BREAST CANCER SPECIFIC DATA ITEMS FOR CLINICAL CANCER REGISTRATION

June 2009

PREPARED BY NATIONAL BREAST AND OVARIAN CANCER CENTRE

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DEPARTMENT OF HEALTH AND AGEING
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FOREWORD

The National Breast Cancer Centre* was established in 1995 to improve outcomes for women with breast cancer. Through collaborative partnerships and the dedication and commitment of clinical experts and consumers, much progress has been made in diagnosis and treatment since then. However, our ability to measure and improve care is heavily reliant on quality data and we have been constrained by significant data gaps and no consistent set of clinical indicators for monitoring care and outcomes at a national level.

National Breast and Ovarian Cancer Centre is grateful for the high quality input of stakeholders in the development of the present breast cancer specific data items for clinical registration. A multidisciplinary working group was chaired by Professor David Roder and broad consultation was held with clinical colleges and cancer organisations in order to select appropriate data items for monitoring, avoid duplication across existing data sets and engage widespread support for the selected items. Pilot testing was undertaken in a number of centres.

We will work with relevant groups to encourage the adoption of these breast items nationally so that there will be a consistent approach to defining and monitoring care into the future. Furthermore, we hope this work may provide a model for the development of specific data items for other cancers.

Dr Helen Zorbas
Chief Executive Officer

* In February 2008, National Breast Cancer Centre changed its name to National Breast and Ovarian Cancer Centre
ACKNOWLEDGEMENTS

National Breast and Ovarian Cancer Centre (NBOCC) gratefully acknowledges the support of the many individuals and groups who contributed to the development of this document.

Funding
Funding was provided by the Australian Government Department of Health and Ageing.

Working Group
The breast cancer specific minimum dataset was developed with input from an expert multidisciplinary Working Group with the following members:

- Professor David Roder (Chair) Epidemiologist (SA)
- Dr Pam Williams Consumer Representative (Vic)
- Professor Ian Olver Medical Oncologist (NSW)
- Associate Professor Michael Bilous Pathologist (NSW)
- Dr Liz Kenny Radiation Oncologist (Qld)
- Dr Vicki White Senior Behavioural Scientist (Vic)
- Associate Professor David Gillett Surgeon (NSW)
- Mr Jim Kollias Surgeon (SA)
- Dr Chris Pyke Surgeon (Qld)

National Breast and Ovarian Cancer Centre Staff
The following NBOCC staff were involved in the development of breast cancer specific minimum dataset:

- Ms Ornella Care
- Ms Jane Francis
- Ms Phillipa Hastings
- Ms Trenna Rowe
- Ms Fleur Webster
- Dr Helen Zorbas

Feasibility study
We are grateful to the Breast Cancer New South Wales Oncology Group and the Cancer Institute New South Wales for funding and coordinating the feasibility study. We would also like to acknowledge the Clinical Cancer Registry, Sydney South West Area Health Service and Royal North Shore Hospital for their participation in the feasibility study.
Consultation
The following stakeholders were consulted for feedback:

Australian Institute of Health and Welfare, Health Registers and Cancer Monitoring Group
Australian Government Department of Health and Ageing, Screening Section
Breast Cancer Network Australia
Cancer Australia
Cancer Institute NSW
Cancer Voices Australia
Clinical Oncological Society of Australia
Medical Oncology Group of Australia
New South Wales Breast Cancer Institute
Queensland Cancer Control Analysis Team
Royal Australian and New Zealand College of Radiologists
Royal Australian and New Zealand College of Radiologists, Faculty of Radiation Oncology
Royal Australasian College of Surgeons, Breast Section
Royal College of Pathologists of Australia
Cancer Council Australia
Cancer Council Australian Capital Territory
Cancer Council New South Wales
Cancer Council Northern Territory
Cancer Council Queensland
Cancer Council South Australia
Cancer Council Tasmania
Cancer Council Victoria
Cancer Council Western Australia
### LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABS</td>
<td>Australian Bureau of Statistics</td>
</tr>
<tr>
<td>ACHS</td>
<td>Australian Council of Healthcare Standards</td>
</tr>
<tr>
<td>ACN</td>
<td>Australian Cancer Network</td>
</tr>
<tr>
<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
</tr>
<tr>
<td>ASCO</td>
<td>American Society of Clinical Oncology</td>
</tr>
<tr>
<td>CISH</td>
<td>Chromogenic In Situ Hybridisation</td>
</tr>
<tr>
<td>DCIS</td>
<td>Ductal Carcinoma In Situ</td>
</tr>
<tr>
<td>ER</td>
<td>Oestrogen Receptor</td>
</tr>
<tr>
<td>FISH</td>
<td>Fluorescence In Situ Hybridisation</td>
</tr>
<tr>
<td>FNA</td>
<td>Fine needle aspiration</td>
</tr>
<tr>
<td>FORDS</td>
<td>Facility Oncology Registry Data Standards: Revised for 2007 (Commission on Cancer, Chicago)</td>
</tr>
<tr>
<td>IHC</td>
<td>Immunohistochemistry</td>
</tr>
<tr>
<td>ISH</td>
<td>In situ hybridisation</td>
</tr>
<tr>
<td>LCIS</td>
<td>Lobular Carcinoma In Situ</td>
</tr>
<tr>
<td>METeOR</td>
<td>Metadata Online Registry</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
</tr>
<tr>
<td>NBCC</td>
<td>National Breast Cancer Centre – change of name in February 2008 to National Breast and Ovarian Cancer Centre</td>
</tr>
<tr>
<td>NBOCC</td>
<td>National Breast and Ovarian Cancer Centre</td>
</tr>
<tr>
<td>NCCI</td>
<td>National Cancer Control Initiative</td>
</tr>
<tr>
<td>NHDD</td>
<td>National Health Data Dictionary (AIHW)</td>
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<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
</tr>
<tr>
<td>PR</td>
<td>Progesterone Receptor</td>
</tr>
<tr>
<td>RACS</td>
<td>Royal Australasian College of Surgeons</td>
</tr>
<tr>
<td>RCPA</td>
<td>Royal College of Pathologists of Australia</td>
</tr>
<tr>
<td>TNM</td>
<td>Tumour, Nodes, Metastasis</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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INTRODUCTION

National clinical cancer core data set (CCCDS)
In its December 1997 report, National Cancer Control and Implementation, the National Cancer Control Initiative (NCCI) identified important gaps in cancer-data availability for cancer control in Australia. In response, a consultative process was arranged involving key stakeholders, which resulted in the development of a data set for clinical cancer registration. Data items covered by the data set were subsequently refined and included in Australia’s National Health Data Dictionary (NHDD).

