TARGIT Collaborative Group Breast Quality Collaborative - version 54.61

Version 54.61 (with Breast Cancer Module version 54.61)

1. First Visit - Date of Visit

Number	Question	Answers
1.1	Type of data collection	Prospective Retrospective
1.2	Date of visit	DD-MM-yyyy

2. First Visit - Demographics

Number	Question	Answers
2.1	Sex Warning: Value of Male is rare or unable that for 10 cancer cohorts. Patient should (for sure)	Male Female
2.2	Weight	kg
2.3	Height	cm

3. First Visit - Karnofsky Performance Status

Number	Question	Answers
3.1	Karnofsky performance status	100 - Normal, no complaints, no evidence of disease 90 - Able to carry on normal activity; minor signs or symptoms of disease 80 - Normal activity with effort; some signs or symptoms of disease 70 - Cares for self; unable to carry on normal activity or to do active work 60 - Requires occasional assistance, but is able to care for most of his/her needs 50 - Requires considerable assistance and frequent medical care 40 - Disabled; requires special care and assistance 30 - Severely disabled; hospitalization is necessary but death is not imminent 20 - Very sick; hospital care necessary; active supportive treatment necessary 10 - Moribund; fatal processes progressing rapidly 0 - Dead

4. First Visit - Tumor Measurements

Number	Question	Answers
4.1	Tumor location (first visit in case of bilateral breast cancer)	Left breast Right breast
4.1.1	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Tumor quadrant (left breast)	UIT - upper inner LIT - lower inner UOT - upper outer LOT - lower outer UC - upper central LC - lower central AC - axillary central N/A - not applicable
4.1.2	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Clinical cT-stadium (pre-operative clinical staging) Warning: cT-stadium should be pre-operative	cTis - carcinoma in situ cT1 - ≤ 2 cm cT2 - > 2 cm ≤ 5 cm cT3 - > 5 cm cT4 - any size, with direct extension to the chest wall or to the skin cT1mic - ≤ 0.1 cm cT1a - > 0.1 cm ≤ 0.5 cm cT1b - > 0.5 cm ≤ 1 cm cT1c - > 1 cm ≤ 2 cm cT4a - extension to the chest wall cT4b - ulceration and/or ipsilateral satellite nodules and/or edema (including peau d'orange) that do not meet the criteria for inflammatory carcinoma cT4c - both cT4a and cT4b cT4d - inflammatory carcinoma cX - cannot be assessed N/A - not applicable
4.1.3	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Clinical cT-stadium (pre-operative clinical staging) method (left breast)	Clinical examination (particularly palpation) Mammography Ultrasound Histopathology Fine needle aspiration Magnetic resonance Other breast imaging (Spiral CT, Lymph Scintigraphy) Other
4.1.4	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Tumor size (left breast) clinical examination (pre-surgery) Value of tumor left breast clinical examination (pre-surgery)	___ cm
4.1.5	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Tumor size (left breast) mammography Value of tumor left breast mammography	___ cm
4.1.6	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Tumor size (left breast) ultrasound Value of tumor left breast ultrasound (pre-surgery)	___ cm
4.1.7	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Tumor size (left breast) other breast imaging Value of tumor left breast other breast imaging (pre-surgery)	___ cm
4.1.8	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Tumor quadrant (right breast)	UIT - upper inner LIT - lower inner UOT - upper outer LOT - lower outer UC - upper central LC - lower central AC - axillary central N/A - not applicable
4.1.9	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Clinical cT-stadium (pre-operative clinical staging) method (right breast)	Clinical examination (particularly palpation) Mammography Ultrasound Histopathology Fine needle aspiration Magnetic resonance Other breast imaging (Spiral CT, Lymph Scintigraphy) Other
4.1.10	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Tumor size (right breast) clinical examination (pre-surgery) Value of tumor right breast clinical examination (pre-surgery)	___ cm
4.1.11	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Tumor size (right breast) mammography Value of tumor right breast mammography	___ cm
4.1.12	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Tumor size (right breast) ultrasound Value of tumor right breast ultrasound (pre-surgery)	___ cm
4.1.13	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Tumor size (right breast) other breast imaging Value of tumor right breast other breast imaging (pre-surgery)	___ cm

5. First Visit - Tumor Staging

Number	Question	Answers
5.1	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Nodal Staging of the tumor located in the left breast	Unknown Sentinel Axillary Supraclavicular
5.2	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Nodal Staging of the tumor located in the right breast	Unknown Sentinel Axillary Supraclavicular N/A - Not Applicable
5.3	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Pathological Staging of tumor in T (pT-stage)	Tis T1 T2 T3 T4 Unknown N/A - Not Applicable
5.4	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Pathological Staging of tumor in T (pT-stage)	Tis T1 T2 T3 T4 Unknown N/A - Not Applicable
5.5	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Pathological Staging of tumor in N (pN-stage)	N0 N1 N2 N3 Unknown N/A - Not Applicable
5.6	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Pathological Staging of tumor in N (pN-stage)	N0 N1 N2 N3 Unknown N/A - Not Applicable
5.7	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Pathological Staging of tumor in M (pM-stage)	M0 M1 Unknown N/A - Not Applicable
5.8	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Pathological Staging of tumor in M (pM-stage)	M0 M1 Unknown N/A - Not Applicable

6. First Visit - Tumor Histopathology

Number	Question	Answers
6.1	If Adverse event cancer assessment method was performed for the left breast 'a recurrence of Histopathology' answer this question: Left Breast: Other Histology with adverse medical consequence (AE)	Invasive breast Ductal carcinoma in situ Other histology Unknown N/A - Not Applicable
6.1.1	If Breast Histology (of Breast) 'Invasive breast' answer this question: Left Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Ductal Lobular Other Unknown
6.1.2	If Breast Histology (of Breast) 'Invasive breast' answer this question: Left Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Yes No Unknown
6.1.3	If Breast Histology (of Breast) 'Ductal carcinoma in situ' answer this question: Left Breast: Ductal carcinoma in situ (with reference tumour for subsequent AE)	Yes No Unknown
6.1.4	If Breast Histology (of Breast) 'Ductal carcinoma in situ' answer this question: Left Breast: Ductal carcinoma in situ (with reference tumour for subsequent AE)	Yes No Unknown
6.1.5	If Breast Histology (of Breast) 'Ductal carcinoma in situ' answer this question: Left Breast: Other Histology with adverse medical consequence (AE)	Yes No Unknown
6.1.6	If Breast Histology (of Breast) 'Ductal carcinoma in situ' answer this question: Left Breast: Other Histology with adverse medical consequence (AE)	Yes No Unknown
6.2	If Adverse event cancer assessment method was performed for the left breast 'a recurrence Invasive breast lesion' answer this question: Left Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Invasive ductal carcinoma Invasive lobular carcinoma Other invasive Unknown N/A - Not Applicable
6.2.1	If Adverse event cancer assessment method was performed for the left breast 'a recurrence Invasive breast lesion' answer this question: Left Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Yes No Unknown
6.2.2	If Adverse event cancer assessment method was performed for the left breast 'a recurrence Invasive breast lesion' answer this question: Left Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Yes No Unknown
6.3	If Left Breast 'Invasive Breast Cancer Date Relative' is equal to 'Invasive Breast Cancer' answer this question: Left Breast: Invasive Breast Cancer (Date Relative)	Positive Negative Unknown (unknown significant) Not known
6.3.1	If Left Breast 'Invasive Breast Cancer Date Relative' is equal to 'Invasive Breast Cancer' answer this question: Left Breast: Invasive Breast Cancer (Date Relative)	___
6.3.2	If Left Breast 'Invasive Breast Cancer Date Relative' is equal to 'Invasive Breast Cancer' answer this question: Left Breast: Invasive Breast Cancer (Date Relative)	___
6.4	If Adverse event cancer assessment method was performed for the left breast 'a recurrence Histopathology' answer this question: Right Breast: Histology	Invasive breast Ductal carcinoma in situ Other histology Unknown N/A - Not Applicable
6.4.1	If Breast Histology (Right Breast) 'Invasive Breast' answer this question: Right Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Ductal Lobular Other Unknown
6.4.2	If Breast Histology (Right Breast) 'Invasive Breast' answer this question: Right Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Yes No Unknown
6.4.3	If Breast Histology (Right Breast) 'Ductal carcinoma in situ' answer this question: Right Breast: Ductal carcinoma in situ (with reference tumour for subsequent AE)	Yes No Unknown
6.4.4	If Breast Histology (Right Breast) 'Ductal carcinoma in situ' answer this question: Right Breast: Ductal carcinoma in situ (with reference tumour for subsequent AE)	Yes No Unknown
6.4.5	If Breast Histology (Right Breast) 'Ductal carcinoma in situ' answer this question: Right Breast: Other Histology with adverse medical consequence (AE)	Yes No Unknown
6.4.6	If Breast Histology (Right Breast) 'Ductal carcinoma in situ' answer this question: Right Breast: Other Histology with adverse medical consequence (AE)	Yes No Unknown
6.5	If Adverse event cancer assessment method was performed for the left breast 'a recurrence Invasive breast lesion' answer this question: Right Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Invasive ductal carcinoma Invasive lobular carcinoma Other invasive Unknown N/A - Not Applicable
6.5.1	If Adverse event cancer assessment method was performed for the left breast 'a recurrence Invasive breast lesion' answer this question: Right Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Yes No Unknown
6.5.2	If Adverse event cancer assessment method was performed for the left breast 'a recurrence Invasive breast lesion' answer this question: Right Breast: Invasive breast lesion (with reference tumour for subsequent AE)	Yes No Unknown
6.6	If Right Breast 'Invasive Breast Cancer Date Relative' is equal to 'Invasive Breast Cancer' answer this question: Right Breast: Invasive Breast Cancer (Date Relative)	Positive Negative Unknown (unknown significant) Not known
6.6.1	If Right Breast 'Invasive Breast Cancer Date Relative' is equal to 'Invasive Breast Cancer' answer this question: Right Breast: Invasive Breast Cancer (Date Relative)	___
6.6.2	If Right Breast 'Invasive Breast Cancer Date Relative' is equal to 'Invasive Breast Cancer' answer this question: Right Breast: Invasive Breast Cancer (Date Relative)	___

