The Clinical Trials Transformation Initiative (https://www.ctti-clinicaltrials.org/)

ITO - Barriers and Possible Solutions to Continued Participation

Thank you for participating in CTTI's Investigator Turnover Survey. Your input is critical to help better understand the barriers and possible solutions to continued investigator engagement. All respondents' answers will be treated confidentially and your response will be aggregated with other respondents for analysis.

Demographics

We'd like to begin by asking a few questions about you.

1. What is your age?
    a. Under 35 years
    b. 35 to 44 years
    c. 45 to 54 years
    d. 55 to 64 years
    e. 65 and over
    f. Prefer not to respond

2. What is your gender?
    a. Female
    b. Male
    c. Prefer not to respond

3. What is your race?
    a. American Indian or Alaska Native
    b. Asian
    c. Black or African American
    d. Native Hawaiian or Other Pacific Islander
    e. White
    f. Other _____
    g. Prefer not to respond

4. What is your ethnicity?
    a. Hispanic or Latino
    b. Not Hispanic or Latino
    c. Prefer not to respond

Introduction

We will now ask you questions about your involvement in FDA-regulated drug trials.

5. From a review of records in the FDA's Bioresearch Monitoring Information System database, you have been identified as a principal investigator who has conducted ONE FDA-regulated drug trial but who has NOT conducted another FDA-regulated drug trial. Is this a true statement? *(If yes is selected, then skip to Q7.)*
    a. Yes
    b. No

6. How many FDA-regulated drug trials you have conducted as the principal investigator? (Please include any current trials.)
    a. 2
    b. 3 to 5
    c. 6 to 10
    d. 11 or more

    For all who answered Q6: Thank you for your time. The remaining questions are for principal investigators who have conducted only one FDA-regulated drug trial. (Skip to End of Survey)

7. You have indicated that you are a principal investigator who has conducted ONE FDA-regulated drug trial but who has NOT conducted another FDA-regulated drug trial. Is that one FDA-regulated drug trial completed or is it still ongoing?
    a. Completed
    b. Ongoing

8. Are you interested in conducting another FDA-regulated drug trial as a principal investigator? *(If Yes or Unsure is Selected, Skip to End of Survey.)*
    a. Yes
    b. No
    c. Unsure

9. Which of the following best describes the reason you did not conduct another FDA-regulated drug trial as the principal investigator? We will ask more detailed questions on this topic later in the survey. *(Only answer IF Q7 answer is Completed AND Q8 answer is No.)*
    a. I made a personal decision to no longer conduct FDA-regulated drug trials as the Principal Investigator
    b. I was interested in serving as a principal investigator for another FDA-regulated drug trial but another trial has not been made available to me
    c. None of the above. (Please specify reason)

10. Who was the funder of the one FDA-regulated drug trial that you conducted as a principal investigator? Please check all that apply. *(Only answer IF Q7 answer is Completed AND Q8 answer is No.)*
    a. Pharmaceutical industry

b. U.S. government
c. Private foundation
d. Non-governmental organization
e. Investigator-initiated and funded
f. Other (please specify)

11. What phase of clinical research was that one FDA-regulated drug trial?
    a. Safety trial (typically Phase I)
    b. Proof of concept or dose-ranging trial (typically Phase IIa/b)
    c. Pivotal trials for registration (typically Phase III)
    d. Other (please specify)

12. Which best describes the type of organization you were with when you conducted the one FDA-regulated drug trial?
    a. Academic institution/academic health system with research and education responsibilities
    b. Community or private practice with a primary clinical responsibility
    c. Hospital with no affiliated academic institution
    d. Dedicated research site with no affiliated clinical practice responsibility
    e. Pharmaceutical industry
    f. Federal government agency
    g. Other (please specify)

13. Where were the sites for your one FDA-regulated drug trial that you conducted?
    a. The study site(s) was in the U.S.
    b. The study site(s) was outside of the U.S.
    c. The sites were in the U.S. and outside of the U.S.