Clinical cancer registries and allied databases collect health-related information on individuals with specified cancers and are used for clinical research and to monitor clinical care, cancer survivals and other outcomes. In addition, they often have a safety and quality monitoring function. These databases may be voluntary. Sometimes they are covered by qualified privilege legislation. Generally they include more detailed data and are complementary to the data collected at a population level under legal mandate by State and Territory cancer registries and complied by the Australian Institute of Health and Welfare (AIHW). These latter population-based data generally include limited clinical information. They have an important role however in the monitoring of broad patterns of incidence, mortality and survival in the Australian population.

The CCCDS was a core data set developed by the NCCI for clinical registration of all cancers. It represented a compromise between collecting excessive clinical detail that would be unsustainable, and undue clinical brevity that would not be informative. The purpose was to provide a guide, such that clinical data sets around Australia would include similar items and definitions, thereby facilitating comparative analysis, and where appropriate, data pooling for rare sub-types of cancers.

Version 12 of the National Health Data Dictionary (AIHW, 2004) describes the data items included as core items for clinical cancer care registration. They comprise: (1) person characteristics, such as name, address, gender, date of birth and death; (2) treatment establishment number; (3) diagnostic characteristics, such as primary cancer site, diagnosis date, cancer morphology and grade, laterality, patient’s performance status, stage characteristics, including TNM or equivalent stage, tumour size, and regional nodal status; (4) features of the primary course of care, such as treatment intent, surgical procedures, radiotherapy types and doses, and names of systemic agents; (5) for the first recurrence, the date of diagnosis and anatomical region involved; and (6) follow-up information including date of last contact. Morphology codes were comprehensive, providing for benign and in situ, as well as invasive lesions.

Extended breast cancer items to supplement generic CCCD items
It was not intended that the CCDS would be sufficient for all clinical applications. In particular, it was anticipated that specialist tumour groups would require additional information. The breast cancer-specific data items in this publication are designed for use by specialist clinicians. They are additional to the core data set and should be considered selectively by those with a special interest in breast cancer data collection. Again, the purpose is to provide a guide, such that specialist breast cancer data sets around Australia may include similar items and definitions, which would facilitate comparative analysis, and where appropriate, data pooling. It is accepted that some groups may choose to exclude certain items, or include additional ones, to better meet their needs.
The items and definitions included in this guide were developed through a NBOCC multidisciplinary Working Group, in consultation with key stakeholders, who have been listed in the Acknowledgements section.
MORPHOLOGY STATEMENT

Specialist breast data collections should record DCIS and invasive cancers, in accordance with NBOCC and Australian Cancer Network’s (ACN) *The pathology reporting of breast cancer. A guide for pathologists, surgeons, radiologists and oncologists*. The proposed guide provides for the recording of these lesions. The guide also accommodates collection of LCIS data. While this would cater for the increasing interest in this condition, not all centres may choose to collect these data.

Final decisions on the content of individual collections would rest with the local administration, but the content should comply with NBOCC and ACN’s *The pathology reporting of breast cancer. A guide for pathologists, surgeons, radiologists and oncologists*. In particular, tumour morphology should be recorded in sufficient detail to enable appropriate data extractions.
BREAST DATA ITEMS

1. Menopausal status
2. Basis of diagnosis
3. Clinical trial enrolment
4. Initial presentation
5. Total extent of lesion (DCIS and invasive)
6. Lymphovascular invasion
7. HER2
8. Oestrogen receptor
9. Progesterone receptor
10. Sentinel lymph node
11. Surgical margin clearance
12. Surgical margin involvement
13. Presence of first distant metastasis
14. Breast reconstruction
15. Arm symptom at review appointment
16. Last contact
1. MENOPAUSAL STATUS

Metadata type: Data element

Definition: The menopausal status of the woman.

Justification: Some treatment recommendations differ by menopausal status. For example, ovarian ablation is not indicated after the menopause and tamoxifen, multi-agent chemotherapy and ovarian ablation all reduce the risk of recurrence and death in women less than 50 years and those at an older age who are still menstruating.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain:
1 premenopausal – has not yet experienced menopause
2 postmenopausal – has experienced menopause and 12 months of spontaneous amenorrhea
3 post-menopausal – as determined by biochemical testing
4 perimenopausal – from the onset of amenorrhea and extending across the subsequent 12 months
5 not female
9 unknown


Validation rule: For cases with an invasive component and for in situ lesions.

ADMINISTRATION:


Source organisation: RACS
2. BASIS OF DIAGNOSIS

Metadata type: Data element

Definition The type of investigation(s) performed to confirm or deny the presence of breast cancer.

Justification: The combination of clinical examination, ultrasound, fine needle aspiration cytology and/or core biopsy, provide the highest diagnostic accuracy and the lowest risk of diagnostic error, particularly in women over 35 years.

REPRESENTATION:

Data type: String

Field size: Min: 9 Max: 9

Representational format: [X(9)]

Data domain:
1  clinical examination y/n
2  mammography y/n
3  magnetic resonance imaging (MRI) y/n
4  ultrasound y/n
5  fine needle aspiration/cytology y/n
6  core biopsy histology y/n
7  open biopsy y/n
8  other y/n
9  unknown y/n

Guide for use: Code for as many procedures as applicable, where y = procedure done and n = procedure not done.

Clinical examination – examination of both breasts and axillae for signs of primary cancer and local spread, and a thorough examination of the rest of the body for signs of distant spread.

