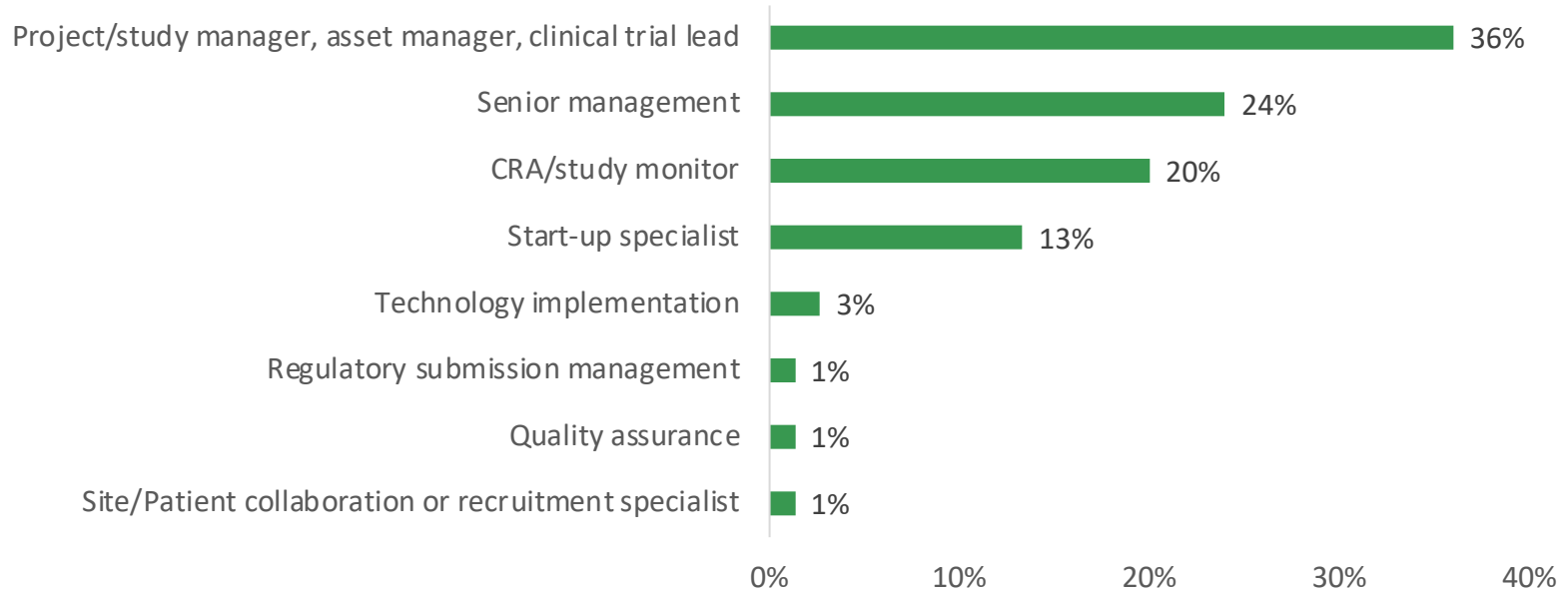
# Primary Role (Med or Sponsor)

What is your primary role at your organization? Select one. (only Med device or Sponsor companies received this question, n=187)



