Tufts CSDD-goBalto Site Selection Market Research (START II)

June 30, 2017

Final Report

Tufts Center for the Study of Drug Development

Tufts CSDD Team

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Overview

- **Executive Summary**
- **Final Report – Core Market Research Study**
- **Four Mini-Reports**
  - Sponsors vs. CROs
  - Fastest vs. Other Companies
  - Centralized vs. Non-Dedicated (Localized) Functional Groups
 - Most Consistent vs. Other Companies

Topline Results

EXECUTIVE SUMMARY

Cycle Times

- Overall
  - *Repeat 25.7 weeks, CoV- .58*
  - *New 35.6 weeks, CoV- .52*
- Site ID Time
  - *Repeat: 3.5 weeks, CoV- 1.25*
  - *New: 6.5 weeks, CoV- .83*
- Site Selection Time
  - *Repeat: 5.2 weeks, CoV- .86*
  - *New: 7.9 weeks, CoV- .68*
- Study Start-Up Time
  - *Repeat: 17.5 weeks, CoV- .71*
  - *New: 22.0 weeks, CoV- .69*

Average Cycle Time Comparisons (Weeks)

	Site ID	Site Selection	Study Start-up
New Sites	6.5	7.9	22
Repeat Sites	3.5	5.2	17.5
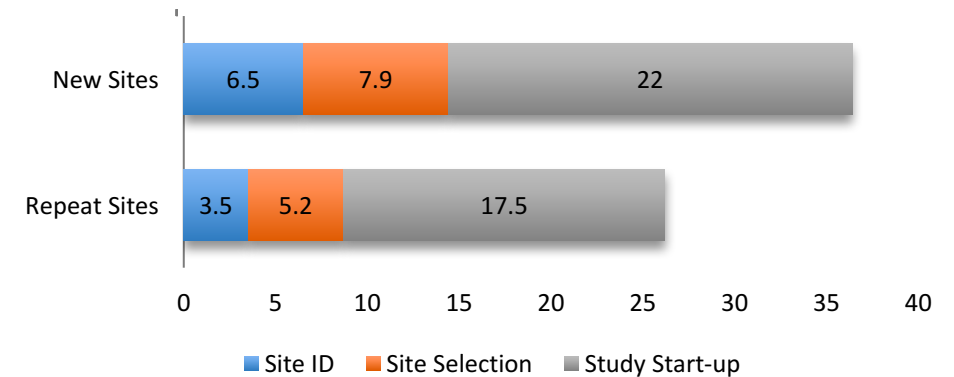
Cycle Times Continued

- **Cycle times are 9.9 weeks (28%) longer on average for new vs. repeat sites**

- **CROs report shorter cycle times compared to sponsors; 20% for repeat sites and 28% for new sites**

- **11% of sites are never activated; this has not changed substantially in over a decade**

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Satisfaction Levels

- **On average 10% of respondents report they are very satisfied, 30-40% report that they are somewhat/completely unsatisfied with their processes**

- **Satisfaction in site ID is correlated with satisfaction in site selection (r=.65) and study start up (r=.54) and satisfaction in site selection is correlated with satisfaction in study start up (r=.60)**

- **Respondents reporting that they are very satisfied have cycle times 57.5% shorter than those that report that they are completely unsatisfied**

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Technology Trends

- **80% of respondents who have invested in technology report time savings**

- **On average CROs report that they invest in technology 10% more than sponsors**

- **On average organizations with dedicated functional groups report more than twice as much investment (49% vs. 22%) than those without a dedicated function**

- **Respondents reporting their technology is adequate have 30% shorter cycle times than those with inadequate technologies**

Key Challenges and Opportunities

- **Factors contributing to ineffective / inefficient processes and key opportunities for improvement:**

	Site Identification	Site Selection	Study Start-Up
Key Factors	There is no single source of data used to identify sites – still very disparate and overall heavy reliance on low tech (non evidence-based approaches)	Lack of site / investigator responsiveness	Budgeting and Contracting
Opportunities for Improvement	Pooled and shared data on site performance	Obtain better evidence of site's true enrollment potential	Centralized ethics review

- **Improvements in all areas are either attributed to new technologies or process change**

Notable Subgroup Findings

- **Company type is an indicator of process satisfaction and cycle time efficiencies**
    - *Sponsors have the greatest need for cycle time improvements regardless of size*
    - *The greatest dissatisfaction was reported by respondents at mid-sized and large CROs, as well as small sponsors*

- **CROs report shorter cycle times compared to sponsors; 5.6 weeks for repeat sites and 11 weeks for new sites**

- **Almost half of the respondents (48%) report they have a centralized function dedicated to these site related activities**

- **Organizations with dedicated functional groups have <u>no</u> improvement in cycle times working with repeat sites but have a 2 week (10%) advantage working with new sites**

OVERVIEW OF THE SURVEY, METHODOLOGY, ANALYSIS AND RESPONDENT CHARACTERISTICS

Collaboration Goals and Overview

- **goBalto engaged Tufts CSDD to conduct a survey of biopharmaceutical and CRO companies in order to gather robust, quantitative insights into the site selection process as a follow-up to prior collaborative goBalto-Tufts CSDD studies**
- **Areas examined in the survey include:**
  - Site selection practices and decision-making, study start up, and site feasibility
  - Implementation of specific tools and resources that impact cycle time, cost, and performance.
  - Factors contributing to poor site selection; improvements made to the site selection and start up processes.
  - Key performance metrics (e.g., cycle time) were gathered.

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Survey Overview

- **591 Total Responses**

- **61 Questions Divided into 9 Sections**

- **Open for About 8 Weeks (January 9-March 3)**

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Survey Categories and Key Themes Explored

- Best data sources to find sites
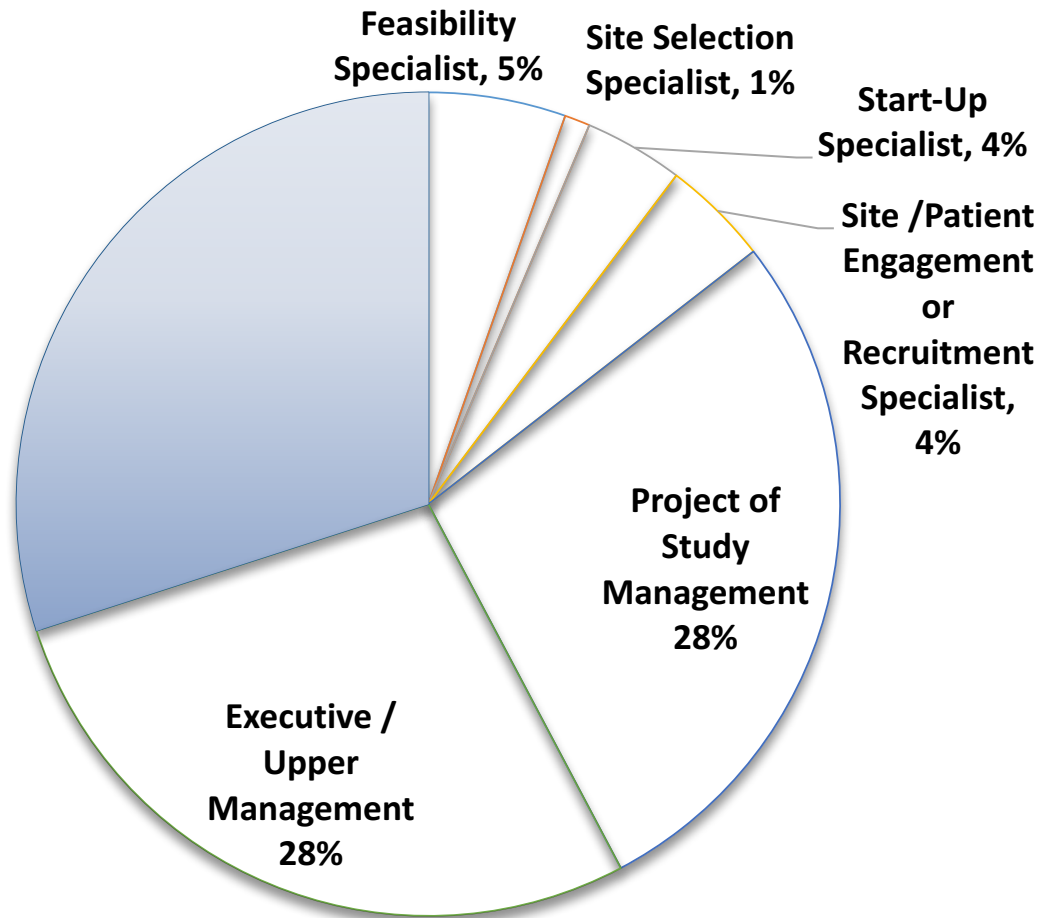- Site utilization

- Predictability considerations

- Requirements and Decision making process
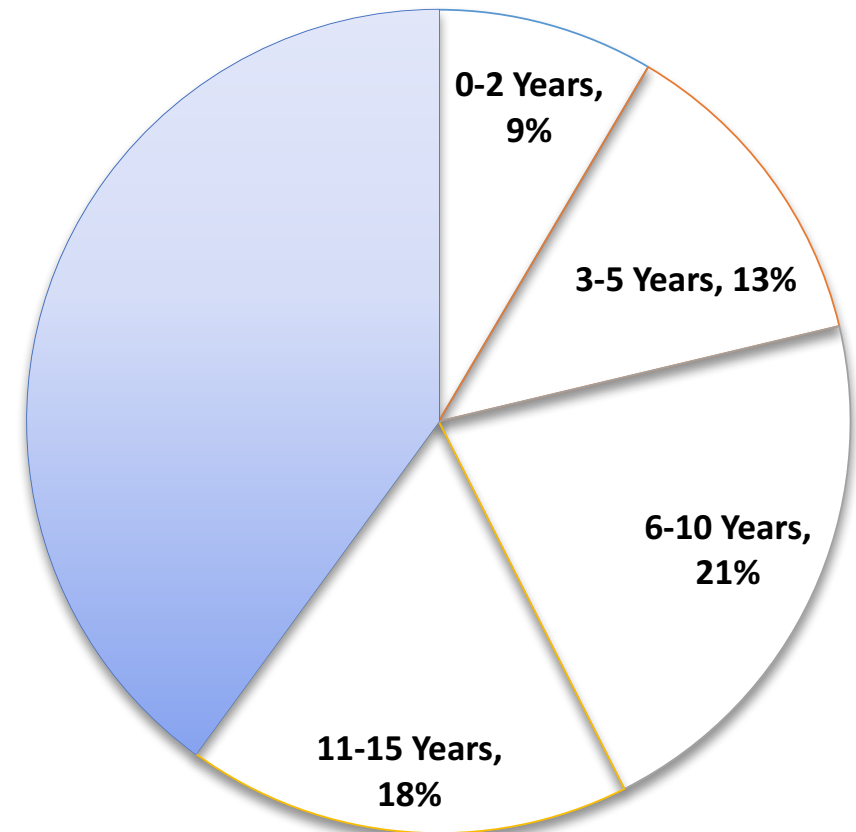
- Tools, processes, technology

- **Cycle time metrics**
- **Issues and opportunities / level of satisfaction with current approach**
- **Type of investments being made to improve processes**
- **Impact of Centralized vs. Decentralized functions on these processes**

Survey Respondent Demographics

Respondent Roles

- Feasibility Specialist, 5%
- Site Selection Specialist, 1%
- Start-Up Specialist, 4%
- Site /Patient Engagement or Recruitment Specialist, 4%
- Project of Study Management 28%
- Executive / Upper Management 28%

Respondent Years of Experience

- 0-2 Years, 9%
- 3-5 Years, 13%
- 6-10 Years, 21%
- 11-15 Years, 18%

Organization Type

403 Unique Organization Responses

75% U.S Based

Y-axis: Number of Responses (N=591)

Sponsor	CRO	Other	Site	Medical Device Company	Academic	Independent Contractor
313	139	61	24	21	18	15
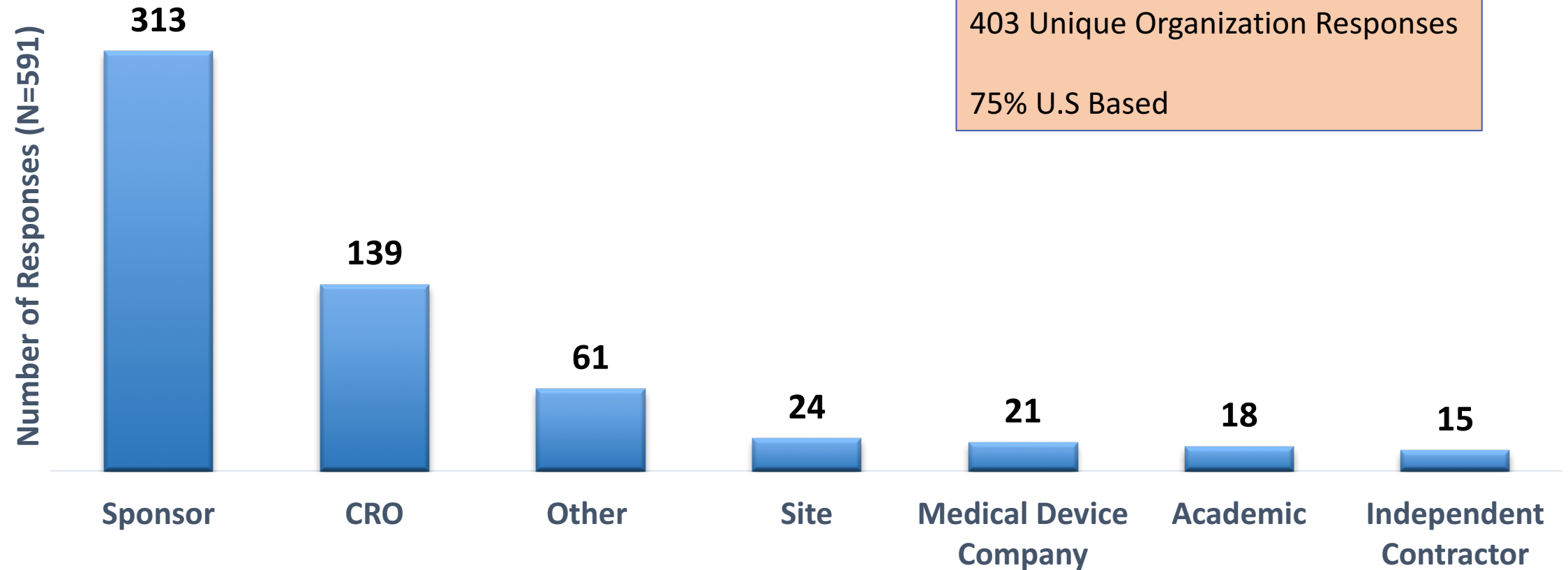
The primary analysis is restricted to sponsor and CRO respondents; others were removed from the analysis

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Organization Profiles
(Primary Sponsor/CRO Respondents)

