

Site Selection Market Research Survey

Start of Block: Demographic Questions

Q1 Section 1: Demographics

Q2 What type of organization do you represent?

- ☐ Sponsor- Pharma (1)
 - ☐ Sponsor- BioPharma* (considered to encompass Biotech as well) (2)
 - ☐ Contract Research Organization (CRO) (3)
 - ☐ Medical Device Company (4)
 - ☐ Independent Contractor (5)
 - ☐ Other (Please Specify) (6) _____
-

Q3 What is your role at your organization?

- ☐ Feasibility Specialist (1)
 - ☐ Site Selection Specialist (2)
 - ☐ Start-up Specialist (3)
 - ☐ Site/Patient Engagement or Recruitment Specialist (4)
 - ☐ Project or Study Manager (5)
 - ☐ Other (Please Specify) (6) _____
-

Q4 How many years of experience do you have performing your role?

- ☐ 0-2 years (1)
- ☐ 3-5 years (2)
- ☐ 6-10 years (3)
- ☐ 10-15 years (4)
- ☐ >15 years (5)
-

Q5 Does the organization you represent currently have a dedicated functional group to support site identification, site selection, and site readiness?

- ☐ Yes (1)
- ☐ No (2)
- ☐ Unsure (3)
-



Q6 In which country are you located?

▼ United States of America (1) ... Zimbabwe (972)



Q7 Approximately how many individuals are employed at your organization?

End of Block: Demographic Questions

Start of Block: Site Identification

Q8 Section 2: Site Identification

Q9 To what extent does your organization use the following resources to identify and rank sites and investigators that you HAVE worked with before and those you have HAVE NOT worked with before?

	Sites and Investigators that HAVE been worked with before				Sites and Investigators that HAVE NOT been worked with before			
	Never (1)	Rarely (2)	Often (3)	Always (4)	Never (1)	Rarely (2)	Often (3)	Always (4)
Proprietary Database (e.g, CTMS, Access, Excel) (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Commercially Available Database (e.g. Citeline, Claims Data) (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Literature Review (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Personal Network (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Recommendation from CRO Partner (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trial Broker/Site Business Development Vendor (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Recommendation from Internal Team Member/Member of your Personal Network (e.g. CRA, project manager) (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (Please Specify) (8)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q10 Please indicate the average amount of time it takes to identify sites:

	Estimated time (in WEEKS) it currently takes	Compared to the time it took 3 years ago, the current time is:				
	Number of Weeks (1)	Much Shorter (1)	Somewhat Shorter (2)	About the Same (3)	Somewhat Longer (4)	Much Longer (5)
Average time to identify a list of suitable sites to approach for Sites/Investigators that you <u>HAVE</u> worked with before (1)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Average time to identify a list of suitable sites to approach for Sites/Investigators that you <u>HAVE NOT</u> worked with before (2)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Display This Question:

If Please indicate the average amount of time it takes to identify sites: : Compared to the time it took 3 years ago, the current time is: = Average time to identify a list of suitable sites to approach for Sites/Investigators that you <u>HAVE </u>worked with before [Array]

Or Please indicate the average amount of time it takes to identify sites: : Compared to the time it took 3 years ago, the current time is: = Average time to identify a list of suitable sites to approach for Sites/Investigators that you <u>HAVE </u>worked with before [Array]

Q11 Which factor(s) do you believe are most responsible for your shortened time to identify a list of suitable sites for Sites/Investigators that you HAVE worked with before? (Select all that apply)

- ☐ Process changes (1)
- ☐ New technology or tools (2)
- ☐ Additional resources (personnel) (3)
- ☐ Creating a dedicated functional group to manage this (4)
- ☐ Other (please specify) (5)

Display This Question:

If Please indicate the average amount of time it takes to identify sites: : Compared to the time it took 3 years ago, the current time is: = Average time to identify a list of suitable sites to approach for Sites/Investigators that you <u>HAVE NOT</u> worked with before [Array]

Or Please indicate the average amount of time it takes to identify sites: : Compared to the time it took 3 years ago, the current time is: = Average time to identify a list of suitable sites to approach for Sites/Investigators that you <u>HAVE NOT</u> worked with before [Array]

Q12 Which factor(s) do you believe are most responsible for your shortened time to identify a list of suitable sites for Sites/Investigators that you HAVE NOT worked with before? (Select all that apply)

- ☐ Process changes (1)
 - ☐ New technology or tools (2)
 - ☐ Additional resources (personnel) (3)
 - ☐ Creating a dedicated functional group to manage this (4)
 - ☐ Other (please specify) (5)
-

Q13 In general, what percentage of sites do you typically reach out to beyond the desired number in order to secure participation from the required number of sites?