14. How did you get involved with FDA-regulated drug trial? Please check all that apply.
    a. Through my medical training program
    b. Through another graduate program
    c. Through a fellowship
    d. Through a mentorship
    e. Through a website that matches upcoming clinical trials with potential study sites
    f. A colleague asked me to collaborate on a trial
    g. A pharmaceutical company reached out to me
    h. I don't remember
    i. Other (please specify)

15. Beyond the one FDA-regulated drug trial you have conducted, have you conducted other medical research as the principal investigator? *(If No, Skip to Next Category – Q17)*
    a. Yes

b. No

16. Who has been the funder(s) of that medical research? Please check all that apply.
    a. Pharmaceutical industry
    b. U.S. government
    c. Private foundation
    d. Non-governmental organization
    e. Investigator-initiated and funded
    f. Other (please specify)

17. What type of research were those studies? Please check all that apply.
    a. Phase I, II, or III drug or device clinical trial without an investigational new drug application (IND) or investigational device exemption (IDE)
    b. Other clinical research (e.g., observational, prognostic, diagnostic)
    c. Epidemiological research (e.g., observation, cohort, case control)
    d. Medical device clinical trials
    e. Post-approval studies (typically Phase IV)
    f. Other (please specify)

Intro 1
Potential Barriers *(Shown this introduction If for Q9, you answer b.)*

We are interested in identifying factors that principal investigators have found challenging when conducting a FDA-regulated drug trial as a principal investigator. We also want to identify factors that may prevent investigators from conducting more FDA-regulated drug trials. Six broad categories will be presented. For each category, we will first ask you to indicate whether you have found that category challenging in general when you conducted the one FDA-regulated drug trial. Then, for each category that you select as being challenging, we will ask you how challenging you found specific factors in that category.

Intro 2
Potential Barriers *(Shown this introduction if for Q9, you answer a OR c OR for Q7, your answer is No.)*

We are interested in identifying factors that principal investigators have found challenging when conducting a FDA-regulated drug trial as a principal investigator. We also want to identify factors that may prevent investigators from conducting more FDA-regulated drug trials. Six broad categories will be presented. For each category, we will first ask you to indicate whether you have found that category challenging in general when you conducted the one FDA-regulated drug trial. Then, for each category that you select as being challenging, we will ask you how challenging you found specific factors in that category. Lastly, we will ask you how these factors affected your decision to no longer conduct FDA-regulated drug trials as a principal investigator.

Category 1: Data and Safety Reporting

This category focuses on data and safety reporting.

18. Did you find data and safety reporting burdensome in some way? *(If No is selected, Skip to Next Category.)*
    a. Yes
    b. No

18a. How burdensome or not burdensome did you find each of the following factors?

	Response option				
	Extremely burdensome	Moderately burdensome	Somewhat burdensome	Not burdensome	Not applicable
Amount of non-safety data to report	☐	☐	☐	☐	☐
Method of reporting non-safety data	☐	☐	☐	☐	☐
Amount of safety data to report	☐	☐	☐	☐	☐
Method of reporting safety data	☐	☐	☐	☐	☐
Frequency of reporting safety data	☐	☐	☐	☐	☐

18b. What effect did each of these factors have, if any, on your decision to no longer conduct FDA-regulated drug trials as a principal investigator?

	Response option				
	Major effect	Moderate effect	Minor effect	No effect	Not applicable
Amount of non-safety data to report	☐	☐	☐	☐	☐
Method of reporting non-safety data	☐	☐	☐	☐	☐
Amount of safety data to report	☐	☐	☐	☐	☐
Method of reporting safety data	☐	☐	☐	☐	☐
Frequency of reporting safety data	☐	☐	☐	☐	☐

18c. List here any other factors related to data and safety reporting that affected your decision to no longer conduct FDA-regulated drug trials as a principal investigator.

Category 2: Finance

This category focuses on finance.

19. Were you unsatisfied with any factor related to budgets and contracts? This includes budget negotiation, the final budget, contract negotiation, the final contract, and site payments. *(If No is selected, Skip to Next Category.)*
    a. Yes
    b. No

19a. How unsatisfied (or satisfied) were you with each of the following factors?

