Breast QC study - version 33.51

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1. First Visit - Date of Visit

Number	Question	Answers
1.1	Date of visit	[ ] [ ] [ ] *(dd-mm-yyyy)*

2. First Visit - Demographics

Number	Question	Answers
2.1	Age: *Warning shown if field's value is smaller than 18: 'Exclusion criterion. Patient should ≥ 18 years.'*	[ ] Years
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 personal needs ◯ 50 - Requires considerable assistance and frequent medical care ◯ 40 - Disabled, requires special care and assistance ◯ 30 - Severely disabled, hospital admission is indicated although death not imminent ◯ 20 - Very sick, hospital admission 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 (tick both in case of bilateral breast cancer):	☐ Left breast ☐ Right breast
4.1.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Specify quadrant left breast:	○ UO: upper outer ○ LI: lower inner ○ UI: upper inner ○ LO: lower outer ○ DC: retromamillary ○ AT: Axillary tail ○ UO + LO ○ UO + AT ○ LI + LO ○ UI + DC ○ UO + UI ○ LI + UI
4.1.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Indicate which tumor assessments methods were performed for the left breast:	☐ Clinical examination (particularly palpation) ☐ Mammography ☐ ultrasonography ☐ Histopathology ☐ Breast MRI ☐ Hormone receptor test ☐ Hereditary Breast Cancer Gene Mutation ☐ Other
4.1.2.1	***If 'Indicate which tumor assessments methods were performed for the left breast:' is equal to 'Clinical examination (particularly palpation)' answer this question:*** Size of tumor left breast (clinical examination as method):	_____ cm
4.1.2.2	***If 'Indicate which tumor assessments methods were performed for the left breast:' is equal to 'Mammography' answer this question:*** Size of tumor left breast (mammography as method):	_____ cm
4.1.2.3	***If 'Indicate which tumor assessments methods were performed for the left breast:' is equal to 'ultrasonography' answer this question:*** Size of tumor left breast (breast ultrasound as method):	_____ cm
4.1.2.4	***If 'Indicate which tumor assessments methods were performed for the left breast:' is equal to 'Breast MRI' answer this question:*** Size of tumor left breast (breast MRI as method):	_____ cm
4.1.2.5	***If 'Indicate which tumor assessments methods were performed for the left breast:' is equal to 'Other' answer this question:*** Please specify "other" tumor evaluation procedure for the Left breast:	_____
4.1.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Specify quadrant right breast:	○ UO: upper outer ○ LI: lower inner ○ UI: upper inner ○ LO: lower outer ○ DC: retromamillary ○ AT: Axillary tail

		◯ UO + LO ◯ UO + AT ◯ LI + LO ◯ UI + DC ◯ UO + UI ◯ LI + UI
4.1.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Indicate which tumor assessments methods were performed for the right breast:	☐ Clinical examination (particularly palpation) ☐ Mammography ☐ ultrasonography ☐ Histopathology ☐ Breast MRI ☐ Hormone receptor test ☐ Hereditary Breast Cancer Gene Mutation ☐ Other
4.1.4.1	***If 'Indicate which tumor assessments methods were performed for the right breast:' is equal to 'Clinical examination (particularly palpation)' answer this question:*** Size of tumor right breast (clinical examination as method):	[ ] cm
4.1.4.2	***If 'Indicate which tumor assessments methods were performed for the right breast:' is equal to 'Mammography' answer this question:*** Size of tumor right breast (mammography as method):	[ ] cm
4.1.4.3	***If 'Indicate which tumor assessments methods were performed for the right breast:' is equal to 'ultrasonography' answer this question:*** Size of tumor right breast (breast ultrasound as method):	[ ] cm
4.1.4.4	***If 'Indicate which tumor assessments methods were performed for the right breast:' is equal to 'Breast MRI' answer this question:*** Size of tumor right breast (breast MRI as method):	[ ] cm
4.1.4.5	***If 'Indicate which tumor assessments methods were performed for the right breast:' is equal to 'Other' answer this question:*** Please specify "other" tumor evaluation procedure for right breast:	[ ]

5. First Visit - Tumor Staging

Number	Question	Answers
5.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Specify focality of the tumor located at the left breast:	◯ Unifocal ◯ Multifocal ◯ Multicentric ◯ Inconclusive
5.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Specify focality of the tumor located at the right breast:	◯ Unifocal ◯ Multifocal ◯ Multicentric ◯ Inconclusive
5.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Pre-surgery staging of primary tumor (T) left breast:	◯ TX ◯ T1 ◯ T2

		◯ T3 ◯ Tis ◯ Not done
5.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Pre-surgery staging of primary tumor (T) right breast:	◯ TX ◯ T1 ◯ T2 ◯ T3 ◯ Tis ◯ Not done
5.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Pre-surgery staging of regional lymph nodes (N) left breast:	◯ NX ◯ N0 ◯ N1 ◯ N2 ◯ N3 ◯ Not done
5.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Pre-surgery staging of regional lymph nodes (N) right breast:	◯ NX ◯ N0 ◯ N1 ◯ N2 ◯ N3 ◯ Not done
5.7	Pre-surgery staging of metastases (M):	◯ MX ◯ M0 ◯ M1 ◯ Not done

6. First Visit - Tumor Histopathology

Number	Question	Answers
6.1	***If 'Indicate which tumor assessments methods were performed for the left breast:' is equal to 'Histopathology' answer this question:*** Results histology Left Breast:	◯ Invasive-ductal ◯ Invasive-lobular ◯ Other histology ◯ Inconclusive
6.1.1	***If 'Results histology Left Breast:' is equal to 'Invasive-ductal' answer this question:*** Left Breast: Invasive-ductal breast cancer with extensive intraductal component (EIC):	◯ Yes ◯ No ◯ Unknown
6.1.2	***If 'Results histology Left Breast:' is equal to 'Invasive-ductal' answer this question:*** Left Breast: Invasive-ductal breast cancer with lymph vessel invasion (L1):	◯ Yes ◯ No ◯ Unknown

6.1.3	***If 'Results histology Left Breast:' is equal to 'Invasive-lobular' answer this question:*** Left Breast: Invasive-lobular breast cancer with extensive intraductal component (EIC):	◯ Yes ◯ No ◯ Unknown
6.1.4	***If 'Results histology Left Breast:' is equal to 'Invasive-lobular' answer this question:*** Left Breast: Invasive-lobular breast cancer with lymph vessel invasion (L1):	◯ Yes ◯ No ◯ Unknown
6.1.5	***If 'Results histology Left Breast:' is equal to 'Other histology' answer this question:*** Left Breast: Please specify "other" histology:	
6.1.6	***If 'Results histology Left Breast:' is equal to 'Other histology' answer this question:*** Left Breast: Other histology with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown
6.1.7	***If 'Results histology Left Breast:' is equal to 'Other histology' answer this question:*** Left Breast: Other histology with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown
6.2	***If 'Indicate which tumor assessments methods were performed for the left breast:' is equal to 'Hormone receptor test' answer this question:*** Left Breast: Hormone receptor:	◯ Hormone receptor positive ◯ Hormone receptor negative ◯ Inconclusive ◯ No hormone receptor test done
6.3	***If 'Indicate which tumor assessments methods were performed for the left breast:' is equal to 'Hereditary Breast Cancer Gene Mutation' answer this question:*** Left Breast: Hereditary Breast Cancer Gene Mutation:	◯ Postitive ◯ Negative ◯ Variant of Uncertain significant ◯ Not known
6.3.1	***If 'Left Breast: Hereditary Breast Cancer Gene Mutation:' is equal to 'Postitive' answer this question:*** Please specify "Postive":	
6.3.2	***If 'Left Breast: Hereditary Breast Cancer Gene Mutation:' is equal to 'Variant of Uncertain significant' answer this question:*** Please specify "Variant of Uncertain significant":	
6.4	***If 'Indicate which tumor assessments methods were performed for the right breast:' is equal to 'Histopathology' answer this question:*** Results histology Right Breast:	◯ Invasive-ductal ◯ Invasive-lobular ◯ Other histology ◯ Inconclusive
6.4.1	***If 'Results histology Right Breast:' is equal to 'Invasive-ductal' answer this question:*** Right Breast: Invasive-ductal breast cancer with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown
6.4.2	***If 'Results histology Right Breast:' is equal to 'Invasive-ductal' answer this question:*** Right Breast: Invasive-ductal breast cancer with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown
6.4.3	***If 'Results histology Right Breast:' is equal to 'Invasive-lobular' answer this question:*** Right Breast: Invasive-lobular breast cancer with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown

6.4.4	***If 'Results histology Right Breast:' is equal to 'Invasive-lobular' answer this question:*** Right Breast: Invasive-lobular breast cancer with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown
6.4.5	***If 'Results histology Right Breast:' is equal to 'Other histology' answer this question:*** Right Breast: Please specify "other" histology:	
6.4.6	***If 'Results histology Right Breast:' is equal to 'Other histology' answer this question:*** Right Breast: Other histology with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown
6.4.7	***If 'Results histology Right Breast:' is equal to 'Other histology' answer this question:*** Right Breast: Other histology with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown
6.5	***If 'Indicate which tumor assessments methods were performed for the right breast:' is equal to 'Hormone receptor test' answer this question:*** Right Breast: Hormone receptor:	◯ Hormone receptor positive ◯ Hormone receptor negative ◯ Inconclusive ◯ No hormone receptor test done
6.6	***If 'Indicate which tumor assessments methods were performed for the right breast:' is equal to 'Hereditary Breast Cancer Gene Mutation' answer this question:*** Right Breast: Hereditary Breast Cancer Gene Mutation:	◯ Postitive ◯ Negative ◯ Variant of Uncertain significant ◯ Not known
6.6.1	***If 'Right Breast: Hereditary Breast Cancer Gene Mutation:' is equal to 'Postitive' answer this question:*** Please specify "Postive":	
6.6.2	***If 'Right Breast: Hereditary Breast Cancer Gene Mutation:' is equal to 'Variant of Uncertain significant' answer this question:*** Please specify "Variant of Uncertain significant":	

7. First Visit - Assessments Risk Structures Pre-Surgery

Number	Question	Answers
7.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Are there any pre-surgery identified risk factors for the left breast:	◯ Yes ◯ No
7.1.1	***If 'Are there any pre-surgery identified risk factors for the left breast:' is equal to 'Yes' answer this question:*** Specify which pre-surgery risk factors are present for the Left Breast (check all that apply):	◯ Tumor with extensive intraductal component ◯ Tumor with lymph vessel invasion ◯ Tumor is multifocal / multicentric ◯ Tumor size > 3.5 cm ◯ Lymph node involvement ◯ Prior ipsilateral radiation ◯ Prior ipsilateral breast radiation ◯ Prior therapeutic chest radiation ◯ Negative hormone receptors

