

1. Baseline

Patient ID

(Use a short abbreviation of the centre as a prefix and an anonymised numeric patient ID (e.g. MMCI-001).)

Input of time/date related items

- ☐ Time-to-event fields only
☐ Date fields only
☐ Both Time-to-event and date fields
(How the time variables are being entered?)

Patient Characteristics

Gender

Biological sex as recorded in the patient's documentation.

- ☐ Female
☐ Male

Date of Birth

Where day of birth is missing, the day should be assumed to be the 15th of the month.

Date of Diagnosis

Where day of diagnosis is missing, the day should be assumed to be the 15th of the month.

Age at diagnosis (derived)

Age (in full completed years) derived using date of birth and diagnosis index date.

Age at diagnosis

Age (in full completed years) derived using date of birth and diagnosis index date. Where day of birth or diagnosis is missing, the day should be assumed to be the 15th of the month.

Menopausal Status

- ☐ Pre-menopausal
☐ Peri/Post-menopausal

ECOG Performance Status

Most recent record prior to or on diagnosis index date.

The equivalents to Karnofsky Performance status:

0 ≈ [90; 100],
1 ≈ [70; 80],
2 ≈ [50; 60],
3 ≈ [30; 40],
4 ≈ [10; 20].

- ☐ 0 = Fully active, able to carry on all pre-disease performance without restriction.
☐ 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.
☐ 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.
☐ 3 = Capable of only limited self-care, confined to bed or chair for more than 50% of waking hours.
☐ 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.

Body Surface Area (BSA)

BSA derived from most recent records of height and weight prior to or on 1st Line of Therapy index date.

(BSA in m2.)

Comorbidity Lookback period for all comorbidities is within six months prior to diagnosis index date. (Example ICD-10 codes can be found in Comorbidities tab of CDM)

	Absent	Present
Peripheral Vascular Disease	<input type="radio"/>	<input type="radio"/>
Cerebrovascular Disease	<input type="radio"/>	<input type="radio"/>
Dementia	<input type="radio"/>	<input type="radio"/>
Diabetes	<input type="radio"/>	<input type="radio"/>
Congestive Heart Failure	<input type="radio"/>	<input type="radio"/>
Liver disease	<input type="radio"/>	<input type="radio"/>
Active smoker	<input type="radio"/>	<input type="radio"/>
Previous or present alcohol abuse	<input type="radio"/>	<input type="radio"/>
Myocardial Infarction	<input type="radio"/>	<input type="radio"/>

Tumour Characteristics at Diagnosis

Mode of Presentation

☐ Screening
☐ Symptomatic
☐ Other

Location
Use ICD-O-3 topographical/site codes.

☐ C50.0 Nipple
☐ C50.1 Central portion of breast
☐ C50.2 Upper-inner quadrant of breast (UIQ)
☐ C50.3 Lower-inner quadrant of breast (LIQ)
☐ C50.4 Upper-outer quadrant of breast (UOQ)
☐ C50.5 Lower-outer quadrant of breast (LOQ)
☐ C50.6 Axillary tail of breast
☐ C50.8 Overlapping lesion of breast
☐ C50.9 Breast, NOS

Laterality

☐ Right/Dex
☐ Left/Sin

Histological type

☐ Invasive ductal carcinoma; no special type
☐ Any special type
☐ Other

Grade
Use ICD-O-3 grade/differentiation codes (values between 1 and 3).

(Leave blank if unknown.)

Clinical T Stage	<input type="radio"/> T0 <input type="radio"/> Tis <input type="radio"/> T1 <input type="radio"/> T1a <input type="radio"/> T1b <input type="radio"/> T1c <input type="radio"/> T2 <input type="radio"/> T3 <input type="radio"/> T4 <input type="radio"/> T4a <input type="radio"/> T4b <input type="radio"/> T4c <input type="radio"/> T4d
Clinical Tumour Size Tumour size before treatment.	<div style="border: 1px solid black; width: 100%; height: 20px;"></div> (Values in millimetres (mm).)
Clinical N Stage	<input type="radio"/> N0 <input type="radio"/> N1 <input type="radio"/> N2 <input type="radio"/> N2a <input type="radio"/> N2b <input type="radio"/> N3 <input type="radio"/> N3a <input type="radio"/> N3b <input type="radio"/> N3c
Inflammatory Breast Cancer	<input type="radio"/> No <input type="radio"/> Yes (Defined as T4d.)
Inflammatory Breast Cancer (derived)	<div style="border: 1px solid black; width: 100%; height: 20px;"></div> (Derived from T stage and defined as T4d.)
Oestrogen Receptor Status Positivity threshold of 10 % (inclusive).	<input type="radio"/> Negative (< 10 %) <input type="radio"/> Positive (≥ 10 %)
Progesterone Receptor Status Positivity threshold of 10 % (inclusive).	<input type="radio"/> Negative (< 10 %) <input type="radio"/> Positive (≥ 10 %)
HER2 Status Results according to local laboratory testing.	<input type="radio"/> Negative <input type="radio"/> IHC2+/ISH+ <input type="radio"/> IHC3+
Ki-67 Marker Of Proliferation	<div style="border: 1px solid black; width: 100%; height: 20px;"></div> (The Ki-67 percentage score between 0 and 100.)
BRCA mutation Results according to local laboratory testing.	<input type="radio"/> Both BRCA1 and BRCA2 negative <input type="radio"/> BRCA1 or BRCA2 positive <input type="radio"/> Unknown test result <input type="radio"/> Not tested
Biological Subtype	<input type="radio"/> TNBC <input type="radio"/> Luminal B HER2+ <input type="radio"/> Non luminal B HER2+

UICC Anatomic Staging

- ☐ IA
☐ IB
☐ IIA
☐ IIB
☐ IIIA
☐ IIIB
☐ IIIC

UICC Anatomic Staging (derived)

UICC Anatomic Staging (derived): 0

UICC Anatomic Staging (derived): IA

UICC Anatomic Staging (derived): IIA

UICC Anatomic Staging (derived): IIB

UICC Anatomic Staging (derived): IIIA

UICC Anatomic Staging (derived): IIIB

UICC Anatomic Staging (derived): IIIC

UICC Anatomic Staging (derived): unknown

AJCC Prognostic Staging

- ☐ IA
☐ IB
☐ IIA
☐ IIB
☐ IIIA
☐ IIIB
☐ IIIC

AJCC Prognostic Staging (derived)

AJCC Prognostic Staging (derived): 0

AJCC Prognostic Staging (derived): IA

AJCC Prognostic Staging (derived): IB

AJCC Prognostic Staging (derived): IIA

AJCC Prognostic Staging (derived): IIB

AJCC Prognostic Staging (derived): IIIA

AJCC Prognostic Staging (derived): IIIB

AJCC Prognostic Staging (derived): IIIC

AJCC Prognostic Staging (derived): unknown