



ICHOM

International Consortium for
Health Outcomes Measurement

BREAST CANCER DATA COLLECTION REFERENCE GUIDE

Version 1.0.1

Revised: March 30, 2017



Measuring
results
that matter

Arm and Breast
symptoms

Breast Cancer



We are thrilled that you are interested in measuring outcomes for your breast cancer patients according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure collection of comparable data for global benchmarking and learning.

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets, comprehensive yet parsimonious sets of outcomes and case-mix variables we recommend all providers track.

Each Standard Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardized outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. We also include high-level treatment variables to allow stratification of outcomes by major treatment types. A comprehensive data dictionary is included in the appendix.

Working Group Members for Breast Cancer

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Breast Cancer in partnership with ICHOM, under the leadership of Dr. Christobel Saunders, Professor of Surgical Oncology and the Head of Unit, General Surgery at The University of Western Australia.

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Supporting Organizations

The Breast Cancer Standard Set is made possible only through the support of the following organizations.

Thank you.



Conditions and Treatment Approaches Covered for Breast Cancer

For Breast Cancer, the following treatment approaches (or interventions) are covered by our Standard Set.

Conditions*	All patients (men and women) with newly pathologically diagnosed invasive breast cancer (stage I-IV) and ductal carcinoma in situ (DCIS).
Treatment Approaches	(Reconstructive) Surgery Radiotherapy Chemotherapy Hormonal Therapy Targeted Therapy

*Excluded Conditions: Rare tumors (e.g. phyllodes tumor), lobular carcinoma in situ (LCIS) and patients with recurrent disease at baseline will be excluded.

ICHOM Standard Set for Breast Cancer

Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
Demographic Factors				
All patients	Gender	N/A	Baseline	Patient-reported
	Date of birth			
	Body mass index	Height and weight		Clinical
	Ethnicity	Determined by country		
	Educational level	Level of schooling completed		Patient-reported
	Relationship status	Relationship status		
	Menopausal status	Current menopausal status		
Baseline Clinical Factors				
All patients	Comorbidities	Modified Self-administered Comorbidity Questionnaire (SCQ)	Baseline, update at least after 5 years	Patient-reported
	Laterality	Laterality of breast cancer	Baseline	Clinical
	First or new primary tumor	First primary or new primary on contralateral or ipsilateral breast		
Baseline Tumor Factors				
All patients	Date of diagnosis	Initial date of histological diagnosis	Baseline	Clinical
	Histological type	Histological type of tumor		
	Mutation status	Genetic mutation predisposing breast cancer	Baseline and 1 year	
	Tumor grade (invasive)	Grade of invasive component of tumor		
	Tumor grade (DCIS)	Grade of DCIS component of tumor		
Patients with neoadjuvant therapy	Clinical stage	Clinical stage per AJCC 7th	Baseline	Clinical
Patients with surgery/biopsy	Pathological M stage	Pathological stage per AJCC 7th		
	Pathological TNM stage			
Patients with surgery	Size of invasive component of tumor	Size of invasive component of largest tumor (in mm)		
	Number of lymph nodes resected	N/A		
	Number of lymph nodes involved	Number of lymph nodes involved according to TNM stage AJCC 7th		
	Estrogen receptor status	Presence of estrogen receptor status		
	Progesteron receptor status	Presence of progesteron receptor status		
	Her-2 receptor status	Presence of Her-2 receptor status		

Treatment Variables

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
All patients	(Reconstructive) Surgery	N/A	Update at least annually	Clinical and patient-reported
	Radiotherapy			
	Chemotherapy			
	Hormonal therapy			
	Targeted therapy			

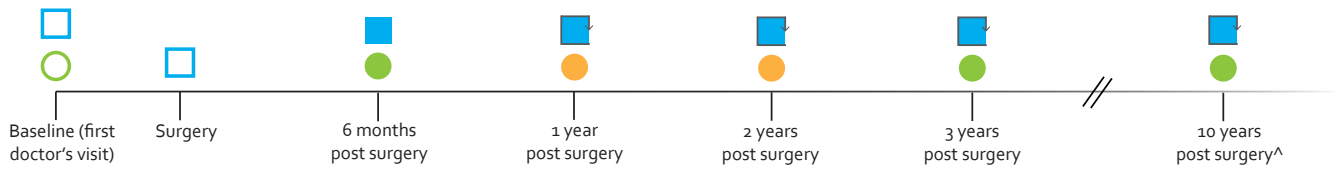
Outcomes

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
Disutility of care				
Patients with surgery/radiotherapy	Reoperation due to positive margins	Reoperation due to positive margins after final surgery	Update at least 6 months after treatment	Clinical and patient-reported
All patients with treatment	Impact of acute complication	Acute complications will be recorded based on the type of therapy needed or action required to correct the complication as described in the Clavien-Dindo Classification and CTCAE v4.0	Updated at least 6 months, 1 year after treatment when a patient received hormonal therapy	Clinical
	Type of acute complication	Name of acute complication		
Degree of Health				
All patients	Overall well-being	Tracked via EORTC QLQ-C30	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years	Patient-reported
	Physical functioning			
	Emotional functioning			
	Cognitive functioning			
	Social functioning			
	Ability to work			
	Anxiety			
	Depression			
	Financial impact			
	Pain			
Patients with surgery/radiotherapy	Satisfaction with breast(s)	Tracked via BREAST-Q - Satisfaction with Breasts	Baseline, 1 and 2 year post treatment	Patient-reported
	Arm symptoms	Tracked via EORTC QLQ-BR23	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years	
Patients with systemic therapy	Breast symptoms			Tracked via EORTC QLQ-LMC21 - single item
	Vasomotor symptoms			
	Peripheral neuropathy			
	Vaginal symptoms			
Patients with systemic therapy	Arthralgia	Tracked via FACT-ES (single items)	Tracked via FACT-ES (single items)	
	Arthralgia			
Survival and Disease Control				
All patients	Overall survival	Date of death	1 year post treatment, tracked annually up to 10 years	Administrative /Clinical
	Cause of death	Death attributed to breast cancer		
Patients with curative intent	Recurrence free survival	Local, regional or distant recurrence	1 year post treatment, tracked annually up to 10 years	Clinical

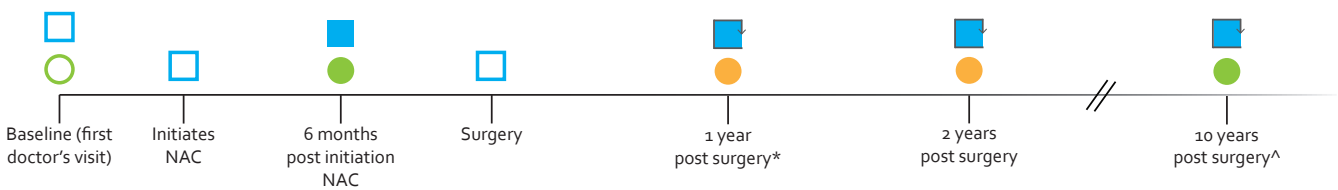
Follow-Up Timeline and Sample Questionnaires

The following timeline illustrates when Standard Set variables should be collected from patients, clinicians, and administrative sources. Links to the sample questionnaires may be found in the legend below.

