eClinical Technology Adoption and Challenges in Study Startup

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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 <u>NOT</u> 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

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 then 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

Higher satisfaction correlated with clear business ownership

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

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[1] 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

View of technology use within site collaboration
- As essential to transforming existing processes — 42%
- As a point solution designed to address a particular change — 22%
- As a means to automate well-defined existing manual processes — 19%
- As a catalyst for holistic changes including other functional groups — 16%
- Other — 1%

Biggest improvement as a result of technology adoption
- Other listed responses — 25%
- Improved quality — 22%
- Improved operational oversight — 21%
- Reduced cycle times — 19%
- Improved collaboration — 13%

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

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)

Criteria	Percentage
Availability of suitable patient population	78%
Experience and qualifications of the investigator	69%
Track record of subject enrollment on similar trials	55%
Anticipated rate of patient accrual	48%
Prior relationship with the site	46%
Experience and qualifications of study coordinator and other staff	43%
Track record of start-up cycle times, on similar trials	38%
Geographic location (including international)	33%
Contractual and budgetary negotiations	31%
Availability of specialized diagnostic or therapeutic equipment	21%
Academic or "thought leader" credentials	20%
Managing timing of Institutional Review Board meetings	15%

Rank Top 5 Criteria for Site Selection/Identification

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (n=262)

Legend: Rank 1 | Rank 2 | Rank 3 | Rank 4 | Rank 5

Criteria	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5	Total
Availability of suitable patient population	34%	23%	15%	2%	4%	78%
Experience and qualifications of the investigator	23%	19%	11%	11%	7%	69%
Track record of subject enrollment on similar trials	10%	10%	13%	13%	8%	55%
Anticipated rate of patient accrual	9%	11%	10%	10%	9%	48%
Prior relationship with the site	7%	5%	8%	10%	16%	46%
Experience and qualifications of study coordinator and other staff	6%	7%	8%	13%	9%	43%
Track record of start-up cycle times, on similar trials	3%	7%	9%	8%	11%	38%
Geographic location (including international)	3%	6%	5%		10%	33%
Contractual and budgetary negotiations	2%	3%	7%		8%	31%
Availability of specialized diagnostic or therapeutic equipment	3%	2%	3%	6%	7%	21%
Academic or "thought leader" credentials	3%	4%	4%		8%	20%
Managing timing of Institutional Review Board meetings	2%	5%	3%		4%	15%

Average Ranking: Top 5 Criteria for Site Selection/Identification

Criteria	Average Ranking
Availability of suitable patient population	2.0
Experience and qualifications of the investigator	2.4
Anticipated rate of patient accrual	3.0
Track record of subject enrollment on similar trials	3.0
Experience and qualifications of study coordinator and other staff	3.3
Track record of start-up cycle times, on similar trials	3.5
Geographic location (including international)	3.5
Prior relationship with the site	3.5
Managing timing of Institutional Review Board meetings	3.5
Availability of specialized diagnostic or therapeutic equipment	3.5
Contractual and budgetary negotiations	3.6
Academic or "thought leader" credentials	3.7

Most important, on average

Criteria for Site Selection/ Identification (prevalence and ranking)

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

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (n=262)

Criteria	Percentage
Availability of suitable patient population (rank = 2.0)	78%
Experience and qualifications of the investigator (rank = 2.4)	69%
Anticipated rate of patient accrual (rank = 3.0)	48%
Experience and qualifications of study coordinator and other staff (rank = 3.3)	43%
Track record of subject enrollment on similar trials (rank = 3.5)	55%
Prior relationship with the site (rank = 3.5)	46%
Track record of start-up cycle times, on similar trials (rank = 3.5)	38%
Geographic location (including international) (rank = 3.5)	33%
Availability of specialized diagnostic or therapeutic equipment (rank = 3.5)	21%
Managing timing of Institutional Review Board meetings (rank = 3.5)	15%
Contractual and budgetary negotiations (rank = 3.6)	31%
Academic or "thought leader" credentials (rank = 3.7)	20%

Sponsors: Rank Top 5 Criteria for Site Selection/Identification

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (sponsors only)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Criteria	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Availability of suitable patient population (n=144)	43%	31%	19%	3%	4%
Experience and qualifications of the investigator (n=129)	29%	30%	16%	13%	12%
Track record of start-up cycle times, on similar trials (n=66)	21%	18%	24%	25%	14%
Anticipated rate of patient accrual (n=89)	18%	21%	21%	21%	18%
Experience and qualifications of study coordinator and other staff (n=82)	17%	15%	20%	27%	22%
Prior relationship with the site (n=84)	14%	11%	19%	20%	36%
Track record of subject enrollment on similar trials (n=102)	11%	21%	20%	21%	27%
Geographic location (including international) (n=66)	11%	15%	15%	32%	27%
Availability of specialized diagnostic or therapeutic equipment (n=41)	10%	12%	17%	34%	27%
Contractual and budgetary negotiations (n=58)	5%	12%	22%	33%	28%
Academic or "thought leader" credentials (n=44)	5%	16%	20%	20%	39%
Managing timing of Institutional Review Board meetings (n=27)	4%	7%	41%	22%	26%

Sponsors: Rank Top 5 Criteria for Site Selection/Identification (prevalence and ranking)

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (sponsors only)

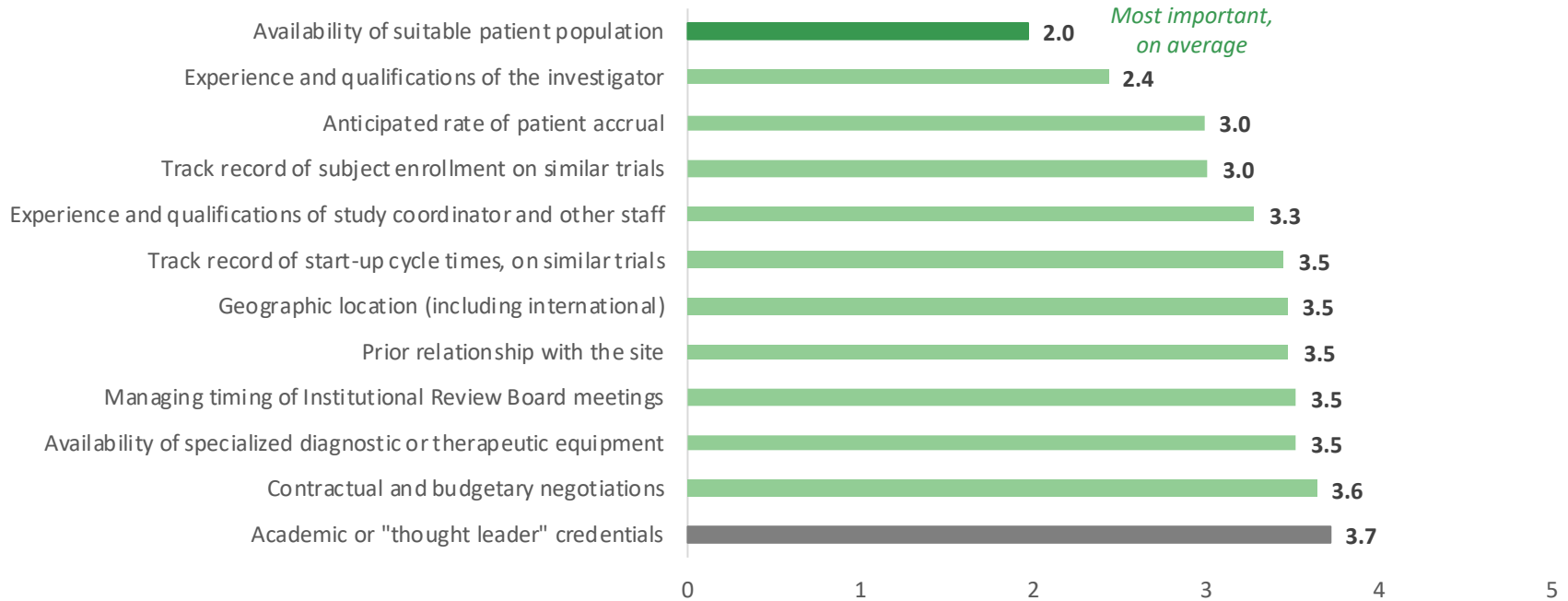| Criteria	Percentage
Availability of suitable patient population (rank =1.9)	77%
Experience and qualifications of the investigator (rank =2.5)	69%
Track record of start-up cycle times, on similar trials (rank =3.0)	35%
Anticipated rate of patient accrual (rank =3.0)	48%
Experience and qualifications of study coordinator and other staff (rank =3.3)	44%
Track record of subject enrollment on similar trials (rank =3.3)	55%
Prior relationship with the site (rank =3.5)	45%
Geographic location (including international) (rank =3.5)	35%
Availability of specialized diagnostic or therapeutic equipment (rank =3.6)	22%
Managing timing of Institutional Review Board meetings (rank =3.6)	14%
Contractual and budgetary negotiations (rank =3.7)	31%
Academic or "thought leader" credentials (rank =3.7)	24%

CROs: Rank Top 5 Criteria for Site Selection/Identification

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (CROs only)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Criteria	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Availability of suitable patient population (n=61)	43%	28%	20%	3%	7%
Experience and qualifications of the investigator (n=53)	42%	19%	13%	21%	6%
Availability of specialized diagnostic or therapeutic equipment (n=15)	27%	7%	13%	7%	47%
Anticipated rate of patient accrual (n=38)	18%	24%	18%		18%
Prior relationship with the site (n=36)	17%	14%	17%		31%
Track record of subject enrollment on similar trials (n=41)	12%	20%	24%	24%	20%
Geographic location (including international) (n=21)	10%	24%	19%	14%	33%
Contractual and budgetary negotiations (n=23)	9%	9%	22%	35%	26%
Experience and qualifications of study coordinator and other staff (n=31)	3%	23%	19%	35%	19%
Track record of start-up cycle times, on similar trials (n=34)		15%	32%	24%	29%
Academic or "thought leader" credentials (n=9)		22%	22%	22%	32%
Managing timing of Institutional Review Board meetings (n=13)		31%	23%	23%	23%

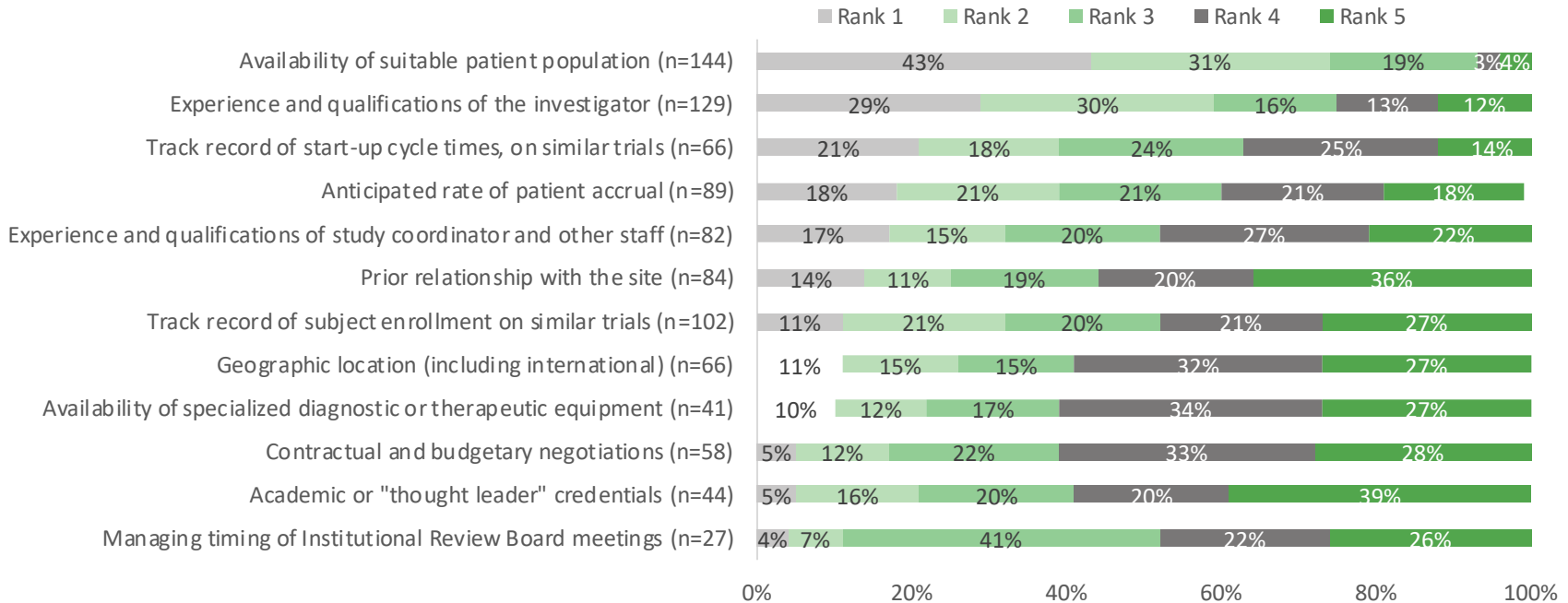**CROs**: Rank Top 5 Criteria for Site Selection/Identification (prevalence and ranking)
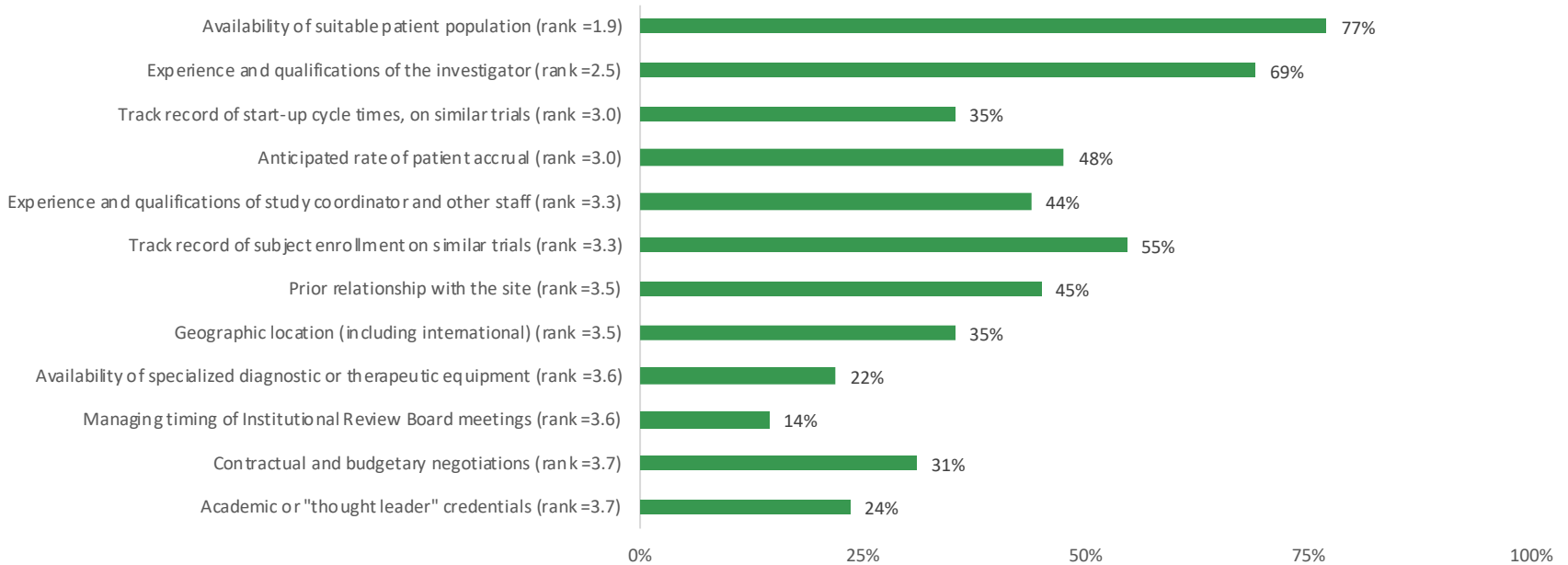
Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (CROs only)

Criteria	Percentage
Availability of suitable patient population (rank=2.1)	81%
Experience and qualifications of the investigator (rank=2.3)	71%
Anticipated rate of patient accrual (rank=2.9)	51%
Track record of subject enrollment on similar trials (rank=3.2)	55%
Availability of specialized diagnostic or therapeutic equipment (rank=3.4)	20%
Prior relationship with the site (rank=3.4)	48%
Geographic location (including international) (rank=3.4)	28%
Experience and qualifications of study coordinator and other staff (rank=3.4)	41%
Managing timing of Institutional Review Board meetings (rank=3.4)	17%
Contractual and budgetary negotiations (rank=3.6)	31%
Academic or "thought leader" credentials (rank=3.6)	12%
Track record of start-up cycle times, on similar trials (rank=3.7)	45%

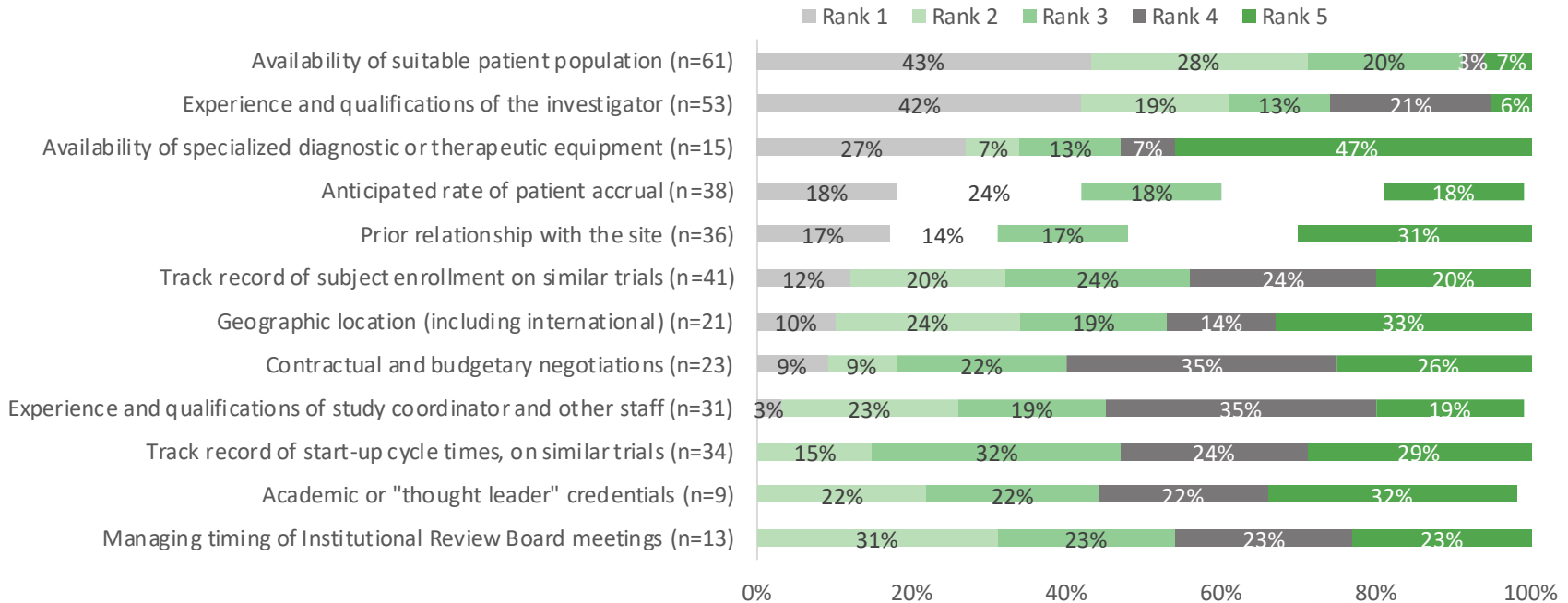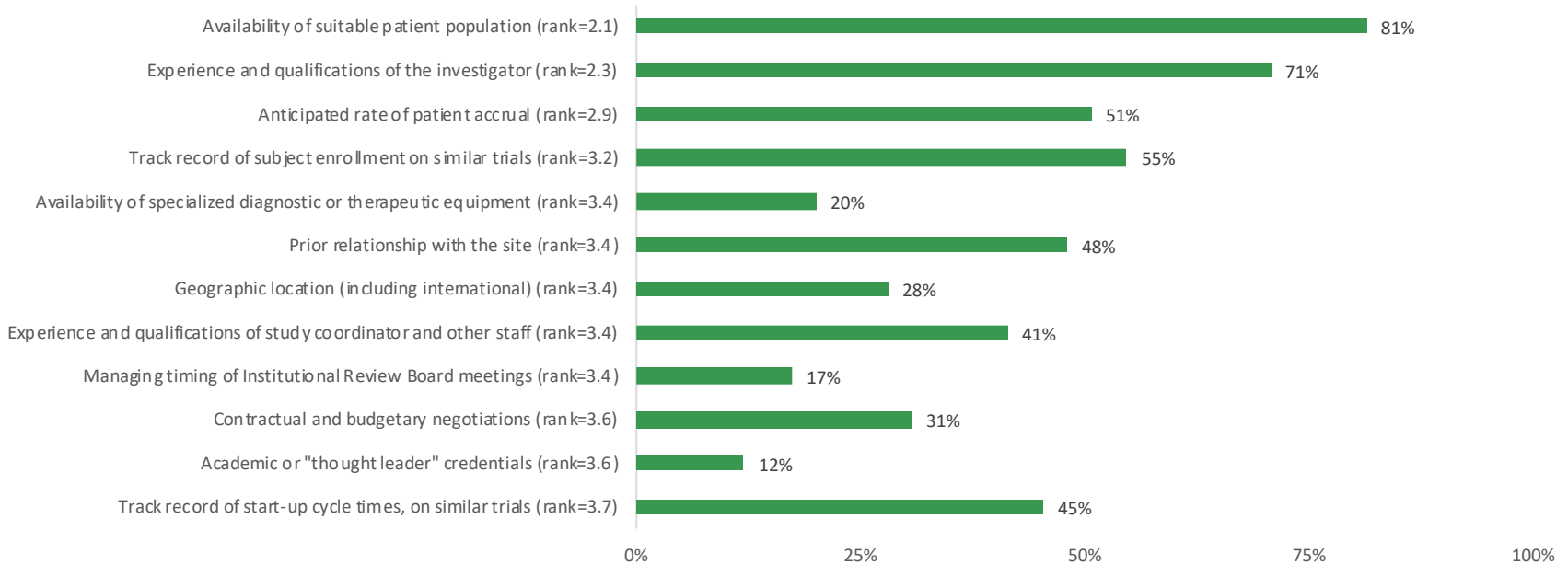# 1-10 Trials: Rank Top 5 Criteria for Site Selection/Identification

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (smaller companies with 1-10 trials only)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Criteria	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Availability of suitable patient population (n=79)	43%	30%	18%	4%	5%
Experience and qualifications of the investigator (n=68)	34%	29%	16%	9%	12%
Anticipated rate of patient accrual (n=54)	22%	22%	15%	20%	20%
Track record of subject enrollment on similar trials (n=54)	17%	20%	20%	30%	13%
Prior relationship with the site (n=42)	14%	5%	24%	19%	38%
Experience and qualifications of study coordinator and other staff (n=52)	13%	21%	21%	29%	15%
Availability of specialized diagnostic or therapeutic equipment (n=21)	10%	24%		33%	33%
Geographic location (including international) (n=39)		21%	21%	21%	31%
Contractual and budgetary negotiations (n=28)		11%	25%	36%	21%
Track record of start-up cycle times, on similar trials (n=36)	6%	17%	25%	25%	28%
Academic or "thought leader" credentials (n=18)	6%	17%	17%	22%	39%
Managing timing of Institutional Review Board meetings (n=13)	8%	31%		31%	31%

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (smaller companies with 1-10 trials only)

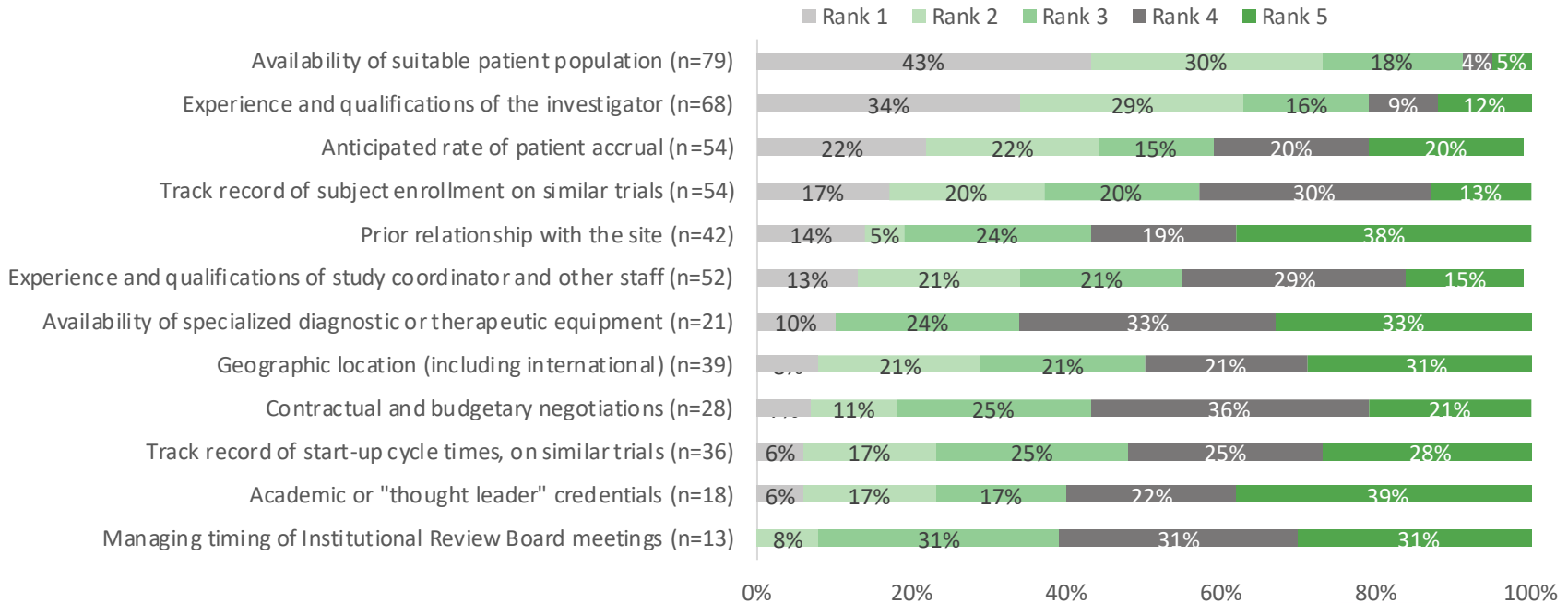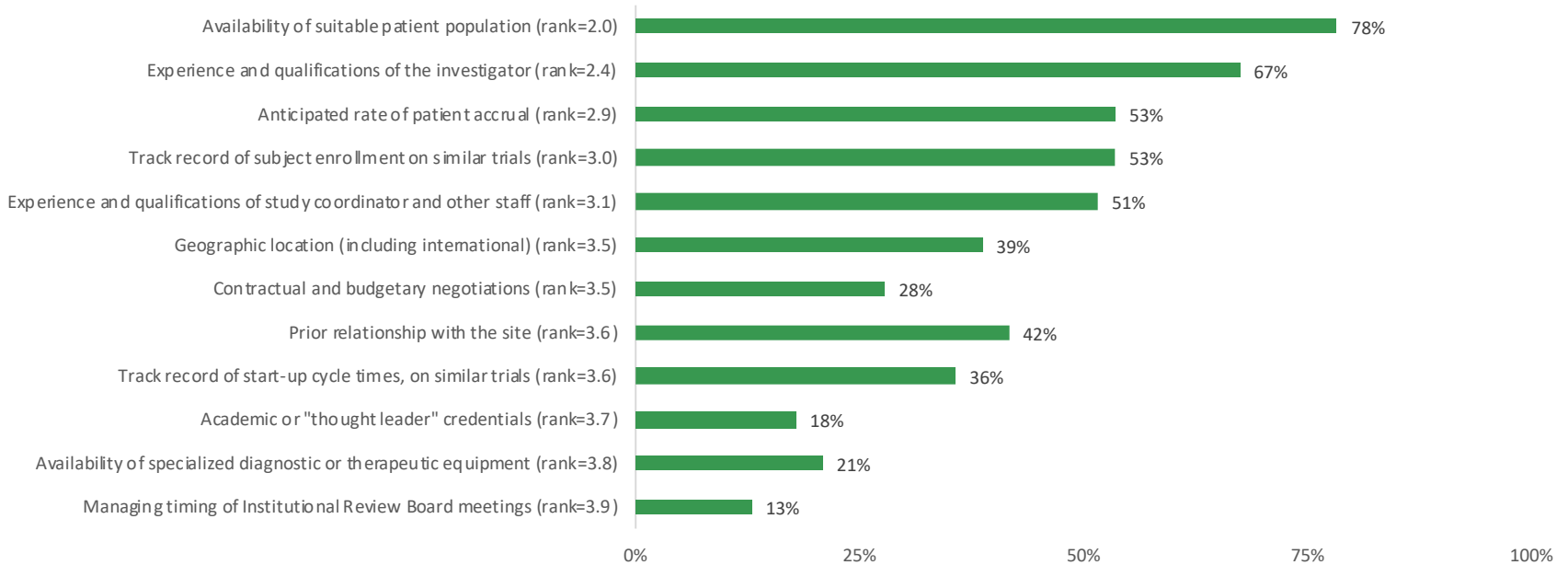| Criteria	Percentage
Availability of suitable patient population (rank=2.0)	78%
Experience and qualifications of the investigator (rank=2.4)	67%
Anticipated rate of patient accrual (rank=2.9)	53%
Track record of subject enrollment on similar trials (rank=3.0)	53%
Experience and qualifications of study coordinator and other staff (rank=3.1)	51%
Geographic location (including international) (rank=3.5)	39%
Contractual and budgetary negotiations (rank=3.5)	28%
Prior relationship with the site (rank=3.6)	42%
Track record of start-up cycle times, on similar trials (rank=3.6)	36%
Academic or "thought leader" credentials (rank=3.7)	18%
Availability of specialized diagnostic or therapeutic equipment (rank=3.8)	21%
Managing timing of Institutional Review Board meetings (rank=3.9)	13%

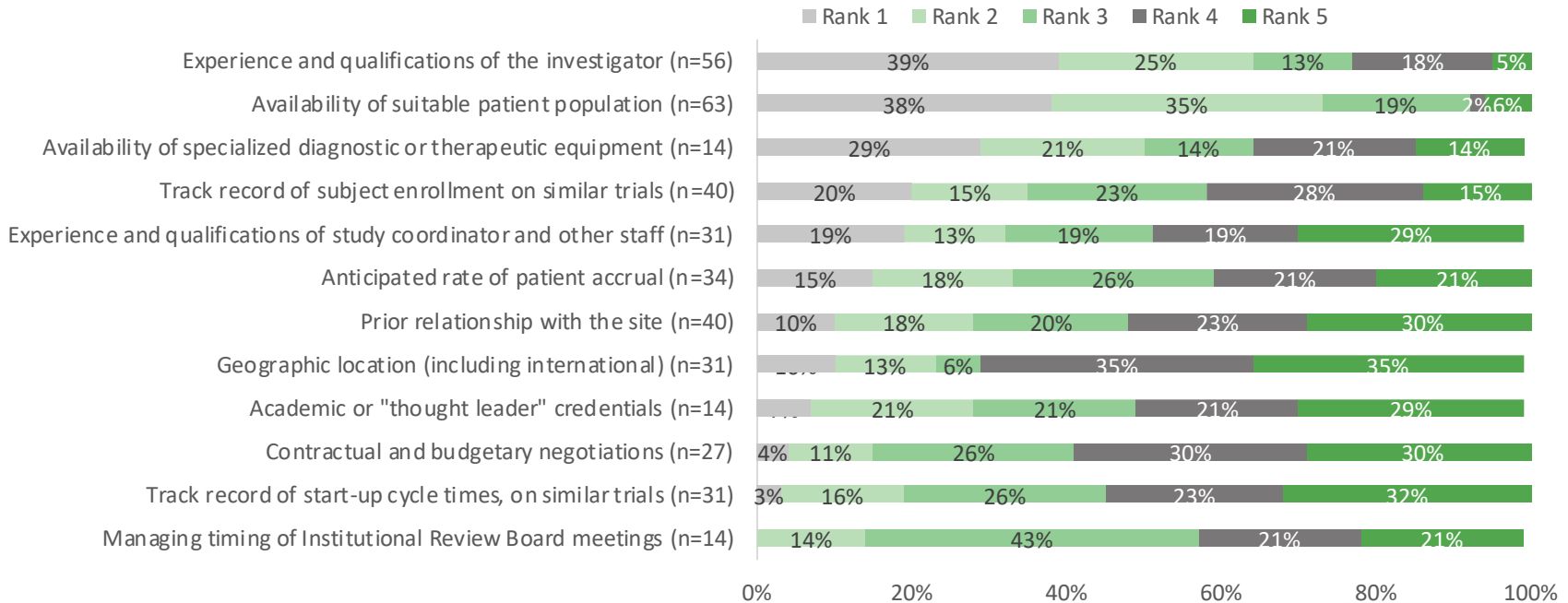# 11-50 Trials: Rank Top 5 Criteria for Site Selection/Identification

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (mid-size companies with 11-50 trials only)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Criteria	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Experience and qualifications of the investigator (n=56)	39%	25%	13%	18%	5%
Availability of suitable patient population (n=63)	38%	35%	19%	2%	6%
Availability of specialized diagnostic or therapeutic equipment (n=14)	29%	21%	14%	21%	14%
Track record of subject enrollment on similar trials (n=40)	20%	15%	23%	28%	15%
Experience and qualifications of study coordinator and other staff (n=31)	19%	13%	19%	19%	29%
Anticipated rate of patient accrual (n=34)	15%	18%	26%	21%	21%
Prior relationship with the site (n=40)	10%	18%	20%	23%	30%
Geographic location (including international) (n=31)		13%	6%	35%	35%
Academic or "thought leader" credentials (n=14)		21%	21%	21%	29%
Contractual and budgetary negotiations (n=27)	4%	11%	26%	30%	30%
Track record of start-up cycle times, on similar trials (n=31)	3%	16%	26%	23%	32%
Managing timing of Institutional Review Board meetings (n=14)		14%	43%	21%	21%

11-50 Trials: Rank Top 5 Criteria for Site Selection/Identification (prevalence and ranking)
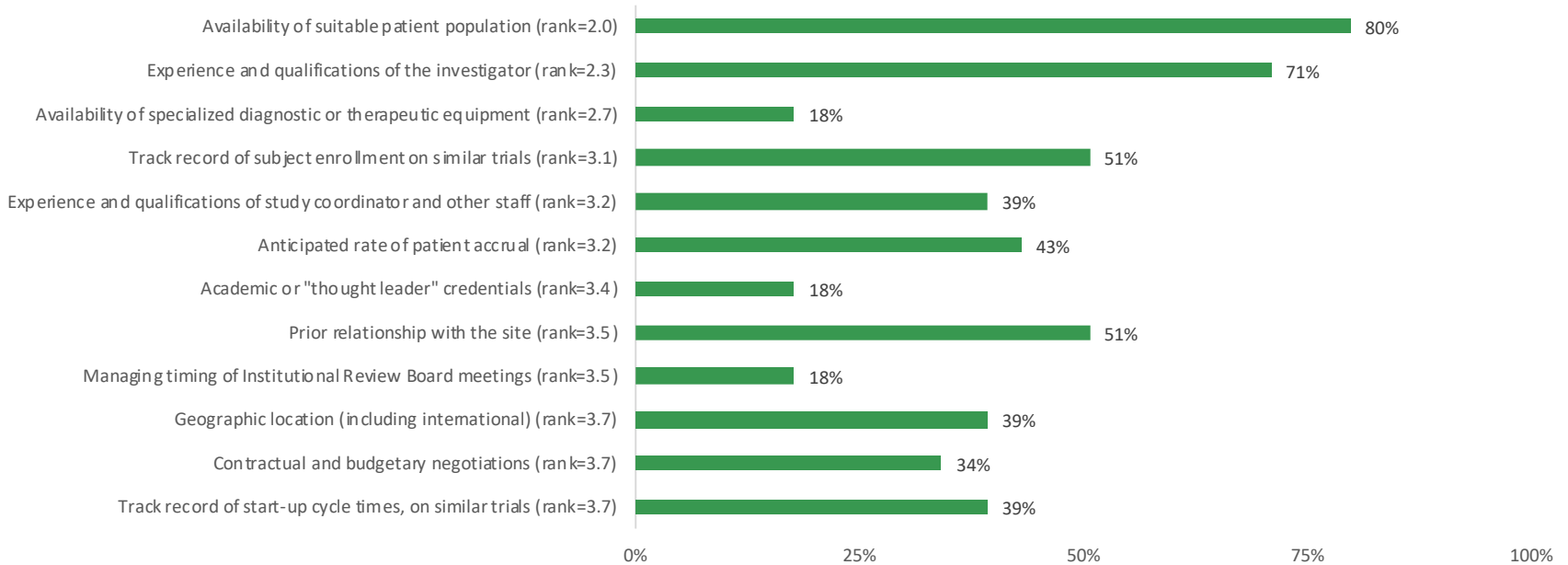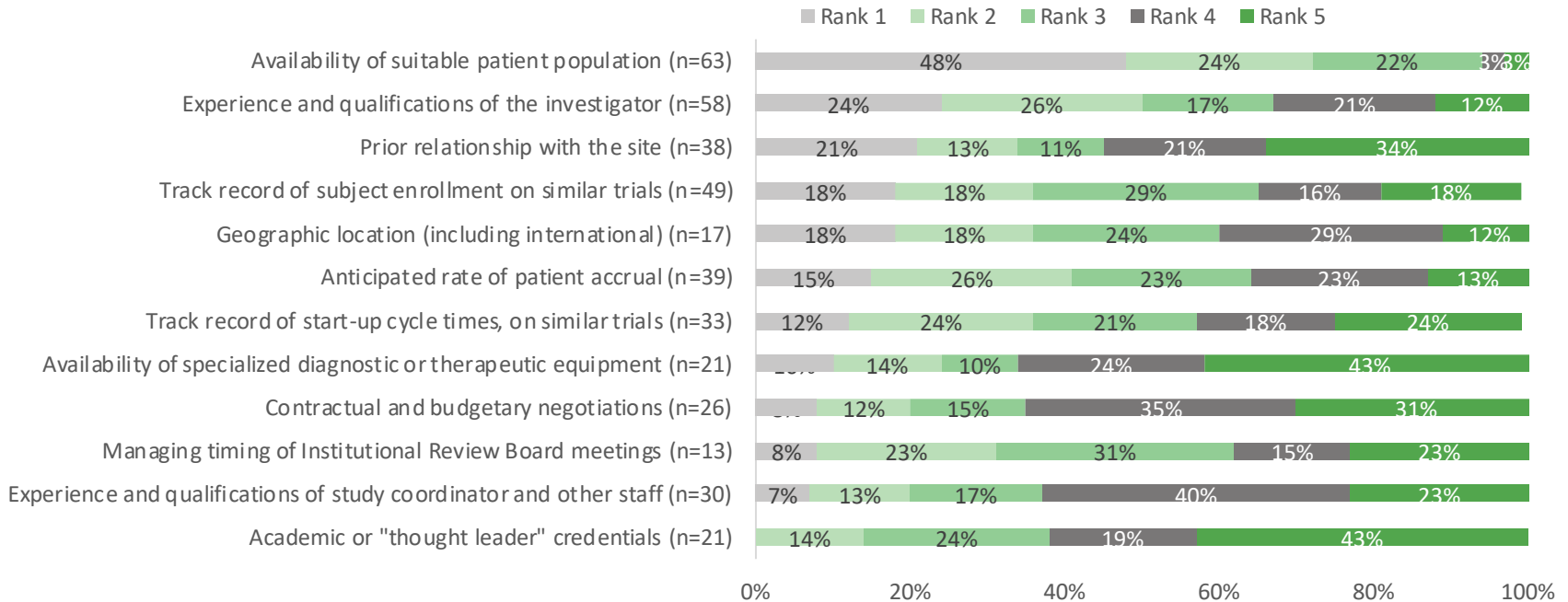
Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (mid-size companies with 11-50 trials only)

Criteria	Percentage
Availability of suitable patient population (rank=2.0)	80%
Experience and qualifications of the investigator (rank=2.3)	71%
Availability of specialized diagnostic or therapeutic equipment (rank=2.7)	18%
Track record of subject enrollment on similar trials (rank=3.1)	51%
Experience and qualifications of study coordinator and other staff (rank=3.2)	39%
Anticipated rate of patient accrual (rank=3.2)	43%
Academic or "thought leader" credentials (rank=3.4)	18%
Prior relationship with the site (rank=3.5)	51%
Managing timing of Institutional Review Board meetings (rank=3.5)	18%
Geographic location (including international) (rank=3.7)	39%
Contractual and budgetary negotiations (rank=3.7)	34%
Track record of start-up cycle times, on similar trials (rank=3.7)	39%

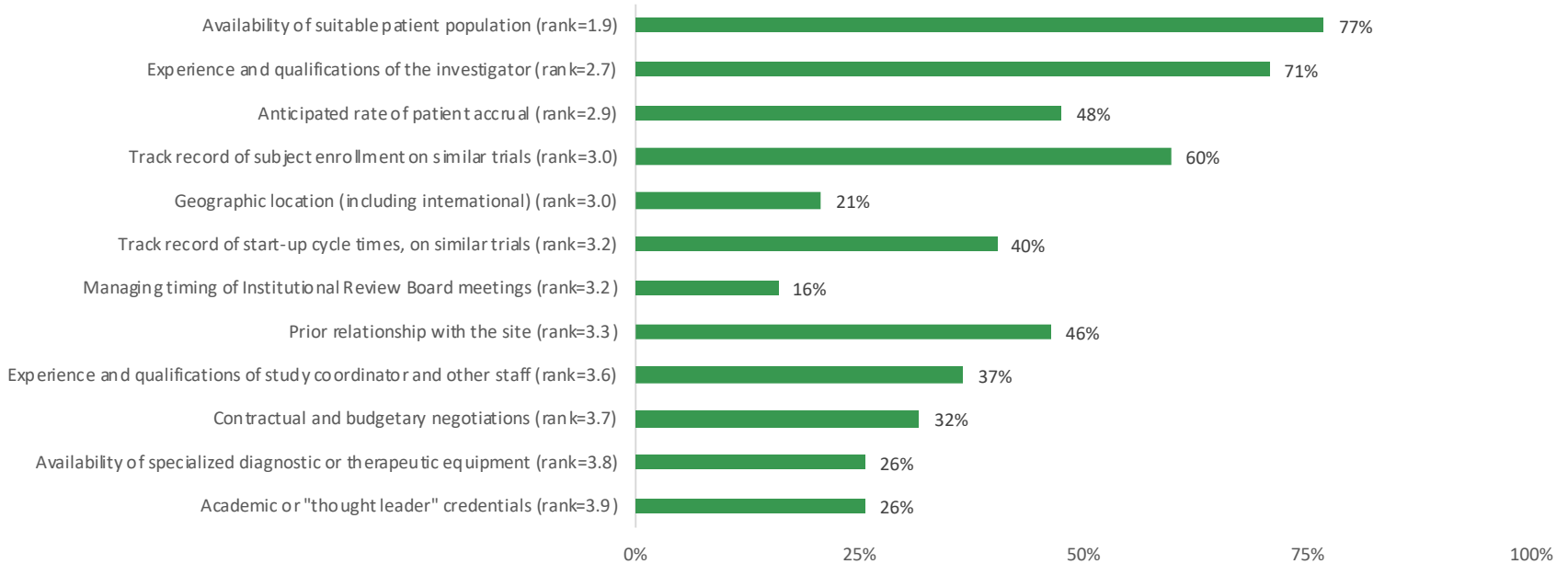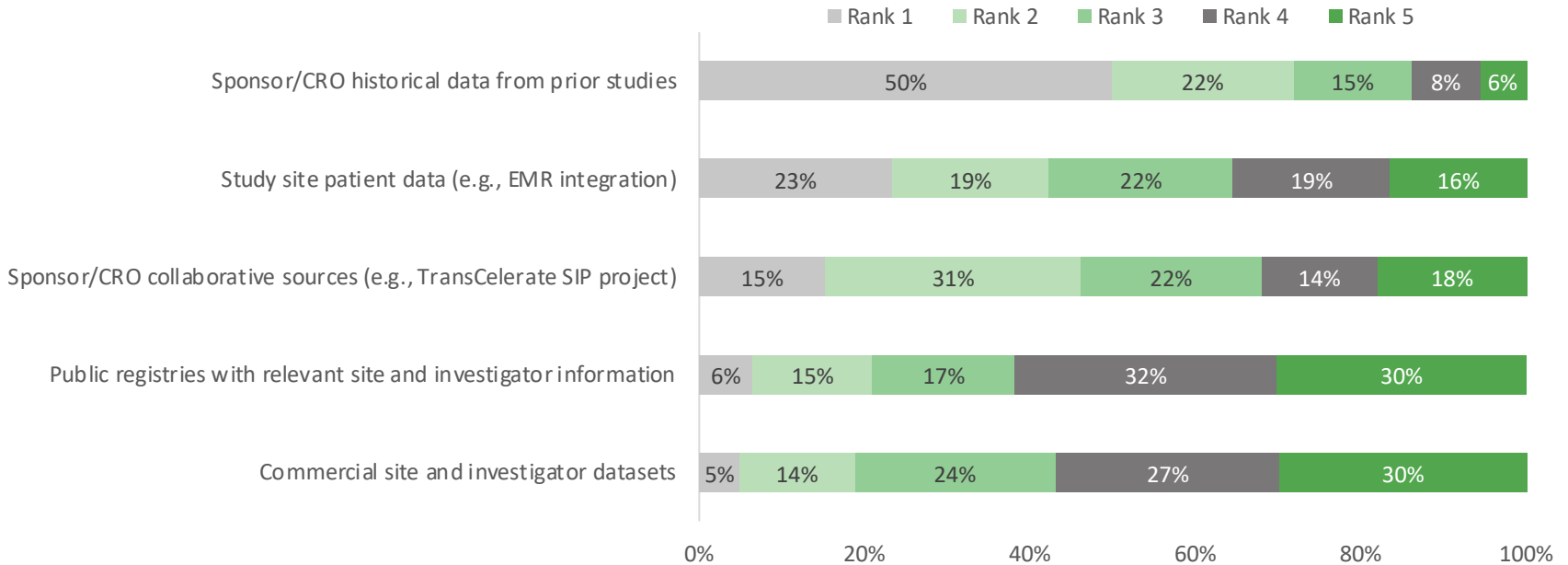# >50 Trials: Rank Top 5 Criteria for Site Selection/Identification