	Non – Centralized Group (14)	Centralized Group (18)
	Non-Centralized Group (13)	Non-Centralized Group (144)
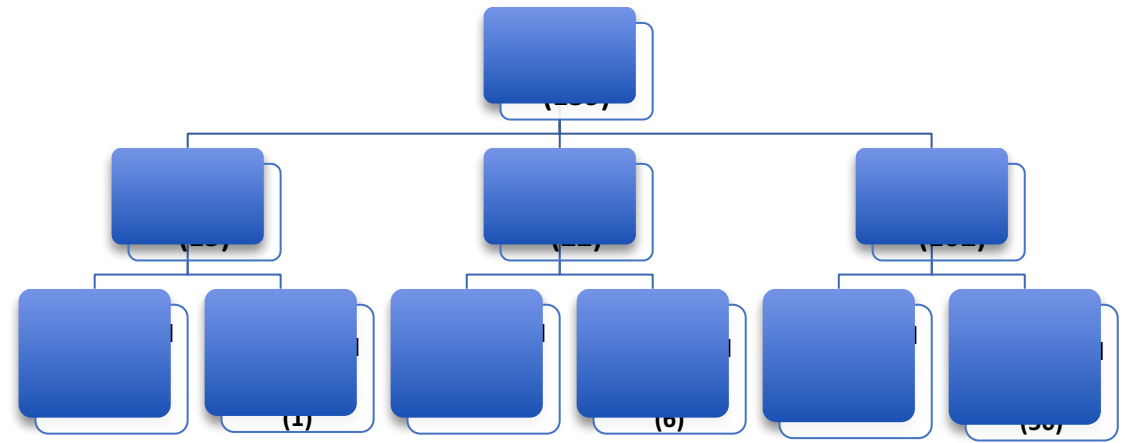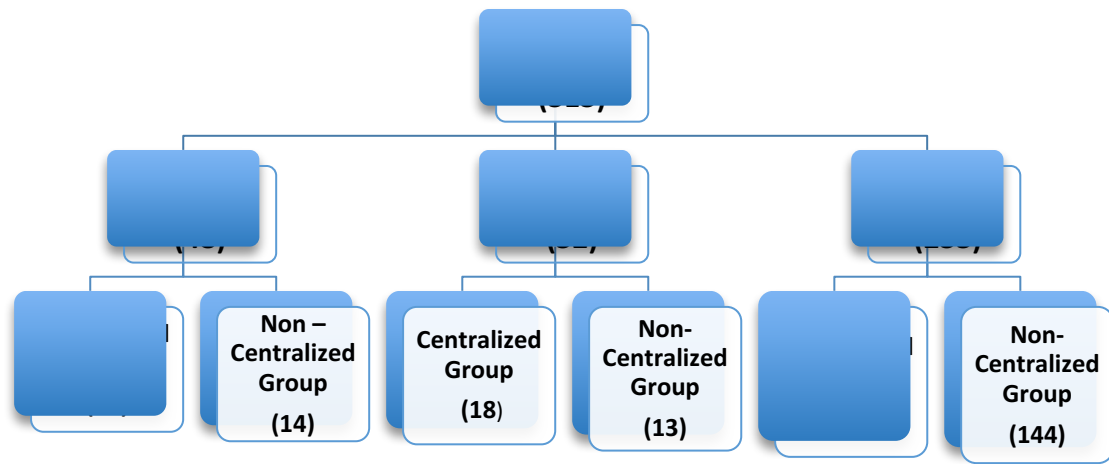
Subcategories may not add up to parent categories due to missing responses

Types of Analyses Performed

- **Simple Frequency Comparisons**

- **Analysis of Mean Response Values with and without Stratification Variables**

- **Significance Testing**

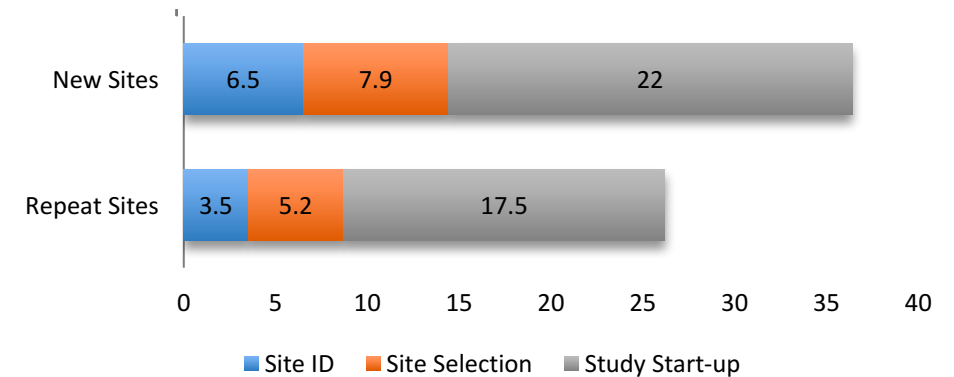- **Correlation Analysis and Predictive Modeling**

Key Conclusion: There were very few correlations or predictors of factors impacting cycletimes and satisfaction with site identification, site selection, study feasibility or study start-up activities.

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CYCLE TIME RESULTS

Cycle Times

- Overall
  - *Repeat 25.7 weeks, CoV- .58*
  - *New 35.6 weeks, CoV- .52*
- Site ID Time
  - *Repeat: 3.5 weeks, CoV- 1.25*
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- Site Selection Time
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- Study Start-Up Time
  - *Repeat: 17.5 weeks, CoV- .71*
  - *New: 22.0 weeks, CoV- .69*

Average Cycle Time Comparisons (Weeks)

	Site ID	Site Selection	Study Start-up
New Sites	6.5	7.9	22
Repeat Sites	3.5	5.2	17.5

Average Overall Cycle Times, CRO vs Sponsor, Repeat vs New Sites

Company Type	Variable	N	Average Number of Weeks	P-Value
CRO	Sites Worked With Before	70	21.8	0.007
	Sites Not Worked With Before	69	28.0	<.0001
Sponsor	Sites Worked With Before	161	27.4	0.007
	Sites Not Worked With Before	163	39.0	<.0001

Key Messages:
- Overall average cycle times (site ID to site readiness to enroll) for repeat sites is 27.4 weeks for sponsors and 21.8 weeks for CROs
- The cycle time increases ~7 weeks (CROs) and ~12 weeks (Sponsors) when working with sites who are new
- Overall, CROs report completing all site related activities 6-11 weeks faster than sponsors

Site Identification Process Cycle Time

Site Identification Cycle Times By Organization (Wks)*

Legend: ■ New ■ Repeat

- CRO
  - New: 4.3
  - Repeat: 2.4
- Sponsor
  - New: 7.3
  - Repeat: 3.6

Site Identification Cycle Times by Functional Group (Wks)

Legend: ■ New* ■ Repeat

- Decentralized
  - New: 7.1
  - Repeat: 3.7
- Centralized Function
  - New: 5.8
  - Repeat: 3.3
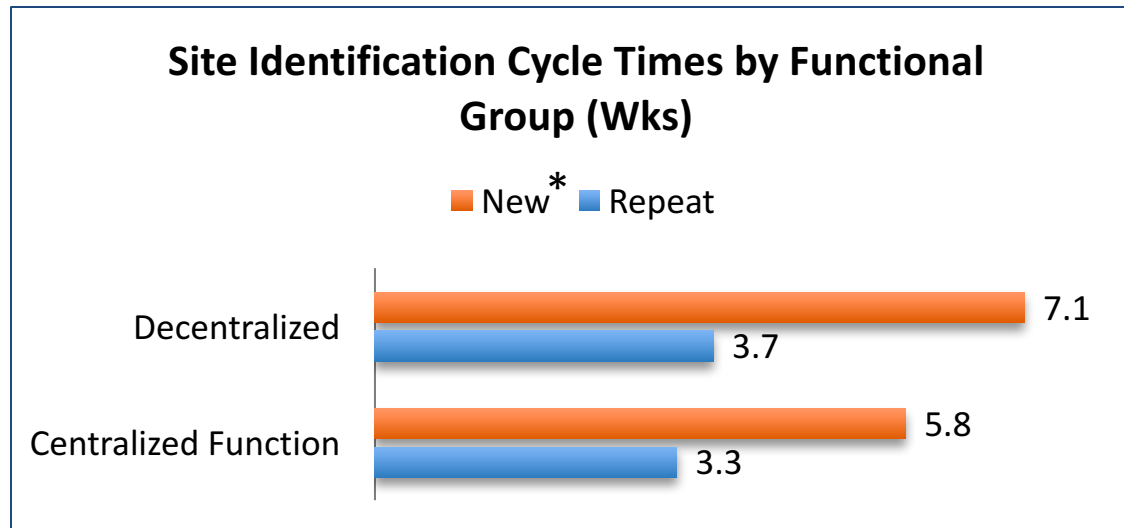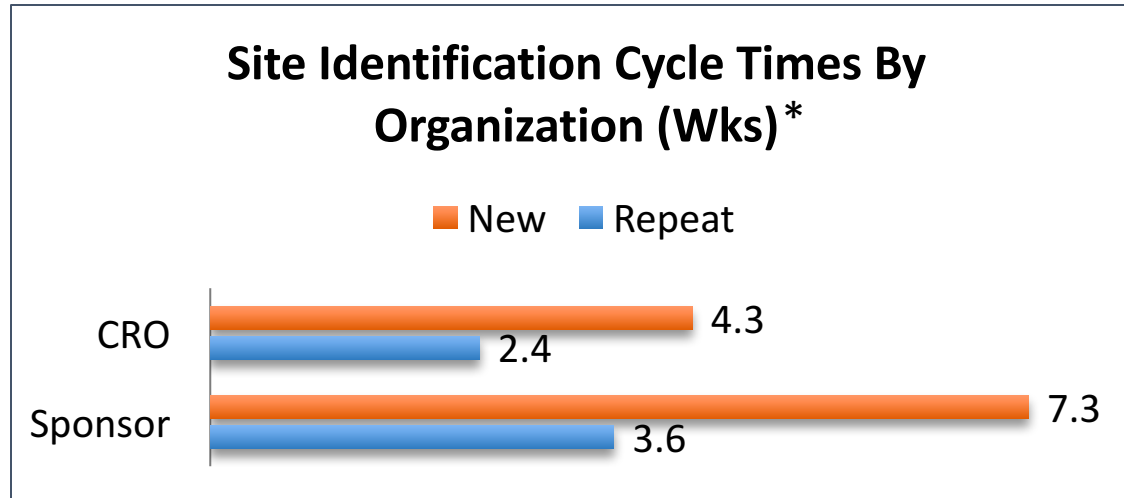
- CROs report completing this activity several weeks faster than Sponsors

- It takes about twice as long to identify new sites compare to repeat sites

- Companies with centralized functions report some time savings but mainly for new sites

*Values significant at the P<.05 level

Site Identification Process Cycle Time

Compared to 3 years ago...

		Percent Very/SW Shorter	Percent Very/SW Longer
Sponsor Companies	Repeat	36.2%	8.0%
	New	32.5%	15.5%
CRO	Repeat	52.5%	7.1%
	New	47.4%	12.4%
Companies with a Centralized Function	Repeat	52.4%	6.5%
	New	47.0%	11.0%
Companies that are Decentralized	Repeat	29.7%	8.8%
	New	25.3%	15.7%

- CROs report greater improvements (i.e., cycle time reduction) compared to sponsors as do organizations with centralized functions

- However, ~10% of the companies report the process taking longer than 3 years ago

Site Selection Process Cycle Time

Site Selection Cycle Times by Organization (Wks)

■ New * ■ Repeat

CRO
- New: 6.7
- Repeat: 5.3

Sponsor
- New: 8.3
- Repeat: 5.6

Cycle Times by Function (Wks)

■ New ■ Repeat

Decentralized
- New: 7.6
- Repeat: 5.2

Centralized Function
- New: 8.2
- Repeat: 5.8
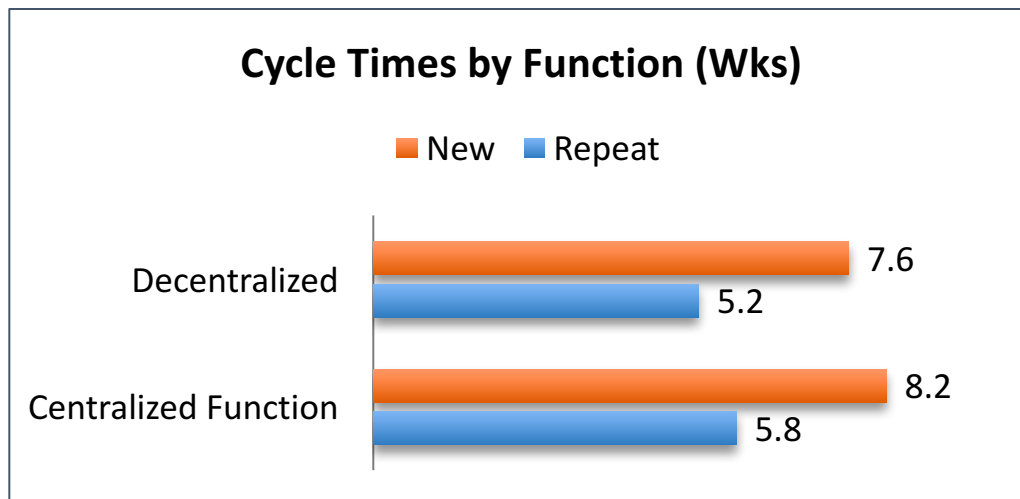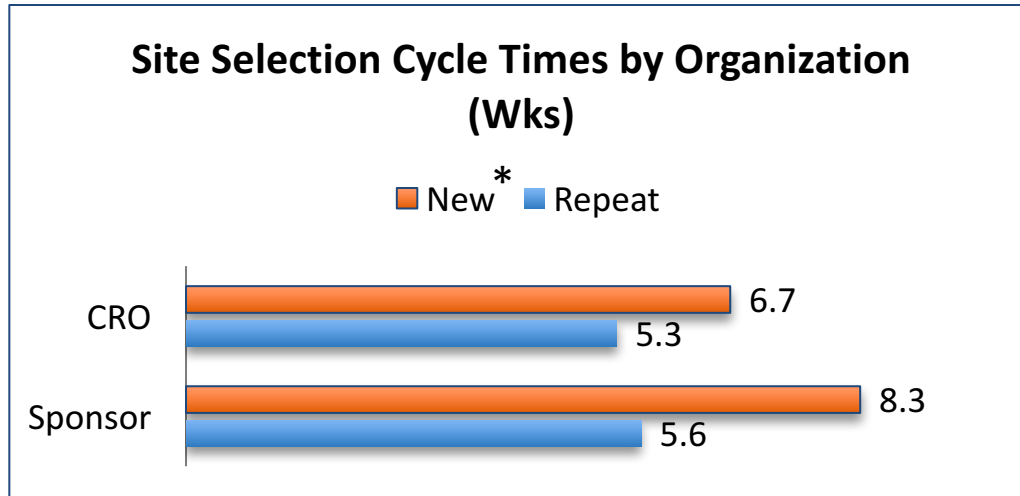
- CROs report completing this activity several weeks faster than Sponsors for **NEW** sites

- It takes about 1-3 weeks longer to select new sites compared to repeat sites

- There is not a significant difference in cycle time based on centralization of the function

*Values significant at the P<.05 level

Site Selection Process Cycle Time

Compared to 3 years ago...