7. First Visit - Assessments Risk Structures Pre-Surgery

Number	Question	Answers
7.1	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Is the Left breast tumour operable?	Yes No
7.2	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Specify which pre-surgery risk factors are present for the Left Breast tumor (at first visit)	Tumor with adverse clinicopathlo prognosis Tumor with adverse clinical stage (cT-stadium) Tumor in multifocal / multicentric Tumor in Axillary Locally advanced tumor Inflammatory breast cancer Prior ipsilateral breast cancer Prior ipsilateral lymph node cancer Negative prognostic factors Other None Not operable (stated medical reason given by surgeon)
7.3	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Is the Right breast tumour operable?	Yes No
7.4	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Specify which pre-surgery risk factors are present for the Right Breast tumor (at first visit)	Tumor with adverse clinicopathlo prognosis Tumor with adverse clinical stage (cT-stadium) Tumor in multifocal / multicentric Tumor in Axillary Locally advanced tumor Inflammatory breast cancer Prior ipsilateral breast cancer Prior ipsilateral lymph node cancer Negative prognostic factors Other None Not operable (stated medical reason given by surgeon)

8. First Visit - Patient Questionnaires

Number	Question	Answers
8.1	EORTC QLQ-C30 questionnaire completed	Yes No
8.1.1	If EORTC QLQ-C30 questionnaire completed 'a' for question 'EORTC QLQ-C30 questionnaire completed': EORTC QLQ-C30 questionnaire completed	Yes No
8.2	If EORTC BR23 questionnaire completed 'a' for question 'EORTC QLQ-C30 questionnaire completed': EORTC BR23 questionnaire completed	Yes No

9. Treatment - Treatment Details Left Breast

Some questions use Left Breast. No data needs to be recorded at this section.

Number	Question	Answers
9.1	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Date of surgery (Left breast)	___ (dd-mm-yyyy)
9.2	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Patient sought at day of surgery (left breast)	Unknown Unplanned
9.3	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Breast conserving surgery (left breast)	Yes No Unknown
9.4	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Mastectomy (left breast)	Yes No Unknown
9.5	If Mastectomy (left breast) 'Yes' answer this question: Was the BR operation done at same day as the surgery (left breast)	Should not be done Done at same day as surgery Done at other day than surgery Technical failure Unknown
9.5.1	If Breast provide some DIEP were given 'a' answer this question: Please specify: "Other"	___
9.5.2	If Mastectomy (left breast) 'Yes' answer this question: Reason for surgery	Cancer Pain Cosmetic Risk Other Unknown N/A - Not Applicable
9.5.3	If Mastectomy (left breast) 'Yes' answer this question: Was the DIEP operation done at same day as the surgery (left breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Yes No Unknown
9.5.4	If Mastectomy (left breast) 'Yes' answer this question: Reason why DIEP operation not done at same day as the surgery (left breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Technical failure Patient Other Unknown N/A - Not Applicable
9.5.5	If Breast provide some DIEP were given 'a' answer this question: Please specify: "Other"	___
9.5.6	If Mastectomy (left breast) 'Yes' answer this question: Reason for surgery	Cancer Pain Cosmetic Risk Other Unknown N/A - Not Applicable
9.6.1	If Mastectomy (left breast) 'Yes' answer this question: Sentinel node biopsy (left breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Yes No Unknown
9.6.2	If Mastectomy (left breast) 'Yes' answer this question: Reason why sentinel node biopsy not done (left breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Technical failure Patient Other Unknown N/A - Not Applicable
9.6.3	If Mastectomy (left breast) 'Yes' answer this question: Axillary lymph node dissection (left breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Yes No Unknown
9.6.4	If Mastectomy (left breast) 'Yes' answer this question: Reason why axillary lymph node dissection not done (left breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Technical failure Patient Other Unknown N/A - Not Applicable
9.6.5	If Breast-sparing surgery (left breast) 'Yes' answer this question: Sentinel node biopsy (left breast)	Yes No Unknown
9.6.6	If Breast-sparing surgery (left breast) 'Yes' answer this question: Reason why sentinel node biopsy not done (left breast)	Technical failure Patient Other Unknown N/A - Not Applicable
9.6.7	If Breast-sparing surgery (left breast) 'Yes' answer this question: Axillary lymph node dissection (left breast)	Yes No Unknown
9.6.8	If Breast-sparing surgery (left breast) 'Yes' answer this question: Reason why axillary lymph node dissection not done (left breast)	Technical failure Patient Other Unknown N/A - Not Applicable

10. Treatment - Treatment Details Right Breast

Some questions use Left Breast. No data needs to be recorded at this section.

Number	Question	Answers
9.1	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Date of surgery (Right breast)	___ (dd-mm-yyyy)
9.2	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Patient sought at day of surgery (right breast)	Unknown Unplanned
9.3	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Breast conserving surgery (right breast)	Yes No Unknown
9.4	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Mastectomy (right breast)	Yes No Unknown
9.5	If Mastectomy (right breast) 'Yes' answer this question: Was the BR operation done at same day as the surgery (right breast)	Should not be done Done at same day as surgery Done at other day than surgery Technical failure Unknown
9.5.1	If Breast provide some DIEP were given 'a' answer this question: Please specify: "Other"	___
9.5.2	If Mastectomy (right breast) 'Yes' answer this question: Reason for surgery	Cancer Pain Cosmetic Risk Other Unknown N/A - Not Applicable
9.5.3	If Mastectomy (right breast) 'Yes' answer this question: Was the DIEP operation done at same day as the surgery (right breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Yes No Unknown
9.5.4	If Mastectomy (right breast) 'Yes' answer this question: Reason why DIEP operation not done at same day as the surgery (right breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Technical failure Patient Other Unknown N/A - Not Applicable
9.5.5	If Breast provide some DIEP were given 'a' answer this question: Please specify: "Other"	___
9.5.6	If Mastectomy (right breast) 'Yes' answer this question: Reason for surgery	Cancer Pain Cosmetic Risk Other Unknown N/A - Not Applicable
9.6.1	If Mastectomy (right breast) 'Yes' answer this question: Sentinel node biopsy (right breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Yes No Unknown
9.6.2	If Mastectomy (right breast) 'Yes' answer this question: Reason why sentinel node biopsy not done (right breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Technical failure Patient Other Unknown N/A - Not Applicable
9.6.3	If Mastectomy (right breast) 'Yes' answer this question: Axillary lymph node dissection (right breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Yes No Unknown
9.6.4	If Mastectomy (right breast) 'Yes' answer this question: Reason why axillary lymph node dissection not done (right breast) Warning: Value of 'Yes' is rare or unlikely for 10 cancer cohorts. Unknown is also possible	Technical failure Patient Other Unknown N/A - Not Applicable
9.6.5	If Breast-sparing surgery (right breast) 'Yes' answer this question: Sentinel node biopsy (right breast)	Yes No Unknown
9.6.6	If Breast-sparing surgery (right breast) 'Yes' answer this question: Reason why sentinel node biopsy not done (right breast)	Technical failure Patient Other Unknown N/A - Not Applicable
9.6.7	If Breast-sparing surgery (right breast) 'Yes' answer this question: Axillary lymph node dissection (right breast)	Yes No Unknown
9.6.8	If Breast-sparing surgery (right breast) 'Yes' answer this question: Reason why axillary lymph node dissection not done (right breast)	Technical failure Patient Other Unknown N/A - Not Applicable

11. Treatment - Final Histopathology Left Breast

Some questions use Right Breast. No data needs to be recorded at this section.