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (large companies with >50 trials only)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Criteria	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Availability of suitable patient population (n=63)	48%	24%	22%	3%	3%
Experience and qualifications of the investigator (n=58)	24%	26%	17%	21%	12%
Prior relationship with the site (n=38)	21%	13%	11%	21%	34%
Track record of subject enrollment on similar trials (n=49)	18%	18%	29%	16%	18%
Geographic location (including international) (n=17)	18%	18%	24%	29%	12%
Anticipated rate of patient accrual (n=39)	15%	26%	23%	23%	13%
Track record of start-up cycle times, on similar trials (n=33)	12%	24%	21%	18%	24%
Availability of specialized diagnostic or therapeutic equipment (n=21)		14%	10%	24%	43%
Contractual and budgetary negotiations (n=26)		12%	15%	35%	31%
Managing timing of Institutional Review Board meetings (n=13)	8%	23%	31%	15%	23%
Experience and qualifications of study coordinator and other staff (n=30)	7%	13%	17%	40%	23%
Academic or "thought leader" credentials (n=21)		14%	24%	19%	43%

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

Now, please rank the following options in order of importance for site selection/identification where "1" is most important and "5" is least important. (large companies with >50 trials only)

Criteria	Percentage
Availability of suitable patient population (rank=1.9)	77%
Experience and qualifications of the investigator (rank=2.7)	71%
Anticipated rate of patient accrual (rank=2.9)	48%
Track record of subject enrollment on similar trials (rank=3.0)	60%
Geographic location (including international) (rank=3.0)	21%
Track record of start-up cycle times, on similar trials (rank=3.2)	40%
Managing timing of Institutional Review Board meetings (rank=3.2)	16%
Prior relationship with the site (rank=3.3)	46%
Experience and qualifications of study coordinator and other staff (rank=3.6)	37%
Contractual and budgetary negotiations (rank=3.7)	32%
Availability of specialized diagnostic or therapeutic equipment (rank=3.8)	26%
Academic or "thought leader" credentials (rank=3.9)	26%

Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (n=262)
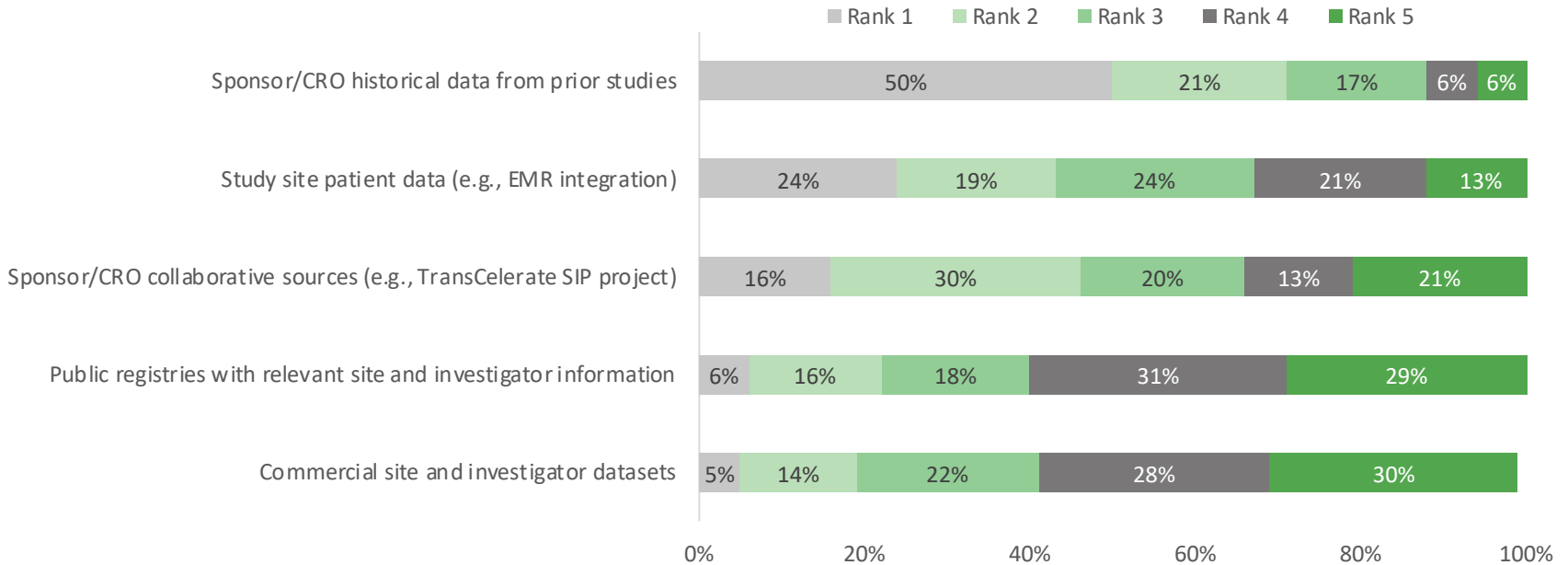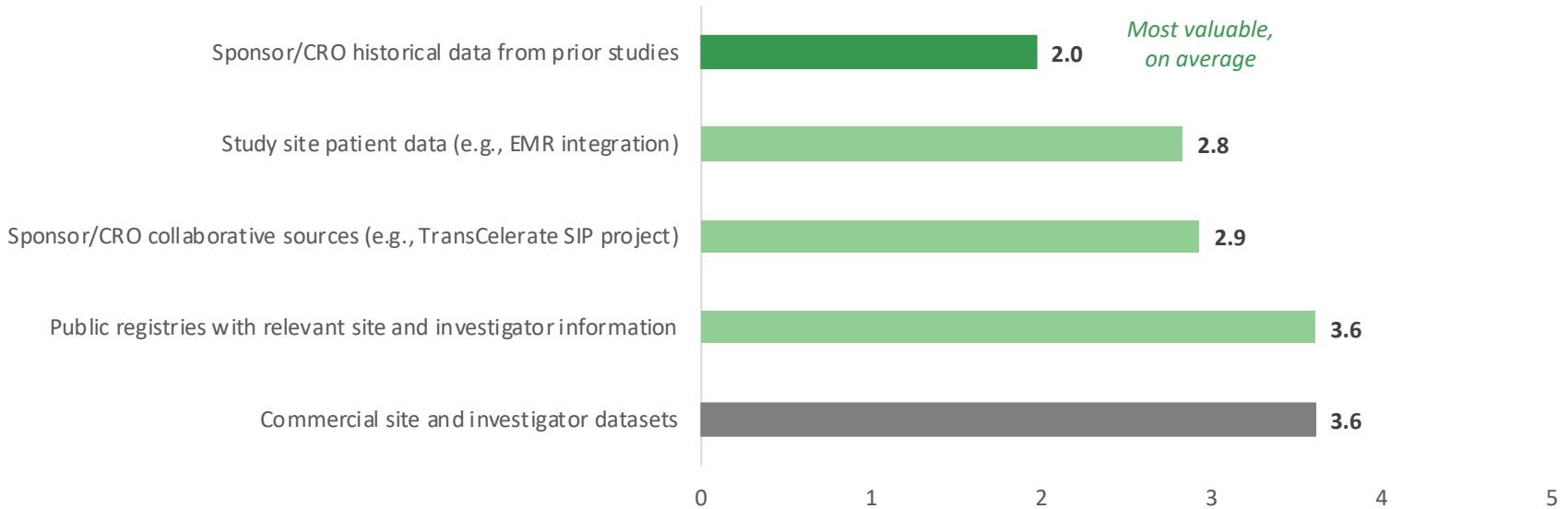
Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

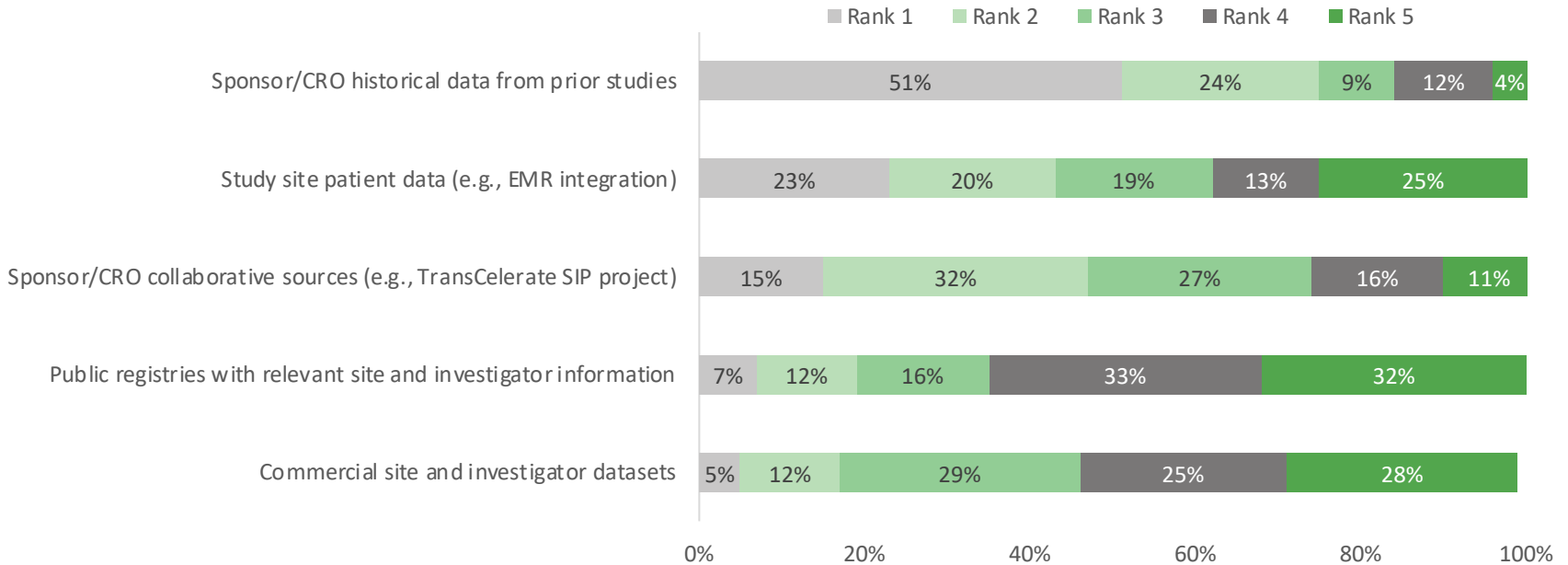| Data Source	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Sponsor/CRO historical data from prior studies	50%	22%	15%	8%	6%
Study site patient data (e.g., EMR integration)	23%	19%	22%	19%	16%
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	15%	31%	22%	14%	18%
Public registries with relevant site and investigator information	6%	15%	17%	32%	30%
Commercial site and investigator datasets	5%	14%	24%	27%	30%

Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (n=262)

Data Source	Average Rank
Sponsor/CRO historical data from prior studies	2.0 *(Most valuable, on average)*
Study site patient data (e.g., EMR integration)	2.9
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	2.9
Public registries with relevant site and investigator information	3.6
Commercial site and investigator datasets	3.6

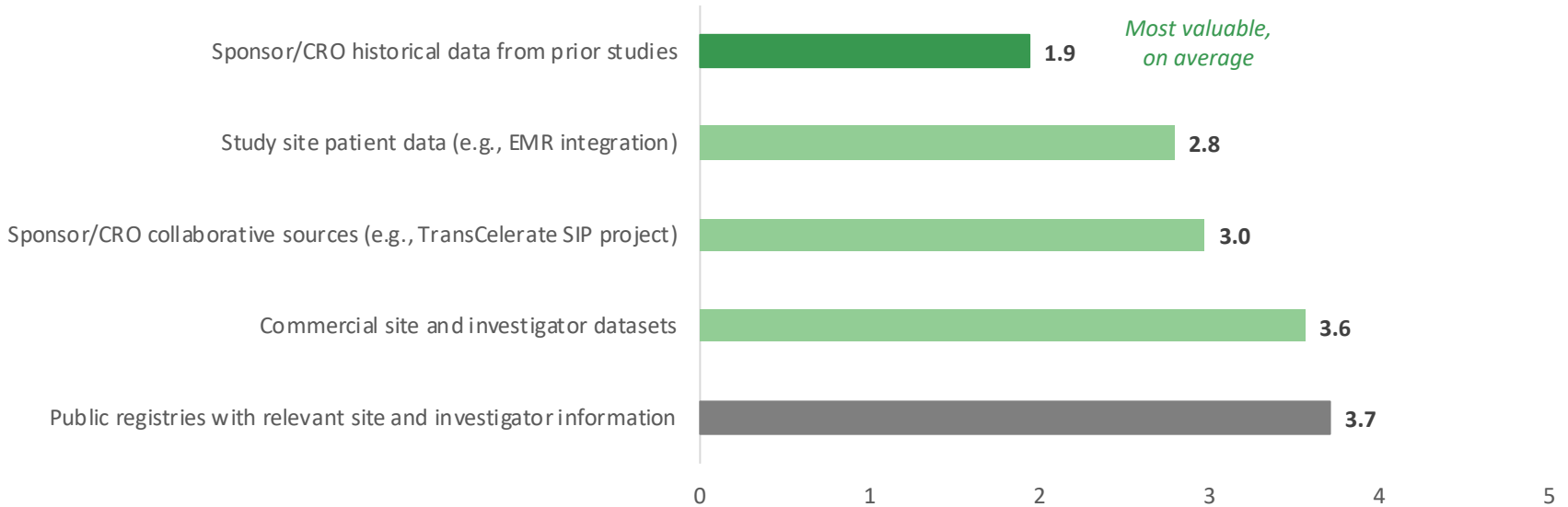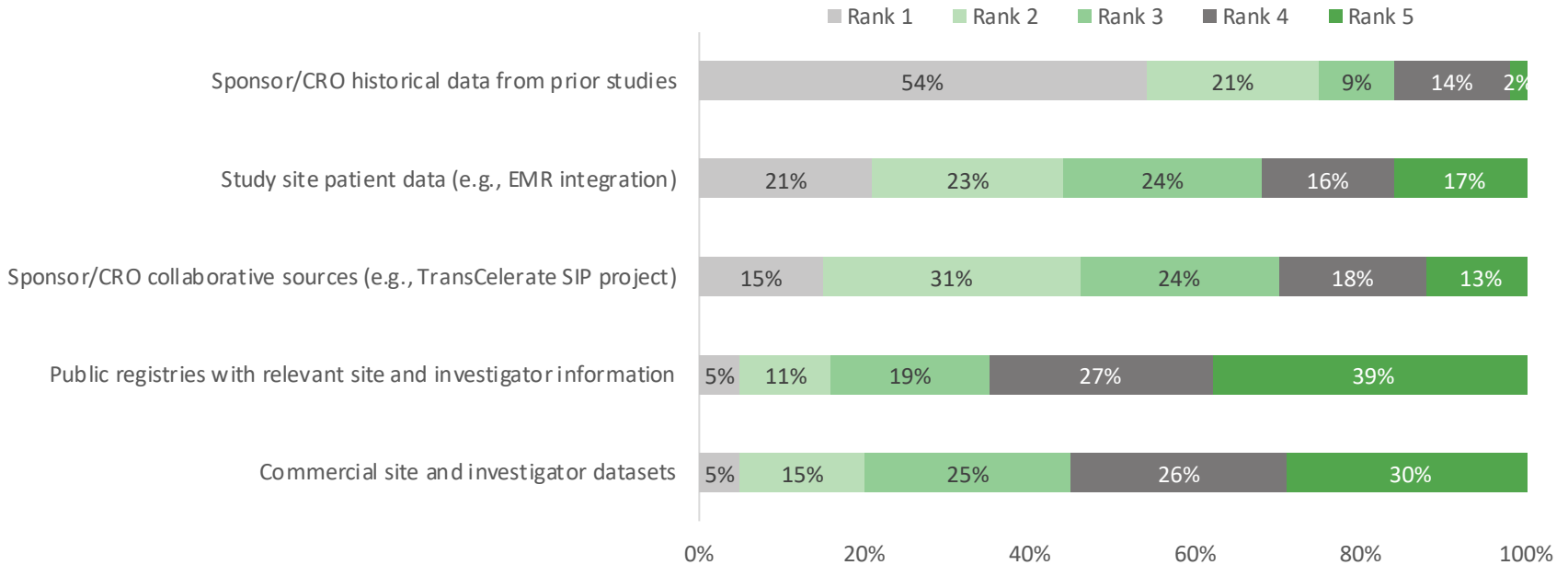# **Sponsors**: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (sponsors only, n=187)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Data Source	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Sponsor/CRO historical data from prior studies	50%	21%	17%	6%	6%
Study site patient data (e.g., EMR integration)	24%	19%	24%	21%	13%
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	16%	30%	20%	13%	21%
Public registries with relevant site and investigator information	6%	16%	18%	31%	29%
Commercial site and investigator datasets	5%	14%	22%	28%	30%

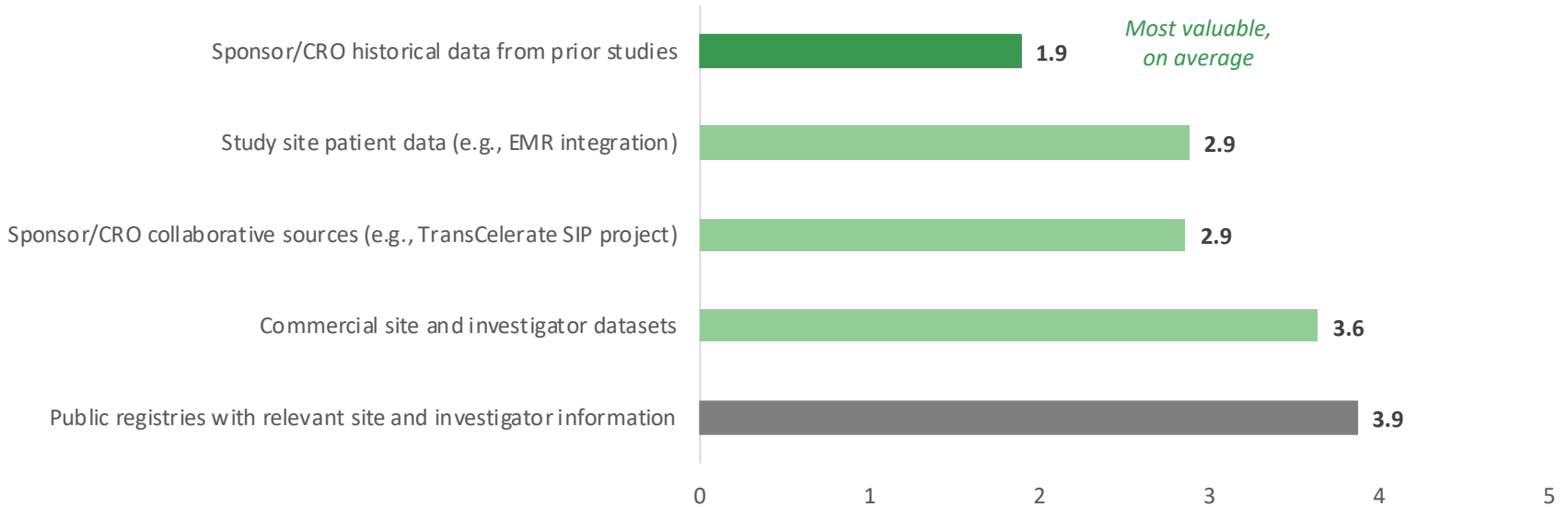# **Sponsors**: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (sponsors only, n=187)

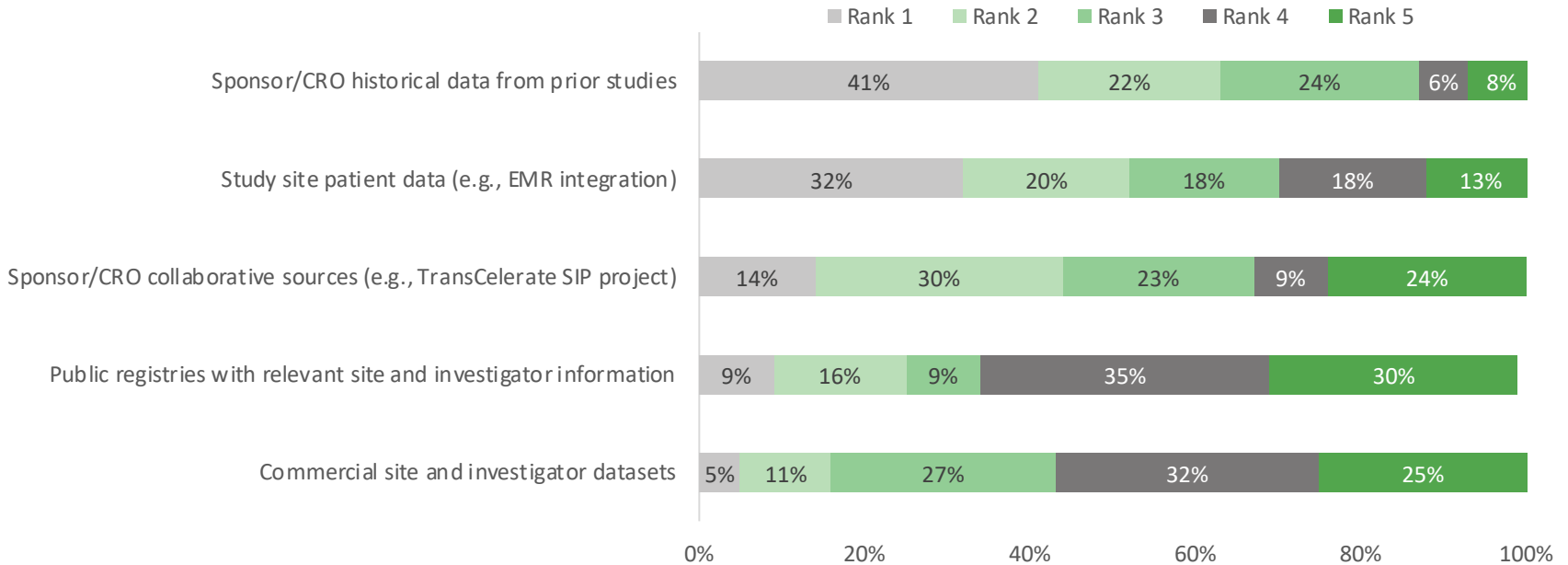| Data Source	Average Rank
Sponsor/CRO historical data from prior studies	2.0 — *Most valuable, on average*
Study site patient data (e.g., EMR integration)	2.8
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	2.9
Public registries with relevant site and investigator information	3.6
Commercial site and investigator datasets	3.6

CROs: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (CROs only, n=75)

Legend: Rank 1, Rank 2, Rank 3, Rank 4, Rank 5

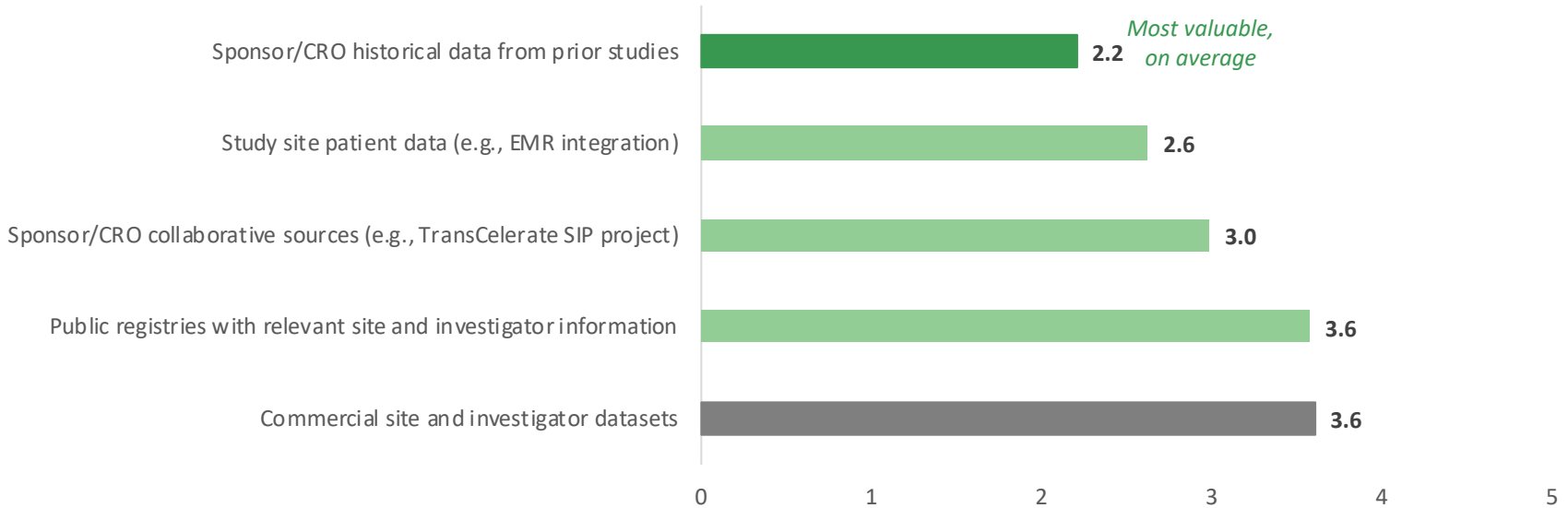| Data Source	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Sponsor/CRO historical data from prior studies	51%	24%	9%	12%	4%
Study site patient data (e.g., EMR integration)	23%	20%	19%	13%	25%
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	15%	32%	27%	16%	11%
Public registries with relevant site and investigator information	7%	12%	16%	33%	32%
Commercial site and investigator datasets	5%	12%	29%	25%	28%

CROs: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (CROs only, n=75)

Data Source	Average
Sponsor/CRO historical data from prior studies	1.9 *Most valuable, on average*
Study site patient data (e.g., EMR integration)	2.8
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	3.0
Commercial site and investigator datasets	3.6
Public registries with relevant site and investigator information	3.7

1-10 Trials: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (smaller companies with 1-10 trials only, n=101)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

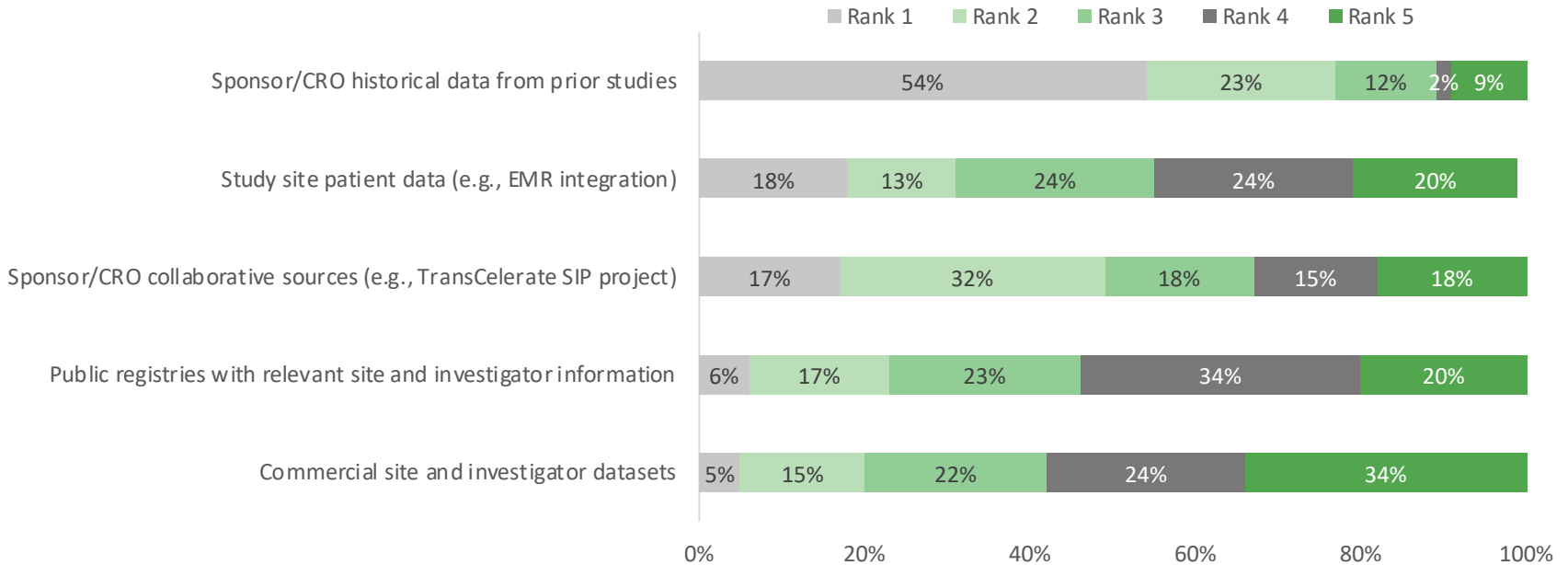| Data Source	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Sponsor/CRO historical data from prior studies	54%	21%	9%	14%	2%
Study site patient data (e.g., EMR integration)	21%	23%	24%	16%	17%
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	15%	31%	24%	18%	13%
Public registries with relevant site and investigator information	5%	11%	19%	27%	39%
Commercial site and investigator datasets	5%	15%	25%	26%	30%

0%   20%   40%   60%   80%   100%

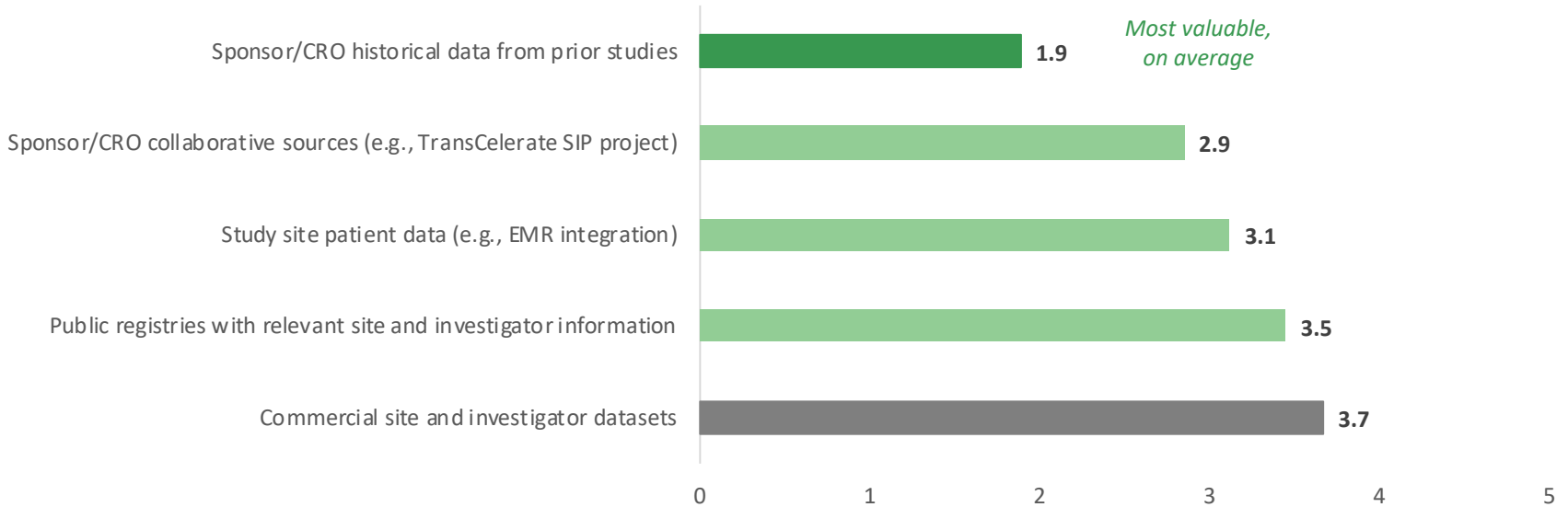# **1-10 Trials**: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (smaller companies with 1-10 trials only, n=101)

Data Source	Value
Sponsor/CRO historical data from prior studies	1.9 — *Most valuable, on average*
Study site patient data (e.g., EMR integration)	2.9
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	2.9
Commercial site and investigator datasets	3.6
Public registries with relevant site and investigator information	3.9

11-50 Trials: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (mid-size companies with 11-50 trials only, n=79)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Data Source	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Sponsor/CRO historical data from prior studies	41%	22%	24%	6%	8%
Study site patient data (e.g., EMR integration)	32%	20%	18%	18%	13%
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	14%	30%	23%	9%	24%
Public registries with relevant site and investigator information	9%	16%	9%	35%	30%
Commercial site and investigator datasets	5%	11%	27%	32%	25%

11-50 Trials: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (mid-size companies with 11-50 trials only, n=79)

Data Source	Average
Sponsor/CRO historical data from prior studies	2.2
Study site patient data (e.g., EMR integration)	2.6
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	3.0
Public registries with relevant site and investigator information	3.6
Commercial site and investigator datasets	3.6

Most valuable, on average

>50 Trials: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (large companies with >50 trials only, n=82)

Legend: Rank 1 | Rank 2 | Rank 3 | Rank 4 | Rank 5

Data Source	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Sponsor/CRO historical data from prior studies	54%	23%	12%	2%	9%
Study site patient data (e.g., EMR integration)	18%	13%	24%	24%	20%
Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project)	17%	32%	18%	15%	18%
Public registries with relevant site and investigator information	6%	17%	23%	34%	20%
Commercial site and investigator datasets	5%	15%	22%	24%	34%

>50 Trials: Ranking of Data Sources Used for Site Selection

What are the most valuable data sources used for site selection? Rank the following options in order of importance where "1" is most valuable and "5" is least valuable. (large companies with >50 trials only, n=82)

Sponsor/CRO historical data from prior studies — **1.9** *Most valuable, on average*

Sponsor/CRO collaborative sources (e.g., TransCelerate SIP project) — **2.9**

Study site patient data (e.g., EMR integration) — **3.1**

Public registries with relevant site and investigator information — **3.5**

Commercial site and investigator datasets — **3.7**

0   1   2   3   4   5

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
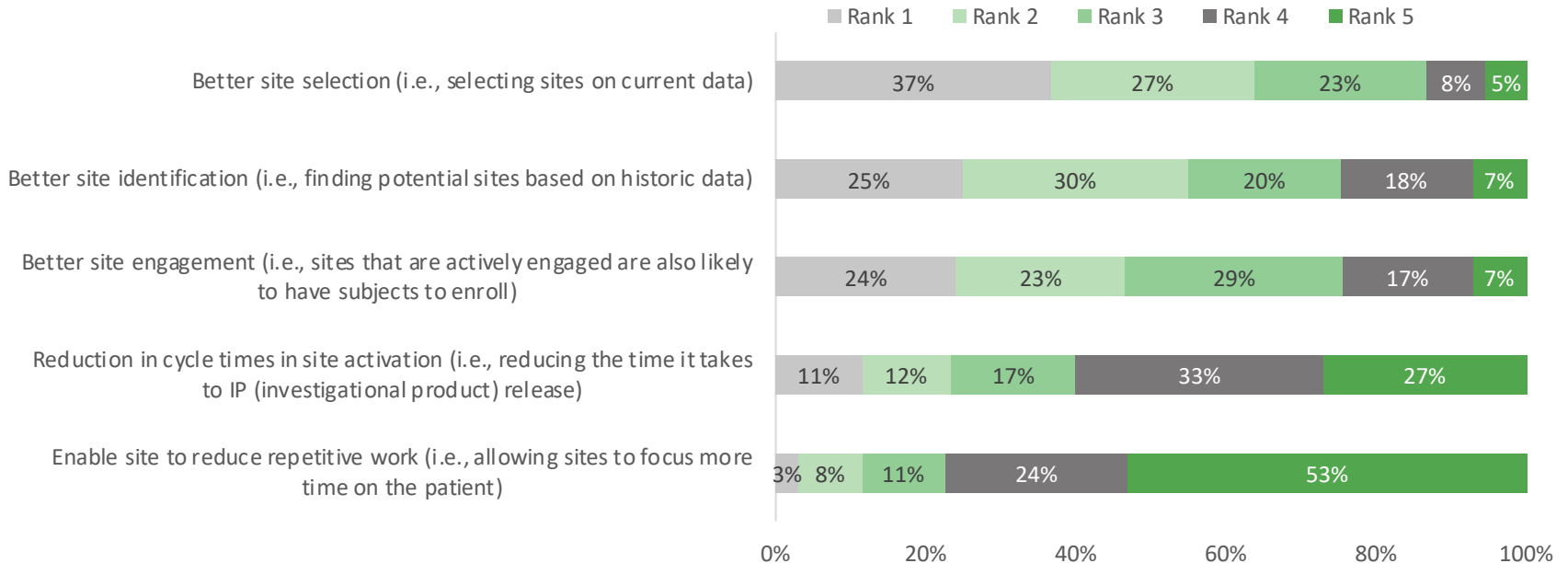- Word of mouth

ECLINICAL TECHNOLOGY IN STUDY STARTUP USAGE & FUTURE DEPLOYMENTS
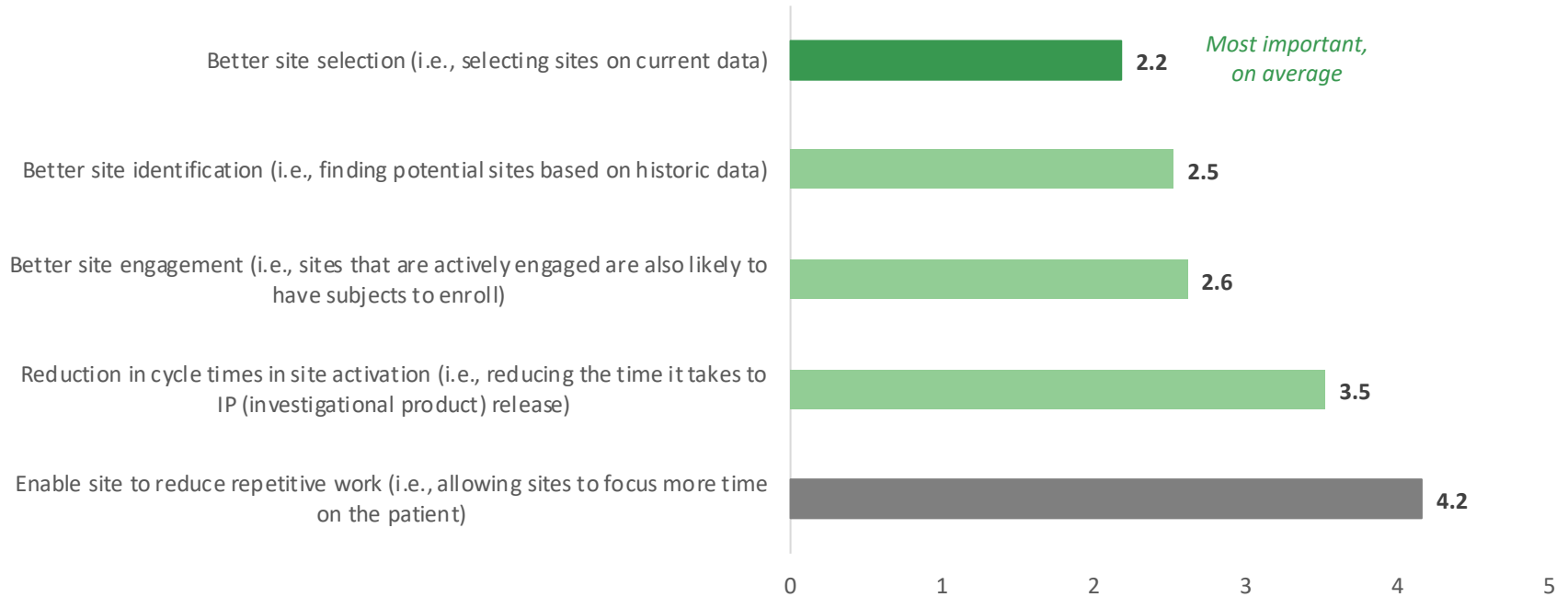
PATIENT RECRUITMENT