		Percent Very/SW Shorter	Percent Very/SW Longer
Sponsor Companies	Repeat	3.9%	11.5%
	New	26%	17.5%
CRO	Repeat	40.3%	27.9%
	New	30.3%	15.8%
Companies with a Centralized Function	Repeat	38.1%	7.5%
	New	37.2%	12.4%
Companies that are Decentralized	Repeat	26.3%	9.6%
	New	19.2%	17.9%

- CROs report greater improvements (i.e., cycle time reduction) compared to sponsors as do organizations with centralized functions

- However, ~7-27% of the companies report the process taking longer than 3 years ago

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Study Start-up Process Cycle Time

Site Start-Up Cycle Time By Organization (Wks)*

Legend: ■ New ■ Repeat

- CRO: New 17.9, Repeat 14.9
- Sponsor: New 24.3, Repeat 18.9

Start-up Cycle Times by Functional Group

Legend: ■ Repeat ■ New

- Centralized Function: Repeat 18.4, New 23
- Decentralized: Repeat 16.9, New 21.3
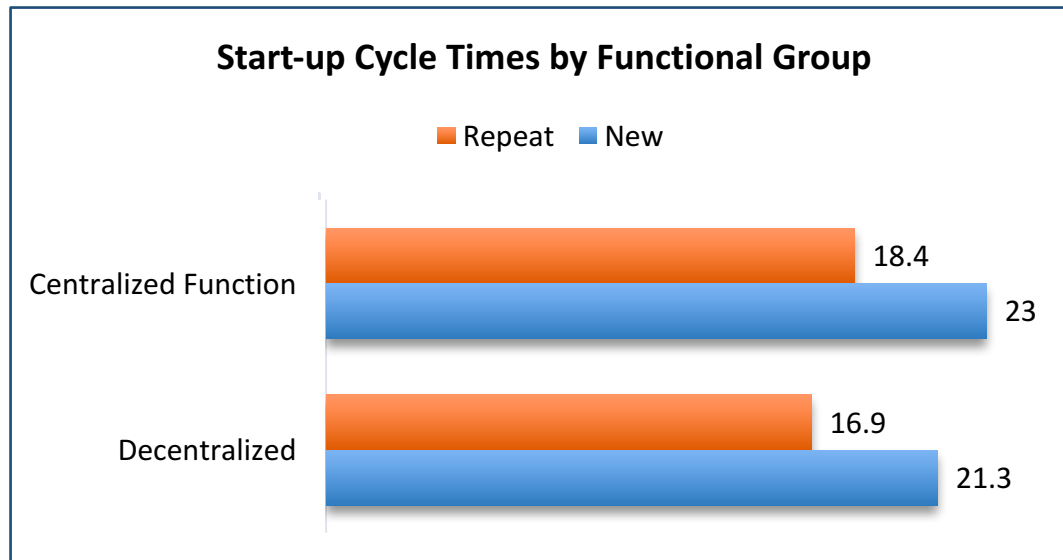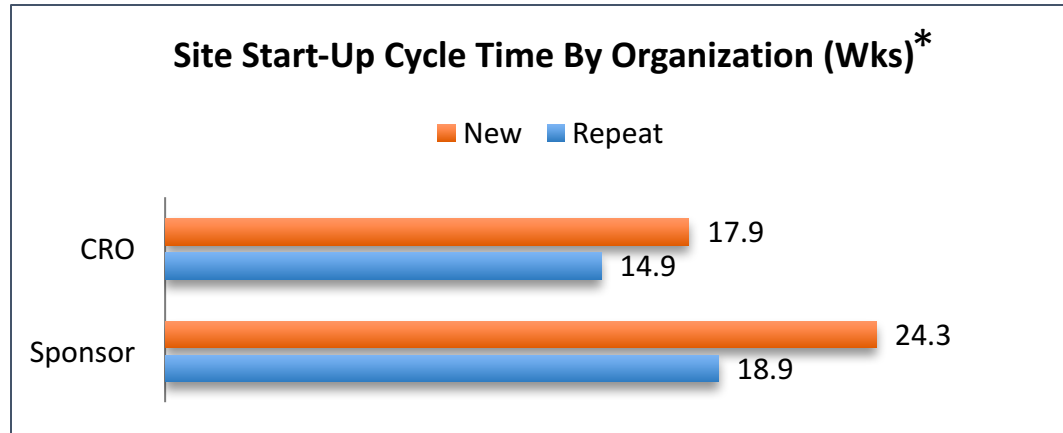
- **CROs report completing this activity several weeks faster than Sponsors**

- **It takes about 3-6 weeks longer to activate new sites compared to repeat sites**

- **Site start-up times appear to be bit shorter for new sites with a decentralized although the difference is slight**

*Values significant at the P<.05 level

Study Start-up Process Cycle Time

Compared to 3 years ago…

		Percent Very/SW Shorter	Percent Very/SW Longer
Sponsor Companies	Repeat	18.9%	27.5%
	New	15.9%	35.0%
CRO	Repeat	36.1%	15.3%
	New	23.9%	15.5%
Companies with a Centralized Function	Repeat	35.9%	17.1%
	New	27.9%	20.7%
Companies that are Decentralized	Repeat	17.7%	27.9%
	New	13.5%	33.3%

- **CROs report greater improvements (i.e., cycle time reduction) compared to sponsors as do organizations with centralized functions**

- **However, ~17-35% of the companies report the process taking longer than 3 years ago**

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SATISFACTION RESULTS

Satisfaction Levels

- **On average 10% of respondents report they are very satisfied, 30-40% report that they are somewhat/completely unsatisfied with their processes**

- **Satisfaction in site ID is correlated with satisfaction in site selection (r=.65) and study start up (r=.54) and satisfaction in site selection is correlated with satisfaction in study start up (r=.60)**

- **Respondents reporting that they are very satisfied have cycle times 57.5% shorter than those that report that they are completely unsatisfied**

Satisfaction with the Site Identification Process

Stacked bar chart showing satisfaction levels across four categories:

Sponsor
- Completely Unsatisfied: 4%
- Somewhat Unsatisfied: 28%
- Somewhat Satisfied: 59%
- Very Satisfied: 9%

CRO
- Completely Unsatisfied: 10%
- Somewhat Unsatisfied: 19%
- Somewhat Satisfied: 59%
- Very Satisfied: 11%

Centralized
- Completely Unsatisfied: 3%
- Somewhat Unsatisfied: 28%
- Somewhat Satisfied: 55%
- Very Satisfied: 14%

Decentralized
- Completely Unsatisfied: 8%
- Somewhat Unsatisfied: 24%
- Somewhat Satisfied: 62%
- Very Satisfied: 6%

Legend: ■ Very Satisfied ■ Somewhat Satisfied ■ Somewhat Unsatisfied ■ Completely Unsatisfied

Satisfaction with the Site Selection Process
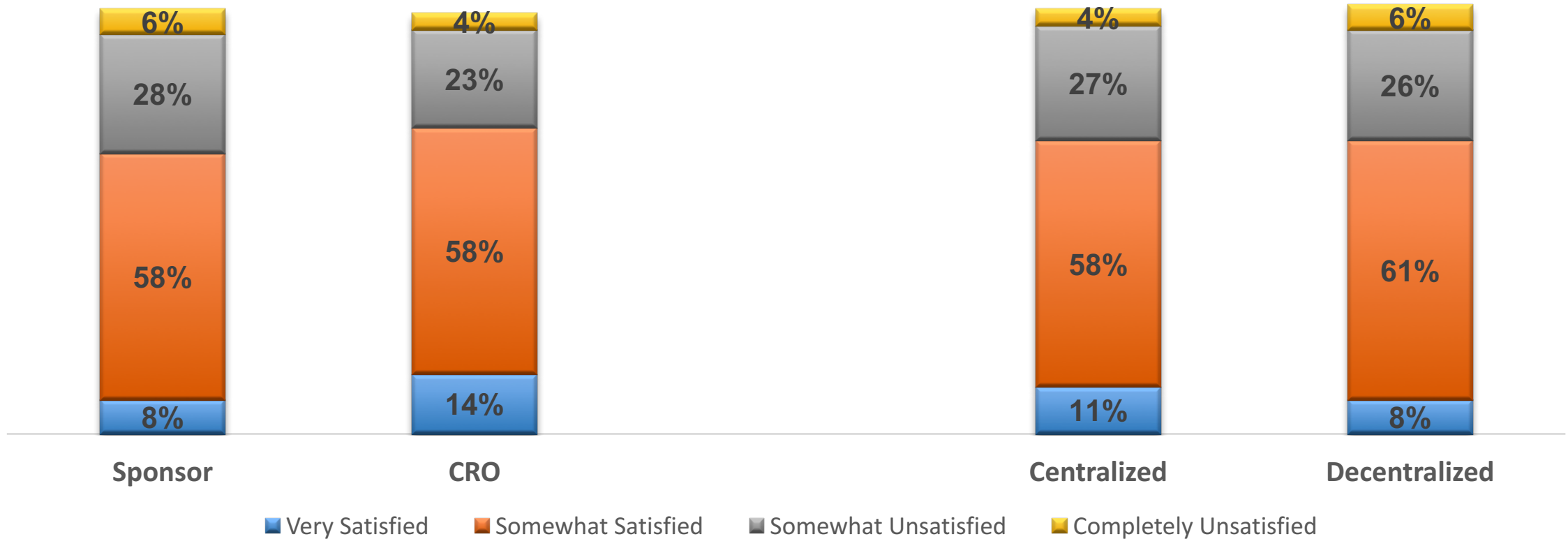
Satisfaction with the Study Start-Up Process
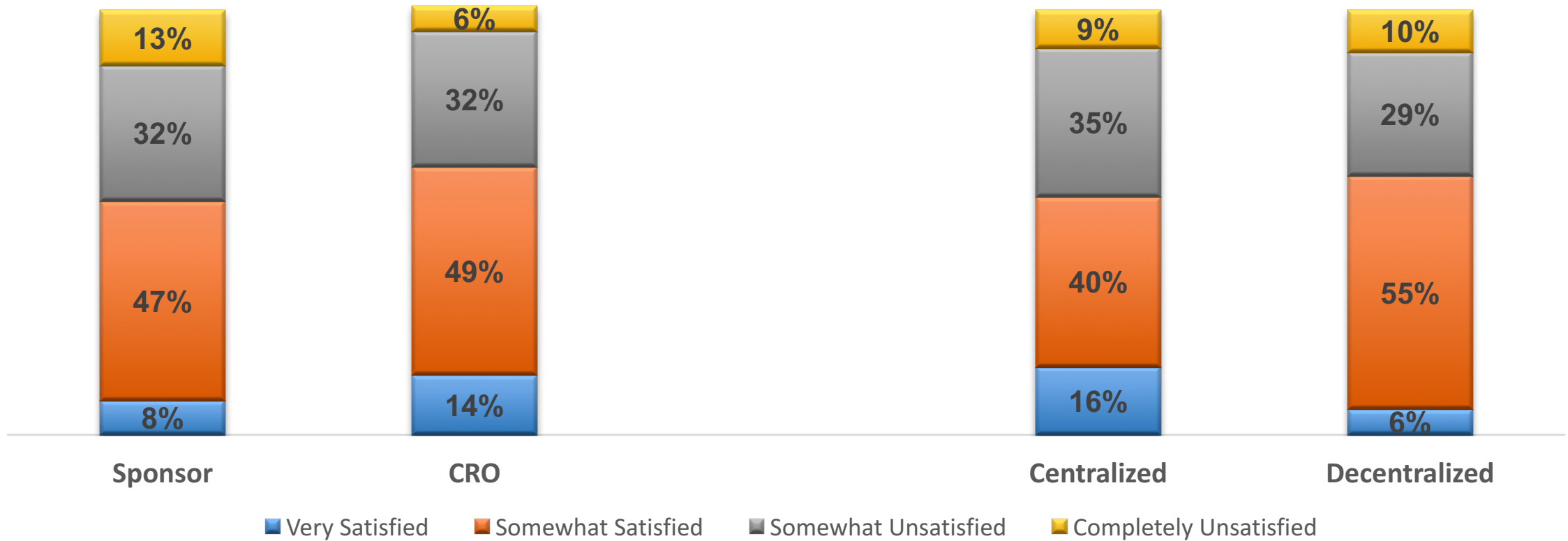
Satisfaction Levels by Phase*, Sponsor vs CRO

Company Type	Variable	N	Average Satisfaction	P-Value
CRO	Site ID Satisfaction	73	2.7	0.99
	Site Selection Satisfaction	73	2.8	0.18
	Study Start-Up Satisfaction	72	2.7	0.06
Sponsor	Site ID Satisfaction	160	2.7	0.99
	Site Selection Satisfaction	156	2.7	0.18
	Study Start-Up Satisfaction	160	2.5	0.06

Scale:
Completely Unsatisfied (1)
Somewhat Unsatisfied (2)
Somewhat Satisfied (3)
Very Satisfied (4)

Key Messages:
- Both organizations are barely more satisfied than unsatisfied overall with their processes
- CRO's are slightly more satisfied with their site selection and study start-up activities compared to sponsors

* = Site Identification, Site Selection, Study Start-Up

Cycle Times by Satisfaction

Repeat Sites

Level of Satisfaction	N	Average Weeks
Completely Unsatisfied	52	32.21
Somewhat Unsatisfied	214	26.96
Somewhat Satisfied	423	25.61
Very Satisfied	74	17.72

New Sites

Level of Satisfaction	N	Average Weeks
Completely Unsatisfied	52	42.63
Somewhat Unsatisfied	214	38.07
Somewhat Satisfied	423	34.34
Very Satisfied	74	25.59

TECHNOLOGY TRENDS

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Technology Trends

- **80% of respondents who have invested in technology report time savings**

- **On average CROs report that they invest in technology 10% more than sponsors**

- **On average organizations with dedicated functional groups report more than twice as much investment (49% vs. 22%) than those without a dedicated function**

- **Respondents reporting their technology is adequate have 30% shorter cycle times than those with inadequate technologies**