Number	Question	Answers
11.1	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Date of surgery (left breast)	___ (dd-mm-yyyy)
11.2	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: Breast-conserving surgery (left breast)	Unknown Unknown (unknown significant) Not known (not recorded, not asked, not applicable, lost to follow-up, refused to participate, DNR)
11.3	If Breast-conserving surgery (left breast) 'Yes' answer this question: Pathological Staging (pT-stage)	Tis T1 T2 T3 T4 Unknown N/A - Not Applicable
11.4	If Breast-conserving surgery (left breast) 'Yes' answer this question: Pathological Staging (pN-stage)	N0 N1 N2 N3 Unknown N/A - Not Applicable
11.5	If Breast-conserving surgery (left breast) 'Yes' answer this question: Pathological Staging (pM-stage)	M0 M1 Unknown N/A - Not Applicable
11.6	If Breast-conserving surgery (left breast) 'Yes' answer this question: Surgical margins status	Tumor cells present Tumor cells absent Unknown N/A - Not Applicable
11.7	If Breast-conserving surgery (left breast) 'Yes' answer this question: Surgical margins status (left breast)	Yes, PRE No Unknown
11.8	If Breast-conserving surgery (left breast) 'Yes' answer this question: Surgical margins status (left breast)	Yes, POST No Unknown
11.9	If Breast-conserving surgery (left breast) 'Yes' answer this question: Surgical margins status (left breast)	Positive Negative Unknown
11.10	If Breast-conserving surgery (left breast) 'Yes' answer this question: Surgical margins status (left breast)	Yes No Unknown

12. Treatment - Final Histopathology Right Breast

Some questions use Left Breast. No data needs to be recorded at this section.

Number	Question	Answers
12.1	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Date of surgery (right breast)	___ (dd-mm-yyyy)
12.2	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Right breast' answer this question: Breast-conserving surgery (right breast) Warning: Value of 'Unknown' is rare or unlikely for 10 cancer cohorts. Unknown (unknown significant) is also possible	Unknown Unknown (unknown significant) Not known (not recorded, not asked, not applicable, lost to follow-up, refused to participate, DNR)
12.3	If Breast-conserving surgery (right breast) 'Yes' answer this question: Pathological Staging (pT-stage)	Tis T1 T2 T3 T4 Unknown N/A - Not Applicable
12.4	If Breast-conserving surgery (right breast) 'Yes' answer this question: Pathological Staging (pN-stage)	N0 N1 N2 N3 Unknown N/A - Not Applicable
12.5	If Breast-conserving surgery (right breast) 'Yes' answer this question: Pathological Staging (pM-stage)	M0 M1 Unknown N/A - Not Applicable
12.6	If Breast-conserving surgery (right breast) 'Yes' answer this question: Surgical margins status	Tumor cells present Tumor cells absent Unknown N/A - Not Applicable
12.7	If Breast-conserving surgery (right breast) 'Yes' answer this question: Surgical margins status (right breast)	Yes, PRE No Unknown
12.8	If Breast-conserving surgery (right breast) 'Yes' answer this question: Surgical margins status (right breast)	Yes, POST No Unknown
12.9	If Breast-conserving surgery (right breast) 'Yes' answer this question: Surgical margins status (right breast)	Positive Negative Unknown
12.10	If Breast-conserving surgery (right breast) 'Yes' answer this question: Surgical margins status (right breast)	Yes No Unknown

13. Treatment - Assessment Risk Factors Post-surgery

Number	Question	Answers
13.1	If Tumor location (first visit in case of bilateral breast cancer) is equal to 'Left breast' answer this question: DIEP reconstruction (Left breast)	Yes No

14. Treatment - Acute Toxicity Evaluations Left Breast

Number	Question	Answers
	Total Acute Lean Left Breast: No data needs to be recorded at this series.	
14.1	If Acute toxicity did not occur in Left Breast then select "Yes" to answer this question Without acute toxicities recorded?	Yes No
14.1.1	If Acute toxicity was performed in regard to "lung" answer this question Acute toxicity in lungs?	Yes No Unknown
14.2	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.2.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.3	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.3.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.4	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.4.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.5	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.5.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.6	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.6.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.7	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.7.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.8	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.8.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.9	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.9.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.10	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.10.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.11	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.11.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.12	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.12.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.13	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.13.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.14	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.14.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
14.15	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
14.15.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown

15. Treatment - Acute Toxicity Evaluations Right Breast

Number	Question	Answers
	Total Acute Lean Left Breast: No data needs to be recorded at this series.	
15.1	If Acute toxicity did not occur in Right Breast then select "Yes" to answer this question Without acute toxicities recorded?	Yes No
15.1.1	If Acute toxicity was performed in regard to "lung" answer this question Acute toxicity in lungs?	Yes No Unknown
15.2	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.2.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.3	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.3.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.4	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.4.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.5	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.5.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.6	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.6.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.7	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.7.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.8	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.8.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.9	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.9.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.10	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.10.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.11	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.11.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.12	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.12.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.13	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.13.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.14	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.14.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
15.15	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
15.15.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown

16. Treatment - Study Status

Number	Question	Answers
16.1	Patient status	Patient is Alive Patient is Deceased Patient lost to follow-up Patient Alive
16.1.1	Patient status "is alive"/"Patient Alive" answer this question Patient is alive?	YYYY-MM-DD
16.1.2	Patient status "is alive"/"Patient Alive" answer this question Patient health	Breast cancer free Contralateral breast cancer Other cancer diagnosed Other
16.1.3	Patient status "is alive"/"Patient Alive" answer this question Patient status?	Alive Deceased
16.1.4	Patient status "is alive"/"Patient Alive" answer this question Patient lost to follow-up?	YYYY-MM-DD

17. Week 8 Visit - Date of Visit

Number	Question	Answers
17.1	Date of visit	YYYY-MM-DD
17.2	Patient weight	kg

18. Week 8 Visit - Karnofsky Performance Status

Number	Question	Answers
18.1	Karnofsky performance status	100 - Normal, no complaints, no evidence of disease 90 - Able to carry on normal activity, minor signs or symptoms of disease 80 - Normal activity with effort, some signs or symptoms of disease 70 - Cares for self, unable to carry on normal activity or to do active work 60 - Requires occasional assistance, but is able to care for most of his needs 50 - Requires considerable assistance and frequent medical care 40 - Disabled, requires special care and assistance 30 - Severely disabled, hospitalization is indicated although death not imminent 20 - Very sick, hospitalization necessary, requires active supportive treatment 10 - Moribund, fatal processes progressing rapidly

