Rapid Feedback Tool to Identify Accrual Problems with Active NCI clinical Trials

Attachment 15A: Oncology Feedback Survey

Attachment 15B: Staff Feedback Survey

OMB #: 0925-0046-1513
Expiry Date: 02/28/1313

WORD VERSION OF ONLINE FEEDBACK SURVEY TEMPLATE

Attachment 15A: ONCOLOGIST SURVEY

INTRO:

The National Cancer Institute (NCI) has developed a **brief online survey** tool to quickly and easily solicit comments from oncologists and research staff about specific NCI clinical trials that have low accrual rates.

We would like your opinions about the [INSERT FULL TRIAL NAME].

Your comments will help NCI and [insert cooperative group name] decide how to move forward with the [INSERT TRIAL NAME] trial and if accrual can be improved. We thank you for your assistance!

If you consent to participate and would like to continue and begin the survey, click the "Next" button below.

PRIVACY STATEMENT/CONSENT:

Your participation in this survey is completely voluntary. Your participation in the survey is anonymous and your responses will never be linked or associated with you.

You may skip any questions that you prefer not to answer. You are also free to stop participating at any point during the survey and have your responses deleted by clicking the "Opt out of survey" box at the bottom of each survey page.

This brief survey should only require approximately 5 minutes of your time.

Please click the “Next” button if you consent to taking this survey.

We would like your feedback on [INSERT FULL TRIAL NAME].

This trial was opened by [insert group] in [insert month/year]. To date, only [#] patients have been accrued to the trial and therefore the trial is at risk of not meeting the NCI CTEP Quarter 5 accrual guidelines. If accrual continues at its current rate, this trial will be considered for termination. As such, NCI is interested in learning from the field issues with the study and possible ways to improve its accrual.

Our records show your site has opened this trial. Please reply to all questions from the perspective of **your** site.

1. Please indicate which best describes your site:

- My practice is located within an academic medical center
- My practice is located within an NCI designated cancer center
- My practice is located within a community hospital
- I/We are a free-standing private practice
- Other:

2. What type of oncology best describes your expertise?

Medical oncology
Surgical oncology
Radiation oncology
Gynecologic oncology
Pediatric oncology
Other _____

3. How long has [INSERT TRIAL NAME] been open at your site?

- one month
- 3 months
- 6 months
- one year
- more than one year

4. How difficult was the [INSERT TRIAL NAME] trial to open at your site?

Not at all difficult Very difficult

If it was difficult, please elaborate on how:
[TEXT BOX]

5. What were the top reasons for opening the [INSERT TRIAL NAME] trial at your site? (Select up to 3.)

- ☐ Scientifically interesting research question(s)
- ☐ Fills unmet need for our current patient population
- ☐ High level of interest by oncologist(s) in the practice
- ☐ Few competing trials for this cancer
- ☐ Limited burden on patient (e.g., logistics, cost)
- ☐ Ease of doing the study (i.e., limited burden on staff)
- ☐ Limited non-reimbursable expenses
- ☐ Ease in accruing to the trial
- ☐ Other:

6. How often do you see patients who may be eligible for the [INSERT TRIAL NAME] trial?

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ Every few months
- ☐ A couple times a year or less

7. To date, how many patients have you accrued to the [INSERT TRIAL NAME] trial at your site?

☐ (Number of patients - integers only)

8. Assuming the [INSERT TRIAL NAME] trial is completed as planned, how strongly do you believe the findings will impact your treatment of [INSERT TYPE OF CANCER] cancer patients?

Limited impact High impact

○ ○ ○ ○ ○

Why or why not?

[TEXT BOX]

9. How much do you agree or disagree with the following statement?

The [INSERT TRIAL NAME] trial is less interesting to me now than when it opened.

Strongly disagree Strongly agree

○ ○ ○ ○ ○

10. How many similar trials are open at your site that compete for the same patient population as the [INSERT TRIAL NAME] trial?

Sponsor	Number	Check which sponsor group most competes for the patient population
NCI sponsored trial (including cooperative group trials)	_____# competing trials from this group	
Pharmaceutical/biotech sponsored trials	_____# competing trials from this group	
Investigator initiated trials from academic medical center	_____# competing trials from this group	
other	_____# competing trials from this group	

11. What do you believe are the top reasons for the low accrual to the [INSERT TRIAL NAME] trial? (Select up to 3.)

- ☐ Inclusion/exclusion criteria of the study are too stringent
- ☐ Competing trials are better suited for our practice/patients
- ☐ Patients are not referred by others at my site to the trial
- ☐ State of science has changed making the trial less interesting
- ☐ It is too burdensome on the patient (e.g., logistics, time)
- ☐ It is difficult to explain to a patient (e.g., complicated trial, multiple correlatives)
- ☐ It is too costly for the patient (e.g., insurance, reimbursement)
- ☐ It is too costly to my site (e.g., low trial reimbursement, too many non-reimbursable expenses)
- ☐ It requires too much staff time
- ☐ Amendments to the trial make accruing difficult
- ☐ Other (please specify:)

12. [IF APPLICABLE] Which specialty at your institution initially sees most of the patients potentially eligible for the [INSERT TRIAL NAME] trial?

a. [insert group 1]
b. [insert group 2]
c. [insert group 3]

13. [IF APPLICABLE] The [INSERT TRIAL NAME] trial requires the cooperation of [#] communities of practice ([insert group names]). To what degree does this need for cooperation impact accrual to the trial?

