

CHAPTER 9. Quality Control and Site Monitoring

9.1 Quality Control Committee

The Quality Control (QC) Committee will oversee the monitoring of clinical sites as far as completeness and accuracy of the data being collected. Site visits can enhance the collaborative relationship between clinical centers (CC) and DCC personnel and provide an opportunity to discuss outstanding questions regarding individual patients or study procedures. Site visits will include sample data audits, reviews of data and lab QC, inspection of facilities, and discussions of recruitment, retention, and adherence as required. Additional “virtual site visit” conference calls can be held and have been a cost-effective approach in our recent studies for reviewing participant recruitment and data completeness/quality.

9.2 Data Edit Checks

Throughout the course of the study, each clinical center's performance will be monitored by a series of data quality reports. These include reports of enrollment, number of missing forms, rates of invalid data and data quality. These reports will routinely be sent to the clinical centers, the Steering Committee, and the NHLBI Program Office.

Edit checks are applied upon data entry and discrepant data will not be accepted into the study database. If data already in the study database appear to be discrepant, a data discrepancy inquiry will be sent to the clinical center. The DCC will track when the inquiry was sent, what item was questioned, who responded to the inquiry, what was the response, whether the database was changed, and if so, when.

9.3 Site Visits

Site visits are to be made to each of the clinical centers during the first two years of recruitment. The primary goals of the site visits are: 1) to observe the clinic under normal operating conditions for adherence to protocol; 2) to provide an opportunity for face-to-face questions and answers on any outstanding problems a clinical center is having with individual patients or with study procedures in general; 3) to increase/improve communication between the study administration, the clinic personnel and the DCC; and 4) to demonstrate the study's concern for the quality of data collection. Site visit teams consist of a site visit chair from the Quality Control Committee, a DCC staff member familiar with the PVDOMICS protocol and procedures (usually a coordinator), a NIH representative, and a study coordinator from another clinical center. Pre-site visit reports will be compiled by the DCC. All site visit teams will compile a post-site visit report which is given to the clinical center PI and to the NIH. These reports are reviewed by the Quality Control Committee.

At the site visits, the DCC will monitor the clinical center's performance in following the protocol by observing PVDOMICS Study procedures. Study patient files will be inspected, and a sample of PVDOMICS Study data forms will be checked against original source documents in the patients' medical records.

9.4 Remote Site Visits

In addition to on-site site visits, remote or virtual site visits will be made to clinical centers. These are done as conference calls between the site visit team and the clinical center. These are done usually on a as needed basis so can occur at any time during the course of the study. The primary goals of these type of visits are to check on the progress and operation of the center and address any specific concerns. A possible agenda is given in Appendix 1.

Appendix 1

Study Site Visit Call Example

Draft agenda for the call, which will be held from
1 to 3 p.m. Eastern Time on XXX
Toll free number: xxxxx Conference code: xxxxxx

Welcome and introductions

Note all members of STUDY SITE staff
Purpose of this call

Summaries from the weekly reports

Ready to enroll: Feb 15, 20xx. First enrollment: March 15, 20xx
Current goal for participants enrolled: XX (based on total enrollment goal of YY)
Percent of goal for randomized patients: ZZ%

Review of individual participants who have enrolled

990001

990002

990003

Promoting recruitment

How is the clinical center publicizing the study to referring physicians?
How is the clinical center publicizing the study to participants?
How will this clinical center team promote recruitment?

Considering which participants to enroll

How does the consent process work?
How does/will the “team meeting” work?

Promoting adherence to the protocol

How are participants scheduled and flow through upcoming visits and procedures?

How does the clinical center staff make sure no forms or procedures are missed?

How will this clinical center team promote adherence?

Issues with central cores

Would the clinical center like to raise any issues/points about the central cores?

Issues with DCC and Study Cores

Would the clinical center like to raise any issues/points where the DCC could be more helpful?

Quality control and review of data from the weekly QC report**Logistics**

How often does this clinical center team meet as a group?

What other methods of communication are used?

When the PI is not available, who serves as the back up PI?

When the study coordinator is not available, who serves as the backup study coordinator?

Are there enough computers available for data entry, and is the internet connection good?

Any issue with contracts or budgets?

Have payments been received as expected?

Institutional support

Member of the institution states that this institution supports the study

Final comments from the clinical center**Closed session for the site visit team**