CASE Follow-up Telephone Interview

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CA. DIAGNOSIS AND TREATMENT OF BREAST CANCER

CA1. [VERIFY DATE OF DIAGNOSIS, IF PROVIDED.]
You have indicated that a doctor first
told you that you had breast cancer on
[fill date]. Is this correct?

YES.............. [CA2A]...............1
NO 2
DK.....................................8

<ASK CA1a IF NO DATE PROVIDED OR IF CA1=NO, DK>
<CHECK ANSWER TO CA1a AGAINST DOB>
CA1a. What is the date a doctor first told you that
you definitely had breast cancer?
[ENTER THE DIAGNOSIS MONTH AS MM]
[ENTER THE DIAGNOSIS YEAR AS YYYY]

|__|__| |__|__|__|__|
MONTH   YEAR
<IF YEAR PROVIDED, GO TO CA2A>

<ASK CA2 ONLY IF CA1 = NO OR DK AND CA1a YEAR = DK>
<CHECK ANSWER TO CA2 AGAINST DOB>
CA2.   How old were you at the time of this diagnosis?

|__|__|__|
AGE

CA2A. Sometimes there is a delay between when a woman
first notices a lump, or a mammogram shows an
abnormality, and the final diagnosis of breast cancer.
How much time went by between when you first
realized there was a problem and when you were told
the diagnosis was breast cancer?
[ENTER NUMBER OF MONTHS]
[IF LESS THAN ONE MONTH, ENTER '0']

< 1 MONTH – DIAGNOSED VERY CLOSE TO
   INITIAL IDENTIFICATION 00

|__|__| MONTHS

CA2B. It sometimes takes several doctor appointments to make sure of the breast cancer diagnosis
and to run laboratory tests to identify its characteristics. When we refer to the 'time of
diagnosis,' we mean this period of time during which your cancer was confirmed and
characterized, not just the day you got the diagnosis.

When you were diagnosed with breast cancer, did you
have any form of general health care coverage,
including health insurance, pre-paid plans such as
HMOs, or government plans such as Medicare or
Medicaid?

YES.....................................1
NO 2
REF 7
DK.....................................8

CA2C. Sometimes it takes several tests and procedures after
the diagnosis to find out how many tumors there are.
After that medical work was completed, how many
tumors had they found?
[IF R SAYS DK, PROBE: How many tumors do you know
about?]

|__| BREAST TUMORS

<IF DK OR REF, COUNT AS 1
TUMOR FOR CA11-CA18, CA54
AND CS54>

CA3. At the time of your breast cancer diagnosis, had the
cancer spread to your lymph nodes?

YES.....................................1
NO 2

REF 7   DK..................................... 8

CA4.   How many lymph nodes were tested?

0 ....[CA6]
|__|__| LYMPH NODES ....[CA5]
REF .... [CA4a]
DK.............................. [CA4a]

<ASK CA4a ONLY IF CA4 IS REF OR DK:>
CA4a. **Approximately** how many lymph nodes were
       tested? Was it...?

0 nodes.......[CA6]...................1
1-3 nodes 2
4-9 nodes 3
10-14 nodes 4
15-19 nodes 5
Or 20 or more nodes 6
REF 7
DK.....................................8

<ASK CA5 ONLY IF CA4 IS NOT 0 OR IF CA4a IS NOT 0:>
   CA5.   How many lymph nodes were positive?

0 ....[CA6]
|__|__| LYMPH NODES ....[CA6]
REF .... [CA5a]
DK.............................. [CA5a]

<ASK CA5a ONLY IF CA5 IS REF OR DK>
   CA5a. **Approximately** how many lymph nodes
         were positive? Was it...?

0 nodes...............................1
1-3 nodes 2
4-9 nodes 3
10-14 nodes 4
15-19 nodes 5
Or 20 or more nodes 6
REF 7
DK.....................................8

<BEGIN REPEATING RECORD>
<FIRST OCCURRENCE>
CA6.   *At the time* of your breast cancer diagnosis, were
     you diagnosed with any other type of cancer or
     was cancer found anywhere else?

YES.....................................1
NO .... [CA8]................2
REF .... [CA8]................7
DK.............. [CA8]................8

<ALL OTHER OCCURRENCES>
CA7Oth. Any other (types of cancer that you where
         diagnosed with or where else cancer found
         <u>at the time</u> of your breast cancer diagnosis)?

<ASK CA7 IF CA6 = YES:>

CA7. What other type or types of cancer were you diagnosed with or where else was cancer found *at the time* of your breast cancer diagnosis?
[CHECK ALL THAT APPLY]
[IF R ANSWERS "SKIN CANCER," PROBE: Was this melanoma or non-melanoma skin cancer?]
[IF R GIVES A CLINICAL RESPONSE THAT DOES NOT MATCH A CATEGORY AND IS NOT A PART OF THE BODY, PROBE: "What specific part of the body did this cancer affect?"]

ABDOMINAL 46
BASAL CELL SKIN CANCER 1
BLADDER 2
BLOOD................................ 3
BONE 23
BOWEL 4
BRAIN................................. 5
BREAST 6
CERVIX, CERVICAL 7
COLON, COLORECTAL 8
DUCTAL CARCINOMA IN SITU 47
ENDOMETRIAL 9
ESOPHAGEAL / ESOPHAGUS 29
HODGKIN'S DISEASE 10
INTESTINE, INTESTINAL 11
KAPOSI'S SARCOMA 30
KIDNEY AND RENAL PELVIS 31
LARYNX............................. 32
LEUKEMIA 12
LIVER 27
LOBULAR CARCINOMA
IN SITU (LCIS) 39
LUNG 13
LYMPH NODES 14
LYMPHOMA 15
MELANOMA SKIN CANCER 16
MULTIPLE MYELOMA............... 33
NON-HODGKIN'S LYMPHOMA 18
ORAL CAVITY AND PHARYNX 34
OVARY, OVARIAN 19
PANCREAS......................... 35
RECTUM, RECTAL 20
SKIN CANCER – OTHER 17
SQUAMOUS CELL SKIN CANCER.... 21
STOMACH 37
THYROID 36
UTERUS, UTERINE 22
OTHER.............................. 99
SPECIFY: _____