19. Week 8 Visit - Adjuvant Systemic Treatment

Number	Question	Answers
19.1	Received patient adjuvant systemic treatment post surgery	Yes No
19.1.1	If Received patient adjuvant systemic treatment post surgery" is "Yes" answer this question Adjuvant systemic treatment post surgery?	Chemotherapy Hormonal therapy Immunotherapy Other
19.1.2	If Adjuvant Systemic Therapy Start was given after all the surgery" is equal to "Chemotherapy" answer this question Start date of chemotherapy	YYYY-MM-DD
19.1.3	If Adjuvant Systemic Therapy Start was given after all the surgery" is equal to "Hormonal therapy" answer this question Start date of hormonal therapy	YYYY-MM-DD
19.1.4	If Adjuvant Systemic Therapy Start was given after all the surgery" is equal to "Biotherapy" answer this question Start date of biotherapy	YYYY-MM-DD
19.1.5	If Adjuvant Systemic Therapy Start was given after all the surgery" is equal to "Antihormonal therapy" answer this question Start date of antihormonal therapy	YYYY-MM-DD
19.1.6	If Adjuvant Systemic Therapy Start was given after all the surgery" is equal to "Immunotherapy" answer this question Start date of immunotherapy	YYYY-MM-DD
19.1.7	If Adjuvant Immunotherapy" is equal to "Other" answer this question Other adjuvant therapy	Trastuzumab Other

20. Week 8 Visit - EBRT details

Number	Question	Answers
	EBRT Left breast: No data needs to be recorded at this series. EBRT Left breast lymph Node: Contours is not saved.	
20.1	If the patient EBRT treatment is left to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Was the patient EBRT treatment left to the presence of post-surgery tumor bed performed?	Yes No
20.1.1	If the the patient EBRT treatment left to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Start date of the patient EBRT treatment left to the presence of post-surgery tumor bed	YYYY-MM-DD
20.1.2	If the the patient EBRT treatment left to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question End date of the patient EBRT treatment left to the presence of post-surgery tumor bed	YYYY-MM-DD
20.1.3	If the the patient EBRT treatment left to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Dose of the patient EBRT treatment left to the presence of post-surgery tumor bed (Gy) Total dose of the patient EBRT treatment left to the presence of post-surgery tumor bed (Gy) Fractionation of the patient EBRT treatment left to the presence of post-surgery tumor bed Total number of fractions of the patient EBRT treatment left to the presence of post-surgery tumor bed	
20.1.4	If the the patient EBRT treatment left to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Technique of the patient EBRT treatment left to the presence of post-surgery tumor bed	Standard 2D 3DCRT IMRT Other
20.1.5	If the the patient EBRT treatment left to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Other technique of the patient EBRT treatment left to the presence of post-surgery tumor bed	Text
20.2	If EBRT is a prescribed for the Right Breast" is equal to "Yes" answer this question Was the patient EBRT treatment Right Breast performed?	Yes No
20.2.1	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Start date of the patient EBRT treatment (RB)	YYYY-MM-DD
20.2.2	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question End date of the patient EBRT treatment (RB)	YYYY-MM-DD
20.2.3	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Dose of the patient EBRT treatment (RB) (Gy) Total dose of the patient EBRT treatment (RB) (Gy) Fractionation of the patient EBRT treatment (RB) Total number of fractions of the patient EBRT treatment (RB) Technique of the patient EBRT treatment (RB) Other technique of the patient EBRT treatment (RB)	
20.2.4	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Technique of the patient EBRT treatment (RB)	Standard 2D 3DCRT IMRT Other
20.2.5	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Other technique of the patient EBRT treatment (RB)	Text
20.3	If EBRT is a prescribed for the Right Breast" is equal to "Yes" answer this question Was the patient EBRT treatment Right Breast performed?	Yes No
20.3.1	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Start date of the patient EBRT treatment (RB)	YYYY-MM-DD
20.3.2	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question End date of the patient EBRT treatment (RB)	YYYY-MM-DD
20.3.3	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Dose of the patient EBRT treatment (RB) (Gy) Total dose of the patient EBRT treatment (RB) (Gy) Fractionation of the patient EBRT treatment (RB) Total number of fractions of the patient EBRT treatment (RB) Technique of the patient EBRT treatment (RB) Other technique of the patient EBRT treatment (RB)	
20.3.4	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Technique of the patient EBRT treatment (RB)	Standard 2D 3DCRT IMRT Other
20.3.5	If the the patient EBRT treatment (RB) due to the presence of post-surgery tumor bed was performed" is equal to "Yes" answer this question Other technique of the patient EBRT treatment (RB)	Text

21. Week 8 Visit - Tumor Evaluations Left Breast

Number	Question	Answers
	Total Acute Lean Left Breast: No data needs to be recorded at this series.	
21.1	If Acute toxicity did not occur in Left Breast then select "Yes" to answer this question Without acute toxicities recorded?	Clinical examination Mammography Ultrasound of the breast MRI breast Other imaging technique
21.1.1	If Acute toxicity was performed in regard to "lung" answer this question Acute toxicity in lungs?	YYYY-MM-DD
21.2	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
21.2.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	YYYY-MM-DD
21.3	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
21.3.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	YYYY-MM-DD
21.4	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
21.4.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	YYYY-MM-DD
21.5	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
21.5.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	YYYY-MM-DD
21.6	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
21.6.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	YYYY-MM-DD
21.7	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
21.7.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	YYYY-MM-DD
21.8	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
21.8.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	YYYY-MM-DD

22. Week 8 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Total Acute Lean Left Breast: No data needs to be recorded at this series.	
22.1	If Acute toxicity did not occur in Right Breast then select "Yes" to answer this question Without acute toxicities recorded?	Clinical examination Mammography Ultrasound of the breast MRI breast Other imaging technique
22.1.1	If Acute toxicity was performed in regard to "lung" answer this question Acute toxicity in lungs?	YYYY-MM-DD
22.2	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
22.2.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	YYYY-MM-DD
22.3	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
22.3.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	YYYY-MM-DD
22.4	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
22.4.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	YYYY-MM-DD
22.5	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
22.5.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	YYYY-MM-DD
22.6	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
22.6.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	YYYY-MM-DD
22.7	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
22.7.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	YYYY-MM-DD
22.8	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
22.8.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	YYYY-MM-DD

23. Week 8 Visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Total Acute Lean Left Breast: No data needs to be recorded at this series.	
23.1	If Acute toxicity did not occur in Left Breast then select "Yes" to answer this question Without acute toxicities recorded?	Yes No
23.2	If Acute toxicity was performed in regard to "lung" answer this question Acute toxicity in lungs?	Yes No Unknown
23.3	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.3.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.4	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.4.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.5	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.5.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.6	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.6.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.7	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.7.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.8	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.8.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.9	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.9.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.10	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.10.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.11	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.11.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.12	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.12.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.13	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.13.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.14	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.14.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown
23.15	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Left breast?	Yes No
23.15.1	If Acute toxicity was performed in regard to "Left Breast" answer this question Acute toxicity in Left Breast?	Yes No Unknown

24. Week 8 Visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Total Acute Lean Left Breast: No data needs to be recorded at this series.	
24.1	If Acute toxicity did not occur in Right Breast then select "Yes" to answer this question Without acute toxicities recorded?	Yes No
24.2	If Acute toxicity was performed in regard to "lung" answer this question Acute toxicity in lungs?	Yes No Unknown
24.3	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
24.3.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
24.4	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
24.4.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
24.5	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
24.5.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
24.6	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
24.6.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
24.7	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
24.7.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown
24.8	If Acute toxicity was not in a grade of bilateral breast cancer in regard to "Left breast" answer this question Acute toxicity in Right breast?	Yes No
24.8.1	If Acute toxicity was performed in regard to "Right Breast" answer this question Acute toxicity in Right Breast?	Yes No Unknown

Number	Question	Answers
B01-1-1	Patient Identifier	
B01-1-2	Patient Initials	
B01-1-3	Patient Gender	Male Female Other Unknown
B01-1-4	Patient Ethnic Group	Hispanic or Latino Not Hispanic or Latino Unknown (unable to ascertain) Other ethnic group Refused to answer
B01-1-5	Patient Date of Birth	
B01-1-6	Patient Age	
B01-1-7	Patient Weight	
B01-1-8	Patient Height	
B01-1-9	Patient Smoking Status	Never smoked Ex-smoker Current smoker Unknown
B01-1-10	Patient Alcohol Consumption	Never Ex-drinker Current drinker Unknown
B01-1-11	Patient Performance Status	0 - Fully active, able to carry on all pre-disease performance without restriction 1 - Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work 2 - Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours 3 - Capable of only limited self-care, confined to bed or chair more than 50% of waking hours 4 - Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair 5 - Dead
B01-1-12	Patient Diagnosis	Breast cancer Colorectal cancer Lung cancer Other
B01-1-13	Patient Diagnosis Date	
B01-1-14	Patient Diagnosis Confirmed	Yes No Unknown