Mammography – process whereby dedicated mammographic imaging techniques are used to detect breast lesions (includes techniques such as galactography).

Magnetic resonance imaging (MRI) – use of a powerful magnetic field and radio frequency fields to construct an image of the body.

Ultrasound – the process whereby dedicated ultrasonic imaging techniques are used to detect breast lesions.
Fine needle aspiration/cytology – the sampling of cells from breast tissue for cytological examination using a needle size 23 gauge or smaller. When suction is applied during the sampling, this is referred to as a fine needle aspiration biopsy. Cytology refers to the assessment of cellular detail and abnormalities in a preparation of cells obtained by FNA or other methods such as duct discharge cytology.

Open biopsy – an incision is made and all or part of the abnormal tissue is removed for microscopic examination.

Other – a method of detection not listed above. Diagnostic procedures coded as ‘other’ should be described in the clinical notes section.

Validation rule: For cases with an invasive component and in situ lesions.

ADMINISTRATION:

Source organisation: NBOCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
3. CLINICAL TRIAL ENROLMENT

3.1 CLINICAL TRIAL ENROLMENT STATUS

Metadata type: Data element

Definition: Indicates whether patient is enrolled in a clinical trial. According to WHO, a clinical trial is 'Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes.'

Justification: Being involved in a clinical trial may result in the patient’s treatment departing from the expected path. This item also allows for collection of information about the type of patients selected for trials.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain: 1 yes 2 no 9 not stated/inadequately described

Guide for use: This item refers to clinical trials for any aspect of treatment, such as surgical, radiation, drug or hormonal therapy, or a sentinel node trial.

Validation rule: This data item is for both invasive cancer and in situ lesions.

ADMINISTRATION:


Source organisation: RACS
3.2 CLINICAL TRIAL NAME

Metadata type: Data element

Definition: The name of the clinical trial in which patient is enrolled.

Justification: Allows for collection of information about types of clinical trials in which patients are enrolled.

REPRESENTATION:

Data type: String

Field size: Min: 1 Max: 40

Representational format: [X(40)]

Data domain: Text

Guide for use: Blanks, spaces, hyphens, special characters and punctuation marks are allowed.

Validation rules: This item is to be completed only if the data element Clinical trial enrolment status is coded as 1.

This data item is for both invasive cancer and in situ lesions.

ADMINISTRATION:

Source organisations: NBOCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration

NHMRC, Australian Clinical Trials Registry
4. INITIAL PRESENTATION

Metadata type: Data element

Definition: Records the principal method by which the breast cancer was detected at initial presentation.

Justification: Information is relevant for clinical and population health research.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain: 1 screening – mammography
2 screening – MRI
3 screening – other
4 symptomatic
5 other
9 not stated/inadequately described

Guide for use: It is assumed that ‘screening mammography’, ‘screening MRI’ and ‘screening – other’ are used for asymptomatic women.

Symptomatic presentation may include a breast lump, nipple discharge, change in breast shape, change in nipple shape, or significant or new pain.

‘Screening – other’ may include screening through ultrasound or other clinical examination.

‘Other’ may include incidental detection through modalities such as ultrasound.

Validation rule: This data item is for both invasive cancer and in situ lesions.

ADMINISTRATION:

Source organisation: NBOCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
5. TOTAL EXTENT OF LESION (DCIS AND INVASIVE)

Metadata type: Data element

Definition: Indicates the maximum diameter in millimetres of the furthest points of extension of the whole lesion including any DCIS which extends beyond the invasive component.

Justification: Presence of DCIS in adjacent breast tissue can have prognostic and treatment implications. In cases where there is extensive DCIS beyond the invasive tumour component of the lesion, treatment options may be affected.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 2

Representational format: N

Data domain: Input total extent of lesion in mm

0 not stated/inadequately described

Guide for use: Total extent of lesion (DCIS + invasive carcinoma)

For a single focus of invasive carcinoma associated with DCIS, the “whole-lesion size” includes any associated DCIS seen beyond the margin of the invasive carcinoma.

For a lesion predominantly composed of DCIS, with multiple foci of invasive carcinoma, the whole lesion is measured.

For discrete foci of invasive carcinoma arising in a background of DCIS, the size of each invasive carcinoma is measured separately (the largest of these is regarded to be the invasive tumour size). The “whole lesion size” includes the invasive foci and all associated DCIS.

For more than one focus of invasive carcinoma, each with associated areas of DCIS that are not confluent, each focus is regarded as a separate lesion and measured accordingly.

Validation rule: This data item is for combined invasive/in situ lesions.
ADMINISTRATION:


Source organisations: NBOCC
                     ACN
6. LYMPHOVASCULAR INVASION

Metadata type: Data element

Definition: The presence of tumour cells in endothelium-lined spaces (lymphatics or blood vessels).

Justification: Lymphovascular invasion is a predictor of lymph node metastasis and recurrence.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain: 1 present 2 absent 3 suspicious 9 not stated or unknown

Guide for use: It is very difficult to distinguish between lymphatics and veins; therefore the term ‘lymphovascular’ is used to cover both possibilities.

Validation rule: This data item is for invasive cancer only.

ADMINISTRATION:


Source organisations: AIHW NBOCC ACN
7. HER2

7.1 HER2 STATUS

Metadata type: Data element

Definition: The presence or absence of HER2 (Human Epidermal Growth Factor Receptor 2) receptors on tumour cells.

Justification: HER2 status predicts the response to specific antibody therapy and several other systematic therapies, as well as being a general prognostic marker. Testing for HER2 status is now recommended for all newly diagnosed early invasive breast cancers, and is also likely to be requested in the setting of recurrent or metastatic disease.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1  Max: 1

Representational format: N

Data domain: 1 positive
              2 negative
              3 equivocal
              7 unknown (test results not available)
              8 not applicable (test not done)

Guide for use: Use code 8 to show that lack of results is due to test not being performed. Use code 7 if test results are unknown.