<FOR EACH TYPE OF CANCER>

CA7a. Was the [CANCER TYPE FROM CA7] cancer a primary tumor or was it a tumor that had metastasized or spread from your breast cancer or some other cancer

PRIMARY 1
METASTASIS—BREAST................ 2
METASTASIS—OTHER 3
METASTASIS—DK SOURCE 4
REF 7
DK.................................... 8

<BEGIN REPEATING RECORD>
<FIRST OCCURRENCE>
CA8.   *Since the time* you were first diagnosed with   YES..1
        breast cancer, have you been diagnosed with any   NO .... [CA11] 2
        other cancers, or has cancer been found anywhere   REF .... [CA11] 7
        else, including another breast cancer?   DK............. [CA11] 8

<ALL OTHER OCCURRENCES>
CA9Oth. Any other (types of cancer that you where
         diagnosed with or where else cancer found
         <u>since the time</u> of your breast cancer diagnosis)?

         <ASK CA9 IF CA8 = YES:>
         CA9.   What type or types of cancer were you   ABDOMINAL 46
                 diagnosed with or where else was cancer   BASAL CELL SKIN CANCER 1
                 found *after* your original breast cancer   BLADDER 2
                 diagnosis? [BLOOD.................................3
                 [CHECK ALL THAT APPLY]   BONE 23
                 [IF R ANSWERS "SKIN CANCER," PROBE: BOWEL 4
                 Was this melanoma or non-melanoma skin   BRAIN.................................5
                 cancer?]   BREAST 6
                 [IF R GIVES A CLINICAL RESPONSE THAT   CERVIX, CERVICAL 7
                 DOES NOT MATCH A CATEGORY AND IS NOT   COLON, COLORECTAL 8
                 A PART OF THE BODY, PROBE: "What   DUCTAL CARCINOMA IN SITU 47
                 specific part of the body did this cancer   ENDOMETRIAL 9
                 affect?"]   ESOPHAGEAL / ESOPHAGUS 29
                                                              HODGKIN'S DISEASE 10
                                                              INTESTINE, INTESTINAL 11
                                                              KAPOSI'S SARCOMA 30
                                                              KIDNEY AND RENAL PELVIS 31
                                                              LARYNX............................. 32
                                                              LEUKEMIA 12
                                                              LIVER 27
                                                              LOBULAR CARCINOMA
                                                              IN SITU (LCIS) 39
                                                              LUNG 13
                                                              LYMPH NODES 14
                                                              LYMPHOMA 15
                                                              MELANOMA SKIN CANCER 16
                                                              MULTIPLE MYELOMA............... 33
                                                              NON-HODGKIN'S LYMPHOMA 18
                                                              ORAL CAVITY AND PHARYNX 34
                                                              OVARY, OVARIAN 19
                                                              PANCREAS.......................... 35
                                                              RECTUM, RECTAL 20
                                                              SKIN CANCER – OTHER 17
                                                              SQUAMOUS CELL SKIN CANCER.... 21
                                                              STOMACH 37
                                                              THYROID 36
                                                              UTERUS, UTERINE 22
                                                              OTHER.............................. 99
                                                              SPECIFY: _____

<FOR EACH TYPE OF CANCER:>

CA9a. Was the [CANCER TYPE FROM CA9] cancer a
primary tumor or was it a tumor that had
metastasized or spread from your breast
cancer or some other cancer?

PRIMARY 1
METASTASIS—BREAST 2
METASTASIS—OTHER 3
METASTASIS—DK SOURCE 4
REF 7
DK 8

<CHECK ANSWER TO CA9b AGAINST DOB>
<ASK CA9b – CA9c IF CA9 ≠ BREAST>

CA9b. What is the date a doctor first told you that you
definitely had **this** [CANCER TYPE FROM CA9]
cancer?
[ENTER THE DIAGNOSIS MONTH AS MM]
[ENTER THE DIAGNOSIS YEAR AS YYYY]

|__|__| |__|__|__|__|
MONTH   YEAR
 <IF YEAR PROVIDED, GO TO CA9a
 .OR CA10 IF NO OTHER CANCERS.>

<ASK CA9c ONLY IF CA9b YEAR = DK>
<CHECK ANSWER TO CA9c AGAINST DOB>

CA9c. How old were you at the time of this diagnosis?

|__|__|__|
AGE

<END REPEATING RECORD>

<IF CA8 = 1, ASK CA10, ELSE GO TO CA11>

CA10. Are you currently undergoing treatment for
[this cancer/these cancers]?

YES 1
NO 2
REF 7
DK 8

CA11. The next questions are about the characteristics of your breast cancer.

<FOR WOMEN REPORTING MULTIPLE BREAST CANCERS DIAGNOSED AT DIFFERENT TIMES (CA9 = BREAST):>
We would like to find out about each of your breast cancer diagnoses. Please answer the following questions referring to your first breast cancer diagnosis in [month, year]. Later in this interview, we will ask similar questions about your [second/other] breast cancer [diagnosis/diagnoses].

<FOR WOMEN REPORTING MULTIPLE BREAST TUMORS DIAGNOSED AT TIME OF FIRST DIAGNOSIS: CA2C > 1 OR CA7 = BREAST>
You indicated that you had [FILL CA2c (+ 1 IF CA7 = BREAST)] breast tumors diagnosed in [month, year]. Please answer these questions separately for each tumor.