	Response option				
	Extremely Satisfied	Moderately Satisfied	Somewhat Satisfied	Not Satisfied	Not Applicable
Sponsor/site budget negotiations	☐	☐	☐	☐	☐
Final site budget	☐	☐	☐	☐	☐
Sponsor/site contract negotiations	☐	☐	☐	☐	☐
Final contract	☐	☐	☐	☐	☐
Schedule of site payments	☐	☐	☐	☐	☐

19b. What effect did these factors have, if any, on your decision to no longer conduct FDA-regulated drug trials as a principal investigator?

	Response option				
	Major effect	Moderate effect	Minor effect	No effect	Not Applicable
Sponsor/site budget negotiations	☐	☐	☐	☐	☐
Final site budget	☐	☐	☐	☐	☐
Sponsor/site contract negotiations	☐	☐	☐	☐	☐
Final contract	☐	☐	☐	☐	☐
Schedule of site payments	☐	☐	☐	☐	☐

19c. List here any other factors related to finance that affected your decision to no longer conduct FDA-regulated drug trials as a principal investigator.

Category 3: Study Protocol and Study Procedures

This category focuses on study protocol and study procedures.

20. Did you find any factor related to the study protocol and study procedures difficult to implement? This includes the study inclusion/exclusion criteria; identifying, recruiting, and retaining patients; frequency of patient study visits; drug storage and accountability requirements; and integration of study protocol procedures with standard-of-care procedures. *(If No is selected, Skip to Next Category.)*
    a. Yes
    b. No

20a. How difficulty (or easy) did you find each of the following factors to implement?

	Response option					
	Very difficult	Difficult	Neutral	Easy	Very Easy	Not Applicable
Study inclusion and exclusion criteria	☐	☐	☐	☐	☐	☐
Identifying patients	☐	☐	☐	☐	☐	☐
Recruiting patients	☐	☐	☐	☐	☐	☐
Retaining patients	☐	☐	☐	☐	☐	☐
Frequency of patient study visits	☐	☐	☐	☐	☐	☐
Drug storage and accountability requirements	☐	☐	☐	☐	☐	☐
Integration of study protocol procedures with standard-of-care procedures	☐	☐	☐	☐	☐	☐

20b. What effect did these factors have, if any, on your decision to no longer conduct FDA-regulated drug trials as a principal investigator?

	Response option				
	Major effect	Moderate effect	Minor effect	No effect	Not Applicable
Study inclusion and exclusion criteria	☐	☐	☐	☐	☐
Identifying patients	☐	☐	☐	☐	☐
Recruiting patients	☐	☐	☐	☐	☐
Retaining patients	☐	☐	☐	☐	☐
Frequency of patient study visits	☐	☐	☐	☐	☐
Drug storage and accountability requirements	☐	☐	☐	☐	☐

Integration of study protocol procedures with standard-of-care procedures	☐	☐	☐	☐	☐

20c. List here any other factors related to the study protocol and study procedures that affected your decision to no longer conduct FDA-regulated drug trials as the principal investigator.

Category 4: Time Commitments

This category focuses on time commitments.

21. Did you find any factor related to the amount of time required to be involved in the trial challenging? This includes the amount of time needed for study start up and implementation, and the amount of your time and site staff time needed to conduct the trial. *(If No is selected, Skip to Next Category.)*
    a. Yes
    b. No

21a. How challenging (or not challenging) did you find each of the following factors?

	Response option				
	Very challenging	Challenging	Somewhat Challenging	Not Challenging	Not Applicable
Amount of time required to prepare for trial start-up	☐	☐	☐	☐	☐
Amount of time required to implement the trial	☐	☐	☐	☐	☐
Amount of time required by you, the investigator, to support the trial and site staff	☐	☐	☐	☐	☐
Amount of time required by your staff to support the trial	☐	☐	☐	☐	☐

21b. What effect did these factors have, if any, on your decision to no longer conduct FDA-regulated drug trials as a principal investigator?

	Response option				
	Major effect	Moderate effect	Minor effect	No effect	Not Applicable

Amount of time required to prepare for trial start-up	☐	☐	☐	☐	☐
Amount of time required to implement the trial	☐	☐	☐	☐	☐
Amount of time required by you, the investigator, to support the trial and site staff	☐	☐	☐	☐	☐
Amount of time required by your staff to support the trial	☐	☐	☐	☐	☐

21c. List here any other factors related to time that affected your decision to no longer conduct FDA-regulated drug trials as a principal investigator.