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Areas of Investment by Company Type
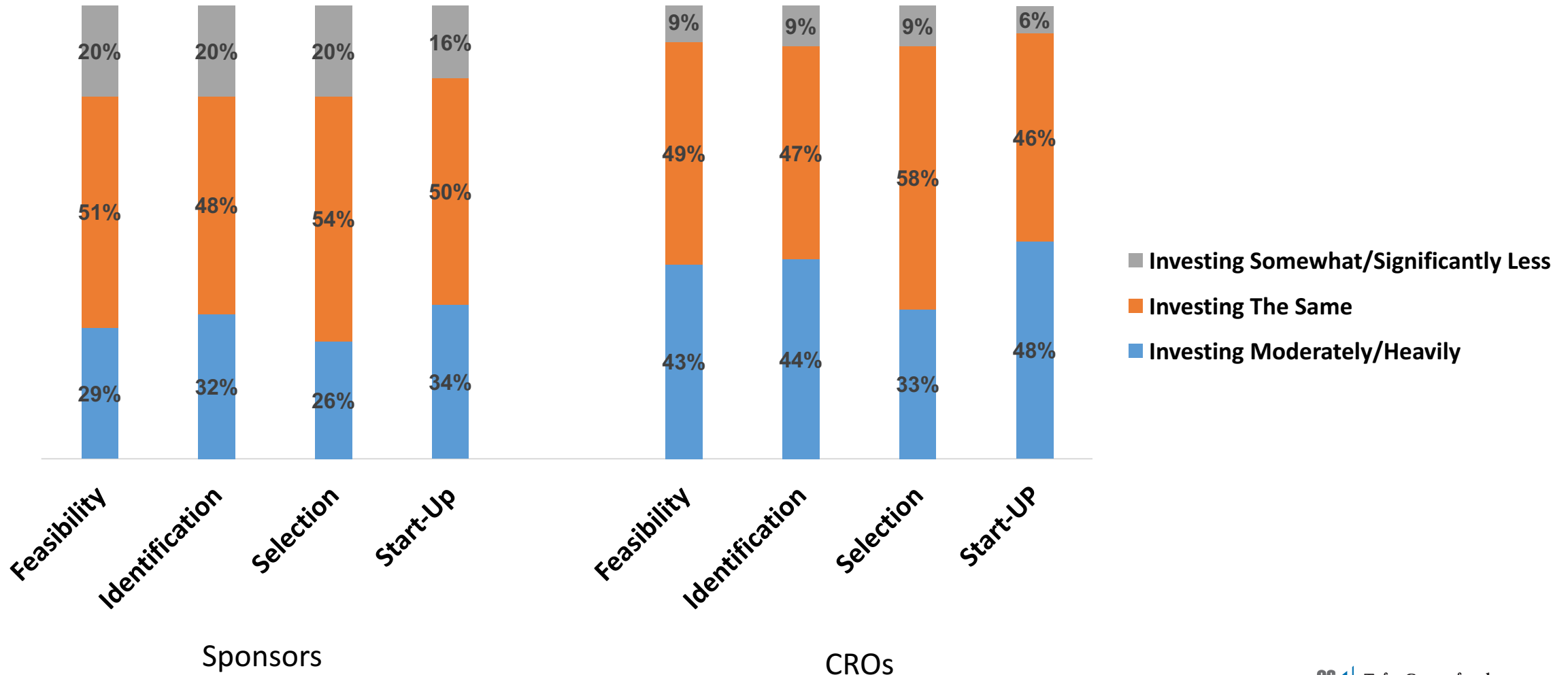
Areas of Investment by Functional Approach

Legend:
- Investing Somewhat/Significantly Less
- Investing The Same
- Investing Moderately/Heavily

Dedicated Functional Group

	Feasibility	Identification	Selection	Start-Up
Investing Somewhat/Significantly Less	11%	11%	11%	8%
Investing The Same	39%	37%	48%	38%
Investing Moderately/Heavily	50%	52%	41%	54%

No Dedicated Functional Group

	Feasibility	Identification	Selection	Start-UP
Investing Somewhat/Significantly Less	22%	21%	21%	17%
Investing The Same	60%	56%	59%	56%
Investing Moderately/Heavily	18%	23%	20%	27%

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Study Start-Up Management Technology

Start-Up Technologies

Overall, nearly 40% of respondents are still using unsophisticated methods which may contribute to lower satisfaction levels

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Overall Technology Adequacy

Tool/Technology Effectiveness	Frequency	Percent
Our current tools/technology are adequate to support our needs	52	20.3
Our current tools/technology could be improved somewhat	153	59.8
Our current tools/technology are woefully inadequate and need to be improved greatly	51	19.9

Frequency Missing = 335

Key Messages:
- About 80% of respondents feel there is a need to improve tools / technology to enable more effective and efficient processes

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Satisfaction per Technological Adequacy

Tool/Technology Effectiveness	Variable	N	Average Satisfaction	P-Value
Our current tools/technology are adequate to support our needs	Site ID Satisfaction	50	3.1	.0001
	Site Selection Satisfaction	49	2.9	.007
	Study Start-Up Satisfaction	50	2.9	<.0001
Our current tools/technology could be improved somewhat	Site ID Satisfaction	151	2.7	.0001
	Site Selection Satisfaction	149	2.7	.007
	Study Start-Up Satisfaction	150	2.6	<.0001
Our current tools/technology are woefully inadequate and need to be improved greatly	Site ID Satisfaction	51	2.5	.0001
	Site Selection Satisfaction	50	2.5	.007
	Study Start-Up Satisfaction	50	2.2	<.0001

Key Message:
- Respondents reporting that their tools / technology are adequate are generally more satisfied with their site related processes

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Cycle Times by Technological Adequacy

Tool/Technology Effectiveness	Variable	N	Average Weeks	P-Value
Our current tools/technology are adequate to support our needs	Sites Worked With Before	46	21.4	.03
	Sites Not Worked With Before	45	29.1	.03
Our current tools/technology could be improved somewhat	Sites Worked With Before	135	25.8	.03
	Sites Not Worked With Before	134	34.5	.03
Our current tools/technology are woefully inadequate and need to be improved greatly	Sites Worked With Before	47	29.8	.03
	Sites Not Worked With Before	47	42.1	.03

Frequency of Time Savings Reported Due to Technology

Tool/Technology Time Savings	Frequency	Percent
Large time savings	48	18.75
Small time savings	133	51.95
No time savings	58	22.66
Time lost	17	6.64

Frequency Missing = 335

Key Message:
- About 80% of respondents who have invested in technology report time savings
- CROs report greater time savings compared to sponsors

Challenges and Opportunities for Improvement

Key Challenges and Opportunities

- **Factors contributing to ineffective / inefficient processes and key opportunities for improvement:**

	Site Identification	Site Selection	Study Start-Up
Key Factors	There is no single source of data used to identify sites – still very disparate and overall heavy reliance on low tech (non evidence-based approaches)	Lack of site / investigator responsiveness	Budgeting and Contracting
Opportunities for Improvement	Pooled and shared data on site performance	Obtain better evidence of site's true enrollment potential	Centralized ethics review

- **Improvements in all areas are either attributed to new technologies or process change**

Site Activation Rates

Percentage of Sites Never Activated

11.1%	8.7%	10.6%	11.2%
Sponsor Company*	CRO *	Centralized Function	Decentralized
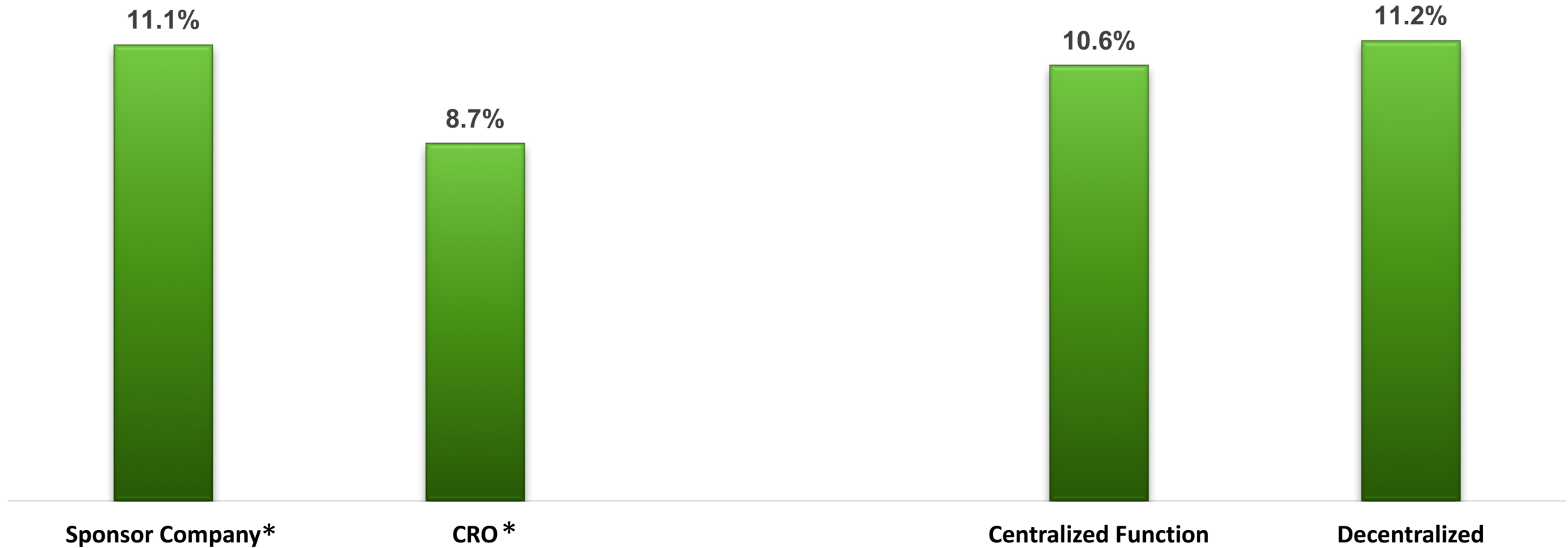
*Values significant at the P<.05 level

Primary Reasons for Activation Failures

	Sponsor Companies	CROs	Centralized Function	Decentralized
Budgeting & Contracting	50.5%	54.3%	49.6%	49.4%
Investigator loses Interest	9.0%	4.9%	7.3%	9.2%
Investigator leaves institution	4.3%	1.2%	2.9%	3.7%
Staff or Resource Issues at the Site Level	13.3%	12.4%	13.9%	10.4%
Too Many Competing Studies	11.2%	14.8%	14.6%	11.6%

Factors Influencing Assessment of Investigator's Enrollment Potential
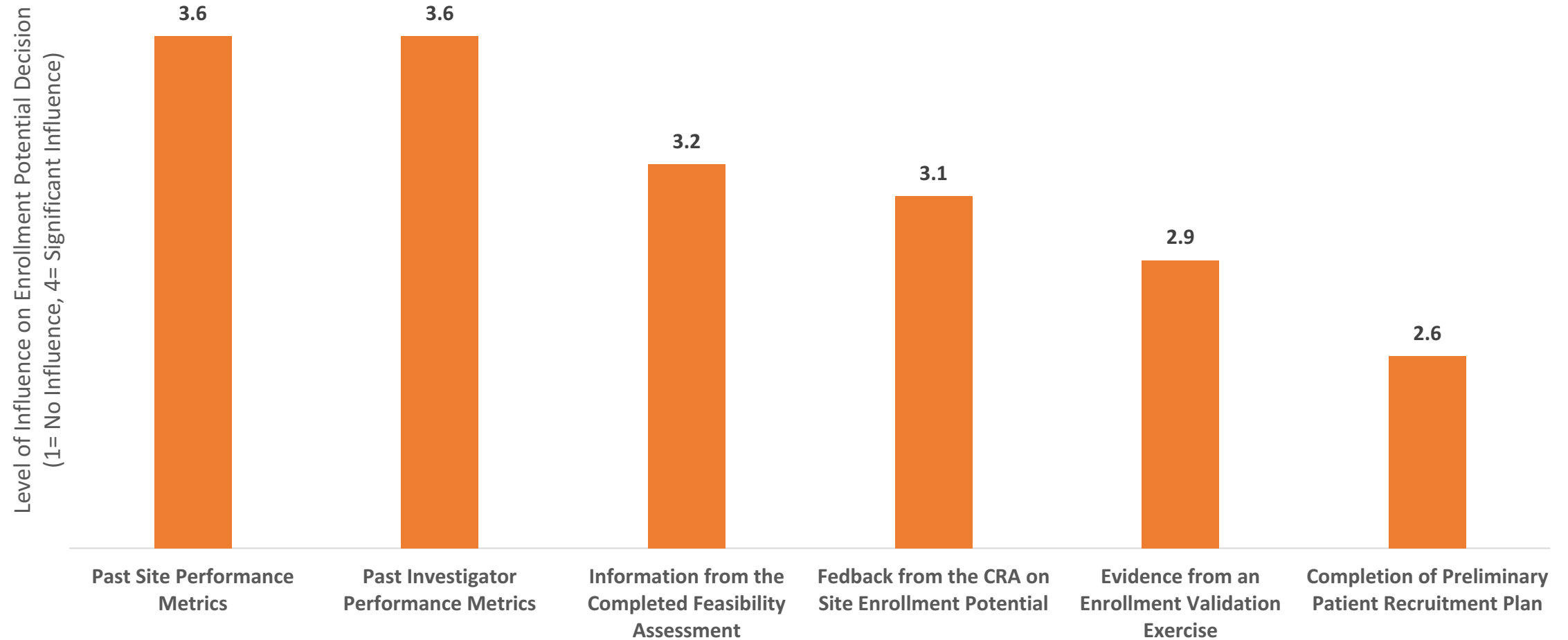
Top Factors Contributing to an Ineffective Site Selection Process

Factors having a contribution to inefficiencies:

- **Responsiveness of Sites / Investigators**
- **Quality / Performance Issues**
- **Timeliness Issues**
- **Information Issues**

Factor	Average Contribution Rating (1= No Contribution, 4= Significant Contribution)	Example
Responsiveness of Sites / Investigators	3.7	e.g., no response, delayed response
Timeliness Issues	3.2	e.g. the amount of time it takes to get sites identified and selected
Quality / Performance Issues	3.3	e.g. sites who overestimate their enrollment potential and do not deliver
Cost/Resource issues	2.9	e.g. the resources it takes to get sites identified and selected
Information Issues	3.0	e.g. not having enough information about the protocol when starting site selection or not having enough historical information about a site's past performance
Performance Issues	2.9	e.g. cumbersome and time consuming process to identify, contact and interact with sites or not having consensus on the criteria for selecting sites

Looking Ahead: Enhancing Site Identification

(Percentage SW/Great Deal)	Sponsor Companies	CROs	Centralized Functions	Decentralized
Pooled and Shared Data on Site Performance	**89.5%**	**94.4%**	**85.4%**	**91.5%**
Stricter Site Requirements for Site Accreditation/ Certification	**50.7%**	**62.0%**	**55.3%**	**54.6%**
More Stringent Site Competency Requirements	**64.9%**	**80.3%**	**67.7%**	**72.3%**

Looking Ahead: Enhancing Site Selection

(Percentage SW/Great Deal)	Sponsor Companies	CROs	Centralized Functions	Decentralized
Better Evidence of Site's True Enrollment	95.4%	97.2%	96.2%	95.7%
Share more information on site early	84.3%	84.5%	83.7%	85.1%
Conversation; not a form	82.2%	84.3%	80.6%	83.6%
More information about potential new sites	87.6%	91.6%	91.4%	86.5%
Consensus from all stakeholders on key criteria	68.0%	74.7%	76.0%	66.4%
Plan for more back-up sites	60.8%	71.4%	62.1%	66.7%
Leverage better study planning tools and software	72.6%	82.9%	76.9%	72.1%