		◯ Age < 50 years ◯ Her2/neu ◯ Positive hereditary breast cancer gene mutation
7.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Are there any pre-surgery identified risk factors for the Right Breast: *Notice shown if field's value is equal to No: 'Patient can be enrolled in the study and planned for IORT treatment.'*	◯ Yes ◯ No
7.2.1	***If 'Are there any pre-surgery identified risk factors for the Right Breast:' is equal to 'Yes' answer this question:*** Specify which pre-surgery risk factors are present for the Right Breast (check all that apply)::	◯ Tumor with extensive intraductal component ◯ Tumor with lymph vessel invasion ◯ Tumor is multifocal / multicentric ◯ Tumor size > 3.5 cm ◯ Lymph node involvement ◯ Prior ipsilateral radiation ◯ Prior ipsilateral breast radiation ◯ Prior therapeutic chest radiation ◯ Negative hormone receptors ◯ Age < 50 years ◯ Her2/neu ◯ Positive hereditary breast cancer gene mutation

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:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-C30	
8.2	EORTC BR23 questionnaire completed:	◯ Yes ◯ No
8.2.1	***If 'EORTC BR23 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-BR23	

9. Treatment - Treatment Details Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
9.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Date breast conserving surgery (BSC) and IORT treatment:	☐ ☐ ☐ *(dd-mm-yyyy)*
9.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Patient weight at day of surgery Left Breast:	☐ Kilogram
9.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Sentinel Node Examination performed:	○ Yes ○ No ○ Unknown
9.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Was IORT applied after resection:	○ Yes ○ No
9.4.1	***If 'Was IORT applied after resection:' is equal to 'No' answer this question:*** Please provide reason IORT was not given:	○ Wound cavity too big ○ Skin-applicator distance < 5 mm ○ Organisatory failure ○ Technical failure ○ Other
9.4.1.1	***If 'Please provide reason IORT was not given:' is equal to 'Other' answer this question:*** Please specify "other":	☐
9.4.2	***If 'Was IORT applied after resection:' is equal to 'Yes' answer this question:*** Applicator size (cm):	○ 1.5 ○ 2.0 ○ 2.5 ○ 3.0 ○ 3.5 ○ 4.0 ○ 4.5 ○ 5.0
9.4.3	***If 'Was IORT applied after resection:' is equal to 'Yes' answer this question:*** Radiation treatment time: *Notice shown if field's value is smaller than 20: 'Please check entry. Minimum treatment time is 20 minutes.'* *Notice shown if field's value is larger than 50: 'Please check entry. Minimum treatment time is 20 minutes.'*	☐ minutes
9.4.4	***If 'Was IORT applied after resection:' is equal to 'Yes' answer this question:*** Planned dose left breast (surface of the applicator): *Warning shown if field's value is larger than 20: 'Protocol violation. Delivered dose applicator size should be 20 Gy'* *Warning shown if field's value is smaller than 20: 'Protocol violation. Delivered dose applicator size should be 20 Gy'*	☐ Gy
9.4.5	***If 'Was IORT applied after resection:' is equal to 'Yes' answer this question:*** Delivered dose same as planned dose?	○ Yes ○ No

9.4.5.1	***If 'Delivered dose same as planned dose?' is equal to 'No' answer this question:*** Delivered dose (surface of the applicator): *Warning shown if field's value is larger than 20: 'Protocol violation. Delivered dose applicator size should be 20 Gy'* *Warning shown if field's value is smaller than 20: 'Protocol violation. Delivered dose applicator size should be 20 Gy'*	Gy
9.4.5.2	***If 'Delivered dose same as planned dose?' is equal to 'No' answer this question:*** Specify reason Delivered Dose deviates from the Planned Dose?	☐ Logistical reasons ☐ Technical issues ☐ Other, please specify
9.4.5.2.1	***If 'Specify reason Delivered Dose deviates from the Planned Dose?' is equal to 'Other, please specify' answer this question:*** Specify other:	

10. Treatment - Treatment Details Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
10.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Date breast conserving surgery (BSC) and IORT treatment:	*(dd-mm-yyyy)*
10.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Patient weight at day of surgery Right Breast:	Kilogram
10.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Sentinel Node Examination performed:	○ Yes ○ No ○ Unknown
10.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Was IORT applied after resection:	○ Yes ○ No
10.4.1	***If 'Was IORT applied after resection:' is equal to 'No' answer this question:*** Please provide reason IORT was not given:	○ Wound cavity too big ○ Skin-applicator distance < 5 mm ○ Organisatory failure ○ Technical failure ○ Other
10.4.1.1	***If 'Please provide reason IORT was not given:' is equal to 'Other' answer this question:*** Please specify "other":	
10.4.2	***If 'Was IORT applied after resection:' is equal to 'Yes' answer this question:*** Applicator size (cm):	○ 1.5 ○ 2.0 ○ 2.5

		◯ 3.0 ◯ 3.5 ◯ 4.0 ◯ 4.5 ◯ 5.0
10.4.3	***If 'Was IORT applied after resection:' is equal to 'Yes' answer this question:*** Radiation treatment time: *Notice shown if field's value is smaller than 10: 'Please check entry. Minimum treatment time is 10 minutes.'*	[ ] minutes
10.4.4	***If 'Was IORT applied after resection:' is equal to 'Yes' answer this question:*** Planned dose right breast (surface of the applicator): *Warning shown if field's value is larger than 20: 'Protocol violation. Delivered dose applicator size should be 20 Gy'* *Warning shown if field's value is smaller than 20: 'Protocol violation. Delivered dose applicator size should be 20 Gy'*	[ ] Gy
10.4.5	***If 'Was IORT applied after resection:' is equal to 'Yes' answer this question:*** Delivered dose same as planned dose?	◯ Yes ◯ No
10.4.5.1	***If 'Delivered dose same as planned dose?' is equal to 'No' answer this question:*** Delivered dose (surface of the applicator): *Warning shown if field's value is larger than 20: 'Protocol violation. Delivered dose applicator size should be 20 Gy'* *Warning shown if field's value is smaller than 20: 'Protocol violation. Delivered dose applicator size should be 20 Gy'*	[ ] Gy
10.4.5.2	***If 'Delivered dose same as planned dose?' is equal to 'No' answer this question:*** Specify reason Delivered Dose deviates from the Planned Dose?	☐ Logistical reasons ☐ Technical issues ☐ Other, please specify
10.4.5.2.1	***If 'Specify reason Delivered Dose deviates from the Planned Dose?' is equal to 'Other, please specify' answer this question:*** Specify other:	[ ]

11. Treatment - Final Histopathology Left Breast

Number	Question	Answers
	Tumor location was Right Breast, No data needs to be recorded at this section.	
11.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Size of the resected tumor:	[ ] mm
11.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Minimal resection margin after final resection: *Notice shown if field's value is smaller than 2: 'Resection margins < 2 mm should be considered as a risk factor resulting in postoperative EBRT.'*	[ ] millimeters

11.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Final staging of primary tumor (T):	◯ TX ◯ T1 ◯ T2 ◯ T3 ◯ Tis ◯ Not done
11.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Final staging of regional lymph nodes (N):	◯ NX ◯ N0 ◯ N1 ◯ N2 ◯ N3 ◯ Not done
11.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Final staging of metastases (M):	◯ MX ◯ M0 ◯ M1 ◯ Not done
11.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Histopathological grade:	◯ GX ◯ G1 ◯ G2 ◯ G3 ◯ Not done
11.7	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Lymphatic vessel invasion:	◯ LX ◯ L0 ◯ L1 ◯ Not done
11.8	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Venous invasion	◯ VX ◯ V0 ◯ V1 ◯ Not done
11.9	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Residual tumor:	◯ RX ◯ R0 ◯ R1 ◯ R2 ◯ Not done
11.10	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Results histology:	◯ Invasive-ductal ◯ Invasive-lobular ◯ Other histology ◯ Inconclusive
11.10.1	***If 'Results histology:' is equal to 'Invasive-ductal' answer this question:*** Invasive-ductal breast cancer with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown
11.10.2	***If 'Results histology:' is equal to 'Invasive-ductal' answer this question:*** Invasive-ductal breast cancer with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown

11.10.3	***If 'Results histology:' is equal to 'Invasive-lobular' answer this question:*** Invasive-lobular breast cancer with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown
11.10.4	***If 'Results histology:' is equal to 'Invasive-lobular' answer this question:*** Invasive-lobular breast cancer with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown
11.10.5	***If 'Results histology:' is equal to 'Other histology' answer this question:*** Please specify "other" histology:	
11.10.6	***If 'Results histology:' is equal to 'Other histology' answer this question:*** Other histology with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown
11.10.7	***If 'Results histology:' is equal to 'Other histology' answer this question:*** Other histology with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown
11.11	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Estrogen receptor score:	IRS
11.12	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Progesterone receptor (PR) score:	IRS
11.13	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Her2neu receptor:	◯ Positive ◯ Negative
11.14	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Ki-67 expression:	
11.15	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Genomic Assay; Oncotype Recurrence Score:	
11.16	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Genomic Assay; Mammaprint:	◯ High Risk ◯ Low Risk

12. Treatment - Final Histopathology Right Breast

Number	Question	Answers
	Tumor location was Left Breast, No data needs to be recorded at this section.	
12.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Size of the resected tumor:	mm

12.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Minimal resection margin after final resection: *Notice shown if field's value is smaller than 2: 'Resection margins < 2 mm should be considered as a risk factor resulting in postoperative EBRT.'*	☐ millimeters
12.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Final staging of primary tumor (T):	○ TX ○ T1 ○ T2 ○ T3 ○ Tis ○ Not done
12.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Final staging of regional lymph nodes (N):	○ NX ○ N0 ○ N1 ○ N2 ○ N3 ○ Not done
12.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Final staging of metastases (M):	○ MX ○ M0 ○ M1 ○ Not done
12.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Histopathological grade:	○ GX ○ G1 ○ G2 ○ G3 ○ Not done
12.7	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Lymphatic vessel invasion:	○ LX ○ L0 ○ L1 ○ Not done
12.8	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Venous invasion	○ VX ○ V0 ○ V1 ○ Not done
12.9	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Residual tumor:	○ RX ○ R0 ○ R1 ○ R2 ○ Not done
12.10	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Results histology:	○ Invasive-ductal ○ Invasive-lobular ○ Other histology ○ Inconclusive