ENTER '1' TO CONTINUE 1

<BEGIN REPEATING RECORD IF (CA2C > 1) OR (CA7 = BREAST)>
<FIRST OCCURRENCE>
<FOR EACH TUMOR REPORTED AT INITIAL DIAGNOSIS. IF ONLY ONE BREAST TUMOR REPORTED AT INITIAL DIAGNOSIS, ONLY GO THROUGH SERIES CA12 – CA18A ONCE>

CA12. <IF CA2C > 1 OR CA7 = BREAST: For the first tumor... / second tumor ...>
In which breast was the [first] tumor found?

LEFT BREAST 1
RIGHT BREAST........................2

<ALL OTHER OCCURRENCES>
In which breast was the [second/third...] tumor found?

REF 7
DK.......................................8

CA13. Was this tumor invasive or in situ cancer?

INVASIVE 1
IN SITU 2
REF 7
DK.......................................8

CA14. Was the tumor in ducts (ductal) or lobules (lobular) or both?

DUCTS 1
LOBULES 2
BOTH 3
OTHER..................................4
REF 7
DK.......................................8

<ASK CA15 IF CA13 IS NOT IN SITU:>
CA15. At the time of diagnosis, what was the size of the tumor?

|__|__|.|__| cm ....[CA15B]
REF ....[CA15C].............7
DK 8

[RECORD THE SIZE OF TUMOR IN CM AS XX.X]
[PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.]
[PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.]

<ASK CA15A ONLY IF CA15 = DK:>
CA15A. Even though you don't know the exact size, at the time of diagnosis, what was the **approximate** size of the tumor? Was it...?

Less than or equal to 1.0 cm [CA16]1
1.1 to 2.0 cm. [CA16] 2
2.1 to 4.0 cm [CA16]...............3
4.1 cm or more 4
REF .... [CA15C] 7
DK............. [CA15C] 8

[PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.]
[PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.]

<ASK CA15B IF CA15 OR CA15A > 4 CM, ELSE GO TO CA16:>
CA15B. I want to confirm, you said this tumor was more than 4 centimeters or more than an inch and a half. Is that correct?

YES.............. [CA16] 1
NO .... [CA15] 2
REF .... [CA16] 7
DK.............. [CA16] 8

[PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.]
[PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.]

<ASK CA15C IF CA15 = DK OR REF AND CA15A = DK OR REF:>
CA15C. Could you tell us in your own words what you know about the size of this tumor?

RECORD VERBATIM:

_____

CA16. Was this tumor estrogen receptor positive, that is, "ER positive?"

YES (ER POSITIVE) 1
NO (ER NEGATIVE) 2
BORDERLINE / MARGINAL........... 3
TEST NOT DONE..................... 4
REF 7
DK.................................... 8

CA17. Was this tumor progesterone receptor positive, that is, "PR positive?"

YES (PR POSITIVE) 1
NO (PR NEGATIVE) 2
BORDERLINE / MARGINAL........... 3
TEST NOT DONE..................... 4
REF 7
DK.................................... 8

CA18. Was the HER2 (HER2NEU) test performed for this tumor?

YES.................................... 1
NO .... [CA19] 2
REF .... [CA19] 7
DK.............. [CA19] 8

<ASK CA18A IF CA18 = YES:>
CA18A. Was the HER2 (HER2NEU) test positive?

YES.................................... 1
NO 2
REF 7
DK.................................... 8

<END REPEATING RECORD IF CA2C > 1 OR CA7 = BREAST>

CA19. Now we'd like to ask you a few questions about your treatment.

When you were undergoing diagnosis and treatment of your [IF CA9 = BREAST: first] breast cancer, did financial constraints keep you from receiving medical treatment your doctors recommended?

YES, SPECIFY: 1
_____
NO 2
REF 7
DK.......................................8

[IF YES, ASK FOR DETAILS]

CA20. Have you had surgery, not counting a biopsy, to remove the breast cancer?

YES......................................1
NO .... [CA24]..............2
REF .... [CA24]..............7
DK............... [CA24]..............8

<IF CA12 = RIGHT, ASK ABOUT RIGHT BREAST. IF CA12=LEFT, ASK ABOUT LEFT BREAST. IF CA12=BOTH, VERIFY BOTH BREASTS. IF DK OR REF ASK IF LEFT OR RIGHT.>

<IF CA20 = YES AND CA12 = BOTH, ASK CA21 FOR EACH BREAST THEN SKIP TO CA23. IF CA20 = YES AND CA12 = LEFT OR RIGHT, ASK CA21 FOR THE AFFECTED BREAST, THEN GO TO CA22.>	<ASK CA22 ONLY IF CA12 = LEFT OR RIGHT.>	<ASK CA23 FOR EACH BREAST WHERE CA21=1 OR 2>
CA21. For your [*left/right*] breast, did you have a mastectomy, or did you have a lumpectomy, or partial removal of breast tissue [? / IF CA9 = BREAST: the first time you were diagnosed with breast cancer?] [IF R HAD >1 SURGERY, PROBE: What was the last procedure you had / IF CA9 = BREAST: the first time you were diagnosed with breast cancer?]	CA22. For your other breast, did you also have a mastectomy to **prevent** breast cancer, that is, a prophylactic mastectomy? [PLEASE CONFIRM THAT IT WAS THE REMOVAL OF A HEALTHY BREAST TO PREVENT CANCER. IF NOT< CHANGE ANSWER FOR QUESTION CA22 TO BE 'NO']	CA23. Did you have reconstructive breast surgery?
a. LEFT BREAST:	MASTECTOMY ....1 LUMPECTOMY OR PARTIAL REMOVAL OF BREAST ....2 REF ....7 DK 8	YES ....1 NO ....2 REF ....7 DK 8	YES ....1 NO......................2 REF ....7 DK 8
b. RIGHT BREAST:	MASTECTOMY ....1 LUMPECTOMY OR PARTIAL REMOVAL OF BREAST ....2 REF ....7 DK 8	YES ....1 NO ....2 REF ....7 DK 8	YES ....1 NO......................2 REF ....7 DK 8

CA24. Were you having regular menstrual periods at the time you were diagnosed with breast cancer in [month, year] and before you started treatment?