25. Week 6 Visit - Patient Questionnaires

Number	Question	Answers
B01-2-1	EORTC QLQ-C30 questionnaire completed	Yes No
B01-2-2	If EORTC QLQ-C30 questionnaire completed, is a score? Yes answer this question	
B01-2-3	EORTC QLQ-C30 questionnaire score	
B01-2-4	If EORTC QLQ-C30 questionnaire completed, is a score? Yes answer this question	
B01-2-5	EORTC QLQ-BR23 questionnaire completed	Yes No
B01-2-6	If EORTC QLQ-BR23 questionnaire completed, is a score? Yes answer this question	
B01-2-7	EORTC QLQ-BR23 questionnaire score	

26. Week 6 Visit - Study Status

Number	Question	Answers
B01-3-1	Patient status	Patient Active Patient Withdrawn Patient Dead
B01-3-2	If Patient status = is equal to 'Patient Dead' answer this question	DD-MM-YYYY
B01-3-3	If Patient status = is equal to 'Patient Dead' answer this question	Breast cancer related Unrelated to breast cancer Unknown Other
B01-3-4	If Patient status = is equal to 'Patient Dead' answer this question	
B01-3-5	Patient death 'is equal to' Other answer this question	
B01-3-6	Patient status = is equal to 'Patient Alive' answer this question	Yes Pending assessment Unknown

27. Month 9 Visit - Date of Visit

Number	Question	Answers
B01-4-1	Date of visit	DD-MM-YYYY
B01-4-2	Patient weight	kg

28. Month 9 Visit - Karnofsky Performance Status

Number	Question	Answers
B01-4-3	Karnofsky performance score	100 - Normal, no complaints; no evidence of disease 90 - Able to carry on normal activity; minor signs or symptoms of disease 80 - Normal activity with effort; some signs or symptoms of disease 70 - Cares for self; unable to carry on normal activity or to do active work 60 - Requires occasional assistance, but is able to care for most of his needs 50 - Requires considerable assistance and frequent medical care 40 - Disabled; requires special care and assistance 30 - Severely disabled; hospitalization is indicated although death is not imminent 20 - Very sick; hospitalization necessary; active supportive treatment necessary 10 - Moribund; fatal processes progressing rapidly 0 - Dead

29. Month 9 Visit - Adjuvant Systemic Treatment

Number	Question	Answers
B01-4-4	Received adjuvant systemic hormonal and/or not (not taxane 6)	Yes No
B01-4-5	If Received adjuvant systemic hormonal and/or not (not taxane 6) is equal to 'Yes' answer this question Regimen for current adjuvant hormonal treatment	Chemotherapy Hormonal therapy Immunotherapy Other
B01-4-6	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Chemotherapy' answer this question Regimen for current adjuvant chemotherapy	DD-MM-YYYY
B01-4-7	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Hormonal therapy' answer this question Regimen for current adjuvant hormonal treatment	Tamoxifen Aromatase inhibitor Ovarian suppression Other
B01-4-8	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Immunotherapy' answer this question Regimen for current adjuvant immunotherapy	Trastuzumab Other
B01-4-9	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Immunotherapy' answer this question Regimen for current adjuvant immunotherapy	
B01-4-10	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Other' answer this question Regimen for current adjuvant other treatment	

30. Month 9 Visit - Tumor Evaluations Left Breast

Number	Question	Answers
Tumor Evaluations Left Breast: No data needs to be recorded on this section.		
B01-5-1	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Method used to assess the tumor response to the left breast	Clinical examination Mammography Ultrasound of the breast MRI Other imaging technique
B01-5-2	If Method used to assess the tumor response to the left breast is equal to 'Mammography' answer this question Date of mammogram	DD-MM-YYYY
B01-5-3	If Method used to assess the tumor response to the left breast is equal to 'Ultrasound of the breast' answer this question Date of ultrasound	DD-MM-YYYY
B01-5-4	If Method used to assess the tumor response to the left breast is equal to 'MRI' answer this question Date of MRI	DD-MM-YYYY
B01-5-5	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Left breast tumor present	Yes No Unknown
B01-5-6	If Left breast tumor present is yes or is equal to 'Yes' answer this question Date of the diagnosis left breast	DD-MM-YYYY
B01-5-7	If Left breast tumor present is yes or is equal to 'Yes' answer this question Tumor measurement (longest diameter)	Yes No Unknown
B01-5-8	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Left breast tumor measurement (longest diameter)	
B01-5-9	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Tumor measurement (perpendicular)	
B01-5-10	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Tumor measurement (perpendicular)	
B01-5-11	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Left breast metastasis	Yes No Unknown
B01-5-12	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Lymphatic metastasis in axilla present	Yes No Unknown
B01-5-13	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Lymphatic metastasis in the internal mammary	Yes No Unknown
B01-5-14	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Lymphatic metastasis in other lymphatic	Yes No Unknown

31. Month 9 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
Tumor Evaluations Right Breast: No data needs to be recorded on this section.		
B01-6-1	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Method used to assess the tumor response to the right breast	Clinical examination Mammography Ultrasound of the breast MRI Other imaging technique
B01-6-2	If Method used to assess the tumor response to the right breast is equal to 'Mammography' answer this question Date of mammogram	DD-MM-YYYY
B01-6-3	If Method used to assess the tumor response to the right breast is equal to 'Ultrasound of the breast' answer this question Date of ultrasound	DD-MM-YYYY
B01-6-4	If Method used to assess the tumor response to the right breast is equal to 'MRI' answer this question Date of MRI	DD-MM-YYYY
B01-6-5	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Right breast tumor present	Yes No Unknown
B01-6-6	If Right breast tumor present is yes or is equal to 'Yes' answer this question Date of the diagnosis right breast	DD-MM-YYYY
B01-6-7	If Right breast tumor present is yes or is equal to 'Yes' answer this question Tumor measurement (longest diameter)	Yes No Unknown
B01-6-8	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Right breast tumor measurement (longest diameter)	
B01-6-9	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Tumor measurement (perpendicular)	
B01-6-10	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Tumor measurement (perpendicular)	
B01-6-11	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Right breast metastasis	Yes No Unknown
B01-6-12	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Lymphatic metastasis in axilla present	Yes No Unknown
B01-6-13	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Lymphatic metastasis in the internal mammary	Yes No Unknown
B01-6-14	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Lymphatic metastasis in other lymphatic	Yes No Unknown

32. Month 9 Visit - Toxicity Evaluations Left Breast

Number	Question	Answers
Toxicity Evaluations Left Breast: No data needs to be recorded on this section.		
B01-7-1	If Toxicity Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Adverse events performed	Yes No
B01-7-2	If Adverse events performed is equal to 'Yes' answer this question Number of adverse events	
B01-7-3	If Toxicity Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Adverse events present	Yes No Unknown
B01-7-4	If Adverse events present is yes or is equal to 'Yes' answer this question Adverse events grade	1-4
B01-7-5	If Toxicity Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Adverse events grade	Yes No Unknown
B01-7-6	If Adverse events grade is equal to '4' answer this question Adverse events grade	1-4
B01-7-7	If Adverse events grade is equal to '4' answer this question Adverse events grade	1-4
B01-7-8	If Toxicity Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Adverse events reported as the clinical assessment	No reactions Local skin reaction Arm lymphedema Other
B01-7-9	If Adverse events reported as the clinical assessment is equal to 'Yes' answer this question Adverse events	Hematologic Toxicity (including Neutropenia, Thrombocytopenia, Anemia) Cardiac Toxicities Pulmonary Toxicities Hepatic Toxicities Neuropathy Other
B01-7-10	If Adverse events is equal to 'Hematologic Toxicity (including Neutropenia, Thrombocytopenia, Anemia)' answer this question Grade for "Hematologic Toxicity"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences
B01-7-11	If Adverse events is equal to 'Cardiac Toxicities' answer this question Grade for "Cardiac Toxicities"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty
B01-7-12	If Adverse events is equal to 'Pulmonary Toxicities' answer this question Grade for "Pulmonary Toxicities"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty
B01-7-13	If Adverse events is equal to 'Hepatic Toxicities' answer this question Grade for "Hepatic Toxicities"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty
B01-7-14	If Adverse events is equal to 'Neuropathy' answer this question Grade for "Neuropathy"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty
B01-7-15	If Adverse events is equal to 'Other' answer this question Grade for "Other"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty

33. Month 9 Visit - Toxicity Evaluations Right Breast

Number	Question	Answers
Toxicity Evaluations Left Breast: No data needs to be recorded on this section.		
B01-8-1	If Toxicity Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Adverse events performed	Yes No
B01-8-2	If Adverse events performed is equal to 'Yes' answer this question Number of adverse events	
B01-8-3	If Toxicity Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Adverse events present	Yes No Unknown
B01-8-4	If Adverse events present is yes or is equal to 'Yes' answer this question Adverse events grade	1-4
B01-8-5	If Toxicity Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Adverse events grade	Yes No Unknown
B01-8-6	If Adverse events grade is equal to '4' answer this question Adverse events grade	1-4
B01-8-7	If Adverse events grade is equal to '4' answer this question Adverse events grade	1-4
B01-8-8	If Toxicity Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Adverse events reported as the clinical assessment	No reactions Local skin reaction Arm lymphedema Other
B01-8-9	If Adverse events reported as the clinical assessment is equal to 'Yes' answer this question Adverse events	Hematologic Toxicity (including Neutropenia, Thrombocytopenia, Anemia) Cardiac Toxicities Pulmonary Toxicities Hepatic Toxicities Neuropathy Other
B01-8-10	If Adverse events is equal to 'Hematologic Toxicity (including Neutropenia, Thrombocytopenia, Anemia)' answer this question Grade for "Hematologic Toxicity"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty
B01-8-11	If Adverse events is equal to 'Cardiac Toxicities' answer this question Grade for "Cardiac Toxicities"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty
B01-8-12	If Adverse events is equal to 'Pulmonary Toxicities' answer this question Grade for "Pulmonary Toxicities"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty
B01-8-13	If Adverse events is equal to 'Hepatic Toxicities' answer this question Grade for "Hepatic Toxicities"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty
B01-8-14	If Adverse events is equal to 'Neuropathy' answer this question Grade for "Neuropathy"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty
B01-8-15	If Adverse events is equal to 'Other' answer this question Grade for "Other"	Grade 0 - 1 or 2 or 3 or 4 Grade Grade 1 - 2 or 3 or 4 Grade Grade 2 - 3 or 4 Grade Grade 3 - 4 Grade Grade 4 - Life-threatening consequences, Angioplasty

34. Month 9 Visit - Patient Questionnaires

Number	Question	Answers
B01-9-1	EORTC QLQ-C30 questionnaire completed	Yes No
B01-9-2	If EORTC QLQ-C30 questionnaire completed, is a score? Yes answer this question	
B01-9-3	EORTC QLQ-C30 questionnaire score	
B01-9-4	If EORTC QLQ-C30 questionnaire completed, is a score? Yes answer this question	
B01-9-5	EORTC QLQ-BR23 questionnaire completed	Yes No
B01-9-6	If EORTC QLQ-BR23 questionnaire completed, is a score? Yes answer this question	
B01-9-7	EORTC QLQ-BR23 questionnaire score	

35. Month 9 Visit - Study Status

Number	Question	Answers
B01-9-8	Patient status	Patient Active Patient Withdrawn Patient Dead
B01-9-9	If Patient status = is equal to 'Patient Dead' answer this question Patient death	DD-MM-YYYY
B01-9-10	If Patient status = is equal to 'Patient Dead' answer this question Patient death	Breast cancer related Unrelated to breast cancer Unknown Other
B01-9-11	Patient death 'is equal to' Other answer this question Patient death	
B01-9-12	If Patient status = is equal to 'Patient Dead' answer this question Pending assessment	Yes No Unknown

36. Month 12 Visit - Date of Visit

Number	Question	Answers
B01-10-1	Date of visit	DD-MM-YYYY
B01-10-2	Patient weight	kg

37. Month 12 Visit - Karnofsky Performance Status

Number	Question	Answers
B01-10-3	Karnofsky performance score	100 - Normal, no complaints; no evidence of disease 90 - Able to carry on normal activity; minor signs or symptoms of disease 80 - Normal activity with effort; some signs or symptoms of disease 70 - Cares for self; unable to carry on normal activity or to do active work 60 - Requires occasional assistance, but is able to care for most of his needs 50 - Requires considerable assistance and frequent medical care 40 - Disabled; requires special care and assistance 30 - Severely disabled; hospitalization is indicated although death is not imminent 20 - Very sick; hospitalization necessary; active supportive treatment necessary 10 - Moribund; fatal processes progressing rapidly 0 - Dead

38. Month 12 Visit - Adjuvant Systemic Treatment

Number	Question	Answers
B01-10-4	Received adjuvant systemic hormonal and/or not (not taxane 6)	Yes No
B01-10-5	If Received adjuvant systemic hormonal and/or not (not taxane 6) is equal to 'Yes' answer this question Regimen for current adjuvant hormonal treatment	Chemotherapy Hormonal therapy Immunotherapy Other
B01-10-6	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Chemotherapy' answer this question Regimen for current adjuvant chemotherapy	DD-MM-YYYY
B01-10-7	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Hormonal therapy' answer this question Regimen for current adjuvant hormonal treatment	Tamoxifen Aromatase inhibitor Ovarian suppression Other
B01-10-8	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Immunotherapy' answer this question Regimen for current adjuvant immunotherapy	Trastuzumab Other
B01-10-9	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Immunotherapy' answer this question Regimen for current adjuvant immunotherapy	
B01-10-10	If Regimen for Adjuvant Systemic Therapy Plan was given (Not all that apply) is equal to 'Other' answer this question Regimen for current adjuvant other treatment	

39. Month 12 Visit - Tumor Evaluations Left Breast

Number	Question	Answers
Tumor Evaluations Left Breast: No data needs to be recorded on this section.		
B01-11-1	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Method used to assess the tumor response to the left breast	Clinical examination Mammography Ultrasound of the breast MRI Other imaging technique
B01-11-2	If Method used to assess the tumor response to the left breast is equal to 'Mammography' answer this question Date of mammogram	DD-MM-YYYY
B01-11-3	If Method used to assess the tumor response to the left breast is equal to 'Ultrasound of the breast' answer this question Date of ultrasound	DD-MM-YYYY
B01-11-4	If Method used to assess the tumor response to the left breast is equal to 'MRI' answer this question Date of MRI	DD-MM-YYYY
B01-11-5	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Left breast tumor present	Yes No Unknown
B01-11-6	If Left breast tumor present is yes or is equal to 'Yes' answer this question Date of the diagnosis left breast	DD-MM-YYYY
B01-11-7	If Left breast tumor present is yes or is equal to 'Yes' answer this question Tumor measurement (longest diameter)	Yes No Unknown
B01-11-8	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Left breast tumor measurement (longest diameter)	
B01-11-9	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Tumor measurement (perpendicular)	
B01-11-10	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Tumor measurement (perpendicular)	
B01-11-11	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Left breast metastasis	Yes No Unknown
B01-11-12	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Lymphatic metastasis in axilla present	Yes No Unknown
B01-11-13	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Lymphatic metastasis in the internal mammary	Yes No Unknown
B01-11-14	If Tumor Evaluations Left Breast: No data needs to be recorded on this section. is equal to 'Left breast' answer this question Lymphatic metastasis in other lymphatic	Yes No Unknown

40. Month 12 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
Tumor Evaluations Right Breast: No data needs to be recorded on this section.		
B01-12-1	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Method used to assess the tumor response to the right breast	Clinical examination Mammography Ultrasound of the breast MRI Other imaging technique
B01-12-2	If Method used to assess the tumor response to the right breast is equal to 'Mammography' answer this question Date of mammogram	DD-MM-YYYY
B01-12-3	If Method used to assess the tumor response to the right breast is equal to 'Ultrasound of the breast' answer this question Date of ultrasound	DD-MM-YYYY
B01-12-4	If Method used to assess the tumor response to the right breast is equal to 'MRI' answer this question Date of MRI	DD-MM-YYYY
B01-12-5	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Right breast tumor present	Yes No Unknown
B01-12-6	If Right breast tumor present is yes or is equal to 'Yes' answer this question Date of the diagnosis right breast	DD-MM-YYYY
B01-12-7	If Right breast tumor present is yes or is equal to 'Yes' answer this question Tumor measurement (longest diameter)	Yes No Unknown
B01-12-8	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Right breast tumor measurement (longest diameter)	
B01-12-9	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Tumor measurement (perpendicular)	
B01-12-10	If Tumor measurement (longest diameter) is equal to 'Yes' answer this question Tumor measurement (perpendicular)	
B01-12-11	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Right breast metastasis	Yes No Unknown
B01-12-12	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Lymphatic metastasis in axilla present	Yes No Unknown
B01-12-13	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Lymphatic metastasis in the internal mammary	Yes No Unknown
B01-12-14	If Tumor Evaluations Right Breast: No data needs to be recorded on this section. is equal to 'Right breast' answer this question Lymphatic metastasis in other lymphatic	Yes No Unknown