☐ Percentage of additional sites reached out to: (1)

☐ Do not know (2)

End of Block: Site Identification

Start of Block: Study Feasibility/Recruitment Planning Questions

Q14 **Section 3: Study Feasibility/Recruitment Planning**

Q15 When estimating a site's true enrollment potential for a given trial, to what extent do the following data influence your decision?	No Influence (1)	Little Influence (2)	Some Influence (3)	Significant Influence (4)
Past Performance Metrics for the <u>Site</u> (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Past Performance Metrics for the <u>Investigator</u> (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Information from the Completed Feasibility Assessment (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Evidence from an Enrollment Validation Exercise (e.g. sample chart review matching potential patients against inclusion/exclusion criteria) (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feedback from the CRA on the Site's Enrollment Potential (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Completion of a Preliminary Patient Recruitment Plan (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify) (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q16 To what extent, if any, do you adjust the site's proposed enrollment potential at the feasibility stage?

- ☐ We adjust the site's estimate about 25% (1)
- ☐ We adjust the site's estimate about 50% (2)
- ☐ We adjust the site's estimate about 75% or more (3)
- ☐ We never adjust the site's estimate and trust their projections (4)
- ☐ Not applicable- as per ICH GCP 4.2.1 we ask for hard evidence from sites to confirm their enrollment potential (5)

End of Block: Study Feasibility/Recruitment Planning Questions

Start of Block: Criteria for Site Selection Questions

Q17 Section 4: Criteria for Site Selection

Q18 In what percentage of studies do you outline objective site selection scoring criteria up front so that sites can be effectively evaluated once background/feasibility information has been gathered?

- ☐ 0-25% (1)
 - ☐ 26-50% (2)
 - ☐ 51-75% (3)
 - ☐ 76-100% (4)
 - ☐ Do Not Know or N/A (5)
-

Q19 In what percentage of studies do you get alignment from all decision makers on the objective site selection scoring criteria up-front so that sites can be effectively evaluated once background/feasibility information has been gathered?

- ☐ 0-25% (1)
- ☐ 26-50% (2)
- ☐ 51-75% (3)
- ☐ 76-100% (4)
- ☐ N/A- We do not create objective scoring criteria so no need to get alignment on this (5)

Q20 To what extent do the following criteria influence your <u>site selection</u> decision in the following scenarios?	When working with sites who have previously worked with your clinical team before				When working with sites who are new to your organization			
	Never Influences (1)	Rarely Influences (2)	Some what Influences (3)	Always/Greatly Influences (4)	Never influences (1)	Rarely Influences (2)	Some what Influences (3)	Always/Greatly Influences (4)