12.10.1	***If 'Results histology:' is equal to 'Invasive-ductal' answer this question:*** Invasive-ductal breast cancer with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown
12.10.2	***If 'Results histology:' is equal to 'Invasive-ductal' answer this question:*** Invasive-ductal breast cancer with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown
12.10.3	***If 'Results histology:' is equal to 'Invasive-lobular' answer this question:*** Invasive-lobular breast cancer with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown
12.10.4	***If 'Results histology:' is equal to 'Invasive-lobular' answer this question:*** Invasive-lobular breast cancer with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown
12.11	***If 'Results histology:' is equal to 'Other histology' answer this question:*** Please specify "other" histology:	
12.10.5	***If 'Results histology:' is equal to 'Other histology' answer this question:*** Other histology with extensive intraductal component (EIC)	◯ Yes ◯ No ◯ Unknown
12.10.6	***If 'Results histology:' is equal to 'Other histology' answer this question:*** Other histology with lymph vessel invasion (L1)	◯ Yes ◯ No ◯ Unknown
12.12	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Estrogen receptor score:	IRS
12.13	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Progesterone receptor (PR) score:	IRS
12.14	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Her2neu receptor:	◯ Positive ◯ Negative
12.15	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Ki-67 expression:	
12.16	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Genomic Assay; Oncotype Recurrence Score:	
12.17	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Genomic Assay; Oncotype Recurrence Score:	◯ High Risk ◯ Low Risk

13. Treatment - Assessment Risk Factors Post-surgery

Number	Question	Answers
13.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Will EBRT be scheduled for the Left Breast:	◯ Yes ◯ No
13.1.1	***If 'Will EBRT be scheduled for the Left Breast:' is equal to 'No' answer this question:*** Specify reason no EBRT is scheduled for Left Breast:	◯ No risk factor factors present ◯ Risk factors identified but no EBRT will be scheduled ◯ Other
13.1.1.1	***If 'Specify reason no EBRT is scheduled for Left Breast:' is equal to 'Risk factors identified but no EBRT will be scheduled' answer this question:*** Specify reason why no EBRT is scheduled despite the presence of risk factors for the Left Breast::	
13.1.1.2	***If 'Specify reason no EBRT is scheduled for Left Breast:' is equal to 'Other' answer this question:*** Specify "other":	
13.1.2	***If 'Will EBRT be scheduled for the Left Breast:' is equal to 'Yes' answer this question:*** Specify reason conventional radiotherapy is scheduled in addition to IORT for the Left Breast::	◯ Local policy (in absence of any risk factors) ◯ Presence of risk factors ◯ Other
13.1.2.1	***If 'Specify reason conventional radiotherapy is scheduled in addition to IORT for the Left Breast::' is equal to 'Presence of risk factors' answer this question:*** Specify the post-surgery risk factors for the Left Breast (check all that apply):	◯ Tumor with extensive intraductal component ◯ Tumor with lymph vessel invasion ◯ Tumor is multifocal / multi centric ◯ Tumor size > 3.5 cm ◯ Lymph node involvement (SNE) ◯ Prior ipsilateral radiation ◯ Bilateral breast cancer ◯ Resection margin < 2 mm (or is risk factor re-resection..) ◯ Prior ipsilateral breast radiation ◯ Negative hormone receptor ◯ Age < 50 years ◯ Prior therapeutic chest radiation
13.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Will EBRT be scheduled for the Right Breast:	◯ Yes ◯ No
13.2.1	***If 'Will EBRT be scheduled for the Right Breast:' is equal to 'No' answer this question:*** Specify reason no EBRT is scheduled for Right Breast:	◯ No risk factor factors present ◯ Risk factors identified but no EBRT will be scheduled ◯ Other
13.2.1.1	***If 'Specify reason no EBRT is scheduled for Right Breast:' is equal to 'Risk factors identified but no EBRT will be scheduled' answer this question:*** Specify reason why no EBRT is scheduled despite the presence of risk factors for the Right Breast::	
13.2.1.2	***If 'Specify reason no EBRT is scheduled for Right Breast:' is equal to 'Other' answer this question:*** Specify "other":	

13.2.2	***If 'Will EBRT be scheduled for the Right Breast:' is equal to 'Yes' answer this question:*** Specify reason conventional radiotherapy is scheduled in addition to IORT for the Right Breast::	◯ Local policy (in absence of any risk factors) ◯ Presence of risk factors ◯ Other
13.2.2.1	***If 'Specify reason conventional radiotherapy is scheduled in addition to IORT for the Right Breast::' is equal to 'Presence of risk factors' answer this question:*** Specify the post-surgery risk factors for the Right Breast (check all that apply):	◯ Tumor with extensive intraductal component ◯ Tumor with lymph vessel invasion ◯ Tumor is multifocal / multi centric ◯ Tumor size > 3.5 cm ◯ Lymph node involvement (SNE) ◯ Prior ipsilateral radiation ◯ Bilateral breast cancer ◯ Resection margin < 2 mm (or is risk factor re-resection..) ◯ Prior ipsilateral breast radiation ◯ Negative hormone receptor ◯ Age < 50 years ◯ Prior therapeutic chest radiation

14. Treatment - Acute Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast, No data needs to be recorded at this section.	
14.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Palpable seroma present:	◯ Yes ◯ No
14.1.1	***If 'Palpable seroma present:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
14.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	
14.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Wound break down:	◯ Yes ◯ No ◯ Unknown
14.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Were there any indications for re-excision?	◯ Yes ◯ No
14.3.1	***If 'Were there any indications for re-excision?' is equal to 'Yes' answer this question:*** Please click to report re-resection	
14.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No

14.4.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Clinical relevant abnormalities observed for any laboratory values?	◯ Yes ◯ No
14.4.1.1	***If 'Clinical relevant abnormalities observed for any laboratory values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
14.4.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
14.4.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
14.4.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
14.4.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
14.4.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
14.4.1.1.6	***If 'Please select the abnormalities:' 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
14.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Physical examination performed of the surgical scar / irradiation field of the left breast?	◯ Yes ◯ No
14.5.1	***If 'Physical examination performed of the surgical scar / irradiation field of the left breast?' is equal to 'Yes' answer this question:*** Where acute skin toxicities observed:	◯ Yes ◯ No

14.5.1.1	***If 'Where acute skin toxicities observed:' is equal to 'Yes' answer this question:*** Select the skin toxicities that were present:	☐ Erythema ☐ Wound infection ☐ Other
14.5.1.1.1	***If 'Select the skin toxicities that were present:' is equal to 'Erythema' answer this question:*** Grade for "erythema":	○ No symtoms ○ Grade 1: Mild ○ Grade 2: Moderate ○ Grade 3: Severe ○ Grade 4: Life-threatening, disabling ○ Grade 5: Death, related to event
14.5.1.1.2	***If 'Select the skin toxicities that were present:' is equal to 'Wound infection' answer this question:*** Grade for "wound infection":	○ No symtoms ○ Grade 1: Mild ○ Grade 2: Moderate ○ Grade 3: Severe ○ Grade 4: Life-threatening, disabling ○ Grade 5: Death, related to event
14.5.1.1.3	***If 'Select the skin toxicities that were present:' is equal to 'Wound infection' answer this question:*** Please specify wound infection:	
14.5.1.1.4	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other" skin toxicity:	
14.5.1.1.5	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Grade for "other" skin toxicity:	○ No symtoms ○ Grade 1: Mild ○ Grade 2: Moderate ○ Grade 3: Severe ○ Grade 4: Life-threatening, disabling ○ Grade 5: Death, related to event
14.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any irradiation toxicities observed for organs at risk (heart, lung, ribs)	○ Yes ○ No ○ Unknown
14.6.1	***If 'Where any irradiation toxicities observed for organs at risk (heart, lung, ribs)' is equal to 'Yes' answer this question:*** Please describe the toxicity for the organs at risk:	
14.6.2	***If 'Where any irradiation toxicities observed for organs at risk (heart, lung, ribs)' is equal to 'Yes' answer this question:*** Grade for the "organ at risk" toxicity:	○ No symtoms ○ Grade 1: Mild ○ Grade 2: Moderate ○ Grade 3: Severe ○ Grade 4: Life-threatening, disabling ○ Grade 5: Death, related to event
14.7	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any observed toxicities considered serious (e.g., meets the SAE	○ Yes ○ No

	definitions)?	
14.7.1	***If 'Where any observed toxicities considered serious (e.g., meets the SAE definitions)?' is equal to 'Yes' answer this question:*** Where any serious toxicities related to radiation (eg, rrSAE):	◯ Yes ◯ No
14.7.1.1	***If 'Where any serious toxicities related to radiation (eg, rrSAE):' is equal to 'Yes' answer this question:*** Please complete rrSAE report	

15. Treatment - Acute Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast, No data needs to be recorded at this section.	
15.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Palpable seroma present:	◯ Yes ◯ No
15.1.1	***If 'Palpable seroma present:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
15.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	
15.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Wound break down:	◯ Yes ◯ No ◯ Unknown
15.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Were there any indications for re-excision?	◯ Yes ◯ No
15.3.1	***If 'Were there any indications for re-excision?' is equal to 'Yes' answer this question:*** Please click to report re-resection	
15.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
15.4.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Clinical relevant abnormalities observed for any laboratory values?	◯ Yes ◯ No
15.4.1.1	***If 'Clinical relevant abnormalities observed for any laboratory values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
15.4.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate

		◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
15.4.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
15.4.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
15.4.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
15.4.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
15.4.1.1.6	***If 'Please select the abnormalities:' 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
15.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Physical examination performed of the surgical scar / irradiation field of the right breast?	◯ Yes ◯ No
15.5.1	***If 'Physical examination performed of the surgical scar / irradiation field of the right breast?' is equal to 'Yes' answer this question:*** Where acute skin toxicities observed:	◯ Yes ◯ No
15.5.1.1	***If 'Where acute skin toxicities observed:' is equal to 'Yes' answer this question:*** Select the skin toxicities that were present:	☐ Erythema ☐ Wound infection ☐ Other
15.5.1.1.1	***If 'Select the skin toxicities that were present:' is equal to 'Erythema' answer this question:*** Grade for "erythema":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event

15.5.1.1.2	***If 'Select the skin toxicities that were present:' is equal to 'Wound infection' answer this question:*** Grade for "wound infection":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
15.5.1.1.3	***If 'Select the skin toxicities that were present:' is equal to 'Wound infection' answer this question:*** Please specify wound infection:	
15.5.1.1.4	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other" skin toxicity:	
15.5.1.1.5	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Grade for "other" skin toxicity:	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
15.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Where any irradiation toxicities observed for organs at risk (heart, lung, ribs)	◯ Yes ◯ No ◯ Unknown
15.6.1	***If 'Where any irradiation toxicities observed for organs at risk (heart, lung, ribs)' is equal to 'Yes' answer this question:*** Please describe the toxicity for the organs at risk:	
15.6.2	***If 'Where any irradiation toxicities observed for organs at risk (heart, lung, ribs)' is equal to 'Yes' answer this question:*** Grade for the "organ at risk" toxicity:	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
15.7	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Where any observed toxicities considered serious (e.g., meets the SAE definitions)?	◯ Yes ◯ No
15.7.1	***If 'Where any observed toxicities considered serious (e.g., meets the SAE definitions)?' is equal to 'Yes' answer this question:*** Where any serious toxicities related to radiation (eg, rrSAE):	◯ Yes ◯ No
15.7.1.1	***If 'Where any serious toxicities related to radiation (eg, rrSAE):' is***	

