

ITO Demographic Questionnaire

No.	Question	Answer
1.	What is your age today? <i>Write age in years</i>	_____
2.	What is your gender? <i>Select the gender with which you identify</i>	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Prefer not to respond
3.	What is your race? <b>[Read aloud categories]</b> <i>Select all that apply</i>	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Prefer not to respond
4.	What is your ethnicity? <b>[Read aloud categories]</b> <i>Select only one</i>	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Prefer not to respond
5.	Which best describes the type of organization with which you are currently affiliated? <b>[Read aloud categories]</b> <i>Select only one</i>  <i>If the participant does not fall into one of these categories, end the interview (does not meet eligibility criteria).</i>	<input type="checkbox"/> Academic institution or academic health system with research and education opportunities <input type="checkbox"/> Community-based out-patient clinic or private practice with primary clinical responsibilities <input type="checkbox"/> Community-based hospital with no affiliated academic institution <input type="checkbox"/> Dedicated research site with no affiliated clinical practice responsibility
6.	How many years have you been with this institution?	_____

No.	Question	Answer
7.	What is your terminal degree? <b>[Read aloud categories]</b> <i>Select only one</i>	<input type="checkbox"/> MD <input type="checkbox"/> MD/PhD <input type="checkbox"/> Other (specify): _____
8.	What is your primary therapeutic area of practice?	
<p><i>For the following questions:</i></p> <ul style="list-style-type: none"> <li>▪ <i>Answer only about distinct FDA-regulated drug trials. Meaning, that separate FDA Forms 1572 were completed for each trial.</i></li> <li>▪ <i>Answer only about the FDA-regulated drug trials for which you served as the PI, sub-PI, or co-PI, as appropriate.</i></li> <li>▪ <i>Some questions will ask about when you were a PI and others will ask about when you were a sub-PI or co-PI.</i></li> <li>▪ <i>When answering the questions, do not include:</i> <ul style="list-style-type: none"> <li>• <i>Device trials</i></li> <li>• <i>Drug trials that were NOT regulated by the FDA</i></li> <li>• <i>Other clinical research that was not regulated by the FDA</i></li> </ul> </li> </ul>		
9.	In what year did you participate in your first FDA-regulated drug trial <b>as the PI</b> ?	_____
10.	In what year did you participate in your first FDA-regulated drug trial <b>as the sub-PI or co-PI</b> ?	_____
11.	Including current trials, what is the total number of FDA-regulated drug trials for which <b>you have served as the PI</b> ?	_____
12.	How many of these trials did you participate in <b>as the PI</b> in the past 2 years?  <i>“Participated” means that between June 1, 2014 and May 31, 2016, you were the PI on FDA-regulated drug trials that were:</i> <ul style="list-style-type: none"> <li>• <i>Activated during the two year period</i></li> <li>• <i>On-going during the two-year period</i></li> <li>• <i>Closed to data collection during the two year period but where study results had not yet been released</i></li> </ul>	_____

No.	Question	Answer
13.	Including current trials, what is the total number of FDA-regulated drug trials for which <b><u>you have served as the sub-PI or co-PI?</u></b>	_____
14.	How many of these trials did you participate in as <b>the sub-PI or co-PI</b> in the past 2 years?  <i>Use the same definition as given for PI</i>	_____
<p><b><i>The remaining questions focus on the studies in which you were the principal investigator.</i></b></p> <p><b><i>When answering the questions, consider all of your FDA-regulated drug trials that you conducted as the PI.</i></b></p> <p><b><i>You can select more than one answer.</i></b></p>		
15.	Who sponsored the FDA-regulated drug trials for which you served as the PI?  <b><i>[Read aloud categories]</i></b>  <i>Consider all of your FDA-regulated drug trials and select all that apply</i>	<input type="checkbox"/> Pharmaceutical industry <input type="checkbox"/> U.S. government <input type="checkbox"/> Private foundation <input type="checkbox"/> Non-governmental organization <input type="checkbox"/> Investigator-initiated and funded <input type="checkbox"/> Other (specify):
16.	What phase of clinical research were the FDA-regulated drug trials for which you served as the PI?  <b><i>[Read aloud categories]</i></b>  <i>Consider all of your FDA-regulated drug trials and select all that apply</i>	<input type="checkbox"/> Safety trial (typically Phase I) <input type="checkbox"/> Proof of concept or dose-ranging trial (typically Phase IIa/b) <input type="checkbox"/> Pivotal trials for registration (typically Phase III) <input type="checkbox"/> Other (specify):
17.	Where were the study sites for the FDA-regulated drug trials for which you served as the PI?  <b><i>[Read aloud categories]</i></b>  <i>Consider all of your FDA-regulated drug trials and select all that apply</i>	<input type="checkbox"/> The study sites were in the U.S. <input type="checkbox"/> The study sites were outside of the U.S. <input type="checkbox"/> The sites were in the U.S. and outside of the U.S.

