CASE Follow-up Telephone Interview

Table of Contents

CA.  DIAGNOSIS AND TREATMENT OF BREAST CANCER

CS.  DIAGNOSIS AND TREATMENT OF SECOND BREAST CANCER
CA. Diagnosis and treatment of Breast cancer

CA1. Before we get started, I want to remind you that all of the information we collect will be kept strictly confidential. If, for any reason, you would rather not answer a question, just tell me and we can go on to the next one.

[VERIFY DATE OF DIAGNOSIS, IF PROVIDED.]
You have indicated that a doctor first told you that you had breast cancer in [fill month and year]. 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 month and year that a doctor first told you that you definitely had breast cancer?

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?

< 1 MONTH – DIAGNOSED VERY CLOSE TO INITIAL IDENTIFICATION ............ 00

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?

|__|__| 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. For the next few questions, when we refer to the ‘time of diagnosis,’ we mean this period of time when you were having those tests done, 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. Omitted

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?

[ASK CA4a ONLY IF CA4 IS REF OR DK:]

CA4a. Approximately how many lymph nodes were tested? Was it...?

[ASK CA5 ONLY IF CA4 IS NOT 0 OR CA4a IS NOT 0:]

CA5. How many lymph nodes were positive?

[ASK CA5a ONLY IF CA5 IS REF OR DK]

CA5a. Approximately how many lymph nodes were positive? Was it...?

CA6. At the time of your breast cancer diagnosis, had the breast cancer spread to any other part of your body?
[ASK CA7 IF CA6 = YES;]
CA7. Where else had the breast cancer spread 
at the time of your breast cancer diagnosis?
CHECK ALL THAT APPLY
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 affect?”

<table>
<thead>
<tr>
<th>Location</th>
<th>Count</th>
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<tbody>
<tr>
<td>ABDOMEN</td>
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<td>BRAIN</td>
<td>5</td>
</tr>
<tr>
<td>BREAST</td>
<td>6</td>
</tr>
<tr>
<td>COLON, COLORECTAL (LARGE BOWL)</td>
<td>8</td>
</tr>
<tr>
<td>INTESTINE, INTESTINAL</td>
<td>11</td>
</tr>
<tr>
<td>LIVER</td>
<td>28</td>
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<tr>
<td>LUNG</td>
<td>13</td>
</tr>
<tr>
<td>LYMPH NODES</td>
<td>14</td>
</tr>
<tr>
<td>OVARY, OVARIAN</td>
<td>19</td>
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<tr>
<td>RECTUM, RECTAL</td>
<td>20</td>
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<tr>
<td>UTERUS, UTERINE</td>
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<td>OTHER1 SPECIFY:</td>
<td>99</td>
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<td>SPECIFY</td>
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</table>

CA7b. Where else has the breast cancer spread since the time of your breast cancer diagnosis?
CHECK ALL THAT APPLY
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 affect?”

<table>
<thead>
<tr>
<th>Location</th>
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<tr>
<td>NOWHERE</td>
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<td>ABDOMEN</td>
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<td>RECTUM, RECTAL</td>
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<td>UTERUS, UTERINE</td>
<td>22</td>
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<tr>
<td>OTHER SPECIFY:</td>
<td>99</td>
</tr>
<tr>
<td>SPECIFY</td>
<td></td>
</tr>
</tbody>
</table>
CA8. **Since the time** you were first diagnosed with breast cancer, have you been diagnosed with another cancer, including another breast cancer?