A positive, negative or equivocal result is based on immunohistochemistry or in situ hybridisation.

HER2 immunohistochemistry
3+ (HER2 positive) >30% of cancer cells show strong, complete membrane staining without cytoplasmic staining and without staining of normal breast tissue. (ASCO/CAP: 30% rather than 10%).
2+ (equivocal) <10% of cancer cells show strong complete membrane staining (rare) or 10–30% of cancer cells show weak to moderate complete membrane staining or strong cytoplasmic staining is present, making an assessment of membrane staining difficult.
0 or 1+ (HER2 negative) No staining (0) or <10% of cancer cells show staining (1+).
In situ hybridisation
Positive – >6 copies of the HER2 gene per nucleus or ratio of HER2 gene signals to chromosome 17 signals of >2.2
Equivocal – an average of 4–6 HER2 gene copies per nucleus with a single probe or a ratio of HER2 gene signals to chromosome 17 signals in the range of 1.8–2.2
Negative – <4 copies of the HER2 gene per nucleus or a ratio of HER2 gene signals to chromosome 17 of <1.8

Validation rule: This data item is for invasive cancer only.

ADMINISTRATION:


Source organisations: AIHW
NBOCC
ACN
7.2 HER2 TEST TYPES

Metadata type: Data element

Definition: Test used to assess HER2 status.

Justification: The percentage of breast carcinomas that are HER2 positive varies depending on the method used.

REPRESENTATION:

Data type: String

Field size: Min: 7 Max: 7

Representational format: [X(7)]

Data domain: 1 IHC y/n
2 ISH – Brightfield (includes CISH, SISH etc) y/n
3 ISH – Fluorescent (FISH) y/n
4 other y/n. (if y, specify)
5 HER2 test done but type not known y/n
6 not done (y)
7 not known (y)

Guide for use: Code as many items as required, by indicating y/n, where y = test done and n = test not done. Where another test was used, code "y" and specify test.

Use code "y" to show that test was not done or not known to have been performed, as indicated.

Under the Pharmaceutical Benefits Scheme (PBS), patients with early breast cancer are eligible for immunotherapy with trastuzumab (Herceptin, Roche) only if HER2 gene amplification has been demonstrated by in situ hybridisation.

Patients with metastatic disease are eligible for trastuzumab therapy if a 3+ positive result has been demonstrated by immunohistochemistry or HER2 gene amplification has been demonstrated by in situ hybridisation.

In Australia, HER2 testing is being performed principally by Brightfield ISH with FISH reserved for difficult/equivocal cases. There has been a reduction in the use of IHC, driven in part by the PBS requirement for an ISH result before treatment by trastuzumab is supported for patients with early breast cancer.

Validation rule: This data item is for invasive cancer only.
ADMINISTRATION


Source organisations: NBOCC
ACN
8. OESTROGEN RECEPTOR (ER)

8.1 OESTROGEN RECEPTOR (ER) STATUS

Metadata type: Data element

Definition: Records results of oestrogen receptor assay at diagnosis of primary breast tumour.

Justification: Oestrogen receptor status is an indicator of responsiveness to hormonal therapies. High ER expression is associated with a good prognosis and with a response to hormonal therapy.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain: 1 positive ≥ 1% nuclei staining
2 negative < 1% nuclei staining
7 unknown
8 not applicable (test not done)

Guide for use: Immunochemical assays of oestrogen receptor (ER) are now routinely performed on invasive breast carcinoma because they provide independent prognostic information to predict response to hormonal therapy.

Use code 8 to show that lack of results is due to test not being performed. Use code 7 if test results are unknown.

Validation rule: For cases with an invasive component.

ADMINISTRATION:


Source organisations:  
AIHW  
NBOCC  
ACN  
RACS
8.2 OESTROGEN RECEPTOR (ER) PERCENTAGE OF NUCLEI STAINED

Metadata type: Data element

Definition: Records the percentage of the nuclei stained.

Justification: Hormone receptor status has prognostic significance. Only nuclear staining indicates a positive result for ER status.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 3

Representational format: N

Data domain: Input value of nuclei stained (1–100%)

Guide for use: Use only when Oestrogen Receptor Status has been coded 1–positive.

Validation rule: For cases with an invasive component.

ADMINISTRATION:


Source organisations: NBOCC ACN
8.3 OESTROGEN RECEPTOR (ER) INTENSITY OF NUCLEAR STAINING

Metadata type: Data element

Definition: Records the predominant intensity of staining of the nuclei.

Justification: Only nuclear staining indicates a positive result for ER status.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain:
1    low intensity
2    intermediate intensity
3    high intensity
9    not known

Guide for use: Immunochemical assays of ER are now routinely performed on invasive breast carcinoma because they provide independent prognostic information to predict response to hormonal therapy.

Use only when Oestrogen Receptor Status has been coded 1–positive.

Validation rule: For cases with an invasive component.

ADMINISTRATION:


Source organisations: NBOCC
                  ACN
                  RACS
9. PROGESTERONE RECEPTOR (PR)

9.1 PROGESTERONE RECEPTOR (PR) STATUS

Metadata type: Data element
Definition: Records presence or absence of PRs on tumour cells.
Justification: Progesterone receptors (PRs) are prognostic indicators. They are intra cellular receptor proteins that bind progestins and antiprogestins. Expression of PR is mediated through the activation of the oestrogen receptor (ER) therefore the presence of PR indicates functional ER status. High expression of PR is associated with a good prognosis.

REPRESENTATION:

Data type: Numeric
Field size: Min: 1 Max: 1
Representational format: N
Data domain: 1 positive ≥ 1% nuclei staining
2 negative < 1% nuclei staining
7 unknown
8 not applicable (test not done)
Guide for use: Use code 8 to show that lack of results is due to test not being performed. Use code 7 if test results are unknown.
Validation rule: For cases with an invasive component.