Category 5: Staff Involvement and Investment

This category focuses on investigator and staff involvement and investment.

22. Were you unsatisfied with any factor related to investigator and staff involvement and investment? This includes investigator input on protocol design and staff training.
    a. Yes
    b. No

22a. How unsatisfied (or satisfied) were you with each of the following factors?

	Response option				
	Extremely Satisfied	Moderately Satisfied	Somewhat Satisfied	Not Satisfied	Not Applicable
Investigator input on protocol design	☐	☐	☐	☐	☐
Training for investigators	☐	☐	☐	☐	☐
Training for site staff	☐	☐	☐	☐	☐
Opportunities for investigators to learn about new studies	☐	☐	☐	☐	☐

22b. What effect did these factors have, if any, on your decision to no longer conduct FDA-regulated drug trials as a principal investigator?

	Response option

	Major effect	Moderate effect	Minor effect	No effect	Not Applicable
Lack of investigator input on protocol design	☐	☐	☐	☐	☐
Inadequate training for investigators	☐	☐	☐	☐	☐
Inadequate training for study staff	☐	☐	☐	☐	☐
Excessive training for investigators	☐	☐	☐	☐	☐
Excessive training for study staff	☐	☐	☐	☐	☐
Limited opportunities for investigators to learn about new studies	☐	☐	☐	☐	☐

22c. List here any other factors related to investigator and staff involvement and investment that affected your decision to no longer conduct FDA-regulated drug trials as a principal investigator.

Category 6: Workload

This category focuses on workload.

23. Did you find any factor challenging that was related to balancing the hours necessary to implement the trial with other work obligations and opportunities? *(If No is selected, Skip to Next Category.)*
    a. Yes
    b. No

23a. How challenging (or not challenging) did you find each of the following factors?

	Response option				
	Very Challenging	Challenging	Somewhat Challenging	Not Challenging	Not Applicable
Unpredictable work hours	☐	☐	☐	☐	☐
Long work hours	☐	☐	☐	☐	☐
Finding time to devote to activities fostering academic promotion	☐	☐	☐	☐	☐
Finding time to devote to other work activities (non-clinical)	☐	☐	☐	☐	☐

Finding time to devote to other work activities (clinical)	☐	☐	☐	☐	☐

23b. What effect did these factors have, if any, on your decision to no longer conduct FDA-regulated drug trials as a principal investigator?

	Response option				
	Major effect	Moderate effect	Minor effect	No effect	Not Applicable
Unpredictable work hours	☐	☐	☐	☐	☐
Long work hours	☐	☐	☐	☐	☐
Finding time to devote to activities fostering academic promotion	☐	☐	☐	☐	☐
Finding time to devote to other work activities (non-clinical)	☐	☐	☐	☐	☐
Finding time to devote to other work activities (clinical)	☐	☐	☐	☐	☐

23c. List here any other factors related to workload that affected your decision to no longer conduct FDA-regulated drug trials as a principal investigator.

24. Are there any other factors that you would like to share about why you are no longer conducting FDA-regulated drug trials as a principal investigator?

Potential Solutions

We would like to identify ways to improve the experiences of principal investigators and site staff who are engaged in FDA-regulated drug trials. By doing this, we aim to increase their initial and sustained involvement in these trials. For reach proposed solution below, please indicate how effective it would be to you personally at encouraging you to stay involved in FDA-regulated drug trials. If you have any additional suggestions, please provide them in the text bottom at the bottom.