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. (n=262)
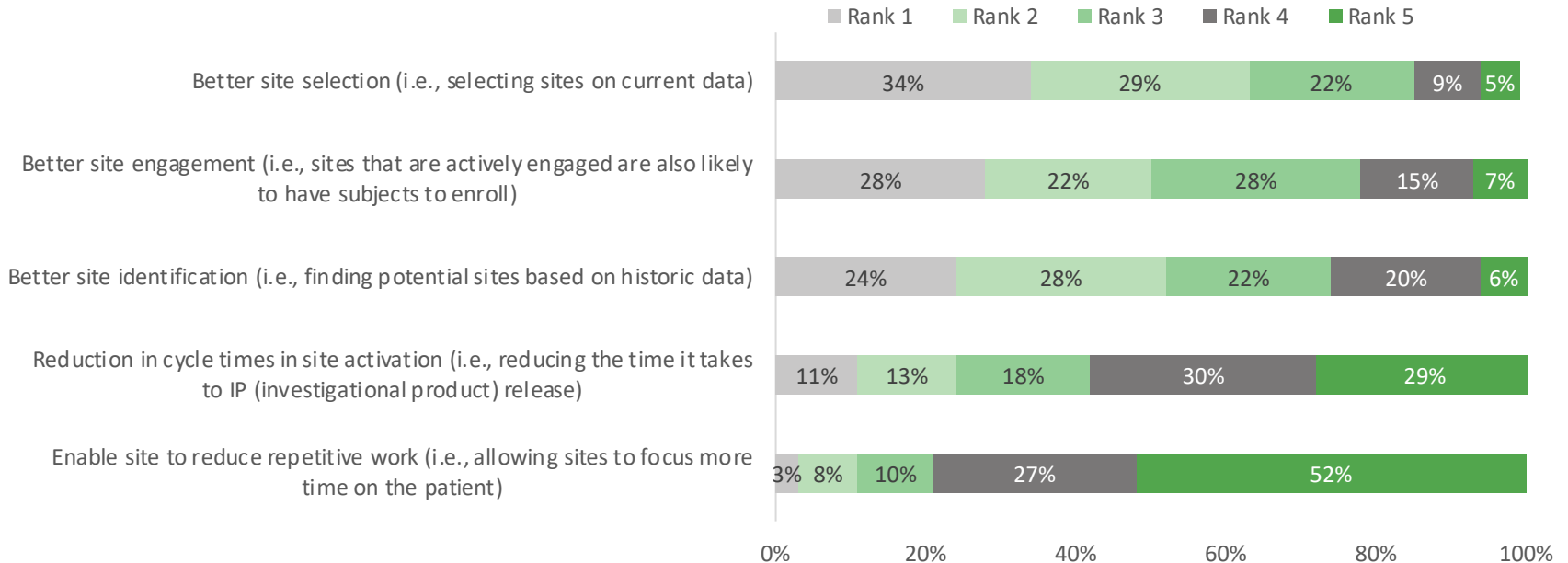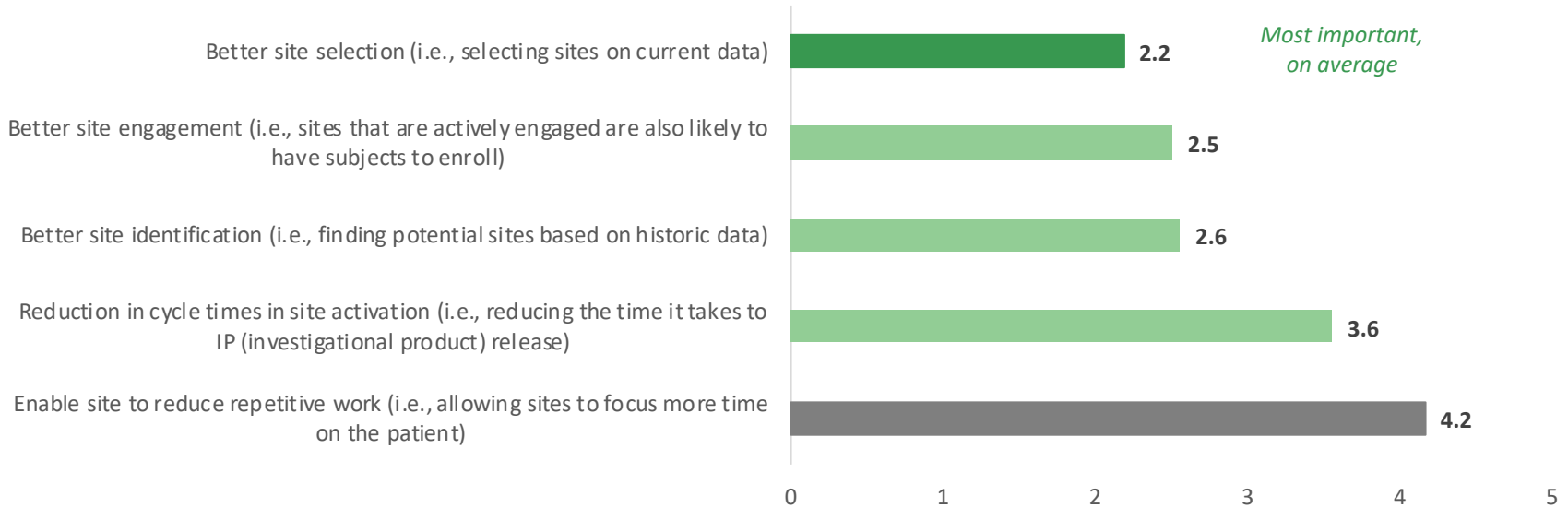
Aspect	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Better site selection (i.e., selecting sites on current data)	37%	27%	23%	8%	5%
Better site identification (i.e., finding potential sites based on historic data)	25%	30%	20%	18%	7%
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	24%	23%	29%	17%	7%
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	11%	12%	17%	33%	27%
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	3%	8%	11%	24%	53%

Average Ranking: Aspects that Speed Patient Recruitment

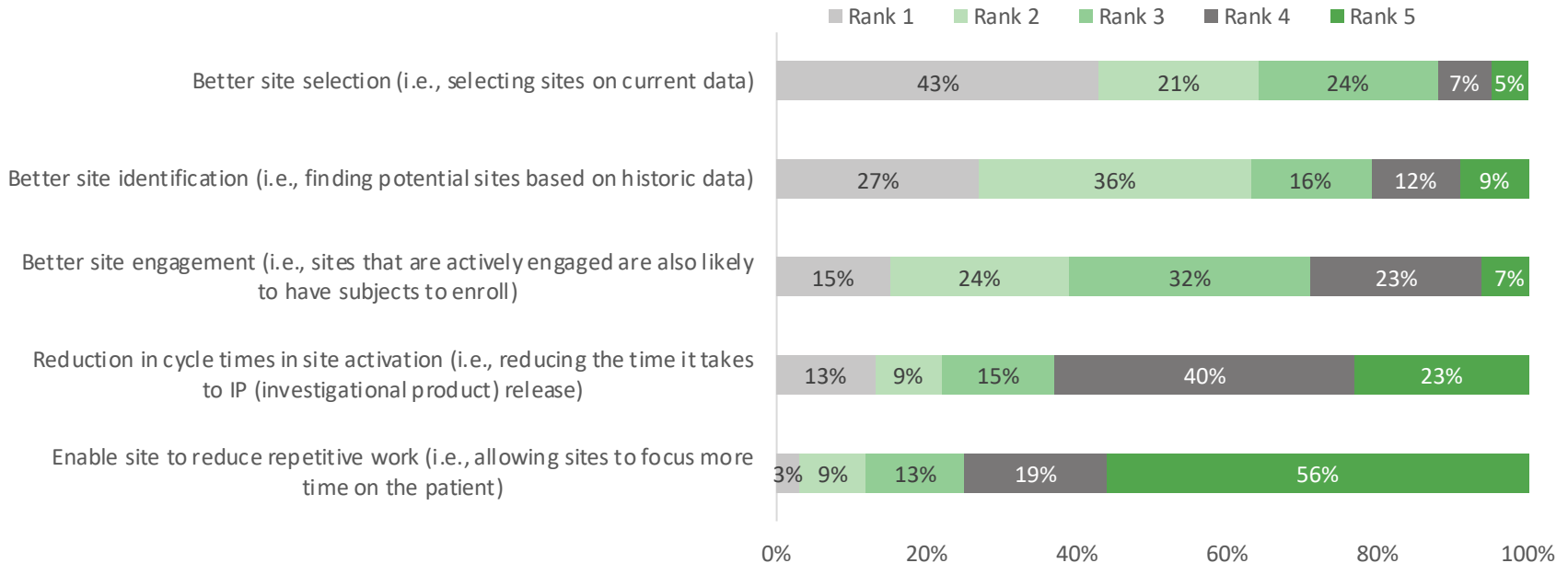| Aspect	Ranking
Better site selection (i.e., selecting sites on current data)	2.2
Better site identification (i.e., finding potential sites based on historic data)	2.5
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	2.6
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	3.5
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	4.2

Most important, on average

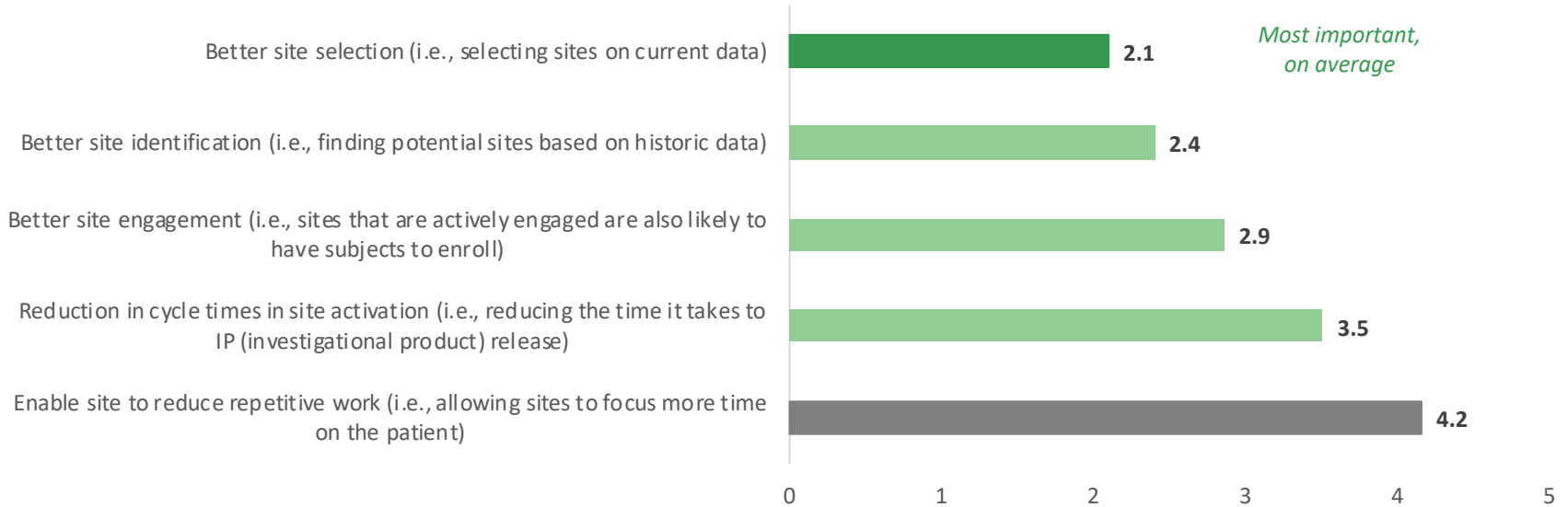# **Sponsors**: Ranking of Aspects that Speed Patient Recruitment

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. (sponsors only, n=187)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Aspect	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Better site selection (i.e., selecting sites on current data)	34%	29%	22%	9%	5%
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	28%	22%	28%	15%	7%
Better site identification (i.e., finding potential sites based on historic data)	24%	28%	22%	20%	6%
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	11%	13%	18%	30%	29%
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	3%	8%	10%	27%	52%

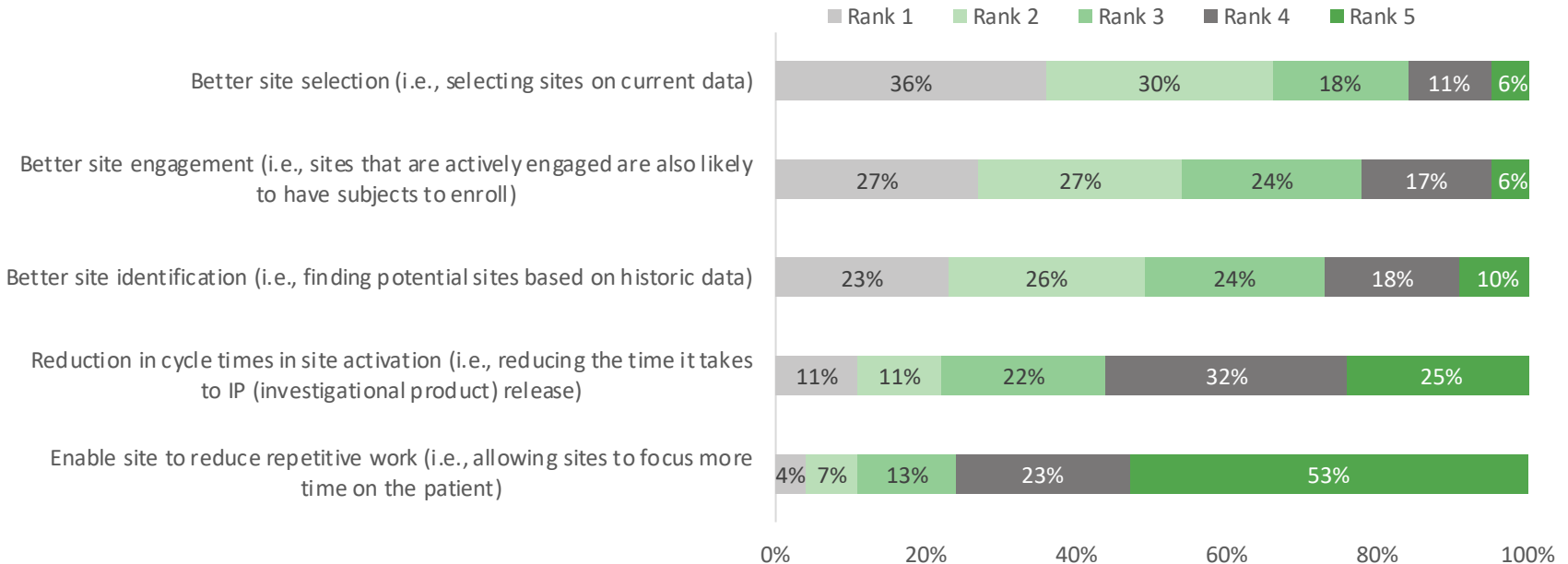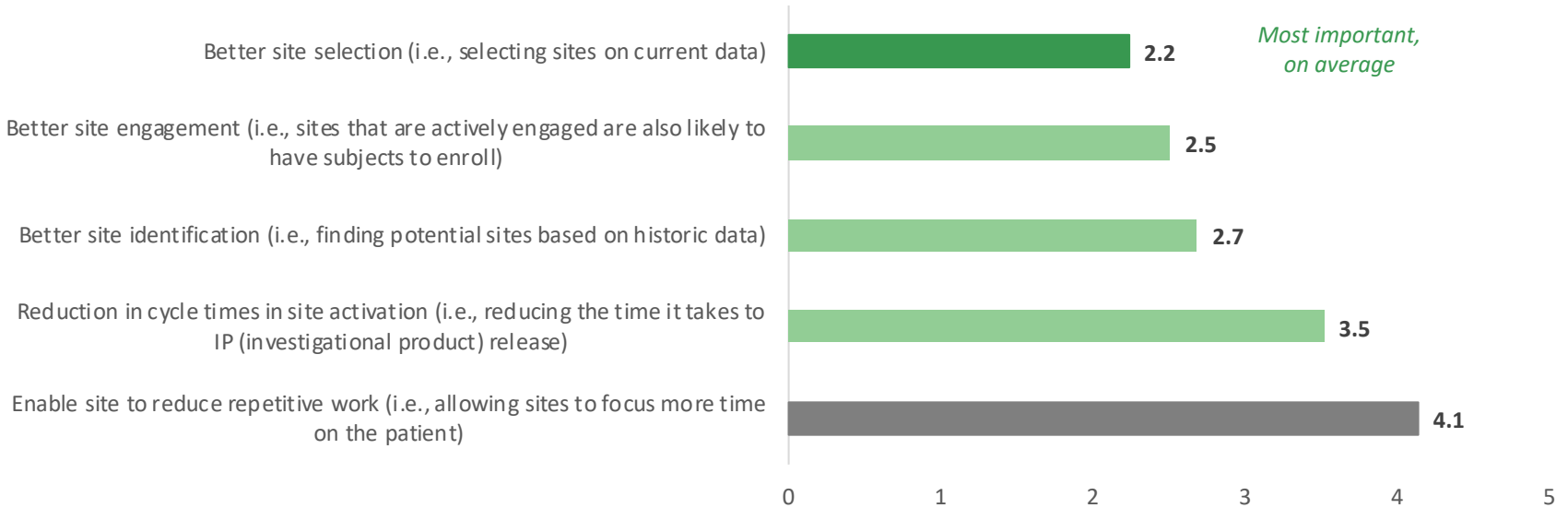# **Sponsors**: Ranking of Aspects that Speed Patient Recruitment

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. (sponsors only, n=187)

Aspect	Average Rank
Better site selection (i.e., selecting sites on current data)	2.2
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	2.5
Better site identification (i.e., finding potential sites based on historic data)	2.6
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	3.6
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	4.2

Most important, on average

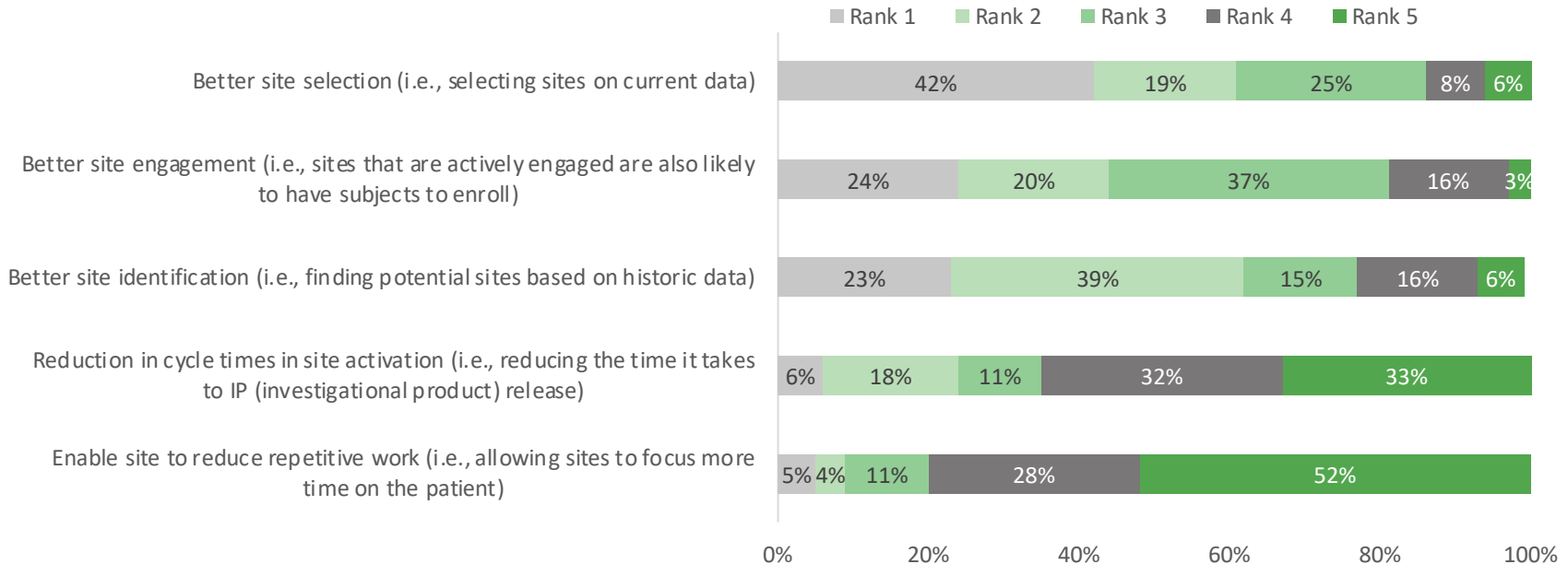# **CROs**: Ranking of Aspects that Speed Patient Recruitment

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. (CROs only, n=75)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Aspect	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Better site selection (i.e., selecting sites on current data)	43%	21%	24%	7%	5%
Better site identification (i.e., finding potential sites based on historic data)	27%	36%	16%	12%	9%
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	15%	24%	32%	23%	7%
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	13%	9%	15%	40%	23%
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	3%	9%	13%	19%	56%

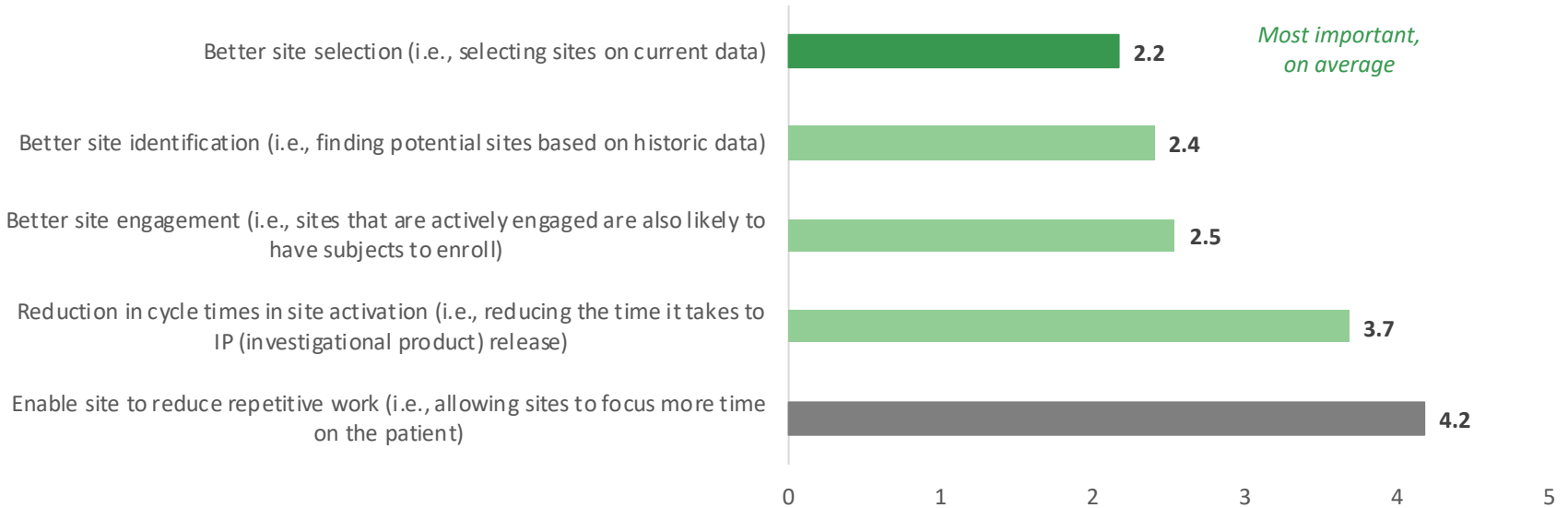# CROs: Ranking of Aspects that Speed Patient Recruitment

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. (CROs only, n=75)

Aspect	Average
Better site selection (i.e., selecting sites on current data)	2.1
Better site identification (i.e., finding potential sites based on historic data)	2.4
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	2.9
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	3.5
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	4.2

Most important, on average

1-10 Trials: Ranking of Aspects that Speed Patient Recruitment

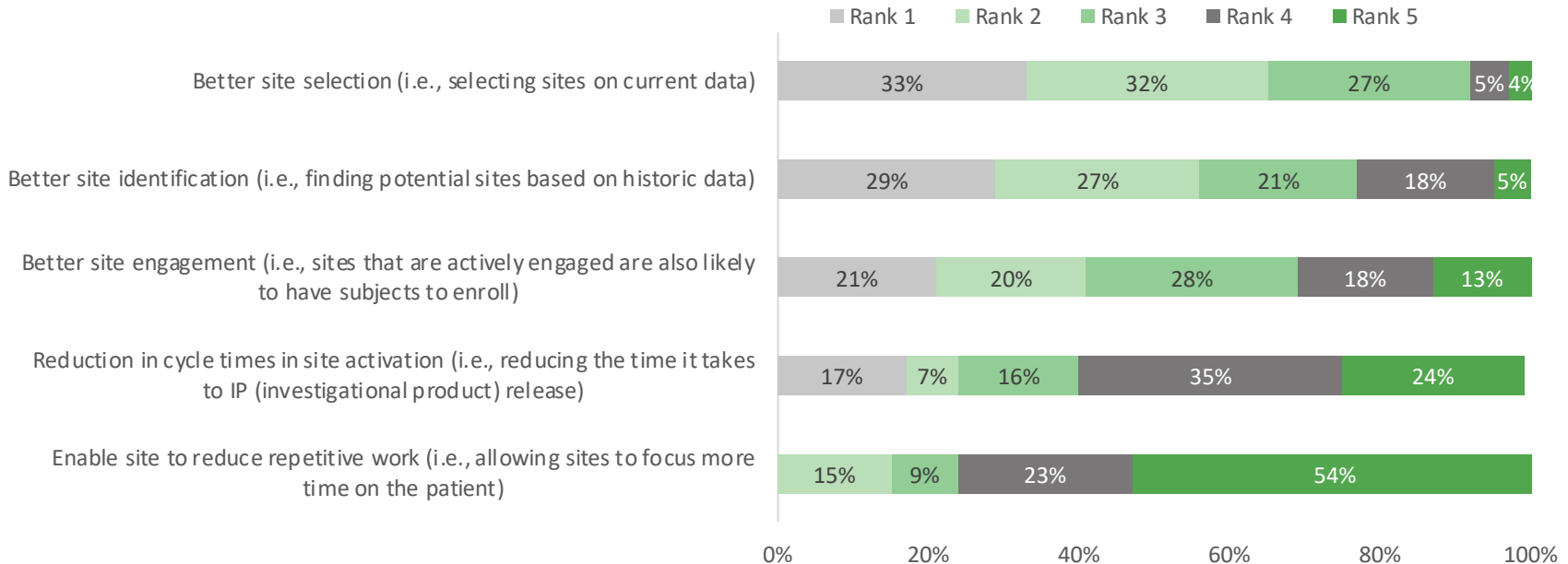*What are the most important aspects that can speed patient recruitment in clinical trials? Rank the following options in order of importance where "1" is most important and "5" is least important. (smaller companies with 1-10 trials only, n=101)*

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Aspect	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Better site selection (i.e., selecting sites on current data)	36%	30%	18%	11%	6%
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	27%	27%	24%	17%	6%
Better site identification (i.e., finding potential sites based on historic data)	23%	26%	24%	18%	10%
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	11%	11%	22%	32%	25%
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	4%	7%	13%	23%	53%

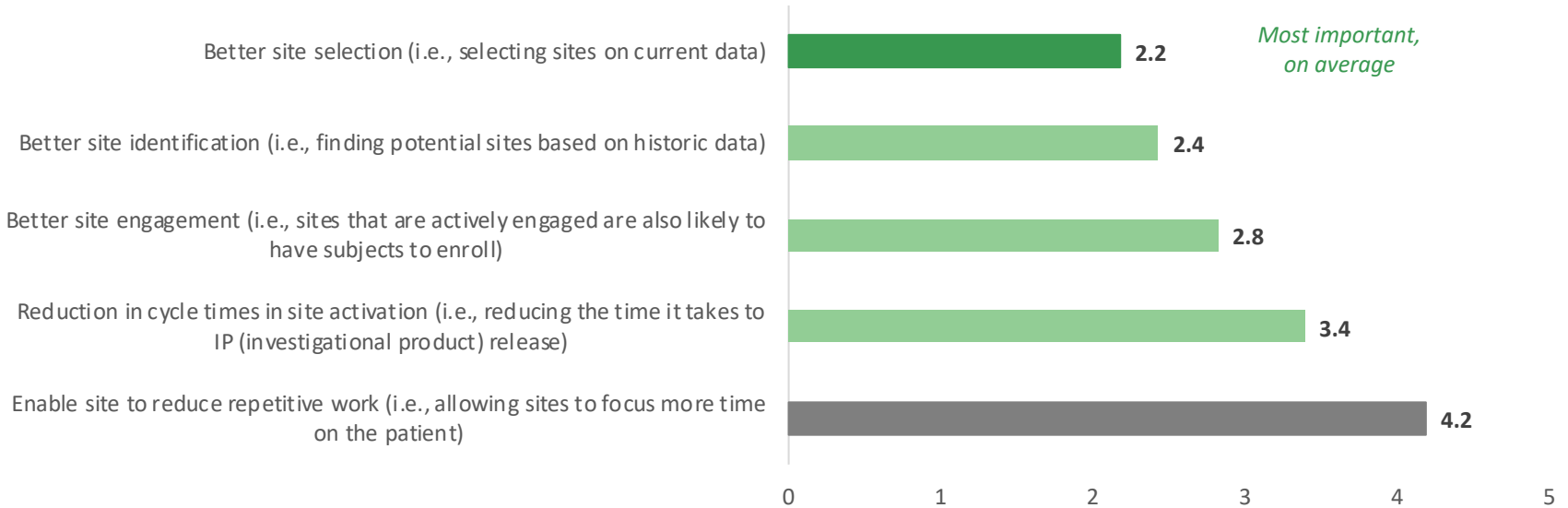# **1-10 Trials**: Ranking of Aspects that Speed Patient Recruitment

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. (smaller companies with 1-10 trials only, n=101)

Chart data:

- Better site selection (i.e., selecting sites on current data): 2.2 — *Most important, on average*
- Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll): 2.5
- Better site identification (i.e., finding potential sites based on historic data): 2.7
- Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release): 3.5
- Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient): 4.1

11-50 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. (mid-size companies with 11-50 trials only, n=79)

Legend: ■ Rank 1　■ Rank 2　■ Rank 3　■ Rank 4　■ Rank 5

Aspect	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Better site selection (i.e., selecting sites on current data)	42%	19%	25%	8%	6%
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	24%	20%	37%	16%	3%
Better site identification (i.e., finding potential sites based on historic data)	23%	39%	15%	16%	6%
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	6%	18%	11%	32%	33%
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	5%	4%	11%	28%	52%

11-50 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. (mid-size companies with 11-50 trials only, n=79)

Aspect	Score
Better site selection (i.e., selecting sites on current data)	2.2 — *Most important, on average*
Better site identification (i.e., finding potential sites based on historic data)	2.4
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	2.5
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	3.7
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	4.2

>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)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Aspect	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Better site selection (i.e., selecting sites on current data)	33%	32%	27%	5%	4%
Better site identification (i.e., finding potential sites based on historic data)	29%	27%	21%	18%	5%
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	21%	20%	28%	18%	13%
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	17%	7%	16%	35%	24%
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)		15%	9%	23%	54%

>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)

Aspect	Value
Better site selection (i.e., selecting sites on current data)	2.2
Better site identification (i.e., finding potential sites based on historic data)	2.4
Better site engagement (i.e., sites that are actively engaged are also likely to have subjects to enroll)	2.8
Reduction in cycle times in site activation (i.e., reducing the time it takes to IP (investigational product) release)	3.4
Enable site to reduce repetitive work (i.e., allowing sites to focus more time on the patient)	4.2

Most important, on average

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
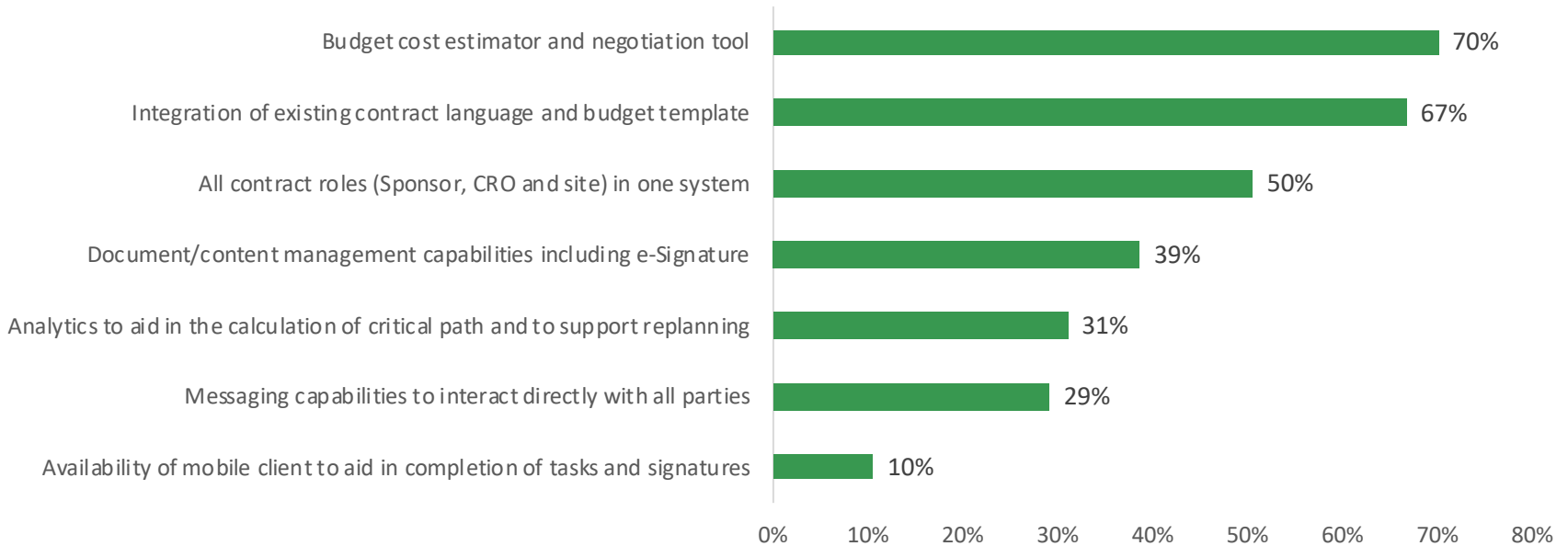- Use of referral system, eventually patient associations/advocacy groups

ECLINICAL TECHNOLOGY IN STUDY STARTUP USAGE & FUTURE DEPLOYMENTS

CONTRACTING AND PROCESS OPTIMIZATION

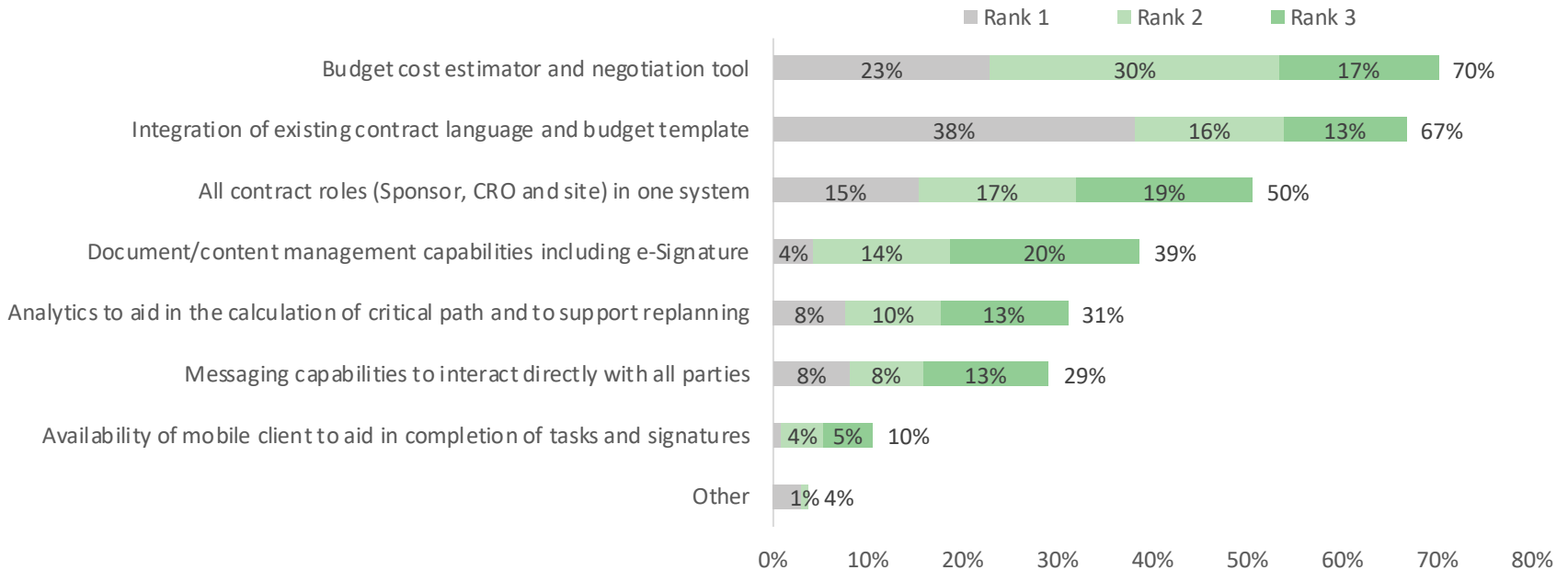# Aspects that Help Manage Contracting with a Site

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)
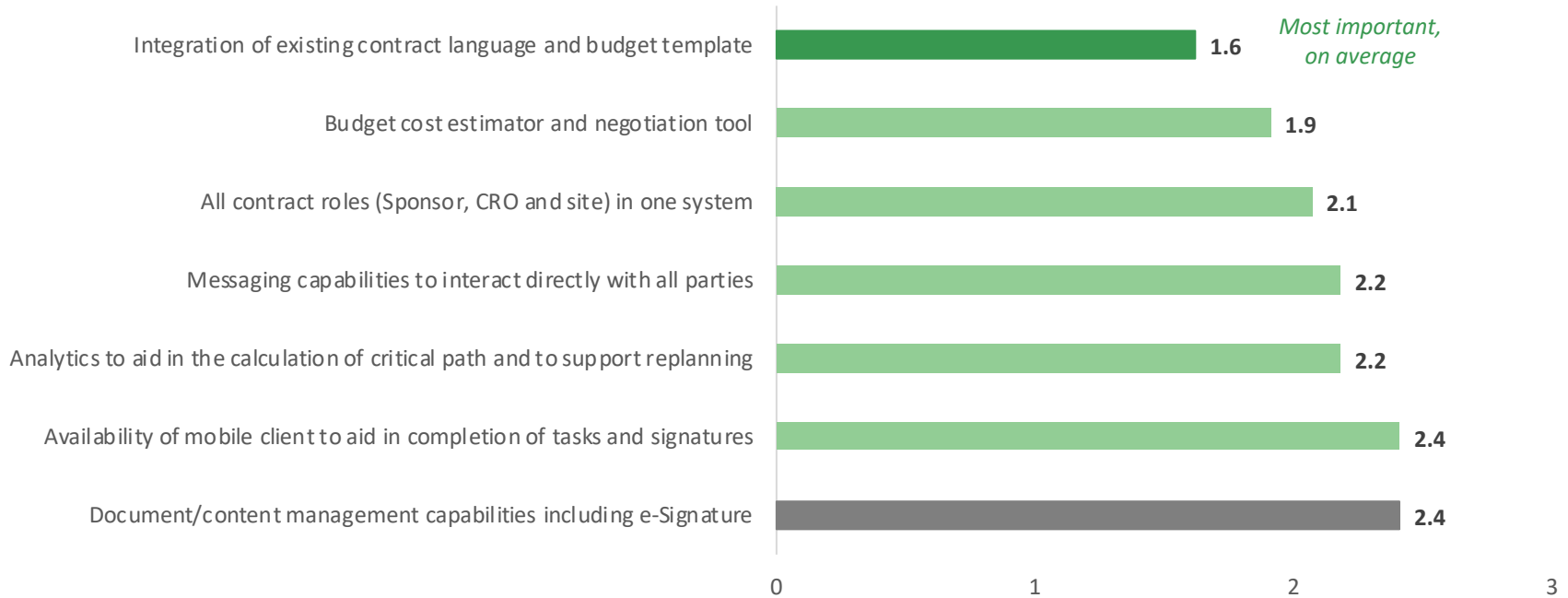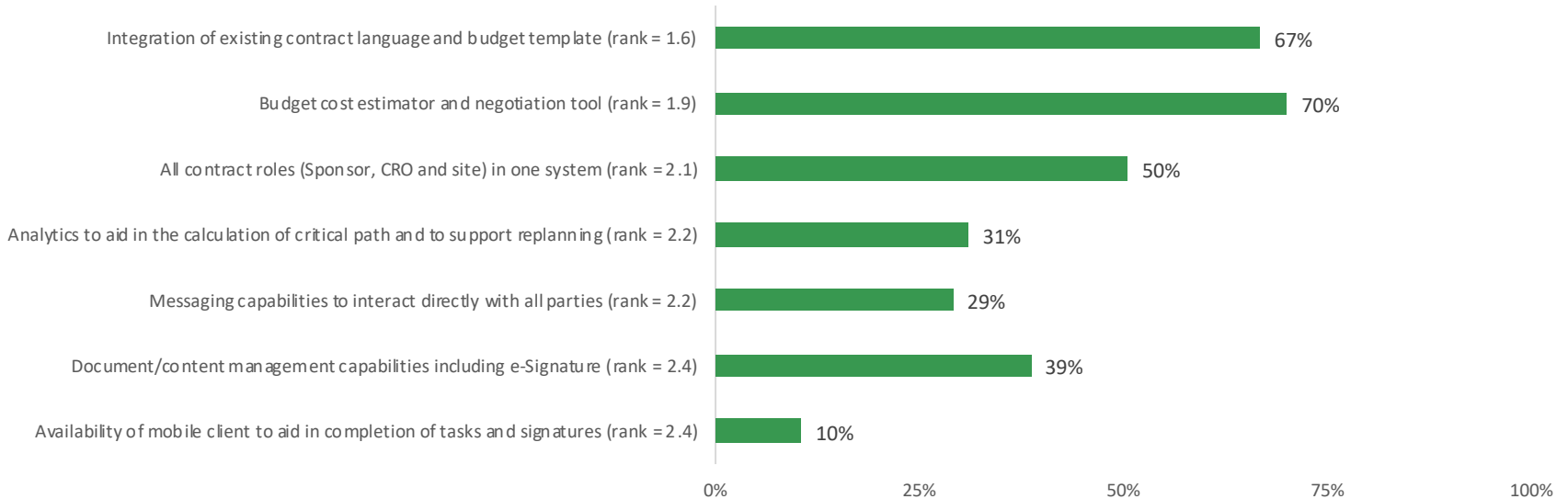
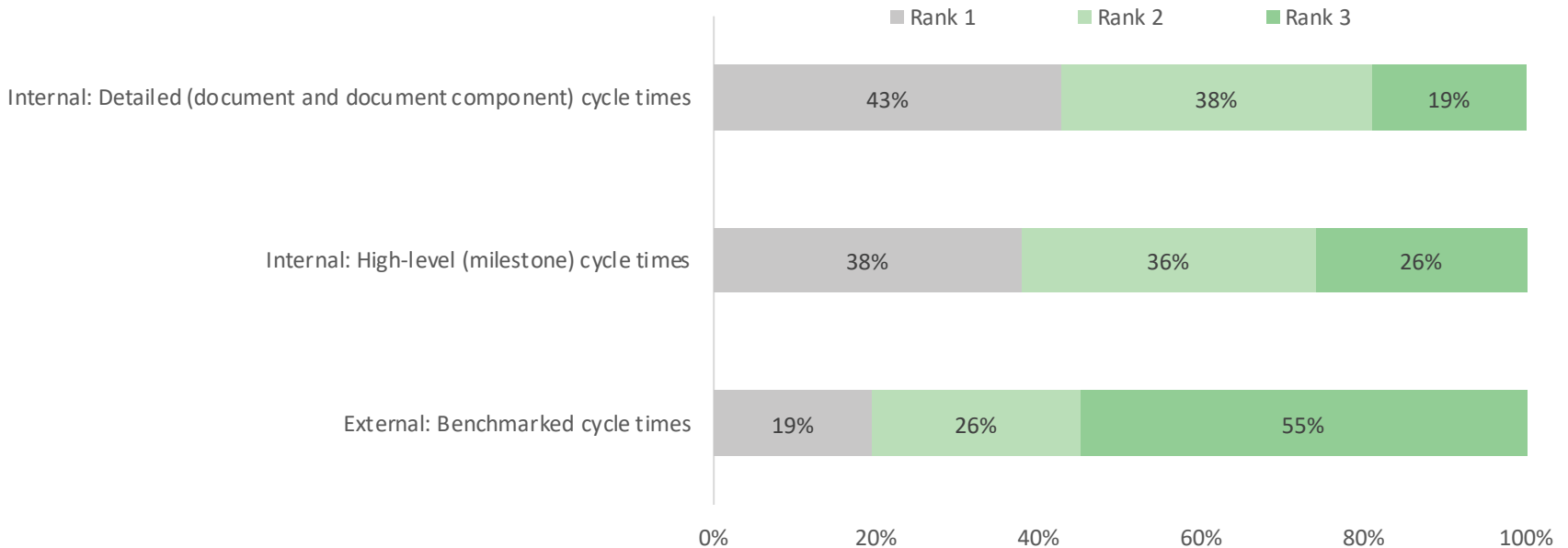| Aspect	Percentage
Budget cost estimator and negotiation tool	70%
Integration of existing contract language and budget template	67%
All contract roles (Sponsor, CRO and site) in one system	50%
Document/content management capabilities including e-Signature	39%
Analytics to aid in the calculation of critical path and to support replanning	31%
Messaging capabilities to interact directly with all parties	29%
Availability of mobile client to aid in completion of tasks and signatures	10%