YES......................................1
NO 2
REF 7
DK.......................................8

CA24a. Since the time of that diagnosis, have you   had both your ovaries

removed?	YES............. [CA25] ....1 NO .... [CA25] ....2 NO-REMOVED BEFORE CANCER DX..3 REF .... [CA25] ....7 DK.............. [CA25] 8

<ASK C24B ONLY IF CA24a = 3>
CA24b. What month and year did you have both
     ovaries removed?
     [ENTER MONTH AS MM]
     [ENTER YEAR AS YYYY]

|__|__| |__|__|__|__|
MONTH   YEAR

CA25. Did you have chemotherapy for this breast cancer?

YES......................................1
NO .... [CA31] 2
REF .... [CA31] 7
DK.............. [CA31] 8

<ASK CA25A IF CA25 = YES>
CA25A. Did you get your chemotherapy as part of
     a clinical trial?

YES......................................1
NO.............. [CA26] 2
REF............. [CA26] 7
DK.............. [CA26] 8

<ASK CA25B IF CA25A = YES>
CA25B. Do you know what drug or
     regimen you actually received?

YES......................................1
NO......................................2
REF......................................7
DK......................................8

<BEGIN REPEATING RECORD IF CA25 = YES>
<FIRST OCCURRENCE>
CA26. <IF CA25A = YES AND CA25B ≠ YES>
     What chemotherapy drugs were being tested in
     this trial?
     <IF CA25A ≠ YES OR CA25B = YES>
     What chemotherapy drugs were you given for
     this cancer?

(Self-Report: Drop Down List of
medications)
REF......................................7
DK......................................8

<ALL OTHER OCCURRENCES>
CA26a. <IF CA25A = YES AND CA25B ≠ YES AND
     CA26 ≠ REF, DK>
     Were there other chemotherapy drugs
     being tested in this trial?
     <IF (CA25A ≠ YES OR CA25B = YES)
     OR (CA25B ≠ YES AND CA26 = REF, DK)>
     Were you given other chemotherapy
     drugs for this cancer?

YES............. [CA26] 1
NO.............. [CA27] 2
REF............. [CA27] 7
DK.............. [CA27] 8

CA27. What month and year did your chemotherapy begin for this cancer?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__| MONTH |2|0|__|__| YEAR

CA28. Have you completed your chemotherapy treatment for this cancer?

YES.......................................1
NO .... [CA30] 2
REF .... [CA30] 7
DK............ [CA30] 8

<ASK C29 IF CA28 = YES:>
CA29. What month and year did your chemotherapy end?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__| MONTH |2|0|__|__| YEAR

<ASK CA30 IF CA24 = YES:>
CA30. Did your menstrual periods stop when you were having chemotherapy treatments?

YES.......................................1
NO 2
REF 7
DK.......................................8

<ASK CA31 IF CA24 = YES:>
CA31. Since the time of your diagnosis, have you had shots or other medications that stopped your menstrual periods?

YES.......................................1
NO 2
REF 7
DK.......................................8

<ASK CA32 IF CA30 = YES OR CA31 = YES>
CA32. Did you go back to having regular menstrual periods?

YES.......................................1
NO 2
REF 7
DK.......................................8

CA33. Have you taken Tamoxifen, Evista, or Raloxifene as part of this breast cancer treatment?

YES.......................................1
NO .... [CA38] 2
UNSURE, WAS IN TRIAL[CA38] 3
REF .... [CA38] 7
DK.............. [CA38] 8

<ASK CA34 – CA35 IF CA33 = YES:>
CA34. What month and year did you begin taking Tamoxifen, Evista or Raloxifene?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__| MONTH |2|0|__|__| YEAR

CA35. Are you currently taking Tamoxifen, Evista or Raloxifene?

YES............. [CA38] 1
NO 2
REF .... [CA38] 7
DK.............. [CA38] 8

<ASK CA36 IF CA35 = NO:>
CA36. What month and year did you stop taking Tamoxifen, Evista or Raloxifene?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

| | | | | 2 | 0 | | |
MONTH   YEAR

CA37. Omitted

CA38. Have you taken aromatase inhibitors like Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane) as part of this breast cancer treatment?

YES..................................... 1
NO .... [CA43] 2
UNSURE, WAS IN TRIAL[CA43] 3
REF .... [CA43] 7
DK.............. [CA43] 8

<ASK CA39 - CA40 IF CA38 = YES:>
CA39. What month and year did you begin taking Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane)?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

| | | | | 2 | 0 | | |
MONTH   YEAR

CA40. Are you currently taking Arimidex (anastrozole) Femara (letrozole), or Aromasin (exemestane)?

YES............. [CA43] 1
NO 2
REF .... [CA43] 7
DK.............. [CA43] 8

<ASK CA41 IF CA40 = NO:>
CA41. What month and year did you stop taking Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane)?

| | | | | 2 | 0 | | |
MONTH   YEAR

CA42. Omitted

CA43. Since your breast cancer diagnosis, have you taken Herceptin (Trastuzumab)?

YES..................................... 1
NO .... [CA48] 2
UNSURE, WAS IN TRIAL[CA48] 3
REF .... [CA48] 7
DK.............. [CA48] 8

<ASK CA44 – CA45 IF CA43 = YES:>

CA44. What month and year did you begin
taking Herceptin (Trastuzumab)?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__| |2|0|__|__|
MONTH   YEAR

CA45. Are you currently taking Herceptin
(Trastuzumab)?