Number	Question	Answers
	Complete sarcoma?	
		Yes No Unknown
B1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Laryngeal metastasis in the sarcoma?	Yes No Unknown
B1-2	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Lung metastasis in the sarcoma?	Yes No Unknown
B1-3	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Other metastasis?	Yes No Unknown

40. Month 12 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Tumor location over all Breast. No data needs to be recorded at this series.	
A1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Pathologic evaluation of the tumor?	Chest wall Skin Chest wall and skin Other Pathologic Evaluation
B1-2	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Pathologic evaluation of the tumor?	Yes No Unknown
B1-3	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-4	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-5	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-6	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-7	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-8	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown

41. Month 12 Visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location over Left Breast. No data needs to be recorded at this series.	
A1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
A1-2	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Pathologic evaluation of the tumor?	Chest wall Skin Chest wall and skin Other Pathologic Evaluation
B1-2	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Pathologic evaluation of the tumor?	Yes No Unknown
B1-3	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-4	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-5	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-6	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-7	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-8	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown

42. Month 12 Visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location over Left Breast. No data needs to be recorded at this series.	
A1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
A1-2	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-1	Patient weight (kg)	[ ] kg
B1-2	Patient height (cm)	[ ] cm
B1-3	Patient ethnicity	Hispanic or Latino Not Hispanic or Latino Unknown
B1-4	Patient race	American Indian or Alaska Native Asian Black or African American Native Hawaiian or other Pacific Islander White Other Unknown
B1-5	Patient gender	Male Female Unknown
B1-6	Patient date of birth	[ ] MM-DD-YYYY
B1-7	Patient weight	[ ] kg

46. Month 24 visit - Karnofsky Performance Status

Number	Question	Answers
B1-1	Karnofsky performance score	100 - Normal, no complaints; no evidence of disease 90 - Able to carry on normal activity; minor signs or symptoms of disease 80 - Normal activity with effort; some signs or symptoms of disease 70 - Cares for self; unable to carry on normal activity or to do work 60 - Requires occasional assistance, but is able to care for most of his needs 50 - Requires considerable assistance and frequent medical care 40 - Disabled; requires special care and assistance 30 - Severely disabled; hospitalization is indicated although death is not imminent 20 - Very sick; hospitalization necessary; active supportive treatment necessary 10 - Moribund; fatal processes progressing rapidly 0 - Dead

47. Month 24 visit - Adjuvant Systemic Treatment

Number	Question	Answers
A1-1	Received patient adjuvant Systemic treatment since last visit (Month 12)?	Yes No Unknown
A1-2	If Received patient adjuvant Systemic treatment since last visit (Month 12) is equal to 'Yes' answer this question: Received patient adjuvant Systemic treatment since last visit (Month 12)?	Chemotherapy Hormonal therapy Immunotherapy Other
A1-3	If Select the Adjuvant Systemic Therapy that was given after all other surgery? is equal to 'Chemotherapy' answer this question: Specify the current administered therapy?	Chemotherapy Hormonal therapy Immunotherapy Other
A1-4	If Select the Adjuvant Systemic Therapy that was given after all other surgery? is equal to 'Hormonal therapy' answer this question: Specify the current administered therapy?	Tamoxifen Aromatase inhibitor Other
A1-5	If Select the Adjuvant Systemic Therapy that was given after all other surgery? is equal to 'Immunotherapy' answer this question: Specify the current administered therapy?	Herceptin Other
A1-6	If Select the Adjuvant Systemic Therapy that was given after all other surgery? is equal to 'Other' answer this question: Specify the current administered therapy?	Other

48. Month 24 visit - Tumor Evaluations Left Breast

Number	Question	Answers
	Tumor location over Left Breast. No data needs to be recorded at this series.	
A1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Chest wall/skin Mastectomy Chest wall/skin and mastectomy Biopsy site Other Pathologic Evaluation
B1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Lung metastasis?	Yes No Unknown
B1-2	Patient weight (kg)	[ ] kg
B1-3	Patient height (cm)	[ ] cm
B1-4	Patient date of visit	[ ] MM-DD-YYYY
B1-5	Patient weight	[ ] kg

49. Month 24 visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Tumor location over Left Breast. No data needs to be recorded at this series.	
A1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Chest wall/skin Mastectomy Chest wall/skin and mastectomy Biopsy site Other Pathologic Evaluation
B1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Lung metastasis?	Yes No Unknown
B1-2	Patient weight (kg)	[ ] kg
B1-3	Patient height (cm)	[ ] cm
B1-4	Patient date of visit	[ ] MM-DD-YYYY
B1-5	Patient weight	[ ] kg

50. Month 24 visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location over Left Breast. No data needs to be recorded at this series.	
A1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
A1-2	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Left breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-1	Patient weight (kg)	[ ] kg
B1-2	Patient height (cm)	[ ] cm
B1-3	Patient ethnicity	Hispanic or Latino Not Hispanic or Latino Unknown
B1-4	Patient race	American Indian or Alaska Native Asian Black or African American Native Hawaiian or other Pacific Islander White Other Unknown
B1-5	Patient gender	Male Female Unknown
B1-6	Patient date of birth	[ ] MM-DD-YYYY
B1-7	Patient weight	[ ] kg

51. Month 24 visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location over Left Breast. No data needs to be recorded at this series.	
A1-1	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
A1-2	If Bone tumors did not in use of bilateral breast cancer? is equal to 'Right breast' answer this question: Tissue or bone excavated and sent for pathologic evaluation?	Yes No Unknown
B1-1	Patient weight (kg)	[ ] kg
B1-2	Patient height (cm)	[ ] cm
B1-3	Patient ethnicity	Hispanic or Latino Not Hispanic or Latino Unknown
B1-4	Patient race	American Indian or Alaska Native Asian Black or African American Native Hawaiian or other Pacific Islander White Other Unknown
B1-5	Patient gender	Male Female Unknown
B1-6	Patient date of birth	[ ] MM-DD-YYYY
B1-7	Patient weight	[ ] kg

Number	Question	Answers
8.1.1	**Patient has been diagnosed with a type of breast cancer suitable for Right Breast** *(select the possible answer)*	Yes / No
8.1.2	**Where was tumorectomy performed at the clinical examination?** *(select the possible answer)*	Skin excision Breast excision Axillary dissection
8.1.3	**Specify the detected tumorectomy** *(select the possible answer)*	Ductal carcinoma Lobular carcinoma Other
8.1.4	**Specify the detected tumorectomy** *(select the possible answer)*	Grade 1 - G1 Low Grade Grade 2 - G2 Intermediate Grade 3 - G3 High Grade Grade 4 - G4 Undifferentiated
8.1.5	**Specify the detected tumorectomy** *(select the possible answer)*	Tis - Carcinoma in situ T1 - Tumor < 2 cm T2 - Tumor > 2 cm T3 - Tumor > 5 cm T4 - Tumor of any size with direct extension (fixation, infiltration)
8.1.6	**Specify the detected tumorectomy** *(select the possible answer)*	Stage 0 (Tis) Stage I (T1) Stage II (T2, T3) Stage III (T4) Stage IV (Metastasis)
8.1.7	**Specify the detected tumorectomy** *(select the possible answer)*	Ductal carcinoma Lobular carcinoma Tubular carcinoma Medullary carcinoma Mucinous carcinoma Papillary carcinoma Other
8.1.8	**Specify the detected tumorectomy** *(select the possible answer)*	Yes No
8.1.9	**Specify the detected tumorectomy** *(select the possible answer)*	Yes No Unknown
8.1.10	**Specify the detected tumorectomy** *(select the possible answer)*	Stage 0 Stage I Stage II Stage III Stage IV Unknown
8.1.11	**Specify the detected tumorectomy** *(select the possible answer)*	Yes No Unknown
8.1.12	**Specify the detected tumorectomy** *(select the possible answer)*	Grade 1 - Well differentiated Grade 2 - Moderate differentiated Grade 3 - Poorly differentiated Grade 4 - Undifferentiated
8.1.13	**Specify the detected tumorectomy** *(select the possible answer)*	Grade 1 - Tubule formation Grade 2 - Nuclear pleomorphism
8.1.14	**Specify the detected tumorectomy** *(select the possible answer)*	Grade 1 - Low Grade 2 - Intermediate Grade 3 - High
8.1.15	**Specify the detected tumorectomy** *(select the possible answer)*	Grade 1 - Low Grade 2 - Intermediate Grade 3 - High
8.1.16	**Specify the detected tumorectomy** *(select the possible answer)*	Grade 1 - Low Grade 2 - Intermediate Grade 3 - High