Looking Ahead: Enhancing Study Start-Up

(Percentage SW/Great Deal)	Sponsor Companies	CROs	Centralized Functions	Decentralized
Use preferred Site Network	77.3%	81.7%	82.7%	75.4%
Centralized Ethics Review	92.9%	97.1%	95.2%	93.6%
Create Dedicated Study Start-up Team	77.1%	85.9%		73.1%
Track Site's Mandatory Terms	86.4%	91.6%	90.4%	83.1%
Implement more MSAs	85.3%	87.1%	89.2%	82.7%
Standardized Contracting	89.0%	91.3%	91.4%	88.6%
Leverage Technology and Tools	81.2%	91.3%	87.5%	80.7%

Summary of Mini-Reports

Original Ideas

- **Sponsors vs. CROs**

- **Impact of Technology Adoption**

- **Budget Optimization**
  - Focus on the biggest efficiency gains for a limited budget

- **Centralized vs. Non-Dedicated (Localized) Functional Groups**

Revised Reports – Based on Patterns and Trends from the Additional Analysis

- **Sponsors vs. CROs**

- **Fastest vs. Other Companies**

- **Centralized vs. Non-Dedicated (Localized) Functional Groups**

- **Most Consistent vs. Other Companies**

- **Note: Differences based on technology adoption incorporated throughout primary as well as mini-reports**

Sponsors vs. CROs

Mini-Report #1

Cycle Times

- Overall
  - *Repeat 25.7 weeks, CoV .58*
  - *New 35.6 weeks, CoV .52*
- Site ID Time
  - *Repeat: 3.5 weeks, CoV 1.25*
  - *New: 6.5 weeks, CoV .83*
- Site Selection Time
  - *Repeat: 5.2 weeks, CoV .86*
  - *New: 7.9 weeks, CoV .68*
- Study Start-Up Time
  - *Repeat: 17.5 weeks, CoV .71*
  - *New: 22.0 weeks, CoV .69*

Average Cycle Time Comparisons (Weeks)

New Sites: 6.5 | 7.9 | 22 — 36.4 weeks
Repeat Sites: 3.5 | 5.2 | 17.5 — 26.2 weeks

■ Site ID ■ Site Selection ■ Study Start-up
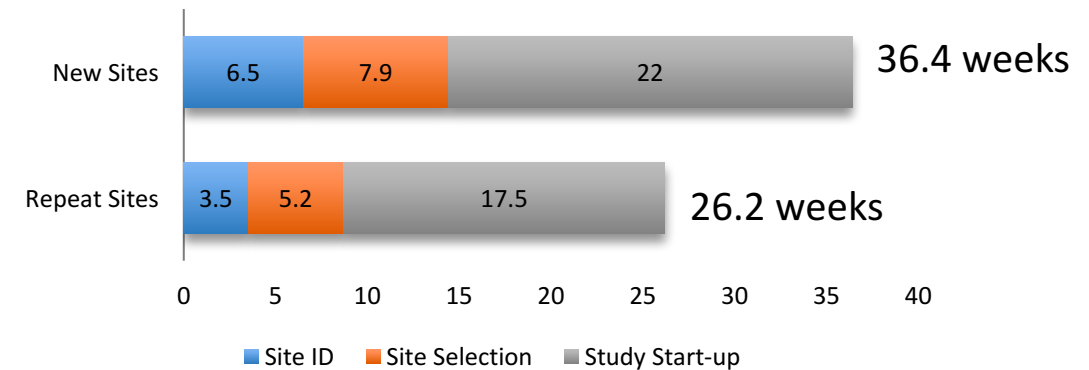
On Average, for a given multicenter study, sponsors report that 28% of the sites that they engage are 'new' relationships; of which 13% are new to clinical research

Cycle times are 9.9 weeks (28%) longer on average for new vs. repeat sites

Average Overall Cycle Times, CRO vs. Sponsor, Repeat vs. New Sites

Company Type	Variable	N	Average Number of Weeks	P-Value
CRO	Sites Worked With Before	70	21.8	0.007
	Sites Not Worked With Before	69	28.0	<.0001
Sponsor	Sites Worked With Before	161	27.4	0.007
	Sites Not Worked With Before	163	39.0	<.0001

Key Messages:
- Overall average cycle times (site ID to site readiness to enroll) for repeat sites is 27.4 weeks for sponsors and 21.8 weeks for CROs
- The cycle time increases ~7 weeks (CROs) and ~12 weeks (Sponsors) when working with sites who are new
- Overall, CROs report completing all site related activities 6-11 weeks faster than sponsors

Cycle Times by Specific Task

Site Identification Cycle Times By Organization (Wks)*

■ New ■ Repeat

CRO
- New: 4.3
- Repeat: 2.4

Sponsor
- New: 7.3
- Repeat: 3.6

Site Start-Up Cycle Time By Organization (Wks)*

■ New ■ Repeat

CRO
- New: 17.9
- Repeat: 14.9

Sponsor
- New: 24.3
- Repeat: 18.9

Site Selection Cycle Times by Organization (Wks)*

■ New ■ Repeat

CRO
- New: 6.7
- Repeat: 5.3

Sponsor
- New: 8.3
- Repeat: 5.6
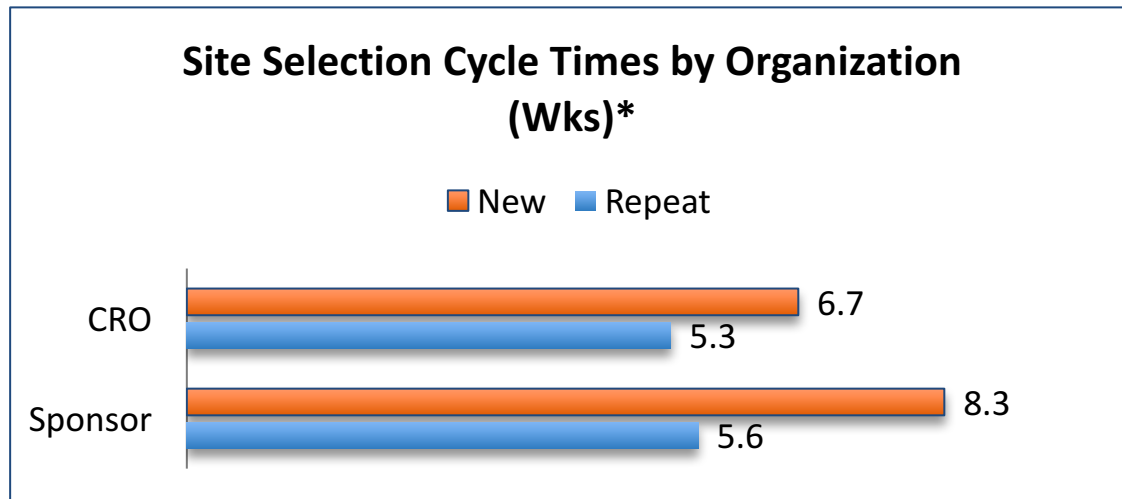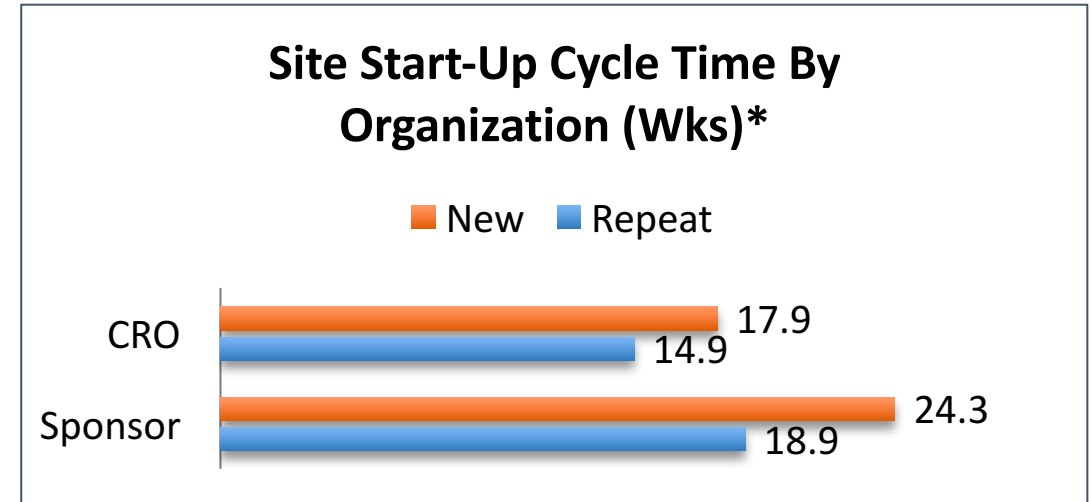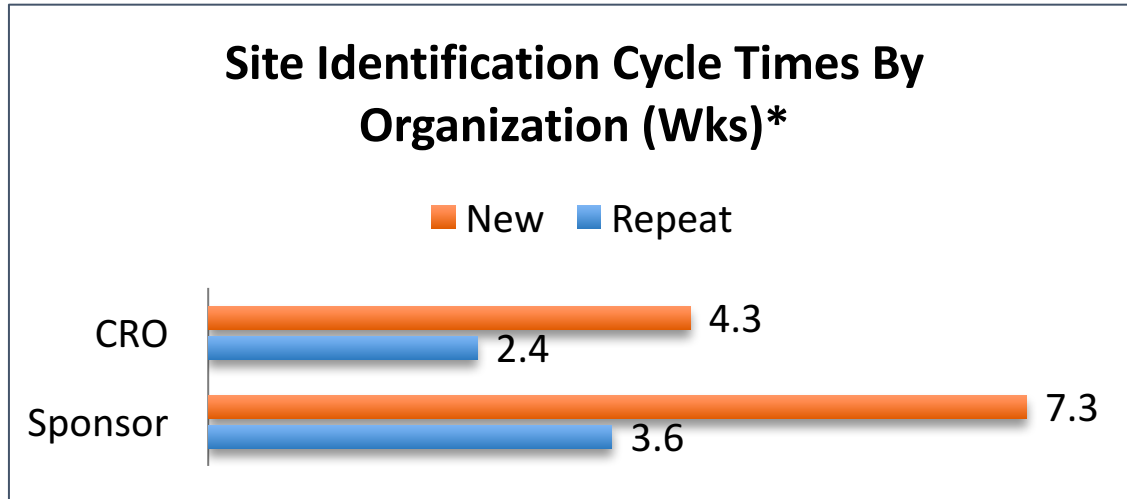
Key Messages:
- Across all tasks, CROs report shorter cycle times consistently when working with new or repeat sites, compare to their sponsor counterparts

*Values significant at the P<.05 level

Satisfaction Levels by Task*, Sponsor vs CRO

Company Type	Variable	N	Average Satisfaction	P-Value
CRO	Site ID Satisfaction	73	2.7	0.99
	Site Selection Satisfaction	73	2.8	0.18
	Study Start-Up Satisfaction	72	2.7	0.06
Sponsor	Site ID Satisfaction	160	2.7	0.99
	Site Selection Satisfaction	156	2.7	0.18
	Study Start-Up Satisfaction	160	2.5	0.06

Scale:
Completely Unsatisfied (1)
Somewhat Unsatisfied (2)
Somewhat Satisfied (3)
Very Satisfied (4)

Key Messages:
- Both organizations are barely more satisfied than unsatisfied overall with their processes
- CRO's are slightly more satisfied with their site selection and study start-up activities compared to sponsors

* = Site Identification, Site Selection, Study Start-Up

Areas of Technology Investment by Company Type

Investing Somewhat/Significantly Less
Investing The Same
Investing Moderately/Heavily

Sponsors

Stage	Less	Same	More
Feasibility	20%	51%	29%
Identification	20%	48%	32%
Selection	20%	54%	26%
Start-Up	16%	50%	34%

CROs

Stage	Less	Same	More
Feasibility	9%	49%	43%
Identification	9%	47%	44%
Selection	9%	58%	33%
Start-UP	6%	46%	48%
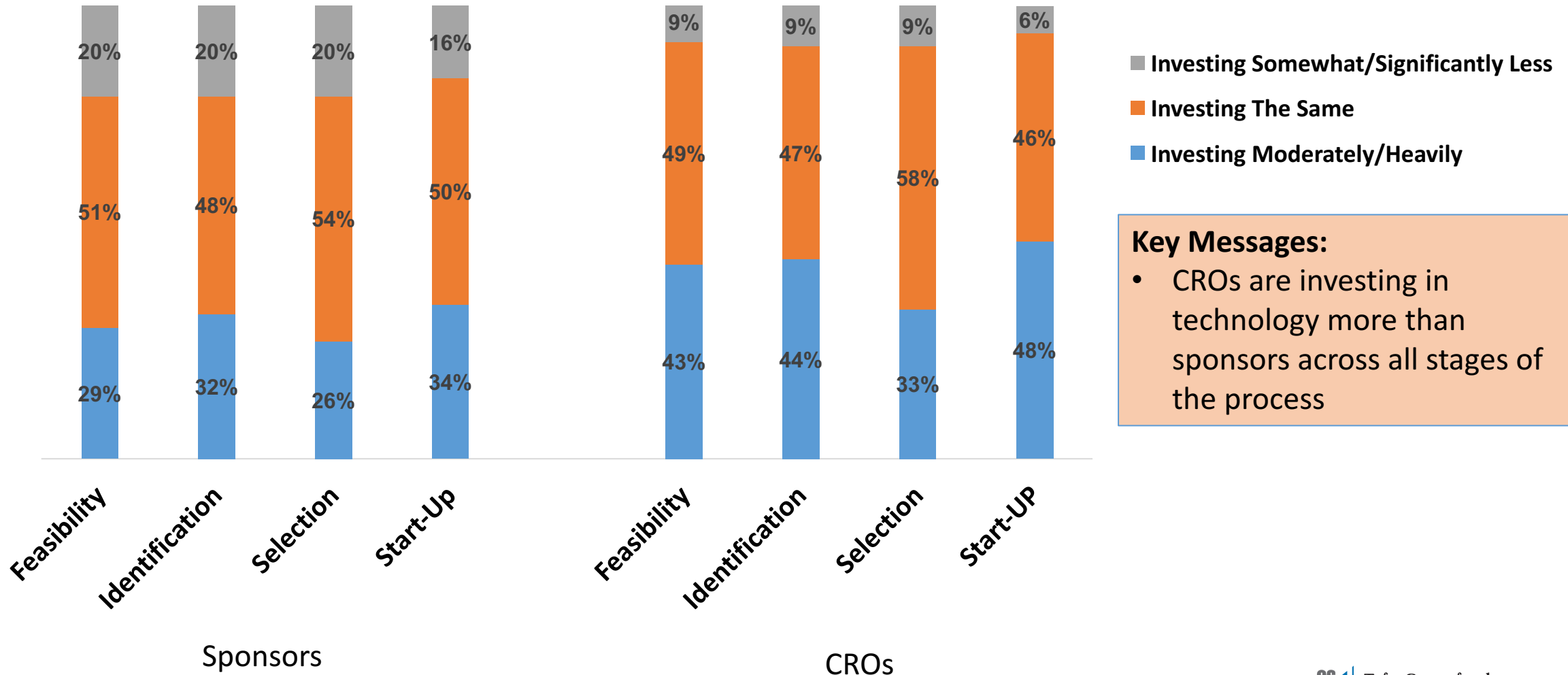
Key Messages:
- CROs are investing in technology more than sponsors across all stages of the process