16.1.1.1	***If 'Were any serious toxicities related to radiation (eg, rrSAE)?' is equal to 'Yes' answer this question:*** Please complete rrSAE report	

16. Treatment - Study Status

Number	Question	Answers
16.1	Patient status:	◯ Patient is Alive ◯ Patient Discontinued ◯ Patient Died
16.1.1	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Date of death:	☐ ☐ ☐ *(dd-mm-yyyy)*
16.1.2	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Reason death:	◯ Breast cancer related ◯ Cardiac/circulation ◯ Other malignant disease ◯ Other
16.1.2.1	***If 'Reason death:' is equal to 'Other' answer this question:*** Please specify "other":	☐
16.1.3	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Autopsy performed:	◯ Yes ◯ No ◯ Unknown

17. Week 6 Visit - Date of Visit

Number	Question	Answers
17.1	Date of visit:	☐ ☐ ☐ *(dd-mm-yyyy)*
17.2	Patient weight:	☐ Kg

18. Week 6 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 personal needs ◯ 50 - Requires considerable assistance and frequent medical care ◯ 40 - Disabled, requires special care and assistance ◯ 30 - Severely disabled, hospital admission is indicated although death not imminent ◯ 20 - Very sick, hospital admission necessary, active supportive treatment necessary ◯ 10 - Moribund, fatal processes progressing rapidly ◯ 0 – Dead

19. Week 6 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 equal to 'Yes' answer this question:*** Select the Adjuvant Systemic Therapy that was given (tick all that apply):	☐ Chemotherapy ☐ Antihormonal treatment ☐ Immunotherapy ☐ Other
19.1.1.1	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Specify the adjuvant chemotherapy	
19.1.1.2	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Start date adjuvant chemotherapy:	*(dd-mm-yyyy)*
19.1.1.3	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Specify the current antihormonal treatment:	◯ Tamoxifen ◯ Aromatase-inhibitor ◯ Tamoxifen + Zoladex ◯ Other
19.1.1.4	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Immunotherapy' answer this question:*** Specify immunotherapy:	☐ Trastuzumab ☐ Other
19.1.1.4.1	***If 'Specify immunotherapy:' is equal to 'Other' answer this question:*** Specify "other" immunotherapy:	

20. Week 6 Visit - EBRT details

Number	Question	Answers
	EBRT not planned for left breast. Continue to next section	
	EBRT not planned for right breast. Continue to next section	
20.1	***If 'Will EBRT be scheduled for the Left Breast:' is equal to 'Yes' answer this question:*** Was the planned EBRT treatment (LB) due to the presence of post-surgery risk factors performed:	◯ Yes ◯ No
20.1.1	***If 'Was the planned EBRT treatment (LB) due to the presence of post-surgery risk factors performed:' is equal to 'No' answer this question:*** Specify why planned EBRT was not performed:	
20.1.2	***If 'Was the planned EBRT treatment (LB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Start date EBRT:	*(dd-mm-yyyy)*
20.1.3	***If 'Was the planned EBRT treatment (LB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Number of days between IORT and start EBRT: *Notice shown if field's value is smaller than 35: 'Protocol violation. WBRT should not start within 5 weeks after surgery/IORT.'*	
20.1.4	***If 'Was the planned EBRT treatment (LB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Number of days between start adjuvant chemotherapy and start EBRT *Notice shown if field's value is smaller than 14: 'Protocol violation. A delay of at least 14 days (21 days recommended) is requested between chemotherapy and initiation of WBRT.'*	
20.1.5	***If 'Was the planned EBRT treatment (LB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** End date EBRT:	*(dd-mm-yyyy)*
20.1.6	***If 'Was the planned EBRT treatment (LB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Cumulative dose:	Gy
20.1.7	***If 'Was the planned EBRT treatment (LB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Dose per fraction:	Gy
20.1.8	***If 'Was the planned EBRT treatment (LB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** EBRT method:	◯ Standard (3D) ◯ IMRT ◯ Other ◯ Proton Therapy
20.2	***If 'Will EBRT be scheduled for the Right Breast:' is equal to 'Yes' answer this question:*** Was the planned EBRT treatment (RB) due to the presence of post-surgery risk factors performed:	◯ Yes ◯ No

20.2.1	***If 'Was the planned EBRT treatment (RB) due to the presence of post-surgery risk factors performed:' is equal to 'No' answer this question:*** Specify why planned EBRT was not performed:	
20.2.2	***If 'Was the planned EBRT treatment (RB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Start date EBRT:	*(dd-mm-yyyy)*
20.2.3	***If 'Was the planned EBRT treatment (RB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Number of days between IORT and start EBRT: *Notice shown if field's value is smaller than 35: 'Protocol violation. WBRT should not start within 5 weeks after surgery/IORT.'*	
20.2.4	***If 'Was the planned EBRT treatment (RB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Number of days between start adjuvant chemotherapy and start EBRT *Notice shown if field's value is smaller than 14: 'Protocol violation. A delay of at least 14 days (21 days recommended) is requested between chemotherapy and initiation of WBRT.'*	
20.2.5	***If 'Was the planned EBRT treatment (RB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** End date EBRT:	*(dd-mm-yyyy)*
20.2.6	***If 'Was the planned EBRT treatment (RB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Cumulative dose:	Gy
20.2.7	***If 'Was the planned EBRT treatment (RB) due to the presence of post-surgery risk factors performed:' is equal to 'Yes' answer this question:*** Dose per fraction:	Gy

21. Week 6 Visit - Tumor Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
21.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Please select the tumor evaluations methods that were performed for the left breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
21.1.1	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Mammography' answer this question:*** Date mammography:	*(dd-mm-yyyy)*
21.1.2	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Ultrasound of the breast' answer this***	*(dd-mm-yyyy)*

	question: Date breast ultrasound:	
21.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Local relapse (within 2 cm)	◯ Yes ◯ No ◯ Unknown
21.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
21.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	◯ Yes ◯ No
21.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
21.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Contralateral carcinoma:	◯ Yes ◯ No ◯ Unknown
21.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	◯ Yes ◯ No ◯ Unknown
21.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Ipsilateral secondary carcinoma:	◯ Yes ◯ No ◯ Unknown
21.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Distant metastasis:	◯ Yes ◯ No ◯ Unknown

22. Week 6 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
22.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Please select the tumor evaluations methods that were performed for the right breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
22.1.1	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
22.1.2	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Ultrasound of the breast' answer this question:***	☐ ☐ ☐ *(dd-mm-yyyy)*

	Date breast ultrasound:	
22.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Local relapse (within 2 cm)	◯ Yes ◯ No ◯ Unknown
22.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
22.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	◯ Yes ◯ No
22.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
22.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Contralateral carcinoma:	◯ Yes ◯ No ◯ Unknown
22.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	◯ Yes ◯ No ◯ Unknown
22.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Ipsilateral secondary carcinoma:	◯ Yes ◯ No ◯ Unknown
22.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Distant metastasis:	◯ Yes ◯ No ◯ Unknown

23. Week 6 Visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
23.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Palpable seroma present at left breast:	◯ Yes ◯ No
23.1.1	***If 'Palpable seroma present at left breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
23.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	☐
23.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Breast volume assessed with planning CT:	◯ Yes ◯ No ◯ Unknown

23.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	____ ml
23.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
23.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	____ ml
23.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
23.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
23.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
23.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
23.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
23.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
23.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling

		◯ Grade 5: Death, related to event
23.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	[ ]
23.3.1.1.6	***If 'Please select the abnormalities:' 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
23.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any toxicities observed at the clinical examination:	◯ Yes ◯ No
23.4.1	***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
23.4.1.1	***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
23.4.1.2	***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
23.4.1.3	***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
23.4.1.3.1	***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
23.4.1.3.2	***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

23.4.1.3.3	***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
23.4.1.3.4	***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:
23.4.1.3.5	***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
23.4.1.3.6	***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
23.4.1.3.7	***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
23.4.1.3.8	***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
23.4.1.3.9	***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 cm^2 ◯ Grade 3: Ulceration including subcutis ◯ Grade 4: Free bone, necrosis
23.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
23.4.1.3.11	***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
23.5	***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
23.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:***	◯ Yes ◯ No

	Where any toxicities considered serious (e.g., meets the SAE definitions)?	
23.6.1	***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
23.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

24. Week 6 Visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
24.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Palpable seroma present at right breast:	◯ Yes ◯ No
24.1.1	***If 'Palpable seroma present at right breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
24.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	____
24.2	***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
24.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	____ ml
24.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
24.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	____ ml
24.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
24.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
24.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other

24.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
24.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
24.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
24.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
24.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
24.3.1.1.6	***If 'Please select the abnormalities:' 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
24.4	***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
24.4.1	***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
24.4.1.1	***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

24.4.1.2	***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
24.4.1.3	***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
24.4.1.3.1	***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
24.4.1.3.2	***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
24.4.1.3.3	***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
24.4.1.3.4	***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:
24.4.1.3.5	***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
24.4.1.3.6	***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
24.4.1.3.7	***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

24.4.1.3.8	***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
24.4.1.3.9	***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
24.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
24.4.1.3.11	***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
24.5	***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
24.6	***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
24.6.1	***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
24.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

25. Week 6 Visit - Patient Questionnaires

Number	Question	Answers
25.1	EORTC QLQ-C30 questionnaire completed:	◯ Yes ◯ No
25.1.1	***If 'EORTC QLQ-C30 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-C30	
25.2	EORTC BR23 questionnaire completed:	◯ Yes ◯ No
25.2.1	***If 'EORTC BR23 questionnaire completed:' is equal to 'Yes' answer***	

this question:
Upload EORTC QLQ-BR23

26. Week 6 Visit - Study Status

Number	Question	Answers
26.1	Patient status:	◯ Patient is Alive ◯ Patient Discontinued ◯ Patient Died
26.1.1	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Date of death:	☐ ☐ ☐ *(dd-mm-yyyy)*
26.1.2	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Reason death:	◯ Breast cancer related ◯ Cardiac/circulation ◯ Other malignant disease ◯ Other
26.1.2.1	***If 'Reason death:' is equal to 'Other' answer this question:*** Please specify "other":	☐
26.1.3	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Autopsy performed:	◯ Yes ◯ No ◯ Unknown