YES ............... .......................... 1
NO .............. [CA11] .................. 2
REF ............ [CA11] .................. 7
DK .............. [CA11] .................. 8

[ASK CA9 IF CA8 = YES:]

CA9. What type or types of cancer were you diagnosed with or where else was cancer found after your original 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 .................. 37
BLADDER ...................... 1
BLOOD ......................... 3
BONE ......................... 23
BOWEL ......................... 4
BRAIN ......................... 5
BREAST ....................... 6
CERVIX, CERVICAL ............ 7
COLON, COLORECTAL ......... 8
DUCTAL CARCINOMA IN SITU .... 46
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 SPECIFY: ............. 99
SPECIFY _______________________


[BEGIN REPEATING RECORD]
[CHECK ANSWER TO CA9b AGAINST DOB]
[ASK CA9b - CA9c IF CA9 ≠ BREAST]
CA9b. What is the month and year a doctor first told you that you definitely had this cancer? [CANCER TYPE FROM CA9] cancer? |__|__| |__|__|__|__| MONTH YEAR IF YEAR PROVIDED, GO TO 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].

ENTER ‘1’ TO CONTINUE............ 1
CA12. In which breast was the cancer found?

- LEFT BREAST ............... 1
- RIGHT BREAST ............. 2
- BOTH BREASTS .......... 3
- REF .......................... 7
- DK ............................ 8

CA13. Was this invasive or in situ cancer?

- INVASIVE  ...................... 1
- IN SITU  ......................... 2
- BOTH  ........................... 3
- REF  .............................. 7
- DK  ................................. 8

CA14. Was the cancer 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 ONLY:]

CA15. At the time of 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.

- If more than one tumor:
  What was the size of the largest tumor?

IF R IS UNSURE WHICH MEASUREMENT TO USE:
What was the single longest dimension?

[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...

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

- If more than one tumor:
  What was the size of the largest tumor?

IF R IS UNSURE WHICH MEASUREMENT TO USE:
What was the single longest dimension?
[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?

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

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

[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 the tumor?

RECORD VERBATIM:

______________________________

CA16. Was this cancer 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 cancer 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?

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
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 concern about the cost keep you from receiving medical treatment your doctors recommended?

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

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.]

<table>
<thead>
<tr>
<th>[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.]</th>
<th>[ASK CA22 ONLY IF CA12 = LEFT OR RIGHT]</th>
<th>[ASK CA23 FOR EACH BREAST WHERE CA21=1, 2 OR 3]</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA21. For your [left/right] breast, did you have a mastectomy (complete removal of breast tissue), or did you have partial removal of breast tissue (sometimes called “lumpectomy”)? [IF CA9 = BREAST: the first time you were diagnosed with breast cancer?]</td>
<td>CA22. For your other breast, did you also have a mastectomy to prevent breast cancer, that is, a prophylactic mastectomy? IF YES, CONFIRM: This is the removal of a healthy breast to prevent cancer.</td>
<td>CA23. Did you have reconstructive breast surgery?</td>
</tr>
<tr>
<td>a. LEFT BREAST:</td>
<td>b. RIGHT BREAST:</td>
<td></td>
</tr>
<tr>
<td>MASTECTOMY .................</td>
<td>MASTECTOMY .................</td>
<td>YES .................</td>
</tr>
<tr>
<td>LUMPECTOMY OR PARTIAL REMOVAL OF BREAST .......</td>
<td>LUMPECTOMY OR PARTIAL REMOVAL OF BREAST .......</td>
<td>YES .................</td>
</tr>
<tr>
<td>BOTH .........................</td>
<td>BOTH .........................</td>
<td>NO .................</td>
</tr>
<tr>
<td>REF .........................</td>
<td>REF .........................</td>
<td>REF .........................</td>
</tr>
<tr>
<td>DK .........................</td>
<td>DK .........................</td>
<td>DK .........................</td>
</tr>
<tr>
<td>YES .................</td>
<td>YES .................</td>
<td>1</td>
</tr>
<tr>
<td>NO .................</td>
<td>NO .................</td>
<td>2</td>
</tr>
<tr>
<td>REF .........................</td>
<td>REF .........................</td>
<td>7</td>
</tr>
<tr>
<td>DK .........................</td>
<td>DK .........................</td>
<td>8</td>
</tr>
<tr>
<td>CA24. Were you having regular menstrual periods at the time you were diagnosed with breast cancer in [month, year] and before you started treatment?</td>
<td>YES .................</td>
<td>1</td>
</tr>
<tr>
<td>NO .................</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>REF .........................</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>DK .........................</td>
<td>8</td>
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</tr>
</tbody>
</table>
CA24a. Have you had both your ovaries removed?

