



CTTI Recruitment Survey

Clinical trial sponsors are experiencing an increasing number of clinical trials that fail to meet recruitment goals. In the spring of 2013, CTTI undertook a study project to address identify barriers to clinical trial recruitment and retention and to identify possible solutions to those barriers.

This survey represents a critical new phase for the project. We are contacting you and other important stakeholders to ask about we are interested in your opinions and experience with recruitment barriers, and strategies to overcoming the barriers, and your outlook on the future of clinical research.

Your answers will not be linked with any information that identifies you personally. Your responses will remain confidential. This The survey takes about 10 15 minutes to complete.

[insert new page before C1 to read:

“To navigate through this survey, use the Next and Back buttons that appear at the bottom of each screen. Do NOT press the back arrow on your browser, or your responses will be lost.”

C_Intro. The first questions ask about your organization or site and experience with clinical trials.

C1 Which of the following best describes your organization or site?

1. Academic Research Organization
2. Clinical Research Organization
3. Clinical Research Site
4. Federal Government: Regulatory (FDA)
5. Federal Government: Research (NIH, VA)
6. Federal Government: Other
7. Industry: Biotechnology
8. Industry: Medical Devices
9. Industry: Pharmaceuticals
10. Patient Advocacy, no sponsorship of trials
11. Patient Advocacy, including sponsorship of trials
12. Trade Organization / Professional Society
13. Something else

[IF C1=13/SOMETHING ELSE ASK C1OTH]

C1OTH Please describe your organization or site _____

C2. What is your organization's role in clinical trials? Check all that apply.

1. Sponsor-Federal
2. Sponsor-Industry
3. CRO
4. Research Site
5. Patient Advocacy
6. Other

[IF C2=6/OTHER ASK C2OTH]

C2OTH. Please describe your organization's role in clinical trials _____

C2a What is your professional role in clinical trials? Check all that apply.

1. Sponsor-Federal
2. Sponsor-Industry
3. CRO
4. Research Site
5. Patient Advocacy
6. Other

C3. How long has your organization been involved in clinical trials?

1. 5 years or less
2. 6-10 years
3. 11-2524 years
4. 25 years or more
5. Not involved in clinical trials

B_Intro. The next questions ask about specific barriers to clinical recruitment that have been identified by researchers.

B1. From your perspective, **how significant** is each of the following barriers to clinical trial recruitment?

a Finding or identifying patients who meet eligibility criteria

1. Very significant barrier
2. Somewhat significant barrier
3. A minor barrier
4. Not a barrier at all

b Insufficient staff time for recruitment activity

1. Very significant barrier
2. Somewhat significant barrier
3. A minor barrier
4. Not a barrier at all

c Length and complexity of consent forms

1. Very significant barrier
2. Somewhat significant barrier
3. A minor barrier
4. Not a barrier at all

d Patient mistrust of research

- 1 Very significant barrier
- 2 Somewhat significant barrier
- 3 A minor barrier
- 4 Not a barrier at all

e Difficulty scheduling trial study visits

- 1 Very significant barrier
- 2 Somewhat significant barrier
- 3 A minor barrier
- 4 Not a barrier at all

f Transportation to trial study visits

- 1 Very significant barrier
- 2 Somewhat significant barrier
- 3 A minor barrier
- 4 Not a barrier at all

g Out-of-pocket costs for patients

- 1 Very significant barrier
- 2 Somewhat significant barrier
- 3 A minor barrier
- 4 Not a barrier at all

- h Protocol requirements other than eligibility requirements (e.g., procedures, number of visits)
 - 1 Very significant barrier
 - 2 Somewhat significant barrier
 - 3 A minor barrier
 - 4 Not a barrier at all
- i Negative attitudes among patients' physicians regarding referral to clinical trials
 - 1 Very significant barrier
 - 2 Somewhat significant barrier
 - 3 A minor barrier
 - 4 Not a barrier at all
- j Patient concerns about randomization or study design
 - 1 Very significant barrier
 - 2 Somewhat significant barrier
 - 3 A minor barrier
 - 4 Not a barrier at all
- k Patient concerns about safety
 - 1 Very significant barrier
 - 2 Somewhat significant barrier
 - 3 A minor barrier
 - 4 Not a barrier at all
- l Social risk or stigma associated with enrollment for disease/condition
 - 1 Very significant barrier
 - 2 Somewhat significant barrier
 - 3 A minor barrier
 - 4 Not a barrier at all

[FOR EACH OF THE QUESTIONS B1a-B1l THAT IS ANSWERED "1=Very significant barrier" OR "Somewhat significant barrier" ASK A FOLLOWUP QUESTION TO RECORD OPEN-ENDED RESPONSES IN A TEXT BOX:

"From your perspective tell us briefly how this barrier can be overcome or what steps have been taken by your organization to overcome this barrier."

