

CP-CTNet QKREFGD12 Completing the CP-CTNet Pre-Screening Form

General Form Overview

General, Recruitment Strategies, and Demography Questions

This section provides an overview of the *General, Recruitment Strategies, and Demography* questions on the *CP-CTNet Pre-Screening Form*. Users must complete the *Date of Pre-Screen* and *Protocol Staff Recruitment/Specify* fields. Users must also complete all recruitment strategies that apply. At least one recruitment strategy must be completed for each participant. Any demography data that is available at pre-screening should be completed. **Note:** Click the question mark icon within Rave to access field help text, which provides instructions and/or definitions regarding the field information/selection.

Field Label	Form Field	Instructions
External Participant ID (PID)	Patient: PS100200 Page: CP-CTNet Pre-Screening Form - Pre-Screening External Participant ID (PID) [10]:	Enter site-specific PID (if assigned at site).
Protocol Staff Recruitment*	Date of Pre-Screen: Protocol Staff Recruitment: [?] Specify [200]:	Select the title and specify the name of site staff who performed the recruitment.
U.S. Postal Service or Email	Recruitment Strategies: Please see the list of strategies below and complete all strategies that apply. Existing Database: [?] Specify [200]: U.S Postal Service or Email:	Select the type of letter/message.
Referral	Telephone Calls: Referral: [?] Specify [200]:	Select the role of the individual who referred the participant and specify as per help text.
Social/Digital Media	Non-Digital Mass Media: Social/Digital Media: [?] Specify [200]:	Select the type of social/digital media used and specify as per help text.
Patient Issues/Concerns	Community Contacts: Patient Issues/Concerns: [?] Other [200]:	Select the type of community contact.
Birth Date	Note: Birth Date, Sex, Race, and Ethnicity should be completed if information is available at Pre-Screening. Birth Date: [?] Sex:	Indicate the strategy used if the above strategies do not apply.
Race	Race: [?] American Indian or Alaska Native: Asian: Black or African American: Native Hawaiian or other Pacific Islander: Not Reported: Unknown: White: Ethnicity:	Select the participant's sex (if available).
		Select the participant's ethnicity (if available).

*Indicates a field that is always required.

General Form Overview (continued)

Pre-Screen Process and Reason(s) Consent NOT Signed Questions

This section provides an overview of the *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions on the CP-CTNet Pre-Screening Form. Users must complete the *Pre-Screen Outcome* field. The remaining fields in this section are completed if they are relevant to the pre-screen outcome (e.g., reason not eligible for contact, contact made with participant, consent status, etc.).

Pre-Screen Outcome* ➤ Select whether the participant is eligible for contact.	Reason NOT Eligible for Contact ➤ Select the reason that the participant is not eligible for contact and specify as per help text.
Successful Contact ➤ Indicate if contact was made and specify as per help text.	First Contact Date ➤ Enter the first date of contact with the participant.
Consent Status ➤ Select if consent is signed, pending, or not signed.	Consent Date ➤ Enter the date that consent was signed.
Eligibility Criteria Not Met ➤ Select the eligibility criteria not met that led to consent not being signed and specify as per help text.	Logistics ➤ Select the logistics that led to consent not being signed and specify as per help text.
Study Related Issues ➤ Select the study related issue that led to consent not being signed.	Participant Attitude and Concern ➤ Select the attitude and concern that led to consent not being signed.
Other ➤ Select any other reason that led to consent not being signed and specify as per help text.	Comments ➤ Enter any additional information.

Pre-Screen Outcome: ...

Reason NOT Eligible for Contact: ? ...

Specify [200]:

Was contact successfully made with the patient? ? ...

Reason Not Contacted [100]:

First Contact Date: ...

Consent Status: ? ...

Consent Date: ...

Reason(s) Consent NOT Signed: Please see the list of reasons below and complete all reasons that apply.

Eligibility Criteria Not Met: ? ...

Specify [200]:

Logistics: ? ...

Specify [200]:

Study Related Issues: ? ...

Participant Attitude and Concern: ? ...

Other: ? ...

Specify [200]:

Comments [200]:

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*Indicates a field that is always required.

CP-CTNet Pre-Screening Form Examples Overview

The *General*, *Recruitment Strategies*, and *Demography* questions are completed based on the information available at pre-screening, independent of the results of the pre-screen process. However, the *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions are dependent on the results of the pre-screen process. The rest of this document details how the *General*, *Recruitment Strategies*, and *Demography* questions are completed across participants, followed by examples that detail how the *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions are completed for different pre-screen outcomes.

- [General, Recruitment Strategies, and Demography Questions](#)
- [Participant Not Eligible for Contact](#)
- [Participant Eligible for Contact, Not Contacted](#)
- [Participant Eligible for Contact, Did Not Sign Consent](#)
- [Participant Eligible for Contact, Signed Consent](#)

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Example 1: General, Recruitment Strategies, and Demography for All Participants

General, Recruitment Strategies, and Demography Questions

This section provides an overview of the *General, Recruitment Strategies, and Demography* questions on the *CP-CTNet Pre-Screening Form* that are completed for a pre-screened participant. The questions that should be completed are identified by blue highlights and callout buttons, while questions that have been completed based on this example are identified by red highlights and callout buttons. **Note:** Click the question mark icon within Rave to access field help text, which provides instructions and/or definitions regarding the field information/selection.