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Overall Technology Adequacy

Tool/Technology Effectiveness	CRO		Sponsors	
	Frequency	**Percent**	**Frequency**	**Percent**
Our current tools/technology are adequate to support our needs	15	20.3%	30	18.9%
Our current tools/technology could be improved somewhat	46	62.2%	96	60.4%
Our current tools/technology are woefully inadequate and need to be improved greatly	13	17.6%	33	20.8%

Key Messages:
- The majority of sponsors and CROs both feel there are opportunities to improve their current tools and technologies with no significant differences between the groups

Frequency of Time Savings Reported Due to Technology

Tool/Technology Time Savings	CRO		Sponsor	
	Frequency	**Percent**	**Frequency**	**Percent**
Large time savings	16	21.6%	25	15.8%
Small time savings	45	60.8%	77	48.7%
No time savings	10	13.5%	44	27.9%
Time lost	3	4.1%	12	7.6%

Key Message:
- About 80% of respondents who have invested in technology report at least some time savings
- Sponsors report having achieved **no time savings** due to their technology investment twice as much compared to their CRO counterparts (28%; 14%)

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Looking Ahead: Opportunities for Improvement

Site Identification

(Percentage SW/Great Deal)	Sponsor Companies	CROs
Pooled and Shared Data on Site Performance	**89.5%**	**94.4%**
Stricter Site Requirements for Site Accreditation/ Certification	50.7%	62.0%
More Stringent Site Competency Requirements	64.9%	80.3%

Site Selection

(Percentage SW/Great Deal)	Sponsor Companies	CROs
Better Evidence of Site's True Enrollment	**95.4%**	**97.2%**
Share more information on site early	84.3%	84.5%
Conversation; not a form	82.2%	84.3%
More information about potential new sites	87.6%	91.6%
Consensus from all stakeholders on key criteria	68.0%	74.7%
Plan for more back-up sites	60.8%	71.4%
Leverage better study planning tools and software	72.6%	82.9%

Study Start-Up

(Percentage SW/Great Deal)	Sponsor Companies	CROs
Use preferred Site Network	77.3%	81.7%
Centralized Ethics Review	92.9%	97.1%
Create Dedicated Study Start-up Team	77.1%	85.9%
Track Site's Mandatory Terms	86.4%	91.6%
Implement more MSAs	85.3%	87.1%
Standardized Contracting	89.0%	91.3%
Leverage Technology and Tools	81.2%	91.3%

Key Messages:
- In terms of opportunities for improvement in the processes, sponsors and CROs were consistent in their identification of the top areas for improvement with rankings for the other areas showing some differences between the organizations

Sponsor Vs. CRO Conclusions

- **Overall, CROs report completing all site related activities 6-11 weeks faster than sponsors**
  - CRO cycle times working with repeat sites is ~6 weeks faster and ~11 weeks faster when working with new sites
- **CROs report shorter cycle times across all individual tasks as well (site ID, site selection, study start-up)**
- **CROs report making greater investments in technology than do sponsors and report slightly greater levels of satisfaction with their processes than do sponsors**
- **Overall sponsors and CROs have generally consistent views in terms of areas for improvement**

Fastest Companies vs Other Companies

Mini-Report #2

Group with Fastest Cycle Time Overall

- **83 (33%) respondents were determined to have the fastest cycle times while 172 (67%) were slower**

	Variable	N	Average Number of Weeks	P-Value
Fastest	Sites Worked With Before	83	14.1	<.0001
	Sites Not Worked With Before	83	20.8	<.0001
Other	Sites Worked With Before	172	31.2	<.0001
	Sites Not Worked With Before	172	42.4	<.0001

Key Message:
- Fastest groups reach site initiation (on average) in less than half the time of other companies when working with new or repeat sites

Fastest Cycle Time Segments

	Variable	Phase	Average Number of Weeks
Fastest	Sites Worked With Before	Site ID	1.7
		Site Selection	3.1
		Study Start Up	9.3
	Sites Not Worked With Before	Site ID	3.7
		Site Selection	4.9
		Study Start Up	12.2
Other	Sites Worked With Before	Site ID	3.8
		Site Selection	6.5
		Study Start Up	20.9
	Sites Not Worked With Before	Site ID	7.6
		Site Selection	9.1
		Study Start Up	25.7

Key Messages:
- When working with repeat sites, the fastest groups achieve site ID and selection ~2-3 weeks faster, and study start up nearly 12 weeks faster than their counterparts
- The time savings are even greater for the fastest companies when working with new sites

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Average Overall Cycle Times: Dedicated vs. Non-Dedicated Functional Group

Repeat Site Cycle Time

Sponsors		CROs	
Centralized	**Non-Centralized**	**Centralized**	**Non-Centralized**
29.1 Weeks	26.4 Weeks	22.5 Weeks	20.9 Weeks

New Site Cycle Time

Sponsors		CROs	
Centralized	**Non-Centralized**	**Centralized**	**Non-Centralized**
40.1 Weeks	38.5 Weeks	28.9 Weeks	27.0 Weeks

Key Messages:
- 38% of fastest respondents and 47% of other respondents have a centralized functional group to support site ID, site selection, and study start-up activities
- Regardless of organization, centralized groups have longer cycle times however the differences are not statistically significant

Mix of New Vs. Repeat Sites

	Phase II			Phase III		
	Clinical Team Worked With Before	**Company Worked With Before**	**New Sites**	**Clinical Team Worked With Before**	**Company Worked With Before**	**New Sites**
Fastest Group	54.8%	32.0%	30.5%	54.1%	29.8%	**27.7%**
Other Group	51.6%	31.0%	29.2%	51.4%	30.3%	**32.6%**

Key Message:
- There is no significant difference in terms of the mix of sites used for phase II and III trials across the groups however the fastest group works with new sites about 5% less in phase III compared to other companies

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Fastest Group Company Size

- **A greater percentage of small companies were represented by the fastest respondents (81%) vs other respondents (71%)**
  - The fastest groups have an average of 8.75 fewer FTEs allocated to all tasks

Fastest Group

Phase	Number of FTEs	% Respondents Increasing FTEs
Site Feasibility	3.6	29%
Site ID	5.7	28%
Site Selection	8.4	27%
Study Start Up	9.8	34%

Other Group

Phase	Number of FTEs	% Respondents Increasing FTEs
Site Feasibility	10.7	32%
Site ID	14.2	29%
Site Selection	15.8	29%
Study Start Up	21.8	33%

Fastest Group Investment in Technology

Percentage of Respondents Investing Greater Resources in Technology

- Site Feasibility: Fastest Group 27%, Other Respondents 33%
- Site ID: Fastest Group 28%, Other Respondents 39%
- Site Selection: Fastest Group 23%, Other Respondents 32%
- Study Start-Up: Fastest Group 31%, Other Respondents 40%

Fastest Group (N=71) ■ Other Respondents (N=153)

Technology Used For Start-Up Activities

- Use CTMS to Manage This: Fastest Group 37%, Other Respondents 21%
- Primarily Use Spreadsheets: Fastest Group 28%, Other Respondents 39%
- Rely on CRO to do This: Fastest Group 20%, Other Respondents 22%
- Specific, non-CTMS system for this: Fastest Group 14%, Other Respondents 13%
- Other Paper-Based System: Other Respondents 3%

Fastest Group (N=76) ■ Other Respondents (N=150)
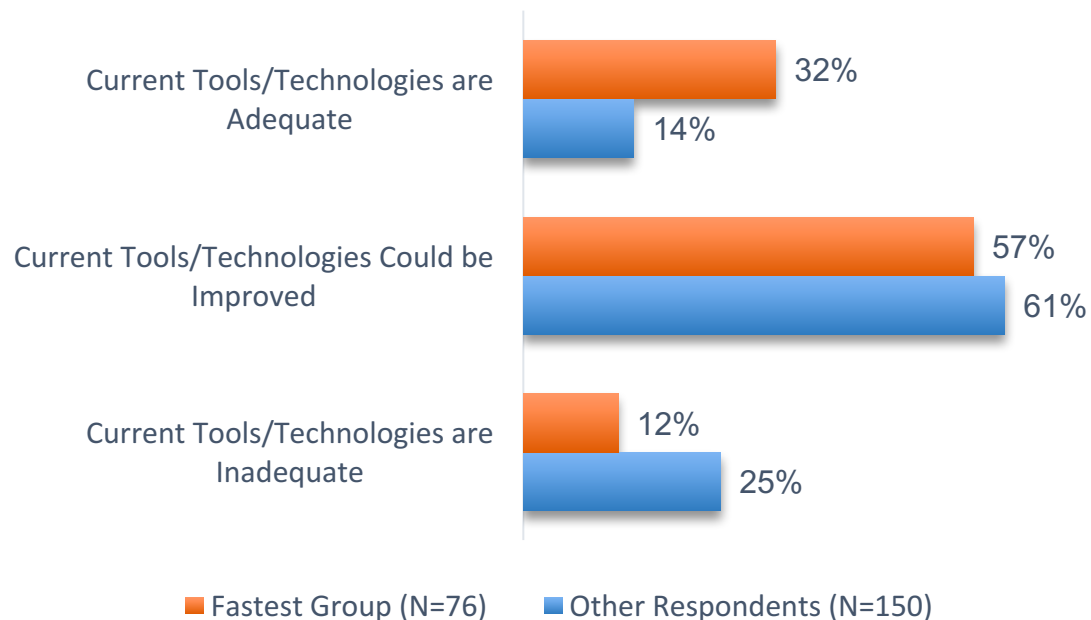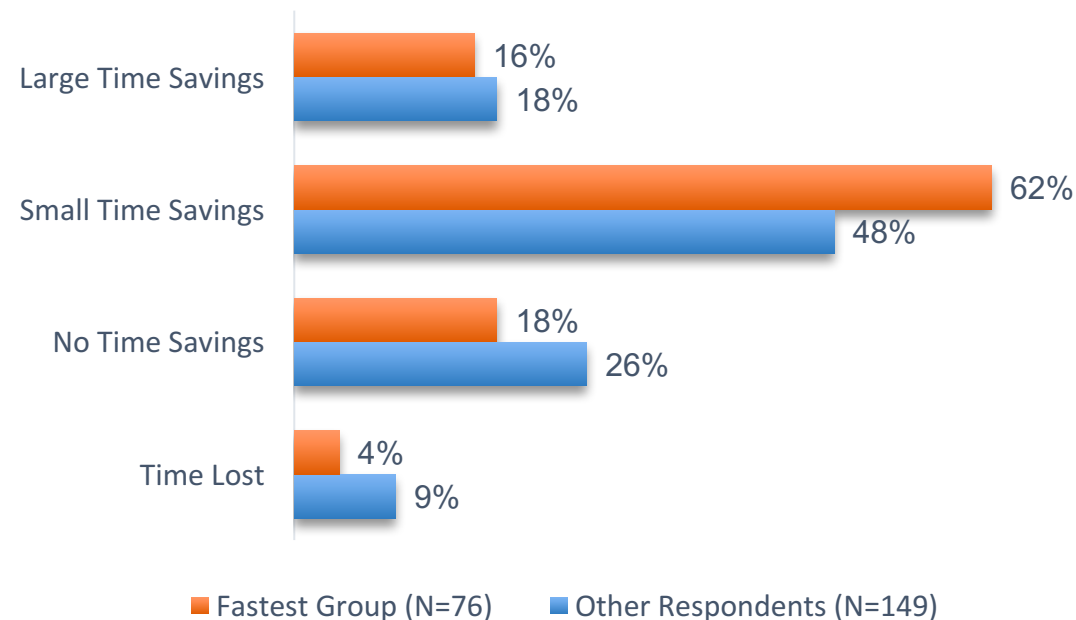
Key Messages:
- The fastest groups are investing less in technology suggesting they may have already achieved some cycle time advantages based on prior technology investments
- The fastest companies rely more on technology or more sophisticated tools to manage their processes than their counterparts

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Fastest Group Technology Used and Time Saved

Technology/Tool Adequacy*

Current Tools/Technologies are Adequate — Fastest Group: 32%, Other Respondents: 14%

Current Tools/Technologies Could be Improved — Fastest Group: 57%, Other Respondents: 61%

Current Tools/Technologies are Inadequate — Fastest Group: 12%, Other Respondents: 25%

Fastest Group (N=76) Other Respondents (N=150)

Technology/Tool Time Savings

Large Time Savings — Fastest Group: 16%, Other Respondents: 18%

Small Time Savings — Fastest Group: 62%, Other Respondents: 48%

No Time Savings — Fastest Group: 18%, Other Respondents: 26%

Time Lost — Fastest Group: 4%, Other Respondents: 9%

Fastest Group (N=76) Other Respondents (N=149)

Key Messages:
- The fastest groups indicate they are more satisfied with their current tools / technologies (reinforcing that they may be benefitting from prior investments in this area)
- The fastest groups report a greater percept of small time savings and less no time savings or time lost from their technology investments) but don't report substantial time savings compared to the other companies

*Results found to be significant (Chi-Square P <.05)

Fastest Company Conclusions

- **Fastest companies enjoy a significant speed advantage in their end-to-end process**

- **Tend to be smaller companies**

- **Tend to be CROs**

- **Less likely to have centralized or dedicated functional groups**

- **Less likely to be currently investing in technology but have a higher usage of more sophisticated tools and feel their technologies are more adequate**

- **There is no real significant difference in terms of the mix of sites (new vs. repeat) that the fastest companies use compared to the others**