## ITO Active Investigators Qualitative Question Guide

### SECTION A: Motivation and Reasons for Success

1. I would like to begin our discussion by talking about some of your earlier experiences with FDA-regulated clinical drug trials.
  - a. When were you first exposed to FDA-regulated drug trials? **[Probe: during medical training, residency, fellowship]**
2. You mentioned earlier that you conducted your first FDA-regulated drug trial as the PI in \_\_\_\_\_ **[refer to Q9 in Demographic Questionnaire].**
  - a. At what point in your career was this?
  - b. What type of organization were you with?
  - c. How did you learn about the opportunity to be the PI for this trial?
  - d. What motivated you to conduct that trial as the PI?
  - e. What motivated you to conduct FDA-regulated drug trials compared to focusing only on clinical research that is not regulated by the FDA?
3. Since that initial trial, how did you find other opportunities to be the PI on FDA-regulated drug trials? **[Probe about industry contacting you; you contacting industry; being invited by a colleague; being part of an industry database; being part of trial network].**
  - a. What advice would you have for less-experienced PIs who want to conduct FDA-regulated drug trials but who don't know how to initiate the process?
4. You have been successful in being the PI for multiple FDA-regulated drug trials over the years. In your opinion, what factors have contributed to this success? **[Probe: specific infrastructure or services provided by internal or external sources; individual motivation]**
  - a. If you were asked to give advice to less-experienced PIs on how to be a successful investigator of FDA-regulated trials, name three factors you would tell them that you feel are very important?
    - i. [Ask for each factor] What makes that factor important?

### SECTION B: Barriers Experienced

Let us change topics. Now I'd like to talk about the challenges you have experienced in conducting FDA-regulated drug trials as the PI. Please think back to some of the most difficult FDA-regulated drug trials that you participated in as the PI.

5. What were some of the challenges you faced when conducting these trials? By "challenge" I mean a demanding or burdensome situation that made it either difficult to conduct the trial or less enjoyable.
  - a. **[Probe with "anything else" until all challenges are mentioned]**
6. Of all these challenges, which ones did you feel were outside of your control?
  - a. **[For each challenge mentioned]**
    - i. Why was this challenge outside of your control?

- ii. Were you able to overcome this challenge or did you have to learn to cope with it?
    - 1. What was done to overcome it?/What did you do to cope with it?  
***[Probe: specific infrastructure or services provided by internal or external sources; individual motivation ]***
  - iii. If this challenge was within your control, what would you do specifically to address it?
  - iv. How common do you think this challenge is?
  - v. What advice do you have for less experienced investigators to help them manage this challenge?
7. Now let us talk about the challenges that were within your control to change. Of the challenges you mentioned earlier, which ones were within your control?
- a. ***[For each challenge mentioned]***
    - i. What did you do to manage or overcome it?
8. How have the challenges you faced participating in FDA-regulated drug trials changed over the years?
- a. ***[Probe: new/different institutional, sponsor and FDA policies that relieved or added to the burden of investigators]***
  - b. How have challenges varied across the types of studies you have conducted?
    - i. Are there specific types of studies that you feel are more prone to challenges?
      - 1. ***[If yes]*** Which studies?
        - a. What kind of challenges are common with those studies?
9. ***[If several challenges were mentioned above]*** Given all the challenges you have experienced, what personal reasons motivate you to continue participating in FDA-regulated drug trials as the PI?
- a. What about factors related to organizational or site infrastructure? ***[Probe about infrastructure or services provided by internal or external sources]***

<b>SECTION C: Other Investigator Barriers</b>
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I'd now like to get your feedback on challenges that PIs who have participated in only a single FDA-regulated drug trial as the PI have experienced. These data come from a previous survey we conducted with PIs who had only conducted one FDA-regulated drug trial and who said they did not want to conduct another one.

Please pull out the document we emailed you earlier. On the top of the sheet, it reads, "One and Done: Reasons investigators conduct only one FDA-regulated drug trial."

## **One and done: Reasons investigators conduct only one FDA-regulated drug trial**

The following three categories of barriers were found to be generally burdensome or challenging in some way in the conduct of FDA-regulated clinical trials by the majority of investigators surveyed. These barriers also affected investigators' decisions to no longer participate in FDA-regulated drug trials.