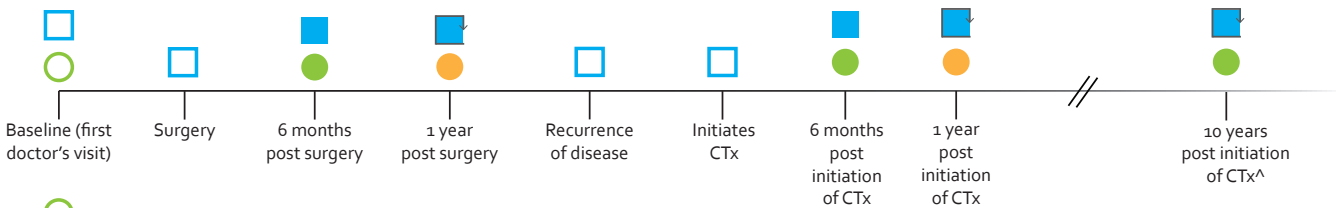
EXAMPLE 1: Patient diagnosed with breast cancer, receives surgery only










EXAMPLE 2: Patient diagnosed with breast cancer, receives neoadjuvant chemotherapy (NAC) and surgery



EXAMPLE 3: Patient diagnosed with breast cancer, receives surgery, recurs and receives chemotherapy (CTx)



-  Baseline Clinical Form ([link](#))
-  Baseline Patient-Reported Form ([link](#))
-  Follow-Up Patient-Reported Form (6 months, 3-10 years) ([link](#))*
-  Follow-Up Patient-Reported Form (1 and 2 years) ([link](#))*
-  *BREAST-Q will only be collected at baseline, 1 and 2 years
-  Follow-Up Clinical 6 months Form ([link](#))
-  Follow-up Clinical Annual Form ([link](#))

*Annual follow-up reassessed from date of surgery so that it will run parallel with annual outpatient visit.

^ Distinction for long-term follow-up:

- Local disease
Up to 10 years follow-up
- Metastatic disease:
Annually for life

Collecting Patient-Reported Outcome Measures

Survey(s) Used	Licensing Information	Scoring Guide
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)	The EORTC QLQ-C30 is free for all health care organizations, but a license is needed for use. More information can be found at http://groups.eortc.be/qol/eortc-qlq-c30	See link at left
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-BR23)	The EORTC QLQ-BR23 is free for all health care organizations, but a license is needed for use. More information can be found at http://groups.eortc.be/qol/eortc-qlq-c30	See link at left
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-LMC21)	Licensing information: The EORTC-LMC21 is free for all health care organizations, but a license is needed for use. For more information, please visit: http://groups.eortc.be/qol/eortc-qlq-c30	See link at left
BREAST-Q Patient Reported Outcomes Instrument (BREAST-Q)	Licensing information: The BREAST-Q is free for any not-profit health care organizations, but a user agreement is needed. For any for-profit healthcare organization a license fee has to be paid and a license agreement is required. For more information, please visit: https://eprovide.mapi-trust.org/instruments/breast-q#contact_and_conditions_of_use	See link at left
Functional Assessment of Cancer Therapy Endocrine Subscale (FACT-ES)	The English version of the FACT-ES is free for anyone to use and can be found at http://www.facit.org/facitorg/questionnaires . Over 25 translations of the FACT-ES have been published but are not available on the website and may require a fee. Requests for translated questionnaires and cost information are processed through the FACIT website (registration required).	See link at left

The Growing ICHOM Community

By implementing the ICHOM Standard Sets, you become part of an expanding, international community of innovative health care providers dedicated to improving value for patients. To learn more about how ICHOM can assist your organization in implementing outcome measurement, contact us at implement@ichom.org, or visit <http://www.ichom.org/measure>.

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Breast Cancer Standard Set as consistently as possible to the Working Group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **We are happy to provide an Excel version of this data dictionary for technical use.**

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

CASE-MIX VARIABLES

Variable ID:	N/A
Variable:	Patient ID
Definition:	Indicate the patient's medical record number:
Supporting Definition:	This number will not be shared with ICHOM. In the case patient-level data is submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating institution
Inclusion Criteria:	All patients
Timing:	On all forms
Reporting Source:	Administrative or clinical
Type:	Numerical
Response Options:	According to institution

Variable ID:	LASTNAME
Variable:	Patient's last name
Definition:	Patient's last name:
Supporting Definition:	The patients' name will not be shared with ICHOM.
Inclusion Criteria:	All patients
Timing:	On all forms
Reporting Source:	Administrative or clinical
Type:	Free text
Response Options:	N/A

Demographic Factors

Variable ID:	SEX
Variable:	Gender
Definition:	Please indicate your sex:
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Male 2 = Female

	999 = Undisclosed
Variable ID:	DOB
Variable:	Date of birth
Definition:	What is your date of birth?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported and clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	COUNTRY
Variable:	Country
Definition:	What is your country of residence?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	N/A
Variable ID:	ETNIC
Variable:	Ethnicity
Definition:	Varies by country and should be determined by country (not for cross country comparison)
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	N/A
Variable ID:	EDUCATION
Variable:	Educational Level
Definition:	Please indicate highest level of schooling completed. This response option is based upon the ISCED for the United States, and reflects standards in the U.S. Please adapt questions according to your country's guidelines.
Supporting Definition:	This is based upon the International Standard Classification of Education for the United States, and reflects standards in the U.S. Please adapt questions according to your country's guidelines. Primary refers to the first 8 years of formal education in elementary school in the US. Secondary school refers to the last four years of statutory formal education (grade 9-12) at high school in the US. Tertiary refers to colleges or universities, including undergraduate and postgraduate education in the US.
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None 1 = Primary 2 = Secondary 3 = Tertiary
Variable ID:	MARITAL
Variable:	Relationship status
Definition:	What is your relationship status?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline

Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Never married/partnered
 1 = Married/partnered
 2 = Divorced/separated
 3 = Widowed

Variable ID: MENOPAUSE
Variable: Menopause status
Definition: What is your current menopausal status?
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Pre-menopause
 1 = Post-menopause (natural/surgical) - if you have not had your period >12 months, caused by natural decline of hormones or due to surgery (e.g. menopause that develops after the ovaries are surgically removed)
 3 = I don't know what my current menopausal status is

Baseline Clinical Factors

Variable ID: COMORB
Variable: Comorbidities
Definition: Have you been told by a doctor that you have any of the following? (select all that apply)
Supporting Definition: Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003)
Inclusion Criteria: All patients
Timing: Baseline and after 5 years
Reporting Source: Patient-reported
Type: Multiple answer
 Separate multiple entries with ";"
Response Options: 0 = I have no other diseases
 1 = Heart disease (For example, angina, heart attack, or heart failure)
 2 = High blood pressure
 3 = Leg pain when walking due to poor circulation
 4 = Lung disease (For example, asthma, chronic bronchitis, or emphysema)
 5 = Diabetes
 6 = Kidney disease
 7 = Liver disease
 8 = Problems caused by stroke
 9 = Disease of the nervous system (For example, Parkinson's disease or multiple sclerosis)
 10 = Other cancer (within the last 5 years)
 11 = Depression
 12 = Arthritis