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)
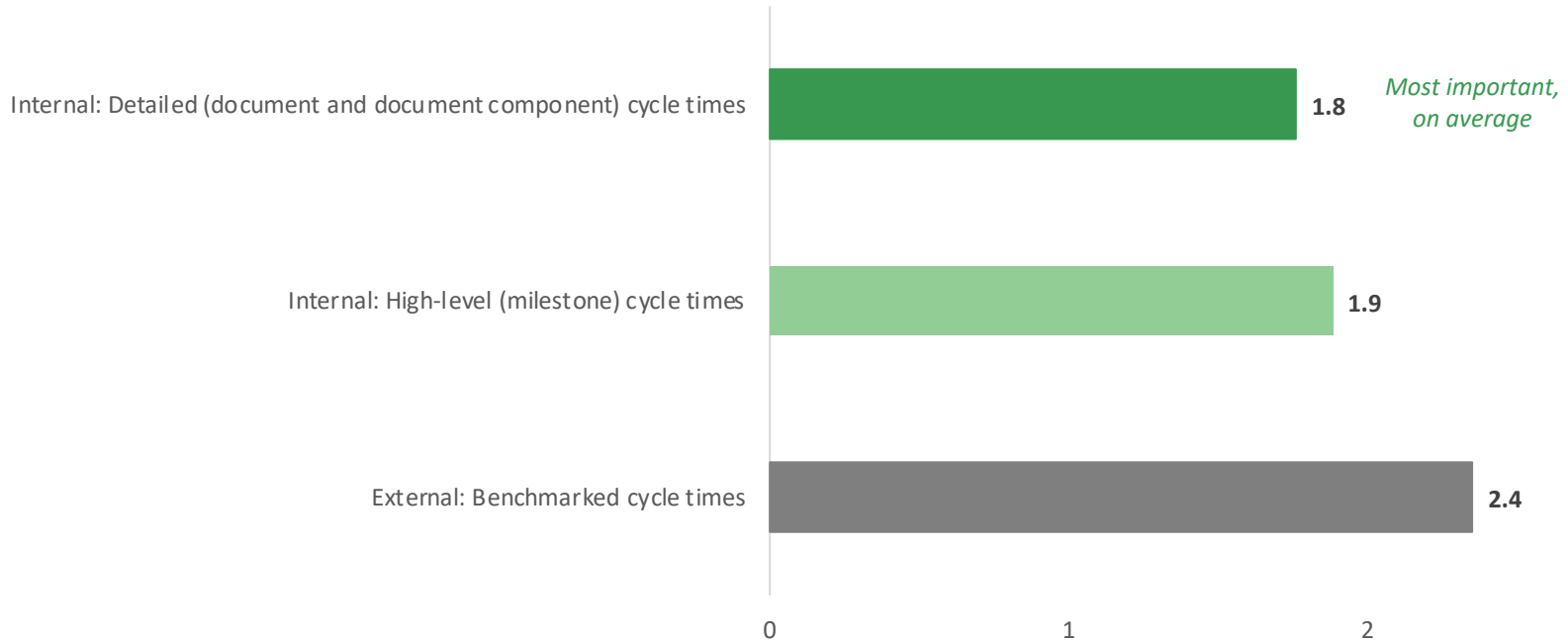

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3

Aspect	Rank 1	Rank 2	Rank 3	Total
Budget cost estimator and negotiation tool	23%	30%	17%	70%
Integration of existing contract language and budget template	38%	16%	13%	67%
All contract roles (Sponsor, CRO and site) in one system	15%	17%	19%	50%
Document/content management capabilities including e-Signature	4%	14%	20%	39%
Analytics to aid in the calculation of critical path and to support replanning	8%	10%	13%	31%
Messaging capabilities to interact directly with all parties	8%	8%	13%	29%
Availability of mobile client to aid in completion of tasks and signatures		4%	5%	10%
Other	1%	4%		

Average Ranking: Top 3 Aspects that Help Manage Contracting

Integration of existing contract language and budget template — 1.6 *Most important, on average*

Budget cost estimator and negotiation tool — 1.9

All contract roles (Sponsor, CRO and site) in one system — 2.1

Messaging capabilities to interact directly with all parties — 2.2

Analytics to aid in the calculation of critical path and to support replanning — 2.2

Availability of mobile client to aid in completion of tasks and signatures — 2.4

Document/content management capabilities including e-Signature — 2.4

0   1   2   3

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)

Aspect	Prevalence
Integration of existing contract language and budget template (rank = 1.6)	67%
Budget cost estimator and negotiation tool (rank = 1.9)	70%
All contract roles (Sponsor, CRO and site) in one system (rank = 2.1)	50%
Analytics to aid in the calculation of critical path and to support replanning (rank = 2.2)	31%
Messaging capabilities to interact directly with all parties (rank = 2.2)	29%
Document/content management capabilities including e-Signature (rank = 2.4)	39%
Availability of mobile client to aid in completion of tasks and signatures (rank = 2.4)	10%

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)

	Rank 1	Rank 2	Rank 3
Internal: Detailed (document and document component) cycle times	43%	38%	19%
Internal: High-level (milestone) cycle times	38%	36%	26%
External: Benchmarked cycle times	19%	26%	55%

Average Ranking: Aspects that Help with Process Optimization

Internal: Detailed (document and document component) cycle times — 1.8 — *Most important, on average*

Internal: High-level (milestone) cycle times — 1.9

External: Benchmarked cycle times — 2.4

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
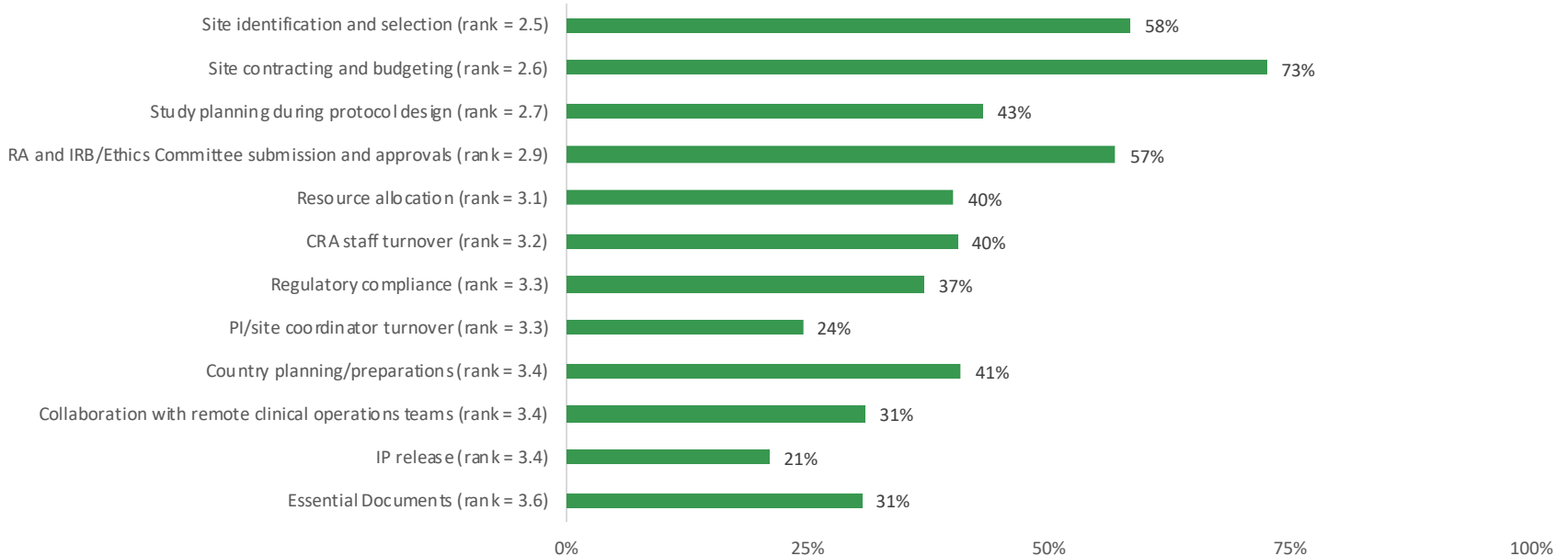- Ways to normalize data between different studies (size, location, TA); hard to compare apples to oranges

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)

Process	Percentage
Site contracting and budgeting	73%
Site identification and selection	58%
RA and IRB/Ethics Committee submission and approvals	57%
Study planning during protocol design	43%
Country planning/preparations	41%
CRA staff turnover	40%
Resource allocation	40%
Regulatory compliance	37%
Collaboration with remote clinical operations teams	31%
Essential Documents	31%
PI/site coordinator turnover	24%
IP release	21%
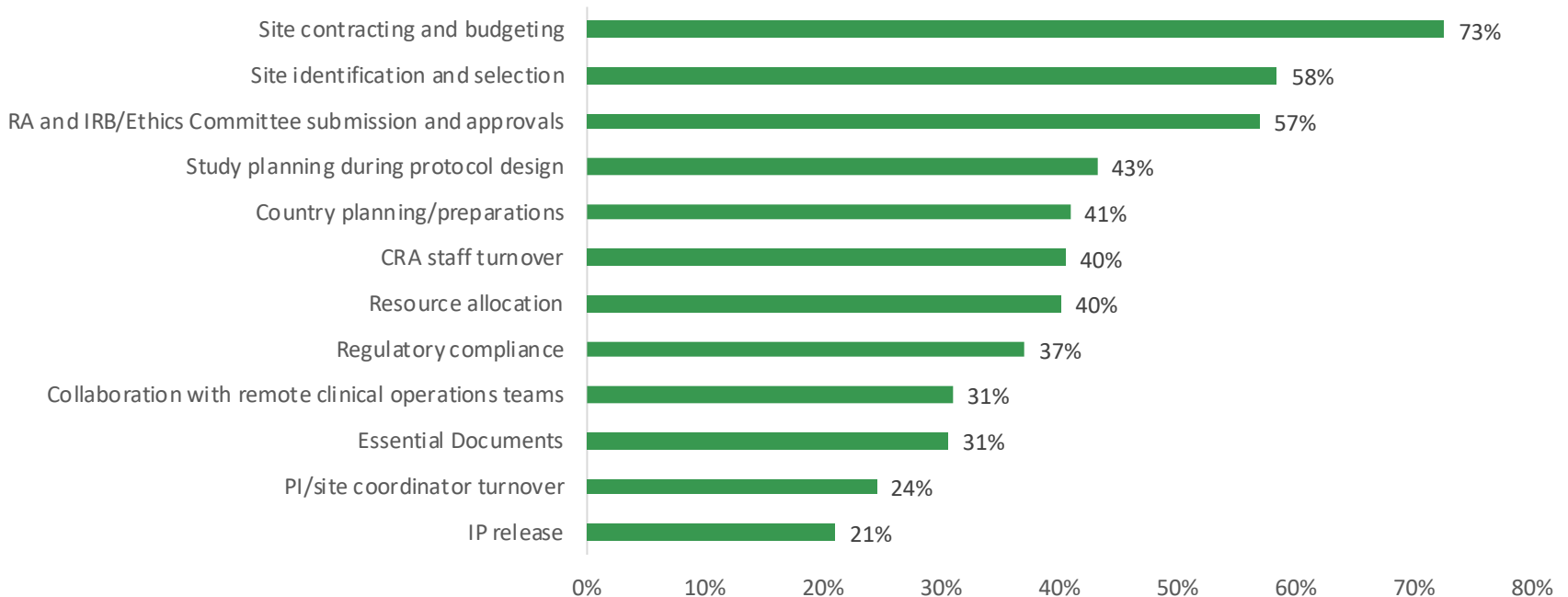
Rank Top 5 Site Collaboration Processes

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)
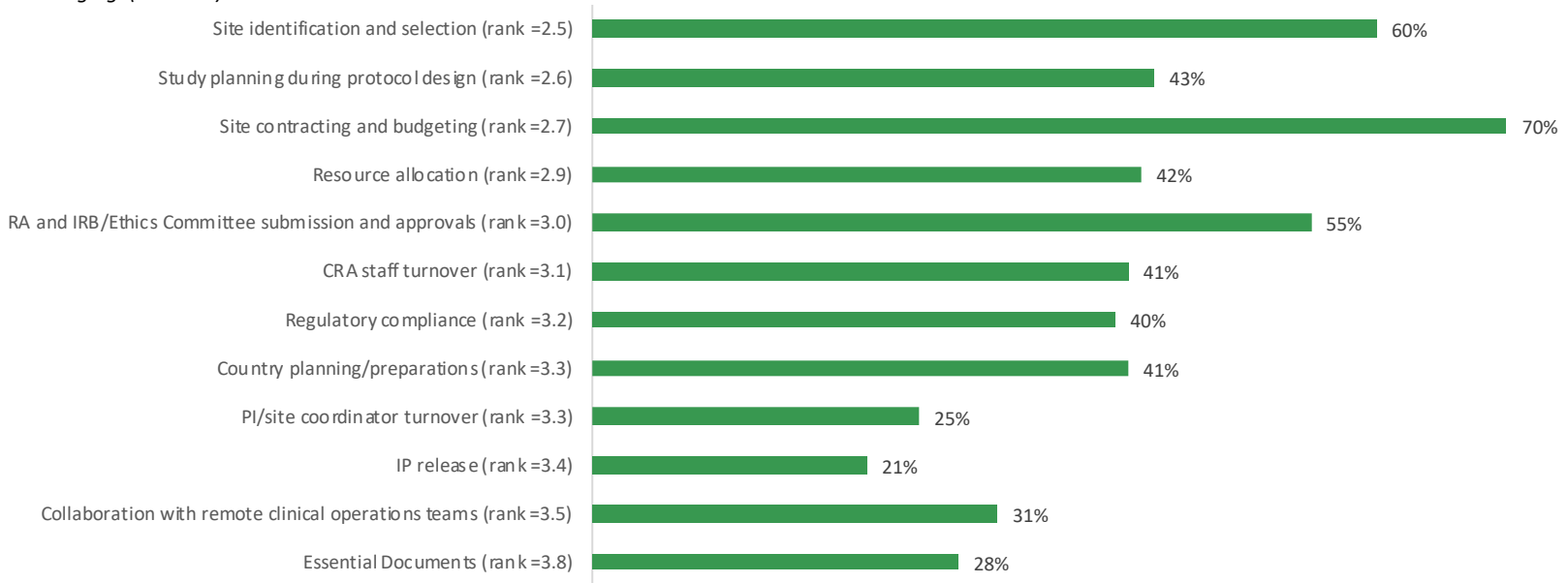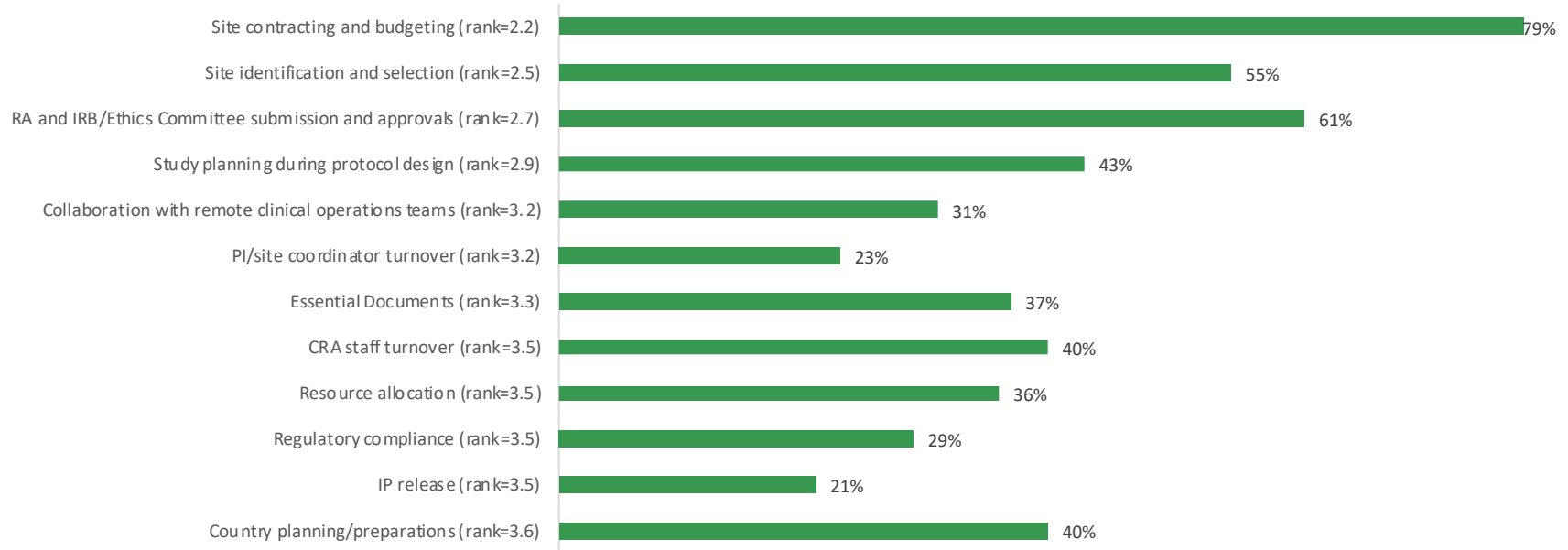
Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Process	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5	Total
Site contracting and budgeting	20%	15%	19%	12%	6%	73%
Site identification and selection	17%	17%	9%	10%	5%	58%
RA and IRB/Ethics Committee submission and approvals	12%	11%	14%	10%	10%	57%
Study planning during protocol design	13%	9%	5%	12%	5%	43%
Country planning/preparations	4%	9%	8%	7%	13%	41%
CRA staff turnover	6%	8%	9%	8%	10%	40%
Resource allocation	7%	8%	8%	10%	7%	40%
Regulatory compliance	7%	5%	6%	7%	12%	37%
Collaboration with remote clinical operations teams	5%	4%	6%	8%	9%	31%
Essential Documents		6%	8%	6%	10%	31%
PI/site coordinator turnover	4%	4%	5%	4%	7%	24%
IP release		4%	5%	6%	5%	21%
Other						4%

Average Ranking: Top 5 Site Collaboration Processes

Process	Average Ranking
Site identification and selection	2.5
Site contracting and budgeting	2.6
Study planning during protocol design	2.7
RA and IRB/Ethics Committee submission and approvals	2.9
Resource allocation	3.1
CRA staff turnover	3.2
PI/site coordinator turnover	3.3
Regulatory compliance	3.3
Country planning/preparations	3.4
Collaboration with remote clinical operations teams	3.4
IP release	3.4
Essential Documents	3.6

Most challenging, on average

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)
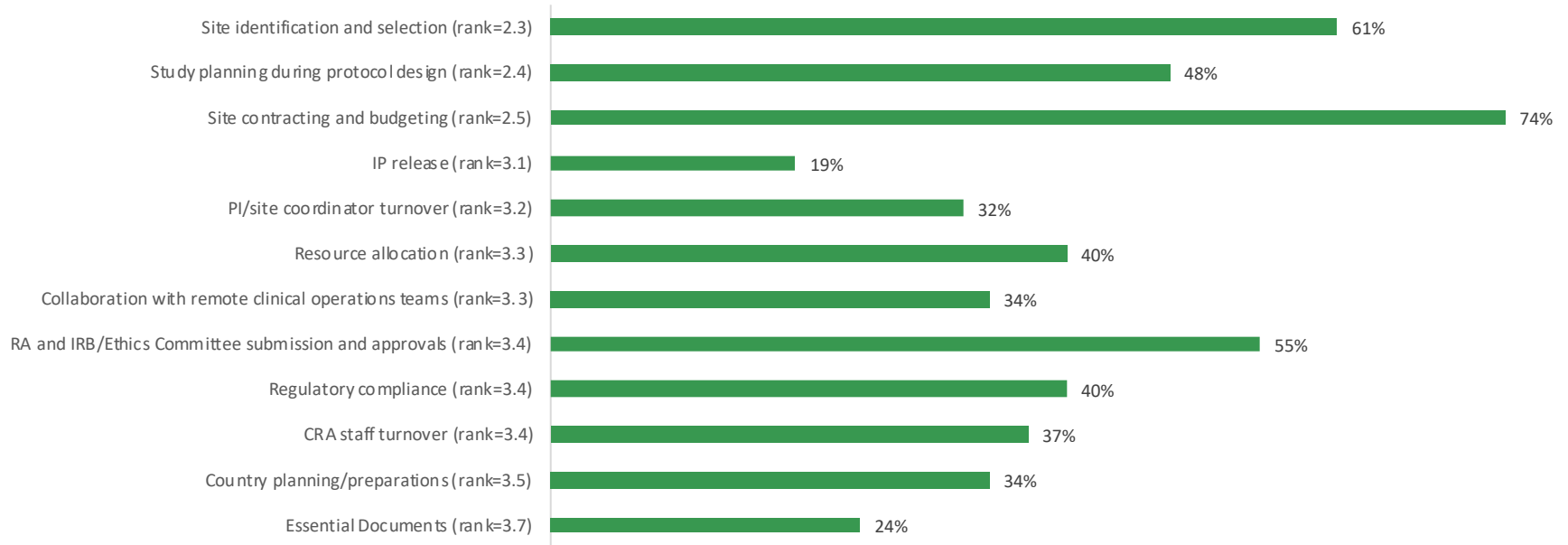
Process	Prevalence
Site identification and selection (rank = 2.5)	58%
Site contracting and budgeting (rank = 2.6)	73%
Study planning during protocol design (rank = 2.7)	43%
RA and IRB/Ethics Committee submission and approvals (rank = 2.9)	57%
Resource allocation (rank = 3.1)	40%
CRA staff turnover (rank = 3.2)	40%
Regulatory compliance (rank = 3.3)	37%
PI/site coordinator turnover (rank = 3.3)	24%
Country planning/preparations (rank = 3.4)	41%
Collaboration with remote clinical operations teams (rank = 3.4)	31%
IP release (rank = 3.4)	21%
Essential Documents (rank = 3.6)	31%

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)
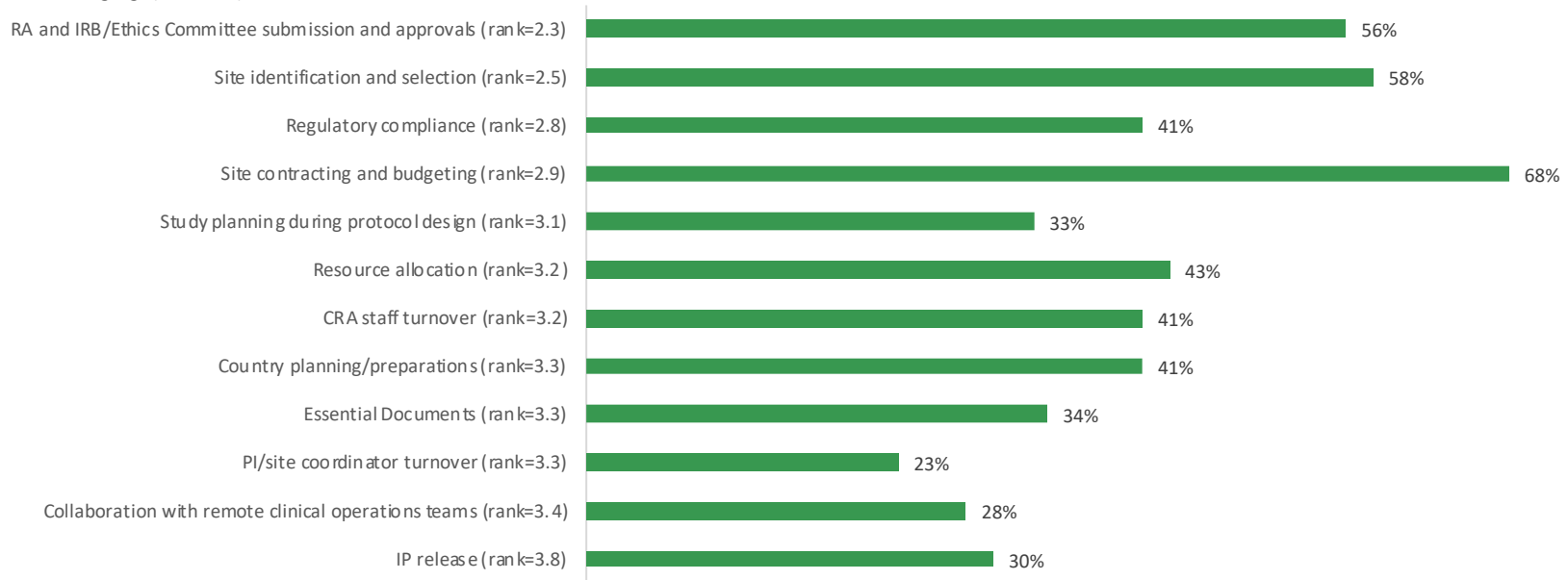
Process	Percentage
Site identification and selection (rank =2.5)	60%
Study planning during protocol design (rank =2.6)	43%
Site contracting and budgeting (rank =2.7)	70%
Resource allocation (rank =2.9)	42%
RA and IRB/Ethics Committee submission and approvals (rank =3.0)	55%
CRA staff turnover (rank =3.1)	41%
Regulatory compliance (rank =3.2)	40%
Country planning/preparations (rank =3.3)	41%
PI/site coordinator turnover (rank =3.3)	25%
IP release (rank =3.4)	21%
Collaboration with remote clinical operations teams (rank =3.5)	31%
Essential Documents (rank =3.8)	28%

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)
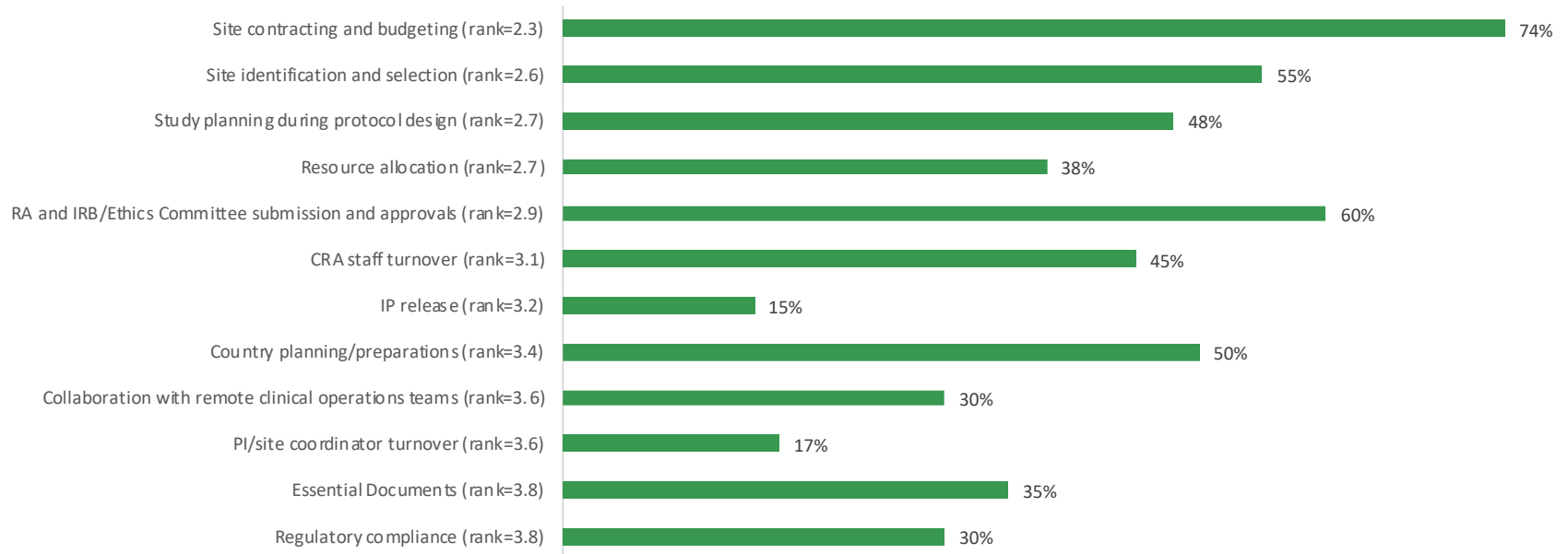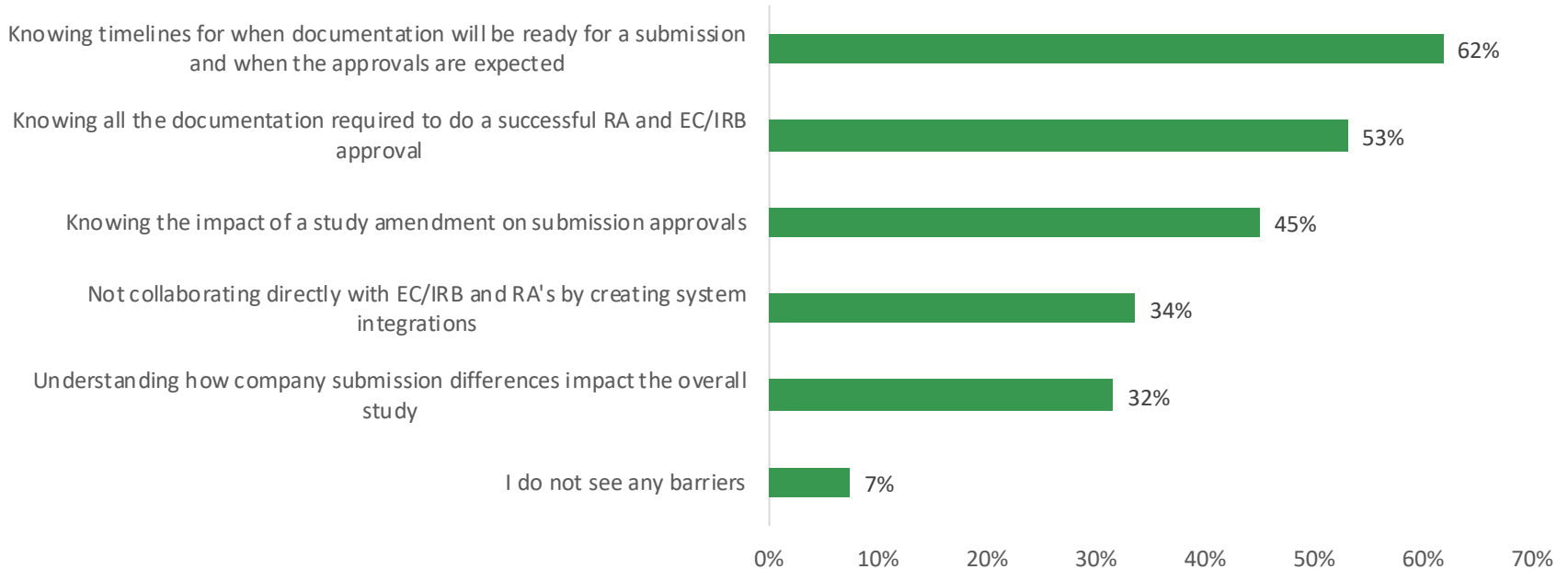
Process	Percentage
Site contracting and budgeting (rank=2.2)	79%
Site identification and selection (rank=2.5)	55%
RA and IRB/Ethics Committee submission and approvals (rank=2.7)	61%
Study planning during protocol design (rank=2.9)	43%
Collaboration with remote clinical operations teams (rank=3.2)	31%
PI/site coordinator turnover (rank=3.2)	23%
Essential Documents (rank=3.3)	37%
CRA staff turnover (rank=3.5)	40%
Resource allocation (rank=3.5)	36%
Regulatory compliance (rank=3.5)	29%
IP release (rank=3.5)	21%
Country planning/preparations (rank=3.6)	40%

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)

Process	Percentage
Site identification and selection (rank=2.3)	61%
Study planning during protocol design (rank=2.4)	48%
Site contracting and budgeting (rank=2.5)	74%
IP release (rank=3.1)	19%
PI/site coordinator turnover (rank=3.2)	32%
Resource allocation (rank=3.3)	40%
Collaboration with remote clinical operations teams (rank=3.3)	34%
RA and IRB/Ethics Committee submission and approvals (rank=3.4)	55%
Regulatory compliance (rank=3.4)	40%
CRA staff turnover (rank=3.4)	37%
Country planning/preparations (rank=3.5)	34%
Essential Documents (rank=3.7)	24%

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)

Process	Percentage
RA and IRB/Ethics Committee submission and approvals (rank=2.3)	56%
Site identification and selection (rank=2.5)	58%
Regulatory compliance (rank=2.8)	41%
Site contracting and budgeting (rank=2.9)	68%
Study planning during protocol design (rank=3.1)	33%
Resource allocation (rank=3.2)	43%
CRA staff turnover (rank=3.2)	41%
Country planning/preparations (rank=3.3)	41%
Essential Documents (rank=3.3)	34%
PI/site coordinator turnover (rank=3.3)	23%
Collaboration with remote clinical operations teams (rank=3.4)	28%
IP release (rank=3.8)	30%

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)

Process	Percentage
Site contracting and budgeting (rank=2.3)	74%
Site identification and selection (rank=2.6)	55%
Study planning during protocol design (rank=2.7)	48%
Resource allocation (rank=2.7)	38%
RA and IRB/Ethics Committee submission and approvals (rank=2.9)	60%
CRA staff turnover (rank=3.1)	45%
IP release (rank=3.2)	15%
Country planning/preparations (rank=3.4)	50%
Collaboration with remote clinical operations teams (rank=3.6)	30%
PI/site coordinator turnover (rank=3.6)	17%
Essential Documents (rank=3.8)	35%
Regulatory compliance (rank=3.8)	30%

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)

Barrier	Percentage
Knowing timelines for when documentation will be ready for a submission and when the approvals are expected	62%
Knowing all the documentation required to do a successful RA and EC/IRB approval	53%
Knowing the impact of a study amendment on submission approvals	45%
Not collaborating directly with EC/IRB and RA's by creating system integrations	34%
Understanding how company submission differences impact the overall study	32%
I do not see any barriers	7%

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)

Application	Percentage
eTMF	66%
EDC	65%
IVRS	60%
CTMS	59%
Excel	52%
Internally developed system	36%
Study start-up application	19%
Full solution provider	19%
None	2%
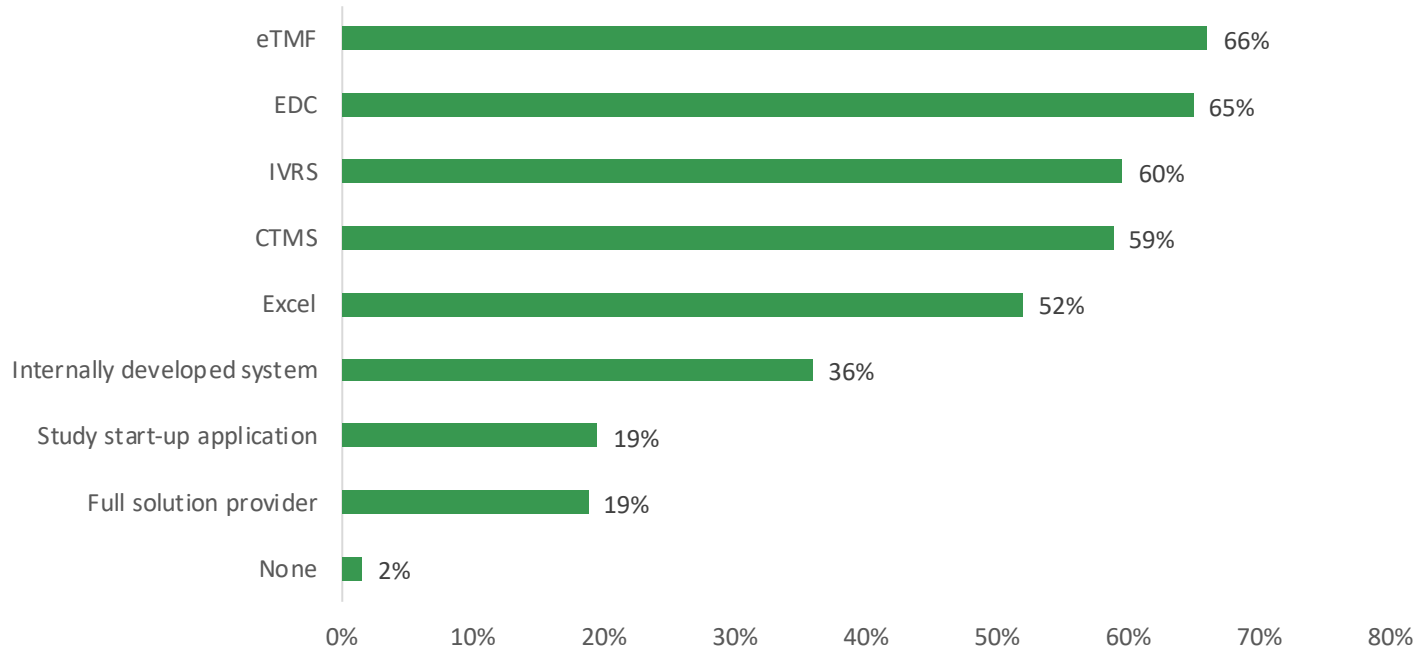
Subset Comparison: Applications to Manage Site Collaboration Process (sponsors and CROs)

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

Application	Sponsor (n=187)	CRO (n=75)
eTMF	66%	70%
EDC	65%	69%
IVRS	60%	62%
CTMS	56%	69%
Excel	50%	59%
Internally developed system	36%	38%
Study start-up application	18%	23%
Full solution provider	18%	20%
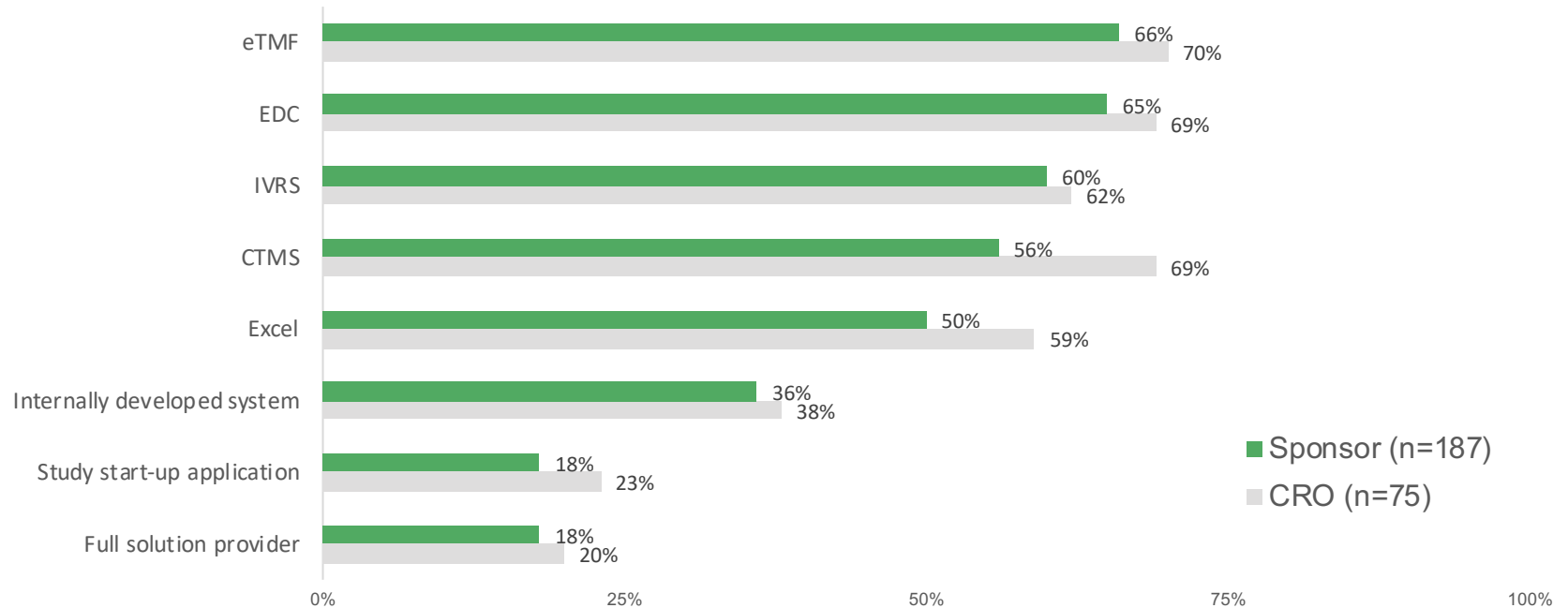
Subset Comparison: Applications to Manage Site Collaboration Process (by trial volume)

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

| Application	1-10 trials (n=101)	11-50 trials (n=79)	>50 trials (n=82)
eTMF	61%	62%	79%
EDC	65%	63%	69%
IVRS	49%	68%	67%
CTMS	44%	66%	73%
Excel	55%	56%	47%
Internally developed system	35%	42%	33%
Study start-up application	15%	24%	21%
Full solution provider	11%	27%	21%
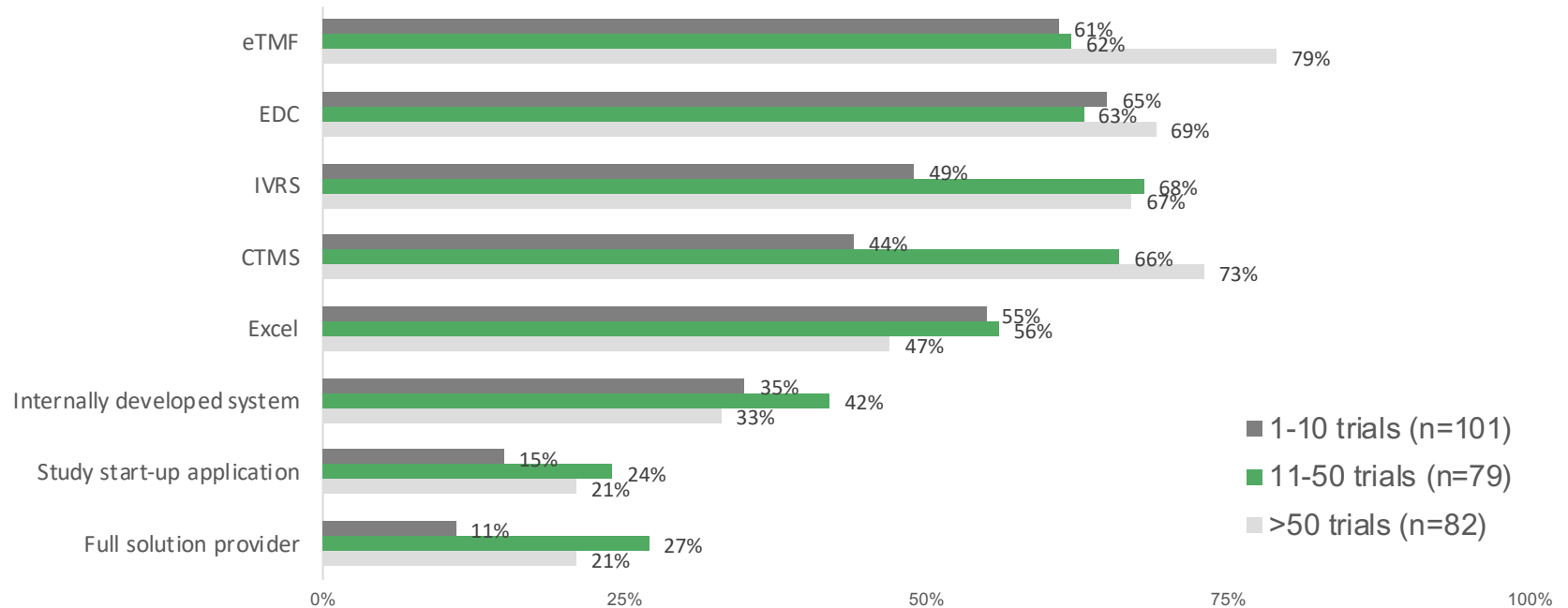
Challenges/Satisfaction: CTMS