27. Month 6 Visit - Date of Visit

Number	Question	Answers
27.1	Date of visit:	☐ ☐ ☐ *(dd-mm-yyyy)*
27.2	Patient weight:	☐ Kg

28. Month 6 Visit - Karnofsky Performance Status

Number	Question	Answers
28.1	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 personal needs ◯ 50 - Requires considerable assistance and frequent medical care ◯ 40 - Disabled, requires special care and assistance ◯ 30 - Severely disabled, hospital admission is indicated although death not imminent ◯ 20 - Very sick, hospital admission necessary, active supportive treatment necessary ◯ 10 - Moribund, fatal processes progressing rapidly ◯ 0 – Dead

29. Month 6 Visit - Adjuvant Systemic Treatment

Number	Question	Answers
29.1	Received patient adjuvant systemic treatment since last visit (week 6):	◯ Yes ◯ No
29.1.1	***If 'Received patient adjuvant systemic treatment since last visit (week 6):' is equal to 'Yes' answer this question:*** Select the Adjuvant Systemic Therapy that was given (tick all that apply):	☐ Chemotherapy ☐ Antihormonal treatment ☐ Immunotherapy ☐ Other
29.1.1.1	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Specify the adjuvant chemotherapy	☐
29.1.1.2	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Start date adjuvant chemotherapy:	☐ ☐ ☐ *(dd-mm-yyyy)*
29.1.1.3	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Specify the current antihormonal treatment:	◯ Tamoxifen ◯ Aromatase-inhibitor ◯ Tamoxifen + Zoladex ◯ Other
29.1.1.4	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Immunotherapy' answer this question:*** Specify immunotherapy:	☐ Trastuzumab ☐ Other

29.1.1.4.1	***If 'Specify immunotherapy:' is equal to 'Other' answer this question:*** Specify "other" immunotherapy:	

30. Month 6 Visit - Tumor Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
30.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Please select the tumor evaluations methods that were performed for the left breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
30.1.1	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
30.1.2	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	☐ ☐ ☐ *(dd-mm-yyyy)*
30.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Local relapse (within 2 cm)	○ Yes ○ No ○ Unknown
30.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
30.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	○ Yes ○ No
30.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
30.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Contralateral carcinoma:	○ Yes ○ No ○ Unknown
30.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	○ Yes ○ No ○ Unknown
30.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Ipsilateral secondary carcinoma:	○ Yes ○ No ○ Unknown
30.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Distant metastasis:	○ Yes ○ No ○ Unknown

31. Month 6 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
31.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Please select the tumor evaluations methods that were performed for the right breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
31.1.1	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
31.1.2	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	☐ ☐ ☐ *(dd-mm-yyyy)*
31.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Local relapse (within 2 cm)	○ Yes ○ No ○ Unknown
31.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
31.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	○ Yes ○ No
31.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
31.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Contralateral carcinoma:	○ Yes ○ No ○ Unknown
31.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	○ Yes ○ No ○ Unknown
31.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Ipsilateral secondary carcinoma:	○ Yes ○ No ○ Unknown
31.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Distant metastasis:	○ Yes ○ No ○ Unknown

32. Month 6 Visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
32.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Palpable seroma present at left breast:	◯ Yes ◯ No
32.1.1	***If 'Palpable seroma present at left breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
32.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	
32.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Breast volume assessed with planning CT:	◯ Yes ◯ No ◯ Unknown
32.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	ml
32.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
32.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	ml
32.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
32.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
32.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
32.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event

32.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
32.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
32.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
32.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
32.3.1.1.6	***If 'Please select the abnormalities:' 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
32.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any toxicities observed at the clinical examination:	◯ Yes ◯ No
32.4.1	***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
32.4.1.1	***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
32.4.1.2	***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
32.4.1.3	***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

32.4.1.3.1 ***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

32.4.1.3.2 ***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

32.4.1.3.3 ***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

32.4.1.3.4 ***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:

32.4.1.3.5 ***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

32.4.1.3.6 ***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

32.4.1.3.7 ***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

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32.4.1.3.8 ***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

32.4.1.3.9 ***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 cm^2
- ( ) Grade 3: Ulceration including subcutis

		◯ Grade 4: Free bone, necrosis
32.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
32.4.1.3.11	***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
32.5	***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
32.6	***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
32.6.1	***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
32.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

33. Month 6 Visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
33.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Palpable seroma present at right breast:	◯ Yes ◯ No
33.1.1	***If 'Palpable seroma present at right breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
33.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:***	

Number of punctures:

33.2	***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
33.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	[ ] ml
33.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
33.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	[ ] ml
33.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
33.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
33.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
33.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
33.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
33.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
33.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling

		◯ Grade 5: Death, related to event
33.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	[ ]
33.3.1.1.6	***If 'Please select the abnormalities:' 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
33.4	***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
33.4.1	***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
33.4.1.1	***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
33.4.1.2	***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
33.4.1.3	***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
33.4.1.3.1	***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
33.4.1.3.2	***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

33.4.1.3.3	***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
33.4.1.3.4	***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:
33.4.1.3.5	***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
33.4.1.3.6	***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
33.4.1.3.7	***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
33.4.1.3.8	***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
33.4.1.3.9	***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
33.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
33.4.1.3.11	***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
33.5	***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
33.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:***	◯ Yes ◯ No

	Where any toxicities considered serious (e.g., meets the SAE definitions)?	
33.6.1	***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
33.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

34. Month 6 Visit - Patient Questionnaires

Number	Question	Answers
34.1	EORTC QLQ-C30 questionnaire completed:	◯ Yes ◯ No
34.1.1	***If 'EORTC QLQ-C30 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-C30	
34.2	EORTC BR23 questionnaire completed:	◯ Yes ◯ No
34.2.1	***If 'EORTC BR23 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-BM22	

35. Month 6 Visit - Study Status

Number	Question	Answers
35.1	Patient status:	◯ Patient is Alive ◯ Patient Discontinued ◯ Patient Died
35.1.1	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Date of death:	☐ ☐ ☐ *(dd-mm-yyyy)*
35.1.2	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Reason death:	◯ Breast cancer related ◯ Cardiac/circulation ◯ Other malignant disease ◯ Other
35.1.2.1	***If 'Reason death:' is equal to 'Other' answer this question:*** Please specify "other":	☐

35.1.3	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Autopsy performed:	◯ Yes ◯ No ◯ Unknown

36. Month 12 Visit - Date of Visit

Number	Question	Answers
36.1	Date of visit:	[ ] [ ] [ ] *(dd-mm-yyyy)*
36.2	Patient weight:	[ ] Kg

37. Month 12 Visit - Karnofsky Performance Status

Number	Question	Answers
37.1	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 personal needs ◯ 50 - Requires considerable assistance and frequent medical care ◯ 40 - Disabled, requires special care and assistance ◯ 30 - Severely disabled, hospital admission is indicated although death not imminent ◯ 20 - Very sick, hospital admission necessary, active supportive treatment necessary ◯ 10 - Moribund, fatal processes progressing rapidly ◯ 0 – Dead

38. Month 12 Visit - Adjuvant Systemic Treatment

Number	Question	Answers
38.1	Received patient adjuvant systemic treatment since last visit (Month 6):	◯ Yes ◯ No

38.1.1	***If 'Received patient adjuvant systemic treatment since last visit (Month 6):' is equal to 'Yes' answer this question:*** Select the Adjuvant Systemic Therapy that was given (tick all that apply):	☐ Chemotherapy ☐ Antihormonal treatment ☐ Immunotherapy ☐ Other
38.1.1.1	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Specify the adjuvant chemotherapy	
38.1.1.2	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Start date adjuvant chemotherapy:	*(dd-mm-yyyy)*
38.1.1.3	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Specify the current antihormonal treatment:	○ Tamoxifen ○ Aromatase-inhibitor ○ Tamoxifen + Zoladex ○ Other
38.1.1.4	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Immunotherapy' answer this question:*** Specify immunotherapy:	☐ Trastuzumab ☐ Other
38.1.1.4.1	***If 'Specify immunotherapy:' is equal to 'Other' answer this question:*** Specify "other" immunotherapy:	

39. Month 12 Visit - Tumor Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
39.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Please select the tumor evaluations methods that were performed for the left breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
39.1.1	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Mammography' answer this question:*** Date mammography:	*(dd-mm-yyyy)*
39.1.2	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	*(dd-mm-yyyy)*
39.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Local relapse (within 2 cm)	○ Yes ○ No ○ Unknown
39.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	*(dd-mm-yyyy)*
39.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	○ Yes ○ No

39.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
39.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Contralateral carcinoma:	◯ Yes ◯ No ◯ Unknown
39.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	◯ Yes ◯ No ◯ Unknown
39.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Ipsilateral secondary carcinoma:	◯ Yes ◯ No ◯ Unknown
39.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Distant metastasis:	◯ Yes ◯ No ◯ Unknown

40. Month 12 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
40.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Please select the tumor evaluations methods that were performed for the right breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
40.1.1	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
40.1.2	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	☐ ☐ ☐ *(dd-mm-yyyy)*
40.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Local relapse (within 2 cm)	◯ Yes ◯ No ◯ Unknown

		◯ Unknown
40.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
40.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	◯ Yes ◯ No
40.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
40.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Contralateral carcinoma:	◯ Yes ◯ No ◯ Unknown
40.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	◯ Yes ◯ No ◯ Unknown
40.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Ipsilateral secondary carcinoma:	◯ Yes ◯ No ◯ Unknown
40.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Distant metastasis:	◯ Yes ◯ No ◯ Unknown

41. Month 12 Visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
41.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Palpable seroma present at left breast:	◯ Yes ◯ No
41.1.1	***If 'Palpable seroma present at left breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
41.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	☐
41.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Breast volume assessed with planning CT:	◯ Yes ◯ No ◯ Unknown
41.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	☐ ml

41.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
41.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	____ ml
41.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
41.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
41.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
41.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
41.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
41.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
41.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
41.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	____
41.3.1.1.6	***If 'Please select the abnormalities:' 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
41.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any toxicities observed at the clinical examination:	◯ Yes ◯ No
41.4.1	***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
41.4.1.1	***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
41.4.1.2	***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
41.4.1.3	***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
41.4.1.3.1	***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
41.4.1.3.2	***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
41.4.1.3.3	***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

41.4.1.3.4	***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:
41.4.1.3.5	***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
41.4.1.3.6	***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
41.4.1.3.7	***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
41.4.1.3.8	***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
41.4.1.3.9	***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 cm^2 ◯ Grade 3: Ulceration including subcutis ◯ Grade 4: Free bone, necrosis
41.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
41.4.1.3.11	***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
41.5	***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
41.6	***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
41.6.1	***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
41.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

