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The Continuing Review Report for Protocols

Client guidance

This document provides guidance on completing certain sections of the **Continuing Review Report for Protocols**. Please don't hesitate to contact Quorum Review if you have questions about completing the report.

All questions

- Please complete **every question** — or if you are unable to answer a question, please provide an attachment explaining why.
- In addition, please provide attachments as needed to clarify responses to questions.

Question 2 Enrollment numbers

In general, when **added together**, your answers for **Question 2.C, 2.D,** and **2.E** should **equal** your answer for **Question 2.B**.

- If the numbers do not add up, please explain why in an attachment to your report.
- Note that for studies conducted under a waiver of consent, you should provide the number of charts reviewed for the study, specimens obtained or analyzed, and so forth.

Question 2.B

Please do not include SCREEN FAILURES in Question 2.B.

- A screen failure is someone who does not get enrolled into the study for various reasons, documented during the screening process.
- Screen failures signed the consent form and may have had screening procedures but did not undergo any other study procedure.
- Reasons for the participant to fail screening may include, but are not limited to, the participant not meeting inclusion criteria or meeting exclusion criteria (ineligibility).

Questions 2.C.I and 2.C.II

Please only include PARTICIPANTS WHO WITHDREW in Questions 2.C.I and 2.C.II.

- A "participant who withdrew" is a participant who either 1.) stopped the study before completing the full schedule of study visits (including follow-up) or 2.) transferred sites.
- Some protocols may have a variable number of visits and consider participants as completing, rather than withdrawing, in the case of disease progression or similar clinical outcome. In such cases, the protocol definition should be followed, with the withdrawal category reserved for participants who withdrew for other reasons.
- If the study design is such that these categories do not naturally apply, please provide an explanation in an attachment.

Questions 2.C.I and 2.C.II do not include participants who withdrew from the intervention but are still in follow-up per protocol. Those participants are addressed in **Question 2.E.**

Please continue reading for more guidance on **Questions 2.C.I and 2.C.II.**

Questions 2.C.I and 2.C.II (continued)

Question 2.C.I

Your answer to **Question 2.C.I** should be the total number of participants who withdrew because of an adverse event or unanticipated problem.

Question 2.C.II

Your answer to **Question 2.C.II** should include the total number of participants who withdrew for any reason other than an adverse event or unanticipated problem. Your answer should include participants who withdrew for reasons such as:

- Withdrawing consent.
- Becoming lost to follow-up.
- Transferring sites
- Being terminated by the sponsor or investigator.
- Other reasons listed in the protocol for withdrawal.

Please note that participants that who are still being followed should be included in your answer to **Question 2.E**.

Question 2.D

This answer should include participants who completed the study as defined by the protocol.

Question 2.E

Please only include PARTICIPANTS WHO ARE STILL IN THE STUDY for Question 2.E.

Participants who are still in the study include:

- Participants who still come to the site for study visits or still receive study product.
- Participants in follow-up (with or without study visits) even if a participant has no other involvement with the study.
- Any other participant who is still in the study.

Questions 4, 5, 7, 9, 10, 11, 12, and 13

Only answer "yes" if the information has not already been reported to Quorum. If you answer "yes," please attach relevant documents or information.

Question 6

- If the safety monitoring group has not met, provide details on when the group is expected to meet.
- If the group has met, only submit reports that have not already been reported.

  If needed, contact Quorum for the number and dates of reports that have been previously submitted for your study.
- If the group has met but did not provide a written report, provide an attachment detailing the findings of the meeting.

Please note that the term "safety monitoring group", as used in the Continuing Review Report, includes **any monitoring board**, such as

- Data safety monitoring board (DSMB)
- Data monitoring committee (DMC)

Question 14

- **Only list the current version** of all product information previously submitted or currently in use. Make sure to include product information for any of the following that is used in the study:
  - The study product.
  - In-combination drugs or other products used in conjunction with the study product.
  - Comparator products.
- **Attach copies of any product information that has not been previously submitted.** If needed, contact Quorum for a list of product information that has been previously submitted for your study.

Signature

- Remember to **sign and date** the form. A signature is not required if you are submitting through the OnQ Portal, but a signature is required if you are submitting via any other format (i.e. email, fax, hard copy mail).
- Please also include your **printed name and title**.

Thank you for using Quorum Review when performance matters.

If you have questions at any time while completing your Continuing Review Report, please call Quorum at 206-448-4082 (or 877-472-9883).