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)
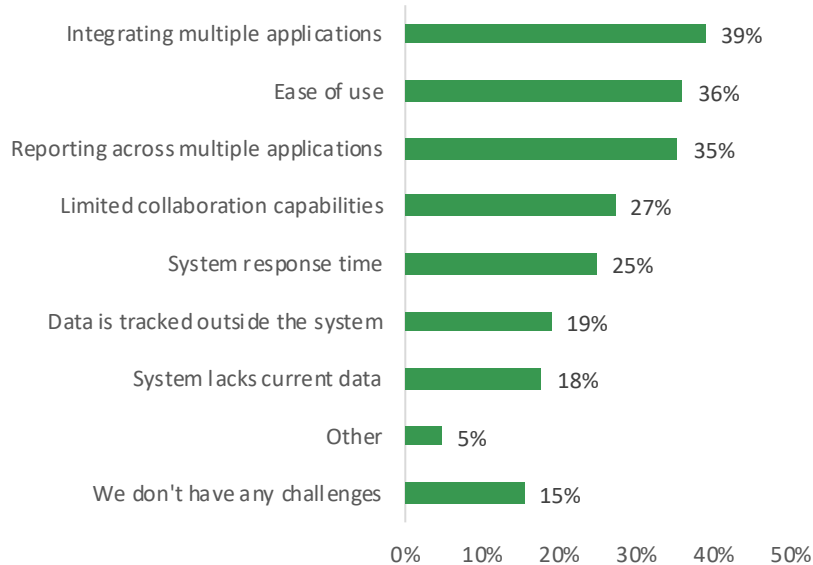
Challenge	%
Integrating multiple applications	45%
Reporting across multiple applications	44%
Ease of use	44%
Limited collaboration capabilities	31%
Data is tracked outside the system	29%
System lacks current data	26%
System response time	25%
Other	1%
We don't have any challenges	9%
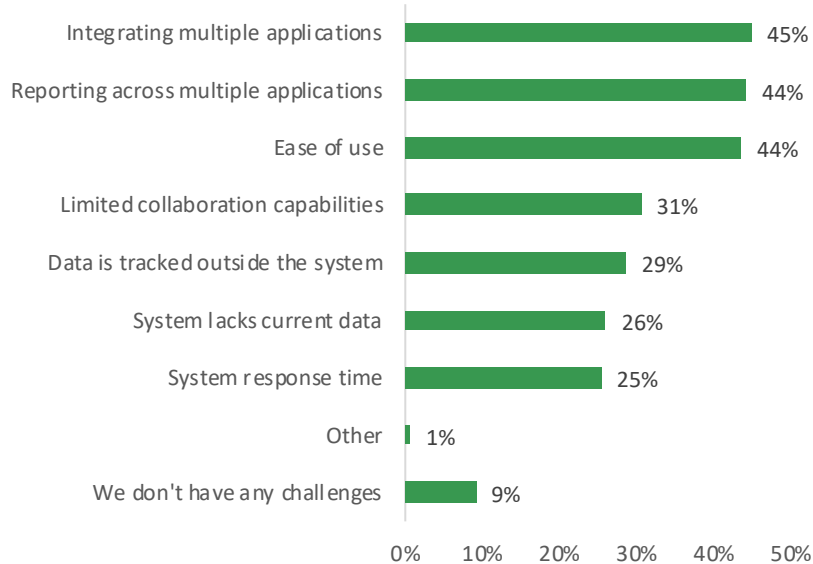
How satisfied are you with your current CTMS application? (only those who selected "CTMS" received this question, n=154)

- Highly satisfied — 18%
- Moderately satisfied — 51%
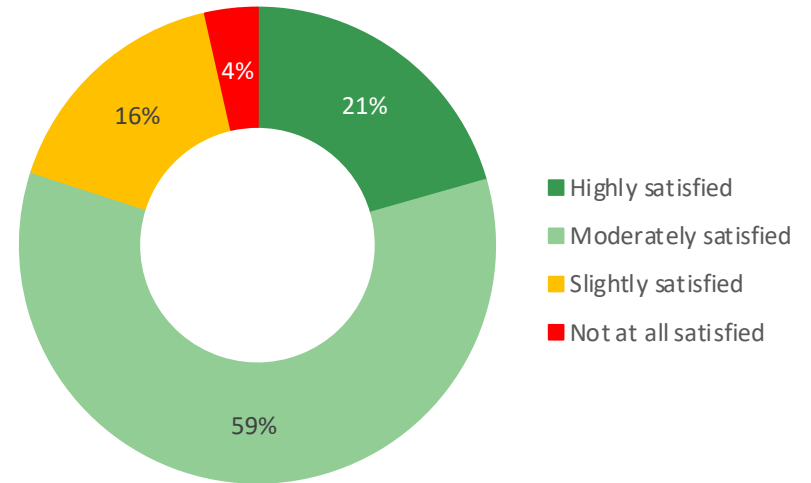- Slightly satisfied — 27%
- Not at all satisfied — 4%
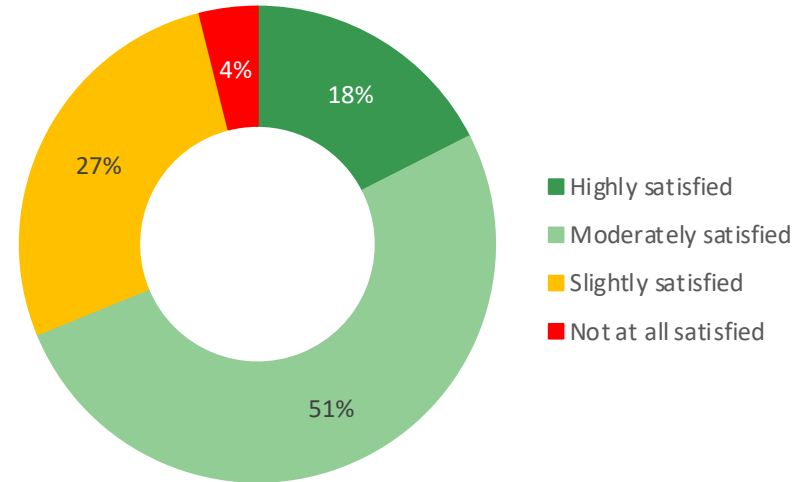
Challenges/Satisfaction: IVRS

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)

Challenge	%
Integrating multiple applications	39%
Reporting across multiple applications	30%
System response time	23%
Ease of use	22%
Data is tracked outside the system	22%
Limited collaboration capabilities	22%
System lacks current data	12%
Other	4%
We don't have any challenges	24%
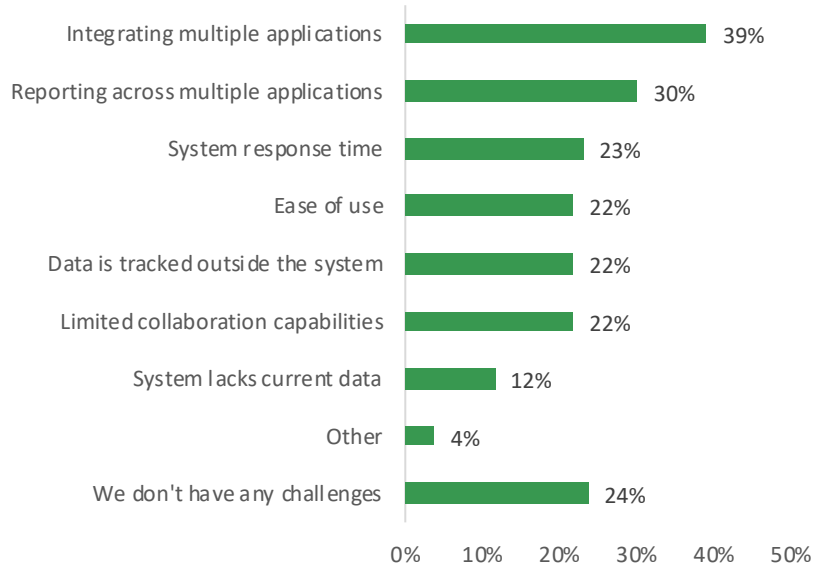
How satisfied are you with your current IVRS application? (only those who selected "IVRS" received this question, n=156)

- Highly satisfied: 26%
- Moderately satisfied: 62%
- Slightly satisfied: 12%
- Not at all satisfied: 1%
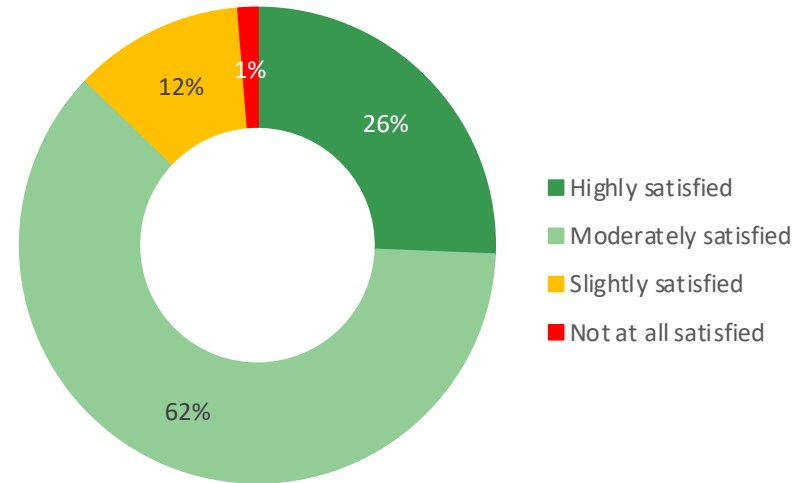
Challenges/Satisfaction: eTMF

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)
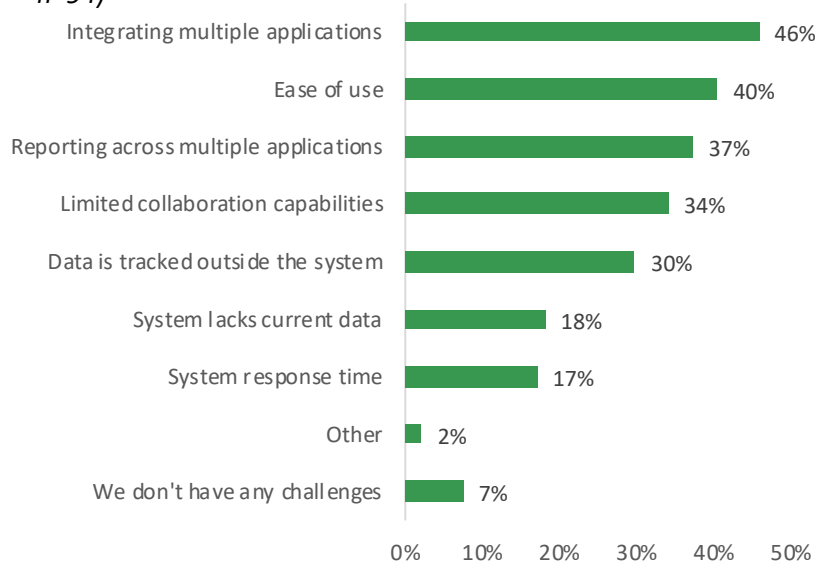
Challenge	%
Ease of use	45%
Limited collaboration capabilities	30%
Integrating multiple applications	30%
Reporting across multiple applications	26%
Data is tracked outside the system	24%
System response time	23%
System lacks current data	20%
Other	5%
We don't have any challenges	14%
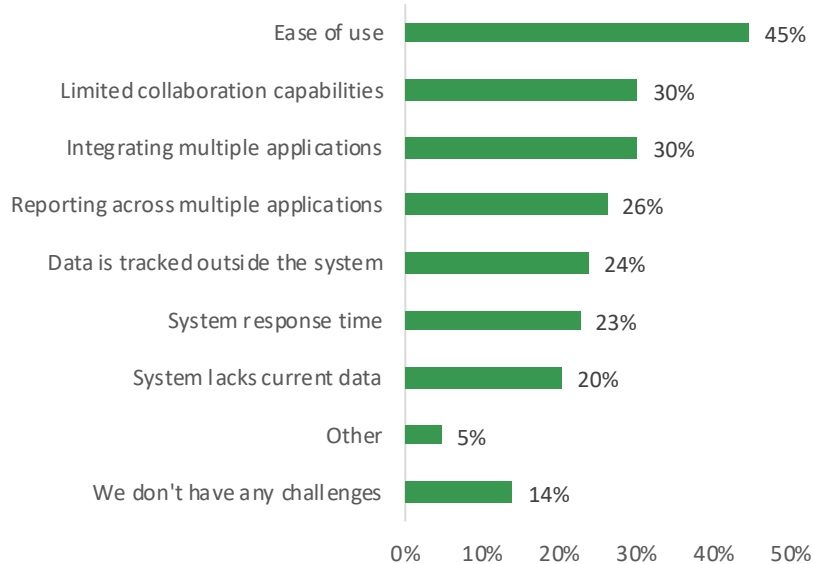
How satisfied are you with your current eTMF application? (only those who selected "eTMF" received this question, n=173)

- Highly satisfied — 14%
- Moderately satisfied — 61%
- Slightly satisfied — 20%
- Not at all satisfied — 5%
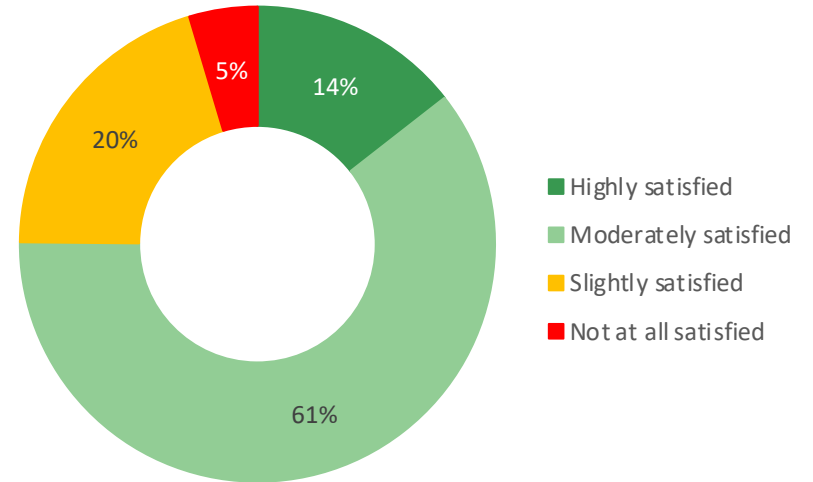
Challenges/Satisfaction: EDC

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)

Challenge	%
Integrating multiple applications	39%
Ease of use	36%
Reporting across multiple applications	35%
Limited collaboration capabilities	27%
System response time	25%
Data is tracked outside the system	19%
System lacks current data	18%
Other	5%
We don't have any challenges	15%

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

- Highly satisfied: 21%
- Moderately satisfied: 59%
- Slightly satisfied: 16%
- Not at all satisfied: 4%

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)
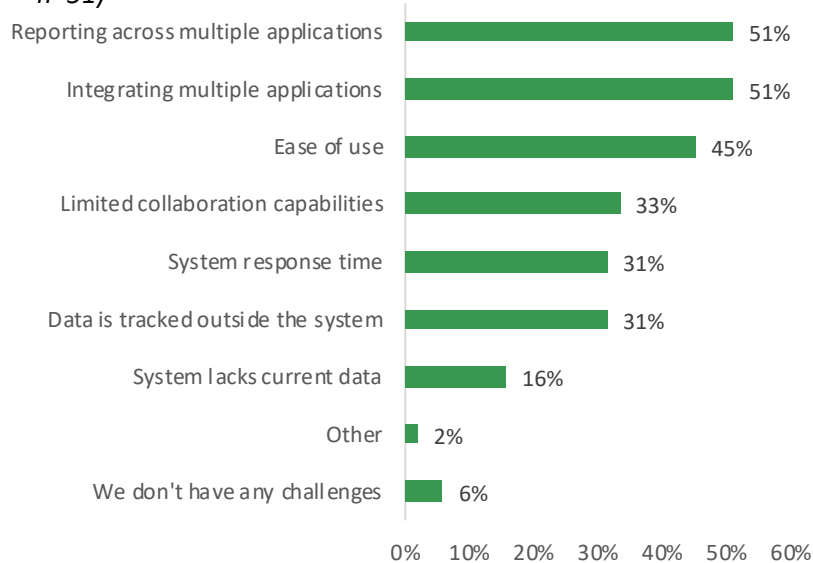

- Integrating multiple applications: 46%
- Ease of use: 40%
- Reporting across multiple applications: 37%
- Limited collaboration capabilities: 34%
- Data is tracked outside the system: 30%
- System lacks current data: 18%
- System response time: 17%
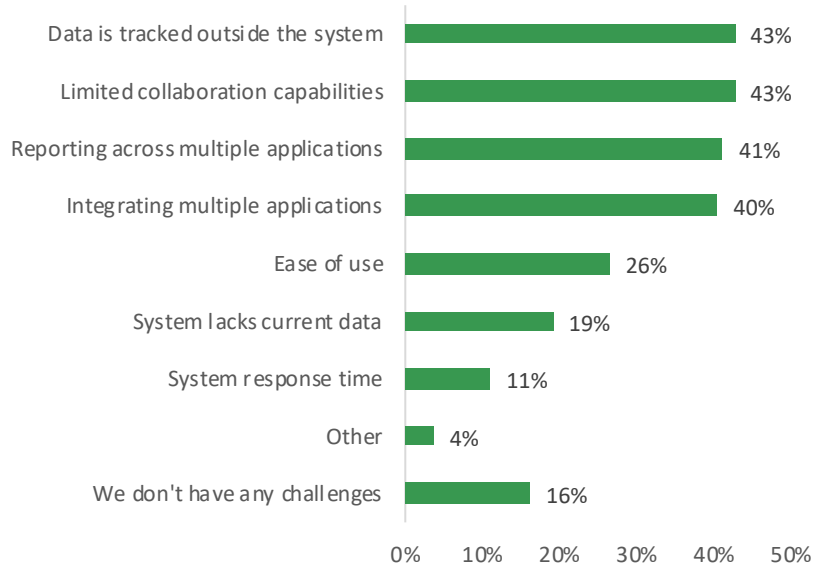- Other: 2%
- We don't have any challenges: 7%

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

- Highly satisfied: 9%
- Moderately satisfied: 60%
- Slightly satisfied: 22%
- Not at all satisfied: 10%
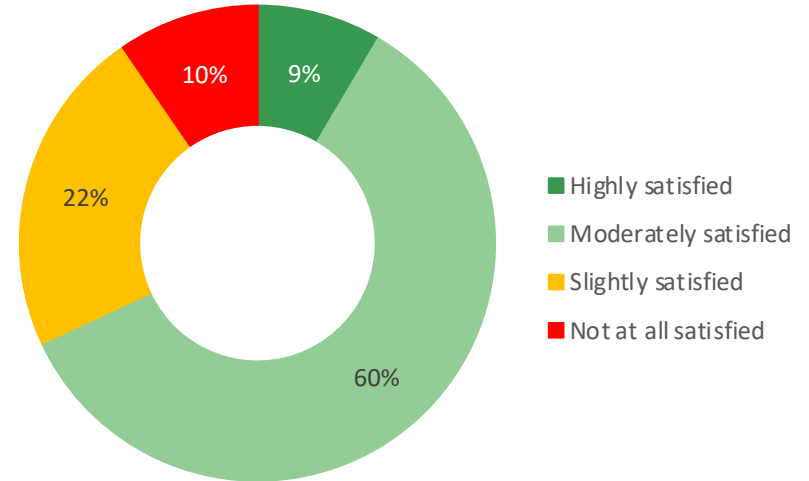
Challenges/Satisfaction: Study Startup Application

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)

Challenge	%
Reporting across multiple applications	51%
Integrating multiple applications	51%
Ease of use	45%
Limited collaboration capabilities	33%
System response time	31%
Data is tracked outside the system	31%
System lacks current data	16%
Other	2%
We don't have any challenges	6%

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

- Highly satisfied — 14%
- Moderately satisfied — 63%
- Slightly satisfied — 20%
- Not at all satisfied — 4%
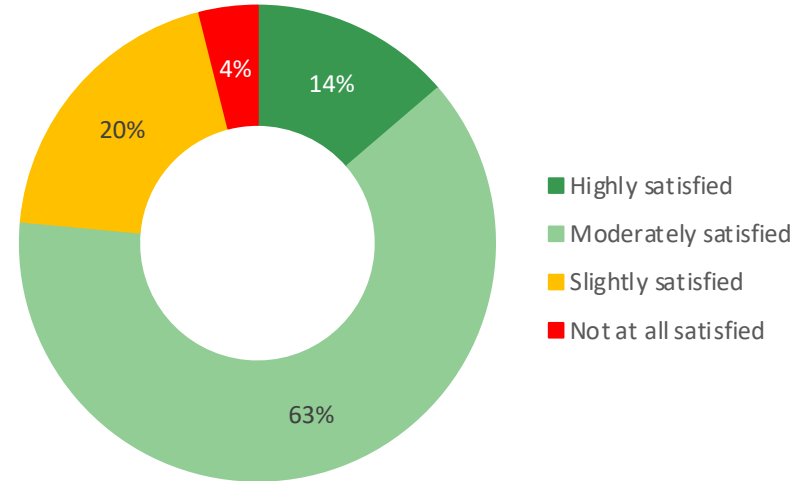
Challenges/Satisfaction: Excel

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)
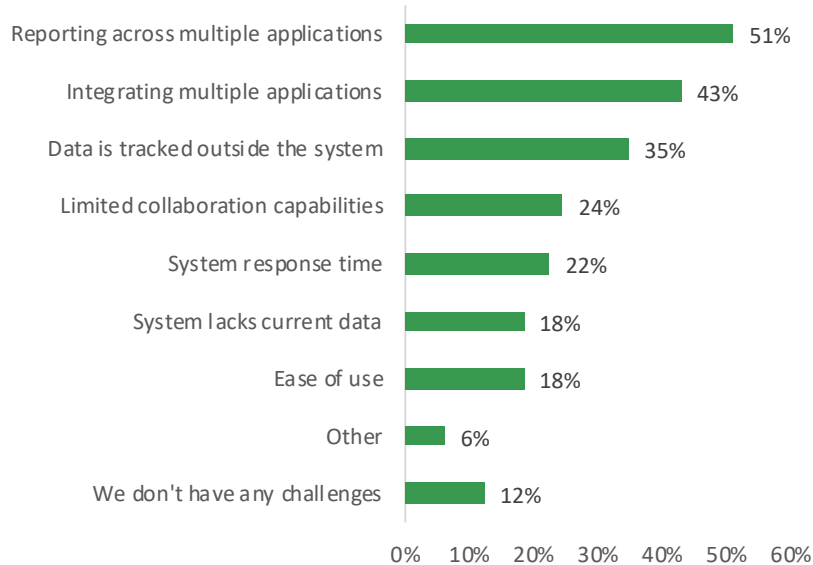
Challenge	%
Data is tracked outside the system	43%
Limited collaboration capabilities	43%
Reporting across multiple applications	41%
Integrating multiple applications	40%
Ease of use	26%
System lacks current data	19%
System response time	11%
Other	4%
We don't have any challenges	16%

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

- Highly satisfied — 24%
- Moderately satisfied — 37%
- Slightly satisfied — 28%
- Not at all satisfied — 12%
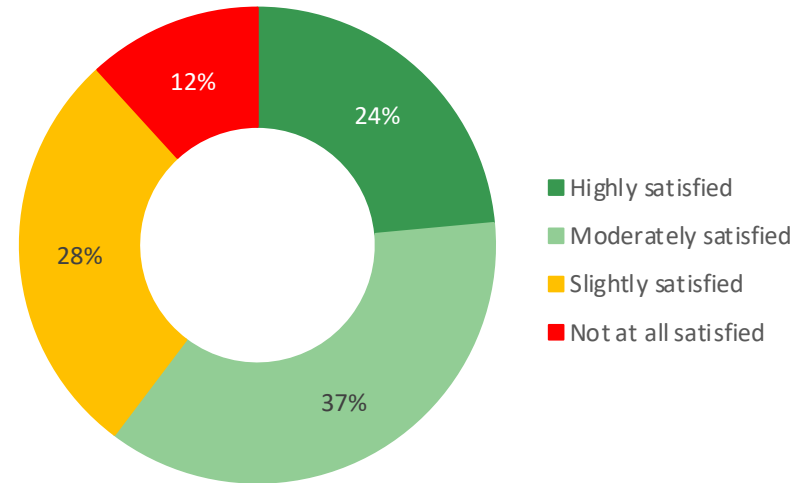
Challenges/Satisfaction: Full Solution Provider

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)
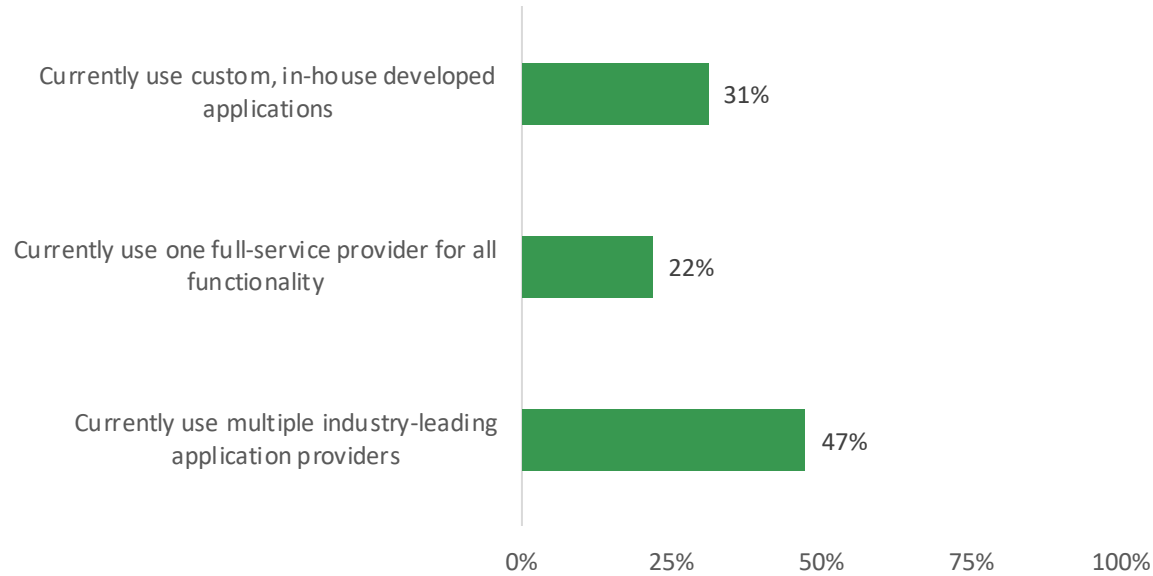
Challenge	Percentage
Reporting across multiple applications	51%
Integrating multiple applications	43%
Data is tracked outside the system	35%
Limited collaboration capabilities	24%
System response time	22%
System lacks current data	18%
Ease of use	18%
Other	6%
We don't have any challenges	12%

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

Satisfaction	Percentage
Highly satisfied	20%
Moderately satisfied	53%
Slightly satisfied	27%
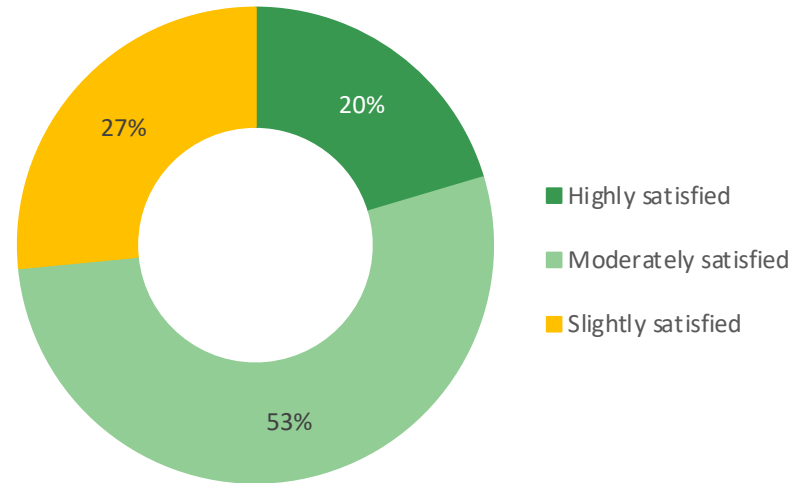
Application Provider Use

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)

Currently use custom, in-house developed applications — 31%

Currently use one full-service provider for all functionality — 22%

Currently use multiple industry-leading application providers — 47%

0%   25%   50%   75%   100%

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)
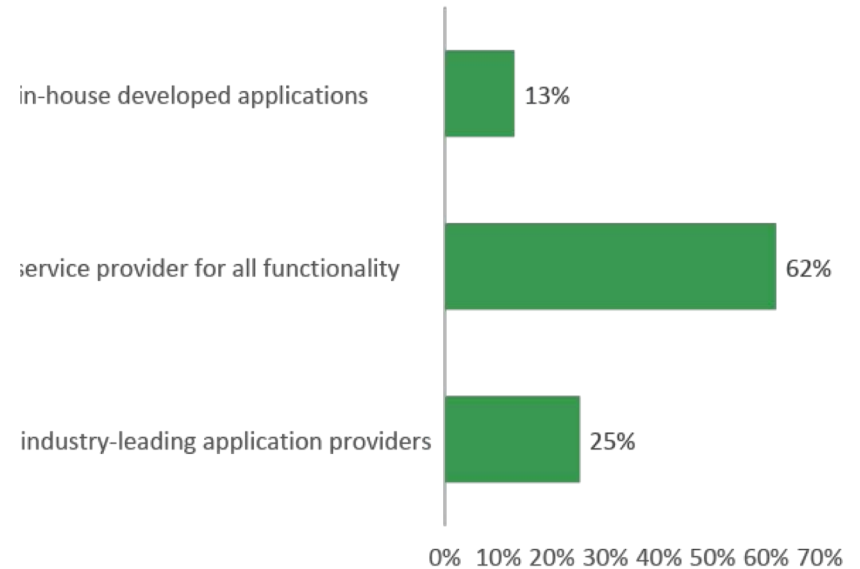

Category	Percentage
One-stop-shop	42%
Best-of-breed	36%
In-house development	23%
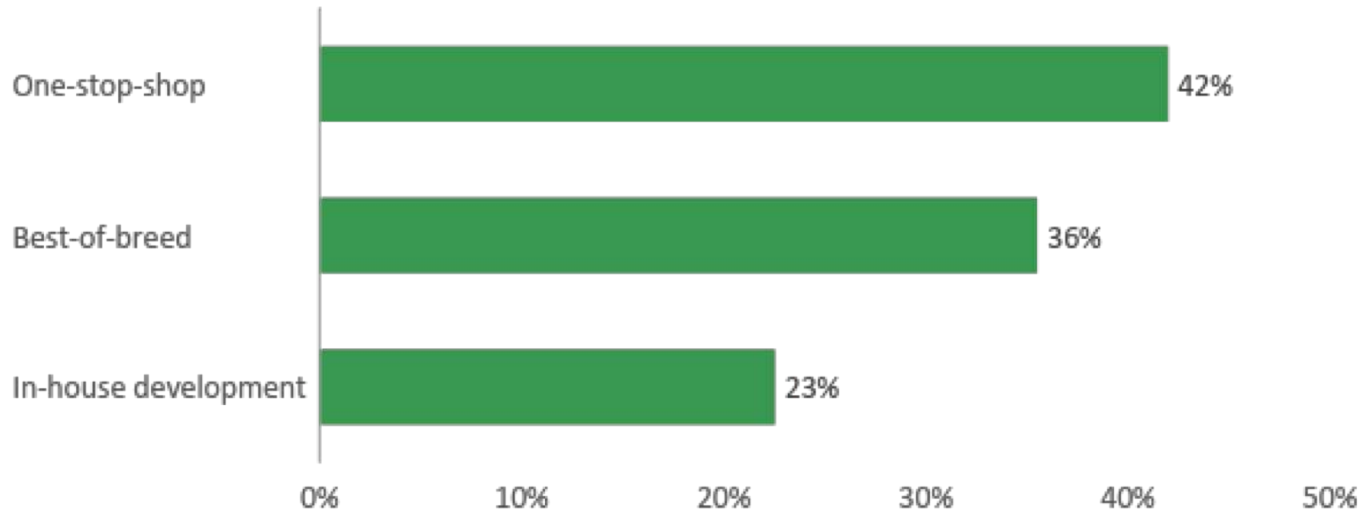
Application Provider Use vs. Preference

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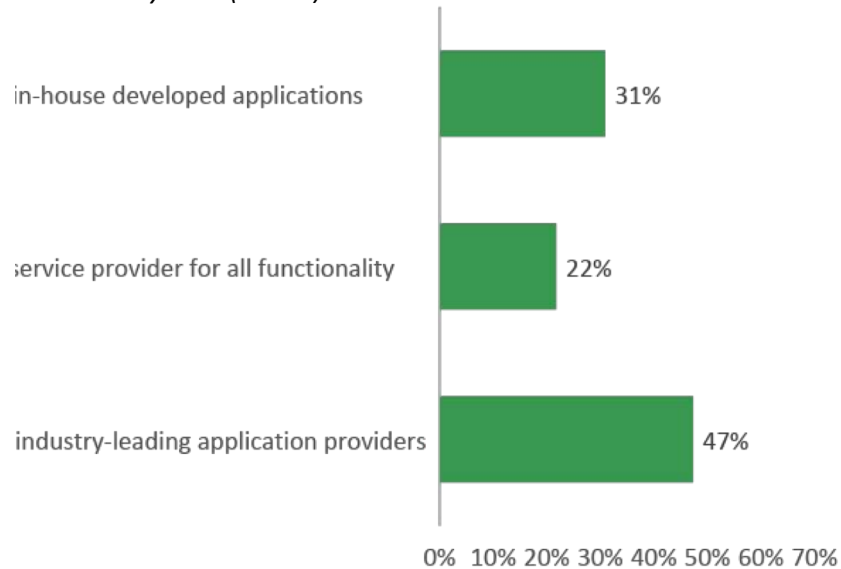
If the choice were completely up to you, what would you prefer to use for "site selection", "site activation", "quality management system", and "study execution software"? (n=262)

Left chart:
- in-house developed applications — 31%
- service provider for all functionality — 22%
- industry-leading application providers — 47%

Right chart:
- in-house developed applications — 13%
- service provider for all functionality — 62%
- industry-leading application providers — 25%

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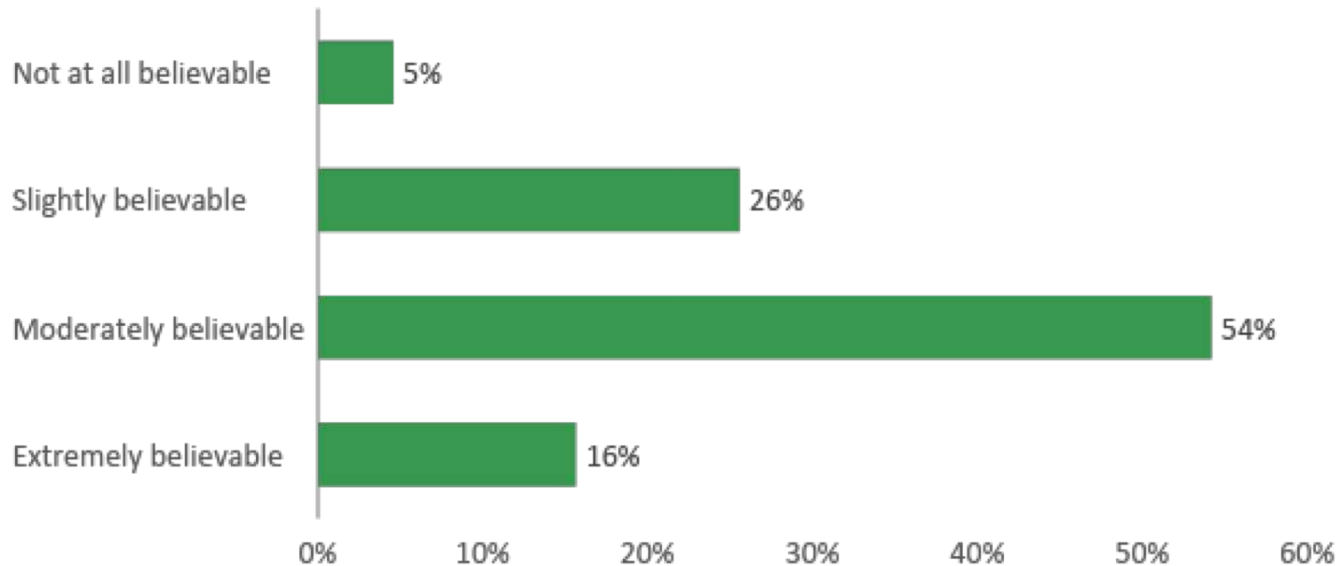
Technology Implementation Plans to Meet Challenges
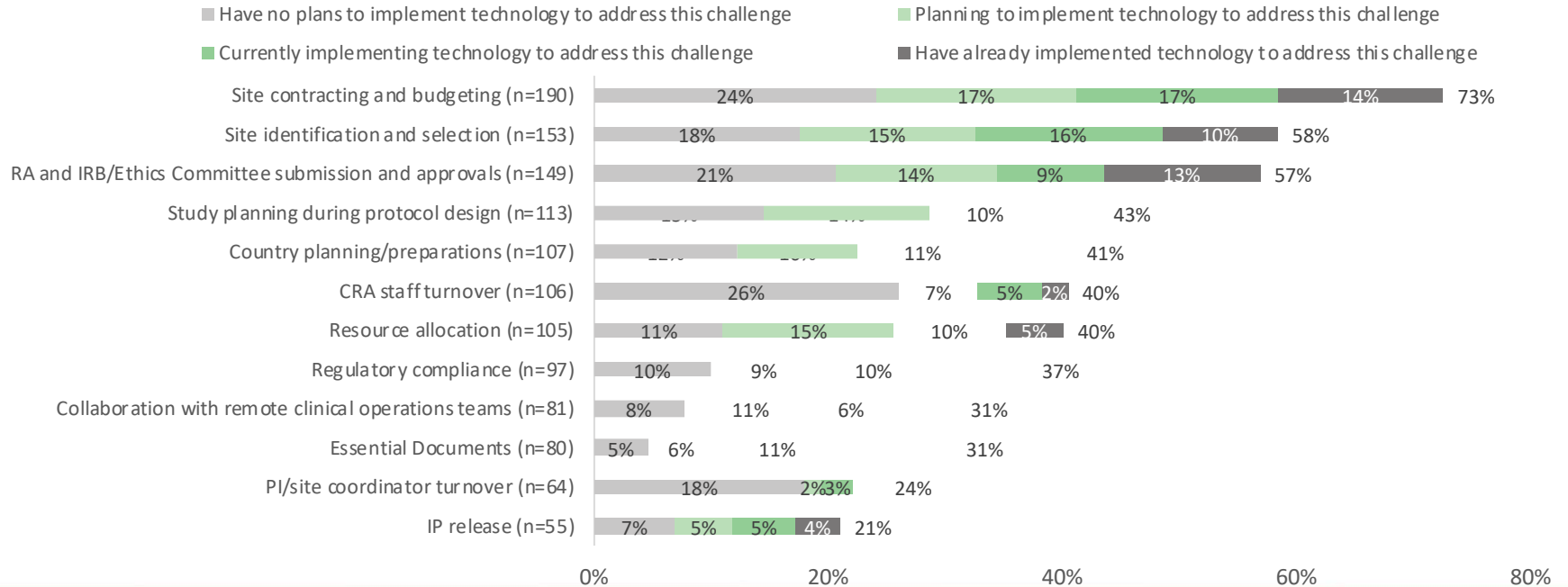
Below are the five challenges you previously selected regarding the site collaboration processes. For each (row), please select your company's technology implementation plans to meet those challenges, if any. (analysis based on challenge n/262)

Legend:
- Have no plans to implement technology to address this challenge
- Planning to implement technology to address this challenge
- Currently implementing technology to address this challenge
- Have already implemented technology to address this challenge

Challenge	No plans	Planning	Currently	Already	Total
Site contracting and budgeting (n=190)	24%	17%	17%	14%	73%
Site identification and selection (n=153)	18%	15%	16%	10%	58%
RA and IRB/Ethics Committee submission and approvals (n=149)	21%	14%	9%	13%	57%
Study planning during protocol design (n=113)			10%		43%
Country planning/preparations (n=107)			11%		41%
CRA staff turnover (n=106)	26%	7%	5%	2%	40%
Resource allocation (n=105)	11%	15%	10%	5%	40%
Regulatory compliance (n=97)	10%	9%	10%		37%
Collaboration with remote clinical operations teams (n=81)	8%	11%	6%		31%
Essential Documents (n=80)	5%	6%	11%		31%
PI/site coordinator turnover (n=64)	18%	2%	3%		24%
IP release (n=55)	7%	5%	5%	4%	21%

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)

Legend:
- Not looking at options, no budget or plan in place
- Currently looking at options, but no budget allocated
- Implementation plans are budgeted and planned for, but not in pilot stage
- Pilot implementations are currently in progress
- Enterprise/full deployments are in place

Application	Not looking at options	Currently looking at options	Budgeted and planned	Pilot in progress	Enterprise/full deployment
Full solution provider	43%	26%	8%	11%	12%
Internally developed system	39%	13%	13%	12%	22%
Study start-up application	39%	23%	13%	13%	13%
IVRS	37%	11%	10%	9%	33%
CTMS	33%	19%	11%	12%	25%
EDC	30%	16%	9%	10%	36%
eTMF	28%	16%	10%	14%	32%

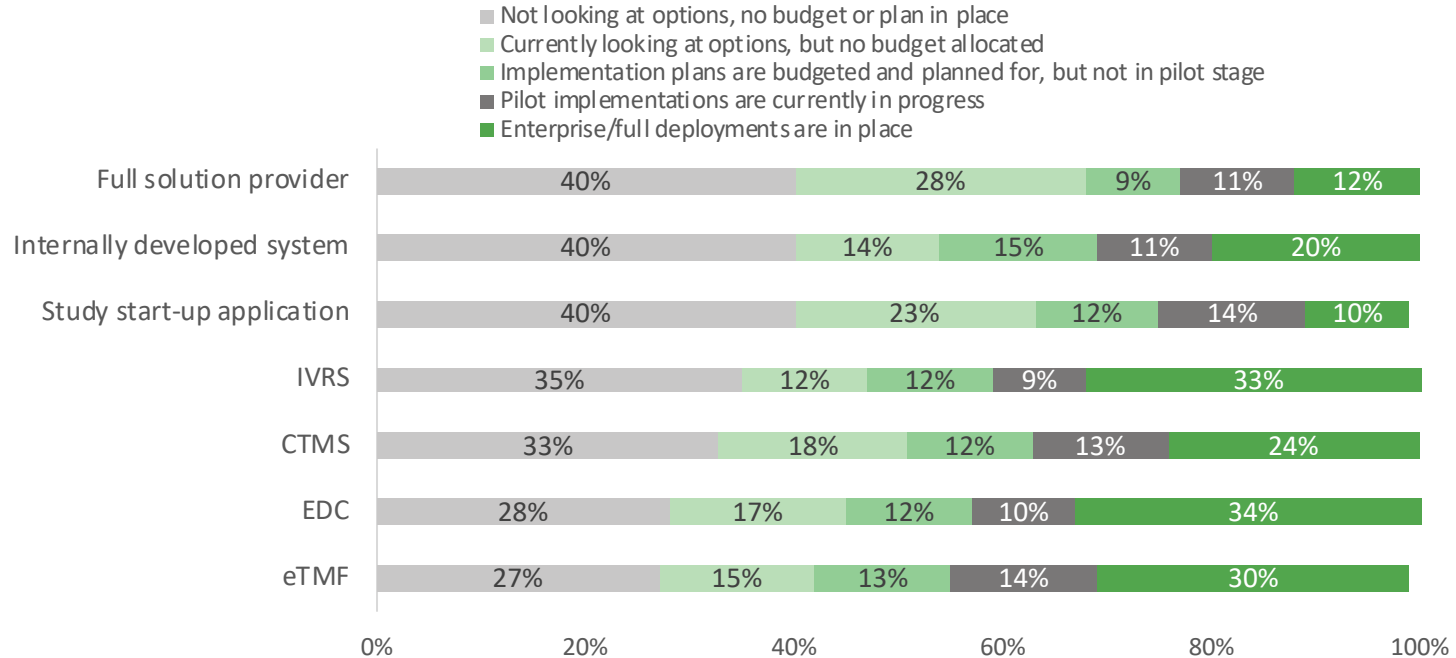# **Sponsors**: Technology Implementation Plans by Application

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)