42. Month 12 Visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
42.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Palpable seroma present at right breast:	◯ Yes ◯ No
42.1.1	***If 'Palpable seroma present at right breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
42.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	[ ]
42.2	***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
42.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	[ ] ml
42.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
42.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	[ ] ml
42.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
42.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
42.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
42.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event

42.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
42.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
42.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
42.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
42.3.1.1.6	***If 'Please select the abnormalities:' 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
42.4	***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
42.4.1	***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
42.4.1.1	***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
42.4.1.2	***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
42.4.1.3	***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

42.4.1.3.1 ***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

42.4.1.3.2 ***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

42.4.1.3.3 ***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

42.4.1.3.4 ***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:

42.4.1.3.5 ***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

42.4.1.3.6 ***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

42.4.1.3.7 ***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

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42.4.1.3.8 ***If 'Select the skin toxicities that were present:' is equal to 'Retraction (Lent Soma)' answer this question:***

- ( ) Grade 1: > 10 - 25%
- ( ) Grade 2: > 25 - 40%

	Grade for "Retraction":	◯ Grade 3: > 40 - 75% ◯ Grade 4: Whole breast
42.4.1.3.9	***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
42.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
42.4.1.3.11	***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
42.5	***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
42.6	***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
42.6.1	***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
42.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

43. Month 12 Visit - Patient Questionnaires

Number	Question	Answers
43.1	EORTC QLQ-C30 questionnaire completed:	◯ Yes ◯ No
43.1.1	***If 'EORTC QLQ-C30 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-C30	
43.2	EORTC BR23 questionnaire completed:	◯ Yes ◯ No
43.2.1	***If 'EORTC BR23 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-BM22	

44. Month 12 Visit - Study Status

Number	Question	Answers
44.1	Patient status:	◯ Patient is Alive ◯ Patient Discontinued ◯ Patient Died
44.1.1	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Date of death:	☐ ☐ ☐ *(dd-mm-yyyy)*
44.1.2	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Reason death:	◯ Breast cancer related ◯ Cardiac/circulation ◯ Other malignant disease ◯ Other
44.1.2.1	***If 'Reason death:' is equal to 'Other' answer this question:*** Please specify "other":	☐
44.1.3	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Autopsy performed:	◯ Yes ◯ No ◯ Unknown

45. Month 24 visit - Date of Visit

Number	Question	Answers
45.1	Date of visit:	☐ ☐ ☐ *(dd-mm-yyyy)*
45.2	Patient weight:	☐ Kg

46. Month 24 visit - Karnofsky Performance Status

Number	Question	Answers
46.1	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 personal needs
- ◯ 50 - Requires considerable assistance and frequent medical care
- ◯ 40 - Disabled, requires special care and assistance
- ◯ 30 - Severely disabled, hospital admission is indicated although death not imminent
- ◯ 20 - Very sick, hospital admission necessary, active supportive treatment necessary
- ◯ 10 - Moribund, fatal processes progressing rapidly
- ◯ 0 – Dead

47. Month 24 visit - Adjuvant Systemic Treatment

Number	Question	Answers
47.1	Received patient adjuvant systemic treatment since last visit (Month 12):	◯ Yes ◯ No
47.1.1	***If 'Received patient adjuvant systemic treatment since last visit (Month 12):' is equal to 'Yes' answer this question:*** Select the Adjuvant Systemic Therapy that was given (tick all that apply):	☐ Chemotherapy ☐ Antihormonal treatment ☐ Immunotherapy ☐ Other
47.1.1.1	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Specify the adjuvant chemotherapy	☐
47.1.1.2	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Start date adjuvant chemotherapy:	☐ ☐ ☐ *(dd-mm-yyyy)*
47.1.1.3	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Specify the current antihormonal treatment:	◯ Tamoxifen ◯ Aromatase-inhibitor ◯ Tamoxifen + Zoladex ◯ Other
47.1.1.4	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Has there been a planned switch in antihormonal treatment:	◯ Yes ◯ No
47.1.1.5	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Immunotherapy' answer this question:*** Specify immunotherapy:	☐ Trastuzumab ☐ Other
47.1.1.5.1	***If 'Specify immunotherapy:' is equal to 'Other' answer this question:*** Specify "other" immunotherapy:	☐

48. Month 24 visit - Tumor Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
48.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Please select the tumor evaluations methods that were performed for the left breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
48.1.1	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
48.1.2	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	☐ ☐ ☐ *(dd-mm-yyyy)*
48.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Local relapse (within 2 cm)	○ Yes ○ No ○ Unknown
48.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
48.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	○ Yes ○ No
48.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
48.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Contralateral carcinoma:	○ Yes ○ No ○ Unknown
48.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	○ Yes ○ No ○ Unknown
48.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Ipsilateral secondary carcinoma:	○ Yes ○ No ○ Unknown
48.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Distant metastasis:	○ Yes ○ No ○ Unknown

49. Month 24 visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
49.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Please select the tumor evaluations methods that were performed for the right breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
49.1.1	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
49.1.2	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	☐ ☐ ☐ *(dd-mm-yyyy)*
49.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Local relapse (within 2 cm)	○ Yes ○ No ○ Unknown
49.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
49.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	○ Yes ○ No
49.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
49.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Contralateral carcinoma:	○ Yes ○ No ○ Unknown
49.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	○ Yes ○ No ○ Unknown
49.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Ipsilateral secondary carcinoma:	○ Yes ○ No ○ Unknown
49.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Distant metastasis:	○ Yes ○ No ○ Unknown

50. Month 24 visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
50.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Palpable seroma present at left breast:	◯ Yes ◯ No
50.1.1	***If 'Palpable seroma present at left breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
50.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	☐
50.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Breast volume assessed with planning CT:	◯ Yes ◯ No ◯ Unknown
50.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	☐ ml
50.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
50.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	☐ ml
50.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
50.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
50.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
50.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
50.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling

		◯ Grade 5: Death, related to event
50.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
50.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
50.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
50.3.1.1.6	***If 'Please select the abnormalities:' 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
50.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any toxicities observed at the clinical examination:	◯ Yes ◯ No
50.4.1	***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
50.4.1.1	***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
50.4.1.2	***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
50.4.1.3	***If 'Specify the observed toxicities:' is equal to 'Skin toxicities' answer this question:***	☐ Skin (CTC) ☐ Wound infection (CTC)

	Select the skin toxicities that were present:	☐ Dermatitis radiation (CTC) ☐ Erythema (Lent Soma) ☐ Pigmentation (Lent Soma) ☐ Teleangiectasia (Lent Soma) ☐ Fibrosis (Lent soma) ☐ Retraction (Lent Soma) ☐ Ulceration (Lent Soma) ☐ Other
50.4.1.3.1	***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
50.4.1.3.2	***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
50.4.1.3.3	***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
50.4.1.3.4	***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:
50.4.1.3.5	***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
50.4.1.3.6	***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
50.4.1.3.7	***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
50.4.1.3.8	***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

50.4.1.3.9	***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 cm^2 ◯ Grade 3: Ulceration including subcutis ◯ Grade 4: Free bone, necrosis
50.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
50.4.1.3.11	***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
50.5	***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
50.6	***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
50.6.1	***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
50.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

51. Month 24 visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
51.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Palpable seroma present at right breast:	◯ Yes ◯ No
51.1.1	***If 'Palpable seroma present at right breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
51.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	

51.2	***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
51.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	[ ] ml
51.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
51.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	[ ] ml
51.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
51.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
51.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
51.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
51.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
51.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
51.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event

51.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
51.3.1.1.6	***If 'Please select the abnormalities:' 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
51.4	***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
51.4.1	***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
51.4.1.1	***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
51.4.1.2	***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
51.4.1.3	***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
51.4.1.3.1	***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
51.4.1.3.2	***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

51.4.1.3.3	***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
51.4.1.3.4	***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:
51.4.1.3.5	***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
51.4.1.3.6	***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
51.4.1.3.7	***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
51.4.1.3.8	***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
51.4.1.3.9	***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 cm^2 ◯ Grade 3: Ulceration including subcutis ◯ Grade 4: Free bone, necrosis
51.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
51.4.1.3.11	***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
51.5	***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
51.6	***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

51.6.1	***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
51.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

52. Month 24 visit - Patient Questionnaires

Number	Question	Answers
52.1	EORTC QLQ-C30 questionnaire completed:	◯ Yes ◯ No
52.1.1	***If 'EORTC QLQ-C30 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-C30	
52.2	EORTC BR23 questionnaire completed:	◯ Yes ◯ No
52.2.1	***If 'EORTC BR23 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-BM22	

53. Month 24 visit - Study Status

Number	Question	Answers
53.1	Patient status:	◯ Patient is Alive ◯ Patient Discontinued ◯ Patient Died
53.1.1	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Date of death:	☐ ☐ ☐ *(dd-mm-yyyy)*
53.1.2	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Reason death:	◯ Breast cancer related ◯ Cardiac/circulation ◯ Other malignant disease ◯ Other
53.1.2.1	***If 'Reason death:' is equal to 'Other' answer this question:*** Please specify "other":	

53.1.3	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Autopsy performed:	◯ Yes ◯ No ◯ Unknown

54. Month 36 Visit - Date of Visit

Number	Question	Answers
54.1	Date of visit:	[ ] [ ] [ ] *(dd-mm-yyyy)*
54.2	Patient weight:	[ ] Kg

55. Month 36 Visit - Karnofsky Performance Status

Number	Question	Answers
55.1	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 personal needs ◯ 50 - Requires considerable assistance and frequent medical care ◯ 40 - Disabled, requires special care and assistance ◯ 30 - Severely disabled, hospital admission is indicated although death not imminent ◯ 20 - Very sick, hospital admission necessary, active supportive treatment necessary ◯ 10 - Moribund, fatal processes progressing rapidly ◯ 0 – Dead

56. Month 36 Visit - Adjuvant Systemic Treatment

Number	Question	Answers

56.1	Received patient adjuvant systemic treatment since last visit (Month 12):	◯ Yes ◯ No
56.1.1	***If 'Received patient adjuvant systemic treatment since last visit (Month 12):' is equal to 'Yes' answer this question:*** Select the Adjuvant Systemic Therapy that was given (tick all that apply):	☐ Chemotherapy ☐ Antihormonal treatment ☐ Immunotherapy ☐ Other
56.1.1.1	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Specify the adjuvant chemotherapy	
56.1.1.2	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Start date adjuvant chemotherapy:	*(dd-mm-yyyy)*
56.1.1.3	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Specify the current antihormonal treatment:	◯ Tamoxifen ◯ Aromatase-inhibitor ◯ Tamoxifen + Zoladex ◯ Other
56.1.1.4	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Has there been a planned switch in antihormonal treatment:	◯ Yes ◯ No
56.1.1.5	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Immunotherapy' answer this question:*** Specify immunotherapy:	☐ Trastuzumab ☐ Other
56.1.1.5.1	***If 'Specify immunotherapy:' is equal to 'Other' answer this question:*** Specify "other" immunotherapy:	