Experience in the therapeutic area or indication (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Number of previous studies conducted in similar patient population (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Previous recruitment success (ability to meet or exceed enrollment targets) (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Number of ongoing or competing trials in the indication (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Speed in which site can be initiated (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Previous retention success (ability to retain subjects) (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Data entry timeliness and accuracy based on prior studies (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
High satisfaction ratings from CRAs (8)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The strength of the site's recruitment planning process (9)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The strength of the site's quality management processes (10)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The strength of our relationship with the site staff (11)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The level of PIs interest and enthusiasm for the compound/trial (12)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
They are part of a preferred site network or site center of excellence (13)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Recommendation from our business/commercial marketing organization (14)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please describe) (15)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q21 To what extent do the following criteria influence your <u>site selection</u> decision when working with sites who are new to research (i.e. research naive)?	Never Influences (1)	Rarely Influences (2)	Somewhat Influences (3)	Always/Greatly Influences (4)
Experience in the therapeutic area or indication (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Speed in which site can be initiated (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The strength of the site's recruitment planning process (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The strength of the site's quality management processes (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The level of Pls interest and enthusiasm for the compound/trial (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Recommendation from our business/commercial marketing organization (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please describe) (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q22 To what extent do you believe the following have an impact in terms of predicting how well a site will ultimately perform from a recruitment/retention perspective?	No Impact (1)	Little Impact (2)	Some Impact (3)	Significant Impact (4)
Their historical performance across all indications (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Their historical performance or the extent to which they have met enrollment goals in similar trials (therapeutic area/indication) (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The data they provide to demonstrate their known patients match the core eligibility criteria (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How well thought out their initial patient recruitment plan addresses potential challenges and how they will overcome these (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How well resourced they are in terms of recruitment support staff (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Principal Investigator's knowledge of and/or experience with treating the indication/disease (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please describe) (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q23 Do you have a mandate for using a given percentage of new or naive sites for each trial?

☐ Yes (1)

☐ No (2)

Display This Question:

If Do you have a mandate for using a given percentage of new or naive sites for each trial? = Yes

Q24 What percentage of sites for a given trial must be:

☐ Percentage new to the company (1)

☐ Percentage new to working in research (i.e. research naive) (2)

Q25 Do you have a mandate for selecting sites who can deliver a given percentage of patients from minority or underrepresented populations?

☐ Yes (1)

☐ No (2)

End of Block: Criteria for Site Selection Questions

Start of Block: Site Selection Process

Q26 Section 5: Site Selection Process

Q27 In general, what percentage of the sites you select are never activated (i.e. initiated or ready to enroll)?

☐ Percentage of sites that are never activated/initiated (1)

☐ Not Sure (2)

Q28 For sites who are selected but never activated, what is the primary reason for this?

☐ Budget and contract issues (1)

☐ Investigator loses interest (2)

☐ Investigator leaves institution (3)

☐ Staff or resource issues at the site (4)

☐ Too many competing studies in progress by the time the decision to activate the site is made (5)

☐ Other (please specify) (6) _____

Q29 Please indicate the average amount of time it takes to make the site selection decision:

	Estimated time (in WEEKS) it currently takes	Compared to the time it took 3 years ago, the current time is:				
	Number of Weeks (1)	Much Shorter (1)	Somewhat Shorter (2)	About the Same (3)	Somewhat Longer (4)	Much Longer (5)

<p>Average time to make the final site selection decision (from the time of site identification to the time feasibility and site qualification information is received to the time the final site selection decision is made): for Sites/Investigators that you <u>HAVE</u> worked with before (1)</p>		○	○	○	○	○
<p>Average time to make the final site selection decision (from the time of site identification to the time feasibility and site qualification information is received to the time the final site selection decision is made): for Sites/Investigators that you <u>HAVE NOT</u> worked with before (2)</p>		○	○	○	○	○

Display This Question:

If Please indicate the average amount of time it takes to make the site selection decision: : Compared to the time it took 3 years ago, the current time is: = Average time to make the final site selection decision (from the time of site identification to the time feasibility and site qualification

information is received to the time the final site selection decision is made): for Sites/Investigators that you <u>HAVE </u>worked with before [Array]

Or Please indicate the average amount of time it takes to make the site selection decision: : Compared to the time it took 3 years ago, the current time is: = Average time to make the final site selection decision (from the time of site identification to the time feasibility and site qualification information is received to the time the final site selection decision is made): for Sites/Investigators that you <u>HAVE </u>worked with before [Array]

Q30 Which factor(s) do you believe are most responsible for your shortened time to make the final site selection decision for Sites/Investigators that you HAVE worked with before(Select all that apply)

- ☐ Process changes (1)
- ☐ New technology or tools (2)
- ☐ Additional resources (personnel) (3)
- ☐ Creating a dedicated functional group to manage this (4)
- ☐ Other (please specify) (5)

Display This Question:

If Please indicate the average amount of time it takes to make the site selection decision: : Compared to the time it took 3 years ago, the current time is: = Average time to make the final site selection decision (from the time of site identification to the time feasibility and site qualification information is received to the time the final site selection decision is made): for Sites/Investigators that you <u>HAVE NOT </u>worked with before [Array]

Or Please indicate the average amount of time it takes to make the site selection decision: : Compared to the time it took 3 years ago, the current time is: = Average time to make the final site selection decision (from the time of site identification to the time feasibility and site qualification information is received to the time the final site selection decision is made): for Sites/Investigators that you <u>HAVE NOT </u>worked with before [Array]

Q31 Which factor(s) do you believe are most responsible for your shortened time to make the final site selection decision for Sites/Investigators that you HAVE NOT worked with before? (Select all that apply)

- ☐ Process changes (1)
 - ☐ New technology or tools (2)
 - ☐ Additional resources (personnel) (3)
 - ☐ Creating a dedicated functional group to manage this (4)
 - ☐ Other (please specify) (5)
-

<p>Q32 To what extent does the time to complete the <u>site identification</u> and <u>site selection</u> process vary by site type or phase of trial?</p>	No Difference (1)	Slight Difference (2)	Moderate Difference (3)	Significant Difference (4)
<p>What extent does your process vary from phase I, II, III, or IV trials? (1)</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>To what extent does your process vary considering different site settings? (e.g. Academic medical center, dedicated research site, part-time investigator community hospital, etc.) (2)</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q33 To what extent do the following contribute to an ineffective <u>site selection</u> process?	No Contribution at All (1)	Little Contribution (2)	Some Contribution (3)	Significant Contribution (4)
Responsiveness of Sites/Investigators (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Timeliness issues (e.g. the amount of time it takes to get sites identified and selected) (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Quality issues/performance issues (e.g. sites who overestimate their enrollment potential and do not deliver) (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cost/Resource issues (e.g. the resources it takes to get sites identified and selected) (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Information issues (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) (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Process issues
(e.g. cumbersome
and time
consuming process
to identify, contact
and interact with
sites or not having
consensus on the
criteria for selecting
sites) (6)

Other (please
describe) (7)

☐
☐
☐
☐
☐
☐
☐
☐

Q34 Which of the following cycle times do you find the most useful when considering selecting a site?

- ☐ Protocol finalization to site initiation/activation (1)
- ☐ Contract/budget draft to contract/budget execution (2)
- ☐ Site receipt of all essential documents to site initiation/activation (3)
- ☐ Site receipt of all essential documents to IRB/EC approval (4)
- ☐ Time from site selection notification to contract completion (5)
- ☐ Time from site selection notification to IRB/Ethics approval (6)
- ☐ Time from protocol package sent to all essential documents completed and submitted (7)
- ☐ Full cycle time from protocol package sent to site to site initiation visit (8)
- ☐ Other (please list) (9) _____



Q35 Please indicate the typical site mix for phase II and III trials:

	Approximate percentage of sites your clinical team has worked with before (1)	Approximate percentage of sites your company has worked with in the past but not with your team specifically (2)	Approximate percentage of sites that are completely new to the company/team (3)
Phase II Trials (1)			
Phase III Trials (2)			

End of Block: Site Selection Process

Start of Block: Study Start-Up Process

Q36 Section 6: Study Start-Up Process

Q37 Please indicate the average amount of time it takes to get all sites activated (i.e. initiated or ready to enroll):

	Estimated time (in WEEKS) it currently takes	Compared to the time it took 3 years ago, the current time is:				
	Number of Weeks (1)	Much Shorter (1)	Somewhat Shorter (2)	About the Same (3)	Somewhat Longer (4)	Much Longer (5)

<p>Average time to get all initial sites (i.e. non back-up or contingency sites) activated - from the time the site selection decision is made until all sites are initiated and enrollment ready: for Sites/Investigators that you <u>HAVE</u> worked with before (1)</p>		○	○	○	○	○
<p>Average time to get all initial sites (i.e. non back-up or contingency sites) activated - from the time the site selection decision is made until all sites are initiated and enrollment ready: for Sites/Investigators that you <u>HAVE NOT</u> worked with before (2)</p>		○	○	○	○	○