ADMINISTRATION:


Source organisations: NBOCC
ACN
RACS
9.2 PROGESTERONE RECEPTOR (PR) PERCENTAGE OF NUCLEI STAINED

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<tbody>
<tr>
<td>Definition:</td>
<td>Records the percentage of the nuclei stained.</td>
</tr>
<tr>
<td>Justification:</td>
<td>Only nuclear staining indicates a positive result for PR status.</td>
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</table>

**REPRESENTATION:**

<table>
<thead>
<tr>
<th>Data type:</th>
<th>Numeric</th>
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</thead>
<tbody>
<tr>
<td>Field size:</td>
<td>Min: 1  Max: 3</td>
</tr>
<tr>
<td>Representational format:</td>
<td>N</td>
</tr>
<tr>
<td>Data domain:</td>
<td>Input value of nuclei stained (1–100%)</td>
</tr>
<tr>
<td>Guide for use:</td>
<td>Use only when Progesterone Receptor Status has been coded 1–positive.</td>
</tr>
</tbody>
</table>

**VALIDATION RULE:** For cases with an invasive component.

**ADMINISTRATION:**

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<tbody>
<tr>
<td>Source organisations:</td>
<td>NBOCC ACN</td>
</tr>
</tbody>
</table>
9.3 PROGESTERONE RECEPTOR (PR) INTENSITY OF NUCLEAR STAINING

Metadata type: Data element

Definition: Records the predominant intensity of staining of the nuclei.

Justification: Only nuclear staining indicates a positive result for PR status.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain: 1 low intensity 2 intermediate intensity 3 high intensity 9 not known

Guide for use: For use when Progesterone Receptor Status has been coded 1–positive.

Validation rule: For cases with an invasive component.

ADMINISTRATION:


Source organisations: NBOCC ACN RACS
10. SENTINEL LYMPH NODE

10.1 ATTEMPT TO IDENTIFY SENTINEL LYMPH NODE

Metadata type: Data element

Definition: Whether or not identification of sentinel lymph node attempted.

Justification: Identification and removal of the sentinel lymph node is undertaken to determine nodal status in patients where there is no clinical evidence of nodal involvement. If the sentinel node biopsy shows no tumour cells, an extensive regional lymph node dissection normally would not be undertaken, reducing the potential for lymphoedema and other surgical complications.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain: 1 yes
2 no
9 not known

Validation rule: This data item is for invasive cancer and in situ lesions.

ADMINISTRATION:


Source organisations: NBOCC
ACN
10.2 NUMBER OF SENTINEL LYMPH NODES EXAMINED

Metadata type: Data element

Definition: The number of sentinel nodes examined by the pathologist.

Justification: A definitive negative result on assessment of the sentinel node may negate the need for secondary surgery. If the biopsy shows no tumour cells, an extensive regional lymph node dissection normally would not be undertaken, reducing the possibility of lymphoedema.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 2

Representational format: N

Data domain: Input value for number of nodes examined

0 no (zero) nodes examined
99 unknown

Guide for use: Input value for number of nodes examined, as required. Use code 0 if no nodes have been examined.

If sentinel lymph node biopsy has not been performed, the absence of axillary lymph node involvement by metastatic carcinoma cannot reliably be made on an examination of fewer than six nodes. Among breast cancer patients reported as node-negative, examination of fewer than six dissected nodes is a risk factor for poor clinical prognosis, possibly due to understaging.

Validation rule: This data item is for invasive cancer and in situ lesions.

ADMINISTRATION:


Source organisations: AIHW
NBOCC
ACN
10.3 SIZE OF METASTASIS IN SENTINEL LYMPH NODES

Metadata type: Data element

Definition: Records the size of the metastasis in millimetres (mm) for each sentinel lymph node examined.

Justification: The number of lymph nodes with metastasis is important for cancer staging and treatment options. If no tumour cells are found, it is unnecessary to perform an extensive regional lymph node dissection.

REPRESENTATION:

Data type: String

Field size: Min: 6 Max: 24

Representational format: [X(24)]

Data domain: Node Involved Isolated cancer cells Size of mets (mm)

Node 1 y/n y/n
Node 2 y/n y/n
Node 3 y/n y/n
Node 4 y/n y/n
Node 5 y/n y/n
Node 6 y/n y/n

Guide for use: Indicate y or n to indicate involvement of each lymph node and y or n to indicate if isolated tumour cells. If involved with non-isolated tumour cells, indicate size of metastasis in mm.

Sentinel nodes are the first nodes that filter fluid draining away from the area of cancer. The presence of cancer cells in these lymph nodes indicates that the cancer has already spread outside the primary site and may have spread to another part of the body.

Validation rule: This data item is for invasive cancer only.

ADMINISTRATION:


Source organisations: NBOCC

ACN
11. SURGICAL MARGIN CLEARANCE

11.1 SURGICAL MARGIN CLEARANCE (INVASIVE COMPONENT)

Metadata type: Data element

Definition: The extent of invasive carcinoma at resection margin.

Justification: Margin status is associated with risk of recurrence.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain:
1 invasive carcinoma present at margin
2 no invasive carcinoma present at margin
9 unknown/not stated

Guide for use: As recorded in the pathology report.

Care should be taken in interpreting the true margin when ink has penetrated the specimen.

Validation rule: This data item is for invasive cancer only.

ADMINISTRATION:


Source organisations: NBOCC ACN
11.2 DISTANCE FROM MARGIN/S (INVASIVE COMPONENT)

Metadata type: Data element

Definition: The distance from nearest margin/s in millimetres (mm).

Justification: Margin status is associated with risk of recurrence.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 2

Representational format: N

Data domain: Value in millimetres

Guide for use: This is for use when Surgical Margin (Invasive Component) is coded 2.

The distance from the nearest resection margins should be initially assessed on macroscopic examination of the specimen.

Validation rule: This data item is for invasive cancer only.

ADMINISTRATION:


Source organisations: NBOCC ACN
11.3 SURGICAL MARGIN CLEARANCE (IN SITU COMPONENT)

Metadata type: Data element
Definition: The extent of DCIS at resection margin.
Justification: Margin status is associated with risk of recurrence.