Variable ID: HEIGHTCIIN
Variable: Height
Definition: Indicate height in centimeters or inches
Supporting Definition: Height and weight are used to calculate BMI
Inclusion Criteria: All patients
Timing: Baseline
Reporting Source: Clinical
Type: Numerical value
Response Options: Numerical value of height in cm or in

Variable ID: HEIGHTUNITCIIN
Variable: Height units
Definition: Indicate units of height

Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline
Reporting Source: Clinical
Type: Single answer
Response Options: 1 = centimeters
 2 = inches

Variable ID: WEIGHTCLIN
Variable: Weight
Definition: Indicate weight in kilograms or pounds
Supporting Definition: Height and weight are used to calculate BMI
Inclusion Criteria: All patients
Timing: Baseline
Reporting Source: Clinical
Type: Numerical value
Response Options: Numerical value of weight in kg or lbs

Variable ID: WEIGHTUNITCLIN
Variable: Weight units
Definition: Indicate units of weight
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline
Reporting Source: Clinical
Type: Single answer
Response Options: 1 = kilograms
 2 = pounds

Variable ID: LATERAL
Variable: Laterality
Definition: Indicate the laterality of breast cancer:
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline
Reporting Source: Clinical
Type: Single answer
Response Options: 0 = Left breast
 1 = Right breast
 3 = Both breasts

Variable ID: FIRSTBC
Variable: First breast cancer
Definition: Indicate if this is first breast cancer or new cancer on contralateral or ipsilateral breast:
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline
Reporting Source: Clinical
Type: Single answer
Response Options: 0 = Primary tumor
 1 = New ipsilateral
 2 = New contralateral

Baseline Tumor Factors

Variable ID: DIAGDATE
Variable: Histological diagnosis
Definition: Initial date of histological diagnosis
Supporting Definition: The first time that histology of the tumor is examined, after biopsy or surgery, whichever came first
Inclusion Criteria: All patients
Timing: Baseline

Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY
Variable ID:	HISTOTYPE
Variable:	Histological type
Definition:	Indicate histologic type of the tumor (select all that apply):
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Ductal carcinoma in situ 1 = Invasive ductal carcinoma 2 = Invasive lobular carcinoma 3 = Other 999=unknown
Variable ID:	MUTBC
Variable:	Genetic mutation
Definition:	Indicate if the patient carries a genetic mutation predisposing breast cancer:
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and after 1 year
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = No mutation 1 = BRCA 1 2 = BRCA 2 3 = Other mutation 4 = Not tested
Variable ID:	GRADEINV
Variable:	Invasion grade
Definition:	Indicate grade of invasive component of tumor:
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Grade 1 1 = Grade 2 2 = Grade 3 3 = Not reported
Variable ID:	GRADEDNIS
Variable:	Tumor grade
Definition:	Indicate tumor grade of DCIS component of tumor:
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Low 1 = Intermediate 2 = High 3 = Not reported
Variable ID:	TNMCT
Variable:	Clinical tumor stage
Definition:	Clinical tumor stage (per AJCC 5th - 7th Ed.)
Supporting Definition:	Tumor stage (AJCC 5th -7th edition): TX: primary tumor cannot be assessed

To: no evidence of primary tumor
 Tis: intraepithelial or invasion of lamina propria
 T1: tumor confined to the submucosa
 T2: tumor has grown into (but not through) the muscularis propria
 T3: tumor has grown into (but not through) the serosa
 T4: tumor has penetrated through the serosa and the peritoneal surface.

Inclusion Criteria: All patients that received neoadjuvant therapy

Timing: Baseline

Reporting Source: Clinical

Type: Single answer

Response Options: 0 = cTX
 1 = cTo
 2 = cTis
 3 = cT1
 4 = cT2
 5 = cT3
 6 = cT4
 999 = Unknown

Variable ID: TNMCN

Variable: Clinical nodal stage

Definition: Clinical nodal stage (per AJCC 5th - 7th Ed.)

Supporting Definition: Nodal stage (AJCC 5th -7th edition):

NX: lymph nodes were not assessed

No: no lymph nodes contain tumor cells

N1: there are tumor cells in up to 3 regional lymph nodes

N2: there are tumor cells in 4 or more regional lymph nodes

Inclusion Criteria: All patients that received neoadjuvant therapy

Timing: Baseline

Reporting Source: Clinical

Type: Single answer

Response Options: 0 = cNX
 1 = cNo
 2 = cN1
 3 = cN2
 4 = cN3
 999 = Unknown

Variable ID: TNMCM

Variable: Clinical distant metastasis

Definition: Clinical distant metastasis (per AJCC 5th - 7th Ed.)

Supporting Definition: Distant metastasis (AJCC 5th- 7th edition):

Mx: presence of metastasis cannot be assessed

Mo: no metastasis to distant organs

M1: metastasis to distant organs

Inclusion Criteria: All patients that received neoadjuvant therapy

Timing: Baseline

Reporting Source: Clinical

Type: Single answer

Response Options: 0 = cMX
 1 = cMo
 2 = cM1
 999 = Unknown

Variable ID: TNMPT

Variable: Pathological tumor stage

Definition: Pathological tumor stage (per AJCC 5th - 7th Ed.)

Supporting Definition: Tumor stage (AJCC 5th -7th edition):

TX: primary tumor cannot be assessed

To: no evidence of primary tumor

Tis: intraepithelial or invasion of lamina propria
 T1: tumor confined to the submucosa
 T2: tumor has grown into (but not through) the muscularis propria
 T3: tumor has grown into (but not through) the serosa
 T4: tumor has penetrated through the serosa and the peritoneal surface.

Inclusion Criteria: If the patient received surgery

Timing: Baseline

Reporting Source: Clinical

Type: Single answer

Response Options: 0 = pTX
 1 = pT0
 2 = pTis
 3 = pT1
 4 = pT2
 5 = pT3
 6 = pT4
 999 = Unknown

Variable ID: TNMPN

Variable: Pathological nodal stage

Definition: Pathological nodal stage (per AJCC 5th - 7th Ed.)

Supporting Definition: Nodal stage (AJCC 5th -7th edition):

NX: lymph nodes were not assessed

No: no lymph nodes contain tumor cells

N1: there are tumor cells in up to 3 regional lymph nodes

N2: there are tumor cells in 4 or more regional lymph nodes

Inclusion Criteria: If the patient received surgery

Timing: Baseline

Reporting Source: Clinical

Type: Single answer

Response Options: 0 = pNX
 1 = pNo
 2 = pN1
 3 = pN2
 4 = pN3
 999 = Unknown

Variable ID: TNMPM

Variable: Pathological distant metastasis

Definition: Pathological distant metastasis (per AJCC 5th - 7th Ed.)