Legend:
- Not looking at options, no budget or plan in place
- Currently looking at options, but no budget allocated
- Implementation plans are budgeted and planned for, but not in pilot stage
- Pilot implementations are currently in progress
- Enterprise/full deployments are in place

Application	Not looking at options, no budget or plan in place	Currently looking at options, but no budget allocated	Implementation plans are budgeted and planned for, but not in pilot stage	Pilot implementations are currently in progress	Enterprise/full deployments are in place
Full solution provider	40%	28%	9%	11%	12%
Internally developed system	40%	14%	15%	11%	20%
Study start-up application	40%	23%	12%	14%	10%
IVRS	35%	12%	12%	9%	33%
CTMS	33%	18%	12%	13%	24%
EDC	28%	17%	12%	10%	34%
eTMF	27%	15%	13%	14%	30%

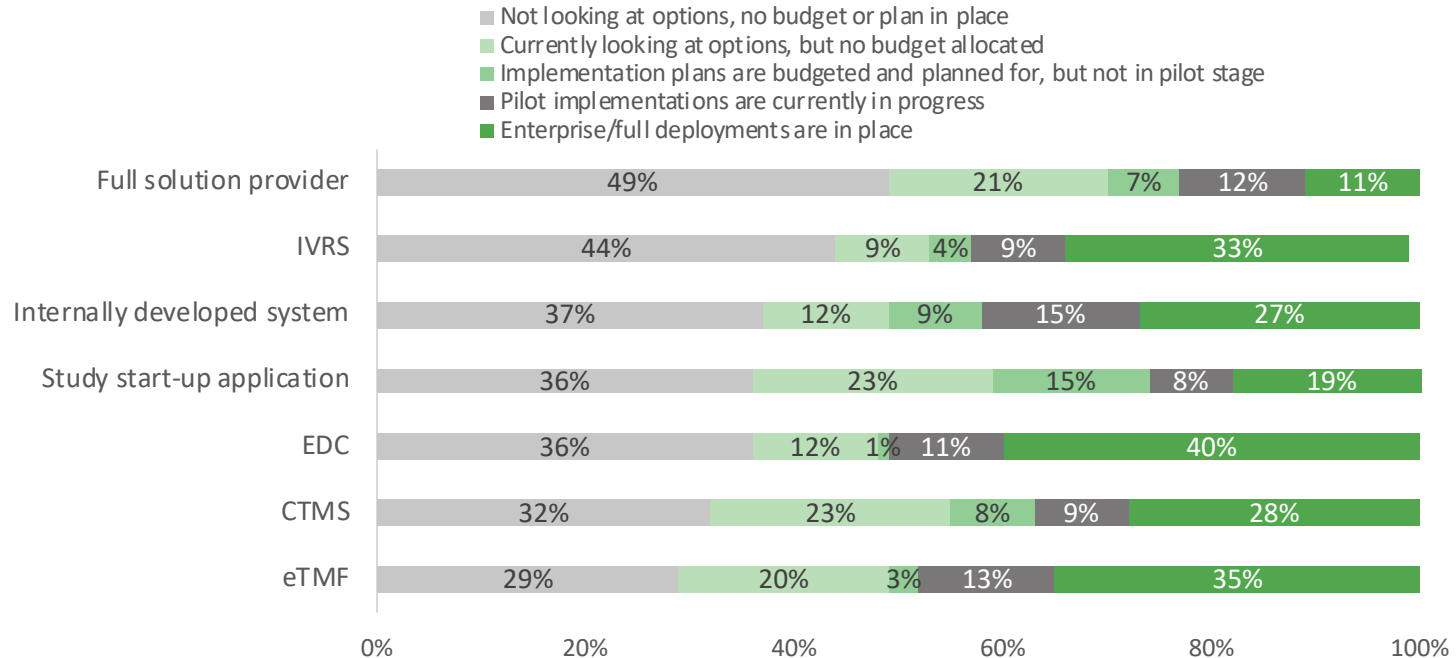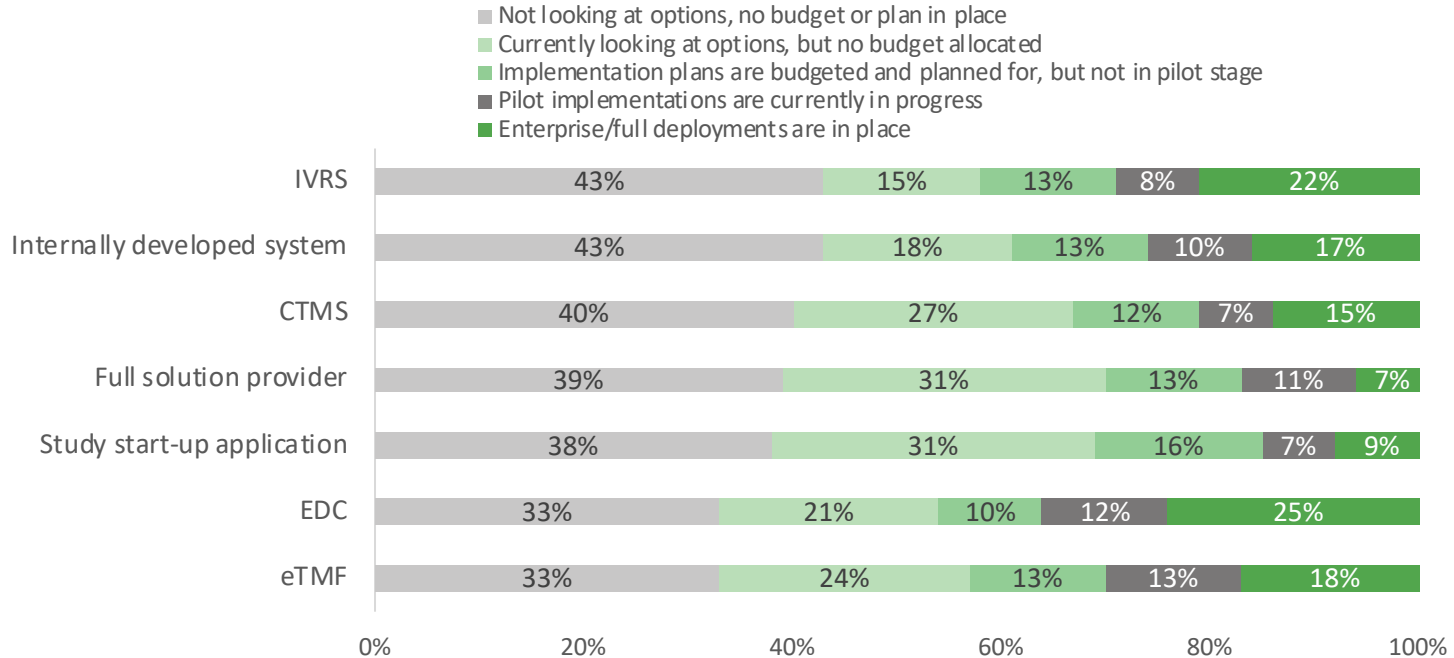# **CROs**: Technology Implementation Plans by Application

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)

Legend:
- ☐ Not looking at options, no budget or plan in place
- ☐ Currently looking at options, but no budget allocated
- ☐ Implementation plans are budgeted and planned for, but not in pilot stage
- ☐ Pilot implementations are currently in progress
- ☐ Enterprise/full deployments are in place

Application	Not looking at options, no budget or plan in place	Currently looking at options, but no budget allocated	Implementation plans are budgeted and planned for, but not in pilot stage	Pilot implementations are currently in progress	Enterprise/full deployments are in place
Full solution provider	49%	21%	7%	12%	11%
IVRS	44%	9%	4%	9%	33%
Internally developed system	37%	12%	9%	15%	27%
Study start-up application	36%	23%	15%	8%	19%
EDC	36%	12%	1%	11%	40%
CTMS	32%	23%	8%	9%	28%
eTMF	29%	20%	3%	13%	35%

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)
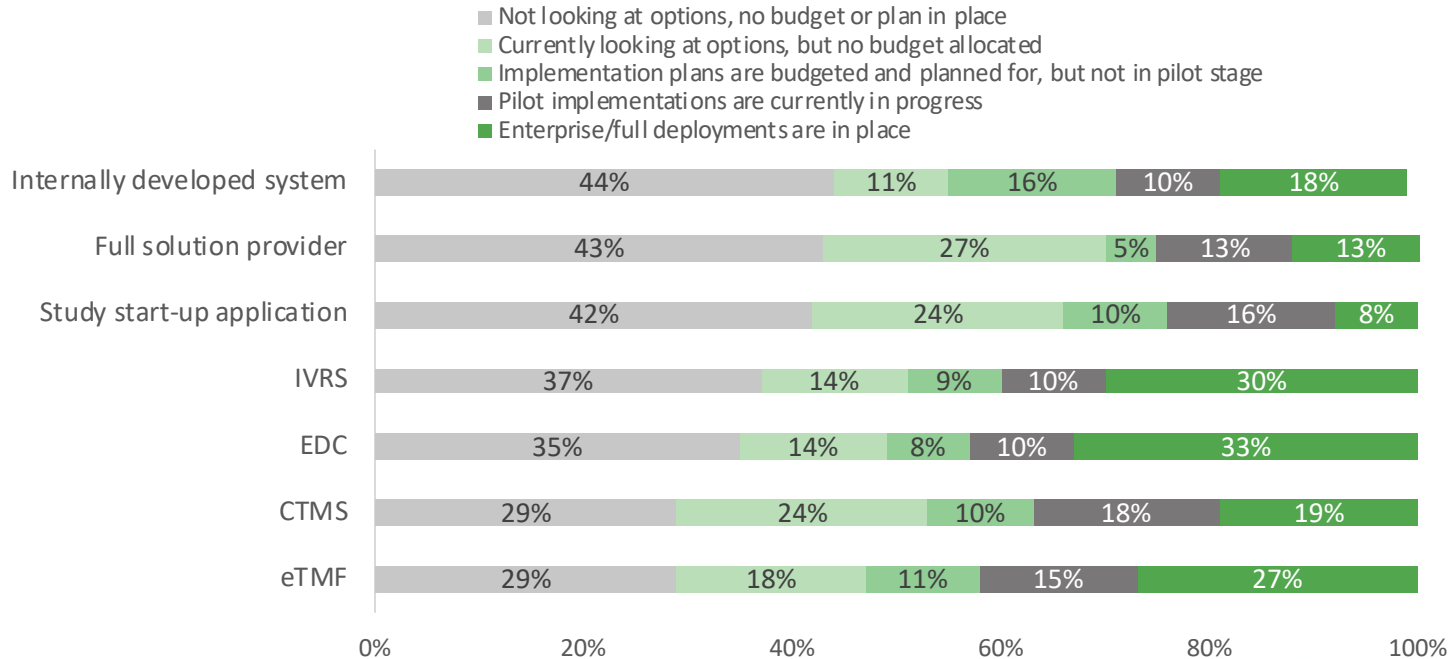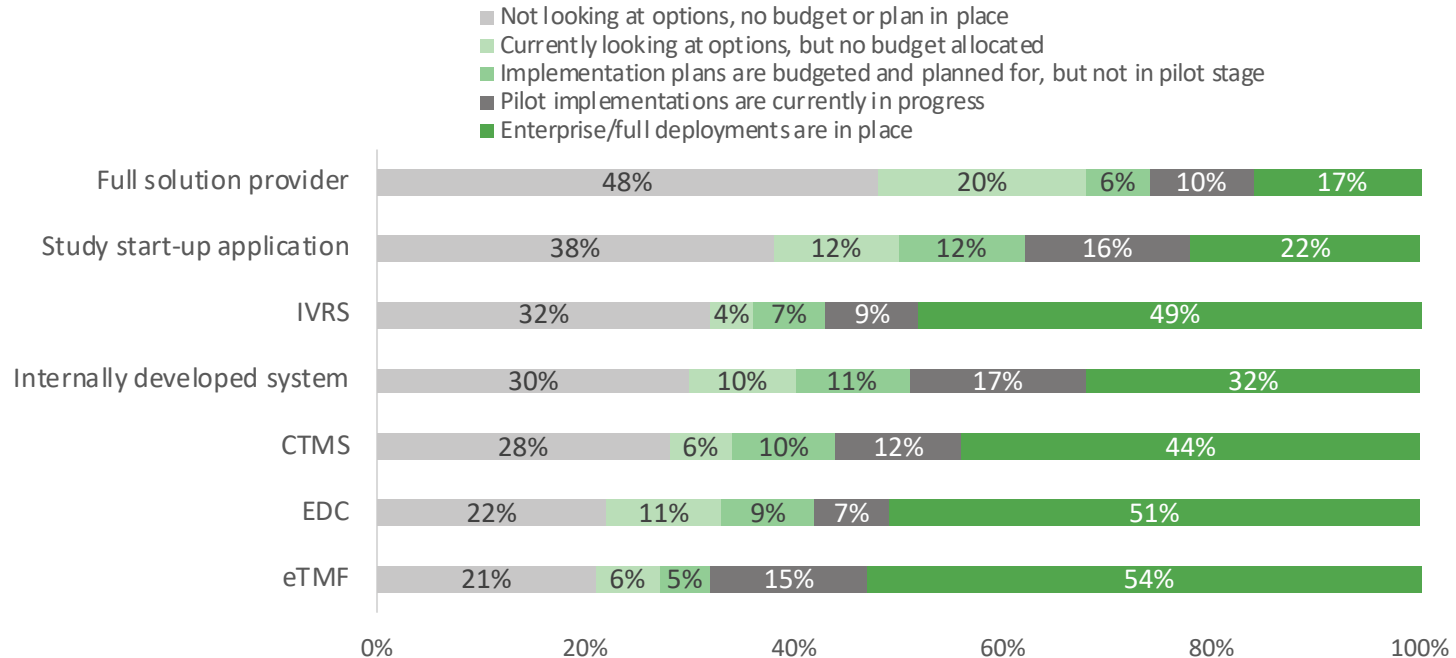
Legend:
- Not looking at options, no budget or plan in place
- Currently looking at options, but no budget allocated
- Implementation plans are budgeted and planned for, but not in pilot stage
- Pilot implementations are currently in progress
- Enterprise/full deployments are in place

Application	Not looking at options	Currently looking	Budgeted/planned	Pilot in progress	Enterprise/full
IVRS	43%	15%	13%	8%	22%
Internally developed system	43%	18%	13%	10%	17%
CTMS	40%	27%	12%	7%	15%
Full solution provider	39%	31%	13%	11%	7%
Study start-up application	38%	31%	16%	7%	9%
EDC	33%	21%	10%	12%	25%
eTMF	33%	24%	13%	13%	18%

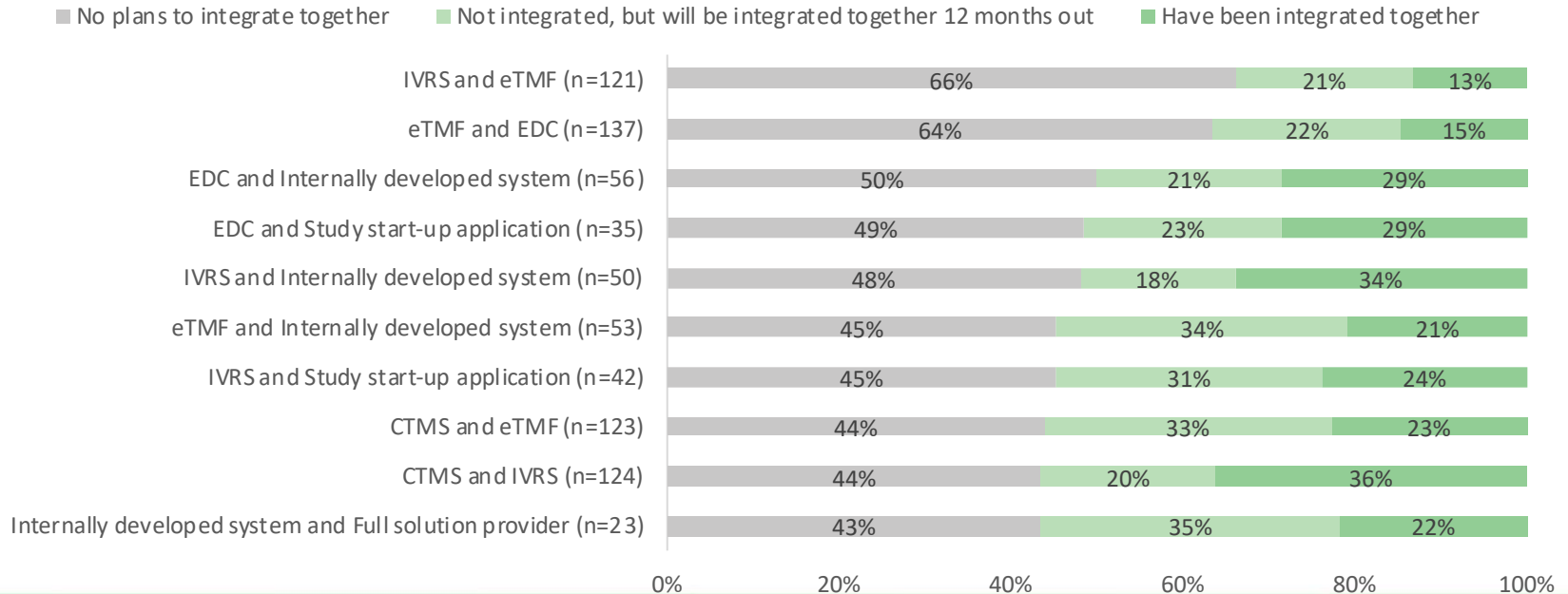# 11-50 Trials: Technology Implementation Plans by Application

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)

Legend:
- Not looking at options, no budget or plan in place
- Currently looking at options, but no budget allocated
- Implementation plans are budgeted and planned for, but not in pilot stage
- Pilot implementations are currently in progress
- Enterprise/full deployments are in place

Application	Not looking at options, no budget or plan in place	Currently looking at options, but no budget allocated	Implementation plans are budgeted and planned for, but not in pilot stage	Pilot implementations are currently in progress	Enterprise/full deployments are in place
Internally developed system	44%	11%	16%	10%	18%
Full solution provider	43%	27%	5%	13%	13%
Study start-up application	42%	24%	10%	16%	8%
IVRS	37%	14%	9%	10%	30%
EDC	35%	14%	8%	10%	33%
CTMS	29%	24%	10%	18%	19%
eTMF	29%	18%	11%	15%	27%

>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)

Legend:
- Not looking at options, no budget or plan in place
- Currently looking at options, but no budget allocated
- Implementation plans are budgeted and planned for, but not in pilot stage
- Pilot implementations are currently in progress
- Enterprise/full deployments are in place

Application	Not looking	Currently looking	Budgeted/planned	Pilot in progress	Enterprise/full
Full solution provider	48%	20%	6%	10%	17%
Study start-up application	38%	12%	12%	16%	22%
IVRS	32%	4%	7%	9%	49%
Internally developed system	30%	10%	11%	17%	32%
CTMS	28%	6%	10%	12%	44%
EDC	22%	11%	9%	7%	51%
eTMF	21%	6%	5%	15%	54%

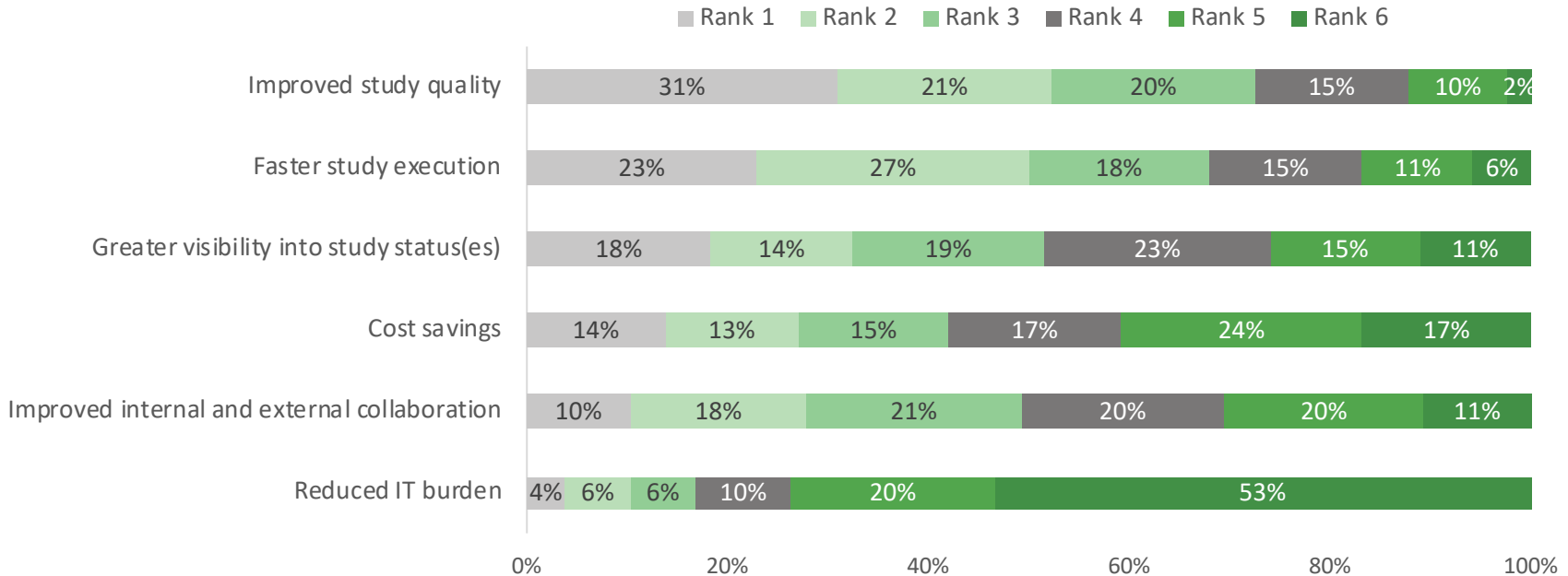# Integration of Current Applications: Respondent Selected (1)

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)

Legend:
- No plans to integrate together
- Not integrated, but will be integrated together 12 months out
- Have been integrated together

Pairing	No plans to integrate together	Not integrated, but will be integrated together 12 months out	Have been integrated together
IVRS and eTMF (n=121)	66%	21%	13%
eTMF and EDC (n=137)	64%	22%	15%
EDC and Internally developed system (n=56)	50%	21%	29%
EDC and Study start-up application (n=35)	49%	23%	29%
IVRS and Internally developed system (n=50)	48%	18%	34%
eTMF and Internally developed system (n=53)	45%	34%	21%
IVRS and Study start-up application (n=42)	45%	31%	24%
CTMS and eTMF (n=123)	44%	33%	23%
CTMS and IVRS (n=124)	44%	20%	36%
Internally developed system and Full solution provider (n=23)	43%	35%	22%

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)

- No plans to integrate together
- Not integrated, but will be integrated together 12 months out
- Have been integrated together

Pairing	No plans to integrate together	Not integrated, but will be integrated together 12 months out	Have been integrated together
Internally developed system and Study start-up application (n=20)	40%	10%	50%
CTMS and EDC (n=126)	40%	24%	37%
eTMF and Study start-up application (n=38)	39%	32%	29%
CTMS and Internally developed system (n=50)	38%	30%	32%
eTMF and Full solution provider (n=33)	36%	42%	21%
IVRS and EDC (n=130)	35%	22%	44%
Study start-up application and Full solution provider (n=13)	31%	15%	54%
CTMS and Study start-up application (n=39)	31%	44%	26%
CTMS and Full solution provider (n=30)	27%	37%	37%
EDC and Full solution provider (n=33)	24%	48%	27%
IVRS and Full solution provider (n=33)	21%	39%	39%
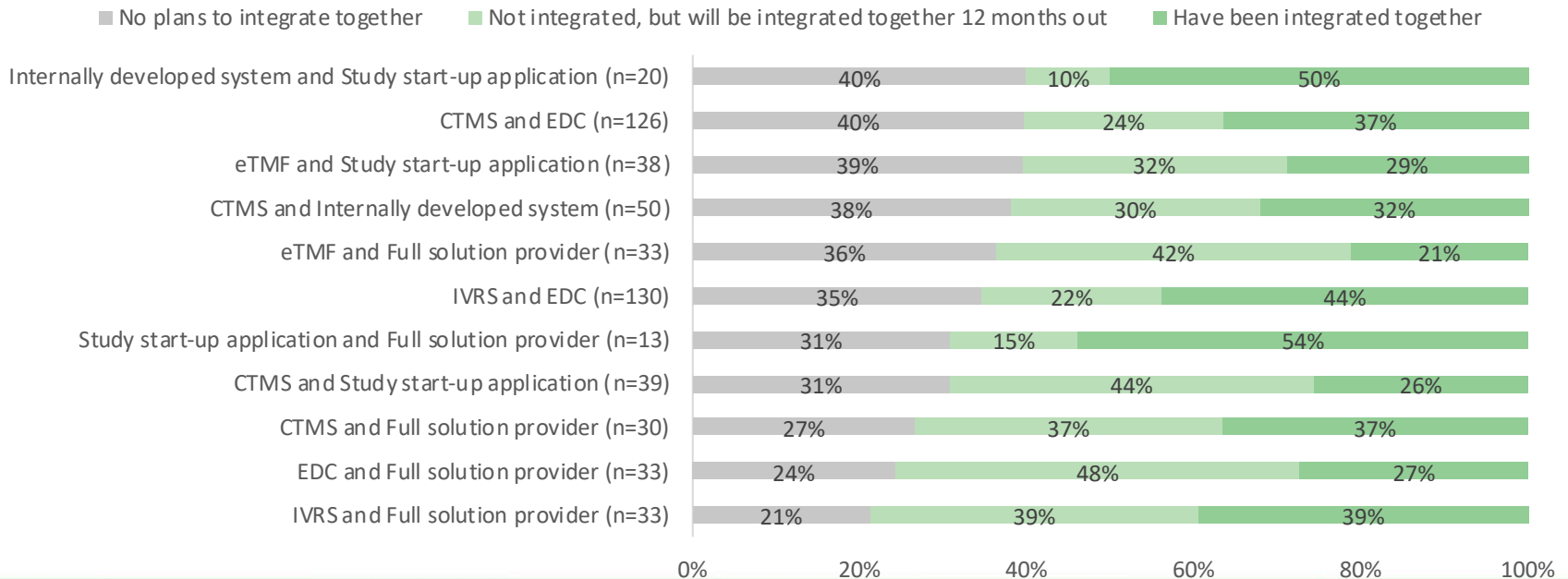
Ranking of Drivers for Clinical Application Integration

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)

Legend: Rank 1, Rank 2, Rank 3, Rank 4, Rank 5, Rank 6

Driver	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5	Rank 6
Improved study quality	31%	21%	20%	15%	10%	2%
Faster study execution	23%	27%	18%	15%	11%	6%
Greater visibility into study status(es)	18%	14%	19%	23%	15%	11%
Cost savings	14%	13%	15%	17%	24%	17%
Improved internal and external collaboration	10%	18%	21%	20%	20%	11%
Reduced IT burden	4%	6%	6%	10%	20%	53%

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)

Driver	Average Ranking
Improved study quality	2.6
Faster study execution	2.8
Greater visibility into study status(es)	3.4
Improved internal and external collaboration	3.5
Cost savings	3.8
Reduced IT burden	5.0

Most important, on average
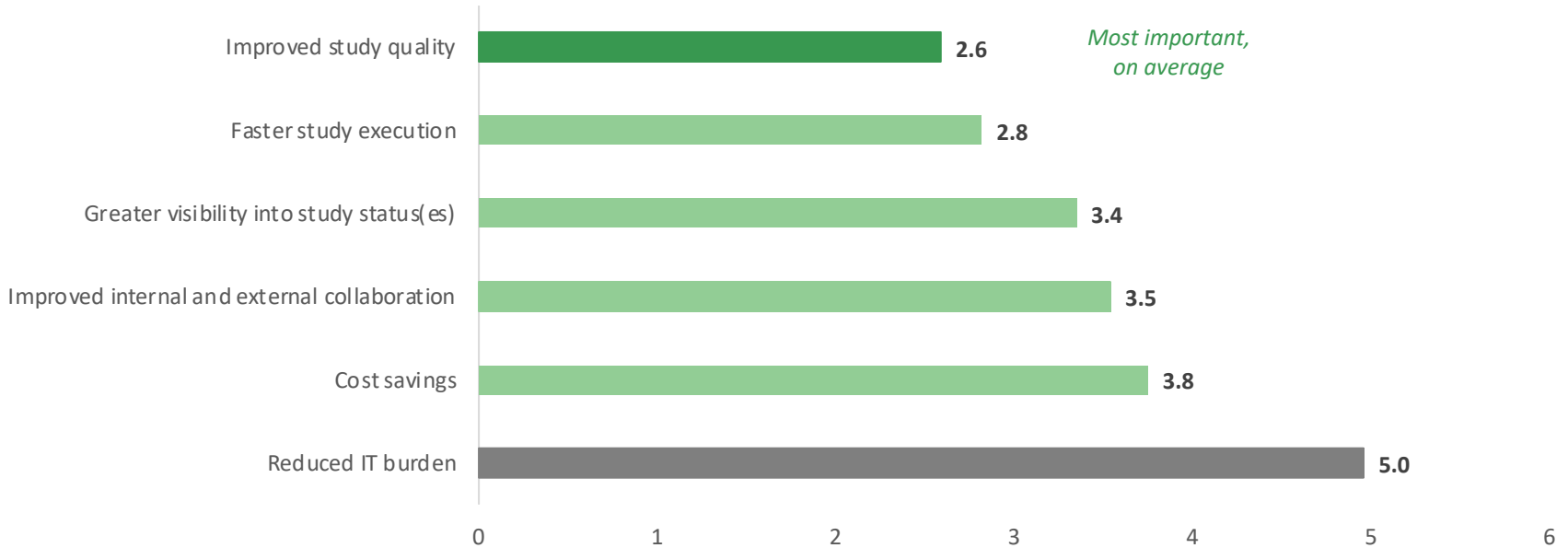
Are There Barriers for Successful Outsourcing?

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

No concerns
41%

Yes
59%
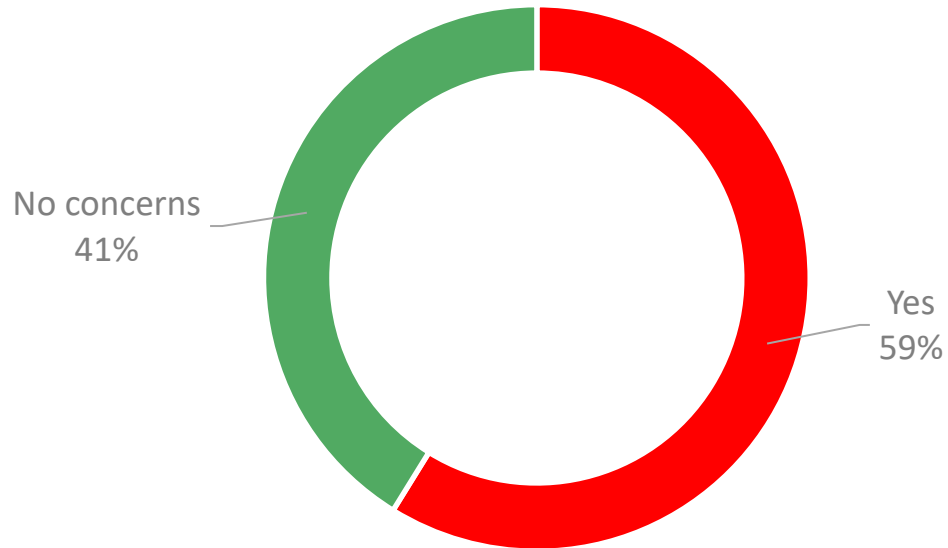
Barriers for Successful Outsourcing

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)

Barrier	Percentage
Difficulties in identifying qualified CROs	72%
Cost of outsourcing is higher than insourcing	68%
Cost of CRO regulatory oversight	57%
Low-tech and difficult options for real-time operation and quality insight	56%
Low-tech and difficult options for regulatory oversight	35%
Other	11%
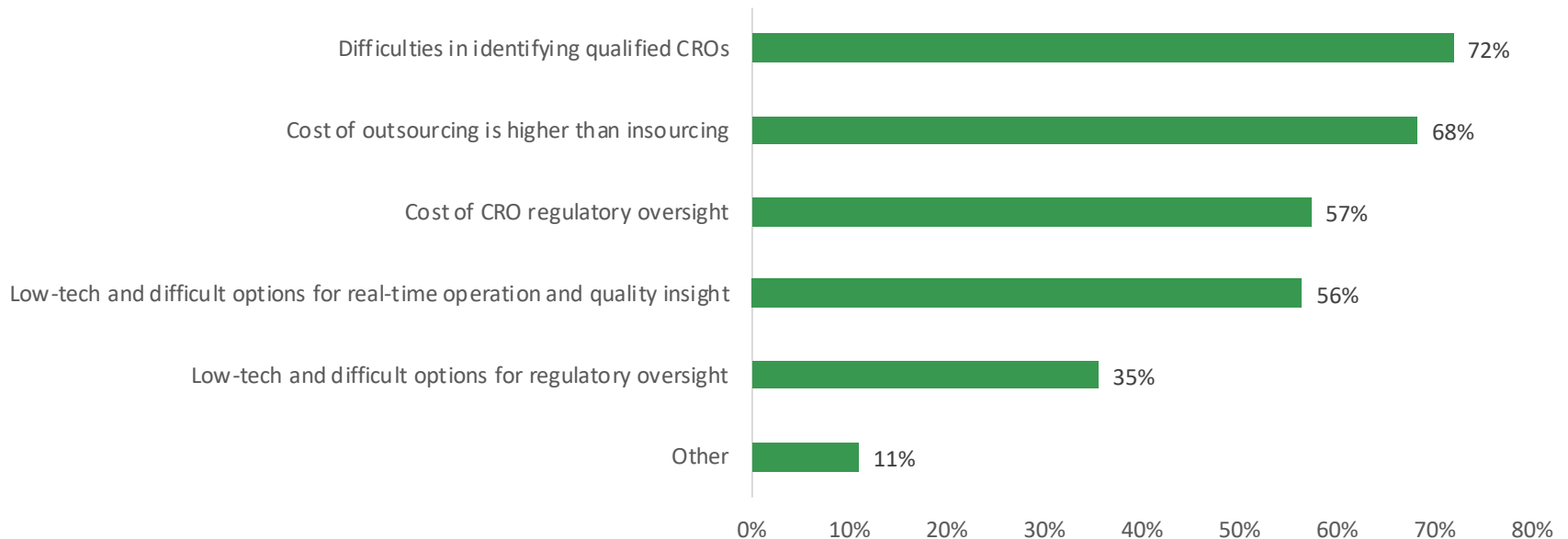
'Other Specify' Barriers

- "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)
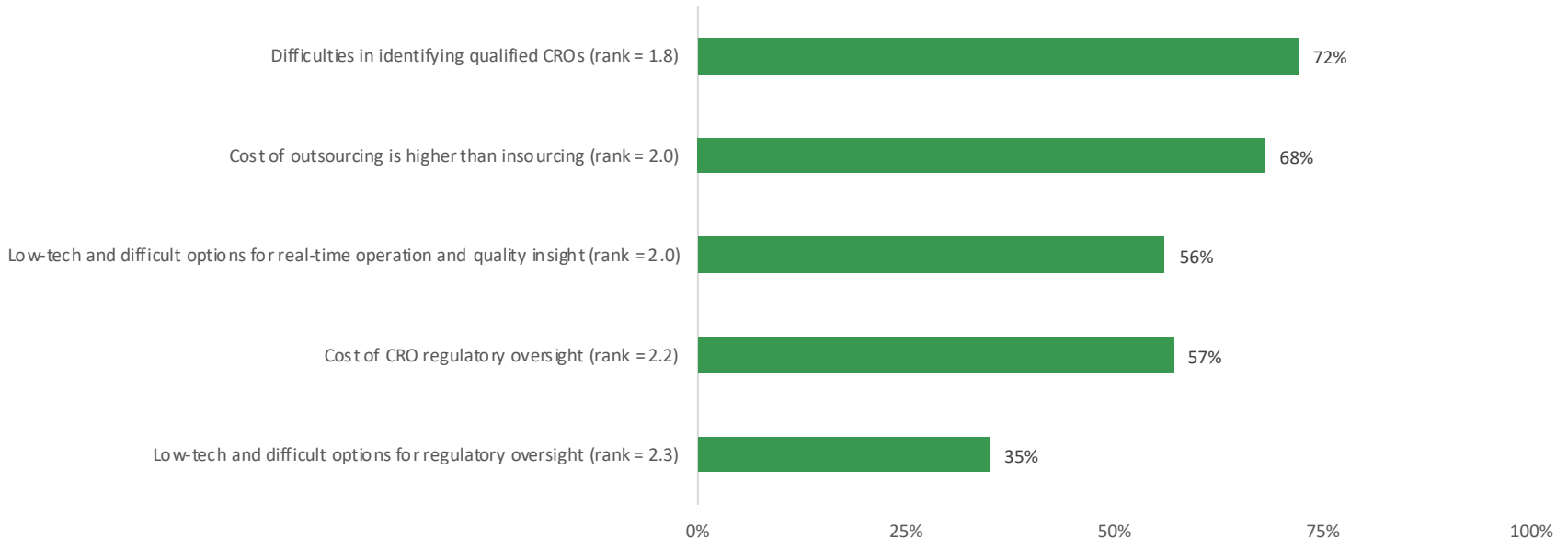

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3

Barrier	Rank 1	Rank 2	Rank 3	Total
Difficulties in identifying qualified CROs	32%	24%	16%	72%
Cost of outsourcing is higher than insourcing	25%	18%	25%	68%
Cost of CRO regulatory oversight	14%	18%	25%	57%
Low-tech and difficult options for real-time operation and quality insight	16%	24%	16%	56%
Low-tech and difficult options for regulatory oversight	5%	15%	16%	35%
Other	8%	2%		11%
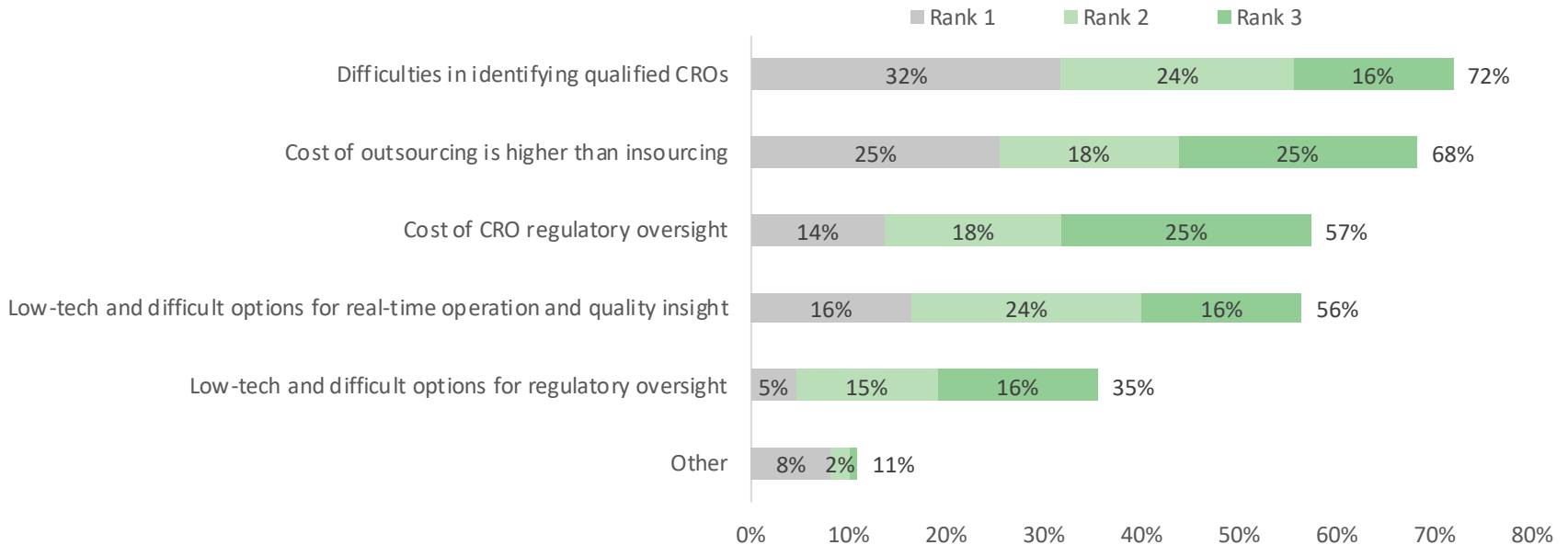
Average Ranking: Top 3 Barriers for Successful Outsourcing

Barrier	Average Ranking
Difficulties in identifying qualified CROs	1.8 — *Most challenging, on average*
Cost of outsourcing is higher than insourcing	2.0
Low-tech and difficult options for real-time operation and quality insight	2.0
Cost of CRO regulatory oversight	2.2
Low-tech and difficult options for regulatory oversight	2.3
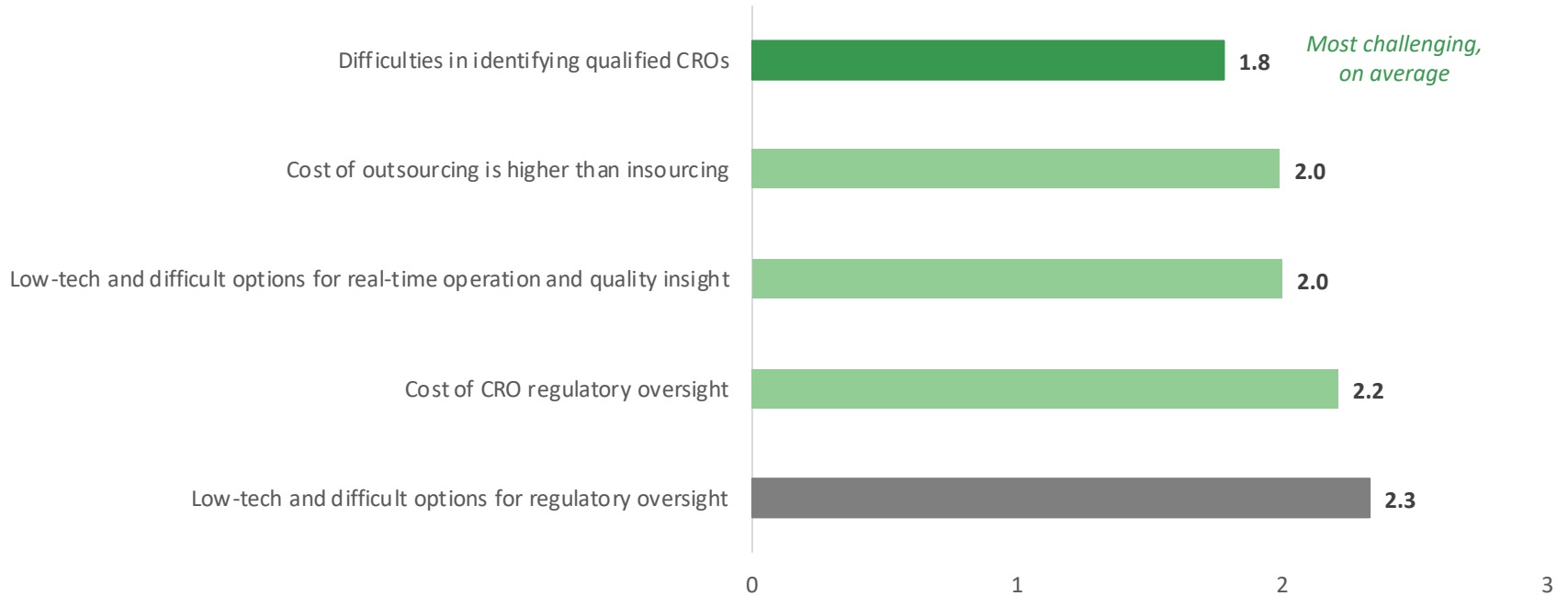
Top 3 Barriers for Successful Outsourcing (prevalence and ranking)

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)

Difficulties in identifying qualified CROs (rank = 1.8) — 72%

Cost of outsourcing is higher than insourcing (rank = 2.0) — 68%

Low-tech and difficult options for real-time operation and quality insight (rank = 2.0) — 56%

Cost of CRO regulatory oversight (rank = 2.2) — 57%

Low-tech and difficult options for regulatory oversight (rank = 2.3) — 35%

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)
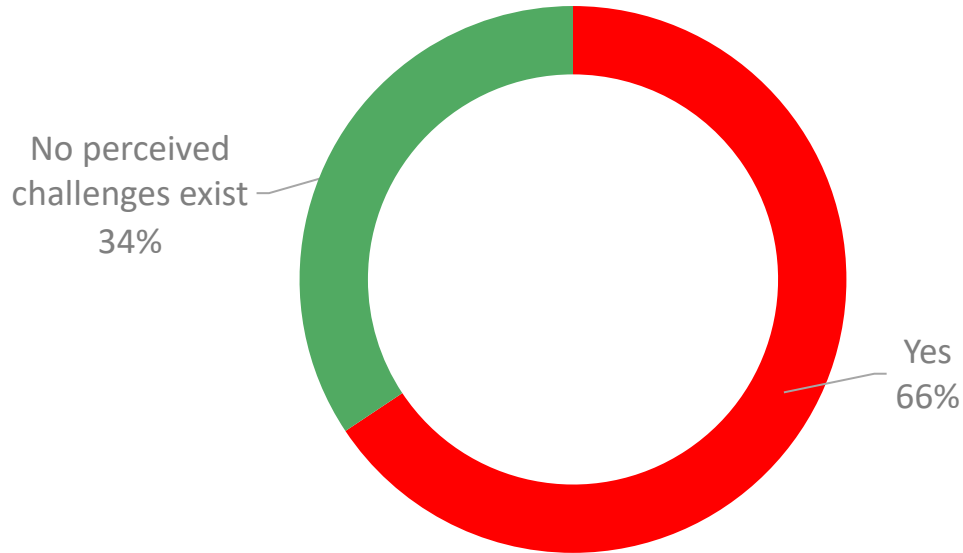

Category	Percentage
Less than 10%	30%
10 to 25%	44%
26 to 50%	5%
More than 50%	2%
I don't know	19%
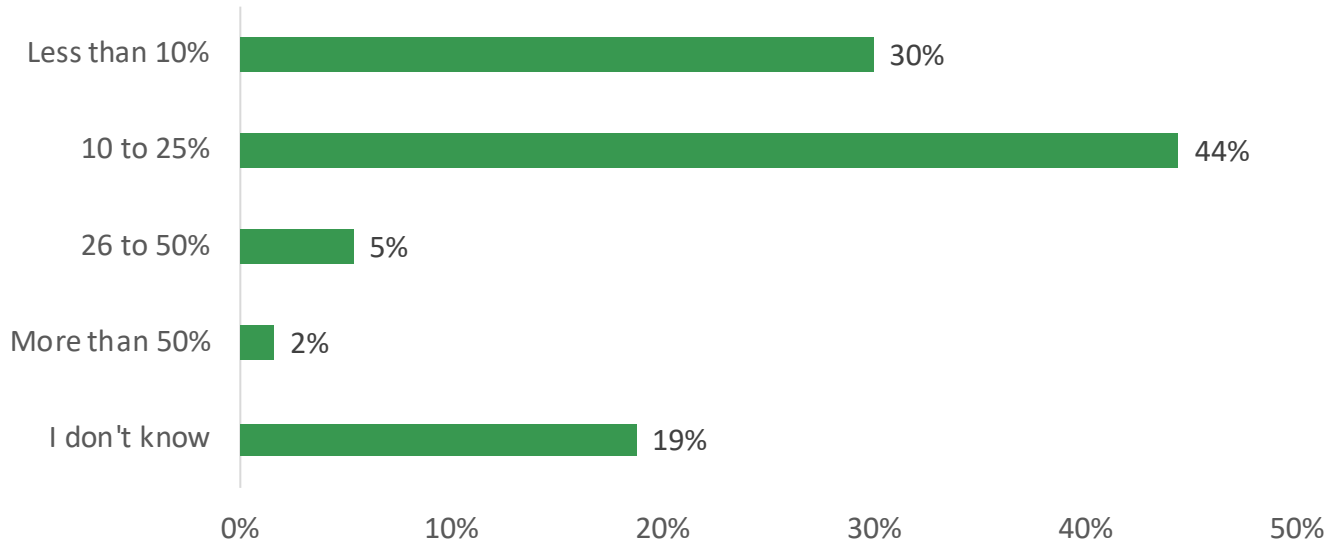
BARRIERS TO ADOPTING ECLINICAL SOLUTIONS IN STUDY STARTUP

Are There Challenges in Adopting New Clinical Systems?