REPRESENTATION:

Data type: Numeric
Field size: Min: 1 Max: 1
Representational format: N
Data domain: 1 DCIS present at margin
2 no DCIS present at margin
9 unknown/not stated
Guide for use: The status of the resection margins for DCIS in association with invasive carcinoma can only be assessed microscopically. A specimen is reported as having a 'positive margin' if there is ink on carcinoma cells (DCIS or invasive).

Validation rule: This data item is for DCIS only.

ADMINISTRATION:


Source organisations: NBOCC
ACN
11.4 DISTANCE FROM MARGIN/S (IN SITU COMPONENT)

Metadata type: Data element
Definition: The distance from nearest margin/s in millimetres (mm).
Justification: Margin status is associated with risk of recurrence.

REPRESENTATION:

Data type: Numeric
Field size: Min: 1 Max: 2
Representational format: N
Data domain: Value in millimetres
Guide for use: This is for use when Surgical Margin (In Situ Component) is coded 2.

The distance from the nearest resection margins should be initially assessed on macroscopic examination of the specimen.

Validation rule: This data item is for DCIS only.

ADMINISTRATION:


Source organisations: NBOCC ACN
12. SURGICAL MARGIN INVOLVEMENT

12.1 SURGICAL MARGIN INVOLVEMENT ORIENTATION (INVASIVE COMPONENT)

Metadata type: Data element

Definition: The orientation of margin involvement by the invasive cancer.

If a re-excision is required, the margin involvement should be the final margin involvement following this secondary procedure.

Justification: Margin involvement is a prognostic indicator and indicator of treatment needs.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain: Orientation

1 deep (pectoral fascia)
2 superficial (subcutaneous adipose tissue)
3 other
4 unknown

Guide for use: This is for use where Surgical Margin Clearance (Invasive Component) has been coded as 1.

A specimen is reported as having a ‘positive margin’ if there is ink on carcinoma cells (DCIS or invasive).

Record orientation.

Validation rule: This data item is for invasive cancer only.

ADMINISTRATION:


Source organisations: NBOCC ACN
12.2 SURGICAL MARGIN INVOLVEMENT EXTENT (INVASIVE COMPONENT)

Metadata type: Data element

Definition: The extent in millimetres (mm) of margin involvement by the invasive cancer.

If a re-excision is required, the margin involvement should be the final margin involvement following this secondary procedure.

Justification: Margin involvement is a prognostic indicator and indicator of treatment needs.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 2

Representational format: N

Data domain: Value in millimetres

Guide for use: This is for use where Surgical Margin Clearance (Invasive Component) has been coded as 1.

A specimen is reported as having a ‘positive margin’ if there is ink on carcinoma cells (DCIS or invasive).

Record extent of involvement. For oriented specimens, these measurements should be given in millimetres from the named circumferential margins and including the superficial (subcutaneous adipose tissue) and deep (pectoralis fascia) margins. After painting the margins with coloured inks, the measurements should be confirmed microscopically and blocks taken accordingly.

Validation rule: This data item is for invasive cancer only.

ADMINISTRATION:


Source organisations: NBOCC ACN
12.3 SURGICAL MARGIN INVOLVEMENT ORIENTATION (IN SITU COMPONENT)

Metadata type: Data element

Definition: The orientation of involvement of DCIS at margin.

If a re-excision is required, the margin involvement should be the final margin involvement following this secondary procedure.

Justification: For positive margins, the extent of margin involvement has both prognostic and management implications.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain: Orientation

1 deep (pectoral fascia)
2 superficial (subcutaneous adipose tissue)
3 other
4 unknown

Guide for use: This is for use where Surgical Margin Clearance (In Situ Component) has been coded as 1.

A specimen is reported as having a ‘positive margin’ if there is ink on carcinoma cells (DCIS or invasive).

Record orientation.

Validation rule: This data item is for DCIS only.

ADMINISTRATION:


Source organisations: NBOCC
ACN
12.4 SURGICAL MARGIN INVOLVEMENT EXTENT (IN SITU COMPONENT)

Metadata type: Data element

Definition: The extent of involvement of DCIS at margin in millimetres (mm).

If a re-excision is required, the margin involvement should be the final margin involvement following this secondary procedure.

Justification: For positive margins, the extent of margin involvement has both prognostic and management implications.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 2

Representational format: N

Data domain: Value in millimetres

Guide for use: This is for use where Surgical Margin Clearance (In Situ Component) has been coded as 1.

A specimen is reported as having a ‘positive margin’ if there is ink on carcinoma cells (DCIS or invasive).

Record extent of involvement. For oriented specimens, these measurements should be given in millimetres from the named circumferential margins and including the superficial (subcutaneous adipose tissue) and deep (pectoralis fascia) margins. After painting the margins with coloured inks, the measurements should be confirmed microscopically and blocks taken accordingly.

Validation rule: This data item is for DCIS only.

ADMINISTRATION:


Source organisations: NBOCC ACN
13. PRESENCE OF FIRST DISTANT METASTASIS

13.1 DATE OF FIRST DISTANT METASTASIS

Metadata type:  Data element

Definition: The date of the presence of first metastatic event, either at diagnosis or recurrence.

Justification: This item is collected to determine the number of women with a history of a distant metastasis and the survival duration following a distant metastasis.

REPRESENTATION:

Data type: Date

Field size: Min: 8 Max: 8

Representational format: DDMMYYYY (Day/Month/Year)

Data domain: Valid date

Guide for use: The date of presence of first distant metastasis could be noted either at time of diagnosis or at time of recurrence.

Validation rule: This data item is for invasive cancer only.

ADMINISTRATION:

Source organisation: NBOCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
13.2 SITE OF FIRST DISTANT METASTASIS

Metadata type: Data element

Definition: The site of the metastasis at first metastatic event, either at diagnosis or recurrence.

Justification: This item is collected to determine the number of women with a history of a distant metastasis.