- ○ It negatively impacts accrual a lot
- ○ It somewhat negatively impacts accrual
- ○ It makes no difference
- ○ It somewhat positively impacts accrual
- ○ It positively impacts accrual a lot

13a. At your site, how supportive are each of the following groups to referring patients to the [INSERT TRIAL NAME] trial?

[insert group 1]

a. Minimally supportive

b. Somewhat supportive

c. Highly supportive

[insert group 2]

a. Minimally supportive

b. Somewhat supportive

c. Highly supportive

[insert group 3…]

a. Minimally supportive

b. Somewhat supportive

c. Highly supportive

14. [IF APPLICABLE] To what degree has accrual to the [INSERT TRIAL NAME] trial been delayed by drug sourcing or availability issues?

- We do not have trouble obtaining the trial drug
- We used to have trouble obtaining the trial drug but now receive it when needed
- We continue to have trouble obtaining the trial drug

15. How often are patients ineligible for the [INSERT TRIAL NAME] trial because they have already been treated by the time they are screened for this trial (and are, therefore, ineligible)?

- All the time
- Sometimes
- Rarely/never

16. Have you presented the [INSERT TRIAL NAME] trial to a patient who then declined to enroll?

- Yes
- No

16a. If yes, what are the most common reasons patients decline to enroll in the [INSERT TRIAL NAME] trial? (Please be as specific as possible.)

[TEXT BOX]

17. If you had the option, what key change(s) would you make to improve this trial with respect to accrual? Please be as specific as possible.

[TEXT BOX]

THANK YOU!

We appreciate your feedback regarding the accrual challenges for the [INSERT TRIAL NAME] trial.

Your answers have been submitted anonymously.

If you would like a summary of the findings after the survey closes, please send an email to survey@user-centereddesign.com.

You may now close this window.

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Attachment 15B: WORD VERSION OF ONLINE FEEDBACK SURVEY TEMPLATE

STAFF SURVEY

INTRO:

The National Cancer Institute (NCI) has developed a **brief online survey** tool to quickly and easily solicit comments from oncologists and research staff about specific NCI clinical trials that have low accrual rates.

We would like your opinions about [INSERT FULL TRIAL NAME].

Your comments will help NCI and [insert cooperative group name] decide how to move forward with the [INSERT TRIAL NAME] trial and if accrual can be improved. We thank you for your assistance!

If you consent to participate and would like to continue and begin the survey, click the "Next" button below.

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This brief survey should only require approximately 5 minutes of your time.
Please click the “Next” button if you consent to taking this survey.

We would like your feedback on [INSERT FULL TRIAL NAME].

This trial was opened by [insert group] in [insert month/year]. To date, only [#] patients have been accrued to the trial and therefore the trial is at risk of not meeting the NCI CTEP Quarter 5 accrual guidelines. If accrual continues at its current rate, this trial will be considered for termination. As such, NCI is interested in learning from the field issues with the study and possible ways to improve its accrual.

Our records show your site has opened this trial. Please reply to all questions from the perspective of **your** site.

1. Please indicate which best describes your site:

- ○ Our practice is located within an academic medical center
- ○ Our practice is located within an NCI designated cancer center
- ○ Our practice is located within a community hospital
- ○ We are a free-standing private practice
- ○ Other:

[ ]

2. When did you open the [INSERT TRIAL NAME] trial at your site?

Month Day Year

[-------] [--] [----]

3. How difficult was the [INSERT TRIAL NAME] trial to open at your site?

Not at all difficult Very difficult

○ ○ ○ ○ ○

If it was difficult, please elaborate on how:
[TEXT BOX]

4. To date, how many patients have you accrued at your site to the [INSERT TRIAL NAME] trial?

[ ] (Number of patients - integers only)

5. How often do new patients with [INSERT TYPE OF CANCER] cancer come to your site?

NUMBER DAY/WEEK/MONTH/YEAR

[--] per [---]

6. In the past 30 days, how many patients have you screened for the [INSERT TRIAL NAME] trial who were not eligible (i.e., screen failures)?

-- screen failures in the past 30 days

☐ I don't know

7. How easy or difficult is it to consent patients to this trial who might be eligible?

Very easy Very difficult

○ ○ ○ ○ ○

8. What are the most common reasons patients decline to participate in the [INSERT TRIAL NAME] trial? (Please be as specific as possible.)

9. How easy or difficult is it to conduct the [INSERT TRIAL NAME] trial at your site?

Very easy Very difficult

○ ○ ○ ○ ○

10. What are the primary challenges in conducting the [INSERT TRIAL NAME] trial at your site? Please be as specific as possible.

11. What do you believe are the top reasons for the low accrual to the [INSERT TRIAL NAME] trial? (Select up to 3.)

☐ Inclusion/exclusion criteria of the study are too stringent
☐ Competing trials are better suited for our practice/patients
☐ Patients are not referred by others at my site to the trial
☐ State of science has changed making the trial less interesting
☐ It is too burdensome on the patient (e.g., logistics, time)
☐ It is difficult to explain to a patient (e.g., complicated trial, multiple correlatives)
☐ It is too costly for the patient (e.g., insurance, reimbursement)
☐ It is too costly to my site (e.g., low trial reimbursement, too many non-reimbursable expenses)

- ☐ It requires too much staff time
- ☐ Amendments to the trial make accruing difficult
- ☐ Other (please specify:)

12. If you had the option, what key change(s) would you make to improve this trial with respect to accrual? Please be as specific as possible.

THANK YOU!
We appreciate your feedback regarding the accrual challenges for the [INSERT TRIAL NAME] trial.

Your answers have been submitted anonymously.

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