[ASK C24B ONLY IF CA24a = 1]

[CA24b. What month and year did you have both ovaries removed?]

| __ | __ | __ | __ |
|___|    |___|________|
|   | MONTH |   | YEAR     |

CA25. Did you have chemotherapy for this breast cancer?

[ASK CA25A IF CA25 = YES]

CA25A. Were you in a clinical trial that was testing the chemotherapy you received?

[ASK CA25B IF CA25A = YES]

CA25B. Do you know what drug or regimen you actually received?

[BEGIN REPEATING RECORD IF CA25 = YES]

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]

What chemotherapy drugs were you given for this cancer?

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?

[END REPEATING RECORD]

CA27. What month and year did your chemotherapy begin for this cancer?

MONTH    20    YEAR
CA28. Have you completed your chemotherapy treatment for this cancer?

[ASK C29 IF CA28 = YES:]
CA29. What month and year did your chemotherapy end?

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

[ASK CA31 IF CA24 = YES:]
CA31. Have you had shots or other medications besides chemotherapy that stopped your menstrual periods?

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

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

[ASK CA34 - CA35 IF CA33 = YES:]
CA34. What month and year did you begin taking Tamoxifen, Evista or Raloxifene?

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

[ASK CA36 IF CA35 = NO:]
CA36. What month and year did you stop taking Tamoxifen, Evista or Raloxifene?
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)?

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

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)?

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

CA42. Omitted

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

- YES ................ [CA48] ................. 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)?

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

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)?
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?

MONTH 2 0 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?

MONTH 2 0 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 .............. [CA52] ............... 8

CA52A. Omitted
[BEGIN REPEATING RECORD]
[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 - AFTER FIRST ITERATION] Were you enrolled in another clinical trial or research study for this breast cancer treatment or management?

[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?

[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?

[IF YES, RECORD VERBATIM:] ________________________________

CA54. Omitted
CA55. Omitted
DIAGNOSIS AND TREATMENT OF BREAST CANCER
SECOND SERIES OF QUESTIONS FOR WOMEN WITH MULTIPLE
BREAST CANCER DIAGNOSES AT DIFFERENT TIME POINTS

[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 month and year that a doctor first told you that you definitely had a second breast cancer?

|__|__|      |__|__|__|__|
|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?

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?

< 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. For the next few questions, when we refer to the ‘time of diagnosis,’ we mean this period of time when you were having those tests done, 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. Omitted

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?

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>REF</th>
<th>DK</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
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</tbody>
</table>

**[ASK CS4a ONLY IF CS4 IS REF OR DK:]**

**CS4a.** Approximately how many lymph nodes were tested? Was it...

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>REF</th>
<th>DK</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-3 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4-9 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-14 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15-19 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Or 20 or more nodes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CS5.** How many lymph nodes were positive?

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>REF</th>
<th>DK</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**[ASK CS5 ONLY IF CS4 IS NOT 0 OR IF CS4a IS NOT 0:]**

**CS5a.** Approximately how many lymph nodes were positive? Was it...

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>REF</th>
<th>DK</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-3 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4-9 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-14 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15-19 nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Or 20 or more nodes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CS6.** OMITTED

**CS7.** OMITTED

**CS7a.** OMITTED

**CS7b.** OMITTED

**CS8.** OMITTED

**CS9.** OMITTED

**CS9a.** OMITTED

**CS9b.** OMITTED

**CS9c.** OMITTED

**CS10.** OMITTED
CS11. The next questions are about the characteristics of your second breast cancer.

ENTER ‘1’ TO CONTINUE ............. 1

CS12. In which breast was the cancer found?

LEFT BREAST ......................... 1
RIGHT BREAST ......................... 2
BOTH BREASTS ........................ 3
REF ..................................... 7
DK ....................................... 8

CS13. Was this invasive or in situ cancer?