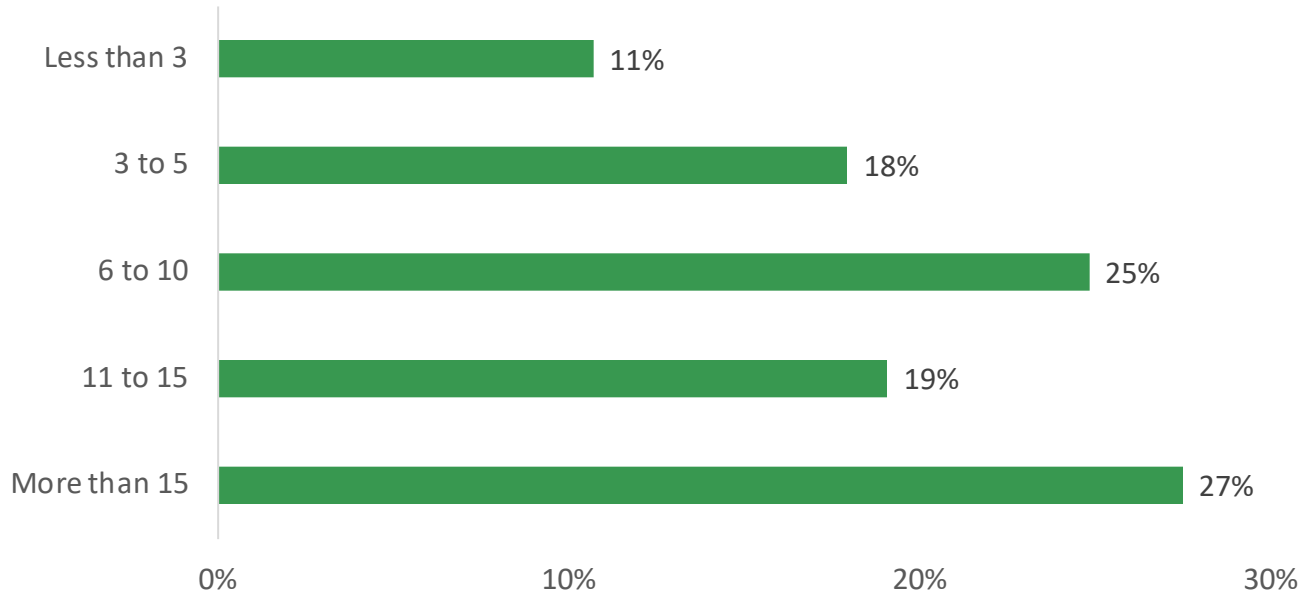
# Primary Role (CRO)

What is your primary role at your organization? Select one. (only CRO companies received this question, n=75)



# Years of Experience

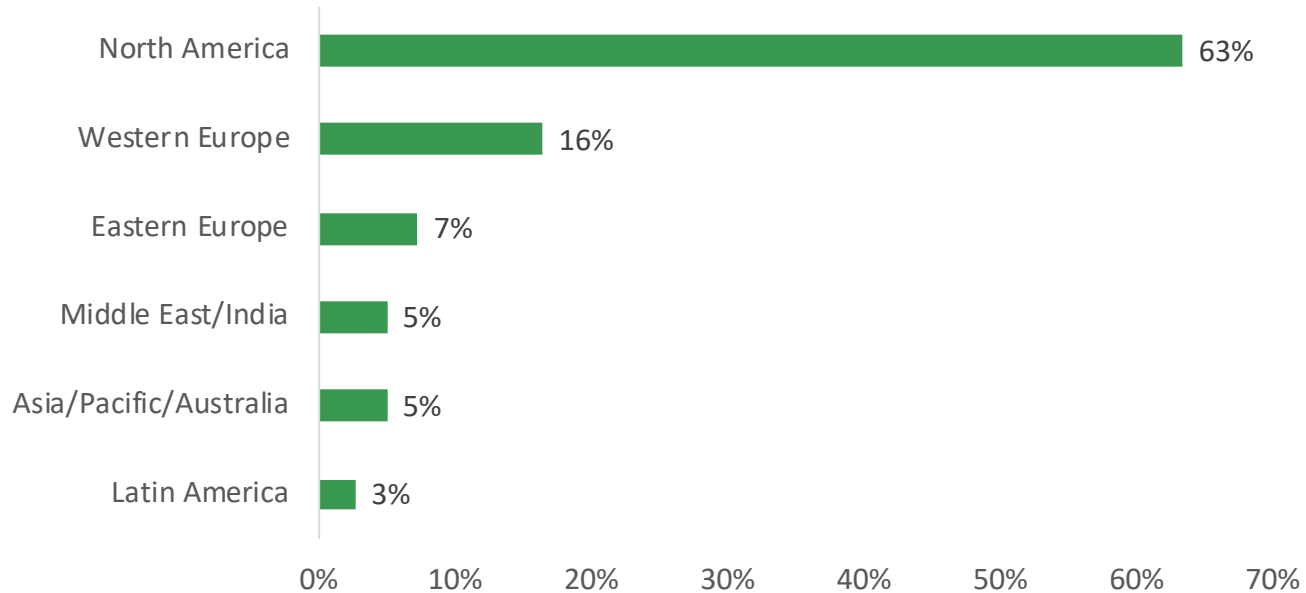
*How many years of experience do you have performing your current role? (n=262)*