Display This Question:

If Please indicate the average amount of time it takes to get all sites activated (i.e. initiated or... : Compared to the time it took 3 years ago, the current time is: = Average time to get all initial sites (i.e. non back-up or contingency sites) activated - from the time the site selection decision is made until all sites

are initiated and enrollment ready: for Sites/Investigators that you <u>HAVE </u>worked with before [Array]

Or Please indicate the average amount of time it takes to get all sites activated (i.e. initiated or... : Compared to the time it took 3 years ago, the current time is: = Average time to get all initial sites (i.e. non back-up or contingency sites) activated - from the time the site selection decision is made until all sites are initiated and enrollment ready: for Sites/Investigators that you <u>HAVE </u>worked with before [Array]

Q38 Which factor(s) do you believe are most responsible for your shortened time to to get all initial sites activated for Sites/Investigators that you HAVE worked with before? (Select all that apply)

- ☐ Process changes (1)
- ☐ New technology or tools (2)
- ☐ Additional resources (personnel) (3)
- ☐ Creating a dedicated functional group to manage this (4)
- ☐ Other (please specify) (5)

Display This Question:

If Please indicate the average amount of time it takes to get all sites activated (i.e. initiated or... : Compared to the time it took 3 years ago, the current time is: = Average time to get all initial sites (i.e. non back-up or contingency sites) activated - from the time the site selection decision is made until all sites are initiated and enrollment ready: for Sites/Investigators that you <u>HAVE NOT </u>worked with before [Array]

Or Please indicate the average amount of time it takes to get all sites activated (i.e. initiated or... : Compared to the time it took 3 years ago, the current time is: = Average time to get all initial sites (i.e. non back-up or contingency sites) activated - from the time the site selection decision is made until all sites are initiated and enrollment ready: for Sites/Investigators that you <u>HAVE NOT </u>worked with before [Array]

Q39 Which factor(s) do you believe are most responsible for your shortened time to to get all initial sites activated for Sites/Investigators that you HAVE NOT worked with before? (Select all that apply)

- ☐ Process changes (1)
- ☐ New technology or tools (2)
- ☐ Additional resources (personnel) (3)
- ☐ Creating a dedicated functional group to manage this (4)
- ☐ Other (please specify) (5)

Q40 To what extent does the time to complete the study start vary by site type or phase of trial?

	There is no real difference in the time it takes (1)	There is a slight difference in the cycle time (2)	There is a moderate difference in cycle time (3)	There is a significant difference in cycle time (4)
What extent does your process vary from phase I, II, III, or IV trials? (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
To what extent does your process vary considering different site settings? (e.g. Academic medical center, dedicated research site, part-time investigator community hospital, etc.) (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q41 What do you consider to be the most important milestone in measuring the progress of study start-up?

- ☐ 1st site activated (1)
 - ☐ First patient screened/enrolled (FPI) (2)
 - ☐ 50% of sites activated (3)
 - ☐ All sites activated (4)
 - ☐ Other (please list) (5) _____
-

Q42 To what extent do the following categories contribute to an ineffective study <u>start-up process</u> ?	No Contribution at All (1)	Little Contribution (2)	Some Contribution (3)	Significant Contribution (4)
Timeliness issues (e.g. the amount of time it takes to get sites identified and selected) (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Quality issues/performance issues (e.g. sites who overestimate their enrollment potential and do not deliver) (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cost/Resource issues (e.g. the resources it takes to get sites identified and selected) (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Information issues (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) (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Process issues (e.g. cumbersome and time consuming process to identify, contact and interact with sites or not having consensus on the criteria for selecting sites) (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Are there any other issues that lead to inefficient study start up? (6)

End of Block: Study Start-Up Process

Start of Block: Staffing and Resource Questions

Q43 Section 7: Staffing and Resources

Q44 Please indicate how many FTEs (Full Time Equivalent employees) are involved in the following processes at your organization:

Estimated FTEs dedicated to this function currently	Number of FTEs allocated to this function compared to 3 years ago:					
Approximate Number of FTEs dedicated to: (1)	Significantly Fewer FTEs (1)	Some Fewer FTEs (2)	About the Same Number of FTEs (3)	Some Additional FTEs (4)	Many More FTEs (5)	

