

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.

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

*Indicates a field that is always required.

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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.).

<p>Pre-Screen Outcome*</p> <p>➤ Select whether the participant is eligible for contact.</p>	<p>Pre-Screen Outcome: <input type="text"/></p>	<p>Reason NOT Eligible for Contact</p> <p>➤ Select the reason that the participant is not eligible for contact and specify as per help text.</p>
<p>Successful Contact</p> <p>➤ Indicate if contact was made and specify as per help text.</p>	<p>Reason NOT Eligible for Contact: <input type="text"/></p> <p>Specify [200]: <input type="text"/></p>	<p>First Contact Date</p> <p>➤ Enter the first date of contact with the participant.</p>
<p>Consent Status</p> <p>➤ Select if consent is signed, pending, or not signed.</p>	<p>Was contact successfully made with the patient?: <input type="text"/></p> <p>Reason Not Contacted [100]: <input type="text"/></p>	<p>Consent Date</p> <p>➤ Enter the date that consent was signed.</p>
<p>Eligibility Criteria Not Met</p> <p>➤ Select the eligibility criteria not met that led to consent not being signed and specify as per help text.</p>	<p>First Contact Date: <input type="text"/></p> <p>Consent Status: <input type="text"/></p> <p>Consent Date: <input type="text"/></p>	<p>Logistics</p> <p>➤ Select the logistics that led to consent not being signed and specify as per help text.</p>
<p>Study Related Issues</p> <p>➤ Select the study related issue that led to consent not being signed.</p>	<p>Reason(s) Consent NOT Signed: Please see the list of reasons below and complete all reasons that apply.</p> <p>Eligibility Criteria Not Met: <input type="text"/></p> <p>Specify [200]: <input type="text"/></p>	<p>Participant Attitude and Concern</p> <p>➤ Select the attitude and concern that led to consent not being signed.</p>
<p>Other</p> <p>➤ Select any other reason that led to consent not being signed and specify as per help text.</p>	<p>Logistics: <input type="text"/></p> <p>Specify [200]: <input type="text"/></p>	<p>Comments</p> <p>➤ Enter any additional information.</p>
<p>Study Related Issues: <input type="text"/></p> <p>Participant Attitude and Concern: <input type="text"/></p> <p>Other: <input type="text"/></p> <p>Specify [200]: <input type="text"/></p> <p>Comments [200]: <input type="text"/></p>	<p>Printable Version View PDF Icon Key <input type="button" value="Save"/> <input type="button" value="Cancel"/></p>	

*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.

Subject: 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

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]:

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

Birth Date: 15 Jun 1990

Gender: 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

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.

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.

Existing Database

Birth Date

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

Gender

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

Gender

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.

Ethnicity

*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]:		  
Printable Version View PDF Icon Key		<input type="button" value="Save"/> <input type="button" value="Cancel"/>

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)

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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*

➤ *Eligible for Contact* has been selected.

Pre-Screen Outcome:	Eligible for Contact	ⓘ
Reason NOT Eligible for Contact: [?]	...	ⓘ
Specify [200]:	<input type="text"/>	ⓘ
Was contact successfully made with the patient? [?]	No	ⓘ
Reason Not Contacted [100]:	No response after multiple contact attempts	ⓘ
First Contact Date:	<input type="text"/> ... <input type="text"/>	ⓘ
Consent Status: [?]	...	ⓘ
Consent Date:	<input type="text"/> ... <input type="text"/>	ⓘ
Reason(s) Consent NOT Signed: Please see the list of reasons below and complete all reasons that apply.		
Eligibility Criteria Not Met: [?]	...	ⓘ
Specify [200]:	<input type="text"/>	ⓘ
Logistics: [?]	...	ⓘ
Specify [200]:	<input type="text"/>	ⓘ
Study Related Issues: [?]	...	ⓘ
Participant Attitude and Concern: [?]	...	ⓘ
Other: [?]	...	ⓘ
Specify [200]:	<input type="text"/>	ⓘ
Comments [200]:	<input type="text"/>	ⓘ

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Save Cancel

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*	Pre-Screen Outcome: Eligible for Contact	First Contact Date	First Contact Date: 16 Mar 2021
Eligible for Contact	Reason NOT Eligible for Contact: [?]	Consent Status	Consent Status: Not Signed
➤ Eligible for Contact has been selected.	Specify [200]:	Study Related Issues	Study Related Issues: Too Many Visits or Length of Appointments
Successful Contact	Was contact successfully made with the patient? [?]	Participant Attitude and Concern	Participant Attitude and Concern: [?]
➤ Yes has been selected to indicate that contact was made.	Reason Not Contacted [100]:	Other	Other: [?]
Consent Status	First Contact Date: 16 Mar 2021	Comments	Comments [200]:
➤ Not Signed has been selected.	Consent Status: Not Signed		
	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.

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.

<p>Pre-Screen Outcome*</p> <p>➤ <i>Eligible for Contact</i> has been selected.</p>	<p>Pre-Screen Outcome: Eligible for Contact <input type="radio"/> <input type="radio"/> <input type="radio"/></p> <p>Reason NOT Eligible for Contact: <input type="text"/> <input type="radio"/> <input type="radio"/> <input type="radio"/></p> <p>Specify [200]: <input type="text"/></p>	
<p>Successful Contact</p> <p>➤ Yes has been selected to indicate that contact was made.</p>	<p>Was contact successfully made with the patient? <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/></p> <p>Reason Not Contacted [100]: <input type="text"/></p> <p>First Contact Date: <input type="text"/> 22 <input type="text"/> Oct <input type="text"/> 2022 <input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>First Contact Date</p> <p>➤ The first date that contact was made with the participant has been entered.</p>
<p>Consent Status</p> <p>➤ <i>Signed</i> has been selected.</p>	<p>Consent Status: Signed <input type="radio"/> <input type="radio"/> <input type="radio"/></p> <p>Consent Date: <input type="text"/> 22 <input type="text"/> Oct <input type="text"/> 2022 <input type="radio"/> <input type="radio"/> <input type="radio"/></p> <p>Reason(s) Consent NOT Signed: Please see the list of reasons below and complete all reasons that apply.</p> <p>Eligibility Criteria Not Met: <input type="text"/> <input type="radio"/> <input type="radio"/> <input type="radio"/></p> <p>Specify [200]: <input type="text"/></p> <p>Logistics: <input type="text"/> <input type="radio"/> <input type="radio"/> <input type="radio"/></p> <p>Specify [200]: <input type="text"/></p> <p>Study Related Issues: <input type="text"/> <input type="radio"/> <input type="radio"/> <input type="radio"/></p> <p>Participant Attitude and Concern: <input type="text"/> <input type="radio"/> <input type="radio"/> <input type="radio"/></p> <p>Other: <input type="text"/> <input type="radio"/> <input type="radio"/> <input type="radio"/></p> <p>Specify [200]: <input type="text"/></p> <p>Comments [200]: <input type="text"/></p> <p>Printable Version View PDF Icon Key <input type="button" value="Save"/> <input type="button" value="Cancel"/></p>	<p>Consent Date</p> <p>➤ The date that consent was signed has been entered.</p>

➤ *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