YES............. [CA48] 1
NO 2
REF .... [CA48] 7
DK.............. [CA48] 8

<ASK CA46 IF CA45 = NO:>

CA46. What month and year did you stop taking
Herceptin (Trastuzumab)?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__| |2|0|__|__|
MONTH   YEAR

CA47. Omitted

CA48. Have you had radiation therapy for this breast cancer?

YES...................................... 1
NO .... [CA52B] 2
REF .... [CA52B] 7
DK............. [CA52B] 8

<ASK CA49 – CA50 IF CA48 = YES:>

CA49. What month and year did your radiation
therapy begin?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__| |2|0|__|__|
MONTH   YEAR

CA50. Are you still going through radiation
therapy for this breast cancer?

YES............. [CA52] 1
NO 2
REF .... [CA52] 7
DK.............. [CA52] 8

<ASK CA51 IF CA50 = NO:>

CA51. What month and year did your radiation
therapy end?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__| |2|0|__|__|
MONTH   YEAR

CA52. To which areas did you have radiation for this breast cancer?
[CHECK ALL THAT APPLY]

Breast: Whole Breast................1
Breast: "Limited field" just to
where your tumor was............2
Chest wall 3
Underarm (Axillary nodes) 4
Other
(internal breast nodes or other
nodes not in your armpit) 5
Other 6
specify_____
REF 7
DK....................................8

<ASK CA52A IF CA20 = YES>
CA52A. When was your radiation given? Was it...?
[CHECK ALL THAT APPLY]

Before surgery 1
During surgery 2
After surgery 3
REF 7
DK....................................8

<BEGIN REPEATING RECORD>
<FIRST OCCURRENCE>
<FOR EACH TRIAL R WAS IN FOR INITIAL BC DIAGNOSIS>
CA52B. **<IF CA33 ≠ 3 AND CA38 ≠ 3 AND CA43 ≠ 3 AND CA52A ≠>1>**
Were you enrolled in a clinical trial or research study for this breast cancer treatment or management?
<IF CA33 = 3 OR CA38 = 3 OR CA43 = 3 OR CA25A = 1>
You mentioned earlier that you were enrolled in a clinical trial or research study for this breast cancer treatment or management – is that correct?
<ALL OTHER OCCURRENCES>
Were you enrolled in another clinical trial or research study for this breast cancer treatment or management?

YES...................................1
NO .... [CA53]...............2
REF .... [CA53]...............7
DK............. [CA53]...............8

<ASK CA52C-CA52F IF CA52B = YES:>
CA52C. What was the name, sponsor, or identification number of the study, if known?

[RECORD VERBATIM:] _____

CA52D. What was being tested in this trial?
[CHECK ALL THAT APPLY]

Chemotherapy type,
   timing, or dose 1
Radiation type, timing, or dose ... 2
Hormonal treatment 3
Supportive care to prevent
   complications of treatment 4
Surgical treatments 5
OTHER................................ 6
SPECIFY

_____
REF 7
DK.................................... 8

CA52E. Is your participation in that study
        ongoing?

YES............ [CA52B] 1
NO 2
REF .... [CA52B] 7
DK............. [CA52B] 8

<ASK CA52F IF CA52E = NO:>
CA52F. Did you complete all the treatments for
       this study, leave the study before it
       ended, or did the trial end before you
       had finished all the treatments?

COMPLETED ALL TREATMENTS 1
LEFT BEFORE STUDY ENDED 2
TRIAL ENDED EARLY 3
REF 7
DK.................................... 8

<END REPEATING RECORD>

CA53. Are there any other treatments for this breast cancer
       you have had or plan to have that you can tell
       us about?

YES.................................... 1
[IF YES, RECORD VERBATIM:]

_____
NO 2

<IF CA9 = BREAST SKIP TO CS1, ELSE CONTINUE>

<TOTAL NUMBER OF TUMORS REPORTED: CA2C + (1 IF CA7 = BREAST)>
CA54. I have recorded that you have been diagnosed
       with a total of [FILL NUMBER] breast tumors to
       date. Is that correct?

YES........... [MRIntro1] 1
NO 2
DK.................................... 7
REF .... [MRIntro1] 8

<ASK CA55 IF CA54 = NO OR DK:>
CA55. Can you describe in your own words any breast cancer tumors that we did not ask you
       about?

       [RECORD VERBATIM] _____

<IF CA9 = BREAST, CONTINUE, ELSE SKIP TO SECTION MR>

CS1.   OMITTED

<CHECK ANSWER TO CS1A AGAINST DOB>
CS1A. You have indicated you were diagnosed with another breast cancer after your first diagnosis in [month, year]. What was the date a doctor first told you that you definitely had a second breast cancer?
[ENTER THE DIAGNOSIS MONTH AS MM]
[ENTER THE DIAGNOSIS YEAR AS YYYY]

|__|__| |__|__|__|__|
MONTH   YEAR

<IF YEAR PROVIDED, GO TO CS2A>

<ASK CS2 ONLY IF CS1A YEAR = DK>
<CHECK ANSWER TO CS2 AGAINST DOB>
CS2.   How old were you at the time of this diagnosis? |__|__| AGE

CS2A. Sometimes there is a delay between when a woman first notices a lump, or a mammogram shows an abnormality, and the final diagnosis of breast cancer. How much time went by between when you first realized there was a problem and when you were told the diagnosis was a second breast cancer?
[ENTER NUMBER OF MONTHS]
[IF LESS THAN ONE MONTH, ENTER '0']

< 1 MONTH – DIAGNOSED VERY CLOSE TO
    INITIAL IDENTIFICATION 00

|__|__| MONTHS

CS2B. It sometimes takes several doctor appointments to make sure of the breast cancer diagnosis and to run laboratory tests to identify its characteristics. When we refer to the 'time of diagnosis,' we mean this period of time during which your cancer was confirmed and characterized, not just the day you got the diagnosis.