Centralized Group vs. Non-Dedicated Group Report

Mini-Report #3

Organization Profiles
(Primary Sponsor/CRO Respondents)
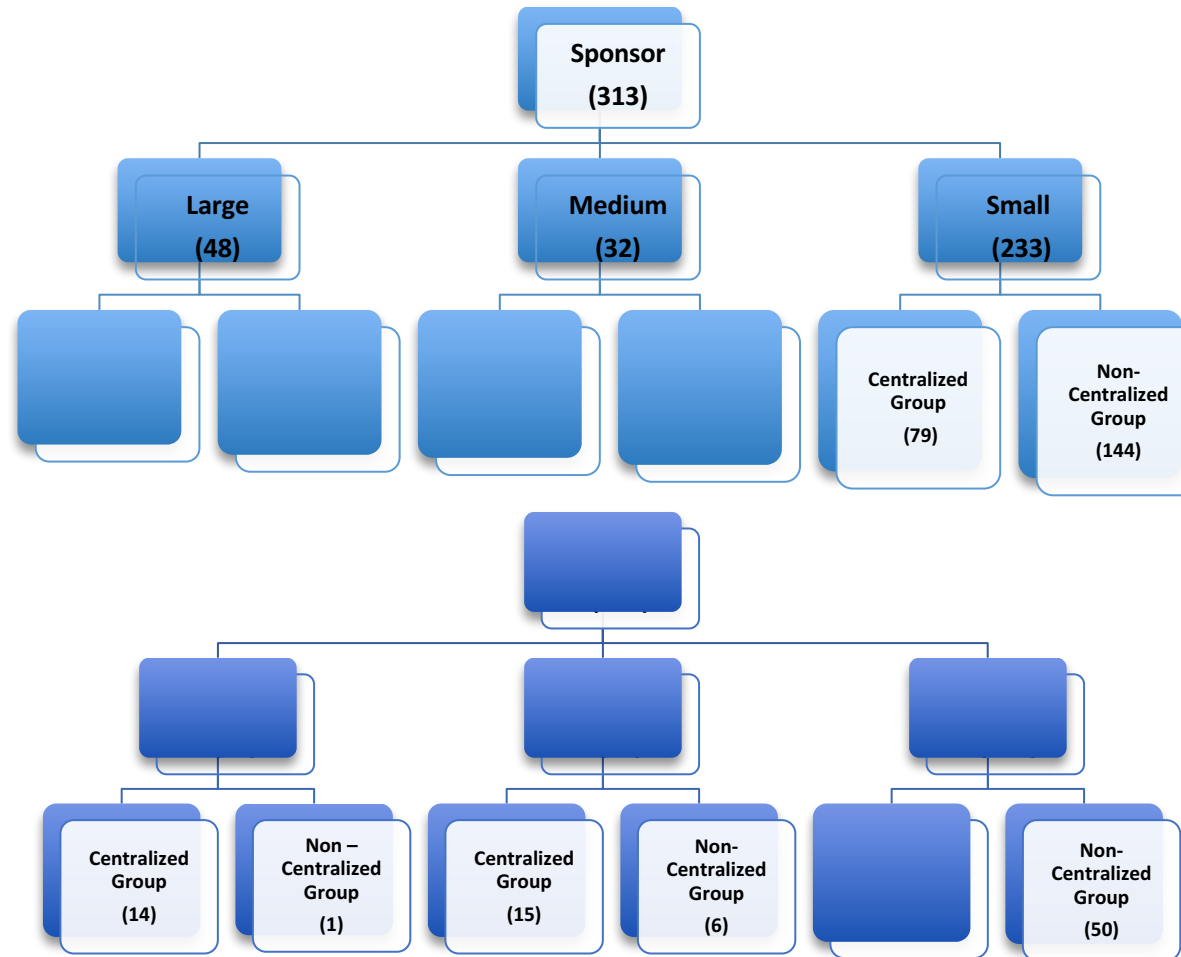
Subcategories may not add up to parent categories due to missing responses

Centralized Function Regional Split

Type of Function	U.S. and Canada		Europe	
	N	%	N	%
Centralized Group	199	47.5%	43	55.1%
Localized Group	220	52.5%	35	44.9%

Key Message:
- European respondents reflect slightly higher percentage who work in centralized groups compared to US and Canada but the difference is not significant

Average Overall Cycle Times: Dedicated vs. Non-Dedicated Functional Group

Repeat Site Cycle Time

Sponsors		CROs	
Centralized	**Non-Centralized**	**Centralized**	**Non-Centralized**
29.1 Weeks	26.4 Weeks	22.5 Weeks	20.9 Weeks

New Site Cycle Time

Sponsors		CROs	
Centralized	**Non-Centralized**	**Centralized**	**Non-Centralized**
40.1 Weeks	38.5 Weeks	28.9 Weeks	27.0 Weeks

Key Messages:
- Regardless of organization, centralized groups have longer cycle times however the differences are not statistically significant

Repeat Site Cycle Times for Centralized vs Localized (non-dedicated) Functions

- **Overall Repeat**
  - Centralized: 26.6 weeks, CoV .56
  - Localized: 25.1 weeks, CoV .60

- **Repeat Site ID Time**
  - Centralized: 3.3 weeks, CoV 1.42
  - Localized: 3.7 weeks, CoV 1.1

- **Repeat Site Selection Time**
  - Centralized: 5.9 weeks, CoV .77
  - Localized: 5.3 weeks, CoV .96

- **Repeat Study Start-Up Time**
  - Centralized: 18.4 weeks, CoV .67
  - Localized: 16.9 weeks, CoV .75

Average Cycle Time Comparisons (Weeks)

	Site ID	Site Selection	Study Start-up	Total
Centralized	3.3	5.9	18.4	27.6 weeks
Localized	3.7	5.3	16.9	25.9 weeks

On Average, for a given multicenter study, sponsors report that 28% of the sites that they engage are 'new' relationships; of which 13% are new to clinical research

Localized functions are 6.2% faster when working with repeat sites

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New Site Cycle Times for Centralized vs Localized Functions

- **Overall New**
  - Centralized: 36.0 weeks, CoV .50
  - Localized: 35.5 weeks, CoV .54

- **New Site ID Time**
  - Centralized: 5.8 weeks, CoV .80
  - Localized: 7.1 weeks, CoV .76

- **New Site Selection Time**
  - Centralized: 8.3 weeks, CoV .61
  - Localized: 7.6 weeks, CoV .74

- **New Study Start-Up Time**
  - Centralized: 23.0 weeks, CoV .72
  - Localized: 21.3 weeks, CoV .67
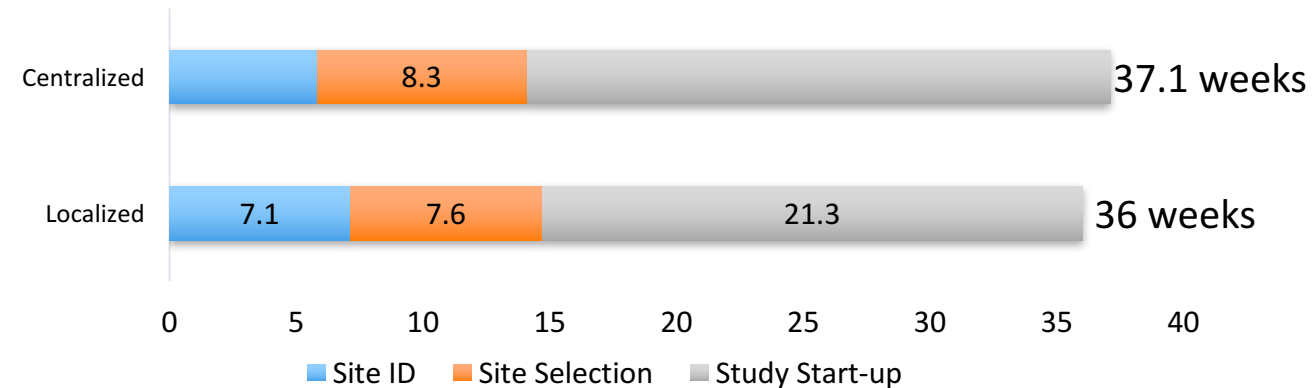
**Average Cycle Time Comparisons (Weeks)**

On Average, for a given multicenter study, sponsors report that 28% of the sites that they engage are 'new' relationships; of which 13% are new to clinical research

Localized functions are 3% faster when working with new sites

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Does Having a Centralized Function Impact the % of Sites Not Activated

Percentage of Sites Never Activated

Centralized Function	10.5%
Decentralized Function	11.2%
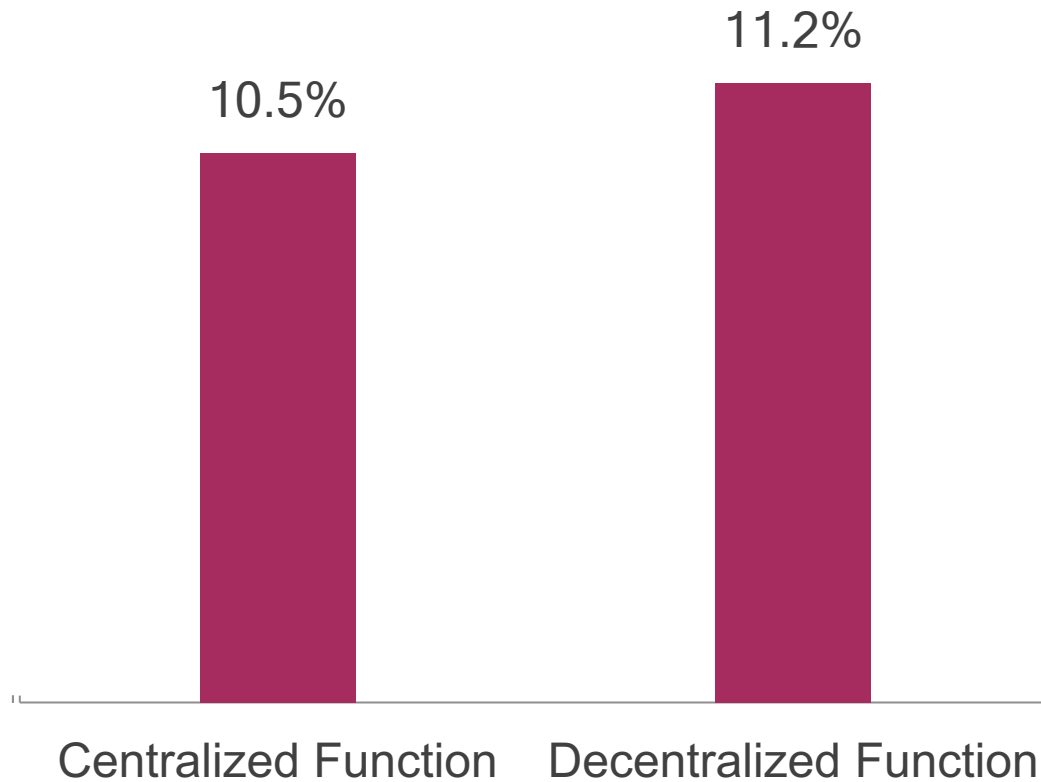
Primary Reason for Activation Failure	Percent of Centralized Functions
Budgeting & Contracting Problems	50.0%
Investigator loses Interest	2.9%
Investigator leaves institution	7.3%
Staff or Resource Issues at the Site Level	13.8%
Too Many Competing Studies	14.5%

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Study Start-Up Management Technology

Start-Up Technologies

Centralized groups appear to take more advantage of technologies than do decentralized groups

% of Respondents

- **Use CTMS to mange this**: Centralized 36%, Localized 19%
- **Primarily use spreadsheets**: Centralized 31%, Localized 40%
- **Specific, non-CTMS system (e.g. vendor software, portal) dedicated to this function**: Centralized 19%, Localized 9%
- **Rely on a CRO to do this**: Centralized 8%, Localized 29%
- **Primarily use other paper-based systems**: Centralized 3%, Localized 1%
- **Multiple**: Centralized 3%, Localized 2%

■ Centralized Function   ■ Localized Function

Perceived Adequacy of Technology Solutions

Tool/Technology Effectiveness	Centralized Function		Localized Function	
	N	%	N	%
Our current tools/technology are adequate to support our needs	20	18.5%	30	21.1%
Our current tools/technology could be improved somewhat	19	17.6%	32	22.5%
Our current tools/technology are completely inadequate and need to be improved greatly	69	63.9%	80	56.3%

Key Message:
- About **80%** feel there is a need to improve tools / technology to enable more effective and efficient processes
- No significant differences across centralized vs. decentralized groups

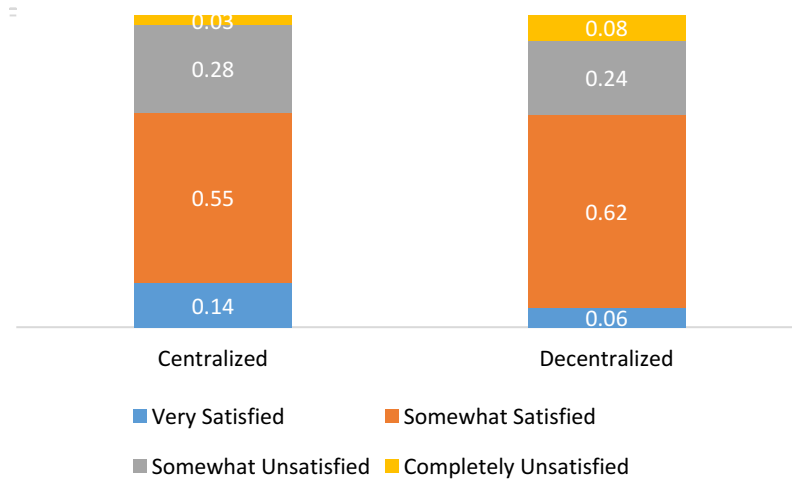# Frequency of Time Savings Reported Due to Technology for Centralized Functions

Tool/Technology Time Savings	Centralized Function		Localized Function	
	N	Percent	N	Percent
Large time savings	28	25.9%	18	12.8%
Small time savings	55	50.9%	75	53.2%
No time savings	18	16.7%	39	27.7%
Time lost	7	6.5%	9	6.4%

Key Message:
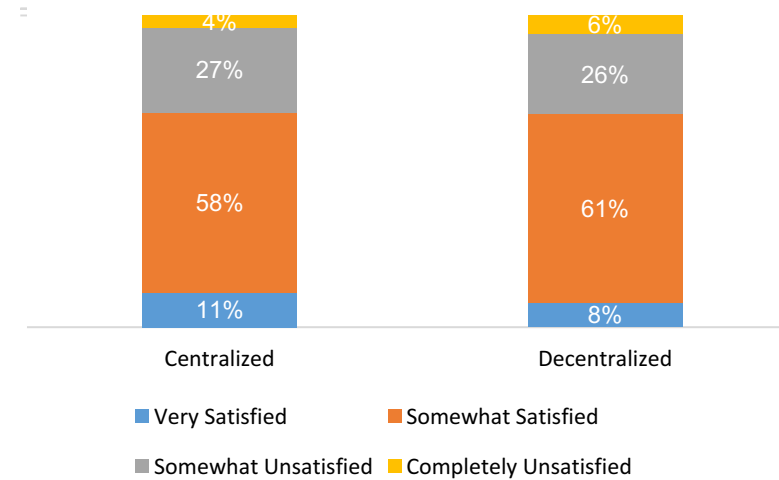- Twice as many organizations with centralized functions report large time savings than organizations with localized functions
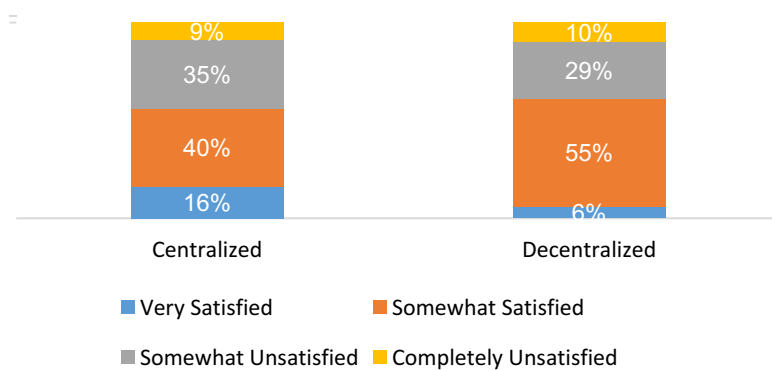
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Satisfaction Levels by Functional Group