THESE WILL BE QUESTIONS B2A-B2L]

T_Intro. The next questions ask about the use of various methods for clinical trial recruitment.

T1. In your opinion, **how much** can each of the following methods increase clinical trials accrual?

- a Identifying individual patients using medical records
 - 1 Very much
 - 2 Somewhat
 - 3 Not at all
- b Identifying patients using hospital-based registries or other databases
 - 1 Very much
 - 2 Somewhat
 - 3 Not at all
- c Electronic alerts to physicians about clinical trials available to specific patients
 - 1 Very much
 - 2 Somewhat
 - 3 Not at all
- d Electronic alerts to clinical trial staff about eligible patient's appointments
 - 1 Very much
 - 2 Somewhat
 - 3 Not at all
- e Promoting clinical research through social media such as Facebook or Twitter
 - 1 Very much
 - 2 Somewhat
 - 3 Not at all
- f Promoting recruitment through social media such as Facebook or Twitter
 - 1 Very much
 - 2 Somewhat
 - 3 Not at all
- g Deploying a mobile health unit or mobile research unit
 - 1 Very much
 - 2 Somewhat
 - 3 Not at all
- h Recruiting through public events such as farmers' markets or health fairs
 - 1 Very much
 - 2 Somewhat
 - 3 Not at all

T2. Tell us about your organization's **experience** using these methods to support clinical trials recruitment.

- a Identifying patients using medical records
 - 1 We have done this and found it effective
 - 2 We have done this and found it ineffective
 - 3 We plan to try this in the future
 - 4 We have no plans to try this in the future
 - 5 Do not know

- b Identifying patients using hospital-based registries or other databases
 - 1 We have done this and found it effective
 - 2 We have done this and found it ineffective
 - 3 We plan to try this in the future
 - 4 We have no plans to try this in the future
 - 5 Do not know

- c Electronic alerts to physicians about trials available to specific patients
 - 1 We have done this and found it effective
 - 2 We have done this and found it ineffective
 - 3 We plan to try this in the future
 - 4 We have no plans to try this in the future
 - 5 Do not know

- d Electronic alerts to clinical trial staff about eligible patients' appointments
 - 1 We have done this and found it effective
 - 2 We have done this and found it ineffective
 - 3 We plan to try this in the future
 - 4 We have no plans to try this in the future
 - 5 Do not know

- e Promoting clinical research through social media such as Facebook or Twitter
 - 1 We have done this and found it effective
 - 2 We have done this and found it ineffective
 - 3 We plan to try this in the future
 - 4 We have no plans to try this in the future
 - 5 Do not know

- f Promoting recruitment through social media such as Facebook or Twitter
 - 1 We have done this and found it effective
 - 2 We have done this and found it ineffective

- 3 We plan to try this in the future
- 4 We have no plans to try this in the future
- 5 Do not know

g Deploying a mobile health unit or mobile research unit

- 1 We have done this and found it effective
- 2 We have done this and found it ineffective
- 3 We plan to try this in the future
- 4 We have no plans to try this in the future
- 5 Do not know

h Recruiting through public events such as farmers' markets or health fairs

- 1 We have done this and found it effective
- 2 We have done this and found it ineffective
- 3 We plan to try this in the future
- 4 We have no plans to try this in the future
- 5 Do not know

T3 In the space below, feel free to describe any other community-based method(s) that can increase clinical enrollment. Press Next to continue. _____

F_INTRO. The next questions ask about your views on the future of clinical trials recruitment.

F1. What is your outlook on increasing national clinical trial recruitment rates in the next 5 years?

Would you say that you are...

1. More optimistic than pessimistic
2. More pessimistic than optimistic
3. Undecided

F2. What is your outlook on increasing national clinical trial recruitment rates in the next 10 years?

Would you say that you are...

1. More optimistic than pessimistic
2. More pessimistic than optimistic
3. Undecided

F3. Which combination of sectors would form the most successful partnership to increase national clinical trial recruitment rates? Check two or more.

- 1 Researchers
- 2 Patient Advocates
- 3 Government Regulators
- 4 Funders
- 5 Sponsors
- 6 Trade Organizations
- 7 Professional Societies
- 8 Other

[IF F3=87/OTHER ASK F3OTH]

F3OTH What other sector(s) would form a successful partnership? _____

F4. Are there recent or emerging strategies that hold promise for increasing national clinical trial recruitment rates? If so, please describe. Press Next to continue.