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

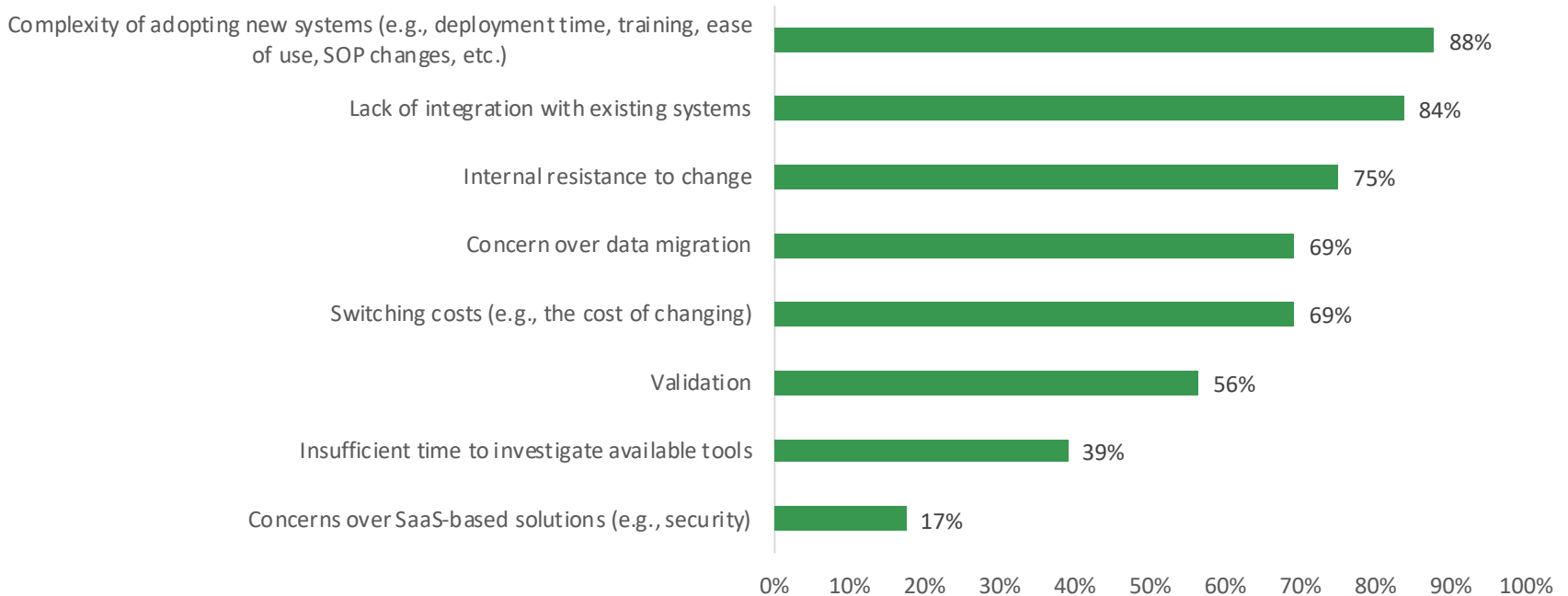No perceived challenges exist
34%

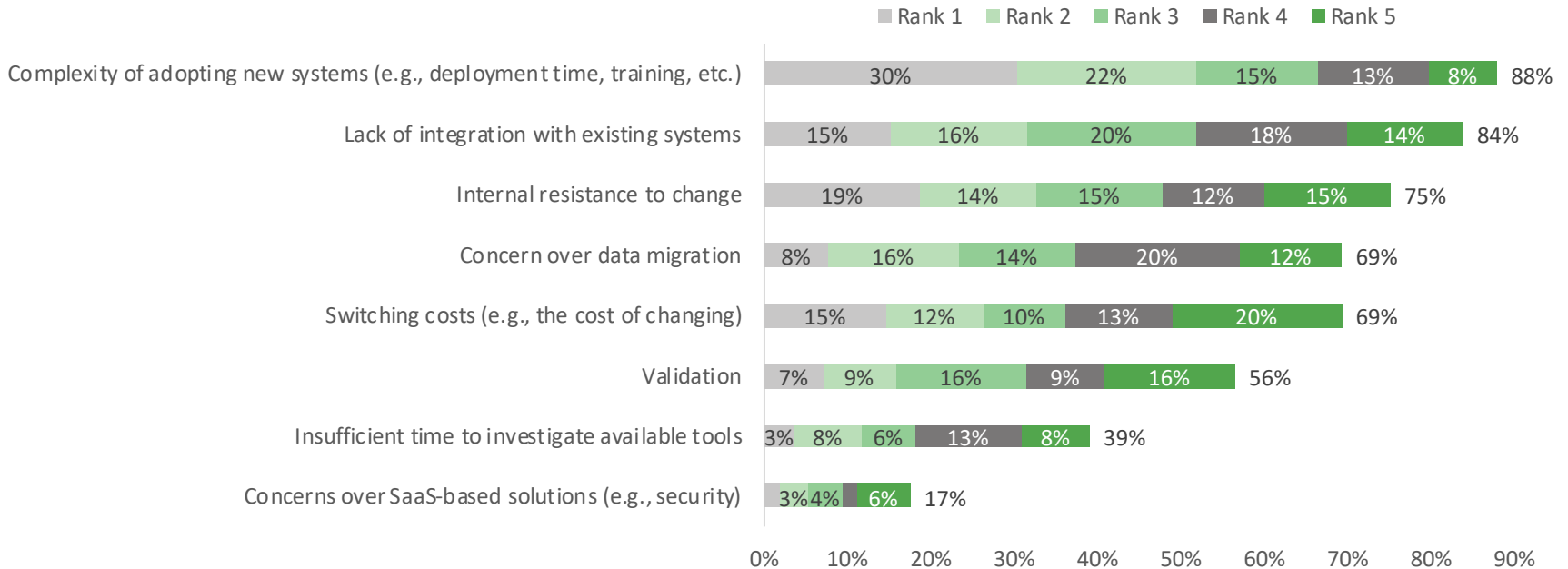Yes
66%

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)

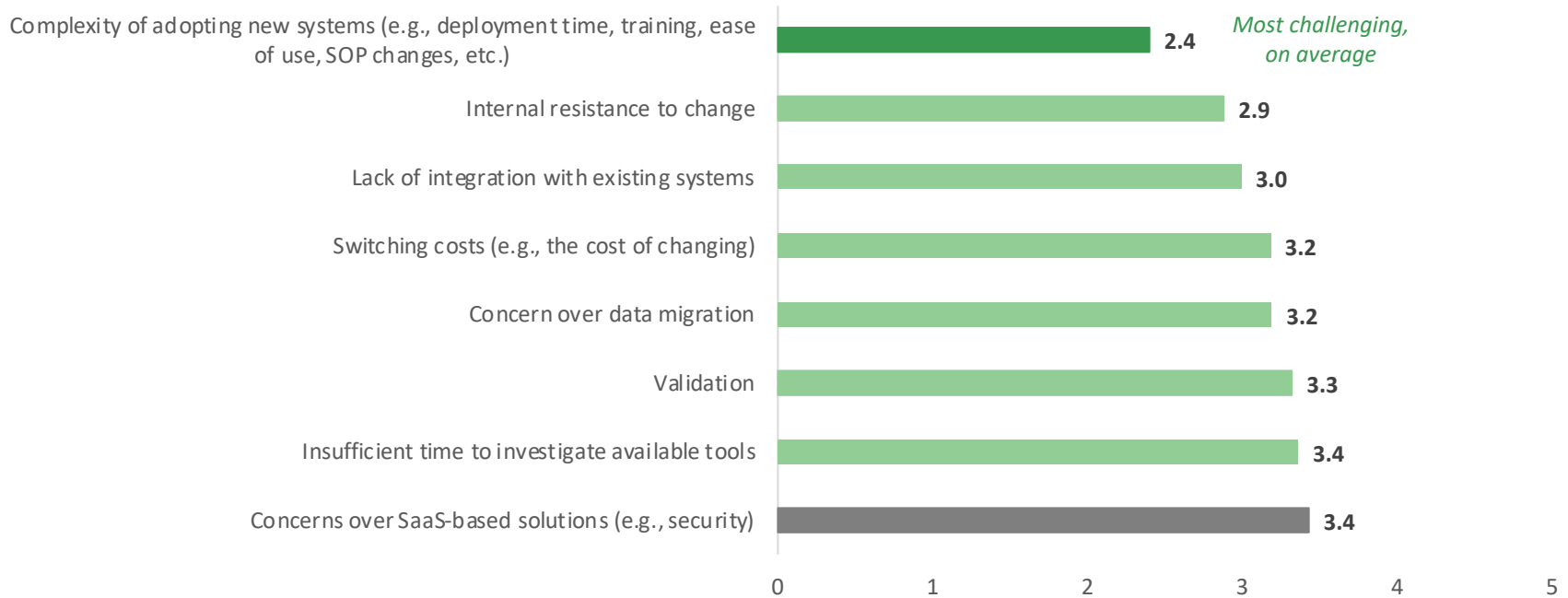| Challenge	Percentage
Complexity of adopting new systems (e.g., deployment time, training, ease of use, SOP changes, etc.)	88%
Lack of integration with existing systems	84%
Internal resistance to change	75%
Concern over data migration	69%
Switching costs (e.g., the cost of changing)	69%
Validation	56%
Insufficient time to investigate available tools	39%
Concerns over SaaS-based solutions (e.g., security)	17%

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)

Legend: Rank 1, Rank 2, Rank 3, Rank 4, Rank 5

Challenge	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5	Total
Complexity of adopting new systems (e.g., deployment time, training, etc.)	30%	22%	15%	13%	8%	88%
Lack of integration with existing systems	15%	16%	20%	18%	14%	84%
Internal resistance to change	19%	14%	15%	12%	15%	75%
Concern over data migration	8%	16%	14%	20%	12%	69%
Switching costs (e.g., the cost of changing)	15%	12%	10%	13%	20%	69%
Validation	7%	9%	16%	9%	16%	56%
Insufficient time to investigate available tools	3%	8%	6%	13%	8%	39%
Concerns over SaaS-based solutions (e.g., security)	3%	4%			6%	17%

Average Ranking: Top 5 Challenges in Adoption

Challenge	Average Ranking
Complexity of adopting new systems (e.g., deployment time, training, ease of use, SOP changes, etc.)	2.4
Internal resistance to change	2.9
Lack of integration with existing systems	3.0
Switching costs (e.g., the cost of changing)	3.2
Concern over data migration	3.2
Validation	3.3
Insufficient time to investigate available tools	3.4
Concerns over SaaS-based solutions (e.g., security)	3.4

Most challenging, on average

# 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)

Challenge	Percentage
Complexity of adopting new systems (e.g., deployment time, training, ease of use, SOP changes, etc.) (rank = 2.4)	88%
Internal resistance to change (rank = 2.9)	75%
Lack of integration with existing systems (rank = 3.0)	84%
Concern over data migration (rank = 3.2)	69%
Switching costs (e.g., the cost of changing) (rank = 3.2)	69%
Validation (rank = 3.3)	56%
Insufficient time to investigate available tools (rank = 3.4)	39%
Concerns over SaaS-based solutions (e.g., security) (rank = 3.4)	17%
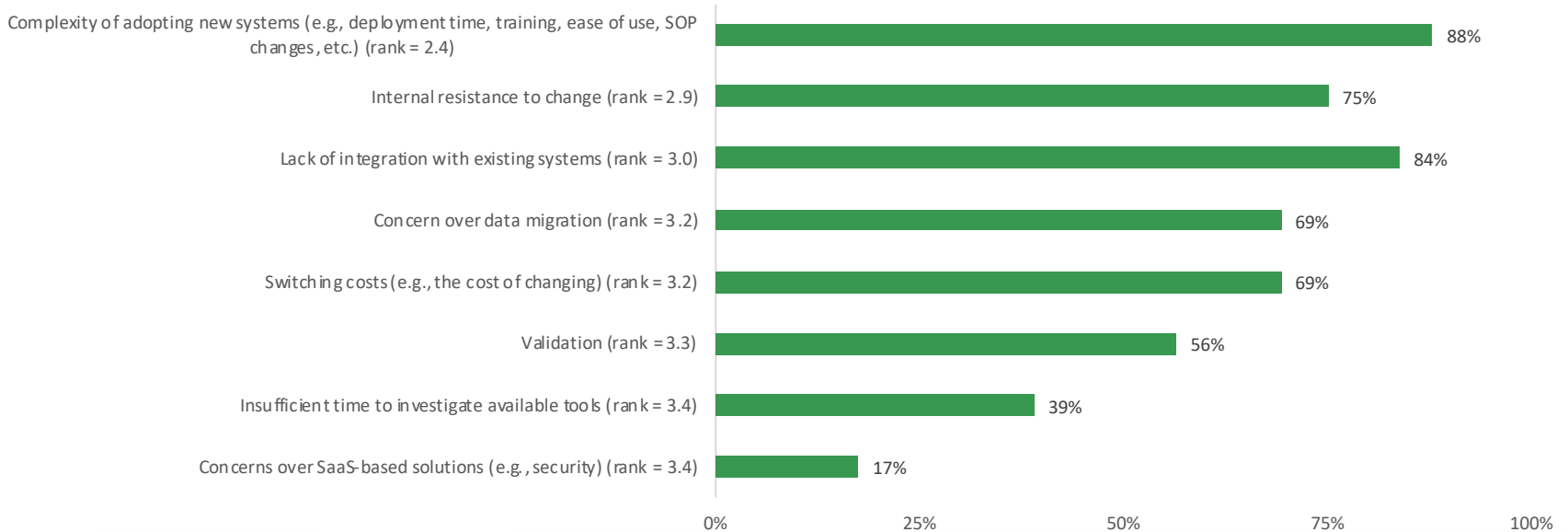
Is There Resistance to Adopting New Technologies?

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

No resistance, our organization embraces change 40%

Yes 60%
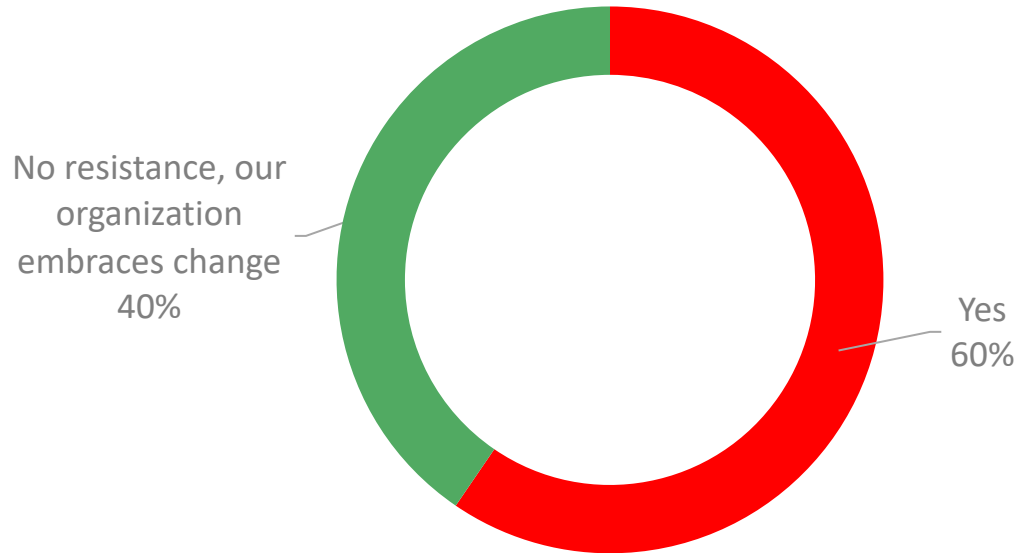
Reasons for Resistance to Adopting New Technologies

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)

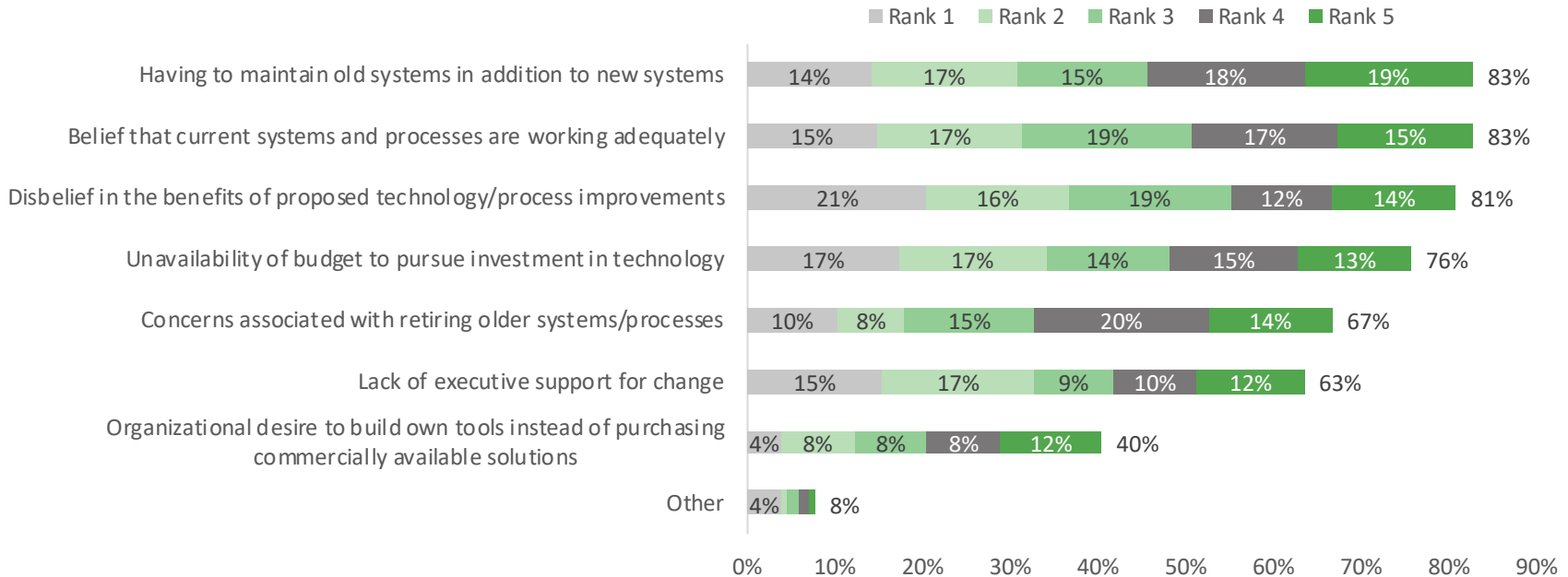| Reason	Percentage
Having to maintain old systems in addition to new systems	83%
Belief that current systems and processes are working adequately	83%
Disbelief in the benefits of proposed technology/process improvements	81%
Unavailability of budget to pursue investment in technology	76%
Concerns associated with retiring older systems/processes	67%
Lack of executive support for change	63%
Organizational desire to build own tools instead of purchasing commercially available solutions	40%
Other	8%
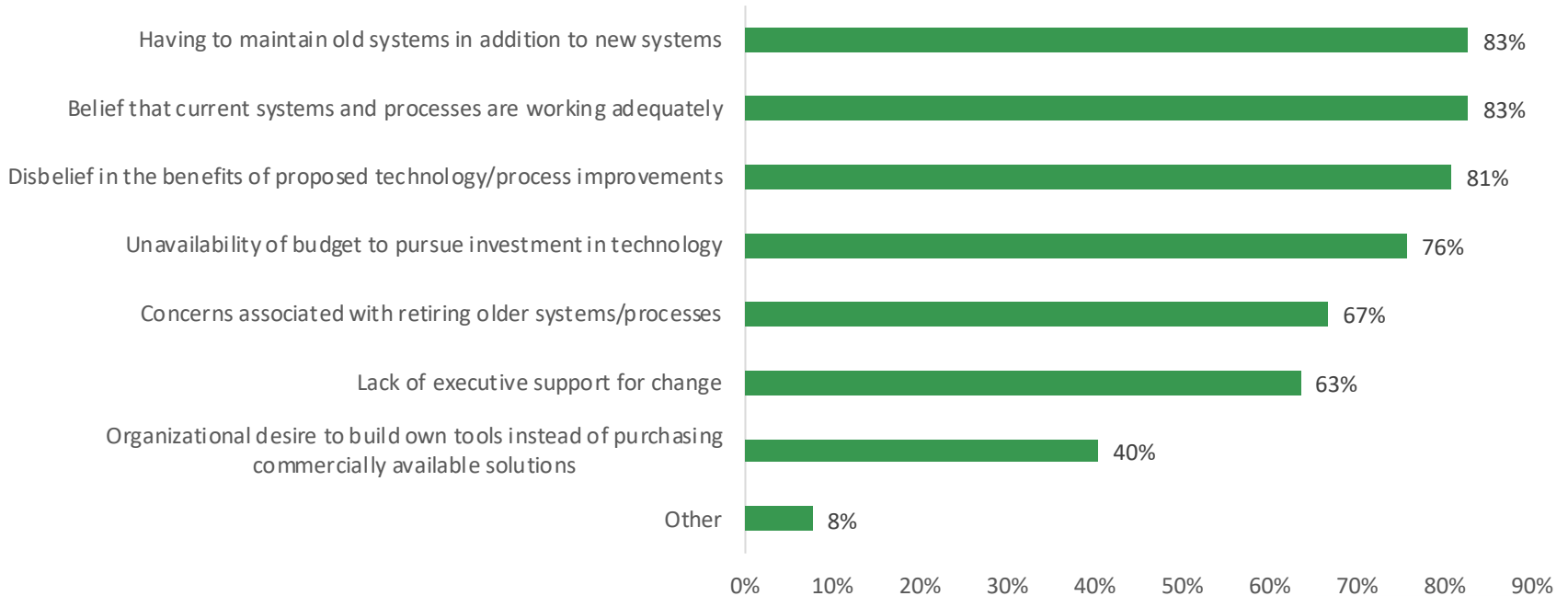
'Other Specify' Reasons

- 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
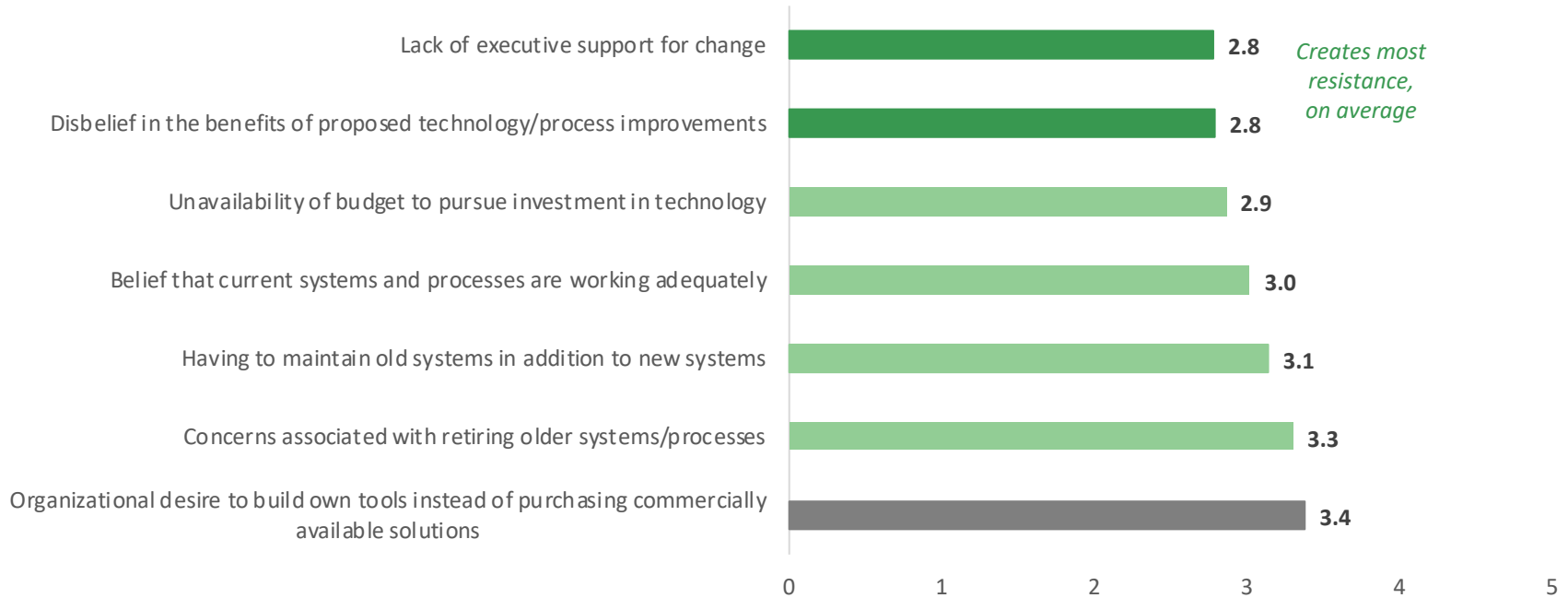
Rank Top 5 Reasons for Resistance

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)
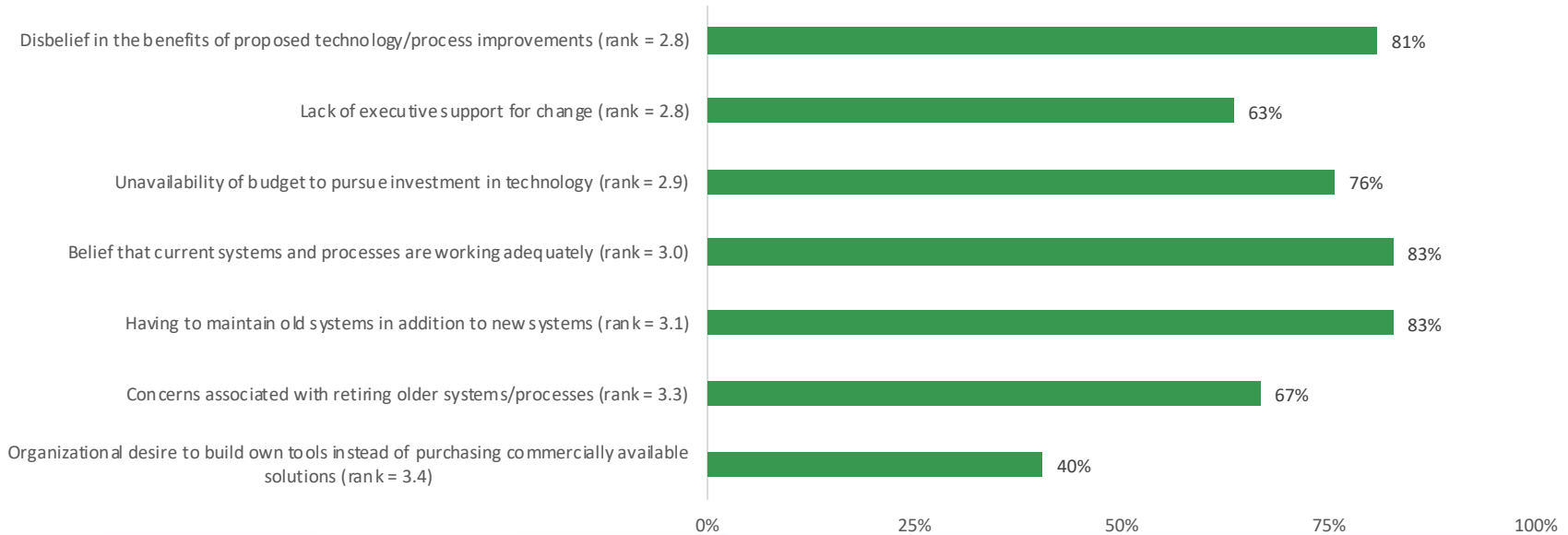

Legend: Rank 1, Rank 2, Rank 3, Rank 4, Rank 5

Reason	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5	Total
Having to maintain old systems in addition to new systems	14%	17%	15%	18%	19%	83%
Belief that current systems and processes are working adequately	15%	17%	19%	17%	15%	83%
Disbelief in the benefits of proposed technology/process improvements	21%	16%	19%	12%	14%	81%
Unavailability of budget to pursue investment in technology	17%	17%	14%	15%	13%	76%
Concerns associated with retiring older systems/processes	10%	8%	15%	20%	14%	67%
Lack of executive support for change	15%	17%	9%	10%	12%	63%
Organizational desire to build own tools instead of purchasing commercially available solutions	4%	8%	8%	8%	12%	40%
Other	4%					8%

Average Rank Top 5 Reasons for Resistance

Lack of executive support for change — **2.8**

Disbelief in the benefits of proposed technology/process improvements — **2.8**

Creates most resistance, on average

Unavailability of budget to pursue investment in technology — **2.9**

Belief that current systems and processes are working adequately — **3.0**

Having to maintain old systems in addition to new systems — **3.1**

Concerns associated with retiring older systems/processes — **3.3**

Organizational desire to build own tools instead of purchasing commercially available solutions — **3.4**

0 1 2 3 4 5

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)
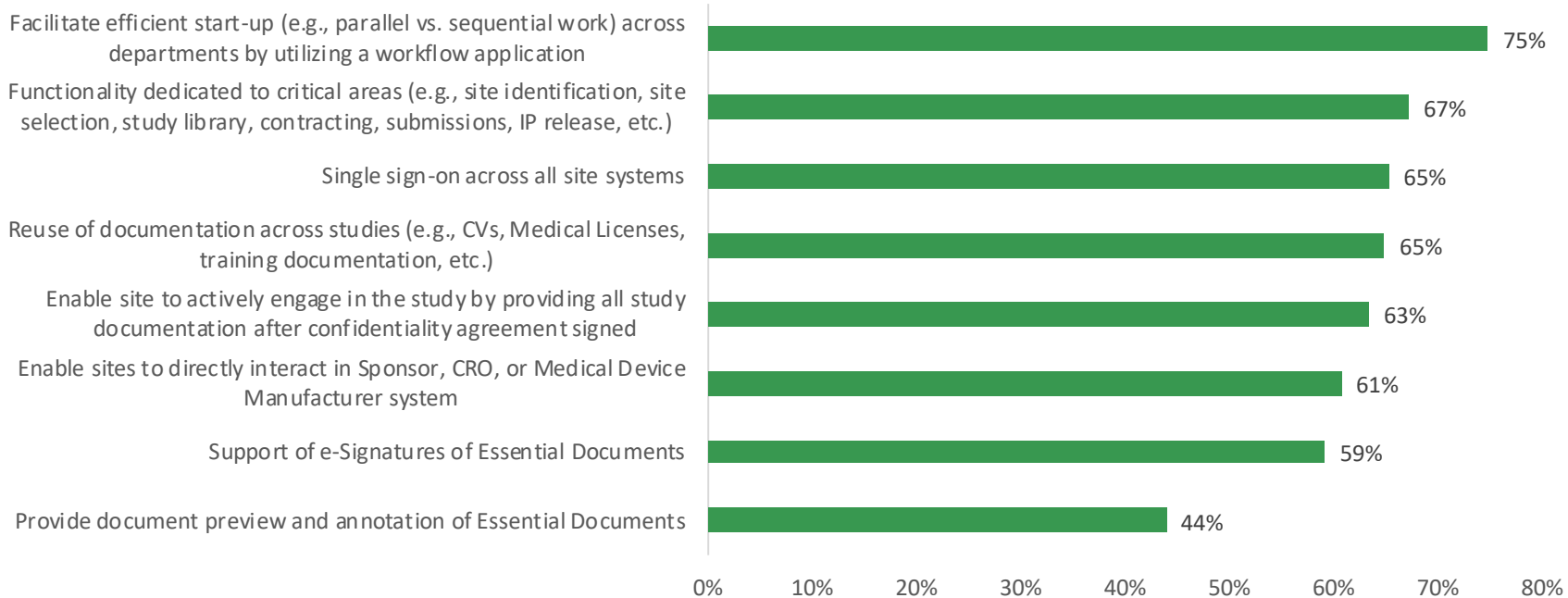
Reason	Percentage
Disbelief in the benefits of proposed technology/process improvements (rank = 2.8)	81%
Lack of executive support for change (rank = 2.8)	63%
Unavailability of budget to pursue investment in technology (rank = 2.9)	76%
Belief that current systems and processes are working adequately (rank = 3.0)	83%
Having to maintain old systems in addition to new systems (rank = 3.1)	83%
Concerns associated with retiring older systems/processes (rank = 3.3)	67%
Organizational desire to build own tools instead of purchasing commercially available solutions (rank = 3.4)	40%

CHANGE MANAGEMENT IN STUDY STARTUP TECHNOLOGY PROJECTS
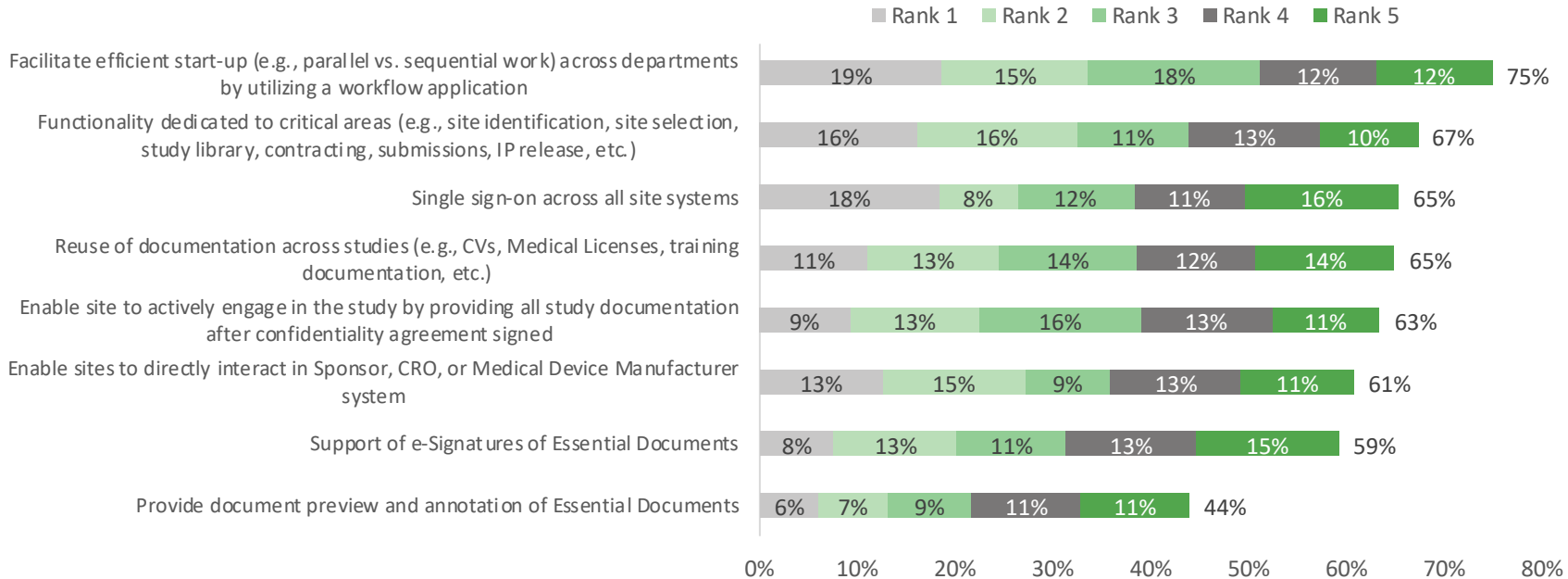
Elements for Successful Technology Implementation