When you were diagnosed with breast cancer for a second time, did you have any form of general health care coverage, including health insurance, pre-paid plans such as HMOs, or government plans such as Medicare or Medicaid?

YES 1
NO 2
REF 7
DK 8

CS2C. Sometimes it takes several tests and procedures after the diagnosis to find out how many tumors there are. After that medical work was completed for your second breast cancer, how many tumors had they found?
[IF R SAYS DK, PROBE: How many tumors do you know about?]

|__| BREAST TUMORS

<IF DK OR REF, COUNT AS 1 TUMOR FOR CS11-CS18 AND CS54>

CS3. At the time of your second breast cancer diagnosis, had the cancer spread to your lymph nodes?

YES.. 1
NO 2
REF 7
DK... 8

CS4. How many lymph nodes were tested?

0 .... [CS6]
|__|__| Lymph Nodes .... [CS5]
REF .... [CS4a]
DK................................ [CS4a]

<ASK CS4a ONLY IF CS4 IS REF OR DK:>
CS4a. **Approximately** how many lymph nodes were tested? Was it…?

0 nodes...... [CS11] 1
1-3 nodes 2
4-9 nodes 3
10-14 nodes 4
15-19 nodes 5
Or 20 or more nodes 6
REF 7
DK................................... 8

<ASK CS5 ONLY CS4 IS NOT 0 OR IF CS4a IS NOT 0:>
CS5. How many lymph nodes were positive?

0 .... [CS11]
|__|__| Lymph Nodes .... [CS11]
REF .... [CS5a]
DK................................ [CS5a]

<ASK CS5a ONLY IF CS5 IS REF OR DK>
CS5a. **Approximately** how many lymph nodes were positive? Was it…?

0 nodes............................... 1
1-3 nodes 2
4-9 nodes 3
10-14 nodes 4
15-19 nodes 5
Or 20 or more nodes 6
REF 7
DK................................... 8

CS6.   OMITTED
CS7.   OMITTED
CS7a. OMITTED
CS8.   OMITTED
CS9.   OMITTED
CS9a. OMITTED
CS10. OMITTED

CS11. The next questions are about the characteristics of your second breast cancer.

<FOR WOMEN REPORTING TWO BREAST TUMORS DIAGNOSED AT SAME TIME: (CS2C > 1)>
You indicated that you had [FILL CS2C] breast tumors diagnosed in [month, year]. Please answer these questions separately for each tumor.

ENTER '1' TO CONTINUE............1

<BEGIN REPEATING RECORD IF CS2C > 1>
<FIRST OCCURRENCE>
<FOR EACH TUMOR REPORTED AT TIME OF SECOND DIAGNOSIS. IF ONLY ONE BREAST TUMOR REPORTED AT TIME OF SECOND DIAGNOSIS, ONLY GO THROUGH SERIES CS12 – CS18A ONCE.>

CS12. In which breast was the tumor found?

<ALL OTHER OCCURRENCES>
<IF CS2C > 1: For the first tumor… / second tumor …>
In which breast was the [first/second…] tumor found?

LEFT BREAST 1
RIGHT BREAST........................2
REF 7
DK..8

CS13. Was this tumor invasive or in situ cancer?

INVASIVE 1
IN SITU 2
REF 7
DK..8

CS14. Was the tumor in ducts (ductal) or lobules (lobular) or both?

DUCTS 1
LOBULES 2
BOTH 3
OTHER..................................4
REF 7
DK..8

<ASK CS15 IF CS13 IS NOT IN SITU:>
CS15. At the time of the second diagnosis, what was the size of the tumor?

[PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.]
[PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.]

|__|__|.|__| cm .... [CS15B]
REF ....[CS15C] 7
DK..8

<ASK CS15A ONLY IF CS15 = DK:>
CS15A. Even though you don't know the exact size, at the time of the second diagnosis, what was the **approximate** size of the tumor? Was it…?

[PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.]
[PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.]

Less than or equal to 1.0 cm [CS16]1
1.1 to 2.0 cm. [CS16] 2
2.1 to 4.0 cm   [CS16] 3
4.1 cm or more 4
REF ....[CS15C] 7
DK..............[CS15C] 8

<ASK CS15B IF CS15 OR CS15A > 4 CM, ELSE GO TO CS16:>
CS15B. I want to confirm, you said this tumor was
more than 4 centimeters or more than an
inch and a half. Is that correct?

YES............. [CS16] 1
NO .... [CS15] 2
REF .... [CS16] 7
DK............. [CS16] 8

[PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.]
[PROBE: IF A TUMOR IS VERY SMALL IT MAY
BE MEASURED IN MILIMETERS.]

<ASK CS15C IF CS15 = DK OR REF AND CS15A = DK OR REF:>
CS15C. Could you tell us in your own words what
you know about the size of this tumor?

[RECORD VERBATIM:]

_____

CS16. Again, referring to the breast cancer diagnosed in
[month, year], was this tumor estrogen receptor
positive, that is, "ER positive?"

YES (ER POSITIVE) 1
NO (ER NEGATIVE)...................2
BORDERLINE / MARGINAL...........3
TEST NOT DONE......................4
REF 7
DK......................................8

CS17. Was this tumor progesterone receptor positive,
that is, "PR positive?"

YES (PR POSITIVE) 1
NO (PR NEGATIVE)...................2
BORDERLINE / MARGINAL...........3
TEST NOT DONE......................4
REF 7
DK......................................8

CS18. Was the HER2 (HER2NEU) test performed for this
tumor?

YES......................................1
NO .... [CS19] 2
REF .... [CS19] 7
DK............. [CS19] 8

<ASK CS18A IF CS18 = YES:>
CS18A. Was the HER2 (HER2NEU) test positive?