- 1. Too much time required to lead trial.** This included the amount of time:
  - It took to prepare for trial set up
  - Required by the PI to support trial and staff
  - Required by staff to support the trial
  - Needed to implement the trial in general
  
- 2. The time it took to lead the trial took time away from other necessary activities.** This included:
  - Long work hours
  - Unpredictable work hours
  - Difficulty in devoting time to:
    - Clinical and non-clinical activities
    - Activities fostering academic promotion.
  
- 3. The burden of data and safety reporting.** This included the:
  - Amount of safety and non-safety data to report
  - Method of reporting safety and non-safety data
  - Frequency of reporting safety data

Additionally, one-time investigators described **dissatisfaction with trial finances**. This included dissatisfaction with:

- Sponsor/site contract negotiations
- Sponsor/site budget negotiations
- Final contracts
- Final site budgets
- Schedule of site payments

10. Take a moment to look at the specific barriers listed under each broad category. Are there any barriers listed here that you have experienced in the past but that we didn't talk about earlier? This could be for any of the trials you have conducted in the past.
- a. ***[If yes]*** Which ones?
    - i. ***[For each barrier identified]***. Tell me about it. What was the context surrounding the barrier?
      1. How did you manage the challenge in that case? ***[Probe: specific infrastructure or services provided by internal or external sources; individual motivation]***
    - ii. For some of the investigators we previously interviewed, these barriers proved to be too much of a burden and it influenced their decision to no longer conduct FDA-regulated clinical trials. What kept you motivated to continue conducting FDA-regulated clinical trials after experiencing some of these challenges?
11. Are there any barriers listed here that you **did not** experience in the past?
- a. ***[If yes]*** Which ones?
    - i. ***[For each barrier identified]*** Why do you think you didn't experience this barrier?
      1. ***[Probe: specific infrastructure or services provided by internal or external sources, prior skills/knowledge/experience, interpersonal support (mentor, quality support staff)]***

<b>SECTION D: Supporting investigators</b>
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Now let us move on to the last topic that I'd like your advice about. It's on strategies for encouraging and supporting physicians to become involved in and stay involved in FDA-regulated clinical trials as the PI, like yourself.

12. What strategies would you suggest that physicians do so they can be prepared to participate in FDA-regulated drug trials as the PI? ***[Probe with "anything else"; then follow-up with topics below if not mentioned:]***
- a. ***Research knowledge***
    - i. What kind of knowledge should physicians have before becoming a PI of a FDA-regulated clinical trial?
    - ii. How should they obtain this knowledge? ***[Probe: during medical/graduate school, during residency, during fellowship, experiential learning as sub-investigators, mentorships]***
  - b. ***Research skills experience***
    - i. What kind of experience should physicians have before becoming a PI of a FDA-regulated clinical trial?
    - ii. How should they get this experience? ***[Probe: during medical/graduate school, during residency, during fellowship, experiential learning as sub-investigators, mentorships]***

- c. **Formal mentorship structure**
  - i. Who should provide opportunities for mentorship or collegial support (e.g., the physicians' institutions, research sponsors)?
  - ii. How can mentorship or collegial support happen outside of the academic environment? **[Probe about apprenticeship]**
  - iii. What do you think are the key elements of a successful mentorship program or collegial support?
    - 1. **[Probe: compensation/incentive for mentors, training for mentors, matching mentees with appropriate mentors]**
  - iv. What are key characteristics of an effective mentor?
  - v. How can continued learning happen?
- d. **Greater institutional or site support [Contextualize question if types of support were described earlier]**
  - i. What kind of support from physician's own institutions or site do you think physician's need to be successful and motivated to participate in FDA-regulated drug trials?
    - 1. **[Probe: motivating institutional policies (e.g., professional recognition for conducting industry trials, debt abatement); more time allowed to dedicate to research, infrastructure provided by institution to conduct the research]**
  - ii. How could institutions or sites be encouraged to provide greater support to physicians who want to participate in FDA-regulated drug trials?

13. To conclude, what do you wish you had known when you first started in clinical research that you know now?

<b>SECTION E: Closing</b>
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- That's the end of the questions that I have for you today. Do you have any final thoughts or questions?
- I want to sincerely thank you for your time and for the helpful information that you provided.
- Once all of the interviews have been completed and the data analyzed, would you like for us to send you a summary of the results?
- **[If yes]** What is an appropriate email address for me to use to send you the study findings?
- Thank you very much and I hope that you have a great day!