INVASIVE ............................... 1
IN SITU ................................. 2
BOTH ................................... 3
REF ..................  .................. 7
DK ....................  .................. 8

CS14. Was the cancer 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 ONLY:]

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.

IF MORE THAN ONE TUMOR:
What was the size of the largest tumor?

IF R IS UNSURE WHICH MEASUREMENT TO USE:
What was the single longest dimension?

[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.

IF MORE THAN ONE TUMOR:
What was the size of the largest tumor?

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 ..................  .................... 8
IF R IS UNSURE WHICH MEASUREMENT TO USE:
What was the single longest dimension?

[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 the tumor?

RECORD VERBATIM:
______________________________

CS16. Again, referring to the breast cancer diagnosed in
[month, year], was this cancer 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 cancer 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
cancer?

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
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 concern about the cost keep you from receiving medical treatment your doctors recommended?

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

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

[3 = IF R REPORTED “TUMOR REMOVED DURING PROPHYLACTIC MASTECTOMY AT THE TIME OF THE FIRST DIAGNOSIS”]

[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]

<table>
<thead>
<tr>
<th>[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.]</th>
<th>[ASK CS22 ONLY IF CS12 = LEFT OR RIGHT]</th>
<th>[ASK CS23 FOR EACH BREAST WHERE CS21=1, 2 OR 3]</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS21. For your [left/right] breast, did you have a mastectomy (complete removal of breast tissue), or did you have partial removal of breast tissue (sometimes called “lumpectomy”) the second time you were diagnosed with breast cancer?</td>
<td>CS22. For your other breast, did you also have a mastectomy to prevent breast cancer, that is, a prophylactic mastectomy? IF YES, CONFIRM: This is the removal of a healthy breast to prevent cancer.</td>
<td>CS23. Did you have reconstructive breast surgery?</td>
</tr>
<tr>
<td><strong>a. LEFT BREAST:</strong></td>
<td>YES .......................... 1</td>
<td>YES .......................... 1</td>
</tr>
<tr>
<td>MASTECTOMY .................. 1</td>
<td>NO .......................... 2</td>
<td>NO .......................... 2</td>
</tr>
<tr>
<td>LUMPECTOMY OR PARTIAL REMOVAL OF BREAST .... 2</td>
<td>REF ....................... 7</td>
<td>REF ....................... 7</td>
</tr>
<tr>
<td>BOTH .......................... 2</td>
<td>DK .......................... 8</td>
<td>DK .......................... 8</td>
</tr>
<tr>
<td>REF .......................... 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DK .......................... 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. RIGHT BREAST:</td>
<td>YES .......................... 1</td>
<td>YES .......................... 1</td>
</tr>
<tr>
<td>MASTECTOMY .................. 1</td>
<td>NO .......................... 2</td>
<td>NO .......................... 2</td>
</tr>
<tr>
<td>LUMPECTOMY OR PARTIAL REMOVAL OF BREAST .... 2</td>
<td>REF ....................... 7</td>
<td>REF ....................... 7</td>
</tr>
<tr>
<td>BOTH .......................... 2</td>
<td>DK .......................... 8</td>
<td>DK .......................... 8</td>
</tr>
<tr>
<td>REF .......................... 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DK .......................... 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CS24. Omitted</td>
<td></td>
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<tr>
<td>CS24a. Omitted</td>
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</tbody>
</table>
CS24b. Omitted

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

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<tbody>
<tr>
<td>YES</td>
<td>[CS31]</td>
<td>1</td>
</tr>
<tr>
<td>NO</td>
<td>[CS31]</td>
<td>2</td>
</tr>
<tr>
<td>REF</td>
<td>[CS31]</td>
<td>7</td>
</tr>
<tr>
<td>DK</td>
<td>[CS31]</td>
<td>8</td>
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</tbody>
</table>

[ASK CS25A IF CS25 = YES]
CS25A. Were you in a clinical trial that was testing the chemotherapy you received?