REPRESENTATION:

Data type: String
Field size: Min: 5 Max: 6
Representational format: [X(6)]

Data domain: Site(s) of first distant metastasis
1 brain y/n
2 liver y/n
3 lung y/n
4 bone y/n
5 other y/n
9 unknown

Guide for use: The presence of first distant metastasis could be noted either at time of diagnosis or at time of recurrence.

Validation rule: This data item is for invasive cancer only.

ADMINISTRATION:

Source organisation: NBOCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
14. BREAST RECONSTRUCTION

14.1 DATE OF BREAST RECONSTRUCTION

Metadata type: Data element

Definition: Indicates date of breast reconstruction (where undertaken). Breast reconstruction is where a prosthesis or tissue from other parts of the body is used to rebuild a breast removed by mastectomy.

Justification: For patient follow-up and outcome studies.

REPRESENTATION:

Data type: Date

Field size: Min: 8 Max: 8

Representational format: DDMMYYYY (Day/Month/Year)

Data domain: Valid Date

Guide for use: Date of breast reconstruction start must be:
• Greater than the date of diagnosis
• Less than or equal to the date of death

Validation rule: This data item is for both invasive cancer and in situ lesions.

ADMINISTRATION:

Source organisation: NBOCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
14.2 TYPE OF BREAST RECONSTRUCTION

Metadata type: Data element
Definition: Indicates type of breast reconstruction procedure. Breast reconstruction is where a prosthesis or tissue from other parts of the body is used to rebuild a breast removed by mastectomy.
Justification: For patient follow-up and outcome studies.

REPRESENTATION:

Data type: Numeric
Field size: Min: 1 Max: 1
Representational format: N
Data domain: Type
1 no reconstruction
2 autologous reconstruction
3 prosthetic reconstruction
4 prosthetic and autologous reconstruction
5 reconstruction done but inadequately described
9 not known

Guide for use: Indicates type of procedure where breast reconstruction undertaken.

Validation rule: This data item is for both invasive cancer and in situ lesions.

ADMINISTRATION:

Source organisation: NBOCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
15. ARM SYMPTOM AT REVIEW APPOINTMENT

Metadata type: Data element

Definition: Records the nature and extent of dominant symptom such as swelling, pain or discomfort, or other symptom associated with the current treatment episode (both surgical and non-surgical) at the review appointment. Indicate whether symptom impacts on daily functioning.

Justification: Arm symptoms can be associated with axillary radiotherapy and axillary node dissection. This data item can be used to investigate the effect of conservative management and/or sentinel node dissection on the incidence of lymphoedema and other arm symptoms.

REPRESENTATION:

Data type: Numeric
Field size: Min: 1 Max: 1
Representational format: N
Data domain: 1 swelling – impacts on daily functioning
2 swelling – does not impact on daily functioning
3 pain – impacts on daily functioning
4 pain – does not impact on daily functioning
5 other symptom – impacts on daily functioning
6 other symptom – does not impact on daily functioning
9 no symptoms reported

Guide for use: Individual self-reporting of dominant arm symptoms should be used.

Validation rule: This data item is for both invasive cancer and in situ lesions.

ADMINISTRATION:

Source organisation: RACS
16. LAST CONTACT

16.1 DATE OF LAST CONTACT

Metadata type: Data element  
Definition: The date of last contact with the patient.  
Justification: For patient follow-up and outcome studies.

REPRESENTATION:

Data type: Date  
Field size: Min: 8 Max: 8  
Representational format: DDMMYYYY (Day/Month/Year)  
Data domain: Valid date  
Validation rules: This data item is for both invasive cancer and in situ lesions.  
Date of last contact must be:  
- Greater than date of diagnosis  
- Less than or equal to date of death

ADMINISTRATION:

Source document: Commission on Cancer, Facility Oncology Registry Data Standards Revised for 2007 (FORDS).  
Source organisation: Commission on Cancer, American College of Surgeons
16.2 CANCER STATUS AT LAST CONTACT

Metadata type: Data element

Definition: Records the presence or absence of clinical evidence of the patient’s tumour as applying at the date of last contact.

Justification: For patient follow-up and outcome studies.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data domain:
0  no cancer detected
1  local recurrence
2  regional recurrence
3  visceral distant metastasis
4  other distant metastasis
5  distant metastases inadequately described
8  cancer status unknown

Guide for use: Cancer status is based on information from the patient’s physician or other official source such as a death certificate.

- The patient’s cancer status should be changed only if new information is received from the patient’s physician or other official source. If information is obtained from the patient, a family member, or other non physician, then cancer status is not updated.
- Cancer status changes if the patient has a recurrence or relapse.
- If a patient has multiple primaries, each primary could have a different cancer status.

Note: Code the most advanced recurrence if more than one applies.

While this codes cancer status at last contact with the patient, it need not override previous records. Retention of successive values can be considered by individual clinicians.

Validation rule: This data item is for both invasive cancer and in situ lesions.

ADMINISTRATION:

Source document: Commission on Cancer, Facility Oncology Registry Data Standards Revised for 2007 (FORDS).

Source organisations: Commission on Cancer, American College of Surgeons NBOCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration.
APPENDIX 1

EXEMPLARY FROM THE NATIONAL HEALTH DATA DICTIONARY VERSION 12 SUPPLEMENT

DATA SET SPECIFICATION (DSS) CANCER (CLINICAL)

Admin status: CURRENT 04/06/2004 Version number: 1

Metadata type: Data Set Specification

Start date: 04/06/2004

Scope: This cancer (clinical) data set specification is not mandated for collection but is recommended as best practice if cancer clinical data are to be collected. The cancer (clinical) data set underpins the evaluation of cancer treatment services and this can occur at a number of levels; i.e., at the individual clinician, the health care institution, and state or territory level, and at a national level. Clinicians use such data for ongoing patient management. The ability to link patient management to outcomes allows treatments or outcomes to be identified and assessed. Institutions can monitor throughput in their centres for planning and resource allocation purposes, in order to obtain optimum return for cancer expenditure. Endpoints can be monitored to ensure that objectives are being met. The principal aim of good quality and consistent data is to provide information that can lead to improved quality and length of life for all patients by providing a systematic foundation for evidence-based medicine, informing quality assurance and improvement decisions, and for guiding successful planning and evaluation of cancer control activities.