57. Month 36 Visit - Tumor Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
57.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Please select the tumor evaluations methods that were performed for the left breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
57.1.1	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Mammography' answer this question:*** Date mammography:	*(dd-mm-yyyy)*
57.1.2	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	*(dd-mm-yyyy)*
57.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Local relapse (within 2 cm)	◯ Yes ◯ No ◯ Unknown

57.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
57.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	○ Yes ○ No
57.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
57.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Contralateral carcinoma:	○ Yes ○ No ○ Unknown
57.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	○ Yes ○ No ○ Unknown
57.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Ipsilateral secondary carcinoma:	○ Yes ○ No ○ Unknown
57.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Distant metastasis:	○ Yes ○ No ○ Unknown

58. Month 36 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
58.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Please select the tumor evaluations methods that were performed for the right breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
58.1.1	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
58.1.2	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	☐ ☐ ☐ *(dd-mm-yyyy)*
58.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Local relapse (within 2 cm)	○ Yes ○ No ○ Unknown

58.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
58.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	◯ Yes ◯ No
58.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
58.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Contralateral carcinoma:	◯ Yes ◯ No ◯ Unknown
58.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	◯ Yes ◯ No ◯ Unknown
58.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Ipsilateral secondary carcinoma:	◯ Yes ◯ No ◯ Unknown
58.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Distant metastasis:	◯ Yes ◯ No ◯ Unknown

59. Month 36 Visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
59.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Palpable seroma present at left breast:	◯ Yes ◯ No
59.1.1	***If 'Palpable seroma present at left breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
59.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	☐
59.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Breast volume assessed with planning CT:	◯ Yes ◯ No ◯ Unknown
59.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	☐ ml

59.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
59.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	____ ml
59.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
59.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
59.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
59.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
59.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
59.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
59.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
59.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	____
59.3.1.1.6	***If 'Please select the abnormalities:' 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
59.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any toxicities observed at the clinical examination:	◯ Yes ◯ No
59.4.1	***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
59.4.1.1	***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
59.4.1.2	***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
59.4.1.3	***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
59.4.1.3.1	***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
59.4.1.3.2	***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
59.4.1.3.3	***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

59.4.1.3.4	***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:
59.4.1.3.5	***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
59.4.1.3.6	***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
59.4.1.3.7	***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
59.4.1.3.8	***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
59.4.1.3.9	***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 cm^2 ◯ Grade 3: Ulceration including subcutis ◯ Grade 4: Free bone, necrosis
59.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
59.4.1.3.11	***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
59.5	***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
59.6	***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
59.6.1	***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
59.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

60. Month 36 Visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
60.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Palpable seroma present at right breast:	◯ Yes ◯ No
60.1.1	***If 'Palpable seroma present at right breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
60.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	[ ]
60.2	***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
60.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	[ ] ml
60.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
60.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	[ ] ml
60.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
60.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
60.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
60.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for the leukocytes:	◯ No symtoms ◯ Grade 1: Mild

	Grade for 'leukocytes":	◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
60.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
60.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
60.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
60.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
60.3.1.1.6	***If 'Please select the abnormalities:' 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
60.4	***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
60.4.1	***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
60.4.1.1	***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
60.4.1.2	***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
60.4.1.3	***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
60.4.1.3.1	***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
60.4.1.3.2	***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
60.4.1.3.3	***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
60.4.1.3.4	***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:
60.4.1.3.5	***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
60.4.1.3.6	***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
60.4.1.3.7	***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
60.4.1.3.8	***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
60.4.1.3.9	***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
60.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
60.4.1.3.11	***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
60.5	***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
60.6	***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
60.6.1	***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
60.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

61. Month 36 Visit - Patient Questionnaires

Number	Question	Answers
61.1	EORTC QLQ-C30 questionnaire completed:	◯ Yes ◯ No
61.1.1	***If 'EORTC QLQ-C30 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-C30	
61.2	EORTC BR23 questionnaire completed:	◯ Yes ◯ No
61.2.1	***If 'EORTC BR23 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-BM22	

62. Month 36 Visit - Study Status

Number	Question	Answers
62.1	Patient status:	◯ Patient is Alive ◯ Patient Discontinued ◯ Patient Died
62.1.1	***If 'Patient status:' is equal to 'Patient Discontinued' answer this question:*** Reason discontinuation:	◯ Withdrawal of informed consent ◯ Lack of compliance ◯ Sponsor stopped the study ◯ Lost to follow-up ◯ Other
62.1.2	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Date of death:	☐ ☐ ☐ *(dd-mm-yyyy)*
62.1.3	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Reason death:	◯ Breast cancer related ◯ Cardiac/circulation ◯ Other malignant disease ◯ Other
62.1.3.1	***If 'Reason death:' is equal to 'Other' answer this question:*** Please specify "other":	☐
62.1.4	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Autopsy performed:	◯ Yes ◯ No ◯ Unknown

63. Month 48 Visit - Date of Visit

Number	Question	Answers
63.1	Date of visit:	☐ ☐ ☐ *(dd-mm-yyyy)*
63.2	Patient weight:	☐ Kg

64. Month 48 Visit - Karnofsky Performance Status

Number	Question	Answers
64.1	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 personal needs ◯ 50 - Requires considerable assistance and frequent medical care ◯ 40 - Disabled, requires special care and assistance ◯ 30 - Severely disabled, hospital admission is indicated although death not imminent ◯ 20 - Very sick, hospital admission necessary, active supportive treatment necessary ◯ 10 - Moribund, fatal processes progressing rapidly ◯ 0 – Dead

65. Month 48 Visit - Adjuvant Systemic Treatment

Number	Question	Answers
65.1	Received patient adjuvant systemic treatment since last visit (Month 12):	◯ Yes ◯ No
65.1.1	***If 'Received patient adjuvant systemic treatment since last visit (Month 12):' is equal to 'Yes' answer this question:*** Select the Adjuvant Systemic Therapy that was given (tick all that apply):	☐ Chemotherapy ☐ Antihormonal treatment ☐ Immunotherapy ☐ Other
65.1.1.1	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Specify the adjuvant chemotherapy	☐
65.1.1.2	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Start date adjuvant chemotherapy:	☐ ☐ ☐ *(dd-mm-yyyy)*
65.1.1.3	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Specify the current antihormonal treatment:	◯ Tamoxifen ◯ Aromatase-inhibitor ◯ Tamoxifen + Zoladex ◯ Other
65.1.1.4	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Has there been a planned switch in antihormonal treatment:	◯ Yes ◯ No
65.1.1.5	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Immunotherapy' answer this question:*** Specify immunotherapy:	☐ Trastuzumab ☐ Other

65.1.1.5.1	***If 'Specify immunotherapy:' is equal to 'Other' answer this question:*** Specify "other" immunotherapy:	

66. Month 48 Visit - Tumor Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
66.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Please select the tumor evaluations methods that were performed for the left breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
66.1.1	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Mammography' answer this question:*** Date mammography:	*(dd-mm-yyyy)*
66.1.2	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	*(dd-mm-yyyy)*
66.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Local relapse (within 2 cm)	○ Yes ○ No ○ Unknown
66.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	*(dd-mm-yyyy)*
66.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	○ Yes ○ No
66.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
66.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Contralateral carcinoma:	○ Yes ○ No ○ Unknown
66.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	○ Yes ○ No ○ Unknown
66.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Ipsilateral secondary carcinoma:	○ Yes ○ No ○ Unknown
66.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Distant metastasis:	○ Yes ○ No ○ Unknown

67. Month 48 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
67.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Please select the tumor evaluations methods that were performed for the right breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
67.1.1	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
67.1.2	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	☐ ☐ ☐ *(dd-mm-yyyy)*
67.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Local relapse (within 2 cm)	○ Yes ○ No ○ Unknown
67.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
67.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	○ Yes ○ No
67.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
67.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Contralateral carcinoma:	○ Yes ○ No ○ Unknown
67.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	○ Yes ○ No ○ Unknown
67.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Ipsilateral secondary carcinoma:	○ Yes ○ No ○ Unknown

67.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Distant metastasis:	◯ Yes ◯ No ◯ Unknown

68. Month 48 Visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
68.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Palpable seroma present at left breast:	◯ Yes ◯ No
68.1.1	***If 'Palpable seroma present at left breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
68.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	[ ]
68.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Breast volume assessed with planning CT:	◯ Yes ◯ No ◯ Unknown
68.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	[ ] ml
68.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
68.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	[ ] ml
68.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
68.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
68.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other

68.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
68.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
68.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
68.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
68.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
68.3.1.1.6	***If 'Please select the abnormalities:' 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
68.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any toxicities observed at the clinical examination:	◯ Yes ◯ No
68.4.1	***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
68.4.1.1	***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

68.4.1.2	***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
68.4.1.3	***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
68.4.1.3.1	***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
68.4.1.3.2	***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
68.4.1.3.3	***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
68.4.1.3.4	***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:
68.4.1.3.5	***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
68.4.1.3.6	***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
68.4.1.3.7	***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

68.4.1.3.8	***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
68.4.1.3.9	***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
68.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
68.4.1.3.11	***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
68.5	***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
68.6	***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
68.6.1	***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
68.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

69. Month 48 Visit - Toxicity Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
69.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Palpable seroma present at right breast:	◯ Yes ◯ No
69.1.1	***If 'Palpable seroma present at right breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown

69.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	
69.2	***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
69.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	ml
69.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
69.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	ml
69.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
69.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
69.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
69.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
69.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
69.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event

69.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
69.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
69.3.1.1.6	***If 'Please select the abnormalities:' 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
69.4	***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
69.4.1	***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
69.4.1.1	***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
69.4.1.2	***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
69.4.1.3	***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
69.4.1.3.1	***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

69.4.1.3.2	***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
69.4.1.3.3	***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
69.4.1.3.4	***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:
69.4.1.3.5	***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
69.4.1.3.6	***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
69.4.1.3.7	***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
69.4.1.3.8	***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
69.4.1.3.9	***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
69.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
69.4.1.3.11	***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

69.5	***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
69.6	***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
69.6.1	***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
69.6.1.1	***If 'Where any serious toxicities related to surgery or radiation?' is equal to 'Yes' answer this question:*** Please complete SAE report	