<u>Study Feasibility</u> (1)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Site Identification</u> (2)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Site Selection</u> (3)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Study Start-Up</u> (4)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q45 Please indicate how much of the study budget is typically allocated to support the following activities:

	Estimated % of study budget currently allocated to support this activity				Estimated % of study budget allocated to support this activity 3 years ago				
	0-25 % (1)	26-50 % (2)	51-75 % (3)	76-100 % (4)	Significantly smaller % of funds (1)	Some fewer funds (2)	About the same amount of funds (3)	Some additional funds allocated (4)	Significantly greater % of funds (5)

<u>Study Feasibility</u> (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Site Identification</u> (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Site Selection</u> (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Study Start-Up</u> (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q46 Please indicate the extent to which you are investing in additional technology (e.g. software, informatics) to support the following activities:

	We are investing significantly less in this area (1)	We are investing somewhat less in this area (2)	We are making about the same investment in this area (3)	We are investing moderately in this area (4)	We are investing heavily in this area (5)
<u>Study Feasibility</u> (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Site Identification</u> (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Site Selection</u> (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Study Start-Up</u> (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Display This Question:

If Please indicate the extent to which you are investing in additional technology (e.g. software, in... = <u>Study Feasibility</u> [Array]

Or Please indicate the extent to which you are investing in additional technology (e.g. software, in... = <u>Study Feasibility</u> [Array]

Q47 Please specify what type of investments you have made in the area of study feasibility

Display This Question:

If Please indicate the extent to which you are investing in additional technology (e.g. software, in... =
<u>Site Identification</u> [Array]

Or Please indicate the extent to which you are investing in additional technology (e.g. software, in... =
<u>Site Identification</u> [Array]

Q48 Please specify what type of investments you have made in the area of site identification

Display This Question:

If Please indicate the extent to which you are investing in additional technology (e.g. software, in... =
<u>Site Selection</u> [Array]

Or Please indicate the extent to which you are investing in additional technology (e.g. software, in... =
<u>Site Selection</u> [Array]

Q49 Please specify what type of investments you have made in the area of site selection

Display This Question:

If Please indicate the extent to which you are investing in additional technology (e.g. software, in... =
<u>Study Start-Up</u> [Array]

Or Please indicate the extent to which you are investing in additional technology (e.g. software, in... =
<u>Study Start-Up</u> [Array]

Q50 Please specify what type of investments you have made in the area of study start up

Q51 Typically, how do you manage and track study start-up activities from a tools/technology perspective?

- ☐ Not sure. We rely on our CRO to do this (1)
 - ☐ We primarily use spreadsheets (2)
 - ☐ We primarily use other paper-based systems (3)
 - ☐ We use our CTMS to manage this (4)
 - ☐ We use a specific, non-CTMS system (e.g. vendor software, portal) dedicated to this function (7)
 - ☐ Other (please specify) (6) _____
-

Q52 How would you rate the tools/technologies you use from a usability and effectiveness perspective?

- ☐ Our current tools/technology are woefully inadequate and need to be improved greatly (1)
 - ☐ Our current tools/technology could be improved somewhat (2)
 - ☐ Our current tools/technology are adequate to support our needs (3)
-

Q53 How would you rate the tools/technologies you use in terms of time savings?

- ☐ Large time savings (1)
- ☐ Small time savings (2)
- ☐ No time savings (3)
- ☐ Time lost (4)

End of Block: Staffing and Resource Questions

Start of Block: Site Selection-Study Start-Up Process Improvements and Improvement Opportunities

Q54 Section 8: Study Start-Up Process Improvements and Opportunities

Q55 To what extent are you satisfied with your site identification process (in terms of the ability to select sites who deliver predictable patients and high quality data)?

- ☐ Completely Unsatisfied (1)
 - ☐ Somewhat Unsatisfied (2)
 - ☐ Somewhat Satisfied (3)
 - ☐ Very Satisfied (4)
-

Q56 To what extent are you satisfied with your site selection process (in terms of the ability to select sites who deliver predictable patients and high quality data)?