Collection methodology: This data set is primarily concerned with the clinical use of cancer data. It can also be used by a wider range of health and health-related establishments that create, use, or maintain records on health-care clients.

Data elements included:
Address line, version 1
Cancer initial treatment — completion date, version 1
Cancer initial treatment — starting date, version 1
Cancer staging — M stage code, version 1
Cancer staging — N stage code, version 1
Cancer staging — T stage code, version 1
Cancer staging — TNM Stage grouping code, version 1
Cancer treatment type, version 1
Cancer treatment — target site, version 1
Date of birth, version 5
Date of death, version 1
Date of diagnosis of cancer, version 1
Date of diagnosis of first recurrence, version 1
Date of surgical treatment for cancer, version 1

Establishment number, version 4
Family name, version 2
Given name(s), version 2
Histopathological grade, version 1
Intention of treatment for cancer, version 1
Laterality of primary cancer, version 1
Medicare card number, version 2
Morphology of cancer, version 1
Most valid basis of diagnosis of cancer, version 1
Oestrogen receptor assay status, version 1
Outcome of initial treatment, version 1
Person identifier, version 2
Primary site of cancer, version 1
Progesterone receptor assay status, version 1
Radiotherapy treatment type, version 1
Received radiation dose, version 1
Region of first recurrence, version 1
Regional lymph nodes examined, version 1
Regional lymph nodes positive, version 1
Sex, version 4
Staging basis, version 1
Staging scheme source, version 1
Staging scheme source edition number, version 1
Surgical treatment procedure for cancer, version 1
Systemic therapy agent name, version 1
Tumour size at diagnosis – solid tumours, version 1
Tumour thickness at diagnosis – melanoma, version 1
APPENDIX 2

CLINICAL CANCER REGISTRATION DATA ITEMS – BREAST CANCER
(INVASIVE CANCER & IN SITU LESIONS)

GENERIC PLUS SPECIALIST ITEMS (IN BRACKETS)

* new items
** items better placed in specialist data sets
*** deleted item/s

Person characteristics
Family name
Given name(s)
Address line
Sex – male/female
Date of birth
Indigenous status*
Medicare card number
Person identifier
(Menopausal status – pre/post/post as determined by biochemical testing/peri/not female/uk)
Date of death
Cause of death

Provision of care
Establishment number

Diagnosis
Primary site
Date of diagnosis
Morphology
Histopathology grade
Laterality
(Basis of diagnosis – clinical exam/mammography/MRI/ultrasound/FNA/core biopsy/open biopsy/other/uk)
Performance status at diagnosis*
(Initial presentation – screening – mammography/screening – MRI/screening – other/symptomatic/other/not stated/inadequately described)
For TNM staging system:
- T, N, M, TNM stage group
For other staging system:
- Name of staging system*
- Staging scheme source/edition number
For all staging systems:
- Staging basis
- Staging scheme source/edition number
(Presence of first distant metastases – date and sites – brain/liver/lung/bone/other/uk)
Tumour size at diagnosis (solid tumours)
(Lymphovascular invasion – present/absent/suspicious/not stated/unknown)
(Total extent of lesion – DCIS and invasive (mm)/not stated)
(Sentinel lymph node – attempt to identify – attempted y/n/not unknown)
(Sentinel lymph nodes examined – input number of nodes examined/no nodes examined/uk)
(Size of metastasis in sentinel lymph node – for nodes 1–6 – involved, isolated cancer cells,
size of nodal metastasis (mm)/uk)
Number of regional lymph nodes examined
Number of regional lymph nodes positive
(Oestrogen receptor status – positive/negative/unknown/not applicable)
(Oestrogen receptor percentage nuclei stained)
(Oestrogen receptor intensity of staining – low/intermediate/high/uk)
(Progesterone receptor status – positive/negative/unknown/not applicable)
(Progesterone receptor percentage nuclei stained)
(Progesterone receptor intensity of staining – low/intermediate/high/uk)
(HER2 status – positive/negative/equivocal/unknown/not applicable)
(HER 2 test type – IHC/ISH – Brightfield/ISH – Fluorescent/other/type not known/not done/unknown)

**Treatment (initial episode)**
(Clinical trial enrolment – yes/no/not stated. If yes – name of trial)
Target sites (surgery/radiotherapy)
Treatment type (i.e. none/surg/radio/systemic/etc)
Surgical procedure date
Surgical procedure
(Surgical outcome – invasive component/DCIS component – invasive carcinoma present at margin/no invasive carcinoma at margin/uk; DCIS present at margin/DCIS not present at margin/uk)
(Surgical outcome – distance from margins – invasive component/DCIS component
Surgical margin involvement – invasive component/DCIS component – orientation (deep/superficial/other/uk); involvement in mm)
Radiotherapy start date/completion date
Radiotherapy type
Radiotherapy fractions*
Radiotherapy dose
Systemic therapy start date*
Systemic therapy agent/protocol
Systemic therapy cycles*
All treatment – start date
All treatment – completion date
Outcome – complete/partial response/stable disease/progressive disease**
(Outcome – Arm symptoms at review appointment – swelling (impacts on daily functioning)/swelling (no impact on daily functioning)/pain (impacts on daily functioning)/pain (no impact on daily functioning)/other symptom (impacts on daily functioning)/other symptom (no impact on daily function/no symptoms reported)

**First recurrence**
Date of diagnosis
Region (local/regional/distant)
Basis of diagnosis (i.e. death certificate, clinical, clinical investigation, tumour marker (e.g. biochemical), cytology, histology, other (specify))

(Breast reconstruction – date (day/month/year)/type (autologous/prosthetic/autologous and prosthetic/reconstruction inadequately described/uk)

Follow up
Date of last contact*
(Cancer status at last contact – none detected/local recurrence/regional recurrence/distant metastasis) – if yes to distant specify visceral/other/location of metastasis unknown/uk cancer status)