Supporting Definition: Distant metastasis (AJCC 5th- 7th edition):

Mx: presence of metastasis cannot be assessed

Mo: no metastasis to distant organs

M1: metastasis to distant organs

Inclusion Criteria: If the patient received surgery

Timing: Baseline

Reporting Source: Clinical

Type: Single answer

Response Options: 0 = pMx
 1 = pMo
 2 = pM1
 999 = Unknown

Variable ID: SIZEINV

Variable: Size of invasive tumor

Definition: Indicate size of invasive component of tumor (in mm):

Supporting Definition: N/A

Inclusion Criteria: If the patient received surgery

Timing: Baseline

Reporting Source: Clinical

Type:	Numerical value; Please enter "999" if size of invasive component is unknown.
Response Options:	N/A
Variable ID:	LYMPHNR
Variable:	Lymph nodes resected
Definition:	Number of lymph nodes resected:
Supporting Definition:	N/A
Inclusion Criteria:	If the patient received surgery
Timing:	Baseline
Reporting Source:	Clinical
Type:	Numerical value; Please enter "999" if number of resected lymph nodes is unknown.
Response Options:	N/A
Variable ID:	LYMPHINV
Variable:	Lymph nodes involved
Definition:	Number of lymph nodes involved according to the TNM stage AJCC 7th Ed.:
Supporting Definition:	N/A
Inclusion Criteria:	If the patient received surgery
Timing:	Baseline
Reporting Source:	Clinical
Type:	Numerical value; Please enter "999" if number of involved lymph nodes is unknown.
Response Options:	N/A
Variable ID:	ERSTATUS
Variable:	Estrogen receptor status
Definition:	Indicate if the estrogen receptor status is positive:
Supporting Definition:	N/A
Inclusion Criteria:	If the patient received surgery
Timing:	Baseline
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes 2 = Not performed 999=Unkown
Variable ID:	PRSTATUS
Variable:	Progesterone receptor status
Definition:	Indicate if the progesterone receptor status is positive:
Supporting Definition:	N/A
Inclusion Criteria:	If the patient received surgery
Timing:	Baseline
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes 2 = Not performed 999=Unkown
Variable ID:	HER2STATUS
Variable:	HER2 receptor status
Definition:	Indicate if the HER2 receptor status is positive:
Supporting Definition:	By immunohistochemistry or ISH, whichever was considered most definitive
Inclusion Criteria:	If the patient received surgery
Timing:	Baseline
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Negative 1 = Positive 2 = Equivocal 3 = Not performed

Treatment Variables

Treatment Variables

Variable ID:	TREATMENT
Variable:	Treatment
Definition:	Indicate whether the patient received one of the following treatments during the last year: (select all that apply)
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Multiple answers
Response Options:	0 = No treatment 1 = Surgery 2 = Surgery to axilla 3 = Delayed reconstruction 4 = Radiotherapy 5 = Chemotherapy 6 = Hormonal therapy 7 = Targeted therapy 8 = Best supportive care 999 = Unknown
Variable ID:	SURGERY
Variable:	Surgery
Definition:	Indicate whether the patient received surgery during the last year:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "surgery" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Breast conserving surgery (BCS) 1 = BCS with mastoplasty 2 = Mastectomy without immediate reconstruction 3 = Mastectomy with immediate reconstruction (direct/staged implant) 4 = Mastectomy with immediate reconstruction (autologous) 5 = Mastectomy with immediate reconstruction (direct/staged implant and autologous) 999 = Unknown
Variable ID:	SURGERYDATE
Variable:	Surgery date
Definition:	Provide the date of surgery:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "surgery" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	SURGERYAX
Variable:	Surgery axilla
Definition:	Indicate whether the patient received surgery to the axilla during the last year:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "surgery to axilla" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Sentinel lymph node biopsy

	1 = Axillary sampling 2 = Axillary clearance 999 = Unknown
Variable ID:	SURGERYAXDATE
Variable:	Surgery axilla date
Definition:	Please provide the date of surgery to the axilla (DD/MM/YYYY):
Supporting Definition:	N/A
Inclusion Criteria:	If answered "surgery to axilla" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	SURGERYAX2
Variable:	Axillary clearance
Definition:	Indicate whether the patient received axillary clearance due to lymph node involvement after sentinel lymph node biopsy during the last year:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "sentinel lymph node biopsy" or "axillary sampling on surgery axilla" [SURGERYAX]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes 999 = Unknown
Variable ID:	SURGERYAX2DATE
Variable:	Axillary clearance date
Definition:	Please provide the date of axillary clearance (DD/MM/YYYY):
Supporting Definition:	N/A
Inclusion Criteria:	If answered "yes" on axillary clearance [SURGERYAX2]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	RECONSTRUCT
Variable:	Reconstruction
Definition:	Indicate whether the patient received a delayed reconstruction during the last year:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "delayed reconstruction" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Delayed reconstruction (direct/staged implant) 1 = Delayed reconstruction (autologous) 2 = Delayed reconstruction (implant/autologous) 999 = Unknown
Variable ID:	RECONSTRUCTDATE
Variable:	Reconstruction date
Definition:	Please provide the date of delayed reconstruction (DD/MM/YYYY):
Supporting Definition:	N/A
Inclusion Criteria:	If "yes" on reconstruction
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	RADIOTX

Variable:	Radiotherapy
Definition:	Indicate whether the patient received radiotherapy during the last year:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "radiotherapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Neoadjuvant 1 = Adjuvant 999 = Unknown
Variable ID:	RADIOTXTYPE
Variable:	Radiotherapy type
Definition:	Indicate location/type of radiotherapy:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "radiotherapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Multiple answer
Response Options:	0 = Breast 1 = Chest wall 2 = Axillary nodal irradiation 3 = Supraclavicular irradiation 4 = Internal mammary node irradiation 5 = Tumor bed boost 6 = Brain metastases 7 = Bone metastases 8 = Any metastatic site 9 = Other 999 = Unknown
Variable ID:	RADIOTXSTARTDATE
Variable:	Start of radiotherapy
Definition:	Please provide the start date of radiotherapy:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "radiotherapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	RADIOTXSTOPDATE
Variable:	End of radiotherapy
Definition:	Please provide the stop date of radiotherapy:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "radiotherapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	CHEMOTX
Variable:	Chemotherapy
Definition:	Indicate whether the patient received chemotherapy neoadjuvant or adjuvant:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "chemotherapy" on treatment
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Neoadjuvant 1 = Adjuvant

	999 = Unknown
Variable ID:	CHEMOTXTYPE
Variable:	Type of chemotherapy
Definition:	Indicate what type of chemotherapy (select all that apply)
Supporting Definition:	N/A
Inclusion Criteria:	If answered "chemotherapy" on treatment
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Multiple answer Separate multiple entries with ";"
Response Options:	0 = Anthracycline containing 1 = Taxane containing 2 = Platinum containing 3 = Other 999 = Unknown
Variable ID:	CHEMOTXSTARTDATE
Variable:	Start of chemotherapy
Definition:	Please provide the start date of chemotherapy:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "chemotherapy" on treatment
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	CHEMOTXSTOPDATE
Variable:	End of chemotherapy
Definition:	Please provide the stop date of chemotherapy, if applicable:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "chemotherapy" on treatment
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	HORMONTX
Variable:	Hormonal therapy
Definition:	Indicate whether the patient received hormonal therapy neoadjuvant or adjuvant:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "hormonal therapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Neoadjuvant 1 = Adjuvant 999 = Unknown
Variable ID:	HORMONTXTYPE
Variable:	Hormonal therapy type
Definition:	Indicate what type of hormonal therapy (select all that apply)
Supporting Definition:	N/A
Inclusion Criteria:	If answered "hormonal therapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Multiple answer Separate multiple entries with ";"
Response Options:	0 = Aromatase inhibitor 1 = Selective estrogen-receptor modulator (e.g. Tamoxifen) 2 = Oophorectomy 3 = LHRH agonist