Number	Question	Answers
	Study Subjects with Right Breast: No data needs to be recorded in this section.	
66-1.1.0	If Tumor Excisions (left breast or right breast) or Tumor Lumpectomy (left breast or right breast) answer this question: Please select the tumor excision method that was performed for the right breast.	Clinical examination Mammography Ultrasound Image-MR Other diagnostic test Other
66-1.1.1	If Tumor excision (left breast or right breast) answer this question: Please enter the tumor excision methods that were performed for the right breast, in order.	Clinical examination Mammography Ultrasound Image-MR Other diagnostic test Other Unknown
66-1.2	If Tumor excision (left breast or right breast) answer this question: Please enter the number of tumors excised from the right breast.	[ ] [ ] [ ]

77.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Signs of osteoradionecrosis:	◯ Yes ◯ No ◯ Unknown
77.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any toxicities considered serious (e.g., meets the SAE definitions)?	◯ Yes ◯ No
77.5.1	***If 'Where any toxicities considered serious (e.g., meets the SAE definitions)?' is equal to 'Yes' answer this question:*** Where any serious toxicities related to surgery or radiation?	◯ Yes ◯ No
77.5.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

78. Month 60 Visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
78.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Seroma intervention performed:	◯ Yes ◯ No
78.1.1	***If 'Seroma intervention performed:' is equal to 'Yes' answer this question:*** Number of aspirations:	[ ]
78.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Breast volume assessed with planning CT:	◯ Yes ◯ No ◯ Unknown
78.2.1	***If 'Breast volume assessed with planning CT:' is eqal to 'Yes' answer this question:*** Breast volume (CT):	[ ] ml
78.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
78.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	[ ] ml
78.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Where any toxicities observed at the clinical examination:	◯ Yes ◯ No
78.3.1	***If 'Where any toxicities observed at the clinical examination:' is equal to 'Yes' answer this question:*** Specify the observed toxicities:	☐ Skin toxicities ☐ Breast edema ☐ Arm lymphedema ☐ Pain
78.3.1.1	***If 'Specify the observed toxicities:' is equal to 'Breast edema' answer this question:*** Grade for "Breast edema":	◯ Grade 1: Asymptomatic Symptomatic Secundary dysfunction ◯ Grade 2: Symptomatic ◯ Grade 3: Secondary dysfunction
78.3.1.2	***If 'Specify the observed toxicities:' is equal to 'Arm lymphedema' answer this question:*** Grade for "Arm lymphedema":	◯ Grade 1: 2 – 4 cm increase ◯ Grade 2: > 4 – 6 cm increase ◯ Grade 3: > 6 cm increase ◯ Grade 4: Arm with complete dysfunction, Angiosarcoma
78.3.1.3	***If 'Specify the observed toxicities:' is equal to 'Skin toxicities' answer this question:*** Select the skin toxicities that were present:	☐ Skin (CTC) ☐ Wound infection (CTC) ☐ Dermatitis radiation (CTC) ☐ Erythema (Lent Soma) ☐ Pigmentation (Lent Soma) ☐ Teleangiectasia (Lent Soma) ☐ Fibrosis (Lent soma) ☐ Retraction (Lent Soma) ☐ Ulceration (Lent Soma) ☐ Other
78.3.1.3.1	***If 'Select the skin toxicities that were present:' is equal to 'Skin (CTC)' answer this question:*** Grade for "skin" toxicity:	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
78.3.1.3.2	***If 'Select the skin toxicities that were present:' is equal to 'Wound infection (CTC)' answer this question:*** Grade for "wound infection": *Warning shown if field's value is equal to Grade 4: Life-threatening, disabling: 'Grade IV skin toxicities are reasons for discontinuation'*	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
78.3.1.3.3	***If 'Select the skin toxicities that were present:' is equal to 'Dermatitis radiation (CTC)' answer this question:*** Grade for "dermatitis radiation": *Warning shown if field's value is equal to Grade 4: Life-threatening, disabling: 'Grade IV skin toxicities are reasons for discontinuation'*	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
78.3.1.3.4	***If 'Select the skin toxicities that were present:' is equal to 'Erythema (Lent Soma)' answer this question:*** Grade for "erythema": *Warning shown if field's value is equal to : 'Grade IV skin toxicities are reasons for discontinuation'*	◯ Grade 1: ◯ Grade 2: ◯ Grade 3:
78.3.1.3.5	***If 'Select the skin toxicities that were present:' is equal to 'Pigmentation (Lent Soma)' answer this question:*** Grade for "pigmentation":	◯ Grade 1: Transitory, slight ◯ Grade 2: Permanent marked
78.3.1.3.6	***If 'Select the skin toxicities that were present:' is equal to 'Teleangiectasia (Lent Soma)' answer this question:*** Grade for "Teleangiectasia":	◯ Grade 1: < 1cm2 ◯ Grade 2: 1 - 4 cm2 ◯ Grade 3: > 4 cm2
78.3.1.3.7	***If 'Select the skin toxicities that were present:' is equal to 'Fibrosis (Lent soma)' answer this question:*** Grade for "Fibrosis":	◯ Grade 1: Barely palpable, induration/increased density ◯ Grade 2: Marked palpable, induration/increased density ◯ Grade 3: Massive palpable induration/increased density and fixation
78.3.1.3.8	***If 'Select the skin toxicities that were present:' is equal to 'Retraction (Lent Soma)' answer this question:*** Grade for "Retraction":	◯ Grade 1: > 10 - 25% ◯ Grade 2: > 25 - 40% ◯ Grade 3: > 40 - 75% ◯ Grade 4: Whole breast
78.3.1.3.9	***If 'Select the skin toxicities that were present:' is equal to 'Ulceration (Lent Soma)' answer this question:*** Grade for "Ulceration":	◯ Grade 1: Epidermal detachment, < 1 cm ◯ Grade 2: Dermal detachment, > 1 cm² ◯ Grade 3: Ulceration including subcutis ◯ Grade 4: Free bone, necrosis
78.3.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	[ ]
78.3.1.3.11	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Grade for "other":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
78.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Signs of osteoradionecrosis:	◯ Yes ◯ No ◯ Unknown
78.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Where any toxicities considered serious (e.g., meets the SAE definitions)?	◯ Yes ◯ No
78.5.1	***If 'Where any toxicities considered serious (e.g., meets the SAE definitions)?' is equal to 'Yes' answer this question:*** Where any serious toxicities related to surgery or radiation?	◯ Yes ◯ No
78.5.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

79. Month 60 Visit - Patient Questionnaires

Number	Question	Answers
79.1	EORTC QLQ-C30 questionnaire completed:	◯ Yes ◯ No
79.1.1	***If 'EORTC QLQ-C30 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-C30	
79.2	EORTC BR23 questionnaire completed:	◯ Yes ◯ No
79.2.1	***If 'EORTC BR23 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-BM22	

80. Month 60 Visit - Study Status

Number	Question	Answers
80.1	Patient status:	◯ Patient is Alive ◯ Patient Discontinued ◯ Patient Died
80.1.1	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Date of death:	[ ] [ ] [ ] *(dd-mm-yyyy)*
80.1.2	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Reason death:	◯ Breast cancer related ◯ Cardiac/circulation ◯ Other malignant disease ◯ Other
80.1.2.1	***If 'Reason death:' is equal to 'Other' answer this question:*** Please specify "other":	[ ]
80.1.3	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Autopsy performed:	◯ Yes ◯ No ◯ Unknown