Category #1: Data and Safety Reporting

	Response option				
	Very effective	Moderately effective	Slightly effective	Not effective	Neutral
Having clearer data reporting requirements	☐	☐	☐	☐	☐

Having fewer data reporting requirements	☐	☐	☐	☐	☐
Using electronic case report forms to collect and report data	☐	☐	☐	☐	☐

Category #2: Finance

	Response option				
	Very effective	Moderately effective	Slightly effective	Not effective	Neutral
Providing funding that covers full costs of trial implementation	☐	☐	☐	☐	☐
Providing timely payments to ensure that trial account is always cash positive	☐	☐	☐	☐	☐
Providing site payments no later than 30 days after payment is due	☐	☐	☐	☐	☐
Providing funding for other investigator considerations such as grants to fund speaker series, CME programs, investigator-initiated research, etc.	☐	☐	☐	☐	☐
Providing pay-for-performance incentives	☐	☐	☐	☐	☐
Providing funding to cover a higher percentage of the principal investigator's time	☐	☐	☐	☐	☐
Providing funding to cover a higher percentage of staff time	☐	☐	☐	☐	☐

Category #3: Protocol and Study Procedures

	Response option				
	Very effective	Moderately effective	Slightly effective	Not effective	Neutral
Using inclusion and exclusion criteria that are	☐	☐	☐	☐	☐

in line with current standard of care and general patient population					
Increasing investigator access to patient recruitment base by establishing a database across multiple practices	☐	☐	☐	☐	☐
Streamlining requirements for data collection (e.g., shorter forms, data collected at fewer time points)	☐	☐	☐	☐	☐

Category #4: Investigator and Staff Investment

	Response option				
	Very effective	Moderately effective	Slightly effective	Not effective	Neutral
Creating a mechanism where investigators provide input on protocol design	☐	☐	☐	☐	☐
Providing a central mechanism for investigators to learn about new study opportunities	☐	☐	☐	☐	☐
Providing exposure to site-based research during medical education and training years	☐	☐	☐	☐	☐
Providing education about constraints and processes of industry research	☐	☐	☐	☐	☐
Implementing standardized investigator and study staff training across sponsors	☐	☐	☐	☐	☐
Allowing reciprocity for similar standardized investigator and site staff training already completed through another sponsor	☐	☐	☐	☐	☐

25. List here any other potential solutions you may have.

26. Benefits/Value of Research: For our last set of questions, we want to learn your views on the benefits and value of leading FDA-regulated drug trials. For each factor below, please indicate how much benefit it was for you to :

	Significant benefit	Moderate benefit	Small benefit	No benefit
Contribute to advancing science	☐	☐	☐	☐
Contribute to society	☐	☐	☐	☐
Contribute to the commercialization of product	☐	☐	☐	☐
Fulfill personal interest in the research process	☐	☐	☐	☐
Have an opportunity to lead cutting-edge research	☐	☐	☐	☐
Be recognized as a thought leader	☐	☐	☐	☐
Advance in career	☐	☐	☐	☐
Have an opportunity to present at conferences	☐	☐	☐	☐
Have an opportunity to publish in peer-review journals	☐	☐	☐	☐
Have an opportunity to lead subsequent drug trials	☐	☐	☐	☐
Enhance local practice status	☐	☐	☐	☐
Access additional patient therapies that are not available through other means	☐	☐	☐	☐
Increase expertise with particular therapeutics	☐	☐	☐	☐
Gain early familiarity with new therapeutics	☐	☐	☐	☐
Have an opportunity for variety from the routine of daily practice	☐	☐	☐	☐
Interact with trial patients	☐	☐	☐	☐
Engage with thought leaders	☐	☐	☐	☐
Engage with sponsors	☐	☐	☐	☐
Be exposed to the drug approval process	☐	☐	☐	☐
Receive financial incentives	☐	☐	☐	☐

27. List here any other benefits you found.

We will end the survey by asking you about the number of employees at your company.

28. How many full-time equivalent employees (40 hours per week)***** working at your site are committed to conducting clinical research?

a. Fewer than 5
b. Between 6 and 10
c. Between 11 and 20
d. Between 21 and 35
e. More than 35

***Note**: One full time equivalent employee (FTE) can be a combination of employees of whom individually the work is less than 40 hours a week. For example, a site may have 4 individual employees who each contribute 10 hours per week to clinical research. Those four employees equal one FTE. Alternately, two employees working 20 hours per week, or one employee working 40 hours a week, are other examples of one FTE. Any other iteration that combines to 40 hours per week also qualifies as one FTE.

Thank you for your time. Your input will be critical to identifying barriers and possible solutions to continued investigator involvement in FDA-regulated drug trials. We will use this information to develop recommendations to encourage on-going involvement of investigators in FDA-regulated drug trials.