YES......................................1
NO 2
REF 7
DK......................................8

<END REPEATING RECORD IF CS2C > 1>

CS19. Now we'd like to ask you a few questions about your treatment the second time you were diagnosed with breast cancer.

When you were undergoing diagnosis and treatment of your second breast cancer, did financial constraints keep you from receiving medical treatment your doctors recommended?

YES, SPECIFY: 1
_____
NO 2
REF 7
DK....................................... 8

[IF YES, PROBE FOR DETAILS]

CS20. Have you had surgery not counting a biopsy to remove the second breast cancer?

YES..................................... 1
NO .... [CS25].............. 2
REF .... [CS25].............. 7
DK................ [CS25].............. 8

<IF CS12 = RIGHT, ASK ABOUT RIGHT BREAST. IF CS12=LEFT, ASK ABOUT LEFT BREAST. IF CS12=BOTH, VERIFY BOTH BREASTS. IF DK OR REF ASK IF LEFT OR RIGHT.>

<IF MASTECTOMY REPORTED IN FIRST DIAGNOSIS (CA21a THROUGH CA22b), SKIP CS21a – CS22b AS NEEDED>

<IF CS20 = YES AND CS12 = BOTH, ASK CS21 FOR EACH BREAST THEN SKIP TO CS23. IF CS20 = YES AND CS12 = LEFT OR RIGHT, ASK CS21 FOR THE AFFECTED BREAST, THEN GO TO CS22.>		<ASK CS22 ONLY IF CS12 = LEFT OR RIGHT.>	<ASK CS23 FOR EACH BREAST WHERE CS21=1 OR 2>
CS21. For your [*left/right*] breast, did you have a mastectomy, or did you have a lumpectomy, or partial removal of breast tissue the second time you were diagnosed with breast cancer? [IF R HAD >1 SURGERY, PROBE: What was the last procedure you had the second time you were diagnosed with breast cancer?]		CS22. For your other breast, did you also have a mastectomy to **prevent** breast cancer, that is, a prophylactic mastectomy? [PLEASE CONFIRM THAT IT WAS THE REMOVAL OF A HEALTHY BREAST TO PREVENT CANCER. IF NOT< CHANGE ANSWER FOR QUESTION CS22 TO BE 'NO']	CS23. Did you have reconstructive breast surgery?
a. LEFT BREAST:	MASTECTOMY ....1 LUMPECTOMY OR PARTIAL REMOVAL OF BREAST ....2 REF ....7 DK 8	YES ....1 NO ....2 REF ....7 DK 8	YES................... 1 NO..................... 2 REF.................... 7 DK 8
b. RIGHT BREAST:	MASTECTOMY ....1 LUMPECTOMY OR PARTIAL REMOVAL OF BREAST ....2 REF ....7 DK 8	YES ....1 NO ....2 REF ....7 DK 8	YES................... 1 NO..................... 2 REF.................... 7 DK 8

CS24. Omitted
CS24a. Omitted
CS24b. Omitted

CS25. Did you have chemotherapy for your second breast cancer?

YES...1
NO............. [CS31] 2
REF............. [CS31] 7
DK............. [CS31] 8

<ASK CS25A IF CS25 = YES>
CS25A. Did you get your chemotherapy as part of a clinical trial?

YES...1
NO............. [CS26] 2
REF............. [CS26] 7
DK............. [CS26] 8

<ASK CS25B IF CS25A = YES>
CS25B. Do you know what drug or regimen you actually received?

YES...1
NO...2
REF...7
DK...8

<BEGIN REPEATING RECORD IF CS25 = YES>
<FIRST OCCURRENCE>
CS26. <IF CS25A = YES AND CS25B ≠ YES>
What chemotherapy drugs were being tested in this trial?
<ALL OTHER OCCURRENCES>
<IF CS25A ≠ YES OR CS25B = YES>
What chemotherapy drugs were you given for your second breast cancer?

(Self-Report: Drop Down List of medications)
Other 1
SPECIFY: _____
REF...7
DK...8

CS26a. <IF CS25A = YES AND CS25B ≠ YES AND CS26 ≠ REF, DK>
Were there other chemotherapy drugs being tested in this trial?
<IF (CS25A ≠ YES OR CS25B = YES) OR (CS25B ≠ YES AND CS26 = REF, DK)>
Were you given other chemotherapy drugs for your second breast cancer?

YES............. [CS26] 1
NO............. [CS27] 2
REF............. [CS27] 7
DK............. [CS27] 8

<END REPEATING RECORD>

CS27. What month and year did your chemotherapy begin for your second breast cancer?
[ENTER MONTH AS MM]
[ENTER YEAT AS YYYY]

|__|__| MONTH |2|0|__|__| YEAR

CS28. Have you completed this chemotherapy treatment?

YES...1
NO............. [CS33] 2
REF............. [CS33] 7
DK............. [CS33] 8

<ASK CS29 IF CS28 = YES:>
CS29. What month and year did your chemotherapy end?

|__|__| MONTH |2|0|__|__| YEAR

[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

CS30. Omitted
CS31. Omitted
CS32. Omitted

CS33. Have you taken Tamoxifen, Evista, or Raloxifene as part of your treatment for the second breast cancer?

YES..1
NO.............. [CS38] 2
UNSURE–WAS IN TRIAL .....[CS38]....3
REF............. [CS38] 7
DK.............. [CS38] 8

<ASK CS34 - CS35 IF CS33 = YES:>
CS34. What month and year did you begin taking Tamoxifen, Evista or Raloxifene?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__|__| |2|0|__|__|
MONTH   YEAR

CS35. Are you currently taking Tamoxifen, Evista or Raloxifene?

YES............. [CS38] 1
NO 2
REF .... [CS38] 7
DK.............. [CS38] 8

<ASK CS36 IF CS35 = NO:>
CS36. What month and year did you stop taking Tamoxifen, Evista or Raloxifene?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__|__| |2|0|__|__|
MONTH   YEAR

CS37. Omitted

CS38. Have you taken aromatase inhibitors like Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane) as part of your treatment for the second breast cancer?