D_Intro. These last questions ask about your professional role and your organization.

[IF C1=7, 8, OR 9 (INDUSTRY), OR IF C1=2 (CRO), C1=1 (ARO), OR C1=4 (GOVERNMENT-REGULATORY), ASK D1a]

D1a. Which of the following most closely describes your current position?

1. Executive leadership
2. Senior management (portfolio lead)
3. Middle management (program/project lead)
4. Study Management (study team member)
5. Other

[IF D1a=5/OTHER ASK D1OTH]

[IF C1=3 (CLINICAL RESEARCH SITE), ASK D1b]

D1b. Which of the following most closely describes your current position?

1. Director
2. Administrator
3. Investigator (Principal Investigator and Sub/Co-Investigator)
4. Site Coordinator / Other Research Staff
5. Other

[IF D1b=5/OTHER, ASK D1OTH]

[IF C1= 5, 6 (FEDERAL GOVERNMENT-RESEARCH OR OTHER) OR C1=12 (TRADE ORGANIZATION), ASK D1c]

D1c. Which of the following most closely describes your current position?

1. Executive leadership
2. Division leadership
3. Scientific / Research Program leader
4. Senior Administrator
5. Research Investigator / Analyst
6. Research Support
7. Other

[IF D1a=5/OTHER OR D1b=5/OTHER OR D1c=7/OTHER OR C1=10 OR 11 (PATIENT ADVOCACY) OR C1=13 (SOMETHING ELSE), ASK D1OTH]

D1OTH Please describe your current position _____

D2. Do you have significant influence in determining recruitment strategies for trials that you lead or manage?

1. Yes
2. No

D3. How many employees work in your organization?

1. 10 or fewer
2. 11-1,000
3. 1,001-5,000
4. 5,001-25,000
5. 25,001 or more
6. Not applicable/Not employed in an organization

D4. Does your organization conduct business outside the United States?

1. Yes
2. No

[IF C3=5 (NOT INVOLVED IN CLINICAL TRIALS), SKIP TO D6]

D5. In which of the following **geographic areas** does your organization conduct or support clinical trials? Check all that apply.

- 1 Africa
 - 2 Asia
 - 3 Canada
 - 4 Central America
 - 5 Eastern Europe
 - 6 European Union
 - 7 Middle East
 - 8 The Caribbean
 - 9 South America
 - 10 Australia/Oceania
 - 11 United Kingdom
 - 12 United States
 - 13 Organization does not conduct or support clinical trials
- 1 Africa
 - 2 Asia (includes Middle East)
 - 3 Australia/Oceania
 - 4 Canada
 - 5 The Carribbean
 - 6 Europe
 - 7 South America
 - 8 United Kingdom
 - 9 United States
 - 10 Organization does not conduct or support clinical trials

D6. In which of the following **therapeutic areas** does your organization work? Check all that apply.

- 1 Allergy
- 2 Arthritis
- 3 Blood
- 4 Cancer
- 5 Diabetes
- 6 Digestive
- 7 Genetic
- 8 Heart
- 9 Infectious disease
- 10 Kidney
- 11 Lung
- 12 Mental health
- 13 Musculoskeletal
- 14 Neurological
- 15 Skin
- 16 Stroke
- 17 All of the above
- 18 Other

[IF D6=18/OTHER ASK D6OTH]

D6OTH Describe other therapeutic area(s) in your organization. _____

D7. In which of the following therapeutic areas do you work? In what therapeutic area or areas do you specialize? Check all that apply.

- 1 Allergy
- 2 Arthritis
- 3 Blood
- 4 Cancer
- 5 Diabetes
- 6 Digestive
- 7 Genetic
- 8 Heart
- 9 Infectious Disease
- 10 Kidney
- 11 Lung
- 12 Mental health
- 13 Musculoskeletal
- 14 Neurological
- 15 Skin
- 16 Stroke
- 17 All of the above
- 18 Other

[IF D7=18/OTHER ASK D7OTH]

D7OTH Describe other therapeutic area(s) in which you work. _____

D8. About how long have you been involved in clinical trials?

1. 5 years or less
2. 6-10 years
3. 11-25 years
4. 25 years or more

D9. Are there other remarks you want to make about clinical trial recruitment? Please add them below.

END Thank you for your time and assistance completing this survey. Press the Submit button to save your final responses.