4 = Other
999 = Unknown

Variable ID:	HORMONTXSTARTDATE
Variable:	Start of hormonal therapy
Definition:	Please provide the start date of hormonal therapy:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "hormonal therapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	HORMONTXSTOPDATE
Variable:	Stop of hormonal therapy
Definition:	Please provide the stop date of hormonal therapy, if applicable:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "hormonal therapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	TARGETTX
Variable:	Targeted therapy
Definition:	Indicate what type of targeted therapy:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "targeted therapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Her-2 targeting therapy 1 = Other 999 = Unknown
Variable ID:	TARGETTXSTARTDATE
Variable:	Start of targeted therapy
Definition:	Please provide the start date of targeted therapy:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "targeted therapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	TARGETTXSTOPDATE
Variable:	Stop of targeted therapy
Definition:	Please provide the stop date of targeted therapy, if applicable:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "targeted therapy" on treatment [TREATMENT]
Timing:	Update at least annually
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	SURGERYPATIENT
Variable:	Surgery
Definition:	Have you had one of the following re-operations since your surgery for breast cancer? (select all that apply)
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported

Type:	Multiple answer Separate multiple entries with ";"
Response Options:	0= No 1 = Breast reconstruction surgery 2= Mastectomy 3= Axillary dissection 999 = Unknown
Variable ID:	SURGERYDATEPATIENT
Variable:	Surgery date
Definition:	If yes, when did you have your re-operation?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	SYSTPATIENT
Variable:	Systemic therapy
Definition:	Are you currently receiving systemic (ie drug) treatment for breast cancer?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Multiple answer Separate multiple entries with ";"
Response Options:	0=no, never had systemic treatment 1=yes, but the treatment has stopped 2=yes, on chemotherapy 3=yes, on targeted therapy 4= yes, on hormone therapy 999=unkown
Variable ID:	SYSTDATEPATIENT
Variable:	Systemic therapy date
Definition:	If the treatment has stopped, when did you stop your treatment?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY

Outcomes

Disutility of care

Variable ID:	REOP
Variable:	Involved margins reoperation
Definition:	Indicate if the patient has undergone a reoperation due to involved margins after primary surgery:
Supporting Definition:	N/A
Inclusion Criteria:	Only if the patient received surgery/radiotherapy.
Timing:	Update at least 6 months after treatment
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes, breast conserving therapy 2=Yes, mastectomy 999 = Unknown
Variable ID:	REOPDATE
Variable:	Positive margins reoperation date
Definition:	Please provide the date of the reoperation due to positive margins:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "yes" on reoperation [REOP]
Timing:	Update at least 6 months after treatment
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	COMPLIMPACT
Variable:	Complications
Definition:	Indicate whether the patient experienced a complication while on treatment or 90 days following treatment (multiple answers possible):
Supporting Definition:	These response options are based on the Clavien-Dindo classification for surgical complications and the Common Terminology Criteria version 4 (CTCAE v4). To collect the most severe complications, grade 3 -5 of both classification systems are included in the Standard Set.
Inclusion Criteria:	Only if the patient received treatment.
Timing:	Updated at least 6 months after treatment completion, except for patients with hormonal therapy which will be updated at least 6 months and 1 year after treatment initiation
Reporting Source:	Clinical
Type:	Multiple answers
Response Options:	0 = No complication 1 = Complication requiring intervention (surgical, radiological, endoscopic) 2 = Complication leading to prolonged hospitalization (>14days) 3 = Complication leading to unplanned readmission 4 = Complication leading to ICU admission 5 = Complication leading to discontinuing of treatment 6 = Complication leading to reduced dosing 7 = Complication leading to death 8 = Complication, but did not result in any of the abovementioned 999 = Unknown
Variable ID:	DEATHBCCOMPL
Variable:	Death of complication
Definition:	Please provide the date of death:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "Complication leading to death" on experience of complication [COMPLIMPACT]
Timing:	Updated at least 6 months after treatment completion, except for patients with

	hormonal therapy which will be updated at least 6 months and 1 year after treatment initiation
Reporting Source:	Clinical
Type:	Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options:	DD/MM/YYYY
Variable ID:	COMPLTX
Variable:	Complication attribute
Definition:	Indicate whether the complication is attributable to breast cancer treatment:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "yes" on experience of complication [COMPLIMPACT]
Timing:	Updated at least 6 months after treatment completion, except for patients with hormonal therapy which will be updated at least 6 months and 1 year after treatment initiation
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes 999 = Unknown
Variable ID:	COMPL
Variable:	Complication type
Definition:	Please indicate the type of complication:
Supporting Definition:	N/A
Inclusion Criteria:	If answered "yes" on complication attributable to breast cancer treatment [COMPLTX]
Timing:	Updated at least 6 months after treatment completion, except for patients with hormonal therapy which will be updated at least 6 months and 1 year after treatment initiation
Reporting Source:	Clinical
Type:	Single answer
Response Options:	0 = Wound infection 1 = Seroma/hematoma 2 = Hemorrhage 3 = Mastectomy skin flap necrosis 4 = Partial autologous graft loss 5 = Total autologous graft loss 6 = Loss of implant 7 = Thromboembolic event 8 = Nerve damage 9 = Delay wound healing/dehiscence 10 = Skin toxicity 11 = Pneumonia 12 = Neutropenic sepsis 999 = unknown

Degree of Health

Variable ID:	EORTCQLQC30_Q01
Variable:	Question 1 of EORTC-QLQ-C30
Definition:	We are interested in some things about you and your health. Please answer all of the questions yourself by selecting the answer that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential. 1: Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported

Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q02
Variable:	Question 2 of EORTC-QLQ-C30
Definition:	2: Do you have any trouble taking a long walk?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
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Variable ID:	EORTCQLQC30_Q03
Variable:	Question 3 of EORTC-QLQ-C30
Definition:	3: Do you have any trouble taking a short walk outside of the house?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
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Variable ID:	EORTCQLQC30_Q04
Variable:	Question 4 of EORTC-QLQ-C30
Definition:	4: Do you need to stay in bed or a chair during the day?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
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Variable ID:	EORTCQLQC30_Q05
Variable:	Question 5 of EORTC-QLQ-C30
Definition:	5: Do you need help with eating, dressing, washing yourself or using the toilet?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
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Variable ID:	EORTCQLQC30_Q06
Variable:	Question 6 of EORTC-QLQ-C30
Definition:	During the past week: 6: Were you limited in doing either your work or other daily activities?

Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q07
Variable:	Question 7 of EORTC-QLQ-C30
Definition:	7: Were you limited in pursuing your hobbies or other leisure time activities?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q08
Variable:	Question 8 of EORTC-QLQ-C30
Definition:	8: Were you short of breath?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q09
Variable:	Question 9 of EORTC-QLQ-C30
Definition:	9: Have you had pain?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q10
Variable:	Question 10 of EORTC-QLQ-C30
Definition:	10: Did you need to rest?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much

Variable ID:	EORTCQLQC30_Q11
Variable:	Question 11 of EORTC-QLQ-C30
Definition:	11: Have you had trouble sleeping?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q12
Variable:	Question 12 of EORTC-QLQ-C30
Definition:	12: Have you felt weak?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q13
Variable:	Question 13 of EORTC-QLQ-C30
Definition:	13: Have you lacked appetite?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q14
Variable:	Question 14 of EORTC-QLQ-C30
Definition:	14: Have you felt nauseated?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q15
Variable:	Question 15 of EORTC-QLQ-C30
Definition:	15: Have you vomited?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all

1 = A little
2 = Quite a bit
3 = Very much

Variable ID:	EORTCQLQC30_Q16
Variable:	Question 16 of EORTC-QLQ-C30
Definition:	16: Have you been constipated?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q17
Variable:	Question 17 of EORTC-QLQ-C30
Definition:	17: Have you had diarrhea?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q18
Variable:	Question 18 of EORTC-QLQ-C30
Definition:	18: Were you tired?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q19
Variable:	Question 19 of EORTC-QLQ-C30
Definition:	19: Did pain interfere with your daily activities?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q20
Variable:	Question 20 of EORTC-QLQ-C30
Definition:	20: Have you had difficulty in concentrating on things, like reading a newspaper or watching television?
Supporting Definition:	N/A
Inclusion Criteria:	All patients

Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Not at all
 1 = A little
 2 = Quite a bit
 3 = Very much

Variable ID: EORTCQLQC30_Q21
Variable: Question 21 of EORTC-QLQ-C30
Definition: 21: Did you feel tense?
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Not at all
 1 = A little
 2 = Quite a bit
 3 = Very much

Variable ID: EORTCQLQC30_Q22
Variable: Question 22 of EORTC-QLQ-C30
Definition: 22: Did you worry?
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Not at all
 1 = A little
 2 = Quite a bit
 3 = Very much

Variable ID: EORTCQLQC30_Q23
Variable: Question 23 of EORTC-QLQ-C30
Definition: 23: Did you feel irritable?
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Not at all
 1 = A little
 2 = Quite a bit
 3 = Very much

Variable ID: EORTCQLQC30_Q24
Variable: Question 24 of EORTC-QLQ-C30
Definition: 24: Did you feel depressed?
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Not at all
 1 = A little
 2 = Quite a bit
 3 = Very much

Variable ID: EORTCQLQC30_Q25
Variable: Question 25 of EORTC-QLQ-C30

Definition:	25: Have you had difficulty remembering things?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q26
Variable:	Question 26 of EORTC-QLQ-C30
Definition:	26: Has your physical condition or medical treatment interfered with your family life?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q27
Variable:	Question 27 of EORTC-QLQ-C30
Definition:	27: Has your physical condition or medical treatment interfered with your social activities?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q28
Variable:	Question 28 of EORTC-QLQ-C30
Definition:	28: Has your physical condition or medical treatment caused you financial difficulties?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQC30_Q29
Variable:	Question 29 of EORTC-QLQ-C30
Definition:	For the following questions please select the number between 1 and 7 that best applies to you 29: How would you rate your overall health during the past week?
Supporting Definition:	Range from 1 to 7, with 1 = Very poor and 7 = Worst pain imaginable 1-7 denotes 1-7 correspondingly
Inclusion Criteria:	All patients

Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	Numerical value of 1 - 7
Variable ID:	EORTCQLQC30_Q30
Variable:	Question 30 of EORTC-QLQ-C30
Definition:	30: How would you rate your overall quality of life during the past week?
Supporting Definition:	Range from 1 to 7, with 1 = Very poor and 7 = Worst pain imaginable 1-7 denotes 1-7 correspondingly
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	Numerical value of 1 - 7
Variable ID:	EORTCQLQBR23_Q31
Variable:	Question 31 of EORTC-QLQ- BR23
Definition:	Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by selecting the answer that best applies to you. During the past week
Supporting Definition:	31: Did you have a dry mouth? N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q32
Variable:	Question 32 of EORTC-QLQ- BR23
Definition:	32: Did food and drink taste different than usual?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q33
Variable:	Question 33 of EORTC-QLQ- BR23
Definition:	33: Were you eyes painful, irritated or watery?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q34
Variable:	Question 34 of EORTC-QLQ- BR23
Definition:	34: Have you lost any hair?

Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q35
Variable:	Question 35 of EORTC-QLQ- BR23
Definition:	35: Answer this question only if you had any hair loss: Were you upset by the loss of your hair?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q36
Variable:	Question 36 of EORTC-QLQ- BR23
Definition:	36: Did you feel ill or unwell?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q37
Variable:	Question 37 of EORTC-QLQ- BR23
Definition:	37: Did you have hot flushes?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q38
Variable:	Question 38 of EORTC-QLQ- BR23
Definition:	38: Did you have headaches?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit

	3 = Very much
Variable ID:	EORTCQLQBR23_Q39
Variable:	Question 39 of EORTC-QLQ- BR23
Definition:	39: Have you felt physically less attractive as a result of your disease or treatment?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q40
Variable:	Question 40 of EORTC-QLQ- BR23
Definition:	40: Have you been feeling less feminine as a result of your disease or treatment?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q41
Variable:	Question 41 of EORTC-QLQ- BR23
Definition:	41: Did you find it difficult to look at yourself naked?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q42
Variable:	Question 42 of EORTC-QLQ- BR23
Definition:	42. Have you been dissatisfied with your body?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q43
Variable:	Question 43 of EORTC-QLQ- BR23
Definition:	43. Were you worried about your health in the future?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer

Response Options: 0 = Not at all
1 = A little
2 = Quite a bit
3 = Very much

Variable ID: EORTCQLQBR23_Q44

Variable: Question 44 of EORTC-QLQ- BR23

Definition: During the past four weeks:
44. To what extent were you interested in sex?

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years

Reporting Source: Patient-reported

Type: Single answer

Response Options: 0 = Not at all
1 = A little
2 = Quite a bit
3 = Very much

Variable ID: EORTCQLQBR23_Q45

Variable: Question 45 of EORTC-QLQ- BR23

Definition: 45. To what extent were you sexually active? (with or without intercourse)

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years

Reporting Source: Patient-reported

Type: Single answer

Response Options: 0 = Not at all
1 = A little
2 = Quite a bit
3 = Very much

Variable ID: EORTCQLQBR23_Q46

Variable: Question 46 of EORTC-QLQ- BR23

Definition: 46. Answer this question only if you have been sexually active: To what extent was sex enjoyable for you?

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years

Reporting Source: Patient-reported

Type: Single answer

Response Options: 0 = Not at all
1 = A little
2 = Quite a bit
3 = Very much

Variable ID: EORTCQLQBR23_Q47

Variable: Question 47 of EORTC-QLQ- BR23

Definition: During the past week:
47. Did you have any pain in your arm or shoulder?