External Participant ID (PID)

- A site-specific PID has been entered since it was assigned at the site.

Patient: **PS100200**
Page: **CP-CTNet Pre-Screening Form - Pre-Screening**

External Participant ID (PID) [10]: 123456

Date of Pre-Screen: 01 Jan 2020

Protocol Staff Recruitment: ? Site Coordinator

Specify [200]: John Doe

Date of Pre-Screen*

- The date the participant was pre-screened has been entered.

Protocol Staff Recruitment*

- The title of the site staff who performed the recruitment has been selected and their name has been entered as per the question's help text.

Recruitment Strategies: Please see the list of strategies below and complete all strategies that apply.

Existing Database: ? Clinic Schedules

Specify [200]:

U.S Postal Service or Email: ...

Telephone Calls: ...

Referral: ? ...

Specify [200]:

Non-Digital Mass Media: ...

Social/Digital Media: ? ...

Specify [200]:

Community Contacts: ...

Patient Issues/Concerns: ...

Other [200]:

Existing Database

- Complete at least one strategy for each participant. The type of database has been selected since this was the recruitment strategy used for this participant. Additional details have not been entered since they are not required as per the question's help text.

Birth Date

- The participant's birth date has been entered since it was available at pre-screening.

Note: Birth Date, Sex, Race, and Ethnicity should be completed if information is available at Pre-Screening.

Birth Date: ? 15 Jun 1990

Sex: Male

Race: ?

American Indian or Alaska Native: ☐

Asian: ☐

Black or African American: ☐

Native Hawaiian or other Pacific Islander: ☐

Not Reported: ☐

Unknown: ☐

White: ☒

Ethnicity: Not Hispanic or Latino

Sex

- The participant's sex has been selected since it was available at pre-screening.

Race

- The participant's race has been selected since it was available at pre-screening.

Ethnicity

- The participant's ethnicity has been selected since it was available at pre-screening.

*Indicates a field that is always required.

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Example 2: Participant Not Eligible for Contact

Pre-Screen Process and Reason(s) Consent NOT Signed Questions

This section provides an overview of the *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions on the *CP-CTNet Pre-Screening Form* that are completed for a pre-screened participant who is not eligible for contact. The questions that should be completed are identified by blue highlights and callout buttons.

Pre-Screen Outcome*

- *Not Eligible for Contact* has been selected.

Pre-Screen Outcome:	Not Eligible for Contact
Reason NOT Eligible for Contact: ?	Prohibited Concomitant Medication
Specify [200]:	On a Statin
Was contact successfully made with the patient? ?	...
Reason Not Contacted [100]:	
First Contact Date:	
Consent Status: ?	...
Consent Date:	
Reason(s) Consent NOT Signed: Please see the list of reasons below and complete all reasons that apply.	
Eligibility Criteria Not Met: ?	...
Specify [200]:	
Logistics: ?	...
Specify [200]:	
Study Related Issues: ?	...
Participant Attitude and Concern: ?	...
Other: ?	...
Specify [200]:	
Comments [200]:	
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Reason NOT Eligible for Contact

- Since the participant was Not Eligible for Contact, the reason not eligible for contact has been selected. Additional details have been entered in the *Specify* field since they are required as per the question's help text.

- *Indicates a field that is always required.

Example 2: Participant Not Eligible for Contact Summary

In summary, the *General*, *Recruitment Strategies*, and *Demography* questions should be completed for all participants based on the information that is available at pre-screening. The following *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions should be completed for participants who are not eligible for contact:

- ☐ Pre-Screen Outcome
- ☐ Reason NOT Eligible for Contact
- ☐ Reason NOT Eligible for Contact: Specify (if associated with the selected reason, see help text)

Example 3: Participant Eligible for Contact, Not Contacted**Pre-Screen Process and Reason(s) Consent NOT Signed Questions**

This section provides an overview of the *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions on the CP-CTNet Pre-Screening Form that are completed for a pre-screened participant who is eligible for contact but was not contacted. The questions that should be completed are identified by blue highlights and callout buttons. **Note:** Since the participant was not contacted, the *Reason(s) Consent NOT Signed* section should not be completed.

Pre-Screen Outcome*

Pre-Screen Outcome:

Eligible for Contact

Reason NOT Eligible for Contact: ?

Specify [200]:

Was contact successfully made with the patient? ?

No

Reason Not Contacted [100]:

No response after multiple contact attempts

First Contact Date:

Consent Status: ?

Consent Date:

Reason(s) Consent NOT Signed: Please see the list of reasons below and complete all reasons that apply.