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<tr>
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<tbody>
<tr>
<td>YES</td>
<td>[CS26]</td>
<td>1</td>
</tr>
<tr>
<td>NO</td>
<td>[CS26]</td>
<td>2</td>
</tr>
<tr>
<td>REF</td>
<td>[CS26]</td>
<td>7</td>
</tr>
<tr>
<td>DK</td>
<td>[CS26]</td>
<td>8</td>
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</tbody>
</table>

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

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</thead>
<tbody>
<tr>
<td>YES</td>
<td>[CS26]</td>
<td>1</td>
</tr>
<tr>
<td>NO</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>REF</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>DK</td>
<td></td>
<td>8</td>
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</tbody>
</table>

[BEGIN REPEATING RECORD IF CS25 = YES]

CS26. [IF CS25A = YES AND CS25B ≠ YES]
What chemotherapy drugs were being tested in this trial?

[Self-Report: Drop Down List of medications]

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<tr>
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<tbody>
<tr>
<td>YES</td>
<td>[CS26]</td>
<td>1</td>
</tr>
<tr>
<td>NO</td>
<td>[CS26]</td>
<td>2</td>
</tr>
<tr>
<td>REF</td>
<td>[CS26]</td>
<td>7</td>
</tr>
<tr>
<td>DK</td>
<td>[CS26]</td>
<td>8</td>
</tr>
</tbody>
</table>

[IF CS25A ≠ YES OR CS25B = YES]
What chemotherapy drugs were you given for your second breast cancer?

CS26a. [IF CS25A = YES AND CS25B ≠ YES AND CS26 ≠ REF, DK]
Were there other chemotherapy drugs being tested in this trial?

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<tbody>
<tr>
<td>YES</td>
<td>[CS27]</td>
<td>1</td>
</tr>
<tr>
<td>NO</td>
<td>[CS27]</td>
<td>2</td>
</tr>
<tr>
<td>REF</td>
<td>[CS27]</td>
<td>7</td>
</tr>
<tr>
<td>DK</td>
<td>[CS27]</td>
<td>8</td>
</tr>
</tbody>
</table>

[END REPEATING RECORD]

CS27. What month and year did your chemotherapy begin for your second breast cancer?

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<td>2 0</td>
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</table>

MONTH YEAR

CS28. Have you completed this chemotherapy treatment?

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<tr>
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</thead>
<tbody>
<tr>
<td>YES</td>
<td>[CS33]</td>
<td>1</td>
</tr>
<tr>
<td>NO</td>
<td>[CS33]</td>
<td>2</td>
</tr>
<tr>
<td>REF</td>
<td>[CS33]</td>
<td>7</td>
</tr>
<tr>
<td>DK</td>
<td>[CS33]</td>
<td>8</td>
</tr>
</tbody>
</table>

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

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<tbody>
<tr>
<td></td>
<td></td>
<td>2 0</td>
</tr>
</tbody>
</table>

MONTH YEAR
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?

[  ] [  ] 20[  ]
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?

[  ] [  ] 20[  ]
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)?

[  ] [  ] 20[  ]
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)?

CS42. Omitted

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

[ASK CS44 - CS45 IF CS43 = YES:]
CS44. What month and year did you begin taking Herceptin (Trastuzumab)?

CS45. Are you currently taking Herceptin (Trastuzumab)?

[ASK CS46 IF CS45 = NO:]
CS46. What month and year did you stop taking Herceptin (Trastuzumab)?

CS47. Omitted

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

[ASK CS49 - CS50 IF CS48 = YES:]
CS49. What month and year did radiation therapy begin for your second breast cancer?

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

[ASK CS51 IF CS50 = NO:]
CS51. What month and year did your radiation therapy begin?
therapy end?

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

[ASK CS52A IF CS20 = YES]
CS52A. Omitted

[BEGIN REPEATING RECORD]
[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?

[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 - AFTER FIRST ITERATION] Were you enrolled in another clinical trial or research study for treatment or management of your second breast cancer?

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

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

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

NO ...................................... 2

CS54. Omitted

CS55. Omitted