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years

Reporting Source: Patient-reported

Type: Single answer

Response Options: 0 = Not at all
1 = A little
2 = Quite a bit
3 = Very much

Variable ID: EORTCQLQBR23_Q48

Variable: Question 48 of EORTC-QLQ- BR23

Definition:	48. Did you have a swollen arm or hand?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q49
Variable:	Question 49 of EORTC-QLQ- BR23
Definition:	49. Was it difficult to raise your arm or to move it sideways?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q50
Variable:	Question 50 of EORTC-QLQ- BR23
Definition:	50. Have you had any pain in the area of your affected breast?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q51
Variable:	Question 51 of EORTC-QLQ- BR23
Definition:	51. Was the area of your affected breast swollen?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	EORTCQLQBR23_Q52
Variable:	Question 52 of EORTC-QLQ- BR23
Definition:	52. Was the area of your affected breast oversensitive?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit

	3 = Very much
Variable ID:	EORTCQLQBR23_Q53
Variable:	Question 53 of EORTC-QLQ- BR23
Definition:	53. Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Quite a bit 3 = Very much
Variable ID:	BREASTQMAST_Q01
Variable:	Question 1 of BREASTQ
Definition:	With your breasts in mind, or if you have had a mastectomy, with your breast area in mind, in the past 2 weeks, how satisfied or dissatisfied have you been with: 1. How you look in the mirror clothed?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with mastectomy
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQMAST_Q02
Variable:	Question 2 of BREASTQ
Definition:	2. How comfortable your bras fit?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with mastectomy
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQMAST_Q03
Variable:	Question 3 of BREASTQ
Definition:	3. Being able to wear clothing that is more fitted?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with mastectomy
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQMAST_Q04
Variable:	Question 4 of BREASTQ
Definition:	4. How you look in the mirror unclothed?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with mastectomy

Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQBCT_Qo1
Variable:	Question 1 of BREASTQ
Definition:	With your breasts in mind, or if you have had a mastectomy, with your breast area in mind, in the past 2 weeks, how satisfied or dissatisfied have you been with: 1. How you look in the mirror clothed?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQBCT_Qo2
Variable:	Question 2 of BREASTQ
Definition:	2. How comfortable your bras fit?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQBCT_Qo3
Variable:	Question 3 of BREASTQ
Definition:	3. Being able to wear clothing that is more fitted?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQBCT_Qo4
Variable:	Question 4 of BREASTQ
Definition:	4. How you look in the mirror unclothed?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied

Variable ID:	BREASTQREC_Qo1
Variable:	Question 1 of BREASTQ
Definition:	With your breasts in mind, or if you have had a mastectomy, with your breast area in mind, in the past 2 weeks, how satisfied or dissatisfied have you been with: 1. How you look in the mirror clothed?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with reconstruction
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQREC_Qo2
Variable:	Question 2 of BREASTQ
Definition:	2. How comfortable your bras fit?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with reconstruction
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQREC_Qo3
Variable:	Question 3 of BREASTQ
Definition:	3. Being able to wear clothing that is more fitted?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with reconstruction
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQREC_Qo4
Variable:	Question 4 of BREASTQ
Definition:	4. How you look in the mirror unclothed?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with reconstruction
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQMASTP_Qo1
Variable:	Question 1 of BREASTQ
Definition:	With your breasts in mind, or if you have had a mastectomy, with your breast area in mind, in the past 2 weeks, how satisfied or dissatisfied have you been with: 1. How you look in the mirror clothed?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with mastectomy

Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQMASTP_Qo2
Variable:	Question 2 of BREASTQ
Definition:	2. How comfortable your bras fit?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with mastectomy
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQMASTP_Qo3
Variable:	Question 3 of BREASTQ
Definition:	3. Being able to wear clothing that is more fitted?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with mastectomy
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQMASTP_Qo4
Variable:	Question 4 of BREASTQ
Definition:	4. How you look in the mirror unclothed?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with mastectomy
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQBCTP_Qo1
Variable:	Question 1 of BREASTQ
Definition:	With your breasts in mind, or if you have had a mastectomy, with your breast area in mind, in the past 2 weeks, how satisfied or dissatisfied have you been with: 1. How you look in the mirror clothed?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied

Variable ID:	BREASTQBCTP_Qo2
Variable:	Question 2 of BREASTQ
Definition:	2. The shape of your lumpectomy breast when you are wearing a bra?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQBCTP_Qo3
Variable:	Question 3 of BREASTQ
Definition:	3. How normal you feel in your clothes?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	2 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQBCTP_Qo4
Variable:	Question 4 of BREASTQ
Definition:	4. Being able to wear clothing that is more fitted?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	3 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQBCTP_Qo5
Variable:	Question 5 of BREASTQ
Definition:	5. How your lumpectomy breast sits/hangs?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	4 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQBCTP_Qo6
Variable:	Question 6 of BREASTQ
Definition:	6. How smoothly shaped your lumpectomy breast looks?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with breast conserving therapy
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	5 = Very dissatisfied

1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQBCTP_Qo7
Variable: Question 7 of BREASTQ
Definition: 7. The contour (outline) of your lumpectomy breast?
Supporting Definition: N/A
Inclusion Criteria: Patients with breast conserving therapy
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 6 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQBCTP_Qo8
Variable: Question 8 of BREASTQ
Definition: 8. How equal in size your breasts are to each other?
Supporting Definition: N/A
Inclusion Criteria: Patients with breast conserving therapy
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 7 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQBCTP_Qo9
Variable: Question 9 of BREASTQ
Definition: 9. How normal your lumpectomy breast looks?
Supporting Definition: N/A
Inclusion Criteria: Patients with breast conserving therapy
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 8 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQBCTP_Q10
Variable: Question 10 of BREASTQ
Definition: 10. How much your breast look the same?
Supporting Definition: N/A
Inclusion Criteria: Patients with breast conserving therapy
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 9 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQBCTP_Q11
Variable: Question 11 of BREASTQ
Definition: 11. How you look in the mirror <u>unclothed</u>?
Supporting Definition: N/A
Inclusion Criteria: Patients with breast conserving therapy
Timing: 1 and 2 year post treatment

Reporting Source: Patient-reported
Type: Single answer
Response Options: 10 = Very dissatisfied
 1 = Somewhat dissatisfied
 2 = Somewhat satisfied
 3 = Very satisfied

Variable ID: BREASTQRECP_Qo1

Variable: Question 1 of BREASTQ

Definition: With your breasts in mind, or if you have had a mastectomy, with your breast area in mind, in the past 2 weeks, how satisfied or dissatisfied have you been with:
 1. How you look in the mirror clothed?

Supporting Definition: N/A

Inclusion Criteria: Patients with reconstruction

Timing: 1 and 2 year post treatment

Reporting Source: Patient-reported

Type: Single answer

Response Options: 0 = Very dissatisfied
 1 = Somewhat dissatisfied
 2 = Somewhat satisfied
 3 = Very satisfied

Variable ID: BREASTQRECP_Qo2

Variable: Question 2 of BREASTQ

Definition: 2. The shape of your reconstructed breast(s) when you are wearing a bra?

Supporting Definition: N/A

Inclusion Criteria: Patients with reconstruction

Timing: 1 and 2 year post treatment

Reporting Source: Patient-reported

Type: Single answer

Response Options: 1 = Very dissatisfied
 1 = Somewhat dissatisfied
 2 = Somewhat satisfied
 3 = Very satisfied

Variable ID: BREASTQRECP_Qo3

Variable: Question 3 of BREASTQ

Definition: 3. How normal you feel in your clothes?

Supporting Definition: N/A

Inclusion Criteria: Patients with reconstruction

Timing: 1 and 2 year post treatment

Reporting Source: Patient-reported

Type: Single answer

Response Options: 2 = Very dissatisfied
 1 = Somewhat dissatisfied
 2 = Somewhat satisfied
 3 = Very satisfied

Variable ID: BREASTQRECP_Qo4

Variable: Question 4 of BREASTQ

Definition: 4. The size of your reconstructed breast(s)?