70. Month 48 Visit - Patient Questionnaires

Number	Question	Answers
70.1	EORTC QLQ-C30 questionnaire completed:	◯ Yes ◯ No
70.1.1	***If 'EORTC QLQ-C30 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-C30	
70.2	EORTC BR23 questionnaire completed:	◯ Yes ◯ No
70.2.1	***If 'EORTC BR23 questionnaire completed:' is equal to 'Yes' answer this question:*** Upload EORTC QLQ-BM22	

71. Month 48 Visit - Study Status

Number	Question	Answers
71.1	Patient status:	◯ Patient is Alive ◯ Patient Discontinued ◯ Patient Died
71.1.1	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Date of death:	☐ ☐ ☐ *(dd-mm-yyyy)*
71.1.2	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Reason death:	◯ Breast cancer related ◯ Cardiac/circulation ◯ Other malignant disease ◯ Other

71.1.2.1	***If 'Reason death:' is equal to 'Other' answer this question:*** Please specify "other":	
71.1.3	***If 'Patient status:' is equal to 'Patient Died' answer this question:*** Autopsy performed:	◯ Yes ◯ No ◯ Unknown

72. Month 60 Visit - Date of Visit

Number	Question	Answers
72.1	Date of visit:	*(dd-mm-yyyy)*
72.2	Patient weight:	Kg

73. Month 60 Visit - Karnofsky Performance Status

Number	Question	Answers
73.1	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 personal needs ◯ 50 - Requires considerable assistance and frequent medical care ◯ 40 - Disabled, requires special care and assistance ◯ 30 - Severely disabled, hospital admission is indicated although death not imminent ◯ 20 - Very sick, hospital admission necessary, active supportive treatment necessary ◯ 10 - Moribund, fatal processes progressing rapidly ◯ 0 – Dead

74. Month 60 Visit - Adjuvant Systemic Treatment

Number	Question	Answers
74.1	Received patient adjuvant systemic treatment since last visit (Month 12):	◯ Yes ◯ No
74.1.1	***If 'Received patient adjuvant systemic treatment since last visit (Month 12):' is equal to 'Yes' answer this question:*** Select the Adjuvant Systemic Therapy that was given (tick all that apply):	☐ Chemotherapy ☐ Antihormonal treatment ☐ Immunotherapy ☐ Other
74.1.1.1	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Specify the adjuvant chemotherapy	☐
74.1.1.2	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Chemotherapy' answer this question:*** Start date adjuvant chemotherapy:	☐ ☐ ☐ *(dd-mm-yyyy)*
74.1.1.3	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Specify the current antihormonal treatment:	◯ Tamoxifen ◯ Aromatase-inhibitor ◯ Tamoxifen + Zoladex ◯ Other
74.1.1.4	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Antihormonal treatment' answer this question:*** Has there been a planned switch in antihormonal treatment:	◯ Yes ◯ No
74.1.1.5	***If 'Select the Adjuvant Systemic Therapy that was given (tick all that apply):' is equal to 'Immunotherapy' answer this question:*** Specify immunotherapy:	☐ Trastuzumab ☐ Other
74.1.1.5.1	***If 'Specify immunotherapy:' is equal to 'Other' answer this question:*** Specify "other" immunotherapy:	☐

75. Month 60 Visit - Tumor Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
75.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Please select the tumor evaluations methods that were performed for the left breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
75.1.1	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
75.1.2	***If 'Please select the tumor evaluations methods that were performed for the left breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	☐ ☐ ☐ *(dd-mm-yyyy)*

75.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Local relapse (within 2 cm)	◯ Yes ◯ No ◯ Unknown
75.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
75.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	◯ Yes ◯ No
75.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
75.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Contralateral carcinoma:	◯ Yes ◯ No ◯ Unknown
75.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	◯ Yes ◯ No ◯ Unknown
75.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Ipsilateral secondary carcinoma:	◯ Yes ◯ No ◯ Unknown
75.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Distant metastasis:	◯ Yes ◯ No ◯ Unknown

76. Month 60 Visit - Tumor Evaluations Right Breast

Number	Question	Answers
	Tumor location was Left Breast. No data needs to be recorded at this section.	
76.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Please select the tumor evaluations methods that were performed for the right breast:	☐ Clinical examination ☐ Mammography ☐ Ultrasound of the breast ☐ Breast MRI ☐ Other imaging techniques
76.1.1	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Mammography' answer this question:*** Date mammography:	☐ ☐ ☐ *(dd-mm-yyyy)*
76.1.2	***If 'Please select the tumor evaluations methods that were performed for the right breast:' is equal to 'Ultrasound of the breast' answer this question:*** Date breast ultrasound:	☐ ☐ ☐ *(dd-mm-yyyy)*

76.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Local relapse (within 2 cm)	◯ Yes ◯ No ◯ Unknown
76.2.1	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Date of first diagnosis local relapse:	☐ ☐ ☐ *(dd-mm-yyyy)*
76.2.2	***If 'Local relapse (within 2 cm)' is equal to 'Yes' answer this question:*** Was re-resection performed due to the presence of positive margins:	◯ Yes ◯ No
76.2.2.1	***If 'Was re-resection performed due to the presence of positive margins:' is equal to 'Yes' answer this question:*** Click to record re-resection procedure.	
76.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Contralateral carcinoma:	◯ Yes ◯ No ◯ Unknown
76.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Lymphnode metastases at axilla ipsilateral:	◯ Yes ◯ No ◯ Unknown
76.5	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Ipsilateral secondary carcinoma:	◯ Yes ◯ No ◯ Unknown
76.6	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Right breast' answer this question:*** Distant metastasis:	◯ Yes ◯ No ◯ Unknown

77. Month 60 Visit - Toxicity Evaluations Left Breast

Number	Question	Answers
	Tumor location was Right Breast. No data needs to be recorded at this section.	
77.1	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Palpable seroma present at left breast:	◯ Yes ◯ No
77.1.1	***If 'Palpable seroma present at left breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
77.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	☐
77.2	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Breast volume assessed with planning CT:	◯ Yes ◯ No ◯ Unknown

77.2.1	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Breast volume (CT):	ml
77.2.2	***If 'Breast volume assessed with planning CT:' is equal to 'Yes' answer this question:*** Seroma visible on planning CT:	◯ Yes ◯ No ◯ Unknown
77.2.2.1	***If 'Seroma visible on planning CT:' is equal to 'Yes' answer this question:*** Seroma volume:	ml
77.3	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Were laboratory parameters assessed:	◯ Yes ◯ No
77.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
77.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils ☐ Platelets ☐ Other
77.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
77.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
77.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
77.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	◯ No symtoms ◯ Grade 1: Mild ◯ Grade 2: Moderate ◯ Grade 3: Severe ◯ Grade 4: Life-threatening, disabling ◯ Grade 5: Death, related to event
77.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	

77.3.1.1.6	***If 'Please select the abnormalities:' 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
77.4	***If 'Tumor location (tick both in case of bilateral breast cancer):' is equal to 'Left breast' answer this question:*** Where any toxicities observed at the clinical examination:	◯ Yes ◯ No
77.4.1	***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
77.4.1.1	***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
77.4.1.2	***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
77.4.1.3	***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
77.4.1.3.1	***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
77.4.1.3.2	***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
77.4.1.3.3	***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
77.4.1.3.4	***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:
77.4.1.3.5	***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
77.4.1.3.6	***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
77.4.1.3.7	***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
77.4.1.3.8	***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
77.4.1.3.9	***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
77.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
77.4.1.3.11	***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
77.5	***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

77.6	***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
77.6.1	***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
77.6.1.1	***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:*** Palpable seroma present at right breast:	◯ Yes ◯ No
78.1.1	***If 'Palpable seroma present at right breast:' is equal to 'Yes' answer this question:*** Seroma puncture performed:	◯ Yes ◯ No ◯ Unknown
78.1.1.1	***If 'Seroma puncture performed:' is equal to 'Yes' answer this question:*** Number of punctures:	[ ]
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 equal 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:*** Were laboratory parameters assessed:	◯ Yes ◯ No
78.3.1	***If 'Were laboratory parameters assessed:' is equal to 'Yes' answer this question:*** Any clinical relevant abnormalities observed for the blood values?	◯ Yes ◯ No
78.3.1.1	***If 'Any clinical relevant abnormalities observed for the blood values?' is equal to 'Yes' answer this question:*** Please select the abnormalities:	☐ Leukocytes (total WBC) ☐ Lymphopenia ☐ Neutrophils

		☐ Platelets ☐ Other
78.3.1.1.1	***If 'Please select the abnormalities:' is equal to 'Leukocytes (total WBC)' answer this question:*** Grade for 'leukocytes":	○ No symtoms ○ Grade 1: Mild ○ Grade 2: Moderate ○ Grade 3: Severe ○ Grade 4: Life-threatening, disabling ○ Grade 5: Death, related to event
78.3.1.1.2	***If 'Please select the abnormalities:' is equal to 'Lymphopenia' answer this question:*** Grade for 'lymphopenia":	○ No symtoms ○ Grade 1: Mild ○ Grade 2: Moderate ○ Grade 3: Severe ○ Grade 4: Life-threatening, disabling ○ Grade 5: Death, related to event
78.3.1.1.3	***If 'Please select the abnormalities:' is equal to 'Neutrophils' answer this question:*** Grade for 'neutrophils":	○ No symtoms ○ Grade 1: Mild ○ Grade 2: Moderate ○ Grade 3: Severe ○ Grade 4: Life-threatening, disabling ○ Grade 5: Death, related to event
78.3.1.1.4	***If 'Please select the abnormalities:' is equal to 'Platelets' answer this question:*** Grade for 'platelets":	○ No symtoms ○ Grade 1: Mild ○ Grade 2: Moderate ○ Grade 3: Severe ○ Grade 4: Life-threatening, disabling ○ Grade 5: Death, related to event
78.3.1.1.5	***If 'Please select the abnormalities:' is equal to 'Other' answer this question:*** Describe "other" abnormality:	
78.3.1.1.6	***If 'Please select the abnormalities:' 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:*** Where any toxicities observed at the clinical examination:	○ Yes ○ No
78.4.1	***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
78.4.1.1	***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

78.4.1.2	***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
78.4.1.3	***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
78.4.1.3.1	***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
78.4.1.3.2	***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
78.4.1.3.3	***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
78.4.1.3.4	***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:
78.4.1.3.5	***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
78.4.1.3.6	***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
78.4.1.3.7	***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

78.4.1.3.8	***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
78.4.1.3.9	***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 cm^2 ◯ Grade 3: Ulceration including subcutis ◯ Grade 4: Free bone, necrosis
78.4.1.3.10	***If 'Select the skin toxicities that were present:' is equal to 'Other' answer this question:*** Please specify "other":	
78.4.1.3.11	***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
78.5	***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
78.6	***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
78.6.1	***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
78.6.1.1	***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