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)
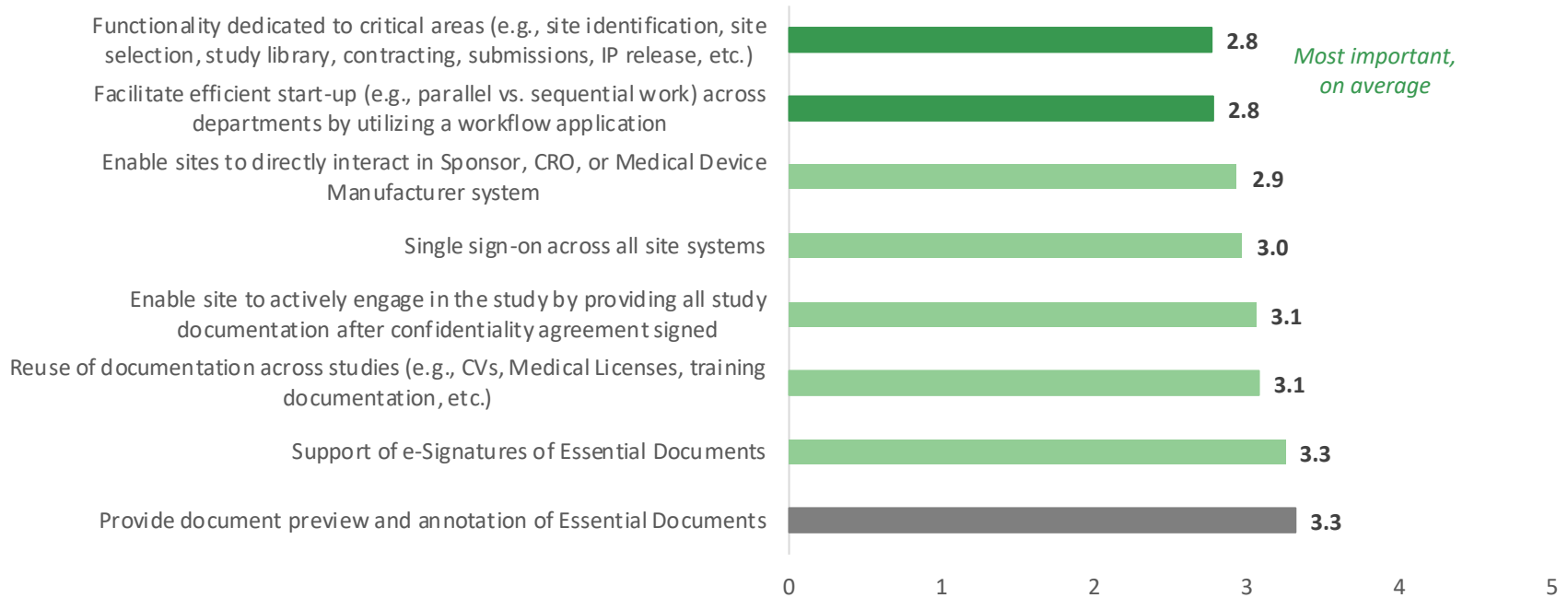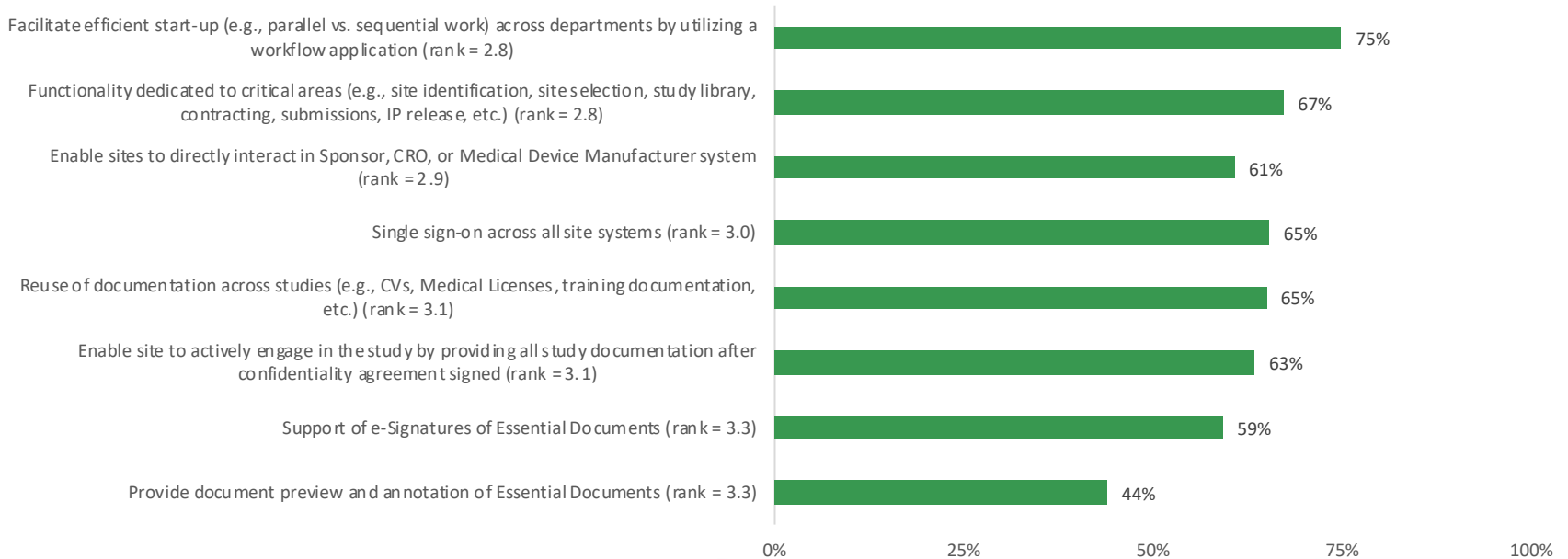
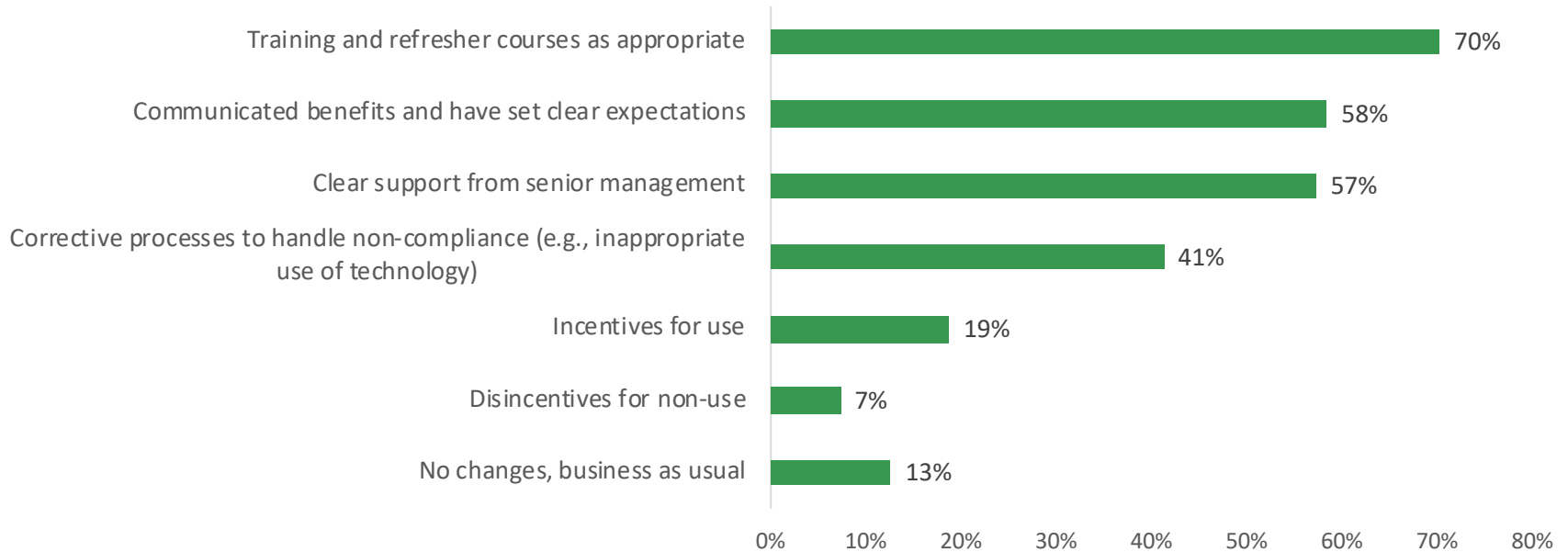| Element	Percentage
Facilitate efficient start-up (e.g., parallel vs. sequential work) across departments by utilizing a workflow application	75%
Functionality dedicated to critical areas (e.g., site identification, site selection, study library, contracting, submissions, IP release, etc.)	67%
Single sign-on across all site systems	65%
Reuse of documentation across studies (e.g., CVs, Medical Licenses, training documentation, etc.)	65%
Enable site to actively engage in the study by providing all study documentation after confidentiality agreement signed	63%
Enable sites to directly interact in Sponsor, CRO, or Medical Device Manufacturer system	61%
Support of e-Signatures of Essential Documents	59%
Provide document preview and annotation of Essential Documents	44%

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)

Legend: ■ Rank 1 ■ Rank 2 ■ Rank 3 ■ Rank 4 ■ Rank 5

Element	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5	Total
Facilitate efficient start-up (e.g., parallel vs. sequential work) across departments by utilizing a workflow application	19%	15%	18%	12%	12%	75%
Functionality dedicated to critical areas (e.g., site identification, site selection, study library, contracting, submissions, IP release, etc.)	16%	16%	11%	13%	10%	67%
Single sign-on across all site systems	18%	8%	12%	11%	16%	65%
Reuse of documentation across studies (e.g., CVs, Medical Licenses, training documentation, etc.)	11%	13%	14%	12%	14%	65%
Enable site to actively engage in the study by providing all study documentation after confidentiality agreement signed	9%	13%	16%	13%	11%	63%
Enable sites to directly interact in Sponsor, CRO, or Medical Device Manufacturer system	13%	15%	9%	13%	11%	61%
Support of e-Signatures of Essential Documents	8%	13%	11%	13%	15%	59%
Provide document preview and annotation of Essential Documents	6%	7%	9%	11%	11%	44%

Average Ranking: Top 5 Elements

Element	Value
Functionality dedicated to critical areas (e.g., site identification, site selection, study library, contracting, submissions, IP release, etc.)	2.8
Facilitate efficient start-up (e.g., parallel vs. sequential work) across departments by utilizing a workflow application	2.8
Enable sites to directly interact in Sponsor, CRO, or Medical Device Manufacturer system	2.9
Single sign-on across all site systems	3.0
Enable site to actively engage in the study by providing all study documentation after confidentiality agreement signed	3.1
Reuse of documentation across studies (e.g., CVs, Medical Licenses, training documentation, etc.)	3.1
Support of e-Signatures of Essential Documents	3.3
Provide document preview and annotation of Essential Documents	3.3

Most important, on average

0   1   2   3   4   5

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)

Element	Percentage
Facilitate efficient start-up (e.g., parallel vs. sequential work) across departments by utilizing a workflow application (rank = 2.8)	75%
Functionality dedicated to critical areas (e.g., site identification, site selection, study library, contracting, submissions, IP release, etc.) (rank = 2.8)	67%
Enable sites to directly interact in Sponsor, CRO, or Medical Device Manufacturer system (rank = 2.9)	61%
Single sign-on across all site systems (rank = 3.0)	65%
Reuse of documentation across studies (e.g., CVs, Medical Licenses, training documentation, etc.) (rank = 3.1)	65%
Enable site to actively engage in the study by providing all study documentation after confidentiality agreement signed (rank = 3.1)	63%
Support of e-Signatures of Essential Documents (rank = 3.3)	59%
Provide document preview and annotation of Essential Documents (rank = 3.3)	44%

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Steps Taken to Ensure Technology Deployments

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

Step	Percentage
Training and refresher courses as appropriate	70%
Communicated benefits and have set clear expectations	58%
Clear support from senior management	57%
Corrective processes to handle non-compliance (e.g., inappropriate use of technology)	41%
Incentives for use	19%
Disincentives for non-use	7%
No changes, business as usual	13%

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)

Challenge	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Not involving end users in the decision-making process	35%	17%	18%	14%	16%
System is not a complete replacement for incumbent system	25%	24%	21%	15%	15%
Not being able to show immediate value to end users	21%	15%	27%	22%	15%
Rollout plan is not communicated or implemented to ensure successful use of new system	11%	26%	19%	23%	22%
No desired benchmarking for outcomes to be achieved with new system	8%	18%	15%	26%	32%

Average Ranking: Challenges of Implementing New Clinical System

Challenge	Rating
Not involving end users in the decision-making process	2.6 *Most challenging, on average*
System is not a complete replacement for incumbent system	2.7
Not being able to show immediate value to end users	3.0
Rollout plan is not communicated or implemented to ensure successful use of new system	3.2
No desired benchmarking for outcomes to be achieved with new system	3.6
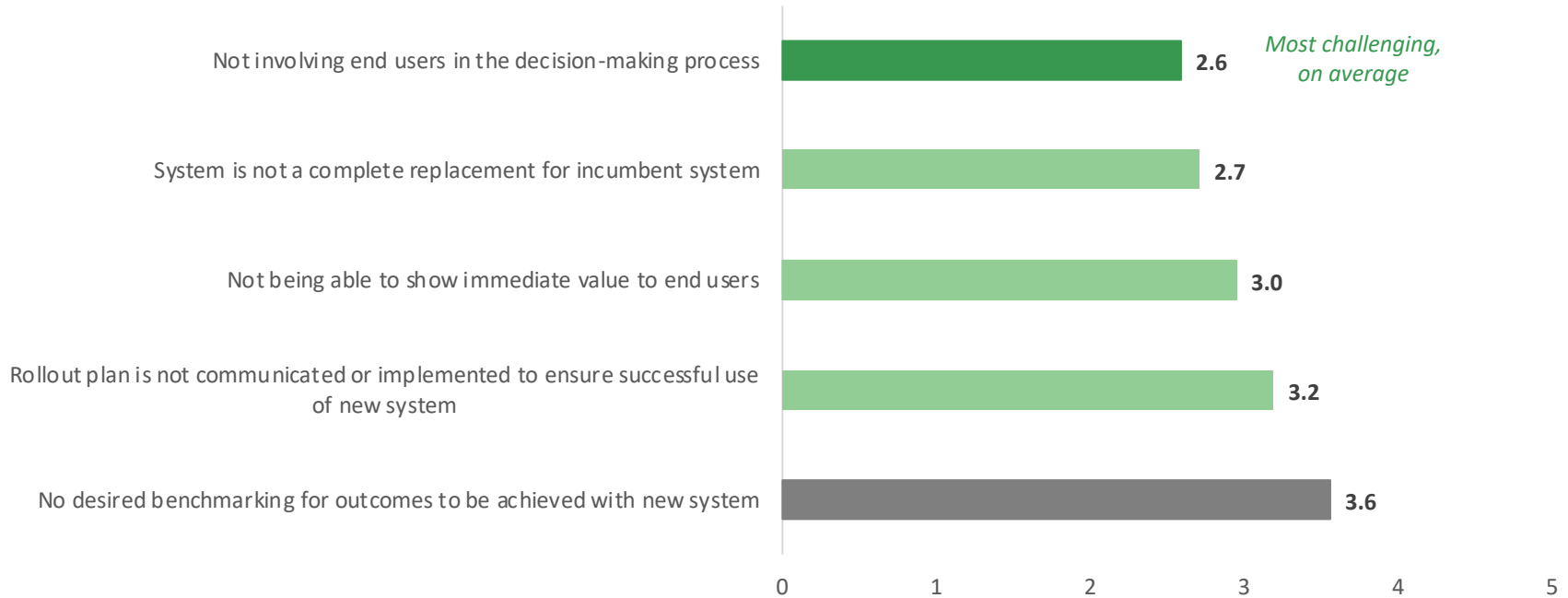
Implemented Other Changes?

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)
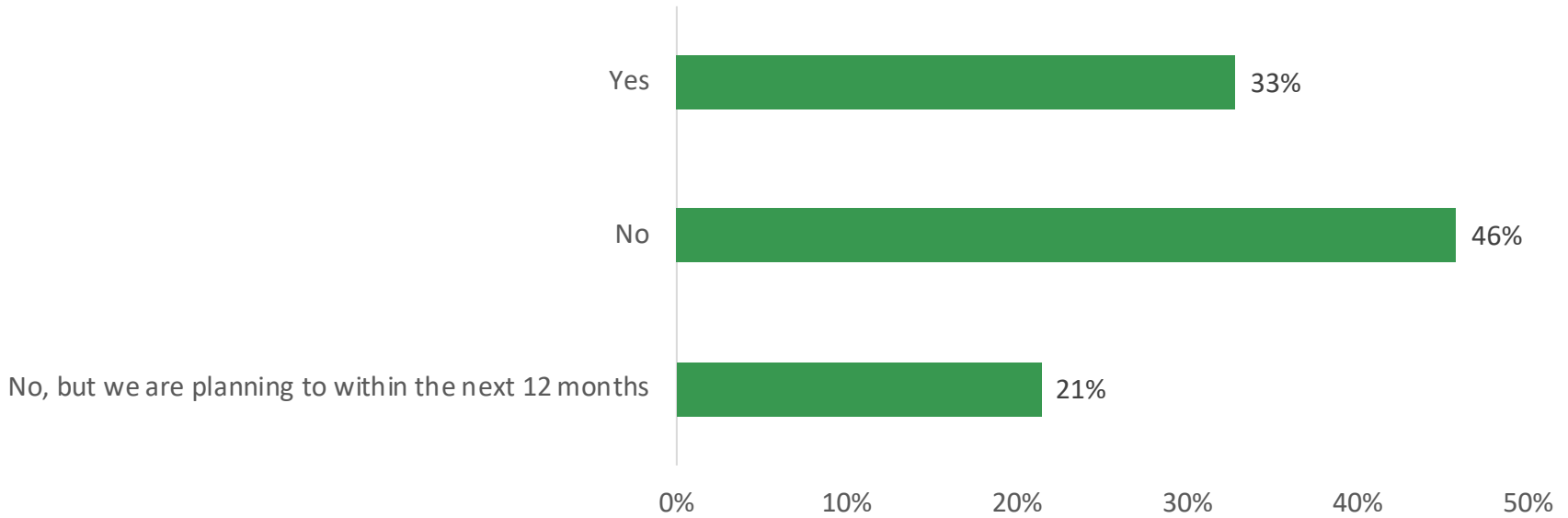
Address Challenges of Site Collaboration

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)

Category	Percentage
Align processes to maximize the effectiveness of technology adoption	56%
Implementation of cross-functional teams	55%
The formation of a dedicated study start-up team	46%
Creation of a dedicated innovations group to look at new technologies and processes	40%
Reduction in functional groups (e.g., flattening of organization)	36%
No changes have been made	8%

View Technology Use

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

Category	Value
As essential to transforming existing processes (e.g., providing transparency, reducing cycle times)	42%
As a point solution designed to address a particular challenge	22%
As a means to automate well-defined existing manual processes	19%
As a catalyst for holistic changes including other functional groups (e.g., quality, regulatory management)	16%
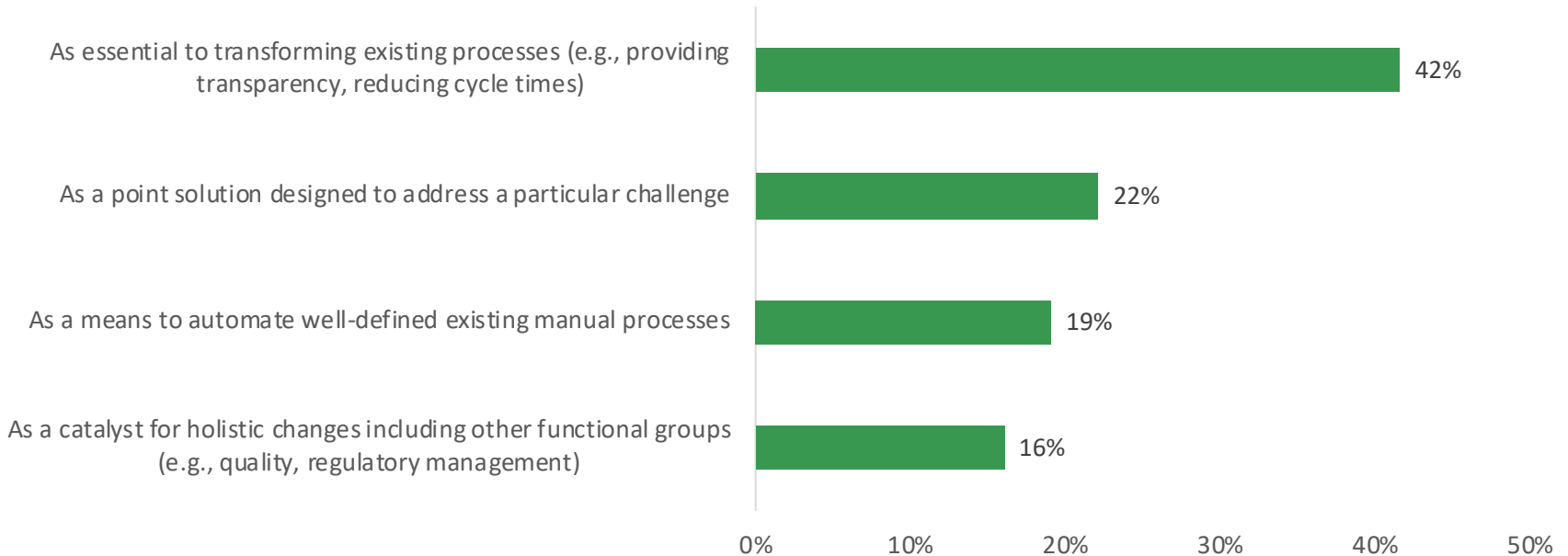
EFFECTIVENESS OF STUDY STARTUP TECHNOLOGY IMPLEMENTATIONS

Measure Effectiveness of Technology Projects

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

Measure	Percentage
Key Performance Indicators (KPIs)	69%
Meeting established goals (e.g., cycle time reductions)	54%
Return on Investment (ROI) calculations	35%
Operational insights or Business Intelligence (e.g., identification of process improvement areas, improvement in risk identification, etc.)	34%
Improvements in baselines	33%
Intangible improvements (e.g., staff morale, cross-functional collaborations, etc.)	28%
No formal measurements	7%

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)

Category	Percentage
System reporting showing utilization	52%
Deployments are mandatory	42%
Indirectly (e.g., requests for additional licenses, training, upgrades, etc.)	28%
No formal measurements	18%
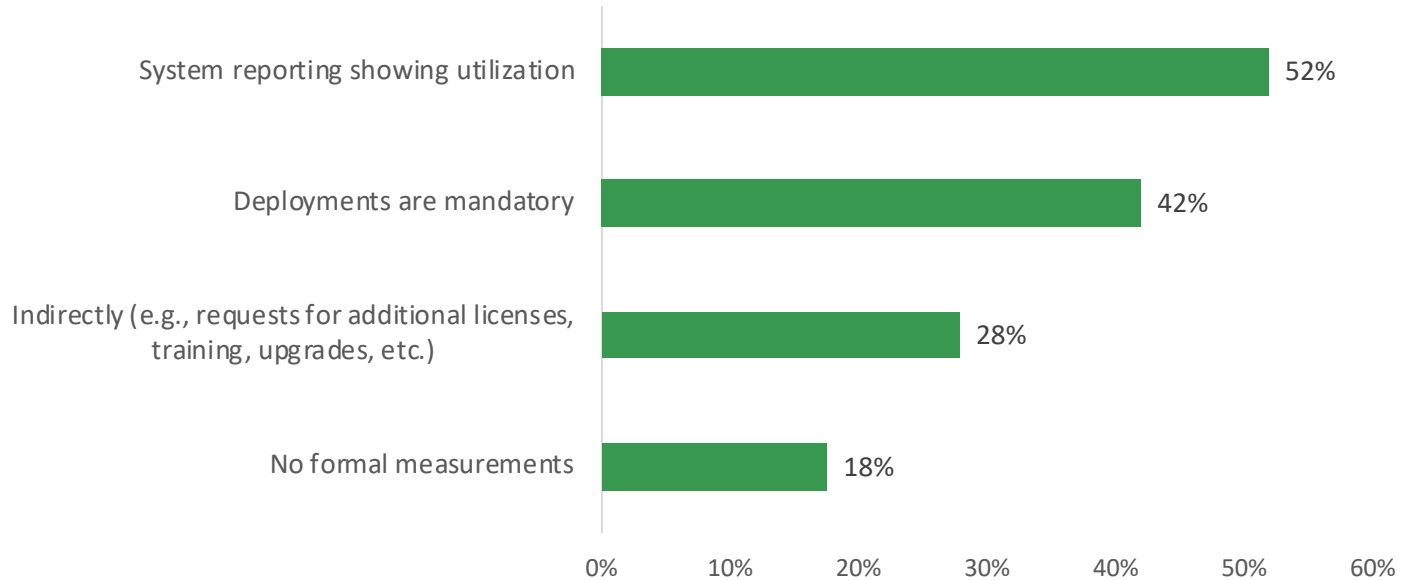
Improvements as a Result of Technology Adoption

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)

Category	Percentage
Improved quality	56%
Improved collaboration	49%
Improved operational oversight	49%
Reduced cycle times	48%
Proactive planning	40%
Efficient resource allocation	34%
Aided risk identification and mitigation	30%
No improvement	9%
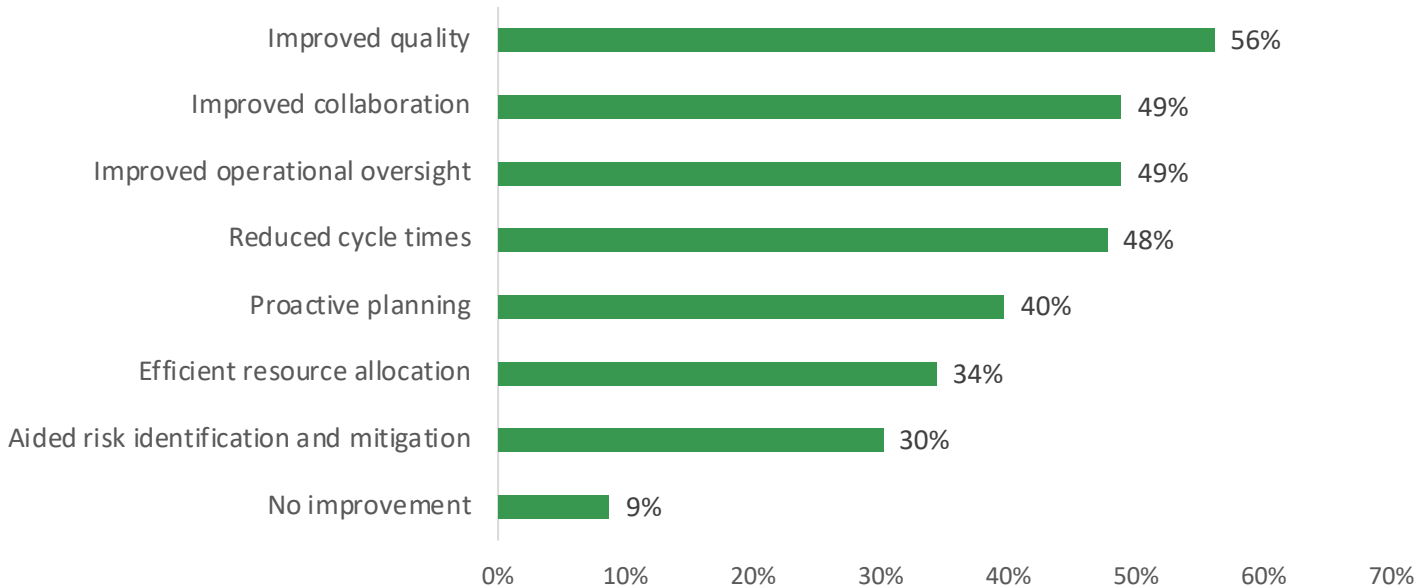
Biggest Improvement

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)
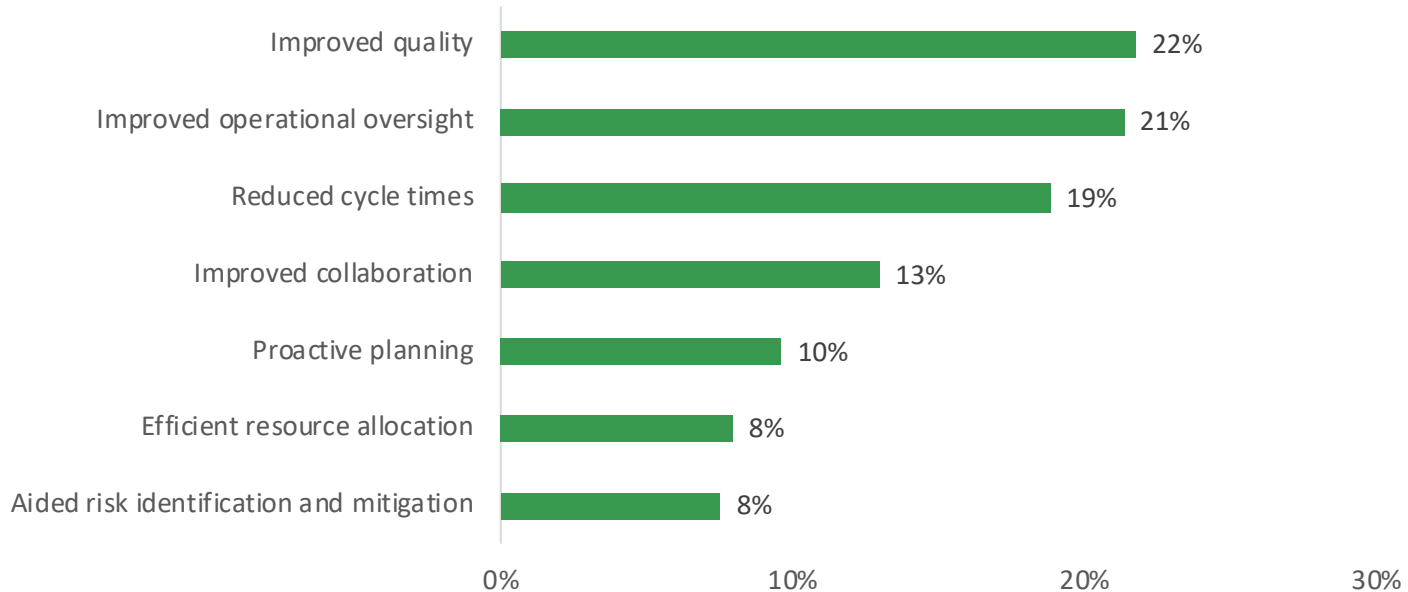
RESPONDENT CHARACTERISTICS

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)

No, 20%

Yes, 80%
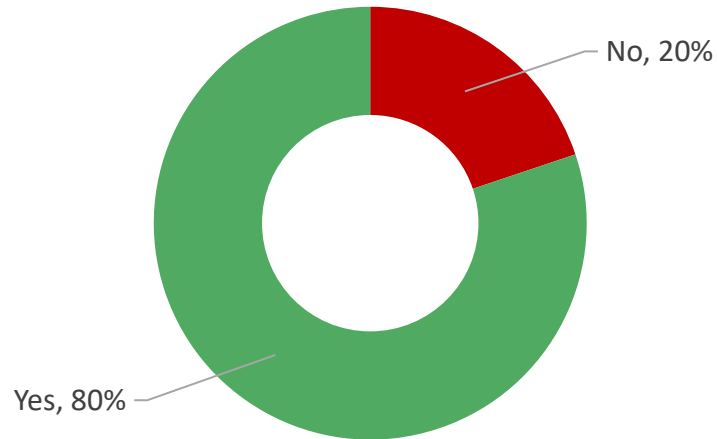
Type of Organization

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

Organization	Percentage
Pharma/BioPharma sponsor/innovator	67%
CRO	29%
Medical device manufacturer	5%
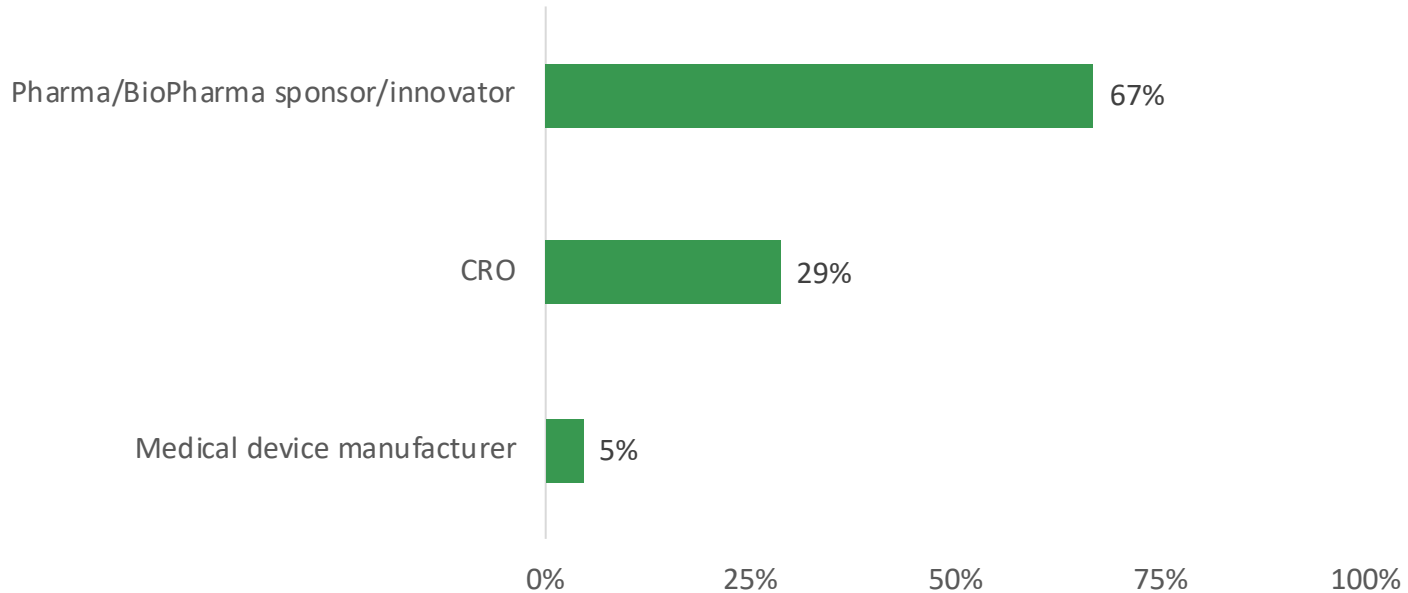
Primary Role (Med or Sponsor)

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

Role	Percentage
Clinical operations or study start-up	78%
Business technology development, capabilities, solutions, innovation, system integration	8%
Procurement, alliance, vendor, partner, outsourcing or category management	8%
Quality assurance	6%
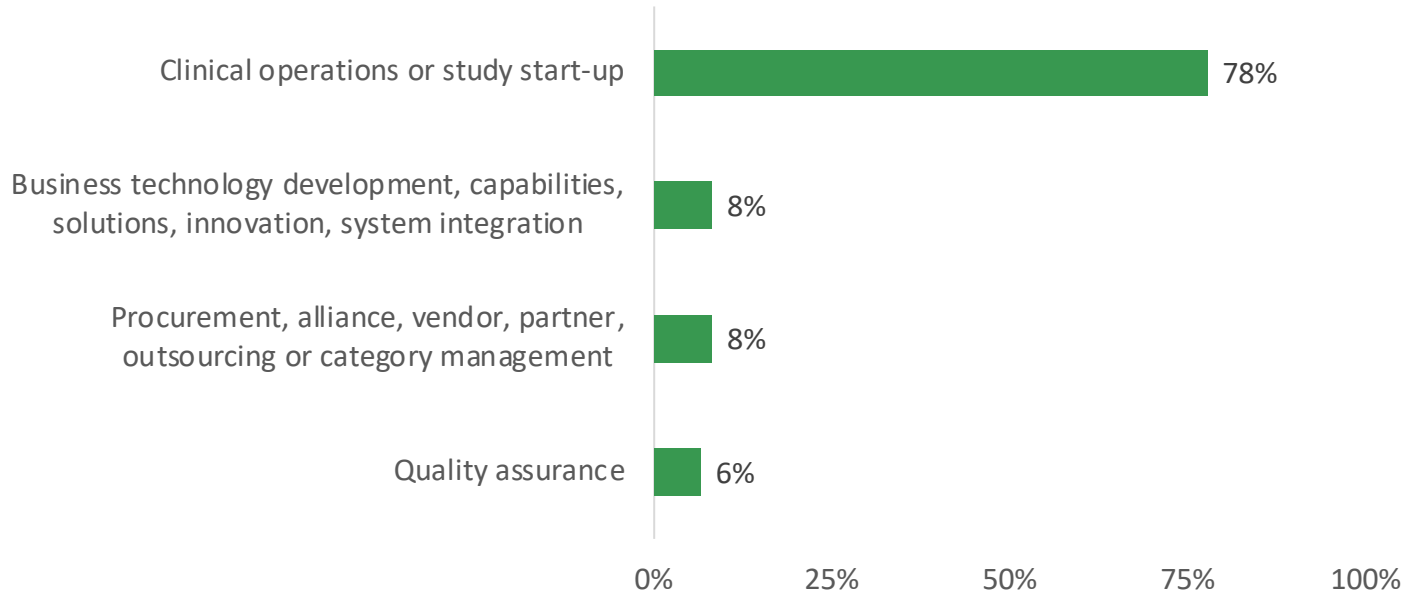
Primary Role (CRO)

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

Role	Percentage
Project/study manager, asset manager, clinical trial lead	36%
Senior management	24%
CRA/study monitor	20%
Start-up specialist	13%
Technology implementation	3%
Regulatory submission management	1%
Quality assurance	1%
Site/Patient collaboration or recruitment specialist	1%
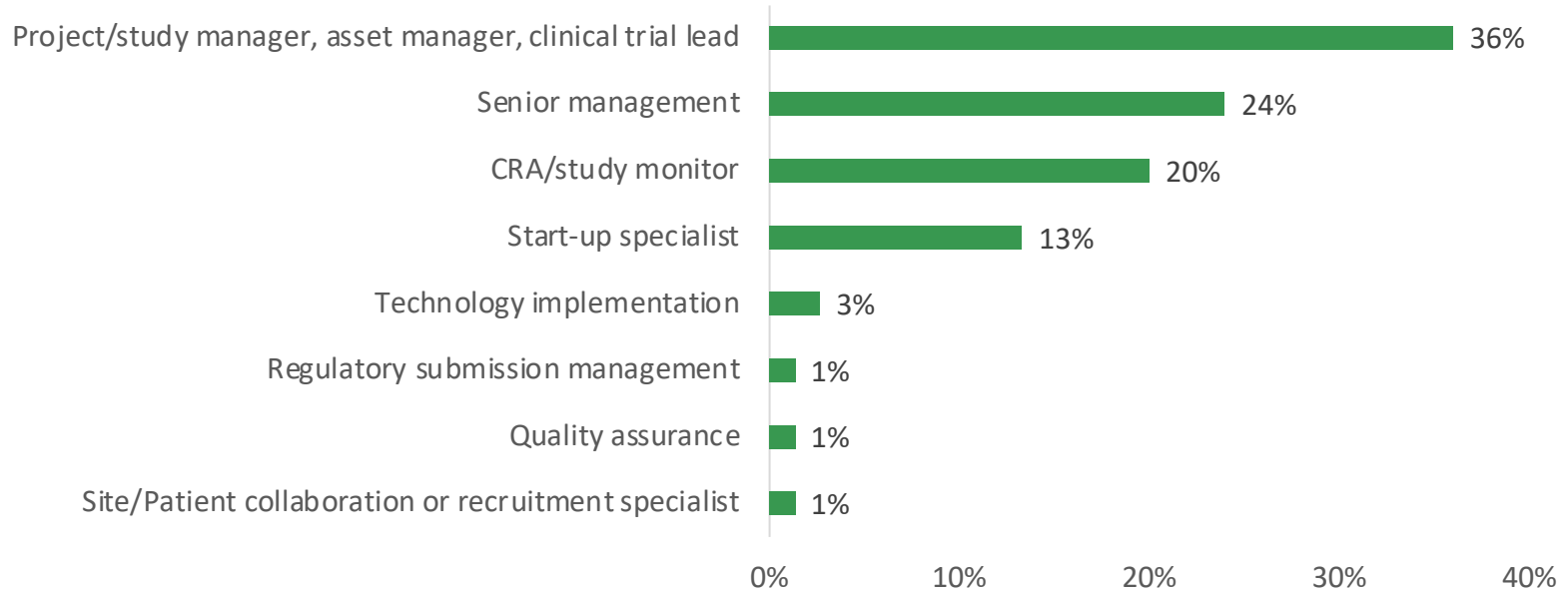
Years of Experience

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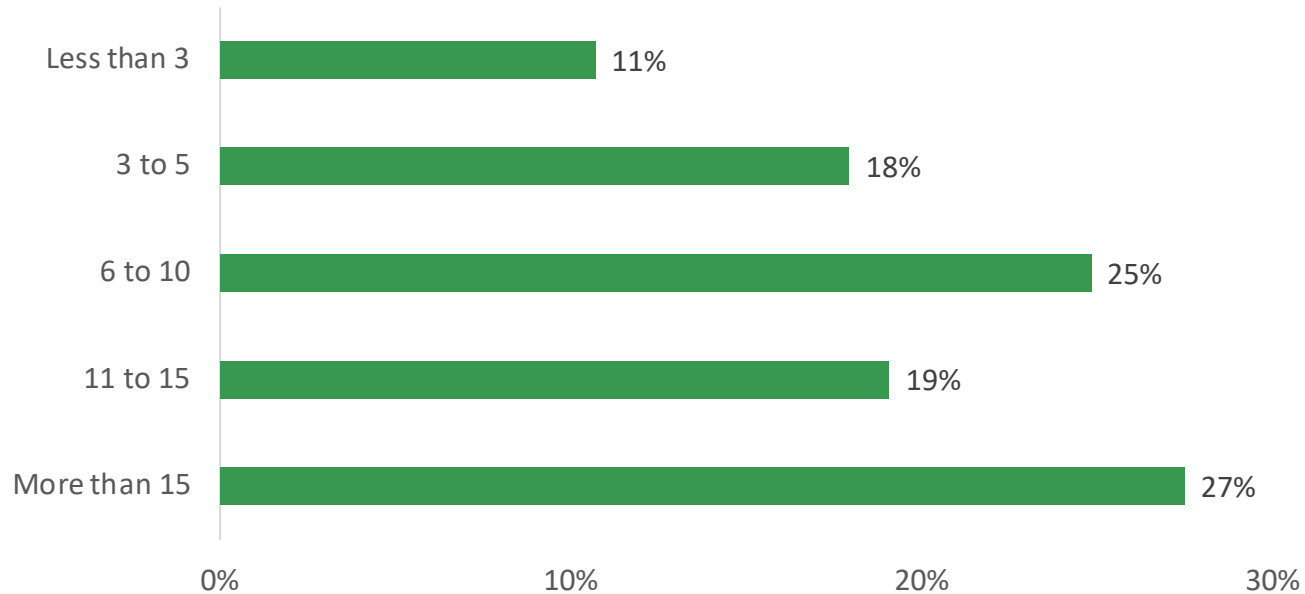
Location (region)

Where are you located? (n=262)
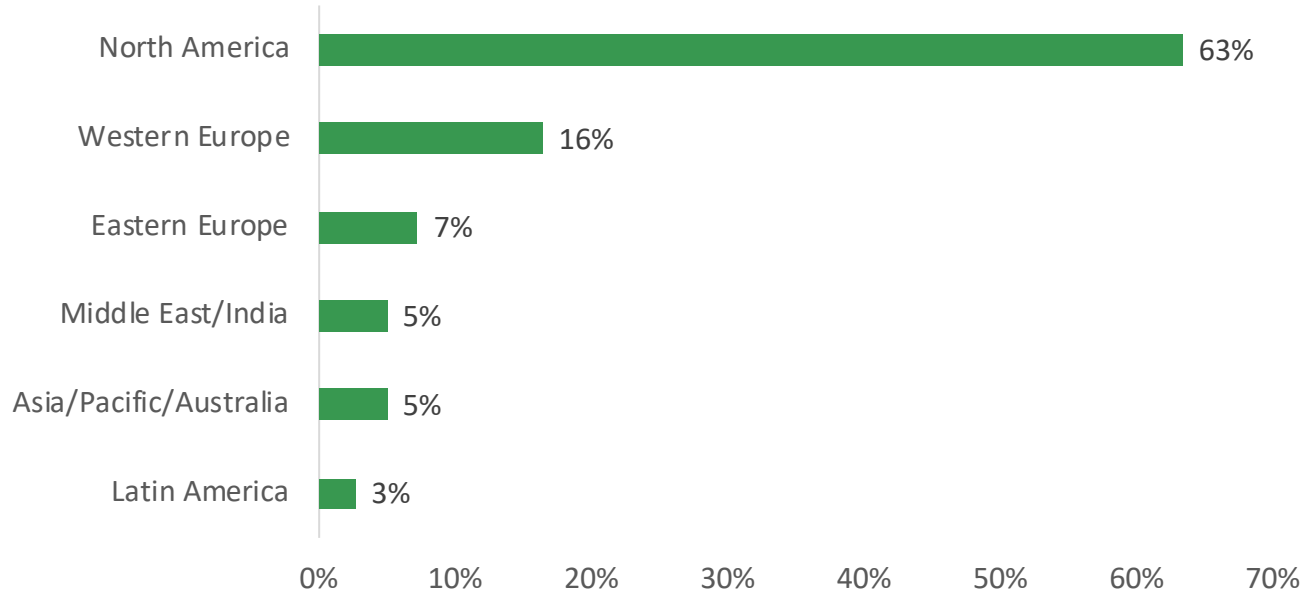
North America — 63%
Western Europe — 16%
Eastern Europe — 7%
Middle East/India — 5%
Asia/Pacific/Australia — 5%
Latin America — 3%
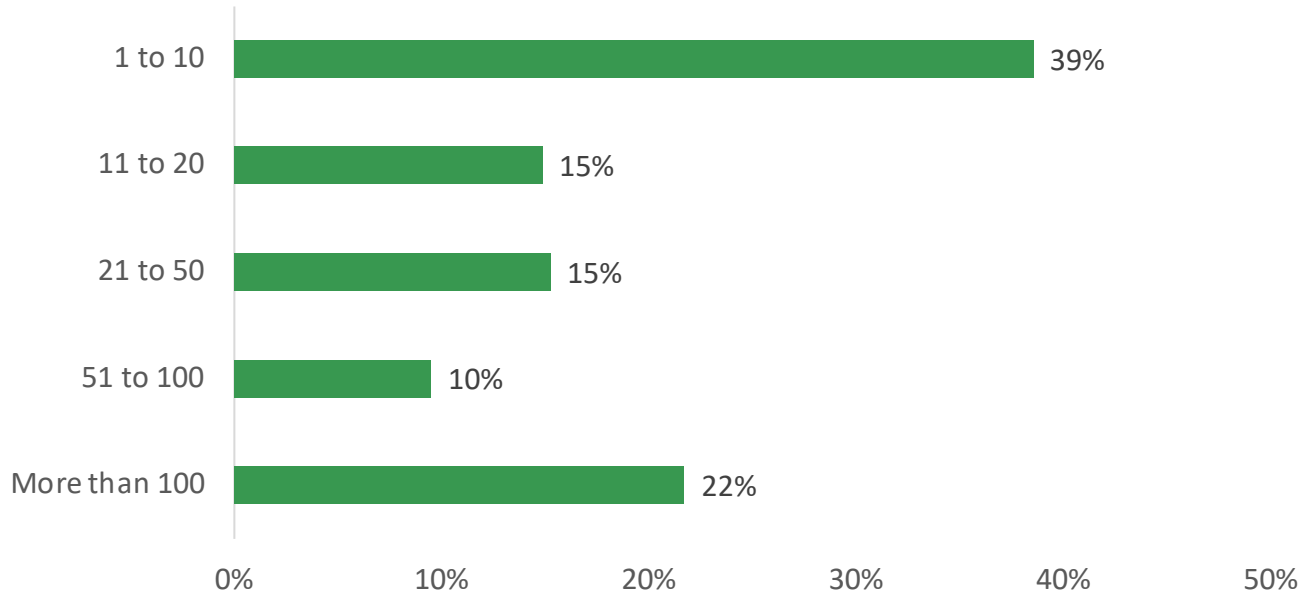
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