Satisfaction with Site Identification Process

	Centralized	Decentralized
Completely Unsatisfied	0.03	0.08
Somewhat Unsatisfied	0.28	0.24
Somewhat Satisfied	0.55	0.62
Very Satisfied	0.14	0.06

■ Very Satisfied ■ Somewhat Satisfied
■ Somewhat Unsatisfied ■ Completely Unsatisfied

Satisfaction with Site Selection Process

	Centralized	Decentralized
Completely Unsatisfied	4%	6%
Somewhat Unsatisfied	27%	26%
Somewhat Satisfied	58%	61%
Very Satisfied	11%	8%

■ Very Satisfied ■ Somewhat Satisfied
■ Somewhat Unsatisfied ■ Completely Unsatisfied

Satisfaction with Start-Up Process

	Centralized	Decentralized
Completely Unsatisfied	9%	10%
Somewhat Unsatisfied	35%	29%
Somewhat Satisfied	40%	55%
Very Satisfied	16%	6%

■ Very Satisfied ■ Somewhat Satisfied
■ Somewhat Unsatisfied ■ Completely Unsatisfied

Centralized groups are slightly more satisfied with their processes (particularly with Start-up) compared to their non-centralized counterparts

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Looking Ahead: Enhancing Site Identification

(Percentage SW/Great Deal)	Centralized Functions	Decentralized
Pooled and Shared Data on Site Performance	85.40%	91.50%
More Stringent Site Competency Requirements	67.70%	72.30%
Stricter Site Requirements for Site Accreditation/Certification	55.30%	54.60%

Key Messages:
- While the %'s vary, the top areas for opportunity improvements are the same regardless of function centralization
- This applies to all of the forward looking opportunities

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Looking Ahead: Enhancing Site Selection

(Percentage SW/Great Deal)	Centralized Functions	Decentralized
Better Evidence of Site's True Enrollment	96.20%	95.70%
More information about potential new sites	91.40%	86.50%
Share more information on site early	83.70%	85.10%
Conversation; not a form	80.60%	83.60%
Leverage better study planning tools and software	76.90%	72.10%
Consensus from all stakeholders on key criteria	76.00%	66.40%
Plan for more back-up sites	62.10%	66.70%

Looking Ahead: Enhancing Study Start-Up

(Percentage SW/Great Deal)	Centralized Functions	Decentralized
Centralized Ethics Review	95.20%	93.60%
Standardized Contracting	91.40%	88.60%
Track Site's Mandatory Terms	90.40%	83.10%
Implement more MSAs	89.20%	82.70%
Create Dedicated Study Start-up Team	87.50%	73.10%
Leverage Technology and Tools	87.50%	80.70%
Use preferred Site Network	82.70%	75.40%

To Centralize or Not Re-Cap

▶ **Centralized functional groups:**
- Report slightly more satisfaction with their processes
- Appear to adopt technology more
- Have only very slightly less % of sites that are not activated

▶ **Decentralized or localized functional groups:**
- Slightly better at cycle times with new and repeat sites

Key Messages:
- Both groups face similar challenges and see same opportunities for improvement
- No conclusive evidence that centralizing the function of site ID through Start-Up achieves significant improvements

Most Consistent vs. Other Groups

Mini-Report #4

Most Consistent Respondent Definition

- **81 (31.8%) respondents were found to have the most consistent cycle times in all activities when compared to the mean while 174 (68.2%) were slower**

- **Consistent respondents were those whose cycle times were within ± 0.9 Standard Deviations of the overall cycle mean across all three activities, for both repeat sites and new sites**

  - Stated differently, these companies had the smallest deviation across their end-to-end processes

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Most Consistent Respondent Overall Cycle Times vs Other Respondents

	Variable	N	Average Number of Weeks	P-Value
Consistent	Sites Worked With Before	81	20.8	<.0001
	Sites Not Worked With Before	81	30.1	<.0001
Other	Sites Worked With Before	174	27.9	<.0001
	Sites Not Worked With Before	174	37.9	<.0001

Key Message:
- The most consistent group reach site initiation about 7 weeks earlier than other companies when working with both new or repeat sites

Cycle Time Segments – Consistent vs. Other Groups

	Variable	Phase	Average Number of Weeks
Consistent	Sites Worked With Before	Site ID	2.2
		Site Selection	4.3
		Study Start Up	14.3
	Sites Not Worked With Before	Site ID	5.0
		Site Selection	7.0
		Study Start Up	18.2
Other	Sites Worked With Before	Site ID	3.6
		Site Selection	5.9
		Study Start Up	18.4
	Sites Not Worked With Before	Site ID	7.0
		Site Selection	8.1
		Study Start Up	22.8

Key Messages:
- Companies who have the least variability in their cycle times are also faster in all activities than those companies with less consistent processes

Mix of New Vs. Repeat Sites

	Phase II			Phase III		
	Clinical Team Worked With Before	**Company Worked With Before**	**New Sites**	**Clinical Team Worked With Before**	**Company Worked With Before**	**New Sites**
Most Consistent Group	51.9%	29.0%	**34.4%***	50.2%	30.2%	**35.6%***
Other Group	52.9%	32.5%	**27.4%***	53.3%	30.0%	**28.8%***

Key Message:
- Respondents in the most consistent group were more likely to work with sites that are new to the company than the other group

*Results found to be significant (P <.05)

Most Consistent Group Company Size

- **A greater percentage of small companies were represented by the most consistent respondents (80%) vs other respondents (71%)**

Phase	Most Consistent Group Number of FTEs	Other Group Number of FTEs
Site Feasibility	5.0	9.9
Site ID	4.4	14.6
Site Selection	5.4	17.0
Study Start Up	8.7	22.1

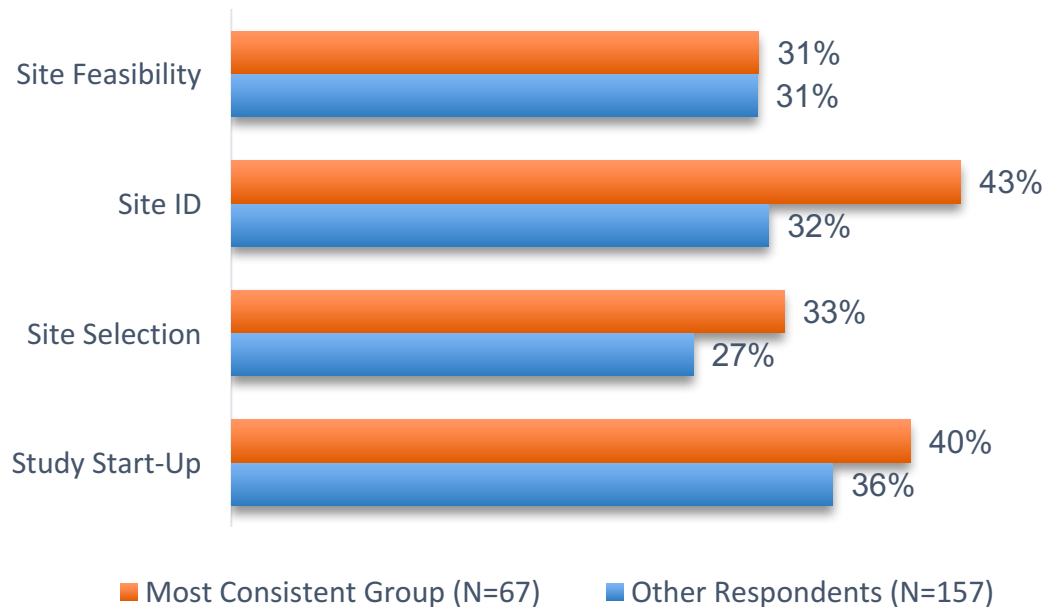# % of Sites Not Activated
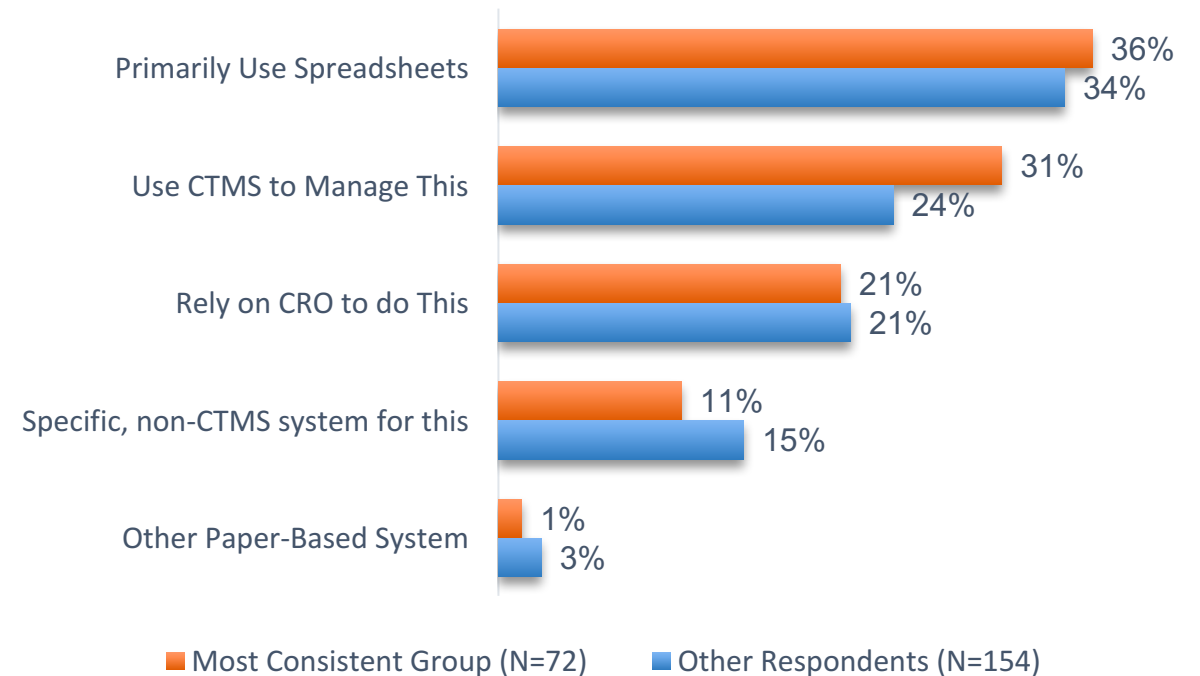
Percentage of Sites Never Activated
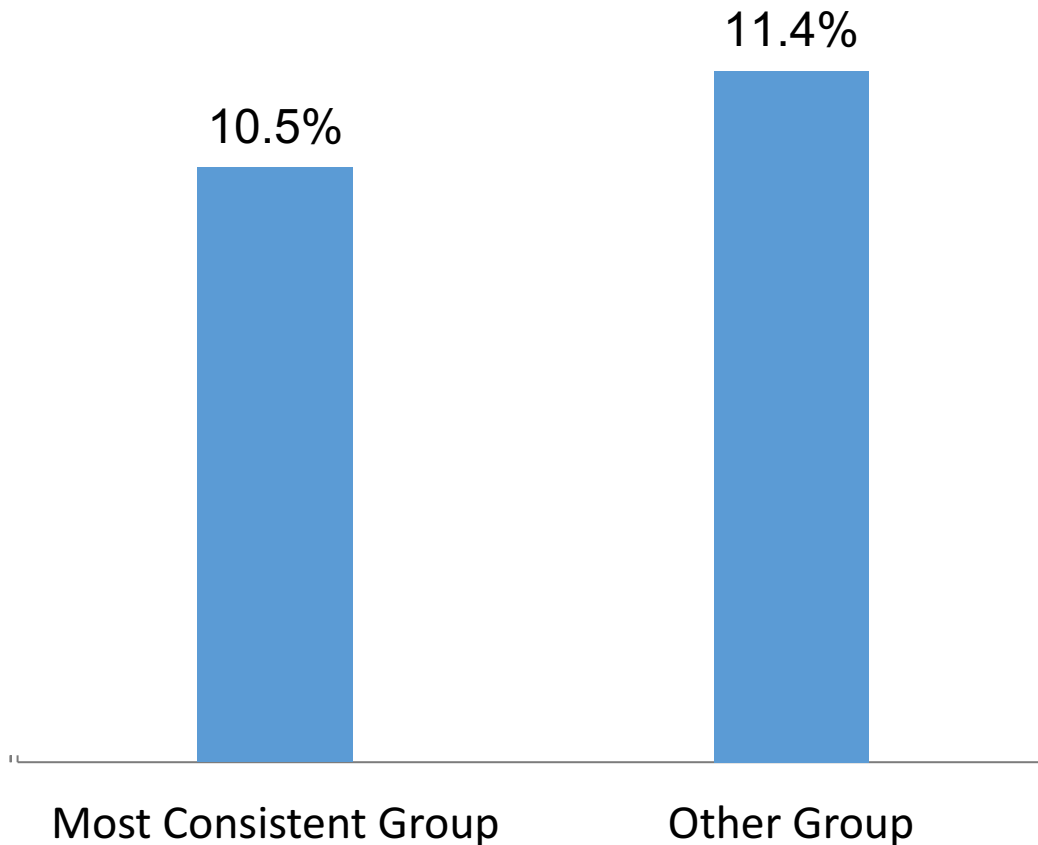
Key Messages:
- The companies with the most consistent processes report a lower percentage of non-activated sites compared to their counterparts

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Fastest Group Investment in Technology

Percentage of Respondents Investing Greater Resources in Technology

- Site Feasibility: 31% / 31%
- Site ID: 43% / 32%
- Site Selection: 33% / 27%
- Study Start-Up: 40% / 36%

■ Most Consistent Group (N=67)   ■ Other Respondents (N=157)

Technology Used For Start-Up Activities

- Primarily Use Spreadsheets: 36% / 34%
- Use CTMS to Manage This: 31% / 24%
- Rely on CRO to do This: 21% / 21%
- Specific, non-CTMS system for this: 11% / 15%
- Other Paper-Based System: 1% / 3%

■ Most Consistent Group (N=72)   ■ Other Respondents (N=154)

Key Messages:
- The most consistent groups are investing more in technology, especially in Site ID, suggesting that they spend greater resources finding the right sites
- The most consistent companies rely more on CTMS tools to manage their processes than their counterparts

Most Consistent Company Conclusions

- **The most consistent respondents also benefit from a speed advantage in their end-to-end process**
- **They have a lower percentage of site non-activation**
- **They work with new sites more frequently than other respondents**
- **Tend to be smaller companies**
- **They make greater investment in technology with somewhat more advanced tools**