Supporting Definition: N/A

Inclusion Criteria: Patients with reconstruction

Timing: 1 and 2 year post treatment

Reporting Source: Patient-reported

Type: Single answer

Response Options: 3 = Very dissatisfied
 1 = Somewhat dissatisfied
 2 = Somewhat satisfied
 3 = Very satisfied

Variable ID: BREASTQRECP_Qo5

Variable: Question 5 of BREASTQ
Definition: 5. Being able to wear clothing that is more fitted?
Supporting Definition: N/A
Inclusion Criteria: Patients with reconstruction
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQRECP_Qo6
Variable: Question 6 of BREASTQ
Definition: 6. How your breasts are lined up in relation to each other?
Supporting Definition: N/A
Inclusion Criteria: Patients with reconstruction
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 4 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQRECP_Qo7
Variable: Question 7 of BREASTQ
Definition: 7. How comfortable your bras fit?
Supporting Definition: N/A
Inclusion Criteria: Patients with reconstruction
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQRECP_Qo8
Variable: Question 8 of BREASTQ
Definition: 8. The softness of your reconstructed breast(s)?
Supporting Definition: N/A
Inclusion Criteria: Patients with reconstruction
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 5 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQRECP_Qo9
Variable: Question 9 of BREASTQ
Definition: 9. How equal in size your breasts are to each other?
Supporting Definition: N/A
Inclusion Criteria: Patients with reconstruction
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 6 = Very dissatisfied
1 = Somewhat dissatisfied

	2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQRECP_Q10
Variable:	Question 10 of BREASTQ
Definition:	10. How natural your reconstructed breast(s) looks?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with reconstruction
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	7 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQRECP_Q11
Variable:	Question 11 of BREASTQ
Definition:	11. How naturally your reconstructed breast(s) sits/hangs?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with reconstruction
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	8 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQRECP_Q12
Variable:	Question 12 of BREASTQ
Definition:	12. How your reconstructed breast(s) feel to touch?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with reconstruction
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	9 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQRECP_Q13
Variable:	Question 13 of BREASTQ
Definition:	13. How much your reconstructed breast(s) feels like a natural part of your body?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with reconstruction
Timing:	1 and 2 year post treatment
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	10 = Very dissatisfied 1 = Somewhat dissatisfied 2 = Somewhat satisfied 3 = Very satisfied
Variable ID:	BREASTQRECP_Q14
Variable:	Question 14 of BREASTQ
Definition:	14. How closely matched your breasts are to each other?
Supporting Definition:	N/A
Inclusion Criteria:	Patients with reconstruction
Timing:	1 and 2 year post treatment

Reporting Source: Patient-reported
Type: Single answer
Response Options: 11 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQRECP_Q15
Variable: Question 15 of BREASTQ
Definition: 15. How your reconstructed breast(s) look now compared to before you had any breast surgery?

Supporting Definition: N/A
Inclusion Criteria: Patients with reconstruction
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 12 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: BREASTQRECP_Q16
Variable: Question 16 of BREASTQ
Definition: 16. How you look in the mirror unclothed?

Supporting Definition: N/A
Inclusion Criteria: Patients with reconstruction
Timing: 1 and 2 year post treatment
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Very dissatisfied
1 = Somewhat dissatisfied
2 = Somewhat satisfied
3 = Very satisfied

Variable ID: EORTC QLQ-LMC21
Variable: Question 1 of EORTC-QLQ-LMC
Definition: Please indicate the extent to which you have experienced the following symptom during the past week. During the past week:
1. Have you had tingling hands or feet?

Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Not at all
1 = A little
2 = Quite a bit
3 = Very much

Variable ID: FACTES_Q01
Variable: Question 1 of FACT-ES
Definition: Please circle or mark one number per line to indicate your response as it applies to the past 7 days:
1. I have pain in my joints

Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Not at all
1 = A little

	2 = Somewhat 3 = Quite a bit 4 = Very much
Variable ID:	FACTES_Qo2
Variable:	Question 2 of FACT-ES
Definition:	2. I have vaginal discharge
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Somewhat 3 = Quite a bit 4 = Very much
Variable ID:	FACTES_Qo3
Variable:	Question 3 of FACT-ES
Definition:	3. I have vaginal itching/irritation
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Somewhat 3 = Quite a bit 4 = Very much
Variable ID:	FACTES_Qo4
Variable:	Question 4 of FACT-ES
Definition:	4. I have vaginal bleeding or spotting
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Somewhat 3 = Quite a bit 4 = Very much
Variable ID:	FACTES_Qo5
Variable:	Question 5 of FACT-ES
Definition:	5. I have vaginal dryness
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = Somewhat 3 = Quite a bit 4 = Very much
Variable ID:	FACTES_Qo6

Variable: Question 6 of FACT-ES
Definition: 6. I have pain or discomfort with intercourse
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Baseline, 6 months, 1 year post treatment, tracked annually up to 10 years
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Not at all
 1 = A little
 2 = Somewhat
 3 = Quite a bit
 4 = Very much

Survival and Disease Control

Variable ID: RECUR
Variable: Recurrence
Definition: Indicate whether there is evidence of local, regional or distant recurrence.
Supporting Definition: N/A
Inclusion Criteria: Only if the intent of treatment is curative
Timing: 1 year post treatment, tracked annually up to 10 years
Reporting Source: Clinical
Type: Single answer
Response Options: 0 = No
 1 = Yes, local recurrence
 2 = Yes, regional recurrence
 3 = Yes, distant recurrence
 999 = Unknown

Variable ID: RECURMETH
Variable: Recurrence method
Definition: Provide method of confirmation:
Supporting Definition: N/A
Inclusion Criteria: Only if answered "yes" on recurrence [RECUR]
Timing: 1 year post treatment, tracked annually up to 10 years
Reporting Source: Clinical
Type: Single answer
Response Options: 0 = Radiological diagnosis
 1 = Histological diagnosis
 2 = Radiological and histological diagnosis
 3 = Unknown

Variable ID: RECURDATE
Variable: Recurrence date
Definition: Provide the date of the recurrence:
Supporting Definition: N/A
Inclusion Criteria: Only if answered "yes" on recurrence [RECUR]
Timing: 1 year post treatment, tracked annually up to 10 years
Reporting Source: Clinical
Type: Date by DD/MM/YYYY; Please enter "999" if date is unknown
Response Options: DD/MM/YYYY

Variable ID: DEATH
Variable: Death
Definition: Indicate whether the patient has died
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: 1 year post treatment, tracked annually up to 10 years
Reporting Source: Clinical

Type: Single answer
Response Options: 0 = No
1 = Yes
999 = Unknown

Variable ID: DEATHDATE

Variable: Date of death

Definition: Provide the date of the death:

Supporting Definition: N/A

Inclusion Criteria: If answered "yes" on patient died [DEATH]

Timing: 1 year post treatment, tracked annually up to 10 years

ICHOM Contact Information

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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
1.0.1	Collecting Patient-Reported Outcome Measures	Revised licensing and scoring information for the FACT-ES
1.0.1	Contact Information	Removed inactive email address: ichomteam@ichom.org