YES......................................1
NO .... [CS43] 2
UNSURE–WAS IN TRIAL ...[CS43]....3
REF .... [CS43] 7
DK.............. [CS43] 8

<ASK CS39 - CS40 IF CS38 = YES:>
CS39. What month and year did you begin taking Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane)?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__|__| |2|0|__|__|
MONTH   YEAR

CS40. Are you currently taking Arimidex
(anastrozole) Femara (letrozole), or
Aromasin (exemestane)?

YES............. [CS43] 1
NO 2
REF .... [CS43] 7
DK.............. [CS43] 8

<ASK CS41 IF CS40 = NO:>
CS41. What month and year did you stop taking
Arimidex (anastrozole), Femara (letrozole),
or Aromasin (exemestane)?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

| | | | | 2 | 0 | | |
MONTH   YEAR

CS42. Omitted

CS43. Since your second breast cancer diagnosis, have
you taken Herceptin (Trastuzumab)?

YES...................................... 1
NO ....[CS48]..............2
UNSURE, WAS IN TRIAL ...[CS48]...3
REF ....[CS48]..............7
DK.................[CS48]..............8

<ASK CS44 – CS45 IF CS43 = YES:>
CS44. What month and year did you begin
taking Herceptin (Trastuzumab)?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

| | | | | 2 | 0 | | |
MONTH   YEAR

CS45. Are you currently taking Herceptin
(Trastuzumab)?

YES............. [CS48] 1
NO 2
REF .... [CS48] 7
DK.............. [CS48] 8

<ASK CS46 IF CS45 = NO:>
CS46. What month and year did you stop taking
Herceptin (Trastuzumab)?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

| | | | | 2 | 0 | | |
MONTH   YEAR

CS47. Omitted

CS48. Have you had radiation therapy for your
second breast cancer?

YES...................................... 1
NO ....[CS52B] 2
REF ....[CS52B] 7
DK.............[CS52B] 8

CS49. What month and year did radiation
therapy begin for your second breast cancer?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__| |2|0|__|__|
MONTH   YEAR

CS50. Are you still going through radiation
therapy for this breast cancer?

YES............ [CS52] 1
NO 2
REF .... [CS52] 7
DK.............. [CS52] 8

CS51. What month and year did your radiation
therapy end?
[ENTER MONTH AS MM]
[ENTER YEAR AS YYYY]

|__|__| |2|0|__|__|
MONTH   YEAR

CS52. To which areas did you have radiation for your
second breast cancer?

[CHECK ALL THAT APPLY]

Breast: Whole Breast.................1
Breast: "Limited field" just to
   where your tumor was.............2
Chest wall 3
Underarm (Axillary nodes) 4
Other
   (internal breast nodes or other
   nodes not in your armpit) 5
Other 6
specify_____
REF 7
DK.....................................8

CS52A. When was your radiation given? Was it...
[CHECK ALL THAT APPLY]

Before surgery 1
During surgery 2
After surgery 3
REF 7
DK.....................................8

<BEGIN REPEATING RECORD>
<FIRST OCCURRENCE>
<FOR EACH TRIAL R WAS IN AT TIME OF SECOND BC DIAGNOSIS>

CS52B. **<IF CS33 ≠ 3 AND CS38 ≠ 3 AND CS43 ≠ 3 AND CS52A ≠1>**
Were you enrolled in a clinical trial or research study for the treatment or management of your second breast cancer?

YES......................................1
NO .... [CS53] 2
REF .... [CS53] 7
DK.............. [CS53] 8

<IF CS33 = 3 OR CS38 = 3 OR CS43 = 3 OR CS25A = 1>
You mentioned earlier that you were enrolled in a clinical trial or research study for the treatment or management of your second breast cancer – is that correct?

<ALL OTHER OCCURRENCES>
Were you enrolled in another clinical trial or research study for treatment or management of your second breast cancer?

<ASK CS52C-CS52F IF CS52B = YES:>
CS52C. What was the name, sponsor, or identification number of the study, if known?

[RECORD VERBATIM:] _____

CS52D. What was being tested in this trial?
[CHECK ALL THAT APPLY]

Chemotherapy type, timing,
  or dose 1
Radiation type, timing, or dose ...2
Hormonal treatment 3
Supportive care to prevent
  complications of treatment.......4
Surgical treatments 5
OTHER................................6
SPECIFY:_____
REF 7
DK....................................8

CS52E. Is your participation in that study ongoing?

YES.............[CS52B] 1
NO 2
REF ....[CS52B] 7
DK..............[CS52B] 8

<ASK CS52F IF CS52E = NO:>
CS52F. Did you complete all the treatments for this study, leave the study before it ended, or did the trial end before you had finished all the treatments?

COMPLETED ALL TREATMENTS......1
LEFT BEFORE STUDY ENDED 2
TRIAL ENDED EARLY 3
REF 7
DK....................................8

<END REPEATING RECORD>

CS53. Are there any other treatments for your second

YES......................................1

breast cancer you have had or plan to have that you can tell us about?

[IF YES, RECORD VERBATIM:]

_____

NO 2

<TOTAL NUMBER OF TUMORS REPORTED: CA2C + (1 IF CA7 = BREAST) + (CS2C IF CA9 = BREAST)>

CS54.   I have recorded that you have been diagnosed with a total of [FILL NUMBER] breast tumors to date. Is that correct?

YES........... [MRIntro1] 1
NO 2
DK..................................... 7
REF .... [MRIntro1] 8

<ASK CS55 IF CS54 = NO OR DK:>

CS55.   Can you describe in your own words any breast cancer tumors that we did not ask you about?

RECORD VERBATIM: _____