Breast Cancer Data Endpoints Documentation

Four clinical sites individually collect SOF breast cancer data. Participants are asked about breast cancer history annually.   In addition, participants are asked to complete tri-annual questionnaires in regards to the occurrence of breast cancer during the previous four-month interval. When questionnaires are not returned, participants are then contacted by phone. When participants died, death certificates and hospital discharge summaries are searched for the diagnosis of breast cancer.

Adjudication process begins with the clinic Principal Investigator's diagnosis based on the pathology reports and medical records pertinent to the case. After local adjudication completed, reports and records are sent to the Coordinating Center for review. Clinic Principal Investigators can flag the case for central adjudication if they are uncertain about the diagnosis on several areas regarding tumor. In addition, the Coordinating Center periodically randomly selects 10% of the local adjudication cases and sends them to an expert pathologist for a final adjudication.

Breast cancer features collected during adjudication include:

1. Tumor behavior (V#TUMBEH)
2. Diagnostic confirmed status either microscopically or non-microscopically (V#COMICR)
3. Staging of tumor (V#TSTAGE)
4. Estrogen receptor assay status (V#ERSTAT)
5. Progesterone receptor assay status (V#PRSTAT)

Once the breast cancer data are entered and coded, a number of variables are calculated. For example, indicators of occurrence of a breast cancer (V#BRSTCA) and corresponding follow-up time (V#BCFU, time to cancer diagnosis, for survival model) are calculated and can be used for analysis.