- ☐ Completely Unsatisfied (1)
 - ☐ Somewhat Unsatisfied (2)
 - ☐ Somewhat Satisfied (3)
 - ☐ Very Satisfied (4)
-

Q57 To what extent are you satisfied with your study start-up process (in terms of the ability to get sites activated and initiated in a timely fashion)?

- ☐ Completely Unsatisfied (1)
 - ☐ Somewhat Unsatisfied (2)
 - ☐ Somewhat Satisfied (3)
 - ☐ Very Satisfied (4)
-

Q58 Of the following processes, for which have you made **substantial improvements in the last 3 years?** (check all that apply)

- ☐ Site Identification (1)
 - ☐ Site Selection (2)
 - ☐ Study Start-Up (3)
-

Display This Question:

If Of the following processes, for which have you made substantial improvements in the last 3 years?... = <u>Site Identification</u>

Q59 To what degree have the improvements in site identification reduced cycle times for processes?

- ☐ No Reductions in Cycle Times (1)
 - ☐ Some Reductions in Cycle Times (2)
 - ☐ Significant Reductions in Cycle Times (3)
 - ☐ Too Early to Tell (4)
 - ☐ Not Sure- We Have No Way to Assess or Measure the Impact (5)
-

Display This Question:

If Of the following processes, for which have you made substantial improvements in the last 3 years?... = <u>Site Selection</u>

Q60 To what degree have the improvements in site selection reduced cycle time for processes?

- ☐ No Reductions in Cycle Times (1)
 - ☐ Some Reductions in Cycle Times (2)
 - ☐ Significant Reductions in Cycle Times (3)
 - ☐ Too Early to Tell (4)
 - ☐ Not Sure- We Have No Way to Assess or Measure the Impact (5)
-

Display This Question:

If Of the following processes, for which have you made substantial improvements in the last 3 years?... = <u>Study Start-Up</u>

Q61 To what degree have the improvements in study start-up reduced cycle time for processes?

- ☐ No Reductions in Cycle Times (1)
 - ☐ Some Reductions in Cycle Times (2)
 - ☐ Significant Reductions in Cycle Times (3)
 - ☐ Too Early to Tell (4)
 - ☐ Not Sure- We Have No Way to Assess or Measure the Impact (5)
-

Q62 To what extent do you believe the following would enhance the site identification process?

	Not at All (1)	Not Very Much (2)	Somewhat (3)	A Great Deal (4)
Pooled and shared data on site performance (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stricter requirements for site Accreditation/Certification (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
More stringent requirements of site competency (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify) (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q63 To what extent do you believe the following would enhance the <u>site selection</u> process?	Not at All (1)	Not Very Much (2)	Somewhat (3)	A Great Deal (4)
Get better evidence of a site's true enrollment potential before selection (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Share more information with the site early on so they can truly assess study feasibility (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having a conversation rather than completing a form (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Get more information about potential new sites rather than recycling variably performing known sites (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Gain consensus from all stakeholders on the key criteria for site selection in advance to avoid emotionally based decisions (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Plan for more back-up sites as contingency (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Leverage better
site selection
and study
planning tools
and software (7)

☐☐☐☐

Other (please
specify) (8)

☐☐☐☐

Q64 To what extent do you believe the following would enhance the <u>study start-up</u> process?	Not at All (1)	Not Very Much (2)	Somewhat (3)	A Great Deal (4)
Use of preferred site networks/partners (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Central IRB/Ethics approval process (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Create a dedicated study start-up team to support this function (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Track site's mandatory terms and previously negotiated language in greater detail to quickly get to study specific negotiations and/or determine if contracting will be a deal-breaker (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Implement more MSAs with sites to budget and contract process can progress more smoothly (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Standardized contracting for industry sponsored clinical trials (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Leverage technology and tools for more efficient document exchange and greater transparency and efficiency in tracking progress (7)

☐☐☐☐

Other (please describe) (8)

☐☐☐☐

End of Block: Site Selection-Study Start-Up Process Improvements and Improvement Opportunities