Eligibility Criteria Not Met: ?

Specify [200]:

Logistics: ?

Specify [200]:

Study Related Issues: ?

Participant Attitude and Concern: ?

Other: ?

Specify [200]:

Comments [200]:

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Successful Contact

No has been selected to indicate that contact was not made. Additional details have been entered in the *Reason Not Contacted* field since they are required as per the question's help text.

*Indicates a field that is always required.

Example 3: Participant Eligible for Contact, Not Contacted Summary

In summary, the *General*, *Recruitment Strategies*, and *Demography* questions should be completed for all participants based on the information that is available at pre-screening. The following *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions should be completed for participants who are eligible for contact but were not contacted:

- ☐ Pre-Screen Outcome
- ☐ Was contact successfully made with the patient?
- ☐ Reason Not Contacted

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Example 4: Participant Eligible for Contact, Did Not Sign Consent

Pre-Screen Process and Reason(s) Consent NOT Signed Questions

This section provides an overview of the *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions on the CP-CTNet Pre-Screening Form that are completed for a pre-screened participant who is eligible for contact and is contacted, but did not sign consent. The questions that should be completed are identified by blue highlights and callout buttons, while the question that has been completed based on this example is identified by a red highlight and callout button.

Pre-Screen Outcome*

➤ *Eligible for Contact* has been selected.

Successful Contact

➤ Yes has been selected to indicate that contact was made.

Consent Status

➤ *Not Signed* has been selected.

Pre-Screen Outcome:	Eligible for Contact
Reason NOT Eligible for Contact: [?]	...
Specify [200]:	
Was contact successfully made with the patient? [?]	Yes
Reason Not Contacted [100]:	
First Contact Date:	16 Mar 2021
Consent Status: [?]	Not Signed
Consent Date:	
Reason(s) Consent NOT Signed: Please see the list of reasons below and complete all reasons that apply.	
Eligibility Criteria Not Met: [?]	...
Specify [200]:	
Logistics: [?]	...
Specify [200]:	
Study Related Issues: [?]	Too Many Visits or Length of Appointments
Participant Attitude and Concern: [?]	...
Other: [?]	...
Specify [200]:	
Comments [200]:	

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First Contact Date

➤ The first date that contact was made with the participant has been entered.

Study Related Issues

➤ Complete at least one reason for each participant who did not sign consent. The study related issue that led to consent not being signed for this participant has been selected.

➤ *Indicates a field that is always required.

Example 4: Participant Eligible for Contact, Did Not Sign Consent Summary

In summary, the *General*, *Recruitment Strategies*, and *Demography* questions should be completed for all participants based on the information that is available at pre-screening. The following *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions should be completed for participants who are eligible for contact and are contacted, but did not sign consent:

- ☐ Pre-Screen Outcome
- ☐ Was contact successfully made with the patient?
- ☐ First Contact Date
- ☐ Consent Status
- ☐ At least one Reason Consent NOT Signed: e.g., Study Related Issues
- ☐ Reason Consent NOT Signed: Specify (if associated with the selected reason, see help text)

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Example 5: Participant Eligible for Contact, Signed Consent

Pre-Screen Process and Reason(s) Consent NOT Signed Questions

This section provides an overview of the *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions on the CP-CTNet Pre-Screening Form that are completed for a participant who is eligible for contact, is contacted, and signed consent. The questions that should be completed are identified by blue highlights and callout buttons.

Pre-Screen Outcome*

➤ *Eligible for Contact* has been selected.

Successful Contact

➤ Yes has been selected to indicate that contact was made.

Consent Status

➤ *Signed* has been selected.

Pre-Screen Outcome:	Eligible for Contact
Reason NOT Eligible for Contact: ?	...
Specify [200]:	
Was contact successfully made with the patient? ?	Yes
Reason Not Contacted [100]:	
First Contact Date:	22 Oct 2022
Consent Status: ?	Signed
Consent Date:	22 Oct 2022
Reason(s) Consent NOT Signed: Please see the list of reasons below and complete all reasons that apply.	
Eligibility Criteria Not Met: ?	...
Specify [200]:	
Logistics: ?	...
Specify [200]:	
Study Related Issues: ?	...
Participant Attitude and Concern: ?	...
Other: ?	...
Specify [200]:	
Comments [200]:	

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First Contact Date

➤ The first date that contact was made with the participant has been entered.

Consent Date

➤ The date that consent was signed has been entered.

➤ *Indicates a field that is always required.

Example 5: Participant Eligible for Contact, Signed Consent Summary

In summary, the *General*, *Recruitment Strategies*, and *Demography* questions should be completed for all participants based on the information that is available at pre-screening. The following *Pre-Screen Process* and *Reason(s) Consent NOT Signed* questions should be completed for participants who are eligible for contact, are contacted, and signed consent:

- ☐ Pre-Screen Outcome
- ☐ Was contact successfully made with the patient?
- ☐ First Contact Date
- ☐ Consent Status
- ☐ Consent Date