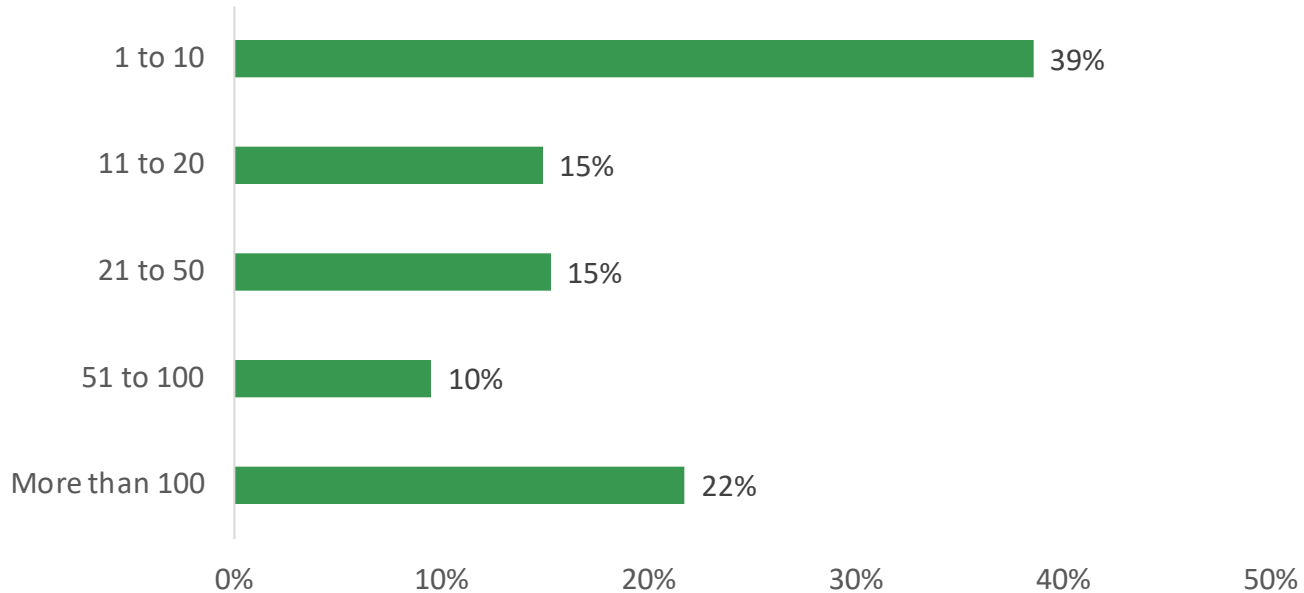
# Location (region)

Where are you located? (n=262)



# Number of Clinical Trials

*How many clinical trials (Phase II-IV) is your organization currently responsible for? If you work for a sponsor/manufacturer, this would include both in-house and outsourced clinical trials. (n=262)*



## INDUSTRY-LEADING SYNDICATED & CUSTOM **MARKET RESEARCH** WITH ACCESS TO...



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